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Hybrid versus in vitro fenestration for preserving the left subclavian artery in patients undergoing thoracic endovascular aortic repair with unfavorable proximal landing zone

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Abstract

Purpose: To compare hybrid and in vitro fenestration procedures for preserving the left subclavian artery in thoracic endovascular aortic repair (TEVAR) with unfavorable proximal landing zone.

Methods: Retrospective comparison of data from 49 consecutive patients who underwent left subclavian artery revascularization during TEVAR by either hybrid or fenestration approaches from January 2015 to March 2018. Procedural duration, and 30-day rates of procedural success, mortality and complications (endoleaks, cerebral infarction, spinal cord ischemia, left arm ischemic symptoms, and delirium) were compared.

Results: For hybrid procedure ($n = 32$) vs. fenestration ($n = 17$) groups, which were age and gender matched: procedural success rate was 100%, with significantly longer procedural duration (248.4 ± 40.9 vs. 60.6 ± 16.8 min; $t = -22.653$, $P = 0.000$) and similar 30-day complication rate (18.8% vs. 11.8%; $\chi^2 = 0.397$, $P = 0.529$). At 12.7 ± 9.3 months' follow-up, there were no cases of death, spinal cord ischemia, or other complications in either group.

Conclusions: In this retrospective, single-center comparison, both hybrid and in vitro fenestration approaches for reconstructing the left subclavian artery in TEVAR with unfavorable proximal landing zone appeared safe and effective, with shorter procedural duration for fenestration. Larger studies with longer term follow-up are warranted.

Keywords

Aortic dissection, hybrid procedure, fenestration, thoracic endovascular aortic repair, left subclavian artery

Introduction

In recent years, thoracic endovascular aortic repair (TEVAR) has developed into a dominant treatment procedure for aortic dissection (AD).[1,2] A precondition of conventional TEVAR is that the lesions should be more than 15 mm from the left subclavian artery (LSA), otherwise the handling of LSA becomes a concern. With an increasing incidence of ADs, to reduce complications such as postoperative cerebral infarction, more and more cases of ADs require reconstruction of LSA.[3] The currently available methods for reconstructing LSA mainly include the hybrid techniques (including subclavian carotid artery bypass and LSA transposition), the chimney techniques (including the branch stent technique), and in situ fenestration and pre-fenestration (or slotting) techniques, among others. We performed hybrid or pre-fenestration techniques to reconstruct LSA, and we compared their outcomes in the present study.

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Materials and methods

Study population and study design

Between January 2015 and March 2018, a total of 49 consecutive patients (42 men; mean age, 53.7 ± 11.8 (range, 29–77 years)) with Stanford type B AD who were admitted to the Department of Vascular Surgery of the Shandong Provincial Hospital to undergo TEVAR treatment and required LSA reconstruction were included in this retrospective analysis. All patients underwent preprocedural computed tomography angiography (CTA) assessment, based on which the diagnosis was confirmed and a treatment plan was developed.

Patients were included retrospectively if they met all of the following criteria: history of hypertension; Stanford type B AD; and TEVAR should have sufficient anchoring zone to cover LSA for reconstruction based on preprocedural CTA and intraprocedural angiography findings. Patients were excluded if they met any of the following criteria: cases involving the brachiocephalic trunk and the left common carotid artery; LSA reconstruction cases by the chimney and in situ fenestration technique or other techniques; traumatic AD caused by injury and other factors; AD caused by connective tissue diseases such as Marfan syndrome; cases with limb and visceral ischemia requiring emergency surgery; known sensitivities or allergies to contrast agents.

Cases were grouped according to the LSA treatment method. A total of 32 patients were included in the hybrid procedure group, and 17 patients were included in the pre-fenestration group.

Procedures

Hybrid procedure. Under general anesthesia, the patients first underwent left common carotid artery–LSA artificial vessel bypass (Figure 1) or LSA transposition (the LSA was transpositioned to the left common carotid artery for end-to-side anastomosis). Then, TEVAR was performed with one femoral artery incised or directly punctured for access, and a suitable coated stent, which was selected according to the contrast findings to completely cover the LSA, was advanced and released after accurate positioning. Angiographic examination was used to ascertain treatment outcome, any possible endoleak, and LSA blood flow (Figure 2).

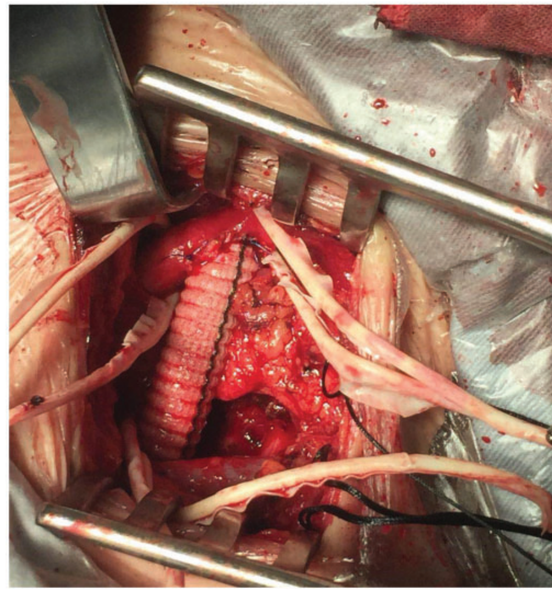

Figure 1. Left common carotid artery–left subclavian artery bypass.

Figure 2. After hybrid procedure, angiography showing accurate and fixed stent position, completely isolated rupture, left common carotid artery–left subclavian artery bypass graft patency, and smooth left distal subclavian artery blood flow.

Pre-fenestration technique. Under general anesthesia, one femoral artery was incised or directly punctured for access; using CTA and intraprocedural angiography, the distance of the rupture from the LSA and the distal end of the left common carotid artery was determined, and the diameter of the proximal anchorage zone of the rupture, the diameter of the LSA, and other measurements were taken. Based on the latter measurements, the coated stent underwent pre-fenestration and was introduced and released (Figure 3). Accurate positioning was confirmed by postprocedural angiography, and the insulation effect of the main coated stent, any possible endoleak, and LSA blood flow were evaluated (Figure 4).

Figure 3. Devices required for pre-fenestration: sterile marker pen, ruler, sharp knife, and infusion rubber tubing.

Figure 4. Angiography after pre-fenestration showing good isolation effect, accurate fenestration alignment, and well-developed left subclavian artery.

Study outcomes and definitions

Study outcomes were: (1) rate of procedural success, defined as successful completion of left common carotid artery-LSA bypass or LSA transposition, with successful placement and release of the aortic stent graft at the predetermined position for hybrid procedure; or successful placement and release of the aortic stent graft at the predetermined position, with fenestration position well aligned with the LSA (effective alignment area > 1/2 LSA fenestration area) for pre-fenestration approach; (2) Procedural duration, defined as the time taken from initial puncture or incision to completing dressing of the puncture point or incision site; and (3) Rate of complications including type I to IV endoleak, ipsilateral and contralateral cerebral infarction, spinal cord ischemia (bilateral or unilateral limb sensory and/or movement disorder), left upper limb ischemia (including ischemic necrosis, rest pain, labor pain, and inability to lift), and postprocedural delirium (disorder of consciousness, disorders of behavior, aimlessness, inability to concentrate), and death defined as all-cause mortality.

Follow-up

All patients were followed up by a combination of telephone interview, and outpatient review and assessment including physical examination, and B-ultrasound or CTA, which were generally recommended at three to six months post procedure.

Statistical analysis

The SPSS16.0 statistical software was used for statistical analysis of data. Continuous variables are expressed as mean ± standard deviation and were compared using the *t*-test. Categorical variables are expressed as frequency and percentage and were compared using the Chi square or Fisher's exact tests. $P < 0.05$ was considered statistically significant.

Results

Baseline characteristics were similarly distributed between hybrid procedure group and pre-fenestration group: mean age was 52.4 ± 12.3 years and 56.0 ± 10.6 years, respectively ($t = -1.011$, $P = 0.317$); and male to female ratio was 28:4 and 14:3, respectively ($\chi^2 = 0.240$, $P = 0.624$). All patients had stable B-type AD, combined with hypertension and no limb or visceral ischemia requiring emergency surgery. All patients were excluded from genetic diseases such as Marfan syndrome. Baseline characteristics between the two groups are listed in Table 1.

In hybrid procedure group vs. pre-fenestration group: procedural success rate was 100%, without spinal cord ischemia or left upper limb ischemia cases post procedure; mean procedural duration was significantly higher (248.4 ± 40.9 vs. 60.6 ± 16.8 min, respectively; $t = -22.653$, $P = 0.000$); there were three cases of

Table 1. Baseline characteristics.

	Hybrid procedure group	Pre-fenestration group	P
Mean age	52.4 ± 12.3 years	56.0 ± 10.6 years	0.317
Male to female ratio	28:4	14:3	0.624

Table 2. Treatment outcomes.

	Hybrid procedure group	Pre-fenestration group	P
Procedural success rate	100%	100%	0.000
Mean procedural duration	248.4 ± 40.9 min	60.6 ± 16.8 min	0.000
Incidence of complications within 30 days	18.8%	11.8%	0.529

endoleak (one receiving intra-operative phase I treatment and two no treatment) vs. one case of endoleak that did not require further treatment before patient discharge, respectively, and similar incidence of complications in the early postprocedural period (i.e. within 30 days: 18.8% vs. 11.8%, respectively; $\chi^2 = 0.397$, $P = 0.529$). In the hybrid procedure group, there was one case of postoperative cerebral infarction with symptom resolution by one-month re-examination post procedure, and two cases of delirium with symptom resolution within seven days. In the pre-fenestration group, one case of delirium was noted, with symptom resolution within three days. Treatment outcomes of the two groups are listed in Table 2.

All patients were followed up for 1–36 months. At mean 12.7 ± 9.3 months' follow-up, there were no deaths, and CTA revealed no secondary endoleaks, graft displacement, artificial vessel or LSA stenosis, occlusion or dissecting aneurysm, among other possible complications.

Discussion

In the present retrospective, single-center analysis, reconstruction of LSA by hybrid surgery or fenestration was associated with similar safety and effectiveness outcomes in TEVAR with unfavorable landing zone. The fenestration approach had shorter procedural duration, which might have implications on lowering the incidence of postoperative brain-related complications, such as cerebral infarction and delirium.

TEVAR has become the preferred treatment of Stanford type B AD.[4] In some cases, covering LSA and obtaining adequate stent anchoring area is the basic guarantee for improving the indications and efficacy of thoracic aortic endovascular repair procedures. Directly covering LSA is the easiest way to extend the proximal anchoring zone, but this method on the other hand increases the risk of cerebral ischemia and paraplegia.[5] Therefore, LSA becomes a key factor of consideration for TEVAR.[6] Reconstruction of the LSA ensures the blood flow in the vertebral artery after operation, and thus reduces the risk of cerebral infarction; meanwhile, it reduces the incidence of paraplegia and left limb ischemia symptoms.[7] Therefore, we believe that, in order to further ensure the safety of the procedure, reduce the occurrence of postoperative complications, and improve the quality of life of patients, careful imaging evaluation should be carried out in the perioperative period, and the LSA should be reconstructed by various technical means only if possible.

The currently available methods for reconstructing LSA mainly include the hybrid techniques (subclavian carotid artery bypass, LSA transposition, etc.), the chimney techniques (including the branch stent technique), in situ fenestration, and pre-fenestration (or slotting) techniques, etc. The chimney techniques are an optional way to rebuild LSA, but more attention should be paid to postoperative complications including type I endoleaks and patency of branch vessels.[8] The in situ fenestration technique, developed in recent years, features low endoleak rate, high success rate, high accuracy, and high practicability.[9] However, the in situ fenestration technique is restricted by difficulty in breaking through the membrane technique, long operation time in some cases, and increased duration of cerebral ischemia due to blockage of the blood flow in the branch artery after the coated stent is released, which may cause complications such as craniocerebral ischemia; fragments after breaking the membrane, if not effectively controlled, may cause arterial embolism with the corresponding symptoms. Fenestration-type or branch-type stents need to be customized, resulting in long waiting time and high price rendering it difficult to promote their clinical application in China. Therefore, it is of significance to explore extracorporeal pre-fenestration for reconstruction of the supra-arch vessel.[10] There have been reports on the use of aortic-coated stent for extracorporeal pre-fenestration.[11] The extracorporeal pre-fenestration technique allows timely treatment of more patients with high-risk complex abdominal aortic aneurysms that are near rupture. Pre-fenestration extends the anchoring zone to completely close the rupture of dissection while ensuring the patency of the branch arteries. The extracorporeal pre-fenestration technique can effectively shorten procedural duration with high operability, safety, and reliability. This study preliminarily proved that we have made full use of the existing stents and techniques to achieve satisfactory pre-fenestration results with domestic coated stents during the operation.

Buth et al. first reported successful use of bypass surgery to treat aortic arch lesions involving the supra-arch branch.[12] Currently, hybrid surgery reconstruction of LSA has become one of the mainstream treatment strategies for Stanford type B AD.[13] The combination of debranching treatment and TEVAR by hybrid surgery not only avoids the serious complications caused by conventional cryogenic extracorporeal circulation, large trauma and massive blood transfusion, but also compensates for the shortcomings of the TEVAR surgery in the treatment of complex arch lesions, extending the anchoring zone of Stanford type B AD and thus the indications of TEVAR.[14]

Our single-site experience with reconstruction of LSA by hybrid surgery or fenestration in TEVAR with unfavorable landing zone would favor the following practices: If in preoperative evaluation, the patient's general status is deemed poor, hybrid surgery under general anesthesia is disfavored because of its longer duration. In such a case, CTA evaluation for the pre-fenestration approach should aim to assess the patency of the bilateral carotid arteries, the degree of arteriosclerosis, the diameter and patency of the bilateral vertebral arteries and of the circle of Willis with particular focus on the patency of the basilar artery, and the bilateral posterior communicating arteries.

In general, hybrid surgery duration should be shortened as much as possible. During the operation, the nerves should be protected, and bleeding should be stopped expediently and thoroughly. If the proximal end of the LSA can be relatively easily dissociated, and if of sufficient length and closeness to the LSA, LSA transposition can be considered to avoid the use of artificial blood vessels and reduce cost and the incidence of complications such as postoperative graft infection. In addition, it is particularly important to note that reasonable vascular anastomotic sites and skilled surgical techniques are crucial to the success of LSA transposition. Therefore, we do not recommend inexperienced sites to discretionarily perform LSA transposition.

In the case of coated stent fenestration, the positioning marks of the commercial coated stent should be utilized, and the surrounding coating should be partially removed, with a diameter slightly larger than the LSA rupture. It is required to observe from the front and sides and keep in mind the shape of the metallic framework, the positioning marks, and their relative relationship with the fenestration. Changes to the stent structure should be minimized, and care should be taken not to rotate the stent when retracting it into the delivery system. Accurate CTA measurements before surgery and pre-definition of intraoperative angiography projection angles are key factors for extracorporeal stent fenestration.

We believe that extracorporeal pre-fenestration is more suitable for Stanford type B AD with the rupture at the lesser curvature side of the aortic arch because it keeps fenestration away from the AD rupture, thereby greatly reducing the chance for postoperative endoleaks. When performing the pre-fenestration technique, the guide wire should be kept in the ascending aorta. Poor alignment between the fenestration and the LSA can directly affect the reconstruction of the LSA. Lifelong follow-up visits should be mandatory for all patients because timely perioperative and postoperative management helps to avoid serious adverse events and to handle promptly any possible problems.[15,16]

Considering direct or partial coverage of LSA as an option when feasible would avoid the increased risks and costs of a hybrid procedure. However, the indications of selective LSA coverage to obtain an appropriate anchoring zone in TEVAR should be limited. Selectively rebuilding the LSA should follow an individualized treatment plan that considers disease status and consequences for the patient; preference of the patient should never be a decisive factor.

In summary, with the improvement of intracavity techniques and stent design, the comprehensive application of TEVAR in combination with hybrid and pre-fenestration techniques offers alternatives in dealing with the LSA during the treatment of Stanford type B ADs, rendering it is possible to reduce the incidence of postprocedural complications and mortality. This study has preliminarily confirmed that, provided careful evaluations are carried out, both the hybrid and pre-fenestration approaches provide safe and effective means to reconstruct LSA with satisfactory results in TEVAR with unfavorable landing zone. In view of the small number of cases in this study, the long-term efficacy of both approaches warrants further study in larger populations with longer term follow-up.

Declaration of conflicting interests

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

Ethical approval

The acquisitions were performed with the approval of the Human Research Ethics Committee of Shandong Provincial Hospital Affiliated to Shandong University.

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Informed consent

Written informed consents were obtained from all participants for their clinical records to be used in this study.

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