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ORIGINAL ARTICLE

A SELF-EXPANDING ENDOLUMINAL GRAFT FOR TREATMENT OF ANEURYSMS: RESULTS THROUGH THE DEVELOPMENT PHASE

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Background: The results of two and a half years' experience of endoluminal treatment of aneurysmal disease (from March 1993 to December 1995) are reported.

Methods: The endoluminal grafts were individually made at Royal Perth Hospital. They are based on Dacron-covered stainless steel self-expanding 'Z' stents with Gianturco barbed stents (Cook Pty, Australia) for proximal anchorage for grafts within the aorta.

Results: Fourteen straight tube grafts (nine for aortic aneurysm, four for iliac aneurysm and one for subclavian aneurysm) and 24 bifurcate grafts were deployed; all were in patients considered high-risk for conventional repair. Seventy-two per cent of the straight tube grafts successfully excluded the aneurysm. The bifurcate grafts, in use since July 1994, successfully excluded the aneurysm in 88%. There were two delayed deaths from rupture after the grafts failed to exclude the aneurysms; two patients required conversion to open repair and survived; three patients have persistent endoleaks; and three of the bifurcate grafts subsequently occluded a graft limb but did not require further intervention. Ninety per cent of these complications occurred in the first half of the series (prior to January 1995).

Conclusions: A learning and development curve was clearly apparent. The results thereafter compare favourably to those for open repair in similar high-risk groups, suggesting that these techniques hold promise for all patients with aneurysms.

Key words: aortic aneurysm, bifurcate, endoluminal, graft.

INTRODUCTION

This paper presents the results of two and a half years' experience in endoluminal grafting of abdominal aortic aneurysms. Endoluminal grafting is emerging as a real alternative to open surgery. Subsequent to Parodi *et al.*'s initial report in 1991, May *et al.*, Dake *et al.* and Chuter *et al.* have confirmed the technique is possible in selected cases.[1–4] However, long-term results remain unknown.

Conventional open repair of abdominal aortic aneurysms has become a well-established procedure in the four decades since this procedure was first described by Dubost *et al.*[5] Apart from modification in the 1960s where endo-aneurysmal repair replaced aneurysm resection, as popularized by DeBakey[6] and Creech,[7] little change has occurred in the basic technique. Results have been proven with time. Aneurysm exclusion is certain and durability is excellent; patency rates for the grafts long-term are high, and infective complications are minimal. However, morbidity and mortality remain significant. Published mortality rates vary widely, with a rate of 4–9% for unselected population,[8,9] higher rates for octogenarians[10] and lower rates for groups where preliminary cardiac and cerebral vascular revascularization is aggressive.[11]

Much of the morbidity of conventional repair relates to trauma of access, and haemodynamic changes induced by aortic cross clamping. These effects are minimized by endoluminal repair. These potential advantages must be compared to the expense and uncertaintly of the endoluminal technique. We document the results of 38 endoluminal procedures for arterial aneurysm in 37 patients, using a self-expanding graft system developed conjointly by the Royal Perth Hospital Departments of Vascular Surgery and Radiology.

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METHODS

Patient selection

Criteria have remained stringent due to lack of long-term data and have been based on these indications: (i) the risk of death by aneurysm rupture is thought to exceed the risk of death by concurrent disease; for aortic aneurysm the diameter was greater than 50 mm and for iliac aneurysm the diameter was greater than 40 mm; (ii) life expectancy is less than normal for age, due to co-morbidity; or (iii) advanced age (greater than 80); and (iv) quality of life is good.

Assessment of the aneurysm

This is carried out with a spiral computed tomography (CT) scan and aortobifemoral angiogram. Each patient is assessed individually for the stented graft, which is tailored to precise measurements of diameters and lengths taken from spiral CT images. Spatial appreciation is improved with 3D reconstruction. Angiography is performed to allow assessment of: patency; number and position of the renal arteries; the contribution of the inferior mesenteric artery to the collateral circulation of the mid gut, particularly any hypertrophy at the marginal artery of Drummond; and the state of the iliac arteries.

Assessment of the patient

Operative fitness is assessed with anaesthetic consultation, as for open surgery, with medical specialty consultation as

required. Although high-risk patients have been selected, some prospect of surviving salvage surgery (should it be necessary) is requisite. Ischaemic heart disease, as an indication for endoluminal repair, was based on coronary angiography, cardiac catheter studies and the patient's prospects of withstanding open aneurysm surgery, or cardiac and aneurysm surgery.

Stented graft construction

Each graft is individualized to each patient, using commercially available woven Dacron with the crimps ironed out. Stainless steel 'Z' stents line the graft, sutured in place with Prolene. For aneurysms of the aorta, an uncovered Gianturco barbed stainless steel stent is sewn to the proximal end of the graft assembly. The stented graft is soaked in heparin (100 000 units/L) and compressed into a haemostatic sheath delivery system (ranging from 14 F to 22 F) using the narrowest sheath allowing the assembly to slide within. The system is held in place by the barbs of the uncovered Gianturco stent in the proximal aorta and by shear forces elsewhere.

Construction and technical details of the Perth Bifurcated Graft for aortic aneurysms have been described elsewhere by this group[12] and we now report our overall experience with endoluminal grafting. For the bifurcated graft, using the same delivery principles (proximal Gianturco stent and whole length stent support), a commercial bifurcated graft is employed with one limb of the bifurcate graft cut off 12 mm below the bifurcation (Fig. 1). The remainder of this limb is introduced via the contralateral femoral artery and deployed as an extension piece. This docks into the expanded stump of the main graft already placed in the aorta.

Anaesthesia

In this series three anaesthetic techniques have been used to provide anaesthesia for the patients: (i) regional anaesthesia (provided by an epidural technique); (ii) general anaesthesia (using a muscle relaxant, intubation and controlled ventilation); and (iii) general anaesthesia (with spontaneous ventilation via a laryngeal mask airway).

Fully informed consent was obtained from the patients and their families, and hospital ethical committee approval was given.

RESULTS

Thirty-eight endoluminal covered stents were deployed in 37 patients since March 1993 (Fig. 2) (14 straight tubes and 24 bifurcate grafts). All but one of the bifurcate systems have been deployed for abdominal aortic aneurysms, with either common iliac artery involvement or poor inferior necks. The other patient had large bilateral iliac aneurysms that developed subsequent to an open repair (of a ruptured abdominal aortic aneurysm by straight tube graft) 3 years previously.

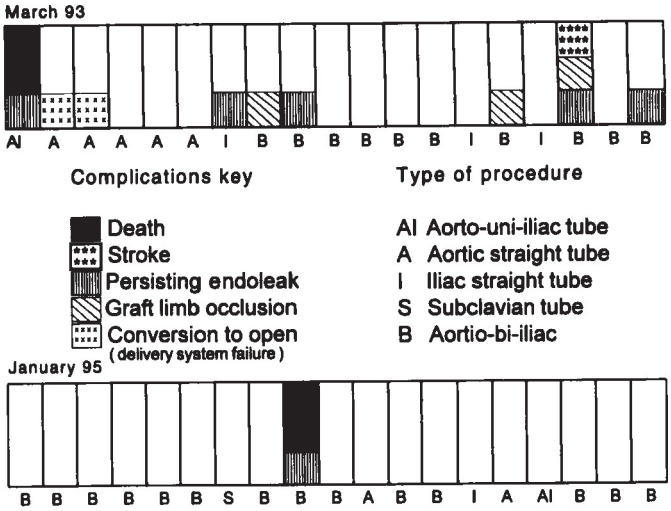

Fig. 2. Timing and type of major complications of the 38 procedures performed.

Twenty-nine patients had endoluminal grafts inserted as their first treatment for infrarenal abdominal aortic aneurysms. Twenty-two of these were bifurcated and two were aorto-uni-iliac. Two bifurcated grafts were inserted primarily for common iliac artery disease, where there was insufficient wall contact in the proximal common iliac artery to provide a secure seal for a tube iliac graft. A total of 24 bifurcated grafts were inserted.

Of the 14 straight tube grafts, four were deployed to treat false aneurysms at the aortic (2) or iliac (2) anastomosis of grafts placed previously at open surgery. One straight tube covered stent was used to exclude a subclavian artery aneurysm, and two were used for isolated common iliac aneurysms. Five aortic aneurysms with adequate inferior necks allowed deployment of straight tube grafts. Two aorto-uni-iliac grafts were used. In both patients the contralateral iliac artery was chronically occluded. A fem–fem cross-over graft was not used in either case as neither patient was claudicating within their exercise distance.

Figure 2 demonstrates the significant complications experienced and shows where these occurred within the series. Table 1 lists minor complications.

Patients ranged in age from 60 years to 95 years (average 74 years), and all were selected for an endoluminal procedure because of perceived high risk for conventional surgery and/or advanced age. The more frequent conditions contributing to an assessment of high risk are listed in Table 2, with many patients having multiple risk factors. The aneurysm was successfully

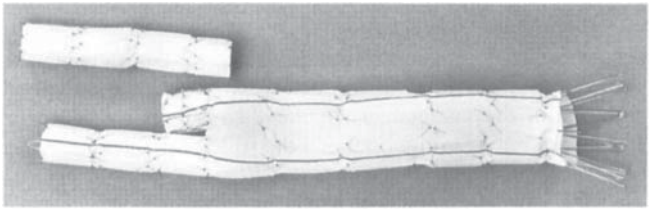

Fig. 1. The Royal Perth Bifurcate Graft with detached limb extension piece.

Table 1. Minor complications

Complication	*n* (%)
Wound infection	1 (3)
Haematoma/seroma	2 (5)
URTI	2 (5)
UTI	1 (3)
Small bowel obstruction	1 (3)

URTI, upper respiratory tract infection; UTI, urinary tract infection.

Table 2. Indications for endoluminal repair

Indication	*n* (%)
Ischaemic heart disease	21 (55)
Respiratory insufficiency	14 (37)
Hostile abdomen	9 (24)
Age > 80 years	8 (21)
Renal failure	7 (18)
Poor left ventricular function	6 (16)
Major cardiac valve disease	5 (13)
Obesity	4 (10)
Cerebrovascular disease	3 (8)
Thrombocytopenia	2 (6)
Jehovah's Witness	1 (3)
Colonic stoma	1 (3)
Peritoneal dialysis	1 (3)

excluded in 31 of 38 patients (81%) at the initial procedure, and in one further patient after deployment of an extension piece to his iliac straight tube graft (85% total). Two patients required conversion to open surgery when graft deployment failed. There were two peri-operative deaths (5.4%) where incomplete exclusion of the aneurysm occurred, and one further patient suffered a debilitating stroke. Three patients sustained occlusion of bifurcate graft limbs. The longest period of follow up is 33 months, with a range of 1–33 months and a median of 12 months.

DISCUSSION

The results presented span the development period of this unit's (Vascular Department, Royal Perth Hospital) endoluminal stented graft and delivery system. Despite disappointments, the remarkable benefits noted in the early convalescence phase provided a constant incentive. The learning curve is well demonstrated (Fig. 2) by the decrease in number of complications; all but one significant complication occurred in the first half of the series.

Two deaths (5.4%) occurred on the fifth and twelfth postoperative days; both from aneurysm rupture subsequent to stenting. This mortality rate is comparable to published results for open repair in unselected populations.[8] In both cases a complete seal was unable to be obtained at the superior neck, but the seal at the inferior neck(s) was complete. The aneurysm sac remained exposed to inflow at arterial pressure but without outflow. Minor leaks were detected at the top end around the graft at completion angiography and were eliminated by balloon expansion. Bedding of the graft with balloons is now routine prior to completion angiography. If completion angiography is satisfactory, a duplex ultrasound scan is performed on the first postoperative day to confirm aneurysm exclusion. Any unexplained finding on duplex ultrasound is immediately examined with a spiral CT; otherwise follow-up CT are performed at 6 weeks, 6 months and then annually. Because a proximal leak without distal re-entry and outflow is associated with rupture of the aneurysm, correction with early intervention is performed.

Two patients required conversion to open operation; in both instances the delivery system failed. In one patient the graft was deployed successfully at the upper neck and at operation this attachment was found to be very secure. The proximal part of this graft was therefore left attached by the Gianturco stent, and the lower end was secured by conventional anastomosis at the aortic bifurcation.

Persistent incomplete aneurysm exclusion (endoleak) continues in two patients; one at the superior neck and one at the iliac neck. A leak persists at the superior neck of one patient who sustained displacement of one iliac limb of his endoluminal prosthesis when angioplasty to improve the seal at the superior neck was attempted. Attempted angioplasty via a brachial approach was complicated by a severely debilitating stroke. His ischaemic leg did not require intervention due to immobility and adequate perfusion at rest. Where successful occlusion of the aneurysm was achieved and confirmed with a CT scan, no new endoleaks have been noted in the follow-up period so far.

One leak about an iliac straight tube graft was corrected with a covered stent extension piece. A subsequent correction procedure was successful on one side but not on the contralateral side of the second patient with an iliac endoleak. A conservative approach was adopted due to his failing health. The principal cause of leakage from the iliac limbs in bifurcate grafts was underestimation of the lengths of the common iliac artery due to tortuosity and a foreshortened apparent length on arteriogram. Curviplanar reconstructed images allowed for by the CT software have subsequently improved estimation of the correct length of the iliac limbs.

A transient leak from the superior neck was noted in one patient where a graft was well lodged within an adequate superior neck, and this spontensously sealed within 1 week.

We remain concerned about the safety and durability of 'endoleaks' at the superior neck sealed by thrombosis. Endoleaks may occur where inadequate superior neck length, or excessive angulation at the neck, causes minimal contact between graft and true aortic wall. Although a temporary seal may be obtained by apposition of the graft against the laminar thrombus, aneurysm exclusion is not achieved. In the above patient there was at least 1.5 cm of contact length between the graft and the sound aortic neck, with no interposed thrombus. The transient endoleak was thought due to poor bedding of the self-expanding anchorage segment of the graft against the aortic wall. We now routinely bed this segment with a soft latex balloon. The latex balloon is used rather than an angioplasty balloon because the relative rigidity of an angioplasty balloon, applied across an angulated neck, tends to cause traction on the inferior anchorage point(s) and can cause displacement. Intensive follow up is planned to monitor for recurrance of the endoleak or continued aneurysm expansion.

Graft limb occlusion has been discovered incidentally at follow up in two patients. Limited exercise tolerance from coexistent disease rendered both patients asymptomatic. However, this raises concerns about the compromise situation of aorto-uni-iliac grafts. Here, the whole lower body is dependent upon a single outflow limb, and collaterals are unlikely to be sufficient to maintain viability of the legs in the event of occlusion. Both occlusions in our series occurred early in the development of a bifurcate system. The system was modified to include self-expanding 'Z' stents along the entire length of the iliac limbs, which should resist kinking and twisting.

In the graft system described, the uncovered portion of the Gianturco stent anchoring the graft proximally in the aorta frequently extends above the renal artery origins. A fine wire may therefore cross one or both renal artery origins. Lawrence *et al.* demonstrated no deterioration in renal function in the canine model with the use of the fine wire of this type of stent.[13] Significant deterioration of renal function (> 10%) was seen in three patients in our series, each with significant pre-operative renal

failure. In two cases, a long superior neck allowed deployment of the Gianturco stent completely below the renal artery origin. In the third patient pre-operative stenting of a tight (> 60%) renal artery stenosis was performed, to preserve function of this single kidney. Although the uncovered portion of the stent extended above this renal artery origin, follow up on duplex and renal nuclear scans showed that renal blood flow was well preserved. Progression of the underlying renal disease was thought to explain the deterioration in the patient's renal biochemistry, an opinion sustained by the renal team responsible for his long-term care.

A significant impact has not yet been seen on hospital stay (7.5 days average postoperative stay). Although disappointing, this is explained in part by the frail condition of the majority of patients selected. Almost all patients treated to date have exhibited a significant fever for 3–7 days. Blood cultures were universally negative. Patients were kept until afebrile, usually well past the date on which they considered themselves ready for discharge. This fever is thought to result from thrombosis within the aneurysm sac. The fever now has less influence on our decision for timing of discharge.

Minor complications were infrequent (Table 1). Upper respiratory tract infection/basal atelectasis was radiologically evident in only two patients, despite being frequently looked for as a potential cause of the fever seen in the majority of patients post-procedure. One groin wound infection in an obese patient healed readily in the absence of graft material external to the arterial wall.

It is necessary for the patient to remain still during the acquisition of digital subtraction angiography. Respiration therefore needs to be controlled. This can be achieved with a co-operative patient under epidural; otherwise general anaesthesia with relaxation, intubation and controlled ventilation is necessary. Spontaneous ventilation via a laryngeal mask airway is unsuitable when using digital subtraction angiography.

Endovascular stenting removes many of the major stresses of an open procedure; the anaesthetist has only to provide a light level of anaesthesia. The cardiovascular stresses of cross-clamping and unclamping the aorta were not seen, although looked for during the brief periods of balloon inflation used to bed the graft in the aorta. Blood pressure manipulation is not required with the self-expanding stent, as opposed to a balloon-expanded stent. The only major problem for the anaesthetist was that the procedures were undertaken in an area containing sophisticated X-ray equipment. Reduced access and lighting, moving operating tables, and limited space combine to create what anaesthetists commonly regard as a 'hostile environment', emphasizing the need for the combination of high-quality imaging with the facilities of advanced operating theatres.

All patients were monitored in the Royal Perth Hospital intensive care unit for the immediate postoperative period. All were returned to the vascular ward within 24 h. As no patient required significant intervention during this period, we no longer plan intensive care observation as a routine.

The learning curve has been well demonstrated in this series. All but one significant complication (Fig. 2) occurred in the first half of our series. Overall, 75% of patients had an uncomplicated procedure and a further 10% had endoleaks corrected subsequently. In the second half of this series 95% had an uncomplicated procedure. Modifications to the grafts were effective in addressing technical failures associated with delivery and short-term patency. The techniques and lessons learned can be passed on to new groups in training programmes.

The introduction of new minimally invasive techniques prompted concerns recently, typified by laparoscopic surgery. The debate in the UK has reached parliamentary level. Areas of particular concern include:

(1) A procedure should not be modified to an inferior technique to suit the method of access.

(2) Unacceptable morbidity should not eventuate as each surgeon goes through the learning curve.

(3) The procedure should remain cost-effective.

(4) Indications for treatment should not be modified without justification.

Studies evaluating the suitability of aneurysms for endoluminal techniques suggest that only a minority > 5 cm in diameter have an inferior neck suitable for a straight tube graft.[14] The prevalence of small aneurysms in screening studies exceeds that of aneurysms > 5 cm in diameter by ten times.[15] Given that the incidence of rupture is rare in small aneurysms (< 5 cm)[16] and growth rates are slow in the vast majority,[17] those endoluminal systems suited only to smaller aneurysms cannot be justified on either medical or economic grounds. The system described allowed deployment of both straight tube and bifurcate grafts, and was only used in clinically significant aneurysms from 5 to 9.5 cm in diameter (average 6 cm).

Many important lessons were learnt during the development period. Most of the morbidity of the learning curve was due to the development of the graft, delivery system and imaging techniques, and should be largely avoidable for new surgeons learning under an 'apprenticeship'. Failure to seal at the superior neck appears to be a potentially lethal complication, perhaps increasing the risk of rupture.

A tendency for the aorta to dilate with time in the perirenal segment was noted by some investigators,[18] and dilatation > 10% was seen in one of our patients. It remains to be established whether this will be a self-limiting phenomenon, or whether it will progress to threaten the superior seal in an unacceptable number of patients. Also uncertain is whether the Gianturco self-expanding stent, with its ability to continue to expand (up to 40 mm in diameter at the anchorage barbs), will provide greater security at the superior seal in this event than the fixed diameter of balloon expandable stents such as the Palmaz (Johnson & Johnson, USA).

Results justify continuing use of the technique in patients at higher than average risk for conventional surgery, but we consider open repair to be the current procedure of choice in those of average risk until the durability and efficacy of the endoluminal grafts are proven in time.

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