

Ten-year experience in the endovascular repair of complex and thoracoabdominal aortic aneurysms by an off-the-shelf multibranched thoracoabdominal endograft

Enrico Gallitto, MD, PhD,^{a,b} Gian Luca Faggioli, PhD,^{a,b} Antonio Cappiello, MD,^a Stefania Caputo, MD,^a Chiara Mascoli, MD, PhD,^b Paolo Spath, MD, PhD,^b Eleonora Acquisti, MD,^a Rodolfo Pini, MD, PhD,^{a,b} Andrea Vacirca, MD, PhD,^{a,b} and Mauro Gargiulo, PhD,^{a,b} *Bologna, Italy*

ABSTRACT

Objective: To report outcomes of endovascular repair of complex (CAAAAs) and thoracoabdominal aortic aneurysms (TAAAs) by an off-the-shelf multibranched thoracoabdominal endograft (T-Branch; Cook Medical).

Methods: This single-center, retrospective study analyzed all consecutive CAAAs and TAAAs managed in elective and urgent setting by T-Branch, between 2014 and 2024. Outcomes were reported according to the Society for Vascular Surgery reporting standards. Technical success (TS), spinal cord ischemia (SCI), and 30-day mortality were assessed as early outcomes. Freedom from reinterventions, target artery (TA) instability, and survival were assessed during follow-up.

Results: Of 130 cases, 71 (55%) and 59 (45%) patients were managed in urgent and elective setting, respectively. One hundred fifteen (89%) cases were TAAAs, and 15 (11%) were juxtarenal/pararenal aneurysms. Sixty-seven (52%) cases were performed outside the manufacturer's instructions for use (IFUs). TS was achieved in 118 (91%) cases (elective: 90% vs urgent: 92%) without difference between cases inside and outside IFUs (inside: 92% vs outside: 90%; $P = .7$). There were 10 (8%) SCI events (elective: 2% vs urgent: 13%) with 3 (2%) cases of paraplegia (elective: 2% vs urgent: 3%). Ruptured TAAAs ($P = .02$; odds ratio [OR]: 9; 95% confidence interval [CI]: 1.4-58.9) and postoperative mesenteric events ($P = .01$; OR: 30; 95% CI: 2.1-424.2) were risk factors for SCI. Twelve (9%) patients died within 30 days (elective: 7% vs urgent: 11%). Urgent setting ($P = .03$; OR: 5; 95% CI: 1.5-30.2), iliac conduit ($P = .05$; OR: 5; 95% CI: 1.3-9.2), and postoperative cardiac morbidity ($P = .001$; OR: 15; 95% CI: 1.6-18.5) were risk factors for 30-day mortality. The mean follow-up was 39 ± 22 months. Estimated 3-year freedom from TA occlusion, instability, and reinterventions was 89%, 92%, and 70%, respectively. Urgent TAAA repair ($P = .003$; hazard ratio [HR]: 2; 95% CI: 1.1-4.2) and Crawford's extent I-III ($P = .04$; HR: 3; 95% CI: 1.1-5.9) were risk factors for follow-up reinterventions. Estimated 3-year survival was 64%. Urgent TAAAs ($P = .03$; HR: 3; 95% CI: 1.4-5.8), paraplegia ($P = .04$; HR: 10; 95% CI: 1.1-86.1), and major adverse events ($P = .003$; HR: 2; 95% CI: 1.1-3.8) were risk factors for follow-up mortality.

Conclusions: Endovascular repair of CAAAs and TAAAs by T-Branch is effective with excellent early outcomes and satisfactory midterm TA instability, reinterventions, and survival. Predictors of early/midterm failures were identified, and they should be considered to optimize patient selection and postoperative management. (J Vasc Surg 2026;83:1058-69.)

Keywords: Complex aneurysm; Off the shelf multibranched endograft; Thoracoabdominal aneurysm; T-branch; Urgent endovascular repair

From the Vascular Surgery, Department of Medical and Surgical Sciences (DIMEC), University of Bologna,^a and the Vascular Surgery Unit, IRCCS Sant'Orsola, Azienda Ospedaliero-Universitaria.^b

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Correspondence: Enrico Gallitto, MD, PhD, Vascular Surgery, University of Bologna, IRCCS S. Orsola, Massarenti St 9th, Bologna 40138, Italy (e-mail: enrico.gallitto@gmail.com; enrico.gallitto2@unibo.it).

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Fenestrated and branched endovascular aneurysm repair (F/BEVAR) is considered the first approach for complex (CAAAAs) or thoracoabdominal aortic aneurysms (TAAAs) in patients at high surgical risk and anatomical suitability.^{1,2} In the past few decades, single-/multicenter experiences have demonstrated excellent perioperative and satisfactory midterm outcomes in both degenerative and postdissection aneurysms, as well as in case of previous aortic repairs.³⁻⁸ This technology requires custom-made endografts, tailored to patients' specific anatomy, with 4 to 12 weeks of manufacturing time, limiting the widespread use in urgent clinical setting.⁹⁻¹¹

Off-the-shelf multibranched endografts have been proposed to overcome this problem and manage

urgent CAAAs or TAAAs in anatomically selected patients. On the other hand, these devices are not patient specific and require anatomical compromises with potential drawbacks in comparison with patient-specific endografts. For example, the extensive and necessary length of healthy aortic coverage leads to an increased risk of spinal cord ischemia (SCI).¹² Furthermore, the branch graft design may affect the target artery (TA) instability during follow-up, especially for renal arteries.^{13,14} Finally, the delivery systems (22F-24F) require ideal femoral/iliac access without stenosis, calcifications, or narrow diameters.

Artivion E-nside (Artivion), Cook T-Branch (Cook Medical), and Gore Tambe (Gore) are the 3 different off-the-shelf platforms currently available in Europe (E-nside, T-Branch) and the United States (Tambe).

T-Branch was the first commercially available off-the-shelf device in Europe (CE mark, September 2012), and it was adopted in our clinical practice as the first endovascular solution for urgent CAAAs or TAAAs.¹⁵ In the present article, we report the outcomes of T-Branch in the elective and urgent repair of CAAAs and TAAAs, in a single-center experience, through a 10-year clinical practice.

METHODS

Study design and patient selection

This is a single-center, retrospective study, conducted without funding from companies or organizations and approved by local review boards (T.Ev.AAA-155/2015/U/Oss). All patients with CAAAs or TAAAs who underwent endovascular repair by T-Branch between 2014 and 2024 were included. Cases were deidentified with a coding number and clustered in an electronic database. Anatomical, procedural, and postoperative data were analyzed. The STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) guidelines for observational clinical studies were followed for conducting the present study.¹⁶

Endograft. The endograft characteristics have been extensively described in previously published reports.^{15,17} Briefly, the endograft is loaded into a 22F hydrophilic delivery sheath (outer diameter: 8.5 mm); proximal and distal endograft diameters are 34 mm and 18 mm, respectively, and the overall endograft length is 202 mm. The active fixation is associated with a series of hooks in the proximal of the three sealing stents. Four downward outer branches are allocated in the tapering/narrow part of the endograft (measures/orientations reported in Fig 1). The endograft can be used in a modular configuration with an extensive series of standard endografts, including tapered thoracic and abdominal devices. The anatomical requirements for the endograft suitability are summarized in [Supplementary Table I](#) (online only).

ARTICLE HIGHLIGHTS

- **Type of Research:** Observational, single-center, retrospective study
- **Key Findings:** T-Branch was adopted in 130 complex or thoracoabdominal aneurysms managed in urgent and elective situations. Technical success, paraplegia, and 30-day mortality were 91%, 2%, and 9%, respectively. The median follow-up was 39 months, and 3-year survival, freedom from target artery instability, and reinterventions were 64%, 92%, and 70%, respectively.
- **Take Home Message:** T-Branch is an effective off-the-shelf solution for complex or thoracoabdominal aneurysms, showing satisfactory midterm outcomes regardless of instructions for use adherence. Identifying predictors of outcome is crucial to optimize patient selection and postoperative management.

Inclusion criteria. T-Branch was proposed for the endovascular repair of urgent CAAAs or TAAAs.^{15,17} This group included ruptured aneurysms with hemodynamic stable parameters,² symptomatic patients (acute pain or peripheral embolization), and asymptomatic aneurysms with diameter >80 mm.^{15,17} T-Branch was also considered in elective cases (diameter <80 mm) with anatomical feasibility and when the use of this off-the-shelf device did not increase the healthy aortic coverage compared with custom-made endograft.

Procedure. The standard approach consists of transfemoral introduction and deployment of T-Branch with subsequent TA cannulation and stenting from an upper limb access (first choice: left axillary/brachial artery; second choice: right axillary artery). T-Branch is deployed with distal ends of each visceral branch 15 of 30 mm above the ostia of TAs.^{15,17} The distal abdominal implant is completed, and the large femoral introducers are removed to allow early restoration of blood flow to the pelvis and lower limbs.¹⁵⁻¹⁸ Through a brachial/axillary access (45-cm-long 12F plus 70-cm-long 8/10F Cook-flexor sheath), each branch and its corresponding artery are catheterized and stented with a balloon or self-expanding covered stents (Fig 2, A-C).^{15,17} This maneuver is completed one branch at a time, from below (renal arteries) to above (celiac artery). In cases of renal arteries with hostile anatomy (type B/D orientation),¹⁹ the hybrid stent-graft configuration, consisting of a distal self-expandable and proximal balloon expandable stent-graft, is adopted to optimize flexibility and radial force.²⁰ In case of a preoperative occlusion of one of the four TAs, a balloon expandable covered stent (diameter: 6-8 mm; length: 32-59 mm) and vascular plug (three-lobe 12 mm) are used to close the related branch.²¹

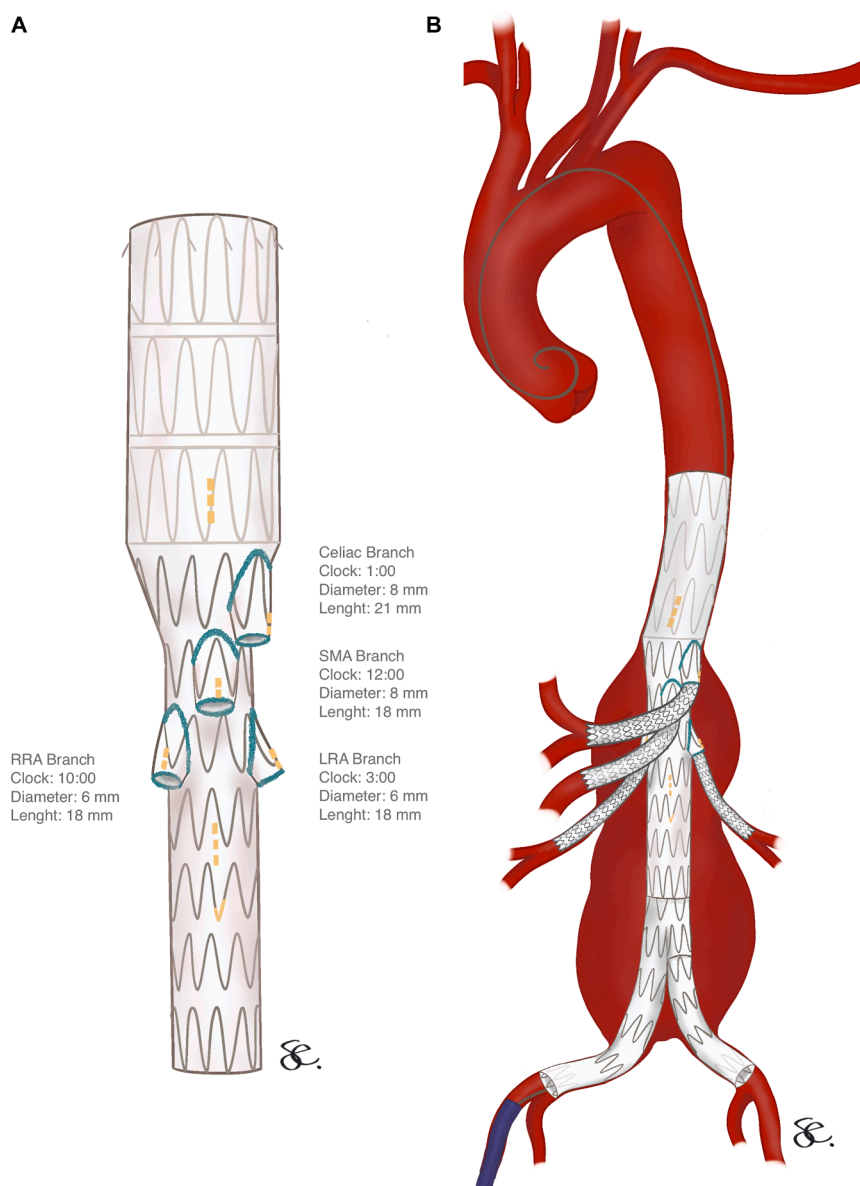


Fig 1. T-Branch endograft (Cook Medical). **(A)** Endograft radiopaque markers and branch measures/characteristics and **(B)** endograft implanted. *LRA*, Left renal artery; *RRA*, right renal artery; *SMA*, superior mesenteric artery.

The T-Branch partial deployment technique is adopted in case of narrow/angulated paravisceral aorta to guarantee a safer TA cannulation.²² This approach consists of deploying the endograft only partially, just enough to release the proximal target vessel cuff, while keeping the remaining branches and distal portion of the graft undeployed.²² At this stage, the gold handle is partially retracted to create sufficient space to remove the black handle and open the proximal portion of the T-Branch to engage the graft from above.²² Subsequently, TA is catheterized through the corresponding branch from above.²²

Finally, a total transfemoral approach for TA cannulation and stenting is adopted in cases of unavailability

of an upper arm access (previous ARCH-BEVAR and previous supra-aortic debranching), shaggy aorta, stenosis/occlusion of the supra-aortic trunks, or a severe atherosclerotic arch. An Aptus steerable sheath (Medtronic) (16F- 22F) and a coaxial 6F-8F, 90-110 mm flexor are used for this purpose (Fig 2, D).

SCI prevention protocol. A dedicated multidisciplinary SCI prevention protocol consisting of pre-, intra-, and postoperative measures was implemented.

First, the patency of the left subclavian and both hypogastric arteries was preserved whenever possible through surgical/endovascular procedures. Second multistaged procedures were planned whenever clinically and anatomically possible. Third, prophylactic cerebral

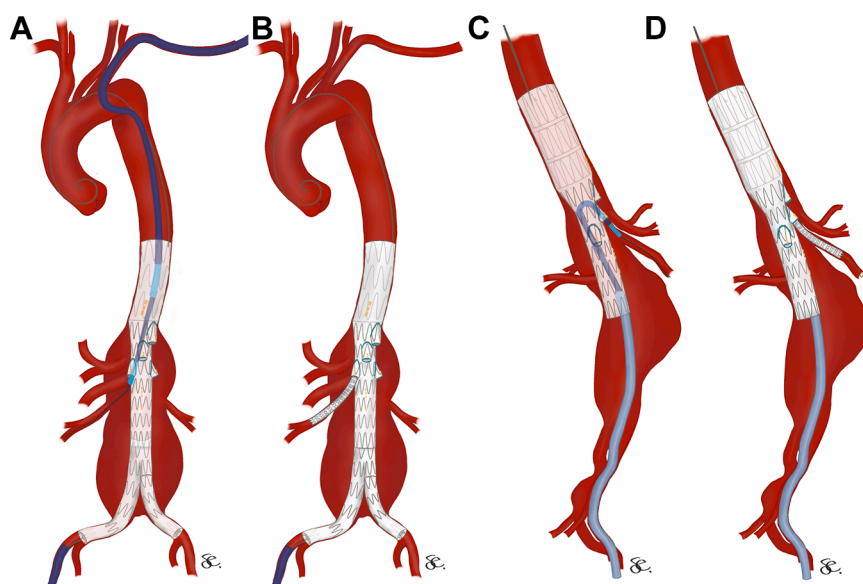


Fig 2. Bridging stent grafting in T-Branch. **A** and **B**, Standard approach with left brachial/axillary access. **C** and **D**, Total transfemoral approach by a steerable introducer.

fluid spinal (CSF) drainage (Liquogard; Moller Medical GmbH) was routinely used from 2014 to 2020 (except for emergencies or in case of absolute contraindications) and maintained for at least 72 hours, postoperatively. Since 2021, the use of prophylactic CSF drainage has been reserved for patients at high risk of SCI (Crawford's extent I-III TAAAs with preoperative occlusion of hypogastric or subclavian arteries or previous symptoms of SCI), while intraoperative neuromonitoring with somatosensitive and motor-evoked potentials was performed in all patients. In addition, early lower limb/pelvic reperfusion, perioperative high mean arterial pressure (>80 mm Hg), and a hemoglobin level of >10 mg/dL were used.¹⁸

End points and definitions. Technical success (TS), SCI, and 30-day/in-hospital mortality were assessed as early outcomes. Freedom from reinterventions, TA instability, and survival were assessed during follow-up. Outcomes and definitions were reported according to the Society for Vascular Surgery reporting standards for endovascular aortic repair of aneurysms involving the renal-mesenteric arteries.¹

Statistical analysis. Continuous data were reported as mean or median and standard deviation or interquartile range, respectively. Categorical data were expressed as frequency. Survival, freedom from reinterventions, and TA instability were estimated by the Kaplan-Meier analysis. Risk factors for early and follow-up outcomes were analyzed by univariable/multivariable analysis and Cox's regression, respectively. A P value of $<.05$ was considered significant. Statistical analyses were performed by SPSS 28.0 (SPSS Inc).

RESULTS

Patient selection. Four hundred seventy-eight patients with CAAAs or Crawford's extent I-III TAAAs underwent F/BEVAR during the study period. One hundred thirty (27%) patients were treated by T-Branch and included in the study analysis. Ninety-eight (76%) patients were male, and the mean age and aneurysm diameter were 75 ± 7 years and 76 ± 13 mm, respectively. Demographics, cardiovascular risk factors, and preoperative comorbidities are reported in Table I. Seventy-one (55%) patients were managed in an urgent clinical setting: ruptures, 26 (20%); symptoms, 43 (33%); and aneurysm with diameter >80 mm, 41 (32%), respectively.

Anatomical details and endograft planning. One hundred fifteen (89%) cases were TAAAs (Crawford's extent I-III: 91), and 15 (11%) were juxtarenal/pararenal aneurysms. Sixty-one (47%) patients had previous thoracic/abdominal aortic repairs (open: 42%-32%; endo: 28%-22%), and there were 11 (9%) postdissection TAAAs. Debranching of supra-aortic trunks or ARCH-BEVAR was necessary in 19 (15%) and 2 (2%) cases, respectively. An adjunctive proximal thoracic endograft (new thoracic aortic coverage) was necessary in 111(85%) cases. Overall, 489 TAs (3.7/patient) were planned for revascularization, whereas 31 TAs were preoperatively occluded, requiring embolization of the corresponding endograft branches. Sixty-seven (52%) cases were performed outside the manufacturer's instructions for use (IFUs); the reasons of this occurrence are summarized in Table II. Fifteen (12%) patients had a preoperative chronic occlusion of the hypogastric artery (bilateral: 3). The distal sealing was

Table I. Demographic, cardiovascular risk factors and preoperative comorbidities

Variable	Value
Male	98 (76)
Hypertension	122 (94)
Active tobacco use	59 (45)
History of tobacco abuse	38 (30)
Dyslipidemia	93 (72)
Diabetes	13 (10)
Chronic obstructive pulmonary disease	51 (39)
Coronary artery disease	44 (34)
Peripheral artery obstructive disease	17 (13)
Atrial fibrillation	22 (17)
Chronic kidney disease	59 (45)
History of stroke	13 (10)
BMI >30 kg/m ²	14 (11)
ASA score 3	50 (38)
ASA score 4	80 (62)
Age, years	75 ± 7
Aneurysm diameter, mm	76 ± 13
ASA, American Society of Anesthesiologists; BMI, body mass index; SD, standard deviation. Data are presented as number (%) and mean ± standard deviation.	

Table II. Cases performed outside the manufacturer's instructions for use (IFUs)

Variable	Value, No. (%)
Cases treated outside IFUs	67 (52)
Cases with multiple-IFU violation	19 (15)
Reason of IFU violation	N = 67
Preoperative chronic occlusion of one of the 4 TAs	31 (46)
Narrow (<25 mm)/angulated (≥90°) paravisceral aortic lumen	47 (70)
Femoral/iliac access	8 (12)
TA, Target artery.	

achieved by an aortic tube in 25 (19%) cases, and an iliac branch device was adopted in 15 (12%) cases (bilateral: 4).

Procedure. Prophylactic CSF drainage and multistage repair were adopted in 90 (69%) and 104 (80%) cases, respectively. The mean time between the first and last stages was 9 ± 4 days. Eight (6%) patients needed a concomitant planned surgical iliac conduit. The brachial/axillary access was performed in 116 patients: right in 23 (20%) and left in 93 (80%) cases. The technique of partial deployment was adopted in 47 (36%) cases, whereas a total transfemoral approach for TA cannulation and stenting was used in 14 (11%) patients. Procedural details and perioperative morbidities are reported in [Supplementary Table II](#) (online only). All patients were admitted in the intensive care unit with a mean stay of 3 ± 2 days.

Perioperative outcomes. TS was achieved in 118 (91%) cases (elective: 90% vs urgent: 92%) with no difference between cases managed inside and outside IFUs (inside: 92% vs outside: 90%; $P = .7$). Technical failures consist of 9 (7%) patients who experienced intraoperative/perioperative TA loss (14/489 TAs: 3%), 1 (0.8%) intraoperative mortality, 1 procedure-related mortality (0.8%, massive cerebral hemorrhage in the first operative hours), and 1 death between steps.

There were 10 (8%) SCI events (elective: 2% vs urgent: 13%), with 3 (2%) cases of paraplegia (elective: 2% vs urgent: 3%). Of these, 9 occurred before 2021 (routine use of prophylactic CSF drainage). Ruptured TAAAs ($P = .02$; odds ratio [OR]: 9; 95% confidence interval [CI]: 1.4-58.9) and postoperative mesenteric events ($P = .01$; OR: 30; 95% CI: 2.1-424.2) were independent risk factors for SCI ([Table III](#)).

Table III. Risk factors for spinal cord ischemia and 30-day mortality at univariate and multivariable analysis

Risk factor	Univariate	Multivariate	
	P value	OR (95% CI)	P value
Risk factors for spinal cord ischemia			
Preoperative factors			
Thoracoabdominal aneurysm	.60		
Crawford's extent I-III thoracoabdominal aneurysm	1.0		
Postdissection thoracoabdominal aneurysms	1.0		
History of aortic surgery	.70		
History of endovascular aortic repair	1.0		
Aneurysm diameter ≥ 80 mm	0.7		
Urgent repair	.01	4.9 (0.3-79.8)	.20
Symptomatic patients	.30		
Ruptured thoracoabdominal aneurysm	.001	9 (1.4-58.9)	.02
Preoperative chronic kidney disease	.50		
BMI ≥ 31	1.0		
Peripheral arterial occlusive disease	.70		
Hypogastric arteries patency	1.0		
Subclavian artery patency	.90		
Procedural factors			
Distal seal with tube endograft	1.0		
Multiple stage repair	.30		
Percutaneous accesses	.30		
Iliac conduit	1.0		
Partial deployment	1.0		
Loss of TAs	.10		
Treatment outside IFUs	.20		
Primary technical success	.20		
Postoperative factors			
Cardiac dysfunction	.30		
Respiratory dysfunction	.08		
Acute kidney injury	1.0		
Dialysis	.50		
Mesenteric complication	.001	30 (2.1-424.2)	.01
Reinterventions within 30 days	.30		
Major adverse events ^a	.001	35 (0.4-552.4)	1.0
Risk factors for 30-day mortality			
Preoperative factors			
Male	1		
Octogenarians	.50		
Urgent repair	.009	5 (1.5-30.2)	.03
Aneurysm diameter ≥ 80 mm	1.0		
Ruptured thoracoabdominal aneurysm	.30		
Hypertension	1.0		
Tobacco use	.80		
Dyslipidemia	.50		
Diabetes	1.0		
Chronic obstructive pulmonary disease	.50		
Coronary artery disease	1.0		
Peripheral arterial occlusive disease	.60		

(Continued on next page)

Table III. Continued.

Risk factor	Univariate	Multivariate	
	<i>P</i> value	OR (95% CI)	<i>P</i> value
Atrial fibrillation	.40		
Chronic kidney disease	1.0		
Dialysis	1.0		
History of aortic surgery	.40		
History of endovascular aortic repair	.70		
Thoracoabdominal aneurysm	.60		
Crawford's extent I-III thoracoabdominal aneurysm	.30		
Postdissection thoracoabdominal aneurysms	1.0		
Procedural factors			
Treatment outside IFUs	.10		
Multiple stage	.07		
Debranching of supra-aortic trunk	.70		
Distal seal with aortobiiliac	.70		
Distal seal with tube endograft	1.0		
Distal seal with iliac branch device	.60		
Iliac conduit	.005	5 (1.3-9.2)	.05
Postoperative factors			
Medical complications	.20		
Stroke	.09		
Spinal cord ischemia	1.0		
Paraplegia	.30		
Cardiac dysfunction	.001	15 (1.6-18.5)	.001
Respiratory dysfunction	.10		
Acute kidney injury	.09		
Mesenteric events	.50		
30-day reinterventions	.50		

BMI, Body mass index; CI, confidence interval; IFU, instructions for use; OR, odd ratio; TA, target artery.

^aExcluded spinal cord ischemia.

Acute kidney injury was reported in 20 (15%) patients, with 4 (3%) cases of dialysis (permanent: 2 and temporary: 2) not related to intraperioperative renal arteries loss.

Twelve (9%) patients died within 30 days (elective: 7% vs urgent: 11%). Urgent setting ($P = .03$; OR: 5; 95% CI: 1.5-30.2), iliac conduit ($P = .05$; OR: 5; 95% CI: 1.3-9.2), and postoperative cardiac morbidity ($P = .001$; OR: 15; 95% CI: 1.6-18.5) were risk factors for 30-day/in-hospital mortality (Table III).

Follow-up outcomes. The mean follow-up was 39 ± 22 months.

Fifteen patients (12%) experienced TA instability (TA events: 21). There were 9 endoleaks (celiac trunk: 4, superior mesenteric artery: 4, and renal arteries: 1) and 12 TA occlusions (all renal arteries). Causes, timing, and solution of each event are summarized in Supplementary Table III (online only). Estimated freedom from TA occlusion and instability at 3 years was 89% and 92%, respectively (Fig 3, A and B).

Overall, 41 (32%) patients underwent reinterventions, including 17 who required multiple procedures. Causes and timing of reinterventions are summarized in Supplementary Table III (online only). There was no conversion or semiconversion to open repair. Estimated freedom from reinterventions was 70% at 3 years (Fig 3, C). Urgent TAAA repair ($P = .003$; hazard ratio [HR]: 2; 95% CI: 1.1-4.2) and Crawford's extent I-III ($P = .04$; HR: 3; 95% CI: 1.1-5.9) were independent risk factors for follow-up reinterventions (Table IV).

There were 3 (2%) cases of aortic-related mortality (early: 2; late: 1). The first case was an intraoperative death due to bleeding from iliac vein during a surgical iliac conduit in a ruptured TAAA with prohibitive iliac access. The second case was a cerebral hemorrhage in the first postoperative hours in an asymptomatic Crawford's extent III TAAA. The third case was an aortic rupture caused by a proximal type I endoleak (isolated T-Branch for Crawford's extent IV TAAA) at 118 months of follow-up. This was a fragile 85-year-old man who has refused

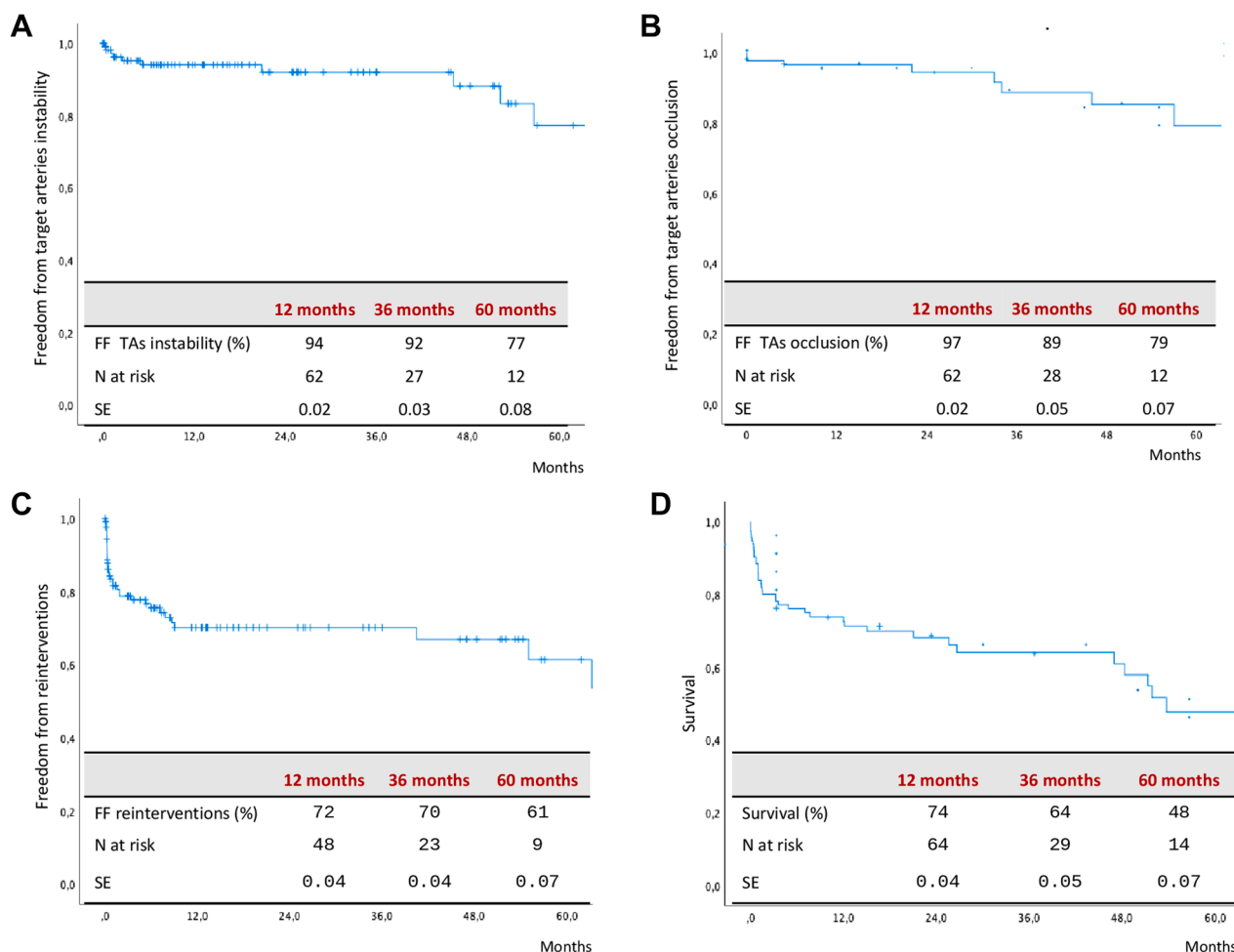


Fig 3. Freedom from (FF) target artery (TA) instability (**A**), TA occlusion (**B**), reinterventions (**C**), and follow-up survival (**D**) by the Kaplan-Meier analysis. SE, Standard error.

secondary intervention 1 year before. Estimated survival was 64% at 3 years (Fig 3, D). Urgent TAAAs ($P = .03$; HR: 3; 95% CI: 1.4-5.8), paraplegia ($P = .04$; HR: 10; 95% CI: 1.1-86.1), and major adverse events ($P = .003$; HR: 2; 95% CI: 1.1-3.8) were risk factors for follow-up mortality (Table IV).

DISCUSSION

In the present article, we report a single-center, retrospective experience of 130 TAAAs and CAAAs treated by T-Branch over a 10-year period, representing the 27% of our overall complex endovascular aortic procedures. Early results were satisfactory with 91% TS, 2% permanent paraplegia, 2% dialysis, and 9% 30-day/in-hospital mortality. Follow-up data were also encouraging with 3-year freedom from TA instability, freedom from reintervention, and survival of 92%, 70%, and 64%, respectively. Overall, these results are favorable, considering that 70% of cases were Crawford's extent I-III TAAAs, 55% were ruptured/symptomatic TAAAs,

and the cohort of patients was at high risk for open surgery (mean age: 75 years; American Society of Anesthesiologists III and IV: 60% and 40%; previous aortic surgery: 47%).

Off-the-shelf multibranched devices were introduced in the market to treat acute TAAAs or CAAAs and nowadays are available in both outer and inner branch configurations.²³ A systematic review and metaanalysis by Karaolanis et al²⁴ reported the use of these devices in elective (64%), urgent (16%), and emergent (19%) cases, with a pooled TS, 30-day mortality, and TA instability of 94%, 10%, and 4%, respectively. In another systematic review and metaanalysis on the endovascular repair of nonelective TAAAs and CAAAs, T-Branch was the most frequently used endograft (54% of cases).²⁵

Preliminary experiences have demonstrated its safety and effectiveness in both elective and urgent TAAAs.²⁶⁻²⁹ In 2020, Konstantinou et al³⁰ reported a systematic review of all published experiences on this

Table IV. Risk factors for follow-up reinterventions and mortality at univariate and Cox regression analysis

Risk factors	Univariate	Multivariate	
	<i>P</i> value	HR (95% CI)	<i>P</i> value
Risk factors for follow-up reintervention			
Urgent repair	.003	2 (1.1-4.2)	.03
Ruptured TAAAs	.05	1.2 (0.5-3)	.60
Treatment outside IFUs	.10		
Crawford's extent I-III TAAAs	.001	3 (1.1-5.9)	.04
Postdissection TAAAs	.02	2.1 (0.7-6.4)	.20
Primary technical success	.09		
Risk factors for follow-up mortality	Univariate	Multivariate	
	<i>P</i> value	OR (95% CI)	<i>P</i> value
Urgent repair	.002	3 (1.4-5.8)	.03
Ruptured TAAAs	.20		
Peripheral arterial occlusive disease	.03	1.4 (0.6-3.3)	.40
Octogenarians	.10		
Crawford's extent I-III TAAAs	.90		
Treatment outside IFUs	.70		
Chronic kidney disease	.01	1.1 (0.6-2.3)	.60
History of aortic surgery	.70		
Spinal cord ischemia	.40		
Paraplegia	.001	10 (1.1-86.1)	.04
Major adverse events ^a	.005	2 (1.1-3.8)	.003
TA instability	.20		
Multiple reinterventions	.50		

CI, Confidence interval; HR, hazard ratio; IFU, instruction for use; OR, odd ratio; TA, target artery; TAAA, thoracoabdominal aortic aneurysm.
^aExcluded spinal cord ischemia.

device, collecting 197 cases (symptomatic: 45%; rupture: 19%) managed between 2014 and 2018. TS, SCI, and early mortality were 93%, 12%, and 6%, respectively.³⁰ Acute renal failure and stroke were reported in 19% and 4% of cases, and the mean follow-up was 15 ± 7 months.³⁰ The largest literature experience on early T-Branch outcomes was reported by Kölbel et al³¹ in a two-center retrospective analysis; of 542 cases, TS, SCI, and early mortality were 97%, 11%, and 12%, respectively.

Our series included both urgent (55%) and elective (45%) cases; outcomes were, as expected, worse in urgent cases compared with elective cases in terms of early mortality (11% vs 7%) and SCI (13% vs 2%). However, it is important to underline that these are two totally different clinical scenarios and should be analyzed separately rather than directly compared.

One of the main issues in the use of T-Branch for elective cases is the extensive proximal healthy aortic coverage with a higher risk of SCI in comparison with a patient specific device.¹² In our series, only 15% of cases received an isolated T-Branch, whereas most patients required at least one adjunctive proximal thoracic endovascular aortic repair. This can be explained considering

that 70% of cases were Crawford's extent I-III TAAAs, requiring an aortic repair from zone 3 to 4, with no differences between the off-the-shelf and patient-specific endograft. Differently, this problem should be accurately considered in cases of juxta/para-renal aneurysms (J/PAAAs), where an off-the-shelf device gives an additional coverage of 74 ± 19 mm when compared with patient-specific endograft.¹² In a multicenter series of urgent J/PAAAs managed by T-Branch, the rate of SCI and paraplegia was 10% and 6%, respectively.³² These figures are not negligible, but they could have been influenced also by the urgent setting, with hemodynamic unstable patient conditions, and impossibility to stage the procedure and use a prophylactic CSF drainage. However, it is interesting to note that no cases of SCI were registered in J/PAAAs in our series.

The anatomical feasibility of the T-Branch was reported from 40% to 80% of TAAAs managed by a custom-made device.^{23,32} In our series, 52% of cases were treated outside the IFU, and it reflects the high number of cases managed in urgent setting, where this endograft was used as a life-saving approach. Variable percentages (45%-72%) of cases managed outside the IFU were

previously reported in literature in the presence of urgent/emergent situations.^{17,28,33}

In our series, the most frequent reasons of anatomical IFU violation were preoperative occlusion of one of the four TAs, narrow/severe angulated paravisceral aorta, and severe femoral-iliac access. For the first issue, we adopted the technique of the intentional occlusion of directional branch by its extension with a covered stent, followed by the placement of an endovascular plug. Tenorio et al²¹ reported a multicenter data collection of 110 occluded branches with no cases of endoleak or reinterventions related to the branch occluded.

The narrow/angulated paravisceral aorta was managed by the partial deployment technique.²² We already have reported the results of this technique in 33 patients with excellent TS (100%) and early TA instability (0.8%).²² Finally, adjunctive planned maneuvers such as standard or intravascular lithotripsy balloon angioplasty or endoconduits may be helpful to guarantee the navigation of the endograft in the iliac axis. According to these adjuncts, there were no differences in terms of TS between cases managed inside and outside the IFU. Even if procedures outside the IFU are more technically demanding and time-consuming than cases inside the IFU, nevertheless similar findings were previously reported by Spanos et al.²⁸ Accordingly, it is crucial to underline the key role of the operator skills and learning curve to manage these challenging situations without life-altering events.²⁸

The rate of SCI was 8% (urgent: 13% vs elective: 2%), with only 2% of permanent paraplegia. This was comparable with literature data of endovascular TAAA repair by both off-the-shelf and patient-specific endografts,^{3-18,28-31} and it should be considered satisfactory considering that 70% of cases were Crawford's extent I-III TAAAs, and 55% of patients received urgent repairs. We reported a high rate of staged repairs (80%) and prophylactic CSF drainage (69%). If the multistage TAAA repair is nowadays considered an effective strategy in these procedures,³⁴ there is an ongoing literature debate on the effectiveness of prophylactic CSF drainage. In the past few years, because of potential CSF drainage-related complications, there was a remarkable decline in prophylactic CSF drainage despite a continued reduction of SCI events.³⁵ In the U.S. Aortic Research Consortium, the prophylactic CSF drainage was adopted in 100% of cases in 2011 and in 11% of cases in 2023.³⁵ In our experience, there was a similar trend of using prophylactic CSF drainage only in patients at high risk (2014-2020: 83% vs 2024: 6%), and we did not observe an increase of the SCI in the past few years. Postoperative mesenteric events and TAAA ruptures were independent risk factors for SCI. Probably, they are both associated with hemodynamic instability due to the low hemoglobin levels or septic shock and should be accurately considered in the postoperative

patient management. Once again, the role of the multidisciplinary SCI prevention protocol with the effective hemodynamic support in the early postoperative course is crucial.

The 30-day mortality was 9% (elective: 7% vs urgent: 11%), and it is in line with previous T-Branch experience (6%-12%)^{24,30,31} and custom-made device (3%-10%) for TAAAs.^{3-5,36} Independent risk factors for early mortality were urgent setting, postoperative cardiac events, and need of iliac conduit. The latter factor, as well as the peripheral arterial occlusive disease, was previously reported as a predictor of perioperative morbidity/mortality.^{37,38} A surgical iliac-femoral conduit was necessary in 6% of cases with inadequate iliac access,³⁹ and it was effective to allow endovascular repair of urgent TAAAs (delivery system 22F) despite the increased perioperative morbidity/mortality.^{40,37} An alternative solution may be the availability of the off-the-shelf device with the same configuration of T-Branch in a low-profile nitinol platform (18F).⁴¹ It can be useful to reduce the rate of surgical iliac conduits or adjunctive maneuvers in urgent setting, saving procedural time and reducing technical difficulties of the repair.

The mean follow-up was 39 months, and it favorably compares with the range of 6 to 18 months reported in the literature review by Konstantinou et al.³⁰ Estimated freedom from TA instability was 92% at 3 years and can be considered satisfactory bearing in mind that we are analyzing an off-the-shelf platform, used in 52% of cases outside the IFU and 55% in urgent setting. These were endoleaks and occlusions in 43% and 57% of cases, respectively. Unlike the endoleaks, which are reported in the celiac trunk and superior mesenteric artery, all the occlusions involved renal arteries. It should also be considered that the branched design in renal arteries is a well-known risk factor for TA instability.^{3,14,19} A specific consideration has to be given to the management of renal arteries in the presence of hostile anatomies (type B/D orientation).¹⁹ We usually adopted the hybrid stent-graft technique to combine distal adaptability and proximal radial force.²⁰ The advantage of this technique was recently reported in a multicenter experience, with 3-year primary and secondary patency of 97% and 99% as well as freedom from TA instability and reinterventions of 91% and 95%, respectively.²⁰

Overall, reinterventions occurred in up to 30% of patients, and they were access related, TA related, and aortic/iliac related in 14%, 12%, and 3% cases, respectively. The majority occurred within 30 days, and it is in line with previous literature data on reinterventions after F/BEVAR.⁴² Independent risk factors were urgent setting and Crawford's extent I-III TAAAs. Of course, the urgent setting is associated with more technically demanding and life-saving procedures, and the assisted TS may be achieved in the early postoperative period after achieving a first clinical stabilization of acute patients.

Finally, survival was 64% at 3 years, which can be considered acceptable in a similar clinical setting. As reported in the literature, follow-up survival after these procedures should be critically discussed because the estimated 5-year survival after endovascular TAAA or CAAA repair is approximately 50%.^{4,36} We are analyzing frail and sick patients unfit for open procedures, and most events are not aortic related.³⁶ At the same time, series focusing on nonelective TAAA and CAAA repairs reported 1-year survival between 65% and 86%.²⁵ In our experience, independent risk factors for follow-up mortality were urgent setting, paraplegia, and postoperative major adverse events. These factors should be considered during patient selection and in the postoperative management in order to optimize overall outcomes.

The present study has several limitations. It is a single-center, retrospective study, with small sample size and midterm follow-up. Moreover, the study reports the outcomes of 10 years of clinical practice, and during this long period, there were important advancements in adjunctive/ancillary materials and operative/hybrid rooms, and finally there was a significant improvement in the operator's ability. The operator and team's learning curve has a crucial role in the outcome's improvement,⁴³ and because of the study design and small sample size, a subanalysis was not feasible. Finally, SCI and 30-day mortality have a low event rate, and this may reduce the power of the multivariate analysis due to overfitting.

CONCLUSIONS

Endovascular repair of CAAAs and TAAAs by T-Branch is effective, with favorable early outcomes and satisfactory midterm TA instability, reinterventions, and survival. Approximately 50% of cases were managed outside the IFUs, but this did not affect TS. Predictors of early/midterm failures were identified, and they should be considered to optimize patient selection and postoperative management.

AUTHOR CONTRIBUTIONS

Conception and design: EG, MG

Analysis and interpretation: EG, GF, CM, PS, RP, AV, MG

Data collection: AC, SC, CM, PS, EA, RP, AV, MG

Writing the article: EG

Critical revision of the article: EG, GF, AC, SC, CM, PS, EA, RP, AV, MG

Final approval of the article: EG, GF, AC, SC, CM, PS, EA, RP, AV, MG

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Supplementary Table I (online only). Anatomical requirements for the t-Branch suitability

Length of proximal sealing	≥25 mm
Paravisceral aortic lumen	≥25 mm
Paravisceral aortic angle (relative to the long aneurysm's axis)	≤90°
No. of TAs	4
Diameter of CT and SMA	6-10 mm
Diameter of RAs	4-8 mm
Distance between the end of the branch and the origin TAs	<50 mm and angle line <45°
Iliac/femoral accesses	22F OD: 8.5 mm

CT, Celiac trunk; OD, outer diameter; RA, renal artery; SMA, superior mesenteric artery; TA, target artery.

Supplementary Table II (online only). Procedural details (data are reported as the sum of parameters in both stages)

Variable	Value
Procedural data	
Main femoral access (total n = 130), No. (%)	
Percutaneous approach	37 (28)
Surgical approach	93 (72)
Iliac conduit	8 (6)
Contralateral femoral access (total n = 121), No. (%)	
Percutaneous approach	39 (32)
Surgical approach	82 (68)
Upper extremity access (total n = 116), No. (%)	
Surgical approach	116 (100)
Right	23 (20)
Left	93 (80)
CO ₂ angiography, No. (%)	72 (55)
Neuromonitoring by MEPs/SSEPs	67 (52)
Prophylactic CSF drainage	90 (69)
Therapeutic CSF drainage, No. (%)	5 (4)
Partial deployment	47 (36)
Supra-aortic trunk debranching	19 (15)
Arch-BEVAR	2 (2)
Total operating time, minutes, mean (IQR)	503 (345-620)
Total fluoroscopy time, minutes, mean (IQR)	114 (75-136)
DAP, mGy/cm ² , mean (IQR)	1,222,194 (504,818-1,553,898)
Iodinated contrast media, mL, mean (IQR)	212 (144-273)
Blood transfusion, mL, mean (IQR)	600 (300-900)
Postoperative morbidities, No. (%)	
Stroke	1 (1)
SCI	10 (8)
Paraplegia	3 (2)
Cerebral hemorrhage	8 (6)
Cardiac events	13 (10)
Respiratory events	14 (11)
Acute kidney injury	20 (15)
Dialysis	4 (3)
Mesenteric events	7 (5)

BEVAR, Branched endovascular aneurysm repair; CSF, cerebrospinal fluid; DAP, dose area product; IQR, interquartile range; MEP/SSEP, motor evoked/somatosensory evoked potentials; SCI, spinal cord ischemia.

Supplementary Table III (online only). Target arteries instability and reinterventions

Patients	TA event	Time, months	Reintervention	Results
1	Endoleak IIIb from CT	63	Yes	Sealed
2	Endoleak Ic from CT	51	Yes	Sealed
	Endoleak Ic from SMA	51	Yes	Sealed
3	Occlusion of LRA	71	No	—
4	Endoleak IIIc from SMA	100	Yes	Sealed
5	Occlusion of RRA	5	Yes	Recanalized
	Occlusion of LRA	5	No	—
6	Endoleak Ic from CT	71	Yes	Sealed
7	Endoleak IIIb from SMA	55	Yes	Sealed
8	Occlusion of RRA	46	No	—
	Occlusion of LRA	46	No	—
9	LRA occlusion	67	No	—
	Endoleak IIIc from SMA	67	Yes	Solved
10	LRA occlusion	57	No	—
11	Endoleak Ic from CT	41	Yes	Solved
12	Occlusion of RRA	9	Yes	Occluded
	Occlusion of LRA	9	Yes	Recanalized
13	RRA occlusion	34	No	—
14	Endoleak Ic from RRA	9	Yes	Sealed
15	Occlusion of RRA	6	Yes	Occluded
	Occlusion of LRA	6	Yes	Recanalized
Reinterventions			No.	%
Patients with reintervention			41/130	32
Patients with multiple reinterventions			17/130	13
Within 30 days				
Patients with reintervention			29	
Reinterventions			33	
Access related			19	
TAs related			6	
Aortic—iliac related			3	
Others			5	
After 30 days				
Patients with reintervention			12	
Reinterventions			14	
TAs related			11	
Aortic—iliac related			2	
Others			1	

CT, Celiac trunk; LRA, left renal artery; RRA, right renal artery; SMA, superior mesenteric artery; TA, target artery.