Twelve-year results of fenestrated endografts for juxtarenal and group IV thoracoabdominal aneurysms

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Objective: **The practice of using fenestrated endografts to treat juxtarenal and group IV thoracoabdominal aortic aneurysms (TAAAs) has become more accepted, but long-term outcomes are still unknown. We report long-term survival, complications, and branch-related outcomes from a single-center experience.**

Methods: **The study included consecutive patients enrolled prospectively into a physician-sponsored investigational device exemption classified as undergoing group IV TAAA or juxtarenal aneurysm repair by the treating surgeon using fenestrated endografts. Device morphology was used to subclassify this group of patients. Long-term survival and a composite outcome of secondary intervention, branch occlusion, stent migration, endoleak, aneurysm growth, or spinal cord injury were calculated. Descriptive analysis of branch-related outcomes and need for any reintervention was performed. Univariate and multivariate analysis of mortality and the composite outcome was performed to determine associative risks.**

Results: **Long-term survival for patients with juxtarenal and group IV TAAA aneurysms treated with fenestrated stent grafts was 20% at 8 years. Multivariate analysis showed long-term survival for this patient population was negatively associated with increasing age, congestive heart failure, cancer, and previous aneurysm repair. The risk of spinal cord ischemia (SCI) in this group was 1.2% and of aortic-related mortality was 2%. The risk of a spinal event increased with coverage above the celiac artery (52 mm of coverage above the celiac artery in patients with SCI vs 33 mm without SCI; $P = .099$). More complex device configurations were more likely to require an increased rate of reinterventions, and patients with celiac fenestrations were more likely to experience celiac occlusion over time (3.5% vs 0.5%; $P = .019$). However, less complex designs were complicated by an increased risk of type I endoleak over time (10.4% for renal fenestrations only vs 1.9% for others; $P < .01$). As experience evolved, there was a trend to increase the number of fenestrations in devices treating the same anatomy.**

Conclusions: **The use of fenestrated devices to treat juxtarenal and group IV TAAA is safe and effective in long-term follow-up. Mortality in this patient population is largely not aortic-related. Devices designed for fenestrated repair of juxtarenal and group IV thoracoabdominal aneurysms within a physician sponsored investigational device exemption have changed over time. Further research is needed to determine the best configuration to treat aneurysms requiring coverage proximal to the celiac artery. (J Vasc Surg 2015;61:355-64.)**

The use of fenestrated stent grafts to treat aneurysms with short infrarenal necks began in 1999.[1] After proof-of-concept was established, the number of branches routinely incorporated has increased with time, complexity of disease, and surgeon confidence.[2] The use of fenestrated stent grafts has grown, and the long-term durability of these devices has recently been reported.[3,4] Analysis of these long-term results suggests that longer landing zones are favored by some expert groups in patients with similar anatomy, compared with previous practice, because of the risk of long-term progression of aortic disease and the threat of device failure.[2,5]

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Author conflict of interest: T.M.M. reports proctorship and consultation for Cook Medical. M.J.E. reports consultation for Cook Medical.

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The editors and reviewers of this article have no relevant financial relationships to disclose per the JVS policy that requires reviewers to decline review of any manuscript for which they may have a conflict of interest.

0741-5214

http://dx.doi.org/10.1016/j.jvs.2014.09.068

With the advent of off-the-shelf devices and the recent interest in chimney and snorkel techniques, surgeons will have more options for treating aneurysms with landing zones in the visceral aorta.[6] Although technical success is important, the focus of clinical decision making should be long-term durability as it relates to preoperative variables such as device design and aortic anatomy.[3,5] The literature is difficult to interpret because of overlapping definitions of juxtarenal, suprarenal, and type IV thoracoabdominal aortic aneurysm (TAAA).

This report describes our outcomes with devices sealing in or near the visceral aorta, which have been classified as juxtarenal and type IV thoracoabdominal aneurysms by the treating surgeon. Short-term technical and perioperative outcomes are described as well as long-term success and durability. Our goal was to determine the long-term durability and risk of failure of fenestrated devices for type IV TAAA and juxtarenal aneurysms.

METHODS

The series included all patients who underwent placement of a branched or fenestrated endograft for treatment of juxtarenal or type IV thoracoabdominal aneurysm, as classified by the treating surgeon, under a physician-sponsored investigational device exemption protocol between 2001 and December 2013 (ClinicalTrials.gov identifier NCT00583050). Details of the patient population, device design, and methods of implantation have been previously described.[3,7-10] Design of the devices was determined by the treating surgeon and evolved over time based on the experience accrued at our center. All patients signed an informed consent approved by the Investigational Review Board before device implantation.

Study outcomes. Patient outcome data and information about imaging end points were included in a prospectively maintained database (Oracle Clinical; Oracle Corporation, Redwood Shores, Calif). A standard procedure was followed for assessing imaging outcome events by the treating vascular surgeon and a trained vascular imaging specialist using a high-resolution, contrast-enhanced computed tomography scan. Additional information was acquired from duplex ultrasound studies and abdominal radiography, where appropriate. Criteria for duplex imaging and methods for computed tomography scan interpretation have been previously reported.[9,10] Discrepancies were adjudicated independently by a surgeon with expertise in the field. Reporting standards documented for thoracic aneurysm repair were followed to report imaging outcomes.[11]

The graft plans of all patients noted to have juxtarenal or type IV thoracoabdominal aneurysm were reanalyzed and captured retrospectively by one author (T.M.M.) because this was not captured in our prospective database. In analyzing these data, it became clear that the definitions of type IV TAAA and juxtarenal aneurysm evolved over time and were not consistent between operators. To create more objective groups, patients were recategorized into one of four groups depending on the most proximal fenestration or scallop, which we defined as "device morphology:" fenestrated devices involving only renals (renal), devices with fenestrations or scallops for the superior mesenteric artery (SMA), devices with scallops for the celiac artery (celiac scallop), and devices with fenestrations to the celiac, or landing zones above the celiac, implying a length of graft material above the celiac (supraceliac). The type of fenestration or scallop was then documented for each vessel in each graft. When necessary, original imaging was reviewed to be sure that documentation was accurate.

The main outcome was long-term durability of juxtarenal and type IV thoracoabdominal aneurysm repair using fenestrated devices, as characterized by a composite of mortality, reintervention, and branch occlusion. In addition, we assessed perioperative factors such as technical success rate, branch-related outcomes, spinal cord injury, renal complications, secondary intervention, development of type I endoleak, and rupture.

We further assessed the durability of different fenestration types and related mating stent configurations to determine if there was a more successful combination. Another goal was to assess the learning curve associated with different branch configurations based on perioperative complications and determine whether this had any effect on long-term durability of the device. The short-term and long-term outcomes of patients with single-wide scallops were analyzed. Using these data, we hoped to better distinguish between anatomic factors that would improve outcome and lead to a clinically useful classification of "juxtarenal" and "type IV thoracoabdominal" aneurysms.

Statistical plan. Statistical analyses were performed using χ^2 or the Fisher exact test for categoric variables. Time-to-event analyses of the long-term outcomes for survival, freedom from reintervention, and freedom from the composite end point (need for secondary intervention, branch occlusion, stent migration, endoleak, aneurysm growth, or spinal cord injury) are depicted graphically using Kaplan-Meier curves. The recurrence of multiple branch-related secondary interventions was also examined using a proportional means model with sandwich variance estimators to account for the within-patient correlation. Hazard ratios (HRs) and 95% confidence intervals (CIs) for recurrent secondary interventions are provided for each graph classification (using the renals-only group as the reference).

Univariable and multivariable analysis for each outcome was also performed to determine factors independently associated with mortality, reintervention, and the composite end point. Bootstrap sampling methods were used to determine candidate variables for the multivariable model. Variables included in the final multivariable models were retained at the $\alpha = .20$ level and met criteria from bootstrapping sampling or were thought to be clinically relevant (eg, age). All analyses were performed using SAS 9.2 software (SAS Institute Inc, Cary, NC).

RESULTS

All patients treated with juxtarenal and type IV repairs between 2001 and December 2013 were reviewed, and 610 patients met the criteria to be included in this analysis, with a mean of 8 years of follow-up. The demographics and baseline characteristics are available in the Supplementary Table. This includes 349 patients with type IV repair, 258 patients with juxtarenal repairs, and three patients who remained unclassified due to missing documentation. For the alternate classification according to the original graft design, the number of patients in each group and their baseline demographics are also in the Supplementary Table. Baseline demographics appeared to be balanced through the four groups, with the exception of chronic obstructive pulmonary disease, where people with renal fenestrations were more likely to have this as a preoperative diagnosis ($P = .007$). Technical success for these procedures was 97%.

Long-term outcomes. The survival curve for patients undergoing juxtarenal or type IV TAAA repair in a physician-sponsored investigational device exemption is depicted in Fig 1, and outcomes are described in Table I. Survival at 8 years was 20%, and aneurysm-related mortality was 2%. Spinal cord injury occurred in seven patients (1.16%). Spinal cord events did appear to be associated with length of graft coverage: in the four patients with spinal cord ischemia (SCI), the average length of coverage