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Favorable Early Outcomes for Patients with Extended Indications for Thoracic Endografting

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ABSTRACT

Background: Endografts originally designed and approved for the treatment of thoracic aortic aneurysms have rapidly been adopted for nonapproved use in the treatment of disorders of the thoracic aorta, including aortic transection, dissection, pseudoaneurysms, and thoracoabdominal aneurysms. The purpose of this study was to evaluate the early outcomes of patients treated with thoracic endografts for nonapproved indications at our institution.

Methods: The medical records of patients undergoing thoracic endografting at our institution from August 2005 until March 2008 were reviewed. Patients undergoing endografting for uncomplicated thoracic aortic aneurysms were excluded. The outcomes of patients with extended indications for thoracic endografting were studied.

Results: During the study period, endografting was performed in 31 patients for nonapproved aortic conditions. Patients underwent endografting for a spectrum of indications, including aortic transection (n = 12), complications of type B aortic dissection including rupture (n = 9), thoracoabdominal aneurysm with visceral debranching (n = 6), aortic arch debranching (n = 2), and pseudoaneurysm associated with prior coarctation repair (n = 2). Early outcomes were favorable. All patients had successful endograft repair of their anatomic lesion. There were no endoleaks. There was no hospital mortality. Average hospitalization was 15 days for patients with aortic transection and 9 days for all other patients.

Conclusions: Thoracic endografts are versatile devices that with appropriate expertise can be used effectively to treat a spectrum of disorders of the thoracic aorta, including acute emergencies. Early outcomes of patients with extended indications for thoracic endografting compare favorably to published series of patients treated with open procedures. Further study is required to assess the long-term efficacy of these devices.

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INTRODUCTION

Disorders of the descending thoracic aorta, including aneurysms, pseudoaneurysms, traumatic transections, and type B dissections, remain clinically challenging. Patients with these conditions frequently present acutely with life-threatening complications, such as hemorrhage and malperfusion syndromes [Johansson 1995; Coady 1999]. The treatment of these disorders is complex, with high rates of morbidity, mortality, and surgical procedures. Early mortality rates for open repair of complicated type B aortic dissections have been reported to be as high as 57% [Fann 1990; Glower 1990; Fann 1995; Schor 1996; Safi 1998; Elefteriades 1999; Lansman 2002; Umana 2002]. Operative mortality rates for open repair of aortic transection have ranged from 0% to 54%, with the incidence of paraplegia ranging from 0% to 36% [von Oppell 1994; Fabian 1997; Gammie 1998; Moainie 2008].

Vascular endografts suitable for delivery into the thoracic aorta have been developed during the past several years, leading to the approval of devices for the endovascular treatment of descending thoracic aortic aneurysms [Makaroun 2005; Hassoun 2006; Fairman 2008]. The early and midterm outcomes of endografting for the treatment of descending thoracic aortic aneurysms has been encouraging [Makaroun 2005; Hoornweg 2006; Wheatley 2006; Bavaria 2007; Fairman 2008]. This early success has encouraged the use of endografting techniques for nonapproved indications, including pseudoaneurysms, transections, and type B dissections [Orend 2002; Umana 2002; Orford 2003; Hoornweg 2006;Wheatley 2006; Kaufman 2007; Szeto 2008]. The purpose of this study was to evaluate the early outcomes of patients treated at our institution with endografting techniques for nonapproved, extended conditions of the thoracic aorta.

MATERIALS AND METHODS

This study was approved by the institutional review board at Oregon Health and Science University. Individual consent was waived.

Demographic and clinical data from all patients undergoing cardiovascular surgical procedures at our institution were prospectively entered into a database. In the period from April 2005 to April 2008, 31 of these patients underwent thoracic

Table 1. Preoperative Characteristics of Patients Undergoing Thoracic Endografting for Extended Indications

Extended Indication for Endografting	Pseudoaneurysm	Acute Type B Aortic Dissection	Aortic Transection	Aortic Arch or Thoracoabdominal Aneurysm
Number of patients	2	9	12	8
Age range, y	25-33	48-89	13-78	44-75
Mean age, y	29	70	40	64
Sex				
Male	100%	67%	50%	62%
Prior operation	100%	0%	8%	50%
Comorbidities				
Multisystem trauma	0%	0%	100%	0%
Hypertension	50%	11%	8%	50%
Coronary artery disease	0%	0%	25%	0%
Atrial fibrillation	0%	0%	8%	12%
Chronic obstructive pulmonary disease	0%	11%	8%	25%
Chronic renal insufficiency	0%	0%	8%	12%
Peripheral vascular disease	0%	11%	8%	25%
Congenital heart disease	100%	0%	0%	0%
Indication for stent grafting				
Pseudoaneurysm	100%	0%	0%	0%
Malperfusion	0%	11%	0%	0%
Rupture with hemothorax	0%	89%	0%	0%
Transection	0%	0%	100%	0%
Aortic arch aneurysm	0%	0%	0%	25%
Thoracoabdominal aneurysm	0%	0%	0%	75%
Status				
Elective	0%	0%	0%	88%
Urgent	100%	11%	0%	12%
Emergent	0%	89%	100%	0%

endografting for the nonapproved indications of pseudoaneurysm, transection, type B dissection, and arch or visceral debranching. Patients undergoing endografting for uncomplicated thoracic aortic aneurysms were excluded from the study. The demographic and clinical information for the 31 patients was recorded and grouped by diagnosis for analysis.

All endovascular procedures were performed while patients were under general anesthesia in an angiographic operating suite with fixed fluoroscopic equipment. To minimize endograft collapse, upsizing in all procedures was limited to 3 to 4 mm (<15%).

RESULTS

Preoperative Characteristics

Thoracic aortic endografting for nonapproved aortic conditions was performed in 31 patients during the study period. The preoperative characteristics of these patients are summarized in Table 1. The conditions for which endografting was performed were pseudoaneurysm, traumatic transection of the descending thoracic aorta, type B aortic dissection, and aortic arch and thoracoabdominal aneurysms, which were treated with arch and visceral debranching procedures, respectively.

The 2 patients who underwent endografting for pseudoaneurysm were both young men (ages 25 and 33 years) who had a history of aortic coarctation with prior open repair. These patients presented with large symptomatic pseudoaneurysms but otherwise had uncomplicated past medical histories. Endografting was preferred to open repair in both of these patients because of the history of prior surgery and a desire to avoid redo thoracotomy in the setting of a large pseudoaneurysm.

Patients undergoing endografting for type B aortic dissection all presented acutely. This group had the oldest mean age at 70 years. The most common immediate indication for

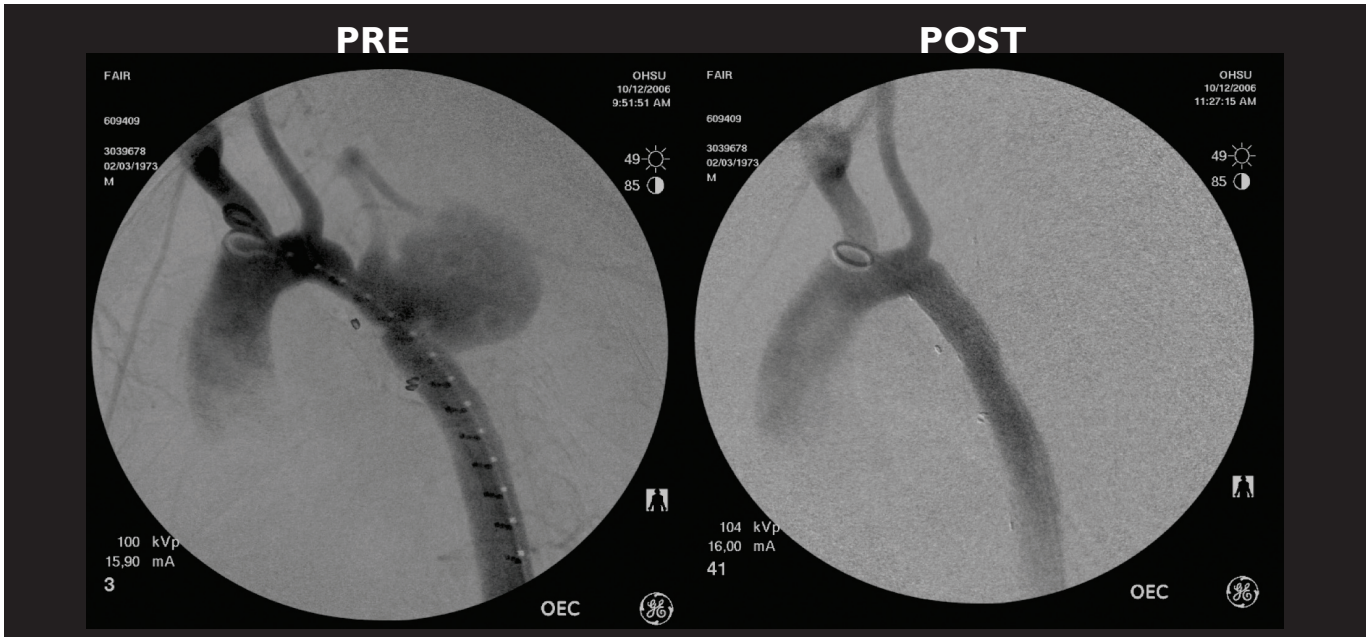

Figure 1. Representative images before (Pre) and after (Post) endovascular repair of aortic pseudoaneurysm, which was performed in 2 patients (mean age 29 years); 100% of patients had congenital heart disease, 50% had hypertension, and 100% had undergone prior surgery.

endografting in this group was rupture with hemothorax. All of these patients were treated emergently. One patient had visceral malperfusion and underwent urgent endgrafting.

During the study period thoracic endografting was used as front-line therapy for traumatic aortic transection at our institution. The average age of patients in this group was 40 years, but the ages varied widely, from 13 to 78 years. Patients with traumatic aortic transection all presented with complex constellations of multisystem trauma, including closed head injury, lung contusion, intraabdominal organ injuries, pelvic fractures, and extremity injuries. All patients with aortic transection were treated emergently.

Eight patients with aortic arch or thoracoabdominal aneurysms were treated with debranching procedures during the study period. The mean age for these patients was 64 years, and these procedures were performed prophylactically for the treatment of enlarging aneurysms. This group had the highest incidence of medical comorbidities, including hypertension (50%), chronic obstructive pulmonary disease (25%), and peripheral vascular disease (25%). This group also had a high incidence of prior aortic procedures (50%).

Intraoperative Details

The intraoperative details of thoracic endografting procedures performed for extended indications in this series are summarized in Table 2.

In 2 patients treated for pseudoaneurysm, Gore iliac limbs (16 mm × 18 mm × 95 mm and 16 mm × 20 mm × 95 mm) were used because of considerations of aortic diameter. In both cases, the left subclavian artery was covered because of the proximity of this arterial branch to the prior coarctation repair. Percutaneous access was available by femoral artery closure with a Perclose device (Abbott Laboratories; Abbott Park, IL, USA) in 1 patient, and the other patient required an iliac artery cutdown. Both procedures were successful acutely, with no endoleaks or device collapse at the time of operation or at discharge (Figure 1).

The majority of patients treated for type B aortic dissection received a device designed for deployment in the thoracic aorta. Device sizing ranged from 31 mm × 150 mm to 37 mm × 200 mm. Percutaneous access was available in a majority of patients, and femoral and iliac artery cutdowns were required in 4 patients. All procedures were successful acutely, with no endoleaks or device collapse at the time of operation or at discharge (Figure 2). Because of aortic diameter considerations, abdominal devices such as Zenith abdominal aortic cuffs (Cook Medical, Bloomington, IN, USA) were frequently used in patients treated for aortic transection. The left subclavian was covered in 17% of the cases. Sizes of devices ranged from 28 mm × 100 mm to 24 mm × 55 mm. Aortic cuff size averaged 31 mm × 40 mm. Five patients required 2 devices for adequate coverage, and 1 patient required 3 devices (22 mm × 55 mm). Percutaneous access was available in 92% of patients. All procedures were successful acutely, with no endoleaks or device collapse at the time of operation or at discharge (Figure 3).

The 8 patients treated for aortic arch or thoracoabdominal aneurysms were treated with a device designed for deployment in the thoracic aorta. Coverage of the left subclavian artery was necessary in 25% of the cases. Sizes ranged from 26 mm × 100 mm to 40 mm × 200 mm. The majority of patients required only a single device. One patient required 2 devices and another required 3. Because of the need for visceral or arch vessel bypass, ready open access to the iliac

artery or ascending aorta was typically made available for all patients. All lesions in this series were successful acutely with no endoleaks detected at the time of operation or prior to discharge (Figures 4 and 5).

Postoperative Outcomes

There was no hospital mortality in this series of patients. One patient treated for type B aortic dissection developed unilateral lower-extremity weakness related to spinal cord ischemia. His symptoms resolved during the long-term follow-up period. The majority of patients treated for transection required prolonged ventilation because of their other traumatic injuries. The incidence of prolonged ventilation was lower in other patient groups. One patient who underwent an arch debranching procedure suffered an embolic stroke but had no residual neurologic symptoms at the time of his discharge. One patient who underwent visceral debranching required revision for thrombosis of a renal artery bypass graft. There were no vascular complications related to arterial access in this series. The majority of patients in this series were discharged to home. Because of their associated injuries aortic transection patients were discharged to skilled nursing facilities more frequently than patients in other groups.

Because of the contemporary nature of this series, medium-term follow-up imaging was not complete at the time of this report. Follow-up imaging has been performed for 18 of the 31 patients, with the duration of follow-up ranging from 223 to 444 days. The follow-up imaging results available at the time of this report were encouraging, with 100% of endovascular repairs intact with no endoleaks.

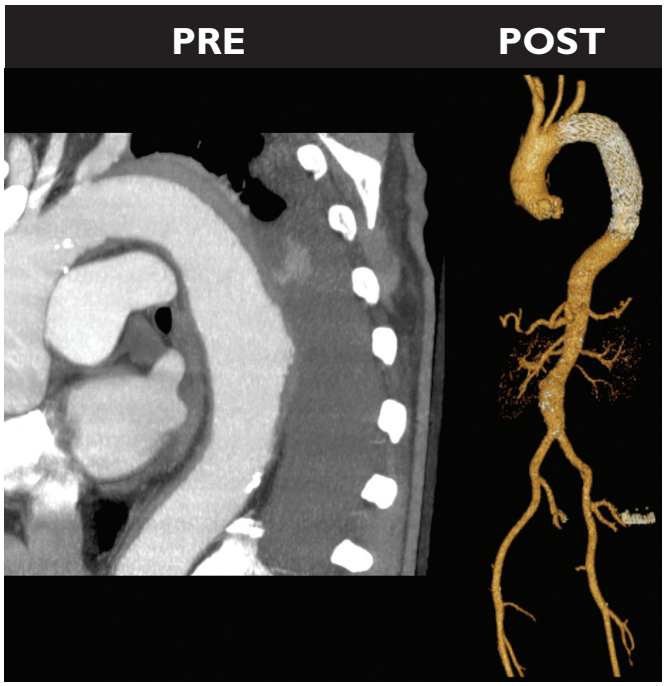

Figure 2. Representative images before (Pre) and after (Post) endovascular repair of type B aortic dissection, which was performed in 9 patients with (mean age 70 years); 89% had aortic rupture with hemothorax, and none had a prior operation.

DISCUSSION

Thoracic endografts approved for the treatment of thoracic aortic aneurysms have been available in the United States since 2005. Since the development of these endografts and the proliferation of other vascular endoprostheses on the marketplace, endovascular techniques have rapidly been extended to the treatment of nonapproved conditions of the thoracic aorta, such as type B aortic dissection and transection. The purpose of this study was to assess the early outcomes of patients with extended indications for thoracic endografting at our institution.

Table 2. Intraoperative Details of Thoracic Endografting Procedures Performed for Extended Indications

Extended Indication for Endografting	Pseudoaneurysm	Acute Type B Aortic Dissection	Aortic Transection	Aortic Arch or Thoracoabdominal Aneurysm
Arterial access				
Percutaneous	50%	55%	92%	12%
Femoral artery cutdown	0%	22%	8%	12%
Iliac artery cutdown	50%	22%	0%	50%
Ascending aorta	0%	0%	0%	25%
Device				
Gore iliac limb	100%	0%	0%	0%
Gore TAG	0%	89%	42%	100%
Zenith aortic cuff	0%	11%	58%	0%
Left subclavian artery covered	100%	11%	17%	25%
Acute procedural success	100%	100%	100%	100%
Endoleak	0%	0%	0%	0%

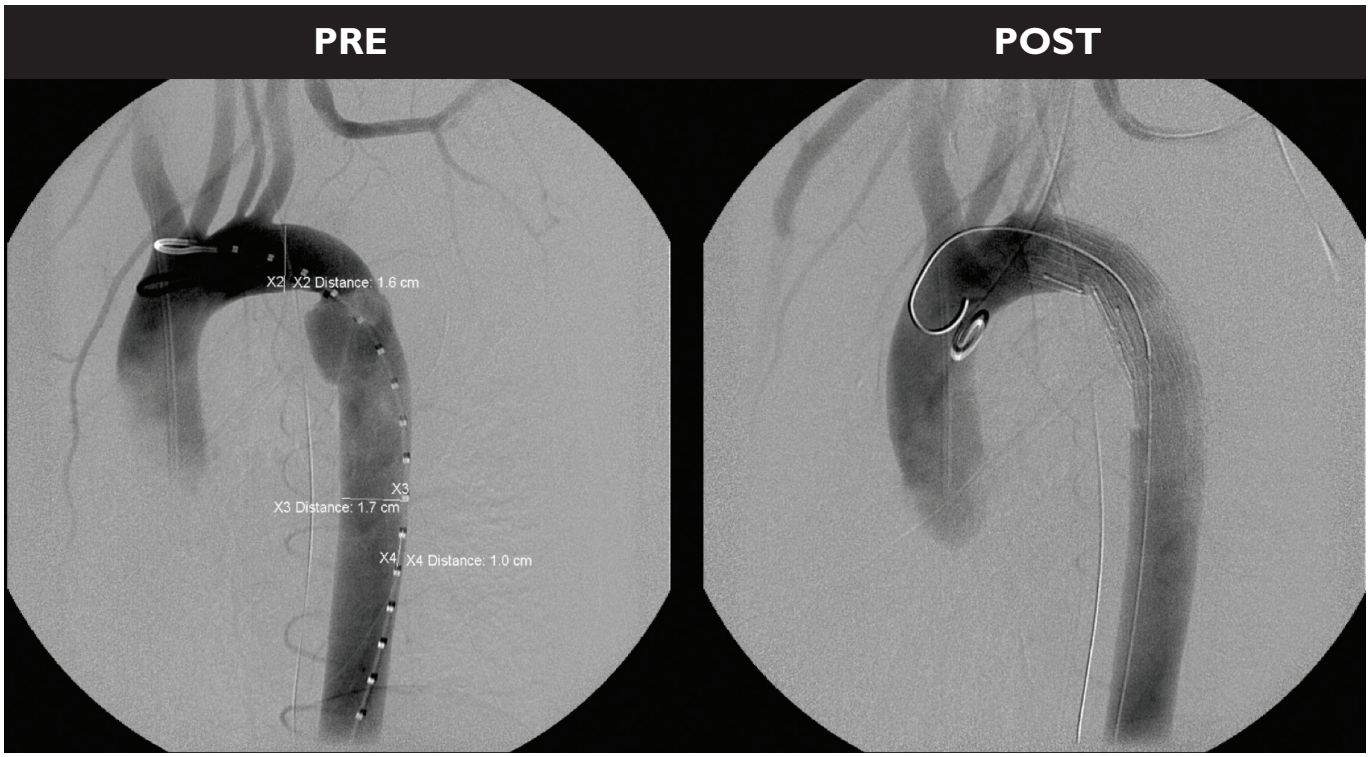

Figure 3. Representative images before (Pre) and after (Post) endovascular repair of traumatic aortic transaction, which was performed in 12 patients (mean age 40 years); 100% had multisystem trauma, and 0% had prior operation.

Table 3. Postoperative Outcomes of Patients Undergoing Thoracic Endografting for Extended Indications

	Extended Indication for Endografting			
	Pseudoaneurysm	Acute Type B Aortic Dissection	Aortic Transection	Aortic Arch or Thoracoabdominal Aneurysm
Mortality	0%	0%	0%	0%
Complications				
Cerebrovascular accident	0%	0%	0%	12%
Spinal cord ischemia/paralysis	0%	11%	0%	0%
Prolonged ventilation	0%	33%	92%	25%
Renal failure	0%	0%	0%	12%
Vascular	0%	0%	0%	12%
Length of stay, d	7	10	17	18
Disposition				
Home	100%	78%	58%	75%
Skilled-nursing facility	0%	22%	42%	25%
Follow-up				
Medium-term follow-up available	50%	44%	42%	100%
Mean length of follow-up, d	223	444	433	400
Intact repair	100%	100%	100%	100%

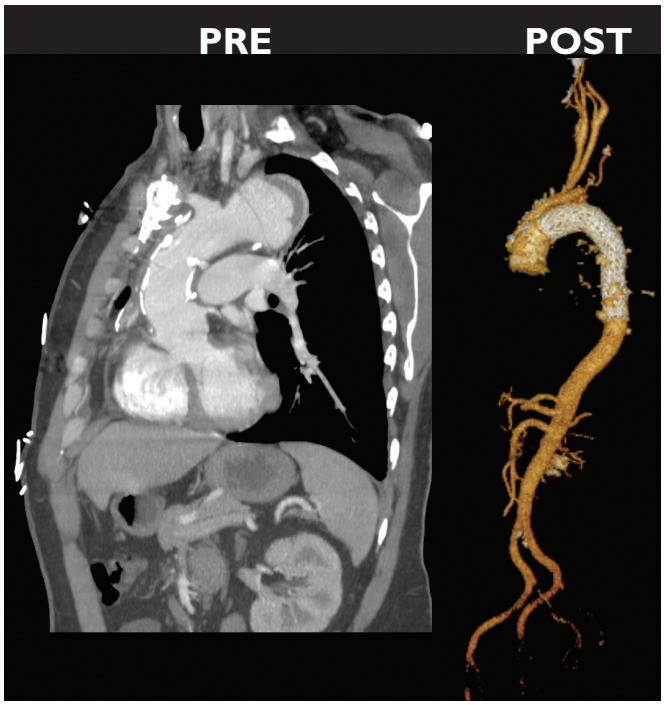

Figure 4. Representative images before (Pre) and after (Post) endovascular repair of aortic arch aneurysm, which was performed in 2 patients (mean age 56 years); 100% of patients had comorbidities, and 100% had prior operation.

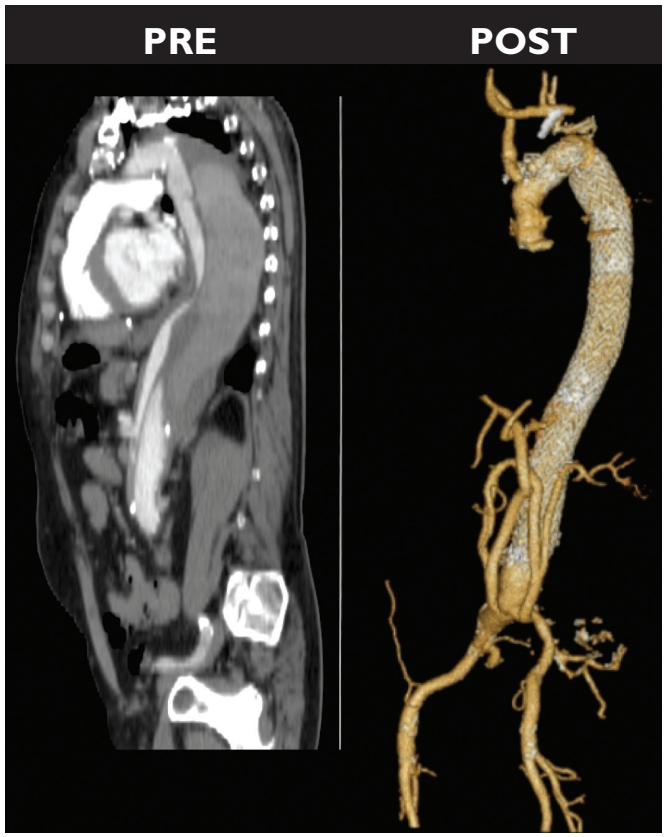

Figure 5. Representative images before (Pre) and after (Post) endovascular repair of thoracoabdominal aneurysm, which was performed in 6 patients (mean age 64 years); 83% of patients had comorbidities, and 66% had prior operation.

Early procedural outcomes in this series were excellent. All patients had successful repair of their thoracic aortic lesion with the endografting procedure. Many procedures were performed percutaneously, without the need for femoral artery cutdown or other access procedure. Early clinical outcomes were also encouraging. There was no mortality, and the frequency of complications, including neurologic complications, was low. The historical morbidity and mortality associated with open repair of type B aortic dissection are particularly high, with reported mortality in the 25% to 57% range [Fann 1990; Glower 1990; Fann 1995; Schor 1996; Safi 1998; Lansman 2002; Umana 2002; Elefteriades 2005]. These early clinical outcomes compare favorably to the reported outcomes for open procedures and are consistent with other recent case series on early outcomes for thoracic endograft procedures [Orend 2002; Umana 2002; Orford 2003; Hoornweg 2006; Wheatley 2006; Kaufman 2007; Szeto 2008].

Limitations of the study include the fact that it is a retrospective analysis, a design with the potential to introduce bias, and that medium-term follow-up is incomplete in this series. Not all patients received a computed tomographic scab during the follow-up period, so it is impossible to compare findings in patients who undergo complete follow-up studies and those who did not. However, the available serial imaging on those patients who had completed follow-up studies at the time of this report is encouraging. All follow-up imaging to date has demonstrated intact endograft repairs. The high rate of procedural success is likely related to the nature of the aortic lesions treated. Treatment of pseudoaneurysm, dissection, and transection required a relatively small segment of aorta to be covered by the endograft to exclude an intimal disruption, in contrast to treatment of thoracic aneurysms, which requires larger areas of aorta to be excluded. Patients undergoing debranching procedures benefited from relatively long landing zones, which also made the endografting procedure more likely to be successful.

Long-term follow-up is necessary to validate this approach and rule out late complications, including aortic wall perforation and pseudocoarctation syndrome, among the various patient groups. Because long-term results with these devices have not been exhaustively examined, prudent patient selection and diligent follow-up is required. We have been sufficiently encouraged by our early results with thoracic endografting for extended indications to continue its use in select patients. Currently, we consider thoracic endografting to be first-line therapy for patients presenting to our institution with pseudoaneurysm, aortic transection, and complications arising from acute type B aortic dissection. We reserve thoracic endografting debranching procedures for patients with aortic arch and thoracoabdominal aneurysms who are poor candidates for open repair because of comorbidities, including prior aortic surgery.

It is important to inform patients about the advantages and disadvantages, risks, and alternatives with regard to thoracic endografting in the treatment of conditions that are not approved indications. Informed consent for procedures was obtained from all patients in this study. Specific outcomes such as the reduced need for blood transfusion, the avoidance of thoracotomy, and the potential for reduced length of stay provide strong support for the use of thoracic endografting in patients presenting without contraindications.

The procedures in this study were performed by experienced practitioners, and the results may not be representative of typical practice. Careful patient selection and sufficient surgeon training and experience with these procedures and devices are essential in considering the application of these technologies to the extended indications investigated.

There are currently 3 approved devices for thoracic endografting, including the original Gore TAG device (W.L. Gore & Associates, Inc., Flagstaff, AZ, USA), approved in 2005, the Talent™ Thoracic Stent Graft (Medtronic, Inc., Minneapolis, MN, USA), and the Zenith TX2 Thoracic TAA endovascular graft (Cook Medical, Bloomington, IN, USA), both approved in 2008. In addition, a wider array of device sizes is now available for the treatment of thoracic aneurysm. For the nonaneurysmal aorta, however, there is still a need for endoprostheses of appropriate size mounted on delivery systems long enough for deployment in the thoracic aorta. As these are developed and long-term studies are completed, the number of patients who may benefit from endografting will expand considerably beyond those with thoracic aortic aneurysms.

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