Fate of target visceral vessels in fenestrated and branched complex endovascular aortic repair

Aaron Thomas Fargion, MD,[a] Davide Esposito, MD,[a] Sara Speziali, MD,[a] Raffaele Pulli, MD,[a]
Enrico Gallitto, MD,[b,c] Gianluca Faggioli, MD,[b,c] Mauro Gargiulo, MD,[b,c] Luca Bertoglio, MD,[d]
Germano Melissano, MD,[d] Roberto Chiesa, MD,[d] Gioele Simonte, MD,[e] Giacomo Isernia, MD,[e]
Massimo Lenti, MD,[e] *and* Carlo Pratesi, MD,[a] on behalf of the Italian Multicentre Fenestrated and Branched (IMF&B) Study Group, *Florence, Bologna, and Perugia, Italy*

ABSTRACT

Objective: To assess branch vessel outcomes after endovascular repair of complex aortic aneurysms analyzing possible factors influencing early and long-term results.

Methods: The Italian Multicentre Fenestrated and Branched registry enrolled 596 consecutive patients treated with fenestrated and branched endografts for complex aortic disease from January 2008 to December 2019 by four Italian academic centers. The primary end points of the study were technical success (defined as target visceral vessel [TVV] patency and absence of bridging device-related endoleak at final intraoperative control), and freedom from TVV instability (defined as the combined results of type IC/IIIC endoleaks and patency loss) during follow-up. Secondary end points were overall survival and TVV-related reinterventions.

Results: We excluded 591 patients (3 patients with a surgical debranching and 2 patients who died before completion from the study cohort) were treated for a total of 1991 visceral vessels targeted by either a directional branch or a fenestration. The overall technical success rate was 98.4%. Failure was related to the use of an off-the-shelf (OTS) device (custom-made device vs OTS, HR, 0.220; $P = .007$) and a preoperative TVV stenosis of >50% (HR, 12.460; $P < .001$). The mean follow-up time was 25.1 months (interquartile range, 3-39 months). The overall estimated survival rates were 87%, 77.4%, and 67.8% at 1, 3, and 5 years, respectively (standard error [SE], 0.015, 0.022, and 0.032). During follow-up, TVV branch instability was observed in 91 vessels (5%): 48 type IC/IIIC endoleaks (2.6%) and 43 stenoses-thromboses (2.4%). The extent of aneurysm disease (thoracoabdominal aortic aneurysm [TAAA] types I-III vs TAAA type IV/juxtarenal aortic aneurysm/pararenal aortic aneurysm) was the only independent predictor for developing a TVV-related type IC/IIIC endoleak (HR, 3.899; 95% confidence interval [CI]:, 1.924-7.900; $P < .001$). Risk of patency loss was independently associated with branch configuration (HR, 8.883; $P < .001$; 95% CI, 3.750-21.043) and renal arteries (HR, 2.848; $P = .030$; 95% CI, 1.108-7.319). Estimated rates at 1, 3, and 5 years of freedom from TVV instability and freedom from TVV-related reintervention were 96.6%, 93.8%, and 90% (SE, 0.005, 0.007, and 0.014) and 97.4%, 95.0%, and 91.6% (SE, 0.004, 0.007, and 0.013), respectively.

Conclusions: Intraoperative failure to bridge a TVV was associated with a preoperative TVV stenosis of >50% and the use of OTS devices. Midterm outcomes were satisfying, with an estimated 5-year freedom from TVV instability and reintervention of 90.0% and 91.6%, respectively. During follow-up, the larger extent of aneurysm disease was associated with an increased risk of TVV-related endoleaks, whereas a branch configuration and renal arteries were more prone to patency loss. (J Vasc Surg 2023;78:584-92.)

Keywords: Thoracoabdominal aortic aneurysm; Target visceral vessels; Patency; Endoleaks; Endovascular procedures

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From the Vascular Surgery, Department of Cardiothoracic and Vascular Surgery, Careggi University Teaching Hospital, University of Florence, Florence[a]; the Vascular Surgery, Department of Experimental, Diagnostic and Specialty Medicine, University of Bologna, Sant'Orsola-Malpighi Hospital,[b] the Vascular Surgery Unit, IRCCS, University Hospital Sant'Orsola,[c] Bologna; the Division of Vascular Surgery, IRCCS San Raffaele Scientific Institute, Vita-Salute San Raffaele University, Milan[d]; and the Vascular and Endovascular Surgery Unit, S. Maria Misericordia Hospital, University of Perugia, Perugia.[e]

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Italian Multicentre Fenestrated and Branched (IMF&B) Study Group: Luca Bertoglio (Milan), Roberto Chiesa (Milan), Davide Esposito (Florence), Gianluca Faggioli (Bologna), Aaron Thomas Fargion (Florence), Cecilia Fenelli (Bologna), Enrico Gallitto (Bologna), Mauro Gargiulo (Bologna), Giacomo Isernia (Perugia), Andrea Kahlberg (Milan), Massimo Lenti (Perugia), Antonino Logiacco (Bologna), Chiara Mascoli (Bologna), Germano Melissano (Milan), Rodolfo Pini (Bologna), Carlo Pratesi (Florence), Gioele Simonte (Perugia), Sara Speziali (Florence).

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Correspondence: Aaron Thomas Fargion, MD, Department of Cardiothoracic and Vascular Surgery, Careggi University Teaching Hospital, University of Florence, Largo Brambilla 3, 50134 Florence, Italy (e-mail: aaronthomas.fargion@unifi.it).

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Despite the growing diffusion of complex aortic endovascular repair with fenestrated and branched endografts (F/B-EVAR) among referral vascular centers, secondary procedures related to branch instability and consequent events on target visceral vessels (TVVs) remain a major concern. The lack of dedicated bridging stent grafts (BSGs) has been advocated as the Achille's heel of these procedures,[1] and several recent articles pointed out the impact of geometrical aspects dependent on graft configuration.[2,3] The aim of this study was to assess branch vessel outcomes during endovascular repair of complex aortic aneurysms analyzing possible factors influencing early and long-term results in a multicenter registry. The present article reports a large sample of patients with complex aortic disease collected over a period of 12 years by a multicenter Italian study group. In this context, we performed a TVVs analysis of patients treated with F/B-EVAR, with the intention of investigating the burden of visceral vessels anatomical characteristics, graft configuration, and bridging stent type on procedural outcomes and long-term results.

METHODS

Study design. The Italian Multicentre Fenestrated and Branched (IMF&B) registry is a physician-initiated, observational, multicenter, retrospective registry gathering data of F/B-EVAR performed in four Italian vascular academic hospitals (Bologna, Firenze, Perugia, Milano) using off-the-shelf (OTS) or custom-made devices (CMD) from a unique manufacturer (Cook Medical, Bloomington, IN). All consecutive treatments performed from January 2008 to December 2019 in each participating center, both in elective and urgent settings, were captured originally in the institution's database; the anonymized data, according with the European General Data Protection Regulation, were added to the database retrospectively for the multicenter registry. Inclusion criteria for the registry followed the standards of the Society for Vascular Surgery[4-6] and have been discussed in the previously published reports on the IMF&B Registry.[7-10] The registry was conducted based on the Declaration of Helsinki; informed consent for the F/B-EVAR procedures was obtained from all the patients per local regulations, and each institution's ethics committee approved participation in the registry. No funding was obtained from companies or other institutions for conducting the registry and the present study. Our checklist of items followed the STROBE statement.[11]

Definitions, reporting standards, and results analysis. The procedure, based on individual anatomy and operating physician, was performed according to the standard practice and following the instruction for use of CMD stent graft or an OTS Zenith t-Branch device. Reported risk factors and definitions of the outcomes are in accordance with the Society for Vascular Surgery/American Association for Vascular Surgery current reporting standards.[4-6]

Technical success was defined as placement of the BSG in the desired position with TVV patency and absence of bridging device-related endoleak at final intraoperative control (angiography or cone beam computed tomography scan); TVV instability was defined as the combined results of type IC/IIIC endoleaks and occlusions for each BSG during follow-up[12]; TVV instability was always confirmed by computed tomography angiography (CTA) if previously diagnosed through duplex ultrasound examination. The study period (from January 2008 to December 2019) was equally divided in two subgroups (early experience 2008-2013 vs late experience 2014-2019) to compare results.

Preoperative demographics, anatomical characteristics, status of all aortic side branches, graft design, and procedural and follow-up data were collected. Device planning, procedural staging strategies (ie, staged proximal thoracic stent grafting or temporary aneurysm sac perfusion), and type of bridging stents were at the discretion of the implanting physicians according to each individual center protocol. Perioperative mortality and major complication (renal, cardiac, pulmonary, bowel, neurologic) rates were recorded during each procedural step.

ARTICLE HIGHLIGHTS

- **Type of Research:** Physician-initiated, observational, multicenter, retrospective registry
- **Key Findings:** We included 1991 visceral vessels targeted for complex aortic disease exclusion with fenestrated and branched endografts with an overall technical success of 98.4%. Failure was related to preoperative target visceral vessel stenosis of >50% (hazard ratio [HR], 12.460; $P < .001$) and the use of off-the-shelf devices (custom-made device vs off-the-shelf, HR, 0.220; $P = .007$). Target visceral vessel type IC/IIIC endoleaks were independently associated with the extent of aneurysm disease (HR, 3.899; $P < .001$), whereas risk of patency loss was associated with a branch graft configuration (HR, 8.883; $P < .001$) and renal arteries (HR, 2.848; $P = .030$).
- **Take Home Message:** A preoperative stenosis of >50% was strongly associated with failure to revascularize TVV and should be considered for procedural planning; preliminary angioplasty/stenting and intraoperative double stenting should be considered to improve technical success. In addition, off-the-shelf devices, even if used mostly for urgent repairs, presented lower rates of technical success. Thoracoabdominal aortic aneurysms type I to III were associated with type IC/IIIC endoleaks during follow-up, and branches and renal arteries confirm to be at increased risk of occlusion.

Systemic complication rates were reported considering the highest severity grade developed during the whole therapeutic process. The follow-up protocol was shared and approved by each center and consisted of perioperative (within 1 month from index procedure) CTA, 3- and 6-month duplex ultrasound examination, annual CTA thereafter; follow-up protocol deviations were at center's discretion in case of complications and/or diagnostic uncertainties. During follow-up all deaths, number and type of reinterventions and all data concerning each TVV were recorded.

Study end points. The primary end points of the study were technical success and freedom from TVV instability. The secondary end points were overall survival and TVV-related reinterventions during follow-up. Furthermore, preoperative anatomical characteristics and procedural, postoperative, and device-related data were analysed to identify independent predictors.

Statistical analyses. Continuous data are presented as means ± standard deviation; categorical data are presented as the number/sample (percentage) and the χ^2 and Fischer exact tests were used for analysis. Univariable analysis was not adjusted for covariates. A Cox regression model (multivariable) used stepwise selection and identified independent predictors of the study end point. Data were entered into the model if they had a P value of <.2 on the univariate analysis. In multivariate analyses, clinical factors or potential confounding variables were expressed as hazard ratio (HR) with 95% confidence interval (CI). The Kaplan-Meier method was used to evaluate overall patient survival and freedom from TVV occlusion, type IC and IIIC endoleaks, and all-cause reinterventions. Receiver operating characteristic curve analysis was used to establish the cut-off value for TVV diameters and both primary patency and type IC/IIIC endoleaks. Estimates are presented with the 95% CI. Statistical significance was set at a P value of <.05. Analyses were performed using SPSS software (version 25; IBM Corporation, Armonk, NY).

RESULTS

Patient sample. The IMF&B registry enrolled 596 consecutive patients treated with F/B-EVAR for complex aortic disease (508 males, 85.2%; mean age, 73.4 ± 6.9 years) during the study period, of which 76 (12.8%) were treated in an urgent setting (16 ruptures, 11 symptomatic patients, and 49 aneurysms >8 cm). Three patients (0.5%) who had a previous surgical abdominal aortic repair with bypasses to the visceral vessels and two patients (0.3%) who died before the visceral stage of a multistep procedure were excluded from the study.

Intraoperative and perioperative results. The final cohort was composed of 591 patients, of whom 77 (13%) were treated with an OTS and 514 (87%) with a CMD. Preoperative demographics and anatomical characteristics were already presented in previously presented papers,[7-10] and the status of all aortic side branches is presented in Table I. The number of TVVs/patient incorporated in the graft design is presented in Supplementary Fig 1 (online only). A total of 1991 visceral vessels (378 celiac trunks [CT], 492 superior mesenteric arteries [SMA], 551 right renal arteries [RRA], 552 left renal arteries [LRA], and 18 accessory or independent arteries) were targeted by either a directional branch or a fenestration. The 18 accessory or independent arteries were excluded from the analysis. During the first 6 years of the study, 460 visceral vessels (23.3%) were targeted, and during the late experience 1513 (76.7%). The visceral graft component was implanted during a single-step (68%) or a multistep (32%) procedure (different strategies for staged treatment were already discussed in a previous paper from the Registry Group).[8] Four patients died before completion of the visceral step (one intraoperatively, one multiorgan failure, one subarachnoid hemorrhage, and one respiratory failure) and one was converted to open surgical repair; therefore 0.6% of TVVs were considered uncompleted (12/1973). The overall technical success rate was 98.4% (1930/1961). Technical success for fenestrations was 98.8% (1301/1317), with one patient requiring temporary and two permanent (one patient with a solitary kidney) dialysis. Technical success for directional branches was 97.7% (629/644). Intraoperative details of TVVs revascularization during visceral step of the procedure are presented in Table II.

Six patients (two RRA and four LRA) presented a transient increase in serum creatinine, the patient with occlusion of the SMA branch underwent an urgent common iliac-to-mesenteric surgical bypass. Thirteen patients died in the perioperative period of the last procedural step.

Graft configuration. The choice between a branch or fenestrated configuration depended on anatomy- and device-related characteristics, among which the extension of the aneurysmatic pathology (thoracoabdominal aortic aneurysm [TAAA] types I-III vs TAAA type IV [TAAA IV]/juxtarenal aortic aneurysm [JAA]/pararenal aortic aneurysm [PAA]). Overall, fenestrations were preferred over branches (1318/1973 vs 655/1973; $P < .001$). The rate of fenestration was even higher when looking at the early phase of the experience (74.4% vs 67%; $P = .004$). A fenestration was preferred over a branch in TAAA IV/JAA/PAA extensions (907 fenestrations vs 130 branches), and branches were more used in case of extensive pathology such as TAAA I to III (411 fenestrations vs 525 branches). When excluding vessels targeted with OTS devices from the analysis (256/1973 target vessels), the trend of fenestration preference was confirmed for CMD only devices (1284/1717 vs 433/1717; $P < .001$), both in TAAA IV/JAA/PAA

Table I. Preoperative status of all target visceral vessels (TVVs)

	CT (589/596)	SMA (590/596)	RRA (591/596)	LRA (592/596)
Patent	458 (77.8)	557 (94.4)	509 (86.1)	486 (82.1)
Stenosis <50%	31 (5.3)	12 (2.0)	17 (2.9)	25 (4.2)
Stenosis 50%-75%	31 (5.3)	8 (1.4)	23 (3.9)	23 (3.9)
Stenosis >75%	32 (5.4)	2 (0.3)	15 (2.5)	20 (3.4)
Occluded	28 (4.8)	4 (0.7)	21 (3.6)	28 (4.7)
Dissected from TL	5 (0.8)	5 (0.8)	3 (0.5)	3 (0.5)
Dissected from FL	2 (0.3)	–	1 (0.2)	5 (0.8)
Dissected from TL+FL	2 (0.3)	2 (0.3)	2 (0.3)	2 (0.3)

CT, Celiac trunk; *FL*, false lumen; *LRA*, left renal artery; *RRA*, right renal artery; *SMA*, superior mesenteric artery; *TL*, true lumen.
Values are number (%).

Table II. Intraoperative details of target visceral vessels (TVVs) revascularization during visceral step

	SE-CS		BE-CS		SE + BE-CS			
TVV (1973)	Ad-BMS	Alone	Ad-BMS	Alone	Ad-BMS	Alone	Failure/plug	Uncompleted[a]
CT (377/378)								
FEN (183)	3 (1.6)	7 (3.8)	9 (4.9)	155 (84.7)	–	1 (0.5)	8 (4.4)	–
BRANCH (194)	46 (23.7)	61 (31.4)	22 (11.3)	51 (26.2)	4 (2.0)	3 (1.5)	3 (1.5)	4 (2.0)
SMA (480/492)								
FEN (297)	6 (2.0)	3 (1.0)	46 (15.5)	242 (81.5)	–	–	–	–
BRANCH (183)	53 (28.9)	58 (31.7)	15 (8.2)	51 (27.9)	3 (1.6)	–	1 (0.5)	2 (1.1)
RRA (538/551)								
FEN (405)	3 (0.7)	12 (2.9)	12 (2.9)	374 (92.3)	–	1 (0.2)	3 (0.7)	–
BRANCH (133)	30 (22.5)	45 (33.8)	10 (7.5)	18 (13.5)	7 (5.2)	14 (10.5)	6 (4.5)	3 (2.2)
LRA (544/552)								
FEN (418)	5 (1.2)	9 (2.1)	22 (5.3)	374 (89.5)	2 (0.5)	–	5 (1.2)	1 (0.2)
BRANCH (126)	26 (20.6)	45 (35.7)	6 (4.8)	19 (15.1)	6 (4.8)	17 (13.5)	5 (3.9)	2 (1.6)

Ad-BMS, Adjunctive bare metal stent; *BE-CS*, balloon-expandable covered stent; *CT*, celiac trunk; *FEN*, fenestration; *LRA*, left renal artery; *RRA*, right renal artery; *SE-CS*, self-expanding covered stent; *SMA*, superior mesenteric artery.
[a] Uncompleted: Left unstented on purpose/visceral stage procedure not executed.

extensions (873 fenestrations vs 86 branches), and TAAA I to III extensions (411 fenestrations vs 347 branches).

Technical results. Among possible independent predictors of technical failure, both the use of an OTS device (CMD 52/1554 vs OTS 17/201; HR, 0.220; $P = .007$) and a preoperative TVV stenosis of >50% (12/130 vs 19/1831; HR, 12.460; $P < .001$) showed a significant association at multivariate analysis (Table III). A trend toward higher technical failure was found for branch configuration (15/644 vs 16/1317; $P = .063$), while leaving one or more branches open in a multistep procedure did not result in an increased risk of TVV loss (3/70 vs 12/574; $P = .172$). Different types of bridging stents were used to revascularize TVVs: a self-expanding covered stent (SE-CS) in 427 (22.2 %), a balloon-expandable covered stent (BE-CS) in 1.441 (74.8%) or both (SE + BE-CS) in 58 (3%). A SE-CS was the main type used for branch configuration (379/626 vs 193/626; $P < .001$), and a BE-CS was coupled with a fenestration in 96% (1248/1300; $P < .001$). Furthermore, an adjunctive bare metal stent (Ad-BMS) was used in 17.7% of TVVs (336/1896). The need for an Ad-BMS was significantly higher for branches compared with fenestrations (228/610 vs 108/1286; $P < .001$), for visceral (CT + SMA) compared with renal arteries (RRA + LRA) (207/839 vs 129/1057; $P < .001$) and when bridging with a SE-CS (172/412 vs 142/1426; $P < .001$). Twenty-eight additional covered stents (4 in CT, 8 in SMA, 26 in renal arteries) were used intraoperatively to solve type IC/IIIC endoleaks caused by inadequate stent extension either into TVVs or aortic graft.

Follow-up results. Follow-up data were available for 98% of the patients (562/573) for a total of 1824 TVVs (339 CT, 460 SMA, 513 RRA, and 512 LRA). The mean follow-up time for the study cohort was 25.1 months (interquartile range, 3-39 months). The overall estimated survival rates were 87.0%, 77.4%, and 67.8% at 1, 3, and 5 years, respectively (SE, 0.015, 0.022, and 0.032) (Supplementary Fig 2, online only).

Table III. Predictors of technical failure at logistic regression analysis

	Univariate	Multivariate		
	P value	HR	95% CI	*P* value
Early vs late experience	.237			
Extent of aneurysm disease	.630			
Type of TVV	.545			
TVV preoperative stenosis >50%	<.001	12.460	5.460-28.433	<.001
Graft configuration	.063	.688	0.237-2.004	.493
CMD vs OTS	.007	.220	0.073-0.660	.007
Staged procedure	.172	.965	0.399-2.334	.938

CI, Confidence interval; *CMD*, custom-made device; *HR*, hazard ratio; *OTS*, off-the-shelf; *TVV*, target visceral vessel.

During follow-up, 48 type IC/IIIC endoleaks (11 CT, 15 SMA, 11 RRA, 11 LRA) from TVVs (48/1824 [2.6%]) in 34 patients were reported (11/34 presenting multiple endoleaks). All patients except one presented with a small type IIIC endoleak from a LRA still under surveillance and underwent a reintervention with deployment of additional covered stents (33/562 [5.9%]). The extent of aneurysm disease (TAAA I-III vs TAAA IV/JAA/PAA) was the only independent predictor for developing a TVV-related type IC/IIIC endoleak (HR, 3.899; 95% CI, 1.924-7.900; $P < .001$) (Table IV); receiver operating characteristic curve analysis identified a TVV diameter of 6 mm (sensitivity, 51.9%; specificity, 65.1%) as the cut-off value for primary patency and 7 mm (sensitivity, 64.6%; specificity, 52.5%) as the cut-off value for type IC/IIIC endoleaks (Supplementary Figs 3 and 4, online only).

In addition, 10 stenoses of >50% (3 CT, 3 SMA, 1 RRA, and 3 LRA) and 33 thromboses (3 CT, 1 SMA, 13 RRA, and 16 LRA) of TVVs (43/1824 [2.4%]) were found in 32 (32/562 [5.7%]) patients (8/32 presenting stenoses-occlusion of ≥2 TVVs). Eighteen of these patients (18/562 [3.2%]) were treated to assist (all 10 detected stenoses) or restore (13 thromboses: 1 SMA, 6 RRA, and 6 LRA) patency of TVVs. Three patients with a bilateral occlusion of renal arteries and acute kidney injury, underwent endovascular thrombectomy and relining with a BMS (in one case. flow was restored only for one renal artery), with consequent mild worsening in renal function (two transient and no permanent dialysis). A patient with an unknown prothrombotic state presenting with an acute kidney injury at 3 months showed at CTA scan contemporary occlusion of all four visceral branches and underwent an urgent procedure of endovascular thrombectomy and fibrinolysis to recover SMA and both renal arteries without clinical sequelae. Risk of patency loss was independently associated with graft configuration (branches vs fenestrations: HR, 8.883; $P < .001$; 95% CI, 3.750-21.043) and type of TVV (RRA + LRA vs CT + SMA: HR, 2.848; $P = .030$; 95% CI, 1.108-7.319) (Table V).

Estimated freedom from TVV instability and freedom from TVV-related reintervention rates at 1, 3, and 5 years of were 96.6%, 93.8%, and 90.0% (SE, 0.005, 0.007, and 0.014) and 97.4%, 95.0%, and 91.6% (SE, 0.004, 0.007, and 0.013), respectively (Fig).

DISCUSSION

Overall results. In our cohort, technical success rate was >98%, similar to what was previously reported in papers by highly experienced vascular centers.[13,14] Even if low, failure was not generally ascribed to preoperative anatomical characteristics of visceral vessels. Our analysis showed that there was a trend of higher risk of failure for a branch configuration (2.3% vs 1.2%; $P = .08$); most notably, failure was found to be associated with a visceral vessel preoperative stenosis of >50% ($P < .001$), but not with the type of TVV. In a recent series of 287 patients, Scott et al[15] analysed the effects of preoperative CT and SMA stenosis on F/B-EVAR outcomes. The authors found that only a baseline CT stenosis was associated with decreased CT branch patency and freedom from target vessel instability during follow-up, but no effect was recorded on technical success. In contrast, in our experience a preoperative TVV stenosis of >50% did not influence any of the follow-up results (patency, TVV-related instability, or TVV-related reinterventions). Furthermore, in our series another factor that influenced technical success was the use of OTS devices, as previously reported in recent literature.[16] Although widely preferred in daily practice owing to their immediate availability when compared with the long production times for a CMD, OTS devices were not highly represented in our study, and their use was mostly limited to urgent situations; we believe that their higher chance of technical failure might be determined by forcing these grafts into anatomies not intended for these type of configurations, and it seems that <40% of patients' anatomies would be suitable for their implant.[17] Our belief was confirmed by increased rate of technical failure with the use of OTS devices, even if, as mentioned, their use was mostly limited to the urgent setting (73/77 [94.8%]).

Table IV. Risk factors for target visceral vessel (*TVV*)-related type IC/IIIC endoleaks at Cox regression model

	Univariate		Multivariate		
	Log rank	*P* value	HR	95% CI	*P* value
Early vs late experience	4.246	.039	1.767	0.847-3.685	.129
Extent of aneurysm disease	25.021	<.001	3.899	1.924-7.900	<.001
Type of TVV	3.322	.068	1.085	0.506-2.323	.835
TVV ∅ ≥ 7 mm	6.864	.009	1.640	0.736-3.652	.226
Graft configuration	.105	.746			
CMD vs OTS	.268	.605			
Type of BSG	2.694	.101	1.101	0.633-1.915	.733
BSG relining	12.148	<.001	1.501	0.812-2.773	.195

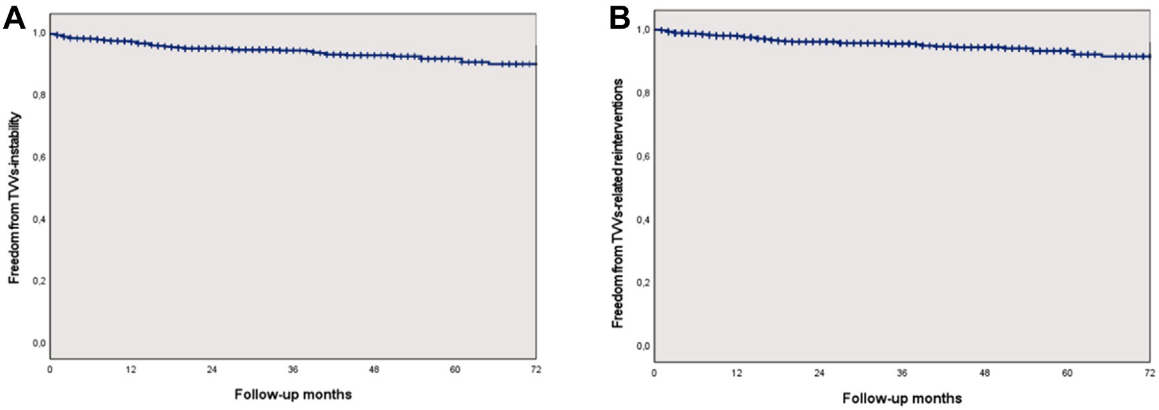
BSG, Bridging stent graft; *CI*, confidence interval; *CMD*, custom-made device; *HR*, hazard ratio; *OTS*, off-the-shelf.

Table V. Risk factors for target visceral vessel (*TVV*) primary patency loss at Cox regression model

	Univariate		Multivariate		
	Log rank	*P* value	HR	95% CI	*P* value
Early vs late experience	.108	.742			
Extent of aneurysm disease	7.805	.005	.925	0.440-1.945	.838
Type of TVV	6.407	.011	2.848	1.108-7.319	.030
TVV ∅ ≤ 6 mm	3.807	.051	.644	0.274-1.513	.312
TVV preoperative stenosis >50%	.043	.836			
Graft configuration	38.524	<.001	8.883	3.750-21.043	<.001
CMD vs OTS	16.646	<.001	.735	0.365-1.479	.388
Type of BSG	1.020	.313			
BSG relining	4.713	.030	.887	0.448-1.758	.732

BSG, Bridging stent graft; *CI*, confidence interval; *CMD*, custom-made device; *HR*, hazard ratio; *OTS*, off-the-shelf.

Branches vs fenestrations. Many authors in recent years pointed out several outcomes of directional branches and fenestrations during complex endovascular aortic repair, especially focusing on the impact on renal arteries. Over a 9-year period of follow-up, Mastracci et al[18] reported that secondary procedures were performed for 0.6% of CT, 4.0% of SMA, 6.0% of RRA, and 5.0% of LRA branches. Pini et al[19] observed that the use of a branch configuration was associated with a greater incidence of perioperative visceral vessel complications compared with fenestration (9% vs 2%) and the risk was higher for renal arteries (13.0% vs 2.5%); additionally, Martin-Gonzalez et al[20] reported a 2-year freedom from renal occlusion rate of 90.4% (SE, 85.8%-95.3%) after B-EVAR and 97.1% (SE, 94.6%-99.7%) after F-EVAR ($P < .01$). Our experience confirmed an increased risk of patency loss during follow-up for renal arteries (HR, 2.848; $P =$ .030) and when using a directional branch (HR, 8.883; $P <$ .001), probably related to the greater degree of geometrical modifications (curvature) and shear stress at the end of the BSG, as previously demonstrated both with computational model by Georgakarakos et al[21] and with CTA analysis by de Niet et al[22] and Fidalgo-Domingos et al,[23] and also related to the take-off angle of the visceral vessel, which is capable of predicting worse outcomes in specific anatomies.[24] Furthermore, TVV-related secondary endoleaks, ranging between 1% and 14% in different series, have been already demonstrated to be probably the main reason for secondary intervention after F/B-EVAR procedures.[25-29] We found TVV-related endoleaks 48 (2.6%) over a mean follow-up period of 2 years, and all of them except one underwent a secondary procedure. Our analysis showed that the only independent predictor of endoleak was the extension of the aortic disease, with thoracoabdominal aneurysm extension presenting with a significantly higher risk ($P <$ .001), even if our data lack of possibly relevant information such as true aneurysmatic lumen dimensions and thrombus characteristics, which could play an important role in the mechanism of endoleak appearance. This finding may be better explained by the higher risk of BSG displacement or migration over time in patients presenting with extensive aneurysms with large aortic inner lumen at the level of TVV origin, rather than by graft configuration (branch vs fenestration), as recently reported by Kärkkäinen et al.[30]



Follow-up months	0	12	24	36	48	60
TVVs at risk	1824	980	677	479	304	182
Estimated rates	1	.966	.944	.938	.922	.900
Standard error	0	.005	.007	.007	.009	.014

Follow-up months	0	12	24	36	48	60
TVVs at risk	1824	993	688	484	307	184
Estimated rates	1	.974	.956	.950	.939	.916
Standard error	0	.004	.006	.007	.008	.013

Fig. Kaplan-Meier curves for **(A)** freedom from TVV instability and **(B)** freedom from TVV-related reinterventions. *TVV*, Target visceral vessel.

BE-CS vs SE-CS. One of the main discussed issues of F/B-EVAR procedures is the lack of a dedicated BSG developed specifically for this purpose. Different BE-CSs and SE-CSs have been used during years, but their results seem to be heterogeneous and debatable.[1] Motta et al,[31] analyzing 179 target vessels mated with directional branches using a BE-CS (54%) or SE-CS (46%), observed that primary patency at 24 months (BE-CS, 98.1%; SE-CS, 98.6%; log-rank, $P = .95$), freedom from endoleak (BE-CS, 95.6%; SE-CS, 98.6%; log-rank, $P = .66$), freedom from secondary intervention (BE-CS, 94.7%; SE-CS, 98.1%; log-rank, $P = .33$), and freedom from branch instability (BE-CS, 95.6%; SE-CS, 97.2%; log-rank, $P = .77$) were similar between the two groups.[31] Tenorio et al[32] noted that primary patency, freedom from target artery instability, and freedom from type IC or type IIIC endoleaks were lower for BE-CS compared with SE-CS on a total of 335 renal-mesenteric arteries; Torsello et al[33] instead, evaluating the clinical performance of BE-CS on 50 patients operated on for F/B-EVAR demonstrated promising results and a technical success rate of 98.6%. Last, Farivar et al[34] proved that there were no significant differences in short-term or long-term patency, branch-related endoleaks, or reintervention rates in the renal or visceral vessels stented with different BE-CSs in the 918 F-EVARs collected in their prospective cohort. According to our data, SE-CS were the mainly used for branching, whereas BE-CSs were preferred in almost all cases of fenestrations; however, the type of BSG was not found to be related to TVV-related instability at follow-up directly.

Relining or Ad-BMS. The use of an Ad-BMS for BSG relining, often used intraoperatively at operating surgeon discretion, seems to be a common procedure but its clinical impact is not clear. Khoury et al[35] focused specifically on how a BMS to smooth distal transition and prevent kinking of covered stents influenced primary patency rates during F-EVAR procedures, not finding any significant difference compared with covered stents alone. In our cohort an additional relining with a BMS was necessary in 17.7% of TVVs. Another aspect reported by Farivar et al[34] in their experience was the high proportion of BSG for SMA fenestrations distally extended with an additional stent (84%). Even with significantly lower rates, our cohort showed as well that SMA needed the most additional stents among fenestrations (15.5% of cases, ranging from 1% to 5% for others TVVs). Reason was to smooth the sharp angle that may be found at the transition from the rigid BE-CS, used as BSG in this fenestration in the vast majority of patients, and proximal physiological curvature of the SMA, even if in our experience an Ad-BMS was also implanted in 37.1% when using a branch configuration as well (highest value for all TVV branches). Similar results were also presented by the aforementioned Torsello et al[33] experience, with a BMS relining in 33% of CT and 25% of SMA branches and no relining in renal arteries. In contrast, Martin-Gonzalez et al,[20] when analyzing their results for different renal configurations in F/B-EVAR, reported a stent relining in branches well above 50% (56.3% RRA and 55.9% LRA). Our results showed that the need for stent relining was significantly higher for visceral (CT + SMA) compared with renal arteries ($P < .001$) and for branches compared with fenestrations ($P < .001$), confirming high heterogeneity of results in current literature.

Study limitations. The present study has several limitations. First, it is a retrospective, multicenter experience, reporting cases treated in four academic hospitals. Even if preoperative and follow-up imaging were evaluated by experienced operators, no external core laboratory review was made. The graft configuration for CMD and BSG selection was at the complete discretion of operating surgeon of each individual center, such as Ad-BMS placement. Furthermore, different SE and BE stents were used across a 16-year period and their choice was influenced by the availability in each different center. Follow-up was limited to early and mid-term outcomes (mean, 25.1 months); enrolment in the registry and follow-up data acquisition ended in December 2019. The rate of time-dependent outcomes, such as BSG stenosis or occlusion, type IC and type IIIC endoleaks, and branch-related reinterventions, still needs to be determined with longer follow-up. Results could have been biased by the different learning curves of each center, even if dividing the experience in two different time points (early and late experiences) there were no statistically significant differences in the outcomes between the two periods. Strength of this study include the large sample of analysed visceral vessels with an exhaustive preoperative anatomical assessment and detailed procedural data.

CONCLUSIONS

Technical success for F-EVAR and B-EVAR confirmed to be high in experienced centers dedicated to complex endovascular procedures. Failure to revascularize TVVs was strongly associated with a preoperative TVV stenosis of >50% (HR, 12.460), which therefore should be carefully evaluated during procedural planning. For this reason, additional preliminary procedures such as target vessel angioplasty and/or stenting, or intraoperative double stenting might be adopted to improve technical success when the vessel should be preserved. Furthermore, OTS devices presented lower rates of technical success, even though in our registry these grafts were principally used for urgent repairs (CMD vs OTS: HR, 0.220). Mid-term freedom from TVV instability was 90% at 5 years, similar to what was reported previously in other series. BSGs choice did not seem to affect branch vessel durability during follow-up. Thoracoabdominal extent of the aneurysmal disease was associated with a higher risk of developing a TVV-related endoleak (type IC/IIIC), and directional branch configuration and renal arteries were more prone to patency loss.

AUTHOR CONTRIBUTIONS

Conception and design: ATF, CP
Analysis and interpretation: ATF
Data collection: ATF, DE, SS, RP, EG, GF, MG, LB, GM, RC, GS, GI, ML, CP
Writing the article: ATF, DE
Critical revision of the article: ATF, DE, SS, RP, EG, GF, MG, LB, GM, RC, GS, GI, ML, CP
Final approval of the article: ATF, DE, SS, RP, EG, GF, MG, LB, GM, RC, GS, GI, ML, CP
Statistical analysis: ATF
Obtained funding: Not applicable
Overall responsibility: ATF

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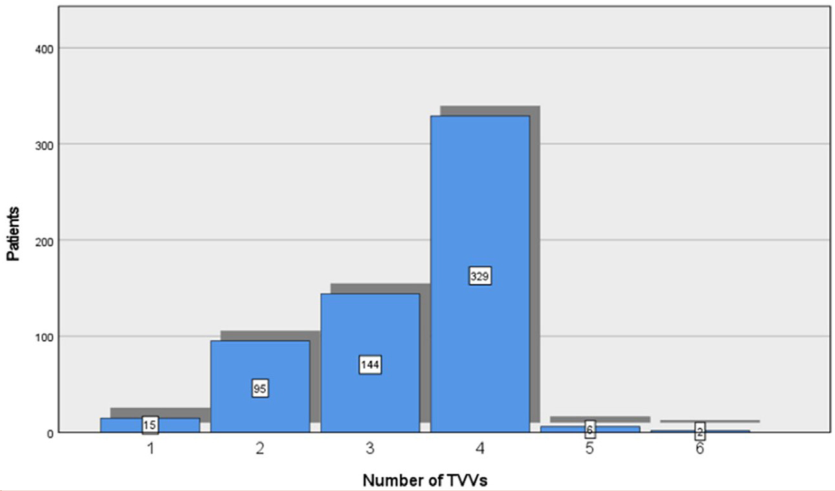
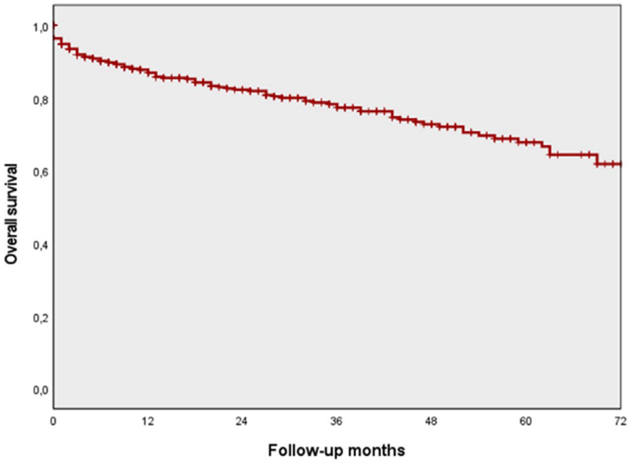
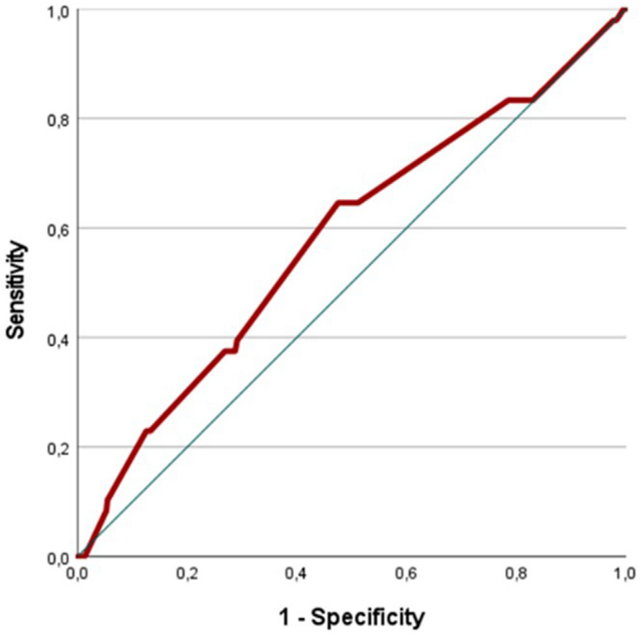


Supplementary Fig 1 (online only). Number of TVVs/patient incorporated in the graft design. *TVV,* Target visceral vessel.

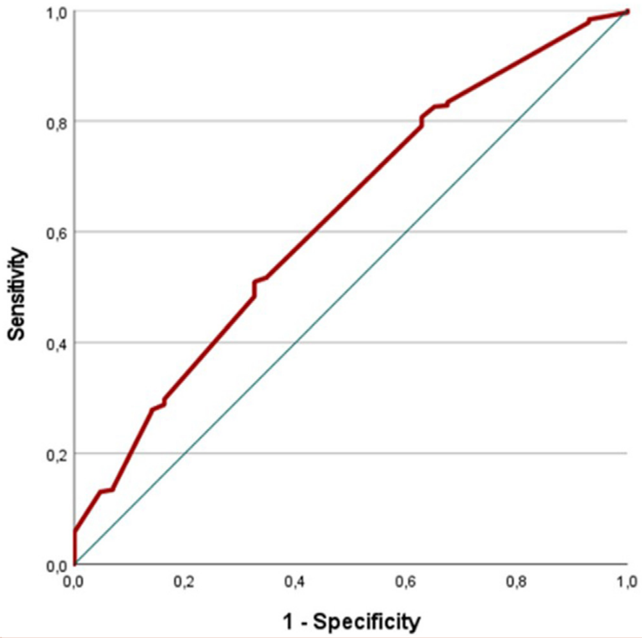


Follow-up months	0	12	24	36	48	60
Patients at risk	591	320	233	164	108	65
Estimated rates	1	.870	.823	.774	.728	.678
Standard error	0	.015	.019	.022	.026	.032

Supplementary Fig 2 (online only). Kaplan-Meier curve of overall survival.



Supplementary Fig 3 (online only). Receiver operating characteristic curve analysis for TVVs diameter and type IC/IIIC endoleaks (area, 58%; $P = .059$; standard error, 0.044; 95% confidence interval, 0.494-0.665). Cut-off value, 7 mm (sensitivity, 64.6%; specificity, 52.5%). *TVV,* target visceral vessel.



Supplementary Fig 4 (online only). Receiver operating characteristic curve analysis for TVVs diameter and loss of primary patency (area, 62.6%; $P = .043$; standard error, 0.005; 95% confidence interval, 0.540-0.710). Cut-off value, 6 mm (sensitivity, 51.9%; specificity, 65.1%). *TVV,* Target visceral vessel.