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Five Year Patient Outcomes of Endovascular Abdominal Aortic Aneurysm Repair in the ENDURANT France Registry

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WHAT THIS PAPER ADDS

This analysis of the ENDURANT France registry provides five year outcomes from a French population treated under real life conditions. Patients experienced a 69.9% ± 3.5% Kaplan–Meier overall survival, 97.6% ± 1.2% freedom from aneurysm related mortality, low rates of type IA endoleaks, few secondary procedures, and showed positive signs of remodelling. These outcomes are similar to other recent global registries and better than the outcomes with earlier generation devices. With the current focus on managing costs and re-imbursements, these five year outcomes of a French specific cohort provide further evidence of the long term durability and success with the Endurant stent graft system.

Objective: Endovascular repair is the preferred method of treatment for infrarenal abdominal aortic aneurysms with numerous publications from multiple geographic regions showing excellent patient outcomes. Since the original ACE (Anevrysme de l'aorte abdominale: Chirurgie versus Endoprothese) randomised control trial, studies of French specific population have also contributed significantly to the body of evidence in support of endovascular abdominal aortic repair.

Methods: In the ENDURANT France registry, 180 patients were consecutively enrolled from 20 French centres starting in 2012. Investigational sites included public and private practice and differing centre volumes to be as representative of real world French experience as possible. The aim of this study was to present the five year outcomes from this registry.

Results: Instructions for use (IFU) were respected in 97.8% (176/180) of patients. At five years, the Kaplan–Meier overall survival was 69.9% ± 3.5% and the freedom from aneurysm related death was 97.6% ± 1.2%. The freedom from Type IA endoleaks was 94.5% ± 1.7%, freedom from endoleaks of any type was 70.1 ± 3.4%, and freedom from secondary endovascular procedure 90.4% ± 2.6%. In addition, 61.6% (45/73) of patients exhibited sac shrinkage at five years.

Conclusion: In this five year report of the Endurant France registry, survival, re-intervention, and freedom from endoleak rates were comparable to recent EVAR registries and there was a high sac shrinkage rate. Secondary procedure and aneurysm rupture were lower than those of ACE, the French RCT which included older generation devices. This prospective registry demonstrates favourable five year outcomes of the Endurant stent graft used within IFU.

Keywords: Endurant stent graft, EVAR, France, Long term outcomes
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INTRODUCTION

Endovascular abdominal aortic aneurysm repair (EVAR) has better short term outcomes than open surgical repair (OSR)[1–3] but in the long term there was concern for a higher risk of migration, endoleaks, and rupture with a need for re-intervention with older generation devices.[4–6] Improvements in the design and delivery of modern stent grafts have reduced the frequency of those adverse events

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leading to EVAR becoming the first line treatment for infrarenal abdominal aortic aneurysms (AAAs).[7,8] There are currently numerous publications showing excellent outcomes in terms of survival, freedom from type I endoleaks, and re-interventions over five years and beyond.[9–12]

Patient data from French specific cohorts have contributed significantly to the literature surrounding the adoption and use of EVAR. The ACE (Anevrysme de l'aorte abdominale: Chirurgie versus Endoprothese) randomised controlled trial[5] compared OSR with EVAR similar to the other landmark trials, EVAR-1,[13] DREAM,[14] and OVER trial.[15] ECAR (Endovasculaire ou Chirurgie dans les Anévrysmes aorto-iliaques Rompus) randomised controlled trial[16] has investigated ruptured aorto-iliac aneurysms and the Windows registry has examined the use of fenestrated graft designs for complex aneurysm repair.[17,18] French specific post-market studies of all stent grafts are required by the French National Authority for Health (HAS) in order to receive reimbursement. This paper reports the five year results of the ENDURANT stent graft in the treatment of infrarenal abdominal aortic aneurysms (ENDURANT France registry) in a French population.

MATERIALS AND METHODS

The ENDURANT France registry (NCT01526811) is a prospective, multicentre single arm post-market registry. Between March 2012 and April 2013, 180 eligible patients were enrolled from 20 French centres (Supplementary Material 1) that included public/private practice, various geographical locations, and differing centre volumes to be as representative as possible of the real world French experience. Consecutive enrolment by the participating centres was required and subjects were considered enrolled on selection of the Endurant stent graft system[19] (Medtronic Inc., Santa Rosa, CA). To avoid any bias, study subjects in whom the stent graft was selected but not implanted (counted as a device failure) were still included in the study and clinically followed through the one month follow up before exiting. To reflect the real world EVAR experience, eligibility criteria were relatively liberal as regards instructions for use (IFU). Patients who fell outside of the IFU guidance were allowed to be enrolled into the study with physician and patient agreement with a protocol deviation form. As this was a non-interventional post-approval study, ethics committee approval was not required, and the registry adheres to the Declaration of Helsinki and applicable local regulations. All subjects were informed about the nature of data to be released including the study objectives, expected use of the data, beneficiaries, rights of access, rectification, and opposition and provided informed consent at the time of enrolment.

Study follow up and endpoints

The ENDURANT France registry did not require changes to routine clinical practice and follow up schedules. Subjects were recommended to have a follow up within 30 days following intervention, at six months, one year, and then annually over five years. Clinical and radiological follow up was conducted according to standard practice at each clinical site and included assessment of the AAA by either computed tomography (CT) or magnetic resonance angiogram or Doppler ultrasound (DUS) paired with abdominal X-rays. In addition, to stent performance measures such as fractures, occlusions, kinking, and twisting, the following endpoints were assessed at all time points over the five years: all cause mortality, aneurysm related mortality (ARM), conversion to open surgical repair (OSR), endovascular re-interventions, aneurysm diameter change, all types of endoleak, endograft migration.

All data were investigator reported as there was no clinical events committee for adjudicating events for this trial. Follow up compliance was carefully monitored by the Medtronic Bakken Research Centre B.V.

Statistical analysis. Data are presented with a mean $\pm$ standard deviation for continuous variables while a percentage of patients was reported for categorical variables. Outcomes such as all cause or aneurysm related mortality, and freedom from endoleaks or secondary endovascular interventions, were assessed over the five years with Kaplan–Meier survival analyses along with Greenwood standard error. All analyses were performed using SAS 9.4 (SAS Institute Inc, Cary, NC).

RESULTS

Baseline and procedural results

There were 74 subjects of the original 180 enrolled that left the study prematurely. There were 58 deaths, five subjects were lost to follow up, one patient opposed the release of personal data, and 10 were not seen for their five year follow up. Of the patients with a five year follow up form, the clinical and imaging follow up compliance was 82.4% (108/131) and 63.4% (83/131), respectively. The mean duration of clinical follow up for the implanted subjects was 1580.9 $\pm$ 543.2 days with half of the study population reaching 1805 days of follow up or more.

The baseline demographics and medical history of the ENDURANT France cohort are summarised in Table 1. The ENDURANT France population was 90.0% (162/180) male with a mean age of 74.6 $\pm$ 8.7 years old. The most common conditions in the medical history included 73.3% (132/180) with hypertension, 63.3% (114/180) with hyperlipidaemia, and 43.3% (78/180) with tobacco use within the last 10 years. Although eligibility criteria were minimal, 97.8% (176/180) of patients were implanted in accordance with the IFU. Of the four subjects that were implanted off label, one had a proximal non-aneurysmal aortic neck diameter of 18 mm, two had neck lengths $\geq$10 mm and $<$15 mm but infrarenal angles $>60^{\circ}$, and one subject had a neck length $\geq$15 mm but infrarenal neck angle $>75^{\circ}$.

The baseline anatomical characteristics and procedural data are reported in Table 2. Some challenging features of this cohort included 19.4% (35/180) of patients having aneurysms that involved an iliac artery, 22.8% (41/180)

Table 1. Baseline demographics and medical history of 180 patients treated with the Endurant stent graft for abdominal aortic aneurysm between March 2012 and April 2013 (ENDURANT France registry)

Patient characteristic	Patients (n = 180)
Age − y	74.6 ± 8.7
<65	31 (17.2)
65–75	58 (32.2)
>75	91 (50.6)
Gender − male	162 (90)
Risk factors	
Tobacco use in the last 10 years	78 (43.3)
Hypertension	132 (73.3)
Hyperlipidaemia	114 (63.3)
Diabetes	31 (17.2)
Obstructive arteriopathy of lower limbs	37 (20.6)
Coronary artery disease*	47 (26.1)
Chronic respiratory insufficiency†	11 (6.1)
Renal failure‡	10 (5.6)
SVS/ISCVS score	
0	0 (0)
1	24 (13.3)
2	85 (47.2)
3	59 (32.8)
Unknown	12 (6.7)
ASA classification	
Class I	12 (6.7)
Class II	63 (35)
Class III	95 (52.8)
Class IV	10 (5.6)
Indication for implant in accordance with IFU	176 (97.8)

Data are presented as n (%) or mean ± standard deviation. SVS/ISCVS = Society of Vascular Surgery/International Society of Cardiovascular Surgery; ASA = American Society of Anesthesiologists; IFU = instructions for use.

* Coronary artery disease (history of myocardial infarction or angina) with positive functional test and coronary lesions for which a revascularisation procedure is impossible or not indicated.

† Quantified by one of the following criteria: forced expiratory volume in 1 s (FEV1) < 1.2 L/s; vital capacity (VC) < 50% of the value predicted by age, sex and weight; arterial gases in the absence of oxygen: $PaCO_2$ > 45 mmHg or PaO_2 < 60 mmHg; domiciliary oxygen therapy.

‡ Serum creatinine > 200 µmol/L or 2.26 mg/dL before contrast injection.

Table 2. Anatomical characteristics and procedural data of 180 patients treated with the Endurant stent graft for abdominal aortic aneurysm between March 2012 and April 2013 (ENDURANT France registry)

	Patients (n = 180)
Infrarenal aortic aneurysm morphology	
Infrarenal angle − degrees	20.1 ± 20.6
Mean diameter − mm	56.6 ± 8.5
Non-aneurysmal aortic neck − mm	
Length	26.7 ± 12.2
Proximal diameter	24.1 ± 3.3
Distal diameter	25.1 ± 3.8
Diameter of access vessels − mm	
Right femoral artery	9.3 ± 2.0
Left femoral artery	9.3 ± 1.9
Subjects with aneurysm of iliac artery	35 (19.4)
Non-aneurysmal neck of iliac artery − mm	
Distal diameter of right iliac artery	14.4 ± 3.8
Distal diameter of left iliac artery	14.3 ± 3.1
Characteristics of proximal aortic neck	
Tapered	41 (22.8)
Presence of circumferential thrombus	40 (22.2)
Presence of major calcifications	16 (8.8)
Acute procedural data	
Duration of procedure − min	114.8 ± 52.1
Access technique	
Surgical	109 (60.6)
Percutaneous	71 (39.4)
Type of anaesthesia	
General	162 (90)
Local/Regional	18 (10)
Volume of contrast used − mL	123.0 ± 65.8
Fluoroscopy time − min	18.1 ± 13.5
Duration of ICU stay − h	22.6 ± 31.3
In hospital stay − d*	6.0 ± 5.0
Technical success	178 (98.9)
Surgical conversion at time of index procedure	0 (0)
Adjunctive procedure performed (surgical or endovascular)	39 (21.7)

Data are presented as mean ± standard deviation or as n (%).

* Procedural hospital stay = date of hospital discharge − date of initial procedure. In the case where hospital discharge was on the same day of initial procedure, procedural hospital stay was considered to be 0.5 day.

with tapered proximal aortic necks, 22.2% (40/180) with circumferential thrombus, and 6.1% (11/180) with major calcification of the proximal neck. Investigators assessed the index procedure technical success rate to be 98.9% (178/180).

All cause mortality and aneurysm related mortality

The five year Kaplan–Meier overall survival was 69.9% ± 3.5% (Fig. 1A) while freedom from aneurysm related death was 97.6% ± 1.2% with four deaths in the five years (Fig. 1B). Of the four ARMs, one patient died due to mesenteric infarction with a left colon necrosis and because this was four days after the procedure it was considered by definition to be aneurysm related. Another patient underwent a secondary procedure to treat thrombosis of the left limb of the stent graft which was complicated post-operatively by acute pulmonary oedema, heart failure, and eventually death 3.8 months after the index procedure. The third patients had an aorto-enteric fistula and following OSR had renal failure leading to death on day 929. The fourth patient presented with AAA rupture after repeated falls and had a technically successful open surgical repair as assessed by the investigator. Unfortunately, due to the patient's physical status, the open repair was followed by multiple organ failure and death 3.3 years after the index procedure.

Endoleaks

The freedom from Type IA endoleaks over the five years was 94.5% ± 1.7% (Fig. 2A). While the freedom from endoleaks of any type was 70.1% ± 3.4% (Fig. 2B), the majority of these endoleaks were Type II due to retrograde filling from collateral branches. Of the subjects that

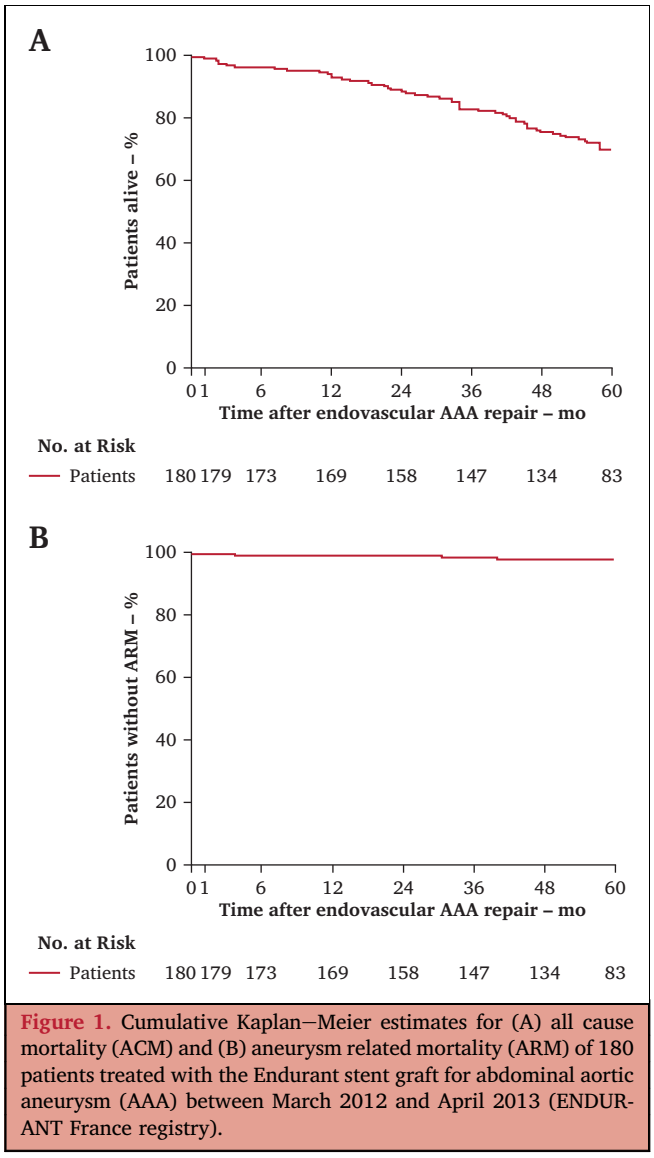

Figure 1. Cumulative Kaplan–Meier estimates for (A) all cause mortality (ACM) and (B) aneurysm related mortality (ARM) of 180 patients treated with the Endurant stent graft for abdominal aortic aneurysm (AAA) between March 2012 and April 2013 (ENDURANT France registry).

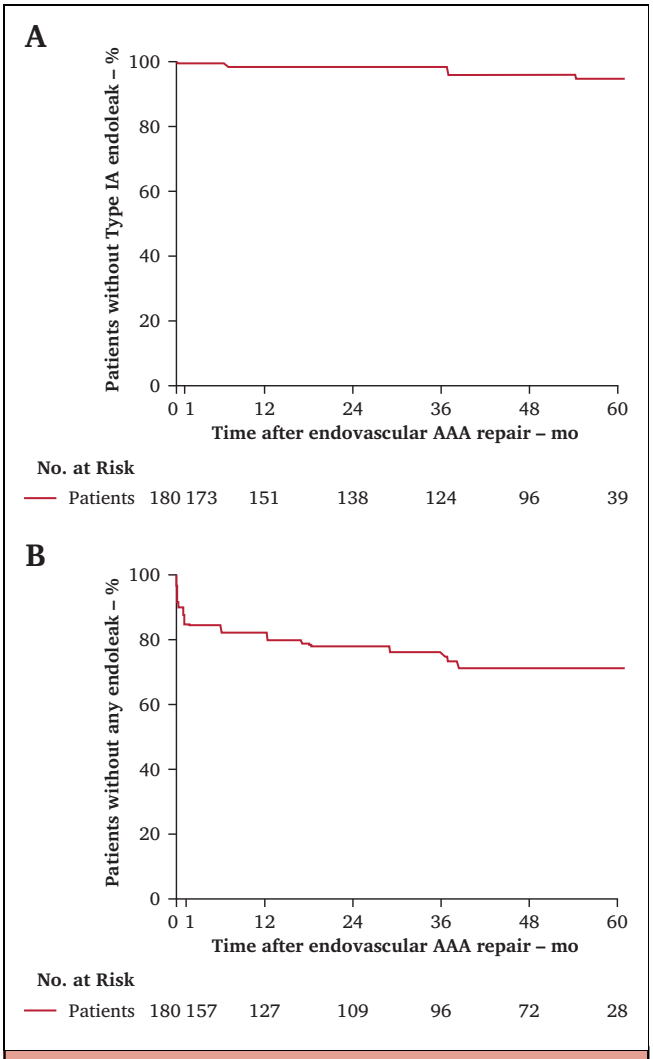

Figure 2. Interval censored freedom from estimates for (A) Type IA endoleaks and (B) any endoleaks in five year follow up of 180 patients treated with the Endurant stent graft for abdominal aortic aneurysm (AAA) between March 2012 and April 2013 (ENDURANT France registry).

presented with endoleaks, nine patients underwent 10 secondary procedures. There were three Type I, 4 Type II, 1 Type III, and 1 both Type I and II endoleaks that were treated endovascularly while 1 Type II endoleaks were treated surgically. There were no instances of stent graft migration, twisting, or fracture over the five years of follow up.

Secondary endovascular procedures, rupture, and conversion to open surgical repair

At five years, the freedom from secondary endovascular procedure was 90.4% ± 2.6% (Fig. 3). There was a total of 32 secondary procedures performed in 29 subjects with the 18 non-endovascular procedures consisting of extra-anatomic bypasses to treat stent graft limb occlusion ($n = 310$), conversion to open surgery ($n = 35$), and other ($n = 33$). Of the 14 patients that had secondary endovascular procedures, the reasons for the intervention were to treat endoleaks ($n = 39$), stenosis/occlusion/kinking ($n = 33$), and AAA growth ($n = 32$). Freedom from aneurysm rupture was 99.3% ± 0.7% with only one patient experiencing a rupture as described above. The freedom from conversion to OSR was 96.8% ± 1.4% at five years.

Aneurysm sac diameter and serious adverse events

Fig. 4 shows the proportion of patients with aneurysm sac diameter change over the five years of the study. Patients were grouped based on an increase of >5 mm in AAA diameter, a decrease of >5 mm in AAA diameter, or an absolute change in diameter of 5 mm or less with the AAA diameter at the one month follow up used as the baseline

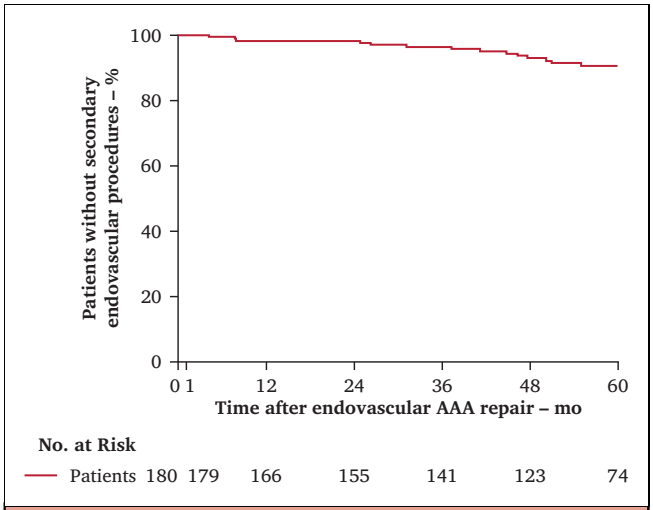

Figure 3. Cumulative Kaplan–Meier estimate of freedom from secondary endovascular procedures of 180 patients treated with the Endurant stent graft for abdominal aortic aneurysm (AAA) between March 2012 and April 2013 (ENDURANT France registry).

Table 3. Serious adverse events at 30 days and over five years in 180 patients treated with the Endurant stent graft for abdominal aortic aneurysm between March 2012 and April 2013 (ENDURANT France registry)

Serious adverse event in five years	Patients (n = 180)*	
	0–30 days	0–1826 days
Patients experiencing one or more SAEs†	14 (7.8)	86 (47.8)
Bleeding complications	3 (1.7)	5 (2.8)
Cardiac complications	2 (1.1)	16 (8.9)
Gastrointestinal complications	1 (0.6)	4 (2.2)
Neurological complications	0 (0)	5 (2.8)
Cerebrovascular accident – stroke	0 (0)	3 (1.7)
Pulmonary complications	0 (0)	12 (6.7)
Renal function complications	1 (0.6)	7 (3.9)
Technical observations	2 (1.1)	8 (4.4)
Stent graft infection	0 (0)	1 (0.6)
Stent graft occlusion	2 (1.1)	7 (3.9)
Vascular complications	2 (1.1)	26 (14.4)
Abdominal aortic aneurysm rupture	0 (0)	1 (0.6)
Aortic dissection	0 (0)	1 (0.6)

Data presented as n (%). SAE = serious adverse event.
* Number of patients at risk at the beginning of the time period.
† A patient may report multiple adverse events and in different categories; hence, number of patients in each category may not be the sum of those in each subcategory. Each patient was only counted once in each category.

measurement. A clear trend toward sac shrinkage was evident as 61.6% (45/73) of patients had a decreased sac diameter at five years. At the five year time point, 27.4% (20/73) patients had stable sac diameters and 11.0% (8/73) had an increase in sac diameter. Serious adverse events at 30 days as well as five years are presented in Table 3. Notably, the stroke rate was 1.7% (3/180) at five years and while 14.4% (26/180) had vascular complications, the majority of those were the endoleaks as detailed above.

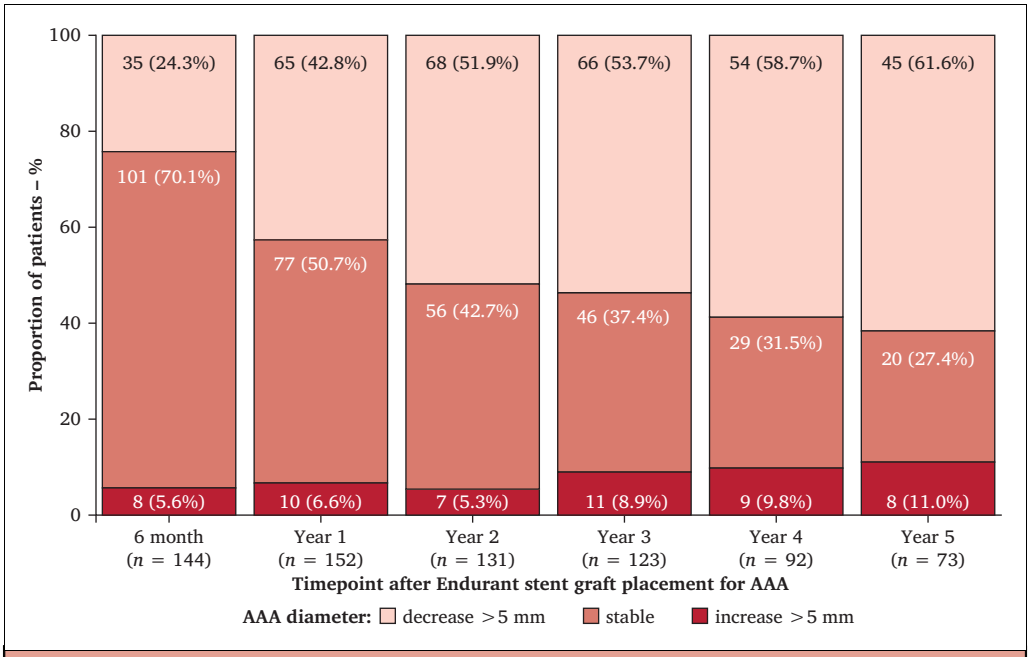

Figure 4. Change in maximum aneurysm diameter over time in 180 patients treated with the Endurant stent graft for abdominal aortic aneurysm (AAA) between March 2012 and April 2013 (ENDURANT France registry).

DISCUSSION

In this analysis of the ENDURANT France registry, the results show positive outcomes over the five years of follow up similar to other recent publications of current generation stent grafts. The ENGAGE registry which included data from 79 centres across 30 countries reported a 67.4% freedom from all cause mortality over the five years.[20] Other recent stent graft studies[10,11] also have survival rates of around 70% at five years. The freedom from aneurysm related mortality with recent generation devices,[21] in the ENGAGE registry,[20] and in this French cohort all exceeded 96%. Paired with 99.3% freedom from aneurysm rupture, this suggests that stent graft design is mature and that attention to other causes of death may be necessary in order to improve long term all cause mortality rates.

One outcome that continues to require monitoring post index procedure is endoleaks as they can lead to serious adverse events. This French cohort showed a high freedom from Type IA endoleak and any endoleak rate of around 95% and ~70%, in the range of previous publications[9,20] as well as reported in the current ESVS guidelines.[22] Not all patients with Type IA endoleaks received a secondary intervention which is concerning given the seriousness of this adverse event. Given the variation in types of centres in the study and without further details on the patients that were not treated, the authors can only speculate that patient decision, patients not returning to clinic, or other unknown factors could have led to the discrepancy between the occurrence of Type IA endoleaks and secondary procedures to treat them.

The majority of endoleaks in the cohort were Type II which are the most common.[23–25] Recommended management strategies for Type IIs are still under consideration as there are risks and benefits to early intervention *vs.* conservative management.[24,26] The ESVS guidelines support secondary interventions for Type II endoleak with significant aneurysm growth and a conservative approach in other cases.[27] While determining the best Type II management strategy is beyond the scope of this study, these data show that French surgeons generally preferred conservative management and followed ESVS guidelines. Only five patients underwent secondary procedures (four endovascular, one surgical) to treat Type II endoleaks and all procedures were considered successful by the investigator. There were few Type Ia endoleaks and a previous publication reported that the funnel shaped necks and mural thrombus that was evident in this cohort can be protective factors against the development of endoleaks.[28]

Notably 61% of patients had a decrease in aneurysm sac diameter at their five year follow up which is a strong indicator of device efficacy and could have played a role in the good survival outcomes in this cohort. The proportion of patients with sac diameter decrease is identical to what was reported at five years in the ENGAGE registry.[20] Although hypothetical, a multicentre registry from Ontario Canada reported thrombogenicity of the polyester fabric and good proximal sealing may play a role inducing thrombosis in the sac.[29] Furthermore, early sac shrinkage is associated with better long term results. Conversely, a recent report concluded that a stable sac is not as benign as once thought and both stable and enlarging sacs are associated with poorer long term survival.[30]

Another area of focus post-EVAR is the need for secondary procedures. The 81.5% freedom from any secondary procedure in this trial is very similar to several randomised controlled trials in which patients had strict inclusion criteria with regards to IFU compliance.[4,21] The majority of patients in this registry were also implanted in accordance with IFU, and this fact may explain the more favourable results of the French study with 90.4% freedom from secondary endovascular procedures, compared with 84.3% for the ENGAGE world registry.[20] In the ENGAGE world registry 17.8%[20] of patients were outside of the instructions for use while only 2.2% of the French cohort was implanted off label. The protocols for the ENGAGE and Endurant FRANCE studies were both designed to be “all comer” and specified the enrolment of consecutive patients to be reflective of the real world use. The difference in off label use suggests a difference of practice and that physicians adhering more strictly to the IFU are keen to offer alternative options for patients outside IFU. The rate of conversion to open repair was higher than was reported in the ENGAGE registry,[20] but still in line with a clinical trial of another current generation stent graft.[11]

The need for secondary procedures to treat limb occlusions in this trial was higher than those studies that only included Endurant stent grafts.[31] Studies on limb occlusions have reported risk factors such as distal landing zones in the external iliac artery (EIA) or smaller diameter of the EIAs.[32] Inaba *et al.* reported that use of an Endurant graft is a risk factor for limb occlusion[33] while other studies concluded earlier generation stent grafts are more likely to have occlusions compared with the current grafts.[34] It was beyond the scope of this study to assess potential causes leading to the limb occlusion rate although smaller arteries are unlikely as this registry cohort had iliac artery diameters similar to those reported in the ENGAGE registry.[20] Notably secondary procedures for limb occlusions are generally successful[31] with only one of the secondary procedures in this trial not resolving the problem. The authors stress the importance of the current ESVS guidelines that recommend assessing for potential graft occlusion if patients have a new onset or worsening of lower limb ischaemia after EVAR.[27] Identifying patients at high risk of limb occlusions[32] as demonstrated by the algorithm of Faure *et al.* is of paramount importance since additional intra-operative manoeuvres for example kissing balloon angioplasty and stenting of the graft and or the limbs could prevent occlusion.[35]

As the baseline characteristics of this cohort were very similar to other registries, it would be expected that the outcomes should also be in line with existing publications. This was also generally true when putting the Endurant France results in context with the French RCT, the ACE trial.

Overall survival, major adverse events including stroke, renal failure, and paraplegia were all very similar between the two French studies. Some notable differences were in the rates of secondary procedures in which 16% of the ACE population required re-interventions at three years[5] while a Kaplan–Meier estimate of 11.2% of patients needed a secondary procedure in the Endurant France cohort at three years. In the ACE trial, 2.0% of patients suffered aneurysm rupture after three years while in the Endurant France registry, there were no ruptures after three years and a Kaplan Meier estimate of 0.7% of patients with rupture after five years. The older generation stent grafts in the ACE trial performed similarly in older studies such at the EUROSTAR registry.[36] Current generation devices have been reported to have lower re-intervention and complication rates.[7,8,20] These favourable results are probably multifactorial: improved devices design, better pre-operative imaging, progress in software used for graft sizing, improved intra-operative imaging facilities, and improved surgeon training and experience.

Limitations

The Endurant France study was a real world registry that did not impose changes to routine clinical practices. Although the follow up compliance was generally satisfactory, long term surveillance is not easy, especially in an ageing population who may become reluctant to attend yearly medical visits and examinations. As expected with long term follow up, physicians often transition to using DUS for imaging and only pursuing a CT scan if there are concerns about endoleaks. This could lead to some inherent bias in comparing CT to DUS measurements in the calculations of maximum AAA diameter. In addition, this registry was observational in nature and without a control group, and there were no comparisons with open repair or other stents grafts. To assess if the trends noted here were mostly due to the peculiar design of the Endurant graft, in terms of the aneurysm shrinkage and low re-intervention and rupture rates the comparison with larger registries including all post-market stents grafts that were used in France during this time frame would be of value.

Conclusions

This five year report of the Endurant France registry showed that survival and freedom from endoleaks, aneurysm shrinkage and freedom from secondary re-intervention were very satisfactory compared with previous reports in this country. Respect for IFU probably played a major role for these favourable outcomes.

CONFLICT OF INTEREST

J.P.B. receives honoraria from Medtronic. None of the other authors have a financial relationship with a commercial entity that has an interest in the subject of the presented manuscript or other conflicts of interest to disclose.

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APPENDIX A. SUPPLEMENTARY DATA

Supplementary data to this article can be found online at https://doi.org/10.1016/j.ejvs.2020.08.034.

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