Title:	**MRI for staging rectal carcinoma – June 2008**
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Aim

To assess the safety, effectiveness and cost effectiveness of using magnetic resonance imaging (MRI) for staging newly diagnosed rectal carcinoma, restaging rectal carcinoma after neaodjuvant therapy, and diagnosis/staging of patients suspected of having carcinoma recurrence. MRI is proposed as an alternative to endorectal ultrasound (ERUS), and an addition to multi-slice computed tomography (MSCT).

Results and conclusions

Safety:

A diagnostic or staging test may harm patients in two main ways: direct physical or psychological harms from the procedure itself or its results; or harms from inappropriate management subsequent to an incorrect diagnosis/staging result. While it is expected that an incorrect staging result from MRI may harm patients, no direct or indirect harms were reported in the studies included in the systematic review.

Effectiveness:

Two studies (level III-2 and III-3 interventional evidence) reported direct evidence of the effect of MRI on a surrogate health outcome (the circumferential resection margin; CRM) to stage newly diagnosed rectal carcinoma patients. However, these results were not applicable to the Australian healthcare setting, so a linked evidence approach was also assessed. One level III-2 diagnostic study compared MRI against MSCT on the primary accuracy outcome of the CRM, however, these results were considered clinically irrelevant due to the unusual definition of the CRM used. Six further studies reported moderately high overall accuracy from MRI when compared against the reference standard of histopathology (73 – 100%). One study compared the neoadjuvant treatment strategies that would have been used if MRI or ERUS were the determining factors for treatment strategies, but as these strategies would be used in combination with MSCT, not alone, these results also did not reflect the Australian situation. If the CRM is able to be accurately visualised, it is assumed that selection of patients for neoadjuvant treatment would be based on the CRM results, not on tumour stage. One randomised controlled trial reported less carcinoma recurrence after two years when patients had neoadjuvant therapy, rather than primary surgery with/without adjuvant therapy, regardless of CRM status. However, the absolute rates of recurrence were greater when patients had an involved CRM, hence it is expected that patients with a low risk of recurrence would benefit from reduced use of neoadjuvant therapy, through avoidance of associated toxicities. It is therefore expected that the ability to visualise the CRM (through MRI or possibly MSCT) would result in management strategies that would benefit patient outcomes.

MRI was less accurate at visualising the CRM after patients had received neoadjuvant therapy than prior to neoadjuvant therapy. Two studies (level III-2 diagnostic evidence) reported MRI to be 77 – 82% accurate compared to histopathology, with the majority of the incorrectly staged patients being over-staged, due to the inability to distinguish between residual tumour or fibrosis from the neoadjuvant therapy. There were no studies that compared the accuracy of MRI against MSCT or ERUS for visualising the CRM in patients who received neoadjuvant therapy.

No studies were available reporting on the ability of MRI to stage patients with recurrent rectal carcinoma. Three level III-2 diagnostic studies reported that MRI has moderate – high diagnostic accuracy (75 – 94%) in patients suspected of having carcinoma recurrence.

Cost-effectiveness:

There was insufficient data on the accuracy of MRI plus MSCT compared to MSCT alone to warrant a cost-effectiveness analysis. A financial analysis found that the addition of MRI to MSCT would result in additional staging costs to the Australian government ($1,103,174 per year) and society ($1,162,024 per year). However, these costs would likely be offset by a decreased rate of neoadjuvant therapy use through visualisation of the CRM.

Recommendations

MSAC has considered the safety, effectiveness and cost-effectiveness of magnetic resonance imaging (MRI) for the initial staging, restaging and diagnosis of recurrence of rectal carcinoma in addition to conventional imaging.

MSAC finds that MRI for the initial staging, restaging and diagnosis of recurrence of rectal carcinoma is safe.

MSAC finds MRI for the initial staging of rectal cancer to be effective because MRI is able to define the circumferential resection margin of rectal carcinoma, which is highly predictive of the rate of local recurrence.

MSAC finds that MRI for the initial staging of rectal carcinoma is likely to be cost-effective.

MSAC recommends that public funding is supported for the initial staging of rectal carcinoma by MRI.

There is insufficient evidence to support public funding for the restaging and diagnosis of recurrence of rectal carcinoma by MRI.

The Minister for Health and Ageing noted this advice on 28 August, 2008.

Methods

Medline, Embase, The Cochrane Library, and several other biomedical databases, HTA and other internet sites were searched (1995- June 2007). Specific journals were handsearched and reference lists pearled. Studies were included in the review using pre-determined PICO selection criteria and reasons for exclusion were documented. Study quality was appraised, data extracted in a standardised manner, and findings synthesised narratively.

Prepared by Adelaide Health Technology Assessment (AHTA) on behalf of the MSAC