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Original Article

Early Outcomes of Left Subclavian Artery Revascularization Using Castor Single-Branched Stent-Graft in the Treatment of Type B Aortic Dissection or Intramural Hematoma

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Background: More evidence was required to guide the management of left subclavian artery (LSA) during thoracic endovascular aortic repair (TEVAR). The present study aimed to compare the outcomes of LSA coverage with LSA revascularization. Another purpose of this study was to share our experience of LSA revascularization with castor single-branched stent-graft.
Methods: From January 2016 to December 2019, 134 patients with type B aortic dissection (TBAD) or intramural hematoma (IMH) were enrolled and divided into two groups, the LSA-covered group (n = 61) and the LSA-revascularized group (with castor single-branched stent-graft, n = 73). The results, such as in-hospital and 30-day mortality, stroke, paraplegia, left arm ischemia, operation time, endoleak, were compared between the two groups.
Results: The incidence of 30-day stroke in the LSA-covered group (8.2%) was significantly higher compared with the LSA-revascularized group (0%, P = 0.018). 30-day ischemia of left arm occurred in more patients in the LSA-covered group (11.5%, P = 0.003). No statistical difference was found in the incidences of paraplegia, endoleak, in-hospital mortality, and 30-day mortality.
Conclusions: LSA should be revascularized during TEVAR to reduce the incidences of stroke and left arm ischemia. Castor single-branched stent-graft was feasible and safe for treating TBAD or IMH.

Keywords: castor single-branched stent-graft, left subclavian artery, thoracic endovascular aortic repair

Introduction

Type B aortic dissection (TBAD) or intramural hematoma (IMH) is catastrophic and life-threatening. Risk factors for aortic dissection include arterial hypertension, trauma, atherosclerosis, drug use, obesity, aorta coarctation, and some congenital syndromes.[1,2] If untreated, mortality rate can be high.[3] Before the early 2000s, thoracic aortic diseases were mainly treated by open surgery, which had a high mortality rate from 7.5 to 11.1%.[4] In recent years, thoracic endovascular aortic repair (TEVAR), a less invasive technique, has developed rapidly and shows a reduced mortality rate compared with

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open repair.[5] For these advantages, TEVAR has been widely used for the treatment of TBAD or IMH.

Although TEVAR has dramatically altered the management methods for thoracic aortic diseases, it also shows limitations. One limitation is the necessity of sufficient proximal landing zone (PLZ) from 1.5 to 2.0 cm.[6] If PLZ is insufficient, covering the left subclavian artery (LSA) with a thoracic stent-graft is sometimes inevitable. Several studies have concluded that LSA coverage is associated with an increased risk of stroke, spinal cord ischemia, and upper extremity ischemia.[7–9] Conversely, some studies identified that the risks of covering LSA were low and that the LSA should be revascularized only in the presence of stroke or upper extremity ischemia.[10,11] Therefore, to answer the controversy above, more studies are needed to figure it out.

In this study, we used castor single-branched aortic stent-graft to reconstruct the LSA in situ and further compared the outcomes of patients who had their LSAs totally covered with those who had the LSAs reconstructed.

Materials and Methods

Study population

The study was conducted according to the principles of the Declaration of Helsinki and approved by the Ethics Committee of Qilu Hospital of Shandong University (February, 2017; KYLL-2017KS-195). Consent of patients has been obtained for the study. From January 2016 to December 2019, 387 patients with TBAD or IMH underwent TEVAR in our department. The indications for TEVAR were as follows: aortic rupture, pleural effusion, refractory arterial hypertension, descending aorta diameter >5.5 cm, persistent pain. In all, 134 patients were included in the present study. The inclusion criteria were as follows: (1) acute TBAD or IMH; (2) the LSA was involved by aortic dissection or hematoma; (3) the distance between the left common carotid artery (LCCA) and aortic dissection or hematoma is more than 15 mm. The exclusion criteria were as follows: (1) congenital connective tissue disease such as Marfan syndrome; (2) previous history of TEVAR; and (3) dominant left vertebral artery, right vertebral artery occlusion, and bilateral internal carotid artery stenosis. Choice of LSA management was determined by aortic anatomy and surgeon. According to the LSA management, patients were divided into two groups, LSA-covered group (n = 61) and LSA-revascularized group (with castor single-branched stent-grafts, n = 73). Aortic disease diagnosis was determined by computerized tomographic angiography (CTA). Preoperative CTA of circulus Willisii was not performed in all patients.

TEVAR procedure

All TEVAR procedures were performed under general anesthesia in a hybrid operation room. For the LSA-covered group, operation details have been described previously.[12] Initially, a 5-F angiographic pigtail catheter was inserted into the ascending aorta via the left radial artery, and angiography was performed to get the measurements of the thoracic aorta. Afterwards, according to the preoperative CTA and intraoperative angiography measurements, the stent-grafts, which were oversized by 5%–15%, were deployed over a stiff wire via open femoral access. Choice of suitable oversizing was determined by aortic anatomy and surgeon preference. Because of insufficient PLZ, all the patients' LSAs in this group were totally covered. After this, angiography was reperformed to assess distal perfusion and endoleak.

Castor single-branched stent-graft (Microport Medical, Shanghai, China) has been approved by the Chinese Food and Drug Administration and it was the first domestic unibody branch stent-graft (**Fig. 1**).[13,14] The anatomical criteria for castor device is as follows: (i) thoracic aortic dissection or hematoma, in which the LSA is involving and (ii) thoracic aortic dissection or hematoma, in which the distance between aortic dissection and LCCA is more than 15 mm. The procedures of castor single-branched stent-graft in the LSA-revascularized group were different from that in the LSA-covered group. Initially, two 6-F sheaths were inserted percutaneously into the left brachial artery and the left femoral artery, respectively. A 5-F angiographic pigtail catheter (Catheter A) with a guidewire was led from the left femoral artery to the ascending aorta via the true lumen and angiography was performed to get the measurements of the thoracic aorta. Another 5-F catheter (Catheter B) combined with a guidewire was introduced via the true lumen from the left brachial artery to the right femoral artery and it was exteriorized from the right femoral artery. The third pigtail catheter (Catheter C) with a guidewire was led via the true lumen from the right femoral artery to the ascending aorta and exchanged for a Lunderquist stiff guidewire. Afterwards, the traction wire on the end of the branch graft was inserted into the catheter B and exteriorized from the left brachial artery. The main body of castor single-branched stent-graft was sent to the descending aorta along the stiff guidewire. Meanwhile,

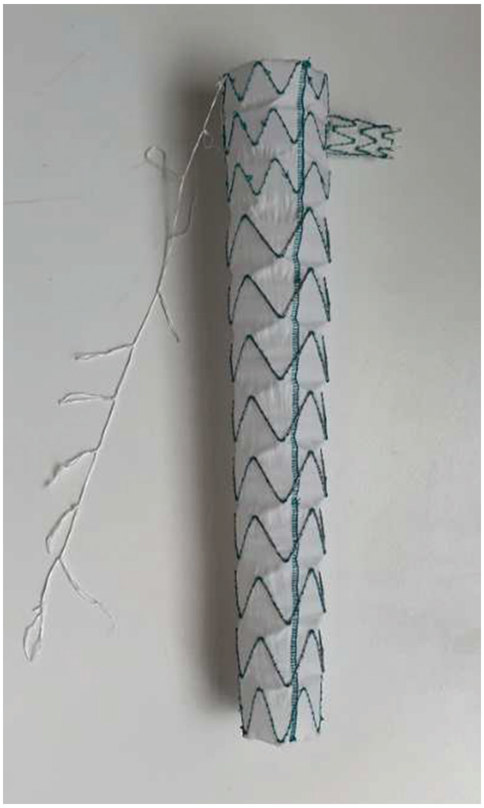

Fig. 1 Castor single-branched stent-graft.

the catheter B combined with the traction wire was kept moving with the main body of castor single-branched stent-graft. The position of the stent-graft was adjusted according to the marks and then both of the outer sheath and the soft sheath were removed. After this, the branch graft was dragged into the LSA by pulling the traction wire. Finally, the main body of castor single-branched stent-graft was deployed by pulling the trigger wire and the branch graft was subsequently deployed by withdrawing the traction wire (**Fig. 2**). The technical success rate of TEVAR was calculated according to the definition of technical success by Fillinger et al.[15] Patients in both groups were given aspirin (100 mg/per day) after TEVAR.

Data collection

Collected data included perioperative characteristics of patients, postprocedural morbidities, postprocedural mortality, 30-day morbidities, and 30-day mortality. The in-hospital outcomes were based on the medical records, and the 30-day outcomes were obtained by telephone interview. Sudden death with undetected blood pressure was regarded as aorta-related death. Stroke in the present study was determined by brain CT scan. The complications, such as pulselessness of left arm, intermittent claudication of left arm, and cold shoulder feeling, were used to evaluate the left arm ischemia. Endoleak definitions were as follows: type Ia (leak from the proximal stent-graft attachment site); type Ib (leak from the distal stent-graft attachment site); and type II (blood retrograde via branch arteries arising from the sealed segment).[15]

Statistical analysis

SPSS (Released 2012. IBM SPSS Statistics for Windows, Version 21.0, IBM Corp, Armonk, NY, IBM Corp.) was used for analysis. Continuous variables were compared by a t-test or the Mann–Whitney U test according to whether they were normally distributed and were expressed as the mean ± standard deviation (M ± SD) or median (interquartile range). Categorical variables were expressed as percentages, and analyzed by chi-square and Fisher's exact tests. $P < 0.05$ was considered statistically significant.

Results

Patient characteristics

There were 61 and 73 patients in the LSA-covered group and the LSA-revascularized group, respectively. The mean age of patients in the LSA-covered group was 57.3 ± 13.8 years, and male patients accounted for 82.0%. Hypertension was found in 91.8% patients in the LSA-covered group, and smoking was confirmed in 21.3% patients. Additional details of patient characteristics are listed in **Table 1**. All these data of patient characteristics did not show significant differences between the two groups.

Operation data related with TEVAR

The technical success rate of TEVAR in the LSA-revascularized group was 98.6%. The median operation time was 75 minutes (interquartile range: 40 minutes) in the LSA-revascularized group and 70 minutes (interquartile range: 30 minutes) in the LSA-covered group ($P = 0.42$). The incidence of endoleak Ia in the LSA-revascularized group was 1.4%, which was not statistically lower compared with the LSA-covered group (3.3%, $P = 0.59$). The incidences of endoleak Ib and endoleak II were similar between the LSA-revascularized and the LSA-covered group. There were also no significant differences in hospital stay, stent-graft length, and stent-graft number between the two groups (**Table 2**). The brand and number of the aortic stent-grafts are presented in **Table 2**.

Fig. 2 TBAD (**A** and **B**) and IMH (**C** and **D**) were treated by TEVAR with Castor single-branched stent-graft. The LSA was revascularized in situ. IMH: intramural hematoma; LSA: left subclavian artery; TBAD: type B aortic dissection; TEVAR: thoracic endovascular aortic repair

In-hospital complications after TEVAR

In-hospital complications are presented in **Table 3**. In-hospital death was observed in two patients and one patient in the LSA-covered group versus the LSA-revascularized group (P = 0.59), respectively. In the LSA-covered group, two patients were diagnosed with brain stem stroke and the other two patients were confirmed with occipital lobe stroke. The stroke incidence in the LSA-covered group was statistically higher than that in the LSA-revascularized group (P = 0.041). Six patients in the LSA-covered group were observed with ischemia of the left arm such as pulselessness of left arm, intermittent claudication of left arm, and cold shoulder feeling (P = 0.008). The total number of complications in the

Table 1 Patient characteristics

	LSA-covered group (n = 61)	LSA-revascularized group (n = 73)	P value
Age, years, M±SD	57.3 ± 13.8	57.1 ± 12.7	0.95
Male	50/61 (82.0%)	57/73 (78.1%)	0.58
Hypertension	56/61 (91.8%)	61/73 (83.6%)	0.15
Drinking	7/61 (11.5%)	15/73 (20.5%)	0.16
Smoking	13/61 (21.3%)	25/73 (34.2%)	0.098
Uremia	0/61 (0%)	1/73 (1.4%)	1.00
Diabetes mellitus	4/61 (6.6%)	4/73 (5.5%)	1.00
COPD	2/61 (3.3%)	1/73 (1.4%)	0.59
Cardiac disease	5/61 (8.2%)	13/73 (17.8%)	0.13
SCr, μmol/L, median (IQR)	76 (26)	73 (30.5)	0.71
Aortic disease type			0.063
TBAD	46/61 (75.4%)	44/73 (60.3%)	
IMH	15/61 (24.6%)	29/73 (39.7%)	
PLD diameter, mm	30.7 ± 2.4	31.0 ± 1.8	0.36
PLD length in Zone 2, mm	19.9 ± 3.1	19.2 ± 2.7	0.17
Aortic arch type			0.63
Type I	7	10	
Type II	45	56	
Type III	9	7	
Dominant vertebral artery			0.96
Right dominant	27/61 (44.3%)	32/73 (43.8%)	
Equally dominant	34/61 (55.7%)	41/73 (56.2%)	
History of cerebral infarction	2/61 (3.3%)	5/73 (6.8%)	0.45
Upper limb ischemia	0/61 (0%)	0/73 (0%)	–

COPD: chronic obstructive pulmonary disease, IMH: intramural hematoma, IQR: interquartile range; LSA: left subclavian artery; PLD: proximal landing zone; SCr: serum creatinine; TBAD: type B aortic dissection

LSA-covered group was much higher than that in the LSA-revascularized group. There were no statistical differences in paraplegia, myocardial infarction, pulmonary infection, renal failure, and puncture site infection between the two groups.

30-day complications after TEVAR

The 30-day complications after TEVAR are listed in **Table 4**. One more death was observed during the 30-day follow-up in the LSA-covered group (total number of 30-day death = 3, P = 0.33). The incidence of 30-day stroke in the LSA-covered group is significantly higher than that in the LSA-revascularized group (5 vs. 0, P = 0.018). A statistical difference in the occurrence of the left arm ischemia was observed between the two groups (7 vs. 0, P = 0.003).

Discussion

The present study aimed to present the early outcomes of LSA coverage and revascularization during TEVAR. The results showed that the incidence of stroke was significantly higher in the LSA-covered group compared with the LSA-revascularized group. Ischemia of the left arm occurred in more patients in the LSA-covered group. The operation time in the LSA-revascularized group using castor single-branched stent-graft was not statistically longer compared to the LSA-covered group. No statistical difference was found in the incidences of paraplegia, endoleak, in-hospital mortality, and 30-day mortality.

TEVAR has been widely used for the treatments of TBAD or IMH.[16,17] An adequate PLZ (>1.5 cm) was the key for a successful TEVAR to avoid stent-graft migration.[18] It has been shown that nearly 40% LSA needed to be covered intentionally to obtain an adequate landing zone.[19] LSA coverage reduces the blood supply of the left arm, spinal cord, and posterior cerebral circulation and patients may not tolerate this change. There were several options available to revascularize LSA, including carotid-subclavian bypass, fenestrated stent-graft, chimney technique, hybrid technique. Compared to the extensive trauma and the higher risks of carotid-subclavian bypass and hybrid technique, endovascular repair is a minimally invasive procedure with mature operation

Table 2 The operation data

	LSA-covered group (n = 61)	LSA-revascularized group (n = 73)	P value
Technical success	59/61 (96.7%)	72/73 (98.6%)	0.59
Operation time, min, median (IQR)	70 (30)	75 (40)	0.42
Stent-graft length, mm, M±SD	198.4 ± 44.5	204.4 ± 22.7	0.34
Hospital stay, days, median (IQR)	10 (6)	10 (4.5)	0.62
Patients with one stent-graft	53/61 (86.9%)	70/73 (95.9%)	–
Ankura (Lifetech, China)	9	0	–
Hercules-T (Microport, China)	22	0	–
Castor-TM (Microport, China)	0	70	–
Grikin (Grikin, China)	22	0	–
Patients with two stent-grafts	8/61 (13.1%)	2/73 (2.7%)	–
Ankura+ Ankura	2	0	–
Hercules-T+ Hercules-T	5	0	–
Castor-TM+ Hercules-T	0	2	–
Grikin+ Grikin	1	0	–
Patients with three stent-grafts	0/61 (0%)	1/73 (1.4)	–
Castor-TM +2 Hercules-T	0	1	–
Total number of aortic stent-grafts	69	77	–
Endoleak			
Type Ia	2/61 (3.3%)	1/73 (1.4%)	0.59
Type Ib	1/61 (1.6%)	1/73 (1.4%)	1.00
Type II	1/61 (1.6%)	1/73 (1.4%)	1.00

IQR: interquartile range; LSA: left subclavian artery; M ± SD: mean ± standard deviation

technology. In the present study, we observed that the operation time was not significantly longer in the LSA-revascularized group using castor single-branched stent-graft compared with the LSA-covered group using conventional thoracic stent-graft. We also found that the procedure of castor single-branched stent-graft was less complicated compared with fenestrated stent-graft. In addition, the revascularization of the LSA in situ with castor single-branched stent-graft was physiological. The results suggested that castor single-branched stent-graft may be a good choice for the LSA revascularization.

The LSA is the main source of blood flow to the left arm. It has three main branches, the left vertebral artery, the left internal thoracic artery, and the left thyrocervical trunk. Through these branches, the LSA has collateral circulations with other organs. If the collateral circulations are not enough, an acute coverage of the LSA may induce the left arm ischemia and cause complications, such as pulselessness of left arm, intermittent claudication of left arm, and cold shoulder feeling. In our experience, partial coverage of the LSA did not cause the left arm ischemia in patients undergoing TEVAR. However, the consequence of total LSA coverage is unclear. In the present study, seven patients in the LSA-covered group were observed with left arm complications, while no patient in the LSA-revascularized group suffered from these complications (P = 0.003). This result suggested that the LSA should be revascularized during TEVAR to reduce the risks of the left arm ischemia.

The left vertebral artery originating from the LSA is a basic component of the vertebrobasilar artery, which blood flow accounts for two-fifths of the supply of the posterior cerebral artery.[20] The total coverage of LSA orifice will dramatically reduce the blood flow of the LSA and may reverse the blood direction in the left vertebral artery, which is called subclavian steal syndrome. If the Willis circle is intact, and the right vertebral artery is not narrow, the LSA coverage may not increase the risk of stroke.[21,22] However, it is difficult to accurately assess the integrality of the Willis circle for all patients, especially in an emergency. Several studies have concluded that the incidence of stroke was higher in the LSA-covered patients compared with those who have the LSA revascularized.[9,23,24] In the present study, the incidences of in-hospital and 30-day stoke in the LSA-covered group were significantly higher compared with the LSA-revascularized group. In the LSA-revascularized group, no patient suffered from stoke during in-hospital period or 30-day follow-up. Therefore, we further confirmed that the LSA should be prophylactically revascularized to avoid stroke during TEVAR. Stroke during TEVAR could occur for other reasons

Table 3 In-hospital complications after TEVAR

	LSA-covered group (n=61)	LSA-revascularized group (n=73)	P value
Paraplegia	0/61 (0%)	0/73 (0%)	–
Myocardial infarction	0/61 (0%)	0/73 (0%)	–
Stroke	4/61 (6.6%)	0/73 (0%)	0.041
Pulmonary infection	3/61 (4.9%)	1/73 (1.4%)	0.33
Puncture site infection	2/61 (3.3%)	1/73 (1.4%)	0.59
Renal failure	0/61 (0%)	0/73 (0%)	–
Access vessel complication	0/61 (0%)	1/73 (1.4%)	1.00
Ischemic symptoms of the left arm	6/61 (9.8%)	0/73 (0%)	0.008
In-hospital mortality	2/61 (3.3%)	1/73 (1.4%)	0.59
In-hospital aortic-related mortality	0/61 (0%)	0/73 (0%)	–
Total number of complications	17	4	–

LSA: left subclavian artery; TEVAR: thoracic endovascular aortic repair

Table 4 30-day complications after TEVAR

	LSA-covered group (n = 61)	LSA-revascularized group (n = 73)	P value
30-day mortality	3/61 (4.9%)	1/73 (1.4%)	0.33
30-day aortic-related mortality	0/61 (0%)	0/73 (0%)	–
Stroke	5/61 (8.2%)	0/73 (0%)	0.018
Ischemic symptoms of the left arm	7/61 (11.5%)	0/73 (0%)	0.003
Paraplegia	0/61 (0%)	0/73 (0%)	–
P-SINE	0/61 (0%)	0/73 (0%)	–
D-SINE	0/61 (0%)	0/73 (0%)	–

D-SINE: distal stent graft-induced new entry; LSA: left subclavian artery; P-SINE: proximal stent graft-induced new entry; TEVAR: thoracic endovascular aortic repair

besides LSA malperfusion. As we know, aortic atheromatous plaque and air embolism may also lead to stroke. In the present study, we took some measures to prevent atheromatous and air embolism. For every TEVAR, air in the stent-graft sheath was fully eliminated with abundant heparin physiological saline. To prevent atheromatous embolism, procedures of TEVAR were delicate and gentle along the guide wire.

The blood flow of spinal cord is mainly supplied by anterior median longitudinal arterial trunk and a pair of posterolateral trunks. The size of these arteries is much smaller in the thoracic region compared with that in the cervical and lumbar region. Therefore, the blood supply of spinal cord in the thoracic region is the poorest.[25,26] As an important supplement, the radiculo-medullary arteries, especially the Adamkiewicz artery, reinforce the blood supply of spinal cord in the thoracic region.[27] The stent-grafts in TEVAR need to cover a segment of thoracic aorta, which may cause the ischemia of spinal cord. Paraplegia, as a result of the ischemia of spinal cord, is a catastrophic complication of TEVAR. The risk factors for paraplegia have been reported including long segment coverage of thoracic aorta, advanced age, LSA coverage, prior abdominal aortic repair, and perioperative hypotension.[28] In our present study, the average stent-graft length in the LSA-covered group and the LSA-revascularized group were 198.4 ± 44.5 mm and 204.4 ± 22.7 mm, respectively. No patient, even in the LSA-covered group suffered from paraplegia during the in-hospital period or 30-day follow-up. According to the results, we concluded that when the LSA was totally covered in TEVAR, long segment coverage of thoracic aorta should be avoided to prevent paraplegia.

Endoleak was the most common complication in TEVAR. It has been reported that the LSA coverage could reduce the incidence of endoleaks in patients with inadequate PLZ.[29] In the present study, only two patients in the LSA-covered group were observed with type Ia endoleak, which was in accordance with previous studies. Chimney technique in TEVAR was widely used to revascularized the LSA. However, more and more evidence has shown that chimney technique increased the incidence of endoleaks and brought a higher reintervention rate. Lindblad et al.[30] revealed that the early incidence of endoleak

I of chimney technique was 11%, and 42% of these endoleaks needed reinterventions. In the present study, the incidence of endoleak Ia in the LSA-revascularized group was 1.4%, which was much lower compared with that of chimney technique. The incidence of type Ib endoleak in the LSA-revascularized group was also 1.4%, which suggested that the branch of the castor stent-graft could be closely attached to the wall of the LSA and effectively avoided blood retrograde from the LSA.

The present study was also with several limitations. First, it was a retrospective study and the selection bias may have influenced the results. Second, the sample in this study was small, and all the patients were from a single center. Besides, the long-term follow-up should be carried out to obtain the complete and precise results. Carotid subclavian bypass is also widely used for the LSA revascularization. As another limitation, we will carry out the comparison of outcomes between carotid subclavian bypass and Castor stent-graft in the future study.

Conclusion

The LSA should be revascularized during TEVAR to reduce the incidences of stroke and left arm ischemia. The castor single-branched stent-graft was feasible and safe for treating TBAD or IMH involving the LSA.

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Disclosure Statement

The authors have no conflicts of interest to declare.

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