SECTION I Thoracic aortic aneurysms

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CASE 1

Endovascular repair of descending thoracic aortic aneurysms using the Gore TAG stent graft



Introduction

A descending thoracic aneurysm (DTA) is defined as a localized or diffuse dilation of an artery with a diameter at least 50% greater than an adjacent normal size artery. Thoracic aortic aneurysms are estimated to affect 10 per 100,000 elderly adults with 30-40% of those occurring in the descending portion of the thoracic aorta. The consensus size for intervention is generally 5.5 cm in the ascending aorta and somewhere in the range of 6.0–7.0 cm in the descending aorta. The most common risk factors include smoking, hypertension, atherosclerosis, bicuspid or unicuspid aortic valves, and genetic disorders. Potential symptoms from DTAs include back pain localized between the scapulae and midback and epigastric pain located at the level of the diaphragmatic hiatus. DTAs and thoracoabdominal aneurysms may compress the trachea or bronchus, cause stridor, wheezing, or dysphagia through compression of the esophagus. Erosion into surrounding structures may result in hemoptysis, hematemesis, or gastrointestinal bleeding. Erosion into the spine may cause back pain or instability. Spinal cord compression or thrombosis of spinal arteries may result in neurologic symptoms of paraparesis or paraplegia. DTAs may thrombose or embolize clot and atheromatous debris distally to visceral, renal, or lower extremities. The most common complications of thoracic aortic aneurysms are acute rupture or dissection. Some patients present with tender or painful nonruptured aneurysms. Although debate continues, these patients are thought to be at increased risk for rupture and should undergo surgical repair on an emergent basis. Endovascular stent grafting is fast becoming the accepted treatment modality for managing DTAs [1, 2] and has been approved for the US market since March 2005 (Figure 1).

Case scenario

A 71-year-old lady was diagnosed with a DTA of 4.4 cm \times 5.2 cm approximately 18 months before intervention. She was now symptomatic with a complaint of chest pain that would radiate to the back. Her medical history was significant for hypertension, emphysema requiring nocturnal oxygen supplementation and a 120-pack year smoking history. Her medications included a couple of antihypertensive medications and inhalers for her emphysema. The remainder of her history and physical examination were essentially normal. A CT scan of the chest conducted within 3 months of intervention demonstrated a DTA of 6.0×5.3 cm (Figure 2a and 2b). Due to the expansion of the aneurysm and her prohibitive medical history, she was referred for endovascular repair.

Recommendation

Due to the patient's requirement for home oxygen and other severe comorbidities, she was felt to be a prohibitive risk for open surgery. Measurements

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Figure 1 Illustration of a partially deployed Gore-TAG device.

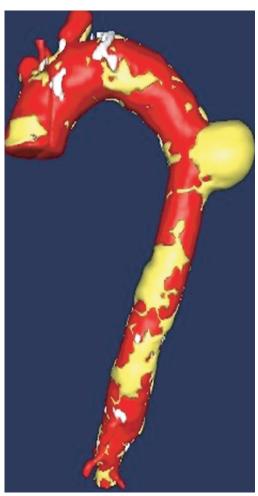


(a)



(C)

Figure 2 (a) A CT scan of the chest with IV contrast demonstrating a DTA with mural thrombus measuring 6.0 cm \times 5.3 cm in diameter. (b) A 3-D reconstruction showing the patient's anatomy and dimensions of the proximal and





distal landing zones. (c) An axial CT image demonstrating adequate-sized iliac arteries with mild calcification in the posterior wall of right iliac artery.

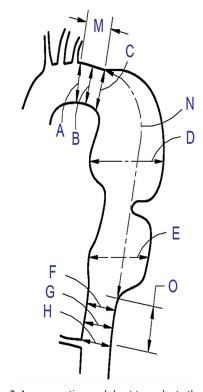


Figure 3 A preoperative worksheet to evaluate the candidacy for stent-graft placement. A, proximal implantation site, 30 mm; B, 1 cm proximal to implantation site; C, 2 cm from implantation site, 32 mm; D, aneurysm diameter, 60 mm; E, secondary aneurysm N/A; F, 2 cm distal to implantation site; G, 1 cm from distal implantation site, 29 mm; H, distal implantation site, 28 mm; N, distal neck, distance from aneurysm to celiac axis, 3 cm; O, total treatment length 9 cm.

obtained from the diagnostic CT scans of the chest, abdomen, and pelvis indicated that the patient met the criteria for endoluminal stent grafting using the preoperative work sheet (Figure 3). A Gore TAG endoluminal graft (W.L. Gore & Associates, Flagstaff, AZ) $34 \text{ mm} \times 15 \text{ cm}$ would provide a 10-15% oversizing in the landing zones (Table 1) and would be adequate in length to exclude the aneurysm. A CT scan of the pelvis helped assess the size, tortuosity, and amount of calcification of the iliac vessels. The iliac arteries were 10 mm in diameter and free of significant disease or tortuousity (Figure 2c) and were adequately sized for deployment of an endograft (Table 2).

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 Table 1 Gore TAG sizing chart.

Device diameter (mm)	Vessel diameter (mm)	Oversizing (%)
26	23–24	8–14
28	24–26	8–17
31	26–29	7–19
34	29–32	9–16
37	32–34	9–16
40	34–37	9–18

Procedure

Under general anesthesia, open retrograde cannulation of the right common femoral artery was performed with an 18-G needle and a 0.035-in. soft-tip angled glide wire (Medi-tech/Boston Scientific, Natick, MA) was passed into the distal thoracic aorta and exchanged to a 9-F (French) sheath under fluoroscopic visualization. Percutaneous access of the left common femoral artery was similarly performed with a 5-F sheath. Five thousand units of heparin were given to keep the activated clotted time greater than 200 seconds. A 5-F pigtail catheter was advanced through the left groin sheath into the thoracic aorta. The fluoroscopic C-arm was positioned in a left anterior oblique angle, and an oblique thoracic arch aortogram was performed to visualize the arch vessels and the descending thoracic aortic aneurysm (Figure 4). Intravascular ultrasound (IVUS) is routinely performed in our institution using an IVUS 8.2-F probe (Volcano Therapeutics, Inc., Rancho Cordova, CA). The IVUS probe was advanced through the right groin sheath to confirm the size of the aneurysm, presence or absence of thrombus, proximal neck diameter and length, and distal neck diameter and length. The $34 \,\mathrm{mm} imes 15 \,\mathrm{cm}$

 Table 2 Recommended iliac diameter for the introduction of Gore delivery sheaths.

Size (F)	ID (mm)	OD (mm)
20	6.7	7.6
22	7.3	8.3
24	8.1	9.1

ID, inner diameter; OD, outer diameter.

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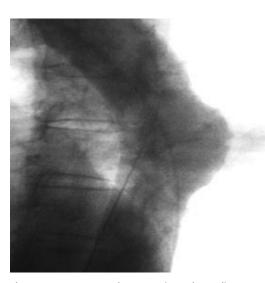


Figure 4 An aortogram demonstrating a descending thoracic aortic aneurysm with adequate proximal and distal neck length.

TAG stent graft was chosen (Figure 5). The IVUS catheter was exchanged for an extra-stiff 260-cm double curve Lunderquist wire (Cook Inc., Bloomington, IN). The right 9-F sheath was exchanged for a 22-F Gore sheath and a 34 mm \times 15 cm TAG stent-graft device was advanced through the Gore sheath (Figure 6). Prior to deployment, the proximal and distal landing zones were identified and marked on angiographic road map. At the time of deployment

of the endoluminal graft, a systolic blood pressure of 90 mm Hg is achieved to decrease the "windsock" effect in the thoracic aorta. We have not felt the need for adenosine-induced asystole. A Gore trilobe balloon (Figure 7) was used to perform postdeployment balloon angioplasty to both the proximal and distal segments of the graft for good fixation. A completion angiogram demonstrated exclusion of the aneurysm with no endoleak (Figure 8). All wires and sheaths were removed from the right common femoral artery with the incision closed in a transverse fashion. A 6-F angioseal vascular closure device (St. Judes Medical, Inc., St. Paul, MN) was deployed to the left common femoral artery. At the end, the patient had bilateral peripheral pulses was extubated prior to leaving the OR and transferred to the recovery room. She was discharged on postoperative day (POD) 2 in satisfactory condition. A CT scan of the chest performed on POD 1 showed exclusion of the 6-cm aneurysm with no evidence of an endoleak (Figure 8a and 8b).

Discharge CT scan Discussion

The management of DTAs has traditionally been by open surgical repair. Open surgical repair requires performing a left thoracotomy, aortic cross clamping, possible left heart bypass, and some degree of



Figure 5 A 22-F Gore delivery sheath introduced through the femoral artery for deployment of endoluminal graft.

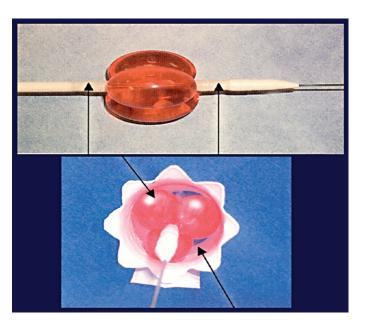


Figure 6 Gore trilobed balloon used for profiling the Gore TAG stent graft.

hypothermia that can increase the morbidity and mortality of the procedure. Thoracic endoluminal grafting has recently gained wide acceptance as a treatment modality for managing various aortic pathologies including DTAs [2–4]. From September

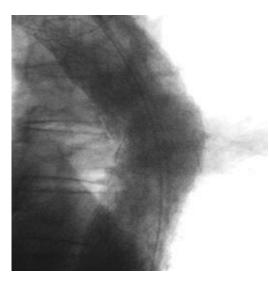


Figure 7 A postdeployment angiogram demonstrating exclusion of the thoracic aneurysm.

1999 through May 2001, 140 patients with DTAs were evaluated and enrolled at 17 sites across the United States. An open surgical control arm consisting of 94 patients was identified by enrolling both historical controls and concurrent subjects. Results of this US multicenter comparative trial (TAG 99-01) [5] showed a perioperative mortality in the endograft arm of 2.1% (n = 3) versus 11.7% (n =11, p < .001) in the open surgery cohort. A 30-day analysis revealed a statistically significant lower incidence of the following complications in the endovascular cohort versus surgical cohort: spinal cord ischemia (3% vs 14%), respiratory failure (4% vs 20%), and renal insufficiency (1% vs 13%). The endovascular group had a higher incidence of peripheral vascular complications (14% vs 4%). The mean intensive care and hospital stay were shorter in the endovascular cohort group. Accepted, commercial indications for a thoracic endoluminal graft include DTAs deemed to warrant surgical repair, fusiform aneurysm greater than two times diameter of normal adjacent aorta, and saccular aneurysms. A minimum of 2-cm nonaneurysmal segment in both the proximal and distal landing areas are needed for successful deployment of a thoracic endoluminal graft. Angles less than 60°

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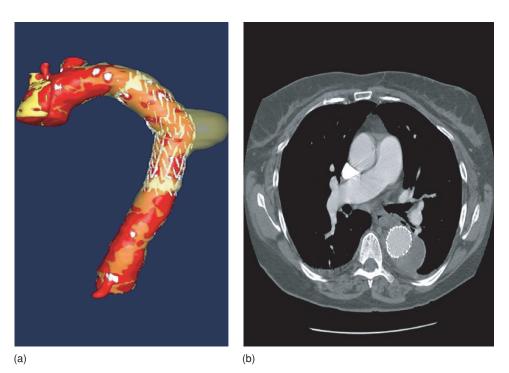


Figure 8 (a and b) A CT scan showing successful exclusion of the DTA.

between the aortic arch and the descending thoracic aorta may require additional length of nonaneurysmal segment, and coverage of the left subclavian artery may be required. Late complications associated with endografting include aortic wall perforation from the proximal bare spring configuration of earlier devices, device collapse from oversizing the endograft greater than 20% of the thoracic aortic neck diameter metal fracture, fabric erosion, and suture breakage associated with circumferential, radial, and tensional stresses from repetitive aortic pulsations [6]. Two-year followup data from the TAG 01 US multicenter trial showed a 6% endoleak rate detected at 1 year and 9% endoleak at 2 years postprocedure. During that time, three reinterventions in the endograft cohort were done with none in the open surgical cohort [7]. Five-year follow-up data show freedom from device-related complications to be very low with no aneurysm-related deaths, conversions, or ruptures for the control subjects enrolled in the pivotal and confirmatory studies (TAG 99-01 and TAG 03-03) [8]. Recommendations for endograft surveillance include a 4-view chest X-ray to assess for device migration or stent fracture and a CT scan of the chest at periodic intervals (1 mo, 6 mo, 1 yr, and annually thereafter).

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