From the Society for Vascular Surgery

Early experience with the Gore TAG thoracic branch endoprosthesis for treatment of acute aortic pathology

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ABSTRACT

The Gore TAG thoracic branch endoprosthesis (TBE) is the first Food and Drug Administration—approved device for zone 2 thoracic endovascular aortic repair, allowing for graft placement proximal to the left subclavian artery origin and maintaining vessel patency through a side branch. We describe our experience with the Gore TBE device in 20 patients for acute indications, including blunt thoracic aortic injuries, complicated dissections, and ruptured aneurysms. Technical success, with exclusion of pathology and left subclavian patency, was 100% without major complications within 30 days. Our early Gore TBE device experience demonstrates safe use in acute aortic pathology without an increased risk of complications. (J Vasc Surg Cases Innov Tech 2024;10:101363.)

Keywords: Thoracic endovascular aortic repair; Branched endograft; Aortic transection

With the advent of new endovascular technology, practice paradigms for the management of thoracic aortic pathology have shifted. Thoracic endovascular aortic repair (TEVAR) has largely replaced open reconstruction for blunt thoracic aortic injuries, complicated aortic dissections, and aneurysmal disease.[1,2] Standard practice includes revascularization of the left subclavian artery (LSA), either concomitantly or in a staged fashion for elective repairs and as needed in emergent scenarios.[3,4] Prior options for LSA revascularization included left carotid to subclavian bypass or transposition, parallel grafting, and custom graft modification such as laser fenestration.[5-9] The introduction of the Gore TAG thoracic branch endoprosthesis (TBE; W.L. Gore & Associates, Inc) represents the first Food and Drug Administration—approved device for zone 2 aortic repairs, specifically for dissection, transection, and aneurysmal pathology, that allows for graft placement proximal to the LSA while maintaining perfusion through a specifically designed side branch.[10]

Although use of a TBE potentially requires a longer index operation for management of acute pathology than traditional TEVAR, the ease of LSA revascularization prevents the morbidity traditionally associated with LSA coverage, including vertebral territory stroke and arm claudication or ischemia and lowers the risk of spinal cord ischemia.[11] The benefits of the device are particularly appealing for use in acute pathology such as blunt thoracic aortic injury (BTAI), when concomitant injuries might prevent reliable neurologic examinations, or complicated dissections, for which extensive aortic coverage could be required for treatment, increasing the risk of spinal cord ischemia.

Despite its approval for use in multiple aortic pathologies, the feasibility study for the TBE device primarily explored aneurysmal disease, with limited reported data describing the device outcomes in acute aortic pathology, such as dissection or BTAI.[12,13] We sought to describe our early experience with the Gore TBE device in urgent settings.

METHODS

All patients undergoing TEVAR with the TBE at a large tertiary care institution between 2022 and 2023 were retrospectively identified. The patient demographics, lesion characteristics, and procedural details and outcomes were collected from review of the electronic medical records.

The pathology treated included ruptured thoracic aneurysms, acute complicated dissections, BTAI (as described by the Society for Vascular Surgery [SVS] grading criteria), and hemorrhage during open repair of a type A dissection. The zone of entry tear or relevant pathology was determined by the previously described Ishimaru zones reported by the SVS Ad Hoc Committee on TEVAR Reporting Standards.[14]

Imaging studies were reviewed using centerline technology for all cases (TeraRecon, Inc) preoperatively to ensure the patient anatomy was appropriate for TBE

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device use and to allow for graft sizing. Aortic grafts were oversize by 10% to 20% based on the aortic diameter at the anticipated seal zone. In the setting of BTAI, the size was again confirmed intraoperatively with the use of intravascular ultrasound during systole after appropriate volume resuscitation from the initial trauma to prevent inadvertent undersizing. Approximately 10% oversizing was used for side branch selection at the anticipated seal zone.

Selection of the ascending aorta was accomplished with an angled Glidewire and Glide catheter (Terumo Interventional Systems), except in the setting of complicated dissection, for which intravascular ultrasound was used to confirm true lumen wire access. Repair was accomplished over through and through wire access from the left arm and groin, except in the setting of a single zone 0 repair, which required right arm access. The main body device was tracked over a stiff double curved Lunderquist wire (Cook Medical Inc), and the side branch was delivered over through and through access using a 480-cm Metro wire (Cook Medical Inc). Rapid ventricular pacing was only required for deployment during the zone 0 repair. In all other cases, maintaining the mean arterial pressure at 60 mm Hg was sufficient to allow for graft deployment at the target site without incident. In all cases, a Gore TBE side branch was used (W.L. Gore & Associates, Inc). A molding and occlusion balloon (W.L. Gore & Associates, Inc) was then used to balloon the side branch overlap within the main graft to ensure full expansion and prevent a type Ic endoleak. Balloon angioplasty was only completed in the arch if a proximal cuff was placed to secure the graft overlap (n = 3). Otherwise, an adequate proximal seal was achieved with graft oversizing.

The outcomes of interest included the safety and efficacy of the TBE in acute settings requiring urgent or emergent intervention. General safety was described as freedom from 30-day aortic-related mortality, stroke, and new-onset renal failure (beginning immediately after the procedure and requiring hemodialysis at discharge). Additional safety outcomes were defined by the pathology type. In the setting of acute complicated dissection, additional outcomes measured included freedom from spinal cord ischemia and retrograde aortic dissection.

Efficacy was evaluated in terms of technical procedural success, defined as exclusion of the relevant pathology and side branch patency confirmed at case conclusion with angiography. When possible, postoperative side branch patency, persistent exclusion of the pathology, and a lack of endoleak were confirmed using computed tomography angiography.

Statistical analyses were completed using Stata, version 17 (StataCorp, LLC). Categorical variables are described as frequencies and percentages and continuous variables as the mean ± standard deviation. Given the differing mechanisms behind the described pathologic entities, the analysis results are presented by lesion type. The University of California Davis institutional review board approved the present study.

RESULTS

Between 2022 and 2023, 38 patients underwent TBE placement at our institution, 20 for urgent or emergent indications. Of the 20 urgent cases, 5 were for zone 2 or proximal zone 3 SVS grade III BTAI, 1 for a proximal zone 3 grade IV BTAI, 11 for complicated aortic dissection (Stanford type B dissection, 10; type A dissection, 1), 1 for a ruptured thoracic aortic aneurysm in zone 3, 1 for a zone 2 SVS grade II BTAI with extensive dissection propagation and associated renal malperfusion, and 1 placed intraoperatively during acute type A dissection open repair for uncontrolled hemorrhage when weaning the patient off cardiopulmonary bypass (Table I). The 11 patients with a complicated dissection were treated for a combination of mesenteric ischemia (n = 2), lower extremity paraplegia (n = 2), renal malperfusion (n = 6), uncontrolled hypertension and/or chest pain (n = 2), esophageal ischemia (n = 1), and aortic rupture (n = 1). One patient had a zone 0 repair (seal proximal to the innominate artery) with open arch debranching, including right carotid-to-left carotid and left carotid-to-LSA bypasses, and subsequent side branch placement into the innominate artery. The remainder (n = 10) underwent zone 2 repair with the TBE device with side branch placement into the LSA.

When considering the location of the relevant pseudoaneurysm lesions, in all cases of grade III or IV BTAI, the injury was located in zone 2 or very proximally in zone 3, requiring coverage of the LSA for adequate exclusion. In the grade II BTAI, the flap was identified at the start of zone 3; however, thrombus was present up to the origin of the LSA, necessitating coverage of the LSA for exclusion. In the patient with hemorrhage, the origin of bleeding was located in zone 2 proximal to the LSA origin. The patient had undergone valve replacement, ascending aortic repair, and partial arch replacement of the innominate and left common carotid arteries, with placement of a frozen elephant trunk distal to the origin of the LSA. When weaning off cardiopulmonary bypass, the friable tissue in zone 2 had significant bleeding, and the operating cardiac surgeons determined that endovascular exclusion of this region rather than resuming cardiopulmonary bypass offered the patient the best chance for a favorable outcome. A TBE device was successfully placed, and the hemorrhage was successfully controlled without the need for resuming cardiopulmonary bypass. Among the patients with acute complicated dissections, the entry tear was located in zone 2 in 10 patients and zone 0 for the final patient on review of the imaging studies and reconstruction using centerline software. Distal extension of the

Table I. Patient characteristics

Variable	Age, years	Male sex	Hypertension	Tobacco use	Coronary artery disease	History of stroke
Overall cohort (n = 20)	59 ± 15.9	13 (65)	15 (75)	12 (60)	2 (10)	3 (15)
Grade III and IV BTAI (n = 6)	65 ± 15.8	4 (67)	1 (17)	2 (33)	0 (0)	0 (0)
Complicated aortic dissection (n = 11)	52 ± 13.4	7 (64)	11 (100)	8 (73)	2 (18)	3 (27)
Grade II BTAI with malperfusion (n = 1)	86	1 (100)	1 (100)	0 (0)	0 (0)	0 (0)
Uncontrolled hemorrhage (n = 1)	59	1 (100)	1 (100)	1 (100)	0 (0)	0 (0)
Ruptured thoracic aneurysm (n = 1)	74	1 (100)	1 (100)	1 (100)	0 (0)	0 (0)

BTAI, Blunt thoracic aortic injury.
Data presented as mean ± standard deviation or number (%).

dissection was to zone 5 (n = 1), zone 6 (n = 1), zone 8 (n = 1), zone 10 (n = 7), and zone 11 (n = 1).

With regard to the procedural approach, all 20 patients were able to support device and branch delivery via percutaneous femoral artery access, aside from 4 patients (20%), who required a femoral cutdown for access. In all the patients save one who required percutaneous brachial access (5%), percutaneous radial artery access was used to facilitate through and through wire access and allow for alignment of the portal and side branch. In nine patients, the femoral access site was managed with two Perclose devices (Abbott Laboratories). No groin or upper extremity access site complications were observed in the cohort.

The mean operative time was 126 ± 45 minutes, and mean fluoroscopic time was 31 ± 18 minutes. A single 150-mm TBE device was sufficient to exclude the ruptured thoracic aneurysm, the six BTAIs, and to stop the bleeding in the patient undergoing open type A repair (Table II). Eight of the complicated type B dissections required a second covered stent, six of these patients required uncovered dissection stents distally, and one required just the TBE device. The remaining two cases of complicated dissection only required uncovered dissection stents distal to the TBE device. In the patient with an extensive dissection originating from blunt trauma, one dissection stent was required distal to the TBE device. The average covered length was 198 ± 59 mm, and no lumbar drains were required postoperatively for procedure-related ischemia.

Technical procedural success, with exclusion of the tear or injury and LSA patency, was 100% in the cohort. The patient with the type A dissection experienced multiple bilateral strokes in the carotid and vertebral territories. Although the left vertebral territory strokes were possibly related to TBE placement, the wide distribution seemed more likely to be associated with arch manipulation and replacement, although this could not be confirmed. Two patients with complicated dissections required an urgent intervention with TBE placement for acute renal failure requiring dialysis. Both patients continued to require hemodialysis temporarily in the immediate postoperative period, although both recovered kidney function and were stable without dialysis at the time of discharge. In the remaining patients, no strokes, retrograde dissections, spinal cord ischemia, access site issues, or other major complications were observed. The patient with the zone 0 repair required multiple interventions for management of necrotic esophagus and bowel due to the initial ischemic insult, although no new ischemia was observed after the aortic repair.

Follow-up imaging was obtained for 18 patients (90%) at a mean of 27 days (range, 2-144 days). All lesions continued to be excluded by the endograft, and the side branches were patent with no evidence of endoleak or progression of the pathology. We observed no graft slippage and no stenosis of the side branch in the portal (graft overlap) or within the target vessel. In the patients with complicated dissections, we observed continued exclusion of the proximal entry tear, without further degeneration identified. No patient has thus far required reintervention.

DISCUSSION

The use of the Gore TBE offers an option for zone 2 aortic repair while maintaining antegrade LSA perfusion, without the need for endograft modification, parallel stenting techniques, or additional open revascularization. The feasibility study for the device to demonstrate safety and efficacy predominantly included patients in need of elective TEVAR.[15] A later prospective trial included patients with BTAIs and patients with dissections, although the published data on these outcomes remain limited.[16] Our initial experience included a wide range of acute aortic pathologies, including aneurysmal disease, which was managed effectively with the TBE device. In our experience, the use of the device in these settings is both effective and safe for patients.

A prospective trial for the TBE device to demonstrate safety and efficacy included 85 patients (35% of the total described cohort) treated for aneurysmal disease, and only 8 patients were managed in an urgent or emergent setting. Additional feasibility investigation is ongoing for zone 0 repairs with the TBE device. Before the availability

Table II. Indication for intervention and procedural details

Variable	Zone of injury/entry tear	Distal extent of dissection	Total coverage length, mm	Grafts used for intervention	Indication for intervention
Grade III BTAI (n = 5)					
Patient 1	Zone 2	—	150	150-mm TBE	Pseudoaneurysm
Patient 2	Zone 2	—	150	150-mm TBE	Pseudoaneurysm
Patient 3	Zone 2	—	150	150-mm TBE	Pseudoaneurysm
Patient 4	Zone 2	—	150	150-mm TBE	Pseudoaneurysm
Patient 5	Zone 3	—	150	150-mm TBE	Pseudoaneurysm
Grade IV BTAI (n = 1)	Zone 3	—	150	150-mm TBE	Rupture with extravasation
Grade II BTAI with dissection (n = 1)	Zone 3	Zone 5	150	150-mm TBE	Embolism to renal arteries, renal ischemia
Uncontrolled hemorrhage (type A repair; n = 1)	Zone 2	—	150	150-mm TBE	Hemorrhage
Acute complicated dissection (n = 11)					
Patient 1	Zone 2	Zone 11	267	150-mm TBE; 167-mm Cook Alpha; 180-mm Cook dissection stent	Mesenteric malperfusion
Patient 2	Zone 2	Zone 6	267	150-mm TBE; 167-mm Cook Alpha; 120-mm Cook dissection stent	Lower extremity paraplegia
Patient 3	Zone 2	Zone 10	250	150-mm TBE; 150-mm Gore cTAG	Uncontrolled hypertension, chest pain
Patient 4	Zone 0	Zone 10	279	150-mm TBE; 179-mm Cook Alpha; 185-mm Cook dissection stent	Esophageal, mesenteric, and renal ischemia
Patient 5	Zone 2	Zone 10	150	150-mm TBE; 200-mm Cook dissection stent	Renal ischemia
Patient 6	Zone 2	Zone 8	150	150-mm TBE; 185-mm Cook dissection stent	Mesenteric ischemia
Patient 7	Zone 2	Zone 10	150	150-mm TBE	Renal ischemia, refractory chest pain
Patient 8	Zone 2	Zone 5	267	150-mm TBE; 167-mm Cook Alpha; 120-mm Cook dissection stent	Aortic rupture
Patient 9	Zone 2	Zone 10	290	150-mm TBE; 150-mm Gore cTAG; 150-mm Gore cTAG (40 mm of proximal coverage)	Renal ischemia
Patient 10	Zone 2	Zone 10	250	150-mm TBE; 200-mm Gore cTAG; 180-mm Cook dissection stent	Renal ischemia
Patient 11	Zone 2	Zone 10	270	150-mm TBE; 42-mm Gore proximal cuff; 150-mm Gore cTAG; 185-mm Cook dissection stent	Renal ischemia
Thoracic aneurysm (n = 1)	Zone 3	—	150 mm	150-mm TBE	Rupture

BTAI, Blunt thoracic aortic injury; *cTAG*, conformable TAG stent graft; *TBE*, thoracic branch endoprosthesis.

of the TBE device, repair in urgent scenarios was accomplished with TEVAR, with management of LSA perfusion as possible or indicated. Similarly, our practice included repair with TEVAR and delayed LSA revascularization if the patient became symptomatic. Although this approach was effective for the large majority of patients, one patient did suffer a vertebral stroke from LSA coverage while sedated for other traumatic injuries. The stroke was not diagnosed until sedation was weaned many days later. A review of BTAI repairs at our institution

before the availability of the TBE device included 155 total endovascular repairs, with required coverage of 48 LSAs for repair (31%), with subsequent revascularization required in eight patients (17%). Our practice includes a large number of BTAIs secondary to the large catchment area and rural mountain highways in the region surrounding our institution. Access to this device allows for the option for repair with a decreased risk of vertebral stroke and spinal cord ischemia, because monitoring can be difficult with concomitant intracranial injuries.

In the setting of acute complicated dissections, an entry tear near the LSA can require coverage of the LSA origin for appropriate seal. Although coverage for BTAIs is typically accomplished with a single stent, dissections frequently require coverage more distally to exclude large fenestrations. It is not uncommon for coverage to extend to the level of the celiac artery. The TBE device allows for more proximal coverage, while maintaining antegrade LSA perfusion, decreasing the risk of spinal cord ischemia with more extensive coverage. It is also not uncommon for these patients to have aortic degeneration distally, requiring additional interventions over time. Maintaining perfusion of the LSA offers some additional protection against spinal cord ischemia during these later interventions.

Finally, although the TBE device offers an ideal solution for lesions requiring coverage in zone 2, a slight learning curve is required when using the device. For those unfamiliar, management of a wire wrap can require additional manipulation of the TBE device in the arch, increasing the risk of stroke. Similarly, zone 0 repairs require slightly more nuance, such as the need for rapid pacing for accurate deployment. Experience in elective settings allows surgeons the opportunity to develop comfort with the device and improve success in more urgent settings.

Our study was subject to multiple limitations. The retrospective nature of the study might limit its broad applicability. The small patient sample size further limits our data and resulting conclusions. A larger cohort of patients with acute pathology is needed to confirm our observations that the TBE device is both safe and effective in these scenarios. Finally, our results demonstrate early success with the TBE device in acute settings; however, additional follow-up is needed to confirm that the TBE device can offer long-term patency and lesion exclusion similar to that achieved in current prospective trials with stricter exclusion criteria.

CONCLUSIONS

Our early institutional experience with the Gore TBE device demonstrates effective and safe use in acute aortic pathology, such as BTAIs, complicated dissections, and ruptured aneurysms without an increased risk of major complications. Additional follow-up is needed to confirm the long-term benefits.

DISCLOSURES

S.M. is a paid consultant for W.L. Gore & Associates. K.D., C.P., T.H., M.H., and M.K. have no conflicts of interest.

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