International multicenter experience on early and late outcomes after endovascular repair of ruptured abdominal aortic aneurysms in patients with vs without type II endoleaks

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ABSTRACT

Background: Ruptured abdominal aortic aneurysms (rAAAs) remain as a great clinical challenge for vascular surgeons and endovascular aortic repair (EVAR), which is currently regarded as the first-line treatment for rAAA in patients with appropriate anatomy. While recommendations for management of type II endoleaks (T2ELs) are well-established in the elective setting, data after rAAAs are limited.

Methods: Between January 2018 and December 2022, all patients who were treated with EVAR for rAAA in three tertiary referral centers from different countries (Germany, Italy, and Switzerland) were screened for inclusion in the study. The patients were divided into two groups based on the presence or absence of early T2EL (at completion angiography or at first postoperative computed tomography angiography). The primary end points for this study were 30-day mortality and long-term survival.

Results: Overall, 123 patients were included in the final analysis. Of these, 73 were categorized as not having an early T2EL (group A) and 50 presented an early T2EL (group B). Except for a significantly lower proportion of males in group A as compared with group B (79.5% vs 92%; $P = .05$), no significant baseline differences were found. At 30 days, the overall mortality rate was not significantly different between study groups (22% vs 16%; $P = .16$). Using binary regression, the presence of a T2EL was not associated independently with 30-day mortality (odds ratio, 1.712; 95% confidence interval, 0.591-3.964; $P = .54$). Five-year survival estimates in the whole study cohort did not show any significant difference in patients without a T2EL as compared to those with a T2EL (53% vs 59%; log-rank $P = .31$). Using Cox proportional hazard regression, the presence of T2ELs was not independently associated with increased risk for long-term mortality (hazard ratio. 1.068; 95% confidence interval, 0.437-2.611; $P = .079$).

Conclusions: Although the occurrence of a T2EL seems to be a relatively common scenario after EVAR for rAAA, their presence does not seem to be associated with worse outcomes in the immediate perioperative period or to decrease long-term survival. Therefore, careful observation may be warranted in the early phase, with selective treatment only in cases of ongoing hemodynamic decompensation. In the long run, it seems prudent to assume that the same indication for treatment as for standard EVAR could be recommended in the presence of T2EL. (J Vasc Surg 2025;82:457-64.)

Keywords: Ruptured abdominal aortic aneurysm; Endovascular aortic repair; Type II endoleak

Ruptured abdominal aortic aneurysms (rAAAs) remain as a great clinical challenge for vascular surgeons, with high associated morbidity and mortality rates despite the many advances in diagnosis, surgical and anesthetic management, and postoperative care. Endovascular aortic repair (EVAR), which is currently regarded as the first-line treatment for rAAA in patients with appropriate anatomy, has played an increasingly larger role in recent years, owing to excellent results in the immediate perioperative period as well as good outcomes during midterm follow-up.[1-6] Indeed, large, contemporary, randomized, controlled trials have suggested several advantages of EVAR over open surgical repair, including lower mortality, faster discharge, a gain in quality-adjusted life-years, and lower costs.[7]

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However, the long-term outcomes of EVAR in the elective setting are characterized by a greater need for reintervention in comparison with open surgical repair, most of which are related to the occurrence of endoleaks, which are classified according to their origin. A type II endoleak (T2EL) occurs when blood flows in a retrograde direction into the aneurysm sac. If a T2EL persist and lead to an aneurysm sac enlargement of >1 cm within 12 months as compared with the preintervention baseline measurements, invasive treatment is generally recommended. This procedure primarily involves endovascular means using various embolization techniques to prevent subsequent complications such as sac expansion and/or secondary rupture.[8,9]

Although these recommendations are well-established for T2ELs after elective EVAR, data on T2EL after rAAAs are limited, and only a few relevant studies have been published to date.[10-12] In effect, it may be counterintuitive not to treat a continuous (although low-pressure) sac flow in the setting of rAAA, because this strategy may lead to ongoing blood loss and contribute to hemodynamic instability. However, given the immediate life-threatening nature of rAAA, it should be borne in mind that a damage control-like approach must be endorsed, which entails the immediate treatment of the aortic rupture and delayed final management as appropriate. Therefore, the additional time needed to try to achieve the simultaneous treatment of T2EL during EVAR must be balanced against more pressing concerns to the early restoration of patients' hemodynamic stability. Nonetheless, several questions remain unanswered and more data for better evidence-based recommendations are needed.[11]

Therefore, the purpose of this study was to analyze the early and late outcomes after EVAR of rAAA in patients with or without T2EL leveraging data from a multicenter international experience.

ARTICLE HIGHLIGHTS

- **Type of Research:** Multicentric observational retrospective research
- **Key Findings:** In this study, 123 patients who were treated with endovascular aortic repair for ruptured abdominal aortic aneurysms in three tertiary referral centers were included. The patients were divided into two groups based on the presence or absence of early type II endoleak (T2EL) (at completion angiography or at first post-operative computed tomography angiography): 73 were categorized as not having an early T2EL (group A) while 50 presented an early T2EL (group B). At 30 days, the overall mortality rate was not significantly different between study groups (22% vs 16%; $P = .16$). Five-year survival estimates in the whole study cohort did not show any significant difference in patients without a T2EL as compared with those with a T2EL (53% vs 59%; log-rank $P = .31$).
- **Take Home Message:** Although the occurrence of a T2EL seems a relatively common scenario after endovascular aortic repair for ruptured abdominal aortic aneurysms, their presence does not seem to be associated with worse outcomes in the immediate perioperative period or to decrease long-term survival.

METHODS

Study design. Between January 2018 and December 2022, all patients who were treated with EVAR for rAAA in three tertiary referral centers from different countries (Germany, Italy, and Switzerland) were screened for inclusion in the study. The exclusion criteria were as follows: thoracoabdominal, suprarenal, or pararenal aortic aneurysms not suitable for standard EVAR; dissecting aneurysm and penetrating aortic ulcers; secondary rupture after prior EVAR; EVAR with planned adjunctive procedures including parallel grafts, in situ fenestration, or endoanchors; symptomatic patients without radiologically confirmed rupture; mycotic or inflammatory AAA; and patients <18 years of age. All data were extracted from the hospitals' medical records retrospectively, and patients were divided in two groups based on the presence or absence of an early T2EL (at completion angiography or at first postoperative computed tomography angiography [CTA]) for the purpose of statistical analysis. All centers adopted a similar protocol that comprised performing in-hospital CTA in patients with clinical and laboratory signs of hemodynamic deterioration without any other plausible explanation (eg, after ruling out acute myocardial infarction or abdominal compartment syndrome). In all other instances, following discharge patients underwent a first postoperative CTA within 2 months from the index EVAR.

All these centers were able to provide 24/7 at least two surgeons with a minimum of 5 years of experience who could equally perform open and endovascular surgery such that the treatment could be customized with respect to a single patient according to clinical practice guidelines. Moreover, local institutional protocols were in place at each center for the care of acute aortic diseases. All patients underwent preoperative CTA with ≥1.5 mm reconstruction of the entire aorta. The management of T2ELs at the three institutions was similar, based on previously published pragmatical algorithms.[13] Each institution received local institutional review board/ethical committee approval for conduct of the study. The need for informed consent was waived owing to the retrospective nature of the study.

End points and definitions. The primary end points for this study were 30-day mortality and long-term survival. Secondary end points included technical success,

Table I. Baseline characteristics of the study cohort

Variables	Group A, no T2EL (n = 73)	Group B, T2EL (n = 50)	*P* value
Male sex	79.5 (58)	92 (46)	.05
Age, years	73.3 ± 9.9	72.3 ± 9.8	.82
Body mass index, kg/m^2	26.8 ± 3.6	28.3 ± 4.1	.08
Smoking			
Never	38.4 (28)	48 (24)	
Former	26 (19)	28 (14)	.26
Current	35.6 (26)	22 (11)	
Hypertension	80.8 (59)	84 (42)	.38
Hyperlipidaemia	47.9 (35)	46 (23)	.48
Diabetes mellitus	15.1 (11)	20 (10)	.36
Severe chronic kidney disease (eGFR <60 mL/kg/min)	19.2 (14)	18 (9)	.45
Hemodialysis	4.1 (3)	0	.17
Congestive heart failure	5.5 (4)	12 (6)	.19
Coronary artery disease	32.9 (24)	40 (20)	.32
Chronic obstructive pulmonary disease	17.8 (13)	20 (10)	.45
Maximum aneurysm diameter, mm	70.5 ± 17.9	73.3 ± 14.3	.36
Shock at presentation (SBP <90 mm Hg or cardiac arrest or need for vasopressors)	37 (27)	46 (23)	.32

eGFR, Estimated glomerular filtration rate; *SBP*, systolic blood pressure; *T2EL*, type II endoleak.
Values are percent (n) or mean ± standard deviation.

perioperative major adverse events, length of hospital stay, and rate of secondary interventions after discharge. The reporting of clinical events was done according to the Society for Vascular Surgery reporting standards.[14]

Statistical analysis. Continuous data were expressed as the mean ± standard deviation or median ± interquartile range values when necessary. Categorical data were expressed as absolute count with percentages. Statistical significance was defined at the $P < .05$ level. For long-term survival, given the expected high frequency of early deaths owing to the severity of underlying disease, we also performed a sensitivity analysis in the restricted cohort of patients who were alive ≥30 days after the index EVAR. Logistic regression was used to evaluate potential associations between variables of interest and binary 30-day mortality. The Kaplan-Meier method was used to estimate time-dependent outcomes, with Cox proportional hazard regression to evaluate potential associations between dependent variables and outcomes of interest. The incidence rate of secondary interventions after hospital discharge was calculated and its ratio evaluated for statistical significance. In addition to the main exposure variable (ie, presence or absence of T2EL), independent variables for regression analyses were selected based on clinical and/or statistical significance at univariate analysis. All statistical analyses were performed using SPSS software (version 24.0 for Apple; IBM, Armonk, NY).

RESULTS

Study population. Overall, 123 patients were included in the final analysis. Of these, 73 were categorized as not having an early T2EL (group A) and 50 patients (38%) were categorized as having an early T2EL (group B). Overall, 22 T2ELs were observed at final angiography (of which 17 came from lumbar arteries, 3 came from the inferior mesenteric artery, and 2 came from both sources), while 28 T2ELs were observed de novo at the first postoperative CTA (of which 17 came from lumbar arteries, 7 came from the inferior mesenteric artery, and 4 came from both sources). None of the T2ELs observed at final angiography were treated during the index EVAR. With the exception of a significantly lower proportion of males in group A as compared with group B (79.5% vs 92%; $P = .05$), no significant baseline differences were otherwise found (Table I), including mean age (73 years vs 72 years; $P = .82$), maximal aneurysm diameter (70.5 mm vs 73.0 mm; $P = .36$), and the presence of hemodynamic instability at presentation (37% vs 46%; $P = .32$).

Procedural details and 30-day outcomes. No significant differences were noted in main procedural metrics including mean operating time (137 minutes vs 113 minutes; $P = .16$) and the preferential use of bifurcated stent-grafts (92% vs 98%; $P = .34$); however, significantly more patients received general anesthesia in groups A as compared with group B (51% vs 24%; $P = .007$). Two

Table II. Procedural details of index endovascular intervention

Variables	Group A, no T2EL (n = 73)	Group B, T2EL (n = 50)	*P* value
Operative time, minutes	136.9 ± 92.9	113.3 ± 66	.16
Stent graft type			
Bifurcated	92 (67)	98 (49)	
Aortomonoiliac	8 (6)	2 (1)	.34
Graft fixation			
Infrarenal	27.4 (20)	26 (13)	.86
Suprarenal	72.6 (53)	74 (37)	
Intraoperative adjuncts			
No	76.7 (56)	64 (32)	
Renal chimney	2.7 (2)	0	
Hypogastric embolization	2.7 (2)	6 (3)	.27
Proximal cuff	1.3 (1)	4 (2)	
Adjunctive iliofemoral procedure	12.3 (9)	22 (11)	
Hypogastric embolization + adjunctive iliofemoral procedure	4.1 (3)	4 (2)	
Intraoperative mortality	0	0	
Intraoperative complications	13.7 (10)	26 (13)	.00
Technical success	89 (65)	88 (44)	.86
Percutaneous access			
None	20.5 (15)	8 (4)	.14
Unilateral	9.6 (7)	8 (4)	
Bilateral	69.9 (51)	84 (42)	
Anesthesia			
General	50.7 (37)	24 (12)	.007
Local	49.3% (36)	74% (37)	

T2EL, type II endoleak.
Values are percent (n) or mean ± standard deviation.

patients in group A received unplanned single chimney grafting for rescue of an occluded renal artery. No instances of intraoperative mortality were reported in the whole study cohort (Table II).

At 30 days, the overall mortality rate was not significantly different between study groups (22% vs 16%; *P* = .16) (Table III). Using binary regression, the presence of T2EL was not independently associated with 30-day mortality (odds ratio, 1.712; 95% confidence interval [CI], 0.591-3.964; *P* = .54), nor was the type of anesthesia (odds ratio, 0.928; 95% CI, 0.267-2.223; *P* = .08).

The rate of perioperative secondary unplanned interventions was not significantly different between study groups (27.4% vs 22.0%; *P* = .28), nor was the incidence of abdominal compartment syndrome requiring decompressive laparotomy (13.7% vs 16.0%; *P* = .74). In addition to decompressive laparotomies, other secondary unplanned interventions included coronary angiography and stenting for acute myocardial infarction (n = 6) and access-related issues requiring surgical and endovascular management (n = 7).

Follow-up outcomes. Five-year survival estimates in the whole study cohort did not show any significant differences in patients without a T2EL as compared with those with a T2EL (53% vs 59%; log-rank *P* = .31) (Fig 1). As a sensitivity analysis, survival was estimated in the restricted cohort of patients who were alive at 30 days after the index EVAR, again without any significant differences at five years between groups (69% vs 67%; log-rank *P* = .85) (Fig 2). Using Cox proportional hazard regression, the presence of a T2EL was not independently associated with increased risk for long-term mortality (hazard ratio, 1.068; 95% CI, 0.437-2.611; *P* = .079). Similarly, no independent associations were found for age, gender, or maximal aneurysm sax diameter (Supplementary Table, online only).

The incidence rate of secondary interventions in the two groups was 0.0912 events per patient per year and 0.0847 events per patient per year, respectively. The incidence rate ratio was 1.077 (95% CI, 0.5522-2.1536) with a *P* value of .816, thus indicating the absence of statistically significant differences. Notably, in only two cases was a reintervention required because of an enlarging aneurysm sac from a T2EL, thereby accounting for 4% to 5% of patients with a T2EL who were alive at discharge (n = 44). Additionally, four patients required proximal placement of an aortic

Table III. Postoperative outcomes in the first 30 days after index endovascular intervention

Variables	Group A, no T2EL (n = 73)	Group B, T2EL (n = 50)	*P* value
Mortality	21.9 (16)	12 (6)	.16
Major adverse events	57.5 (42)	58 (29)	.96
Single antiplatelet at discharge	65.8 (48)	78 (39)	.34
Dual antiplatelet at discharge	6.8 (5)	4 (2)	.51
Oral anticoagulants at discharge	48.3 (29)	61.4 (27)	.19
Any endoleaks at first postoperative CT scan	15.3 (11)	90 (45)	.00
Type of endoleaks			
IA	11 (8)	2 (1)	
IB	2.7 (2)	0	
II	0	78 (39)	.00
IA + II	0	6 (3)	
IB + II	0	0	
III	1.4 (1)	0	
II + III	0	4 (2)	
Secondary unplanned interventions	27.4 (20)	22 (11)	.28
Abdominal compartment syndrome	13.7 (10)	16 (8)	.74
Hospital stay, days	13.9 ± 12.3	15.9 ± 10.6	.35
ICU stay, days			
0	11.4 (8)	18 (9)	
1-5	67.1 (47)	50 (25)	.308
6-14	12.9 (9)	20 (10)	
>15	8.6 (6)	12 (6)	
No. of blood transfusion (PRBC units)			
0	21 (13)	29.8 (14)	
1-3	35.5 (22)	27.7 (13)	.305
4-9	25.8 (16)	34 (16)	
>8	17.7 (11)	8.5 (4)	

ICU, Intensive care unit; *PRBC*, packed red blood cells; *T2EL*, type II endoleak.
Values are percent (n) or mean ± standard deviation.

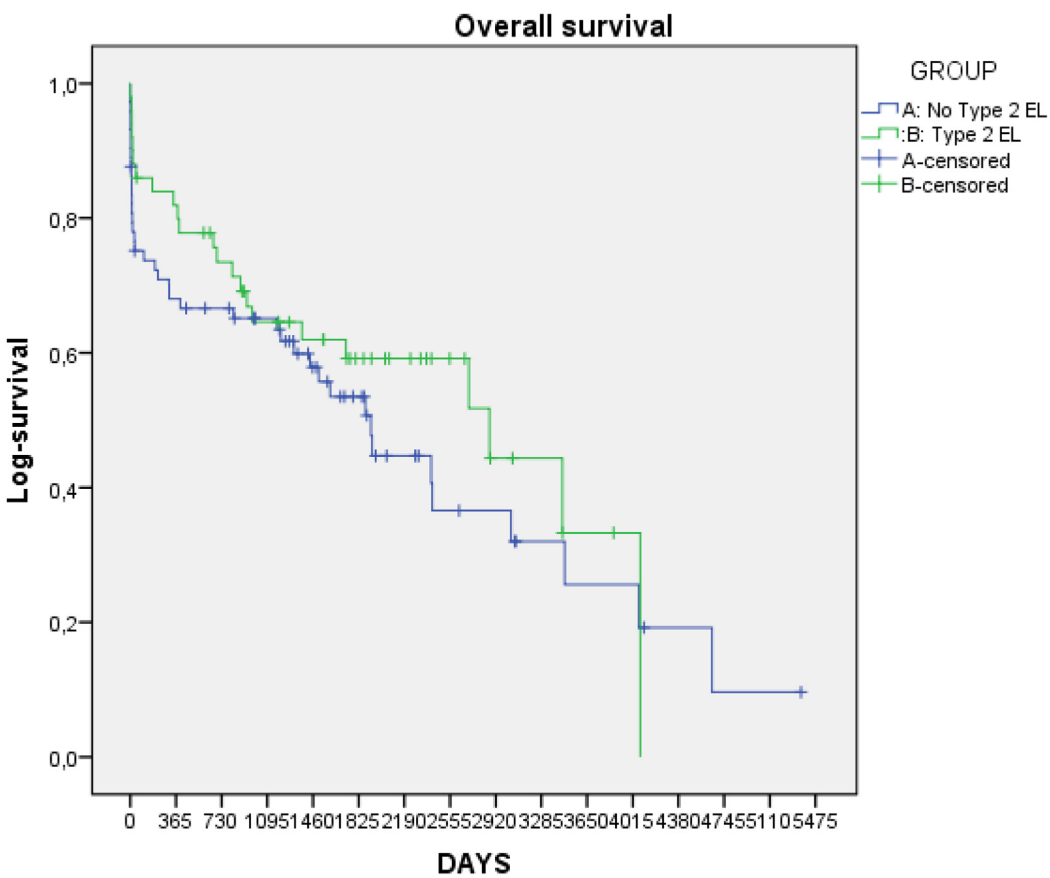
cuff because of type IA endoleak and one patient developed iliac limb occlusion requiring revascularization.

DISCUSSION

Summary of findings. This study investigated early and long-term outcomes of patients with rAAAs treated with EVAR, focusing on the presence of T2ELs. The results showed that although T2ELs were common, their presence did not significantly affect 30-day mortality or long-term survival. At 5 years, survival rates were similar between patients with and without T2ELs. Additionally, the rate of secondary interventions owing to T2ELs was low, and no significant differences were observed between the groups.

Comparison with prior literature. The study findings align with some previous literature. The incidence of T2ELs of 38% in our study is slightly higher than other relevant studies reporting rates of 16% to 29% in patients with rAAA,[10-12] but still lower than the reported incidence of T2ELs after elective EVAR, which can reach up to 60%.[15] Early mortality, defined as 30-day or in-hospital mortality depending on the study design, varied between 6% and 14% in previous studies, which also aligns with the 12% to 16% found in this study. The finding that T2ELs neither influence 30-day mortality nor long-term survival has also been described in earlier single-center studies. This finding suggests that T2ELs, although relatively common after EVAR for both elective and ruptured aneurysms, do not invariably result in worse outcomes. Prior studies on elective EVAR have similarly found that T2ELs are often asymptomatic and do not always necessitate intervention unless associated with aneurysm sac enlargement or rupture.[16]

Implications for clinical practice. This study has important implications for clinical practice. It suggests that, in most cases, T2ELs after EVAR for rAAA do not require aggressive intervention, especially in the immediate perioperative period. These findings can help to guide clinical



GROUP A (No Type 2 EL)

YEAR	1°	2°	3°	4°	5°	6°	7°
N° at risk	48	45	39	28	21	13	9
KM estimated	68.1%	66.6%	65.1%	57.9%	53.5%	44.7%	36.6%
Standard Error	.055	.056	.056	.061	.064	.071	.078

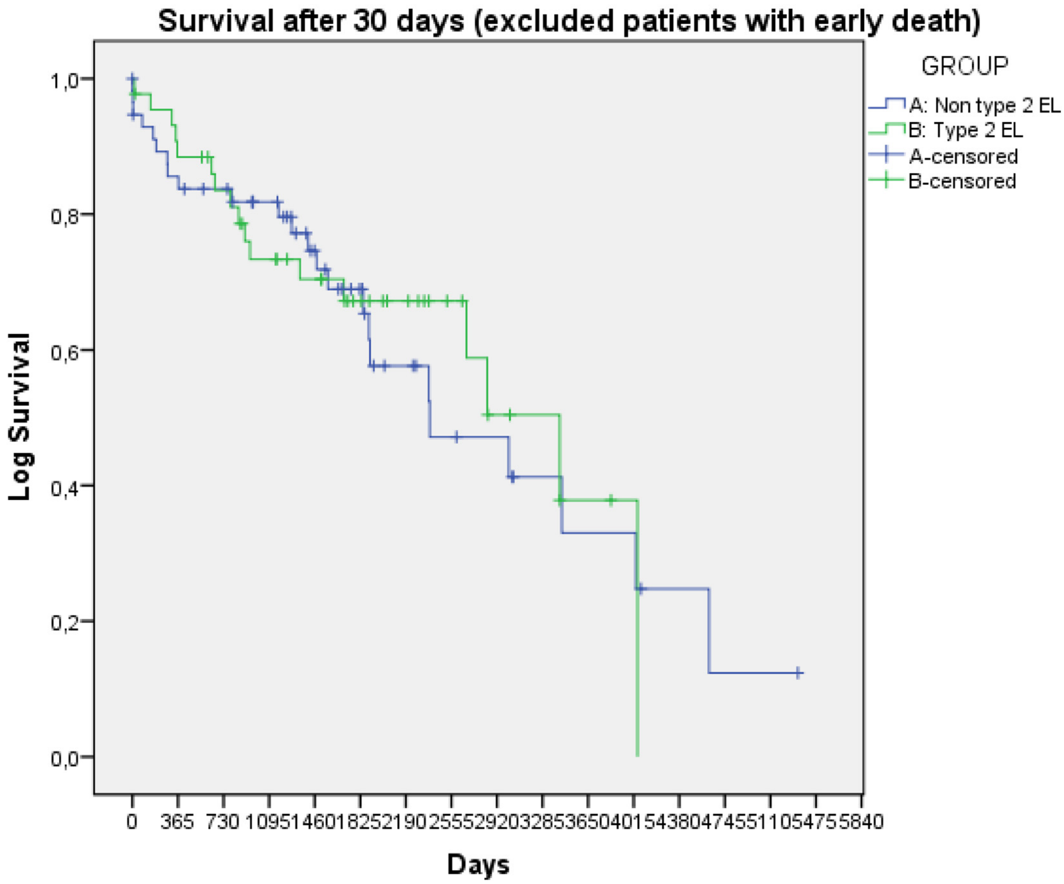
GROUP B (Type 2 EL)

YEAR	1°	2°	3°	4°	5°	6°	7°
N° at risk	40	34	28	24	18	14	9
KM estimated	81.9%	73.5%	64.6%	62%	59.2%	59.2%	59.2%
Standard Error	.055	.063	.070	.071	.074	.074	.074

Fig 1. Kaplan-Meier (*KM*) analysis of survival after index intervention in the whole cohort (log-rank $P = .31$). *EL*, endoleak.

decision-making, decreasing the potential for over-treatment and the associated risks of unnecessary interventions.

However, the study also highlights the nuanced decision-making required in the management of rAAA. The acute, life-threatening nature of rAAA often



GROUP A: No type 2 EL

YEAR	1°	2°	3°	4°	5°	6°	7°
N° at risk	47	44	38	27	20	13	9
KM estimated	85.6%	83.7%	81.8%	74.6%	69%	57.7%	47.2%
Standard Error	.047	.050	.052	.062	.069	.083	.095

GROUP B: Type 2 EL

YEAR	1°	2°	3°	4°	5°	6°	7°
N° at risk	38	34	28	24	18	14	9
KM estimated	88.4%	83.5%	73.4%	70.4%	67.2%	67.2%	67.2%
Standard Error	.049	.057	.069	.072	.076	.076	.076

Fig 2. Kaplan-Meier (*KM*) analysis of survival only in patients alive at 30 days after index intervention (log rank $P =$ .85). *EL*, endoleak.

necessitates an immediate, damage control approach, focusing on the primary goal of achieving hemodynamic stability. The management of T2ELs should, therefore, be secondary to this primary objective; in the authors' opinion, selective treatment for T2ELs should be considered only in cases of hemodynamic decompensation in the early postoperative phase, as reported in previous studies[13] or significant aneurysm sac expansion on the long run, such as in elective EVAR.

Study limitations. This study has some limitations. The primary limit is the retrospective nature of data collection, which may be particularly challenging in the setting of emergency surgery. Then, despite the multicenter nature of the data, the relatively small sample size may decrease the sensitivity of multivariate analyses and, therefore, the generalizability of results. Last, all outcomes were self-reported and there was no formal core-laboratory adjudication of imaging findings, which may introduce potential variability in the assessment of findings. Last, because autopsy rates varied between centers and countries, complete information was not available on causes of late death, which hindered precise assessment of aortic-related mortality over time.

CONCLUSIONS

Although the occurrence of a T2EL seems to be a relatively common scenario after EVAR for rAAA, their presence does not seem to be associated to worse outcomes in the immediate perioperative period or to decrease long-term survival. Therefore, careful observation may be warranted in the early phase, with selective treatment only in case of ongoing hemodynamic decompensation. In the long run, it seems prudent to assume that the same indication for treatment as for standard EVAR could be recommended in the presence of T2EL.

AUTHOR CONTRIBUTIONS

Conception and design: MDO, PD
Analysis and interpretation: MDO, BG, AM, AI, SL, AO, AZ, BR, AD, CC, CZ, PD
Data collection: MDO, BG, AM, AI, SL, AO, AZ, BR, AD, CC, CZ, PD
Writing the article: MDO, PD
Critical revision of the article: MDO, BG, AM, AI, SL, AO, AZ, BR, AD, CC, CZ, PD
Final approval of the article: MDO, BG, AM, AI, SL, AO, AZ, BR, AD, CC, CZ, PD
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Additional material for this article may be found online at www.jvascsurg.org.

Supplementary Table (online only). Proportional Cox hazards for independent predictors of late survival

Variables	*P* value	Hazard ratio	95% CI
Age (per year)	.074	.924	0.466-1.830
Female sex	.046	1.077	1.035-1.121
T2EL	.079	1.068	0.437-2.611
Max AAA diameter (per 5 mm)	.083	.987	0.965-1.01

AAA, Abdominal aortic aneurysm; *CI*, confidence interval; *T2EL*, type II endoleak.