Eur J Vasc Endovasc Surg (2025) 70, 437–444

EJVES Open Access

Inner Branch Off the Shelf Technology for Chronic Post-dissection Thoraco-Abdominal Aneurysm with Narrow True Lumen: Results of a European Multicentre Study

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WHAT THIS PAPER ADDS

This is the first multicentre clinical study to analyse the use of a novel off the shelf pre-loaded inner branched endograft (E-nside; JOTEC, CryoLife, Inc.) for the treatment of chronic post-dissection thoraco-abdominal aneurysm. The successful technical implantation, and favourable early and midterm outcomes, suggest that this endograft can be considered a valid option for the treatment of this complex disease, providing a readily available solution to address the anatomical challenges and variability of aortic dissection.

Objective: This study aimed to evaluate the early and midterm outcomes of endovascular repair of aortic dissection (AD) using a new pre-cannulated, inner branch based, off the shelf stent graft (E-nside; JOTEC, CryoLife, Inc.).

Methods: Data from an international multicentre registry on patients treated with the E-nside endograft for AD were analysed. Pre-operative clinical and anatomical characteristics, procedural data, and early and follow up outcomes were recorded in a dedicated electronic data capture system. The primary endpoint was technical success. Secondary endpoints were overall death, aortic related death, aortic related re-intervention rate, endoleak rate, and target vessel instability (TVI) at 30 days and during follow up.

Results: Thirty four patients treated in 14 high volume European institutions between January 2020 and May 2024 were included. The mean patient age ± standard deviation was 66 ± 9.8 years, and 30 (88%) were male. The mean true lumen aortic diameter at the visceral aorta was 24.5 ± 7.7 mm. The median procedure time was 300 minutes (interquartile range 215, 373). The technical success rate was 97%, due to one case of placement of the coeliac trunk covered stent into the branch of the superior mesenteric artery and *vice versa*. The 30 day mortality and re-intervention rates were 6% ($n = 2$) and 9% ($n = 3$), respectively. At a mean follow up of 15.1 ± 7.5 months, there were no aortic related deaths. Freedom from aortic related death and all cause death at 12 months was 97% and 94%, respectively. The TVI rate during the follow up was 13% (four of 32). The total re-intervention rate was 16% (five of 32).

Conclusion: Endovascular treatment of AD with an off the shelf, inner branched endograft is feasible, with acceptable short and midterm outcomes. The results showed good technical implantation safety and efficacy. Long term follow up results are needed to better define the clinical role of this novel endograft.

Keywords: Aortic dissection, Branched endovascular aortic repair, Endovascular repair, Multicentre study, Thoraco-abdominal aortic aneurysm
Article history: Received 25 October 2024, Accepted 18 April 2025, Available online 25 April 2025

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https://doi.org/10.1016/j.ejvs.2025.04.044

INTRODUCTION

Aortic dissection (AD) is the second most common aetiology of aortic aneurysms after atherosclerotic degenerative aneurysms, accounting for 15 — 20% of all thoraco-abdominal aortic aneurysms (TAAAs).[1]

During follow up, it has been reported that AD aneurysmal degeneration occurs in 73.3% of patients with medical therapy and in 62.7% of patients after thoracic endovascular aortic repair (TEVAR).[2] Moreover, the rate of post-dissection TAAA may be underestimated due to the absence of proper follow up in these patients.[3]

The risk of rupture and aneurysm related death in TAAAs is estimated to be 3.7% and 12% per year, respectively, with aneurysm size being the major predictive factor for rupture.[4] The reported aortic diameter growth rate in patients with chronic AD is 4.1 — 7.1 mm/year due to false lumen perfusion originating from multiple distal entry tears.[5,6]

The unpredictable nature and potential severity of AD necessitate innovative and effective treatment approaches to enhance patient prognosis. In recent years, endovascular repair has emerged as a promising alternative to traditional open surgery, offering less invasive options with reduced mortality and recovery times.[7,8]

Endovascular treatment aims to cover the entry tears, thereby promoting thrombosis and false lumen remodelling.[9] In single arm studies, fenestrated and branched endografting (FB/EVAR) have shown favourable early results.[3,10—12] Other procedures, such as false lumen embolisation or candy plug techniques, have been used to induce false lumen thrombosis, with good midterm outcomes.[13] Among these, the development of a pre-cannulated, inner branch based, off the shelf stent graft for thoraco-abdominal aortic disease represents a significant advance in the treatment of complex aortic pathologies. This novel device, combining the advantages of branched (inner branches) and fenestrated (absence of outer branch portion) repair, is designed to provide a readily available solution that addresses the anatomical challenges and variability of dissection, and may be suitable for enhanced performance in narrow anatomies. Although some studies have been published regarding the feasibility of this graft, and its use on a broad range of aortic pathologies,[14—16] there are no dedicated studies focusing on chronic post-dissection TAAA.

This study aimed to evaluate the early and midterm outcomes of endovascular AD repair using the new E-nside (Artivion, Kennesaw, GA, USA) multibranch stent graft system.

MATERIALS AND METHODS

Study design

This was a single arm, non-randomised, multicentre study including all prospectively collected consecutive patients who were electively treated with the E-nside multibranch stent graft system (Supplementary Fig. S1) for chronic post-dissection TAAA in 14 high volume European centres (Supplementary Table S1) between January 2020 and May 2024. The study received institutional review board and ethics committee approval (Ethic Committee for Clinical Experimentation, Rome, Italy; study ID 6036). Individual consent for intervention and retrospective analysis was obtained from all patients. Data privacy was managed according to the National Privacy Act. Study data were collected at each centre and gathered anonymously in a single electronic database. The database included pre-operative demographics, risk factors, anatomical features, procedural details, and follow up outcomes (post-operative clinical events and imaging examinations).

Study population

Patients with chronic thoraco-abdominal AD with an aortic diameter >55 mm or rapid growth (>10 mm/year) were included. The anatomical criteria were: length of proximal and distal landing zone ≥ 30 mm; absence of severe angulation in the thoracovisceral segment; minimum true lumen aortic diameter ≥ 16 mm; and total (true and false lumen) aortic diameter ≥ 24 mm. Patients with aortic rupture or in an emergency setting, including haemodynamic instability at the time of enrolment, were excluded from the study.

The treatment strategy was decided for each case after multidisciplinary discussion. Each case was analysed, planned, and performed by an experienced operator (>50 aortic procedures/year). The procedural steps have been reported previously.[14,17] A summary of all chronic thoraco-abdominal ADs treated with different strategies is presented in Supplementary Table S2.

Follow up protocol

Patients were observed at regular post-operative appointments. Computed tomography angiography (CTA) was performed one and six months post-operatively, and yearly thereafter.

Endpoints

Outcomes were described in accordance with current reporting standards.[18,19] The primary endpoint was technical success, defined as successful introduction and deployment of the device and all the branch components at the intended location without the occurrence of surgical conversion or death, type I or type III endoleak, branch occlusion, or graft obstruction. The secondary endpoints were overall death, aortic related death, aortic related re-intervention rate, endoleak rate, and target vessel instability (TVI) at 30 days and during follow up.

Statistical analysis

Quantitative variables were reported as mean $\pm$ standard deviation, or in case of non-normality as median and interquartile range (IQR). Qualitative variables were reported as absolute and relative frequency (percentage). Overall survival and disease free survival were estimated using the Kaplan—Meier method. Categorical data were reported as the number and its accompanying percentage of the whole. Data analysis was performed using STATA 15.1 (StataCorp, College Station, TX, USA).

RESULTS

Patient population and anatomical details

Thirty four patients treated with the E-nside endograft at 14 different institutions between 1 January 2020 and 30 April 2024 (mean of 2.3 patients per centre, range 1 — 6) were included. Comorbidities included arterial hypertension in 30 patients (88%) and dyslipidaemia in 20 patients (59%). Eighteen patients (53%) had had previous type A AD. The mean true lumen aortic diameter at the visceral aorta was 24.5 ± 7.7 mm (Fig. 1). Patient demographics and anatomical details are reported in Table 1.

Procedural data

The femoral access was percutaneous in 21 patients (62%); access for target vessel cannulation was the brachial or axillary artery in 26 patients (76%), while contralateral femoral access was used in eight cases (24%). The median bridging time per vessel was 20 minutes (IQR 10, 25). All procedural data are reported in Table 2.

The technical success rate was 97% (33 of 34), due to one case of placement of the coeliac trunk covered stent into the branch of the superior mesenteric artery (SMA) and *vice versa*. At final angiography, no type I or III endoleaks were observed; there were nine type II endoleak cases (26%). The median total duration of the operation was 300 minutes (IQR 215, 373). No intra-operative deaths were registered.

Early outcomes

The mean hospitalisation time was 12.1 ± 7.5 days. Three (9%) permanent spinal cord ischaemia (SCI) cases with complete motor deficit were observed. There were two (6%) minor strokes, both with upper extremity access, and two cases (6%) of acute kidney injury requiring permanent dialysis. There were three (9%) early re-interventions: one case of femoral artery pseudoaneurysm with access site infection requiring common femoral artery ligation and iliac to superficial femoral artery extra-anatomical bypass; one case of coeliac trunk and SMA aspiration thrombectomy; and one case of bladder bleeding requiring cystoscopy. There were two (6%) aortic related deaths: one in hospital death due to acute thrombotic occlusion of the coeliac trunk and SMA requiring unsuccessful aspiration thrombectomy, and one case of spontaneous iliac artery rupture 16 days after the procedure.

At the one month CTA, there was evidence of one case (3%) of type Ic endoleak due to inadequate seal of the distal branch attachment to the coeliac trunk artery. The nine cases (26%) of type II intra-operative endoleaks were confirmed in the first post-operative CTA with stability of the aneurysm diameter. Early results are summarised in Table 3.

Midterm outcomes and overall follow up

The mean follow up was 15.1 ± 7.5 months. During this time, four patients (13%) had target vessel occlusion. There

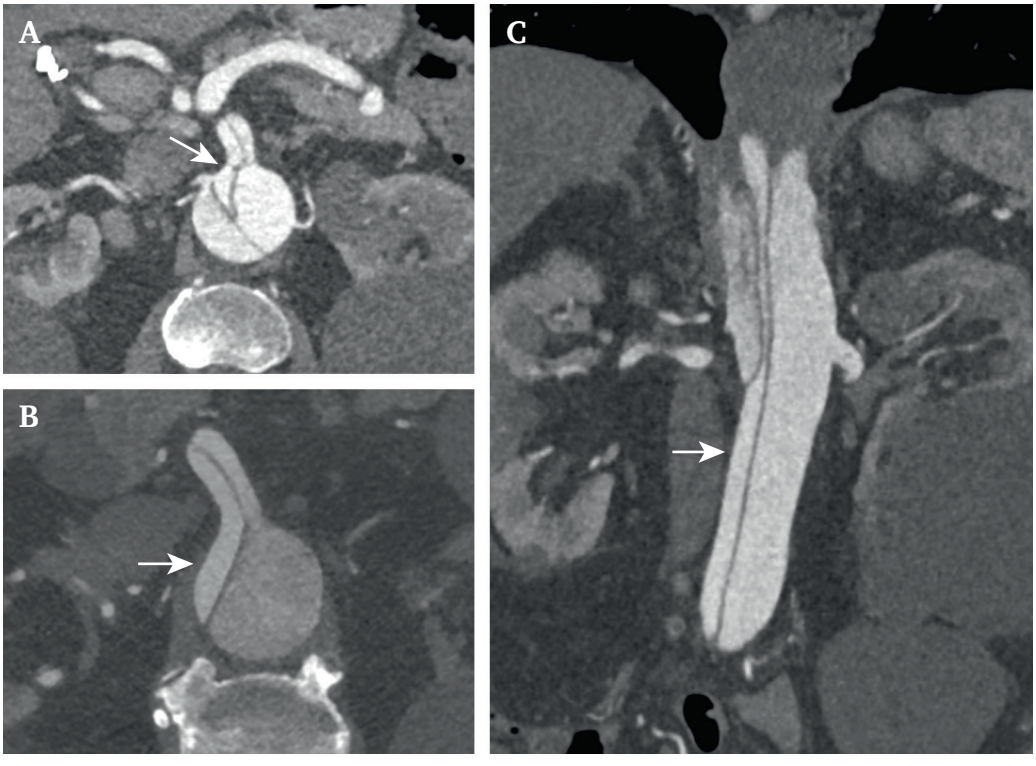

Figure 1. Pre-operative computed tomography angiography showing the narrow (< 25 mm) true lumen (arrows) at the level of the (A) coeliac trunk, (B) superior mesenteric artery, and (C) renal arteries.

Table 1. Baseline demographic and anatomical characteristics of patients (n = 34) treated with the E-nside endograft for chronic post-dissection thoraco-abdominal aortic aneurysm.

Characteristic	Patients (n = 34)
Male sex	30 (88)
Age − y	66 ± 9.8 (42–84)
BMI − kg/m^2	26.3 ± 4.0 (20–35)
Smoking	10 (29)
Hypertension	30 (88)
Diabetes mellitus	7 (21)
Dyslipidaemia	20 (59)
Coronary artery disease	11 (32)
Congestive heart failure	6 (18)
Chronic kidney disease	5 (15)
Dialysis	2 (6)
COPD	8 (24)
Cerebral vessel disease	10 (29)
Connective tissue disease	5 (15)
Previous acute aortic dissection	
Type A	18 (53)
Type B	16 (47)
Previous open ascending aorta repair	18 (53)
Previous TEVAR	26 (76)
Anatomical characteristics	
Maximum aortic diameter (TL+FL) − mm	61.4 ± 10.9
Aortic TL minimum diameter − mm	18.3 ± 7.7
Aortic TL diameter at visceral level − mm*	24.5 ± 7.7
Mean visceral arteries arising from FL − n	0.95 ± 0.95
Iliac access minimum diameter − mm	12.8 ± 18.8

Data are presented as n (%) or mean ± standard deviation (range). BMI = body mass index; COPD = chronic obstructive pulmonary disease; TEVAR = thoracic endovascular aortic repair; FL = lumen; TL = true lumen.
* Visceral level = 3 cm above the coeliac trunk to the lowest renal artery.

Table 2. Procedural details for patients (n = 34) treated with the E-nside endograft for chronic post-dissection thoraco-abdominal aortic aneurysm.

Procedural data	Patients (n = 34) and bridging stents (n = 136)
Femoral access approach	
Percutaneous	21 (62)
Cutdown	13 (38)
Surgical iliac conduit	4 (12)
Upper extremity access	26 (76)
Staged procedure	26 (76)
Prophylactic spinal drain	14 (41)
E-nside proximal diameter − mm	
33	12 (35)
38	22 (5)
E-nside distal diameter − mm	
26	28 (82)
30	6 (18)
Type of bridging stent	
Ballon expandable	108 (79.4)
Self expanding	24 (17.6)
Intentional branch occlusion	4 (2.9)
Bridging stent length − mm	
Coeliac artery	59.4 ± 11.9
Superior mesenteric artery	64.2 ± 10.9
Right renal artery	61.4 ± 13.3
Left renal artery	64.6 ± 14.6
Use of a pre-loaded system	27 (79)
Total bridging time − min	20 (10, 25)
Total operating time − min	300 (215, 373)
Total contrast volume − mL	160 (126, 244)
Total fluoroscopy time − min	76 (68.5, 106)
Technical success	33 (97)
Main graft deployment failure	0 (0)
Major adverse events	0 (0)
Endoleak on final angiography	
Type I or III	0 (0)
Type II	9 (26)
Intra-operative death	0 (0)

Data are presented as n (%), mean ± standard deviation, or median (interquartile range).

were three (9%) cases of renal arteries occlusion: one case involved bilateral renal artery occlusion in a patient resistant to clopidogrel, which was managed with percutaneous thrombectomy and stenting two months post-procedure; the other two cases were asymptomatic right renal artery occlusions detected in the one year CTA. In these three cases, the aortic true lumen diameter at visceral level was < 20 mm. Additionally, there was one case (3%) of acute occlusion of all four target vessels, due to a hypercoagulable state, requiring visceral debranching. The total target vessel patency rate was 93.5% (116 of 124 target vessels). One (3%) right renal artery stenosis required relining. The type Ic endoleak observed at one month CTA required relining to the common hepatic artery and embolisation of the splenic artery two months after the index operation. One patient (3%) required re-intervention after three months for a left common femoral artery pseudoaneurysm. The TVI rate during follow up (> 30 days) was 13% (four of 32). The total re-intervention rate was 16% (five of 32). One patient (3%) died, for non-aortic reasons, during the follow up period. Freedom from aortic related death and all cause death at 12 months was 97% and 94%, respectively (Fig. 2). Overall freedom from re-intervention at 12 months was 73% (Fig. 3).

During follow up, 29 patients (91%) had the one year CTA. There were eight (28%) type II endoleaks with aneurysm sac stability, and complete false lumen thrombosis with aneurysm shrinkage was detected in 16 of 29 cases (55%).

DISCUSSION

Endovascular treatment of chronic post-dissection TAAA represents a significant advance in the management of this complex disease. Several studies have described favourable outcomes with fenestrated and outer branched endografts. Oikonomou *et al.* reported a technical success rate of 96% and peri-operative mortality rate of 5.6% in 71 patients undergoing FB/EVAR for post-dissection aneurysms.[12] Similarly, Gallitto *et al.* reported a technical success rate of 92% with no 30 day deaths in 37 patients with AD among 351 patients who underwent FB/EVAR for TAAAs.[3]

Table 3. Early outcomes of patients (n = 34) after treatment with the E-nside endograft for chronic post-dissection thoraco-abdominal aortic aneurysm.

Outcome	Patients (n = 34)
Hospitalisation time − d	12.1 ± 7.5
Spinal cord ischaemia	3 (9)
Permanent	3 (9)
Temporary	0 (0)
Stroke	2 (6)
Myocardial infarction	0 (0)
Respiratory failure	2 (6)
Acute kidney insufficiency	2 (6)
Gastrointestinal complications	0 (0)
Target vessel complications	1 (3)
Target vessel instability	1 (3)
Access site complications	1 (3)
Endoleak	
Type Ia	0 (0)
Type Ib	0 (0)
Type Ic	1 (3)
Type II	9 (26)
30 day death	2 (6)
Re-intervention	3 (9)

Data are presented mean ± standard deviation or as n (%).

Nevertheless, management of chronic post-dissection TAAAs with FB/EVAR has specific anatomical and technical challenges, requiring an adequate aortic diameter and accurate planning, with six to eight weeks manufacturing time for custom made endografts.[20] Particularly in patients who present with symptoms or giant aneurysms, the time required to produce custom made endografts may pose an unjustified risk of rupture and encourage the use of off the shelf branched devices.[21] The first off the shelf BEVAR device available in Europe (t-Branch; Cook Medical, Bloomington, IN, USA) was based on outer branch technology and without pre-cannulation.

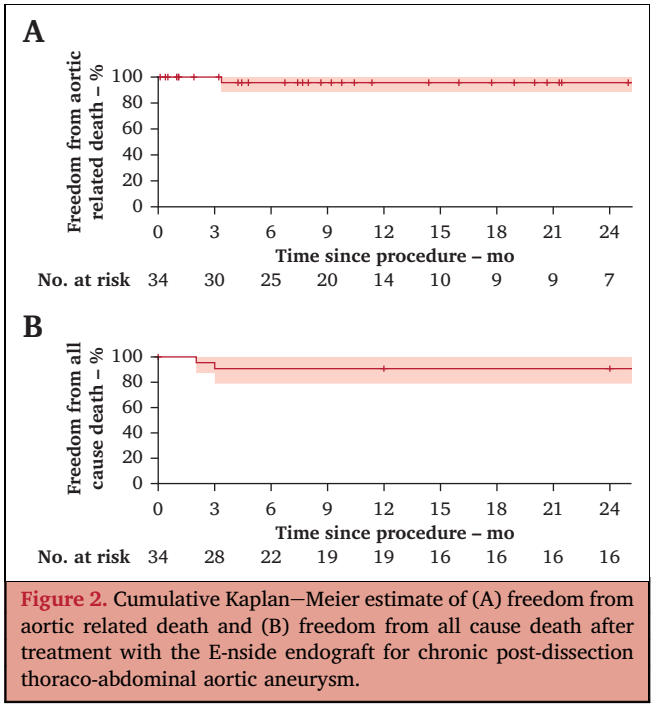

Figure 2. Cumulative Kaplan–Meier estimate of (A) freedom from aortic related death and (B) freedom from all cause death after treatment with the E-nside endograft for chronic post-dissection thoraco-abdominal aortic aneurysm.

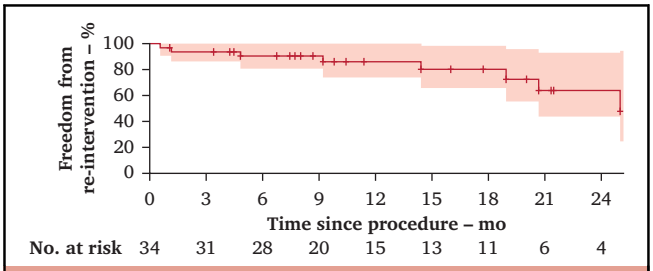

Figure 3. Cumulative Kaplan–Meier estimate of freedom from re-intervention after treatment with the E-nside endograft for chronic post-dissection thoraco-abdominal aortic aneurysm.

In contrast, the E-nside endograft, characterised by an inner branch design with antegrade orientation and a dedicated pre-cannulated tube for each branch, is a new technology for treating TAAAs. This multicentre study is the first to report the early and midterm outcomes of the off the shelf, inner branch technology in the treatment of chronic post-dissection TAAAs. The results showed satisfactory early technical and clinical outcomes, with 97% technical success and a 3% mortality rate at 90 days. These data, combined with the previously reported promising early clinical outcomes,[14] indicate that this technology may be considered an additional tool for managing complex aortic pathologies, including AD. The use of stent grafts in chronic dissection aims to depressurise the false lumen by covering the entry tears, thereby promoting progressive false lumen thrombosis. In the present series, 91% of cases had radiological follow up at 12 months, with satisfactory false lumen thrombosis and aneurysm shrinkage of 55%, in line with the current literature.[11,22]

However, some anatomical challenges represented by a narrow true lumen and stiff aortic septum should be considered. According to the current literature, a narrow aorta is defined by a perivisceral transverse aortic diameter < 25 mm.[23,24] In the current study, the mean true lumen aortic diameter at the level of the visceral aorta was 24.5 ± 7.7 mm and the mean minimum aortic diameter was 18.3 ± 7.7 mm. It is reported that a narrow aortic lumen is predictive of bridging stent occlusion and outer branch instability, particularly in cases of longitudinal extent > 25 mm or severe wall calcification.[23] Inner branch technology has been designed to ensure proper branch positioning within the main graft, minimising the risk of compression in narrow aortic zones and stent graft kinking.[15] Abisi *et al.* reported that the main indication for using inner branch technology in their experience was a narrow aortic lumen.[25] In a preliminary clinical experience using a custom made inner branch device in 14 patients with a narrow aorta, they reported 100% technical success and 12 month patency rate.[26] In the current study, the total target vessel patency rate was 93.5%; in the majority, target vessel occlusion occurred in cases of aortic true lumen diameter < 20 mm,

potentially influenced by the mechanical behaviour of the inner branches. Moreover, in two patients with a narrow true lumen of 16 mm, high pressure ballooning was performed after main graft implantation and before bridging stent graft implantation at the site of the inner branches. This planned procedure demonstrated a resulting endograft expansion of the true lumen and the compression resistance of the E-nside inner branches, which may be associated with their unique design with asymmetrical compression springs.[17]

In addition, the visceral arteries originating from the false lumen represent a technical challenge. To correctly catheterise these target vessels, the thick chronic dissection flap has to be perforated, or a re-entry tear found.[27] Different methods for membrane fenestrations are described, including wires with tips that can be stiffened, the back end of a wire, a wire with support of a guiding sheath, re-entry catheters, or transcatheter electrosurgical septotomy.[27,28] Nevertheless, it is reported that branch vessel involvement in the false lumen is an independent risk factor for target vessel related endoleaks, owing to the high probability of entries around the opening of the branch vessels and the gap between the vessels and the fenestrations.[10,29] In the current series, the mean number of target vessels originating from the false lumen was 1 ± 1 and no correlation with target vessel related endoleaks was observed. In the setting of AD, inner branch technology gives the advantage of keeping the main graft diameter wide, resulting in closer contact with the aortic wall,[21] and reducing the distance between the branch outlet and target vessel, extending the bridging stents deeper into the target vessel beyond the dissection flap.

Due to pre-cannulation, the 24 F delivery system of the E-nside stent graft must remain in the vessel until all branches and target arteries are addressed, increasing the risk of peripheral ischaemia or even SCI.[17] However, the time to cannulation can usually be kept very short. In the current study, the median bridging time was 20 minutes, in line with the reported mean time for each vessel cannulation of 21.8 ± 28 minutes.[23] This may be explained by the smoother advance of the sheath over the pre-cannulation wire directly into the inner branch and down to the level of the target vessel. This provides additional stability during cannulation, as the through and through wire is only removed when introducing the bridging stent graft. Moreover, one potential disadvantage of the pre-loaded system is the supra-aortic trunk manipulation to snare the guidewire from the upper extremity with possible cerebral and systemic embolisation. Westin *et al.* reported a stroke rate of 1.5% in 3 374 FB/EVAR patients, with an increased risk in the 17.3% of cases requiring an upper extremity access (2.3% *vs.* 0.9%; $p = .002$).[30] To avoid the risk of peri-operative stroke, pre-loaded guidewires should be snared in the descending thoracic aorta or via a transfemoral approach,[31] particularly in case of previous ascending aorta and arch repair. In the present study, the stroke rate was 6% and all neurological events occurred in upper extremity access cases. Similarly, Piazza *et al.* reported a stroke rate of 4.2% in upper limb access cases and 0% in femoral access cases.[14]

The risk of SCI remains a significant concern during complex endovascular aortic repair. Techniques such as staged procedures, monitoring of spinal cord perfusion, cerebrospinal fluid drainage, and permissive hypertension are employed to enhance spinal cord protection. Despite these strategies, the incidence of SCI after TAAA endovascular repair ranges 0 — 35%.[32] A recent study comparing the two commercially available off the shelf branched endografts (E-nside and t-Branch) reported that E-nside may require shorter thoracic aorta coverage with less frequent thoracic endografting (14% *vs.* 76%; $p < .001$) and distal bifurcated endograft (53% *vs.* 80%; $p < .001$).[33] Nevertheless, in AD cases, extended aortic coverage is necessary to maximise aortic remodelling,[34] requiring a staged approach to slowly expand the compressed true lumen and decrease the risk of SCI. In the present study, the SCI rate was 9%, observed in three patients with TAAA > 8 cm that required complete one stage aortic coverage owing to the risk of rupture. In this context, it is important to emphasise that the availability of an off the shelf thoraco-abdominal device represents a solution for patients at high risk of aortic rupture, offering prompt lifesaving treatment.

One significant issue is the high rate of late re-interventions. The reported re-intervention rate ranges 19 — 53%, with heterogeneous causes.[3,35,36] In the present study, the re-intervention rate was 16%, primarily due to vessel occlusion during follow up. The development of new generation bridging stent grafts has reduced the incidence of TVI, although failures may still occur.[37] Moreover, anatomical factors—such as target vessel diameter and orientation, bridging stent graft kinking, and primary involvement of the vessel in the AD process—may further impact TVI during follow up.[38,39] This study and previous reports show that renal arteries are more frequently affected by patency loss after BEVAR compared with visceral arteries, with frequently oligosymptomatic renal branch thrombosis or stenosis.[38] Therefore, it is crucial to maintain a strict follow up regimen to promptly detect any irregularities in target vessel patency or bridging stent graft integrity, and to consider re-intervention as soon as stenosis or endoleaks are identified.

Study limitations

The accuracy of these findings might have been affected by the multicentre design of the study and the absence of core lab imaging analysis, although this may have also increased the generalisability. The sample size was too small to draw strong conclusions. Even though the device was deemed appropriate for the anatomical features of the reported cases, the overall applicability of this endograft in AD cannot be determined. Furthermore, no direct comparison could be made with custom made multibranched or fenestrated endografts.

Conclusions

Use of the E-nside endograft represents a viable treatment option for chronic post-dissection TAAA. The study demonstrates the short and midterm effectiveness of this new

endograft, showing high technical success and low mortality rates. However, future research, particularly long term outcome data, is needed to fully establish the advantages and durability of this device.

CONFLICTS OF INTEREST

None.

FUNDING

This research did not receive any specific grant from funding agencies in the public, commercial, or not for profit sectors.

APPENDIX A. SUPPLEMENTARY DATA

Supplementary data to this article can be found online at https://doi.org/10.1016/j.ejvs.2025.04.044.

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