

***Endoluminal
grafting for
abdominal aortic
aneurysm***

May 1999

MSAC application 1006

Final assessment report

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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 11 May 1999.

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

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Executive summary

The procedure

The technique of endoluminal repair of abdominal aortic aneurysm involves inserting a graft/stent/prosthesis using a catheter, via a peripheral artery (usually the femoral artery), to the site of the aneurysm. The graft is expanded and secured in place to restore a more normal blood flow channel through the aorta. Simultaneous imaging, usually by angiography, is essential for accurate placement and deployment of the prosthesis. These grafts are designed to provide an alternative conduit for blood flow, to exclude completely the aneurysm from the blood stream and to eliminate or greatly reduce its potential for rupture.

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.

Assessment of endoluminal grafting of aneurysms

For endoluminal grafting of aneurysms, most of the studies identified did not have control groups, and were quasi-experimental in design. The results of a systematic literature search undertaken at the Centre for Clinical Effectiveness at Monash Medical Centre were also incorporated in the assessment. Amongst the studies identified in the Monash report, two were protocols for well-designed controlled trials and three were studies that contained comparison groups. The results of these trials are expected in 1999–2000.

Clinical need

Abdominal aortic aneurysms are usually asymptomatic and are often only discovered as a result of investigation of other medical problems. The risk of abdominal aortic aneurysm rupture increases with the size of the aneurysm, and the related mortality is about 50%.

In 1996 (the latest year when cause of death data are available from the Australian Bureau of Statistics), there were 482 male and 214 female deaths from abdominal aortic aneurysm with rupture in Australia. The aortic wall deteriorates with age, and as the population continues to age, this may become a more common problem. Studies suggest that the incidence of abdominal aortic aneurysm increases in men rapidly after 55 years of age and peaks at age 80. Among women, the incidence increases rapidly after 70 years of age and peaks at age 90.

For patients with abdominal aortic aneurysms who are considered medically unfit for operation, the only alternative to endoluminal abdominal aortic aneurysm is best supportive care.

Safety

While the endoluminal grafting procedure appears effective in the short term (level IV evidence), there are insufficient data available to demonstrate its long-term safety. The long-term safety of the graft devices used is also not established.

Effectiveness

The effectiveness and durability of the repair have not been established. There are limited short-term studies available (level IV evidence), but long-term outcomes of the procedure are not known.

Cost effectiveness

No rigorous Australian cost comparisons of the endoluminal repair procedure with the comparator, the open repair procedure, are available.

Recommendations

MSAC noted that endoluminal grafting of abdominal aortic aneurysm is already claimable under the Medicare Benefits Schedule (MBS), and that for some patients, no other treatment is possible.

MSAC therefore recommended that:

- the current MBS items for abdominal aortic aneurysm be restricted to open aortic repair; but endoluminal repair continue to receive public funding under alternative arrangements;
- as the long-term outcomes of the procedure are not clear, an informed consent protocol must be formulated and must be provided to each prospective patient;
- MSAC explores the issue of data collection on this procedure with stakeholders, with a view to developing a collaborative partnership in obtaining the data required; and
- a further review of the procedure be undertaken when additional Australian and/or overseas data become available.

Introduction

The Medicare Services Advisory Committee (MSAC) has assessed endoluminal grafting for abdominal aortic aneurysm, which is a procedure for the repair of abdominal aortic aneurysms. MSAC evaluates new health technologies and procedures for which funding is sought under the Medicare Benefits Scheme in terms of their safety, effectiveness and cost-effectiveness, taking into account other issues such as access and equity. MSAC uses an evidence-based approach for 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 endoluminal grafting for abdominal aortic aneurysm.

Background

Ageing and certain diseases can cause degeneration and weakening of the aorta (the main artery to the lower body). In response to this degeneration, over a variable period from months to years, the aorta in the abdomen may balloon or dilate (aortic aneurysm) and eventually rupture. It is generally accepted that there is a significant risk of rupture when the aortic aneurysm diameter exceeds 5 cm. Untreated rupture of an abdominal aortic aneurysm is usually fatal and death is rapid. Patients who reach hospital may be treated by emergency surgery, but operative mortality is high.

When the risk of rupture is judged to exceed the risk of operating, elective surgery is undertaken to replace the diseased part of the aorta by a synthetic fabric tube graft (prosthesis). The operation involves a large abdominal incision and has significant risk of complications, particularly as patients with aortic aneurysm often have coexistent cardiac, respiratory or renal diseases. In such situations conventional operative treatment may be too dangerous. In some patients, the operation may be difficult or impossible because of previous complex abdominal operations or other conditions.

Endoluminal grafting for abdominal aortic aneurysm

How it works

Recent developments in treatment have enabled the placement of a graft or prosthesis from within the lumen of the aorta. The technique of endoluminal repair of abdominal aortic aneurysm involves inserting a graft/stent/prosthesis using a catheter, via a peripheral artery (usually the femoral artery), to the site of the aneurysm. The graft is expanded and secured in place to restore a more normal blood flow channel through the aorta. Simultaneous imaging, usually by angiography, is essential for accurate placement and deployment of the prosthesis. The grafts are designed to provide an alternative conduit for blood flow, to exclude completely the aneurysm from the blood stream and to eliminate or greatly reduce its potential for rupture. Insertion of an endovascular stent protects the aneurysm sac (dilated lumen) from abrupt pressure rises responsible for further dilation of the aneurysm, without compromising perfusion of the distal bed. Several models of endovascular stents are being investigated in clinical trials.¹ A diagram of categories of grafts for endoluminal repair is shown at Figure 1.

Until recently, the absence of any commercially available device resulted in the repair being performed with a variety of improvised devices. Most consisted of tubular or bifurcated graft material fixed in position with a metallic expanding skeleton to anchor the graft material to nondilated arterial wall above and below the aneurysm. Some prostheses are 'tailor-made' for the individual patient but modular systems are being developed and are now either available commercially or undergoing commercial evaluation.² In contrast to open repair, where the vascular surgeon can adapt both graft and anastomoses to the aneurysm morphology, endoluminal repair requires the graft device to be of the correct diameter, length and configuration before deployment. Most centres use contrast-enhanced spiral computed tomography (CT) to assess the specific aneurysm characteristics to plan required prosthesis specifications. Future developments in preoperative imaging may include the application of magnetic resonance imaging (MRI).

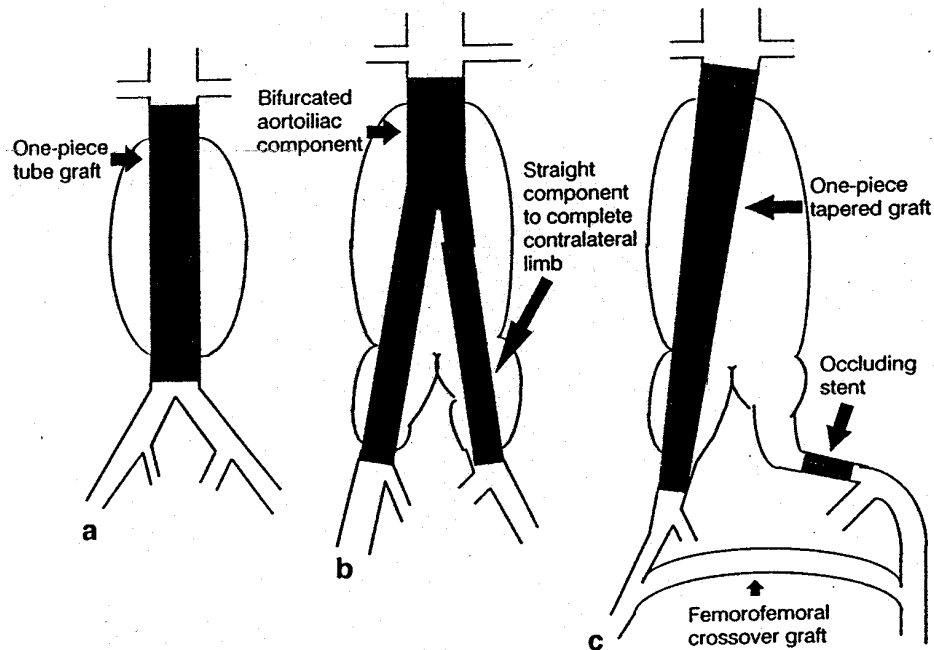


Figure 1 The three main categories of grafts for endoluminal repair of abdominal aortic aneurysm: (a) aorto-aortic tube graft; (b) aorto-bi-iliac graft; (c) aorto-uni-iliac graft with occlusion of contralateral iliac artery and femorofemoral crossover graft.²

Intended purpose

Initially, the endoluminal repair procedure for abdominal aortic aneurysm was designed for use in patients with coexistent morbidities that preclude open surgical repair. Cardiac, respiratory and renal diseases are common in patients with aneurysm. Multiple previous abdominal operations or the presence of enteric or urinary stomas create a 'hostile' abdomen making conventional operation risky, difficult or impossible. The use of endoluminal techniques for the exclusion of abdominal aortic aneurysm has now been proposed for patients without comorbid conditions and in those with small asymptomatic aneurysms.³ Endoluminal grafting may be considered in patients with nonruptured aneurysms greater than 5 cm in diameter, or patients who are not suitable for conventional open surgery on medical grounds. The aneurysm to be repaired should not involve the renal arteries. May et al notes the requirement for a proximal neck of at least 1.5 cm in length between the renal arteries and the aneurysm.⁴

Potential advantages of an endovascular approach to abdominal aortic aneurysm repair are:

1. reduced time under general anaesthesia;
2. avoidance of arterial cross-clamping, as decreased blood flow to vital organs and the lower extremities is either eliminated or reduced in duration;
3. elimination of the pain and trauma of major abdominal surgery, which enables a shorter recovery time, allows patients to resume normal activities more rapidly and may reduce the postoperative respiratory problems often associated with conventional surgery;
4. reduced hospital length of stay;
5. reduced length of stay in an intensive care unit (ICU); and
6. reduced blood loss.

Potential disadvantages are:

1. development of endoleaks, whereby the lumen of the aneurysm outside the endoprosthesis continues to be perfused because the graft does not seal completely or there is backfilling of the aneurysm from other small vessels arising from the wall of the aneurysm (typically lumbar arteries or the inferior mesenteric artery);
2. dislodgment of solid debris from within the aneurysm (embolus) during graft manipulation causing flow problems in more peripheral arteries; and
3. conversion to open operation in patients deemed unfit for open surgical procedures due to failure or complication during endoluminal procedures.

The mean duration of the procedure is reported to vary between 88 and 193 minutes, with an overall range of 25–480 minutes. With increased experience in endoluminal techniques and improved devices and delivery systems, operating times are expected to decrease significantly.²

Several studies have noted that, with experience, the endoluminal procedure reduces the length of hospital stay by about 50% compared to open repair. One study reported the mean hospital stay following successful endoluminal repair to range from 3 to 12 days with up to 72% of patients discharged within 3 days of surgery.²

May et al reported a mean stay of 0.8 days for admission to an ICU for patients undergoing endoluminal repair, compared with a mean stay of 2.1 days in ICU for patients undergoing open repair.⁵ No patients undergoing endoluminal repair required ventilation. It should be noted that hospital department policy required patients undergoing open repair to go routinely to an ICU.

The open repair procedure does not require any special follow-up of patients. Patients undergoing endoluminal repair, however, need regular postoperative CT scans to ascertain that no late endoleaks have occurred. Late endoleaks have been reported up to 3 years after the initial procedure⁵ and the prognosis is poor for such patients⁶.

Clinical need/burden of disease

Abdominal aortic aneurysms are usually asymptomatic and are often only discovered as a result of investigation of other medical problems; for example a CT scan for prostate cancer.⁷ The risk of abdominal aortic aneurysm rupture increases with the size of the aneurysm, and the related mortality remains about 50%.² Abdominal aortic aneurysms greater than 5 cm in diameter have been associated with annual rupture rates of 4.1–19%.⁸

In 1996 (the latest year available from the Australian Bureau of Statistics causes of death data) there were 482 male and 214 female deaths from abdominal aortic aneurysm with rupture (International Classification of Diseases code 441.3) in Australia. Smoking, high blood pressure and a family history of abdominal aortic aneurysm are associated with an increased risk of development of an abdominal aortic aneurysm.

The aortic wall deteriorates with age and as the population continues to age this may become a more common problem. Studies suggest that in men the incidence of abdominal aortic aneurysm increases rapidly after 55 years of age and peaks at age 80 (approximately 6%

incidence rate). Among women, the incidence increases rapidly after 70 years of age and peaks at age 90 (approximately 4.5% incidence rate).⁷

The proportion of patients with abdominal aortic aneurysm suitable for endoluminal abdominal aortic aneurysm repair is currently quoted to be 30–50%.² This figure may be increased by treating smaller aneurysms that have morphology more suited to successful endoluminal repair; however there is no justification for this approach until the results of endoluminal surgery are improved significantly.²

Table 1 shows the number of abdominal aortic resection and replacement procedures performed in Australia in 1995–96 and 1996–97⁹ for the *International Classification of Diseases, Clinical Modification, 9th Revision* (ICD-9-CM) procedure code 3844 (resection of vessel with replacement—aorta, abdominal).¹⁰ The information includes public and private hospitals combined.

It should be noted that the ICD-9-CM code 3844 does not distinguish between open and endoluminal repair but includes both types of procedure together. With the adoption of the *ICD, Clinical Modification, 10th Revision* (ICD-10-CM), endoluminal repair of aneurysm was assigned a separate procedure code (ICD-10-CM 90228-00).¹¹ From 1 July 1998, Victoria, New South Wales, the Northern Territory and the Australian Capital Territory have been collecting patient data using ICD-10-CM procedure codes; the remaining States intend to use ICD-10-CM procedure codes from 1 July 1999. No data are currently available on ICD-10-CM procedure code 90228-00.

Table 1 Procedures performed for resection and replacement of abdominal aorta (ICD-9-CM code 3844)

Year	Number of procedures
1995–96	2294
1996–97	2587

Source: Health and Aged Care National Hospital Morbidity (Casemix) Database.⁹

These numbers include both where the procedure was listed as the main procedure performed and where it was listed as one of the procedures performed (ie total numbers recorded).

Existing procedures

For patients with abdominal aortic aneurysms who are medically fit for operation, the traditional treatment is conventional open surgery in which a graft is inserted to replace the dilated segment of the artery. If patients are considered medically unfit for operation, best supportive care is given.

During open surgical repair an incision is made in the abdomen and the diseased aorta is exposed. The aorta is visually examined to determine the proper size and configuration of the synthetic graft (usually Dacron polyester) that will be used to replace the diseased vessel. If the iliac arteries are involved or if the amount of healthy aorta distal to the aneurysm is insufficient, then a bifurcated graft is used. The aorta (or the aorta and iliacs) is cross-clamped proximal and distal to the aneurysm and the diseased section is replaced by a prosthetic graft that is attached to non-aneurysmal artery proximally and distally with a suture anastomosis.

Although the risks of surgery are considered to be less than those associated with the rupture of a large aneurysm, the surgical risks remain significant. In open repair, the mortality rate is approximately 5% and the morbidity rate 25–40%.² Complications are commonly associated with previous comorbidities, the use of general anaesthesia and the duration of cross-clamp time. Efforts continue to find less invasive procedures to reduce the associated expense, complications and disability among elderly patients with comorbidities.¹²

Comparator

For medically fit patients, the appropriate comparator for endoluminal abdominal aortic aneurysm repair is the open aortic repair procedure.

For patients who are considered unsuitable for open abdominal aortic aneurysm repair, the appropriate comparator for endoluminal abdominal aortic aneurysm repair is best supportive care.

Marketing status

The Therapeutic Goods Administration (TGA) has confirmed ‘listing status’ for several stents on the Australian Register of Therapeutic Goods (see Table 2).

Table 2 Stents with TGA listing status^a on the Australian Register of Therapeutic Goods

Manufacturer	Device	Configuration
Boston Scientific	Vanguard	Bifurcated/tubular
Medtronic	AneuRx	Bifurcated/tubular
World Medical	Talent	Bifurcated/tubular
Cook	H & L-B	Bifurcated
Guidant (listed as Getz Brothers not Guidant)	Endovascular Technologies Endograft (EVT)	Bifurcated/tubular and aortoiliac

^a Marketing approval without clinical evaluation.

Current reimbursement arrangements

Currently both open and endoluminal grafting/repair of abdominal aortic aneurysms are covered under the existing Medicare Benefit Schedule items 33103, 33115, 33118, 33121, 33124 and 33127 as no surgical approach is specified for the item. However, it should be noted that while these items were developed for the open aortic aneurysm repair procedure; the cost structure for open surgical repair is different from that of the endoluminal approach.

Approach to assessment

In undertaking its assessment MSAC reviewed the literature available on endoluminal grafting of abdominal aortic aneurysms and convened a supporting committee to evaluate the evidence of the procedure and provide expert advice.

Review of literature

The medical literature was searched to identify relevant studies and reviews. Searches were via Medline, Biosis, EmBase and Pascal, the Cochrane Library (3/98) and the International Society for Technology Assessment in Health Care (ISTAHC) (edition 1) CDs, for the period of the commencement of each database until September 1998.

The following search terms were used:

Endoluminal or intravascular or endovascular; AND

Graft or stent or prosthesis or endograft; AND

(Abdomen or abdominal) + aneurysm; AND

Random or meta-analysis or randomised controlled trial or rct or double-blind or systematic review?

From this search 57 studies were identified, most of which were without control groups and quasi-experimental in design. 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 3.¹³

Table 3 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: NHMRC¹³

Anderson and Fennessy (Centre for Clinical Effectiveness at Monash Medical Centre) recently conducted a literature search and evaluation of the evidence of the effectiveness of endoluminal graft procedures for the treatment of abdominal aortic aneurysms.¹⁴ Their report evaluated the scientific literature up to June 1998 and identified more than 60 research studies, of which two were protocols for well-designed controlled trials commencing from late 1997 to early 1998, three were completed studies containing comparison groups, and two were economic studies.

The findings of the MASAC literature search and the Anderson and Fennessy literature search¹⁴ are presented in the results section of this assessment report.

It should be noted that, as this is a new procedure, teams performing these interventions are still on a 'learning curve'. Device modifications continue and patients have shown a preference for the less invasive surgery by withdrawing from some trials and enrolling in others if they have not been given their treatment of choice. Also, authors in different case-series studies use different selection criteria to recruit subjects for trials and different reporting methodologies; this creates difficulties in interpretation of the available literature. Comparison with historical or unmatched controls is therefore a necessary compromise.

Expert advice

A supporting committee with expertise in general surgery, vascular surgery, clinical effectiveness and epidemiology was convened to assess the evidence on the procedure. In selecting members for supporting committees, MSAC's practice is to approach the relevant colleges, associations or specialist societies for nominees. The supporting committee membership is shown at Appendix B.

Results of assessment

The number of controlled studies on the effectiveness and safety of endoluminal grafting of abdominal aortic aneurysm is small, with several limited short-term studies with only level IV evidence. Anderson and Fennessy found the interpretation of the available research to be hampered by 'methodological procedures, in particular concerning selection criteria, small subject numbers, nonstandardised reporting of results and the large number of different device types currently under investigation'.¹⁴ For these reasons, any conclusive view on the procedure is limited.

Further data are expected in 1999–2000 from at least three controlled trials (level III evidence) and from evaluation of data registries. A level III controlled trial commenced in early 1998 to compare the safety and efficacy of the Vanguard-Passager endoluminal device with open repair using a control group of equal surgical risk. This study is still recruiting patients and results are expected in mid-1999.¹⁵ The United Kingdom Department of Health commissioned a trial comparing endoluminal repair with open repair in low surgical risk patients and conservative management in high-risk patients to commence in 1998.¹⁶

A level III prospective, multicentre, concurrently controlled clinical trial of Medtronic AneuRx endovascular device and open surgical repair of abdominal aortic aneurysms in terms of acute and long-term effectiveness and safety commenced in 1998.¹⁷ The trial is nonrandomised and nonblind in design. Up to 20 centres in the United States are participating in this trial. Patient baseline characteristics in both treatment arms will be evaluated and compared. The main inclusion criterion is aneurysm size greater than 5 cm in diameter or 4–5 cm in diameter with increase in size by 0.5 cm in the preceding 6 months. Follow-up is scheduled for 1, 6 and 12 months after open abdominal aortic aneurysm repair and 1, 6 and 12 months, and annually for up to 5 years, after endovascular prosthesis procedure. Results from this study will be submitted to the United States Food and Drug Administration and should be available by mid-1999.

Prospective data registries have been developed recently in Britain (Registry of Endovascular Treatment of Aneurysms)¹⁸ and in Europe (EUROSTAR, which involves 19 European centres)¹⁹ to redress the lack of available comparative data on endoluminal repair, in particular on issues of procedural safety, device durability and long-term effect on the aneurysm.

A well-designed and randomised clinical trial with a large number of subjects and long-term follow-up is required before a definitive conclusion may be drawn regarding safety and effectiveness of endoluminal abdominal aortic aneurysm repair. However, according to May et al, a randomised trial may actually be impractical.⁵ It is becoming apparent that patients may withdraw from a randomised study if they fail to draw the less invasive procedure, because the two procedures are so different in terms of level of discomfort. However, concerns have been voiced about introducing 'minimally invasive' techniques before a rigorous prospective comparison has been made.²⁰

Is it safe?

The level of safety is currently supported by level IV evidence. The long-term outcome of endoluminal procedure is not known: the longest follow-up of any reported series has been 5 years.¹⁴

The literature evaluation by Anderson and Fennessy concluded that:

at least for patients with low surgical risk, endoluminal treatment for abdominal aortic aneurysm is relatively safe if aneurysm exclusion occurs during primary intervention. However, high surgical risk patients will have resultant high morbidity and mortality rates, especially if problems are encountered during the endoluminal procedure necessitating conversion to an open procedure.¹⁴

Comparative mortality and morbidity would be best demonstrated by large-scale, randomised comparative trials between endovascular and surgical abdominal aortic aneurysm repair for operable patients and endovascular repair and best supportive care for patients unsuitable for open repair.

Perioperative mortality

The perioperative period is defined as the 30 days following a procedure. The mortality rate for endoluminal repair of abdominal aortic aneurysm in low-risk patients is reported as 2.5%, and in high-risk patients as 8%.⁴ Saha et al have reported mortality rates of 3–5% for open repair.¹² Most of the published reports indicate that the perioperative mortality rate following endoluminal repair is similar to that reported for open repair.²

Small aneurysm repair

A comparison of endoluminal repair of small aneurysms and the open procedure cannot be made as open surgery is generally not performed for small aneurysms. Guidelines based on epidemiological evidence and clinical follow-up do not recommend conventional surgery for aneurysms less than 5 cm in diameter.¹⁴

A comparison of endoluminal repair of small aneurysms and the probability of rupture without intervention would be useful. The yearly probability of rupture of aneurysms less than 5 cm in diameter is 0.5%²¹ and of aneurysms 5–6 cm in diameter is 5%, increasing exponentially for larger aneurysms.^{21,22} The long-term morbidity and mortality following endoluminal repair of small aneurysms is not known, and the current morbidity of this method is high even with small aneurysms.^{4,5}

Although the yearly probability of rupture is low for small aneurysms, intervention is being considered for two reasons (reviewed by Anderson and Fennessy).¹⁴ Firstly, in specific situations of severe hypertension with severe chronic obstructive pulmonary disease, aneurysms as small as 3 cm have a 94% risk of rupture in 5 years. Secondly, small aneurysms are theoretically more accessible to endoluminal repair due to their larger proximal aortic necks.

Complications

The review by Anderson and Fennessy¹⁴ concurred with that of Woodburn et al² that complication rates for endoluminal repair are similar to those following conventional open repair. However continued perfusion of the aneurysm sac around the graft (endoleak) remains

a major problem following endoluminal repair, with a reported incidence of 6–33%.² It is caused by incomplete sealing or exclusion of the aneurysm sac, by blood flow from collateral arterial branches, or by migration of the graft device. This complication is exclusive to the endoluminal procedure and carries a risk of rupture of the aneurysm. Approximately half of the initial endoleaks seal spontaneously. Persistent endoleak may require further intervention. Late endoleak events can occur up to 3 years after apparently successful intervention⁵ and the prognosis is poor⁶. This necessitates regular postoperative CT scans to determine the occurrence of late endoleaks (this follow-up is not required for the open procedure).

Tortuosity, stenosis and calcification of the iliac arteries or extended aneurysms increase the risk of intraoperative complications and the rate of postoperative complications.²³ Complications such as leakage from satellite arteries, dislocating emboli, may result in ischaemia of the foot or one or more toes, or even death. Some new endovascular devices with systems to filter emboli have recently been developed.²⁴

Table 5 summarises the adverse outcomes as reported by Woodburn et al.²

Safety of devices

The rapid rate of technological change in the delivery and manufacture of graft devices used in endoluminal abdominal aortic aneurysm repair makes it difficult to assess and compare different devices in terms of effectiveness and safety. There is no available research evidence on the relative performances of different types and developments of graft device technology.¹⁴

The large size and inflexibility of early graft devices made them prone to access difficulties and complications such as embolisation of the device and endoleaks. For example, a high incidence of endoleaks (47%) associated with mechanical faults in the earlier Endovascular Technologies (EVT) endograft led to its withdrawal and subsequent redesign.³ However, technical advances appear to be reducing the rate of complications such as endoleaks and thrombosis.³ For example, Miahle et al claimed that the incidence of endoleaks has decreased and that a recent series displayed an overall incidence of 14–16% (of which approximately half seal spontaneously).²² Anderson and Fennessy concluded that ‘there is a general agreement that more flexible devices of smaller diameter ... offer significant operative advantages and seem associated with a decreased incidence of complications’¹⁴; however, they note that this conclusion cannot be made with complete certainty given the methodological difficulties in the available research.

Long-term follow-up is required, however, to accurately determine the ideal attachment system and graft material,²⁵ particularly as stent fracture, graft migration and other late complications such as buckling and suture breakage have been reported¹⁴.

Is it effective?

Despite enthusiasm for less invasive techniques, it has yet to be proven that endoluminal abdominal aortic repair is at least as durable and effective as conventional transabdominal aortic resection and grafting.⁶

The effectiveness of endoluminal repair is currently supported only by level IV evidence. May et al⁵ performed a concurrent comparison of endoluminal and open graft groups. However, the groups were deemed poorly matched in terms of comorbidity and hence the level of evidence was considered to be at level IV.¹⁴

Primary technical success

The primary technical success rate for endoluminal repair is defined as proper placement of the graft using endoluminal techniques without perigraft endoleak, death or graft occlusion within 30 days of implantation. Cases requiring further placement of additional stents and devices to complete the exclusion of the aneurysm sac or to correct leaks noted at the time of initial deployment are not classed as primary technical successes.

Primary technical success rates range from 48 to 95% depending on the device deployed (see Table 4). This range is much lower than that of conventional surgery, which exceeds 93%. Where an additional endoluminal procedure has resulted in successful repair of the abdominal aortic aneurysm, the success rate increases to 100% for some graft configurations.²

May et al have reported from retrospective observational studies that the primary technical success rate for the implementation of endovascular grafts is about 90% in low-risk patients and 80% in mid- to high-risk patients.⁴

Anderson and Fennessy found that several studies were able to demonstrate radiologically diminishing aneurysm size subsequent to technically successful placement of endoluminal grafts.¹⁴

The learning curve for a new procedure such as endoluminal abdominal aortic repair was raised in several studies as an issue that can impact on the success rate of the procedure and associated complications. Furthermore, success may depend on appropriate patient selection, which is under review.²

Late technical failure

Long-term durability and effectiveness of endoluminal abdominal aortic aneurysm repair have yet to be established. Technical improvements in the devices have a potential impact on the long-term effectiveness, as evidenced by the modification of early stent devices, in particular bifurcated devices. At present, late endoleaks occur in 5% of repairs (Table 5) and are the most common late complication of endoluminal abdominal aortic aneurysm repair (see previous sections on Complications, and Safety of devices).

Quality of life

Studies on the quality of life of patients following endoluminal repair have not been undertaken.

Table 4 Evidence summary: reported results of endoluminal repair of abdominal aortic aneurysm

Reference	Year	Device	n	Primary success ^a	Number needed to treat (NNT) ^b	Secondary success ^a	Conversion to open repair	Persisting endoleak or other late failure	Other postoperative complications	30-day mortality
Blum et al	1997	Aorto-aortic	21	18 (86)	1.2	21 (100)	0			
		Aorto-bi-iliac (Vanguard or Passager)	133	116 (87)	1.1	128 (96) [3] ^c	(3)	(6)	15 (10)	1(1)
Parodi et al	1995	Aorto-aortic	51	} 81 (74)	1.4	93 (85) [2] ^c	4	16 (15)	8 (7)	5 (5)
	1997	Aorto-uni-iliac	46							
		Aorto-bi-iliac (Parodi device)	12							
Chuter et al	1997	Aorto-bi-iliac (Chuter–Gianturco)	54	43 (80)	1.3	na	3	14 (26)	na	3 (6)
Moore and Rutherford	1996	Aorto-aortic (EVT ^e)	46	22 (48)	2.1	32 (70) [9] ^c	7	7 (15)	27 complications (rate not stated)	0 (0)
Balm et al	1996	Aorto-aortic (EVT)	31	24 (77)	1.3	27 (87) [3] ^c	1	3 (10)	34 complications in 23 patients	1 (3)
Yusef et al	1997	Aorto-uni-iliac (Ivancev-Malmo)	30	25 (83)	1.2	25 (83)	5	3 (10)	6 (20)	2 (7) 3(10) in hospital
Lawrence-Brown et al	1996	Aorto-bi-iliac (Perth device)	21	17 (81)	1.2	na	0	7 (33)	11 (52)	1 (5)
White et al	1997	Aorto-aortic	36	29 (81)	1.2	32 (89) [1] ^c	2	6		
		Aorto-uni-iliac	20	19 (95)	1.1	19 (95)	1	0 (8)	(33)	3 (4)
		Aorto-bi-iliac (White-Yu GAD ^d)	20	15 (75)	1.3	15 (75)	5 ^d	0		
May et al	1996 1997	Aorto-aortic	54	} 106 (88)	1.1	na	15	na	(15)	6 (5)
		Aorto-uni-iliac	26							
		Aorto-bi-iliac (GAD & others)	41							
Martin et al	1995	All types (EVT & Parodi)	18	16 (89)	1.1	na	na	0 (0)	8 (44)	5 (28)
Thompson et al	1997	Aorto-uni-iliac (Leicester device)	25	20 (80)	1.3	na	5	na	6(24)	2 (8)

EVT = Endovascular Technologies endograft; GAD = graft attachment device; na = data not available

^a NNT(number needed to treat) is the number of patients with a particular condition who must receive a treatment for a prescribed period in order to prevent the occurrence of specified adverse outcomes of the condition (the reciprocal of the absolute risk reduction).

^b Primary success refers to primary technical success rate as defined in the SVS/ISCVS (Society for Vascular Surgery/International Society for Cardiovascular Surgery) reporting standards.

^c Totals include cases in which spontaneous thrombosis of endoleaks occurred (number in square brackets) within 6 months of surgery (primary clinical success).

^d Includes one failed deployment treated by axillofemoral grafting.

Note: Values in parentheses are percentages. All data meet level IV criteria. **Source:** Woodburn et al.²

Table 5 Safety summary: complications reported following endoluminal repair of abdominal aneurysm

Complication	Blum (n=154)	Parodi (n=109)	Moore (n=31)	Balm (n=30)	Yusuf (n=30)	Lawrence -Brown (n=21)	May (n=25)	Thompson (n=25)	Total complications ^a (n=537/425 cases)	Number needed to harm (NNH) ^b
Local vascular complications										
Arterial access injury requiring surgery	3	1	8	6	–	–	9	–	27 (5)	20
Persistent endoleaks	2	10	1	2	3	4	3	–	25 (5)	20
Late onset endoleaks	7	6	7	–	–	–	5	–	25 (5)	20
Wound or minor graft infection	–	–	6	1	–	1	6	2	16 (3)	33
Thromboembolic events leading to surgery	4	–	–	1	–	3	4	1	13 (2)	50
Minor embolic events	1	3	2	2	1	–	–	–	9 (2)	50
Blood loss requiring >2 units transfusion	–	–	–	6	–	–	1	–	7 (1)	100
Fatal embolic events	–	4	–	–	–	–	–	1	5 (1)	100
Lymph leak	2	–	1	1	–	–	–	–	4 (1)	100
Haematoma requiring surgical treatment	1	–	–	–	–	–	–	1	2	
Arteriovenous fistula	1	–	–	–	–	–	–	–	1	
Colonic ischaemia	–	–	–	–	1	–	–	–	1	
Bowel perforation	–	–	–	–	–	–	–	1	1	
Remote systemic complications										
Pyrexia	87	–	9	5	–	–	–	–	101 (19)	5.3
Renal failure	2	–	–	2	–	–	7	1	12 (2)	50
Myocardial infarct, cardiac failure or arrhythmia	–	–	–	2	1	1	8	–	6 (1)	100
Cerebrovascular event	–	–	–	1	1	1	3	–	6 (1)	100
Pneumonia	–	–	–	1	2	1	–	–	4 (1)	100
Respiratory failure	–	–	–	2	–	–	–	1	3 (1)	100
Hepatic or multiorgan failure	1	–	–	1	–	–	–	–	2	

– = not reported

^a Figures in brackets are percentages^b NNH (number needed to harm): when the treatment increases the risk of outcome, NNH is the inverse of the absolute risk reduction.**Notes:** Only series in which individual complications are specified have been included. Complications are categorised according to SVS/ISCVS (Society for Vascular Surgery/International Society for Cardiovascular Surgery) reporting standards for infrarenal aortic aneurysm repair. All data meet MSAC level IV criteria.**Source:** Woodburn et al.²

What are the economic considerations?

Saha et al claimed that there are substantial benefits in length of stay and cost for patients treated by endoluminal repair of abdominal aortic aneurysms compared with open repair.¹² In a group of patients at high risk of cardiac problems, endoluminal repair cost US\$14,600 compared to US\$26,200 for open repair. For patients at high risk for noncardiac associated problems, endoluminal repair costs were US\$13,000.

Holzenbein et al retrospectively compared the cost of endoluminal abdominal aortic aneurysm repair ($n=22$) with that of the open technique ($n=22$) (level IV evidence).²⁶ They found that the total cost in hospital for open surgery exceeded that for the endoluminal procedure by 13.5%, even though the actual cost of the endoluminal procedure was more than double that of the open operation. This was principally due to an apparent shorter recovery time for endoluminal patients reflected in a reduced mean length of hospital stay (endoluminal 6.9 days; open 14.1 days) and reduced mean ICU stay (endoluminal 22.7 hours; open 55.0 hours). It should be noted that it may be hospital department policy that patients undergoing the open repair procedure go routinely to an ICU. Anderson and Fennessy noted that this study included only low surgical risk patients in whom conversion to open surgery, if required, would not have markedly increased morbidity and mortality rates.¹⁴

It should be noted that overseas economic analyses cannot be applied directly to the Australian health system because of major differences in overseas patterns of health resource utilisation and unit costs compared to those in Australia.

An Australian study of 10 endoluminal repairs using the Stentor graft device at the Monash Medical Centre, Victoria, identified the cost of the repairs as A\$19,671 per patient (level of evidence IV).²⁹ This analysis included nonprocedural costs, but did not involve a complete economic evaluation including clinical outcomes and cost-effectiveness.

A further study reported on the direct and indirect costs for endoluminal repair: the total cost of the endoluminal procedure (A\$21,050) was 71.6% greater than that of the open procedure (A\$12,267).²⁸ It was noted that the cost of the endovascular graft comprises more than 50% of the total cost of the endoluminal repair.

Because of the uncertain outcome of endoluminal repair, follow-up should be intensive and protracted. To date, only admitted patient costs have been considered and the costs to the health system of outpatient follow-up, imaging and consultation have not been factored into economic analyses. These are likely to add more to the overall cost of the endoluminal procedure compared with open repair because of the present requirement of follow-up CT scans.

Conclusions

Safety

There are insufficient data available to demonstrate the safety of the endoluminal abdominal aortic aneurysm repair procedure. Mortality rates appear to be similar in both procedures (level IV evidence); however, high surgical risk patients may have higher morbidity and mortality rates. Persistent endoleaks are a serious problem with endoluminal repair, and concern remains about the long-term outcome of endoluminal surgery. Technological advances in devices may be reducing complication rates, but this is unclear.

There are insufficient data available to demonstrate the safety and advantage of endoluminal repair for small aneurysms.

Effectiveness

The effectiveness and durability of endoluminal abdominal aortic aneurysm repair have not been established. There are limited short-term studies with level IV evidence available on this new procedure. There appears to be a higher failure rate in endoluminal procedures compared with open repair procedures, but in successful endoluminal procedures there is a shorter length of stay in hospital and ICU (level IV evidence).

Prospective data collections have been established recently to document the role of the endoluminal procedure in the management of abdominal aortic aneurysm repair. These, together with the findings from currently running controlled trials, will provide further evidence on which conclusions about this procedure may be drawn. There is also a need for the development of an informed consent protocol for people participating in prospective data collections.

Cost-effectiveness

No rigorous Australian cost comparisons of the endoluminal repair procedure with the comparator, the open repair procedure for abdominal aortic aneurysm, are available. The available studies cover admitted patient costs and do not factor in outpatient costs.

Collection of cost data (including post-discharge follow-up costs for patients undergoing this procedure) will be necessary to establish comparisons of the endoluminal repair procedure with the comparator.

Recommendations

MSAC noted that endoluminal grafting of abdominal aortic aneurysm is already claimable under the Medicare Benefits Schedule (MBS), and that for some patients, no other treatment is possible.

MSAC therefore recommended that:

- the current MBS items for abdominal aortic aneurysm be restricted to open aortic repair; but endoluminal repair continue to receive public funding under alternative arrangements;
- as the long-term outcomes of the procedure are not clear, an informed consent protocol must be formulated and must be provided to each prospective patient;
- MSAC explores the issue of data collection on this procedure with stakeholders, with a view to developing a collaborative partnership in obtaining the data required; and
- a further review of the procedure be undertaken when additional Australian and/or overseas data become available.

? The Minister for Health and Aged Care accepted these recommendations on 11 May 1999 ?

Appendix A MSAC terms of reference and membership

The terms of reference of the Medicare Services Advisory Committee are to advise the 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 the Medicare Services Advisory Committee 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
Dr Richard King	gastroenterology
Dr Michael Kitchener	nuclear medicine
Professor Peter Phelan	paediatrics
Dr David Robinson	plastic surgery
Ms Penny Rogers	Assistant Secretary of the Diagnostics and Technology Branch of the Commonwealth Department of Health Aged Care
Associate Professor John Simes	clinical epidemiology and clinical trials
Dr Bryant Stokes	neurological surgery, representing the Australian Health Ministers' Advisory Council
Dr Doris Zonta	population health, representing the Australian Health Ministers' Advisory Council (until 31/12/98)

Appendix B Supporting committee

Supporting committee for MSAC application 1006 — Endoluminal grafting for abdominal aortic aneurysm

Mr Stephen Blamey (Chair) BSc, MBBS, FRACS Consultant General and Gastrointestinal Surgeon, Monash Medical Centre	member of MSAC
Associate Professor Jeremy Anderson MB, ChB, MSC (Epid), MD, FRANZCP Department of Psychological Medicine, Monash University; Director, Centre for Clinical Effectiveness, Southern Health Care Network	co-opted Member
Professor James May MD, MS, FRACS, FACS BOSCH Professor of Surgery, University of Sydney; President of the International Society for Cardiovascular Surgery (Australian and New Zealand Chapter)	nominated by the Royal Australasian College of Surgeons
Clinical Associate Professor Ken Myers MS, FRACS (Vasc) FACS Department of Surgery, Monash Medical Centre, Monash University; Consultant Surgeon, Vascular Surgical Unit, Monash Medical Centre	nominated by the Royal Australasian College of Surgeons
Dr John Primrose MB, BS(Hons), FRACR Senior Medical Adviser, Health Access and Financing Division, Commonwealth Department of Health and Aged Care	medical Adviser to MSAC
Mr John Royle MBBS, FRCS(Eng), FRCS(Edin), FRACS, FACS Director, Vascular Surgery Unit, Austin and Repatriation Medical Centre	nominated by the Royal Australasian College of Surgeons

Abbreviations

CT	computed tomography
EVT	Endovascular Technologies Endograft
GAD	graft attachment device
ICD	International Classification of Diseases
ICU	intensive care unit
ISCVS	International Society for Cardiovascular Surgery
ISTAHC	International Society for Technology Assessment in Health Care
MRI	magnetic resonance imaging
MSAC	Medicare Services Advisory Committee
NHMRC	National Health and Medical Research Council
SVS	Society for Vascular Surgery
TGA	Therapeutic Goods Administration

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