Thoracic and Cardiovascular Surgery

Endovascular Repair of Descending Thoracic Aortic Aneurysm: Review of Literature

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Descending thoracic aortic aneurysmal disease is associated with poor 5-year survival rates as low as 10%-15% if untreated. This is probable because of a combination of the aneurysmal disease, comorbidities, and in many patients advanced age. In the search for better outcomes and newer techniques, the endovascular approach for the treatment of these aneurysms has developed over the last 20 years. Many advances in the materials and techniques have been made since the first reports of abdominal and thoracic aortic endovascular repair in the early 1990s. Currently, clinical trials have proven that several different commercially available endovascular grafts can be deployed safely, with early results equal to or better than conventional open repairs. Most of the data reported have been on early and midterm results. Now with continued observation, the long-term outcomes of these novel techniques can be determined over the next decade.
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Enlargement of the thoracic aorta to a size greater than 1.5 times the normal diameter is considered an aortic aneurysm.[1] The etiology of these aneurysms can be caused by many factors or conditions, such as atherosclerosis, cystic medial degeneration, connective tissue disorders (Marfan syndrome or Ehlers–Danlos syndrome), inflammatory disorders, infectious processes, or chronic dissections. Approximately 50% of all thoracic aneurysms are located in the descending thoracic aorta. The natural history of these aneurysms, if untreated, has been shown to be quite poor with estimated 5-year survival between 10% and 20%.[2-5] These poor outcomes have led to the development of surgical techniques to repair these aneurysms. The first replacement of the thoracic aorta was by Gross et al[6] for coarctation in Boston in 1948. Swan et al[7] and Lam and Aram[8] described the repair of a thoracic aneurysm using allografts in the early 1950s. Later in the 1950s Debakey and Cooley replaced the descending thoracic aorta and the ascending aorta with and without cardiopulmonary bypass.[9-11] The initial reports of these repairs led to the treatment of aortic disease in both the thoracic and abdominal aorta over the next 40 years, but these repairs were associated with increased morbidity and mortality. More recent reports of the open surgical treatment of the descending thoracic aorta using advanced techniques have shown significant improvements in morbidity and mortality, although still higher than desired.[12-16] This has led to the development of an endovascular approach for the treatment of thoracic aortic disease over the last 15-20 years. The endovascular treatment of peripheral arterial disease began in an animal model with Dotter in as early as 1969.[17] In 1986, Palmaz et al[18] described a feasibility study for the placement of a balloon expandable stent in the abdominal aorta, carotid, iliac, femoral, superior mesenteric, and renal arteries using a canine model. Later in 1991, Parodi et al[19] reported their experience with "Transfemoral intraluminal graft implantation for abdominal aortic aneurysms" using a custom-made balloon expandable stent sutured to a tubular knitted Dacron graft. The initial experience included use in an animal model and in 5 human subjects.[19] These results were promising and led to the rapid development of endovascular techniques and materials for the treatment of abdominal and thoracic aortic aneurysms.

First Generation Thoracic Endovascular Stent Grafts

The development of some of the first generation thoracic endovascular stent grafts (many of which were custom-made) took place over the span of the 1990s. Several reports of the safety and efficacy of these stent grafts were published

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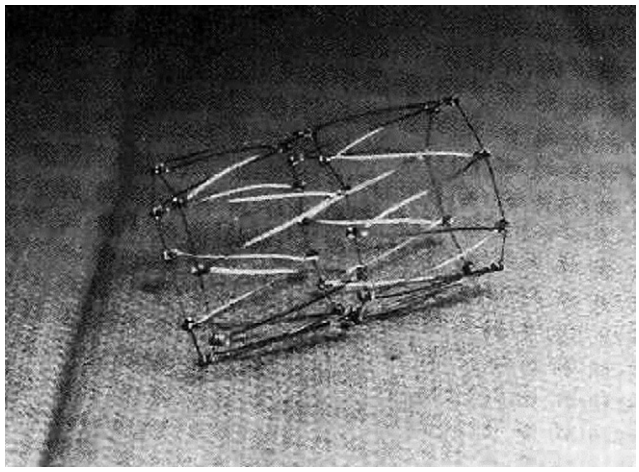

Figure 1 Original custom fabricated stainless-steel endoskeleton composed of Z-shaped stent bodies. (Reprinted with permission from Dake et al,[20] © 1994 Massachusetts Medical Society. All rights reserved.)

in the 1990s and early 2000s.[20-26] The first report of early first generation stent grafts for the treatment of thoracic aortic aneurysms in the United States was by Dake et al[20] at Stanford University in 1994. The graft used was a custom-designed endovascular stent graft composed of a stainless steel endoskeleton consisting of Z-shaped stent elements in a woven Dacron graft material (Fig. 1).[20] The dimensions of each graft were determined and constructed individually from the patients computed tomography scans. The study began in July 1992 and ended in January 1994. Thirteen patients (11 male) with a mean age of 61 years (range: 39-77) and the mean aneurysmal diameter of 6.1 cm (range: 5-8 cm) were treated. The mean hospital stay was 4.8 days (range: 2-11 days) and the mean follow-up was 11.6 months (range: 6-24 months). The deployment of the graft was successful in all patients and at last follow-up no major events or deaths were reported in the initial study in 1994.[20]

The Stanford group also continued the use of their custom fabricated stent graft over the next several years and reported early (1999) and midterm results of the procedure in 2004.[27,28] Between July 1992 and November 1997 they treated 103 patients (71% male) with their first generation graft. Of these patients 62 (60%) were deemed not to be open surgical candidates. The mean age of the patients was 76 ± 12 years and the mean aneurysmal diameter was 6.2 ± 1.3 cm.[27] At 2 years, the aneurysmal sac had thrombosed in 83% of the patients and the 30-day mortality was 9 ± 3%. Seven (6.8%) patients had cerebral vascular accidents (CVA) and 3 (2.9%) suffered permanent paraplegia.[27] They found that the overall actuarial survival was 82 ± 4%, 49 ± 5%, and 27 ± 6% at 1, 5, and 8 years, respectively. The group that was deemed open surgical candidates had better 5-year survival versus the nonoperative candidates (71% vs 31%).[28] This study showed the overall acceptable outcomes in this high-risk group of patients with multiple comorbidities and led to the development of second and now third generation thoracic endovascular stent grafts.

Second and Third Generation Thoracic Endovascular Stent Grafts

With the encouraging results of the early first generation mostly custom-made thoracic endoprosthesis, several manufactures began developing commercially available thoracic aortic stent graft alternatives. Over the last 10-15 years the GORE TAG thoracic endoprosthesis (TAG; W. L. Gore and Associates, Flagstaff, AZ), Medtronic, Talent Thoracic Stent Graft System, and Medtronic Valiant TM Endoprosthesis with Xcelerent TM delivery system (Medtronic Vascular, Santa Rosa, CA), Cook Zenith TX2 thoracic endograft (Cook Endovascular, Bloomington, IN), and the Bolton Relay stent graft (Bolton Medical, Sunrise, FL) have been developed.[29-33] The Gore TAG, Medtronic, Talent, and Cook Zenith endografts will be discussed in more detail because they are the most widely used thoracic endovascular grafts in the world and in the United States.

GORE TAG Thoracic Endoprosthesis

The GORE TAG thoracic endoprosthesis (TAG; W. L. Gore and Associates, Flagstaff, AZ) was the first thoracic endoprosthesis to enter clinical trials in the United States for the treatment of thoracic aortic aneurysmal disease in 1998. The trial was stopped in 2001 for longitudinal spine fractures, but restarted in 2003 after the device was modified.[29,34] The GORE TAG endoprosthesis is an asymmetrically expanded polytetrafluoroethylene graft attached to a flexible nitinol-support system (Fig. 2).[29] The grafts are available in sizes from 26 to 40 mm (a 45 mm graft is currently under investigation in the United States) and lengths of 10, 15, and 20 cm.[29] Deployment of the graft begins from the middle of the device and is introduced through a 20 F , 22 F, or 24 F sheath. The promising early results of the GORE TAG endoprosthesis led to the phase II prospective multicenter nonrandomized trial that was reported in January 2005.[29,35]

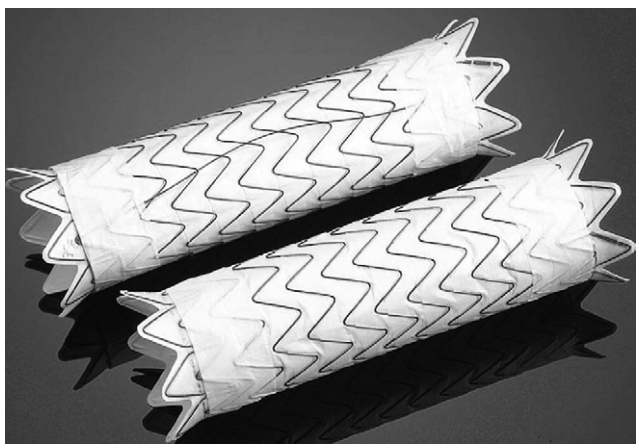

Figure 2 GORE TAG devices: Original (left) with longitudinal spine and the newer design (right) (TAG; W.L. Gore and Associates, Flagstaff, AZ). (Reprinted with permission from Makaroun et al.[29])