Online October 24, 2023
doi: 10.5761/atcs.oa.23-00098

Original Article

Long-Term Outcomes of Simple Endovascular Aneurysm Repair Based on the Initial Aortic Diameter

Yuki Orimoto, Hiroyuki Ishibashi, Takahiro Arima, Yusuke Imaeda, Yuki Maruyama, Hiroki Mitsuoka, and Akio Kodama

Purpose: We aimed to investigate the effects of initial abdominal aortic aneurysm (AAA) diameter on aneurysmal sac expansion/shrinkage, endoleaks, and reintervention post-elective simple endovascular aneurysm repair (EVAR).

Methods: Overall, 228 patients monitored for >1 year after EVAR were analyzed. Male and female participants with initial AAA diameters <55 mm and <50 mm, respectively, composed the small group (group S), while those with initial AAA diameters ≥55 mm (men) and ≥50 mm (women) composed the large group (group L). Aneurysmal sac expansion of 10 mm and/or reintervention during follow-up (composite event) and its related factors were evaluated.

Results: The 5-year freedom from composite event rate was significantly higher in group S (92.4 ± 2.8%) than that in group L (79.1 ± 4.9%; P <0.01). Multivariate analysis revealed AAA diameters before EVAR in group S (hazard ratio, 0.38; 95% confidence interval, 0.18–0.81; P = 0.01) and type II endoleak (T2EL) at discharge (hazard ratio, 2.83; 95% confidence interval, 1.29–6.20; P <0.01) as factors associated with the composite event. The freedom from composite event rate decreased to 51 ± 13% at 5 years in group L with T2EL.

Conclusions: Group S had high freedom from composite event rate; in group L, the rate decreased to 51% at 5 years with T2EL at discharge.

Keywords: aortic aneurysm, endovascular aneurysm repair, initial diameter, reintervention

Introduction

Endovascular aneurysm repair (EVAR) is less invasive than open surgical repair (OSR); however, its long-term and aneurysm-related mortality rates are higher than those of OSR.[1)]

Abdominal aortic aneurysm (AAA) sac shrinkage 1 year after EVAR can serve as a surrogate marker for decreased risk of late complications and durable success[2–4)] and is related to the initial diameter of the AAA.[5)] The Society for Vascular Surgery (SVS)[6)] and European Society for Vascular Surgery (ESVS)[7)] guidelines recommend an elective repair of fusiform AAAs of diameters 55 mm in men and 50 mm in women. However, a retrospective analysis of prospectively collected Vascular Quality Initiative data revealed that EVAR non-compliant with AAA guideline-recommended diameter thresholds (<55 mm in men and <50 mm in women) was associated with better rates of reintervention, rupture, and survival than EVAR compliant with

Department of Vascular Surgery, Aichi Medical University, Nagakute, Aichi, Japan

Received: June 8, 2023; Accepted: October 10, 2023
Corresponding author: Yuki Orimoto. Department of Vascular Surgery, Aichi Medical University, 1-1 Yazakokarimata, Nagakute, Aichi 480-1195, Japan
Email: oriyuki@aichi-med-u.ac.jp

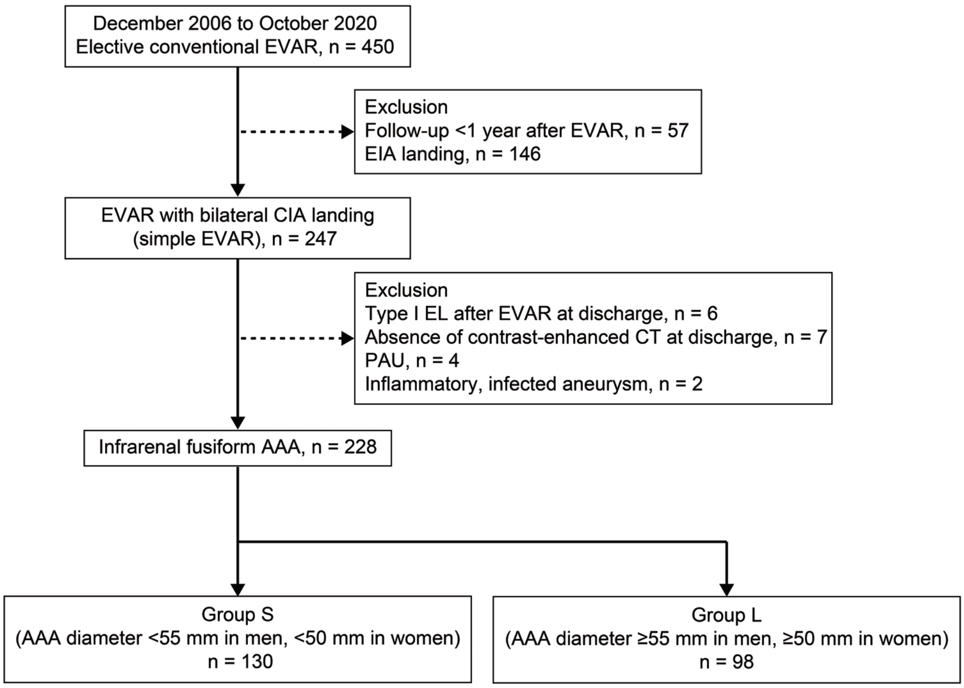


Fig. 1 Flowchart for patient selection. EVAR: endovascular aneurysm repair; EIA: external iliac artery; CIA: common iliac artery; EL: endoleak; CT: computed tomography; PAU: penetrating atherosclerotic ulcer; AAA: abdominal aortic aneurysm

the recommended thresholds.[8] However, limited information is currently available on the expansion/shrinkage of the aneurysm sac, endoleaks, and reintervention after EVAR. Furthermore, an aneurysm diameter threshold of 50 mm is generally adopted in Japan.[9–11] Therefore, the present study aimed to examine the effects of adhering to the SVS/ESVS guidelines recommended for initial AAA diameter thresholds on the long-term outcomes of Japanese patients after simple EVAR.

Materials and Methods

Patients

This was a retrospective analysis conducted at a single center. The Institutional Review Board of Aichi Medical University approved the present study (approval number: 2020-211). Due to the study's retrospective nature, neither patient approval nor informed consent was required for the review of medical records and computed tomography (CT) or aortography images.

Between December 2006 and October 2020, 450 patients underwent elective EVAR with bifurcated devices at our institution. Preemptive inferior mesenteric artery (IMA) embolization at EVAR was not performed during this study period. Cases of rupture, thoracoabdominal aortic aneurysm, fenestrated EVAR (FEVAR), and chimney EVAR (ChEVAR) were excluded. Furthermore, patients with the following characteristics were excluded: (1) follow-up for >1 year after EVAR, (2) distal landing on the external iliac artery, (3) type I endoleaks at discharge, (4) absence of contrast-enhanced CT at discharge, and (5) presence of penetrating atherosclerotic ulcer or saccular, inflammatory, and infected types of aneurysms.

A total of 228 consecutive patients with infrarenal fusiform aneurysms who underwent EVAR by bilateral common iliac artery landing (simple EVAR) were enrolled in the present study. A group of 130 patients who underwent EVAR for initial aneurysm diameters of <55 mm in men and <50 mm in women (small group; group S) and a group of 98 patients who underwent EVAR for initial aneurysm diameters of ≥55 mm in men and ≥50 mm in women (large group; group L) were retrospectively reviewed (**Fig. 1**).

Definitions and variables

The aneurysm diameter was measured at the maximum minor axis on contrast-enhanced cross-sectional CT images, where the maximum minor axis was represented by the shortest outer wall-to-outer wall diameter on the largest cut of the aneurysm. This measurement was performed independently by three vascular surgeons.

Initial 3D CT angiography was used for planning in all cases. Images were transferred to a workstation (Aquarius Net Viewer; TeraRecon Inc., San Mateo, CA, USA) for multiplane reconstructions. The selection of stent-graft devices was based on the specific characteristics and surgeons' preferences. The proximal neck characteristics outside of the devices' instructions for use (IFU) were defined based on the criteria for each device. The IFU of the distal landing was adhered to in all patients. Patients' medical records were reviewed to collect clinical parameters. The use of antiplatelets and anticoagulants was defined as receiving therapy at initial EVAR. All patients underwent contrast-enhanced CT before discharge to confirm endoleaks.

Follow-up and reintervention protocol

Contrast-enhanced CT was performed a month after EVAR. In cases of severely decreased renal function (typically an estimated glomerular filtration rate <30 mL/min/1.73 m^2), contrast-enhanced CT was substituted by plain CT.

Plain CT was performed 6 and 12 months after EVAR and yearly thereafter. The condition of the patients was confirmed by medical examination. The aneurysmal sac size was measured as the maximum minor axis on CT axial images.

In patients with complications, such as sac enlargement or stent-graft migration, contrast-enhanced CT and duplex ultrasound studies were added to assess endoleaks. When type I or III endoleaks were identified, prompt reintervention was planned. Transarterial or translumbar embolization was considered for type II endoleaks (T2ELs) when aneurysmal sac growth was >10 mm. Late open conversion was performed on type Ia endoleaks when it was not possible to control aneurysmal sac growth by adding an aortic cuff or coil embolization to the proximal neck. In addition, it was performed in T2EL cases with aneurysmal sac growth and size >70 mm, even after transarterial or translumbar embolization. Furthermore, late open conversion was performed in patients with rupture excluding type Ib endoleaks. The decision for reintervention was made after a conference and was dependent on changes in the aneurysmal sac size and the patient's general condition.

Endpoints

The primary endpoint included aneurysmal sac expansion of 10 mm and/or reintervention during the follow-up period as a composite event. Furthermore, factors related to the composite event were analyzed. The secondary endpoint included aneurysmal sac shrinkage of 10 mm.

Statistical analysis

Data were retrospectively collected and analyzed. Continuous data were reported as mean ± standard deviation and categorical data as absolute numbers and percentages in the study cohort. As the continuous data were distributed normally, the Student's t-test was performed to evaluate differences between the groups. The χ^2 test or Fisher's exact test was performed to compare categorical variables.

The Kaplan–Meier analysis was performed to estimate differences in freedom from the composite event (sac expansion of 10 mm and/or reintervention) between the groups. The significance of differences in Kaplan–Meier curves was assessed using the log-rank test. Factors related to the composite event were analyzed using univariate and multivariate Cox proportional hazards models.

According to data from previous reports, age, male sex, occlusion of the IMA, the number of patent lumbar arteries, outside IFU, T2EL at discharge, antiplatelet therapy, and initial AAA diameters <55 mm in men and <50 mm in women were included when evaluating the effect of the composite event after EVAR.[12–14] Statistical analyses were performed using SPSS version 28 (IBM Corp., Armonk, NY, USA). P-values of <0.05 were considered to be statistically significant.

Results

Patient characteristics

Patient characteristics before EVAR in groups S and L are summarized in **Table 1**. The rates of male sex (P <0.01), coronary artery disease (P = 0.05), and antiplatelet therapy (P = 0.04) were significantly higher in group S. In contrast, patients in group L were significantly older (P = 0.02) and more likely to have chronic renal failure (P = 0.04). The initial AAA diameter was 49.9 ± 2.9 mm in group S and 60.9 ± 7.4 mm in group L. Of the 118 men in group S, 82 (69.5%) had an initial AAA diameter between 50 and 54 mm. In group S, the initial AAA diameter was 46.8 ± 1.9 mm for female participants and 50.2 ± 2.8 mm for male participants. On the other hand, in group L, the initial AAA diameter was 55.0 ± 5.4 mm for female participants and 62.7 ± 6.9 mm for male participants.

Table 1 Baseline characteristics stratified by the initial AAA diameter

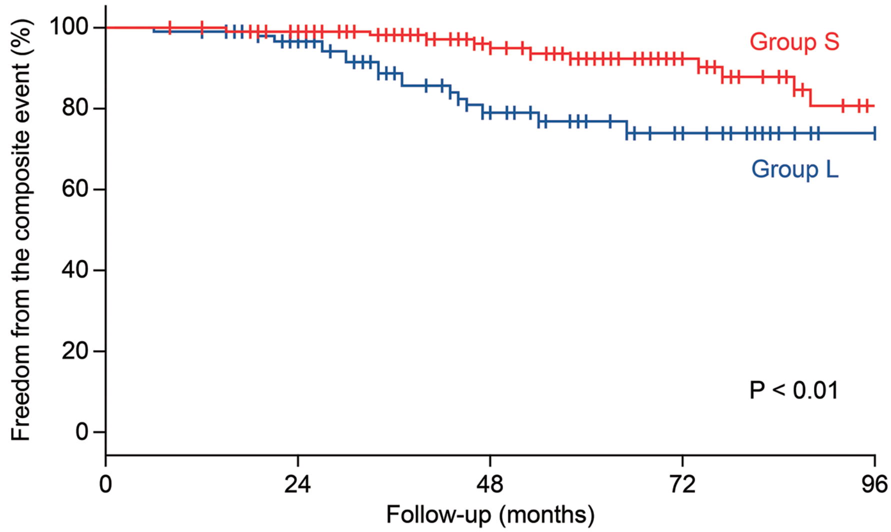
	Group S (men <55 mm, women <50 mm), n = 130	Group L (men ≥55 mm, women ≥50 mm), n = 98	P value
Age (years)	75 ± 8	77 ± 8	0.02
Male	118 (90.8)	75 (76.5)	<0.01
Hypertension	85 (65.4)	56 (57.1)	0.20
Diabetes mellitus	18 (13.8)	17 (17.3)	0.47
Coronary artery disease	32 (24.6)	14 (14.3)	0.05
Cerebrovascular disease	17 (13.1)	11 (11.2)	0.67
Pulmonary disease	19 (14.6)	18 (18.4)	0.45
Chronic kidney disease (eGFR <30)	3 (2.3)	8 (8.2)	0.04
Antiplatelet therapy	51 (39.2)	26 (26.5)	0.04
Anticoagulant therapy	10 (7.7)	10 (10.2)	0.51
Aneurysm diameter (mm)	49.9 ± 2.9	60.9 ± 7.4	<0.01
Occlusion of IMA	41 (31.5)	36 (36.7)	0.41
Patent IMA diameter (mm)	3.4 ± 0.7	3.1 ± 0.7	0.04
Number of patent lumbar arteries	5.3 ± 2.0	5.1 ± 1.9	0.45
Outside IFU	30 (23.1)	40 (40.8)	<0.01
Angulated neck >60°	30 (23.1)	40 (40.8)	
Large neck (>32 mm)	0	2 (2.0)	
Short neck (<10 mm)	0	0	
Stent-graft device			0.35
Zenith	31 (23.8)	12 (12.2)	
Excluder	28 (21.5)	20 (20.4)	
Endurant	59 (45.5)	53 (54.2)	
Powerlink	1 (0.8)	4 (4.1)	
Aorfix	4 (3.1)	3 (3.1)	
AFX	2 (1.5)	2 (2.0)	
Talent	2 (1.5)	2 (2.0)	
Others	3 (2.3)	2 (2.0)	
Type II EL (at discharge)	25 (19.2)	26 (26.5)	0.19
Type II EL from IMA (at discharge)	12 (9.2)	14 (14.2)	0.23
Follow-up, months	66 ± 34	55 ± 31	0.02

Data are presented as mean ± standard deviation (range) and categorical data as numbers (%). AAA: abdominal aortic aneurysm; eGFR: estimated glomerular filtration rate (mL/min/1.73 m²); IMA: inferior mesenteric artery; IFU: instructions for use; EL: endoleak

In terms of anatomical features, the diameter of the patent IMA at the origin in group S (n = 89) was larger than that in group L (n = 62; P = 0.04). Group L included 40.8% cases outside IFU, which was significantly higher than the 23.1% in group S (P <0.01). The type of stent-graft device used was not significantly different between the two groups. Furthermore, no significant differences were observed in T2EL or T2EL from IMA at discharge between the two groups. The mean follow-up period in group S was significantly longer than that in group L (P = 0.02).

Outcomes

Shrinkage of 10 mm was observed in 46 cases (35.4%) in group S, which was significantly higher than that in group L (P = 0.05). The composite event (sac expansion of 10 mm and/or reintervention) was observed in 13 cases (10%) in group S and 19 cases (19.4%) in group L (P = 0.04). The frequency of reintervention alone was significantly less in group S (P = 0.03). In contrast, no significant differences were observed in type 1a endoleaks, rupture, or late open conversion between the two groups. The Kaplan–Meier curve of freedom from composite event rate was significantly higher in group S than that in group L (**Fig. 2**); additionally, the freedom from composite event rate was compared between the two groups by sex. For men, the rate was 91.6 ± 3.1% at 5 years in group S and 76.5 ± 5.9% at 5 years in group L, indicating a significant difference (P = 0.01). For women, the rate was 100 ± 0% at 5 years in group S



		0	24	48	72	96
Small group	No. at risk	130	122	101	44	17
	%		99	95	92	81
	SE		0.8	2.2	2.8	6.1
Large group	No. at risk	98	81	44	20	7
	%		97	79	74	74
	SE		1.9	4.9	5.8	5.8

Fig. 2 Kaplan–Meier curves for freedom from the composite event of sac expansion of 10 mm and/or reintervention after EVAR in group S with initial AAA diameters of <55 mm in men and <50 mm in women and in group L with initial AAA diameters of ≥55 mm in men and ≥50 mm in women. EVAR: endovascular aneurysm repair; AAA: abdominal aortic aneurysm; SE: standard error

Table 2 Factors related to the composite event of sac expansion of 10 mm and/or reintervention after EVAR

Variable	Univariate analysis			Multivariate analysis		
	HR	95% CI	P value	HR	95% CI	P value
Age (years)	1.05	0.99–1.11	0.06	–	–	–
Male	0.65	0.31–2.08	0.65	–	–	–
Occlusion of IMA	0.8	0.37–1.75	0.58	–	–	–
No. of patent lumbar arteries	1.19	1.00–1.42	0.05	–	–	–
Outside IFU	1.96	0.95–4.03	0.07	–	–	–
Type II EL	3.84	1.90–7.76	<0.01	2.83	1.29–6.20	<0.01
Antiplatelet therapy	0.86	0.41–1.82	0.69	–	–	–
Men <55 mm, women <50 mm	0.35	0.17–0.72	<0.01	0.38	0.18–0.81	0.01

EVAR: endovascular aneurysm repair; HR: hazard ratio; CI: confidence interval; EL: endoleak; IFU: instructions for use; IMA: inferior mesenteric artery

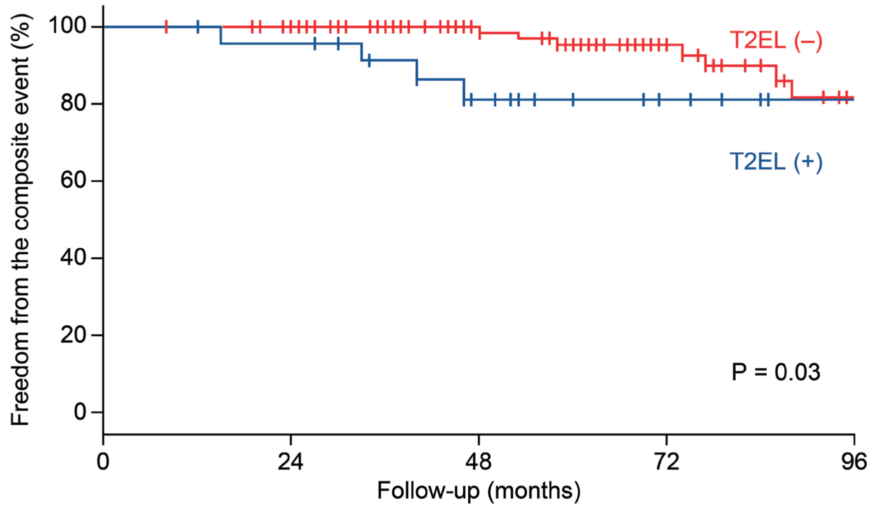
and 78.9 ± 11% at 5 years in group L, but no significant difference was observed (P = 0.08).

The multivariate analysis identified initial AAA diameters before EVAR of <55 mm in men and <50 mm in women (hazard ratio, 0.38; 95% confidence interval, 0.18–0.81; P = 0.01) and T2EL at discharge (hazard ratio, 2.83; 95% confidence interval, 1.29–6.20; P <0.01) as factors associated with the composite event (**Table 2**).

Subgroup analysis with T2EL

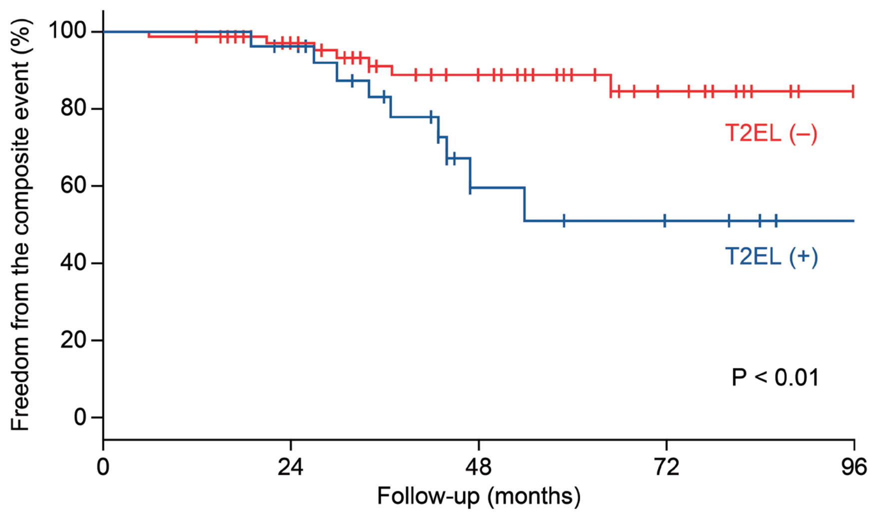
Figure 3 shows the freedom from composite event rates classified by T2EL at discharge for the two groups. In group S, the rate was 95.4% at 5 years without T2EL

A



		0	24	48	72	96
T2EL (–)	No. at risk	105	99	67	37	14
	%		100	99	95	82
	SE		0	1.5	2.6	6.9
T2EL (+)	No. at risk	25	23	14	7	3
	%		96	81	81	81
	SE		4.1	8.5	8.5	8.5

B



		0	24	48	72	96
T2EL (–)	No. at risk	72	55	37	15	6
	%		97	89	85	85
	SE		2.2	4.4	5.9	5.9
T2EL (+)	No. at risk	26	24	7	5	1
	%		96	60	51	51
	SE		3.8	12	13	13

Fig. 3 Kaplan–Meier curves for freedom from the composite event of sac expansion of 10 mm and/or reintervention after EVAR in the (**A**) small group with initial AAA diameters of <55 mm in men and <50 mm in women with T2EL at discharge and (**B**) large group with initial AAA diameters of ≥55 mm in men and ≥50 mm in women with T2EL at discharge. EVAR: endovascular aneurysm repair; AAA: abdominal aortic aneurysm; T2EL: type II endoleak; SE: standard error

and 81.4% at 5 years with T2EL, showing a significant difference (P = 0.03). However, 7 years 3 months after the initial EVAR, the rates converged to 81.7% without T2EL and 81.4% with T2EL, regardless of T2EL at discharge. In contrast, in group L, the freedom from composite event rate was 84.6% at 5 years without T2EL and 51% at 5 years with T2EL, showing a significant difference (P <0.01), which remained significant even after 5 years.

Five out of 13 patients with composite events (38.5%) in group S and 10 out of 19 (52.6%) in group L had T2EL at discharge, with no significant difference. T2EL from the IMA was not observed in group S but in six cases (31.6%) in group L, showing a significant difference (P = 0.02).

Discussion

In the present study, the rate of aneurysm sac shrinkage of 10 mm and freedom from the composite event (sac expansion of 10 mm and/or reintervention) rate were significantly higher in group S than those in group L. Group S had more cases of coronary artery disease than group L; therefore, significantly more patients received antiplatelet therapy. Many patients were regularly examined by cardiologists and cardiovascular surgeons; accordingly, early EVAR may have been recommended for AAA. In addition, although no significant difference was observed in the patency of the IMA, the patent IMA was significantly larger in group S than that in group L; however, we did not find any specific reason for this difference. In contrast, group L included many cases of not complying with the IFU due to angulated neck. A multivariate analysis identified T2EL at discharge and initial AAA diameters of <55 mm in men and <50 mm in women as predictors for the composite event. Although various studies have reported factors for aneurysmal sac expansion/shrinkage,[12–15] a systematic review found no consistent evidence of anatomical predictors of aneurysm remodeling.[13] In the present study, no significant difference was observed in T2EL at discharge between the two groups; however, group S included more cases of antiplatelet therapy, which is considered to affect aneurysmal sac expansion. Nevertheless, shrinkage of 10 mm and freedom from composite event rates were high in group S.

An analysis of the Japanese registry revealed that persistent T2EL is a significant predictor of future aneurysmal sac expansion.[16] In the present study, T2EL at discharge was a factor for the composite event. In contrast, in some cases, the aneurysmal sac shrank even with T2EL after EVAR. In the subgroup analysis, the comparison of the freedom from composite event rate for T2EL at discharge was significantly different in group S; however, the rates converged approximately 7 years after EVAR in both with and without T2EL, regardless of T2EL at discharge. However, in group L, the freedom from composite event rate decreased to 51% at 5 years with T2EL at discharge.

Moreover, although no significant difference in T2EL at discharge was found with composite events between the two groups, the involvement of the IMA was significantly higher in group L. Transarterial embolization was not effective for T2EL after EVAR with an aneurysm diameter ≥55 mm.[17] Recently, successful preemptive IMA and lumbar artery embolization have been performed during EVAR.[18,19] Therefore, preemptive IMA embolization to prevent T2EL at discharge may prove beneficial in treating patients with large aneurysms such as group L. However, in general, preemptive IMA and lumbar artery embolization are time consuming and entails higher radiation exposure, contrast agent use, and costs. In group S, there was no significant difference in expansion or reintervention in the long term, regardless of T2EL at discharge. Routine preemptive IMA embolization may not be necessary for simple small aneurysm as observed in group S. Since oral tranexamic acid suppresses the fibrinolytic system, it may be effective in preventing T2EL.[20] Patients in group S who present with T2EL at discharge may be treated effectively using tranexamic acid.

Four randomized control trials (two OSR[21,22] and two EVAR[23,24]) have been reported in which the treatment strategies for AAAs with an aneurysm diameter <55 mm were selected. Since there was no significant difference in the long-term survival rate between the follow-up and early surgery groups, long-term follow-up is preferred in terms of healthcare costs. However, in the CAESAR trial, in which 96% of patients were male, 90% of patients with a baseline AAA diameter >50 mm in the surveillance group required surgery at 36 months. In the PIVOTAL trial, 31% of patients in the surveillance group underwent surgery. The average time from randomization to repair was 370 days, and the average size of AAA at the last imaging report before repair was 49 mm. According to the Vascular Quality Initiative data, 26% of patients underwent EVAR for aneurysms with diameters <50 mm, and this rate is increasing. In addition, the group with a large aneurysm diameter included many cases outside IFU.[8)] Similarly, in the present study, there were many cases with outside IFU in group L; however, outside IFU was not a factor for composite events. The Japanese guidelines recommend EVAR for patients with small AAAs (45–55 mm) who have risk factors for rupture, including saccular aneurysms, female sex, rapid aneurysm growth, and the presence of symptoms.[11)] Based on the postoperative outcomes in the present study, surgery may be indicated for AAAs of 50 mm diameter, particularly in the case of EVAR. In Japan, the outcomes of elective surgery are good, and there are many facilities that indicate intervention for AAAs with diameter ≥50 mm. At our hospital, surgery is also indicated for AAAs with diameter ≥50 mm.

There are several limitations in this study. This was a single-center retrospective study, and the sample size was small because it was restricted to patients with infrarenal fusiform AAAs followed up for >1 year after EVAR. Thus, a subgroup analysis for T2EL was not statistically meaningful. There was patient selection bias, resulting in more patients in group S. Furthermore, in group S, some patients developed rupture or late open conversion during the follow-up period even though there was no T2EL at discharge, and we could not identify the responsible factors. Group S had a significantly longer follow-up period than group L, which may have affected the outcomes.

Conclusions

Group S had a high rate of aneurysmal sac shrinkage of 10 mm and freedom from the composite event (sac expansion of 10 mm and/or reintervention) rate. Factors associated with the composite event in the multivariate analysis were initial AAA diameters <55 mm in men and <50 mm in women and T2EL at discharge. A subgroup analysis of freedom from composite event rate in group S converged approximately 7 years after EVAR in both with and without T2EL, regardless of T2EL at discharge. However, in group L, the freedom from composite event rate decreased to 51% at 5 years with T2EL. Thus, our study showed that nonadherence to the SVS/ESVS guidelines recommended for initial AAA diameter thresholds improves the long-term outcomes of Japanese patients after simple EVAR. It is more important to prevent T2EL at discharge, especially for large aneurysms, as observed in group L.

Author Contribution

Conception and design: YO and TA
Analysis and interpretation: YO, HI, TA, and AK
Data collection: YO, HI, TA, YI, YM, and HM
Writing the article: YO
Critical revision of the article: YO, HI, TA, YI, YM, HM, and AK
Final approval of the article: YO, HI, TA, YI, YM, HM, and AK
Statistical analysis: YO and TA
Obtained funding: Not applicable
Overall responsibility: YO

Declarations

Data availability statement

Not applicable.

Acknowledgments

The authors would like to thank *Editage* (www.editage.com) for English language editing.

Funding

This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

Disclosure Statement

All authors declare no conflicts of interest relevant to the present study.

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