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Occurrence and outcomes of type 3 endoleaks in endovascular aortic repair within the Vascular Quality Initiative database

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ABSTRACT

Objectives Type 3 endoleaks (T3ELs) represent a lack of aneurysm protection from systemic pressure. Previous studies have found a ~2% incidence of T3EL after standard infrarenal endovascular aneurysm repair (EVAR); however, no prior studies with new-generation devices have been able to determine an association between T3EL and clinical outcomes. Here we examine T3EL within the Society for Vascular Surgery Vascular Quality Initiative (VQI) to define rates of occurrence, rates and modes of reintervention, and clinical consequences of these endoleaks.

Design and setting Participants receiving infrarenal EVAR in the VQI from January 2003 to September 2018 were analyzed in a retrospective cohort study.

Participants Of 42 246 entries in the EVAR procedural registry, 41 604 had complete procedural information and were included in analysis. Of these, 36 082 had long-term follow-up, and 26 422 had follow-up (9–21 months per VQI reporting standards) with complete endoleak data recorded.

Interventions All patients included in this study underwent an infrarenal EVAR.

Results Within the VQI database, the rate of T3EL in infrarenal EVAR during index hospitalization was 0.37% (n=157/41 604), of which 85% were due to midgraft separation and 15% were due to fabric disruptions. Out of the 157 index hospitalization T3ELs, 4.5% (n=7) received procedural reintervention during that hospitalization, which accounted for 1% of all index hospitalization reinterventions. During the 21-month follow-up, the rate of incident T3EL was 0.7% (n=205/26 422), which accounted for 5% of all endoleaks seen during follow-up. Reinterventions for incident T3EL at follow-up were done in 30 patients (rate 0.1%), which accounted for 9% of endoleak reinterventions and 3.3% of all reinterventions. The presence of incident T3EL found during follow-up was associated with a significant decrease in 5-year survival (74% vs 80%, respectively; p=0.041) in Kaplan-Meier analysis.

Conclusion T3ELs rates at placement and follow-up remain low; however, the majority reported in long-term follow-up are incident and these incident endoleaks are associated with decreased survival in EVAR.

Key messages

What is already known about this subject?

► Type 3 endoleaks (T3EL) occur following endovascular aortic repairs; however, their national frequency and clinical relevance have not yet been well delineated.

What are the new findings?

► This study demonstrates that T3ELs occur primarily in long-term follow-up and have an association with decreased survival.

How might these results affect future research or surgical practice?

► Given these results, providers should remain vigilant in life-long post-operative surveillance of aortic endografts.

INTRODUCTION

Endovascular aneurysm repair (EVAR) is a well-established method for thoracic and abdominal aortic aneurysm repair, and currently, 28%–79% of all aneurysms worldwide are repaired with an endovascular approach, with the USA having the highest application of endovascular technology.[1 2] Despite the rapid advances in endovascular therapy and numerous benefits, this approach is not without complications. The complication of endoleaks, defined as persistent flow into the aneurysm sac, remains of concern at the time of initial repair and beyond.

Endoleaks were first categorized in 1997 by White *et al*[3] into four major categories, with a fifth type defined roughly a decade later.[4] Type 3 endoleaks (T3EL) were defined as persistent flow into the aneurysm sac through graft components and were then subcategorized in 1998 as either modular disconnections (3a) or graft fabric disruptions (3b). T3ELs have historically been difficult to study, and although their presence and resulting complications can be devastating, the breadth of their clinical impact is yet unknown.

Of the endoleak categories, T3ELs are the least frequent and consequently the least well understood. This is especially true given that their rate of occurrence, implications and morphology are very device specific. Due to their relative rarity, initial knowledge of T3EL was derived from case reports.[5 6] In the early 2000s, as endovascular aortic therapy burgeoned, large-scale studies such as Endovascular vs Open Repair of Abdominal Aortic Aneurysm (EVAR1) and EUROpean collaborators on Stent-graft Techniques for Abdominal aortic aneurysm Repair (EUROSTAR) began to reliably report T3EL incidence rates between 3.0% and 4.5%.[6 7] Since then, the landscape of endovascular aortic repair has changed dramatically, but there have been few new large-scale trials describing current rates of T3EL or attempting to catalogue their resulting complications.

Several single-center institutions have presented their individual data on T3ELs. However, no prior studies within recent years and new-generation devices have identified risk factors for these endoleaks, nor have any prior studies been able to determine a link between T3EL and aneurysm rupture, reintervention, mortality or overall survival. This lack of association likely does not represent a true lack of relationship between T3EL and clinical outcomes, but instead highlights the fact that the low occurrence rate of T3EL identified at any one institution is of little statistical significance. In one major paper published in the *Journal of Vascular Surgery*, a total of eight T3ELs were identified out of 151 patients, a number probably too small from which to draw any conclusions.[8] This study aimed to objectively evaluate T3EL on a national level in modern endovascular aneurysm repairs to better define rates of occurrence, rates and modes of reintervention, and clinical consequences of these endoleaks.

METHODS

Vascular Quality Initiative (VQI) database

The Society for Vascular Surgery (SVS) VQI is a patient safety organization initially formed in 2001 as the Vascular Study Group of New England which served as a voluntary cooperative regional database for local quality improvement and expanded yearly thereafter. It joined with the SVS and became national in 2011 and is now composed of 18 regional groups with registry data representing more than 650 community and academic hospitals in the USA and Canada.[9] Entry of data and procedures, now totaling well over 800 000 procedures crossing nine major vascular catagories, is maintained by individual centers and physicians and ensured by annual audits against hospital claims data.[10] Follow-up data are required for 1 year following procedure but, at the discretion of individual centers, can be entered indefinitely. Data entry and completeness, and therefore integrity, are assisted at the time of data entry by detailed definitions, prompts and incomplete data warnings.[11] The VQI is the largest database dedicated to quantifying vascular procedural outcomes and is unique from other large databases in its longitudinal follow-up.[12] This project was screened and approved by the VQI Research Advisory Council and was reviewed and approved by the institutional review board at the University of Alabama at Birmingham.

Cohort selection

A retrospective cohort of deidentified patients undergoing standard elective endovascular abdominal aortic aneurysm repair for non-ruptured aneurysms within the VQI from January 2003 to September 2018 was identified. Standard EVAR was defined as infrarenal device deployment without use of complex techniques such a custom/physician modified devices, fenestrated/branched EVAR or parallel stenting techniques. Analysis of case variables allowed duplicate patient entries to be consolidated and duplicate data eliminated. Manufacturer data for each stentgraft was not directly characterized, although the restricted data were collected in the VQI.

Standard endoleak definitions were used (full definitions are provided in online supplemental table 1). T3ELs are defined as persistent flow into the aneurysm sac through graft components (modular disconnections or graft fabric defects).[13] Cases were included in the final analysis if they had non-missing responses to initial endoleak evaluation. If no evaluation for endoleak was ever documented, the cases were removed. Two time frames of endoleaks were defined; index and incident endoleaks. Index endoleaks were defined as any endoleak discovered during the index hospitalization, which was defined as within the procedure to time of hospital discharge. Incident endoleaks were defined as any new endoleak discovered at follow-up that was not present during initial hospitalization. This categorization prevented endoleaks from being included as duplicate entries and ensured that a patient could not have both an index hospital T3EL and incident T3EL. Patients without documented follow-up were included in procedural and index hospitalization analysis but were not included in the long-term follow-up (incident) cohort. Long-term follow-up data were defined as the period between 9 and 21 months after initial procedure and index hospitalization. All patients included in this study had endoleak documentation at index procedure and at long-term follow-up within the 9–21 months of follow-up reporting interval. The timing of post-operative CT scans for endoleak surveillance in this procedural registry is up to individual surgeons based on clinical discretion, though time to imaging and time to reinterventions from index procedure are captured.

Covariates and outcomes examined

Preoperative demographics analyzed included age, race, gender, primary insurer and weight (kg). Comorbidities assessed included coronary artery disease, chronic obstructive pulmonary disease, cerebrovascular disease, congestive heart failure, hypertension, dialysis-dependent end-stage renal disease (ESRD), preoperative creatinine, preoperative ejection fraction, stress test results, diabetes mellitus (insulin or non-insulin requiring), smoking (current/former/never), prior percutaneous coronary intervention and/or coronary artery bypass grafting, and preoperative ambulatory status), where available.

Intraoperative variables analyzed included procedure time (in hours), American Society of Anesthesiologists class, intraoperative heparin administration, proximal extent of aortic disease by zone, intraoperative crystalloid volume infused (in litres), intraoperative transfusions, intraoperative estimated blood loss (in litres), return to operating room, concomitant procedures and intraoperative complications.

Postoperatively, variables were assessed at two timeframes: index hospitalization, defined at the period between procedure and first discharge, and follow-up, defined as 9–21 months post-operatively. Variables examined included reinterventions which was defined per VQI standards as any repeat surgical procedure to address a complication of the primary procedure. Aortic reinterventions were defined per VQI standards as involving any of the following: aneurysm sac growth, aneurysm rupture, device migration or misalignment, device occlusion or stenosis, device infection or endoleak development (with subcatagories of endoleaks represented). Access reinterventions were defined as bleeding, stenosis, thrombosis, pseudoaneurysm or distal embolization of any vessel accessed for device delivery.

Statistical analysis

Collected data were analyzed in SPSS statistical software V.23.0. Continuous variables were presented as mean±SD and were compared using an independent Student t-test. Categorical variables were presented as number and percentage and were compared using a χ^2 test. Kaplan-Meier curve analysis and log-rank analysis were used to plot outcomes related to survival and freedom from intervention. A p value of <0.05 defined statistical significance. Missing values were automatically recognized by SPSS and treated as system-missing and corresponding cases were omitted in a pairwise manner from descriptive statistics, frequencies, correlations, and regressions.

Study endpoints

Primary endpoints of this study were to determine the occurrence rate of T3ELs at both placement and follow-up, and to determine the association of T3ELs with reinterventions and all-cause mortality.

RESULTS

Demographics

Between 2003 and 2018, a total of 42 246 individual EVAR cases with recorded endoleak evaluation were entered into the VQI database. Of those, 41 604 had appropriate procedural data available and were included in final analysis. Out of the initial EVAR cohort, 63.5% (n=26 422) had any follow-up data recorded. All patients included in follow-up had appropriate endoleak documentation during index hospitalization and up to at least 9 months postoperatively, per VQI follow-up standards. Cohort demographics are presented in table 1 and are notable for predominately male populations of current and former smokers with expected aneurysm comorbidities. Within the VQI, EVAR procedure case numbers demonstrated a linear year-over-year increase in case entry starting in 2003. Time until first imaging was highly variable, and this variable had significant incompleteness (84%) and was therefore not analyzed. Figure 1 demonstrates cohort paths based on occurrence of T3EL, mortality, and follow-up.

Table 1 Demographics

Variable	EVAR (N=41 604)
Age (years) (mean±SD)	73.3±8.8
Gender	
Male	33 656 (80%)
Female	7948 (20%)
Smoking	
Never	5839 (14%)
Prior	22 358 (53.7%)
Current	13 330 (32%)
Hypertension	34 585 (83.1%)
Diabetes mellitus	8422 (20%)
CAD	12 262 (29%)
Prior CABG	6602 (15%)
Hemodialysis	5214 (12.5%)
COPD	13 747 (33%)
Prior CEA	1357 (3%)
Prior bypass	1177 (2.8%)
Prior aneurysm	1529 (3.6%)
AAA diameter (mm) (mean±SD)	56±19.9

AAA, abdominal aortic aneurysm; CABG, coronary artery bypass graft; CAD, coronary artery disease; CEA, carotid endarterectomy; COPD, chronic obstructive pulmonary disease; EVAR, endovascular aortic aneurysm repair.

Index hospitalization T3EL rates and reinterventions

At index hospitalization, the rate of any endoleak around initial EVAR placement was 23% (n=9548). Overall endoleak rates and distribution of endoleak types for standard EVAR at index hospitalization are presented in table 2. The rate of T3EL in EVAR at index hospitalization was 0.4% (n=157), which accounted for 1.6% of all the initial endoleaks (table 2).

Within these 157 endoleaks, 85% (n=133) were attributed to mid-graft separation and 15% (n=24) were attributed to mid-graft fabric holes. The raw number of T3EL peaked in 2014 and has since been downtrending, likely due to changes in device availability and overall device design. Similarly, the rate of T3EL has been downtrending since 2014 (online supplemental figure 1). Within standard EVAR, Type 2 endoleaks were the most

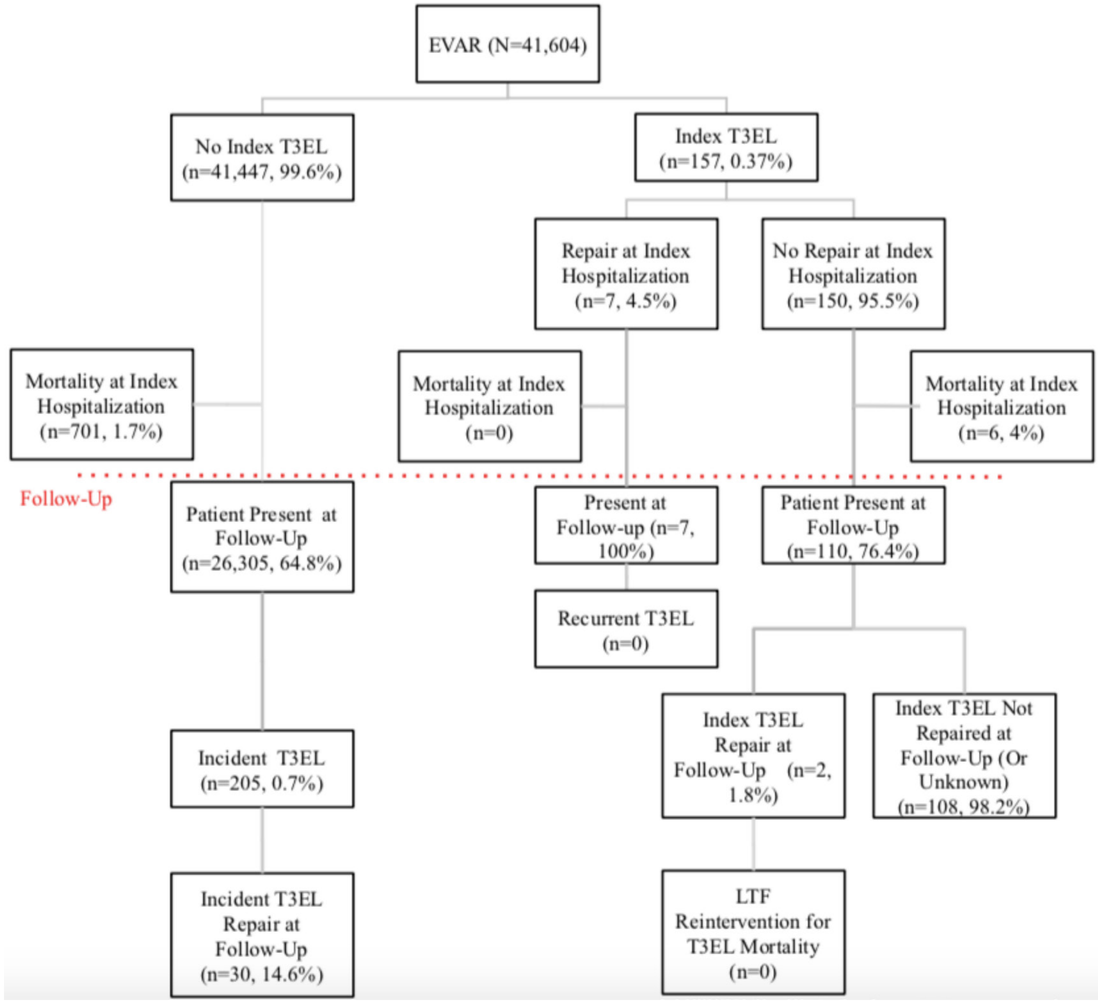

Figure 1 Flow diagram of cohort based on the presence of T3ELs. EVAR, endovascular aortic aneurysm repair; T3EL, type 3 endoleak; LTF, long-term follow-up.

common, comprising 71% of all initial endoleaks. The rate of indeterminate endoleaks within standard EVAR at placement was 2.3% (n=942), which accounts for 9.8% of all of the endoleaks.

In standard EVAR at index hospitalization, the overall rate of reintervention for any indication was 1.8% (n=766). The rate of reinterventions for any endoleak type was 0.12% (n=50/41,604), which accounts for 6.5% of all reinterventions (n=50/766) in standard EVAR during index hospitalization (table 3).

The rate of reintervention for T3EL during index hospitalization was 0.02% (n=7). Out of the 157 T3EL discovered during index hospitalization, 4.5% received procedural intervention during that hospitalization. Reinterventions for T3EL account for 14% of endoleak reinterventions and 1% of all reinterventions (table 4).

Type 3 endoleak rates and reinterventions at follow-up

The overall rate of any endoleak at follow-up was 16%. Endoleak rates overall and by endoleak type for standard EVAR at follow-up are presented in table 2. The rate of incident T3EL in standard EVAR at follow-up was 0.7% (n=205), which accounts for 4.7% of all the endoleaks seen at follow-up. Type 2 endoleaks were the most common endoleak, comprising 58% (n=196) of all endoleaks in standard EVAR. The rate of indeterminate endoleaks within standard EVAR at follow-up was 2% (n=509), which accounts for roughly 11.7% of all the endoleaks.

The overall follow-up reintervention rate for standard EVAR for any indication was 3.4% (n=899). The overall rates of reintervention for endoleaks at follow-up in standard EVAR are presented in table 3. The overall rate of reintervention for any endoleak was 1.3% (n=335), which accounts for 37% of all reinterventions. Of the 205 incident T3EL discovered at long-term follow-up, only 30 (15%) were recorded as treated with reintervention. Reintervention for T3EL occurred in 0.1% of the population, accounting for 8.9% (n=30/335) of the endoleak reinterventions and 3.3% of all reinterventions (table 4).

Survival and type 3 endoleaks

By the end of the observational study time frame concluding in 2018, 8.7% (n=2455) of the cohort was deceased. The mean follow-up time in surviving patients was 4.4 years.The presence of an index hospitalization

Table 2 Endoleak rates in EVAR

Index hospitalization	
	EVAR (N=41 604)
Any endoleak	9548 (23%)
Type 1 endoleak	1417 (3.4%)
Type 1a*	1201 (85%)
Type 1b*	216 (15%)
Type 2 Endoleak	6855 (16%)
T3EL	157 (0.4%)
Mid-graft separation*	133 (85%)
Fabric tear*	24 (15%)
Type 4 endoleak	177 (0.7%)
Indeterminate	942 (2.3%)
Follow-up	
	EVAR (N=26 422)
Any endoleak	4338 (16%)
Type 1 endoleak	1608 (6%)
Type 2 endoleak	2016 (7.6%)
T3EL	205 (0.7%)
Type 4 endoleak	0
Indeterminate	509 (2%)

*Per cents are shown as relative proportions within initial endoleak type.
EVAR, endovascular aortic aneurysm repair; T3EL, type 3 endoleak.

Table 3 Endoleak reintervention rates

Index hospitalization	
	EVAR (N=41 604)
All endoleaks	50 (0.12%)
Type 1	31 (0.07%)
Type 2	12 (0.3%)
Type 3	7 (0.02%)
Type 4	0.0%
Indeterminate	0.0%
Follow-up	
	EVAR (N=26 422)
All endoleaks	335 (1.3%)
Type 1	81 (0.3%)
Type 2	196 (0.7%)
Type 3	30 (0.1%)
Type 4	0.0%
Indeterminate	28 (0.1%)

EVAR, endovascular aortic aneurysm repair.

Table 4 Indications for reintervention in standard EVAR

Indication	Index hospitalization (N=41 604)	Follow-up (N=26 422)
Any reintervention	766 (1.8%)	899 (3.5%)
Access	149 (19.5%)	0
Endoleak	50 (6.5%)	335 (37%)
Type 1*	31 (4%)	81 (2.5%)
Type 2*	12 (1.5%)	196 (22%)
Type 3*	7 (1%)	30 (3.3%)
Type 4*	0.0%	0.0%
Indeterminate*	0.0%	28 (3%)
Graft misplacement	102 (13%)	0
Graft migration	2 (0.2%)	37 (4%)
Graft occlusion	21 (3%)	162 (18%)
Graft stenosis	10 (1.5%)	31 (3.5%)
Aneurysm rupture	7 (1%)	24 (3%)
Sac growth	5 (0.5%)	232 (25%)
Other	420 (55%)	78 (9%)

*Per cents are shown relative to total interventions.
EVAR, endovascular aortic aneurysm repair.

T3EL (present in 0.4% of standard EVAR) did not affect overall mortality. Analysis of long-term follow-up data in standard EVAR did demonstrate a significant relationship between the presence of an incident T3EL and overall survival (figure 2). The overall mortality rate for standard EVAR patients with incident T3EL was 25%. We did not identify any mortalities within 30 days of T3EL reintervention. The presence of an incident T3EL was associated with decreased survival at 5 years compared with cases without incident T3EL (74% vs 80%, p=0.041).

DISCUSSION

EVAR was first developed in 1990 and revolutionized the treatment of aortic aneurysms and rapidly became standard practice internationally. The technology and outcomes of EVAR have improved dramatically with each new generation of stent graft; however, the procedure is still associated with complications. Endoleaks, persistent flow of blood into the aneurysm sac, were first classified in 1997 and remain the most frequent technical complication of endovascular repair. Of the five endoleak subcategories, T3ELs remain one of the least well understood due to their relative scarcity.

This study is the single largest retrospective study to evaluate T3ELs. The first series of EVAR in the 1990s had a T3EL rate of 17%.[14] Second-generation and third-generation grafts in the early 2000s improved those rates to 1.9%.[15] In 2014, the Veterans Affairs prospective multicenter Open Versus Endovascular Aneurysm Repair (OVER) trial examined their predictors and outcomes

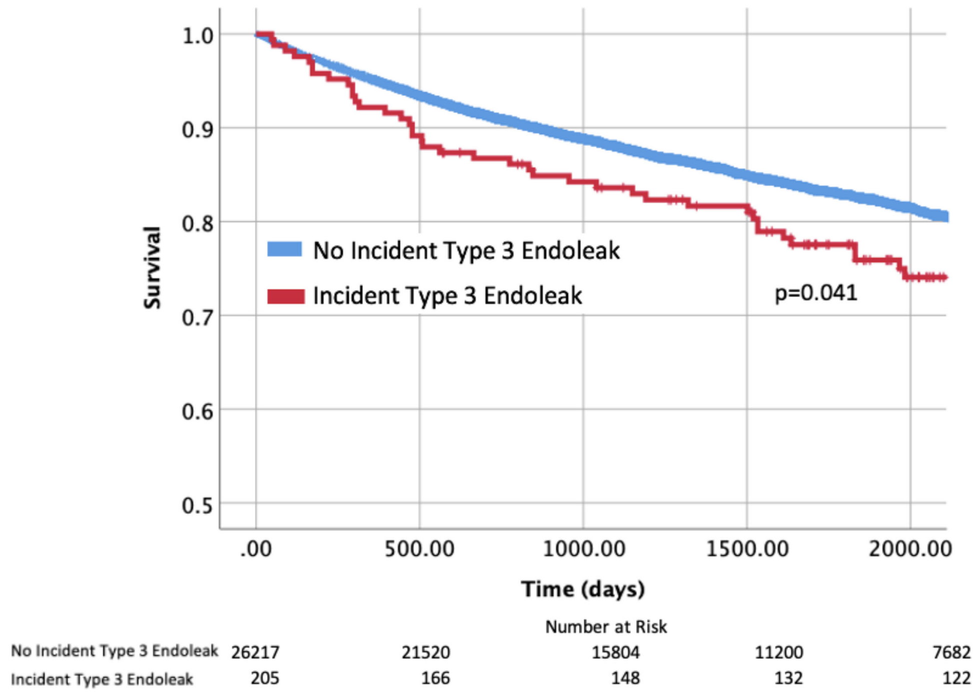

Figure 2 Survival outcomes in standard endovascular aortic aneurysm repair through 5 years by incident type 3 endoleak status.

of endoleaks; they described a 3% rate of T3EL, with the majority being detected more than 2 years after the initial procedure.[16] Similarly, in 2017, a retrospective single-center study described a T3EL rate of 2.6% with an average time until diagnosis of 5.6 years.[17] In our study, the overall rate of any T3EL in patients with standard EVAR derived over a time period of obligatory reporting up to 21 months and optional reintervention reporting following was 1.1%. These rates are lower than what has previously been described in the literature, likely due to differences in device generations captured by previous studies.[18] This current study does not capture data from before 2003, and thus does not account for the early devices that had high rates of endoleak, and additionally captures more recent data and newer grafts that are thought to have a lower rate of endoleaks. We place our T3EL rates in context to existing literature in online supplemental table 2.

Unlike previous studies, this study subdivides the overall rate of T3EL in standard EVAR into leaks identified during index hospitalization (T3EL rate 0.4%) and leaks identified at long-term follow-up (T3EL rate 0.7%). This demonstrates that the majority of T3ELs were identified at follow-up and were not present during the initial hospitalization. Although previous studies do not denote different rates for different time periods, all previous studies highlight the fact that the majority of T3ELs were found at follow-up, making the results of this study consistent with previous research. Overall, this research indicates that the registry-identified rate of T3EL is lower than previously demonstrated in smaller series, and trials and that appropriate imaging surveillance must be maintained, as the majority of these endoleaks occur at follow-up.

T3ELs occur through two modalities, modular disconnections (3a) or graft fabric disruptions (3b). The exact cause of these disconnections and disruptions has been evaluated by several institutions and occur through multiple mechanisms. In cases of type 3a endoleaks, studies have demonstrated modular disconnections at every level of graft overlap.[19] Several studies hypothesize that fabric disruptions are related to excessive endovascular graft manipulation, excessive ballooning, or fabric degradation over time.[20 21] The results of this study are consistent with previous series that describe the majority T3EL occurring secondary to modular disconnections.[17] In this study, for both endoleaks discovered during index hospitalization and at long-term follow-up, 85% were attributed to mid-graft separation and 15% were attributed to mid-graft fabric holes.

Endoleaks are a feared complication due to their potential to increase the risk of rupture by exposing the aneurysm sac to systemic blood pressure. Previous studies, including case studies and large-scale studies such as the OVER trial[11] and EUROSTAR registry,[6] have found a relationship between T3EL and aneurysm sac growth and rupture. Studies comparing the total mortality benefit of EVAR compared with open repair have shown that the overall mortality benefit of EVAR is lost over long-term follow-up after 1–2 years in the OVER trial,[16] 2 years in the EVAR1 trial,[7] and 5 years in the DREAM trial.[22] In 2015, Schermerhorn *et al*[23] published the long-term results of EVAR in Medicare patients and found that after 3 years, the mortality was equal between EVAR and open repairs due to higher late rupture rates in EVAR. In 2016, 15-year follow-up of the EVAR1 data was published, which demonstrated an association between endoleaks (type 1, type 2, and type 3) and secondary aortic sac rupture leading to an increased risk for mortality.[7] The data presented in our study align with the results of these large trials. Within this study, T3EL found during follow-up in standard EVAR cases were associated with decreased 5-year survival (74% vs 80%, p=0.041). Our dataset has capture of rupture events, but we are unable to characterize within the database reporting which patients with rupture may have also had T3EL. Given this association, it is imperative to understand how to best prevent, detect, and treat these endoleaks.

Limitations

Although every effort was made to ensure accuracy and reproducibility of this study, several limitations must be addressed. While the 2019 Annual VQI report indicates strong sustained enrollment of centers across the USA with the addition of 110 new reporting centers, the VQI is not yet entirely comprehensive in its representation of EVAR implantations in the country.[24] Additionally, early procedural volumes in the VQI are less robust, given given the national expansion that occurred after 2011 and subsequent extension of the registry to Canadian centers; however, annual EVAR procedural volumes in VQI remain significantly higher than those available in other US national surgical quality databases.[12 25] An additional limitation is inherent to analysis of the VQI, in that the data are derived on a voluntary basis from individual surgeons, and assumptions must be made regarding the veracity of the data. Thus, although the VQI compares entries against hospital claims data, it is possible that discrepancies, intentional or unintentional, exist within the data due to its self-reported nature. Despite these factors, specificity in endoleak reporting for this EVAR-specific complications is unavailable in other surgical quality databases or claims-based administrative data, currently making VQI our most representative sample of clinical practice in North America.

With regard to diagnosis of T3EL, there is no absolute certainly of when a T3EL occurred, unless it occurred during the index procedure where completion angiographic runs are standard of care. Postprocedural imaging studies prior to discharge are not mandatory or advised in the absence of patient clinical indications. Therefore, a T3EL could develop during index hospitalization but not be diagnosed until follow-up imaging; modalities and duration of long-term follow-up imaging in the window of 9–21 months are recorded but pose potential for lack of documentation in the registry of findings from commonly employed 1-month procedural scans. Ultimately, the nature of the endoleak type (fabric hole or device modular disconnection) makes it unlikely that a T3EL would spontaneously resolve or be missed at the long-term follow-up interval if a reintervention had not been recorded. In the future, if needed to better understand the exact timing, a more explicit time to diagnosis variable in VQI could reduce uncertainty or creation of type-specific endoleak billing codes could facilitate linkage to claims data. A final significant limitation seen in this study is the lack of continuity within patients' follow-up. Of the initial patients who had an EVAR device implanted, 37% were lost to follow-up. This presents several analytical difficulties, and whether this represents poor documentation of the behalf of physicians or if patients are truly not returning for surveillance after surgical intervention is unknown. Further, the lack of follow-up makes drawing conclusions regarding survival, both positive and negative, difficult. Initial attempts to address the limitations presented earlier include the MDEpiNet Vascular Implant Surveillance & Interventional Outcomes Network coordinated research network initiative expanding administrative claims and other data source linkages to VQI data which can aid in extension of long-term capture of patient care.[26]

Despite the aforementioned shortcomings, the VQI database represents the single largest well-regulated data available for analysis with the granular detail to study T3ELs. While these limitations should be taken into consideration when evaluating the conclusions presented in this paper, all studies that interpret the VQI data face the aforementioned difficulties and the limitations do not invalidate the findings or conclusions.

Finally, the presence of a T3EL at 9–21 months was associated with trends toward decreased survival; we suspect this trend would continue if data were available for follow-up in ensuing years; however, consistent reporting of 5 and 10 years is unavailable in this observational database at present. Future analyses using linkage of EVAR patients to Medicare claims data may allow for further longitudinal assessment of the mortality impact.

CONCLUSION

T3ELs rates at placement and follow-up remain low; however, the majority reported in long-term follow-up are incident and are associated with decreased survival in endovascular aortic repair. This study is the largest review of T3ELs and the first to isolate their occurrence by time frame. The presence of incident endoleaks developing at follow-up and their association with decreased survival align with previous published research and reinforces the importance of adequate follow-up imaging and surveillance after EVAR. These data also suggest that while contemporary devices may have lower rates of T3EL compared with earlier-generation devices, modern devices are not immune to T3EL and as EVAR becomes more complex and involves a greater number of device interactions, it is possible that T3ELs will represent a growing threat in the future.

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