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One Year Stable Sac Predicts Worse Overall Survival and Midterm Outcomes Compared with Sac Regression after Complex Abdominal Aortic Aneurysm Repair with Fenestrated and Branched Endografts[☆]

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WHAT THIS PAPER ADDS

This multicentre study demonstrates that the dynamics of the aneurysm sac after fenestrated and branched endovascular repair for complex abdominal aortic aneurysm are significant predictors of midterm outcomes. At the 1 year follow up, sac regression was observed in 35.6% of patients and was associated with better overall midterm outcomes and survival rates. In contrast, 61.4% of patients showed sac stability, which correlated with more endoleaks, re-interventions, and sac expansion at later follow up. The findings suggest that monitoring sac behaviour can help predict patient prognosis, with sac regression indicating a more favourable outcome and stable sacs requiring vigilant follow up to anticipate potential risks.

Objective: This multicentre, retrospective, observational study investigated the correlation between sac dynamics and outcomes in patients with complex abdominal aortic aneurysms (AAAs) after fenestrated and branched endovascular repair (FBEVAR).

Methods: Consecutive patients undergoing FBEVAR for short neck infrarenal, juxtarenal, pararenal, and paravisceral AAAs between 2015 and 2022 were included. Based on one year sac dynamics, patients with sac expansion were excluded. Comparisons were made between patients with sac regression and those with sac stability. Primary endpoints included overall survival, freedom from re-interventions, and last follow up sac regression. Secondary outcomes included freedom from aorta related death, freedom from any endoleak, and freedom from cumulative adverse events.

Results: The study cohort included 98 patients, 36 with sac regression and 62 with sac stability at 1 year. Median follow up was 34 months (interquartile range 32). The 4 year estimated overall survival was lower for patients with sac stability (57.2 *vs.* 87.5%, $p = .029$), which also demonstrated a lower freedom from re-interventions (89.2 *vs.* 94.4%, $p = .11$). The 4 year estimates of last follow up sac regression were statistically significantly higher in those with initial sac regression (46 *vs.* 94.7%, $p < .001$). Cox regression analysis identified treatment of all renal and visceral vessels (hazard ratio [HR] 2.18, $p = .035$) and sac regression at 1 year (HR 2.37, $p = .015$) as independent predictors of follow up sac regression. Conversely, the presence of an endoleak (HR 0.31, $p = .050$) predicted the absence of sac regression. 1 year sac regression was an independent predictor of survival (HR 3.11, $p = .050$). Freedom from aorta related death (96.6 *vs.* 100%, $p = .26$), endoleak (66.3 *vs.* 90.2%, $p = .035$), and cumulative adverse events (89.7 *vs.* 94.4%, $p = .080$) were in favour of patients with sac regression.

Conclusion: Sac dynamics correlate with midterm outcomes after FBEVAR for complex AAAs. One year sac regression predicted better outcomes and survival, suggesting the need for closer surveillance in patients with stable sacs.

Keywords: Abdominal aortic aneurysms, Aneurysm sac dynamics, Endovascular procedures, Surveillance, Survival
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INTRODUCTION

Aortic sac regression is widely recognised as a reliable predictor of favourable long term outcomes following endovascular aneurysm repair (EVAR) for abdominal aortic aneurysms (AAAs).[1—3] A decrease in sac size over time is generally associated with a reduced risk of complications, including endoleak, rupture, and re-intervention. Conversely, a stable aneurysm sac following EVAR has been found to be a less reliable indicator of favourable outcomes, as it does not necessarily correlate with freedom from re-intervention or death during follow up.[4—6]

Given these considerations, monitoring the post-procedural behaviour of the aneurysm sac plays a crucial role in guiding surveillance protocols and optimising patient management strategies.[7] Aortic sac dynamics, whether regression, stability, or expansion, can provide valuable insights into the durability of the repair and the likelihood of long term success. Indeed, continued growth of the aneurysm sac has been recognised as a core outcome that should be reported in studies evaluating AAA treatment.[8] However, despite the well established importance of sac behaviour following standard EVAR, there remains a significant gap in the literature regarding its implications after more complex endovascular interventions.

Specifically, fewer studies have explored sac regression and stability following the treatment of complex abdominal aortic aneurysms (cAAAs), such as short neck infrarenal, juxtarenal, pararenal, and paravisceral aneurysms, using fenestrated and branched endovascular repair (FBEVAR). These procedures, which are designed to extend the applicability of endovascular repair to anatomically challenging aneurysms, involve a more intricate technique and potentially different follow up outcomes compared with standard EVAR. Given the greater technical demands and the involvement of vital branch vessels, understanding the post-procedural sac response in this subset of patients is essential for refining follow up strategies and improving patient risk assessment.

Therefore, the primary objective of this study was to assess and compare follow up outcomes in patients with sac regression *vs.* those with stable aneurysm sacs following cAAA repair using FBEVAR. By evaluating differences in clinical outcomes between these two groups, the aim was to provide valuable insights into the prognostic significance of sac behaviour in patients undergoing advanced endovascular treatments for cAAAs.

METHODS

Study design

This study was a multicentre, retrospective, observational study. All consecutive patients who underwent FBEVAR for cAAA between January 2015 and December 2022 at four high volume centres were collected from each institutional dataset. Patients who had undergone either elective or urgent endovascular repair for a short neck (4 — 10 mm) infrarenal, juxtarenal, pararenal, and paravisceral AAA with a fenestrated or branched stent graft and had completed at least 1 year follow up were included in the study. Patients treated for thoraco-abdominal aortic aneurysm or post-dissection pathology and patients who had undergone prior open or endovascular aortic repair were excluded.

All patients provided informed consent for their data to be recorded in institutional databases and used for research purposes. Given the retrospective nature of this study and the use of pseudonymised data, ethics committee approval was waived in accordance with institutional policies. The procedures were conducted in accordance with national and international guidelines.[9,10] Pre-operative demographics, anatomical characteristics, status of all aortic side branches, graft design, procedural details, and follow up data were collected. Disease extent and anatomical characteristics were assessed on pre-operative computed tomography angiography (CTA). Device planning and the selection of bridging stents were based on centreline measurements and determined by the implanting physicians according to each centre's protocol. Perioperative mortality and major complication rates were documented. The follow up protocol consisted of an early CTA (within 3 months of the index procedure) and annual CTAs thereafter. Deviations from the follow up protocol were allowed at the centre's discretion, in cases of complications or diagnostic uncertainties. Along with imaging assessments, the follow up data retrieval process encompassed in person consultations, as well as telephone interviews with patients or their family members, a review of medical records, and consultation of electronic databases linked to relevant mortality registries. Pre- and post-operative CTAs were evaluated by two dedicated physicians at each institution, who were responsible for image reconstruction and measurement of the maximum AAA diameter using centreline projections. Image reconstruction and measurements were performed using Aquarius iNtuition (Tera Recon, Durham, NC, USA) and 3mensio Medical Imaging (Pie Medical Imaging, Maastricht, the Netherlands) software. The maximum AAA diameter was compared with pre-operative measurements to allow sac dynamics stratification.

Throughout the follow up period, all deaths, endoleaks, as well as the number and type of re-interventions were recorded.

The checklist of items adhered to the guidelines of the STrengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement.[11]

Definitions and endpoints

Patients were divided in three groups based on 1 year sac behaviour: expanded, stable, or regressed. According to reporting standards, sac regression was defined as a reduction of > 5 mm in sac diameter compared with the baseline measurement taken before stent graft implantation. Stability was defined as a change in sac size ≤ 5 mm, while an expansion was identified when the sac enlarged by > 5 mm.[12]

After aneurysm sac analysis, patients presenting with sac expansion at 1 year follow up were excluded, and comparisons were performed between the stable sac and sac regression groups. The classification based on the extent of the aortic aneurysm, as well as all the other definitions adhered to reporting standards for endovascular repair of

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aortic aneurysms involving the renal and mesenteric arteries.[12]

Primary outcomes were estimates of overall survival, freedom from re-intervention, and last follow up sac regression ($>$ 5 mm compared with maximum sac pre-operative dimensions). Secondary outcomes were estimates of freedom from aorta related death, freedom from any endoleak, and freedom from cumulative adverse events (defined as a composite outcome including aorta related deaths, type I or III endoleaks, and re-interventions). An additional analysis was conducted on the entire cohort to identify potential predictors of the primary outcomes during follow up.

Statistics

The statistical analysis was conducted using SPSS v. 29 statistical software (IBM Corporation, Armonk, NY, USA). Statistical and data reporting adhered to established guidelines and recommendations.[13]

Continuous variables were tested for normality using the Shapiro—Wilk test and visual assessment of quantile—quantile plots; they were presented as mean ± standard deviation if normally distributed or otherwise as median and interquartile range (IQR). Categorical variables were presented as frequencies and percentages. Quantitative variables were compared using one way ANOVA, the Mann—Whitney *U* test, or the Student's *t* test, while qualitative variables were compared using the Pearson χ^2 or Fisher's exact test.

To ensure the reliability of maximum AAA diameter measurements, intra-observer and interobserver variability were assessed. Two independent physicians at each institution performed the measurements. For intra-observer variability, each observer repeated the measurements on all scans after a pre-defined interval, ensuring they were blinded to their initial readings. For interobserver variability, measurements from the two observers were compared for the same set of images. The degree of agreement for both intra-observer and interobserver measurements was quantified using the intraclass correlation coefficient (ICC). The ICC was calculated using a single measurement, absolute agreement, two way random effects model. A high ICC ($>$ 0.9) was considered indicative of strong reliability.[14] The Kaplan—Meier method was employed to assess follow up outcomes, with comparisons made using the log rank test.

The Cox regression model using the Wald's backward stepwise analysis was used to identify potential predictors of the primary outcomes at follow up. Data were entered into the Cox model if they had $p < .20$ at the univariable analysis; in multivariable analyses, covariables were expressed as hazard ratios (HRs) with 95% confidence intervals (CIs). Statistical significance was defined as $p < .050$.

RESULTS

Study group characteristics

During the study period, 200 consecutive patients underwent FBEVAR for abdominal aortic pathologies. Of these, 99 patients were excluded for not meeting the inclusion criteria or for lacking a 1 year or last follow up CTA exam. The remaining 101 patients were examined for potential inclusion in the study. Indications for treatment consisted of 12.9% short neck infrarenal AAAs, 36.6% juxtarenal, 37.6% pararenal, and 12.9% paravisceral AAAs. At 1 year follow up, 36 (35.6%) patients showed aneurysm sac regression, whereas 62 (61.4%) patients presented with a stable sac. Three patients (3%, one juxtarenal, one pararenal, and one paravisceral AAA) demonstrated 1 year sac expansion and were excluded from the analysis. The final study cohort included 98 patients.

Patients who presented with a stable sac at 1 year were older than those with sac regression (75.6 ± 8 *vs.* 72.8 ± 8 years, respectively), but there was no statistically significant difference between the two groups ($p = .98$). No differences between the groups were found in terms of pre-operative characteristics, risk factors, medical therapy, or anatomy (Table 1). Four patients (4.1%) were operated on in an urgent setting with an off the shelf outer branch device, two of which were for a ruptured pararenal AAA and two for a symptomatic paravisceral AAA. One of the four patients underwent a re-intervention 1 month post-procedure for a type IIIc endoleak from the left renal artery. This patient had a stable sac on the 1 year CTA but exhibited sac expansion (a 6 mm increase from the pre-operative maximum AAA diameter) at the last follow up. Another patient demonstrated sac regression on the 1 year CTA, which was maintained at the final follow up. The remaining two patients had a stable sac both at the 1 year and last follow up evaluations.

Intra- and peri-operative details, as well as events occurring within 1 year from the FBEVAR procedure are shown in Tables 2 and 3, respectively. At the 1 year follow up, all patients demonstrated a preserved proximal and distal sealing zone. Additionally, five patients (14.3%) with a regressed sac and 15 patients (24.6%) with a stable sac exhibited a type II endoleak at the same follow up ($p = .23$).

The intra- and interobserver ICCs for the maximum AAA diameters, calculated on pre-operative, 1 year post-operative, and last follow up CTAs, demonstrated strong measurement reliability. Specifically, the intra-observer ICCs were 0.956 (95% CI 0.932 — 0.976) for pre-operative, 0.993 (95% CI 0.988 — 0.996) for 1 year post-operative, and 0.994 (95% CI 0.989 — 0.997) for the last follow up CTA. The interobserver ICCs were 0.981 (95% CI 0.969 — 0.988), 0.961 (95% CI 0.938 — 0.976), and 0.988 (95% CI 0.980 — 0.993), respectively.

Follow up results

Primary outcomes. The median follow up was 34 months (IQR 32, mean 38.6 ± 21.2 months), while the median radiological follow up was 33 months (IQR 32, mean 38.3 ± 21.1 months). The 4 year overall survival in patients with a stable sac was 57.2% compared with 87.5% in patients with sac regression (log rank 4.78, $p = .029$).

The 4 year freedom from re-interventions was worse in the stable sac group (89.2 *vs.* 94.4%, log rank 2.54), but with no statistically significant difference ($p = .11$). One re-intervention was registered in the sac regression group and consisted of a

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Table 1. Pre-operative patient characteristics, adhering to the definitions of the reporting standards.[12]

Baseline characteristic	Overall	Sac regression	Sac stability	*p* value
Demographics and comorbidities				
Male sex	91 (92.9)	34 (94.4)	57 (91.9)	>.99
Age − y	74.6 ± 8.1	72.8 ± 8	75.6 ± 8	.98
Elective repair	94 (95.9)	35 (97.2)	59 (95.2)	.62
Hypertension	84 (85.7)	33 (91.7)	51 (82.3)	.20
Dyslipidaemia	62 (63.9)	24 (66.7)	38 (62.3)	.67
Diabetes	20 (20.4)	8 (22.2)	12 (19.4)	.73
Heart disease	41 (41.8)	16 (44.4)	25 (40.3)	.69
COPD	53 (54.1)	18 (50)	35 (56.5)	.54
Chronic kidney disease	22 (22.4)	7 (19.4)	15 (24.2)	.59
Cerebrovascular disease	12 (12.2)	3 (8.3)	9 (14.5)	.53
Peripheral artery disease	15 (15.3)	8 (22.2)	7 (11.3)	.15
Smoking history	65 (78.3)	24 (82.8)	41 (75.9)	.48
Medical therapy				
SAPT	35 (59.3)	12 (57.1)	23 (60.5)	.80
DAPT	5 (8.5)	3 (14.3)	2 (5.3)	.23
DOAC or NOAC	8 (13.6)	2 (9.5)	6 (15.8)	.50
Statins	52 (88.1)	20 (95.2)	32 (84.2)	.20
Metformin	11 (18.6)	5 (23.8)	6 (15.8)	.45
Anatomical characteristics				
Short neck infrarenal AAA	13 (13.3)	5 (13.9)	8 (12.9)	.89
Juxtarenal AAA	37 (37.8)	15 (41.7)	22 (35.5)	.54
Pararenal AAA	37 (37.8)	13 (36.1)	24 (38.7)	.80
Paravisceral AAA	11 (11.2)	3 (8.3)	8 (12.9)	.49
Max aortic diameter − mm	61.4 ± 11.9	62.4 ± 11.3	60.2 ± 13	.60
Severe aortic neck thrombus	6 (10.2)	3 (14.3)	3 (7.9)	.44
Right CIA diameter − mm	17.1 ± 2.8	17.6 ± 4.7	16.3 ± 4.1	.36
Left CIA diameter − mm	16.5 ± 3.1	15.6 ± 4.1	15.9 ± 4.3	.86
IMA patency	42 (75.0)	13 (68.4)	29 (78.4)	.42
Patent lumbar arteries	6 (2)	7 (3)	6.5 (2)	.22

Data are presented as *n* (%), mean ± standard deviation, or median (interquartile range). COPD = chronic obstructive pulmonary disease; SAPT = single antiplatelet therapy; DAPT = dual antiplatelet therapy; DOAC = direct oral anticoagulant; NOAC = novel oral anticoagulant; AAA = abdominal aortic aneurysm; CIA = common iliac artery; IMA = inferior mesenteric artery.

Table 2. Intra- and peri-operative details.

Operative details	Overall	Sac regression	Sac stability	*p* value
CMD	84 (92.3)	32 (97)	52 (89.7)	.21
Four fenestration CMD	47 (56.0)	19 (59.4)	28 (53.8)	.62
Four branch CMD	1 (1.2)	1 (3.1)	0 (0)	.020
Three fenestrations + one branch CMD	2 (2.4)	0 (0)	2 (3.8)	.26
Two fenestrations + two branches CMD	1 (1.2)	1 (3.1)	0 (0)	.020
Three fenestrations + scallop CMD	7 (8.3)	2 (6.3)	5 (9.6)	.59
Three fenestrations CMD	7 (8.3)	1 (3.1)	6 (11.5)	.18
Two fenestrations + scallop CMD	10 (11.9)	4 (12.5)	6 (11.5)	.90
Two fenestrations CMD	8 (9.5)	3 (9.4)	5 (9.6)	.97
One fenestration CMD	1 (1.2)	1 (3.1)	0 (0)	.020
Off the shelf branched device	14 (7.7)	4 (3)	10 (10.3)	.47
Local anaesthesia	13 (16.3)	3 (10)	10 (20)	.24
Bilateral percutaneous femoral access	66 (73.3)	26 (78.8)	40 (70.2)	.37
Upper arm access	11 (12.2)	4 (12.1)	7 (12.3)	.98
Residual T2EL on completion angiography	26 (41.3)	10 (40)	16 (42.1)	.87
Fluoroscopy time − min	83.5 ± 34.3	86.6 ± 36	82.5 ± 32.3	.24
ICU stay − d	2 (2)	2 (2)	1 (2)	.37
Total hospital stay − d	6 (3)	6 (2)	6 (4)	.22

Data are presented as *n* (%), mean ± standard deviation, or median (interquartile range). CMD = custom made device; T2EL = type II endoleak; ICU = intensive care unit.

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Table 3. Events occurring within 1 year of the fenestrated and branched endovascular repair procedure.

	Overall	Sac regression	Sac stability	*p* value
TV related re-interventions	3 (3.2)	2 (5.9)	1 (1.7)	.30
Access related re-interventions	2 (2.1)	0 (0)	2 (3.3)	.53
T1EL related re-interventions	5 (5.3)	1 (2.9)	4 (6.7)	.65
T2EL	20 (20.8)	5 (14.3)	15 (24.6)	.23
T2EL related re-interventions	0 (0)			
T3EL related re-interventions	2 (2.1)	0 (0)	2 (3.3)	.53
Overall EL related re-interventions	7 (7.3)	1 (2.9)	6 (9.8)	.20
Iliac leg thrombosis related re-interventions	1 (1.1)	0 (0)	1 (1.7)	>.99

Data are presented as *n* (%). TV = target vessel; T1EL = type I endoleak; T2EL = type II endoleak; T3EL = type III endoleak; EL = endoleak.

33 month iliac limb relining for stenosis due to a flow limiting thrombus. The seven re-interventions registered in the stable sac group consisted of two cases of iliac extensions for a type Ib endoleak, one case of graft embolectomy for iliac leg thrombosis, one case of inferior mesenteric artery embolisation for a type II endoleak and concomitant superior mesenteric artery relining for partial occlusion, one case of sac coil embolisation for type II endoleak from lumbar arteries, one case of renal artery relining for a type Ic endoleak, and one case of superior mesenteric artery relining for asymptomatic stent occlusion. No patients who showed sac regression on the 1 year CTA presented with a sac dimension increase at the latest follow up scan, with the stable group showing statistically significantly worse 4 year estimates of last follow up sac regression (46 *vs.* 94.7%, log rank 14.8, $p < .001$). Kaplan—Meier curves of the primary outcomes are presented in Figure 1.

Cox regression analysis indicated that the treatment of all renal and visceral vessels (HR 2.18, $p = .035$), as well as evidence of sac regression at 1 year (HR 2.37, $p = .015$), were independent predictors of sac regression at follow up. Conversely, the presence of an endoleak at 1 year (HR 0.31, $p = .050$) predicted the absence of sac regression. One year sac regression was confirmed to be an independent predictor of survival during follow up (HR 3.11, $p = .050$).

Neither the use of a custom made device *vs.* an off the shelf branched device, nor the treatment of short neck infrarenal AAAs compared with more extensive aneurysms was found to predict any of the primary outcomes in the regression analysis. The results of uni- and multivariable analyses are presented in Table 4.

Secondary outcomes. There were two aorta related deaths in the stable group, while none were registered in the sac regression group, determining an estimated 4 year freedom from aorta related death of 96.6% and 100%, respectively (log rank 1.25, $p = .26$). One aorta related death occurred at 80 months due to aortic rupture in a patient who refused follow up after the 1 year CTA. The patient presented with a ruptured aortic sac of 100 mm and a type IIIc endoleak from the left renal artery. Initially, the patient had a 58 mm pararenal AAA treated with a fenestrated custom made device, which was stable at the 1 year follow up. The other aorta related death occurred at 37 months in a patient treated for a short neck infrarenal AAA of 81 mm. This patient had a stable sac on the 1 year CTA, with an occluded asymptomatic left renal artery stent. However, the patient later presented with a 10 mm ruptured sac and a type Ib endoleak due to the proximal migration of the left iliac limb endoprosthesis. Despite undergoing an emergency left limb extension, the patient did not survive.

Patients with a 1 year stable sac had lower estimates of 4 year freedom from any endoleak (66.3 *vs.* 90.2%, log rank 4.46, $p = .035$). The estimated 4 year freedom from cumulative adverse events (including aorta related deaths, type I or III endoleak, and re-interventions) was lower in the stable group (89.7 *vs.* 94.4%, log rank 3.07), with a trend towards a statistically significant difference between the two groups ($p = .080$). Kaplan—Meier curves of the secondary outcomes are illustrated in Figure 2.

DISCUSSION

This study has shown that 1 year sac dynamics might be a reliable surrogate marker of good outcomes after FBEVAR for cAAAs. There were 3% of patients who presented with a sac increase compared with pre-operative dimensions, whereas most patients (61.4%) showed a stable sac. One year sac regression was associated with better midterm outcomes compared with sac stability at that time point. Patients in the sac regression group showed better overall survival during follow up (87.5 *vs.* 57.2%), and no aneurysm ruptures were registered in this group. Moreover, regression analysis indicated that patients with 1 year sac regression had a three fold higher likelihood of overall survival (HR 3.1), although the CI was relatively wide (95% CI .99 — 9.8). The 4 year estimates of freedom from any endoleak were statistically significantly better in the sac regression group compared with patients with sac stability group (90.2 *vs.* 66.3%, $p = .035$), which contributed to an inferior, although not statistically different, incidence of re-interventions (estimated 4 year freedom from re-intervention was 94.4% in the sac regression group and 89.2% in the stable sac group, $p = .11$).

In contrast to a previous study involving 463 patients treated with FBEVAR, where aneurysm sac regression at 1 year was observed in approximately 58% of cases, this analysis demonstrated a lower regression rate of 35.6% at 1 year.[15] Although the aforementioned study included aneurysms with thoraco-abdominal extension (328 patients, 70.8%) and sac expansion (19 patients, 4.1%), similar to the

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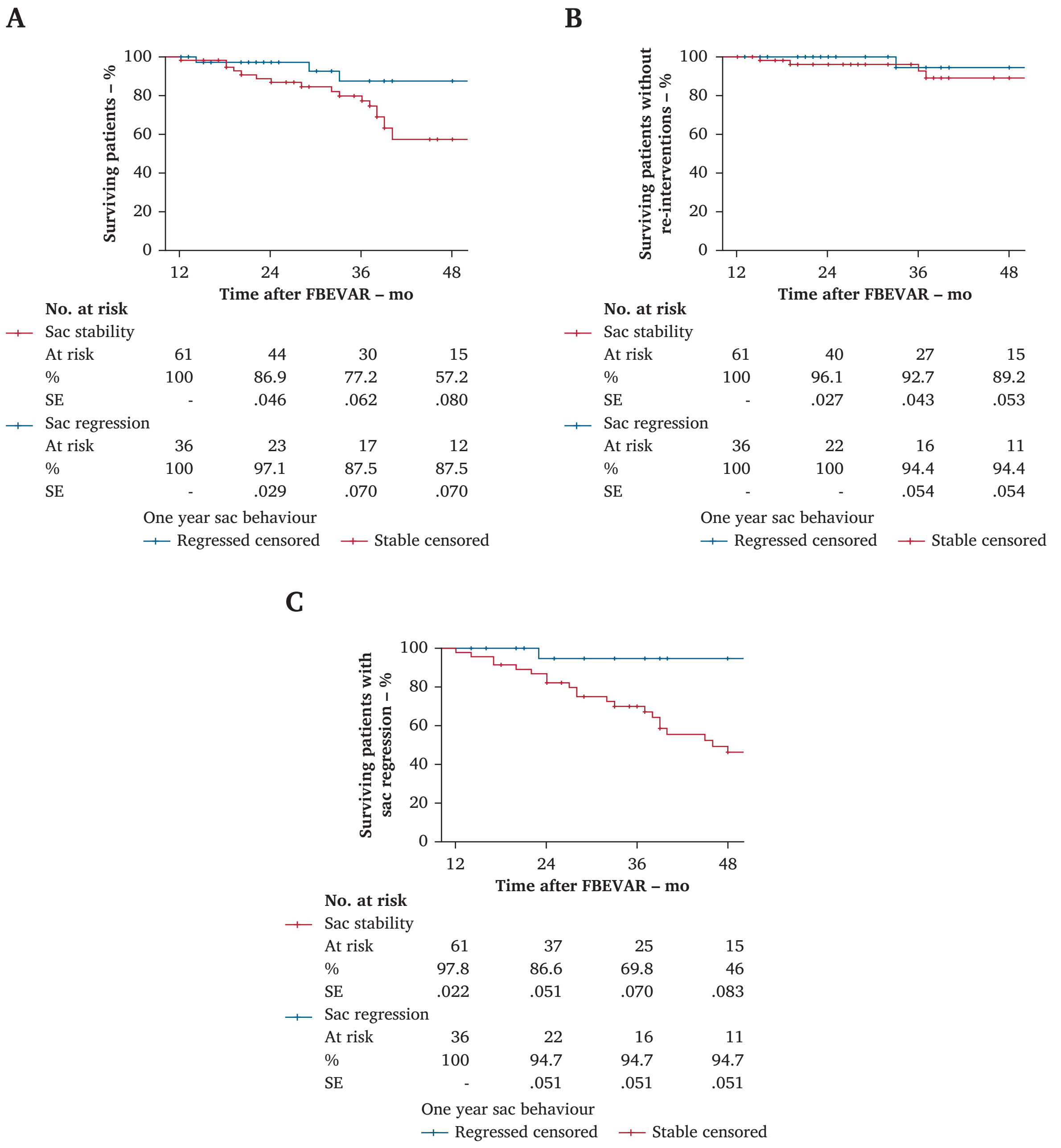

A

No. at risk				
Sac stability				
At risk	61	44	30	15
%	100	86.9	77.2	57.2
SE	-	.046	.062	.080
Sac regression				
At risk	36	23	17	12
%	100	97.1	87.5	87.5
SE	-	.029	.070	.070

B

No. at risk				
Sac stability				
At risk	61	40	27	15
%	100	96.1	92.7	89.2
SE	-	.027	.043	.053
Sac regression				
At risk	36	22	16	11
%	100	100	94.4	94.4
SE	-	-	.054	.054

C

No. at risk				
Sac stability				
At risk	61	37	25	15
%	97.8	86.6	69.8	46
SE	.022	.051	.070	.083
Sac regression				
At risk	36	22	16	11
%	100	94.7	94.7	94.7
SE	-	.051	.051	.051

Figure 1. Cumulative Kaplan–Meyer estimates of the primary outcomes: (A) overall survival, (B) freedom from re-interventions, and (C) last follow up sac regression. Standard error (SE) < 10%.

current findings, the authors reported a statistically significantly better 5 year survival estimate of 69% for the sac regression group and 46% for the failure to regress group, with comparable re-intervention rates between the two.[15] It is believed that the difference in the current results is attributable to the focus on a more homogenous anatomical area, excluding thoraco-abdominal extensions, thereby enhancing the reliability of comparisons. Indeed, different regions of the aorta have distinct embryonic origins and, consequently, different contractile properties. Neural crest derived vascular smooth muscle cells in the thoracic aorta are presumably better suited for adaptive remodelling than those in the abdominal aorta. They are capable of withstanding higher pulse pressures and ejection volumes by laying down more elastic lamellae during development.[16,17] These factors influence the aortic wall's capacity to respond to wall stresses induced by changes in fluid dynamics post-endograft implantation and by endoleaks, with the response rate potentially differing between the abdominal and thoracic aortic regions.

In this series, all patients who exhibited sac regression 1 year after the procedure maintained this outcome at the latest follow up, with a more than two fold likelihood of midterm sac regression according to regression analysis. In

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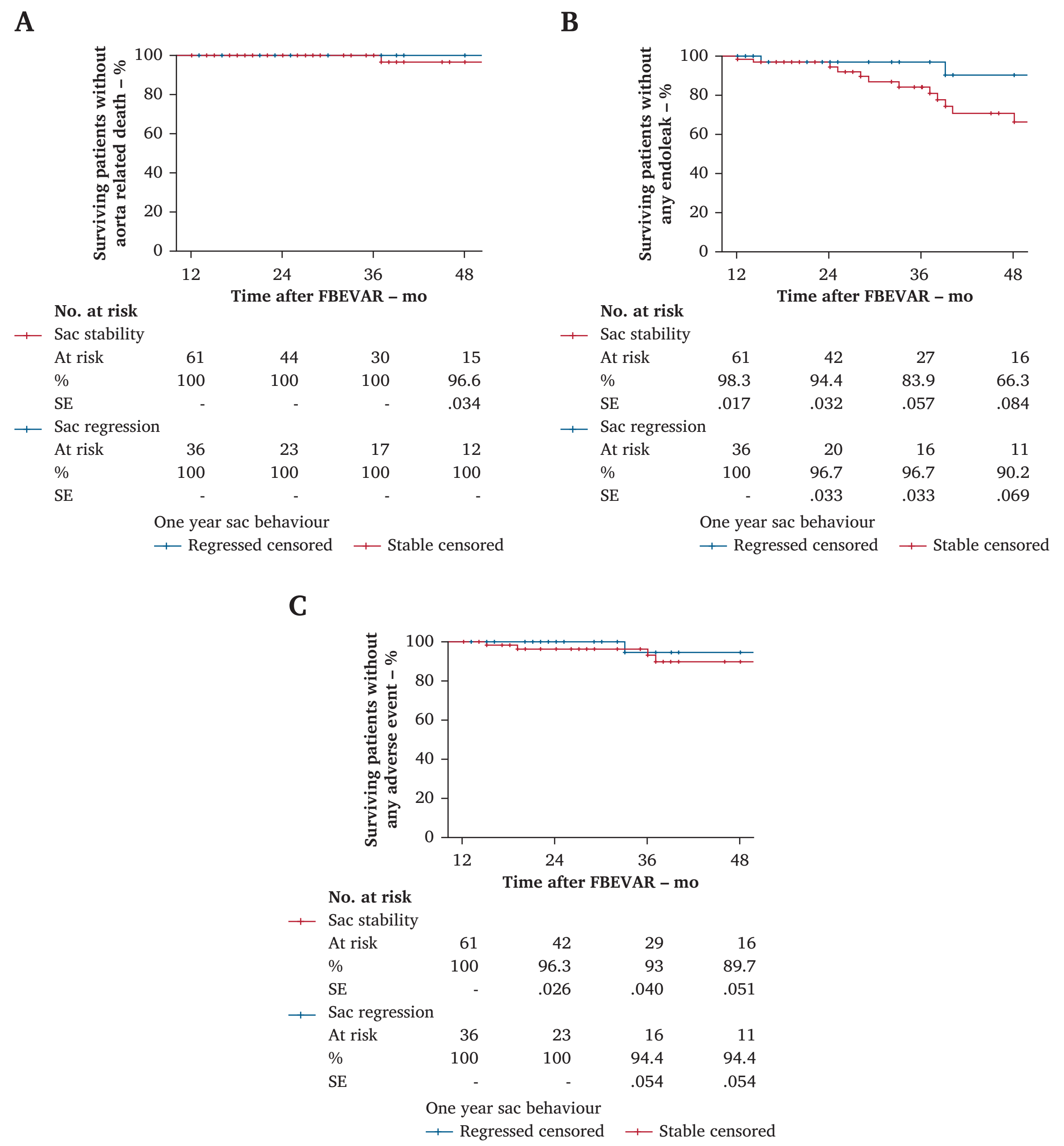
Table 4. Cox regression analysis of potential predictors of the primary outcomes.

Predictor	Overall survival			Freedom from re-intervention			Last follow up sac regression		
	Univariable	Multivariable		Univariable	Multivariable		Univariable	Multivariable	
	p value	HR (95% CI)	*p* value	*p* value	HR (95% CI)	*p* value	*p* value	HR (95% CI)	*p* value
Short neck infrarenal AAA	.76			.86			.71		
Custom made device	.43			.75			.51		
Four vessel treatment	.42			.80			.062	2.18 (1.06–4.48)	.035
One year endoleak	.59			.43			.011	.31 (.09–1.01)	.050
One year sac regression	.029	3.11 (.99 – 9.8)	.05	.11			.010	2.37 (1.18–4.75)	.015

HR = hazard ratio; CI = confidence interval; AAA = abdominal aortic aneurysm.



A

No. at risk				
Sac stability				
At risk	61	44	30	15
%	100	100	100	96.6
SE	-	-	-	.034
Sac regression				
At risk	36	23	17	12
%	100	100	100	100
SE	-	-	-	-

B

No. at risk				
Sac stability				
At risk	61	42	27	16
%	98.3	94.4	83.9	66.3
SE	.017	.032	.057	.084
Sac regression				
At risk	36	20	16	11
%	100	96.7	96.7	90.2
SE	-	.033	.033	.069

C

No. at risk				
Sac stability				
At risk	61	42	29	16
%	100	96.3	93	89.7
SE	-	.026	.040	.051
Sac regression				
At risk	36	23	16	11
%	100	100	94.4	94.4
SE	-	-	.054	.054

Figure 2. Cumulative Kaplan–Meyer estimates of the secondary outcomes: (A) freedom from aorta related death, (B) freedom from any endoleak, and (C) freedom from cumulative adverse events. Standard error (SE) < 10%.

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contrast, the sac regression estimates at the latest follow up in the stable sac group was significantly lower (46% estimated at 4 years). Moreover, these findings indicate that opting for complete treatment of all four renal and visceral vessels, rather than using scallop techniques or omitting treatment, is a significant independent predictor of sustained sac regression at follow up. This suggests that comprehensive management of this aortic segment may lead to more favourable follow up outcomes by promoting effective sac remodelling and reducing implant instability, which could otherwise contribute to endograft displacement and subsequent sac expansion.

Conversely, the presence of an endoleak 1 year post-treatment emerged as a predictor of absent sac regression at follow up, highlighting its role as a potential impediment to effective sac shrinkage over time. This relationship underscores the importance of early detection and potential management of endoleaks, as their presence may compromise the durability of aneurysm repair by allowing persistent pressurisation of the aneurysm sac, which could ultimately necessitate open surgical conversion.[18,19]

Regarding type Ia endoleaks, which have been associated with proximal neck remodelling after standard EVAR, no re-interventions were observed in this cohort during midterm follow up.[20] This may be attributed to the fact that FBEVAR procedures typically allow for more extensive proximal landing zones within healthy aortic segments, making proximal neck remodelling a less significant concern in this setting. Instead, other factors, such as type Ic or IIIc endoleaks, related to the treatment and anatomical characteristics of target vessels may play a more prominent role in influencing sac behaviour over time.[21–23] These endoleaks may occasionally go undetected, underscoring the need for more accurate diagnostic approaches in the future, such as dynamic CTA assessments.[24]

The recent study by Rastogi *et al.*, which closely resembles the current study, involved 165 patients and investigated the correlation between sac dynamics and long term outcomes by classifying patients into regression and non-regression groups based on a $>$ 5% proportional volume change at 1 year compared with 30 days. The cohort included both abdominal and thoraco-abdominal aortic aneurysms, with the study concluding that non-regression at 1 year imaging is associated with a higher 5 year all cause mortality rate and an increased risk of graft related events after FBEVAR.[25] While it is agreed that assessing sac volume change is a valuable method for stratifying patients based on sac dynamics, it is argued that combining patients with sac expansion and those with stable sacs may introduce bias, as the management of an enlarging sac differs from that of a stable sac.[9,10] Therefore, although reducing follow up assessments for patients showing sac regression may be appropriate, those with stable sacs should not be exempt from regular monitoring. However, unlike patients with expanding sacs, it is the current authors' opinion that they should continue to undergo annual assessments. More specifically, based on the current findings, it would be reasonable to consider that patients treated for cAAA, such as short neck infrarenal, juxtarenal, pararenal, and paravisceral aneurysms with FBEVAR, who exhibit sac regression at 1 year in the absence of endoleaks, may benefit from less frequent follow up. Implementing a follow up strategy that alternates annual assessments between CTA and Doppler ultrasound is suggested to minimise both radiation exposure and costs. In contrast, patients with a stable sac should continue with annual CTA evaluations to monitor for any potential increase in the risk of adverse events during follow up.

Study limitations

This study had several limitations that should be considered. Firstly, it was a retrospective multicentre study, which introduced variability due to differences in surgeons' expertise and the types of materials used across different centres. Such variability may have influenced the outcomes related to aneurysm sac dynamics. Additionally, although aortic measurements demonstrated strong reliability in the ICC analysis, they were not independently validated by an external core lab, which raises the possibility of inaccuracies that could have affected the classification and interpretation of sac dynamics. Another limitation was the absence of volume measurements, which could offer additional insights into sac behaviour. While it was chosen not to include them due to the technical challenges and variability associated with volume calculations, this is an area for potential exploration in future studies, especially with the use of artificial intelligence driven techniques to improve accuracy and consistency.[26,27] Lastly, the relatively small sample size may have limited the statistical power of the study and hindered its ability to generalise the findings to broader populations. This is particularly reflected in the wide CI for the HR for survival associated with 1 year sac regression, which may be attributed to the limited sample size of the comparison groups. While the HR suggests a potential association, the wide CI indicates a degree of uncertainty. These limitations highlight the need for larger, prospective studies to validate these results and provide more precise estimates.

Nevertheless, at the time of writing, this study represents one of the first to compare sac regression and sac stability following FBEVAR treatment of complex aneurysms solely involving the abdominal aortic segment. Like EVAR treatment, correlating long term outcomes with sac dynamics could help identify patient subcategories that may benefit from less frequent follow up, thereby reducing both radiation exposure and the associated costs of potentially unnecessary scans.

Conclusions

This multicentre study confirms that, as shown in standard EVAR, the behaviour of the aneurysm sac is also linked to midterm outcomes following more extensive treatment with FBEVAR for cAAA. Sac regression at the 1 year follow up demonstrated better outcomes in terms of overall survival, as well as nearly significant better overall freedom from procedure related adverse outcomes at midterm follow up. Nevertheless, patients with a stable sac might necessitate a closer surveillance.

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CONFLICTS OF INTEREST

None.

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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.2025.06.027.

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