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Background—In this study, we report the late outcomes of a large, decade-long single-center thoracic endovascular aortic repair experience.

Methods and Results—A prospectively maintained registry and the electronic medical records of 400 consecutive thoracic endovascular aortic repair performed at a tertiary care center were reviewed. The distribution of pathologies treated included aneurysms (198, 49%), dissections (100, 25%), penetrating ulcers (54, 14%), traumatic transections (25, 6%), and other pathologies (23, 6%). Spinal drains were placed prophylactically in 127 cases (32%) of planned extended aortic coverage. There were no acute surgical conversions. Adjunctive surgical procedures were performed on 94 patients (24%). Subclavian revascularizations were performed selectively in only 15% of zone 0 to 2 deployments. The median length of stay was 5 days (limits, 1 and 79 days). Overall 30-day mortality was 6.5% (elective, 2.6%; urgent, 9.5%; and emergent, 20%). Permanent spinal cord ischemia occurred in 4.5% and stroke in 3%. Kaplan-Meier estimates of survival were 82%, 76%, 68%, and 60% and freedom from secondary intervention was 90%, 86%, 81%, and 78% at 6, 12, 24, and 36 months, respectively. Risk factors for mortality included stroke, urgent/emergent repair, age ≥80 years, general anesthesia, and dissection pathology.

Conclusions—Thoracic endovascular aortic repair may be used to treat a variety of thoracic aortic pathologies with a very low risk of intraoperative conversion. Overall rates of mortality and neurological complications were relatively low but significantly increased in emergent repairs. There appeared to be a substantial number of late deaths, which may represent a combination of poor patient selection and treatment failures. **(*Circulation*. 2011;123:2938-2945.)**

Key Words: aneurysm ■ aorta ■ endovascular ■ morbidity ■ mortality ■ stents ■ thoracic

Operative repair of thoracic aortic pathologies is accompanied by significant morbidity and mortality. Thoracic endovascular aortic repair (TEVAR) has become a minimally invasive alternative to open repair in anatomically suitable patients. Although the therapy remains indicated primarily for and its safety and efficacy have been established for the treatment of degenerative thoracic aortic aneurysms and penetrating ulcers, other off-label pathologies, such as traumatic aortic transections and acute and chronic dissections, have been treated successfully after commercial availability of thoracic endografts and increasing collective experience of endovascular operators.

Clinical Perspective on p 2945

Thoracic aortic aneurysms are relatively uncommon, with an estimated incidence of 6 per 100 000 person-years, but if left untreated, patients are more likely to die of complications from their aneurysm than any other cause. Indeed, survival in patients with untreated thoracic aneurysms is relatively poor, with 1-, 3-, and 5-year survivals of 65%, 36%, and 20%, respectively.[1] More specifically, the so-called hinge point for descending thoracic aneurysms occurred at 7.0 cm, with a 43% risk of acute dissections or ruptures, which led to a recommendation for elective repair at 6.0 cm.[2] Elective open thoracic aortic repairs carry a risk of mortality ranging from 3% to 9%, whereas emergent repairs continue to suffer from an even higher mortality ranging from 16% to 59%.[1,3,4]

Early outcomes from TEVAR have been promising, but to date most published reports involve limited numbers of patients and are restricted to perioperative outcomes with relatively short-term follow-up. In this study, we examined the early and late outcomes of a decade-long, real-world, single-institution experience with endovascular repair of thoracic aortic pathologies.

Methods

A prospectively maintained registry of all TEVARs performed at a tertiary care academic medical center was retrospectively examined to identify the first 400 consecutive cases. All of these cases were

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performed between September 2000 and April 2009. Case numbers increased dramatically after a thoracic endograft became commercially available in 2005, and 91% of cases were performed in the second half of the study period. The database and the electronic medical records were reviewed for patient demographics, adjunctive procedures, intraoperative procedural measures, and postoperative outcomes, including secondary procedures. The online Social Security Death Index (http://ssdi.rootsweb.ancestry.com/) was also queried to determine any late deaths of patients who have been lost to follow-up. Routine preoperative imaging consisted of a head/neck/chest/abdomen/pelvic computed tomography (CT) angiogram using a 64-, 128-, or 320-slice multidetector array scanner (Aquilion, Toshiba America, New York, NY). The data set was postprocessed with 3-dimensional reconstructions (centerline orthogonal multiplanar reformats) for case planning and device sizing (Aquarius, TeraRecon, San Mateo, CA). Magnetic resonance angiography or contrast angiography was seldom used. Intravascular ultrasound (Galaxy, Boston Scientific, Natick, MA) was used only during repair of aortic dissections to confirm preoperative imaging and true-lumen guidewire passage. Each case was performed by a core team of cardiac and vascular surgeons who evaluated the indications and therapeutic options and planned the conduct of the endovascular procedures together.

Preoperative left subclavian revascularization, with either a transposition or bypass, was performed selectively for a dominant left vertebral artery or a patent left internal mammary artery to coronary artery bypass when zone 2 deployment was planned. Other less common indications have included left-handedness, aberrant arch origin of the left vertebral artery, functional left arm arteriovenous shunt for hemodialysis, and rare cases of a left axillary–femoral bypass for iliac occlusive disease. Adjunctive procedures such as arch and/or visceral vessel debranching were performed as necessitated by each patient's anatomy.

Indications for prophylactic spinal drainage evolved over the decade studied. In the first half of the experience, spinal drainage was generally performed for postoperative symptoms of spinal cord ischemia (SCI). In the latter half of the series, spinal drains were placed preoperatively if there was planned coverage of >150 mm of the thoracic aorta or if coverage extended to within 5 cm of the celiac artery.[5] For emergent cases, or in the setting of other physiological or anatomic conditions that precluded safe placement of a spinal drain, TEVAR was performed and a drain was placed postoperatively if the patient subsequently developed symptoms.

Management of SCI involved blood pressure elevation and spinal drainage. Blood pressure was augmented with intravenous fluid infusion and vasopressor support to achieve a target of either 160 mm Hg systolic or 100 mm Hg mean blood pressure. Spinal drainage was initiated by placing the drain 10 cm above the level of the right atrium. Spinal pressure was not actively monitored; rather, with the use of a passive drainage system (EDS 3 CSF External Drainage System, Codman, Raynham, MA), the level of the drain provided a popoff valve if the intrathecal pressure exceeded the hydrostatic column of pressure. This level was adjusted either higher or lower, depending on the symptomatic response and amount of drainage. As long as symptoms improved or the patient remained asymptomatic, there was no minimum target for rate or volume of drainage. Conversely, if the patient was not responding, the drain was lowered to 5 or even 0 cm to increase the rate of drainage. Drainage was strictly monitored and maintained to <15 mL/h or <350 mL/d to avoid potential complications of subdural hemorrhage.[6,7] Spinal drains placed prophylactically in asymptomatic patients were left open for 24 hours, clamped 12 hours, and removed. Drains placed either therapeutically or when symptoms developed with a prophylactic drain in place were kept open for 72 hours, clamped for 24 hours (if symptoms resolved), and then removed. Patients with SCI who did not initially respond to drainage were still drained for 72 hours, and the catheter was removed without a period of trial clamping. It has been our observation that if there is no clinical response within the first 24 hours, the likelihood of symptomatic recovery diminishes considerably. In general, spinal catheters were not left in for >5 days owing to the risk of infection, and if a longer period of drainage was required, a new catheter was placed through a new puncture site and the old catheter was removed.

Table 1. Endografts Used in the 400 Patients

Device	n	%
W.L. Gore TAG	258	64.5
Cook TX2	72	18.0
Medtronic Talent	22	5.5
Medtronic Valiant	17	4.3
Bolton Relay	17	4.3
Cook Zenith cuff*	12	3.0
Medtronic AneuRx cuff*	2	0.5

W.L. Gore, Flagstaff, AZ; Cook, Bloomington, IN; Medtronic, Santa Rosa, CA; Bolton, Sunrise, FL.

*Medtronic AneuRx and Cook Zenith are abdominal aortic devices.

Although general anesthesia was routinely used early in the experience, regional techniques were used preferentially in the latter half of the series when circumstances permitted. If a spinal drainage catheter was placed preoperatively, this catheter was used to administer intermittent intrathecal anesthetic during the procedure (continuous spinal technique) and then opened for drainage during the postoperative period. General anesthesia was reserved for cases in which the patient was unable to cooperate during the procedure or when spinal anesthesia was contraindicated or ineffective.

Iliac conduits were performed with 10-mm Dacron grafts through standard pelvic retroperitoneal exposures based on the size and quality of the common femoral and external iliac arteries. At the conclusion of the procedure, the conduit was either oversewn or converted to an iliofemoral bypass, depending on the degree of occlusive disease, distal pulse examination, or predicted need for future intervention. Thoracic endovascular aortic repairs were performed with a variety of devices from different manufacturers (Table 1), and a large inventory of endografts was maintained that allowed emergent and urgent treatment of acute aortic conditions. Balloon molding was performed per the manufacturer's instructions for use and as needed with one of the commercially available compliant aortic balloons (Tri-Lobe, W.L. Gore, Flagstaff, AZ; Reliant, Medtronic, Santa Rosa, CA; Coda, Cook Medical, Bloomington, IN).

Routine postoperative surveillance included clinic visits and triple-phase contrast-enhanced chest/abdomen/pelvis CT angiogram at 1, 6, and 12 months and yearly thereafter. Predischarge CT scans were not typically performed except for acute aortic pathologies such as ruptured aneurysms and as long as there was no contraindication to contrast. Aneurysm diameter change was defined as ≥5 mm on centerline orthogonal multiplanar reconstructions compared with the first postoperative CT angiogram.

Continuous variables were compared between groups by use of the Student *t* test, and categorical variables were compared between groups by use of the Fisher exact test, with 2-sided values of $P<0.05$ considered statistically significant. Kaplan-Meier curves were computed for patient survival. Freedom from intervention was assessed using the cumulative incidence function with death as a competing risk.[8] Risk models and a risk scoring system were developed for all-cause late mortality.

Derivation of Risk Scores for Late Mortality

To identify potential risk factors for all-cause late mortality, individual proportional hazards regression models were fit for 31 postoperative variables (Table I in the online-only Data Supplement). Covariates that were significant from individual analysis ($P<0.05$) and those that were included in a multivariable model fit by either forward or backward selection (forward entry criterion, 0.05; back stay criterion, 0.10) were considered possible covariates. Given the number of late deaths (n=118), up to 14 risk factors were considered. The best model was chosen using the Akaike informa-

Table 2. Preexisting Comorbidities

Comorbidity	n	%
Hypertension	285	71
Smoking	169	42
Hyperlipidemia	137	34
Coronary disease	94	24
Pulmonary disease	81	20
Renal insufficiency	60	15
Diabetes mellitus	46	12
Carotid disease	39	10
Peripheral arterial disease	39	10
Arrhythmia	24	6
Congestive heart failure	21	5
Cardiomyopathy	6	2

tion criterion.[9] Because of the computational difficulty in examining all models with up to 14 covariates, the following strategy was used to choose the best model. First, the best model with up to 5 covariates was identified by use of the Akaike information criterion. Second, if the best model had 5 covariates, additional covariates were included until either the Akaike information criterion increased or any of the hazard ratios (or their inverse) fell below 1.5. To assess the predictive ability of the model, the c statistic was computed and adjusted for overfitting with a bootstrap approach.[10] In addition, we computed the percentage of times each variable in our final risk model was included in the best model on the basis of the bootstrap procedure; this provides additional information on the stability of the model. The overall bootstrap approach is an internal validation procedure. The risk score for each covariate was derived by multiplying the log hazard ratio by 2 and rounding to the nearest integer. For comparison, we also compared our final risk model to one chosen by a more standard forward selection procedure.

This study was approved by the Institutional Review Board.

Results

The mean age of the patients was 65±16 years (limits, 16 and 92 years); 276 (69%) were male. Preoperative comorbidities were notable for a high incidence of hypertensive smokers (Table 2). Sixty-five cases (16%) were performed emergently for ruptures, and 63 (16%) were performed urgently for symptomatic pathologies. The majority of the patients (69%) were in American Society of Anesthesiology class IV. Sixty-one percent of the cases were performed under general anesthesia, 38% with spinal anesthesia, and 3 cases (1%) were performed using local anesthesia only. Previous abdominal aortic replacement had been performed on 18% of patients.

Thoracic endovascular aortic repair was performed to treat a variety of thoracic aortic conditions. The distribution of pathologies treated included aneurysms (198, 49%), acute and chronic dissections (100, 25%), penetrating ulcers (54, 14%), traumatic transections (25, 6%), and other pathologies (23, 6%), which were mostly made up of anastomotic pseudoaneurysms, severe symptomatic aortic atheromatous disease (shaggy aorta), and aortobronchial/esophageal fistulas. Dissections represented the fastest-growing segment of aortic diseases being treated with TEVAR and made up 35% of the last 100 cases performed. The primary indications for treatment of acute type B dissections included malperfusion and rupture.[11] Uncomplicated acute dissections were managed medically. For chronic dissections, the main indication was for late aneurysmal dilation of the false lumen. The mean transverse diameter of the thoracic aorta treated in the entire series was 64±13 mm.

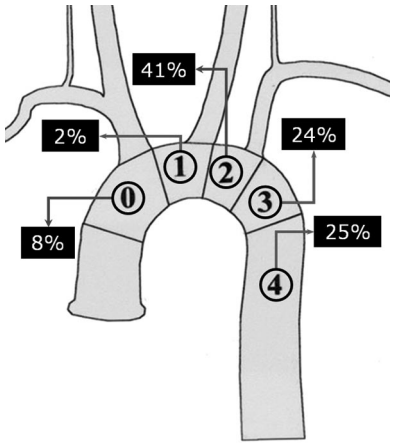

Figure 1. Distribution of proximal landing zones (Mitchell et al[12] classification).

Spinal drains were placed prophylactically in 136 patients (34%). Twenty-six patients who did not have a spinal drain placed preoperatively developed neurological symptoms requiring urgent placement of a drain. Attempts at placing a spinal drain were unsuccessful in only 3 patients in the entire series, and there were no major catheter-related complications. Three patients developed spinal headaches requiring a blood patch, and another developed a small epidural hematoma that did not require an intervention.

The mean number of endografts per case was 2.3±1.1, and 63% of cases were completed with only 1 or 2 devices. The mean fluoroscopy time was 24±15 minutes; contrast, 139±54 mL; estimated blood loss, 309±316 mL; and total procedure time, 116±5 minutes. Sixteen percent of patients required iliac conduits as a result of small and/or diseased access vessels. The distribution of proximal landing zones is shown in Figure 1.[12] There were no intraoperative surgical conversions.

Adjunctive procedures were performed either preoperatively or simultaneously with the index TEVAR to extend or create a suitable landing zone or to revascularize branch vessels that were intentionally or inadvertently occluded during the procedure. A total of 101 adjunctive procedures were performed in 94 patients (24%). The most commonly performed procedures included left carotid to subclavian revascularization (29, 7%), visceral debranching (23, 6%), arch debranching (22, 6%), and first-stage elephant trunk (20, 5%). A less common right carotid–subclavian bypass was performed in 2 patients with a Kommerell diverticulum arising from an aberrant right subclavian artery and a dominant right vertebral artery.

Left subclavian revascularization was typically performed with a carotid-subclavian bypass, but a subclavian-carotid transposition was also used in a few select cases. In this series, the proximal landing zone involved coverage of the left subclavian origin in 202 patients (51%) (Figure 1). Left subclavian revascularization was performed before the

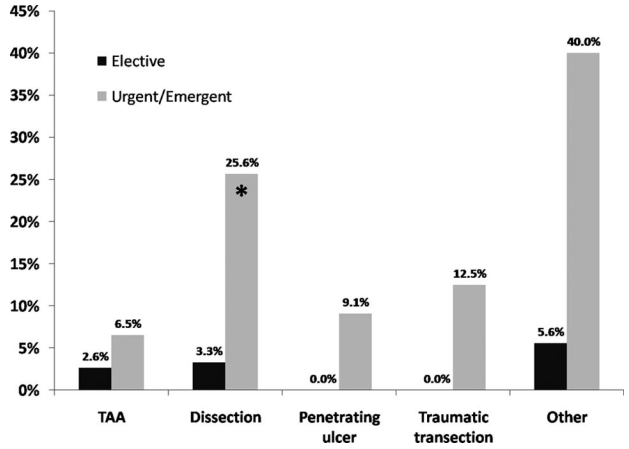

Figure 2. Pathology-specific mortality between elective and nonelective mortality. TAA indicates thoracic aortic aneurysm. *P=0.001.

TEVAR in only 15% of zone 0 to 2 deployments (29 left carotid–to-subclavian revascularizations and 2 aortic debranchings). Nine patients who did not undergo preemptive left subclavian revascularization became symptomatic, but only 5 of those 9 patients required a secondary procedure. Three patients developed significant left arm ischemia, and 1 had coronary ischemia after inadvertent occlusion of a patent left internal mammary artery coronary graft; all 4 underwent a carotid subclavian bypass. The fifth patient underwent ligation of a left arm dialysis arteriovenous fistula for hand ischemia. Overall, of the 171 patients who had left subclavian artery (LSA) coverage without preemptive revascularization, only 9 (5%) had symptoms of arm ischemia.

Early Outcomes

The overall 30-day/in-hospital mortality was 6.5%. Compared with elective procedures (2.6%), mortality was significantly higher for symptomatic pathologies requiring urgent (9.5%) or emergent (20%) interventions (P<0.0001). There were also significant differences in the pathology-specific mortality (thoracic aortic aneurysm, 3.5%, dissection, 12%; penetrating ulcer, 3.7%; traumatic transection, 8%; and other, 13%; P=0.036; Figure 2). The median length of stay was 5 days (limits, 1 and 79 days). Overall, two thirds of the patients underwent their TEVAR without any complication or secondary intervention (Table 3). Wound or access-site complications occurred in 5% of patients (n=21), of whom only 2% (n=8) required treatment beyond antibiotics or local wound care. Acute renal insufficiency occurred in 4%, but only 2% required hemodialysis for any length of time.

Spinal cord ischemia resulted in permanent paraparesis in 4.5% of patients (n=18), whereas an additional 4.8% of patients (n=19) developed transient symptoms that completely resolved with spinal drainage and elevation of blood pressure. Of these 37 patients, 14 had complete and 23 had partial deficits. Of these 37 patients, 27 (73%) had spinal drains placed postoperatively; the remainder did not have drains because of either anatomic/technical reasons or uncorrectable coagulopathy. Of the 27 patients, 14 (52%) had completely resolved symptoms and 13 (48%) did not. Interestingly, of the 11 patients with complete deficits who had spinal drains placed, only 1 (9%) experienced total reversal of symptoms, whereas of the 16 patients with partial deficits and spinal drains, 13 (81%) had total reversal of symptoms (P=0.0003).

Table 3. Postoperative Complications

Complication	n	%
None	267	67
Permanent paraparesis	18	4.5
Transient paraparesis	19	4.8
Stroke	12	3.0
Arm ischemia	8	2.0
Cardiac	7	1.8
Respiratory	16	4.0
Renal (HD)	17 (8)	4.3 (2.0)
Gastrointestinal	3	0.8
Wound	21	5.3
Endograft infection	5	1.3

HD indicates hemodialysis.

Rates of any SCI (permanent or transient) between patients who had prior abdominal aortic replacements (12.5%) and those who did not (8.5%) were not significantly different (P=0.37). The incidence of SCI was similar for proximal landing zones 0 to 2 (LSA coverage) and zones 3 to 4 (10% versus 8%, respectively; P=0.49). In the subset who had their LSA covered (zones 0 to 2), the rates of SCI were almost identical between those who were and those who were not revascularized (10% versus 11%, respectively; P=1.0). Procedure-related stroke occurred in 3% (n=12) of all the patients; 8 of the 12 died in the perioperative period. Although the risk of stroke was significantly increased with the extent of proximal coverage (5.4% in zones 0 to 2 versus 0.5% in zones 3 to 4; P=0.006), the rates were similar for zones 0 to 2 between those who did and those who did not have preemptive revascularizations (9.7% versus 5.3%; P=0.40).

Late Outcomes

Follow-up was current in 72% of the patients with a median duration of 299 days (limits, 1 and 2736 days). Kaplan-Meier estimates of survival for the entire cohort were (P±SE) 82±2.1%, 76±2.4%, 68±3.0%, 60±3.6%, and 53±4.3% at 6, 12, 24, 36, and 48 months, respectively (Figure 3). Median survival was 48.8 months. The known causes of death are listed in Table 4. Very few deaths were verified by autopsy, and most of the causes were obtained from telephone interviews with the family of the deceased.

Late Outcomes: Multivariable Risk Model

The best model contained the following 8 risk factors: stroke, urgency (elective versus urgent/emergent), age (<60 versus 60 to 69 versus 70 to 79 versus >80 years), peripheral vascular occlusive disease, length of stay >7 days, estimated blood loss >300 mL, anesthesia (general versus regional), and indication (dissection versus other pathologies; Table 5). The c statistic for this model was 0.74 and, after the bootstrap

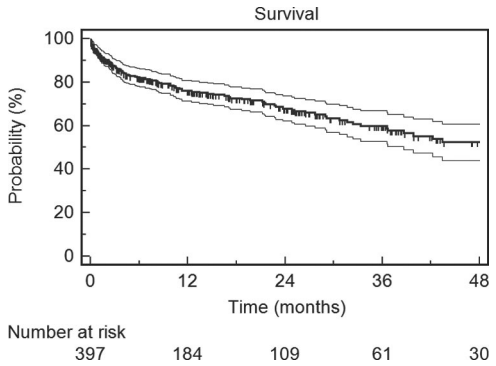

Figure 3. Kaplan-Meier estimate (K-M Est) of survival (±SE; bars, light lines).

adjustment, 0.69, indicating good predictive ability. Of the 5 risk factors with the highest scores (Table 5), 4 appeared in ≥90% of the models in the bootstrap samples (and the fifth in >70% of the models); this demonstrates the stability of our model. The sum of the covariate risk scores was categorized into low-, medium-, and high-risk groups defined as low (≤3), medium (4 to 7), and high (≥8). The corresponding Kaplan-Meier curves and 6-, 12-, 24- and 36-month survival estimates can be found in Figure 4.

As a comparison, we also constructed a multivariable risk model based on a forward selection procedure. This model included 7 risk factors (including three of the largest from our risk model): SCI, stroke, urgency (elective versus urgent/emergent), peripheral vascular occlusive disease, congestive heart failure, number of adjunct procedures (≤2 versus >2), and iliac condition. The c statistic for this model, 0.66 (0.60 after adjustment), was lower than for our model but had similar stability.

Endoleak rates are shown in Figure 5. A total of 89 secondary procedures were performed in 17% of the cohort (n=68), distributed as follows: 55 (13.8%) had 1 procedure, 9 (2.3%) had 2 procedures, 1 (0.3%) had 3 procedures, 2 (0.5%) had 4 procedures, and 1 (0.3%) had 5 procedures; 83% did not require any procedures. Most of the procedures were performed for treatment of type I endoleak, component separation or migration, or aneurysm enlargement. Table 6 lists the types of secondary procedures performed. The estimated cumulative incidence function for freedom from secondary procedure is given in Figure 6. This estimates the probability of having a secondary procedure before time t (in the presence of the competing risk of death).[8]

Table 4. Causes of Deaths

Cause	n	%
Cardiac	16	13.8
Stroke	12*	10.3
MSOF/sepsis	12	10.3
Pulmonary	9	7.8
Rupture	8	6.9
Gastrointestinal	5	4.3
Dissection	1	0.9
Endograft infection	1	0.9
Endograft collapse	1	0.9
Alzheimer disease	1	0.9
Unknown	50	43.1

MSOF indicates multisystem organ failure.
*Eight of these were procedure-related events and 4 were late events.

Table 5. Risk Factors for Mortality

Covariate	HR	95% CI	Risk Score	PI, %
Stroke	5.20	2.33–11.60	3	90
Urgent/emergent	2.41	1.54–3.77	2	90
Age ≥80 y	4.95	2.45–10.00	3	99
Age 70–79 y	5.55	3.01–10.22	3	98
PVOD	2.74	1.60–4.68	2	72
LOS >7 d	1.61	1.03–2.51	1	60
EBL >300 mL	1.56	1.04–2.34	1	38
Age 60–69 y	2.18	1.12–4.23	2	69
General anesthesia	1.59	1.02–2.50	1	43
Dissection	1.65	1.02–2.66	1	65

HR indicates hazard ratio; CI, confidence interval; PI, percent of times included in the final model by the bootstrap procedure; PVOD, peripheral vascular occlusive disease; LOS, length of stay; and EBL, estimated blood loss.

Discussion

This study represents one of the largest tertiary care single-center, real-world experiences of endovascular treatment of thoracic aortic diseases spanning nearly a decade of clinical practice. Our results showed an elective mortality of 2.6%, stroke rate of 3.0%, and permanent paraparesis/paraplegia rate of 4.5%. These findings are comparable to those reported for the Gore TAG, Cook TX2, and Medtronic Talent thoracic investigational device exemption clinical trials.[13–15] The overall 30-day/in-hospital mortality was 6.5%. This did not differ significantly from that of a recent study using the National Inpatient Sample, which found an in-hospital mortality of 7.7% for the 267 TEVARs sampled with a median length of stay of 5 days.[4] A meta-analysis of 17 studies of TEVAR versus open surgery found a mortality rate of 5.6% in the TEVAR versus 16.5% in the open surgery group.[16] Lack of uniformity in the case mix of the studies used in the meta-analysis, especially in terms of the inclusion of emergent cases for which mortality may be almost 10-fold higher than elective cases, may have accounted for the slightly lower pooled estimate of mortality.

All-cause late mortality after TEVAR was quite sobering. The probability of survival continued to decline throughout the follow-up period. Indeed, the 48-month survival of 53% was considerably lower than what was reported in the 5-year follow-up of the TAG pivotal trial for both the endovascular (70%) and open (65%) treatment arms of the study[17] and that of patients undergoing repair of abdominal aortic aneurysms (5-year survival, 66%).[18,19] Some of this disparity may be accounted for by the unselected nature of the patients treated in the present series, which involved a wide heterogeneity of pathologies, higher acuity of the procedures, and a worse comorbid status of the cohort. In the final analysis, despite only 8 cases of (presumed) rupture after TEVAR, the efficacy

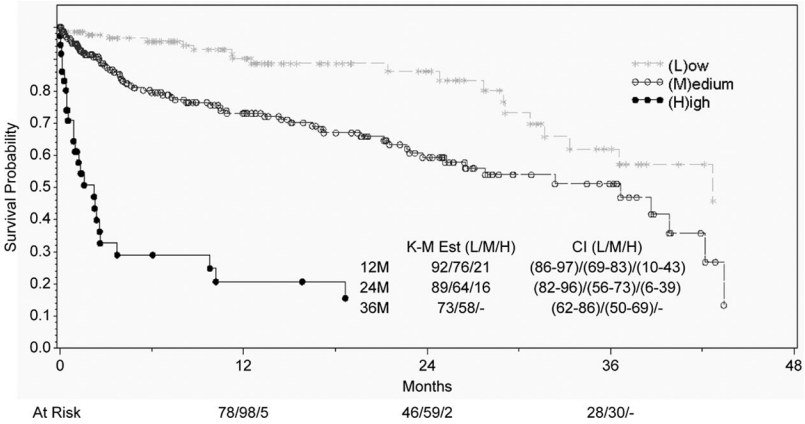

Figure 4. Risk-stratified Kaplan-Meier estimates of survival.

of the therapy in significantly altering the natural history of the aortic disease of these patients is uncertain.

A number of independent risk factors were related to survival after TEVAR in this series, which included both preexisting conditions and intraoperative factors (Table 5). Advanced age, nonelective surgery, and perioperative stroke contributed significantly to late mortality. Indeed, on the basis of the risk scoring system presented in this study, an urgent procedure performed in an 81-year-old man that is complicated by a procedure-related stroke has nearly an 80% risk of death at 12 months.

Need for late secondary procedures has been an ongoing issue with endovascular aortic repairs. However, unlike mortality, the risk of a secondary intervention more closely paralleled that of EVAR,[19] with most of these procedures occurring in the first 12 months and a relatively constant annualized risk of 4% to 5% in the subsequent years of follow-up. These estimates are similar to a recently published series of 255 TEVARs, which reported a 19% rate of reintervention at 3 years.[20]

Prevention and management of SCI remain controversial subjects in TEVAR. In the 17 years since the initial report of this therapy by Dake et al,[21] there has been a paucity of good scientific evidence to support a consensus on this issue, in large part because of insufficient center-specific clinical volume and heterogeneity of anatomies and pathologies. Although multiple risk factors have been reported, including length of aortic coverage,[22] prior abdominal aortic aneurysm repair,[23] hypotension,[24] renal failure,[25] and LSA coverage,[26] the occurrence of SCI has been relatively infrequent even in the presence of some or all of these factors. Our policy of prophylactic drainage focused mainly on the extent of aortic coverage because this was one parameter that seemed most reasonable and predictable. On the basis of a quantitative analysis of preoperative and postoperative CT angiogram data,[5] we derived guidelines for prophylactic placement of spinal drains as described in the Methods. In this series, as demonstrated in our previous study,[26] abdominal aortic replacement alone was not associated with an increased risk of spinal ischemia.

The higher incidence of spinal deficits seen in the present series is likely attributable to the higher-risk status of these cases. Unlike many of the multicenter clinical trials, 32% of the cases were performed under emergent/urgent circumstances. Furthermore, there was a greater heterogeneity of pathologies, with 25% of the cases performed for acute and chronic dissections; in the US multicenter pivotal trials, the inclusion criteria specifically excluded nonelective, surgically high-risk patients and allowed only degenerative aneurysms or penetrating ulcers.

The so-called focal mid-descending aneurysm was seen relatively rarely; indeed, the majority of the pathologies were localized to either the proximal or distal thoracic aorta. This was reflected in the fact that, in more than half of the cases, LSA coverage was required to gain an adequate proximal

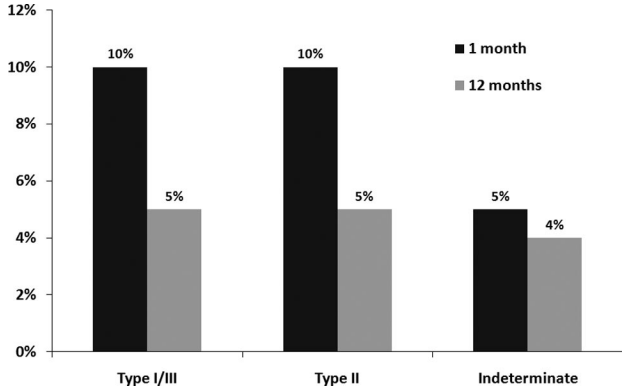

Figure 5. Endoleak at 1 and 12 months.

Table 6. Secondary Procedures

Secondary Procedure	n	%
Additional endograft placement	27	30.3
Major aortic reconstruction	21	23.6
Ascending/arch replacement	7	
Aortic banding	7	
Descending aortic replacement*	4	
Arch debranching	2	
Visceral debranching	1	
Major nonaortic vascular reconstruction	20	22.5
Major nonvascular procedure	8	9.0
Peripheral intervention	7	7.9
Surgical conversion	6	6.7

*Aneurysmal progression of distal thoracic aorta.

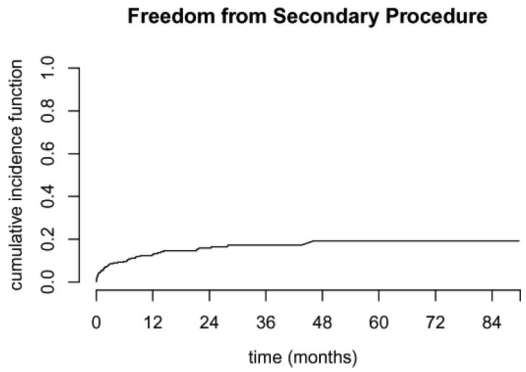

Figure 6. Product-limit estimate of freedom from secondary procedure with death as a competing risk.

landing zone. As noted in prior reports,[27,28] this was associated with a significantly higher risk of stroke, which at least in the present series was not attenuated by elective revascularization.

Preemptive LSA revascularization has been an unresolved issue that remains in evolution. In the recent publication of clinical practice guidelines by the Society for Vascular Surgery,[29] which were based on a rigorous meta-analysis of the literature, routine revascularization was suggested despite the very low quality of evidence. In our practice, the decision to bypass (versus transpose) the LSA was based mainly on cerebral, cardiac, and more rarely arm ischemia considerations. This strategy of selective revascularization resulted in a prevention of >160 potentially unnecessary procedures in patients who remained completely asymptomatic in the vascular territories directly perfused by the LSA. In terms of SCI, in a multivariable analysis performed previously,[5] LSA revascularization was not shown to be an independent risk factor for the development of this complication. Furthermore, in the present series, the incidence of any SCI was nearly identical between those who did and those who did not have their LSA covered and, within the former subset, between those who did and those who did not undergo a revascularization.

There are a number of weaknesses in this study. Despite the large cohort size, a considerable proportion of subjects had incomplete follow-up. The probability analysis of the late outcome measures should therefore be interpreted with due caution. The catchment basin of the practice drew from a population of nearly 20 million in a tri-state area. Many of these patients refused their postoperative imaging even locally or could not be contacted at all after discharge. This was particularly frustrating in terms of determining the causes of death, which remained unknown in >40% of the cases and could not be objectively validated in the remainder. Furthermore, the case mix of pathologies and adjunctive procedures of the present series likely reflects the patterns of a tertiary care practice, not necessarily those in regional or local settings. This may affect such parameters as the distribution of the proximal landing zones and the extent of aortic coverage, which in turn could affect some of the primary outcomes such as death, stroke, and SCI.

Conclusions

Although the technology and the therapy have been approved only for the treatment of atherosclerotic aneurysms and penetrating ulcers, TEVARs can be performed under elective conditions relatively safely, with a low risk of mortality and morbidity for a variety of other aortic pathologies. Despite concerns during the inception of this therapy, the risk of intraoperative surgical conversion is extremely low. The importance of careful case planning and a core multidisciplinary approach cannot be overemphasized. It is again sobering to reflect on the high rate of late mortality of these patients. Even if we accept the known causes of death and assume that the unknown causes were not aortic ruptures, the data would still suggest that patients with thoracic aortic diseases represent a subset whose underlying comorbidities may pose a greater threat to their lives than the aortic disease itself. Moving forward, then, perhaps the greatest challenge for all of us is not the search for a better widget or another new technique to try to fit a round peg in a square hole, but improved patient selection to identify those who will benefit from this therapy and those for whom the therapy truly represents a futility of care.

Disclosures

None.

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CLINICAL PERSPECTIVE

Operative repair of thoracic aortic pathologies is accompanied by significant morbidity and mortality. Thoracic endovascular aortic repair has become a minimally invasive alternative to open repair in anatomically suitable patients. Although the therapy remains indicated primarily for aneurysms and penetrating ulcers, other pathologies, such as traumatic transections and dissections, have been treated successfully after commercial availability of devices and increasing collective experience of endovascular operators. Early outcomes after thoracic endovascular aortic repair have been promising, but to date most published reports involve limited numbers of patients and are restricted to perioperative outcomes with relatively short-term follow-up. This study represents one of the largest single-center, real-world thoracic endovascular aortic repair experiences, spanning nearly a decade of practice. Our results showed an overall 30-day/in-hospital mortality of 6.5%, an elective mortality of 2.6%, a stroke rate of 3.0%, and a rate of permanent paraparesis/paraplegia of 4.5%. Survival at 3 years was 60%. The risk of intraoperative surgical conversion was extremely low. The importance of careful case planning and a core multidisciplinary approach cannot be overemphasized. The high rate of late mortality suggests that patients with thoracic aortic diseases may represent a subset whose underlying comorbidities may pose a greater threat to their lives than the aortic disease itself. Perhaps the greatest challenge is not the search for a better widget, but improved patient selection to identify those who will truly benefit from this therapy and those for whom the therapy may represent a futility of care.

SUPPLEMENTAL TABLE 1

Appendix 1. Potential predictors of early mortality examined using univariate analysis. COPD=chronic obstructive pulmonary disease, CVOD=cerebrovascular occlusive disease, PVOD=peripheral vascular occlusive disease, AAA=abdominal aortic aneurysm, LZ=landing zone.

Variable	OR	95% CI	*p*
Demographics			
Age >80 years	2.75	1.14 to 6.65	0.02
Female	0.65	0.26 to 1.66	0.37
Congestive heart failure	1.56	0.34 to 7.08	0.57
COPD	1.83	0.77 to 4.38	0.17
Chronic renal insufficiency	1.78	0.68 to 4.63	0.24
CVOD	3.10	1.16 to 8.26	0.02
PVOD	3.81	1.49 to 9.72	0.01
Anatomic			
Thoracic aortic aneurysm	0.51	0.22 to 1.18	0.12
Dissection	1.97	0.86 to 4.50	0.11
Penetrating ulcer	0.83	0.24 to 2.85	0.76
Traumatic transection	0.58	0.08 to 4.49	0.60
Other	2.44	0.67 to 8.84	0.18
Proximal neck diameter ≥37 mm	1.04	0.30 to 3.64	0.95
Proximal neck length <30 mm	1.54	0.60 to 3.93	0.37
Distal neck diameter ≥37 mm	0.97	0.21 to 4.44	0.97
Distal neck length <30 mm	1.07	0.23 to 4.93	0.93
Lesion diameter ≥80 mm	0.67	0.09 to 5.20	0.70
Lesion length ≥200 mm	1.41	0.48 to 4.18	0.54
Unrepaired AAA	1.20	0.44 to 3.30	0.73
Previous AAA repair	2.15	0.90 to 5.17	0.09
Procedural			
W.L. Gore TAG	1.91	0.75 to 4.86	0.18
Cook TX2	1.07	0.39 to 2.94	0.89
Medtronic Talent	0.67	0.09 to 5.21	0.70
Later 200 cases	0.61	0.27 to 1.37	0.23
ASA class III	0.09	0.01 to 0.63	0.02
Urgent/emergent repair	6.60	2.70 to 16.15	0.00
Regional anesthesia	0.28	0.10 to 0.83	0.02
Adjunctive procedure (each one)	0.64	0.47 to 0.88	0.01
Iliac conduit	1.67	0.64 to 4.34	0.29
Proximal LZ 3-4	4.43	1.64 to 12.00	0.00
Infraceliac distal LZ	1.32	0.30 to 5.80	0.72
Procedure time ≥180 min	3.78	1.53 to 9.30	0.00
Blood loss ≥300 ml	3.80	1.66 to 8.73	0.00
Length of stay >7 days	2.55	1.15 to 5.69	0.02
Stroke	12.48	3.65 to 42.67	0.00
Spinal cord ischemia (any)	3.32	1.24 to 8.88	0.02