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The Vanguard Endovascular Stent-graft: Mid-term Results from a Single Centre

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Purpose. *Despite initial enthusiasm for endovascular aortic repair, few descriptions of longer-term follow-up of any endovascular device have been published. This paper represents the experience of a single centre with the Vanguard device over a 5-year period.*
Methods. *Fifty-five patients with a median age of 71 years (range 45–87 years) and aneurysm diameter of 59 mm (45–84 mm) received a bifurcated Vanguard stent-graft between December 1995 and July 1999. Follow-up was according to the Eurostar criteria (clinical assessment, plain film radiography and computed tomography) at 1, 3, 6, 12, 18 and 24 months and then annually thereafter.*
Results. *All primary stent deployments were successful. Median duration of surgery was 120 min (70–360 min). Median post-operative stay was 3 days (1–19 days) with a peri-operative mortality of 5.5%. In the follow-up period (median 40 months, range 6–64 months) there was one aneurysm associated death, and 14 deaths due to other causes. There have been three device migrations, 12 occluded graft limbs, four type II endoleaks and nine type III endoleaks. At 48 months, this has resulted in a survival rate of 67%, an endoleak free survival of 81% and intervention free survival of 59% (Kaplan–Meier).*
Conclusion. *Medium term results with the Vanguard device appear to be at least equivalent to open repair with regard to morbidity and mortality. Nevertheless, several delayed complications appear to be related to endograft limb distortion. Important lessons have been learnt in relation to the deployment of bifurcated endografts to reduce the incidence of secondary limb related problems.*

Key Words: Vanguard; Endovascular stent-graft; Mid-term reliability.

Introduction

Since the inception of 'Endovascular Aortic Aneurysm Repair' (EVAR) in the last decade of the 20th century, the feasibility of the procedure has been demonstrated with many different home made and commercial devices. The earliest reports described the application of tube grafts fixed to the endoluminal aspect of the aorta with either Palmaz or Gianturco Z stents.[1,2] These first studies showed that endoluminal methods were sufficient to exclude an aneurysm in the short term, but further follow-up data demonstrated an unacceptable incidence of distal endoleak. This was related to the relatively short distal aortic necks present in the majority of patients and also to the natural history, whereby there is continued expansion of the distal aortic neck despite aneurysm exclusion.[3,4]

The next generation of endograft designs were centred on the tapered aorto-iliac graft with femoro-femoral crossover[5] or the bifurcate configuration. The 'aorto-mono-iliac' endografts expanded the range of anatomical settings in which EVAR could be applied and could easily be made up in theatre, whereas the bifurcate systems were emerging through trials by the pioneers[6,7] in a 'semi-commercial' setting. The first commercially available bifurcated endografts were the EVT device (Endo Vascular Technologies, Menlo Park, CA) and the Stentor (Mintec Ltd, Bahamas; precursor of the Vanguard).

Several groups reported early success in abdominal aortic aneurysm (AAA) exclusion using the Stentor/Vanguard I systems.[6] The device had been subjected to two main design changes after Boston Scientific took over manufacture in 1996: application of a seamless Meadox surgical grade polyethylene graft material (Fig. 1) and improvements in the number and grade of sutures between the graft material and the supporting stent framework. However, the early enthusiasm for the Vanguard system was subsequently tempered by reports of suture breakage, endograft distortion and

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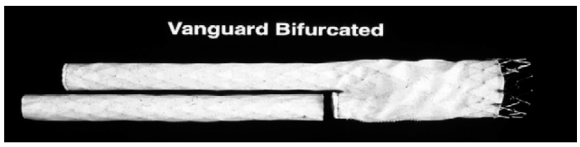

Fig. 1. The Vanguard bifurcated endovascular aortic graft (Boston Scientific Ltd). The device comprises of a primary component (the aorto-iliac endoprosthesis) with an attachment site for a secondary component or contralateral iliac limb. The device is made up of a nitinol framework covered by a polyester fabric.

junctional disconnections.[8,9] These complications appeared to indicate potential weaknesses in the basic structure of the early Vanguard system and perhaps heralded further problems in the medium term.[8]

The Vanguard device fell out of favour in the United Kingdom in 1998, when rival stent graft systems appeared to offer more robust designs with a wider size range and thus greater applicability to the AAA population. In addition, the Medical Devices Agency (of the UK National Health Service) issued a 'safety notice' later in 1999, warning users of the possibility of suture breakages[10] and to follow strict guidelines in terms of the regular surveillance of each implanted Vanguard system.

Despite the initial world-wide enthusiasm for EVAR, and perhaps because of the reported mechanical problems with several of the first and second generation devices, few descriptions of the longer term follow up of any endovascular device have been published. This paper represents the experience of a single centre with the Vanguard device over a period of 5 years and which effectively includes the 'learning curve' for EVAR.

Materials and Methods

Recruitment of AAA patients for endovascular repair took place between December 1995 and July 1999. The EVAR programme was approved by the Local Ethical Committee and every patient informed of the investigational nature of the technique. All devices were implanted by an 'endovascular team' which contained both vascular surgeons and interventional radiologists. The first 25 EVAR procedures were performed in the Angiographic suite in Radiology. The subsequent cases have been undertaken in a dedicated Endovascular Operating Theatre on a fixed angiographic table with a ceiling-mounted C-arm. All cases were done under general anaesthetic.

Study patients

Fifty-five patients received a bifurcated Vanguard stent-graft during the study period. These 55 patients consisted of 49 men (89.1%) and six women (10.9%) with a median age of 71 years (range 45–87 years). Forty-eight patients presented with an asymptomatic aneurysm, six patients were symptomatic and one patient presented with a contained rupture. Preoperative anaesthetic risk was measured by the American Society of Anaesthesiologists' (ASA) score. Twenty nine (52.7%) patients were graded as ASA II, 23 (41.8%) were graded ASA III and three (5.5%) were ASA IV.

Median aneurysm diameter was 59 mm (range 45–84 mm) with a median neck diameter of 22 mm (range 14.7–24.5 mm). Median proximal neck length was 21 mm (range 14–100 mm).

Device

The Vanguard bifurcated endovascular aortic graft (Boston Scientific Ltd, St Albans, Herts.) is a modular device derived from the Mintec Stentor system in 1996. It is composed of a primary component, the aorto-iliac endoprosthesis, with an attachment site for a secondary component or contralateral iliac limb (Fig. 1). Both these components are made of a nitinol wire framework covered by a polyester fabric. On exposure to blood at body temperature, the nitinol wire self-expands to a pre-set diameter. In this way the stent-graft becomes closely applied to the endoluminal surfaces of the aorta in the proximal neck and the iliac vessels at the distal attachment sites. Three pairs of externally projecting barbs help to further anchor the device in the proximal neck. The contralateral limb expands within the junctional area of the aorto-iliac prosthesis and is thus stabilised by a combination of radial force and friction. The primary and secondary components are each completely sealed within polyethylene introduction catheters, 22 French Gauge (FG) and 12 FG, respectively. Each introduction system required preparation by flushing with ice-cold saline.

Procedure

All patients received a general anaesthetic in this early series. The procedure was covered by a single intravenous injection of gentamicin (160 mg) and metronidazole (400 mg). The main device was usually inserted *via* the common femoral artery through a small transverse inguinal incision. A bolus of 5000 IU heparin was given prior to device insertion. The

secondary component was generally inserted into the contralateral femoral artery using a standard percutaneous Seldinger technique.

Angiography was performed in two planes after device insertion in order to assess the integrity of the proximal and distal fixation sites, as well as the junctional area of the completed bifurcated graft. If there was evidence of a significant leak of contrast into the aneurysm sac then a further intervention was usually indicated, either additional balloon expansion of the graft, insertion of a proximal cuff or a distal extension.

Follow up

All patients were entered into both the National (RETA) and the European (EUROSTAR) EVAR Registries and underwent regular evaluation by clinical assessment, plain film radiography and computed tomography (CT). These tests were performed in the first week following EVAR and then at 1, 3, 6, 12, 18 and 24 months. Subsequent assessments were at 12-month intervals. Morbidity and mortality were recorded. All endoleaks, graft limb occlusions or other device related complications were investigated. When re-intervention was indicated, endovascular methods of treatment were considered prior to open surgery.

Statistical analysis

Median values and ranges were calculated, with statistical significance determined by the Wilcoxon signed rank test. Cumulative survival tables were calculated by the Kaplan–Meier method.

Results

All primary stent graft deployments in this study were successful and there were no open conversions. The median duration of surgery was 120 min (range 70–360 min) with an estimated median blood loss of 200 ml (range 30–1000 ml). One patient had a total blood loss of 2500 ml, due to an additional procedure that was unrelated to the Vanguard insertion.

Difficulty in deploying the stent was found in 18 (32.7%) patients. Twenty-four additional procedures were performed intraoperatively (Table 1) to improve access, to treat an endoleak or to resolve a graft limb occlusion. All these procedures contributed to successful stent deployment.

Post-operative course

Twelve (21.8%) patients required admission to the intensive care unit post-operatively. Median stay for these patients was 12 h (range 4–48 h). The median total post-operative stay (including ICU and ward stay) was 3 days (range 1–19 days).

There were a total of 10 (19%) post-operative systemic complications (renal impairment 5, myocardial infarction 2, stroke 1, transient ischaemic attack 1, transfusion reaction 1) and three false aneurysms, each at a site of femoral artery puncture for the deployment of an introducer (Table 2). All were treated surgically. The peri-operative mortality was 5.5% (Table 3).

Early device related complications

Pre-discharge CT scans revealed six endoleaks (11.5%). These consisted of one type I endoleak (1.9%) and five type II endoleaks (9.6%). The patient with the type I endoleak underwent laparotomy with external banding of the proximal neck. This patient subsequently died in the post-operative period. Of the five type II endoleaks, four had sealed spontaneously by the time of the first CT scan at 1 month. The type II endoleak in the fifth patient persisted and was embolised at 6 and 12 months.

Survival

The median follow-up period for the 51 patients who survived beyond 30 days was 40 months (range 6–64 months), with a mean of 38.6 ± 14.9 months. There were 15 further deaths (29.4%) in this follow-up period and the causes of death are listed in Table 4. One patient was lost to follow-up after 18 months. CT scans up to this point had shown no evidence of a leak or any increase in aneurysm size (Fig. 2).

Two of the late deaths were related to the AAA and subsequent endovascular repair. The first was a 74-year-old female (ASA II) who underwent an uneventful primary procedure. She was admitted as an emergency to an outlying hospital, 16 months after the initial operation. The cause of death was a ruptured AAA. The protocol CT scan at 12 months had shown no sign of an endoleak although, in retrospect, the plain film demonstrated possible distal migration of the proximal margin of the stent graft. It is probable that an endoleak had developed shortly prior to aneurysm rupture.

The second patient, a 71-year-old female (ASA II) with no pre-existing renal disease developed renal impairment following partial obstruction of the left

Table 1. Additional intra-operative procedures required

Procedure	Number
Additional introducer required	5
Additional limb extension	3
Proximal cuff	2
Wallstent	9
Fem-fem crossover	1
Endarterectomy	1
Thrombolysis	1
Placement of second stent co-axially	2

renal artery ostium with the proximal margin of the graft material. Initially, the renal function appeared to improve and serial CT scans to 18 months showed no endoleak. However, the left kidney did reduce in size over a period of months. The patient eventually died 22 months after stent insertion, having developed end-stage renal failure.

Delayed device related complications

During the follow-up period after the first month, there have been 26 device related complications in 20 patients.

Device migration

There have been three device migrations. The first, which was not associated with an endoleak, was successfully treated with an aortic cuff at 33 months (Fig. 3). The second, which was associated with a proximal type III endoleak, required graft revision with an aorto-uni-iliac device at 59 months. The third graft migration was associated with buckling of the graft limbs and this patient is currently awaiting further investigations and treatment.

Graft limb occlusions

There were 12 occluded graft limbs (12%) in 11 (21.6%) patients with a median onset of 18 months (range 24 h to 36 months) (Fig. 4). One patient was treated conservatively. The remaining 10 patients (with 11 episodes of graft occlusion) were successfully treated by embolectomy (1), thrombectomy (1), thrombolysis (1) and femoro-femoral crossover graft (8).

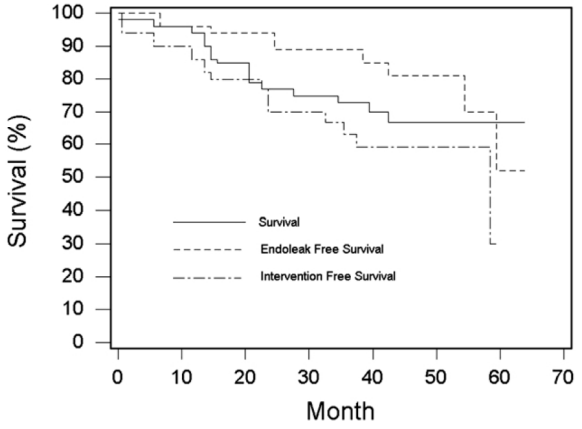

Fig. 2. Kaplan–Meier survival curves of patient survival, freedom from intervention and freedom from secondary endoleak.

There has been one disconnection of an occluded graft limb at 3 years. This was asymptomatic and no treatment has been necessary. One patient developed buckling of the graft at the contra-limb junction at 3 years and this has simply been observed. One patient developed intermittent claudication due to pre-existing atheromatous disease at 12 months and improved following the insertion of bilateral iliac Wallstents.

Endoleaks

In the follow-up period, 13 endoleaks have been identified in eight patients (15.7%).

Of the 13 endoleaks that developed, median onset 24 months (range 3–59 months), during the follow-up period, there have been four type II endoleaks and nine type III endoleaks.

Half of the type II endoleaks sealed spontaneously within 2 months of being identified and no further

Table 2. Post-operative complications

Systemic	Access site
Renal impairment (5)	False aneurysm (3)—All required intervention
Renal artery embolization (1)	
Cholesterol microembolization (1)	
Graft occluded single renal artery (1)	
Cause not determined (2)	
Myocardial infarction (2)	
Stroke (1)	
Transient ischaemic attack (1)	
Transfusion reaction (1)	

Table 3. Peri-operative mortality (30 days)

Age	Sex	ASA	Cause of death	Time of event
79	F	III	Myocardial infraction (following laparotomy for proximal endoleak)	Day 6 post-op
81	M	IV	Myocardial infraction	Day 3 post-op
61	M	III	Spontaneous cerebral haemorrhage (following thrombolysis for occluded graft limb)	24 h post-op
74	M	II	Sepsis (unknown aetiology)	30 days post-op

Peri-operative mortality: 5.5%. 30-day mortality: 7.3%.

treatment was necessary. The remaining two type II endoleaks have only recently occurred and are under observation. Of the nine type III endoleaks (Fig. 5(A) and (B)), one patient developed a proximal type III endoleak following graft migration and a tear in the device between the upper body ring and the main body at 59 months. This was treated by re-stenting. Six type III endoleaks have required limb extensions and two have required a further aorto-uni-iliac device. All have remained sealed at follow-up.

Aneurysm evolution

Within the follow-up period, there has been only a small decrease in the median aneurysm diameter (Fig. 6) and this has not been shown to be statistically significant (Table 5).

Discussion

This single centre experience with the Vanguard endovascular device is based on the comprehensive follow up of all patients treated since the device became available in 1995. No patient required conversion to open repair during the primary procedures in this series. The rate of primary endoleak was only 11%, which is well within the rate quoted in the literature of 10–47%.[11,12] Most of these early leaks were dealt with by endovascular means and none resulted in surgical conversion.

Table 4. Cause of death in follow-up period

Cause of death	Months survived
Debility/MRSA	6
Carcinoma bronchus	12
Unknown cause	14
Congestive cardiac failure	14
Oesophageal carcinoma	15
AAA rupture	16
UTI/Septicaemia	17
Myocardial infarction	20/20
Gastric carcinoma	21
Chronic renal failure	21/22
Non-Hodgkins lymphoma	24
Bladder carcinoma	35
Pneumonia	43

There was no evidence to suggest that peri-operative morbidity or mortality was significantly increased during this early experience. A peri-operative mortality of 5.5% is similar to that associated with open repair. It has been suggested that the less traumatic endovascular procedure may be a more appropriate method of treatment for patients at higher surgical risk. Our experience is that patients who are graded ASA IV appear to do relatively poorly in the post-operative period and this has led us to consider the use of regional or local anaesthesia for selected cases. The Zurich endovascular group have reported significantly lower peri-operative mortality using local anaesthesia for EVAR procedures.[13]

However, the main reason for our study was to assess the longer-term outcome after EVAR and during the follow-up period at least one of our stented patients died with a ruptured AAA. The CT scans prior to this event had not shown any evidence of an endoleak or increasing aneurysm diameter. It has been postulated that this patient may have developed a proximal endoleak that rapidly increased the size of the aneurysm and caused the subsequent rupture. The possibility of such an event draws attention to the fact that EVAR is still an investigational procedure. Nevertheless, whilst surveillance is important, present protocols and the sudden nature of some problems suggests that even extreme diligence to follow up will not prevent all complications. At present, however, regular surveillance is a mandatory requirement for patients entering the UK EVAR trials or the national registry.[14]

The high incidence of delayed or secondary device related complications in this series (35%) is related to the frequent occurrence of 'kinking' or angulation of the stent graft within the aneurysm sac. The Liverpool group has extensively investigated this problem[15,16] and suggests the cause is related to shortening of the excluded aneurysm sac as it reduces in volume with time. The endoleaks that result from limb kinking are type III endoleaks[17] in relation to either disconnection of the contralateral limb from the main device or due

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