The Sac Evolution Imaging Follow-Up after EVAR: an international expert opinion-based Delphi consensus study

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The Sac Evolution Imaging Follow-Up after EVAR: an international expert opinion-based Delphi consensus study

Short Title:

Sac evoLution IMaging Follow-Up after EVAR (SLIM F-U EVAR)

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ARTICLE HIGHLIGHTS

Type of Research: Multicenter Expert Consensus Delphi study

Key Findings: Fifteen statements (55.6%) were classified as grade I, while twelve (44.4%) were classified as grade II.

Take home Message: Experts agreed that sac regression should be considered an important indicator of EVAR success and always be assessed during follow-up after EVAR

Table of Contents Summary

Currently, there are no surveillance protocols related to aneurysm shrinkage after EVAR. The present international expert-based Delphi consensus document details the practices endorsed at high volume aortic centres, creating the basis for future studies, and highlighting the need for dedicated reporting standards in future guidelines.

Abstract

Objective. Management of follow-up protocols after endovascular aortic repair (EVAR), vary significantly between centres and is not standardized according to the sac regression. By designing an international expert-based Delphi consensus, the study aimed to create recommendations on follow-up after EVAR according to sac evolution.

Methods. Eight facilitators created appropriate statements regarding the study topic that were voted, using a 4-point Likert scale, by a selected panel of international experts using a three-round modified Delphi consensus process. Based on the experts' responses, only those statements reaching a Grade A (full agreement ≥75%) or B (overall agreement ≥80% and full disagreement <5%) were included in the final document.

Results. One-hundred and seventy-four participants were included in the final analysis, and each voted the initial 29 statements related to the definition of sac regression (Q1-Q9), EVAR follow-up (Q10-Q14), and the assessment and role of sac regression during follow-up (Q15-Q29). At the end of the process, 2 statements (6.9%) were rejected, 9 statements (31%) received a grade B consensus strength, and 18 (62.1%) reached a grade A consensus strength. Out of twenty-seven final statements, fifteen statements (55.6%) were classified as grade I, while twelve (44.4%) were classified as grade II. Experts agreed that sac regression should be considered an important indicator of EVAR success and always be assessed during follow-up after EVAR.

Conclusions. Based on the elevated strength and high consistency of this international expert-based Delphi consensus, most of the statements might guide current clinical management of follow-up after EVAR according to the sac regression. Future studies are needed to clarify debated issues.

Introduction

Endovascular aneurysm repair (EVAR) is the preferred choice of treatment for abdominal aortic aneurysm (AAA) in suitable patients, with reduced perioperative mortality compared with open repair.[1-3]

Current recommendations from the Society for Vascular Surgery (SVS) for surveillance after EVAR include a Computed Tomography Angiography (CTA) scan at 1 month, and an annual duplex ultrasound study if the initial CTA showed no endoleak.[4] According to the European Society for Vascular Surgery (ESVS) guidelines, all patients should be offered lifelong follow up after EVAR, including a CTA scan at least every 5 years due to the risk of late failure and aneurysm progression. If necessary, more frequent imaging may be performed with CTA or duplex ultrasound based on the risk stratification of late complications after the first post-operative examination.[5,6]

Aneurysm sac shrinkage following EVAR has been proposed to indicate successful aneurysm exclusion, and to be associated with significantly lower risk of mortality, reinterventions rate and improved outcomes.[7-11]

Nevertheless, follow-up protocols vary significantly between centres regarding both modality and frequency and there are no surveillance protocols related to aneurysm sac shrinkage following EVAR.

Using an international expert-based Delphi consensus, this paper aims to investigate the practices endorsed at high-volume aortic centers and create recommendations on follow-up after EVAR according to sac evolution.

Methods

Study design. A modified Delphi consensus process, following the methodology applied in prior literature, was used to obtain expert consensus on the role of sac regression during follow-up after EVAR.[12]

All surveys were submitted online and recorded through SurveyMonkey® (https: //www.surveymonkey.com). Invited experts were unaware of the identity of any other members of the international panel.

Institutional Review Board approval was not required due to the nature of the study (not involving patients data).

Core Team & Selection of the panel of international experts. The members of the Core Team were identified among the study principal investigators (Authors: GT, MD, SS,). To ensure proper statistical analysis, a professional biostatistician with prior experience in Delphi-based research was also invited to join the Core Team (Author: FB). Potential international experts to be included as panel members were selected among active physicians with specialization in vascular surgery or interventional radiology practicing in Europe, America, Asia, and Oceania. Physicians were identified based on prior publications in high-ranked vascular scientific journals and/or from international conferences' presentations on endovascular procedures, and/or among researchers serving on editorial boards for peer-reviewed journals relevant to the study practice. To be eligible for the expert panel, physicians were required to practice in a department that had performed more than 50 endovascular aortic cases yearly and they had demonstrated competence as first operator with more than 50 EVAR procedures during their career.

Delphi methodology. A modified Delphi method was used to construct the expert consensus.[13] To develop the initial lists of statements for expert evaluation, a preliminary exploratory

questionnaire (with multiple choice questions and option for open-ended suggestions) was administered to investigate the daily practice of follow-up after EVAR at each center or division. The answers provided by the questionnaire were analysed by the Core Team, and the statements were designed accordingly. A compressed four-point Likert-type scale was used to grade statements based on the level of agreement: agree (score 1), somewhat agree (score 2), somewhat disagree (score 3), disagree (score 4). The central fifth grade of the Likert scale (eg. "no opinion") was omitted in view of the panel expertise and based on the assumption that invited experts would be able to offer their opinion for each statement. An open-ended question was used to guide changes to statements during the first two rounds. The statements were submitted to three rounds for evaluation, and eventually modified by the Core Team to increase consensus according to the experts' open comments during the first two rounds. The first round was intended to submit the first formulation of the statements and collect a broad indication of the consensus strength. The second round was intended to obtain a detailed estimate of the consensus change from the original formulations to the modified formulations after they had been implemented as per the above process. The third round was intended to confirm the strength of consensus from the second to the third formulation

Statistical analysis, Evaluation of consensus strength & Consistency of scoring. Statistical analysis was performed with STATA 17.0 software (Stata Corporation, College Station, TX, USA).

The statements were tested in a three-round Delphi, using a 4-point Likert scale. The proportion of experts rating a single item with a score of 1 "Agree" or 2 "Somewhat agree" compared with the total number of experts involved determined the Content Validity Index (CVI), which ranged from 0% to 100%.

At consensus, the statements were evaluated according to the strength of agreement, and the consistency ranking, calculated from the previous round. The methodology is reported in Table I.

In addition to the agreement, the mean score and standard deviation, the significance of the change from the previous round according to Wilcoxon's test and Pearson's correlation were evaluated. These items were used to confirm the strength of consensus. A p-value <0.25 was considered a significant variation, considering that some degree of multiplicity was expected. Consistency was assessed by considering intraclass correlation coefficients and p-values, Cohen's kappa, and Fleiss' pi and test-rest reliability by Bland-Altman plot.

The proportion of ratings exceeding the critical difference was estimated to monitor test-retest reliability according to Bland and Altman and was considered as a modifier of consistency: a proportion of outliers above 10 percent was considered indicative of significant heterogeneity among the experts and was used as a cut-off for downgrading consistency.

At the time of consensus, statements with strength grades A and B were considered of sufficient quality to be included in the final set of recommendations.

Criteria for selection or change of statements selection. The decision to refuse or modify and resubmit a statement was taken based on a composite of different statistical criteria. The predefined criteria for submission/resubmission after the first round was set as follows: statements with a proportion of full disagreement ≥10% and/or a mean score <2.0 were not resubmitted; all other statements were resubmitted after textual adaptations and/or statements merging, as appropriate. The predefined criteria for submission/resubmission after the second round was set as follows:

a. statements with a proportion of overall agreement <80% and a proportion of full disagreement >5% (Grade C and D) were removed from the consensus;

b. statements with at least five among: a proportion of "fully agree" >75% or a proportion of overall agreement >80%, a proportion of full disagreement <5%, a mean score change from first to second round not statistically significant (Wilcoxon test – see above), a significant score correlation between first and second round, a significant measure of agreement (Cohen's k – see above), a significant intraclass correlation coefficient set for consistency, and a good test-retest reliability, were to be accepted in their current form, unless suggestions from the Core team recommended resubmission.

At the third and last round, only statements with grade of strength A and B were considered of sufficient quality to be included in the final set of recommendations.

Results

Overview of participants and flow of Delphi exercise. Three-hundred and forty-three experts were initially contacted and invited to participate in the SLIM-FU study. One-hundred and seventy-four participants, all meeting the pre-specified inclusion criteria, actively answered to all the three Delphi the survey rounds; 181 experts completed Round 1, and 177 completed Round 2.

The Core Team members designed 29 initial statements for the first round related to the definition of sac regression (Q1-Q9), EVAR follow-up (Q10-Q14), and the assessment and role of sac regression during follow-up (Q15-Q129). After round 1, eighteen statements were modified (Q3, Q6-Q10, Q12, Q14, Q16, Q19-Q21, Q24-Q29); after round 2, two statements were rejected (Q9 and Q27).

Table II summarizes the proportion of consensus obtained by each statement at the third round. At the end of the process, 2 statements (6.9%) were rejected, 9 statements (31%) received a grade B consensus strength, and 18 statement (62.1%) reached a grade A consensus strength.

Table III summarizes the estimates of overall consistency across rounds estimated using Cohen's kappa and Fleiss' pi evaluation. Out of twenty-seven final statements, fifteen statements (55.6%) were classified as grade I, while twelve (44.4%) were classified as grade II. No grade III-IV statements were reported.

The complete text of 27 statements that received a Grade A or Grade B consensus and, in the formulation, submitted to the final round are listed in Table IV.

Definition of sac regression and its prognostic relevance. The experts suggested (Grade A) that sac regression should be defined as reduction in maximum diameter of the aneurysm sac by ≥ 5 mm (statement 1). According to the experts' opinion, aneurysm sac regression should be considered an important indicator of EVAR success (Grade A) and different dedicated statements regarding its role (statements 3-8) were voted. Aneurysm sac regression is usually correlated to the absence of:

- endoleaks (I-III) that require secondary intervention after EVAR
- secondary intervention
- aneurysm rupture
- aneurysm-related mortality (Grade A)

Grade B agreement was reached (statement 7) regarding the correlation to low rates of aneurysm-related complications after EVAR.

Follow-up after EVAR. The first follow-up after patient discharge following an elective EVAR should be a DUS or CT-angiography within 3 months (Grade A, Consistency II). Experts identified different statements (11,12,14) with high strength (Grade A) and consistency (I) regarding the follow-up: the imaging modality should be a DUS or a CTA (if DUS is not available or not diagnostic) at 1-year, 2-year, and 5-year follow-up.

Assessment and role of sac regression during follow-up. According to the experts' opinion, sac regression should always be assessed during follow-up after EVAR (Statement 15 - grade A). A DUS or a CTA should be used as first-line imaging modality to assess sac regression during follow-up (Grade A, Consistency II). However, the comparison of two CTA (baseline vs follow-up) is the most accurate imaging to detect sac regression after EVAR. In case of DUS imaging modality, the sac regression should be measured in two projections at least; in case of CTA imaging modality, the sac regression should be measured on the orthogonal axis using a dedicated reconstruction software (Statement 18, 19 – grade A).

The experts agree that sac regression can be usually expected to occur within 2 years after EVAR, and that a diameter change within ± 4.9 mm may be considered a clinically relevant parameter during follow-up (Statement 21, 22 – grade B). However, a grade A agreement was reached (statement 23) regarding the clinically relevance of sac increase (diameter change ≥ 5 mm).

In the case of sac regression, the follow-up protocol after EVAR should be continued (Statement 24 - Grade B, Consistency I). However, in case of EVAR within the instruction for use, sac regression is one of the parameters to consider for possible follow-up protocol changes (Statement 26 - Grade B, Consistency I).

Volumetric analysis and machine learning models may represent, in the future, an adjunctive tool to analyse AAA sac evolution during follow-up after EVAR (Statement 28, 29 – grade B).

Discussion

Endovascular treatment of abdominal aortic pathologies has evolved over the last two decades to the point of being the current first-line treatment modality for a large proportion of patients.[4,14] Owing to the inherent risk of endograft-related complications and secondary

rupture that may occur during extended follow-up after EVAR, regular imaging surveillance is mandatory and dedicated recommendations have been formulated by vascular societies of Europe and North America.[4,5,15] However, several unanswered questions remain, including the true benefits of prophylactic regular imaging follow-up after EVAR. Furthermore, despite clear guidelines, follow-up routines may vary significantly between centres and some of this variability may be related to heterogeneity in the imaging metrics used to assess EVAR success.[16]

Our international expert-based Delphi exercise was able to achieve a remarkable consensus amongst a large group of EVAR experts regarding the importance of sac regression as a marker for EVAR success and clarify experts' opinions regarding its definitions, assessment, and natural history. Sac shrinkage during follow-up indicates successful exclusion of the aneurysm from arterial pressure, and has been consistently shown to be a predictor of low risk of EVAR failure and overall mortality during post-operative follow-up.[9,17-19]

To the authors' knowledge, this is the first study to report a pragmatic approach to establish broad expert-based consensus on sac regression post-EVAR. The majority of experts agreed on several key aspects including but not limited to: the definition of sac regression as more than 5 mm as compared to baseline, the expectancy of sac regression to occur within the first two years after EVAR, the use of CTA as the optimal method to analyse sac regression, and the association of sac regression with the absence of clinically-relevant endoleaks. It should be underlined that there is a broad consensus that assessment of sac regression should be performed at each EVAR follow-up, and that this assessment should be performed systematically both on CTA and DUS with a defined methodology, that compared diameter of the aneurysm at time of measurement to previous measurements including the baseline evaluation close to the time of repair. Sac regression should be included in a broader evaluation of the patient-specific risk profile for EVAR failure which include details of aortic anatomy

and specific endograft characteristics. Further evidence from prospective trials is still needed to define more tailored follow-up protocols that could be safely end cost-effectively implemented by taking into consideration sac regression.

Our findings correlate well with available evidence surrounding the incidence and role of sac regression in EVAR patients. A large observational study conducted in Japan documented cumulative rates of sac regression (>5 mm) at 1 year and 5 years in 50% and 62% of patients, respectively.[20] Similarly, a study from Ontario demonstrated a pattern of sac diameter change after EVAR, with the majority of sac regression occurring within the first 2 years.[21] Finally, other studies have identified that early sac regression of greater than 5 mm within 1 to 2 years after implantation was associated with a significantly lower probability for delayed sac expansion, although a small proportion of patients would still go on to develop delayed sac expansion.[7, 19-22] In fact, variability in sac regression can also be influenced by non-anatomic variables including age, sex, and original AAA diameter, even after controlling for the presence or absence of an endoleak. Indeed, the ultimate biophysical relationship between specific endograft design and materials, and sac regression is yet to be determined.[21,23-25]

ESVS guidelines stratify patients after EVAR in low, intermediate, and high risk groups based on presence of endoleaks, adequate sealing and overlap zones, anatomy within Instructions for Use (IFU), and sac shrinkage.[5] In patients with adequate seal, no endoleak type I or III, but with presence of endoleak type II, sac evolution determinates patient's follow-up: if there is expansion ≥ 1 cm, the evaluation for re-intervention is suggested; if the shrinkage is ≥ 1 cm instead of annual DUS, CTA at least every 5 years is suggested.

In the present study experts agreed that CTA is the most accurate imaging modality to detect sac regression after EVAR. A metanalysis comparing DUS and CTA showed that the pooled sensitivity and specificity of DUS were 0.77 and 0.94, respectively.[26] Compared to CTA, it is reported that DUS has an overall lower sensitivity in the follow-up of patients after EVAR with

39% of positive predictive value.[27] However, DUS offers several potential advantages, including lower cost, no radiation exposure, shorter scan times and the lack of any toxicity risk. Despite the widespread application of DUS worldwide, no recommendations have been published regarding the preferred method of maximum abdominal aortic diameter measurement that obtains the most reproducible aortic dimensions.[28]

In the current Delphi process, the participants agreed that during EVAR follow-up at 3 months, 1, 2, 3 and 5-years, imaging modality should be DUS or CTA if DUS is not available or not diagnostic. As the focus of the current consensus process was not to assess imaging frequency during follow-up, we cannot comment on the expert opinion on imaging frequency in patients with low risk for EVAR failure, including patients with significant sac shrinkage already early during follow-up. As agreed in the Delphi process, future development of AI-based tools that may automate both evaluation of sac dynamics as well as post-EVAR seal zone and endoleak evaluation may facilitate decision making regarding EVAR follow-up algorithms.[29]

Interestingly, the expert panel did not rate the use of artificial intelligence (AI) and machine learning as very strong and with very high consistency. AI could reduce human error in aneurysm sac measurement, is available 24/7 and could take into account all potential risk factors for aneurysm sac development: technical problems (with persistent or new endoleaks), aneurysm wall properties (potentially different biomechanical wall properties in patients with atherosclerosis and genetic aortopathies), and pure influences of pre- and post-operative thrombus volume after EVAR. Good quality data for sac evolution analysis to create AI is also paramount, so it is possible that the algorithm will be biased by poor output data.[30-32] It could be that some panel experts do not believe that accurate data will ever be available and that the use of AI could ever be a comprehensive tool to analyse aneurysm sac evolution after EVAR.

Study limitations. This study must be interpreted within the context of its limitations. First, the Delphi methodology has accepted inherent shortcomings. Delphi studies have been criticized because the included items are chosen by the researchers, thereby potentially introducing bias. Second, since random selection was not feasible, because of the experts' inclusion criteria, a large pre-selected group of international experts proposed by the Core Team was invited, potentially introducing selection bias since they might not fully represent the real worldwide expertise, and results might also be partly influenced by local regulations and hospital policies. Third, the strength of consensus among experts is often considered to represent the same level of evidence as literature-based guidelines, although this might not necessarily hold true because guidelines, which are graded with a definition of strength recommendations, are based on literature analysis, whereas consensuses derived from the Delphi process can only be indicative of hints at good practice. Nonetheless, for clinical scenarios in which high-quality evidence may be difficult to obtain, the recommendations derived from a large body of experts may be seen as an important adjunct to support decision-making. To mitigate this limitation, whenever present, clinical practice guidelines from recognized scientific societies were consulted to ensure that the proposed statements would not be discordant.

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Table I: Strength and consistency grading definitions for statement submitted to the experts panel during the Delphi rounds.

Grade	**Rating**	**Definition**
A	Very strong	Full agreement ≥75%
B	Strong	Full agreement <75% Overall agreement ≥80% Full disagreement <5%
C	Fair	Full agreement <75% Overall agreement ≥80% Full disagreement ≥5%
D	Poor	Full disagreement ≥10%
Consistency	**Rating**	**Definition**
I	Very high	Cohen's k p value ≤ .001 Intraclass correlation p value ≤ .001
II	High	Cohen's k and intraclass correlation coefficient p value ≤ .001 in one and ≤ .01 in the other analysis
III	Fair	Cohen's k p value > .05 Fleiss's k p value ≤ .0001
IV	Poor	Cohen's k p value > .05 Fleiss's k p value >.01

Table II: Proportion of consensus obtained by each statement at the third round.

Statement	Full agreement %	Overall agreement %	Full disagreement %	Mean	SD	Wilcoxon's test p value	Pearson correlation	Final grade
1	85.63	97.70	0.57	1.172	0.461	0.212	<0.0001	A
2	83.33	96.55	2.30	1.224	0.58	0.880	<0.0001	A
3	75.29	97.70	0.57	1.276	0.52	0.048	1.000	A
4	85.06	97.13	0.57	1.184	0.482	0.396	<0.0001	A
5	90.23	98.85	0.57	1.115	0.385	0.644	0.3466	A
6	77.01	97.70	0.57	1.259	0.512	0.241	0.0247	A
7	71.84	98.28	0.57	1.305	0.52	0.058	<0.0001	B
8	79.31	97.13	0.57	1.241	0.515	0.844	<0.0001	A
10	75.86	91.38	2.87	1.356	0.721	0.029	1.000	A
11	79.31	95.98	1.15	1.259	0.566	0.201	<0.0001	A
12	81.61	97.13	0	1.213	0.476	0.465	<0.0001	A
13	80.46	95.40	0.57	1.247	0.55	0.738	0.0007	A
14	78.16	94.25	1.15	1.287	0.606	0.094	<0.0001	A
15	95.40	99.43	0.57	1.057	0.299	0.146	<0.0001	A
16	87.93	98.28	0	1.138	0.393	0.110	1.000	A
17	89.08	99.43	0	1.115	0.337	0.393	<0.0001	A
18	83.91	97.70	0	1.184	0.444	0.687	<0.0001	A
19	78.74	97.70	0	1.236	0.477	0.012	0.0011	A
20	74.71	93.68	2.87	1.345	0.686	0.014	1.000	B
21	63.79	94.83	1.72	1.431	0.648	0.839	<0.0001	B
22	66.67	97.70	0.57	1.362	0.549	0.858	<0.0001	B
23	87.36	98.28	0.57	1.149	0.431	0.460	<0.0001	A
24	74.71	93.10	0.57	1.328	0.619	0.402	<0.0001	B
25	68.39	91.95	2.30	1.42	0.707	0.402	0.4080	B
26	68.97	91.38	2.30	1.42	0.715	0.991	<0.0001	B
28	74.71	96.55	1.72	1.305	0.593	0.8490	<0.0001	B
29	73.56	97.13	0.57	1.299	0.54	0.587	<0.0001	B

Table III: Overall consistency across rounds estimated using Cohen's kappa and Fleiss' pi evaluation

Statement	Agreement %	Cohen's Kappa		Fleiss Pi		Intraclass Correlation		Test-retest	Overall consistency
		Coeff.	P value	Coeff.	P value	Coeff. (95%CI)	P value		
1	0.874	0.564	<0.001	0.564	<0.001	0.628 (0.529-0.71)	<0.001	12.64	II
2	0.833	0.429	<0.001	0.440	<0.001	0.474 (0.351-0.582)	<0.001	2.87	I
3	0.684	0.277	<0.001	0.277	<0.001	0.198 (0.051-0.336)	0.004	5.17	I
4	0.828	0.398	<0.001	0.402	<0.001	0.493(0.372-0.598)	<0.001	9.20	I
5	0.862	0.277	0.006	0.288	0.004	0.292 (.15-.422)	<0.001	13.79	II
6	0.782	0.346	<0.001	0.346	<0.001	0.323 (.184-.45)	<0.001	9.20	I
7	0.770	0.386	<0.001	0.380	<0.001	0.453 (.327-.563)	<0.001	8.62	I
8	0.805	0.432	<0.001	0.434	<0.001	0.453 (.327-.564)	<0.001	3.45	I
10	0.626	0.196	0.002	0.185	0.004	0.224 (.0782-.36)	0.001	8.05	II
11	0.782	0.426	<0.001	0.421	<0.001	0.635 (0.537-0.716)	<0.001	7.47	I
12	0.776	0.322	<0.001	0.317	<0.001	0.491 (0.369-.0595)	<0.001	9.20	I
13	0.741	0.237	0.002	0.238	0.002	0.385 (.251-.504)	<0.001	2.87	II
14	0.707	0.289	<0.001	0.287	<0.001	0.412 (0.281-0.528)	<0.001	6.32	I
15	0.919	0.349	0.003	0.367	0.003	0.457 (0.332-0.567)	<0.001	8.05	II
16	0.805	0.260	0.003	0.263	0.003	0.242 (0.098-0.377)	0.001	2.87	II
17	0.851	0.320	0.001	0.315	0.001	0.411 (0.28-0.527)	<0.001	14.94	II
18	0.828	0.350	<0.001	0.355	<0.001	0.461 (0.336-0.57)	<0.001	17.24	II
19	0.741	0.381	<0.001	0.385	<0.001	0.347 (0.209-0.471)	<0.001	3.45	I
20	0.661	0.291	<0.001	0.281	<0.001	0.237 (0.092-0.372)	0.001	9.20	I
21	0.776	0.540	<0.001	0.541	<0.001	0.511 (0.393-0.613)	<0.001	2.30	I
22	0.701	0.356	<0.001	0.359	<0.001	0.47 (0.346-0.578)	<0.001	1.15	I
23	0.879	0.412	<0.001	0.406	<0.001	0.557 (0.445-0.651)	<0.001	12.07	II
24	0.753	0.326	<0.001	0.319	<0.001	0.432 (0.303-0.545)	<0.001	2.87	I
25	0.632	0.188	0.002	0.186	0.003	0.29 (0.149-0.42)	<0.001	6.90	II
26	0.649	0.253	<0.001	0.253	<0.001	0.452 (0.325-0.562)	<0.001	4.60	I
28	0.793	0.466	<0.001	0.475	<0.001	0.612 (0.51-0.697)	<0.001	20.69	II
29	0.770	0.408	<0.001	0.404	<0.001	0.569(0.46-0.661)	<0.001	22.99	II

Table IV: Complete text of the 27 statements submitted to the fourth round.

Statement number	**Statement**	**Grade**	**Consistency**
1	Sac regression definition Sac regression should be defined as reduction in maximum diameter of the aneurysm sac by ≥ 5 mm	A	II
2	Sac regression role Aneurysm sac regression should be considered an important indicator of EVAR success.	A	I
3	Sac Regression and endoleak Aneurysm sac regression is usually correlated to the absence of endoleaks that require secondary intervention after EVAR.	A	I
4	Sac Regression and endoleak Aneurysm sac regression is usually correlated to the absence of type I and III endoleaks after EVAR.	A	I
5	Sac Regression and aneurysm rupture Aneurysm sac regression is correlated to low rates of aneurysm rupture after EVAR.	A	II
6	Sac Regression and secondary intervention Aneurysm sac regression is usually correlated to low rates of secondary intervention after EVAR.	A	I
7	Sac Regression and aneurysm-related complications	B	I

	Aneurysm sac regression is usually correlated to low rates of aneurysm-related complications after EVAR.		
8	Sac Regression and aneurysm-related mortality Aneurysm sac regression is usually correlated to reduced aneurysm-related mortality after EVAR.	A	I
10	Follow-up The first follow-up after discharge of elective EVAR should be a DUS or CT-angiography within 3 months.	A	II
11	Follow-up At 1-year follow-up, the imaging modality should be a DUS or a CTA (if DUS is not available or not diagnostic).	A	I
12	Follow-up At 2-year follow-up, the imaging modality should be a DUS or a CTA (if DUS is not available or not diagnostic).	A	I
13	Follow-up At 3-year follow-up, the imaging modality should be a DUS or a CTA (if DUS is not available or not diagnostic).	A	II
14	Follow-up At 5-year follow-up, the imaging modality should be a DUS or a CTA (if DUS is not available or not diagnostic).	A	I
15	Sac Regression assessment	A	II

	Sac regression should always be assessed during follow-up after EVAR.		
16	Sac regression assessment A Duplex Ultrasound (DUS) or a CTA should be used as first-line imaging modality to assess sac regression during follow-up.	A	II
17	Sac regression assessment The comparison of two CTA (baseline vs follow-up) is the most accurate imaging to detect sac regression after EVAR.	A	II
18	Sac regression assessment In case of DUS imaging modality, the sac regression should be measured in two projections at least (AL and PP).	A	II
19	Sac regression assessment In case of CTA imaging modality, the sac regression should be measured on the orthogonal axis using a dedicated reconstruction software.	A	I
20	Sac regression assessment The baseline imaging used to assess sac regression after EVAR should be the pre-operative CTA (done within 6 months before EVAR) or the first post-operative DUS or CTA (done within 3 months after EVAR).	B	I
21	Sac regression follow-up	B	I

	Sac regression can be usually expected to occur within 2 years after EVAR.		
22	Sac stable: role Sac stability (diameter change within ± 4.9 mm) may be considered a clinically relevant parameter during follow-up after EVAR.	B	I
23	Sac increase: role Sac increase (diameter change ≥ 5 mm) should be considered a clinically relevant parameter during follow-up after EVAR.	A	II
24	Sac regression: role In case of sac regression, the follow-up protocol after EVAR should be continued.	B	I
25	Sac regression: role In case of sac regression, the follow-up protocol after EVAR may be modified according to case-specific features (e.g. on-IFU vs off-IFU, age of the patient, chronic anticoagulation, etc).	B	II
26	Sac regression: exception In case of EVAR within the IFU, sac regression is one of the parameters to consider for possible follow-up protocol changes.	B	I
28	Follow-up: adjunctive tools	B	II

	Volumetric analysis may represent, in the future, an adjunctive tool to analyze AAA sac evolution during follow-up after EVAR.		
29	Follow-up: adjunctive tools Artificial Intelligence and Machine Learning may represent, in the future, an adjunctive tool to analyze sac evolution during follow-up after EVAR.	B	II