Observations on the failure of stent-grafts in the aortic arch

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Abstract

Introduction

The results of endovascular stent-grafts in the abdominal aorta and descending thoracic aorta have been encouraging. Expanding the use of thoracic stent-grafts in to the aortic arch has been associated with increasing numbers of complications. Recently isolated cases of stent-graft collapse have been reported.

Methods

This was a multi-centre European case series. Data was collected retrospectively on seven patients from five experienced endovascular centres with thoracic stent-graft collapse.

Results

Of the seven patients four were treated for traumatic aortic rupture. Six were male, median age 33 (range 17 – 54) years. During the ensuing 2 months all patients suffered stent-graft collapse. This was symptomatic in 3 patients and the rest were identified on CT. Endovascular management was possible in 6/7 patients using either a balloon expandable stent (n=6) or further stent-graft (n=1). Two patients had persistent type I endoleak despite treatment. Two of the 7 patients died, both of which presented with symptomatic thoracic stent-graft occlusion. Both deaths were a direct result of stent-graft collapse.

Conclusions

Thoracic stent-graft collapse may be asymptomatic underscoring the importance of stent-graft surveillance. Endovascular management of collapse is possible in most

cases using a large balloon expandable stent. Symptomatic collapse is associated with high morbidity and mortality.

Procedures were performed in an operating theatre with the patient under general anaesthesia (n=6) ir in an angio-suite with open surgical facilities (n=1). Access was via a percutaneous or open approach to the common femoral arteries, depending upon local preferences. Patients were systemically heparinised if haemodynamically stable. After deployment the stent-grafts were ballooned at the proximal and distal landing zones with a compliant angiographic balloon to improve wall apposition (6/7 patients). Completion angiography was performed in all patients to assess aneurysm exclusion.

Patient follow-up was subject to post-operative recovery (polytrauma), co-morbidity and local preferences. All patients received a follow-up CT scan within the first 10 days post-operatively or when they presented with symptoms of graft failure. Patients were enrolled in a stent-graft surveillance programme. Stent-graft collapse was detected on CT scanning and these patients form the study group.

Results

Seven patients were identified with thoracic stent-graft collapse from five European centres, Malmö (n=1); Nijmegen (n=3); Gothenburg (n=1); Klagenfurt (n=1) and San Sebastian (n=1).

Median age of patients was 33 years (range 17 – 54) and six were male (Table 1). Four of the stent-grafts were placed in polytrauma patients with traumatic aortic rupture. Two patients were treated with distal arch pseudoaneurysms. One of these patients had been involved in a road traffic accident (RTA) 21 years previously, which was responsible for the pseudoaneurysm and the other had previously undergone aortic coarctation repair. One patient was treated for an aorto-oesophageal fistula. He had an infected open aortic graft which was inserted for type A dissection

7 months previously. The graft infection presented with haematemesis. Upper gastrointestinal endoscopy and contrast spiral CT confirmed the diagnosis of an aorto-oesophageal fistula.

Six patients underwent repair with a Gore TAG (W.L. Gore & Associates, Evry, France) and one with a Zenith (Cook Europe, Bjaeverskov, Denmark) stent-graft (Table 2). The median proximal aortic neck diameter was 21mm (inter-quartile range 20 – 28).

Three patients required occlusion of the left subclavian artery (LSA) during the procedure due to a short proximal neck. In one patient the LSA was partially covered (50%). In another the LSA was occluded on the first post-operative CT.

One stent-graft (patient 4) was deployed too proximally and covered the ostium of the left common carotid artery (LCCA). The stent-graft was successfully manipulated distally using traction on a balloon inflated within the stent-graft. The LCCA remained patent.

There were two endoleaks on completion angiography (at the end of the procedure). One was a type II endoleak, from retrograde flow in an intercostal vessel. The other was a small proximal type I endoleak. There was evidence of continued type II endoleak on post-operative CT but the type I endoleak appeared to have resolved spontaneously.

There were no intra-operative strokes or paraplegia. There was one stent-graft related complication. This was a groin haematoma, which required exploration after failure of a percutaneous closure device. All patients suffering traumatic aortic rupture had a variety of other injuries (polytrauma).

The patient (patient 1) who underwent stent-grafting for a bleeding aorto-enteric fistula continued to receive antibiotics post-operatively.

All patients presented with stent-graft collapse within three months of stent-graft implantation (Table 3). Four of the seven patients had one post-operative CT scan before the stent-graft collapsed. All of these scans showed an intact stent-graft. There was no evidence of migration or endoleak. However, all of the stent-grafts had adopted a similar lie on completion angiography or CT scan. All stent-grafts demonstrated poor apposition of the stent-graft along the inner curve of the aortic arch with the stent-graft protruding into the lumen of the aorta (Figure 1.)

Four patients were asymptomatic and the collapsed stent-grafts were identified on routine post-operative CT. The other three patients presented as an emergency with symptoms consistent with thoracic aortic occlusion including chest pain and lower extremity ischaemia. All patients had stent-graft collapse confirmed on CT (Figure 2.)

Six of the seven patients underwent endovascular treatment of their stent-graft collapse. One of these patients underwent placement of a second stent-graft within the first in order to cause re-expansion. The stent-graft re-expanded after re-lining but there remained a small proximal type I endoleak on completion angiography. The other five underwent angioplasty (PTA) with a compliant angioplasty balloon catheter (26x40mm Gore Tri-Lobe Balloon, W.L. Gore & Associates or 40mm CODA balloon, Cook Europe, Bjaeverskov, Denmark). PTA was insufficient to re-expand any of the collapsed stent-grafts. They all required treatment with a large balloon expandable stent in the proximal stent-graft (Palmaz stent, Cordis Endovascular, Warren, NJ, USA or CP giant stent, NuMed, Heart Medical Europe BV). Deployment of a large balloon expandable stent successfully re-expanded the five collapsed stent-grafts which did not respond to PTA (Figure 3). Stents were deployed under adenosine induced asystole in two patients (Nijmegen) to assist precise placement.

One patient had a persistent small proximal type I endoleak despite the use of a balloon expandable stent. This endoleak is being observed.

One patient (Patient 2) underwent axillo-bifemoral bypass for collapse associate with aortic occlusion. Because of multiple stent fractures and complete collapse it was not possible to insert another stent-graft or balloon expandable stent. He was not medically fit enough at that stage to withstand open repair.

Two of the three patients who presented with symptomatic stent-graft collapse died as a result of complications. None of the patients died who had asymptomatic collapse. Patient 2 died from multiple organ failure consequent to thoracic aortic occlusion despite an emergency axillo-bifemoral bypass graft. Patient 1 who had (open) aortic graft and then stent-graft sepsis represented at 2 months with recurrent sepsis and bleeding. He died six weeks following conversion to open repair as a result of complications of the surgery and sepsis. The third patient with symptomatic collapse underwent successful re-expansion of the stent-graft with a balloon expandable stent. However, as a result of the ischaemia he developed acute renal failure, paraparesis and required bowel resection.

During the course of radiological follow-up 3 (IQR 1 – 9) months of the five surviving patients there is one persistent type I endoleak (patient 5), which is being observed. All the other traumatic ruptures and one pseudoaneurysm remain satisfactorily excluded.

Discussion

Collapse of thoracic aortic stent-grafts is associated with major morbidity and mortality. In this series two of seven patients died as a result of the collapse and another suffered major morbidity (acute renal failure, paraparesis and required

multiple laparotomies and bowel resection). Those patients presenting with symptomatic collapse, in the form of acute aortic occlusion are at particularly high risk of complications and death, even though they can usually be managed endovascularly.

Patients with asymptomatic collapse (likely to represent a less extreme form of collapse earlier in the natural history) can invariably be managed via the endovascular route and a good early outcome can be expected. The stents are fractured and do not retain any expansile force. Consequently the collapsed stent-grafts do not respond to simple PTA. They invariably require deployment of a large balloon expandable stent proximally to achieve re-expansion and seal the associated endoleak.

The true incidence of thoracic stent-graft collapse is unknown, in part because some remain asymptomatic. In one of the largest series of endovascular management of traumatic aortic rupture, from four trauma centres in the Netherlands, there was one patient with asymptomatic collapse in a total of 28 patients treated.[6]

The natural history of stent-graft collapse is not fully understood. Stent-grafts appear to collapse within the first months of insertion (within three months in this study). The presence of a fully expanded stent-graft on CT during the first week does not exclude subsequent collapse. However, all of the post-operative CT scans revealed the stent-grafts protruded significantly in to the lumen of the aorta (>50%). Analysis of explanted specimens revealed multiple stent fractures and collapse (Figure 4.) A possible mechanism for stent-graft collapse based on these observations of protrusion in to the aortic lumen might be thus; during systole the stent-graft collapses due to aortic flow and the pressure gradient across it, followed by stent re-expansion during diastole. Gross movements of the stent are likely to result in excessive metal fatigue

with subsequent stent fracture and collapse. Once the process starts failure is inevitable.

A pragmatic approach to image based follow-up to detect asymptomatic collapse, based on these seven patients studied, might be to perform a CT scan during the first post-operative week and then at three months.

Patients in this study were young with a narrow median proximal aortic neck diameter (median 21mm). All of the arches were highly angulated and the aneurysms were close to the left subclavian artery ostia, resulting in overstenting of the LSA origin in 5/7 patients. On completion angiography all of the stent-grafts had poor apposition to the inner curve of the aortic arch. The stent-grafts tended to protrude significantly (>50%) in to the lumen of the aortic arch. These patients may benefit from early placement of a large balloon expandable stent.

An alternative approach to try and improve the conformity of thoracic stent-grafts in the arch is to deploy them more proximally and occlude the LSA. Although this is a relatively innocuous procedure in an elderly population, it can be associated with complications. Young patients are at risk of left arm claudication (one patient in this study). Another patient required extensive endovascular manipulation to avoid occlusion of the LCCA. However, pushing the stent-grafts further around the arch and covering the ostium of the LSA did not appear to confer any protection against collapse. In this study 5/7 patients underwent overstenting of the LSA.

A variety of endovascular techniques have recently been described to treat aortic arch pathology. These include fenestrated and modular branch stent-grafts or hybrid procedures with complete de-branching of the arch and bypass at sternotomy.[3 7] The techniques are not yet in widespread use and are, at present, probably inappropriate in the emergency situation.

Previous reports of collapse were associated with one variety of stent-graft (TAG). In this study we have also seen collapse of the Zenith stent-graft (one patient). These observations confirm that collapse of stent-grafts in the arch is most likely related to their inability to conform to the angulation of the arch rather than to any other specific design flaw. In the infra-renal aorta, uncovered supra-renal stents have been used to improve the conformability of stent-grafts in the aortic neck and reduce complications such as endoleak and migration. Early experiences with this approach were met with a number of problems, most notably, erosion of the bare stent through the arch.[8]

The degree of oversizing of stent-grafts in this series of patients may have been a contributory factor to collapse. In the multicentre Netherlands study of traumatic aortic rupture there was only one case of collapse among 28 patients treated.[6] In that study the aortic diameter was greater (25mm versus 21mm) than in the present study. In the present study stent-grafts were oversized considerably more (7mm versus 3mm). A major limitation of current thoracic stent-grafts is their size. The smallest available thoracic stent-graft diameter TAG is 26mm and 22mm for the Zenith. The smaller sizes may not be kept in stock for emergency procedures.

Current stent-graft technology is inadequate for the demands of the angulation of the arch. Recent developments in abdominal aortic stent-graft technology may provide some solution for the difficulties encountered in the arch. In particular, one flexible stent-graft has been designed specifically to deal with neck angulation.[9]

In conclusion, until new technology becomes available, endovascular specialists should be aware of the potential limitations of current stent-grafts in the aortic arch. They should maintain a high degree of vigilance for stent-graft collapse, especially in young patients with narrow and angulated aortic arches. In these young patients with

adverse arch morphology and traumatic aortic rupture, consideration should be given to open repair.

Introduction

Endovascular stent-grafts have proven successful in the abdominal aorta and descending thoracic aorta. Early and mid-term results compare favourably with open surgical techniques.[1 2] The use of stent-grafts has been expanded to lesions in challenging anatomical areas such as the aortic arch. These lesions have traditionally been associated with high morbidity and mortality rates following standard open surgical techniques.

However, the results of stent-grafting in the arch have not matched those in other areas of the aorta.[3] There have been significant numbers of complications, including stroke. Recent isolated reports have identified patients with stent-graft collapse.[4 5] This paper reports a series of patients from five experienced European endovascular centres with thoracic stent-graft collapse.

Methods

We retrospectively reviewed patients from five experienced endovascular centres (Malmö University Hospital, Malmö, Sweden; University Medical Centre, Nijmegen, The Netherlands; Sahlgrenska University Hospital, Gothenburg, Sweden; Klagenfurt General Hospital, Klagenfurt, Austria, Hospital de Guipuzcoa and Hospital Donostia, San Sebastian, Spain) between June 2003 and July 2006 who were treated with thoracic endovascular stent-grafts and subsequently developed stent-graft collapse. Pre-operative contrast spiral CT scans were performed in all patients to confirm the diagnosis and size the stent-graft.

Patients were treated by a vascular surgeon or interventional radiologist experienced in thoracic endovascular procedures. The centres involved in the study perform on average three cases of thoracic stent-grafting for traumatic aortic rupture per year.

Legends

Table 1. Patient demographics

Table 2. Endovascular management of primary aortic pathology

Table 3. Presentation and management of stent-graft collapse

Figure 1. Arch aortogram of typical lie of thoracic stent-graft in arch with poor apposition along the inner curve

Figure 2. CT scan of stent-graft collapse with infolding of the graft

Figure 3. Re-expansion of collapsed stent-graft using large balloon-expandable stent (Palmaz).

Figure 4. Radiograph of collapsed thoracic aortic stent-graft and thoracic aorta explanted *en bloc* from deceased patient. Note multiple collapsed stents and migration of the stent-graft

Table 1.

Patient	Centre	Age	Sex	Co-morbidity	Indication for stent-graft
1	Gothenburg	54	M	Open repair type A dissection 7 months previously	Aorto-oesophageal fistula
2	San Sebastian	33	M	Nil	Distal arch pseudoaneurysm (previous RTA)
3	Klagenfurt	22	M	Nil	Traumatic aortic rupture
4	Nijmegen	48	F	Nil	Traumatic aortic rupture
5	Nijmegen	43	M	Aortic coarctation repair previously	Distal arch pseudoaneurysm
6	Nijmegen	24	M	Nil	Traumatic aortic rupture
7	Malmö	17	M	Nil	Traumatic aortic rupture

Table 2.

Patient	Aortic proximal neck diameter (mm)	Stent-graft	Stent-graft dimensions (mm)	LSA occluded	Intra-operative complications
1	29	TAG	34x34x100	50% stenosis	Nil
2	20	Zenith	26x26x138	Yes	Nil
3	20	TAG	26x26	No	Nil
4	28	TAG	31x31x150	Yes	LCCA covered (manipulated distally with balloon)
5	27	TAG	31x31x150	Yes	Type II endoleak
6	21	TAG	26x26x100	No	Small proximal type I endoleak
7	20	TAG	28x28x150	Occluded on fist post-operative CT scan	Nil

LSA = left subclavian artery
LCCA = left common carotid artery
TAG = Gore TAG thoracic stent-graft
Stent-graft dimensions = proximal diameter, distal diameter and length

Table 3.

Patient	CT scan prior to collapse / findings	Time of presentation	Stent-graft related complication	Symptoms	Secondary intervention	Outcome (complications and death)
1	No	2 months	Structural collapse with infolding and multiple stent fractures	Chest pain	Stent-graft re-lining	Small persistent proximal type I endoleak. Represented 2 months later with sepsis and haematemesis. Died following open repair
2	Yes (6 days post-op)	10 days	Collapse with stent fracture, migration and thoracic aortic occlusion	Lower limb paraesthesia	Axillo-bifemoral graft	Died 36 hours post-op (multiple organ failure)
3	Yes (6 days post-op	1 month	Collapse and thoracic aortic occlusion	Chest and lower limb pain	Giant Palmaz stent	Renal failure, bowel resection and paraparesis
4	No	1 week	Collapse	Asymptomatic	CP giant stent	Uneventful
5	Yes Type II endoleak (1 day post-op)	3 months	Collapse and aneurysm growth	Asymptomatic	CP giant stent	Persistent small proximal type I endoleak
6	No	3 days	Collapse	Asymptomatic	Giant Palmaz stent	Uneventful
7	Yes (3 days post-op)	20 days	Collapse	Asymptomatic	Giant Palmaz stent	Ischaemic symptoms left arm (LSA occluded)

All CT scans showed evidence of poor stent-graft apposition in the aortic arch

Time of presentation – time elapsed after primary thoracic stent-graft deployed

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