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Original Article

As the sac grows, the window closes: Aneurysm size, IFU compliance, and outcomes after endovascular aneurysm repair

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Abstract

Aim: Current guidelines recommend endovascular aneurysm repair (EVAR) for infrarenal abdominal aortic aneurysm (iAAA) at a ≥ 55 mm threshold, based primarily on rupture risk. Whether sac diameter and instructions-for-use (IFU) compliance independently influence outcomes remains unclear. We examined how sac size relates to neck anatomy, IFU compliance, and long-term outcomes.

Material and Methods: In this single-centre retrospective study, 383 of 435 consecutive patients undergoing elective EVAR (January 2016-January 2026) were analysed. ROC-derived cut-offs stratified patients into small (≤ 55 mm), medium (56 – 64 mm), and large (≥ 65 mm) groups. IFU compliance was assessed against device anatomical criteria. Late mortality, endoleak, and secondary intervention were analysed with Kaplan-Meier and univariable/multivariable Cox regression, with sac size and IFU compliance as covariates.

Results: The cohort was 92.9% male (median age 72). Non-IFU treatment increased with sac size (49.5% small, 60.4% medium, 80.6% large; $p < 0.001$), paralleling progressive neck deterioration (widening alpha angle, shortening neck, increasing thrombus; all $p < 0.001$). Non-IFU patients had more Type I endoleaks (14.9% vs 3.7%, $p = 0.001$) and secondary intervention (19.3% vs 6.0%, $p = 0.001$), whereas late mortality was similar (22.5% vs 23.9%, $p = 0.75$). In multivariable analysis, IFU non-compliance was the only independent predictor of secondary intervention (HR 2.91, 95% CI 1.34 – 6.29, $p = 0.007$), while large sac size independently predicted late mortality (HR 1.75, 95% CI 1.02 – 3.28, $p = 0.050$).

Conclusion: Sac enlargement progressively compromises proximal neck anatomy and reduces the feasibility of IFU-compliant EVAR. IFU non-compliance drives reintervention, whereas large sac size predicts late mortality. Beyond its rupture-risk role, the ≤ 55 mm threshold may also represent an important anatomical window for IFU-compliant EVAR.

Keywords: Abdominal aortic aneurysm; endovascular repair; instructions for use; sac diameter

INTRODUCTION

Infrarenal abdominal aortic aneurysm (iAAA) was traditionally managed through open surgical repair; however, endovascular aneurysm repair (EVAR) has become the predominant treatment modality in contemporary practice [1]. Compared to open surgery, EVAR is well established to be associated with lower rates of early postoperative morbidity and mortality. According to standard European Society for Vascular Surgery (ESVS) guideline recommendations [2], an aneurysm diameter of 55 mm or greater is accepted as the threshold for men, 50mm or greater in women for operative intervention. Also, it is indicated for the expansion of the aneurysm sac > 10 mm in a single year and symptomatic patients, regardless of sac diameter. Aneurysm size has been further classified as small, medium, and large [3,4]. It has been reported that rupture-related mortality rates in small aneurysms are significantly lower compared to those observed in medium and large aneurysms [5,6].

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Sac dynamics and anatomical suitability represent critical determinants in the selection of EVAR as a treatment modality. In particular, the instructions for use (IFU) established for these devices define notably strict anatomical criteria. These devices are designed for use within specific anatomical boundaries. When anatomy falls outside set parameters, achieving the desired procedural outcomes becomes considerably more challenging. Nevertheless, contemporary EVAR demonstrates a highly promising profile, with considerable mid-term efficacy and favourable early procedural success rates. Deciding between EVAR and open surgery carries significant clinical implications. Complication rates, hospital and ICU length of stay, morbidity, and mortality have all been shown to vary considerably depending on the surgical approach employed [7]. Consequently, many surgeons may opt to apply endovascular techniques without strictly adhering to IFU-defined anatomical eligibility criteria, in an effort to circumvent the adverse outcomes potentially associated with open surgical repair.

As the aneurysm sac enlarges, the proximal neck becomes shorter and wider, while tortuosity progressively increases within the aortic neck, aneurysm sac, and iliac arteries. Concurrently, thrombus deposition and calcification may develop, extending to involve the proximal neck as well [8,9]. This progression leads to deterioration of IFU compliance for EVAR, potentially exposing the patient to significantly worse clinical outcomes. If anatomy deteriorates with aneurysm growth, the question becomes straightforward yet critical: is < 55 mm the optimal window for EVAR?

To address this question, we analysed EVAR outcomes stratified by aneurysm sac diameter, placing IFU compliance at the centre of our investigation, asking whether smaller aneurysms, treated within favourable anatomical boundaries, translate into measurably better clinical outcomes.

MATERIAL AND METHODS

This study is a single-centre, retrospective cohort analysis of consecutive patients who underwent EVAR between January 2016 and January 2026. A total of 435 patients were screened, and 383 were included in the final analysis. Patients were included if they had (i) an infrarenal abdominal aortic aneurysm treated with elective EVAR, (ii) complete preoperative computed tomography angiography (CTA), and (iii) at least 12 months of imaging follow-up. Patients with ruptured aneurysms, emergency procedures, prior aortic repair, or inadequate imaging quality were excluded.

Preoperative data included demographic characteristics, history of previous abdominal surgery, CTA-based aneurysm diameter measurements, presence and localisation of intraluminal thrombus within the aneurysm sac, presence of thrombus and calcification at the proximal neck, iliac artery tortuosity, and presence of concomitant iliac aneurysm. Postoperative data included postoperative complications, time to discharge, and 30-day mortality. Follow-up data included serial CTA-based diameter measurements, endoleak detection and classification, need for secondary interventions, and late mortality.

Aneurysm sac diameter was initially analysed as a continuous variable. Receiver operating characteristic (ROC) curve analysis was performed to determine optimal cut-off values for the primary outcome, and thresholds were identified using the Youden index. Based on these data-driven cut-offs, patients were categorised into three groups: small (48- 55 mm), medium (56 – 64 mm), and large (65- 118 mm), which were used for all subgroup analyses. Patients with aneurysms below the guideline threshold (≤ 55 mm) underwent repair for guideline-concordant indications other than maximal diameter, namely symptomatic presentation, rapid sac expansion (>10 mm/year), and/or saccular morphology.

The primary endpoint was freedom from secondary intervention, defined as any aneurysm-related reintervention after the index EVAR procedure (including endoleak treatment, proximal neck extension, limb-related reintervention, and conversion to open repair). Secondary endpoints included late all-cause mortality, aneurysm-related mortality, the incidence and type of endoleak (with particular attention to Type I endoleak), and 30-day perioperative morbidity and mortality.

The Ankura™ AAA and Cuff Stent Graft System (Lifetech Scientific, Shenzhen, China) was used in accordance with the manufacturer's Instructions for Use. The system is indicated for EVAR in patients with a non-aneurysmal proximal aortic neck length ≥ 15 mm, a proximal aortic neck diameter of 18 – 32 mm, a proximal neck angulation ≤ 60°, a distal iliac anchorage zone ≥ 15 mm, and adequate iliac/femoral access compatible with the delivery system. The stent graft is a modular, ePTFE-based device supported by a nitinol stent structure, pre-loaded into an 18F-22F delivery system and deployed under fluoroscopic guidance via femoral arteriotomy. Device sizing was performed according to IFU recommendations, with stent graft diameter selected at 10 – 20% oversizing relative to the proximal aortic neck inner diameter. Patients not meeting one or more of these criteria were classified as non-IFU.

All anatomical measurements were obtained from CTA using centreline reconstruction to ensure accurate assessment of aortic morphology. The Ethics Committee of Ankara Bilkent City Hospital (TEBAD 1-26-2583/06.05.2026) approved this study.

Statistical analysis

Statistical analyses were performed using IBM SPSS Statistics version 27.0 (IBM Corp., Armonk, NY, USA) and R software, version 4.4.1 (R Foundation for Statistical Computing, Vienna, Austria). Descriptive statistics were expressed as frequency and percentage for categorical variables, and as mean ± standard deviation or median with interquartile range for continuous variables, as appropriate. Normality of data distribution was

assessed using the Kolmogorov-Smirnov test. Categorical variables were compared using the Chi-square (χ^2) test. For continuous variables, the Independent Samples t-test was used for normally distributed data, whereas the Mann-Whitney U test was applied for non-normally distributed data. ROC curve analysis was performed to identify optimal cut-off values for aneurysm sac diameter, with the Youden index used to determine the most discriminative thresholds. Time-to-event outcomes were analysed using Kaplan-Meier survival estimates with log-rank tests and pairwise comparisons adjusted by the Bonferroni method. Independent predictors of late mortality, endoleak, and secondary intervention were identified using univariable and multivariable Cox proportional hazards regression, with aneurysm sac size and IFU compliance entered as covariates. Individual anatomical variables were not entered separately into the regression models, as they constitute the defining criteria of IFU compliance. The proportional hazards assumption was assessed using scaled Schoenfeld residuals. Hazard ratios (HR) are reported with 95% confidence intervals (CI). Missing data were handled using complete-case analysis. A p-value of less than 0.05 was considered statistically significant.

RESULTS

A total of 383 patients were included, of whom 356 (92.9%) were male, with a median age of 72 years (IQR 67 – 77). Hypertension was the most prevalent comorbidity (82.0%), followed by coronary artery disease (53.0%) and hyperlipidemia (45.4%). Aneurysm sacs were stratified into small, medium, and large groups; no significant differences were observed between groups in terms of demographic characteristics, comorbidities, or ASA classification ($p > 0.05$). Also, baseline demographic and clinical characteristics did not differ significantly between IFU-compliant and IFU-non-compliant patients (Table 1). Among small aneurysms (≤ 55 mm), 52 (49.5%) were non-compliant; among medium aneurysms (56 – 64 mm), 81 (60.4%) were non-compliant; and among large aneurysms (≥ 65 mm), 116 (80.6%) were non-compliant. The difference in IFU compliance across the three size groups was statistically significant ($p < 0.001$).

Table 1. Baseline demographic and clinical characteristics by IFU compliance status

Parameters	IFU (n = 134)	Non-IFU (n = 249)	p
Median age, IQR	71 (66-77)	73 (68-77)	0.10†
Male, n (%)	125 (93.3%)	231 (92.8%)	0.85*
Hypertension, n (%)	108 (80.6%)	206 (82.7%)	0.60*
Coronary artery disease, n (%)	68 (50.7%)	135 (54.2%)	0.51*
Hyperlipidemia, n (%)	60 (44.8%)	114 (45.8%)	0.85*
Chronic kidney disease, n (%)	11 (8.2%)	17 (6.8%)	0.62*
Type 2 diabetes, n (%)	32 (23.9%)	76 (30.5%)	0.16*
Congestive heart failure, n (%)	6 (4.5%)	25 (10.1%)	0.057*
COPD/Asthma, n (%)	38 (28.4%)	58 (23.3%)	0.27*
Smoking, n (%)	89 (66.4%)	180 (72.2%)	0.24*
Metformin, n (%)	29 (21.6%)	72 (28.9%)	0.12*
Statin therapy, n (%)	77 (57.5%)	134 (53.8%)	0.49*
Dual-anti platelet therapy, n (%)	37 (27.6%)	76 (30.5%)	0.55*
ASA, n (%)			
I	0 (0%)	0 (0%)	
II	16 (11.9%)	21(8.4%)	
III	85 (63.4%)	148 (59.4%)	0.15§
IV	32 (23.9%)	80 (32.1%)	
V	1 (0.7%)	0 (0%)	

Data are presented as median for continuous variables and as n (%) for categorical variables. Continuous variables were compared using the Mann-Whitney U test (†). Categorical variables were compared using the Pearson χ^2 test (*), or Fisher's exact test (§). All tests were two-sided, and a p-value < 0.05 was considered statistically significant. Abbreviations: ASA, American Society of Anesthesiologists; COPD, chronic obstructive pulmonary disease.

Aneurysm sac diameter was strongly associated with progressive deterioration of proximal neck anatomy. As sac size increased, the alpha angle widened ($p < 0.001$), proximal neck length shortened ($p < 0.001$), and the prevalence of neck thrombus rose ($p < 0.001$). Consequently, the proportion of patients treated outside IFU criteria escalated from 49.5% in small aneurysms to 60.4% in medium and 80.6% in large aneurysms ($p < 0.001$) (Table 2 and Table 3).

Table 2. Anatomical and morphological characteristics of the aortic neck stratified by aneurysm sac diameter

Variable	≤ 55 mm small (n = 105)	56 – 64 mm medium (n = 134)	≥ 65 mm large (n = 144)	p
α-angle, ° (median, IQR)	15 (0 – 30)	25 (10 – 45)	40 (20 – 50)	**< 0.001‡**
Infrarenal aortic diameter, mm (median, IQR)	22 (20 – 23)	23 (21 – 25)	24 (21 – 26)	**< 0.001‡**
Proximal neck length, mm (median, IQR)	25 (22 – 38)	24 (21 – 24)	21 (20 – 22)	**0.001‡**
Proximal neck thrombus, n (%)	6 (5.7%)	27 (20.1%)	85 (59.0%)	**< 0.001***
Proximal neck calcification, n (%)	14 (13.3%)	22 (16.4%)	34 (23.6%)	0.09*
Non-IFU treatment, n (%)	52 (49.5%)	81 (60.4%)	116 (80.6%)	**< 0.001***

Abbreviations: IFU, instructions for use.

Table 3. Binary comparison: ≤ 55 mm vs > 55 mm

Variable	≤ 55 mm (n = 105)	> 55 mm (n = 278)	p
α-angle, ° (median, IQR)	15 (0 – 30)	30 (10 – 50)	**< 0.001‡**
Infrarenal aortic diameter, mm (median, IQR)	22 (20 – 23)	23 (21 – 26)	**< 0.001‡**
Proximal neck length, mm (median, IQR)	25 (22 – 38)	23 (21 – 27)	**0.002‡**
Proximal neck thrombus, n (%)	6 (5.7%)	112 (40.3%)	**< 0.001***
Proximal neck calcification, n (%)	14 (13.3%)	56 (20.1%)	0.12*
Non-IFU treatment, n (%)	52 (49.5%)	197 (70.9%)	**< 0.001***

Data are presented as median for continuous variables and as n (%) for categorical variables. Continuous variables were compared across the three groups using the Kruskal-Wallis test (‡). Categorical variables were compared using the Pearson χ^2 test (*). All tests were two-sided, and a p-value < 0.05 was considered statistically significant. Abbreviations: IFU, instructions for use.

Postoperative and follow-up outcomes were compared between IFU-compliant and IFU-non-compliant patients (Table 4). Procedural safety was excellent in both groups, with no 30-day mortality and no graft migrations recorded. Overall, late mortality did not differ significantly between IFU-compliant and non-compliant groups (p = 0.75), indicating that the IFU non-compliant group was not associated with increased long-term survival risk. In contrast, device-related complications were significantly more frequent in non-IFU patients (p = 0.003), with a nearly fourfold increase in Type I endoleaks and a more than threefold increase in secondary interventions (p = 0.001). Consistent with these findings, the rate of secondary intervention was more than three times higher in the non-IFU group (p = 0.001). Other complications did not differ significantly between groups.

Table 4. Postoperative and follow-up outcomes according to IFU compliance

Outcome	IFU (n = 134)	Non-IFU (n = 249)	p
30-day mortality, n (%)	0 (0%)	0 (0%)	—
Overall (late) mortality, n (%)	32 (23.9%)	56 (22.5%)	0.75*
Any endoleak, n (%)	23 (17.2%)	77 (30.9%)	0.003*
Type I endoleak, n (%)	5 (3.7%)	37 (14.9%)	0.001*
Secondary intervention, n (%)	8 (6.0%)	48 (19.3%)	0.001*
Graft migration, n (%)	0 (0%)	0 (0%)	—
Distal embolization, n (%)	1 (0.7%)	6 (2.4%)	0.24§
Access-site/wound complications, n (%)	9 (6.7%)	19 (7.6%)	0.73*

Data are presented as n (%). Categorical variables were compared using the Pearson χ^2 test (*), or Fisher's exact test (§) where expected cell frequencies were below 5. Outcomes with no events in either group (30-day mortality, graft migration) were not tested. All tests were two-sided, and a p-value < 0.05 was considered statistically significant. Abbreviations: IFU, instructions for use.

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Kaplan-Meier survival analysis demonstrated significant differences across aneurysm size groups for both endoleak (log-rank p = 0.03) and secondary intervention (log-rank p = 0.05), but not for late mortality (log-rank p = 0.10). Pairwise comparisons with Bonferroni correction revealed that the small aneurysm group had significantly lower endoleak rates compared with large aneurysms (p = 0.015). When stratified by IFU compliance, IFU-non-compliant patients exhibited significantly higher rates of both endoleaks (log-rank p = 0.01) and secondary intervention (log-rank p < 0.001), whereas late mortality did not differ between IFU groups (p = 0.90). Kaplan-Meier curves are presented in Figure 1, Figure 2 and Figure 3.

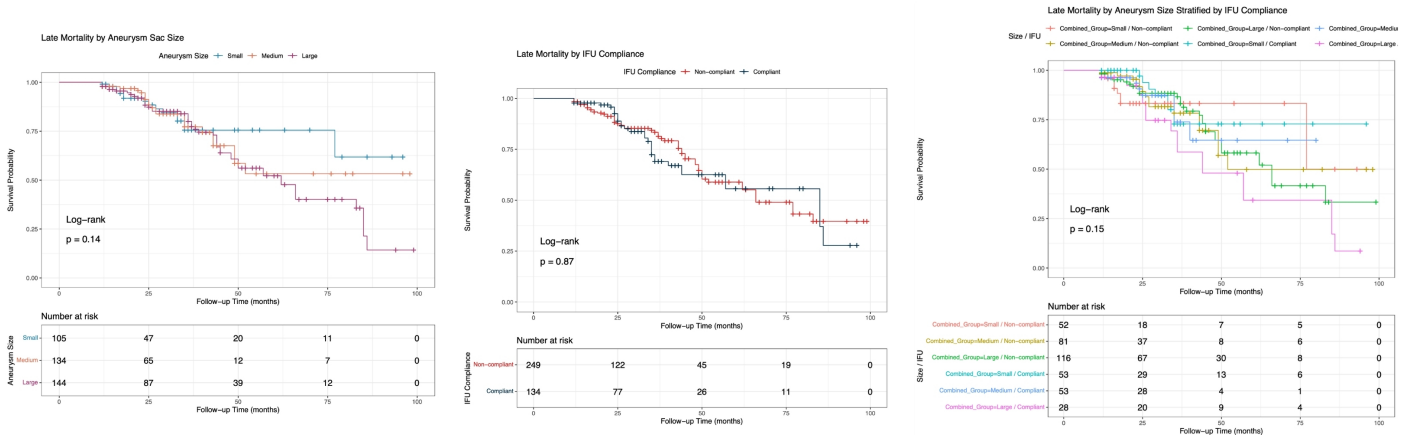


Figure 1. Kaplan-Meier analysis for late mortality and IFU compliance. Abbreviations: IFU, instructions for use.

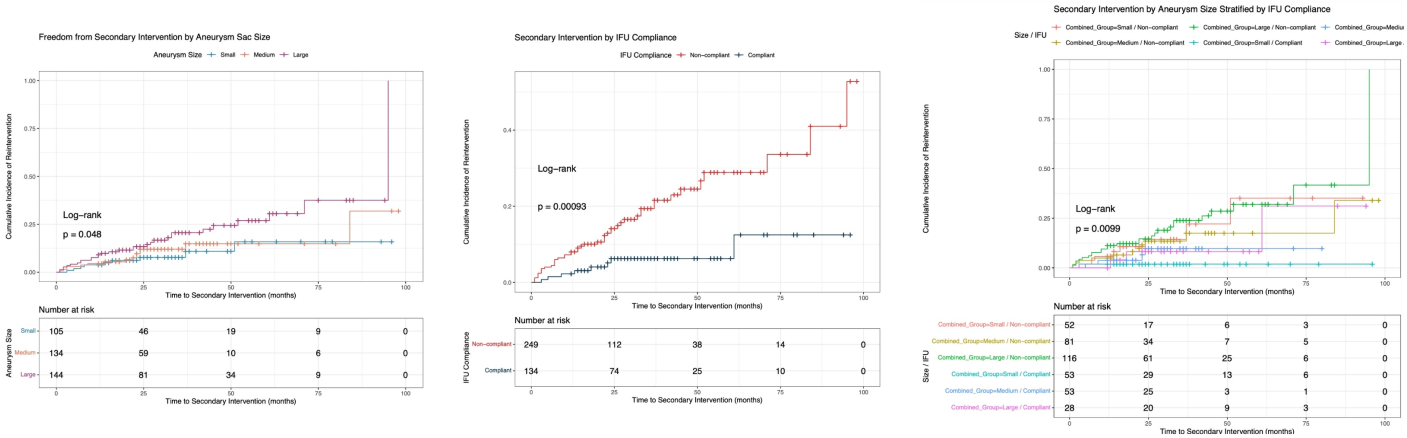


Figure 2. Kaplan-Meier analysis for secondary ıntervention and IFU compliance. Abbreviations: IFU, instructions for use.

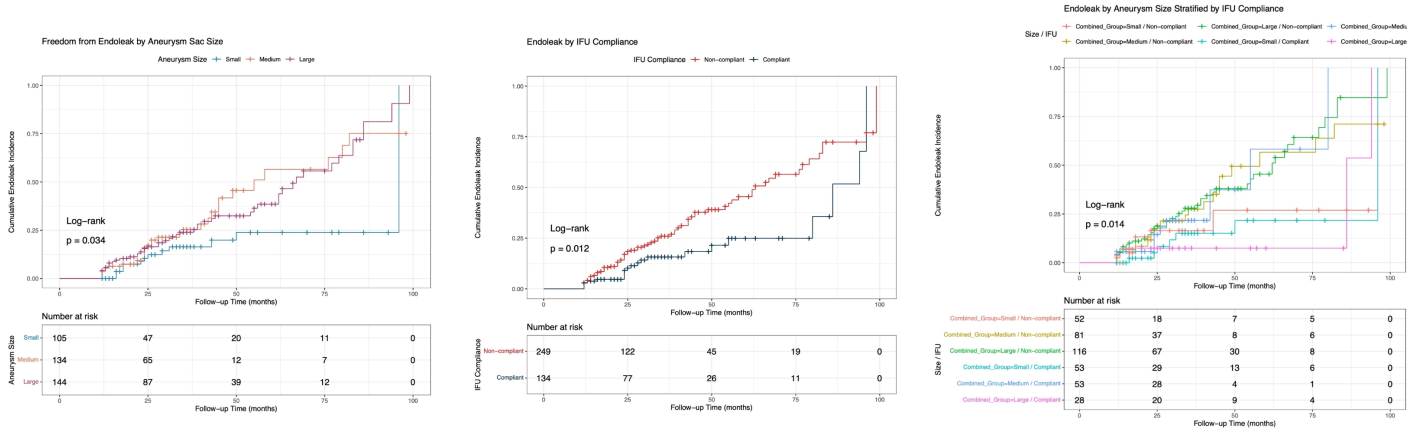


Figure 3. Kaplan-Meier analysis for endoleak and IFU compliance. Abbreviations: IFU, instructions for use.

Univariable and multivariable Cox proportional hazards regression analyses were performed to identify independent predictors of late mortality, endoleak, and secondary intervention, in Table 5. In multivariable analysis, IFU non-compliance remained the only independent predictor of secondary intervention.

Table 5. Cox proportional hazards regression analysis for late mortality, endoleak, and secondary intervention

Outcome / Variable	Univariable HR (95% CI)	p	Multivariable HR (95% CI)	p
Late mortality (n events = 88)				
Aneurysm size				
Small (reference)	1.00	—	1.00	—
Medium	1.31 (0.70 – 2.45)	0.406	1.09 (0.56 – 2.13)	0.803
Large	1.72 (0.99 – 2.99)	0.056	1.75 (1.02 – 3.28)	**0.050**
IFU compliance				
Compliant (reference)	1.00	—	1.00	—
Non-compliant	0.96 (0.62 – 1.49)	0.866	1.26 (0.77 – 2.07)	0.350
Age (per year)	0.97 (0.94-1.002)	0.060	0.95 (0.91-0.98)	**0.004**
Coronary artery disease	1.12 (0.71-1.77)	0.605	1.75 (1.03-3.29)	**0.020**
Chronic kidney disease	1.42 (1.20-1.91)	**0.020**	1.13 (1.05-1.36)	**0.050**
Congestive heart failure	0.88 (0.44-1.78)	0.736	0.48 (0.20-1.17)	0.105
COPD/Asthma	1.07 (0.67-1.70)	0.767	0.71 (0.37-1.38)	0.314
ASA class				
ASA II	1.00	—	1.00	—
ASA III	1.04 (0.47-2.28)	0.908	1.12 (0.49 – 2.14)	0.870
ASA IV	0.88 (0.41-1.90)	0.757	0.95 (0.56 – 1.85)	0.640
ASA V	1.67 (0.20-13.66)	0.630	1.78 (0.26-12.56)	0.528
Smoking	1.72 (1.06-2.78)	**< 0.001**	3.01 (1.72 – 5.28)	**< 0.001**
Endoleak (n events = 100)				
Aneurysm size				
Small (reference)	1.00	—	1.00	—
Medium	1.95 (1.07 – 3.54)	**0.029**	1.74 (0.95 – 3.20)	0.073
Large	1.99 (1.13 – 3.51)	**0.017**	1.72 (0.95 – 3.08)	0.071
IFU compliance				
Compliant (reference)	1.00	—	1.00	—
Non-compliant	1.79 (1.12 – 2.86)	**0.015**	1.57 (0.97 – 2.55)	0.067
Secondary intervention (n events = 56)				
Aneurysm size				
Small (reference)	1.00	—	1.00	—
Medium	1.40 (0.61 – 3.20)	0.428	1.14 (0.49 – 2.64)	0.755
Large	2.31 (1.10 – 4.87)	**0.028**	1.68 (0.78 – 3.63)	0.182
IFU compliance				
Compliant (reference)	1.00	—	1.00	—
Non-compliant	3.31 (1.56 – 7.01)	**0.002**	2.91 (1.34 – 6.29)	**0.007**

Abbreviations: ASA, American Society of Anesthesiologists; COPD, chronic obstructive pulmonary disease, IFU, instructions for use.

Late mortality occurred in 88 patients during follow-up. In univariable Cox regression analysis, aneurysm size showed a trend toward increased mortality risk in large aneurysms (HR 1.72, 95% CI 0.99 – 2.99, p = 0.056), while IFU non-compliance was not associated with mortality (HR 0.96, 95% CI 0.62 – 1.49, p = 0.866). In multivariable analysis, large aneurysm size emerged as an independent predictor of late mortality (HR 1.75, 95% CI 1.02 – 3.28, p = 0.050), whereas IFU non-compliance remained non-significant (HR 1.26, 95% CI 0.77 – 2.07, p = 0.350).

Aneurysm-related mortality was rare (n = 1) and therefore not included in regression analyses.

DISCUSSION

EVAR has become the standard treatment for iAAA, largely replacing open repair due to its lower perioperative morbidity and mortality [10]. Current ESVS guidelines recommend intervention at ≥ 55 mm, based primarily on rupture risk [2]. However, rupture risk is not the only factor that changes as aneurysms grow; so does the anatomy.

Our study yields three principal findings. First, IFU non-compliance was the only independent predictor of secondary intervention (HR 2.91, 95% CI 1.34 – 6.29, p = 0.007), indicating that patients treated outside device criteria were nearly three times more likely to require reintervention. Second, late mortality was influenced by aneurysm size, with large aneurysms carrying a significantly higher risk (HR 1.75, p = 0.050), whereas IFU compliance did not significantly affect survival. Third, IFU compliance declined sharply with increasing sac size, reaching only 19.4% in large aneurysms, highlighting that larger aneurysms are not only riskier to leave untreated but are also more difficult to treat optimally.

Our findings show that anatomical suitability deteriorates progressively with sac enlargement, and that IFU compliance, not aneurysm size, is the strongest determinant of device-related complications and secondary interventions.

Previous studies have demonstrated that increasing aneurysm size is associated with progressive deterioration of proximal neck morphology, including shortening, angulation, and thrombus accumulation [8,9,11,12]. Some authors have therefore proposed that an intervention between 40 and 54 mm may offer a more favourable anatomical window [13]. Adherence to IFU criteria is associated with fewer device-related complications [14]. In real-world practice, strict IFU eligibility is met by approximately 30% of patients, with rates ranging from 20% to 80% across published series [13]. In our cohort, even among small aneurysms (≤ 55 mm), only 50.5% were IFU-compliant. This proportion declined to 39.6% in medium aneurysms and to only 19.4% in large ones, with statistically significant differences between size groups (small vs large p < 0.001; medium vs large p = 0.001). Consistent with this progressive anatomical degradation, the alpha angle widened (15° → 25° → 40°), the proximal neck shortened, and neck thrombus became markedly more common (5.7% → 59%) as aneurysm size increased, all reaching statistical significance.

IFU compliance declined sharply with increasing sac size, reaching only 19.4% in large aneurysms, highlighting that larger aneurysms are not only riskier to leave untreated but are also more difficult to treat optimally. This pattern suggests that aneurysm enlargement is not merely a marker of rupture risk but a process that actively compromises the anatomical feasibility of optimal EVAR deployment. These findings suggest that waiting longer not only increases rupture risk but also narrows the anatomical window for a technically sound EVAR procedure. Although this has been proposed before, the present study provides one of the clearest single-cohort demonstrations of this relationship.

The technical success of EVAR is determined by surgeon experience, patient selection, and adherence to IFU criteria [14]. Recognised early complications include endoleak, particularly Type I endoleak, graft migration, and perioperative mortality [15,16]. In our cohort, device-related complications were considerably more common in non-IFU patients. Type I endoleak occurred nearly four times more frequently, endoleak of any type at almost twice the rate, and secondary interventions more than three times as often compared with IFU-compliant patients.

We sought to evaluate whether 55 mm represents the optimal timing for EVAR. Our data support this threshold, not only as a rupture-risk boundary, but as the critical window beyond which proximal neck anatomy progressively deteriorates and IFU-compliant repair becomes increasingly unfeasible. The 55-mm threshold is well-established in current guidelines on rupture-risk grounds [2], but our findings indicate it is equally critical from an anatomical standpoint. IFU compliance fell from 50.5% in small aneurysms to 19.4% in large ones, representing an approximate 60% relative reduction. Postponing intervention until an aneurysm reaches ≥ 65 mm implies that approximately eight of ten patients will be treated outside IFU criteria. Intervening at or below 55 mm therefore confers a dual advantage: reduced rupture risk together with a substantially higher probability of achieving an IFU-compliant repair, which in turn reduces the risk of subsequent secondary interventions.

The observation that IFU compliance did not affect late mortality warrants further consideration. Large aneurysm size was an independent predictor of death (HR 1.75, p = 0.05), whereas operating outside IFU criteria was not (HR 1.26, p = 0.35). This suggests that IFU compliance primarily influences long-term device durability rather than directly determining patient survival. Late deaths in this cohort were predominantly

attributable to non-aneurysmal causes, mainly cardiovascular events and malignancy, which may explain why device-related factors had limited impact on overall survival. One important caveat is that the proportional hazards assumption for aneurysm size showed borderline violation (Schoenfeld residuals, p = 0.037), indicating that the effect of size on mortality may not be uniform throughout follow-up and should be interpreted with caution. Also, the inverse association between age and late mortality should not be interpreted causally; it likely reflects the fitness-based selection of older patients for elective EVAR and the correlation between age and aneurysm size, whereby adjustment for size isolates a conditional rather than a marginal effect of age.

Kaplan-Meier analysis demonstrated distinct patterns across the three outcomes examined. Late mortality did not differ significantly across aneurysm size groups (p = 0.10) or between IFU-compliant and non-compliant patients (p = 0.90), indicating that IFU adherence did not show a meaningful influence on long-term survival in this cohort. By contrast, both secondary intervention and endoleaks showed significant separation between groups. The cumulative incidence of reintervention was significantly higher in large aneurysms compared with small aneurysms (p = 0.05) and was markedly elevated in IFU-non-compliant patients throughout follow-up (p < 0.001). Similarly, the cumulative endoleak incidence diverged significantly across size groups (p = 0.03), with large aneurysms consistently demonstrating the highest endoleak burden, and was substantially greater in IFU-non-compliant patients (p = 0.01). These findings collectively suggest that aneurysm sac size and IFU compliance are clinically relevant determinants of device-related events but not of overall survival after EVAR.

For endoleak, both aneurysm size and IFU non-compliance were significant predictors in univariable analysis, but both became borderline after adjusting for each other (HR ~1.7 each). This suggests that they largely act through the same pathway, progressive neck deterioration leading to inadequate proximal seal, though each may contribute independently. For secondary intervention, the picture is more straightforward: aneurysm size appeared significant when analysed alone (HR 2.31, p = 0.028), but this effect disappeared after adjusting for IFU compliance (HR 1.68, p = 0.182). This indicates that larger aneurysms do not independently drive reintervention; they simply tend to be treated outside IFU criteria more often, and it is that non-compliance that ultimately leads to reintervention.

Limitations

This study has several limitations. Its single-centre, retrospective design introduces the potential for selection bias and limits generalisability to other institutions. Since our cohort was 92.9% male, the findings should be applied with caution to female patients. Follow-up duration may be insufficient to capture all late endoleaks and reinterventions, which tend to accumulate over years after EVAR. The absence of 30-day mortality likely reflects careful patient selection at our institution rather than a generalisable finding. Aneurysm-related mortality was too infrequent (n = 1) to permit meaningful statistical analysis. In addition, anatomical assessment was limited to the time of surgery, precluding evaluation of longitudinal changes in IFU eligibility at the individual level. Also, we used a single device for all patients; therefore, we cannot generalise our findings to all EVAR devices. By requiring a minimum of 12 months of imaging follow-up, the study may have excluded patients with early mortality, early complications, or loss to follow-up, introducing a potential survivor bias. Finally, the borderline violation of the proportional hazards assumption for aneurysm size constrains how the hazard ratio can be interpreted across the full follow-up period.

CONCLUSION

Aneurysm sac enlargement is associated with progressive deterioration of aortic neck anatomy and a marked decline in IFU compliance for EVAR. While aneurysm size influences mortality risk, IFU non-compliance is the principal determinant of device-related complications and secondary interventions. The decision to operate should therefore not rest on rupture risk alone; anatomical suitability must also be considered, as it deteriorates steadily with aneurysm growth. Operating at or below 55 mm offers the highest probability of a technically optimal, IFU-compliant repair, and our data show this translates directly into fewer secondary interventions. Prospective multicentre studies comparing outcomes between early intervention (below 55 mm) and standard-threshold repair, with IFU compliance as a primary endpoint, are warranted to validate these findings and potentially inform future guideline updates.

Ethics Committee Approval: The Ethics Committee of Ankara Bilkent City Hospital (TEBAD 1-26-2583/ 06.05.2026) approved this study.

Patient Consent for Publication: Written informed consent to participate was obtained from the patients.

Data Sharing Statement: The data that support the findings of this study are available from the corresponding author upon reasonable request.

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