From the Society for Vascular Surgery

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

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ABSTRACT

Objective: The aim of this study was to report the outcomes of endovascular urgent thoracoabdominal aortic (TAAA) repair, using an off-the-shelf preloaded inner branch device (E-nside; Artivion).

Methods: Data from a physician-initiated national multicenter registry, including patients treated with E-nside endograft (INBREED) were prospectively collected (2020-2024); only urgent cases were included in this study. Primary outcomes were technical success and mortality at 30 days. Secondary outcomes were spinal cord ischemia rate, stroke rate, major adverse events (MAE) as also branch instability at 12 months.

Results: Of 185 patients enrolled in the INBREED, 64 (34.5%) were treated in a urgent setting and were included in the study. Reason for urgent repair was presence of aneurysm-related symptoms in 31 patients (48.4%), a contained rupture in eight (12.5%), and a large aneurysm >80 mm in 25 (39.1%). Extent of repair was I to III in 32 patients (50%) and IV in 32 (50%); 18 (28%) had a narrow (<25 mm) paravisceral aortic lumen. An adjunctive proximal thoracic endograft was deployed in 29 patients (45.3%); a distal bifurcated abdominal endograft was used in 33 (51.5%). Two hundred forty-nine target vessels (97.2%) were successfully incorporated through an inner branch from an upper arm (81.2%) or femoral (18.8%) access. A balloon expandable stent was used in 184 (75.7%) target vessels, a self-expandable stent in 59 (24.3%). Mean time for target vessel bridging was 39.9 ± 28.4 minutes per target vessel. Thirty-day cumulative major adverse event (MAE) rate was 28%, and mortality occurred in five patients (9.1%). There was one postoperative stroke (1.6%), and the spinal cord ischemia (SCI) rate was 8% (n = 5). For the 249 target vessels successfully incorporated through an inner branch, 1-year freedom from target vessel instability was 93% ± 3% after 1 year.

Conclusions: The E-nside represents a valid solution for the urgent treatment of TAAAs, including symptomatic and ruptured TAAAs, as well as large asymptomatic TAAAs that cannot wait for a custom-made device. The preloaded inner branches and available proximal and distal graft diameters might be useful in urgent settings and provided satisfactory early and 1-year results, in terms of both endograft and target vessel stability. Further studies are required to assess the clinical role of E-nside for urgent TAAA repair. (J Vasc Surg 2024;■:1-11.)

Keywords: Aortic aneurysm; Abdominal; Thoracoabdominal; Endovascular aneurysm repair; Urgent; Aneurysm; Ruptured aortic; Off the shelf; Branched endovascular aortic repair; BEVAR; Inner branches

Endovascular repair of thoracoabdominal aortic aneurysms (TAAAs) today represents a valid alternative to traditional open repair, especially in high-risk patients, owing to its lower perioperative mortality and morbidity.[1-6] However, the endovascular approach also represents a complex situation for operators; the long aortic segment extension of the disease and vital branch vessels involvement are major issues. Fenestrated and

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branched endovascular aneurysm repair (F-BEVAR) has emerged in the past decade as a valid option thanks to dedicated graft customization based on patients' anatomy.

TAAA repair becomes even more difficult when the TAAA requires urgent or emergent repair because of large symptomatic aneurysm or rupture; in this particular scenario, few branched off-the-shelf devices have been developed, with the objective of having a standard graft conformation that may fit different patient aortic anatomies. These devices are very useful, especially in cases where rapid repair is required and there is no time for production of a custom-made endograft.

Since it has been the first introduced in the market, the outer branches T-Branch (Cook Medical) is the off-the-shelf branched endograft for TAAA repair that has the larger clinical experience reported both for elective and urgent repair. More recently, an off-the shelf endograft with preloaded inner branches (E-nside, Artivion) came into the market. We recently published the overall initial early outcomes of this graft in the treatment of complex aortic pathologies, using the multicenter collaboration of the ItaliaN Branch Registry of E-nside Endograft (INBREED).[7] The main indications for using an off-the-shelf device are represented by presence of a large aneurysm at risk for imminent rupture, where it is not possible to wait for a custom-made device, a symptomatic status, or a ruptured aneurysm. However, at the moment, there are no reported outcomes of E-nside endograft in the specific setting of urgent TAAA repair.

The aim of this study is to evaluate early and midterm outcomes from the INBREED registry focusing the analysis only on patients treated for urgent or emergent repair of TAAAs using this off-the-shelf inner branched endograft.

ARTICLE HIGHLIGHTS

- **Type of Research:** Multicenter cohort study of prospectively collected data
- **Key Findings:** The E-nside endograft (Artivion) is a novel off-the-shelf inner branched thoracoabdominal endograft that was used for urgent thoracoabdominal aortic repair in 64 patients, with 249 incorporated target vessels. Concomitant proximal thoracic endografting was required in 45% of patients, whereas the infrarenal aorta was used as distal landing zone in one-half of patients. Overall technical success was 97%, with a 9% mortality and 28% major adverse events rate. Spinal cord ischemia occurred in 8%, with paraplegia in 3%. One-year freedom from target vessel instability was 93.3% (95% confidence interval, 90%-97%).
- **Take Home Message:** The E-nside represents a valid solution for urgent thoracoabdominal aortic repair, providing satisfactory early and 1-year clinical results. The preloaded system, inner branch conformation, and two available proximal and distal graft diameters may be helpful to fit several anatomical characteristics in urgent setting and reduce the overall length of aortic coverage.

METHODS

Study design. Data from the ItaliaN Branched Registry of E-nside EnDograft (INBREED) were collected and analyzed. The INBREED is a physician-initiated, non-sponsored multicenter prospective registry including consecutive patients treated with the E-nside endograft.[7] The registry was initiated in June 2021 and collects data from 35 vascular surgery centers. Patients treated from June 2021 to March 2024 were included on an intention-to-treat basis; decisions on surgical indications, patient selection, surgical technique, and perioperative care were not standardized and were left to each treating center. Only patients treated for extent I to IV thoracoabdominal pathology in an urgent setting were included in the present analysis; those with juxtarenal or pararenal aortic aneurysm or those treated in an elective setting were excluded. This was to allow us to focus the analysis only on urgent cases. Urgent cases were defined by the presence of aneurysm-related pain, peripheral embolization, contained rupture, or diameter >80 mm. The 80-mm cutoff was selected as previously defined by other authors[8,9] and identifies asymptomatic patients with a large TAAA that is deemed at high risk for imminent rupture, thus excluding them from the use of custom-made devices. Also, different cutoffs (70-75 mm) have been proposed in the literature,[10,11] based on the risk of rupture during the waiting time for a custom-made device, but a more restricted definition was adopted for this study, to allow for a more reliable comparison with similar papers[8,9] and to reduce the potential bias related to a less restricted definition of urgent cases. Institutional Review Board and ethics committee approval were obtained (ID 21,175).

Data collection and definitions. Anonymized data were entered by each participating center; one coordinating center was responsible for the electronic data capture system (RedCap[12]), for checking the quality of the imputed data, requiring audits as needed, and for the final data analysis for this study. Each center was responsible for the internal data collection and imaging evaluation. The data quality assessment was based on general audits every 6 months and specific queries in case of missing, incomplete, or unclear data. The rate of missing data for this specific study was 4%.

Demographics, clinical characteristics, cardiovascular risk factors, operative data, and 30-days outcomes were collected. Aneurysm classification was based on extent of aneurysmal disease evaluated by computed

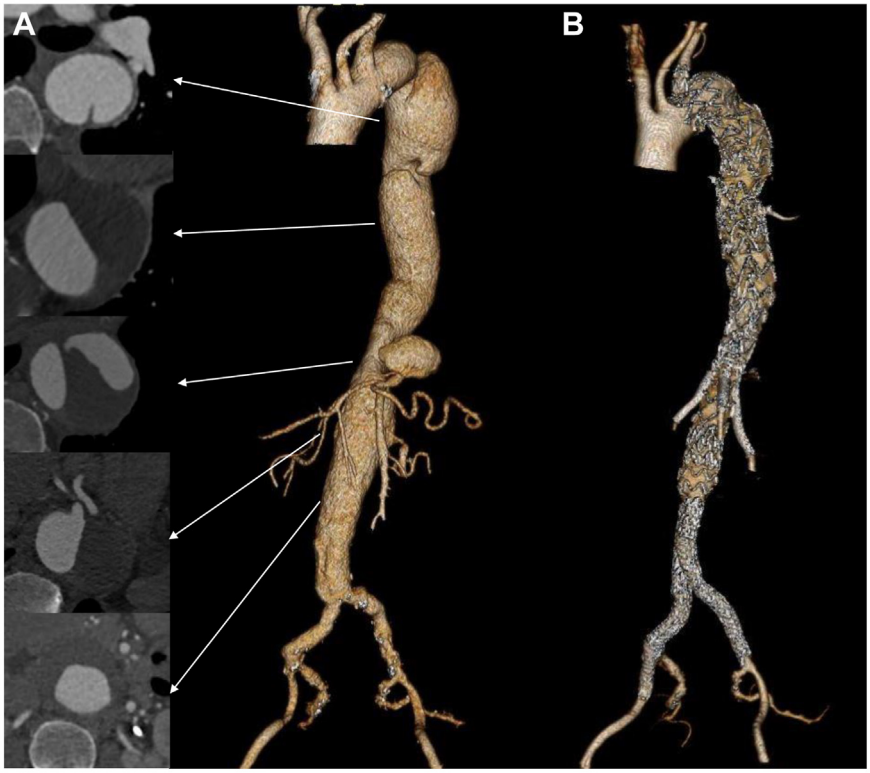

Fig 1. A, Three-dimensional (3D) reconstruction of the preoperative computed tomography angiography (CTA) of a large thoracoabdominal aortic aneurysm (TAAA) urgently treated. **B,** 3D reconstruction of the postoperative CTA after urgent treatment with E-nside.

tomography angiography (CTA) according to the current reporting standards.[13] Other preoperative anatomical characteristics such as aortic diameter and iliac access characteristics were assessed at the preoperative CTA. Major adverse events (MAEs) included severe acute kidney injury (>50% decrease in estimated glomerular filtration rate), new-onset dialysis, myocardial infarction, respiratory failure requiring prolonged mechanical ventilation or reintubation, paraplegia, stroke, bowel ischemia requiring surgical resection or intensive medical care, and estimated blood loss >1 L. Spinal cord ischemia (SCI) was classified according to the current reporting standards.[13] Imaging follow-up protocol was standardized and included a CTA within 1 month, and at 6 and 12 months (Fig 1). Endoleaks were classified according to prior reports.[13,14]

Device and technique. Detailed device design and operative technique have been described elsewere.[7,15] Briefly, the E-nside is an off-the-shelf inner branched endograft with a 24 Fr outer diameter delivery system, available in four different sizes, with a proximal diameter measuring 38 or 33 mm and a distal diameter of 30 or 26 mm. The total device length is 222 mm, extending 93 mm above the outlet for the celiac trunk and 76 mm below the outlets for the renal branches. Although it is not strictly necessary, it is common practice to use a 24 Fr introducer sheath to facilitate endograft advancement, orientation, and deployment. All four inner branches are preloaded and can be cannulated with a 0.018" wire from the handle system (Supplementary Fig, online only); the wire is intended to be snared from above the top of the graft using an upper arm approach. Although outside the instructions for use (IFU), the preloaded wire can be snared also from a contralateral femoral access.[16] The use of the preloaded system is optional and left to the decision of the operator. In some cases, the preloaded catheters were intentionally removed, and the target vessels were cannulated and stented from a total transfemoral approach with the use of a steerable sheath.[17] Bridging stent choice was at discretion of the treating center, based on availability, operators' experience, and preference. In case of a total transfemoral access, balloon-expandable stents were preferentially used. By manufacturer's IFU, the device should land on a thoracic endograft, but in the real-word clinical practice, it has been safely used also without a proximal thoracic endovascular aneurysm repair (TEVAR).[7] Procedure staging, with complete aneurysm exclusion performed typically after 10 to 15 days, was considered for large asymptomatic aneurysms, whereas procedures for symptomatic or ruptured aneurysms were not staged.

Table I. Preoperative demographics and risk factor of the 64 patients with thoracoabdominal aortic aneurysms (TAAAs) treated with E-nside in an urgent setting

	Extent I-III (n = 32)	Extent IV (n = 32)	Total (N = 64)	*P* value
Age, years	71.3 ± 8.9	77.6 ± 5.2	74.5 ± 7.9	.001[a]
Male gender	22 (68.8)	26 (81.2)	48 (75.0)	.248
BMI, kg/m^2	27.3 ± 5.3	24.9 ± 6.4	26.0 ± 6.0	.184
Hypertension[b]	29 (90.6)	31 (96.9)	60 (93.8)	.302
Hypercholesterolemia[c]	18 (56.2)	25 (78.1)	43 (67.2)	.062
Tobacco use	13 (40.6)	19 (59.4)	32 (50.0)	.134
COPD[d]	11 (34.4)	17 (53.1)	28 (43.8)	.131
Diabetes	4 (12.5)	5 (15.6)	9 (14.1)	.719
Chronic kidney disease[e]	8 (25.0)	10 (31.2)	18 (28.1)	.578
Dialysis	0 (0.0)	2 (6.2)	2 (3.1)	.151
Coronary artery disease[f]	10 (31.2)	10 (31.2)	20 (31.2)	1.000
Peripheral artery disease[g]	5 (15.6)	6 (18.8)	11 (17.2)	.740
Prior stroke or TIA	4 (12.5)	6 (18.8)	10 (15.6)	.491
Prior endovascular repair				.013[a]
EVAR	2 (16.7)	6 (85.7)	8 (42.1)	
TEVAR	9 (75.0)	1 (14.3)	10 (52.6)	
EVAR + TEVAR	1 (8.3)	0 (0.0)	1 (5.3)	
Prior open aortic repair				.251
Ascending/arch	6 (60.0)	3 (33.3)	9 (47.4)	
Thoracic	1 (10.0)	0 (0.0)	1 (5.3)	
Abdominal	3 (30.0)	4 (44.4)	7 (36.8)	
Thoracoabdominal	0 (0.0)	2 (22.2)	2 (10.5)	

BMI, Body mass index; *COPD*, chronic obstructive pulmonary disease; *EVAR*, endovascular aortic repair; *TEVAR*, thoracic endovascular aortic repair; *TIA*, transient ischemic attack.
Data are presented as number (%) or mean ± standard deviation.
[a]Statistically significant.
[b]Blood pressure >140/90 mm Hg or specific medical therapy.
[c]Total cholesterol >200 mg/dL (5.2 mmol/L), low-density lipoprotein cholesterol >120 mg/dL (3.1 mmol/L), or specific medical therapy.
[d]FEV_1/FVC <70% and/or specific medical therapy.
[e]Glomerular filtration rate <60 mL/min/1.73 m^2.
[f]Prior myocardial infarction, coronary artery bypass graft, percutaneous coronary intervention, or specific signs of coronary artery disease.
[g]Symptomatic for intermittent claudication, rest pain, or tissue loss, or prior intervention for peripheral artery disease.

Endpoints. Study endpoints were technical success, 30-day MAEs, and freedom from branch instability. Both endograft-related and branch-related technical success were evaluated according to current reporting standards.[13] Branch instability was defined as any target vessel-related complication leading to aneurysm rupture, death, occlusion, component separation, or reintervention to maintain target vessel patency or to treat a target vessel-related component separation or endoleaks.[13] Endograft instability was defined by any event related to the aortic graft component that was associated with patient death, aneurysm rupture, infection, or reintervention, excluding target vessel-related events, which are described under the definition of branch instability.[13]

Statistical analysis. Results were reported as a number and percentage for categorical variables and mean ± standard deviation for continuous variables. Continuous variables were compared with the Wilcoxon rank sum test or the *t*-test as appropriate. The Pearson χ^2 and Fisher exact test were used for analysis of categorical variables. A *P* value of less than .05 was used to determine statistical significance. The R 4.0 software (R Foundation for Statistical Computing) was used for the analysis.

RESULTS

Patient population. Of 185 patients enrolled in the INBREED, 64 (34.5%) were treated in a urgent setting and were included in the present analysis. Reason for urgent repair was presence of aneurysm-related symptoms in 31 patients (48.4%), a contained rupture in eight (12.5%), and a large aneurysm >80 mm not amenable for a deferred treatment in 25 (39.1%). Mean age was 75 ± 8 years, and 48 patients (75%) were males. Preoperative cardiovascular risk factors are described in Table I. Twelve patients (18.7%) had a history of prior thoracic aortic repair (11 endovascular and 1 surgical repair), 16 (25%) had

Table II. Anatomical data of the 64 patients with thoracoabdominal aortic aneurysms (TAAAs) treated with E-nside in an urgent setting

	Extent I-III (n = 32)	Extent IV (n = 32)	Total (N = 64)	*P* value
Aortic pathology				.002[a]
Acute or subacute dissection	4 (12.5)	0 (0.0)	4 (6.2)	
Chronic dissection	4 (12.5)	0 (0.0)	4 (6.2)	
Degenerative aneurysm	23 (71.9)	19 (59.4)	42 (65.6)	
Intramural hematoma	0 (0.0)	1 (3.1)	1 (1.6)	
Penetrating aortic ulcer	0 (0.0)	3 (9.4)	3 (4.7)	
Pseudoaneurysm	1 (3.1)	9 (28.1)	10 (15.6)	
Crawford classification				<.001[a]
Extent I	0 (0.0)	11 (34.3)	11 (17.2)	
Extent II	0 (0.0)	15 (46.8)	15 (23.4)	
Extent III	0 (0.0)	6 (18.7)	6 (9.3)	
Extent IV	32 (100)	0 (0.0)	32 (50)	
Aortic status				.028[a]
Contained rupture	2 (6.3)	6 (18.7)	8 (12.5)	
Non ruptured, symptomatic	20 (62.5)	11 (34.4)	31 (48.4)	
Non ruptured, asymptomatic	10 (31.2)	15 (46.8)	25 (39.1)	
Largest aortic diameter, mm	69.9 ± 17.0	77.7 ± 24.3	73.8 ± 21.2	.143
Maximum diameter >80 mm	11 (34.4)	14 (15.6)	25 (39.1)	.442
Aortic diameter CT level, mm	44.9 ± 15.4	34.3 ± 10.3	39.6 ± 14.0	.002[a]
Aortic diameter SMA level, mm	38.0 ± 13.6	38.7 ± 17.2	38.3 ± 15.4	.850
Aortic diameter RRA level, mm	34.3 ± 10.6	41.8 ± 23.7	38.1 ± 18.6	.113
Aortic diameter LRA level, mm	33.8 ± 10.8	42.4 ± 24.5	38.1 ± 19.3	.082
Minimum iliac artery diameter, mm	9.1 ± 2.0	9.3 ± 2.5	9.3 ± 1.8	.920

CT, Celiac trunk; *LRA*, left renal artery; *SMA*, superior mesenteric artery; *RRA*, right renal artery.
Data are presented as number (%) or mean ± standard deviation.
[a]Statistically significant.

a prior abdominal aortic repair (9 endovascular and 7 surgical); two patients (3.1%) had prior surgical thoracoabdominal repair. Details on aortic pathology are presented in Table II. Most patients (n = 42; 65.6%) had a degenerative aneurysm; four (6.2%) had an acute or subacute dissection, four (6.2%) had a symptomatic intramural hematoma or penetrating aortic ulcer, four (6.2%) had a chronic dissection, and 10 (15.6%) had a pseudoaneurysm after prior open surgery. Mean aneurysm diameter was 73.8 ± 21.2 mm, and a narrow paravisceral aortic diameter <25 mm was present in 18 patients (28.1%); mean diameter in those with a narrow aorta was 23 ± 4 mm. Anatomical classification of extent of the aneurysm was I to III in 32 (50%) patients and extent IV in 32 (50%).

Comparing large aneurysms vs ruptured/symptomatic aneurysms, patients with ruptured or symptomatic TAAAs were more likely to be females (96% vs 59%; $P < .001$); there were no significant differences in age (74 ± 7 vs 73 ± 8 years; $P = .636$), aneurysm extension (extent IV: 64% vs 43%; $P = .109$), and other preoperative clinical characteristics.

Procedural data. A percutaneous femoral access was obtained in most patients (n = 37; 57.8%) for the E-nside advancement and deployment (Table III). An adjunctive proximal thoracic endograft was used in 29 patients (45.3%), and mean length of aortic coverage above the level of the celiac trunk was 19 ± 14 cm. Prophylactic spinal drain was placed in 17 patients (26.6%), 12 (37.5%) with extent I to III and five (15.6%) with extent IV TAAA ($P = .048$). Procedure staging was performed in 19 patients (29.6%) with an asymptomatic non-ruptured large aneurysm and was obtained by staging BEVAR after TEVAR in 10 extent I to III TAAAs, and by temporary aneurysm sac perfusion (TASP) in eight patients (leaving an open unstented branch in 6, an open iliac limb in 3). Mean time between stages was 15 ± 3 days. Endovascular repair was completed by deployment of a distal infrarenal bifurcated endograft in 33 patients (51.5%). Distal landing was achieved in a prior endovascular or surgical graft in 14 patients (21.9%), whereas the native infrarenal aorta was used as distal sealing zone in 17 patients (26.6%) with type I or V TAAA. Endograft-related technical success was 100%.

Table III. Procedural data of the 64 patients with thoracoabdominal aortic aneurysms (TAAAs) treated with E-nside in an urgent setting

	Extent I-III (n = 32)	Extent IV (n = 32)	Total (N = 64)	*P* value
Femoral access				.035[a]
Percutaneous, bilateral	19 (59.4)	18 (56.2)	37 (57.8)	
Surgical, bilateral	11 (34.4)	5 (15.6)	16 (25.0)	
Percutaneous, unilateral	2 (6.2)	9 (28.1)	11 (17.2)	
Upper arm access				.026[a]
No	8 (25.0)	4 (12.5)	12 (18.8)	
Left	14 (43.8)	24 (75.0)	38 (59.4)	
Right	10 (31.3)	4 (12.5)	14 (21.9)	
Proximal E-NSIDE diameter				.031[a]
33 mm	6 (18.8)	14 (43.8)	20 (31.2)	
38 mm	26 (81.2)	18 (56.2)	44 (68.8)	
Distal E-NSIDE diameter				.564
26 mm	25 (78.1)	23 (71.9)	48 (75.0)	
30 mm	7 (21.9)	9 (28.1)	16 (25.0)	
Thoracic aorta coverage, cm	24.5 ± 6.7	16.4 ± 16.6	19.2 ± 14.2	.273
Prophylactic spinal drainage	12 (37.5)	5 (15.6)	17 (26.6)	.048[a]
Adjunctive thoracic endograft	23 (71.9)	6 (18.8)	29 (45.3)	<.001[a]
Adjunctive distal bifurcated endograft	13 (40.1)	20 (62.5)	33 (51.5)	.728
Procedure staging	13 (40.1)	6 (18.8)	19 (29.6)	.095
CT stent				
Balloon expandable	25 (78.1)	26 (81.3)	51 (79.6)	1.00
Self-expandable	4 (12.5)	4 (12.5)	8 (12.5)	
Intentional occlusion	3 (9.4)	2 (6.2)	5 (7.8)	
Adjunctive relining stent	4 (12.5)	9 (28.1)	13 (20.3)	.213
SMA stent				
Balloon expandable	23 (71.8)	27 (84.3)	50 (78.1)	.365
Self-expandable	9 (38.1)	5 (15.6)	14 (21.9)	
Intentional occlusion	0 (0)	0 (0)	0 (0)	
Adjunctive relining stent	4 (12.5)	7 (21.8)	11 (18.2)	.509
RRA stent				
Balloon expandable	20 (62.5)	23 (71.8)	43 (67.2)	.595
Self-expandable	11 (34.4)	9 (38.1)	20 (31.3)	
Intentional occlusion	1 (3.1)	0 (0)	1 (1.6)	
Adjunctive relining stent	8 (25.0)	8 (25.0)	16 (25.0)	1.00
LRA stent				
Balloon expandable	19 (59.4)	21 (65.6)	40 (625)	.777
Self-expandable	9 (38.1)	8 (25.0)	17 (26.6)	
Intentional occlusion	4 (12.5)	3 (9.4)	7 (10.9)	
Adjunctive relining stent	7 (21.8)	8 (25.0)	15 (23.4)	1.00
Procedural metrics				
Bridging time, minutes				
CT	58.8 ± 17.8	19.2 ± 8.3	51.0 ± 19.9	.238
SMA	49.2 ± 36.8	17.9 ± 14.2	32.8 ± 16.4	.253
RRA	50.1 ± 34.9	19.4 ± 9.3	42.2 ± 12.3	.219
LRA	40.2 ± 39.4	27.4 ± 13.4	32.8 ± 25.7	.193
Total contrast, mL	225.3 ± 100.1	170.7 ± 106.4	196.0 ± 105.9	.100
Total fluoroscopy time, minutes	108.8 ± 52.7	98.5 ± 40.9	103.5 ± 46.9	.438

Table III. Continued.

	Extent I-III (n = 32)	Extent IV (n = 32)	Total (N = 64)	*P* value
Total operating time, minutes	312.1 ± 103.8	265.1 ± 85.0	288.6 ± 97.0	.069
Dose area product, Gy*cm^2	311.1 ± 200.6	362.9 ± 225.5	340.1 ± 213.9	.448

CT, Celiac trunk; *LRA*, left renal artery; *SMA*, superior mesenteric artery; *RRA*, right renal artery.
Data are presented as number (%) or mean ± standard deviation.
[a]Statistically significant.

Of the 256 E-nside inner branches, 249 (97.2%) were successfully bridged; inability to cannulate and stent occurred in five target vessels (1.9%, 4 renal and 1 celiac arteries); of these, a severe stenosis was present in one celiac and three renal arteries; three renals had a vessel diameter <5 mm, and two had an upward orientation. An intentional occlusion by vascular plug deployment was performed in eight branches (4 celiac and 4 renal arteries) owing to a preoperative native artery occlusion or severe stenosis. Access for target vessels cannulation and stenting was the upper arm in 52 patients (81.3%), whereas a total transfemoral access was used in 12 cases (18.8%). A balloon expandable stent was used as main bridging stent in 184 (75.7%) target vessels, a self-expandable stent in 59 (24.3%); an adjunctive bare metal relining stent was deployed in 55 target vessels (22.1%). Bridging time (time required from preloaded catheter removal to successful bridging stent deployment) was 51 ± 19 minutes for the celiac trunk, 32.8 ± 16.4 minutes for the superior mesenteric artery (SMA), and 37.3 ± 35.9 minutes for the renal arteries. Other detailed procedural metrics stratified by aneurysm extent are shown in Table III.

Thirty-day outcomes. Thirty-day mortality was 9.1%. Five patients (2 with aortic rupture, 2 symptomatic, and 1 with large aneurysm) died within 30 days owing to respiratory failure in two, multiorgan failure in two, and hemorrhagic shock in one. Mortality was 25% for ruptured and 5% for non-ruptured aneurysms ($P = .113$); mortality for large asymptomatic aneurysms was 8% ($P = .937$ vs ruptured/symptomatic TAAAs). There was a trend of reduction in mortality in urgent cases from the start of the registry (12.5% during 1st and 2nd quartiles vs 3% in the 3rd and 4th quartiles; $P = .196$). Cumulative MAE rate was 28.1% (21.9% in extent I-III and 34.4% in extent IV; $P = .266$). The MAE rate was 50% in case of ruptured aneurysms and 25.8% in case of non-ruptured aneurysms ($P = .605$); the MAE rate was 30% in large asymptomatic aneurysms ($P = .672$ vs ruptured/symptomatic TAAs). Detailed 30-day outcomes are presented in Table IV, and specific factors associated with 30-days MAEs are presented in Supplementary Table (online only). There was one stroke (1.6%) and five SCIs (7.8%), with paraplegia in two (3.1%). The SCI rate was 8.0% in large asymptomatic aneurysms and 7.7% in ruptured or symptomatic aneurysms ($P = 1.00$), 12% in ruptured and 9.4% in symptomatic non-ruptured TAAAs ($P = .512$). Among patients with type IV TAAAs, those receiving an adjunctive proximal TEVAR had a higher mortality (33% vs 4%; $P = .029$) and SCI (16% vs 8%; $P = .459$), and similar rates of MAEs (34% vs 33%; $P = .952$).

Within 30 days from the index procedure, there were eight reinterventions (13.3%): three (4.7%) were related to vascular access complications, four (7.8%) to a target vessel complication (2 type Ic endoleak and 2 target vessel occlusions), and one (1.6%) to a type 1a endoleak. Thirty-day freedom from target vessel instability was 96.4% owing to two type Ic endoleaks (1 SMA and 1 renal artery), and seven branch occlusions (3 celiac and 4 renal arteries, of which 2 received an early reintervention).

Comparing patients with a narrow paravisceral aorta vs those with paravisceral aortic size >25 mm, there were no differences in technical success (97.1% vs 97.2%; $P = .989$), early reintervention (5.9% vs 16.7%; $P = .248$), mortality (5.9% vs 12.5%; $P = .127$), and any MAE (28.7% vs 26.2%; $P = .899$).

One-year outcomes. Median follow-up was 11 months. During 1-year follow-up, there were seven deaths (10.9%), of which five were within 30 days. The two deaths occurring after 30 days were not aortic related. There were no endograft-related complications or reinterventions during 1-year follow-up. Three target vessel endoleaks (2 SMAs and 1 renal artery) and 13 target vessel loss of patency (4 celiac arteries, 1 SMA, 5 right renal arteries, 3 left renal arteries) occurred in 12 patients during follow-up, leading to seven reinterventions (1 SMA occlusion, 3 symptomatic renal artery occlusions, 3 target vessel endoleaks). One-year estimated freedom from branch instability per target vessel was 93.3% (95% confidence interval [CI], 90%-97%) (Fig 2, *A*), with a 94.5% (95% CI, 92%-98%) primary patency and a 98.8% (95% CI, 97%-100%) freedom from target vessel endoleak. Freedom from branch instability was 94.5% (95% CI, 90%-97%) for celiac-mesenteric arteries and 91.9% (95% CI, 87%-97%) for renal arteries ($P = .512$) (Fig 2, *B*). Freedom from target vessel instability per patient was 74.2% (95% CI, 51%-94%).

Table IV. Thirty-day outcomes of the 64 patients with thoracoabdominal aortic aneurysms (TAAAs) treated with E-nside in an urgent setting

	Extent I-III (n = 32)	Extent IV (n = 32)	Total (N = 64)	*P* value
Mortality	2 (6.3)	3 (9.3)	5 (9.1)	.697
Any MAE	7 (21.9)	11 (34.4)	18 (28.1)	.266
EBL >1000 ml	2 (6.2)	3 (9.4)	5 (7.8)	.641
Myocardial infarction	1 (3.1)	0 (0.0)	1 (1.6)	1.00
Respiratory failure	2 (6.2)	2 (6.2)	4 (6.2)	.1.00
Acute kidney insufficiency	3 (9.4)	6 (18.8)	9 (14.1)	.281
GI complications	0 (0)	0 (0)	0 (0)	1.00
Stroke	0 (0.0)	1 (3.1)	1 (1.6)	.313
SCI				.839
No	30 (93.8)	29 (90.6)	59 (92.2)	
Sensory deficit	1 (3.1)	2 (6.2)	3 (4.7)	
Motor not able to ambulate	1 (3.1)	1 (3.1)	2 (3.1)	
Early reintervention	5 (16.1)	3 (10.3)	8 (13.3)	.510
Access site complication	2 (40.0)	1 (33.3)	3 (37.5)	
Branch complication	2 (40.0)	2 (66.7)	4 (50.0)	
Main graft complication	1 (20.0)	0 (0.0)	1 (12.5)	

EBL, Estimated blood loss; *GI,* gastrointestinal; MAE, major adverse event; *SCI,* spinal cord ischemia.
Data are presented as number (%).

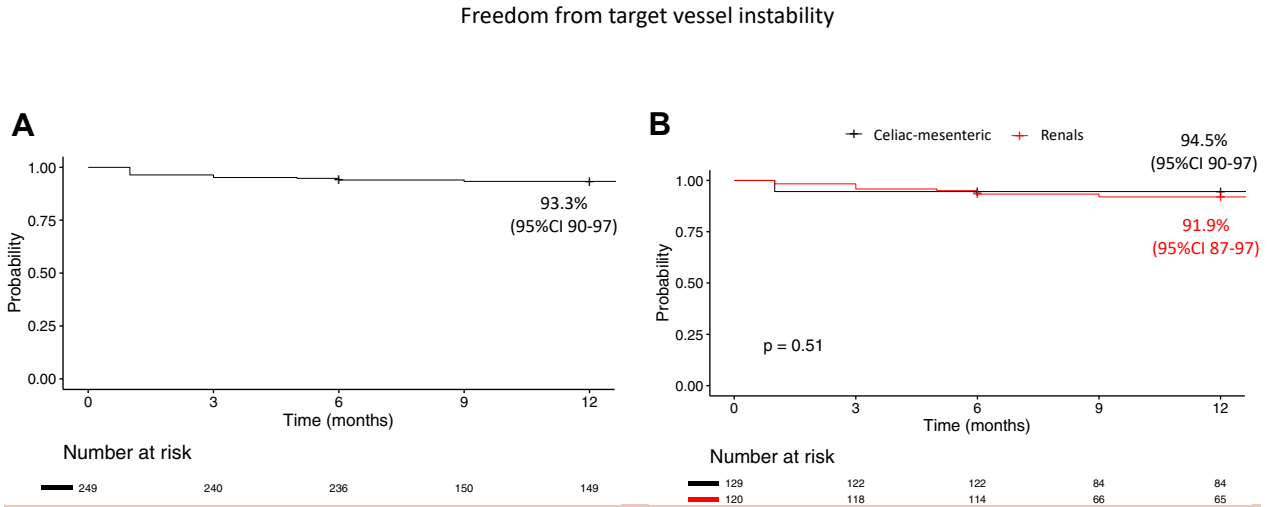

Fig 2. A, Kaplan-Meier curve of 1-year freedom from branch instability for the 249 target vessels incorporated through an inner branch. Standard error <10%. **B,** Kaplan-Meier curve of 1-year freedom from branch instability for the 249 target vessels incorporated through an inner branch, stratified by type of target vessel (renal vs celiac/mesenteric arteries). Standard error <10%. *CI,* Confidence interval.

Presence of a narrow paravisceral aorta <25 mm did not affect target vessel instability (92.1%; 95% CI, 88%-97% vs 94.8%; 95% CI, 90%-99%; $P = .857$).

DISCUSSION

Urgent thoracoabdominal repair represents a challenging situation, which is associated with high mortality and morbidity rates related to the clinical status of patients presenting in an urgent situation, the complexity and extent of the disease, and the technical complexity of the procedure. Large series on open repair in high-volume centers reported a 12% to 35% mortality and 12% SCI rate. Our study is the first analyzing the clinical outcomes of endovascular repair using an inner-branched off-the-shelf[18,19] device for the urgent treatment of TAAAs. Overall urgent TAAA repair with E-nside was feasible, with a high technical success (97%), an acceptable mortality rate (9%), and satisfactory early

and 1-year results. Compared with elective cases in the same registry,[7] urgent cases had a greater aneurysm diameter (74 mm vs 64 mm), and a higher rate of perioperative mortality (9% vs 2%), SCI (8% vs 6%), and MAE (28% vs 20%).

Most available clinical experience in urgent TAAA repair with off-the-shelf devices derives from the T-branch.[8,9,20-22] Spanos et al in 2018[8] described a series of 66 patients treated in a urgent or emergent setting (of which 28% had a contained rupture and 28% a large asymptomatic TAAA), with a 93% technical success, 21% SCI, and 14% mortality. Kolbel et al[22] reported a 97% technical success, with a 15% mortality in urgent cases and 30% in ruptured TAAAs. More recently Eleshra et al[9] published their experience with a 16% mortality and 10% SCI in urgent setting (including both symptomatic and large aneurysms) and a 24% mortality and 38% SCI in ruptured TAAAs. The results of each experience are difficult to compare, since the outcomes are usually not stratified by clinical presentation, and large asymptomatic and symptomatic aneurysms are usually merged under the definition of "urgent." Overall our results seem to be favorable, in terms of both mortality (9%) and SCI (8%). However, the results might reflect a lower percentage of cases with contained rupture (13%) and a higher number of asymptomatic large aneurysms (39%), and further comparative studies are necessary to establish if there is any difference in clinical outcomes between the two endograft platforms.[23] Also, a trend of mortality reduction was observed from the start of the registry, possibly related to increased experience in patient selection and technical skills.

The other main available off-the-shelf device is the TAMBE (W.L. Gore & Associates), a multi-branched device that recently received United States Food and Drug Administration approval for the treatment of complex aortic aneurysms. The available literature on this device is still scarce,[24] with no reported urgent case, and the TAMBE applicability worldwide is limited by its absence from the European market.

The E-nside carries some technical characteristics that might be advantageous in the urgent setting. The availability of four graft size conformations, with two possible proximal and two distal diameters, allows to adapt the endograft size to the patients' anatomy, reducing the need for a proximal tapered TEVAR in case of extent IV TAAAs.[25] A proximal thoracic endograft was deployed in 45% of cases of the overall cohort, and only in 19% of patients with type IV TAAAs. It has to be considered that by IFU the device should land on a proximal thoracic endograft, since it is not provided with an active fixation; the standalone use of E-nside may still be considered to reduce the length of thoracic aorta coverage, but physicians should be aware that this is an outside IFU practice, and long-term results on device stability are still not investigated. Also, a proximal TEVAR is necessary in cases with an ectatic descending thoracic aorta (>35 mm), where the larger E-nside (38 mm) could not guarantee an adequate proximal sealing. In our series, patients with type IV TAAAs receiving a proximal TEVAR had a higher mortality (33% vs 4%; $P = .029$) and SCI rate (16% vs 8%; $P = .459$), but the number of cases was low, and larger data are required to better understand the impact of adjunctive TEVAR in patients with extent IV TAAA treated in a urgent setting. Also, physician-modified grafts or off-the-shelf graft modifications[26,27] may be considered in these settings; future dedicated off-the-shelf endografts may be developed with a shorter length of proximal coverage.

A distal bifurcated graft was used in 52%, as a non-aneurysmal infrarenal aorta or a prior surgical graft was used as distal landing zone in 48%. This aspect may be particularly important to reduce the overall length of coverage of the thoracoabdominal aorta, thus theoretically reducing the risk of SCI in a urgent setting, when procedure staging may not be feasible, and hypotension and anemia are possible additional risk factors for SCI.[28,29] This may contribute to the low rate of SCI that was observed in our cohort (8%), with paraplegia in 3%. Also, procedure staging[30] whenever possible, may help to mitigate the risk of SCI, and was performed in 30% of patients with non-ruptured asymptomatic aneurysms. There were no reported aneurysm-related deaths or other adverse events during the waiting time between the first stage and aneurysm exclusion completion.

The availability of the preloaded inner branches may facilitate target vessel cannulation and stenting, reducing operating time, radiation exposure, and contrast media. The preloaded system was preferentially used to create a through-and-through femoral-brachial system (82% of cases), but also snare from the contralateral femoral access or intentional removal of the preloaded catheters were sometimes performed, at the discretion of operators. The use of a brachial access has been shown to increase the risk for ischemic cerebrovascular accidents.[31,32] Nevertheless, in our experience with this specific device in urgent cases, the use of the preloaded system may be useful for a fast inner branches catheterization and target vessel bridging. On the other side, intentional removal of the precannulation and full endograft deployment before target vessel cannulation may be convenient to restore a faster reperfusion of the hypogastric artery in those patients deemed at higher risk for SCI. A larger experience is still needed to establish which is the optimal technique for target vessels cannulation with this specific endograft.

Compared with other available off-the-shelf devices, the E-nside is the only endograft with incorporated inner branches. From a theoretical standpoint, the inner branches conformation may represent an advantage in anatomical situations characterized by a narrow para-visceral aortic diameter or severe aortic angulation.[33,34]

Outer branches may be preferrable in large aneurysms with downward-directed target vessels, and carry the advantage of a more extended clinical experience and scientific literature. The use of fenestrations in physician-modified endografts may have the advantage of reducinge the length of thoracic aorta coverage, but should be limited to extent IV TAAAs with a limited size of the paravisceral aorta, where the fenestration-to-target vessel distance can be maintained <5 mm.[35] However, the current clinical evidence on the use of inner branches is still limited,[7,23,36-39] and the only available comparative study with outer branches[23] did not find any significant difference in terms of technical success and branch stability.[33,34] In our series, a paravisceral aorta <25 mm was present in 23% of cases, and did not affect 1-year freedom from target vessel instability. The graft diameter at the level of the branches outlet is 24 mm, but the inner branch configuration limits the length of bridging stent subject to possible compression; these cases may also take advantage from a "low" deployment of the device, positioning the branch outlets at the same level of the target artery. This is possible owing to the large branches outlet area, allowing for some degree of misalignment,[40] and may avoid the risk of bridging stent compression in the context of a narrow aorta; however, this approach limits the range of suitable anatomies in terms of vertical distance and orientation of the target vessels. Further comparative data are necessary to clarify the rational for the use of inner branches vs other off-the-shelf solutions, according to the aneurysm anatomical characteristics.

This study had some limitations that are worthy of mention. This was a single-arm study without a comparison group and with a limited number of patients. The number of ruptured aneurysms was low, and the reported results mostly reflect the outcomes of patients with large asymptomatic or symptomatic non-ruptured aneurysms. The indications, procedural steps, and perioperative clinical management were not standardized and were left to the treating center. Technical and anatomical details on the upper extremity access, such as modality for vascular access (percutaneous or surgical), puncture site, and type of sheath, or are not captured by the registry. The investigated device has been only recently introduced in the market, and a longer follow-up is still not available.

CONCLUSION

In this multicenter registry, we described the clinical outcomes of an inner-branched off-the-shelf thoracoabdominal device in the specific setting of urgent TAAA repair, including symptomatic and ruptured TAAAs, as well as large asymptomatic TAAAs that cannot wait for a custom-made device. The use of E-nside provided satisfactory early and 1-year results, in terms of both endograft and target vessel stability. The results can be used as benchmarks for future study comparisons; further studies are still required to assess the clinical role of E-nside for urgent TAAA repair.

AUTHOR CONTRIBUTIONS

Conception and design: MP, FS, MF, GP, EG, MO, RG, MA
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DISCLOSURES

M.P. reports consulting agreement with Artivion. G.P. reports fee for employ tutoring with Artivion. M.A. reports consulting agreement with Artivion.

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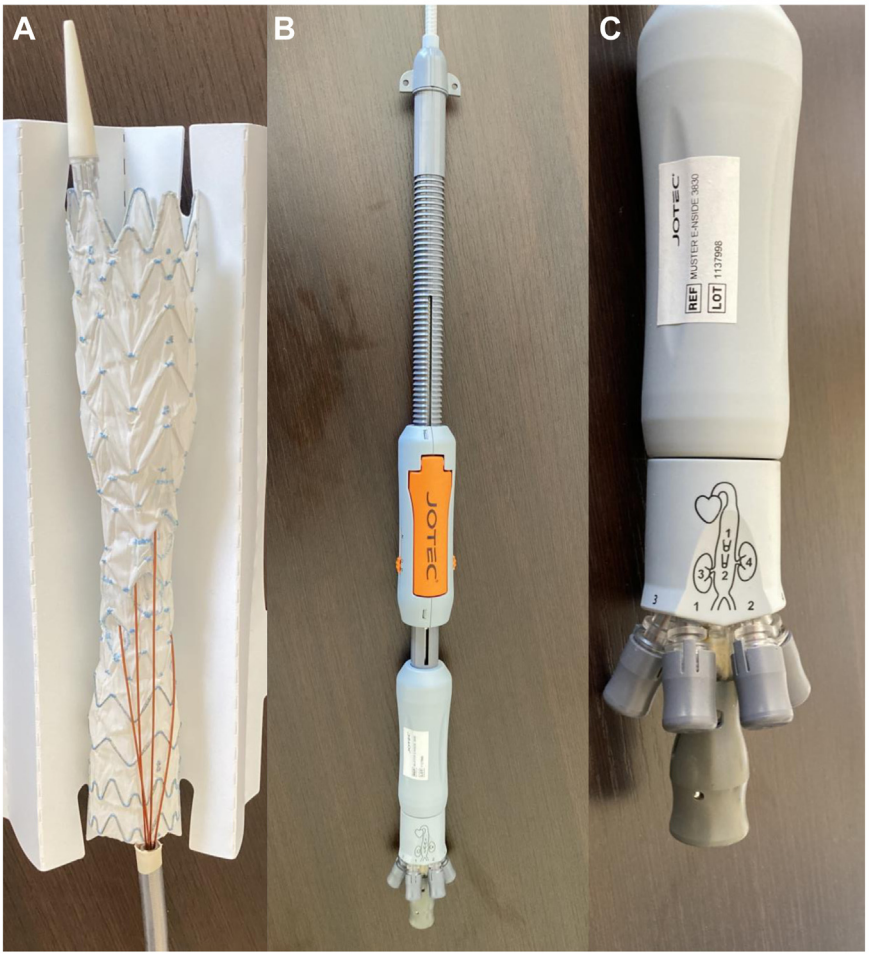

Supplementary Fig (online only). A, On-bench picture of the E-nside after deployment. Note the preloaded catheters. **B**, Image of the device handle, "including the squeeze to release" handle and the port for the preloaded catheters. **C**, Detail of the port of the preloaded catheters. Each catheter is preloaded with a safety wire; this has to be removed and exchanged for a working guidewire, which is then snared from an upper arm or contralateral femoral access.

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Supplementary Table (online only). Univariate analysis for any major adverse event (MAE) after urgent thoracoabdominal aortic aneurysm (*TAAA*) repair with E-nside

	OR	95% CI		P
Age, years	1.099	1.016	1.206	.029[a]
Male	1.970	0.535	9.513	.341
Coronary artery disease	3.182	1.015	10.254	.048[a]
Cerebrovascular disease	1.114	0.218	4.610	.886
Hypercholesterolemia	2.052	0.618	8.147	.264
Hypertension	0.364	0.041	3.235	.332
Chronic heart failure	2.143	0.553	7.937	.253
Chronic kidney disease	5.937	1.827	20.697	.004[a]
COPD	1.944	0.649	6.010	.237
Aortic dissection	0.242	0.013	1.443	.194
Extent IV TAAA	1.871	0.625	5.907	.269
Aneurysm presentation				
Large asymptomatic	Ref	–	–	–
Symptomatic TAAA	0.730	0.237	2.195	.576
Ruptured TAAA	1.250	0.162	7.089	.807
Minimum iliac artery diameter, mm	1.068	0.794	1.434	.656
Narrow paravisceral aorta <25 mm	1.084	0.294	3.651	.899
Aneurysm diameter, mm	0.999	0.971	1.025	.932
Total thoracic aorta coverage, cm	0.941	0.820	1.023	.266
Total operative time, minutes	1.002	0.995	1.008	.613
Adjunctive thoracic endograft	0.952	0.311	2.851	.930
Total transfemoral access	0.725	0.180	2.478	.624

CI, Confidence interval; *COPD*, chronic obstructive pulmonary disease; *OR*, odds ratio; *Ref*, reference.
[a]Statistically significant.