Case Report

ANNALS OF MEDICINE & SURGERY

OPEN

Clinical efficacy of TEVAR utilizing fenestrated stent-grafts for zone 0 in an elderly frail patient with giant aortic arch aneurysm

Hirotsugu Kurobe, MD, PhD[a,b,*], Takaki Hori, MD, PhD[c], Hiroshi Fujita, MD[b], Tomohide Higaki, MD[a], Takuma Fukunishi, MD, PhD[a], Hitoshi Sogabe, MD[b], Hironori Izutani, MD, PhD[a]

Introduction and importance: Elderly and frail patients with thoracic aortic aneurysms (TAAs) near to origins of cervical arteries present facing challenges with aortic arch replacement with cardiopulmonary bypass, and traditional tube-type stent-grafts are also inadequate for transcatheter endovascular aortic repair (TEVAR). Thus, necessitating precise treatment with fenestrated stent-grafts from zone 0. This approach is crucial for achieving favorable postoperative outcomes without compromising activities of daily living (ADL).

Case presentations: An 85-year-old-man admitted to the hospital for treatment of a large TAA. While arch replacement is a definitive procedure, it is highly invasive, and the postoperative ADL are expected to be significantly lower than preoperative levels. Therefore, we performed a debranching TEVAR from Zone 0 with fenestrated stent-graft. The patient was discharged from the hospital on the 11th postoperative day.

Clinical discussion: In frail and elderly patients for whom conventional surgery may not be viable, TEVAR emerges as a preferred alternative. However, TEVAR of TAA proximal to the aortic arch continues to pose challenges, necessitating meticulous attention to the cervical branches in the intervention strategy. While surgical intervention in these patients necessitates careful consideration of its suitability, including the potential for postoperative enhancement in ADL, the use of fenestrated stent-grafts from Zone 0 emerges as one of the treatment modalities.

Conclusion: The authors present a very elderly case in which fenestrated stent-grafts were used to avoid aortic arch replacement for a large aortic arch aneurysm, resulting in a good postoperative course with no decline in ADL.

Keywords: aortic arch aneurysm, case report, fenestrated stent-graft, NAJUTA, thoracic endovascular aortic repair (TEVAR), Zone 0

Introduction

Thoracic aortic aneurysms (TAAs) are often discovered incidentally due to the aging of the population and the widespread use of computed tomography (CT) scans. The number of surgeries has also increased with the spread of thoracic stent-grafts [thoracic endovascular aortic repair(TEVAR)][1].

However, elderly and frail patients who have difficulty undergoing open thoracotomy and have TAAs near the origin of the brachiocephalic artery, left carotid artery, or left subclavian artery cannot be treated with TEVAR using a conventional tube-type stent graft, and we face difficulties in their treatment[2].

NAJUTA (manufactured by SB-KAWASUMI LABORATORIES, INC), approved and used since 2013, is the only semi-customized fenestrated stent graft available today that can be implanted from Zone 0 according to the opening of the cervical branch origin. If sufficient case studies and treatment simulations are performed, this device can be expected to treat aortic arch aneurysms that are difficult to manage with conventional tube-type stent-grafts[3–5].

HIGHLIGHTS

- Surgical intervention by aortic arch replacement with both cardiopulmonary bypass and selective cerebral perfusion with hypothermia are high risk in elderly and frail patients.
- Thoracic aortic arch aneurysm near the origin of cervical arteries cannot be treated with thoracic endovascular aortic repair (TEVAR) of tube-type stent-graft.
- Performing intervention with fenestrated stent-graft from Zone 0 is challenging; however, that become one of the options to avoid aortic arch replacement in elderly patients.
- Fenestrated stent-grafts from Zone 0 are resulting in a good postoperative course with no decline in activities of daily living (ADL).

[a]Department of Cardiovascular & Thoracic Surgery, Graduate School of Medicine, EHIME University, Toon, [b]Division of Cardiovascular Surgery, Shinsenkai Imabari Daiichi Hospital, Imabari and [c]Division of Cardiovascular Surgery, Kamagaya General Hospital, Kamagaya, Japan

Sponsorships or competing interests that may be relevant to content are disclosed at the end of this article.

*Corresponding author. Address: Department of Cardiovascular and Thoracic Surgery, Ehime University Graduate School of Medicine [Address] Shitsugawa, Toon-shi, EHIME, 7910295, JAPAN. Tel.: +81 89 960 5331.
E-mail: kurobe.academia@gmail.com (H. Kurobe).

Annals of Medicine & Surgery (2024) 86:4854–4860

Received 3 April 2024; Accepted 2 June 2024

Published online 13 June 2024

http://dx.doi.org/10.1097/MS9.0000000000002268

We encountered a case involving a large aortic aneurysm situated in the anterolateral wall of the aortic arch, posing challenges for treatment with a conventional tube-type stent-graft due to inadequate aortic anatomy and sealing margin. Additionally, considering the patient's frail condition, conventional aortic arch replacement surgery with cardiopulmonary bypass and selective cerebral perfusion with hypothermia was deemed difficult. We hereby present a case that was successfully managed with a single-debranched TEVAR procedure employing two NAJUTA stent-grafts. The SCARE 2023 guideline criteria have been followed in this case report[6].

Presentation of case

An 85-year-old male with a medical history significant for hypertension, paroxysmal atrial fibrillation (pAf), and chronic renal failure (CRF) presented with an abnormal chest X-ray during a visit to his family hospital. Subsequent CT imaging revealed a distal aortic arch aneurysm with a maximum short diameter of 70 mm. Despite his advanced age and reduced mobility, the patient exhibited no cognitive impairment. Both the patient and his family expressed a desire for surgical intervention. However, given his age and frailty, open-heart surgery was deemed challenging, prompting consideration of stent-graft treatment.

Clinical findings

The patient presented with a height of 164 cm and a weight of 79 kg. Laboratory investigations revealed a white blood cell (WBC) count of 6000/μl, a red blood cell (RBC) count of 459 $\times 10^4$/μl, hemoglobin level of 14.5 g/dl, hematocrit of 42.8%, platelet count of 20.3 $\times 10^4$/μl, total bilirubin level of 0.6 mg/dl, aspartate aminotransferase (AST) level of 18 U/l, alanine aminotransferase (ALT) level of 14 U/l, blood urea nitrogen (BUN) level of 35 mg/dl, creatinine level of 1.92 mg/dl, estimated glomerular filtration rate (eGFR) of 26.6 ml/min/1.73m^2, glycated hemoglobin (HbA1c) level (NGSP) of 5.8%, and brain natriuretic peptide (BNP) level of 27.3 pg/ml.

Diagnostic studies

Chest X-ray demonstrated a cardiothoracic ratio of 48% with left first arch protrusion.

Electrocardiography revealed a heart rate of 64 beats/min with sinus rhythm.

Transthoracic echocardiography demonstrated an ejection fraction of 51.1%, valvular aortic regurgitation graded as 3/4, and an aortic regurgitation pressure half-time of 391 ms.

Contrast-enhanced CT scan revealed the following findings: ascending aorta measuring 39 mm, arch aorta measuring 37 mm, maximum short diameter of the arch aortic aneurysm of 75 mm (with partial thrombosis) (Fig. 1A, B), descending aorta measuring 34 mm, and a "U"-shaped arch aorta configuration when viewed from above (Fig. 1C). The arch exhibited meandering with a convex point at the location of the aneurysm. Vascularity was relatively good, with mild calcification observed.

Treatment and progress

The fundamental principle was to prioritize aortic arch replacement for its procedural certainty. However, considering the patient's functional independence limited to walking with a cane and evaluating his operative tolerance and postoperative quality of life (QOL), a treatment plan was formulated, giving precedence to stent graft treatment.

Contrast-enhanced CT scans initially suggested 2-debranching TEVAR with conventional tube-type stent-grafts. However, the following concerns were noted:

(1) Difficulty in securing a sufficient sealing margin from the margin of the aortic aneurysm on the aorta lesser curvature side.
(2) The steep angle of the aorta lesser curvature side, hindering the adequate deployment of the stent graft along the aorta and posing a risk of floating.
(3) High probability of the peripheral stent graft falling into the aneurysm, potentially leading to endoleakage due to incomplete sealing between the aortic arch and the stent graft.

Consequently, we opted to explore the feasibility of treatment with NAJUTA. Initially, a peripheral stent could be placed up to the brachiocephalic artery origin while preserving the left carotid artery using this fenestrated stent graft, thereby minimizing the risk of aneurysm involvement. Moreover, NAJUTA's endoskeleton/external graft stent-graft structure allows for adherence of the graft outside the skeleton to the aortic wall due to bodily blood pressure. This feature ensures effectiveness even if the stent skeleton does not perfectly match the aortic geometry. Furthermore, by employing a fenestrated stent graft and implanting the central stent from Zone 0, it was deemed feasible to achieve a sealing zone from the aneurysmal margin with a 1-debranching TEVAR while preserving both the brachiocephalic artery and the left carotid artery.

The calculated sealing zone using NAJUTA measured 15.6 mm from the aneurysmal margin to the left carotid artery and 26.8 mm from the aneurysmal margin to the brachiocephalic artery (Fig. 2A, B).

Additionally, a fenestrated stent graft was fabricated (Fig. 2C, D), and ex-vivo validation was performed using a three-dimensional (3D)-printed mass model derived from contrast-enhanced CT scans (Fig. 2E, F). The endoscopic analysis was conducted to assess the patency of both the brachiocephalic trunk and the left cervical artery following the implantation of a fenestrated stent-graft in ex-vivo experiments. The analysis confirmed the patency of these two cervical arteries (Fig. 2G, H, I).

This validation demonstrated high treatment efficacy, albeit with residual risk.

The patient and their family were comprehensively briefed on the aforementioned analysis results, leading to the decision to proceed with the surgery.

Surgical findings

Surgery commenced under general anesthesia under intubation with both inhalation and intravenous anesthetics. Subsequently, the right femoral artery, both left and right subclavian artery were exposed. An 8Fr. Sheath (Radifocus Introducer II H: TERUMO Corporation) was inserted following the application of a double Purse-string suture to the right femoral artery on the NAJUTA insertion site. Additionally, a 5Fr. Sheath (Radifocus Introducer II H: TERUMO Corporation) was punctured into the left brachial artery for balloon occlusion and coiling after subclavian bypass. Another 4Fr. Sheath (Radifocus Introducer II H: TERUMO Corporation) was punctured in the right brachial artery for the pull-through wire technique during NAJUTA device insertion. Lastly, a further 4Fr. sheath was punctured into

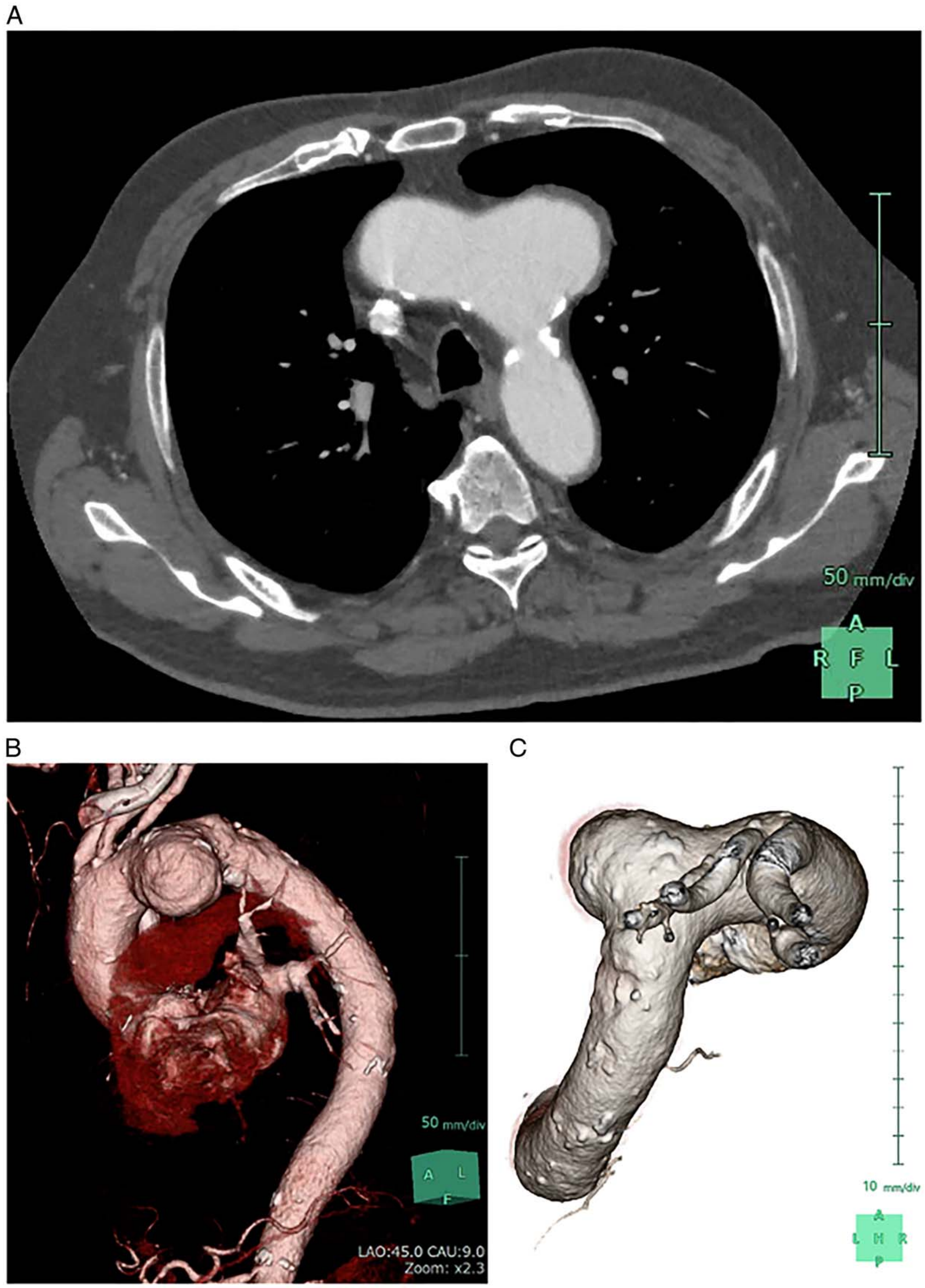

Figure 1. Preoperative enhanced computed tomography (CT). (A) The axial view shows a large aortic aneurysm located anteriorly on the aortic arch. (B, C) Preoperative three-dimensional (3D) CT images.

the left femoral artery for aortography employing a 4Fr. pig-tail catheter.

Following systemic heparinization [Activated Clotting Time (ACT) 300–350], a bypass from the right subclavian artery to the left subclavian artery was performed utilizing a 7 mm artificial vessel (Fusion: Getinge Japan K.K., Japan) with end-to-side anastomosis. Subsequent to the anastomosis, a 5Fr balloon-loaded catheter (Selecon MP Catheter II: TERUMO) was introduced from the left brachial artery to occlude the origin of the left subclavian artery.

A wire-catcher device for the pull-through wire (COOK Indy OTW Vascular Retriever: Cook Medical Japan) was threaded through an 8Fr. sheath inserted into the right femoral artery, and a 4Fr. Pig-tail catheter was inserted through the right brachial artery. Following insertion, a 0.035" Radifocus® guidewire 400 cm (TERUMO Corporation) was inserted, and the guidewire was withdrawn from the right femoral artery sheath after being caught with the wire-catcher.

Initially, a NAJUTA with a single fenestration for the left carotid artery orifice was inserted into the ascending aorta while

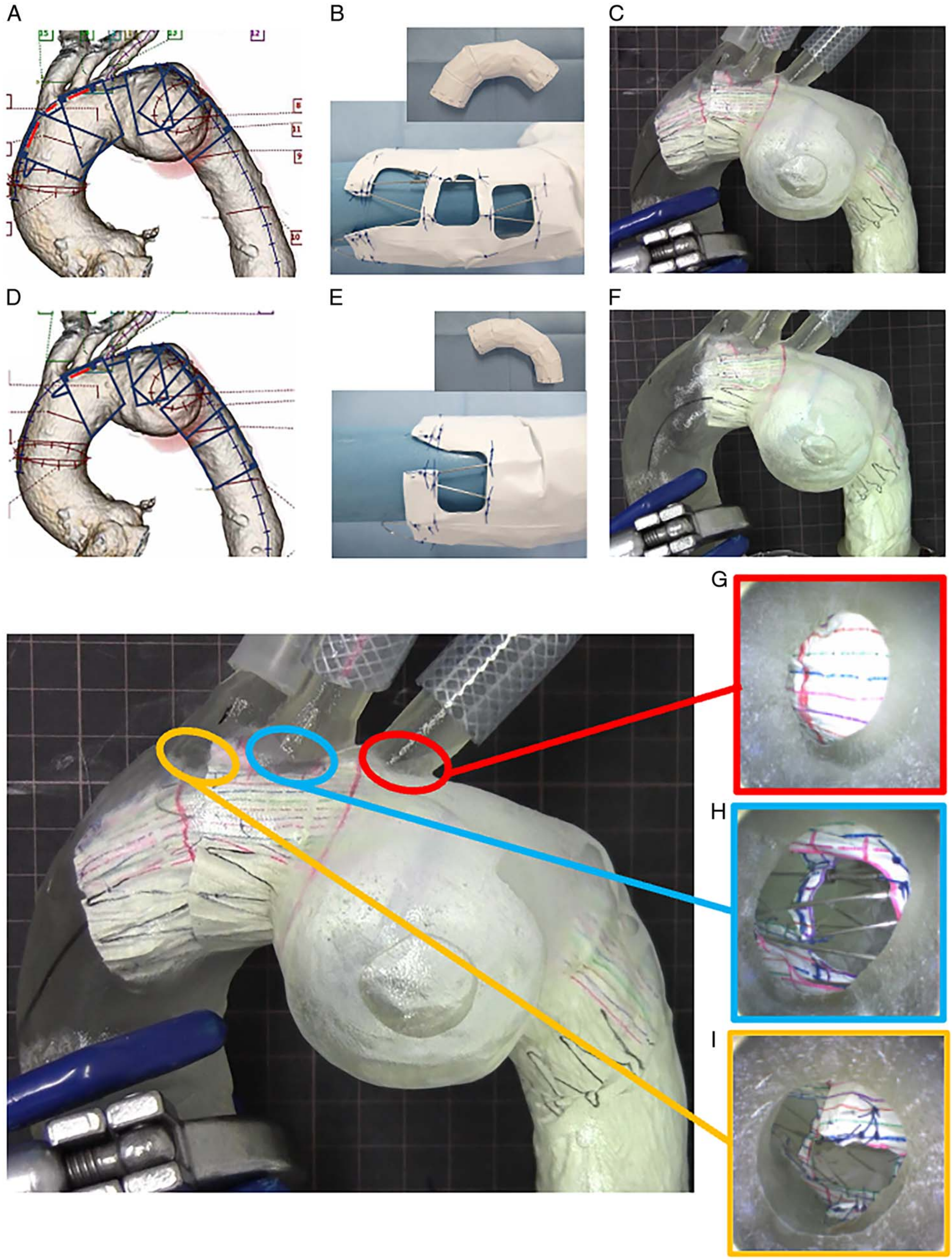

Figure 2. Preoperative Simulations. (A) Three-dimensional computed tomography (3D CT) image after implanting a proximal-side 3-fenestrated stent-graft. The red bow indicates the position of the fenestrations. The square with a navy line shows the structure outline of the stent inside the grafts. (B) 3D CT image after implanting a distal-side 1-fenestrated stent-graft. The red bow indicates the position of the fenestrations. The square with a navy line shows the structure outline of the stent inside the grafts. (C) The photo of fenestrations in proximal-side stent-grafts. (D) The photo of fenestrations in distal-side stent-grafts. (E) Implanting simulation of distal-side stent-graft with 3D models in *ex vivo.* (F) Implanting simulation of proximal-side stent-graft with 3D models in *ex vivo.* (G) Endoscopic images of orifice for left subclavian artery. Left subclavian artery was occluded with Stentgraft. (H) Endoscopic images of orifice for left cervical artery. Left cervical artery was patent. (I) Endoscopic images of orifice for brachiocephalic trunk. Brachiocephalic trunk was patent.

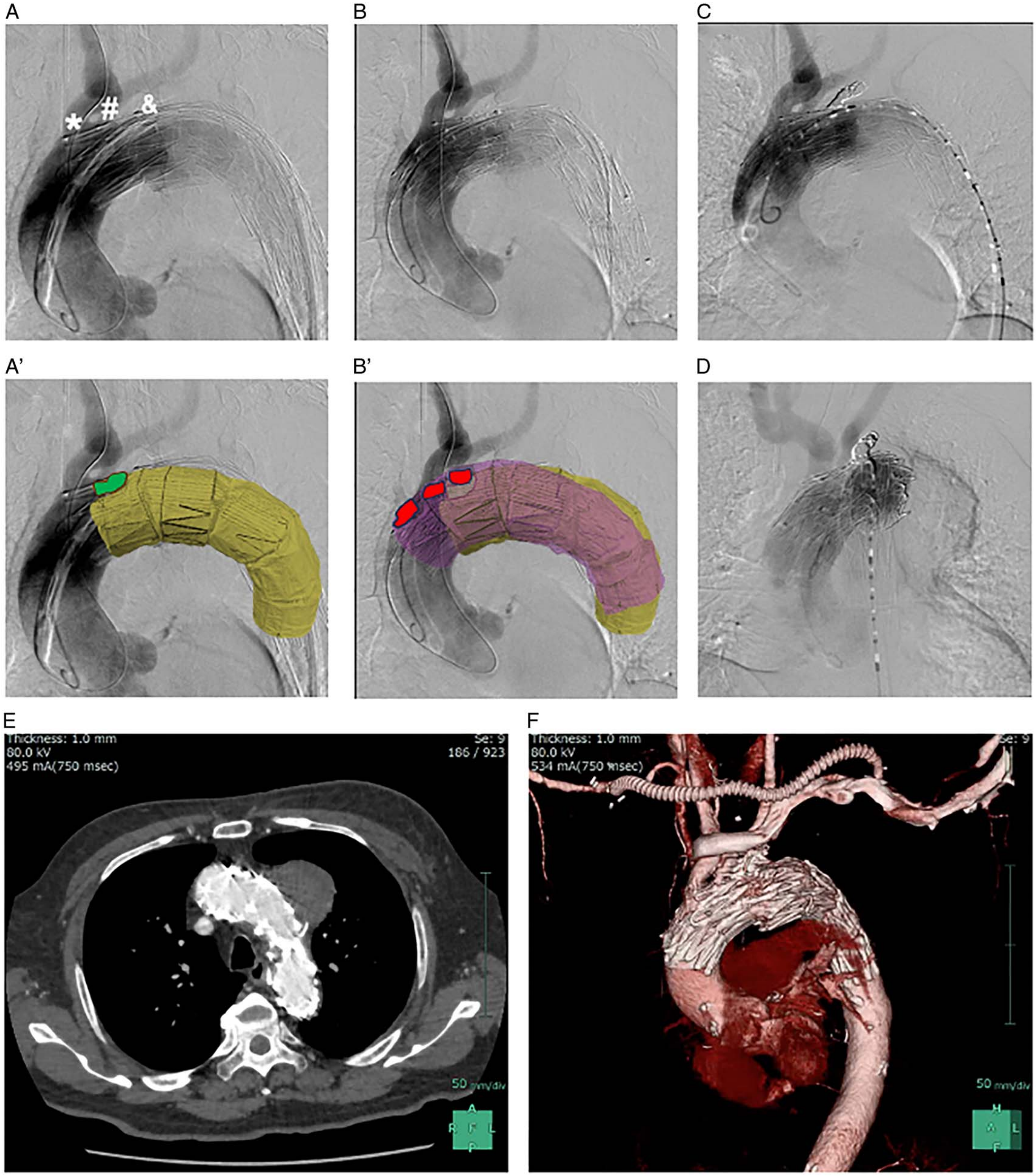

Figure 3. Perioperative images of angiography. (A) Angiography after implanting the distal-side stent-graft shows the patency of both the left cervical artery and the brachiocephalic trunk were maintained. (*: brachiocephalic trunk, #: Left cervical artery, &: Balloon for occlusion of left subclavian artery). (A') The distal-side stent-graft position was visualized using previous angiography image. The yellow portion indicates the body of one fenestrated-stentgraft, while the green segment indicate the locations of one fenestration aperture of this stentgraft. (B)Angiography after implanting the proximal-side stent-graft shows the patency of both the left cervical artery and the brachiocephalic trunk were maintained. (B') The proximal-side stent-graft position was also using angiography image. The purple portion indicates the body of the proximal-side stent-graft, while three red segments indicate the locations of three-fenestration apertures of this stentgraft. (C, D) Final angiographies after coiling the left subclavian artery showed that the patency of both the left cervical artery and the brachiocephalic trunk was ultimately maintained, and there were no endoleakages. (D) Postoperative enhanced computed tomography (CT) at 1week after surgery. The axial view indicates the absence of endoleakages and the thrombosis of the cavity of the aortic aneurysm outside the stent-graft. (A) Postoperative three-dimensional CT images at 1 week after surgery.

applying tension to the wire. Subsequently, aortography was performed to confirm the carotid branch orifice, after which the peripheral side stent was deployed to align the single fenestration of the stent with the left carotid artery orifice (This fenestrated-stentgraft was deployed so that the central marker of the first stent (Fig. 2B) was positioned at the peripheral left carotid artery (Fig. 3 A, A')).

Next, a three-fenestrated NAJUTA for the central side (for the brachiocephalic and left carotid artery orifice) was inserted into the ascending aorta while controlling the wire tension. Aortography was performed, and the orifices of the carotid branches were confirmed. The stent was then deployed so that the second and third fenestrations of this stentgraft (the central marker of the second stent is located on the peripheral side of the left common carotid artery (Fig. 2A)) (Fig. 3B, B').

After complete deployment, confirmatory aortography was conducted to ensure the brachiocephalic artery and left carotid artery were patent without any complications, and the origin of the left subclavian artery was occluded with coiling.

A final confirmatory aortography validated the absence of endoleakage, confirmed the patency of the brachiocephalic artery and left carotid artery, and verified the success of the right subclavian artery to left subclavian artery bypass (Fig. 3C, D), thus concluding the operation. This operation time was 3 h and 26 min.

Postoperative course

The patient was extubated in the operating room, and no complications such as cerebral infarction or tetraplegia were observed. Contrast-enhanced CT imaging for postoperative evaluation revealed no endoleakages or other complications attributable to this intervention (Fig. 3E, F). Postoperative rehabilitation and wound healing progressed smoothly, with no complications noted, leading to the patient's discharge 11 days after surgery.

Discussion

Thoracic endovascular aortic repair (TEVAR) for thoracic aortic aneurysms in Japan has rapidly gained popularity since its reimbursement in 2008. Particularly, TEVAR for descending aortic aneurysms beyond the aortic arch has demonstrated superior postoperative outcomes compared to conventional descending aortic replacement with artificial graft[7]. Although clinical trial results for TEVAR and open repair of the descending aorta are generally not directly comparable, the TEVAR group has shown significantly lower operative mortality (2.1% vs. 11.7%), spinal cord ischemia (3% vs. 14%), and respiratory impairment (4% vs. 20%)[8].

However, the treatment of aortic aneurysms proximal to the aortic arch via TEVAR still presents challenges, requiring careful consideration of the cervical branches in the treatment plan. In some frail cases where conventional surgical treatment may not be feasible, TEVAR remains a preferable option.

Our case involved an 86-year-old frail patient who was able to live independently but also exhibited reduced renal function. Considering the potential challenges and the impact on quality of life associated with aortic arch replacement, involving both cardiopulmonary bypass and selective cerebral perfusion (SCP) with hypothermia, or an extended period of rehabilitation, the feasibility of TEVAR intervention was investigated. However, the steep angle on the aorta lesser curvature side posed challenges, leading to inadequate sealing zone assessment even if the stent was placed just at the orifice of the brachiocephalic artery. Additionally, the meandering of the aortic arch made it difficult to crimp the stent graft into the aortic lumen with the exoskeleton and internal graft structure, ultimately necessitating the abandonment of the implantation idea.

Therefore, we opted to pursue treatment with NAJUTA, a fenestrated stent, considering its Zone 0 implantation capability, adequate sealing on the lesser curvature side, and its endoskeletal-external graft design, which facilitates adherence to the inner aortic wall even in complex aortic anatomy. While there were considerations regarding whether to employ 1 or 2-debranching procedures, our decision was influenced by two main factors: (1) a desire to minimize invasiveness in this case and (2) the ability to achieve a sealing margin of 15.6 mm from the aortic aneurysm margin to the left carotid artery, mitigating the risk of leakage. With the high likelihood of preventing leakage, we proceeded with a single debranching TEVAR as the initial step.

However, there remained a concern regarding the 15 mm sealing margin between the carotid artery and the aortic aneurysm margin, with a potential risk of Type 1a occurrence depending on implantation conditions. Thus, it was decided that additional treatment could be considered later with 2-debranching TEVAR using a tube-type stent graft if necessary. Consequently, the patient underwent successful treatment with 1-debranching TEVAR and was discharged on the 11th postoperative day without any complications.

The aggressive utilization of such treatment modalities in patients with above-average life expectancy remains a subject of debate, as it cannot be universally applied to all patients. However, our patient exhibited several factors influencing our decision: (1) he had consistently maintained independence in his activities of daily living, albeit with the aid of a cane, (2) he lived independently and resided alone without experiencing cognitive decline, (3) he possessed a thorough understanding of her illness, as did his family, (4) he harbored a strong fear of the risk of rupture associated with his large aortic aneurysm, (5) both he and his family expressed a strong desire for endovascular intervention, and (6) he was expected to provide support to his family following the operation (postoperative family support was cooperative and promising). Based on these overall assessments, the surgical policy was determined after ensuring thorough informed consent regarding the treatment and potential complications.

Conclusion

Fenestrated stent-grafts offer a viable solution for safely addressing aortic arch aneurysms that present challenges for treatment with conventional tube-type stent-grafts. This alternative therapeutic approach holds potential as a valuable option in such clinical scenarios.

Ethical approval

This was an isolated case report done with the consent of the patient. No further research studies are being pursued.

Consent

Written informed consent was obtained from the patient for publication of this case and any accompanying images. A copy of the written consent is available for review by the Editor-in-Chief of this journal on request.
This article type (case report) that does not require a formal ethical committee approval.

Source of funding

The authors declare that they have no funding.

Author contribution

H.K.: writing the paper, data analysis, data collection. T.H.: data analysis, data interpretation. H.F.: data collection. T.H.: data collection. T.F.: data collection. H.S.: data interpretation. H.I. writing the paper, data interpretation.

Conflicts of interest disclosure

Not applicable.

Research registration unique identifying number (UIN)

Not applicable.

Guarantor

Hironori Izutani.

Data availability statement

Not applicable.

Provenance and peer review

Not commissioned, externally peer-reviewed.

References

[1] Committee for Scientific Affairs TJAfTSMinatoya K, Sato Y, *et al*. Thoracic and cardiovascular surgeries in Japan during 2019: Annual report by the Japanese Association for Thoracic Surgery. Gen Thorac Cardiovasc Surg 2023;71:595–628.
[2] Fritzke J, Luciano E, Alashari A, *et al*. Novel TEVAR technique for thoracic aortic aneurysm repair: a case report. Int J Surg Case Rep 2023;110: 108651.
[3] Furuta A, Azuma T, Yokoi Y, *et al*. The midterm results of thoracic endovascular aortic repair with a precurved fenestrated endograft in zone 0-1. Eur J Cardiothorac Surg 2020;58:722–9.
[4] Toya N, Shukuzawa K, Fukushima S, *et al*. Aortic arch aneurysm repair using the Najuta stent graft in a challenging compromised seal zone. J Vasc Surg Cases 2016;2:21–4.
[5] Kawaguchi S, Yokoi Y, Shimazaki T, *et al*. Thoracic endovascular aneurysm repair in Japan: experience with fenestrated stent grafts in the treatment of distal arch aneurysms. J Vasc Surg 2008;48(6 suppl): 24S–9S; discussion 29S.
[6] Sohrabi C, Mathew G, Maria N, *et al*. The SCARE 2023 guideline: updating consensus Surgical CAse REport (SCARE) guidelines. Int J Surg 2023;109:1136–40.
[7] Wiedemann D, Mahr S, Vadehra A, *et al*. Thoracic endovascular aortic repair in 300 patients: long-term results. Ann Thorac Surg 2013;95: 1577–83.
[8] Bavaria JE, Appoo JJ, Makaroun MS, *et al*. Endovascular stent grafting versus open surgical repair of descending thoracic aortic aneurysms in low-risk patients: a multicenter comparative trial. J Thorac Cardiovasc Surg 2007;133:369–77.