



Fate of Pure Type II Endoleaks Following Endovascular Aneurysm Repair

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Purpose: Type II endoleaks (T2ELs) are the most common type of endoleaks observed after endovascular aneurysm repair (EVAR). However, whether T2ELs should be treated remains debatable. In the present study, we aimed to describe the natural course of T2ELs and suggest the direction of their management.

Materials and Methods: We reviewed the data of 383 patients who underwent EVAR between 2007 and 2016. Data, including demographic and anatomical details, were collected, and patients with T2ELs were compared to those without them. Patients with T2ELs were categorized into subgroups according to changes in sac size and treatment requirement.

Results: We found patent lumbar artery count and lesser thickness of mural thrombi to be significant risk factors for T2ELs. Among the 383 patients, 85 (22.2%) patients were diagnosed with pure T2ELs. Among these 85 patients, the sac size increased in 29 (34.1%) patients, showed no significant change in 39 (45.9%) patients, and decreased in 17 (20.0%) patients. Fifteen (17.6%) patients, among 85 with initial pure T2ELs, showed spontaneous resolution. Five (5.9%) patients among 29, in whom the sac size increased, developed combined-type endoleaks. No sac ruptures were noted among the patients with T2ELs.

Conclusion: T2ELs with sac expansion potentially contribute to other types of endoleaks. Therefore, periodic screening is important for these patients, particularly for those showing an increasing sac size. In addition, intervention should be considered when other types of endoleaks occur.

Key Words: Aortic aneurysm, Endoleak, Inferior mesenteric artery, Endovascular procedures

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INTRODUCTION

The beneficial perioperative outcomes of endovascular aneurysm repair (EVAR) for abdominal aortic aneurysm (AAA) have resulted in a rapid increase in the use of EVAR since its introduction in 1991 [1-5]. However, a troublesome complication of this technique is the incidence of endoleaks, which has been reported to be as high as 50% [6,7]. Type II endoleaks (T2ELs) are the most common type of

endoleaks observed following EVAR.

However, whether T2ELs should be treated remains debatable. The risk of sac expansion among patients with T2ELs is unclear. The current guidelines of European Society of Vascular Surgery recommend a conservative approach for managing T2ELs. If sac diameter increases by more than 10 mm, re-intervention is recommended; and if endovascular treatment fails, open surgery is recommended [8].

The current study aimed to describe the natural course of T2ELs and to suggest the direction of T2EL management based on our hospital data. Additionally, we investigated the risk factors for T2ELs and sac expansion in patients with T2ELs.

MATERIALS AND METHODS

This study was approved by the Institutional Review Board of Asan Medical Center (2019-0878). The requirement for informed consent was waived due to the retrospective nature of this study. We retrospectively reviewed the data of 383 patients who had undergone EVAR between 2007 and 2016. This study included patients with bifurcated stent grafts inserted for degenerative AAAs. We excluded patients treated for infectious aneurysms, those with straight stent grafts, and those who were lost to follow-up after operation.

EVAR and additional procedures were performed by one expert vascular surgeon and three expert interventional radiologists. Six brands of devices were used for EVAR (Medtronic AneuRex, Santa Rosa, CA, USA), Medtronic Endurant (Santa Rosa, CA, USA), Gore Excluder (Flagstaff, AZ, USA), S&G Seal (Seongnam, Korea), Medtronic Talent (Santa Rosa, CA, USA), and Cook Zenith (Bloomington, IN, USA). The choice of device depended on the operator's preference and anatomical characteristics of each AAA. All procedures were performed in accordance with the instructions for use (IFU) for each device.

Computed tomography (CT) was used for follow-up imaging. The scans were taken at 3 days, 3 months, and 6 months postoperatively, and then annually. T2EL was diagnosed by CT scan or angiography.

In cases where T2EL was detected, the follow-up interval was adjusted for evaluating sac size changes. In cases where

sac expansion was over 5 mm, the patient was followed up at 3-month intervals.

The indications of additional procedures for T2EL were as follows: (1) patients suspected of having a T2EL combined with another type of endoleak, and (2) sac diameter increase of more than 1 cm per year, or consistent increase potentially leading to the development of other types of endoleak. Additional procedures for T2ELs included lumbar artery (LA) embolization, inferior mesenteric artery (IMA) embolization, and open LA ligation.

The patients were divided into two groups: T2EL group and control group. The T2EL group included only the patients with initial pure T2ELs, and the control group included patients without T2EL, regardless of other types of endoleaks. We defined initial pure T2ELs as the T2EL that occurred during the follow-up period, without any previous or simultaneous endoleaks of other types. Patients who had T2EL following other types of endoleaks (either developing later or discovered simultaneously) were excluded from the investigation of the natural course of T2ELs.

Statistical analyses were performed using PASW Statistics ver. 18.0 (SPSS Inc., Chicago, IL, USA). The collected and reviewed data included treatment details, sac size changes, resolution, and endoleak types (T2ELs and others). All T2ELs were categorized according to the above-mentioned variables, and a flow chart was generated to report the data in a chronological order. Chi-square test and Student's t-test were used for comparisons between the patients with and without T2ELs. Logistic regression was used for multivariate analysis. Same statistical techniques were used for analyzing risk factors for sac expansion among T2EL patients.

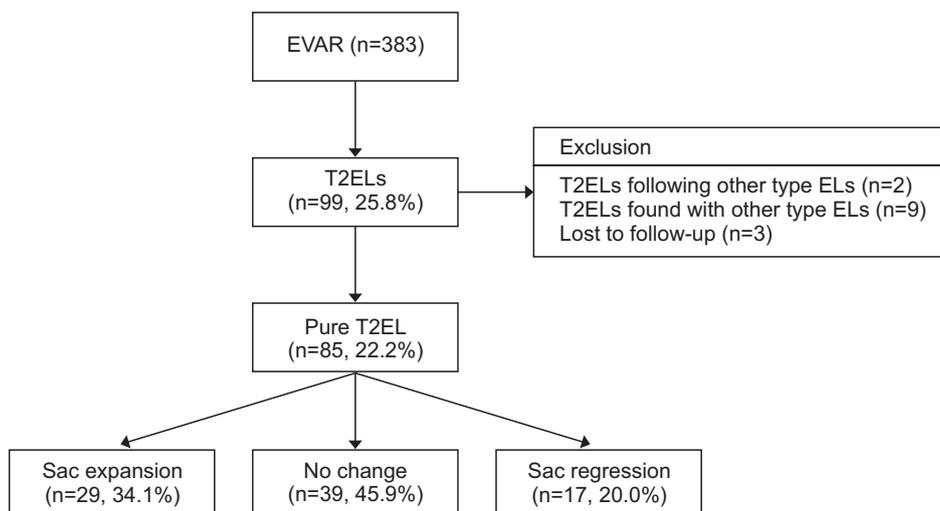


Fig. 1. Study flow chart. EVAR, endovascular aneurysm repair; T2EL, type II endoleak; EL, endoleak.

RESULTS

Overall, 383 patients underwent EVAR between 2007 and 2016. Among them, 317 (82.8%) had EVAR performed within, and 66 (17.2%) had EVAR performed outside the IFU guidelines. Of the outside-IFU patients, 14 (21.2%) had short neck length, 27 (40.9%) had greater neck angulation, 9 (13.6%) did not meet neck diameter criteria, and 28 (42.4%) did not meet iliac diameter criteria.

Among all patients, 99 (25.8%) had T2ELs. Median follow-up duration was 39 months (interquartile range=18-69 months) in the T2EL group, whereas, it was 19 months (interquartile range=3-51 months, $P<0.001$) in the control group. Among 99 patients, 14 were excluded: 9 of them had T2ELs simultaneously with other types of endoleaks, 2 had T2ELs that occurred following other types of endoleaks, and 3 of them were lost to follow-up. Finally, 85 patients (22.2%) were categorized as having initial pure T2ELs (Fig. 1). Among them, 63 patients (74.1%) were classified as early T2EL patients (T2EL occurred before six months from operation) and 22 patients (25.9%) were classified as late T2EL patients (T2EL occurred after six months from operation). Among 63 patients, 52 (82.5%) early T2EL patients showed persistent T2EL after six months from occurrence.

In this study, male:female ratio was significantly higher in the control group than in the T2EL group. The higher number of patent LAs and lesser thickness of mural thrombi were significant risk factors for T2ELs. Patients with T2ELs had a mean of 6.16 patent LAs, whereas, patients without T2ELs had a mean of 5.48 patent LAs ($P=0.001$). IMA patency was found to have no association with T2ELs (Tables 1, 2). We additionally analyzed the relationship of IMA-related T2EL with IMA patency. Total number of IMA-related T2EL patients was 18, and the patients with patent IMA had more chance of IMA-related T2EL incidence. However, it did not show statistical significance (5/59 vs. 13/324, $P=0.172$).

Among the 85 patients with pure T2ELs, sac expansion during the follow-up period was detected in 29 patients (34.1%). The sac diameter showed no significant changes in 39 patients (45.9%), and the sac diameter decreased in 17 patients (20.0%) (Fig. 1). Median follow-up duration was 59.5 months (interquartile range=39-92.5 months) in sac expansion group, and 27 months in the others (interquartile range=16-56 months, $P<0.001$). However, adjusted median follow-up duration before sac expansion in sac expansion group was similar with the others (22.5 months, interquartile range=12-37.75 months; $P=0.227$).

Follow-up frequency was increased in the sac expansion group. In these patients, follow-up CT scan was performed at 3-month intervals. Among them, the T2ELs continued

during follow-up period in 21 patients. However, the T2ELs resolved spontaneously or after additional treatment in 8 patients. Among the patients whose T2ELs were resolved, 5 had received treatment and 3 had their T2ELs resolved without treatment. The size of aneurysm sac decreased following the resolution of T2ELs in these patients. Among the 29 patients in sac expansion group, 5 patients developed other types of endoleaks. The T2ELs in these patients were early and persistent, which remained for more than two years, except in 1 patient who had spontaneously resolved T2EL 15 months after occurrence. In another 4 patients who had ongoing T2ELs, the aneurysm sacs expanded gradually at 3.5 ± 1.5 mm/year. Other types of endoleaks occurred 62.5 \pm 27.4 months after operation. Two patients had type Ia endoleaks, and 3 patients had type Ib endoleaks (Fig. 2). Type I endoleaks were initially suspected in CT scan, and

Table 1. Demographic and clinical characteristics of the control group and type II endoleak group

Characteristic	Control group (n=284)	Type II endoleak group (n=99)	P-value
Age (y)	72.1 \pm 6.65	71.12 \pm 7.68	0.26
Sex			
Male:female	10.8:1	5.2:1	0.04
Height (cm)	165.99 \pm 7.23	165.29 \pm 8.99	0.49
BMI (kg/m ²)	23.96 \pm 4.21	31.57 \pm 7.06	0.29
Hypertension	186 (65.5)	70 (70.7)	0.39
Diabetes	52 (18.3)	22 (22.2)	0.46
Smoker	183 (64.4)	59 (59.6)	0.399
CVA	31 (10.9)	10 (10.1)	1.0
CAD	76 (26.8)	26 (26.3)	1.0
CKD	17 (6.0)	9 (9.1)	0.35
Brand of devices			
Medtronic AneuRex (Santa Rosa, CA, USA)	2	2	
Medtronic Endurant (Santa Rosa, CA, USA)	128	39	
Gore Excluder (Flagstaff, AZ, USA)	31	23	
S&G Seal (Seongnam, Korea)	10	4	
Medtronic Talent (Santa Rosa, CA, USA)	6	2	
Cook Zenith (Bloomington, IN, USA)	107	29	

Values are presented as mean \pm standard deviation, number only, or number (%).

BMI, body mass index; CVA, cerebrovascular accident; CAD, coronary artery disease; CKD, chronic kidney disease.

Table 2. Factors assessed for association with type II endoleaks

	Control group (n=284)	Type II endoleak group (n=99)	P-value	Multivariate logistic regression	P-value
Number of patent lumbar arteries	5.48±1.92	6.16±1.65	0.001	1.199 (1.018-1.411)	0.029
Patent IMA	47 (16.5)	12 (12.1)	0.709		
Proximal neck diameter (mm)	23.91±3.23	23.54±2.81	0.28		
Distal neck diameter (mm)	26.22±3.76	25.85±3.60	0.39		
Aortic neck angle (°)	25.44±18.11	29.57±23.59	0.11		
Maximal sac diameter (mm)	57.11±10.50	57.25±10.33	0.91		
Sac length (mm)	89.59±37.76	86.86±18.87	0.27		
Right common iliac artery					
Diameter (mm)	19.60±7.29	20.73±6.92	0.17		
Length (mm)	54.28±22.10	50.61±15.41	0.07		
Tortuosity index ^a	1.20±0.43	1.14±0.27	0.12		
Left common iliac artery					
Diameter (mm)	17.96±6.82	18.86±7.37	0.29		
Length (mm)	59.93±18.41	56.95±17.75	0.16		
Tortuosity index ^a	1.34±0.39	1.31±0.34	0.61		
Presence of mural thrombus ^b	193 (68.0)	65 (65.7)	0.674		
Thrombus thickness (mm) ^c	18.43±8.13	15.07±6.82	0.001	0.939 (0.899-0.981)	0.005

Values are presented as mean±standard deviation, number (%), or odds ratio (95% confidence interval).

IMA, inferior mesenteric artery.

^aActual vascular length/straight line distance, ^bthickness of mural thrombus ≥5 mm, ^cmaximum mural thrombus thickness.

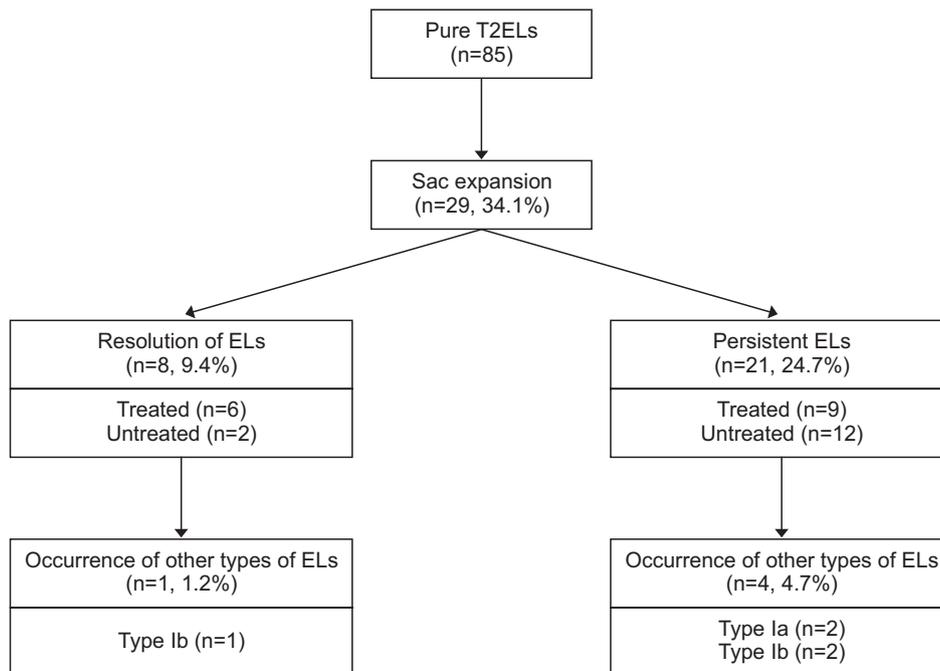


Fig. 2. Types of ELs encountered, and proportions of treated and untreated patients. T2EL, type II endoleak; EL, endoleak.

then, diagnostic angiography was performed. In the cases where type I endoleak was confirmed on angiography and was treatable, therapeutic intervention was performed simultaneously. In one case of type Ia endoleak that was not resolved by endovascular treatment, open surgical repair

including aneurysm sac exploration and neck banding was performed. Other type Ia endoleak patients were treated with aortic cuff insertion and sac embolization. Three patients with type Ib endoleak underwent limb extension with or without internal iliac artery embolization [9,10]. Among

the 3 patients, T2EL disappeared spontaneously in one patient 15 months after operation and regression of aneurysm sac was observed in follow-up CT scan. However, common iliac artery diameter enlarged gradually, regardless of sac regression, and type Ib endoleak occurred 4 years after operation.

Among the 39 patients in whom the sac size did not change, 3 patients underwent additional procedures for T2ELs because other types of endoleaks were not ruled out. They were treated with IMA and LA embolization. Among 36 untreated patients, the T2ELs were ongoing in 29 patients during the follow-up period. In 17 patients, sac size decreased despite their persistence of T2ELs. None of the 17 patients underwent additional interventions, and the en-

doleaks spontaneously disappeared in 6 patients. The other types of endoleaks did not occur in patients whose sac size was reduced or remained unchanged (Fig. 3).

Tables 3 and 4 show the demographic characteristics and anatomical features that were compared among the groups classified by sac size change. An increase in sac size was found to be more frequent among patients with underlying hypertension ($P=0.05$). Patients who showed sac expansion had a mean of 6.82 patent LAs, and patients who did not show sac expansion had a mean of 5.7 patent LAs ($P=0.003$). IMA patency was not a risk factor for sac expansion. Preoperative maximal sac diameter was suspected to be associated with increase in sac size, but it was not a statistically significant risk factor. None of the T2EL patients experi-

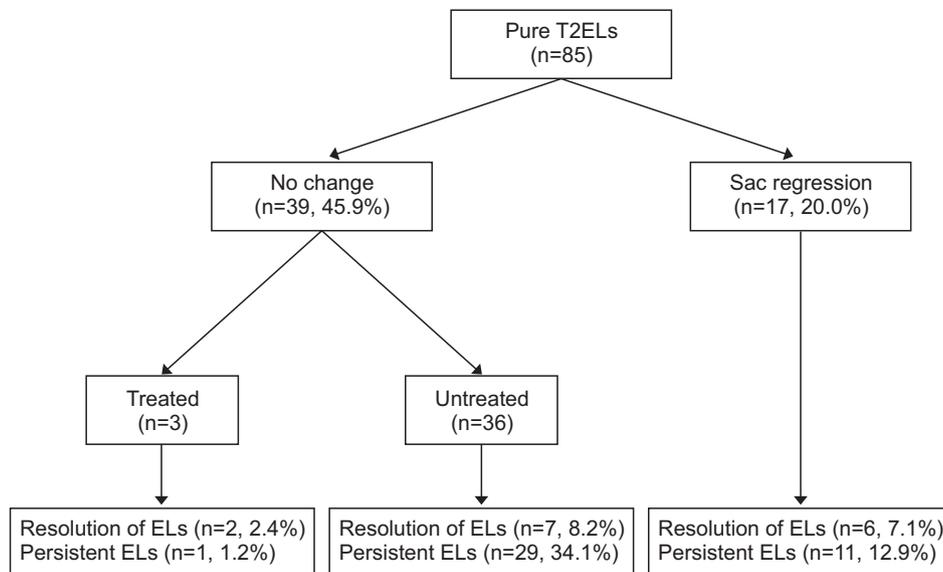


Fig. 3. Frequencies by changes in sac size, treatment status, and resolution status among patients with initial isolated type II endoleaks (T2ELs). EL, endoleak.

Table 3. Demographic and clinical characteristics according to the presence or absence of sac expansion

Characteristic	Sac expansion (n=29)	No change or sac regression (n=56)	P-value	Exp(β)	P-value
Age (y)	71.52 \pm 7.49	72.95 \pm 7.15	0.8		
Sex					
Male:female	3.14:1	8.33:1	0.121		
Height (cm)	163.33 \pm 9.2	166.94 \pm 7.95	0.08	0.949 (0.897-1.004)	0.067
BMI (kg/m ²)	24.88 \pm 3.68	23.86 \pm 3.49	0.222		
Hypertension	24	34	0.05	3.3 (1.070-10.175)	0.038
Diabetes	7	11	0.78		
Smoker	14 (48.3)	39 (69.6)	0.054	0.576 (0.195-1.697)	0.314
CVA	2	8	0.483 ^a		
CAD	9	14	0.611		
CKD	2	4	1.0 ^a		

Values are presented as mean \pm standard deviation, number only, odds ratio (95% confidence interval), or number (%). BMI, body mass index; CVA, cerebrovascular accident; CAD, coronary artery disease; CKD, chronic kidney disease.

^aFisher's exact test.

Table 4. Factors assessed for association with increasing sac size

	Sac expansion (n=29)	No change or sac regression (n=56)	P-value
Number of patent lumbar arteries	6.82±1.56	5.7±1.64	0.003
Patent IMA	4 (13.8)	5 (8.9)	0.483 ^a
Proximal neck diameter (mm)	23.59±2.24	23.59±3.04	0.993
Distal neck diameter (mm)	25.97±3.5	25.31±3.34	0.407
Aortic neck angle (°)	41.17±24.31	41.74±24.1	0.918
Maximal sac diameter (mm)	57.95±10.9	55.42±8.99	0.288

Values are presented as mean±standard deviation or number (%). IMA, inferior mesenteric artery.

^aFisher's exact test.

enced rupture during follow-up.

Among 85 patients with initial pure T2EL, 15 patients (17.6%) showed spontaneous resolution. The sac size remained unchanged in 9 patients and regressed in 6 patients. We additionally identified the factors associated with spontaneous resolution of T2EL. Number of LAs was higher in the ongoing endoleak group; however, it did not reach statistical significance. Non-smokers and patients with coronary artery disease (CAD) seemed to have more chance of ongoing endoleak; however, it also failed to achieve statistical significance (Table 5).

DISCUSSION

According to previous studies, there are several risk factors for the development of T2ELs, including the number of patent LAs, the diameter of the LAs, patency of the IMA, and maximum thrombus thickness [11]. In our study, male:female ratio was significantly higher in the control group than in the T2EL group, and the significant risk factor for T2EL development was an increased number of patent LAs. T2EL patients had more patent LAs than patients in the control group. As mentioned by Marchiori et al. [12], the greater the number of patent LAs, the greater the risk of increased sac size. Velazquez et al. [13] reported that patients with T2ELs arising from the IMA had more chance of having patent IMA before EVAR. In this study, occurrence of T2EL was not related to IMA patency. However, although statistically non-significant, IMA-related T2EL was detected more frequently in patients with patent IMA. It was probably affected by confounding factors such as systemic hypertension or IMA diameter [14].

Table 5. Factors associated with spontaneous resolution of type II endoleak

	Ongoing endoleak (n=70)	Spontaneous resolution (n=15)	P-value
Number of patent lumbar arteries	6.16±1.58	5.73±2.15	0.48
Presence of mural thrombus ^b	46 (65.7)	11 (73.3)	0.764 ^a
Thrombus thickness (mm) ^c	25.97±3.5	25.31±3.34	0.407
Maximal sac diameter (mm)	56.09±9.43	57.21±11.15	0.721
Height (cm)	165.71±8.8	165.65±7.35	0.981
BMI (kg/m ²)	24.2±3.48	24.24±4.09	0.972
Hypertension	49 (70)	9 (60.0)	0.544
Diabetes	17 (24.3)	1 (6.7)	0.175 ^a
Smoker	41 (58.6)	12 (80.0)	0.15 ^a
CVA	7 (10.0)	3 (20.0)	0.371 ^a
CAD	22 (31.4)	1 (6.7)	0.059 ^a
CKD	4 (5.7)	2 (13.3)	0.285 ^a

Values are presented as mean±standard deviation or number (%). BMI, body mass index; CVA, cerebrovascular accident; CAD, coronary artery disease; CKD, chronic kidney disease.

^aFisher's exact test, ^bthickness of mural thrombus ≥5 mm, ^cmaximum mural thrombus thickness.

Sac expansion was more frequently identified in patients with underlying hypertension (P=0.04). The relationship between increased sac size and hypertension has been reported by Hiramoto et al. [15] In their study, multivariate regression analysis demonstrated increased systolic blood pressure to be an independent predictor of aneurysm enlargement (P=0.05). Patients with systolic hypertension and untreated T2ELs are more likely to demonstrate aneurysm enlargement after EVAR. Aggressive blood pressure control may be an important adjunct in the management of patients with T2ELs after EVAR [15].

Gelfand et al. [16] found that the incidence of T2ELs ranged from 6% to 17% upon discharge or 30 days post-EVAR but decreased to between 1% and 8% at six months after surgery. There were no aneurysmal ruptures related to T2ELs in their study. They also reported that up to 58% of the T2ELs are expected to disappear spontaneously. However, in our study, the incidence was 24%, which was slightly higher than the previous study, and the spontaneous disappearance rate was low at 17.6% (n=15). The discrepancies may be attributed to the difference that the previous study reported only T2ELs observed immediately after operation. It may also be due to the improvement in detection tools [17] or the differences among races.

In our study, 5 patients (5.9%) with T2ELs associ-

ated with sac expansion further developed other types of endoleaks. Several previous studies have reported this phenomenon. Aziz et al. [18] and Madigan et al. [19] have described that T2ELs in combination with sac growth may be the result of an unexpected underlying type I or type III endoleak. The authors have suggested that in such context, T2ELs might be seen as sentinel endoleaks, which warrant a thorough assessment of graft integrity and the proximal and distal seal [20]. Although no statistical analysis was conducted, the cases with combined other types endoleak in our study showed that the neck diameter was wider among patients with combined type Ia endoleaks, and the common iliac artery diameter tended to be larger among patients with combined type Ib endoleaks. Statistical analysis should be conducted in future studies when enough patients with combined other types endoleaks are encountered.

Fifteen patients (17.6%) in our study showed spontaneous resolution of T2EL. We tried to identify factors associated with this phenomenon. There are some previous studies, which have shown the association between number of patent LAs, CAD, smoking habit, and T2EL. In our study, although it was not statistically significant, non-smokers, patients with CAD, and with many patent LAs appeared to have higher risk for ongoing T2EL. It has been suggested that antiplatelet agents probably affect the T2EL in CAD patients [21,22]. However, more patients with spontaneously resolved T2ELs would be needed to prove this relationship.

This study has several limitations. First, data were obtained retrospectively from a single-center registry. Second, several different brands of stent grafts were used for EVAR. Device selection depended on the circumstances surrounding the individual cases at that time. However, the

operations were carried out with a similar technique by one expert surgeon and three interventional radiologists. Third, the analysis for investigating the risk factors for developing other types of endoleaks was not performed due to the small number of patients with other types of endoleaks subsequent to T2ELs. Further research will be needed in the future.

CONCLUSION

Controversy exists regarding the necessity to treat T2ELs. In this study, T2ELs associated with sac expansion were shown to potentially contribute to the development of other types of endoleaks, which could lead to aneurysmal rupture. Therefore, regular follow-up and surveillance are highly important for the management of T2EL patients with sac expansion.

CONFLICTS OF INTEREST

The authors have nothing to disclose.

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