Type 1b Endoleaks After Thoracic Endovascular Aortic Repair are Inadequately Reported: A Systematic Review

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Background: Complications after thoracic endovascular aortic repair (TEVAR) are common. Even after a successful TEVAR, a late endoleak (>30 days) can occur. The objective of this study is to summarize the current evidence and, if lacking, the need of evidence regarding the incidence and predictive factors for type 1b endoleak in patients with aortic aneurysm treated with TEVAR.

Methods: A systematic review of the literature was performed on endoleak type 1b, in patients with aortic aneurysm, after TEVAR. The PubMed and Embase databases were systematically searched for articles regarding endoleak type 1b up to January 2019. The main subjects discussed are the incidence, risk factors, treatment, and prognosis.

Results: About 722 articles were screened, and 16 articles were included in this review. The reported incidence of endoleak is between 1.0% and 15.0%, with a mean follow-up duration of at least 1 year. Type 1b endoleak is associated with an increased aortic tortuosity index (>0.15 cm^{-1}). No significant difference is found in relation to age and gender. Treatment is required in most cases (22/27) and is usually performed with distal extension of the stent graft (21/27). There are no data regarding stent graft oversizing, length of distal landing zone, and differences between devices or the prognosis for patients with type 1b endoleak.

Conclusions: Limited literature is available on the occurrence of type 1b endoleak after TEVAR. A tortuous aorta can be associated as a predictive factor for the occurrence of type 1b endoleak. Data clearly delineating the anatomic variables predicting type 1b endoleak should be examined and listed. Likewise, the impact of more recent conformable devices to prevent complications like type 1b endoleaks from occurring should be elucidated.

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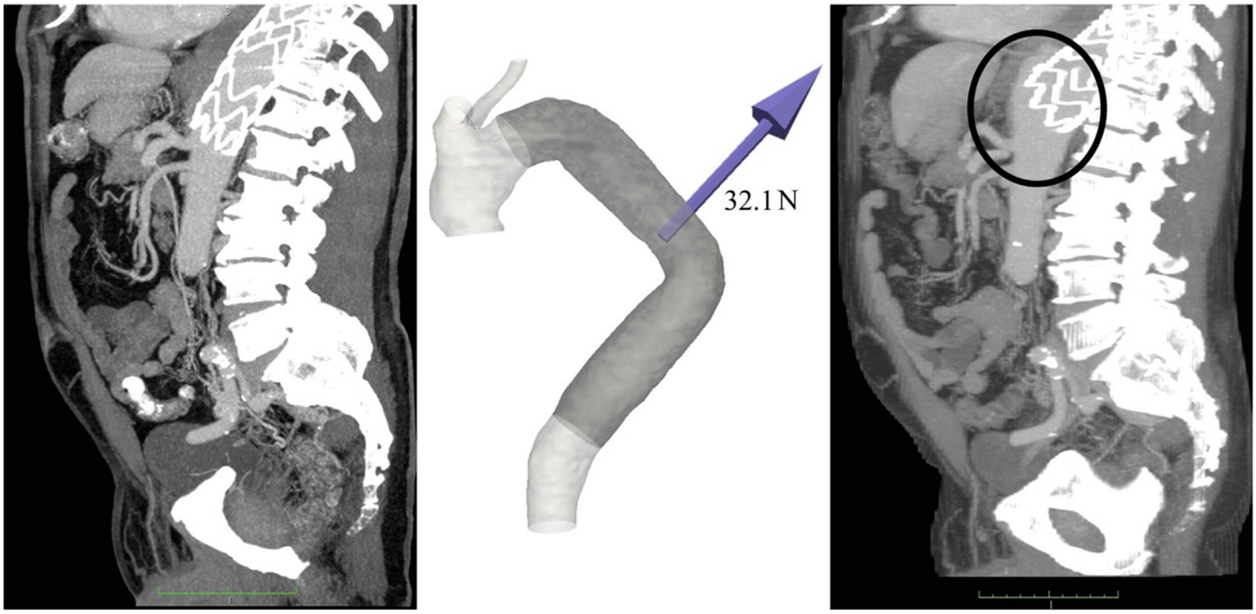

Fig. 1. Displacement force and type 1b endoleak at 1-year follow-up. (*Left*) 1-month postoperative computed tomography angiography scan. (*Middle*) Postoperative computational fluid dynamic model with calculated displacement force vector. (*Right*) 1-Year postoperative scan showing type 1b endoleak and proximal stent graft migration. Reprinted from van Bakel et al. with permission of AORTA, Thieme Publishers.[1]

INTRODUCTION

After our electrocardiographic-gated computed tomography (CT) and magnetic resonance studies before and after thoracic endovascular aortic repair (TEVAR) in combination with computational fluid dynamic simulation, a late type 1b endoleak occurred.[1] The simulation showed that the stent graft migrated 17.1 mm in dorsocranial direction, which correlated with the displacement force (Fig. 1). The suspicion arose whether this phenomenon was seen more often by other institutions and what the anatomic and morphologic risks factors are for this feature.

Traditionally, the standard treatment for thoracic aortic diseases was open surgery, which is associated with high rates of morbidity and mortality.[2] In 1994, Dake et al.[3] introduced the endovascular stent graft in the repair of descending thoracic aortic aneurysms (TAAs), which rapidly gained popularity.[4]

After a successful and state-of-the-art TEVAR, significant upward drag forces were observed in the curvature of the aortic arch. The forces going into the descending aorta, pushing the aorta laterally oblique in the thorax cavity, provoke a proximal migration force to the distal end of the thoracic stent graft, resulting in endoleaks. The definition of type 1 endoleak is flow entering into the aneurysm sac from either the proximal or the distal end of the stent graft with higher risk of aneurysm sac expansion and rupture.[5–7] As type 1 endoleak develops, the renewed pressure on the weakened aortic wall has an increased rupture risk in comparison to an unrepaired aneurysm with the same diameter.[8] Therefore, both proximal and distal type 1 endoleaks need reintervention.[7]

There is lack of evidence on type 1b endoleak, as many articles only focus on the proximal type 1 endoleak.[9–11] This is mostly attributable to the angulation of the aortic arch, which is a risk factor for bird-beak configuration and suboptimal stent graft deployment.[12] The ever-evolving technology has brought on the development of more conformable stent grafts to minimize this complication. Type 1b endoleaks in endovascular aortic repair (EVAR) are much more substantiated by published evidence. Among other elements, tortuosity of the iliac arteries and the influence of drag forces for abdominal aortic aneurysms have been investigated. Likewise, an increase in neck angulation, resulting in higher drag forces, could cause endoleaks.[13,14]

In our studies, we documented an increase of the aortic diameter over time at the transition zone from the stent graft into the nonstented aorta.[15] The spiraling blood stream enters the stent graft and has to change its original vortex because of a significant change in shear stresses inside a long-segmental stent graft compared with the elastic properties of a native nonstented aorta. This might be responsible for an energy burst at the outlet of the stent graft inducing dilatation of the native aorta at this transition zone.

To investigate whether more institutions have observed type 1b endoleak with or without proximal migration of the distal part of the thoracic stent graft at long-term follow-up, we started a systematic review, with emphasis on late type 1b endoleaks, after initial successful implantation in patients with TAA.

MATERIALS AND METHODS

The PubMed and Embase databases were systematically searched. The search was last updated in January 2019. The following keywords were used to search the electronic databases: ‘‘endoleak,’’ ‘‘endovascular repair,’’ ‘‘endovascular procedures,’’ ‘‘endovascular aortic repair,’’ and ‘‘thoracic aorta.’’ For the PubMed database, the following search was used: (Endoleak [Mesh] OR Endoleak) AND (Endovascular Procedures[Mesh] OR Endovascular repair OR Endovascular Procedures) AND (Aorta, Thoracic[Mesh] OR thoracic aorta). A similar search was applied for the Embase database.

The articles were screened for eligibility based on title and abstract by 2 independent reviewers (V.M.B. and H.W.L.d.B.). The quality measurement was done using the Newcastle Ottawa Scale.[16] Inclusion criteria included incidence and description of data specifically on predictors of type 1b endoleak after TEVAR, with a mean follow-up period of at least 1 year. Exclusion criteria included variables of interest for type 1b endoleak not specified, type 1b endoleak after TEVAR in dissections, variables of interest for type 1b after EVAR, emergency and extended surgery (e.g., chimney technique), and study population of less than 20. Reference lists of the included articles were searched for potentially relevant additional articles.

The articles were reviewed using the Meta-analysis of Observational Studies in Epidemiology guidelines.[17] Because of heterogeneity between the articles it was not possible to perform a meta-analysis, so only a pooled analysis was performed for the incidence, follow-up, and treatment.

RESULTS

A total of 828 articles were found, and after removing duplicates 683 articles were left. After reading all titles and abstracts, 80 full-text articles were read, and a total of 16 articles were included in this systematic review, all retrospective small cohort studies. For full search strategy, see Figure 2 and articles listed in Table I.

Incidence

Sixteen articles reported the incidence of endoleak type 1b after TEVAR.[9,11,18–31] The mean follow-up duration was between 12 and 76 months. In the selected articles, the incidence for the overall endoleak type 1b was between 1.0% and 15.0%. Type 1b endoleak can occur as an early (<30 days) or late (>30 days) endoleak. Early type 1b endoleak occurred in 1.3–8.1%, and late type 1b endoleak occurred in 3.1–5.0%. There were 3 articles describing the incidence of type 1b endoleak beyond 5 years of follow-up, which was 1.1–3.1%, although it was not reported at what point during the follow-up period the endoleaks occurred.[20,25]

When dividing the incidence in 2 periods (1–2 and 3–5 years), the incidence remains the same. Ten articles with a 1–2-year follow-up duration had an incidence between 1.0% and 15.0%,[9,11,18,22,26–31] and 6 articles with a follow-up duration of 3–5 years had an incidence between 0.4% and 16%.[19–21,23–25]

A pooled analysis was performed for the 16 articles, which gives a mean incidence of 4.3% (Table I).

Risk Factors

Morphologic/anatomic tortuosity. One of the 16 selected articles addresses the influence of tortuosity of the aorta on endoleak formation.[27] Nakatamari et al.[27] looked at the association between native thoracic aortic curvature and the development of endoleaks in 40 patients. A higher curvature index (>0.15 cm^{-1}) was associated with a higher incidence of type 1b endoleak. The curvature ratio was measured as the inverse radius of curvature (cm^{-1}) at 10-mm intervals along the median luminal centerline on 3-dimensional reconstructions of CT angiograms.[27]

Related to extreme tortuosity in the descending thoracic aorta, Kratimenos et al.[23] reported a technical failure; the deployment of the endograft was unsuccessful because of tortuosity (Table II).

Clinical characteristics. No articles report on the clinical characteristics of type 1b endoleak. It is important to know whether the diameter of the aneurysm is of influence, length of the landing zone, or other stent graft or aneurysmal-related characteristics.

Treatment

In most cases, treatment is required to prevent expansion of the aneurysm sac,[6,32] although in

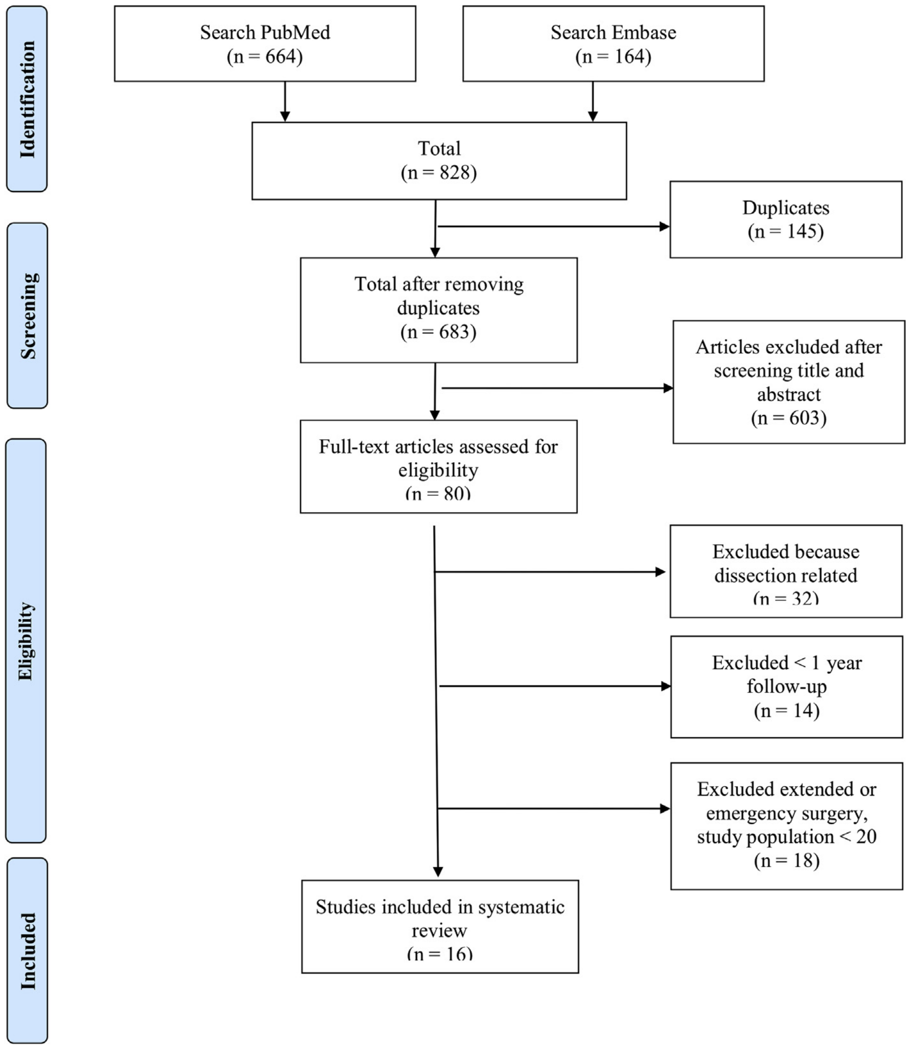

Fig. 2. Flow diagram search.

some cases, early type 1 endoleaks may resolve without interventions.[33,34] Most articles report that reinterventions were performed to treat type 1b endoleak. Of the 63 reported type 1b endoleaks, the management is described for 27 cases. This included 21 secondary TEVARs/distal stent graft extensions (76.9%), 1 embolization (3.8%), 0 open repairs (0%), and 5 had no reintervention (19.2%). One type 1b endoleak resulted in death because of aneurysm rupture.[21] See also Table I for further specifications.

Prognosis

One article in this systematic review reported that type 1b endoleak was spontaneously resolved.[9] Of the 5 patients who had type 1b endoleak but did not undergo reintervention, 3 endoleaks (60%) resolved spontaneously and 2 patients (40%) refused reintervention. No reasons were given on how it was possible that the endoleaks resolved spontaneously. The study did not specify whether the endoleaks presented early or late in the patient's postoperative course. There were no articles comparing the prognosis of patients with type 1b endoleak to patients versus those who did not have type 1b endoleak.

DISCUSSION

This article shows there is lack of data surrounding type 1b endoleaks in TEVAR. Unfortunately because of the paucity of data, no firm conclusions can be made regarding morbidity, mortality, risk factors,

Table I. Overview of selected articles; incidence, study population, follow-up, reintervention, and Newcastle Ottawa Score

Study	Year	Number of patients in the study	Incidence of type 1b endoleak	Follow-up duration	Reinterventions for type 1b endoleak	Newcastle Ottawa Score[a]
			n (%)	Mean (range)		
Ammar et al.[18]	2016	62	Early: 5 (8.1) Late: 2 (3.2)	15.3 months (0–44)	• 6 secondary TEVAR • 1 embolization	S: 3 C: 1 O: 2
Czerny et al.[19]	2004	54	2 (3.7)	38 months (1–72)	• Reintervention not specified	S: 4 C: 1 O: 2
Farber et al.[20]	2017	133	2 (1.5)	60 months (54 patients completed the study)	• Reinterventions not specified	S: 3 C: 1 O: 2
Geisbüsch et al.[21]	2019	37	1 (2.7)	36 months (6–120)	• 1 death because of aneurysm rupture	S: 4 C: 1 O: 2
Hughes et al.[22]	2010	210	2 (1.0)	23 months (6–55)	• 1 no reintervention • secondary TEVAR	S: 3 C: 1 O: 2
Kratimenos et al.[23]	2019	30	1 (3.3)	31.7 months	• 1 secondary TEVAR	S: 4 C: 1 O: 2
Makaroun et al.[24]	2008	140	Early: 2 (1.4) Late: 7 (5.0)	37 months (1–66)	• Reintervention not specified	S: 3 C: 1 O: 2
Matsumura et al.[25]	2014	160	Early: 2 (1.3) Late: 5 (3.1)	60 (53 completed study)	• 4 secondary TEVAR • 3 not specified	S: 4 C: 1 O: 2
Melissano et al.[26]	2011	158	2 (1.3)	24 months	• Reintervention not specified	S: 4 C: 1 O: 2
Morales et al.[11]	2008	200	Early: 5 (2.5)	30 months (12–73)	• 3 secondary TEVAR • 2 reinterventions not specified	S: 4 C: 1 O: 2
Nakatamari et al.[27]	2011	40	6 (15.0)	2 months	• Reintervention not specified	S: 4 C: 1 O: 2
Parmer et al.[9]	2006	69	7 (10.1)	17.3 months (3–71)	• 3 no reinterventions • 4 secondary TEVARs	S: 3 C: 1 O: 2

Piffaretti et al.[28]	2009	61	1 (1.6)	32.4 months (1−96)	• Reintervention not specified	S: 4 C: 1 O: 2
Riambau et al.[29]	2019	24	1 (4.2)	13.5 months	• 1 secondary TEVAR	S: 4 C: 1 O: 2
Rylski et al.[30]	2013	105	10 (9.5)	18 months	• Reintervention not specified	S: 3 C: 1 O: 2
Yunoki et al.[31]	2015	36	2 (5.6)	33.2 months	• No reintervention • 1 secondary TEVAR	S: 4 C: 1 O: 2
Total		1,519	65 (4.3)		Secondary TEVAR: 21 Embolization: 1 Open repair: 0 Death: 1 No reintervention: 5 Reintervention not specified: 37	

Good quality: 3−4 in selection, 1−2 in comparability, and 2−3 in outcome. *Fair quality*: 2 in selection, 1−2 in comparability, and 2−3 in outcome. *Poor quality*: 0−1 in selection, 0 in comparability, and 0−1 in outcome.

[a]NOS: selection criteria based on selection (0−4), comparability (0−2), and outcome (0−3).

Table II. Risk factors type 1b endoleak

No.	Study	Aim	Study design	Risk factors related to type 1b endoleak
1.	Nakatamari et al.[27]	Impact of thoracic aortic morphology on development of endoleaks	Retrospective observational study	Large curvature index at the thoracoabdominal junction (related to endoleak type 1b)

aortic interventions, and prognosis. Most commonly, type 1 endoleak is described without differentiating between the proximal or distal type 1 endoleak. Typically, the focus has been on the proximal type 1a endoleaks. This may stem from a heightened awareness because of an advanced understanding and greater interest in the more challenging treatment of the aortic arch because of curvature and the supraaortic trunks.[35] However, both proximal and distal type 1 endoleaks need treatment because of the high risk of aneurysm rupture.[32]

As the overall quality of the articles included in this review is mediocre and consist of only retrospective reviews of small case series, there are some limitations to this review. There are no randomized controlled trials included, and because of heterogeneity, a metaanalysis could not be conducted. In all studies, it has not been described whether the Instructions for Use (IFU) for the devices was followed. A study by Schanzer et al.[36] reported that complications in EVAR are not always caused by device failure. A great part is also dedicated to the physicians who are not following the IFU for the devices and use them in poorly suited anatomy. Furthermore, nothing is reported on the postoperative imaging protocol to give a better insight in the follow-up period and when type 1b endoleaks were discovered. The variable length of follow-up, with only 3 articles reporting on endoleaks with a mean follow-up of 5 years, shows the need of better postoperative protocol. This is to understand the natural habitat of endoleaks and obtain durable results. Likewise, no articles report on the differences between older and newer generations of stent grafts. Technologies are evolving, so the complication rate might be lower in the more conformable stent grafts. No articles report characteristics related to type 1b endoleak, such as the influence of distal neck length (i.e., the distal sealing zone), which preferably should be 20 mm, the amount of oversizing, and different brands of stent grafts. Some stent grafts have designed components for active fixation after EVAR.[37] The effect of active fixation on the prevention of endoleaks should be investigated for endoleaks after TEVAR. A recent study shows that the use of EndoAnchors (Medtronic Vascular, Santa Rosa, CA, USA) prevents complications after TEVAR,[38] but still no long data are available. Future studies need to address the more clinical and anatomic risk factors for type 1b endoleak.

The incidence of type 1b endoleak seems to be between 1.0% and 15.0%, which is relatively high compared with major endograft trials where the incidence lies between 1.3% and 5.6%.[20,24–26,31] An explanation might be selection bias or lower incidence in the major trials because of strict adherence to anatomic inclusion criteria. Type 1a endoleak incidence lies between 0% and 11.4%,[20,24–26,31] which is similar to the incidence of type 1b. As the incidence is similar, it is likely that both endoleaks have the same pathophysiology and are equally important. Nowadays, more conformable stent grafts minimize bird beaking from happening related to type 1a endoleak.[39] Comparing type 1 endoleak in TEVAR to EVAR, the incidence for type 1 endoleak in TEVAR is relatively higher.[14] According to the literature this could be due to the size of the thoracic aorta and angulations of the arch[14] or due to the change of diameter of the thoracic aorta in the cardiac cycle.[40] The occurrence of type 1b endoleak in TEVAR is difficult to predict and often results in reinterventions or even treatment failure.[41,42] In EVAR type 1b, endoleaks are more common in patients with dilated, calcified, short, and tortuous iliac arteries.[14] This has not been investigated in such a granular fashion for type 1b endoleaks after TEVAR.

One of the articles included reports on a relationship between a highly tortuous aorta and the incidence of endoleak type 1b.[27] Two other studies, which were not selected for this systematic review because of short follow-up duration, reported similar outcomes.[43,44] Both investigated the influence of aortic tortuosity on the occurrence of type 1b endoleak. Kotelis et al.[43] researched aortic conicity and stent graft oversizing on the occurrence of endoleaks in a patient sample of 57. The study by Ueda et al.[44] assessed the native thoracic aortic tortuosity and the development of endoleaks in 40 patients, which is similar to the study by Nakatamari et al.[27]

Measurements done with CT angiography showed a larger tortuosity index at the distal fixation zone in patients with type 1b endoleak compared with those with no endoleak.[44]

Piffaretti et al.[28] looked at different clinical characteristics related to endoleaks; however, not specified for type 1b endoleak. In endoleak versus no endoleak, the TAA diameter reached statistical significance ($P = 0.03$; 7.7 vs. 5.4 mm). Likewise, a number of stent graft variables were measured; stent diameter (39 vs. 34.8 mm) and aortic length coverage (20.7 vs. 18.3 mm) and number of stents (1.9 vs. 1.2), with each of these reaching statistical significance[28] ($P = 0.003$; $P = 0.022$; $P = 0.002$). No articles reported other factors, which influenced type 1b endoleak (Table II). The correlation with an increasing incidence of endoleaks could not be shown for parameters, such as type of aneurysm, age, gender, or atherosclerotic burden, but again, it was not specified whether type 1b endoleaks were expressly being addressed.[9,28,45] Consequently, the data are limited, and more research is needed to be able to draw any conclusions, particularly as it relates to clinical outcomes.

One of the purported theories for the development of type 1b endoleaks is supported by flow studies, which demonstrates that in long thoracic aortic stent grafts high shear stress creates an explosion of energy at the end of the stent graft.[15] This phenomenon has been observed to create a dilation of the native aorta at the transition between the stent and the aorta. High displacement forces have been shown to push the stent graft retrograde with potentially causing type 1b endoleak at long-term follow-up. These observations should be investigated prospectively to get a better awareness of the occurrence of type 1b endoleak.

Whether this is ultimately one of the main causes of type 1b endoleaks, it is clear from our review with only 1 case describing spontaneous resolution of type 1b endoleak,[9] we can likely draw a safe conclusion that most will probably require an intervention. The paucity of data allow us to draw neither any conclusions as to the number of endoleaks that will require reintervention nor the ideal approach to managing this event.

In this review, dissections have not been included because it is widely acknowledged that the criteria for the definition of endoleaks for aneurysm are not fully applicable to dissections.[46] A variety of definitions have been used for type 1b endoleak after TEVAR in dissections. Some authors reported endoleak as flow into the false lumen (FL) because of an ineffective seal at 1 extremity of the stent graft,[47] others as any failure of entry tear closure resulting in continued antegrade or retrograde FL perfusion,[48] or as any radiologic evidence of blood flow outside the stent graft, except persistent retrograde FL perfusion.[49] Consensus reporting criteria are required to account for situations unique to dissection.[46]

In conclusion, long-term follow-up should be not only recommended but also documented. Sustainable safety and efficacy is of utmost importance in endovascular treatment for aorta pathology. Possible late complications, such as type 1b endoleaks in initial successful TEVAR, can only be determined when long-term follow-up is taken seriously with a minimum of lost to follow-up. Our systematic review has demonstrated that there is a serious need for better registration and publication of possible complications, which might not be expected after an initial successful TEVAR. Data clearly delineating the anatomic variables predicting type 1b endoleak should be examined and listed. Likewise, the impact of more recent conformable devices to prevent complications like type 1b endoleaks from occurring should be elucidated.

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