Intravascular extraction of chronically implanted permanent transvenous pacing leads

August 1999

MSAC application 1010

Final assessment report

ISBN <insert ISBN number from public affairs>

First printed October 1999

Electronic copies of the report can be obtained from the Medicare Service Advisory Committee's Internet site at:

http://www.health.gov.au/haf/msac

Hard copies of the report can be obtained from:

The Secretary
Medicare Services Advisory Committee
Department of Health and Aged Care
Mail Drop 107
GPO Box 9848
Canberra ACT 2601

Enquiries about the content of the report should be directed to the above address.

The Medicare Services Advisory Committee is an independent committee which has been established to provide advice to the Commonwealth Minister for Health and Aged Care on the strength of evidence available on new medical technologies and procedures in terms of their safety, effectiveness and cost-effectiveness. This advice will help to inform Government decisions about which new medical services should attract funding under Medicare.

This report was prepared by the Medicare Services Advisory Committee (MSAC). The report was endorsed by the Commonwealth Minister for Health and Aged Care on 8 September 1999.

MSAC recommendations do not necessarily reflect the views of all individuals who participated in the MSAC evaluation.

Contents

Tables

Executive summary

The procedure

Intravascular extraction of chronically implanted permanent transvenous pacing leads is a procedure designed for the removal of leads which have been implanted for more than three months and have become entrapped by fibrous tissue attachments to the vein and heart wall. The technique involves the use of specialised surgical tools (locking stylets and extractions sheaths) inserted either via the venous route used to implant the leads or via another venous route. These tools allow leads to be extracted by the application of traction to the tip of the lead and countertraction to the heart wall, and the freeing of fibrous tissue attachments.

Medicare Services Advisory Committee – role and approach

The Medicare Services Advisory Committee (MSAC) is a key element of a measure taken by the Commonwealth Government to strengthen the role of evidence in health financing decisions in Australia. MSAC advises the Minister for Health and Aged Care on the evidence relating to the safety, effectiveness and cost-effectiveness of new medical technologies and procedures, and under what circumstances public funding should be supported.

A rigorous assessment of the available evidence is thus the basis of decision making when funding is sought under Medicare. The medical literature available on the technology is searched and the evidence is assessed and classified according to the National Health and Medical Research Council (NHMRC) four-point hierarchy of evidence. A supporting committee with expertise in this area then evaluates the evidence and provides advice to MSAC.

MSAC's assessment of the procedure

For this procedure, all studies identified were uncontrolled case series, which is level IV evidence. There were no studies comparing the technique with open heart surgery, and given the ethical considerations, a clinical trial of this type is unlikely to be conducted.

Clinical need

Pacing lead extraction is necessary in the clinical management of life-threatening complications of pacemaker implantation eg septicaemia or cardiac arrhythmia. This procedure provides a minimally invasive alternative to open heart surgery, where extraction by simple traction is difficult or hazardous due to entrapment of the lead by fibrous tissue attachments to the vein and heart wall. This usually occurs with leads which have been implanted for more than six months but may occur after three months.

Safety

A review of the literature indicates that complications related to the procedure are uncommon. However, death and life-threatening complications have been reported

(haemopericardium, cardiac tamponade, haemothorax, pulmonary embolism, migrating lead fragment). The comparative safety profile with open heart surgery is not available.

Because of the risks present when using this procedure, it should be performed by trained cardiologists or cardiothoracic surgeons in cardiac catheter laboratories or operating theatres equipped for cardiac surgery, with cardiovascular surgical backup on standby.

Effectiveness

It appears that intravascular extraction of chronically implanted transvenous pacing leads using surgical tools and countertraction is an effective procedure with minimal invasiveness. The complete lead removal rate achieved in the studies reviewed in this report was 78-97 per cent, with about 4-7 per cent of patients failing the procedure, and no more than 5 per cent of patients (70% of those who have failed) requiring open surgery.

Cost effectiveness

Due to insufficient data on comparative efficacy/effectiveness and adverse events, an economic analysis was not conducted.

Recommendations

MSAC noted that the procedure is being performed by a small number of cardiologists and that it can be claimed under the Medicare Benefits Schedule(MBS). However, additional remuneration has been sought.

MSAC also noted that the available evidence indicates the extraction of chronically implanted permanent transvenous pacemaker leads using surgical tools and countertraction is an effective procedure which offers a minimally invasive and generally safe alternative to open heart surgery when performed by skilled operators with specialised training and experience. It is a much longer, more difficult and skilled procedure than extraction of leads not entrapped by fibrous tissue, which is performed by simple traction without the use of surgical tools. Currently, both procedures are remunerated at the same rate.

MSAC therefore recommended that, on the strength of the evidence pertaining to the extraction of chronically implanted permanent transvenous pacemaker leads:

- additional public funding should be supported for the extraction of chronically implanted permanent transvenous pacemaker leads which have been implanted more than three months and require use of surgical tools and countertraction for their removal; and
- the performance of the procedure should be restricted to cardiologists and cardiothoracic surgeons who have undergone specialist training in the procedure and are willing to participate in an audit program administered by the Cardiac Society of Australia and New Zealand, in order to achieve accreditation as a specialist provider of the procedure.

Introduction

The Medicare Services Advisory Committee (MSAC) has reviewed the use of intravascular extraction of chronically implanted permanent transvenous pacing leads.

MSAC evaluates new health technologies and procedures for which funding is sought under the Medicare Benefits Schedule (MBS) in terms of their safety, effectiveness and cost-effectiveness, while taking into account other issues such as access and equity. MSAC adopts an evidence-based approach to its assessments, based on reviews of the scientific literature and other information sources, including clinical expertise.

MSAC's terms of reference and membership are at Appendix A. MSAC is a multidisciplinary expert body, comprising members drawn from such disciplines as diagnostic imaging, pathology, surgery, internal medicine and general practice, clinical epidemiology, health economics and health administration.

This report summarises the assessment of current evidence for intravascular extraction of chronically implanted permanent transvenous pacing leads using the surgical tools described and countertraction.

Background

Intravascular extraction of chronically implanted permanent transvenous pacing leads

The procedure

Pacemaker leads are generally implanted via a superior approach using the subclavian, cephalic or jugular vein and are fixed to either the atrial wall when using the VVI pulse generator or the atrial and ventricular walls when using the DDD pulse generator. Chronically implanted pacing leads which have been in situ for more than three months, can become entrapped by fibrous and scar tissue along the wall of the veins and at the fixation site in the heart. The leads also may become fragile. Therefore, freeing and removing the leads intravascularly when clinically indicated becomes difficult.

The details of the approach used may vary depending on the patient's circumstances and the operator's preference. In general, the procedure employs an intravascular countertraction technique using a set of surgical tools which usually includes a locking stylet, snare and laser sheath. The locking stylet has a filament of fine wire at its tip which enables it to be trapped at the distal end of the inner core of the pacing lead. Most frequently, leads are extracted via the implant vein under fluoroscopic guidance, or via the inferior approach (femoral vein) if the lead is inaccessible from the superior approach or is broken. The locking stylet is advanced through the coil lumen of the pacing lead and secured at the most distal aspect of it. Then a set of two dilator sheaths is advanced over the lead. The inner and outer sheaths are manipulated to disrupt fibrous attachments and scar tissue along the venous path to free the lead. Once this has been achieved, the inner sheath is retracted and the outer sheath is carefully advanced to within 1cm of the myocardium, and countertraction applied against the myocardial wall. The locking stylet is then pulled back by applying gentle constant traction to the tip of the lead until the lead and sheath have been extracted.

Extraction may be attempted more than once or from a different approach if initially unsuccessful. A wire guide may be placed through the sheath prior to extraction to allow a replacement of pacing lead if indicated.

The procedure requires general anaesthesia and full preparation for temporary pacing, emergency thoracotomy and blood transfusion. The estimated operating time is about 3-5 hours. The patients are generally discharged from the coronary care unit the following day.

Intended purpose

The procedure is proposed for the extraction of a permanent transvenous pacing lead implanted for more than 3 months where extraction by simple traction is difficult or hazardous due to entrapment of the lead by fibrous attachments.

The need for lead extraction is often associated with the following clinical situations:

- **Mandatory conditions:** pacemaker hardware-related septicaemia and/or endocarditis, migration of severed transvenous leads causing cardiac, especially ventricular, arrythmias;
- **Necessary conditions:** pocket infection where conservative management has failed; abandonment of leads which is likely to create potential for thrombosis; and
- **Discretionary conditions:** abandonment of a site due to chronic pain or malignancy.

Clinical need/burden of disease

Abandonment of inactive chronically implanted pacing leads has proved to have little long-term risk and has been adopted frequently. However, if there are indications that the lead is associated with a life-threatening condition, eg septicaemia and cardiac arrhythmia, then the lead has to be extracted.

It is not known how many patients currently have pacemakers implanted in Australia, and therefore it is difficult to estimate the likely population that might undergo the lead extraction procedure. It is estimated by the applicant that between 20 to 30 patients per year in Australia would require extraction of chronically implanted leads.

Only a small number of specialists (one in most of the major capital cities) currently perform extractions of chronically implanted transvenous pacing leads in Australia.

Existing procedures

A surgical approach, ie open heart surgery, was commonly required to extract chronically implanted pacing leads prior to the introduction of intravascular countertraction techniques. Open heart surgery is now reserved for problem cases only, where the superior and inferior intravascular extraction approaches have failed.

Comparator

Open heart surgery is the only appropriate comparator. However, there were no studies found in the literature comparing the technique with open heart surgery and, given the ethical considerations, a clinical trial of this type is unlikely to be conducted.

Marketing status of the device

The locking stylets, extraction sheaths and other general surgical tools and instruments used in the procedure are listed on the Australian Register of Therapeutic Goods.

Current reimbursement arrangement

Extraction of pacemaker leads is currently covered under MBS item number 38259, which includes both the extraction of leads requiring simple traction alone and the extraction of chronically implanted leads requiring surgical tools and countertraction described here. Additional remuneration has been sought for the latter procedure in recognition of the fact that it carries significant risk and is a much longer, more difficult and skilled procedure requiring specialised training and experience, and special tools.

Approach to assessment

Review of literature

The medical literature was searched to identify relevant studies and reviews for the period between 1966 and June 1999. The search was conducted using the Medline and HealthSTAR databases.

The search terms used were 'lead extraction', 'pacemaker' and 'pacing electrode'. Articles selected for inclusion were clinical studies on the extraction of chronically implanted pacing leads involving the use of locking stylets and/or extraction sheaths and countertraction. Articles excluded were general reviews of the technique.

Of the thirteen publications retrieved, 8 papers were selected for consideration following application of the inclusion and exclusion criteria described above.

The evidence presented in the selected studies was assessed and classified according to the National Health and Medical Research Council (NHMRC) revised hierarchy of evidence shown in Table 1. All of the studies were uncontrolled case series which constitute level IV evidence.

Table 1 Designation of levels of evidence

I	Evidence obtained from a systematic review of all relevant randomised controlled trials.
II	Evidence obtained from at least one properly designed randomised controlled trial.
III–1	Evidence obtained from well-designed pseudo-randomised controlled trials (alternate allocation or some other method).
III–2	Evidence obtained from comparative studies with concurrent controls and allocation not randomised (cohort studies), case-control studies or interrupted time series with control group.
III–3	Evidence obtained from comparative studies with historical control, two and more single arm studies or interrupted time series without a parallel control group.
IV	Evidence obtained from case series, either post-test or pre-test and post-test.

Source: NHMRC[1]

Expert advice

A supporting committee with expertise in cardiology and vascular surgery was established to evaluate the evidence and provide advice to MSAC from a clinical perspective. In selecting members for supporting committees, MSAC's practice is to approach the appropriate medical colleges, specialist societies and associations for nominees. Membership of the supporting committee is provided at Appendix B.

Results of assessment

Is it safe?

It appears that complications when using this procedure are uncommon. However, death and life threatening events , including haemopericardium, cardiac tamponade, haemothorax, pulmonary embolism, and migrating lead fragments, have been reported in recent studies. Compared with open heart surgery, intravascular extraction avoids the peri-operative morbidity, lengthy stay in hospital and complications normally associated with the open operation.

Adverse events associated with the procedure are summarised in Table 2.

Table 2 Adverse Events

Author	Outcomes
Colavita et al 1993[2]	no significant complications.
	1/56 had transient hypotension; 2/56 had transient arm edema.
Alt et al 1996[3]	no significant complications.
	a lost lead tip migrated to hepatic vein in 1/105 patients, but no complications reported at 1.5 yrs.
Smith et al 1994[4]	fatal/near fatal complications: 2.5%, including death: 0.6% (8/1299)
	(haemopericardium/tamponade 1.2%, haemothorax 0.5%,
	pulmonary embolism 0.2%, migrating lead fragment 0.3%)
Daoud et al 1996[5]	1/85 had leukocytosis,; 1/85 had embolus
Manolis et al 1998[6]	no complications.
Kennergren 1998[7]	no complications.
Friedman et al 1996[8]	1/13 had late wound dehiscence.
Lloyd et al 1996[9]	n/a

Is it effective?

Based on the evidence presented in this assessment, the proposed method for intravascular pacing lead extraction, using locking stylet and electrocautery or laser sheaths, appears to be an effective procedure with minimal invasiveness. In the studies reviewed, the complete lead removal rate was 78- 97 per cent, with about 4-7 per cent of patients failing the procedure, and no more than 5 per cent (70% of those who have failed) of patients requiring open surgery.

Outcome measures used were as follows:

- **Complete removal:** The entire pacing lead including the tip was extracted via the superior and/or inferior approach;
- **Partial removal:** Pacing lead was extracted via the superior and/or inferior approach, but the tip (sometimes with a portion of coil and/or insulation attached) was left embedded in myocardial scar tissue; and

- **Failed (may require open surgery):** Pacing lead extraction attempts failed, open heart surgery may be required. As discussed Section 5.1, not all patients who have failed the procedure would require open surgery.

A summary of results reported in each study can be found in Table 3.

There is insufficient data to allow a comparison of the intravascular approach with open heart surgery in terms of clinical efficacy, including complete lead removal. However according to the applicant it may be more effective than open heart surgery which is not always able to disrupt intravascular attachments in the access vein to free the lead. A literature search of Medline (1966-1999) did not retrieve sufficient evidence to demonstrate the efficacy/effectiveness of open heart surgery in the extraction of chronically implanted leads.

What are the economic considerations?

Due to insufficient data on comparative efficacy/effectiveness and adverse events, an economic analysis was not conducted.

Table 3 Evidence Summary

Level of Evidence	Author	Subjects	Approach and Duration	Outcomes
IV	Colavita et al 1993[2]	n[a]=86 (ventricular: 54; atrial:32) mean age: 63±15 yrs median implant time: 49.5mon (1-264mon)	approach subclavian: 76 cephalic: 7 internal jugular: 1 and/or femoral: 2 duration: 20-260min	complete removal 97.6% partial removal 2.4% failed 0 %
IV	Alt et al 1996[3]	n=150 (ventricular: 110; atrial:40) mean age: 65 yrs (26-92) median implant time: 55.2mon (3-168mon)	approach superior: 133 and/or femoral: 17 duration: n/a	complete removal 81% partial removal 12% failed 7% (7/10 pts underwent surgery)
IV	Smith et al 1994[4]	n=2,195 (ventricular:1470; atrial:725) mean age: 64±17 yrs (8-97) median implant time: 45.6mon (5days-288mon)	approach superior: 1800 and/or femoral: 395 second attempt: 189 duration (n=195) mean: 84 - 160min	complete removal 86.6% partial removal 7.5% failed 5.7%
IV	Daoud et al 1996[5]	n=18 (j wire) mean age: 67±15 yrs mean implant time: 20 ± 11mon	approach superior: 10 and/or femoral: 4 duration mean: 64 - 144min	complete removal 78% (14/18) partial removal n/a failed n/a 4 pts underwent extraction at another centre, no results provided
IV	Manolis et al 1998[6]	n=25 (ventricular: 19; atrial:6) mean age: 70±9 yrs mean implant time: 46.8 ± 45.6mon	approach superior: 21 and/or femoral: 4 duration n/a	complete removal 96% partial removal n/a failed 4%
IV	Kennergren 1998[7]	n=50 (ventricular: 19; atrial:6) mean age: 65.1 yrs (32-94) mean implant time: 47.7mon (10.5-351.7mon)	approach superior: 21 and/or femoral: 4 duration mean: 10min (1-50min)	complete removal 96% partial removal n/a failed 4%
IV	Friedman et al 1996[8]	n=18 median age: 13 yrs (9-26) mean implant time: 54±24mon (19-94mon)	approach superior: 18 and/or femoral: 0 duration mean: n/a	complete removal 94% partial removal 0.6% failed 0
IV	Lloyd et al 1996[9]	n=96 mean age: 65.7±1.6 yrs mean implant time: 31±1.4mon	approach superior: 64 and/or femoral: 32 duration mean: n/a	complete removal 98% partial removal n/a failed 0

[a]n = number of leads

Conclusions

Safety

The evidence available indicates that extraction of chronically implanted pacemaker leads using surgical tools and countertraction has a low incidence of complications, but a significant number of these may be fatal or near–fatal due to serious myocardial or vascular injury or lead fracture.

However, it is minimally invasive and the only alternative to open heart surgery for the removal of chronically-implanted leads entrapped by fibrous tissue. It avoids peri-operative morbidity and the risk of complications normally associated with thoracotomy.

Effectiveness

The evidence available indicates that this is an effective procedure with the advantage of providing easy access to free the lead from fibrous attachments in the access vein, which may not always be achievable via open heart surgery.

Cost-effectiveness

Due to insufficient data on comparative efficacy/effectiveness and adverse events, an economic analysis was not conducted.

Recommendations

MSAC noted that the procedure is being performed by a small number of cardiologists and that it can be claimed under the MBS. However, additional remuneration has been sought.

MSAC also noted that the available evidence indicates the extraction of chronically implanted permanent transvenous pacemaker leads using surgical tools and countertraction is an effective procedure which offers a minimally invasive and generally safe alternative to open heart surgery when performed by skilled operators with specialised training and experience. It is a much longer, more difficult and skilled procedure than extraction of leads not entrapped by fibrous tissue, which is performed by simple traction without the use of surgical tools. Currently, both procedures are remunerated at the same rate.

MSAC therefore recommended that, on the strength of the evidence pertaining to the extraction of chronically implanted permanent transvenous pacemaker leads:

- additional public funding should be supported for the extraction of chronically implanted permanent transvenous pacemaker leads which have been implanted more than three months and require use of surgical tools and countertraction for their removal; and
- the performance of the procedure should be restricted to cardiologists and cardiothoracic surgeons who have undergone specialist training in the procedure and are willing to participate in an audit program administered by the Cardiac Society of Australia and New Zealand, in order to achieve accreditation as a specialist provider of the procedure.

— The Minister for Health and Aged Care accepted this recommendation on 8 September 1999 —

Appendix A MSAC terms of reference and membership

The terms of reference of MSAC are to advise the Commonwealth Minister for Health and Aged Care on:

- the strength of evidence pertaining to new and emerging medical technologies and procedures in relation to their safety, effectiveness and cost-effectiveness and under what circumstances public funding should be supported;
- which new medical technologies and procedures should be funded on an interim basis to allow data to be assembled to determine their safety, effectiveness and cost-effectiveness; and
- references related either to new and/or existing medical technologies and procedures.

The membership of MSAC comprises a mix of clinical expertise covering pathology, nuclear medicine, surgery, specialist medicine and general practice, plus clinical epidemiology and clinical trials, health economics, consumers, and health administration and planning:

Member	Expertise
Professor David Weedon (Chair)	pathology
Ms Hilda Bastian	consumer health issues
Dr Ross Blair	vascular surgery (New Zealand)
Mr Stephen Blamey	general surgery
Dr Paul Hemming	general practice
Dr Terri Jackson	health economics
Professor Brendon Kearney	health administration and planning
Mr Alan Keith	Assistant Secretary, Diagnostics and Technology Branch, Commonwealth Department of Health and Aged Care (from 3 May 1999)
Dr Richard King	gastroenterology
Dr Michael Kitchener	nuclear medicine
Professor Peter Phelan	paediatrics
Dr David Robinson	plastic surgery
Ms Penny Rogers	Assistant Secretary, Diagnostics and Technology Branch, Commonwealth Department of Health and Aged Care (until 3 May 1999)
Associate Professor John Simes	clinical epidemiology and clinical trials
Dr Bryant Stokes	neurological surgery, representing the Australian Health Ministers' Advisory Council (from 1 January 1999)
Dr Doris Zonta	population health, representing the Australian Health Ministers' Advisory Council (until 31 December 1998)

Appendix B Supporting committee

Supporting committee for MSAC application 1010 – Intravascular extraction of chronically implanted permanent transvenous pacing leads

Dr Richard King (Chair) MBBS, FRACP Consultant Gastroenterologist, Head of General & Emergency Medicine, Southern Health Care Network	member of MSAC
Dr Ross Blair MBChB, RACS Thoracic and Vascular Surgeon, Director of Vascular Surgery, Waikato Hospital, New Zealand.	member of MSAC
Dr Michael Davis MB BS, FRACP Cardiologist, Head of Department of Cardiology, Royal Perth Hospital	nominated by the Cardiac Society of Australia and New Zealand

Abbreviations

MSAC	Medicare Services Advisory Committee
MBS	Medicare Benefits Schedule
NHMRC	National Health and Medical Research Council

References

1 National Health and Medical Research Council, A guide to the development, implementation and evaluation of clinical practice guidelines. Canberra: NHMRC, 1999.

2 Colavita PG, Zimmern SH et al. Intravascular extraction of chronic pacemaker leads: efficacy and follow-up. Pacing & Clinical Electrophysiology 1993; 16:2333-36.

3 Alt E, Neuzner J et al. Three-year experience with a stylet for lead extraction: a multicenter study. Pacing & Clinical Electrophysiology 1996; 19:18-25.

4 Smith HJ, Fearnot NE et al. Five-years experience with intravascular lead extraction. Pacing & Clinical Electrophysiology 1994; 17:2016-20.

5 Daoud EG, Kou W et al. Evaluation and extraction of the Accufix atrial J lead. American Heart Journal 1996; 131:266-9.

6 Manolis AS, Maounis TN et al. Successful percutaneous extraction of pacemaker leads with a novel (VascoExtor) pacing lead removal system. American Journal of Cardiology 1998; 81(7):935-8.

7 Kennergren C. First European experience using excimer laser for the extraction of permanent pacemaker leads. Pacing & Clinical Electrophysiology 1998; 21(1 Part II): 268-70.

8 Friedman RA, Van Zandt H et al. Lead extraction in young patients with and without congenital heart disease using the subclavian approach. Pacing & Clinical Electrophysiology 1996; 19(5):778-83.

9 Lloyd MA, Hayes DL et al. Extraction of the Telectronics Accufix 330-801 atrial lead: the Mayo Clinic experience. Mayo Clinic Proceedings 1996; 71(3):230-4.