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Risk Factors for Proximal Neck Complications After Endovascular Aneurysm Repair Using the Endurant Stentgraft

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WHAT THIS PAPER ADDS

Endograft selection may play an important role in the outcome of EVAR. This study assesses and grades the influence of several patient related characteristics on the occurrence of proximal neck related complications using a late generation device that was designed specifically to cope with more challenging proximal neck anatomy. The results suggest that neck length remains the most relevant risk factor. Moreover, other conventional risk factors such as angulation or neck taper seem to have little influence in the short and mid-term. Comparing these results with those of other large single device registries may help clinicians select the correct endoprosthesis for individual patients, optimizing the results of EVAR.

Objective: To assess the incidence and risk factors for proximal aneurysm neck related complications with a late generation device for endovascular abdominal aneurysm repair (EVAR).

Methods: Data were retrieved from a prospective registry (Endurant Stent Graft Natural Selection Global Postmarket Registry) involving 79 institutions worldwide. The risk factors tested were age, gender, surgical risk profile, proximal neck length (<10 mm), diameter (>30 mm), supra- and infrarenal angulation (>60° and 75°), mural thrombus/calcification (>50%) and taper (>10%), and AAA diameter (>65 mm). Two neck related composite endpoints were used, for intra-operative (type-1a endoleak, conversion, deployment/retrieval complication or unintentional renal coverage) and post-operative (type-1a endoleak or migration) adverse events. Independent risk factors were identified using multivariable backwards modeling.

Results: The study included 1263 patients (mean age 73, 10.3% female) from March 2009 to May 2011. Twenty three (1.8%) intra-operative adverse events occurred. Neck length <10 mm (OR 4.9, 95% CI 1.1–22.6) and neck thrombus/calcification >50% (OR 4.8, 95% CI 1.7–13.5) were risk factors for intra-operative events. The planned 1 year follow up visit was reached for the entire cohort, and the 2 year visit for 431 patients. During this time, 99 (7.8%) events occurred. Female gender (HR 1.9, 95% CI 1.1–3.2), aneurysm diameter >65 mm (HR 2.8, 95% CI 1.9–4.2), and neck length <10 mm (HR 2.8, 95% CI 1.1–6.9) were significant post-operative risk factors. Neck angulation, neck taper, large diameter neck, and presence of thrombus/calcification were not predictors of adverse outcome in this study.

Conclusion: These results support the adequacy of this device in the face of adverse neck anatomy, and confirm neck length as the most relevant anatomical limitation for EVAR. Additionally, the study confirms the decline in early to mid-term intervention rates with a newer generation device in a large patient sample. Lastly, it suggests that neck related risk factors affect outcome and impact on prognosis in varying degrees.

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INTRODUCTION

Endovascular aneurysm repair (EVAR) is an accepted treatment modality for infrarenal abdominal aortic aneurysms (AAA). Technical and technological innovations have been progressively introduced over the last two decades, generally leading to improved early and late outcomes. Careful evaluation of newly introduced devices for EVAR is essential

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to guarantee patient safety and provide evidence for the gradually expanding indications.

The most limiting factor for EVAR is adverse proximal neck anatomy.[1] Extensive research has shown that characteristics of the proximal neck, such as length, diameter, angulation, taper, and irregularity affect outcome significantly.[1–6] Manufacturers have focused much attention on proximal neck limitations in their Instructions For Use (IFU), which are the most common reason for ruling out EVAR.

The Endurant Stent Graft System (Medtronic, Santa Rosa, CA, USA) has been specifically designed to cope with unfavorable anatomic characteristics, therefore potentially expanding the treatment range for EVAR. Specifically, the proximal geometry of the main body stents allow for extra flexibility and conformability, while maintaining adequate radial force. Also, the suprarenal active fixation and precise tip capture deployment mechanism are designed for more precise and controlled deployment and durable fixation. The manufacturers' expectations on the performance of this device are reflected in the IFU, which are among the most liberal. Even so, physicians often exceed these recommendations, with the expectation of reduced complications during follow up.

Very favorable outcomes have been reported in small series of patients with adverse neck features. However, these studies are generally retrospective and based on single institution experiences, and therefore subject to publication bias. The objective of this study is to assess the importance of different adverse anatomical characteristics of the proximal attachment site when using a late generation device. To do so, a large prospective, multicenter cohort of patients from the Endurant Stent Graft Natural Selection Global Postmarket Registry (ENGAGE) was studied.

METHODS

Eligibility

Patients with AAAs considered suitable for elective endovascular repair were eligible for inclusion in this registry. Although adherence to IFU was advised, enrollment of patients outside IFU was permitted. Enrolment was conducted on an intention to treat basis, and a minimum of five consecutive patients per center was advised. Unfortunately, no information is available on the number of patients offered EVAR with other devices, open repair, or no treatment for each participating center, and therefore the extent of selection bias is impossible to determine. However, all patients included in the registry were also included in this study. All patients were asked for signed informed consent. The study was conducted according to the Helsinki declaration on research ethics and registered under the ClinicalTrials.gov Identifier> NCT00890051.

Data collection and definitions

Individual patient data were entered prospectively by participating hospitals and stored electronically locally. The pre-operative data collected included demographics, medical comorbidities (smoking, hypertension, hyperlipidemia, diabetes, cardiac disease, pulmonary disease, renal insufficiency, cerebrovascular disease, and peripheral arterial disease), and anatomical characteristics (proximal neck diameter, length, angle, presence of mural neck thrombus/calcification, neck taper, and AAA maximum diameter). Intra-operative details included technical success, presence of type Ia or undetermined endoleak, additional devices used, and procedures performed during the implant procedure. Follow up visits were scheduled at 30 days, 1, and 2 years, with mandatory imaging studies. At follow up visits, any protocol defined adverse event was registered and imaging studies were assessed for the presence of complications and AAA maximum diameter changes. Any secondary procedures were also registered. External auditors closely monitored all clinical data in this registry.

For this study, candidate adverse neck characteristics were selected on the basis of previous literature and accounting for the recommended anatomical limits for this particular device. Specifically, the chosen cutoffs for adverse neck were length $<$10 mm, presence of thrombus/calcification $>$50%, and neck angulation greater than 60° (suprarenal) or 75° (infra-renal). In addition, the presence of neck taper $>$15% and large diameter aortic necks (requiring 32 or 36 mm proximal diameter endoprosthesis) were considered as potential risk candidates based on previous literature. Surgical risk was calculated according to the modified Lee score and ASA classification. Migration was defined as downward displacement of the endograft by at least 10 mm. Sac growth was defined as an increase in maximum aneurysm diameter of at least 5 mm, as recommended in the SVS reporting standards.[7]

Study endpoints

For this study, two composite endpoints were chosen: for intra-operative neck related adverse events, the endpoint was composed of intra-operative (or undetermined) type Ia endoleak, unintentional renal artery coverage, presence of deployment or retrieval complication or need for conversion to open repair. For post-operative neck related adverse events, the endpoint was composed of any postoperative type Ia (or undetermined) endoleak, proximal device migration, need for proximal neck secondary intervention or post-implantation rupture. The individual components of each endpoint were also studied to assess their specific contribution to the endpoint.

Statistical methods

Categorical variables were presented as count and percentage and compared with Pearson's chi-square tests. Continuous variables were presented as mean and standard deviation (SD) and compared using Student *t* tests if normally distributed, or presented as median and interquartile range (IQR) and compared with Mann–Whitney U tests if the distribution was skewed. Each variable of interest (age, gender, baseline AAA diameter, ASA classification, proximal

neck diameter, proximal neck length, proximal neck thrombus or calcification, proximal neck taper, supra- and infra-renal angle) was tested separately as a risk factor for intra-operative and post-operative neck related adverse events, and independent significance was tested for variables with $p < .1$ using multivariate logistic regression and proportional hazard regression, respectively. Based on the hazard ratios obtained for significant risk factors for post-operative neck related adverse events, a risk model was generated and tested using the area under the curve of the resulting receiver operating characteristic curve (ROC). A cutoff was determined based on the optimal sensitivity and specificity of the test (maximum sum value method), and patients scoring greater than the cutoff were considered high risk. Kaplan–Meier survival estimates were calculated for freedom from neck related adverse events and compared using the Log Rank (Mantel-Cox) test of equality. Differences were considered significant if $p < .05$. Statistical analysis was performed by an independent statistical office (Secic Statistical Consulting, Inc), using IBM SPSS Statistics 20 (IBM Inc., Chicago, IL, USA).

RESULTS

From March 2009 to May 2011, 1263 patients were included in the ENGAGE registry and were included in the present study. All patients had an expected minimum follow up of 1 year and a maximum of 3 years. At the time of this study, all surviving patients had reached the 1 year mark and 431 (38%) had reached the 2 year mark. Baseline characteristics are detailed in Table 1.

Intra-operative neck related adverse events

Twenty three patients (1.9%) suffered from intra-operative neck related adverse events. The majority were type Ia endoleaks ($N = 12$, 1.0%), of which seven were corrected intra-operatively. For the remaining five patients, three resolved spontaneously at the 1 month CTA, and no further adverse events were reported through 24 months. One patient was treated successfully with a proximal extension after 5 days and died after 1.5 years because of lung cancer. The last patient died 5 days after the procedure because of bowel ischemia and myocardial infarction. None of the intra-operative conversions were caused by type Ia endoleaks. Of the five renal coverage cases, one was subjected to hepato-renal bypass and died after 22 days because of multiorgan failure, one was successfully converted to open repair, one was treated with renal artery stenting, and the remaining two were treated conservatively without significant worsening of renal function. Only one of the delivery/retrieval complications was possibly caused by complex proximal anatomy. In this case, inability to withdraw the delivery system was reported and the patient underwent successful open conversion. The contribution of individual adverse events to the composite endpoint is described in Table 2.

Only neck length <10 mm (OR 4.9, 95% CI 1.1–22.6) and presence of neck thrombus/calcification (OR 4.8, 95% CI 1.7–3.5) were independent risk factors for intra-operative neck related adverse events (Table 3).

Intra-operative neck related adverse events occurred in two (7.4%) patients with neck length <10 mm, and in five (6.8%) patients with neck thrombus or calcification in >50% of the neck circumference.

Table 1. Baseline characteristics.

Variable	$N = 1263$ N (%)
Age ≥80	290 (23.0)
Female gender	133 (10.5)
ASA III/IV	658 (52.1)[a]
Proximal graft diameter 32 or 36	398 (31.5)
Neck length <10 mm	27 (2.2)[a]
Neck thrombus/calcification (>50%)	74 (6.0)[b]
Neck taper ≥15%	218 (17.5)[b]
Maximum AAA diameter ≥65	317 (25.4)[b]
Suprarenal angle >60°	44 (3.6)[b]
Infrarenal angle >75°	62 (5.1)[b]

[a] Missing values ≤1%.
[b] Missing values >1% and ≤3%.

Table 2. Intra-operative neck related adverse events.

Intra-operative neck related adverse events	$N = 1263$ N (%)
Endoleak type 1a	12 (1.0)
Corrected by remodeling the stent graft	3/12 (25)
Corrected with extension cuffs (prox or dist)	3/12 (25)
Corrected (others)	1/12 (8)
Conversion to open repair	4 (0.3)
Unintentional renal artery coverage (partial/total)	5 (0.4)
Deployment/retrieval complication	7 (0.6)
Total (patients)	23 (1.8)

Post-operative neck related adverse events

After the index operation, 18 patients suffered neck related adverse events. Of these, one was also included in the intra-operative adverse events and the remaining 17 were additional events. There were no endograft migrations, and

Table 3. Uni- and multivariate model for intra-operative adverse events.

Characteristic	Event ($n = 23$)	Univariate p value	Multivariate OR (95% CI)
Age ≥80	7 (2.4%)	0.39	–
Female gender	4 (3.0%)	0.29	–
ASA III/IV	14 (2.1%)	0.40	–
Proximal graft diameter 32 or 36	8 (2.0%)	0.73	–
Neck length <10 mm	2 (7.4%)	0.047	4.9 (1.1–22.6)
Neck thrombus/calcification (>50%)	5 (6.8%)	0.003	4.8 (1.7–13.5)
Neck taper ≥15%	2 (0.9%)	0.28	–
Maximum AAA diameter ≥65	9 (2.8%)	0.13	–
Suprarenal angle >60°	2 (4.5%)	0.18	–
Infrarenal angle >75°	2 (3.2%)	0.39	–

Table 4. Post-operative neck related adverse events.

Post-operative neck related adverse events	$N = 1263$ *N* (%)
Endoleak type 1a	18 (1.4)
Corrected by remodeling the stent graft	2/18 (11)
Corrected with extension cuffs (prox or dist)	6/18 (33)
Corrected (others)	4/18 (22)
Proximal device migration (>10 mm)	0 (0)
Total (patients)	18 (1.4)

all events corresponded to type Ia endoleaks. All these endoleaks were imaging findings resulting from post-operative surveillance, with no associated symptoms (Table 4). Treatment was not offered to six patients for the following reasons: metastatic cancer with very short life expectancy ($N = 2$), decision for surveillance with spontaneous resolution without intervention ($N = 2$), one because of decision of the patient, and another because of a decision of the physician (unfit for open conversion and no endovascular solution available).

Female gender (HR 5.6, 95% CI 2.0—15.3), neck length <10 mm (HR 8.9, 2.5—31.2), and AAA maximum diameter ≥65 mm (HR 6.4, 95% CI 2.3—17.7) were identified as independent risk factors for post-operative neck related adverse events (Table 5). For patients with <10 mm proximal neck, the crude complication rate was 11.1% (3/27 patients). For patients with large AAAs it was 3.5% (11/317), and for female patients it was 4.5% (6/133).

A risk model was created, based on the proportional HR obtained from the multivariate analysis. This model was highly predictive of post-operative neck related adverse events, with an AUC of 0.80 (Fig. 1), and a cutoff point of 6 was obtained. Based on this, patients were categorized into high or low risk groups for post-operative adverse neck events. This resulted in 335 patients, having a neck length <10 mm or AAA maximum diameter >65 mm. Nine patients (2.7%) had both AAA diameter >65 mm and neck length <10 mm. At 2 years, the event free survival expectancy was 99% for low risk patients and 96% for high risk patients ($p < .001$, Fig. 2).

Table 5. Risk factors for post-operative neck related adverse events.

Characteristic	Event total = 18 *N* (%)	Univariate *p* value	Multivariate HR (95% CI)
Age ≥80	6/290 (2.1)	0.26	—
Female gender	6/133 (4.5)	0.003	5.6 (2.0—15.3)
ASA III/IV	12/658 (1.8)	0.20	—
Proximal graft diameter 32 or 36	4/398 (1.0)	0.40	—
Neck length <10 mm	3/27 (11.1)	0.040	8.9 (2.5—31.2)
Neck thrombus/ calcification >50%	0/74 (0)	—	
Neck Taper ≥15%	4/218 (1.8)	0.99	—
Maximum AAA diameter ≥65	11/317 (3.5)	0.61	6.4 (2.3—17.7)
Suprarenal angle >60°	3/44 (6.8)	0.003	—
Infrarenal angle >75°	3/62 (4.8)	0.010	—

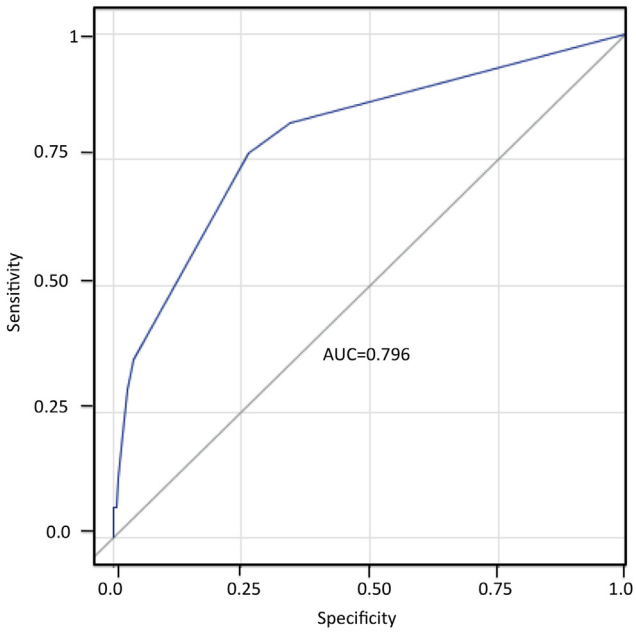
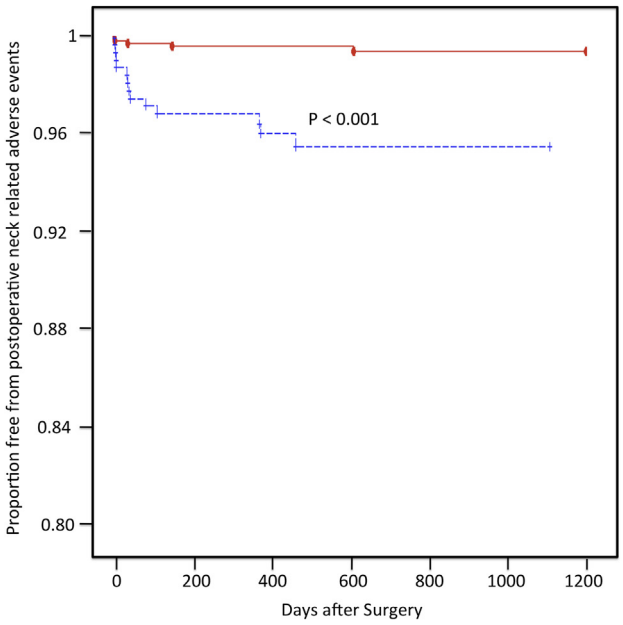


Figure 1. Receiver operating characteristic curve for the post-operative risk model.

DISCUSSION

The proximal attachment site is a major contributor for adverse outcome after EVAR, and is generally considered the primary reason for EVAR turndown.[8] The main finding of this study is that risk factors for intra- and post-operative neck related complications differ in type and relative importance. Neck length was the most relevant predictor, increasing the risk of intra-operative complications fivefold and the risk of mid-term complications ninefold, and angulation, neck taper or diameter and presence of significant thrombus/calcification had no important contribution for neck related adverse events at mid-term. Additionally, this study suggests that the overall risk of neck related complications is reduced compared with historical series, implying an improvement in safety and efficacy for EVAR.

The association between anatomical characteristics and increase in risk has been well characterized in several retrospective studies and registries and recently compiled into two systematic reviews.[9,10] In the meta-analysis by Antoniou et al.,[9] patients treated outside neck IFU were compared with those treated according to different manufacturer's recommendations. These authors found that hostile neck patients had a threefold increase in the need for intra-operative adjuncts to achieve proximal seal and a fourfold increase in the risk of developing type 1 endoleaks within the first year. Stather et al.[10] used different classification criteria, defining hostile neck anatomy as any of the following: neck length <15 mm, neck diameter >28 mm, and angulation >60°. They found a near twofold increase in



Final Risk	Days after EVAR	KM Event Free (%)	Standard Error	N
Low	0	100	0	908
Low	2	100	0,0011	907
Low	35	100	0,00157	894
Low	148	100	0,00194	867
Low	608	99	0,00285	476
Low	1199	99	-	0
High	0	100	0	335
High	2	100	0,00299	333
High	4	99	0,00423	331
High	5	99	0,00518	329
High	6	99	0,00597	328
High	32	98	0,0067	321
High	34	98	0,00735	320
High	38	98	0,00795	317
High	42	98	0,0085	315
High	80	97	0,00904	309
High	110	97	0,00956	303
High	369	97	0,0103	252
High	373	96	0,011	243
High	461	96	0,0121	183
High	1106	96	-	0

Figure 2. Estimated event free survival for patients at low and high risk for post-operative neck related complications.

both the risk of intra-operative complications and of type I endoleaks over time. Although these studies did not attempt to evaluate the independent contribution of each adverse neck characteristic, the proportional risk increase for patients with adverse necks was comparable with this study.

The determinant difference is, however, in the total number of complications. Although both meta-analyses identified the need for intra-operative adjunctive neck procedures in 3% to 5%, only 1.8% of 1263 patients included on an intention to treat basis in this registry suffered intra-operative neck related complications, and of these only 12 (0.9%) were type Ia endoleaks. More importantly, only 1.5% of patients suffered from subsequent neck related complications, whereas meta-data revealed a much higher proportion, ranging from 5% to 11%, in an equivalent time interval. In Engage patients, freedom from neck related adverse events at 2 years was 96% for patients at high risk for complications, and 99% for patients at low risk. Because of the prospective and multicenter nature of this registry, the chance of publication bias is smaller than in single center observational studies, suggesting the reduction in incidence may be even greater. The results of this study corroborate that specific characteristics of this device make it a good choice for treatment of less favorable neck anatomy. It also confirms the results of smaller, single center retrospective studies that could be the reflection of bias and/or irreproducible experience of centers of excellence.[11–15]

The independent contribution of each patient characteristic for neck related complications is a relevant finding. Although the ENGAGE protocol recommended against inclusion of patients treated outside IFU, these were allowed in the logic of consecutive enrollment. A total of 226 patients (18%) included were outside IFU, of which 112 (9%) were caused by adverse proximal neck anatomy. These inclusions made it possible to test the influence of each individual neck related risk factor in a multivariate model, allowing grading of individual risk with a high degree of certainty, as reflected by the AUC of 0.8.

For intra-operative neck related adverse events, only neck thrombus/calcification >50% and neck length <10 mm were independent risk factors. These both increased risk approximately fivefold. The present findings are compatible with previous literature on risk factors for intra-operative complications, although thrombus could not be differentiated from calcification. Interestingly, angulation outside the IFU (supra-renal >60° and/or infra-renal >75°) was not a risk factor for intra-operative complications, which confirms a previous observation on the early results of this endograft in patients with extreme angulation of the proximal neck.[16]

At mid-term, the most important predictor for adverse outcome was neck length, with <10 mm necks having a ninefold risk increase. It is important to note that 3/27 patients (11.1%) of patients with neck length <10 mm were identified as having a type Ia endoleak during follow up. As no migrations were observed, it can be concluded that neck length does not increase mid-term risk of migration with this device, but does increase the risk of developing type 1a endoleaks. This was expected, and parallels previous large studies on the adverse influence of neck length.[9] Given the cost and treatment delay involved, fenestrated or branched alternatives for patients with neck length <10 mm should outweigh the risk involved in treatment of these adverse neck patients with standard off the shelf infrarenal devices.[17–19] Also, fenestrated and branched technology cannot be universally applied, because of anatomical constraints. The chimney techniques for endovascular repair of short necks should be reserved, in the authors' view, for urgent or bailout cases, as the results are largely unknown. It is not the intention of this study to defend standard EVAR for patients with short proximal neck, but to present data on the expected outcome if this solution is considered the

most adequate for an individual patient. Open surgical repair may still be the preferred strategy for low risk patients with adverse proximal anatomy.

Aside from neck length, also female gender and maximum AAA diameter were found to be risk factors at mid-term, increasing risk 5.6 and 6.4-fold, respectively. These differences cannot be explained by difficulties during implantation, as these risk factors are not predictors of technical failure. Aneurysm diameter is a well characterized risk factor,[20,21] probably because of the risk of graft displacement in the aneurysm sac over time. Information of the luminal volume (rather than diameter) or on endograft displacement over time in patients at risk could help clarify this issue. The gender effect is enigmatic, but may reflect a higher anatomical complexity, not identified by the variables used for this study. This is a topic requiring further clarification.

As a prospective registry, ENGAGE is limited by the voluntary nature of inclusion. Also, it is a single graft study and the results may not be applicable to other late generation devices. Despite these limitations, the ENGAGE registry provides multicenter, worldwide data on a large sample of patients reducing greatly the risk of selection bias and type II statistical errors. Another relevant shortcoming is the relatively low number of patients with neck length $<$10 mm, which restricts the analysis for this most interesting subgroup. Although this risk factor emerged in multivariate models as highly predictive for both intra- and post-operative complications, the conclusions must be interpreted with care because of the overall low number of events. Another important limitation is that the cutoff for migration in the Registry was 10 mm as recommended in the Reporting Standards,[7] which may be excessive especially when considering patients with complex anatomy. For illustration purposes, patients were artificially divided into low and high risk for post-operative adverse events using a cutoff. However, it is not suggested that this classification should be used in clinical practice, instead the hazard ratio for each predictor is recommended as a more reliable method of estimating risk. Finally, it is acknowledged that individual features may have specific interactions that increase risk exponentially (such as short + angulated proximal anatomy), and this is not fully expressed in this or other publications regarding adverse proximal anatomy. Expert opinion for case selection is still a valuable asset for risk estimation in cases where multiple adverse features co-exist.

In conclusion, the results of this study support the adequacy of this device in the face of adverse neck anatomy, and confirm neck length as the most relevant anatomical limitation for EVAR. Additionally, it confirms the decline in early to mid-term intervention rates with a newer generation device in a large patient sample. Lastly, it suggests that neck related risk factors affect outcome and impact on prognosis with varying degrees.

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CONFLICT OF INTEREST

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