Thoracic Endograft Explant Analysis

Lessons learned from experiences with surgical conversion after failed endovascular thoracic aortic repair.

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The role of the endovascular stent graft in the management of abdominal aortic aneurysm has been firmly established over the past decade as multiple randomized studies have demonstrated the clinical benefits of this technology.[1,2] As this treatment becomes more widespread, procedural-related complications have also become widely recognized. Although the majority of these treatment-related problems can be managed with catheter-based interventions, certain complications, such as aneurysm enlargement, device infection, or migration, may invariably require endograft removal followed by conventional open aneurysm repair.[3]

A strikingly similar evolution is taking place in the endovascular treatment of descending thoracic aortic aneurysms. Since the FDA approved the first thoracic endograft in 2005, this minimally invasive treatment strategy has dramatically changed the therapeutic paradigm of thoracic aortic aneurysms because the operative stress of this endovascular treatment has been uniformly recognized as being significantly less than the surgical stress of a conventional open repair via a thoracotomy approach. As this treatment strategy becomes more widely adopted, serious complications either due to device failure or catastrophic adverse events may occur, which will require endograft explant with conversion to open repair. In this article, we describe our institutional experience with surgical conversion after failed endovascular thoracic aortic repair.

PATIENTS AND METHODS

Between November 2002 and August 2008, a total of 253 patients underwent endovascular thoracic aortic repair for various indications at the Baylor College of Medicine–affiliated hospitals. Stent graft placement for descending thoracic aortic aneurysms occurred in 201 patients, while 28 patients (11%) received endovascular repair due to type B dissection. Seven patients (3%) received endovascular treat-
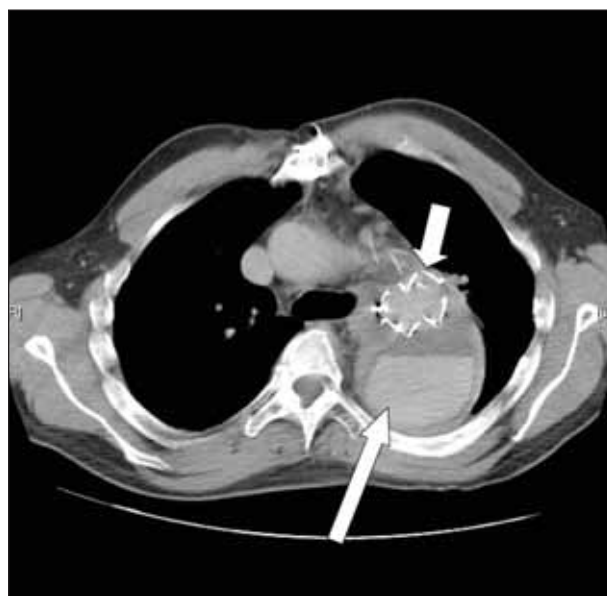

Figure 1. A CT scan of the chest revealed persistent false lumen pressurization (long arrow) after thoracic endograft implantation (short arrow) in the true lumen in a patient with acute type B dissection. The patient developed continual back pain with progressive false lumen enlargement.

ment due to traumatic aortic injury, eight patients (3%) were treated due to either penetrating ulcer or intramural hematoma, and nine patients (4%) received endografts due to an anastomotic aneurysm due to a previous descending thoracic aortic repair.

Patients routinely underwent postoperative surveillance protocol with contrast spiral computed tomography (CT) and clinical evaluation at 6 and 12 months and annual examination thereafter.

All procedures were performed in the operating room under general anesthesia with the patient prepared for conventional operation. Surgical access was established via common femoral artery exposure in 225 patients (89%), and iliac conduit was necessary in 28 patients (11%) for device delivery. Brachial access for angiographic catheter placement was performed in 25 patients (10%). Technical success with adequacy of aneurysm exclusion was assessed with completion contrast angiography.

Surgical conversion with endograft removal followed by open repair of the descending thoracic aorta was performed in seven patients (4.4%) from our own patient cohorts. Because of the tertiary referral pattern of our institution, we performed surgical conversions on an additional nine patients whose initial thoracic endovascular procedures were performed elsewhere. These 16 patients who underwent surgical conversion formed the basis of this endograft explant analysis.

We defined primary conversion as immediate open surgery during the same anesthetic session, and secondary conversion was defined as surgical procedures that necessitated a second anesthesia at a later date. During conversion, the endograft was removed, and the aorta with surrounding vessels was inspected for damage. Aortic reconstruction via thoracoabdominal incision with a Dacron graft was performed in all cases of surgical conversion.

RESULTS

With a total of 16 patients who underwent surgical conversion due to failed endovascular thoracic repair in this series, the mean age was 67 years (range, 59–79 years). Primary conversion occurred in two patients due to retrograde aortic dissection. All remaining 14 patients underwent secondary conversion. Among them, indications for conversion included (1) persistent aneurysm enlargement due to type I endoleak (n=3); (2) persistent aneurysm enlargement due to device failure (n=1); (3) complications related to acute type B aortic dissection (n=4) (Figures 1 through 3); (4) complications related to aortic dissection and connective tissue disorders (n=6). The in-hospital mortality rate of all patients who underwent surgical conversion was 18.8% (3/16). Among them, two fatalities were related to primary conversion in which retrograde aortic dissection occurred
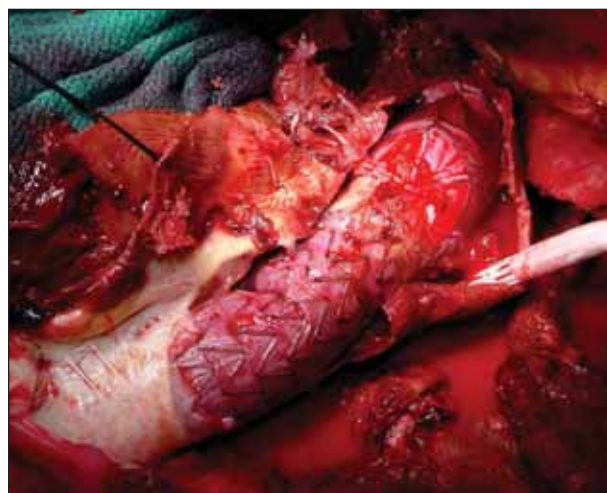

Figure 2. At the time of surgical conversion, the thoracic endograft was found to be partially positioned within the true and false lumen, which contributed to the persistent false lumen pressurization. This finding was not recognized at the time of the initial endovascular procedure.

after thoracic endograft deployment. Among the remaining 14 patients who underwent secondary conversion, the time interval between endovascular procedure and surgical repair of the descending thoracic aorta varied between 5 days and 43 months (mean, 11 months).

DISCUSSION

The current series of 16 surgical conversions after thoracic endograft placement provides additional patient cohorts to the literature regarding the utility of surgical treatment to salvage failed endovascular thoracic aortic procedures. Excluding the nine patients whose initial endovascular procedures were performed at outside institutions, the conversion rate from our own patient cohort was 4.4%. This was similar to conversion rates of 3.8% as recently reported in the Talent Thoracic Registry in which the Medtronic Talent thoracic stent graft (Medtronic Vascular, Santa Rosa, CA) was used to treat 457 patients from various European institutions.[4] Compared to other institutional experiences, our results were in line with the 5% conversion rate reported by Grabenwoger and colleagues, who treated 80 patients with endovascular thoracic aortic interventions.[5]

There were several noteworthy findings in our patients as we reflected on this clinical experience. Detailed analysis revealed that when a thoracic endograft was appropriately sized and used based on FDA-approved clinical indications, excellent results could be achieved, with only one patient (0.4%) requiring late surgical conversion. This patient developed a wire fracture that was attributable to device failure. He developed progressive aneurysm enlargement without

detectable endoleak, which ultimately required surgical conversion. All remaining patients who required surgical conversion were predominantly related to various deviations of manufacturer's Instruction for Use (IFU), either with inappropriate device size or unsuitable patient selection with nonapproved treatment indications. The following brief descriptions summarize the lessons learned from our experiences.

Device-Related Failure

One patient developed persistent aneurysm enlargement after an initial successful endovascular thoracic repair. Follow-up CT scan at 18 months revealed a longitudinal support wire fracture of the Gore TAG endograft device (W. L. Gore & Associates, Flagstaff, AZ), which was regarded as a device-related failure. This phenomenon could possibly be due to excessive shear stress exerted on the endograft resulting in device fatigue. In theory, excessive endograft oversizing relative to the aortic landing zone may result in added hemodynamic stress on the longitudinal support wire of the Gore TAG endoprosthesis. This possibility was ruled out in this patient, as his endograft was appropriately sized based on the device's IFU. Because of his progressive aneurysm enlargement, a surgical conversion was necessary to remove the endograft and reconstruct his aorta. At the time of endograft explant, a fracture of the longitudinal support wire was confirmed, which in part contributed to his aneurysm enlargement.

The phenomenon of longitudinal wire fracture of the Gore TAG endoprosthesis has been reported previously.[6] To date, 18 wire fractures have been reported in the US phase II trial of the original Gore thoracic device, the majority involving the longitudinal support wire.[7] One patient from this
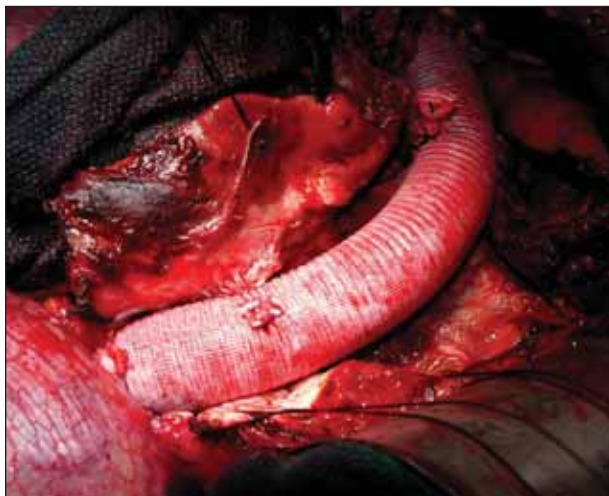

Figure 3. Completion image of the surgical conversion in which a thoracoabdominal approach was used to remove the endograft and reconstruct the thoracic aorta.

trial also developed a persistent endoleak, which required endograft explantation. The discovery of this device-related failure led to a rapid response by the manufacturer that redesigned the endograft. The longitudinal support wire was eliminated in a modified version of the Gore TAG endograft, and the phase III study was subsequently completed in June 2004. This modified thoracic endoprosthesis also incorporated other features, including a stronger polytetra-fluoroethylene (PTFE) graft material reinforced with a PTFE/fluorinated ethylene propylene film to achieve longitudinal stiffness and device conformability without the longitudinal support.[8] The modified endograft design provides flexibility and sufficient radial force in the angulated thoracic aorta as well as device fixation in the distal aortic arch.

Off-Label Use of Thoracic Aortic Stent Grafts

In our series, 12 patients (75%) who required surgical conversion had undergone endovascular thoracic aortic repair based on off-label treatment indications. Among them, aortic dissection was the most common off-label indication for thoracic endograft placement. Eight patients had complicated acute type B dissection as evidenced by persistent back pain or end-organ malperfusion. All patients who underwent endovascular repair due to aortic dissection received the Gore TAG device. Because all of these patients who underwent secondary conversion at our institution received the thoracic endograft at outside facilities, analysis of their operative report and preoperative imaging revealed the underlying treatment goals by the initial treating physician to exclude the proximal entry point that caused the aortic dissection. Contrary to the intended treatment objective, these thoracic devices failed to exclude proximal entry points in all cases. Based on both operative findings and postprocedural image analysis, possible modes of treatment failure include (1) lack of adequate proximal and distal landing zone and (2) inappropriate device sizing. Although these two mechanisms of treatment failure constitute a deviation from the IFU per device manufacturer, it simply cannot be overemphasized that aortic dissection remains a treatment contraindication for thoracic stent graft implantation based on current devices approved by the FDA.

Because the Gore TAG endoprosthesis was the most commonly utilized thoracic stent graft in the US and the predominant device in which we explanted in our series, familiarity with the IFU is critical. This is particularly important because 94% of thoracic endograft explants in our series were related to off-label use of thoracic stent grafts. Since the Gore TAG device received the FDA approval in March 2005, it has become the most widely used thoracic stent graft in the US. The approval of this device was based on a prospective nonrandomized multi-institutional trial comparing results of stent graft repair of descending tho-

racic aortic aneurysms with those of open surgical graft replacement or the control group in low-risk patients.[8,9] There were 17 institutions in the US that participated in the trial by contributing both endovascular and open surgical control patients. In total, there were 140 stent graft patients and 94 open repair patients that formed the basis of this study, which ultimately gained FDA approval for clinical application.

The IFU of this device was primarily based on various stringent inclusion and exclusion criteria defined patient suitability for the trial. Inclusion criteria required aneurysms >5 cm in diameter or requiring surgical treatment in patients with a life expectancy >2 years who were suitable candidates for open operation. Specifically excluded were patients with aneurysms of mycotic origin, aortic dissection, hemodynamically unstable patients, patients having a myocardial infarction or stroke within the previous 6 weeks, a creatinine level of >2 mg/dL, and patients with Marfan syndrome or other connective tissue disorders. Inclusion criteria specific to the stent graft group involved an aortic landing-zone diameter measuring between 23 and 37 mm because available devices ranged from 26 to 40 mm. Also, the proximal and distal landing zones had to be >2 cm in length and without substantial laminated thrombus or circumferential calcification.

Based on the inclusion guidelines, 94% of the patients in our series who underwent secondary conversion had failed to meet the required IFU for thoracic endograft implantation. Specifically, two patients had aortic diameters >38 mm in which even the largest Gore TAG device of 40 mm would represent significant device undersize, and this invariably contributed to persistent type I endoleak. Three patients had an inadequate landing zone, and an additional four patients had significant laminated thrombus or calcification at the site of endograft implantation. In these incidences, failure to comply with the specified IFU, as well as off-label usage of the thoracic endograft resulted in treatment failure as persistent clinical sequelae including type I endoleak and aneurysm enlargement became the basis of endograft explant.

Aortic Dissection of the Descending Thoracic Aorta

The perceived advantage of minimally invasive endovascular thoracic repair in terms of faster recovery and lower procedural-related complications, in contrast to traditional open repair, has created a widespread enthusiasm among many physicians to broaden this treatment application beyond the current FDA-approved treatment indications. Device application in patients with acute aortic dissection remains a subject of controversy, as an increasing body of literature has both supported and condemned the use of tho-

racic stent grafts for this treatment application. In our series, four patients who received thoracic stent graft for acute aortic dissection (defined by symptoms <14 days) developed complications related to their endovascular repair that ultimately required stent graft removal. Although the number of this subset of patient cohorts who required endograft explant remains small, the experience in this series continues to underscore the controversy of endovascular treatment strategy as well as the lack of long-term clinical durability of this treatment indication.

Dake and colleagues deserve credit for their pioneering work in 1999 in which they demonstrated the initial benefit of thoracic stent graft placement in patients with acute type B aortic dissection.[10] During the same year, Nienaber and colleagues from Germany reported their results with endovascular treatment in patients with subacute and chronic type B dissection.[11,12] In this study, endovascular treatment with a stent graft was successfully performed in 12 patients with no morbidity or mortality. In contrast, open operation in 12 other patients was associated with four deaths (33%) and five serious adverse events (42%) within 1 year. The finding of this study, which suggested that endografting might be a safer treatment in selected patients with subacute or chronic dissection, became the impetus for the INSTEAD (INvestigation of STEnt grafts in patients with type B Aortic Dissection) randomized study, which compared endovascular stent grafting versus medical treatment. Early findings from the INSTEAD study revealed that 1-year mortality rates for medically treated patients were significantly lower compared to endovascular patients at 3% and 10%, respectively. Among those treated medically, 11% crossed over to stent graft or surgical treatment. Consequently, elective, prophylactic stent grafting does not appear to be justified in asymptomatic medically controlled patients with subacute or chronic type B aortic dissection.[12]

In our series, 10 patients (63%) developed complications after thoracic endografting procedures in which the treatment indications included one subacute and three acute thoracic dissections. These complications included expansion of false lumen with back pain and renal failure. Two patients with acute dissection developed end-organ malperfusion due in part to inadequate exclusion of the proximal entry tear. The high incidence of endograft-related treatment complications in patients with acute dissection was highlighted in a recent compendium summary analysis, which included more than 609 patients with aortic dissection after endovascular treatment.[13] Among them, more than 42% of patients had a subacute or chronic aortic dissection. The technical success of endovascular treatment, which was achieved in 96% of patients, was high, while only 2.3% of patients required in-hospital surgical conversion. One striking finding was related to the complication rate

because complications occurred less frequently in patients with chronic dissections than in those undergoing endovascular repair for acute dissection. Remarkably, the complication rates for acute and chronic dissection were 21.7% and 9.1% (*P*=.05), respectively.

Retrograde Aortic Dissection Caused by Aortic Stent Graft Placement

Although the treatment objective of thoracic stent graft placement in aortic dissection is to exclude the proximal entry tear so that false lumen thrombosis is induced, failure to cover the proximal entry tear by inadvertent distal endograft deployment can lead to retrograde aortic dissection, resulting in a catastrophic sequelae of ascending and aortic arch dissection. Conversely, retrograde aortic dissection can also be caused by tearing of the proximal landing zone by endograft with excessive radial force or protruding metal stents. The risk of retrograde aortic dissection after thoracic endograft implantation has been already reported.[14] We encountered two cases of this devastating complication in which endovascular repair was attempted in acute and chronic aortic dissection. The diagnosis of retrograde aortic dissection extending to the ascending aorta and aortic arch was immediately recognized as evidenced by hypotension and cardiac arrhythmia, as well. Additionally, the sudden loss of carotid pulses and arterial blood pressure tracing signified an immediate catastrophic event. Both patients underwent immediate surgical conversion of median sternotomy with arch replacement under circulatory arrest, which resulted in fatal outcomes.

In one patient, we postulate that intimal tear caused by the inadequate landing placement of an endograft, which sheared the septum separating the true and false lumen, resulted in a sudden retrograde aortic dissection. In another case, we suspected an uncovered proximal entry tear after endograft implantation developed retrograde aortic flow, which propagated to a retrograde dissection. It is noteworthy that in both cases, every effort was made to identify anatomy of aortic dissection, including transesophageal echocardiography, intravascular ultrasound, and contrast angiography. The catastrophic events in these cases further underscored the technical challenge of endovascular repair of acute aortic dissection.

Given these two treatment failures in our series, as well as other similar negative experiences in the literature, a specific thoracic endograft designed for aortic dissection is needed.

Implantation of a self-expanding endograft in a highly friable aortic wall adjacent to the area of aortic dissection is drastically different compared to deploying endovascular prosthesis for atherosclerotic aortic aneurysms. In the latter case, device fixation of a thoracic endograft is based on appropriate radial force to achieve complete circumferential attachment against a short and relatively normal aortic segment. Placement of the aortic device in acute aortic dissection, however, requires greater device flexibility and less radial force while achieving full device fixation without damaging the surrounding aortic wall. A high degree of device compliance to allow graduated true lumen expansion over time while compressing against a false lumen is also an essential device feature to ensure treatment success for acute aortic dissection.

Disappointing Outcomes With Thoracic Endografting in Patients With Connective Tissue Disorder

In our series, six patients received thoracic endografts due to underlying aortic aneurysm or dissection caused by congenital connective tissue disorder. Specifically, three patients were diagnosed with Marfan syndrome, and three patients had Ehlers-Danlos syndrome. All of them had symptomatic aortic aneurysm or dissection as evidenced by either back pain or end-organ malperfusion. The treatment strategy using an endovascular approach in these patients with congenital connective tissue abnormality deserves particular consideration. Although a few case reports have documented the feasibility with short-term success with endovascular repair of descending aortic aneurysm in patients with Marfan syndrome,[15-18] there remains a significant controversy regarding the durability of endograft placement in these patients. Limited information is available to analyze the consequence of persistent radial force of a thoracic endograft in an aortic dissection containing both true and false lumens or in aortic aneurysm with abnormal and weakened aortic structural integrity in these patients with congenital connective tissue abnormality.

Six patients in our series were diagnosed with aortic dissection with associated connective tissue disorder and underwent thoracic endograft implantation at outside institutions. In each of these circumstances, the physician who performed the endovascular procedure reportedly used intravascular ultrasound to delineate aortic true and false lumen prior to endograft implantation. Five of these patients developed evidence of organ malperfusion or severe back pain after endograft implantation due to either rapid aneurysm enlargement or progressive worsening of aortic dissection, which warranted urgent endograft removal.

In all cases, a thoracoabdominal approach was utilized in which the descending aorta was exposed, and the endograft was removed surgically. It is noteworthy that multiple true and false lumens were identified in many of these patients with underlying connective tissue disorder. Moreover, thoracic endografts were found to span across various true and false lumens, which clearly contributed to persistent pressurization in the false lumen. Intraoperative findings clearly

demonstrated the failure of thoracic endograft to seal the proximal entry site of aortic dissection, despite the initial aortogram from outside institutions, which reportedly revealed satisfactory radiography results after the thoracic endograft placement. In reality, patients with Marfan or Ehlers-Danlos syndrome appear to be at substantial risk for aortic dissection after insertion of stent grafts, presumably due to the weakened aortic wall, that could not withstand the constant radial force exerted by the thoracic stent grafts.

The disappointing experience of thoracic endografting in patients with Marfan syndrome or other congenital connective tissue disorders was further resonated by the recent expert consensus document published by the Society of Thoracic Surgeons on descending thoracic aortic disease management using endovascular stent grafts.[19]

In this report, the authors uniformly cited the lack of clinical evidence to support the use of thoracic endografts in the management of either aortic aneurysm or dissection in patients with known connective tissue disorder. Moreover, the expert panel regards the presence of Marfan syndrome or a connective tissue disorder an absolute exclusion criterion in thoracic endograft implantation. This is also supported by the IFU of all commercially approved thoracic endograft devices, which uniformly stated that Marfan syndrome or connective tissue disorder constitutes a contraindication for endograft deployment. Additionally, these patients are typically young, and, due to the unknown durability of this technology in long-term outcomes, thoracic stent graft implantation should be avoided. In centers of excellence with a high volume of thoracoabdominal aortic repair, this procedure can be performed safely with proven durability and excellent outcomes.[20]

SUMMARY OF LESSONS LEARNED

Although remarkable clinical experiences of endovascular thoracic repair are continually reported in the literature since this technology was first introduced in 1991, this technology remains embryonic. Undoubtedly, device modifications with smaller introducer sheaths, a more flexible device, and secured fixation mechanisms will improve the clinical outcome of this treatment strategy. Our clinical results show that strict adherence to the device IFU in terms of device sizing and treatment indication will yield excellent treatment outcomes.

Off-label device usage, particularly with treatment indications that have not been substantiated with convincing clinical evidence, will likely lead to treatment failure and possibly require surgical conversion with endograft explantation. Inappropriate device sizing similarly may lead to suboptimal device fixation with resultant aneurysm enlargement. Our experience also suggests that patients with aortic dissection and connective tissue disorder should not undergo endovascular treatment until more evidence is available to support this clinical application. ■

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