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THE THORACIC AORTA:



The Next Frontier in Endovascular Therapy

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THE THORACIC AORTA: The Next Frontier in Endovascular Therapy

As endovascular techniques continue to undergo development and refinement, researchers are exploring new applications of endovascular therapy. Until recently, the only treatment options for thoracic aortic aneurysms (TAAs) were surgical repair or medical management. There is increasing evidence that endovascular therapy will have utility in treating thoracic aortic disease, with the possibility that it will become the preferred approach.

Many researchers are exploring and defining the role of endovascular techniques in the treatment of thoracic aortic disease. This educational supplement to *Endovascular Today* includes detailed articles that address specific TAA challenges: Ronald M. Fairman, MD, presents data from clinical trials that support the use of stent grafts to treat TAAs; Frank J. Criado, MD, et al explore the utility of stent graft intervention to treat a variety of morphologies relating to TAAs; Manish Mehta, MD, et al present a case report that outlines the successful use of endovascular techniques to treat a ruptured thoracic ulcer; and Christoph A. Nienaber, MD, et al discuss the use of endovascular techniques to treat acute aortic

This supplement was designed to assist endovascular specialists when considering treatment for patients with thoracic aortic disease.

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Stent Grafting in the Thoracic Aorta

An evaluation of the Medtronic Talent Thoracic Stent Graft System for the treatment of thoracic aortic aneurysms.

BY RONALD M. FAIRMAN, MD

or the past several years, endovascular specialists have been gaining experience with stent grafts designed to treat abdominal aortic aneurysms (AAAs). When compared to conventional open repair, the endovascular approach has clearly been demonstrated to result in reduced 30-day morbidity, equivalent 30-day and 12-month survival and treatment success, less use of general anesthesia, less procedure time, less blood loss and use of blood products, and decreased length of stay with more rapid return to baseline level of function. Alternatively, endovascular repair has been associated with a reintervention rate that approximates 11% at 1 year compared to 2% to 3% for open repair.

There is no debate that for the elderly debilitated patient who has a large AAA and multiple serious comorbidities, the endovascular approach is the procedure of choice. As compelling as this therapy may be for elderly patients with large AAAs, the need for endovascular approaches to treat thoracic aortic pathology is paramount. Although thoracic aortic aneurysms (TAAs) are less common than AAAs, the detection of TAAs and dissections is increasing, possibly due to increased prevalence, increased patient access to sophisticated imaging techniques, as well as an aging population. The natural history of TAAs is progressive enlargement and rupture, with >70% of untreated patients dying within 5 years. Page 14.

Standard surgical technique mandates thoracotomy, resection, and replacement with a polyester graft. The operative morbidity is formidable and includes renal and visceral ischemia, reperfusion injury, paraplegia, marked blood loss, acidosis, and coagulopathy, as well as cardiac ischemia and pulmonary failure. Despite these technical challenges, the operative mortality is low at approximately 15% when performed by experienced surgeons in relatively low-risk patients. The operative mortality, when coupled with multiple comorbidities such as advanced age, may rise as high as 50%. It is important to appreciate, and also rather discouraging that, in the thoracic aorta, a technically superb procedure may not correlate with favorable outcome. These





Figure 1. The lower thoracic aorta is often not vertical, and may, in fact, assume a horizontal course just above the diaphragm. Tracking 24-F to 25-F delivery systems through this tortuous anatomy is challenging. These two axial CT angiographic images demonstrate this feature.

operative procedures involve substantial manpower issues both intraoperatively and postoperatively; as a result, the cases tend to be referred to regional centers of excellence.

For these reasons, many patients with TAAs are, in fact, managed with benign neglect. Less-invasive innovative endovascular approaches to diseases of the thoracic aorta are likely to have an even greater impact on outcome than in the abdominal aorta. It is important to recognize the variety of thoracic lesions that might be amenable to this strategy, including fusiform and saccular aneurysms, acute and chronic dissections, traumatic transections or disruptions with pseudoaneurysms, and acute aortic syndromes such as penetrating ulcers, intramural hematoma, aortopulmonary fistula, and aortic rupture. Many of these lesions may be found in the proximal descending thoracic aorta or just distal to the left subclavian artery.

STENT GRAFTS

There is a critical need for a commercially available FDA-approved thoracic aortic endovascular device. The world-wide experience with endovascular techniques in the thoracic aorta has been growing since 1998, when Ehrlich et al⁴ reported their experience using the Talent Thoracic Stent

Graft System (Medtronic, Santa Rosa, CA) as an alternative to open surgical repair of TAAs in low-risk patients. The reported outcomes in the endovascular group were superior to the surgical group, including 30-day mortality (10% vs 31%), case duration (150 minutes vs 320 minutes), spinal cord injury (0% vs 12%), and intensive care unit stay (4 days vs 13 days). Eighty percent of patients developed complete thrombosis of the TAA, whereas 20% required reintervention and restenting for endoleak.

The safety and efficacy of the first-generation Talent stent graft to treat type B aortic dissection was prospectively evaluated by Nienaber et al in 1999. Stent graft treatment in this small series of patients resulted in no morbidity or mortality, whereas surgery was associated with 33% mortality and 42% morbidity. Stent graft insertion was successful in all patients with no endoleaks and no paraplegia.

More recently, Fattori et al⁶ reported their results in 70 patients who presented with a host of thoracic pathologies, including aortic dissection, intramural hemorrhage, degenerative and posttraumatic aneurysm, penetrating ulcer, and pseudoaneurysm. Complete aneurysm exclusion was achieved in 97% of the cases. There were no hospital deaths, and paraplegia was not observed. Late endoleaks occurred in 7% of patients, which was most often due to progressive aortic dilatation of aortic necks. Aortic disease-related mortality or conversion to surgery occurred in 9% of patients.

Technical approaches to treating thoracic aortic lesions in close proximity to the arch have been described by Hausegger et al, who reported a small series of patients who had intentional covering of the left subclavian artery without transposition. In long-term follow-up, no symptoms of left arm ischemia or neurologic deficits were encountered. It would seem prudent, however, to first assess contralateral vertebral artery patency before embarking on this approach. In addition, many of these patients may have undergone previous coronary revascularization, and it could be catastrophic if the subclavian artery was covered in the setting of a previous left internal mammary artery reconstruction.

Criado et al⁸ have recently reported successful "debranching" techniques to allow stent graft repair in the arch to treat pathology involving one or more branches of the aortic arch.

TRIALS

At the Hospital of the University of Pennsylvania, we were involved in the US IDE Phase I Talent Thoracic Stent Graft experience. Our results with both the first-generation Talent device, as well as the newer CoilTrac delivery system, have led us to several conclusions, which appear to be compatible with the broader experience. Endovascular repair in the thoracic aorta has its own learning curve, distinct from the





Figure 2. Saccular thoracic aortic aneurysm just distal to the left subclavian artery before deployment of the Talent stent graft (A). Postdeployment ateriogram reveals complete exclusion of the aneurysm (B).

abdominal aorta, and is not just a simple matter of placing a tube graft in a vertically oriented artery. The thoracic aorta frequently is quite elongated and tortuous and may commonly assume a horizontal course, actually crossing over to the right chest before entering the abdomen (Figure 1). Tracking 24-F or 25-F delivery systems is technically challenging, and controlled deployment in an angulated vessel is precarious. This is especially true of an angulated aortic arch (Figure 2). Conceptually, it is far more important to think of the thoracic aorta in three dimensions, compared to the abdominal aorta. One needs to carefully define arch anatomy. Adjunctive fluoroscopic maneuvers, including LAO projections, are routinely necessary to layout the aortic arch, whereas lateral projections are needed distally to prevent inadvertent coverage of the celiac artery (Figure 3).

Traditional ballooning techniques are not applicable in the thoracic aorta, especially when working in the arch. There can be no tolerance for air bubbles when flushing catheters or performing injections. Although we routinely oversize diameters when designing our abdominal aortic endografts, in the thoracic aorta, one needs to considerably oversize length measurements as well. Centerline measurements are crucial when designing thoracic endografts. It is essential that one understand exactly where the aneurysm begins in the thoracic aorta before proceeding to the operating room. It is difficult to judge the extent of the aneurysm from the intraoperative aortogram.

Surgically placed conduits are more often needed to gain access to the infrarenal aorta. We typically find that a 10-mm polyester graft sewn into the common iliac artery will allow a 24-F to 25-F delivery system to track over a stiff wire without difficulty. A greater proportion of our patients with thoracic aortic pathology are women (compared to our abdominal aortic population, in which most are men), and smaller iliac arteries are the norm. Our early experience with these first-generation devices required conduits to achieve access in 25% of our patients. If access arteries are

adequate, only one groin cutdown is necessary, and we frequently place our pigtail catheter from a percutaneous left brachial approach, a technique that has been popularized by Criado et al.⁸ The radiopaque pigtail catheter entering the arch from the left subclavian artery is a nice landmark and limits the need for repeated contrast injections.

There is no utility for short endografts when working in the thoracic aorta. Main sections as well as extensions should be longer, and one needs to trombone (overlap) modular junctions liberally. The caveat is to cover more rather than less of the thoracic aorta. Endoleaks are virtually all either proximal or distal attachment site (type I) or junctional (type III) in origin. Type II or collateral endoleaks appear less frequently in the thoracic aorta than was initially anticipated. Delayed or late endoleaks appear to be related to the dynamic nature of the thoracic aorta, which also supports the concept of covering more rather than less. One must always use current or recent imaging to design a thoracic stent graft. A 6-month-old angiogram may no longer be representative of the anatomy, especially with regard to the diameters of the proximal and distal landing zones.

We have not seen paraplegia in our experience to date, which totals approximately 75 cases. Alternatively, we are concerned about the potential for paraplegia when contemplating simultaneous thoracic and abdominal aortic procedures, as well as in patients who have undergone previous aneurysm repair.

The VALOR Trial is a prospective, nonrandomized, multicenter, consecutive IDE phase II study enrolling patients in three separate arms. The trial will be carried out at 35 clinical study sites in the US, and its objective is to determine whether the Talent Thoracic Stent Graft is a safe and effective method of treating thoracic aortic aneurysms. The test group (n=195 patients) will consist of patients diagnosed with a fusiform focal TAA and who are considered candidates for open surgical repair who are low-to-moderate risk per Society for Vascular Surgery criteria (SVS classification





Figure 3. Lateral views of the lower thoracic aorta are necessary to prevent inadvertent coverage of the celiac artery (black arrow).

0-2). The aneurysm must be located at least 20 mm distal to the left common carotid artery and 20 mm proximal to the celiac artery with distinct proximal and distal necks. Focal saccular aneurysms or penetrating atherosclerotic ulcers are also acceptable inclusion criteria. Proximal and distal aortic nonaneurysmal neck diameter measurements must be \geq 18 mm and \leq 42 mm.

The Registry arm (n=150) will include surgical candidates of low-to-moderate risk who have shorter proximal or distal neck lengths (<20 mm) and may, in addition, include cases of dissecting aneurysm, acute or chronic type B dissection, pseudoaneurysm, and stable but chronic traumatic injury. With regard to patients who present with acute or chronic type B dissection, there should be evidence of malperfusion or signs suggesting imminent aortic rupture.

The final arm of the study is the high-risk group (n=150) and includes patients who are at high risk for open repair (SVS classification 3) or who are nonsurgical candidates. In addition to the diagnoses listed previously, this arm includes patients with acute transection and contained rupture. Proximal and distal nonaneurysmal neck diameter measurements are limited to \geq 18 mm and \leq 42 mm in both the Registry and high-risk arms.

Enrollment in the high-risk arm has begun. This is a very ambitious clinical trial because it affords physicians the latitude to utilize endovascular approaches to treat a broad range of thoracic aortic pathology. In addition to testing the safety and efficacy of the Talent device specifically, it will no doubt advance our knowledge and understanding of the diseased thoracic aorta. The results will establish the utility of endovascular therapy using the second-generation CoilTrac Talent thoracic device.

Ronald M. Fairman, MD, is Chief of Vascular Surgery at the Hospital of the University of Pennsylvania and Associate Professor of Surgery and Radiology at the University of Pennsylvania in Philadelphia, Pennsylvania. He is Principal Investigator for the VALOR Trial and he has received research support from Medtronic. Dr. Fairman may be reached at ron.fairman@uphs.upenn.edu.

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The Talent Thoracic Stent Graft: A 6-Year Experience

This rapidly evolving new standard of care for treating aneurysmal disease and aortic dissection may prove to be the preferred treatment approach.

BY FRANK J. CRIADO, MD; CHRISTINE McKENDRICK, RN; KERRY MONAGHAN, BS; NANCY S. CLARK, MD; GREGORY S. DOMER, MD; AND HILDE JERIUS, MD

neurysms, dissections, and other thoracic aortic lesions—such as traumatic injury, penetrating ulcers, pseudoaneurysms, and intramural hematoma—occur with considerable frequency. The incidence is likely higher than previously estimated, and is especially true for thoracic aortic aneurysms (TAA). 1-3 Until recently, surgical reconstruction was the only possible treatment option. Such operative repairs carry substantial risks of serious complications and mortality, which have diminished only slightly in recent years despite significant advances in perioperative care and surgical techniques. 4-7 Endovascular stent graft repair is a truly innovative, less-invasive treatment modality that can offer hope where none existed before.

THE BALTIMORE TALENT THORACIC EXPERIENCE

One hundred fifty-six patients were referred for repair of thoracic aortic lesions during the 6-year period ending August 31, 2003. Thirty-one patients (20%) were excluded from consideration of endovascular treatment because of anticipated access failure related to small and/or diseased femoral-iliac arteries (n=10), or because of extensive

aneurysmal disease without identifiable fixation zones for endograft attachment and seal (n=21). Surgeons (cardiac or vascular) referred the majority of patients after ruling out operative intervention. One hundred twenty-five patients (80%) were accepted for stent graft intervention. Seventy-four had TAA (aneurysms, pseudoaneurysms, and penetrating ulcers), and 51 had type B aortic dissection (TBAD). Aneurysms were considered for repair when one or more of the following criteria were present: symptoms (pain),

or a sac with a maximum diameter measuring >5 cm or more than twice the diameter of an adjacent nonaneurysmal segment of the thoracic aorta. Only three treated TAA patients had aneurysms <6 cm (range, 4.8-12.5 cm; mean, 6.8 cm). Indications for stent graft intervention in TBAD cases included one or more of the following: continuing pain despite optimal medical management, evidence or suspicion of aortic branch and/or lower extremity ischemia (malperfusion), and hemothorax. Thirteen patients (25%) with TBAD treated with endograft repair had no clinical imperative for intervention.

THORACIC STENT GRAFT TECHNIQUES AND STRATEGIES

Stent graft placement for aneurysm exclusion was designed to cover the length of the lesion and extend (if possible) 20 mm proximally and distally. The strategy for treatment of TBAD involved endograft coverage of the entry site to redirect blood flow down the true lumen exclusively; it also extended 20 mm in either direction if anatomically possible. With evolving experience, more

extensive endograft coverage of the full length of the descending thoracic aorta (DTA) (to the level of the diaphragm) became the routine approach (Figure 1). Intravascular access (for 123 patients actually receiving an implant) was achieved by singlegroin femoral cutdown in 111 instances and a temporary iliac conduit in 12 (9.6%). A diagnostic pigtail catheter was used in all cases: transfemoral in 26 and transbrachial in 99 (79%). The device used on all patients was the Talent Thoracic Stent Graft System (Medtronic, Santa Rosa, CA), with

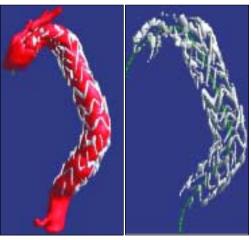


Figure 1. Typical extent of endograft coverage used today for most cases of acute TBAD.

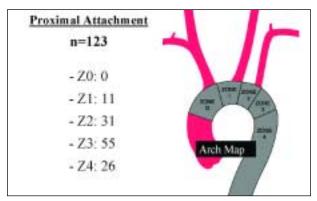


Figure 2. This Arch Map documents the proximal fixation site.

a 2- to 6-mm diameter oversize, and a proximal bare spring. Proximal endograft attachment was in the DTA more than 2 cm distal to the origin of the left subclavian artery (LSA) (zone 4) in 26 cases, within 2 cm of the LSA (the parasubclavian aorta) (zone 3) in 55 cases, and proximal to the LSA (zones 1 and 2) in 42 cases (Figure 2). The stent graft was placed over (occluding) the origin of the LSA (without revascularization) in 31 instances. Fourteen patients had preliminary adjunctive cervical operations designed to disconnect or revascularize the LSA and/or the left common carotid artery (LCCA) to enable stent graft placement in the more proximal aortic arch (Figures 3 and 4).

RESULTS

Two procedures (1.6%) were aborted because of access failure. Two patients experienced procedure-related iliac artery rupture, which proved to be fatal in one. Thirty-day mortality was 4.8% (n=6); all but one death occurred in the setting of a ruptured TAA or TABD. Five patients (4%) developed symptoms of spinal cord ischemia (paraplegia in two, paraparesis in two, and monoparesis in one). Neurologic deficits resolved in three patients; one patient was left with

a monoparesis affecting one leg. The fifth patient (with paraplegia) died after treatment of a ruptured TAA. There were no surgical conversions.

Twelve patients (9.6% overall, or 16% of TAA cases) were shown to have an endoleak on the 30-day contrast CT scan. They underwent further evaluation with catheter angiography, which demonstrated a type I (attachment site) or type III (junctional) endoleak in 10, and no contrast extravasation in two. There were no confirmed type II endoleaks.



Figure 3. Techniques of LSA disconnection/bypass: carotid-subclavian bypass + proximal (infravertebral) ligation of LSA (left) and subclavian-to-carotid transposition (right).

Ten patients (8%) underwent secondary intervention for endoleak treatment, consisting of placement of endograft extension in nine (successful in eight) (Figure 5) and coil embolization of endoleak nidus in one (successful). The remaining two patients with CT-detected but angiogramnegative endoleaks continue to be observed; the TAA sac has remained stable in both. Among the 51 cases of TBAD, the false lumen (FL) became completely thrombosed after stent graft placement in 34 of 46 (74%) patients who had a patent FL preoperatively, and only partially thrombosed in six additional patients. Preoperative thrombosis of the FL was noted in five patients.

Length of follow-up ranged from 1 to 70 months (mean, 35 months); six patients were lost to follow-up, and three withdrew from the study. Patient surveillance involved contrast/noncontrast CT scan and plain-film radiographs of the stent graft device within the first 30 days, at 6-month intervals for 2 years, and yearly thereafter. Eight deaths occurred during follow-up (2 to 28 months); five were unrelated to the device or aortic pathology, one was due to a ruptured TAA with a distal type I endoleak, and two were due to unknown causes.

DISCUSSION

Dake et al have led the way, accumulating one of the most impressive series. 8-11 Endovascular exclusion of TAA can be a straightforward procedure, especially for those aneurysms that begin more than 2 cm distal to the LSA. Aneurysms that involve the parasubclavian aorta or extend into the arch itself offer a much greater challenge. Lengthening the branchless DTA is an effective strategy to expand applicability of stent graft repair with endograft attachment as proximal as the LCCA, and even up to the innominate artery. Coverage of the origin of the LSA has been reported to be safe, and our own experience supports this. 12-14 However, caution should be exercised and patency with

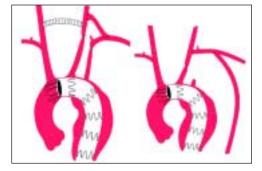


Figure 4. Retropharyngeal right-to-left carotid-carotid bypass, carotid-subclavian bypass, and ligation of proximal LCCA and LSA (left); left femoro-axillary bypass and subclavian-to-carotid transposition (right).

antegrade flow in the contralateral vertebral artery should be ascertained beforehand (by angiography, duplex ultrasound, or MRA). Aneurysmal involvement of, or close proximity to the LSA, on the other hand, poses a different kind of concern that relates to the potential for backflow endoleak. Preliminary transposition/bypass of the LSA has been the preferred strategy for such cases, ¹³ although we are now more inclined to coiling the LSA after endograft placement (Figure 6), which offers the advantage of preserving an available pathway for intraprocedural placement of the all-important left brachial artery-LSA catheter that constitutes the critical landmark for endograft deployment in the region of the aortic arch (Figure 7).

Acute aortic dissection is a potentially catastrophic condition, quite distinct from aneurysmal disease. A management consensus of sorts has evolved in which TBAD is often treated medically in the absence of imperatives for intervention (such as continued severe pain, acute aneurysmal expansion of the false lumen, rupture, and visceral branch or leg ischemia). Surgical treatment usually involves graft replacement of the segment containing the entry point to redirect blood flow exclusively down the true lumen. Unfortunately, surgeons are (understandably) reluctant to recommend an aggressive management strategy because of the high risk for serious complications and mortality. Endovascular repair represents a more appealing, less-invasive approach. However, significant questions remain concerning indications and best strategy.

Today, it would seem most prudent to reserve stent graft intervention for patients with significant aneurysmal dilata-

tion, imminent rupture, malperfusion, or for those who have failed medical treatment. Compression of the true lumen (by the FL), as assessed by CT imaging, may well prove to be a good predictor of ischemic complications and the need for intervention. The need exists for a randomized clinical trial to compare stent graft repair with

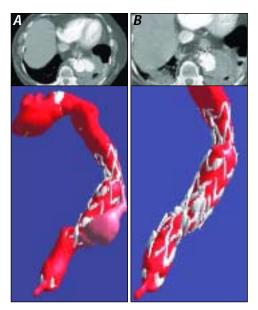


Figure 5. Type I distal attachment-site endoleak (A). Treatment with placement of distal extension cuff (B).

conservative treatment in the management of patients with uncomplicated TBAD.

MORPHOLOGIC EVALUA-TION AND IMPLANT TECH-NIQUES: KEY ISSUES

Detailed preoperative evaluation is obtained using CT, angiography, and IVUS. IVUS performed in conjunction with angiography and has been found to add very useful information, especially in cases of dissection.

The implant procedure is performed in the operating room using a high-resolution, mobile C-arm. The unit is positioned at the patient's left side. Because the best LAO angle of visualization has been determined during the preoperative angiogram, it can be duplicated in the operationing

room. Only limited angiography and contrast administration are required during stent graft placement. The origin of the LSA constitutes the best reference in the majority of cases because most lesions are located in the proximal DTA and distal arch. We use catheterization of the left brachial artery with placement of a 5-F sheath and a diagnostic pigtail catheter that is kept (in the ascending aorta) within the lumen of the LSA throughout the procedure (Figure 8).

The device is introduced via single groin cutdown, and over a Lunderquist guidewire. In some cases, an iliac access conduit serves as the best pathway for stent graft introduction and deployment.

Ideally, stent graft coverage should include a minimum of 20 mm of nondiseased aorta, proximally and distally. This may not be achievable in some cases, especially at the cranial end within the aortic arch. Coverage of <15 mm





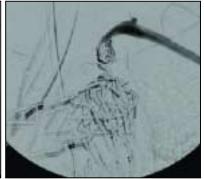


Figure 6. Transcatheter coil embolization of LSA after endograft coverage.

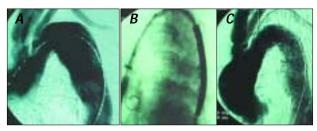


Figure 7. Large proximal TAA associated with "tight" arch anatomy (A). Aneurysm exclusion with Talent thoracic stent graft (B and C). Residual ascending aortic aneurysm was subsequently treated surgically.

beyond the lesion, especially aneurysms, should be viewed as suboptimal. With regard to total length of stent graft coverage, the dictum "when in doubt, cover more, not less!" has emerged in our endograft thoracic practice after having had experience with several cases in which an attachment site (proximal or distal) type I endoleak resulted from nonadherence to such principle. ¹⁷ The "fear of paraplegia" is largely unfounded and can lead to insufficient coverage and incomplete exclusion of the target lesion. The risk of clinically significant spinal cord ischemia is <5%, with the exception perhaps of patients who have had previous infrarenal aortic replacement; such patients should be considered for prophylactic placement of a CSF drain catheter.

OVERVIEW AND PERSONAL OBSERVATIONS

Stent graft repair of TAA and TBAD is feasible and frequently applicable, and can be achieved with high technical success rates. Thirty-day operative morbidity and mortality rates compare favorably with historical surgical results.

The Medtronic Talent Thoracic Stent Graft System has proved versatile for endovascular exclusion in a variety of morphologies. Recent improvements of the delivery system allow for easier and sufficiently precise deployment in the

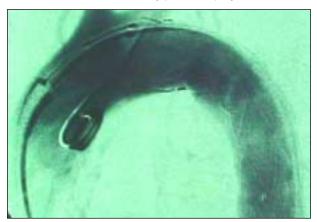


Figure 8. Left brachial/subclavian artery catheter marks position of the LSA at all times during the procedure.

aortic arch. Stent graft repair can be expanded through adjunctive surgical techniques designed to transpose arch branches to "lengthen" the DTA.

Clinical indications for intervention in TBAD remain unclear. Data from a prospective, randomized clinical trial comparing stent graft repair with noninterventional medical management would be most welcome. Endograft coverage/occlusion of the LSA is well tolerated in most instances and can be performed safely in the absence of previous left internal mammary-based coronary bypass and when normal antegrade flow in the contralateral vertebral artery has been ascertained preoperatively.

Very little is known about long-term (>5 years) durability of either the device or the repair after thoracic aortic placement. In short, thoracic endograft techniques are advancing rapidly. Although currently available data are limited, these newly acquired capabilities are undeniably impressive. Endograft repair may well prove to be the preferred treatment approach for the majority of patients presenting with potentially life-threatening lesions of the thoracic aorta.

Frank J. Criado, MD, is Director for the Center of Vascular Intervention and Chief of Vascular Surgery, Union Memorial Hospital-MedStar Health, Baltimore, Maryland. He is a consultant for Medtronic Vascular. Dr. Criado may be reached at (410) 235-6565; frank.criado@medstar.net.

All coauthors are from the Division of Vascular Surgery and Center for Vascular Intervention, Union Memorial Hospital-MedStar Health, Baltimore, Maryland.

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Case Report: Endovascular Treatment of a Ruptured Thoracic Aortic Ulcer

Approaching this challenging case by endovascular means offered reduced morbidity and mortality in a minimally invasive procedure.

BY MANISH MEHTA, MD; R. CLEMENT DARLING III, MD; PHILIP S.K. PATY, MD; PAUL B. KREIENBERG, MD; KATHLEEN OZSVATH, MD; BENJAMIN B. CHANG, MD; SEAN P. RODDY, MD; AND DHIRAJ M. SHAH, MD

enetrating thoracic ulcers most commonly result from a disruption in the aortic wall. Such a disruption can be limited to the media resulting in dissection, adventitia resulting in pseudoaneurysm, or transmural, all of which can result in rupture. The natural history of asymptomatic thoracic aortic ulcers remains unknown, although when the ulcers are symptomatic, they can be associated with >50% risk of rupture. Given the morbidity associated with open surgical repair, particularly in emergent circumstances, endovascular techniques offer promising preliminary results with decreased morbidity and mortality. This

"The natural history of asymptomatic thoracic aortic ulcers remains unknown, although when the ulcers are symptomatic, they can be associated with >50% risk of rupture."

article details a case involving a patient with ruptured thoracic aortic ulcers who underwent successful endovascular repair with the Talent Thoracic Stent Graft System (Medtronic, Santa Rosa, CA).

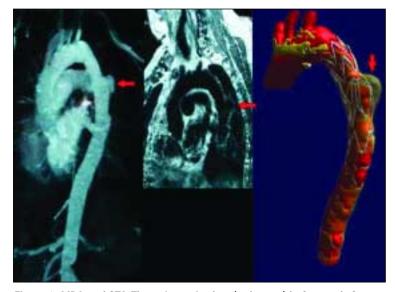


Figure 1. MRA and CTA. Thoracic aortic ulcer (red arrow) before and after exclusion with Talent Thoracic Stent Graft.

CASE PRESENTATION

A 78-year-old man with significant coronary artery disease (CAD), chronic obstructive pulmonary disease (COPD) requiring home oxygen, and chronic renal insufficiency not on dialysis, presented with new onset of chest and back pain. The patient's blood pressure was 180/100 mm Hg, and his electrocardiogram/cardiac enzymes were normal. A chest x-ray suggested left pleural effusions, and an MRA indicated a penetrating descending thoracic aortic ulcer. The patient was admitted to the surgical intensive care unit, and his blood pressure was controlled by intravenous antihypertensives. Regardless, he remained symptomatic with chest and back pain. Based on the MRA findings, the patient was evaluated for the possibility of

endovascular repair with the Talent Thoracic Stent Graft System. The descending thoracic aorta proximal and distal to the ulcer measured 34 mm and 30 mm, respectively.

On the day of the planned repair, the patient was found to be hypotensive, hypoxic, and confused. He

was resuscitated and immediately rushed to the operating room for an endovascular repair for presumed rupture of his thoracic aortic ulcer.

Once the patient was in the operating room, access to the left brachial artery was obtained percuta-

neously to facilitate placement of an aortic occlusion balloon if necessary; the right femoral artery was exposed to facilitate placement of the stent graft. After the initial episode of hypotension, the patient remained hemodynamically stable, and the aortic occlusion balloon was not needed. Under fluoroscopic guidance, a guiding catheter was used to place a stiff guidewire (Lunderquist, Cook Inc., Bloomington, IN) up to the ascending thoracic aorta. A left transbrachial marker pigtail catheter was used for diagnostic arteriography, which indicated extravasation at the site of the ulcer. Talent self-expanding thoracic stent grafts (two-piece) were used to completely exclude the thoracic ulcer, and the completion arteriogram indicated adequate proximal and distal fixation without any evidence of endoleak or extravasation (Figure 1). After discharge from the hospital, the patient remained asymptomatic without evidence of extravasation or endoleak on CT at 6-month follow-up.

DISCUSSION

The advantages of endovascular techniques have changed the practice of vascular surgery. The minimally invasive means of placing stent grafts across aortic aneurysms, ^{2,3} dissections, ⁴ and ulcers, ^{5,6} have led to the obvious avoidance of major surgery and aortic cross clamping, which even under elective circumstances has been associated with significant morbidity and mortality ^{7,8}

Penetrating aortic ulcers usually arise in atheromatous plaques located in the descending thoracic aorta that can burrow through the internal elastic lamina into the media, leading to a variable amount of intramural hematoma formation, and may be complicated by aortic dissection, progressive aneurysmal dilatation, pseudoaneurysm formation, or rupture. ^{9,10} The typical

patient is elderly with multiple cardiac risk factors who presents with acute onset of chest and back pain. Diagnosis is generally confirmed by CT, MRA, or arteriography.

Although surgical repair for descending thoracic aorta is not necessarily a complex procedure, in emer-

"Endovascular repair of descending

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gent circumstances, it can be associated with significant morbidity of spinal cord ischemia (8%), myocardial infarction (20%), respiratory complications (33%), renal complications (15%), and death (60%). 11 Endovascular

repair of descending thoracic aorta is an appealing alternative to open surgery and is likely to have an even greater impact than in abdominal aorta, where open surgical repair offers a low morbidity and mortality rate.

Our experience with endovascular repair of ruptured and symptomatic thoracic aortic ulcers indicates that the procedure is technically feasible, and associated with a limited morbidity. Further evaluation of long-term durability of these devices is needed.

Manish Mehta, MD, is from The Vascular Institute of Health & Disease, Albany Medical Center, Albany, New York. He hold no financial interest in any product or manufacturer mentioned herein. Dr. Mehta may be reached at mehtam@mail.amc.edu.

All coauthors are from The Vascular Institute of Health & Disease, Albany Medical Center, Albany, New York.

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Endovascular Treatment of Acute Aortic Syndrome

Use of the Talent stent graft to repair acute aortic syndrome has merit in certain patients.

BY CHRISTOPH A. NIENABER, MD; HÜSEYIN INCE, MD; MICHAEL PETZSCH, MD; TIM REHDERS, MD; THOMAS KÖRBER, MD; HENDRIK SCHNEIDER, MD; AND FRANK WEBER, MD

side from the classic form of aortic dissection, the clinical presentation of acute aortic syndrome (AAS) ranges from penetrating atherosclerotic aortic ulcer (PAU) to aortic intramural hematoma (IMH) and thus, represents an inhomogeneous group of patients with a polyfaceted clinical profile. AAS always represents a potentially life-threating situation. Although great efforts have recently been made for patients with AAS using new surgical techniques, both postoperative morbidity and mortality remain high. The afflicted population is usually older and characterized by a variety of comorbidities with significant impact on postsurgical outcome. Postoperative complications, such as paraplegia and renal insufficiency, contribute to prolonged hospital stays and higher medical costs. Conversely, interventional stent graft placement may be a promising nonsurgical strategy for treating select cases of acute aortic pathology confined to the descending aorta and aiming for reconstruction of the diseased aortic segment.

SYMPTOMS

The typical clinical symptomatology of aortic pathology is the sudden onset of crushing chest and/or back pain representing AAS. AAS includes PAU, aortic IMH, and classic aortic dissection. The pathophysiological mechanism that precipitates the appearance of each of these entities, however, is different.

Typically, all aortic pathologies are preceded by a long history of hypertension. The recognition of pain associated with progressive aortic lesions is of paramount importance. A severely intense, acute, throbbing, and migratory chest pain may be characteristic. Anterior chest, neck, throat, and even jaw pain is likely to be related to involvement of the ascending aorta, whereas back and abdominal pain more often indicates affection of the descending aorta. The pain description and clinical presentation of patients with PAU and aortic IMH can be confused with that of classic aortic dissection. Aortic root stretching and distension (without dissection) are likewise mechanisms

for pain in these patients. Moreover, aortic pain may be confused with coronary ischemic syndromes. Besides hypertension, inheritable connective tissue disorders such as Marfan syndrome also predispose to the development of classic aortic dissection, as does previous aortic valve surgery. Similarly, hypertension is the most common comorbid disease associated with PAU and aortic IMH or both. 3,4

DIAGNOSIS

The common denominator in all scenarios of AAS is its unpredictable nature, often with an unfavorable outcome. Therefore, early diagnosis and appropriate treatment are essential. The most important diagnostic imaging modalities in AAS are TEE, contrast-enhanced CT, and MRI. ^{5,6} Computer-enhanced 3D reconstruction of the aorta can serve as a blueprint for surgical or interventional reconstructive procedures. Exact morphometry of the aorta and side branches allows individual endovascular protheses to be constructed.



Figure 1. MRA of type B dissection showing the communication between true and false lumen (A). MRA of type B dissection after stent graft placement with complete reconstruction and remodeling of the aorta (B).

Table 1. Medical Treatment vs Stent Graft in Emergent Type B Aortic Dissection

	Medical	Stent Graft	P Value
Mortality (%)	niculcai	o o	
30 days 1 year	4	0	ns <.05
Morbidity (%) 30 days 1 year	2 2	2 2	ns ns

STENT GRAFT PLACEMENT

The Talent Thoracic Stent Graft System (Medtronic, Santa Rosa, CA) is a self-expanding endoprosthesis consisting of circumferential nitinol stent springs arranged as a tube and covered on its exterior with a Dacron graft. The tube is customized with respect to width, length, and the configuration of each end (as a bare spring or a covered web for optimal conformance with the aorta) and is compressed in a 22-F to 27-F polytetrafluoroethylene sheath; the nitinol rings are interconnected by a longitudinal wire to ensure stabilization and separation of all the rings and to prevent twisting. Each device is custom made according to morphometric measurements obtained from each patient's MRI scan.

IMPLANTATION TECHNIQUE

Stent graft placement was performed in the cardiac catheterization laboratory with the patients under general anesthesia and ventilation. Patients were prepared to undergo surgery in case the procedure failed. The procedure was begun by injecting 5,000 U of heparin and introducing a 6-F pigtail catheter (Cordis Corporation, a Johnson & Johnson company, Miami, FL) into the left subclavian artery for precise guidance near the subclavian artery and for intraprocedural aortography. The Talent prosthesis was introduced through femoral or distal iliac artery exposures over a .035-inch guidewire to the entry tear under TEE guidance.

Before deployment, blood pressure was titrated to 50 mm Hg with sodium nitro-prusside. The stent graft was deployed at the designated position and apposition was achieved by balloon molding (at 2 to 3 atm). With optimal apposition and cessation of flow in the false lumen, the infusion of sodium nitroprusside was stopped. Care was taken to completely seal the entry

with Dacron and to protect the left subclavian artery with the bare-spring end of the stent graft. Both the sheath and the guidewire were then removed, and the incision was closed. No additional heparin or antiplatelet medication was administered.

RESULTS

Emergency Stent Graft Placement

Considering a mortality rate of 29% to 50% associated with emergency surgical repair, the concept of endovascular stent graft placement may become a life-saving option in impending or evolving rupture by endovascular sealing of the entry tear and subsequent abortion of leakage. This concept was tested by comparing short-term and the 1-year outcomes of 11 patients after emergency endovascular stent graft placement with matched control patients subjected to medical therapy. All patients had acute type B dissection complicated by loss of blood into periaortic spaces. ⁷

Three patients who underwent conventional treatment died within 9 hours of arrival, one developed paraplegia at day 3, and one died after 9 months of complete aortic rupture. Considering both excessive surgical risk and adverse short-term outcome with conservative treatment in such patients, interventional stent graft placement was executed in 11 cases with similar risk profile. Aortic endovascular stent grafts were correctly positioned to seal the proximal

Table 2. 30-Day and 1-Year Complications			
Early Complications (30 Days)	Own Experience (n=127)	Meta- Analysis (n=113)	Palma JH, et al ²¹ (n=70)
Technical success	100%	92%	93%
Mortality	2 (Fem)	3	6
Progression to AD	1	2	2
- surgery	1	3 2	6
Rupture of the aorta	0	2	0
Paraplegia/paresis	1	3	0
TIA/insult	1	1	2
Wound infection	1	1	2
Late Complications (1 Year)	20	20	20
Mean follow-up (months)	28	30	29
Progression/perforation	3	6	6
- second stent graft	3	4	34
Incomplete entry closure		5	5
1-year survival	97%		91%
Peripheral Interventions - PCI + stents (coronary)	5	*	*
- Stenting of renal arteries	2	*	*
- Stenting of Iliac arteries	1	*	*
- Stenting of mac arteries - Stenting of abdominal aorta	1	*	*
- Fenestration	Ó	1	*
1 0110011111111	Ŭ	,	* = unknown

Table 3. Our Results of Stent Graft Placement in Type B Dissection, AIH, and PAU

	7.		
Entity*	Success	30-Day Mortality	1-Year Mortality
А	98%	(1.7%)	(1.7%)
В	100%	0	0
С	100%	0	0
* $A = Type\ B\ dissection\ (n = 127);\ B = IMH\ (n = 4);\ C = PAU\ (n = 15)$			

entry tear in all patients. There were no procedure-related complications, and median hospitalization was 9 days (range, 6-38 days). At a mean follow-up of 15 ± 6 months, no deaths were recorded in the stent graft group compared to four deaths with conventional treatment (P<.01).

Although follow-up imaging at 7 days and 3 months failed to demonstrate any recurrent leakage from the stented aorta (or adjacent segments), two patients did not recover completely from neurological symptoms already acquired before stent placement (one of paraplegia and one of incomplete brachiofacial neuroplegia from right-side stroke). Moreover, one patient with retrograde dissection developed posterior MI with total AV block and required a permanent dual-chamber pacemaker. Conversely, for the patients subjected to medical treatment only, median hospitalization was 21 days (range, 12-41 days); four had died at 1 year, three of which were within the initial 24 hours of diagnosis. Careful monitoring and titration to ~55 mm Hg mean arterial pressure by intravenous metoprolol, blood transfusion (if necessary), and sedation was used irrespective of treatment in all patients. These results are summarized in Table 1.

Elective Stent Graft Placement

Both safety and efficacy of elective transluminal endovascular stent grafts in type B aortic dissection were recently compared to surgery in a series of matched controls. In both groups, the dissection involved the aortic arch in three patients and the descending thoracic aorta in all remaining patients. With the patient under general anesthesia, either surgical resection was undertaken or a custom-designed endovascular stent graft was placed via unilateral femoral arteriotomy. Initial findings suggested that nonsurgical reconstruction may constitute a viable therapeutic option for patients with descending dissection of the thoracic aorta and an indication for surgical repair, such as an aortic diameter greater than 5.5 cm, a patent false lumen with potential for expansion, or recurrent pain. 9-12 In contrast to thoracic surgery for type B dissection, transfemoral stent grafting was

not associated with early or longer-term mortality or with serious morbidity; preliminary analysis even suggests that substantial cost savings could result from the reduced need for intensive care and the shorter hospital stay. The current literature and our own results with respect to 30-day and 1-year complication rates are summarized in Table 2.

We have expanded the use of nonsurgical stent graft placement to 127 patients with type B dissection with suitable anatomical characteristics (accessible proximal entry, at least one femoral artery without dissection, and no substantial tortuosity of access vessels). Moreover, four patients with IMH and para-aortic blood leakage, and 15 patients with a PAU have received an endovascular stent graft showing an extremly low early and 1-year mortality (Table 3).

Tables 4 and 5 summarize the results of medical, surgical, and endoluminal treatment of type B dissections as reported from recent literature. These results reveal an advantage for the endovascular approach, although they are based on retrospective data analysis rather than prospective studies, 8,14-18

DISCUSSION

According to recent literature and with respect to our large series of aortic dissection and its variants, there is growing evidence that stent graft placement has emerged as a valid, prognostically beneficial concept in treating both emergency and subacute elective descending thoracic aortic pathology. In experienced hands and with appropriate logistics, the therapeutic concept of endoluminal reconstruction appears more favorable than surgery or medical therapy alone. Associated morbidity as known from the surgical approach (with paraplegia, etc.) is virtually absent with endoluminal interventions and proper patient selection.

Stent Graft-Induced Aortic Remodeling

The initiation of the natural healing process (false lumen thrombosis) by sealing the proximal entry induces both consolidation of the false lumen and remodeling of the aortic wall. Aortic stability results from both thrombosis of the false lumen and the endoprosthesis itself; relatively short stent grafts can cover the proximal entry and induce false lumen thrombosis over the entire length of the dissected

Table 4. Type B Dissection: Survival of Nonoperated Vs Operated Patients

Survival 1 year	Nonoperated (%) 73-92	Operated (%) 47
3 years	63	40
5 years	58-89	28
10 years	25-76	N/A
		(Data from reference 22)

Table 5. Type B Dissection: Surgical vs		
Endovascular Results		

Events	Emergency Surgery (%)	Elective Surgery (%)	Endovascular Stent Grafts (%)
Mortality	10-45	14-6	16
Paraplegia	20	10	0
Resp. Insuf	f. 6-31	15-40	5
Stroke	7	2	_
		(Data from r	eferences 8, 14, 16, and 18)

aorta. Aortic remodeling consists of an active component (stent-induced expansion of the true lumen) and a passive component (thrombus retraction in the false lumen) and mimics the natural healing process because a thrombosed false lumen is associated with a lower risk for future adverse events and better survival. Although conceptually promising, the management of aortic syndromes by stent graft placement requires the scrutiny of long-term follow-up data. Conversely, over several years of follow-up, late adverse effects were infrequent, justifying the use of stent grafts in patients too sick for classic surgery. ^{13,18,19}

Moreover, the custom design of each stent graft currently limits the concept to patients undergoing elective procedures or requires a large stock to treat acutely ill patients. Finally, sophisticated imaging techniques, such as MRA, intraprocedural TEE, and digital angiography appear to be necessary to ensure optimal results. Stent graft placement may be a promising nonsurgical strategy for treatment of acute aortic pathology, such as type B dissection, aortic IMH, and PAU. Whereas dissection may develop rupture and expansion, IMH and PAU eventually predispose to full-fledged local dissection (Figures 1A,B and 2A,B).

SUMMARY

For the spectrum of type B aortic dissection, and even in the presence of distal malperfusion syndrome, interventional stent graft placement may be offered to selected patients in lieu of surgical repair. With further refinement of endovascular procedures, more patients with severe coexsisting conditions and elevated surgical risk may be considered for endovascular procedures. Although the initial results of stent graft treatment of AAS are promising, the concept of nonsurgical reconstruction in all entities of AAS should be subjected to randomized long-term evaluation.

Christoph A. Nienaber, MD, is Professor of Cardiology/ Internal Medicine, Rostock Medical School, Division of Cardiology, Rostock, Germany. Dr. Nienaber may be reached at christoph.nienaber@med.uni-rostock.de.

All coauthors are from the Rostock Medical School, Division of Cardiology, Rostock, Germany.

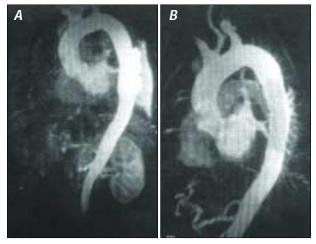


Figure 2. MRA of a patient with an aortic IMH before (A) and after percutaneous stenting with complete reconstruction and aortic remodeling (B). Note that the preinterventional extra-aortic leakage of blood is completely abolished.

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