Durability of the Endurant stent graft in patients undergoing endovascular abdominal aortic aneurysm repair

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Objective: **Several studies have confirmed the excellent early performance of the Endurant (Medtronic Endovascular, Santa Rosa, Calif) endoprosthesis to treat abdominal aortic aneurysms (AAAs). However, data about the long-term durability of the device are still lacking. We conducted this prospective two-center single-arm study to assess the late outcomes of the endograft in patients undergoing AAA repair.**

Methods: **An intention-to-treat analysis was performed for all comers with AAAs who were implanted with an Endurant endograft between November 2007 and December 2010. Clinical and radiologic data were prospectively collected and analyzed. The primary end point was any AAA-related reintervention. Secondary end points were overall mortality, aneurysm shrinkage, all types of endoleak, and device-related complications.**

Results: **During the study period, 273 patients underwent implantation of the Endurant stent graft. The median follow-up time for the primary end point was 42 months (interquartile range, 30.7-50.7). AAA-related reinterventions were required in 26 patients (10%), resulting in a reintervention-free probability of 93%, 90%, and 87% at 3, 4, and 5 years, respectively. The leading cause for reintervention was iliac limb occlusion (n = 10). Only one AAA-related death (0.3%) was reported within an overall mortality of 29% (n = 78). The median aneurysm shrinkage was 9 mm (interquartile range, 3-15). Five type I (2%) and one type III (0.4%) endoleaks were identified. No proximal and two distal limb migrations (1%) were observed.**

Conclusions: **Our study confirms late durability of the Endurant endoprosthesis for AAA repair, with very encouraging freedom from reintervention rates and overall outcomes. (J Vasc Surg 2014;60:1125-31.)**

Although different randomized controlled trials and meta-analyses have shown comparable survival rates between open and endovascular repair of abdominal aortic aneurysms (AAAs), the issue of higher reintervention rates in endovascular AAA repair (EVAR) has challenged its efficacy and durability.[1-3] Whether these results adequately reflect the on-going transformational progress and refinements of the device design that have expanded the applicability of the EVAR to even more challenging anatomies remain controversial.[4]

In this context, the Endurant stent graft (Medtronic Endovascular, Santa Rosa, Calif) was designed to expand EVAR applicability to challenging AAA anatomy and to prevent reintervention in the long-term.[5] The unique aspects of the device are (1) the sinusoidal M-shaped form of the individual stents, (2) the small amplitude of the stent graft rings, (3) the active suprarenal fixation, and (4) the absence of a virtual columnar strength.[6] These characteristics aim to optimize sealing in short and angulated proximal necks by increasing the flexibility and theoretically preventing the proximal migration of the endograft.[6] The early and midterm evaluation of the device's performance revealed encouraging outcomes not only in friendly but also in challenging anatomic scenarios.[6-9] A number of series proved also early efficacy even outside of the instructions for use (IFU).[7,10]

The literature to date still lacks late results with this endograft to prove its durability and effectiveness.[4] The aim of this single-arm study was to evaluate the longer-term performance of the Endurant endoprosthesis in patients undergoing EVAR in two vascular centers.

METHODS

The design of this study was approved by the local Ethics Committee (Approval No. 2007-179-f-M) and all patients provided written informed consent.

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Author conflict of interest: none.

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Study cohort. Follow-up data of all consecutive patients undergoing implantation of the Endurant stent graft for AAA repair between November 2007 and December 2010 were prospectively collected and analyzed in an intention-to-treat fashion. The specific features of the Endurant stent graft and the procedural details have been described extensively elsewhere.[6] Of note, a balloon-expandable stent in each limb (by means of kissing-balloon technique or single placement) was routinely used in case of a narrow distal aortic neck (<2.0 cm) or evidence of >70° stenosed Endurant limb after removal of the stiff wires and performance of the final angiography.

Demographics, comorbidities, and clinical data from all patients were recorded in a prospective vascular database. The clinical follow-up included the findings of the most current clinical investigation in our outpatient department or by the attending general practitioner. In addition, a telephone interview with all patients or their relatives was performed to assess survival status. Causes of death were clarified by contacting the treating general practitioner.

The strict imaging surveillance protocol of EVAR patients is well standardized in both institutions and previously published.[6] Patients with a glomerular filtration rate >60 mL/min/1.73 m^2 or requiring dialysis underwent computed tomography angiography (CTA) of the abdomen before discharge, after 1 year (duplex ultrasound imaging at 6 months), and then annually up to 5 years in case of an uncomplicated postinterventional course.

Patients with chronic or acute renal disease (glomerular filtration rate between 15 and <60 mL/min/1.73 m^2) underwent duplex ultrasound imaging and native computed tomography at the same intervals. In case of AAA-related symptoms or high suspicion of endoleaks, a magnetic resonance angiography or CTA was performed. Our protocol for unscheduled CTA in patients with renal disease consists of (1) hydration with *N*-acetyl-cysteine before and after the investigation, (2) consultation by the institution's nephrologist, and (3) CTA by contrast agent administration through a transbrachially placed 5F straight angiographic Radiofocus catheter (Terumo Medical Corp, Somerset, NJ). The angiographic catheter is placed at the level of the proximal descending aorta, and only 20 to 40 mL contrast agent are used. The straight catheter can be safely removed in the ward.

End points and definitions. The primary end point of the study was any AAA-related reintervention. Secondary end points included (1) aneurysm shrinkage, (2) occurrence of endoleak (all types),[3] (3) device-related complications, including migration and graft/iliac limb occlusion, and (4) death for any reason during the long-term (overall mortality).

All measurements before EVAR were performed directly only by vascular surgeons. In the framework of this study, all postoperative imaging studies were reanalyzed by an independent radiologist with advanced experience in endovascular aortic surgery and two experienced vascular surgeons.

Table I. Patient characteristics and demographics at time of endovascular abdominal aortic aneurysm (AAA) repair (EVAR) with the Endurant[a] endograft

Variables	*No. (%) or mean ± SD (N = 273)*
Male	246 (90)
Age, years	73 ± 9
Comorbidities	
Arterial hypertension	226 (83)
Diabetes mellitus	45 (17)
Dyslipidemia	126 (46)
Tobacco use	182 (67)
Coronary artery disease	150 (55)
Myocardial infarction <6 months	89 (33)
Chronic obstructive pulmonary disease	100 (37)
Obesity	88 (32)
Creatinine >1.7 mg/dL	31 (11)
Previous laparotomy	50 (18)
Symptomatic aneurysms	18 (7)
Contained ruptured aneurysms	5 (2)

SD, Standard deviation.
[a]Medtronic Endovascular, Santa Rosa, Calif.

Table II. Anatomic characteristics and reasons for implantation outside the instructions for use (*IFU*) in 79 patients within our study cohort

Characteristics and reasons	*Median (range) or No. (%) (N = 79)*
Anatomic characteristics	
Angulation,°	65 (10-90)
Left iliac artery	45 (15-110)
Right iliac artery	45 (10-90)
Length of proximal neck, mm	9 (7-39)
Maximal AAA diameter mm	57 (40-87)
Proximal neck diameter, mm	26 (17-33)
Reasons[a]	
Infrarenal angulation >60° and	
Neck length >10 mm	31 (39)
Neck length <10 mm	9 (11)
Neck length <10 mm	37 (47)
Reverse tapered proximal neck	32 (41)
Circumferential thrombus at proximal neck	17 (22)

AAA, Abdominal aortic aneurysm.
[a]In 13 of 79 patients (16%), the IFU were exceeded in more than one categories.

Statistical analysis. For all analyses and graphs, MedCalc 9.4.2.0 software (Mariakerke, Belgium) was used. Categoric variables are presented as percentages, and continuous variables as mean ± standard deviation or median and interquartile ranges (IQRs) or range. Distribution was assessed by the D'Agostino-Pearson test. Continuous normally distributed variables were compared with the *t*-test for paired samples (AAA shrinkage), and non-normally distributed variables were compared with the Mann-Whitney test. The survival- and reintervention-free probability rates were demonstrated by means of Kaplan-Meier curves. Cox regression analysis with backward stepwise selection was performed to identify

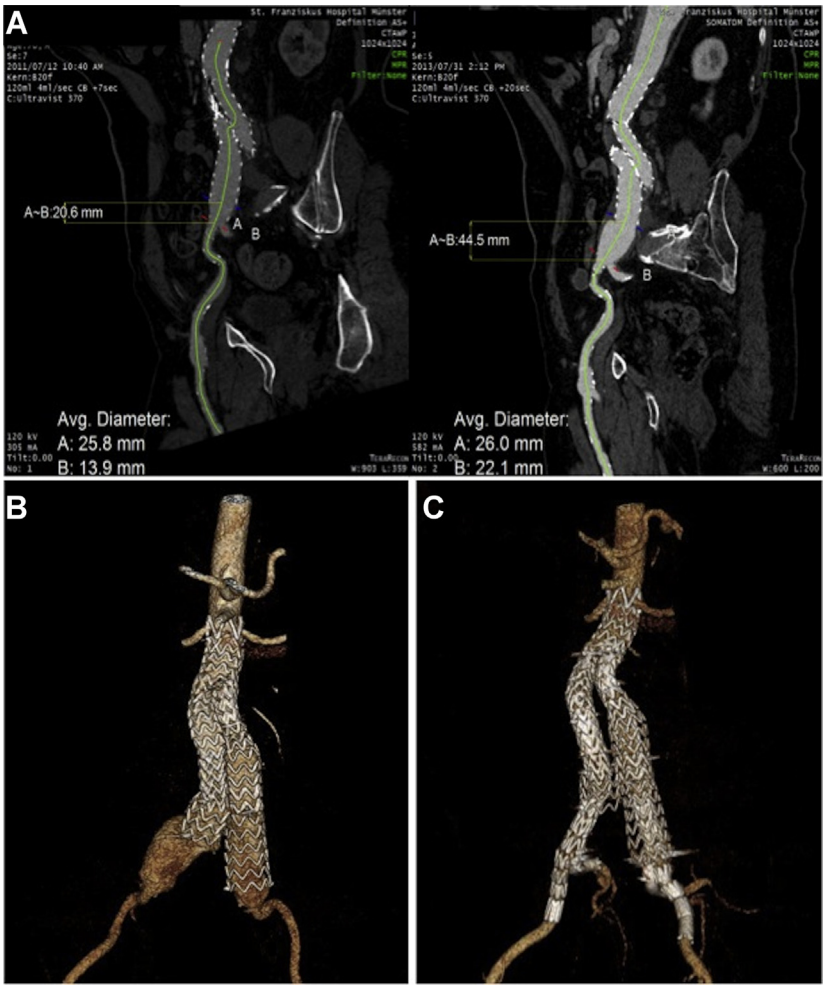

Fig 1. A, The centerline (*green line*), calibrated with Aquarius software (TeraRecon, Foster City, Calif), is used to assess the migration of the distal iliac limb. **B,** Type Ib endoleak due to aneurysmatic degeneration of both common iliac arteries. **C,** Endovascular repair of both iliac arteries with an iliac side branch device (Cook Medical, Bloomington, Ind).

potential independent risk factors for the primary end point in the long-term. A *P* value of <.05 was considered statistically significant.

RESULTS

During the study period, 277 patients underwent implantation of an Endurant stent graft. Four patients (1%) could not be contacted during follow-up (among whom two live abroad). The final study cohort consisted of 273 patients. Table I summarizes demographics and characteristics of the study cohort at the time of intervention.

The median duration of the initial intervention was 69 minutes (IQR, 60-90 minutes). The device could not be implanted in one patient due to stenotic iliac vessels, and the procedure was abandoned (technical success, 99.7%). General anesthesia was used in 34 patients (13%).

Among the study population, 86 patients (48%) showed a patent inferior mesenteric artery on the preoperative CTA. Only one patient underwent embolization of the inferior mesenteric artery during EVAR. The reason was the existence of a prominent inferior mesenteric artery and the inability of the patient to follow our surveillance protocol. Perioperative type II endoleak was detected in 133 patients (49%).

Table II presents the anatomic characteristics of the 79 patients (29%) who were treated outside of the device IFU during the study period. The three most common reasons for the endograft being used outside of the IFU were a neck length <10 mm (47%), a reverse tapered neck (41%), and an infrarenal angulation of the proximal neck >60° (39%). A narrow distal neck, as defined above, was present in 20 of 273 patients (7%) at the time of stent graft implantation.

Primary end point. The median clinical follow-up time for the primary end point was 42 months (IQR, 31-50 months). During the follow-up period, 26 patients

Table III. Indications for reintervention and secondary procedures in 26 patients

Indications	*No.*	*Secondary procedure*	*No.*
Type Ia endoleak[a]	3	Explantation of the endograft and open repair[a]	1
		Proximal cuff[b]	1
		Chimney endografting and use of Onyx[b,c]	1
Type Ib endoleak	2	Iliac side branch device	2
Type II endoleak	4	Embolization of the inferior mesenteric artery	3
		Open repair[d]	1
Type III endoleak	1	Implantation of an additional Endurant limb[e]	1
Renal artery occlusion	1	Chimney endografting (unsuccessful) and iliac-to-renal bypass (no dialysis)	1
Progression of aneurysmal disease distal (common iliac artery)	1	Iliac side-branch device	1
Limb occlusion	10	Thrombectomy and stenting	6
		Cross-over bypass	4
Bowel ischemia	1	Hemicolectomy	1
False aneurysm	1	Overstitch of the common femoral artery	1
Distal popliteal artery embolization[e,f]	1	Thrombectomy, distal extension of the iliac limb with Advanta V12 stent graft[g]	1
Groin infection	1	Vacuum-assisted closure device	1

[a]Crawford type A aortic dissection.
[b]Aneurysmatic degeneration without migration.
[c]ev3 Endovascular Inc, Plymouth, Minn.
[d]In this patient, the type II endoleak could not be identified in the computed tomography angiography (CTA); due to aneurysm growth, an open repair confirmed the type II endoleak (lumbar arteries).
[e]Medtronic Endovascular, Santa Rosa, Calif.
[f]Thrombus distal to the iliac limb of the endograft.
[g]Atrium Europe, Mijdrecht, Netherlands.

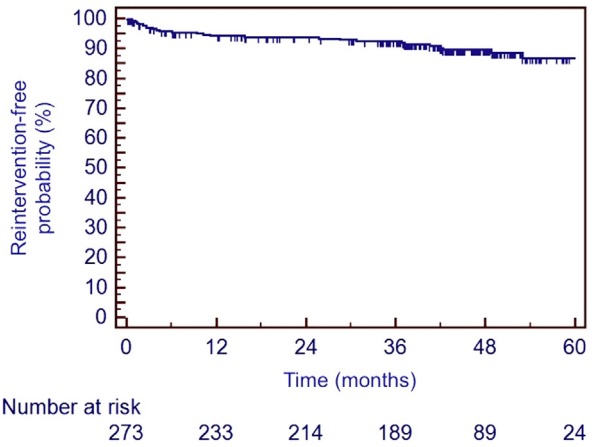

Fig 2. Kaplan-Meier curve presents the reintervention-free probability in our study cohort (standard error >10% at 49 months).

(10%) reached the primary end point. The indications for reinterventions and the respective secondary procedures (Fig 1) are summarized in Table III. The freedom from reintervention rate was 93%, 90%, and 87% at 3, 4, and 5 years, respectively (Fig 2). The Cox regression analysis revealed that type II endoleak (intraoperatively or postoperatively identified), implantation against IFU, peripheral vascular disease, and gender were not risk factors for reintervention. Early reinterventions (<1 year) were performed in 13 of 26 patients (50%) and late secondary procedures (>4 years) in four of 26 patients (15%).

Secondary end points. The overall mortality was 29% (n = 78). The causes of death are presented in Table IV.

Table IV. Causes of death in our study cohort

Cause of death	*Patients (N = 273), No. (%)*[a]
Death	78 (29)
AAA-related	1 (2)
Cardiac	29 (43)
Carcinoma	13 (19)
Pulmonary	14 (21)
Sepsis	6 (9)
Stroke	4 (6)
Suicide	1 (2)
Unknown	10 (13)

AAA, Abdominal aortic aneurysm.
[a]The cause of death was known in 68 patients, and the percentages were calculated with this number.

The survival rates during a median follow-up of 43 months (IQR, 35-59 months) were 77%, 73%, and 67% at 3, 4, and 5 years, respectively (Fig 3). Only one AAA-related death was observed in the case of the only technical failure to advance the endograft. The patient was denied open repair due to severe heart insufficiency (New York Heart Association class IV), and the aneurysm ruptured 2 weeks later.

Type Ia and Ib endoleaks were reported in three and two patients (2%), respectively. Mean time of radiologic diagnosis of the type I endoleak was at 42 months (IQR, 26-51 months). The diameters of the index common iliac artery at the time of implantation in the two patients with type Ib endoleak were 13 and 22 mm, respectively. Type III endoleak was observed in one patient (0.3%; Table III) at 10 months. Persistent type II endoleaks were reported in 26 patients (10%; Table II), with a median

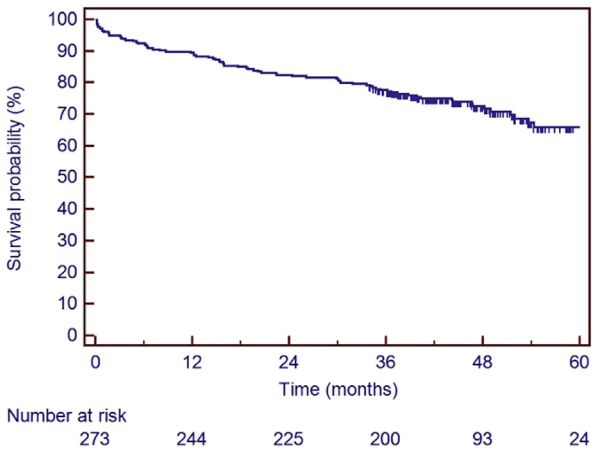

Fig 3. Kaplan-Meier curve presents the probability of survival in our study cohort (standard error >10% at 57 months).

time of CTA-based diagnosis of 22 months (IQR, 6-39 months).

Mean aneurysm shrinkage was 9 mm (IQR, 3-15 mm; $P < .0001$; Figs 4 and 5). Aneurysm shrinkage >5 mm was observed in 158 patients (58%; Fig 4). Patients with aneurysm shrinkage >5 mm also lived statistically significantly longer than these without shrinkage during the surveillance period, with a median survival time of 45 months (IQR, 39-54 months) vs 37 months (IQR, 13-47 months; $P < .0001$). Device-related complications consisted of iliac limb thrombosis in 10 (4%) and distal migration in two patients (1%; Table III). No patients required operations due to stent graft infection.

DISCUSSION

Numerous studies have shown excellent early outcomes and rates of technical success with the Endurant endograft for AAA repair.[5-13] We have already published outcomes at 2 years with this endograft in a part of the present study cohort.[6] However, a particular scepticism about the durability of the device has been expressed, considering the high rates of EVAR-related reinterventions in all randomized controlled trials of EVAR compared with open repair.[1-4] To contribute to the debate, we conducted this retrospective analysis of our prospectively collected data to assess the late performance of the Endurant stent graft. To our knowledge, the present article represents the largest series of patients to date treated by the Endurant device for the mentioned study period reporting on late clinical and radiologic outcomes. Our results showed an excellent durability of the device, with a reintervention-free probability of 93%, 90%, and 87% at 3, 4, and 5 years, respectively.

Our overall reintervention rates (10%) were lower compared with the reported secondary procedures in all randomized controlled trials.[1-3] However, we acknowledge that the study period, the number of centers, and the devices used in the randomized trials are totally different from our study design, where only one stent graft of the last generation was tested. The reintervention-free survival rates in Dutch Randomised Endovascular Aneurysm Management (DREAM) trial at 5 years were <80% with reported 6-year rates of 70%.[1] The Veterans Affairs Open vs Endovascular Repair (OVER) trialists reported 22% reintervention rates after a mean follow-up of 5.2 years.[2] Similar reintervention rates of 23% were observed by the Comparison of Endovascular Aneurysm Repair with Open Repair in Patients with Abdominal Aortic Aneurysm (EVAR) trialists after a median follow-up time of 6 years.[3]

An additional finding in our study was that implantation of the device against the IFU seems not to be a risk factor for reintervention, confirming our already 1-year published experience.[10] Of note, the shortest proximal neck length and the maximum proximal neck diameter treated by means of EVAR in this cohort were 7 mm and 33 mm, respectively. In case of shorter neck lengths, we advocate open repair in fit patients and fenestrated or chimney endografting in asymptomatic or symptomatic high-risk patients, respectively. Our algorithm has been previously published.[12] Furthermore, in case of a symptomatic presentation, aneurysms <5 cm were also endovascularly repaired.

In our study cohort, 50% of the secondary procedures were performed during the first year after EVAR. Two patients showed a late type Ib endoleak, one at 49 months and the other at 53 months, due to progression of the aneurysmatic disease at the level of the common iliac arteries (Fig 1). One type Ia endoleak was diagnosed at 3 months; in this patient, the endograft was placed outside of the IFU (8 mm proximal neck length, reverse tapered neck). Two type Ia endoleaks were also diagnosed at 51 and 54 months after EVAR, one due to progression of the aneurysmatic disease at the level of the suprarenal aorta and one due to a Crawford type A dissection. In both patients, the implantation was performed inside the IFU. All late endoleaks were asymptomatic and first identified thanks to our strict surveillance and imaging protocol.

Another important finding was the limb/branch occlusion. Although the rate of occlusion was low (4%), it still remains the leading cause for reintervention. A similar occlusion rate of 4% (20 patients) was also shown by van Zeggeren et al[14] in 496 patients with the Endurant stent graft and a median follow-up of 1.7 years. Limb occlusion rates seem to be similar (~4%) between the studies, regardless the type of the device.

Currently, Cieri et al[15] reported 40 occlusions (3%) in 1450 different endovascular devices for AAA repair (83 Endurant stent grafts) during a comparable median follow-up of 45 months. Verhoeven et al[16] observed a 4% (n = 16) limb occlusions/kinking rate during a mean follow-up of 40 months in 365 patients with the Talent (Medtronic) endograft. In contrast to all other studies, Bos et al[17] found no graft limb occlusion with the Gore Excluder (W. L. Gore and Associates, Flagstaff, Ariz) in 92 selective cases (not all comers) during a median follow-up of 36 months.

In our analysis, implantation against IFU or peripheral vascular disease could not be identified as risk factors for

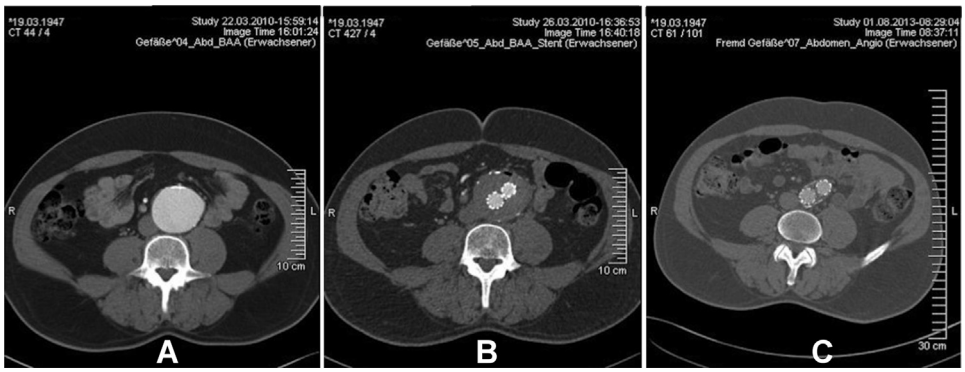

Fig 4. Computed tomography imaging (CTA) shows impressive aneurysm shrinkage 3 years after implantation of the Endurant (Medtronic Endovascular, Santa Rosa, Calif) stent graft. **A,** Preoperative CTA shows a 6-cm abdominal aortic aneurysm (AAA) without thrombus. **B,** Postoperative CTA after endovascular repair and before discharge. **C,** Postoperative CTA at 3 years shows the complete shrinkage of the aneurysm.

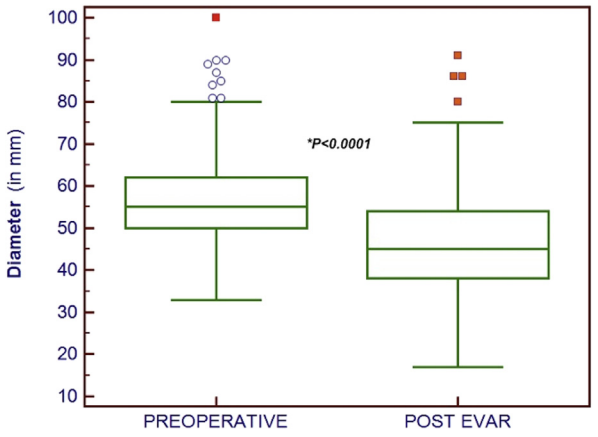

Fig 5. Box-and-whisker plot shows aneurysm diameter before and after endovascular aneurysm repair (*EVAR*) at the last follow-up in overall study cohort. The *horizontal line* in the middle of each box indicates the median; the *top and bottom borders* of the box mark the 75th and 25th percentiles, respectively, and the *whiskers* mark the 90th and 10th percentiles. The *circles* and *red squares* mark outliers.

limb occlusion. Our hypothesis for this complication is that the distal end of the iliac limbs is not always in an optimal apposition to the vessel wall of a tortuous or heavily calcified iliac artery, causing a form of high-grade stenosis or local vessel damage with intimal hyperplasia. This might be a reason of limb thrombosis in the long-term, but this hypothesis should be further investigated and proved.

Meanwhile, we have changed our policy by routinely relining the distal limbs of the device with an additional self-expanding stent in cases of tortuous or with a balloon-expandable stent in case of heavily calcified iliac arteries. Our aim is to achieve a gradual transition of the stent graft to the iliac anatomy and to configure a conic shape of the distal end of the Endurant limb.[18] Noteworthy is that the literature lacks data about the effect of the distal neck on limb patency, and this issue was outside of the topics of this study.

Impressing indeed was the rate of aneurysm shrinkage (Figs 4 and 5). Aneurysm shrinkage >5 mm was observed in 58% of our patients. Houbballah et al[19] showed that AAA shrinkage >5 mm after EVAR is associated with statistically significantly longer survival. This was also confirmed in our study, where the median survival time of patients with aneurysm shrinkage >5 mm was 8 months longer ($P < .0001$). In contrast to our study, Cieri et al[15] found lower but still comparable rates of aneurysm shrinkage of 40% (33 of 83 patients) in the Endurant group. However, their study did not report the exact follow-up time in patients receiving this specific device.

The migration rate of the Endurant endograft was also very low in this cohort (n = 2 [1%]), and no proximal migrations were reported. The progression of the aneurysmatic disease at the level of the common iliac arteries was the main reason (Fig 1). Compared with the predecessors, the AneuRx (Medtronic) and Talent endografts, the addition of the active suprarenal fixation seems to solve the past issue of high proximal migration rates of 6% reported by Verhoeven et al[16] investigating the Talent endoprosthesis. Of note, Bos et al[17] observed 3% type I endoleak and 2% migration with the Gore Excluder.

The last outcome analyzed in this study was the survival of our patients, with survival rates of 77%, 73%, and 67% at 3, 4, and 5 years, respectively. Similar trends were also observed in the randomized trials as well as in most retrospective studies.[1-3,15,16] In contrast to the randomized trials, we report no device-related deaths and only one AAA-related death caused by unsuccessful stent graft implantation. Nevertheless, the survival rates are very encouraging considering that we have included all consecutive patients, including many multimorbid patients unfit for open repair.

This study has some limitations. The design was nonrandomized, and no control arm was used. Despite the prospective design, the cause of death remained unknown

in 10 of 78 patients (13%). Thus, AAA-related deaths could not be definitely excluded in those patients, and this could be a bias of our study. Furthermore, the focus for the sepsis-related multiple organ failure in six patients was not confirmed. Considering that all six patients had pneumonia at admission, we did not count them as graft-related complications. Finally, no volumetric analysis of the aortic thrombus and no assessment of the severity of calcification and tortuosity were performed; thus, their exact effect on the outcomes could not be assessed and was outside of the topics of this study.

CONCLUSIONS

This study presents very promising late outcomes with the Endurant endograft for endovascular AAA repair. The results showed high freedom from reintervention rates, low rates of type I or III endoleaks, no proximal migration, and an impressive rate of aneurysm shrinkage in more than the half of the patients. Iliac limb occlusions rates are comparable with other devices and remain the leading cause of reintervention. The pathogenesis of iliac limb occlusion after EVAR requires further investigation. In any case, the results of this study confirm our hypothesis about the excellent late performance and durability of the Endurant endoprosthesis.

AUTHOR CONTRIBUTIONS

Conception and design: GT, TB, KD
Analysis and interpretation: TB, GT, MA, KD
Data collection: KW, ME
Writing the article: TB, KD, GT
Critical revision of the article: TB, KW, ME, KD, MA, GT
Final approval of the article: TB, KW, ME, MA, GT, KD
Statistical analysis: TB
Obtained funding: Not applicable
Overall responsibility: GT

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