Appendix F Diagnostic accuracy study profiles

Table F1 – Study profiles – Localisation rates and false negative rates

Study identifier	Procedure	Patient characteristics
Acosta, Contreras, Ravelo, Hurtado, Marín, Manso, Pérez & Longobardi, 2003. **Number of patients** 57 **Number of attempted mappings** 57 **Study period** February 1998 to August 2001 **Institution** Centro Clinico de Estereotaxia, Caracas, Veneuela, South America. **Incorporated studies** None **Inclusion/exclusion criteria** Inclusions: patients with histologic diagnosis of breast cancer with tumour size ≤2cm (determined by clinical examination, mammography, and ultrasound) and larger than 4 cm in cases of ductal carcinoma *in situ*. Exclusions: patients with multiple local lesions, pregnant women and male patients. **Study included for review of..…** Localisation rates	**Radiocolloid/dye combination** Radiocolloid only: 0 Dye only: 6 Radiocolloid and dye: 51 **Radiocolloid** Type: ^{99m}Tc-labelled colloidal sulphide Dose: average 1μCi Colloid size: not stated Filtration: unfiltered Injection location: peritumoural Injection timing: 4 to 18 hours (average 12 hours) before surgery. Massage: not stated Intraoperative probe: Europrobe (Eurorad, Strasbourg, France). **Dye** Type: isosulphan blue or patent blue Amount: average dose 2.5cc. Injection location: peritumoural Injection timing: 10 minutes before axillary incision. Massage: not stated **Preoperative lymphoscintigraphy** Timing: whether preoperative lymphoscintigraphy was performed was not stated. **Surgery** Surgeon details: not stated Anaesthesia: not stated Axillary clearance: 19 axillary dissections (level not stated) were carried out, 3 because sentinel node could not be identified. Sentinel node definition: not stated Final breast procedure: presurgical lymphatic mapping, mastectomy, axillary dissection. **Histologic analysis of sentinel nodes** Intraoperative analysis:: frozen section stained with H&E. Sectioning: not stated Permanent section: not stated IHC: not stated Micrometastases definition: not stated **Histologic analysis of axillary nodes** Not stated	**Age** Mean 52, range 32 to 73 years. **Tumour characteristics** Biopsy method Not stated Size Not stated Stage Not stated Histology Not stated Location Not stated Palpability Not stated Multifocality/multicentricity Patients with multiple local lesions were excluded. **Axilla characteristics** Clinical axillary status Not stated **Neoadjuvant chemotherapy** Not stated

Study identifier	Procedure	Patient characteristics
Ahrendt, Laud, Tjoe, Eastwood, Walker, Otterson & Redlich, 2002. **Number of patients** 174 (173 female:1 male) **Number of attempted mappings** 177 (3 bilateral) **Study period** October 1996 to January 2000 **Institution** Departments of Surgery and Biostatistics, Medical College of Wisconsin, Milwaukee, Wisconsin; Department of Surgery, The University of Rochester School of Medicine and Dentistry, Rochester, NY, USA. **Incorporated studies** None **Inclusion/exclusion criteria** Inclusions: patients presenting to the Medical College of Wisconsin Breast Care Center at Froedtert Memorial Lutheran Hospital, with operable breast cancer were prospectively entered into a clinical database. Exclusions: none stated **Study included for review of……** Localisation rates and false negative rates	**Radiocolloid/dye combination** Radiocolloid only: 34 Dye only: 31 Radiocolloid and dye: 112 **Radiocolloid** Type: ^{99m}Tc-labelled sulphur colloid Dose: 800μCi in 16ml Colloid size: not stated Filtration: filtered Injection location: in four locations in the breast parenchyma around the tumour or biopsy cavity, guided by either palpation or the location of the guidewire tip. Injection timing: approximately 2 hours before surgery Massage: breast massage, length of massage not stated. Intraoperative probe: Navigator (US Surgical). **Dye** Type: isosulphan blue dye Amount: 4 to 5ml Injection location: into the breast parenchyma surrounding the tumour or biopsy site. Injection timing: not stated Massage: 5 minutes of breast massage. **Preoperative lymphoscintigraphy** Timing: performed in nearly all cases, but the timing after the injection of radiocolloid was not stated. **Surgery** Surgeon details: performed at a single institution by four surgeons. Anaesthesia: not stated Axillary clearance: a standard level I and II node dissection was performed in all patients. Sentinel node definition: blue stained nodes, nodes with a blue stained afferent lymphatic, or nodes containing radioactive tracer, ie. "hot", measured intraoperatively via a hand-held gamma probe. Final breast procedure: lumpectomy 129/177 (72.9%); total mastectomy 48/177 (27.1%). **Histologic analysis of sentinel nodes** Intraoperative analysis:: frozen section was not performed. Sectioning: serial step sectioning. Permanent section: H&E IHC: staining for cytokeratin (sentinel nodes with cytokeratin positive cells identified by IHC that could not be confirmed by deeper sections and H&E staining were not considered positive). Micrometastases definition: not stated **Histologic analysis of axillary nodes** Not stated	**Age** Mean 59.1, median 60, range 32 to 89 years **Tumour characteristics** Biopsy method FNA: 10/177 (5.6%) Core: 63/177 (35.6%) Image-guided core: 73/177 (41.2%) Excisional biopsy: 30/177 (16.9%) Undocumented: 1/177 (0.6%) Size Mean 1.92, median 1.5, range 0.1 to 11cm 0.1 to 1cm: 49/177 (27.7%) 1 to 2cm: 77/177 (43.5%) 2 to 5cm: 49/177 (27.7%) >5cm: 2/177 (1.1%) Stage T1a/T1b: 49/177 (27.7%) T1c: 77/177 (43.5%) T2: 49/177 (27.7%) T3: 2/177 (1.1%) Histology Invasive ductal: 153/177 (86.4%) Invasive lobular: 16/177 (9.0%) Mixed ductal and lobular: 2/177 (1.1%) Tubular: 2/177 (1.1%) Medullary: 1/177 (0.6%) Mucinous: 3/177 (1.7%) Location UOQ: 82/177 (46.3%) LOQ: 26/177 (14.7%) UIQ: 19/177 (10.7%) LIQ: 17/177 (9.6%) Subareolar/central: 28/177 (15.8%) Undocumented: 5/177 (2.8%) Palpability Palpable: 118/177 (66.7%) Nonpalpable: 59/177 (33.3%) Multifocality/Multicentricity Not stated **Axilla characteristics** Clinical axillary status Negative: 177/177 (100%) **Neoadjuvant chemotherapy** Not stated

Study identifier	Procedure	Patient characteristics
Allen, Campbell, Desai, Dray & Scarlet, 2001. **Number of patients** 36 **Number of attempted mappings** 36 **Study period** August 1998 to March 2000 **Institution** Department of Nuclear Medicine, Surgery and Pathology and Research Nurse Breast Care Centre, Waikato Hospital, Hamilton, New Zealand. **Incorporated studies** None **Inclusion/exclusion criteria** Inclusions: women with cytologically or histologically confirmed operable invasive breast cancer who required axillary node staging or dissection as part of their standard breast cancer treatment, and where it was logistically feasible to perform lymphoscintigraphy. Exclusions: previous carcinoma in the ipsilateral breast, previous axillary surgery or radiotherapy, or previous major breast surgery or breast radiotherapy. Women over 70 with no palpable axillary nodes were not invited to participate due to a conflicting study protocol. **Study included for review of……** Localisation rates and false negative rates	**Radiocolloid/dye combination** Radiocolloid only: 0 Dye only: 0 Radiocolloid and dye: 36 **Radiocolloid** Type: ^{99m}Tc-labelled antimony sulphide (Radiopharmacy Unit, Royal Adelaide Hospital, Australia) or reduced heating preparation (unfiltered rhenium sulphur colloid, Nanocis CIS bio international France) Dose: 20 to 55MBq Colloid size: not stated Filtration: the rhenium sulphur colloid was unfiltered. Injection location: four samples of antimony sulphide were injected concentrically around the tumour and at tumour depth. The sulphur colloid was injected similarly, consiting of four 0.8ml injections. For patients with nonpalpable lesions, the colloid was either injected under ultrasound guidance or at the time of breast hookwire placement. Injection timing: 4 to 22 hours before surgery. Massage: patients performed gentle massage of the injection site for ten minutes. Intraoperative probe: Navigator (US Surgical Corp., Norwalk, CT, USA); Gammasonics probe (Gammasonics Ltd., Fivedock, Sydney, Australia). **Dye** Type: Patent Blue Dye (Rhone Poulenc Rorer) Amount: 2.0ml of dye was diluted to 4.0ml with normal saline Injection location: injected peritumourally, or adjacent to the hookwire or skin marker for non-palpable lesions. Injection timing: not stated Massage: the injection site was massaged for 5 to 8 minutes prior to skin incision. **Preoperative lymphoscintigraphy** Timing: commenced immediately post injection and was generally completed within three hours post injection. **Surgery** Surgeon details: not stated Anaesthesia: general anaesthesia Axillary clearance: all patients underwent formal axillary dissection. Sentinel node definition: blue and/or 'hot' lymphatic channels and lymph nodes. Final breast procedure: not stated **Histologic analysis of sentinel nodes** Intraoperative analysis: not stated Sectioning: nodes <5mm were embedded whole in paraffin; ≥5 mm were sectioned and embedded. Blocks were sectioned in 3μm slices. Permanent section: stained with H&E. IHC: if H&E negative, a further two levels were examined and stained for cytokeratin (AE1/AE3 – DAKO). Micrometastases definition: not stated **Histologic analysis of axillary nodes** Not stated	**Age** Range 30 to 82 years, mean not stated. **Tumour characteristics** Biopsy method Not stated Size Mean 23, SD 13.6, range <5 to >50mm. Stage Not stated Histology Not stated Location Not stated Palpability Palpable and nonpalpable, numbers not stated. Multifocality/multicentricity Not stated **Axilla characteristics** Clinical axillary status Positive and negative axillary patients were included. **Neoadjuvant chemotherapy** Not stated

Study identifier	Procedure	Patient characteristics
Altinyollar, Kapucuoglu, Pak & Berberoglu, 2000. **Number of patients** 60 **Number of attempted mappings** 60 **Study period** Not stated **Institution** Departments of General Surgery and Pathology, Ankara Onkoloji Hospital, Ankara, Turkey **Incorporated studies** None **Inclusion/exclusion criteria** Inclusions: clinical stage I and II breast carcinoma patients treated at Ankara Oncology Hospital who did not have palpable axillary nodes. Exclusions: pregnant women. **Study included for review of……** Localisation rates and false negative rates	**Radiocolloid/dye combination** Radiocolloid only: 0 Dye only: 60 Radiocolloid and dye: 0 **Radiocolloid** Radiocolloid was not used. Type: not applicable Dose: not applicable Colloid size: not applicable Filtration: not applicable Injection location: not applicable Injection timing: not applicable Massage: not applicable Intraoperative probe: not applicable **Dye** Type: patent blue dye Amount: 4ml (2.5% solution in distilled water, prepared by adding 0.6% sodium chloride and 0.05% disodium hydrogen phosphate). Injection location: into the breast parenchyma at four quadrants (1ml in each quadrant) around the biopsy cavity. Injection timing: 5 minutes before surgical incision. Massage: injection sites were gently massaged for 2 to 3 minutes. **Preoperative lymphoscintigraphy** Timing: not applicable **Surgery** Surgeon details: not stated Timing: incision was performed five minutes after the injection of blue dye. Anaesthesia: general anaesthesia Axillary clearance: Level I, II and III *en bloc* dissection. Sentinel node definition: blue stained lymph nodes. Final breast procedure: modified radical mastectomy 60/60 (100%). **Histologic analysis of sentinel nodes** Intraoperative analysis: frozen section on H&E slides. Sectioning: not stated Permanent section: stained with H&E. IHC: all sentinel nodes were stained with anticytokeratin antibody (AE1/AE3). Micrometastases definition: not stated **Histologic analysis of axillary nodes** H&E	**Age** Median 51, range 31 to 74 years. **Tumour characteristics** Biopsy method Excisional biopsy 60/60 (100%) Size See Stage Stage T1 (<2cm) 19/60 (31.7%) T2 (2 to 5cm) 41/60 (68.3%) Stage I and II Histology Invasive ductal carcinoma 51/60 (85.0%) Invasive lobular carcinoma 4/60 (6.7%) Atypic medullary carcinoma 3/60 (5.0%) Mucinous carcinoma 2/60 (3.3%) Location UOQ 46/60 (76.7%) UIQ 4/60 (6.7%) LOQ 5/60 (8.3%) LIQ 2/60 (3.3%) Subareolar 3/60 (5%) Palpability Not stated Multifocality/multicentricity Not stated **Axilla characteristics** Clinical axillary status Negative 60/60 (100%) **Neoadjuvant chemotherapy** Not stated

Study identifier	Procedure	Patient characteristics
Aras, Arican, Çam, Kücük, İbiş, Tüzüner & Soylu, 2002. **Number of patients** 30 **Number of attempted mappings** 30 **Study period** Not stated **Institution** Departments of Nuclear Medicine and Surgery, Ankara University Medical Facility, Ankara, Turkey. **Incorporated studies** None **Inclusion/exclusion criteria** Inclusions: breast cancers stages as I and II without any indication of axillary lymph node involvement. Exclusions: none stated **Study included for review of……** Localisation rates	**Radiocolloid/dye combination** Radiocolloid only: 14 Dye only: 0 Radiocolloid and dye: 16 **Radiocolloid** Type: ^{99m}Tc-labelled MIBI Dose: each injection was 74MBq in 0.2ml Colloid size: not stated Filtration: not stated Injection location: peritumourally in 4 different locations. Injection timing: 2 to 24 hours before surgery (2 to 6 hours in 11 patients, 6 to 12 hours in 13 patients and 12 to 24 hours in 5 patients). Massage: not stated Intraoperative probe: Europrobe **Dye** Type: not stated Amount: 1 to 5ml Injection location: peritumourally Timing: just before operation. Massage: not stated **Preoperative lymphoscintigraphy** Timing: images were taken immediately after injection at 10, 30, 45, 60 and 120 minutes. **Surgery** Surgeon details: all operations performed by the same surgeon. Anaesthesia: not stated Axillary clearance: total axillary lymphadenectomy performed on all patients. Sentinel node definition: node with the highest radioactivity cound and closest to the tumour. Final breast procedure: modified radical mastectomy 30/30 (100%). **Histologic analysis of sentinel nodes** Intraoperative analysis:: not stated Sectioning: not stated Permanent section: stained with H&E. IHC: not stated Micrometastases definition: not stated **Histologic analysis of axillary nodes** Not stated	**Age** Mean 46.4 ± 8.4, range 32 to 61 years. **Tumour characteristics** Biopsy method Not stated Size Not stated Stage All patients were stage I or II Histology Not stated Location Left breast: 14/30 (46.7%) Right breast: 16/30 (53.3%) UIQ: 15/30 (50.0%) UOQ: 3/30 (10.0%) LOQ: 6/30 (20.0%) LIQ: 5/30 (16.7%) Subareolar: 1/30 (3.3%) Palpability Not stated Multifocality/multicentricity Not stated **Axilla characteristics** Clinical axillary status Negative: 30/30 (100%) **Neoadjuvant chemotherapy** Not stated

Study identifier	Procedure	Patient characteristics
Baichev, Sergieva & Gorchev, 2001. **Number of patients** 238 **Number of attempted mappings** 238 **Study period** February 1995 to June 2000 **Institution** Department of Surgical Oncology, University Centre of Oncology, Pleven and Department of Nuclear Medicine, National Centre of Oncology, Sofia, Bulgaria. **Incorporated studies** None **Inclusion/exclusion criteria** Inclusions: patients with breast cancer. Exclusions: pregnant or lactating women, those who had previously undergone biopsy or radiotherapy to the axilla and those with multifocal breast carcinoma (mammographically confirmed). **Study included for review of……** False negative rates	**Radiocolloid/dye combination** Radiocolloid only: unsure Dye only: unsure Radiocolloid and dye: unsure **Radiocolloid** Type: ^{99m}Tc- labelled sulphur colloid (Solco Lymphoscint, Sorin). Dose: 20MBq in 0.2 to 0.3ml Colloid size: average particle diameter 50nm Filtration: not stated Injection location: subareolar Injection timing: not stated Massage: not stated Intraoperative probe: not stated **Dye** Type: 192/238 (80.7%) Lymphotrophic blue dye, (147/192 (76.6%) Patent Blue V (BYK Gulden), 19/192 (9.9%) Drimaren Brilliant Blue (Fluka), 26/192 (13.5%) Mitoxantrone (Novantrone, Wyeth-Lederle). Amount: 2ml Injection location: patent blue V or drimarin brilliant blue was injected peritumourally; Mitoxantrone (0.5ml/1mg) was injected in two sites around the tumour), In 46/238 (19.3%) of patients, a subareolar injection in two different zones (0.5 to 1.5ml each), into the respective quadrant of the tumour, was performed. Injection timing: immediately before induction of anaesthesia. Massage: not stated **Preoperative lymphoscintigraphy** Timing: Images (in frontal and inclined positions) were acquired 20 minutes and 120 to 180 minutes after radiocolloid injection. Lymphoscintigraphy was performed in 9/238 (3.8%) patients. **Surgery** Surgeon details: not stated Anaesthesia: not specifically stated, anaesthesia was presumed to be general ('induction of anaesthesia'). Axillary clearance: in 215/238 (90.3%) cases, levels I, II and III were cleared, in 23/238 (9.7%) cases, where the tumour was <1cm, levels I and II were cleared. Sentinel node definition: not stated Final breast procedure: modified radical mastectomy 201/238 (84.5%); quadrantectomy 37/238 (15.5%). **Histologic analysis of sentinel nodes** Intraoperative analysis: not stated Sectioning: not stated Permanent section: H&E IHC: not performed Micrometastases definition: not stated	**Age** Median 56.1, range 24 to 75 years **Tumour characteristics** Biopsy method Not stated Size Not stated Stage T1 or T2 Histology Not stated Location Of tumours where a positive sentinel node was mapped (80 patients) Lateral: 53/80 (66.2%) Central: 16/80 (20%) Medial: 11/80 (13.8%) Palpability Not stated Multifocality/multicentricity Patients with multifocal carcinoma were excluded. **Axilla characteristics** Clinical axillary status Negative and positive axillary patients included. **Neoadjuvant chemotherapy** Perioperative chemotherapy was given in 26/238 (10.9%) patients using Mitaxantron which was also used as the dye.

	Histologic analysis of axillary nodes H&E	

Study identifier	Procedure	Patient characteristics
Baitchev, Gortchev & Todorova, 2002. **Number of patients** 95 **Number of attempted mappings** 95 **Study period** February 2000 to September 2001 **Institution** Department of Surgical Oncology, University Centre of Oncology, Pleven and Department of Pathology, Medical University, Pleven, Bulgaria. **Incorporated studies** Deliiski *et al.* 1999 **Inclusion/exclusion criteria** Inclusions: consecutive patients with early (T1 to T2, N0, M0) invasive breast cancer. Exclusions: none stated **Study included for review of……** Localisation rates and false negative rates	**Radiocolloid/dye combination** Radiocolloid only: 0 Dye only: 95 Radiocolloid and dye: 0 **Radiocolloid** Radiocolloid was not used. Type: not applicable Dose: not applicable Colloid size: not applicable Filtration: not applicable Injection location: not applicable Injection timing: not applicable Massage: not applicable Intraoperative probe: not applicable **Dye** Type: patent blue V (BYK Gulden, Konstanz, Germany). Amount: 2ml Injection location: peritumoural Massage: not stated **Preoperative lymphoscintigraphy** Timing: not applicable **Surgery** Surgeon details: not stated Anaesthesia: not stated Axillary clearance: a level I and II axillary lymphadenectomy was performed. Sentinel node definition: blue stained lymphatic tract and node. Final breast procedure: modified radical mastectomy 35/87 (40.2%); breast-conserving, 52/87 (59.8%). **Histologic analysis of sentinel nodes** Intraoperative analysis:: touch preparation were made from each of the sides, fixed in ethanol and stained with H&E. Imprints were interpreted as negative, suspicious (regarded as negative to reduce false positives) or positive (malignant). Sectioning: sentinel nodes smaller than 1.0cm were bisected, and nodes larger than 1.0cm were lamellated into pieces of approximately 0.5cm. All lymph nodes were fixed in formalin and embedded in paraffin and one 4µm thick H&E section was made for each block from sentinel nodes. When negative, the sentinel nodes were serially sectioned at 100 or 250µm intervals and stained with H&E. Permanent section: H&E IHC: all H&E negative cases had IHC for cytokeratin (MNF 116). Micrometastases definition: not stated **Histologic analysis of axillary nodes** Nonsentinel nodes were examined by conventional histology with no serial sectioning or immunostaining.	**Age** Median 53.6, range 28 to 73 years. **Tumour characteristics** Biopsy method Not stated Size Median 2.2, range 0.8 to 3.7cm (pathological) Stage T1 to T2 Histology Not stated Location Not stated Palpability Not stated Multifocality/multicentricity M0: 95/95 (100%) **Axilla characteristics** Clinical axillary status Negative: 95/95 (100%) **Neoadjuvant chemotherapy** Not stated

Study identifier	Procedure	Patient characteristics
Balch, Mithani, Richards, Beauchamp & Kelley, 2003. **Number of patients** 122 **Number of attempted mappings** 122 **Study period** July 1997 to February 2002 **Institution** Division of Surgical Oncology, Vanderbilt University Medical Center, Nashville, Tennessee, USA. **Incorporated studies** None **Inclusion/exclusion criteria** Inclusions: patients with breast cancer. Exclusions: none stated **Study included for review of……** Localisation rates and false negative rates	**Radiocolloid/dye combination** Radiocolloid only: 0 Dye only: 0 Radiocolloid and dye: 122 **Radiocolloid** Type: ^{99m}Tc-labelled sulphur colloid Dose: 450μCi (peritumourally); 300μCi (intradermally) Colloid size: not stated Filtration: filtered Injection location: patients were injected peritumourally, and in the last 26/32 (81.3%) patients were injected pertumorally and intradermally. Mammographic or US guidance was used for patients with nonpalpable tumours. Injection timing: 2 to 6 hours before surgery Massage: not stated Intraoperative probe: Navigator (US Surgical Corp., Norwalk, CT, USA). **Dye** Type: isosulphan blue dye (1%) Amount: 5ml Injection location: peritumourally Injection timing: after induction of anaesthesia. Massage: the breast was massaged for 5 minutes. **Preoperative lymphoscintigraphy** Timing: lymphoscintigraphy was performed in most patients, timing was not stated. **Surgery** Surgeon details: not stated Anaesthesia: not specifically stated, anaesthesia was presumed to be general ('induction of anaesthesia'). Axillary clearance: standard axillary lymph node dissection, level I and II. Sentinel node definition: all blue or significantly radioactive nodes (≥5 times background in the nodal basin and/or ≥ 30 counts *in vivo*) Final breast procedure: (for patients receiving neoadjuvant chemotherapy) total mastectomy 17/32 (53.1%); segmental mastectomy 15/32 (46.9%). **Histologic analysis of sentinel nodes** Intraoperative analysis:: not stated Sectioning: 1mm serial sections. Permanent section: H&E IHC: anticytokeratin (AE1/AE3) used selectively at the pathologists discretion to clarify questionable areas on H&E staining. Micrometastases definition: not stated **Histologic analysis of axillary nodes** Standard processing and H&E.	**Age** Mean 51, range 28 to 75 years. **Tumour characteristics** Biopsy method Diagnosis established by FNA, CB or incisional or excisional biopsy. Size Not stated Stage American Joint Committee on Cancer Stage of all patients within study I 72/122 (59.0%) IIa 23/122 (18.9%) IIb 11/122 (9.0%) IIIa 9/122 (7.4%) IIIb 7/122 (5.7%) Stage of NC patients only IIa 8/32 (25.0%) IIb 9/32 (28.1%) IIIa 8/32 (25.0%) IIIb 7/32 (81.9%) Stage of NC patients only T0 Before NC: 0/31 (0%) After NC: 5/31 (16.1%) Tis Before NC: 0/31 (0%) After NC: 3/31 (9.7%) T1 Before NC: 0/31 (0%) After NC: 8/31 (25.8%) T2 Before NC: 9/31 (29.0%) After NC: 11/31 (35.5%) T3 Before NC: 16/31 (51.6%) After NC: 3/31 (9.7%) T4 Before NC: 6/31 (19.4%) After NC: 1/31 (3.2%) (Note: clinical tumour stage only given for patients in which sentinel node localisation was successful). Histology Not stated Location Not stated Palpability Not stated Multifocality/multicentricity Not stated **Axilla characteristics** Clinical axillary status FNA was performed on all patients with clinically positive axillary nodes, and a preoperative clinical stage was based on these results. N0 Before NC: 20/31 (64.5%) After NC: 27/31 (87.1%) N1 Before NC: 11/31 (34.5%) After NC: 4/31 (12.9%) (Note: clinical axillary status only given for patients with successful sentinel node localisation). **Neoadjuvant chemotherapy** 12/32 (37.5%) received 5-fluororocil, cyclophosphamide and doxorubicin for 4 cycles; 13/32 (40.6%) received doxorubicin and cyclophosphamide for 4 cycles; 7/32 (21.9%) received 175mg/m^2 paxlitaxel intravenously every 3 weeks for 3 cycles, followed by 60mg/m^2 paclitaxel intravenously twice a week for 6 weeks, and radiotherapy (46.8Gy over 6 weeks to the whole breast and supraclavicular fossa). Pathologic response to neoadjuvant therapy Complete 2/32 (6.3%) Major partial 25/32 (78.1%) Minor partial 3/32 (9.4%)

		Stable	2/32 (6.3%)	
		Downstaged	22/32 (68.8%)	

Study identifier	Procedure	Patient characteristics
Barnwell, Arredondo, Kollmorgen, Gibbs, Lamonica, Carson, Zhang, Winston & Edge, 1998. **Number of patients** 42 **Number of attempted mappings** 42 **Study period** October 1995 to January 1997 **Institution** Divisions of Surgical Oncology, Radiology and Pathology, Roswell Park Cancer Institute, State University of New York at Buffalo, Buffalo, New York, USA. **Incorporated studies** Sabel *et al.* 2001 **Inclusion/exclusion criteria** Inclusions: patients with T1 or T2 breast cancer for who a level I/II axillary clearance was recommended were offered enrolment in this study. Exclusions: pregnant women and women with multiple tumours were excluded. **Study included for review of……** Localisation rates and false negative rates	**Radiocolloid/dye combination** Radiocolloid only: 0 Dye only: 0 Radiocolloid and dye: 42 **Radiocolloid** Type: ^{99m}Tc-labelled sulphur colloid (mixed with dye). Dose: 1mCi/ml (1ml mixed with 2ml dye). Colloid size: not stated Filtration: filtered (0.22µm) Injection location: radiocolloid injected peritumourally into the breast parenchyma, 1ml into each of four quadrants. In case of excisional biopsy, the mixture was injected into the parenchyma immediately surrounding the cavity. For patients that underwent mammographic needle localisation, the mixture was injected at the same depth as the Kopan wire in four quadrants surrounding the wire. Injection timing: approximately 60 to 90 minutes before surgery. Massage: not stated Intraoperative probe: Neoprobe 1000 (Neoprobe Corporation, Dublin, OH, USA). **Dye** Type: isosulphan blue (Lymphazurin 1%; Ben Venue Laboratories Inc, Bedford, OH). Amount: 2ml Injection location: as for radiocolloid. Injection timing: as for radiocolloid. Massage: not stated **Preoperative lymphoscintigraphy** Timing: not stated **Surgery** Surgeon details: not stated Anaesthesia: general anaesthesia Axillary clearance: axillary clearance or mastectomy included levels I and II. Sentinel node definition: not stated Final breast procedure: mastectomy, 7/42 (16.7%); breast conserving, 35/42 (83.3%). **Histologic analysis of sentinel nodes** Frozen section: not stated Sectioning: all specimens were fixed in formalin, and nodes were identified and bisected and placed in paraffin blocks. One section taken from the cross section of each block. Permanent section: H&E IHC: not stated **Histologic analysis of axillary nodes** H&E	**Age** Median 51, range 33 to 81 years. **Tumour characteristics** Biopsy method Excisional biopsy: 21/42 (50.0%) Size Median 1.8, range 0.4 to 4.5cm Stage T1: 28/42 (66.7%) T2: 14/42 (33.3%) Histology Not stated Location UOQ: 22/42 (52.4%) UIQ: 10/42 (23.8%) LOQ: 6/42 (14.3%) LIQ: 2/42 (4.8%) Central: 2/42 (4.8%) Palpability Palpable and nonpalpable tumours were included. Multifocality/multicentricity Patients with multifocal tumours were excluded. **Axilla characteristics** Clinical axillary status Not stated **Neoadjuvant chemotherapy** Not stated

Study identifier	Procedure	Patient characteristics
Barranger, Grahek, Antoine, Montravers, Talbot & Uzan, 2003. **Number of patients** 32 **Number of attempted mappings** 32 **Study period** March 2001 to September 2001 **Institution** Departments of Gynaecologic and Breast Cancers, Nuclear Medicine and Pathology, Hôpital Tenon, Paris, France. **Incorporated studies** None **Inclusion/exclusion criteria** Inclusions: consecutive patients with malignant breast tumour and clinically negative axillary nodes were included. Exclusions: pregnancy, diabetes and neoadjuvant chemotherapy. **Study included for review of……** Localisation rates and false negative rates	**Radiocolloid/dye combination** Radiocolloid only: 0 Dye only: 4 Radiocolloid and dye: 28 **Radiocolloid** Type: ^{99m}Tc-labelled sulphur colloid (Nanocis, CIS Bio International) Dose: 30MBq per 0.2ml injection to a total of 120MBq. Colloid size: not stated Filtration: unfiltered Injection location: four peritumoural injections, made under US guidance when the tumour was not palpable. Injection timing: day before surgery. Massage: not stated Intraoperative probe: Gammed 2 (Eurorad, Strasbourg, France). **Dye** Type: patent blue dye (Bleu Patenté V, Guerbet Laboratory, Issy les Moulineaux, France). Amount: 2ml Injection location: subdermally above the tumour. Injection timing: after induction of general anaesthesia. Massage: breast massage for 3 minutes. **Preoperative lymphoscintigraphy** Timing: images were obtained 1 hour after radiocolloid injection, and then every 30 minutes until the sentinel node was visualised. **Surgery** Surgeon details: one surgeon (Barranger) participated in the study. Anaesthesia: general anaesthesia. Axillary clearance: lymph node dissection including levels I and II. Sentinel node definition: not stated Final breast procedure: breast conserving therapy 29/32 (90.6%); mastectomy 3/32 (9.4%). **Histologic analysis of sentinel nodes** Intraoperative analysis:: not stated Sectioning: each half sentinel node was sectioned at 3mm. Each 3mm section was analysed by four additional levels of 150µm. Permanent section: H&E (1 level) IHC: H&E negative sections were examined using and anticytokeratin antibody cocktail (AE1/AE3). Micrometastases definition: a single focus of metastatic disease per node, measuring no more than 2mm. **Histologic analysis of axillary nodes** H&E	**Age** Mean 58, range 29 to 77 years. **Tumour characteristics** Biopsy method Core needle biopsy or fine-needle aspiration. Size Mean 17.9, range 7 to 40 mm. Stage T0: 9/32 (28.1%) T1: 18/32 (56.3%) T2: 5/32 (15.6%) Histology Infiltrating ductal: 30/32 (93.8%) Infiltrating lobular: 2/32 (6.3%) Location Not stated Palpability Palpable: 23/32 (71.9%) Nonpalpable: 9/32 (28.1%) Multifocality/Multicentricity Not stated **Axilla characteristics** Clinical axillary status Negative: 31/32 (100.0%) **Neoadjuvant chemotherapy** Patients who had had neoadjuvant therapy were excluded.

Study identifier	Procedure	Patient characteristics
Bass, Dauway, Mahatme, Ku, Berman, Reintgen & Cox, 1999b **Number of patients** 700 (186 Phase I patients included for analysis of false negative rates). **Number of attempted mappings** 700 **Study period** April 1994 to April 1998 **Institution** Comprehensive Breast Cancer Program, H. Lee Moffitt Cancer Center and Research Institute, Tampa, Florida, USA. **Incorporated studies** Albertini *et al.* 1996; Bass *et al.* 1999a; Cox *et al.* 1998a **Study included for** False negative rates **Inclusion/exclusion criteria** Inclusions: patients with invasive breast cancer or high-grade DCIS comedo-type carcinoma. Exclusions: pregnant women, patients with multicentric tumours, clinically positive axillary nodes, previous breast surgery that could interfere with lymphatic drainage or allergies to isosulphan blue dye.	**Radiocolloid/dye combination** Radiocolloid only: 0 Dye only: 0 Radiocolloid and dye: 700 **Radiocolloid** Type: ^{99m}Tc-labelled sulphur colloid (Syncor International, Tampa, FL). Dose: 450μCi, in 6 cc of saline. Colloid size: not stated Filtration: filtered (0.2μm) Injection location: intraparenchymally in six aliquots at the periphery of the lesion or biopsy cavity. Injection timing: approximately 1 to 6 hours before surgery. Massage: not stated Intraoperative probe: Navigator System (US Surgical Corp., Norwalk, CT, USA). **Dye** Type: isosulphan blue dye (Lymphazurin blue dye, US Surgical Corp.). Amount: 5cc Injection location: injected intraparenchymally in approximately the same location as the radiocolloid. Injection timing: not stated Massage: not stated **Preoperative lymphoscintigraphy** Timing: not stated **Surgery** Surgeon details: not stated Anaesthesia: not stated Axillary clearance: complete axillary lymph node dissection after sentinel node biopsy. Sentinel node definition: any blue node and/or any hot node with an *ex vivo* radioactivity count ratio of SLN: nonSLN of 10:1 and/or *in vitro* radioactivity count ratio of SLN:background of 3:1. Final breast procedure: lumpectomy 516/700 (73.7%); mastectomy 184/700 (26.3%). **Histologic analysis of sentinel nodes** Intraoperative analysis:: not stated Sectioning: not stated Permanent section: not stated IHC: not stated Micrometastases definition: not stated **Histologic analysis of axillary nodes**	**Age** Mean 58.1 ± 13.2 years **Tumour characteristics** Biopsy method Not stated Size Not stated Stage T1a: 40/700 (5.7%) T1b: 156/700 (22.3%) T1c: 227/700 (32.4%) T2: 111/700 (15.9%) T3: 16/700 (2.3%) DCIS: 150/700 (21.4%) Histology Not stated Location Not stated Palpability Not stated Multifocality/multicentricity Patients with multicentric tumours were excluded. **Axilla characteristics** Clinical axillary status Negative: 700/700 (100%) **Neoadjuvant chemotherapy** Not stated

	Not stated	

Study identifier	Procedure	Patient characteristics
Bauer, Spitz, Callans, Alavi, Mick, Weinstein, Bedrosian, Fraker, Bauer & Czerniecki, 2002. **Number of patients** 332 (225 women from the University of Pennsylvania and 107 women form York Hospital). **Number of attempted mappings** 332 **Study period** April 1998 to July 2000 **Institution** Departments of Surgery, Nuclear Medicine, Radiology, Biostatistics and Epidemiology, School of Medicine, University of Pennsylvania, Philadelphia, Pennsylvania; Department of Surgery, York Hospital, York, Pennsylvania, USA. **Incorporated studies** Bedrosian *et al.* 2000; Reynolds *et al.* 1999 **Inclusion/exclusion criteria** Inclusions: biopsy-proven operable breast cancer or ductal carcinoma in situ and clinically negative axilla. Exclusions: none stated **Study included for review of……** Localisation rates	**Radiocolloid/dye combination** Radiocolloid only: 0 Dye only: 0 Radiocolloid and dye: 332 **Radiocolloid** Type: ^{99m}Tc-labelled sulphur colloid Dose: 1mCi in 6ml of saline at the University of Pennsylvania and 450µCi in 8ml of saline at York Hospital. Colloid size: not stated Filtration: filtered (0.22µm) Injection location: into the breast tissue around the primary tumour. University of Pennsylvania patients underwent injection by US guidance for lesions visible by US. Lesions not visible by US were injected by palpation or by needle localisation if nonpalpable. In York Hospital patients, US guidance was used in patients who had a previous excisional biopsy to avoid injection of colloid into the biopsy cavity, whereas patients with nonpalpable, needle-localised tumours underwent peritumoural injection without US guidance. Injection timing: on the day of surgery. Massage: not stated Intraoperative probe: gamma detecting probe (US Surgical Corp., Norwalk, CT, USA). **Dye** Type: 1% Lymphazurin™ blue dye. Amount: see below Injection location: 83 patients (from April to November 1998; Group 1) were injected peritumourally (4 to 6ml in four quadrants around the primary tumour site). For patients with prior excisional biopsy, blue dye was injected adjacent to the biopsy cavity. 249 patients (from November 1998 to July 2000; Group 2) were injected with 3 to 4ml Lymphazurin™ in the subareolar location. Injection timing: not stated Massage: breast massage was used in some patients who underwent peritumoural injection. **Preoperative lymphoscintigraphy** Timing: 1 to 2 hours after injection of radiocolloid (for patients at the University of Pennsylvania only). **Surgery** Surgeon details: not stated Anaesthesia: not stated Axillary clearance: a level I and II axillary clearance was performed if no sentinel node was identified or if a sentinel node was positive for metastases. Sentinel node definition: blue or if the node had *in vivo* counts of at least three times the background counts of the axilla, or both. Final breast procedure: lumpectomy/re-excisions 228/332 (68.7%); mastectomy 46/332 (13.9%); no additional excision 58/332 (17.5%). **Histologic analysis of sentinel nodes** Intraoperative analysis:: not stated Sectioning: not stated. Permanent section: formalin fixed and paraffin embedded and stained with H&E. IHC: with a cytokeratin antibody (AE1/AE3). Micrometastases definition: not stated	**Age** Group 1 (peritumoural dye injection): median 55, range 28 to 84 years. Group 2 (subareolar dye injection): median 55, range 29 to 88 years. **Tumour characteristics** Biopsy method Group 1: FNA/CB 39/83 (47.0%); Excisional 44/83 (53.0%) Group 2: FNA/CB 135/249 (54.2%); Excisional 114/249 (45.8%) Size Not stated Stage Group 1: Tis 12/83 (14.5%); T1a 7/83 (8.4%); T1b 17/83 (20.5%); T1c 31/83 (37.3%); T2 14/83 (16.9%); T3 2/83 (2.4%) Group 2: Tis 34/249 (13.7%); T1a 25/249 (10%); T1b 52/249 (20.9%); T1c 85/249 (34.1%); T2 44/249 (17.7%); T3 9/249 (3.6%) Histology Group 1: Invasive ductal 59/83 (71.1%); Invasive lobular 9/83 (10.8%); Other invasive 3/83 (3.6%); DCIS 12/83 (14.5%) Group 2: Invasive ductal 173/249 (69.5%); Invasive lobular 28/249 (11.2%); Other invasive 14/249 (5.6%); DCIS 34/249 (13.7%) Location Group 1: UOQ 56/83 (67.5%); UIQ 4/83 (4.8%); LOQ 7/83 (8.4%); LIQ 3/83 (3.6%); Central 13/83 (15.7%) Group 2: UOQ 130/249 (52.2%); UIQ 35/249 (14.1%); LOQ 21/249 (8.4%); LIQ 24/249 (9.6%); Central 35/249 (14.1%) Palpability Palpable and nonpalpable Multifocality/multicentricity Four patients (1.6%) from the subareolar dye injection group (Group 2) had multicentric carcinoma. **Axilla characteristics** Clinical axillary status Negative: 332/332 (100%) **Neoadjuvant chemotherapy**

	Histologic analysis of axillary nodes H&E	Not stated

Study identifier	Procedure	Patient characteristics
Beitsch, Clifford, Whitworth & Abarca, 2001. **Number of patients** 85 **Number of attempted mappings** 85 **Study period** December 1997 to March 1998 **Institution** General Surgery Department, St Paul Medical Center, Dallas, Texas, USA. **Incorporated studies** None **Inclusion/exclusion criteria** Inclusions: patients with operable breast cancer, documented by core or excisional biopsy and clinically negative axillary lymph nodes. Exclusions: patients with multiple primaries, prior axillary dissection, prior radiation therapy or pregnancy. **Study included for review of……** Localisation rates	**Radiocolloid/dye combination** Radiocolloid only: 0 Dye only: 0 Radiocolloid and dye: 85 **Radiocolloid** Type: ^{99m}Tc-labelled sulphur colloid Dose: 1.0mCi in 2ml of normal saline Colloid size: not stated Filtration: unfiltered Injection location: injected in Sappey's subareolar plexus in the clock position of the tumour. Injection timing: 30 minutes to 4.5 hours before surgery, median 1.75 hours. Massage: not stated Intraoperative probe: C-trak or Neoprobe. **Dye** Type: isosulphan blue (1%) Amount: 2 to 5cc Injection location: peritumoural, for patients with a prior excisional biopsy, the injection was performed under US guidance into the biopsy cavity walls. Injection timing: after adequate anaesthesia. Massage: breasts were massaged for several minutes prior to any incision. **Preoperative lymphoscintigraphy** Timing: routinely performed, timing not stated. **Surgery** Surgeon details: there were three surgeons involved in the trial in two different cities. Anaesthesia: 'adequate anaesthesia' Axillary clearance: patients underwent a complete axillary lymph node dissection at the time if the sentinel node was confirmed to contain metastasis. Any patient with metastatic disease in their sentinel lymph node on permanent section were brought back to theatre for complete axillary clearance. Sentinel node definition: blue and/or radioactive nodes. Final breast procedure: breast conserving 91% (percentage given as patient numbers were not stated). **Histologic analysis of sentinel nodes** Intraoperative analysis:: not stated Sectioning: serial section Permanent section: not stated IHC: immunostains performed. Micrometastases definition: not stated **Histologic analysis of axillary nodes** Routine surgical pathologic techniques.	**Age** Median 58, range 35 to 82 years. **Tumour characteristics** Biopsy method Core biopsy 84% Excisional biopsy 16% Note: Percentages given as patient numbers were not stated. 24/85 (28.2%) of patients had a previous or current upper outer quadrant breast biopsy. Size Median 2.1, range 0.1 to 6cm Stage Not stated Histology Invasive ductal 87% Invasive lobular 8% Medullary 1% DCIS 4% Note: Percentages given as patient numbers were not stated. Location UOQ 50/85 (58.8%) UIQ 15/85 (17.6%) LOQ 8/85 (9.4%) LIQ 4/85 (4.7%) Central 8/85 (9.4%) Palpability Palpable 42/85 (49.4%) Nonpalpable 43/85 (50.6%) Multifocality/multicentricity Patients with multiple primary tumours were excluded. **Axilla characteristics** Clinical axillary status Negative 85/85 (100%) **Neoadjuvant chemotherapy** Not stated

Study identifier	Procedure	Patient characteristics
Bembenek, Reuhl, Markwardt, Schneider & Schlag, 1999. **Number of patients** 146 (4 male) **Number of attempted mappings** 146 **Study period** November 1995 to March 1999 **Institution** Sugery and Surgical Oncology, Nuclear Medicine and Pathology, Robert-Rössle-Klinik, Universitätsklinikum Charité, Berlin, Germany. **Incorporated studies** None **Study included for review of..…** Localisation rates **Inclusion/exclusion criteria** Inclusions: patients with invasive breast cancer. Note: 9 patients had recurrent tumours after breast conserving surgery. Exclusions: none stated	**Radiocolloid/dye combination** Radiocolloid only: 146 Dye only: 0 Radiocolloid and dye: 0 **Radiocolloid** Type: ^{99m}Tc-labelled colloid (Nanocoll®). Dose: 0.5 to 1ml, dose not stated. Colloid size: not stated Filtration: not stated Injection location: injected into the parenchyma surrounding the tumour, if the tumour was not palpable, the injection was performed under ultrasound guidance. Injection timing: 17 hours before surgery. Massage: not stated Intraoperative probe: type not stated. **Dye** Dye was not used. Type: not applicable Amount: not applicable Injection location: not applicable Injection timing: not applicable Massage: not applicable **Preoperative lymphoscintigraphy** Timing: 17 hours after radiocolloid injection, just before surgery. **Surgery** Surgeon details: not stated Anaesthesia: not stated Axillary clearance: standard axillary dissection, including levels I and II. Sentinel node definition: not stated Final breast procedure: not stated **Histologic analysis of sentinel nodes** Frozen section: not stated Sectioning: 2 to 6 serial sections. Permanent section: H&E IHC: if H&E section was negative, IHC with an anticytokeratin (antiCK-19) antibody was performed. Micrometastases definition: not stated **Histologic analysis of axillary nodes** Not stated	**Age** Not stated **Tumour characteristics** Biopsy method Not stated Size <table><tr><td><1cm</td><td>16/146 (11.0%)</td></tr><tr><td>1 to 3cm</td><td>88/146 (60.3%)</td></tr><tr><td>3 to 5cm</td><td>23/146 (15.8%)</td></tr><tr><td>>5cm</td><td>19/146 (13.0%)</td></tr></table> Stage <table><tr><td>pT1 to pT2</td><td>127/146 (87.0%)</td></tr><tr><td>pT4</td><td>19/146 (13.0%)</td></tr></table> Histology Not stated Location Not stated Palpability Palpable and nonpalpable Multifocality/multicentricity Not stated **Axilla characteristics** Clinical axillary status Not stated **Neoadjuvant chemotherapy** 2/146 (1.4%) underwent neoadjuvant radiochemotherapy for histopathologically advanced breast cancer.

Study identifier	Procedure	Patient characteristics
Bergkvist, Frisell, Liljegren, Celebioglu, Damm & Thörn, 2001. **Number of patients** 498 (17 participating hospitals) **Number of attempted mappings** 498 **Study period** August 1997 and December 1999 **Institution** Department of Surgery and Centre for Clinical Research, Uppsala University; Department of Clinical Physiology and Nuclear Medicine, Central Hospital, Västerås; Department of Surgery, Huddinge University Hospital, Stockholm; Department of Surgery and Centre for Assessment of Medical Technology, University Hospital, Örebro; Department of Surgery and Centre for Clinical Research, Central Hospital, Västerås, Sweden. **Incorporated studies** Frisell *et al.* 2001 **Inclusion/exclusion criteria** Inclusions: patients with operable unifocal breast cancer, T1 to T3, without suspicious palpable axillary lymph nodes and scheduled to have an operation that included axillary dissection. Exclusions: patients with multicentric or multifocal tumours on preoperative mammography, those who previously had undergone breast biopsy or who had received preoperative radiotherapy or systemic therapy. **Study included for review of……** Localisation rates and false negative rates	**Radiocolloid/dye combination** Radiocolloid only: unsure Dye only: unsure Radiocolloid and dye: 465 **Radiocolloid** Type: ^{99m}Tc-labelled colloid (Solco Nanocoll® or Albures®; Nycomed, Amersham, UK). Dose: 40MBq Colloid size: not stated Filtration: not stated Injection location: peritumourally, subcutaneously, intradermally or a combined technique. Injection timing: patients were injected either on the same day or the day before surgery, with the maximum interval between radiocolloid injection and surgery being 27 hours. Massage: not stated Intraoperative probe: Navigator®, (USS Corporation, Norwalk, CT, USA); Neo-Probe®, (Neoprobe Corporation, Dublin, OH, USA); C-Trac®, (Care Wise Medical Products, Morgan Hill, CA, USA); Europrobe®, (Eurorad, Sevres, France); Crystal Probe®, (Nuclear Fields System, Des Plaines, IL, USA). **Dye** Type: Patent Blue V® (Guerbet, Paris, France). Amount: 1ml Injection location: peritumourally, subcutaneously, intradermally or a combined technique. Injection timing: immediately before surgery. Massage: not stated **Preoperative lymphoscintigraphy** Timing: immediately after injection of radiocolloid and then after approximately 60 minutes. If a sentinel node was not identified, another image was taken after 2 to 3 hours. Imaging techniques may have varied between centres. **Surgery** Surgeon details: not stated Anaesthesia: not stated Axillary clearance: a level I and II axillary dissection was performed after the removal of sentinel nodes. Sentinel node definition: a blue node or a node with radioactivity (or both). Final breast procedure: breast conserving 80% (percentage give as patient numbers were not stated). **Histologic analysis of sentinel nodes** Intraoperative analysis:: not stated Sectioning: sentinel nodes were bisected if larger than 4mm and each part was embedded and sectioned. Permanent section: H&E or Van Gieson staining. If metastases were not detected, a further two to three sections were examined after staining with both H&E and Van Gieson stains. IHC: if no metastases were detected by the original permanent section, sections were examined with cytokeratin antibodies (type of antibodies varied between laboratories). Micrometastases definition: not stated **Histologic analysis of axillary nodes** Routine staining.	**Age** Not stated **Tumour characteristics** Biopsy method Patients with previous breast biopsy were excluded. Size Mean 20, median 18, range 1 to 100mm. Stage T1 to T3 Histology Not stated Location Not stated Palpability Not stated Multifocality/multicentricity Patients that had multifocal or multicentric carcinoma on preoperative mammography were excluded. Multifocal tumours were found intraoperatively; pathological examination revealed foci of tumour tissue at some distance from the original tumour, not seen on preoperative mammography. **Axilla characteristics** Clinical axillary status Negative: 498/498 (100%) **Neoadjuvant chemotherapy** Patients that received preoperative systemic therapy were excluded.

Study identifier	Procedure	Patient characteristics
Birdwell, Smith, Betts, Ikeda, Strauss & Jeffrey, 2001. **Number of patients** 136 **Number of attempted mappings** 136 **Study period** February 1997 to January 2000 **Institution** Departments of Radiology, Health Research and Policy Division of Biostatistics, and Surgery, Stanford University Medical Center, Stanford, California, USA. **Incorporated studies** None **Inclusion/exclusion criteria** Inclusions: patients with breast cancer. Exclusions: 19/155 women originally invited were excluded due to incomplete surgical records (n=8), preoperative chemotherapy (n=5), lesion size >5cm in maximum diameter (n=3), subareolar injection site prescribed by a different trial (n=2), or clinically positive axillary nodes (n=1). **Study included for review of……** Localisation rates	**Radiocolloid/dye combination** Radiocolloid only: 37 Dye only: 11 Radiocolloid and dye: 88 **Radiocolloid** Type: ^{99m}Tc-labelled sulfur colloid Dose: 29.6 to 37.0MBq (800 to 1000μCi). Colloid size: not stated Filtration: filtered Injection location: four equal doses were injected around the periphery of the tumour or biopsy cavity at the 12-, 3-, 6- and 9-o'clock position within 1cm of the tumour or cavity edge. Injection was guided by either tumour or cavity palpation or with imaging (US or radiographic). Injection timing: not stated Massage: patient gently massaged whole breast. Intraoperative probe: Neoprobe 1500 and 2000 (Neoprobe, Dublin, Ohio); Navigator (US Surgical, Norwalk, CT). **Dye** Type: isosulphan blue dye (1%; Lymphazurin; US Surgical) Amount: 4 to 5ml Injection location: injected around the margins of the tumour or biopsy cavity. Injection timing: not stated Massage: not stated **Preoperative lymphoscintigraphy** Timing: immediately following injection and up to 6 hours afterward. **Surgery** Surgeon details: surgical procedures were performed by three surgeons (including Jeffrey). Anaesthesia: not stated Axillary clearance: of 136 patients, 120 who had invasive breast cancer underwent level I and II axillary dissection, five patients with DCIS only and 11 patients who had small invasive tumours underwent sentinel lymph node biopsy only. Sentinel node definition: identified by radioactivity using the gamma probe, with visualisation of a bright blue node, a blue lymphatic track leading directly to a lymph node, or both. Final breast procedure: not stated **Histologic analysis of sentinel nodes** Intraoperative analysis: frozen sectioning was not performed. Sectioning: serial sectioning Permanent section: H&E IHC: if H&E was negative, cytokeratin immunostaining was performed. Micrometastases definition: not stated **Histologic analysis of axillary nodes** The remainder of the axillary nodes were	**Age** Mean 54.1, range 29 to 81 years. **Tumour characteristics** Biopsy method FNA: 30/136 (22.1%) CB: 58/136 (42.6%) Excisional: 46/136 (33.8%) Incisional: 2/136 (1.5%) Size ≤2cm: 82/136 (60.3%) >2cm to 5cm: 42/136 (30.9%) >5cm: 2/136 (1.5%) Not stated (DCIS): 10/136 (7.4%) Stage T1: 82/136 (60.3%) T2: 42/136 (30.9%) T3: 2/136 (1.5%) DCIS: 10/136 (7.4%) Histology Invasive carcinoma: 126/136 (92.6%) DCIS: 10/136 (7.4%) Location UOQ: 63/136 (46.3%) UIQ: 16/136 (11.8%) LOQ: 8/136 (5.9%) LIQ: 14/136 (10.3%) Central portion: 24/136 (17.6%) Medial portion: 3/136 (2.2%) Lateral portion: 8/136 (5.9%) Palpability Palpable: 62/136 (45.6%) Nonpalpable: 74/136 (54.4%) Multifocality/multicentricity Not stated **Axilla characteristics** Clinical axillary status Negative: 136/136 (100%) **Neoadjuvant chemotherapy** Patients that had had neoadjuvant chemotherapy were excluded.

	processed in a standard bivalved fashion without serial sectioning or immunostaining.	

Study identifier	Procedure	Patient characteristics
Blessing, Stolier, Teng, Bolton & Fuhrman, 2002. **Number of patients** 199 **Number of attempted mappings** 199 **Study period** April 1 2001 to March 31 2002 **Institution** Department of Surgery, Ochsner Clinic Foundation, New Orleans, Louisiana, USA. **Incorporated studies** None **Inclusion/exclusion criteria** Inclusions: patients with clinically negative axillae with T1 and T2 breast cancer. The use of sentinel lymph node mapping inpatients with intraductal carcinoma was reserved for patients undergoing mastectomy or patients diagnosed by image-guided core needle biopsy with an associated mass on breast imaging. Exclusions: patients that had prior neoadjuvant chemotherapy or radiotherapy. **Study included for review of……** Localisation rates	**Radiocolloid/dye combination** Radiocolloid only: 0 Dye only: 0 Radiocolloid and dye: 199 **Radiocolloid** Type: not stated Dose: not stated Colloid size: not stated Filtration: not stated Injection location: injection technique varied among the four surgeons at the institution. Techniques included a four-injection peritumoural technique, and a 1cc subcutaneous injection directly overlying the tumour. Injection timing: not stated Massage: not stated Intraoperative probe: not stated **Dye** Type: 87 patients received lymphzurin (Group 1) and 112 patients received methylene blue (Group 2); patients were evaluated with methylene blue dye, between August 15 and December 17, as lymphzurin was not available in the institution, but during the final 3.5 months of the study, the choice of dye was left to the discretion of the surgeon. Amount: 3 to 5cc Injection location: injected peritumourally (3cc was injected when the tumour was located in the UOQ of a small sized breast and 5cc was used for all other cases). Injection timing: injected after intravenous sedation or general anaesthesia was achieved. Massage: a 5 minute breast massage followed the injection. **Preoperative lymphoscintigraphy** Timing: preoperative lymphoscintigraphy was not performed. **Surgery** Surgeon details: four surgeons participated in the study. Anaesthesia: intravenous sedation or general anaesthesia. Axillary clearance: not performed on all patients. Sentinel node definition: the definition of a radioactive or hot node was a node that has a gamma probe count that is 10 times the background count in the axilla, or 10% of the count in the most radioactive node. A node was defined as sentinel if it contains blue dye or has a blue-stained lymphatic channel leading to it. Final breast procedure: not stated **Histologic analysis of sentinel nodes** Intraoperative analysis:: if axillary clearance was planned at the current operation, touch preparation cytology was performed. If the touch preparation was negative, a frozen section was examined. Serial sectioning: see below Permanent section: if axillary clearance for a positive node was to be deferred to a second operation or the intraoperative examination was negative, the nodes were examined by serial section, with at least three levels examined with H&E. IHC: IHC staining for cytokeratins was performed if routine histology was negative. Nodes were considered positive if more than a single cytokeratin stained cell was identified in the sentinel node. Micrometastases definition: not stated	**Age** Group 1: 61.2 years Group 2: 57.7 years (No significant differences between groups, p>0.05). **Tumour characteristics** Biopsy method Not stated Size Group 1: 1.43cm Group 2: 1.45cm (No significant differences between groups, p>0.05). Stage T1 or T2 Histology Group 1: intraductal 8/87 (9.2%) Group 2: intraductal 7/112 (6.3%) (No significant differences between groups, p>0.05). Location Not stated Palpability Not stated Multifocality/multicentricity Not stated **Axilla characteristics** Clinical axillary status Negative: 199/199 (100%) **Neoadjuvant chemotherapy** Patients that had had neoadjuvant chemotherapy were excluded.

	Histologic analysis of axillary nodes Not stated	

Study identifier	Procedure	Patient characteristics
Bobin, Zinzindohoue, Isaac, Saadat & Roy, 1999. **Number of patients** 100 **Number of attempted mappings** 100 **Study period** January 1997 to July 1997 **Institution** Department of Surgical Oncology and Pathology of Oncological Methology, Centre Hospitalier, Pierre Bénite Cedex, France. **Incorporated studies** None **Inclusion/exclusion criteria** Inclusions: patients with breast cancer when either mastectomy or lumpectomy was indicated. Exclusions: patients with *in situ* multicentric or multifocal cancers, or who had relapsed after previous breast conservative surgery. **Study included for review of……** Localisation rates and false negative rates	**Radiocolloid/dye combination** Radiocolloid only: 0 Dye only: 100 Radiocolloid and dye: 0 **Radiocolloid** Radiocolloid was not used. Type: not applicable Dose: not applicable Colloid size: not applicable Filtration: not applicable Injection location: not applicable Injection timing: not applicable Massage: not applicable Intraoperative probe: not applicable **Dye** Type: Evans clue dye (Pharmacie des Hôpitaux de Paris). Amount: 5ml Injection location: injected into the tissue surrounding the tumour. Injection timing: not stated Massage: the breast was massaged for 8-10 minutes. **Preoperative lymphoscintigraphy** Timing: not stated **Surgery** Surgeon details: all operations were performed by the senior surgeon (Bobin). Anaesthesia: not stated Axillary clearance: a standard level I and II (or level II in the presence of visibly suspicious nodes) was performed on all patients. The interpectoral lymph node (Rotter's node) was always explored. Sentinel node definition: blue stained lymphatics and/or blue node. Final breast procedure: mastectomy 62/100 (62.0%); breast conserving 22/100 (22.0%). **Histologic analysis of sentinel nodes** Intraoperative analysis: frozen section was not performed. Sectioning: nodes were fixed in Bouin fluid and after 24 hours they were cut into 3mm sections, embedded in paraffin. Permanent section: stained with haematoxylin-phloxin-saffron (HPS). IHC: if no malignancy was noted, IHC was performed with cytokeratin (KL1). Micrometastases definition: not stated **Histologic analysis of axillary nodes** Haematoxylin-phloxin-saffron (HPS).	**Age** Median 50.5, range 30 to 82 years **Tumour characteristics** Biopsy method Invasive cancer was diagnosed either by preoperative microbiopsy, FNA or excisional biopsy and frozen sections before sentinel node biopsy. Size Not stated Stage T0: 13/100 (13.0%) T1: 45/100 (45.0%) T2: 27/100 (27.0%) T3: 8/100 (8.0%) T4: 5/100 (5.0%) Tx: 2/100 (2.0%) Histology Ductal: 85/100 (85.0%) Lobular: 9/100 (9.0%) Miscellaneous: 6/100 (6.0%) Location UOQ: 33/100 (33.0%) Upper median/central: 7/100 (7.0%) UIQ: 22/100 (22.0%) Central: 11/100 (11.0%) LOQ: 21/100 (21.0%) Lower median/central: 3/100 (3.0%) LIQ: 3/100 (3.0%) Palpability Not stated Multifocality/multicentricity Patient with multicentric or multifocal tumours were excluded. **Axilla characteristics** Clinical axillary status N0-N1a: 94/100 (94%) N1b: 6/100 (6%) **Neoadjuvant chemotherapy** 16 patients with inflammatory cancers receive neoadjuvant chemotherapy after (therefore no neoadjuvant) axillary clearance.

Study identifier	Procedure	Patient characteristics
Borgstein, Meijer, Pijpers & van Diest, 2000. **Number of patients** 217 (1 male) **Number of attempted mappings** 220 (3 bilateral) **Study period** September 1996 to April 1999 **Institution** Departments of Surgical Oncology, Nuclear Medicine and Pathology, Academic Hospital of the Vrije Universiteit, Amsterdam, The Netherlands. **Incorporated studies** Borgstein *et al.* 1997; Borgstein *et al.* 1998; Pijpers *et al.* 1997 **Inclusion/exclusion criteria** Inclusions: consecutive patients with clinical stage T1 to T2, N0 breast cancer. Exclusions: patients with palpable axillary nodes, large tumours (>5cm), multifocal disease, prior radiation therapy, or extensive surgery to the breast or axilla, and pregnant women. **Study included for review of……** Localisation rates	**Radiocolloid/dye combination** Radiocolloid only: 0 Dye only: 0 Radiocolloid and dye: 220 **Radiocolloid** Type: ^{99m}Tc-labelled colloidal albumin (Nanocoll; Sorin Biomedica, Saluggia, Italy) Dose: 40 to 60MBq in 4ml saline Colloid size: not stated Filtration: not stated Injection location: peritumoural in two to four depots surrounding the primary tumour guided by palpation, or adjacent to the biopsy scar. For nonpalpable lesions, stereotatic or US guidance was used. Injection timing: day before surgery. Massage: not stated Intraoperative probe: C-track (Care Wise, Morgan Hill, CA, USA). **Dye** Type: Patent Blue V (2.5%; Laboratoire Guebet, Aulnay-sous-Bois, France). Amount: 0.5 to 1ml Injection location: intradermally, in the skin directly overlying the corresponding tumour site in group 1 and in a consective group of patients, group 2, intracutaneous injection was consistenly placed along the lateral border of the areola, irrespective of the tumour location. Injection timing: after induction of general anaesthesia, 5 minutes before incision. Massage: the injection site was gently massaged for 5 minutes. **Preoperative lymphoscintigraphy** Timing: lymphscintigraphy was performed 2 and 18 hours after radiocolloid injection. **Surgery** Surgeon details: not stated Anaesthesia: general anaesthesia Axillary clearance: the initial study design required SLNB to be followed by a full (level I to III) axillary clearance; this procedure adapted during the study. Since November 1997, axillary clearance performed if: SLNB failed; there were metastases; or any doubts concerning the reliability of the procedure. Sentinel node definition: blue nodes, and radioactive nodes that were >50% of the highest count rate. Final breast procedure: lumpectomy 170/220 (77.3%); mastectomy 50/220 (22.7%) **Histologic analysis of sentinel nodes** Intraoperative analysis: intraoperative analysis via frozen section. Sectioning: nodes <0.5cm embedded whole, 0.5 to 1cm halved and >1cm cut into ±0.5cm slices. Five level skip sectioning. Permanent section: H&E IHC: IHC using CAM 5.2 antibodies. Micrometastases definition: not stated	**Age** Mean 56 ±12(SD), range 31 to 87 years Group 1: Mean 57 ±12 (SD), range 31 to 87 years. Group 2: Mean 55 ±12 (SD), range 31 to 87 years. **Tumour characteristics** Biopsy method {table} Size Mean 1.9 ±1.0 (SD). Stage {table} 208 invasive cancers, 4 tumours were benign, 8 were pure DCIS Histology {table} * DCIS with microinvasion in two tumours Location {table} Palpability {table} Multifocality/multicentricity Patients with mutifocal tumours were excluded. **Axilla characteristics** Clinical axillary status {table} **Neoadjuvant chemotherapy** Not stated

	Group 1	Group 2	Total
Excisional biopsy	13/90 (14.4%)	34/130 (26.2%)	47/220 (21.4%)

	Group 1	Group 2	Total
T1a-b	16/88 (18.2%)	24/120 (20.0%)	40/208 (19.2%)
T1c	45/88 (51.1%)	57/120 (47.5%)	102/208 (49.0%)
T2+	27/88 (30.7%)	39/120 (32.5%)	66/208 (31.7%)

	Group 1	Group 2	Total
Benign	1/90 (1.1%)	3/130 (2.3%)	4/220 (1.8%)
DCIS	1/90 (1.1%)	7/130 (5.4%)	8/220 (3.6%)
Ductal*	68/90 (75.6%)	96/130 (7.4%)	164/220 (74.5%)
Lobular	13/90 (14.4%)	9/130 (6.9%)	22/220 (10.0%)
Other	7/90 (7.8%)	15/130 (11.5%)	22/220 (10.0%)

UOQ	114/220 (51.8%)
UIQ	31/220 (14.1%)
LOQ	35/220 (15.9%)
LIQ	13/220 (5.9%)
Central	27/220 (12.3%)

	Group 1	Group 2	Total
Non-palpable	14/90 (15.6%)	23/130 (17.7%)	37/220 (16.8%)

Negative	220/220 (100%)

	Histologic analysis of axillary nodes H&E	

Study identifier	Procedure	Patient characteristics
Bourgeois, Nogaret, Veys, Hertens, Dagnelie, Vanhaudenaerde, Verdebout & Larsimont, 2003b. **Number of patients** 181 **Number of attempted mappings** 181 **Study period** October 1997 to July 2001 **Institution** Services of Nuclear Medicine, Surgery, Pathology and Radiology, Institut Jules Bordet, Université, Libre de Bruxelles, Brussels, Belgium. **Incorporated studies** None **Inclusion/exclusion criteria** Inclusions: patients with invasive breast cancer as proven by biopsy, or for highly suspicious mammary lesions detected by radiological techniques. Exclusions: none stated **Study included for review of..…** Localisation rates	**Radiocolloid/dye combination** Radiocolloid only: 181 Dye only: 0 Radiocolloid and dye: 0 **Radiocolloid** Type: ^{99m}Tc-labelled human serum albumin (Nanocoll®, Sorin). Dose: 0.2mL per site, total activity 296MBq. Colloid size: not stated Filtration: not stated Injection location: four intramammary and peritumoural injections. Injection timing: not stated Massage: not stated Intraoperative probe: Navigator® **Dye** Dye was not used. Type: not applicable Amount: not applicable Injection location: not applicable Injection timing: not applicable Massage: not applicable **Preoperative lymphoscintigraphy** Timing: 2 to 18 hours after radiocolloid injection. **Surgery** Surgeon details: not stated Anaesthesia: not stated Axillary clearance: complete axillary dissection was performed. Sentinel node definition: all radioactive foci removed. Final breast procedure: tumourectomy or mammectomy, numbers not stated. **Histologic analysis of sentinel nodes** Intraoperative analysis: not stated Sectioning: serial sectioning used when H&E staining was negative. Permanent section: H&E IHC: used when H&E negative. Micrometastases definition: metastases with a diameter <2mm. **Histologic analysis of axillary nodes** Not stated	**Age** Mean 54.05, range 28 to 77 years. **Tumour characteristics** Biopsy method Not stated Size T2 diameter <31mm. Stage T0: 24/181 (13.3%) T1: 107/181 (59.1%) T2: 46/181 (25.4%) Size not determined: 4/181 (2.2%) Histology Not stated Location Not stated Palpability Palpable: 157/181 (86.7%) Nonpalpable: 24/181 (13.3%) Multifocality/multicentricity Lesions not multifocal in any of the cases. **Axilla characteristics** Clinical axillary status N0: 168/181 (92.8%) N1a: 13/181 (7.2%) N1a = inflammatory nodes **Neoadjuvant chemotherapy** Not stated

Study identifier	Procedure	Patient characteristics
Bourgeois, Nogaret, Veys, Hertens, Noterman, Dagnelie, Vanhaudenarde, Barette & Larsimont, 2003a. **Number of patients** 393 **Number of attempted mappings** 393 **Study period** October 1997 to 1st December 2001 **Institution** Services of Nuclear Medicine and Radiology, Departments of Surgery and Pathology, and Data Centre Institut Jules Bordet, Université Libre de Bruxelles, Brussels, Belgium. **Incorporated studies** None **Inclusion/exclusion criteria** Inclusions: patients with biopsy proven invasive breast cancer or highly suspicious mammary lesions by radiological techniques. Exclusions: none stated **Study included for review of……** False negative rates	**Radiocolloid/dye combination** Radiocolloid only: 393 Dye only: 0 Radiocolloid and dye: 0 **Radiocolloid** Type: ^{99m}Tc-labelled human serum albumin (Nanocoll ®; Solmed). Dose: 0.2mL per site, total activity 296 MBq (for 366/393 (93.1%) cases); single 0.4mL injection, total activity 148MBq (for 27/393 (6.9%) cases). Colloid size: not stated Filtration: not stated Injection location: patients were given four intraparenchymatous and peritumoural injections. For patients with an unpalpable tumour or where a radiologist was not available (n=28), one intradermal and paratumoural injection given. Injection timing: day before surgery. Massage: not stated Intraoperative probe: Navigator® **Dye** Dye was not used Type: not spplicable Amount: not applicable Injection location: not applicable Injection timing: not applicable Massage: not applicable **Preoperative lymphoscintigraphy** Timing: images taken 2 to 18 hours following radiocolloid injection (most between 3 and 6 hours after radiocolloid injection). **Surgery** Surgeon details: not stated Anaesthesia: not stated Axillary clearance: complete axillary node dissection. Sentinel node definition: not stated Final breast procedure: tumourectomy or mastectomy, numbers not stated. **Histologic analysis of sentinel nodes** Intraoperative analysis:: not stated Sectioning: serial section was performed if H&E negative. Permanent section: routine H&E staining. IHC: performed if H&E negative. Micrometastases definition: not stated **Histologic analysis of axillary nodes** Routine H&E staining.	**Age** Mean 54.05, range 25 to 83 years. **Tumour characteristics** Biopsy method Excisional biopsy: 31/393 (7.9%) Size T2 diameter < 31mm Stage T0: 71/393 (18.1%) T1: 212/393 (53.9%) T2: 100/393 (25.4%) Size not determined: 8/393 (2.0%) Not stated: 2/393 (0.5%) Histology Not stated Location Not stated Palpability Palpable: 366/393 (93.1%) Nonpalpable: 27/393 (6.9%) Multifocality/multicentricity Multifocality was observed in none of the cases. **Axilla characteristics** Clinical axillary status N0: 264*/393 (67.2%) N1a: 27/393 (6.9%) Not stated: 2/393 (0.5%) * includes 8 patients where size not specified N1a = inflammatory nodes **Neoadjuvant chemotherapy** Not stated

Study identifier	Procedure	Patient characteristics
Brady, 2002. **Number of patients** 14 **Number of attempted mappings** 14 **Study period** February 1998 to July 2000 **Institution** The Partnership for Breast Care, Connecticut Surgical Group, Hartford, Connecticut, USA. **Incorporated studies** None **Inclusion/exclusion criteria** Inclusions: consecutive women who underwent neoadjuvant chemotherapy as treatment for invasive breast carcinoma, determined by core tissue biopsy. Exclusions: none stated **Study included for review of……** Localisation rates and false negative rates	**Radiocolloid/dye combination** Radiocolloid only: 0 Dye only: 13 Radiocolloid and dye: 1 (final patient). **Radiocolloid** Type: ^{99m}Tc- sulfur colloid Dose: 1mCi diluted in 4cc of normal saline. Colloid size: not stated Filtration: unfiltered Injection location: injected into the subareolar region. Injection timing: approximately 90 minutes before surgery. Massage: not stated Intraoperative probe: not stated **Dye** Type: 1% lymphazurin blue dye. Amount: 4cc (1cc per injection). Injection location: injected peritumourally (12, 3, 6 and 9o'clock; 1cc per injection) into the breast parenchyma. Injection timing: at the time of surgery. Massage: gentle massage was performed for 10 to 15 minutes. **Preoperative lymphoscintigraphy** Timing: not performed **Surgery** Surgeon details: a single surgeon performed all procedures. Anaesthesia: not stated Axillary clearance: all patients underwent complete axillary dissection. Sentinel node definition: not stated Final breast procedure: breast conserving 7/14 (50.0%); mastectomy 7/14 (50.0%) **Histologic analysis of sentinel nodes** Intraoperative analysis: not stated Sectioning: not stated Permanent section: H&E IHC: cytokeratin Micrometastases definition: not stated **Histologic analysis of**	**Age** Median 42, range 34 to 65 years. **Tumour characteristics** Biopsy method Core biopsy: 14/14 (100%) Size Not stated Stage Before neoadjuvant chemotherapy I: 1/14 (7.1%) IIA: 5/14 (35.7%) IIB: 5/14 (35.7%) IIIA: 2/14 (14.3%) IIIB: 1/14 (7.1%) After neoadjuvant chemotherapy No evidence of disease: 1/14 (7.1%) I: 2/14 (14.3%) IIA: 6/14 (42.9%) IIB: 2/14 (14.3%) IIIA: 2/14 (14.3%) IIIB: 1/14 (7.1%) Histology Not stated Location Not stated Palpability Not stated Multifocality/multicentricity Not stated **Axilla characteristics** Clinical axillary status Not stated **Neoadjuvant chemotherapy** 14/14 (100%) of patients underwent neoadjuvant chemotherapy. Stage at diagnosis / Clinical response to chemotherapy / At surgery / Type of chemotherapy IIB / Partial / I / DC IIA / Stable / IIA / DC IIA / Partial / I / DC IIA / Stable / IIB / DC IIB / Stable / IIA / DC + paclitaxel IIB / Partial / IIIA / DC IIA / Stable / IIA / DC + docetaxel IIIA / Partial / IIA / DC IIB / Complete / IIA / DC IIA / Stable / IIA / DC + docetaxel IIB / Progressive / IIIB / DC I / Complete / No evidence of disease / DC + paclitaxel/Tr IIIB / Partial / IIIA / DC IIIA / Stable / IIB / DC **Abbreviations**: DC, doxorubicin/cyclophosphamide; Tr, trastuzumab

	axillary nodes Not stated	

Study identifier	Procedure	Patient characteristics
Branagan, Hughes, Jeffrey, Crane-Robinson & Perry, 2002. **Number of patients** 52 (50 female:2 male) **Number of attempted mappings** 52 **Study period** Not stated **Institution** Departments of Surgery and Pathology, Queen Alexandra Hospital and Department of Biological Sciences, University of Portsmouth, Portsmouth, UK. **Incorporated studies** None **Inclusion/exclusion criteria** Inclusions: patients with breast cancer. Exclusions: none stated **Study included for review of...:** Localisation rates	**Radiocolloid/dye combination** Radiocolloid only: 0 Dye only: 0 Radiocolloid and dye: 52 **Radiocolloid** Type: ^{99m}Tc-labelled sulphur colloid* Dose: approximately 0.4mCi in 0.5ml saline* Colloid size: not stated* Filtration: not stated* Injection location: a total of five 0.1ml injections into the normal breast tissue adjacent to the lesion or biopsy site, performed along a 180° perimeter on the side of the tumour facing the axilla.* Injection timing: 1 to 9 hours prior to surgery* Massage: not stated* Intraoperative probe: C-Trak (Care Wise Medical Products, Morgan Hill, CA, USA).* **Dye** Type: isosulphan blue dye† Amount: not specifically stated† Injection location: into the breast mass and surrounding parenchyma, or if the primary tumour had been excised, the dye was injected into the wall of the biopsy cavity and surrounding breast parenchyma through several points along the incision.† Injection timing: not stated† Massage: not stated† **Preoperative lymphoscintigraphy** Timing: not stated* **Surgery** Surgeon details: not stated Anaesthesia: not stated Axillary clearance: completion level I axillary clearance. Sentinel node definition: not stated Final breast procedure: not stated **Histologic analysis of sentinel nodes** Intraoperative analysis: not stated Sectioning: nodes were bisected with a scalpel, and one half of each node was formalin fixed and embedded and divided into 0.5cm block, from each of which two sections were taken. Permanent section: sections were stained with H&E. IHC: not stated Micrometastases definition: not stated The other half of the bisected nodes were kept in RNAlater® (Ambion, Austin, TX, USA) before storage at -70°C. Batches of frozen half nodes were then defrosted and each was cut into samples of between 30 and 100mg. Each sample was homogenised and the RNA was isolated. Reverse transcription and amplification were conducted. **Histologic analysis of axillary nodes** Not stated	**Age** Mean 59, range 28 to 84 years. **Tumour characteristics** Biopsy method Not stated Size Not stated Stage Not stated Histology Not stated Location Not stated Palpability Not stated Multifocality/multicentricity Not stated **Axilla characteristics** Clinical axillary status Not stated **Neoadjuvant chemotherapy** Not stated

* from Krag *et al.* 1993
† from Giuliano *et al.* 1994

Study identifier	Procedure	Patient characteristics
Brenot-Rossi, Houvenaeghel, Jacquemier, Bardou, Martino, Hassan-Sebbag & Pasquier, 2003. **Number of patients** 332 **Number of attempted mappings** 332 **Study period** March 1999 to December 2001 **Institution** Departments of Nuclear Medicine, Surgery, Pathology and Biostatistics, Institut Paoli-Calmettes, Regional Cancer Center, Université de la Méditerranée, Marseille, France. **Incorporated studies** None **Inclusion/exclusion criteria** Inclusions: consecutive women with invasive breast cancer or high grade ductal carcinoma in situ (T0-T2 <30mm, N0) Note: study also had patients with tumours >30mm. Exclusions: patients with clinically positive lymph nodes, multicentric tumours, and neoadjuvant therapy. **Study included for review of……** Localisation rates	**Radiocolloid/dye combination** Radiocolloid only: 0 Dye only: 0 Radiocolloid and dye: 332 **Radiocolloid** Type: ^{99m}Tc-labelled sulphur colloid (Nanocis; Schering). Dose: 37MBq (1mCi) in a total volume of 0.4ml physiologic saline Colloid size: not stated Filtration: not stated Injection location: four equal doses were injected above (intradermally) and around (intraparenchymally) the tumour or biopsy site at a distance of <1cm, usually 5mm. Injection timing: patients were injected on the day before surgery. Massage: massaged gently for 5 minutes. Intraoperative probe: Neoprobe 2000 (MDS Nordion) **Dye** Type: patent blue dye (Bleu Patente Laboratoire Guerbet). Amount: 2ml Injection location: peritumoural or subareolar. Injection timing: intraoperatively Massage: not stated **Preoperative lymphoscintigraphy** Timing: performed 10 minutes after radiocolloid injection. **Surgery** Surgeon details: not stated Anaesthesia: not stated Axillary clearance: breast surgery preceded the axillary surgery and axillary levels I and II were removed in patients with tumours >3cm, mapping failure or a positive sentinel node. Sentinel node definition: blue and/or radioactive nodes. Final breast procedure: breast-conserving surgery 262/332 (78.9%); modified radical mastectomy 70/332 (21.1%). **Histologic analysis of sentinel nodes** Intraoperative analysis:: imprint cytology was performed in all cases, or frozen sections were prepared if the node was macroscopically abnormal or >5mm. Sectioning: 150µm serial sections Permanent section: H&E (approximately 6 serial sections). IHC: adjacent sections stained with anticytokeratin antibodies (KL1). Micrometastases definition: <2mm and >0.1mm diameter. **Histologic analysis of axillary nodes** Standard H&E staining.	**Age** Mean 59, range 30 to 88 years |	
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<70 years	263/332 (79.2%)
>70 years	69/332 (20.8%) | **Tumour characteristics** Biopsy method |	
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FNA or percutaneous biopsy	288/332 (86.7%)
Excisional	44/332 (13.3%) | Size Mean pathologic invasive tumour size 20, range 0 to 170mm |	
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<2cm	140/304 (46.1%)
2 to 5cm	133/304 (43.8%)
>5cm	31/304 (10.2%) | (Invasive tumour size, n=304) Stage |	
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Grade I	116/332 (34.9%)
Grade II	125/332 (37.7%)
Grade III	81/332 (24.4%)
Not stated	10/332 (3.0%) | (10 values missing) Histology |	
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pTis	28/332 (8.4%)
Invasive ductal	225/332 (67.8%)
Invasive lobular	39/332 (11.7%)
Other invasive	40/332 (12.1%) | Location |	
---	---
Right	171/332 (51.5%)
Left	161/332 (48.5%)
UOQ	185/332 (55.7%)
LOQ	44/332 (13.3%)
UIQ	50/332 (15.1%)
LIQ	32/332 (9.6%)
Central	21/332 (6.3%) | Palpability |	
---	---
Palpable	85/332 (25.6%)
Nonpalpable	247/332 (74.4%) | Multifocality/multicentricity Patients with multicentric tumours were excluded. **Axilla characteristics** Clinical axillary status |	
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Negative	332/332 (100%)	 **Neoadjuvant chemotherapy** Patients who had had neoadjuvant chemotherapy were excluded.

Study identifier	Procedure	Patient characteristics
Breslin, Cohen, Sahin, Fleming, Kuerer, Newman, Delpassand, House, Ames, Feig, Ross, Singletary, Buzdar, Hortobagyi & Hunt, 2000. **Number of patients** 51 **Number of attempted mappings** 51 **Study period** 1994 to 1999 **Institution** Departments of Surgical Oncology, Pathology, Breast Medical Oncology and Nuclear Medicine, University of Texas, MD Anderson Cancer Center, Houston, Texas, USA. **Incorporated studies** None **Inclusion/exclusion criteria** Inclusions: patients with T1N1M0 or T2-3N0-1M0 were eligible for neoadjuvant chemotherapy, and for the current study, all patients who had lymphatic mapping and sentinel biopsy after neoadjuvant chemotherapy were evaluated. Exclusions: none stated **Study included for review of.....** Localisation rates	**Radiocolloid/dye combination** Radiocolloid only: 0 Dye only: 23 Radiocolloid and dye: 28 **Radiocolloid** Type: ^{99m}Tc-labelled sulfur colloid Dose: not stated Colloid size: not stated Filtration: not stated Injection location: injected peritumourally around the primary tumour or excisional biopsy site. Patients with nonpalpable tumours were injected under mammographic or US guidance. Injection timing: not stated Massage: not stated Intraoperative probe: not stated **Dye** Type: not stated Amount: not stated Injection location: injected peritumourally around the primary tumour or excisional biopsy site. Patients with nonpalpable tumours were injected under mammographic or US guidance. Injection timing: not stated Massage: not stated Blue dye was injected alone (23/51 (45.1%) patients) or in combination with radiocolloid (28/51 (54.9%) patients). **Preoperative lymphoscintigraphy** Timing: whether preoperative lymphoscintigraphy was performed was not stated. **Surgery** Surgeon details: not stated Anaesthesia: not stated Axillary clearance: all patients were offered concomitant axillary clearance. Of the 41 patients who underwent breast conserving surgery, 38 underwent complete axillary clearance and 3 patients declined. Sentinel node definition: nodes with blue dye uptake or radioactivity as detected by an intraoperative gamma probe. Final breast procedure: breast conserving 41/51 (80.4%); modified radical mastectomy 10/51 (19.6%). **Histologic analysis of sentinel nodes** Intraoperative analysis: not stated Sectioning: see below Permanent section: not stated IHC: in the first 31 successful mapping cases, negative sentinel and axillary nodes were subjected to serial step sectioning and IHC staining with an anticytokeratin antibody cocktail (AE1/AE3) to detect micrometastases. The remaining patients underwent sentinel node biopsy and axillary clearance with serial sectioning of the	**Age** Median 45, range 25 to 68 years. **Tumour characteristics** Biopsy method FNA: 6/51 (11.8%) CB: 35/51 (68.6%) Excisional: 5/51 (9.8%) Incisional: 5/51 (9.8%) Note: biopsy was obtained by FNA of the breast and an axillary node in 6/51 (11.7%) patients, and needle biopsy of the axilla proved the presence of invasive disease by confirming axillary lymph node metastases. Size Median 5.0, range 1.0 to 13.0cm (in 41 assessable patients, 10 patients had tumours that could not be evaluated at the time due to previous excisional or incisonal biopsy) Stage IIA: 25/51 (49.0%) IIB: 12/51 (23.5%) IIIA: 14/51 (27.5%) Histology Infiltrating ductal: 44/51 (86.3%) Infiltrating lobular: 4/51 (7.8%) Mixed ductal and lobular: 1/51 (2.0%) Mucinous: 1/51 (2.0%) Medullary: 1/51 (2.0%) Location UOQ: 27/51 (52.9%) UIQ: 12/51 (23.5%) LOQ: 6/51 (11.8%) LIQ: 2/51 (3.9%) Central: 4/51 (7.8%) Palpability Palpable: 27/51 (52.9%) Nonpalpable: 24/51 (47.1%) Multifocality/multicentricity Not stated **Axilla characteristics** Clinical axillary status Negative: 32/51 (62.7%) Positive: 19/51 (37.3%) 16/19 (84.2%) of patients with clinically palpable axillary lymph nodes were evaluated with FNA, and 14 of these patients were positive for malignant cells. **Neoadjuvant chemotherapy** 51/51 (100%) of patients had neoadjuvant chemotherapy. FAC: 35/51 (68.6%) High dose FAC: 2/51 (3.9%) Paclitaxel followed by FAC: 8/51 (15.7%) Doxorubicin + docetaxel: 5/51 (9.8%) Tamoxifen: 1/51 (2.0%) 43/51 (84.3%) patients received four cycles of chemotherapy before surgery, 6/51 (11.8%) received 3 cycles, 1/51 (2%) received 2 cycles

	sentinel nodes only. In this group, IHC analysis was only used to confirm malignancy in cells with a suspicious appearance. Micrometastases definition: not stated **Histologic analysis of axillary nodes** Serial sectioning and IHC fro the first 31 successful mapping cases.	and 1/51 (2%) received 1 cycle. In the 41/51 (80.4%) of patients with measurable disease in the breast, the median clinical tumour size was reduced from 5cm to 2cm (all but one of the patients demonstrated a decrease in size of the primary tumour). Only 6/19 (31.6%) of patients with palpable disease had residual axillary adenopathy (palpable or sonigraphically detectable) after chemotherapy. After three to four weeks of postoperative recovery, all patients received an additional 4 cycles of adjuvant chemotherapy and radiotherapy to either the breast (for patients undergoing breast-conserving therapy) or the chest wall and regional lymph nodes, as indicated.

Abbreviations: FAC, fluorocil/cyclophosphamide/doxorubicin

Study identifier	Procedure	Patient characteristics
Burak, Walker, Yee, Kim, Saha, Hinkle, Olsen, Pozderac & Farrar, 1999. **Number of patients** 50 **Number of attempted mappings** 50 **Study period** Not stated **Institution** Division of Surgical Oncology, Department of Surgery and the Division of Nuclear Medicine, Department of Radiology, Arthur G. James Cancer Hospital and Research Institute, Ohio State University Comprehensive Cancer Center, Columbus, Ohio, USA. **Incorporated studies** None **Inclusion/exclusion criteria** Inclusions: patients who had histologic or cytologic diagnosis of breast carcinoma and were to undergo axillary dissection were included if they had unifocal disease, were not pregnant, and had no palpable axillary adenopathy. Exclusions: patients with a history of inflammatory breast carcinoma or neoadjuvant therapy were excluded. **Study included for review of……** False negative rates	**Radiocolloid/dye combination** Radiocolloid only: 0 Dye only: 0 Radiocolloid and dye: 50 **Radiocolloid** Type: ^{99m}Tc-labelled sulfur colloid Dose: each of the four injections was composed of 1ml of saline containing 100µCi of colloid. Colloid size: not stated Filtration: filtered (0.22 micron) Injection location: injected into the breast parenchyma in a 4-quadrant technique around the palpable tumour or biopsy cavity. For patients who had either a stereotactic or US-guided core needle biopsy, a single injection of 400µCi of colloid in 4ml of saline was given under mammographic or US-guidance at the same time as the needle-wire localisation procedure. Injection timing: not stated Massage: not stated Intraoperative probe: Neoprobe (Neoprobe Corporation, Dublin, OH, USA). **Dye** Type: isosulphan blue dye (1% Lymphazurin; Ben Venue Laboratories, Bedford, OH, USA). Amount:4 to 5ml Injection location: injected into the breast parenchyma in the same fashion as the radiocolloid, using either a four-quadrant technique or through the previously placed localisation needle. Injection timing: not stated Massage: not stated **Preoperative lymphoscintigraphy** Timing: the first 24/50 (48%) patients underwent preoperative lymphoscintigraphy, followed by sentinel lymph node biopsy, while the remaining 26/50 (52%) underwent sentinel lymph node biopsy without preoperative lymphoscintigraphy. Preoperative lymphoscintigraphy was performed 30 minutes and at least 2 hours following injection. **Surgery** Surgeon details: not stated Anaesthesia: not stated Axillary clearance: a level I and II axillary dissection was carried out after removal of the sentinel nodes. The axillary contents wer then probed to identify any additional radioactive nodes. Sentinel node definition: nodes that demonstrated the presence of blue dye (or had a blue afferent lymphatic) and/or had the presence of radioactive counts above the surrounding tissues. Excised nodes were probed and counts were obtained to compare with counts of excised adjacent fat to ensure the node had counts at least twice that of the surrounding fat. Final breast procedure: breast conserving 40/50 (80.0%); modified radical mastectomy 10/50 (20.0%). **Histologic analysis of sentinel nodes** Intraoperative analysis: not stated Sectioning: not stated Permanent section: H&E IHC: not stated Micrometastases definition: not stated **Histologic analysis of axillary nodes** H&E	**Age** Not stated **Tumour characteristics** Biopsy method FNA: 5/50 (10.0%) CB: 15/50 (30.0%) Excisional: 30/50 (60.0%) Size Mean 1.6, range0.5 to 3.5cm Stage Not stated Histology Not stated Location UOQ: 24/50 (48.0%) UIQ: 9/50 (18.0%) LOQ: 7/50 (14.0%) LIQ: 4/50 (8.0%) Subareolar: 6/50 (12.0%) Palpability Palpable: 22/50 (44.0%) Nonpalpable: 28/50 (56.0%) Multifocality/multicentricity Patients were excluded if they had multifocal disease. **Axilla characteristics** Clinical axillary status Negative: 50/50 (100%) **Neoadjuvant chemotherapy** Patients were excluded if they had had neoadjuvant therapy.

Study identifier	Procedure	Patient characteristics
Byrd, Dunnwald, Mankoff, Anderson, Moe, Yeung, Schubert & Eary, 2001. **Number of patients** 220 (219 female:1 male) **Number of attempted mappings** 220 **Study period** October 1996 to November 1999 **Institution** Department of General Surgery, Section of Surgical Oncology, and the Division of Nuclear Medicine, University of Washington Medical Center, Seattle, Washington, USA. **Incorporated studies** None **Study included for review of……** Localisation rates **Inclusion/exclusion criteria** Inclusions: patients undergoing preoperative lymphoscintigraphy before sentinel lymph node biopsy. Exclusions: none stated	**Radiocolloid/dye combination** Radiocolloid only: 0 Dye only: 0 Radiocolloid and dye: 220 **Radiocolloid** Type: ^{99m}Tc-labelled sulphur colloid Dose: 1mCi in 6 to 10ml Colloid size: not stated Filtration: filtered Injection location: injected in four quadrants around the tumour or biopsy cavity, for nonpalpable lesions, the injection was made through a localisation needle using a catheter placed under mammographic or US guidance. Injection timing: on the day of surgery, with the exception of four patients who were injected the evening before surgery. Massage: not stated Intraoperative probe: Neoprobe (Neoprobe Corp., Dublin, OH); Navigator (US Surgical Corp., Norwalk, CT, USA). **Dye** Type: isosulphan blue dye Amount: 3 to 5ml Injection location: peritumoural Injection timing: not stated Massage: not stated **Preoperative lymphoscintigraphy** Timing: immediately post radiocolloid injection, and until a node was visualised or a maximum of 2 to 3 hours postinjection (except 4 patients who were injected the evening before surgery, where an immediate postinjection image and delayed imaging was performed the next morning). **Surgery** Surgeon details: not stated Anaesthesia: not stated Axillary clearance: level I and II, after April 1998, the practice plan changed to sentinel lymph node biopsy without completion axillary clearance for patients with T1 tumours, diagnosed by core needle biopsy, for who the sentinel node was without metastases. Sentinel node definition: not stated Final breast procedure: not stated **Histologic analysis of sentinel nodes** Intraoperative analysis: not stated Sectioning: not stated Permanent section: not stated IHC: not stated Micrometastases definition: not stated **Histologic analysis of axillary nodes** Not stated	**Age** Mean 55, range 26 to 88 years. **Tumour characteristics** Biopsy method Core needle biopsy: 167/220 (75.9%) Excisional biopsy: 37/220 (16.8%) Not stated: 16/220 (7.3%) Size ≤2cm: 145/220 (65.9%) 2 to 5cm: 52/220 (23.6%) >5cm: 12/220 (5.5%) Any size: 2/220 (0.9%) Not stated (DCIS): 9/220 (4.1%) Stage T1: 145/220 (65.9%) T2: 52/220 (23.6%) T3: 12/220 (5.5%) T4: 2/220 (0.9%) DCIS: 9/220 (4.1%) Histology Invasive breast cancer: 211/220 (95.9%) DCIS (patients had a high clinical suspicion of invasive disease): 9/220 (4.1%) Location UOQ: 110/220 (50.0%) UIQ: 30/220 (13.6%) LOQ: 49/220 (22.3%) LIQ: 24/220 (10.9%) Subareolar/central: 7/220 (3.2%) Palpability Palpable: 122/220 (55.5%) Nonpalpable: 98/220 (44.5%) Multifocality/multicentricity Not stated **Axilla characteristics** Clinical axillary status Not stated **Neoadjuvant chemotherapy** 14/220 (6.4%) of patients had neoadjuvant chemotherapy, and 2/220 (0.9%) had prior excisional biopsy and neoadjuvant chemotherapy.

Study identifier	Procedure	Patient characteristics
Canavese, Gipponi, Catturich, Di Somma, Vecchio, Rosato, Percivale, Moresco, Nicolò, Spina, Villa, Bianchi & Badellino, 2000a. **Number of patients** 55 **Number of attempted mappings** 55 **Study period** May 1996 to May 1997 **Institution** Division of Surgical Oncology and Pathology Laboratory, Istituto Nazionale per la Ricerca sul Cancro, Genoa; Department of Experimental and Clinical Oncology and Nuclear Medicine Service, University of Genoa, School of Medicine, Genoa, Italy. **Incorporated studies** None **Inclusion/exclusion criteria** Inclusions: patients with suspected or confirmed breast cancer. Exclusions: patients >80 years of age, that had previous incisional or excisional biopsy of the breast cancer or axillary operations, nonpalpable tumour, locally advanced breast cancer or previous diagnosis of invasive cancer, known adverse reactions to contrast media or pregnancy were excluded. **Study included for review of……** False negative rates	**Radiocolloid/dye combination** Radiocolloid only: 0 Dye only: 55 Radiocolloid and dye: 0 **Radiocolloid** Radiocolloid was not used. Type: not applicable Dose: not applicable Colloid size: not applicable Filtration: not applicable Injection location: not applicable Injection timing: not applicable Massage: not applicable Intraoperative probe: not applicable **Dye** Type: patent blue V Amount: 1 to 2ml Injection location: injected peritumourally. After tumorectomy and after interoperative histologic confirmation of invasive carcinoma, another 2ml of blue dye was injected into the wall of the biopsy cavity and surrounding breast parenchyma through different points along the incision. Injection timing: at least 5 minutes before the axillary mapping. Massage: not stated **Preoperative lymphoscintigraphy** Timing: not applicable **Surgery** Surgeon details: not stated Anaesthesia: general anaesthesia. Axillary clearance: total axillary dissection (level I, II, III). Sentinel node definition: the sentinel node was identified as the first lymph node draining a blue-stained lymphatic channel. Final breast procedure: breast-conserving surgery or radical mastectomy, proportions not stated. **Histologic analysis of sentinel nodes** Intraoperative analysis: not stated Sectioning: not stated Permanent section: not stated IHC: not stated Micrometastases definition: not stated **Histologic analysis of axillary nodes** Not stated	**Age** Median 65, range 40 to 80 years **Tumour characteristics** Biopsy method The tumour was removed and evaluated intraoperatively in all patients, directly before sentinel biopsy. Size Not stated Stage Not stated Histology Not stated Location Not stated Palpability Not stated Multifocality/multicentricity Not stated **Axilla characteristics** Clinical axillary status Positive or negative, proportions not stated. **Neoadjuvant chemotherapy** Not stated

Study identifier	Procedure	Patient characteristics
Canavese, Gipponi, Catturich, Vecchio, Tomei, Nicolò, Carli, Spina, Bonelli, Villa, Buffoni, Bianchi, Agnese & Mariani, 2001. **Number of patients** 212 **Number of attempted mappings** 212 **Study period** October 1997 to December 1999 **Institution** Division of Surgical Oncology, Pathology Laboratory, Unit of Clinical Epidemiology and Trials, Istituto Nazionale per la Ricerca sul Cancro, Genoa and Nuclear Medicine Service, University of Genoa, School of Medicine, Genoa, Italy. **Incorporated studies** Canavese *et al.* 1998; Canavese *et al.* 2000b **Inclusion/exclusion criteria** Inclusions: patients with either suspected or cytologically confirmed breast cancer and a clinically node-negative axilla. Exclusion: patients >80 years of age, prior major breast or axillary operations that could interfere with lymphatic drainage, multifocal or locally advanced breast cancer, patients with known reactions to any contrast media and pregnant women. **Study included for review…** False negative rates	**Radiocolloid/dye combination** Radiocolloid only: 29 Dye only: 0 Radiocolloid and dye: 183 **Radiocolloid** Type: radiolabelled compounds (microcolloid sulphide <50nm in size (Lymphoscint), or minimicrospheres of human serum albumin with a particle size between 50 and 80nm (Nanocol; Nycomed-Amersham-Sorin, Sallugia, Italy) or between 200 and 1000nm (Albures; Sorin BioMedica, Saluggia, Italy) radiolabelled with ^{99m}Tc-pertechnetate). Dose: see below Colloid size: see above Filtration: not stated Injection location: injected in four peritumoural sites (0.2ml; 300μCi) in 29 patients, or subdermally (0.1-0.3ml; 300 μCi) immediately above the tumour in the remaining 183 patients. Injection timing: approximately 16 to 18 hours before surgery. Massage: gentle massage was applied to the injected part. Intraoperative probe: Neoprobe 1000, (Neoprobe Corp, Dublin, OH or Scintiprobe MR 100, (Pol.Hi.Tech, Carsoli, AQ, Italy). **Dye** Type: patent blue V Amount: 1 to 2ml Injection location: injected peritumourally in 30 patients, and 0.4ml was injected subdermally, immediately above the breast lesion, in 153 patients (29 patients did not have blue dye mapping due to technical reasons). Patients who had invasive carcinoma confirmed intraoperatively were injected with another 0.2 to 0.4ml of dye into the biopsy walls, 20 to 25 minutes after the former injection, to improve blue dying of the SN. Injection timing: not stated Massage:not stated **Preoperative lymphoscintigraphy** Timing: 10 minutes after radiocolloid injection, then every 10 to 15 minutes up to a maximum of 2 hours. **Surgery** Surgeon details: not stated Anaesthesia: general anaesthesia. Axillary clearance: patients underwent a level I and II axillary lymph node dissection after lumpectomy or the axilla was cleared as part of the modified radical mastectomy procedure. Sentinel node definition: blue-stained, or with an *in vivo* radioactive localisation index (node/background ratio) >5, and an *ex vivo* ratio >10. Final breast procedure: lumpectomy 188/212 (88.7%); modified radical mastectomy 24/212 (11.3%). **Histologic analysis of sentinel nodes** Intraoperative analysis: at frozen section, the node was bisected along its major axis, and 5 sections obtained from each half at different levels (10 to 20μm); 3 sections stained with H&E and if negative or doubtful the other 2 sections were examined with IHC using an antibody directed against cytokeratin. Sectioning: the remaining frozen and unfrozen tissue was fixed and embedded, method of sectioning not specified. Permanent section: H&E IHC: see above (IHC performed on frozen section). Micrometastases definition: not stated	**Age** Mean 61, range 40 to 79 years. **Tumour characteristics** Biopsy method Not stated Size ≤ 5mm: 13/212 (6.1%) 6 to 10mm: 26/212 (12.3%) 11 to 20mm: 116/212 (54.7%) >20 but ≤ 5mm: 57/212 (26.9%) Stage T1a: 13/212 (6.1%) T1b: 26/212 (12.3%) T1c: 116/212 (54.7%) T2: 57/212 (26.9%) Histology Not stated Location Not stated Palpability Not stated Multifocality/multicentricity Patients with multifocal breast cancer were excluded. **Axilla characteristics** Clinical axillary status Negative: 212/212 (100%) **Neoadjuvant chemotherapy** Not stated

	Histologic analysis of axillary nodes Not stated	

Study identifier	Procedure	Patient characteristics
Casalegno, Sandrucci, Bellò, Durando, Danese, Silvestro, Pellerito, Testori, Roagna, Giai, Giani, Bussone, Favero, Bisi, Massobrio, Giardina, Mussa, Sismondi & Mussa, 2000. **Number of patients** 102 **Number of attempted mappings** 102 **Study period** December 1996 to January 1999 **Institution** Unità Operativa di Chirurgia Oncologica; Servizio di Medicine Nucleare; Dipartimento di Ginecologia ed Ostetricia, I Clinica; Dipartimento di Ginecologia Oncologica, Università di Torino; Divisione A Ginecologia ed Ostetricia and Servizio di Medicina Nucleare A.O. OIRM-S. Anna, Turin; Servizio di Medicina Nucleare, Ospedale Mauriziano Umberto I, Turin; I Chirurgia, Ospedale S. Giovanni Antica Sede, Turin, Italy. **Incorporated studies** Sandrucci & Mussa, 1998 **Inclusion/exclusion criteria** Inclusions: only FNA documented cases. Exclusions: presence of palpable axillary lymph nodes, previous breast surgery, neoadjuvant chemotherapy, mammary of axillary irradiation, pregnancy or breast feeding. **Study included for review of……** Localisation rates and false negative rates	**Radiocolloid/dye combination** Radiocolloid only: 102 Dye only: 0 Radiocolloid and dye: 0 **Radiocolloid** Type: ^{99m}Tc-labelled human albumin colloid particles (Nanocoll®, Sorin Biomedica, Saluggia). Dose: mean activity 5.2 ± 2.5 MBq. Colloid size: not stated Filtration: not stated Injection location: injected subdermally into the skin overlying the tumour. Injection timing: day before surgery, mean injection-to-intervention time was 15 hours and 30 minutes ± 8 hours and 36 minutes. Massage: not stated Intraoperative probe: Scintiprobe MR 100, (Pol.Hi.Tech, Carsoli, Italy) **Dye** Dye was not used. Type: not applicable Amount: not applicable Injection location: not applicable Injection timing: not applicable Massage: not applicable **Preoperative lymphoscintigraphy** Timing: 30 and 60 minutes after radiocolloid injection. **Surgery** Surgeon details: not stated Anaesthesia: not stated Axillary clearance: three-level lymphadenectomy completed in the standard fashion. Sentinel node definition: a target-to-background ratio of 5 counts per second or more, was considered sufficient to identify a hot spot as a sentinel node. Final breast procedure: patients had lumpectomy, quadrantectomy or modified radical mastectomy (proportions not stated). **Histologic analysis of sentinel nodes** Intraoperative analysis: not stated Sectioning: standard (4 sections)and serial sectioning (up to 20 when initial stains negative). Permanent section: H&E IHC: not performed Micrometastases definition: not stated **Histologic analysis of axillary nodes** Not stated	**Age** Mean 57.3 ± 11.2 years. **Tumour characteristics** Biopsy method FNA: 102/102 (100%) Size Mean diameter 1.9 ± 0.8cm. Stage T1 or T2 Histology Invasive ductal carcinoma: 71.4% Invasive lobular carcinoma: 19.0% Medullary carcinoma: 4.8% Tubular carcinoma: 4.8% Note: patient numbers were not stated. Location UOQ: 54.0% UIQ: 12.0% LOQ: 19.0% LIQ: 7.0% Periareolar region: 8.0% Note: patient numbers were not stated. Palpability Not stated Multifocality/multicentricity Not stated **Axilla characteristics** Clinical axillary status Negative: 102/102 (100%) **Neoadjuvant chemotherapy** Patients that had had neoadjuvant chemotherapy were excluded.

Study identifier	Procedure	Patient characteristics
Choi, Barsky & Chang, 2003. **Number of patients** 81 **Number of attempted mappings** 83 (2 bilateral) **Study period** September 1998 to May 2000 **Institution** Departments of Surgery and Pathology, Revlon/UCLA Breast Center, UCLA Medical Center, Los Angeles, California, USA. **Incorporated studies** None **Inclusion/exclusion criteria** Inclusions: consecutive patients with unicentric, histologically proven and clinically small (mainly T1) breast cancers and negative axilla. Exclusions: none stated **Study included for review of……** Localisation rates	**Radiocolloid/dye combination** Radiocolloid only: 8 Dye only: 0 Radiocolloid and dye: 75 **Radiocolloid** Type: ^{99m}Tc-labelled sulphur colloid Dose: 1 to 2mCi in a total of 8ml. Colloid size: not stated Filtration: unfiltered Injection location: intramammary injection in 4 divided doses around the tumour or biopsy cavity (2mCi), or after placement of tumour localisation wire (1mCi). Injection timing: day before surgery for palpable or excised tumours, day of surgery for nonpalpable tumours Massage: not stated Intraoperative probe: C-trak (Care Wise, Morgan Hill, CA, USA). **Dye** Type: isosulphan blue dye Amount: 3 to 8ml Injection location: as for radiocolloid. Injection timing: 5 to 10 minutes before skin incision. Massage: not stated **Preoperative lymphoscintigraphy** Timing: not stated. **Surgery** Surgeon details: not stated Anaesthesia: not stated Axillary clearance: axillary clearance recommended to all patients with a metastatic SN by H&E; optional if SN positive only with IHC. Sentinel node definition: not stated Final breast procedure: lumpectomy 77/83 (92.8%); mastectomy 6/83 (7.2%) (sometimes lumpectomy was performed before sentinel lymph node biopsy to remove radioactivity interfering with the localisation of the sentinel node). **Histologic analysis of sentinel nodes** Intraoperative analysis:: not stated Sectioning: not stated Permanent section: all sentinel nodes examined by H&E. IHC: sentinel nodes negative by H&E were examined by cytokeratin IHC. Micrometastases definition: not stated **Histologic analysis of axillary**	**Age** Mean 56.2 ±(SD) 12.2, range 26 to 81 years 20 to 29 years: 2/81 (2.5%) 30 to 39 years: 5/81 (6.2%) 40 to 49 years: 17/81 (21.0%) 50 to 59 years: 30/81 (37.0%) 60 to 69 years: 13/81 (16.0%) 70 to 79 years: 11/81 (13.6%) 80 to 89 years: 3/81 (3.7%) **Tumour characteristics** Biopsy method Tumours were histologically proven, and there were some excisional biopsies. Size Mean 1.55 ±(SD) 1.31 (palpable tumours were slightly larger than nonpalpable tumours (mean 2.04cm vs 1.14cm, p=0.001) Stage Tis: 1/83 (1.2%) T1a (≤0.5cm): 7/83 (8.4%) T1b (0.6-1.0cm): 19/83 (22.9%) T1c (1.1-2.0cm): 44/83 (53.0%) T2: 11/83 (13.3%) T3: 1/83 (1.2%) Stage 0: 1/83 (1.2%) Stage I: 50/83 (60.2%) Stage IIA: 29/83 (34.9%) Stage IIB: 2/83 (2.4%) Stage IIIA: 1/83 (1.2%) Histology Invasive ductal: ~80% Invasive lobular: 9.6% Mixed invasive ductal and lobular: 8.8% DCIS: 1/83 (1.2%) Note: Number of patients not stated for invasive cancers. Location Right: 44/81 (54.3%) Left: 35/81 (43.2%) Bilateral: 2/81 (2.5%) UOQ: 51/83 (61.4%) UIQ: 15/83 (18.1%) LOQ: 7/83 (8.4%) LIQ: 8/83 (9.6%) Central: 1/83 (1.2%) UIQ + LIQ: 1/83 (1.2%) Palpability Palpable: 42/83 (50.6%) Nonpalpable: 41/83 (49.4%) Multifocality/multicentricity Only unicentric patients were included, but one patient appeared to have multifocal tumour, located in the upper and lower inner quadrants. **Axilla characteristics** Clinical axillary status Negative: 83/83 (100%)

	nodes Not stated	**Neoadjuvant chemotherapy** Not stated

Study identifier	Procedure	Patient characteristics
Chua, Ung, Taylor, Bilous, Salisbury & Boyages, 2001. **Number of patients** 167 **Number of attempted mappings** 174 **Study period** June 1998 to May 2000 **Institution** Division of Radiation Oncology and Department of Surgery, Westmead Hospital, Westmead; New South Wales Breast Cancer Institute, Westmead Hospital, University of Sydney, Westmead; Department of Public Health and Community Medicine, University of Sydney, Sydney; Institute of Clinical Pathology and Medical Research, Westmead, New South Wales, Australia. **Incorporated studies** None **Inclusion/exclusion criteria** Inclusions: patients who were treated for invasive breast carcinoma. Exclusions: patients with clinical T4, N2-N3 or M1 disease. **Study included for review of.....** Localisation rates	**Radiocolloid/dye combination** Radiocolloid only: patients underwent lymphoscintigraphy and gamma probe-guided surgery alone prior to December 1998. Dye only: 0 Radiocolloid and dye: unsure **Radiocolloid** Type: ^{99m}Tc-labelled antimony sulphide colloid (Royal Adelaide Hospital Radiopharmacy, Adelaide or Westmead Hospital Radiopharmacy, Sydney, Australia). Dose: 80MBq in four doses of 20MBq each. Colloid size: not stated Filtration: not stated Injection location: injected interstitially in four quadrants around the primary tumour or biopsy cavity. Nonpalpable lesions were localised using US or stereotactically, with a hookwire that was imaged by ultrasound during injection of the radiopharmaceutical around the tumour. Injection timing: not stated Massage: not stated Intraoperative probe: Navigator System (USSC, Norwalk, CT, USA). **Dye** Type: patent blue V Amount: 4ml (2ml of 50mg/2ml, diluted in 2ml of 0.9% saline w/v) Injection location: injected interstitially in four quadrants around the primary tumour or biopsy cavity. Injection timing: not stated Massage: not stated **Preoperative lymphoscintigraphy** Timing: images were taken for up to 12 hours after radiocolloid injection. **Surgery** Surgeon details: not stated Anaesthesia: general anaesthesia Axillary clearance: level I, II and III (seven patients underwent a level I dissection only, 10 patients did not undergo axillary dissection). Sentinel node definition: nodes identified by gamma probe and/or blue stain. Final breast procedure: total mastectomy 21/51 (41.2%); wide local incision 27/51 (52.9%); reexcision of the biopsy cavity 3/51 (5.9%). Note: numbers only stated for 51 patients that had a successful sentinel lymph node biopsy and also had one or more tumour-involved axillary sentinel nodes. **Histologic analysis of sentinel nodes** Intraoperative analysis: not stated Sectioning: embedded whole or bisected if >5mm thick, 4µm thick sections taken at 4µm intervals. Permanent section: H&E (6 sections). IHC: antihuman epithelial membrane antigen and antihuman cytokeratin and AE1/AE3 (2 sections). Micrometastases definition: not stated **Histologic analysis of axillary nodes** At least one section evaluated with H&E.	Note: numbers only stated for 51 patients with a successful SLNB and also one or more tumour-involved axillary sentinel nodes. **Age** Median 50, range 27 to 83 years. ≤50 years: 26/51 (51.0%) >50 years: 25/51 (49.0%) **Tumour characteristics** Biopsy method Not stated Size Mean 24, range 2 to 85mm. ≤10mm: 3/51 (5.9%) 10 to 20mm: 21/51 (41.2%) 20 to 50mm: 25/51 (49.0%) >50mm: 2/51 (3.9%) Stage Not stated Histology Ductal/other: 43/51 (84.3%) Lobular: 8/51 (15.7%) Location Not stated Palpability Palpable: 46/51 (90.2%) Nonpalpable: 5/51 (9.8%) Multifocality/multicentricity No: 37/51 (72.5%) Yes: 14/51 (27.5%) **Axilla characteristics** Clinical axillary status Negative: 41/51 (80.4%) Positive: 10/51 (19.6%) **Neoadjuvant chemotherapy** Not stated

Study identifier	Procedure	Patient characteristics
Chua, Olivotto, Donald, Hayashi, Doris, Turner, Cuddington, Davis & Rusnak, 2003. **Number of patients** 540 **Number of attempted mappings** 547 (7 bilateral) **Study period** October 1996 to July 2001 **Institution** Radiation Therapy Program, BC Cancer Agency and Department of Surgery, Vancouver Island Health Authority, Victory, BC; Department of Surgery, Fraser Health Authority, Surrey, BC; Department of Surgery, Fraser Health Authority, New Westminster, BC; Department of Surgery, Fraser Health Authority, Burnaby, BC; Department of Surgery, University of British Columbia, Vancouver and Victoria, BC, Canada; Department of Radiation Oncology, Peter MacCallum Cancer Institute, Melbourne, Victoria, Australia. **Incorporated studies** None **Inclusion/exclusion criteria** Inclusions: patients with breast cancer who had one or more SNLB were identified from a database. Exclusions: not stated. **Study included for review of...** Localisation rates	**Radiocolloid/dye combination** Radiocolloid only: 33 Dye only: 83 Radiocolloid and dye: 430 Unknown: 1 **Radiocolloid** Type: ^{99m}Tc-labelled sulphur colloid Dose: 15 to 30 MBq in 3 to 12 ml per procedure Colloid size: not stated Filtration: filtered Injection location: around the tumour or cavity postexcision of the primary tumour in 4 to 6 aliquots; a subdermal injection overlying the breast tumour given in one department. Injection timing: 2 to 24 hours prior to surgery. Massage: injection followed by breast massage. Intraoperative probe: type not stated **Dye** Type: 1% isosulphan blue dye Amount: 2 to 10 ml Injection location: around or lateral to the tumour or cavity. Injection timing: after anaesthesia Massage: not stated **Preoperative lymphoscintigraphy** Timing: preoperative lymphoscintigraphy was performed in 372/463 (80.3%) cases were radiocollod was used, typically performed 1 to 2 hours after radiocolloid injection. **Surgery** Surgeon details: procedures performed by 29 surgeons at 12 hospitals (2 surgeons performed only one and four procedures, respectively) Anaesthesia: general Axillary clearance: standard level I and II axillary dissection was usually performed (performed 509/547 (93%); not performed 38/547 (7%)) Sentinel node definition: identified by gamma probe or its blue stain or both; definition of a hot spot varied amongst the surgeons, and included an area of localised radioactivity separate from the injection site with counts ≥ 25 per 10 seconds or an *in vivo* count at least 3 times the background count. Final breast procedure: conservative surgery 383/547 (70%); total mastectomy 164/547 (30%) **Histologic analysis of sentinel nodes** Intraoperative analysis: not stated Sectioning: 3/7 pathology departments single stained section; 4/7 pathology departments 3 to 4 sections of each SN were stained. Permanent section: H&E IHC: IHC evaluation of SNs performed in ¾ pathology departments where 3 to 4 sections of each SN were stained with H&E Micrometastases definition: not stated **Histologic analysis of axillary nodes** In all pathology departments a single H&E-stained section of each non-SN was examined without IHC	**Age** Median 59 years (range 31-92) < 50 years: 146/547 (26.7%)* ≥ 50 years: 401/547 (73.3%)* **Tumour characteristics** Biopsy method None/FNA/CB only: 426/547 (77.9%)* Incisional/excisional biopsy: 120/547 (21.9%)* Unknown: 1/547 (0.2%)* *Size Median pathological tumour size 17, range 1 to 110mm Stage T1: 393/547 (71.8%)* T2: 128/547 (23.4%)* T3/4: 11/547 (2.0%)* Unknown: 15/547 (2.7%)* Histology Ductal: 468/547 (85.6%)* Lobular: 62/547 (11.3%)* Other: 3/547 (0.5%)* DCIS: 14/547 (2.6%)* Location Outer: 297/547 (54.3%)* Midline: 102/547 (18.6%)* Inner: 112/547 (20.5%)* Unknown: 16/547 (2.9%)* Palpability Yes: 405/547 (74.0%)* No: 139/547 (25.4%)* Unknown: 3/547 (0.6%)* Multifocality/multicentricity Multifocal: 20/547 (3.7%) **Axilla characteristics** Clinical axillary status N0: 515/547 (94.1%)* N1: 32/547 (5.9%)* **Neoadjuvant chemotherapy** Not stated *Data provided per SLNB procedure, not per patient

Study identifier	Procedure	Patient characteristics
Chung, Ye & Giuliano, 2001a. **Number of patients** 41 **Number of attempted mappings** 41 **Study period** September 1991 and August 2000 **Institution** Joyce Eisenberg Keefer Breast Center, John Wayne Cancer Institute at Saint John's Health Center, Santa Monica, California, USA. **Incorporated studies** None **Inclusion/exclusion criteria** Inclusions: a prospective database was used to identify women who underwent sentinel lymph node biopsy followed by axillary clearance for cancers ≥ 5cm in diameter within the study period. Patients were ≥ 18 years of age, histopathologic evidence of invasive breast cancer ≥ 5cm in greatest diameter, and clinically normal axillae. Exclusions: pregnancy, hypersensitivity to vital blue dye (Lymphazurin™, US Surgical Corp, Norwalk, CT) from previous exposure, history of axillary surgery, inflammatory cancer, chest wall involvement, and clinical or radiographical evidence of American Joint Committee on Cancer (AJCC) stage III or IV. **Study included for review of...** Localisation rates and false negative rates	**Radiocolloid/dye combination** Radiocolloid only: 0 Dye only: 41 Radiocolloid and dye: 0 **Radiocolloid** Radiocolloid was not used. Type: not applicable Dose: not applicable Colloid size: not applicable Filtration: not applicable Injection location: not applicable Injection timing: not applicable Massage: not applicable Intraoperative probe: not applicable **Dye** Type: Lymphazurin (1%) Amount: 3 to 5ml Injection location: injected peritumourally. Injection timing: after induction of general anaesthesia or IV sedation. Massage: the breast was gently massaged for 3 to 5 minutes. **Preoperative lymphoscintigraphy** Timing: not applicable **Surgery** Surgeon details: not stated Anaesthesia: general anaesthesia or local anaesthesia with IV sedation. Axillary clearance: a level I and II axillary clearance was performed. Sentinel node definition: blue stained lymph nodes reached by an afferent blue –stained lymphatic channel. Final breast procedure: lumpectomy 17/41 (41.5%); mastectomy 24/41 (58.5%) **Histologic analysis of sentinel nodes** Intraoperative analysis: not stated Sectioning: not stated Permanent section: H&E IHC: if no tumour was identified, IHC staining with a cytokeratin-binding antibody cocktail (MAK-6™) was performed. IHC-positive stains were confirmed by reinspection with H&E. Micrometastases definition: a tumour deposit ≤ 2mm. If the sentinel nodes contained multiple tumour deposits, the sum of the diameters of these deposits was used to classify the metastasis as a micro- or macrometastasis. **Histologic analysis of axillary nodes** Processed by routine pathologic techniques and examined only with H&E.	**Age** Median 52, mean 50.9, range 31 to 86 years. **Tumour characteristics** Biopsy method Not stated Size Median 7.1, range not stated 5 to 9.9cm: 35/41 (85.4%) 10 to 15cm: 5/41 (12.2%) >15cm: 1/41 (2.4%) Stage Not stated Histology Ductal: 24/41 (58.5%) Lobular: 17/41 (41.5%) Location Not stated Palpability Not stated Multifocality/multicentricity Not stated **Axilla characteristics** Clinical axillary status Negative: 41/41 (100%) **Neoadjuvant chemotherapy** Yes: 2/41 (4.9%) No: 39/41 (95.1%)

Study identifier	Procedure	Patient characteristics
Chung, Hung, Chan, Lau, Mak & Yip, 2001b. **Number of patients** 30 **Number of attempted mappings** 30 **Study period** January 1996 to October 1999 **Institution** Breast Centre, Department of Surgery and Department of Pathology, Kwong Wah Hospital, Hong Kong. **Incorporated studies** None **Inclusion/exclusion criteria** Inclusions: patients with invasive carcinoma of the breast measuring <3cm in size, with no palpable axillary nodes, and who were candidates for breast conservation treatment with a separate axillary incision for axillary lymph node dissection were included. Exclusions: patients who had undergone previous excisional biopsy, who had received chemotherapy or with an allergic history to blue dye were excluded. **Study included for review of...** Localisation rates and false negative rates	**Radiocolloid/dye combination** Radiocolloid only: 0 Dye only: 30 Radiocolloid and dye: 0 **Radiocolloid** Radiocolloid was not used. Type: not applicable Dose: not applicable Colloid size: not applicable Filtration: not applicable Injection location: not applicable Injection timing: not applicable Massage: not applicable Intraoperative probe: not applicable **Dye** Type: Methylene blue was used early in the study (27 patients); changed to Patent Blue V in the last 3 patients. Amount: mean 4, range 1 to 10ml. Injection location: injected subdermally and peritumourally. Injection timing: approximately 10 minutes before surgery. Massage: not stated **Preoperative lymphoscintigraphy** Timing: not applicable **Surgery** Surgeon details: not stated Anaesthesia: not stated Axillary clearance: level I and II axillary dissection. Sentinel node definition: a blue stained lymph node or a lymph node that received a blue stained lymphatic vessel. Final breast procedure: wide local excision 30/30 (100%). **Histologic analysis of sentinel nodes** Intraoperative analysis: not stated Sectioning: not stated Permanent section: H&E IHC: not used Micrometastases definition: not stated **Histologic analysis of axillary nodes** H&E	**Age** Mean 50, range 34 to 81 years. **Tumour characteristics** Biopsy method Patients who had exisional biopsies were excluded. Size Mean 1.7cm, range 0.8 to 3.0cm. Stage T1a (≤0.5cm): 0/30 (0%) T1b (>0.5 to 1.0cm): 5/30 (16.7%) T1c (1.0 to 2.0cm): 17/30 (56.7%) T2 (>2.0 to 5.0cm): 8/30 (26.7%) Histology Not stated Location Not stated Palpability Not stated Multifocality/multicentricity Not stated **Axilla characteristics** Clinical axillary status Negative: 30/30 (100%) **Neoadjuvant chemotherapy** Patient that had had neoadjuvant chemotherapy were excluded.

Study identifier	Procedure	Patient characteristics
Classe, Curtet, Campion, Rousseau, Fiche, Sagan, Resche, Pioud, Andrieux & Dravet, 2003. **Number of patients** 200 **Number of attempted mappings** 200 **Study period** June 1999 to November 2001 **Institution** Service de Chirurgie Oncologique, Centre René Gauducheau, Site Hôpital Nord; Institute National de Santé et de Recherche Médicale; Service de Biostatistique et DIM and Service de Médecine Nucléaire, Centre René Gauducheau; Service d'Anatomie Pathologique Centre Hospitalier Universitaire, Site Hôpital Nord, Nates, France. **Incorporated studies** None **Inclusion/exclusion criteria** Inclusions: preoperative diagnosis (cytopuncture or microbiopsy) of invasive carcinoma, and indication for conservative surgical treatment (T0, T1, T2), clinically negative axillary lymph nodes (N0) and signed consent. Exclusions: pregnancy, palpable suspicious axillary lymph nodes (N1, N2), neoadjuvant treatment (including surgery, neoadjuvant chemotherapy), and indication for radical surgical treatment and refusal by the patient to give informed consent. **Study included for review of...** Localisation rates	**Radiocolloid/dye combination** Radiocolloid only: 0 Dye only: 0 Radiocolloid and dye: 200 **Radiocolloid** Type: ^{99m}Tc-labelled rhenium sulphate Dose: 0.8mCi (29.6MBq) in 0.2ml (when injected the day before surgery); 0.5mCi (18.5MBq) in 0.2ml (when injected the day of surgery) Colloid size: not stated Filtration: unfiltered Injection location: injected intraparenchymally as two injections of 0.1ml, towards the axillary ends of the tumour. Injection timing: day before or day of surgery Massage: not stated Intraoperative probe: Modelo 2^{R} (DAMRI, CEA, France). **Dye** Type: Patent blue dye Amount: 2ml Injection location: two intraparenchymal injections of 1ml. Injection timing: 10 minutes before axillary incision. Massage: not stated **Preoperative lymphoscintigraphy** Timing: 2 hours after injection of the radiocolloid, or the day after (morning of surgery). **Surgery** Surgeon details: surgeon A and surgeon B performed 100 cases each Anaesthesia: general Axillary clearance: level I and II Sentinel node definition: any node that was blue, both blue and hot (hot defined as an *in vivo* count of two time the background or more), or hot alone. Final breast procedure: inclusion criteria included patients with indications for conservative surgical treatment, patients indicated for radical surgical treatment were excluded. **Histologic analysis of sentinel nodes** Intraoperative analysis: frozen sectioning not performed. Sectioning: embedded whole and slices prepared perpendicularly to the nodes largest axis, and ten 4µm sections were prepared. Permanent section: sections 1, 4 and 7 were stained with H&E IHC: when H&E was negative, IHC was carried out on 3 intermediate sections using an antibody specific for keratin. Micrometastases definition: metastasis <2mm **Histologic analysis of axillary nodes** One node per block, one section per block, stained with H&E.	**Age** Mean 57, range 30 to 79 years. **Tumour characteristics** Biopsy method Cytopuncture or microbiopsy, proportions not stated. Size 2.44, range 1.2 to 6.1cm. Stage T0: 34/200 (17.0%) T1: 88/200 (44.0%) T2: 78/200 (39.0%) Grade I: 65/199 (32.7%) Grade II: 89/199 (44.7%) Grade III: 45/199 (22.6%) (Histoprognostic grade not specified in one case) Histology Invasive ductal cancer: 149/200 (74.5%) Invasive lobular cancer: 19/200 (9.5%) Carcinoma:other: 32/200 (16.0%) Location Not stated Palpability Not stated Multifocality/multicentricity Not stated **Axilla characteristics** Clinical axillary status N0: 200/200 (100%) **Neoadjuvant chemotherapy** Patients who had had neoadjuvant chemotherapy were excluded.

Study identifier	Procedure	Patient characteristics
Cohen, Breslin, Kuerer, Ross, Hunt & Sahin, 2000. **Number of patients** 38 **Number of attempted mappings** 38 **Study period** September 1994 to November 1998 **Institution** Departments of Pathology and Surgical Oncology, The University of Texas MD Anderson Cancer Center, Houston, Texas, USA. **Incorporated studies** None **Inclusion/exclusion criteria** Inclusions: consecutive patients with stage II or III breast carcinoma treated with neoadjuvant chemotherapy at The University of Texas M.D. Anderson Cancer Center, within the study period. Exclusions: none stated **Study included for review of...** False negative rates	**Radiocolloid/dye combination** Radiocolloid only: 0 Dye only: 23 Radiocolloid and dye: 15 **Radiocolloid** Type: ^{99m}Tc-labelled sulphur colloid Dose: not stated Colloid size: not stated Filtration: not stated Injection location: not stated Injection timing: not stated Massage: not stated Intraoperative probe: not stated **Dye** Type: Isosulphan blue dye (1%) Amount: not stated Injection location: injected peritumourally. Injection timing: not stated Massage: not stated **Preoperative lymphoscintigraphy** Timing: whether lymphoscintigraphy was performed was not stated. **Surgery** Surgeon details: not stated Anaesthesia: not stated Axillary clearance: level I and II axillary clearance Sentinel node definition: not stated Final breast procedure: segmental or total mastectomy, proportions not stated. **Histologic analysis of sentinel nodes** Intraoperative analysis: frozen section was not performed. Sectioning: sentinel nodes were serially sectioned along the short axis to permit evaluation of the greatest number of histologic faces, fixed in formalin, embedded in paraffin. If metastatic disease identified in the sentinel node, no further histologic analysis was performed, if the sentinel node was tumour free, all nodes evaluated with 4 additional levels at 25μm intervals. Permanent section: H&E (if initial section negative, additional sections at levels 1, 3 and 4). IHC: if initial section negative, level 2 was stained for cytokeratin (monoclonal antibodies (AE1/AE3). Micrometastases definition: not stated **Histologic analysis of axillary nodes** Serially sectioned along the long axis if the node was > 4mm, fixed in formalin, embedded in paraffin and H&E staining.	**Age** Median 45, range 29 to 71 years. **Tumour characteristics** Biopsy method FNA: 9/38 (23.7%) CB: 20/38 (52.6%) Incisional: 5/38 (13.2%) Excisional: 4/38 (10.5%) Size Median 4.5, range 2 to 13cm. Stage II to III Histology Invasive ductal: 33/38 (86.8%) Invasive lobular: 3/38 (7.9%) Mixed ductal/lobular: 1/38 (2.6%) Mucinous: 1/38 (2.6%) Location UOQ: 16/38 (42.1%) UIQ: 11/38 (28.9%) LOQ: 3/38 (7.9%) LIQ: 1/38 (2.6%) Central: 4/38 (10.5%) 6 o'clock: 1/38 (2.6%) 12 o'clock: 2/38 (5.3%) Palpability Not stated Multifocality/multicentricity Not stated **Axilla characteristics** Clinical axillary status N0: Before NC 20/38 (52.6%); After NC 31/38 (81.6%) N1: Before NC 14/38 (36.8%); After NC 7/38 (18.4%) N2: Before NC 2/38 (5.3%); After NC 0/38 (0%) Undetermined: Before NC 2/38 (5.3%); After NC 0/38 (0%) **Neoadjuvant chemotherapy** All patients received neoadjuvant chemotherapy.

Study identifier	Procedure	Patient characteristics
Cox, Dupont, Whitehead, Ebert, Nguyen, Peltz, Peckham, Cantor & Reintgen, 2002. **Number of patients** 1356 **Number of attempted mappings** 1356 **Study period** April 1994 to May 1999 **Institution** H. Lee Moffitt Cancer Center and Research Institute, University of South Florida in Tampa, Tampa, Florida, USA. **Incorporated studies** Bass *et al.* 1999c; Bass *et al.* 2001; Cox *et al.* 1998b; Cox *et al.* 1998c; Cox *et al.* 2000a; Cox *et al.* 2000b; Reintgen *et al.* 1997; Kamath *et al.* 2001 **Inclusion/exclusion criteria** Inclusions: study group was selected form a 1356 patient database accumulated at the H. Lee Moffitt Cancer and Research Institute from April 1994 to May 1999. Exclusions: none stated **Study included for review of...** Localisation rates	**Radiocolloid/dye combination** Radiocolloid only: 0 Dye only: 0 Radiocolloid and dye: 1356 **Radiocolloid** Type: ^{99m}Tc-labelled sulphur colloid (Syncor International, Tampa, FL). Dose: mean 450, range 425 to 495μCi, was diluted in 6 x 1ml aliquots. Colloid size: not stated Filtration: filtered Injection location: injected into 6 separate sites at the periphery of the tumour or at the site of the previous excisional biopsy, as directed by palpation or US. Injection timing: performed 1 to 6 hours before the operative procedure. Massage: not stated Intraoperative probe: Neoprobe 1000 or 1500, (Neoprobe Corp., Dublin, Ohio, USA). **Dye** Type: isosulphan blue (Lymphazurin, Zenith Parenterals, Rosemont, IL). Amount: mean 5, range 2.5 to 7.5ml. Injection location: not stated Injection timing: at operative intervention. Massage: not stated **Preoperative lymphoscintigraphy** Timing: whether preoperative lymphoscintigraphy was performed was not stated. **Surgery** Surgeon details: not stated Anaesthesia: not stated Axillary clearance: not stated Sentinel node definition: any blue and/or hot node with an *in vivo* gamma probe count of > 3:1 background counts. Final breast procedure: not stated **Histologic analysis of sentinel nodes** Intraoperative analysis: not stated Sectioning: not stated Permanent section: not stated IHC: not stated Micrometastases definition: not stated **Histologic analysis of axillary nodes** Not stated	**Age** Mean 58.6, range 22 to 98 years. **Tumour characteristics** Biopsy method Not stated Size Not stated Stage Not stated Histology Not stated Location Not stated Palpability Not stated Multifocality/multicentricity Not stated **Axilla characteristics** Clinical axillary status Not stated **Neoadjuvant chemotherapy** Not stated

Study identifier	Procedure	Patient characteristics
Crossin, Johnson, Stewart & Turner, 1998. **Number of patients** 50 **Number of attempted mappings** 50 **Study period** 27 month period, year(s) not stated **Institution** Surgery Education Program, Methodist Hospital of Indiana, and the Indiana University School of Medicine, Indianapolis, Indiana, USA. **Incorporated studies** None **Inclusion/exclusion criteria** Inclusions: women with invasive breast cancers and clinically negative axillary nodes. Exclusions: women with prior axillary lymphadenectomies, pregnancy, palpable axillary nodes or multiple tumours. **Study included for review of...** Localisation rates and false negative rates	**Radiocolloid/dye combination** Radiocolloid only: 50 Dye only: 0 Radiocolloid and dye: 0 **Radiocolloid** Type: ^{99m}Tc-labelled sulfur colloid Dose: 1mCi added to normal saline to a total volume of 4ml. Colloid size: not stated Filtration: not stated Injection location: injected into the breast superiorly, medially, inferiorally and laterally to the primary tumour or biopsy site (1ml per injection). The injection was distributed from the deepest to the most superficial level of the tumour of biopsy site. Injection timing: 1 to 4 hours preoperatively. Massage: not stated Intraoperative probe: C-Trak, (Care Wise Medical Products, Morgan Hill, CA, USA). **Dye** Dye was not used. Type: not applicable Amount: not applicable Injection location: not applicable Injection timing: not applicable Massage: not applicable **Preoperative lymphoscintigraphy** Timing: whether lymphoscintigraphy was performed was not stated. **Surgery** Surgeon details: not stated Anaesthesia: not stated Axillary clearance: including level I and II. Sentinel node definition: hot spots, defined as areas separate from the injection sites with >25 counts per 10 seconds. Final breast procedure: partial mastectomy 40/50 (80.0%); total mastectomy 10/50 (20.0%). **Histologic analysis of sentinel nodes** Intraoperative analysis: not stated Sectioning: not stated Permanent section: 'usual procedure' IHC: not stated Micrometastases definition: not stated **Histologic analysis of axillary nodes** 'Usual procedure'	**Age** Range 26 to 90 years | <30 | 1/50 (2.0%) | | 30 to 39 | 5/50 (10.0%) | | 40 to 49 | 6/50 (12.0%) | | 50 to 59 | 12/50 (24.0%) | | 60 to 69 | 13/50 (26.0%) | | 70 to 79 | 11/50 (22.0%) | | >80 | 2/50 (4.0%) | **Tumour characteristics** Biopsy method | Excisional | 30/50 (60.0%) | | FNA | 8/50 (36.0%) | | Incisional | 2/50 (4.0%) | Size | 0 to 0.9cm | 10/50 (20.0%) | | 1 to 1.9cm | 25/50 (50.0%) | | 2 to 2.9cm | 10/50 (20.0%) | | 3 to 3.9cm | 5/50 (10.0%) | Stage Not stated Histology | Ductal adenocarcinoma | 46/50 (92.0%) | | Lobular adenocarcinoma | 3/50 (6.0%) | | Mixed ductal and lobular | 1/50 (2.0%) | Location | UOQ | 16/50 (32.0%) | | UIQ | 5/50 (10.0%) | | Central | 23/50 (46.0%) | | LOQ | 2/50 (4.0%) | | LIQ | 4/50 (8.0%) | Palpability Not stated Multifocality/multicentricity Patients with multiple tumours were excluded. **Axilla characteristics** Clinical axillary status | Negative | 50/50 (100%) | **Neoadjuvant chemotherapy** Not stated

Study identifier	Procedure	Patient characteristics
Cserni, 2002a. **Number of patients** 201 **Number of attempted mappings** 201 **Study period** August 1997 to August 2000 **Institution** Bács-Kiskun County Teaching Hospital, University of Szeged Medical School, Szeged, Hungary. **Incorporated studies** Cserni, 1999b; Cserni *et al.* 2000b; Cserni *et al.* 2000c; Cserni *et al.* 2001a; Cserni *et al.* 2001b; Cserni *et al.* 2002 **Inclusion/exclusion criteria** Inclusions: patients with primary operable breast cancer. Exclusions: none stated **Study included for review of...** Localisation rates	**Radiocolloid/dye combination** Radiocolloid only: not clear Dye only: not clear Radiocolloid and dye: all patients were mapped with blue dye, and some patients were mapped in combination with radiocolloid. **Radiocolloid** Type: ^{99m}Tc-labelled human colloidal albumin Dose: not stated Colloid size: not stated Filtration: not stated Injection location: injected peritumourally. All nonpalpable tumours and some palpable tumours were injected under US or mammographic guidance. Injection timing: the day before surgery in all but a few cases. Massage: not stated Intraoperative probe: not stated **Dye** Type: Patent blue dye Amount: not stated Injection location: dye was injected peritumourally. Injection timing: 5 to 10 minutes before the procedure. Massage: not stated **Preoperative lymphoscintigraphy** Timing: timing not stated. **Surgery** Surgeon details: not stated Anaesthesia: not stated Axillary clearance: in all except one case of invasive carcinoma, a level I and II or complete axillary clearance was performed. A total of ten cases of DCIS were mapped and axillary clearance only carried out in 6 cases. Sentinel node definition: blue and/or radioactive nodes, counting 10-fold *ex vivo* relative to the background. Final breast procedure: not stated **Histologic analysis of sentinel nodes** Intraoperative analysis: not stated Sectioning: serial sectioning at 50 to 100μm^3 or 250μm Permanent section: H&E staining IHC: IHC with cytokeratin cocktails if H&E slides did not demonstrate nodal involvement. Micrometastases definition: not stated **Histologic analysis of axillary nodes** Investigated at 2 to 5 levels close to the central cross section by H&E staining.	**Age** Not stated **Tumour characteristics** Biopsy method Most cases were diagnosed by FNA and/or CB preoperatively, but a few were diagnosed by intraoperative imprint cytology and/or frozen sections. Size Not stated Stage Not stated Histology Invasive and DCIS. Location Not stated Palpability Palpable and nonpalpable Multifocality/multicentricity Not stated **Axilla characteristics** Clinical axillary status Not stated **Neoadjuvant chemotherapy** Not stated

Study identifier	Procedure	Patient characteristics
Cserni, Rajtár & Boross, 2000c **Number of patients** 112 **Number of attempted mappings** 130 **Study period** August 1997 and August 1999 **Institution** Departments of Surgical Pathology, Nuclear Medicine and Surgery, Bács-Kiskun County Teaching Hospital affiliated with the Alber Szent-Györgyi Medical University, Kecskemét, Hungary. **Incorporated studies** Cserni, 1999b; Cserni *et al.* 2000b; Cserni, 2001b **Inclusion/exclusion criteria** Inclusions: a retrospective analysis of all primary operable breast cancer patients with successful lymphatic mapping at the authors' institution between August 1997 and August 1999. Exclusions: none stated **Study included for review of...** False negative rates	**Radiocolloid/dye combination** Radiocolloid only: 0 Dye only: 100 Radiocolloid and dye: 30 **Radiocolloid** Type: ^{99m}Tc-labelled colloidal human albumin Dose: 50 to 60 MBq in 0.5ml Colloid size: mean particle size <80nm for some patients, >200nm for others. Filtration: not stated Injection location: injected peritumourally. Injection timing: day before surgery. Massage: not stated Intraoperative probe: sentinel nodes were not detected intraoperatively. **Dye** Type: Patent blue dye (Patentblau 2.5%, Byk Gulden, Konstantz, Germany). Amount: 2 to 4ml Injection location: injected peritumourally. Injection timing: 5 to 10 minutes before surgery. Massage: not stated **Preoperative lymphoscintigraphy** Timing: performed 30 minutes to 2 hours after radiocolloid injection. **Surgery** Surgeon details: not stated Anaesthesia: not stated Axillary clearance: formal level I and II axillary dissection. Sentinel node definition: all blue nodes were considered sentinel nodes. In the cases were radiocolloid was used, all recovered nodes were assessed with an external gamma well counter postoperatively. Nodes with high counts (at least 10 times higher than the rest of the nodes) were marked and the overlap between these nodes and blue stained sentinel nodes was evaluated. Final breast procedure: breast conservation 101/112 (90.2%); mastectomy 11/112 (9.8%) **Histologic analysis of sentinel nodes** Intraoperative analysis: frozen sectioning not performed, imprint cytology was introduced at the end of the series. Sectioning: formalin fixed and paraffin embedded sentinel nodes were serially sectioned. Permanent section: H&E IHC: examined with IHC for epithelial markers (cytokeratins and epithelial membrane antigen). Micrometastases definition: not stated **Histologic analysis of axillary nodes** Processed conventionally.	**Age** Mean 57.9, median 57, range 34 to 85 years. **Tumour characteristics** Biopsy method Not stated Size* Mean 2.4, median 2.3, range 0.1 to 6cm Not stated (pTis) 1/112 (0.9%) ≤1mm 2/112 (1.8%) ≤5mm 1/112 (0.9%) >5 and ≤ 10mm 5/112 (4.5%) >10 and ≤ 20mm 37/112 (33.0%) >20 and ≤ 50mm 63/112 (56.3%) >50mm 3/112 (2.7%) Stage* pTis 1/112 (0.9%) pT1mic 2/112 (1.8%) pT1a 1/112 (0.9%) pT1b 5/112 (4.5%) pT1c 37/112 (33.0%) pT2 63/112 (56.3%) pT3 3/112 (2.7%) Grade I 38/112 (33.9%) Grade II 39/112 (34.8%) Grade III 32/112 (28.6%) Histology* DCIS 1/112 (0.9%) Invasive ductal carcinoma with extensive intraductal component 4/112 (3.6%) Invasive ductal carcinoma 87/112 (77.8%) Mixed tubular carcinoma 8/112 (7.1%) Invasive lobular carcinoma 4/112 (3.6%) Others 8/112 (7.1%) Location Not stated Palpability Not stated Multifocality/multicentricity Not stated **Axilla characteristics** Clinical axillary status Not stated **Neoadjuvant chemotherapy** Not stated * successfully mapped patients.

Study identifier	Procedure	Patient characteristics
Czerniecki, Scheff, Callans, Spitz, Bedrosian, Conant, Orel, Berlin, Helsabeck, Fraker & Reynolds, 1999. **Number of patients** 43 **Number of attempted mappings** 44 (on lymphoscintigrapy 1 patient had exclusive drainage to the internal mammary chain and was dropped from the study). **Study period** April 1997 to March 1998 **Institution** Departments of Surgery, Radiology, Surgery Education, Radiology (Breast Imaging Division), and Clinical Epidemiology, University of Pennsylvania, Philidelphia, Pennsylvania and Department of Pathology, Division of Anatomic Pathology, Mayo Clinic, Rochester, Minnesota, USA. **Incorporated studies** None **Inclusion/exclusion criteria** Inclusions: patients with biopsy proven breast carcinoma, with clinically negative lymph nodes were included. Exclusions: patients with only internal mammary drainage and no axillary drainage were dropped from the study and went on to axillary clearance. **Study included for review of...** Localisation rates and false negative rates	**Radiocolloid/dye combination** Radiocolloid only: 0 Dye only: 0 Radiocolloid and dye: 43 **Radiocolloid** Type: ^{99m}Tc-labelled sulfur colloid or ^{99m}Tc-labelled human serum albumin. Dose: 2mCi Colloid size: not stated Filtration: the sulphur colloid was filtered (0.22μm). Injection location: patients with palpable tumours were injected in 6 to 8cc volumes into the breast tissue around the tumour. For patients with nonpalpable tumours or those who had previous excisional biopsy, the radiocolloid was injected under US guidance outside the biopsy cavity. Injection timing: day of surgery. Massage: not stated Intraoperative probe: Neoprobe, (Neoprobe Corp., Dublin, OH, USA). **Dye** Type: 1% lymphazurin blue dye (US Surgical Corp., Norwalk, CT). Amount: 4 to 8cc Injection location: injected around the tumour site. US localisation was not used. Injection timing: not stated Massage: not stated **Preoperative lymphoscintigraphy** Timing: 1 to 2 hours after radiocolloid injection. **Surgery** Surgeon details: not stated Anaesthesia: not stated Axillary clearance: for patients undergoing lumpectomy and axillary node dissection, the sentinel node biopsy was performed first followed by completion axillary node dissection (level I and II) and lumpectomy or re-excision of the prior biopsy site. For patients undergoing mastectomy, the sentinel node was identified at the time of axillary lymph node dissection either before (skin sparing) or after the mastectomy. Sentinel node definition: blue with a feeding blue lymphatic channel or if the lymph node had *in vivo* counts at least three times tbackground of negative lymph nodes or fat. Final breast procedure: lumpectomy 35/43 (81.4%); modified radical mastectomy 8/43 (18.6%). **Histologic analysis of sentinel nodes** Intraoperative analysis: not stated Sectioning: examined on two faces by routine histology, method of sectioning not stated. Permanent section: H&E IHC: all negative lymph nodes were evaluated at four additional levels with IHC using cytokeratin antibodies AE1/3 and Pan-CK and negative controls. Micrometastases definition: a tumour deposit ≤ 2.0mm. **Histologic analysis of axillary nodes** Examined on two faces by routine histology using H&E staining.	**Age** Mean 55.3, range 32 to 79 years **Tumour characteristics** Biopsy method Excisional: 19/43 (44.2%) FNA/CB: 24/43 (55.8%) Size <2.0cm: 26/43 (60.5%) 2 to 5cm: 16/43 (37.2%) >5cm: 1/43 (2.3%) Stage T1: 26/43 (60.5%) T2: 16/43 (37.2%) T3: 1/43 (2.3%) Histology Not stated Location Not stated Palpability Palpable and nonpalpable tumours were included. Multifocality/multicentricity Not stated **Axilla characteristics** Clinical axillary status Negative: 43/43 (100%) **Neoadjuvant chemotherapy** Not stated

Study identifier	Procedure	Patient characteristics
Dale & Williams, 1998. **Number of patients** 20 **Number of attempted mappings** 21 (1 bilateral) **Study period** 1 July 1995 to 31 December 1996 **Institution** Division of Surgical Oncology, Mercer University School of Medicine, Macon, Georgia, USA. **Incorporated studies** None **Inclusion/exclusion criteria** Inclusions: all patients were considered for the study, whether the primary tumour was still *in vivo* and diagnosed with percutaneous needle biopsy was previously removed by excisional biopsy. Exclusions: of 28 patient evaluated , 20 agreed to sentinel node biopsy (3/8 not undergoing sentinel node biopsy had palpable nodes preoperatively, 1/8 had previous excision of an axillary lymph node, 1/8 had inflammatory breast carcinoma with preoperative radiation and chemotherapy, 3/8 patients elected not to consent to sentinel node biopsy). **Study included for review of...** Localisation rates and false negative rates	**Radiocolloid/dye combination** Radiocolloid only: 0 Dye only: 21 Radiocolloid and dye: 0 **Radiocolloid** Radiocolloid was not used. Type: not applicable Dose: not applicable Colloid size: not applicable Filtration: not applicable Injection location: not applicable Injection timing: not applicable Massage: not applicable Intraoperative probe: not applicable **Dye** Type: Isosulphan Blue dye (1% Lymphazurin, Hirsch Industries, Inc., Richmond, VA, USA). Amount: 3 to 5cc Injection location: injected into the breast tissue in a four-quadrant location surrounding the primary breast tumour or the previous excisional biopsy site (attempts were made not to inject into the biopsy cavity). Injection timing: after general anaesthesia. Massage: not stated **Preoperative lymphoscintigraphy** Timing: not applicable **Surgery** Surgeon details: injection was performed by the primary investigator or by surgical residents. All surgical procedures were performed by the same primary surgeon (Dale). Anaesthesia: general anaesthesia Axillary clearance: level I, II and partial level III. Sentinel node definition: not stated Final breast procedure: modified radical mastectomy 13/21 (62.0%); breast-conserving 8/21 (38.0%) **Histologic analysis of sentinel nodes** Intraoperative analysis: not stated Sectioning: not stated Permanent section: standard H&E with staining of the entire submitted specimen. IHC: not stated Micrometastases definition: not stated **Histologic analysis of axillary nodes** Not stated	**Age** Median 51, range 27 to 80 years **Tumour characteristics** Biopsy method Excisional: 16/21 76.2% Stereotactic or US directed biopsy: 5/21 (23.8%) Size Median 1.9, range 0.7 to 8cm Stage Not stated Histology Infiltrating ductal carcinoma: 6/21 (28.6%) Infiltrating ductal carcinoma with a component of DCIS: 12/21 (57.1%) Lobular carcinoma: 1/21 (4.8%) Inflammatory carcinoma: 2/21 (9.5%) Location Not stated Palpability Not stated Multifocality/multicentricity Not stated **Axilla characteristics** Clinical axillary status Negative: 21/21 (100%) **Neoadjuvant chemotherapy** Two patients with inflammatory breast cancer had had neoadjuvant chemotherapy.

Study identifier	Procedure	Patient characteristics
de Kanter, van Geel, Paul, Van Eijck, Henzen-Logmans, Kruyt, Krenning, Eggermont & Wiggers, 2000. **Number of patients** 232 (1 male) **Number of attempted mappings** 232 **Study period** December 1996 to November 1998 **Institution** Departments of Surgery, Pathology and Radiology, University Hospital Rotterdam/Daniel den Hoed Cancer Center; Department of Surgery, Zuiderziekenhuis Rotterdam; and Departments of Surgery and Nuclear Medicine, University Hospital Rotterdam/Dijkzigt Hospital, The Netherlands. **Incorporated studies** None **Inclusion/exclusion criteria** Inclusions: consecutive patients with operable breast cancer, diagnosed by mammography, palpation and cytology, visiting one of three participating hospitals. Exclusions: patients with palpable lymph nodes, necessity for neoadjuvant chemotherapy or multifocal tumours. **Study included for review of...** Localisation rates and false negative rates	**Radiocolloid/dye combination** Radiocolloid only: 0 Dye only: 0 Radiocolloid and dye: 232 **Radiocolloid** Type: ^{99m}Tc-labelled nanocolloid (Solconanocoll®) Dose: 30 to 40MBq (if surgery was planned for the day after injection, the amount of radiocolloid was doubled). Colloid size: not stated Filtration: not stated Injection location: subcutaneously and peritumourally, if the tumour had previously been excised, the radiocolloid was injected cranially of the scar in health breast tissue. Injection timing: at least 2.5 hours before operation Massage: not stated Intraoperative probe: RND-CTC4 or C-trac probe. **Dye** Type: Patent blue dye Amount: 0.5ml Injection location: intradermally above the tumour, or if the tumour had been previously excised, cranially of the scar. Injection timing: at the beginning of operation. Massage: not stated **Preoperative lymphoscintigraphy** Timing: two hours after injection of radiocolloid. Lymphoscintigraphy was performed in all but 23 patients (not performed for logistic reasons). **Surgery** Surgeon details: a total of 12 surgeons performed the procedures in 3 hospitals. Anaesthesia: not stated Axillary clearance: complete axillary lymph node dissection. Sentinel node definition: not stated (note: the sentinel node was traced in the axillary specimen in the first 10 pateints, later the sentinel node was identified and excised before the axillary clearance. Final breast procedure: modified radical mastectomy, 40%; modified radical mastectomy after diagnostic lumpectomy (17%), lumpectomy and axillary clearance (29%) or axillary clearance alone after diagnostic lumpectomy (14%). **Histologic analysis of sentinel nodes** Intraoperative analysis: not stated Sectioning: 4 to 8 sections. Permanent section: H&E IHC: using cytokeratin antibody (CAM 5.2) Micrometastases definition: not stated **Histologic analysis of axillary nodes** H&E	**Age** Not stated **Tumour characteristics** Biopsy method Cytology: 232/232 (100%) Diagnostic and therapeutic lympectomy: 71/232 (30.6%) Size Not stated Stage Not stated Histology Not stated Location Lateral quadrant, approximately 50%. Palpability In 69% of patients the tumour was discovered by physical examination. Multifocality/multicentricity Patients with multifocal tumours were excluded. **Axilla characteristics** Clinical axillary status Negative: 232/232 (100%) The axilla was also examined by ultrasound and fine needle aspiration cytology was performed on suspicious nodes. Patients with positive cytology underwent axillary clearance, not sentinel lymph node biopsy. **Neoadjuvant chemotherapy** Patients who needed neoadjuvant chemotherapy were excluded.

Study identifier	Procedure	Patient characteristics
de Rubeis, Bafile, Resta & Vicentini, 2000. **Number of patients** 21 **Number of attempted mappings** 21 **Study period** 1 December 1998 to 15 December 1999 **Institution** Department of Oncology and Senology, Hospital of L'Aquila, L'Aquila, Italy. **Incorporated studies** None **Inclusion/exclusion criteria** Inclusions: patients with breast cancer. Exclusions: none stated **Study included for review of...** Localisation rates and false negative rates	**Radiocolloid/dye combination** Radiocolloid only: 19 Dye only: 0 Radiocolloid and dye: 2 **Radiocolloid** Type: ^{99m}Tc-labelled colloid (Nanocoll) Dose: 0.2ml Colloid size: not stated Filtration: not stated Injection location: injected peritumourally. Injection timing: 12 to 16 hours before surgery in 18/21 (85.7%) patients, 5 hours before surgery in 2/21 (9.5%) patients and 24 hours before surgery in 1/21 (4.8%). Massage: not stated Intraoperative probe: not stated **Dye** Type: patent blue V Amount: 1ml Injection location: injected subcutaneously at the projection site over the tumour. Injection timing: 30 minutes before incision. Massage: not stated **Preoperative lymphoscintigraphy** Timing: performed 1 hour after colloid injection and repeated 3 times at 20 minute intervals. **Surgery** Surgeon details: not stated Anaesthesia: not stated Axillary clearance: complete three-level axillary dissection. Sentinel node definition: not stated Final breast procedure: not stated **Histologic analysis of sentinel nodes** Intraoperative analysis: not stated Sectioning: not stated Permanent section: traditional histological examination. IHC: not stated Micrometastases definition: not stated **Histologic analysis of axillary nodes** Not stated	**Age** Range 37 to 68 years. **Tumour characteristics** Biopsy method Excisional: 1/21 (4.8%) Size Not stated Stage T1: 21/21 (100%) Histology Not stated Location Not stated Palpability Not stated Multifocality/multicentricity Not stated **Axilla characteristics** Clinical axillary status N0: 21/21 (100%) **Neoadjuvant chemotherapy** Not stated

Study identifier	Procedure	Patient characteristics
d'Eredita, Ferrarese, Cecere, Massa, de Carne & Fabiano, 2003. **Number of patients** 155 **Number of attempted mappings** 155 **Study period** January 1999 to October 2002 **Institution** Department of General and Special Surgery, University of Bari, Bari, Italy. **Incorporated studies** d'Eredita *et al.* 2001; d'Eredita *et al.* 2002 **Inclusion/exclusion criteria** Inclusions: patients with localised breast cancer, with a histological or cytological diagnosis. Exclusions: Patients with palpable axillary nodes, DCIS histology, previous radiotherapy to the breast, prior axillary surgery or women who were pregnant. **Study included for review of...** Localisation rates	**Radiocolloid/dye combination** Radiocolloid only: 0 Dye only: 0 Radiocolloid and dye: 155 **Radiocolloid** Type: ^{99m}Tc-labelled human albumin colloid (Nanocol; Nycomed-Amersham, Sorin, Italy). Dose: 8 to 12 MBq in 0.4ml saline Colloid size: 80 to 200nm Filtration: not stated Injection location: four peritumoural injections immediately around the breast lesion. Patients with nonpalpable lesions were injected using using US guidance. Injection timing: patients were injected on the day before surgery. Massage: not stated Intraoperative probe: Neoprobe (Dublin, OH, USA). **Dye** Type: methylene blue dye Amount: 4ml Injection location: Group 1 (n=115), injected subdermally, above the breast mass, in four subdermal injections; Group 2 (n=40), subareolar injection, dye injected into the upper, outer edge of the areola and directed medially toward the nioole, in a single injection site. Injection timing: 10 to 20 minutes before axillary incision. Massage: not stated **Preoperative lymphoscintigraphy** Timing: 15 to 30minutes and 3 hours after radiocolloid injection. **Surgery** Surgeon details: not stated Anaesthesia: not stated Axillary clearance: the first 50 cases underwent SLNB followed by axillary clearance, the procedure was then modified so that axillary clearance was not performed in patients that had sentinel nodes negative by H&E and IHC. Sentinel node definition: blue nodes and/or nodes emitting the highest activity or with counts ≥ 10% of the *ex vivo* count of the most radioactive lymph node. Final breast procedure: quadrantectomy 75/155 (48.4%); modified radical mastectomy 80/155 (51.6%) **Histologic analysis of sentinel nodes** Intraoperative analysis: not stated Sectioning: sentinel nodes were sectioned along the long axis and submitted for routine processing. Each tissue block was sectioned serially (successive 5μm sections). Permanent histology: H&E. IHC: IHC was performed using a cytokeratin cocktail of three monoclonal antibodies (AE1/AE3; CAM 5.2; MNF 116). Micrometastases definition: not stated **Histologic analysis of axillary nodes** Not stated	**Age** Group 1: mean 57, range 27 to 87 years. Group 2: mean 57.6, range 40 to 78 years. **Tumour characteristics** Biopsy method Needle: 53/155 (34.2%) Open: 102/155 (65.8%) Size Not stated Stage T1a: 14/155 (9.0%) T1b: 31/155 (20.0%) T1c: 65/155 (41.9%) T2: 45/155 (29.0%) Grade I: 29/155 (18.7%) Grade II: 62/155 (40.0%) Grade III: 64/155 (41.3%) Histology Invasive ductal: 79/155 (51.0%) Invasive lobular: 11/155 (7.1%) Invasive ductal + DCIS: 46/155 (29.7%) Other invasive: 19/155 (12.3%) Location UOQ: 70/155 (45.2%) UIQ: 15/155 (9.7%) LOQ: 18/155 (11.6%) LIQ: 11/155 (7.1%) Central: 42/155 (27.1%) Palpability Palpable and nonpalpable tumours were included. Multifocality/multicentricity Not stated **Axilla characteristics** Clinical axillary status Negative: 155/155 (100%) **Neoadjuvant chemotherapy** Not stated

Study identifier	Procedure	Patient characteristics
Derossis, Fey, Cody III & Borgen, 2003. **Number of patients** 2495 (some male patients) **Number of attempted mappings** 2495 **Study period** September 1996 to June 2001 **Institution** Breast Service, Department of Surgery, Memorial Sloan-Kettering Cancer Center, New York, New York, USA. **Incorporated studies** Boobol *et al.* 2001; Cody *et al.* 1999; Cody *et al.* 2001; Derossis *et al.* 2001; Hill *et al.* 1999; Linehan *et al.* 1999a; Linehan *et al.* 1999b; Martin *et al.* 2001a; Martin *et al.* 2001b; McCarter *et al.* 2001a; McCarter *et al.* 2001b; O'Hea *et al.* 1998; Olson *et al.* 2000; Weiser *et al.* 2000; Yeung *et al.* 2001 **Inclusion/exclusion criteria** Inclusions: data retrieved from electronic charts corresponding to the date of operation. These measurements were retrieved from the anaesthesia perioperative evaluation, the anaesthesia intraoperative record and preadmission assessment records. Clinical staging ranged from T1N0 to T3 N0. Exclusions: none stated **Study included for review of...** Localisation rates	**Radiocolloid/dye combination** Radiocolloid only: 0 Dye only: 0 Radiocolloid and dye: 2495 **Radiocolloid** Type: ^{99m}Tc-labelled sulphur colloid Dose: 0.1mCi in 0.05ml if injected on the morning of surgery, 0.5mCi if injected on the afternoon before surgery. Colloid size: not stated Filtration: unfiltered Injection location: intradermal injection over the tumour site Injection timing: afternoon before or the morning of surgery Massage: not stated Intraoperative probe: not stated **Dye** Type: isosulphan blue dye Amount: 4 to 5ml Injection location: intraparenchymal around the tumour site. Injection timing: Massage: not stated **Preoperative lymphoscintigraphy** Timing: timing not stated **Surgery** Surgeon details: not stated Anaesthesia: not stated Axillary clearance: not stated Sentinel node definition: blue or focally hot nodes. Final breast procedure: not stated **Histologic analysis of sentinel nodes** Intraoperative analysis: not stated Sectioning: not stated IHC: not stated Micrometastases definition: not stated **Histologic analysis of axillary nodes** Not stated	**Age** Not stated for the entire study population. **Tumour characteristics** Biopsy method Not stated Size Not stated Stage T1 to T3 Histology Not stated Location Not stated Palpability Not stated Multifocality/multicentricity Not stated **Axilla characteristics** Clinical axillary status N0: 2495/2495 (100%) **Neoadjuvant chemotherapy** Not stated

Study identifier	Procedure	Patient characteristics
Donahue, 2001. **Number of patients** 42 **Number of attempted mappings** 42 **Study period** Not stated **Institution** Department of Surgery, St. Joseph's Hospital and Medical Center, Phoenix, Arizona, USA. **Incorporated studies** None **Inclusion/exclusion criteria** Inclusions: patients with breast cancer. Exclusions: none stated **Study included for review of...** Localisation rates	**Radiocolloid/dye combination** Radiocolloid only: 0 Dye only: 0 Radiocolloid and dye: 42 **Radiocolloid** Type: type not stated. Dose: 1.6 to 1.8μCi Colloid size: not stated Filtration: filtered Injection location: radiocolloid was injected intraparenchymally. The radiologist used either US or stereotactic guidance to inject into the tumour bed. Injection timing: 3 to 18 hours before surgery. Massage: not stated Intraoperative probe:Navigator, (US Surgical Corp., Norwalk, CT, USA). **Dye** Type: isosulphan blue dye Amount: 5cc Injection location: injected into the subareolar lymphatic plexus, with care being taken not to place the injection into an intradermal location. Injection timing: after anaeasthesia. Massage: breast massage was not performed. **Preoperative lymphoscintigraphy** Timing: conducted for as long as 4 hours after the injection of the isotope. **Surgery** Surgeon details: not stated Anaesthesia: general anaesthesia Axillary clearance: axillary lymph node dissection was performed in all patients with invasive cancer. Sentinel node definition: blue stained lymph nodes or hot nodes. Final breast procedure: lumpectomy or mastectomy, proportions not stated. **Histologic analysis of sentinel nodes** Intraoperative analysis: not stated Sectioning: not stated Permanent section: H&E IHC: not stated Micrometastases definition:not stated **Histologic analysis of axillary nodes** Not stated	**Age** Not stated **Tumour characteristics** Biopsy method Image-guided breast biopsy: 39/42 (92.9%) Size Not stated Stage Not stated Histology Invasive breast cancer: 34/42 (81.0%) DCIS: 8/42 (19.0%) Location Not stated Palpability Not stated Multifocality/multicentricity Not stated **Axilla characteristics** Clinical axillary status Not stated **Neoadjuvant chemotherapy** Not stated

Study identifier	Procedure	Patient characteristics
Doting, Jansen, Nieweg, Piers, Tiebosch, Koops, Rutgers, Kroon, Peterse, Valdés Olmos & de Vries, 2000. **Number of patients** 136 **Number of attempted mappings** 136 **Study period** October 1996 to January 1999 **Institution** Departments of Surgical Oncology, Nuclear Medicine, Pathology and Laboratory Medicine, Groningen University Hospital, Groningen; Departments of Surgery, Pathology and Nuclear Medicine, Netherlands Cancer Institute (Antoni van Leeuwenhoek Hospital), Amsterdam, The Netherlands. **Incorporated studies** None **Inclusion/exclusion criteria** Inclusions: patients with palpable breast carcinoma presenting at either the University Hospital Groningen or the Netherlands Cancer Institute (Antoni van Leeuwenhoek Hospital). Exclusions: patients with multicentric breast carcinoma, prior breast surgery, suspected axillary involvements, distant metastases or pregnancy. **Study included for review of...** False negative rates	**Radiocolloid/dye combination** Radiocolloid only: 0 Dye only: 0 Radiocolloid and dye: 136 **Radiocolloid** Type: ^{99m}Tc-labelled nanocolloid (Nanocoll; Amersham Cygne, Eindhoven, The Netherlands). Dose: 40 to 60MBq in 0.2ml normal saline. Colloid size: not stated Filtration: not stated Injection location: injected into the primary tumour, in multiple sites if the lesion was large. Injection timing: day before surgery Massage: not stated Intraoperative probe: Neoprobe 1000/1500 (Neoprobe Corporation, Dublin, OH, USA) and Navigator (Autosuture Europe, Elancourt, France). **Dye** Type: Patent blue dye (Blue Patenté V; Laboratoire Guebet, Aulnay-sous-Bois, France). Amount: 1.0ml Injection location: into the primary tumour. Injection timing: after the induction of general anaesthesia Massage: in the latter part of the study, the area around the tumour and in between the tumour and axilla was massaged for several minutes. **Preoperative lymphoscintigraphy** Timing: immediately after injection of radiocolloid and at 2 hours (and 4 and 7 hours, if necessary) after injection. **Surgery** Surgeon details: surgery performed by 4 surgeons. Anaesthesia: general anaesthesia. Axillary clearance: half the patients had an axillary clearance (Berg levels I, I and III) and half underwent a modified mastectomy (Madden) which included axillary clearance. Sentinel node definition: hot nodes and nodes with an afferent blue or radioactive lymphatic duct coming from the direction of the breast. Nodes that received blue dye from another blue node not considered sentinel nodes. Final breast procedure: not stated **Histologic analysis of sentinel nodes** Intraoperative analysis: not stated Sectioning: embedded and step-sectioned with 500µm intervals at 3 levels. Permanent section: H&E performed at each level. IHC: using a monoclonal antibody directed at cytokeratin (CAM 5.2) performed at each level. Micrometastases definition: not stated **Histologic analysis of axillary nodes** Examined with IHC at one level.	**Age** Mean 59, range 30 to 89 years.* **Tumour characteristics** Biopsy method Not stated Size Mean 1.9, range 0.4 to 6.0cm. Stage T1: 70/136 (51.5%) T2: 61/136 (44.9%) T3: 5/136 (3.7%) Histology Type of carcinoma: Ductal: 123/136 (90.4%) Lobular: 11/136 (8.1%) Tubular: 1/136 (0.7%) Mucinous: 1/136 (0.7%) Location UOQ: 63/136 (46.3%) UIQ: 28/136 (20.6%) LOQ: 19/136 (14.0%) LIQ: 11/136 (8.1%) Central: 15/136 (11.0%) Palpability Palpable: 136/136 (100%) Multifocality/multicentricity Patients with multicentric breast carcinoma were excluded. **Axilla characteristics** Clinical axillary status Negative: 136/136 (100%) **Neoadjuvant chemotherapy** Not stated * mean age of the 141 patients before the exclusion of 5 patients.

Study identifier	Procedure	Patient characteristics
Dowlatshahi, Fan, Bloom, Spitz, Patel & Snider, 1999. **Number of patients** 54 **Number of attempted mappings** 54 **Study period** December 1997 and July 1998 **Institution** Departments of General Surgery and Pathology, Rush-Presbyterian-St. Luke's Medical Center, Chicago, Illinois and Department of Surgery, Baptist Medical Center, Montgomery, Alabama, USA. **Incorporated studies** None **Inclusion/exclusion criteria** Inclusions: patients with invasive breast carcinoma who underwent partial mastectomy and sentinel lymph node biopsy. Exclusions: none stated **Study included for review of...** Localisation rates and false negative rates	**Radiocolloid/dye combination** Radiocolloid only: 51 Dye only: 0 Radiocolloid and dye: 3 **Radiocolloid** Type: ^{99m}Tc-labelled sulphur colloid Dose: 1mCi in 4ml Colloid size: not stated Filtration: unfiltered Injection location: around the tumour or excisional biopsy cavity, using US guidance to avoid the seroma or scar if the patient had a previous biopsy Injection timing: preoperatively, mean injection-resection interval 150, range 60 to 315 minutes. Massage: not stated Intraoperative probe:C-Trak (Carewise, Morgan Hill, CA), used prior to taking patients into the operating room and sentinel node location were marked on the skin. **Dye** Only used when no hot spot was identified preoperatively. Type: isosulphan blue Amount: 5ml Injection location: not stated Injection timing: 15 minutes prior to axillary incision. Massage: not stated **Preoperative lymphoscintigraphy** Timing: not performed, hot spots located preoperatively with a hand-held gamma-probe. **Surgery** Surgeon details: not stated Anaesthesia: not stated Axillary clearance: not stated Sentinel node definition: not stated Final breast procedure: not stated **Histologic analysis of sentinel nodes** Intraoperative analysis: not stated Sectioning: each sentinel node was serially sectioned at 2mm intervals perpendicular to the long axis, formalin fixed and paraffin embedded. Permanent section: one section, 5µm thick was stained with H&E. IHC: performed with cytokeratin (CK 8/18). Micrometastases definition: not stated **Histologic analysis of axillary nodes** Not stated	**Age** * Mean 55, 33 to 80 years. **Tumour characteristics** Biopsy method Diagnosis of invasive carcinoma was made by needle core or excisional biopsy. Size* Mean 1.35, range 0.2 to 3.6cm. Stage* T1a: 6/52 (11.5%) T1b: 19/52 (36.5%) T1c: 14/52 (26.9%) T2: 13/52 (25.0%) Histology* Invasive ductal (not otherwise specified): 28/52 (53.8%) Tubular: 5/52 (9.6%) Colloid: 2/52 (3.8%) Invasive lobular: 17/52 (32.7%) Location Not stated Palpability* Palpable: 29/52 (55.8%) Nonpalpable: 23/52 (44.2%) Multifocality/multicentricity Not stated **Axilla characteristics** Clinical axillary status Negative: 54/54 (100%) **Neoadjuvant chemotherapy** Not stated * for 52 patients with operable breast carcinoma treated with lumpectomy and SLNB.

Study identifier	Procedure	Patient characteristics
Dunnwald, Mankoff, Byrd, Anderson, Moe, Yeung & Eary, 1999. **Number of patients** 93 **Number of attempted mappings** 93 **Study period** Not stated **Institution** Division of Nuclear Medicine and Department of Surgery, University of Washington, Seattle, Washington, USA. **Incorporated studies** Morgan *et al.* 1999 **Inclusion/exclusion criteria** Inclusions: patients with known invasive breast carcinoma, 68/93 (73.1%) patients were on a research protocol. Exclusions: none stated **Study included for review of...** Localisation rates	**Radiocolloid/dye combination** Radiocolloid only: 0 Dye only: 0 Radiocolloid and dye: 93 **Radiocolloid** Type: ^{99m}Tc- labelled sulphur colloid Dose: 1.0mCi (37MBq) compined with 2ml sodium bicarbonate and normal saline to 6ml total volume, dose reduced to 0.5mCi in patients whose injection sites were not going to be reexcised. Colloid size: not stated Filtration: filtered (0.2µm) Injection location: four injections (1.5ml each) at the midplane of the lesion or biopsy cavity. For nonpalpable lesions, a single 6ml injection was made through tubing connected directly to the localisation wire introducer needle (tube was flushed with saline before and after injection) Injection timing: not stated Massage: not stated (but between lymphoscintigraphic images, the patient was encouraged to walk around and exercise the ipsilateral arm, except if they had wire localisation) Intraoperative probe: type not stated. **Dye** Type: Lymphazurin Amount: 5ml Injection location: perilesional if tumour was palpable, or via tubing connected to localisation wire introducer needle. Injection timing: at the time of surgical incision. Massage: massage was performed **Preoperative lymphoscintigraphy** Timing: performed 1 to 3 hours prior to surgery. **Surgery** Surgeon details: not stated Timing: 1 to 3 hours after lymphoscintigraphy Anaesthesia: not stated Axillary clearance: axillary node dissection in all 'on protocol' patients. In the 25 patients undergoing SLNB only, axillary clearance was performed when the sentinel node could not be located or if positive for metastases (clearance performed at a later time). Sentinel node definition: blue and/or ratio of radioactive counts in the lymph node excised versus final surgical bed background was ≥ 3:1 or the ratio of *ex vivo* radioactive counts in the sentinel lymph node versus any nonsentinel lymph nodes removed was ≥ 10:1. Final breast procedure: not stated **Histologic analysis of sentinel nodes** Intraoperative analysis: not stated Sectioning: not stated Permanent section: not stated IHC: not stated Micrometastases definition: not stated **Histologic analysis of axillary nodes** Not stated	**Age** Mean 55.9, range 26 to 88 years. **Tumour characteristics** Biopsy method In most, diagnosis had been made by core needle biopsy 24/93 (25.8%) had prior surgery or excisional biopsy Size ≤2cm: 12/30 (40.0%) 2cm but ≤ 5cm: 17/30 (56.7%) >5cm: 1/30 (3.3%) In patients with no prior intervention Stage T1: 12/30 (40.0%) T2: 17/30 (56.7%) T3: 1/30 (3.3%) In patients with no prior intervention Histology Not stated Location Not stated Palpability 55/93 (59.1%) lesions or biopsy cavities were palpable, 13/93 (14.0%) required US localisation or mammography. Multifocality/multicentricity Not stated **Axilla characteristics** Clinical axillary status Not stated **Neoadjuvant chemotherapy** 12/93 (12.9%) patients had locally advanced breast cancer and were treated with neoadjuvant chemotherapy.

Study identifier	Procedure	Patient characteristics
Estourgie, Nieweg, Valdés Olmos, Rutgers, Peterse & Kroon, 2003a. **Number of patients** 599 **Number of attempted mappings** 606 (7 bilateral) **Study period** January 1997 to November 2001 **Institution** Departments of Surgery, Nuclear Medicine and Pathology, The Netherlands Cancer Institute, Amsterdam, The Netherlands. **Incorporated studies** Nieweg *et al.* 2003; Rutgers & Nieweg 2000; Tanis *et al.* 2001a; Tanis *et al.* 2002a; Tanis *et al.* 2002b; Valdes Olmos *et al.* 2000; Valdes Olmos *et al.* 2001 **Inclusion/exclusion criteria** Inclusions: clinically N0 breast cancer patients. Exclusions: none stated **Study included for review of...** Localisation rates	**Radiocolloid/dye combination** Radiocolloid only: 0 Dye only: 0 Radiocolloid and dye: 606 **Radiocolloid** Type: ^{99m}Tc-labelled nanocolloid (Nanocoll®; Amersham Cygne, Eindhoven, The Netherlands). Dose: mean 2.8mCi (105.4MBq) in a mean of 0.2ml. Colloid size: not stated Filtration: not stated Injection location: into the lesion, in the case of nonpalpable breast cancer, the intratumoural injection was guided by ultrasound or sterotaxis. Injection timing: injected on the day before surgery. Massage: not stated Intraoperative probe: Neoprobe ®, (Johnson & Johnson Medical, Hamburg, Germany). **Dye** Type: Patent blue dye (Laboratoire Guerbet, Aulnay-Sous-Bois, France) Amount: mean 1.0ml Injection location: into the palpable lesion or through a catheter placed over the localisation wire. Injection timing: not stated Massage: not stated **Preoperative lymphoscintigraphy** Timing: immediate imaging was performed, followed by imaging at 30min and 4 hours postinjection. **Surgery** Surgeon details: all procedures were performed by one of four experienced surgeons or under their supervision by a resident or fellow. Anaesthesia: not stated Axillary clearance: routine axillary clearance was performed until January 1999, in 81 patients as part of the learning phase, in later patients, axillary clearance was omitted in the case of a tumour-negative sentinel nodes. Sentinel node definition: a hotspot on lymphoscintigraphy if an afferent lymphatic channel was visualised and the hotspot was the first one seen in a sequential pattern or the only one depicted. An afferent blue lymphatic vessel coming directly from the tumour was also defined as a sentinel node. Final breast procedure: not stated **Histologic analysis of sentinel nodes** Intraoperative analysis: frozen section was performed on most sentinel nodes. Sectioning: formalin fixed and bisected, paraffin embedded; a minimum of 6 levels at 50 to 150μm steps. Permanent section: H&E IHC: CAM 5.2 Micrometastases definition: not stated **Histologic analysis of axillary nodes** IHC used in the learning phase.	**Age** Not stated **Tumour characteristics** Biopsy method Core biopsy or fine needle aspiration, no excisional biopsy. Size Not stated Stage Not stated Histology Not stated Location Not stated Palpability Palpable: 487/599 (81.3%) Nonpalpable: 112/599 (18.7%) Multifocality/multicentricity Not stated **Axilla characteristics** Clinical axillary status N0: 606/606 (100%) **Neoadjuvant chemotherapy** Not stated

Study identifier	Procedure	Patient characteristics
Euhus, Peters, Leitch, Saboorian, Mathews, Erdman, Anglin & Huth, 2002. **Number of patients** 153 **Number of attempted mappings** 156 (3 bilateral) **Study period** 27 November 1996 to 27 August 1998 **Institution** Division of Surgical Oncology and Departments of Pathology and Radiology, U.T. Southwestern Medical Center, Dallas, Texas, USA. **Incorporated studies** None **Inclusion/exclusion criteria** Inclusions: women with clinical stage I (T1N0M0) or stage IIa (T2N0M0) breast cancer. Exclusions: none stated **Study included for review of...** Localisation rates	**Radiocolloid/dye combination** Radiocolloid only: 0 Dye only: 0 Radiocolloid and dye: 156 **Radiocolloid** Type: ^{99m}Tc-labelled sulphur colloid Dose: 0.5-1.5mCi, 4 to 5ml in the first 60 cases (intraparenchymally) reduced to 0.5ml (subdermally) in the remaining cases Colloid size: not stated Filtration: filtered (0.2µm) Injection location: into the parenchyma in four sites near the tumour or seroma cavity (in the first 60 cases) or subdermally in two to four sites (in the remaining cases). Injection timing: 1 to 28 hours prior to surgery Massage: not stated Intraoperative probe: Neoprobe, (Neoprobe Corporation, Dublin, OH, USA). **Dye** Type: Isosulphan blue Amount: 5ml Injection location: 4 sites near the tumour, initially deep in the parenchyma, but more superficial into the subcutaneous fat in the final 100 injections. Injection timing: at the time of surgery. Massage: vigorous breast massage was performed after the first 50 cases. **Preoperative lymphoscintigraphy** Timing: imaging commenced immediately after injection and continued until a node was visualised or for two hours. **Surgery** Surgeon detatils: two surgeons had prior experience in sentinel node biopsy for melanoma and the third had no prior sentinel node biopsy experience. One surgeon attended a training course and all surgeons cooperated together on the initial cases. Anaesthesia: not stated Axillary clearance: completion axillary dissection performed in the first 78 cases, and for subsequent cases, axillary dissection was performed when frozen section of the sentinel node revealed metastases or a sentinel node was not located. Patients returned for axillary clearance if metastases were later diagnosed on permanent section. Sentinel node definition: blue in colour or had gamma emissions ≥ 5 times operating room background. Final breast procedure: mastectomy 53/156 (34%); breast conservation 103/156 (66%). **Histologic analysis of sentinel nodes** Intraoperative analysis: each sentinel node was evaluated by frozen section at one level at the time of surgery. Sectioning: not stated Permanent section: standard histological methods IHC: not performed in the first 68 cases, but performed for every histologically negative sentinel node after that. Micrometastases definition: not stated **Histologic analysis of axillary nodes** Bivalved and evaluated at one level.	**Age** Not stated **Tumour characteristics** Biopsy method Not stated Size ≤2cm: 111/156 (71.2%) 2.1 to 5.0cm: 40/156 (25.6%) >5cm: 5/156 (3.2%) Stage Stage I (T1N0M0) and Stage IIA (T2N0M0) Histology Infiltrating ductal: 137/156 (87.8%) Infiltrating lobular: 19/156 (12.2%) Location Not stated Palpability Not stated Multifocality/multicentricity Not stated **Axilla characteristics** Clinical axillary status Negative: 156/156 (100%) **Neoadjuvant chemotherapy** Not stated

Study identifier	Procedure	Patient characteristics
Feezor, Krasraeian, Copeland, Schell, Hochwald, Cendan, Drane, Mastin, Wilkinson & Lind, 2002. **Number of patients** 118 **Number of attempted mappings** 118 **Study period** Not stated **Institution** Departments of Surgery, Radiology (Nuclear Medicine) and Pathology, University of Florida College of Medicine, Gainesville, Florida, USA. **Incorporated studies** None **Inclusion/exclusion criteria** Inclusions: patients who underwent sentinel lymph node biopsy for clinical Tis, T1, T2 and N0 breast cancer (retrospective review). Exclusions: none stated **Study included for review of...** Localisation rates	**Radiocolloid/dye combination** Radiocolloid only: unsure Dye only: unsure Radiocolloid and dye: unsure (dye used at surgeon's discretion). **Radiocolloid** Type: ^{99m}Tc-labelled sulphur colloid Dose: 0.5 to 1.0mCi (dermal injection); 3 to 4mCi (peritumoural injection). Colloid size: not stated Filtration: 50:50 filtered:unfiltered Injection location: into the dermis overlying the tumour (65/118); a peritumoural injection (6/118); or both dermal and peritumoural injection (47/118). Injection timing: 12 to 18 hours prior to surgery. Massage: not stated Intraoperative probe: hand-held gamma probe, type not stated. **Dye** Blue dye used at surgeon's discretion Type: not stated Amount: not stated Injection location: not stated Injection timing: not stated Massage: not stated **Preoperative lymphoscintigraphy** Timing: dynamic lymphoscintigraphy performed the day before surgery, but precise timing not stated. **Surgery** Surgeon details: not stated Anaesthesia: not stated Axillary clearance: not performed in all patients, precise numbers not given. Sentinel node definition: any lymph node with a radioactive count greater than 10% of the *ex vivo* count of the most radioactive node. Final breast procedure: not stated **Histologic analysis of sentinel nodes** Intraoperative analysis: not stated Sectioning: not stated Permanent section: not stated IHC: not stated Micrometastases definition: not stated **Histologic analysis of axillary nodes** Not stated	**Age** Dermal injection (n=65): mean 57.1 ± (SD) 12.6 years. Peritumoural injection (n=6): mean 53.3 ± (SD) 10.5 years. Sequential dermal-peritumoural injection (n=47): mean 56.9 ± (SD) 11.0 years. **Tumour characteristics** Biopsy method 92/118 (78.0%) had a prior surgical procedure. Size Not stated Stage Tis, T1, and T2. Histology Not stated Location Not stated Palpability Not stated Multifocality/multicentricity Not stated **Axilla characteristics** Clinical axillary status N0: 118/118 (100%) **Neoadjuvant chemotherapy** Not stated

Study identifier	Procedure	Patient characteristics
Feggi, Querzoli, Prandini, Corcione, Bergossi, Basaglia & Carcoforo, 2000. **Number of patients** 60 **Number of attempted mappings** 60 **Study period** October 1997 to October 1999. **Institution** Departments of Nuclear Medicine and Senology of the Azienda Ospedaliera Arcispedale S. Ann, Ferrara and Sections of General Surgery and Pathology of the University of Ferrara, Italy. **Incorporated studies** Carcoforo *et al.* 1999 **Inclusion/exclusion criteria** Inclusions: patients with biopsy proven breast cancer scheduled to undergo lumpectomy or mastectomy and axillary node dissection. Exclusions: none stated **Study included for review of...** Localisation rates and false negative rates	**Radiocolloid/dye combination** Radiocolloid only: 21 Dye only: 0 Radiocolloid and dye: 39 **Radiocolloid** Type: not stated Dose: 70MBq in 0.4cc saline (standard procedure). In 9 patients injected on the day of surgery 10 MBq was used. Colloid size: 200 to 1000nm in 17 patients; <80nm in 43 patients (as other colloid ceased to be available in Italy from August 1998 to October 1999). Filtration: not stated Injection location: four injections at the cardinal points around the site of the lesion or subdermally around the surgical scar. Injection timing: day before surgery in the 17 patients receiving colloid of 200 to 1000nm, day before surgery in 34/43 patients receiving colloid of <80nm and on the day of surgery in 9/43. Massage: not stated Intraoperative probe: Pol.Hi.Tech. (Carsoli, Italy). **Dye** Used in the final 39/60 (65%) patients. Type: not stated Amount: not stated Injection location: not stated Injection timing: not stated Massage: not stated **Preoperative lymphoscintigraphy** Timing: lymphoscintigraphy was performed but the timing was not stated. **Surgery** Surgeon details: not stated Anaesthesia: not stated Axillary clearance: not stated Sentinel node definition: not stated Final breast procedure: not stated **Histologic analysis of sentinel nodes** Intraoperative analysis: sentinel nodes bisected longitudinally and frozen: one section was examined with H&E, one section was examined for cytokeratins. Sectioning: see above Permanent section: not stated IHC: intraoperative rapid staining for cytokeratins. Micrometastases definition: not stated **Histologic analysis of axillary nodes** Not stated	**Age** Mean 60, range 35 to 80 years. **Tumour characteristics** Biopsy method Biopsy proven in all patients, type not stated. Size <3.0cm in all patients. Stage Not stated Histology Not stated Location UOQ 30/60 (50.0%) UIQ 9/60 (15.0%) LOQ 6/60 (10.0%) LIQ 5/60 (8.3%) Central 10/60 (16.7%) Palpability Not stated Multifocality/multicentricity Not stated **Axilla characteristics** Clinical axillary status Not stated **Neoadjuvant chemotherapy** Not stated

Study identifier	Procedure	Patient characteristics
Feggi, Basaglia, Corcione, Querzoli, Soliani, Ascanelli, Prandini, Bergossi & Carcoforo, 2001. **Number of patients** 73 **Number of attempted mappings** 73 **Study period** Not stated **Institution** Departments of Nuclear Medicine and Radiology, S. Anna Hospital, Ferrara, Italy, Departments of General Surgery and Pathology, University of Ferrara, Italy. **Incorporated studies** None **Inclusion/exclusion criteria** Inclusions: patients with nonpalpable lesions identified by screening mammography and/or ultrasound with clinically negative axillae. Exclusions: none stated **Study included for review of...** Localisation rates	**Radiocolloid/dye combination** Radiocolloid only: 73 Dye only: 0 Radiocolloid and dye: 0 **Radiocolloid** Type: ^{99m}Tc-labelled Nanocoll (Nycomed Amersham Sorin, Saluggia, Italy). Dose: 130MBq, range 110-150MBq in 0.3 to 0.4cc. Colloid size: average size <80nm. Filtration: not stated Injection location: half the dose (0.2ml maximum) given intratumorally and half superficially, but very close to the tumour (performed under ultrasound or sterotactic guidance), and if the lesion consisted only of microcalcifications, the entire dose was distributed among the calcifications. Injection timing: day before surgery. Massage: a breast massage by the patient was encouraged. Intraoperative probe: Scintiprobe MR 100 or Neoprobe NEO 2000. **Dye** Type: not applicable Amount: not applicable Injection location: not applicable Injection timing: not applicable Massage: not applicable **Preoperative lymphoscintigraphy** Timing: performed on the morning of surgery, 15 to 19 hours (average 17 hours) after injection of radiocolloid. **Surgery** Surgeon details: not stated Anaesthesia: general anaesthesia was used. Axillary clearance: not stated Sentinel node definition: not stated Final breast procedure: conservative surgery (quadrantectomy) in 73/73 (100%). **Histologic analysis of sentinel nodes** Intraoperative analysis: not stated Sectioning: multilevel sectioning (100µm intervals). Permanent section: stained with H&E. IHC: performed using anticytokeratin antibodies (AE1/AE3, PCK26). Micrometastases definition: not stated **Histologic analysis of axillary nodes** Not stated	**Age** Median 60, range 46 to 80 years. **Tumour characteristics** Biopsy method All patients had positive needle cytology. Size Not stated Stage pT1a: 6/73 (8.2%) pT1b: 15/73 (20.5%) pT1c: 41/73 (56.2%) pT2: 2/73 (2.7%) pTis: 9/73 (12.3%) Staging (AJCC) 0: 8/73 (11.0%) I: 45/73 (61.6%) IIA: 18/73 (24.7%) IIB: 1/73 (1.4%) IIIB: 1/73 (1.4%) Histology Infiltrating ductal carcinoma (+ intraductal component): 34/73 (46.6%) (20) Infiltrating lobular carcinoma (+ intraductal component): 15/73 (20.5%) (9) Infiltrating lobular + tubular carcinoma: 13/73 (17.8%) Infiltrating cribriform + tubular carcinoma: 2/73 (2.7%) DCIS: 9/73 (12.3%) Location Not stated Palpability Nonpalpable: 73/73 (100%) Multifocality/multicentricity M0: 73/73 (100%) **Axilla characteristics** Clinical axillary status N0: 53/73 (72.6%) N1: 19/73 (26.0%) N3: 1/73 (1.4%) **Neoadjuvant chemotherapy** Not stated

Study identifier	Procedure	Patient characteristics
Feldman, Krag, McNally, Moor, Weaver & Klein, 1999. **Number of patients** Phase I: 57 Phase II: 18 Total: 75 (1 male) **Number of attempted mappings** Phase I: 57 Phase II: 18 Total : 75 **Study period** Phase I: February 1996 to June 1997 Phase II: July 1999 to February 1998 **Institution** Departments of Surgery, Radiology and Outcomes and Research, Benedictine Hospital, Kingston, New York; Departments of Surgery and Pathology, University of Vermont, Burlington, Vermont; Department of Pathology, Albany Medical Center, Albany, New York, USA. **Incorporated studies** None **Inclusion/exclusion criteria** Inclusions: Phase I – patients with invasive breast cancer accrued into a prospective multicentre trial. Phase II – patients with invasive breast cancer who were not enrolled in the multicentre trial. Exclusions: Phase I- patients were excluded if pregnant, if they had prior axillary dissection, multiple primary tumours, or if axillary nodes were clinically suspicious or positive. **Study included for review of...** Localisation rates and false negative rates.	**Radiocolloid/dye combination** Radiocolloid only: 75 Dye only: 0 Radiocolloid and dye: 0 **Radiocolloid** Type: ^{99m}Tc-labelled sulphur colloid (CIS US Inc, Bedford, MA, USA). Dose: Phase I: 1mCi in 4ml; Phase II: 1mCi in 8ml. Colloid size: not stated Filtration: unfiltered Injection location: Phase I: injected into breast tissue immediately surrounding the primary tumour or biopsy cavity, by palpation, with one 1ml injection each at the 12, 3, 6 and 9 o'clock positions. In patients who had a prior exisional biopsy, the syringe was aspirated before injection to ensure that the injection was not into the seroma cavity. Ultrasound guidance was not used; Phase II: altered to 2ml per injection site. Injection timing: between 0.5 and 7.25 hours before surgery, mean time 138 ± 91 minutes. Massage: not stated Intraoperative probe: handheld gamma probed, C-Trak (Care Wise Medical, Morgan Hill, CA, USA). **Dye** Type: not applicable Amount: not applicable Injection location: not applicable Injection timing: not applicable Massage: not applicable **Preoperative lymphoscintigraphy** Timing: no lymphoscintrigrams were performed. **Surgery** Surgeon details: all procedures performed by a signle surgeon (SF) after receiving observed training during the first two cases by Dr Krag. Anaesthesia: not stated Axillary clearance: Phase I: standard level I and II; Phase II: level I unless there were clinically suspicious level II nodes, or the sentinel node was located in level II, extent was at the discretion of the surgeon. Sentinel node definition: hotspots were defined as a discrete area of radiocolloid uptake, separate from the injection site with counts >25 per 10 seconds, clearly higher than background. Sentinel nodes were removed until the background count was <10% of the most radioactive resected sentinel node. No set ratio of activity between sentinel node and background defined. Final breast procedure: partial mastectomy (73%); modified radical mastectomy (27%). **Histologic analysis of sentinel nodes** Intraoperative analysis: not stated Sectioning: nodes up to 0.8cm were embedded whole; nodes >0.8cm were bisected and embedded in one cassette. Standard formalin fixation and processing was used. One section initially used, if negative H&E sections and 100 and 200 μm and cytokeratin IHC stains at 100 μm deeper into the blocks used. Permanent section: H&E IHC: the nodes initially negative were analysed with cytokeratin IHC. Micrometastases definition: not stated **Histologic analysis of axillary nodes** Not stated.	**Age** Mean 59.1, range 25 to 84 years. **Tumour characteristics** Biopsy method Phase I: Excisional biopsy: 48/57 (84.2 %) Core biopsy: 9/57 (15.8 %) Phase II: Excisional biopsy: 0/17 (0.0%) Core biopsy: 16/17 (94.1%) No biopsy: 1/17 (5.9%) Size Mean 1.9 ± 1.0cm. Stage Not stated Histology Ductal: 81% Lobular: 4% Mixed: 4% Other: 11% Location Not stated for whole study population. Palpability Not stated Multifocality/multicentricity Phase I: patients with multiple primary tumours were excluded. **Axilla characteristics** Clinical axillary status Phase I: patients with clinically suspicious or positive axillary nodes were excluded. **Neoadjuvant chemotherapy** Not stated

Study identifier	Procedure	Patient characteristics
Fenaroli, Tondini, Motta, Virotta & Personeni, 2000. **Number of patients** 14 (consecutive). **Number of attempted mappings** 14 **Study period** February 2000 to March 2000 **Institution** Breast Cancer Unit, Department of Surgical Oncology, Divisions of Medical Oncology, Pathology, Nuclear Medicine and Radiation Therapy, Ospedali Riuniti, Bergamo, Italy. **Incorporated studies** None **Inclusion/exclusion criteria** Inclusions: patients with T1N0M0 breast cancer who signed an informed consent form for sentinel node biopsy and agreed to undergo the procedure using local anaesthesia. Exclusions: none stated **Study included for review of...** Localisation rates	**Radiocolloid/dye combination** Radiocolloid only: 14 Dye only: 0 Radiocolloid and dye: 0 **Radiocolloid** Type: ^{99m}Tc-human serum albumin (Albures). Dose: 20MBq Colloid size: microcolloidal particles, precise size not stated. Filtration: not stated Injection location: subdermally, close to the tumour Injection timing: injection performed the day before surgery. Massage: not stated Intraoperative probe: handheld gamma detecting probe, type not stated. **Dye** Type: not applicable Amount: not applicable Injection location: not applicable Injection timing: not applicable Massage: not applicable **Preoperative lymphoscintigraphy** Timing: images taken 10 minutes, 30 minutes and 3 hours after radiocolloid injection. **Surgery** Surgeon details: not stated Anaesthesia: local anaesthesia (20ml Carbocaine 2% without adrenaline). Axillary clearance: not performed at same surgical setting; only one patient had later axillary dissection. Sentinel node definition: not stated Final breast procedure: sentinel node biopsy only (under local anaesthesia). **Histologic analysis of sentinel nodes** Intraoperative analysis: frozen sections Sectioning: a median of 20 frozen sections per node were used during surgery. After the surgery was complete the pathologist analysed more sections where appropriate; a median of 30 sections per node were used. Permanent section: not stated IHC: IHC used where appropriate. Micrometastases definition: not stated **Histologic analysis of axillary nodes** Not stated	**Age** Median 54, range 35 to 82 years. **Tumour characteristics** Biopsy method Core biopsy: 6/14 (42.9%) Radioguided biopsy: 8/14 (57.1%) Size Not stated Stage T1N0M0 Histology Not stated Location Not stated Palpability Not stated Multifocality/multicentricity M0: 14/14 (100%) **Axilla characteristics** Clinical axillary status N0: 14/14 (100%) **Neoadjuvant chemotherapy** Not stated

Study identifier	Procedure	Patient characteristics
Fernández, Cortés, Benito, Azpeitia, Prieto, Moreno, Ricart, Mora, Escobedo & Martín Comín, 2001. **Number of patients** 76 (consecutive). Group 1 – 40 patients whom had previously received neoadjuvant chemotherapy. Group 2 – 36 patients who had not received neoadjuvant chemotherapy. **Number of attempted mappings** 76 **Study period** Not stated **Institution** Servicios de Medicina Nuclear and Unitat Funcional de Mama, Hospital de Bellvitge, Barcelona, Spain. **Incorporated studies** None **Inclusion/exclusion criteria** Inclusions: female patients with single breast cancer who had not received surgery or radiotherapy. Exclusions: none stated **Study included for review of...** Localisation rates and false negative rates	**Radiocolloid/dye combination** Radiocolloid only: 76 Dye only: 0 Radiocolloid and dye: 0 **Radiocolloid** Type: ^{99m}Tc-nanocolloid Dose: 111MBq (3mCi) Colloid size: not stated Filtration: not stated Injection location: injected peritumourally at four different points (0.75ml per injection). Injection timing: 18 to 24 hours prior to surgery, 2 hours prior to lymphoscintigraphy. Massage: not stated Intraoperative probe: GAMMED 2 gamma probe. **Dye** Type: not applicable Amount: not applicable Injection location: not applicable Injection timing: not applicable Massage: not applicable **Preoperative lymphoscintigraphy** Timing: performed two hours after injection of radiocolloid. **Surgery** Surgeon details: not stated Anaesthesia: not stated Axillary clearance: all patients underwent total axillary lymph node dissection. Sentinel node definition: not stated Final breast procedure: not stated **Histologic analysis of sentinel nodes** Intraoperative analysis: not stated Sectioning: lymph nodes were paraffin embedded intact and lamellated into pieces approximately 1cm in size. Three sections were made per block and analysed by two expert pathologists. Permanent section: H&E (3 sections). IHC: performed in 10 cases in order to detect micrometastases. Micrometastases definition: not stated **Histologic analysis of axillary nodes** Not stated	**Age** Group 1 – mean 52, range 36 to 69 years. Group 2 – mean 55, range 31 to 87 years. **Tumour characteristics** Biopsy method Not stated Size Group 1 (n=40) / Group 2 (n=36) ≤ 2cm: 4 (10%) / 15 (41.7%) >2cm but ≤ 5cm: 17 (42.5%) / 18 (50.0%) > 5cm: 16 (40%) / 3 (8.3%) Any size: 3 (7.5%) / 0 (0.0%) Stage T1: 4 (10%) / 15 (41.7%) T2: 17 (42.5%) / 18 (50.0%) T3: 16 (40%) / 3 (8.3%) T4: 3 (7.5%) / 0 (0.0%) Histology Ductal grade 1: 1 (2.5%) / 2 (5.6%) Ductal grade 2: 12 (30.0%) / 20 (55.6%) Ductal grade 3: 24 (60.0%) / 13 (36.1%) Others: 3 (7.5%) / 1 (2.8%) Location UOQ: 24 (60.0%) / 17 (47.2%) LOQ: 7 (17.5%) / 8 (22.2%) UIQ: 3 (7.5%) / 4 (11.1%) LIQ: 6 (15%) / 7 (19.4%) Palpability Not stated Multifocality/multicentricity Not stated **Axilla characteristics** Clinical axillary status N0: 28 (70%) / 35 (97.2%) N1: 12 (30%) / 1 (2.8%) **Neoadjuvant chemotherapy** There were 40 patients (Group 1) who had previously received neoadjuvant chemotherapy and 36 patients (Group 2) who had not.

Study identifier	Procedure	Patient characteristics
Fernández, Escobedo, Benito, Azpeitia, Gumà, Prieto, Moreno & Martín Comin, 2002. **Number of patients** 110 (consecutive) Group 1 – 80 patients who had palpable breast cancer. Group 2 – 30 patients who had nonpalpable breast cancer detected mammographically. **Number of attempted mappings** 110 **Study period** Not stated **Institution** S. Medicina Nuclear and Unidad Funcional de Mama, CSUB, Hospital de Bellvitge, Barcelona, Spain. **Incorporated studies** None **Inclusion/exclusion criteria** Inclusions: patients with unilateral breast cancer. Exclusions: patients who had received chemotherapy, prior breast surgery or radiotherapy, pregnancy, multiple/bilateral tumours and palpable axillary nodes. **Study included for review of...** Localisation rates and false negative rates	**Radiocolloid/dye combination** Radiocolloid only: 110 Dye only: 0 Radiocolloid and dye: 0 **Radiocolloid** Type: 99mTc-albumin nanocolloid (Nanocoll®, Amersham Health S.A., Spain). Dose: 3mCi (111MBq) in 1ml Colloid size: not stated Filtration: not stated Injection location: peritumourally in Group 1; into the tumour area, guided by ultrasound and a previously placed guide in Group 2. Injection timing: 24 hours before surgery in Group 1; on the day of surgery after guide placement in Group 2. Massage: not stated Intraoperative probe: Europrobe; Euromedical Instruments, Le Chesnay, France. **Dye** Type: not applicable Amount: not applicable Injection location: not applicable Injection timing: not applicable Massage: not applicable **Preoperative lymphoscintigraphy** Timing: performed 2 hours after radiocolloid injection in both groups. **Surgery** Surgeon details: not stated Anaesthesia: not stated Axillary clearance: total lymphadenectomy after SLNB and tumour exision. Sentinel node definition: search for additional sentinel nodes continued until activity in surgical bed was negligible; definition of sentinel node not stated. Final breast procedure: the breast tumour was excised; exact procedure not stated. **Histologic analysis of sentinel nodes** Intraoperative analysis: not performed Sectioning: sentinel nodes were paraffin embedded and divided into pieces approximately 1cm (3 sections per block). Permanent section: H&E (3 sections) IHC: performed in 30 cases to detect micrometastases using CAM 5.2 antibody. Micrometastases definition: not stated **Histologic analysis of axillary nodes** Not stated	**Age** Group 1 – mean 58, range 28 to 87 years Group 2 – mean 55, range 31 to 79 years **Tumour characteristics** Biopsy method Not stated Size Group 1 (n=80) / Group 2 (n=30) ≤ 2cm: 28 (35%) / 26 (86.7%) >2cm and <5cm: 49 (61.3%) / 4 (13.3%) >5cm: 2 (2.5%) / 0 (0%) Any size: 1 (1.3%) / 0 (0%) Stage Group 1 (n=80) / Group 2 (n=30) T1: 28 (35%) / 26 (86.7%) T2: 49 (61.3%) / 4 (13.3%) T3: 2 (2.5%) / 0 (0%) T4: 1 (1.3%) / 0 (0%) Histology Group 1 (n=80) / Group 2 (n=30) Lobular carcinoma: 2 (2.5%) / 2 (6.7%) Ductal carcinoma: 78 (97.5%) / 28 (93.3%) Location Group 1 (n=80) / Group 2 (n=30) Internal quadrants: 25 (31.3%) / Not stated External quadrants: 52 (65.0%) / Not stated Retroareolar: 3 (3.7%) / Not stated Palpability Group 1 – 80/110 (72.7%) patients who had palpable breast cancer. Group 2 – 30/110 (27.3%) patients who had nonpalpable breast cancer detected mammographically. Multifocality/multicentricity Patients with multiple tumours were excluded. **Axilla characteristics** Clinical axillary status Negative: 110/110 (100%) **Neoadjuvant chemotherapy** Patients who received neoadjuvant chemotherapy were excluded.

Study identifier	Procedure	Patient characteristics
Fialdini, Troiani, Manfredini, Bertolaccini, Bonini, Spinelli, Lambruschi, Plancentini, Pietrini, Gentili, Barbieri, Maneschi & Sicari, 2000. **Number of patients** 25 **Number of attempted mappings** 25 **Study period** April 1999 to October 1999 **Institution** Departments of Surgery, Nuclear Medicine, Medical Oncology, Radiology, Radiotherapy and Pathology, Civic Hospital, Mass e Carrara, Italy. **Incorporated studies** None **Inclusion/exclusion criteria** Inclusions: patients with infiltrating breast cancer classified as T1N0. Exclusions: none stated **Study included for review of...** Localisation rates	**Radiocolloid/dye combination** Radiocolloid only: 25 Dye only: 0 Radiocolloid and dye: 0 **Radiocolloid** Type: ^{99m}Tc-human albumin (Nanocoll, Amersham-Sorin) Dose: 5 to 10MBq in 0.2 to 0.3ml Colloid size: 80nm Filtration: not stated Injection location: injection was subdermally into the tissue overlying the tumour when the tumour was superficial; around the tumour when the tumour was deeply located. Injection timing: day before surgery Massage: performed for 2 minutes following injection. Intraoperative probe: Neoprobe 2000 (Neoprobe Corporation, Dublin, Ohio). **Dye** Type: not applicable Amount: not applicable Injection location: not applicable Injection timing: not applicable Massage: not applicable **Preoperative lymphoscintigraphy** Timing: lymphoscintigraphy was performed but the timing after radiocolloid injection was not stated. **Surgery** Surgeon details: not stated Anaesthesia: not stated Axillary clearance: axillary dissection was performed in 4 patients with metastases detected in the sentinel nodes (in one histology was inconclusive). Sentinel node definition: not stated Final breast procedure: quadrantectomy 24/25 (96%); total mastectomy 1/25 (4%) because of retro-areolar tumour localisation. **Histologic analysis of sentinel nodes** Intraoperative analysis: frozen section Sectioning: frozen node cut at one level. Paraffin embedded tissue sectioned with an average of five sections of 40 μm at two levels. Permanent section: H&E IHC: cytokeratin IHC was routinely used. Micrometastases definition: not stated **Histologic analysis of axillary nodes** Not stated	**Age** Mean 59, range 40 to 75 years. **Tumour characteristics** Biopsy method Not stated Size ≤ 2cm: 25/25 (100%) Stage T1: 25/25 (100%) Histology Infiltrating breast cancer. Location Not stated Palpability Not stated Multifocality/multicentricity Not stated **Axilla characteristics** Clinical axillary status N0: 25/25 (100%) **Neoadjuvant chemotherapy** Not stated

Study identifier	Procedure	Patient characteristics
Fleming, Hill, Kavanagh, Quinn, O'Doherty, Collins, McDermott & O'Higgins, 2003. **Number of patients** 125 Group 1: radiocolloid injected intraparenchymally around the tumour (n=80); Group 2: radiocolloid injected intradermally over the tumour site (n=45). **Number of attempted mappings** 125 **Study period** July 1999 to November 2002 **Institution** Departments of Surgery, Pathology and Radiology, St. Vincent's University Hospital and Conway Institute of Biomolecular and Biomedical Research University College Dublin, Dublin, Ireland. **Incorporated studies** Manecksha *et al*. 2001 **Inclusion/exclusion criteria** Inclusions: patients with clinically node negative breast cancer and histologically confirmed (before operation) invasive carcinoma were included in study. Exclusions: patients with clinically node positive disease were excluded from this study. **Study included for review of...** Localisation rates and false negative rates.	**Radiocolloid/dye combination** Radiocolloid only: Dye only: Radiocolloid and dye: **Radiocolloid** Type: Nanocis radiocolloid isotope. Dose: dose not stated, in a volume of 2 cc. Colloid size: not stated Filtration: not stated Injection location: first 80 patients (group 1) injected intraparenchymally around the tumour; remaining 45 patients (group 2) injected intradermally over the tumour site. Injection timing: not stated Massage: not stated Intraoperative probe: Neoprobe 2000 **Dye** Type: isosulphan blue dye Amount: 4 cc Injection location: dye injected around the tumour or immediately adjacent to the biopsy cavity if an open biopsy had previously been preformed. Injection timing: dye was injected perioperatively prior to making the first skin incision. Massage: not stated **Preoperative lymphoscintigraphy** Timing: lymphoscintigraphy was performed 90 minutes after injection using a gamma-camera. **Surgery** Surgeon details: not stated Anaesthesia: not stated Axillary clearance: complete level three axillary dissection was performed. Sentinel node definition: sentinel nodes identified using a combination of lymphoscintigraphy, blue dye and an intraoperative hand-held gamma probe; a successful radioisotope localisation occurred when the axillary background had counts of 25% or less compared with the sentinel node counts *ex vivo*. Final breast procedure: breast conserving surgery or mastectomy. **Histologic analysis of sentinel nodes** Intraoperative analysis: not stated Sectioning: each sentinel node had 3 sections examined. Permanent section: H&E IHC: specimens that were negative for metastatic disease on H&E staining were further evaluated by IHC (using CAM 5.2 for cytokeratin). Micrometastases definition: not stated **Histologic analysis of axillary nodes** Not stated.	**Age** Median (years): Group 1 (n=80) 54.5; Group 2 (n=45) 58 **Tumour characteristics** Biopsy method Not stated Size ≤ 2cm: Group 1 (n=80) 40/80 (50.0%); Group 2 (n=45) 17/45 (37.8%) >2cm and <5cm: Group 1 (n=80) 36/80 (45.0%); Group 2 (n=45) 25/45 (55.6%) >5cm: Group 1 (n=80) 4/80 (5.0%); Group 2 (n=45) 3/45 (6.7%) Stage T1: Group 1 (n=80) 40/80 (50.0%); Group 2 (n=45) 17/45 (37.8%) T2: Group 1 (n=80) 36/80 (45.0%); Group 2 (n=45) 25/45 (55.6%) T3: Group 1 (n=80) 4/80 (5.0%); Group 2 (n=45) 3/45 (6.7%) Note: % stated in tables and numbers extrapolated. Histology Ductal: Group 1 (n=80) 61/80 (76.3%); Group 2 (n=45) 34/45 (75.6%) Lobular: Group 1 (n=80) 12/80 (15.0%); Group 2 (n=45) 5/45 (11.1%) Mixed: Group 1 (n=80) 3/80 (3.8%); Group 2 (n=45) 5/45 (11.1%) Other: Group 1 (n=80) 4/80 (5.0%); Group 2 (n=45) 1/45 (2.2%) Location Lateral: Group 1 (n=80) 37/80 (46.3%); Group 2 (n=45) 26/45 (57.8%) Central/ medial: Group 1 (n=80) 36/80 (45.0%); Group 2 (n=45) 19/45 (42.2%) Missing data: Group 1 (n=80) 7/80 (8.7%); Group 2 (n=45) 0/45 Palpability Not stated Multifocality/multicentricity Not stated **Axilla characteristics** Clinical axillary status Negative: 125/125 (100%) **Neoadjuvant chemotherapy** Not stated

Study identifier	Procedure	Patient characteristics
Flett, Going, Stanton & Cooke, 1998. **Number of patients** 68 (consecutive) **Number of attempted mappings** 68 **Study period** Not stated **Institution** University Departments of Surgiry and Pathology, Glasgow Royal Infirmary, Glasgow, UK. **Incorporated studies** None **Inclusion/exclusion criteria** Inclusions: patients with primary invasive breast cancer. Exclusions: none stated **Study included for review of...** Localisation rates	**Radiocolloid/dye combination** Radiocolloid only: 0 Dye only: 68 Radiocolloid and dye: 0 **Radiocolloid** Type: not applicable Dose: not applicable Colloid size: not applicable Filtration: not applicable Injection location: not applicable Injection timing: not applicable Massage: not applicable Intraoperative probe: not applicable **Dye** Type: Patent Blue dye, 2.5% (Laboratoire Guerbet, Aulney-Sous-Bois, France). Amount: 2 to 4ml Injection location: dye was injected into adjacent breast tissue on the axillary side of the primary tumour. Injection timing: 5 to 10 minutes before exploration of the axilla. Massage: not stated **Preoperative lymphoscintigraphy** Timing: not applicable **Surgery** Surgeon details: not stated Anaesthesia: not stated Axillary clearance: formal/standard axillary dissection was performed. Sentinel node definition: not stated Final breast procedure: wide local excision 30/68 (44.1%); mastectomy 38/68 (55.9%). **Histologic analysis of sentinel nodes** Intraoperative analysis: frozen section Sectioning: frozen section and paraffin sections were made; details of sectioning not given. Permanent section: staining of paraffin sections not stated. IHC: not stated Micrometastases definition: not stated **Histologic analysis of axillary nodes** Not stated	**Age** Mean 62, range 33 to 86 years. **Tumour characteristics** Biopsy method Not stated Size Not stated Stage Not stated Histology Invasive: 68/68 (100%) Location Not stated Palpability Not stated Multifocality/multicentricity Not stated **Axilla characteristics** Clinical axillary status Not stated **Neoadjuvant chemotherapy** Not stated

Study identifier	Procedure	Patient characteristics
Formisano, Limite, Lamberti, Fonti & Forestieri, 2000. **Number of patients** 42 **Number of attempted mappings** 42 **Study period** May 1999 to July 2000 **Institution** Departments of General Surgery and Biomorphologic and Functional Sciences, University of Naples "Federico II", Italy. **Incorporated studies** None **Inclusion/exclusion criteria** Inclusions: patients with T1N0 breast cancer for whom a level I/II axillary clearance was recommended. Exclusions: pregnant women, women with multicentric breast cancer. **Study included for review of...** Localisation rates and false negative rates.	**Radiocolloid/dye combination** Radiocolloid only: 42 Dye only: 0 Radiocolloid and dye: 0 **Radiocolloid** Type: ^{99m}Tc-albumin Dose: not stated Colloid size: not stated Filtration: not stated Injection location: injection in the subdermal tissue around the primary tumour, for patients with nonpalpable lesions, the colloid was injected by stereotaxis or ultrasound guidance. Injection timing: not stated Massage: not stated Intraoperative probe: probe type not stated. **Dye** Type: not applicable Amount: not applicable Injection location: not applicable Injection timing: not applicable Massage: not applicable **Preoperative lymphoscintigraphy** Timing: performed but details were not stated. **Surgery** Surgeon details: not stated Anaesthesia: general anaesthesia was used. Axillary clearance: level I/II axillary clearance was performed. Sentinel node definition: the lymph node concentrating the colloid. Final breast procedure: breast conservative therapy in 42/42 patients (100%). **Histologic analysis of sentinel nodes** Intraoperative analysis: not stated Sectioning: not stated Permanent section: permanent histology, staining method not stated. IHC: not stated Micrometastases definition: not stated **Histologic analysis of axillary nodes** Permanent histology of axillary lymph nodes performed, staining method not stated.	**Age** Median 51, range 33 to 81 years. **Tumour characteristics** Biopsy method Not stated Size ≤ 2cm: 42/42 (100%) Stage T1: 42/42 (100%) Histology Not stated Location Not stated Palpability Palpable and nonpalpable tumours were included. Multifocality/multicentricity Not stated **Axilla characteristics** Clinical axillary status N0: 42/42 (100%) **Neoadjuvant chemotherapy** Not stated

Study identifier	Procedure	Patient characteristics
Fraile, Rull, Julián, Fusté, Barnadas, Llatjós, Castellà, Gonzalez, Vallejos, Alastrué & Broggi, 2000. **Number of patients** 132 **Number of attempted mappings** 132 **Study period** October 1997 to November 1999 **Institution** Departments of Nuclear Medicine, General Surgery, Gynaecology, Medical Oncology, Pathology and the Breast Disease Unit, Hospital Universitari Germans Trias I Puhol, Bardalona, Barcelona and Cancer Epidemiology, Institut Català d'Oncologia, L'Hospitalet del Llobregat, Barcelelona, Spain. **Incorporated studies** None **Inclusion/exclusion criteria** Inclusions: patients scheduled for primary surgical treatment of a recently diagnosed breast cancer of <5cm. Exclusions: patients with clinically enlarged axillary nodes and a positive nodal FNA biopsy, or with locally advanced or disseminated breast cancer, or who had undergone previous axillary surgery or radiotherapy and primary chemotherapy. **Study included for review of...** Localisation rates and false negative rates	**Radiocolloid/dye combination** Radiocolloid only: 132 Dye only: 0 Radiocolloid and dye: 0 **Radiocolloid** Type: ^{99m}Tc-albumin Dose: 11MBq in 2ml saline to a total volume of 6ml. Colloid size: 200 to >1000nm Filtration: not stated Injection location: intersitially injected around the tumour; for nonpalpable lesions, the localisation wire was used to guide the intraparenchymal injection. Injection timing: radiocolloid was injected 2 to 20 hours before surgery. Massage: not stated Intraoperative probe:type not stated **Dye** Type: not applicable Amount: not applicable Injection location: not applicable Injection timing: not applicable Massage: not applicable **Preoperative lymphoscintigraphy** Timing: images taken immediately after radiocolloid injection. **Surgery** Surgeon details: not stated Anaesthesia: not stated Axillary clearance: axillary dissection was performed in all patients. Sentinel node definition: gamma probe readings >10 x background. Final breast procedure: breast-conserving surgery performed in 77/132 (58.3%) patients. **Histologic analysis of sentinel nodes** Intraoperative analysis: not stated Sectioning: 2mm inclusion blocks and several sections per block, up to 30 or more slices in a standard 1cm sentinel lymph node. Permanent section: H&E IHC: performed using a commercially available anti-cytokeratin antibody. Micrometastases definition: nodal groups of epithelial neoplastic cells with a diameter <2mm; if initially detected using IHC, had to be morphologically noticeable on the corresponding H&E sections or they were not considered. **Histologic analysis of axillary nodes** Bisected and assessed with H&E	**Age** Mean 60.3, range 32 to 86 years. **Tumour characteristics** Biopsy method Fine needle aspiration or core biopsy, numbers not stated. Size Mean 1.9 ± SD1.0, range 0.7 to 5cm. Stage Not stated Histology DCIS: 5/132 (3.8%) Infiltrating ductal: 114/132 (86.4%) Lobular: 5/132 (3.8%) Medullar: 5/132 (3.8%) Other: 3/132 (2.3%) Note: only percentages given, numbers extrapolated. Location Not stated Palpability Palpable: 97/132 (73.5%) Nonpalpable: 35/132 (26.5%) Multifocality/multicentricity Patient who had "disseminated" breast cancer were excluded. **Axilla characteristics** Clinical axillary status Negative: 132/132 (100%) **Neoadjuvant chemotherapy** Patients who with "primary" chemotherapy were excluded.

Study identifier	Procedure	Patient characteristics
Galli, Massaza, Chiappo, Paduos & Rosso, 2000. **Number of patients** 46 **Number of attempted mappings** 46 **Study period** January 1 1999 to September 30 1999 **Institution** Surgery Department, Hospital of Biella, Biella, Italy. **Incorporated studies** None **Inclusion/exclusion criteria** Inclusions: T1 to T2 tumours with a clinically negative axilla. Exclusions: none stated **Study included for review of...** Localisation rates and false negative rates	**Radiocolloid/dye combination** Radiocolloid only: 46 Dye only: 0 Radiocolloid and dye: 0 **Radiocolloid** Type: ^{99m}Tc- labelled human albumin Dose: 'a small amount' Colloid size: not stated Filtration: not stated Injection location: subdermally at the site corresponding to the cutaneous projection of the palpable tumours or peritumourally under ectomographic guidance in case of deep lesions. Injection timing: the day before surgery. Massage: not stated Intraoperative probe: type not stated. **Dye** Dye was not used. Type: not applicable Amount: not applicable Injection location: not applicable Injection timing: not applicable Massage: not applicable **Preoperative lymphoscintigraphy** Timing: lymphoscintigraphy was performed but the timing after radiocolloid injection not stated. **Surgery** Surgeon details: not stated Anaesthesia: not stated Axillary clearance: levels I/II/III Sentinel node definition: not stated Final breast procedure: not stated **Histologic analysis of sentinel nodes** Intraoperative analysis: not stated Sectioning: not stated Permanent section: not stated IHC: not stated Micrometastases definition: not stated **Histologic analysis of axillary nodes** Not stated	**Age** Mean 63.5, range 39 to 88 years. **Tumour characteristics** Biopsy method Not stated Size ≤ 5cm: 46/46 (100%) Stage T1 to T2: 46/46 (100%) Grade 1/Grade 2: 42/46 (91.3%) Grade 3: 4/46 (8.7%) Histology Infiltrating ductal: 41/46 (89.1%) Infiltrating lobular: 4/46 (8.7%) Medullary: 1/46 (2.2%) Location Not stated Palpability Not stated Multifocality/multicentricity Not stated **Axilla characteristics** Clinical axillary status Negative: 46/46 (100%) **Neoadjuvant chemotherapy** Not stated

Study identifier	Procedure	Patient characteristics
Gray, Giuliano, Dauway, Cox & Reintgen, 2001. **Number of patients** 43 **Number of attempted mappings** 43 **Study period** November 1999 to March 2001 **Institution** Department of Surgery, H.Lee Moffitt Cancer Center at the University of South Florida, Tampa, Florida, USA. **Incorporated studies** None **Inclusion/exclusion criteria** Inclusions: retrospective review of a prospective database was performed to identify patients who had undergone dual isotope radioguided surgery for breast cancer (i.e. radioactive seed localisation of the tumour and sentinel lymph node biopsy using ^{99m}Tc-labelled sulphur). **Study included for review of...** Localisation rates	**Radiocolloid/dye combination** Radiocolloid only: 0 Dye only: 0 Radiocolloid and dye: 43 **Radiocolloid** Type: ^{99m}Tc-labelled sulphur colloid Dose: 0.45mCi Colloid size: not stated Filtration: not stated Injection location: six aliquots injected around the circumference of the lesion in an intraparenchymal location. Injection timing: 2 to 18 hours before surgery. Massage: not stated. Intraoperative probe: type not stated. **Dye** Type: isosulphan blue Amount: 5ml Injection location: 4 to 6 aliquots injected around the circumference of the lesion in an intraparenchymal location. Injection timing: in the operating room. Massage: not stated **Preoperative lymphoscintigraphy** Timing: whether lymphoscintigraphy was performed was not stated. **Surgery** Surgeon details: not stated Anaesthesia: not stated Axillary clearance: not stated Sentinel node definition: not stated Final breast procedure: lumpectomy 43/43 (100%) **Histologic analysis of sentinel nodes** Intraoperative analysis: not stated Sectioning: not stated Permanent section: not stated IHC: not stated Micrometastases definition: not stated **Histologic analysis of axillary nodes** Not stated	**Age** Not stated **Tumour characteristics** Biopsy method Percutaneous biopsy techniques: 43/43 (100%) Size Mean 1.1, range 0.3 to 4.0cm (pathologic size) Stage Not stated Histology Final pathology Infiltrating ductal: 35/43 (81.4%) Infiltrating lobular: 2/43 (4.7%) Intraductal papillary: 1/43 (2.3%) DCIS: 5/43 (11.6%) Location Not stated Palpability Nonpalpable: 43/43 (100%) Multifocality/multicentricity Multifocal: 2/43 (4.7%) **Axilla characteristics** Clinical axillary status Not stated **Neoadjuvant chemotherapy** Not stated

Study identifier	Procedure	Patient characteristics
Gucciardo, Schiavo, Grillo, Mencacci, Mango & Tersigni, 2000. **Number of patients** 50 (49 female:1 male) **Number of attempted mappings** 50 **Study period** November 1998 and January 2000 **Institution** Modulo Interdipartimentale Chirurgia Oncologica della Mammella; Servizio di Medicina Nucleare; UO Anatomia Patologica; UO Chirurgia Generale "Flajani", Azienda Ospedaliera San Camilla-Forlanini, Rome, Italy. **Incorporated studies** None **Inclusion/exclusion criteria** Inclusions: 151 operations were performed on 145 patients, and 60 met the criteria for sentinel lymph node biopsy. Fifty were included. Exclusions: 10/60 (16.7%) were not available for the procedure. Patients with multifocal disease, T3 tumours, positive clinical nodes, microcalcifications, two step procedures and previous breast biopsies were excluded. **Study included for review of...** Localisation rates and false negative rates	**Radiocolloid/dye combination** Radiocolloid only: 50 Dye only: 0 Radiocolloid and dye: 0 **Radiocolloid** Type: ^{99m}Tc-labelled human serum albumin microcolloidal particles Dose: 10 to 15MBq in 0.2 to 0.4ml Colloid size: not stated Filtration: not stated Injection location: subdermally, close to the tumour site. Injection timing: 3 to 24 hours before surgery. Massage: not stated Intraoperative probe: Navigator (Tyco Health Care, USA). **Dye** Dye was not used. Type: not applicable Amount: not applicable Injection location: not applicable Injection timing: not applicable Massage: not applicable **Preoperative lymphoscintigraphy** Timing: performed 20min to 3 hours after radiocolloid injection. **Surgery** Surgeon details: not stated Anaesthesia: not stated Axillary clearance: complete axillary dissection in 42/50 (84.0%) and Level I and II in 8/50 (16.0%). Sentinel node definition: not stated Final breast procedure: not stated **Histologic analysis of sentinel nodes** Intraoperative analysis: not stated Sectioning: not stated Permanent section: not stated IHC: not stated Micrometastases definition: not stated **Histologic analysis of axillary nodes** Not stated	**Age** Not stated **Tumour characteristics** Biopsy method Patients who had excisional biopsy were excluded. Size Not stated Stage Not stated (not T3). Histology Not stated (invasive). Location Not stated Palpability Not stated Multifocality/multicentricity Patients with multifocal disease were excluded. **Axilla characteristics** Clinical axillary status Negative: 50/50 (100%) **Neoadjuvant chemotherapy** Not stated

Study identifier	Procedure	Patient characteristics
Guenther, Krishnamoorthy & Tan, 1997. **Number of patients** 145 **Number of attempted mappings** 145 **Study period** September 1994 and June 1996 **Institution** Department of Surgery, Kaiser Permanente Medical Center, Los Angeles, California, USA. **Incorporated studies** None **Inclusion/exclusion criteria** Inclusions: consecutive women with potentially curable breast cancer. Exclusions: none stated. **Study included for review of...** False negative rates	**Radiocolloid/dye combination** Radiocolloid only: 0 Dye only: 145 Radiocolloid and dye: 0 **Radiocolloid** Radiocolloid was not used. Type: not applicable Dose: not applicable Colloid size: not applicable Filtration: not applicable Injection location: not applicable Injection timing: not applicable Massage: not applicable Intraoperative probe: not applicable **Dye** Type: Isosulphan blue (Lymphazurin; Hirsch Industries, Inc., Richmond, VA, USA). Amount: 3 to 5cc Injection location: near the primary tumour site in a circumferential pattern, if gross tumour was present, dye was injected at the tumour-breast interface, or if patients had undergone excisional biopsy, dye was injected into the walls of the biopsy cavity. Injection timing: not stated Massage: 3 to 5 minutes of breast massage **Preoperative lymphoscintigraphy** Timing: not applicable **Surgery** Surgeon details: all operations performed by one of two surgeons (Tan and Guenther) assisted by surgical residents. Guenther had observed about 15 sentinel lymph node mapping/biopsies and Tan had no previous experience. Anaesthesia: not stated Axillary clearance: levels I/II Sentinel node definition: not stated Final breast procedure: breast conservation 95/145 (65.5%); modified radical mastectomy/simple mastectomy 50/145 (34.5%). **Histologic analysis of sentinel nodes** Intraoperative analysis: not stated Sectioning: node was sectioned into five segments Permanent section: segments were stained with H&E IHC: not routinely employed Micrometastases definition: not stated **Histologic analysis of axillary nodes** Routinely sectioned and stained with H&E.	**Age** Mean 55.3, range 33 to 88 years **Tumour characteristics** Biopsy method FNA: 43/145 (29.7%) Excisional biopsy: 97/145 (66.9%) Stereotactic biopsy: 5/145 (3.4%) Size Mean 2.09, range 0.6 to 7.0cm Stage T1: 66/145 (45.5%) T2: 46/145 (31.7%) T3: 3/145 (2.1%) T4: 1/145 (0.7%) DCIS: 6/145 (4.1%) Not stated: 23/145 (15.9%) Grade 1*: 29/145 (20.0%) Grade 2*: 58/145 (40.0%) Grade 3*: 38/145 (26.2%) Not stated: 20/145 (13.8%) Histology Ductal: 130/145 (89.7%) Lobular: 8/145 (5.5%) DCIS: 7/145 (4.8%) Location Not stated Palpability Not stated Multifocality/multicentricity Not stated **Axilla characteristics** Clinical axillary status Not stated **Neoadjuvant chemotherapy** Not stated * Bloom-Richardson grading system

Study identifier	Procedure	Patient characteristics
Guenther, 1999. **Number of patients** 260 **Number of attempted mappings** 260 **Study period** September 1994 to July 1998 **Institution** Department of Surgery, Souther California Permanente Medical Group, Los Angeles, California, USA. **Incorporated studies** Guenther *et al.* 2000 **Inclusion/exclusion criteria** Inclusions: consecutive women with potentially curable, unilateral breast cancer. Exclusions: none stated **Study included for review of...** Localisation rates	**Radiocolloid/dye combination** Radiocolloid only: 0 Dye only: 260 Radiocolloid and dye: 0 **Radiocolloid** Radiocolloid was not used. Type: not applicable Dose: not applicable Colloid size: not applicable Filtration: not applicable Injection location: not applicable Injection timing: not applicable Massage: not applicable Intraoperative probe: not applicable **Dye** Type: isosulphan blue (Lymphazurin; United States Surgical Corporation, Norwalk, CT, USA). Amount: $5cm^3$ Injection location: into the tumour-breast interface or biopsy cavity wall. Injection timing: not stated Massage: approximately 5 minutes of active breast compression. **Preoperative lymphoscintigraphy** Timing: not applicable **Surgery** Surgeon details: all operations performed by a single surgeon assisted by surgical residents. Anaesthesia: not stated Axillary clearance: the first 135 patients had sentinel node biopsy in conjunction with a standard level I/II axillary clearance, the final 124 patients had level I/II axillary clearance if no sentinel node was located or the sentinel node was tumour positive. Sentinel node definition: blue stained node(s). Final breast procedure: breast-conserving surgery 199/260 (76.5%); modified radical mastectomy 61/260 (23.5%). **Histologic analysis of sentinel nodes** Intraoperative analysis: not stated Sectioning: sentinel nodes underwent serial sectioning Permanent section: multiple levels were stained with H&E IHC: with cytokeratin for nodes tumour free by H&E Micrometastases definition: not stated **Histologic analysis of axillary nodes** Standard pathology using nodal sectioning and H&E staining.	**Age** Mean 56, range 34 to 80 years (age of non localised patients). **Tumour characteristics** Biopsy method Not stated Size Mean 1.99, range 0.5 to 5cm (tumour size of non localised patients). Stage T1 (≤2cm) 164/260 (63.1%) T2 (.2cm) 89/260 (34.2%) Not stated 7/260 (2.7%) Histology Ductal 232/260 (89.2%) Lobular 18/260 (6.9%) DCIS 10/260 (3.8%) Location Lateral 209/260 (80.4%) Medial 49/260 (18.8%) Not stated 2/260 (0.8%) Palpability Not stated Multifocality/multicentricity Not stated **Axilla characteristics** Clinical axillary status Not stated **Neoadjuvant chemotherapy** Not stated

Study identifier	Procedure	Patient characteristics
Gulec, Su, O'Leary & Stolier, 2001. **Number of patients** 165 **Number of attempted mappings** 165 **Study period** 2 year period (years not stated) **Institution** Departments of Surgery and Public Health and Preventive Medicine, Louisiana State University Health Sciences Center, and Memorial Medical Center, New Orleans, Louisiana, USA. **Incorporated studies** None **Inclusion/exclusion criteria** Inclusions: retrospective analysis of consecutive clinically node-negative breast cancer cases treated at the Memorial Medical Center over a period of 2 years. Exclusions: none stated **Study included for review of...** Localisation rates	**Radiocolloid/dye combination** Radiocolloid only: 14 Dye only: 41 Radiocolloid and dye: 110 **Radiocolloid** Type: not stated Dose: not stated Colloid size: not stated Filtration: not stated Injection location: not stated Injection timing: not stated Massage: not stated Intraoperative probe: C-Trak, (Carewise Medical, Morgan Hill, CA, USA). **Dye** Type: not stated Amount: not stated Injection location: not stated Injection timing: Massage: not stated **Preoperative lymphoscintigraphy** Timing: not stated **Surgery** Surgeon details: not stated Anaesthesia: not stated Axillary clearance: level I/II when frozen section indicated metastatic carcinoma, if frozen section was negative no further surgical treatment was directed to the axilla, unless positive by permanent section or IHC where axillary clearance was completed within a week of the sentinel lymph node biopsy. Sentinel node definition: not stated Final breast procedure: breast conservation 133/165 (80.1%); mastectomy 32/165 (19.4%). **Histologic analysis of sentinel nodes** Intraoperative analysis: frozen section was performed in all patients. Sectioning: multiple sections Permanent section: H&E. IHC: cytokeratins (multiple sections). Micrometastases definition: not stated **Histologic analysis of axillary nodes** Not stated	**Age** Mean 58.5, range 30 to 85 years **Tumour characteristics** Biopsy method Excisional biopsy: 26/165 (15.8%) CB: 101/165 (61.2%) FNA: 36/165 (21.8%) Punch: 2/165 (1.2%) Size Mean 1.55, range 0.2 to 4.5cm Stage T1a: 14/165 (8.5%) T1b: 35/165 (21.2%) T1c: 80/165 (48.5%) T2: 36/165 (21.8%) Histology Infiltrating ductal: 142/165 (86.1%) Infiltrating lobular: 8/165 (4.8%) Tubular: 4/165 (2.4%) Mucinous: 3/165 (1.8%) DCIS: 4/165 (2.4%) Microinvasive: 3/165 (1.8%) Invasive papillary: 1/165 (0.6%) Location UOQ: 88/165 (53.3%) Other: 77/165 (46.7%) Palpability Palpable: 123/165 (74.5%) Nonpalpable: 42/165 (25.5%) Multifocality/multicentricity Not stated **Axilla characteristics** Clinical axillary status Negative: 165/165 (100%) **Neoadjuvant chemotherapy** Not stated

Study identifier	Procedure	Patient characteristics
Haid, Tausch, Lang, Lutz, Fritzche, Peschina, Breitfellner, Sega, Aufschnaiter, Sturn & Zimmermann, 2001. **Number of patients** 33 **Number of attempted mappings** 33 **Study period** Not stated **Institution** Departments of Surgery, Internal Medicine and Biostatistics, and Institute of Nuclear Medicine, Landekrankehaus Feldkirch, Feldkirch, Austria and Departments of Surgery and Internal Medicine and Institute of Pathology, Krankenhaus der Barmherzigen Schwestern in Linz, Linz, Austria. **Incorporated studies** None **Inclusion/exclusion criteria** Inclusions: patients that had received preoperative chemotherapy. Note: one patient had bilateral breast carcinoma, but SLNB only performed on the left side as there were enlarged, clinically involved lymph nodes in the right axilla. Exclusions: none stated **Study included for review of...** False negative rates	**Radiocolloid/dye combination** Radiocolloid only: 0 Dye only: 1 Radiocolloid and dye: 32 **Radiocolloid** Type: AlbuRes® in the first 8 patients; Nanocoll® in the remaining 25 patients. Dose: AlbuRes®, 400µCi in 2ml; Nanocoll®, 0.1 to 1.2mCi in 2 ml. Colloid size: not stated Filtration: not stated Injection location: peritumoural Injection timing: 18 to 20 hours prior to surgery Massage: not stated Intraoperative probe: not stated **Dye** Type: Patent Blue 2.5% Guerbet Amount: 4ml Injection location: peritumoural, controlled clinically and/or sonographically or by means of previously radiologically controlled placement of a localisation wire. Injection timing: 5 to 10 minutes before surgery. Massage: not stated **Preoperative lymphoscintigraphy** Timing: performed in 32/33 (97.0%) of patients 18 to 20 hours prior to surgery. **Surgery** Surgeon details: not stated Anaesthesia: not stated Axillary clearance: all patients underwent axillary clearance after sentinel node biopsy. Sentinel node definition: not stated Final breast procedure: segmental mastectomy 23/33 (69.7%); total mastectomy 10/33 (30.3%) **Histologic analysis of sentinel nodes** Intraoperative analysis: not stated Sectioning: nodes were fixed and embedded and 4 sections taken from each node or part of the node (node bisected if >0.5cm) at different levels. Permanent section: H&E (3 sections) IHC: cytokeratins (1 section) Micrometastases definition: not stated **Histologic analysis of axillary nodes** Not stated	**Age** Mean 53.4, range 31 to 77 years. **Tumour characteristics** Biopsy method Not stated Size Before chemotherapy: 33.4, range 12 to 70mm After chemotherapy: 20.0, range 0 to 47mm Stage T0: Before 0/33 (0.0%); After 3/33 (9.1%) T1: Before 2/33 (6.1%); After 16/33 (48.5%) T2: Before 30/33 (91.0%); After 14/33 (42.4%) T3: Before 1/33 (3.0%); After 0/33 (0.0%) Histology Not stated Location Not stated Palpability Palpable and nonpalpable Multifocality/multicentricity Not stated **Axilla characteristics** Clinical axillary status Not stated **Neoadjuvant chemotherapy** Neoadjuvant chemotherapy: 33/33 (100%) Complete: Clinical 12/33 (36.4%); Type of chemotherapy 9 TE; 3EC Partial: Clinical 11/33 (33.3%); Type of chemotherapy 4 TE; 5 EC; 2 CMF No change: Clinical 10/33 (30.3%); Type of chemotherapy 4 TE; 4 EC; 2 CMF Pathohistologic Complete: 3/33 (9.1%); 2 TE; 1 EC Partial: 12/33 (36.4%); 5 TE; 6 EC; 1 CMF No change: 18/33 (54.5%); 10 TE; 5 EC; 3 CMF TE, taxotere/epirubicin; EC, epirubicin/cyclophosphamide; CMF, cyclophosphamide/methotrexate/5-fluororacil

Study identifier	Procedure	Patient characteristics
Haigh, Hansen, Qi & Giuliano, 2000. **Number of patients** 283 **Number of attempted mappings** 284 (1 bilateral) **Study period** October 1991 to December 1995 **Institution** Joyce Eisenberg Keefer Breast Center, and the Division of Surgical Oncology, John Wayne Cancer Institute at Saint John's Health Center, Santa Monica, California, USA. **Incorporated studies** Bilchik *et al.* 1998; DiFronzo *et al.* 2000; Guiliano *et al.* 1994; Guiliano *et al.* 1995; Giuliano *et al.* 1997; Grube *et al.* 2002; Turner *et al.* 1997 **Inclusion/exclusion criteria** Inclusions: consecutive patients with breast cancer who underwent sentinel lymph node biopsy followed by axillary clearance. In the early phase of the study, patients were initially part of the development of the sentinel node biopsy technique and there were no exclusions. Exclusions: during the study period, 331 patients had sentinel node biopsy followed by axillary clearance but 48 patients were excluded from further analysis as data was incomplete for excision volume, biopsy interval or tumour location. **Study included for review of...** Localisation rates and false negative rates	**Radiocolloid/dye combination** Radiocolloid only: 0 Dye only: unsure Radiocolloid and dye: unsure (in the latter part of the study, patients with inner quadrant lesions had intraoperative radioguided surgery with a gamma probe). **Radiocolloid** Type: not stated Dose: not stated Colloid size: not stated Filtration: not stated Injection location: not stated Injection timing: not stated Massage: not stated Intraoperative probe: not stated **Dye** Type: isosulphan blue dye (Lymphazurin 1%; United States Surgical Corporation, Norwalk, CT, USA). Amount: up to 5ml Injection location: into the breast parenchyma adjacent to the tumour, or into the wall of the biopsy cavity if previous excisional biopsy had taken place. Injection timing: not stated Massage: not stated **Preoperative lymphoscintigraphy** Timing: in the latter part of the study, patients with inner quadrant lesions had properative lymphoscintigraphy. **Surgery** Surgeon details: all operations were performed by Giuliano. Anaesthesia: not stated Axillary clearance: standard clearance of levels I/II, if any axillary lymph nodes were palpable with metastases, then level III was also removed. Sentinel node definition: not stated Final breast procedure: segmental mastectomy 236/284 (83.1%); total mastectomy 48/284 (16.9%) **Histologic analysis of sentinel nodes** Intraoperative analysis: frozen section was used to ensure specimen was lymph node tissue rather than for identifying metastases. Sectioning: not stated Permanent section: H&E IHC: using cytokeration (MAK-6) performed if H&E negative (6 to 8 node faces). Micrometastases definition: not stated **Histologic analysis of axillary nodes** Processed routinely, and one or two levels were stained with H&E.	**Age** Median 55, range 28 to 84 years **Tumour characteristics** Biopsy method Surgery (excisional): 181/284 (63.7%) CB: 41/284 (14.4%) FNA: 62/284 (21.8%) Size Mean 2.0 ± 1.6, median 1.5, range 0.1 to 11cm Stage Tis: 15/284 (5.3%) T1: 184/284 (64.8%) T2: 72/284 (25.4%) T3: 13/284 (4.6%) Histology Infiltrating ductal: 227/284 (79.9%) Infiltrating lobular: 24/284 (8.5%) Mixed: 2/284 (0.7%) Other: 16/284 (5.6%) DCIS: 15/284 (5.3%) Location UOQ: 174/284 (61.3%) UIQ: 42/284 (14.8%) LOQ: 37/284 (13.0%) LIQ: 9/284 (3.2%) Subareolar: 22/284 (7.7%) Palpability Not stated Multifocality/multicentricity Not stated **Axilla characteristics** Clinical axillary status Not stated **Neoadjuvant chemotherapy** Not stated

Study identifier	Procedure	Patient characteristics
Hansen, Grube & Giuliano, 2002. **Number of patients** 238 **Number of attempted mappings** 238 **Study period** 1 October 1995 to 30 April 1999 **Institution** Joyce Eisenberg Keefer Breast Center, John Wayne Cancer Institute at St John's Health Center, Santa Monica, California, USA. **Incorporated studies** Giuliano *et al.* 2000 **Inclusion/exclusion criteria** Inclusions: patients with invasive breast cancer and clinically negative lymph nodes. Exclusions: patients enrolled in the American College of Surgeons Oncology Group (ACSOG) sentinel node trials, patients with tumours >5cm, multicentric tumours, locally advanced disease, DCIS or stage IV disease at presentation. **Study included for review of...** Localisation rates	**Radiocolloid/dye combination** Radiocolloid only: 0 Dye only: 128 Radiocolloid and dye: 110 **Radiocolloid** Type: ^{99m}Tc-labelled sulphur colloid Dose: not stated Colloid size: not stated Filtration: filtered Injection location: not stated Injection timing: not stated Massage: not stated Intraoperative probe: not stated **Dye** Type: Lymphazurin (1%; US Surgical, Norwalk, CT, USA). Amount: 3 to 5ml Injection location: into the breast parenchyma surrounding the tumour or into the walls of the biopsy cavity. If the tumour was not palpable, a localisation procedure was performed preoperatively, and the dye was injected around the localising wire. Injection timing: not stated Massage: manual compression of the breast for 3 to 7 minutes. **Preoperative lymphoscintigraphy** Timing: whether lymphoscintigraphy was performed in those patients injected with radiocolloid was not stated. **Surgery** Surgeon details: not stated Anaesthesia: not stated Axillary clearance: not stated Sentinel node definition: blue-stained nodes. Final breast procedure: breast conserving 238/238 (100%). **Histologic analysis of sentinel nodes** Intraoperative analysis: in the early part of the study, frozen section was used to ensure specimen was lymph node tissue rather than for identifying metastases, but this was abandoned. Sectioning: examined at two step-section levels of each paraffin block, each separated by 40µm. Permanent section: H&E (each level). IHC: if metastases were not identified using H&E, cytokeratin IHC performed. Micrometastases definition: not stated **Histologic analysis of axillary nodes** Not stated	**Age** Median 58.4, range 29 to 89 years. **Tumour characteristics** Biopsy method FNA 12.0% CB 24.0% Excisional 64.0% Note: Percentages given as patient numbers were not stated. Size Median 1.3, range 0.01 to 4.5cm Stage Stage I 85.0% Stage IIA 15% Note: Percentages given as patient numbers were not stated. Histology Infiltrating ductal carcinoma (associated with extensive DCIS) 85.7% (9.8%) Invasive lobular carcinoma 10.1% Features of ductal and lobular carcinoma 1.3% Mucinous carcinoma 1/238 (0.8%) Tubular carcinoma 5/238 (2.1%) Note: Percentages given as patient numbers were not stated. Location Not stated Palpability Palpable 48.3% Nonpalpable 51.7% Note: Percentages given as patient numbers were not stated. Multifocality/multicentricity Patients with multicentric tumours were excluded. **Axilla characteristics** Clinical axillary status Negative 238/238 (100%) **Neoadjuvant chemotherapy** Not stated

Study identifier	Procedure	Patient characteristics
Hoar & Stonelake, 2003. **Number of patients** 66 **Number of attempted mappings** 67 (1 bilateral) **Study period** February 2000 to July 2001 **Institution** Department of Surgery, City Hospital, Birmingham, England, UK. **Incorporated studies** None **Inclusion/exclusion criteria** Inclusions: consecutive women with primary invasive breast cancer. Exclusions: none stated **Study included for review of...** Localisation rates and false negative rates	**Radiocolloid/dye combination** Radiocolloid only: 0 Dye only: 0 Radiocolloid and dye: 67 **Radiocolloid** Type: ^{99m}Tc-labelled human colloid (Nanocoll, Amersham Healthcare Ltd). Dose: 20 MBq, volume 2mL in all but 10 patients (Other 10 injected with 20 or 40 MBq on day prior to surgery). Colloid size: not stated Filtration: not stated Injection location: peritumoural Injection timing: all except 10 injected on day of surgery, 10 patients early in series injected on day prior to surgery. Massage: Not stated Intraoperative probe:Navigator GPS ™, (US Surgical Corp., USA). **Dye** Type: Patent Blue V (Laboratoires Guerbet, France). Amount: 2mL diluted to 5mL Injection location: peritumoural Injection timing: immediately preoperatively. Massage: area lightly massaged. **Preoperative lymphoscintigraphy** Timing: median injection-scan interval of 180 min (range 90 to 210 minutes). **Surgery** Surgeon details: all patients were operated on by Stonelake. Anaesthesia: not stated Axillary clearance: level II Sentinel node definition: 'hot and blue', 'hot' or 'blue' (hot nodes have an *ex vivo* count at least 10 times the background count). Final breast procedure: wide local excision 44/67 (65.7%); mastectomy 23/67 (34.3%). **Histologic analysis of sentinel nodes** Intraoperative analysis: not stated Sectioning: not stated Permanent section: single H&E section. IHC: not stated Micrometastases definition: not stated **Histologic analysis of axillary nodes** Not stated	**Age** Median 55, range 27 to 86 years. **Tumour characteristics** Biopsy method Fine needle aspiration: 1/67 (1.5%) Core needle biopsy: 58/67 (86.6%) Diagnostic excision biopsy or wide local excision: 8/67 (11.9%) Size ≤ 2cm: 27/67 (40.3%) >2cm but ≤ 5cm: 30/67 (44.8%) >5cm: 6/67 (9.0%) Any size: 4/67 (6.0%) Stage T1: 27/67 (40.3%) T2: 30/67 (44.8%) T3: 6/67 (9.0%) T4: 4/67 (6.0%) Grade I: 13/67 (19.4%) Grade II: 34/67 (50.7%) Grade III: 20/67 (29.9%) Histology Not stated Location UOQ: 33/67 (49.3%) UIQ: 11/67 (16.4%) LOQ: 6/67 (9.0%) LOQ: 5/67 (7.5%) Central: 12/67 (17.9%) Palpability Palpable: 56/67 (83.6%) Nonpalpable: 11/67 (16.4%) Multifocality/multicentricity Not stated **Axilla characteristics** Clinical axillary status Negative: 67/67 (100%) **Neoadjuvant chemotherapy** 1/66 (1.5%) patients received neoadjuvant chemotherapy.

Study identifier	Procedure	Patient characteristics
Hodgson, Zabel, Mattar, Engel, Girvan & Holliday, 2001. **Number of patients** 47 **Number of attempted mappings** 47 **Study period** September 1998 to December 1999 **Institution** Departments of Surgery and Nuclear Medicine, London Health Sciences Center, University of Western Ontario, London, Ontario, Canada. **Incorporated studies** None **Inclusion/exclusion criteria** Inclusions: presence of invasive breast cancer and a clinically negative axilla. Exclusions: clinically suspicious/abnormal lymph nodes, previous axillary lymphadenectomy, tumour size ≥ 5cm or evidence of distant metastases. **Study included for review of...** Localisation rates and false negative rates	**Radiocolloid/dye combination** Radiocolloid only: 0 Dye only: 0 Radiocolloid and dye: 47 **Radiocolloid** Type: ^{99m}Tc-labelled cysteine-rhenium colloid. Dose: dose not stated, in a volume of 4ml. Colloid size: not stated Filtration: 85 to 95% of the radiocolloid preparation passes through a 0.1 micron low protein binding filter, therefore 85% of the radiocolloid in <0.1 microns (10 to 12nm). Injection location: 4 to 6 peritumoural sites injected intraparenchymally. Injection timing: 2 to 4 hours prior to surgery. Massage: not stated Intraoperative probe: Navigator (Autosuture Co., UK). **Dye** Type: Patent blue dye Amount: 2ml Injection location: intraparenchymally along the axillary border of the tumour. Injection timing: not stated Massage: the breast was massaged for 10 minutes. **Preoperative lymphoscintigraphy** Timing: performed but the timing after radiocolloid injection was not stated. **Surgery** Surgeon details: not stated Anaesthesia: not stated Axillary clearance: completion axillary dissection was performed. Sentinel node definition: blue nodes or lymph nodes that did not stain blue but the *in vivo* gamma-probe counts were ≥ 4 times background. Final breast procedure: lumpectomy 89.4%; mastectomy 10.6%. **Histologic analysis of sentinel nodes** Intraoperative analysis: not stated Sectioning: for nodes < 0.5cm whole nodes were examined, half nodes were examined for nodes 1 to 0.5cm and multiple sections of 0.5cm were made for nodes 0.5 to 1.0cm. Permanent section: routine H&E staining. IHC: staining for cytokeratin was performed on all negative sentinel nodes. Micrometastases definition: not stated **Histologic analysis of axillary nodes** Routine H&E staining.	**Age** Mean 54± 5 years (variance not stated). **Tumour characteristics** Biopsy method Not stated Size Not stated Stage T1a: 1/47 (2.1%) T1b: 2/47 (4.3%) T1c: 29/47 (61.7%) T2: 15/47 (31.9%) Histology Ductal: 44/47 (93.6%) Lobular: 1/47 (2.1%) Other: 2/47 (4.3%) Location Not stated Palpability Palpable: 44/47 (93.6%) Nonpalpable: 3/47 (6.4%) Multifocality/multicentricity Not stated **Axilla characteristics** Clinical axillary status Negative: 47/47 (100%) **Neoadjuvant chemotherapy** Not stated [ ], type of variance not stated

Study identifier	Procedure	Patient characteristics
Hung, Chan, Chong, Mak, Lau & Yip, 2002. **Number of patients** 50 **Number of attempted mappings** 50 **Study period** March 2000 to November 2001 **Institution** Departments of Surgery, Radiology and Pathology, Kwong Wah Hospital, Kowloon, Hong Kong. **Incorporated studies** None **Inclusion/exclusion criteria** Inclusions: patients with operable breast cancer <4cm, confirmed by FNA or Trucut biopsy. Exclusions: patients with multifocal cancers, palpable axillary lymph nodes or pregnancy. **Study included for review of...** Localisation rates and false negative rates	**Radiocolloid/dye combination** Radiocolloid only: 0 Dye only: 0 Radiocolloid and dye: 50 **Radiocolloid** Type: ^{99m}Tc-labelled rhenium sulphide (for the 1st 10 cases; Nanocis®, CIS Biointernational, Cedex, France); ^{99m}Tc-labelled sulfur colloid (for the remaining cases). Dose: mean 0.33, range 0.2 to 1.0mCi. Colloid size: mean size of rhenium colloid was 100nm; mean size of sulphur colloid was 500nm. Filtration: the sulphur colloid was unfiltered. Injection location: peritumourally for the first 7 cases, subdermally from case 8 onwards. Injection timing: not stated Massage: not stated Intraoperative probe: Navigator® (US Surgical Corp., Norwalk, CT, USA). **Dye** Type: Patent blue dye Amount: mean 1.7, range 1 to 5ml Injection location: peritumourally for the first 16 cases, subdermally from case 17 onwards Injection timing: after induction of anaesthesia. Massage: not stated **Preoperative lymphoscintigraphy** Timing: the majority was performed within 2 hours of radiocolloid injection. **Surgery** Surgeon details: not stated Anaesthesia: assumed general Axillary clearance: level I/II Sentinel node definition: hot, blue or hot and blue. Final breast procedure: breast conservation 21/50 (42.0%); modified radical mastectomy 29/50 (58.0%). **Histologic analysis of sentinel nodes** Intraoperative analysis: performed starting from case 19, three serial sections taken from each block (the sentinel node was cut into blocks measuring 5mm) and stained with H&E. Sectioning: three more sections from each paraffin block taken. Permanent section: H&E IHC: performed using CAM5.2 and AE1/AE3 if H&E staining was negative Micrometastases definition: not stated **Histologic analysis of axillary nodes** One section per 5mm block was examined using H&E staining.	**Age** Mean 52, range 32 to 84 years **Tumour characteristics** Biopsy method FNA or Trucut biopsy Size ≤1cm: 1/50 (2.0%) >1 to 2cm: 18/50 (36.0%) > 2 to 3cm: 24/50 (48.0%) > 3cm: 7/50 (14.0%) Stage Grade 1: 2/50 (4.0%) Grade 2: 20/50 (40.0%) Grade 3: 20/50 (40.0%) Special type: 6/50 (12.0%) Lobular: 2/50 (4.0%) Histology Not stated Location Lateral: 33/50 (66.0%) Medial: 14/50 (28.0%) Central: 3/50 (6.0%) Palpability Not stated Multifocality/multicentricity Patients with multifocal cancers were excluded **Axilla characteristics** Clinical axillary status Negative: 50/50 (100%) **Neoadjuvant chemotherapy** Not stated

Study identifier	Procedure	Patient characteristics
Ilum, Bak, Olsen, Kryh, Berg & Axelsson, 2000. **Number of patients** 159 (consecutive) **Number of attempted mappings** 161 **Study period** August 1998 to June 1999 **Institution** Departments of Surgery and Pathology, Odense University Hospital, Odense, Denmark. **Incorporated studies** None **Inclusion/exclusion criteria** Inclusions: operable primary breast cancer (including patients with enlarged axillary lymph nodes, patients with multifocal or bilateral tumours and patients with a previous excisional biopsy). Exclusions: previous axillary dissection, neoadjuvant chemotherapy. **Study included for review of...** Localisation rates and false negative rates	**Radiocolloid/dye combination** Radiocolloid only: 0 Dye only: 161 Radiocolloid and dye: 0 **Radiocolloid** Type: not applicable Dose: not applicable Colloid size: not applicable Filtration: not applicable Injection location: not applicable Injection timing: not applicable Massage: not applicable Intraoperative probe: not applicable **Dye** Type: Patent Blue V (Laboratoire Guebert, France). Amount: 0.5 mL, 1.0mL for those with previous tumour excision, extra 0.25mL after first 103 cases. Injection location: intradermally over primary tumour. In case of previous tumour excision, 1.0mL injected intradermally at site 2 cm in axillary direction from cicatrix. After first 103 dissections, additional 0.25mL injected subdermally. Injection timing: injection immediately following induction of general anaesthesia. Massage: none performed **Preoperative lymphoscintigraphy** Timing: not applicable **Surgery** Surgeon details: 10 surgeons, all with experience in axillary dissections, participated. The principal investigator (CKA) had conducted a small pilot study; the other surgeons were supervised in their first 3 to 6 operations. Anaesthesia: general anaesthesia was used. Axillary clearance: axillary lymphadenectomy performed. Sentinel node definition: a blue lymph node or a lymph node with blue lymphatics entering the capsule. If the blue node was intimately coherent with other lymph nodes all were considered sentinel nodes. Localisation allowed no more than 15 minutes of operating time. Final breast procedure: modified radical mastectomy (67/161) or lumpectomy (94/161). **Histologic analysis of sentinel nodes** Intraoperative analysis: no frozen sections taken. Sectioning: all nodes embedded separately. Nodes >4mm were bisected. Permanent sections cut from one level. If no metastases found, step-sectioning done at 6 levels. Permanent section: H&E IHC: when no metastases were found on first section, IHC using the CAM 5.2 monoclonal antibody agains cytokeratin 8 and 18 (Becton-Dickinson) used (6 levels). Micrometastases definition: IHC considered positive if malignant-looking immunoreactive cells identified within the lymph node, whether located in clusters or individually. **Histologic analysis of axillary nodes** Permanent sections taken from 2 levels and stained with H&E.	**Age** Mean 59, range 28 to 84 years. **Tumour characteristics** Biopsy method Not stated Size Mean diameter in ductal carcinomas 17 mm (range 2 to 55 mm). Stage Not stated Histology Invasive ductal carcinoma: 126/161 (78.3%) Invasive lobular carcinoma: 19/161 (11.8%) Invasive ductal carcinoma of special type: 16/161 (9.9%) Location Medial: 46/161 (28.6%) Lateral: 107/161 (66.5%) Palpability Not stated Multifocality/multicentricity Not stated **Axilla characteristics** Clinical axillary status Axillary metastases in 77/161 operations and in 42/97 cases where SN found by surgeon. **Neoadjuvant chemotherapy** None

Study identifier	Procedure	Patient characteristics
Imoto & Hasebe, 1999. **Number of patients** 86 **Number of attempted mappings** 88 **Study period** January to July 1998 **Institution** Division of Breast Surgery, National Cancer Center Hospital East, Kashiwa, Chiba and Pathology Division, National Cancer Center Research Institute East, Kashiwa, Chiba, Japan. **Incorporated studies** None **Inclusion/exclusion criteria** Inclusions: Stage 0 to IIIB breast cancer. Exclusions: none stated **Study included for review of...** Localisation rates and false negative rates.	**Radiocolloid/dye combination** Radiocolloid only: 0 Dye only: 88 Radiocolloid and dye: 0 **Radiocolloid** Radiocolloid was not used. Type: not applicable Dose: not applicable Colloid size: not applicable Filtration: not applicable Injection location: not applicable Injection timing: not applicable Massage: not applicable Intraoperative probe: not applicable **Dye** Type: indigocarmine (Daiichi Pharmaceutical, Japan) Amount: 4 to 5 mL (4mg/mL) Injection location: Two or three sites of subcutaneous injection around primary tumour. If primary tumour already excised, dye injected near the scar. Injection timing: in patients undergoing breast conserving surgery, partial mastectomy performed 15 minutes after injection of dye. Massage: breast lesions were rubbed well. **Preoperative lymphoscintigraphy** Timing: not applicable **Surgery** Surgeon details: not stated Anaesthesia: general anaesthesia Axillary clearance: completed up to Levels I or II or more. Sentinel node definition: blue-staining lymph nodes or blue staining afferent lymphatic tracts. Final breast procedure: modified radical mastectomy (55/88) or breast conserving surgery with axillary lymph node dissection (33/88). **Histologic analysis of sentinel nodes** Intraoperative analysis: frozen sections in some cases. Sectioning: paraffin embedded sections were taken, the method of sectioning not stated. Permanent section: H&E IHC: not stated Micrometastases definition: not stated **Histologic analysis of axillary nodes** Paraffin embedded sections with H&E stains of all axillary lymph nodes.	**Age** Median 53, range 30 to 81 years. **Tumour characteristics** Biopsy method Aspiration biopsy cytology, excisional biopsy or intraoperative tumour biopsy. Size 0.0 to 2.0 cm: 24/88 (27.3%) 2.1 to 5.0 cm: 52/88 (59.1%) >5.1cm: 12/88 (13.6%) Median 3.0cm, range 0.0 to 12.0cm. Stage 0, I: 26/88 (29.5%) IIA: 34/88 (38.6%) IIB: 13/88 (14.7%) IIIA: 11/88 (12.5%) IIIB: 4/88 (4.5%) Histology Non invasive ductal carcinoma: 4/88 (4.5%) IDCPIC*: 8/88 (9.1%) Intraductal carcinoma: 64/88 (72.7%) Intralobular carcinoma: 6/88 (6.8%) Others: 6/88 (6.8%) *IDCPIC: invasive ductal carcinoma with predominantly intraductal component. Location UOQ: 43/88 (48.9%) UIQ: 28/88 (31.8%) Central: 8/88 (9.1%) LOQ: 3/88 (3.4%) LIQ: 2/88 (2.3%) Whole: 4/88 (4.5%) Palpability Not stated Multifocality/multicentricity Not stated **Axilla characteristics** Clinical axillary status N0: 61/88 (69.3%) N1: 23/88 (26.1%) N2: 4/88 (4.5%) **Neoadjuvant chemotherapy** Not stated

Study identifier	Procedure	Patient characteristics
Imoto, Fukukita, Murakami, Iked & Moriyama, 2000. **Number of patients** 58 **Number of attempted mappings** 59 **Study period** August 1998 to January 1999 **Institution** Divisions of Breast Surgery and Radiology, National Cancer Center Hospital East, Kashiwa, Chiba and Division of Radiology, National Cancer Center Hospital, Tokyo, Japan. **Incorporated studies** None **Inclusion/exclusion criteria** Inclusions: stage 0 to IIIB breast cancer. Exclusions: none stated **Study included for review of...** Localisation rates and false negative rates.	**Radiocolloid/dye combination** Radiocolloid only: 0 Dye only: 15 Radiocolloid and dye: 43 **Radiocolloid** Type: ^{99m}Tc human serum albumin or ^{99m}Tc tin colloid (Nihon Medi-Physics, Tokyo, Japan). Dose: 30-50MBq (0.8-1.4mCi) in 2.5mL saline. Colloid size: ^{99m}Tc-HSA ≤5nm, ^{99m}Tc-TC ≥500nm. Filtration: not stated Injection location: subcutaneously at 2 or 3 sites around primary tumour or near scar following excisional biopsy Injection timing: radiocolloid injected about 24 hours before surgery. Massage: not stated Intraoperative probe: hand hled gamma detector (Navigator; USSC, Norwalk, CT) or a portable scintillation survey meter. **Dye** Type: Indigo carmine Amount: 5mL (20mg) Injection location: subcutaneously at 2 or 3 sites around primary tumour, or near the scar following excisional biopsy. Injection timing: dye injected 15 minutes before axilla incision. Massage: breast lesions rubbed well for about 30 seconds. **Preoperative lymphoscintigraphy** Timing: (43/59 cases) **Surgery** Surgeon details: not stated Anaesthesia: general anaesthesia was used. Axillary clearance: completed to level I, II or more. Sentinel node definition: blue-stained afferent lymphatic tracts traced to lymph nodes which were partially stained blue. Usually sentinel nodes ad 2- to 8-fold radioactivity compared to non-sentinel nodes. Final breast procedure: total mastectomy (43/59) or breast conserving surgery (16/59) perfomed. **Histologic analysis of sentinel nodes** Intraoperative analysis: frozen sections Sectioning: paraffin embedded sectioning also performed; method of sectioning not stated. Permanent section: H&E IHC: not stated Micrometastases definition: not stated **Histologic analysis of axillary nodes** H&E sections used for all axillary lymph nodes.	**Age** ≤ 35 years: 1/59 (1.7%) 36 to 50 years: 28/59 (47.5%) ≥ 51 years: 30/59 (50.8%) **Tumour characteristics** Biopsy method In 7/59 patients previous excisional biopsy was performed. Size 0.0 to 2.0cm: 13/59 (22.0%) 2.1 to 3.0cm: 21/59 (35.6%) 3.1 to 5.0cm: 25/59 (42.4%) Stage 0, 1: 12/59 (20.3%) IIA: 28/59 (47.5%) IIB: 18/59 (30.5%) IIIB: 1/59 (1.7%) Histology Grade I: 9/59 (15.3%) Grade II: 24/59 (40.7%) Grade III: 26/59 (44.1%) Location Dominant primary site Lateral: 35/59 (59.3%) Medial or central: 24/59 (40.7%) Palpability Not stated Multifocality/multicentricity Not stated **Axilla characteristics** Clinical axillary status N0: 40/59 (67.8%) N1: 18/59 (30.5%) N2: 1/59 (1.7%) **Neoadjuvant chemotherapy** Not stated

Study identifier	Procedure	Patient characteristics
Intra, Veronesi, Mazzarol, Galimberti, Luini, Sacchini, Trifirò, Gentilini, Pruneri, Naninato, Torres, Paganelli, Viale & Veronesi, 2003b. **Number of patients** 223 **Number of attempted mappings** 223 **Study period** March 1996 to December 2001 **Institution** Departments of Breast Surgery, Pathology and Laboratory Medicine, and Nuclear Medicine, European Institute of Oncology, Milan, Italy; Department of Milan School of Medicine, Milan, Italy; Breast Service, Department of Surgery, Memorial Sloan-Kettering Cancer Center, New York, New York, USA. **Incorporated studies** None **Inclusion/exclusion criteria** Inclusions: patients with clinically node-negative breast carcinoma. Exclusions: ductal carcinoma *in situ* with microinvasion. **Study included for review of...** Localisation rates	**Radiocolloid/dye combination** Radiocolloid only: 223 Dye only: 0 Radiocolloid and dye: 0 **Radiocolloid** Type: ^{99m}Tc-albumin colloid (Nanocol, Nycomed Amersham-Sorin, Italy). For nonpalpable primary tumours, ^{99m}Tc-macroaggregates used (0.5mg ^{99m}Tc-albumin aggregated, 10-150μm, Macrotec, Nycomed Amersham-Sorin). Dose: ^{99m}Tc-albumin colloid: 0.15 to 0.30mCi (5 to 10MBq) in 0.2mL isotonic sodium chloride solution; ^{99m}Tc-macroaggregates: 0.20 to 0.30 mCi (7 to 10MBq) in 0.2mL isotonic sodium chloride solution. Colloid size: 20-80nm (^{99m}Tc-albumin colloid); 10 to 150 μm (^{99m}Tc-macroaggregates). Filtration: not stated Injection location: ^{99m}Tc-albumin colloid: subdermally or peritumourally close to tumour. ^{99m}Tc-macroaggregates: under ultrasonographic guidance or mammographic guidance into centre of lesion. Injection timing: radiocolloid injected 4 to 20 hours before SLNB. Massage: not stated Intraoperative probe: Neoprobe 2000, (Ethicon Inc, Somerville, NJ). **Dye** Dye was not used. Type: not applicable Amount: not applicable Injection location: not applicable Injection timing: not applicable Massage: not applicable **Preoperative lymphoscintigraphy** Timing: performed 15 to 30 minutes after injection of colloid, repeated after 3 hours if no SLNs evident in early images. **Surgery** Surgeon details: not stated Anaesthesia: not stated Axillary clearance: not stated Sentinel node definition: all nodes that absorbed the radiotracer were classified as sentinel nodes. Final breast procedure: 184/223 wide resection; 39/223 mastectomy. **Histologic analysis of sentinel nodes** Intraoperative analysis: not stated Sectioning: sentinel nodes bisected fresh along the major axis if >5mm and fixed in formalin then embedded in paraffin. Nodes ≤ 5mm embedded uncut. 15 pairs of paraffin sections (4μm thick) were cut at 50μm intervals. If residual tissue was left additional pairs of sections cut at 100μm intervals until node entirely sectioned. Permanent section: one section of each pair stained with H&E. IHC: to ascertain the nature of atypical cells on the H&E sections the mirror sections were immunostained for cytokeratins using a rapid staining method (EPOS anti-cytokeratins/HRP; Dako, Copenhagen, Denmark). Micrometastases definition: not stated **Histologic analysis of axillary nodes** Not stated	**Age** Mean 50.1, range 30 to 80 years. **Tumour characteristics** Biopsy method Vacuum assisted biopsy 51/216 Excisional biopsy 32/216 (patients with negative nodes) Size Mean 25.7mm, range 6 to 55mm in 7 patients with positive sentinel nodes. Stage Grade 1: 43/223 (19.3%) Grade 2: 99/223 (44.4%) Grade 3: 81/223 (36.3%) Histology Ductal carcinoma Location Not stated Palpability Not stated Multifocality/multicentricity Not stated **Axilla characteristics** Clinical axillary status Negative: 223/223 (100%) **Neoadjuvant chemotherapy** Not stated

Study identifier	Procedure	Patient characteristics
Intra, Zurrida, Maffini, Sonzogni, Trifirò, Gennari, Arnone, Bassani, Opazo, Paganelli, Viale & Veronesi, 2003a. **Number of patients** 41 **Number of attempted mappings** 41 **Study period** March 1996 to December 2002 **Institution** Department of Surgery, Breast Unit and Department of Pathology and Laboratory Medicine, University of Milan School of Medicine; Department of Nuclear Medicine and Division of Chemoprevention, European Institute of Oncology, Milan, Italy. **Incorporated studies** None **Inclusion/exclusion criteria** Inclusions: patients had to have cytologically or histologically verified breast carcinoma 3cm or less in size (measured clinically and/or by imaging techniques) and clinically uninvolved axillary lymph nodes, and be affected by ductal carcinoma *in situ* with microinvasion. Exclusions: none stated **Study included for review of...** Localisation rates	**Radiocolloid/dye combination** Radiocolloid only: 41 Dye only: 0 Radiocolloid and dye: 0 **Radiocolloid** Type: ^{99m}Tc-labelled colloidal human albumin (Nanocol; Nycomed Amersham-Sorin, Saluggia-VC, Italy). Dose: 5 to 10MBq in 0.2ml of isotonic sodium chloride solution. Colloid size: 20 to 80nm Filtration: not stated Injection location: injected close to the tumour, subdermally or peritumourally, or in the case of diffuse microcalcifications in which total mastectomy was indicated, a single subdermal periareolar injection was used. Injection timing: radiocolloid injected 4 to 20 hours before sentinel node biopsy. Massage: not stated Intraoperative probe: Neoprobe 2000 (Ethicon Inc., Somerville, NY, USA). **Dye** Dye was not used. Type: not applicable Amount: not applicable Injection location: not applicable Injection timing: not applicable Massage: not applicable **Preoperative lymphoscintigraphy** Timing: 5 to 30 minutes after radiocolloid injection and repeated after 3 hours if no sentinel nodes were evident. **Surgery** Surgeon details: not stated Anaesthesia: not stated Axillary clearance: not stated Sentinel node definition: all the nodes uptaking the radiotracer were classified as sentinel nodes. Final breast procedure: wide resection 31/41 (75.6%); mastectomy 10/41 (24.4%). **Histologic analysis of sentinel nodes** Intraoperative analysis: not stated Sectioning: bisected fresh along major axis if >5mm or embedded uncut if <5mm, 15 pairs of paraffin-embedded sections, 4µm thick, were cut at 50µm intervals. If there was any residual tissue, sections were made at 100µm intervals until the entire node was sectioned. Permanent section: one section of each pair was stained with H&E. IHC: whenever needed, to ascertain the nature of atypical cells seen with H&E, the mirror sections were stained for cytokeratins (rapid staining method; EPOS Anticytokeratins/HRP, Dako, Copenhagen, Denmark). Micrometastases definition: not stated **Histologic analysis of axillary nodes** Axillary lymph nodes were bisected if >5mm and processed routinely for paraffin embedding. Sections (3	**Age** Mean 35.6, range 29 to 67 years. **Tumour characteristics** Biopsy method Not stated Size Not stated Stage Grade 1: 7/41 (17.1%) Grade 2: 14/41 (34.1%) Grade 3: 19/41 (46.3%) Unknown: 1/41 (2.4%) Histology Ductal: 37/41 (90.2%) Lobular: 3/41 (7.3%) Other: 1/41 (2.4%) Location Not stated Palpability Palpable: 20/41 (48.8%) Diffuse microcalcifications: 3/41 (7.3%) Nonpalpable opacity: 3/41 (7.3%) Cluster microcalcifications: 14/41 (34.1%) Unknown: 1/41 (2.4%) Multifocality/multicentricity Multifocal: 5/41 (12.2%) Not multifocal: 36/41 (87.8%) **Axilla characteristics** Clinical axillary status Negative: 41/41 (100%) **Neoadjuvant chemotherapy** All patients were evaluated for adjuvant therapy according to the main predictive and prognostic factors.

	to 6 H&E per node) cut at 100 to 500μm intervals.	

Study identifier	Procedure	Patient characteristics
Ishida, Kitamura, Kinoshita, Sasaki, Kuwahara & Sugimachi, 2002. **Number of patients** 44 (1 male) **Number of attempted mappings** 44 **Study period** December 1999 to March 2001 **Institution** Department of Surgery and Science, Graduate School of Medical Sciences, and the Department of Clinical Radiology, Kyshu University, Fukuoka, Japan. **Incorporated studies** None **Inclusion/exclusion criteria** Inclusions: patients with breast cancer. Exclusions: none stated **Study included for review of...** Localisation rates and false negative rates.	**Radiocolloid/dye combination** Radiocolloid only: 0 Dye only: 0 Radiocolloid and dye: 44 **Radiocolloid** Type: ^{99m}Tc-labelled human serum albumin. Dose: not stated Colloid size: not stated Filtration: not stated Injection location: radiocolloid injected at four sites into the mammary parenchyma surrounding the primary tumour. Injection timing: about 4 hours before surgery. Massage: not stated Intraoperative probe: Navigator GPS (Auto Suture, Japan Inc.). **Dye** Type: activated charcoal particle emulsion (CH40; provided by Dr Sawai, Kyoto Prefectural University of Medicine, Kyoto, Japan). Amount: 1ml Injection location: injected into the four sites of primary breast tumours (ie. peritumoural). Injection timing: dye was injected just before making a skin incision. Massage: not stated **Preoperative lymphoscintigraphy** Timing: scanning performed at 10, 15, 20, 30, 60 and 120 minutes after radiocolloid injection. **Surgery** Surgeon details: surgical procedures were performed by the same surgeon. Anaesthesia: not stated Axillary clearance: back up axillary clearance was performed in all patients. Sentinel node definition: sentinel nodes were stained with CH40. Final breast procedure: mastectomy 17/44 (38.6%); mastectomy with reconstruction 15/44 (34.1%); breast-conserving treatment 12/44 (27.3%). **Histologic analysis of sentinel nodes** Intraoperative analysis: not stated Sectioning: the sentinel nodes were divided into 3 blocks, one block was minced for RT-PCR and two blocks formalin fixed and embedded in paraffin and sectioned at 5μm. Permanent section: H&E (two levels). IHC: IHC with anticytokeratin 19. Micrometastases definition: not stated **Histologic analysis of axillary nodes** Not stated	**Age** Mean 52.6±11.4 (SD), range 26 to 78 years. **Tumour characteristics** Biopsy method Not stated Size Mean 2.3 ± 1.3, range 0 to 6.7cm Stage T0: 2/44 (4.5%) T1: 20/44 (45.5%) T2: 20/44 (45.5%) T3: 2/44 (4.5%) Histology Invasive ductal carcinomas: 42/44 (95.5%) Others: 2/44 (4.5%) Location Medial: 17/44 (38.6%) Lateral: 27/44 (61.4%) Palpability Not stated Multifocality/multicentricity Not stated **Axilla characteristics** Clinical axillary status N0: 30/44 (68.2%) N>0: 14/44 (31.8%) **Neoadjuvant chemotherapy** No patients had been given neoadjuvant therapy but almost all patients were given adjuvant therapy (peroral or drip in vein).

Study identifier	Procedure	Patient characteristics
Jaderborg, Harrison, Kiser & Maynard, 1999. **Number of patients** 91-12 = 79 **Number of attempted mappings** 79 **Study period** April 1997 to July 1998 **Institution** Departments of Surgery and Radiology, The University of Kansas School of Medicine – Wichita, Wichita, Kansas, USA. **Incorporated studies** None **Inclusion/exclusion criteria** Inclusions: patients over 18 years of age with invasive breast cancer or ductal carcinoma *in situ*, comedo-type. Exclusions: pregnant females, male patients (n=1), wrong sized filter for radionucleotide (n=5), improper injection of dye or radionucleotide (n=4), no pathology report for sentinel lymph node specimen (n=1), no axillary dissection done (n=1). **Study included for review of...** Localisation rates and false negative rates	**Radiocolloid/dye combination** Radiocolloid only: 0 Dye only: 0 Radiocolloid and dye: 79 **Radiocolloid** Type: ^{99m}Tc sulphur colloid Dose: 250 to 400μCi in 2 to 6 mL saline, injected in 0.5 to 1.5mL aliquots. Colloid size: not stated Filtration: not stated Injection location: injected at 4 to 6 points surrounding the tumour. Injection timing: injected on morning of surgery, 2 to 6 hours before surgical procedure. Massage: not stated Intraoperative probe: Neoprobe (Neoprobe Corporation, Dublin, OH, USA). **Dye** Type: isosulphan vital blue (Lymphozurin; Hirsch Industries, Inc., Richmond, VA, USA). Amount: 2 to 5 mL Injection location: dye was injected peritumourally. Injection timing: dye was injected before making an incision (lumpectomy or development of the flaps of the mastectomy was performed before locating the sentinel lymph node). Massage: not stated **Preoperative lymphoscintigraphy** Timing: in most cases immediately following injection of colloid, about 2 hours after injection. **Surgery** Surgeon details: 12 surgeons participated in study (1 surgeon performed 30 (38%) of procedures). Anaesthesia: not stated Axillary clearance: completed, including levels I, II and occasionally III. Sentinel node definition: the gamma probe and blue dye were used to locate the sentinel node(s); definition not stated. Final breast procedure: modified radical mastectomy 42/79 (53.2%) or lumpectomy with axillary dissection 37/79 (46.8%). **Histologic analysis of sentinel nodes** Intraoperative analysis: some had touch-prep cytology, others frozen section, and others only permanent sections (depending on surgeons' request). Sectioning: not stated Permanent section: not stated IHC: not stated Micrometastases definition: not stated **Histologic analysis of axillary nodes** Axillary contents of all patients examined by pathologist to detect and remove all lymph nodes which were fixed for permanent sectioning. Each node examined microscopically for evidence of metastasis; axillary nodes sent separately from the sentinel nodes.	**Age** Mean 59.3±13.5 (SD), range 32 to 84 years. **Tumour characteristics** Biopsy method Excisional: 27/79 (34.2%) Stereotactic core: 32/79 (40.5%) Fine-needle aspirations: 20/79 (25.3%) Previous breast biopsy: 16/79 (20.3%) Size 1.7±1.0(SD)cm, range 0.5 to 5.0 cm. Stage T1: 50/79 (63.3%) T2: 25/79 (31.6%) T3: 3/79 (3.8%) Histology Not stated Location Not stated Palpability Not stated Multifocality/multicentricity Not stated **Axilla characteristics** Clinical axillary status Not stated **Neoadjuvant chemotherapy** 7 patients had a 12 week course of neoadjuvant chemotherapy before their surgical treatment.

Study identifier	Procedure	Patient characteristics
Jastrzębski, Kopacz & Lass, 2002. **Number of patients** 123 Group 1(n=51) Group 2(n=72) **Number of attempted mappings** 123 **Study period** September 1998 to August 2002 **Institution** Departments of Surgical Oncology and Nuclear Medicine, Medical University of Gdańsk, Poland. **Incorporated studies** None **Inclusion/exclusion criteria** Inclusions: patients with primary operative breast cancer without clinical palpable axillary lymph nodes. Exclusions: none stated **Study included for review of...** Localisation rates	**Radiocolloid/dye combination** Radiocolloid only: 0 Dye only: 0 Radiocolloid and dye: 123 **Radiocolloid** Type: ^{99m}Tc sulphur colloid Dose: Group I (n=51) 1.0mL 16MBq; Group II (n=72) 0.5 to 1.0mL 16MBq. Colloid size: not stated Filtration: not stated Injection location: Group I: parenchymal peritumoural injection; Group II: intradermal periareolar one site injection. Injection timing: colloid injected one day before surgery for both groups. Massage: not stated Intraoperative probe: not stated **Dye** Type: blue-dye marker Amount: 0.5 to 1.0 mL Injection location: single intradermal injection over tumour (Group I), periareolar intradermal injection (Group II). Injection timing: dye was injected 15 minutes before the surgical procedure. Massage: not stated **Preoperative lymphoscintigraphy** Timing: performed in all cases on day before surgery. **Surgery** Surgeon details: not stated Anaesthesia: not stated Axillary clearance: not stated Sentinel node definition: not stated Final breast procedure: not stated **Histologic analysis of sentinel nodes** Intraoperative analysis: not stated Sectioning: not stated Permanent section: not stated IHC: not stated Micrometastases definition: not stated **Histologic analysis of axillary nodes** Not stated	**Age** Group I: Mean 52 years (n=51) Group II: Mean 53.8 years (n=72) **Tumour characteristics** Biopsy method Not stated Size Median 22.8mm (Group I), 22.1mm (Group II) Stage Group I T0 7/51(13.7%) T1a 0/51(0%) T1b 1/51(2.0%) T1c 15/51(29.4%) T2 28/51(54.9%) Group II T0 10/72 (13.9%) T1a 1/72 (1.4%) T1b 1/72 (1.4%) T1c 31/72 (43.1%) T2 29/72 (40.3%) Histology Not stated Location Group I UO 26/51(51.0%) UI 1/51(2.0%) LO 1/51(2.0%) LI 1/51(2.0%) UO/UI 10/51(19.6%) UI/LI 1/51(2.0%) LO/LI 3/51(5.9%) UO/LO 6/51(11.8%) Central 2/51(3.9%) Group II UO 31/72 (43.1%) UI 10/72 (13.9%) LO 4/72 (5.6%) LI 3/72 (4.2%) UO/UI 13/72 (18.1%) UI/LI 2/72 (2.8%) LO/LI 4/72 (5.6%) UO/LO 4/72 (5.6%) Central 1/72 (1.4%) Palpability Not stated Multifocality/multicentricity Not stated **Axilla characteristics** Clinical axillary status Negative 123/123(100%) **Neoadjuvant chemotherapy** Not stated

Study identifier	Procedure	Patient characteristics
Jianjun, Yu, Kui & Wuke, 2001. **Number of patients** 94 **Number of attempted mappings** 94 **Study period** October 1999 to April 2001 **Institution** Department of Surgical Oncology, First Hospital of Xi'an Jiaotong University, Xi'an, China. **Incorporated studies** None **Inclusion/exclusion criteria** Inclusions: patients with operable breast cancer, clinically positive or negative axillary lymph nodes. Exclusions: nonpalpable breast tumour, larger size primary tumour (>6cm diameter) and metastatic breast cancer. **Study included for review of...** Localisation rates and false negative rates	**Radiocolloid/dye combination** Radiocolloid only: 0 Dye only: 94 Radiocolloid and dye: 0 **Radiocolloid** Radiocolloid was not used. Type: not applicable Dose: not applicable Colloid size: not applicable Filtration: not applicable Injection location: not applicable Injection timing: not applicable Massage: not applicable Intraoperative probe: not applicable **Dye** Type: Group I (n=32): 0.028mmol/L Methylene blue (China); Group II (n=62): 0.018mmol/L Patent blue violet (Sigma Chemical Co.). Amount: 2mL both groups Injection location: dye injected into the breast parenchyma surrounding the primary tumour. Injection timing: 10 to 15 minutes before surgery. Massage: not stated **Preoperative lymphoscintigraphy** Timing: not applicable **Surgery** Surgeon details: same surgical cooperative group performed all operations. Anaesthesia: epidural block anaesthesia was used. Axillary clearance: Not stated Sentinel node definition: blue-impregnated lymphatic channel followed proximally and distally until the first node identified. Final breast procedure: radical or modified radical mastectomy. **Histologic analysis of sentinel nodes** Intraoperative analysis: not stated Sectioning: all nodes submitted entirely for paraffin blocks, method of sectioning not stated. Permanent section: H&E IHC: not stated Micrometastases definition: not stated **Histologic analysis of axillary nodes** Not stated	**Age** Mean 48, range 32 to 68 years. **Tumour characteristics** Biopsy method Diagnosed by fine needle aspiration, breast biopsy or intraoperative excisional biopsy. Size Mean 2.4cm, range 0.5 to 6.0 cm. Stage T1: 24/94 (25.5%) T2: 66/94 (70.2%) T3: 4/94 (4.3%) Histology Invasive ductal carcinoma: 79/94 (84.0%) Invasive lobular carcinoma: 10/94 (10.6%) Special subtypes: 5/94 (5.3%) Location Not stated Palpability Palpable: 94/94 (100%) Multifocality/multicentricity Not stated **Axilla characteristics** Clinical axillary status Patients with both clinically positive and negative axillary lymph nodes were included. **Neoadjuvant chemotherapy** Not stated

Study identifier	Procedure	Patient characteristics
Jinno, Ikeda, Matsui, Kitagawa, Kitajima, Fujii, Nakamura & Kubo, 2002. **Number of patients** 184 Group 1: n=74, 400-1000 nm radiocolloid injection; Group 2: n=110, 200-400 nm radiocolloid injection. **Number of attempted mappings** 184 **Study period** September 1998 to February 2002 **Institution** Departments of Surgery and Radiology, Keio University School of Medicine, Shinjuku-ku, Tokyo, Japan. **Incorporated studies** Ikeda *et al.* 2000 **Inclusion/exclusion criteria** Inclusions: patients with clinically T1-T2 N0 breast cancer were studied; both mastectomy and breast conserving surgery were eligible. Exclusions: pregnancy and clinical node postivity. **Study included for review of...** Localisation rates	**Radiocolloid/dye combination** Radiocolloid only: 0 Dye only: 0 Radiocolloid and dye: 184 **Radiocolloid** Type: ^{99m} Tc-labelled tin colloid Dose: 74 MBq/ml; 0.5 ml per three points around the tumour, one 0.3 ml subdermal injection. Colloid size: initial 74 patients regular-sized colloid (400 to 1000 nm); next 110 patients small-sized colloid (200 to 400 nm). Filtration: not stated Injection location: injected at three points around the tumour and subdermally just above the tumour; in patients with previous excisional biopsy colloid was injected into the wall of the cavity. Injection timing: radiocolloid injected the day before surgery. Massage: not stated Intraoperative probe: Navigator (Tyco Healthcare Japan, Tokyo, Japan). **Dye** Type: Isosulphan blue dye (Lymphazurin, US Surgical Co., Norwalk, CT). Amount: 1 ml Injection location: dye was injected around the tumour and subcutaneously. Injection timing: dye was injected before surgery. Massage: not stated **Preoperative lymphoscintigraphy** Timing: performed 3 hours after radiocolloid injection. **Surgery** Surgeon details: not stated Anaesthesia: general anesthesia was used. Axillary clearance: standard axillary clearance up to the second level. Sentinel node definition: sentinel nodes were defined by both the gamma probe and the appearance of blue dye in the lymphatic vessels and nodes; counts were taken of the nodes *ex vivo* and then of the axillary background, defining sentinel nodes as those containing 10 times more radioactivity than the surrounding tissue. Final breast procedure: mastectomy or breast-conserving surgery. **Histologic analysis of sentinel nodes** Intraoperative analysis: not stated Sectioning: paraffin embedded sections used, method of sectioning not stated. Permanent section: H&E IHC: not stated Micrometastases definition: not stated **Histologic analysis of axillary nodes** One H&E section of all lymph nodes harvested was examined.	**Age** Group 1 (n=74): Age 54.2±12.3 Group 2 (n=110): Age 53.9±12.4 Note: (mean±SD); parameter not stated, assumed it was years. **Tumour characteristics** Biopsy method Aspiration biopsy cytology or excisional biopsy used for clinical diagnosis. Size Group 1 (n=74): Tumour size (cm) 2.3±0.9 Group 2 (n=110): Tumour size (cm) 2.3±0.8 (mean±SD) Stage Clinically T1-T2 patients were enrolled in the study. Histology Group 1 / Group 2 Scirrhous: 43.2% / 53.6% Solid-tubular: 27% / 19.1% Papillotubular: 9.5% / 10.9% Not stated: 20.3% / 16.4% Note: percentages only given in table. Location Not stated Palpability Not stated Multifocality/multicentricity One false-negative case in Group 2 had multifocal tumours. **Axilla characteristics** Clinical axillary status Negative: 184/184 (100%) **Neoadjuvant chemotherapy** One false-negative case in the small-sized colloid group received preoperative chemotherapy.

Study identifier	Procedure	Patient characteristics
Johnson, Orr & Moline, 2001. **Number of patients** 119-23=96 **Number of attempted mappings** 96 **Study period** February 1998 to December 2000 (retrospective study) **Institution** Department of Medical Education (Surgery), Spartanburg Regional Medical Center, Spartanburg, South Carolina, USA. **Incorporated studies** None **Inclusion/exclusion criteria** Inclusions: patients with breast cancer. Exclusions: 23 patients were excluded from learning curve analysis. **Study included for review of...** Localisation rates	**Radiocolloid/dye combination** Radiocolloid only: 4/119 or 3/96 Dye only: 0 Radiocolloid and dye: 97% (115/119 or 93/96) Note: not clear whether the numbers related to the total group or the group after exclusions. **Radiocolloid** Type: sulphur colloid Dose: not stated Colloid size: not stated Filtration: unfiltered Injection location: radiocolloid injected typically peritumourally. Injection timing: not stated Massage: not stated Intraoperative probe: not stated **Dye** Type: lymphazurin blue Amount: 5 to 6 mL (in most cases). Injection location: dye usually injected peritumourallyn Injection timing: not stated Massage: injection usually followed by breast massage. **Preoperative lymphoscintigraphy** Timing: performed but timing not stated. **Surgery** Surgeon details: multiple surgeons were involved in the study; three nuclear radiologists were responsible for injecting the radiocolloid. Anaesthesia: not stated Axillary clearance: not stated; 5 surgeons have used SLNB without full axillary clearance. Sentinel node definition: not stated Final breast procedure: not stated **Histologic analysis of sentinel nodes** Intraoperative analysis: not stated Sectioning: not stated Permanent section: not stated IHC: not stated Micrometastases definition: not stated **Histologic analysis of axillary nodes** Not stated	**Age** Not stated **Tumour characteristics** Biopsy method Not stated Size Not stated Stage Not stated Histology Not stated Location Not stated Palpability Not stated Multifocality/multicentricity Not stated **Axilla characteristics** Clinical axillary status Not stated **Neoadjuvant chemotherapy** Not stated

Study identifier	Procedure	Patient characteristics
Kapteijn, Nieweg, Petersen, Rutgers, Hart, van Dongen & Kroon, 1998. **Number of patients** 30 **Number of attempted mappings** 30 **Study period** June 1994 to June 1996 **Institution** Departments of Surgery, Pathology and Radiotherapy, The Netherlands Cancer Institute/Antoni van Leeuwenhoek Ziekenhuis, Amsterdam, The Netherlands. **Incorporated studies** None **Inclusion/exclusion criteria** Inclusions: patients scheduled for a modified radical mastectomy or a segmental mastectomy with *en bloc* lymph node dissection with: diagnosis of a clinically palpable breast cancer, confirmed by mammography and fine needle aspiration; absence of multicentric breast cancer; absence of clinically suspected nodal and/or distant metastases. Patients with medial tumours were included. Exclusions: patients who had undergone prior treatment (excluding an axillary level III biopsy, 'apex node biopsy'), pregnant patients. **Study included for review of...** False negative rates	**Radiocolloid/dye combination** Radiocolloid only: 0 Dye only: 30 Radiocolloid and dye: 0 **Radiocolloid** Radiocolloid was not used. Type: not applicable Dose: not applicable Colloid size: not applicable Filtration: not applicable Injection location: not applicable Injection timing: not applicable Massage: not applicable Intraoperative probe: not applicable **Dye** Type: patent blue dye Amount: 1ml Injection location: dye was injected intratumorally, given in three injections at different angles. Injection timing: dye was injected immediately before surgery. Massage: not stated **Preoperative lymphoscintigraphy** Timing: not applicable **Surgery** Surgeon details: not stated Anaesthesia: general anaesthesia was used. Axillary clearance: an *en bloc* axillary clearance was performed, including levels I, II and sometimes III. Sentinel node definition: not stated. The sentinel nodes were dissected out from the *ex vivo* specimen. Final breast procedure: standard or segmental mastectomy. **Histologic analysis of sentinel nodes** Intraoperative analysis: not stated Sectioning: not stated Permanent section: H&E IHC: CAM 5.2 (Becton Dickinson, San José, California, USA). Micrometastases definition: not stated **Histologic analysis of axillary nodes** Evaluated in a similar fashion to sentinel nodes.	**Age** Mean 57, range 35 to 82 years. **Tumour characteristics** Biopsy method FNA: 30/30 (100%) Size Mean 2.9, range 1.1 to 5.0cm Stage Not stated Histology Ductal: 22/30 (73.3%) Lobular: 5/30 (16.7%) Ductolobular: 2/30 (6.7%) DCIS: 1/30 (3.3%) Location Right: 16/30 (53.3%) Left: 14/30 (46.7%) UOQ: 21/30 (70.0%) LOQ: 1/30 (3.3%) UIQ: 3/30 (10.0%) LIQ: 2/30 (6.7%) Central: 3/30 (10.0%) Palpability Palpable: 30/30 (100%) Multifocality/multicentricity Patients with multicentric breast cancer were excluded. **Axilla characteristics** Clinical axillary status Negative: 30/30 (100%) **Neoadjuvant chemotherapy** Patient who had undergone prior treatment were excluded.

Study identifier	Procedure	Patient characteristics
Kataoka, Mori, Sadanaga, Ueo, Tsuji, Rai, Barnard and Sugimachi, 2000. **Number of patients** 70 **Number of attempted mappings** 70 **Study period** July 1998 to March 1999 **Institution** Department of Surgery, Medical Institute of Bioregulation, Kyushu University, Beppu, Japan; Departments of Surgery and Pathology, Oita Prefectural Hospital, Oita, Japan; Department of Surgery, National Beppu Hospital, Beppu, Japan; Division of Digestive Disease and Nutrition, University of Massachusetts Medical Center, Worcester, Massachusetts, USA; Department of Surgery II, Faculty of Medicine, Kyushu University, Fukuoka, Japan. **Incorporated studies** None **Inclusion/exclusion criteria** Inclusions: patients with operable primary breast cancer (UICC T1 to T3, N0, Stage I to II). Exclusions: patients with clinically metastatic lymph nodes in the axilla, or skin invasion. **Study included for review of...** Localisation rates and false negative rates	**Radiocolloid/dye combination** Radiocolloid only: 0 Dye only: 70 Radiocolloid and dye: 0 **Radiocolloid** Radiocolloid was not used. Type: not applicable Dose: not applicable Colloid size: not applicable Filtration: not applicable Injection location: not applicable Injection timing: not applicable Massage: not applicable Intraoperative probe: not applicable **Dye** Type: India ink (Kuretake Co., Kyoto, Japan; n=10); activated charcoal particles emulsion (CH40; given by Dr Hagiwara and Dr Sawai, Kyoto Prefectural University of Medicine, Kyoto, Japan; n=60). Amount: 2ml Injection location: into the breast tissue adjacent to the primary tumour or into the induration site of a previous exisional biopsy. Injection timing: dye was injected just before skin incision. Massage: not stated **Preoperative lymphoscintigraphy** Timing: not applicable **Surgery** Surgeon details: not stated Anaesthesia: general anaesthesia was used. Axillary clearance: formal axillary dissection (levels II or III). Sentinel node definition: the first lymph node(s) partially or completely stained black, following a black-stained lymphatic. Final breast procedure: partial mastectomy 25/70 (35.7%); modified radical mastectomy 45/70 (64.3%) **Histologic analysis of sentinel nodes** Intraoperative analysis: not stated Sectioning: sentinel nodes were cut in two, one piece snap frozen for RNA extraction. The other half was fixed in formalin and embedded in paraffin; method of sectioning not stated. Permanent section: H&E IHC: not stated Micrometastases definition: not stated **Histologic analysis of axillary nodes** Routine H&E.	**Age** Mean 56.6, range 34 to 84 years. **Tumour characteristics** Biopsy method Excisional biopsy: 17/70 (24.3%) None: 53/70 (75.7%) Size Mean 2.2, range 0.6 to 9.8cm. Stage I: 32/70 (45.7%) IIa: 35/70 (50.0%) IIb: 3/70 (4.3%) Histology Invasive ductal: 63/70 (90.0%) Invasive lobular: 1/70 (1.4%) Other: 6/70 (8.6%) Location Medial or central: 25/70 (35.7%) Lateral: 45/70 (64.3%) Palpability Not stated Multifocality/multicentricity Not stated **Axilla characteristics** Clinical axillary status N0: 70/70 (100%) **Neoadjuvant chemotherapy** Not stated

Study identifier	Procedure	Patient characteristics
Kern, 1999 **Number of patients** 40 **Number of attempted mappings** 40 **Study period** August 1998 to May 1999 **Institution** Department of Surgery, Hartford Hospital and University of Connecticut School of Medicine, Farmington, Connecticut, USA. **Incorporated studies** Kern *et al.* 2001 **Inclusion/exclusion criteria** Inclusions: patients with operable breast cancer in stage I and II were enrolled. Exclusions: none stated **Study included for review of...** Localisation rates and false negative rates.	**Radiocolloid/dye combination** Radiocolloid only: 0 Dye only: 40 Radiocolloid and dye: 0 **Radiocolloid** Radiocolloid was not used. Type: not applicable Dose: not applicable Colloid size: not applicable Filtration: not applicable Injection location: not applicable Injection timing: not applicable Massage: not applicable Intraoperative probe: not applicable **Dye** Type: 1% isosulphan blue Amount: 5 ml Injection location: into the areolar dermis and breast tissue immediately beneath the areolar (the subareolar lymphatic plexus). Injection timing: dye was injected immediately before the axillary dissection. Massage: subareolar area of the breast was massaged for 1 to 2 minutes. **Preoperative lymphoscintigraphy** Timing: not applicable **Surgery** Surgeon details: all injections were performed by Kern. Anaesthesia: not stated Axillary clearance: level I and II axillary dissection, with preservation of the intercostal-brachial nerves where possible. Sentinel node definition: any node partially or completely staned by blue dye, or any non-blue node connected to a blue-stained lymphatic channel. Final breast procedure: 33/40 (82.5%) partial mastectomies; 7/40 (17.5%) modified radical mastectomies. **Histologic analysis of sentinel nodes** Intraoperative analysis: not stated Sectioning: each sentinel node was evaluated at three separate levels through the tissue block. Permanent section: H&E IHC: all histologically negative nodes were investigated using cytokeratin analysis; a panel of cytokeratin stains were used. Micrometastases definition: not stated **Histologic analysis of axillary nodes** Not stated	**Age** Mean 58±13.5 years, range 32 to 83 years. (type of variance not stated) **Tumour characteristics** Biopsy method Minimally invasive biopsy (core needle biopsy or stereotactic biopsy): 31/40 (77.5%) Surgical excisional biopsy as a separate operation.: 9/40 (22.5%) Note: excisional biopsies evenly distributed among the upper outer quadrants, lower outer quadrants and upper inner quadrants of both breasts. Size Mean 1.9±1.4 cm, range 0.1 to 6.6cm; mean tumour volume 11 ±27 cm^3, range 0.01 to 150 cm^3. Stage Patients with stage I and II were enrolled in the study. Histology All tumours were invasive carcinomas of either ductal or lobular type. No cases of DCIS were included in the study. Location Not stated Palpability Not stated Multifocality/multicentricity Not stated **Axilla characteristics** Clinical axillary status Not stated **Neoadjuvant chemotherapy** Not stated

Study identifier	Procedure	Patient characteristics
Kern, 2002. **Number of patients** 185 (consecutive) **Number of attempted mappings** 187 **Study period** September 1999 to February 2002 **Institution** Department of Surgery, Hartford Hospital and University of Connecticut School of Medicine, Farmington, Connecticut, USA. **Incorporated studies** Kern, 2001 **Inclusion/exclusion criteria** Inclusions: patients with operable breast cancer, stages Ia to IIIa, including palpable high grade ductal carcinoma *in situ*. Exclusions: none stated **Study included for review of...** Localisation rates	**Radiocolloid/dye combination** Radiocolloid only: 0 Dye only: 0 Radiocolloid and dye: 187 **Radiocolloid** Type: TcSc (CIS-US Inc, Bedford, MA, USA). Dose: 1 mCi (37 MBq), in 4 ml of saline. Colloid size: not stated Filtration: unfiltered Injection location: radiocolloid injected superficially into the subareolar lymphatic plexus (undersurface of areolar dermis). Injection timing: 30 minutes before operation. Massage: no manual massage was used. Intraoperative probe: hand-held gamma probe, type not specified. **Dye** Type: 1% isosulfan blue dye (Lymphazurin, United Stated Surgical Corp, Norwalk, CT) Amount: 3 ml Injection location: injected in the same location as radiocolloid (SA injection), intraoperatively Injection timing: dye was gien immediately after induction of anaesthesia. Massage: no manual massuage was used. **Preoperative lymphoscintigraphy** Timing: performed in all patients immediately after radiocolloid injection. Continued until sentinel nodes were visulaised (generally within 30 minutes) or to a maximum of 45 minutes. **Surgery** Surgeon details: not stated Anaesthesia: general anaesthesia was used. Axillary clearance: complete axillary dissection carried out as clinically indicated in 70/187 (37.4%) patients (50 of these had positive nodes, in 20 dissections performed to confirm the findings of a negative sentinel node, performed because of patient preference, physician request, or as clinically indicated by the type of procedure). Sentinel node definition: each case was classified according to three types of sentinel nodes identified: those containing both blue dye and radioactivity ("blue-hot" nodes), those containing radioactivity alone ("hot-only" nodes) and those containing blue dye alone ("blue-only" nodes). Final breast procedure: partial mastectomies 153/187 (81.8%); complete mastectomies 34/187 (18.2%). **Histologic analysis of sentinel nodes** Intraoperative analysis: frozen section (39 of 50 positive nodes identified by intraoperative frozen section). Sectioning: permanent sections used, method of sectioning not stated. Permanent section: H&E IHC: stated sentinel node considered negative if it contained a limited number of cytokeratin-positive cells, not stated whether IHS was used to identify these cells. Micrometastases definition: not stated **Histologic analysis of axillary nodes** Not stated.	**Age** Mean 56.3±13.2 (SD) years, range 31 to 90 years. **Tumour characteristics** Biopsy method Not stated Size Mean 1.8 cm±1.5 (SD), range 0.1 to 9.0 cm. ≤ 0.5 cm: 26/187 (13.9%) 0.5-1.0cm: 38/187 (20.3%) 1.0-2.0: 66/187 (35.3%) 2.0-5.0 cm: 47/187 (25.1%) > 0.5 cm: 4/187 (2.1%) Not stated: 6/187 (3.2%) Stage T1a: 26/187 (13.9%) T1b: 38/187 (20.3%) T1c: 66/187 (35.3%) T2: 47/187 (25.1%) T3: 4/187 (2.1%) T0*: 6/187 (3.2%) *: palpable high-grade DCIS Histology Ductal: 139/187 (74.3%) Lobular: 15/187 (8.0%) Ductal-lobular: 21/187 (11.2%) Palpable high-grade DCIS*: 12/187 (6.4%) *: with necrosis Location Right: 89/187 (47.6%) Left: 98/187 (52.4%) Palpability Palpable: 127/187 (67.9%) Nonpalpable: 60/187 (32.1%) Multifocality/multicentricity Not stated **Axilla characteristics** Clinical axillary status Not stated **Neoadjuvant chemotherapy** Not stated

Study identifier	Procedure	Patient characteristics
Kim, Osaki, Kojima & Toge, 2001. **Number of patients** 23 **Number of attempted mappings** 23 **Study period** December 1999 to September 2000 **Institution** Department of Surgical Oncology, Research Institute for Radiation Biology and Medicine, Hiroshima University, Hiroshima, Japan. **Incorporated studies** None **Inclusion/exclusion criteria** Inclusions: patients with histologically confirmed breast cancer. Tumour size was not an issue. Exclusions: i) suspicion of node involvement, ii) prior surgical biopsy, iii) multifocal carcinoma, iv) prior axillary surgery, v) pregnant or lactating patients. **Study included for review of...** Localisation rates and false negative rates	**Radiocolloid/dye combination** Radiocolloid only: 0 Dye only: 0 Radiocolloid and dye: 23 **Radiocolloid** Type: ^{99m}Tc human serum albumin (HSA) and ^{99m}Tc tin colloid. Dose: 1mL, 37MBq (^{99m} -Tc HAS); 1.5mL, 50MBq (^{99m}tin colloid). Both diluted in physiological saline. Colloid size: not stated Filtration: not stated Injection location: single subcutaneous injection above tumour (^{99m}Tc HAS); and two peritumoural subcutaneous injections in direction of nipple and axillary sides (^{99m}tin colloid). Injection timing: injections on day before surgery Massage: mild hand massage for 10 to 15 seconds after injection. Intraoperative probe: gamma probe (Navigator, United States Surgical, CT, USA). **Dye** Type: indigocalmine Amount: 5mL Injection location: 2mL subcutaneously above tumour, 3 mL in two peritumoural subcutaneous injections in direction of nipple and axillary sides. Injection timing: dye was injected before surgery. Massage: not stated **Preoperative lymphoscintigraphy** Timing: performed at 5, 10, 15, 20, 35, 40 minutes and 2 hours after injection of colloid. **Surgery** Surgeon details: not stated Anaesthesia: not stated Axillary clearance: standard axillary lymph node dissection in all patients. Sentinel node definition: stained with blue dye in drainage lymph ducts and lymph nodes plus radioactivity more than 10-fold compared to background. Final breast procedure: breast conserving surgery or radical mastectomy. **Histologic analysis of sentinel nodes** Intraoperative analysis: frozen section Sectioning: lymph node bisected along major axis before frozen and permanent sectioning. Permanent sections made by making several thin slices of nodes at 2mm intervals. Permanent section: H&E IHC: not stated Micrometastases definition: not stated **Histologic analysis of axillary nodes** Non-sentinel nodes examined by bisecting the node along the major axis.	**Age** Mean 55.5, range 39 to 73 years. **Tumour characteristics** Biopsy method Patients with prior surgical bopsy were excluded. Size ≤ 2cm: 3/23 (13.0%) >2cm but ≤ 5cm: 17/23 (73.9%) >5cm: 3/23 (13.0%) Stage I: 3/23 (13.0%) II: 17/23 (73.9%) IIIa: 1/23 (4.3%) IIIb: 2/23 (8.7%) Histology Not stated Location Not stated Palpability Not stated Multifocality/multicentricity Patients with multifocal carcinoma were excluded. **Axilla characteristics** Clinical axillary status N0: 20/23 (87.0%) N1a: 3/23 (13.0%) **Neoadjuvant chemotherapy** Not stated

Study identifier	Procedure	Patient characteristics
Kitapçi, Mentes, Üner, Abamor, Dursun, Kaplan, Ferahköşe & Tatlicioğlu, 2001. **Number of patients** 14 **Number of attempted mappings** 14 **Study period** Not stated **Institution** Departments of Nuclear Medicine, Surgery, Oncology and Pathology, Gazi University Medical School, Ankara, Turkey. **Incorporated studies** None **Inclusion/exclusion criteria** Inclusions: patients with primary breast carcinomas confirmed by incisional or excisional biopsies performed within the previous two weeks. Exclusions: no patients had received prior breast surgery, chemotherapy or radiotherapy. Patients with advanced tumour necessitating neoadjuvant chemotherapy were excluded. **Study included for review of...** Localisation rates and false negative rates.	**Radiocolloid/dye combination** Radiocolloid only: 14 Dye only: 0 Radiocolloid and dye: 0 **Radiocolloid** Type: ^{99m}Tc-nanocolloid (Amersham, Sorin Sr1, Sallugia, Italy). Dose: 1mCi in 0.8mL saline. Colloid size: almost 80% of particles smaller than 30nm, 20% particles between 30 and 80nm. Filtration: not stated Injection location: four injections spaced equal distance apart circumferentially injected into breast tissue around primary tumour or biopsy cavity if excisional biopsy already performed. Injection timing: not stated Massage: not stated Intraoperative probe: Neoprobe 1500 (Neoprobe Corp, Ohio, USA). **Dye** Dye was not used. Type: not applicable Amount: not applicable Injection location: not applicable Injection timing: not applicable Massage: not applicable **Preoperative lymphoscintigraphy** Timing: performed day before surgery, images taken from immediately after radiocolloid injection then every 30 minutes for four hours. **Surgery** Surgeon details: Not stated Anaesthesia: Not stated Axillary clearance: complete axillary dissection performed in levels I, II and III. Sentinel node definition: node(s) emitting highest activity within axillary region, all nodes from the axilla were examined to check for extra sentinel nodes. Final breast procedure: total mastectomy (n=13) or quadrantectomy (n=1). **Histologic analysis of sentinel nodes** Intraoperative analysis: not stated Sectioning: stated sentinel nodes examined using standard technique. Permanent section: not stated IHC: not stated Micrometastases definition: not stated **Histologic analysis of axillary nodes** It was stated all nodes examined by pathologist using standard technique.	**Age** Not stated **Tumour characteristics** Biopsy method Excisional or incisional biopsies were performed to confirm the diagnosis. Size ≤ 2cm: 6/14 (42.9%) >2cm but ≤ 5cm: 8/14 (51.1%) Stage T1: 6/14 (42.9%) T2: 8/14 (51.1%) Histology Not stated Location Not stated Palpability Palpable: 5/14 (35.7%) Non-palpable: 9/14 (64.3%) Multifocality/multicentricity No distant metastases: 14/14 (100%) **Axilla characteristics** Clinical axillary status N0: 10/14 (71.4%) N1: 4/14 (28.6%) **Neoadjuvant chemotherapy** Patients who needed neoadjuvant chemotherapy were excluded from the study.

Study identifier	Procedure	Patient characteristics
Klimberg, Rubio, Henry, Cowan, Colvert & Korourian, 1999. **Number of patients** 68 **Number of attempted mappings** 69 **Study period** October 1997 to November 1998 **Institution** Department of Surgery, Division of Surgical Oncology and the Departments of Pathology and Radiology, University of Arkansas for Medical Sciences, Arkansas Cancer Research Center, John L. McClellan Veterans Administration Hospital, Little Rock, Arkansas, USA. **Incorporated studies** None **Inclusion/exclusion criteria** Inclusions: operable breast cancer documented by fine-needle aspiration, core biopsy or excisional biopsy and clinically negative axillary nodes by physical examination Exclusions: patients with prior axillary surgical procedures, multiple primary tumours and/or pregnancy. **Study included for review of...** Localisation rates	**Radiocolloid/dye combination** Radiocolloid only: 0 Dye only: 0 Radiocolloid and dye: 69 **Radiocolloid** Type: ^{99m}Tc-sulphur colloid Dose: 4.0mL, 1.0mCi Colloid size: not stated Filtration: unfiltered Injection location: radiocolloid injected in the subareolar area of the tumour-bearing breast. Injection timing: radiocolloid injected the morning of surgery, 30 minutes to 8 hours before coming to operating room. Massage: Intraoperative probe: Neoprobe (Dublin, OH) or C-Trak (Morgan Hill, CA). **Dye** Type: 1% isosulphan blue Amount: 2 to 5mL Injection location: dye was injected around the tumour, but not into tumour or biopsy cavity. Injection timing: dye injected in the operating room, 10 to 15 minutes before surgical procedure. Massage: not stated **Preoperative lymphoscintigraphy** Timing: **Surgery** Surgeon details: not stated Anaesthesia: not stated Axillary clearance: if lymph node had metastatic disease, axillary lymph node dissection performed at same setting. Sentinel node definition: blue staining and/or counts >10% of background. Final breast procedure: modified radical mastectomy (33.4%) or lumpectomy (66.6%), depending on presentation of tumour and personal preferences. **Histologic analysis of sentinel nodes** Intraoperative analysis: touch preps: sentinel nodes bisected with a clean blade and touched to a slide, immediately fixed in 70% ethanol then stained with H&E. Cytological features of malignancy included: cellular smears, loosely cohesive and individually scattered malignant cells, malignant epithelial cells arranged in three-dimensional clusters, syncytial group and occasional acinar pattern, tumour diathesis and nonpolar naked nuclei. Sectioning: each sentinel node labelled separately and processed routinely, method of sectioning not stated. Permanent section: H&E IHC: not stated Micrometastases definition: not stated **Histologic analysis of axillary nodes** Axillary lymph nodes were dissected fresh using routine surgical pathology techniques and permanent sections.	**Age** Mean 55.2±13.4 (SD) years, range 28 to 86 years. **Tumour characteristics** Biopsy method Fine-needle aspiration or core biopsy (58%); excisional biopsy (42%). Size Mean 1.9 ± 1.5 cm, range 0.1 to 9.5cm. Stage T1: 52/69 (75.4%) T2: 14/69 (20.3%) T3: 3/69 (4.3%) Histology Invasive ductal carcinoma: 75.4% Invasive lobular carcinoma: 14.5% Mixed: 2.9% Tubular: 4.3% Medullary carcinoma: 1.5% Mucinous carcinoma: 1.5% Location UOQ: 50.7% UCQ: 24.6% LOQ: 7.2% LC: 4.3% IC: 4.3% OC: 4.3% LIQ: 1.4% UIQ: 1.4% C: 1.4% Note: percentages only given in paper. Palpability Not stated Multifocality/multicentricity Patients with multiple primary tumours were excluded from the study. **Axilla characteristics** Clinical axillary status Negative: 69/69 (100%) **Neoadjuvant chemotherapy** Not stated

Study identifier	Procedure	Patient characteristics
Koizumi, Nomura, Yamada, Takiguchi, Tanaka, Yoshimoto, Makita, Sakamoto, Kasumi & Ogata, 2003. **Number of patients** 60 **Number of attempted mappings** 60 **Study period** Not stated **Institution** Departments of Nuclear Medicine, Breast Surgery, Breast Pathology and Internal Medicine, Cancer Institute Hospital, Tokyo, Japan. **Incorporated studies** None **Inclusion/exclusion criteria** Inclusions: patients with stage T1-T2 breast cancer, no clinical evidence of axillary node metastases, scheduled for either lympectomy or mastectomy and axillary node dissection. Exclusions: none stated **Study included for review of...** Localisation rates and false negative rates	**Radiocolloid/dye combination** Radiocolloid only: 0 Dye only: 0 Radiocolloid and dye: 60 **Radiocolloid** Type: ^{99m}Tc-rhenium sulphide (Nanocis; CIS Bio International, Gif-sur-Yvette, CEDEX, France). Dose: total volume 1.0mL (4 injections, each 0.2 to 0.3mL). 1 day protocol: 7.4MBq (0.2mCi), 11.1MBq (0.3mCi), 14.8MBq (0.4mCi), 18.5MBq (0.5mCi), 22.2MBq (0.6mCi), 29.6MBq (0.8mCi), 37MBq (1mCi). 2 day protocol: 37MBq (1mCi), 44.4MBq (1.2mCi), 55.5MBq (1.5mCi), 74MBq (2mCi). 5 consecutive patients for each dose schedule. Colloid size: mean particle size 100nm. Filtration: not stated Injection location: radiocolloid injected peritumourally at 4 sites; injections at a depth of about 1 to 1.5cm below the skin to place colloid in the mammary gland. Injection timing: 3.5 hours (1 day protocol) or 17 hours (2 day protocol) before operation started. Massage: gentle massage to site for 1 to 2 minutes after injection. Intraoperative probe: Neoprobe 2000 (Neoprobe, OH, USA). **Dye** Type: indigocamine Amount: 5mL Injection location: dye injected at four peritumoural sites and one subdermal site. Injection timing: dye injected just before surgery began. Massage: not stated **Preoperative lymphoscintigraphy** Timing: images taken 10 minutes and 2 (1 day protocol) or 16 hours (2 day protocol) after injection. **Surgery** Surgeon details: not stated Anaesthesia: not stated Axillary clearance: standard axillary dissection was performed. Sentinel node definition: detected by dye colour and with a hand-held gamma probe. Final breast procedure: lumpectomy or mastectomy. **Histologic analysis of sentinel nodes** Intraoperative analysis: frozen sections, cut into 3 pieces and reported during surgery. Sectioning: standard histological examination performed, method of sectioning not stated. Permanent section: standard histology IHC: not stated Micrometastases definition: not stated **Histologic analysis of axillary nodes** Standard histological examination of all axillary node tissue specimens.	**Age** Median 54, range 31 to 75 years. **Tumour characteristics** Biopsy method Not stated Size Not stated Stage T1-T2: 60/60 100% Histology Not stated Location Not stated Palpability Not stated Multifocality/multicentricity M0: 60/60 100% **Axilla characteristics** Clinical axillary status Negative: 60/60 100% **Neoadjuvant chemotherapy** Not stated

Study identifier	Procedure	Patient characteristics
Koller, Barsuk, Zippel, Engelberg, Ben-Ari & Papa, 1998. **Number of patients** 98 **Number of attempted mappings** 98 **Study period** Not stated **Institution** Breast Cancer Service and Department of Surgical Oncology, Chaim Sheba Medical Center, Tel Hashomer, and the Tel Aviv University Medical School, Ramat Aviv, Israel. **Incorporated studies** None **Inclusion/exclusion criteria** Inclusions: patients with breast cancer. Exclusions: none stated **Study included for review of...** Localisation rates and false negative rates	**Radiocolloid/dye combination** Radiocolloid only: 0 Dye only: 98 Radiocolloid and dye: 0 **Radiocolloid** Radiocolloid was not used. Type: not applicable Dose: not applicable Colloid size: not applicable Filtration: not applicable Injection location: not applicable Injection timing: not applicable Massage: not applicable Intraoperative probe: not applicable **Dye** Type: methylene blue 1% or Patent Blue V dye Amount: 3 to 5 cc Injection location: subcutaneously at biopsy site around region of tumour. Injection timing: dye injected at the time of excision or relumpectomy, 10 minutes before axillary dissection. Massage: not stated **Preoperative lymphoscintigraphy** Timing: not applicable **Surgery** Surgeon details: not stated Anaesthesia: not stated Axillary clearance: formal axillary dissection done in the usual manner. Sentinel node definition: blue stained afferent lymphatics were located and traced to lymph nodes which, if partially or completely stained, were identified as sentinel nodes. Final breast procedure: not stated **Histologic analysis of sentinel nodes** Intraoperative analysis: not stated Sectioning: nodes were sent for pathological examination, method of sectioning not stated. Permanent section: not stated IHC: not stated Micrometastases definition: not stated **Histologic analysis of axillary nodes** Findings in axillary nodes given, method of examination not stated.	**Age** Mean 55±14 (variance not stated), range 37 to 70 years. **Tumour characteristics** Biopsy method Not stated Size Mean 2.3 ± 0.86 cm (variance not stated). Stage Grade 1: 15% (15/98) Grade 2: 50% (49/98) Grade 3: 35% (34/98) Histology Infiltrating ductal carcinoma: 92% (90/98) Infiltrating lobular carcinoma: 8% (8/98) Percentages from text, no actual figures given. Location Not stated Palpability Not stated Multifocality/multicentricity Not stated **Axilla characteristics** Clinical axillary status Not stated **Neoadjuvant chemotherapy** Not stated

Study identifier	Procedure	Patient characteristics
Krag, Harlow, Weaver & Ashikaga, 2001. **Number of patients** 145 **Number of attempted mappings** 145 **Study period** 1993 to 1997 **Institution** Department of Surgery, Division of Surgery Oncology, University of Vermont, Burlington, Vermont, USA. **Incorporated studies** Krag *et al.* 1993 **Inclusion/exclusion criteria** Inclusions: eligible patients had operable invasive breast cancer and clinically negative lymph nodes, and they were to undergo planned surgical lymphadenectomy. Exclusions: none stated **Study included for review of...** Localisation rates and false negative rates	**Radiocolloid/dye combination** Radiocolloid only: 145 Dye only: 0 Radiocolloid and dye: 0 **Radiocolloid** Type: ^{99m}Tc-sulfur colloid Dose: Amount of radiation: < 37 MBq (1 mCi): 24/145 (16.6%) ≥ 37 M Bq (1 mCi): 121/145 (83.4%) Volume injected: < 3 ml: 29/145 (20%) 3 to < 8 ml: 62/145 (42.8%) ≥ 8 ml: 54/145 (37.2%) Colloid size: not stated Filtration: unfiltered Injection location: injected into the breast parenchyma surrounding the primary tumour (at 3, 6, 9and 12 o'clock) or for mammographically localised lesions, parallel to the guidewire to the appropriate depth. Injection timing: time between injection and surgery; ≤ 1 hour: 21/145 (14.5%) 1 to 3 hours: 54/145 (37.2%) ≥ 3 hours: 68/145 (46.9%) Massage: not stated Intraoperative probe: C-Trak (Care Wise, Morgan Hill, CA, USA). **Dye** Type: not applicable Amount: not applicable Injection location: not applicable Injection timing: not applicable Massage: not applicable **Preoperative lymphoscintigraphy** Timing: gamma camera imaging was not performed routinely as part of this protocol. **Surgery** Surgeon details: all patients were operated on by two surgeons (DNK and SH). Anaesthesia: not stated Axillary clearance: conventional lymphadenectomy in all cases. Sentinel node definition: any area with discrete radioactivity separate from the injection site with a cumulative 10 second count ≥ 25 considered a hot spot; background counts defined as the 10 second count measured within ≤ 2 cm of the hot spot. Measurements made before making an incision. If any radioactive nodes were identified in the excised lymphadenectomy speciment these were not considered sentinel nodes, but submitted separately. Final breast procedure: not stated **Histologic analysis of sentinel nodes** Intraoperative analysis: not stated Sectioning: each sentinel or radiolabeled node submitted in a separate cassette for analysis and all nodes > 8 mm were bisected; 1 or 2 sections (4μm) from each paraffin block mounted on a single slide. Permanent section: H&E IHC: IHC was not used. Micrometastases definition: not stated **Histologic analysis of axillary nodes** All palpable nodules within the axillary adipose tissue suspected to be lymph noes were submitted for histologic evaluation.	**Age** Mean 53±10.3 (SD) years. < 50 years: 59/145 (40.7%) ≥ 50 years: 86/145 (59.3%) **Tumour characteristics** Biopsy method Needle/ core aspiration/ none: 97/145 (66.9%) Excisional biopsy: 48/145 (33.1%) Note: only percentages given in text. Size ≤ 2cm: 91/145 (62.8%) >2cm but ≤ 5cm: 47/145 (32.4%) T3: 7/145 (4.8%) Stage T1a: 5/145 (3.4%) T1b: 33/145 (22.8%) T1c: 53/145 (36.6%) T2: 47/145 (32.4%) T3: 7/145 (4.8%) Histology Ductal: 123/148 (84.8%) Lobular: 13/145 (9.0%) Mixed: 6/145 (4.1%) Other: 3/145 (2.0%) Location Medial: 31/145 (21.4%) Central: 37/145 (25.5%) Outer: 77/145 (53.1%) Palpability Not stated Multifocality/multicentricity Not stated **Axilla characteristics** Clinical axillary status Negative: 145/145 (100%) **Neoadjuvant chemotherapy** Not stated

Study identifier	Procedure	Patient characteristics
Kumar, Jana, Heiba, Dakhel, Axelrod, Siegel, Bernik, Mills, Wallack & Abdel-Dayem, 2003. **Number of patients** 59 **Number of attempted mappings** 59 **Study period** July 1998 to June 2001 **Institution** Departments of Nuclear Medicine, Endocrinology, Surgery and St. Vincent's Comprehensive Cancer Center, St. Vincent's Catholic Medical Centers of New York, New York Medical College, Valhalla, New York, USA. **Incorporated studies** None **Inclusion/exclusion criteria** Inclusions: patients with histologic diagnosis of multifocal or multicentric breast carcinoma by biopsy, clinical or histologic diagnosis. Exclusions: none stated **Study included for review of...** Localisation rates	**Radiocolloid/dye combination** Radiocolloid only: 13 Dye only: 0 Radiocolloid and dye: 46 **Radiocolloid** Type: ^{99m}Tc-Sulphur colloid (CIS-US, Bedford, MA). Dose: approximately 10MBq in 0.3 to 0.4mL normal saline solution. Colloid size: 160 to 5 600 millimicron, mean particle size 0.3 ± 0.2 millimicron. Filtration: unfiltered Injection location: intra- or subdermally over each clinically palpable tumour, or above and below the scar in case the patient had a lumpectomy or excision biopsy. Injection timing: radiocolloid injected 2 to 4 hours before surgery. Massage: not stated Intraoperative probe: CTC-4 (Radiation Monitoring Devices, Inc., MA). **Dye** Type: isosulphan blue vital dye Amount: 2 to 5 mL Injection location: injected intraparenchymally at 4 to 6 sites around the breast mass. Injection timing: dye injected 10 to 15 minutes before surgery. Massage: gentle massage performed for 5 minutes after the injection. **Preoperative lymphoscintigraphy** Timing: performed but timing not stated. **Surgery** Surgeon details: not stated Anaesthesia: not stated Axillary clearance: 48/59 patients had axillary node dissection irrespective of the results of pathogenic examination of the sentinel node. Sentinel node definition: all lymph nodes having counts ≥ 10 times that of background counts, irrespective of blue dye or blue nodes. Final breast procedure: Lumpectomy or mastectomy and sentinel node excision **Histologic analysis of sentinel nodes** Intraoperative analysis: frozen sections Sectioning: method of sectioning not stated. Permanent section: H&E IHC: cytokeratin staining used for detection of micrometastases in negative H&E sections. Micrometastases definition: not stated **Histologic analysis of axillary nodes** Other axillary lymph nodes had frozen sectioning, H&E staining and IHC for detection of micrometastases.	**Age** Mean 55.75, range 34 to 80 years. **Tumour characteristics** Biopsy method Fine-needle aspiration: 19/59 (32.2%) Core biopsy: 32/59 (54.2%) Lumpectomy: 8/59 (13.6%) Size Not stated Stage Not stated Histology Not stated Location Not stated Palpability 27/59 patients had palpable breast masses. Multifocality/multicentricity Multifocal: 27/59 (45.8%) Multicentric: 32/59 (54.2%) **Axilla characteristics** Clinical axillary status Not stated **Neoadjuvant chemotherapy** Not stated

Study identifier	Procedure	Patient characteristics
Lauridsen, Garne, Hessov, Sørensen, Melsen, Lernevall & Christiansen, 2000. **Number of patients** 80 **Number of attempted mappings** 80 **Study period** August 1998 to February 2000 **Institution** Departments of Surgery, Pathology and Radiology, Aarhus University Hospital, Amtssygehuset, Aarhus, Denmark. **Incorporated studies** None **Inclusion/exclusion criteria** Inclusions: women newly diagnosed with invasive breast cancer by fine-needle aspiration biopsy or core biopsy and with surgery planned according to the Danish Breast Cancer Cooperative Group 89 Protocol. Exclusions: patients with non-palpable tumours (n=27), multifocal tumours verified by mammography/ultrasonography (n=26), axillary lymph node metastases verified by ultrasonography and fine needle aspiration (n=36), advanced cancer (n=10) or scheduled for frozen sectioning (n=27). Another 14 patients declined to participate and 124 patients did not enter the study because of lack of capacity in the operating theatre. **Study included for review of...** Localisation rates and false negative rates	**Radiocolloid/dye combination** Radiocolloid only: 0 Dye only: 0 Radiocolloid and dye: 80 **Radiocolloid** Type: ^{99m}Tc Albures Dose: 1.0cc, 15MBq in saline solution. Colloid size: not stated Filtration: not stated Injection location: injected around and close to the tumour. Injection timing: injection was 2 hours preoperatively. Massage: not stated Intraoperative probe: C-trak **Dye** Type: Patent Blue V Amount: 1.5cc, 150 mg/cc Injection location: dye was injected around the tumour. Injection timing: dye was injected 10 to 15 minutes before surgery. Massage: not stated **Preoperative lymphoscintigraphy** Timing: lymphoscintigraphy was not performed. **Surgery** Surgeon details: not stated Anaesthesia: not stated Axillary clearance: axillary dissection was performed. Sentinel node definition: any blue and/or 'hot' lymph node. Final breast procedure: breast conserving surgery or mastectomy. **Histologic analysis of sentinel nodes** Intraoperative analysis: frozen section, probably not performed intraoperatively. Sectioning: nodes were divided in half, one half for frozen section and subsequent paraffin embedding and one half for paraffin embedding. Frozen sections stained with H&E. Paraffin embedded specimens serial sectioned with sampling from 4 levels. Permanent section: H&E IHC: stained for cytokeratin. If positive for cytokeratin the pathologist re-examined the H&E slides for confirmation of the diagnosis. Micrometastases definition: not stated **Histologic analysis of axillary nodes** Not stated	**Age** Not stated **Tumour characteristics** Biopsy method Fine needle aspiration biopsy or core biopsy. Size Median 21, range 9 to 45 mm. Stage Not stated Histology Not stated Location Not stated Palpability Patients with non-palpable tumours excluded Multifocality/multicentricity Patients with multifocal tumours verified by mammography / ultrasonography excluded. **Axilla characteristics** Clinical axillary status Not stated **Neoadjuvant chemotherapy** Not stated

Study identifier	Procedure	Patient characteristics
Layeeque, Henry-Tillman, Korourian, Kass & Klimberg, 2003. **Number of patients** 40 (prospective) **Number of attempted mappings** 40 **Study period** January 1996 to July 2002 **Institution** Departments of Surgery and Pathology, Arkansas Cancer Research Center, Central Arkansas Healthcare System, Little Rock, Arkansas; Department of Surgery and Pathology, University of Arkansas for Medical Sciences, Little Rock, Arkansas, USA. **Incorporated studies** None **Inclusion/exclusion criteria** Inclusions: patients with biopsy proven invasive breast cancer, clinically negative axilla, and more than one lesion in the same breast at least 2 cms apart. Exclusions: none stated **Study included for review of...** Localisation rates and false negative rates	**Radiocolloid/dye combination** Radiocolloid only: 0 Dye only: 0 Radiocolloid and dye: 40 **Radiocolloid** Type: ^{99m}Tc-sulphur colloid Dose: not stated Colloid size: not stated Filtration: unfiltered Injection location: subareolar lymphatic plexus. Injection timing: not stated Massage: not stated Intraoperative probe: Neoprobe (Dublin, Ohio). **Dye** Type: 1% Lymphazurin blue dye (US surgical Corp, Norwalk, CN). Amount: not stated Injection location: the injection needle was inserted at the limbus of the areola in the same clock position as the tumour, and advance at 45 degrees into the subareolar space with the needle tip just underneath the nipple. Correct injection of the subareolar plexus confirmed by an immediate blue flush of the nipple areolar complex. Injection timing: not stated Massage: not stated **Preoperative lymphoscintigraphy** Timing: not stated **Surgery** Surgeon details: not stated Anaesthesia: not stated Axillary clearance: dissection of level I and II axillary lymph nodes was completed. Sentinel node definition: all hot, blue and palpable nodes (hot node defined as more than 10% of background). Blue nodes identified by tracing blue-stained lymphatics. Final breast procedure: complete mastectomy **Histologic analysis of sentinel nodes** Intraoperative analysis: not stated Sectioning: formalin fixed, serially sectioned at 5mm intervals. Sentinel nodes >5mm were sectioned at 3mm intervals along the long axis. Permanent section: H&E IHC: not stated Micrometastases definition: not stated **Histologic analysis of axillary nodes** Nonsentinel nodes were bisected along the long axis and one section submitted for each node for H&E.	**Age** Mean 56.4±13.1 (SD), range 34 to 81 years. **Tumour characteristics** Biopsy method Excisional biopsy: 5/40 (12.5%) Core needle biopsy: 35/40 (87.5%) Size Mean tumour dimension of largest lesion 2.6cm ±1.6cm (SD), range 0.2 to 7.2 cm. Stage Not stated Histology Ductal only: 31/40 (77.5%) Lobular only: 4/40 (10%) Ductal + lobular: 4/40 (10%) Ductal + lobular + tubular: 1/40 (2.5%) Location Number of quadrants involved 1: 19/40 (47.5%) 2: 19/40 (47.5%) 3: 1/40 (2.5%) 4: 1/40 (2.5%) Palpability Not stated Multifocality/multicentricity Not stated **Axilla characteristics** Clinical axillary status Negative: 40/40 (100%) **Neoadjuvant chemotherapy** Not stated

Study identifier	Procedure	Patient characteristics
Leidenius, Krogerus, Toivonen, Leppänen & von Smitten, 2003. **Number of patients** 395-32=363 **Number of attempted mappings** 363 **Study period** March 2001 to July 2002 **Institution** Breast Surgery Unit, Maria Hospital; Departments of Pathology and Nuclear Medicine, Helsinki University Hospital, Helsinki, Finland. **Incorporated studies** None **Inclusion/exclusion criteria** Inclusions: patients with clinical stage T1 to T2 breast cancer, all axillary node negative. Exclusions: patients with sentinel nodes not found in the axilla (n=32). **Study included for review of...** Localisation rates	**Radiocolloid/dye combination** Radiocolloid only: 0 Dye only: 0 Radiocolloid and dye: 363 **Radiocolloid** Type: ^{99m}Tc-HSA (Nanocoll®, Nycomed Amersham Sorin s.r.l. Saluggia, Italy). Dose: 80 to 100 MBq, 0.2mL Colloid size: <80nm Filtration: not stated Injection location: single intratumoural injection, or in patients with previous excisional biopsy, tracer injected in two foci around biopsy cavity. Performed manually in patients with a clearly palpable tumour and with ultrasound or sterotactic guidance when impalpable. Injection timing: injected the day before surgery. Massage: not stated Intraoperative probe: gamma probe, type not stated. **Dye** Type: Patent Blue dye (Bleu Patenté V, Laboratoire Geuerbet, Aulnay-sous-Bois, France). Amount: 1mL Injection location: dye was injected intratumourally. Injection timing: at least 5 minutes before surgery. Massage: not stated **Preoperative lymphoscintigraphy** Timing: performed the day before surgery, a median of 4 hours after injection of radiocolloid. **Surgery** Surgeon details: not stated Anaesthesia: not stated Axillary clearance: level I-II axillary clearance performed when metastases found in histological examination of sentinel nodes or in other suspicious nodes. During same operation (n=113) or as a second operation in (n=21). Careful palpation of the open axilla was performed and all palpably suspicious lymph nodes removed. Sentinel node definition: sentinel nodes harvested using gamma probe and by searching for the blue stained lymphatic vessels and nodes. Node focally radioactive when its activity exceeded the background activity measured from the ipsilateral shoulder. Final breast procedure: not stated **Histologic analysis of sentinel nodes** Intraoperative analysis: fresh specimens slind into 1 to 1.5mm thick sections perpendicular to the long axis and arranged on pre-frozen Tissue-Tek® OCT™-compound. Touch preps from the surface and frozen sections from two levels were made, stained with toluidine blue, viewed, and results sent back to operating room. Sectioning: remaining tissue formalin fixed, method of sectioning of sentinel nodes not stated. Permanent section: H&E (2 sections). IHC: if H&E sections negative, another 2 sections stained with CAM 5.2 (Becton Dickinson Immunocytometry Systems, San Jose, CA, USA). When a metastesis found in frozen section, all nodes Cam 5.2 stained. Micrometastases definition: metastases of 2mm or less. **Histologic analysis of axillary nodes** Lymph nodes paraffin embedded; H&E sections prepared	**Age** Median 57, range 36 to 91 years. **Tumour characteristics** Biopsy method Not stated Size Median 15, range 2 to 70 mm. Stage T0: 12/363 (3.3%) T1: 269/363 (74.1%) T2: 82/363 (22.6%) T3: 1/363 (0.3%) T4: 1/363 (0.3%) Total=365, percentage total=100.6 Histology DCIS: 12/363 (3.3%) Ductal: 186/363 (51.2%) Lobular: 96/363 (26.4%) Tubular: 18/363 (5.0%) Medullary: 9/363 (2.5%) Tubulobular: 25/363 (6.9%) Other types: 17/363 (4.7%) Grade 1: 133/363 (36.6%) Grade 2: 150/363 (41.3%) Grade 3: 66/363 (18.2%) Not applicable: 14/363 (3.9%) Location Central: 29/363 (8.0%) Upper medial: 73/363 (20.1%) Lower medial: 27/363 (7.4%) Upper lateral: 201/363 (55.4%) Lower lateral: 33/363 (9.1%) Palpability Both palpable and impalpable tumours were included. Multifocality/multicentricity Not stated **Axilla characteristics** Clinical axillary status Negative: 363/363 (100%) **Neoadjuvant chemotherapy** Not stated

	from 2 levels, 200μm apart. When a metastasis found in frozen section, nodes were stained with Cam 5.2.	

Study identifier	Procedure	Patient characteristics
Liang, Craik, Juhasz & Harman, 2003. **Number of patients** 20 (consecutive) **Number of attempted mappings** 21 **Study period** January to March 2002 **Institution** Departments of Surgery and Pathology, North Shore Hospital, Auckland, New Zealand. **Incorporated studies** None **Inclusion/exclusion criteria** Inclusions: patients with cytological or histological diagnosis of breast cancer who would have received axillary lymph node dissection as standard treatment. Exclusions: none stated **Study included for review of...** Localisation rates and false negative rates	**Radiocolloid/dye combination** Radiocolloid only: 0 Dye only: 0 Radiocolloid and dye: 21 **Radiocolloid** Type: ^{99m}Tc-antimony colloid Dose: 40MBq Colloid size: not stated Filtration: not stated Injection location: not stated Injection timing: not stated Massage: not stated Intraoperative probe: hand held gamma probe used, type not stated. **Dye** Type: Patent Blue V dye Amount: 2mL Injection location: dye injected at 4 sites peritumourally. Injection timing: not stated Massage: 10 minutes after injection. **Preoperative lymphoscintigraphy** Timing: Not stated **Surgery** Surgeon details: all procedures carried out by one of two surgeons certified to perform sentinel node biopsies for the SNAC Trial. Anaesthesia: not stated Axillary clearance: performed in all but 2 patients who were randomised in the SNAC Trial to receive sentinel node biopsy only. Sentinel node definition: not stated Final breast procedure: not stated **Histologic analysis of sentinel nodes** Intraoperative analysis: nodes sliced at 3mm intervals; frozen section and imprint bytology performed on all nodes >1.0cm. Nodes <1.0cm had imprint cytoloty only. During this time the surgeon completed the primary breast procedure. Sectioning: all nodes routinely processed for permanent paraffin sections, method of sectioning not stated. Permanent section: H&E IHC: if negative for malignancy, nodes went on to four-step sections at 200μm intervals and AE1/AE3 cytokeratin staining. Micrometastases definition: not stated **Histologic analysis of axillary nodes** Axillary specimen processed routinely and all nodal tissue submitted for H&E staining.	**Age** Mean 59 years. **Tumour characteristics** Biopsy method Patients had cytological or histological diagnosis of breast cancer, method of biopsy not stated. Size Not stated Stage Not stated Histology Not stated Location Not stated Palpability Not stated Multifocality/multicentricity Not stated **Axilla characteristics** Clinical axillary status Not stated **Neoadjuvant chemotherapy** Not stated

Study identifier	Procedure	Patient characteristics
Liberman & Cody, 2001. **Number of patients** 197 (consecutive) **Number of attempted mappings** 200 **Study period** August 1998 to June 2000 **Institution** Department of Radiology, Breast Imaging Section and Breast Service, Department of Surgery, Memorial Sloan-Kettering Cancer Center, New York, New York, USA. **Incorporated studies** None **Inclusion/exclusion criteria** Inclusions: mammographically detected nonpalpable carcinomas and findings negative for tumour in axillae on preoperative physical examination. Exclusions: none stated **Study included for review of...** Localisation rates	**Radiocolloid/dye combination** Radiocolloid only: 0 Dye only: 0 Radiocolloid and dye: 200 **Radiocolloid** Type: ^{99m}Tc-sulphur colloid Dose: 0.1mCi (3.7MBq) in 0.5mL saline. Colloid size: not stated Filtration: unfiltered Injection location: injected intradermally, superolateral to site of primary tumour. In patients having lumpectomy needle localisation was performed. Injection timing: the time between injection and surgery ranged from 2 to 4 hours. Massage: not stated Intraoperative probe: C-Trak (Care-Wise Medical, Morgan, CA). **Dye** Type: Isosulphan Blue (Lymphazurin, Zenith Parenterals, Rosemont, IL). Amount: 4mL, (1 to 3 aliquots). Injection location: dye injected in 1 to 3 aliquots around the tumour site into the breast parenchyma. Injection timing: 5 to 10 minutes before axillary incision. Massage: not stated **Preoperative lymphoscintigraphy** Timing: began approximately 20 minutes after injection. **Surgery** Surgeon details: not stated Anaesthesia: not stated Axillary clearance: if frozen or paraffin section of sentinel nodes yielded carcinoma, axillary lymph node dissection performed. If sentinel nodes free of tumour on intraoperative examination, no further axillary surgery was performed. If sentinel nodes not found, axillary dissection performed. No axillary dissection in 158 patients. Sentinel node definition: blue staining at surgery and/or its removal resulted in a fourfold or greater reduction in axillary counts. Final breast procedure: wide excision (197/200), mastectomy (3/200). **Histologic analysis of sentinel nodes** Intraoperative analysis: frozen section Sectioning: paraffin sections obtained, method of routine sectioning not stated. If initial sections were negative, two immediately adjacent sections (IHC) and three deeper levels 50µm apart (H&E). Permanent section: H&E IHC: when initial H&E negative, 2 immediately adjacent sections evaluated with cytokeratin IHC (AE1/3 and CAM 5.2 antibodies). Micrometastases definition: not stated **Histologic analysis of axillary nodes** Nonsentinel lymph nodes examined with a single H&E section.	**Age** Median 59, range 33 to 85 years. **Tumour characteristics** Biopsy method Percutaneous biopsy, sonographic guidance: 108 Percutaneous biopsy, stereotactic guidance: 92 14 gauge automated needle: 136 Vacuum assisted biopsy probe: 63 Large biopsy cannula: 1 Size Median 1.1, range 0.1 to 2.8cm (infiltrating carcinoma). Stage Not stated Histology Infiltrating ductal carcinoma (including DCIS): 161/200 (80.5%); (143/200) Mixed infiltrating ductal and lobular carcinoma (including DCIS): 27/200 (13.5%); (21/200) Infiltrating lobular carcinoma (including DCIS): 12/200 (6%); (3/200) Location OUQ: 125/200 (62.5%) LOQ: 19/200 (9.5%) UIQ: 31/200 (15.5%) LIQ: 25/200 (12.5%) Palpability Nonpalpable: 200/200 (100%) Multifocality/multicentricity Not stated **Axilla characteristics** Clinical axillary status Negative: 200/200 (100%) **Neoadjuvant chemotherapy** Not stated

Study identifier	Procedure	Patient characteristics
Liberman, Cody III, Hill, Rosen, Yeh, Akhurst, Morris, Abramson, Borgen & Dershaw, 1999. **Number of patients** 33 (retrospective) **Number of attempted mappings** 33 **Study period** June 1997 to April 1998 (surgical records) **Institution** Breast Imaging Section and Nuclear Medicine Service, Department of Radiology; The Breast Service, Department of Surgery and the Department of Pathology, Memorial Sloan-Kettering Cancer Center, New York, New York, USA. **Incorporated studies** None **Inclusion/exclusion criteria** Inclusions: women who had percutaneous core biopsy diagnosis of nonpalpable infiltrating breast carcinoma. All women had mammographically detected carcinomas and clinically negative nodes at preoperative physical examination. Exclusions: none stated **Study included for review of...** Localisation rates	**Radiocolloid/dye combination** Radiocolloid only: 0 Dye only: 0 Radiocolloid and dye: 33 **Radiocolloid** Type: ^{99m}Tc-sulfur colloid (CIS-US, Mass) Dose: (into breast parenchyma) 0.3mCi (11.1MBq) in 4mL normal saline; (intradermally) 0.1mCi (3.7MBq) in 0.05mL. Colloid size: not stated Filtration: unfiltered Injection location: intraparenchymal injection (n=28) adjacent to the tumour at the 12, 3, 6 and 9 o'clock positions around the localising wire in patients having breast conserving surgery, and around the prior percutaneous biopsy site in patients having mastectomy. Intradermal (n=5) in women part of an ongoing study investigating intradermal injection for sentinel node biopsy. Injection timing: between 2 and 4 hours before surgery. Massage: not stated Intraoperative probe: C-Trak (Care-Wise Medical, Morgan, CA). **Dye** Type: Isosulphan blue (Lymphazurin, Zenith Parenteraksm Rosemont, Ill) Amount: 4mL, in 1 to 3 aliquots Injection location: dye injected at 1 to 3 sites around tumour. Injection timing: dye injected 5 to 10 minutes before axilla incision. Massage: not stated **Preoperative lymphoscintigraphy** Timing: median interval between injection and acquisition of last image 50 minutes (Mean 55, range 35 to 158 minutes). **Surgery** Surgeon details: not stated Anaesthesia: not stated Axillary clearance: axillary dissection performed if frozen section, paraffin section, or IHC analysis of sentinel nodes yielded carcinoma. Sentinel node definition: defined as node with blue staining at surgery and/or following removal 4-fold or greater reduction observed in axillary counts. Final breast procedure: breast conserving surgery (30/33), mastectomy (3/33). **Histologic analysis of sentinel nodes** Intraoperative analysis: frozen section Sectioning: paraffin embedded sections performed, method of routine sectioning not stated. If initial H&E negative, 3 additional levels examined. Permanent section: H&E IHC: if initial H&E negative, stained for cytokeratin with AE1/3 and CAM 5.2 antibodies. Micrometastases definition: a lymph node considered to contain metastatic carcinoma if 1 or more tumour cells identified in H&E or IHC section. **Histologic analysis of axillary nodes** Examined with a single H&E section.	**Age** Median 60, range 42 to 82 years. **Tumour characteristics** Biopsy method Percutaneous biopsy, 14-gauge needle: 21/33 63.6%) Percutaneous biopsy, vacuum-assisted biopsy probe: 9/33 (27.3%) Unknown: 3/33 (9.1%) Size Median 1.1, range 0.1 to 1.9cm. Stage Not stated Histology Infiltrating ductal carcinoma (Including DCIS): 26/33 (78.8%) (21/33) Mixed infiltrating ductal and lobular carcinoma (Including DCIS): 5/33 (15.2%) (3/33) Infiltrating lobular carcinoma: 2/33 (6.1%) Location UOQ: 18/33 (54.5%) UIQ: 7/33 (21.2%) LIQ: 4/33 (12.1%) LOQ: 4/33 (12.1%) Left: 20/33 (60.6%) Right: 13/33 (39.4%) Palpability Nonpalpable: 33/33 (100%) Multifocality/multicentricity Not stated **Axilla characteristics** Clinical axillary status Negative: 33/33 (100%) **Neoadjuvant chemotherapy** Not stated

Study identifier	Procedure	Patient characteristics
Liu, Yeh, Wu, Wang & Ho, 2000a. **Number of patients** 62 **Number of attempted mappings** 62 **Study period** August 1998 to October 1999 **Institution** Departments of Surgery, Nuclear Medicine and Pathology, Taichung Veterans' General Hospital, and National Yan Ming University, Chung Shan Medical and Dental College, Taichung, Taiwan, Republic of China. **Incorporated studies** Hsieh *et al.* 2000 **Inclusion/exclusion criteria** Inclusions: patients with T1 to T2 primary tumours with nonpalpable lymph nodes. Exclusions: multiple lesions, pregnancy and age over 80 years. **Study included for review of...** Localisation data and false negative rates.	**Radiocolloid/dye combination** Radiocolloid only: 62 Dye only: 0 Radiocolloid and dye: 0 **Radiocolloid** Type: technetium-99m labelled in 10 ml sulphur colloid (1mCi or 37 MBq). Dose: mean 1.51±0.45 mCi (range 1-2.35 mCi) for patients with injection on day of surgery; mean 1.32±0.44 mCi (range 0.98-2.46) for patients with injection the day before surgery. Volume 4mL in two aliquots. Colloid size: see filtration below Filtration: initially a nonfiltered (1000 nm) sulphur colloid was used on the first five patients, and then the sulphur colloid was filtered and prepared in a 200-nm size for the remaining patients. If the hot spot was not demonstrated, a 500-nm sulphur colloid was prepared and used. Injection location: one injection subdermally in the area above the tumour, and injections in each of the four directions around the tumour. Injection timing: injection was at least 3 hours before surgery or in the afternoon before the day of surgery, depending on the operating schedule; 24/58 (41.4%) patients had injection on day of surgery (mean time from surgery 4.63±1.54 hours, range 3-7.5 hours); 34/58 (58.6%) had injection the day before surgery (mean time from surgery 18.57±2.06 hours, range 16-33). Massage: not stated Intraoperative probe: Navigator (USSC, Norwalk, CT, USA). **Dye** Type: not applicable Amount: not applicable Injection location: not applicable Injection timing: not applicable Massage: not applicable **Preoperative lymphoscintigraphy** Timing: performed at 15, 30 and 60 minutes. **Surgery** Surgeon details: not stated Anaesthesia: not stated Axillary clearance: all patients underwent a standard Patey axillary lymphadenectomy, from level I to III. Sentinel node definition: the completion of the sentinel node resection was defined as the radioactivity level at the resection bed being undetectable or equal to the background, or remaining at 10% of the original amount. Background was recorded in the liver area when the primary tumour was on the right side and in the spleen area when it was on the left side. Final breast procedure: total or partial mastectomy as clinically indicated. **Histologic analysis of sentinel nodes** Intraoperative analysis: not stated Sectioning: checked by pathological examination, methods not stated. Permanent section: not stated IHC: not stated Micrometastases definition: not stated **Histologic analysis of axillary nodes** Axillary lymph nodes were pathologically examined, method not stated.	*Data on 58 patients with a SN detected. **Age** Mean 49.2 years (range 29 to 79 years)* **Tumour characteristics** Biopsy method Not stated Size Primary tumour diameter*: 1 cm: 4/58 (6.9%) 1 to 2 cm: 22/58 (37.9%) 2 to 3 cm: 19/58 (32.8% 3 to 4 cm: 5/58 (8.6%) 4 to 5 cm: 8/58 (13.8% Stage Not stated Histology* Ductal: 51/58 (87.9%) Lobular: 1/58 (1.7%) DCIS: 6/58 (10.3%) Location* Outer, upper breast: 26/58 (45%) All of the other quadrants also had tumour allocation. Palpability Not stated Multifocality/multicentricity Patients with multiple lesions were excluded from the study. **Axilla characteristics** Clinical axillary status Negative: 58/58 (100%) **Neoadjuvant chemotherapy** Not stated

Study identifier	Procedure	Patient characteristics
Liu, Fan, Tang, Yang, Fu, Zhang & Song, 2000b. **Number of patients** 33 **Number of attempted mappings** 33 **Study period** December 1998 to August 1999 **Institution** Bethune-Laval Oncology Unit, First Teaching Hospital, Norman Bethune University of Medical Sciences, Changchun, China. **Incorporated studies** None **Inclusion/exclusion criteria** Inclusions: patients with breast cancer diagnosed by core biopsy or intraoperative frozen sections. Exclusions: suspected multicentric or distant metastases breast cancer, previous surgical treatment, recurrence, or pregnant. **Study included for review of...** Localisation rates and false negative rates.	**Radiocolloid/dye combination** Radiocolloid only: 0 Dye only: 33 Radiocolloid and dye: 0 **Radiocolloid** Radiocolloid was not used. Type: not applicable Dose: not applicable Colloid size: not applicable Filtration: not applicable Injection location: not applicable Injection timing: not applicable Massage: not applicable Intraoperative probe: not applicable **Dye** Type: Patent Blue V dye (SIGMA); diluted to 1% with distilled, pressure filtered through 0.22 μm millipore filter, underwent high sterilization, stored in 5mL at -4 °C Amount: 1 mL at 4 locations. Injection location: injected at 12, 3, 6 and 9 o'clock positions into the subcutaneous or breast parenchyma at the biopsy site around the region of the tumour. Injection timing: immediately before surgery. Massage: injected area pressed slightly by palm for 10 minutes. **Preoperative lymphoscintigraphy** Timing: not applicable **Surgery** Surgeon details: not stated Anaesthesia: general or peridural anaesthesia. Axillary clearance: not stated Sentinel node definition: blue-stained lymphatic vessels traced, most proximal lymph node(s) of the mass defined as sentinel. Final breast procedure: standard modified radical mastectomy. **Histologic analysis of sentinel nodes** Intraoperative analysis: serial frozen section histological examination Sectioning: routine pathological examination, method of sectioning not stated. Permanent section: not stated IHC: not stated Micrometastases definition: not stated **Histologic analysis of axillary nodes** Routine pathological examination, method not stated.	**Age** Mean 41 years. **Tumour characteristics** Biopsy method Diagnosed by core biopsy or intraoperative frozen sections Size Mean diameter 2.3, range 1.0 to 5.5 cm. Stage Stage I: 5/33 (15.2%) Stage II: 27/33 (81.8%) Stage III: 1/33 (3.0%) Histology Infiltrating ductal: 16/33 (48.5%) Medullary: 3/33 (9.1%) Simple: 5/33 (15.2%) Scirrhous: 2/33 (6.1%) Adenocarcinoma: 3/33 (9.1%) Canceration of intraductal papilloma: 1/33 (3.0%) Infiltrating lobular: 3/33 (9.1%) Location Left: 16/33 (48.5%) Right: 17/33 (51.5%) UOQ: 23/33 (69.7%) LOQ: 3/33 (9.1%) UQ: 4/33 (12.1%) LIQ: 2/33 (6.1%) Medial: 1/33 (3.0%) Palpability Not stated Multifocality/multicentricity Patients with suspected multicentric or distant metastases were excluded. **Axilla characteristics** Clinical axillary status Not stated **Neoadjuvant chemotherapy** Not stated

Study identifier	Procedure	Patient characteristics
Liu, Siziopikou, Gabram & McClatchey, 2000c. **Number of patients** 38 **Number of attempted mappings** 38 **Study period** October 1998 to July 1999 **Institution** Departments of Pathology and Surgery, Loyola University Medical Center and Stritch School of Medicine, Maywood, Illinois, USA. **Incorporated studies** None **Inclusion/exclusion criteria** Inclusions: patients with primary invasive breast carcinoma and clinically negative axilla. Initially selected for the sentinel node protocol under a verification study for participation in the sentinel node trials by the American College of Surgeons. Exclusions: none stated **Study included for review of...** Localisation rates	**Radiocolloid/dye combination** Radiocolloid only: 0 Dye only: 0 Radiocolloid and dye: 38 **Radiocolloid** Type: radionuclide colloid, type not stated. Dose: not stated Colloid size: not stated Filtration: not stated Injection location: not stated Injection timing: not stated Massage: not stated Intraoperative probe: not stated **Dye** Type: Isosulphan blue dye Amount: not stated Injection location: not stated Injection timing: not stated Massage: not stated **Preoperative lymphoscintigraphy** Timing: Not stated **Surgery** Surgeon details: not stated Anaesthesia: not stated Axillary clearance: complete axillary dissection performed. Sentinel node definition: not stated Final breast procedure: Re-excision/lumpectomy: 18/38 (47.4%) Mastectomy: 10/38 (26.3%) Axillary dissection only: 10/38 (26.3%) **Histologic analysis of sentinel nodes** Intraoperative analysis: bisected if >4 mm, frozen section examination. Sectioning: remainder of frozen section and all remnants of sentinel nodes formalin fixed, method of sectioning not stated. Slides for additional H&E and IHC recut together in one setting. Permanent section: H&E; all negative sentinel nodes examined for micrometastases by 3 additional H&E sections. IHC: cytokeratin; AE1/AE3 (Zymed Laboratories Inc, South San Fransisco, CA) used when initial H&E negative. Micrometastases definition: not stated **Histologic analysis of axillary nodes** Not stated	**Age** Mean 59, range 36 to 79 years. Note: this was for the initial 41 patients; only 38 patients had sentinel node biopsy. **Tumour characteristics** Biopsy method Excisional biopsy/lumpectomy: 20/38 (52.6%) Core biopsy: 9/38 (23.7%) Fine needle aspiration: 9/38 (23.7%) Size Not stated Stage Not stated Histology Ductal: 25/38 (65.8%) Lobular: 5/38 (13.2%) Tubular: 4/38 (10.5%) Mixed: 4/38 (10.5%) Location Not stated Palpability Not stated Multifocality/multicentricity Not stated **Axilla characteristics** Clinical axillary status Negative: 38/38 (100%) **Neoadjuvant chemotherapy** Not stated

Study identifier	Procedure	Patient characteristics
Liu, Yang & Chen, 2003. **Number of patients** 38 **Number of attempted mappings** 38 **Study period** January 1999 to June 2002 **Institution** Departments of General Surgery and Pathology, Mackay Memorial Hospital, Taipei, Taiwan, Republic of China. **Incorporated studies** None **Inclusion/exclusion criteria** Inclusion: patients with ductal carcinoma *in situ*, or intraductal carcinoma with microinvasion, diagnosed via core-needle biopsy. Exclusions: patients with nonpalpable lesions detected by mammography or sonography, patients receiving breast-conserving surgery (fear of possible tattooing effect over the skin of the preserved breast). **Study included for review of...** Localisation rates	**Radiocolloid/dye combination** Radiocolloid only: 0 Dye only: 38 Radiocolloid and dye: 0 **Radiocolloid** Radiocolloid was not used. Type: not applicable Dose: not applicable Colloid size: not applicable Filtration: not applicable Injection location: not applicable Injection timing: not applicable Massage: not applicable Intraoperative probe: not applicable **Dye** Type: activated carbon particles (provided by the pharmacy, Taichung Veterans General Hospital, Taiwan). Amount: 0.4 to 0.6cc Injection location: into the breast parenchyma around the primary lesion or the subdermis of the areola. Injection timing: 5 minutes before surgery. Massage: not stated **Preoperative lymphoscintigraphy** Timing: not applicable **Surgery** Surgeon details: not stated Anaesthesia: not stated Axillary clearance: dissection of level I axillary nodes with sampling of level II was performed if the sentinel node was negative, complete axillary clearance was performed if the sentinel node was not localised or if it was positive. Sentinel node definition: black stained nodes. Final breast procedure: modified radical mastectomy **Histologic analysis of sentinel nodes** Intraoperative analysis: frozen section using two H&E sections. Sectioning: paraffin fixed and sectioned at 2mm intervals. Permanent section: H&E IHC: stain of smooth muscle actin and S-100 protien for cases with equivocal stromal invasion seen on H&E slides, cytokeratin staining was not performed. Micrometastases definition: 'micro-invasion' defined as an extension of cancer cells beyond the basement membrane into the stromal tissue with no focus >1.0cm in greatest dimension. **Histologic analysis of axillary nodes** H&E stained sections.	**Age** Not stated **Tumour characteristics** Biopsy method CB: 38/38 (100%) Size Mean 2.08, range 1.2 to 3cm. Stage Stage 1: 10/38 (26.3%) Stage 2: 5/38 (13.2%) Unknown: 23/38 (60.5%) Histology DCIS: 28/38 (73.7%) Intraductal carcinoma with microinvasion: 10/38 (26.3%) Note: this was the initial diagnosis. Location Not stated Palpability Palpable: 38/38 (100%) Multifocality/multicentricity Not stated **Axilla characteristics** Clinical axillary status Not stated **Neoadjuvant chemotherapy** Not stated

Study identifier	Procedure	Patient characteristics
Llatjós, Castellá, Fraile, Rull, Julián, Fusté, Rovira & Fernández-Llamazares, 2002. **Number of patients** 76 (1 male) **Number of attempted mappings** 76 **Study period** May 1999 to June 2000 **Institution** Breast Disease Unit, Departments of Pathology, Nuclear Medicine, General surgery and Gynaecology and Obstetrics, Hospital Universitari Germans Trias i Pujol, Barcelona; Facultat de Medicine UAB, Barcelona, Spain. **Incorporated studies** None **Inclusion/exclusion criteria** Inclusions: breast cancer patients scheduled to undergo primary surgery, recruited from the multidisciplinary Breast Disease Unit of a university hospital within the Barcelona area. Patients had T1 to T2 tumours, clinically negative lymph nodes, and had a successful sentinel lymph node biopsy. Exclusions: none stated. **Study included for review of...** False negative rates	**Radiocolloid/dye combination** Radiocolloid only: 76 Dye only: 0 Radiocolloid and dye: 0 **Radiocolloid** Type: ^{99m}Tc-labelled microcolloidal albumin Dose: 3 to 4 injections of 2ml at 11 MBq per dose. Colloid size: not stated Filtration: not stated Injection location: peritumoural Injection timing: radiocolloid injected 2 to 20 hours before surgery. Massage: not stated Intraoperative probe: 14-mm handheld gamma probe, type not specified. **Dye** Dye was not used. Type: not applicable Amount: not applicable Injection location: not applicable Injection timing: not applicable Massage: not applicable **Preoperative lymphoscintigraphy** Timing: stated preoperative lymphoscintigraphy was always performed to plan sentinel node biopsy in the operating room, precise time not stated. **Surgery** Surgeon details: not stated Timing: 2 to 20 hours after radiocolloid injection. Anaesthesia: not stated Axillary clearance: not stated Sentinel node definition: defined as a lymph node with radioactive counts >10 times background level. Final breast procedure: breast-conserving surgery 60/76 (78.9%); mastectomy 16/76 (21.1%). **Histologic analysis of sentinel nodes** Intraoperative analysis: imprint smears (obtained by scraping the cut surfaces), between 2 and 8 smears prepared depending on the size of the node. Half stained with a rapid variation of the May-Grünwald-Giemsa method. Performed by two experience cytopathologists. The other half kept for delayed staining with the Dako enhanced polymer one-step staining method (EPOS; Dakopatts, Glostrup, Denmark). Sectioning: serial sectioning performed using 2mm slices embedded in paraffin blocks. Multiple sections were cut per block (≥ 30 in a standard 1cm sentinel node). Permanent section: H&E IHC: IHC with MNF-116 (Dakopatts; only metastases that were confirmed with H&E were noted as positive). Micrometastases definition: neoplastic cell clusters within the lymphoid tissue <2mm in greatest dimension. **Histologic analysis of axillary nodes** Not stated	**Age** Mean 57, range 32 to 85 years. **Tumour characteristics** Biopsy method Not stated Size Mean 1.8, range 0.4 to 4.3cm. Stage T1 to T2 tumours. Histology Infiltrating ductal carcinoma: 65/76 (85.5%) Infiltrating lobular carcinoma: 3/76 (3.9%) Tubular carcinoma: 2/76 (2.6%) DCIS: 6/76 (8.9%) Location Not stated Palpability Palpable: 54/76 (71.1%) Nonpalpable: 22/76 (28.9%) Multifocality/multicentricity Not stated **Axilla characteristics** Clinical axillary status Negative: 76/76 (100%) **Neoadjuvant chemotherapy** Not stated

Study identifier	Procedure	Patient characteristics
Lloyd, Wesen & McCallum, 2002. **Number of patients** 107 **Number of attempted mappings** 107 **Study period** Not stated **Institution** Department of Surgery, St.John Hospital and Medical Center, Detroit, Michigan, USA. **Incorporated studies** None **Inclusion/exclusion criteria** Inclusions: patients with breast cancer. Exclusions: none stated **Study included for review of...** Localisation rates	**Radiocolloid/dye combination** Radiocolloid only: 0 Dye only: 0 Radiocolloid and dye: 107 (All patients injected by single person) **Radiocolloid** Type: ^{99m}Tc Dose: 1 mCi in volume 8cm^3: 80/107 (74.8%) 16cm^3: 27/107 (25.2%) Note: 16cm^{3}was used following the National Surgical Adjuvant Breast and Bowel Project (NSABP) protocol. Colloid size: not stated Filtration: Filtered: 27/107 (25.2%) Unfiltered: 80/107 (74.8%) Injection location: injected peritumourally in 4 quadrants. Injection timing: radiocolloid injected 1 to 6 hours before surgery. Massage: not stated Intraoperative probe: not stated Patient Groups I: 27/107 (25.2%) 8cm^3 filtered II: 53/107 (49.5%) 8cm^3 unfiltered III: 27/107 (25.2%) 16cm^3 unfiltered **Dye** Type: Lymphazurin (United States Surgical, Norwalk, CT). Amount: 5cm^3 Injection location: peritumourally in 4 quadrants. Injection timing: dye was injected at the time of surgery. Massage: not stated **Preoperative lymphoscintigraphy** Timing: Not stated **Surgery** Surgeon details: not stated Anaesthesia: not stated Axillary clearance: 94/107 (87.9%) had completion axillary dissection; 12/107 did not according to the NSABP protocol and 1 patient refused. Sentinel node definition: not stated Final breast procedure: not stated **Histologic analysis of sentinel nodes** Intraoperative analysis: not stated Sectioning: not stated Permanent section: not stated IHC: not stated Micrometastases definition: not stated **Histologic analysis of axillary nodes** Not stated	**Age** Not stated **Tumour characteristics** Biopsy method Not stated Size Not stated Stage Not stated Histology Not stated Location UOQ: 59/107 (55.1%) LOQ: 6/107 (5.6%) UIQ: 18/107 (16.8%) LIQ: 11/107 (10.3%) Central: 13/107 (12.1%) Palpability Not stated Multifocality/multicentricity Not stated **Axilla characteristics** Clinical axillary status Not stated **Neoadjuvant chemotherapy** Not stated

Study identifier	Procedure	Patient characteristics
Luini, Gatti, Frasson, Naninato, Magalotti, Arnone, Viale, Pruneri, Galimberti, De Cicco & Veronesi, 2002. **Number of patients** 115 **Number of attempted mappings** 115 **Study period** September 2000 to December 2001 **Institution** Divisions of Senology, Pathology and Nuclear Medicine, European Institute of Oncology, Milan, Italy, and the Pontificia University Cattolica, Rio Grande del Sud, Brazil, South America. **Incorporated studies** None **Inclusion/exclusion criteria** Inclusions: patients with invasive T1/T2-N0 breast cancer, histologically proven, invasive, unifocal breast carcinoma with maximal mammographic/ ultrasonographic diameter of 2.5 cm. No clinical and ultrasonographic evidence of axillary node involvement. Exclusions: none stated **Study included for review of...** Localisation rates	**Radiocolloid/dye combination** Radiocolloid only: 115 Dye only: 0 Radiocolloid and dye: 0 **Radiocolloid** Type: colloidal human albumin particles labelled with ^{99m}Tc. Dose: not stated Colloid size: not stated Filtration: not stated Injection location: not stated Injection timing: the day before surgery, or the same day, a few hours before surgery. Massage: not stated Intraoperative probe: gamma probe (Neoprobe; Ethicon Endosurgery, Cincinnati, OH). **Dye** Dye was not used. Type: Not stated Amount: Not stated Injection location: Not stated Injection timing: Massage: Not stated **Preoperative lymphoscintigraphy** Timing: Not stated **Surgery** Surgeon details: not stated Anaesthesia: intradermal 2 to 5 mL of carbocaine without adrenaline (2% mepivacaine, 4 mg/kg, maximum 400 mg, total 10 to 20 mL) and sodium bicarbonate (1:10). At the end of injection before surgical incision, 0.05mg of intravenous fenanyl given, repeated after 5 minutes in case of pain. In anxious patients, 1 mg of midazolam given. For prolonged surgery, repeated administration of fentanyl and midazolam after 30 minutes. Axillary clearance: complete axillary dissection in 20/115 patients with macrometastatic sentinel nodes, and 21/28 wuth micrometastatic sentinel nodes. Sentinel node definition: detected by the gamma probe, not specifically defined. Final breast procedure: Conservative surgery for breast carcinoma 1 week after SNLB. For negative SLNs breast is treated with quadrantectomy with or without intraoperative radiotherapy, for positive SLNs patient undergoes quadrantectomy and complete axillary dissection with or without intraoperative radiotherapy **Histologic analysis of sentinel nodes** Intraoperative analysis: not performed Sectioning: fixed uncut if <5mm; if 5 to 10 mm thick, bisected along the major axis; >1cm sliced at 3 to 4mm intervals before fixing. Pairs of sections cut at 50 μm intervals until the nodes completely sectioned. Permanent section: one section of each pair routinely stained with H&E. IHC: when needed to assess atypical cells in the H&E section, MNF116 monoclonal antibody (Daok, Glostrub, Denmark)IHC analysis performed. Micrometastases definition: metastatic foci < 2 mm on greatest dimension. **Histologic analysis of axillary nodes** Not stated	**Age** Mean 54, range 27 to 77 years. **Tumour characteristics** Biopsy method Not stated Size Maximum diameter 2.5 cm Mean primary tumour diameter 1.44, range 0.2 to 4.5, median 1.4 cm. Stage T1/T2 Histology Infiltrating ductal: 79/115 (68.7%) Infiltrating lobular: 13/115 (11.3%) Other: 21/115 (18.3%) Non-infiltrating: 2/115 (1.7%) Note: 1 patient had a non-Hodgkin lymphoma. Location Not stated Palpability Palpable breast tumour Multifocality/multicentricity All tumours were unifocal. **Axilla characteristics** Clinical axillary status N0: 115/115 (100%) **Neoadjuvant chemotherapy** Not stated

Study identifier	Procedure	Patient characteristics
Macmillan, Barbera, Hadjiminas, Rampaul, Lee, Pinder, Ellis, Blamey and Geraghty, 2001. **Number of patients** 200 (consecutive) **Number of attempted mappings** 200 **Study period** January 1998 to October 1999 **Institution** The Breast Unit, Nottingham City Hospital, Nottingham, UK. **Incorporated studies** None **Inclusion/exclusion criteria** Inclusions: patients undergoing surgery (mastectomy or wide local excision) for primary invasive breast cancer. All were clinically node negative (T1-2, N0, M0) and had a preoperative diagnosis of invasive breast cancer confirmed by core biopsy or fine needle cytology. Exclusions: none stated **Study included for review of...** Localisation rates	**Radiocolloid/dye combination** Radiocolloid only: 200 Dye only: 0 Radiocolloid and dye: 0 **Radiocolloid** Type: ^{99m} -Tc-labelled colloid (Nanocoll, Amersham Healthcare Ltd, Buckinghamshire, UK) Dose: 27 MBq in 0.3 mL Colloid size: not stated Filtration: not stated Injection location: injection was adjacent to the tumour. Injection timing: median 3 hours, range 20 minutes to 18 hours, before surgery. Massage: not stated Intraoperative probe: c-Trak (Care Wise Medical, CA, USA). **Dye** Dye was not used Type: not applicable Amount: not applicable Injection location: not applicable Injection timing: not applicable Massage: not applicable **Preoperative lymphoscintigraphy** Timing: performed to confirm sentinel node location for first 15 patients. Discontinued as felt to be an unnecessary procedure. Timing not stated. **Surgery** Surgeon details: not stated Anaesthesia: not stated Axillary clearance: four nodes routinely taken, plus internal mammary node biopsy in medial cancers. Level III axillary clearance later performed if patient undergoing further breast surgery. Sentinel node definition: routine four node sampling was performed, then a search made to find a node with a higher count or an additional sentinel node *in vivo*. Sentinel nodes were the 'hottest' node, and any nodes at least 25% as 'hot' with at least 25 counts per 10 second. Final breast procedure: mastectomy or wide local excision. **Histologic analysis of sentinel nodes** Intraoperative analysis: Not stated Sectioning: 3 to 5 mm intervals Permanent section: Each lymph node sliced after fixation at 3 to 5 mm intervals perpendicular to the long axis. All slices were embedded in one or more paraffin blocks and examined by routine H&E stained sections. IHC: Not stated Micrometastases definition: Not stated **Histologic analysis of axillary nodes** Not stated.	**Age** Not stated **Tumour characteristics** Biopsy method Core biopsy or fine needle cytology. Size Not stated Stage T1-2 Histology Not stated Location Not stated Palpability Not stated Multifocality/multicentricity M0: 200/200 (100%) **Axilla characteristics** Clinical axillary status N0: 200/200 (100%) **Neoadjuvant chemotherapy** Not stated

Study identifier	Procedure	Patient characteristics
Mahajna, Hershko, Israelit, Abu-Salih, Keidar & Krausz, 2003. **Number of patients** 100 (consecutive) **Number of attempted mappings** 100 **Study period** December 1998 to December 2001 **Institution** Departments of Surgery A and Nuclear Medicine, Rabam Medical Center, Haifa, Israel (affiliated with Technion Faculty of Medicine, Haifa, Israel). **Incorporated studies** None **Inclusion/exclusion criteria** Inclusions: consecutive patients with early invasive breast cancer, clinical stages T1-T2, N0, M0. Exclusions: patients with clinical evidence of axillary metastases, previous axillary lymphadenectomy, locally advanced disease, ductal carcinoma *in situ*, or pregnant or lactating women. **Study included for review of...** Localisation rates and false negative rates	**Radiocolloid/dye combination** Radiocolloid only: 0 Dye only: 0 Radiocolloid and dye: 100 **Radiocolloid** Type: ^{99m}Tc-labelled rhenium colloid Dose: 400μCi Colloid size: not stated Filtration: not stated Injection location: peritumoural into the breast tissue. Injection timing: injected 4 to 24 hours before surgery; initially injected 16 to 24 hours before surgery, but later 4 hours before surgery. Massage: not stated Intraoperative probe: handheld gamma camera, type not stated. **Dye** Type: 2.5% Isofulfan blue dye (Patent blue, Guerbet, France). Amount: 2ml Injection location: intradermally into the breast surrounding the tumour or biopsy site. Injection timing: dye was injected 5 to 10 minutes before surgery. Massage: not stated **Preoperative lymphoscintigraphy** Timing: 5, 10, 20, 60 and 120 minutes after radiocolloid injection. **Surgery** Surgeon details: performed by 5 surgical residents at different stages of residency, under the supervision of senior attending surgeons. Anaesthesia: not stated Axillary clearance: formal lymphadenectomy including levels I and II. Sentinel node definition: blue stained lymph nodes or localised radioactive sites separate from the injection site with at least 25 counts per 10 seconds. Lymph node counts all performed *ex vivo*. Final breast procedure: conservative breast surgery 82/100 (82%); modified radical mastectomy 18/100 (18%). **Histologic analysis of sentinel nodes** Intraoperative analysis: not stated Sectioning: paraffin sections, at least six serial sections. Permanent section: H&E IHC: one section (usually level III) was stained for anticytokeratin using a cocktail of low and high molecular weight monoclonal antibodies. Micrometastases definition: not stated **Histologic analysis of axillary nodes** Sectioned 2 or 3 times and stained with H&E.	**Age** Mean 51, range 41 to 83 years. **Tumour characteristics** Biopsy method Open biopsy of palpable lesions: 47/100 (47%) Open biopsy of needle localised lesions: 12/100 (12%) Fine needle aspiration: 41/100 (41%) Size ≤ 2cm: 71/100 (71%) 2 to 4cm: 29/100 (29%) Stage T1: 71/100 (71%) T2: 29/100 (29%) Histology Invasive ductal carcinoma: 82/100 (82%) Invasive lobular carcinoma: 8/100 (8%) Invasive tubular carcinoma: 4/100 (4%) Combined invasive tubuloductal carcinoma: 4/100 (4%) Invasive mucinous carcinoma: 2/100 (2%) Location Not stated Palpability Not stated Multifocality/multicentricity M0: 100/100 (100%) **Axilla characteristics** Clinical axillary status N0: 100/100 (100%) **Neoadjuvant chemotherapy** Not stated

Study identifier	Procedure	Patient characteristics
Mann, Buchanan, Collins & Lichtenstein, 2000. **Number of patients** 62 (1 male) **Number of attempted mappings** 62 **Study period** May 1998 and February 2000 **Institution** Departments of Surgery, Pathology and Radiology, Royal Melbourne Hospital, University of Melbourne, Parkville, Victoria, Australia. **Incorporated studies** None **Inclusion/exclusion criteria** Inclusions: patients with localised breast cancer. Initially only palpable tumours included, but after the first five cases impalpable tumour were also considered if tumour visible on ultrasound. Exclusions: patients with clinically involved lymph nodes were excluded (those with clinically equivocal lymph nodes were included). **Study included for review of...** Localisation rates	**Radiocolloid/dye combination** Radiocolloid only: 1 (due to unavailability of dye) Dye only: 7 (logistic reasons) Radiocolloid and dye: 54 **Radiocolloid** Type: ^{99m}Tc-labelled antimony Dose: 7MBq in 4 x 0.5ml aliquots. Colloid size: not stated Filtration: not stated Injection location: four injections around the tumour or biopsy cavity. In cases where the tumour was nonpalpable but visible using ultrasound, radiocolloid was injected using ultrasound guidance and a localising hookwire. Injection timing: between 1 and 20 hours before surgery. Massage: Intraoperative probe: Navigator (Autosuture, USSC, Norwalk, CT, USA). **Dye** Type: Patent blue V dye Amount: 2ml Injection location: dye injected peritumourally in four aliquots around the tumour, or for nonpalpable lesions, the mammogram and the hookwire were used as a guide. Injection timing: dissection started a minimum of 5 minutes after dye injection. Massage: the breast was gently massaged. **Preoperative lymphoscintigraphy** Timing: performed where logistically possible (47/55 of patients who had radiocolloid injection) at 30 and 90 minutes after radiocolloid injection. **Surgery** Surgeon details: not stated Anaesthesia: "induction of anaesthesia" Axillary clearance: in most cases, a full axillary dissection was performed but in two cases the patient refused full dissection. Recommended in patients with a clinically and radiologically malignant breast lump if fine needle aspiration revealed malignant cells. Sentinel node definition: blue and/or hot.. If the axillary count was >10% the excised node further nodes were sought. Final breast procedure: not stated **Histologic analysis of sentinel nodes** Intraoperative analysis: frozen section was not used. Sectioning: each sentinel node was bisected, fixed in formalin and paraffin embedded. Method of sectioning not stated. Permanent section: H&E IHC: if H&E was negative, a single slide was examined with a polyclonal anticytokeratin antibody (AE1/AE3; Dako. Carpentaria, CA, USA). Micrometastases definition: not stated **Histologic analysis of axillary nodes** Not stated	**Age** Median 60, range 28 to 85 years. **Tumour characteristics** Biopsy method Fine needle aspiration: 41/62 (66.1%) Core biopsy: 5/62 (8.1%) Surgical biopsy: 16/62 (25.8%) Size Not stated Stage T1a: 4/51 (7.8%) T1b: 13/51 (25.5%) T1c: 21/51 (41.2%) T2: 13/51 (25.5%) (Patients that were successfully localised, n=51) Histology Infiltrating ductal carcinoma: 32/62 (51.6%) Infiltratin lobular carcinoma: 4/62 (6.5%) Other: 2/62 (3.2%) Unknown: 24/62 (38.7%) Location Not stated Palpability Palpable and nonpalpable tumours were included. Multifocality/multicentricity Not stated **Axilla characteristics** Clinical axillary status Negative: 62/62 (100%) Note: patients with clinically equivocal lymph nodes were included. **Neoadjuvant chemotherapy** Not stated

Study identifier	Procedure	Patient characteristics
Mariotti, Buonomo, Guadagni, Spila, Schiaroli, Cipriani, Simonetti, Felici, Granai, Bellotti, Cabassi, Casciani and Roselli, 2002. **Number of patients** 45 (76 enrolled, 45 invasive carcinomas). **Number of attempted mappings** 45 **Study period** Not stated **Institution** Division of Medical Oncology, Division of Clinical Surgery, Department of Surgery and Division of Clinical Radiology University of Rome "Tor Vergata"; Regina Elena Cancer Institute, Rome; Division of Clinical Pathology, University of Rome "Tor Vergata"; Nuclear Medicine Service, St Eugenio Hospital, Rome; Department of Surgery, St Eugenio Hospital, Rome, Italy. **Incorporated studies** Buonomo *et al.* 2001 **Inclusion/exclusion criteria** Inclusions: women with palpable or non-palpable small (=2 cm) breast lesions documented by mammography and/or ultrasonography and no clinically palpable lymph nodes. Exclusions: none stated **Study included for review of...** Localisation rates and false negative rates	**Radiocolloid/dye combination** Radiocolloid only: 45 Dye only: 0 Radiocolloid and dye: 0 **Radiocolloid** Type: Nanocoll (Amersham Sorin, Saluggia-TO, Italy) Dose: 0.8 mCi; 0.1 ml in two injections. Colloid size: not stated Filtration: not stated Injection location: intralesional and perilesional administration. Injection timing: radiotracer was injected the day before surgery. Massage: not stated Intraoperative probe: Neoprobe 1000 (Columbus, Ohio, USA). **Dye** Dye was not used. Type: not applicable Amount: not applicable Injection location: not applicable Injection timing: not applicable Massage: not applicable **Preoperative lymphoscintigraphy** Timing: lymphoscintigraphy was carried out 30, 60 and 180 minutes after radiotracer administration. **Surgery** Surgeon details: not stated Anaesthesia: nervous block of the ipsilateral intercostal nerves with Ribovacaine. Axillary clearance: when the frozen section was positive the remaining axillary nodes were removed; when negative the surgical plan was stopped. Sentinel node definition: not stated Final breast procedure: when frozen section revealed invasive carcinoma the SN and the non-SNs were removed and a quadranectomy performed under regional anaesthesia. (From Buonomo *et al.* 2001 – 21/63 (33.3%) lumpectomy; 42/63 (66.7%) quadranectomy). **Histologic analysis of sentinel nodes** Intraoperative analysis: frozen section Sectioning: histological assessment, method of sectioning not stated. Permanent section: H&E IHC: not stated Micrometastases definition: not stated **Histologic analysis of axillary nodes** Non-sentinel nodes were submitted for histological assessment.	**Age** Mean 54, range 34 to 76 years. Note: this is for total 76 patients. **Tumour characteristics** Biopsy method Not stated Size Not stated Stage T1a: 2/45 (4.4%) T1b: 11/45 (24.4%) T1c: 32/45 (71.1%) Note: infiltrating carcinomas only. Histology Infiltrating carcinoma: 45/76 (59.2%) DCIS: 24/76 (31.6%) Fibroadenomas: 7/76 (9.2%) Location Not stated Palpability Patients with palpable and non-palpable breast lesions were enrolled in the study. (From Buonomo *et al.* 2001 – 37/63 (58.7%) palpable; 26/63 (41.3%) not palpable) Multifocality/multicentricity Not stated **Axilla characteristics** Clinical axillary status Negative: 76/76 (100%) **Neoadjuvant chemotherapy** Not stated

Study identifier	Procedure	Patient characteristics
Mateos, Vidal-Sicart, Zanón, Pahisa, Fuster, Martín, Ortega, Fernández & Pons, 2001. **Number of patients** 80 **Number of attempted mappings** 80 **Study period** Not stated **Institution** Nuclear Medicine, Gynaecology and Histology Departments of the Hospital Clinic de Barcelona, Spain. **Incorporated studies** None **Inclusion/exclusion criteria** Inclusions: patients with breast cancer, previously diagnosed by mammography and fine needle aspirate biopsy. Non-palpable tumours included in peritumoural group, palpable tumours alternately included into subdermal or peritumoural group. Exclusions: none stated **Study included for review of...** Localisation rates and false negative rates	**Radiocolloid/dye combination** Radiocolloid only: 15 Dye only: 0 Radiocolloid and dye: 65 (31 in Group A and 34 in Group B; 15 patients refused dye because of possible tattoo). **Radiocolloid** Type: ^{99m}Tc -nanocolloid (Lymphoscint, Nycomed Amersham-Sorin, Saluggia, Italy). Dose: 74 to 111 MBq Colloid size: mean 50 nm Filtration: not stated Injection location: Group A (subdermal): 4 injections of 0.1 mL administered subdermally surrounding tumour site (36/80) Group B (peritumoural): 1 injection of 3 mL administered peritumourally. Patients with non-palpable tumours injected with ultrasound guidance. (44/80) Injection timing: radiocolloid was injected the day before surgery. Massage: not stated Intraoperative probe: handheld gamma probe (Navigator, USSC, Norwalk, USA). **Dye** Type: Blue dye Amount: not stated Injection location: Similarly to radiocolloid Group A: 31/36 (86.1%) Group B: 34/44 (77.3%) Injection timing: dye was injected before surgical incision. Massage: not stated **Preoperative lymphoscintigraphy** Timing: in Group A images were taken immediately after injection; in Group B images were taken from 15 minutes after injection until identification of the sentinel node. **Surgery** Surgeon details: not stated Anaesthesia: not stated Axillary clearance: complete axillary dissection, including the third Berg's level. Sentinel node definition: not stated Final breast procedure: not stated **Histologic analysis of sentinel nodes** Intraoperative analysis: not stated Sectioning: step H&E sections through the tissue blocks at 250 μm intervals. Permanent section: H&E IHC: not stated Micrometastases definition: not stated **Histologic analysis of axillary nodes** All axillary nodes examined using H&E making step H&E sections through tissue blocks at 250 μm interval.	**Age** Mean 56, range 23 to 79 years. **Tumour characteristics** Biopsy method Fine needle aspirate biopsy. Size Mean 1.86, range 0.5 to 5 cm. Group A: Mean 1.77, SD 1.08 cm Group B: Mean 1.94, SD 0.95 cm Stage T1: 34/80 (42.5%) T2: 46/80 (57.5%) Group A: T1: 16/36 (44.4%) T2: 20/36 (55.6%) Grade I: 11/36 (30.6%) Grade II: 11/36 (30.6%) Grade III: 14/36 (38.9%) Note: Bloom Richardson grade Group B: T1: 18/44 (40.9%) T2: 26/44 (59.1%) Grade I: 15/44 (34.1%) Grade II: 16/44 (36.4%) Grade III: 13/44 (29.5%) Note: Bloom Richardson grade Histology Group A: Infiltrating ductal: 29/36 (80.6%) Intraductal: 5/36 (13.9%) Lobular: 2/36 (5.6%) Group B: Infiltrating ductal: 36/44 (81.8%) Intraductal: 2/44 (4.5%) Lobular: 4/44 (9.1%) Medullar: 2/44 (4.5%) Location Right: 35/80 (43.8%) Left: 45/80 (56.3%) Right UOQ: 20/80 (25.0%) Right UIQ: 5/80 (6.3%) Right LOQ: 8/80 (10%) Right LIQ: 2/80 (2.5%) Left UOQ: 25/80 (31.25%) Left UIQ: 7/80 (8.8%) Left LOQ: 8/80 (10.0%) Left LIQ: 5/80 (6.3%) Palpability Palpable: 67/80 (83.8%) Nonpalpable: 13/80 (16.3%) Multifocality/multicentricity Not stated **Axilla characteristics** Clinical axillary status Not stated **Neoadjuvant chemotherapy** Not stated

Study identifier	Procedure	Patient characteristics
McIntosh, Ravichandran, Balan, Bobrow, Wishart & Purushotham, 2001. **Number of patients** 27 **Number of attempted mappings** 27 **Study period** October 1998 to October 1999 **Institution** Departments of Surgery, Nuclear Medicine and Pathology, Addenbrooke's Hospital, Cambridge, UK. **Incorporated studies** None **Inclusion/exclusion criteria** Inclusions: impalpable breast lesion histologically proven to be invasive carcinoma. Patients were part of a larger study evaluating a combined technique of sentinel node biopsy in tumours <30mm in diameter. Exclusions: none stated **Study included for review of...** False negative rates	**Radiocolloid/dye combination** Radiocolloid only: 0 Dye only: 0 Radiocolloid and dye: 27 **Radiocolloid** Type: ^{99m}Tc -labelled nanocolloid (Nanocoll, Sorin Biomedica, Vercelli, Italy). Dose: 40 MBq Colloid size: not stated Filtration: not stated Injection location: injection peritumourally down localization needle. Injection timing: not stated Massage: not stated Intraoperative probe: handheld gamma detection probe (C-Trak, Care-Wise Medical Products, Morgan Hill, California). **Dye** Type: Patent blue-V dye (Laboratoire Guerbet, Aulney-Sous-Bois, France). Amount: 2 mL of 2.5%, diluted to 5 mL in 0.9% NaCl. Injection location: around tip of localization wire. Injection timing: dye was injected after induction of anaesthesia, before axillary incision. Massage: for 5 minutes after dye injection. **Preoperative lymphoscintigraphy** Timing: where practical, 2 hours following isotope injection (operating surgeon blinded to result). **Surgery** Surgeon details: not stated Anaesthesia: not stated Axillary clearance: a standard level 2 axillary clearance. Sentinel node definition: 'hot' and/or blue. Final breast procedure: the primary tumour was excised widely. **Histologic analysis of sentinel nodes** Intraoperative analysis: not stated Sectioning: routine staining was performed, the method of sectioning not stated. Permanent section: H&E IHC: not stated Micrometastases definition: not stated **Histologic analysis of axillary nodes** Routine H&E staining of all retrieved lymph nodes.	**Age** Not stated **Tumour characteristics** Biopsy method Not stated Size Mean 12.2 mm Stage Not stated Histology Not stated Location Not stated Palpability Nonpalpable: 27/27 (100%) Multifocality/multicentricity Not stated **Axilla characteristics** Clinical axillary status Not stated **Neoadjuvant chemotherapy** Not stated

Study identifier	Procedure	Patient characteristics
Meyer-Rochow, Martin & Harman, 2003. **Number of patients** 104 Patent blue (PB) group: n=63 Triple modality (TM)group: n=41 Note: patient randomisation to the TM group depended on availability of lymphoscintigraphy, which was limited to 1 day per week. **Number of attempted mappings** 104 **Study period** December 1998 to December 2001 **Institution** Department of General Surgery, Waitemata Health, Northshore Hospital, Auckland, New Zealand. **Incorporated studies** None **Inclusion/exclusion criteria** Inclusions: patients with palpable breast lump confirmed to be malignant by radiology and cytology and a clinical diagnosis of stage I or stage II breast cancer. Exclusions: patients without palpable breast lump, or radiological or clinical evidence of multifocal tumours or extranodal spread. Pregnancy, previous axillary nodal or breast cancer surgery, or patients unfit for surgery were other exclusions. **Study included for review of...** Localisation rates and false negative rates	**Radiocolloid/dye combination** Radiocolloid only: 0 Dye only: 63 (PB group) Radiocolloid and dye: 41 (TM group) **Radiocolloid** Type: ^{99m}Tc -antimony sulphur colloid. Dose: 40 Mbq Colloid size: not stated Filtration: not stated Injection location: radiocolloid was injected around the tumour. Injection timing: day prior to surgery. Massage: not stated Intraoperative probe: Navigator Probe (Tyco Healthcare, Pembroke, Bermuda). **Dye** Type: Patent Blue V 2.5% (Rhone-Poulenc Rorer Pharmaceuticals, Collegeville, PA, US) Amount: 2 mL Injection location: dye was injected eritumourally. Injection timing: dye was injected once the patient was anaesthetised. Massage: after injection the area was gently massaged. **Preoperative lymphoscintigraphy** Timing: the day of radiocolloid, or the day before surgery. **Surgery** Surgeon details: surgery performed by 3 surgeons who were experienced in the technique. Anaesthesia: not stated Axillary clearance: level II axillary node dissection. Sentinel node definition: not stated Final breast procedure: not stated **Histologic analysis of sentinel nodes** Intraoperative analysis: not stated Sectioning: histopathological assessment was performed, the method of sectioning was not stated. Permanent section: not stated IHC: not stated Micrometastases definition: not stated **Histologic analysis of axillary nodes** Axillary nodes were sent separately for histopathological assessment.	**Age** PB: Mean 59 years TM: Mean 57 years **Tumour characteristics** Biopsy method Fine needle aspiration or core biopsy. Size PB: Mean 22.9 mm TM: Mean 23.6 mm Stage Stage I or II Histology Not stated Location Not stated Palpability Palpable inclusion criteria Multifocality/multicentricity Multifocal Total: 7/104 (6.7%) PB: 1/63 (1.6%) TM: 6/41 (14.6%) Note: this is from operative histopathology results. **Axilla characteristics** Clinical axillary status It was stated patients with clinical evidence of multifocal tumours were excluded, so they were unlikely to have positive axillary nodes. **Neoadjuvant chemotherapy** Not stated

Study identifier	Procedure	Patient characteristics
Miller, Thomason, Yeh, Alrahwan, Sharkey, Stauffer, Otto, McKay, Kahlenberg, Phillips & Cruz, 2002. **Number of patients** 35 **Number of attempted mappings** 35 **Study period** January 1997 to June 2000 **Institution** Divisions of Surgery, Pathology and Radiology, University of Texas Health Science Center at San Antonio, Texas, USA. **Incorporated studies** None **Inclusion/ exclusion criteria** Inclusions: patients with preoperative chemotherapy, unifocal tumours and clinically negative axillae. Exclusions: none stated **Study included for review of...** Localisation rates and false negative rates	**Radiocolloid/dye combination** Radiocolloid only: 1 Dye only: 15 Radiocolloid and dye: 19 **Radiocolloid** Type: ^{99m}Tc sulphur colloid Dose: 2 mL, 0.250 mCi per quadrant. Colloid size: not stated Filtration: unfiltered Injection location: palpable tumours had 4-quadrant intraparenchymal injection adjacent the tumour. Nonpalpable tumour intraparenchymally injected in 4-quadrants after radiologically guided needle localisation. Injection timing: injected 2 to 6 hours before the sentinel nodes were mapped using a handheld gamma probe. Massage: not stated Intraoperative probe: Navigator ™ (US Surgical) and C trak ™ Care Wise, Morgan Hill, CA). **Dye** Type: Lymphazurin Amount: 3 to 5 mL Injection location: palpable tumours injected in 4-quadrants intra-parenchymally round tumour. Nonpalpable tumours injected in 4-quadrants round needle localisation wire, no extra radiological guidance. Injection timing: 5 minutes before the axillary incision. Massage: not stated **Preoperative lymphoscintigraphy** Timing: Not stated **Surgery** Surgeon details: not stated Anaesthesia: not stated Axillary clearance: axillary lymph node dissection. Sentinel node definition: a blue node or blue lymphatics draining from a lymph node, or gamma counts > 3x background within the node. Final breast procedure: 10/35 (28.6%) mastectomy, 25/35 (71.4%) breast conserving surgery. **Histologic analysis of sentinel nodes** Intraoperative analysis: for frozen section (n=7) one half of the lymph node was embedded in OCT and Tissue-Tek (Sakura, Torrance, CA). Quick freezing was performed with Histobath II (Shandon Lipshaw, Pittsburgh, PA), and frozen sections (4 μm thick) stained with H&E. For cytological analysis (n=14) preps were made of the cut nodal surface on glass slides using touch preparation technique or scraping. Slides were air dried and stained with Diff-Quik (Dade Behring, Deerfield, IL), alcohol fixed and stained by H&E, or both. Three patients had both frozen section and cytological analysis. Specimens sent for immediate pathological review in 24/35 cases, final review only in 6 cases (an experienced pathologist was unavailable or there was a miscommunication with operating room personnel). Method of intraoperative analysis determined by pathologist preference. Sectioning: all remaining sentinel node tissue fixed in formalin and processed in paraffin blocks. Nodes serially sectioned at 2 mm intervals if ≥ 4 mm and bisected if <4 mm. 1 to 6 blocks were examined in each patient, ie. 1 to 5 sentinel nodes. Permanent section: H&E (1 initial, if negative another 2 levels). IHC: if initial H&E section was negative IHC stain for keratin (AE1) performed. 19 cases were also examined by keratin AE3 antibody. Micrometastases definition: not stated **Histologic analysis of axillary nodes** Not stated.	**Age** Not stated **Tumour characteristics** Biopsy method Not stated Size Median 3.5, range 0.8 to 10 cm before chemotherapy. Median 1.1, range 0 to 3.5 cm at time of surgery Stage Not stated Histology Not stated Location Not stated Palpability Not stated Multifocality/multicentricity Unifocal **Axilla characteristics** Clinical axillary status Negative: 35/35 (100%) **Neoadjuvant chemotherapy** 31/35 as part of National Surgical Adjuvant Breast and Bowel Project B-27: 4 cycles of doxorubicin and cyclophosphamide (n=25), alone or followed by 4 doses of docetaxel (n=6). 4/35 off protocol: 4 cycles of doxorubicin before surgery Patients were treated with a median of 4.6, range 3 to 8, cycles of chemotherapy.

Study identifier	Procedure	Patient characteristics
Minato, Hirose, Sasa, Nishitani, Hori & Morimoto, 2003. **Number of patients** 35 (consecutive) **Number of attempted mappings** 35 **Study period** June 2002 to November 2002 **Institution** Department of Radiology, National Higashi-Tokushima Hospital, Ohmukai-kita, Ootera, Itano, Tokushima; Department of Surgery, Tokushima Breast Care Clinic, Nakashimada-Cho, Tokushima; Department of Radiology, School of Medicine and School of Health Sciences, University of Tokushima, Kuramoto-Cho, Tokushima, Japan. **Incorporated studies** None **Inclusion/exclusion criteria** Inclusions: patients with T1 or T2 breast cancer without clinical lymph node metastasis. Exclusions: none stated **Study included for review of...** Localisation rates	**Radiocolloid/dye combination** Radiocolloid only: 0 Dye only: 0 Radiocolloid and dye: 35 **Radiocolloid** Type: ^{99m}Tc-labelled phytate Dose: about 4mCi Colloid size: not stated Filtration: not stated Injection location: injected subdermally around and above the tumour or the scar of lumpectomy. Injection timing: not stated Massage: not stated Intraoperative probe: not used **Dye** Type: indigocarmine Amount: 3 to 5ml Injection location: injected subdermally around and above the tumour or the scar of lumpectomy. Injection timing: 20 minutes before surgery. Massage: not stated **Preoperative lymphoscintigraphy** Timing: not stated but lymphoscintigraphy was performed at a different institution (university hospital) compared to the surgery. **Surgery** Surgeon details: not stated Anaesthesia: not stated Axillary clearance: not stated Sentinel node definition: blue stained and identified by a combination of lymphoscintigraphy and CT scanning. Final breast procedure: not stated **Histologic analysis of sentinel nodes** Intraoperative analysis: not stated Sectioning: not stated Permanent section: not stated IHC: not stated Micrometastases definition: not stated **Histologic analysis of axillary nodes** Not stated	**Age** Mean 54.5 ± 14.5(SD), range 40 to 69 years. 40 to 49 years: 11/35 (31.4%) 50 to 59 years: 13/35 (37.1%) 60 to 69 years: 11/35 (31.4%) **Tumour characteristics** Biopsy method Some tumours were biosied via lumpectomy. Size ≤2cm: 33/35 (94.3%) >2cm but ≤ 5cm: 2/35 (5.7%) Stage T1: 33/35 (94.3%) T2: 2/35 (5.7%) Histology Not stated Location Not stated Palpability Not stated Multifocality/multicentricity Not stated **Axilla characteristics** Clinical axillary status Negative: 35/35 (100%) **Neoadjuvant chemotherapy** Not stated

Study identifier	Procedure	Patient characteristics
Miner, Shriver, Jaques, Maniscalco-Theberge & Krag, 1998. **Number of patients** 42 **Number of attempted mappings** 42 **Study period** April 1996 to June 1997 **Institution** General Surgery Service, Walter Reed Army Medical Center, Washington DC; The Vermont Cancer Center, Bulington, Vermont, USA. **Incorporated studies** None **Inclusion/exclusion criteria** Inclusions: nonpregnant patients with recently diagnosed biopsy-proven breast cancer. No patient was excluded on the basis of biopsy type or whether the patient had a palpable lesion at the time of the procedure. Exclusions: patients with multicentric breast cancer or noninvasive breast cancer. **Study included for review of...** False negative rates	**Radiocolloid/dye combination** Radiocolloid only: 42 Dye only: 0 Radiocolloid and dye: 0 **Radiocolloid** Type: ^{99m}Tc-labelled sulphur colloid (prepared in the Department of Nuclear Medicine). Dose: 1mCi in 4.0ml saline Colloid size: not stated Filtration: unfiltered Injection location: injected around the perimeter of the breast lesion or biopsy site using the LAD technique, which emphasizes tumour location (L), angle (A) and depth (D). Ultrasound was used to define the location of the lesion or prior biopsy cavity. Injection timing: between 1 and 9 hours (median 3.5 hours) before surgery. Massage: not stated Intraoperative probe: C-Trak® (Care Wise Medical Products, Morgan Hill, CA, USA). **Dye** Dye was not used. Type: not applicable Amount: not applicable Injection location: not applicable Injection timing: not applicable Massage: not applicable **Preoperative lymphoscintigraphy** Timing: not stated. **Surgery** Surgeon details: one surgeon performed all radiocolloid injections. Anaesthesia: not stated Axillary clearance: all patients had a complete axillary lymph node dissection (level I, II and III). Sentinel node definition: hot-spots, areas having greater than 25 counts per 10 seconds and a target to background ratio of greater than 3:1. Final breast procedure: lumpectomy 21/42 (50.0%); total mastectomy 15/42 (35.7%); axillary clearance only (adequate control of lesion at time of biopsy) 6/42 (14.3%). **Histologic analysis of sentinel nodes** Intraoperative analysis: not stated Sectioning: all nodes fixed in formalin and routinely processed, the method of sectioning was not stated. Permanent section: H&E IHC: not stated Micrometastases definition: not stated **Histologic analysis of axillary nodes** Not stated	**Age** Mean 55.5 ± 1.7(SD), median 58.3 years. **Tumour characteristics** Biopsy method Excisional biopsy: 53% Fine needle aspiration or core biopsy: 26% Incisional biopsy: 21% Size Mean 1.83 ± 0.25cm (SD). Stage Not stated Histology Infiltrating ductal carcinoma: 92% Infiltrating lobular carcinoma: 8% Location UOQ: 20/42 (47.6%) UIQ: 5/42 (11.9%) LOQ: 5/42 (11.9%) LIQ: 1/42 (2.4%) Upper central: 4/42 (9.5%) Lower central: 2/42 4.8%) Outer central: 4/42 (9.5%) Inner central: 1/42 (2.4%) Palpability Palpable and nonpalpable Multifocality/multicentricity Multicentric: 0/42 (0%) **Axilla characteristics** Clinical axillary status Not stated **Neoadjuvant chemotherapy** Not stated

Study identifier	Procedure	Patient characteristics
Miner, Shriver, Jaques, Maniscalco-Theberge & Krag, 1999. **Number of patients** 82 (1 male) **Number of attempted mappings** 82 **Study period** April 1996 to December 1998 **Institution** General Surgery Service, Walter Reed Army Medical Center, Washington DC; The Vermont Cancer Center, Burlington, Vermont, USA. **Incorporated studies** None **Inclusion/exclusion criteria** Inclusions: nonpregnant patients with biopsy-proven breast cancer. No patient was excluded on the basis of biopsy type or whether the patient had a palpable lesion at the time of the procedure. Exclusions: patients with multicentric breast cancer or noninvasive breast cancer. **Study included for review of...** Localisation rates	**Radiocolloid/dye combination** Radiocolloid only: 82 Dye only: 0 Radiocolloid and dye: 0 **Radiocolloid** Type: ^{99m}Tc-labelled sulphur colloid Dose: 1mCi in 4.0ml saline. Colloid size: not stated Filtration: unfiltered Injection location: injected around the perimeter of the breast lesion, nonpalpable masses or prior biopsy sites were injected using ultrasound guidance. Injection timing: radiocolloid was injected before the patient was taken to the operating room. Massage: not stated Intraoperative probe: C-Trak® (Care Wise Medical Products, Morgan Hill, CA, USA). **Dye** Dye was not used. Type: not applicable Amount: not applicable Injection location: not applicable Injection timing: not applicable Massage: not applicable **Preoperative lymphoscintigraphy** Timing: Not stated. **Surgery** Surgeon details: not stated Anaesthesia: not stated Axillary clearance: first 57/82 received a complete axillary lymph node dissection. Subsequent patients offered sentinel node biopsy with/ without full axillary dissection. Not offered sentinel node biopsy alone if they had lesions > 3cm or palpable axillary nodes. Patients who having metastatic disease in the sentinel node had a completion axillary dissection at a later date. Sentinel node definition: hot-spots, areas with > 25 counts per 10 seconds and a target to background ratio > 3:1. Final breast procedure: partial mastectomy 43/82 (52.4%); total mastectomy 26/82 (31.7%); axillary clearance and/or sentinel node biopsy only 13/82 (15.9%). **Histologic analysis of sentinel nodes** Intraoperative analysis: not stated Sectioning: all specimens processed routinely, the method of sectioning was not stated. Permanent section: H&E IHC: not stated Micrometastases definition: not stated **Histologic analysis of axillary nodes** Not stated	**Age** Mean 55.2 ± 1.5 (SD), median 58.7 years. **Tumour characteristics** Biopsy method Excisional biopsy: 65% Fine needle aspiration or core biopsy: 20% Incisional biopsy: 15% Size Mean 1.8 ± 0.16cm (SD) Stage Not stated Histology Infiltrating ductal carcinoma: 90% Infiltrating lobular carcinoma: 10% Note: numbers not given. Location Lateral: 58% Medial: 30% Central: 12% Palpability Palpable and nonpalpable tumours were included. Multifocality/multicentricity Patients with multicentric breast cancer were excluded. **Axilla characteristics** Clinical axillary status Not stated **Neoadjuvant chemotherapy** Not stated

Study identifier	Procedure	Patient characteristics
Mirzaei, Rodrigues, Hoffmann, Knoll, Riegler-Keil, Kreuzer, Salzer, Köhn, Polyák & Jánoki, 2003. **Number of patients** 128 (consecutive) **Number of attempted mappings** 128 **Study period** June 1998 to June 2002 **Institution** Departments of Nuclear Medicine and Ludwig Boltzmann Institute of Nuclear Medicine, Departments of Surgery and Gynaecology, Wilhelminenspital, Vienna, Austria; NCPH – "FJC" National Research Institute for Radiobiology and Radiohygiene, Institute of Radiology and Radiohygiene, Budapest, Hungary. **Incorporated studies** None **Study included for review of...** Localisation rates **Inclusion/exclusion criteria** Inclusions: patients with histologically confirmed breast cancer and absence of palpable lymph nodes. Exclusions: patients with infected or indurated areas, poorly healed scars, haematomas, multicentric primary disease, clinical suspicion of axillary metastasis, known metastatic disease, pre-operative chemotherapy and previous radiation therapy to the chest, which would preclude adequate flow of the colloid. **Study included for review of...** Localisation rates	**Radiocolloid/dye combination** Radiocolloid only: 0 Dye only: 0 Radiocolloid and dye: 128 **Radiocolloid** Type: ^{99m}Tc-labelled human serum albumin colloid (SentiScint, MEDI-Radiopharma, Budapest, Hungary). Dose: 15 MBq in 0.4 mL Colloid size: >90% were 100 to 600 nm; mean 205 nm. Filtration: not stated Injection location: injected subcutaneously between skin and tumour. Site chosen according to mammographic and/or ultrasound findings. Injection timing: 18 hours prior to surgery. Massage: immediately after injection the patient massaged the site for 5 minutes. Intraoperative probe: type not stated. **Dye** Type: Lymphazurin 1% (USSC, Norwalk, Canada) Amount: not stated Injection location: subareolar Injection timing: dye was injected during surgery. Massage: not stated **Preoperative lymphoscintigraphy** Timing: 30, 60 minutes and, if necessary, up to 4 hours, post-injection. **Surgery** Surgeon details: three surgeons participated in all operations, two at the department of surgery, and one at the department of gynaecology Anaesthesia: not stated Axillary clearance: axillary lymph node dissection of levels 1 and 2 in first 50 patients. Axillary node dissection immediately if sentinel node positive for metastasis. Later operation if positive on further testing. Sentinel node definition: blue and radioactive lymph nodes. Final breast procedure: mastectomy or lumpectomy. **Histologic analysis of sentinel nodes** Intraoperative analysis: rapid frozen multiple section. Sectioning: not stated Permanent section: H&E IHC: cytokeratin antibodies (Cytokeratin AE1/AE3, IgG1-M3515, Dako, Calif., USA). Micrometastases definition: not stated **Histologic analysis of axillary nodes** Routine H&E staining.	**Age** Mean 62.56±13.03, range 33 to 90 years. **Tumour characteristics** Biopsy method Excisional biopsy. Size Mean 17.36±7.97, range 5 to 40 mm. Stage Not stated Histology DCIS: 14/128 (10.9%) Ductal invasive: 76/128 (59.4%) Lobular invasive: 35/128 (27.3%) Tubular invasive: 3/128 (2.3%) Location UIQ: 14/128 (10.9%) UOQ: 76/128 (59.4%) LIQ: 17/128 (13.3%) LOQ: 6/128 (4.7%) Nipple: 15/128 (11.7%) Palpability Palpable Tumour: 92/128 (71.9%) Multifocality/multicentricity Multicentric primary disease was an exclusion criteria. **Axilla characteristics** Clinical axillary status Negative: 128/128 (100%) **Neoadjuvant chemotherapy** Not stated

Study identifier	Procedure	Patient characteristics
Moffat, Gulec, Sittler, Serafini, Sfakianakis, Boggs, Franceschi, Pruett, Pop, Gurkok, Livingstone & Krag, 1999. **Number of patients** 73 (3 excluded because of contraindication for general anaesthesia). **Number of attempted mappings** 70 **Study period** Not stated **Institution** Divisions of Surgical Oncology and Nuclear Medicine, and Department of Pathology, University of Miami Sylvester Comprehensive Cancer Center and Jackson Memorial Hospital, Miami, Florida and Division of Surgical Oncologym Vernibt Cancer Center, and the University of Vermont Colleg of Medicine, Burlington, Vermont, USA. **Incorporated studies** Gulec *et al.* 1998 **Inclusion/exclusion criteria** Inclusions: patients ≥ 18 years of age with a Karnofsky performance status of at least 70, who were scheduled to undergo total or segmental mastectomy with axillary lymphadenectomy for unifocal, invasive, cN- breast cancer were eligible. Exclusions: none stated **Study included for review of...** Localisation rates and false negative rates	**Radiocolloid/dye combination** Radiocolloid only: 0 Dye only: 0 Radiocolloid and dye: 70 **Radiocolloid** Type: ^{99m}Tc-sulfur colloid (^{99m}TcSc, Mallinckrodt, St Louis, MO). Dose: 1 mCi (in normal saline); 61/70 (87.1%) total injectate 4 ml, 9/70 (12.9%) total injectate 8 ml. Colloid size: not stated Filtration: unfiltered Injection location: injected into the normal breast parenchyma in four equal aliquots around the primary tumour or biopsy cavity. Injection timing: patients were taken to the operating room within 8 hours of radiocolloid injection; time elapsed from radiocolloid injection to start of surgery was 3.1±1.4 (SD) hours (median 2.5, range 0.75-6.25). Massage: not stated Intraoperative probe: C-Trak GDP (CareWise Medical, Morgan Hill, CA). **Dye** Dye was not used. Type: not applicable Amount: not applicable Injection location: not applicable Injection timing: not applicable Massage: not applicable **Preoperative lymphoscintigraphy** Timing: lymphoscintigraphy was not performed. **Surgery** Surgeon details: not stated Anaesthesia: general anaesthesia Axillary clearance: axillary lymphadenectomy in all patients. Sentinel node definition: cutaneous hot spots defined as discrete foci of radioactiviy with a 10-second count of at least 25; all specimens with ≥ 10% of the *ex vivo* count of the hottest specimen were considered sentinel, and SLNB was deemed complete when a 10-second count of the SLN bed was < 10% of that of the hottest SN specimen. Final breast procedure: total or segmental mastectomy. **Histologic analysis of sentinel nodes** Intraoperative analysis: not stated Sectioning: all lymph nodes were bivalved and two sections from each examined. Permanent section: H&E IHC: not stated Micrometastases definition: not stated **Histologic analysis of axillary nodes** All lymph nodes were bivalved and two sections of each examined by H&E section.	**Age** Mean 54±10 (variance not stated), range 34 to 86 years. **Tumour characteristics** Biopsy method 41/70 (58.6%) excisonal biopsy; 29/70 (41.4%) FNA cytology or core-needle biopsy (3 of these underwent stereotactic core biopsy). Size Mean: 1.8±1.2 cm Median: 1.5 cm Range: 0.1-6.0 cm Stage T1: 45/70 (64.3%) T2: 23/70 (32.9%) T3: 2/70 (2.9%) Histology Ductal, not otherwise specified: 57/70 (81.4%) Colloid/mucinous: 3/70 (4.3%) Tubular: 1/70 (1.4%) Papillary: 1/70 (1.4%) Ductal and lobular: 3/70 (4.3%) Lobular: 5/70 (7.1%) Location Upper outer: 17/70 (24.3%) Upper inner: 11/70 (15.7%) Lower outer: 2/70 (2.9%) Lower inner: 3/70 (4.3%) Central: 13/70 (18.6%) Superior: 10/70 (14.3%) Lateral: 9/70 (12.9%) Inferior: 3/70 (4.3%) Medial: 2/70 (2.9%) Palpability Not stated Multifocality/multicentricity Patients with unifocal cancer were eligible for the study. **Axilla characteristics** Clinical axillary status Negative: 70/70 (100%) **Neoadjuvant chemotherapy** Not stated

Study identifier	Procedure	Patient characteristics
Mokbel & Mostafa, 2001. **Number of patients** 35 **Number of attempted mappings** 35 **Study period** The study was performed over a four month period. **Institution** St George's Breast Cancer Centre, St George's Hospital, London, UK. **Incorporated studies** None **Inclusion/exclusion criteria** Inclusions: operable infiltrating carcinoma of the breast, and clinically negative axilla. Exclusions: none stated **Study included for review of...** Localisation rates and false negative rates	**Radiocolloid/dye combination** Radiocolloid only: 0 Dye only: 35 Radiocolloid and dye: 0 **Radiocolloid** Radiocolloid was not used. Type: not applicable Dose: not applicable Colloid size: not applicable Filtration: not applicable Injection location: not applicable Injection timing: not applicable Massage: not applicable Intraoperative probe: not applicable **Dye** Type: Methylene blue (1%) Amount: 1 mL Injection location: dye was injected subdermally in the subareolar region. Injection timing: dye was injected 5 to 10 minutes before the axillary incision. Massage: the area of injection was gently massaged for approximately 1 to 2 minutes after injection. **Preoperative lymphoscintigraphy** Timing: not applicable **Surgery** Surgeon details: not stated Anaesthesia: not stated Axillary clearance: axillary node dissection was performed. Sentinel node definition: a blue node, or a node receiving a blue lymphatic. Final breast procedure: Total Mastectomy: 17/35 (48.6%) Breast Conserving Surgery: 18/35 (51.4%) **Histologic analysis of sentinel nodes** Intraoperative analysis: not stated Sectioning: not stated Permanent section: not stated IHC: not stated Micrometastases definition: not stated **Histologic analysis of axillary nodes** Not stated	**Age** Mean 58, range 31 to 85 years. **Tumour characteristics** Biopsy method Fine needle aspiration of core biopsy (only one patient required wire-guided excision biopsy prior to definintive cancer surgery). Size Mean 18.9, range 7 to 40 mm; 16/35 (45.7%) were >20mm. Stage T2: 16 (45.7%) Grade I: 6/35 (17.1%) Grade II: 12/35 (34.3%) Grade III: 17/35 (48.6%) Histology Infiltrating carcinoma inclusion criteria Location UOQ: 22/35 (62.9%) LOQ: 7/35 (20%) UIQ: 2/35 (5.7%) Centre: 4/35 (11.4%) Palpability Non-palpable: 8/35 (22.9%) Multifocality/multicentricity Multifocal: 3/35 (8.6%) **Axilla characteristics** Clinical axillary status Negative: 35/35 (100%) **Neoadjuvant chemotherapy** Not stated

Study identifier	Procedure	Patient characteristics
Molland, Dias & Gillett, 2000. **Number of patients** 104 (1 patient was excluded as the radiocolloid localised to an internal mammary node only). **Number of attempted mappings** 104 (1 patient was excluded as the radiocolloid localised to an internal mammary node only). **Study period** January 1998 to July 1999 **Institution** Breast Endocrine Unit, Concord Repatriation General Hospital and Strathfield Breast Centre, Strathfield, New South Wales, Australia. **Incorporated studies** None **Inclusion/exclusion criteria** Inclusions: patients with T1-3, N0-1 breast carcinoma. Exclusions: none stated **Study included for review of...** Localisation rates	**Radiocolloid/dye combination** Radiocolloid only: 0 Dye only: 0 Radiocolloid and dye: 104 **Radiocolloid** Type: ^{99m}Tc-labelled antimony sulphide Dose: total dose 20 to 40Mbq in four aliquots of 0.2 to 0.5ml (total 0.8 to 2ml). Colloid size: not stated Filtration: not stated Injection location: intramammary injection at the 3, 6, 9 and 12 o'clock positions around the tumour margins at tumour depth. Ultrasound used in majority of cases to locate the tumour. Injection timing: between 2 and 24 hours before surgery. Massage: the breast was massaged for 3 to 5 minutes by the patient. Intraoperative probe: Gammasonics (Gammasonics Institute, Five Dock, NSW, Australia); Navigator (Autosuture Co. Australia, Adelaide, SA, Australia). **Dye** Type: Patent blue V Amount: 2ml Injection location: dye was injected around the lesion. Injection timing: dye was injected after induction of general anaesthesia. Massage: the breast was gently massaged for 3 to 5 minutes. **Preoperative lymphoscintigraphy** Timing: early dynamic images and later (1hour) static images. **Surgery** Surgeon details: not stated Anaesthesia: general anaesthesia Axillary clearance: axillary clearance to at least level II was completed in most patients; node sampling or sentinel lymph node biopsy only was performed in the remainder. Sentinel node definition: blue and/or hot. Final breast procedure: not stated **Histologic analysis of sentinel nodes** Intraoperative analysis: not stated Sectioning: nodes were transected, the method of sectioning was not stated. Permanent section: H&E IHC: if negative by H&E, three further step sections, 20 to 30μm apart, were taken and stained for cytokeratin AE1/AE3 and in some cases, Cam 5.2. Micrometastases definition: not stated **Histologic analysis of axillary nodes** Not stated	**Age** Range 28 to 82 years. **Tumour characteristics** Biopsy method Not stated Size ≤ 5mm: 2/103 (1.9%) 6 to 10mm: 16/103 (15.5%) 11 to 20mm: 47/103 (45.6%) 21 to 50mm: 36/103 (35.0%) >50mm: 2/103 (1.9%) Stage Grade 1: 32/103 (31.1%) Grade 2: 32/103 (31.1%) Grade 3: 32/103 (31.1%) DCIS: 7/103 (6.8%) Histology Invasive carcinoma: 96/103 (93.2%) DCIS: 7/103 (6.8%) Location Not stated Palpability Palpable and nonpalpable tumours were included. Multifocality/multicentricity Not stated **Axilla characteristics** Clinical axillary status Both N0 and N1 tumours were included. **Neoadjuvant chemotherapy** Not stated

Study identifier	Procedure	Patient characteristics
Morrow, Rademaker, Bethke, Talamonti, Dawes, Clauson & Hansen, 1999. **Number of patients** 139 Group 1: dye alone (n=50) Group 2: dye+radiocolloid (n=42) Group 3: dye alone, needle localisation (n=47) **Number of attempted mappings** 139 **Study period** February 1997 to January 1999. **Institution** Department of Surgery, and the Lynn Sage Comprehensive Breast Center, the Department of Preventive Medicine, Northwestern University Medical School, Chicago, Illinois and The John Wayne Cancer Institute, St Johns Hospital and Health Center, Santa Monica, California, USA. **Incorporated studies** None **Study included for review of...** False negative rates **Inclusion/exclusion criteria** Inclusions: patients with T1 or T2 invasive breast carcinoma and clinically negative axillary nodes. Exclusions: multicentric tumours, prior axillary operation, pregnancy. **Study included for review of...** False negative rates	**Radiocolloid/dye combination** Radiocolloid only: 0 Dye only: 97 (Groups 1 and 3). Radiocolloid and dye: 42 **Radiocolloid** Type: ^{99m}Tc- sulphur colloid Dose: 1 mCi in 2.0 mL sterile saline Colloid size: not stated Filtration: filtered Injection location: not stated Injection timing: mean 242± 106(SD) minutes, range 1 hour 24 minutes to 7 hours 49 minutes before operation. Massage: not stated Intraoperative probe: hand-held gamma counter, type not specified. **Dye** Type: 1% isosulphan blue dye Amount: 5 mL Injection location: dye injected into the breast parenchyma immediately surrounding the tumour. In patients with prior excisional biopsy, dye was injected into the breast tissue immediately beyond the palpable edge of the biopsy cavity. Injection timing: time between injection of dye and excision: (mins) Total: Mean 13.8 [7.9] Group 1: Mean 10.9 (0.8) Group 2: Mean 15.9(1.6) Group 3: Mean 14.7(1.2) (p=0.01 between groups; Group 2 significantly different than Group 1). Massage: manual breast compression for 5 minutes after injection. **Preoperative lymphoscintigraphy** Timing: Not performed **Surgery** Surgeon details: none of the participating surgeons had prior experience with SN localisation for breast cancer, taught by a surgeon with prior experience; randomisation began with each surgeon's first case. Anaesthesia: not stated Axillary clearance: level 1 and 2 axillary dissection in all patients. Sentinel node definition: nodes identified as 'hot' in vivo were examined with gamma detector after removal and only considered to be sentinel nodes if increased radioactivity compared with axillary counts or blue staining was observed. Final breast procedure: all patients had breast-conserving surgery. **Histologic analysis of sentinel nodes** Intraoperative analysis: frozen sections were not used. Sectioning: nodes bisected, a section taken from each face. Permanent section: H&E IHC: used, but the method not reported. Not used diagnostically: a positive SN defined as one with positive tumour cells using H&E. Micrometastases definition: not stated **Histologic analysis of axillary nodes** H&E as for sentinel nodes.	**Mean Age (years) n=139** Total: 53.4[10.0] Group 1: 52.2(1.5) Group 2: 52.1(1.5) Group 3: 55.7(1.4) (p=0.14 between groups) **Tumour characteristics** Biopsy method Prior excisional biopsy: 57/139 (41.0%) Mean Size (cm) Total (n=139): 1.7[1.1] (range 0.1 to 6.5) Group 1: Mean 1.8(0.2) Group 2: Mean 1.9(0.2) Group 3: Mean 1.4(0.2) (p=0.10 between groups) Stage T1: 66/92 (71.7%) T2: 26/92 (28.3%) (n=92 – randomised arm only) Histology Not stated Location UOQ: 48% (67/139) UIQ: 15% (21/139) Upper central: 10% (14/139) Central: 6% (8/139) Lower central: 3% (4/139) LOQ: 13% (18/139) LIQ: 4% (6/139) (1 patient not stated) Palpability Group 1: 62% (31/50) Group 2: 55% (23/42) Group 3: 11% (5/47)* * 4 tumours in the localisation group ? palpable, but had a wire placed to ensure appropriate excision. Fifth patient had bilateral lesions, one of which required localisation, so palpable tumour not randomised. Multifocality/multicentricity Not stated **Axilla characteristics** Clinical axillary status Negative: 139/139 (1005) **Neoadjuvant chemotherapy** Not stated

Study identifier	Procedure	Patient characteristics
Motomura, Inaji, Komoike, Kasugai, Shinzaburo, Noguchi & Koyama, 1999a. **Number of patients** 172 (consecutive) **Number of attempted mappings** 172 **Study period** December 1997 to October 1998 **Institution** Departments of Surgery and Pathology, Osaka Medical Center for Cancer and Cardiovascular Diseases, Osaka, and Department of Surgical Oncology, Osaka University Medical School, Osaka, Japan. **Incorporated studies** Motomura *et al.* 1999b **Study included for review of...** Localisation rates and false negative rates **Inclusion/exclusion criteria** Inclusions: patients with stage I or II breast cancer. Exclusions: women with multiple primary tumours, non-palpable breast cancer, prior excisional biopsy or axillary surgery or pregnancy were excluded. **Study included for review of...** Localisation rates and false negative rates	**Radiocolloid/dye combination** Radiocolloid only: 0 Dye only: 172 Radiocolloid and dye: 0 **Radiocolloid** Radiocolloid was not used. Type: not applicable Dose: not applicable Colloid size: not applicable Filtration: not applicable Injection location: not applicable Injection timing: not applicable Massage: not applicable Intraoperative probe: not applicable **Dye** Type: Indocyanin green (Diagnogreen 0.5%, Daiichi Pharmaceutical, Nihonbashi, Tokyo). Amount: 5 ml Injection location: dye injected into the breast parenchyma surrounding the primary tumour. Injection timing: dye injected 10 minutes before axillary incision. Massage: not stated **Preoperative lymphoscintigraphy** Timing: not applicable **Surgery** Surgeon details: not stated Timing: surgery was perormed 10 minutes after dye injection Anaesthesia: not stated Axillary clearance: axillary lymph node dissection performed in all patients. Sentinel node definition: blunt dissection was performed until a green-stained lymphatic tract or SN was identified. Final breast procedure: breast conserving surgery 119/172 (69.2%) patients; mastectomy 53/172 (30.8%) patients. **Histologic analysis of sentinel nodes** Intraoperative analysis: not stated Sectioning: sentinel nodes were serially sectioned at 2 mm intervals. Permanent section: H&E IHC: not stated Micrometastases definition: not stated **Histologic analysis of axillary nodes** Axillary nodes examined separately from sentinel nodes; one-level sectioning was examined with H&E.	**Age** Median 51, range 28 to 75 years. > 50 years: 88/172 (51.2%) < 50 years: 84/172 (48.8%) **Tumour characteristics** Biopsy method All patients were diagnosed as having breast cancer by fine needle aspiration. Size Median 2.1, range 0.5 to 5.0 cm. > 2 cm: 76/172 (44.2%) < 2 cm: 96/172 (55.8%) Stage T1: 96/172 (55.8%) T2: 76/172 (44.2%) Histology Intraductal: 27/172 (15.7%) Ductal: 135/172 (78.5%) Other: 10/172 (5.8%) Location Upper outer: 107/172 (62.2%) Upper inner: 37/172 (21.5%) Lower outer: 16/172 (9.3%) Lower inner: 8/172 (4.7%) Central: 4/172 (2.3%) Palpability Patients with non-palpable breast cancer were excluded from the study. Multifocality/multicentricity Patients with multiple primary tumours were excluded from the study. **Axilla characteristics** Clinical axillary status Positive: 58/172 (33.7%) Negative: 114/172 (66.3%) **Neoadjuvant chemotherapy** Not stated

Study identifier	Procedure	Patient characteristics
Motomura, Komoike, Inaji, Hasegawa, Kasugai, Noguchi & Koyama, 2002a. **Number of patients** 154 (consecutive) **Number of attempted mappings** 154 **Study period** December 1998 to July 2000 **Institution** Departments of Surgery, Nuclear Medicine and Pathology, Osaka Medical Center for Cancer and Cardiovascular Diseases, Higashinari-ku, Osaka, and Department of Surgical Oncology, Osaka University Medical School, Suita City, Osaka, Japan. **Incorporated studies** Motomura *et al.* 2002b **Study included for review of...** Localisation rates and false negative rates **Inclusion/exclusion criteria** Inclusions: consecutive patients with T1/T2 breast cancer and clinically negative lymph nodes. Exclusions: patients with multiple primary tumours, nonpalpable breast cancer, prior axillary surgery or pregnancy. **Study included for review of...** Localisation rates and false negative rates	**Radiocolloid/dye combination** Radiocolloid only: 0 Dye only: 0 Radiocolloid and dye: 164 **Radiocolloid** Type: ^{99m}Tc-labelled tin colloid Dose: 37MBq in 0.3ml Colloid size: not stated Filtration: not stated Injection location: radiocolloid injection was subdermal. Injection timing: radiocolloid injected the day before surgery. Massage: not stated Intraoperative probe: Neo 2000 (Neoprobe Corporation, Dublin, Ohio) and/or Navigator (USSC, Norwalk, CT). **Dye** Type: Indocyanine green Amount: 5ml Injection location: dye was injected peritumourally. Injection timing: dye was injected 10 minutes before axillary incision. Massage: not stated **Preoperative lymphoscintigraphy** Timing: performed 1 to 2 hours after radiocolloid injection. **Surgery** Surgeon details: sentinel lymph node biopsy was performed by a single surgeon (Motomura). Anaesthesia: not stated Axillary clearance: levels I and II axillary lymph node dissection. Sentinel node definition: a node with an *ex vivo* radioisotope count of two or greater than the axillary background. Final breast procedure: breast conservation 147/154 (95.5%); mastectomy 7/154 (4.5%). **Histologic analysis of sentinel nodes** Intraoperative analysis: not stated Sectioning: not stated Permanent section: not stated IHC: not stated Micrometastases definition: not stated **Histologic analysis of axillary nodes** Not stated	**Age** Median 51.2, range 28 to 77 years. | <60 years | 122/154 (79.2%) | | ≥60 years | 32/154 (20.8%) | **Tumour characteristics** Biopsy method Previous surgical biopsy: | Done | 17/154 (11.0%) | | Not done | 137/154 (89.0%) | Size Median 19.1, range 5.0 to 40.0mm. | ≤2cm | 99/154 (64.3%) | | >2cm | 55/154 (35.7%) | Stage Patients had T1/T2 breast cancer. Histology | Intraductal carcinoma (DCIS) | 9/154 (5.8%) | | Invasive ductal carcinoma | 130/154 (8.4%) | | Others | 15/154 (9.7%) | Location | Inner | 46/154 (29.9%) | | Outer | 108/154 (70.1%) | Palpability Patients with nonpalpable tumours were excluded. Multifocality/multicentricity Patients with multiple primary tumours were excluded. **Axilla characteristics** Clinical axillary status | Negative | 154/154 (100%) | **Neoadjuvant chemotherapy** Not stated

Study identifier	Procedure	Patient characteristics
Motta, Cartia, Muni, Giudici, Falcetto, Castaldo & Galli, 2000. **Number of patients** 54 (1 male) **Number of attempted mappings** 54 **Study period** June 1998 to November 1999 **Institution** UOA Medicina Nucleare, UOA Anatomia Patologica, Divisione Chirurgia A, Divisione Chirurgia B, Ospedale degli Infermi, Biella, Italy. **Incorporated studies** None **Study included for review of...** Localisation rates **Inclusion/exclusion criteria** Inclusions: surgical indication for conservative treatment, absence of palpable axillary nodes, age < 75 years, Karnofsky index > 70, no radioactive substances administered in the past week. Exclusions: none stated **Study included for review of...** Localisation rates	**Radiocolloid/dye combination** Radiocolloid only: Dye only: Radiocolloid and dye: **Radiocolloid** Type: ^{99m} Tc-labelled human albumin Dose: Group A: 3 to 4MBq (44 patients); Group B: 7 to 8MBq (10 patients) in 0.10 to 0.20ml (both groups). Colloid size: 50 to 80nm Filtration: not stated Injection location: transdermal supralesional injection in 49 patients with palpable lesions and intraparenchymally around the tumour under ultrasound guidance in patients with nonpalpable or deep lesions. Injection timing: 16 to 18 hours before surgery. Massage: massage was applied to the injection site in all cases to facilitate lymphatic drainage. Intraoperative probe: MR 100 (Pol.Hi.Tech). **Dye** Dye was not used. Type: not applicable Amount: not applicable Injection location: not applicable Injection timing: not applicable Massage: not applicable **Preoperative lymphoscintigraphy** Timing: started 5 minutes after radiocolloid injection (16 to 18 hours before surgery); continued to 80 minutes (early migration) or 180 minutes (late migration) and after 14 to 16 hours in 10 patients. **Surgery** Surgeon details: not stated Anaesthesia: not stated Axillary clearance: standard axillary dissection. Sentinel node definition: not stated Final breast procedure: not stated **Histologic analysis of sentinel nodes** Intraoperative analysis: frozen section Sectioning: each node was bisected through its short axis and four sections of 4 to 6μm thickness prepared. Permanent section: H&E (first section). IHC: negative control (second section); IHC with anti-EMA (clone Vu 4H5-Bio-Optica or clone E29, Dako; third section); IHC with MNF_{116} (fourth section). Four other sections obtained at a 10μm distance were similarly prepared. Micrometastases definition: not stated **Histologic analysis of axillary nodes** Not stated	**Age** Mean 59, range 31 to 75 years. **Tumour characteristics** Biopsy method Not stated Size Not stated Stage Not stated Histology Not stated Location Not stated Palpability Palpable and nonpalpable tumours were included. Multifocality/multicentricity Not stated **Axilla characteristics** Clinical axillary status Negative: 54/54 (100%) **Neoadjuvant chemotherapy** Not stated

Study identifier	Procedure	Patient characteristics
Nährig, Richter, Kowolik, Kuhn, Avril, Höfler and Werner, 2000. **Number of patients** 40 **Number of attempted mappings** 40 **Study period** Not stated **Institution** Institute of Pathology and Departments of Gynaecology and Nuclear Medicine, Technical University Munich, Munich, Germany. **Incorporated studies** Kowolik *et al.* 2000 **Study included for review of...** Localisation rates and false negative rates **Inclusion/exclusion criteria** Inclusions: patients with invasive breast carcinoma. Exclusions: none stated **Study included for review of...** Localisation rates and false negative rates	**Radiocolloid/dye combination** Radiocolloid only: 40 Dye only: 0 Radiocolloid and dye: 0 **Radiocolloid** Type: ^{99m} Tc-labelled nanocolloid (Nanocoll®) Dose: not stated Colloid size: not stated Filtration: not stated Injection location: radiocolloid injected peritumourally. Injection timing: not stated Massage: not stated Intraoperative probe: gamma probe, type not stated. **Dye** not used Type: not applicable Amount: not applicable Injection location: not applicable Injection timing: not applicable Massage: not applicable **Preoperative lymphoscintigraphy** Timing: lymphoscintigraphy performed, timing not stated. **Surgery** Surgeon details: not stated Anaesthesia: not stated Axillary clearance: level I and II axillary dissection. Sentinel node definition: not stated Final breast procedure: not stated (From Kowolik *et al.* 2000 – conserving surgery 33/37 (89.2%); modified radical mastectomy 4/37 (10.8%) **Histologic analysis of sentinel nodes** Intraoperative analysis: frozen section (three consecutive, one H&E two IHC). Microscopic examination of the specimens done independently by two experienced pathologists (JN, MW). Sectioning: lymph nodes > 5mm bisected through long axis and frozen sections prepared. Remaining fixed in paraffin; one section routinely H&E stained and 5 sections performed with spacing of 150µm between following sections. Permanent section: H&E IHC: ultra-rapid-IHC performed intraoperatively on frozen sections (clone MNF116, EPOS™, DAKO; and clones 2B11 and PD7/26, EPOS, DAKO, Copenhagen, Denmark). Micrometastases definition: according to UICC, metastases defined as macrometastasis (pN1b) if > 2 mm in size and micrometastasis (pN1a) < 2 mm with stromal infiltration. **Histologic analysis of axillary nodes** Routine sections stained with H&E.	**Age** Median 58, range 29-80 years. **Tumour characteristics** Biopsy method Not stated Size < 20 mm: 26/40 (65%) 21-35 mm: 14/40 (35%) Stage pT1: 26/40 (65%) pT2: 14/40 (35%) Histology Invasive ductal carcinomas: 37/40 (92.5%) Invasive lobular: 2/40 (5%) Medullary: 1/40 (2.5%) Location Not stated Palpability Not stated Multifocality/multicentricity Not stated **Axilla characteristics** Clinical axillary status Not stated **Neoadjuvant chemotherapy** Not stated

Study identifier	Procedure	Patient characteristics
Nano, Kollias, Farshid, Gill & Bochner, 2002. **Number of patients** 328 (consecutive) **Number of attempted mappings** 328 **Study period** January 1995 to March 2001 **Institution** Breast Unit and Women's Health Centre, Royal Adelaide Hospital Cancer Centre; Department of Surgery, Adelaide University and Department of Tissue Pathology, Institute of Medical and Veterinary Science, Adelaide, South Australia, Australia. **Incorporated studies** Kollias *et al.* 1999, Kollias *et al.* 2000; Sutton *et al.* 2002 **Inclusion/exclusion criteria** Inclusions: patients with operable primary breast cancer (≤ 5cm), detected clinically and by imaging, confirmed by cytology, core biopsy or open biopsy; clinically impalpable axillary lymph nodes; the usual surgical indications for axillary dissection (ie. invasive, operable cancer). (described previously in Kollias *et al.* 1999 and Kollias *et al.* 2000) Exclusions: patients not fulfilling the previously mentioned criteria; were pregnant or breast feeding; high clinical suspicion or preoperative verification of axillary nodal involvement; metastatic breast carcinoma; preoperative diagnosis of ductal carcinoma *in situ*. **Study included for review of...** Localisation rates and false negative rates	**Radiocolloid/dye combination** Radiocolloid only: 56 Dye only: 0 Radiocolloid and dye: 272 **Radiocolloid** Type: ^{99m}Tc-antimony sulphide ('Lymph-Flo', Royal Adelaide Hospital Radiopharmacy) Dose: activity not stated, but 0.5ml injected in the first 82 patients, increased to 4.0ml in the remaining patients. Colloid size: not stated Filtration: not stated Injection location: peritumoural Injection timing: radiocolloid was injected on the morning of the day of surgery. Massage: not stated Intraoperative probe: RMD CTC 4 (Gammasonics, Melbourne, Victoria, Australia). **Dye** Type: 2.5% Patent Blue V (Guerbet Laboratories, Villepente, France). Blue dye used alone for the first 19 procedures, in conjunction with the guidance of the lymphoscintogram markings. Amount: 1 to 2ml Injection location: dye was injected around the periphery of the tumour. Injection timing: dye was injected on the induction of anaesthesia. Massage: minimum of 5 minutes. **Preoperative lymphoscintigraphy** Timing: immediately after injection of the radiocolloid and every 15 minutes until a sentinel node was detected. **Surgery** Surgeon details: not stated Anaesthesia: general Axillary clearance: level II/III axillary node dissection. Sentinel node definition: blue and/or hot lymph nodes. Final breast procedure: not stated **Histologic analysis of sentinel nodes** Intraoperative analysis: not stated Sectioning: between 1995 to 1998 nodes submitted whole and bisected if >1cm. After 1998, all sentinel nodes were serially sectioned into 1 to 2mm slices. Permanent section: between 1995 and 1998 at least one H&E section examined. After 1998, at least three H&E sections were examined. IHC: between 1995 and 1998, IHC was performed using anticytokeratin antibody (CAM 5.2; Becton Dickinson, San Jose, California, USA) if the H&E section was suspicious, after 1998, at least one section per sentinel node was examined via IHC. Micrometastases definition: not stated **Histologic analysis of axillary nodes** At least one section per node examined using H&E.	**Age** Median 60, range 31 to 82 years. **Tumour characteristics** Biopsy method Cytology, core biopsy or open biopsy. Size All tumours were ≤ 5cm. Stage Not stated Histology Not stated Location Not stated Palpability Palpable: 161/328 (49.1%) Nonpalpable: 167/328 (50.9%) Multifocality/multicentricity Not stated **Axilla characteristics** Clinical axillary status Negative: 328/328 (100%) **Neoadjuvant chemotherapy** Not stated

Study identifier	Procedure	Patient characteristics
Nason, Anderson, Byrd, Dunnwald, Eary, Mankoff, Livingston, Schmidt, Jewell, Yeung & Moe, 2000. **Number of patients** 82 **Number of attempted mappings** 82 **Study period** October 1996 to June 1999 **Institution** Section of Surgical Oncology, Department of Surgery; Division of Nuclear Medicine, Department of Radiology; Division of Medical Oncology, Department of Medicine and Department of Pathology, Bio-Clinical Breast Care Program, University of Washington School of Medicine, University of Washington, Seattle, Washington, USA. **Incorporated studies** Eary *et al.* 1999; Morgan *et al.* 1999 **Inclusion/exclusion criteria** Inclusions: patients with known invasive breast carcinoma. Exclusions: patients with palpable suspicious lymph nodes at the time of surgery, preoperatively identified multicentric tumours or concurrent pregnancy. **Study included for review of...** False negative rates	**Radiocolloid/dye combination** Radiocolloid only: 0 Dye only: 0 Radiocolloid and dye: 82 **Radiocolloid** Type: ^{99m} Tc-labelled sulphur colloid Dose: 1.0mCi Colloid size: not stated Filtration: the colloid was filtered. Injection location: in patients with palpable masses the colloid was given via 4 x 1.5ml injections intraparenchymally and peritumourally; in patients with nonpalpable masses, 6ml of colloid was injected through one or two needles placed for wire localisation. Injection timing: not stated Massage: the area was massaged gently for a minimum of 5 minutes. Intraoperative probe: Neoprobe®; Navigator® **Dye** Type: Isosulphan blue dye Amount: 5ml Injection location: dye was injected intraparenchymally and peritumourally in the same site as the radiocolloid. Injection timing: dye was injected intraoperatively. Massage: not stated **Preoperative lymphoscintigraphy** Timing: a lymphoscintigram was obtained, but the timing not stated. **Surgery** Surgeon details: all sentinel node biopsies were performed by one of four surgeons. Anaesthesia: not stated Axillary clearance: complete axillary dissection in all patients. Sentinel node definition: blue and/or hot (a sentinel node not staining blue was considered to be mapped successfully if the radioactive count of the node was 3-fold higher than the surrounding background count in the axilla, and/or 10-fold higher than the count of an excised nonsentinel node of axillary tissue). Final breast procedure: not stated **Histologic analysis of sentinel nodes** Intraoperative analysis: not stated Sectioning: a minimum of three levels of H&E stains were used. Permanent section: H&E IHC: if H&E stains were negative, IHC for cytokeratin 8 (35BH11; Dako, Carpenteria, CA) on one level. Micrometastases definition: not stated **Histologic analysis of axillary nodes** Not stated	**Age** Not stated **Tumour characteristics** Biopsy method FNA and/or CB: 52/82 (63.4%) Excisional biopsy: 30/82 (36.6%) Size (Of patients who were successfully mapped, 66/82 (80.5%)) ≤ 2cm: 38/82 (46.3%) >2cm but ≤ 5cm: 33/82 (40.2%) >5cm: 11/82 (13.4%) Stage T1: 38/82 (46.3%) T2: 33/82 (40.2%) T3: 10/82 (12.2%) T4: 1/82 (1.2%) Histology Not stated Location Not stated Palpability Palpable and nonpalpable tumours were included. Multifocality/multicentricity Patients were excluded if they had preoperatively identified multicentric tumours. **Axilla characteristics** Clinical axillary status Negative: 82/82 (100%) **Neoadjuvant chemotherapy** 15/82 (18.3%) patients underwent neoadjuvant chemotherapy (selected for neoadjuvant chemotherapy when they had a tumour size of > 5cm (T3) or T2 but were borderline breast conservation candidates), receiving three or four monthly cycles of the University of Washington AC+G protocol (24mg/m^2/week of doxorubicin intravenously and 60mg/m^2/day cyclophosphamide by mouth, in addition, patients received filgrastrim (granulocyte colony-stimulating factor) at 5µg/kg/day for 6 out of 7 days, omitted on the intravenous chemotherapy days.

Study identifier	Procedure	Patient characteristics
Noguchi, Bando, Tsugawa, Miwa, Yokoyama, Nakajima, Michigishi, Tonami, Minato & Nonomura, 1999. **Number of patients** 72 **Number of attempted mappings** 72 **Study period** February 1996 to February 1998 (dye only) March 1998 to May 1998 (dye plus radiocolloid) **Institution** Operation Center, Department of Surgery, Department of Nuclear Medicine and Division of Pathology, Kanazawa University Hospital, School of Medicine, Kanazawa University, Kanazawa, Japan. **Incorporated studies** None **Inclusion/exclusion criteria** Inclusions: patients with TIS, or clinical stage I or stage II breast cancer (TNM classification). Exclusions: patients with primary tumour >5 cm in greatest diameter (T3), and those with metastatic axillary nodes fixed to one another or to other structures (N2). **Study included for review of...** Localisation rates and false negative rates	**Radiocolloid/dye combination** Radiocolloid only: 0 Dye only: 47 Radiocolloid and dye: 25 **Radiocolloid** Type: ^{99m}Tc-labeled human serum albumin (Dai-ichi Radioisotope Institute, Tokyo, Japan). Dose: 3 mCi in 0.3 mL saline Colloid size: not stated Filtration: not stated Injection location: injected at three points into the peritumoural area. Injection timing: two hours before surgery. Massage: not stated Intraoperative probe: gamma-detection probe (C-Trak, Care-Wise Medical, Morgan, CA, USA). **Dye** Type: 1% patent blue dye (CI 42045, Wako Pure Chemical Industry, Osaka, Japan) Amount: 4 mL Injection location: at 4 points (12, 3, 6 and 9 o'clock positions) around the tumour or biopsy site in the breast. Injection timing: approximately 5 minutes before surgery for dye only, 15 minutes for dye and colloid. Massage: not stated **Preoperative lymphoscintigraphy** Timing: Not stated **Surgery** Surgeon details: not stated Anaesthesia: general anaesthesia Axillary clearance: complete axillary lymph node dissection. Sentinel node definition: a lymph node with any visible blue staining. Final breast procedure: modified radical mastectomy 43/72 (59.7%); breast conserving therapy 29/72 (40.3%). **Histologic analysis of sentinel nodes** Intraoperative analysis: imprint cytology: nodes were bisected and the cut surface touched onto clean slides, dried and stained with May-Giemsa and cytokeratin (MAS 494; Harlan Sera-Lab, Loughborough, England) The node was then frozen and sections cut and stained with H&E. Sectioning: remaining frozen tissue was thawed, formalin fixed and processed routinely, the method of sectioning was not stated. Permanent section: H&E (1 section) IHC: if H&E sections negative then cytokeratin IHC staining was performed on one section. Micrometastases definition: not stated **Histologic analysis of axillary nodes** Axillary nodes were dissected fresh and processed using routine surgical pathology techniques for the isolation of lymph nodes. The nodes were then bisected, embedded in paraffin blocks and examined with H&E staining, but not with IHC.	**Age** Mean 54±13 (SD), range 28 to 82 years. **Tumour characteristics** Biopsy method Surgical Biopsy: 27/72 (37.5%) FNA and/or CB: 45/72 (62.5%) Size Mean 23±13 (SD) mm. Stage TIS: 7/72 (9.7%) Stage I: 30/72 (41.7%) Stage II: 35/72 (48.6%) T0-1: 44/72 (61.1%) T2: 28/72 (38.9%) Histology Non-invasive ductal: 7/72 (9.7%) Invasive ductal: 61/72 (84.7%) Invasive mucinous: 3/72 (4.2%) Invasive lobular: 1/72 (1.4%) Location Not stated Palpability Not stated Multifocality/multicentricity Not stated **Axilla characteristics** Clinical axillary status No, N1a: 57/72 (79.2%) N1b: 15/72 (20.8%) Involvement Present: 30/72 (41.7%) Absent: 42/72 (58.3%) **Neoadjuvant chemotherapy** Not stated

Study identifier	Procedure	Patient characteristics
Noguchi, Motomura, Imoto, Miyauchi, Sato, Iwata, Ohta, Kurosumi & Tsugawa, 2000a. **Number of patients** 674 **Number of attempted mappings** 674 **Study period** May 1998 to April 1999 **Institution** Operation Center and Department of Surgery (II), Kanazawa University Hospital, Kanazawa; Department of Surgery, Osaka Medical Center for Cancer and Cardiovascular Diseases, Osaka; Division of Breast Surgery, National Cancer Center East Hospital, Kashiwara; Division of Breast Surgery, Chiba Cancer Center, Chiba; Department of Surgery (I), National Defence Medical College, Tokorozawa; Division of Breast Surgery, Aichi Cancer Center, Nagoya; Department of Surgery, Tokai University Tokyo Hospital, Tokyo; Division of Pathology, Saitama Cancer Center, Saitama, Japan. **Incorporated studies** Noguchi *et al.* 2000b; Motomura *et al.* 2001 **Inclusion/exclusion criteria** Inclusions: patients with DCIS and clinical stage I or II breast cancer; clinically palpable axillary nodes (N1a – movable homolateral axillary nodes not considered to contain tumour and N1b – nodes considered to contain tumour). Exclusions: primary tumour >5.0cm in its greatest diameter (T3) or metastatic axillary nodes fixed to one another or adjacent tissue (N2). Also excluded were patients with a history of previous axillary lymph node biopsy, multiple primary tumours or pregnancy. **Study included for review of...** Localisation rates.	**Radiocolloid/dye combination** Radiocolloid only: 0 Dye only: 447 Radiocolloid and dye: 227 **Radiocolloid** Type: ^{99m}Tc-labelled human serum albumin (HSA)(n=80; Daiichi Radioisotope Institute, Tokyo, Japan) or ^{99m}Tc-labelled tin colloid (n=147; Nihon Mediphysics, Tokyo, Japan) Dose: 3mCi of ^{99m}Tc-HSA in 3ml of saline; 1 to 5mCi of ^{99m}Tc-labelled tin colloid in 0.5 to 2.5ml of saline. Colloid size: not stated Filtration: not stated Injection location: in 3 to 4 sites into the breast parenchyma surrounding the primary tumour. Injection timing: approximately 2 hours before surgery. Massage: not stated Intraoperative probe: C-trak (Care-Wise Medical Products, Morgan Hill, CA, USA) or Navigator (RMD Inc., Watertown, MA, USA). **Dye** Type: Patent blue dye (n=91; CI 42045; Wako Pure Chemical Industry, Osaka, Japan); indocyanine green (n=255; Diagnogreen, Daiichi Pharmaceutical Co., Tokyo, Japan); indigocarmine (n=298; Daiichi Pharmaceutical); charcoal emulsion was injected at one institute (n=30). Amount: about 4ml Injection location: into the parenchyma at four sites surrounding the primary tumour; or if the tumour had been excised into the wall of the biopsy cavity and surrounding tissue. Injection timing: dye injected 5 to 15 minutes before surgery. Massage: not stated **Preoperative lymphoscintigraphy** Timing: whether preoperative lymphoscintigraphy was performed was not stated. **Surgery** Surgeon details: not stated Anaesthesia: general anaesthesia Axillary clearance: axillary clearance to at least level I and II. Sentinel node definition: not stated Final breast procedure: breast conserving surgery 320/674 (47.5%); modified radical mastectomy 354/674 (52.5%). **Histologic analysis of sentinel nodes** Intraoperative analysis: in four of the institutions the sentinel node was immediately bisected during surgery and examined histologically on one or more frozen sections. Sectioning: multiple sections. Permanent section: H&E. IHC: not stated Micrometastases definition: not stated **Histologic analysis of axillary nodes** H&E.	**Age** Mean 53 ± 11(SD) years. <table><tr><td><36 years</td><td>23/674 (3.4%)</td></tr><tr><td>36 to 50 years</td><td>284/674 (42.1%)</td></tr><tr><td>>50 years</td><td>367/674 (54.5%)</td></tr></table> **Tumour characteristics** Biopsy method <table><tr><td>FNA or CB</td><td>622/674 (92.3%)</td></tr><tr><td>Excisional</td><td>52/674 (7.7%)</td></tr></table> Size Mean 23±11(SD) mm. <table><tr><td>≤15mm</td><td>163/674 (24.2%)</td></tr><tr><td>16 to 30mm</td><td>354/674 (52.5%)</td></tr><tr><td>≥31mm</td><td>157/674 (23.3%)</td></tr></table> Stage <table><tr><td>T0</td><td>15/674 (2.2%)</td></tr><tr><td>T1</td><td>277/674 (41.1%)</td></tr><tr><td>T2</td><td>382/674 (56.7%)</td></tr></table> Histology <table><tr><td>Non-invasive ductal carcinoma</td><td>48/674 (7.1%)</td></tr><tr><td>Invasive ductal carcinoma</td><td>575/674 (85.3%)</td></tr><tr><td>Other invasive</td><td>51/674 (7.7%)</td></tr></table> Location <table><tr><td>Lateral</td><td>469/674 (69.6%)</td></tr><tr><td>Medial</td><td>205/674 (30.4%)</td></tr></table> Palpability Not stated Multifocality/multicentricity Patients with multiple tumours were excluded. **Axilla characteristics** Clinical axillary status <table><tr><td>Negative (N0)</td><td>490/674 (72.7%)</td></tr><tr><td>Negative (N1a)</td><td>112/674 (16.6%)</td></tr><tr><td>Positive (N1b)</td><td>72/674 (10.7%)</td></tr></table> **Neoadjuvant chemotherapy** Not stated

Study identifier	Procedure	Patient characteristics
Nos, Fréneaux, Louis-Sylvestre, Hurren, Heitz, Sastre-Garau & Clough, 2003. **Number of patients** 324 **Number of attempted mappings** 324 **Study period** December 1997 to August 2000 **Institution** Departments of Surgery and Pathology, Institut Curie, Paris, France. **Incorporated studies** Nos *et al.* 2001; Fréneaux *et al.* 2002 **Inclusion/exclusion criteria** Inclusions: patients with breast cancer. Exclusions: none stated **Study included for review of...** Localisation rates and false negative rates	**Radiocolloid/dye combination** Radiocolloid only: 0 Dye only: 324 Radiocolloid and dye: 0 **Radiocolloid** Radiocolloid was not used. Type: not applicable Dose: not applicable Colloid size: not applicable Filtration: not applicable Injection location: not applicable Injection timing: not applicable Massage: not applicable Intraoperative probe: not applicable **Dye** Type: Patent blue dye (Laboratoire Guerbet, Villepinte, France). Amount: 2ml Injection location: into the immediate area surrounding the tumour (72%); or tumour bed if the tumour had been previously excised (28%). Injection was into the parenchyma next to and on the axillary side of the tumour. Injection timing: not stated Massage: not stated **Preoperative lymphoscintigraphy** Timing: not applicable **Surgery** Surgeon details: the operations were performed by seven different surgeons. Anaesthesia: not stated Axillary clearance: levels I and II axillary dissection. Sentinel node definition: not stated Final breast procedure: lumpectomy 298/324 (92.0%); mastectomy 26/324 (8.0%). **Histologic analysis of sentinel nodes** Intraoperative analysis: frozen section not performed. Sectioning: bisected and fixed in AFA (5% acetic acid, 75% absolute ethyl alcohol, 18% distilled water and 2% formalin) and the two half-nodes embedded in paraffin separately. One or two levels from each node were used. Permanent section: H&E (1 or 2 levels) IHC: for blue nodes with negative H&E, 2 further sections cut, at each of 6 different levels separated by 150μm, from both halves of the lymph node (ie. 24 sections). One of each pair was stained. Micrometastases definition: nodes where at least two isolated cells stained positive on IHC were described as 'IHC micrometastatic nodes'. **Histologic analysis of axillary nodes** H&E Note: Quality control was performed where the negative sentinel node had a pathologic colour quality assessment (PCQA) for presence of dye. The pathologist checked the paraffin block macroscopically and assessed if at least one sentinel node identified by the surgeon was blue. If it was blue, in the opinion of the pathologist, the node was "confirmed blue". If none of the sentinel nodes were blue, the PCQA was "not blue". This result was expressed as a percentage, where the PCQA rate = confirmed blue + (positive sentinel nodes)/total number of patients.	**Age** Mean 58, range 28 to 87 years. **Tumour characteristics** Biopsy method Not stated Size Mean 16, range 3 to 50mm. Stage T0: 32/324 (9.9%) T1: 167/324 (51.5%) T2: 125/324 (38.6%) Tumour grade Grade I: 144/319 (45.1%) Grade II: 132/319 (41.4%) Grade III: 37/319 (11.6%) Undetermined: 6/319 (1.9%) Histology Ductal: 253/324 (78.1%) Lobular: 53/324 (16.4%) Other: 18/324 (5.6%) Location Not stated Palpability Not stated Multifocality/multicentricity Not stated **Axilla characteristics** Clinical axillary status Not stated **Neoadjuvant chemotherapy** Not stated

Study identifier	Procedure	Patient characteristics
Nwariaku, Euhus, Beitsch, Clifford, Erdman, Mathews, Albores-Saavedra, Leitch & Peters, 1998. **Number of patients** 119 **Number of attempted mappings** 119 **Study period** October 1995 to February 1998 **Institution** Departments of Surgery, Nuclear Medicine and Surgical Pathology, University of Texas Southwestern Medical Center and St. Paul Medical Center, Dallas, Texas, USA. **Incorporated studies** None **Inclusion/exclusion criteria** Inclusions: patients with tissue diagnosis of invasive breast carcinoma, enrolled regardless of tumour size, stage of disease or need for adjuvant therapy. Exclusions: pregnancy **Study included for review of...** False negative rates	**Radiocolloid/dye combination** Radiocolloid only: 0 Dye only: 0 Radiocolloid and dye: 119 **Radiocolloid** Type: ^{99m}Tc- sulfur colloid (Mallinckrodt, St Louis, Missouri). Dose: not stated Colloid size: not stated Filtration: not stated Injection location: around primary tumour or prior biopsy cavity. Injection timing: not stated Massage: not stated Intraoperative probe: Neoprobe 1000 gamma probe (Neoprobe Corp., Dublin, Ohio). **Dye** Type: Isosulphan blue vital dye Amount: 3 to 4 mL Injection location: subcutaneous injection. Injection timing: not stated Massage: not stated **Preoperative lymphoscintigraphy** Timing: performed, but timing not stated. **Surgery** Surgeon details: procedures performed by five surgeons at two institutes. Anaesthesia: SLNB and axillary lymphadenectomy under same anaesthetic. Axillary clearance: axillary lymphadenectomy. Sentinel node definition: not stated Final breast procedure: Axillary lymphadenectomy alone, or in conjunction with lumpectomy: 70/119 (58.8%) Modified radical mastectomy: 49/119 (41.2%) **Histologic analysis of sentinel nodes** Intraoperative analysis: not stated Sectioning: SLNs were divided into 5 segments and 3 sections were performed on each segment, allowing examination of 15 faces of the SLN. Permanent section: H&E (15 sections) IHC: not stated Micrometastases definition: not stated **Histologic analysis of axillary nodes** Not stated	**Age** Mean 53, range 30 to 83 years. **Tumour characteristics** Biopsy method Biopsy of primary tumour prior to SNLB: 56/119 (47.1%) Size Mean 2.1±1 cm (variance not stated). Stage Not stated Histology Invasive ductal: 80% (95/119) Invasive lobular: 14% (17/119) Ductal *in situ*: 6% (7/119) Note: only percentages stated in text. Location Medial: 37/119 (31.1%) (others not stated) Palpability Not stated Multifocality/multicentricity Not stated **Axilla characteristics** Clinical axillary status Not stated **Neoadjuvant chemotherapy** Not stated

Study identifier	Procedure	Patient characteristics
Offodile, Hoh, Barsky, Nelson, Elashoff, Eilber, Economou & Nguyen, 1998. **Number of patients** 41 **Number of attempted mappings** 41 **Study period** February 1997 to September 1997 **Institution** Departments of Surgery, Radiology, Pathology and Biomathematics, University of California – Los Angeles Medical Center, Los Angeles, USA. **Incorporated studies** None **Inclusion/exclusion criteria** Inclusions: patients with operable breast carcinoma (an axillary lymph node dissection had already been determined to be part of the planned surgical procedure, even if the patient did not participate in this study). Exclusions: pregnancy, allergy to radiopharmaceutical products. **Study included for review of...** Localisation rates and false negative rates	**Radiocolloid/dye combination** Radiocolloid only: 41 Dye only: 0 Radiocolloid and dye: 0 **Radiocolloid** Type: ^{99m}Tc-dextran Dose: 1 mCi in 0.5 mL Colloid size: not stated Filtration: not stated Injection location: Breast tumour: 23/41 (56.1%) Site of tumour biopsy: 18/41 (43.9%) Injection Technique - Palpable Mass: 14/40 (35%) Needle Localized: 8/40 (20%) Biopsy Site: 18/40 (45%) (One patient not included as SLN not localised) Injection timing: not stated Massage: not stated Intraoperative probe: portable gamma detector, type not specified. **Dye** Type: dye was not used Amount: not applicable Injection location: not applicable Injection timing: not applicable Massage: not applicable **Preoperative lymphoscintigraphy** Timing: Not stated **Surgery** Surgeon details: four surgeons participated in the study. Anaesthesia: general anaesthesia Axillary clearance: routine level I/II axillary lymph node dissection. Sentinel node definition: The first lymph node to receive drainage from a primary tumour. Final breast procedure: Not stated **Histologic analysis of sentinel nodes** Intraoperative analysis: not stated Sectioning: not stated Permanent section: H&E IHC: Cytokeratin IHC (murine monoclonal antibodies to low-molecular-weight cytokeratin; 39, 43 and 50 kDa) Micrometastases definition: not stated **Histologic analysis of axillary nodes** H&E staining	**Age** Not stated **Tumour characteristics** Biopsy method Not stated Size ≤ 0.5 cm: 2/40 (5%) > 0.5 and ≤ 1 cm: 11/40 (27.5%) > 1 and ≤ 2 cm: 10/40 (25%) > 2 and ≤ 5 cm: 14/40 (35%) > 5 cm: 3/40 (7.5%) (One patient not included as SLN not localised) Stage Not stated Histology Infiltrating Ductal: 33/40 (82.5%) Infiltrating Lobular: 3/40 (7.5%) Both: 2/40 (5%) DCIS: 2/40 (5%) (One patient not included as SLN not localised) Differentiation: Well differentiated: 6/40 (15%) Moderately: 12/40 (30%) Poorly: 18/40 (45%) Unknown: 4/40 (10%) (One patient not included as SLN not localised) Location UOQ: 16/40 (40%) UIQ: 9/40 (22.5%) LIQ: 4/40 (10%) LOQ: 7/40 (17.5%) Retroareolar: 4/40 (10%) (One patient not included as SLN not localised) Palpability Both palpable and nonpalpable tumours were included. Multifocality/multicentricity Not stated **Axilla characteristics** Clinical axillary status Not stated **Neoadjuvant chemotherapy** Not stated

Study identifier	Procedure	Patient characteristics
Ozmen, Muslumanoglu, Cabioglu, Tuzlali, Ilhan, Igci, Kecer, Bazfakioglu & Dagoglu, 2002. **Number of patients** 122 **Number of attempted mappings** 122 **Study period** March 1998 to March 2001 **Institution** Departments of Surgery and Pathology, Istanbul Medical Faculty, Istanbul University, Turkey. **Incorporated studies** None **Inclusion/exclusion criteria** Inclusions: patients with T1-3 breast cancer and clinically negative nodes Exclusions: patients with multicentric cancer; pregnancy. **Study included for review of...** Localisation rates and false negative rates	**Radiocolloid/dye combination** Radiocolloid only: 0 Dye only: 122 Radiocolloid and dye: 0 **Radiocolloid** Type: radiocolloid was not used. Dose: not applicable Colloid size: not applicable Filtration: not applicable Injection location: not applicable Injection timing: not applicable Massage: not applicable Intraoperative probe: not applicable **Dye** Type: Isosulphan blue dye (Lymphazurin; Zenith Parenterals, Rosemont, IL) Amount: 5cm^3 Injection location: into breast parenchyma surrounding the tumour in a four-quadrant technique (1.25mL per injection). Injections were carried out between two tumours and around them in patients with multifocal cancer. In patients with previous excisional biopsy, the cavity was opened and aspirated, and blue-dye was injected into the wall of the cavity in a four-quadrant technique. Injection timing: 5 to 10 minutes before surgery. Massage: not stated **Preoperative lymphoscintigraphy** Timing: not applicable **Surgery** Surgeon details: two experienced surgeons performed operations. Anaesthesia: not stated Axillary clearance: standard axillary lymph node dissection. Sentinel node definition: blue stained node Final breast procedure: mastectomy 66/122 (54.1%); breast conservation 56/122 (45.9%). **Histologic analysis of sentinel nodes** All sentinel and non-sentinel nodes were examined by two histopathologists specialised in breast disease. Intraoperative analysis: sentinel nodes sent for immediate frozen-section examination and imprint cytologic examination were bisected, one-half was frozen and cut. Nodes >0.5cm were bisected, those <0.5cm were embedded uncut. At least two consecutive sections of the frozen tissue were examined. Sectioning: after frozen sectioning, both halves were fixed and embedded in paraffin. At least four sections were obtained from each block of sentinel node in a different level (100 to 500 μm apart). Permanent section: H&E. Up to 10 additional sections stained with H&E were examined in cases with negative sentinel lymph nodes. IHC: not stated Micrometastases definition: not stated **Histologic analysis of axillary nodes** H&E	**Age** 47, range 30 to 79 years. < 50 years: 70/122 (57.4%) ≥ 50 years: 52/122 (42.6%) **Tumour characteristics** Biopsy method Not stated Size Not stated Stage T1: 65/122 (53.3%) T1a: 1/122 (0.8%) T1b: 18/122 (14.8%) T1c: 46/122 (37.7%) T2: 50/122 (41.0%) T3: 7/122 (5.7%) Histology Ductal: 83/122 (68.0%) Lobular: 3/122 (2.5%) Combined: 18/122 (14.8%) Medullar: 4/122 (3.3%) Other: 5/122 (4.1%) Missing: 9/122 (7.4%) Location UOQ: 64/122 (52.5%) LOQ: 16/122 (13.1%) UIQ: 17/122 (13.9%) LIQ: 6/122 (4.9%) Central: 19/122 (15.6%) Palpability Not stated Multifocality/multicentricity Multifocal: 21/122 (17.2%) Multicentric: 0/122 Multifocality defined as multiple foci of the same tumour, within the same quadrant at a distance ≤ 5 cm from the reference tumour demonstrated either by gross examination of the specimen and/or microscopic histopathologic examination. **Axilla characteristics** Clinical axillary status Negative: 122/122 (100%) **Neoadjuvant chemotherapy** Not stated

Study identifier	Procedure	Patient characteristics
Paganelli, Trifirò, Intra, Cremonesi & de Cicco, 2002a. **Number of patients** 882 (consecutive) **Number of attempted mappings** 882 **Study period** March 1996 to December 1999 **Institution** Division of Nuclear Medicine and Breast Surgery Unit, European Institute of Oncology, Milano, Italy. **Incorporated studies** Veronesi *et al.* 2001a; Viale *et al.* 2001; Zurrida *et al.* 2000; Zurrida *et al.* 2000 **Inclusion/exclusion criteria** Inclusions: patients with T1 to T3 breast cancer, without clinical evidence of metastatic axillary involvement, who underwent lymphoscintigraphy. Exclusions: patients who were pregnant, breast-feeding or who had previously undergone breast surgery and radiotherapy and patients with clinical evidence of metastatic axillary involvement. **Study included for review of...** Localisation rates	**Radiocolloid/dye combination** Radiocolloid only: 882 Dye only: 0 Radiocolloid and dye: 0 **Radiocolloid** Type: ^{99m}Tc-labelled antimony sulphide; ^{99m}Tc-labelled human serum albumin Dose: 10-15MBq, mean volume 0.3ml. Colloid size: antimony sulphide <50nm (n=100); human serum albumin <80nm (n=410) and 0.2 to 1μm (n=382). Filtration: not stated Injection location: radiocolloid injected around the breast lesion (peritumoural) or above the tumour (subdermal). Injection timing: patients were injected on the day before surgery. Massage: local massage and heat application. Intraoperative probe: C-Trak (Care Wise, Morgan Hill, CA, USA) or Scintiprobe-MR100 (Pol.hi.tech, Carsoli, Italy). **Dye** Dye was not used Type: not applicable Amount: not applicable Injection location: not applicable Injection timing: not applicable Massage: not applicable **Preoperative lymphoscintigraphy** Timing: 30 minutes after radiocolloid injection, additional delayed images if no tracer migration detected in the axillary region; performed the day before surgery. **Surgery** Surgeon details: not stated Anaesthesia: not stated Axillary clearance: total axillary dissection in 716/882 (81.2%). Sentinel node definition: radioactive nodes, when two or more nodes were detected intraoperatively, the node with the highest activity was labelled the sentinel node. Final breast procedure: not stated **Histologic analysis of sentinel nodes** Intraoperative analysis: not stated Sectioning: not stated Permanent section: not stated IHC: not stated Micrometastases definition: not stated **Histologic analysis of axillary nodes** Not stated	**Age** Not stated **Tumour characteristics** Biopsy method Not stated Size Not stated Stage T1 to T3 Histology Not stated Location Not stated Palpability Not stated Multifocality/multicentricity Multifocal cancer was found intraoperatively in 5 patients. **Axilla characteristics** Clinical axillary status Negative: 882/882 (100%) **Neoadjuvant chemotherapy** Not stated

Study identifier	Procedure	Patient characteristics
Patel, Dusi, Bragdon & Julian, 2003. **Number of patients** 125 **Number of attempted mappings** 125 **Study period** May 1997 to November 2001 **Institution** Departments of Human Oncology and Surgery, Allegheny General Hospital, Pittsburgh, Pennsylvania, USA. **Incorporated studies** Julian *et al.* 2001; Julian *et al.* 2002 **Inclusion/exclusion criteria** Inclusions: patients presenting to a single surgeon, with operable breast cancer and undergoing a formal axillary clearance. Exclusions: none stated **Study included for review of...** Localisation rates and false negative rates	**Radiocolloid/dye combination** Radiocolloid only: 0 Dye only: 0 Radiocolloid and dye: 125 **Radiocolloid** Type: ^{99m}Tc-labelled sulphur colloid Dose: 1mCi Colloid size: not stated Filtration: unfiltered Injection location: four peritumoural injections, for nonpalpable lesions, injections were performed using mammographic localisation or ultrasound guidance. Injection timing: radiocolloid injected preoperatively. Massage: not stated Intraoperative probe: intraoperative gamma scanning performed, type not specified. **Dye** Type: Isosulphan blue Amount: 5cm^3 Injection location: injected intraparenchymally around the tumour; for nonpalpable lesions, injections were performed using mammographic localisation or ultrasound guidance. Injection timing: dye was injected intraoperatively. Massage: not stated **Preoperative lymphoscintigraphy** Timing: whether preoperative lymphoscintigraphy was performed was not stated. **Surgery** Surgeon details: single surgeon Anaesthesia: not stated Axillary clearance: standard axillary clearance, levels not stated. Sentinel node definition: blue stained and/or radioactive or grossly replaced by tumour. Final breast procedure: not stated **Histologic analysis of sentinel nodes** Intraoperative analysis: not stated Sectioning: 2 to 3mm serial sectioning. Permanent section: H&E IHC: not stated Micrometastases definition: not stated **Histologic analysis of axillary nodes** Bivalved and examined using H&E sections.	**Age** Mean 52 years <table><tr><td><50 years</td><td>58/125 (46.4%)</td></tr><tr><td>≥50 years</td><td>67/125 (53.6%)</td></tr></table> **Tumour characteristics** Biopsy method Prior excisional biopsy (average excisional biopsy volume was 104cm^3) <table><tr><td>Yes</td><td>42/125 (33.6%)</td></tr><tr><td>No</td><td>83/125 (66.4%)</td></tr></table> Size Mean 1.5cm <table><tr><td><2cm</td><td>103/125 (82.4%)</td></tr><tr><td>≥2cm</td><td>22/125 (17.6%)</td></tr></table> Stage Not stated Histology Not stated Location <table><tr><td>UOQ</td><td>48/125 (38.4%)</td></tr><tr><td>Other</td><td>76/125 (60.8%)</td></tr></table> Palpability Not stated Multifocality/multicentricity Not stated **Axilla characteristics** Clinical axillary status Not stated **Neoadjuvant chemotherapy** <table><tr><td>Yes</td><td>31/125 (24.8%)</td></tr><tr><td>No</td><td>94/125 (75.2%)</td></tr></table>

Study identifier	Procedure	Patient characteristics
Péley, Tóth, Csuka, Sinkovics, Farkas & Köves, 2001. **Number of patients** 68 **Number of attempted mappings** 68 **Study period** December 1998 to March 2000 **Institution** Departments of Surgery, Pathology, Pathogenetics and Nuclear Medicine, National Institute of Oncology, Budapest, Hungary. **Incorporated studies** None **Inclusion/exclusion criteria** Inclusions: patients with primary palpable invasive, clinically node-negative breast cancer. Exclusions: none stated **Study included for review of...** Localisation rates and false negative rates	**Radiocolloid/dye combination** Radiocolloid only: 0 Dye only: 0 Radiocolloid and dye: 68 **Radiocolloid** Type: ^{99m}Technetium-labelled colloidal human serum albumin (Senti-Scint, NCPH-NRIRR, Budapest, Hungary). Dose: 0.4 mL, dose not stated. Colloid size: 200 to 600 nm Filtration: not stated Injection location: Subareolar: 38/68 (55.9%) Peritumourally: 30/68 (44.1%) Injection timing: injected the afternoon prior to surgery. Massage: not stated Intraoperative probe: Neoprobe 1000, Neoprobe Corp, Dublin, OH, USA: 34/68 (50%) Navigator GPS, USSC Norwalk, CT, USA: 26/68 (38.2%) Europrobe, Eurorad, Strasbourg, France: 8/68 (11.8%) **Dye** Type: 2.5% Patent blue dye (Patentblau V 2.5%, Byk Gulden Konstanz, Germany) Amount: 2 mL Injection location: peritumourally in four depots. Injection timing: dye was injected 10 minutes before surgery. Massage: not stated **Preoperative lymphoscintigraphy** Timing: performed the morning after radiocolloid injection, before surgery. **Surgery** Surgeon details: not stated Anaesthesia: not stated Axillary clearance: complete axillary node dissection Sentinel node definition: blue lymph nodes with a feeding blue lymphatic channel and/or hot lymph nodes with *in vivo* counts at least two times background tissues. Final breast procedure: Breast conserving surgery: 58/68 (85.3%) Mastectomy: 10/68 (14.7%) **Histologic analysis of sentinel nodes** Intraoperative analysis: not stated Sectioning: routine H&E staining at 2 μm levels Permanent section: H&E IHC: H&E negative nodes were serially sectioned and examined at 250 μm levels by anticytokeratin IHC (AE1/AE3). In 14 patients the SLNs were also investigated with cytokeratin 20 RT-PCR Micrometastases definition: not stated **Histologic analysis of axillary nodes** Evaluated at 1 to 3 levels according to size by routine H&E staining.	**Age** Mean 58, range 24 to 80 years. **Tumour characteristics** Biopsy method Fine needle aspiration, core biopsy, or excisional biopsy. Size ≤ 2cm: 48/68 (70.6%) >2cm but ≤ 5cm: 20/68 (29.4%) Stage pT1: 48/68 (70.6%) pT2: 20/68 (29.4%) Histology Ductal invasive: 57/68 (83.8%) Lobular invasive: 11/68 (16.2%) Location Not stated Palpability Palpable: 68/68 (100%) Multifocality/multicentricity Not stated **Axilla characteristics** Clinical axillary status Negative: 68/68 (100%) **Neoadjuvant chemotherapy** Not stated

Study identifier	Procedure	Patient characteristics
Pelosi, Baiocco, Ala, Gay, Bellò, Varetto, Giani, Bussone & Bisi, 2003. **Number of patients** 148 (150 biopsy proven breast cancers) Group 1: 99 consecutively enrolled patients with 100 breast cancers, in which mapping was performed by subdermal injection of dye and radiocolloid; Group 2: 49 consecutively enrolled patients with 50 breast cancers, in which mapping was performed by a combination of periareolar dye injection and subdermal radiocolloid injection. **Number of attempted mappings** 150 **Study period** January 2001 to July 2002 (Group 1 from January to December 2001; Group 2 from January to June 2002). **Institution** Servizio di Medicina Nucleare Universitario, Ospedale S Giovanni Battista, Torino and Reparto di Chirurgica Oncologica, Ospedale S Giovanni Battista, Torino, Italy. **Incorporated studies** Pelosi *et al.* 2002 **Inclusion/exclusion criteria** Inclusions: patients with biopsy proven breast cancer. Exclusions: patients with palpable axillary lymph nodes, tumours > 2.5 cm in diameter, multifocal or multicentric cancer and patients who were pregnant or older than 80 years. **Study included for review of...** Localisation rates	**Radiocolloid/dye combination** Radiocolloid only: 0 Dye only: 0 Radiocolloid and dye: 150 **Radiocolloid** Type: ^{99m}Tc labelled Nanocoll (Amersham-Sorin) Dose: 25 to 37 MBq in 0.5 ml. Colloid size: not stated Filtration: not stated Injection location: for palpable tumours, subdermal injection above the tumour; for non-palpable lesions, patients underwent ultrasound and/or mammography to localise the tumour, then overlying skin was marked with ink to guide injection above the tumour. Injection timing: for palpable tumours, radiocolloid injection occurred 12-24 hours before surgery. Massage: not stated Intraoperative probe: NeoProbe 2000 **Dye** Type: 1% Lymphazurin blue dye Amount: 1 ml Injection location: Group 1: subdermal injection of dye above the tumour; Group 2: injection in the periareolar area of the tumour bearing breast. Injection timing: dye was injected 10 to 20 minutes before surgery. Massage: not stated **Preoperative lymphoscintigraphy** Timing: lymphoscintigraphy was performed 1-3 hours after radiocolloid injection. **Surgery** Surgeon details: not stated Anaesthesia: not stated Axillary clearance: Level I and II ALND was perfomed if no sentinel nodes were identified or if sentinel nodes were positive for tumour metastasis. Sentinel node definition: if it was blue and/or if it had *in vivo* radioactive counts at least 3 times the background counts of the axilla. Radioactive lymph nodes were removed until the background radioactivity of the axilla was < 10% of the hottest node removed. Final breast procedure: not stated **Histologic analysis of sentinel nodes** Intraoperative analysis: not stated Sectioning: paraffin embedded, method of sectioning not stated. Permanent section: H&E IHC: lymph nodes also evaluated by cytokeratin antibody (AE1/3, monoclonal antibody, 1:250, Boehringer Mannheim, Indianapolis, IN). Micrometastases definition: not stated **Histologic analysis of axillary nodes** All axillary nodes were evaluated with standard sections stained with H&E.	**Age** Mean 61.5±10.4 (SD) years. **Tumour characteristics** Biopsy method Not stated Size Patients with tumours > 2.5 cm in diameter were excluded from the study. Stage Not stated Histology Not stated Location Not stated Palpability Palpable and non-palpable tumours were included. Multifocality/multicentricity Patients with multifocal or multicentric cancer were excluded from the study. **Axilla characteristics** Clinical axillary status Negative: 148/148 (100%) **Neoadjuvant chemotherapy** Not stated

Study identifier	Procedure	Patient characteristics
Pizzocaro, Rossini, Terzi, Farfaglia, Lazzari, Simoncini & Giubbini, 2000. **Number of patients** 83 (consecutive) **Number of attempted mappings** 83 **Study period** Not stated **Institution** Divisione di Medicina Nucleare, Secondo Reparto di Chirurgia and Divisione di Oncologia Medica, Spedali Civili, Brescia, Italy. **Incorporated studies** None **Inclusion/exclusion criteria** Inclusions: patients with monofocal T_{1-2} carcinoma, who were clinically N_0 and who underwent lymphoscintigraphy with ^{99m}Tc-colloid integrated with intraoperative SLN detection by a portable probe. Exclusions: none stated **Study included for review of...** Localisation rates and false negative rates	**Radiocolloid/dye combination** Radiocolloid only: 83 Dye only: 0 Radiocolloid and dye: 0 **Radiocolloid** Type: ^{99m}Tc-colloid Dose: 10 to 20 MBq in 0.4 to 0.6 mL. Colloid size: < 50 nm: 16/83 (19.3%) < 80 nm: 42/83 (50.6%) 200 to 3000 nm: 25/83 (30.1%) Filtration: not stated Injection location: 1 or 2 peritumoural intradermic injections with superficial lesions: 72/83 (86.7%) Ultrasound-guided peritumoural injection: 11/83 (13.3%) Injection timing: day before surgery Massage: not stated Intraoperative probe: portable probe, type not specified. **Dye** Type: dye was not used Amount: not applicable Injection location: not applicable Injection timing: not applicable Massage: not applicable **Preoperative lymphoscintigraphy** Timing: 10 minutes and 2 hours following injection; plus at 4 hours when sentinel nodes not detected at 2 hours. **Surgery** Surgeon details: not stated Anaesthesia: not stated Axillary clearance: not stated Sentinel node definition: not stated Final breast procedure: not stated **Histologic analysis of sentinel nodes** Intraoperative analysis: not stated Sectioning: not stated Permanent section: not stated IHC: immunostaining performed, antibody not specified. Micrometastases definition: not stated **Histologic analysis of axillary nodes** H&E	**Age** Not stated **Tumour characteristics** Biopsy method Not stated Size ≤ 0.5cm: 4/83 (4.8%) 0.5 to 1.0cm: 22/83 (26.5%) 1 to 2cm: 38/83 (45.8%) >2 but ≤ 5cm: 19/83 (22.9%) Stage T_{1a}: 4/83 (4.8%) T_{1b}: 22/83 (26.5%) T_{1c}: 38/83 (45.8%) T_2: 19/83 (22.9%) Histology Not stated Location Not stated Palpability Palpable and nonpalpable tumours were included. Multifocality/multicentricity Patients with monofocal cancers were included. **Axilla characteristics** Clinical axillary status Negative: 83/83 (100%) **Neoadjuvant chemotherapy** Not stated

Study identifier	Procedure	Patient characteristics
Ponzone, Biglia, Maggiorotto, Kubatzki, Elia, De Rosa & Sismondi, 2003. **Number of patients** 212 (consecutive) **Number of attempted mappings** 212 **Study period** May 1999 to May 2002 **Institution** Academic Gynaecological Oncology Unit, Nuclear Medicine Unit and Pathology Unit, Institute for Cancer Research and Treatment (IRCC) of Candiolo, Mauriziano Umberto I° Hospital, Turin, Italy. **Incorporated studies** None **Inclusion/exclusion criteria** Inclusions: patients with primary invasive breast tumours < 3 cm in diameter and no axillary lymphadenopathy. Exclusions: patients with multifocal tumours or previous excision of the primary lesion. **Study included for review of...** Localisation rates	**Radiocolloid/dye combination** Radiocolloid only: 212 Dye only: 0 Radiocolloid and dye: 0 **Radiocolloid** Type: ^{99m}Tc-colloidal albumin (Nanocoll) Dose: 300 μCi Colloid size: not stated Filtration: not stated Injection location: subdermally, exactly above tumour location. Injection timing: radiocolloid injected the day before surgery. Massage: not stated Intraoperative probe: Neoprobe®, Ethicon Endosurgery Inc., Cincinnati, USA). **Dye** Type: dye was not used. Amount: not applicable Injection location: not applicable Injection timing: not applicable Massage: not applicable **Preoperative lymphoscintigraphy** Timing: performed, timing not stated. **Surgery** Surgeon details: not stated Anaesthesia: not stated Axillary clearance: completion axillary node dissection if sentinel nodes contained metastases or if no sentinel nodes identified. Sentinel node definition: any location with discrete radioactivity separate from the injection site with more than 10 times background counts was considered a 'hot spot.' Final breast procedure: wide local excision 205/212 (96.7%); total mastectomy 7/212 (3.3%). **Histologic analysis of sentinel nodes** Intraoperative analysis: nodes cut longitudinally and imprint cytological samples were made from cut surfaces by touching to a glass slide, fixing in 95% ethanol, and Papanicolau staining. After imprint cytology, one-half was frozen for immediate examination. Sectioning: up to five frozen sections were stained with H&E. The other half of the node was used for conventional histology, method of sectioning not stated. Permanent section: H&E IHC: uncertain cases were immunostained for cytokeratins using the MNF 116 monoclonal anticytokeratin antibody (Dako, Copenhagen, Denmark). Micrometastases definition: tumour deposits measuring ≤ 2mm. **Histologic analysis of axillary nodes** Suspicious palpable nodes were submitted for histology.	**Age** Mean 58, median 59, range 33 to 82 years. **Tumour characteristics** Biopsy method Not stated Size SLN negative (n=150): Mean 1.38, range 0.07 to 3.0 cm SLN positive (n=57): Mean 1.86, range 0.7 to 3.0 cm p=0.000 between SLN positive and negative (only patients where SLN localised) Stage Tx: 13/212 (6.1%) T1a: 10/212 (4.7%) T1b: 45/212 (21.2%) T1c: 105/212 (49.5%) T2: 39/212 (18.4%) Grade I*: 33/212 (15.6%) Grade II: 112/212 (52.8%) Grade III: 67/212 (31.6%) * Elston-Ellis grading Histology Ductal: 165/212 (77.8%) Lobular: 29/212 (13.7%) Other: 18/212 (8.5%) Location UOQ: 100/212 (47.2%) LOQ: 32/212 (15.1%) UIQ: 54/212 (25.5%) LIQ: 14/212 (6.6%) Subareolar: 12/212 (5.7%) Palpability Palpable: 86/212 (40.6%) Nonpalpable: 126/212 (59.4%) Multifocality/multicentricity Patients with multifocal tumours were excluded. **Axilla characteristics** Clinical axillary status Negative: 212/212 (100%) **Neoadjuvant chemotherapy** Not stated

Study identifier	Procedure	Patient characteristics
Povoski, Dauway & Ducatman, 2002. **Number of patients** 113 (1 male) **Number of attempted mappings** 113 **Study period** January 1999 to January 2001 **Institution** Section of Surgical Oncology of the Department of Surgery, and Department of Pathology, Robert C. Byrd Health Science Center and Mary Babb Randolph Cancer Center of West Virginia University, West Virginia; Division of Surgical Oncology, Department of Surgery, The Arthur G James Cancer Hospital and Richard J Solove Research Institute, The Ohio State University, Ohio; Department of Surgery, Virgina Mason Medical Center, Washington, USA. **Incorporated studies** None **Inclusion/exclusion criteria** Inclusions: patients with newly diagnosed breast cancer (invasive and DCIS). Exclusions: patients with extensive multifocal or multicentric disease (n=7), clinically palpable axillary nodes (n=6), preoperative clinical T3 to T4 tumours with/ without preoperative chemotherapy (n=14), previous axillary surgery (n=1), patients declining SLNB (n=1)or elderly patients with known poor health/medical status with clinically negative axillae who would not be considered candidates for axillary	**Radiocolloid/dye combination** Radiocolloid only: 0 Dye only: 0 Radiocolloid and dye: 113 **Radiocolloid** Type: ^{99m}Tc-labelled sulphur colloid Dose: not stated Colloid size: not stated Filtration: filtered (0.2μm). Injection location: Group 1: intraparenchymal injection – peritumourally for patients with palpable lesions, with ultrasound guidance around an excisional biopsy site, or with image guidance (ultrasound or mammography) at the time of needle-localisation for nonpalpable tumours. Group 2: intradermal injection –either in the skin overlying a palpable tumour, around the skin incision of an excisional biopsy site, or periareolar for nonpalpable lesions, based on the clock position of the tumour. Injection timing: injected on the day of surgery, immediately after localisation using lymphoscintigraphy was completed, generally 1 to 4 hours before surgery. Massage: 2 to 3 minutes of massage generally performed for intradermal injection, but not for intraparenchymal injection. Intraoperative probe: Navigator (USSC, Norwalk, CT, USA). **Dye** Type: 1% isosulphan blue dye Amount: not stated Injection location: injection by the same route as for radiocolloid. Intraparenchymal injection was not assisted by image guidance. Injection timing: dye injected after the patients was prepared and draped. Massage: five minutes of massage generally performed after intraparenchymal injection. **Preoperative lymphoscintigraphy** Timing: performed at the discretion of the surgeon, timing was not stated; images at 10 to 15 minute intervals obtained until localisation confirmed. **Surgery** Surgeon details: two surgical oncologists, recently fellowship-trained in the techniques of sentinel node mapping and biopsy (during the period of formal axillary validation) at the Memorial Sloan-Kettering Cancer Center and the H. Lee Moffitt Cancer Center and Research Institute. Anaesthesia: general anaesthesia or monitored sedation anaesthesia. Axillary clearance: axillary clearance performed if the sentinel node had metastases on intraoperative frozen section. Sentinel node definition: 'hot' and/or blue. 'Hot' defined as a level of radioactivity ≥ 10% of the total level of radioactivity found in the hottest sentinel lymph node. Blue defined as any node stained blue and/or a contiguous blue-stained afferent lymphatic. Final breast procedure: not stated **Histologic analysis of sentinel nodes**	**Age** Median 55, range 31 to 86 years. **Tumour characteristics** Biopsy method Fine needle aspiration: 1/113 (0.9%) Core biopsy: 71/113 (62.8%) Excisional biopsy: 41/113 (36.3%) Size Median 1.8, range 0.1 to 9.0cm. Stage T1a: 6/113 (5.3%) T1b: 21/113 (18.6%) T1c: 45/113 (39.8%) T2: 26/113 (23.0%) T3: 4/113 (3.5%) DCIS: 11/113 (9.7%) *Grade I: 14/102 (13.7%) Grade II: 46/102 (45.1%) Grade III: 42/102 (41.2%) *Elson modification of the Scarff, Bloom and Richardson system, invasive cancers only, n=102. Histology Ductal: 82/102 (80.4%) Lobular: 7/102 (6.9%) Mixed ductal/lobular: 10/102 (9.8%) Mucinous: 3/102 (2.9%) Invasive cancers only, n=102. Location UOQ: 67/113 (59.3%) UIQ: 18/113 (15.9%) LOQ: 12/113 (10.6%) LIQ: 8/113 (7.1%) Central: 8/113 (7.1%) Palpability Palpable and nonpalpable tumours were included. Multifocality/multicentricity Patients with extensive multifocal or multicentric disease were excluded. **Axilla characteristics** Clinical axillary status Negative: 113/113 (100%) **Neoadjuvant chemotherapy** Some patients had received preoperative chemotherapy.

clearance (n=5). **Study included for review of...** Localisation rates	Intraoperative analysis: each node bivalved along its long axis and each half frozen and a section stained with H&E. Sectioning: remaining tissue was formalin fixed and embedded. If frozen section positive a single section made from each block; if negative 8 levels were cut on each block. Permanent section: H&E (1 section for positive; the 1st, 5th and 8th levels if negative; after September 2000 only a single section used). IHC: if permanent section was negative, IHC with pancytokeratin perfomed on a single section. Micrometastases definition: not stated **Histologic analysis of axillary nodes** Not stated	

Study identifier	Procedure	Patient characteristics
Quan, McCready, Temple & McKinnon, 2002. **Number of patients** 152 (1 male) **Number of attempted mappings** 152 **Study period** January 1997 to June 1999 **Institution** Division of General Surgery, University of Calgary, Calgary, Alberta; Division of General Surgery, University of Toronto, Toronto, Ontario, Canada. **Incorporated studies** None **Inclusion/exclusion criteria** Inclusions: patients with invasive breast cancer, diagnosed by fine needle aspiration or core or excisional biopsy, who underwent sentinel lymph node biopsy by three surgeons at the Princess Margaret Hospital, Toronto, Ontario, and the Foothills Medical Center, Calgary, Alberta within the study period. Exclusions: patients with clinically positive axillae. **Study included for review of...** Localisation rates and false negative rates	**Radiocolloid/dye combination** Radiocolloid only: not stated Dye only: 0 Radiocolloid and dye: 152 (blue dye used in some cases according to surgeon preference, numbers not stated) **Radiocolloid** Type: ^{99m}Tc-labelled sulphur colloid Dose: 1mCi in 8ml Colloid size: not stated Filtration: unfiltered Injection location: into the breast parenchyma surrounding the tumour or into the wall of the biopsy cavity, in some cases, ultrasound was used to guide the injection. Injection timing: between 2 and 24 hours before surgery. Massage: not stated Intraoperative probe: C-trak (Care Wise Medical, Morgan Hill, CA, USA). **Dye** Dye was used in some cases according to surgeon preference. Type: not stated Amount: not stated Injection location: not stated Injection timing: not stated Massage: not stated **Preoperative lymphoscintigraphy** Timing: performed, but timing not stated. **Surgery** Surgeon details: three surgeons from the Princess Margaret Hospital, Toronto, Ontario, and the Foothills Medical Center, Calgary, Alberta. Anaesthesia: general anaesthesia Axillary clearance: completion level I/II axillary dissection. Sentinel node definition: not stated, but grossly positive nodes were excluded from analysis. Final breast procedure: segmental or total mastectomy, numbers not stated. **Histologic analysis of sentinel nodes** Intraoperative analysis: not stated Sectioning: blocks 2 to 3mm thickness, 104/152 (68.4%) had serial sectioning. Permanent section: H&E IHC: 104/152 (68.4%) IHC, type not specified. Micrometastases definition: not stated **Histologic analysis of axillary nodes** H&E	**Age** Mean 52, range 35 to 75 years. (sentinel node positive patients, n=54). **Tumour characteristics** Biopsy method Patients had fine needle aspiration, core biopsy, or excisional biopsy. Size Mean 2.5, range 0.7 to 7.0 cm. (sentinel node positive patients, n=54). Stage T I: 24/54 (44.4%) T II: 25/54 (46.3%) T III: 4/54 (7.4%) Unknown: 1/54 (1.9%) (sentinel node positive patients, n=54). Histology Not stated Location Not stated Palpability Not stated Multifocality/multicentricity Not stated **Axilla characteristics** Clinical axillary status Negative: 152/152 (100%) **Neoadjuvant chemotherapy** Not stated

Study identifier	Procedure	Patient characteristics
Rahusen, Pijpers, van Diest, Bleichrodt, Torrenga & Meijer, 2000a. **Number of patients** 115 (consecutive) **Number of attempted mappings** 115 **Study period** November 1997 to March 1999 **Institution** Departments of Surgical Oncology, Nuclear Medicine and Pathology, Academic Hospital Vrije Universiteit, Amsterdam, The Netherlands. **Incorporated studies** None **Inclusion/exclusion criteria** Inclusions: tumours < 5 cm on clinical examination and the patient's consent and understanding of procedure. Exclusions: negative preoperative lymphoscintigraphy after a previous excision and when palpable axillary nodes present. **Study included for review of...** Localisation rates	**Radiocolloid/dye combination** Radiocolloid only: 0 Dye only: 0 Radiocolloid and dye: 115 **Radiocolloid** Type: ^{99m}Tc-colloidal albumin (Nanocoll, Sorin Biomedica, Saluggia, Italy). Dose: 40 to 80 MBq Colloid size: not stated Filtration: not stated Injection location: injection nto breast parenchyma around tumor in 2 to 4 depots. Injection timing: within 24 hours before surgery. Massage: not stated Intraoperative probe:Handheld gamma probe (C-trak, Care Wise Medical Products, Morgan Hill, Calif) **Dye** Type: 2.5% Patent Blue V (Guerbet, Aulnay-sous-Bois, France). Amount: 0.5 mL Injection location: intradermally in the periareolar skin corresponding with the quadrant in which the tumor resided. Injection timing: dye injected approximately 5 minutes before axilla incision. Massage: massage of injection site was routinely performed. **Preoperative lymphoscintigraphy** Timing: performed at least 2, and up to 18 hours after injection. **Surgery** Surgeon details: each participating surgeon had gained ample experience during a validation study. Anaesthesia: Not stated Axillary clearance: axillary dissection performed at same time when sentinel node positive by frozen section, not successful, or when lymphoscintigraphy showed only extra-axillary focal accumulations. All palpable enlarged non-SLNs were excised. Sentinel node definition: blue and 'hot'; a node blue only was not considered a sentinel node. The number of radioactive nodes was adequate only when residual radioactivity in the axilla was <10% of the hottest *ex vivo* node. Final breast procedure: not stated **Histologic analysis of sentinel nodes** Intraoperative analysis: nodes < 1cm in diameter were halved, and nodes ≥ 1 cm were lamellated in pieces of approximately 0.5 cm. Lymph node parts were separately frozen in Tissue-Tek compound (Sakura Finetek Europe, Zoeterwoude, The Netherlands). Quick freezing performed with a cooled flat weight to give a flat section. Frozen sections stained with H&E. Sectioning: frozen sections were cut at 4 μm. After frozen section all lymph node pieces were fixed in formalin and paraffin embedded. If the initial paraffin sections were all negative, 4 skip ribbons were cut from each block. Whne original H&E negative, 10 slides were prepared from each block. Permanent section: H&E (if initial H&E negative another H&E of 1 section stained with H&E). IHC: 1 section from each skip ribbon was used for IHC with CAM5.2 (Beckton Dickinson, San Jose, CA). Micrometastases definition: diameter < 2 mm. **Histologic analysis of axillary nodes** Any enlarged non-sentinel nodes were sent for histology.	**Age** Mean 54, range 30 to 81 years. **Tumour characteristics** Biopsy method Excisional biopsy of lumpectomy: 25/98 (25.5%) Incisional biopsy elsewhere: 4/98 (4.1%) CB of FNA: 69/98 (70.4%) (only 98 patients with a preoperative diagnosis established; patients with a failed needle biopsy diagnosis were included in the study when lesion were highly suspicious on mammography and physical examination) Size Not stated Stage Not stated Histology Invasive carcinoma: 96/106 (90.6%) DCIS: 8/106 (7.5%) Paget's disease of nipple: 2/106 (1.9%) (only SLN localised patients) Location Not stated Palpability Not stated Multifocality/multicentricity Not stated **Axilla characteristics** Clinical axillary status Negative: 106/106 (100%) **Neoadjuvant chemotherapy** Not stated

Study identifier	Procedure	Patient characteristics
Rahusen, Meijer, Taets van Amerongen, Pijpers & van Diest, 2003. **Number of patients** 67 **Number of attempted mappings** 67 **Study period** Not stated **Institution** Departments of Surgical Oncology, Radiology, Nuclear Medicine and Pathology, Academic Hospital Vrije Universiteit, Amsterdam, The Netherlands. **Incorporated studies** None **Inclusion/exclusion criteria** Inclusions: patients with nonpalpable, mammographically suspect breast lesions. Exclusions: none stated **Study included for review of...** Localisation rates	**Radiocolloid/dye combination** Radiocolloid only: 0 Dye only: 0 Radiocolloid and dye: 67 **Radiocolloid** Type: ^{99m}Tc- colloidal albumin (Nanocoll, Sorin Biomedica, Saluggia, Italy). Dose: 40 to 80 MBq Colloid size: not stated Filtration: not stated Injection location: radiocolloid injected in the breast parenchyma around the tumour (either sterotactically or with ultrasound guidance) in initial patients (n=35); later subdermal of para-areolar injections in the tumour quadrant (n=32). Injection timing: within 24 hours of surgery. Massage: not stated Intraoperative probe: C-trak (Care Wise Medical Products, Morgan Hill, CA); since 1999 Navigator (Radiation Monitoring Devices, Watertown, MA). **Dye** Type: 2.5% Patent Blue V (Guerbt, Aulnay-sous-Bois, France) Amount: 0.5ml Injection location: intradermally in the para-areolar skin in tumour quadrant. Injection timing: dye injected approximately 5 minutes before axilla incision. Massage: not stated **Preoperative lymphoscintigraphy** Timing: performed 2 to 18 hours after injection. **Surgery** Surgeon details: not stated Anaesthesia: not stated Axillary clearance: axillary lymph node dissection in patients with positive metastatic involvement of sentinel nodes, and those with invasive breast cancer with unsuccessful SLNB. Sentinel node definition: focal tracer activity and blue staining. Final breast procedure: not stated **Histologic analysis of sentinel nodes** Intraoperative analysis: not stated Sectioning: nodes < 1 cm in diameter were halved, nodes ≥ 1 cm were lamellated in parts of approximately 0.5 cm. All node pieces were fixed in formalin and paraffin embedded. If the initial paraffin sections were negative, four skip ribbons were cut from each block ie. 10 slides per block. Permanent section: H&E IHC: one section when initial sections were negative using CAM5.2 (Becton-Dickinson, San Jose, CA). Micrometastases definition: diameter < 2 mm. **Histologic analysis of axillary nodes** Pathologically enlarged non-sentinel nodes were sent separately for pathology.	**Age** Mean 61, range 33 to 84 years. **Tumour characteristics** Biopsy method Core needle biopsy: 50/67 (74.6%) Fine needle aspiration: 5/67 (7.5%) Negative needle biopsy*: 12/67 (17.9%) *lesion were highly suggestive of malignancy on mammography. Size Mean 1.2, range 0.4 to 2.6 cm (n= 51, patients with invasive malignancy) Stage Not stated Histology Preoperatively Invasive malignancy: 42/67 (62.7%) DCIS or positive cytology: 13/67 (19.4%) No tissue diagnosis: 12/67 (17.9%) Irregular density: 5 Microcalcifications: 4 Radial scar lesions: 3 Postoperatively Invasive Carcinoma: 51/67 (76.1%) DCIS: 8/67 (11.9%) No malignancy: 8/67 (11.9%) Location Not stated Palpability Nonpalpable: 67/67 (100%) Multifocality/multicentricity Not stated **Axilla characteristics** Clinical axillary status Not stated **Neoadjuvant chemotherapy** Not stated

Study identifier	Procedure	Patient characteristics
Ratanawichitrasin, Levy, Myles & Crowe, 1998. **Number of patients** 40 **Number of attempted mappings** 40 **Study period** February to June 1997 **Institution** Department of General Srugery. Cleveland Clinic Breast Center and Department of Anatomica Pathology, Cleveland Clinic Foundation, Cleveland, Ohio, USA. **Incorporated studies** None **Inclusion/exclusion criteria** Inclusions: patients with breast tumours either present or recently excised. Intraductal, invasive ductal, or invasive lobular tumours included, regardless of tumor/nodes/metastasis staging. Exclusions: patients with previous ipsilateral axillary surgery or radiation therapy, preoperative chemotherapy for breast cancer, or inflammatory breast cancer. **Study included for review of...** Localisation rates and false negative rates	**Radiocolloid/dye combination** Radiocolloid only: 0 Dye only: 40 Radiocolloid and dye: 0 **Radiocolloid** Type: radiocolloid was not used Dose: not applicable Colloid size: not applicable Filtration: not applicable Injection location: not applicable Injection timing: not applicable Massage: not applicable Intraoperative probe: not applicable **Dye** Type: 1% isosulphan blue dye (Lymphazurin, Ben Venue Labs, Bedford, OH). Amount: mean 4.0±1.2, range 2 to 5 mL. Injection location: in approximately 0.5 mL quantities into the breast parenchyma surrounding the tumour or around the prior breast biopsy site. Mean 6.2±1.3, range 4 to 8 injection sites per patient. In cases of a previous biopsy and a long excision injections made on the axillary side of the incision. Around tumor: 7/40 (17.5%) Around biopsy cavity: 33/40 (82.5%) Injection timing: within around 20 minutes of surgery (mean 19.6±12.7, range 5 to 63 minutes). Massage: injection site gently compressed for a few minutes to enhance the uptake of the dye by the lymphatic system, but with an effort to avoid potential dissemination of tumor cells. **Preoperative lymphoscintigraphy** Timing: not applicable **Surgery** Surgeon details: two experienced breast surgeons, who did not have experience with the technique before the study. Anaesthesia: general anaesthesia Axillary clearance: standard level I and II axillary clearance. Sentinel node definition: blue-staining lymphatic tract traced to blue-staining node. Final breast procedure: modified radical mastectomy 13/40 (32.5%), lumpectomy or partial mastectomy plus ALND 15/40 (37.5%), ALND alone 12/40 (30%). **Histologic analysis of sentinel nodes** Intraoperative analysis: not stated Sectioning: nodes were divided, fixed and sectioned, the method of sectioning not stated. Permanent section: H&E IHC: not stated Micrometastases definition: not stated **Histologic analysis of axillary nodes** Routine histological analysis.	**Age** Median 57, range 30 to 78 years. **Tumour characteristics** Biopsy method Not stated Size Mean 2.0±1.4 (variance not stated), range 0.5 to 6.0 cm. Stage Not stated Histology Not stated Location UOQ: 17/40 (42.5%) UIQ: 8/40 (20%) LOQ: 7/40 (17.5%) LIQ: 1/40 (2.5%) Upper central: 3/40 (7.5%) Lower central: 2/40 (5%) Subareolar: 2/40 (5%) Palpability Not stated Multifocality/multicentricity Not stated **Axilla characteristics** Clinical axillary status Not stated **Neoadjuvant chemotherapy** Patients with preoperative chemotherapy were excluded from the study.

Study identifier	Procedure	Patient characteristics
Ratanawichitrasin, Biscotti, Levy & Crowe, 1999. **Number of patients** 55 **Number of attempted mappings** 60 **Study period** September to December 1997 **Institution** Breast Center, Department of General Surgery and Department of Pathology, The Cleveland Clinic Foundation, Cleveland, Ohio, USA. **Incorporated studies** None **Inclusion/exclusion criteria** Inclusions: patients who had undergone SLNB and axillary lymph node dissection. Exclusions: patients with previous breast or axillary radiation therapy, axillary surgery or chemotherapy. **Study included for review of...** Localisation rates and false negative rates	**Radiocolloid/dye combination** Radiocolloid only: 0 Dye only: 60 Radiocolloid and dye: 0 **Radiocolloid** Type: radiocolloid was not used Dose: not applicable Colloid size: not applicable Filtration: not applicable Injection location: not applicable Injection timing: not applicable Massage: not applicable Intraoperative probe: not applicable **Dye** Type: isosulphan blue dye (Lymphazurin, Ben Venue Laboratories, Bedford, Ohio, USA). Amount: not stated Injection location: dye injected into the breast tissue around the primary tumour or around the cavity from a previous biopsy. Injection timing: not stated Massage: not stated **Preoperative lymphoscintigraphy** Timing: NA **Surgery** Surgeon details: not stated Anaesthesia: not stated Axillary clearance: axillary lymph node dissection in all patients. Sentinel node definition: first blue lymph node in the lymphatic chain. Final breast procedure: not stated **Histologic analysis of sentinel nodes** Intraoperative analysis: each node was divided into two if the diameter < 8mm, or cut into multiple sections of 3-mm thickness if the diameter was > 8 mm. A cellular smear was prepared by scraping one surface of each serial section with a slide and then smearing this material on to a second slide. This second slide, the touch imprint slide, was fixed immediately in 95% alcohol and stained with H&E. One touch imprint slide was prepared from each serial section of the SLNs for each patient, all prepared in operating room and stained by a surgeonInterpreted by cytopathologist blinded to histological results Sectioning: corresponding part of node labelled separately, formalin fixed, paraffin embedded; method of sectioning not stated. Permanent section: H&E IHC: not stated Micrometastases definition: not stated **Histologic analysis of axillary nodes** Speciments from axillary lymph node dissections were submitted separately for routine pathological examination.	**Age** Mean 56±12.8 (SD) years. **Tumour characteristics** Biopsy method Not stated Size Mean diameter 1.7± 1.1 (SD) cm. Stage Not stated Histology Invasive cancer: 17/55 (30.9%) Invasive *in situ* cancer: 34/55 (61.8%) *In situ* cancer: 3/55 (5.5%) Medullary cancer: 1/55 (1.8%) Location Not stated Palpability Not stated Multifocality/multicentricity Not stated **Axilla characteristics** Clinical axillary status Not stated **Neoadjuvant chemotherapy** Patients with previous chemotherapy were excluded.

Study identifier	Procedure	Patient characteristics
Reitsamer, Peintinger, Rettenbacher & Prokop, 2003a. **Number of patients** 30 **Number of attempted mappings** 30 **Study period** May 1998 to May 2002 **Institution** Departments of Senology and Pathology, General Hospital Salzburg, Salzburg, Austria; Departments of Gynaecology and Obstetrics, and Nuclear Medicine and Endocrinology, General Hospital Leoben, Leoben, Austria. **Incorporated studies** Rink *et al.* 2001a; Heuser *et al.* 2001 **Inclusion/exclusion criteria** Inclusions: patients with advanced breast cancer stage II or III who were treated with neoadjuvant chemotherapy. Exclusions: patients with inflammatory (T4d) or ulcerated (T4b) carcinoma. **Study included for review of...** Localisation rates and false negative rates	**Radiocolloid/dye combination** Radiocolloid only: 0 Dye only: 0 Radiocolloid and dye: 30 **Radiocolloid** Type: ^{99m}Tc labelled human albumin (Nanocoll) Dose: 30 to 60 MBq Colloid size: not stated Filtration: not stated Injection location: radiocolloid injected peritumourally. Injection timing: 16 to 18 hours before surgery. Massage: not stated Intraoperative probe: C-Trak® (Care Wise). **Dye** Type: Patent blue V® Amount: not stated Injection location: injected in subareolar location. Injection timing: 5 minutes before surgery. Massage: not stated **Preoperative lymphoscintigraphy** Timing: performed, timing not stated. **Surgery** Surgeon details: not stated Anaesthesia: not stated Axillary clearance: ALND was performed in all patients. Sentinel node definition: not stated Final breast procedure: mastectomy 10/30 (33.3%), wide excision 20/30 (66.7%). **Histologic analysis of sentinel nodes** Intraoperative analysis: not stated Sectioning: serial sections with 250 µm distance. From each level two slides taken. Permanent section: H&E (1 section from each level). IHC: cytokeratin IHC AE1/AE3 (1 section from each level). Micrometastases definition: **Histologic analysis of axillary nodes** Examined with H&E and cytokeratin IHC, as for sentinel nodes.	**Age** Median 47, range 31 to 74 years. **Tumour characteristics** Biopsy method Core biopsy: 30/30 (100%) Size Median 40.0, range 24.0 to 70.0 mm. Stage G1: 0/30 (0%) G2: 11/30 (36.7%) G3: 19/30 (63.3%) Histology Invasive ductal: 26/30 (86.7%) Invasive lobular: 4/30 (13.3%) Location Not stated Palpability Not stated Multifocality/multicentricity Not stated **Axilla characteristics** Clinical axillary status Negative: 17/30 (56.7%) Positive: 13/30 (43.3%) **Neoadjuvant chemotherapy** epirubicin/docetaxel (3 or 6 cycles): 26/30 (86.7%) exirubicin/ cyclosphosphamide (4 cycles): 4/30 (13.3%) Clinical partial response: 20/30 (66.7%) Clinical complete response: 10/30 (33.3%) Pathologic complete response: 4/30 (13.3%)

Study identifier	Procedure	Patient characteristics
Reitsamer, Peintinger, Rettenbacher, Prokop & Sedlmayer, 2003b. **Number of patients** 154 (consecutive) **Number of attempted mappings** 157 **Study period** August 1999 to August 2002 **Institution** Departments of Senology, Nuclear Medicine and Endocrinology, Pathology, and Radiotherapy and Radiooncology, General Hospital Salzburg, Salzburg, Austria; Department of Gynaecology and Obstetrics, General Hospital Bruck/Leoben, Leoben, Austria. **Incorporated studies** Rink *et al.* 2001a; Heuser *et al.* 2001 **Inclusion/exclusion criteria** Inclusions: patients with newly diagnosed T1 or T2 invasive breast cancer. Exclusions: patients with clinically or sonographically positive lymph nodes. **Study included for review of...** Localisation rates and false negative rates	**Radiocolloid/dye combination** Radiocolloid only: 0 Dye only: 0 Radiocolloid and dye: 157 **Radiocolloid** Type: ^{99m}Tc-labeled colloidal albumin (Nanocoll; Sorin Biomedica, Saluggia, Italy). Dose: 40 to 60 MBq Colloid size: not stated Filtration: not stated Injection location: peritumourally in the breast parenchyma at four points (12, 3, 6, and 9 o'clock). For nonpalpable tumours injection performed using ultrasound guidance. Injection timing: 18 to 20 hours before surgery Massage: not stated Intraoperative probe:Gamma probe C-Trak (Care Wise, Morgan Hill, CA, USA) **Dye** Type: Patent Blue V (Laboratoire Guerbet, Aulnay-sous-Bois, France). Amount: 2 mL Injection location: subcutaneously into subareolar plexus. Injection timing: dye was injected after preparing the patient for surgery and sterile draping, approximately 5 minutes before axillary incision.. Massage: gentle massage for exactly 5 minutes. **Preoperative lymphoscintigraphy** Timing: 1 to 2 hours after tracer injection, and again 18 hours later on day of surgery, before patient moved to operating room. **Surgery** Surgeon details: not stated Anaesthesia: not stated Axillary clearance: ALND performed in all patients with multifocal breast cancer. No ALND were performed in patients with unifocal breast cancer if SLN negative. Performed in patients with positive sentinel nodes. Sentinel node definition: first blue lymph node to which a blue lymph channel was leading. Final breast procedure: wide excision 137/157 (87.3%), mastectomy 20/157 (12.7%). **Histologic analysis of sentinel nodes** Intraoperative analysis: frozen section intraoperatively. Sectioning: after frozen sections prepared nodes were cut into 2- to 3-mm slices and embedded in paraffin. Paraffin blocks were cut in 250 µm levels. Permanent section: H&E (1 section from each level) IHC: cytokeratin IHC using AE1/3 (1 section from each level). Micrometastases definition: not stated **Histologic analysis of axillary nodes** Not stated	**Age** Mean 58.2, median 59, range 22 to 84 years. **Tumour characteristics** Biopsy method High-speed core needle biopsy. Size Mean 19.1, median 18, range 5 to 45 mm. < 10 mm: 15/157 (9.6%) ≥ 10 but < 20 mm: 82/157 (52.2%) ≥ 20 but < 50 mm: 60/157 (38.2%) (per tumour) Stage T1: 97/157 (61.8%) T2: 60/157 (38.2%) G1: 9/157 (5.7%) G2: 106/157 (67.5%) G3: 42/157 (26.8%) (per tumour) Histology Invasive ductal: 142/157 (90.4%) Invasive lobular: 15/157 (9.6%) (per tumour) No ductal carcinoma *in situ* patients included Location Left side: 81/154 (52.6%) Right side: 70/154 (45.5%) Bilateral: 3/154 (1.9%) (per patient) UOQ: 91(58.0%) LOQ: 27(17.2%) UIQ: 23(14.6%) LIQ: 10(6.4%) Centrally: 6(3.8%) (per tumour) Palpability Not stated Multifocality/multicentricity Not stated **Axilla characteristics** Clinical axillary status Negative: 154/154 (100%) **Neoadjuvant chemotherapy** Not stated

Study identifier	Procedure	Patient characteristics
Rettenbacher, Kässmann, Galvan, Menzel, Reitsamer & Holzmannhofer, 2000. **Number of patients** 45 (consecutive) **Number of attempted mappings** 45 **Study period** Not stated **Institution** Institute für Nuklearmedizin und Endokrinologie und Sonderfrauenklinik, Landeskliniken Salzburg, Austria. **Incorporated studies** None **Inclusion/exclusion criteria** Inclusions: patients with palpable invasive breast cancer. Exclusions: presence of clinically suspicious axillary nodes, pregnancy, previous axillary lymphadenectomy or multiple breast cancer tumours. **Study included for review of...** Localisation rates	**Radiocolloid/dye combination** Radiocolloid only: 25 Dye only: 0 Radiocolloid and dye: 20 **Radiocolloid** Type: ^{99m}Tc- nanocolloid Dose: Peritumourally: 30 MBq (~1ml; 4 aliquots at 3, 6, 9 and 12 o'clock positions) Intradermally: 30 MBq (~0.5ml; 4 aliquots, 1 cm apart) Note: patients had both injections. Colloid size: 5 to 80 nm Filtration: not stated Injection location: peritumoural around primary tumour and intradermally above tumour. Injection timing: peritumourally around primary tumour on first day, intradermally above tumour on separate day. Massage: short massage of the injected area. Intraoperative probe: C-Trak (Care Wise, Morgan Hill, CA, USA). **Dye** Type: Patent blue V Amount: not stated Injection location: dye was injected peritumourally. Injection timing: dye was injected at surgery. Massage: not stated **Preoperative lymphoscintigraphy** Timing: performed twice on two separate days. Dynamic images up to 10 minutes, followed by static images up to 18 hours (20, 40, 60 minutes and 18 hours) when injecting peritumourally and up to 1 hour when injecting intradermally. **Surgery** Surgeon details: two surgeons who had performed more than 50 SLN biopsies using lymphoscintigraphy and a hand-held gamma probe. Anaesthesia: not stated Axillary clearance: complete axillary dissection performed if one of the methods didn't detect a SLN or if the excised SLN tested positive for metastatic disease. Sentinel node definition: not stated Final breast procedure: not stated **Histologic analysis of sentinel nodes** Intraoperative analysis: not stated Sectioning: not stated Permanent section: H&E IHC: cytokeratin AE1/3 Micrometastases definition: not stated **Histologic analysis of axillary nodes** H&E	**Age** Mean 58, range 34 to 84 years. **Tumour characteristics** Biopsy method Core needle biopsy at least one week before surgery. Size Mean 2.1, range 1.0 to 5.0 cm. Stage Not stated Histology Not stated Location Lateral: 27/45 (60%) Central: 8/45 (17.8%) Medial: 10/45 (22.2%) Palpability Palpable: 45/45 (100%) Multifocality/multicentricity Patients with multiple tumours were excluded from the study. **Axilla characteristics** Clinical axillary status Negative: 45/45 (100%) **Neoadjuvant chemotherapy** 2/45 (4.4%) patients had undergone previous chemotherapy.

Study identifier	Procedure	Patient characteristics
Rink, Heuser, Fitz, Schroth, Weller & Zippel, 2001b. **Number of patients** 155 (consecutive) **Number of attempted mappings** 155 **Study period** Not stated **Institution** Departments of Nuclear Medicine, Gynecology and Pathology, Municipal Hospital, Hanau, Germany. **Incorporated studies** Rink *et al.* 2001a; Heuser *et al.* 2001 **Inclusion/exclusion criteria** Inclusions: women with breast cancer stage Tis to T2, scheduled for lumpectomy or mastectomy and axillary clearance. Exclusions: patients with stage T3 and T4 tumours, due to the known high failure rate for sentinel node detection plus the necessity to perform axillary clearance anyway due to an increased risk of axillary involvement. **Study included for review of...** Localisation rates and false negative rates	**Radiocolloid/dye combination** Radiocolloid only: 155 Dye only: 0 Radiocolloid and dye: 0 **Radiocolloid** Type: ^{99m}Tc-labelled human serum albumin (Nanocoll®, Amersham Buchler GmbH & Co. KG, Braunschweig, Germany). Dose: four injections of 10 to 15MBq in 0.1ml physiologic saline. Colloid size: <80nm Filtration: not stated Injection location: injected at the 3, 6, 9 and 12 o'clock positions in the skin (intra- and subdermally) overlying the tumour to make sure that the entire mass was surrounded. In the case of a nonpalpable tumour, the skin projection determined by mammography, ultrasound or MRI. Injection timing: 3 to 20 hours before surgery. Massage: not stated Intraoperative probe: Navigator® (Auto Suture Deutschland GmbH, Tönisvorst, Germany); Europrobe® with CdTe probe (Eurorad, Strasbourg Cedex 2, France). **Dye** Type: dye was not reported. Amount: not applicable Injection location: not applicable Injection timing: not applicable Massage: not applicable **Preoperative lymphoscintigraphy** Timing: scans obtained once between 2.5 and 18 hours after radiocolloid injection. In first 10 patients obtained after 30 minutes, 3, 5 and 15 to 18 horus. **Surgery** Surgeon details: surgery was always performed by the same experienced team. Anaesthesia: not stated Axillary clearance: complete axillary clearance in all patients. Sentinel node definition: not stated Final breast procedure: not stated **Histologic analysis of sentinel nodes** Intraoperative analysis: not stated Sectioning: sliced in blocks of 3 to 5mm thickness if >5mm, otherwise embedded whole; 2 to 3 sections taken from each block; in case of nodes with detectable radioactivity serial section of up to 10 sections per block performed. Permanent section: H&E (up to 10 sections) IHC: if H&E sections did not reveal metastases, at least 1 section per block was examined using the KL1 cytokeratin antibody. Micrometastases definition: not stated **Histologic analysis of axillary nodes** 2 to 3 sections per block examined with H&E.	**Age** Not stated **Tumour characteristics** Biopsy method Core biopsy: 60/155 (38.7%) Excisional: 23/155 (14.8%) No biopsy*: 72/155 (46.5%) * carcinoma suspected by physical examination, mammorgarphy and breast ultrasound. Size Tis (size not specified): 9/155 (5.8%) ≤ 2cm: 82/155 (52.9%) >2cm but ≤ 5cm: 64/155 (41.3%) Stage Tis: 9/155 (5.8%) T1: 82/155 (52.9%) T2: 64/155 (41.3%) Histology Not stated Location Not stated Palpability Not stated Multifocality/multicentricity 12/155 (7.7%) patients had multifocal cancer found during surgery. **Axilla characteristics** Clinical axillary status Negative: 139/155 (89.7%) Suspicious: 16/155 (10.3%) **Neoadjuvant chemotherapy** Not stated

Study identifier	Procedure	Patient characteristics
Rodier, Routiot, Mignotte, Janser, Bremond, David, Barlier, Ghnassia, Treilleux, Chassagne & Velten, 2000. **Number of patients** 73 **Number of attempted mappings** 74 **Study period** January 1996 to June 1997 **Institution** Department of Surgical Oncology, Paul Strauss Compreshensive Cancer Center, Strasbourg Cedex and Léon Bérard Comprehensive Cancer Center, Lyon Cedex, France. **Incorporated studies** Rodier *et al.* 1996; Rodier and Janser, 1997 **Inclusion/exclusion criteria** Inclusions: patients with invasive, operable (cT0, cT1, cT2 <3cm) breast cancer referred to the French Comprehensive Cancer Centers of Strasbourg (n=41) and Lyon (n=32). Exclusions: pregnancy, large tumours (cT2 >3cm, cT3 and cT4), multicentric tumours, metastatic disease, allergic patients (to avoid any patent blue dye induced anaphylactic reactions), patients with previous breast tumour excision or axillary surgery, or treated with preoperative chemotherapy or radiotherapy. **Study included for review of...** Localisation rates and false negative rates	**Radiocolloid/dye combination** Radiocolloid only: 0 Dye only: 73 Radiocolloid and dye: 0 **Radiocolloid** Radiocolloid was not used. Type: not applicable Dose: not applicable Colloid size: not applicable Filtration: not applicable Injection location: not applicable Injection timing: not applicable Massage: not applicable Intraoperative probe: not applicable **Dye** Type: Patent blue dye (Guerbet, Aulnany-sous-Bois, France). Amount: 2ml Injection location: four peritumoural injections of 0.5ml aliquots. Nonpalpable lesions were localised by needle puncture with intramammary wire setting or by skin reference marks. Injection timing: 10 minutes before surgery. Massage: gentle circular motions of the breast performed after injection. **Preoperative lymphoscintigraphy** Timing: not applicable **Surgery** Surgeon details: surgery was performed by four senior surgeons (Rodier, Janser, Mignotte and Bremond). Anaesthesia: not stated Axillary clearance: levels I and II, *en bloc* for modified radical mastectomy. Sentinel node definition: blue stained nodes. Final breast procedure: breast conservation surgery 60/74 (81.1%); modified radical mastectomy 14/74 (18.9%). **Histologic analysis of sentinel nodes** Intraoperative analysis: frozen sections not used routinely. Sectioning: each sentinel node was cut into sections of 2 to 3mm and embedded in paraffin. Multiple step sections used in sentinel nodes free of metastases. Permanent section: H&E IHC: not stated Micrometastases definition: not stated **Histologic analysis of axillary nodes** H&E	**Age** Mean 59.5, range 39 to 80 years. **Tumour characteristics** Biopsy method Fine-needle or core biopsy: 74/74 (100%) Size Mean diameter 1.45, range 0 to 3cm. Stage cT0: 13/74 (17.6%) cT1: 47/74 (63.5%) cT2 <3cm: 14/74 (18.9%) pT1a: 5/74 (6.8%) pT1b: 13/74 (17.6%) pT1c: 34/74 (45.9%) pT2: 22/74 (29.7%) Grade 1*: 37/74 (50.0%) Grade 2: 27/74 (36.5%) Grade 3: 8/74 (10.8%) Note: c: clinical tumour stage: p: histopathologic tumour stage. *: Scarff Bloom Richardson grade Histology Not stated Location Outer quadrant: 44/74 (59.5%) Inner quadrant: 17/74 (23.0%) Centre-line or retroareolar: 13/74 (17.6%) Palpability Palpable: 61/73 (83.6%) Nonpalpable: 12/73 (16.4%) Multifocality/multicentricity Patients with multicentric tumours were excluded. **Axilla characteristics** Clinical axillary status Negative: 70/74 (94.6%) Positive: 4/74 (5.4%) **Neoadjuvant chemotherapy** Patients with neoadjuvant chemotherapy were excluded.

Study identifier	Procedure	Patient characteristics
Roumen, Valkenburg & Geuskens, 1997. **Number of patients** 83 **Number of attempted mappings** 83 **Study period** December 1995 to June 1997 **Institution** Departments of Surgery and Nuclear Medicine, Sint Joseph Hospital, The Netherlands. **Incorporated studies** None **Inclusion/exclusion criteria** Inclusions: patients with potentially curable T1/T2, clinically N0 breast cancer. Exclusions: none stated **Study included for review of...** Localisation rates and false negative rates	**Radiocolloid/dye combination** Radiocolloid only: 83 Dye only: 0 Radiocolloid and dye: 0 **Radiocolloid** Type: ^{99m}TC-colloidal albumin (Solco R/Nanocoll, Sorin Biomedica Diagnostics, Vercelli, Italy). Dose: 2 ml 60MBq Colloid size: not stated Filtration: not stated Injection location: peritumourally Injection timing: radiocolloid injected either during the morning of surgery, or the afternoon of the day before. Massage: not stated Intraoperative probe: RMD CTC-4 **Dye** Type: not stated Amount: not stated Injection location: not stated Injection timing: not stated Massage: not stated **Preoperative lymphoscintigraphy** Timing: performed 4 or 18 hours after radiocolloid injection. **Surgery** Surgeon details: not stated Anaesthesia: not stated Axillary clearance: performed, levels not stated Sentinel node definition: the highest activity in the axillary specimen was defined as the surgical sentinel node. Final breast procedure: breast conserving 51/83 (61%); modified radical mastectomy 32/83 (29%). **Histologic analysis of sentinel nodes** Intraoperative analysis: not stated Sectioning: not stated Permanent section: H&E IHC: not stated Micrometastases definition: not stated **Histologic analysis of axillary nodes** Routine H&E staining.	**Age** Mean 59, range 37 to 86 years. **Tumour characteristics** Biopsy method Excisional biopsy was performed in at least 28/83 patients. Size Mean 21, range 2 to 60 mm. Stage T1 to T2 Histology Infiltrating ductal: 58/83 (69.9%) Infiltrating lobular: 20/83 (24.1%) Other: 5/83 (6%) Location UOQ: 30/83 (36.1%) UIQ: 12/83 (14.5%) LOQ: 17/83 (20.5%) LIQ: 8/83 (9.6%) Upper central: 7/83 (8.4%) Lower central: 2/83 (2.4%) Subareolar: 7/83 (8.4%) Right: 36/83 (43.4%) Left: 47/83 (56.6%) Palpability Not stated Multifocality/multicentricity Not stated **Axilla characteristics** Clinical axillary status N0: 83/83 (100%) **Neoadjuvant chemotherapy** Not stated

Study identifier	Procedure	Patient characteristics
Rubio, Korourian, Cowan, Krag, Colvert & Klimberg, 1998b. **Number of patients** 55 **Number of attempted mappings** 55 **Study period** March 1996 to August 1997 **Institution** Department of Surgery, Division of Surgical Oncology and the Departments of Pathology and Radiology, University of Arkansas for Medical Sciences, Arkansas Cancer Research Center, John L. McClellan Veteran's Administration Hospital, Little Rock, Arkansas; and the Department of Surgery, University of Vermont, Burlington, Vermont, USA. **Incorporated studies** Rubio *et al.* 1998a **Inclusion/exclusion criteria** Inclusions: patients with operable invasive breast cancer documented by FNA, core biopsy or excisional biopsy. All patients were clinically node-negative by physical examination. Exclusions: patients with prior axillary operation, multiple primary tumours and pregnancy were excluded. **Study included for review of...** Localisation rates and false negative rates	**Radiocolloid/dye combination** Radiocolloid only: 55 Dye only: 0 Radiocolloid and dye: 0 **Radiocolloid** Type: ^{99}Tc sulphur colloid (CIS, US Inc, Bedford, Massachusetts). Dose: 1.0 mCi; 4 ml (1.0 ml per injection site; diluted in saline). Colloid size: not stated Filtration: not stated Injection location: injected superior, inferior, medial and lateral to the tumour but not into the tumour or biopsy cavity. Injection timing: radiocolloid injection performed on morning of surgery, 30 minutes to 6 hours before patients taken to operating room. Massage: not stated Intraoperative probe: C-Trak (Carewise Medical, Morgan Hill, California). **Dye** not used Type: not applicable Amount: not applicable Injection location: not applicable Injection timing: not applicable Massage: not applicable **Preoperative lymphoscintigraphy** Timing: lymphoscintigraphy was not performed. **Surgery** Surgeon details: all operations were performed by the same surgeon. Timing: patients came to the operating room 30 minutes to 6 hours after radiocolloid injection. Anaesthesia: not stated Axillary clearance: level I and II ALND; 32.4% had only ALND at time of SLNB, having already had a definitive breast segmentectomy. Sentinel node definition: areas of radiolocalisation, apart from the diffusion zone, were named 'hot spots' measuring at least 25 counts per 10 seconds. Nodes with ≥ 10% counts of the 'hot spot' were removed and termed radiolabelled lymph nodes. Final breast procedure: Modified radical mastectomy: 21/55 (38.2%) Breast conservation: 34/55 (61.8%) ALND alone: 11/55 (20.0%) **Histologic analysis of sentinel nodes** Intraoperative analysis: touch preparations were done on the radiolabeled lymph nodes as previously reported (Rubio *et al.* 1998). Sectioning: not stated Permanent section: nodes were processed for permanent section. IHC: not stated Micrometastases definition: not stated **Histologic analysis of axillary nodes** Not stated	**Age** Mean 56, range 29 to 79 years. **Tumour characteristics** Biopsy method FNA: 17/55 (30.9%) Core biopsy: 12/55 (21.8%) Excisional biopsy: 26/55 (47.3%) Size Pathological mean tumour size 2, range 0.2 to 9cm. ≤ 1 cm: 17/55 (30.9%) > 1 cm but ≤ 2 cm: 18/55 (32.7%) > 2 cm: 20/55 (36.4%) Stage Stage 1: 28/55 (50.9%) Stage II: 25/55 (45.5%) Stage III: 2/55 (3.6%) Histology (From Rubio *et al.* 1998b – Most of the tumours were invasive ductal carcinoma (50/55 (90.9%) and only 5/50 (9.1%) were invasive lobular carcinoma.) Location UOQ: 23/56 (41.1%) UIQ: 7/56 (12.5%) LIQ: 5/56 (8.9%) LOQ: 7/56 (12.5%) Central upper: 10/56 (17.9%) Central lower: 4/56 (7.1%) Note: numbers add to 56. Palpability Not stated Multifocality/multicentricity Patients with multiple primary tumours were excluded from the study. **Axilla characteristics** Clinical axillary status Negative: 55/55 (100%) **Neoadjuvant chemotherapy** Not stated

Study identifier	Procedure	Patient characteristics
Rufino, Baracat, Madeiro & Lippi, 2003. **Number of patients** 25 **Number of attempted mappings** 25 **Study period** March 1998 to September 1998 **Institution** Department of Gynaecology, Piauí State University and Division Obstetrics and Gynaecology, Hospital do Servidor Público Estadual, São Paulo, Brazil, South America. **Incorporated studies** None **Inclusion/exclusion criteria** Inclusions: patients with palpable T1 or T2 tumours and clinically negative axillary lymph nodes. Exclusions: none stated **Study included for review of...** Localisation rates and false negative rates	**Radiocolloid/dye combination** Radiocolloid only: 0 Dye only: 25 Radiocolloid and dye: 0 **Radiocolloid** Radiocolloid was not used. Type: not applicable Dose: not applicable Colloid size: not applicable Filtration: not applicable Injection location: not applicable Injection timing: not applicable Massage: not applicable Intraoperative probe: not applicable **Dye** Type: 2.5% blue-violet dye Amount: 4ml Injection location: peritumoural Injection timing: dye was injected 15 to 20 minutes before surgery. Massage: posterior massage at the place of injection for 3 to 5 minutes. **Preoperative lymphoscintigraphy** Timing: not applicable **Surgery** Surgeon details: not stated Anaesthesia: not stated Axillary clearance: performed in all patients at levels I, II and III. Sentinel node definition: blue stained lymphatic channels were searched for, with stained or unstained lymph nodes. Final breast procedure: quadrantectomy 5/25 (20.0%); Patey modified radical mastectomy 20/25 (80.0%). **Histologic analysis of sentinel nodes** Intraoperative analysis: not stated Sectioning: nodes fixed in 10% formol, method of sectioning not stated. Permanent section: not stated IHC: not stated Micrometastases definition: not stated **Histologic analysis of axillary nodes** Not stated	**Age** Mean 62.5 ± 13, range 42 to 82 years. (variance not stated) **Tumour characteristics** Biopsy method Incisional biopsy: 25/25 (100%) Size ≤2cm: 8/25 (32.0%) >2cm but ≤ 5cm: 17/25 (68.0%) Stage T1: 8/25 (32.0%) T2: 17/25 (68.0%) Histology Not stated Location External quadrants: 15/25 (60.0%) Internal quadrants: 10/25 (40.0%) Palpability Palpable: 25/25 (100%) Multifocality/multicentricity Two patients had multicentric tumours where the anatomicopathological examination of the mastectomy material showed another tumour focus 3cm away from the initial lesion. **Axilla characteristics** Clinical axillary status Negative: 25/25 (100%) **Neoadjuvant chemotherapy** Not stated

Study identifier	Procedure	Patient characteristics
Sabel, Schott, Kleer, Merajver, Cimmino, Diehl, Hayes, Chang & Pierce, 2003. **Number of patients** 25 **Number of attempted mappings** 26 **Study period** January 2001 to July 2002 **Institution** Breast Oncology Program, Division of Medical Oncology, Department of Pathology, Department of Radiation Oncology, University of Michigan Comprehensive Cancer Center, Ann Arbor, Michigan; Division of Surgical Oncology, Cancer Center, E. Medical Center Drive, Ann Arbor, Michigan, USA. **Incorporated studies** None **Inclusion/exclusion criteria** Inclusions: patients with clinically negative nodes with clinical primary tumors ≥ 1.5cm. Exclusions: none stated **Study included for review of...** Localisation rates	**Radiocolloid/dye combination** Radiocolloid only: 0 Dye only: 0 Radiocolloid and dye: 26 **Radiocolloid** Type: ^{99m}Tc labeled sulphur colloid Dose: 3 to 4 mCi Colloid size: not stated Filtration: not stated Injection location: radiocolloid injected intradermally or perilesionally. Injection timing: not stated Massage: not stated Intraoperative probe: Navigator (US Surgical, Norwalk, CT). **Dye** Type: isosulphan blue dye Amount: 3 to 5 ml Injection location: performed in 4 quadrants adjacent to the tumour. Injection timing: Massage: not stated **Preoperative lymphoscintigraphy** Timing: Not stated **Surgery** Surgeon details: not stated Anaesthesia: not stated Axillary clearance: standard level I and II ALND was performed at the time of extirpative surgery after completion of chemotherapy. Sentinel node definition: nodes with evidence of blue dye uptake or radioactivity. Lymph nodes that appeared suspicious on exploration were also labelled as sentinel nodes. Final breast procedure: mastectomy 9/25 (36%; 1/25 had bilateral mastectomy) lumpectomy 17/25 (68%; 3 of these ultimately had a mastectomy). **Histologic analysis of sentinel nodes** Intraoperative analysis: not stated Sectioning: each node cut along its longitudinal axis into 1.5 to 2 mm sections, paraffin embedded, and each block sectioned at three levels. Permanent section: not stated IHC: no cytokeratin stain was perfomed. Micrometastases definition: not stated **Histologic analysis of axillary nodes** Not stated	**Age** Mean 45.13±9, range 31 to 65 years. (variance not stated) **Tumour characteristics** Biopsy method Not stated Size Mean 2.90±1.0, range 1.5 to 4.7 cm. Stage T1c 5/25 (20%) T2 20/25 (80%) Histology Not stated Location Not stated Palpability Not stated Multifocality/multicentricity Not stated **Axilla characteristics** Clinical axillary status Negative 25/25 (100%) **Neoadjuvant chemotherapy** SLNB performed prior to initiating neoadjuvant chemotherapy. In patients who presented with clinical evidence of nodal involvement, ALND was performed after chemotherapy (n=12). Chemotherapy included doxorubicin and docetaxel.

Study identifier	Procedure	Patient characteristics
Sachdev, Murphy, Derzie, Jaffer, Bleiweiss & Brower, 2002. **Number of patients** 212 (consecutive) **Number of attempted mappings** 212 **Study period** July 1997 to December 1999 **Institution** Departments of Pathology and Surgery, Mount Sinai Medical Center, New York, New York, USA. **Incorporated studies** None **Inclusion/exclusion criteria** Inclusions: patients with breast cancer who underwent sentinel lymph node biopsy followed by completion axillary dissection. Exclusions: during the study, no sentinel lymph node was identified in 22 patients. These patients were excluded from further statistical analysis. **Study included for review of...** Localisation rates and false negative rates	**Radiocolloid/dye combination** Radiocolloid only: 0 Dye only: 149 (18 patients excluded as procedure unsuccessful) Radiocolloid and dye: 63 (4 excluded as procedure unsuccessful) **Radiocolloid** Type: ^{99m}Tc- sulfur Dose: not stated Colloid size: not stated Filtration: not stated Injection location: at the site of the primary lesion. Injection timing: radiocolloid injected 1 to 4 hours preoperatively. Massage: not stated Intraoperative probe: not stated **Dye** Type: 1% isosulphan blue dye Amount: not stated Injection location: at the site of the primary lesion. Injection timing: dye was injected intraoperatively. Massage: not stated **Preoperative lymphoscintigraphy** Timing: whether lymphoscintigraphy was performed in patients injected with radiocolloid was not stated. **Surgery** Surgeon details: not stated Anaesthesia: not stated Axillary clearance: completion axillary clearance dissection was performed. Sentinel node definition: not stated Final breast procedure: breast conservation surgery or modified radical mastectomy. **Histologic analysis of sentinel nodes** Intraoperative analysis: not stated Sectioning: nodes bisected; 5 stained levels of each block were made. Permanent section: H&E IHC: cytokeratin IHC (CAM5.2 and AE1/AE3). (5 levels) Micrometastases definition: <1mm **Histologic analysis of axillary nodes** Routine H&E staining.	**Age** Mean 57 years **Tumour characteristics** Biopsy method Core biopsy, excisional biopsy or needle localisation. Size Mean 1.3 cm Stage T1a: 23/190 (12.1%) T1b: 53/190 (27.9%) T1c: 84/190 (44.2%) T2: 29/190 (15.3%) T3: 0/190 (0%) T4: 1/190 (0.5%) Histology Lymphatic invasion: 53/190 (27.9%) No lymphatic invasion: 137/190 (72.1%) Invasive ductal: 129/190 (67.9%) Invasive lobular: 29/190 (15.3%) Invasive ductal and lobular: 32/190 (16.8%) Location Not stated Palpability Not stated Multifocality/multicentricity There were distance metastases in 2/190 patients. **Axilla characteristics** Clinical axillary status Not stated **Neoadjuvant chemotherapy** Not stated

Study identifier	Procedure	Patient characteristics
Sardi, Spiegler, Colandrea, Frishberg, Singh, Regan, Totoonchie, Merchant, Hochuli, Setya & Singer, 2002. **Number of patients** 58 **Number of attempted mappings** 58 **Study period** April 1998 to May 1999 **Institution** Departments of Surgery, Nuclear Medicine, Pathology, Radiology and Clinical Research Center, St. Agnes Hospital, Baltimore, Maryland, USA. **Incorporated studies** Rehman *et al.* 1999 **Inclusion/exclusion criteria** Inclusions: patients scheduled to undergo either breast-conserving therapy or modified radical mastectomy at a community teaching hospital, all diagnosed with invasive breast carcinoma. Exclusions: none stated **Study included for review of...** Localisation rates and false negative rates	**Radiocolloid/dye combination** Radiocolloid only: 1 Dye only: 2 (patients refused radiocolloid) Radiocolloid and dye: 55 **Radiocolloid** Type: ^{99m}Tc -labelled sulphur colloid. Dose: 0.3 to 1.96 mCi; diluted to 4 ml. Colloid size: not stated Filtration: filtered Injection location: injected in four quadrants of the primary tumour in patients previously diagnosed by core needle biopsy. In patients who had stereotactic-guided needle biopsy, the radiocolloid was given during needle localisation. In those with previously excised lesions, the radiocolloid was injected around the biopsy cavity. Injection timing: radiocolloid injection was 2 to 3 hours before surgery. Massage: not stated Intraoperative probe: Neo2000 (Neoprobe Corporation, Dublin, Ohio) **Dye** Type: isosulphan blue dye Amount: 3 to 5 ml Injection location: dye was injected around the periphery of the tumour or the wall of the biopsy site. (intradermal injection was avoided to prevent tattooing that may persist for a long time). Injection timing: dye was injected before incision. Massage: injection site was then massaged for a period of 3-5 minutes. **Preoperative lymphoscintigraphy** Timing: patients underwent lymphoscintigraphy 2 hours after radiocolloid injection. **Surgery** Surgeon details: ten surgeons participated in the study. Anaesthesia: not stated Axillary clearance: complete ALND was performed on all patients. Sentinel node definition: all nodes with radioactivity counts *ex vivo* or stained blue were considered sentinel nodes. Final breast procedure: breast conserving methods (lumpectomy, ALND and irradiation; 17/58, 29.3%); modified radical mastectomy, 41/58 (70.7%). **Histologic analysis of sentinel nodes** Intraoperative analysis: not stated Sectioning: seven slices, each 5 µm thick were made of each node. Permanent section: H&E (5 sections) IHC: if there was no evidence of tumour cells with H&E staining, the remaining 2 slices were IHC stained with cytokeratin. The pan-keratin monoclonal mouse antibodies consisted of clonse AE1, AE3, CAM 5.2, and 35BBH11 (Ventana Medical System, Tucson, AZ, USA). (nodes positive by this method underwent further morphological examination to confirm the presence of malignant epithelial cells and not stains picked up by dendritic cells or plasma cells). Micrometastases definition: occult micrometastasis (tumour detected by IHC) **Histologic analysis of axillary nodes** H&E only.	**Age** Not stated **Tumour characteristics** Biopsy method Core, stereotactic or open biopsy. Size Not stated Stage Not stated Histology Ductal 53/58 (91.4%) Lobular 3/58 (5.2%) Tubular 1/58 (1.7%) DCIS 1/58 (1.7%) Location Not stated Palpability Not stated Multifocality/multicentricity Not stated **Axilla characteristics** Clinical axillary status Not stated **Neoadjuvant chemotherapy** Not stated

Study identifier	Procedure	Patient characteristics
Sato, Tamaki, Takeuchi, Tsuda, Kosuda, Kusano, Hiraide & Mochizuki, 2001a. **Number of patients** 110 (results reported for 108 patients with successful SLNB) **Number of attempted mappings** 110 **Study period** May 1997 to February 2001 **Institution** Department of Surgery I, Department of Pathology II, Department of Radiocology and Research Institute, National Defense Medical College, Tokorozawa, Saitama, Japan. **Incorporated studies** Sato *et al.* 2000; Sato *et al.* 2001b; Ishikawa *et al.* 2002 **Inclusion/exclusion criteria** Inclusions: patients with an operable breast tumour that appeared malignant on fine needle aspiration cytology or core-needle biopsy. Exclusions: patients with a large biopsy cavity, tumour >5cm (clinically), clinical evidence of axillary node metastases or neoadjuvant chemotherapy had been administered. **Study included for review of...** False negative rates	**Radiocolloid/dye combination** Radiocolloid only: 0 Dye only: 0 Radiocolloid and dye: 110 **Radiocolloid** Type: ^{99m}Tc-labelled tin colloid (Nihon Mediphysics, Tokyo, Japan). Dose: 74 to 222MBq in 1 to 3ml. Colloid size: not stated Filtration: not stated Injection location: injected subdermally and peritumourally. Injection timing: approximately 2 hours before surgery. Massage: not stated Intraoperative probe: Auto Well Gamma System (Aloka, Tokyo, Japan); Navigator (Auto Suture Japan, Tokyo, Japan). **Dye** Type: indigocarmine Amount: 5ml Injection location: injected concomitantly with the radiocolloid to make the colloid run into the sentinel nodes by an increase in interstitial pressure. Injection timing: approximately 2 hours before surgery. Massage: not stated **Preoperative lymphoscintigraphy** Timing: lymphoscintigraphy was not reported. **Surgery** Surgeon details: surgery was performed by one surgeon. Anaesthesia: not stated Axillary clearance: dissection of at least level I and II. Sentinel node definition: high radioactive nodes. Final breast procedure: modified radical mastectomy 66/108 (61.1%); quadrantectomy 6/108 (5.6%); lumpectomy 36/108 (33.3%). **Histologic analysis of sentinel nodes** Intraoperative analysis: not stated Sectioning: section(s) taken at the level of the hilus. Permanent section: H&E IHC: not stated Micrometastases definition: not stated **Histologic analysis of axillary nodes** H&E	**Age** Mean 54.8, range 28 to 87 years. **Tumour characteristics** Biopsy method Patient had a FNA, CB or exicisional biopsy. Size ≤ 1cm: 9/108 (8.3%) >1 to ≤ 2cm: 36/108 (33.3%) >2 to ≤ 3cm: 33/108 (31.6%) >3cm: 30/108 (27.8%) Stage T1: 30/108 (27.8%) T2: 78/108 (72.2%) Histology No special type: 92/108 (85.2%) Lobular: 4/108 (3.7%) Tubular: 3/108 (2.8%) Other: 9/108 (8.3%) Location Not stated Palpability Not stated Multifocality/multicentricity Not stated **Axilla characteristics** Clinical axillary status N0: 108/108 (100%) **Neoadjuvant chemotherapy** Patients who had neoadjuvant chemotherapy were excluded.

Study identifier	Procedure	Patient characteristics
Sato, Tamaki, Shigekawa, Tsuda, Kosuda, Kusano, Hiraide & Mochizuki, 2003. **Number of patients** 186 **Number of attempted mappings** 186 **Study period** May 1997 to December 2001 **Institution** Departments of Surgery I, Pathology II, Radiology and Research Institute, National Defense Medical College, Tokorozawa, Saitama, Japan. **Incorporated studies** None **Inclusion/exclusion criteria** Inclusions: patients with clinical stage T1-2, N0 breast cancer were eligible for participation in this study. Exclusions: the presence of clinically suspicious or overtly abnormal axillary nodes on ultrasonography, pregnancy, and multiple primary breast tumours. **Study included for review of...** Localisation rates	**Radiocolloid/dye combination** Radiocolloid only: 0 Dye only: 0 Radiocolloid and dye: 186 **Radiocolloid** Type: ^{99m}Tc tin colloid (Nihon, Mediphysics, Tokyo, Japan). Dose: 74MBq/ml, 1 to 3 ml. Colloid size: not stated Filtration: not stated Injection location: 3 sites around the tumor or biopsy cavity under ultrasonographic guidance with or without subdermal injection (0.5ml of radiocolloid over the tumor). Injection timing: 2 hours before surgery Massage: manual compression and gentle massaged for 1 minute. Intraoperative probe: Navigator System (USSC, Norwalk, CT, USA). **Dye** Type: indigocarmine (Daiichi Pharmaceutical, Japan). Amount: 5ml Injection location: dye injected in the same area as the radiocolloid. Injection timing: dye was injected just before surgery. Massage: 1 minute **Preoperative lymphoscintigraphy** Timing: Not stated **Surgery** Surgeon details: not stated Anaesthesia: not stated Axillary clearance: after May 1999, standard level I and II lymph-node dissections were performed only after the sentinel node was found positive for metastasis by intraoperative pathological examination of a frozen section. In 58 patients ALND was not performed. Sentinel node definition: any hot node with an *ex vivo* radioactivity count of ≥ 10 times the background count; analysis done on node with highest radioactivity. Final breast procedure: not stated **Histologic analysis of sentinel nodes** Intraoperative analysis: frozen section performed after May 1999. Sectioning: all sentinel nodes were serially sectioned. Permanent section: H&E. IHC: not stated Micrometastases definition: not stated **Histologic analysis of axillary nodes** Not stated	**Age** Mean 53.5, range 28 to 83 years. **Tumour characteristics** Biopsy method Open biopsy in 21 patients, others not stated. Size Tumor size / Low uptake group / High uptake group < 3 cm / 45/60 (75%) / 78/123 (63.4%) ≥ 3 cm / 15/60 (25%) / 45/123 (36.6%) (in the 183 patients where sentinel nodes were identified) Stage T1 to T2 Histology Not stated Location Tumor location / Low uptake group / High uptake group Upper quadrants / 44/60 (73.3%) / 104/123 (84.6%) Lower quadrants / 16/60 (26.7%) / 19/123 (15.4%) (in the 183 patients where sentinel nodes were identified) Palpability Not stated Multifocality/multicentricity Patients with multiple primary breast tumours were excluded. **Axilla characteristics** Clinical axillary status N0 / 186/186 (100%) **Neoadjuvant chemotherapy** Not stated

Study identifier	Procedure	Patient characteristics
Schneebaum, Stadler, Cohen, Yaniv, Baron & Skornick, 1998. **Number of patients** 30 **Number of attempted mappings** 30 **Study period** Not stated **Institution** Departments of Surgery "A" and Department of Nuclear Medicine, Ichilov Hospital, Tel-Aviv Sourasky Medical Center, Tel Aviv, Israel. **Incorporated studies** None **Inclusion/exclusion criteria** Inclusions: patients with palpable tumours diagnosed by fine-needle aspiration were included in a Phase I/II feasibility study. Exclusions: none stated **Study included for review of...** Localisation rates and false negative rates	**Radiocolloid/dye combination** Radiocolloid only: 0 Dye only: 0 Radiocolloid and dye: 30 **Radiocolloid** Type: ^{99m}Tc-rhenium colloid (CIS Bio International, Gif Sur Yvette Cedex, France; rhenium sulphide 0.15mg, gelatine 9.6mg, ascorbic acid 7.0mg, water for injection 1.0mg) Dose: 60 MBq Colloid size: Not stated Filtration: Not stated Injection location: Injection timing: "Should the findings no longer be traceable at 6 hours post-injection, the protocol would be adjusted accordingly and the injection given 4 hours before the operation. In the event of loss of image 24 hours post-injection, the protocol would be altered and the injection given on the morning of the operation." Massage: not stated Intraoperative probe: Neoprobe 1000 (Dublin, Ohio). A special small probe (experimental 510K) was used in some patients. **Dye** Type: patent blue V (Guerbet, France) Amount: 2ml Injection location: not stated Injection timing: dye was given 10 minutes before operation. Massage: not stated **Preoperative lymphoscintigraphy** Timing: 20 min, 2, 6 and 24 hours post-injection. If the injection was no longer traceable at 6 hours, the protocol was adjusted and the injection given 4 hours before operation. If the image was lost 24 hours post-injection, the injection was given on the morning of operation. **Surgery** Surgeon details: not stated Anaesthesia: not stated Axillary clearance: axillary dissection in all patients. Sentinel node definition: not stated Final breast procedure: lumpectomy + axillary dissection 19/30 (63.3%); modified radical mastectomy 11/30 (36.7%). **Histologic analysis of sentinel nodes** Intraoperative analysis: frozen section Sectioning: not stated Permanent section: H&E IHC: not stated Micrometastases definition: not stated **Histologic analysis of axillary nodes** H&E	**Age** Mean 51, range 33 to 75 years. **Tumour characteristics** Biopsy method Fine needle aspiration. Size Not stated Stage Not stated Histology Ductal 24/30 (80%) Lobular 2/30 (6.7%) Mucinous 3/30 (10%) Other 1/30 (3.3%) Location Not stated Palpability All tumours were palpable. Multifocality/multicentricity Not stated **Axilla characteristics** Clinical axillary status Not stated **Neoadjuvant chemotherapy** 2 patients had undergone previous radiation treatment::one for non-Hodgkin's lymphoma (diagnosed 19 years earlier) and one as part of a neoadjuvant treatment protocol.

Study identifier	Procedure	Patient characteristics
Schrenk, Wölfl, Tausch, Mauritz, Konstantiniuk, Haid, Riegler-Keil & Rudas, 2002. **Number of patients** 48 **Number of attempted mappings** 48 **Study period** Not stated **Institution** Second Department of Surgery, Ludwig Boltzmann Institute for Surgical Laparoscopy, Allgemein Öffentliches Krankenhaus Linz, Department of Pathology, Allgemein Öffentliches Krankenhaus Linz, Department of Surgery, Barmberzige Schwestern Hospital Linz, Second Department of Surgery, Landeskrankenhaus Graz, Department of Surgery, Landeshrankenhaus Feldkirch, Department of Gynaecology, Wilhelminenspital, Vienna and Department of Pathology, University of Vienna, Austria. **Incorporated studies** Schrenk and Wayand, 2001. **Inclusion/exclusion criteria** Inclusions: patients with multicentric carcinoma of the breast prospectively undergoing SLNB. All were patients included in a multicentre register of the Austrian Sentinel Node Study Group. A multicentric tumour defined as a tumour in 2 or more different breast quadrants. Exclusions: none stated **Study included for review of...** False negative rates	**Radiocolloid/dye combination** Radiocolloid only: 0 Dye only: 22 Radiocolloid and dye: 26 **Radiocolloid** Type: ^{99m}Tc-nanocolloid (Nanocoll®) Dose: 20 to 40 MBq Colloid size: not stated Filtration: not stated Injection location: injected in the subareolar area. Injection timing: not stated Massage: not stated Intraoperative probe: Neoprobe 1000® C-trak **Dye** Type: 1% isosulphan blue (Lymphazurin®) or 2.5% patent blue V Guerbet. Amount: 5 ml of isosulphan blue or 2 to 4 ml of patent blue. Injection location: not stated Injection timing: not stated Massage: not stated **Preoperative lymphoscintigraphy** Timing: preoperative lymphoscintigraphy was performed, timing not stated. **Surgery** Surgeon details: not stated Anaesthesia: not stated Axillary clearance: axillary dissection of levels I and II in all patients. Sentinel node definition: when the node was blue, when blue-stained lymphatic channels led directly to a node, or a 'hot' node was found with the gamma camera. Final breast procedure: quadrantectomy (due to personal preference of patients) 5/48 (10.4); mastectomy 43/48 (89.6%). **Histologic analysis of sentinel nodes** Intraoperative analysis: a frozen section was performed in 39/46 (84.8%) patients. Sectioning: 4 to 6 sections for frozen section; serial sectioning for H&E; when no frozen section was performed or when frozen section examination was negative, serial sections at 250 µm intervals. Permanent section: H&E IHC: in negative nodes IHC, using an antibody cocktail to cytokeratin (at 250µm intervals). Micrometastases definition: a micrometastasis was defined as a lymph node metastasis of ≤ 2 mm. **Histologic analysis of axillary nodes** Fixed in formalin, sectioned and stained with H&E. No IHC was performed in these nodes.	**Age** Mean 56.6±12.9 (SD), range 35 to 82 years. **Tumour characteristics** Biopsy method FNA or core-needle biopsy: 36/48 (75%) Intraoperatively by frozen section biopsy: 12/48 (25%) Size Mean 15.1±8.8 (SD), range 2 to 55 mm. Stage T1b: 1/48 (2.1%) T1c: 27/48 (56.3%) T2: 19/48 (39.6%) T3: 1/48 (2.1%) Histology Ductal: 39/48 (81.3%) Lobular: 5/48 (10.4%) Papillary: 1/48 (2.1%) Ductal and lobular: 2/48 (4.2%) Ductal and tubular: 1/48 (2.1%) Differentiation Well: 2/48 (4.2%) Moderate: 24/48 (50.0%) Poor: 17/48 (35.4%) Poor and moderate: 5/48 (10.4%) Location Number of quadrants involved: 2: 43/48 (89.6%) 3: 5/48 (10.4%) Tumour quadrant: Central: 13/101 (12.9%) Upper outer: 36/101 (35.6%) Upper inner: 21/101 (20.8%) Lower outer: 18/101 (17.8%) Lower inner: 13/101 (12.9%) Palpability Not stated Multifocality/multicentricity Multicentric: 101/101 (100%) **Axilla characteristics** Clinical axillary status Not stated **Neoadjuvant chemotherapy** Not stated

Study identifier	Procedure	Patient characteristics
Schrenk, Rehberger, Shamiyeh & Wayand, 2002b. **Number of patients** 284 (2 males) **Number of attempted mappings** 284 **Study period** June 1996 to May 2001 **Institution** Second Department of Surgery, Ludwig Boltzmann Institute for Surgical Laparoscopy, AKH Linz, Austria. **Incorporated studies** Schrenk *et al.* 2001 **Inclusion/exclusion criteria** Inclusions: patients with clinically node negative breast cancer. Exclusions: none stated **Study included for review of...** Localisation rates	**Radiocolloid/dye combination** Radiocolloid only: 0 Dye only: 181 Radiocolloid and dye: 82 **Radiocolloid** Type: ^{99m}Tc-labelled nanocolloid Dose: 40MBq in 0.5ml. Colloid size: not stated Filtration: not stated Injection location: injected into the parenchyma surrounding the tumour. Injection timing: 18 hours before surgery. Massage: not stated Intraoperative probe: Neoprobe 1000 (Neoprobe Corp, OH, USA). **Dye** Type: 1% isosulphan blue (Lymphazurin; Ben Venue Labs., Inc, Bedford, OH, USA). Amount: 5ml Injection location: injected into the parenchyma surrounding the tumour, ultrasound guidance used for injection around nonpalpable tumours; in tumours excised previously, dye was injected into the wall of the biopsy cavity. Injection timing: dye was injected during surgery. Massage: not stated **Preoperative lymphoscintigraphy** Timing: timing of lymphoscintigraphy was not stated. **Surgery** Surgeon details: all but 10 biopsies performed by the same surgeon (Schrenk), and this surgeon supervised those 10 procedures. Anaesthesia: not stated Axillary clearance: complete axillary dissection performed in all patients with a positive sentinel node (n=105), and in patients with node-negative disease who either gave no informed consent for SLNB alone, or were participants in a feasibility study, where SLNB was followed by axillary clearance (n=62). In remaining 96 node-negative patients, only the sentinel node was removed. Sentinel node definition: blue stained node, when a blue-stained lymphatic channel led directly to a node or a hot node was found with a gamma probe ('hot' defined as the count of the excised node > 10 times the count in the axilla after removal of the sentinel node. Final breast procedure: quadrantectomy 187/263 (71.1%); mastectomy 76/263 (28.9%). **Histologic analysis of sentinel nodes** Intraoperative analysis: frozen sections performed in 208/263 (79.1%) of successful mappings. Nodes were bivalved and frozen sections taken from 4 to 8 levels of one half. Sectioning: when frozen sections tumour free, additional paraffin sections of 200 to 250μm. Permanent section: H&E. IHC: nodes negative by frozen section and H&E stained with a cytokeratin antibody cocktail (CKKES, CKEMS; Immunostain, Euro/DPC Ltd., Gwynedd, UK) in 250 μm sections. Regarded as positive when there was a cluster of positive stained tumour cells. Micrometastases definition: a metastases <2mm. **Histologic analysis of axillary nodes** H&E (4 sections per node).	**Age** Mean 61.6±14.2 (SD), range 27 to 86 years. (for 263/284 (92.6%) successfully mapped) **Tumour characteristics** Biopsy method Fine needle aspiration or core biopsy, or frozen section during surgery. Size Mean 16.6±8.2, range 1 to 45mm. (for 263/284 (92.6%) successfully mapped) Stage T1a: 10/263 (3.8%) T1b: 30/263 (11.4%) T1c: 119/263 (45.2%) T2: 104/263 (39.5%) (for 263/284 (92.6%) successfully mapped patients) Histology Ductal: 225/263 (85.6%) Lobular: 19/263 (7.2%) Papillary: 11/263 (4.2%) Tubular: 7/263 (2.7%) Medullary: 1/263 (0.4%) Differentiation: Well: 32/263 (12.2%) Moderate: 112/263 (42.6%) Poor: 119 (45.2%) (for 263/284 (92.6%) successfully mapped) Location UOQ: 108/263 (41.1%) UIQ: 37/263 (14.1%) LOQ: 56/263 (21.3%) LIQ: 20/263 (7.6%) Central: 42/263 (16.0%) (for 263/284 (92.6%) successfully mapped) Palpability Palpable and nonpalpable tumours were included. Multifocality/multicentricity Not stated **Axilla characteristics** Clinical axillary status Negative: 284/284 (100%) **Neoadjuvant chemotherapy** Not stated

Study identifier	Procedure	Patient characteristics
Schrenk, Hochreiner, Fridrik & Wayand, 2003. **Number of patients** 21 **Number of attempted mappings** 21 **Study period** December 1998 to May 2002 **Institution** Second Department of Surgery, Ludwig Boltzmann Institute and Department of Surgical Oncology, Allgemein Öffentliches Krankenhaus Linz, Austria. **Incorporated studies** None **Inclusion/exclusion criteria** Inclusions: women with invasive breast cancer who were not candidates for breast-conserving surgery due to large tumor size or an anatomically unfavourable tumor location. Exclusions: none stated **Study included for review of...** Localisation rates and false negative rates	**Radiocolloid/dye combination** Radiocolloid only: 0 Dye only: 11 Radiocolloid and dye: 10 **Radiocolloid** Type: ^{99m}Tc-nanocolloid (Nanocoll) Dose: 40 MBq, volume 0.5ml. Colloid size: not stated Filtration: not stated Injection location: into the parenchyma surrounding the tumor. Injection timing: 18 hours prior to surgery Massage: not stated Intraoperative probe: Neoprobe 1000 (Neoprobe Corp., Dublin, Ohio). **Dye** Type: 1% isosulphan blue (lymphazurin; Ben Venue Laboratories, Bedford, OH). Amount: 5ml Injection location: dye injected into the parenchyma surrounding the tumour. Injection timing: injected intraoperatively. Massage: not stated **Preoperative lymphoscintigraphy** Timing: 18 hours prior to surgery. **Surgery** Surgeon details: not stated Anaesthesia: local anaesthesia 7/21 (33.3%) general anaesthesia 14/21 (66.7%). Axillary clearance: complete axillary dissection of levels I and II (and III). Sentinel node definition: blue nodes, when blue-stained lymphatic channels led directly to a node, or when a 'hot' node (the counts of the excised SN had to be greater than 10 times the count in the axilla after removal of the SN) was found with the gamma probe. Final breast procedure: performed following preoperative chemotherapy; quadrantectomy 14/21 (66.7%); mastectomy 7/21 (33.3%). **Histologic analysis of sentinel nodes** Intraoperative analysis: no frozen sections performed. Sectioning: paraffin blocks serial sectioned at 200 μm. Permanent section: H&E IHC: nodes negative with H&E were further investigated with cytokeratin IHC stain with an antibody cocktail to cytokeratin (CKKES, CKEMS, Immunostain; Euro/DPC Ltd., Gwynedd, UK). Positive when tehre was a cluster of positive tumour cells. Micrometastases definition: a lymph node metastasis < 2mm. **Histologic analysis of axillary nodes** Fixed in formulin, sectioned (~4 to 8 sections per node) and stained with H&E. No IHC was routinely done, but was performed in 2 patients with micrometastatic SNs.	**Age** Mean 54.9±10.6 (SD), range 31 to 74 years. **Tumour characteristics** Biopsy method Core needle biopsy. Size Mean preoperative tumor size 40.2±10.7 (SD), range 25 to 60 mm. Mean postoperative tumor size 17.7±15.1 (SD), range 0 to 60 mm. Stage T2N0: 15/21 (71.4%) T2N1: 1/21 (4.8%) T3N0: 3/21 (14.3%) T3N1: 2/21 (9.5%) Histology Ductal: 19/21 (90.5%) Lobular: 2/21 (9.5%) Differentiation Well: 0/21 Moderate: 11/21 (52.4%) Poor: 10/21 (47.6%) Location Not stated Palpability Not stated Multifocality/multicentricity Not stated **Axilla characteristics** Clinical axillary status N1: 2/21 (9.5%) N0: 19/21 (90.5%) Note: stated enlarged axillary lymph nodes present in 3 patients. **Neoadjuvant chemotherapy** After SLNB patients received either ipirubicin (50mg/m^2), fluorouracil (500 mg/m^2), and cyclophosphamide (500 mg/m^2) (n=4) or epirubicin (75 mg/m^2) and docetaxel (75 mg/m^2) (n=17) intravenously every 21 days for a mean of 4±1.8 (SD) cycles (range 1 to 8).

Study identifier	Procedure	Patient characteristics
Shenoy, Ravichandran & Ralphs, 2002. **Number of patients** 100 (50 had massage and 50 did not have massage). **Number of attempted mappings** 100 **Study period** Not stated **Institution** Department of General Surgery, Norfolk and Norwich University Hospital, Norwich, UK. **Incorporated studies** None **Inclusion/exclusion criteria** Inclusions: patients with invasive breast cancer who underwent sentinel node biopsy followed by level II axillary clearance as well as the removal of the primary tumour by wide local excision or mastectomy were prospectively studied. Exclusions: none stated **Study included for review of...** Localisation rates	**Radiocolloid/dye combination** Radiocolloid only: 0 Dye only: 100 Radiocolloid and dye: 0 **Radiocolloid** Type: radiocolloid not used. Dose: not applicable Colloid size: not applicable Filtration: not applicable Injection location: not applicable Injection timing: not applicable Massage: not applicable Intraoperative probe: not applicable **Dye** Type: patent blue V dye (Guerbet Laboratories Ltd, Milton Keynes, UK). Amount: 2ml Injection location: in the subdermal space overlying the tumour. Injection timing: no massage group, surgery performed immediately after injection; massage group, surgery performed after 3 to 5 minutes massage. Massage: no massage 50/100 (50%); 3 to 5 minutes massage 50/100 (50%). **Preoperative lymphoscintigraphy** Timing: not applicable **Surgery** Surgeon details: 2 surgeons with equal experience in the identification of the sentinel lymph node. Anaesthesia: not stated Axillary clearance: level II axillary clearance Sentinel node definition: not stated Final breast procedure: wide local excision or mastectomy . **Histologic analysis of sentinel nodes** Intraoperative analysis: not stated Sectioning: routine histological analysis, method of sectioning not stated. Permanent section: not stated IHC: not stated Micrometastases definition: not stated **Histologic analysis of axillary nodes** Sent for routine histological analysis.	**Age** Not stated **Tumour characteristics** Biopsy method Not stated Size Not stated Stage Not stated Histology Not stated Location Not stated Palpability Not stated Multifocality/multicentricity Not stated **Axilla characteristics** Clinical axillary status Not stated **Neoadjuvant chemotherapy** Not stated

Study identifier	Procedure	Patient characteristics
Schwartz & Meltzer, 2003 **Number of patients** 21 **Number of attempted mappings** 21 **Study period** 1997 to 2002 **Institution** Department of Surgery, Jefferson Medical College, Surgical Service, Thomas Jefferson University Hospital, Breast Health Institute, Philadelphia, Pennsylvania; Bryn Mawr Hospital and Department of Surgery, Massachusetts General Hospital, Massachusetts, Boston, USA **Incorporated studies** None **Inclusion/exclusion criteria** Inclusions: patients who initially presented with stage II (> 3cm) or stage III breast cancer and underwent induction chemotherapy. A patient was considered for this study only if the axilla was clinically negative (N0) following induction chemotherapy, irrespective of pre-treatment node status. Exclusions: none stated **Study included for review of...** Localisation rates	**Radiocolloid/dye combination** Radiocolloid only: 0 Dye only: 21 Radiocolloid and dye: 0 **Radiocolloid** Type: radiocolloid was not used. Dose: not applicable Colloid size: not applicable Filtration: not applicable Injection location: not applicable Injection timing: not applicable Massage: not applicable Intraoperative probe: not applicable **Dye** Type: 1% isosulphan blue dye Amount: 1ml as an intradermal injection and 2 to 3ml into the peritumoural parenchyma. Injection location: into the breast outside the biopsy cavity as an intradermal injection; into the peritumoural parenchyma in line with the lower third of the hair-bearing area of the breast. Injection timing: not stated Massage: 4 to 7 minutes of vigorous massage. **Preoperative lymphoscintigraphy** Timing: not applicable **Surgery** Surgeon details: one surgeon (G.F. Schwartz) Anaesthesia: not stated Axillary clearance: level I and II axillary dissection. Sentinel node definition: any blue stained node or any node into which a blue lymphatic vessel was draining, even if the node itself had not yet turned blue. Final breast procedure: breast conserving surgery - local excision of the residual breast tumour. Surgery performed less than 2 weeks before SLNB. **Histologic analysis of sentinel nodes** Intraoperative analysis: frozen section Sectioning: each node was divided into 2 to 3mm sections along the longitudinal axis. Each section was separately submitted in formalin, and each block sectioned at three levels. Permanent section: H&E IHC: not stated Micrometastases definition: not stated **Histologic analysis of axillary nodes** Nodes bisected and one H&E stained section made from each slice (usually two per node).	**Age** Median 50, range 33 to 71 years. **Tumour characteristics** Biopsy method Fine needle aspiration or core biopsy. Size < 2cm: 1/21 (4.8%) >2cm but ≤ 5cm: 13/21 (61.9%) >5cm: 7/21 (33.3%) Stage At presentation: T1N1: 1/21 (4.8%) T2N0: 6/21 (28.6%) T2N1: 6/21 (28.6%) T2N2: 1/21 (4.8%) T3N0: 3/21 (14.3%) T3N1: 3/21 (14.3%) T3N2: 1/21 (4.8%) Histology Invasive ductal: 14/21 (66.7%) Invasive ductal + DCIS: 4/21 (19.0%) Invasive ductal + invasive lobular: 1/21 (4.8%) Invasive ductal, medullary type: 1/21 (4.8%) Invasive lobular: 1/21 (4.8%) Location Not stated Palpability Not stated Multifocality/multicentricity Not stated **Axilla characteristics** Clinical axillary status At presentation: N0: 9/21 (42.9%) N1: 10/21 (47.6%) N2: 2/21 (9.5%) All patients N0 after chemotherapy. **Neoadjuvant chemotherapy** Doxorubicin (Adriamycin) and cyclophosphamide (Cytoxan) (AC) cyclic chemotherapy. Induction chemotherapy was continued until a "plateau" was reached, ie. No further progression in size of the primary tumour or axillary lymph nodes from one cycle to the next. Chemotherapy regimen AC: 13/21 (61.9%) CAF: 4/21 (19.0%) AC + T: 4/21 (19.0%) A, Adriamycin (doxorubicin); C, Cytoxan (cyclophosphamide); F, 5-flourouracil; T, Taxol (paclitaxel).

Study identifier	Procedure	Patient characteristics
Shimazu, Tamaki, Taguchi, Takamura & Noguchi, 2002. **Number of patients** 155 (1 male) Phase 1: dye only (n=62) Phase 2: Group A: dye+radiocolloid (peritumoural injection; n=41) Group B: dye+radiotracer (periareolar injection; n=52) **Number of attempted mappings** 155 **Study period** December 1997 to October 2000 **Institution** Department of Surgical Oncology, Osaka University Medical School, Osaka, Japan. **Incorporated studies** None **Inclusion/exclusion criteria** Inclusions: patients with T1 to T2 breast cancer. Exclusions: pregnant patients, or those previously treated by radiotherapy or chemotherapy. **Study included for review of...** Localisation rates and false negative rates	**Radiocolloid/dye combination** Radiocolloid only: 0 Dye only: 62 Radiocolloid and dye: 93 **Radiocolloid** Type: ^{99m}Tc-labelled tin colloid (Nihon Medi-Physics Co, Hyogo, Japan). Dose: 30 to 80MBq in 2ml saline. Colloid size: not stated Filtration: not stated Injection location: injected pertiumorally (Group A: injections made at 3, 6, 9 & 12 o'clock positions, in the parenchyma surrounding the tumour or of the wall of the biopsy cavity) or periareolarly (Group B: injections made at 3, 6, 9 & 12 o'clock positions around the areola, each injection composed of an intradermal followed by a subdermal injection of 0.25ml each). Injection timing: radiocolloid was injected 19 to 29 hours before surgery. Massage: not stated Intraoperative probe: Navigator (US Surgical Co., Norwalk, CT, USA). **Dye** Type: 1% isosulphan blue dye (Lymphazurin; US Surgical Co., Norwalk, CT, USA). Amount: 2ml Injection location: injected into the parenchyma surrounding the tumour or into the wall of the biopsy cavity. Injection timing: approximately 5 minutes before surgery. Massage: the injection site was massaged manually for about 5 minutes. **Preoperative lymphoscintigraphy** Timing: performed 1 to 2 hours after radiocolloid injection. **Surgery** Anaesthesia: local anaesthesia used for injection of radiocolloid. Axillary clearance: Phase 1: complete axillary clearance perfomed in every patient. Phase 2: axillary clearance was performed when the sentinel node could not be identified, when the tumour size was >3cm or when intraoperative frozen section revealed metastases. Sentinel node definition: Phase 1: blue nodes, defined as a node partially or completely stained blue dye or connected to a blue stained afferent lymphatic tract; Phase 2: blue and/or hot nodes, where hot nodes had *ex vivo* counts ≥ 400% axillary background. Final breast procedure: mastectomy 68/155 (43.9%); breast conservation 87/155 (56.1%). **Histologic analysis of sentinel nodes** Intraoperative analysis: frozen section using the largest cut surface of approximately 2mm thickness. Sectioning: remaining parts of the sentinel node were formalin fixed, paraffin embedded and serially sectioned in slices of 2mm. Permanent section: H&E IHC: anticytokeratin antibody (AE1/AE3; Histofine; Nichirei Co., Tokyo, Japan). Considered positive only when a cluster of positive cells were identified. Micrometastases definition: not stated **Histologic analysis of axillary nodes** H&E (1 section from each node).	**Age** Phase I: mean 52.3, range 26 to 82 years. Phase 2: Group A: mean 53.9, range 36 to 74 years. Group B: mean 51.5, range 32 to 86 years. **Tumour characteristics** Biopsy method FNA 119/155 (76.8%) CB 22/155 (14.2%) Excisional 14/155 (9.0%) Size Phase I: mean 2.4±1.0(SD) cm. Group A: mean 1.9± 0.8(SD) cm. Group B: mean 1.8±0.9(SD) cm. Stage T1 88/155 (56.8%) T2 67/155 (43.2%) Histology Invasive ductal 132/155 (85.2%) Invasive lobular 11/155 (7.1%) Other 4/155 (2.6%) DCIS 8/155 (5.2%) Location UOQ 80/155 (51.6%) UIQ 37/155 (23.9%) LOQ 16/155 (10.3%) LIQ 15/155 (9.7%) Central 7/155 (4.5%) Palpability Not stated Multifocality/multicentricity Not stated **Axilla characteristics** Clinical axillary status N0 148/155 (95.5%) N1 7/155 (4.5%) **Neoadjuvant chemotherapy** Patients with previous radiotherapy or chemotherapy were excluded.

Study identifier	Procedure	Patient characteristics
Shiver, Creager, Geisinger, Perrier, Shen & Levine, 2002. **Number of patients** 132 (consecutive) **Number of attempted mappings** 133 **Study period** December 1998 to June 2001 **Institution** Department of Surgery, Surgical Oncology Service and Department of Pathology, Wake Forest University School of Medicine, Winston-Salem, North Carolina and Department of Pathology, Duke University Medical Center, Durham, North Carolina, USA. **Incorporated studies** None **Inclusion/exclusion criteria** Inclusions: patients with Stage cT1 to 2N0M0 carcinomas of the breast. Exclusions: patients receiving preoperative chemotherapy. **Study included for review of...** Localisation rates	**Radiocolloid/dye combination** Radiocolloid only: 0 Dye only: 0 Radiocolloid and dye: 133 **Radiocolloid** Type: ^{99m}Tc -sulphur colloid Dose: 0.5 to 1 mCi. Colloid size: not stated Filtration: unfiltered Injection location: radiocolloid was injected into the tumour bed. Injection timing: preoperatively Massage: not stated Intraoperative probe: Neoprobe 2000 (Dublin, Ohio). **Dye** Type: isosulphan blue Amount: not stated Injection location: perilesional injections of dye were performed. Injection timing: intraoperatively Massage: not stated **Preoperative lymphoscintigraphy** Timing: not stated **Surgery** Surgeon details: not stated Anaesthesia: not stated Axillary clearance: not stated Sentinel node definition: not stated Final breast procedure: not stated **Histologic analysis of sentinel nodes** Intraoperative analysis: fresh nodes bisected along the long axis with care taken to obtain complete cross sections of the maximum diameter. For each half a pair of mprints made by gently touching the cut surface to a glass slide. One imprint of each pair air dried and stained with Diff-Quik (Dade Behring, Newark, Delaware); second imprint fixed in 95% ethanol for 3 minutes then stained with H&E. Sectioning: nodes fixed in formalin, paraffin embedded, and an initial section cut; in this was negative 3 additional levels were cut at 50 μm intervals. Permanent section: H&E (1 section initially, if negative 3 additional sections). IHC: cytokeratin, antibody not stated, if initial H&E was negative. Micrometastases definition: not stated **Histologic analysis of axillary nodes** Not stated	**Age** Mean 60, range 31 to 87 years. **Tumour characteristics** Biopsy method Not stated Size ≤ 0.5cm: 7/127 (5.5%) 0.5 to 1 cm: 34/127 (26.8%) 1 to 2 cm: 50/127 (39.4%) >2cm but ≤ 5cm: 29/127 (22.8%) Not stated: 7/127 Stage Tis: 1/127 (0.8%) T1mic: 6/127 (4.7%) T1a: 7/127 (5.5%) T1b: 34/127 (26.8%) T1c: 50/127 (39.4%) T2: 29/127 (22.8%) Histology Ductal: 112/127 (88.2%) Lobular: 15/127 (11.8%) Location Not stated Palpability Not stated Multifocality/multicentricity M0: 127/127 (100%) **Axilla characteristics** Clinical axillary status N0: 127/127 (100%) **Neoadjuvant chemotherapy** Not stated

Study identifier	Procedure	Patient characteristics
Shivers, Cox, Leight, Beauchamp, Blumencranz, Ross, Reintgen, & the Department of Defense Breast Lymphatic Mapping Investigators, 2002. **Number of patients** 965 (complete data available in 734 patients) **Number of attempted mappings** 961 **Study period** July 1997 to January 1999 **Institution** Department of Surgery, Moffitt Cancer Center and Research Institute, University of South Florida, Tampa, Florida, USA. **Incorporated studies** None **Inclusion/exclusion criteria** Inclusions: women with invasive breast cancer enrolled in a national, multi-institutional Department of Defense clinical trial. Exclusions: patients who were pregnant or with clinically positive lymph nodes. **Study included for review of...** False negative rates	**Radiocolloid/dye combination** Radiocolloid only: 0 Dye only: 348 Radiocolloid and dye: 617 **Radiocolloid** Type: ^{99m}Tc sulphur colloid Dose: approximately 450µMi (6ml). Colloid size: not stated Filtration: 0.22µm filtered Injection location: in palpable tumours, 6 injections made around the periphery of the tumour at the depth of the mass. No attempt was made to inject above or below the tumour (breast parenchymal injection). Women with an excisional biopsy were injected around the rim of the biopsy cavity, making sure the injection was outside the cavity. For patients with mammographic abnormalities, injections were around the previously placed localisation wire (injection outside the cancer diffusely around the circumference, not down the localisation wire). Injection timing: on the day of operation. Massage: breast massage was used in the later part of the study. The breast massage was intermittent to allow the valves in the lymphatic channels time to open and the mapping agents to flow. Intraoperative probe: 'very sensitive' handheld gamma probe, type not specified. **Dye** Type: 1% isosulphan blue (Lymphazurin, USSC, Norwalk, CT). Amount: 5ml Injection location: dye injected into the breast parenchyma around the: palpable tumour, excisional biopsy scar, or mammographic abnormality. Injection timing: approximately 5 minutes before axillary incision. Massage: 5 minutes of massage was performed. **Preoperative lymphoscintigraphy** Timing: performed from 15 minutes after radiocolloid injection. **Surgery** Surgeon details: a total of 111 surgeons from 42 institutions attended a 2-day formal training course and served as principal investigators. Anaesthesia: general anaesthesia Axillary clearance: complete axillary lymph node dissection (level I and II) in the initial phase (protocol 1). In protocol 2, if no sentinel node was found a level I and II axillary dissection was performed. Sentinel node definition: a blue stained node, or a node with a blue stained afferent lymphatic entering it (to cover the situation of a node completely replaced by tumor that may not take up much of the dye), or a node with radioactivity counts with a 10:1 ratio, the denominator activity in a neighbouring non-SLN. Final breast procedure: lumpectomies and breast conservation in 75% of patients. **Histologic analysis of sentinel nodes** Intraoperative analysis: Sectioning: nodes with a measurement ≤ 5mm in maximal diameter were bivalved, and nodes >5mm in diameter were serially sectioned a 2- to 3mm intervals. Method of sectioning not stated. If routine H&E stains were negative additional sectioning was performed. Permanent section: H&E IHC: performed at selected centres if initial H&E negative; cytokeratin-19. All positive IHC confirmed by adjacent H&E section. Micrometastases definition: not stated **Histologic analysis of axillary nodes** One or two sections of central cross-section using H&E staining.	**Age** Mean 59, range 27 to 89 years. **Tumour characteristics** Biopsy method FNA: 95 Incisional: 41 Stereotactic core: 306 Excisional: 268 Note: denominator not stated Size Not stated Stage Mostly T1 or T2. Histology Ductal: 77% Lobular: 10% Other: 13% Note: numbers not given Location Inner quadrant: 170 Outer quadrant: 419 Upper quadrant: 454 Lower quadrant: 135 Central: 117 Note: numbers add to 1295, may be more than one tumour per patient. Palpability Both palpable and nonpalpable tumours were included. Multifocality/multicentricity Not stated **Axilla characteristics** Clinical axillary status Negative: 965/965 (100%) **Neoadjuvant chemotherapy** Not stated

Study identifier	Procedure	Patient characteristics
Simmons, Thevarajah, Brennan, Christos & Osborne, 2003. **Number of patients** 112 **Number of attempted mappings** 113 **Study period** January 1999 to July 2001 **Institution** Department of Surgery, Weill Cornell Breast Center, New York Presbyterian Hospital, and Department of Public Health, Weill Cornell Medical College, New York, New York, USA. **Incorporated studies** Simmons *et al.* 2001 **Inclusion/exclusion criteria** Inclusions: patients with Tis-T3N0M0 biopsy proven breast tumours. Exclusions: none stated **Study included for review of...** Localisation rates	**Radiocolloid/dye combination** Radiocolloid only: 0 Dye only: 0 Radiocolloid and dye: 113 **Radiocolloid** Type: ^{99m}Tc-labeled sulphur colloid Dose: not stated Colloid size: not stated Filtration: not stated Injection location: radiocolloid was injected subdermally. Injection timing: injection was performed at a minimum of 2 hours and up to 24 hours before surgery. Massage: not stated Intraoperative probe: handheld gamma probe, type not specified. **Dye** Type: 1% methylene blue dye Amount: 5 ml Injection location: dye injected intraparenchymally around either the tumour mass or around the biopsy cavity if a previous excision had been performed. Injection timing: approximately 5 minutes before axillary incision. Massage: the breast was massaged for 5 minutes. **Preoperative lymphoscintigraphy** Timing: lymphoscintigraphy was not performed. **Surgery** Surgeon details: two surgeons (RS and MO) performed the procedures. Anaesthesia: not stated Axillary clearance: if SN positive for metastasis from frozen section a complete ALND was performed; if either permanent section or IHC analysis was positive for metastasis then the patient was recommended to undergo a subsequent ALND. Sentinel node definition: radioactive and/or blue nodes. Radioactive nodes had >10 times the counts of the background. Final breast procedure: Segmental mastectomy: 71/113 (62.8%) Modified radical mastectomy: 42/113 (37.2%) **Histologic analysis of sentinel nodes** Intraoperative analysis: frozen-section analyses were performed on all SNs. Sectioning: if frozen-section analysis of the SN was negative then permanent sections made, method of sectioning not stated. Permanent section: H&E IHC: if H&E sections were negative IHC was performed using standard techniques, antibody not stated. Micrometastases definition: not stated **Histologic analysis of axillary nodes** Not stated.	**Age** Mean 56, range 30 to 86 years. **Tumour characteristics** Biopsy method All patients had biopsy-proven malignancy, method of biopsy not stated. Size Mean 1.2, range 0.3 to 5.7cm. ≤ 1 cm: 52/104 (50.0%) > 1, ≤ 2 cm: 40/104 (38.5%) > 2, ≤ 3 cm: 11/104 (10.6%) > 5 cm: 1/104 (0.9%) n=104 patients with SLN identified with methylene blue. Stage Not stated Histology DCIS: 10/104 (9.6%) Ductal: 85/104 (81.7%) Lobular: 7/104 (6.7%) Ductal and lobular: 1/104 (1.0%) Paget's disease: 1/104 (1.0%) Grade I: 20/104 (19.2%) Grade II: 42/104 (40.4%) Grade III: 24/104 (23.1%) Unknown: 18/104 (17.3%) n=104 patients with SLN identified with methylene blue. Location Left LIQ: 9/104 (8.7%) Left LOQ: 8/104 (7.7%) Left UIQ: 5/104 (4.8%) Left UOQ: 32/104 (30.8%) Right LIQ: 3/104 (2.9%) Right LOQ: 5/104 (4.8%) Right UIQ: 10/104 (9.6%) Right UOQ: 19/104 (18.3%) Subareolar/ central: 11/104 (10.6%) Diffuse: 2/104 (1.9%) n=104 patients with SLN identified with methylene blue. Palpability Not stated Multifocality/multicentricity M0: 113/113 (100%) **Axilla characteristics** Clinical axillary status N0: 113/113 (100%) **Neoadjuvant chemotherapy** Not stated

Study identifier	Procedure	Patient characteristics
Smillie, Hayashi, Rusnak, Dunlop, Donald & van der Westhuizen, 2001. **Number of patients** 106 (158 enrolled but 52 did not meet the inclusion criteria). **Number of attempted mappings** 106 **Study period** June 1999 to August 2000 **Institution** Department of Surgery, Capital Health Region, Victoria, British Columbia, Canada. **Incorporated studies** None **Inclusion/exclusion criteria** Inclusions: patients with histologic diagnosis of T1 or T2 breast cancer, a clinically node axilla and a treatment plan that included a complete ALND. Exclusions: failure to meet the criteria of T1 or T2 breast cancer (n=8); grossly positive nodes intraoperatively (n=13); incomplete surgical data records (n=11); blue dye not used (n=4); gamma probe not used (n=1); previous radiation therapy (n=1); and patients who declined complete axillary node dissection (n=14). **Study included for review of...** Localisation rates and false negative rates	**Radiocolloid/dye combination** Radiocolloid only: 0 Dye only: 0 Radiocolloid and dye: 106 **Radiocolloid** Type: ^{99m}Tc labelled sulphur colloid Dose: not stated, 4ml volume used. Colloid size: not stated Filtration: 0.1 μm filter Injection location: injected into the breast parenchyma in four quadrants around the tumour and anterior and posterior to the tumour; radiocolloid was injected under ultrasound guidance in patients with nonpalpable tumours or previous excisional biopsy Injection timing: radiocolloid injected 4 to 16 hours before surgery. Massage: not stated Intraoperative probe: handheld gamma probe, type not specified. **Dye** Type: isosulphan blue dye Amount: 5 ml Injection location: dye was injected around the tumour into the breast parenchyma. Injection timing: dye was injected at the time of surgery. Massage: 5 minutes of massage. **Preoperative lymphoscintigraphy** Timing: lymphoscintigraphy was not performed **Surgery** Surgeon details: four general surgeons and one radiologist attended a sentinel node biopsy course to receive 'hands-on' training. All nine general surgeons participating in study were involved in an education day, with five breast cancer cases. Following this each surgeon received intraoperative mentoring by a colleague with sentinel node experience. The results from the training cases were not included in data analysis. The goals for each surgeon were to complete 25 SLNB with concurrent axillary node dissections and to maintain a SN rate > 90% and a false negative rate < 5%. Anaesthesia: not stated Axillary clearance: standard axillary level I and II dissection. Sentinel node definition: 'hot spots' defined as localised radioactivity with counts > 25 per 10 seconds; SLNB was guided by radioactivity detected by the gamma probe and blue dye in the lymph node or nodes and lymphatics; successful SLNB was defined as a postexcision bed count < 10% of the SN *ex vivo* count and no remaining visible blue staining nodes in the axilla. Final breast procedure: lumpectomy or modified radical mastectomy. **Histologic analysis of sentinel nodes** Intraoperative analysis: not stated Sectioning: three levels of H&E staining Permanent section: H&E IHC: cytokeratin immunohistochemical staining used adjacent to the second level, antibody not stated. Micrometastases definition: not stated **Histologic analysis of axillary nodes** All non-SNs examined by H&E staining only.	**Age** Not stated **Tumour characteristics** Biopsy method Not stated Size Not stated Stage Patients with T1or T2 breast cancer were included in the study. Histology Not stated Location Not stated Palpability Palpable and non-palpable tumours were included. Multifocality/multicentricity Not stated **Axilla characteristics** Clinical axillary status N0: 106/106(100%) **Neoadjuvant chemotherapy** Not stated

Study identifier	Procedure	Patient characteristics
Smith, Cross & Klimberg, 2001. **Number of patients** 38 (Peritumoural n=19; Subareolar n=19) **Number of attempted mappings** 38 **Study period** July 1998 to September 1999 **Institution** Department of Surgery, Division of Breast Surgical Oncology, and Department of Pathology, University of Arkansas for Medical Sciences, John L. McClellan Memorial Veterans Hospital, Little Rock, Arkansas and Breast Treatment Associates, PA, Fayetteville, Arkansas, USA. **Incorporated studies** None **Inclusion/exclusion criteria** Inclusions: women with clinically stage I, node negative breast cancer. Exclusions: none stated **Study included for review of...** Localisation rates	**Radiocolloid/dye combination** Radiocolloid only: 0 Dye only: 0 Radiocolloid and dye: 38 **Radiocolloid** Type: ^{99m}Tc labelled sulphur colloid Dose: peritumoural: mean 1.02±0.11, range 0.75 to 1.2 mCi; subareolar: mean 0.99±0.12, range 0.5 to 1.1 mCi (Note: several radiologists determined the dose and performed the injection of radiocolloid; variance not stated). Colloid size: not stated Filtration: peritumoural: unfiltered 1/19, filtered 18/19. subareolar: unfiltered 10/19, filtered 9/19. Injection location: peritumoural: injection in 4 locations around the periphery of the biopsy cavity or lesion; subareolar: injection made in the subareolar lymphatic plexus from four locations around the circumference of the areolae. Injection timing: peritumoural: mean 302.9±31.9, range 180 to 420 minutes prior to surgery; subareolar: mean 318.4±66.1, range 240 to 360 minutes prior to surgery (variance not stated). Massage: not stated Intraoperative probe: Neoprobe (Dublin, Ohio) or C-Trak (Morgan Hill, California). **Dye** Type: 1% isosulphan blue dye Amount: 2 to 5 cc Injection location: dye injected into the parenchyma of the breast around the periphery of the tumour or biopsy cavity. Injection timing: intraoperative Massage: the breast was massaged after injection. **Preoperative lymphoscintigraphy** Timing: not stated **Surgery** Surgeon details: surgery performed at two community hospitals by a single board-certified surgeon. Anaesthesia: not stated Axillary clearance: standard axillary dissection to level I and II in 34/38 patients. Performed if the patient requested it, or if later analysis positive for tumour cells. Sentinel node definition: blue nodes or nodes with counts >10% of background. Final breast procedure: peritumoural: modified radical mastectomy 11/19 (57.9%), lumpectomy with SLNB followed by level I and II axillary dissection 8/19 (42.1%); subareolar: lumpectomy with SLNB followed by level I and II axillary dissection 15/19 (78.9%), lumpectomy with SLNB alone 4/19 (21.1%). **Histologic analysis of sentinel nodes** Intraoperative analysis: not stated Sectioning: node cut at 2 to 3 mm intervals for paraffin embedding. Method of sectioning not stated. Permanent section: H&E IHC: cytokeratin using CAM 5.2. Micrometastases definition: not stated **Histologic analysis of axillary nodes** Bivalved and standard permanent sections completed.	**Age** Peritumoural: 59.5±12.9 years Subareolar: 54.9 ± 12.7 years Variance not stated. **Tumour characteristics** Biopsy method Peritumoural group Excisional biopsy: 12/19 (63.2%) Ultrasound guided or stereotactic core biopsy: 7/19 (36.8%) Subareolar group Excisional biopsy: 12/19 (63.2%) Image guided core biopsy: 7/19 (36.8%) Size Peritumoural: Mean 1.87±0.09, range 0.4 to 3.5 cm. Subareolar: Mean 1.58±0.67, range 0.4 to 3.0 cm. Variance not stated. Stage All patients had Stage I breast cancer. Histology Peritumoural Ductal: 19/19 (100%) Subareolar Ductal: 17/19 (89.5%) Medullary: 1/19 (5.3%) Metaplastic: 1/19 (5.3%) Location Peritumoural UOQ: 7/19 (36.8%) UIQ: 4/19 (21.1%) LOQ: 2/19 (10.5%) LIQ: 1/19 (5.3%) Upper central: 1/19 (5.3%) Lower central: 3/19 (15.8%) Central: 1/19 (5.3%) Subareolar UOQ: 12/19 (63.2%) UIQ: 2/19 (10.5%) LOQ: 2/19 (10.5%) LIQ: 1/19 (5.3%) Upper central: 0/19 (0%) Lower central: 0/19 (0%) Central: 2/19 (10.5%) Palpability Not stated Multifocality/multicentricity Not stated **Axilla characteristics** Clinical axillary status Negative: 38/38 (100%) **Neoadjuvant chemotherapy** Not stated

Study identifier	Procedure	Patient characteristics
Snider, Dowlatshahi, Fan, Bridger, Rayudu & Oleske, 1998. **Number of patients** 80 (Baptist n=48; Rush n-32) **Number of attempted mappings** 80 **Study period** January 1995 to October 1997 **Institution** Departments of Surgery, Pathology and Nuclear Medicine, Baptist Medical Center, Montgomery, Alabama, and the Departments of Surgery, Nuclear Medicine and Preventive Medicine, Rush-Presbyterian-St. Luke's Medical Center, Chicago, Illinois, USA. **Incorporated studies** Jannink *et al.* 1998 **Inclusion/exclusion criteria** Inclusions: patients with invasive breast cancer with clinically negative axillary nodes. Exclusions: none stated **Study included for review of...** Localisation rates and false negative rates	**Radiocolloid/dye combination** Radiocolloid only: 80 Dye only: 0 Radiocolloid and dye: 0 **Radiocolloid** Type: ^{99m}Tc-sulphur colloid (prepared in nuclear medicine department immediately prior to use; kit was CIS-US, Inc, Bedford, Massachusetts, USA). Dose: 1 mCi, diluted to 4 cc with sterile saline or 1% xylocaine. Colloid size: not stated Filtration: at Baptist, the preparation was passed through a 0.45 μm millipore filter (Millipore, Bedford, Massachussets); at Rush, the solution was used unfiltered. Injection location: radiocolloid was injected around the area of the tumour; in the 41/80 (51.3%) patients in whom the tumour had been previously excised, the injection was given into the tissue immediately surrounding the biopsy cavity, aspirating first to ensure the cavity was not being injected; patients whose palpable masses had not been previously excised were also injected by palpation; nonpalpable masses not previously excised were injected with image-guided localisation (3 (4.0%) stereotaxic guidance, 3 (4.0%) mammographic needle localisation prior to wire placement, 9 (11.0%) ultrasound guidance). Injection timing: radiocolloid injected was injected a mean of 97, range 45 to 310 minutes before surgery. Massage: not stated Intraoperative probe: C-Trak (Care-Wise, Morgan Hill, California). **Dye** not used Type: not applicable Amount: not applicable Injection location: not applicable Injection timing: not applicable Massage: not applicable **Preoperative lymphoscintigraphy** Timing: lymphoscintigraphy not performed. **Surgery** Surgeon details: not stated Anaesthesia: not stated Axillary clearance: level I and II axillary dissection. Sentinel node definition: the first node to become radioactive the only true sentinel node. Final breast procedure: partial mastectomy, 42/80 (52.5%); total mastectomy, 15/80 (18.8%); ALND only, 23/80 (28.8%). **Histologic analysis of sentinel nodes** Intraoperative analysis: not stated Sectioning: at Baptist, small SNs were bisected across the short axis; larger SNs were serially sectioned at 2-mm intervals across the short axis. Limited portions (480 μm) of 2-mm blocks were examined at 80 μm intervals with H&E. At Rush, all nodes were sectioned along the longitudinal axis; half the patients in whom the nodes were found were processed in routine manner by sectioning through the centre of the node, and the other half had serial sectioning at 500 μm intervals through the entire node. Permanent section: H&E IHC: at Baptist, patients who had lobular carcinoma, but inconclusive findings on H&E had one section stained with cytokeratin (CAM 5.2). At Rush, half the nodes had serial sectioning with H&E and Cam 5.2 staining of all sections. Micrometastases definition: not stated **Histologic analysis of axillary nodes** Axillary nodes were examined using two levels 80 to 100 μm apart and stained with H&E.	**Age** Mean 62, range 32 to 85 years. **Tumour characteristics** Biopsy method Not stated Size Mean 13.3, range 2 to 29mm. Stage Not stated Histology Lobular 13/80 (16.3%) Ductal 61/80 (76.3%) Ductal and lobular 3/80 (3.8%) Colloid 2/80 (2.5%) Tubular 1/80 (1.3%) Location Not stated Palpability Both palpable and nonpalpable lesions were included. Multifocality/multicentricity Not stated **Axilla characteristics** Clinical axillary status Negative 80/80 (100%) **Neoadjuvant chemotherapy** Not stated

Study identifier	Procedure	Patient characteristics
Solorzano, Ross, Delpassand, Mirza, Akins, Kuerer, Meric, Ames, Newman, Feig, Singletary & Hunt, 2001. **Number of patients** 117 **Number of attempted mappings** 117 **Study period** January to August 2000 **Institution** Departments of Surgical Oncology and Diagnostic Radiology, The University of Texas, M.D. Anderson Cancer Center, Houston, Texas, USA. **Incorporated studies** None **Inclusion/exclusion criteria** Inclusions: patients with clinically negative axillae and biopsy-proven breast cancer who underwent SLN biopsy. Exclusions: none stated **Study included for review of...** Localisation rates	**Radiocolloid/dye combination** Radiocolloid only: 0 Dye only: 0 Radiocolloid and dye: 117 **Radiocolloid** Type: ^{99m}Tc sulphur colloid (CIS-US, Bedford, MA). Dose: 2.5mCi in a volume of 4ml Colloid size: not stated Filtration: filtered Injection location: injected in divided aliquots into the breast tissue surrounding the primary tumour or biopsy cavity. For nonpalpable lesions injections performed under sonographic or mammographic guidance. Injection timing: radiocolloid was injected the day before surgery. Massage: not stated Intraoperative probe: Neo 2000 (Neoprobe Corporation, Dublin, OH). **Dye** Type: 1% isosulphan blue dye (Lymphazurin, US Surgical Corporation, Norwalk, CT). Amount: 5ml Injection location: dye was injected around the tumour. Injection timing: dye was injected just prior to incision. Massage: not stated **Preoperative lymphoscintigraphy** Timing: performed but timing not stated. **Surgery** Surgeon details: not stated Anaesthesia: not stated Axillary clearance: performed if intraoperative analysis positive for metastases, SLN could not be identified, and when the surgeon had performed relatively few SLNB and was trying to determine their false-negative rate; 41/117 (35%) patients had completion axillary clearance. Some patients had micrometastases on detailed examination of sentinel nodes and did not undergo completion axillary dissection. Sentinel node definition: blue stained nodes and/or those with counts ≥ 5 times background counts *in vivo*. Final breast procedure: segmental mastectomy 88/117 (75.2%), mastectomy 26/117 (22.2%) or lumpectomy 3/117 (2.6%). **Histologic analysis of sentinel nodes** Intraoperative analysis: touch preparation techniques used while patient in operating room. If this was inconclusive, frozen sections performed. Sectioning: if intraoperative analyses negative, nodes embedded in paraffin and serial sectioned. Permanent section: H&E IHC: performed using anticytokeratin antibodies. Micrometastases definition: Not stated **Histologic analysis of axillary nodes** Not stated.	**Age** Median 54, range 34 to 84 years. **Tumour characteristics** Biopsy method Excision: 54/117 (46.2%) Core needle biopsy: 59/117 (50.4%) Fine needle aspiration: 4/117 (3.4%) Size ≤ 2cm: 75/117 (64.1%) >2cm but ≤ 5cm: 32/117 (27.4%) >5cm: 1/117 (0.9%) Not stated: 9/117 (7.7%) Stage Tis: 9/117 (7.7%) T1: 75/117 (64.1%) T2: 32/117 (27.4%) T3: 1/117 (0.9%) Histology Invasive: 108/117 (92.3%) Ductal: 97/117 (86.6%) Lobular: 5/117 (4.3%) Other: 6/117 (5.1%) Noninvasive: 9/117 (7.7%) Location Outer quadrant: 65/117 (55.6%) Inner quadrant: 28/117 (23.9%) Central: 24/117 (20.5%) Palpability Not stated Multifocality/multicentricity One of the patients in whom mapping failed to identify an SLN had multicentric DCIS. **Axilla characteristics** Clinical axillary status Negative: 117/117 (100%) **Neoadjuvant chemotherapy** 26 patients underwent preoperative chemotherapy as a component of their treatment.

Study identifier	Procedure	Patient characteristics
Spanu, Dettori, Chessa, Porcu, Cottu, Solinas, Falchi, Solinas, Scanu, Nuvoli & Madeddu, 2001. **Number of patients** 101 (1 male) **Number of attempted mappings** 101 **Study period** Not stated **Institution** Departments of Nuclear Medicine and Surgery, University of Sassari, Sassari, Italy. **Incorporated studies** None **Inclusion/exclusion criteria** Inclusions: patients with proven unifocal primary breast cancer. Exclusions: patients with palpable axillary lymph nodes, pregnancy or lactation. **Study included for review of...** Localisation rates and false negative rates	**Radiocolloid/dye combination** Radiocolloid only: 101 Dye only: 0 Radiocolloid and dye: 0 **Radiocolloid** Type: ^{99m}Tc-labelled sulphur colloid (Lymphoscint; Amersham-Sorin). Dose: mean 37MBq in 0.2 to 0.3ml. Colloid size: ≤ 50nm Filtration: unfiltered Injection location: injected subdermally into one point overlying the lesion, in nonpalpable lesions, the cutaneous projection was obtained using ultrasound or stereotactic mammography. Injection timing: 18 to 24 hours before surgery. Massage: not stated Intraoperative probe: Navigator (Gamma Guidance System, USSC, Norwalk, USA). **Dye** Dye was not used. Type: not applicable Amount: not applicable Injection location: not applicable Injection timing: not applicable Massage: not applicable **Preoperative lymphoscintigraphy** Timing: immediately after radiocolloid injection, and at 75, 90, 105 and 120 minutes and 5 to 6 hours post injection. **Surgery** Surgeon details: not stated Anaesthesia: not stated Axillary clearance: complete axillary lymph node dissection was performed in all cases. Sentinel node definition: counts at least 3 times higher than adjacent normal skin. Final breast procedure: mastectomy or quadrantectomy (numbers not stated). **Histologic analysis of sentinel nodes** Intraoperative analysis: not stated Sectioning: sentinel nodes were formalin fixed and paraffin embedded (<0.5cm embedded whole and 0.5 to 1cm halved, >1cm were cut into slices of about 0.5cm). Sections of 4μm thickness cut, method of sectioning not stated. IHC: all nodes stained with CAM 5.2. Micrometastases definition: tumour deposit <2mm. **Histologic analysis of axillary nodes** H&E, IHC also used if H&E results were doubtful.	**Age** Mean 55.7 ± 10.6, range 32 to 75 years (variance not stated) **Tumour characteristics** Biopsy method FNA: 10/101 (9.9%) CB: 91/101 (90.1%) Size ≤ 0.5cm: 2/101 (2.0%) 0.5 to 1.0cm: 23/101 (22.8%) 1 to 2cm: 62/101 (61.4%) > 2cm but < 2.1cm: 1/101 (1.0%) 2.5cm: 8/101 (7.9%) 3.0cm: 2/101 (2.0%) 3.5cm: 2/101 (2.0%) 4.0cm: 1/101 (1.0%) Stage T1a: 2/101 (2.0%) T1b: 23/101 (22.8%) T1c: 62/101 (61.4%) T2: 14/101 (13.9%) Histology Infiltrating: Ductal: 85/101 (84.2%) Lobular: 15/101 (14.9%) Medullary: 1/101 (1.0%) Location External upper: 31/101 (30.7%) Areolar: 18/101 (17.8%) Middle upper: 14/101 (13.9%) External: 12/101 (11.9%) Internal upper: 9/101 (8.9%) Internal lower: 7/101 (6.9%) External lower: 5/101 (5.0%) Middle of the lower: 4/101 (4.0%) Internal: 1/101 (1.0%) Palpability Palpable: 85/101 (84.2%) Nonpalpable: 16/101 (15.8%) Multifocality/multicentricity Unifocal: 101/101 (100%) **Axilla characteristics** Clinical axillary status Negative: 101/101 (100%) **Neoadjuvant chemotherapy** Not stated

Study identifier	Procedure	Patient characteristics
Stearns, Ewing, Slack, Penannen, Hayes & Tsangaris, 2002. **Number of patients** 34 **Number of attempted mappings** 34 **Study period** November 1997 to July 2000 **Institution** Breast Cancer Program, Departments of Oncology, Pathology, Surgery and Biostatistics Unit, Lombardi Cancer Center, Georgetown University School of Medicine, Washington DC, USA. **Incorporated studies** None **Inclusion/exclusion criteria** Inclusions: women, 18 years or older, who received primary chemotherapy or endocrine therapy for histologically proven infiltrating carcinoma of the breast (T3 or T4) and who underwent an SL during the definitive surgical procedure were included. Exclusions: none stated **Study included for review of...** Localisation rates and false negative rates	**Radiocolloid/dye combination** Radiocolloid only: Dye only: Radiocolloid and dye: **Radiocolloid** Type: radiocolloid was not reported. Dose: not applicable Colloid size: not applicable Filtration: not applicable Injection location: not applicable Injection timing: not applicable Massage: not applicable Intraoperative probe: not applicable **Dye** Type: 1% isosulphan blue Amount: 3 to 5 ml Injection location: dye was injected around the primary breast tumour. If no palpable tumour was identified at the time of procedure the dye was injected around the area where the tumour was previously palpaed. Injection timing: dye was injected immediately prior skin incision. Massage: not stated **Preoperative lymphoscintigraphy** Timing: Not stated **Surgery** Surgeon details: not stated Anaesthesia: not stated Axillary clearance: full level I and II axillary dissection in all patients. Sentinel node definition: blue nodes Final breast procedure: lumpectomy 14/34 (41.2%); mastectomy 20/34 (58.8%). **Histologic analysis of sentinel nodes** Intraoperative analysis: nodes were bivalved along the long axis and two levels of H&E stained frozen sections made at time of surgery. Sectioning: nodes fixed, paraffin embedded and processed, method of sectioning not stated. If metastatic disease detected, no further analysis. In false-negative nodes, serial step sectioning was used with 4 additional levels. Permanent section: H&E (1 section if positive; extra 3 sections if negative). IHC: false negative sentinel nodes were further evaluated for presence of micrometastases by use of IHC using pankeratin antibody cocktail (ChemMate™ Primary Antibody Pan Keratin Clones AE1, AE3, CAM 5.2 and 35βH11; Ventana, Tuscon, AZ, USA). IHC considered positive if positive clusters of atypical cells or multiple single atypical cells in a node. Micrometastases definition: not stated **Histologic analysis of axillary nodes** Standard histopathological evaluation	**Age** Median 46, range 29 to 79 years. **Tumour characteristics** Biopsy method Not stated Size Not stated Stage T3: 25/34 (73.5%) T4: 9/34 (26.5%) Histology Not stated Location UOQ: 16/34 (47.1%) UIQ: 3/34 (8.8%) LOQ: 1/34 (2.9%) LIQ: 1/34 (2.9%) Central: 5/34 (14.7%) Inflammatory: 8/34 (23.5%) Palpability Not stated Multifocality/multicentricity Not stated **Axilla characteristics** Clinical axillary status N0: 8/34 (23.5%) N1: 12/34 (35.3%) N2: 13/34 (38.2%) N3: 1/34 (2.9%) **Neoadjuvant chemotherapy** AC x 4[a]: 7/34 (20.6%) AC x 4, T[b]: 6/34 (17.6%) Dose-dense single-agent AT: 18/34 (52.9%) AC x 4, T and H weekly x 10[c]: 1/34 (2.9%) Endocrine therapy: 2/34 (5.9%) AC doxorubicin 60 mg/m² and cyclophosphamide 6000 mg/m² every 3 weeks; T, paclitaxel 175 mg/m² every 3 weeks; H, Trastuzumab 2 mg/kg; Dose-dense AT, single-agent sequential doxorubicin (A) and paclitaxel (T) administered every 2 weeks with filgrastim. Patient received either 3 cycles of each (A 90 mg/m² and T 250 mg/m², n=11) or four cycles of each (A 60 mg/m² and T 175 mg/m², n=7). [a] 1 woman received three cycles only. [b] 1, 3 and 4 cycles of T in 1, 2, and 3 women, respectively. [c] Weekly paclitaxel 80 mg/m².

Study identifier	Procedure	Patient characteristics
Stitzenberg, Calvo, Iacocca, Neelon, Sansbury, Dressler & Ollila, 2002. **Number of patients** 78 (3 males) **Number of attempted mappings** 80 **Study period** July 1998 to August 1999 **Institution** Departments of Surgery and Pathology; Center for Biostatistics; Lineberger Cancer Center, University of North Carolina, Chapel Hill, North Carolina, USA. **Incorporated studies** None **Inclusion/exclusion criteria** Inclusions: patients with clinical T1 or T2 N0M0 breast cancer. Exclusions: none stated **Study included for review of...** Localisation rates and false negative rates	**Radiocolloid/dye combination** Radiocolloid only: Dye only: Radiocolloid and dye: **Radiocolloid** Type: ^{99m}Tc -labelled sulphur colloid (Nicomed Amersham Canada, Oakville, Ontario, USA). Dose: 250 μCi (9.25 MBq) in each of four 3ml syringes (total 1mCi). Colloid size: not stated Filtration: unfiltered (first 10 patients), then filtered at 0.22μm (Millex-GV filter unit; Millipore SA, Malsheim, France). Injection location: injected into parenchyma adjacent primary tumour or into the wall of the biopsy cavity under sonographic guidance; when tumour was not palpable, radiocolloid injected adjacent a previously placed localisation needle. Injection timing: not stated Massage: if migration was slow or absent, breast compression, warm compresses and position modification were used. Intraoperative probe: handheld gamma probe, type not specified. **Dye** Type: isosulphan blue dye (Lymphazurin; Hirsch Industries, Richmond, VA, USA). Amount: 3 to 5ml Injection location: injected into the breast tissue adjacent to the primary tumour or the wall of the biopsy cavity, when the tumour was not palpable, the dye was injected adjacent a localisation needle. Injection timing: dye was injected in the operating room. Massage: the area was compressed for 3 to 7 minutes. **Preoperative lymphoscintigraphy** Timing: not stated. **Surgery** Surgeon details: five surgeons participated, their experience varied: one surgeon trained formally in lymphatic mapping and sentinel lymphadenectomy for both breast cancer and melanoma; three had experience with lymphatic mapping and sentinel lymphadenectomy for melanoma; one did not have experience but learned under guidance of the other surgeons throughout the validation trial. Anaesthesia: not stated Axillary clearance: level I and II axillary dissection. Sentinel node definition: blue nodes; if the ratio of *ex vivo* SN to background counts was > 10:1 after removal of the SN, the dissection was continued to find additional nodes. Final breast procedure: modified radical mastectomy or lumpectomy (numbers not stated). **Histologic analysis of sentinel nodes** Intraoperative analysis: at the initiation of the validation trial, sentinel nodes were bisected and examined in the frozen section room. If any 'suspicious' areas from this examination found, this portion of the node was processed and stained with H&E. About halfway through the study, non-SN metastases were identified from two cases with tumour free sentinel nodes. The frozen tissue from the sentinel nodes were retrieved and subsequent H&E analysis revealed sentinel node metastases in both cases. From this point forward, gross handling was changed: the node was bivalved along the short axis and each half rotated so the cut surface was up and the halves were placed adjacent to each other. The nodes were then cut at 1mm slices, parallel to the cut surface, and alternating slices sent to surgical	**Age** Mean 55.2, range 26 to 87 years (n= 74 successfully mapped cases) **Tumour characteristics** Biopsy method Not stated Size Mean 2.2, range 0.3 to 11.3cm (n= 74; successfully mapped cases). Stage Not stated Histology Not stated Location Not stated Palpability Palpable and nonpalpable tumours were included. Multifocality/multicentricity |	
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M0	78/78 (100%) | **Axilla characteristics** Clinical axillary status |	
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N0	78/78 (100%)	 **Neoadjuvant chemotherapy** Not stated

	pathology and the tissue procurement facility. Sectioning: if no suspicious gross abnormalities were found, one half of the node was processed and the other half was cryopreserved and sent elsewhere for future study. The tissue submitted to surgical pathology was formalin fixed and paraffin embedded. A single H&E slide was made from each 1mm slice; if metastases found, no further sections made. If negative, 4 levels separated by 15 to 20 μm made from the cut face of the node. After the change in protocol 4 additional levels separated by 15 to 20 μm were made from each 1mm slice. Permanent section: H&E. Initial protocol, single section if positive; sections at levels 1, 3 and 4 from additional sectioning if negative. Final protocol: single section if positive; sections at levels 1, 3 and 4 from additional sectioning of each 1mm slice if negative. IHC: if initial H&E negative, IHC of level 2 section using cytokeratin stain CAM 5.2 (Becton Dickinson, San Jose, CA). Stain considered positive if positive cells were cytologically maliganant or if they were arranged so the architecture was concordant with the primary tumour. Micrometastases definition: not stated **Histologic analysis of axillary nodes** If a node was large it was bisected and put in 2 cassettes. Nodes from cases with negative SNs had additional sectioning and staining identical to the SN (a minimum of 1 level of IHC and 4 levels of H&E).	

Study identifier	Procedure	Patient characteristics
Stradling, Aranha and Gabram, 2002. **Number of patients** 24 (consecutive) **Number of attempted mappings** 24 **Study period** September 19, 2001 to November 18, 2001 **Institution** Chicago College of Osteopathic Medicine of Midwestern University, Chicago, Illinois and Department of Surgery, Loyola University Medica Center, Maywood, Illinois, USA. **Incorporated studies** None **Inclusion/exclusion criteria** Inclusions: consecutive patients who had methylene blue injection for SLNB. Exclusions: none stated **Study included for review of...** Localisation rates	**Radiocolloid/dye combination** Radiocolloid only: 0 Dye only: 0 Radiocolloid and dye: 24 **Radiocolloid** Type: ^{99m}Tc- sulphur colloid Dose: not stated Colloid size: not stated Filtration: not stated Injection location: radiocolloid was injected in the periareolar region. Injection timing: prior to surgery. Massage: not stated Intraoperative probe: not stated **Dye** Type: 1% methylene blue dye Amount: 3 to 5cc Injection location: dye injected into the deep parenchyma and intradermally around the tumour or biopsy cavity. After the first half of patients intradermal injections were discontinued and lonely deep parenchymal injections used. Injection timing: dye was injected in the operating room. Massage: 5 minutes **Preoperative lymphoscintigraphy** Timing: not stated. **Surgery** Surgeon details: two surgeons performed the surgery. Anaesthesia: not stated Axillary clearance: not stated Sentinel node definition: not stated Final breast procedure: not stated **Histologic analysis of sentinel nodes** Intraoperative analysis: not stated Sectioning: not stated Permanent section: not stated IHC: not stated Micrometastases definition: not stated **Histologic analysis of axillary nodes** Not stated	**Age** Not stated **Tumour characteristics** Biopsy method Not stated Size Not stated Stage Not stated Histology Not stated Location Not stated Palpability Not stated Multifocality/multicentricity Not stated **Axilla characteristics** Clinical axillary status Not stated **Neoadjuvant chemotherapy** Some patients had adjuvant therapy after SLNB.

Study identifier	Procedure	Patient characteristics
Tafra, Verbanac & Lannin, 2001b. **Number of patients** 968 **Number of attempted mappings** 968 **Study period** February 1997 to March 2001 **Institution** The Breast Center, Lesly and Pat Sajak Pavilion, Anne Arundel Medical Center, Annapolis, Maryland and Department of Surgery, East Carolina University School of Medicine, Greenville, North Carolina, USA. **Incorporated studies** Tafra *et al.* 2001a **Inclusion/exclusion criteria** Inclusions: patients with breast cancer enrolled from surgical investigators that participated in a formal lymphatic mapping and SL course from both private practice and academic centres. Exclusions: clinically suspicious or positive axillary nodes, pregnancy and extensive cardiac, pulmonary or renal disease. **Study included for review of...** Localisation rates	**Radiocolloid/dye combination** Radiocolloid only: 0 Dye only: 0 Radiocolloid and dye: 968 **Radiocolloid** Type: ^{99m}Tc- sulphur colloid (Tc99; CIS-US, Bedford, Massachusetts). Dose: 1 mCi (37 MBq) Colloid size: not stated Filtration: each site had a choice of using filtered (passed through a 0.2-µm filter) or unfiltered radiocolloid. Injection location: peritumoural Injection timing: timing of radiocolloid injection was not restricted. Massage: not stated Intraoperative probe: C-track (Carewise, Morgan Hill, California); Neoprobe (Neoprobe Corp., Dublin, Ohio); Navigator (US Surgical Corp., Bedford, Ohio). **Dye** Type: Isosulphan blue (American Regent Laboratories, Inc., Shirley, New York). Amount: 2 to 5 ml Injection location: peritumoural Injection timing: immediately prior to surgery. Massage: not stated **Preoperative lymphoscintigraphy** Timing: lymphoscintigraphy was not performed. **Surgery** Surgeon details: surgical investigators were participating in a formal lymphatic mapping and SL course (multicentre trial). Anaesthesia: not stated Axillary clearance: standard level I and II lymph node dissection (preoperative chemotherapy group 26/29 (89.7%) patients had complete lymph node dissection; no preoperative chemotherapy group 663/939 (70.6%) patients had complete lymph node dissection). Sentinel node definition: a SN was defined as any node that was blue, both blue and hot (with hot defined as an *ex vivo* count equal to or greater than 10 times background count), or hot only node. Final breast procedure: not stated **Histologic analysis of sentinel nodes** Intraoperative analysis: not stated Sectioning: all SNs were serially sectioned, and every other section submitted for polymerase chain reaction studies as part of laboratory protocol; each section submitted to pathology was analysed using multiple sections. Permanent section: H&E IHC: the majority of H&E negative SNs were analysed by IHC with cytokeratin cocktail (Cytokeratin AE1:3, Boehringer Mannheim Corp., Indianapolis, Indiana). Micrometastases definition: not stated **Histologic analysis of axillary nodes** Not stated	**Age** Preoperative chemotherapy: Mean 48±13 No preoperative chemotherapy: Mean 58±14 (variance not stated) **Tumour characteristics** Biopsy method Open biopsy, FNA biopsy or core biopsy (including patients undergoing prior lumpectomy). Size Preoperative chemotherapy: Mean 1.4±1.7 cm No preoperative chemotherapy: Mean 0.6±1.3 cm Stage Not stated Histology Ductal: Preoperative chemotherapy 21/29 (72.4%); No preoperative chemotherapy 613/939 (65.3%) Lobular: Preoperative chemotherapy 1/29 (3.4%); No preoperative chemotherapy 73/939 (7.8%) Not stated: Preoperative chemotherapy 7/29 (24.1%); No preoperative chemotherapy 253/939 (26.9%) Location (from Tafra *et al.* 2001a) Upper outer: 244/535 (4.5%) Upper inner: 66/535 (12.3%) Lower outer: 45/535 (8.4%) Lower inner: 39/535 (7.3%) Central: 56/535 (10.5%) Other: 70/535 (13.1%) Unknown: 15/535 (2.8%) Palpability Not stated Multifocality/multicentricity Not stated **Axilla characteristics** Clinical axillary status Negative: 968/968 (100%) **Neoadjuvant chemotherapy** 29/968 (3.0%) preoperative chemotherapy; 939/968 (97.0%) no preoperative chemotherapy.

Study identifier	Procedure	Patient characteristics
Tausch, Konstantiniuk, Jörg, Dubsky, Denison, Haid, Pichler-Gebhard & Rudas, 2002. **Number of patients** 1637 Non-neoadjuvant chemotherapy group: n=1567 Adjuvant chemotherapy group: n=70 **Number of attempted mappings** 1637 **Study period** May 1996 to October 2001 **Institution** Department of Surgery and Institute of Nuclear Medicine, Barmherzige Schwestern Hospital, Linz, the Second Department of Surgery, Landeskrankenhaus Graz, Department of General Surgery, University of Vienna, the Department of Gynaecology, Krankenhaus Lainz, Vienna, the Deparmtent of Surgery, Landeskrankenhaus Feldhirch, the Department of Surgery, Landeshrankenhaus Vöcklabruck and the Institute of Clinical Pathology, University of Vienna, Austria. **Incorporated studies** Gallowitsch *et al.* 2002; Pichler-Gebhard *et al.* 2002 **Inclusion/exclusion criteria** Inclusions: patients with breast cancer. Exclusions: none stated **Study included for review of...** Localisation rates	**Radiocolloid/dye combination** Radiocolloid only: 410 Dye only: 463 Radiocolloid and dye: 766 **Radiocolloid** Type: Nanocoll® and others. Dose: mean activity of 31.7MBq in 1.5cc (neoadjuvant chemotherapy group); 26.5MBq in 1.3cc (non-neoadjuvant chemotherapy group). Colloid size: not stated Filtration: not stated Injection location: peritumourally in 663 patients; subdermally in 479 patients; other in 32 patients. Injection timing: not stated Massage: not stated Intraoperative probe: not stated **Dye** Type: Lymphazurin®, Patent Blue®, and others. Amount: mean volume 3.3cc (neoadjuvant chemotherapy group); 3.2cc (non-neoadjuvant chemotherapy group). Injection location: in the non-neoadjuvant group: peritumourally in 333 patients; subdermally in 294 patients; other/combination in 600 patients. Not stated in the adjuvant chemotherapy group. Injection timing: not stated Massage: not stated **Preoperative lymphoscintigraphy** Timing: whether preoperative lymphoscintigraphy was performed was not stated **Surgery** Surgeon details: not stated Anaesthesia: not stated Axillary clearance: in the initial phase, a complete axillary lymph node dissection was performed after a successful sentinel node biopsy. Sentinel node definition: not stated Final breast procedure: breast-conserving therapy 50/70 (71.4%); mastectomy 20/70 (28.6%) (given for neoadjuvant chemotherapy patients only) **Histologic analysis of sentinel nodes** Intraoperative analysis: not stated Sectioning: not stated Permanent section: not stated IHC: not stated Micrometastases definition: not stated **Histologic analysis of axillary nodes** Not stated	**Age** Mean 59.9 years (non-neoadjuvant chemotherapy group).). Median 51.7 years (neoadjuvant chemotherapy group). **Tumour characteristics** Biopsy method Not stated Size Preoperative chemotherapy reduced an average tumour size of 33, range 8 to 80mm to an average size of 21, range 0 to 70mm. Sizes were not reported for the non-neoadjuvant chemotherapy. Stage T classification after NC: N=70 T0: 6/70 (8.6%) Tis: 2/70 (2.9%) T1a: 4/70 (1.4%) T1b: 5/70 (7.1%) T1c: 21/70 (30.0%) T2: 22/70 (31.4%) T3: 5/70 (7.1%) T4: 2/70 (2.9%) Tx: 3/70 (4.3%) Histology Not stated Location Not stated Palpability Not stated Multifocality/multicentricity Not stated **Axilla characteristics** Clinical axillary status Palpable axillary nodes were present in 17 cases (in the neoadjuvant chemotherapy group) which were completely downstaged in all instances. **Neoadjuvant chemotherapy** n=70 Schedule Cyclophosphamid/ Methotrexate/ Fluorouracil: 4/70 (5.7%) Epirubicin/ Cyclophosphamid: 13/70 (18.6%) Epirubicin/Taxotere: 44/70 (62.9%) Adriamycin/Taxotere: 6/70 (8.6%) Others: 3/70 (4.3%) *Effect of PC* Clinical complete remission: 14/70 (20.0%) Pathological complete remission: 12/70 (17.1%) Partial remission: 23/70 (32.9%) Stable disease: 18/70 (25.7%) Progressive disease: 2/70 (2.9%) Not available: 1/70 (1.4%)

Study identifier	Procedure	Patient characteristics
Tavares, Sapienza, Galeb, Belfort, Costa, Osorio, Goes, Endo, Soares, Lewin & Marone, 2001. **Number of patients** 62 **Number of attempted mappings** 62 **Study period** March 1998 to July 2000 **Institution** UDDO-Nuclear Medicine Department, Avenida Alcantara Machado, Mooca, and The Brazilian Institute of Cancer Control (IBCC), Sao Paulo, Brazil, South America. **Incorporated studies** None **Inclusion/exclusion criteria** Inclusions: patients presented with breast cancer or suspicious mammographic findings, with tumour diameters of less than 5 cm, clinically negative axillae and no distant metastases (T1/T2N0M0). Exclusions: patients with multifocal tumours and those who had previously received chemotherapy were excluded. There was no history of previous breast surgery. **Study included for review of...** Localisation rates and false negative rates	**Radiocolloid/dye combination** Radiocolloid only: 0 Dye only: 21 Radiocolloid and dye: 41 **Radiocolloid** Type: ^{99m}Tc- phytate radionuclide. The phytate (IPEN, São Paulo) containing 20mg phytate and 1mg lyophilised tin chloride was reconstituted into a volume of 3ml, obtained in the form of sodium pertechnetate from a molybdenum-Tc generator (IPEN, São Paulo). Dose: 55-74MBq (1.5-2 mCi) in 3 ml. Colloid size: not stated Filtration: not stated Injection location: radiocolloid injected at four or more distinct points on the cutaneous projection of the palpable breast tumour. Injection timing: not stated Massage: local massage was performed in all patients. Intraoperative probe: GAMMED II-Eurorad gamma probe with a CdTe detector. **Dye** Type: 2% patent blue dye Amount: 4ml Injection location: dye was injected around the tumour. Injection timing: dye was injected approximately 30 minutes before surgery. Massage: not stated **Preoperative lymphoscintigraphy** Timing: images taken 18 to 24 hours prior to surgery, from 10 to 60 minutes after radiocolloid injection; late images were taken up to 4 hours after injection if necessary. **Surgery** Surgeon details: not stated Anaesthesia: not stated Axillary clearance: radical node dissection was carried out. Sentinel node definition: not stated Final breast procedure: not stated **Histologic analysis of sentinel nodes** Intraoperative analysis: the sentinel node was longitudinally incised, and imprinting of the two halves performed using H&E. If the lymph node was >1cm frozen section analysis was also performed, preferentially on the half displaying positive imprinting. Sectioning: the half of the sentinel node not subjected to frozen section (plus any sentinel nodes <1cm) were paraffin embedded, and 3µm slices obtained and stained with H&E. Permanent section: H&E. IHC: not stated Micrometastases definition: not stated **Histologic analysis of axillary nodes** Not stated	**Age** Mean 58, range 34 to 81 years. **Tumour characteristics** Biopsy method Not stated Size Not stated Stage T1/T2N0M0 Histology Not stated Location Not stated Palpability Multifocality/multicentricity Patients with multifocal tumours were excluded. **Axilla characteristics** Clinical axillary status Negative: 62/62 (100%) **Neoadjuvant chemotherapy** Not stated

Study identifier	Procedure	Patient characteristics
Tousimis, Van Zee, Fey, Hoque, Tan, Cody, Borgen & Montgomery, 2003. **Number of patients** 70 **Number of attempted mappings** 70 **Study period** September 1996 to August 2001 **Institution** Breast Service, Department of Surgery and Department of Pathology, Memorial Sloan-Kettering Cancer Center, New York, New York, USA. **Incorporated studies** None **Inclusion/exclusion criteria** Inclusions: patients with multicentric (invasive tumours >5cm apart or in clearly separate quadrants of the breast as documented by initial physical examination) or multifocal (defined as distinct tumours <5cm apart) invasive breast cancer with clinically negative axillary lymph nodes by preoperative physical examination who required a mastectomy. Exclusions: multicentric and multifocal *in situ* carcinoma; breast conservation; neoadjuvant chemotherapy; previous ALND, SLNB, or breast irradiation; recurrent breast cancer; a SLNB performed at an outside institution; or male breast cancer. Also excluded were patients in whom the ALND was performed solely on the basis of an intraoperative frozen-section diagnosis of metastatic carcinoma in the SLN. **Study included for review of...** False negative rates	**Radiocolloid/dye combination** Radiocolloid only: 1 Dye only: 2 Radiocolloid and dye: 67 **Radiocolloid** Type: Not stated Dose: Not stated Colloid size: Not stated Filtration: Not stated Injection location: 5/70 patients had 4 intraparenchymal injections around the tumour or biopsy cavity; 63/70 received one intradermal injection directly over the largest invasive tumour. If the tumours were equivalent in size, the intradermal injection was placed over the tumour closest to the axilla. Injection timing: not stated Massage: not stated Intraoperative probe: not stated **Dye** Type: Isosulphan blue Amount: Not stated Injection location: 67 patients received a single intraparenchymal injection adjacent to the superolateral side of the largest invasive tumour or biopsy cavity, if the tumours were equivalent in size the injection was placed adjacent to the tumour closest to the axilla; 2 patients received intraparenchymal injections adjacent to the second focus of invasive carcinoma after intradermal radioisotope injection over the dominant invasive tumour. Injection timing: not stated Massage: Not stated **Preoperative lymphoscintigraphy** Timing: Whether lymphoscintigraphy was performed in those patients injected with radiocolloid was not stated. **Surgery** Surgeon details: not stated Anaesthesia: not stated Axillary clearance: all patients had 10 or more axillary lymph nodes excised (including the SLNs) as a planned procedure. Sentinel node definition: not stated Final breast procedure: mastectomy **Histologic analysis of sentinel nodes** Intraoperative analysis: not stated Sectioning: not stated Permanent section: not stated IHC: not stated Micrometastases definition: not stated **Histologic analysis of axillary nodes** Not stated	**Age** Mean 52.9, range 31 to 79 years. **Tumour characteristics** Biopsy method Not stated Size Mean 1.8, range 0.2 to 6.5 cm ≤ 0.5cm: 6 (8.6%) 0.5 to 1cm: 13 (18.6%) 1 to 2cm: 27 (38.6%) >2 but ≤ 5cm: 20 (28.6%) >5cm: 4 (5.7%) Stage T1: 46/70 (65.7%) T1a: 6 (8.6%) T1b: 13 (18.6%) T1c: 27 (38.6%) T2: 20 (28.6%) T3: 4 (5.7%) Histology Invasive ductal: 49/70 (70%) Invasive lobular: 18/70 (25.7%) Both: 3/70 (4.3%) Location UOQ: 39/70 (55.7%) LOQ: 13/70 (18.6%) UIQ: 13/70 (18.6%) LIQ: 5/70 (7.1%) Palpability Not stated Multifocality/multicentricity Multicentric: 44/70 (62.9%) Multifocal: 26/70 (37.1%) **Axilla characteristics** Clinical axillary status Negative: 70/70 (100%) **Neoadjuvant chemotherapy** Neoadjuvant chemotherapy was not used.

Study identifier	Procedure	Patient characteristics
Travagli, Atallah, Mathieu, Rochard, Camatte, Lumbroso, Garbay & Rouzier, 2003. **Number of patients** 165 **Number of attempted mappings** 165 **Study period** January 1999 to July 2001 **Institution** Departments of Surgical Oncology, Pathology and Nuclear Medicine, Gustave Roussy Institute, Villejuif, France. **Incorporated studies** None **Inclusion/exclusion criteria** Inclusions: women with T0 or T1≤15mm cytologically-proven breast carcinoma. Exclusions: none stated **Study included for review of...** Localisation rates	**Radiocolloid/dye combination** Radiocolloid only: 35 Dye only: 0 Radiocolloid and dye: 130 **Radiocolloid** Type: ^{99m}Tc sulfur colloid (Nanocis, Cis Bio International, Gif sur Yvette, France). Dose: 15 to 30MBq in 0.05 to 0.4ml Colloid size: not stated Filtration: not stated Injection location: 4 peritumoural injections Injection timing: 4 to 15 hours prior to scintigraphic mapping. Massage: not stated Intraoperative probe: Europrobe (Euromédical, 78150 LeChesnay, France). **Dye** Type: blue dye Amount: not stated Injection location: dye was injected intradermally in the region of the tumour site. Injection timing: dye was injected 10 minutes before skin incision. Massage: not stated **Preoperative lymphoscintigraphy** Timing: performed 4 to 15 hours after colloid injection and 1-4 hours before surgery. **Surgery** Surgeon details: not stated Anaesthesia: not stated Axillary clearance: complete axillary dissection was performed in the patients where the SLN procedure failed, 5/165 (3.0%) and in patients with a positive SLN. Sentinel node definition: blue and hot Final breast procedure: not stated **Histologic analysis of sentinel nodes** Intraoperative analysis: imprint cytology and frozen section analysis carried out if SLN was macroscopically suspicious (1cm and/or firm). Sectioning: fixed SLN was cut in 1.5mm sections. For each section, one level was examined routinely with H&E. If no metastasis was found, H&E was done on three levels at 150µm intervals. Permanent section: H&E IHC: with cytokeratin antibodies (CK22) on initial level and three other levels. Micrometastases definition: not stated **Histologic analysis of axillary nodes** Not stated	**Age** Mean 52.3 years, Median 52 years (SD 10.6). **Tumour characteristics** Biopsy method Not stated Size Mean 12.8mm (SD 3.08). Stage T1a: 4/160 (2.5%) T1b: 42/160 (26.3%) T1c<15mm: 114/160 (71.2%) Note: denominator of 160 used in table instead of n=165. Histology Invasive ductal: 134/160 (83.8%) Invasive lobular: 10/160 (6.3%) Mixed: 6/160 (3.8%) Other: 10/160 (6.3%) Note: denominator of 160 used in table instead of n=165. Location Inner quadrants: 53/160 (33.1%) Outer quadrants: 107/160 (66.9%) Note: denominator of 160 used in table instead of n=165. Palpability Not stated Multifocality/multicentricity Not stated **Axilla characteristics** Clinical axillary status Negative: 165/165 (100%) **Neoadjuvant chemotherapy** Not stated

Study identifier	Procedure	Patient characteristics
Tsugawa, Noguchi, Miwa, Bando, Yokoyama, Nakajima, Michigishi, Tonami, Minato & Nonomura, 2000. **Number of patients** 48 **Number of attempted mappings** 48 **Study period** March 1998 to April 1999 **Institution** Department of Surgery II, Operation Ceneter, Department of Nuclear Medicine and Division of Pathology, Kanazawa University Hospital, Kanazawa University School of Medicine, Kanazawa, Japan. **Incorporated studies** Noguchi *et al.* 2000c **Inclusion/exclusion criteria** Inclusions: women with Tis, clinical stage I or II primary operable breast cancer were enrolled. Exclusions: none stated **Study included for review of...** False negative rates	**Radiocolloid/dye combination** Radiocolloid only: 0 Dye only: 0 Radiocolloid and dye: 48 **Radiocolloid** Type: ^{99m}Tc-HAS (Dai-ichi Radioisotope Laboratory Co Ltd, Tokyo, Japan). Dose: 3 mCi, in a volume of 0.3 ml Colloid size: not stated Filtration: not stated Injection location: radiocolloid injected into the subdermal tissue above the primary tumour or biopsy cavity; if the primary tumour was previously excised, radiocolloid was injected into the walls of the biopsy cavity and surrounding tissues, avoiding putting radiocolloid in the biopsy cavity. Injection timing: radiocolloid injection occurred 30 minutes to 2 hours before patients went in the operating room. Massage: not stated Intraoperative probe: C-Trak System (Care-Wise Medical Product, Morgan Hill, CA, USA); Navigator System (RMD Inc, Watertown, MA, USA). **Dye** Type: 1% patent blue dye (CI 42045; Wako Pure Chemical Industries, Ltd, Osaka, Japan). Amount: 4 ml Injection location: dye was injected into the peritumoural area, with injections placed at 12, 3, 6 and 9 o'clock positions surrounding the breast tumour; if the primary tumour had previously been excised, the dye was injected into the walls of the biopsy cavity and surrounding tissues, avoiding putting dye in the biopsy cavity. Injection timing: 5 to 15 minutes prior to surgery. Massage: not stated **Preoperative lymphoscintigraphy** Timing: both 10 minutes and 1 hour after radiocolloid injection lymphoscintigraphy was performed. **Surgery** Surgeon details: not stated Anaesthesia: general anaesthesia Axillary clearance: complete ALND (level I-III). Sentinel node definition: SN was defined as any blue and/or hot node with a 10:1 *ex vivo* ratio of SN to non-SN. Final breast procedure: modified radical mastectomy 18/48 (37.5%); breast conserving therapy 30/48 (62.5%). **Histologic analysis of sentinel nodes** Intraoperative analysis: not stated Sectioning: at least 3 sections were obtained from each SN at different levels (100-500 μm apart). Permanent section: H&E staining on permanent sections. IHC: if no tumour was identified on H&E staining, another section was stained with IHC using anti-cytokeratin antibody, monoclonal mouse anti-keratins 8, 18 and 19 (MAS 494, Harlan Sera-Lab Ltd, Loughborough, UK). Micrometastases definition: not stated **Histologic analysis of axillary nodes** Complete ALND specimens (& intramammary nodes) were dissected fresh and processed by routine surgical	**Age** Mean 52±12 (SD), range 30 to 86 years. **Tumour characteristics** Biopsy method Surgical: 12/48 (25%) FNA &/or core needle: 36/48 (75%) Size Mean 22±12 (SD) mm ≤ 10 mm: 8/48 (16.7%) >10 mm, ≤ 20 mm: 17/48 (35.4%) >20 mm: 23/48 (47.9%) Stage T0-1: 25/48 (52.1%) T2: 23/48 (47.9) Histology Invasive ductal: 40/48 (83.3%) Other invasive type: 4/48 (8.3%) DCIS: 4/48 (8.3%) Location Medial: 18/48 (37.5%) Lateral: 30/48 62.5%) Palpability Not stated Multifocality/multicentricity Not stated **Axilla characteristics** Clinical axillary status N0 or N1a: 38/48 (79.2%) N1b: 10/48 (20.8%) **Neoadjuvant chemotherapy** Not stated

	pathology techniques for isolation of the lymph nodes; lymph nodes > 5 mm were bisected, and lymph nodes < 5 mm were fixed and embedded uncut; 3 sections were obtained from each lymph node at different levels (100-500 μm apart) and stained with H&E.	

Study identifier	Procedure	Patient characteristics
Tuthill, Reynolds & Goulet Jr, 2001. **Number of patients** 119 **Number of attempted mappings** 120 **Study period** October 1997 to July 1999 **Institution** Departments of Radiology and Surgery, Indiana University School of Medicine, Indiana University Hospital, Indianapolis, Indiana, USA. **Incorporated studies** None **Inclusion/exclusion criteria** Inclusions: women with breast cancer who underwent sentinel node biopsy in the institution. Exclusions: none stated **Study included for review of...** Localisation rates	**Radiocolloid/dye combination** Radiocolloid only: 0 Dye only: 0 Radiocolloid and dye: 119 **Radiocolloid** Type: ^{99m}Tc sulfur colloid Dose: 1.0 mCi Colloid size: not stated Filtration: radiocolloid was filtered. Injection location: into the breast parenchyma around the tumour site. Injection timing: immediately after the final lymphoscintigraphy (up to 60 minutes after injection) the patient was taken to the operating room. Massage: not stated Intraoperative probe: Neo2000 (Neoprobe, Dublin, OH). **Dye** Type: isosulphan blue dye (Lymphazurin: Zenith Parenterals, Rosemont, IL). Amount: 5 ml Injection location: dye was injected around the tumour site. Injection timing: an axillary incision was performed 5 minutes after dye injection. Massage: not stated **Preoperative lymphoscintigraphy** Timing: 15 and 30 min post-injection, an additional image was obtained at 60 mins if sentinel node not identified in initial images. **Surgery** Surgeon details: not stated Anaesthesia: not stated Axillary clearance: in 13 of the initial 16 attempted sentinel node biopsies performed, a planned conventional axillary dissection was also performed. Axillary dissection was also performed in the other 103 patients if frozen section revealed axillary metastases and in women with unsuccessful identification of the sentinel node. Sentinel node definition: blue stained nodes or those that resulted in a decrease of axillary counts after removal, or both. Final breast procedure: not stated **Histologic analysis of sentinel nodes** Intraoperative analysis: frozen sections Sectioning: not stated Permanent section: H&E IHC: was performed on 26 sentinel nodes retrieved in a subset of 13 of the 99 successful sentinel node biopsies. Micrometastases definition: not stated **Histologic analysis of axillary nodes** Not stated	**Age** Median 53, range 27 to 82 years. **Tumour characteristics** Biopsy method Not stated Size Median 1.4, range 0.3 to 7.3 cm. Stage Tis-T1: 87/120 (72.5%) T2-T4: 29/120 (24.2%) Unknown: 4/120 (3.3%) Histology Infiltrating ductal*: 88/120 (73.3%) Infiltrating lobular: 13/120 (10.8%) Mixed: 4/120 (3.3%) Mucinous: 1/120 (0.8%) Medullary: 1/120 (0.8%) Tubular: 2/120 (1.7%) Tubulolobular: 2/120 (1.7%) Ductal# carcinoma *in situ*: 9/120 (7.5%) *: including 4 patients with ductal carcinoma *in situ* with microinvasion. #: either high-grade comedo-type, multifocal, extensive ductal carcinoma *in situ*, or a combination of these. Location Right: 62/119 (52.1%) Left: 56/119 (47.1%) Bilateral: 1/119 (0.8%) Palpability Not stated Multifocality/multicentricity There were no specific criteria for selecting the women with ductal carcinoma in situ who would undergo sentinel node biopsy, but findings in the nine patients selected were either high-grade comedo-type, multifocal, extensive ductal carcinoma *in situ* , or a combination of these diseases. **Axilla characteristics** Clinical axillary status Negative: 119/119 (100%) **Neoadjuvant chemotherapy** Not stated

Study identifier	Procedure	Patient characteristics
Tuttle, Colbert, Christensen, Ose, Jones, Wetherille, Friedman, Swenson & McMasters, 2002. **Number of patients** 158 **Number of attempted mappings** 159 **Study period** August 1999 to December 2000 **Institution** Department of Surgery and the Institute of Research and Education, Park Nicollet Clinic, Menneapolis, Minnesota and the Department of Surgery, University of Minnesota, Minneapolis, Minnesota, and the Department of Surgery, University of Louisville, Louisville, Kentucky, USA. **Incorporated studies** None **Inclusion/exclusion criteria** Inclusions: women with biopsy-proven breast cancer, clinical stage T1N0 to T2N0 were eligible. Exclusions: none stated **Study included for review of...** Localisation rates	**Radiocolloid/dye combination** Radiocolloid only: 0 Dye only: 0 Radiocolloid and dye: 159 **Radiocolloid** Type: ^{99m}Tc-labeled sulfur colloid Dose: 0.75 mCi given in 5ml (5/158) or 0.5ml (153/158). Colloid size: not stated Filtration: radiocolloid was filtered. Injection location: the needle entered the skin below the nipple at the 6:00 position regardless of tumour location, and the radiocolloid was injected into the subareolar location. Injection timing: 1 to 4 hours prior to injection of blue dye. Massage: not stated Intraoperative probe: Neoprobe (Dublin, OH). **Dye** Type: 1% isosulphan blue (Lymphazurin; US Surgical Corporation, Norwalk, CT). Amount: 5ml Injection location: into the breast parenchyma surrounding the tumour. For patients with intact, palpable tumours, the blue dye was injected at the 12:00, 3:00, 6:00 and 9:00 positions. In patients with intact nonpalpable tumours the dye was given as a single injection adjacent to the tumour using radiographic guidance. For patients who had previous excisional biopsies, blue dye was injected around the biopsy cavity. Injection timing: 10 minutes before surgery. Massage: not stated **Preoperative lymphoscintigraphy** Timing: lymphoscintigrams were not routinely obtained. **Surgery** Surgeon details: all procedures performed by one of 7 surgeons with specific training and experience with SLN biopsy for breast cancer. Anaesthesia: Not stated Axillary clearance: completion axillary lymph node dissection was performed in 27/159 (17%) patients; usually when the sentinel nodes contained metastatic disease. Sentinel node definition: nodes with counts ≥ 10% of the *ex vivo* counts of the most radioactive lymph node; or any lymph node staining blue or as any nonblue node connected to a clearly identified blue afferent lymphatic channel. Final breast procedure: partial (74%)or total (26%) mastectomy. **Histologic analysis of sentinel nodes** Intraoperative analysis: not stated Sectioning: each sentinel node analysed with serial sectioning with 6 levels of H&E. Permanent section: H&E IHC: 2 levels of IHC for cytokeratin routinely performed. Micrometastases definition: sentinel nodes considered positive only if tumour cells were clearly identified on H&E staining. Nodes containing scattered, indicidual cytokeratin-positive cells not clearly recognised as tumour cells on H&E were considered negative. **Histologic analysis of axillary nodes** Not stated	**Age** Mean 60, range 31 to 88 years. **Tumour characteristics** Biopsy method Needle 86%; Open 14% Size Mean 1.7, range microinvasion to 8.7 cm. Stage T1 109/159 (68.6%); T1a 13/159 (8.2%); T1b 25/159 (15.7%); T1c 71/159 (44.7%); T2 45/159 (28.3%); T3 5/159 (3.1%); Grade I 27%; Grade II 53%; Grade III 20% Histology Infiltrating ductal or mixed ductal/lobular 87%; Other 13% Location Not stated Palpability Not stated Multifocality/multicentricity Not stated **Axilla characteristics** Clinical axillary status Negative 158/158 (100%) **Neoadjuvant chemotherapy** Not stated

Study identifier	Procedure	Patient characteristics
Uğur, Bozkurt, Sayek, Gedíkoğlu, Baykal, Hamaloğlu, Etíkan, Konan & Erbaş, 2003. **Number of patients** 28 (1 male) **Number of attempted mappings** 29 **Study period** Not stated **Institution** Departments of Nuclear Medicine, Surgery, Pathology and Biostatistics, Hacettepe University Faculty of Medicine, Ankara, Turkey. **Incorporated studies** None **Inclusion/exclusion criteria** Inclusions: Patients with unifocal primary invasive breast cancer with clinically negative axilla scheduled for mastectomy or lumpectomy and axillary clearance. Exclusions: patients with multicentric primary breast cancer or clinically positive regional lymph nodes. **Study included for review of...** Localisation rates and false negative rates	**Radiocolloid/dye combination** Radiocolloid only: 0 Dye only: 0 Radiocolloid and dye: 28 **Radiocolloid** Type: ^{99m}Tc-labelled rhenium sulphide (Nanocolloid, CIS biointernational, France) or ^{99m}Tc-labelled colloidal tin (Amerscan Hepatate II Agent, Nycomed Amersham plc, UK). Dose: 500 to 2500μCi Colloid size: not stated Filtration: not stated Injection location: injected intradermally at the same quadrant as the tumour. Injection timing: radiocolloid was injected 2 to 12 hours before surgery. Massage: not stated Intraoperative probe: Neoprobe 2000 (Neoprobe Corporation, Dublin, OH, USA). **Dye** Type: Isosulphan blue dye (1%) prepared by the Department of Pharmaceutical Technology at Hacettepe University Faculty of Pharmacy using stock solution (Sigma-Aldrich Chemical Co., Deisenhofen, Germany). Amount: 5ml Injection location: not stated Injection timing: dye was injected after the induction of general anaesthesia. Massage: gentle massage was applied for a few minutes. **Preoperative lymphoscintigraphy** Timing: performed immediately following radiocolloid injection; images recorded every minute for 30 minutes. **Surgery** Surgeon details: not stated Anaesthesia: general anaesthesia Axillary clearance: axillary lymph node dissection through levels 1, 2 and/or 3. Sentinel node definition: nodes with *in vivo* counts at least 3 times background and *ex vivo* counts of at least 10 times background. Final breast procedure: mastectomy **Histologic analysis of sentinel nodes** Intraoperative analysis: not stated Sectioning: sentinel nodes were bivalved and three sections were taken. Permanent section: H&E IHC: cytokeratin and epithelial membrane antigen (EMA) IHC was also applied to the sentinel node. Micrometastases definition: not stated **Histologic analysis of axillary nodes** One section was taken from non-sentinel nodes.	**Age** Individual ages were stated, range 25 to 74 years. **Tumour characteristics** Biopsy method Not stated Size Individual sizes were stated, range <2mm (DCIS) to 6cm (not given in 3 patients). ≤ 1cm: 5/25 (20.0%) 1 to 2cm: 12/25 (48.0%) 2 to 3cm: 4/25 (16.0%) > 3cm: 4/25 (16.0%) Stage T1: 16/28 (57.1%) T2: 6/28 (21.4%) T3: 3/28 (10.7%) DCIS: 3/28 (10.7%) Histology Infiltrating ductal: 18/28 (64.3%)* Infiltrating lobular: 1/28 (3.6%) Mixed infiltrating ductal/lobular: 3/28 (10.7%) Mucinous: 1/28 (3.6%) Intraductal carcinoma: 2/28 (7.1%) DCIS/intraductal: 3/28 (10.7%) * Including 2 microinvasive ductal carcinomas. Location UOQ: 15/29 (51.7%) UIQ: 2/29 (6.9%) LOQ: 6/29 (20.7%) Central: 6/29 (20.7%) Palpability Not stated Multifocality/multicentricity Patients with multicentric breast cancer were excluded. **Axilla characteristics** Clinical axillary status Negative: 28/28 (100%) **Neoadjuvant chemotherapy** Not stated

Study identifier	Procedure	Patient characteristics
Upponi, McIntosh, Wishart, Balan & Purushotham, 2002. **Number of patients** 62 **Number of attempted mappings** 62 **Study period** Not stated **Institution** Cambridge Breast Unit and Department of Nuclear Medicine, Addenbrooke's Hospital, Cambridge, UK. **Incorporated studies** None **Inclusion/exclusion criteria** Inclusions: women undergoing sentinel node biopsy for core-biopsy proven invasive breast cancer less then 30 mm on ultrasound were included. Exclusions: none were stated. **Study included for review of...** Localisation rates	**Radiocolloid/dye combination** Radiocolloid only: 0 Dye only: 0 Radiocolloid and dye: 62 **Radiocolloid** Type: ^{99m}Tc -labelled nanocolloid Dose: 45 MBq in 0.5ml. Colloid size: Not stated Filtration: not stated Injection location: in patients with palpable tumours radiocolloid was injected via the localisation needle. Injection timing: on the day prior to surgery for patients with palpable tumours; on the day of surgery for those with impalpable lesions. Massage: not stated Intraoperative probe: gamma probe **Dye** Type: patent blue-V dye (Laboratoire Guerbet, Aulney-Sous-Bois, France). Amount: not stated Injection location: peritumourally Injection timing: dye was injected intraoperatively. Massage: after injection 5 minutes of massage at the injection site was performed. **Preoperative lymphoscintigraphy** Timing: performed 2 hours after radiocolloid injection. **Surgery** Surgeon details: sentinel node biopsy was performed or supervised by the same surgeon in all cases (A.D. Purushotham). Anaesthesia: not stated Axillary clearance: performed in patients where axillary sentinel node detection failed (2/62). Sentinel node definition: not stated Final breast procedure: not stated **Histologic analysis of sentinel nodes** Intraoperative analysis: not stated Sectioning: not stated Permanent section: not stated IHC: not stated Micrometastases definition: not stated **Histologic analysis of axillary nodes** Not stated	**Age** Not stated **Tumour characteristics** Biopsy method Core-biopsy Size < 30 mm Stage Not stated Histology Not stated Location Not stated Palpability Some tumours were palpable (figures not stated). Multifocality/multicentricity Not stated **Axilla characteristics** Clinical axillary status Not stated **Neoadjuvant chemotherapy** Not stated

Study identifier	Procedure	Patient characteristics
Vagelli, Castagnoli, Distante, Orzalesi, Cataliotti & Cesco, 2000. **Number of patients** Group 1: 35 Group 2: 41 **Number of attempted mappings** Group 1: 35 Group 2: 41 **Study period** Not stated **Institution** U.O. Medicina Nucleare Careggi, Azienda Ospedaliera Careggi, and Clinica Chirurgica, Florence, Italy. **Incorporated studies** None **Inclusion/exclusion criteria** Inclusions: Group 1: consecutive patients with biopsy-proven breast cancer, irrespective of the size of the primary tumour or the clinical involvement of axillary lymph nodes. Group 2: patients whose primary lesions measured less than 3cm in diameter. Exclusions: Group 1: none stated Group 2: clinical evidence of axillary metastases. **Study included for review of...** Localisation rates and false negative rates	**Radiocolloid/dye combination** Radiocolloid only: 76 Dye only: 0 Radiocolloid and dye: 0 **Radiocolloid** Type: ^{99m}Tc-micro-nanocolloids Dose: 20 to 37 MBq in 1ml Colloid size: not stated Filtration: not stated Injection location: Group 1: subdermally in four depots (0.2 to 0.3ml x 4) around the primary lesion; Group 2: peritumoural in deeply located mammary nodules. Injection timing: radiocolloid was injected the day before surgery (18-24 hours). Massage: performed in group 2. Intraoperative probe: collimated gamma probe. **Dye** It was not stated that dye was used. Type: not applicable Amount: not applicable Injection location: not applicable Injection timing: not applicable Massage: not applicable **Preoperative lymphoscintigraphy** Timing: dynamic images were taken starting just after injection; static images were taken at 10 to 30 mins and 1 to 3 hours post injection. **Surgery** Surgeon details: not stated Anaesthesia: not stated Axillary clearance: axillary lymph node dissection was performed. Sentinel node definition: when scintigraphy images showed two or more lymph nodes simultaneously, the SN was defined as the one with the highest activity or with an evident afferent lymphatic vessel. Final breast procedure: Not stated **Histologic analysis of sentinel nodes** Intraoperative analysis: frozen sections Sectioning: nodes of major axis smaller than 1 cm were bisected; 4 sections for nodes >1 cm. The sections were frozen and from each section, four 5 μm thick sections were obtained. After intraoperative analysis remaining tissue was thawed, fixed and embedded. For each node, 8 to 16 sections were stained with H&E. Permanent section: H&E; when the sentinel node was tumour negative up to 50 sections were analysed. IHC: when the sentinel node appeared negative, cytokertain staining was performed. Micrometastases definition: not stated **Histologic analysis of axillary nodes** Not stated	**Age** Not stated **Tumour characteristics** Biopsy method Not stated Size Group 2: all primary lesions were less then 3cm in diamter. Stage Not stated Histology Not stated Location Not stated Palpability Not stated Multifocality/multicentricity Not stated **Axilla characteristics** Clinical axillary status Negative: Group 1: not stated; Group 2: 41/41 (100%) **Neoadjuvant chemotherapy** Not stated

Study identifier	Procedure	Patient characteristics
van Berlo, Hess, Nijhuis, Leys, Gerritsen & Schapers, 2003. **Number of patients** 290 (3 males) Series I: 58 patients (2 male) Series II: 70 patients Series III: 162 patients (1 male) **Number of attempted mappings** 290 **Study period** July 1997 to February 2002 Series I: July 1997 to December 1998 Series II: January 1999 to August 2000 Series III: September 2000 to February 2002 **Institution** Departments of Surgery, Nuclear Medicine and Pathology, VieCuri Medical Center, Venlo, The Netherlands. **Incorporated studies** None **Inclusion/exclusion criteria** Inclusions: patients with early breast cancer; Series III, patients with proven breast cancer. Exclusions: Series III: evidence of regional or distant metastases by pulmonary X-ray and axillary ultrasound. None stated for Series I and II. **Study included for review of...** Localisation rates and false negative rates.	**Radiocolloid/dye combination** Radiocolloid only: 0 Dye only: 0 Radiocolloid and dye: 290 **Radiocolloid** Type: ^{99m}Tc-labelled nanocolloid Dose: 1mCi Colloid size: not stated Filtration: not stated Injection location: intradermally until January 2001, then half intradermally and half peritumourally. Injection timing: radiocolloid was injected 18 hours before surgery. Massage: not stated Intraoperative probe:Neoprobe 1000 (until February 2000), later Neoprobe 2000 (Neoprobe Corporation, Dublin, Ohio, USA). **Dye** Type: Patent blue V (Blue Patenté V; Laboratoire Guerbet, Aulnaysous-Bois, France) Amount: 0.5cc Injection location: intradermally Injection timing: dye was injected 5 minutes before incision. Massage: not stated **Preoperative lymphoscintigraphy** Timing: on the day of surgery, timing not stated. **Surgery** Surgeon details: not stated Anaesthesia: general anaesthesia (Series I and II), local anaesthesia without sedation (Series III). Axillary clearance: axillary clearance was performed in 58 patients up to level III after the sentinel node was found (Series I). In Series 2 and 3 patients axillary clearance up to level III was only performed in patients with positive sentinel nodes (n=100). Sentinel node definition: a sentinel node had to show at least 10% of the activity of the tumour. Final breast procedure: breast-conserving 216/290 (74.5%), mastectomy 74/290 (25.5%). **Histologic analysis of sentinel nodes** Intraoperative analysis: not stated Sectioning: not stated Permanent section: histological examination was performed. IHC: IHC was performed. Micrometastases definition: not stated **Histologic analysis of axillary nodes** Not stated	**Age** Not stated **Tumour characteristics** Biopsy method Not stated Size Carcinoma *in situ*: 3/290 (1.0%) ≤ 2cm: 209/290 (72.1%) >2cm but ≤ 5cm: 65/290 (22.4%) >5cm: 11/290 (3.8%) Unknown size: 2/290 (0.7%) Stage Tis: 3/290 (1.0%) T1: 209/290 (72.1%) T2: 65/290 (22.4%) T3: 11/290 (3.8%) T4: 2/290 (0.7%) Histology Ductal: 234/290 (80.7%) Lobular: 31/290 (10.7%) Other: 25/290 (8.6%) Location Left: 170/290 (58.6%) Right: 120/290 (41.4%) Palpability Not stated Multifocality/multicentricity Not stated **Axilla characteristics** Clinical axillary status In Series III patients with evidence of axillary metastases were excluded. **Neoadjuvant chemotherapy** Not stated

Study identifier	Procedure	Patient characteristics
van der Ent, Kengen, van der Pol, Povel, Stroeken & Hoofwijk, 2001. **Number of patients** 256 **Number of attempted mappings** 256 **Study period** April 1997 to February 2000 **Institution** Departments of Surgery and Nuclear Medicine, Maaslandziekenhuis Sittard, The Netherlands. **Incorporated studies** van der Ent *et al.* 1999 **Inclusion/exclusion criteria** Inclusions: consecutive patients with clinically node-negative operable primary breast cancer were included in a prospective study. Exclusions: pregnant women and those with T4 tumours. **Study included for review of...** Localisation rates and false negative rates.	**Radiocolloid/dye combination** Radiocolloid only: 0 Dye only: 0 Radiocolloid and dye: 256 **Radiocolloid** Type: ^{99m}Tc-nanocolloid (Nanocoll, Nycomed Amersham Sorin, Saluggia, Italy). Dose: 10 mCi (370 MBq), in 4 ml saline. Colloid size: not stated Filtration: not stated Injection location: peritumourally or into the breast tissue adjacent to the cavity of the previous excisional biopsy. Injection timing: radiocolloid injection was performed a mean interval of 16 hours (range 12-18) before lymphoscintigraphy. Massage: not stated Intraoperative probe: RMD 10 mm (Radiation Monitoring Devices, Inc., Watertown, MA). **Dye** Type: Patent Blue V (Laboratoire Guerbet, Aulnay-sous-Bois, France). Amount: 0.8-1.0 ml Injection location: intradermally above the tumour or alongside the scar of the excisional biopsy. Injection timing: dye was injected 10 to 15 minutes before the incision. Massage: not stated **Preoperative lymphoscintigraphy** Timing: lymphoscintigraphy was performed after a mean interval of 16 hours (range 12-18) after radiocolloid injection. **Surgery** Surgeon details: not stated Anaesthesia: general anaesthesia Axillary clearance: In phase I (137 patients), SLNB was followed by completion axillary lymph node dissection in all patients; after validation of the technique in the institute in phase 2 completion axillary lymph node dissection was performed only in cases of a tumour-positive axillary SN, or after a doubtful or unsuccessful SN procedure. Sentinel node definition: not stated Final breast procedure: (From van der Ent *et al.* 1999) Breast-conserving surgery 29/70 (41.4%); modified radical mastectomy 41/70 (58.6%). **Histologic analysis of sentinel nodes** Intraoperative analysis: not stated Sectioning: routine H&E of sentinel nodes, followed by serial sectioning when routine staining did not reveal metastases. Permanent section: routine H&E staining IHC: IHC performed whenever routine H&E staining did not reveal metastases. Micrometastases definition: not stated **Histologic analysis of axillary nodes** Not stated	**Age** (From van der Ent *et al.* 1999 – 70 patients) Mean 53.7, range 32-83 years. **Tumour characteristics** Biopsy method FNA or core biopsy: 160/256 (62.5%) Excisional biopsy: 96/256 (37.5%) Size (From van der Ent *et al.* 1999) Clinical tumour size: < 20 mm: 30/70 (42.9%) 20-49 mm: 35/70 (50%) > 49 mm: 5/70 (7.1%) Stage T1: 119/256 (46.5%) T2: 117/256 (45.7%) T3: 20/256 (7.8%) *Histlogy* (From van der Ent *et al.* 1999) Ductal: 51/70 (72.9%) Lobular: 10/70 (14.3%) Ductal and lobular: 5/70 (7.1%) Other: 4/70 (5.7%) Location Upper outer: 116/256 (45.3%) Lower outer: 36/256 (14.1%) Upper inner: 58/256 (22.7%) Lower inner: 26/256 (10.2%) Central: 20/256 (7.8%) Palpability Not stated Multifocality/multicentricity Not stated **Axilla characteristics** Clinical axillary status Clinically node-negative patients were included in the study. (From van der Ent *et al.* 1999 – palpable axillary lymph nodes 11/70 (15.7%)) **Neoadjuvant chemotherapy** Not stated

Study identifier	Procedure	Patient characteristics
Vargas, Tolmos, Agbunag, Mishkin, Vargas, Diggles, Gonzalez, Venegas, Klein & Khalkhali, 2002a. **Number of patients** 73 **Number of attempted mappings** 73 **Study period** 1999 to 2000 **Institution** Departments of Surgery, Nuclear Medicine and Pathology, Harbor-UCLA Medical Center, Torrence, California, USA. **Incorporated studies** None **Inclusion/exclusion criteria** Inclusions: women with T1, T2 and selected T3 breast cancer who underwent sentinel lymph node biopsy. Exclusions: no patients with clinically suspicious axilla were included. **Study included for review of...** Localisation rates	**Radiocolloid/dye combination** Radiocolloid only: 0 Dye only: 0 Radiocolloid and dye: 73 **Radiocolloid** Type: ^{99m}Tc-sulfur colloid Dose: 0.5 μCi in 1 cm^3 Colloid size: not stated Filtration: 0.22 μm filtered Injection location: one injection medial and one lateral to the tumour. Injection timing: radiocolloid injection performed 10 to 30 mins prior to sentinel lymph node biopsy Massage: 3 to 5 minutes Intraoperative probe: C-Trak gamma probe (Care-Wise Medical, Morgan, CA) for first part of study; neo-2000 handheld gamma probe (Ethicon, Cincinnati, OH) for second part. **Dye** Type: 1% isosulphan blue (Ben VenueLabs, Inc., Bedford, OH) Amount: 5 cm^3 Injection location: 4 aliquots of dye were injected in the parenchyma surrounding palpable masses. A single injection was used for nonpalpable breast lesions either under ultrasound guidance or adjacent to the wire guide placed for wire-localised excisional biopsy Injection timing: dye was injected approximately 5 to 10 minutes before biopsy. Massage: the injection site was massaged for approximately 5 minutes. **Preoperative lymphoscintigraphy** Timing: no external imaging or lymphoscintigraphy was performed **Surgery** Surgeon details: operations performed by a single team of surgeons. Anaesthesia: not stated Axillary clearance: not stated Sentinel node definition: blue stained or radioactive. A blue stained node defined as a lymph node that stained blue or a lymph node in the path of a blue afferent lymphatic. Radioactivity *in vivo* defined as a twofold increase over the background counts in the axilla and the presence of any radioactivity *ex vivo*. After excision of the sentinel node counts above 10 per cent of the *ex vivo* counts were considered significant. Final breast procedure: **Histologic analysis of sentinel nodes** Intraoperative analysis: not stated Sectioning: 20 levels were processed in sentinel node serial sectioning. Permanent section: H&E IHC: cytokeratin used when nodes found to be negative during H&E staining. Micrometastases definition: not stated **Histologic analysis of axillary nodes** Not stated	**Age** Median 56, range 32 to 75 years. **Tumour characteristics** Biopsy method Core: 60/73 (82.2%) Excisional: 13/73 (17.9%) Size Carcinoma *in situ*: 3/73 (4.1%) ≤ 2cm: 33/73 (45.2%) >2cm but ≤ 5cm: 31/73 (42.5%) >5cm: 6/73 (8.2%) Stage Tis (high grade): 3/73 (4.1%) T1: 33/73 (45.2%) T2: 31/73 (42.5%) T3: 6/73 (8.2%) Histology Not stated Location UOQ: 39/73 (53.4%) LOQ: 16/73 (21.9%) UIQ: 9/73 (12.3%) Central: 6/73 (8.2%) LIQ: 3/73 (4.1%) Palpability Some tumours were palpable and some were not. Multifocality/multicentricity Not stated **Axilla characteristics** Clinical axillary status Negative: 73/73 (100%) **Neoadjuvant chemotherapy** Not stated

Study identifier	Procedure	Patient characteristics
Vargas, Vargas, Gonzalez, Burla, Venegas, Diggles, Mishkin, Klein & Khalkhakli, 2002b. **Number of patients** 39 **Number of attempted mappings** 70 (31 patients did not have axillary clearance unless sentinel node positive. As this study is included for false negative rates only, these patients are not reported.) **Study period** January 2000 to December 2000 **Institution** Departments of Surgery, Pathology and Radiology, Harbor-UCLA Medical Center, Torrance, California, USA. **Incorporated studies** None **Inclusion/exclusion criteria** Inclusions: patients with biopsy-proven breast cancer, selected Tis stages (percutaneous biopsy, high nuclear grade and extensive), T1 and T2 stages and selected T3 stages (low to intermediate histologic grade). Exclusions: clinically positive axilla. **Study included for review of...** False negative rates	**Radiocolloid/dye combination** Radiocolloid only: 0 Dye only: 0 Radiocolloid and dye: 39 **Radiocolloid** Type: ^{99m}Tc-sulphur colloid Dose: 500μCi (1 ml) Colloid size: not stated Filtration: 0.22μm-filtered Injection location: subdermal, administered as a single injection in the subdermal space of the skin overlying the breast tumour. Injection timing: injection of radiocolloid performed immediately upon entering the operating room. Massage: not stated Intraoperative probe: Neo2000™ (Neoprobe, Dublin, OH, USA). **Dye** Type: Isosulphan blue dye (1% Lymphazurin™, USSC, Norwalk, CT, USA). Amount: not stated Injection location: peritumoural Injection timing: dye was injected after sedation or induction of anaesthesia. Massage: the site of injection was massaged gently for several minutes. **Preoperative lymphoscintigraphy** Timing: intraoperative lymphoscintigraphy was performed in 7 patients. **Surgery** Surgeon details: a single team of surgeons, pathologists and nuclear medicine physicians followed a standardised technique in all cases. Anaesthesia: sedation or general ("induction of anaesthesia"). Axillary clearance: completion axillary dissection. Sentinel node definition: a node in the path of a blue stained lymphatic, a blue node, or a node with counts at least four times those of background. Final breast procedure: not stated **Histologic analysis of sentinel nodes** Intraoperative analysis: not stated Sectioning: 20 levels were processed in sentinel node serial sectioning (Vargas *et al.* 2002a). Permanent section: H&E IHC: cytokeratin used when nodes found to be negative during H&E staining (Vargas *et al.* 2002a). Micrometastases definition: not stated **Histologic analysis of axillary nodes** Not stated	Patient characteristics are for all 70 patients **Age** Median 56, range 35 to 75 years. **Tumour characteristics** Biopsy method Core: 32/70 (45.7%) Vacuum-assisted core: 32/70 (45.7%) ABBI-Siteselect: 1/70 (1.4%) Excisional: 5/70 (7.1%) Size Carcinoma *in situ*: 7/70 (10.0%) ≤ 2cm: 34/70 (48.6%) >2cm but ≤ 5cm: 24/70 (34.3%) >5cm: 5/70 (7.1%) Stage Tis: 7/70 (10.0%) T1: 34/70 (48.6%) T2: 24/70 (34.3%) T3: 5/70 (7.1%) Histology Not stated Location UOQ: 35/70 (50.0%) UIQ: 15/70 (21.4%) LOQ: 5/70 (7.1%) LIQ: 0/70 (0.0%) Retroareolar: 15/70 (21.4%) Palpability Not stated Multifocality/multicentricity Not stated **Axilla characteristics** Clinical axillary status Negative: 39/39 (100%) **Neoadjuvant chemotherapy** Not stated

Study identifier	Procedure	Patient characteristics
Vargas, Vargas, Venegas, Gonzalez, Burla, Mishkin & Khalkhali, 2003a. **Number of patients** 110 **Number of attempted mappings** 110 **Study period** January 2001 to December 2002 **Institution** Departments of Surgery, Radiology and Pathology, Harbor-UCLA Medical Center, Torrance California, USA. **Incorporated studies** None **Inclusion/exclusion criteria** Inclusions: patients with biopsy-proven breast cancer, selected Tis stages (percutaneous biopsy, high nuclear grade and extensive), T1 and T2 stages and selected T3 stages (low to intermediate histologic grade). Exclusions: clinically positive axilla. **Study included for review of...** Localisation rates	**Radiocolloid/dye combination** Radiocolloid only: 0 Dye only: 0 Radiocolloid and dye: 110 **Radiocolloid** Type: ^{99m}Tc-labelled sulphur colloid Dose: 500μCi in 5ml Colloid size: not stated Filtration: 0.22μm-filtered Injection location: intraparenchymal, peritumoural Injection timing: radiocolloid injection given within an hour of surgical incision. Massage: not stated Intraoperative probe:not stated **Dye** Type: Isosulphan blue dye (1% Lymphazurin, USSC, Norwalk, CT, USA) or methylene blue. Amount: 5cc Injection location: peritumoural Injection timing: injection of dye after sedation or induction of anaesthesia. Massage: the site of injection was massaged gently for several minutes. **Preoperative lymphoscintigraphy** Timing: preoperative lymphoscintigraphy was not performed. **Surgery** Surgeon details: a single team of surgeons, pathologists and nuclear medicine physicians followed a standardised technique in all cases. Anaesthesia: sedation or general ("induction of anaesthesia"). Axillary clearance: completion axillary dissection was performed on patients in whom the sentinel node was not found or if the sentinel node contained metastatic cancer on H&E stain. Sentinel node definition: a node in the path of a blue stained lymphatic, a blue node, or a node with counts at least four times those of background. Final breast procedure: wide local excision 69/110 (62.7%); mastectomy 41/110 (37.3%) **Histologic analysis of sentinel nodes** Intraoperative analysis: frozen section Sectioning: 20 levels were processed in sentinel node serial sectioning (Vargas *et al.* 2002a). Permanent section: H&E IHC: cytokeratin used when nodes found to be negative during H&E staining (Vargas *et al.* 2002a). Micrometastases definition: not stated **Histologic analysis of axillary nodes** Not stated	**Age** Mean 54, range 30 to 85 years. **Tumour characteristics** Biopsy method Biopsy proven cancer, methods not stated. Size Mean 25, range 4 to 72mm. Stage Tis: 13/110 (11.8%) T1: 48/110 (43.6%) T2: 43/110 (39.1%) T3: 5/110 (4.5%) T4: 1/110 (0.9%) Histology Infiltrating ductal carcinoma: 70/110 (63.6%) Infiltrating lobular carcinoma: 7/110 (6.4%) DCIS: 13/110 (11.8%) Colloid: 8/110 (7.3%) Papillary: 1/110 (0.9%) Medullary: 1/110 (0.9%) Other: 10/110 (9.1%) Location Not stated Palpability Not stated Multifocality/multicentricity Not stated **Axilla characteristics** Clinical axillary status Negative: 110/110 (100%) **Neoadjuvant chemotherapy** Not stated

Study identifier	Procedure	Patient characteristics
Veronesi, Paganelli, Viale, Galimberti, Luini, Zurrida, Robertson, Sacchini, Veronesi, Orvieto, De Cicco, Intra, Tosi & Scarpa, 1999. **Number of patients** 371 **Number of attempted mappings** 376 (five patients were excluded as lymphoscintigraphy failed to show lymphatic drainage). **Study period** March 1996 to March 1998 **Institution** Divisions of Senology, Nuclear Medicine, Pathology, Epidemiology and Biostatistics, Medical Physics and Anesthesiology, Instituto Europeo di Oncologia, Milan, Italy. **Incorporated studies** de Cicco *et al.* 1998a, de Cicco *et al.* 1998b; Galimberti *et al.* 1998; Galimberti *et al.* 2000; Paganelli *et al.* 1998; Veronesi *et al.* 1997; Veronesi *et al.* 2001b; Viale *et al.* 1999; Zurrida *et al.* 2000; Zurrida *et al.* 2001. **Inclusion/exclusion criteria** Inclusions: consecutive patients with operable breast carcinoma. Exclusions: pregnancy, lactation, noninfiltrating carcinoma, previous excisional biopsy, clinical evidence of metastases to the axilla. Five patients were excluded as lymphoscintigrapy failed to show lymphatic drainage. **Study included for review of...** False negative rates	**Radiocolloid/dye combination** Radiocolloid only: 317 Dye only: 0 Radiocolloid and dye: 54 **Radiocolloid** Type: ^{99m} Tc-labelled colloidal particles of human albumin (Albures; Sorin Biomedica, Sallugia, Italy). Dose: 5 to 10MBq Colloid size: range 200 to 1000nm in 0.2ml saline Filtration: not stated Injection location: subdermal if the tumour was superficial; peritumoural if the tumour was deep. Injection timing: day before surgery, usually 14-20 hours. Massage: not stated Intraoperative probe: Scinti Probe (MR100, Pol.Hi.Tech, L'Aguila, Italy). **Dye** Type: blue dye, type not stated. Amount: 4ml Injection location: subdermally or peritumourally, depending on the depth of the tumour. Injection timing: dye was injected 5 minutes before skin incision. Massage: not stated **Preoperative lymphoscintigraphy** Timing: preoperative lymphoscintigraphy was performed the day before surgery, on the day of radiocolloid injection. **Surgery** Surgeon details: not stated Anaesthesia: not stated Axillary clearance: total axillary dissection, removing all lymph nodes including those at the third level as defined by Berg. Sentinel node definition: blue and/or radioactive nodes. Final breast procedure: quadrantectomy 342/371 (92.2%); modified radical mastectomy 292/371 (78.7%). **Histologic analysis of sentinel nodes** Intraoperative analysis: frozen section (final 311 patients). Sectioning: frozen sections analysed by lymph node bisection followed by freezing half of the lymph node and examination of at least three serial sections (first 192 frozen sections). Technique changed to removal of the fibrous fatty tissue from around the sentinel node without breaking the capsule, the node was then bisected along the major axis (lymph nodes <5mm were embedded uncut) and both halves were embedded in freezing medium, cut surfaces up, and frozen with isopentane cooled liquid nitrogen (last 119 patients). At least 3 serial sections used for frozen section analysis (first 192 frozen sections). In the last 119 patients, 15 pairs of frozen sections 4µm thick were cut at 50µm intervals, ~60 sections/node. If there was residual tissue, extra pairs of sections cut at 100µm intervals until the SN was completely sampled. Permanent section: H&E in the first 60 patients. IHC: if the H&E stain was negative or doubtful, the other slide was stained for cytokeratins using a rapid method (EPOS Anti-cytokeratin/HRP; Dako, Copenhagen, Denmark) using the MNF116 monocolonal antibody. Micrometastases definition: not stated **Histologic analysis of axillary nodes** Other axillary lymph nodes isolated from fat tissue without freezing or preservation and examined by standard technique. Lymph nodes > 0.5 cm were bisected, <0.5 cm were fixed and embedded uncut. Three sections from each lymph node at different levels (100-500 µm apart) were stained with H&E.	**Age** Mean 52, range 25 to 77 years. **Tumour characteristics** Biopsy method Patient s having previous excisional biopsy were excluded. Size Mean pathologic diameter 1.7cm | | | | |---|---| | <1.5cm | 142/376 (37.8%) | | 1.5 to 1.9cm | 115/376 (30.6%) | | >1.9cm | 114/376 (30.3%) | Stage Not stated Histology Not stated Location | | | |---|---| | Right | 189/371 (50.9%) | | Left | 182/371 (49.1%) | | UOQ | 206/371 (55.5%) | | UIQ | 66/371 (17.8%) | | LOQ | 57/371 (15.4%) | | LIQ | 25/371 (6.7%) | | Central | 17/371 (4.6%) | Palpability Not stated Multifocality/multicentricity Not stated **Axilla characteristics** Clinical axillary status | | | |---|---| | Negative | 371/371 (100%) | **Neoadjuvant chemotherapy** Not stated

Study identifier

Veronesi, Paganelli, Viale, Luini, Zurrida, Galimberti, Intra, Veronesi, Robertson, Maisonneuve, Renne, De Cicco, De Lucia & Gennari, 2003.

Number of patients
257

Number of attempted mappings
649 (subjected to exclusions; only 257 patients had sentinel lymph node biopsy and axillary clearance).

Study period
March 1998 to December 1999

Institution
Divisions of Senology, Nuclear Medicine, Pathology, Epidemiology and Anaesthesiology, European Institute of Oncology and the University of Milan School of Medicine, Milan, Italy.

Incorporated studies
None

Inclusion/exclusion criteria
Inclusions: patients, 40 to 75 years of age, with invasive carcinoma and no history of any cancer except skin cancer were eligible. Patients with primary breast cancer in whom the tumour was ≤ 2cm in diameter were randomly assigned to undergo, after breast-conserving surgery, either sentinel node biopsy and total axillary dissection (the axillary dissection group) or sentinel node biopsy followed by axillary dissection only if the sentinel node contained metastatic breast cancer (the sentinel node group).
Exclusions: patients who had multicentric cancer or who had previously undergone excisional biopsy were not eligible. See table below for further exclusions.

Patients	No.
Initially considered for enrolment	649
Not eligible	78
Noninvasive breast cancer	12
Tumour diameter >2cm	32
Multicentric disease	26
Sentinel node not revealed by scintigraphy	8
Eligible for enrolment	571
Not randomly assigned to a study group	39
Patients decision	25
Sentinel node not	3

Procedure

Radiocolloid/dye combination
Radiocolloid only: 257
Dye only: 0
Radiocolloid and dye: 0

Radiocolloid
Type: ^{99m}Tc-labelled colloidal human albumin.
Dose: 5 to 10MBq in 0.2ml of saline.
Colloid size: 50 to 200nm
Filtration: not stated
Injection location: subdermal if the tumour was superficial; peritumoural if the tumour was deep.
Injection timing: radiocolloid was injected 4 to 20 hours before surgery.
Massage: not stated
Intraoperative probe: gamma-ray-detecting probe.

Dye
Dye was not used.
Type: not applicable
Amount: not applicable
Injection location: not applicable
Injection timing: not applicable
Massage: not applicable

Preoperative lymphoscintigraphy
Timing: although preoperative lymphoscintigraphy was performed, the timing was not stated.

Surgery
Surgeon details: not stated
Anaesthesia: not stated
Axillary clearance: all three levels (Berg levels – I, lateral; II, posterior; III, medial to the minor pectoralis muscle).
Sentinel node definition: radioactive nodes.
Final breast procedure: all patients underwent quadrantectomy or wide resection.

Histologic analysis of sentinel nodes
Intraoperative analysis: frozen section
Sectioning: sentinel nodes were bisected and embedded (cut surface up) in CellPath, and frozen in isopentane cooled liquid nitrogen (nodes <5mm were embedded uncut). If more than one sentinel node was localised in a patient, all nodes were examined. For each node large enough to be cut, 15 pairs of frozen sections, 4μm thick, were cut at 50μm intervals for each half (approximately 60 sections total). If residual tissue was left, additional

Patient characteristics

Age

40 to 45 years	35/257 (13.6%)
46 to 55 years	88/257 (34.2%)
56 to 65 years	92/257 (35.8%)
66 to 75 years	42/257 (16.3%)

Tumour characteristics
Biopsy method
Patients with previous excisional biopsy were excluded.
Size

<1.0cm	65/257 (25.3%)
1.1-1.5cm	123/257 (47.9%)
>1.5cm	69/257 (26.8%)

Stage

Grade I	81/257 (31.5%)
Grade II	119/257 (46.3%)
Grade III	54/257 (21.0%)

Histology

Ductal infiltrating	212/257 (82.5%)
Lobular infiltrating	20/257 (7.8%)
Other	20/257 (7.8%)

Location

Outer quadrant	187/257 (72.8%)
Inner or central quadrant	70/257 (27.2%)

Palpability
Not stated
Multifocality/multicentricity
Patients with multicentric disease were excluded.

Axilla characteristics
Clinical axillary status
Not stated

Neoadjuvant chemotherapy
Patients with unfavourable prognostic characteristics were given systemic adjuvant therapy according to standard protocols. All patients also received radiation to the ipsilateral breast over a period of 8 weeks.

evident on preoperative probe-guided inspection	
Frozen sectioning not feasible	3
Other	8
Randomly assigned to a study group	532
Not able to be evaluated	6
Multicentric, bilateral, or extensive multifocal disease	5
Sentinel node not identified at surgery	5
Benign lesion on final histologic examination	4
Metastatic disease	2

Study included for review of...
False negative rates

pairs of sections were cut at 100μm intervals until the entire node was sampled. One section in each pair was stained with H&E.
Permanent section: permanent section was not performed.
IHC: if the result of the H&E stain was ambiguous, the other section was stained for cytokeratins by means of a rapid method (EPOS Cytokeratin reagent with HRP, Dako, Copenhagen, Denmark) and stained for the monoclonal antibody MNF116.
Micrometastases definition: not stated.

Histologic analysis of axillary nodes
Other axillary lymph nodes isolated from fat tissue without freezing or preservation and examined by standard technique. Lymph nodes > 0.5 cm were bisected, <0.5 cm were fixed and embedded uncut. Three to six sections obtained from each lymph node at different levels (100-500 □ m apart) were stained with H&E.

Study identifier	Procedure	Patient characteristics
Vigário, Sapienza, Sampaio, Piato, Barros, Barros, Pinotti & Buchpiguel, 2003. **Number of patients** 83 Group 1: preoperative chemotherapy 37/83 (44.6%); Group 2: no preoperative chemotherapy 46/83 (55.4%). **Number of attempted mappings** 83 **Study period** June 1999 to February 2001 **Institution** Departments of Nuclear Medicine, Gynaecology and Radiology, Hospital Clinics of the Faculty of Medicine, University of São Paulo, São Paulo, Brazil, South America. **Incorporated studies** Piato *et al.* 2003 **Inclusion/exclusion criteria** Inclusions: women with single breast cancer, diagnosed by core biopsy or FNA were included in the study. Exclusions: palpable axillary lymph nodes before chemotherapy or at the time of surgery; pregnancy, multicentric tumours, previous incisional biopsy, previous breast surgery, clinical evidence of metastases and bone scintigraphy with possible lesions. **Study included for review of...** Localisation rates and false negative rates.	**Radiocolloid/dye combination** Radiocolloid only: 83 Dye only: 0 Radiocolloid and dye: 0 **Radiocolloid** Type: Tc-^{99m} dextran-70 (IPEN, São Paulo, Brazil). Dose: 0.4 mCi (14.8 MBq), in 0.2 ml Colloid size: not stated Filtration: not stated Injection location: ultrasound-guided or mammography-guided peritumoural injection Injection timing: radiocolloid injection performed 3-4 hours before lymphoscintigraphy. Massage: not stated Intraoperative probe:Scinti Probe MR 100 (Pol Hi Tech) **Dye** not used Type: not applicable Amount: not applicable Injection location: not applicable Injection timing: not applicable Massage: not applicable **Preoperative lymphoscintigraphy** Timing: lymphoscintigraphy was performed 3-4 hours after radiocolloid injection on the day before surgery. **Surgery** Surgeon details: not stated Anaesthesia: not stated Axillary clearance: ALND Sentinel node definition: not stated Final breast procedure: lumpectomy or mastectomy. **Histologic analysis of sentinel nodes** Intraoperative analysis: frozen sections were obtained. Sectioning: not stated Permanent section: H&E sections were obtained. IHC: if metastases were not identified using H&E, then IHC was performed using anticytokeratin antibodies. Micrometastases definition: not stated **Histologic analysis of axillary nodes** Not stated	**Age** Group 1: Mean 49.2±8.7 (SD) years Group 2: Mean 56.3±14.2 (SD) years **Tumour characteristics** Biopsy method Core biopsy or FNA Size Tumour size measured after **Surgery** Group 1: Mean 2.03±0.99 (SD) cm Group 2: Mean 2.05±1.19 (SD)cm Stage Group 1 (n=37) T1N0: 17/37 (45.9%) T2N0: 20/37 (54.1%) Group 2 (n=46) T1N0: 24/46 (52.2%) T2N0: 22/46 (47.8%) Histology Not stated Location For 8/70 (11.4%) patients with false negative SN: Patient 1: Superior-external Patient 2: Retroareollar Patient 3: Superior-external Patient 4: Superior-external Patient 5: External Patient 6: Inferior-external Patient 7: Superior-external Patient 8: Superior-external Palpability Not stated Multifocality/multicentricity Patients with multicentric tumours were excluded from the study. **Axilla characteristics** Clinical axillary status Negative: 83/83 (100%) **Neoadjuvant chemotherapy** 37/83 (44.6%) patients received preoperative chemotherapy. The regimen included 3 cycles of doxorubicin (24 mg/m^2 per week, intravenously) and cyclophosphamide (60 mg/m^2 per day, by mouth).

Study identifier	Procedure	Patient characteristics
Villa, Gipponi, Buffoni, Vecchio, Bianchi, Agnese, Di Somma, Catturich, Rosato, Tomei, Nicolò, Badellino, Mariani & Canavese, 2000. **Number of patients** 284 **Number of attempted mappings** 284 **Study period** Not stated **Institution** Nuclear Medicine Service, DIMI, University of Genoa Medical School, Genoa, and Divisions of Surgical Oncology and Pathology, National Cancer Institute, Genoa, Italy. **Incorporated studies** Mariani *et al.* 2000 **Inclusion/exclusion criteria** Not stated **Study included for review of...** Localisation rates	**Radiocolloid/dye combination** Radiocolloid only: 0 Dye only: 0 Radiocolloid and dye: 284 **Radiocolloid** Type: ^{99m}Tc-labeled human albumin nanocolloid. Reagent supplied by Nycomed-Amersham-Sorin (Saluggia, Italy) as a sterile, pyrogen-free, freeze-dried mixture containing stannous chloride as the chelating agent for instant labelling with freshly eluted ^{99m} -Tc-pertechnetate. Dose: about 10 MBq, in 0.15 ml. Colloid size: 50-80 nm Filtration: not stated Injection location: radiocolloid was injected subdermally on the cutaneous projection of the tumour mass. Injection timing: not stated Massage: gentle massage was applied to the injection site in order to ease lymphatic drainage. Intraoperative probe:in most patients two different gamma probes were simultaneously employed: Neoprobe 1000 (Neoprobe Corporation, Dublin, Ohio, USA); ScintiProbe MR 100 (Pol.Hi.Tech, Carsoli, Italy) **Dye** Type: Patent blue violet Amount: 0.5 ml Injection location: dye was injected subdermally. Injection timing: at surgery Massage: not stated **Preoperative lymphoscintigraphy** Timing: all patients underwent lymphoscintigraphy 18 hours before surgery. **Surgery** Surgeon details: not stated Anaesthesia: not stated Axillary clearance: standard axillary dissection (197/284 (69.4%) patients underwent standard axillary dissection irrespective of the SN status). Sentinel node definition: not stated Final breast procedure: not stated **Histologic analysis of sentinel nodes** Intraoperative analysis: not stated Sectioning: not stated Permanent section: H&E IHC: not stated Micrometastases definition: not stated **Histologic analysis of axillary nodes** Not stated	**Age** Mean 59.4±11.1 (variance not stated), range 30-84 years. **Tumour characteristics** Biopsy method Not stated Size ≤ 0.5 cm: 16/284 (5.6%) 0.5 to 1.0cm: 37/284 (13.0%) 1 to 2cm: 211/284 (74.3%) >2cm but ≤ 5cm: 20/284 (7.0%) Stage T1a: 16/284 (5.6%) T1b: 37/284 (13.0%) T1c: 211/284 (74.3%) T2: 20/284 (7.0%) Histology Not stated Location Not stated Palpability Not stated Multifocality/multicentricity Not stated **Axilla characteristics** Clinical axillary status N0: 243/284 (85.6%) N1: 41/284 (14.4%) **Neoadjuvant chemotherapy** Not stated

Study identifier	Procedure	Patient characteristics
Walker, Hussain & Humphrey, 2002. **Number of patients** 122 **Number of attempted mappings** 122 **Study period** November 1998 to August 2001 **Institution** Rochdale Breast Unit, Birch Hill Hospital, Rochdale, UK. **Incorporated studies** None **Inclusion/exclusion criteria** Inclusions: patients with breast cancer. Exclusions: heavy axillary tumour burden as assessed clinically, previous axillary surgery, multifocal disease and therapeutic localisation biopsy. **Study included for review of...** Localisation rates and false negative rates.	**Radiocolloid/dye combination** Radiocolloid only: 0 Dye only: 122 Radiocolloid and dye: 0 **Radiocolloid** Radiocolloid was not used. Type: not applicable Dose: not applicable Colloid size: not applicable Filtration: not applicable Injection location: not applicable Injection timing: not applicable Massage: not applicable Intraoperative probe: not applicable **Dye** Type: patent blue V Amount: 1 to 2 ml (first 25 patients); in remaining 97 patients, dye was infiltrated but the amount was not stated. Injection location: in first 25 patients dye was injected around the tumour ,into the adjacent subcutaneous tissues, and intradermally. In the next patients the axilla was explored first, usually via a separate curvilinear incision. Dye was infiltrated along the border of the tumour nearest the axilla. Injection timing: after induction of general anaesthesia. Massage: In the first 25 patients gentle massage of the area of injection was used. **Preoperative lymphoscintigraphy** Timing: not applicable **Surgery** Surgeon details: single consultant surgeon Anaesthesia: general anaesthesia Axillary clearance: formal four-node sampling was carried out. Sentinel node definition: not stated Final breast procedure: Mastectomy (2/122) or breast conserving procedures (120/122). **Histologic analysis of sentinel nodes** Intraoperative analysis: not stated Sectioning: tissue was paraffin-embedded, but the method of sectioning was not stated. Permanent section: not stated IHC: Not stated Micrometastases definition: not stated **Histologic analysis of axillary nodes** Axillary nodes were paraffin-embedded.	**Age** Mean 56, range 28 to 82 years. **Tumour characteristics** Biopsy method Not stated Size < 2 cm diameter: 49/122 (40.2%) 2 to 3 cm diameter: 67/122 (54.9%) > 3 cm diameter: 5/122 (4.1%) > 3.5 cm: 0/122 Unknown: 1/122 (0.8%) Stage Grade 1: 29/122 (23.8%) Grade 2: 52/122 (42.6%) Grade 3: 35/122 (28.7%) None recorded: 6/122 (4.9%) Histology Infiltrating ductal carcinoma: 93/122 (76.2%) Lobular carcinoma: 16/122 (13.1%) Mixed: 8/122 (6.6%) Mucinous carcinomas: 2/122 (1.6%) Papillary tumours: 2/122 (1.6%) Ductal carcinoma *in situ* with microinvasion: 1/122 (0.8%) Location In 9 cases where no sentinel node was found, 4 patients had tumours in the lower medial quadrant, 3 were centrally and 2 were in the lateral lower quadrant. Palpability Not stated Multifocality/multicentricity Patients with multifocal disease were excluded. **Axilla characteristics** Clinical axillary status Not stated **Neoadjuvant chemotherapy** Not stated

Study identifier	Procedure	Patient characteristics
Wantanabe, Kimijima, Ohtake, Tsuchiya, Shishido & Takenoshita, 2001. **Number of patients** 87 **Number of attempted mappings** 87 **Study period** February 1999 to June 2000 **Institution** Departments of Surgery 2 and radiology, Fujushima Medical University, Fukushima, Japan. **Incorporated studies** None **Inclusion/exclusion criteria** Inclusions: consecutive women with breast cancer. Exclusions: clinical evidence of axillary metastasis. **Study included for review of...** Localisation rates and false negative rates	**Radiocolloid/dye combination** Radiocolloid only: 87 Dye only: 0 Radiocolloid and dye: 0 **Radiocolloid** Type: ^{99m}Technetium colloidal rhenium sulphide Dose: 37 to 185 MBq in 0.3 to 0.4 ml Colloid size: 50 to 200 nm Filtration: Not stated Injection location: at 4 points (3, 6, 9 and 12 o'clock positions) into the breast tissue surrounding the tumour or biopsy cavity. In some patients, radiocolloid was also injected into breast tissue surrounding a second, or multiple, tumours. Injection timing: radiocolloid was injected one day before surgery (usually 20 hours). Massage: Not stated Intraoperative probe: neo 2000™ gamma probe (Neoprobe Corporation, Dublin, OH, USA) **Dye** Dye was not used. Type: not applicable Amount: not applicable Injection location: not applicable Injection timing: not applicable Massage: not applicable **Preoperative lymphoscintigraphy** Timing: in the first 40 patients, lymphoscintigraphy was performed 2, 4 and 19 hours after injection. In other patients it was performed 2 hours after injection **Surgery** Surgeon details: not stated Anaesthesia: not stated Axillary clearance: complete axillary dissection was performed. Sentinel node definition: hottest node Final breast procedure: modified radial mastectomy 44/87 (50.6%); breast conserving operation 43/87 (49.4%). **Histologic analysis of sentinel nodes** Intraoperative analysis: frozen sections Sectioning: frozen sections cut into 2 mm slices. Remaining frozen tissue was thawed, fixed and embedded. Permanent section: standard histological examination IHC: in 65 patients sentinel nodes were stained for cytokeratin. Micrometastases definition:Not stated **Histologic analysis of axillary nodes** Routine H&E	**Age** Mean 51, range 28 to 79 years. **Tumour characteristics** Biopsy method Excision biopsy: 7/87 (8.0%) Fine-needle or core biopsy: 80/87 (92.0%) Size Mean 2.7, range 0 to 7.4 cm. ≤ 2 cm: 33/87 (37.9%) > 2 cm but ≤ 5 cm: 46/87 (52.9%) > 5 cm: 8/87 (9.2%) Stage T1: 33/87 (37.9%) T2: 46/87 (52.9%) T3: 8/87 (9.2%) Histology Not stated Location Not stated Palpability Not stated Multifocality/multicentricity 2 tumours: 6/87 (6.9%) 3 tumours: 1/87 (11.5%) **Axilla characteristics** Clinical axillary status Negative: 87/87 (100%) **Neoadjuvant chemotherapy** Not stated

Study identifier	Procedure	Patient characteristics
Weerts, Maweja, Tamigneaux, Dallemagne, Jourdan, Markiewiez, Monami, Wahlen, Lastra, Ilénon, Gomez, Lilet, Dwelshauwers, Graas, Focan, Lipczei, Abraham & Jehaes, 2002. **Number of patients** 60 **Number of attempted mappings** 60 **Study period** March 1999 to March 2001 **Institution** Departments of Senology, Nuclear Medicine, Oncology, Surgery and Pathology, St. Joseph Clinics, Liége, Belgium and Department of Surgery, A. Renard Clinic, Herstal, Belgium. **Incorporated studies** None **Inclusion/exclusion criteria** Inclusions: consecutive patients undergoing planned axillary node dissection with biopsy-proven invasive breast carcinoma. Exclusions: clinically positive axilla. **Study included for review of...** Localisation rates and false negative rates.	**Radiocolloid/dye combination** Radiocolloid only: 60 Dye only: 0 Radiocolloid and dye: 0 **Radiocolloid** Type: ^{99m}Tc nanocolloid (Nanocol°) Dose: Group 1: 1mCi in 0.2ml; Group 2: 1mCi in 0.1ml of saline Colloid size: not stated Filtration: unfiltered Injection location: Group 1: intramammary peritumoural (four infiltrations); Group 2: intradermal injection (one injection) Injection timing: Group 1: day before surgery; Group 2: four hours prior to surgery. Massage: not stated Intraoperative probe: Neoprobe 2000° (Johnson and Johnson) **Dye** Dye was not used. Type: not applicable Amount: not applicable Injection location: not applicable Injection timing: not applicable Massage: not applicable **Preoperative lymphoscintigraphy** Timing: in Group 2, 2 hours after the injection. **Surgery** Surgeon details: not stated Anaesthesia: not stated Axillary clearance: axillary dissection performed. Sentinel node definition: not stated Final breast procedure: not stated **Histologic analysis of sentinel nodes** Intraoperative analysis: not stated Sectioning: all nodes bisected and routinely examined with H&E. Sentinel nodes negative with routine H&E were serially sectioned. Permanent section: H&E IHC: KLI cytokeratine antibodies in all sentinel nodes negative on initial H&E. Micrometastases definition: not stated **Histologic analysis of axillary nodes** Not stated	**Age** Mean 59.6, range 39-83 years. **Tumour characteristics** Biopsy method Not stated Size Not stated Stage T1: 20/60 (33.3%) T2: 40/60 (66.7%) Histology Invasive ductal: 43/60 (71.7%) Invasive lobular: 10/60 (16.7%) Other: 7/60 (11.7%) Location UO quadrant: 34/60 (56.7%) UI quadrant: 12/60 (20%) LO quadrant: 6/60 (10%) LI quadrant: 5/60 (8.3%) Retroareolar: 3/60 (5%) Palpability Not stated Multifocality/multicentricity Not stated **Axilla characteristics** Clinical axillary status Negative: 60/60 (100%) **Neoadjuvant chemotherapy** Not stated

Study identifier	Procedure	Patient characteristics
Winchester, Sener, Winchester, Perlman, Goldschmidt, Motykie, Martz, Rabbitt, Brenin, Stull & Moulthrop, 1999. **Number of patients** 180 **Number of attempted mappings** 180 **Study period** December 1996 - **Institution** Departments of Surgery, Radiology and Pathology, Evanston Northwestern Healthcare, Evanston, Illinois and Northwestern University Medical School, Chicago, Illinois, USA. **Incorporated studies** None **Inclusion/exclusion criteria** Inclusions: consecutive patients with histologically proven invasive breast cancer. Patients with tumours larger than 2 cm and prior neoadjuvant chemotherapy were still enrolled in the first phase study (72/180). Exclusions: pregnancy, clinically positive ipsilateral axillary nodes. **Study included for review of...** Localisation rates	**Radiocolloid/dye combination** Radiocolloid only: 180 Dye only: 0 Radiocolloid and dye: 0 **Radiocolloid** Type: ^{99m} technetium sulphur colloid Dose: 30 to 37 mBq (0.5 to 1.0 mCi) in 1ml (20/180); 37 mBq (1mCi) in 8ml (160/180 patients). Colloid size: 0.22µm (160/180 patients) Filtration: first 20/180 patients: unfiltered; remaining 160/180 patients, filtered through a 0.22µm filter. Injection location: in a 4-quadrant peritumoural distribution. In patients with nonpalpable tumours, needle localisation was performed first, followed by injection either along the guidewire or in a 4-quadrant distribution around the guidewire. Injection timing: first 80/180 patients, 1 to 4 hours prior to sentinel node excision; remaining 100/180 patients, 16 to 20 hours prior to excision. Massage: not stated Intraoperative probe: hand-held gamma probe **Dye** Dye was not used. Type: not applicable Amount: not applicable Injection location: not applicable Injection timing: not applicable Massage: not applicable **Preoperative lymphoscintigraphy** Timing: performed on the day of surgery. **Surgery** Surgeon details: three surgeons participated in the study. Anaesthesia: not stated Axillary clearance: during the first phase of the study, a standard level I/II node dissection was done (72/180); during second phase (108/180) only patients with positive sentinel nodes had a completion level I/II axillary dissection. Sentinel node definition: a node was considered to be sentinel if the *ex vivo* counts per second exceeded three times the node basin background level. Final breast procedure: not stated **Histologic analysis of sentinel nodes** Intraoperative analysis: frozen sections Sectioning: 10 sections at 20µm intervals, embedded in formalin and stained with H&E If more than 3 sentinel nodes were removed, only the 3 nodes with the highest counts per second were examined with 10 sections. Additional sentinel and nonsentinel nodes were examined by the conventional method of bivalving, creating one slide stained with H&E for each node. Permanent section: H&E. IHC: IHC stains were not used. Micrometastases definition: not stated **Histologic analysis of axillary nodes** Bivalved and stained with H&E.	**Age** Not stated **Tumour characteristics** Biopsy method Not stated Size See below Stage T1a 0-5mm: 7/180 (3.9%) T1b 6-10mm: 48/180 (26.7%) T1c 11-20mm: 78/180 (43.3%) T2 >21mm: 47/180 (26.1%) Histology Not stated Location Not stated Palpability Not stated Multifocality/multicentricity Not stated **Axilla characteristics** Clinical axillary status Negative: 180/180 (100%) **Neoadjuvant chemotherapy** In the first phase of the study (72/180) patients who had prior neoadjuvant chemotherapy were still enrolled.

Study identifier	Procedure	Patient characteristics
Wong, Chao, Edwards, Carlson, Laidley, Noyes, McGlothin, Ley, Tuttle, Schadt, Pennington, Legenza, Morgan & McMasters (for the University of Louisville Breast Cancer Study Group), 2002a. **Number of patients** 3324 **Number of attempted mappings** 3324 **Study period** August 1997 to February 2002 **Institution** Department of Surgery, Division of Surgical Oncology, Louisville, Kentucky, USA. **Incorporated studies** Chao *et al.* 2001; Chao *et al.* 2002; Chao *et al.* 2003; McMasters *et al.* 2000a; McMasters *et al.* 2000b; McMasters *et al.* 2001a; McMasters *et al.* 2001b; Martin *et al.* 2000; Wong *et al.* 2001a; Wong *et al.* 2001b; Wong *et al.* 2001c; Wong *et al.* 2001d; Wong *et al.* 2002b; Wong *et al.* 2002c **Inclusion/exclusion criteria** Inclusions: patients with clinical stage T1 to T2, N0 breast cancer (although some were found to have T3 tumours on pathologic analysis). The following histopathologic subtypes were examined; infiltrating ductal, infiltrating lobular, pure tubular carcinoma, pure medullary carcinoma, pure papillary carcinoma, pure colloid (mucinous) carcinoma and DCIS with microinvasion (DCISM). Exclusions: other categories such as Paget's disease, breast sarcoma, or metaplastic carcinoma represented a tiny number of patients and were not included in this analysis. Patients with mixed subtypes were excluded from this analysis. Patients with atypical medullary carcinoma were not included in the group with pure medullary carcinoma. Findings of DCIS in association with any particular invasive cancer subtype did not affect the author's classification scheme. **Study included for review of...** Localisation rates and false negative rates.	**Radiocolloid/dye combination** Radiocolloid only: 210 Dye only: 231 Radiocolloid and dye: 2883 Sentinel node biopsy was performed using blue dye alone and/or radiocolloid, at the surgeons' discretion. **Radiocolloid** Type: not stated Dose: not stated Colloid size: not stated Filtration: not stated Injection location: not stated Injection timing: not stated Massage: not stated Intraoperative probe:not stated **Dye** Type: not stated Amount: not stated Injection location: not stated Injection timing: not stated Massage: not stated **Preoperative lymphoscintigraphy** Timing: whether preoperative lymphoscintigraphy was performed was not stated. **Surgery** Surgeon details: patients from 300 surgeons. Anaesthesia: not stated Axillary clearance: level I/II axillary dissection. Sentinel node definition: any node that was blue, any node that was the most radioactive or "hottest" node, or any node that contained radioactive counts 10% or more of the *ex vivo* count of the hottest node. Final breast procedure: Partial mastectomy: 2254/3324 (67.8%) Mastectomy: 1070/3324 (37.2%) **Histologic analysis of sentinel nodes** Intraoperative analysis: not stated Sectioning: sections at no greater than 2mm intervals. There was no central pathology review. Permanent section: H&E IHC: IHC was advocated during the initial years of the study, but abandoned thereafter. Micrometastases definition: not stated **Histologic analysis of axillary nodes** Not stated	Patient characteristics were given in the paper as percentages associated with the histopathologic subtypes. Patient numbers have been determined from these percentages, but rounding error may occur and so the patient numbers may be slightly erroneous. **Age** Range 26 to 94 years. **Tumour characteristics** Biopsy method Excisional: 1249/3324 (37.6%) Needle: 2075/3324 (62.4%) Size ≤ 2cm: 2358/3324 (70.9%) > 2cm but ≤ 5 cm: 890/3324 (26.8%) > 5cm: 76/3324 (2.3%) Stage T1: 2358/3324 (70.9%) T2: 890/3324 (26.8%) T3: 76/3324 (2.3%) Histology Infiltrating ductal: 2842/3324 (85.5%) Infiltrating lobular: 301/3324 (9.1%) Tubular: 35/3324 (1.1%) Colloid: 84/3324 (2.5%) Papillary: 14/3324 (0.4%) Medullary: 24/3324 (0.7%) DCISM: 24/3324 (0.7%) Location Not stated Palpability Not stated Multifocality/multicentricity Not stated **Axilla characteristics** Clinical axillary status Negative: 3324/3324 (100%) **Neoadjuvant chemotherapy** Not stated

Study identifier	Procedure	Patient characteristics
Xavier, Amaral, Cerski, Fuchs, Spiro, Oliveira, Menke, Biazús, Cavalheiro & Schwartsmann, 2001. **Number of patients** 56 **Number of attempted mappings** 56 **Study period** April 1999 to August 2000 **Institution** Breast Clinic, Department of Gynaecology and Obstetrics, Academic Hospital, Federal University of Rio Grande do Sul, Porto Alegre, RS, Brazil, South America. **Incorporated studies** None **Inclusion/exclusion criteria** Inclusions: sequential patients with breast cancer and no clinical evidence of axillary involvement; mastectomy or breast conservation patients, minium sample of 10 axillary lymph nodes. Exclusions: multiple primary invasive breast cancer, prior chemotherapy, pregnancy or evidence of distant metastasis. Two additional patients were excluded; one could not be evaluated due to problems with the technique and one was seen to have two primary tumours at operation. **Study included for review of...** Localisation rates and false negative rates.	**Radiocolloid/dye combination** Radiocolloid only: 0 Dye only: 6 Radiocolloid and dye: 50 Radiocolloid: Type: ^{99m}Tc dextran 500 Dose: 37 MBq (1 mCi) in aliquots (size not stated) for a total injected volume of 2ml. Colloid size: not stated Filtration: not stated Injection location: in the parenchyma around the primary tumour and subcutaneous of the breast. Injection timing: 3 to 17 hours before surgery Massage: not stated Intraoperative probe: gamma probe **Dye**: Type: 2.5% blue patent V sodium Amount: 2 ml Injection location: locally into the four quadrants of the surrounding tissue of the tumour, as well as intradermally. Injection timing: at the moment of surgery. Massage: 3 to 5 minutes **Preoperative lymphoscintigraphy** Timing: 1.5 to 2 hours after radiocolloid injection. **Surgery** Surgeon details: not stated Anaesthesia: general anaesthesia Axillary clearance: "classical" Sentinel node definition: blue/green and/or showed *in vivo* radioactivity counts at least twice the background; or when the *ex vivo* counts are at least three times the background counts of normal lymph nodes or fat. Final breast procedure: Breast conservation 44/56 (78.6%); Mastectomy 12/56 (21.4%). **Histologic analysis of sentinel nodes** Intraoperative analysis: frozen section Sectioning: not stated Permanent section: routine H&E IHC: pancytokeratins (AE1 & AE3); if first slides failed to show metastatic foci, two additional series of slides were done. Micrometastases definition: ≤ 2mm **Histologic analysis of axillary nodes** Not stated	**Age** Median 57, range 32 to 82 years **Tumour characteristics** Biopsy method core Size Median 2.3 cm (range 0.8 to 7.0) ≤ 2cm: 32/56 (57.1%) > 2cm: 24/56 (42.9%) Stage Not stated Histology Not stated Location Outer quadrants: 41/56 (73.2%) Inner quadrants: 15/56 (26.8%) Palpability Not stated Multifocality/multicentricity Patients with multiple tumours were excluded. **Axilla characteristics** Clinical axillary status Negative: 56/56 **Neoadjuvant chemotherapy** Patients who had undergone prior (which may not be the same as neoadjuvant chemotherapy) were excluded.

Study identifier	Procedure	Patient characteristics
Xu, Liu, Sun & Chen, 2002. **Number of patients** 42 **Number of attempted mappings** 42 **Study period** March 1999 to May 2000 **Institution** Departments of Nuclear Medicine and Pathology, Cancer Hospital, Peking Union Medical College and Chinese Academy of Medical Sciences, Beijing, China. **Incorporated studies** None **Inclusion/exclusion criteria** Inclusions: women diagnosed with breast cancer by fine needle aspiration or excisional biopsy. Exclusions: pregnant or nursing mothers and patients who had received prior breast surgery, chemotherapy or radiotherapy. **Study included for review of...** Localisation rates and false negative rates.	**Radiocolloid/dye combination** Radiocolloid only: 42 Dye only: 0 Radiocolloid and dye: 0 **Radiocolloid** Type: $^{99m}Tc^{m}$ -dextran (Syncor Pharmic Limited Compnay, Beijing, China). Dose: 37 MBq (0.3 to 0.4 ml) Colloid size: not stated Filtration: not stated Injection location: peritumoural or around the residual cavity. Injection timing: not stated Massage: not stated Intraoperative probe: gamma probe (GDP; Chinese Atomic Energy Institute, China). **Dye** Type: not stated Amount: not stated Injection location: not stated Injection timing: Massage: not stated **Preoperative lymphoscintigraphy** Timing: not stated **Surgery** Surgeon details: not stated Anaesthesia: not stated Axillary clearance: complete Sentinel node definition: "count of the SLN was about 100 000/frame" Final breast procedure: "primary tumour was removed" **Histologic analysis of sentinel nodes** Intraoperative analysis: not stated Sectioning: lymph nodes > 0.5 cm in diameter were bisected longitudinally; those < 0.5 cm were embedded whole. When all sentinel lymph nodes were negative, three more sections of axillary lymph nodes were made 100 μm apart. Permanent section: H&E (2 sections). IHC: cytokeratin (1 section). Micrometastases definition: not stated **Histologic analysis of axillary nodes** Two additional H&E slides and one cytokeratin slide when the sentinel lymph nodes were negative.	**Age** Mean 49.6 years, range 29 to 71 **Tumour characteristics** Biopsy method Fine needle aspiration biopsy 32/42 Excisional biopsy 10/42 Size Mean 2.38 cm {0.92}; range 1.0 to 5.0 cm Stage T1: 21/42 (50%) T2: 21/42 (50%) Histology DCIS: 34/42 (81.0%) Adenocarcinoma: 2/42 (4.8%) Medullary carcinoma: 3/42 (7.1%) Intraductal carcinoma: 1/42 (2.4%) Mixed carcinoma: 2/42 (4.8%) Location UOQ: 17/42 (40.5%) UIQ: 6/42 (14.3%) LOQ: 11/42 (26.2%) LIQ: 3/42 (7.1%) Areola: 5/42 (11.9%) Palpability No palpable axillary nodes. Multifocality/multicentricity Not stated **Axilla characteristics** Clinical axillary status Not stated **Neoadjuvant chemotherapy** Not stated

Study identifier	Procedure	Patient characteristics
Yang, Nam, Lee, Lee, Jung & Kim, 2001. **Number of patients** 18 **Number of attempted mappings** 18 **Study period** March 1996 to July 1998 **Institution** Departments of Surgery and Nuclear Medicine, Sungkyunkwan University; Samsung Medical Center, School of Medicine, Seoul National University Hospital and Chonbuk National University, Seoul, Korea. **Incorporated studies** None **Inclusion/exclusion criteria** Inclusions: women with clinically nonpalpable axillary node (except 1 suspicious case). Exclusions: not stated **Study included for review of...** Localisation rates and false negative rates.	**Radiocolloid/dye combination** Radiocolloid only: 0 Dye only: 18 Radiocolloid and dye: 0 **Radiocolloid** Radiocolloid was not used. Type: not applicable Dose: not applicable Colloid size: not applicable Filtration: not applicable Injection location: not applicable Injection timing: not applicable Massage: not applicable Intraoperative probe: not applicable **Dye** Type: Isosulphan blue dye Amount: 6 ml (50 mg isosulphan dye mixed with 5 ml water) Injection location: breast parenchyme surrounding the primary tumour site. Injection timing: 5 minutes Massage: not stated **Preoperative lymphoscintigraphy** Timing: not applicable **Surgery** Surgeon details: not stated Anaesthesia: not stated Axillary clearance: to Berg's level III Sentinel node definition: blue in colour. Final breast procedure: 4 breast conservative surgery, 14 modified radical mastectomy. **Histologic analysis of sentinel nodes** Intraoperative analysis: frozen section Sectioning: not stated Permanent section: H&E IHC: not stated Micrometastases definition: not stated **Histologic analysis of axillary nodes** H&E	**Age** Mean 45, range 22 to 58 years **Tumour characteristics** Biopsy method Not stated Size Range 1 x 1 to 7 x 4 cm. Stage Clinical DCIS: 2/18 (11.1%) Stage 1(T1N0 5): 5/18 27.8%) Stage IIA (T2N0 6): 6/18 (33.3%) Stage IIB (T3N0 4): 4/18 (22.2%) Stage IIIA (T3N1 1): 1/18 (5.6%) Pathology Tis: 2/18 (11.1%) T1: 7/18 (38.9%) T2: 7/18 (38.9%) T3: 2/18 (11.1%) Histology Not stated Location Not stated Palpability None palpable (except 1 suspicious case). Multifocality/multicentricity Not stated **Axilla characteristics** Clinical axillary status N0: 17/18 (94.4%) N1: 1/18 (5.6%) **Neoadjuvant chemotherapy** Not stated

Study identifier	Procedure	Patient characteristics
Yong, Wong, Lee, Soo, Tan & Goh, 2003 **Number of patients** 312 **Number of attempted mappings** 312 **Study period** August 1996 to December 1998 **Institution** Departments of Surgery, Pathology and Nuclear Medicine, Singapore General Hospital, Singapore **Incorporated studies** None **Inclusion/exclusion criteria** Inclusions: all patients with stage I and II breast cancer and non-palpable axillary nodes, including those with previous excision biopsy. Exclusions: pregnant women, those with previous axillary surgery and women with advanced breast cancer with enlarged axillary nodes. **Study included for review of...** Localisation rates and false negative rates.	**Radiocolloid/dye combination** Radiocolloid only: 0 Dye only: 0 Radiocolloid and dye: 312 **Radiocolloid** Type: ^{99m}Tc tin colloid (prepared in own Department of Nuclear Medicine). Dose: 2.0 ml (5 mCi) Colloid size: 200 to 800 nm Filtration: unfiltered Injection location: peritumoural into the breast parenchyma on the side of the tumour facing the axilla and also on the two adjacent sides of the tumour. Injection timing: 2 to 6 hours prior to surgery. Massage: not stated Intraoperative probe: C-Trak® gamma probe (Care Wise Medical Products Corporation, CA, US) **Dye** Type: 1% patent vital blue Amount: 2.0 ml Injection location: peritumoural or into the surrounding of the previous excision biopsy cavity. Injection timing: when the patients were in the operating theatre and just before general anaesthesia. Massage: 5 minutes **Preoperative lymphoscintigraphy** Timing: not performed **Surgery** Surgeon details: six surgeons with varying levels of experience Anaesthesia: general anaesthesia Axillary clearance: levels I and II Sentinel node definition: node that is stained blue and that gives at least 10 times background radioactivity count. Final breast procedure: not stated **Histologic analysis of sentinel nodes** Intraoperative analysis: not stated Sectioning: all sentinel lymph nodes bisected and each half sectioned; no serial sectioning performed. Permanent section: routine H&E IHC: not performed Micrometastases definition: not stated **Histologic analysis of axillary nodes** Routine H&E	**Age** Mean 53, range 28 to 83 years. **Tumour characteristics** Biopsy method 28/312 patients had excision biopsy. Size Mean 2.6 cm (range 0.6 to 9.0 cm). Stage Not stated except that 5 patients had tumours larger than 5 cm (T3). Histology DCIS 88% Invasive lobular carcinoma 6% Others (including mucinous and papillary carcinoma) 6% Note: patients numbers not given Location Medial 16% Central 43% Lateral 41% Note: patient numbers not given Palpability 286/312 (91.7%) of patients presented with a mass. Multifocality/multicentricity Not stated **Axilla characteristics** Clinical axillary status Negative 312/312 (100%) **Neoadjuvant chemotherapy** Not stated

Study identifier	Procedure	Patient characteristics
Yu, Hsu, Liu, Sheu, Li & Chao, 2002. **Number of patients** 218 **Number of attempted mappings** 221 (3 synchronous bilateral breast cancer). **Study period** October 1998 to December 2000 **Institution** Department of Surgery, Division of General Surgery and Departments of Radiology and Pathology, Tri-Service General Hospital, National Defense Medical Center, Tapei, Taiwan, Republic of China. **Incorporated studies** None **Inclusion/exclusion criteria** Inclusions: women without clinically palpable tumour or tumour < 3 cm. Exclusions: women with prior breast operation, axillary surgery, axillary radiation therapy, or preoperative adjuvant chemotherapy. **Study included for review of...** Localisation rates and false negative rates	**Radiocolloid/dye combination** Radiocolloid only: 0 Dye only: 218 Radiocolloid and dye: 0 **Radiocolloid** not used Type: not applicable Dose: not applicable Colloid size: not applicable Filtration: not applicable Injection location: not applicable Injection timing: not applicable Massage: not applicable Intraoperative probe: not applicable **Dye** Type: methylene blue (Rise Sun Trading Co., Taiwan). Amount: 5 ml Injection location: peritumoural Injection timing: approximately 5 minutes. Massage: not stated **Preoperative lymphoscintigraphy** Timing: not applicable **Surgery** Surgeon details: single surgeon Anaesthesia: general anaesthesia Axillary clearance: level I and II nodes, Rotter's node and level III nodes occasionally (complete axillary clearance if SN not identified). Sentinel node definition: blue staining, followed proximally to the tail of the breast Final breast procedure: 154 (69.7%) modified radical mastectomy or 67 (30.3%) breast conserving surgeries - quadrantectomy **Histologic analysis of sentinel nodes** Intraoperative analysis: air-dried touch imprints of sentinel nodes for cytological examination. Immediately after excision the node was cut bi-valvely or tri-valvely, depending on size (4 slides, each with 2 imperssions). Two slides stained with Quick-Diff, and two slides for IHC. Results within 1 hour. (78 sets of sentinel node imprints available from 77 patients; each set 1 to 5 nodes, 4 imprints of each; reviewed by single experienced cytologist). Sectioning: every node > 2mm was grossly sectioned and all nodal tissues paraffin embedded and stained (4 histological sections of each sentinel node were examined). Permanent section: H&E IHC: cytokeratin, as indicated on embedded sections and CK and epithelial membrane antigen (EMA) on imprint slides. Micrometastases definition: positive staining for CK or EMA in morphologically atypical cells **Histologic analysis of axillary nodes** An experienced histopathologist examined at least 2 sections of other nodes.	**Age** Mean 46, range 26 to 82 years. **Tumour characteristics** Biopsy method Fine needle aspiration in at least some women Size Not palpable: 35/221 (15.8%) ≤ 1 cm: 11/221 (5.0%) 1-2 cm: 88/221 (39.8%) 2-3 cm: 87/221 (39.4%) Stage T0 to T2 Histology Not stated Location Not stated Palpability Tumour palpable at < 3 cm in 183 cases, and not palpable in 35 cases. Multifocality/multicentricity Not stated **Axilla characteristics** Clinical axillary status Negative: 218/218 (100%) **Neoadjuvant chemotherapy** Patients who had preoperative adjuvant chemotherapy were excluded from the study.

Study identifier	Procedure	Patient characteristics
Zavagno, Busolin, Bozza, Ramuscello, Griggio, Montesco, Valsecchi, Capitanio, Casara, Dalla Pozza, Bonazza, Rossi, Meggiolaro & Lise, 2000. **Number of patients** 126 **Number of attempted mappings** 126 **Study period** not stated **Institution** Istituto di Clinica Chirurgica II and Istituto di Anatomia Patologica, Universita di Padova; Divisione Chirurgica II, Servizio di Anatomia Patologica and Servizio di Medicina Nucleare, Axienda Ospedaliera di Mestre; Divisione Chirurgica II, Servizio di Medicina Nucleare, Axienda Ospedaliera di Padova; Divisione Chirurgica, Servizio di Anatomia Patologica, Servizio di Medicina Nucleare, Axienda Ospedaliera di Venezia; Divisione Chirurgica, Azienda, Ospedaliera di Dolo, Italy. **Incorporated studies** None **Inclusion/exclusion criteria** Inclusions: consecutive patients with operable primary T1-T2 breast cancer and clinically negative axilla. Exclusions: *in situ* carcinoma, previous excisional biopsy of the breast tumour, clinical evidence of axillary metastases and women who were pregnant and/or lactating. **Study included for review of...** False negative rates	**Radiocolloid/dye combination** Radiocolloid only: 126 Dye only: 0 Radiocolloid and dye: 0 **Radiocolloid** Type: ^{99m}TC-labelled colloidal human albumin Dose: 30-70 MBq in 0.2 ml saline Colloid size: 200-3000 nm in first 100 patients (Albures, Nicomed-Italia, Saluggia, Italy); ≤ 80 nm in last 26 patients (Nanocoll, Nicomed-Italia, Saluggia, Italy). Filtration: not stated Injection location: subdermal into cutaneous projection of breast tumour. Injection timing: 18 to 24 hours Massage: not stated Intraoperative probe: C – Track-Care Wise, CA or Navigator – USSC, Norwalk, USA **Dye** not used Type: not applicable Amount: not applicable Injection location: not applicable Injection timing: not applicable Massage: not applicable **Preoperative lymphoscintigraphy** Timing: Images obtained 20 minutes and 2 hours after injection. **Surgery** Surgeon details: not stated Anaesthesia: not stated Axillary clearance: complete axillary dissection Sentinel node definition: the node with the highest count; accessory sentinel nodes had a probe count ≥ 10% of the most radioactive lymph node. Final breast procedure: 48 (38%) modified radical mastectomy; 78 (62%) breast conserving surgery (quadrantectomy or tumourectomy with lymphadenectomy). **Histologic analysis of sentinel nodes** Intraoperative analysis: frozen section in 81/115 cases (70.4%); 25 cases were positive and 56 were negative. Sectioning: For frozen sections the sentinel node was bisected and frozen sections taken from both cut surfaces. Tissue then processed for routine histology (34 cases only had routine histology). At least 5 consecutive sections taken from each paraffin block. To enhance detection of micrometastases, nodes <0.5 cm were sectioned each 2-3 mm. For each sample, 2 frozen sections at 40 μm intervals were used. Frozen tissue then thawed, fixed and embedded for permanent sections. Two consecutive 5 μm tissue sections cut from each block at three levels, each 40 um apart. Permanent section: H&E (1 slide X 3 levels). IHC: monoclonal antibody to cytokeratin (1 slide X 3 levels). Micrometastases definition: diameter less than 2 mm. **Histologic analysis of axillary nodes** Nodes < 0.5 cm embedded in entirety; nodes > 0.5 cm sliced at several levels and embedded. Two levels per tissue block were examined using standard technique.	**Age** Not stated **Tumour characteristics** Biopsy method Not stated Size ≤ 0.5 cm: 4/126 (3.2%) 0.5 to 1 cm: 27/126 (21.4%) 1 to 2 cm: 73/126 (57.9%) 2 but ≤ 5 cm: 22/115 (19.1%) Stage T1a: 4/126 (3.2%) T1b: 27/126 (21.4%) T1c: 73/126 (57.9%) T2: 22/115 (19.1%) Histology G1: 23/114 (20.2%) G2: 54/114 (47.4%) G3: 37/114 (32.5%) Location Not stated Palpability Not stated Multifocality/multicentricity Not stated **Axilla characteristics** Clinical axillary status Negative: 126/126 (100%) **Neoadjuvant chemotherapy** Not stated (all women who had conservative surgery received postoperative radiotherapy).

Study identifier	Procedure	Patient characteristics
Zavagno, Meggiolaro, Bozza, Scalco, Racano, Rubello, Pescarini, De Salvo & Lise, 2002a. **Number of patients** 384 (part of an RCT; 189 SLNB followed by standard ALND, 195 SLNB but ALND only if positive on SLNB [frozen section]). **Number of attempted mappings** 384 **Study period** not stated **Institution** Clinica Chirurgica II, Universitá di Padova; Chirurgia Generale II, Azienda Ospedaliera di Padova; Chirurgia Generale, Ospedale Civile di Vicenza; Chirurgia Generale, Ospedale Civile di Cittadella; Medicina Nucleare II, Azienda Ospedaliera di Padova; Senologia Diagnostica, Axienda Ospedaliera di Padova; Ufficio di Epidemiologia Clinica, Centro Oncologico Regionale di Padova, Italy. **Incorporated studies** None **Inclusion/exclusion criteria** Inclusions: patients with invasive breast cancer of up to 3 cm diameter and clinically negative axilla. Exclusions: intraductal carcinoma, multicentric tumours, nonpalpable tumours, clinically positive axilla, distant metastases, neoadjuvant treatment, pregnancy, and age over 80 years. **Study included for review of...** Localisation rates	**Radiocolloid/dye combination** Radiocolloid only: 384 Dye only: 0 Radiocolloid and dye: 0 **Radiocolloid** Type: ^{99m}Tc-albumin nanocolloids (Nanocoll) Dose: 30-40MBq Colloid size: not stated Filtration: not stated Injection location: subdermally into the cutaneous projection of the breast tumour. Injection timing: the day before surgery. Massage: not stated Intraoperative probe: gamma detecting probe in a sterile glove. **Dye** Dye was not used Type: not applicable Amount: not applicable Injection location: not applicable Injection timing: not applicable Massage: not applicable **Preoperative lymphoscintigraphy** Timing: images taken 15-10 minutes and 2 hours after injection. **Surgery** Surgeon details: surgeons had to have performed at least 15 consecutive SLNBs with ALND without false negatives. Anaesthesia: not stated Axillary clearance: standard Sentinel node definition: the node with the highest count; accessory sentinel nodes had a probe count ≥ 10% of the most radioactive lymph node. Final breast procedure: not stated **Histologic analysis of sentinel nodes** Intraoperative analysis: frozen sections (but only in second arm of RCT; n=195/384). Sectioning: for frozen sections, nodes <0.5 cm were sectioned each 2-3 mm. For each sample, 2 frozen sections at 40 μm intervals were used. Frozen tissue then thawed, fixed and embedded for permanent sections. For definitive histology, two consecutive 5 mm thick tissue sections cut from a paraffin block at three levels, each 40 mm apart. Permanent section: H&E (1 slide X 3 levels). IHC: monoclonal antibody to cytokeratin (1 slide X 3 levels). Micrometastases definition: not stated **Histologic analysis of axillary nodes** Not stated	**Age** Not stated **Tumour characteristics** Biopsy method Not stated Size ≤ 0.5 cm: 11/384 (28.6%) 0.5 to 1 cm: 86/384 (22.4%) 1 to 2 cm: 225/384 (58.6%) > 2 but ≤ 5 cm: 62/384 (16.1%) Stage T1a: 11/384 (28.6%) T1b: 86/384 (22.4%) T1c: 225/384 (58.6%) T2: 62/384 (16.1%) Histology G1: 79/384 (20.6%) G2: 191/384 (49.7%) G3: 114/384 (29.9%) Location Not stated Palpability Patients with nonpalpable tumours were excluded from the study. Multifocality/multicentricity Not stated **Axilla characteristics** Clinical axillary status Negative: 384/384 (100%) **Neoadjuvant chemotherapy** Not stated

Study identifier	Procedure	Patient characteristics
Zavagno, Meggiolaro, Rossi, Pescarini, Marchet, Denetto, Baratella & Lise, 2002b **Number of patients** 50 **Number of attempted mappings** 50 **Study period** Not stated **Institution** Clinica Chirurgica II, University of Padova; Medicina Nucleare II, Regional Hospital of Padova; Senologica Diagnostica, University of Padova, Padova, Italy. **Incorporated studies** None **Inclusion/exclusion criteria** Inclusions: consecutive patients with breast tumours less than 3cm in diameter and clinically negative axilla. Exclusions: none stated **Study included for review of...** Localisation rates	**Radiocolloid/dye combination** Radiocolloid only: 0 Dye only: 0 Radiocolloid and dye: 50 **Radiocolloid** Type: ^{99m}Tc-labelled colloidal albumin (Nanocoll; Nicomed-Italia, Saluggia, Italy). Dose: 30 to 40MBq in 0.2cc saline Colloid size: not stated Filtration: not stated Injection location: the radiocolloid was injected subdermally into the cutaneous projection of the tumour. Injection timing: 24 hours before surgery. Massage: not stated Intraoperative probe: ScintiProbe MR100 (Pol.Hi.Tech, Carsoli, Italy) **Dye** Type: Patent blue dye Amount: 2 to 3cc Injection location: subdermally in the upper, outer edge of the areola Injection timing: 10 minutes before skin incision. Massage: not performed **Preoperative lymphoscintigraphy** Timing: lymphoscintigraphy was performed 20 minutes and 2 hours after radiocolloid injection. **Surgery** Surgeon details: not stated Anaesthesia: not stated Axillary clearance: a standard axillary lymph node dissection was performed in 28/50 (56%) of cases; 18 because the sentinel lymph node was metastatic, 3 because the sentinel node was not found, 7 because the patient chose to undergo axillary dissection regardless of sentinel node status. Sentinel node definition: hot and/or blue. Final breast procedure: conservative procedure 38/50 (76.0%); mastectomy 12/50 (24.0%). **Histologic analysis of sentinel nodes** Intraoperative analysis: frozen sections Sectioning: for frozen sections, nodes <0.5 cm were bisected and nodes >0.5 cm were sectioned at each 2-3 mm. Frozen sections made at 40µm intervals were examined. Frozen tissue then thawed, fixed and embedded for permanent sections. Two consecutive 5µm thick tissue sections were cut from a paraffin block at three levels, 40µm apart. Permanent section: H&E (1 slide X 3 levels). IHC: monoclonal antibody to cytokeratin (1 slide X 3 levels). Micrometastases definition: not stated **Histologic analysis of axillary nodes** Not stated	**Age** Mean 58.8, range 36 to 82 years. **Tumour characteristics** Biopsy method Not stated Size Mean 15.6, range 5 to 30mm. Stage T1 to T2 Histology Invasive ductal carcinoma: 40/50 (80.0%) Invasive lobular carcinoma: 5/50 (10.0%) Tubular or mucinous carcinoma: 5/50 (10.0%) Location UOQ: 29/50 (58.0%) UIQ: 4/50 (8.0%) LOQ: 2/50 (4.0%) LIQ: 6/50 (12.0%) Central: 9/50 (18.0%) Palpability Not stated Multifocality/multicentricity Not stated **Axilla characteristics** Clinical axillary status Negative: 50/50 (100%) **Neoadjuvant chemotherapy** Not stated

Study identifier	Procedure	Patient characteristics
Zervos, Badgwell, Abdessalam, Farrar, Walker, Yee & Burak, 2001. **Number of patients** 509 **Number of attempted mappings** 509 **Study period** August 1997 to February 2001 **Institution** Digestive Disorders Center, Tampa General Hospital, University of South Florida, Tampa, Florida and Division of Surgical Oncology, Arthur G. James Cancer Hospital and Richard J. Solove Research Institute, Ohio State University, Columbus, Ohio, USA. **Incorporated studies** Zervos and Burak, 2000 **Inclusion/exclusion criteria** Inclusions: consecutive patients with cytologically or histologically proven breast cancer obtained from core needle biopsy, fine needle aspiration, or excisional biopsy. Exclusions: none stated **Study included for review of...** Localisation rates	**Radiocolloid/dye combination** Radiocolloid only: 0 Dye only: 0 Radiocolloid and dye: 509 **Radiocolloid** Type: ^{99m}Tc -sulphur colloid Dose: 400 μCi Colloid size: 0.2 μm Filtration: filtered Injection location: radiocolloid injected in equal amounts around either the tumour or through the localisation needles placed for the purpose of injection. Injection timing: at least 2 hours prior to surgery. Massage: not stated Intraoperative probe: Navigator (U.S. Surgical, Norwalk, Connecticut) or Neoprobe 2000 (Dublin, Ohio) **Dye** Type: Lymphazurin (vital blue dye) Amount: 5 cc Injection location: dye was injected around the tumour or through the localisation needles. Injection timing: in the operating room. Massage: not stated **Preoperative lymphoscintigraphy** Timing: lymphoscintigraphy not performed. **Surgery** Surgeon details: 8 surgeons contributed, each completed the American Society of Breast Surgeons (ASBS) recommended guidelines for validation and proficiency of the SN technique. Anaesthesia: not stated Axillary clearance: when metastases were present from frozen section analysis, a level I/II ALND was performed under the same anaesthetic; if a SN was negative on frozen section but positive on permanent section, or if the SN was reactive to cytokeratin antibody, then patients were brought back (or offered) complete ALND; 199/509 (39.1%) patients went on to ALND either because they had pathologically positive SNs or they were part of a surgeon's validation series (n=71; some surgeons achieved partial or full validation prior to enrolling patients in this study's database). Sentinel node definition: SNs were charactised as hot only or blue only, or both; nodes that had *ex-vivo* radioactivity counts greater than 2 times background tissue were defined as hot, and *ex-vivo* counts were used to define the hottest node. Final breast procedure: not stated **Histologic analysis of sentinel nodes** Intraoperative analysis: all SNs were sent for frozen section analysis. Sectioning: all sentinel nodes were bivalved and step sections of each half taken at 25%, 50% and 75% of block depth; a total of six sections for each node processed. All nodes submitted for permanent sectioning. Permanent section: all nodes were submitted for permanent sectioning. IHC: when frozen section and permanent sections were negative for metastatic disease, IHC using cytokeratin antibody cocktail was performed on all nodes. Micrometastases definition: not stated **Histologic analysis of axillary nodes** Not stated	**Age** 57.9 {12.53} years **Tumour characteristics** Biopsy method All patients had cytologically or histologically proven breast cancer obtained from core needle biopsy, FNA or excisional biopsy prior to SLNB. (From Zervos & Burak 2000) Core needle: 170/352 (48.3%) Excisional: 160/352 (45.5%) FNA: 22/352 (6.3%) Size 1.75 {1.26} cm Stage Nearly all women had clinical stage I and II breast cancers. Histology Not stated Location Not stated Palpability Not stated Multifocality/multicentricity Not stated **Axilla characteristics** Clinical axillary status Not stated **Neoadjuvant chemotherapy** Not stated

Study identifier	Procedure	Patient characteristics
Zerwes, Frasson, Gutfilen, Barbosa & da Fonseca, 2002. **Number of patients** 29 **Number of attempted mappings** 29 **Study period** Not stated **Institution** Hospital Universitário Clementino Fraga Filho, Universidad Federal do Rio de Janeiro; Centro de Mama, Pontificie Universidade Católica do Rio Grande do Sul; Hospital Universitarió Pedro Ernesto, Universidade do Estado do Rio de Janeiro; Rio de Janeiro, Brazil, South America. **Incorporated studies** None **Inclusion/exclusion criteria** Inclusions: operable infiltrative ductal breast carcinoma (T1-T2). Exclusions: women who were pregnant, nursing, who did not have histologically proven infiltrative ductal carcinoma, those who had T3 and T4 tumours and patients who has previous chemotherapy or radiotherapy. **Study included for review of...** Localisation rates	**Radiocolloid/dye combination** Radiocolloid only: 0 Dye only: 2 Radiocolloid and dye: 27 **Radiocolloid (n=27)** Type: ^{99m}Tc-Dextran 500 Dose: 9.25 MBq (1.5 ml saline in each of 4 injections). Colloid size: not stated Filtration: not stated Injection location: 4 peritumoural injections. When the tumour was deep and unpalpable, the needle was positioned on ultrasound. Injection timing: radiocolloid was injected 3-12 hours before surgery. Massage: point of injection massaged for 5 minutes in all cases. Intraoperative probe: gamma probe (Neoprobe 1500, Neoprobe Corp., Dublin, Ohio, US) **Dye** Type: vital blue dye Amount: 2 ml Injection location: peritumoural Injection timing: just prior to the operation. Massage: points of injection masssged for 5-10 minutes. **Preoperative lymphoscintigraphy** Timing: scans taken 30 minutes, 1, 2 and 3 hours after radiocolloid injection. **Surgery** Surgeon details: not stated Anaesthesia: not stated Axillary clearance: complete in 22/29 patients. Sentinel node definition: node with 10 times more radioactive counts than other nodes; staining blue. Final breast procedure: all patients had breast conservative surgery. **Histologic analysis of sentinel nodes** Intraoperative analysis: frozen sections Sectioning: sentinel nodes (24 nodes) were sectioned in two parts along the longitudinal axis at 3 mm intervals. These slices were frozen at -30 ^{o}C, 8-10 sections of 7 μm made, and they were stained with toluidine blue and examined. Then they were sixed and embedded, and routine histology performed. Permanent section: H&E IHC: not stated Micrometastases definition: not stated **Histologic analysis of axillary nodes** When axillary dissection was performed, nodes were sectioned in the major axis, fixed in paraffin and stained with H&E.	**Age** Mean 51.64 {11.72} years. **Tumour characteristics** Biopsy method Not stated Size No tumours were more than 5 cm in diameter. Stage T1 to T2 Histology All included patients had infiltrative ductal breast carcinoma. Location Not stated Palpability Not stated Multifocality/multicentricity Not stated **Axilla characteristics** Clinical axillary status Not stated **Neoadjuvant chemotherapy** Not stated

Study identifier	Procedure	Patient characteristics
Žgajnar, Bešič, Frković-Grazio, Hoćevar, Vidergar, Rener & Lindtner, 2003. **Number of patients** 17 **Number of attempted mappings** 17 **Study period** not stated **Institution** Institute of Oncology, Ljubljana, Slovenia. **Incorporated studies** None **Inclusion/exclusion criteria** Not stated **Study included for review of...** Localisation rates	**Radiocolloid/dye combination** Radiocolloid only: 0 Dye only: 0 Radiocolloid and dye: 17 **Radiocolloid** Type: ^{TC}99m-labelled nanocolloid (Nanocol®) Dose: 30 MBq in 0.1 ml saline plus 0.1 ml of the radiographic contrast medium Colloid size: not stated Filtration: not stated Injection location: peritumoural Injection timing: radiocolloid was injected on the morning of surgery. Massage: not stated Intraoperative probe: hand-held gamma probe (Navigator GPS). **Dye** Type: Bleu Patente V™ (patent blue) Amount: 1 ml Injection location: injected through the skin mark (of the hottest spot exactly over the nonpalpable lesion) with the depth adjusted to the mammographic position of the lesion. Injection timing: dye was injected 5 minutes before surgery. Massage: the breast was massaged for 5 minutes. **Preoperative lymphoscintigraphy** Timing: images taken immediately and 20 mins and 2 hours after injection, plus if needed static imaging was repeated at 5 hours after injection. **Surgery** Surgeon details: not stated Anaesthesia: general anaesthesia Axillary clearance: performed in 6 patients (2 with localisation failure). Sentinel node definition: first hot spot in regional lymph node basin and staining blue. Final breast procedure: all nonpalpable tumours excised with at least 1 cm surgical margins. **Histologic analysis of sentinel nodes** Intraoperative analysis: imprint cytology Sectioning:not stated Permanent section: not stated IHC: not stated Micrometastases definition: not stated **Histologic analysis of axillary nodes** Not stated	**Age** Not stated **Tumour characteristics** Biopsy method All patients had histologically confirmed tumours, but the method of biopsy was not stated. Size Not stated Stage Not stated Histology Not stated Location Not stated Palpability All patients had nonpalpable tumours. Multifocality/multicentricity Not stated **Axilla characteristics** Clinical axillary status Not stated **Neoadjuvant chemotherapy** Not stated

Study identifier	Procedure	Patient characteristics
Zhang, Kunwei, Nirmal, Guangyu, Jiong, Zhimin & Zhenzhou, 2003. **Number of patients** 95 **Number of attempted mappings** 95 **Study period** May 2000 to December 2001 **Institution** Department of Breast Surgery, Cancer Hospital/Institute, Fu Dan University, Shanghai, China. **Incorporated studies** None **Inclusion/exclusion criteria** Inclusions: breast cancer patients with clinical T1 or T2 tumours, with clinically N0 axillary lymph nodes. Exclusions: none stated **Study included for review of...** Localisation rates and false negative rates.	**Radiocolloid/dye combination** Radiocolloid only: 95 Dye only: 0 Radiocolloid and dye: 0 **Radiocolloid** Type: ^{99m}Tc-labelled sulphur colloid (prepared by the Department of Nuclear Medicine, Cancer Hospital). Dose: 1 to 2 mCi in 3 to 5ml (first 72 patients); 6 to 8 mCi in 2 to 4ml (last 23 patients). Colloid size: not stated Filtration: unfiltered Injection location: into the breast tissue surrounding the primary tumour or biopsy site at the 3, 6, 9 and 12 o'clock positions for the first 72 patients; a single subdermal injection in the last 23 patients. Injection timing: 10 to 16 hours before surgery in the first 72 patients; not stated in last 23 patients. Massage: not stated Intraoperative probe:Capintec Gammed IV (Capintec Inc., New Jersey, USA). **Dye** Dye was not used. Type: not applicable Amount: not applicable Injection location: not applicable Injection timing: not applicable Massage: not applicable **Preoperative lymphoscintigraphy** Timing: static lymphoscintigraphy was performed before operation. **Surgery** Surgeon details: not stated Anaesthesia: not stated Axillary clearance: standard axillary dissection performed in all patients. Sentinel node definition: hot nodes had at least 25 counts per 10 seconds. Final breast procedure: breast conservative surgery 9/95 (9.5%); modified radical mastectomy 75/95 (78.9%); radical mastectomy 11/95 (11.6%). **Histologic analysis of sentinel nodes** Intraoperative analysis: not stated Sectioning: sentinel nodes were sepatately infiltrated into a 10% solution of formalin before delivery. Nodes dissected from surrounding tissue, bisected and embedded. One or two sections from the central cross section of each block were used. When initial H&E stains were negative, another 6 sections were taken. Permanent section: stained with H&E. Whne initial H&E stains were negative an additional H&E slide was stained. IHC: in cases negative by initial H&E stain, IHC was performed using CK8 and CK19 (2 slides). Staining anaplastic cells for CK antibody were evaluated with KP-1 to exclude histiocytes. Micrometastases definition: not stated **Histologic analysis of axillary nodes** H&E	**Age** Mean 51.9 {10.8}, range 25 to 86 years. **Tumour characteristics** Biopsy method Not stated Size |	
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<2cm	34/95 (35.8%)
2 to 3cm	31/95 (32.6%)
>3cm	19/95 (20.0%)
After excision	11/95 (11.6%) | Stage T1N0 or T2N0 Histology |	
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Infiltrating ductal	80/95 (84.2%)
DCIS with early invasion	4/95 (4.2%)
Infiltrating lobular	4/95 (4.2%)
Mucinous	3/95 (3.2%)
Medullary	3/95 (3.2%)
Paget's disease + intraductal carcinoma	1/95 (1.1%) | Location |	
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UOQ	51/95 (53.7%)
LOQ	16/95 (16.8%)
UIQ	15/95 (15.8%)
LOQ	9/95 (9.5%)
Subareolar	4/95 (4.2%) | Palpability Not stated Multifocality/multicentricity Not stated **Axilla characteristics** Clinical axillary status |	
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Negative	95/95 (100%)	 **Neoadjuvant chemotherapy** Not stated

Appendix G Subgroup category descriptions

Table G.1 Subgroup listing

Category	Description	Code	Sets in analysis (localisation)	Sets in analysis (false negative)
Test protocol variables				
Type of tracer				
All colloid, all dye	All patients received radiocolloid and dye	1	94 (41.2)	37 (27.2)
Colloid only	All patients received radiocolloid only	2	50 (21.9)	36 (26.5)
Dye only	All patients received dye only	3	39 (17.1)	33 (24.3)
Some colloid only, some dye only, some colloid + dye or variation or not stated/not clear	Some patients only received radiocolloid or dye only and some received both radiocolloid and dye, or all may have receive colloid, and some dye + colloid, or all may have receive dye and some colloid + dye	4	45 (19.7)	30 (22.1)
Type of colloid				
Sulphur colloid	Including sulphur colloids, Lymphoscint	1	70 (30.7)	36 (26.5)
Albumin colloid	Including albumin, human serum albumin, AlbuRes, Nanocoll, SentiScint	2	53 (23.2)	33 (24.3)
Other colloid	Including rhenium sulphide, Nanocis, cysteine-rhenium, dextran, 2-methoxy isobutyl isonitrile (MIBI), antimony sulphide, tin, phytate, sulphide	3	36 (15.8)	19 (14.0)
Two or more types of colloid used within a study Unspecified colloid or not stated/not clear/unsure/ Not applicable (colloid not used within the study)	Not if both colloids are within the sulphur or albumin subgroups Stated as “nanocolloid” or “radiocolloid” or not specifically stated	4	69 (30.3)	48 (35.3)
Type of dye				
Patent blue dye	Including patent blue dye, patent blue V or patent blue violet	1	56 (24.6)	37 (27.2)
Isosulfan blue dye	Isosulfan blue or lymphazurin	2	75 (32.9)	38 (27.9)
Methylene blue dye		3	8 (3.5)	3 (2.2)
Other dye	Including charcoal, Evans blue dye, India ink, CH40 (activated carbon particles), indigocarmine and indocyanine green	4	18 (7.9)	10 (7.4)
Two or more different types of dye used within a study Unspecified dye or dye not stated/not clear/unsure Not applicable (dye not used within the study)	Not if both dyes are within the patent blue or isosulfan subgroups For example, stated as “blue dye” or not specifically stated	5	71 (31.1)	48 (35.3)

Category	Description	Code	Sets in analysis (localisation)	Sets in analysis (false negative)
Location of injection (colloid or dye)				
Peritumoral	Peritumoral injection, around the tumour with or without mammographic, stereotactic or ultrasound guidance. With or without mammographic, stereotactic or ultrasound guidance, including injection around biopsy cavity, into the wall of the biopsy cavity or into the biopsy cavity (1 study). With or without mammographic, stereotactic or ultrasound guidance, including injection around biopsy cavity, into the wall of the biopsy cavity or into the biopsy cavity, through the localization needle or catheter, around the localization needle or during hookwire placement Including into a single location in the parenchyma, injected adjacent to the tumour, or a single injection into the induration site of a previous excisional biopsy, or described as one injection peritumorally	1	101 (44.3)	58 (42.6)
Subareolar or periareolar	Including, around the circumference of the areola	2	10 (4.4)	4 (2.9)
Intradermal or subdermal or subcutaneous	May be administered in more than one location	3	30 (13.2)	15 (11.0)
Intralesional	Including, intratumoral, into the tumour bed	4	4 (1.8)	2 (1.5)
Two or more methods within a patient or a study, Not stated/Not clear/ Not applicable (radiocolloid or dye not used within the study)		5	83 (36.4)	57 (41.9)
Time of radiocolloid injection				
Day before	Patient injected with radiocolloid on the day (>12 hours) before sentinel lymph node biopsy	1	59 (25.9)	31 (22.8)
Same day	Patient injected with radiocolloid on the same day (<12 hours) as sentinel lymph node biopsy	2	53 (23.2)	31 (22.8)
Combination	Within a study, patients were injected on the day before or the day of sentinel lymph node biopsy or individual patients were injected both on the day before and the day of sentinel lymph node biopsy.	3	42 (18.4)	21 (15.4)
Not applicable/Not stated/Not clear	Radiocolloid not used within the study or timing not stated or not clear.	4	74 (32.5)	53 (39.0)
Histology				
Permanent histology	Including H&E (haematoxylin and eosin staining of permanent section), “definitive histology”, “permanent histology”, “non-permanent and permanent section”, “paraffin embedded”, “permanent section”, “routine pathology”, “standard technique”, “standard permanent histology”, “traditional histology” or “usual procedure”	1	NA	51 (37.5)
Permanent histology and immunohistocytochemistry in all localized patients	Sentinel nodes from all patients were subjected to immunohistochemistry in addition to permanent histology (H&E stained).	2	NA	31 (22.8)
Permanent histology plus immunohistochemistry in a proportion of localized patients	All sentinel nodes were subject to permanent histology, and some were subjected to immunohistochemisty, for example if permanent histology failed to detect metastases.	3	NA	39 (28.7)
Frozen section or Immunohistochemistry only or Not stated/Not clear	Sentinel nodes were subjected to frozen section, not permanent histology Sentinel nodes were subjected to immunohistochemitry only Not stated or not clear	4	NA	15 (11.0)

Category	Description	Code	Sets in analysis (localisation)	Sets in analysis (false negative)
Patient variables				
Biopsy method				
Varied	Patients underwent excisional biopsy, fine needle aspiration, core biopsy or no biopsy	1	100 (43.9)	55 (40.4)
FNA, CB or no biopsy	Patients underwent fine needle aspiration, core biopsy or no biopsy	2	42 (18.4)	29 (21.3)
Excisional biopsy only	Patients underwent an excisional biopsy	3	5 (2.2)	4 (2.9)
Not stated/ Not clear	Biopsy methods used, if any, were not stated, or were unclear	4	81 (35.5)	48 (35.3)
Tumour size				
T0 and/or Tx and/or Tis, T1-T2	Tumour size up to 5cm or specifically stated as T1 or T2, or T0 or Tx	1	117 (51.3)	67 (49.3)
T0 and/or Tx and/or Tis, T1-T2, T3-T4 or T3-T4 only	Tumour size up to or greater than 5cm or specifically stated as T1, T2, T3 or T4, or T0 or Tx	2	82 (36.0)	60 (44.1)
Not stated/Not clear	Not stated/Not clear	3	29 (12.7)	9 (6.6)
Invasivity				
Invasive tumours only	All patients within a study had invasive tumours	1	136 (59.6)	102 (75.0)
Invasive and *in situ*	Some patients within a study had invasive tumours, some patients had ductal carcinoma *in situ*	2	71 (31.1)	26 (19.1)
In situ only	All patients had ductal carcinoma *in situ*	3	1 (0.4)	0 (0.0)
Not stated/not clear		4	20 (8.8)	8 (5.9)
Tumour palpability				
Palpable only	All patients within a study had palpable tumours	1	17 (7.5)	16 (11.8)
Palpable and nonpalpable	Some patients within a study had palpable primary breast tumours, some had nonpalpable tumours	2	79 (34.6)	43 (31.6)
Nonpalpable only	All patients within a study had nonpalpable tumours	3	6 (2.6)	2 (1.5)
Not stated/Not clear	Not stated/Not clear	4	126 (55.3)	75 (55.1)
Clinical axillary status				
Negative	All patients within a study had clinically negative axillary lymph nodes	1	137 (60.1)	76 (55.9)
Negative and positive	Some patients within a study had clinically positive axillary lymph nodes	2	39 (17.1)	27 (19.9)
Positive	All patients within a study had clinically positive axillary lymph nodes	3	0 (0.0)	0 (0.0)
Not stated/Not clear	Not stated/Not clear	4	52 (22.8)	33 (24.3)
Multifocality/multicentricity				
Unifocal tumours	All patients within a study had unifocal tumours	1	59 (25.9)	44 (32.4)
Some multifocal tumours	Some patients within a study had multifocal tumours	2	20 (8.8)	10 (7.4)
All multifocal tumours	All patients within a study had multifocal tumours	3	2 (0.9)	3 (2.2)
Not stated/Not clear	Not stated/Not clear	4	147 (64.5)	79 (58.1)
Neoadjuvant chemotherapy				
No neoadjuvant chemotherapy	No patients within the study had neoadjuvant chemotherapy	1	36 (15.8)	25 (18.4)
Some neoadjuvant chemotherapy	Some patients within the study had neoadjuvant chemotherapy	2	10 (4.4)	7 (5.1)
All neoadjuvant chemotherapy	All patients within the study had neoadjuvant chemotherapy	3	10 (14.4)	9 (6.6)
Not stated/not clear		4	172 (75.4)	95 (69.9)

Table G.2 Subgroup coding of sets included for assessment of localisation rate

Author	Type of tracer	Type of radiocolloid	Location of colloid injection	Timing of colloid injection	Type of dye	Location of dye injection	Biopsy method	Tumour size	Tumour invasiveness	Tumour palpability	Clinical axillary status	Multicentricity / multifocality	Neoadjuvant chemotherapy
Acosta et al. 2003	4	3	1	3	5	1	4	1	2	4	1	1	4
Ahrendt et al. 2002	4	1	1	2	2	1	1	2	1	2	1	4	4
Allen et al. 2001	1	3	1	3	1	1	4	2	1	2	4	4	4
Altiyollar et al. 2000	3	4	5	4	1	1	3	1	1	4	1	4	4
Aras et al. 2002	4	3	1	3	5	1	4	2	1	4	1	4	4
Baitchev et al. 2002	3	4	5	4	1	1	4	1	1	4	1	1	4
Balch et al. 2003	1	1	5	2	2	1	1	2	2	2	2	4	2
Barnwell et al. 1998	1	1	1	2	2	1	1	1	1	4	2	1	4
Barranger et al. 2003	4	1	1	1	1	3	2	1	1	2	1	4	1
Bauer et al. 2002 (1)	1	1	1	2	2	1	1	2	2	2	1	1	4
Bauer et al. 2002 (2)	1	1	1	2	2	2	1	2	2	2	1	2	4
Beitsch et al. 2001	1	1	2	2	2	1	1	2	2	2	1	1	4
Bembenek et al. 1999	2	2	1	1	5	5	4	2	1	2	4	4	2
Bergkvist et al. 2001	1	2	3	3	1	3	4	2	1	4	1	2	1
Birdwell et al. 2001	1	1	1	4	2	1	1	2	2	2	1	4	1
Blessing et al. 2002 (1)	1	4	5	4	2	1	2	1	2	4	1	4	1
Blessing et al. 2002 (2)	1	4	5	4	3	1	2	1	2	4	1	4	1
Bobin et al. 1999	3	4	5	4	4	1	1	2	1	4	2	1	4
Borgstein et al. 2000 (1)	1	2	1	1	1	3	1	1	2	2	1	1	4
Borgstein et al. 2000 (2)	1	2	1	1	1	3	1	1	2	2	1	1	4
Bourgeois et al. 2003a	2	2	1	3	5	5	4	1	1	2	2	1	4
Brady 2002	4	1	2	2	2	1	2	2	1	4	4	4	3
Branagan et al. 2002	1	1	1	2	2	1	4	3	4	4	4	4	4
Brenot-Rossi et al. 2003	1	1	5	1	1	5	1	1	2	2	1	1	1
Breslin et al. 2000	4	1	1	4	5	1	1	2	1	2	2	4	3

Author	Type of tracer	Type of radiocolloid	Location of colloid injection	Timing of colloid injection	Type of dye	Location of dye injection	Biopsy method	Tumour size	Tumour invasiveness	Tumour palpability	Clinical axillary status	Multicentricity / multifocality	Neoadjuvant chemotherapy
Byrd et al. 2001	1	1	1	3	2	1	1	2	2	2	4	4	2
Casalegno et al. 2000	2	2	3	3	5	5	2	1	1	4	1	4	1
Choi et al. 2003	4	1	1	3	2	1	1	2	2	2	1	1	4
Chua et al. 2001	4	3	1	4	1	1	4	2	1	2	2	2	4
Chua et al. 2003	4	1	5	3	2	1	1	2	2	2	2	2	4
Chung et al. 2001a	3	4	5	4	2	1	4	2	1	4	1	4	2
Chung et al. 2001b	3	4	5	4	5	5	4	1	1	4	1	4	1
Classe et al. 2003	1	3	1	3	1	1	2	1	1	4	1	4	1
Cox et al. 2002	4	1	1	2	2	5	4	3	4	4	4	4	4
Crossin et al. 1998	2	1	1	2	5	5	1	1	1	4	1	1	4
Cserni 2002a	4	2	1	3	1	1	4	3	2	2	4	4	4
Czerniecki et al. 1999	1	4	1	2	2	1	1	2	1	2	1	4	4
Dale and Williams 1998	3	4	5	4	2	1	1	2	1	4	1	4	2
de Kanter et al. 2000	1	2	5	3	1	3	1	3	4	2	1	1	1
de Rubeis et al. 2000	4	2	1	3	1	3	1	1	1	4	1	4	4
d'Eredita et al. 2003 (1)	1	2	1	1	3	3	1	1	1	2	1	4	4
d'Eredita et al. 2003 (2)	3	4	5	4	3	2	1	1	1	2	1	4	4
Derossis et al. 2003	1	1	3	3	2	1	4	2	1	4	1	4	4
Donahue 2001	1	4	5	3	2	2	2	3	2	4	4	4	4
Dowlatshahi et al. 1999	4	1	1	4	2	5	1	1	1	2	1	4	4
Dunnwald et al. 1999	1	1	1	2	2	4	1	2	1	2	4	4	2
Estourgie et al. 2003b	1	2	4	1	1	4	2	3	4	2	1	4	4
Euhus et al. 2002	1	1	5	3	2	1	4	2	1	4	1	4	4
Feezor et al. 2002 (1)	4	1	3	3	5	5	4	1	2	4	1	4	4
Feezor et al. 2002 (2)	4	1	1	3	5	5	4	1	2	4	1	4	4
Feezor et al. 2002 (3)	4	1	5	3	5	5	4	1	2	4	1	4	4
Feggi et al. 2000	4	4	1	3	5	5	1	1	1	4	4	4	4

Author	Type of tracer	Type of radiocolloid	Location of colloid injection	Timing of colloid injection	Type of dye	Location of dye injection	Biopsy method	Tumour size	Tumour invasiveness	Tumour palpability	Clinical axillary status	Multicentricity / multifocality	Neoadjuvant chemotherapy
Feggi et al. 2001	2	2	5	1	5	5	2	1	2	3	1	4	4
Feldman et al. 1999	2	1	1	2	5	5	1	1	1	4	1	1	4
Fenaroli et al. 2000	2	2	3	1	5	5	2	1	1	4	1	4	4
Fernandez et al. 2001 (1)	2	4	1	1	5	5	4	2	1	4	2	1	3
Fernandez et al. 2001 (2)	2	4	1	1	5	5	4	2	1	4	2	1	1
Fernandez et al. 2002 (1)	2	2	1	1	5	5	4	2	1	1	1	1	1
Fernandez et al. 2002 (2)	2	2	1	2	5	5	4	2	1	3	1	1	1
Fialdini et al. 2000	2	2	5	1	5	5	4	1	1	4	1	4	4
Fleming et al. 2003 (1)	1	3	1	4	2	1	1	2	1	4	1	4	4
Fleming et al. 2003 (2)	1	3	3	4	2	1	1	2	1	4	1	4	4
Flett et al. 1998	3	4	5	4	1	1	4	3	1	4	4	4	4
Formisano et al. 2000	2	2	3	4	5	5	4	1	1	2	1	1	4
Fraile et al. 2000	2	2	1	3	5	5	2	1	2	2	1	1	1
Galli et al. 2000	2	2	5	4	5	5	4	1	1	2	1	4	4
Gray et al. 2001	2	1	1	3	2	1	2	1	2	3	4	2	4
Gucciardo et al. 2000	2	2	3	3	5	5	2	1	1	4	1	1	4
Guenther 1999	3	4	5	4	2	1	1	1	1	4	4	4	4
Gulec et al. 2001	4	4	5	4	2	5	1	1	2	2	1	4	4
Haigh et al. 2000	4	4	5	4	2	1	1	2	2	4	4	4	4
Hansen et al. 2002	4	1	5	4	2	1	1	1	1	2	1	4	4
Hoar and Stonelake 2003	1	2	1	3	1	1	1	2	1	2	1	4	2
Hodgson et al. 2001	1	3	1	2	1	1	4	1	1	2	1	4	4
Hung et al. 2002	1	4	5	4	1	5	2	1	1	4	1	1	4
Ilum et al. 2000	3	4	5	4	1	3	1	3	4	4	2	2	1
Imoto and Hasebe 1999	3	4	5	4	4	3	1	2	1	4	2	4	4
Imoto et al. 2000	4	4	3	1	4	3	1	2	1	4	2	4	4
Intra et al. 2003b	2	2	5	3	5	5	1	1	3	2	4	4	4

Author	Type of tracer	Type of radiocolloid	Location of colloid injection	Timing of colloid injection	Type of dye	Location of dye injection	Biopsy method	Tumour size	Tumour invasiveness	Tumour palpability	Clinical axillary status	Multicentricity / multifocality	Neoadjuvant chemotherapy
Intra et al. 2003a	2	2	5	3	5	5	4	1	1	2	1	2	4
Ishida et al. 2002	1	2	1	2	4	1	4	2	1	2	2	2	1
Jaderborg et al. 1999	1	1	1	2	2	1	1	2	1	4	4	4	4
Jastrzebski et al. 2002 (1)	1	1	1	1	5	3	4	1	2	4	1	4	4
Jastrzebski et al. 2002 (2)	1	1	2	1	5	5	4	1	2	4	1	4	4
Jianjun et al. 2001 (1)	3	4	5	4	3	1	2	2	1	1	2	4	4
Jianjun et al. 2001 (2)	3	4	5	4	1	1	2	2	1	1	2	4	4
Jinno et al. 2002 (1)	1	3	5	1	2	5	1	1	1	4	1	4	4
Jinno et al. 2002 (2)	1	3	5	1	2	5	1	1	1	4	1	4	4
Johnson et al. 2001	4	1	1	4	2	1	4	3	4	4	4	4	4
Kataoka et al. 2000	3	4	5	4	4	1	1	2	1	4	1	4	4
Kern 1999	3	4	5	4	2	2	1	2	1	4	4	4	4
Kern 2002	1	1	2	2	2	2	4	2	2	2	4	4	4
Kim et al. 2001	1	4	3	1	4	5	4	2	1	4	2	1	4
Kitapci et al. 2001	2	4	1	1	5	5	3	1	1	4	2	4	1
Klimberg et al. 1999	1	1	2	2	2	1	1	2	1	4	1	4	4
Koizumi et al. 2003	1	3	1	3	4	5	4	1	1	4	1	4	4
Koller et al. 1998	3	4	5	4	5	3	4	1	1	4	4	4	4
Krag et al. 2001	2	1	1	2	5	5	1	2	1	2	1	4	4
Kumar et al. 2003	4	1	3	2	2	1	1	3	4	2	4	3	4
Lauridsen et al. 2000	1	2	1	2	1	1	2	1	1	1	1	1	4
Layeeque et al. 2003	4	1	2	4	2	2	1	2	1	4	1	3	4
Leidenius et al. 2003b	1	2	5	1	1	4	1	2	2	2	1	2	4
Liang et al. 2003	4	3	5	4	1	1	1	3	4	4	4	4	4
Liberman and Cody 2001	1	1	5	2	2	1	4	1	2	2	1	4	4
Liberman et al. 1999	1	1	3	2	2	1	2	1	2	3	1	4	4
Liu et al. 2000a	2	1	5	3	5	5	4	1	2	4	1	1	4

Author	Type of tracer	Type of radiocolloid	Location of colloid injection	Timing of colloid injection	Type of dye	Location of dye injection	Biopsy method	Tumour size	Tumour invasiveness	Tumour palpability	Clinical axillary status	Multicentricity / multifocality	Neoadjuvant chemotherapy
Liu et al. 2000b	3	4	5	4	1	5	2	2	1	4	4	1	4
Liu et al. 2000c	1	4	5	4	2	5	4	3	1	4	1	4	4
Liu et al. 2003	3	4	5	4	4	5	2	1	2	1	4	4	4
Lloyd et al. 2002 (1)	1	4	1	2	2	5	4	3	4	4	4	4	4
Lloyd et al. 2002 (2)	1	4	1	2	2	5	4	3	4	4	4	4	4
Luini et al. 2002	2	2	5	3	5	5	4	1	1	1	1	1	4
Macmillan et al. 2001	2	2	1	3	5	5	2	1	1	4	1	4	4
Mahajna et al. 2003	4	3	1	3	5	3	1	1	1	4	1	4	4
Mann et al. 2000	4	3	1	3	1	1	1	1	1	2	1	4	4
Mariotti et al. 2002	2	2	5	1	5	5	2	1	1	2	1	4	4
Mateos et al. 2001 (1)	4	1	3	1	5	3	2	1	1	1	4	4	4
Mateos et al. 2001 (2)	4	1	1	1	5	1	2	1	1	2	4	4	4
Meyer-Rochow et al. [illegible]	3	4	5	4	1	1	2	2	1	1	1	2	4
Meyer-Rochow et al. [illegible]	1	3	1	1	1	1	2	2	1	1	1	2	4
Miller et al. 2002	4	1	1	4	2	1	4	2	1	2	1	4	3
Minato et al. 2003	1	3	3	4	4	3	4	1	1	4	1	4	4
Miner et al. 1999	2	1	1	2	5	5	1	1	1	2	4	1	4
Mirzaei et al. 2003	1	2	3	1	2	2	3	1	2	2	1	1	1
Moffat et al. 1999	2	1	1	2	5	5	1	2	1	4	1	1	4
Mokbel and Mostafa 2001	3	4	5	4	3	2	1	1	1	2	1	2	4
Molland et al. 2000	1	3	1	3	1	1	4	2	2	4	2	4	4
Motomura et al. 1999a	3	4	5	4	4	1	2	1	1	1	4	1	4
Motomura et al. 2002b	1	3	3	1	4	1	1	1	2	1	1	1	4
Motta et al. 2000	2	2	5	1	5	5	4	3	4	2	1	4	4
Nahrig et al. 2000	2	2	1	4	5	5	4	1	1	4	4	4	4
Nano et al. 2002	4	3	1	2	1	1	1	1	1	2	1	4	4
Noguchi et al. 1999 (1)	3	4	5	4	1	1	1	1	2	4	2	4	4

Author	Type of tracer	Type of radiocolloid	Location of colloid injection	Timing of colloid injection	Type of dye	Location of dye injection	Biopsy method	Tumour size	Tumour invasiveness	Tumour palpability	Clinical axillary status	Multicentricity / multifocality	Neoadjuvant chemotherapy
Noguchi et al. 1999 (2)	1	2	1	2	1	1	1	1	2	4	2	4	4
Noguchi et al. 2000a (1)	3	4	5	4	1	1	1	1	2	4	2	1	4
Noguchi et al. 2000a (2)	3	4	5	4	4	1	1	1	2	4	2	1	4
Noguchi et al. 2000a (3)	3	4	5	4	4	1	1	1	2	4	2	1	4
Noguchi et al. 2000a (4)	1	2	1	2	1	1	1	1	2	4	2	1	4
Noguchi et al. 2000a (5)	1	2	1	2	4	1	1	1	2	4	2	1	4
Noguchi et al. 2000a (6)	1	3	1	2	4	1	1	1	2	4	2	1	4
Noguchi et al. 2000a (7)	1	3	1	2	4	1	1	1	2	4	2	1	4
Noguchi et al. 2000a (8)	1	3	1	2	4	1	1	1	2	4	2	1	4
Nos et al. 2003	3	4	5	4	1	1	1	1	1	2	4	4	4
Offodile et al. 1998	2	3	4	4	5	5	4	2	2	2	4	4	4
Ozmen et al. 2002	3	4	5	4	2	1	1	2	1	1	1	2	4
Paganelli et al. 2002a	2	4	5	1	5	5	4	2	1	4	1	2	4
Patel et al. 2003	4	1	1	4	2	1	1	3	4	2	4	4	2
Peley et al. 2001	1	2	5	1	1	1	1	1	1	1	1	4	4
Pelosi et al. 2003 (1)	1	2	3	1	2	3	4	1	1	2	1	1	4
Pelosi et al. 2003 (2)	1	2	3	1	2	2	4	1	1	2	1	1	4
Pizzocaro et al. 2000	2	4	5	1	5	5	4	1	1	2	1	1	4
Ponzone et al. 2003	2	2	3	1	5	5	2	1	1	2	1	1	4
Povoski et al. 2002	4	1	5	2	2	5	1	2	2	2	1	1	2
Quan et al. 2002	4	1	1	3	5	5	1	2	1	4	1	4	4
Rahusen et al. 2000a	1	2	1	1	1	2	1	1	2	4	1	4	4
Rahusen et al. 2003	1	2	5	1	1	2	2	1	2	3	4	4	4
Ratanawichitrasin et al.	3	4	5	4	2	1	1	2	1	4	4	4	1
Ratanawichitrasin et al.	3	4	5	4	2	1	4	1	2	4	4	4	1
Reitsamer et al. 2003a	1	2	1	1	1	2	2	2	1	4	2	4	3
Reitsamer et al. 2003b	1	2	1	1	1	2	2	1	1	2	1	2	4

Author	Type of tracer	Type of radiocolloid	Location of colloid injection	Timing of colloid injection	Type of dye	Location of dye injection	Biopsy method	Tumour size	Tumour invasiveness	Tumour palpability	Clinical axillary status	Multicentricity / multifocality	Neoadjuvant chemotherapy
Rettenbacher et al. 2000	4	4	5	3	1	1	2	1	1	1	1	1	2
Rink et al. 2001b	2	2	5	3	5	5	1	1	2	2	2	2	4
Rodier et al. 2000	3	4	5	4	1	3	2	1	1	2	2	1	1
Roumen et al. 1997	2	2	1	3	5	5	1	1	1	4	1	1	4
Rubio et al. 1998b	2	1	1	2	5	5	1	2	1	4	1	1	4
Rufino et al. 2003	3	4	5	4	5	1	3	1	1	1	1	2	4
Sabel et al. 2003	1	1	5	4	2	1	4	1	1	4	1	4	1
Sachdev et al. 2002	4	1	1	2	2	1	1	2	1	4	4	4	4
Sardi et al. 2002	4	1	1	2	2	1	1	3	2	4	4	4	4
Sato et al. 2003	1	3	5	2	4	5	1	1	1	4	1	1	4
Schneebaum et al. 1998	1	3	5	1	1	5	2	3	4	1	4	4	4
Schrenk et al. 2002b	4	4	1	1	2	1	1	1	1	2	1	4	4
Schrenk et al. 2003	4	2	1	1	2	1	2	2	1	4	2	4	1
Schwartz et al. 2003	3	4	5	4	2	5	3	2	1	4	4	4	3
Shenoy et al. 2002 (1)	3	4	5	4	1	3	4	3	1	4	4	4	4
Shenoy et al. 2002 (2)	3	4	5	4	1	3	4	3	1	4	4	4	4
Shimazu et al. 2002 (1)	1	3	1	1	2	1	1	1	2	4	1	4	1
Shimazu et al. 2002 (2)	1	3	2	1	2	1	1	1	2	4	1	4	1
Shimazu et al. 2002 (3)	3	4	5	4	2	1	1	1	2	4	2	4	1
Shiver et al. 2002	1	1	4	4	2	4	4	1	2	4	1	4	1
Simmons et al. 2003	1	1	3	3	3	1	1	2	2	4	1	2	4
Smith et al. 2000 (1)	1	4	1	4	2	1	1	1	1	4	1	4	4
Smith et al. 2000 (2)	1	4	2	4	2	1	1	1	1	4	1	4	4
Snider et al. 1998	2	1	1	2	5	5	4	1	1	2	1	4	4
Solarzano et al. 2001	1	1	1	1	2	1	1	2	2	2	1	4	4
Spanu et al. 2001	2	1	3	1	5	5	2	1	1	2	1	1	4
Stearns et al. 2002	3	4	5	4	2	1	4	2	1	2	2	4	3

Author	Type of tracer	Type of radiocolloid	Location of colloid injection	Timing of colloid injection	Type of dye	Location of dye injection	Biopsy method	Tumour size	Tumour invasiveness	Tumour palpability	Clinical axillary status	Multicentricity / multifocality	Neoadjuvant chemotherapy
Stitzenberg et al. 2002	4	1	1	4	2	1	1	2	1	2	1	4	4
Stradling et al. 2002	1	1	2	4	3	5	4	3	4	4	4	4	4
Tafra et al. 2001b (1)	1	1	1	4	2	1	1	3	4	4	1	4	3
Tafra et al. 2001b (2)	1	1	1	4	2	1	1	3	4	4	1	4	1
Tausch et al. 2002 (1)	4	4	5	4	5	5	4	2	2	4	2	4	3
Tausch et al. 2002 (2)	4	4	5	4	5	5	4	2	2	4	2	4	1
Tavares et al. 2001	1	3	3	1	1	1	4	1	1	4	1	1	1
Travagli et al. 2003	4	1	1	3	5	3	2	1	1	4	4	4	4
Tuthill et al. 2001	1	1	1	2	2	1	1	2	2	2	1	2	4
Tuttle et al. 2002	1	1	2	2	2	1	1	2	2	2	1	4	4
Ugur et al. 2003	1	3	3	2	2	5	4	2	2	4	1	1	4
Upponi et al. 2002	1	4	1	3	1	1	2	3	1	2	4	4	4
Vaggelli et al. 2000	2	4	3	1	5	5	4	3	4	4	2	4	4
van Berlo et al. 2003 (1)	1	4	3	1	1	3	4	2	1	4	4	4	4
van Berlo et al. 2003 (2)	1	4	5	1	1	3	4	2	2	4	4	4	4
van Berlo et al. 2003 (3)	1	4	5	1	1	3	4	2	2	4	4	4	4
van der Ent et al. 2001	1	2	1	1	1	3	1	2	1	4	1	4	4
Vargas et al. 2002a	1	1	3	2	2	1	1	2	2	2	1	4	4
Vargas et al. 2003a	1	1	1	2	5	1	4	2	2	4	1	4	4
Vigario et al. 2003 (1)	2	3	1	1	5	5	2	1	1	2	1	1	3
Vigario et al. 2003 (2)	2	3	1	1	5	5	2	1	1	2	1	1	1
Villa et al. 2000	1	2	3	1	1	3	4	1	1	4	2	4	4
Walker et al. 2002	3	4	5	4	1	5	4	1	2	4	1	1	4
Watanabe et al. 2001	2	3	1	1	5	5	1	2	1	4	1	2	4
Weerts et al. 2002 (1)	2	2	1	1	5	5	4	1	1	4	1	4	4
Weerts et al. 2002 (2)	2	2	3	2	5	5	4	1	1	4	1	4	4
Winchester et al. 1999 (1)	2	1	1	2	5	5	4	3	4	2	1	4	4

Author	Type of tracer	Type of radiocolloid	Location of colloid injection	Timing of colloid injection	Type of dye	Location of dye injection	Biopsy method	Tumour size	Tumour invasiveness	Tumour palpability	Clinical axillary status	Multicentricity / multifocality	Neoadjuvant chemotherapy
Winchester et al. 1999 (2)	2	1	1	2	5	5	4	3	4	2	1	4	4
Winchester et al. 1999 (3)	2	1	1	1	5	5	4	3	4	2	1	4	4
Wong et al. 2002a	4	4	5	4	5	5	1	2	1	4	1	4	4
Xavier et al. 2001	4	3	1	3	1	5	2	2	1	2	1	1	1
Xu et al. 2002	2	3	1	4	5	5	1	1	2	4	1	4	1
Yang et al. 2001	3	4	5	4	2	1	4	2	2	4	2	4	4
Yong et al. 2003	1	3	1	2	1	1	1	2	1	2	1	4	4
Yu et al. 2002	3	4	5	4	3	1	4	1	1	2	1	4	1
Zavagno et al. 2002a	2	2	3	1	5	5	4	1	1	1	1	1	1
Zavagno et al. 2002b	1	2	3	1	1	2	4	1	1	4	1	4	4
Zervos et al. 2001	1	1	1	2	2	1	1	1	1	4	4	4	4
Zerwes et al. 2002	1	3	1	2	5	1	4	1	1	4	4	4	1
Zgajnar et al. 2003	1	2	4	2	1	4	2	3	1	3	4	1	4
Zhang et al. 2003	2	1	5	3	5	5	1	1	2	4	1	4	4

Table G.3 Subgroup coding of sets included for assessment of false negative rate

Author	Histopathologic method	Type of tracer	Type of radiocolloid	Location of colloid injection	Timing of colloid injection	Type of dye	Location of dye injection	Biopsy method	Tumour size	Tumour invasiveness	Tumour palpability	Clinical axillary status	Multicentricity / multifocality	Neoadjuvant chemotherapy
Ahrendt *et al*. 2002	2	4	1	1	2	2	1	1	2	1	2	1	4	4
Allen *et al*. 2001	3	1	3	1	3	1	1	4	2	1	2	4	4	4
Altiyollar *et al*. 2000	2	3	4	5	4	1	1	3	1	1	4	1	4	4
Baichev *et al*. 2001	1	4	1	2	4	5	5	4	1	1	4	2	1	2
Baitchev *et al*. 2002	3	3	4	5	4	1	1	4	1	1	4	1	1	4
Balch *et al*. 2003	3	1	1	5	2	2	1	1	2	2	2	2	4	2
Barnwell *et al*. 1998	1	1	1	1	2	2	1	1	1	1	4	2	1	4
Barranger *et al*. 2003	3	4	1	1	1	1	3	2	1	1	2	1	4	1
Bass *et al*. 1999b	4	1	1	1	2	2	1	4	2	2	4	1	1	4
Bergkvist *et al*. 2001	3	1	2	3	3	1	3	4	2	1	4	1	2	1
Bobin *et al*. 1999	3	3	4	5	4	4	1	1	2	1	4	2	1	4
Bourgeois *et al*. 2003a	3	2	2	5	1	5	5	1	1	1	2	2	1	4
Brady 2002	2	4	1	2	2	2	1	2	2	1	4	4	4	3
Burak *et al*. 1999	1	1	1	1	2	2	1	1	1	1	2	1	1	1
Canavese *et al*. 2000a	4	3	4	5	4	1	1	4	3	4	1	2	1	4
Canavese *et al*. 2001	1	4	4	5	1	1	5	4	1	1	4	1	1	4
Casalegno *et al*. 2000	1	2	2	3	3	5	5	2	1	1	4	1	4	1
Chung *et al*. 2001a	1	3	4	5	4	2	1	4	2	1	4	1	4	2
Chung *et al*. 2001b	1	3	4	5	4	5	5	4	1	1	4	1	4	1
Cohen *et al*. 2000	3	4	1	5	4	2	5	1	2	1	4	2	4	3
Crossin *et al*. 1998	1	2	1	1	2	5	5	1	1	1	4	1	1	4
Cserni *et al*. 2000c	4	3	4	5	4	1	1	4	2	2	4	4	4	4
Czerniecki *et al*. 1999	3	1	4	1	2	2	1	1	2	1	2	1	4	4
Ahrendt *et al*. 2002	2	4	1	1	2	2	1	1	2	1	2	1	4	4
Allen *et al*. 2001	3	1	3	1	3	1	1	4	2	1	2	4	4	4

Author	Histopathologic method	Type of tracer	Type of radiocolloid	Location of colloid injection	Timing of colloid injection	Type of dye	Location of dye injection	Biopsy method	Tumour size	Tumour invasiveness	Tumour palpability	Clinical axillary status	Multicentricity / multifocality	Neoadjuvant chemotherapy
Altiyollar *et al*. 2000	2	3	4	5	4	1	1	3	1	1	4	1	4	4
Baichev *et al*. 2001	1	4	1	2	4	5	5	4	1	1	4	2	1	2
Baitchev *et al*. 2002	3	3	4	5	4	1	1	4	1	1	4	1	1	4
Balch *et al*. 2003	3	1	1	5	2	2	1	1	2	2	2	2	4	2
Barnwell *et al*. 1998	1	1	1	1	2	2	1	1	1	1	4	2	1	4
Barranger *et al*. 2003	3	4	1	1	1	1	3	2	1	1	2	1	4	1
Bass *et al*. 1999d	4	1	1	1	2	2	1	4	2	2	4	1	1	4
Bergkvist *et al*. 2001	3	1	2	3	3	1	3	4	2	1	4	1	2	1
Bobin *et al*. 1999	3	3	4	5	4	4	1	1	2	1	4	2	1	4
Bourgeois *et al*. 2003a	3	2	2	5	1	5	5	1	1	1	2	2	1	4
Brady 2002	2	4	1	2	2	2	1	2	2	1	4	4	4	3
Burak *et al*. 1999	1	1	1	1	2	2	1	1	1	1	2	1	1	1
Canavese *et al*. 2000a	4	3	4	5	4	1	1	4	3	4	1	2	1	4
Canavese *et al*. 2001	1	4	4	5	1	1	5	4	1	1	4	1	1	4
Casalegno *et al*. 2000	1	2	2	3	3	5	5	2	1	1	4	1	4	1
Chung *et al*. 2001a	1	3	4	5	4	2	1	4	2	1	4	1	4	2
Chung *et al*. 2001b	1	3	4	5	4	5	5	4	1	1	4	1	4	1
Cohen *et al*. 2000	3	4	1	5	4	2	5	1	2	1	4	2	4	3
Crossin *et al*. 1998	1	2	1	1	2	5	5	1	1	1	4	1	1	4
Cserni *et al*. 2000c	4	3	4	5	4	1	1	4	2	2	4	4	4	4
Czerniecki *et al*. 1999	3	1	4	1	2	2	1	1	2	1	2	1	4	4
Dale and Williams 1998	1	3	4	5	4	2	1	1	2	1	4	1	4	2
de Kanter *et al*. 2000	2	1	2	5	3	1	3	1	3	4	2	1	1	1
de Rubeis *et al*. 2000	1	4	2	1	3	1	3	1	1	1	4	1	4	4
Doting *et al*. 2000	2	1	2	4	1	1	4	4	2	1	1	1	1	4
Dowlatshahi *et al*. 1999	2	4	1	1	4	2	5	1	1	1	2	1	4	4

Author	Histopathologic method	Type of tracer	Type of radiocolloid	Location of colloid injection	Timing of colloid injection	Type of dye	Location of dye injection	Biopsy method	Tumour size	Tumour invasiveness	Tumour palpability	Clinical axillary status	Multicentricity / multifocality	Neoadjuvant chemotherapy
Feggi *et al*. 2000	4	4	4	1	3	5	5	1	1	1	4	4	4	4
Feldman *et al*. 1999	2	2	1	1	2	5	5	1	1	1	4	1	1	4
Fernandez *et al*. 2001 (1)	3	2	4	1	1	5	5	4	2	1	4	2	1	3
Fernandez *et al*. 2001 (2)	3	2	4	1	1	5	5	4	2	1	4	2	1	1
Fernandez *et al*. 2002 (1)	3	2	2	1	1	5	5	4	2	1	1	1	1	1
Fernandez *et al*. 2002 (2)	3	2	2	1	2	5	5	4	2	1	3	1	1	1
Fleming et al. 2003	3	1	3	5	4	2	1	1	2	1	4	1	4	4
Formisano *et al*. 2000	1	2	2	3	4	5	5	4	1	1	2	1	1	4
Fraile *et al*. 2000	2	2	2	1	3	5	5	2	1	2	2	1	1	1
Galli et al. 2000	4	2	2	5	4	5	5	4	1	1	2	1	4	4
Gucciardo et al. 2000	4	2	2	3	3	5	5	2	1	1	4	1	1	4
Guenther et al. 1997	1	3	4	5	4	2	1	1	2	2	4	4	4	4
Haid et al. 2001	2	1	2	1	1	1	1	4	1	1	2	4	4	3
Haigh et al. 2000	3	4	4	5	4	2	1	1	2	2	4	4	4	4
Hoar and Stonelake 2003	1	1	2	1	3	1	1	1	2	1	2	1	4	2
Hodgson et al. 2001	3	1	3	1	2	1	1	4	1	1	2	1	4	4
Hung et al. 2002	3	1	4	5	4	1	5	2	1	1	4	1	1	4
Ilum et al. 2000	3	3	4	5	4	1	3	1	3	4	4	2	2	1
Imoto and Hasebe 1999	1	3	4	5	4	4	3	1	2	1	4	2	4	4
Imoto et al. 2000	1	4	4	3	1	4	3	1	2	1	4	2	4	4
Ishida et al. 2002	2	1	2	1	2	4	1	4	2	1	2	2	2	1
Jaderborg et al. 1999	1	1	1	1	2	2	1	1	2	1	4	4	4	4
Jianjun et al. 2001 (1)	1	3	4	5	4	3	1	2	2	1	1	2	4	4
Jianjun et al. 2001 (2)	1	3	4	5	4	1	1	2	2	1	1	2	4	4
Kapteijn et al. 1998	2	3	4	5	4	1	4	2	1	2	1	1	1	4
Kataoka et al. 2000	1	3	4	5	4	4	1	1	2	1	4	1	4	4

Author	Histopathologic method	Type of tracer	Type of radiocolloid	Location of colloid injection	Timing of colloid injection	Type of dye	Location of dye injection	Biopsy method	Tumour size	Tumour invasiveness	Tumour palpability	Clinical axillary status	Multicentricity / multifocality	Neoadjuvant chemotherapy
Kern 1999	3	3	4	5	4	2	2	1	2	1	4	4	4	4
Kim et al. 2001	1	1	4	3	1	4	5	4	2	1	4	2	1	4
Kitapci et al. 2001	1	2	4	1	1	5	5	3	1	1	4	2	4	1
Koizumi et al. 2003	1	1	3	1	3	4	5	4	1	1	4	1	4	4
Koller et al. 1998	4	3	4	5	4	5	3	4	1	1	4	4	4	4
Krag et al. 2001	1	2	1	1	2	5	5	1	2	1	2	1	4	4
Lauridsen et al. 2000	2	1	2	1	2	1	1	2	1	1	1	1	1	4
Layeeque et al. 2003	1	4	1	2	4	2	2	1	2	1	4	1	3	4
Liu et al. 2000a	4	2	1	5	3	5	5	4	1	2	4	1	1	4
Liu et al. 2000b	1	3	4	5	4	1	5	2	2	1	4	4	1	4
Llatjos et al. 2002	2	2	2	1	3	5	5	4	1	2	2	1	4	4
Mahajna et al. 2003	2	4	3	1	3	5	3	1	1	1	4	1	4	4
Mariotti et al. 2002	1	2	2	5	1	5	5	2	1	1	2	1	4	4
Mateos et al. 2001 (1)	1	4	1	3	1	5	3	2	1	1	1	4	4	4
Mateos et al. 2001 (2)	1	4	1	1	1	5	1	2	1	1	2	4	4	4
McIntosh et al. 2001	1	1	2	1	4	1	1	4	3	4	3	4	4	4
Meyer-Rochow et al. 2003 (1)	4	3	4	5	4	1	1	2	2	1	1	1	2	4
Meyer-Rochow et al. 2003 (2)	4	1	3	1	1	1	1	2	2	1	1	1	2	4
Miller et al. 2002	2	4	1	1	4	2	1	4	2	1	2	1	4	3
Miner et al. 1998	1	2	1	1	2	5	5	1	1	1	2	4	1	4
Moffat et al. 1999	1	2	1	1	2	5	5	1	2	1	4	1	1	4
Mokbel and Mostafa 2001	4	3	4	5	4	3	2	1	1	1	2	1	2	4
Morrow et al. 1999	1	4	1	5	2	2	1	4	1	1	2	1	1	4
Motomura et al. 1999a	1	3	4	5	4	4	1	2	1	1	1	4	1	4
Motomura et al. 2002b	4	1	3	3	1	4	1	1	1	2	1	1	1	4
Nahrig et al. 2000	4	2	2	1	4	5	5	4	1	1	4	4	4	4

Author	Histopathologic method	Type of tracer	Type of radiocolloid	Location of colloid injection	Timing of colloid injection	Type of dye	Location of dye injection	Biopsy method	Tumour size	Tumour invasiveness	Tumour palpability	Clinical axillary status	Multicentricity / multifocality	Neoadjuvant chemotherapy
Nano et al. 2002	2	4	3	1	2	1	1	1	1	1	2	1	4	4
Nason et al. 2000	2	1	1	1	2	2	1	1	2	2	2	1	1	2
Noguchi et al. 1999	2	4	2	1	2	1	1	1	1	2	4	2	4	4
Nos et al. 2003	3	3	4	5	4	1	1	1	1	1	2	4	4	4
Nwariaku et al. 1998	1	1	1	1	4	2	3	4	1	2	4	4	4	4
Offodile et al. 1998	2	2	3	4	4	5	5	4	2	2	2	4	4	4
Ozmen et al. 2002	1	3	4	5	4	2	1	1	2	1	1	1	2	4
Patel et al. 2003	1	4	1	1	4	2	1	1	3	4	2	4	4	2
Peley et al. 2001	3	1	2	5	1	1	1	1	1	1	1	1	4	4
Pizzocaro et al. 2000	2	2	4	5	1	5	5	4	1	1	2	1	1	4
Quan et al. 2002	3	4	1	1	3	5	5	1	2	1	4	1	4	4
Ratanawichitrasin et al. 1998	1	3	4	5	4	2	1	1	2	1	4	4	4	1
Ratanawichitrasin et al. 1999	1	3	4	5	4	2	1	4	1	2	4	4	4	1
Reitsamer et al. 2003a	2	1	2	1	1	1	2	2	2	1	4	2	4	3
Rink et al. 2001b	3	2	2	5	3	5	5	1	1	2	2	2	2	4
Rodier et al. 2000	1	3	4	5	4	1	3	2	1	1	2	2	1	1
Roumen et al. 1997	1	2	2	1	3	5	5	1	1	1	4	1	1	4
Rubio et al. 1998b	1	2	1	1	2	5	5	1	2	1	4	1	1	4
Rufino et al. 2003	4	3	4	5	4	5	1	3	1	1	1	1	2	4
Sachdev et al. 2002	2	4	1	1	2	2	1	1	2	1	4	4	4	Sachdev et al.
Sardi et al. 2002	3	4	1	1	2	2	1	1	3	2	4	4	4	Sardi et al.
Sato et al. 2001a	1	1	3	5	2	4	5	2	1	1	4	1	4	Sato et al.
Schneebaum et al. 1998	1	1	3	5	1	1	5	2	3	4	1	4	4	Schneebaum
Schrenk et al. 2002a	3	4	2	2	4	5	2	4	2	1	4	4	3	Schrenk et al.
Schrenk et al. 2003	3	4	2	1	1	2	1	2	2	1	4	2	4	Schrenk et al.
Schwartz et al. 2003	1	3	4	5	4	2	5	3	2	1	4	4	4	Schwartz et al.

Author	Histopathologic method	Type of tracer	Type of radiocolloid	Location of colloid injection	Timing of colloid injection	Type of dye	Location of dye injection	Biopsy method	Tumour size	Tumour invasiveness	Tumour palpability	Clinical axillary status	Multicentricity / multifocality	Neoadjuvant chemotherapy
Shimazu et al. 2002	2	3	4	5	4	2	1	1	1	2	4	2	4	Shimazu et al.
Shivers et al. 2002	3	1	1	1	2	2	1	4	3	4	2	4	4	Shivers et al.
Smillie et al. 2001	2	1	1	1	3	2	1	4	1	1	2	1	4	Smillie et al.
Snider et al. 1998	3	2	1	1	2	5	5	4	1	1	2	1	4	Snider et al.
Spanu et al. 2001	2	2	1	3	1	5	5	2	1	1	2	1	1	Spanu et al.
Stearns et al. 2002	3	3	4	5	4	2	1	4	2	1	2	2	4	Stearns et al.
Stitzenberg et al. 2002	3	4	1	1	4	2	1	1	2	1	2	1	4	Stitzenberg et
Tavares et al. 2001	1	1	3	3	1	1	1	4	1	1	4	1	1	Tavares et al.
Tousimis et al. 2003	4	4	4	5	4	2	1	4	2	1	4	4	3	Tousimis et al.
Tsugawa et al. 2000	2	1	2	3	2	1	1	1	1	2	4	2	4	Tsugawa et al.
Ugur et al. 2003	2	1	3	3	2	2	5	4	2	2	4	1	1	Ugur et al.
Vaggelli et al. 2000	2	2	4	3	1	5	5	4	3	4	4	2	4	Vaggelli et al.
van Berlo et al. 2003	2	1	4	5	1	1	3	4	2	2	4	4	4	van Berlo et
van der Ent et al. 2001	3	1	2	1	1	1	3	4	2	1	4	4	4	van der Ent et
Vargas et al. 2002b	1	1	1	3	2	2	1	1	2	2	4	1	4	Vargas et al.
Veronesi et al. 1999	1	4	2	5	1	5	5	2	1	1	4	1	4	Veronesi et al.
Veronesi et al. 2003	3	2	2	5	3	5	5	2	1	1	4	4	1	Veronesi et al.
Vigario et al. 2003 (1)	3	2	3	1	1	5	5	2	1	1	2	1	1	Vigario et al.
Vigario et al. 2003 (2)	3	2	3	1	1	5	5	2	1	1	2	1	1	Vigario et al.
Walker et al. 2002	1	3	4	5	4	1	5	4	1	2	4	1	1	Walker et al.
Watanabe et al. 2001	3	2	3	1	1	5	5	1	2	1	4	1	2	Watanabe et
Weerts et al. 2002	3	2	2	5	3	5	5	4	1	1	4	1	4	Weerts et al.
Wong et al. 2002a	3	4	4	5	4	5	5	1	2	1	4	1	4	Wong et al.
Xavier et al. 2001	2	4	3	1	3	1	5	2	2	1	2	1	1	Xavier et al.
Xu et al. 2002	3	2	3	1	4	5	5	1	1	2	4	1	4	Xu et al. 2002
Yang et al. 2001	1	3	4	5	4	2	1	4	2	2	4	2	4	Yang et al.

Author	Histopathologic method	Type of tracer	Type of radiocolloid	Location of colloid injection	Timing of colloid injection	Type of dye	Location of dye injection	Biopsy method	Tumour size	Tumour invasiveness	Tumour palpability	Clinical axillary status	Multicentricity / multifocality	Neoadjuvant chemotherapy
Yong et al. 2003	1	1	3	1	2	1	1	1	2	1	2	1	4	Yong et al.
Yu et al. 2002	1	3	4	5	4	3	1	4	1	1	2	1	4	Yu et al. 2002
Zavagno et al. 2000	2	2	2	3	1	5	5	2	1	1	4	1	4	Zavagno et al.
Zhang et al. 2003	3	2	1	5	3	5	5	1	1	2	4	1	4	Zhang et al.

Appendix H Diagnostic accuracy results tables

Table H.1 Raw data – localisation rates and false negative rates

Author	Included for…	Number of patients	Attempted number of mappings	Number successfully mapped	Localisation rate (%)	True positives	False positives	True negatives	False negatives	False negative rate (%)	Sensitivity	Negative Predictive Value	Accuracy	% avoidance
Acosta et al. 2003	L only	57	57	54	94.74									
Ahrendt et al. 2002	L & F	174	177	150	84.75	51	0	97	2	3.77	0.9623	0.9798	0.9867	64.67
Allen et al. 2001	L & F	36	36	34	94.44	17	0	17	0	0.00	1.0000	1.0000	1.0000	50.00
Altiyollar et al. 2000	L & F	60	60	49	81.67	19	0	27	3	13.64	0.8636	0.9000	0.9388	55.10
Aras et al. 2002	L only	30	30	25	83.33									
Baichev et al. 2001	F only			238		69	0	158	11	13.75	0.8625	0.9349	0.9538	66.39
Baitchev et al. 2002	L & F	87	95	87	91.58	25	0	60	2	7.41	0.9259	0.9677	0.9770	68.97
Balch et al. 2003	L & F	122	122	113	92.62	41	0	70	2	4.65	0.9535	0.9722	0.9823	61.95
Barnwell et al. 1998	L & F	42	42	38	90.48	15	0	23	0	0.00	1.0000	1.0000	1.0000	60.53
Barranger et al. 2003	L & F	32	32	32	100.00	14	0	17	1	6.67	0.9333	0.9444	0.9688	53.13
Bass et al. 1999b	F only			173		53	0	119	1	1.85	0.9815	0.9917	0.9942	68.79
Bauer et al. 2002 (1)	L only	83	83	79	95.18									
Bauer et al. 2002 (2)	L only	249	249	241	96.79									
Beitsch et al. 2001	L only	85	85	83	97.65									
Bembenek et al. 1999	L only	146	146	118	80.82									
Bergkvist et al. 2001	L & F	498	498	450	90.36	164	0	266	20	10.87	0.8913	0.9301	0.9556	59.11
Birdwell et al. 2001	L only	136	136	128	94.12									
Blessing et al. 2002 (1)	L only	87	86	86	100.00									
Blessing et al. 2002 (2)	L only	112	112	111	99.11									
Bobin et al. 1999	L & F	100	100	83	83.00	37	0	44	2	5.13	0.9487	0.9565	0.9759	53.01
Borgstein et al. 2000 (1)	L only	217	90	86	95.56									
Borgstein et al. 2000 (2)	L only	3 bilateral	130	126	96.92									
Bourgeois et al. 2003b	L only	181	181	181	100.00									
Bourgeois et al. 2003a	F only			393		147	0	232	14	8.70	0.9130	0.9431	0.9644	59.03
Brady 2002	L & F	14	14	13	92.86	10	0	3	0	0.00	1.0000	1.0000	1.0000	23.08
Branagan et al. 2002	L only	52	52	50	96.15									
Brenot-Rossi et al. 2003	L only	332	332	302	90.96									
Breslin et al. 2000	L only	51	51	43	84.31									

Author	Included for…	Number of patients	Attempted number of mappings	Number successfully mapped	Localisation rate (%)	True positives	False positives	True negatives	False negatives	False negative rate (%)	Sensitivity	Negative Predictive Value	Accuracy	% avoidance
Burak et al. 1999	F only			45		14	0	31	0	0.00	1.0000	1.0000	1.0000	68.89
Byrd et al. 2001	L only	220	220	194	88.18									
Canavese et al. 2000a	F only			36		10	0	23	3	23.08	0.7692	0.8846	0.9167	63.89
Canavese et al. 2001	F only			206		72	0	129	5	6.49	0.9351	0.9627	0.9757	62.62
Casalegno et al. 2000	L & F	102	102	88	86.27	35	0	51	2	5.41	0.9459	0.9623	0.9773	57.95
Choi *et al*. 2003	L only	81	83	82	98.80									
Chua *et al*. 2001	L only	174	174	140	80.46									
Chua *et al*. 2003	L only	540	547	480	87.75									
Chung *et al*. 2001a	L & F	41	41	41	100.00	30	0	10	1	3.23	0.9677	0.9091	0.9756	24.39
Chung *et al*. 2001b	L & F	30	30	25	83.33	9	0	13	3	25.00	0.7500	0.8125	0.8800	52.00
Classe *et al*. 2003	L only	200	200	188	94.00									
Cohen *et al*. 2000	F only			31		16	0	12	3	15.79	0.8421	0.8000	0.9032	38.71
Cox *et al*. 2002	L only	1356	1356	1302	96.02									
Crossin *et al*. 1998	L & F	50	50	42	84.00	7	0	34	1	12.50	0.8750	0.9714	0.9762	80.95
Cserni 2002a	L only	201	201	184	91.54									
Cserni *et al*. 2000c	F only			112		76	0	30	6	7.32	0.9268	0.8333	0.9464	26.79
Czerniecki *et al*. 1999	L & F	44	43	41	95.35	15	0	26	0	0.00	1.0000	1.0000	1.0000	63.41
Dale and Williams 1998	L & F	20	21	14	66.67	5	0	9	0	0.00	1.0000	1.0000	1.0000	64.29
de Kanter *et al*. 2000	L & F	232	232	217	93.53	93	0	119	5	5.10	0.9490	0.9597	0.9770	54.84
de Rubeis *et al*. 2000	L & F	21	21	19	90.48	2	0	16	1	33.33	0.6667	0.9412	0.9474	84.21
d'Eredita *et al*. 2003 (1)	L only	155	115	109	94.78									
d'Eredita *et al*. 2003 (2)	L only		40	39	97.50									
Derossis *et al*. 2003	L only	2495	2495	2433	97.52									
Donahue 2001	L only	42	42	41	97.62									
Doting *et al*. 2000	F only			126		56	0	67	3	5.08	0.9492	0.9571	0.9762	53.17
Dowlatshahi *et al*. 1999	L & F	54	54	52	96.30	30	0	22	0	0.00	1.0000	1.0000	1.0000	42.31
Dunnwald *et al*. 1999	L only	93	93	79	84.95									
Estourgie *et al*. 2003b	L only	599	606	565	93.23									
Euhus *et al*. 2002	L only	153	156	139	89.10									
Feezor *et al*. 2002 (1)	L only	65	65	64	98.46									
Feezor *et al*. 2002 (2)	L only	6	6	5	83.33									
Feezor *et al*. 2002 (3)	L only	47	47	47	100.00									
Feggi *et al*. 2000	L & F	60	58	55	94.83	12	0	43	0	0.00	1.0000	1.0000	1.0000	78.18
Feggi *et al*. 2001	L only	73	73	62	84.93									

Author	Included for…	Number of patients	Attempted number of mappings	Number successfully mapped	Localisation rate (%)	True positives	False positives	True negatives	False negatives	False negative rate (%)	Sensitivity	Negative Predictive Value	Accuracy	% avoidance
Feldman *et al*. 1999	L & F	75	75	70	93.33	17	0	49	4	19.05	0.8095	0.9245	0.9429	70.00
Fenaroli *et al*. 2000	L only	14	14	14	100.00									
Fernandez *et al*. 2001 (1)	L & F	40	40	34	85.00	16	0	14	4	20.00	0.8000	0.7778	0.8824	41.18
Fernandez *et al*. 2001 (2)	L & F	36	36	29	80.56	8	0	19	2	20.00	0.8000	0.9048	0.9310	65.52
Fernandez *et al*. 2002 (1)	L & F	80	76	63	82.89	19	0	38	6	24.00	0.7600	0.8636	0.9048	60.32
Fernandez *et al*. 2002 (2)	L & F	30	29	27	93.10	6	0	20	1	14.29	0.8571	0.9524	0.9630	74.07
Fialdini *et al*. 2000	L only	25	25	25	100.00									
Fleming *et al*. 2003 (1)	L only	80	80	77	96.25									
Fleming *et al*. 2003 (2)	L only	45	45	45	100.00									
Fleming *et al*. 2003 (3)	F only			122		56	0	62	4	6.67	0.9333	0.9394	0.9672	50.82
Flett *et al*. 1998	L only	68	68	56	82.35									
Formisano *et al*. 2000	L & F	42	42	42	100.00	4	0	38	0	0.00	1.0000	1.0000	1.0000	90.48
Fraile *et al*. 2000	L & F	132	132	127	96.21	48	0	77	2	4.00	0.9600	0.9747	0.9843	60.63
Galli *et al*. 2000	L & F	46	46	44	95.65	12	0	29	3	20.00	0.8000	0.9063	0.9318	65.91
Gray *et al*. 2001	L only	43	42	42	100.00									
Gucciardo *et al*. 2000	L & F	50	49	43	87.76	13	0	25	5	27.78	0.7222	0.8333	0.8837	58.14
Guenther 1999	L only	260	260	213	81.92									
Guenther *et al*. 1997	F only			103		28	0	72	3	9.68	0.9032	0.9600	0.9709	69.90
Gulec *et al*. 2001	L only	165	165	157	95.15									
Haid *et al*. 2001	F only			29		18	0	11	0	0.00	1.0000	1.0000	1.0000	37.93
Haigh *et al*. 2000	L & F	283	284	230	80.99	90	0	137	3	3.23	0.9677	0.9786	0.9870	59.57
Hansen *et al*. 2002	L only	238	238	238	100.00									
Hoar and Stonelake 2003	L & F	66	67	65	97.01	24	0	37	4	14.29	0.8571	0.9024	0.9385	56.92
Hodgson *et al*. 2001	L & F	47	47	46	97.87	9	0	36	1	10.00	0.9000	0.9730	0.9783	78.26
Hung *et al*. 2002	L & F	50	50	47	94.00	20	0	27	0	0.00	1.0000	1.0000	1.0000	57.45
Ilum *et al*. 2000	L & F	159	161	97	60.25	42	0	48	7	14.29	0.8571	0.8727	0.9278	49.48
Imoto and Hasebe 1999	L & F	86	88	65	73.86	25	0	36	4	13.79	0.8621	0.9000	0.9385	55.38
Imoto *et al*. 2000	L & F	58	59	55	93.22	25	0	28	2	7.41	0.9259	0.9333	0.9636	50.91
Intra *et al*. 2003b	L only	223	223	223	100.00									
Intra *et al*. 2003a	L only	41	41	37	90.24									
Ishida *et al*. 2002	L & F	44	44	42	95.45	12	0	27	3	20.00	0.8000	0.9000	0.9286	64.29
Jaderborg *et al*. 1999	L & F	79	79	64	81.01	19	0	44	1	5.00	0.9500	0.9778	0.9844	68.75
Jastrzebski *et al*. 2002 (1)	L only	51	51	41	80.39									
Jastrzebski *et al*. 2002 (2)	L only	72	72	67	93.06									

Author	Included for…	Number of patients	Attempted number of mappings	Number successfully mapped	Localisation rate (%)	True positives	False positives	True negatives	False negatives	False negative rate (%)	Sensitivity	Negative Predictive Value	Accuracy	% avoidance
Jianjun *et al*. 2001 (1)	L & F	32	32	21	65.63	8	0	11	2	20.00	0.8000	0.8462	0.9048	52.38
Jianjun *et al*. 2001 (2)	L & F	62	62	55	88.71	23	0	31	1	4.17	0.9583	0.9688	0.9818	56.36
Jinno *et al*. 2002 (1)	L only	74	74	64	86.49									
Jinno *et al*. 2002 (2)	L only	110	110	107	97.27									
Johnson *et al*. 2001	L only	96	96	70	72.92									
Kapteijn *et al*. 1998	F only			26		10	0	16	0	0.00	1.0000	1.0000	1.0000	61.54
Kataoka *et al*. 2000	L & F	70	70	65	92.86	17	0	45	3	15.00	0.8500	0.9375	0.9538	69.23
Kern 1999	L & F	40	40	39	97.50	15	0	24	0	0.00	1.0000	1.0000	1.0000	61.54
Kern 2002	L only	185	187	184	98.40									
Kim *et al*. 2001	L & F	23	23	21	91.30	6	0	12	3	33.33	0.6667	0.8000	0.8571	57.14
Kitapci *et al*. 2001	L & F	14	14	14	100.00	4	0	10	0	0.00	1.0000	1.0000	1.0000	71.43
Klimberg *et al*. 1999	L only	68	69	65	94.20									
Koizumi *et al*. 2003	L & F	60	60	60	100.00	14	0	44	2	12.50	0.8750	0.9565	0.9667	73.33
Koller *et al*. 1998	L & F	98	98	96	97.96	48	0	45	3	5.88	0.9412	0.9375	0.9688	46.88
Krag *et al*. 2001	L & F	145	145	127	87.59	43	0	82	2	4.44	0.9556	0.9762	0.9843	64.57
Kumar *et al*. 2003	L only	59	59	56	94.92									
Lauridsen *et al*. 2000	L & F	80	80	78	97.50	43	0	35	0	0.00	1.0000	1.0000	1.0000	44.87
Layeeque *et al*. 2003	L & F	40	40	40	100.00	25	0	15	0	0.00	1.0000	1.0000	1.0000	37.50
Leidenius *et al*. 2003b	L only	395	395	363	91.90									
Liang *et al*. 2003	L only	20	21	20	95.24									
Liberman and Cody 2001	L only	33	33	30	90.91									
Liberman *et al*. 1999	L only	197	200	200	100.00									
Liu *et al*. 2000a	L & F	62	62	58	93.55	14	0	41	3	17.65	0.8235	0.9318	0.9483	70.69
Liu *et al*. 2000b	L & F	33	33	30	90.91	19	0	10	1	5.00	0.9500	0.9091	0.9667	33.33
Liu *et al*. 2000c	L only	41	41	38	92.68									
Liu *et al*. 2003	L only	38	38	33	86.84									
Llatjos *et al*. 2002	F only			76		29	0	45	2	6.45	0.9355	0.9574	0.9737	59.21
Lloyd *et al*. 2002 (1)	L only	27	27	26	96.30									
Lloyd *et al*. 2002 (2)	L only	80	80	78	97.50									
Luini *et al*. 2002	L only	115	115	115	100.00									
Macmillan *et al*. 2001	L only	200	200	191	95.50									
Mahajna *et al*. 2003	L & F	100	100	92	92.00	39	0	50	3	7.14	0.9286	0.9434	0.9674	54.35
Mann *et al*. 2000	L only	62	62	51	82.26									
Mariotti *et al*. 2002	L & F	45	45	38	84.44	11	0	27	0	0.00	1.0000	1.0000	1.0000	71.05

Author	Included for…	Number of patients	Attempted number of mappings	Number successfully mapped	Localisation rate (%)	True positives	False positives	True negatives	False negatives	False negative rate (%)	Sensitivity	Negative Predictive Value	Accuracy	% avoidance
Mateos *et al*. 2001 (1)	L & F	36	36	33	91.67	6	0	25	2	25.00	0.7500	0.9259	0.9394	75.76
Mateos *et al*. 2001 (2)	L & F	44	44	40	90.91	10	0	27	3	23.08	0.7692	0.9000	0.9250	67.50
McIntosh *et al*. 2001	F only			25		7	0	18	0	0.00	1.0000	1.0000	1.0000	72.00
Meyer-Rochow *et al*. 2003 (1)	L & F	63	63	57	90.48	22	0	34	1	4.35	0.9565	0.9714	0.9825	59.65
Meyer-Rochow *et al*. 2003 (2)	L & F	41	41	40	97.56	21	0	17	2	8.70	0.9130	0.8947	0.9500	42.50
Miller *et al*. 2002	L & F	35	35	30	85.71	9	0	21	0	0.00	1.0000	1.0000	1.0000	70.00
Minato *et al*. 2003	L only	35	35	35	100.00									
Miner *et al*. 1998	F only			41		7	0	33	1	12.50	0.8750	0.9706	0.9756	80.49
Miner *et al*. 1999	L only	82	82	80	97.56									
Mirzaei *et al*. 2003	L only	128	128	112	87.50									
Moffat *et al*. 1999	L & F	70	70	62	88.57	18	0	42	2	10.00	0.9000	0.9545	0.9677	67.74
Mokbel and Mostafa 2001	L & F	35	35	34	97.14	12	0	21	1	7.69	0.9231	0.9545	0.9706	61.76
Molland *et al*. 2000	L only	104	103	88	85.44									
Morrow *et al*. 1999	F only			110		28	0	78	4	12.50	0.8750	0.9512	0.9636	70.91
Motomura *et al*. 1999a	L & F	172	172	127	73.84	40	0	82	5	11.11	0.8889	0.9425	0.9606	64.57
Motomura *et al*. 2002a	L & F	154	154	147	95.45	41	0	105	1	2.38	0.9762	0.9906	0.9932	71.43
Motta *et al*. 2000	L only	54	54	49	90.74									
Nahrig *et al*. 2000	L & F	40	40	40	100.00	22	0	18	0	0.00	1.0000	1.0000	1.0000	45.00
Nano *et al*. 2002	L & F	328	328	285	86.89	93	0	184	8	7.92	0.9208	0.9583	0.9719	64.56
Nason *et al*. 2000	F only			66		26	0	35	5	16.13	0.8387	0.8750	0.9242	53.03
Noguchi *et al*. 1999 (1)	L only	47	47	38	80.85									
Noguchi *et al*. 1999 (2)	L only	25	25	24	96.00									
Noguchi *et al*. 1999 (3)	F only			62		25	0	34	3	10.71	0.8929	0.9189	0.9516	54.84
Noguchi *et al*. 2000a (1)	L only	44	44	37	84.09									
Noguchi *et al*. 2000a (2)	L only	193	193	137	70.98									
Noguchi *et al*. 2000a (3)	L only	210	210	158	75.24									
Noguchi *et al*. 2000a (4)	L only	47	47	43	91.49									
Noguchi *et al*. 2000a (5)	L only	33	33	31	93.94									
Noguchi *et al*. 2000a (6)	L only	55	55	54	98.18									
Noguchi *et al*. 2000a (7)	L only	62	62	56	90.32									
Noguchi *et al*. 2000a (8)	L only	30	30	30	100.00									
Nos *et al*. 2003	L & F	324	324	247	76.23	90	0	155	2	2.17	0.9783	0.9873	0.9919	62.75
Nwariaku *et al*. 1998	F only			96		26	0	69	1	3.70	0.9630	0.9857	0.9896	71.88

Author	Included for…	Number of patients	Attempted number of mappings	Number successfully mapped	Localisation rate (%)	True positives	False positives	True negatives	False negatives	False negative rate (%)	Sensitivity	Negative Predictive Value	Accuracy	% avoidance
Offodile *et al*. 1998	L & F	41	41	40	97.56	18	0	22	0	0.00	1.0000	1.0000	1.0000	55.00
Ozmen *et al*. 2002	L & F	122	122	111	90.98	55	0	49	7	11.29	0.8871	0.8750	0.9369	44.14
Paganelli *et al*. 2002a	L only	892	892	882	98.88									
Patel *et al*. 2003	L & F	125	125	117	93.60	33	0	82	2	5.71	0.9429	0.9762	0.9829	70.09
Peley *et al*. 2001	L & F	68	68	68	100.00	21	0	45	2	8.70	0.9130	0.9574	0.9706	66.18
Pelosi *et al*. 2003 (1)	L only	99	100	100	100.00									
Pelosi *et al*. 2003 (2)	L only	49	50	49	98.00									
Pizzocaro *et al*. 2000	L & F	83	83	75	90.36	23	0	47	5	17.86	0.8214	0.9038	0.9333	62.67
Ponzone *et al*. 2003	L only	212	212	207	97.64									
Povoski *et al*. 2002	L only	113	113	104	92.04									
Quan *et al*. 2002	L & F	152	152	141	92.76	54	0	87	0	0.00	1.0000	1.0000	1.0000	61.70
Rahusen *et al*. 2000a	L only	115	115	106	92.17									
Rahusen *et al*. 2003	L only	67	67	64	95.52									
Ratanawichitrasin *et al*. 1998	L & F	40	40	35	87.50	7	0	26	2	22.22	0.7778	0.9286	0.9429	74.29
Ratanawichitrasin *et al*. 1999	L & F	60	60	55	91.67	14	0	38	3	17.65	0.8235	0.9268	0.9455	69.09
Reitsamer *et al*. 2003a	L & F	30	30	26	86.67	14	0	11	1	6.67	0.9333	0.9167	0.9615	42.31
Reitsamer *et al*. 2003b	L only	154	157	155	98.73									
Rettenbacher *et al*. 2000	L only	45	45	43	95.56									
Rink *et al*. 2001b	L & F	155	154	150	97.40	49	0	97	4	7.55	0.9245	0.9604	0.9733	64.67
Rodier *et al*. 2000	L & F	73	74	61	82.43	23	0	36	2	8.00	0.9200	0.9474	0.9672	59.02
Roumen *et al*. 1997	L & F	83	83	57	68.67	22	0	34	1	4.35	0.9565	0.9714	0.9825	59.65
Rubio *et al*. 1998b	L & F	55	55	53	96.36	15	0	36	2	11.76	0.8824	0.9474	0.9623	67.92
Rufino *et al*. 2003	L & F	25	25	19	76.00	5	0	9	5	50.00	0.5000	0.6429	0.7368	47.37
Sabel *et al*. 2003	L only	25	26	26	100.00									
Sachdev *et al*. 2002	L & F	212	212	190	89.62	55	0	123	12	17.91	0.8209	0.9111	0.9368	64.74
Sardi *et al*. 2002	L & F	58	58	53	91.38	19	0	34	0	0.00	1.0000	1.0000	1.0000	64.15
Sato *et al*. 2001a	F only			108		40	0	67	1	2.44	0.9756	0.9853	0.9907	62.04
Sato *et al*. 2003	L only	186	186	183	98.39									
Schneebaum *et al*. 1998	L & F	30	30	28	93.33	7	0	19	2	22.22	0.7778	0.9048	0.9286	67.86
Schrenk *et al*. 2002a	F only			46		25	0	20	1	3.85	0.9615	0.9524	0.9783	43.48
Schrenk *et al*. 2002b	L only	284	284	263	92.61									
Schrenk *et al*. 2003	L & F	21	21	21	100.00	9	0	12	0	0.00	1.0000	1.0000	1.0000	57.14
Schwartz *et al*. 2003	L & F	21	21	21	100.00	10	0	10	1	9.09	0.9091	0.9091	0.9524	47.62

Author	Included for…	Number of patients	Attempted number of mappings	Number successfully mapped	Localisation rate (%)	True positives	False positives	True negatives	False negatives	False negative rate (%)	Sensitivity	Negative Predictive Value	Accuracy	% avoidance
Shenoy *et al*. 2002 (1)	L only	50	50	47	94.00									
Shenoy *et al*. 2002 (2)	L only	50	50	47	94.00									
Shimazu *et al*. 2002 (1)	L only	41	41	35	85.37									
Shimazu *et al*. 2002 (2)	L only	52	52	51	98.08									
Shimazu *et al*. 2002 (3)	L & F	62	62	50	80.65	17	0	32	1	5.56	0.9444	0.9697	0.9800	64.00
Shiver *et al*. 2002	L only	132	133	127	95.49									
Shivers *et al*. 2002	F only			366		111	0	250	5	4.31	0.9569	0.9804	0.9863	68.31
Simmons *et al*. 2003	L only	112	113	107	94.69									
Smillie *et al*. 2001	F only			89		34	0	53	2	5.56	0.9444	0.9636	0.9775	59.55
Smith *et al*. 2000 (1)	L only	19	19	18	94.74									
Smith *et al*. 2000 (2)	L only	19	19	19	100.00									
Snider *et al*. 1998	L & F	80	80	70	87.50	13	0	56	1	7.14	0.9286	0.9825	0.9857	80.00
Solarzano *et al*. 2001	L only	117	117	114	97.44									
Spanu *et al*. 2001	L & F	101	101	97	96.04	30	0	62	5	14.29	0.8571	0.9254	0.9485	63.92
Stearns *et al*. 2002	L & F	34	34	29	85.29	18	0	8	3	14.29	0.8571	0.7273	0.8966	27.59
Stitzenberg *et al*. 2002	L & F	78	80	76	95.00	28	0	48	0	0.00	1.0000	1.0000	1.0000	63.16
Stradling *et al*. 2002	L only	24	24	24	100.00									
Tafra *et al*. 2001b (1)	L only	29	29	27	93.10									
Tafra *et al*. 2001b (2)	L only	939	939	822	87.54									
Tausch *et al*. 2002 (1)	L only	70	70	59	84.29									
Tausch *et al*. 2002 (2)	L only	1567	1567	1368	87.30									
Tavares *et al*. 2001	L & F	41	41	38	92.68	15	0	21	2	11.76	0.8824	0.9130	0.9474	55.26
Tousimis *et al*. 2003	F only			70		35	0	32	3	7.89	0.9211	0.9143	0.9571	45.71
Travagli *et al*. 2003	L only	165	165	160	97.00									
Tsugawa *et al*. 2000	F only			43		17	0	24	2	10.53	0.8947	0.9231	0.9535	55.81
Tuthill *et al*. 2001	L only	119	120	115	95.83									
Tuttle *et al*. 2002	L only	158	159	159	100.00									
Ugur *et al*. 2003	L & F	28	27	22	81.48	6	0	15	1	14.29	0.8571	0.9375	0.9545	68.18
Upponi *et al*. 2002	L only	62	62	60	96.77									
Vaggelli *et al*. 2000	L & F	76	76	72	94.74	33	0	39	0	0.00	1.0000	1.0000	1.0000	54.17
van Berlo *et al*. 2003 (1)	L only	70	70	69	98.57									
van Berlo *et al*. 2003 (2)	L only	162	162	162	100.00									
van Berlo *et al*. 2003 (3)	L & F	58	58	57	98.28	22	0	34	1	4.35	0.9565	0.9714	0.9825	59.65
van der Ent *et al*. 2001 (1)	F only			137		55	0	81	1	1.79	0.9821	0.9878	0.9927	59.12
van der Ent *et al*. 2001 (2)	L only	256	256	249	97.27									

Author	Included for…	Number of patients	Attempted number of mappings	Number successfully mapped	Localisation rate (%)	True positives	False positives	True negatives	False negatives	False negative rate (%)	Sensitivity	Negative Predictive Value	Accuracy	% avoidance
Vargas *et al*. 2002a	L only	73	73	71	97.26									
Vargas *et al*. 2002b	F only			38		11	0	27	0	0.00	1.0000	1.0000	1.0000	71.05
Vargas *et al*. 2003a	L only	110	110	103	93.64									
Veronesi *et al*. 1999	F only			371		168	0	191	12	6.67	0.9333	0.9409	0.9677	51.48
Veronesi *et al*. 2003	F only			257		83	0	166	8	8.79	0.9121	0.9540	0.9689	64.59
Vigario *et al*. 2003 (1)	L & F	37	37	36	97.30	18	0	11	7	28.00	0.7200	0.6111	0.8056	30.56
Vigario *et al*. 2003 (2)	L & F	46	46	42	91.30	10	0	31	1	9.09	0.9091	0.9688	0.9762	73.81
Villa *et al*. 2000	L only	284	284	278	97.89									
Walker *et al*. 2002	L & F	122	122	113	92.62	39	0	69	5	11.36	0.8864	0.9324	0.9558	61.06
Watanabe *et al*. 2001	L & F	87	87	87	100.00	37	0	50	0	0.00	1.0000	1.0000	1.0000	57.47
Weerts *et al*. 2002 (1)	L only	14	14	9	64.29									
Weerts *et al*. 2002 (2)	L only	46	46	43	93.48									
Weerts *et al*. 2002 (3)	F only			52		13	0	35	4	23.53	0.7647	0.8974	0.9231	67.31
Winchester *et al*. 1999 (1)	L only	20	20	10	50.00									
Winchester *et al*. 1999 (2)	L only	60	60	55	91.67									
Winchester *et al*. 1999 (3)	L only	100	100	97	97.00									
Wong *et al*. 2002a	L & F	3324	3324	3106	93.44	989	0	2034	83	7.74	0.9226	0.9608	0.9733	65.49
Xavier *et al*. 2001	L & F	56	56	56	100.00	29	0	26	1	3.33	0.9667	0.9630	0.9821	46.43
Xu *et al*. 2002	L & F	42	42	39	92.86	13	0	25	1	7.14	0.9286	0.9615	0.9744	64.10
Yang *et al*. 2001	L & F	18	18	18	100.00	5	0	12	1	16.67	0.8333	0.9231	0.9444	66.67
Yong *et al*. 2003	L & F	312	312	267	85.58	90	0	159	18	16.67	0.8333	0.8983	0.9326	59.55
Yu *et al*. 2002	L & F	218	221	189	85.52	50	0	134	5	9.09	0.9091	0.9640	0.9735	70.90
Zavagno *et al*. 2000	F only			115		41	0	69	5	10.87	0.8913	0.9324	0.9565	60.00
Zavagno *et al*. 2002a	L only	384	384	359	93.49									
Zavagno *et al*. 2002b	L only	50	50	47	94.00									
Zervos *et al*. 2001	L only	509	509	465	91.36									
Zerwes *et al*. 2002	L only	29	29	29	100.00									
Zgajnar *et al*. 2003	L only	17	17	15	88.24									
Zhang *et al*. 2003	L & F	95	95	91	95.79	28	0	57	6	17.65	0.8235	0.9048	0.9341	62.64

NOTE: L - localisation rate; F - false negative rate