

Original Article

Adjunctive E-XL stent reinforcement during EVAR and TEVAR in patients with hostile proximal neck anatomy: Early term outcomes

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Abstract

Aim: Hostile proximal neck anatomy may compromise endograft fixation and sealing during endovascular aortic repair. This study evaluated the early outcomes of adjunctive E-XL stent reinforcement during standard endovascular aortic repair (EVAR) or thoracic endovascular aortic repair (TEVAR) in selected patients with hostile proximal neck anatomy.

Material and Methods: Consecutive patients undergoing EVAR or TEVAR with adjunctive E-XL stent placement were retrospectively reviewed. Baseline characteristics, anatomical features, procedural variables, and early outcomes were obtained from medical records and imaging. Clinical follow-up was performed during the first postoperative week and at one month, with contrast-enhanced computed tomography at one month.

Results: Twenty-one patients were included: 12 underwent TEVAR and nine EVAR. All TEVAR patients had proximal neck angulation $> 60^\circ$ (mean $75.4 \pm 6.6^\circ$). In the EVAR group, hostile neck features included severe angulation, neck length < 15 mm, combined short and angulated neck, or circumferential thrombus > 2 mm. Technical success was achieved in all patients. No perioperative cerebrovascular or cardiovascular events, end-organ ischaemia, graft migration, type Ia endoleak, stent collapse, kinking, or limb stenosis occurred. Mild post-implantation syndrome occurred in three patients (14.3%). One patient died within one month from COVID-19, unrelated to the procedure. One distal type Ib endoleak after TEVAR was successfully treated with extension. Mean aneurysm diameter decreased by 1.1 mm after TEVAR and 0.6 mm after EVAR at one month; the clinical relevance of these small changes is uncertain.

Conclusion: Adjunctive E-XL reinforcement was technically feasible and may provide additional proximal fixation support in carefully selected high-risk patients when standard endograft fixation is considered potentially insufficient. These early findings do not establish long-term durability or comparative efficacy. Larger prospective comparative studies with extended imaging follow-up are required before routine use can be recommended.

Keywords: Endovascular aneurysm repair; aortic aneurysm, thoracic; endoleak; prosthesis failure; stents; blood vessel prosthesis

INTRODUCTION

Endovascular repair is now widely used for thoracic and abdominal aortic disease and has reduced early morbidity and mortality compared with open repair in appropriately selected patients [1-5]. However, durable success depends on adequate

proximal sealing and fixation. A hostile proximal neck, commonly characterised by short neck length, severe angulation, heavy thrombus, or circumferential calcification, may compromise endograft apposition and increase the risk of graft migration, proximal type Ia endoleak, sac expansion, and rupture [6-10].

CITATION

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Conventional anatomical criteria for standard endovascular aneurysm repair generally require a proximal landing zone of at least 15 mm, neck angulation of 60 degrees or less, and limited thrombus or calcification. Current guideline-based assessment also considers additional hostile features such as a tapered neck, circumferential calcification, and irregular neck morphology. Patients outside standard device criteria have traditionally been considered for open repair, fenestrated or branched devices, chimney techniques, or adjunctive fixation devices. Although these approaches are valuable, they may require additional planning, device availability, and technical expertise [11-20].

The E-XL stent is a self-expanding uncovered nitinol stent with high radial force and a hybrid open and closed cell design. It has previously been used for complex aortic indications, including tortuous aortic arch anatomy and true lumen stabilisation in aortic dissection [21,22]. On this basis, adjunctive E-XL stent placement may provide additional proximal support after standard endovascular aortic repair (EVAR) or thoracic endovascular aortic repair (TEVAR) in selected hostile neck anatomies.

The aim of this study was to evaluate the technical feasibility and early clinical and radiological outcomes of standard EVAR or TEVAR combined with adjunctive E-XL stent reinforcement in patients with hostile proximal aortic neck anatomy.

MATERIAL AND METHODS

Study Design and Patients

This was a retrospective, single-centre case series of consecutive patients treated with TEVAR or EVAR combined with adjunctive E-XL stent placement for hostile proximal neck anatomy. Procedural and perioperative variables had been recorded routinely at the time of treatment and were subsequently analysed retrospectively. Patients treated with TEVAR or EVAR alone and patients with favourable proximal neck anatomy were excluded. The study was prepared in accordance with the Strengthening the Reporting of observational Studies in Epidemiology (STROBE) recommendations.

Indications for TEVAR included descending thoracic aortic aneurysm ≥ 55 mm, Stanford type B dissection, descending thoracic aortic aneurysm with type B dissection, intramural haematoma, and penetrating aortic ulcer. The indication for EVAR was abdominal aortic aneurysm ≥ 55 mm. Hostile proximal neck anatomy was defined by one or more of the following features: neck length < 15 mm, neck angulation > 60 degrees, circumferential thrombus or calcification > 2 mm, tapered configuration, or irregular proximal neck morphology. The decision to use adjunctive E-XL reinforcement was made by the treating aortic team in high-risk patients when standard

endograft fixation was considered potentially insufficient and when open repair, fenestrated repair, chimney techniques, or EndoAnchor use was considered less suitable because of anatomical, clinical, technical, or availability-related factors.

The study was approved by the institutional ethics committee of University of Health Sciences İzmir Tepecik Training and Research Hospital (approval number 2020/14-65, date 23.12.2020). All procedures were conducted in accordance with internationally accepted ethical principles. Written informed consent for treatment and use of clinical data was obtained from all participants.

Procedure

All interventions were performed by two senior endovascular surgeons. Patients scheduled for TEVAR underwent cerebrospinal fluid drainage catheter placement one day before the procedure. General anaesthesia was induced with propofol, fentanyl citrate, and pancuronium bromide, and maintained with intravenous propofol and fentanyl citrate with inhaled sevoflurane.

Open surgical exposure of the common femoral artery was performed. Bilateral groin exposure was used for EVAR, whereas single groin exposure was used for TEVAR when appropriate. After femoral access, 5000 international units (IU) of heparin was administered. A 0.035-inch Back-up Meier guidewire was advanced under fluoroscopic guidance to the level of the aortic valve using a 6 F pigtail catheter. A contralateral 6 F pigtail catheter was used to identify the proximal landing zone by angiography.

The main endograft was delivered over the guidewire and deployed at the predetermined proximal landing zone. The E-XL stent was then advanced over the same guidewire and deployed across the proximal segment of the previously implanted endograft, with an overlap of approximately 30-50 mm. This overlap was selected to provide sufficient interaction between the two devices while allowing the uncovered stent to conform to the proximal landing zone. In EVAR cases, the contralateral limb was introduced through the contralateral common femoral artery. Completion angiography was performed in all patients. A representative EVAR procedure with adjunctive E-XL stent reinforcement is shown in Figure 1. If no endoleak, migration, limb stenosis, or other procedural problem was observed, the arteriotomy was closed with 6/0 polypropylene suture.

During deployment of the endograft and adjunctive stent, systolic arterial pressure was deliberately maintained between 70 and 90 mmHg as a standard procedural strategy to facilitate controlled positioning and reduce the risk of early migration. Postoperatively, all patients received oral acetylsalicylic acid 150 mg daily.

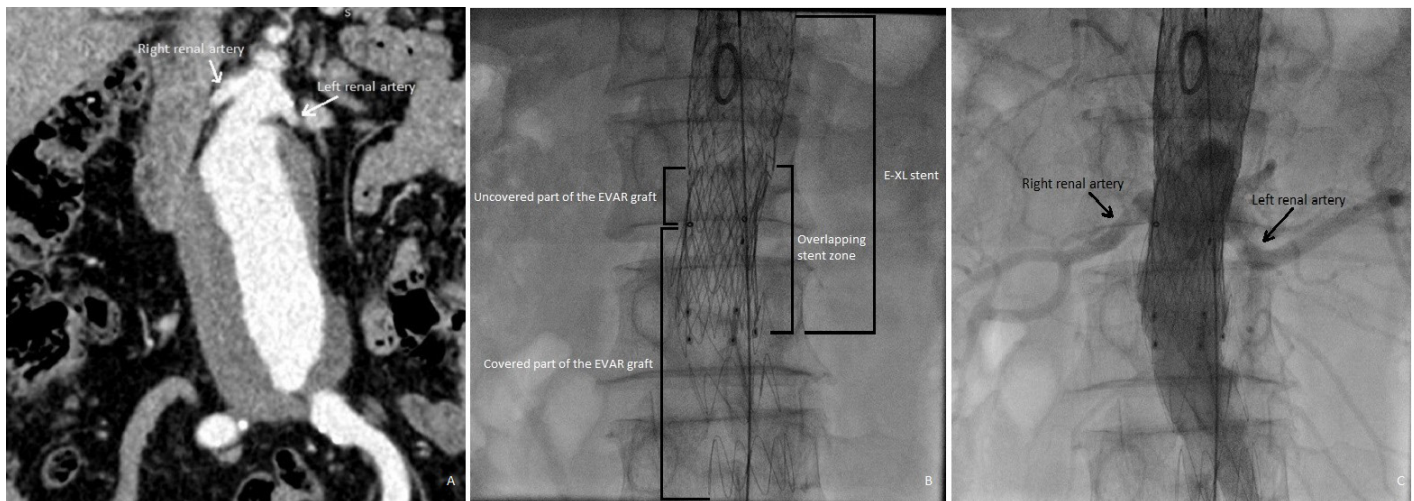


Figure 1. Patient with an abdominal aortic aneurysm and a 0.8 cm infrarenal neck. (A) Pre-operative computed tomography image. (B) Intra-operative image showing the EVAR graft, E-XL stent, and overlap zone. (C) Completion angiography after the procedure.

Device Characteristics

The E-XL stent is a self-expanding nitinol stent with open cells in the mid portion and closed cells at both ends. The open-cell portion is designed to improve flexibility and conformability, whereas the closed-cell ends provide fixation support. The device is available in single-flared and double-flared configurations, with diameters ranging from 14 to 36 mm and lengths from 70 to 130 mm. Depending on the configuration, the diameter is 4 mm wider at one or both ends. The stent has a reported constant outward radial force along the device length. 11-13 A single-flared configuration was selected when the diameter change was predominantly located at one end of the intended landing segment, whereas a double-flared configuration was selected when additional apposition was required at both ends. Final sizing was based on preoperative computed tomography (CT) measurements and intraoperative angiography.

Follow-up and Outcomes

Clinical follow-up was performed during the first postoperative week and at one month. Additional clinical follow-up data were available for a mean of 12.2 ± 8.5 months; however, protocol-based radiological follow-up for the present analysis was limited to contrast-enhanced computed tomography at one month. Preoperative and one-month measurements were compared to assess early sac diameter changes. The absence of systematic 6- and 12-month imaging data was considered a study limitation.

The primary early endpoint was technical success, defined as successful deployment of the planned endograft and E-XL stent with patent treated vessels and no type Ia endoleak or proximal graft migration on completion angiography. Secondary endpoints included procedure-related complications, type Ib

endoleak, re-intervention, mortality, and one-month change in aneurysm diameter.

Statistical Analysis

Continuous variables are reported as mean $\pm$ standard deviation, and categorical variables are reported as number and percentage. Because individual-level data required for reliable additional modelling were limited by the small sample size, the analysis was primarily descriptive. Preoperative and one-month aortic diameters were compared using the paired-samples t-test. The distribution of paired differences was assessed visually and by the Shapiro-Wilk test before parametric analysis. Mean changes should be interpreted together with their small absolute magnitude and the known measurement variability of CT. A p value $< .05$ was considered statistically significant. Analyses were performed using SPSS version 16.0 for Windows (SPSS Inc., Chicago, IL, USA).

RESULTS

Twenty-one patients were included, comprising five women and 16 men. Mean age was 58.9 ± 13.7 years. All patients were considered high risk for open surgical repair, with American Society of Anesthesiologists class 3 or 4 status. Baseline demographic and anatomical characteristics are summarised in Table 1.

Twelve patients underwent TEVAR with E-XL reinforcement. Nine of these patients were treated with the E-vita thoracic endograft (Jotec GmbH, Hechingen, Germany), and three were treated with the Ankura device (Lifetech Scientific Corporation, Shenzhen, China). The TEVAR indications were descending thoracic aortic aneurysm ≥ 55 mm in four patients, Stanford type B dissection in five patients, and descending

thoracic aortic aneurysm with Stanford type B dissection in three patients. Mean descending thoracic aortic aneurysm diameter was 58.4 ± 5.1 mm. All 12 patients had proximal aortic neck angulation > 60 degrees, with a mean angle of 75.4 ± 6.6 degrees. Representative preoperative and one-month postoperative imaging of a TEVAR patient with severe proximal neck angulation is shown in Figure 2.

Nine patients underwent EVAR with E-XL reinforcement. Six patients were treated with the E-tegra device (Jotec GmbH, Hechingen, Germany), and three were treated with the Ankura device. The indication in all EVAR patients was abdominal aortic aneurysm ≥ 55 mm. Mean abdominal aortic aneurysm diameter was 61.1 ± 9.5 mm. Five EVAR patients had proximal neck angulation > 60 degrees (mean 71.0 ± 6.5 degrees), two had proximal neck length < 15 mm (mean 1.1 ± 0.4 cm), one had both a short neck and severe angulation, and one had circumferential thrombus > 2 mm in the proximal neck.

Technical success, according to the prespecified definition, was achieved in all patients. No intraoperative or early postoperative cerebrovascular events, cardiovascular events, end-organ ischaemia, type Ia endoleak, proximal graft migration, stent collapse, graft kinking, or limb stenosis occurred. Eight TEVAR patients received a double-flared E-XL stent and four received a single-flared E-XL stent. Six EVAR patients received a double-flared E-XL stent and three received a single-flared E-XL stent. The E-XL configuration and diameter were selected according to the local aortic diameter and landing-zone morphology.

Preoperative imaging of this patient is shown in Figure 3. The intraoperative appearance following TEVAR and adjunctive E-XL stent deployment is shown in Figure 4.

Mild post-implantation syndrome occurred in three patients (14.3%). The one-month all-cause mortality rate was 4.8% ($n = 1$). This patient died from COVID-19, and the death was not considered procedure-related. One patient in the TEVAR group had a distal type Ib endoleak at one month. One patient in the TEVAR group had a distal type Ib endoleak at one month, as demonstrated on contrast-enhanced computed tomography (Figure 5). The endoleak was treated successfully with a TEVAR extension, and subsequent computed tomography showed no residual endoleak and a smaller aneurysm diameter (Figure 6).

No graft migration or endotension was detected at one month. Mean one-month descending thoracic aortic aneurysm diameter was 57.3 ± 4.8 mm in the TEVAR group, compared with 58.4 ± 5.1 mm preoperatively, corresponding to a mean absolute reduction of 1.1 mm ($p = .001$). Mean one-month abdominal aortic aneurysm diameter was 60.5 ± 9.7 mm in the EVAR group, compared with 61.1 ± 9.5 mm preoperatively, corresponding to a mean absolute reduction of 0.6 mm ($p = .009$). Although statistically significant, these small changes may fall within CT measurement variability and should not be interpreted as evidence of clinically meaningful remodelling at one month. Procedural and one-month outcomes are summarised in Table 2 and Table 3.

Table 1. Baseline demographic and anatomical characteristics

Variable	Value
Age (years), mean $\pm$ SD	58.9 ± 13.7
Female/male, n	5/16
Symptomatic, n (%)	12 (57.1)
ASA class 3/4, n (%)	10/11 (47.6/52.4)
TEVAR: DAA, n (%)	4 (33.3)
TEVAR: Dissection, n (%)	5 (41.7)
TEVAR: DAA + dissection, n (%)	3 (25.0)
EVAR: AAA, n (%)	9 (100)
DAA diameter (mm), mean $\pm$ SD	58.4 ± 5.1
AAA diameter (mm), mean $\pm$ SD	61.1 ± 9.5
Proximal neck angulation > 60 degrees, n (%)	17 (81.0)
Proximal neck length < 15 mm, n (%)	2 (9.5)
Circumferential thrombus/calcification, n (%)	1 (4.8)
More than one hostile-neck feature, n (%)	1 (4.8)

Abbreviations: AAA, abdominal aortic aneurysm; ASA, American Society of Anesthesiologists; DAA, descending aortic aneurysm; EVAR, endovascular aneurysm repair; SD, standard deviation; TEVAR, thoracic endovascular aortic repair.

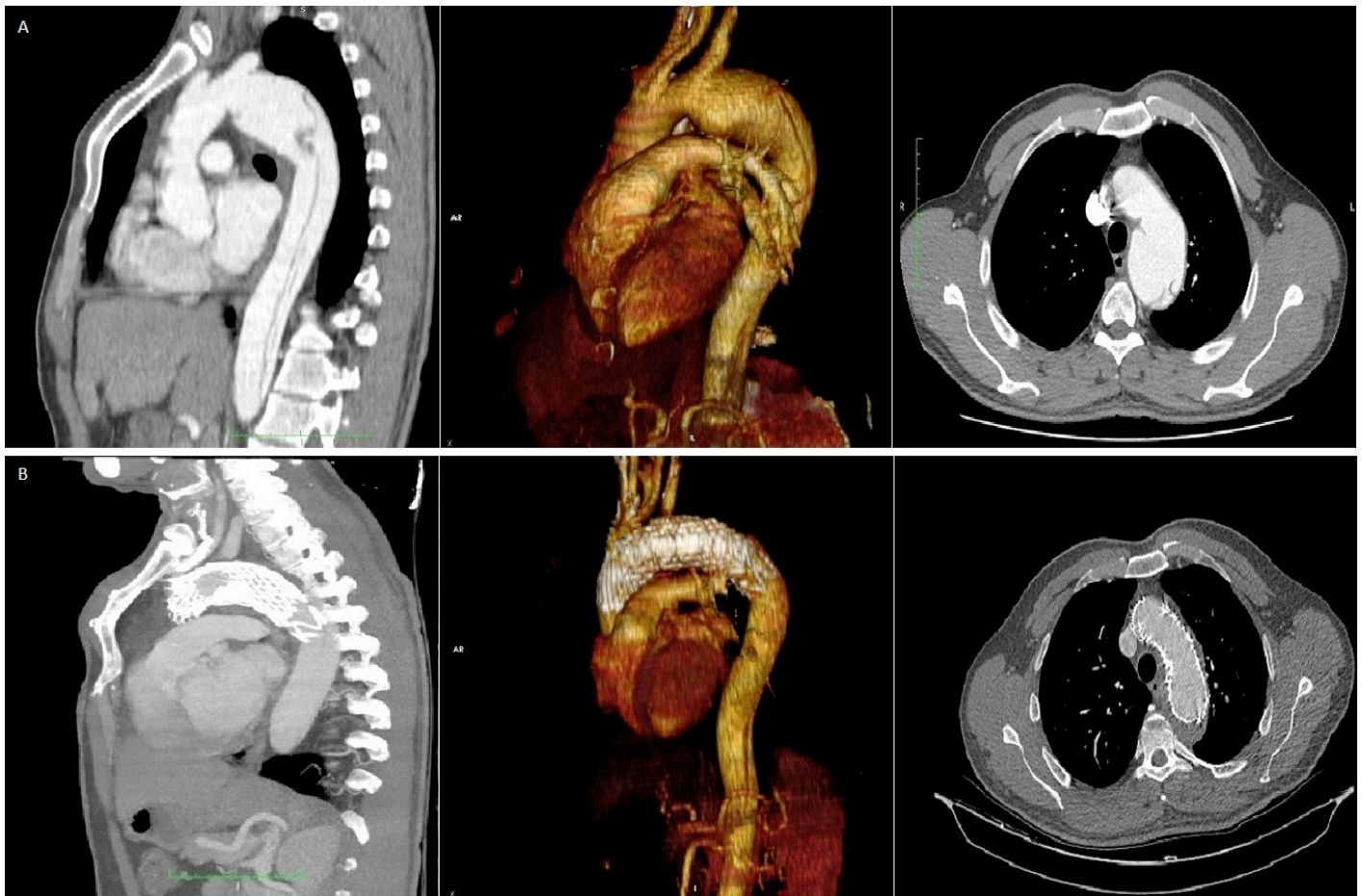


Figure 2. Patient with descending thoracic aortic aneurysm, acute Stanford type B dissection, and proximal aortic neck angulation of 75 degrees. (A) Pre-operative computed tomography image. (B) One-month computed tomography after treatment with TEVAR and adjunctive E-XL stent reinforcement.

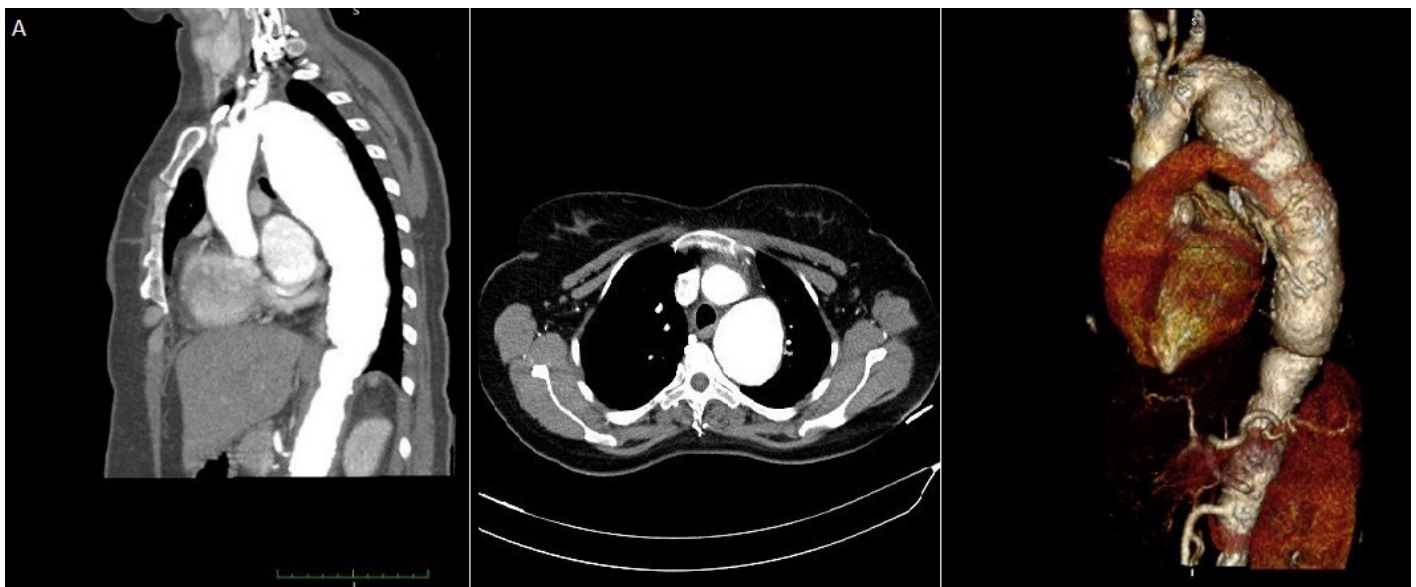


Figure 3. Preoperative computed tomography angiography of a patient undergoing thoracic endovascular aortic repair, showing the descending thoracic aortic pathology and proximal landing-zone anatomy. Multiplanar and three-dimensional reconstructed images are shown.

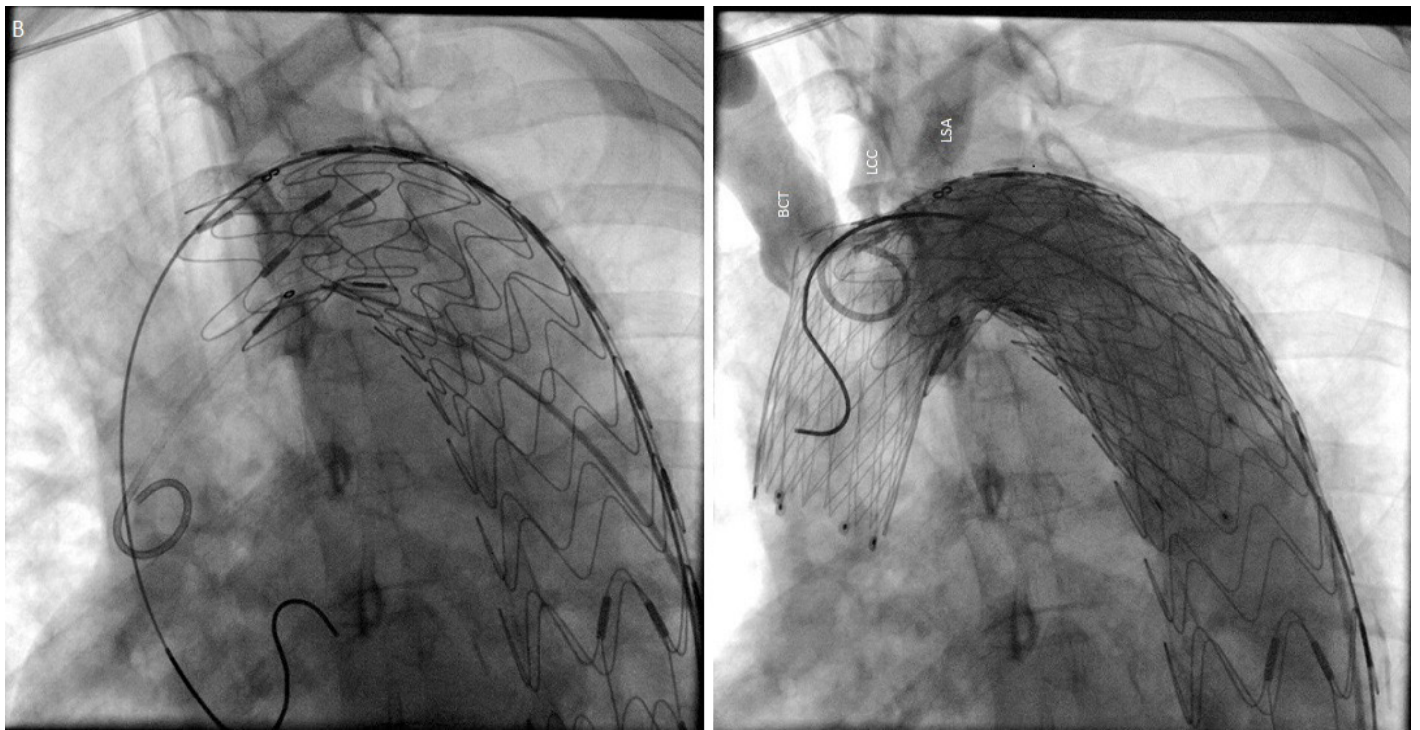


Figure 4. Intraoperative angiographic images following thoracic endovascular aortic repair with adjunctive E-XL stent reinforcement, demonstrating the proximal endograft–stent configuration and preservation of the supra-aortic branch vessels.

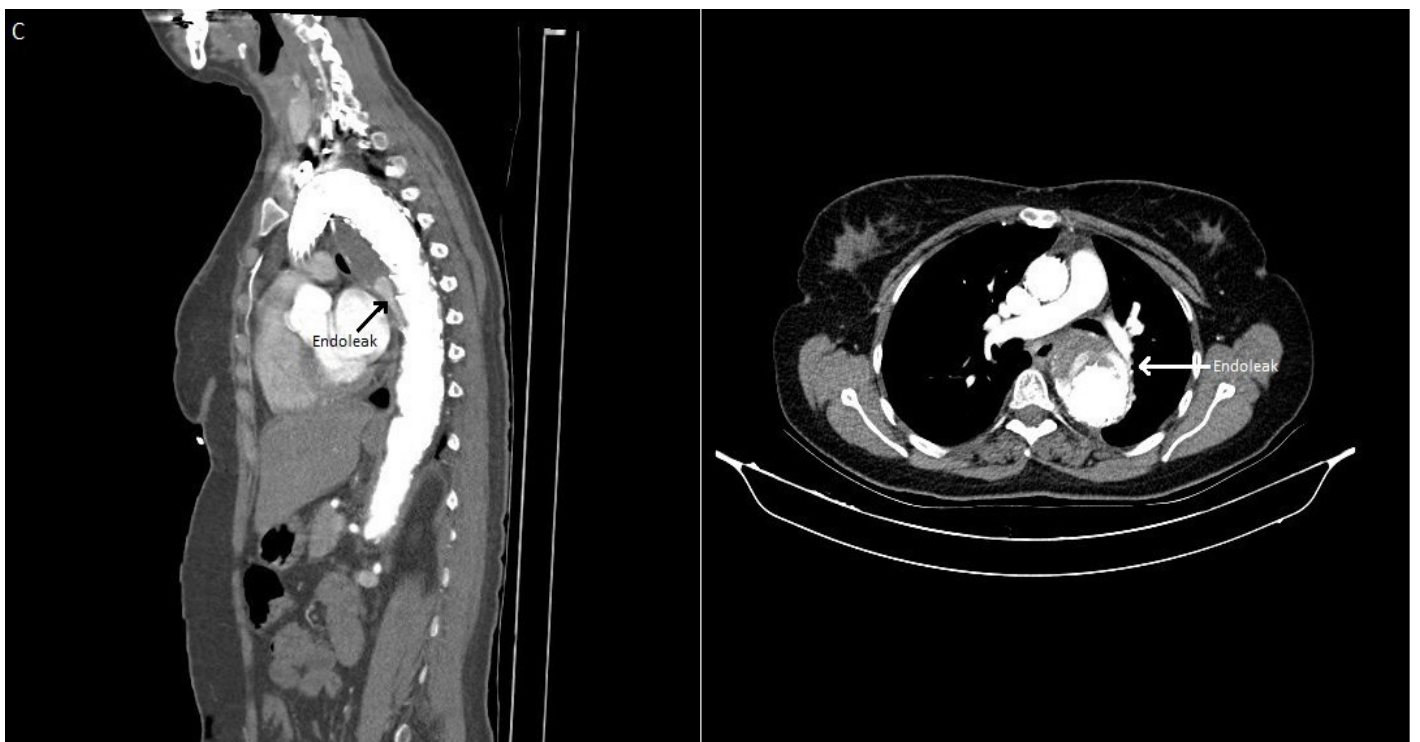


Figure 5. Contrast-enhanced computed tomography demonstrating a distal type Ib endoleak after thoracic endovascular aortic repair. The endoleak is indicated by arrows on sagittal and axial images.

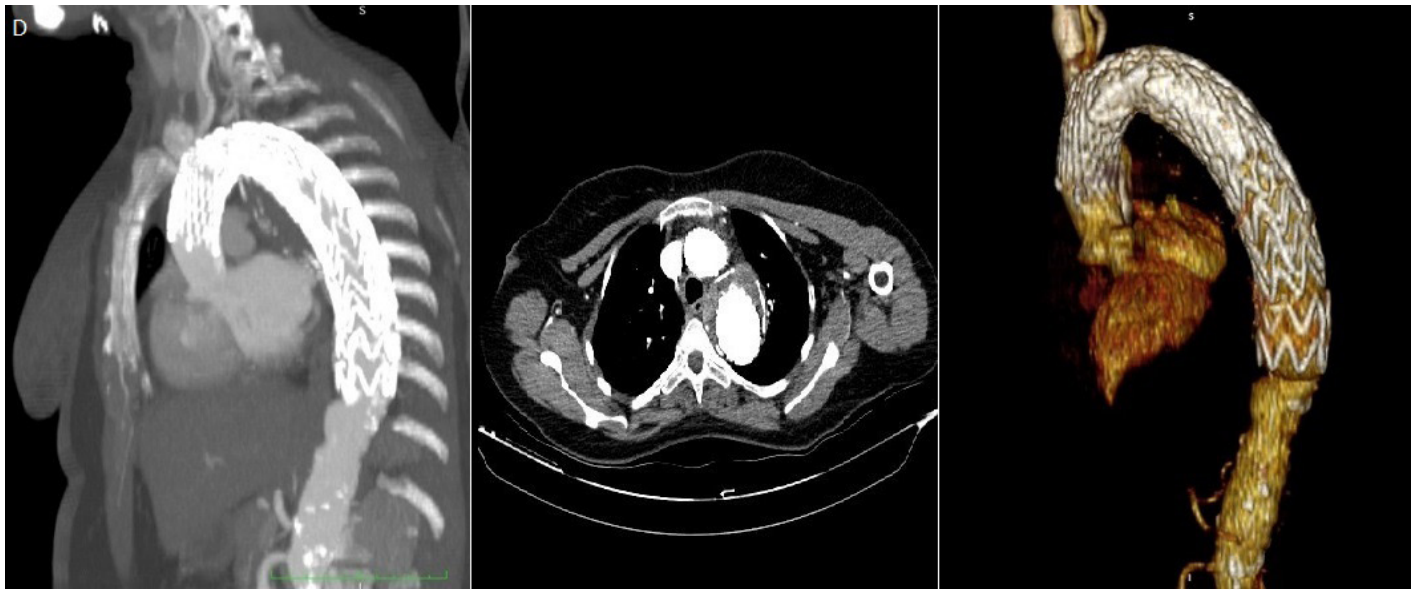


Figure 6. Follow-up computed tomography after endovascular extension for the distal type Ib endoleak, demonstrating exclusion of the endoleak and satisfactory endograft position. Three-dimensional reconstruction demonstrates the final thoracic endograft configuration.

Table 2. Operative and postoperative characteristics

Variable	Value
TEVAR/EVAR, n (%)	12/9 (57.1/42.9)
Single/double-flared E-XL, n (%)	7/14 (33.3/66.7)
Operative morbidity, n (%)	0 (0.0)
Operative mortality, n (%)	0 (0.0)
Operative graft migration, n (%)	0 (0.0)
Operative type Ia endoleak, n (%)	0 (0.0)
Postoperative morbidity, n (%)	3 (14.3)
All-cause mortality, n (%)	1 (4.8)
Procedure-related mortality, n (%)	0 (0.0)
Graft migration, n (%)	0 (0.0)
Type Ia endoleak, n (%)	0 (0.0)
Secondary TEVAR/EVAR intervention, n (%)	1 (4.8)
Clinical follow-up (months), mean $\pm$ SD	12.2 $\pm$ 8.5
Protocol-based CT follow-up	1 month

Abbreviations: EVAR, endovascular aneurysm repair; SD, standard deviation; TEVAR, thoracic endovascular aortic repair.

Table 3. Changes in maximal aortic diameter between preoperative and one-month CT

Measurement	Preoperative	One month	p value
DAA diameter (mm), mean $\pm$ SD	58.4 $\pm$ 5.1	57.3 $\pm$ 4.8	.001
AAA diameter (mm), mean $\pm$ SD	61.1 $\pm$ 9.5	60.5 $\pm$ 9.7	.009

Abbreviations: AAA, abdominal aortic aneurysm; DAA, descending aortic aneurysm; SD, standard deviation.

DISCUSSION

This early experience suggests that adjunctive E-XL stent reinforcement during standard EVAR or TEVAR is technically feasible in selected patients with hostile proximal neck anatomy. In this small cohort, all procedures were completed successfully, and no type Ia endoleak or proximal graft migration was observed at one month. A single distal type Ib endoleak occurred after TEVAR and was corrected with endograft extension. These findings demonstrate successful use of the device in this cohort but do not establish an incremental benefit over standard EVAR or TEVAR because no control group was available.

Hostile neck anatomy remains one of the most important anatomical limitations of standard endovascular aortic repair. Severe angulation, short neck length, and circumferential thrombus or calcification may reduce endograft apposition and proximal fixation, increasing the likelihood of migration and proximal endoleak [6-10]. Open repair remains an established option for anatomically unsuitable cases, but many patients with aortic disease are elderly or have significant comorbidities and may be at high risk for open surgery [14-16].

Several strategies have been developed for endovascular treatment in hostile neck anatomy, including fenestrated or branched endografts, chimney grafts, endografts designed for angulated necks, repositionable devices, polymer-based sealing systems, and EndoAnchors or endostaples [18-20,23-29]. These methods expand endovascular treatment options but differ in availability, planning requirements, anatomical suitability, cost, and technical complexity [30]. Fenestrated and chimney techniques may provide solutions when branch-vessel preservation is required, whereas EndoAnchors and balloon-expandable stents provide alternative methods of proximal fixation. The potential advantage of the E-XL approach is that it uses an off-the-shelf uncovered self-expanding stent after standard endograft deployment and may be technically straightforward in selected anatomies [21,22]. However, these advantages remain theoretical in the absence of direct comparative data, and the technique should not be considered generally superior to established alternatives [31].

The rationale for this method is based on the E-XL stent design. The closed cells at the ends may provide additional fixation, while the open cells in the mid portion may allow conformability in angulated anatomy. Its high radial force may support apposition between the endograft and the aortic wall. These properties may have contributed to the absence of proximal type Ia endoleak and migration in the present cohort, although causality cannot be inferred and the sample size and follow-up duration are insufficient to establish durability.

The technique has important procedural considerations. The standard endograft must remain stable in a hostile proximal neck for a short interval until the E-XL stent is deployed. This interval may be especially risky in patients with very short necks. In the present series, systolic blood pressure was reduced to 70 - 90 mmHg during deployment, and the adjunctive E-XL stent was placed promptly after endograft release. Careful device sizing and selection of single- or double-flared configuration were also considered essential.

This study has several limitations. It was retrospective, single-centre, and included only 21 patients. The TEVAR and EVAR cohorts represented different disease entities and biomechanical environments; therefore, their outcomes were described separately whenever possible, but the small subgroup sizes prevented meaningful comparative analysis. There was no control group of patients treated with standard EVAR or TEVAR alone, and selection bias is likely. Protocol-based radiological follow-up was limited to one month despite a longer mean clinical follow-up, so late migration, type Ia endoleak, sac enlargement, device fatigue, and re-intervention cannot be assessed. The small absolute changes in aneurysm diameter may be within CT measurement variability [32]. This limitation is clinically important because failed endovascular repair may occasionally require complex late surgical conversion [33]. The sample size also precluded reliable multivariable analysis and informative Kaplan-Meier estimates. Finally, the technique should not be interpreted as a substitute for established complex endovascular or open surgical options when anatomy is unsuitable for standard repair.

Further prospective studies with larger cohorts, longer imaging follow-up, and comparison with other hostile neck strategies are required to define which patients may benefit from adjunctive E-XL reinforcement and to determine whether the early technical findings are durable.

CONCLUSION

Adjunctive E-XL stent reinforcement with standard EVAR or TEVAR was technically feasible in this early single-centre experience and was not associated with proximal type Ia endoleak or graft migration at one month. The technique may provide additional proximal fixation support in carefully selected high-risk patients with hostile proximal neck anatomy, particularly when standard endograft fixation is considered potentially insufficient and alternative open or complex endovascular strategies are less suitable. However, the small sample size, absence of a control group, heterogeneous TEVAR and EVAR populations, and short imaging follow-up preclude conclusions regarding comparative efficacy, long-term safety, or durability. Larger prospective comparative studies with extended radiological follow-up are required before routine use can be recommended.

Ethics Committee Approval: The study was approved by the institutional ethics committee of University of Health Sciences İzmir Tepecik Training and Research Hospital (approval number 2020/14-65, date 23.12.2020).

Patient Consent for Publication: Written informed consent was obtained from all participants.

Data Sharing Statement: The data that support the findings of this study are available from the corresponding author upon reasonable request.

Author Contributions: All authors contributed equally to the article.

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