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Three-Year Results of the Endurant Stent Graft System Post-Approval Study (ENGAGE PAS)

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Abstract

Objective—Long-term data following endovascular aortic aneurysm repair (EVAR) exist, but are limited to endografts that are no longer in use. The aim of the ENGAGE Post-Approval Study is to describe the long-term safety and effectiveness data following EVAR using the Endurant stent graft system.

Methods—From August 2011 to June 2012, 178 patients were enrolled and treated with the Endurant stent graft system. Clinical and radiologic data were prospectively collected and analyzed. The primary endpoint was AAA-related mortality, and secondary endpoints were overall mortality, endoleak, secondary interventions, and device-related complications. Kaplan-Meier estimates were used for late outcomes.

Results—A total of 178 patients underwent EVAR with the Endurant stent graft across 24 centers (82% men; median age 71, interquartile range [IQR] 66–79). Median aortic diameter was 55 mm (IQR 51–58 mm). There was a 98.9% technical success rate. Three-year clinical and radiographic follow-up data were available for 87% and 74% of patients, respectively. Median follow-up was 37 months (IQR 30–38 months). Three-year aneurysm-related mortality rate was 1.1%, with two deceased patients in the perioperative period. All-cause mortality rate at three years was 13%. No patients suffered from aneurysm rupture or underwent conversion to open repair through three years of follow-up. Only 11 patients (6.2%) had undergone reintervention at three years. Younger age was associated with reintervention (HR 3.3 per younger decade, 95% Confidence Interval 1.3 – 7.6, $P < .01$), but neck diameter, length, angulation were not significantly associated with reintervention.

Conclusions—The Endurant stent graft system provides a safe, durable approach to treating infrarenal AAA. No patients experienced late rupture or aneurysm-related mortality, and only one in 16 patients underwent reintervention by three years. The rate of reintervention with the

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Endurant graft appears to be lower than other contemporary grafts despite more liberal “Instructions For Use” parameters, but further research including direct graft comparisons will be necessary to guide appropriate graft selection.

Introduction

Endovascular aneurysm repair (EVAR) has become the predominant treatment of abdominal aortic aneurysms (AAA) in patients who are anatomically suitable.^{1, 2} Designs of stent grafts are continuously evolving, with devices now tolerating aneurysm neck anatomy previously considered unsuitable for endovascular treatment of AAA. However, late rupture remains a significant problem after EVAR, with recent follow-up data from Medicare beneficiaries and randomized trials showing significantly higher rates of rupture and mortality following EVAR compared to open repair after 2–4 years.^{3, 4}

Reducing complications and reinterventions whilst safely treating more patients with difficult anatomy is the current challenge in the endovascular treatment of AAA. The Endurant stent graft (Medtronic Cardiovascular, Santa Rosa, CA) is a new-generation graft designed to expand EVAR applicability in the setting of challenging AAA anatomy, especially to treat short infrarenal aortic neck length, and to minimize long-term reinterventions. The Endurant Stent Graft Natural Selection Global Post-Market Registry (ENGAGE) previously evaluated the real-world global experience with the Medtronic graft, which was shown to be safe and effective up to one year.⁵ However, long-term results are still poorly characterized. A previous study of the Endurant stent graft for AAA demonstrated a low AAA-related mortality at 4-year follow-up; importantly, however, 20% of the patients did not meet the Instructions For Use (IFU), and therefore, the results may not accurately represent the performance of the Endurant stentgraft.⁶

The Endurant graft received United States Food and Drug Administration approval in December 2010, at which point the ENGAGE Post-Approval Study (ENGAGE PAS) began to evaluate real-world experience with the graft in accordance with its IFU. The aim of the ENGAGE PAS is to provide the first detailed clinical description of early and late outcomes following approval of the Medtronic Endurant Stent Graft System in the United States.

Methods

The ENGAGE PAS protocol was approved by each study site Institutional Review Board and is registered on clinicaltrials.gov (NCT01379222). All study patients consented to participate in the ENGAGE PAS.

Study Design

As part of the Endurant Stent Graft System Post-Approval Study, patients were prospectively enrolled in one of 24 centers across the United States between June 2011 and August 2012 for EVAR with the Endurant stent graft (Medtronic Vascular, Santa Rosa, CA) after its Food and Drug Administration (FDA) approval. To be enrolled in the study, patients had to be > 18 years old, have the ability and willingness to comply with the Clinical Investigational Plan, and importantly, have an indication for elective surgical repair of an

AAA with an endovascular stent graft in accordance with the Instructions for Use (IFU) of the Endurant Stent Graft System, which have been published previously.⁷ The Endurant design allows for wider neck (≥ 32 mm), shorter neck length (≤ 10 mm), and greater neck angulation (≤ 45° for the suprarenal angle, or ≤ 60° if the neck is ≤ 15 mm, and ≤ 75° for the infrarenal angle, or ≤ 60° if the neck is ≤ 15 mm) than other widely-used contemporary grafts. Notably, although the study design included that each participant's morphological variables be consistent with the Endurant's IFU, 1.7% (N = 3) of patients were enrolled despite falling outside of IFU guidelines. Appropriate indications for elective repair included aneurysm diameter > 5 cm, aneurysm diameter of 4–5 cm with increase by at least 0.5 cm in the last six months, or an aneurysm at least 1.5 times the diameter of the normal infrarenal aorta. Exclusion criteria included: high probability of non-adherence to a physician's follow-up requirements, participation in a concurrent trial which could confound the study results, and being a female of childbearing potential in whom pregnancy cannot be excluded. No patients with ruptured aneurysms were considered for study enrollment.

Definitions and Outcomes

Data for each patient were collected and recorded by, or under the supervision of, each site's principal investigator in a web-based electronic case report form to ensure reliable data collection, data management, secure authentication, and traceability. The primary clinical endpoint was freedom from aneurysm-related mortality. Secondary outcomes included technical success rates, serious adverse events, aneurysm rupture, endoleaks, and secondary endovascular procedures related to the AAA or Endurant device. Technical success was defined as successful delivery and deployment of the Endurant stent graft in the planned location, with no unintentional coverage of either internal iliac artery or any visceral aortic branch and with removal of the delivery system. Perioperative (30-day) serious adverse events were defined as death from any cause and/or the occurrence of bowel ischemia, myocardial infarction, paraplegia, procedural blood loss ≥ 1000 mL, renal failure, respiratory failure, or stroke. Technical observations assessed at yearly intervals postoperatively by imaging included stent graft kinking, stent graft wireform fracture, suprarenal bare stent fracture, anchoring pin fracture, stent graft stenosis, and stent graft occlusion. Device integrity issues that could develop and result in secondary intervention include endoleak of any type, stent fracture, migration, or occlusion. These complications were evaluated by serial imaging with computed tomography and kidney, ureter, and bladder (KUB) X-ray films.

Statistical Analysis

For categorical variables, counts and percentages were calculated. For continuous variables, median, interquartile range (IQR), and minimum and maximum are presented as appropriate. Three-year Kaplan-Meier estimates for late outcomes accounted for differential rates of follow-up. Cox regression analysis was used to identify demographic and anatomic variables associated with late reintervention, using an *a priori* approach to model building. Statistical analysis was conducted using STATA version 14.2 (StataCorp LP, College Station, TX).

Results

A total of 178 patients were recruited across 24 centers with 53 surgeons. The median follow-up time at the time of this analysis was 37 months (IQR: 30 – 38 months). Complete three-year clinical follow-up data were available for 87% of eligible patients, with adequate radiographic follow-up to assess technical observations available for 79% of patients.

Preoperative Variables

As described in Table I, 146 (82%) patients were male, 95% were of white race, and the median age was 71 (IQR 66–79). No patients had prior AAA repair. Other comorbidities were as expected among a cohort of patients with vascular disease, including the presence of coronary artery disease (49%), smoking history (54%), chronic obstructive pulmonary disease (33%), and renal insufficiency (11%). The median aneurysm size was 54.5 mm, and ranged from 42–98 mm (Table II). Of note, only three patients out of 178 (1.7%) were performed outside of the device IFU, for one patient with aneurysm neck diameter > 32 mm (40 mm) and neck length < 10 mm (5 mm) and two patients with aneurysm neck length between 10–15 mm and infrarenal neck angle > 45°.

Operative Variables and Perioperative Outcomes

All patients received an EVAR with the main bifurcated device as well as a contralateral limb (Table IIIa). In 38% of patients, these were the only two devices placed (Table IIIb). Iliac artery extensions were used in 28% of patients, and aortic extensions in 4.0%. Technical success was achieved in 176/178 patients (98.9%). One failure was secondary to unintentional coverage of both renal arteries leading to renal artery occlusion, and another did not receive an Endurant device due to unsuitable anatomy at the time of the index procedure. Two patients (2.2%) died in the first 30 postoperative days, with causes of death listed as cardiac arrest for one and cardiopulmonary failure for the other (Table IV). Other perioperative complications are listed in Table IV, with 25% rate of overall morbidity. At one-month follow-up, 21/178 (12%) of patients had type II endoleaks and one patient had a type I endoleak (0.6%).

Three-Year Outcomes

Three-year outcomes are listed in Table V. Aneurysm-related mortality at three years was 1.1%, with two deaths, both occurring in the first 30-days postoperatively so considered aneurysm-related by default (Figure 1). Neither death occurred in patients with EVAR performed outside of IFU. All-cause mortality was 13% (95% Confidence Interval (CI): 8.8 – 19%). No patients experienced aneurysm rupture or underwent conversion to open repair. Endoleak was noted in 18% of patients by Kaplan-Meier estimation (2.1% type I, 16% type II) at some point within the three-year follow-up period. Of note, three patients developed type I endoleak, all of which underwent placement of proximal extension cuffs and therefore had resolved on repeat post-reintervention imaging. Additionally, of the 26 total patients who at any point had a type II endoleak, 12 (46%) resolved on subsequent imaging, with only one of these patients (3.8%) undergoing reintervention. Therefore, by three-year follow-up, only 14 patients (7.9%) had unresolved type II endoleak, and no patients had

other types of unresolved endoleaks. Graft limb occlusion occurred in 2.3% of patients, and migration occurred in no patients.

Fifteen secondary interventions were performed in 11 (6.2%) patients (Table VI). One patient on postoperative day zero returned to the operating room for a renal artery occlusion, which was treated successfully. Six patients (3.4%) underwent reintervention for graft limb thrombosis within the first year, one of whom underwent three reinterventions in two days. Finally, three patients (1.7%) underwent reintervention for type I endoleak, and one (0.6%) for type II endoleak. Notably, the patient who underwent reintervention for type II endoleak had aneurysm sac diameter decrease of > 5 mm at the follow-up visits before and after reintervention. None of the three patients who had EVAR outside of the device IFU underwent reintervention. Again, no patients underwent conversion to open repair or experienced aneurysm rupture. In a Cox regression model, the only variable independently associated with reintervention throughout follow-up was younger age (Hazard Ratio 3.3 per younger decade, 95% Confidence Interval 1.3 – 7.6, $P < .01$) (Table VII). Female sex and neck diameter, length, and angulation were not associated with reintervention.

Discussion

We report the first detailed clinical prospective outcomes following EVAR using the Medtronic Endurant Stent Graft System after its FDA-approval for use in the United States in which almost all performed procedures met IFU. Stent graft evolution has led to increasingly optimal designs, focusing on improving deployment precision, graft flexibility, and sheath profile, while also accommodating more challenging anatomy, including short infrarenal necks, aortic tortuosity, and calcified and/or stenotic iliac arteries. The Medtronic Endurant was specifically designed to improve upon earlier designs, by allowing for treatment of patients with more complex proximal neck anatomy.

The results following EVAR with the Endurant stent graft were originally described as part of a large global registry prior to approval of the graft in the United States.^{5, 6} In that series of more than 1,200 patients from 79 centers and 30 countries, intraoperative technical success was achieved in 99.0% with a 1.3% perioperative mortality.⁵ We had similar outcomes, with 98.9% technical success and 1.1% perioperative mortality. No patients experienced rupture or conversion to open repair, either in the first 30-days or throughout a median follow-up of 37 months. Furthermore, despite inclusion of all our patients in a clinical trial, the trial was not limited to patients considered high-risk, as in the global series,^{5, 6} or to academic centers of excellence with high EVAR volume, so these results may be more representative of “real-world” outcomes.

More importantly, however, 98.3% of patients met the Instructions for Use for this graft. The Endurant design allows for wider neck, shorter neck length, and greater neck angulation than other commonly used modern endografts. Indeed, 8 of 178 (4.5%) of the patients in this cohort would not have met IFU for the Ovation stent graft, 30 (17%) would not meet IFU for the AFX2 stent graft, 38 (21%) would not meet IFU for the Excluder, and 44 (25%) would not meet IFU for the Zenith stent graft. Therefore, despite almost universal adherence to the IFU of this device, the anatomy of patients included in this series was such that many would

not have met IFU for other modern devices. With this in mind, the results were quite good, with excellent technical success, no conversion to open repair or rupture, and very low rates of reintervention in the first three years. The technical success rate of 98.9% was in line with that identified by the global Endurant registry (99%),⁵ by a large Italian registry using the Gore Excluder (97.5%),⁸ and by the multicenter U.S. series using the Cook Zenith stentgraft (99.5%).⁹ Despite more complex anatomy that is outside of the IFU for other devices, the Endurant is associated with similarly excellent initial technical success.

Furthermore, late graft-related outcomes, including reintervention, are on par if not slightly lower than other similar contemporary grafts. With a median follow-up of 37 months, or just over three years, we identified a 6.7% rate of reintervention, with 15 reinterventions occurring in 11 patients. Of these 11 patients, five patients developed proximal seal issues (2.8%), and six underwent reintervention for graft limb thrombosis (3.4%). These results are comparable to those identified by 't Mannetje et al., who compared the earlier Medtronic Talent device to the Endurant stent graft, and identified varying indications for reintervention, with the Endurant stent graft having fewer proximal neck-related reinterventions (4.8% vs. 18.2%) but more iliac limb stenosis complications (4.8% vs. 0%).¹² Although their follow-up extended to a median of 59 months, we identified fewer reinterventions overall by 3-year follow-up than they identified by 1-year (10.7%) and certainly by 5-years (24.8%), which may perhaps be due to inclusion of fewer patients outside of the device IFU in our series. However, none of the patients who underwent EVAR outside of the device IFU underwent a reintervention in our series. Additionally, none of our patients experienced late aneurysm rupture or underwent conversion to open repair. Interestingly, our paper also has higher rates of inclusion of female patients than other clinical registries, with rates of 18% compared to 6–10%.^{5, 8, 9} While this series did not show female sex to be significantly associated with need for reintervention, it may have been underpowered to detect a difference. As female patients have repeatedly been shown to have worse outcomes following EVAR and more complex anatomy, the low rates of reintervention seen in this series are again quite impressive.^{10, 11}

Comparative studies between grafts are warranted that include anatomic data to most appropriately guide graft selection. While our overall three-year reintervention rate was comparable to if not slightly lower than other contemporary grafts with reintervention rates of more than 10%, these were likely different populations of patients with different demographic and anatomic criteria.^{13–15} General consensus is that outcomes following EVAR are improving over time, likely due to a combination of graft evolution and operator experience.⁴ Several series have directly compared early stent grafts to later stent grafts, and have identified lower perioperative mortality, higher intraoperative technical success, and lower rates of reintervention throughout follow-up in the more contemporary cohort.^{16–18}

This study must be interpreted within the confines of its design. While this was a clinical trial with prospectively-collected data, it was conducted with a single arm and therefore was merely descriptive in nature. Outcomes are per investigator review, without an independent core laboratory review. Additionally, while the inclusion criteria for this device and the study were wide, we do not know how patients were selected for inclusion in this study, or what type of repair or device they were offered if not included in this study. No direct comparison

between the Endurant and other devices could be made, and even a retrospective analysis would be inappropriate given the wider inclusion criteria of the Endurant compared to other modern devices. Furthermore, we were unable to comment on the performance of the Endurant stent graft outside of its IFU, as nearly all patients met IFU in this series. To make any conclusions regarding the appropriateness of one stent graft above another, randomized multicenter studies, ideally stratified on anatomic characteristics, of large patient populations with extended long-term follow-up would be necessary.

Conclusions

The Endurant stent graft system can achieve excellent short-term and mid-term results despite wide anatomic inclusion criteria. Reintervention is low, with only one in 16 patients undergoing reintervention by three-year follow-up. Longer-term follow-up with detailed anatomic data from large, multicenter registries could improve graft selection in the future.

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Figure 1.
Kaplan Meier Estimates for Freedom from Aneurysm-Related Mortality, All-Cause Mortality, and Reintervention through Three Years

Table I**Demographics and Comorbid Conditions**

	N (%) or Median (IQR)
Male	146 (82%)
White Race	169 (95%)
Age, years	71 (66–79)
Prior AAA Repair	9 (5.1%)
Prior TAA Repair	3 (1.7%)
Peripheral Vascular Disease	45 (25%)
Stroke/Transient Ischemic Attack	28 (16%)
Coronary Artery Disease	88 (49%)
Prior CABG	43 (24%)
Prior PCI	38 (21%)
Congestive Heart Failure	17 (9.6%)
Smoker	95 (54%)
Chronic Obstructive Pulmonary Disease	58 (33%)
Renal Insufficiency	20 (11%)
Diabetes	35 (20%)

IQR = interquartile range; AAA = abdominal aortic aneurysm; TAA = thoracic aortic aneurysm; CABG = coronary artery bypass graft; PCI = percutaneous coronary intervention

Table II**Aneurysm Dimensions**

	Median (Range)	IFU	Number Outside of IFU
Maximum Aneurysm Diameter, mm	54.5 (42 – 98)	-	-
Neck Diameter, mm	23.5 (19 – 40)	19 – 32 mm	1/178
Right Iliac Artery, mm	13 (8 – 24)	8 – 25 mm	0
Left Iliac Artery, mm	13 (8 – 25)	8 – 25 mm	0
Neck Length, mm	25 (5 – 76)	10–15 mm	2/178 ^a
Suprarenal Angulation, °	12 (0 – 60)	60°	0
Infrarenal Angulation, °	25 (0 – 60)	75°	0

^aBoth of these patients had aneurysm neck length between 10–15 mm but had infrarenal neck angle 60° (in which patients the neck length should be 15 mm instead of the usual 10 mm).

Table IIIa

Type of Implanted Device

	Percent Used
Main Bifurcated	100%
Contralateral Limb	100%
Extension – any type	32.2%
Extension – iliac	28.2%
Extension – aorta	4.0%

Table IIIb

Number of Implanted Device

# of Devices Implanted	Number
1	0%
2	37.9% (67)
3	35.0% (62)
4	26.0% (46)
5	1.1% (2)

Table IV

Perioperative (30-Day) Outcomes

	N (%) of Patients
All-Cause Mortality ^a	2 (1.1%)
Aneurysm-Related Mortality	2 (1.1%)
Any Serious Adverse Event	44 (25%)
Vascular	7(3.9%)
Neurologic	3 (1.7%)
Respiratory	11 (6.2%)
Cardiac	15 (8.4%)
Gastrointestinal	2 (1.1%)
Renal	6 (3.4%)
Bleeding	15 (8.4%)

^aCause of death listed as cardiac arrest for 1 patient and cardiopulmonary failure for another.

Table V

Kaplan-Meier Estimates for Death and Major Vascular Complications at Three Years

	3-Year Outcomes	95% CI
Aneurysm-Related Mortality ^a	1.1%	0.3 - 4.4%
All-Cause Mortality	13%	8.8 - 19%
Aneurysm Rupture	0%	--
Conversion to Open Repair	0%	--
Any Secondary Intervention	6.1%	3.3 - 11%
Endoleak - any	18%	12 - 25%
Type Ia	2.1%	0.7 - 6.4%
Type II	16%	11 - 23%
Graft Occlusion	2.3%	0.9 - 5.9%
Stent Graft Migration	0%	--
Thrombosis	0.6%	0.1 - 4.1%
Peripheral Ischemia	0.6%	0.1 - 4.2%

^aThe two cases of aneurysm-related mortality were both perioperative (30-day) deaths, with 0% aneurysm-related mortality after the first 30 postoperative days.

Table VI

Indications for Secondary Endovascular Interventions in 11 of 178 (6.2%) of Patients after EVAR

Distinct Patients	Days from Implant	Reason for Secondary Procedure
Patient 1	0	Renal artery occlusion
Patient 2	5	Iliac limb occlusion
Patient 3	8, 9, 10	Iliac limb occlusion
Patient 4	14	Iliac limb occlusion
Patient 5	32	Iliac limb occlusion
Patient 6	32	Type Ia endoleak
Patient 7	109, 110, 110	Iliac limb occlusion and kink in distal aortic section of graft
Patient 8	162	Iliac limb occlusion
Patient 9	343	Type Ia endoleak
Patient 10	819	Type II endoleak
Patient 11	861	Type Ia endoleak

Table VII

Demographic and anatomic variables associated with reintervention throughout follow-up after EVAR

	Hazard Ratio	95% Confidence Interval	P-Value
Age, per younger decade	3.3	1.3 – 7.6	< .01
Female Sex	3.3	0.7 – 15	.14
Neck Diameter	1.05	0.87 – 1.27	.53
Neck Length	1.02	0.97 – 1.07	.46
Suprarenal Angle	1.01	0.96 – 1.07	.60
Infrarenal Angle	1.00	0.95 – 1.04	.92