Reviews in Cardiovascular Medicine

Rev. Cardiovasc. Med. **2022**; 23(3): 099
https://doi.org/10.31083/j.rcm2303099

Original Research

Natural History and Influence on Long-term Outcomes of Isolated Type II Endoleak after Endovascular Aneurysm Repair: A 10-year Experience at a Single Center

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Academic Editors: Carmela Rita Balistreri, Takatoshi Kasai and Brian Tomlinson
Submitted: 14 January 2022 Revised: 16 February 2022 Accepted: 3 March 2022 Published: 12 March 2022

Abstract

Background: The management of type II endoleaks (T2ELs) remains controversial in current literature. Hence, this study aimed to explore the natural history of isolated type II endoleak after endovascular aneurysm repair (EVAR) and its influence on long-term outcomes based on a 10-year follow-up at a tertiary medical center. **Methods**: From January 2011 to April 2021, consecutive patients who underwent elective EVAR were reviewed. The demographics, clinical characteristics, treatment details, imaging information, in the event of T2ELs, and outcomes were extracted. **Results**: A total of 287 patients were included for analysis. Isolated T2EL was identified in 79 patients (27.5%), while no endoleak was found in 208 patients (72.5%). The mean age at EVAR was 68.1 $\pm$ 8.9 years (range, 41–92 years) and the majority of patients were male (81.5%). The mean follow-up duration was 42.7 months (range, 2–119.7 months). Among the 79 patients with isolated T2ELs, 33 (41.8%, 33/79) were early and 46 (58.2%, 46/79) were late. Spontaneous resolution of T2ELs was identified in 29 patients (36.7%, 29/79). Persistent T2ELs were observed in 50 patients (63.3%, 50/79). No sac growth was seen in 33 patients (66%, 33/50) and these patients were managed conservatively. The remaining 17 patients (34%, 17/50) showed significant sac growth. Six of them declined intervention due to various reasons and the remaining 11 patients underwent interventional embolization for T2ELs. Following the embolization, 2 patients had complete resolution of T2ELs and 9 patients had persistent T2ELs. Among the patients with persistent T2ELs, 2 patients (2/9) still showed progressive sac growth, and one of them died from aneurysm rupture; the remaining 7 patients (7/9) showed no sac growth. Patients with isolated T2ELs had a higher incidence of sac growth than patients without any endoleak (21.5% vs 4.3%, $p < 0.001$), while no difference was found in overall survival between the two groups. In Cox regression analysis, only higher age was independently associated with worse survival. **Conclusions**: Type II Endoleak was significantly associated with aneurysm sac growth and no association with survival was observed.

Keywords: aorta; aneurysm; endovascular procedure; EVAR; endoleak

1. Introduction

Endovascular aneurysm repair (EVAR) has become the standard procedure used to treat abdominal aortic aneurysm in patients with suitable anatomy, which is mainly attributed to its lower perioperative mortality, morbidity, and shorter length of hospital stay than conventional open surgery [1–3]. However, postoperative endoleaks, the persistence of blood flow within the aneurysm sac, are the main causes of sac growth and reintervention compromising the long-term durability of EVAR [4,5].

There is no debate that type I and type III endoleaks, which involve the stent landing zones or junction points between the stents, should be treated promptly. However, the management of type II endoleaks (T2ELs), which account for approximately half of all endoleaks and are caused by retrograde flow from the aortic side branches, remains controversial [6–8]. Some reports have shown that the T2ELs are a benign entity [9], while others have associated T2ELs with adverse outcomes such as aneurysm sac growth and aneurysm rupture [10,11]. Current guidelines such as the 2019 European Society for Vascular Surgery (ESVS) guideline and Society for Vascular Surgery implementation of clinical practice guidelines have recommended conservative management and intervention was indicated for significant sac expansion ($\geq$10 mm or 5 mm) [7,12], whereas some have advocated an immediate treatment [13,14].

To explore the optimal management strategy for T2ELs, understanding the natural course of T2EL and its influence on long-term outcomes is necessary. Thus, this study aimed to report the natural history of T2EL based on a 10-year study at a single medical center and analyze the long-term effect of T2EL.

2. Materials and Methods

2.1 Study Design and Study Population

This was a single-center retrospectively observational study following the STROBE guidelines [15]. The study was approved by the institutional ethics review board and written informed consent was waived due to the retrospective nature.

From January 2011 to April 2021, consecutive patients who underwent elective EVAR were reviewed and recorded in a database. The criterion for inclusion included patients undergoing elective EVAR for infrarenal degenerative atherosclerotic aortic or aortoiliac aneurysm, preoperative computed tomographic angiography (CTA) within 3 months before EVAR, and at least one postoperative CTA imaging during the follow-up. The criterion for exclusion included EVAR for a ruptured aneurysm, dissection, and penetrating aortic ulcer; Patients with incomplete preoperative or postoperative clinical data or CTA imaging; Patients with a type 1, 3, or 4 endoleak. If patients had T2ELs during the follow-up period, but another endoleak (type 1, 3, or 4) before rupture, these patients were also excluded.

2.2 Data Collection

Data were collected from the electronic medical records and radiology information system/picture archiving communication system (RIS/PACS). The collected data included the demographics, anatomical characteristics, operative details, complications, in the event of T2ELs, and outcomes. All medical data were reviewed by two independent reviewers (YLW, FY). Data were stored and analyzed anonymously.

2.3 Study Endpoints

The primary endpoint was survival for patients with or without T2EL. The secondary endpoints were aneurysm sac growth, T2EL-related reintervention, and aneurysm rupture.

2.4 Definitions

An isolated T2EL was defined as a persistent retrograde flow from the aortic side branches into the aneurysm sac, without signs of other types of endoleak during the follow-up period. T2EL was classified as early if the endoleak was detected $\leq$30 days of the primary EVAR, and late if it was detected $>$30 days of the primary EVAR. Sac growth was defined as $\geq$5 mm increase in aneurysm diameter when compared with the preoperative diameter. All-cause mortality was defined as all deaths that occurred during the follow-up period.

2.5 Follow-up

All patients undergoing EVAR were prescribed to have a follow-up protocol including assessment of the clinical symptoms and images at 1, 3, 6, and 12 months and then annually thereafter. Patients who demonstrated aneurysm sac growth or endoleaks underwent a more frequent follow-up at 3-month or 6-month intervals. Follow-up data was collected up till October 2021 when follow-up was stopped. The main imaging modality was computed tomography angiography (CTA) and magnetic resonance angiography was performed in patients with contraindication for iodinated contrast media use.

Patients with T2ELs were routinely managed conservatively and intervention was indicated for significant aneurysm sac growth $\geq$10 mm. And the decision of intervention also depended on the patients' consent and anatomical fitness.

2.6 Statistical Analysis

The categorical variables were expressed as numbers with percentages and the continuous variables, as mean with standard deviation (SD). Continuous variables were compared using Student's *t*-test or Wilcoxon rank-sum test, and categorical variables were compared using Fisher exact test. The freedom from all-cause mortality was analyzed using the Kaplan-Meier method, and the log-rank test was used for subgroup comparisons. Cox regression analysis was used to identify the independent factors associated with overall survival. Only variables with a p-value < 0.2 on univariable analysis were included in the multivariable Cox regression model. All statistical analyses were performed using SPSS software (version 19.0, IBM Corp, Armonk, NY, USA). A p-value of $<$0.05 according to a two-sided test was considered to be statistically significant for the test.

3. Results

3.1 Patient Demographics

During a period of 10 years (from January 2011 to April 2021), 449 patients underwent EVAR at our institution. After applying the exclusion criteria, a total of 287 patients were included for analysis. An isolated T2EL was identified in 79 patients (27.5%, 79/287), while no endoleak was found in 208 patients (72.5%, 208/287). Among T2ELs, 53.2% (42/79) originated from the lumbar artery, 26.6% (21/79) originated from the inferior mesenteric artery, 5.1% (4/79) originated from the midsacral artery, 13.9% (11/79) originated from the lumbar and inferior mesenteric artery, and 1.3% (1/79) originated from the lumbar artery and midsacral artery. 24.1% (19/79) of T2ELs showed a flow between $\geq$2 branches. The mean age at EVAR was 68.1 $\pm$ 8.9 years (range, 41–92 years) and the majority of patients were men (81.5%). The mean follow-up duration was 42.7 months (range, 2–119.7 months). The baseline demographics and clinical information stratified by T2EL status are listed in Table 1.

3.2 Type 2 Endoleak Characteristics

Among the 79 patients with isolated T2ELs, 33 (41.8%, 33/79) were early and 46 (58.2%, 46/79) were

Table 1. Baseline characteristics of patients with isolated type II endoleak or no endoleak.

	Isolated type II endoleak (n = 79)	No endoleak (n = 208)	*p*-value
Age, years	67.9 ± 10.1	68.3 ± 8.4	0.765
Gender			0.133
Male	60 (75.9)	174 (83.7)	
Female	19 (24.1)	34 (16.3)	
Hypertension	60 (75.9)	171 (82.2)	0.232
Diabetes	13 (16.5)	38 (18.3)	0.720
Smoking	24 (30.4)	76 (36.5)	0.328
Hyperlipidemia	36 (45.6)	99 (47.6)	0.759
Ischaemic heart disease	27 (34.2)	65 (31.3)	0.635
Pulmonary disease	12 (15.2)	37 (17.8)	0.601
Preoperative aneurysm characteristics			
Proximal neck diameter, mm	20.0 ± 2.0	20.0 ± 2.2	0.919
Proximal neck length, mm	40.0 ± 16.3	40.9 ± 17.5	0.700
Proximal neck angle, degrees	43.3 ± 23.9	39.5 ± 22.4	0.219
Abdominal aortic aneurysm diameter, mm	60.8 ± 9.5	60.2 ± 8.7	0.620
Maximum iliac diameter, mm	15.0 ± 1.6	15.3 ± 1.8	0.338
Stent types			0.705
Medtronic	58 (73.4)	163 (78.4)	
Microport	17 (21.5)	33 (15.9)	
Cordis	2 (2.5)	5 (2.4)	
Lifetech	2 (2.5)	7 (3.4)	
Oversizing, %	23.1 ± 4.4	22.6 ± 4.4	0.400

Continuous data are presented as mean ± standard deviation and categorical data as n (%).

late T2ELs. Spontaneous resolution of T2ELs was identified in 29 patients (36.7%, 29/79). Persistent T2ELs were observed in 50 patients (50/79, 63.3%). No sac growth was seen in 33 patients (66%, 33/50) and these patients were managed conservatively. The remaining 17 patients (34%, 17/50) showed significant aneurysm sac growth, which made the operators consider the secondary intervention. However, 6 of them declined intervention due to various reasons and thus were managed conservatively. The remaining 11 patients underwent interventional embolization for T2ELs. Of which, 8 patients underwent transarterial embolization of the corresponding lumbar artery and 3 patients underwent transarterial embolization of the corresponding inferior mesenteric artery. There was a technical failure in 3 interventions (lumbar artery embolization) which with the small and/or tortuous feeding vessels left because it was unable to cannulate into these vessels. Following the intervention, 2 patients had complete resolution of T2ELs and 9 patients had persistent T2ELs. Among the patients with persistent T2ELs, 2 patients (2/9) still showed progressive aneurysm sac growth, and one of them died from aneurysm rupture (technical failure as stated above); the remaining 7 patients (7/9) showed no aneurysm sac growth (Fig. 1).

3.3 Isolated Type II Endoleak vs no Endoleak

There were no differences in baseline characteristics between patients with isolated T2ELs and those without any endoleaks (Table 1). During the follow-up period, patients with isolated T2ELs had a higher incidence of aneurysm sac growth than patients without endoleaks (21.5% vs 4.3%, $p < 0.001$). There were 5 and 21 patients who died in the T2EL group and no endoleak group, respectively. One patient died of aneurysm rupture in the T2ELs group, and the remaining patients died of various causes including malignant tumor, myocardial infarction, cerebral infarction, pulmonary disease, and unknown causes. The survival showed no significant differences between the two groups (Table 2 and Fig. 2). And this result was also confirmed by cox regression analysis which showed only age was independently associated with survival (Table 3).

3.4 Early vs Late Isolated Type II Endoleak

There were no differences except for stent types in baseline characteristics between patients with early isolated T2ELs and patients with late isolated T2ELs (Table 4). During the follow-up period, 1 patient died of aneurysm rupture in the early T2ELs group and 4 patients died from non-aneurysm-related causes. Spontaneous resolution rate, aneurysm sac growth rate, and all-cause mortality showed no differences between patients in the early T2ELs group and late T2ELs group (Table 5).

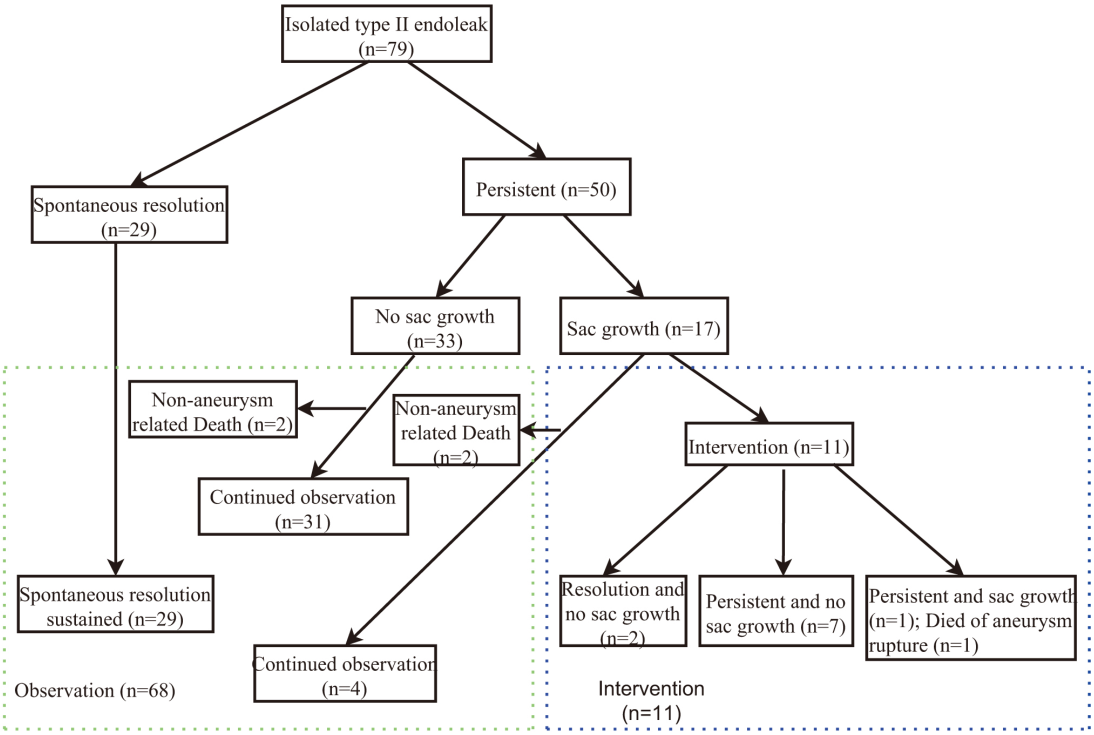

Fig. 1. Management and outcome of patients with type II endoleaks (T2ELs). Isolated T2ELs were identified in 79 patients. Spontaneous resolution of T2ELs was identified in 29 patients (36.7%, 29/79). Persistent T2ELs were observed in 50 patients (63.3%, 50/79). No sac growth was seen in 33 patients (66%, 33/50) and these patients were managed conservatively. The remaining 17 patients (34%, 17/50) showed significant sac growth. Six of them declined intervention due to various reasons and the remaining 11 patients underwent interventional embolization for T2ELs. Following the embolization, 2 patients had complete resolution of T2ELs and 9 patients had persistent T2ELs. Among the patients with persistent T2ELs, 2 patients (2/9) still showed progressive sac growth, and one of them died from aneurysm rupture; the remaining 7 patients (7/9) showed no sac growth.

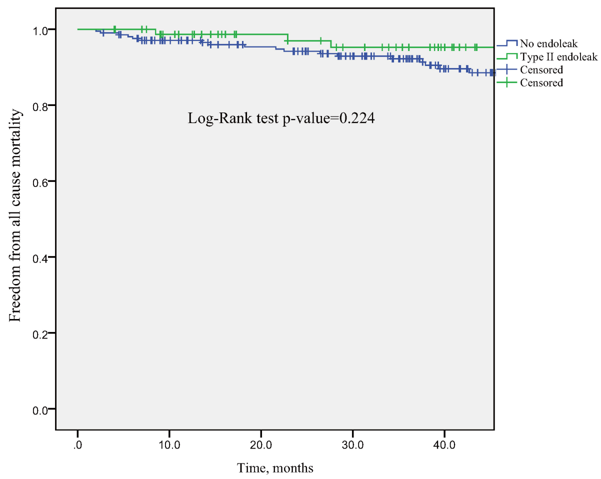

Fig. 2. Kaplan-Meier analysis, freedom from all-cause mortality comparing patients with isolated type II endoleaks vs no endoleaks. No significant difference in overall survival was found between patients with or without isolated type II endoleaks.

4. Discussion

Given the conflicting reports regarding whether T2ELs are a benign entity or related to adverse outcomes, debates remain regarding the optimal management strategy for T2ELs. The present study was conducted to report the natural history of T2EL and its influence on long-term outcomes based on a 10-year study at a tertiary medical center. The presented study found that the incidence of an isolated T2EL was 27.5% (79/287), and 36.7% (29/79) of T2ELs showed spontaneous resolution; patients with an isolated T2EL showed a higher aneurysm sac growth rate than patients without endoleak; no significant difference in overall survival was found between patients with or without an isolated T2EL; no significant differences in overall survival and sac growth were identified in patients with an early T2EL and patients with a late T2EL.

The incidence of isolated T2EL in the present study was in line with the incidence in previously published articles (8%–44%) [16,17]. 36.7% (29/79) of T2ELs showed spontaneous resolution in the present study, which was also consistent with the published reports (30% to 50%) [12]. There was only one (1.3%, 1/79) aortic rupture that oc-

Table 2. Follow-up results of patients with isolated type II endoleak or no endoleak.

	Isolated type II endoleak (n = 79)	No endoleak (n = 208)	*p*-value
Follow-up time, months	47.9 ± 32.1	40.8 ± 24.0	0.077
Sac growth	17 (21.5)	9 (4.3)	<0.001
All cause death	5 (6.3)	21 (10.1)	0.321

Continuous data are presented as mean ± standard deviation and categorical data as n (%).

Table 3. Univariable and multivariable analysis of patients with or without type II endoleaks.

	Univariable analysis Hazard ratio (95% CI)	Multivariable analysis Hazard ratio (95% CI)
Age, years*	1.085 (1.036–1.135)	1.081 (1.033–1.132)
Gender	1.490 (0.625–3.555)	1.248 (0.516–3.017)
Proximal neck diameter	1.018 (0.854–1.212)	
Proximal neck length	0.995 (0.972–1.018)	
Proximal neck angle	1.004 (0.988–1.021)	
Abdominal aortic aneurysm diameter	1.006 (0.971–1.043)	
Maximum iliac diameter	1.008 (0.810–1.254)	
Stent types		
Medtronic	0.244 (0.071–0.840)	0.294 (0.085–1.021)
Microport	0.407 (0.101–1.634)	
Cordis	0.000	
Lifetech	Reference	
Sac growth	0.712 (0.244–2.074)	
Oversizing, %	1.007 (0.920–1.103)	

* Variables significantly related to survival in univariable and multivariable analysis; CI, confidence interval.

curred in patients with T2ELs, which was similar to the rupture rate in current literature (close to 1%) [6]. Patients in the isolated T2ELs group showed a higher incidence of aneurysm sac growth than patients in the no endoleak group (21.5% vs 4.3%, $p < 0.001$). However, the all-cause mortality between the two groups had no significant differences, and other studies have also shown similar results [18,19]. In Cox regression analysis, higher age was independently associated with worse survival, which was consistent with the results in another study [18]. All the data mentioned above confirmed that the majority of isolated T2ELs are clinically not of concern. A "watch and wait" strategy for the management of T2ELs is feasible. Based on the results in the present study, just as recommended by the 2019 ESVS [7] and 2018 SVS guidelines [8], a less firm surveillance protocol for patients undergoing EVAR might be safe. And more future studies are needed to confirm the reasonability of the recommended follow-up protocol. Moreover, the present study included a relatively large sample size in the Asian population, thus the experience could be better applied to manage T2ELs in the corresponding population. Our study showed similar results with western studies which have been mentioned above. Thus, the incidence and management strategy of T2ELs might be comparable in the two different populations (Asian and Western).

Among current reports, the treatment modalities for persistent T2ELs management included transarterial embolization, transcaval or translumbar embolization, laparoscopic ligation, sacotomy, or graft explant [20]. However, the treatment of T2ELs is technically challenging and time-consuming, with unsatisfactory clinical success. The recurrence of T2ELs after intervention can be as high as 60% [14,20]. In the present study, a total of 11 patients with T2ELs received the intervention, but only 2 patients (2/11, 18.2%) showed complete resolution of the endoleak during the follow-up. In Loy's study, there were 14 patients with T2ELs underwent secondary interventions and only 5 patients (5/14, 35.7%) had complete and sustained resolution of T2EL [21]. Moreover, Sana Mulay *et al.* [18] recently reported that neither survival nor aneurysm-related outcomes will be improved for patients treated for T2ELs. Based on the above-mentioned results, a more conservative protocol for selecting high-risk T2ELs patients for intervention is rational.

Some studies have reported prophylactic embolization of aortic side branches or aneurysm sac before or during EVAR to reduce the incidence of T2ELs, and results identified this method might be associated with a lower rate of sac growth and incidence of T2ELs [13,14,22]. However, most of them are single-center retrospective studies with a small sample size. The exact clinical effect other than the reduction of endoleaks is still needed to be explored. The benefit of selective prophylactic embolization and the economic cost, technical fitness also should be considered.

Table 4. Baseline characteristics of patients with early or late type II endoleak.

	Early type II endoleak (n = 33)	Late type II endoleak (n = 46)	*p*-value
Age, years	69.4 ± 9.9	66.8 ± 10.2	0.268
Gender			0.301
Male	27 (81.8)	33 (71.7)	
Female	6 (18.2)	13 (28.3)	
Hypertension	25 (75.8)	35 (76.1)	0.973
Diabetes	4 (12.1)	9 (19.6)	0.379
Smoking	13 (39.4)	11 (23.9)	0.140
Hyperlipidemia	13 (39.4)	23 (50.0)	0.351
Ischaemic heart disease	9 (27.3)	18 (39.1)	0.273
Pulmonary disease	5 (15.2)	7 (15.2)	1.000
Preoperative aneurysm characteristics			
Proximal neck diameter, mm	20.4 ± 2.2	19.7 ± 1.9	0.094
Proximal neck length, mm	41.3 ± 14.1	39.1 ± 17.8	0.565
Proximal neck angle, degrees	44.0 ± 24.0	42.7 ± 24.0	0.818
Abdominal aortic aneurysm diameter, mm	60.3 ± 7.6	61.1 ± 10.8	0.703
Maximum iliac diameter, mm	14.8 ± 1.3	15.2 ± 1.7	0.347
Stent types			<0.01
Medtronic	23 (69.7)	35 (76.1)	
Microport	8 (24.2)	9 (19.6)	
Cordis	1 (3.0)	1 (2.2)	
Lifetech	1 (3.0)	1 (2.2)	
Oversizing, %	22.9 ± 4.6	23.2 ± 4.3	0.783

Continuous data are presented as mean ± standard deviation and categorical data as n (%).

Table 5. Follow-up results of patients with early or late type II endoleak.

	Early type II endoleak (n = 33)	Late type II endoleak (n = 46)	*p*-value
Follow-up time, months	49.4 ± 32.0	46.8 ± 32.6	0.722
Spontaneous resolution	13 (39.4)	16 (34.8)	0.675
Sac growth	7 (21.2)	10 (21.7)	0.955
All cause death	3 (9.1)	2 (6.3)	0.700

Continuous data are presented as mean ± standard deviation and categorical data as n (%).

Thus, prospective randomized trials with a large sample size are needed to evaluate the advantages of prophylactic embolization.

In the present study, no differences were found in spontaneous resolution rate, aneurysm sac growth rate, and all-cause mortality between patients in the early T2ELs group and late T2ELs group. While other studies reported that late T2ELs were less likely to have spontaneous resolution than early T2ELs and patients with early T2ELs were less likely to survive than patients with late T2ELs [18]. The different results might be attributed to the following reasons: First, the sample size in our study was small which may cause selection bias. Second, there is no exact definition for the endoleak stage in current literature. For example, the early T2EL was defined as an endoleak visualized on first-year follow-up in Sidloff DA's study [23]; the early T2EL was defined as an endoleak visualized on 3-month follow-up in Mulay S's study [18], and the early T2EL was defined as an endoleak visualized on 1-month follow-up by other researchers [14,17]. Third, the present study may cause information bias. It is possible that some endoleaks were incorrectly categorized or not detected because the CTA imaging mainly detects relatively large endoleaks, more sensitive imaging such as blood pool MRA may be needed to detect small T2ELs [18]. Thus, more studies are needed to explore the exact clinical significance of the stage of T2ELs.

There are some limitations in the present study. First, 36.1% of patients undergoing EVAR were excluded in the present study because most of our patients undergoing EVAR were lost to follow-up. And this could not be improved due to its retrospective nature and low patients' compliance. Thus, the results of this study should be viewed with an inherent bias due to the retrospective nature and small sample size. Second, this is a single-center study and the follow-up time was variable (range, 2–119.7 months), which may lead to selection bias. Finally, the cause of death in some cases was unknown, it was not possible to evaluate the impact of T2ELs on aneurysm-related mortality.

5. Conclusions

Type II Endoleak was significantly associated with aneurysm sac growth and no association with survival was observed.

Author Contributions

Study conceptualization and design—YLW, FY, YWB; Study supervision—BX; Data collection—WY, CZ, JCL, SGJ, CYW, CTY; Data analysis and interpretation—SJH, CTY, YC, YLW, TQL, JCL; Draft writing—YLW; Draft revising—FY, YWB, CZ, CYW, SGJ, BX; All authors contributed edits, read and approved the final manuscript version.

Ethics Approval and Consent to Participate

The study was conducted in accordance with the Declaration of Helsinki, and the protocol was approved by the Ethics Committee of Wuhan union hospital and written informed consent was waived because of the retrospective nature (Approval number: 20211101).

Acknowledgment

We would like to express my gratitude to Huimin Zhou (Wuhan Tongji Hospital) who helped us edit the language. Thanks to all the peer reviewers for their opinions and suggestions.

Funding

This research received no external funding.

Conflict of Interest

The authors declare no conflict of interest.

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