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In situ needle fenestration for aortic arch conditions during thoracic endovascular aortic repair

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Abstract

Background To evaluate the clinical outcomes and the validity of the in situ needle fenestration (ISNF) technique during thoracic endovascular aortic repair (TEVAR) for patients with aortic arch conditions.

Methods A total of 115 patients with aortic arch conditions treated with ISNF during TEVAR between January 2018 and December 2021 were incorporated.

Results The median age of the patients was 62.0 years, and 10.4% (12/115) were female. The median follow-up time was 31.0 months. A total of 175 supra-arch branches were reconstructed. A single branch was fenestrated in 80 patients, while the left subclavian artery (LSA) and left common carotid artery (LCCA) were fenestrated simultaneously in 11 patients, and all supra-arch branches were fenestrated in 24 patients. The rate of technical success was 100%, 30-day mortality was 3.5% (4/115), overall mortality was 8.7% (10/115), and aortic-related mortality was 2.6% (3/115). Aortic-related reintervention was required in 7.8% (9/115) of patients. Among the major postoperative complications, four patients developed retrograde type A dissection requiring emergent open surgery, three patients had cerebrovascular accidents, and one patient had an endoleak. No occlusions or stenoses of the main or branch aortic stents were observed.

Conclusions The mid-term results of the ISNF technique during TEVAR for aortic arch conditions were within the acceptable range; however, further follow-up results are needed and long-term stability and durability needs to be assessed. Related fenestration devices also require further development.

Keywords Aortic dissection, Thoracic endovascular aortic repair, Aortic arch, In situ fenestration, Endovascular grafts

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Introduction

As a technical means of treating aortic diseases, thoracic endovascular aortic repair (TEVAR) is increasingly preferred by surgeons and patients in clinical practice because of its advantages such as less trauma, faster recovery, and better repair outcomes compared to open surgery, especially for type B aortic dissection [1]. In recent years, new endovascular devices and techniques, including fenestrations, branched devices, and parallel stents, have achieved great progress to address complicated arch conditions, and ensure the length of the proximal landing zone (PLZ) and the patency of the branch blood flow over the arch [2].

The in situ fenestration (ISF) technique involves releasing the main body of the stent graft and puncturing the membrane retrogradely with a needle, laser, or radiofrequency device to reconstruct the supra-arch branch vessels. McWilliams et al. first reported the successful reconstruction of the left subclavian artery (LSA) using ISF [3]. Many subsequent studies have reported their centers' experiences using the ISF technique during TEVAR [4], focusing particularly on laser and radiofrequency modalities [5]. However, ISF using a needle (ISNF) is reported less frequently in the literature and there is no consensus on the most effective method for performing fenestration. The advantage of the laser fenestration methods is that it is rapid and both laser and radiofrequency fenestration can burn a perfect circle on the endograft material. In most reports about patients treated with the in situ aortic arch stent graft fenestration technique, needle punctures were performed for fenestration of the brachiocephalic trunk (BCT) and the left common carotid artery (LCCA), laser or radiofrequency catheters were more frequently used in patients with intended fenestrations for the LSA. There were more cases of fenestrations for the LSA.

Therefore, this study presents our center's clinical practice with the ISNF for the treatment of aortic arch conditions by retrospectively analyzing the perioperative and mid-term follow-up results of patients treated by the technique.

Materials and methods

Study design

All patients underwent a preoperative examination to fully assess their condition and determine the most appropriate surgical modality. The inclusion criteria were as follows: (1) lesions that did not involve the ascending aorta, (2) presence of a suitable vascular approach of the appropriate diameter that can accommodate the stent delivery sheath system, (3) absence of severe lesions in multiple supra-aortic branches, and (4) complete postoperative follow-up data. There were a total of 872 patients with aortic arch conditions, and 398 patients with ascending aorta involvement who underwent open surgery were excluded, the remaining 474 patients underwent endovascular repair treatment. Among these patients, 340 patients who underwent TEVAR combined with chimney stents, in vitro fenestration, and hybrid technique were excluded, as well as 15 patients treated with ISNF were lost follow-up and 4 patients refused follow-up. Finally, a total of 115 patients treated with ISNF during TEVAR for aortic arch and branch reconstruction between January 2018 and December 2021 were selected. The demographics, imaging features, comorbidities, outcomes, and follow-up data were retrospectively reviewed.

The medical ethics committee of the First Affiliated Hospital of Nanjing Medical University approved this study (Number: 2021-SR-381). Due to the retrospective nature of this study, the medical ethics committee of the First Affiliated Hospital of Nanjing Medical University waived the need of patient informed consent. The study was conducted according to the Declaration of Helsinki and institutional guidelines.

Technical aspects

The location and patency of the branches and the number of vessels to be reconstructed were determined preoperatively using computed tomographic angiography and confirmed by intraoperative angiography. A soft guidewire was introduced into the short sheath of the common femoral artery (CFA) with a 5 F pigtail catheter to the root of the aorta, contrasted, measured, positioned, and then exchanged for a Lunderquist guidewire (Cook Medical, Bloomington, IN, USA). The main stent-graft was placed along the guidewire and deployed according to a suitable PLZ.

Fenestrations of the single branch: In general, the single branch referred to the LSA, and the PLZ was the distal end of the opening of the LCCA. To reduce the area of trauma, we chose the micro-puncture approach of the left brachial artery, a balloon-needle (Lifetech, China) was placed through the sheath and adjusted to align the puncture point on the surface of the main stent as vertically as possible. After rupture of the membrane, a guidewire was placed into the ascending aorta through the puncture point, which was dilated by a balloon, a covered stent was inserted as a bridging stent, and balloon dilation was performed again. An adjustable puncture system containing a Fustar Steerable sheath (Lifetech, Shenzhen, China) and a compliant balloon were also used as puncture devices [6].

Fenestrations of multiple branches: Multiple branches included fenestrations of the LSA and LCCA, and fenestrations of all super-aortic branches. The PLZ of the LCCA and BCT fenestrations were at the distal end of the opening of the BCT and ascending aorta, respectively. When performing the fenestration of several branches, from the neck incision, we dissected and freed the target branched arteries of sufficient length, then punctured and inserted the sheath. A home-made pre-prepared needle was placed through the short sheath. It reached and punctured the membrane in a vertical position, the soft guidewire was fed through, and the position was confirmed using multiple-angle angiography. The balloon was dilated, the branch Fluency covered stent was fed through, and the balloon was dilated again after releasing the branch stent. The remaining arterial branches were treated similarly.

To minimize the negative impact on cerebral blood supply, we prepared the left CFA for bilateral common carotid artery bypass before the main stent-graft was deployed and performed fenestrations in the sequence of LCCA, BCT, and LSA. First, the unilateral CFA is punctured with two short sheaths; then, two sheaths are punctured into the proximal and distal ends of the right common carotid artery (RCCA) and LCCA. An infusion tube is cut, and the CFA is connected to the short sheath of the distal end of the RCCA and LCCA to establish a bypass. Blood pressure is raised appropriately and a cerebral oxygen meter is connected beforehand to monitor cerebral oxygen at all times. Normally when we release the stent, we stabilize blood pressure at 90 mmHg to prevent the stent from shifting. However, during ISNF, we will raise blood pressure appropriately around 100–110 mmHg to ensure the brain perfusion pressure through the bypass. Therefore, we were able to maintain the bilateral cerebral blood supply as far as possible. The preoperative and intraoperative conditions are shown in Fig. 1.

Follow-up

Postoperative follow-up was mainly conducted via telephone and outpatient visits. Prior to discharge, patients were informed that they would have an outpatient review at 1 month, 3 months, 6 months, 1 year after surgery, and then annually with a couple of reviews including computed tomographic angiography, medication adjustment and other aspects.

Statistical analysis

Data were analyzed using SPSS software (version 26.0; IBM Corp., Armonk, NY, USA). Categorical variables were presented as frequencies and percentages (%). Continuous variable data were presented as the mean ± standard deviation or median (interquartile range [IQR]; Q25, Q75). The difference of frequency between two or

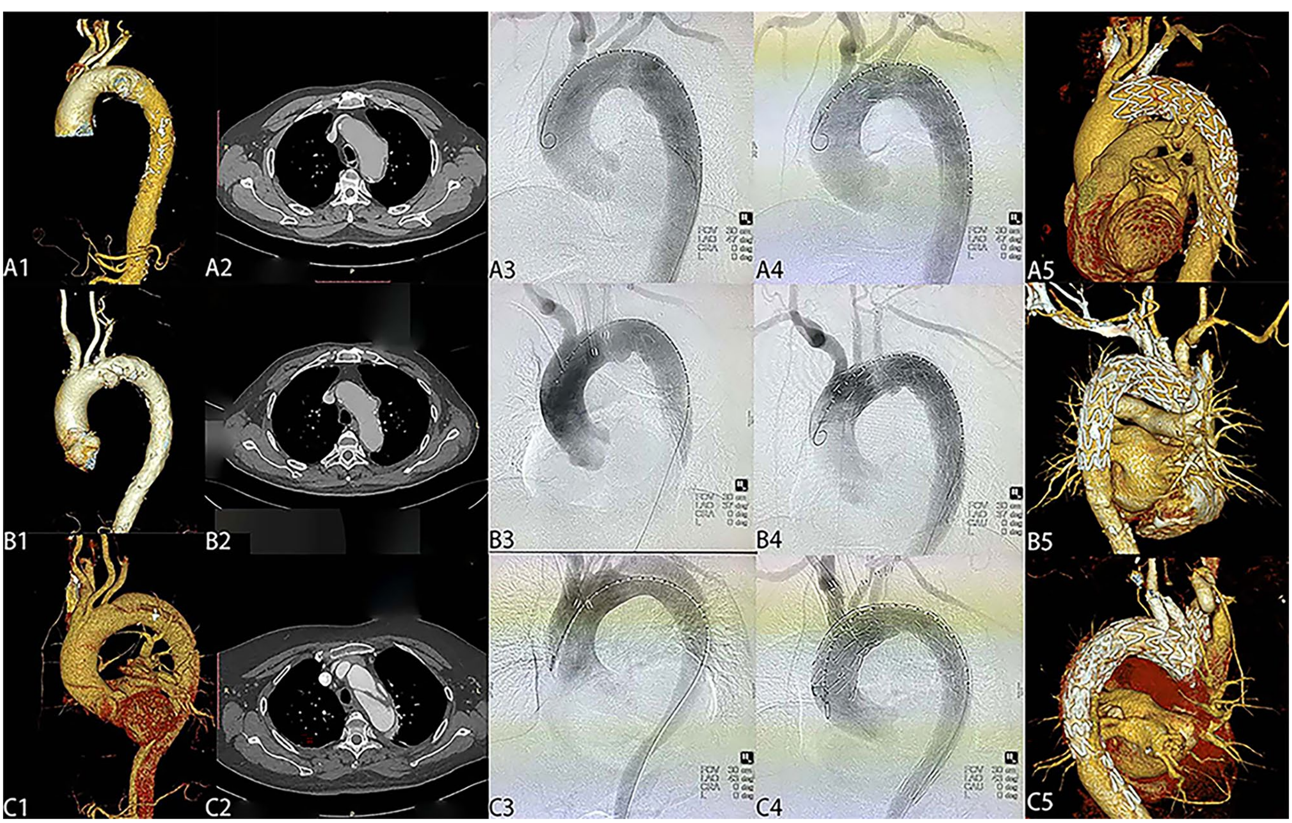

Fig. 1 Picture **A**1-5 shows a patient with fenestration of the LSA, picture **B**1-5 is a patient with fenestrations of the LSA and LCCA, picture **C**1-5 represents a patient who performs fenestrations of all supra-arch branches. 3D vascular modeling and preoperative computed tomographic angiography indicate the lesions of the aortic arch, intraoperative radiograph reveals the situation before and after implanting the stent-grafts. The pictures of vascular reconstruction during postoperative follow-up are shown

more groups was analyzed by x^2 test or Fisher test. Two-way table x^2 test was used for the association between the number of vessel fenestrations and the aortic arch conditions. Linear-by-linear association test was used to explore the relation between the complications and the number of vessel fenestrations. Survival during follow-up was expressed as a Kaplan–Meier survival estimator, which was presented using GraphPad Prism (version 8; GraphPad Software, San Diego, CA, USA).

Results

There were a total of 115 patients who were treated with ISNF during TEVAR for aortic arch and branch reconstruction between January 2018 and December 2021. The median age of the patients was 62.0 (49.0, 72.0) years and 10.4% (12/115) were female. The cohorts of patients were divided into three groups based on the number of fenestrations (Table 1). Among these patients, two patients had preoperative aortic dissection/aneurysm rupture or signs of impending rupture, three showed insufficient blood supply to the lower limbs, and two had vascular ischemia in the visceral area. These patients received emergent TEVAR in the acute phase. The remaining patients received strict blood pressure and heart rate control before surgery, and underwent endovascular treatment after passing the acute phase. After admission, computed tomographic angiography revealed arch conditions, including aortic dissection (n=66), aortic intramural hematoma (n=15), penetrating aortic ulcers (n=9), and thoracic aortic aneurysms (n=25).

Of the 115 patients treated with ISNF, a total of 175 supra-arch branch vessels were reconstructed, with a technical success rate of 100%. Of these, fenestration of a single-branched artery was performed in 80 patients, fenestration of two vessels was performed in 11 patients, and 24 had fenestration of all supra-arch branches. Of the 80 patients with a single-branched artery, LSA fenestration was performed in 78 patients, LCCA fenestration was performed in one patient, and the patient also underwent an LCCA-LSA bypass, BCT fenestration was performed in the other patient who had undergone TEVAR combined with a prior hybrid technique.

Cerebral vascular accidents occurred in three patients (2.6%). The first patient who received LSA-fenestration occurred slight cerebral infarction after surgery, the patient recovered at one week and was asymptomatic during follow-up periods. The second was also a LSA-fenestration patient who had a history of cerebral infarction, the patient occurred cerebral hemorrhage 1 day after surgery, we adjusted the use of anticoagulant drugs during the hospitalization. The patient recovered in the surgical intensive care unit and was discharged 2 weeks later with some deficits. Follow-up CT examination showed the progressive absorption of hematoma. The last patient who received triple aortic arch ISNF occurred major stroke, resulting in the left lower limb paraplegia and continuous rehabilitation treatment after discharge. the Postoperative endoleak we observed was the patient receiving LCCA chimney stent implantation while undergoing LSA-ISNF, with a slight endoleak at the proximal end of the chimney stent.

Table 1 Patients characteristics and complications

	One vessel	Two vessels	Three vessels	Total	P value
Characteristics					
Number	80	11	24	115	
Age, years	63.0(50.3,72.8)	55.0(44.0,72.0)	62.0(50.0,72.8)	62.0(49.0,72.0)	0.936
Male sex	73 (91.3)	9 (81.8)	21 (87.5)	103	0.589
Hypertension	69 (86.3)	8 (72.7)	16 (66.7)	93	0.078
Coronary artery disease	16 (20.0)	2 (18.2)	4 (16.7)	22	0.933
Diabetes mellitus	10 (12.5)	3 (27.3)	3 (12.5)	16	0.404
Aortic arch conditions					0.072
AD	48 (60.0)	5 (45.5)	13 (54.2)	66	
PAU	7 (8.8)	0 (0)	2 (8.3)	9	
IMH	13 (16.3)	0 (0)	2 (8.3)	15	
TAA	12 (15.0)	6 (54.5)	7 (29.2)	25	
Complications					
RTAD	2	1	1	4	
dSINE	4	0	0	4	
Endoleak	1	0	0	1	
Cerebrovascular accident	2	0	1	3	
Aorta related mortality	3	0	0	3	
Total	12 (15.0)	1 (9.1)	2 (8.3)		0.643

AD, Aortic dissection; PAU, Penetrating aortic ulcer ; IMH, Aortic intramural hematoma; TAA, Thoracic aortic aneurysm; RTAD, Retrograde type A dissection; dSINE, distal stent-induced new entry

Retrograde type A dissections after implantation occurred in four patients (3.5%). One at 2 months in LSA-fenestration underwent emergent open surgery; one at 1 month in a three-vessel fenestration underwent Bentall surgery treatment; one at 2 days in a two-vessel fenestration received half aortic arch artificial vascular replacement and the last one at 12 days in LSA-fenestration. Except for the last patient, the other three patients all achieved good recovery. Furthermore, four patients (3.5%) had distal stent-induced new entry (dSINE). These patients underwent the second TEVAR to eliminate the distal tear entry.

The median follow-up time was 31.0 (23.0, 40.0) months, with an overall mortality rate of 8.7% (10/115) and an aortic-related mortality rate of 2.6% (3/115). The 30-day mortality rate was 3.5% (4/115), one from postoperative acute renal failure after TEVAR with LSA-fenestration, the patient underwent intermittent hemodialysis in the hospital and did not continue after discharge, died later due to malignant arrhythmia and severe infection. The second underwent retrograde type A dissections 12 days after TEVAR with LSA-fenestration, the patient experienced sudden chest pain and computed tomographic angiography revealed a tear at the proximal end of the stent. Later, emergency open surgery was performed, but circulatory system collapsed in the ICU 1 day after the open surgery, and died despite emergency rescue efforts. The third was also a LSA-fenestration patient who occurred proximal aortic rupture 2 days after the surgery and the last one suffered from sudden abdominal pain and hypotension probably due to distal aortic rupture 5 days after TEVAR with LSA fenestration. Of the remaining six patients who died, one from renal failure 6 months after TEVAR with two-vessel fenestration; one from acute myocardial infarction 1 year after TEVAR with three-vessel fenestration; one from unknown respiratory and cardiac arrest 2 years after TEVAR with LSA-fenestration, and three from other non-cardiovascular diseases. Survival estimates are shown in Fig. 2. In the Table 1, the total number of complications and aortic arch conditions have no significant statistical difference with the number of vessel fenestrations.

Comment

Complications of aortic arch conditions cannot be resolved using TEVAR alone because of the complex and variable vascular anatomy of the aortic arch, therefore, a combination of techniques such as parallel stents, fenestrations, and branched devices are necessary to address complicated arch conditions [7]. Parallel stents are typically susceptible to endoleaks because of the gutters between the main stent, aortic wall, and chimney stent [8]. Branched stent-grafts require advanced customization and do not meet the needs of the emergency and general public; stroke and thromboembolic accidents remain major problems associated with branched endografts [9]. This makes the ISF a relatively popular choice. In the present study, we found that the mid-term outcomes of ISNF for the treatment of aortic arch conditions during TEVAR were within an acceptable range. Aorta-related mortality and the rate of postoperative major complications were comparatively low. To date, there is no consensus on the best method to perform fenestration. In addition, the fenestration devices must be further developed and improved.

By contrast, in vitro fenestration does not block the blood flow of aortic arch branched vessels and not need brain protective measures, but it is difficult to aim the fenestration at the target branch vessels especially when performing fenestration of all supra-arch branches and prolonged operation of aortic arch leads to additional cerebrovascular accidents. ISF temporarily

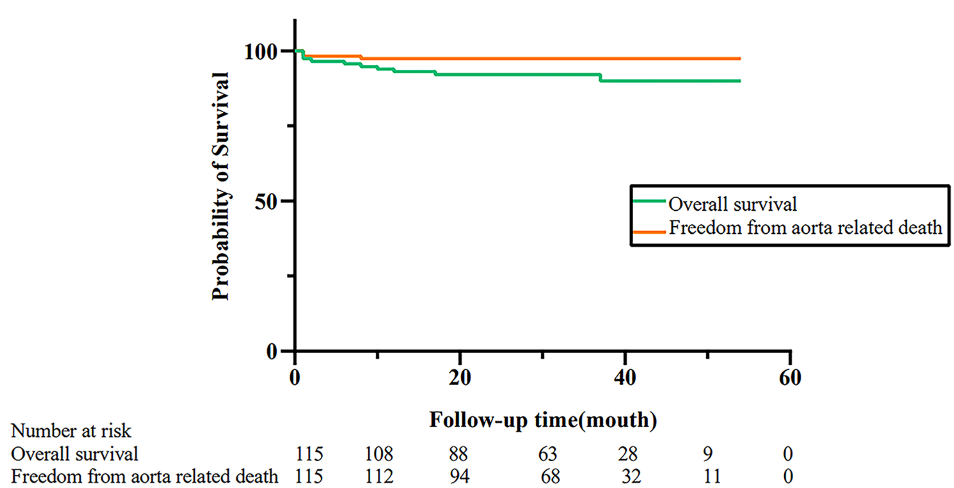

Fig. 2 Kaplan-Meier survival curve for overall survival (solid green line) and freedom from aorta related death (solid orange line)

blocks blood flow to the target branch vessels, particularly when reconstruction of all branches of the superior arch is required and the entire blood supply to the brain is blocked, additional adjunctive cerebral protection techniques are required. Our center uses a simple but effective method for maintaining cerebral perfusion. Follow-up results proved the effectiveness of this method, with a 2.6% (3/115) incidence of postoperative cerebral accidents. In comparison, one study reported a 4.5% incidence of stroke after TEVAR [10]. In addition, there are other ways to protect the brain [11]. Ryuta Seguchi et al. described a new method of cerebral protection using selective cerebral perfusion supported by extracorporeal membrane oxygenation technology [12]. To restore the cerebral blood supply as soon as possible, we fenestrated the LCCA and BCT first and the LSA was fenestrated last [13]. Our approach is relatively simple, does not require the use of extracorporeal circulation machines, and achieves excellent results.

In this study, we chose a needle to perform fenestration. ISNF has been reported less frequently in the literature, and recent studies have focused on the use of thermal methods such as laser [14] or radiofrequency [15] for fenestration. When performing LSA fenestration, we use an angle-adjustable sheath with a flexible needle or an adjustable puncture system [16]. When performing fenestration of several supra-arch branches, we use a homemade fenestration device consisting of a tracheal biopsy needle (Olympus, Tokyo, Japan) and a cerebral surgical metallic suction device. We place the needle into the suction which provides support and guidance. We chose expanded polytetrafluoroethylene membrane stent-grafts because experiments have shown that the expanded polytetrafluoroethylene membrane is easier to puncture, and the fabric is not easy to tear after balloon dilation, thereby forming a relatively higher quality fenestration [17]. When the target vessel is excessively tortuous, twisted, or angulated, it is much more difficult to perform fenestrations. The application of the “squid catch” technique [18] ensures vertical contact between the puncture sheath and the stent graft, broadening the range of application of the ISNF technique.

During the operation, we found that fenestration of the LSA, which is usually much more tortuous, twisted, or angulated, was more difficult than that of the BCT and LCCA. When the LSA had a severe lesion or was extremely difficult to fenestrate, arterial bypass or transposition was performed. After fenestration, an appropriate balloon size was selected according to the diameter of the branch artery. When dilating the puncture site, we used gradual balloon dilation followed by balloon-guided insertion of a branch stent, released the stent slowly, and re-dilation with a balloon to avoid collapse and occlusion of the stent and ensure blood patency of the branch artery. The proximal end of the branch stent extended 1 cm inside the aorta, and the distal end avoided blocking other branched arteries [19]. To prevent endoleaks, fluency-covered stents are usually used; however, some studies have shown that the utilization of a balloon-expanded bare stent is also safe and effective if there is a sufficiently healthy PLZ [20].

To determine the best puncture methods, many studies and experiments have compared different brands of grafts and puncture methods. As for which method results in better fenestration quality, different stent grafts tolerate mechanical and thermal energy differently, and can influence the final fenestration quality. An in vitro study [21] used five commercially-available stent grafts to perform fenestrations using a needle and laser, followed by gradual balloon dilation, to assess the fenestration quality using various quantitative indicators. We can conclude that there is no absolute best way to perform fenestration, and we should choose the appropriate method according to the different stent grafts available and existing technical conditions.

The incidence of cerebrovascular accidents was relatively low at 2.6%, demonstrating the benefits of our method of cerebral protection and simple arch operation without extra procedure; therefore, a good learning curve is also key to the outcomes of ISNF. Firstly, grasping the anatomy of the superior arch branch vessels, the main reason for technical failure of fenestration was tortuosity of the vessel or angulation between the target artery and aortic arch. Secondly, the selection of fenestration tools, some patients are suitable for fenestration using balloon puncture needles, some patients are suitable for tracheal biopsy needles, and even some patients are suitable for fenestration through neck incisions. Thirdly, the selection of the stent-graft fabric, the textile material and the configuration of the metallic struts of the stent-graft may potentially affect the performance of the stent-graft following fenestration, so it is important to select the suitable stent-grafts. Afterwards, the location of the fenestration on stent-graft. If the fenestration was close to the metallic struts of the stent-graft, the bridging stent could not be fully opened due to partially obstruction by stent strut, which may lead to endoleak. The implantation of branch stents is not always smooth, and during the implantation process, various reasons often prevent the branch stents from entering the large stent cavity. Finally, choosing the appropriate size of the branch stents is very important. It was reported that good apposition of the side branch stent to the main stent-graft could decrease the risk of endoleak.

In this study, there was only one case of endoleak. The patient underwent LCCA chimney and LSA fenestration simultaneously, a small amount of endoleak was observed at the proximal end of the stent during postoperative follow-up and was reviewed regularly without intervention. Research shows that chimneys are more prone to Type I endoleaks [22]. New stent-induced entry is a major complication of this procedure. Entry tear can occur at both the proximal and distal ends of the stent. However, proximal entry is problematic and carries the potential danger of retrograde type A dissection. Our follow-up results showed that four patients had dSINE and four patients had retrograde type A dissection. Most studies have shown that the mismatch between stent size and aortic lumen diameter and the fragility of the vascular wall are the main causes of endoleak [23]. Proximal stent sizes larger than the lumen diameter are chosen to prevent type I endoleaks. However, this also increases the risk of rupture, leading to retrograde type A dissection [24]. Furthermore, the distal true cavity is usually smaller and is subjected to excessive radial forces from the stent, making it more prone to entry [25]. Therefore, stents with low radial forces, high compliance, and good fit should be developed [26].

Limitations

First, the study was retrospective with a small sample size and lack of subgroups from a single center, so the results may be limited in terms of generalization to other populations. Second, the follow-up period was short and solid long-term clinical outcomes could not be determined. Third, the thoracic stent graft selection was relatively limited, and there was no comparison with other brands of stents. Finally, we used needles for all fenestrations and there was no comparison with other fenestration methods.

Conclusions

In the mid-term, results of the ISNF technique during TEVAR for aortic arch conditions are within the acceptable range; however, longer follow-up results are still needed to assess long-term stability and durability. Related fenestration devices also require further development. Future studies should compare outcomes of ISNF with other methods of fenestration over longer follow-up periods.

Abbreviations

TEVAR	thoracic endovascular aortic repair
LSA	left subclavian artery
ISNF	in situ needle fenestration
CFA	common femoral artery
LCCA	left common carotid artery
BCT	brachiocephalic trunk
ISF	in situ fenestration
PLZ	proximal landing zone
dSINE	distal stent-induced new entry
RCCA	right common carotid artery

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Author contributions
Data was collected by G.L. and Z.D. G.L., M.L., B.N. made substantial contributions to the design of the work. Data was interpreted by Z.D., J.G., X.X., H.L., M.L. G.L.was responsible for the first draft of the manuscript. The submitted version was revised and edited by W.G., Y.S. and B.N. All authors have reviewed the published version of the manuscript.

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Data availability
The original data will be shared on reasonable request by contacting the corresponding author.

Declarations

Ethics approval and consent to participate
The medical ethics committee of the First Affiliated Hospital of Nanjing Medical University approved this study (Number: 2021-SR-381). Due to the retrospective nature of this study, the medical ethics committee waived the need of patient informed consent. The study was conducted according to the Declaration of Helsinki and institutional guidelines.

Consent for publication
Not applicable.

Clinical trial number
Not applicable.

Competing interests
The authors declare no competing interests.

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