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Prospective, nonrandomized study to evaluate endovascular repair of pararenal and thoracoabdominal aortic aneurysms using fenestrated-branched endografts based on supraceliac sealing zones

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ABSTRACT

Purpose: To investigate outcomes of manufactured fenestrated and branched endovascular aortic repair (F-BEVAR) endografts based on supraceliac sealing zones to treat pararenal aortic aneurysms and thoracoabdominal aortic aneurysms (TAAAs).

Methods: A total of 127 patients (91 male, mean age 75 ± 10 years old) were enrolled in a prospective, nonrandomized single-center study using manufactured F-BEVAR (November 2013-March 2015). Stent design was based on supraceliac sealing zone in all patients with ≥ four vessels in 111 (89%). Follow-up included clinical examination, laboratory studies, duplex ultrasound, and computed tomography imaging at discharge, 1 month, 6 months, and yearly. End points adjudicated by independent clinical event committee included mortality, major adverse events (any mortality, myocardial infarction, stroke, paraplegia, acute kidney injury, respiratory failure, bowel ischemia, blood loss >1 L), freedom from reintervention, and branch-related instability (occlusion, stenosis, endoleak or disconnection requiring reintervention), target vessel patency, sac aneurysm enlargement, and aneurysm rupture.

Results: There were 47 pararenal, 42 type IV, and 38 type I-III TAAAs with mean diameter of 59 ± 17 mm. A total of 496 renal-mesenteric arteries were incorporated by 352 fenestrations, 125 directional branches, and 19 celiac scallops, with a mean of 3.9 ± 0.5 vessels per patient. Technical success of target vessel incorporation was 99.6% (n = 493/496). There were no 30-day or in-hospital deaths, dialysis, ruptures or conversions to open surgical repair. Major adverse events occurred in 27 patients (21%). Paraplegia occurred in two patients (one type IV, one type II TAAAs). Follow-up was >30 days in all patients, >6 months in 79, and >12 months in 34. No patients were lost to follow-up. After a mean follow-up of 9.2 ± 7 months, 23 patients (18%) had reinterventions (15 aortic, 8 nonaortic), 4 renal artery stents were occluded, five patients had type Ia or III endoleaks, and none had aneurysm sac enlargement. Primary and secondary target vessel patency was 96% ± 1% and 98% ± 0.7% at 1 year. Freedom from any branch instability and any reintervention was 93% ± 2% and 93% ± 2% at 1 year, respectively. Patient survival was 96% ± 2% at 1 year for the entire cohort.

Conclusions: Endovascular repair of pararenal aortic aneurysms and TAAAs, using manufactured F-BEVAR with supraceliac sealing zones, is safe and efficacious. Long-term follow-up is needed to assess the impact of four-vessel designs on device-related complications and progression of aortic disease. (J Vasc Surg 2016;■:1-11.)

Fenestrated and branched endovascular aortic repair (F-BEVAR) continues to evolve since the first case performed by John Anderson in 1998.[1] Contemporary reports from large aortic centers worldwide have shown high technical success (>95%), with mortality in the range of 1%-5% for pararenal and 5%-10% for thoracoabdominal aortic aneurysms (TAAAs).[2-9] Improvements in preoperative planning, patient selection, techniques of implantation, and perioperative care have lowered mortality and paraplegia.

Device design has changed substantially in the last decade. Early experiences used one or two renal

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fenestrations and a scallop for the superior mesenteric artery (SMA) in patients with juxtarenal aortic aneurysms.[7,10] With time, the indications of F-BEVAR were broadened to include more complex aneurysms involving the mesenteric arteries, which required placement of sealing stents in the distal thoracic aorta. Because of the risk of disease progression, which can compromise the repair and its targets, several centers including ours have adopted a policy of planning these procedures using more stable segments for sealing zones above the SMA and celiac axis (CA).[7,11] The purpose of this study was to analyze the outcomes of F-BEVAR using manufactured stent grafts based on supraceliac sealing zones.

ARTICLE HIGHLIGHTS

- **Significance:** This manuscript describes outcomes of repairs of complex aneurysms using manufactured fenestrated and branched endovascular aortic repair (F-BEVAR) endografts.
- **Type of Research:** Prospective, single-center cohort study
- **Take Home Message:** F-BEVAR was performed safely in 127 patients without early mortality, dialysis, ruptures, or conversions, with two paraplegias. Renal branch stability remains the rate-limiting step.
- **Recommendation:** The authors suggest that following a strict clinical care pathway can allow for treatment of complex aneurysms with F-BEVAR with excellent short-term outcomes.
- **Strength of Recommendation:** 1. Strong
- **Level of Evidence:** B. Medium

METHODS

This study was a prospective, single-center, nonrandomized trial registered at the www.ClinicalTrials.gov (NCT1937949 and NCT2089607). Participation required informed consent approved by the Institutional Review Board, and compliance with the study inclusion and exclusion criteria (Supplementary Table I, online only). F-BEVAR was performed using manufactured patient-specific or off-the-shelf Cook Zenith (Cook Medical, Inc, Bloomington, Ind) fenestrated and branched stent grafts based on supraceliac sealing zones under physician-sponsored investigational device exemption protocols (number G130030 and G130266). One hundred sixty-nine consecutive patients were enrolled in the study since Food Drug Administration approval of the investigational device exemption in March, 5 2013. Of these, 148 patients underwent device implantation, and 21 await implantation. This report summarizes results from the first 127 patients implanted as of March 30, 2016 who had completed a minimum of 30-day follow-up.

Demographics, clinical characteristics, cardiovascular risk factors, and operative and postoperative variables were collected prospectively and stored on case report forms and MEDIRAVE database. Aneurysm classification was based on extent of aneurysmal disease evaluated by computed tomography angiography (CTA). Clinical comorbidities were assessed using the American Society of Anesthesiology classification and the Society for Vascular Surgery (SVS) comorbidity score system.[12,13] Early postoperative period was defined as occurring within the first 30 days or within the hospital stay if longer than 30 days. Follow-up consisted of clinical examination, laboratory studies, and imaging before discharge and at 1, 6, and 12 months, and annually thereafter for the first 5 years. Imaging evaluation included CTA or computed tomography without contrast and duplex ultrasound of the renal-mesenteric arteries. All imaging studies were independently evaluated by a dedicated group of vascular radiologists. Clinical data entry and case report forms were independently monitored for compliance with regulatory guidelines. Cause of death was determined by review of death certificates and autopsy reports. Adverse events and causes of death were independently reviewed and adjudicated by a clinical event committee and data safety monitoring board. Results of interim analysis were reported annually to the Federal Drug Administration and to the Institutional Review Board.

Device design. Aneurysm morphology was determined by high-resolution CTA datasets. A minimum proximal sealing zone of at least 25 mm was selected in normal supraceliac aortic segments, defined by parallel aortic wall with no evidence of thrombus, calcium, or diameter enlargement >10%. Options for vessel incorporation were doublewide CA scallops (20 × 20 mm), large (8 × 8 mm) or small fenestrations (6 × 6 mm), and directional branches (8 or 6 mm). Specific device design varied depending on aneurysm extent, vessel angulation, and inner aortic diameter, and included either patient-specific devices with up to five fenestrations or branches or off-the-shelf t-Branch multibranch stent graft (Cook Medical, Inc) (Supplementary Fig 1, online only). Selection of design was tailored by the primary investigator (G.O.) depending on aneurysm extent and diameter of aortic lumen. For renal targets, fenestrations were preferred. For extent I-III TAAAs, directional renal branches were used if the aortic lumen was large (>40 mm), and vessel orientation was down-going without excessive tortuosity. The most common designs for pararenal aneurysms were three fenestrations and doublewide celiac scallop or four fenestrations. For TAAAs, the most common designs were four fenestrations for type IV and combination of directional branches and fenestrations for type I-III TAAAs (Supplementary Fig 2, online only).