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AAA with a Challenging Neck: Early Outcomes Using the Endurant Stent-Graft System

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ABSTRACT

Objectives: The efficacy and safety of endovascular aneurysm repair is disputable in aneurysms with a short, angulated, wide, conical, or thrombus-lined neck making a reliable seal difficult to achieve. The influence of a challenging neck on early results using the Endurant stent-graft system in high risk patients was investigated.

Materials and methods: A retrospective study conducted on a prospectively compiled database of 72 elective patients with challenging neck treated with the Endurant system (Endurant Stent Graft, Medtronic AVE, Santa Rosa, CA, USA). These patients were compared to a control group ($n = 65$) without significant neck problems. Endpoints were early technical and clinical success, deployment accuracy and differences in operative details at one month follow-up. Data are reported as mean and standard deviation or as absolute frequency and percentage (%). Normality distribution and homogeneity of variances were tested by Shapiro–Wilks and Levene tests, respectively. Inter-group comparisons for each variable were made by *t*-test or $\chi 2$-test or Fisher exact test. A $p < 0.05$ was considered statistically significant.

Results: Mean age was 76.12 years; 76.6% were males. Risk factors and pre-operative variables did not differ significantly between the two groups. Mean neck length was 10.56 mm in patients with challenging anatomies and 22.85 mm in controls. Patients with a challenging neck differed significantly ($p < 0.001$) from controls in terms of mean infrarenal (37.67° vs. 20.12°) and suprarenal angle (19.63° vs. 15.57°); 82% of patients with a challenging neck were ASA III/IV (vs. 86%). Technical success was 100%, with four unplanned proximal extension in challenging group. No type I endoleaks or aneurysm-related deaths occurred in either group; major complications were 1.54% vs. 1.39% ($p = 0.942$). Operative details were similar in both groups.

Conclusion: Treatment with the Endurant stent-graft is technically feasible and safe, yielding satisfactory results even in challenging anatomies. Medium- and long-term data are needed to verify durability, but early results are promising.

Introduction

Endovascular aneurysm repair (EVAR) is considered a safe and effective alternative to open repair (OR) for the treatment of selected cases of abdominal aortic aneurysm (AAA).[1–4] However, the efficacy and safety of EVAR for aneurysms with challenging anatomies remains disputable, due to the technical difficulties of achieving a reliable seal with a stent-graft. The more frequent complications after EVAR in aneurysms with a complex proximal neck anatomy require intraoperative endovascular adjuncts, with a higher risk of late aneurysm rupture due to proximal type I endoleaks, even in the absence of graft migration.[5,6] Surgical management of challenging necks also presents difficulties related to the possibility of extending the dissection over the renal arteries, with related complications. Nowadays difficult anatomies can also be treated with fenestrated or branched stent-grafts. However, while the results reported in the literature seem promising, these procedures are very expensive.[7] The use of a standard endoprosthesis (when possible) is still the most reliable and cost-effective procedure. It is, therefore, unclear whether EVAR or OR should be offered in the case of aneurysms with a challenging proximal aortic neck.[8] Over the years, many technological advances have been introduced, bringing progressive improvements and allowing aneurysms with challenging necks to be operated on safely. The Endurant endograft (Medtronic AVE, Santa Rosa, CA, USA) is a new-generation device for AAA repair that has been specifically designed to conform to challenging anatomy. With its easy-to-

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handle and precise delivery and deployment system, it may be well suited to treating AAA patients with challenging anatomy. Our study investigated the influence of a challenging neck on early results using the Endurant stent-graft system, compared to a group of patients without significant neck problems. The aim of our study was to demonstrate the effectiveness of the latest generation of endoprostheses in patients with difficult anatomy.

Materials and Methods

Study design and patient selection

A single centre study was conducted on a prospectively compiled computerized database between January 2010 and December 2010, with the aim of demonstrating the early safety and efficacy of EVAR in challenging aortic neck morphologies using the Endurant stent-graft system. In the present study out of 236 patients who received treatment, 137 non-consecutive patients were analyzed and divided into two groups (challenging anatomies vs. controls). The selection of study population was performed including only patients treated by Endurant stent-graft system. The remaining patients were treated with different stent graft and were excluded from the analysis in order to avoid a potential confounding factor. EVAR indications were based on age (>80 years), left ventricular ejection fraction (<25%), hostile abdomen, renal function impairment (serum creatinine > 2.0 mg/dL), or chronic pulmonary disease (forced expiratory volume in 1 s <1 L). AAA morphology was assessed by preoperative contrast-enhanced computed tomography (CT). The aneurysm neck was classified as "challenging" in the presence of one or more of the following criteria[9–12]: (1) hourglass neck, (2) angulated neck: ≥60° angle between the juxtarenal aorta and long axis of the aneurysm sac, (3) short neck: neck length <15 mm, (4) significant thrombus: >50% of the proximal neck circumference covered, (5) reverse conical neck: neck dilated ≥ 2 mm within 10 mm of the most caudal renal artery, or (6) barrel neck: focal neck enlargement ≥ 3 mm within 15 mm of the most caudal renal artery. All other morphologies were classified as "non-challenging". Even in the presence of "challenging neck anatomy" we decide to include patients with a proximal neck length of more than 20 mm and without significant aortic angulations in the control group.

Database interrogation identified 72 elective high-risk patients with AAA and challenging neck anatomy treated with the Endurant stent-graft system. These patients were compared to a control group ($n = 65$) without significant neck problems who had undergone EVAR using the same device during the same period (Table 1).

Table 1
Demographic and preoperative risk factors of the control group and challenging neck group.

	Control group	Challenging group	*p* value
n	65	72	
Age (years)	75.12 (6.35)	77.24 (5.98)	0.05
Gender (male/female)	48/17	57/15	0.546
Smoking	40 (61.54%)	51 (70.83)	0.28
Hypertension	44 (67.69%)	46 (63.89%)	0.72
CAD[§]	37 (56.92%)	36 (50.00%)	0.493
COPD[*]	22 (33.85%)	19 (26.39%)	0.357
Diabetes	17 (26.15%)	18 (25.00%)	0.877
Renal Disease	10 (15.39%)	15 (20.83%)	0.41
PAOD[$]	17 (26.15%)	13 (18.06%)	0.252
CVD[&]	8 (12.31%)	7 (9.72%)	0.628
ASA III/IV[#]	56 (86.15%)	59 (81.94%)	0.503

[§] Coronary Artery Disease; [*] Chronic obstructive pulmonary disease; $ Peripheral Artery Obstructive Disease; & cerebrovascular disease; [#] American Society of Anestesiologist.

Preoperative planning

CT angiography was performed using a 64-slice LightSpeed CT (GE Healthcare, Salt Lake City, UT, USA) with and without contrast medium during arterial and venous phases, at a thickness of 1 mm. All measurements (diameter, length and volume) were performed using a workstation with dedicated reconstruction software and centre lumen line (CLL) reconstruction (OsiriX software version 3.2.1 on a regular Mac OS X computer and 3Mensio Medical Imaging B.V., Bilthoven, The Netherlands). Post-analysis included 3D volume rendering, preoperative simulated angiography and multiplanar reconstruction (Fig. 1). Briefly, to measure aortic angulation, a CLL of the aorta was made, and a three-dimensional (3D) aortic reconstruction was obtained. The 3D reconstruction was turned 360° perpendicular to the CLL in the middle of the flexure. The sharpest angle was considered the true angle of the aortic axis. The angles between the suprarenal aorta and the aneurysm neck (α) and between the aneurysm neck and sac (β) were measured (Fig. 2). After CLL reconstruction, subsequent measurements were performed. The length of the proximal neck was defined as the distance between the origin of the lowermost renal artery and beginning of the aneurismatic dilatation. Volumes were acquired for both the neck (first 10 mm) and total aneurysm (up to the bifurcation). Preoperative planning was performed by the same operators and was always discussed with a Medtronic Products specialist. Postoperative computed tomography angiography (CTA) was performed on all patients within 30 days of surgery.

Surgical procedure

All patients were treated under local anesthesia in an operating theater equipped with a portable fluoroscopy unit (GE-OEC 9900; GE Healthcare, Salt Lake City, UT, USA). Bilateral cut-down of the common femoral artery was performed in 124 (90.5%) cases, a monolateral percutaneous approach using the Perclose Prostar XL device (Abbott Vascular, Redwood City, CA, USA) was chosen for 7 (5.1%) patients, and an all percutaneous approach was selected in the other 6 (4.3%) cases. Based on the preoperative simulated angiography, the C-arm was placed with the right orientation to allow optimum visualization of the proximal aortic neck. We usually perform the first angiography at the level of the renal arteries, which requires lower volume contrast injection, with the stent-graft in place ready for release. In order to avoid unintentional renal artery occlusion in the case of a proximal aortic neck length of less than 10 mm, we always place two guidewires in the renal artery, to facilitate performance of a chimney technique if necessary. When the proximal neck is not completely covered we prefer to place a proximal stent-graft extension after the final angiography, even without a type I endoleak.

Endpoints and definitions

The endpoints were early technical and clinical success. Primary technical success, assessed on an intention-to-treat basis, was defined as successful implantation of a stent-graft in the absence of surgical conversion, mortality, type I or III endoleaks, or stent-graft occlusion in the first 24 h after surgery. The need for postoperative adjunctive endovascular procedures and postoperative reintervention was noted. Clinical success was defined as the absence of any significant intraoperative, 30-day or in-hospital mortality or morbidity. Late rupture, major adverse event (MAE), minor adverse event (minor AE), AAA-related mortality and all-cause mortality were noted. We considered as a MAE acute myocardial infarction (AMI), ileus, spinal cord ischemia (SCI), renal dysfunction (RD), respiratory failure (RF) and blood loss requiring transfusion.

The post-operative permeability of renal arteries was assessed in both groups.

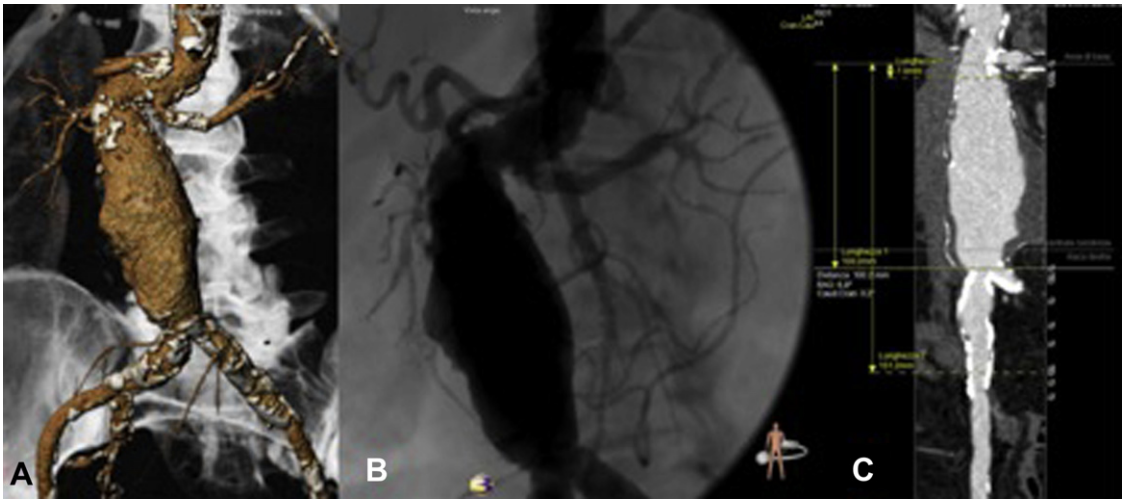

Figure 1. (A) 3-D volume rendering CT reconstruction; (B) preoperative simulated angiography; (C) center-line analysis.

AMI was suggested by electrocardiographic changes and confirmed by the elevation of cardiac enzymes, regardless of symptoms. Ileus was defined as a delay in gut motility lasting for more than 72 h after surgery, while SCI was defined as postoperative evidence of neurological deficits. RD was defined as a rise in serum creatinine exceeding the baseline value by 30% and surpassing an absolute level of 2.0 mg/dL. RF was defined as ventilator dependence of >72 h, and the need for postoperative reintubation. The differences in operative details were also analyzed.

Follow-up protocol

Routine follow-up was planned according to the standard requirements suggested by the European Society for Vascular and Endovascular Surgery's recent clinical practice guidelines.[7] All patients had a CTA and plain radiographs with anteroposterior and lateral projections 30 days after the procedure. In the case of any endoleak, less than one stent component or iliac overlap, CTA with plain radiographs were performed again at 6 and 12 months. In patients with no early endoleak and good component overlap, a CTA alone was performed at 12 months. When there was no endoleak and a stable or shrinking AAA at 12 months, a yearly duplex ultrasound scan was scheduled along with plain radiographs, using a standardized protocol with anteroposterior and lateral projections to assess device migration, stent fractures and/or modular disconnections.

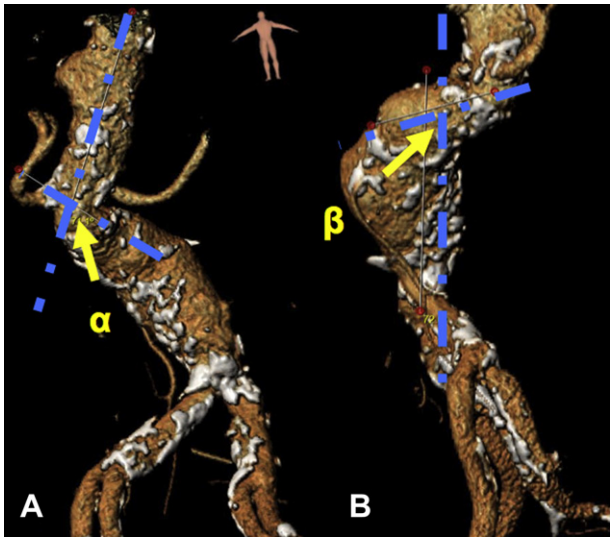

Figure 2. (A) α angle: suprarenal angulation; (B) β angle: iuxtarenal angulation.

Statistical analysis

The data are reported as mean and standard deviations (SD) or as absolute frequencies and percentages (%). Normality distribution and the homogeneity of variances were assessed by the Shapiro–Wilk test and Levene's test, respectively. Inter-group comparisons for each variable were performed using the *t*-test, $\chi 2$-test or Fisher's exact test. A p value < 0.05 was considered statistically significant. All analyses were calculated using SPSS statistical software version 13 (SPSS Inc., Chicago, IL).

Results

Analysis of demographics and preoperative risk factors (Table 1) showed that the two groups were generally comparable: of note was only a p value of 0.05 for the age between the two groups, probably due to the small number of patients analyzed. The mean age was 76.12 years; 76.6% were males. Eighty-two percent of patients with a challenging neck were ASA III/IV, according to the classification of the American Society of Anaesthesiologists (vs. 86% in the control group; $p = 0.503$). Patients with challenging neck anatomies presented higher rates of renal dysfunction (20.83% vs. 15.39%; $p = 0.41$).

Neck morphology

The mean maximum diameter was 65.35 mm in the challenging group versus 67.41 mm in the control group ($p = 0.067$). Neck diameter was quite similar in both groups (24.19 mm vs. 24.35 mm; $p = 0.587$). The mean neck length was 10.56 mm in patients with challenging anatomies and 22.85 mm in the control group ($p < 0.001$). Data regarding neck calcification or thrombosis were statistically comparable in both groups ($p = 0.597$, $p = 0.935$ respectively). Patients with a challenging neck differed significantly ($p < 0.001$) from controls in terms of mean infrarenal angle (37.67° vs. 20.12°) and suprarenal angle (19.63° vs. 15.57°). Neck morphology was classified as one of five different neck shapes: cylindrical, conical, barrel, hourglass, reverse conical. The group distribution is described in Table 2.

Thirteen patients with "challenging neck anatomy" (3 barrel, 3 hourglass and 7 reverse conical necks) were included in the control

Table 2
Group distribution according to aneurysm proximal neck features.

	Control group	Challenging group	*p* value
Max. diameter	67.41 (6.56)	65.35 (6.55)	0.067
Neck diameter	24.35 (1.66)	24.19 (7.76)	0.587
Neck length	22.85 (5.40)	10.56 (1.99)	<0.001
Thrombus >30%	16 (24.62%)	15 (20.83%)	0.597
Calcificaton >30%	13 (20.00%)	14 (19.44%)	0.935
Alfa angle	15.57 (6.92)	19.63 (10.73)	<0.001
Beta angle	20.12 (9.99)	37.67 (19.16)	<0.001
Cylindrical neck	35 (53.85%)	45 (62.50%)	0.305
Conical neck	18 (27.69%)	15 (20.83%)	0.349
Barrel neck	3 (4.62%)	7 (9.72%)	0.332
Hourglass neck	3 (4.62%)	5 (6.94%)	0.721
Reverse conical neck	7 (10.80%)	2 (2.77%)	0.085

group due to their proximal neck length (more than 20 mm) and the absence of significant aortic angulations. Technical success was 100%, with four unplanned proximal aortic cuff extensions in the challenging group. We placed two safety guidewires in 19 (13.68%) "challenging neck" patients with a neck length of less than 10 mm. No type I endoleaks or aneurysm-related deaths occurred in either group; major complications were 1.54% vs. 1.39% ($p = 0.942$). Operative details were similar in both groups. Neck morphology was not related to MAE, minor AE, re-interventions, rupture or AAA-related mortality.

Procedure results

The mean operation times were 84.17 and 83.69 min in the challenging group and control group, respectively ($p = 0.828$). Challenging neck morphology did not significantly modify radiation time (13.67 vs. 13.23 min). Primary technical success was achieved in all cases. Although one of the problems reported with Endurant stent-grafts in short and tightly angulated necks is the difficulty of retrieving the conical proximal shelter for the non-covered proximal stent: fortunately we did not experience this situation. No type I or III endoleaks requiring adjunctive endovascular procedures were detected in our series. All the renal arteries were patent at completion angiography and at the 1 month angio-CT. One case of RD was recorded in both groups, characterized by reversible post-operative elevation of serum creatinine levels by more than 2.0 mg/dL, requiring volume supplementation with sodium bicarbonate plus N-acetylcysteine, according to the REMEDIAL trial protocol.[13] There were 3 minor AE in the challenging neck group (1 surgical wound infection, 2 transient fever) and 2 cases of transient amnesia in the control group. The majority of patients were discharged on postoperative day 3 or 4 (the mean hospital stay was 3.72 days in the challenging group and 3.84 in the control group; *p*:ns). No patients required an ICU stay. We reported 3 non-AAA related deaths: two patients (one in the study group and one in the control group) died from AMI after hospital discharge, and 1 patient in the challenging anatomies group had a sudden death (no autopsy report). (Table 3)

Table 3
Intra operative/30-days complications and operative details.

		Control group	Challenging group	*p* value
Primary technical success		65	72	–
Adjunctive procedure		8 (12.31%)	8 (11.11%)	0.828
Intra OP EL		0	0	–
30d EL		0	0	–
Migration		0	0	–
Duration		83.69 (12.88)	84,17 (12,64)	0.828
Radiation Time		13.23 (7.72)	13,67 (1,89)	0.162
MAE		1 (1.54%)	1 (1.39%)	0.942
Minor AE		2 (3.08%)	3 (4.17%)	0.734
Reintervention		0	0	–
Rupture		0	0	–
AAA-related mortality		0	0	–
All cause mortality		1 (1.54%)	2 (2.77%)	0.621
Hospital stay (days)	3	28 (43.08%)	36 (50.00%)	0.917
	4	27 (41.54%)	26 (36.11%)	
	5	5 (7.69%)	6 (8.33%)	
	6	2 (3.08%)	2 (2.77%)	
	7	3 (4.62%)	2 (2.77%)	

Discussion

An unsuitable proximal neck is one of the main factors limiting the wider applicability of EVAR.[14–16] Until approximately ten years ago, unfavourable anatomy of the proximal aortic neck was responsible for about 60% of patient exclusion from EVAR.[17] Today's advanced technology has increased the number of patients suitable for EVAR, but the choice between OR or EVAR in patients with challenging aortic neck anatomy still remains controversial. Challenging aortic morphology requires adequate preoperative planning in order to minimize procedure-related complications.

In the present series, we compared patients with normal and challenging neck anatomy undergoing EVAR for AAA using the Endurant stent-graft. This newgeneration device obtained the Conformité Européene mark in July 2008 and is commercially available in all European countries. The main features of this endograft have been described in other reports.[18–20] The device has greater flexibility due to shorter and wire-formed M-shaped body stents. This increased flexibility allows the stent-graft to be successfully used in aneurysms with severely angulated and tortuous anatomies. The suprarenal anchoring pins and the controlled release of the top stent ensure exact proximal fixation to the aortic wall and reduce the risk of migration. Recent series have sought to analyze the short-term results of this new stent-graft, particularly in patients with complex aortic morphologies. The final results of the prospective European multicentre non-randomized trial of the Endurant stent-graft for EVAR showed that this stent-graft was successfully delivered and deployed in all cases, with safe and effective performance in all patients, including those with unfavourable (angulated) proximal neck anatomy.[21] Similar results have been published by Bastros Gonçalves et al., who considered treatment with the Endurant stent-graft feasible and safe, achieving satisfactory results in angulated and non-angulated anatomies alike.[22] Off-label indications such as a short ($\leq$15 mm) proximal aortic neck associated with severe infrarenal neck angulation ($\geq$75°) are responsible for procedure-related complications with a greater risk of type I endoleak, although mortality and morbidity remain comparable to those in/the same as in patients without aortic neck problems.[23,24] Our data do not support the conclusions of a previous study regarding postoperative morphology-related complications. The present study suggests that the results of EVAR are similar in challenging neck anatomies and in patients without significant neck problems. The manufacturer's device-specific instructions for use recommend a proximal aortic neck of $\geq$15 mm in length with $\geq$75° infrarenal angulation or a proximal aortic neck of $\geq$10 mm with $\leq$60° infrarenal angulation. We decided to use the stent for "off-label" applications only in patients with serious comorbidities who were unsuitable for OR. None of these patients presented postoperative or 30-day type I endoleak. One patient out of three (33%) with the association between a proximal aortic neck of $\leq$15 mm (but >10 mm) in length and with $\geq$60°infrarenal angulation required an adjunctive procedure of proximal stent-graft extension due to the presence of an additional space between the graft and the lower renal artery. Three patients out of 25 (12%) with a proximal aortic neck length of $\leq$10 mm required an adjunctive procedure for the same reason. Only one patient presented the second manufacture contraindication but fortunately did not

require additional procedures. The appropriate selection of devices for EVAR in challenging cases plays a leading role in avoiding intraoperative complications.[25–27] Longer and stiffer stents make the accommodation of angulated proximal implantation zones more challenging and may contribute to proximal attachment site endoleaks or graft kinking when deployment occurs in tortuous vessels.[28] The deployment of flexible and conformable stent-grafts with proximal anchoring pins appears to be safer in patients with challenging anatomies.[9,24,29] The next generation of stent-graft designs currently evolving are addressing the issues that affect the further expansion of EVAR applicability: the Aorfix (Lombard Medical Technologies plc., Didcot, UK) and the Anaconda device (Vascutek Ltd., Terumo, Renfrewshire, Scotland) have been studied, but usually result in a higher rate of type I endoleak.[28,30]

The use of a mobile c-arm in challenging aortic morphologies is not widely recognised and could be a limiting factor. However, our institution does not have a hybrid operating room: the need to perform these procedures in the operating room therefore implies that we have to use a mobile c-arm.

The retrospective nature of this study may result in significant bias. However, all patients selected for EVAR were treated in a consecutive fashion with the same stent-graft. Patients in the challenging neck group were individually scheduled for OR, EVAR or no treatment primarily according to their comorbidities, thus skewing this group towards a generally lower health status. This did not result in any difference in the short-term, but may do so in the future. Lastly, the relatively small numbers presented may be insufficient to reveal differences between groups.

Conclusions

In our centre treatment with the Endurant stent-graft is technically feasible and safe, yielding satisfactory results even in challenging aortic anatomies.

The duration of procedures, intraoperative contrast use and radiation exposure time were similar in both groups, indirectly demonstrating an absence of additional intraoperative difficulties. The particular characteristics of this device seem to make it appropriate for the treatment of highly angulated and short necks, especially in patients at high surgical risk.

The clinical significance of our study was to demonstrate the effectiveness of the Endurant stent-graft even in the case of difficult anatomies, as well as its postoperative safeness in the case of off-label indications in patients otherwise considered unfit for surgery, although our results are related to only 1-month follow up. It is important to note that this kind of procedure should be performed by skilled operators in high volume centres.

Mid- and long-term data are needed to verify the durability of the procedure, but early results are promising and challenge current opinion concerning the negative influence of challenging neck anatomy on EVAR.

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Conflicts of interest

None.

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