Anatomic factors associated with acute endograft collapse after Gore TAG treatment of thoracic aortic dissection or traumatic rupture

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Objective: **The potentially devastating complication of total or near total thoracic endoprosthesis collapse has been described with the TAG device (W. L. Gore & Associates, Flagstaff, Ariz). This rare complication has resulted in a warning to clinicians and speculation about the etiology of this problem. This report evaluates potential causative anatomic factors that may increase the probability of endoprosthesis collapse in patients undergoing endovascular thoracic aneurysm repair (TEVAR).**

Methods: **Preoperative and postoperative computed tomography scans were collected worldwide representing six patients who had experienced radiologically confirmed TAG endoprosthesis collapse. These were compared with a matched cohort of five patients with a TAG endoprosthesis in the same anatomic position in which no collapse occurred. Anatomic variables of aortic arch angulation, apposition, intraluminal lip length, proximal aortic diameter, distal aortic diameter, intragraft aortic diameter, percentage of oversizing, and angle of the proximal endograft to the aortic arch were compared between groups. Differences between groups were determined using the Student *t* test, with $P < .05$ considered significant.**

Results: **The two groups (collapse vs no collapse) were evenly matched demographically, and all underwent endoluminal treatment with the TAG device, with no differences in gender, graft position in the aorta, operative indication, or age (P = NS). Distal sealing zone aortic diameter ± standard deviation of 18.9 ± 1.7 mm vs 22.7 ± 2.7 mm and minimum aortic diameter within the endograft of 18.6 ± 1.7 mm vs 22.4 ± 3.1 mm predicted collapse ($P < .05$). Proximal aortic diameter, apposition, intraluminal lip length, aortic arch angle, and angle of proximal endograft to aortic arch did not predict collapse (P = NS).**

Conclusion: **Thoracic endograft collapse is an exceedingly rare event. In this series, endoprosthesis collapse occurred in patients who were treated outside the manufacturer's instructions for use for minimum required aortic diameter. Although distal aortic diameter and minimum intragraft aortic diameter predicted collapse, other variables may also influence this complication but were not significant owing to potential type II statistical errors. In the future, caution should be exercised when contemplating TEVAR in patients with small (<23 mm) aortic diameters. (J Vasc Surg 2007; 45:655-61.)**

Endovascular management has emerged during the last 10 years as a valuable treatment modality for thoracic aortic aneurysms that can lessen surgical morbidity and mortality, decrease hospital stay, and provide for improved outcomes in properly selected patients.[1-4] Endovascular thoracic aortic aneurysm repair (TEVAR) has demonstrated excellent short-term and medium-term results for degenerative aneurysms, traumatic aneurysms, and contained traumatic aortic ruptures alike.[5,6] Endovascular procedures of the thoracic aorta are not without complications, however.[7-10]

TEVAR for the treatment of traumatic aortic rupture is particularly promising given the associated serious comorbidities that accompany these polytrauma patients.[11,12] Endovascular repair of traumatic aortic rupture allows for definitive treatment of the vascular injury without the need for bypass or thoracotomy and reduces the recovery time that is associated with these procedures.[6,13] However, many of the complications associated with TEVAR for aneurysmal disease are uncommon in the endovascular treatment of traumatic aortic rupture. Traumatic patients represent a different disease process than aneurysm patients, with dissimilar anatomy, treatment considerations, and complications.

Concerning case reports have described the potentially devastating complication of total or near total acute endoprosthesis collapse or infolding with the TAG system (W. L. Gore & Associates, Flagstaff, Ariz).[14,15] This complication is not unique to the TAG endograft, but has been observed with other brands as well, including the Aneurx (Medtronic, Minneapolis, Minn) and the Zenith (Cook, Bloomington, Ind). This complication has primarily been reported in pa-

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Competition of interest: Dr Muhs receives a speaking honorarium from W. L. Gore & Associates, and Drs White and Verhagen have consulting agreements with W. L. Gore & Associates.

Additional material for this article may be found online at www.jvascsurg.org.

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0741-5214/$32.00

doi:10.1016/j.jvs.2006.12.023

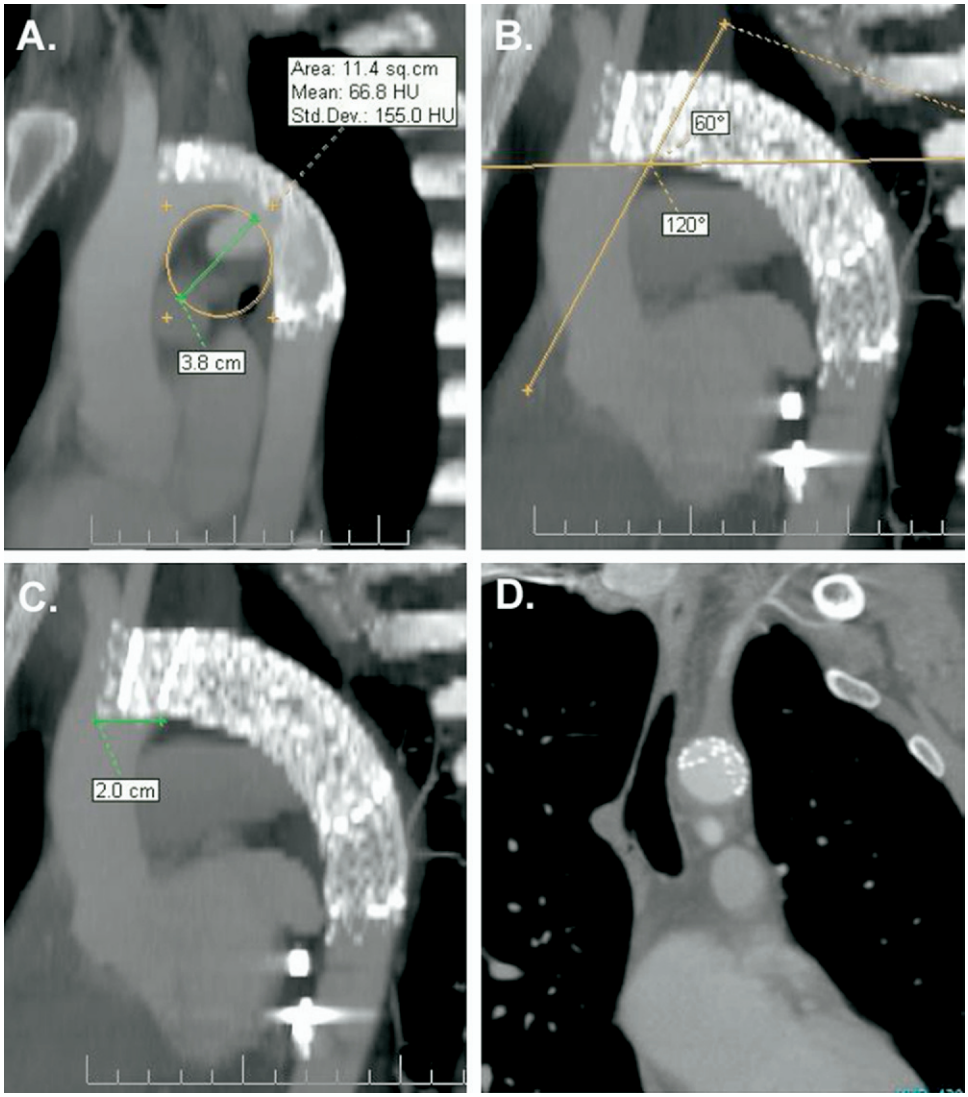

Fig 1. Measurements included **(A)** aortic arch angulation, **(B)** angle of endograft extending into the aortic lumen, **(C)** endograft lip length, **(D)** confirmation of infolding, presence of motion artifact, endograft distance from the subclavian artery, and aortic diameters perpendicular to the center lumen line at the proximal, intragraft, and distal landing zones.

tients treated for traumatic aortic rupture or dissection and rarely in patients treated for thoracic aneurysms.

Patients with traumatic rupture or dissection often have relatively normal, small proximal aortas. These anatomic realities prompted us to question whether specific anatomic factors predispose certain patients to endoprosthesis collapse and if a careful analysis of preoperative anatomy might minimize this risk. This rare complication has resulted in a warning to clinicians and speculation about the etiology of this problem.

The current the market leader in thoracic endografts and the only device approved by United States Food and Drug Administration (FDA) is the Gore TAG endoprosthesis. The purpose of this report is to evaluate potential causative anatomic factors that may increase the probability of endoprosthesis collapse in patients undergoing endovascular repair of aortic trauma and dissection.

METHODS

Indication, preoperative sizing, choice of device, and surgical method was left solely to the discretion of the operating team at each institution. Postoperative imaging and any secondary interventions were also entirely the responsibility of the operating surgeon.

Preoperative or postoperative computed tomography (CT) scans, or both, were collected from three international sites representing six patients who had experienced radiologically confirmed TAG endoprosthesis collapse between 2004 and 2006. Five patients with collapse had been treated for trauma and one for an aortic dissection.

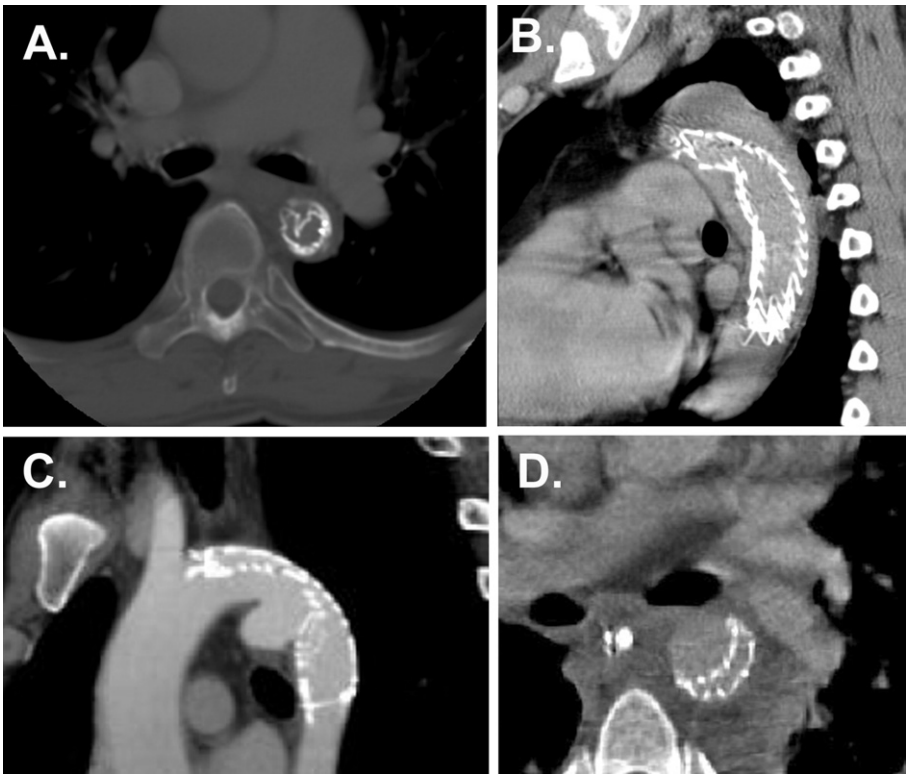

Fig 2. A-D, Representative images of the collapsed endoprosthesis in four patients are shown.

It is known that collapse is not a binary phenomenon. Some degrees of infolding may compromise seal and structural integrity without narrowing the lumen enough to compromise flow. In this report, TAG endoprosthesis collapse was determined solely on CT imaging and not on hemodynamic or clinical parameters. Additional patients with confirmed collapse exist, but were unknown to us or did not have adequate imaging for analysis.

The control group, which was matched for demographics, consisted of five patients from a single institution with a traumatic aortic rupture who were treated with a TAG endoprosthesis and who did not show collapse. The control institution also provided two of the patients with a confirmed endoprosthesis collapse.

All patients in the study had preoperative sizing and postoperative collapse confirmed through the use of CT scanning. Other imaging was used in conjunction with the CT scans, including transesophageal echo, chest radiography, and angiography, but was not used in the analysis of anatomic factors predicting collapse.

The original Digital Imaging and Communication in Medicine (DICOM) data, when available, was provided to an independent imaging company (Medical Metrix Solutions, West Lebanon, NH), which performed the requested measurements (Fig 1). Two CT scans did not have original DICOM data, and measurements on these images were performed manually using commercially available imaging software. Measurements included aortic arch angulation, angle of endograft extending into the aortic lumen, the length of proximal endograft not in apposition to the aortic wall (endograft lip length), presence of motion artifact, endograft distance from the subclavian artery, and aortic diameters perpendicular to the center lumen line at the proximal, intragraft, and distal landing zones (Fig 2).

Statistical analysis. A Student *t* test for unpaired data was used to analyze changes in area and diameters. Significance was assumed at $P < .05$. Data are expressed as mean ± standard deviation.

RESULTS

Image quality was considered good-to-excellent in all images, and satisfactory analysis was performed. The two groups (collapse vs no collapse) were evenly matched demographically, with no differences in gender or age (P = NS). Representative images of the collapsed endoprosthesis are shown (Fig 2). Dynamic cine CT angiography was available in one collapse. This demonstrated video evidence of the enormous forces exerted on stents placed in the aortic arch, the problem of a collapsed graft, and a very small true lumen with a blind-ending false lumen (Video clip, online only).

Endovascular salvage consisting of implantation of additional endoprosthesis inside the collapsed TAG (Fig 3) or ballooning (Fig 4) were attempted in four of the six patients who experienced collapse, with varying results. In one patient, a 28-mm × 10-cm TAG was deployed first, but

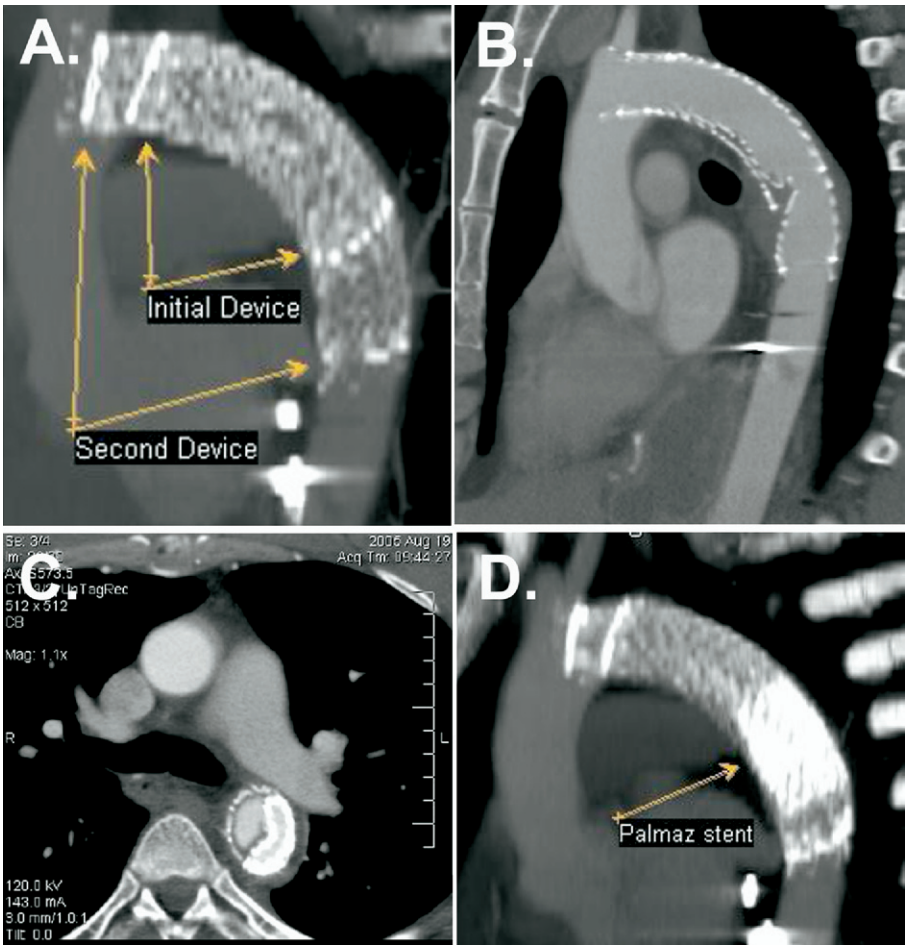

Fig 3. In one patient, attempts were made to correct the graft infolding through endovascular salvage with the implantation of additional endoprosthesis inside a collapsed TAG. This attempt was unsuccessful. **A,** A TAG (28 mm × 10 cm) was deployed first, but owing to a proximal type I endoleak, a second TAG (28 mm × 15 cm) was deployed slightly more proximally. **B** and **C,** Computed tomography (CT) imaging showed clear infolding of the second TAG. **D,** To treat the infolding, a giant Palmaz stent was deployed. A CT scan 1 day after the placement of the Palmaz stent showed complete infolding of both the second TAG as well as the Palmaz stent.

owing to a proximal type I endoleak, a second TAG (28 mm × 15 cm) was deployed slightly more proximally. Clear infolding of the second TAG was seen on CT imaging.

To treat the infolding, a giant Palmaz stent (Cordis, Miami Lakes, Fla) was deployed. A CT scan 1 day after the placement of the Palmaz stent showed complete infolding of both the second TAG as well as the Palmaz stent. In a second patient, infolding was observed on the postoperative CT scan, and the patient underwent balloon angioplasty. The follow-up CT scan after balloon angioplasty demonstrated correction of the infolding. In one patient, open explant and repair was performed successfully. One patient declined further treatment and is currently asymptomatic.

Of the variables compared, distal sealing zone aortic diameter (18.9 ± 1.7 mm vs 22.7 ± 2.7 mm) and minimum aortic diameter within the endograft, defined as the preoperative minimum aortic diameter obtained from the proximal sealing zone to the distal sealing zone taken at 1-m increments (18.6 ± 1.7 mm vs 22.4 ± 3.1 mm), predicted collapse ($P < .05$; Table I). Proximal aortic diameter, apposition, intraluminal lip length, aortic arch angle, and angle of proximal endograft to aortic arch failed to reach statistical significance and therefore did not predict collapse (P = NS; Table I).

No patient who experienced endograft collapse demonstrated radiographic evidence of stent fracture or fabric tear, nor did stent graft migration occur. However, the stent graft from the patient who underwent explantation had two rows of completely fractured stents in the place of infolding (Fig 5).

DISCUSSION

TEVAR has been a significant advance in the treatment of thoracic aneurysmal disease; however, its use has not

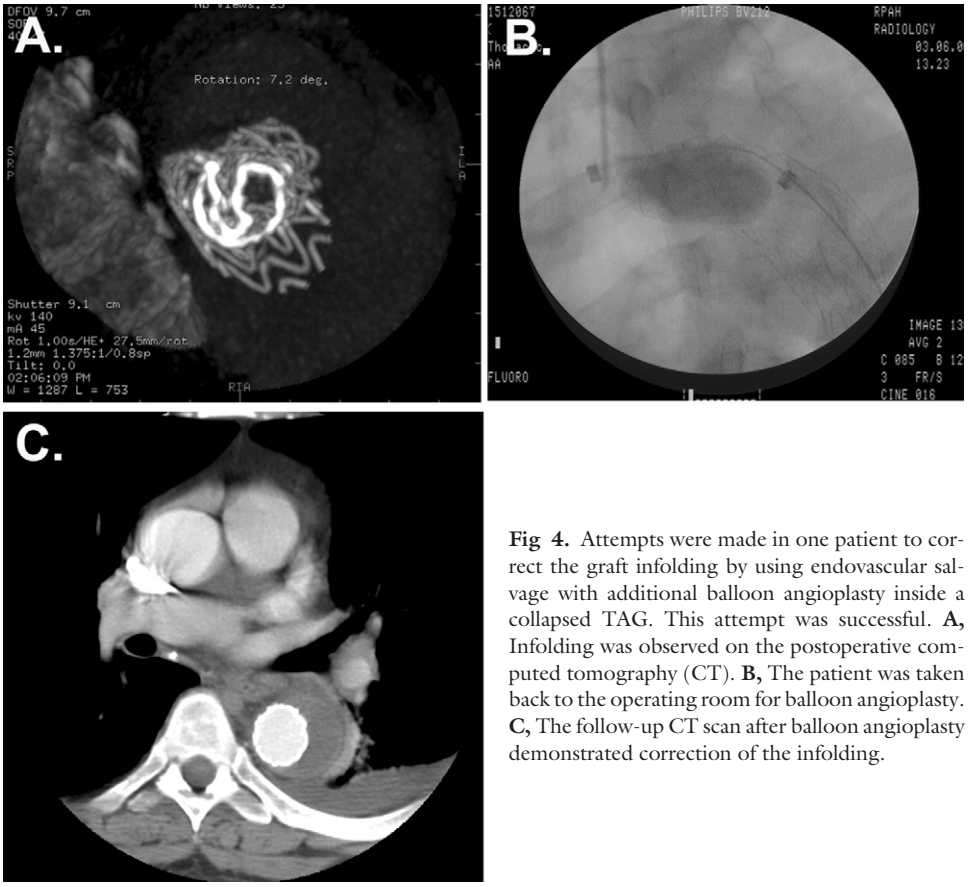

Fig 4. Attempts were made in one patient to correct the graft infolding by using endovascular salvage with additional balloon angioplasty inside a collapsed TAG. This attempt was successful. **A,** Infolding was observed on the postoperative computed tomography (CT). **B,** The patient was taken back to the operating room for balloon angioplasty. **C,** The follow-up CT scan after balloon angioplasty demonstrated correction of the infolding.

Table I. Variables predicting collapse

Variable	P
Proximal aortic diameter	NS
Distal aortic diameter	.02
Smallest aortic diameter (within endograft)	.03
Intraluminal lip length	NS
Arch radius of curvature	NS
Lip to arch angle	NS
Complete stent graft apposition	NS
Coverage of subclavian	NS
Percent oversizing	NS

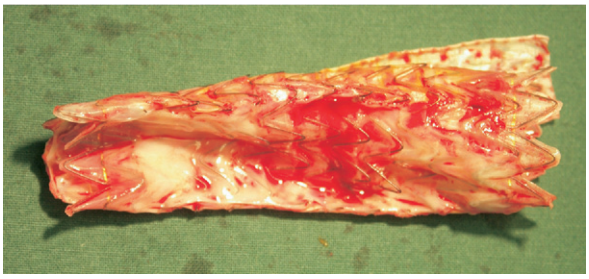

Fig 5. Open explant and repair was performed successfully in one patient. The explanted stent graft demonstrated infolding and two rows of fractured stents.

been without significant adverse events. In low-risk patients, up to 32% experienced at least one acute (<30 days) complication.[16] Procedure-related mortality approaches 17% in high-risk patients with thoracic aortic aneurysm treated with an endovascular approach.[7]

Specifically regarding the TAG device, spine fractures were a problem with the earlier device.[16] Although resulting in minimal adverse clinical events, in the phase II clinical trial of the first generation TAG device, up to 14% of patients experienced a fracture of the longitudinal spine.[16] As a consequence, Gore redesigned the device, which included removal of the longitudinal spine, wires made thicker and stronger, deployment made faster, and fabric changed to a low permeability material. To our knowledge, no collapses of the TAG device had been reported before these changes. The redesigned current device has encountered this problem, however, specifically in patients treated for aortic rupture or dissection, and is the subject of this report. Although this report was not designed to determine design characteristics leading to collapse, one can speculate that removal of the spine resulted in decreased structural support that may have increased the potential of collapse.

A more likely possibility is that as clinicians gain expertise and comfort with TEVAR, the current TAG device is

Table II. Anatomic and device variables for all patients

Patient	*Collapse*	*TAG diamete (mm)*	*Percent oversizing (%)*	*Liplength (mm)*	*Proximal aorta (mm)*	*Distal aorta (mm)*	*Radius curvature (cm)*	*Smallest aorta (mm)*
1	Yes	28	135	20	26.2	20.7	2.2	20.7
2	No	34	138	0	28.3	25	6	24.6
3	No	40	167	8	21.6	21	2.2	24
4	No	28	126	13	25	22.3	5.4	22.3
5	No	39	115	0	25.6	25.7	N/A	24
6	Yes	26	130	18	22	20	3.8	20
7	Yes	26	144	0	21	18	3.1	18

N/A, Not applicable.

being deployed in clinical situations that are less than optimal. Deployment of the TAG outside of Gore's instructions for use (IFU), such as in small diameter aortas, difficult aortic arches, poor sealing zones, and in high-risk patients, virtually assures increased complication rates when compared with the earlier clinical trials.

All of the patients in this series who experienced endoprosthesis collapse were treated outside Gore's IFU for a minimum required aortic diameter of 23 mm. No collapse occurred in patients treated with aortic diameters of ≥23 mm. Clearly, the physicians choosing to deploy the thoracic endografts outside the IFU did so knowing that these patients were severely injured and unfit for open surgical repair. The main issue is that the grafts used were severely oversized because they are indicated for aneurysm patients. If smaller stent grafts had been available, they would have been used.

In our experience and in the experiences described in the literature, most collapses have occurred in patients treated for traumatic aortic trauma or dissection and not in patients with atherosclerotic aneurysms. Although traumatic aortic trauma and thoracic dissection are certainly different disease entities, we believe that they share some anatomic factors that may predispose to acute collapse. Specifically, they are often located in smaller, younger aortas and often extend high into the aortic arch. Collapses occurred when the stent grafts were placed high in the aorta, which always included the distal portion of relatively steeply angulated arches common in young patients, most commonly involved in trauma. Anecdotally, this complication rarely occurs in the longer and wider aortas associated with aneurysmal disease.

These two populations of traumatic aortic injury and dissection vs atherosclerotic aneurysmal disease represent two different populations with dissimilar operative indications and postoperative complications. It is very difficult to follow IFU sizing criteria in most dissection patients, where there is often an acute taper or narrowing of the true lumen.

Based on this potentially devastating complication, many surgeons are reluctant to use the TAG device in any trauma or dissection case. Although this report assesses anatomic factors that may predict collapse, the unique packaging and release mechanism of the TAG device may worsen the problem of infolding. The device is packaged in a furled configuration with inbuilt infolding. Thus, a small aorta prevents it from unfolding completely.

Although distal aortic diameter and minimum intragraft aortic diameter predicted collapse, other variables may have influenced this complication but were not significant in this series owing to potential type II statistical errors related to small sample size. Thoracic endograft collapse is an exceedingly rare event, making it difficult to collect imaging on large patient numbers. However, others have suggested—and it seems intuitive—that factors such as poor apposition of the endograft to the aortic wall, acute aortic arch angulation, and potentially other anatomic factors may play a causative role in endoprosthesis collapse. Nevertheless, we believe that caution should be exercised when these anatomic factors are present.

Dynamic cine CT angiography scanning illustrates the very dynamic interface between blood flow in the lumen and the inner curvature of the graft (Video clip, online only). In this, one observes a TAG in the arch with a significant lip protruding into the aortic lumen. Infolding seems a logical result. Anecdotally, especially in the United States, physicians have implanted aortic extender cuffs to treat traumatic aortic ruptures. These cuffs are very short (3 to 4 cm long), and no infolding has been reported as far as we know. This should not be viewed as an endorsement of this off-label use, however, because there are numerous inherent flaws in using such short, stacked cuffs.

Only within the last 10 years have thoracic endografts been introduced into wide scale clinical practice.[17,18] Significant design modifications have already taken place, and it seems likely that further modifications will continue in an effort to minimize complications and improve clinical outcomes. Although this report was not designed to determine the ideal design of future endografts, we can speculate that future designs incorporating increased radial force, better attachment systems, increased flexibility, preformed stent graft curves, and noncircular stent grafts will be forthcoming.

CONCLUSION

Thoracic endograft collapse is an exceedingly rare event. All of the patients in this series who experienced endoprosthesis collapse were treated outside the manufacturer's IFU for minimum required aortic diameter.

Although distal aortic diameter and minimum intragraft aortic diameter predicted collapse, other variables may also influence this complication but were not significant owing to potential type II statistical errors related to small sample size. In the future, caution should be exercised when contemplating TEVAR with small (<23 mm) aortic diameters when using the current design TAG endoprosthesis. (Table 2).

AUTHOR CONTRIBUTIONS

Conception and design: BM, HV
Analysis and interpretation: BM, HV, RM, GW
Data collection: BM, HV, RM, GW
Writing the article: BM, HV
Critical revision of the article: BM, HV, RM, GW
Final approval of the article: BM, HV, RM, GW
Statistical analysis: BM, HV
Obtained funding: BM
Overall responsibility: BM

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Submitted Oct 7, 2006; accepted Dec 11, 2006.

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