Anatomic and clinical characterization of the narrow distal aorta and implications after endovascular aneurysm repair

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ABSTRACT

Objective: The purpose of this analysis was to compare 1-year clinical outcomes after endovascular repair of abdominal aortic aneurysms with the EXCLUDER device in patients with standard and narrow aortic bifurcations (AOBs).

Methods: Data were prospectively collected from a 1055-participant subset of the multicenter Global Registry for Endovascular Aortic Treatment (GREAT) treated for abdominal aortic aneurysm repair between August 2010 and September 2015. There were 117 patients with a narrow AOB (NB; defined as <16 mm) and 938 patients with a standard bifurcation (SB). The 30-day and 1-year morbidity, mortality, and reintervention outcomes were analyzed, with Kaplan-Meier survival curve analysis conducted on freedom from mortality and freedom from reintervention.

Results: The mean distal aortic neck diameter was 12.4 mm in the NB cohort and 25.3 mm in the SB cohort ($P < .001$), with NB patients also exhibiting significantly smaller diameter proximal aortic necks ($P < .001$). Patients in the NB cohort were more often female (25.6% vs 15.1%; $P = .004$) and with more severe comorbidity burden. There was a significantly higher rate of surgical cutdown access in the NB cohort ($P < .001$). Procedural survival was 100% in both groups. The 30-day mortality and safety outcomes were similar; however, all-cause mortality was significantly higher in the SB cohort through 1 year ($P = .02$). The 1-year freedom from mortality was estimated as 92.1% in the SB cohort and 99.1% in the NB cohort. Freedom from reintervention was estimated as 95.1% in the SB cohort and 92.8% in the NB cohort at 1 year. Through 1-year follow-up, 24 SB patients (2.6%) and 4 NB patients (3.4%) exhibited an endoleak requiring reintervention ($P > .99$). Type II endoleaks represented 72% and 60% of treated endoleaks, respectively. Through 1 year, 10 SB patients (1.0%) and 2 NB patients (1.7%) exhibited occlusive/thrombotic events ($P = .54$). There were no reported instances of kinking, migration, fracture, compression, or dissection through 1 year in either cohort. One SB patient experienced thoracic aortic aneurysm rupture.

Conclusions: The 1-year outcomes after endovascular aneurysm repair with the EXCLUDER device were comparable in the NB and SB cohorts. A narrow AOB was not found to be associated with a higher incidence of later limb occlusions or endoleaks. Female patients were disproportionately more likely to have a narrow AOB, which correlated with narrowed proximal necks and access vessels, and a more severe comorbidity burden. (J Vasc Surg 2018;■:1-9.)

Keywords: EVAR; Narrow bifurcation; Distal aorta; Limb occlusion; EXCLUDER

Endovascular aneurysm repair (EVAR) initially gained popularity as an alternative to open surgical repair because of a robust advantage on short-term outcomes. However, long-term follow-up in both real-world populations and clinical trials has demonstrated that the initial morbidity, mortality, and clinical resource advantages observed with EVAR are not sustained through long-term follow-up. Analyses of anatomic factors influencing device durability have largely focused on the proximal neck, with the progressive issues of migration and type IA endoleak found to be of greater prevalence and severity in patients with hostile proximal necks.[1]

Hostile distal aortas—in particular, narrow aortic bifurcations (AOBs)—also merit close consideration by the clinician during endovascular case planning and are relatively understudied. Narrow distal aortas—often arising from a ring of circumferential calcification—can require additional adjunctive procedures (eg, the "paving and cracking" technique) that carry significant risks for procedural complications, such as aortic rupture. Narrow AOBs have also been posited as a key risk factor for later endograft limb occlusions.[2-5]

In a 173-participant single-center study, Carpenter et al[3] reported 24 endograft limbs requiring reintervention to restore patency during a mean follow-up of 9.7 months, with narrowing at the AOB posited as a key contributor to later limb failure. Numerous case reports have also noted the apparent role that narrowing of the distal aorta plays in subsequent acute limb ischemia.[2,4,5]

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Some authors have suggested that the narrow distal aorta be considered a possible contraindication to EVAR,[2] with current guidelines recommending an AOB diameter >20 mm for use of a bifurcated graft.[6]

Successive generations of endografts and optimization of endovascular techniques in the past decade have sought to address the technical issue of delivering two graft limbs through a narrow distal bifurcation without subsequent limb failure.[7-9]

We compared 1-year registry outcomes in patients treated with the Gore EXCLUDER AAA Endoprosthesis (W. L. Gore & Associates, Flagstaff, Ariz) with an objective of determining the possible effect of a narrow AOB on later outcomes, specifically whether narrow AOBs are associated with an increased rate of type II endoleaks and limb occlusions.

ARTICLE HIGHLIGHTS

- **Type of Research:** Retrospective analysis of prospectively collected data of a multicenter registry
- **Take Home Message:** Endovascular aneurysm repair with the Gore EXCLUDER device with a narrow aortic bifurcation (<16 mm) in 117 patients resulted in similar 1-year rate of endoleaks requiring intervention (3.4% vs 2.6%; $P > .99$) and iliac limb thrombosis or occlusions (1.7% vs 1.0%; $P = .54$) as in 938 patients with larger (≥16 mm) bifurcation.
- **Recommendation:** This study suggests that the Gore EXCLUDER bifurcated device can be used in patients with narrow aortic bifurcations (<16 mm) with low rates of iliac limb complications at 1 year.

METHODS

Study design. The Global Registry for Endovascular Aortic Treatment (GREAT) is an international, multicenter, prospective registry established to collect long-term outcomes on the performance of commercially available Gore aortic endografts in patients indicated for aortic endovascular treatment, such as for abdominal aortic aneurysms (AAAs), thoracic aortic aneurysms, thoracoabdominal aortic aneurysms, and common iliac aneurysms. Enrollment began in August 2010, with a target enrollment of 5000 patients met in October 2016. As of data cutoff in September 2017, there were 2973 enrolled patients at >60 sites in the United States, Europe, Australia, New Zealand, and Brazil. The study was conducted in accordance with the Declaration of Helsinki and Good Clinical Practice guidelines.

Inclusion and exclusion criteria were limited to allow the capture of real-world performance data (including off-label use) and consisted of a signed informed consent form, an indication for endovascular aortic (thoracic aortic or abdominal aortic) repair, and the satisfaction of age requirements of the country of treatment (generally ≥18 years). The study design was approved by each participating institution's Ethics Committee. Further details on the study design were published previously.[10] Site selection for GREAT aimed to encapsulate a variety of center types. Urban, rural, high-volume, and low-volume centers were engaged, with an emphasis placed on first-time study sites for Gore. The registry aimed to collect real-world data on management of events and follow-up patterns that reflect regional variations in standard of care and selection of patients.

Subset analysis. Registry participants with an indication for AAA repair and available AOB measurements were stratified by distal aortic diameter, with a diameter <16 mm considered narrow. The conventional definition of a narrow AOB is generally considered to be 18 mm or 20 mm.[6,11] However, for the purpose of this analysis, the threshold was defined as 16 mm to assess outcome in more severely diseased, challenging aortas. All anatomic measurements were collected by the site and documented the narrowest measurement of the AOB. All patients in this analysis were implanted with at least one Gore aortic device. Gore aortic devices may have been implanted in conjunction with devices from other manufacturers, although these data were not collected in the GREAT registry.

Device description. The EXCLUDER device is a modular device composed of two primary components (the trunk-ipsilateral leg endoprosthesis and contralateral leg endoprosthesis) and two auxiliary components (the aortic extender endoprosthesis and iliac extender endoprosthesis). Active infrarenal fixation is provided by proximal anchors and an expanded polytetrafluoroethylene and fluorinated ethylene propylene sealing cuff. The current instructions for use recommend a minimum distal aortic diameter of 18 mm to accommodate both legs of the EXCLUDER device. Patients in this cohort of the GREAT registry were implanted with the EXCLUDER device using either the Gore SIM-PULL Delivery System or the updated Gore C3 Delivery System (CE mark, August 2011; Food and Drug Administration approval, December 2011), which features a modified delivery catheter, enabling the clinician to position the device up to three times before final release.

Data collection and statistical methodology. The GREAT registry collected data on adverse events that met the International Organization for Standardization definition of a serious adverse event (SAE).[12] This entails that only endoleaks requiring reintervention or resulting in death or serious deterioration in the health of the patient were reported in the GREAT registry. The registry protocol did not specify a structured algorithm for endoleak management. The decision to treat an endoleak was entirely based on the physician's preference and was not