TEVAR: Endovascular Repair of the Thoracic Aorta

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Abstract

Keywords

- ▶ thoracic endograft
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The development of thoracic endovascular aortic repair (TEVAR) has allowed a minimally invasive approach for management of an array of thoracic aortic pathologies. Initially developed specifically for exclusion of thoracic aortic aneurysms, TEVAR is now used as an alternative to open surgery for a variety of disease pathologies due to the lower morbidity of this approach. Advances in endograft technology continue to broaden the applications of this technique.

Objectives: Upon completion of this article, the reader will be able to discuss the indications for TEVAR, anatomic and preoperative planning considerations, common complications and how to manage them, and follow-up surveillance protocols.

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Thoracic endovascular aortic repair (TEVAR) has become the preferred approach for treatment of thoracic aortic pathology since the approval of the first endograft device by the U.S. Food and Drug Administration (FDA) in 2005. Initially utilized in the treatment of aortic aneurysmal disease, TEVAR indications have expanded to include treatment of type B aortic dissection with malperfusion or rup-

ture, traumatic aortic transection, and penetrating aortic ulcer (PAU). Although there are no randomized controlled trials directly comparing TEVAR to open surgery, numerous studies suggest that TEVAR is associated with decreased morbidity compared with open repair.^{1–5} Benefits of the endovascular approach include avoidance of thoracotomy or sternotomy incision, avoidance of aortic cross-clamping, decreased blood loss, and decreased end-organ ischemia.⁶

Indications for TEVAR

Aortic Aneurysm

TEVAR was first approved by the FDA for thoracic aneurysm repair following the Gore TAG pivotal trial in 2005.¹ Indications for repair have typically used an aortic diameter size greater than 6 to 6.5 cm as the threshold where risk of repair is outweighed by the risk of rupture.^{7–9} Patients with aneurysms larger than 6 cm have a 14.1% annual risk of rupture, dissection, or death, compared with 6.5% for patients with aneurysms between 5 and 6 cm.⁹ Some guidelines have suggested that repair is appropriate for aneurysms as small as 5.5 cm, saccular aneurysms greater than 2 cm, or saccular aneurysms associated with a total aortic diameter greater than 5 cm.¹⁰ Symptomatic aneurysms and aneurysms associated with a rapid growth rate of greater than 1 cm per year are considered to be at increased risk for rupture and should also be repaired.¹⁰

Traumatic Aortic Transection

Aortic transection generally occurs at the level of the thoracic aorta just distal to the ligamentum arteriosum, where there is an anatomic tether, and is usually seen with rapid deceleration injuries that often lead to concomitant head, neck, and chest trauma. When the transection is contained and patients survive to treatment, endovascular repair has a significantly lower morbidity and mortality than open repair, even in the younger trauma patient population.¹¹

Management of blunt aortic injury is based on the injury grade.¹² Grade 1 injuries with intimal tear alone may be managed medically with heart rate and blood pressure control. Grade 2 injuries with intramural hematoma (IMH), grade 3 injuries with pseudoaneurysm, and grade 4 injuries with rupture or aortic transection require repair. In hemodynamically stable patients without free rupture, delay of aortic repair until other injuries are addressed is safe and is associated with improved mortality.¹³ One series demonstrated that TEVAR can be performed without heparinization and without thromboembolic consequences if the patient has a high bleeding risk or severe head injury.¹⁴

Management of Type B Dissection

TEVAR is performed for type B dissection complicated by rupture or malperfusion. In cases of malperfusion, coverage of the entry tear with the stent graft allows re-expansion of the true lumen and improved organ perfusion.^{15,16} Intravascular ultrasound is a critical adjunct to this, as it allows real-time confirmation of the location of both the true and false lumens as well as luminal supply of important branch vessels. Concomitant stenting of branch vessels may be required if the dissection flap extends into the branch vessel, causing a static obstruction. Branch vessel stenting is usually obviated in the event of a dynamic obstruction, provided that the true lumen in the aorta above the visceral branches has been maximally expanded.^{17,18}

Uncomplicated type B dissection has classically been managed with antihypertensive therapy targeted at reducing the left ventricular ejection force, or delta pressure/delta time (dP/dt). A short-acting β blocker should be used as the initial drug of choice. Vasodilators such as nitroprusside may also be employed for blood pressure control, but can cause reflex tachycardia and should only be used after initiation of β blockade. These medications should be titrated to keep systolic BP below 120 mm Hg.¹⁹

TEVAR is reserved for patients without an adequate response to medical therapy. This approach was supported by the initial results of the INvestigation of STEnt grafts in patients with acute type B Aortic Dissection (INSTEAD) trial, which compared medical management to TEVAR and found no difference in all-cause mortality at 1 year.²⁰ The initial conclusion was that uncomplicated dissections should be managed with antihypertensive therapy and close monitoring, and that routine stent grafting was unnecessary. The weaknesses of the study included that it was underpowered to evaluate all-cause mortality,²¹ and the inclusion of all patients from 2 weeks postdissection to 52 weeks postdissection raised concerns regarding heterogeneity of the pa-

tient population. In contrast, recently published 5-year follow-up data from the INSTEAD XL trial suggest a long-term benefit to TEVAR, with significant decreases in aorta-specific mortality and disease progression when compared with medical management alone.²² There was also a trend toward improved overall mortality, although this was not statistically significant. This benefit is thought to be related to improvement in false lumen thrombosis and aortic remodeling,²³ thus precluding the need for open thoracoabdominal aortic surgery in the 20 to 30% of patients known to undergo aneurysmal degeneration. Indeed, false lumen thrombosis is thought to be the most important indicator of successful aortic remodeling when performing TEVAR for uncomplicated type B dissections, and suggests that broader use of TEVAR may be of benefit in select patients who have favorable characteristics for remodeling.²⁴ Further study and longer-term follow-up is necessary to delineate the role and optimal timing for TEVAR in uncomplicated type B dissection.

Penetrating Aortic Ulcer/Intramural Hematoma

The spectrum of aortic pathology also includes more focal lesions, such as PAUs and IMHs. PAU is characterized by an ulcerated atheromatous plaque that extends into the aortic media, whereas an IMH is characterized by hemorrhage within the aortic wall without a clear intimal disruption. PAUs with depth greater than 10 mm or diameter wider than 20 mm are at a higher risk of progression and should be considered for repair.²⁵ These lesions are part of the aortic dissection spectrum, and may also increase risk for aortic rupture.²⁶ PAUs also share radiographic characteristics with saccular aneurysms, which frequently require intervention despite some evidence that they have similar growth rates to fusiform aneurysms.²⁷ Endovascular management is similar to that of dissection.

Thoracoabdominal Aneurysms

Treatment options for thoracoabdominal aneurysms have often been limited due to the involvement of the visceral arteries. Commercial devices for the endovascular treatment of this anatomic segment are in trial or are only available at select institutions with investigational device exemption. Alternatives to open repair include hybrid repair, which involves initial open aortic debranching followed by stent graft placement with coverage of the visceral aortic segment.^{28,29} Other techniques described for total endovascular repair include back-table operator modified fenestrated stent grafts or use of the snorkel technique to preserve visceral perfusion.³⁰ Commercial fenestrated and branched endografts will, however, likely supplant these other techniques over time as the technology develops and becomes widely available.

Contraindications to TEVAR

Unfavorable anatomy is the main contraindication to TEVAR, which may include inadequate proximal or distal seal zones, tortuosity, lack of vascular access options, or extremes of aortic diameter. Placement into infected fields should also be avoided, although some small studies have shown that TEVAR

may be useful as a temporizing measure in contaminated fields such as aorto-esophageal fistulae.³¹

Anatomic Considerations

Aortic Arch

The primary features of the thoracic aorta are its relatively large diameter compared with the abdominal aorta, and the anatomy of the aortic arch. There can be significant variability in both the origin of the arch vessels and the degree of arch angulation. The large diameter of the aorta necessitates larger endografts, and the degree of angulation requires a relatively long seal zone (2 cm). Earlier generation stent grafts were characterized by failure of the proximal stent graft to conform to the aortic anatomy leading to "bird beaking," increasing the risk of graft failure, migration, or collapse. Current-generation devices are all characterized by their improved flexibility, a design feature employed to allow for improved conformability to the aortic arch. Aortic arch debranching via ascending aortic-to-innominate and left common carotid artery bypass, carotid-carotid bypass, or left carotid-to-subclavian artery bypass may be required to obtain an adequate seal zone.³²

Access Vessels

Access vessel anatomy is also critical, as the relatively large size of the thoracic endografts in turn requires larger diameter delivery systems. The femoral and iliac systems should be carefully assessed to ensure that passage of the sheath will be possible, and evaluated for small diameter or heavy calcification. If there is concern, alternative approaches may need to be considered.

Intercostal Arteries and Spinal Cord Perfusion

Paired intercostal branches are derived from the descending thoracic aorta and provide collateral flow to the anterior spinal cord via the artery of Adamkiewicz and other radicular branches. The degree of coverage of these branches must be assessed during TEVAR, as extensive coverage is a major risk factor for spinal cord ischemia and postoperative paraplegia. Consideration should also be given to prior EVAR or open aortic repair, as well as to occluded or embolized internal iliac arteries given that lumbar arteries and the internal iliac arteries provide collateral blood flow to the spinal cord.³³

Preoperative Planning and Landing Zones

Adequate preoperative measurements are critical for the correct sizing of thoracic endografts, and are best facilitated by computed tomography angiography (CTA) with three-dimensional reformatting. This provides information about the seal zones, coverage length, and tortuosity and angulation of the aorta. CTA can also provide information about intraluminal thrombus or wall calcification that may have implications for graft placement. The CTA should be continued from the chest to also include the abdomen and pelvis, so that an assessment of the iliac arteries can be made to ensure adequate diameter for passage of the endograft. If the femoral vessels are small in diameter, tortuous, or calcified, alternate

access techniques may be required such as direct retroperitoneal iliac access, iliac bypass conduit, or use of an endoconduit with iliac angioplasty and stent placement.³⁴ Measurements from the CTA can then be used to accurately size the endograft, using oversizing recommendations per the device instructions for use. Magnetic resonance angiography can also be used as a preoperative imaging study, but does not show calcification as well as CT and still has the risk of nephrogenic systemic fibrosis when used in patients with renal insufficiency.³⁵

The commercially available thoracic stent grafts all require a 20-mm-long proximal seal zone. It is critical to obtain good apposition throughout this segment to avoid endoleak or device migration. Depending on the patient's anatomy, it may be necessary to cover one or more of the arch branches to obtain an adequate seal. Not infrequently, coverage of the left subclavian artery is required to obtain an adequate proximal seal, particularly in dissection or traumatic aortic transection cases. When this is necessary, preoperative duplex ultrasound of the carotid and vertebral arteries should be performed, if possible, and consideration given to performing preemptive left carotid-subclavian bypass or subclavian transposition. TEVAR can then be completed as a second-stage procedure with embolization of the native subclavian artery to prevent type II endoleak. If the left carotid or innominate artery would require coverage, then antegrade bypass from the ascending aorta³⁶⁻³⁸ or extra-anatomic bypass via a carotid-carotid bypass³⁹ may be necessary. An endovascular approach to this anatomic problem has also been devised that involves placement of a stent into the branch vessel parallel to the main endograft,^{40,41} and is referred to as the snorkel, periscope, or chimney technique. This can also be used as a bailout technique in the event of inadvertent branch coverage with the main endograft.

Newer off-the-shelf branched devices are currently under investigation to provide a fenestrated endovascular option and allow an additional seal zone proximal to the subclavian artery while maintaining perfusion to the vessel.

Coverage of the subclavian artery without revascularization is generally well tolerated, but may lead to left arm ischemic symptoms in up to a minority of patients.⁴² The Society of Vascular Surgery (SVS) guidelines⁴³ recommend routine preoperative revascularization for planned coverage of the left subclavian artery. Carotid-subclavian bypass should be used in the setting of prior internal mammary coronary graft to prevent interrupting flow to this vessel, while carotid-subclavian transposition has the advantage of not using any prosthetic material.⁴³

The distal landing zone is also critical to avoid type Ib endoleak, and also requires a 20-mm seal zone with the currently available devices. In patients with disadvantaged distal seal zones where adequate seal can only be achieved with celiac artery coverage, selective arteriogram and demonstration of an intact gastroduodenal artery providing collateral flow from the superior mesenteric artery are necessary prior to placement of TEVAR. Reports indicate that coverage of this vessel may have a nominal rate of mesenteric ischemia of only ~6%.^{39,44,45}

Available Endografts for TEVAR

The first stent graft approved by the FDA for treatment of thoracic aortic aneurysms was the Gore TAG device, made of expanded polytetrafluoroethylene with a nitinol exoskeleton. Gore has since introduced a new device called the conformable TAG (cTAG), which provides a wider range of diameters (21–45 mm) and was designed to improve treatment of small diameter, tortuous, and tapered aortic anatomy. This device was the first FDA-approved stent graft for treatment of type B aortic dissection.

The Cook (Bloomington, IN) Zenith TX2 device is a two-piece system, with Dacron graft material and a stainless steel z-stent exoskeleton. The proximal component has active fixation using steel barbs, and the distal component has a bare metal stent component for fixation above the visceral vessels. This graft was modified with the addition of Pro-Form, which allows improved conformability to the arch and limits the “bird-beak” effect. The TX2 device is approved for treatment of aortic aneurysm. Cook has also developed a composite device, the Zenith Dissection Endovascular System, consisting of a covered proximal component for coverage of the entry tear, and an uncovered distal scaffold to assist with compression of the false lumen. The STABLE trial evaluated this device and showed favorable aortic remodeling at 2 years⁴⁶; follow-up is ongoing.

Medtronic's (Oakbrook, IL) initial thoracic aortic graft was the Talent thoracic graft, which was then replaced by the next-generation Valiant device. These were studied in the VALOR I and VALOR II trials, respectively, which demonstrated their efficacy. The Valiant device is made of polyester graft with a nitinol exoskeleton, and has a modified proximal bare stent configuration. The longitudinal connecting bar of the Talent was also removed to improve flexibility. Modification of the Valiant with the addition of the Captivia delivery system allows tip capture and more controlled deployment. It is approved for aortic aneurysm and type B aortic dissection.

The Bolton (Sunrise, FL) Relay is a polyester/nitinol graft, which also has a longitudinal nitinol bar for support and comes with either covered or bare metal proximal graft configuration. It is available in straight or tapered configurations. This device is approved for the treatment of thoracic aortic aneurysmal disease and PAU. Its safety and efficacy have been demonstrated.⁴⁷

The Procedure

The procedure is generally performed under general anesthesia, which allows respiratory control by anesthesia and provides more precise imaging. An important consideration is whether to place a lumbar drain preoperatively. This should be considered in any case with extensive coverage of the thoracic aorta and in patients who have already had abdominal aortic aneurysm (AAA) repair. The goal of this is to allow drainage of cerebrospinal fluid (CSF) and decrease the risk of spinal cord ischemia caused by coverage of the artery of Adamkiewicz or its collaterals. Lumbar drain placement has

been demonstrated to help prevent paraplegia during TEVAR.^{48,49} An additional adjunct is the use of intraoperative neuromonitoring, with measurement of somatosensory evoked potentials (SSEPs). Changes in the SSEPs can be identified in real time and allow treatment with increase in CSF drainage or increase in the mean arterial pressure to improve spinal cord perfusion.

The operation is performed by gaining femoral access for placement of the relatively large sheath required for TEVAR. This may be performed with a groin cutdown, percutaneously using the preclose technique,⁵⁰ or via a retroperitoneal cutdown if needed due to small vessel size. Additional access can be obtained from either the arm or the contralateral groin to allow for control angiography. Wire access is gained into the ascending aorta and exchanged for a stiff wire to allow tracking of the device. The c-arm is positioned in the right posterior oblique position to maximally splay out the arch. Once the device is positioned, angiography is performed with power injection and respiratory arrest by anesthesia to allow for precise graft positioning. Additional techniques to minimize graft movement during deployment include induced hypotension, rapid pacing, and adenosine-induced cardiac arrest.⁵¹ Once the graft is deployed, it may be ballooned at the seal zones and at any overlap zones to ensure full coaptation to the aortic wall. Ballooning should be avoided in dissection cases where there is a significant risk of creating fenestrations or causing aortic rupture. Completion angiography is then performed to assess for endoleak, the sheath and device are removed, and the arteriotomy is closed.

Management of Endoleak at the Time of the Procedure

Type I: Endoleak at the proximal or distal seal zones is usually managed by additional ballooning or by placement of an extension graft, anatomy permitting. Care must be taken with proximal ballooning to avoid causing retrograde dissection.⁵² If proximal or distal seal zones are inadequate, arch or visceral artery debranching may be required by using a hybrid technique. Open surgery and explant may ultimately be required if the above are not feasible.

Type II: Retrograde flow from the intercostal arteries can usually be managed conservatively with follow-up imaging to ensure that the aneurysm sac does not continue to enlarge. In the setting of an enlarging aneurysm sac, embolization may be required.

Type III: Junctional endoleak is usually related to inadequate overlap between components. Management consists of relining of the junction with stent grafts to bridge the defect.

Type IV: Leak due to graft porosity causes type IV endoleak. This typically resolves once the procedural anticoagulation wears off.

Type V: Endotension occurs when sac expansion is identified despite having no evidence of endoleak, and is not encountered at the time of the initial procedure. Relining can be utilized in this case as a last attempt at an endovascular solution prior to explant and open repair.⁵³

Complications

Stroke: Any manipulation of the aortic arch carries the risk of embolization to the carotid artery and subsequent stroke. This risk is magnified in patients with a very proximal seal zone, mural thrombus in the arch, or history of prior stroke.⁵⁴ Posterior circulation stroke can also occur due to coverage of the left subclavian artery or embolization via the subclavian. Posterior circulation strokes have increased morbidity and mortality when compared with anterior circulation strokes.⁵⁵ Performance of a carotid-subclavian bypass prior to TEVAR can decrease this risk, and has the added benefit of improving paraplegia risk.^{56–58}

Paraplegia: Paralysis due to spinal cord ischemia is a much-feared risk of TEVAR. Risk factors include extensive coverage of the thoracic aorta,^{59,60} prior AAA repair,^{60,61} and coverage of the left subclavian artery. As noted elsewhere, neuromonitoring with early recognition and treatment with lumbar drainage and permissive hypertension are the keys to treatment.

Visceral ischemia: Visceral ischemia can occur with intentional or unintentional coverage of the celiac artery origin. An intact pancreaticoduodenal arcade may reduce this risk.³⁹

Access complications: The large diameter of the devices required for TEVAR in turn requires relatively large sheath sizes of 20 to 26F. It is important to assess the patient's access via the femoral and iliac vessels on preoperative CT scan to minimize access problems. Calcified, small, tortuous vessels are most at risk. When iliac rupture occurs, balloon occlusion can be used for temporary vascular control until the artery can be repaired. Reports suggest that 9.4 to 23.8% of patients require nonstandard techniques for safe access.^{3,5}

Postimplantation syndrome: Fever and leukocytosis in the immediate postoperative period may be due to endothelial activation from placement of the stent graft. This should be considered in patients with elevated inflammatory markers and pleural effusions with an otherwise negative infectious work-up.^{62–66}

Device migration and endoleak: Postimplantation graft migration occurs with an incidence of 1 to 2.8%.^{2,3,67} Extensive aortic tortuosity and graft oversizing are associated with migration risk.⁶⁸ Patients with traumatic aortic transection may be at particular risk for graft collapse, possibly due to morphologic differences in the nondiseased aorta.⁶⁹ Endoleak is fairly uncommon after TEVAR, with reported rates ranging in the literature from 3.9 to 15%.^{2,3,67,70}

Postoperative management/surveillance: Patients are monitored in the ICU postoperatively, with careful monitoring of their hemodynamic and neurologic exam. They are usually transferred to the floor by postoperative day 3 and discharged home within 1 week. If there are any concerns about endoleak based on the technical aspects of the case, a CTA is performed prior to discharge. Graft surveillance is performed with CTA at 1 month, 6 months, and then annually to assess for adequate graft position and endoleak.

Clinical outcome: TEVAR has an excellent technical success rate of up to 98%.^{2,3} There is low perioperative mortality compared with open repair, with endovascular repair mortality rates of 1.9 to 2.1%, compared with 5.7 to 11.7% with

open repair.^{2,3,67} Perioperative stroke may occur in 4 to 8%,^{71–73} and spinal cord ischemia in 3 to 5.6% of patients.^{2,3}

Long-term surveillance: The lower risk profile of TEVAR when compared with open repair makes it the preferred modality for many patients. There is the need for ongoing surveillance, as 3.6 to 4.4% of these grafts will require secondary intervention.^{3,67} CTA is the modality of choice and is optimal for the diagnosis of endoleak. Noncontrast CT can also be useful if it shows ongoing shrinkage of the aneurysm sac.

Conclusion

In conclusion, TEVAR has become the preferred approach for patients with thoracic aortic pathology and anatomy amenable to endograft placement. Adequate seal zones, careful preoperative planning, and proper device sizing are critical to obtain a good result and limit complications. Hybrid approach options and fenestrated endografts may further expand the number of patients who can benefit from this treatment modality.

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