Performance of the Endurant stent graft in challenging anatomy

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Objective: **This study aimed to compare perioperative and postoperative outcomes after endovascular repair of abdominal aortic aneurysms (AAAs) in patients with various neck morphologic features.**
Methods: **Data from the Endurant Stent Graft Natural Selection Global Postmarket Registry (ENGAGE) were used for the analyses. Patients were categorized into three different groups according to proximal aortic neck anatomy: regular (REG), intermediate (INT), and challenging (CHA). REG was defined as AAAs with a proximal neck ≥15 mm combined with a suprarenal angulation (α) ≤45 degrees and an infrarenal neck angulation (ß) ≤60 degrees. INT was defined as AAAs with a proximal neck of 10 to 15 mm combined with α ≤45 degrees and ß ≤60 degrees or with a proximal neck of >15 mm combined with α ≤60 degrees and ß = 60 to 75 degrees or α = 45 to 60 degrees and ß ≤75 degrees. CHA was defined as infrarenal necks that exceed at least one of the three defining factors.**
Results: **Overall, 925 patients (75.9%) had REG anatomy, 189 patients (15.5%) had INT anatomy, and 104 patients (8.5%) had CHA anatomy. Patient demographics and risk factors were similar. There was a significant difference in AAA diameter between the REG and CHA groups (59.4 mm vs 65.2 mm; $P < .001$). Technical success was similar among groups (REG 99.1% vs INT 99.5% vs CHA 97.1%). There were no differences in mortality or the need for secondary procedures within 30 days or at 1 year. A significantly higher rate of type I endoleaks within 30 days was seen in CHA compared with REG (adjusted odds ratio, 0.15; 95% confidence interval, 0.05-0.46) and INT (adjusted odds ratio, 0.08; 95% confidence interval, 0.01-0.70), but there was no difference at 1-year follow-up.**
Conclusions: **This real-world, global experience shows promising results and indicates that endovascular AAA repair with the Endurant stent graft (Medtronic Vascular, Santa Rosa, Calif) is safe and effective in patients with challenging aortic neck anatomy. However, long-term follow-up of patients is required to confirm results. (J Vasc Surg 2015;62:312-8.)**

There have been substantial changes in the treatment of abdominal aortic aneurysms (AAAs) since the introduction of endovascular aortic aneurysm repair (EVAR) in 1991.[1] The success of an EVAR procedure, in terms of exclusion of the aneurysm and absence of perioperative and postoperative complications, is closely dependent on the AAA's morphologic features and dimensions.[2] For this reason, each commercially available endograft comes with its own instructions for use (IFU) with clear recommendations on AAA morphology and aortic dimensions. Short infrarenal aortic necks and severe infrarenal aortic neck angulation are likely to cause more intraoperative and postoperative complications, such as graft migration and type I endoleaks.[3-5]

A substantial proportion of AAA patients are not eligible for EVAR because of anatomy outside the endograft inclusion criteria.[6] Unfortunately, these patients are often also considered to be less attractive for open surgery.[7] However, as practitioners become more experienced with endovascular therapy and with improved stent graft technology, increasing numbers of patients with challenging AAA morphology are treated with EVAR.

The main objective of this study was to compare the outcomes of EVAR with a latest generation stent graft system in different infrarenal aortic neck anatomies within the context of contemporary, real-world practice. Retrospective analysis was performed on data from the Endurant Stent Graft Natural Selections Global Postmarket Registry (ENGAGE).

METHODS

Study design. ENGAGE is a multicenter, nonrandomized, prospective observational study of patients

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Table I. Classification of patients based on anatomy of the proximal nonaneurysmal infrarenal neck

Anatomic criteria		*Proximal neck length*		
		>15 mm	*10-15 mm*	*<10 mm*
Proximal neck angulation	Suprarenal ≤45 degrees *and* infrarenal ≤60 degrees	REG (n = 925)	INT (n = 107)	CHA (n = 23)
	Suprarenal ≤60 degrees *and* infrarenal 60-75 degrees *or* Suprarenal 45-60 degrees *and* infrarenal ≤75 degrees	INT (n = 82)	CHA (n = 9)	CHA (n = 2)
	Suprarenal >60 degrees *and/or* infrarenal >75 degrees	CHA (n = 63)	CHA (n = 6)	CHA (n = 1)

CHA, Challenging anatomy (n = 104); *INT,* intermediate anatomy (n = 189); *REG,* regular anatomy (n = 925).

treated with the Endurant Stent Graft System (Medtronic Vascular, Santa Rosa, Calif). This endograft is specifically designed to broaden the EVAR eligibility range. To reflect real-world clinical practice, the eligibility criteria for ENGAGE were minimal, and enrollment of patients outside Endurant's IFU was accepted. Patients needed to be at least 18 years old and to have an indication for elective AAA repair. The only exclusion criteria were the probability of nonadherence to follow-up requirements and the concurrent participation in another trial that might confound results. Centers were selected on the basis of a minimal annual case volume of 20 AAA stent graft procedures in combination with a history of a minimum of three successful Endurant stent graft procedures. To avoid selection bias, participating sites were requested to enroll patients consecutively. Ruptured AAAs were not considered for enrollment into ENGAGE. The trial was conducted according to the Declaration of Helsinki and the International Conference on Harmonization Good Clinical Practice guidelines and approved by local medical ethics committees. Technical specifications of the Endurant Stent Graft System and further methodologic details of the ENGAGE registry have been published previously.[8,9]

Definitions and study end points. For this retrospective analysis, the study population was partitioned on the basis of the IFU criteria of the Endurant. We created three groups divided according to anatomic complexity of the infrarenal neck: regular (REG), intermediate (INT), and challenging (CHA) (Table I). Suprarenal angulation (α) was defined as the angle between the flow axis of the suprarenal aorta and the infrarenal neck. Infrarenal angulation (ß) was defined as the angle between the flow axis of the infrarenal neck and the body of the aneurysm. REG was defined to include AAAs with a proximal neck of >15 mm combined with α ≤45 degrees and ß ≤60 degrees. INT was defined to include AAAs with a proximal neck of 10 to 15 mm combined with α ≤45 degrees and ß ≤60 degrees or with a proximal neck of >15 mm combined with α ≤60 degrees and ß = 60 to 75 degrees or α = 45 to 60 degrees and ß ≤75 degrees. CHA was defined to include infrarenal necks that exceed at least one of the three defining factors (ie, neck length <10 mm, or a neck length of 10 to 15 mm with α >45 degrees or ß >60 degrees, or a neck length >15 mm combined with α >60 degrees or ß >75 degrees). All patients underwent computed tomography angiography (CTA) preoperatively to determine baseline aortic and aneurysmal dimensions. CTA measurements were performed by the participating centers and not reviewed by a central core laboratory. Pre-existing medical comorbidity information was collected immediately after patient enrollment. It was recommended to have annual follow-up imaging after the index procedure. The first choice of imaging modality was CTA.

Technical success was defined as successful delivery and deployment of the Endurant endograft, without unintentional coverage of renal arteries, internal iliac arteries, or visceral branches, with absence of either a type I or type III endoleak, followed by successful removal of the delivery system.[10] A completion angiogram was obtained to document the status of endograft implantation. The necessity of proximal extension cuff placement to correct perioperative type Ia endoleaks was documented. Duration of implant procedure was defined as the time between cutdown or puncture and removal of the last guidewire. Fluoroscopic time, volume of contrast material, postoperative stay, and possible intensive care unit admission were documented. The 30-day and 1-year outcomes included endograft-related complications, mortality rates, and need for secondary interventions. Technical complications included occlusion (100% stent graft obstruction), stenosis (partial stent graft obstruction), kinking (stent graft obstruction in the horizontal plane), and migration (stent graft movement >10 mm). All patients completed 1-year follow-up.

Data collection and statistical analysis. The clinical investigators recorded data on a web-based electronic case report form to ensure reliable data collection, data management, secure authentication, and traceability. All entered data were reviewed, and >40% of patients' source documentation was monitored randomly. Each center's institutional review committee approved the registry, and informed consent was obtained from all patients.

Categorical variables are presented as frequencies (percentages). Continuous variables are presented as