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ORIGINAL ARTICLE

The short-to-midterm results of endovascular stent grafting for acute thoracic aortic diseases in Chinese patients

植入主動脈支架治療急性胸主動脈病變華籍患者的短期和中期結果

Objective. To review the results of endovascular treatment of acute thoracic aortic diseases in a group of Chinese patients.
Design. Retrospective study.
Setting. A tertiary referral hospital with a cardiothoracic surgery service.
Patients. All 15 patients presenting with acute thoracic aortic diseases between September 2001 and October 2005 inclusive, of whom eight had traumatic rupture, four had complicated acute dissections, two had mycotic aneurysms, and one an aneurysm with an aortobronchial fistula.
Interventions. Thoracic aortic stent grafting.
Main outcome measures. Immediate success, 6-month and 1-year survival rates.
Results. The median follow-up period was 20.6 months (range, 0-50.1 months). Stent grafts were deployed with immediate success in all patients. Two patients had ancillary bypass surgery for the supra-aortic branches. There were two in-hospital deaths. Four sustained access artery injury and needed graft repair. Computed tomography at 1 month showed complete thrombosis of the aneurysmal lumen or the thoracic aortic false lumen in 12 of 13 survivors. Computed tomography at 6 months showed complete thrombosis of the aneurysmal lumen or the false lumen in nine of 10 patients due for follow-up. Both 6-month and 1-year survival rates were 87%.
Conclusions. Thoracic aortic stent grafting for acute thoracic aortic disease is feasible and has a high success rate, with good short-to-midterm results. However, the large size of the stent graft introducer set imposes a high risk of access artery injury, for which further improvements are necessary.

目的：檢討以血管內治療法，處理華籍病人急性胸主動脈病變的結果。
設計：回顧性研究。
安排：設有心肺外科手術服務的專上轉介醫院。
患者：2001年9月至2005年10月期間15名急性胸主動脈病變患者；8人屬創傷性破裂，4人出現併發性急性斷裂，2人有真菌感染動脈瘤，1人有主動脈支氣管瘻動脈瘤。
治療：植入胸主動脈支架。
主要結果測量：術後即時成功率、術後6個月和1年的存活率。
結果：跟進期的中位數為20.6個月（介乎0至50.1個月）。所有主動脈支架植入手術均成功。2名病人在上主動脈分支進行輔助分流血管手術。2名病人在醫院死亡。4人因支架途經的動脈受損須作血管修復，及後康復。術後1個月的電腦掃描顯示，13名病人中有12人的動脈瘤腔（或胸主動脈假腔）完全栓塞。術後6個月的電腦掃描則顯示10名病人中有9人之動脈瘤腔完全栓塞。6個月和1年的存活率皆為87%。
結論：為急性胸主動脈病變患者進行主動脈支架植入手術是可行的，不但成功率高，而且達到良好的短期和中期效果。然而，主動脈支架導引器組體積較大，令動脈受傷的風險增加，這方面仍有待改良。

Introduction

Thoracic aortic stent grafts have been used to treat various thoracic aortic diseases, including acute diseases of thoracic aorta. The most common indications are traumatic rupture, complicated acute type B dissection, and impending rupture of a thoracic aortic aneurysm. Other less common though controversial indications include mycotic aneurysm and aorto-esophageal fistula. Although this is a heterogeneous group of indications, the basic principle is to seal off the leakage from the true lumen of the thoracic aorta via an endovascular communication. The preoperative clinical status in this group of patients is usually poor, and so their preoperative workup is often minimal. Thus, higher complication rates and poorer clinical outcomes are to be anticipated than in those having elective endovascular repair of thoracic aortic disease. Moreover, there are few studies in the English medical literature describing such interventions in Chinese patients. We therefore retrospectively reviewed our results in this patient group.

Methods

Our hospital does not require institutional review board approval for retrospective studies, so long as patient confidentiality is maintained. Relevant data were extracted from the records of all patients presenting to our hospital with acute thoracic aortic diseases from September 2001 to October 2005 in whom aortic stent grafts had been implanted. Each patient underwent preoperative contrast enhanced computed tomography (CT) for the diagnosis of the thoracic aortic disease, at least once. This enabled the diameter of the proximal and distal landing zones, and the diameter of the access artery to be measured. Computed tomography angiograms in different orthogonal planes were reconstructed for diameter and length measurement if the images were acquired by multidetector CT. Magnetic resonance angiogram (MRA) of the head and neck was performed if indicated, in order to reveal the status of cross circulation in the brain. Aortogram and selective angiogram of the aortic branches were performed in selected complex cases. Cardiac and the respiratory function were also assessed in some patients in whom endovascular repair was not performed immediately.

Covering one or more of the supra-aortic branches by the stent graft to gain more landing zone could potentially induce major neurological complications. If such an eventuality was anticipated, a preoperative bypass procedure was also performed at the same or separate session. The landing zones were classified according to their relationships with the supra-aortic branches[1] (Fig). The common femoral artery was exposed for vascular access. If the femoral artery was small, the external iliac artery, the common iliac artery or the lower abdominal aorta would be exposed. Immediate preoperative aortogram was performed with a diagnostic catheter via the femoral or left subclavian artery. The catheter from the left subclavian artery also acted
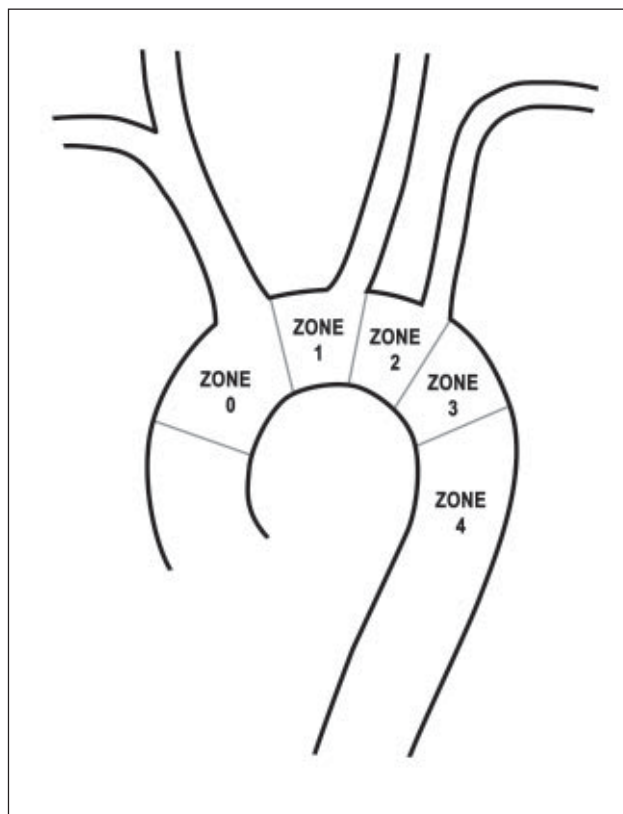

Fig. The schematic of the landing zone
Landing zone for the proximal end of the stent graft in the treatment of thoracic aortic diseases is shown: zone 0 is proximal to the left border of the innominate artery orifice; zone 1 is between zone 0 and the left border of the left common carotid artery; zone 2 is between zone 1 and the left border of the left subclavian artery; zone 3 is between zone 2 and 1.5 cm more distally; zone 4 is distal to zone 3

as a landmark for the origin of that artery. Commercially available aortic stent grafts were implanted. They were directly inserted from the common femoral or external iliac arteries, or via a Dacron graft connected to the common iliac artery or the abdominal aorta. Overlapping stent grafts were used if the length of coverage was long or if there was a large discrepancy in the diameter of the proximal and distal landing zones (ie whenever insertion of tapered grafts was deemed necessary). Balloon moulding of the proximal and distal stent in the stent graft was performed if the intra-operative angiogram showed a type I endoleak. In cases of dissection, only the proximal neck was moulded lightly. After the operation, contrast CT in the arterial and delayed phase was performed on a regular basis, so as to monitor the size of the aneurysm or false lumen and to detect any endoleak or other complications. Secondary interventional procedures were performed when indicated.

The complications of elective aortic stent grafting performed during the same period were compared with this group of patients. The means, standard deviations (SDs), and the medians of the continuous variables were calculated using the Statistical Package for the Social

Table. Relevant details about stent grafting and related procedures undertaken for patients with acute thoracic aortic diseases

Disease	No. of patients	Median interval between presentation and operation in the acute group (days)	Landing zones of the proximal end of the stent graft	Type of bypass procedure
Trauma	8	0.5	Zone 3 (n=8)	-
Dissection	4	3.5	Zone 1 (n=1) Zone 2 (n=1) Zone 3 (n=2)	Carotid-carotid bypass (n=1)
Aneurysm	1	10	Zone 3 (n=1)	-
Infective	2	33.5	Zone 0 (n=1) Zone 3 (n=1)	Total debranching of the supra-aortic branches and aorto-innominate-carotid bypass (n=1)

Sciences (Windows version 11.0; SPSS Inc, Chicago [IL], US). The Kaplan Meier method was used to calculate patient survival rates.

Results

From September 2001 to October 2005 inclusive , thoracic aortic stent grafts were implanted in 29 Chinese patients. There were 15 patients (9 males) with acute thoracic aortic diseases. Their mean age was 49 years (SD, 18 years). Eight had traumatic rupture of the thoracic aorta, four had acute type B dissections, two had mycotic aneurysms, and one an impending rupture of a thoracic aortic aneurysm presenting as an aortobronchial fistula. Three types of commercially available stent grafts were used: Talent from Medtronic AVE (Medtronic Vascular, Santa Rosa [CA], US; n=13); Valiant (replacing Talent, has better control and can be deployed much easier; n=1); Zenith TX1 from Cook (William Cook Europe, Bjaeverskov, Denmark; n=1). The median interval between the presentation of acute symptoms and the operation was 2 days (range, 0-44 days). The longest interval occurred in a patient with mycotic aneurysm of the aortic arch, who received 6 weeks of antibiotic treatment and monitored by regular CT imaging of the mycotic aneurysm before undergoing aorto-innominate, aorto-carotid bypasses, and stent grafting. Other details pertaining to each subgroup (classified according to cause) are summarised in the Table.

The technical success rate of endovascular repair was 100%. Intra-operative angiogram was used to check the immediate success of aneurysm or false lumen exclusion. Immediate complete exclusion was confirmed in 13 (87%) patients. The mean number of stent grafts used was 1.5 (SD, 0.92).

There were two intra-operative complications. One patient's proximal stent graft migrated causing occlusion of the left common carotid artery and a massive left cerebral infarct and later in-hospital death. This patient was operated on in the early phase of the stent graft programme. A Talent stent graft (diameter 42 mm, length 96 mm) had been used. The left common carotid artery was covered after the stent graft was fully deployed. A 7-mm wide, 4-cm long self-expandable metallic stent (SMART stent, Cordis Corporation, Miami [FL], US) was inserted retrogradely from the left common carotid artery, and passed through the covered orifice of the left common carotid artery and its patency immediately restored. However, massive cerebral infarction still occurred. The other patient had a distal tear of the dissection flap.

Femoral arteries were used for stent access in 12 patients, and in the remainder access was via the external iliac, a common iliac conduit, and an aortic conduit. Intimal dissection occurred in four (27%) patients, in whom graft or venous patch repairs were therefore performed.

In-hospital complications included one external iliac artery thrombosis and one delayed but temporary spinal cord ischaemia. External iliac artery thrombosis occurred 1 day after the operation in a patient with traumatic aortic rupture; thrombectomy re-established perfusion. Two days after stent grafting in a patient with acute dissection, spinal cord ischaemia (presenting with left lower limb hemiparesis and hemiparalysis) occurred. The patient recovered after spinal fluid drainage and elevation of the blood pressure. Only one stent graft (Talent stent graft, diameter 34 mm, length 115 mm) was implanted in this patient. The upper end of the covered stent was just distal to the left subclavian artery and its lower end above the T8 vertebral level.

There were two in-hospital deaths due to complicated acute dissections. One was in the patient with proximal stent migration resulting in massive left cerebral infarct. The other was in a patient who remained unconscious after the operation and very likely suffered from cerebral hypoxia. The operation was uncomplicated, except that transient perioperative hypotension may have resulted in hypoxia. Successful exclusion of the ruptured false lumen was confirmed by CT 1 day after the operation.

One-month contrast CTs showed thrombosis of the aneurysm or the thoracic aortic false lumen in 12 (92%) of the 13 surviving patients. There was one proximal type I endoleak in the aneurysm group, and one flap tear in the acute dissection group (which was re-operated on later). Six-month CT follow-ups were available in 10 patients; complete thrombosis of the aneurysmal (or false) lumen was

noted in nine (90%).

The patients were followed up for a median period of 20.6 months (range, 0-50.1 months). In the trauma and infective groups, all pseudoaneurysms remained thrombosed and were smaller or disappeared on follow-up. Two of the four patients with acute dissection died. The third patient (who had experienced transient spinal cord ischaemia) had complete thrombosis of the false lumen in the thoracic aorta but the abdominal aortic false lumen remained patent. The fourth patient (with a flap tear during the first operation) had two further stent grafts implanted 10 months later. Perfusion was still present in the thoracic aortic false lumen, though its size was smaller. The patient with impending rupture of the thoracic aneurysm had a proximal type I endoleak, despite the placement of a proximal extension cuff. His symptoms (haemoptysis, due to an aortobronchial fistula) resolved after stent grafting. He refused further intervention for the endoleak, for which a carotid-carotid bypass and proximal stent graft extension was offered. The 6-month and 1-year survival rates were both 87%.

Secondary interventions were performed in two patients. One had an acute flap tear after stent grafting, though the false lumen continued to expand after the procedure. His stent grafts were extended to the lower thoracic segment 10 months later. Whilst the thoracic aortic false lumen was smaller on follow-up, perfusion was still present. The second patient with aortobronchial fistula experienced a proximal type I endoleak, for which a proximal extension cuff was implanted 1 month after the initial procedure. However, the leak persisted, but the patient declined further intervention.

During the same period (September 2001 to October 2005), we had also performed aortic stent grafting for 14 patients as elective procedures. Intra-operative death occurred in one patient with an arch aneurysm, who died of myocardial infarct after total debranching of the supra-aortic branches as well as aorto-innominate, and carotid bypasses. Severe intimal dissections resulting from the procedure occurred in eight of these electively operated patients, for whom graft repairs or venous patch repairs were performed. Although there was a higher tendency for femoral dissection in those who were electively operated, the incidence of complications in the acutely and electively operated groups was comparable (P=0.14).

One of the electively treated patients with arch aneurysm had right toe gangrene after total debranching surgery, bypass, and stent grafting. Most likely the gangrene was due to distal embolisation, but amputation was not necessary. No patient had spinal cord ischaemia after stenting.

Discussion

Commercially available aortic stent grafts have been used in the treatment of thoracic aortic diseases for over 10 years and are associated with lower morbidity and mortality than open surgery.[2-22] Multicentre registry results[23] and meta-analyses also support their effectiveness in the short and medium term.[24,25] However, few papers in the literature describe the results in Chinese patients, especially for the acute thoracic aortic diseases. Our results for treating traumatic rupture of the aorta with stent grafts has been reported.[26] Since then, we accumulated more experience in the use of these grafts for the treatment of thoracic aortic diseases, both in the acute and non-acute settings. We compared our result with the EUROSTAR-UK registries[23] and the two published meta-analyses.[24,25] Papers published after 2000 and recruiting more than 50 patients in their series were also reviewed.[4,9,10,14,15,20] Not all papers analysed the acute and non-acute results separately. Our technical success rates for acute grafting was 100%, whereas Eggebrecht et al[25] reported that the procedural success rates in their acute group was 93.4%.

Other than endoleak and access artery injuries, four of the patients in the present study encountered major complications (27%), all in the acute dissection subgroup. Complication rates reported by others were: 7.7% by Orend et al,[9] 14.5% by Eggebrecht et al,[25] and 12% (3 of 25 urgent cases) by Bell et al.[10] The EUROSTAR-UK registries report[23] did not detail such data.

Spinal ischaemia and stroke are the two major neurological complications following interventions to treat thoracic aortic diseases. In the meta-analysis by Sayed and Thompson,[24] the overall paraparesis rate was 0.7% and the overall paraplegia rate 1.3%. Factors that may increase the risk of neurological sequelae include long-segment thoracic aortic disease and concomitant or previous abdominal or thoracic aortic replacement. The overall stroke rate was 1.7%. In the meta-analysis of aortic dissection by Eggebrecht et al,[25] the overall paraplegia and stroke rates (mean±SD) were 0.8±0.4%, and 1.9±0.6%, respectively. In acute dissection, the paraplegia rate was 0.9±0.6%, and the stroke rate was 1.1%±0.7%. In the EUROSTAR-UK registries,[23] the overall paraplegia rate was 4% in patients with degenerative aneurysms and 0.8% in those with aortic dissection. In acute dissection, the paraplegia rate was 2.2%. In traumatic rupture, the neurological complication rate was 6%; one third of these were strokes. The rates for paraplegia and stroke detailed in these papers ranged from 0 to 4%. Our rates were higher, being 7% (1/15) for spinal cord ischaemic and 13% (2/15) for stroke.

The access artery complication rate of 27% (4/15) in the present study was higher than that quoted by others (3.8% in the meta-analysis by Eggebrecht et al,[25] and only 2.4% in the EUROSTAR registries[23]). Femoral artery injury is caused by the difference in size between the femoral artery and the sheath of the stent graft. In the Chinese population, the general body built and the

diameter of the femoral artery are smaller. It is not uncommon to see a common femoral artery lumen of less than 8 mm diameter, while the outer diameter of the stent graft sheaths ranged from 7.3 to 8.7 mm (22 to 26 French [F]). In our usual practice, when CT shows that the diameter of the femoral artery lumen is bigger than the stent graft sheath size or is slightly smaller, we will expose the femoral artery and assess the artery intra-operatively. In case of doubt, we will use a 22-F or 24-F dilator to test the lumen. This manoeuvre is especially useful in patients who may be in shock, when the arteries appear small in CT, or there is vasoconstriction. If access to the artery is too tight, we will expose the external iliac or common iliac artery for access. Routinely exposing the iliac artery for borderline small femoral arteries imposes a risk of other complications. To avoid these, the delivery system should be improved, by using stents with smaller outer diameters and improved outer coatings to reduce friction.

The 30-day mortality in our series was 13% (2/15). In the EUROSTAR-UK registries,[23] the rate for the acute group was 18.3%, and in the meta-analysis by Eggebrecht et al[25] on aortic dissection, it was 9.8%. The rate was 15.4% and 16% in the series described by Orend et al,[9] and Bell et al,[10] respectively. Sayed and Thompson[24] did not quote the 30-day mortality; but their total mortality was 14.3%. Even though they used a less invasive method of treatment, the high mortality rate in their series could be explained by the poor general condition of their patients.

In our series, there was a much higher rate of major complications and mortality in the acute dissection group. This was likely related to our use of stent grafts to treat only complicated cases of acute dissection, with either frank or impending rupture of the false lumen. This was also reflected in other reports; mortality reached 63.6% in ruptured thoracic aortic dissection,[27,28] whilst it was much lower in non-ruptured dissection.[16,29]

The 1-year survival in our series was 87%, which is nevertheless a short follow-up period. In the meta-analysis by Eggebrecht et al,[25] the 1-year survival rate was 88% for the acute group.

Major drawbacks in our study are its retrospective design and small sample size, and our 15 patients were subject to high degree of selection bias; For example, the eight patients with traumatic rupture all had good results. However, aortic stent grafting was avoided for patients who were critically ill because of other severe concomitant injuries.

Similar results have been reported in other (mostly retrospective) studies.[11,13,17] Though stent grafting seems to yield better outcomes than surgery for aortic rupture, it is difficult to conduct any randomised controlled trial to confirm such an impression in this particular clinical setting. Similarly in patients with type B acute dissection, we only

treated complicated cases, which may explain the high incidence of complications.

Recently, there was a multicentre trial using aortic stent graft versus medication alone for the treatment of uncomplicated type B dissection.[30] This paper may have an important bearing on the role of stent grafting in this condition, especially for uncomplicated cases. If thrombosis is induced in the false lumen during the early phase, then there is no need to treat an enlarged false lumen in the chronic stage; stent grafting appears to have a lower incidence of complete false lumen thrombosis and shrinkage.

The role of aortic stent graft for the treatment of aortic aneurysm and mycotic aneurysm has been widely discussed. We worked according to similar principles.[31-33] When compared with our electively treated group during the same period, the overall complication rate was similar. However, the spectrum of causes differed and a simple comparison is unlikely to yield useful information.

Stent grafts have been used for the treatment of thoracic aortic diseases for just over 10 years, so the long-term results are not fully known. Rare delayed complications that have been reported include: hypertension in young patients,[34] aorto-esophageal fistula, aortobronchial fistula,[35-37] and fracture of the metallic wire.[19,38] Our group of patients will clearly need long-term follow-up.

In conclusion, we have shown that thoracic aortic stent grafting is feasible in the Chinese population and has a high success rate in selected patients in the acute setting. The short-term results are good, despite a relatively high complication rate in patients with complex acute dissections. The large size of the stent graft introducer set imposes a major risk of access artery injury in the relatively small vessels of Chinese patients. Further improvement in the design of the set for local patients may reduce such access artery injury.

Declaration

Acknowledgement

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