From the New England Society for Vascular Surgery

Outcomes of fenestrated and branched endovascular repair of complex abdominal and thoracoabdominal aortic aneurysms

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ABSTRACT

Background: More than 80% of infrarenal aortic aneurysms are treated by endovascular repair. However, adoption of fenestrated and branched endovascular repair for complex aortic aneurysms has been limited, despite high morbidity and mortality associated with open repair. There are few published reports of consecutive outcomes, inclusive of all fenestrated and branched endovascular repairs, starting from the inception of a complex aortic aneurysm program. Therefore, we examined a single center's consecutive experience of fenestrated and branched endovascular repair of complex aortic aneurysms.

Methods: This is a single-center, prospective, observational cohort study evaluating 30-day and 1-year outcomes in all consecutive patients who underwent fenestrated and branched endovascular repair of complex aortic aneurysms (definition: requiring one or more fenestrations or branches). Data were collected prospectively through an Institutional Review Board-approved registry and a physician-sponsored investigational device exemption clinical trial (G130210).

Results: We performed 100 consecutive complex endovascular aortic aneurysm repairs (November 2010 to March 2016) using 58 (58%) commercially manufactured custom-made devices and 42 (42%) physician-modified devices to treat 4 (4%) common iliac, 42 (42%) juxtarenal, 18 (18%) pararenal, and 36 (36%) thoracoabdominal aneurysms (type I, n = 1; type II, n = 4; type III, n = 12; type IV, n = 18; arch, n = 1). The repairs included 309 fenestrations, branches, and scallops (average of 3.1 branch arteries/case). All patients had 30-day follow-up for 30-day event rates: three (3%) deaths; six (6%) target artery occlusions; five (5%) progressions to dialysis; eight (8%) access complications; one (1%) paraparesis; one (1%) bowel ischemia; and no instances of myocardial infarction, paralysis, or stroke. Of 10 type I or type III endoleaks, 8 resolved (7 with secondary intervention, 1 without intervention). Mean follow-up time was 563 days (interquartile range, 156-862), with three (3%) patients lost to follow-up. On 1-year Kaplan-Meier analysis, survival was 87%, freedom from type I or type III endoleak was 97%, target vessel patency was 92%, and freedom from aortic rupture was 100%. Average lengths of intensive care unit stay and inpatient stay were 1.4 days (standard deviation, 3.3) and 3.6 days (standard deviation, 3.6), respectively.

Conclusions: These results show that complex aortic aneurysms can now be treated with minimally invasive fenestrated and branched endovascular repair. Endovascular technologies will likely continue to play an increasingly important role in the management of patients with complex aortic aneurysm disease. (J Vasc Surg 2017;■:1-8.)

The successful use of fenestrated endograft technologies for complex aortic aneurysms was first published in 1999,[1,2] with subsequent iterative, more versatile fenestrated approaches published shortly thereafter by pioneers in the field.[3] Given the formidable morbidity and mortality associated with open thoracoabdominal aortic aneurysm repair,[4-9] considerable enthusiasm for minimally invasive repairs has been expressed during the nearly two decades since fenestrated endograft technologies were first described. However, relatively few centers have embraced these technologies and published their outcomes in large consecutive series of patients.[10-16]

We are currently in the midst of a rapid evolution of technical advances in endovascular catheter-based treatments for aortic aneurysms. Scallops, fenestrations, and branches can be constructed in endovascular grafts to allow stent grafts to be placed across the visceral arteries while preserving flow to the critical end organs supplied by these arteries. In this way, proximal stent graft seal zones can now be extended, well proximal to

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the infrarenal aorta, into areas of healthy normal aorta. Appropriate use of these technical advances requires not only the acquisition of new techniques and surgical skills but also an understanding of new, rapidly changing endovascular graft design technologies.

Our institution made a collective decision to design a strategic plan to develop a high-impact program for the endovascular treatment of complex aortic aneurysms. The initial planning stages for our complex endovascular aortic program began in 2008 and have continued to the present day.[17] The purpose of this study was to evaluate the outcomes achieved after our first 100 consecutive complex endovascular aortic procedures, each of which incorporates at least 1 branch or fenestration.

ARTICLE HIGHLIGHTS

- **Type of Research:** Single-center retrospective study
- **Take Home Message:** In this single-center series of 100 consecutive endovascular repairs of complex aortic aneurysms, the perioperative mortality rate was 3%, and the 30-day adverse event rate was lower than anticipated.
- **Recommendation:** This paper suggests that complex endovascular aneurysm repair can be performed safely, with superior outcomes in centers of excellence with a dedicated aortic program.

METHODS

This is a single-center prospective observational cohort study. All data were collected prospectively through an Institutional Review Board-approved registry or physician-sponsored investigational device exemption clinical trial (G130210). All procedures were performed at one large academic hospital in a hybrid operating room with high-quality fixed radiology equipment with fusion overlay capabilities between November 2010 and March 2016. Any patient was included in the complex endovascular aortic program if the intended endovascular repair necessitated one or more fenestrations or branches to achieve a durable endograft seal. All patients included in the study were deemed at high risk for open repair by the operating surgeon and by an additional, impartial vascular surgeon reviewer. All patient data were entered into a secure, prospectively maintained database by trained research assistants. Institutional Review Board approval was obtained from the University of Massachusetts Medical School, and written informed consent was obtained for each patient.

Procedure and outcomes. All repairs were planned on the basis of measurements obtained from high-resolution computed tomography (CT) angiography images on a three-dimensional workstation using standard centerline flow orthogonal techniques (TeraRecon, Foster City, Calif).[18] For any patient's anatomy for which a commercially approved fenestrated endograft (ie, Zenith Fenestrated [ZFEN]; Cook Medical, Bloomington, Ind) or a trial device (ie, Cook Iliac Branch Device, Cook p-Branch) was available to the study team, the appropriate commercially manufactured device option was selected. Otherwise, before approval was received for our physician-sponsored investigational device exemption clinical trial in October 2013, a physician-modified device was used.[19-24] Since approval of the physician-sponsored investigational device exemption clinical trial, custom-made commercially manufactured fenestrated or branched devices have been used, unless the treating surgeon has deemed the patient's aneurysm to be at too high risk to wait the required time for manufacture, in which case a physician-modified device was used.

All patients included in the complex endovascular aortic program are observed according to a standardized protocol that consists of postoperative CT angiography at 1 month, at 6 months, and yearly thereafter. In addition, all visceral arteries that are targeted by a fenestration or a branch are evaluated with duplex ultrasound examination at 1 month, at 6 months, and yearly thereafter. All patients, in the absence of a contraindication, are prescribed clopidogrel (Plavix) for 3 months and lifelong aspirin. The 30-day follow-up was 100%, and the mean follow-up time for the entire study group was 563 days (interquartile range, 156-862), with three (3%) patients lost to follow-up.

Technical success was defined as successful delivery and deployment of the endograft with preservation of target vessel patency and absence of a type I or type III endoleak. The outcomes evaluated at 30 days included myocardial infarction (defined according to the American Heart Association's universal definition of myocardial infarction[25]), paraparesis, paralysis, stroke, deterioration in renal function (decrease in glomerular filtration rate >30%), new-onset dialysis, target artery patency, access vessel complications, presence of a type I or type III endoleak, and mortality. The outcomes evaluated at 1 year included target vessel patency, aneurysm sac enlargement (>5 mm), presence of a type I or type III endoleak, and survival. All 30-day outcomes were calculated using standard counts and proportions and are presented as number (%) or number where applicable. All 1-year outcomes were calculated using life-table analyses and the Kaplan-Meier time-to-event method. All analyses were performed using SAS 9.3 software (SAS Institute, Cary, NC).

RESULTS

Cohort description. Between November 2010 and March 2016, we enrolled 100 patients into our complex endovascular aortic disease program (1 in 2010, 7 in 2011, 14 in 2012, 22 in 2013, 13 in 2014, 31 in 2015, and 12 in the first 3 months of 2016). The average age of the