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Outcomes of using endovascular aneurysm repair with active fixation in complex aneurysm morphology

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ABSTRACT

Objective: The ideal treatment option for patients with complex aneurysm morphology remains highly debated. The aim of this study was to investigate the impact of endovascular aneurysm repair (EVAR) with active fixation on outcomes in patients with complex aneurysm morphology.

Methods: There were 340 consecutive patients who underwent EVAR using active fixation devices, 234 with active infrarenal fixation (AIF; Gore Excluder; W. L. Gore & Associates, Flagstaff, Ariz) and 106 with active suprarenal fixation (ASF; 85 Medtronic Endurant [Medtronic, Santa Rosa, Calif] and 21 Cook Zenith [Cook Medical, Bloomington, Ind]). Demographics, comorbidities, anatomic features, and outcomes were analyzed for patients receiving devices with active fixation. Outcomes of using active fixation in necks with <15-mm neck lengths, >60-degree infrarenal neck angle (β), >30-mm infrarenal neck diameter, severe aortic neck calcification or thrombus, and nonstraight neck morphology were evaluated.

Results: Of the 340 patients, 106 (78 men; mean age, 74.5 ± 9.3 years at the time of surgery) received implants with ASF and 234 (191 men; mean age, 74.6 ± 8.9 years at the time of surgery) received implants with AIF. In comparing AIF and ASF devices, patients in the suprarenal fixation group had significantly shorter follow-up time (25 ± 17 months vs 44.3 ± 32 months; $P < .0001$). Patients in the ASF group had shorter aortic neck lengths (25.5 ± 15.1 mm vs 28.6 ± 14.9 mm; $P =$ NS) and significantly larger infrarenal neck diameters (25.9 ± 6.3 mm vs 23.4 ± 3.2 mm; $P < .0001$) and aneurysm diameters (59.9 ± 11.6 mm v. 55.9 ± 10.0 mm; $P = .002$). Outcomes were similar between groups, with no significant differences in reintervention, proximal endoleak, sac growth, abdominal aortic aneurysm-related death, or rupture. Of the complex anatomic neck features investigated, neck diameter >30 mm and nonstraight neck morphology had the highest rates of reintervention in ASF devices.

Conclusions: In cases of hostile infrarenal neck morphology, ASF appears to be used more frequently. Our data suggest that ASF may be useful for certain patients but may be unfavorable for others, such as those with wide necks or several difficult neck features. Nevertheless, further research is needed to evaluate more optimal treatment options, such as fenestrated EVAR, branched EVAR, and endovascular adjuncts such as EndoAnchors (Aptus Endosystems, Sunnyvale, Calif), in dealing with high-risk anatomic characteristics that may not be optimally managed with standard EVAR devices with active fixation. (J Vasc Surg 2018;■:1-10.)

Endovascular aneurysm repair (EVAR) remains a rapidly evolving technique with constant device design modifications and a continuously expanding population of patients. It is well established that a sufficient and healthy proximal segment of aorta is crucial for achieving secure, long-term attachment of endovascular grafts. Importantly, it was noted early on that many infrarenal abdominal aneurysms failed to meet this requirement.[1] A significant proportion with challenging (short, wide, angulated, thrombosed, or calcified) proximal necks were commonly excluded because they failed to meet the manufacturer's instructions for use (IFU) guidelines.[2] Although these characteristics would have previously made a patient ineligible for EVAR, advancements in technique, experience, and prosthetic design have facilitated the transition of many centers to treat aneurysms with complex morphologic features.

Still, the use of standard EVAR in these more complex patients has shown mixed results. Some have demonstrated safety of using commercially available devices,[2-5] whereas others have linked challenging neck characteristics to worse outcomes.[6-9] As such, device selection is strongly driven by a patient's anatomy. With the advent of alternatives such as fenestrated EVAR (FEVAR), branched EVAR (BEVAR), and endovascular adjuncts, such as EndoAnchors (Aptus Endosystems,

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Sunnyvale, Calif), it is important that the durability of devices with active fixation in challenging anatomy is evaluated. To our knowledge, few studies have investigated the implantation of endovascular devices with active fixation in a population of anatomically complex patients. The aim of this study was to report the outcomes of using standard active fixation in patients with challenging proximal neck characteristics.

ARTICLE HIGHLIGHTS

- **Type of Research:** Single-center retrospective cohort study
- **Take Home Message:** In 304 endovascular aneurysm repair patients with either active suprarenal or infrarenal fixation, there were no differences in late reinterventions, endoleak, sac growth, or abdominal aortic aneurysm-related rupture or death with neck diameter >30 mm; angulated necks treated with suprarenal fixation had the highest rates of reintervention.
- **Recommendation:** This study suggests that abdominal aortic aneurysm-related outcomes after endovascular aneurysm repair with either active suprarenal or infrarenal fixation are equivalent; active fixation was the least satisfactory in patients with complex anatomic features.

METHODS

Population of patients. A prospectively maintained database of 1588 EVAR patients was reviewed, and 578 consecutive patients receiving EVAR from 2000 to 2015 were found for whom preoperative and postoperative computed tomography angiography images were available and compatible with modern three-dimensional (3D) reconstruction software. Of these, 564 received five major endovascular grafts (Gore Excluder [W. L. Gore & Associates, Flagstaff, Ariz]; Medtronic Talent, Endurant, and AneuRx [Medtronic, Santa Rosa, Calif]; and Cook Zenith [Cook Medical, Bloomington, Ind]). To better reflect the current practice, we narrowed our study to include only 340 patients with active fixation, 234 with active infrarenal fixation (AIF; Gore Excluder) and 106 with active suprarenal fixation (ASF; 85 Medtronic Endurant and 21 Cook Zenith). A flow chart is provided in the Fig. All patients underwent elective abdominal aortic aneurysm (AAA) EVAR at an urban tertiary care hospital. Many patients included in this study received repair before our institution began using fenestrated devices. The Institutional Review Board of the Icahn School of Medicine at Mount Sinai approved this study. The patients' data were entered prospectively and reviewed retrospectively from patient charts and physician notes with consent of the patients.

Preoperative data included demographics such as age, sex, and comorbidities that are included in the comorbidity severity score, such as coronary artery disease, congestive heart failure, peripheral vascular disease, renal failure, smoking history, previous stroke or transient ischemic attack, pulmonary comorbidities, and hypertension.[9] Outcomes tracked included any incidence of access site infections, endoleaks, reintervention, aneurysm sac enlargement, all-cause mortality, AAA-related rupture, and AAA-related death. This information was collected during follow-up visits, which routinely happened 30 days postoperatively, 6 months postoperatively, and then annually thereafter. All data were stored in an encrypted Mount Sinai Division of Vascular Surgery database.

Anatomic feature data. For each patient in the study, 3D anatomic models were constructed using preoperative computed tomography scans of the abdomen. The modern software systems used were EndoSize (Therenva SAS, Rennes, France) and VitreaWorkstation (Toshiba Medical, Glen Mills, Pa). Using the 3D model and center lumen line technology, features such as aortic and aneurysm diameter, presence of neck calcification and thrombus, aortic neck length, and infrarenal aortic neck angle were measured. Diameters were measured as an axial cut from outer wall (adventitia) to outer wall (adventitia), with measurements taken immediately below the most caudal renal artery and at the largest diameter of the aneurysm sac. The aneurysm neck was graded on a scale of 0 to 4 describing the number of quadrants occupied by calcification or thrombus. We defined severe aortic neck calcification or thrombus as occupation of at least three quadrants. The aneurysm neck length was measured from the most caudal renal artery to the location determined to offer an optimal seal zone proximal to the start of the aneurysm. The infrarenal aortic angle (β) was measured between the aneurysm axis and infrarenal neck.

Statistical analysis. All data was analyzed using SAS software (SAS Institute, Cary, NC). Per the study objective, patients were stratified by the fixation mechanism of their implants into two groups: AIF (Excluder, Food and Drug Administration [FDA] approved in 2002) and ASF (Endurant, FDA approved in 2010; Zenith Flex, FDA approved in 2003). Stratification was made for several complex anatomic characteristics. These included infrarenal neck length <15 mm and <10 mm, infrarenal neck angle (β) >60 degrees, severe aortic neck calcification or thrombus, and nonstraight neck morphology (reverse funnel, funnel, pinched, dilated). Independent *t*-tests were run for integrated and normally distributed variables, such as age and length of stay, as well as for continuous anatomic variables. The χ^2 tests were run for categorical variables, such as sex and comorbidities.

RESULTS

Overall population. In our study population of 340 patients, 234 (69%) received AIF with the Gore Excluder, 85