Thoracic endovascular aortic repair: Evolution of therapy, patterns of use, and results in a 10-year experience

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Objective: The introduction of aortic stent grafting in the treatment of thoracic aortic disease has pioneered unique treatment options and gained rapid clinical adoption despite a paucity of long-term outcome data. The purpose of this analysis is to examine all operations performed using thoracic aortic stent grafts at the University of Pennsylvania Health System.

Methods: A total of 502 operations involving thoracic aortic stent grafting were performed between April 1999 and April 2009. Patients were followed in a prospectively collected clinical perioperative registry, and long-term outcomes were determined from administrative data sources. Aortic pathologies included aortic aneurysm, acute aortic dissection (types A and B), hybrid arch repairs, reinterventions with additional stents, pseudoaneurysm, chronic type B dissection, traumatic transection, penetrating aortic ulcer, and other unique indications.

Results: Patients' mean age at the time of thoracic endovascular aortic repair was 70.1 ± 12.4 years, and 51% of the patients were aged more than 70 years. Some 41% of patients were female, and the majority of patients (87%) were hypertensive. Overall 30-day mortality was 10.1%. Multivariable risk factors for 30-day mortality included urgent/emergency, Stanford type A aortic dissection, perioperative spinal ischemia, type C aortic coverage, hybrid arch operation, aortic transection, chronic renal failure, and age. Neurologic complications included permanent complete or incomplete paraplegia in 17 patients (3.4%), reversible spinal cord ischemia in 26 patients (5.1%), transient stroke in 16 patients (3.2%), and permanent stroke in 23 patients (4.6%). Greater extent of aortic coverage was not associated with risk of spinal cord ischemia. Access complications, stroke, and endoleaks diminished with increased operative experience over time. Risk factors for late mortality included urgent/emergency indications, hybrid procedures, traumatic aortic transection, age, perioperative paralysis, and chronic renal failure. Patients undergoing stent grafting for type B dissection were more likely to survive than patients undergoing stent grafting for aneurysms or other indications.

Conclusions: Thoracic aortic stent grafting has evolved to be a viable option to complement, augment, or even replace traditional treatments for aortic disease. These data illustrate the applicability of this evolving technology in the establishment of new treatment paradigms for complex aortic pathologies. (J Thorac Cardiovasc Surg 2011;142:587-94)

Thoracic endovascular aortic repair (TEVAR) has evolved during the past 15 years from hand-sewn experimental devices to become the predominant technique for repair of most thoracic aortic pathology. We began the TEVAR program at the University of Pennsylvania in 1999, initially treating patients enrolled in pivotal trials with atherosclerotic aneurysms and occasional uses of stent grafts for other indications in dire emergencies. After the first TEVAR

device approval in March 2005 (Gore TAG thoracic nitinol endograft; WL Gore & Associates, Inc, Flagstaff, Ariz), we expanded our indications to include a variety of aortic pathologies, such as type B dissections, transections, hybrid arch replacement, and hybrid treatment of the proximal descending thoracic aorta in acute type A dissections. We present our experiences with TEVAR over the past decade with an emphasis on comparing the differential impact of aortic pathologic diagnosis on early and late outcomes.

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Disclosures: Authors have nothing to disclose with regard to commercial support.

Read at the 35th Annual Meeting of The Western Thoracic Surgical Association,

Banff, Alberta, Canada, June 24–27, 2009.

Received for publication Aug 24, 2009; revisions received Jan 3, 2011; accepted for publication Feb 9, 2011; available ahead of print July 18, 2011.

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doi:10.1016/j.jtcvs.2011.02.050

MATERIALS AND METHODS Surgical Technique

TEVAR at the Hospital of the University of Pennsylvania is performed by a multidisciplinary team, including cardiovascular surgery, vascular surgery, cardiovascular anesthesia, neurology, and diagnostic radiology. The majority of cases were performed in a dedicated hybrid operating room able to accommodate fixed, high-quality, floor-mounted image intensifier transesophageal echocardiography equipment, intravascular ultrasound, neuromonitoring equipment, and a cardiopulmonary bypass pump if necessary, and multiple movable viewing screens that can simultaneously

Abbreviations and Acronyms

CI = confidence interval LSCA = left subclavian artery

OR = odds ratio

TEVAR = thoracic endovascular aortic repair

display angiography, hemodynamics, transesophageal echocardiography, and intravascular ultrasound. Our techniques of TEVAR for atherosclerotic aneurysms, ³ complicated Stanford type B dissections, ⁴ hybrid arch procedures, ⁵ and DeBakey I aortic dissections ⁶ have been published. Briefly, all non-emergency patients undergo 3-dimensional reconstruction of contrast computed tomography scans (M2S, Inc, West Lebanon, NH) for preoperative case planning.

A fairly liberal approach to retroperitoneal access is used in cases of marginal femoral access, which generally occurred in vessels that were small, heavily circumferentially calcified, or extremely tortuous. Hybrid arch replacement cases were generally performed through a side-branch graft of the ascending aorta,⁵ and TEVAR during open repairs of DeBakey type I dissections was performed by deploying the stent just beyond the left subclavian artery (LSCA) origin under direct visualization of the distal arch.6 TEVAR for complicated Stanford type B dissections was directed at sealing the primary intimal tear and reexpansion of the true lumen in the proximal descending thoracic aorta.⁴ Intravascular ultrasound was used to verify presence of the wire in the true lumen before advancement of stiff wires or the device. Ballooning is avoided in dissection cases. In general, we aim for 10% to 20% oversize at the proximal landing zone, which ideally is greater than 2 cm in length (particularly along the lesser curvature), has no thrombus, is not dissected, and has a consistent diameter. In instances of planned LSCA coverage, prophylactic left common carotid artery to LSCA bypass is performed perioperatively. Coiling of the LSCA from the ipsilateral brachial artery is routine in cases of left common carotid artery-LSCA bypass at the time of stent insertion.

Neuroprotective Strategies

Use of somatosensory evoked potential monitoring was not standardized in this population but evolved into a routine with increasing experience. Preoperative spinal drains were used in all patients who were considered high risk for spinal ischemia, including those with previous abdominal aortic aneurysm repair, descending thoracic aortic surgery, or planned complete aortic coverage from left subclavian to celiac axis (type C coverage). Descending thoracic aortic coverage is classified as type A, LSCA to midthoracic aorta (T6); type B, midthoracic aorta (T6) to celiac axis; and type C, left subclavian to celiac axis. The protocol for management of spinal cord ischemia in the postoperative period included spinal drainage to cerebrospinal fluid pressure less than $10~\rm cmH_2O$ and aggressive blood pressure augmentation with mean arterial pressures greater than $90~\rm mm~Hg.^7$

Statistical Methods

The University of Pennsylvania TEVAR Registry is a prospectively maintained perioperative database of thoracic aortic stent-graft procedures. The details of operative procedures are entered and verified by the attending surgeon. Outcomes are verified by the attending surgeon, and neurologic outcomes are verified by an attending neurologist with supportive imaging. Early outcomes were compared using standard univariate statistics, including the Student *t* test for continuous data and Fisher exact test for categoric data. Multivariate analyses for predictors of operative mortality, stroke, and paraplegia were determined using logistic regression. All variables deemed clinically relevant were maintained in the model, and

no automated selection procedures were used. Model discrimination was evaluated with the c-statistic, and model fit was evaluated with the Hosmer and Lemeshow goodness of fit test. Late survival was analyzed using the Kaplan–Meier survival technique, and multivariate predictors of late survival were determined using Cox proportional hazards modeling. Late survival data were determined using a linkage to the national Social Security Death Index. The institutional review board at the University of Pennsylvania approved the study and waived the need for patient consent.

RESULTS

Patient Demographics and Operative Characteristics

We performed 502 thoracic aortic stent grafting procedures from April 1999 to April 2009. Pathologic diagnosis leading to aortic stent grafting included thoracic aneurysms (64%), complicated acute type B dissections (9.7%), chronic type B dissections (2.4%), penetrating atherosclerotic ulcers (1.4%), pseudoaneurysms (3.0%), arch hybrids (5.2%), type A dissections (9.5%), traumatic transections (3.2%), TEVAR reoperations (4.7%), and other indications including 2 ascending aortic stents (1.2%).

Patient demographic characteristics are summarized in Table 1. Patients' mean age at the time of TEVAR was 70.1 ± 12.4 years, and 51% of patients were aged more than 70 years. Some 41% of patients were female, and the majority of patients (87%) were hypertensive.

Stent grafts used included the Gore TAG (WL Gore & Associates, Inc, Flagstaff, Ariz) (346/502, 69%), Medtronic Talent (Medtronic Inc, Minneapolis, Minn) (87, 17%), Medtronic Valiant (Medtronic Inc) (19, 3.4%), Cook Zenith (Cook Medical, Inc, Bloomington, Ind) (35/502, 7%), and others (15/502, 3.0%). Access locations included right femoral artery (51%), left femoral artery (17%), right common iliac artery (12%), left common iliac artery 11%, and others (8%), including abdominal aorta, ascending aorta (hybrid procedures or type A dissection stents), and left ventricular apex. Aortic coverage included 40% type A (LSCA to T6), 23% type B (midthoracic aorta to celiac axis), and 37% type C (left subclavian to celiac axis).

Early Outcomes

Perioperative outcomes are summarized in Table 2. Overall 30-day mortality was 10.1%. Significant multivariable risk factors for 30-day mortality included urgent/emergency operation (odds ratio [OR], 4.9; confidence interval [CI], 2.2–11.2), type A dissection (OR, 3.4; CI, 1.1–10.9), perioperative spinal ischemia (OR, 4.8; CI, 2.1–11.1), type C aortic coverage (OR, 2.1; CI, 1.0–3.4), hybrid arch operation (OR, 2.7; CI, 1.0–9.0), aortic transection (OR, 10.3; CI, 2.3–25.5), chronic renal failure (OR, 6.2; CI, 2.7–14.9), and age (by year) (OR, 1.05; CI, 1.0–1.08) (Table 3).

Neurologic complications included permanent complete or incomplete paraplegia in 17 patients (3.4%), reversible spinal cord ischemia in 26 patients (5.1%), transient stroke in 16 patients (3.2%), and permanent stroke in 23

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