Fate of primary determinate and indeterminate target vessel endoleaks after fenestrated-branched endovascular aortic repair

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ABSTRACT

Objective: The aim of this study was to investigate the outcomes of primary determinate and indeterminate target vessel endoleaks (TVELs) after fenestrated-branched endovascular aortic repair (F-BEVAR).

Methods: We conducted a single-center retrospective study (2014-2023) on F-BEVAR for thoracoabdominal (TAAAs) or pararenal aortic aneurysms (PRAAs). TVELs were classified as "primary" if present at the first postoperative computed tomography angiogram. Endoleaks were defined "determinate" (dELs) if the cause (type Ic or IIIc) and implicated target vessel were identifiable and "indeterminate" (iELs) if contrast enhancement was detectable at the level of fenestrations/branches without any evident source. Endoleaks involving multiple inflows (type II and target vessels) were defined as "complex" (cELs). Endpoints were endoleak spontaneous resolution, 1-year aneurysm sac failure to regress (>5 mm diameter decrease), and 4-year endoleak-related secondary interventions. Kaplan-Meier estimates and Cox regression were used for the analysis.

Results: There were 142 patients with JRAAs/PRAAs (n = 85; 60%) or TAAAs (n = 57; 40%), with 513 target arteries incorporated through a fenestration (n = 294; 57%) or directional branch (n = 219; 43%). Fifty-nine primary TVELs (12%) were identified in 35 patients (25%), a dEL in 20 patients (14%) and iEL in 15 (11%); 22 (15%) had a determinate or indeterminate cEL. Overall spontaneous resolution rate was 75% (95% confidence interval [CI], 51%-87%) at 4 years. cELs (odds ratio [OR], 5.00; 95% CI, 1.10-49.4; $P < .001$) and iELs after BEVAR (OR, 9.43; 95% CI, 3.41-56.4; $P = .002$) were more likely to persist >6 months, and persistent forms were associated with sac failure to regress at 1 year (OR, 1.72; 95% CI, 1.03-12.59; $P = .040$). Overall freedom from endoleak-related reinterventions was 85% (95% CI, 79%-92%) at 4 years, 92% (95% CI, 87%-97%) for those without primary TVELs and 62% (95% CI, 46%-84%) for those with any primary TVEL ($P < .001$). In particular, cELs (hazard ratio, 1.94; 95% CI, 1.4-18.81; $P = .020$) were associated with an increased need for reintervention. In case a secondary intervention was needed, iEL or cEL had an increased risk for multiple secondary procedures (hazard ratio, 2.67; 95% CI, 1.22-10.34; $P = .034$).

Conclusions: Primary TVELs are frequent after F-BEVAR, and a clear characterization of the endoleak source by computed tomography angiogram is not possible in 40% of patients. Most primary TVELs spontaneously resolve, but during follow-up, patients with any primary TVEL experience a worsened freedom from endoleak-related reinterventions that is mostly driven by persistence of cELs and post-BEVAR iELs. Multiple secondary procedures may be required in case of iELs or cELs. (J Vasc Surg 2024;79:207-16.)

Keywords: Aortic aneurysm; Computed tomography angiography; Endoleak; Endovascular aneurysm repair; Fenestrated-branched endovascular aneurysm repair; Target vessel

Complex endovascular aortic repair with fenestrated (FEVAR) or branched (BEVAR) endografts represents a valid option for the treatment of aortic aneurysms involving the renal-mesenteric arteries, providing satisfactory safety, efficacy, and mid-term outcomes.[1-4]

F-BEVAR implies the incorporation of aortic side branches through the deployment of covered bridging stents that connect the target vessels with the main fenestrated/branched aortic endograft. Compared with standard infrarenal endovascular aortic repair, F-BEVAR configuration exposes the endovascular implant to additional risks of endoleaks, as each inter-attachment site between the main endograft and the bridging stents and each sealing zone into the target vessel represents a weak point that may act as a possible source of endoleak after complete implantation. Hence, primary target vessel

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endoleaks (TVELs) may be commonly observed at the first postoperative computed tomography angiogram (CTA) after F-BEVAR.[5] However, a clear identification of the cause (type Ic or IIIc)[2] and specific implicated target vessel is not always possible, and some TVELs may remain "indeterminate." The optimal clinical management of these determinate and indeterminate primary endoleaks is currently not well-established. Although some specific types, such as Ic or disconnections, are the result of an evident technical defect and are usually considered for prompt correction,[2] the natural history of primary interattachment or indeterminate endoleaks (iELs) without a visible structural defect is not clear.

Nevertheless, the identification of primary TVELs at risk of complications may be useful to optimize the follow-up protocol after F-BEVAR, indications to invasive imaging and secondary procedures. The aim of the study was to investigate the outcomes of primary determinate and indeterminate TVELs after F-BEVAR identified at the postoperative CTA, and to characterize those at risk for adverse outcomes during follow-up.

ARTICLE HIGHLIGHTS

- **Type of Research:** Single-center retrospective study
- **Key Findings:** After fenestrated-branched endovascular repair, a primary target vessel endoleak (TVEL) was detected in 25% of patients, in which the source of the leak was not identifiable in 40% (indeterminate endoleak). Most TVELs spontaneously resolved, but during follow-up, patients with any primary TVEL had a lower freedom from endoleak-related reinterventions compared with those without primary TVELs, that was driven by complex and post branched endovascular repair indeterminate endoleaks.
- **Take Home Message:** Primary TVELs are frequent after fenestrated-branched endovascular repair, but a clear characterization of the endoleak source by computed tomography angiography is not always possible. A first-line conservative management may be acceptable; however, patients with persistent endoleaks should be carefully followed, and second-line dynamic imaging studies may be considered for better identification of the source and eventual secondary intervention planning, especially in case of indeterminate or complex endoleaks.

METHODS

Patient population. We conducted a retrospective chart review on consecutive patients (January 2014 to March 2023). Only patients treated by F-BEVAR and follow-up duration >3 months were included in the analysis. Patients treated with physician-modified grafts were excluded. Institutional review board requirements were waived for this retrospective study.

Data collection and definitions. Demographics, clinical characteristics, cardiovascular risk factors, and operative and postoperative variables were collected. Anatomic extent of aneurysm was evaluated by CTA and classified according with the current reporting standards.[2]

Device design. A proximal sealing zone of at least 20 mm in length was selected in normal suprarenal aortic segments, defined by parallel aortic wall with no evidence of thrombus, calcium, or diameter enlargement of >10%. Options for vessel incorporation were large (8 × 8 mm) or small fenestrations (6 × 6 mm) and directional branches (8 or 6 mm). The specific device design varied depending on the aneurysm extent, vessel angulation, and diameter of the aortic lumen.

Fenestrations were preferred for juxtarenal (JRAA) or pararenal (PRAA) aneurysms. FEVAR endografts were based on the Cook Zenith (Cook Medical, Inc) or Terumo Aortic platforms. Directional branches were generally used for extent I to III thoracoabdominal aneurysms (TAAAs), if the aortic lumen was large (>30 mm), and the target vessel orientation was down-going without excessive tortuosity.[6] Inner branches were sometimes selected in case of inner aortic lumen of 25 to 35 mm or angulations[7] at the level of the paravisceral aorta. Custom-made branched devices were based on the Cook Zenith (Cook Medical, Inc) or Artivion E-xtra design platform. The outer-branched Cook T-branch (Cook Medical, Inc) or inner-branched Artivion E-nside were used as off-the-shelf devices.[8]

Target vessel stenting. Catheterization and stenting of fenestrations were usually performed from a femoral access. Fenestrations were stented using a balloon-expandable stent graft as the main bridging stent. The Advanta V12/iCAST (Atrium Maquet Getinge), Lifestream (BARD Peripheral Vascular), Begraft (Bentley InnoMed), Viabahn balloon expandable stent-graft (VBX, W.L. Gore & Associates), and iCover (iVascular) were used. The bridging stent was deployed with the aim to achieve a 15-mm sealing length into the target artery and a protrusion into the aortic graft of 3 to 5 mm.[9] After deployment, the proximal edge was systematically flared using a 12 × 20 mm or 10 × 20 mm balloon (Powerflex Pro PTA; Cordis).

Catheterization and stenting of BEVAR target vessels were usually performed from a surgical left brachial or percutaneous left axillary access. Self-expanding covered stents were preferred for the bridging of directional branches. The Viabahn (W.L. Gore & Associates), VBX (W.L. Gore & Associates), Covera (CR Bard, Inc), or Fluency (CR Bard, Inc) stents were used as bridging stents. The stent was usually deployed to achieve a 20-mm seal length into the target artery. The cuff segment was proximally stabilized with a short balloon-expandable covered stent if the self-expanding bridging stent did

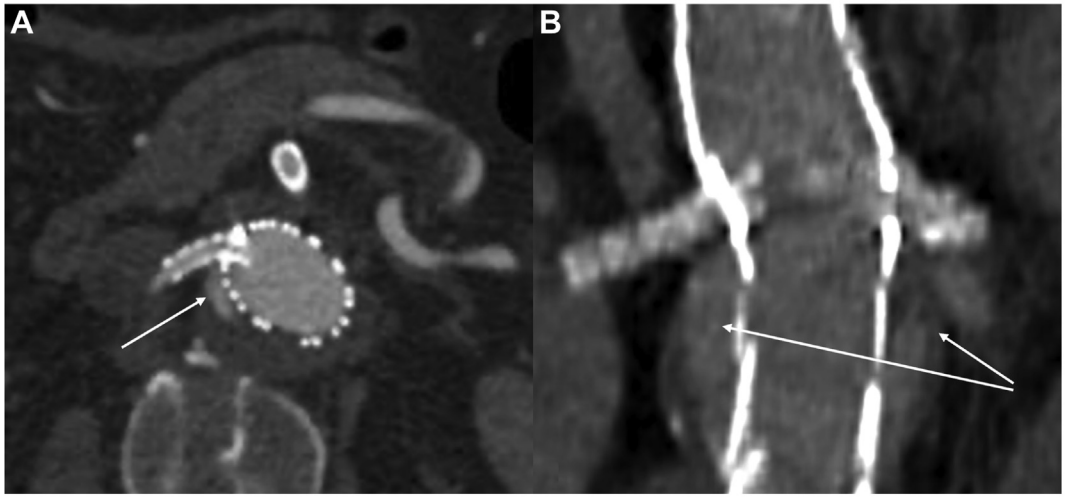

Fig 1. A, Computed tomography angiogram (CTA) axial view of a determinate target vessel endoleak (TVEL) (*white arrow*) arising from the interattachment site (type IIIc) at the level of the right renal fenestration. **B,** CTA coronal view of an indeterminate endoleak after fenestrated endovascular aneurysm repair (FEVAR) (*white arrows*), appearing as a contrast enhancement area at the level of fenestrations, without any clearly identifiable structural defect or source.

not completely overlap with the proximal branch cuff. An adjunctive self-expandable bare metal stent was used in cases of intraoperative evidence of branch or target artery kink or compression after stent graft implantation.[10]

Postoperative medical therapy was standardized and consisted of dual antiplatelet (aspirin 100 mg and clopidogrel 75 mg) therapy for 30 days, followed by long-term single antiplatelet therapy with aspirin.

Imaging follow-up and endoleak assessment. All imaging assessments were performed with the Aquarius iNtuition software (v 4.4.13; TeraRecon). Imaging follow-up consisted of a CTA within 30 days and at 6 months, 12 months, and annually thereafter. In patients with renal function impairment contraindicating contrast dye administration, a CT without contrast and duplex ultrasound of the renal-mesenteric arteries was considered for imaging follow-up ≥6 months. In case of aneurysm sac enlargement, a CTA was always performed for characterization of the type of endoleak and eventual planning of secondary treatment.

Endoleaks were classified as "primary" if present at the first postoperative CTA, "secondary" if development of a new endoleak was detected after the original procedure and the first follow-up CTA had demonstrated absence of an endoleak.[2] TVELs were defined as those arising from fenestration/branches, interattachment between main endografts and bridging stents, bridging stents defect, or inadequate sealing on the target vessel. These were defined "determinate" (dEL) if the cause (type Ic, IIIb, or IIIc) and implicated target vessel were identifiable on the CTA (Fig 1, *A*). If contrast enhancement was detectable outside the endograft at the level of fenestrations/branches, without any evident inflow source or structural defect after assessment by two independent physicians, these were defined as target vessel "indeterminate endoleaks" (iELs) (Fig 1, *B*). The definition of dEL vs iEL was based exclusively on the postoperative CTA, because CTA represents the gold standard for imaging follow-up after F-BEVAR, and to avoid any potential definition bias introduced by the use of different imaging techniques that are not routinely performed. Indeterminate TVELs whose source remained uncertain also after eventual invasive angiography were defined as "re-classified iELs." Determinate or indeterminate TVELs with multiple inflows (typically type II endoleak) were defined as "complex" (cELs). Primary TVELs associated with a clear technical defect, such as a type Ic, fracture, or disconnection, were addressed to early correction. Type IIIc interattachment endoleaks (without evident structural defects) and iEL were typically observed for 3 to 6 months and addressed to secondary procedures if persistent and associated with aneurysm sac growth.[11] Spontaneous resolution was defined as the disappearance of a previously present endoleak on follow-up CTA, without the need for any reintervention. Primary endoleaks lasting for >6 months were defined as "persistent."

Aneurysm size was measured as the maximum aneurysm diameter on orthogonal views. Aneurysm size was assessed after 1 year from the index intervention[12] and classified according to reporting standards as expanded (>5 mm diameter increase), regressed (>5 mm diameter decrease), or stable.[2,12] Aneurysm failure to regress was defined as the presence of an increased or stable sac size without signs of a significant shrinkage at 1 year.[12]

Endpoints. Endpoints were primary TVEL spontaneous resolution, 1-year aneurysm sac failure to regress, and mid-term endoleak-related secondary interventions.

Table I. Demographics, clinical, anatomical, and procedural data of 142 patients treated by fenestrated-branched endovascular aneurysm repair (F-BEVAR), stratified by presence of primary target vessel endoleak (*TVEL*) at the first postoperative computed tomography angiogram (CTA)

	All patients (n = 142)	No primary TVEL (n = 110)	Primary TVEL (n = 32)	*P* value
Demographics				
Age, years	72.2±9.8	71.8±8.8	73.5±12.9	.397
Age >80 years	25 (17)	17 (15)	8 (25)	.289
Male sex	121 (85)	93 (85)	28 (88)	.679
Risk factors				
Hypertension	124 (87)	94 (86)	30 (94)	.214
Diabetes	23 (16)	20 (18)	3 (9)	.234
Dyslipidaemia	90 (63)	70 (64)	20 (63)	.907
CAD	66 (46)	54 (49)	12 (38)	.247
COPD	20 (14)	17 (15)	3 (9)	.384
CKD	46 (32)	32 (28)	14 (45)	.067
PAD	12 (9)	10 (9)	2 (6)	.611
Connective tissue disease	3 (2)	0 (0)	3 (9)	.001[a]
Prior TIA/stroke	15 (11)	11 (10)	4 (13)	.722
Prior laparotomy	46 (48)	34 (46)	12 (56)	.325
Prior aortic surgery	38 (27)	28 (26)	10 (31)	.515
SVS comorbidity score	7.8±3.4	7.5±3.4	8.5±3.2	.115
Anatomical data				
Aneurysm maximum diameter, mm	59.4±11.5	59.2±11.7	60.1±11.0	.732
Aneurysm extent				.728
JRAA/PRAA	85 (59)	67 (61)	18 (56)	
TAAA extent IV	24 (17)	19 (17)	5 (16)	
TAAA extent I-III	33 (23)	24 (22)	9 (28)	
Aortic dissection	5 (4)	3 (3)	2 (6)	.314
Procedural data				
Endograft design				.442
Patient-specific device	115 (81)	87 (79)	28 (87)	
Off-the-shelf device	27 (19)	23 (21)	4 (13)	
Number of target vessels per patient	3.6±0.6	3.6±0.6	3.6±0.7	.359
Target vessel incorporation				.632
Fenestrations only	81 (57)	63 (57)	18 (56)	
Directional branches only	56 (40)	44 (40)	12 (38)	
Mixed	5 (4)	3 (3)	2 (6)	
Fenestrations	(N = 294)	(n = 258)	(n = 36)	
Main bridging stent				.008[a]
Gore VBX	194 (66)	174 (67)	20 (56)	
Bard Lifestream	38 (13)	27 (10)	11 (31)	
Advanta V12/iCast	20 (7)	18 (7)	2 (6)	
iVascular iCover	42 (14)	39 (15)	3 (8)	
Bridging stent diameter, mm	7±1	7±1	7±1	.685
Bridging stent length, mm	31±5	31±5	33±4	.081
Adjunctive self-expandable BMS	6 (2)	5 (2)	1 (3)	.546
Adjunctive BESG	15 (5)	11 (4)	4 (13)	.096
Directional branches	(N = 219)	(n = 198)	(n = 21)	

Table I. Continued.

	All patients (n = 142)	No primary TVEL (n = 110)	Primary TVEL (n = 32)	*P* value
Main bridging stent				.425
Bard Covera	117 (53)	106 (54)	11 (52)	
Bard Fluency	50 (22)	46 (23)	4 (19)	
Gore Viabahn	24 (11)	21 (11)	3 (14)	
Gore VBX	28 (13)	25 (13)	3 (14)	
Bridging stent diameter, mm	7.7±1.5	7.8±1.5	7.5±1.4	.444
Bridging stent length, mm	70.9±20.0	70.8±20.3	71.8±18.9	.815
Adjunctive self-expandable BMS	50 (22)	43 (22)	7 (33)	.159
Adjunctive BESG	69 (32)	61 (31)	8 (38)	.471

BESG, Balloon-expandable stent graft; *BMS*, bare metal stent; *CAD*, coronary artery disease; *CKD*, chronic kidney disease; *COPD*, chronic obstructive pulmonary disease; *JRAA*, juxtarenal aortic aneurysm; *PAD*, peripheral artery disease; *PRAA*, pararenal aortic aneurysm; *SVS*, Society for Vascular Surgery; *TAAA*, thoracoabdominal aortic aneurysm; *TIA*, transient ischemic attack.
Data are presented as number (%) or mean ± standard deviation.
[a]Statistically significant.

Statistical analysis. Results were reported as a number and percentage for categorical variables, mean ± standard deviation or median (interquartile range) for continuous variables. Time-dependent outcomes were reported using Kaplan-Meier estimates. Univariate and multivariable logistic regression models were used to identify factors associated with spontaneous resolution and failure to regress. Patients with follow-up duration shorter than 1 year were excluded from sac regression analysis because it may be clinically not long enough to reliably assess sac size modifications.[12] Cox proportional hazards models were used to identify factors associated with endoleak-related reinterventions. Determinate TVELs associated with structural defects (type Ic or disconnection) that received early treatment before dismissal were excluded from the analysis, since a prompt correction is advocated in these cases. Covariates with univariate significance $P < .200$ were entered into the initial multivariable model; a backward stepwise selection of covariates was performed, and the most parsimonious model with inclusion of significant factors and confounders was selected as the final model. A penalized likelihood method based on Firth's regression[13] was adopted to account for the limited number of events. The unit of the analysis for endoleak resolution and aneurysm failure to regress was the single patient; the analysis of endoleak-related reinterventions was performed by target vessel. A *P* value of less than .05 was used to determine statistical significance. The R 4.0.4 software (R Foundation for Statistical Computing) was used for the analysis.

RESULTS

Patients' cohort. There were 142 patients with JRAA/PRAA (n = 85; 60%), extent IV (n = 24; 17%), or extent I to III (n = 33; 23%) TAAA, with 513 target arteries successfully incorporated through a fenestration (n = 294; 57%) or directional branch (n = 219; 43%). Three patients died within 3 months from the index procedure for non-related causes and were excluded from the present analysis. Mean age was 72 ± 10 years, and 85% of patients were male. Demographics and risk factors of the patient cohort are described in Table I. A patient-specific custom-made endograft was used in 87% of patients, with incorporation of 3.6 ± 0.6 target arteries per patient (Table I). Median follow-up was 25 months, and overall survival at 4 years was 85% (95% CI, 80%-92%).

Endoleak assessment. Twenty-seven (19%) type II and 21 (15%) TVELs were present at the completion angiography. Imaging findings at the first postoperative CTA, including non-TVELs and TVELs, are summarized in Table II. Fifty-nine TVELs (12%) were identified in 35 patients (25%), of which 19 (54%) had a TVEL at the completion angiogram. A dEL was present in 25 target vessels (5%) in 20 patients (14%), including 2 type Ic, 1 disconnection, and 22 IIIc interattachment endoleaks. Thirteen patients (68%) with dEL had a complex endoleak with associated type II component. There were 34 target vessels (7%) in 15 patients (11%) with iEL, of which nine (56%) had associated type II endoleak. Endoleaks type Ic (n = 2) and disconnections (n = 1) were successfully corrected before dismissal and were excluded from the subsequent analysis that included 17 patients with dELs (n = 22 target vessels) and 15 with iELs (n = 34 target vessels) without evident structural defect that did not receive any endoleak-related reintervention during the initial admission (Fig 2).

Considering anatomical and procedural data, aneurysm extension ($P = .728$) and graft design ($P = .632$) were not associated with primary TVELs in the overall cohort. The use of Lifestream stent for the bridging of fenestrations had a higher rate of primary TVELs (31% vs 10%; $P = .008$). Type of bridging stent ($P = .425$), bridging stent reinforcement ($P = .159$), or other procedural data were not significantly associated with primary TVELs

Table II. Characteristics of primary endoleaks on the first postoperative computed tomography angiogram (CTA) of 142 patients treated by fenestrated-branched endovascular aneurysm repair (*F-BEVAR*)

	All patients (n = 142)	FEVAR (n = 85)	BEVAR (n = 57)	*P* value
Any endoleak	60 (42)	34 (40)	26 (46)	.416
Type Ia	0 (0)	0 (0)	0 (0)	.999
Type Ib	1 (1)	0 (0)	1 (2)	.404
Type II[a]	34 (24)	20 (23)	14 (25)	.812
TVEL	35 (25)	22 (26)	13 (23)	.799
Determinate TVELs	20 (14)	12 (14)	7 (12)	.806
Type Ic	2 (1)[b]	1 (1)[b]	1 (2)[b]	.999
Type IIIb	0 (0)	0 (0)	0 (0)	.999
Type IIIc interattachment	17 (12)	11 (13)	6 (11)	.794
Disconnection	1 (1)[b]	0 (0)	1 (2)[b]	.404
Complex	13 (9)	9 (11)	4 (7)	.790
Indeterminate TVEL	15 (11)	10 (12)	6 (11)	.104
Complex	9 (6)	6 (7)	3 (5)	.741

TVEL, Target vessel endoleak.
[a]Indicates type II endoleak alone, not associated with any other type of endoleak.
[b]Type Ic and disconnections received early treatment before dismissal. All cases were successfully treated without evidence of residual leak at the control CTA, therefore were not considered in the analysis as primary TVELs.

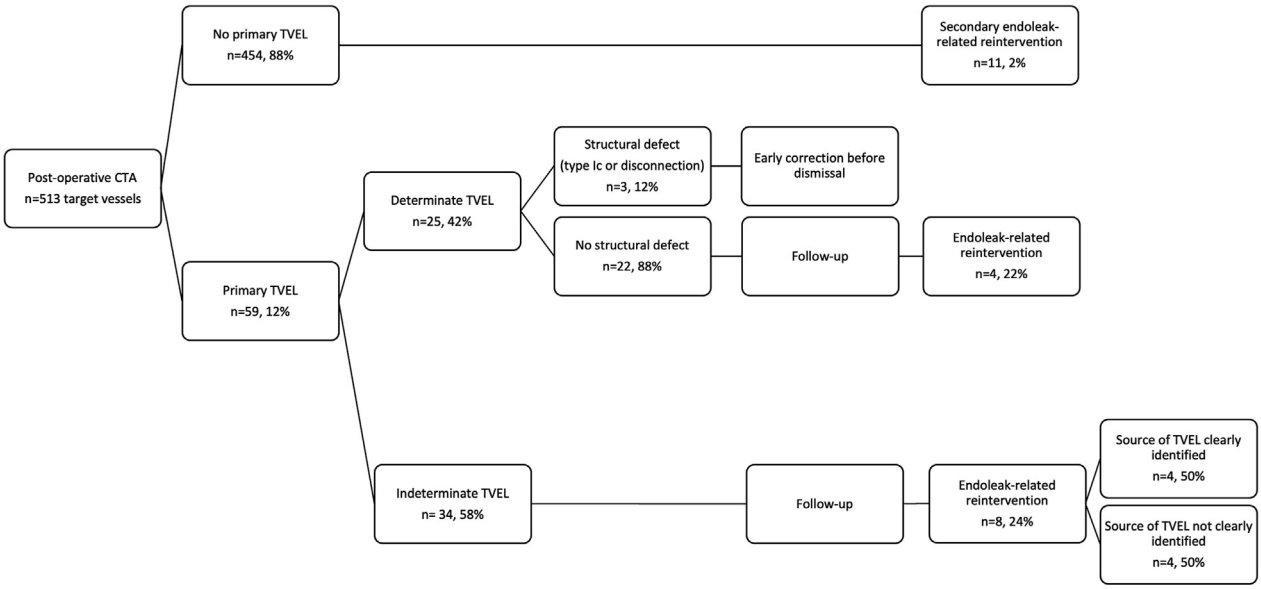

Fig 2. Flowchart representing the natural history of primary target vessel endoleaks (*TVELs*) in the 513 target vessels incoroporated through a fenestration or directional branch. By definition, indeterminate endoleaks (iELs) had no clear technical defect. *CTA*, Computed tomography angiogram.

after BEVAR. Analysis for TVEL is reported in Supplementary Table I (online only).

Endoleak spontaneous resolution and persistence. Spontaneous resolution of primary TVELs occurred in 21 patients. Estimated rate of spontaneous resolution at 48 months was 75% (95% CI, 51%-87%) (Supplementary Fig, online only) in the overall cohort; 79% (95% CI, 34%-94%) for dELs and 73% (95% CI, 32%-87%) for iELs (P = .600). Median persistence of TVELs was 6 months (interquartile range, 3-15 months). Endoleak persistence for more than 6 months was observed in 16 patients (50%), eight with dEls and eight with iELs (P = .479). Number of incorporated target vessels (odds ratio [OR], 2.73; 95% CI, 1.15-9.64; P = .020), presence of an iEL (OR, 9.85; 95% CI, 2.53-45.1; $P < .001$) or a cEL (OR, 5.00; 95% CI, 1.10-49.4; $P < .001$) were associated with TVEL persistence in the overall cohort (Supplementary Table II, online only). After stratification by type of target vessel incorporation, iELs were more likely to persist in case of

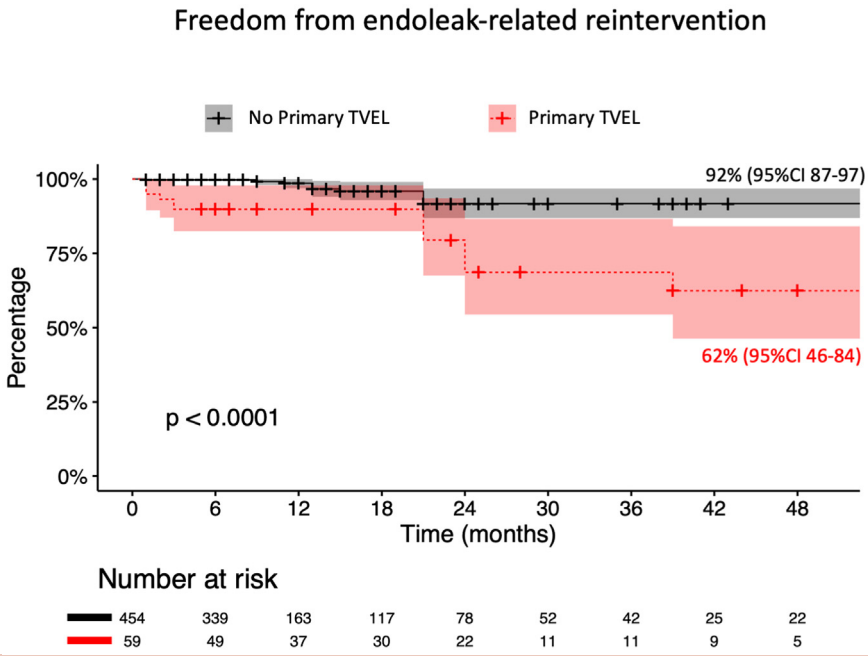

Fig 3. Kaplan-Meier curves of freedom from endoleak-related reinterventions in 513 target vessels incorporated by a fenestration or directional branch, stratified by presence of any primary target vessel endoleak (*TVEL*). Standard error <10%. *CI*, Confidence interval.

BEVAR (OR, 9.43; 95% CI, 3.41-56.4; $P = .002$) rather than FEVAR (OR, 4.81; 95% CI, 0.90-25.9; $P = .065$). Complex endoleaks had an increased risk for persistence after both FEVAR (OR, 3.03; 95% CI, 1.34-32.1; $P < .001$) and BEVAR (OR, 6.14; 95% CI, 1.54-87.1; $P < .001$). Type of bridging stent was not associated with persistence after FEVAR ($P = .325$) and BEVAR ($P = .623$).

Aneurysm sac behavior. Aneurysm size data were available for 112 patients at 1 year. Of the 30 excluded patients, 19 had received intervention for less than 12 months, six were alive at 1 year (with no available 1-year imaging), and five were dead. Aneurysm sac size was classified as regressed in 61 patients (54%); failure to regress was observed in 51 patients (46%), with a stable diameter in 42 (38%), and increased diameter in nine (8%). There were no cases of aneurysm rupture or related death during follow-up. In the overall cohort, the presence of any primary TVEL (OR, 1.85; 95% CI, 1.01-9.90; $P = .038$) was associated with aneurysm failure to regress at the univariate analysis, without significant differences in branches vs fenestrations (OR, 1.16; 95% CI, 0.41-3.50; $P = .785$) and dEL vs iEL (OR, 3.58; 95% CI, 0.42-47.0; $P = .300$). Also cELs (OR, 4.44; 95% CI, 1.02-58.0; $P = .021$) and endoleak persistence (OR, 1.55; 95% CI, 1.00-8.34; $P = .042$) were significantly associated at univariate analysis. After multivariable analysis, increased number of incorporated target vessels (OR, 2.47; 95% CI, 1.29-4.86; $P = .006$), presence of a primary type II endoleak (OR, 7.44; 95% CI, 1.07-31.7; $P = .042$), and persistence of a TVEL (OR, 1.72; 95% CI, 1.03-12.59; $P = .040$) were associated with aneurysm failure to regress (Supplementary Table III, online only). Persistence of primary TVEL was associated with failure to regress both in FEVAR (OR, 1.80; 95% CI, 1.00-18.65; $P = .043$) and BEVAR patients (OR, 1.72; 95% CI, 1.01-8.10; $P = .038$).

Endoleak-related reinterventions. During a 48-month follow-up, an endoleak-related reintervention was performed in 24 target vessels in 14 patients, 13 for a primary TVEL and 11 for a secondary TVEL. There were no reintervention-related deaths. Four patients required multiple secondary procedures owing to failure of reintervention; all of them had a cEL, which was indeterminate in three. Of the eight iELs that required secondary procedures, the source of the leak was identified by selective angiography in four (50%). Overall freedom from TVEL-related reinterventions was 85% (95% CI, 79%-92%), 92% (95% CI, 87%-97%) for those without primary TVEL, and 62% (95% CI, 46%-84%) for those with any primary TVEL ($P < .001$) (Fig 3). In particular, primary iELs (hazard ratio [HR], 3.14; 95% CI, 1.03-17.5; $P = .020$) and cELs (HR, 9.83; 95% CI, 1.3-83.42; $P = .004$) were associated with secondary procedures. After multivariable analysis, the presence of a cEL (HR, 1.94; 95% CI, 1.41-81.81; $P = .020$) was associated with an increased chance for reintervention.

After stratification by endograft design, persistent TVELs were at increased risk for reintervention after FEVAR (HR, 1.70; 95% CI, 1.01-33.63; $P = .048$); iELs (HR, 2.56; 95% CI, 1.01-35.1; $P = .049$), cELs (HR, 9.02; 95% CI, 1.03-76.43; $P = .006$), and persistent TVELs (HR, 3.03; 95% CI, 1.00-10.09;

Table III. Univariate and multivariable Cox proportional hazards for primary target vessel endoleak (TVEL)-related reintervention during follow-up

	Univariate		Multivariable	
	OR (95% CI)	*P* value	OR (95% CI)	*P* value
All patients				
TAAA	1.99 (0.71-5.45)	.190	–	–
Aneurysm max diameter, mm	0.98 (0.94-1.04)	.468	–	–
No. target vessels	0.41 (0.25-0.69)	.002[a]	0.49 (0.31-0.83)	.010[a]
Directional branch	0.44 (0.03-3.40)	.477	–	–
iEL	3.14 (1.03-17.5)	.020[a]	1.87 (0.57-4.88)	.271
Re-classified iEL	1.98 (0.91-22.18)	.118	–	–
cEL primary EL	9.83 (1.31-83.42)	.004[a]	1.94 (1.41-81.81)	.020[a]
Persistent EL	2.46 (1.00-4.46)	.050[a]	–[b]	–
FEVAR				
TAAA	2.26 (0.63-7.13)	.196	–	–
Aneurysm max diameter, mm	0.97 (0.93-1.03)	.264	–	–
No. target vessels	0.63 (0.27-1.58)	.310	–	–
Type of bridging stent, VBX stent-graft	1.21 (0.41-4.36)	.748	–	–
iEL	1.95 (0.33-8.17)	.417	–	–
Re-classified iEL	1.53 (0.30-10.11)	.573	–	–
cEL primary EL	2.22 (0.61-4.84)	.303	–	–
Persistent EL	1.70 (1.01-33.63)	.048[a]	–	–
BEVAR			–	–
TAAA	0.69 (0.13-4.68)	.676	–	–
Aneurysm max diameter, mm	0.91 (0.73-1.06)	.229	–	–
No. target vessels	0.46 (0.18-1.21)	.104	–	–
Type of bridging stent, SES	7.4 (0.71-10.35)	.106	–	–
iEL	2.56 (1.01-35.1)	.049[a]	–	–
Re-classified iEL	2.11 (0.90-39.84)	.139	–	–
cEL primary EL	9.02 (1.03-76.43)	.006[a]	–	–
Persistent EL	3.03 (1.00-10.09)	.047[a]	–	–

BEVAR, Branched endovascular aneurysm repair; *cEL*, complex endoleak; *CI*, confidence interval; *EL*, endoleak; *FEVAR*, fenestrated endovascular aneurysm repair; *iEL*, indeterminate endoleak; *OR*, odds ratio; *SES*, Self-expandable stent; *TAAA*, thoracoabdominal aortic aneurysm.
[a]Statistically significant.
[b]Excluded from multivariate model due to collinearity.

P = .047) had a higher risk for reintervention after BEVAR. In case a secondary intervention was needed, presence of an iEL or cEL had an increased risk for multiple secondary procedures (HR, 2.67; 95% CI, 1.22-10.34; *P* = .034) (Table III).

DISCUSSION

This study sought to investigate the clinical outcomes of primary TVELs after F-BEVAR, with a particular focus on the natural history in relation to the presence of an identifiable source of the leak. The existing literature on this topic is scarce; in 2019, Kärkkäinen et al[5] reported a 10% incidence of primary TVELs after F-BEVAR, with a spontaneous resolution in two-thirds during follow-up. iELs represented just 7% of all endoleaks in their cohort, but the definition of the source was based both on CTA and invasive conventional angiography, and different bridging stents were used. Besides, inclusion of also physician-modified grafts (in 37% of cases) may have contributed to the dissimilar rate of iELs, owing to different mechanical properties of modified fenestrations/branches compared with manufactured grafts, derived from different material used to reinforce the fenestration, and mild irregularities in fenestration shape or diameter.

In our study, we focused on TVELs without a clear technical defect, and detailed the outcomes of three different situations that may be recognized in the clinical practice: dEL, iEL, and cEL. These were defined on the first postoperative CTA, which, compared with completion non-selective aortogram, is more sensitive in endoleak detection and more accurate in the evaluation of morphological aspects as stent apposition, sealing length into the target vessel, protrusion length into the

aorta, and misalignment, that may help in the identification of the leak source. dELs are characterized by an identifiable target vessel origin; these represented 60% of primary TVELs and were not significantly associated with adverse outcomes both after FEVAR and BEVAR. iELs generally have a cloud-like appearance involving multiple fenestrations or branches, without a clear identifiable source. Compared with dELs, iELs are more likely to persist (OR, 9.8; $P < .001$) after BEVAR, and persistent forms are in turn associated with sac failure to regress (OR, 1.55; $P = .040$) and reintervention (HR, 3.14; $P = .020$). cELs consist in TVELs associated with type II endoleaks; they usually appear as multiple interconnected nidi of contrast enhancement within the aneurysm sac, located at the level of bridging stents and aortic side branches (intercostal, lumbar, inferior mesenteric, accessory renal arteries). These represent approximately 10% of primary endoleaks after F-BEVAR and are characterized by tendency to persist (OR, 5.0; $P < .001$) and sac failure to regress (OR, 4.4; $P = .021$). Given the high rate of spontaneous resolution, that is consistent with prior reports,[5] our results suggest that a first-line conservative approach may be acceptable regardless of endoleak type, reserving secondary procedures for those with a clear technical defect (ie, disconnection, fracture, or type Ic),[2] persistent forms, or determining aneurysm sac enlargement. Nevertheless, persistent primary TVELs, cELs, and iELs after BEVAR are responsible for an overall worsened freedom from endoleak-related reinterventions in patients with primary TVELs and should be carefully followed.

The occurrence of iELs or cELs requiring reintervention represents a clinical challenge. The inability to exactly identify each source of the endoleak by CTA may lead to additional repeated imaging and interventions, and unsuccess of secondary procedures, with associated increased costs and exposure to radiation and contrast dye. Our traditional approach in these cases has been based on selective angiography of each target vessel and eventual endovascular correction. However, this approach may also not be accurate in the identification of the actual sources of endoleak, especially in cases with cELs, and multiple secondary procedures may be required (HR, 2.67; $P = .034$).

The results of our study highlight the unmet needs regarding follow-up imaging techniques used for F-BEVAR. The exceptional evolution in endografts and techniques, from simple EVAR to complex F-BEVAR, has not been paralleled by a substantial update in follow-up imaging modalities, and CTA still represents the method of choice; this was not sufficient to identify the source of the endoleak in 40% of cases in our cohort. New-generation noninvasive techniques, such as dynamic CTA[14,15] and photon-counting CTA,[16,17] are promising methods that have been occasionally used to unveil hidden endoleaks or structural graft defects after EVAR. However, these are not routinely used in clinical practice, and their role remains to be investigated.

The choice of the type of bridging stent may be an important factor influencing the rate of TVELs. The Lifestream stent was significantly associated with an increased risk of TVELs after FEVAR ($P = .008$), whereas no specific stent type was associated with TVEL after BEVAR. Prior reports described similar non-negligible rates of primary endoleaks with the Lifestream stent,[18] which may be related to fabric porosity or stent rigidity hindering the complete apposition to the aortic graft fenestration. However, no specific stent type was associated with persistent endoleaks or endoleak-related reinterventions in our series; therefore, there is not sufficient data to support the use of a specific bridging stent type.

The assessment of aneurysm size behavior represents a practical way to follow F-BEVAR patients. It is well-established that sac shrinkage is an hallmark of endovascular treatment success; there is also an increasing evidence that not only sac enlargement, but also aneurysm failure to regress, is associated to worsened clinical outcomes after EVAR.[12] It is unclear if the same concept applies to F-BEVAR, where the knowledge on the evolution of the sac is limited. Prior experiences[19,20] reported failure to regress in approximately 50% of F-BEVAR patients but did not specifically analyze the impact of endoleaks on sac dynamics. Failure to regress at 1 year was observed in 46% of patients in our study, with primary TVELs significantly associated with failure to regress (OR, 1.85; $P = .038$), and the results were mostly driven by persistent TVELs (OR, 1.72; $P = .040$). Besides, persistent endoleaks may also lead to increased chronic mechanical stress on the endovascular components, facilitating other target vessel complications and graft instability,[21,22] and the management of persistent TVEL with a stable non-regressing sac remains controversial.

The present study had some notable limitations. This was a single-center, retrospective study with a limited number of patients and events, which may have limited the power of the statistical analysis. The incidence of dELs and iELs may reflect the specific center's practice, with the use of mostly self-expanding bridging stents for BEVAR and VBX stents for FEVAR, and may not fully extend to other graft-bridging stents combinations. Sac size changes were defined according to solid cutoffs, although also other methods (ie, percentage) may be of value. For the purpose of the study, primary TVELs were classified via CTA only, even though correlation between CTA and completion angiography may be clinically useful. Also, although the indication to secondary procedures followed general criteria, this might have been influenced by the operator and may slightly differ compared with other centers. Our study was strengthened by a detailed CTA evaluation of primary endoleaks, including the description of natural history and impact of dELs, iELs, and cELs after F-BEVAR.

CONCLUSIONS

Primary TVELs are commonly detected at the first post-operative CTA after F-BEVAR, but a clear characterization of the endoleak source is not possible in 40%. Most primary TVELs spontaneously resolve, but during a mid-term follow-up, patients with any primary TVEL experienced a higher rate of sac failure to regress and worsened freedom from endoleak-related reinterventions, that was mostly driven by persistence of cELs and post-BEVAR iELs. Multiple secondary procedures may be required in case of iELs or cELs.

A careful follow-up protocol and/or use of more advanced imaging techniques may be advocated for these patients, to properly identify the source of the endoleak and improve the results of secondary procedures.

AUTHOR CONTRIBUTIONS

Conception and design: FS, MA, FG, MP
Analysis and interpretation: FS, MP
Data collection: FS, MM, EF, EC
Writing the article: FS, MP
Critical revision of the article: FS, MA, MM, EF, EC FG, MP
Final approval of the article: FS, MA, MM, EF, EC FG, MP
Statistical analysis: FS, MM
Obtained funding: Not applicable
Overall responsibility: FS

DISCLOSURES

None.

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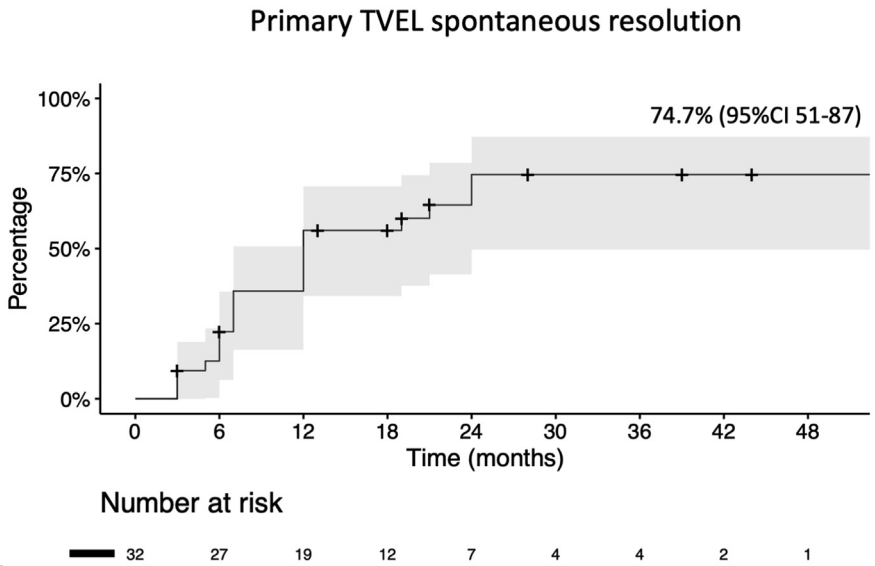

Supplementary Fig (online only). Cumulative incidence of spontaneous resolution of primary target vessel endoleaks (*TVELs*) after fenestrated-branched endovascular aneurysm repair (F-BEVAR). *CI*, Confidence interval.

Supplementary Table I (online only). Univariate and multivariable logistic regression for presence of a primary target vessel endoleak (TVEL) on the first postoperative computed tomography angiogram (CTA)

	Univariate		Multivariable	
	OR (95% CI)	*P* value	OR (95% CI)	*P* value
All patients				
Age	1.02 (0.98-1.07)	.396	–	–
Male sex	1.28 (0.43-4.72)	.679	–	–
Hypertension	2.55 (0.67-16.73)	.229	–	–
Diabetes	0.47 (0.10-1.48)	.243	–	–
Dyslipidemia	0.95 (0.42-2.19)	.907	–	–
CAD	0.62 (0.27-1.38)	.249	–	–
COPD	0.56 (0.13-1.83)	.389	–	–
CKD	2.24 (0.99-5.07)	.050	–	–
Connective tissue disease	26.22 (2.44-356.32)	.005[a]	–	–
TAAA	1.24 (0.55-2.77)	.593	–	–
Aneurysm max diameter, mm	1.02 (0.98-1.05)	.315	–	–
No. target vessels	1.35 (0.74-2.78)	.360	–	–
Fenestrations	1.11 (0.50-2.55)	.799	–	–
CMD	0.83 (0.34-1.95)	.691	–	–
FEVAR				
Age	1.11 (1.03-1.23)	.008[a]	1.09 (1.01-1.20)	.038[a]
Male sex	2.25 (0.36-43.54)	.460	–	–
Hypertension	1.42 (0.32-9.88)	.670	–	–
Diabetes	0.93 (0.21-2.24)	.378	–	–
Dyslipidaemia	1.13 (0.41-3.36)	.815	–	–
CAD	1.22 (0.44-3.40)	.695	–	–
COPD	0.62 (0.09-2.64)	.561	–	–
CKD	7.29 (2.50-23.65)	.004[a]	5.81 (1.84-20.15)	.003[a]
Connective tissue disease	30.52 (3.24-379.64)	.001[a]	82.25 (27.96-172.3)	<.001[a]
TAAA	2.41 (0.65-8.37)	.167	–	–
Aneurysm max diameter, mm	1.01 (0.97-1.05)	.516	–	–
No. target vessels	1.25 (0.60-2.93)	.562	–	–
Bridging stent, Lifestream	1.58 (1.00-5.58)	.042[a]	1.10 (0.89-4.74)	.089
BEVAR				
Age	0.97 (0.92-1.02)	.202	–	–
Male sex	0.88 (0.21-4.53)	.869	–	–
Hypertension	2.11 (0.38-9.78)	.349	–	–
Diabetes	1.13 (0.22-4.69)	.869	–	–
Dyslipidaemia	0.72 (0.19-2.81)	.628	–	–
CAD	0.10 (0.01-5.78)	.340	–	–
COPD	0.48 (0.02-2.14)	.514	–	–
CKD	0.18 (0.09-1.04)	.111	–	–
Connective tissue disease	28.19 (2.56-381.90)	.009[a]	–	–
TAAA	0.84 (0.22-3.59)	.800	–	–
Extent I-III	2.45 (0.67-9.52)	.177	–	–
Aneurysm max diameter, mm	1.03 (0.97-1.09)	.345	–	–
No. target vessels	1.87 (0.62-25.42)	.427	–	–
Balloon expandable main bridging stent	1.07 (0.94-1.22)	.298	–	–

BEVAR, Branched endovascular aneurysm repair; *CAD*, coronary artery disease; *CI*, confidence interval; *CKD*, chronic kidney disease; *COPD*, chronic obstructive pulmonary disease; *CMD*, custom-made device; *FEVAR*, fenestrated endovascular aneurysm repair; *OR*, odds ratio; *SES*, self-expandable stent; *TAAA*, thoracoabdominal aortic aneurysm.
[a]Statistically significant.

Supplementary Table II (online only). Univariate logistic regression for primary target vessel endoleak (TVEL) persistence >6 months

	OR (95% CI)	*P* value
All patients		
TAAA	0.64 (0.24-1.62)	.348
Aneurysm max diameter, mm	0.96 (0.91-1.01)	.120
No. target vessels	2.73 (1.15-9.64)	.020[a]
Patient-specific CMD	1.16 (0.44-3.38)	.775
Directional branch	1.00 (0.39-2.53)	.993
iEL	9.85 (2.53-45.1)	<.001[a]
Re-classified iEL	6.15 (1.21-32.74)	.003[a]
cEL primary EL	5.00 (1.10-49.4)	<.001[a]
FEVAR		
TAAA	0.80 (0.14-3.28)	.774
Aneurysm max diameter, mm	0.99 (0.93-1.04)	.859
No. target vessels	2.77 (1.03-10.5)	.043[a]
iEL	4.81 (0.90-25.9)	.065
Re-classified iEL	3.13 (0.89-18.23)	.142
cEL primary EL	3.03 (1.34-32.1)	<.001[a]
Stent type, VBX	0.89 (0.32-4.38)	.325
BEVAR		
TAAA	0.31 (0.06-1.64)	.162
Aneurysm max diameter, mm	0.91 (0.80-0.99)	.030[a]
No. target vessels	1.64 (0.59-101)	.425
Patient-specific CMD	1.62 (0.33-7.04)	.534
iEL	9.43 (3.41-56.4)	.002[a]
Re-classified iEL		
cEL primary EL	6.14 (1.54-87.1)	<.001[a]
Self-expanding bridging stent	0.91 (0.22-5.67)	.623

BEVAR, Branched endovascular aneurysm repair; *cEL*, complex endoleak; *CI*, confidence interval; *CMD*, custom made device; *EL*, endoleak; *FEVAR*, fenestrated endovascular aneurysm repair; *iEL*, indeterminate endoleak; *OR*, odds ratio; *TAAA*, thoracoabdominal aortic aneurysm.
[a]Statistically significant.

Supplementary Table III (online only). Univariate and multivariable logistic regression for aneurysm sac failure to regress 1 year after fenestrated-branched endovascular aneurysm repair (*F-BEVAR*)

	Univariate		Multivariable	
	OR (95% CI)	*P* value	OR (95% CI)	*P* value
All patients				
TAAA	1.07 (0.38-3.12)	.893	—	—
Aneurysm max diameter, mm	1.02 (0.97-1.08)	.508	—	—
No. target vessels	2.32 (1.27-4.34)	.007[a]	2.47 (1.29-4.86)	.006[a]
Patient-specific CMD	1.09 (0.34-3.20)	.873	—	—
Directional branch	1.16 (0.41-3.50)	.785	—	—
Primary type II EL	4.09 (0.94-38.4)	.062	7.44 (1.07-31.7)	.042[a]
Any primary TVEL	1.85 (1.01-9.90)	.038[a]	—[b]	—
iEL	3.58 (0.42-47.0)	.300	—	—
Re-classified iEL	2.99 (0.40-51.3)	.650	—	—
cEL primary EL	4.44 (1.02-58.0)	.021[a]	—[b]	—
Persistent TVEL	1.55 (1.00-8.34)	.042[a]	1.72 (1.03-12.59)	.040[a]
FEVAR				
TAAA	1.78 (0.35-17.7)	.517	—	—
Aneurysm max diameter, mm	1.05 (0.97-1.17)	.324	—	—
No. target vessels	3.42 (1.43-9.21)	.006[a]	2.91 (1.16-8.15)	.022[a]
Primary type II EL	6.56 (0.99-11.23)	.051	8.65 (0.98-27.11)	.069
Any primary TVEL	2.16 (0.44-21.4)	.375	—[b]	—
iEL	2.70 (0.28-36.3)	.454	—	—
Re-classified iEL	2.19 (0.25-39.84)	.794	—	—
cEL primary EL	3.18 (1.01-42.5)	.037[a]	—[b]	—
Persistent TVEL	1.78 (0.99-17.7)	.051	1.80 (1.00-18.65)	.043[a]
BEVAR				
TAAA	0.29 (0.02-2.9)	.350	—	—
Aneurysm max diameter, mm	0.98 (0.91-1.07)	.670	—	—
No. target vessels	1.63 (0.64-3.71)	.265	—	—
Primary type II EL	1.43 (0.25-15.1)	.710	—	—
Patient-specific CMD	1.43 (0.25-15.1)	.710	—	—
Any primary TVEL	1.11 (0.19-11.8)	.919	—[b]	—
iEL	4.89 (0.84-17.01)	.120	4.25 (0.52-55.23)	.218
Re-classified iEL	3.14 (0.85-21.83)	.199	—	—
cEL primary EL	1.60 (1.00-22.2)	.047[a]	—[b]	—
Persistent TVEL	1.80 (1.01-10.32)	.041[a]	1.72 (1.01-8.10)	.038[a]

cEL, Complex endoleak; *CI*, confidence interval; *CMD*, custom made device; *EL*, endoleak; *iEL*, indeterminate endoleak; *OR*, odds ratio; *TAAA*, thoracoabdominal aortic aneurysm; *TVEL*, target vessel endoleak.
[a]Statistically significant.
[b]Excluded from multivariate model due to collinearity.