The Use of Stent Grafts for the Treatment of Aneurysms and Dissections of the Thoracic Aorta: A Single Centre Experience

P. Matravers,* R. Morgan and A. Belli
St George’s Hospital, Blackshaw Road, London SW17 0QT, UK

Objective. To review the results of stent graft treatment for diseases of the thoracic aorta.
Design. A retrospective study of the results of thoracic stent graft procedures in a single centre.
Methods. The results of 30 procedures performed in 24 patients were analysed. Eleven patients had aneurysmal dilatation of the descending thoracic aorta (>5.5 cm), nine patients had complicated type B dissection, three had penetrating ulcers and one had a traumatic pseudoaneurysm. Imaging follow-up consisted of CT scans performed at one, three, six and 12 months following the procedure and annually thereafter.
Results. One technical failure occurred due to a ruptured external iliac artery. There were no other immediate failures. The primary technical success rate was 83%. The 30-day procedural and patient mortality rates were 7 and 8%, respectively. No neurological complications occurred. Seven patients had the subclavian artery covered without complications. Secondary intervention was required in 21%. During the follow-up period (mean 11 months, range 1–48 months) there were five deaths, two of which were related to stent graft infection.
Conclusion. Thoracic stent grafts offer a realistic alternative to surgery.

Key Words: Thoracic stent grafts; Aneurysms; Thoracic aorta; Aorta.

Introduction

Until recently, aneurysms of the distal aortic arch and descending thoracic aorta have required surgical treatment. Type B dissections have been managed medically with surgery being reserved for those who develop complications. The introduction of stent grafts has opened up new options for the treatment of type B dissections or aneurysmal disease of the descending thoracic aorta, especially in those patients who are considered poor surgical candidates.

We present our experience of thoracic stent grafts for the treatment of aneurysms and dissections of the thoracic aorta.

Materials and Methods

Thirty procedures were performed on 24 patients (16 men and 8 women) between November 1996 and September 2002 (average age 71 years, range 53–81).

The indications for stent grafting were aneurysmal dilatation of the descending thoracic aorta greater than 5.5 cm, smaller aneurysms with evidence of a leak, penetrating ulcers and complicated type B dissections. Exclusion criteria were a proximal or distal neck shorter than 2 cm; and an aortic root diameter wider than 4 cm (this is because the widest available device measures 46 mm). Anatomically, lesions affected the distal arch or descending thoracic aorta. All patients had been turned down for surgical repair due to the presence of significant co-morbidities.

All patients had pre-procedure CT scans of the thoracic aorta. Scans were performed on a GE CTI spiral scanner. Enhanced scans of the thoracic aorta were performed following the injection of 100–150 ml Iohexol 300 at 3 ml/s. A smart prep protocol was used to time the delay. Scans were performed with 3 mm collimation at a pitch of 1.5–2 and reconstructed at 2 mm. Images were reconstructed in multiplanar format. The iliac arteries were assessed for suitability of passage of a stent graft either by CT angiography or by duplex scanning. If it was necessary to cover the left subclavian artery, duplex scanning of the carotids was performed to ensure that the carotid and vertebral arteries were patent prior to the procedure.

*Corresponding author. Dr Paul Matravers, Department of Radiology, St James Wing, St George’s Hospital, Blackshaw Road, London, SW17 0QT, London.
Eleven patients had atherosclerotic aneurysms. The diameter of the aneurysms ranged between 6.0 and 9.7 cm (mean 7.4 cm). Two patients presented with dysphagia, one of whom had a hoarse voice due to left recurrent laryngeal nerve palsy (Fig. 1). One patient had evidence of a recent contained rupture. Nine patients had type B dissection (1 chronic and 8 acute). Six of the patients treated for acute dissection had evidence of contained rupture with blood in the pleural space on pre-procedure CT scans (see Figs. 2–5). One of these patients had, in addition ischaemia of the right renal artery and compromised flow in the SMA. The other patients had acute aneurysmal dilatation of the aorta. The patient with chronic dissection had a saccular aneurysm measuring 6.2 cm. One patient with giant cell arteritis developed a new dissection flap in the thoracic aorta distal to a previous stent graft for the treatment of a more proximal dissection.18 Three patients had penetrating ulcers. One of these patients presented with massive haemoptysis and a CT scan showed the leaking penetrating ulcer which was felt to be communicating with the left main bronchus. One other of these patients showed evidence of a contained leak. One patient had a chronic pseudoaneurysm as a result of a road traffic accident three years previously.

Informed consent was obtained from all patients. The potential risk of left arm ischaemia was discussed with those patients who required coverage of the left subclavian artery. All procedures were performed in the angiography suite of the radiology department under general anaesthesia except for two procedures, which were performed under local anaesthesia. All patients had a prophylactic dose of 1 g vancomycin iv

Fig. 1. CT scan of 80-year-old patient with recurrent laryngeal nerve palsy due to 4 cm saccular thoracic aneurysm. This was successfully excluded following stent graft deployment.

Fig. 2. CT of 74-year-old patient with a type B dissection with proven left haemothorax (drained on ITU) due to rupture.

Fig. 3. Angiogram of type B dissection shown in Fig. 2 prior to stent deployment, showing dissection flap.
prior to the procedure. Local ethics committee approval is not required at our institution but all cases performed are entered into the UK national registry for thoracic aortic stent grafts as recommended by Safety and Efficacy Register for New Interventional Procedures (SERNIP).

A 4F pigtail catheter was inserted into the arch of the aorta via a left brachial approach to enable angiography during stent placement, unless it was planned to cover the left subclavian artery, in which case a right brachial artery approach was used. The common femoral artery was punctured following exposure of the artery via a surgical cut-down. A 260 cm Lunderquist Extra Stiff (Cook) guidewire was positioned in the arch of the aorta. Five thousand units of heparin were administered. The stent graft was passed over the guidewire into the appropriate position within the arch or descending aorta. Angiograms were performed until optimal positioning had been obtained. One or more stent grafts were deployed and final angiograms were performed. Surgical closure of the wound was performed after removal of the device. The left subclavian artery was covered in seven patients. One patient required a right to left common carotid artery bypass prior to the stent graft since it was necessary to cover the left common carotid artery as well as the left subclavian.

Twenty-five Gore Xcluder (W Gore, Flagstaff Az.) stent grafts were deployed in 17 patients, 16 Talent (Medtronic Ave, Santa Rosa Ca) stent grafts were deployed in eight patients and five aneurx (Medtronic Ave, Santa Rosa Ca) stent grafts were inserted in two patients. Single devices were deployed in 11 patients. Multiple devices were deployed in 12 patients. Six patients had two stent grafts, four patients had three stent grafts, one patient had four stent grafts and one patient had seven stent grafts inserted.

Patients on the intensive care unit prior to the procedure returned there for immediate post procedure care. Otherwise, patients spent a short period in the recovery room before returning to the ward. After discharge, all patients had a CT scan within the first three months. Scans were performed at six and 12 months and annually after that. Plain radiography was performed on an annual basis to assess the integrity of the stents. The mean follow-up period was 11 months (range 1–48 months).

Results

There was one immediate technical failure which required immediate left ilio-femoral bypass as a result
of rupture of the external iliac artery. This was in a patient who had undergone previous aorto-iliac endarterectomy and had co-existing abdominal and thoracic aortic aneurysms. The right iliac artery was considered too tortuous and too small calibre for a stent graft to pass. The left iliac artery was felt to be more suitable but this ruptured during passage of the stent graft. All other procedures were successfully carried out with no procedural mortality and no other open conversions. Primary technical success was defined as a successful stent graft procedure with no immediate endoleak present. Twenty-five procedures were performed with no endoleak present immediately after placement giving a primary technical success rate of 83%. The 30 day procedural mortality was 7% (2 of 30 procedures) and the patient mortality was 8% (2 of 24 patients). There were no neurological complications and seven patients had the left subclavian artery covered with no incidence of arm ischaemia. The primary endoleak rate was 36% and the secondary endoleak rate was 12%. Secondary endovascular intervention was performed in four of the 19 patients (21%).

Aneurysms

Nine out of 11 aneurysms were successfully excluded with no endoleak present at the end of the procedure, giving a primary technical success rate of 81% (Table 1). In this group there were three deaths, all of which occurred after 30 days. Two patients died of overwhelming sepsis after developing infected grafts. The first of these was admitted six months post procedure, with fever, pain and septicaemia. A CT scan showed inflammatory tissue and air surrounding the graft and the patient died soon after admission. A post mortem confirmed infection of the graft. The second infected graft was in a patient with known proximal and distal leaks who refused further treatment. He presented two years post procedure with fever, back pain and malaise. A CT scan showed air in the aneurysm sac surrounding the graft consistent with infection and he died soon after. One patient died of unrelated causes at 18 months post procedure. One patient in this group required open conversion for a ruptured external iliac artery (see above).

One patient had a small type one endoleak present immediately post procedure which had sealed by three months. One patient had a small type one endoleak detected at one month, which self sealed at three months. One patient had proximal and distal leaks at one month with an increase in the size of the sac diameter. The patient refused further procedures and the leak and aneurysm sac were stable in appearance at 18 months but he died at two years as a result of an infected graft (see above).

Type B dissections

Seven out of eight procedures for acute dissections were successfully carried out with no leak present giving a primary technical success rate of 88% (Table 2). There were two early deaths in this group. One patient died two days after insertion of three Gore Xcluder devices. A post mortem revealed a retrograde dissection into the ascending aorta with a haemopericardium, which resulted in tamponade and death. One patient died at home within the first 30 days but no post mortem was performed and the cause of death is not known. There have been no late deaths in this group.

One patient had a small type I endoleak present which had self sealed at one month. A CT scan carried out after two weeks in one patient showed continued filling of the false lumen via a re-entry site distal to the previous stent graft but in the thoracic aorta. While distal re-entry sites in the abdomen are not treated, it was felt at the time that a further stent graft was required. In hindsight, a watch and wait policy may have been more appropriate. One patient with known giant cell arteritis developed a new dissection flap in the thoracic aorta during follow-up and this was treated with a further stent graft.

The chronic dissection was successfully performed with no leak on completion angiography. This patient with aneurysmal dilatation had three leaks detected during follow-up (two distal and one proximal) all of which were treated with three further stent grafts. There was a small type I endoleak present after his third procedure but this had sealed at one month. No leak has been detected at eighteen months following the most recent procedure.

Penetrating ulcers and traumatic pseudoaneurysm

All three procedures for penetrating ulcers were successfully carried out. There were no deaths in this group. One of these patients had a leaking penetrating ulcer and a CT scan done in the first week showed continued filling of the ulcer post stent grafting. It was felt that a further stent graft was required to prevent further haemorrhage. No further leak has been detected in either of these patients on further follow-up. At the end of the procedure for the traumatic pseudoaneurysm, there was a small type I endoleak

Eur J Vasc Endovasc Surg Vol 26, December 2003
Table 1. Atherosclerotic aneurysms.

<table>
<thead>
<tr>
<th>Sex</th>
<th>Age</th>
<th>Aetiology and site</th>
<th>Length of aneurysm</th>
<th>Device details</th>
<th>Immediate outcome</th>
<th>Long-term follow-up</th>
</tr>
</thead>
<tbody>
<tr>
<td>F</td>
<td>62</td>
<td>Aneurysm distal descending</td>
<td>13 cm</td>
<td>40 mm Aneurex × 2</td>
<td>Aneurysm excluded</td>
<td>Died cancer oesophagus at 18 months. Sac size stable</td>
</tr>
<tr>
<td>F</td>
<td>79</td>
<td>Aneurysm mid/distal descending</td>
<td>7 cm</td>
<td>34 × 150 mm and 34 × 100 mm Gore Xcluder</td>
<td>Aneurysm excluded</td>
<td>No leak after 24 months. Sac size reduced</td>
</tr>
<tr>
<td>M</td>
<td>76</td>
<td>Aneurysm distal descending</td>
<td>11 cm</td>
<td>Talent × 3</td>
<td>Aneurysm excluded</td>
<td>Prox. and dist. endoleaks at 1 month. Refused intervention. Sac size increased. Died infected graft 2 years</td>
</tr>
<tr>
<td>F</td>
<td>73</td>
<td>Aneurysm distal descending</td>
<td>10 cm</td>
<td>34 × 150 mm Gore Xcluder</td>
<td>Aneurysm excluded</td>
<td>No leak after 6 months. Sac size stable</td>
</tr>
<tr>
<td>F</td>
<td>73</td>
<td>Aneurysm whole descending</td>
<td>20 cm</td>
<td>40 × 100 mm, 40 × 150 mm, 40 × 200 mm and 37 × 200 mm Gore Xcluder</td>
<td>Aneurysm excluded</td>
<td>No leak after 6 months. Sac size reduced</td>
</tr>
<tr>
<td>M</td>
<td>79</td>
<td>Aneurysm proximal descending</td>
<td>17 cm</td>
<td>34 × 150 mm Gore Xcluder × 2</td>
<td>Small leak</td>
<td>Small leak immediately. No leak at 6 months. Sac size stable</td>
</tr>
<tr>
<td>M</td>
<td>72</td>
<td>Aneurysm arch and proximal descending</td>
<td>6 cm</td>
<td>37 × 150 mm Gore Xcluder</td>
<td>Aneurysm excluded</td>
<td>No leak after 6 months. Sac size stable</td>
</tr>
<tr>
<td>M</td>
<td>53</td>
<td>Aneurysm proximal descending</td>
<td>6 cm</td>
<td>38 × 130 mm Talent × 3</td>
<td>Aneurysm excluded</td>
<td>Small leak detected at 1 month. Self sealed at 3 months. Sac size reduced. Died infected graft 6 months</td>
</tr>
<tr>
<td>M</td>
<td>81</td>
<td>Aneurysm arch and proximal descending</td>
<td>3 cm</td>
<td>38 × 130 mm Talent</td>
<td>Aneurysm excluded</td>
<td>No leak after 6 months. Sac size stable</td>
</tr>
<tr>
<td>M</td>
<td>72</td>
<td>Aneurysm aortic arch</td>
<td>2 cm</td>
<td>N/A</td>
<td>Ruptured left external iliac artery</td>
<td>Small leak</td>
</tr>
<tr>
<td>M</td>
<td>72</td>
<td>Aneurysm distal descending</td>
<td>9 cm</td>
<td>3 × Talent</td>
<td>Small leak</td>
<td>No leak after 6 months</td>
</tr>
</tbody>
</table>
present which had sealed at one month. No further leak has been detected at follow-up.

**Follow-up**

The follow-up CT scans were assessed in order to determine the fate of the aneurysms and the false lumen post stent graft insertion. Of the eight patients treated for acute dissection, six had follow-up scans (the two early deaths were in patients treated for dissection). Four patients showed total thrombosis of the false lumen and one showed thrombosis of the false lumen within the chest but some filling of the false lumen within the abdomen. One patient showed reduced residual flow in the thoracic false lumen at two months with no evidence of further leak. Follow-up scans were available in 10 of the patients with atherosclerotic aneurysms. Three patients showed a reduction in sac size of more than 5 mm, six patients showed no change in sac size and one had an increase in sac size. The chronic traumatic pseudoaneurysm was seen to be thrombosed on follow-up with no change in size. Of the penetrating ulcers, one disappeared totally on follow-up, whilst the other was unchanged.

Nine patients (38%) had evidence of leak/contained rupture on pre-procedure. CT scans and were, therefore, treated acutely. Four of these patients have been the subject of a previous report. Six of these were in patients with a type B dissection. One of these patients died three days post procedure but the other five were successful procedures, which showed no evidence of further leak on follow-up CT and four of which showed thrombosis of the false lumen in the thorax. One patient had a 6.2 cm atherosclerotic aneurysm. Following treatment, the sac size was unchanged on follow-up but no further leak was demonstrated. One patient had a leaking penetrating ulcer, which was successfully excluded. During the follow-up period of 12 months, no further leak was demonstrated but the appearances of the ulcer were unchanged. One patient had massive haemoptysis due to leak from a penetrating ulcer into the left main bronchus. At one month there was no evidence of further leak and no haemoptysis.

**Discussion**

Surgical replacement of the descending thoracic aorta is associated with a significant mortality and morbidity. The reported early mortality rate varies between 3 and 21% depending on the technique used. In a study...
by Coselli et al., 198 patients underwent replacement of the descending thoracic aorta for aneurysmal disease with an early mortality rate of 5%. However, a recent audit by the Society of Cardiothoracic Surgeons of Great Britain and Ireland revealed a mortality rate of 34% for those treated with cardiopulmonary bypass and 25% for those treated without. The 30 day mortality rate in this series of patients was 7% which is similar to the results of other endovascular series which range from 4 to 14%. Two studies which is similar to the results of other endovascular series which range from 4 to 14%. Two studies have compared standard surgical treatment with stent grafting. Nienaber et al. compared 12 patients who underwent stent grafting for chronic type B dissection with 12 matched controls who underwent surgical treatment. The 30-day mortality in the patients treated surgically was 8% whilst that in the stent graft group was 0%. Paraplegia rate, average time in ITU and average hospital stay were all reduced in the stent graft group. Ehrlich et al. compared the results of 10 patients who underwent stent grafting for aneurysms of the descending thoracic aorta with 58 patients who had been previously treated with conventional surgery. The 30-day mortality rate was 31% in the surgical group and 10% in the stent group. Again, the stent group showed reduced rate of spinal cord complications and reduced ITU and hospital stays.

In our series no patients developed spinal cord complications. The incidence of spinal cord complications in previous series varies from 0 to 3%. The cause of paraplegia in these patients is thought to be ischaemic in nature and can be treated by prompt insertion of a CSF drainage catheter. Factors, which influence the rate of paraplegia have been investigated by Dake et al. They found that access via the abdominal aorta, simultaneous surgical repair of an abdominal aortic aneurysm, previous ascending aortic aneurysm repair and co-existing ascending aortic aneurysm all increased the risk of paraplegia. The risk of paraplegia increases with the length of aorta covered and in our series only one patient had the whole descending aorta covered.

Seven patients in our series had the left subclavian artery covered by the stent graft with no ischaemic symptoms developing as a result. In the series reported by Taylor et al., three patients had the left subclavian artery covered by the stent graft with no long-term symptoms. We, therefore, deduce that the left subclavian artery can be covered by the stent graft without the need for prophylactic left common carotid to subclavian bypass. However, the patient should be warned that bypass may become necessary if ischaemic symptoms develop. It is necessary to ensure that the carotid and vertebral arteries are intact prior to covering the left subclavian, since some patients rely on the left vertebral artery to provide the posterior cranial circulation.

The main concern with stent grafts is their longevity and durability. Perigraft endoleaks are a concern in both the immediate peri-operative period and in the long-term. The endoleak rate for stent grafts in the descending thoracic aorta has previously been reported as 24%, most of which occur in the first year. In another series, endoleak occurred in nine out of 17 patients (52%) treated with a stent graft for aneurysms of the descending thoracic aorta. In our series, one patient had both distal and proximal type I endoleaks with increasing sac size on follow-up and secondary intervention was thought to be warranted. This patient, however, refused further intervention. Two patients had secondary procedures performed within the first 14 days. All the other primary endoleaks sealed without further intervention within three months. All the secondary endoleaks occurred in one patient, all of which required secondary intervention. No other patient has developed a secondary endoleak.

Endoleaks have been studied more in relation to the treatment of abdominal aortic aneurysms. A meta-analysis of previous clinical studies of stent graft treatment of abdominal aortic aneurysms showed an endoleak rate of 24%. The majority of these were detected at the distal attachment site. The fate of the aneurysm sac showed that overall there was an increase in diameter in 15%, no change in 35% and decreased diameter in 50%. However, when those with an endoleak were considered, there was an increase in 86%, no change in 14% and a decrease in 0%. Spontaneous thrombosis occurred in 21% of all endoleaks. In the fifth report of the registry for the endovascular treatment of aneurysms (RETA), the primary endoleak rate was 14%. In those patients with a persistent proximal endoleak there was a significant risk of rupture, justifying an aggressive approach to their management. The collateral and distal endoleaks appear to show a more benign course. Whether these findings equate to thoracic stent grafts remains to be seen. However, in the light of the evidence for type I leaks in abdominal aortic aneurysms, it is prudent to treat type I endoleaks in patients with thoracic stent grafts.

Graft infection is a serious complication which usually leads to the death of the patient since they are not suitable candidates for surgical intervention. However, stent grafts do not invariably become infected in the presence of active infection. In a series
of 112 patients who underwent stent grafting for thoracic aortic aneurysms, three were deployed across known mycotic aneurysms. No patient developed a persistent bacteremia and complete thrombosis of the aneurysm sacs occurred in all three patients.\textsuperscript{15} Two grafts in our series have become infected and patients died as a consequence. One of these developed two years post implantation and may have been related to the presence of chronic distal and proximal leaks. The other patient presented six months post implantation and this case is likely to be related to the procedure itself. This raises the question of where stent grafting should be performed. Ideally, these procedures would be performed in a dedicated angiography suite, which has the sterile conditions of a surgical theatre. Most operating theatres have the disadvantage of inadequate imaging equipment consisting of a mobile image intensifier with a small field of view. Operating tables are often incompatible with good imaging and the range of catheters and wires, which may be required is not generally available. In addition more contrast medium is used as the whole field is not visible. As this is predominantly an image-guided technique, we perform these procedures in the angiographic suite of the radiology department. Whilst this does provide superior imaging, the environment is not ideal from an infection control point of view. The most effective solution would be to ensure that theatre type conditions are incorporated into the design of angiography suites.

In our institution, a single dose of 1 g intravenous vancomycin was given to all patients in the pre-operative period in an attempt to reduce graft infection. This policy has been changed and two further doses are now given to cover the post-operative period. A recent study suggests that stent grafts are most likely to become infected in the early post-operative period. This study which was carried out in dogs following stent graft insertion would suggest that prophylactic antibiotics should be continued into the post-operative period.\textsuperscript{16}

The fate of the aneurysm sac is important to assess during follow-up. Thirty percent of our patients showed a decrease in size of the aneurysm sac, 60% showed no change in sac size and 10% (one patient) showed an increase in size. The patient who showed an increase in sac size had known distal and proximal leaks. Dak et al. showed decrease sac size in 48%, no change in size. The patient who showed no change in sac size and 10% (one patient) showed a decrease in size of the aneurysm sac, 60% showed an increase in size. The patient who showed a decrease in sac size of a stable sac on follow-up. Does this mean that the aneurysm sac is still being perfused and if so is there an increased risk of rupture? This will become more clear over time as longer follow-up becomes available.

Surgical treatment for rupture of the descending thoracic aorta carries a particularly high morbidity and mortality (up to 50%). Stent grafting offers an alternative treatment in this sub group. In our series, nine patients with evidence of acute rupture were treated with a 30-day mortality of 11% (survival rate of 89%). Semba et al. treated 11 patients with evidence of acute rupture. Two of these patients died in the early post-operative period, giving a survival rate of 82% during the follow-up period.\textsuperscript{7}

In conclusion, thoracic stent grafts offer a realistic alternative to surgery for aneurysmal disease of the descending thoracic aorta, particularly in those patients who represent a significant surgical risk. They are probably the treatment of choice for traumatic pseudoaneurysms and penetrating ulcers, as well as complicated type B dissections and acute aortic rupture when the surgical risk is particularly high. However, further analysis of the long-term outcomes is required.

References

12. Schurink G, Aarts N, Van Bockel J. Endoleak after stent graft

Accepted 22 July 2003