

# Editor's Choice – Implementation of the Updated European Society for Vascular Surgery Proposed Endovascular Aneurysm Repair Surveillance Algorithm in a Multicentre Cohort with a Minimum Five Year Follow Up Adherence: Further Improvement of Results via One Year Sac Dynamics<sup>☆</sup>

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## WHAT THIS PAPER ADDS

This study represents a real life retrospective validation of the post-endovascular aneurysm repair follow up protocol proposed by the European Society for Vascular Surgery (ESVS), focusing on a cohort with at least five years of follow up. According to the ESVS grading system, the protocol for low risk patients demonstrated an acceptable capability of predicting potential adverse events, showing a five year cumulative freedom from ruptures, re-interventions, and or abdominal aortic aneurysm related death of 90.7%. However, an enhanced protocol considering patients as low risk if they meet the ESVS criteria and show sac regression and no endoleak at one year follow up would have yielded superior results, with a five year cumulative freedom from adverse events reaching 97.6%.

**Objective:** This multicentre, retrospective, observational study aimed to identify patients who are suitable for less frequent follow up (FU) checkups after endovascular aneurysm repair (EVAR) through the validation and implementation of the recently updated European Society for Vascular Surgery (ESVS) surveillance algorithm.

**Methods:** An analysis was performed on consecutive patients who underwent EVAR for abdominal aortic aneurysm (AAA) at four high volume centres that demonstrated adherence to FU for at least five years. Patients were divided into high and low risk of adverse event groups, according to ESVS definitions, and compared. A sub-analysis was conducted for patients categorised as low risk who exhibited sac regression and no evidence of endoleak at the one year FU assessment.

**Results:** Of 596 patients meeting the inclusion criteria, 300 (50.3%) fulfilled the ESVS criteria for classification as low risk. At the five year FU, the rates of rupture (0.7% vs. 3%;  $p = .031$ ), AAA related death (0.7% vs. 2.4%;  $p = .089$ ), and re-intervention (9.7% vs. 17.2%;  $p = .007$ ) were lower in the low risk group. Over the initial five years of FU, 84 patients experienced adverse events such as re-interventions, ruptures, and or AAA related death, with 28 occurring in the ESVS low risk group, indicating that the ESVS protocol has a five year capability of predicting 90.7% of potential adverse events in low risk patients. The sub-analysis of ESVS low risk patients who exhibited sac regression and no evidence of endoleak at one year FU (20.1% of the total cohort) revealed a five year modified ESVS protocol capability of potentially predicting 97.6% of adverse events (three re-interventions recorded).

**Conclusion:** The updated ESVS surveillance algorithm provides a consistent prediction of potential adverse events within five years of FU, although refining patient stratification may further improve outcomes. Patients initially classified as low risk and also exhibiting sac regression without endoleaks at one year could be candidates for reduced surveillance.

**Keywords:** Abdominal aortic aneurysm, Endoleak, Endovascular aneurysm repair, Follow up studies

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## INTRODUCTION

With the advance of endovascular aneurysm repair (EVAR) for abdominal aortic aneurysm (AAA) and the implementation of materials and techniques, along with the increased life expectancy of the general population, the need to identify patients who may benefit from less stringent follow up (FU) becomes necessary both for the patient and for reducing the associated costs.

In 2019, the European Society for Vascular and Endovascular Surgery (ESVS) proposed an algorithm designed to direct FU checkups, with a particular emphasis on the first five years post-intervention. This algorithm stratified patients into low, intermediate, and high risk groups based on the risk of late complications, which is assessed after the initial post-operative computed tomography angiography (CTA) examination. According to the algorithm, low risk patients (no endoleak, anatomy within instructions for use [IFU], adequate overlap, and a 10 mm stent graft to wall seal proximally and distally) could have been considered for limited FU, with delayed imaging until five years after repair.<sup>1</sup>

With the most recent 2024 update of the ESVS guidelines, the FU algorithm has also undergone modifications. This time, the criteria for patient stratification are more stringent. To be defined as low risk, a patient must have no endoleak, anatomy within IFU, and no high risk features (proximal neck diameter < 30 mm and angulation < 60°, and iliac diameter < 20 mm) on post-operative imaging. Additionally, there must be adequate overlap and a seal of  $\geq 10$  mm with proximal and distal stent graft apposition to the arterial wall. These newly defined low risk patients could be considered for limited FU, with delayed imaging until five years after repair. In contrast, patients defined as high risk could be considered for yearly examinations.<sup>2</sup> Sac dynamics are another crucial prognostic factor to consider in surveillance strategies. It is well established that sac regression is associated with improved survival and a lower incidence of secondary interventions and EVAR related complications.<sup>3</sup>

The study aimed to identify patients who may be suitable for less frequent post-EVAR FU checkups by validating and implementing the recently updated ESVS surveillance algorithm in a multicentre population with a FU adherence of at least five years.

## MATERIALS AND METHODS

### Study design

A retrospective analysis was conducted on consecutive patients who underwent EVAR for abdominal aortic aneurysm (AAA) between January 2014 and December 2018 at four high volume Italian centres. From this cohort, all patients with a FU adherence of at least five years without any imaging interruptions were included. Patients who died during the first five years of FU, whether or not AAA related, were also included. Patients with less than five years of FU adherence were excluded. The selected patients were stratified into low and high risk groups for adverse events, based on ESVS definitions, and subsequently compared.

Demographic details, comorbidities, pre-operative anatomical characteristics, and FU data were gathered prospectively from individual institutional datasets and subsequently consolidated into a dedicated database for retrospective analysis. Sac dynamics and dimensions were documented at each FU checkup, along with assessment for the presence of endoleaks. The indications for performing an EVAR procedure adhered to national and international guidelines.<sup>1,2,4</sup> All patients from each centre provided informed consent for the inclusion of their information in institutional records and its analysis. Due to the retrospective nature of the study, which used anonymised data, approval from an ethics committee was not required according to the national legislation. The checklist of items followed the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement.<sup>5</sup>

### Definitions

Definitions conformed to the reporting standards.<sup>6</sup> Abdominal aortic aneurysm sac regression was defined as a reduction of > 5 mm in sac diameter compared with the baseline study conducted immediately before stent graft implantation. Conversely, stability was defined as a sac change of  $\leq 5$  mm, and an increase was identified in cases where the sac enlarged by > 5 mm. The ESVS guidelines were used to stratify patients as at low or high risk of adverse events. These guidelines define patients at high risk of adverse events based on pre-operative features (such as non-adherence to the IFU during the procedure, proximal neck diameter > 30 mm, proximal neck angulation > 60°, and iliac diameters > 20 mm) and 30 day post-operative CTA findings (including the presence of endoleak and inadequate overlap or sealing zones).<sup>2</sup>

### Follow up algorithms

All institutional FU protocols included a post-operative CTA within one month of the index procedure. Pre- and post-operative CTAs were assessed by a dedicated physician at each institution, who was responsible for image reconstructions and centre line measurements. A one year FU checkup, comprising either Doppler ultrasound (DUS) or CTA, was consistently conducted at each institution. Either DUS or CTA AAA maximum diameter measurements were compared with pre-operative dimensions to allow sac dynamic stratification. Subsequent FU assessments were performed at the discretion of individual participating centres, typically involving DUS or CTA at least once every year; however, cases of DUS diagnostic uncertainty always warranted either contrast enhanced ultrasound (CEUS) or CTA. In addition to in person consultations and imaging assessments, the FU data retrieval process included telephone interviews with patients or their family members, review of medical records, and consultation of regional electronic databases directly linked to relevant mortality registries.

### Endpoints and sub-analysis

Primary endpoints included rates of rupture, re-intervention, and AAA related death within five years of FU, compared

between groups categorised as low and high risk of adverse events according to ESVS guidelines. The cumulative five year freedom from adverse events, such as ruptures, re-interventions, and or AAA related death, was used to assess the ability of the proposed surveillance algorithm's risk stratification to predict potential adverse events for low risk patients over a five year FU period. Secondary endpoints comprised longer term estimates of freedom from rupture, re-interventions, and AAA related death in the two groups. A sub-analysis was performed to compare the same outcomes in low risk patients who exhibited sac regression and no evidence of endoleak at the one year FU assessment with those of the remaining cohort collectively considered to be high risk.

### Statistics

The statistical analysis was performed using the SPSS v. 25 statistical software (IBM Corporation, Armonk, NY, USA). Statistical and data reporting followed established guidelines and recommendations.<sup>7</sup> Continuous variables were tested for normality through the Shapiro–Wilk test and visual evaluation of quantile–quantile plots; variables were presented as mean  $\pm$  standard deviation (SD) if normally distributed or as median and interquartile range (IQR). Categorical variables were presented as frequencies and percentages. Quantitative variables were compared with one way ANOVA, Mann–Whitney *U* or Student's *t* test; qualitative variables were compared with Pearson's  $\chi^2$  test. The Kaplan–Meier method was used to evaluate freedom from rupture, re-intervention, and AAA related death at FU. Estimates were compared with the log rank test. The strength of the association of variables with the outcome was estimated by calculating odds ratios (ORs) and 95% confidence intervals (95% CIs). Statistical significance was considered for *p* values  $<$  .050.

## RESULTS

### Study group

During a five year period at the four centres, 1301 patients underwent EVAR for AAA treatment. Among them, 270 (20.8%) died due to causes unrelated to AAA and nine (0.7%) had an AAA related death within the five years following the procedure, determining an overall five year mortality rate of 21.4%. As per the aim of this study, 568 patients with less than five years of FU (43.7%) were excluded from the analysis. Omitting 279 patients who died during the first five years, adherence to the five year FU program was 45.2% (462 out of 1022 surviving patients). An additional 137 patients (10.5%) were excluded from the analysis due to missing data required for patient stratification, such as pre-operative anatomical characteristics or FU sac dynamics information. Consequently, the final cohort comprised 596 patients. Within this group, 300 patients (50.3%) met the ESVS criteria for classification as low risk of adverse events (ESVS low risk group), while the remaining 296 patients (49.7%) had at least one feature defining them as high risk (ESVS high risk group). The patient selection process is clarified in [Supplementary](#)

[Figure S1](#). According to the previous ESVS stratification criteria, 391 of 596 patients (65.6%) would have been classified as low risk, indicating that with the newly proposed ESVS criteria, 91 patients (15.3% of the total cohort) no longer fell into this category.

[Table 1](#) presents the characteristics of the two cohorts. No statistically significant differences were observed between the two groups regarding demographic characteristics and comorbidities. The ESVS low risk group had a higher prevalence of pre-operative statin therapy (57.3% vs. 46.6%; *p* = .010). Concerning anatomical characteristics, this group exhibited smaller proximal aortic necks and iliac diameters.

Regarding the diagnostic methods for assessing sac dimensions and dynamics, all patients underwent a pre-operative and 30 day post-operative CTA. For the one year and five year FU imaging assessments, CTA was used in 48.6% and 46.6% of cases, respectively, while DUS was preferred for the remainder, accounting for 51.4% of cases at one year and 53.4% at five years. The distribution of the type of imaging assessment used across the study period is illustrated in [Supplementary Figure S2](#).

### Five year and longer term outcomes

At the five year FU, the rupture rates were significantly lower in the ESVS low risk group (0.7% vs. 3%; *p* = .031) and the AAA related mortality rates tended to be higher in the ESVS high risk group (0.7% vs. 2.4%; *p* = .089). Among the events that occurred in the ESVS low risk group, one patient experienced aneurysm rupture due to sac increase with a type II endoleak and graft infection at 28 months, underwent urgent conversion, and subsequently died. Another patient died six months post-procedure due to sepsis secondary to graft infection. Additionally, one patient underwent successful graft explantation due to an aortic sac increase for a type Ia endoleak and rupture at 59 months.

During the same period, the re-intervention rate was lower in the ESVS low risk group (9.7% vs. 17.2%; *p* = .007). The 29 re-interventions registered in the ESVS low risk group consisted of 11 proximal and or distal graft extensions for a type Ia and or Ib endoleak, two translumbar aneurysm sac embolisations for a type II endoleak, two stent graft re-linings for a type III endoleak, nine iliac leg re-linings for flow obstructing thrombosis, and five open conversions (one semi-conversion with graft preservation for a type II endoleak, three total conversions for concomitant type Ia and II endoleaks, and one total conversion for aneurysm rupture due to a type II endoleak).

Overall, during the initial five years of FU, 84 patients experienced adverse events such as re-interventions, ruptures, and or AAA related death, with 30 (36%) occurring in the ESVS low risk group. Two of the 30 adverse events observed in the ESVS low risk group would probably not have been preventable with FU assessments: one case involved a patient who died at six months due to sepsis following graft infection, and the other was a sudden iliac limb occlusion that occurred 40 months after EVAR due to the suspension of dual antiplatelet therapy for planned

**Table 1.** Pre-operative characteristics of the low and high risk groups classified according to the European Society for Vascular Surgery grading system.

Baseline characteristics	Total cohort (n = 596)	ESVS low risk group (n = 300)	ESVS high risk group (n = 296)	Odds ratio	p value
<i>Demographics</i>					
Age – y	75.1 ± 8.2	75.1 ± 7.8	75.1 ± 8.6		.98
Male sex	539 (90.4)	270 (90.0)	269 (90.9)	1.15	.62
<i>Risk factors</i>					
Emergency or urgent	25 (4.2)	13 (4.3)	12 (4.1)	1.07	.87
Hypertension	457 (76.7)	235 (78.3)	222 (75.0)	1.21	.35
Hypercholesterolaemia	307 (51.5)	165 (55.0)	142 (48.0)	1.34	.090
Tobacco use	249 (41.8)	122 (40.7)	127 (42.9)	1.53	.090
Coronary artery disease	200 (33.6)	107 (35.7)	93 (31.4)	1.21	.28
Peripheral artery disease	20 (3.4)	9 (3.0)	11 (3.7)	.95	.91
Cerebrovascular disease	26 (4.4)	15 (5.0)	11 (3.7)	1.64	.23
Chronic kidney disease	118 (19.8)	68 (22.7)	50 (16.9)	1.44	.080
Chronic obstructive pulmonary disease	254 (42.6)	127 (42.3)	127 (42.9)	.95	.78
Diabetes	109 (18.3)	56 (18.7)	53 (17.9)	1.06	.80
<i>Medications</i>					
Acetylsalicylic acid or clopidogrel	209 (35.1)	102 (34.0)	107 (36.1)	1.33	.21
Dual antiplatelet therapy	15 (2.5)	7 (2.3)	8 (2.7)	1.02	.98
Direct acting or novel oral anticoagulant	6 (1.0)	1 (0.3)	5 (1.7)	.23	.14
Statins	310 (52.0)	172 (57.3)	138 (46.6)	1.66	.010
Metformin	40 (6.7)	17 (5.7)	23 (7.8)	.84	.61
<i>Anatomical characteristics</i>					
Maximum AAA diameter	57.4 ± 12.7	56.4 ± 11.6	58.3 ± 13.6		.15
Proximal neck diameter	24.2 ± 3.4	23.6 ± 2.8	24.8 ± 3.8		<.001
Moderate or severe neck thrombosis	117 (19.6)	55 (18.3)	62 (20.9)	.92	.72
Right iliac artery diameter	17 ± 9.4	13.7 ± 2.6	20.2 ± 12.1		<.001
Left iliac artery diameter	15.8 ± 6.5	13.8 ± 3.3	17.9 ± 8.1		<.001
Patent IMA	257 (43.1)	127 (42.3)	130 (43.9)	.95	.85
Patent lumbar arteries >4	111 (18.6)	48 (16.0)	63 (21.3)	.69	.11

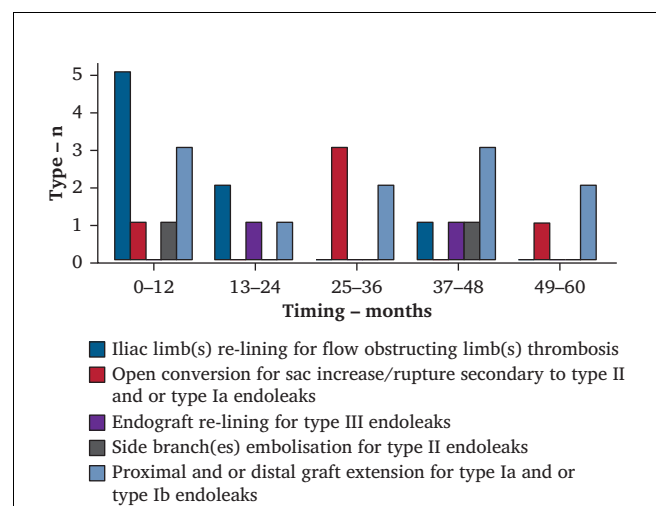
Data are presented as n (%) or mean ± standard deviation. ESVS = European Society for Vascular Surgery; AAA = abdominal aortic aneurysm; IMA = inferior mesenteric artery.

orthopaedic surgery. The remaining 28 adverse events in the ESVS low risk group were captured during routine FU imaging, and they might potentially have not been prevented by following the ESVS proposed FU surveillance algorithm. This indicates that had the ESVS protocol been followed, these low risk patients would have experienced a five year cumulative freedom from adverse events such as re-interventions, ruptures, and or AAA related death of 90.7%. Types and timing of the 28 adverse events recorded and the indications for re-intervention are illustrated in [Figure 1](#) and detailed in [Supplementary Table S1](#). In a subgroup analysis of the 287 electively treated patients in the low risk group (287 excluding 13 treated in urgent or emergency settings), following the ESVS surveillance protocol might have resulted in 26 adverse events being undiagnosed or not prevented, resulting in a five year cumulative freedom from adverse events rate of 90.9% for this subgroup.

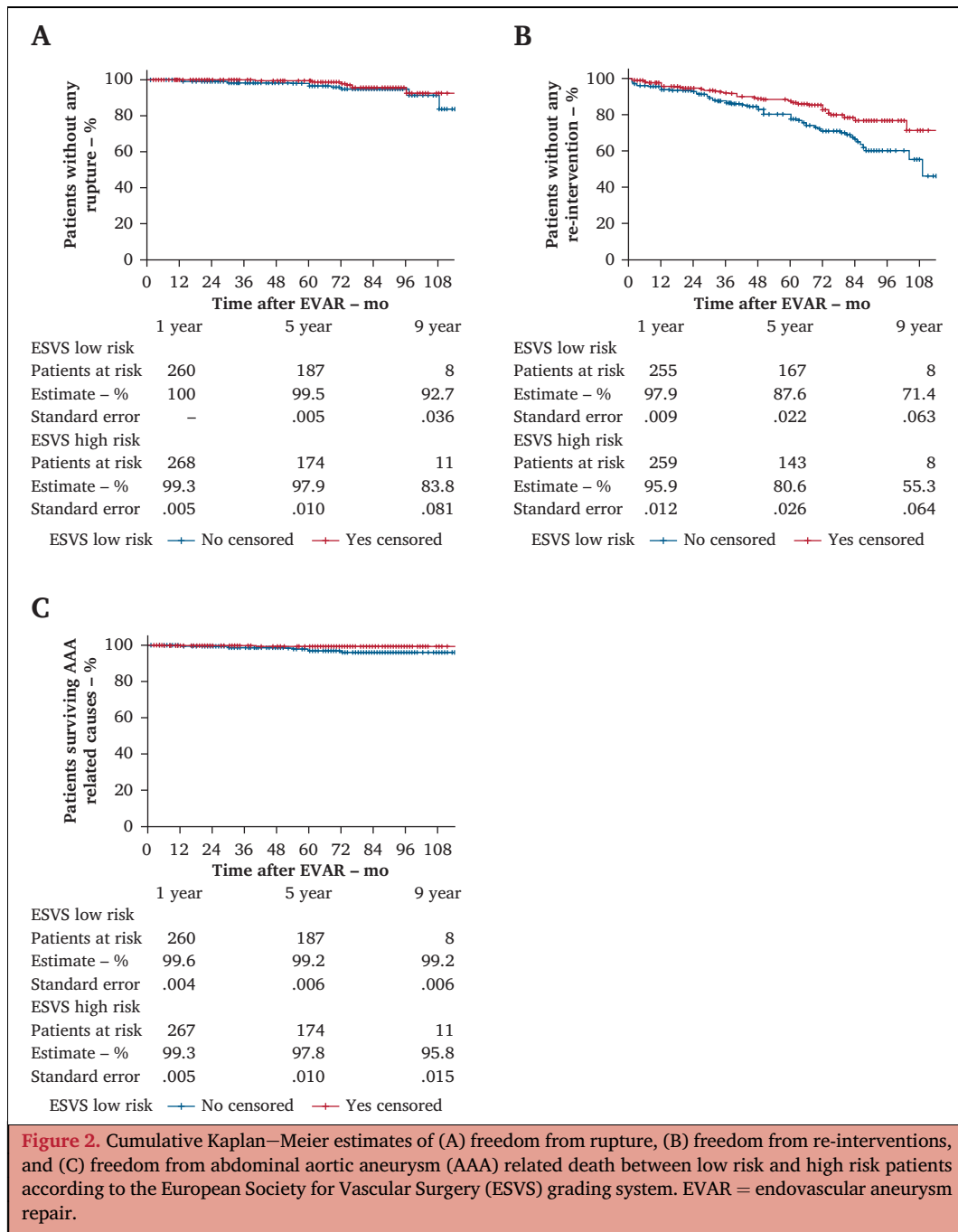
The mean FU was 57.3 ± 30.7 months, and the median was 61 months (IQR 30, 81). Kaplan–Meier curves demonstrated statistically significantly improved nine year estimates of freedom from re-intervention (71.4% vs. 55.3%, log rank = 8.93;  $p = .003$ ) and nearly statistically significantly improved freedom from AAA related death (99.2% vs. 95.8%, log rank = 3.64;  $p = .056$ ) in the ESVS low risk group, with comparable estimates of nine year freedom from rupture (92.7% vs. 83.8%, log rank = 1.31;  $p = .25$ ) between the two groups ([Fig. 2](#)).

### Sub-analysis results

On sub-analysis, 125 of 268 ESVS low risk patients who reached the one year FU (21.0% of the entire cohort of 596 patients) exhibited sac regression and no evidence of

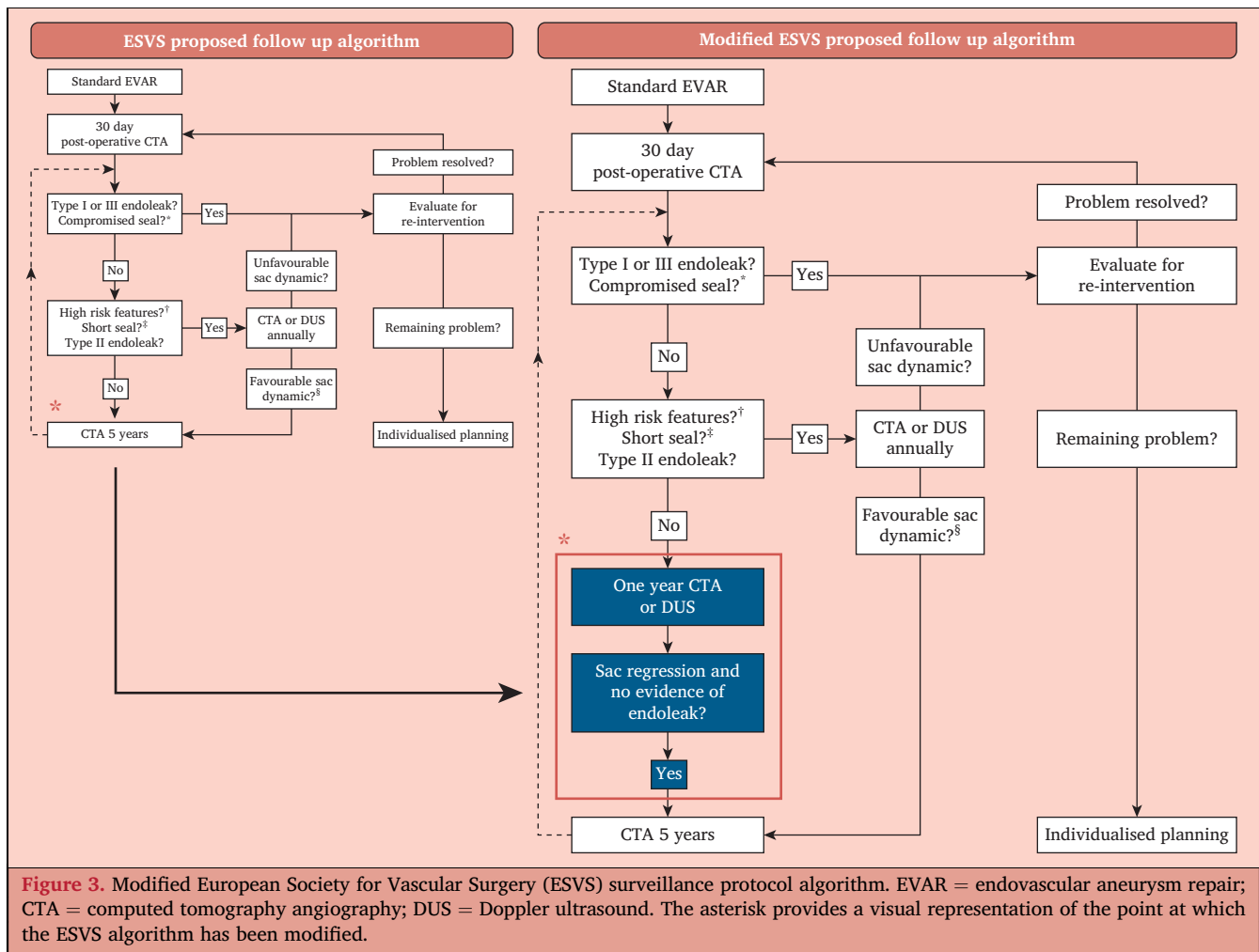


**Figure 1.** Distribution of adverse events over the initial five years of follow up in the low risk cohort (300 patients), which may not have been preventable following the European Society for Vascular Surgery (ESVS) surveillance algorithm.



endoleak at one year FU checkup. Data on this subcategory of low risk patients with one year sac regression and no endoleak revealed further enhanced five year FU results in terms of rupture (no cases recorded), re-interventions (five cases, 4.0%), and AAA related mortality rates (no cases recorded). Two of the five recorded re-interventions were carried out for iliac leg thrombosis caused by flow obstructing stenosis, prior to the one year FU required for patient stratification, at three and six months, respectively, after the index EVAR procedure. Two other re-interventions consisted of stent graft relining for a type III endoleak associated with sac enlargement. One was performed 24 months after the initial EVAR procedure, and the other, on a patient originally treated urgently for a contained AAA

rupture, at 37 months. The remaining re-intervention consisted of a distal endograft extension for a type Ib endoleak associated with sac enlargement performed 47 months after the index EVAR procedure and followed by an iliac leg relining for flow obstructing thrombosis two months later. Adopting a modified ESVS protocol, which further stratifies patients based on the absence of endoleak and evidence of sac regression at the one year FU (Fig. 3), would have resulted in a 97.6% cumulative freedom from adverse events such as re-interventions, ruptures, and or AAA related death occurring between the first and fifth year of FU. This rate increased to 98.3% when considering only the subgroup of 120 patients who were treated electively, with just two recorded adverse events.



When compared with the rest of the cohort (high risk patients), Kaplan–Meier estimates additionally validated improved nine year freedom from rupture, re-intervention, and AAA related death of 100% vs. 83.4% (log rank = 5.55;  $p = .018$ ), 90.1% vs. 54.3% (log rank = 19.53;  $p < .001$ ), and 100% vs. 96.7% (log rank = 3.14;  $p = .077$ ), respectively (Fig. 4) in the subpopulation consisting of ESVS low risk patients showing one year sac regression and no endoleaks.

## DISCUSSION

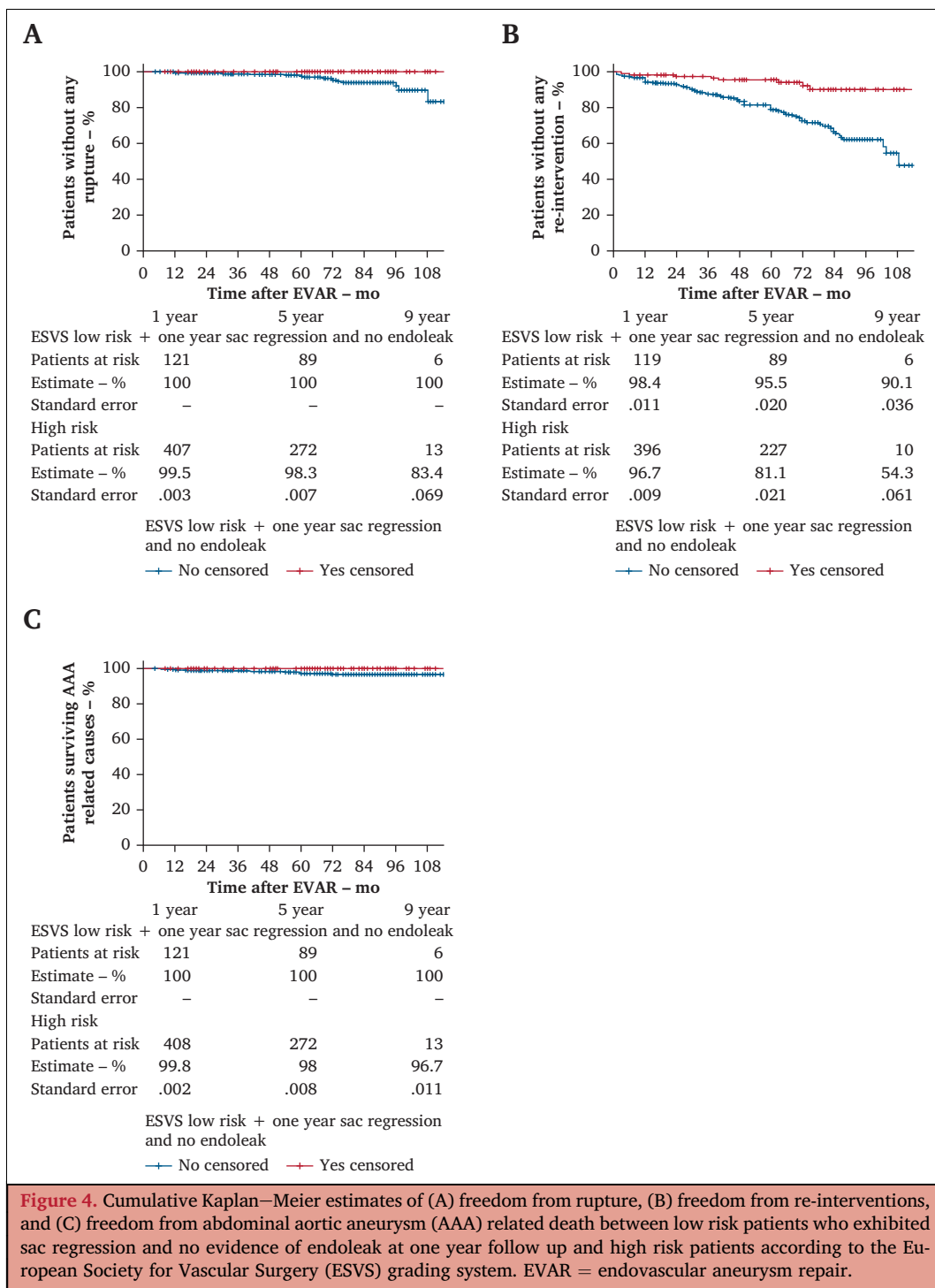
The updated surveillance protocol proposed by the ESVS proved consistent capability in predicting potential adverse events within the first five years of FU after EVAR. Patients stratified as low risk according to the protocol demonstrated a five year freedom from adverse events such as re-interventions, ruptures, and or AAA related death of 90.9%, with 28 adverse events potentially deemed unpreventable when retrospectively evaluating this algorithm in this cohort.

The dynamics of the sac at one year proved crucial in predicting adverse events.<sup>3,8–10</sup> By complementing the ESVS characteristics that define a low risk patient with further stratification at the one year FU based on the behaviour of the aneurysm sac, low risk ESVS patients who also exhibited sac regression and absence of endoleak would have achieved

even better outcomes. When applied to this cohort, the adapted ESVS protocol (Fig. 3) would have predicted 97.6% of potential adverse events, with three adverse events potentially overlooked between the first and fifth years of FU, according to the retrospective assessment of this modified ESVS protocol. Even longer term results have demonstrated a benefit from this implementation, with estimated nine year rates of freedom from aneurysm rupture and freedom from AAA related death reaching 100%.

Several studies have shown that early post-operative imaging performed within 30 post-operative days is important in preventing early re-interventions due to inadequate stent graft positioning.<sup>11–13</sup> The current analysis corroborated this finding, revealing a lower rate of re-intervention in the low risk group compared with the high risk group, both during the initial five years of FU (9.7% vs. 17.2%;  $p = .007$ ) and in the nine year estimates of freedom from re-intervention (71.4% vs. 55.3%;  $p = .003$ ).

However, many studies have demonstrated the long term impact of aneurysm sac behaviour on EVAR outcomes. Data from the Vascular Quality Initiative on 30 074 EVAR procedures showed that any failure of the aneurysm sac to regress at one year from the procedure was associated with the long term mortality rate when compared with sac

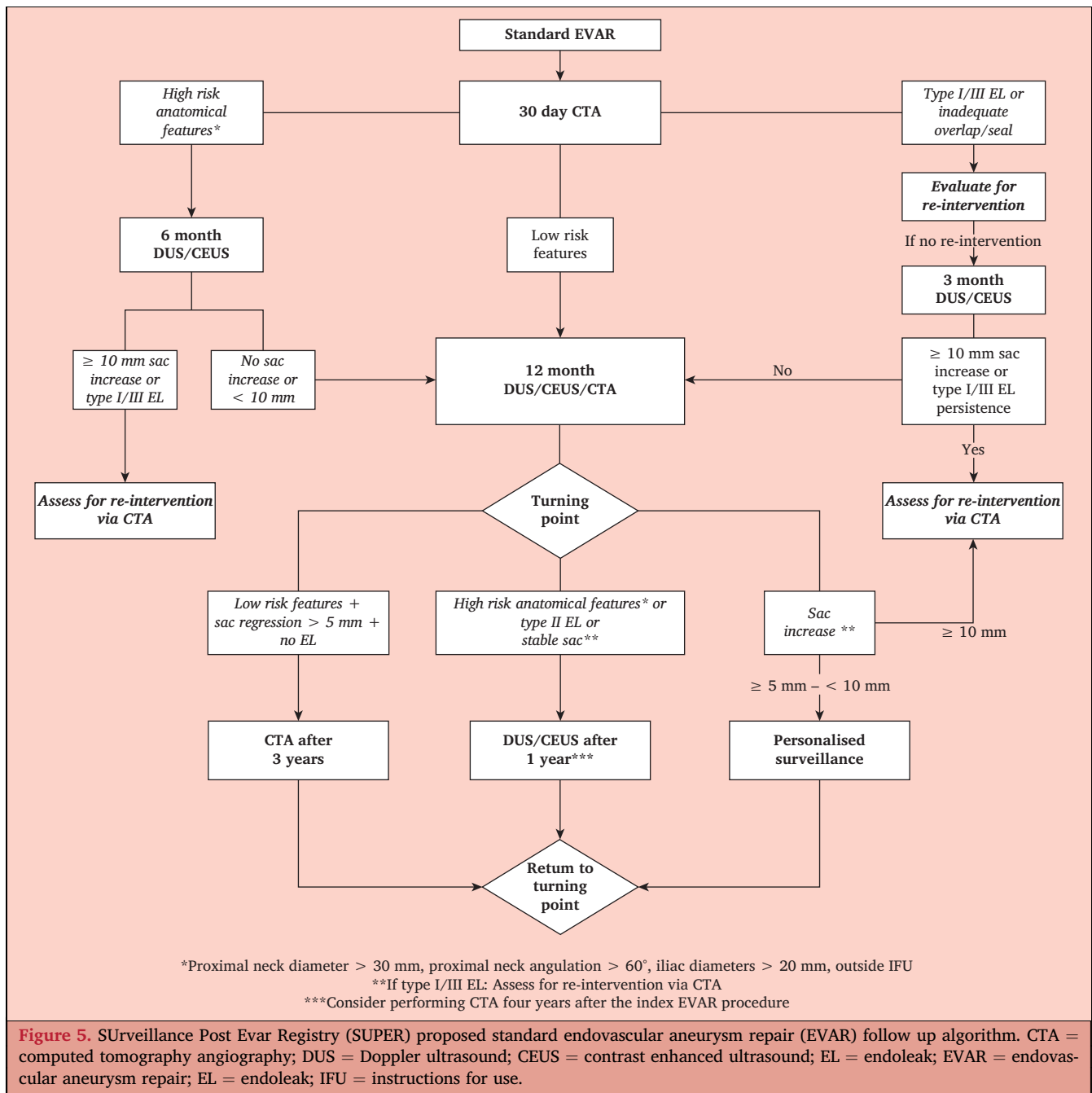


regression, and both sac expansion (OR 2.3;  $p < .001$ ) and a stable sac (OR 3.1;  $p < .001$ ) were associated with the development of new endoleaks.<sup>14</sup>

The reason why patients with aneurysm sacs that do not shrink have worse survival rates is still unknown. One possible explanation is that these patients exhibit a more aggressive pattern of atherosclerotic disease, which might correlate with systemic inflammation and reduced survival rates.<sup>15</sup> Additionally, from the perspective of the aneurysm sac, there may be structural atrophy and a compromised vasa vasorum network in

the aortic wall. This results in a more fragile aorta that might not withstand the intra-sac pressure changes occurring during FU.<sup>16</sup>

Due to the still poorly understood behaviour of the sac, increase in life expectancy, probable advances of aneurysmal pathology, and potential long term fatigue of the endoprosthetic material, it is crucial that patients undergoing EVAR follow a lifelong FU protocol. A recent meta-analysis on FU after EVAR showed contradictory results, which the authors described as paradoxical. It has been noted that the risk of death is comparable between patients



who adhere to FU and those who do not. However, a detailed analysis found that these results are based on very low levels of evidence and exhibit statistically significant heterogeneity due to varying definitions of FU compliance. Additionally, there might be a high probability that aneurysm related adverse events were not recorded in the non-compliant FU group.<sup>17</sup> In this meta-analysis, the pooled proportion of patients who were non-compliant with EVAR surveillance was 43% (95% CI 36 – 51), which closely matched the 43.7% non-adherence rate to FU from the current cohort. Notably, this study benefited from including patients with a minimum FU adherence of five years, thus lending greater significance to the results.

To strengthen this argument, a recent Delphi consensus involving 174 international experts emphasised the crucial importance of ongoing FU, even in patients experiencing sac regression.<sup>18</sup> This serves as a fundamental parameter for defining surveillance protocols, and the benefit of using this parameter was also made clear by the present study. It is believed that the pivotal moment for guiding FU should not rely heavily on the 30 day CTA scan but rather on the one year FU, which might be the turning point for directing further checkups. By integrating pre-operative data with immediate post-operative findings (ESVS criteria) and one year sac dynamics, the outcomes during the initial five years of FU have proven exceptionally favourable. These findings

inspired a new FU algorithm to be created that considers the aforementioned factors, as shown in Fig. 5.

According to the proposed protocol, patients identified as low risk based on ESVS criteria and displaying sac regression without endoleak at the one year FU are those who might experience fewer FU appointments in the initial years following EVAR. In this cohort, this subgroup represented more than one fifth of the analysed population (125 of 596 patients, 21.0%), meaning that a reduction in FU imaging and its associated impact on patients and costs is reasonably achievable for a considerable selected category.

According to meta-analyses examining EVAR failure, the average timeframe for conversion, whether open or necessitating fenestrated and or branched endovascular repair (FB-EVAR) extension, is roughly four years from the index procedure.<sup>19,20</sup> Furthermore, the findings of this study suggest that by following the modified ESVS proposed protocol, which includes one year sac behaviour and endoleaks, two of the three adverse events recorded between the first and fifth years of FU occurred during the fourth year following the procedure. As a result, under the new algorithm, it is advocated that patients exhibiting these benign characteristics may undergo reassessment three years after their one year FU.

The algorithm also suggests a long term FU continuation strategy, where annual DUS and or CEUS checks are reserved for patients classified as high risk according to ESVS criteria, as well as those with sac stability or type II endoleak. This returns to the point for deciding how to proceed with further monitoring.

Additional studies are still required to establish a universally applicable FU protocol after EVAR. Furthermore, it is essential to incorporate more parameters for patient stratification based on sac dynamics, such as sac volume and thrombus burden measurements, as these factors have shown significant potential in predicting sac remodelling and long term outcomes following EVAR.<sup>21,22</sup> Ultimately, understanding the biomechanical factors underlying sac dynamics and using technologies such as artificial intelligence to obtain more precise information on sac characteristics could be pivotal in resolving this ongoing issue.<sup>23–25</sup>

### Study limitations

It is important to mention that this study had several limitations. First, the main limitation is its retrospective nature. A prospective validation of the ESVS protocol would be the most appropriate way to assess its effectiveness. A considerable number of patients were excluded due to the lack of necessary data for stratifying patients into low and high risk categories, mainly due to the multicentre nature of the study and consequent non-availability of some variables in certain centres. Another limitation may be the considerable number of patients excluded for not meeting the definition of FU adherence, which may have led to an indefinite number of missed adverse events. Nevertheless, while the non-adherence rate for FU in this cohort aligns with the literature, it is important to highlight that the adherence rate of this study specifically pertains to a five year period, which is longer than the FU durations typically assessed in similar

research.<sup>17</sup> This distinction emphasises the significance of this study's findings in the context of extended FU.

Another notable limitation is the variability in imaging assessments used to determine maximum AAA diameters at different FU time points and across institutions, which resulted in some instances where sac dimensions were compared across different imaging modalities (DUS and CTA), potentially leading to inaccuracies in patient stratification. This inconsistency reflects common clinical practice: while CTA is the recognised imaging method for pre-operative and 30 day post-operative examinations, there are no specific guidelines on which imaging modality (DUS, CEUS, or CTA) should be preferred during FU, which is reflected in this cohort (Supplementary Figure S2). CTA provides more precise anatomical details and is generally considered the gold standard, although DUS is often preferred due to reduced costs and impact on patients (radiation and contrast exposure). It has been shown that DUS can reliably detect significant sac changes but may be less sensitive in early or subtle measurements of sac regression, potentially affecting the precision of size comparisons between modalities.<sup>26,27</sup> Moreover, adverse events such as graft migration could go undetected with DUS if not reflected by sac enlargement or endoleaks, potentially delaying necessary treatment. Nonetheless, CTA was consistently used in situations of diagnostic uncertainty following ultrasound evaluations or when re-intervention planning was needed in this cohort. Future studies comparing diagnostic techniques for FU after EVAR, possibly across different countries and using an external core lab for imaging evaluations, would be beneficial, as this research could improve the understanding of the most effective imaging modalities, enhance patient outcomes, and address cost considerations, thereby more comprehensively informing clinical practice.

### Conclusions

The recently updated ESVS proposed EVAR surveillance algorithm provides a consistent prediction of potential adverse events during the initial five years of FU, although it may require further refinement to more effectively stratify patients into low and high risk categories. Patients identified as low risk of adverse events based on 30 day CTA findings and who additionally demonstrate sac regression without evidence of endoleak at one year FU may be more appropriate candidates for reduced surveillance. In the light of these findings and building on the ESVS proposal, a new FU algorithm is suggested. Nevertheless, additional studies are essential to thoroughly validate this proposal and to gain a deeper understanding of its very long term outcomes. Furthermore, prospective research is crucial to advance the field of EVAR surveillance, ensuring more comprehensive insights into its effectiveness and long term impact on patient care and outcomes.

### 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.2025.04.019>.

## REFERENCES

- Wanhainen A, Verzini F, Van Herzele I, Allaire E, Bown M, Cohnert T, et al. Editor's Choice – European Society for Vascular Surgery (ESVS) 2019 clinical practice guidelines on the management of abdominal aorto-iliac artery aneurysms. *Eur J Vasc Endovasc Surg* 2019;**57**:8–93. Erratum in: *Eur J Vasc Endovasc Surg* 2020;**59**:494.
- Wanhainen A, Van Herzele I, Bastos Goncalves F, Bellmunt Montoya S, Berard X, Boyle JR, et al. Editor's Choice – European Society for Vascular Surgery (ESVS) 2024 clinical practice guidelines on the management of abdominal aorto-iliac artery aneurysms. *Eur J Vasc Endovasc Surg* 2024;**67**:192–331.
- Antoniou GA, Alfahad A, Antoniou SA, Torella F. Prognostic significance of aneurysm sac shrinkage after endovascular aneurysm repair. *J Endovasc Ther* 2020;**27**:857–68.
- Pratesi C, Esposito D, Apostolou D, Attisani L, Bellosta R, Benedetto F, et al. Guidelines on the management of abdominal aortic aneurysms: Updates from the Italian Society of Vascular and Endovascular Surgery (SICVE). *J Cardiovasc Surg (Torino)* 2022;**63**:328–52.
- von Elm E, Altman DG, Egger M, Pocock SJ, Gøtzsche PC, Vandenbroucke JP, et al. The Strengthening of Reporting of Observational Studies in Epidemiology (STROBE) statement: guidelines for reporting observational studies. *J Clin Epidemiol* 2008;**61**:344–9.
- Chaikof EL, Blankensteijn JD, Harris PL, White GH, Zarins CK, Bernhard VM, et al. Reporting standards for endovascular aortic aneurysm repair. *J Vasc Surg* 2002;**35**:1048–60.
- Hickey GL, Dunning J, Seifert B, Sodeck G, Carr MJ, Burger HU, et al. Statistical and data reporting guidelines for the European Journal of Cardio-Thoracic Surgery and the Interactive Cardio-Vascular and Thoracic Surgery. *Eur J Cardiothorac Surg* 2015;**48**:180–93. Erratum in: *Eur J Cardiothorac Surg* 2016;**49**:1024.
- Houballah R, Majewski M, Becquemin JP. Significant sac retraction after endovascular aneurysm repair is a robust indicator of durable treatment success. *J Vasc Surg* 2010;**52**:878–83. Erratum in: *J Vasc Surg* 2010;**52**:1751.
- Bastos Goncalves F, Baderkhan H, Verhagen HJ, Wanhainen A, Björck M, Stolker RJ, et al. Early sac shrinkage predicts a low risk of late complications after endovascular aortic aneurysm repair. *Br J Surg* 2014;**101**:802–10.
- Ikeda S, Sato T, Kawai Y, Tsuruoka T, Sugimoto M, Niimi K, et al. One-year sac regression is associated with freedom from fatal adverse events after endovascular aneurysm repair. *J Vasc Surg* 2023;**77**:136–42.e2.
- Bastos Goncalves F, van de Luijtgarden KM, Hoeks SE, Hendriks JM, ten Raa S, Rouwet EV, et al. Adequate seal and no endoleak on the first postoperative computed tomography angiography as criteria for no additional imaging up to 5 years after endovascular aneurysm repair. *J Vasc Surg* 2013;**57**:1503–11.
- Baderkhan H, Haller O, Wanhainen A, Björck M, Mani K. Follow-up after endovascular aortic aneurysm repair can be stratified based on first postoperative imaging. *Br J Surg* 2018;**105**:709–18.
- Geraedts ACM, Mulay S, van Dieren S, Koelemay MJW, Balm R, ODYSSEUS Study Group. Analysis of outcomes after endovascular abdominal aortic aneurysm repair in patients with abnormal findings on the first postoperative computed tomography angiography. *J Endovasc Ther* 2021;**28**:878–87.
- O'Donnell TFX, Deery SE, Boitano LT, Siracuse JJ, Schermerhorn ML, Scali ST, et al. Aneurysm sac failure to regress after endovascular aneurysm repair is associated with lower long-term survival. *J Vasc Surg* 2019;**69**:414–22.
- Esposito D, Fargion AT, Dorigo W, Melani A, Capone A, DI Domenico R, et al. Stability of the aneurysmatic sac post-EVAR could no longer be a reliable criterion of healing. *J Cardiovasc Surg (Torino)* 2022;**63**:155–9.
- Menges AL, Busch A, Reutersberg B, Trenner M, Kath P, Chernogubova E, et al. The structural atrophy of the aneurysm wall in secondary expanding aortic aneurysms with endoleak type II. *J Vasc Surg* 2019;**70**:1318–26.e5.
- Antoniou GA, Kontopodis N, Rogers SK, Gollledge J, Forbes TL, Torella F, et al. Editor's Choice – Meta-analysis of compliance with endovascular aneurysm repair surveillance: the EVAR surveillance paradox. *Eur J Vasc Endovasc Surg* 2023;**65**:244–54.
- Tinelli G, D'Oria M, Sica S, Mani K, Rancic Z, Resch TA, et al. The sac evolution imaging follow-up after endovascular aortic repair: an international expert opinion-based Delphi consensus study. *J Vasc Surg* 2024;**80**:937–45.
- Esposito D, Rawashdeh M, Onida S, Turner B, Machin M, Pulli R, et al. Systematic review and meta-analysis of elective open conversion versus fenestrated and branched endovascular repair for previous non-infected failed endovascular aneurysm repair. *Eur J Vasc Endovasc Surg* 2024;**67**:393–405.
- Esposito D, Onida S, Turner B, Rawashdeh M, Jenkins MP, Pulli R, et al. Systematic review and meta-analysis of outcomes after semi-conversion with graft preservation for failed endovascular aneurysm repair. *J Vasc Surg* 2024;**79**:973–81.e4.
- Fujii T, Banno H, Kodama A, Sugimoto M, Akita N, Tsuruoka T, et al. Aneurysm sac thrombus volume predicts aneurysm expansion with type II endoleak after endovascular aneurysm repair. *Ann Vasc Surg* 2020;**66**:85–94.e1.
- van Rijswijk RE, Jebbink EG, Zeebregts CJ, Reijnen MMPJ. A systematic review of anatomic predictors of abdominal aortic aneurysm remodeling after endovascular repair. *J Vasc Surg* 2022;**75**:1777–85.
- Kano M, Nishibe T, Matsumoto R, Fujiyoshi T, Toya N, Dardik A, et al. Significance of perioperative intrasac pressure in sac shrinkage after endovascular abdominal aneurysm repair. *Int Angiol* 2023;**42**:201–8.
- Bogdanovic M, Siika A, Liljeqvist ML, Gasser TC, Hultgren R, Roy J. Biomechanics and early sac regression after endovascular aneurysm repair of abdominal aortic aneurysm. *JVS Vasc Sci* 2023;**4**:100104.
- Adam C, Fabre D, Mougin J, Zins M, Azarine A, Ardon R, et al. Pre-surgical and post-surgical aortic aneurysm maximum diameter measurement: full automation by artificial intelligence. *Eur J Vasc Endovasc Surg* 2021;**62**:869–77.
- Ho VT, Nguyen AT, Stern JR, Asch SM, Owens DK, Salomon JA, et al. Cost-effectiveness of computed tomography versus ultrasound-based surveillance following endovascular aortic repair of intact infrarenal abdominal aortic aneurysms. *J Vasc Surg* 2022;**76**:707–13.e1.
- Smith L, Thomas N, Arnold A, Bell R, Zayed H, Tyrrell M, et al. Editor's Choice – A comparison of computed tomography angiography and colour duplex ultrasound surveillance post infrarenal endovascular aortic aneurysm repair: financial implications and impact of different international surveillance guidelines. *Eur J Vasc Endovasc Surg* 2021;**62**:193–201.