Aortic Diseases

Contemporary Management of Descending Thoracic and Thoracoabdominal Aortic Aneurysms: Endovascular Versus Open

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Aneurysms that originate in the descending thoracic aorta occur at an estimated incidence of 5.9 to 10.4 per 100,000 person-years and rupture at a rate of 3.5 per 100,000 person-years. In a population-based study of patients with untreated thoracic aortic aneurysms (TA), Bickerstaff et al reported an actuarial 5-year survival rate of 19.2% for patients with degenerative aneurysms, and rupture was identified as the cause of death in 51% of patients. This disease presents across a spectrum of anatomic complexity that ranges from isolated descending TA to thoracoabdominal aneurysms (TAA) that can extend from the subclavian artery to the aortic bifurcation. Repair of aneurysms across this spectrum presents a multitude of technical and clinical challenges that span the preoperative and postoperative periods. Indeed, conventional open surgical treatment of TA/TAA is accompanied by significant morbidity and mortality compared, for example, with repair of abdominal aortic aneurysm. Improvements in operative care, particularly an aggressive posture toward intercostal artery preservation and the adoption of protective adjuncts against spinal cord ischemia (SCI) complications, have halved the overall incidence of SCI associated with open operative repair since Crawford’s benchmark series describing a 16% incidence of SCI in 1500 patients. Despite considerable progress, contemporary series from centers of excellence continue to report a consistent overall risk of SCI in the 5% to 10% range. In addition, when ruptures are included, the perioperative mortality of open TA/TAA repair is 8% and has remained essentially unchanged over the last 40 years. The recent emergence of stent graft repair in the thoracic aorta has the potential to substantially diminish the morbidity and mortality of surgical repair and alter long-standing treatment paradigms.

In this article, we review contemporary management of TA/TAA and adjunctive methods to decrease end-organ injury and SCI. We include clinical decision-making analysis and discuss variables influencing the choice between open versus endovascular repair. With the recognition that the ultimate role of stent graft repair is yet to be defined (especially with regard to TAA repair), an update on the results of open surgical and/or endovascular repair is presented.

Natural History and Clinical Decision Making

Since Crawford first noted that 80% of ruptures of TA/TAA occur in patients with aneurysms <10 cm, multiple referral center reports have advanced insight into the expected natural history and rupture risk of patients considered for TA/TAA resection. These data have delineated both patient-specific and aneurysm-specific factors that influence risk of rupture (Table 1). Descending TA appear to expand at more rapid rates as they become larger, and several investigators have correlated increased expansion rates with rupture. Furthermore, these studies indicate that rupture risk is negligible in aneurysms <5 cm, equivalent to the risk of open surgical resection in the 5- to 6-cm range, and increases substantially at aneurysm diameters >6 cm and/or growth rates of ≥10 mm per year. Such natural history observations have led to the general acceptance of 6 cm as an appropriate size threshold for recommendation of surgical intervention for degenerative TA/TAA.

There are consistent themes with regard to the initial presentation of patients with TA/TAA that influence the overall risk of morbidity and mortality from operative repair. One association that is virtually universal is that treatment in other than elective circumstances essentially doubles both the perioperative mortality and the risk of SCI complications. This punctuates the importance of early detection and elective repair of appropriate TA/TAA lesions.

Associated vascular diseases and comorbid conditions are commonplace in patients presenting for treatment of TA/TAA. Synchronous aneurysms typically involving the ascending aorta or arch have been observed in ~10% of patients being evaluated for TA/TAA repair, and a familial history of aneurysmal disease has been identified in 8.4% to 21% of patients presenting for evaluation of TA/TAA. Prior operation for aortic aneurysm disease is seen in one third of patients being evaluated for TA/TAA repair, the most common of which is a previous infrarenal aneurysm repair. Recently, Coselli et al detailed their experience with 123 patients undergoing open TA resection after a prior infrarenal abdominal aneurysm repair and noted that these patients were likely to present with symptoms at a mean interval...
of 8.2±5.4 years after the initial abdominal aortic aneurysm resection.

Because the majority of patients seen in consideration for TA/TAA resection are those with degenerative aneurysms, demographic and clinical features typical of a patient population with diffuse atherosclerosis are the rule. Patients treated for degenerative aneurysms average 70 years in age, and a history of hypertension is nearly universal. Cigarette smoking and/or significant chronic obstructive pulmonary disease (COPD) are encountered frequently. Pulmonary function studies have been routinely performed before open operation, and 25% of patients will have significant COPD, as manifested by an FEV₁ of <50%. Cerebrovascular disease, prior stroke, and symptomatic manifestations of lower extremity arterial occlusive disease occur in 15% of patients.

An accurate assessment of associated comorbid conditions is mandatory to guide appropriate decision making with respect to recommending open surgical repair. All patients should be evaluated with dipyridamole thallium scanning or the equivalent to assess perioperative myocardial ischemic potential. In addition, patients with a history of symptoms suggestive of heart failure should have an assessment of left ventricular function. Although patients with significant impairments of pulmonary reserve can usually be detected on a historical basis alone, we routinely obtain preoperative pulmonary function studies.

Associated visceral and renovascular occlusive disease to some degree has been reported in 30% of patients. Indeed, in our experience, 15% of patients had significant renal insufficiency, as manifested by a preoperative serum creatinine level of ≥1.8 mg/dL. The coexistence of renovascular disease and some degree of renal insufficiency is especially commonplace in patients with TAA and has important implications for accurate assessment of perioperative risk and long-term preservation of renal function. Because the majority of patients with TAA present with involvement of the entire visceral aortic segment, occlusive lesions of the mesenteric and renal arteries or total ostial occlusion of 1 or more of these vessels frequently accompanies aneurysmal dilation of this region of the aorta. Accordingly, extreme levels of preoperative azotemia (serum creatinine >2.5 cm/dL) constitute a relative contraindication to elective operation unless preoperative studies indicate some potential for salvage or retrieval of renal function with renal artery reconstruction. In many series, the presence of an abnormal preoperative serum creatinine level is at least a univariate correlate of perioperative mortality.4,5,29–32 Thus, assessment of renal function and associated renovascular disease is an important component of patient evaluation and choice of therapy.

### Diagnostic Evaluation/Classification

Descending TA are classified on the basis of the proximal and distal extent of aortic dilation, which includes a spectrum of anatomic configurations ranging from true TA (confined to the thoracic aorta) to multiple versions of TAA (involving the thoracic and abdominal aorta). TAA are classified according to the scheme originally devised by Crawford that in the most basic terms considers whether the lesion is primarily a caudal extension of a descending thoracic aneurysm or a cephalad extension of a total abdominal aortic aneurysm (Figure 1). This classification is especially useful when applied to patients requiring operative repair because it has direct implications for both the technical conduct of the operation and the incidence of operative complications, particularly SCI. To this end, TA can be considered equivalent to a type I TAA, and a type II TAA requires the most complex reconstructions and is associated with the highest risk of SCI. In addition, a type IV TAA represents a total abdominal aneurysm because it is limited to the aorta below the diaphragm. Aneurysm extent also has implications for the operative approach because endovascular repair is currently available only for patients with true TA, whereas those with
TAA are eligible only for thoracic endovascular aortic repair (TEVAR) in the setting of a hybrid procedure involving a combined open and endovascular approach.

In contemporary practice, a dynamic, fine-cut, contrast-enhanced computed tomographic (CT) scan with or without helical reconstruction (Figure 2) provides the surgeon with the following information: (1) accurate assessment of aneurysm size and extent; (2) a baseline study with which future images may be compared; (3) determination of anatomic suitability for endovascular repair; and (4) if open surgery is required, the anatomic extent of resection and at least inference regarding the risk of subsequent spinal cord ischemia.

Accurate assessment of the size of TA is contingent on measurement in the appropriate perpendicular plane. When one images a tortuous aorta or evaluates sections through the aortic arch or lower descending aorta, it is important to understand that axial images often section the aorta in a tangential plane (Figure 3). Such measurements result in an erroneous overestimation of aortic diameter and underscore the importance of personally viewing CT scans before initiation of therapy. Three-dimensional reconstructions of the thoracic aorta with determination of the centerline of axis will ensure that cross-sectional measurements are made in an appropriate perpendicular plane.

The anatomic extent of the aneurysm defined by preoperative imaging determines the type of aortic repair required. In our practice, all patients who have anatomic suitability TA are treated with TEVAR, and those with TAA who appear to be appropriate surgical candidates undergo operative repair. Select patients with extensive aneurysms who appear unlikely to tolerate open surgical repair because of cardiac or pulmonary issues have been treated with a combination of open debranching of the visceral aorta or aortic arch followed by TEVAR, the so-called hybrid procedure.

**Open Surgical Repair**

The open surgical approach was of course the only option for TA/TAA repair outside of clinical trial sites until Food and Drug Administration approval and commercial availability of a TA stent graft in April 2005. Such commercial availability has greatly expanded the percentage of patients and TA/TAA anatomy potentially treatable with TEVAR technology (see below). The choice of specific surgical technique is dependent on the aneurysm anatomy, including arch involvement and/or distal extent of the lesion. In contemporary practice, several schemes of open repair of TA/TAA are utilized (Figure 4). Variations on surgical techniques include organ-specific protective adjuncts and/or some form of extracorporeal circulatory support. In circumstances in which proximal cross-clamp application is neither possible nor desirable, total cardiopulmonary bypass with deep hypothermic circulatory arrest can be utilized. Some centers prefer this modality for its at least theoretical benefit for organ preservation. However, because of the bleeding and pulmonary complications that often accompany this technique, most surgeons believe that it should be utilized when no other technical option exists for repair of TA/TAA. Such circumstances are, in fact, rare in our experience. The 2 most commonly applied approaches involve a clamp-and-sew technique, usually supplemented by protective adjuncts, versus the use of distal aortic perfusion usually provided as an atriofemoral bypass circuit. The rationale for distal aortic perfusion is that it reduces ischemic time to the intercostal, visceral, and renal vessels because these vascular beds continue to be perfused by the circuit during creation of the proximal anastomosis; such distal perfusion has been favored for repair of isolated TA. Comparable results have been achieved in contemporary practice with the use of both clamp/sew and distal perfusion techniques. In addition, atriofemoral bypass will provide easily titratable mechanical unloading of the left ventricle, and this may be desirable in patients with antecedent aortic valvular dysfunction or significant degrees of left ventricular dysfunction.

The choice of operative strategy will vary with aneurysm extent, nature of the pathology, and preference/local experi-
ence of the surgical team. Our preference is the selective use of atriofemoral bypass with sequential cross-clamp applications in the following circumstances: (1) anticipated technical complexity of the proximal anastomosis, particularly in chronic dissection; (2) anticipated extensive intercostal reconstruction, usually predicated on CT angiographic images; (3) TA confined to the descending aorta wherein continuous distal organ perfusion is possible; and (4) routinely in type II TAA. Alternatively, a clamp-and-sew technique with adjuncts (Figure 4A) is used routinely in type III and IV TAA.

Although the technical conduct of specific procedures is beyond the scope of this discussion, there are several principles of therapy aimed at reducing complications that apply to all patients. Postoperative paraplegia secondary to interruption of potential blood supply to the spinal cord is by far the most feared nonfatal complication of TA/TAA repair. In an effort to minimize this risk, we developed and applied a technique for the provision of regional hypothermic protection to that segment of the spinal cord typically at risk for ischemic injury during TA/TAA repair that involves an epidural infusion of iced saline during aortic cross-clamping. Other adjuncts aimed at reducing the risk of paraplegia include cerebrospinal fluid drainage, reimplantation of patent critical intercostal arteries (those that actively bleed after the aneurysm has been opened), the use of evoked-potential monitoring, and atriofemoral bypass to maintain distal aortic perfusion. SCI remains an unsolved problem despite considerable improvements in the overall incidence of this complication. As detailed in Table 2, contemporary results from centers of excellence show that although paraplegia rates after TA repair are low, SCI remains a significant risk of open TAA repair.

Renal protection is achieved through the direct installation of renal preservation fluid (4°C lactated Ringer’s solution with 25 g of mannitol per liter and 1 g methyl prednisolone per liter) into the renal artery ostia after the aorta is opened, causing a rapid decline of renal core temperature. Although there is no level I evidence showing the superiority of this solution over cold lactated Ringer’s solution alone, mannitol provides protection by decreasing renal oxygen demand, and steroids are thought to preserve renal function by membrane stabilization during the ischemic period. This adjunct is especially effective in patients with baseline renal insufficiency and those in whom a prolonged (>40 minutes) renal ischemic time is expected because postoperative renal failure (defined as a doubling of baseline creatinine or absolute level >3.0 mg/dL) significantly affects operative mortality. Indeed, in our series, patients who sustained significant postoperative renal failure had an 8-fold increase in operative mortality (odds ratio, 7.8; 95% CI, 3.4 to 17.9; \( P < 0.0001 \)).

The final adjunct in our overall approach involves in-line mesenteric shunting. As displayed in Figure 4, immediately after performance of the proximal anastomosis, prograde pulsatile perfusion can be established into either the celiac axis or superior mesenteric artery to minimize visceral ischemic time and its potential contribution to coagulopathic bleeding and SCI.

In the majority of clinical series, postoperative respiratory failure is the single most common complication after TA/
TAA resection, occurring in 25% to 45% of patients.\textsuperscript{6,7,32,38,43} There may be confusion regarding how this is defined because the term \textit{prolonged} ventilatory support (which is the most common problem) may be variably interpreted. A slow wean from ventilatory support, often planned to proceed over several days, is appropriate management in certain patients after extensive descending thoracic aortic resection, particularly in those with baseline pulmonary insufficiency. Despite varying definitions, postoperative respiratory insufficiency occurs commonly, and the variables predictive of this complication include active cigarette smoking, baseline COPD, especially in those with significant reductions in FEV\textsubscript{1}, and cardiac, renal, or bleeding complications.\textsuperscript{38,44,45} In the circumstance of elective operation, risk factor modification with smoking cessation and bronchodilator therapy for patients with COPD is vital for acceptable outcomes. However, institution of preoperative steroid therapy with the intent of improving respiratory function is contraindicated because we have observed this maneuver to precipitate aneurysm rupture.

Despite the widespread use of the aforementioned adjunctive techniques, representative large clinical series, including the most recent publications, indicate that the mortality of TA/TAA repair remains in the 7% to 10% range (Table 2).\textsuperscript{32} Indeed, the results summarized in Table 2 represent the “best-case” scenario, and the “real-world” experience is likely not as optimistic. Rigberg et al\textsuperscript{54} evaluated 1010 patients from the California Office of Statewide Health Planning and Development database and reported a 30-day elective mortality of 19% that increased to 31% at 1 year. Similarly, Cowan et al\textsuperscript{55} reviewed 1542 patients who underwent elective TAA repair across a spectrum of hospitals throughout the United States from the National Inpatient Sample. The overall mortality for TAA repair was a sobering 22.3%, with higher-volume surgeons having better outcomes.
than low-volume surgeons, leading the authors to conclude that regionalization of TAA repair would improve delivery of care to these complex patients.

A consideration of variables predictive of operative mortality reveals consistent themes. In a recent update of our experience, operative mortality was 6.8% for elective operations, and it increased to 12.9% in nonelective situations ($P=0.06$).6 Another negative predictor reported in the literature is advanced age, although we found that overall functional status is more important than chronological age per se.4,32,56 The presence of increasing numbers of comorbid conditions can naturally be expected to increase overall operative risk. Individual series have demonstrated increased operative risks in patients with antecedent coronary artery disease, significant COPD, and, in particular, preoperative renal insufficiency.4–7,30,32,57 Significant antecedent dysfunction in these respective organ systems increases the risks of organ-specific complications after operation, and patients who sustain major neurological deficits, postoperative renal failure, and cardiopulmonary complications have a significantly increased risk of operative mortality.4,6,32,38,56

### Table 2. Contemporary Clinical Series of Descending TA and TAA Repair

<table>
<thead>
<tr>
<th>Reference</th>
<th>No. of Patients</th>
<th>Operative Mortality, n (%)</th>
<th>Paraplegia/Paraparesis</th>
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<tr>
<td>TA only</td>
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<tr>
<td>Coselli et al (2004)46</td>
<td>387</td>
<td>11 (2.8)</td>
<td>10 (2.6)</td>
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<tr>
<td>Estrera et al (2001)47</td>
<td>182</td>
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<tr>
<td>Galloway et al (1996)48</td>
<td>78</td>
<td>8 (10.3)</td>
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<tr>
<td>Verdant et al (1995)49</td>
<td>366</td>
<td>44 (12)</td>
<td>0 (0)</td>
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<td>Yamauchi et al (2006)50</td>
<td>75</td>
<td>2 (2.7)</td>
<td>9 (12%)</td>
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<tr>
<td>Total</td>
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<td>27 (2.5)</td>
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<td>TAA</td>
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<tr>
<td>Svensson et al (1993)52</td>
<td>1509</td>
<td>155 (10)</td>
<td>234 (16)</td>
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<tr>
<td>Coselli et al (2007)53</td>
<td>2286</td>
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<td>Safi et al (2003)54</td>
<td>1004</td>
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<td>36 (3.6)</td>
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<tr>
<td>Jacobs et al (2002)57</td>
<td>184</td>
<td>20 (10.8)</td>
<td>5 (2.7)</td>
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<tr>
<td>Conrad et al (2007)58</td>
<td>455</td>
<td>39 (8.2)</td>
<td>43 (9.5)</td>
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<tr>
<td>Total</td>
<td>6352</td>
<td>613 (9.7)</td>
<td>477 (7.5)</td>
</tr>
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</table>

*Includes TA patients.

### Endovascular Repair

Endoluminal treatment of isolated TA with stent grafting was introduced in 1994 by Dake et al.58 Since then, comparative (versus open repair) trial data are emerging for the spectrum of thoracic aortic pathology.59–63 Despite a lack of late results from clinical trials and a paucity of level I data from randomized controlled trials, the recent advent of a Food and Drug Administration–approved, commercially available device has caused the treatment paradigm for a variety of thoracic aortic pathologies to evolve toward stent-grafting strategies.

TEVAR offers the benefit of aneurysm exclusion without the physiological insult associated with thoracotomy and clamping of the proximal aorta. The procedure is conceptually simple, involving the insertion of a presized covered stent graft that is deployed under fluoroscopic guidance (Figure 5).
However, there are several anatomic factors, including aortic or iliac artery tortuosity, proximity of the aneurysm to the brachiocephalic or visceral vessels, and occlusive disease of the iliac vessels, that can make device delivery a challenge. Indeed, the success of TEVAR is predicated on obtaining quality aortic imaging, careful patient selection, and appropriate preprocedural planning. There are several anatomic barriers to TEVAR. The first is the diameter and length of the proximal and distal aortic fixation sites. The proximal and distal seal zones should be at least 2 cm in length to ensure an adequate fixation and seal. In addition, the delivery systems for thoracic endografts are larger than their abdominal counterparts, with the largest devices requiring an iliac diameter of 9 mm to pass. In the presence of extensively calcified or narrow iliac arteries, a prosthetic conduit sewn to the common iliac artery may be required for successful device delivery and should be planned in advance.

Unlike open repair, TEVAR does not require a period of aortic clamping, and SCI in these patients is thought to be due to permanent coverage of important intercostal arteries. Thus, there is no role for epidural cooling in these patients. However, spinal drainage is likely beneficial in certain high-risk individuals. It has been our practice to preoperatively place a spinal drain in all patients with a previous aortic repair (usually infrarenal) and in those with acute aortic dissections and stable aortic ruptures. In addition, patients who present in a relatively unstable manner may have a drain placed postoperatively.

In a review of our experience with TEVAR, we noted that the left subclavian artery was covered in 20% of patients. Although several device protocols require carotid subclavian bypass in this situation, it has been generally accepted that this is unnecessary in most patients. Indeed, some type of subclavian revascularization was performed in only 57% of these patients with seemingly little consequence in those who were not bypassed. However, a recent report of the EUROSTAR registry showed that coverage of the left subclavian artery without revascularization was independently associated with paraplegia (odds ratio = 3.9; \( P = 0.23 \)). As such, we now perform elective left subclavian revascularization before TEVAR if the preoperative plan involves coverage of this artery in order to obtain an adequate proximal seal zone.

**Description of Available Devices**

The TAG endograft by Gore (Flagstaff, Ariz) was the first thoracic endoprosthesis to be made widely available in the United States, obtaining Food and Drug Administration approval in March 2005. To date, it remains the only commercially approved device for the treatment of TA. The TAG endoprosthesis is essentially a self-expanding covered stent that consists of a nickel-titanium (nitinol) exoskeleton covered by 3 layers of fluorinated ethylene propylene–reinforced polytetrafluoroethylene. Circumferential, external polytetrafluoroethylene cuffs are located at the proximal and distal ends of the prosthesis to facilitate graft seal with the aorta and prevent endoleaks. In addition, the ends are flared and scalloped to compensate for tortuosity throughout the thoracic aorta.

Other devices that are not yet available in the United States outside of investigational protocols include the Talent th-
The W.L. Gore phase II (PIVITOL) trial is a prospective, nonrandomized, multicenter trial aimed at determining the safety and efficacy of the TAG endoprosthesis in the treatment of descending TA. The investigators compared 140 patients treated with the TAG thoracic endograft with 94 patients treated with open repair (44 acquired prospectively and 50 historical patients enrolled in reverse chronological order). The primary end points of the study chosen to confirm the safety and efficacy of the TAG device included a lower incidence of major adverse events in the TAG group compared with open repair and a 1-year freedom from major device-related events of $\geq 80\%$.66

When the open and endovascular groups were compared, there was no difference in demographic or clinical factors except for presentation with aneurysm-related symptoms (21% in the TAG group, 38% in the open group; $P=0.007$).59 The TAG device was successfully implanted in 98% of patients, with the 3 failures occurring secondary to inability to gain access via the iliac vessels.66 The left subclavian artery was covered in 29 patients to obtain an adequate proximal seal, and before the procedure, prophylactic left carotid to subclavian arterial bypass (mandated by the study protocol) was performed in all but 1 of these patients.

The perioperative mortality was significantly lower in the endovascular group than in the open cohort (2.1% versus 11.7%; $P=0.004$), with respiratory failure and stroke leading to 9 of 11 deaths after open repair.59 Other early major adverse events favored endovascular repair as well, with lower rates of SCI (3% versus 14%; $P=0.003$), respiratory failure (4% versus 20%; $P<0.001$), and renal failure (1% versus 13%; $P=0.01$).59 Spinal drainage was not routinely used in either group and, of the 4 endograft patients with SCI, 1 was immediate and 3 presented with a delayed onset; 2 of the 4 patients recovered neurological function fully. In addition, 3 of the patients with SCI had complete coverage of the thoracic aorta from the subclavian artery to the celiac axis.59,66

The mean follow-up to date in the TAG cohort is 25.8 months, and there has been no difference in all-cause mortality between the 2 groups at the 2-year follow-up mark (78% versus 76%; $P=0.48$).59 However, freedom from aneurysm-related mortality again favored the endograft cohort (97% versus 90%; $P=0.02$), with no aneurysm-related mortalities occurring after the first year.66 When the outcome of freedom from major adverse events was examined, endovascular repair was again superior to open repair at 3 years (48% versus 20%), with 70% of events occurring within 30 days of the original procedure.66 Finally, at present, only 6 patients from the TAG group have required reintervention (5 endovascular and 1 open conversion).66

The Vascular Talent Thoracic Stent Graft System for the Treatment of Thoracic Aortic Aneurysms (VALOR) trial is a multicenter, prospective, nonrandomized observational trial that includes 35 institutions across the United States. There are 3 arms to the study, which concluded enrollment in June 2005, as follows: (1) PIVITOL group, (2) registry group, and (3) high-risk group. The PIVITOL or test group included patients with degenerative TA who were considered low to moderate risk for open surgical repair (on the basis of Society for Vascular Surgery/International Society for Cardiovascular Surgery criteria). The primary safety end point is all-cause mortality at 1 year, and although no surgical control arm was included, open comparisons were derived from the literature. The primary efficacy end point is successful aneurysm treatment at 1 year. Secondary end points include technical success and 30-day death, SCI, secondary procedures due to endoleaks, and major adverse events.66,67

The high-risk group enrolled 150 patients who were Society for Vascular Surgery group 3 or nonsurgical candidates with thoracic aortic pathology. The mean age was 73 years, and the male-to-female ratio was 1.5:1. The majority of patients had degenerative aneurysms (82%), with the remaining having aneurysmal degeneration of a previous dissection (9%), pseudoaneurysm (9%), trauma (6%), and complicated type B dissection (4%). The initial device deployment success rate was 98%. The 30-day mortality was 8.4%, with an 8% incidence of stroke. SCI rates were 5.5% in the perioperative period, with two thirds of patients having recovered by 6 months. The endoleak rate was 10% at 6 months, and 2.8% of patients underwent secondary interventions. These early results with 8.4% mortality and 5.5% paraplegia rates compared favorably with open historical controls and were much better than expected for this group of high-risk operative candidates.67

The VALOR trial completed its enrollment in June 2005, and results of the PIVITOL group were presented by Fairman et al68 at the 2007 meeting of the Society for Vascular Surgery. Of the 195 enrolled subjects, 159 completed at least 12 months of follow-up. The device was successfully deployed in 99.5% of patients. The 30-day mortality was 2.1%, with a paraplegia rate of 1.5% and a 3.6% rate of stroke. The all-cause mortality at 12 months was 16.1%, and aneurysm-related mortality was 3.1%. Successful aneurysm treatment (<5 mm growth of sac between 1- and 12-month visits with no type I endoleak) was achieved in 89.2% of patients.

The Study of Thoracic Aortic Aneurysm Repair With the Zenith TX2 TAA Endovascular Graft (STARZ) trial is a multicenter, nonrandomized, prospective clinical trial involving 35 sites in the United States and Canada.69,70 The goal is to enroll 270 patients with a comparative control group of patients who did not meet anatomic inclusion criteria for
endovascular repair and underwent open repair (either concurrent to the study or as historical controls). The primary safety end point is equivalent 30-day survival rates between the 2 cohorts, with secondary end points involving postoperative complications and device-related events. This trial also includes a quality-of-life measure with the use of the Short-Form 36 questionnaire.\textsuperscript{60,70} The study completed enrollment in July 2006, and Matsumura et al\textsuperscript{60} recently presented early results at the 2007 Society for Vascular Surgery meeting. They enrolled 160 patients in the TEVAR arm and 70 patients in the control group across 42 medical centers. The 30-day mortality was lower in the TEVAR group than in the control group (1.9% versus 5.7%), as were major perioperative adverse events (2.5% in the TEVAR group versus 7.1% in the control group). The paraplegia rate was 1.3% in the TEVAR group and 5.7% in the control group, and renal failure requiring dialysis was also higher in the control group (1.3% in the TEVAR group versus 4.3% in the control group).

Single-Center Experience With TEVAR

Wheatley et al\textsuperscript{61} prospectively evaluated 158 consecutive patients who underwent endovascular repair of various thoracic aortic pathologies with the TAG endoprosthesis, of which 76 (48%) were elective aortic aneurysms. The overall 30-day mortality was 3.8%, with a SCI rate of 2.6% (all reported some element of improvement after institution of therapeutic measures). Endoleaks were identified in 11.5% of patients, and the majority of these (61%) were type I from the proximal or distal seal zones. Reinterventions were performed on 12 patients, usually for persistent endoleaks (75%). The mean follow-up was 21.5 months, and the reported all-cause mortality was 17.5%.\textsuperscript{61} These results are similar to those of the PIVITOL trial and confirmed that multicenter results are reproducible in a single-center experience.

Recently, we compiled our experience with 105 patients undergoing thoracic aortic stent grafting and compared the results with 93 patients treated with open surgery during the same time period. Despite borderline statistical significance, the operative mortality was halved in the stent graft group compared with the open group (7.6% versus 15.1%; \(P=0.09\)).\textsuperscript{64} Although a 7.6% mortality lies in the lower end of reported rates for thoracic endografts, which have been up to 20%,\textsuperscript{73,74} it is substantially higher than that of our updated experience with 873 infrarenal abdominal aortic aneurysm endovascular repairs (1.8%)\textsuperscript{75} or the PIVITOL trial\textsuperscript{59} and may be related to the fact that 30% of the endograft patients were not considered open surgical candidates.\textsuperscript{64} The SCI rate was 6.7% in our stent graft population, with 2 patients experiencing transient paraparesis that had resolved by discharge.\textsuperscript{64} These results are similar to those of several recently published multicenter trials that reported SCI rates of 3% to 4%.\textsuperscript{39,62,63} Recently, Jackson et al\textsuperscript{64} reported that 26% of patients being evaluated for TEVAR were rejected for anatomic reasons, with hostile proximal neck characteristics most commonly cited as the reason for disqualification. Similarly, several reviews have noted that 8% to 43% of landing sites in descending aortic aneurysms will not allow an appropriate 2-cm length for secure proximal fixation.\textsuperscript{73,74,76,77}

Indeed, in 20% of our patients, the left subclavian artery was intentionally covered (11.5% underwent preprocedural subclavian artery bypass). The 4-year survival after endovascular repair was 54%, and the freedom from reintervention rate was 81%.\textsuperscript{64}

The largest single-center series with the TX1/TX2 device is from the Cleveland Clinic and involved 100 patients who underwent endografting, with 81 patients treated for degenerative aneurysms. They reported a technical success rate of 87.6%, but 29% of patients required surgical modification to facilitate device delivery.\textsuperscript{61} The perioperative death rate was 13%. SCI was suspected in 6 patients, with 2 patients developing permanent paraplegia. In addition, 1 patient developed late paraparesis 1 year after implantation after an episode of hypotension. The 1-year follow-up data showed sac regression in 52% of patients and growth in 1 patient. There were no cases of device migration noted.\textsuperscript{61} Endoleaks were detected in 8.5% of patients at 30 days and 6% by 1 year, and secondary interventions were required in 15 patients.\textsuperscript{61}

European Registries

The Talent Thoracic Retrospective Registry is a clinical outcomes database of patients from 7 European referral centers who underwent TEVAR of a spectrum of thoracic aortic diseases with the Talent endoprosthesis. They enrolled 457 patients over an 8-year period (November 1996 to March 2004), of whom 137 (30%) were treated for TA. The in-hospital mortality was 5% (7.9% for acute presentation and 4% for elective cases; \(P=0.11\)), and the median hospital stay was 9 days. The in-house major adverse event rate was 12.5% (not including deaths), and stroke was the most common complication, occurring in 3.7% of patients. Paraplegia occurred in 8 patients (1.7%) (4 with degenerative aneurysms [3%]) and was significantly correlated with coverage of \(>20\) cm of aorta. The mean follow-up was 24 months, and there were 11 late aneurysm-related deaths (7 ruptures) for a 9% risk of aortic death at 36 months. All patients who experienced late aortic rupture had known persistent type I endoleaks, thus reinforcing the importance of early correction of this entity. Secondary endoleaks (types I and III) were reported in 44 patients (10.4%), of whom 21 underwent successful adjunctive endovascular treatment. The 5-year freedom from reintervention was 70%, leading the authors to conclude that the Talent stent graft is a durable device.\textsuperscript{78}

A recent evaluation of the European EUROSTAR and the United Kingdom Thoracic Endograft registries (prospectively gathered databases of aortic pathology) identified 249 patients who underwent TEVAR for degenerative thoracic aneurysms. The primary technical success rate was 87%, and intraoperative device–related complications occurred in 16% of patients. They reported a 30-day mortality of 10% (28% in emergent and 5.3% in elective) and a paraplegia rate of 4% with an 80% 1-year survival.\textsuperscript{62} More than 50% of these patients were considered too high risk for open operative repair, again reaffirming the notion that this procedure can be acceptably applied to high-risk patients.\textsuperscript{62} A cohort of EUROSTAR patients was compared with 177 patients from the randomized controlled Dutch Randomized Endovascular Aneurysm Management
HYBRID PROCEDURES

The anatomic constraints of the 2-cm proximal and distal seal zones will preclude TEVAR in many patients, particularly those with TAA. As descending TA extend to the thoracoabdominal aorta, the extent of surgery with consequent risks of paraplegia, renal insufficiency, and death increases. Although, in our experience, the perioperative mortality after TAA repair is $\approx 8\%$, a recent review of the National Inpatient Sample (a stratified discharge database of a representative 20\% of US hospitals) reported an overall real-world mortality of 22.3\%. Thus, extension of stent graft repair to patients with TA that involve the aortic arch or visceral abdominal aortic segment with a so-called hybrid operation has the potential to afford genuine benefit to such high-risk patients. In this instance, the proximal or distal seal zone can be extended by rerouting or “debranching” bypass grafts from the ascending aorta in the case of arch aneurysms and the infrarenal aorta and/or iliac arteries for lesions extending into or beyond the visceral vessels. This hybrid approach has been advocated by some with early success (Figure 6). Black et al recently reported data on 25 high-risk patients treated with hybrid procedures (80\% had type II or III TAA). They identified an elective mortality of 17\% and no paraplegia with the procedure. Zhou et al performed 31 hybrid procedures in high-risk patients that included 16 patients with ascending or arch aneurysms and 15 patients with visceral aortic segment aneurysms. They noted a perioperative death rate of 3.2\% (1 patient), again with no cases of postoperative paraplegia. Although such procedures seem intuitively logical for patients with large aneurysms who are poor candidates for conventional resection, well-conducted comparative trials in equivalent patient populations are not available. To date, we have applied such hybrid procedures in some 30 patients deemed unfit for conventional open operation. Although many have been salvaged, including cases of ruptured TAA, the open component of the hybrid procedure (illustrated in Figure 6) is in itself a major surgical undertaking. The expected evolution of this concept is, of course, the eventual application of branched graft technology, currently available in only a few centers in the United States, in the form of physician-sponsored investigational device exemption applications. Worldwide, however, $\approx 400$ such cases (largely in Australia) have been performed, and a US phase I trial is imminent. Chuter et al recently reported results with 16 patients treated with customized branched grafts for TAA. Graft deployment was successful in all patients, and a total of 57 visceral branches were treated in the 16 patients. There were significant complications in 4 patients (25\%) that consisted of the following: pneumonia in 2 patients, paraplegia and renal failure resulting in death in 1 patient, and requirement of reintervention for an iatrogenic aortic dissection with resulting type I endoleak in 1 patient. The average follow-up was 180 days, and 98.2\% of branches were patent during this period. These results, although limited by short follow-up, support an expanded role for fenestrated endografts in the treatment of TAA; as this technology improves, it will likely replace the hybrid procedure in high-risk patients.

CONCLUSION

Considerable progress has been made in the overall results of treatment of descending TA and TAA. Open repair, although durable, continues to be plagued by major postoperative complications that have persisted despite considerable effort aimed at risk reduction. The availability of endovascular techniques has changed the way we approach patients with TA as patients who were once considered to have prohibitive comorbid risk factors are now candidates for aneurysm repair. As comparative studies of open TA/TAA repair and stent grafting become available and the technology evolves, it is clear that this will become the primary method of TA repair in anatomically suitable patients.

DISCLOSURES

None.
References


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