CLINICAL RESEARCH STUDIES

From the Society for Vascular Surgery

Multicenter clinical trial of the conformable stent graft for the treatment of acute, complicated type B dissection

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Objective: **The treatment of acute, complicated type B aortic dissection has evolved in the past several decades. Thoracic endovascular aortic repair when anatomy is suitable, has been regarded as the preferable treatment to seal the primary entry tear, redirect and re-establish adequate true lumen flow, and thereby promote aortic remodeling. This study was designed to determine the safety and efficacy of a conformable thoracic endoprosthesis device for patients with acute, complicated type B aortic dissection, defined as malperfusion or rupture or both.**
Methods: **Between January 2010 and January 2012, 50 patients with complicated type B aortic dissection from 26 sites in the United States were included in this prospective, multicenter, nonrandomized single-arm study. The primary safety end point was all-cause mortality through 30 days after treatment, and the primary efficacy end point was exclusion of the primary entry tear (Core Laboratory adjudicated) at 1-month follow-up. Secondary end points included false lumen thrombosis, dissection-based reintervention rate, and aortic rupture.**
Results: **All device implants were successfully completed. Six patients (12%) required additional device implantations ≤1 year from the index procedure. There was no conversion to open repair at 1 year. Exclusion of the primary entry tear at 30 days occurred in 97.5% of patients. All-cause mortality through 30 days was 8%. Survival was 88% at 1 year and 85% at 2 years. At 1 year after treatment, 35.1% of patients had experienced a decrease of ≥5 mm in overall diameter in the treated segment of the aorta. From pretreatment to the 36-month follow-up, the average minimum true lumen area increased by 206.3 mm^2, and the average maximum false lumen area decreased by 313.4 mm^2. The 30-day stroke rate was 18%; none were fatal, and one permanent deficit occurred. Four patients (8%) experienced spinal cord ischemia of any severity but without any permanent or significant deficits. New aortic dissection (3 retrograde, 2 de novo) occurred in five patients (10%). The secondary intervention rate was 18%.**
Conclusions: **Treatment with the conformable thoracic endovascular aortic repair device produced favorable perioperative and intermediate level clinical and anatomic outcomes. In particular, an operative mortality of 8% in this cohort is comparable to that noted in a Society for Vascular Surgery objective performance criteria publication. Late survival in our cohort compares favorably with historical data referable to complicated type B dissection. (J Vasc Surg 2015;62:271-8.)**

Stent graft repair (thoracic endovascular aortic repair [TEVAR]) for acute type B dissection was first described by Dake et al[1] and Nienaber et al[2] in 1999 in companion publications. In the ensuing 15 years, consensus on the application of TEVAR for the various clinical scenarios in which type B dissection can present is as yet evolving.

The important contribution of malperfusion syndromes in the overall mortality of complicated type B dissection was originally described in 1988, an observation subsequently echoed by others, including the International Registry of Acute Aortic Dissection investigators, who also defined outcomes between those who sustained

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complicated vs uncomplicated type B dissections (overall 30% vs 10% mortality, respectively).[3-5] Among the treatment modalities applied to complicated type B dissection during the past several decades, and supported in part by trial data[6,7] and collective reviews,[8] the application of TEVAR to seal the primary entry tear, thus preventing rupture, and to redirect and re-establish adequate true lumen flow, thereby treating dynamic aortic branch obstruction, has emerged as the preferred treatment modality. The availability of TEVAR, albeit applied until recently as an off-label treatment, has clearly produced better results than procedures such as open surgical or endovascular fenestration.[8,9] Furthermore, available data referable to aortic remodeling after TEVAR for a type B aortic dissection strongly suggest that such treatment will also forestall the principle late complications of the disease, namely, aneurysm formation.[10,11]

Recognizing the importance of pathology specific devices, the sponsor for this study re-engineered the original GORE TAG (W. L. Gore and Associates, Flagstaff, Ariz) thoracic endovascular graft to a new design that was a more conformable prosthesis with a much-improved graft-to-aortic diameter ratio profile. The current study investigated the use of this redesigned prosthesis in the management of acute, complicated type B dissection defined in this report as patients with rupture or significant malperfusion syndromes, or both.

METHODS

Study design. The GORE TAG 08-01 study was a prospective, multicenter, nonrandomized, single-arm study of 50 patients from 26 investigative sites in the United States treated between January 2010 and January 2012. Study sites were required to have site-specific Investigational Review Board review and approval, and all participating sites were so approved.

The primary safety end point was all-cause mortality through 30 days after treatment. The primary efficacy end point was exclusion of the primary entry tear at the 1-month follow-up visit as determined by Core Laboratory analysis. Secondary efficacy end points included false lumen thrombosis adjacent to the stent graft (no thrombosis, incomplete thrombosis, or complete thrombosis), reintervention rate, and aortic rupture. Secondary interventions of all types were recorded. A Clinical Events Committee adjudicated clinical events. Other outcomes analyzed included stroke, further aortic dissection events, and spinal cord ischemic complications. Five-year study follow-up is ongoing.

Patient eligibility. Patients aged between 18 and 80 years determined to have an acute, complicated type B aortic dissection were included in the study. Inclusion criteria included symptom onset to dissection diagnosis of ≤14 days with TEVAR treatment ≤48 hours of diagnosis, clinical or radiologic evidence, or both, of malperfusion (visceral, renal, lower extremity, or spinal cord), rupture in the setting of an aortic dissection (hemorrhage outside of aortic boundaries), dissection distal to the left subclavian artery, treatment indication of "classic" aortic dissection (aortic dissection with an intimal flap between the true and false lumen with double-barrel flow in the thoracic aorta and excluding class 2-5 lesions such as intramural hematoma), and primary treatment as an endovascular treatment with the Conformable GORE TAG device. Adjunctive treatments may have included any or all of left subclavian artery revascularization, percutaneous fenestration, aortic or peripheral vessel stenting, surgical fenestration, or peripheral artery bypass. Important primary landing zone characteristics were mandated by protocol: free of dissection, a length of ≥2.0 cm from the left common carotid artery to the primary entry tear, and diameters appropriate to the conformable thoracic endoprosthesis device. If necessary, left subclavian artery coverage could be performed.

Additional exclusion criteria included a prior repair of the descending thoracic aorta, an infected aorta, or a severe systemic infection. Also excluded were patients with persistent refractory shock or bowel necrosis, as characterized by direct or laboratory observations concurrent with computed tomography (CT) findings of portal venous gas, free intra-abdominal air, or pneumatosis intestinalis. Patients exhibiting moderate to severe renal failure, as defined by a baseline creatinine level of ≥2.5 mg/dL, or with tortuous or stenotic iliac or femoral arteries precluding TEVAR were potentially excluded, but all such clinical decisions were at the investigator's discretion. Pregnant women and individuals with syndromic conditions (eg, Marfan) were also excluded. Procedural exclusions included planned coverage of the left carotid or celiac arteries with the TEVAR device or a planned endovascular procedure involving alterations to the study device.

To evaluate patient eligibility, a protocol-defined helical CT angiography scan, physical examination, and serum creatinine level was required preoperatively for each individual.

Device description and implantation procedure. The Conformable GORE TAG thoracic endoprosthesis consists of a flexible, self-expanding endoprosthesis and a delivery catheter. The endoprosthesis is constrained on the leading end of the delivery catheter by a sewn deployment sleeve. An expanded polytetrafluoroethylene sealing cuff is attached over the stent at each end of the device. The device is introduced through a specific introducer sheath. Other technical aspects of the delivery system and deployment mechanism are available online (http://www.goremedical.com/tag/instructions/).

Patient follow-up. Follow-up visits occurred at 1, 6, and 12 months after the initial procedure and annually thereafter through 5 years. Each follow-up visit included a physical examination, four-view chest X-ray imaging, a helical CT angiography of the chest, abdomen, and pelvis, and an assessment for adverse clinical and device-related events.

Data analysis. The current study is of a Bayesian adaptive design. The sample size of the study was not prespecified but rather was determined by primary end point

(30-day mortality) results. Enrollment was judged to be complete when the posterior probability of using the existing sample size was sufficient to meet the performance goal (30-day mortality of 25%) as specified from literature and Society of Vascular Surgery (SVS) master file sources.[12]

Statistical analyses were performed using SAS 9.2 software (SAS Institute Inc, Cary, NC). All-cause mortality was investigated by Kaplan-Meier analysis. Kaplan-Meier analyses for true and false lumen remodeling contain bars indicating the 25th and 75th percentiles and lines to connect median values. Unless otherwise noted, confidence intervals (CIs) exist as score intervals for categoric variables and Wald intervals for continuous variables.

RESULTS

Twenty-six centers enrolled 50 patients between January 2010 and January 2012 after 170 patients were screened for eligibility. Of 120 screen failures, 80% were related to anatomic or comorbidity considerations.

Periprocedural patient characteristics. The patient population was 74% male, 56% Caucasian, and the mean age was 57.1 years (range, 31-83 years). Table I outlines other clinical features of the study cohort.

The median time from symptom onset to diagnosis was 0.4 days (range, 0.0-7.3 days), with 98% of patients appropriately diagnosed ≤1 week of symptom onset. Table II outlines the known distal extent of the dissection as assessed by the Core Laboratory. Note that the distal extent of the dissection was the iliacs in 30 of 50 patients (60%). All patients were treated for malperfusion or rupture or both. Indications for treatment are reported in Table III, with the largest treatment group being malperfusion alone in 78%. The incidence of specific forms of malperfusion is further detailed in Table III (multiple vascular territories were involved in most patients).

All patients received general anesthesia for the procedure. All device implants were successfully completed, with intravascular ultrasound imaging used in 58%. The proximal aortic diameter was a median of 31 mm (range, 24-42 mm). The mean degree of oversizing was 12.5%. Mean treatment length of the descending aorta was 20.6 cm (range, 10-33 cm), with proximal fixation sites ≤2.0 cm (proximal or distal) of the left subclavian artery in all patients. Left subclavian artery management is detailed in Table IV. At the time of the initial treatment, 26 of 50 patients (52%) required additional procedures, which included peripheral branch or aortic stenting in 28 (56%), surgical bypass in 4 (8%), endovascular fenestration in 2 (4%), and adjunctive angioplasty in 5 (10%).

Additional device implants occurred in 12% (6 of 50) of patients (Table V). Two implants occurred ≤30 days of the original procedure, four implants occurred within the first year, and one implant occurred >1 year on postoperative day 861 (Table V). Two separate implant procedures were performed in one patient after the initial treatment; one on postoperative day 49 for flow in the false lumen and the other on postoperative day 84 for worsening intermittent chest pain.

Table I. Baseline clinical features of study cohort

Variables	*No. (%) (N = 50)*
Medical history	
Hypertension	47 (94)
Cigarette smoking	27 (54)
Hypercholesterolemia	16 (32)
Renal insufficiency	11 (22)
Chronic obstructive pulmonary disease	10 (20)
Cardiac arrhythmia	10 (20)
Diabetes mellitus	9 (18)
Coronary artery disease	7 (14)
Myocardial infarction	6 (12)
Cancer	5 (10)
Peripheral vascular disease	5 (10)
Stroke	5 (10)
Congestive heart failure	3 (6)
Coronary artery bypass graft	2 (4)
Cardiac surgery	2 (4)
Carotid disease	2 (4)
Prior aortic dissection	2 (4)
Abdominal aortic aneurysm	1 (2)
Paraplegia	1 (2)
Transient ischemic attack	1 (2)
Risk assessment	
ASA physical status classification	
1	2 (4)
2	2 (4)
3	20 (40)
4	26 (52)
5	0 (0)
NYHA functional classification	
I	11 (22)
II	6 (12)
III	1 (2)
IV	0 (0)
No cardiac disease	32 (64)

ASA, American Society of Anesthesiologists; *NYHA,* New York Heart Association.

Table II. Distal extent of dissection

Distal extent of dissection	*No. (%) (N = 50)*
Descending thoracic aorta	5 (10)
Celiac	4 (8)
Superior mesenteric artery	1 (2)
Renal arteries	5 (10)
Inferior mesenteric artery	5 (10)
Iliac arteries	30 (60)

Operative (30-day) mortality occurred in four patients (8%) and was related to a single case each of mesenteric infarction (present on transfer to treating study institution), retrograde dissection with intrapericardial rupture, persistent type 1A endoleak with rupture, and (autopsy-proven) massive pulmonary embolism on postoperative day 3. At least one serious adverse event occurred postprocedure in 28 of the 50 patients (56%), with more than one event reported in 17. Three adverse events of particular interest were stroke, new aortic dissection events, and paraplegia/paraparesis. Stroke or clinical suspicion thereof occurred in 18% (9 of 50) of patients ≤30 days of the initial

Table III. Indications for treatment

Indication	*No. (%) (N = 50)*
Malperfusion only	39 (78)
Rupture only	9 (18)
Malperfusion and rupture	2 (4)
Total malperfusion	41 (82)
Visceral	15 (36.6)[a]
Renal	30 (73.2)
Lower extremity	18 (43.9)[b]
Spinal cord	3 (7.3)

[a]10 patients with varying degrees of abdominal pain.
[b]7 patients reported ischemic rest pain.

Table IV. Left subclavian artery (*LSA*) coverage or revascularization (N = 50)

	LSA coverage, No. (%)		
LSA procedure	*None*	*Partial*	*Complete*
None	14 (28)	8 (16)	19 (38)
Transposed	0 (0)	0 (0)	2 (4)
Bypassed	0 (0)	1 (2)	6 (12)

treatment. These were adjudicated by the Clinical Events Committee, which included two neurologists who also assessed status at discharge and the effect of the stroke on functional outcome. Among the nine stroke patients, one death (not stroke related) occurred, complete recovery at last follow-up was noted in 75%, and ultimate functional outcome was not negatively affected in seven of eight surviving patients.

New aortic dissection events occurred in 10% (5 of 50) of patients and were retrograde dissection events from the stent graft itself or de novo type A dissections (Table VI). Spinal cord ischemia of any severity occurred in 8% (4 of 50) of patients without relation to left subclavian artery coverage. One patient had a persistent leg monoparesis at discharge, with full recovery ≤1 year. Three others had spinal cord ischemia (two early, one delayed) that resolved after prompt insertion of a cerebrospinal fluid (CSF) drain. Thus, there were no significant total paraplegia events, even though a CSF drain was placed preoperatively in only 11 patients (22%). Paraplegia developed in one patient after a subsequent surgical thoracoabdominal aortic aneurysm graft replacement 2 years after the index procedure.

The efficacy end point of exclusion of primary entry tear at 30 days occurred in 97.5% (39 of 40) of patients by Core Laboratory adjudication. The secondary efficacy end point of false lumen thrombosis adjacent to the stent graft is outlined in Table VII. At 1 and 2 years after treatment, complete false lumen thrombosis in the stented segment occurred in 75% of patients (Table VII). Aortic rupture occurred in 4% (2 of 50) of patients, with one on study day 0 and one on postoperative day 89. One was a rupture in the distal descending thoracic aorta and was unrelated to the TEVAR device or the endovascular procedure, and the other was a retrograde dissection rupture of the ascending aorta (Table VI).

Late clinical events. The mean follow-up interval for survival was 725 days (range, 0-1219 days). Fig 1 displays a Kaplan-Meier graph of overall survival at 12 and 24 months. Survival was 88% (95% CI, 0.75-0.94) at 1 year and 85% (95% CI, 0.71-0.93) at 2 years. Causes of late deaths are detailed in Table VIII.

Late anatomic results. The mean follow-up interval for anatomic remodeling was 647 days (range, 0-1217 days). Change in overall aortic diameter in the treated segment of the aorta was recorded. At 12 months, 54.1% (20 of 37) of patients experienced no change, 35.1% (13 of 37) experienced a decrease of ≥5 mm, and 10.8% (4 of 37) experienced an increase of ≥5 mm. At 24 months, 50% (13 of 26) of patients experienced no change, 38.25% (10 of 26) experienced a decrease of ≥5 mm, and 11.5% (3 of 26) experienced an increase ≥5 mm. Maximum and minimum true and false lumen aortic remodeling up to 36 months is displayed in Fig 2 (diameters) and Fig 3 (areas). The average minimum true lumen area increased by 206.3 mm^2, and the average maximum false lumen area decreased by 313.4 mm^2 from pretreatment to 36 months.

Secondary interventions. At 1 year, there had not been a conversion to open repair in the stented segment for any patient. The secondary intervention rate was 18%, with most of the secondary interventions occurring within the first 30 days. As outlined in Table IX, nine patients underwent 13 procedures after the initial implantation of the Conformable GORE TAG device.

DISCUSSION

This prospective, multicenter, nonrandomized, single-arm study investigated the safety and efficacy of the Conformable GORE TAG device in treating patients with acute, complicated, type B aortic dissection. The primary end points of the study demonstrated an all-cause mortality of 8% and an exclusion of the primary entry tear in 97.5% of patients through 30 days. Long-term survival was 88% at 1 year and 85% at 2 years. The primary safety and efficacy results reported are similar or better than those reported by White et al[12] in an SVS objective performance criteria report of identical patients managed with TEVAR. Furthermore, the overall results, in particular the early mortality, represent a major improvement in a patient cohort where earlier reports detailed an initial 30% mortality.[3,5]

All patients in the current study were treated for malperfusion or acute rupture, or both. Studies with less stringent inclusion criteria (eg, persistent pain, poor blood pressure control) have detailed lower 30-day mortality than reported here, with rates as low as 4%.[7,8] Notable is the fact that this study detailed patients quite similar to 98 patients treated under five separate physician-sponsored investigational device exemption trials, and published by the SVS Outcomes Committee.[12] Another trial similar to the current study investigating a different TEVAR device but also restricted to acute, complicated type B dissection

Table V. Additional device implants in six patients

Postoperative day	*Device used/technique*	*Reason for intervention*
2	CTAG device/standard	Open distal fenestration resulting in persistent flow in false lumen
238	CTAG device/standard	Type II endoleak, type 1A endoleak, enlarging false lumen
861	Abdominal stent graft	Enlarging distal thoracic aorta due to persistent false lumen flow
0	TAG device/chimney	Retrograde dissection
49[a]	CTAG device/standard	Flow in false lumen
84[a]	Abdominal stent graft	Worsening intermittent chest pain
156	TAG device/abdominal debranching	Expanding descending thoracic aortic aneurysm requiring repair

CTAG, Conformable GORE TAG (W. L. Gore and Associates, Flagstaff, Ariz).
[a]Same patient.

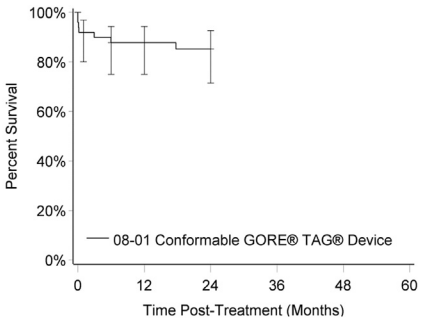
Table VI. Proximal aortic dissection events

Days postprocedure	*Event description*	*Potential mechanism as determined by CEC*
0	Retrograde dissection	Iatrogenic at index procedure[a]
6	Retrograde ascending aortic dissection	Procedural/device related
29	Retrograde type A aortic dissection	Presumed device related
89	Rupture new type A dissection	De novo type A
183	Pseudoaneurysm of ascending aorta related to de novo type A tear 1 cm above sinotubular junction (diameter, 8-9 cm)	De novo type A

CEC, Clinical Events Committee.
[a]Related to device delivery; a retrospective review of the intraprocedural angiogram indicated retrograde dissection was present before device deployment.

Table VII. Incidence of false lumen thrombosis adjacent to the stent graft

Time after procedure	*No. (%)*
1 month	41
Complete thrombosis	26 (63.4)
Partial thrombosis	13 (31.7)
No thrombosis	0 (0)
Unknown	2 (4.9)
12 months	38
Complete thrombosis	29 (76.3)
Partial thrombosis	6 (15.8)
No thrombosis	1 (2.6)
Unknown	2 (5.3)
24 months	36
Complete thrombosis	20 (74.1)
Partial thrombosis	6 (22.2)
No thrombosis	0 (0)
Unknown	1 (3.7)



Time Post-Treatment (Months)	Number of Subjects at Risk
0	50
1	45
6	42
12	38
24	28

Fig 1. Survival at 12 and 24 months. The *range bars* show 95% confidence interval (CI).

patients detailed outcomes strikingly similar to those reported here.[13]

Despite the manifest improvement in overall results with TEVAR for complicated type B dissection (compared with open surgery or medical therapy), these critically ill patients are prone to significant procedure-related complications, and among these, neurologic complications (stroke and spinal cord injury) and retrograde aortic dissection figure prominently. It is intuitively logical that such complications would occur more frequently in the treatment of complicated type B dissection (vs other pathologies) related to aortic fragility, zone 2 proximal seal, and long-segment descending thoracic aorta coverage, which is typically required, at least in cases of rupture. Furthermore, a consensus has emerged that both of these complications are significantly diminished when TEVAR is performed in the subacute (ie, 15-90 days) phase of the disease.[7,11,12,14] However, a delayed therapy approach was not available to the present study cohort.

In consideration of specific complications, our overall 18% stroke rate is at the upper limit of the range of stroke reported in related studies.[7,12,13] Not surprisingly, studies detailing nonacute patients reported significantly lower stroke risk.[8,11,14] Potentially confounding variables, such as left subclavian artery coverage (despite the lack of any

Table VIII. Causes of late deaths

Days postprocedure	*Cause of death*
89	Rupture of de novo type A dissection
182	Acute myocardial infarction
539	Cardiopulmonary arrest with chronic obstructive pulmonary disease as a contributing factor
1055	Renal cell carcinoma

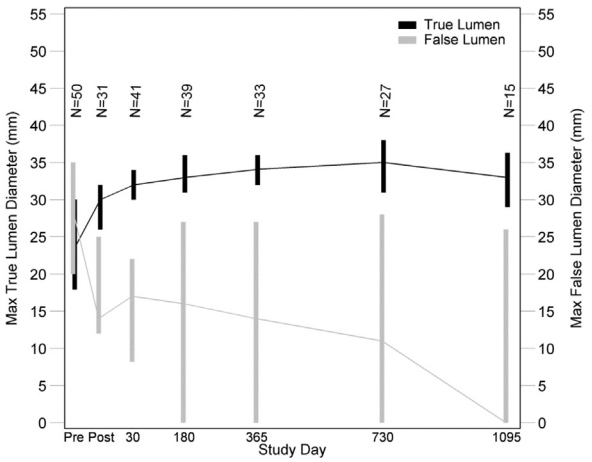


Fig 2. Maximum (diameter) of true and false lumen remodeling through 36 months after treatment. The *range bars* show the 95% confidence interval (CI).

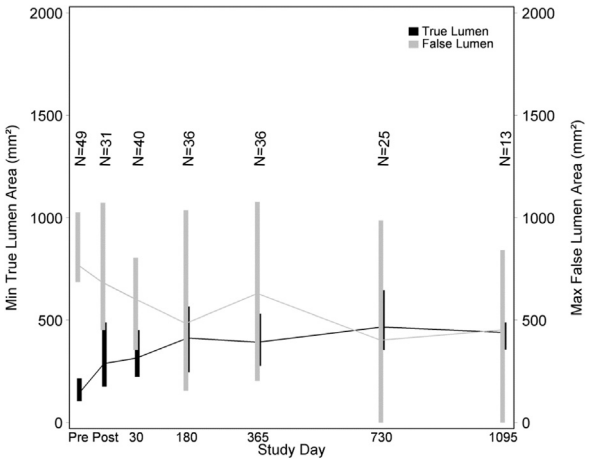


Fig 3. Minimum (area) of true and false lumen remodeling through 36 months after treatment. The *range bars* show the 95% confidence interval (CI).

statistical correlation in this study), perioperative hypoxia/brain hemorrhage, and an atypical atherosclerotic arch (present in one of our patients), clearly increased the stroke risk in our patients. Fortunately, only two patients had permanent negative functional effect related to stroke. Procedure-related retrograde aortic dissection or de novo type A dissection, or both, during follow-up occurred in 10% of our patients, similar to other studies in comparable patients.[12,13] It is clear that this complication can occur with any TEVAR construct and that patients being treated for acute dissection are at significantly higher risk compared with other pathologies.[15] Anatomic considerations of the proximal seal zone, specifically, an adequate nondissected aorta is an important consideration in avoiding this complication, which accounted for one death in the present study. Spinal cord ischemic complications were infrequent in this study despite a mean descending aorta coverage length of 20 cm and infrequent use of prophylactic CSF drainage.

Despite the predominant thought that TEVAR is preferred for complicated type B dissection, the literature base supporting this position contains but two randomized trials, and these trials considered patients without immediate life-threatening dissection complications. The first of these, the Investigation of Stent Grafts in Aortic Dissection (INSTEAD) trial, by its design essentially excluded patients with acute, complicated type B dissection, and because its primary end point was all-cause mortality at 1 year after treatment, it failed to show an advantage for stent graft repair over optimal medical therapy.[11] Ironically, a recent publication from the INSTEAD investigators indicated superior late survival for TEVAR vs medically treated patients who had undergone treatment for essentially uncomplicated type B dissection.[16] The recently published Acute Dissection Stent Grafting or Best Medical Treatment (ADSORB) trial, which had anatomically defined end points, demonstrated that favorable aortic remodeling is facilitated by TEVAR compared with optimal medical therapy.[17]

The current study revealed favorable midterm outcomes after TEVAR and superior late survival in patients with complicated type B aortic dissection treated with TEVAR compared with historical results seen with optimum medical therapy alone.[13,14,18,19] Late survival in the current study was similar to an International Registry of Acute Aortic Dissection study, with an all-cause survival rate of 88% at 1 year and 85% at 2 years.[14] In the study of White et al,[12] survival was 70.6% at 1 year. These findings are consistent with other studies that have shown superior long-term survival in TEVAR-treated patients vs medically treated patients.[14,16,18] Although the option of initial medical therapy was illogical in the patients in this study, it is also well documented that aortic-related mortality is a continued threat after type B aortic dissection, even when the initial course is without complications and medical therapy is typically selected. Indeed, initial medical treatment for acute type B aortic dissection will eventually fail in nearly 60% of patients so treated at a mean follow-up of 4.3 years.[20]

The appropriate consideration for causes of late mortality has been (albeit indirectly) addressed in both a recently reported study[19] and in that of the INSTEAD investigations.[16] Namely, Durham et al[20] found that the preponderance of late interventions when type B dissection is treated with medical therapy are open aneurysm resections. Similarly, the

Table IX. Secondary interventions

Patient	*Days postprocedure*	*Reason for intervention*	*Type of intervention*
1	2	Persistent flow in false lumen resulting from large fenestration distal to original device	Placement of additional TAG device
1	3	Persistent hemothorax	Decortication procedure
2	1	Renal failure	Fenestration of the septum dividing the two aortic channels
	1	Anuria	Endarterectomy of both renal arteries
3	4	Stenosis in iliac artery	Peripheral stenting
4	2	Intestinal infarction	Resection of right colon
5	0	Compartment syndrome	Fasciotomy of left lower extremity
	2	Exploratory laparotomy with total abdominal colectomy	
	4	Excision of small bowel and abdominal cavity washout	
6	6	Retrograde ascending aortic dissection	Ascending aortic replacement
7	183	De novo type A tear 1 cm above sinotubular junction (diameter 8-9 cm)	Ascending aortic replacement
8	676	Aneurysm development distal to thoracic endovascular aortic repair	Open thoracoabdominal repair
9	861	Patent fenestrations contributing to false lumen growth distal to previously placed CTAG	Abdominal stent graft cuff and iliac stent graft limb

CTAG, Conformable GORE TAG (W. L. Gore and Associates, Flagstaff, Ariz).

INSTEAD study detailed the important contribution of aortic-related mortality over time in medically treated type B dissection, reporting an aorta-specific mortality of 6.9% for TEVAR with optimal medical treatment vs 19.3% for optimal medical treatment alone at 5 years.[16]

Although the present study focused on the treatment of life-threatening, complicated acute type B dissection, our secondary findings indicate that TEVAR for type B dissection will have a positive effect on aortic remodeling and ultimately reduce the risk for late aneurysm formation. Conrad et al[10] reviewed the 1-year aortic remodeling after TEVAR for acute type B dissection and found that >90% of patients had false lumen thrombosis across the stented segment with no aneurysmal degeneration. Similar results were seen in the INSTEAD trial, where 90% of patients treated with TEVAR had at least partial false lumen thrombosis at 1 year, which was significantly higher than the 19% reported in the medically treated cohort.[11]

This early false lumen thrombosis likely contributes to long-term stabilization of the aorta, because 79% of patients in the TEVAR arm of the INSTEAD trial showed favorable remodeling at 5 years.[16] The current study shows a similar early aortic response to TEVAR, where all but one patient had some degree of false lumen thrombosis at 1 year and only two patients (4%) required further intervention for aortic growth in the unstented portion of the descending thoracic aorta at 2 and 4 years after the initial TEVAR procedure.

In the Study of Thoracic Aortic type B Dissection using Endoluminal Repair (STABLE) trial, complete obliteration of the false lumen occurred in 44% of patients at 2 years, with some degree of thrombosis documented in all patients. Expansion of the true lumen and stabilization of the aorta was noted in most patients, because 74% had a total aortic diameter that decreased or stayed the same over the same time frame.[21] In the current study, the maximum true lumen diameter increased initially and stayed relatively stable over 36 months, with 90% of patients having a stable aortic diameter at 2 years; however, the data reported here are confined to the stented aortic segment.

CONCLUSIONS

The present study corroborates a consensus that TEVAR is the preferred treatment for acute, complicated type B aortic dissection with improved late survival and positive aortic remodeling. Yet, with the recent, more broadly based United States Food and Drug Administration approval of TEVAR devices (for type B dissection), the task of defining the role of such therapy in so-called uncomplicated acute type B aortic dissection patients, and for those patients with a dissection in the chronic phase of the disease, is the next logical step. As a corollary of the recent approval, the Food and Drug Administration, industry, and the SVS Vascular Quality Initiative have partnered to study the real-world use of TEVAR for type B aortic dissection.

AUTHOR CONTRIBUTIONS

Conception and design: RC, AP, JM
Analysis and interpretation: RC, MC, AM, MF, AP, SC, VP, JM
Data collection: AM, MF
Writing the article: RC, MC, SC, JM
Critical revision of the article: RC, MC, AM, MF, AP, SC, VP, JM
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