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Mid-term outcomes of left subclavian artery revascularization with Castor stent graft in treatment of type B aortic dissection in left subclavian artery

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ABSTRACT

Background: Here we analyzed mid-term data of thoracic endovascular aneurysm repair (TEVAR) surgery with Castor single-branched stent graft placement for the management of Stanford type B aortic dissection (STBAD) involving the left subclavian artery (LSA).
Methods: Between April 2014 and February 2019, 32 patients with STBAD involving a Castor single-branched stent graft were included. We analyzed their outcomes, including technical success rate (TSR), surgical duration (SD), presence of ischemia, perioperative complications, LSA patency, and survival rate (SR), using computed tomography angiography and clinical evaluation during mid-term follow-up.
Results: The mean patient age was 54.63 ± 12.37 years (range, 36–83 years). The TSR was 96.88% (n = 31/32). The mean SD was 87.44 ± 10.89 with a mean contrast volume of 125.31 ± 19.30 mL. No neurological complications or deaths occurred during the study period. The patients had a mean hospital stay of 7.84 ± 3.20 days. At a mean follow-up of 68.78 ± 11.26 months, four non-aortic deaths (12.5%) were observed. The LSA patency rate was 100% (n = 28/28). There was only one case of type I endoleak immediately after surgery (3.12%) (type I from LSA). However, none of the patients experienced type II endoleaks, and there were no cases of retrograde type A aortic dissection or stent graft-driven new distal entry. Finally, all patients exhibited good LSA patency.
Conclusion: TEVAR using a Castor single-branched stent graft may be a highly feasible and efficient procedure for the management of STBAD involving the LSA.

1. Introduction

Thoracic endovascular aneurysm repair (TEVAR) is currently the intervention of choice for Stanford type B aortic dissection (STBAD) involving the LSA[1,2] with multiple benefits.[3,4] However, TEVAR has some limitations. One such limitation involves the need for a sufficient proximal landing zone, particularly 1.5–2.0 cm. An inadequate proximal landing zone may result in inadvertent coverage of the LSA with a thoracic stent graft. In the absence of revascularization, TEVAR can substantially increase the stroke risk. To prevent this, numerous LSA revascularization techniques have been recommended, including carotid–subclavian bypass, fenestrated devices, chimney techniques, and hybrid techniques.[3–6] Among them, the unibody design is the most popular owing to its ability to prevent the gutter endoleak that is normally observed with the chimney technique and its excellent anchoring capability to the branch section, which ensures stable device placement. Here we retrospectively evaluated the efficacy of TEVAR using a Castor single-branched stent graft for managing STBAD involving the LSA.

2. Materials and methods

The institutional review boards of the 3rd Affiliated Hospital of Shenzhen University and the Beijing Chao Yang Hospital approved this study, and all patients provided written informed consent prior to participating.

2.1. Patient identification

Between April 2014 and February 2019, 102 consecutive patients underwent TEVAR at these two hospitals. The indications for TEVAR

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included aortic rupture, pleural effusion, refractory arterial hypertension, a descending aorta diameter of >5.5 cm, and chronic pain. Of the 102 patients who underwent TEVAR, 32 were eligible for this study. The eligibility criteria included: (1) acute/subacute STBAD; (2) LSA affected by aortic dissection or hematoma; (3) left common carotid artery (LCCA) not affected by the aortic dissection with a landing zone length (distance between the LCCA and the proximal edge of the dissected aorta) of >15 mm. The exclusion criteria were: (1) hereditary connective tissue disease like Marfan syndrome; (2) prior TEVAR; (3) no proper access route for the stent graft (diameter of the external iliac artery and common femoral artery <7 mm or severe stenosis and calcification of the LSA); and (4) dominant left and/or right vertebral artery occlusion, and bilateral internal carotid artery stenosis. STBAD involving the LSA was diagnosed using computed tomography angiography (CTA). Not all patients underwent CTA of the circle of Willis muscle prior to surgery.

2.2. Endovascular procedure

The Castor single-branch stent graft (Microport Medical, Shanghai, China) was approved by the Chinese Food and Drug Administration as the first domestic unibody branch stent graft. The anatomical criteria for the Castor device were as follows: (i) thoracic aortic dissection or hematoma involving the LSA; and (ii) thoracic aortic dissection or hematoma in which the distance between the aortic dissection and LCCA is > 15 mm. All TEVAR procedures were performed under general anesthesia by vascular surgeons. The endovascular procedure was described previously.[4–6]

Technical success was related to immediate periprocedural events that occur from the initiation of the procedure and extend through the first 24 h postoperative. Primary technical success was defined on an intent-to-treat basis, starting with the implantation procedure and requiring successful device introduction and deployment in the absence of surgical conversion to open repair, death within 24 h, type I or II endoleaks as evidenced by procedural angiography, or graft obstruction.[7] Immediate aortography was performed to confirm the occurrence of endoleaks and evaluate side branch patency. The balloon catheters were chosen by the operator. All aortic repairs were performed using a Castor branched aortic stent graft system, with an oversizing of 7.1–10.3% and a length of 180–200 mm. After the procedure, aspirin (100 mg) was administered daily as a platelet inhibitor.

2.3. Definitions and data collection

The primary endpoint was defined as the patency of the stent graft and survival rate (SR) over the follow-up period. Additional secondary endpoints included postoperative complications, reintervention events, and morphological changes in the aortic artery. Any complications necessitating rehospitalization and/or reoperation within 30 days after treatment, such as stroke and endoleak, were considered major complications. Any septic, cardiac, renal, or pulmonary complications were considered systemic. Minor complications included those affecting the treated limbs, access site(s), and iatrogenic wounds. Aorta-related death was defined as sudden death resulting from aortic artery rupture due to uncontrollable blood pressure. Finally, endoleaks were defined as type I

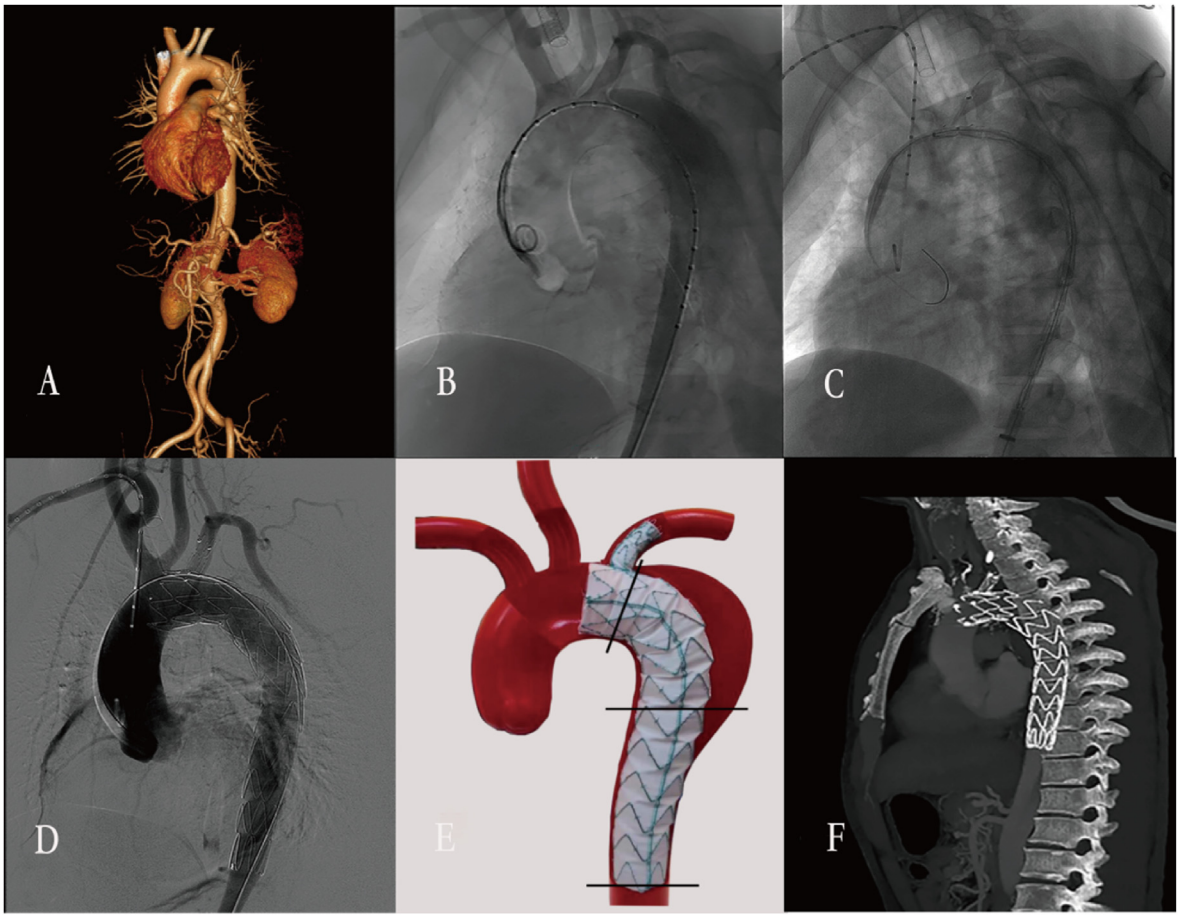

Fig. 1. Endovascular treatment of type B aortic dissection affecting the left subclavian artery (LSA) with a Castor branched stent graft
(A) 3D reconstruction showing the primary tear located close to the LSA; (B) Intraoperative aortogram showing the primary tear; (C) Delivering the stent graft to the planned position; (D) Final aortography showing the complete seal of entry tear; (E) The schematic of the Castor stent graft reconstruction of the LSA, and the diameters at levels A, B and C (black lines) were measured during follow-up in all patients; (F) Good patency of the graft during follow-up.

(leak from the proximal or distal stent graft attachment site) or type II (retrograde blood flow via branch arteries from the sealed tissue).

2.4. Follow-up

The patients were followed up with aortic CTA and cerebral magnetic resonance imaging (MRI) at 6-month intervals in the first year and annually thereafter. Postoperative cerebral MRI was compared with the preoperative cerebral MRI to detect new lesions. Aortic morphological remodeling was evaluated at the orifice of the LSA and the middle and distal ends of the stent graft (Fig. 1E), including the following levels: A aorta, B aorta, B true lumen, B false lumen, C aorta, C true lumen, C false lumen, and maximal false lumen. False lumen thrombosis was evaluated during the delayed CTA phase.

2.5. Statistical analysis

All statistical analyses were performed using SPSS version 21 (IBM Corp., Armonk, NY, USA). Stent graft patency and SR were estimated using Kaplan-Meier analysis. Continuous variables are expressed as mean ± standard deviation, while categorical variables are expressed as proportions. A diameter analysis was performed using a one-way repeated-measures analysis of variance. Values of $P < 0.05$ were considered statistically significant.

3. Results

3.1. Demographics

A total of 31 patients presented with acute STBAD involving the LSA (time from acute onset to TEVAR <2 weeks, 96.88%), while one had subacute STBAD involving the LSA (>2 weeks and <4 weeks, 3.12%). Among the study patients, 26 were men and six were women, with a median age of 54.63 ± 12.37 years (range, 36–83 years). All patients reported sudden-onset severe chest or back pain that lasted 1–15 days before hospital admission. The recorded cardiovascular risk factors were hypertension (100%), smoking (71.88%), coronary artery disease (33%), and others (Table 1).

3.2. TEVAR-related data

The mean surgical duration was 87.44 ± 10.89 min and the mean contrast volume was 125.31 ± 19.30 mL. The technical success rate (TSR), defined as the successful placement of the Castor single-branched stent graft, was 96.88% (31/32). One patient (3.12%) experienced a type I endoleak (type I from the LSA) immediately following the operation due to incomplete adherence of the branch section to the LSA. This was remedied by placing a balloon catheter within the LSA-branched portion of the Castor single-branched stent graft. The mean hospital stay was 7.84 ± 3.20 days (Table 2). No major complications occurred in any patient after surgery. Five patients experienced route complications, namely four hematomas in the left brachial artery access and one infection at femoral cutdown, while two patients exhibited a pulmonary infection. The overall postoperative complications rate was 21.87% (7/32) (Table 3).

Table 2
Clinical data of 32 patients treated with TEVAR.

Variable	value
Technical success	31/32 (96.88%)
Operation time, min	87.44 ± 10.89
volume of contrast (ml)	125.31 ± 19.30
Hospital stay, days,	7.84 ± 3.20
Patients with Castor stent-graft	32/32 (100%)
DMBC	32.19 ± 2.29
DANLSAO	29.53 ± 2.23
TCC	2.53 ± 2.16
Peri-operative Endoleak	1/32 (3.12%)

DMBC:diameter of the main body of castor; DANLSAO:diameters of aorta near LSA orifice.
TCC: time of chief complaint.

3.3. Follow-up outcomes

We retrieved the complete follow-up data for all patients. The median follow-up duration was 68.78 ± 11.26 months. Of the 32 patients, four died during the study period. The time points and causes of death were as follows: 30 months (cerebral hemorrhage); 44 months (myocardial infarction); 52 months (unknown reason); and 58 months (lung cancer). The mortality rate was 12.5% (4/32; Fig. 2). No major complications, namely strokes and/or neurological symptoms, were reported during the length of this study. The LSA patency rate was 100% (28/28), and no Castor single-branched stent graft occlusions were observed (Fig. 3). Additionally, there have been no reports of endoleaks among patients. Significant morphological changes were observed at all three designated levels (Fig. 4). The diameters of the maximal false lumen and false lumens at levels B and C were significantly decreased on the 6-,12-, and 24-month CTA ($P < 0.01$), and the true lumens were significantly expanded ($P < 0.001$). The diameters of the maximally dissected aorta and the aorta at levels A, B, and C showed no significant changes throughout the follow-up period ($P > 0.05$). Finally, all patients ($n = 28$) exhibited complete thrombosis of the false lumen in the thoracic aortic artery at the time of their last follow-up, as evidenced on CTA (Fig. 5).

4. Discussion

Large advancements in endovascular stent graft design have enabled its use in the distal arch and proximal descending aorta.[8,9] However, the size of the proximal landing zone is a limiting factor for TEVAR, particularly when it involves the LSA. Several studies have reported that LSA coverage can increase the risk of arm ischemia, vertebral territory and anterior circulation stroke, and paraplegia.[10–13] To prevent these complications, routine LSA revascularization has been recommended by the

Table 1
Patients' baseline characteristics (N = 32).

Variable	value
Age, years (range)	54.63 ± 12.37 (36–83)
Men	26/32 (81.25%)
Smoker	23/32 (71.88%)
Hypertension	32/32 (100)%
Coronary heart disease	17/32 (53.13%)
Renal insufficiency	4/32 (12.50%)
Chronic obstructive pulmonary disease	4/32 (12.50%)
Diabetes mellitus	5/32 (15.63%)
Peripheral arterial disease	9/32 (28.13%)
Dyslipidemia	3/32 (9.38%)
stroke	2/32 (6.25%)

Table 3
In-hospital complications.

Paraplegia	0/32 (0.00%)
Myocardial infarction	0/32 (0.00%)
Stroke	0/32 (0.00%)
Pulmonary infection	2/32 (6.25%)
Renal failure	0/32 (0.00%)
Access vessel complication	5/32 (16.63%)
hematoma in left brachial artery	4/32 (13.50%)
infection at the femoral site	1/32 (3.13%)
Ischemic symptoms of the left arm	0/32 (0.00%)
In-hospital mortality	0/32 (0.00%)
In-hospital aortic-related mortality	0/32 (0.00%)
Total number of complications	7/32 (21.87%)

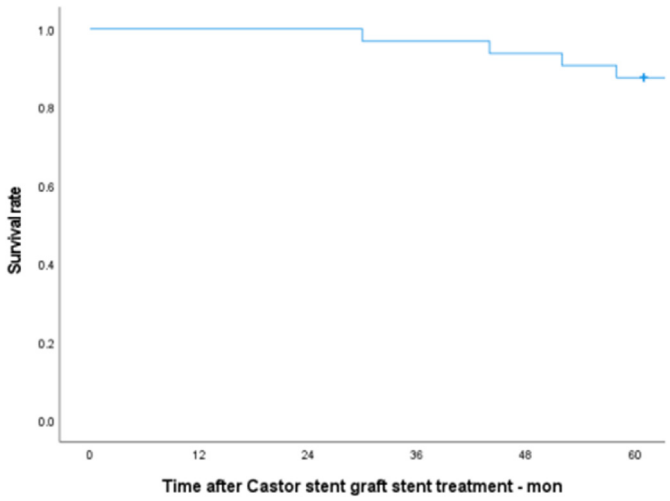

Fig. 2. Cumulative Kaplane Meier estimates of (A) all-cause death.

Society for Vascular Surgery Committee on Aortic Disease in 2009.[14] Additionally, the European Society for Vascular Surgery guidelines strongly suggest LSA revascularization for TEVAR, especially in patients at elevated neurological complication risk.[15]

Multiple LSA revascularization procedures can currently be used during TEVAR, including carotid–subclavian bypass, fenestrated device, chimney technique, and branched stent grafts. As an established debranching procedure for zone II TEVAR, LCCA–LSA bypass has excellent long-term patency and a low rate (2.8%) of repeat surgical interventions.[16,17] In fact, the documented rates of complications requiring repeat surgeries are as follows: hematoma evacuation, 2.1%; chylous leak, 0.7%; sustained nerve injury, 2.1%; and vertebral artery occlusion, 6%. The 1-, 2-, and 5-year primary patency rates were 99.5%, 98.9%, and 98.0%, respectively. However, the acute complications rates were much higher, namely: chronic phrenic nerve palsy, 5%; chronic sympathetic chain nerve palsy, 5%; and chyle leakage, 6%.[18]

In contrast to the significant trauma and associated risks of the carotid–subclavian bypass and hybrid techniques, TEVAR offers minimal invasiveness with its sophisticated technology. In TEVAR, the chimney technique and fenestrated devices are initially used for LSA revascularization. However, emerging evidence suggests that the chimney technique dramatically increases the risk of endoleaks and repeat procedures, particularly in cases of entry tears in close proximity to the origin of the arch branch artery or when the intervals between the arch branches are minimal.[19,20] For the fenestrated device, alignment is an issue owing to the aortic arch curvature. Although a variety of fenestrated endografts and fenestration techniques have been developed, accidental covering of the arch branch arteries and its associated risks are common.[21–23] Hence, there is room for improvement in TSR, surgical safety, and long-term stent graft stability during TEVAR.

The unibody design is uniquely advantageous preventing gutter endoleak associated with the chimney technique and circumvents misalignment complications related to the fenestrated device, thereby ensuring long-term device stability. Inoue et al. reported their initial trial of an aortic arch endovascular branched graft involving the LSA in 1999.[24] Since then, the branched graft technique has been modified, and it is now widely accepted as an intervention for LSA. In a recent series, 73 patients with STBAD or intramural hematoma were treated with Castor single-branched stent graft (Microport Medical) to maintain blood flow,[25] with a TSR of 98.6% and no cases of perioperative mortality. The Castor single-branched stent graft employed in the aforementioned study had a self-expandable nitinol stent and a polyester vascular graft fabric. Moreover, the indications for TEVAR in the aforementioned study were dissection with proximal entry tears in the immediate vicinity of the LSA orifice, and descending aortic dissection with retrograde aortic dissection. In our study, the average stent graft diameter and length of hospital stay were 32.19 mm and 7.84 days, respectively. In addition, our TSR was 96.88% with an operative duration comparable to those of other procedures. Hence, TEVAR using a Castor single-branched stent graft is safe and feasible for correcting aortic aneurysms involving the LSA.

Endoleak is the most prevalent TEVAR complication with the chimney technique and fenestrated device. The early incidence of endoleak is 11%, with 42% requiring reintervention.[26] In our study, only one patient developed an endoleak that required further surgery. In the study by Jing et al., 73 patients underwent TEVAR for a wide range of thoracic aortic pathologies.[27] Among them, 5% (4/73) of patients developed intraoperative endoleaks that were easily repaired by cuff stent graft or a bare

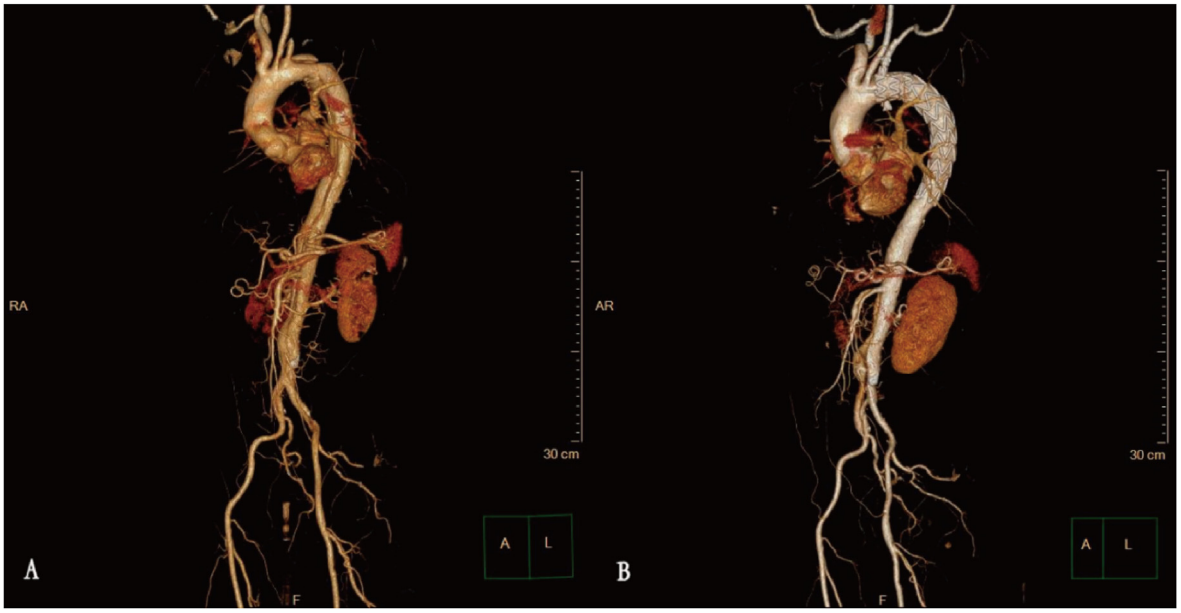

Fig. 3. Preoperative and postoperative CTA and 3D reconstruction of the aorta and branch vessels.
(A) The proximal entry tear located very close to the origin of LSA and the origin of LSA affected by aortic dissection; (B) The three-year follow-up computed tomography angiogram revealed patency of the supra-arch branches and complete thrombosis of the false lumen.

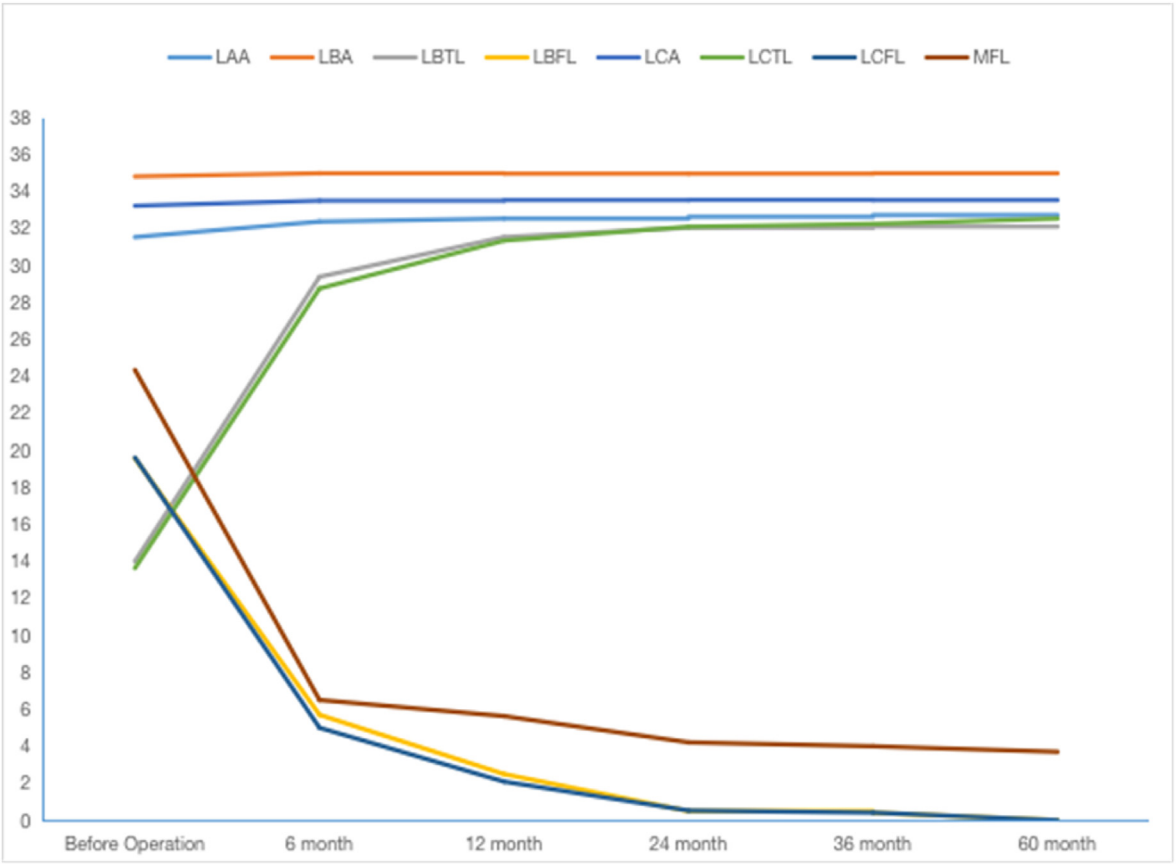

Fig. 4. Morphological changes of the aorta in the 5-year follow-up.

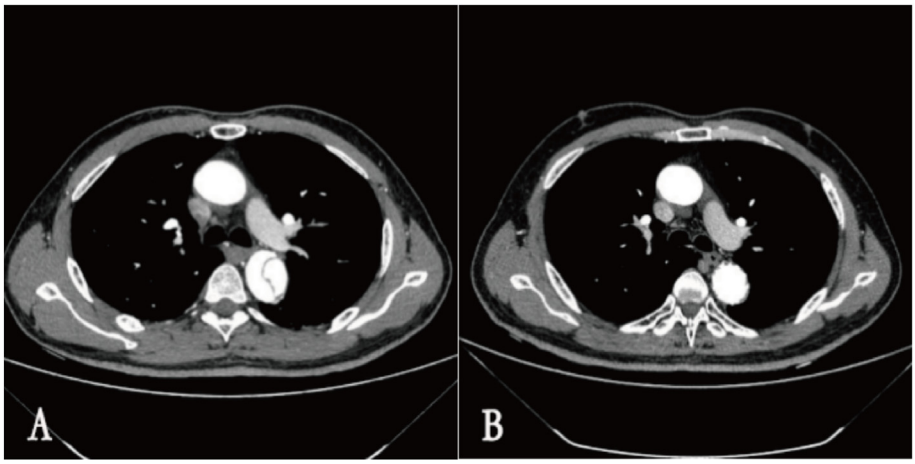

Fig. 5. Cross-sectional view of the thoracic aorta. (A) The Cross-sectional view before the endovascular procedure; (B) Cross-sectional view in the 5-year examination.

stent. Thus, the lower endoleak rates associated with Castor single-branched stent grafts are well accepted compared to other endovascular procedures owing to their unique conformation to the physiological structure and maintenance of stent integrity.

Stroke is another significant complication of STBAD treatment that can be easily managed with LSA revascularization.[27–30] However, few studies have investigated whether the revascularization method affects the stroke rate. In recent research, encouraging outcomes (i.e., no stroke) were observed with LSA revascularization during the hospital stay and at 30-day follow-up.[30,31] Given this evidence, it is clear that the LSA must be prophylactically revascularized during TEVAR with a Castor single-branched stent graft to dramatically reduce stroke risk. However, the incidence of access vessel complications in our study was relatively high compared to those of similar studies. This may be due to two factors: the larger external diameter of the delivery system in the branched artery and the restless movements of patients during general anesthesia during the recovery period. Therefore, appropriate selection of stent size and efficient postoperative management of movement are essential to reducing access vessel complications.

The general goals of TEVAR for STABD are to nullify the false lumen,

patch entry tears, and promote aortic remodeling. In our study, all patients (n = 28) experienced complete thrombosis of the false lumen of the thoracic aortic artery. Moreover, the survival rate at the 60-month follow-up was 87.5% (28/32) and there were no aortic-related deaths. Jing et al. made a similar observation of 68 patients requiring TEVAR with a Castor single-branched stent graft.[27] Emerging evidence suggests that the incidence of endoleaks is closely related to the reintervention rate. As mentioned above, no endoleaks were observed during the follow-up in our study. In addition, the LSA patency rate was 100%, with no patients requiring reintervention. Similar to our work, Jing et al. also observed a 0% endoleak rate, and hence, a 0% reintervention rate.[27] Therefore, we speculate that the reintervention rate with Castor single-branched stent grafts is much lower than that with other methods, likely due to the unique unibody design that facilitates the physiological prevention of endoleaks. Additional observations and investigations are required to fully understand this relationship.

To date, TEVAR with a Castor single-branched stent graft intervention has been proposed for STBAD in China despite few reports of its efficacy.[25,27,30,31] In addition to eliminating proximal entry tears, the major concerns with general stent placement include preventing aortic wall injury and achieving long-term branch arterial patency. The Castor single-branched stent graft avoids intimal injury and cerebral embolization owing to the presence of a soft sheath that covers the stent graft during arch entry.[28] However, this device has certain limitations. First, this stent has a considerably larger external diameter than straight stent grafts, which can inflict greater arterial wall injury. The higher rate of access complications in our study was associated with this feature. Second, the traction wire can twist around the rigid guidewire, causing complications during deployment. This complication was observed in a previous study[25] but not in our study. However, to circumvent these complications, the device requires further improvements. Multiple-branched stent grafts with sophisticated designs were recently introduced to address pathologies related to the ascending aorta and aortic arch. In addition, more work is being conducted on improved branched stent designs in places outside China, such as the Valiant Mona LSA (Medtronic, Santa Rosa, CA, USA) and W.L. Gore (Flagstaff, AZ, USA) arch branch devices.[32,33] The rapid development of sophisticated branched stent graft devices can ensure the development of effective, targeted, and personalized therapies for patients with STBAD.

5. Limitations

Our study has certain limitations. First, as it was retrospective, unintentional selection bias may have been introduced. Second, our sample population was small with a relatively short follow-up period. Finally, this was a two-center study, and its findings cannot be extended to the general population. Therefore, a more exhaustive examination of the device in a multicenter study involving a large patient population is necessary to fully comprehend the safety and effectiveness of Castor single-branched stent grafts.

6. Conclusion

A Castor single-branched stent graft may be a highly feasible, easy-to-use, and efficient endovascular intervention for STBAD, particularly in patients with complex and twisted aortic arches. However, our conclusions are preliminary and require substantiation by investigations involving a larger patient population with an extended follow-up duration before the widespread use of this device may be recommended.

Declaration of competing interest

We declare that we have no financial and personal relationships with other people or organizations that can inappropriately influence our work.

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