



Kansas City

An Independent Licensee of the Blue Cross and Blue Shield Association

Endovascular Stent Grafts for Disorders of the Thoracic Aorta

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Policy

Blue Cross and Blue Shield of Kansas City (Blue KC) will provide coverage for endovascular stent grafts for disorders of the thoracic aorta when it is determined to be medically necessary because the criteria shown below are met.

When Policy Topic is covered

Endovascular stent grafts may be considered **medically necessary** for the treatment of descending thoracic aortic aneurysms without dissection using devices approved by the U.S. Food and Drug Administration for their approved specifications (see Considerations section).

Endovascular stent grafts using devices approved by the U.S. Food and Drug Administration may also be considered **medically necessary** in the following situations:

- Treatment of acute, complicated (organ or limb ischemia or rupture) Type B thoracic aortic dissection

Endovascular stent grafts may be considered **medically necessary** for the treatment of rupture of the descending thoracic aorta.

When Policy Topic is not covered

Endovascular stent grafts are considered **investigational** for the treatment of thoracic aortic lesions that do not meet the above criteria, including but not limited to thoracic aortic arch aneurysms.

Considerations

Endograft placement relies on non-aneurysmal aortic segments proximal and distal to the aneurysm and/or dissection for anchoring, and a maximal graft diameter that varies by device. The GORE TAG® endoprosthesis is approved by the U.S. Food and Drug Administration (FDA) for “>2 cm non-aneurysmal aorta proximal and distal to the aneurysm and an “aortic inner diameter of 23–37 mm.” The Talent™ Thoracic Stent Graft System is approved by the FDA for “non-aneurysmal aortic proximal and distal neck lengths >20mm” and “non-aneurysmal aortic diameter in the range of 18–42 mm.” The Zenith 2X2® device is approved by the FDA for non-aneurysmal aortic segments “of at least 25 mm in length” and “diameter measured outer wall to outer wall of no greater than 38 mm and no less than 24 mm.”

Description of Procedure or Service

Thoracic endovascular aneurysm repair (TEVAR) involves the percutaneous placement of a stent graft in the descending thoracic or thoracoabdominal aorta. It is a less invasive alternative to open surgery for the treatment of thoracic aortic aneurysms, dissections, or rupture, and thus has the potential to reduce the morbidity and mortality of open surgery.

Background

Thoracic Aortic Aneurysms. Aortic aneurysms are arterial dilations that are associated with age, atherosclerosis, and hypertension, as well as some congenital connective tissue disorders. The

likelihood of significant sequelae of aortic aneurysm is dependent on location, size, and underlying disease state. Left untreated, these aneurysms tend to enlarge over time, increasing the risk of rupture or dissection. Of greatest concern is the tendency for aortic aneurysms to rupture, with severe consequences including death. Another significant adverse occurrence of aortic aneurysm is aortic dissection, in which an intimal tear permits blood to enter the potential space between the intima and the muscular wall of the aorta. Stable dissections may be managed medically; however, dissections which impinge on the true lumen of the aorta, or occlude branching vessels are a surgical emergency.

The indications for the elective surgical repair of aortic aneurysms are based on estimates of the prognosis of the untreated aneurysm balanced against the morbidity and mortality of the intervention. The prognosis of thoracic aortic aneurysm (TAA) is typically reported in terms of the risk of rupture according to size and location, i.e., the ascending or descending or thoracoabdominal aorta. While several studies have estimated the risk of rupture of untreated aneurysms, these studies have excluded patients who underwent surgical repair; therefore, the true natural history of thoracic aneurysms is unknown. Clouse and colleagues performed a population-based study of TAA diagnosed in Olmstead County, Minn., between the period of 1980 and 1994. (1) A total of 133 patients were identified; the primary clinical endpoints were cumulative rupture risk, rupture risk as a function of aneurysm size, and survival. The cumulative risk of rupture was 20% after 5 years. The 5-year risk of rupture as a function of aneurysm size at recognition was 0% for aneurysms less than 4 cm in diameter, 16% for those 4 to 5.9 cm, and 31% for aneurysms 6 cm or more. Interestingly, 79% of the ruptures occurred in women. Davies and colleagues reported on the yearly rupture or dissection rates in 721 patients with TAA. (2) A total of 304 patients were dissection-free at presentation; their natural history was followed up for rupture, dissection, and death. Patients were excluded from analysis once the operation occurred. Not surprisingly, the authors reported that aneurysm size had a profound impact on outcomes. For example, based on their modeling, a patient with an aneurysm exceeding 6 cm in diameter can expect a yearly rate of rupture or dissection of at least 6.9% and a death rate of 11.8%. In a previous report, the authors suggested surgical intervention of a descending aorta aneurysm if its diameter measured 6.5 cm. (3)

Surgical morbidity and mortality are typically subdivided into elective versus emergency repair with a focus on the incidence and risk of spinal cord ischemia, considered one of the most devastating complications, resulting in paraparesis or paraplegia. The operative mortality of surgical repair of aneurysm of the descending and thoracoabdominal aorta is estimated at 6–12% and 10–15%, respectively, while mortality associated with emergent repair is considerably higher. (1, 4) In elective cases, predictors of operative mortality include renal insufficiency, increasing age, symptomatic aneurysm, presence of dissection, and other comorbidities, such as cardiopulmonary or cerebrovascular disease. The risk of paraparesis or paraplegia is estimated at 3–15%. Thoracoabdominal aneurysms, larger aneurysms, presence of dissection, and diabetes are predictors of paraplegia. (5, 6) A number of surgical adjuncts have been explored over the years to reduce the incidence of spinal cord ischemia, including distal aortic perfusion, cerebrospinal fluid drainage, hypothermia with circulatory arrest, and evoked potential monitoring. (7-10) However, the optimal protective strategy is still uncertain. (11)

This significant morbidity and mortality makes definitive patient selection criteria for repair of thoracic aneurysms difficult. Several authors have recommended an individual approach based on balancing the patients' calculated risk of rupture with their anticipated risk of postoperative death or paraplegia. However, in general, surgical repair is considered in patients with adequate physiologic reserve when the thoracic aneurysm measures from 5.5 to 6 cm in diameter or in patients with smaller symptomatic aneurysms.

Thoracic Aortic Dissection. Aortic dissection can be subdivided into type A, which involves the aortic arch, and type B, which is confined to the descending aorta. Type A dissections are usually treated surgically, while type B dissections are usually treated medically, with surgery indicated for serious complications, such as visceral ischemia, impending rupture, intractable pain, or sudden reduction in aortic size. Dissections associated with obstruction and ischemia can also be subdivided into an

obstruction caused by an intimal tear at branch vessel orifices, or by compression of the true lumen by the pressurized false lumen. It has been proposed that endovascular therapy can repair the latter group of dissections by redirecting flow into the true lumen. The success of endovascular stent grafts of abdominal aortic aneurysms has created interest in applying the same technology to the aneurysms and dissections of the descending or thoracoabdominal aorta.

As noted previously, type A dissections (involving the ascending aorta) are treated surgically. There is more controversy regarding the optimal treatment of type B dissections (i.e., limited to the descending aorta). In general, chronic, stable type B dissections are managed medically, although some surgeons recommended a more aggressive approach for younger patients in otherwise good health. When serious complications arise from a type B dissection, i.e., shock or visceral ischemia, surgical intervention is usually indicated. However, although there is an estimated 50% 1-year survival rate in those treated with an open surgical procedure, it is not clear whether that is any better or worse than those treated medically. (12) The advent of stent grafting, with the potential of reducing the morbidity and mortality of an open surgical procedure, may further expand the number of patients considered for surgical intervention.

Thoracic Aortic Rupture. Rupture of the thoracic aorta is a life-threatening emergency that is nearly always fatal if untreated. Thoracic artery rupture can result from a number of factors. Aneurysms can rupture due to progressive dilatation and pressure of the aortic wall. Rupture can also occur as a result of traumatic injury to the aorta, such as occurs with blunt chest trauma. Penetrating injuries that involve the aorta can also lead to rupture. Penetrating ulcers can occur in the setting of widespread atherosclerotic disease and lead to aortic rupture.

Emergent repair of thoracic artery rupture is indicated in many cases in which there is free bleeding into the mediastinum and/or complete transection of the aortic wall. In some cases of aortic rupture, where the aortic media and adventitia are intact, watchful waiting with delayed surgical intervention can be performed. With the advent of TEVAR, the decision making for intervention may be altered, as there may be a greater tendency to intervene on borderline cases due to the potential for less adverse events with TEVAR.

Thoracic Endovascular Aneurysm Repair. Thoracic endovascular aneurysm repair (TEVAR) is an alternative to open surgery. TEVAR has been proposed for prophylactic treatment of aneurysms that meet criteria for surgical intervention, as well as for patients in need of emergency surgery for rupture or complications related to dissection. The standard open surgery technique for thoracic aortic aneurysm (TAA) is open operative repair with graft replacement of the diseased segment. This procedure requires lateral thoracotomy, use of cardiopulmonary bypass, long operation times, and is associated with a variety of peri- and postoperative complications, with spinal cord ischemia considered the most devastating.

TEVAR is performed through a small groin incision to access the femoral artery, followed by delivery of catheters across the diseased portion of the aorta. A tubular stent graft composed of fabric and metal is then deployed under fluoroscopic guidance. The stent graft is then fixed to the proximal and distal portions of the aorta. Approximately 15% of patients do not have adequate femoral access, and the procedure can be performed by a retroperitoneal approach in these cases.

Potential complications of TEVAR are bleeding, vascular access site complications, spinal cord injury with paraplegia, renal insufficiency, stroke, and cardiopulmonary complications. Some of these complications are similar to those encountered with open repair, such as paraplegia and cardiopulmonary events, and others are unique to TEVAR, such as access site complications.

Regulatory Status

In March 2005, the GORE TAG® Thoracic Endoprosthesis (W.L. Gore and Associates, Inc. Flagstaff, AZ) was approved by the U.S. Food and Drug Administration (FDA) through the premarket approval (PMA) process for endovascular repair of aneurysms of the descending thoracic aorta. Use of this

device requires patients to have adequate iliac/femoral access, aortic inner diameter in the range of 23–37 mm, and equal to or greater than 2 cm non-aneurysmal aorta proximal and distal to the aneurysm. In January 2012, the FDA granted an expanded indication for the GORE TAG® system to include isolated lesions of the thoracic aorta. Isolated lesions refer to aneurysms, ruptures, tears, penetrating ulcers and/or isolated hematomas, but do not include dissections. Indicated aortic inner diameter is 16–42 mm, with ≥ 20 mm of non-aneurysmal aortic distal and proximal to the lesion.

In May 2008, the Zenith TX2® TAA Endovascular Graft (Cook Incorporated, Bloomington, IN) was approved by the FDA through the PMA process for the endovascular treatment of patients with aneurysms or ulcers of the descending thoracic aorta. Indicated aortic inner diameter is in the range of 24–38 mm.

In June 2008, the Talent™ Thoracic Stent Graft System (Medtronic Vascular, Santa Rosa, CA) was approved by the FDA through the PMA process for the endovascular repair of fusiform and saccular aneurysms/penetrating ulcers of the descending thoracic aorta. Indicated aortic inner diameter is in the range of 18–42 mm.

In September 2012, FDA approved the Relay® Thoracic Stent-Graft with Plus Delivery System (Bolton Medical, Sunrise, FL) for the endovascular repair of fusiform aneurysms and saccular aneurysms/penetrating atherosclerotic ulcers in the descending thoracic aorta in patients having appropriate anatomy, including:

- Iliac or femoral access vessel morphology that is compatible with vascular access techniques, devices and/or accessories
- Non-aneurysmal aortic neck diameter in the range of 19–42 mm
- Non-aneurysmal proximal aortic neck length between 15 and 25 mm and nonaneurysmal distal aortic neck length between 25 and 30 mm depending on the diameter stent-graft required.

In October 2012, the FDA granted approval for the Valiant™ Thoracic Stent Graft with the Captivia® Delivery System (Medtronic Vascular, Santa Rosa, CA) to include isolated lesions of the thoracic aorta. Isolated lesions refer to aneurysms, ruptures, tears, penetrating ulcers and/or isolated hematomas, but not including dissections. Indicated aortic diameter is 18–42 mm for aneurysms and penetrating ulcers, and 18–44 mm for blunt traumatic injuries. In January 2014, the FDA-approved indications for the Valiant™ Thoracic Stent Graft with the Captivia® Delivery System were expanded into include all lesions of the descending thoracic aorta, including type B dissections.⁽¹³⁾ The Valiant graft is intended for the endovascular repair of all lesions of the descending aorta in patients having appropriate anatomy including:

- Iliac/femoral access vessel morphology that is compatible with vascular access techniques, devices, and/or accessories;
- Non-aneurysmal aortic diameter in the range of 18–42 mm (fusiform and saccular aneurysms/penetrating ulcers), 18 mm to 44 mm (blunt traumatic aortic injuries) or 20 mm to 44 mm (dissections) and;
- Non-aneurysmal aortic proximal and distal neck lengths ≥ 20 mm (fusiform and saccular aneurysms/penetrating ulcers), landing zone ≥ 20 mm proximal to the primary entry tear (BTAI, dissection). The proximal extent of the landing zone must not be dissected.

The expanded approval was based on the Medtronic Dissection Trial, a prospective, nonrandomized study to evaluate the performance of the Valiant stent graft for acute, complicated Type B dissection, which included 50 patients enrolled at 16 sites.

Other devices are under development, and in some situations, physicians have adapted other commercially available stent grafts for use in the thoracic aorta.

Rationale

This policy was originally created in 2002 and updated regularly with searches of the MEDLINE database. The most recent literature search was performed for the period of May 2013 to May 29, 2014. The following is a summary of key findings.

LITERATURE REVIEW

Controlled trials of specific patient groups treated with specific procedures are required to determine if endovascular approaches are associated with equivalent or improved outcomes compared to surgical repair. For patients who are candidates for surgery, open surgical resection of the aneurysm with graft replacement is considered the gold standard for treatment of aneurysms or dissections. Some patients who would not be considered candidates for surgical therapy due to unacceptable risks might be considered candidates for an endovascular graft. In this situation, the outcomes of endovascular grafting should be compared to optimal medical management. Comparative mortality rates are of high concern, as are the rates of serious complications such as the incidence of spinal cord ischemia.

Randomization to treatment groups is also very important in this area. This is due to the numerous patient factors (,e.g., age, co-morbidities, location and size of the aneurysm, presence or absence of dissection) and procedure variables involved in surgical repair that are potential confounders of outcome. Selection for either open or endovascular repair involves a complex set of patient and anatomical considerations. As a result, studies are highly prone to selection bias if there is not randomized assignment.

Aneurysms of the descending thoracic aorta

There are no randomized controlled trials (RCTs) of endovascular repair versus open surgery for thoracic aneurysms. The best evidence consists of non-randomized comparative studies and systematic reviews of these studies. The following review includes representative prospective, non-randomized studies and selected systematic reviews.

Systematic reviews

A systematic review of the evidence for endovascular repair of thoracic aneurysms was published by the Cochrane Peripheral Vascular Diseases Group in January 2009 and was based on the literature to October 2008.(14) No RCTs comparing endovascular repair to open surgical interventions for thoracic aneurysms were found in the medical literature. Reports from non-randomized studies suggest that endovascular repair is technically feasible and may reduce early negative outcomes, including death and paraplegia. However, endovascular repair is associated with late complications not often seen in open surgery, such as the development of leaks, graft migration, and need for re-intervention. Patients receiving endovascular grafts also more require frequent surveillance with computed tomography (CT) scans and have increased radiation exposure.

Non-randomized comparative studies

TAG 99-01 study. The TAG 99-01 study was a controlled trial of patients with aneurysms of the descending thoracic aorta treated with either surgical repair (n=94; 50 historical, and 44 concurrent) or stent grafting (n=140) at 17 sites in the United States. Patients for both the graft group and the control group were selected using the same inclusion and exclusion criteria. After fractures in the wire frame of the TAG endoprosthesis were discovered in TAG 99-01, 51 patients underwent stent grafting with a modified TAG endoprosthesis at 11 sites in the subsequent TAG 03-03 study. The primary outcomes assessed in both TAG 99-01 and TAG 03-03 were the number of patients who had 1 or more major adverse events and the number of patients who did not experience device-related events 12 months' post-device deployment. The number of patients in the TAG 99-01 device group who experienced equal to or greater than 1 major adverse event (42%) was significantly lower (p<0.001) than the surgical repair control group (77%) at 1-year follow-up. Major adverse events included major bleeding,

neurologic; pulmonary; renal function; and vascular complications. In the TAG 99-01 device group, 4 of 140 patients (3%) experienced paraplegia or paraparesis versus 13 of 94 patients (14%) in the control group.

In the 12-month follow-up of TAG 99-01, 8 patients (3%) had 1 or more major adverse device-related events, while the 12- to 24-month follow-up in this group only noted 1 major adverse device-related event. No major adverse device-related events occurred in the 30-day follow-up of the TAG 03-03 group. Information on 142 patients from the TAG 99-01 trial was published by Makaroun et al; however, the authors did not report on comparative data with the surgical control group, citing regulatory requirements pending U.S. Food and Drug Administration (FDA) review. (15) The Makaroun et al. report of the TAG 99-01 study reported favorable aneurysm-related (97%) and overall survival (75%) rates and concluded that the GORE TAG device was a safe alternative treatment for descending thoracic aortic aneurysms.

These same authors have also reported 5-year outcomes of the TAG 99-01 trial. (16) In this follow-up of 140 endograft patients and 96 non-contemporaneous controls, the authors concluded that endovascular treatment was superior to surgical repair at 5 years in anatomically suitable patients. At 5 years, aneurysm-related mortality was lower for TAG patients at 2.8% compared with open controls at 11.7% ($p=0.008$). No differences in all-cause mortality were noted, with 68% of TAG patients and 67% of open controls surviving to 5 years. Endoleaks in the TAG group decreased from 8.1% at 1 month to 4.3% at 5 years. Five TAG patients have undergone major aneurysm-related re-interventions at 5 years (3.6%). For this study, significant sac size change was defined as 5 mm or greater increase or decrease from the 1-month baseline measurement. Migration was defined as 10 mm or more cranial or caudal movement of the device inside the aorta. Compared with the 1-month baseline, sac size at 60 months decreased in 50% and increased in 19% of TAG patients. At 5 years, there have been no ruptures, 1 migration, no collapse, and 20 instances of fracture in 19 patients, all before the revision of the TAG graft. They also noted that although sac enlargement was concerning, a modified device may be helping to resolve this issue.

VALOR and VALOR II studies The Evaluation of the Safety and Effectiveness of the Medtronic Vascular Talent Thoracic Stent Graft System for the Treatment of Thoracic Aortic Aneurysms (VALOR) study was a nonrandomized study conducted at 38 sites within the United States. (17) The VALOR trial enrolled patients who were candidates for open surgical repair and compared 195 thoracic aortic aneurysm (TAA) patients (aged: 70.2 \pm 11.1 years; male 59%) to 189 retrospective open surgical repair controls (aged: 69.6 \pm 9.1 years; male: 52.4%). Patients in the Talent endovascular graft group had lower TAA size and were less likely to have a previous aortic aneurysm (37/195 compared to 70/189 in the surgery group). Talent subjects were also less likely to have comorbid conditions including angina (pooled relative risk [PRR]: 1.6; 95% confidence interval [CI]: 1.0, 2.6), coronary artery disease (PRR: 1.2; 95% CI: 1.0, 1.5) and previous myocardial infarction (MI) (PRR: 1.3; 95% CI: 1.0, 1.6). Thirty-day (Talent group: 4/195 vs. surgery group: 15/189; $p<0.1$) and 12-month mortality (Talent group 31/192 vs. surgery group: 39/189; $p<0.01$) was lower in the endovascular graft group compared to open surgery. Fewer endovascular graft patients required blood transfusions (Talent: 22% vs. 93%). Endovascular graft patients had a shorter intensive care unit (Talent: 2 \pm 5.5 days vs. surgery: 8 \pm 8.5 days) and overall hospital stay (Talent: 6 \pm 11.5 days vs. 17 \pm -15 days).

The Evaluation of the Clinical Performance of the Valiant Thoracic Stent Graft in the Treatment of Descending Thoracic of Degenerative Etiology in Subjects Who Are Candidates for Endovascular Repair (VALOR II) was a prospective nonrandomized study at 24 sites that was designed to evaluate the Valiant thoracic stent-graft, as opposed to the VALOR study which was an evaluation of the Talent stent-graft.(18) VALOR II enrolled 160 patients who underwent stent grafting with the Valiant device, using similar enrollment criteria to VALOR. Outcomes were compared to those from the VALOR study. Stent-graft delivery was technically successful in 154 patients. One hundred fifty-one patients were evaluated at 12 months post-procedure; all-cause mortality at 12 months associated with the Valiant stent-graft was statistically noninferior to the Talent stent-graft (12.6% vs 16.1%) and exceeded the

primary effectiveness goal of 12-month successful aneurysm treatment (defined as absence of aneurysm growth >5mm and of secondary procedures for type I/III endoleak).

In 2014, Matsumoto et al reported rates of secondary procedures over 3 years of follow up for patients enrolled in the VALOR and VALOR II studies.(19) Three-year follow up evaluation was available for 127 patients (65.5%) in the TEVAR arm of VALOR and 96 (61.8%) in VALOR II. Freedom from secondary procedures at 3 years was 85.1% (95% CI 78.5-89.8%) in the TEVAR arm of VALOR and 94.9% (95% CI 88.8% to 97.7%) in VALOR II (P<0.001). The overall 3-year difference between groups in secondary procedure rates were driven by differences in early (within 1 year) reintervention rates. This comparison suggests that the newer-generation stent-graft device may be associated with fewer subsequent reinterventions; however, the non-randomized comparison and potential differences between patients in VALOR and VALOR II makes it difficult to draw firm conclusions about the relative efficacy of different devices.

Goodney et al. (20) These authors used Medicare claims data from 1998-2007 to compare thoracic endovascular aneurysm repair (TEVAR) with open surgery in patients with aneurysms of the descending aorta. This study included both intact and ruptured aneurysms. A total of 13,998 patients with intact aneurysms were identified; 11,565 were treated with open surgery and 2,433 with TEVAR. There were baseline differences between the 2 groups, with the TEVAR group being older and more likely to have a variety of medical comorbidities. The authors performed 2 comparisons, an unadjusted comparison of outcomes in all patients and a propensity-matched comparison in a subset of 1,100 patients.

Thirty-day mortality was slightly lower among TEVAR patients compared to open surgery, but this difference did not reach statistical significance (6.1% vs. 7.1%, p=0.07). In the propensity-matched comparison, there was no difference in 30-day mortality between the TEVAR and open surgery group (4.5% vs. 4.2%, p=0.78). Long-term survival was reported by Cox proportional hazards analysis. At 5 years, survival in the TEVAR group was lower than for the open surgery group (62% vs. 72%, p=0.001). In the propensity-matched comparison, the TEVAR group also had lower overall survival at 5 years compared to the open surgery group (73% vs. 81%, p=0.007).

Matsumara et al. The Zenith TX2 device also received premarketing approval (PMA) from the FDA based on results of Matsumara et al. (21) The study was a prospective cohort study that compared 160 thoracic endovascular aneurysm repair patients (aged: 72+/-9.6 years; male: 72%) to 70 open surgery patients (aged: 68+/-12 years; male 60%). The study arms were comparable in previous history of cardiovascular and other vascular disease. The TEVAR patients had a lower American Society of Anesthesiologist classification (p<0.01) and higher Society of Vascular Surgery/International Society of Cardiovascular Surgery risk score (p=0.03).

The 30-day survival rate for the endovascular group was non-inferior (p<0.01) to the control group (98.1% vs. 94.3%, respectively). The 30-day severe morbidity composite index (cumulative mean number of events per patient) was significantly lower in the endovascular group compared to the control group (0.2 ± 0.7 vs. 0.7 ± 1.2; p<0.01). At 12 months, aneurysm growth was identified in 7.1% of the endovascular patients, endoleak occurred in 3.9% (4/103 patients), and migration in 2.8% (3/107 patients). At 12 months, aneurysm growth was identified in 7.1% of the endovascular patients, endoleak occurred in 3.9% (4/103 patients), and migration in 2.8% (3/107 patients).

In 2014, Matsumara et al published 5-year follow up from the Zenith TX2 prospective cohort study described above.(22) The 70 Patients in the open surgical control group underwent clinical evaluation before discharge or at 1 month and then at 12 months and yearly thereafter up to 5 years. Follow up beyond 1 year was unavailable for 24 patients due to institutional review board restrictions and for 4 additional patients who were lost to follow up. TEVAR patients underwent follow up at 1, 6, and 12 months post-procedure and yearly thereafter. Of the 160 TEVAR patients, 2 did not have successful device deployment and only had follow up to 30 days, and an additional 32 were lost to follow up. Five-year survival was 62.9% for the TEVAR group and 62.8% for the open surgical group (nonsignificant

difference between groups). Kaplan-Meier estimates of freedom from severe morbidity composite index was significantly higher in the TEVAR group than the open surgical control group (87.3% vs 64.3% at 1 year and 79.1% vs 61.2% at 5 years, log-rank test, $P < .001$). Secondary interventions occurred at similar rates between the endovascular and open surgical control patient groups during follow-up through 5 years. While this study is somewhat limited by some loss to follow up, it suggests that the early morbidity benefit associated with TEVAR persists over time and that rates of secondary interventions may be comparable to open surgical repair.

Orandi et al. Orandi et al. published a comparative analysis of 1,030 patients undergoing open surgery and 267 undergoing endovascular repair using the Nationwide Inpatient Sample database. (23) In-hospital mortality was similar between open and endovascular patients (adjusted odds ratio [OR]: 1.2, 95% CI: 0.73-2.12). Patients undergoing endovascular repair had fewer cardiac, respiratory, and hemorrhagic complications and a decreased length of hospital stay compared to open surgery patients. Dick et al. compared clinical and quality-of-life outcomes in 52 patients undergoing endovascular repair with 70 patients undergoing open surgical repair. (24) Perioperative mortality rates did not differ between groups (8% vs. 9%, respectively; $p=0.25$). The mean overall quality-of-life score was 93 for the open surgery group compared with 83 for the endovascular group ($p=0.66$). There were no significant differences between groups on anxiety, depression, or other quality-of-life sub-measures.

Section Summary. There are no RCTs of TEVAR versus open surgery for elective repair of thoracic aortic aneurysms, with the best evidence on this question consisting of non-randomized, comparative studies. The main limitation of these studies is non-comparability of groups, with group differences demonstrated between endovascular and surgical patients in nearly all cases. In some instances, TEVAR patients appear to be less severely ill than open surgery patients, but in other instances, the TEVAR population appears to be more severely ill. These group differences preclude definitive conclusions about the comparative efficacy of endovascular versus open surgery for repair of thoracic aneurysms.

The results of these studies are consistent in showing equivalent or reduced short-term mortality and fewer early complications for TEVAR. The consistency of this finding across populations with different characteristics lends support to the conclusion that TEVAR is a safer procedure in the short term. The likely short-term benefits of TEVAR are mitigated by longer-term outcomes that are less favorable for TEVAR. Longer-term mortality appears to be roughly similar for patients undergoing TEVAR or open surgery, and some studies report that long-term survival is better following open surgery. TEVAR patients have a higher rate of long-term complications, primarily from endoleaks, and a higher re-intervention rate. TEVAR patients also require closer monitoring after intervention, with more frequent imaging studies.

Dissection of the descending aorta (type B dissection)

One randomized controlled trial (RCT), the Investigation of Stent Grafts in Patients with type B Aortic Dissection (INSTEAD) trial has been completed for patients with chronic, stable dissections. There are no RCTs for treatment of acute, complicated type B dissections, which is the group for which endovascular repair is often targeted.

Systematic reviews

In 2014, Ramdass reported results from a systematic review of studies reporting the 30-day mortality after TEVAR for acute or chronic symptomatic type B aortic dissection.(25) The review included 69 studies, encompassing 1,574 patients, that met inclusion criteria published between 1998 and 2013, including 1 RCT, 55 retrospective, 3 prospective, 9 case reports, and 1 mixed study. All studies addressed type B aortic dissection, but were heterogeneous in terms of acuity of patient presentation. The overall 30-day mortality for patients treated with TEVAR for type B aortic dissection was 8.07% (127/1574, of which 97 were considered to be procedure-related). A higher proportion of stent-related deaths occurred in patients treated in the 2007 to 2013 period than in patients treated in the 1998 to

2007 period (56.2% vs. 24.0%, $P < 0.05$); however, these rates are calculated as a proportion of the stent-related deaths in each group to the total number of deaths for which a clear cause could be determined. This may not be the most appropriate comparison if non-stent-related deaths or deaths due to unknown causes also differed over the two time periods.

A systematic review by Zhang et al (26) identified 5 non-randomized, controlled trials of endovascular repair versus open surgery for acute type-B dissection, reporting on a total of 318 patients. The quality of the evidence was rated low for the outcome of mortality and very low for other outcomes, according to the GRADE evaluation. Combined results showed a significant reduction for the TEVAR group on short-term mortality (OR: 0.19, 95% CI: 0.09-0.39), but no difference on long-term mortality (OR: 1.40, 95% CI: 0.24-8.18). There were also no differences on adverse event outcomes, including spinal cord injury, renal failure, stroke, myocardial infarction (MI), respiratory failure, bowel ischemia, and lower limb ischemia.

Thrumurthy et al. (27) performed a systematic review of endovascular repair for chronic type B dissections, defined as dissections that present with symptoms for greater than 14 days. There were 17 publications included in this review, consisting of one RCT (the INSTEAD trial, discussed below) and 16 single-arm series. Of the 16 single-arm series, 2 were prospective and 14 were retrospective. At a median of 24 months follow-up, mortality was 9.2% for patients treated with TEVAR, with a range of 0-41% across studies. A total of 8.1% of patients had endoleaks at this follow-up, and there was an increasing rate of endoleaks with longer follow-up times. Delayed aortic rupture occurred in 3.0% of patients. Freedom from reintervention occurred in a range of 40-100% at 24 months' follow-up.

Randomized, controlled trials

INSTEAD trial. One randomized controlled trial (RCT), the Investigation of Stent Grafts in Patients with type B Aortic Dissection (INSTEAD) trial has been completed. (28) This trial compared endovascular stenting with medical management for stable thoracic aortic dissections. Stable, or uncomplicated type B dissections differ from acute lesions in that there is no evidence of ischemia or extension over the time of observation that would necessitate emergency surgery. Patients were randomly assigned to elective stent-graft placement in addition to optimal medical management ($n=72$) or to optimal medical management alone ($n=68$) to maintain arterial pressure below 120/80 mm/Hg. The primary endpoint of all-cause mortality at 1 year did not reach statistical significance between the 2 groups: cumulative survival was 91.3% + 2.1% in the endovascular group and 97.0% + 3.4% in the medical-only group ($p=0.16$). In addition, aorta-related mortality did not differ (5.7% and 3.0%, respectively; $p=0.42$). There were 2 cases of ischemic spinal cord injury with stent-grafting and one in the medical group. Seven patients (10.6%) in the medical group did cross over to the stent-graft group due to deterioration in condition, one patient from each group required open surgical intervention within the 12-month study period. An additional stent-graft for false-lumen expansion was required in 6 patients. A secondary measure of aortic remodeling did occur more frequently in the endovascular repair group (91.3% vs. 19.4%, respectively; $p < 0.001$), but the clinical significance of this is as yet unknown. Three adverse neurologic events occurred in the endovascular group compared to one in the medical-only arm. The authors conclude that elective stent-graft placement does not improve survival at 1 year and call for larger studies with extended follow-up.

In 2013, Nienaber et al published long-term follow up results from the INSTEAD trial (INSTEAD-XL).(29) From 2 to 5 years after the index procedure, rates of aortic aorta-specific mortality, all-cause outcomes, and disease progression were assessed for the 72 patients randomized to stent-graft placement with optimal medical management and the 68 patients randomized to medical management alone. Endpoints evaluated included the following: all-cause mortality; aorta-specific mortality (defined as death from documented aortic rupture, malperfusion, or proximal dissection, or death within 1 hour of onset of signs and symptoms in the absence of coronary or valvular heart disease); and progression of aortic pathology (defined as the combined endpoint of crossover to stent graft, conversion to open repair, additional endovascular or open surgery for rupture, malperfusion or aortic expansion, or enlarging aortic diameter >5.5 cm). Patients were followed for a minimum 5 years (maximum 8 years);

the median interval until death or latest follow up was 69 months (interquartile range 62 to 83); there was no loss to follow up. Twenty-one additional TEVAR procedures were performed in the 5-year follow-up period, 14 in the optimal medical therapy group (5 emergency cases), with conversion to open repair in 4 cases, and 7 in the TEVAR group, with conversion to open repair in 3 cases. Analysis was intention-to-treat.

The risk of all-cause mortality was not statistically significantly different between groups at 5 years post randomization (11.1% in the endovascular repair group vs. 19.3% in the optimal medical therapy group, $P=0.13$). However, Kaplan-Meier curves demonstrated a survival benefit in the endovascular repair group between 2 and 5 years post-randomization (100% in the endovascular group vs. 83.1%, $P=0.0003$), and a test for interaction between treatment effect and time was significant, suggestive of a late survival benefit from endovascular repair. Patients randomized to endovascular repair had lower aorta-specific mortality (6.9% vs. 19.3%, $P=0.04$) and progression of aortic pathology (27.05 vs. 46.1%, $P=0.04$). For the combined endpoint of disease progression (aorta-specific death, crossover/conversion, and secondary procedures) and aorta-specific events, at 5 years of follow up freedom from the combined endpoint was 53.9% with medical therapy alone and 73.0% with TEVAR. Landmark analysis was performed to compare hazard ratios for events occurring from randomization until 24 months post-randomization with events occurring beyond 24 months post-randomization to assess for a time-dependent response to treatment. In landmark analysis, groups had similar patterns of freedom from progression of aortic disease from randomization until 2 years of follow up (76.1% vs. 75.5%; hazard ratio [HR] 0.997; 95% CI 0.51 to 1.95; $P=0.994$). However, from 2 years to 5 years of follow up, the TEVAR group was more likely to have freedom from progression than the medical therapy group (95.9% vs. 71.9%; HR 0.112; 95% CI 0.03 to 0.49; $P=0.004$).

The INSTEAD-XL findings suggest that in stable patients with type B aortic dissection, pre-emptive endovascular repair may be associated with an excess risk of morbidity and mortality in the immediate post-procedural period which is outweighed by a longer-term survival benefit. The authors note that best medical management did not prevent late complications of aortic dissections, including expansion, rupture, and late crossover/conversion to emergent TEVAR.

Non-randomized, comparative trials

Jia et al. performed a prospective, multicenter, nonrandomized comparative study of TEVAR versus optimal medical therapy (OMT) for chronic type B thoracic aortic dissections. (30) A total of 208 patients were treated with TEVAR and 95 patients were treated with OMT. In the TEVAR group, there were no periprocedural deaths and serious complications (retrograde type A dissection; brachial artery pseudoaneurysm; paraplegia; MI) occurred in 12 patients (5.8%). Estimated survival at 2 and 4 years was 87.5% and 82.7% with TEVAR, compared to 77.5% and 69.1% with OMT, both respectively, but this difference in survival did not reach statistical significance ($p=0.068$). The estimated freedom from aorta-related death at 2 and 4 years was 91.6% and 88.1% for the TEVAR group, compared to 82.8% and 73.8% with OMT, both respectively, a difference which was statistically significant ($p=0.039$).

In a retrospective review of the University of Pennsylvania's database of acute type B aortic dissection, Zeeshan et al (31) compared 45 patients who underwent TEVAR to 32 patients who had open surgical repair ($n=20$) or medical management ($n=12$). Two TEVAR patients had died within 30 days or within hospitalization compared to 8 open surgery and 4 medical patients (4% vs. 40% vs. 33%, respectively; $p=0.006$). While not controlled in this study, TEVAR appears to be an option for patients with this catastrophic presentation. One-year survival was 82% for the TEVAR group.

One retrospective study compared outcomes of endovascular repair with medical therapy for acute type B aortic dissections. (32) Of 88 patients presenting with acute dissection over a 12-year period, 50 were treated medically and 38 were treated with endovascular repair. Overall mortality was reported for a mean follow-up of 33–36 months and did not differ between the medical therapy and endovascular groups (24% vs. 23.7%, respectively; p =not significant).

Fattori et al compared long-term survival between TEVAR and best medical therapy for type B acute aortic dissections among 1,129 patients enrolled in an international registry of acute aortic dissections.(33) The registry was a multinational registry of 24 referral centers in 12 countries, which was designed to provide an unbiased representative population of patients with acute aortic dissection. 3,865 patients were enrolled from December 26, 2005, to January 20, 2012. The present study included 1,129 patients with type B acute aortic dissections, who underwent either medical therapy (n=853) or endovascular stent-graft placement (n=276).

Patients who underwent TEVAR were matched in a 2:1 manner to medical therapy patients based on a propensity score created from a multivariable binary logistic regression model for the conditional probability for endovascular treatment versus medical treatment. The groups differed significantly at baseline: patients receiving endovascular treatment were more likely to present with clinical signs of malperfusion, such as leg pain (21.7% vs. 8.4%, $P < 0.001$) and limb ischemia (20.6% vs. 4.8%, $P < 0.001$), were more likely to have preoperative acute renal failure (21.4% vs. 12.4%, $P < 0.001$), any pulse deficit on presentation (28.3% vs. 13.4%, $P < 0.001$), and complicated dissections (defined by the presence of shock, periaortic hematoma, signs of malperfusion, stroke, spinal cord ischemia, mesenteric ischemia/ infarction, and/or acute renal failure (61.7% vs. 37.2%, $p < 0.001$). Kaplan-Meier survival estimates at 5 years showed that patients who underwent TEVAR had a lower death rate than best medical therapy patients (15.5% vs. 29.0%, $P=0.018$).

Single-arm studies

A number of single-arm series have also been performed, and some of these report long-term results for use of TEVAR in complicated type B aortic dissection.

White et al analyzed 1-year outcome after TEVAR in patients with complicated type B aortic dissection (cTBAoD) who had rupture or malperfusion and symptom onset 14 days or less (acute), 15 to 30 days (subacute), and 31 to 90 days (chronic) until required intervention. (34) Their report focused on the acute cohort. Clinical data were systematically collected from 5 physician-sponsored investigational device exemption (IDE) clinical trials between 2000 and 2008. Adverse events were reported early (30 days or less) and late (>30 days). Major adverse events included death, stroke, MI, renal failure, respiratory failure, paralysis, and bowel ischemia. In this study, there were 99 cTBAoD patients: 85 were acute, 11 were subacute, and 3 were chronic. Among the acute patients, 31.8% had rupture and 71.8% had malperfusion, including 55.7% lower extremity, 36.1% renal, 19.7% visceral, 8.2% other, and 3.3% spinal cord (patients may have more than one source). Rupture and malperfusion were both reported for 3 acute patients. Early major adverse events occurred in 37.6% of patients, including death (10.6%), stroke (9.4%), renal failure (9.4%), and paralysis (9.4%); late adverse events included vascular (15.8%), cardiac (10.5%), gastrointestinal (6.6%), and hemorrhage (5.3%). The point-estimate mortality rate was 10.8 (95% CI: 4.1-17.5) at 30 days and 29.4 (95% CI: 18.4-40.4) at 1 year, when 34 patients remained at risk. The authors concluded that emergency TEVAR for patients with cTBAoD (malperfusion or rupture) provides acceptable mortality and morbidity results out to 1 year.

Steuer et al published a retrospective, single-center, consecutive case series from Europe. (35) In this study, during the period 1999-2009, TEVAR was carried out in 50 patients with non-traumatic acute complicated type B dissection and in another 10 patients with acute complications, including rupture, end-organ ischemia, and acute dilatation during the primary hospitalization but more than 14 days after onset of symptoms. In total, 60 patients were included. Within 30 days, 2 (3%) deaths, 1 (2%) paraplegia, and 3 (5%) strokes were observed. Five-year survival was 87% and freedom from re-intervention at 5 years was 65%. The authors concluded that in patients with acute complicated type B aortic dissection, TEVAR can be performed with excellent early and long-term survival.

Hanna et al published a retrospective case series of long-term follow-up (median follow-up 33.8 months) of 50 patients who underwent TEVAR for management of acute complicated type B aortic dissection.(36) At 30 days, no deaths were reported. Overall survival at 5 and 7 years was 84%. No

deaths were attributable to aortic pathology, but a high proportion of patients (26%) required reintervention over the follow-up period.

Ruan et al evaluated predictors of early and late mortality among 62 patients who underwent TEVAR for complicated type B aortic dissection.(37) The 30-day mortality rate was 9.68%; in multivariable modeling, significant periprocedural predictors of early mortality included type I endoleak and cardiac tamponade. Follow-up was available for all 56 survivors at a median 52.8 months, during which time 9 deaths (16.07%) occurred, 4 of which were aorta-related. Independent periprocedural predictors of late mortality included rupture of false lumen, postoperative myocardial infarction, and acute renal failure. The authors suggest that careful evaluation for type I endoleaks during the TEVAR procedure may help reduce early mortality.

Section Summary. For patients with chronic, stable dissections of the thoracic aorta, one RCT reported that short-term outcomes do not differ significantly between TEVAR and best medical management. However, over 5 years of follow up, patients who undergo pre-emptive endovascular repair may demonstrate reduced morbidity and mortality. Single-arm series report relatively high success rates and favorable long-term results compared to historical controls undergoing open surgery.

For patients with acute, complicated type B dissections, there is limited evidence from small, nonrandomized comparative trials, one of which reports a significant early survival advantage for patients treated with TEVAR. This evidence is limited by the small number of studies and non-comparability of treatment groups in the comparative studies. Single-arm series report relatively high success rates and short-term survival that is possibly better than expected with open surgery.

Rupture of the descending aorta

Systematic reviews

In 2010, Jonker et al published a systematic review and meta-analysis of studies published between 1996 and 2009 to evaluate outcomes of open surgical repair (n=81) versus endovascular repair (n=143) for ruptured descending TAA. (38) The 30-day mortality was 19% for patients treated with endovascular repair, compared to 33% for patients treated with open repair (p=0.016). The 30-day incidence of myocardial infarction (MI) was 3.5% for those treated with endovascular repair versus 11.1% in patients treated with open repair (p<0.05). Rates of stroke and paraplegia were also increased in the surgically treated patients but did not reach statistical significance. Additional vascular interventions were performed in 9.1% of endovascular patients versus 2.3% of surgical patients (p=0.169). Regarding safety, during a median follow-up of 17 + 10 months, 5 additional patients in the endovascular group died of aneurysm-related causes, endoleak was reported in 11.1% of patients, and endograft migration was reported in 1 patient. The authors noted that the durability and development of endovascular-related complications remain concerns and that further surveillance of the endografts is required. These data need to be interpreted with caution given the non-random treatment assignment.

Lee et al. summarized data on use of TEVAR for repair of traumatic thoracic aortic injuries to aid development of practice guidelines. (39) The systematic review included 7,768 patients from 139 studies. This review found the mortality rate was significantly lower in patients who underwent endovascular repair, followed by open repair, and nonoperative management (9%, 19%, and 46%, respectively, p<0.01). Based on the overall very low quality of evidence, the committee suggests that endovascular repair of thoracic aortic transection is associated with better survival and decreased risk of spinal cord ischemia, renal injury, graft, and systemic infections, compared with open repair or nonoperative management. In addition to the low quality of the evidence, the authors also note that these conclusions should be tempered by the lack of suitable (anatomic fit) devices, which can lead to severe complications, and to the lack of follow-up data.

Non-randomized, comparative studies

Azizzadeh et al. (40) This non-randomized study compared outcomes of TEVAR and open surgery using prospectively collected data in 106 consecutive patients between 2002 and 2010 at one institution. This time interval covered the period of adoption for TEVAR at this institution, in which the proportion of patients treated with TEVAR increased from 0% to 100%. As a result, the number of procedures done in each group over time varied; 56 patients underwent open surgery and 50 underwent TEVAR. Primary outcomes were in-hospital death and complications. Death occurred in 5/56 (8.9%) patients undergoing open surgery, compared to 2/50 (4.0%) patients undergoing TEVAR. The overall likelihood of complications, including death, was significantly lower in the TEVAR group (odds ratio 0.33, 95% CI 0.11- 0.97). Also, the number of patients with at least one complication was greater in the open surgery group compared to TEVAR (69.6% vs. 48%).

Canaud et al. (41) This study compared outcomes of endovascular and open surgical repair in 75 patients with acute traumatic rupture of the thoracic aorta at one tertiary care center. Open surgery was performed on 35 patients during the time period of 1990-2000, and endovascular repair was performed on 40 patients between 2001 and 2010. Early mortality was lower in the endovascular group compared to open surgery (2.5% vs. 11.4%), but this difference did not reach statistical significance. Serious adverse events occurred in 20% of patients in the endovascular group compared to 14.2% in the open surgery group, which was also not a significant difference. There were no cases of paraplegia or stroke in either group.

Goodney et al. (20) These authors used Medicare claims data from 1998-2007 to compare TEVAR with open surgery in patients with aneurysms of the descending aorta. This study included both intact and ruptured aneurysms. A total of 1,307 patients with ruptured aneurysms were identified, 1,008 were treated with open surgery and 299 with TEVAR. There were baseline differences between the 2 groups, with the TEVAR group being older and more likely to have a variety of medical comorbidities. Thirty-day mortality was significantly lower among TEVAR patients compared to open surgery (28.4% vs. 45.6%, $p=0.0001$). Long-term survival was reported by Cox proportional hazards analysis. At 5 years, survival was low in both groups with no significant difference between the TEVAR and open surgery groups (23% vs. 26%, $p=0.37$).

Gopaldas et al. (42) Gopaldas et al. used the U.S. Nationwide Inpatient Sample database to identify patients who underwent procedures to repair a thoracic artery rupture. A total of 923 patients were identified between the period of 2006-2008, 364 (39.4%) who underwent TEVAR and 559 (60.6%) who underwent open repair. Patients undergoing TEVAR were older and had a significantly higher burden of comorbidities compared to patients undergoing open repair. Overall mortality was 23.4% for TEVAR and 28.6% for open repair, which was not significantly different. There were also no differences in complication rates. TEVAR patients were more likely to have routine discharge from the hospital to home compared to open surgery patients (OR: 3.3, $p<0.001$).

Klima et al.(43) In 2013, Klima et al retrospectively compared outcomes and complications associated with for open repair with endovascular repair for blunt aortic trauma for 49 patients treated at a single nonuniversity hospital from 2004 to 2011. Twenty-one patients underwent open repair, while 28 patients were managed with TEVAR; groups did not differ at baseline with regard to age, gender, or injury severity. Hospital length of stay, intensive care unit length of stay, and ventilator time were similar between groups, but patients in the open repair group had higher in-hospital mortality than the TEVAR group (33% vs. 7%, $P=0.028$).

Single-arm studies

FDA Approval Studies (Single-arm). Data from two uncontrolled clinical series of patients with isolated thoracic artery lesions was reviewed by the FDA as part of the expanded approval for thoracic endografts in 2012. The TAG 08-02 study used the GORE TAG endograft to treat 51 patients with aortic transection due to blunt aortic injury. (44) All 51 patients had successful implantation of the CORE TAG endograft, although 6 patients (11.8%) required deployment of two stent grafts for adequate coverage. There were 4 deaths within 30 days of treatment (7.8%, 95% CI 3.1-18.5%).

Serious adverse events with reported in 39.2% of subjects at 30 days, with the most common events being pleural effusion (5.9%) respiratory failure (5.9%). The primary effectiveness outcome was the number of patients with major device-related events in the first 30 days requiring reintervention. There were no patients who had such an event requiring reintervention. Two patients were identified with type II endoleaks, but neither patient required reintervention.

A similar study (RESCUE) was submitted to the FDA using the Valiant™ Thoracic stent graft in 50 patients with blunt aortic trauma. (45) All patients had successful deployment of the stent, with 2 patients requiring 2 devices. There were 4 deaths within 30 days of the procedure for a perioperative mortality of 8.0%. Serious adverse events occurred in 12.0% of patients, the majority of these were procedure-related events such as femoral artery dissection, localized hematoma, and/or hemothorax. There were 3 patients who required left subclavian artery revascularization to treat arm ischemia.

Other single-arm studies. Since the FDA's approval of thoracic endografts for traumatic aortic rupture, a number of single-arm studies have reported outcomes for TEVAR for this indication. Martinelli et al reported an in-hospital mortality rate of 7.4% in a cohort of 27 patients who underwent TEVAR for blunt aortic trauma.(46) Piffaretti et al reported an in-hospital mortality rate of 6.5% in a cohort of 35 patients who underwent TEVAR for blunt aortic trauma, with no subsequent mortality over a median follow-up of 72 months.(47)

Section Summary. FDA approval was granted for endovascular stent graft treatment of thoracic artery ruptures in 2012. The evidence on TEVAR for treatment of thoracic artery rupture consists of single-arm series and nonrandomized comparative studies. There are no randomized, controlled trials, but RCTs are likely difficult to complete for this indication because of the emergent nature. The available evidence suggests that early mortality and complications are less with TEVAR compared with open surgery, but these data are limited by non-comparability of groups. The longer-term outcomes are uncertain, with no discernible differences between TEVAR and open surgery.

Mixed populations

Several studies have evaluated TEVAR in heterogeneous groups of patients.

In 2005, the National Institute of Clinical Excellence (NICE) conducted a systematic review of 27 case series and 2 comparative observational studies of endovascular repair in the treatment of thoracic aortic disease. (48) Data from the included studies demonstrated technical success in approximately 93% of cases. The short-term (30-day) mortality rate was 5% (range 0-14%), and with a mean follow-up period of 14 months, overall mortality rate was 12% (range 3-24%) across studies. The most frequent technical complications were endoleaks (13%), injury to the access site (6%), and stent fracture (6%). Stroke occurred in 6% and paraplegia in 2% of patients. The evidence base primarily consists of case series that include heterogeneous groups of patients with incomplete outcome data. However, the review concluded that the safety of the procedure must be weighed against the fact that mortality is very high if patients with thoracic aortic aneurysm are untreated and that endovascular stent placement is a suitable alternative to open surgery in appropriately selected patients with aneurysm or dissection.

In 2009, Cambria et al reported on 59 patients who received TEVAR for emergent repair of thoracic aorta pathology due to acute complicated type B dissection, traumatic aortic tear, and ruptured degenerative aneurysm. (49) The authors' own literature review prospectively postulated a combined mortality/paraplegia rate of 12.6% for TEVAR, compared to 29.6% for open surgery for each of the 3 diagnostic conditions, or arms, of the study. Based on pre-study power analysis, it was estimated that 52 test subjects would be required overall to detect a difference of 17% in the composite outcome; 20 subjects were enrolled in each arm, subject to anatomic considerations; at the time of presentation, the final number of subjects drafted was 59 due to a solitary patient reclassification. The combined 30-day mortality/paraplegia endpoint was observed in 13.6% of study participants (7 deaths and 1 paraplegia), significantly lower than the literature-based rate for open surgery (29.6%) previously stated ($p=0.008$). Not surprisingly, 30-day complications in addition to the composite endpoint were high: 48 (81%)

patients experienced at least one major complication. Of these, 11 (18.6%) were attributable to device failure or complication. During mean follow-up time of 409 + 309 days, an additional 12 patients had died, 1 patient was converted to open surgery, and 2 patients had major, device-related events. For the entire study group, survival at 1 year was 66% (n=40). Regression analysis revealed that age and concurrent chronic obstructive pulmonary disease were predictive of death at 1 year.

Naughton et al (50) reported on 100 patients with “acute thoracic aortic catastrophies” treated with either TEVAR (n=76) or open surgery (n=24). Conditions included ruptured aneurysms (n=41), traumatic transection (n=27), complicated acute type B dissections (n=20), penetrating ulcers (n=4), intramural hematoma (n=3), penetrating injury (n=3), and embolizing lesions (n=2). Patients in the open surgery group were older and had more prior episodes of aortic surgery. Overall mortality at 30 days was lower for the TEVAR group compared to open surgery (8% vs. 29%, p=0.007). Respiratory complications (16% vs. 48%, p<0.05) were also lower in the TEVAR group. There were no significant differences in postoperative adverse events or mean length of stay.

In 2013, Alsac et al reported outcomes from for 48 patients treated with TEVAR for a “descending thoracic acute aortic syndrome,” including 19 ruptured aneurysms, 12 acute dissections, and 17 traumatic ruptures.(51) Ten patients died during the periprocedural hospitalization (mortality rate 20.8%), but no later deaths were reported in the 33 patients for whom longer term follow-up was available. Reintervention in the first month post-procedure was required in 8 patients (16.7%), and late reintervention was required in 5 patients (10.4%).

In 2014, Sood et al published a comparison of open repair, hybrid repair, and TEVAR for a mixed population of patients with thoracic aorta aneurysms (n=83) or dissections (n=15) treated at a single institution from 1993 to 2013.(52) Patients treated with TEVAR were older and more likely to have a history of tobacco use. For the study’s primary outcome of all-cause late mortality, Kaplan-Meier analysis showed no significant difference in 5-year survival between TEVAR patients and open/hybrid repair patients.

Botsios et al reported outcomes for 21 patients who underwent emergency TEVAR for nontraumatic rupture of the descending thoracic aorta, due to underlying degenerative aneurysms (n=11), complicated type B dissection (n=9), or erosion due to neoplasia (n=1).(53) Thirty-day mortality was 9.5%; over a median follow-up of 65.6 months (range 1.5–44), 10 additional patients died, leading to a late mortality rate of 52.6%. Late mortality was more likely to be related to non-aortic causes, with 2 aorta-related deaths and 8 non-aorta-related deaths.

Wiedemann et al reported short- and medium-term outcomes for 300 patients who underwent TEVAR at a single institution for a range of thoracic aortic conditions, including 137 descending thoracic aneurysms, 80 type B dissections (60 acute, 20 chronic), 59 perforating aortic ulcer, and 24 traumatic aortic transections.(54) Thirty-day mortality was 5% (15 patients) with no statistically significant differences between the 4 groups. Median follow up is reported as 44 years, although this may be a typographical error. In Kaplan-Meier analysis, overall survival at 1, 5, and 10 years was 86%, 63%, and 44%, with significant differences between groups and the lowest survival for descending thoracic aneurysms.

Clinical Input Received through Physician Specialty Societies and Academic Medical Centers

In response to requests, input was received from one physician specialty society and 4 academic medical centers (5 reviewers) while this policy was under review in 2011. While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted. The majority of those providing input supported use of TEVAR in complicated type B aortic dissections and in certain cases of traumatic thoracic aortic injury.

Summary

Endovascular stenting is an alternative treatment to surgical or medical therapy for thoracic aortic aneurysms, acute and chronic dissections, and traumatic aortic tears. For patients with stable aneurysms, there are no randomized trials of stenting versus open surgery. The non-randomized comparative trials available are consistent in reporting reduced short-term morbidity and mortality, but are prone to selection bias and other methodologic limitations. Multiple studies suggest that for elective repair of descending thoracic aortic aneurysms, stenting is associated with lower short-term mortality and lower complication rates, compared to open surgery. In addition, there was strong clinical vetting support for the use of TEVAR in descending thoracic aortic aneurysms. Thus, use of endovascular stents may be considered medically necessary for aneurysms of the descending thoracic aorta.

The data for complex situations are more limited. Short- and intermediate-term results from a few non-randomized comparative studies and a number of case series suggest a benefit for TEVAR in complicated (organ or limb ischemia or rupture) type B dissection. There was strong clinical support for the use of TEVAR for this indication. Thus, this use of TEVAR is considered medically necessary.

For uncomplicated descending (type B) aortic dissections, the evidence available from one randomized trial did not demonstrate a short-term outcome benefit associated with TEVAR; however, over 5 years of follow-up, TEVAR was associated with a survival benefit after 2 years post-procedure. Additional studies are needed to determine whether TEVAR is associated with net health improvements for uncomplicated type B aortic dissections; thus, the use of endovascular stent grafts in uncomplicated thoracic aortic dissections is considered investigational

For traumatic thoracic aortic injury and aortic rupture, nonrandomized comparative data suggest a benefit for TEVAR in reducing peri-procedural morbidity and mortality. The FDA granted approval for endovascular treatment of thoracic aortic ruptures in 2012, and specialty society recommendations include endovascular stent grafts as a treatment option for acute thoracic aortic rupture. In addition, it is expected that RCTs will be difficult to perform for this indication due to the emergent nature. Therefore, based on the available evidence, FDA approval of stent grafts for rupture, and support in specialty society guidelines, stent grafting for acute rupture of the thoracic descending aorta may be considered medically necessary.

Ongoing Trials

A search of the online database ClinicalTrials.gov using the terms thoracic and endovascular returned 25 active trials of endovascular repair of thoracic artery disorders. The majority of these are single-arm series of different endovascular techniques in various clinical populations. Several post-approval studies for thoracic aortic stent-grafts are ongoing, including NCT00813358 (Zenith TX2® Post-market Approval Study), NCT00805948 (Post-Approval Clinical Study of the Talent Thoracic Stent Graft to Treat Thoracic Aortic Aneurysms), NCT01775046 (Valiant Thoracic Stent Graft With the Captivia Delivery System in the Treatment of Descending Thoracic Aortic Diseases), NCT02104089 (Post-market Observational Study Zenith® t-Branch™)

The following are studies that compare TEVAR to alternative treatments:

- [NCT02043691](#) – Evaluation of the Cook Custom Aortic Endograft and the Zenith t-Branch Endovascular Graft in Treating Aortic Pathologies. This is a non-randomized, open trial to compare the Cook Custom Aortic Endograft and the Zenith t-Branch Endovascular Graft in the treatment of complex juxtarenal, suprarenal and thoracoabdominal aortic pathology including aneurysms and penetrating aortic ulcers. Enrollment is planned for 30 subjects; the planned study completion date is April 2021
- [NCT02010892](#) – Effective Treatments for Thoracic Aortic Aneurysms (ETTAA Study): A Prospective Cohort Study. This is an observational cohort study to compare open surgical repair with endovascular repair, best medical therapy, and watchful waiting for the treatment of chronic

thoracic aortic aneurysm. Enrollment is planned for 2200 subjects; the planned study completion date is July 2019.

- [NCT01852773](#) – Thoracic Endovascular Repair versus Open Surgery for Blunt Injury. This is a prospective observational trial comparing outcomes of endovascular repair with open surgery for patients with trauma and blunt aortic injury. The main outcomes are short-term mortality and short- and long-term complications. Planned enrollment is for 1,300 patients with an estimated completion date of November 2018.
- The STARZ-TX2 Clinical Study: Study of Thoracic Aortic Aneurysm Repair With the Zenith TX2 Endovascular Graft ([NCT00111176](#)) is a non-randomized, comparative trial of TEVAR versus open surgical repair for patients with thoracic aneurysms who are eligible for both procedures. This study of 205 patients was completed in February 2014 with no results posted.
- Trials [NCT00998491](#) (A Clinical Study of the Safety and Efficacy of the Relay Thoracic Stent- Graft in Patients With Thoracic Aortic Pathologies (RELAY)) and [NCT00435942](#) (Phase II Study of the Safety and Efficacy of the Relay Thoracic Stent-Graft) are Phase II studies to evaluate the safety and efficacy of the Relay Stent Graft in patients with descending thoracic aneurysms. NCT00998491 has a planned enrollment of 120 patients, with an estimated completion date in 2015. NCT00435942 has a planned enrollment of 120 patients and an estimated completion date in 2015.
- [NCT00742274](#) – A European Study on Medical Management Versus TAG Device + Medical Management for Acute Uncomplicated Type B Dissection (ADSORB). This was a randomized, open-label trial comparing the Gore TAG Endoprosthesis to best medical therapy for the treatment of acute uncomplicated aortic dissection. Enrollment was planned for 61 subjects. The study status is listed as completed, but no associated publications or results were identified.

Practice Guidelines and Position Statements

The European Association for Cardiovascular Surgery, the European Society of Cardiology, and the European Association of Percutaneous Cardiovascular Interventions published a position statement on TEVAR in 2012. (56) This document made the following statements concerning the use of TEVAR:

- Thoracic Aortic Aneurysms
 - TEVAR is indicated for asymptomatic patients when the maximum diameter of the aneurysm exceeds 5.5 cm or if rapid expansion occurs (>5 mm in 6 months)
 - It may be appropriate to select a larger aortic diameter threshold in patients with increased operative risk.
- Type B aortic dissections
 - For acute, complicated type B dissections, TEVAR is the treatment of choice.
 - For chronic, complicated type B dissections, the treatment approach should be discussed by an interdisciplinary team, considering the risks and benefits of open surgery versus TEVAR
 - For uncomplicated type B dissections, a primary conservative approach with close surveillance for complications is justified.
- Traumatic aortic injury
 - Immediate endovascular treatment is indicated for patients with complete transection of the aortic wall and free bleeding into the mediastinum, or the presence of pseudocoarctation syndrome.
 - Delayed endovascular treatment can be considered when there is limited disruption of the aorta with intact media and adventitia.

In 2010, a joint task force published guidelines on the diagnosis and management of descending thoracic and thoracoabdominal aortic aneurysms. (57) The task force consisted of the American College of Cardiology Foundation, American Heart Association, American Association for Thoracic Surgery, American College of Radiology, American Stroke Association, Society of Cardiovascular Anesthesiologists, Society for Cardiovascular Angiography and Interventions, Society of Interventional Radiology, Society of Thoracic Surgeons, and Society for Vascular Medicine. The task force offered the following Class I recommendations:

- For patients with chronic dissection, particularly if associated with a connective tissue disorder, but without significant comorbid disease, and a descending thoracic aortic diameter exceeding 5.5 cm, open repair is recommended (*Level of Evidence: B*)
- For patients with degenerative or traumatic aneurysms of the descending thoracic aorta exceeding 5.5 cm, saccular aneurysms, or postoperative pseudoaneurysms, endovascular stent grafting should be strongly considered when feasible (*Level of Evidence: B*)
- For patients with thoracoabdominal aneurysms, in whom endovascular stent graft options are limited and surgical morbidity is elevated, elective surgery is recommended if the aortic diameter exceeds 6.0 cm, or less if a connective tissue disorder such as Marfan or Loeys-Dietz syndrome is present (*Level of Evidence: C*)
- For patients with thoracoabdominal aneurysms and with end-organ ischemia or significant stenosis from atherosclerotic visceral artery disease, an additional revascularization procedure is recommended. (470) (*Level of Evidence: B*)

The Clinical Practice Guidelines from the Society of Vascular Medicine survey were noted above. (29) In addition to suggestions related to the data in the systematic review, the committee was also surveyed on a variety of issues that were not specifically addressed by the meta-analysis. On these select matters, the majority opinions of the committee suggest urgent repair following stabilization of other injuries, observation of minimal aortic defects, selective (vs. routine) revascularization in cases of left subclavian artery coverage, and that spinal drainage is not routinely required in these cases.

TEVAR is not a preventive service and is therefore not included in the U.S. Preventive Task Force Recommendations for preventive services.

Medicare National Coverage

No national coverage determination.

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Billing Coding/Physician Documentation Information

- 33880** Endovascular repair of descending thoracic aorta (e.g., aneurysm, pseudoaneurysm, dissection, penetrating ulcer, intramural hematoma, or traumatic disruption); involving coverage of left subclavian artery origin, initial endoprosthesis plus descending thoracic aortic extension(s), if required, to level of celiac artery origin
- 33881** Endovascular repair of descending thoracic aorta (e.g., aneurysm, pseudoaneurysm, dissection, penetrating ulcer, intramural hematoma, or traumatic disruption); not involving coverage of the left subclavian artery origin, initial endoprosthesis plus descending thoracic aortic extension(s), if required, to level of celiac artery origin
- 33883** Placement of proximal extension prosthesis for endovascular repair of descending thoracic aorta (e.g., aneurysm, pseudoaneurysm, dissection, penetrating ulcer, intramural hematoma, or traumatic disruption); initial extension
- 33884** Placement of proximal extension prosthesis for endovascular repair of descending thoracic aorta (e.g., aneurysm, pseudoaneurysm, dissection, penetrating ulcer, intramural hematoma, or traumatic disruption); each additional proximal extension (List separately in addition to code for primary procedure)
- 33886** Placement of distal extension prosthesis delayed after endovascular repair of descending thoracic aorta
- 33889** Open subclavian to carotid artery transposition performed in conjunction with endovascular repair of descending thoracic aorta, by neck incision, unilateral
- 33891** Bypass graft, with other than vein, transcervical retropharyngeal carotid-carotid, performed in conjunction with endovascular repair of descending thoracic aorta, by neck incision
- 75956** Endovascular repair of descending thoracic aorta (e.g., aneurysm, pseudoaneurysm, dissection, penetrating ulcer, intramural hematoma, or traumatic disruption); involving coverage of left subclavian artery origin, initial endoprosthesis plus descending thoracic aortic extension(s), if required, to level of celiac artery origin, radiological supervision and interpretation
- 75957** Endovascular repair of descending thoracic aorta (e.g., aneurysm, pseudoaneurysm, dissection, penetrating ulcer, intramural hematoma, or traumatic disruption); not involving coverage of the left subclavian artery origin, initial endoprosthesis plus descending thoracic aortic extension(s), if required, to level of celiac artery origin, radiological supervision and interpretation
- 75958** Placement of proximal extension prosthesis for endovascular repair of descending thoracic aorta (e.g., aneurysm, pseudoaneurysm, dissection, penetrating ulcer, intramural hematoma, or traumatic disruption), radiological supervision and interpretation
- 75959** Placement of distal extension prosthesis (delayed) after endovascular repair of descending thoracic aorta, as needed, to level of celiac origin, radiological supervision and interpretation

Additional Policy Key Words

N/A

Policy Implementation/Update Information

- 5/1/06 New policy.
5/1/07 No policy statement changes.

5/1/08 No policy statement changes.
5/1/09 No policy statement changes.
5/1/10 No policy statement changes.
5/1/11 Policy statement revised to indicate that use in treatment of uncomplicated dissections is investigational.
5/1/12 Policy statement revised to indicate may be considered medically necessary for complicated Type B dissections.
5/1/13 No policy statement changes.
9/1/13 Medically necessary indication added for acute rupture of the thoracic aorta.
9/1/14 Changed the wording of the investigational policy, but no change in the intent of the statement. No other policy statement changes.

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