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Two Year Outcomes following Off the Shelf Inner Branch Endograft Implantation for the Treatment of Complex Abdominal and Thoraco-Abdominal Aortic Aneurysm: Analysis from the Multicentre ItaliaN Branched Registry of E-nside EnDograft (INBREED)

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WHAT THIS PAPER ADDS

This is the first multicentre study reporting two year results using an off the shelf inner branch endograft for the treatment of complex abdominal and thoraco-abdominal aortic aneurysms. The study included 206 complex or thoraco-abdominal aortic aneurysms, with 795 target vessels incorporated through an inner branch. The endograft achieved overall satisfactory freedom from aortic related death (96%), freedom from endograft instability (97.6%), and freedom from target vessel instability (95.9%) at two years. Although rare, loss of proximal sealing may occur, while renal artery occlusion was the most frequent adverse event during follow up.

Objective: This study aimed to report the two year outcomes obtained with the E-nside endograft (Artivion) for the treatment of complex abdominal aortic aneurysm (cAAA) and thoraco-abdominal aortic aneurysm (TAAA).
Methods: This was a prospective, multicentre study in which data from the multicentre ItaliaN Branched Registry of E-nside EnDograft (INBREED) registry were analysed. Primary endpoints were aortic related death, main endograft instability, and target vessel (TV) instability. Secondary endpoints were any re-intervention, TV related patency and endoleaks, and aneurysm sac dynamics at one year.
Results: There were 206 patients (111 TAAAs, 53.9%; 95 cAAAs, 46.1%), accounting for 795 TVs successfully incorporated through an inner branch; 28.6% had an urgent repair. At two years, overall survival was 90.3% (95% confidence interval [CI] 87 — 97%); freedom from aortic related death was 96% (95% CI 94 — 100%), and freedom from endograft instability related to proximal seal failure was 97.6% (95% CI 95 — 100%). Freedom from TV instability was 95.9% (95% CI 93 — 97%) and freedom from re-intervention was 98% (95% CI 96 — 99%). For renal arteries, primary patency was 96.1% (95% CI 93 — 98%) and freedom from endoleak was 99.4% (95% CI 98 — 100%). At one year, 26% of cases had sac regression and 68% remained stable.
Conclusion: The E-nside endograft demonstrated good two year outcomes for the treatment of cAAA and TAAA. It safely and effectively prevented aneurysm related death and guaranteed low TV instability. During planning, attention should be given to the proximal sealing zone to prevent graft instability during follow up.

Keywords: Aortic aneurysm, Branched endovascular aortic repair, Endovascular aneurysm repair, Multicentre study, Stent, Thoraco-abdominal aortic aneurysm
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† A list of the INBREED Investigators is included in Appendix A.

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INTRODUCTION

Endovascular repair of thoraco-abdominal aortic aneurysms (TAAAs) and complex abdominal aortic aneurysms (cAAAs) with branched and fenestrated endografts has been demonstrated to be an effective and less invasive alternative to traditional open repair.[1,2] The development of readily available off the shelf (OTS) branched endografts, with broad applicability to different visceral and renal target vessel anatomy, has enabled the treatment of a wide range of patients, not only in elective but also in urgent or non-deferrable settings, with low early mortality and complications.[3] Different OTS graft geometrical conformations are currently available, all featuring a branched structure with outer or inner directional cuffs. The first commercially available OTS outer branched endograft was the Zenith t-Branch (Cook Medical, Bloomington, IN, USA), with the first initial preliminary clinical experience published in 2013 by Bosiers *et al.*[4] More recently, a new OTS inner branch endograft (E-nside; Artivion Inc., Kennesaw, GA, USA) was released in the European market in 2020. The E-nside has four pre-cannulated downward oriented inner branches and two different proximal and distal diameter configurations; it is made with polyester fabric and self expanding nitinol stents. The inner branch technology was developed to overcome some anatomical obstacles, such as narrow aortic paravisceral lumen and or unfavourable target vessel trajectory. The first clinical multicentre experience on E-nside was published in 2023, demonstrating good early technical and clinical success.[5]

Over the past decade, the t-Branch has been reported on in several studies, demonstrating its midterm safety and efficacy. However, little information is available on outcomes beyond 90 days[3,6] of the more recently commercialised E-nside.[7] In this regard, it is important to obtain additional information on the main graft performance over time in relation to material fatigue as well as branch stability with the relatively new inner branch technology.

The current study reports the two year outcomes of the E-nside endograft, including $>$ 200 cases collected in the multicentre ItaliaN Branch Registry of E-nside EnDograft (INBREED). This represents a real world experience where the E-nside graft was used in elective and urgent settings, and includes both cAAAs and TAAAs.

METHODS

Study design

INBREED is a physician initiated, non-sponsored, prospective, multicentre, observational cohort registry collecting data on all patients treated with the E-nside endograft in participating centres. Institutional review board and ethics committee approval were obtained (Ethic Committee for Clinical Experimentation, Padua, Italy; study ID 211745). Informed consent was obtained.

Patient population. Patients were included by participating centres on an intention to treat basis. Decisions on indications, patient selection, surgical approach, and post-operative care were not standardised, but based on each single centre's established practice. The post-operative medical protocol generally consisted of dual antiplatelet therapy for 1 month, followed by lifelong single antiplatelet therapy. Early outcomes (90 days) of the initial 116 patients from the same registry were reported in 2023, and the specific short term results obtained in the emergency and urgent setting and for juxta- and pararenal aneurysms have previously been analysed.[5,6,8] The present study was designed to analyse in detail the two year outcomes and to report updated overall results from the same registry, encompassing a total of 220 patients enrolled between 2021 and 2024 from 36 centres. Of these, 14 records had a follow up duration of $<$ 30 days and were excluded from the current analysis, leading to the inclusion of 206 patients.

Data collection and definitions

Anonymised data were entered by delegates from each participating centre. One centre (Vascular and Endovascular Surgery Division, Padua University, Padua, Italy) was responsible for the electronic data capture system (REDCap),[9] checking the quality of the imputed data, and performing the final analysis. A data quality control was performed with regular interval audits (a total of six for this study), and queries were applied for specific errors and missing, incomplete, or unclear data. Baseline demographics, risk factors, clinical characteristics, and anatomical data were collected. Disease extent classification was based on pre-operative computed tomography angiography;[10,11] and according to disease extent, results were stratified into cAAAs (including juxtarenal, pararenal, and Crawford IV thoraco-abdominal aneurysms) and Crawford I — III TAAAs.[11] Operative data on vascular access, staging, spinal cord protection, device size, associated endografts, length of thoracic aorta coverage, target artery bridging stents, and procedural metrics were registered. Technical success and 30 day major adverse events (MAEs) were reported.[5,8] Death, graft stability, and target vessel stability during follow up were assessed based on clinical and imaging assessment at 30 days, six and 12 months, and yearly thereafter. Cause of death was extracted from the local clinical papers.

Endpoints. The primary endpoints were two year aneurysm related death, freedom from graft instability, and freedom from target vessel instability (TVI). Aneurysm related death included any death occurring within the first 30 days or any death resulting from aneurysm rupture, aorta related complications (e.g., infection, occlusion, dissection, haematoma), or a complication of a secondary intervention. Graft instability was defined as a composite endpoint including any E-nside related event associated with patient death, aneurysm rupture, infection, or re-intervention, excluding target vessel related events, which were described under the definition of TVI.[10] TVI was defined as a composite endpoint including any death or rupture related to a side branch complication (endoleak, rupture)

or any secondary intervention indicated for treating a branch related complication, including endoleak, disconnection, kinking, stenosis, occlusion, or rupture.[10] Secondary endpoints were specific rates of target vessel patency, freedom from target vessel endoleak related re-interventions, and sac dynamics at one year. Sac diameter changes at one year were assessed according to previous reports and defined as increase (diameter increase >5 mm), decrease (diameter decrease >5 mm), or stable.[10,12,13]

Statistical analysis

Results were reported as number and percentage for categorical variables and as mean $\pm$ standard deviation or median and interquartile range for continuous variables. Normal distribution was tested with the Shapiro–Wilk test. The Wilcoxon rank sum test or *t* test were used as appropriate. The Pearson's χ^2 test and Fisher's exact test were used for analysis of categorical variables. Time dependent outcomes were reported as Kaplan–Meier estimates using competing risk analysis and were compared using the log rank test. A Cox proportional hazards multivariable model was implemented to investigate risk factors associated with TVI. A frailty term was used to account for variability between centres. It was not possible to implement any reliable regression model for aortic related death and endograft instability owing to the very low number of events. A *p* value of $<.050$ was used to determine statistical significance. R 4.3 software (R Foundation for Statistical Computing, Vienna, Austria) was used for statistical analysis.

RESULTS

Patient population

Two hundred and six patients treated from June 2021 to November 2024 were included in the analysis of two year results of E-nside. Overall, 7.2% of data were missing. The pattern of missing data was completely random, and a pairwise deletion was performed for the analysis; no imputation of missing variables was performed. Patient demographics and risk factors are shown in Table 1. There were 111 TAAAs (53.9%) and 95 cAAAs (46.1%). The mean patient age was 73.3 $\pm$ 8.2 years and 148 (71.8%) were men (cAAA, 78.9% *vs.* TAAA, 65.8%; $p=.036$). Genetically triggered aortic disease (cAAA, 0% *vs.* TAAA, 5.6%; $p=.021$) and previous open (cAAA, 21.3% *vs.* TAAA, 40.4%; $p=.004$) or endovascular (cAAA, 20.2% *vs.* TAAA, 35.2%; $p=.018$) aortic repair were more frequent in patients with TAAA than cAAA.

Specific aortic pathology is reported in Table 2. Most patients had a degenerative aneurysm (78.6%); 22 (10.8%) had a chronic dissection, 10 (5.0%) had acute aortic syndrome, and 12 (5.9%) had an aortic pseudoaneurysm. Urgent treatment was performed in 59 patients (28.6%); 47 patients (22.8%) presented with a contained aortic rupture ($n=7$) or symptomatic status ($n=40$), and 12 patients (5.8%) received urgent treatment because of aneurysm diameter >70 mm. A narrow paravisceral aortic diameter was present in 51 patients (26.6%).

Peri-operative and 30 day data

Peri-operative data are reported in Table 3. Procedure staging to reduce the risk of spinal cord ischaemia was adopted in 87 patients (39.6%) (cAAA, 33.3% *vs.* TAAA, 36.5%; $p=.031$). An adjunctive proximal thoracic endograft was implanted during the index procedure in 13 cAAAs (14.3%) and 67 TAAAs (63.2%), and a distal bifurcated abdominal endograft was more frequently used in cAAA than TAAA (74.7% *vs.* 39.2%; $p<.001$). A total of 795 target vessels (398 coeliac and mesenteric and 397 renals) were successfully incorporated through an inner branch. A balloon expandable bridging stent was used in 585 target vessels (73.6%) and a self expanding stent in 210 (26.4%).

Overall technical success was 98.5% and 30 day death occurred in seven patients (3.3%). Any MAE occurred in 51 patients (24.7%). Specific MAEs stratified by disease extent are reported in Table 4. An early re-intervention was performed in 20 patients (9.7%) owing to access site ($n=10$), target vessel ($n=8$), or main graft ($n=2$) related complications.

Two year outcomes

The median follow up duration was 33 months; the follow up index was 89% (95% after the first year), and 143 patients (70%) had ≥ 24 months of follow up. Overall survival at 2 years was 90.3% (95% confidence interval [CI] 87 – 97%); survival was 93% (95% CI 88 – 98%) for elective treatment and 87% (95% CI 79 – 95%) for urgent treatment ($p=.30$). Beyond 30 days, there was one case of aortic rupture, probably related to a type III endoleak, leading to a freedom from aortic related mortality rate of 96% (95% CI 94 – 100%). Freedom from graft instability at 2 years was 98.7% (95% CI 95 – 100%) (Fig. 1). There were four cases of graft instability related to type Ia endoleak, of which two also displayed graft distal migration. Of these, three E-nsides had been implanted in a native thoracic aorta and one in a thoracic endograft; in the two with distal graft migration, one case had initial signs of aneurysmal wall evolution with a maximum outer diameter of 34 mm at the proximal sealing zone. There were no cases of conversion to open surgery.

Overall freedom from TVI was 95.9% (95% CI 93 – 97%); freedom from branch instability was 95.9% (95% CI 94 – 98%) for the visceral arteries and 94.6% (95% CI 92 – 97%) for the renal arteries ($p=.30$) (Fig. 2). Primary patency was 97.5% (95% CI 95 – 98%); 98.9% (95% CI 97 – 100%) for the visceral arteries and 96.1% (95% CI 93 – 98%) for the renals ($p=.001$) (Fig. 3A). Renal artery patency was better in cases with a reinforced bridging stent (hazard ratio [HR] 0.15, 95% CI 0.03 – 0.70; $p=.016$) and was negatively associated with a target artery diameter <5 mm (HR 1.57, 95% CI 1.02 – 2.68; $p=.001$), while it was not statistically significantly associated with other procedural

Table 1. Demographic characteristics and risk factors of patients (n = 206) treated with the E-nside off the shelf inner branch endograft for complex abdominal or thoraco-abdominal aortic disease.

Characteristic	cAAA (n = 95)	TAAA (n = 111)	Total (n = 206)	p value
Age − y	75.6 ± 6.7	71.3 ± 8.8	73.3 ± 8.2	<.001
Sex, men	75 (78.9)	73 (65.8)	148 (71.8)	.036
BMI − kg/m^2	26.5 ± 5.5	26.6 ± 4.2	26.5 ± 4.9	.85
Coronary artery disease	29 (30.5)	29 (26.6)	58 (28.4)	.53
Hypercholesterolaemia	69 (72.6)	68 (62.4)	137 (67.2)	.12
Hypertension	89 (93.7)	98 (89.9)	187 (91.7)	.33
COPD	51 (53.7)	39 (35.8)	90 (44.1)	.010
Chronic kidney disease	23 (24.2)	26 (23.9)	49 (24.0)	.95
Chronic heart failure	14 (14.7)	13 (11.9)	27 (13.2)	.55
Genetically triggered aortic disease	0 (0)	6 (5.6)	6 (3.0)	.021
Previous open aortic repair	20 (21.3)	44 (40.4)	64 (31.5)	.004
Previous endovascular aortic repair	19 (20.2)	38 (35.2)	57 (28.2)	.018

Data are presented as mean ± standard deviation or n (%). cAAA = complex abdominal aortic aneurysm; TAAA = thoraco-abdominal aortic aneurysm; BMI = body mass index; COPD = chronic obstructive pulmonary disease.

or anatomical factors, such as type of main bridging stent (HR 0.75, 95% CI 0.25 − 2.31; p = .62), narrow paravisceral aortic lumen (HR 1.10, 95% CI 0.41 − 2.95; p = .84), and aneurysm extent (extent I − III, HR 3.01, 95% CI 0.60 − 9.20; p = .20). Freedom from target vessel endoleak was 98.5% (95% CI 97 − 99%); 97.7% (95% CI 96 − 99%) for the visceral arteries and 99.4% (95% CI 98 − 100%) for the renals (p = .030) (Fig. 3B). Specific freedom from re-intervention rates were 98.3% (95% CI 97 − 99%) for the coeliac and mesenteric arteries and 98.1% (95% CI 96 − 99%) for the renals. The presence of a narrow paravisceral aorta < 25 mm did not have a statistically significant impact on freedom from TVI (95% [95% CI 92 − 97%] *vs.* 95% [95% CI 92 − 99%]; p = .57), primary patency (97% [95% CI 95 − 98%] *vs.* 96% [95% CI 93 − 99%]; p = .73), or target vessel endoleak (98% [95% CI 96 − 99%] *vs.* 95% [95% CI 97 − 100; p = .68). Multivariable analysis for TVI is reported in Table 5; urgent repair (HR 2.23, 95% CI 1.01 − 5.11; p = .044) and aneurysm extent (HR 2.273, 95% CI 1.05 − 7.06; p = .038) were associated with TVI, while use of a

Table 2. Clinical and anatomical characteristics of patients (n = 206) treated with the E-nside off the shelf inner branch endograft for complex abdominal or thoraco-abdominal aortic disease.

Characteristic	cAAA (n = 95)	TAAA (n = 111)	Total (n = 206)	p value
Aortic pathology				<.001
Degenerative aneurysm	78 (82.1)	84 (75.2)	162 (78.6)	
Chronic dissection	2 (2.1)	20 (18.3)	22 (10.8)	
Acute or subacute dissection	0 (0.0)	5 (4.6)	5 (2.5)	
IMH or PAU	4 (4.2)	1 (0.9)	5 (2.5)	
Pseudoaneurysm	11 (11.6)	1 (0.9)	12 (5.9)	
Aortic status				.13
Contained rupture	5 (5.3)	2 (1.8)	7 (3.4)	
Non-ruptured symptomatic	14 (14.7)	26 (23.4)	40 (19.4)	
Non-ruptured asymptomatic	76 (80.0)	83 (74.8)	159 (77.2)	
Largest aortic diameter − mm	66.0 ± 14.9	65.3 ± 12.7	65.7 ± 13.8	.73
Aortic diameter >70 mm	24 (6.1)	27 (26.0)	51 (26.0)	.98
Anatomical classification				<.001
Extent I	0 (0.0)	30 (27.0)	30 (14.6)	
Extent II	0 (0.0)	46 (41.4)	46 (22.3)	
Extent III	0 (0.0)	35 (31.5)	35 (17.0)	
Extent IV	39 (41.1)	0 (0.0)	39 (18.9)	
Juxtarenal	10 (10.5)	0 (0.0)	10 (4.9)	
Pararenal	46 (48.4)	0 (0.0)	46 (22.3)	
Minimum paravisceral aortic diameter − mm	30.3 ± 7.9	31.6 ± 8.6	31.0 ± 8.3	.27
Narrow paravisceral aortic lumen, <25 mm	23 (25.8)	28 (27.2)	51 (26.6)	.83
Minimum iliac artery diameter, main shaft side	10.6 ± 12.5	9.6 ± 7.1	10.1 ± 10.0	.51

Data are presented as n (%) or mean ± standard deviation. cAAA = complex abdominal aortic aneurysm; TAAA = thoraco-abdominal aortic aneurysm; IMH = intramural haematoma; PAU = penetrating aortic ulcer.

Table 3. Peri-procedural data of patients (n = 206) treated with the E-nside off the shelf inner branch endograft for complex abdominal or thoraco-abdominal aortic disease.

Parameter	cAAA (n = 95)	TAAA (n = 111)	Total (n = 206)	p value
Staging of the procedure				.031
Single stage	62 (66.7)	57 (54.8)	119 (60.4)	
Staged	33 (33.3)	45 (36.5)	87 (39.6)	
Adjunctive proximal thoracic endograft	13 (14.3)	67 (63.2)	80 (40.6)	<.001
Total thoracic aortic coverage − cm	12.1 ± 5.8	24.1 ± 8.0	17.4 ± 9.0	<.001
Adjunctive distal EVAR	65 (74.7)	40 (39.2)	105 (55.6)	<.001
Prophylactic spinal drainage	23 (24.2)	41 (38.7)	64 (31.8)	.028
Percutaneous femoral access				.39
Bilateral	46 (48.4)	56 (51.9)	102 (50.2)	
Unilateral	24 (25.3)	19 (17.6)	43 (21.2)	
Upper arm access				.39
No	11 (11.5)	27 (24.3)	38 (18.4)	
Left side	62 (73.8)	57 (67.9)	119 (70.8)	
Right side	22 (26.2)	27 (32.1)	49 (29.2)	
Coeliac artery				.53
Balloon expandable stent	64 (67.3)	79 (71.1)	143 (69.4)	
Self expanding stent	26 (27.3)	23 (20.7)	49 (23.7)	
Intentional occlusion	5 (5.7)	9 (8.9)	14 (7.4)	
Adjunctive relining stent	18 (20.5)	10 (10.5)	28 (15.3)	.062
Superior mesenteric artery				.37
Balloon expandable stent	72 (75.8)	88 (79.3)	160 (77.7)	
Self expanding stent	23 (24.2)	23 (2.1)	46 (22.3)	
Adjunctive relining stent	20 (21.5)	12 (11.3)	32 (16.1)	.051
Right renal artery				.38
Balloon expandable stent	66 (69.5)	72 (64.9)	138 (66.9)	
Self expanding stent	28 (29.5)	36 (32.4)	64 (31.1)	
Intentional occlusion	1 (1.1)	3 (2.9)	4 (2.1)	
Adjunctive relining stent	22 (24.2)	19 (19.0)	41 (21.5)	.38
Left renal artery main bridging stent				.51
Balloon expandable stent	68 (71.5)	76 (68.4)	144 (69.9)	
Self expanding stent	23 (24.2)	28 (25.2)	51 (24.7)	
Intentional occlusion	4 (4.3)	7 (6.3)	11 (5.6)	
Adjunctive relining stent	18 (20.5)	22 (23.4)	40 (22.0)	.63
Procedure metrics				
Total operating time − min	253.2 ± 116.1	250.5 ± 140.7	251.8 ± 129.5	.88
Total iodinated contrast − mL	184.3 ± 129.8	198.6 ± 99.9	191.3 ± 115.9	.47

Data are presented as n (%) or mean ± standard deviation. cAAA = complex abdominal aortic aneurysm; TAAA = thoraco-abdominal aortic aneurysm; EVAR = endovascular aneurysm repair.

reinforced stent was protective (HR 0.33, 95% CI 0.13 − 0.91; $p = .034$).

Comparing male and female patients, there were no statistically significant differences in aortic related mortality rate (100% *vs.* 97%; $p = .50$), freedom from device instability (93.9% *vs.* 94.2%; $p = .61$), and TVI (96% *vs.* 96%; $p = .72$).

Data on sac regression at one year were available for 172 patients (83%). Sac increase was observed in 14 (8.1%) and sac regression in 41 (24%); sac diameter remained stable in 117 patients (68.0%).

DISCUSSION

This is the first multicentre study reporting two year results using an OTS inner branch endograft for the treatment of cAAAs and TAAAs. The E-nside achieved overall satisfactory freedom from aortic related death (96%), freedom from endograft instability (98%), and freedom from TVI (97%) at two years.

The E-nside OTS inner branch device is a relatively new tool in the endovascular armamentarium that may be useful for the treatment of a wide range of aortic pathologies.[5,8,14] However, it is not commercially available worldwide, and the largest experience comes from European centres, where the graft has obtained a CE mark for the treatment of the thoraco-abdominal aorta. The Zenith t-Branch is the oldest available OTS platform, while other new OTS devices recently started their clinical application. The TAMBE (W.L. Gore & Associates, Flagstaff, AZ, USA) has been used for cAAA and type IV TAAA repair, the WeFlow (Endonom Medtech, Hangzhou, China) for cAAAs, and the G-Branch (Lifetech Scientific, Shenzhen, China) for TAAA and cAAA repair. However, general clinical outcomes are only available for the TAMBE endograft,[15] which is only available in the US market. Preliminary results have been

Table 4. Early (30 day) outcomes of patients (n = 206) treated with the E-nside off the shelf inner branch endograft for complex abdominal or thoraco-abdominal aortic disease.

Outcome	cAAA (n = 95)	TAAA (n = 111)	Total (n = 206)	p value
Technical success	91 (97.8)	104 (99.0)	195 (98.5)	.49
Death	3 (3.1)	4 (3.8)	7 (3.3)	.49
EBL >1 000 mL	5 (5.6)	3 (3.1)	8 (4.3)	.40
Myocardial infarction	0 (0.0)	3 (2.9)	3 (1.5)	.10
Respiratory failure	2 (2.3)	6 (5.8)	8 (4.2)	.22
Stroke	4 (4.4)	2 (1.9)	6 (3.1)	.31
Spinal cord ischaemia				.66
Motor able to ambulate	1 (1.1)	0 (0.0)	1 (0.5)	
Motor unable to ambulate	7 (7.9)	6 (5.8)	13 (6.7)	
Sensory deficit	3 (3.4)	3 (2.9)	6 (3.1)	
Acute kidney injury	9 (10.0)	9 (8.7)	18 (9.3)	.74
Early re-intervention	11 (11.6)	9 (8.5)	20 (9.7)	.28
Access site complication	6 (54.5)	4 (44.4)	10 (50.0)	.90
Branch complication	4 (36.4)	4 (44.4)	8 (40.0)	
Main graft complication	1 (9.1)	1 (11.1)	2 (10.0)	

Data are presented as n (%). cAAA = complex abdominal aortic aneurysm; TAAA = thoraco-abdominal aortic aneurysm; EBL = estimated blood loss.

reported for the other OTS devices, with a very limited number of cases.[16,17] For these reasons, the only possible reliable comparison of the present two year outcomes of E-nside can be performed with the t-Branch, which has been available in the market for more than ten years. Early results both in elective and urgent settings[8] have been clearly demonstrated for t-Branch; however, also for t-Branch, the longest available reported outcomes are within 24 months, and there remains a lack of evidence for long term results, despite its extended time in clinical use. The most recent paper from Tsilimparis *et al.* reported t-Branch two year outcomes for 80 patients, with a freedom from all cause and aneurysm related death of 78.5% and 98.6%, respectively.[18] In the current experience, overall survival was higher (90.5% at two years), while freedom from aneurysm related mortality was similar (99%). Particularly in the present cohort, survival was higher in elective cases (elective 93% *vs.* urgent 86%), possibly owing to a higher comorbidity rate for urgent cases, as previously also for t-Branch. In this regard, Silingardi *et al.* described a 2% mortality rate for elective cases *vs.* 22% for urgent/emergency cases at 18 months using the t-Branch.[19]

Regarding freedom from branch instability, the current findings with OTS inner branches seem to be extremely positive compared with those reported for OTS outer branches. Tsilimparis *et al.* reported a two year freedom from secondary re-intervention rate with t-Branch for TAAA of 76.3%.[18] Primary patency of renal arteries was 83% in the work by Silingardi *et al.*[19] and 87.5% and 72.2% at one and two years, respectively, in the study by Hongku *et al.*[20]

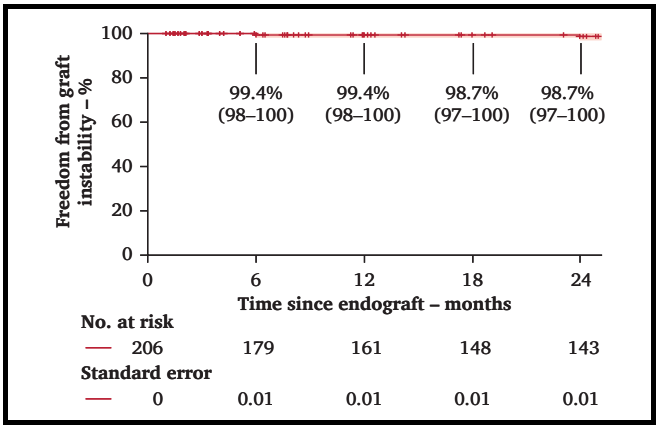

Figure 1. Cumulative Kaplan–Meier estimate of overall freedom from graft instability at two years for patients treated with the E-nside off the shelf inner branch endograft for complex abdominal or thoraco-abdominal aortic disease. Standard error < 10%.

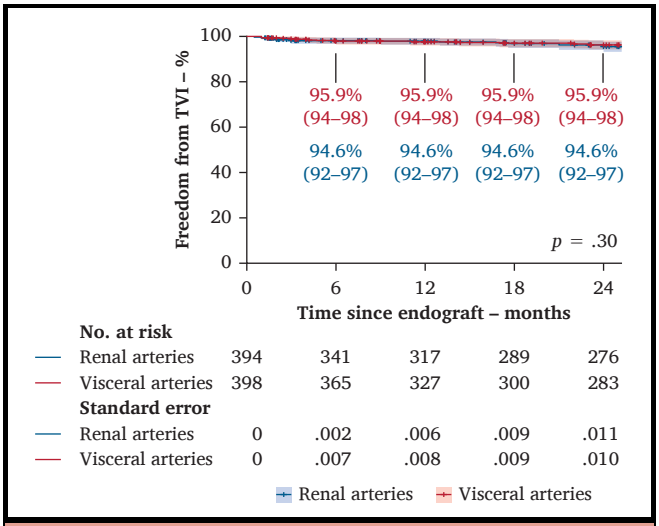

Figure 2. Cumulative Kaplan–Meier estimate of freedom from target vessel instability (TVI) at two years for patients treated with the E-nside off the shelf inner branch endograft for complex abdominal or thoraco-abdominal aortic disease, stratified by type of target vessel. Standard error < 10%.

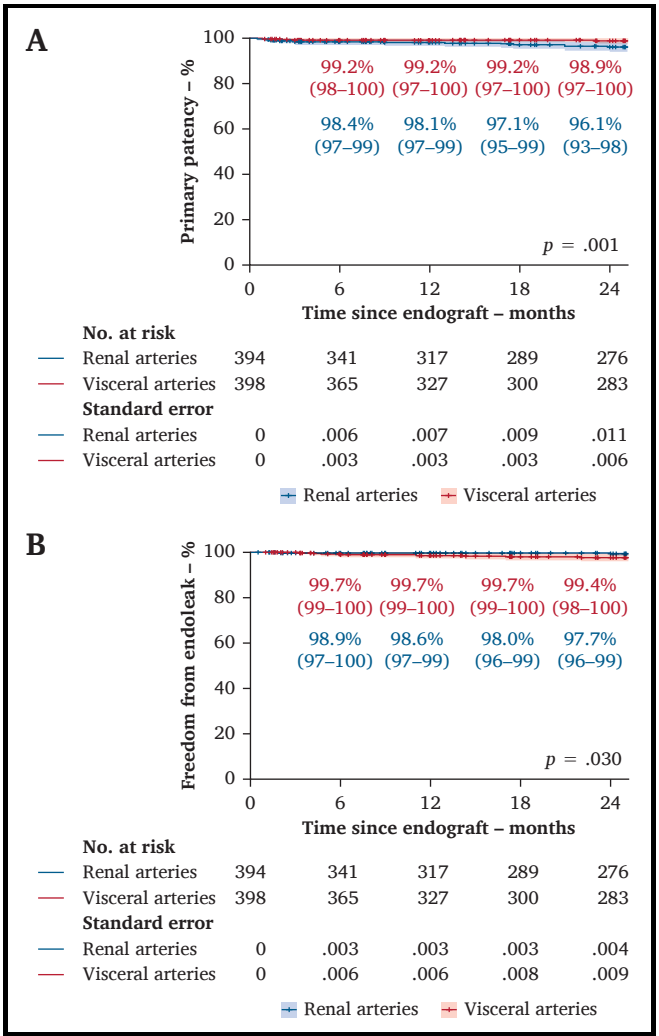

Figure 3. Cumulative Kaplan–Meier estimate of (A) target vessel primary patency and (B) freedom from target vessel endoleak at two years for patients treated with the E-nside off the shelf inner branch endograft for complex abdominal or thoraco-abdominal aortic disease, stratified by type of target vessel. Standard error < 10%.

Table 5. Multivariable Cox regression analysis for target vessel instability with the E-nside off the shelf inner branch endograft for complex abdominal or thoraco-abdominal aortic disease.

Covariable	HR (95% CI)	*p* value
Age, per year	1.01 (0.96–1.04)	.79
Sex, woman	1.44 (0.56–3.70)	.44
Urgent repair	2.23 (1.01–5.11)	.044
TAAA extent I–III	2.73 (1.05–7.06)	.038
Narrow paravisceral lumen	0.37 (0.11–1.35)	.082
Target artery		
Visceral	1.0 (ref.)	–
Renal	1.45 (0.66–3.10)	.46
Bridging stent		
Balloon expandable	1.0 (ref.)	–
Self expanding	0.69 (0.30–2.98)	.72
Reinforced bridging stent	0.33 (0.13–0.91)	.034
Centre volume, quartiles	0.85 (0.75–1.53)	.69

HR = hazard ratio; CI = confidence interval; TAAA = thoraco-abdominal aortic aneurysm.

In the current experience, the two year freedom from branch instability was apparently higher, reaching 95.3%, with a 98.1% freedom from re-intervention rate. This may be related to a larger number of elective cases in the current series, with more that 75% asymptomatic and 3.4% ruptured. Also, the presence of > 30% of cases with juxta- or pararenal aneurysm may reflect a higher number of cases with fewer comorbidities, disease extent, and better target vessel quality compared with the previous studies with t-Branch. In a recent systematic review and meta-analysis comparing OTS inner with outer branch endografts,[16] including 13 studies and 595 patients, the prevalence of late TVI was 6.2% for the outer branch endografts and 1.6% for inner branches. The pooled rate of late re-intervention for outer branches was 9.8%, while it was 8.3% for inner branches. In particular, the occlusion rate was 2.3% for outer branches and 1% for inner branches. In the current series, the occlusion rate with inner branches was 1.3% for viscerals and 4.6% for renals, accounting for an overall 3% at two years. These findings may reflect a trend towards a higher midterm target vessel stability using inner branch technology for extensive aortic aneurysmal disease. In addition, inner branch findings seem not to be influenced by complex anatomies, such as the presence of a narrow paravisceral aorta < 25 mm, that is often associated with aortic angulation (Fig. 4), as this did not influence two year TVI.

It is believed that no previous study on an OTS device has also focused on main endograft stability and performance in terms of sac regression. There was 3.4% main endograft instability in the current cohort, which was related to a type Ia endoleak owing to loss of proximal sealing in all cases. This highlights the fundamental aspect that the E-nside does not have active proximal sealing, and instructions for use suggest landing in a previous thoracic endograft. Of the two reported graft migrations, one case landed in a previous thoracic graft, and the other in the native aorta. Based on these observations, the quality of the aortic sealing is more crucial than the presence of a proximal thoracic endovascular aortic repair in preventing proximal endograft failure. The sealing should be long and consistently uniform in diameter for at least 3 — 4 cm, without any signs of early aneurysmal wall disease. Additionally, significant graft oversizing of at least 30% is recommended, as this ensures a stronger radial force without the risk of infoldings owing to the excellent conformability of the nitinol struts.

The excluded aneurysmal sac remained stable or shrunk in > 90% of cases at one year, with sac regression in 26%. This is in line with previous studies,[12,21] highlighting that the rate of sac regression after branched endovascular aneurysm repair is lower than with standard and fenestrated endovascular aneurysm repair, possibly as a result of the more extensive disease and larger aortic diameter, while most patients exhibit stable sac dynamics during follow up. Nevertheless, a very low aneurysm related mortality rate was observed at two years (1%); collectively,

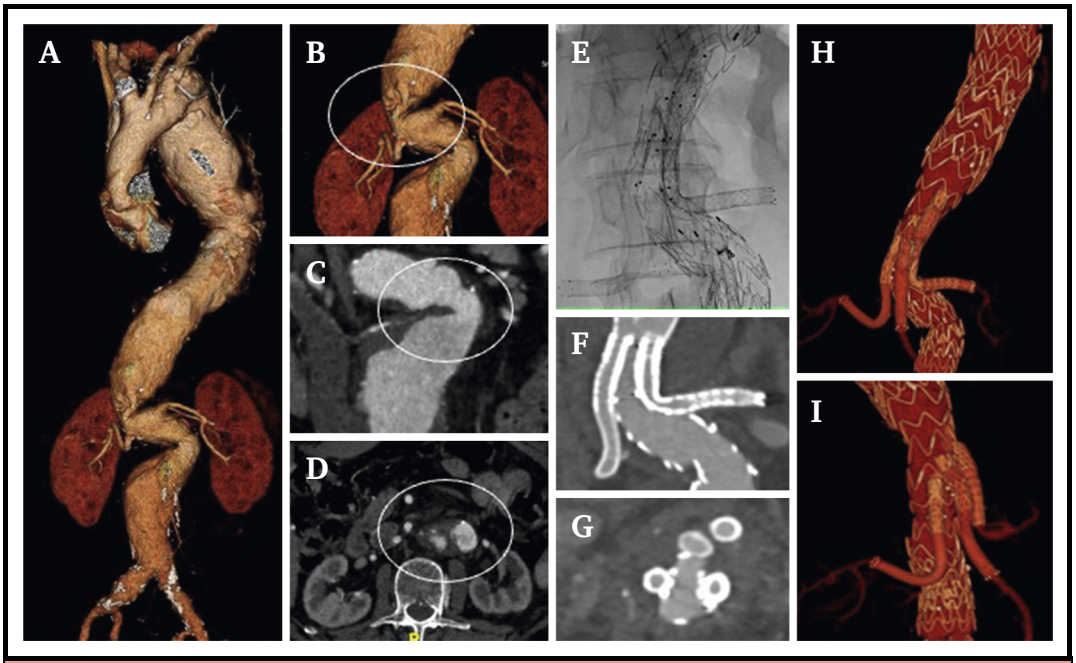

Figure 4. Urgent case of extent II thoracoabdominal aneurysm treated in a urgent setting by E-nside endografting. Patient with (A) extent II thoraco-abdominal aortic aneurysm and (B – D) complex anatomy in the paravisceral segment, with an 18 mm narrow and angulated aorta (white circle). (E) Intra-operative images showing adequate E-nside endograft and branches geometrical conformation. (F, G) Post-operative computed tomography angiogram (CTA) demonstrating patency of renal branches with no kinking or compression (F) and good conformability at the narrowest aortic level in the axial images (G). (H, I) 3D reconstruction of the post-operative CTA showing graft and branches adaptability to this complex anatomy in anteroposterior view (H) and lateral view (I).

these findings provide a reliable conclusion that this graft is effective in stabilising the disease and preventing death in the midterm for both elective and urgent cases.

Although early outcomes were not the primary focus of this study, some observations are worth noting. Comparing the present analysis with the initial early experience,[5] the results are similar regarding technical success, which remained stable at 98%, as well as rates of stroke (3%), MAEs (24%), spinal cord ischaemia with motor deficit (6 – 7%), and early re-intervention (9%). In contrast, the early mortality rate improved from 5.2% to 3.3%, probably due to better selection criteria and increased experience across collaborating centres. While early death was influenced by urgent or elective setting, as expected, this did not influence overall freedom from aneurysm related death; this means that, once overcoming the acute setting of urgent repair, the endograft is effective in preventing two year aneurysm related death.

A comment is warranted on the extensive use of OTS devices for cAAAs, when by instructions for use they are intended for TAAAs only. In this cohort, 46.1% of treated patients had a cAAA, with a 7.9% rate of permanent motor paraplegia. Gallitto *et al.* reported the results of urgent juxta- and pararenal aortic aneurysm repair with t-Branch, showing persistent spinal cord ischaemia rates of 14% in ruptured cases and 5% in non-ruptured cases.[22] In the authors' opinion, also after initial more liberal use of OTS devices in cAAAs, the actual indication is on limiting their application primarily for urgent repair, when no other options are available in place, and to offer dedicated custom device planning to all those cAAAs that are deferrable, with the objective of limiting extrathoracic aortic coverage as much as possible, thus reducing the spinal cord ischaemia rate.

This study is the largest multicentre cohort with two year data on TAAA and cAAA repairs using a single OTS endograft for both elective and urgent cases. The advantages of this study are the real word prospective data collection, large number of cases and target vessels, and a stabilised learning curve on patient selection and graft implantation. Limitations are related to the non-comparative design, the follow up duration of < 5 years (which is categorised as short term for elective repair and midterm for urgent repair),[23] the inclusion of a heterogeneous population, the lack of standardisation across different centres, the presence of missing data, and the integration of high volume with low volume centres. Data on total number of cases and proportion of patients treated by E-nside for each centre were not available. Although the results reflect a real word practice, generalisability may be limited by the selected cohort of patients. The number of events was low for some of the endpoints (aortic related death and device instability), leading to a risk of type II statistical error.

Conclusions

This study is the first multicentre collaboration evaluating the two year outcomes of an OTS endograft for treating cAAAs and TAAAs in both elective and urgent settings. The

use of this inner branch device yielded excellent results both in preventing aneurysm related death and ensuring the stability of visceral and renal target vessels. During planning, attention should be directed to the proximal aortic sealing zone to prevent graft instability during follow up.

CONFLICTS OF INTEREST

M.P. has a consulting agreement with Artivion; all fees are paid to the Department of Cardiac, Thoracic, Vascular Sciences and Public Health of Padua University. G.P. receives a fee for employ tutoring with Artivion. M.A. has a consulting agreement with Artivion; all fees are paid to the Department of Cardiac, Thoracic, Vascular Sciences and Public Health of Padua University. G.I. has a consulting agreement with Artivion. G.S. has consulting agreement with Artivion. All other authors have no conflicts of interest to declare.

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None.

APPENDIX A. SUPPLEMENTARY DATA

Supplementary data to this article can be found online at https://doi.org/10.1016/j.ejvs.2025.08.042.

REFERENCES

1 Verhoeven ELG, Katsargyris A, Bekkema F, Oikonomou K, Zeebregts CJAM, Ritter W, et al. Editor's Choice — Ten-year experience with endovascular repair of thoracoabdominal aortic aneurysms: results from 166 consecutive patients. *Eur J Vasc Endovasc Surg* 2015;**49**:524–31.

2 Austermann M, Donas KP, Panuccio G, Troisi N, Torsello G. Pararenal and thoracoabdominal aortic aneurysm repair with fenestrated and branched endografts: lessons learned and future directions. *J Endovasc Ther* 2011;**18**:157–60.

3 Piazza M, Squizzato F, Pratesi G, Parlani G, Simonte G, Giudice R, et al. Editor's Choice — Outcomes of off the shelf outer branched versus inner branched endografts in the treatment of thoracoabdominal aortic aneurysm in the B.R.I.O. (BRanched Inner — Outer) study group. *Eur J Vasc Endovasc Surg* 2024;**68**:50–9.

4 Bosiers MJ, Bisdas T, Donas KP, Torsello G, Austermann M. Early experience with the first commercially available off-the-shelf multibranched endograft (t-branch) in the treatment of thoracoabdominal aortic aneurysms. *J Endovasc Ther* 2013;**20**:719–25.

5 Piazza M, Squizzato F, Pratesi G, Tshomba Y, Gaggiano A, Gatta E, et al. Early outcomes of a novel off the shelf preloaded inner branch endograft for the treatment of complex aortic pathologies in the ItaliaN Branched Registry of E-nside EnDograft (INBREED). *Eur J Vasc Endovasc Surg* 2023;**65**:811–7.

6 Squizzato F, Piazza M, Isernia G, Pratesi G, Gatta E, Ferri M, et al. Use of an off the shelf inner branch thoraco-abdominal endograft for the treatment of juxtarenal and pararenal aortic aneurysms. *Eur J Vasc Endovasc Surg* 2025;**69**:837–45.

7 Konstantinou N, Antonopoulos CN, Jerkku T, Banafsche R, Kölbel T, Fiorucci B, et al. Systematic review and meta-analysis of published studies on endovascular repair of thoracoabdominal aortic aneurysms with the t-Branch off-the-shelf multibranched endograft. *J Vasc Surg* 2020;**72**:716–25.e1.

8 Piazza M, Squizzato F, Ferri M, Pratesi G, Gatta E, Orrico M, et al. Outcomes of off-the-shelf preloaded inner branch device for urgent endovascular thoraco-abdominal aortic repair in the ItaliaN Branched Registry of E-nside EnDograft. *J Vasc Surg* 2024;**80**:1350–60.e4.

9 Harris PA, Taylor R, Thielke R, Payne J, Gonzalez N, Conde JG. Research electronic data capture (REDCap)—a metadata-driven methodology and workflow process for providing translational research informatics support. *J Biomed Inform* 2009;**42**:377–81.

10 Oderich GS, Forbes TL, Chaer R, Davies MG, Lindsay TF, Mastracci T, et al. Reporting standards for endovascular aortic repair of aneurysms involving the renal-mesenteric arteries. *J Vasc Surg* 2021;**73**(1S):4S–52S.

11 Wanhainen A, Van Herzeele I, Bastos Goncalves F, Bellmunt Montoya S, Berard X, Boyle JR, et al. Editor's Choice — European Society for Vascular Surgery (ESVS) 2024 clinical practice guidelines on the management of abdominal aorto-iliac artery aneurysms. *Eur J Vasc Endovasc Surg* 2024;**67**:192–331.

12 Squizzato F, Antonello M, Modena M, Forcella E, Colacchio EC, Grego F, et al. Fate of primary determinate and indeterminate target vessel endoleaks after fenestrated-branched endovascular aortic repair. *J Vasc Surg* 2024;**79**:207–16.e4.

13 O'Donnell TFX, Deery SE, Boitano LT, Siracuse JJ, Schermerhorn ML, Scali ST, et al. Aneurysm sac failure to regress after endovascular aneurysm repair is associated with lower long-term survival. *J Vasc Surg* 2019;**69**:414–22.

14 Squizzato F, Piazza M, Piffaretti G, Gatta E, Tshomba Y, Orrico M, et al. Evolution of practice patterns and learning curve of aortic repair using the E-nside off-the-shelf inner branch thoracoabdominal endograft. *J Vasc Surg* 2025;**82**:1168–78.e4.

15 Farber MA, Matsumura JS, Han S, Makaroun MS, Suckow BD, Timaran CH, et al. Early outcomes from the pivotal trial of a four-branch off-the shelf solution to treat complex abdominal and type IV thoracoabdominal aortic aneurysms. *J Vasc Surg* 2024;**80**:1326–35.e4.

16 Karaolanis GI, Makaloski V, Jungi S, Weiss S, Kotopoulos K, Chaikhouni B, et al. Endovascular repair of pararenal and thoracoabdominal aortic aneurysms with inner and outer off-the-shelf multibranched endografts: a systematic review and meta-analysis. *J Vasc Surg* 2025;**81**:251–60.e3.

17 Zhang HP, Ge YY, Wang JB, Fan TT, Guo W. Off the shelf multibranched endograft for thoraco-abdominal and pararenal abdominal aortic aneurysms: a prospective, single centre study of the G-Branch endograft. *Eur J Vasc Endovasc Surg* 2024;**67**:417–25.

18 Tsilimparis N, Bosiers M, Resch T, Torsello G, Austermann M, Rohlffs F, et al. Two-year target vessel-related outcomes following use of off-the-shelf branched endografts for the treatment of thoracoabdominal aortic aneurysms. *J Vasc Surg* 2023;**78**:289–98.

19 Silingardi R, Gennai S, Leone N, Gargiulo M, Faggioli G, Cao P, et al. Standard "off-the-shelf" multibranched thoracoabdominal endograft in urgent and elective patients with single and staged procedures in a multicenter experience. *J Vasc Surg* 2018;**67**:1005–16.

20 Hongku K, Sonesson B, Björses K, Holst J, Resch T, Dias NV. Mid-term outcomes of endovascular repair of ruptured thoracoabdominal aortic aneurysms with off the shelf branched stent grafts. *Eur J Vasc Endovasc Surg* 2018;**55**:377–84.

21 Rastogi V, Sulzer TAL, de Bruin JL, Oliveira-Pinto J, Alberga AJ, Hoeks SE, et al. Aneurysm sac dynamics and its prognostic significance following fenestrated and branched endovascular aortic aneurysm repair. *Eur J Vasc Endovasc Surg* 2024;**67**:728–36.

22 Gallitto E, Faggioli G, Austermann M, Kölbel T, Tsilimparis N, Dias N, et al. Urgent endovascular repair of juxtarenal/pararenal aneurysm by off-the-shelf multibranched endograft. *J Vasc Surg* 2024;**80**:1336–49.e4.

23 de Borst GJ, Boyle JR, Dick F, Kakkos SK, Mani K, Mills JL, et al. Editor's Choice — European Journal of Vascular and Endovascular Surgery publication standards for reporting vascular surgical research. *Eur J Vasc Endovasc Surg* 2025;**69**:9–22.