Cardiovasc Intervent Radiol (2019) 42:19–27
https://doi.org/10.1007/s00270-018-2079-9

Fenestrated Thoracic Endovascular Aortic Repair Using Physician-Modified Stent Grafts (PMSGs) in Zone 0 and Zone 1 for Aortic Arch Diseases

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Received: 28 June 2018 / Accepted: 14 September 2018 / Published online: 11 October 2018

Abstract

Purpose To evaluate the outcomes of fenestrated thoracic endovascular aortic repair (f-TEVAR) using physician-modified stent grafts (PMSGs) in zone 0 and zone 1 for aortic arch diseases.

Methods f-TEVAR using PMSGs in Z0 and Z1 was performed on ten high-risk patients for open surgery from November 2015 to September 2017. Indications were complicated acute type B dissection (ABAD) with retrograde dissection involving the mid-arch (n = 1), distal arch aneurysms (n = 3), mid-arch aneurysms of the inner arch curvature (n = 3) and penetrating aortic ulcer located in the mid- or proximal arch (n = 3). Pre-, intra- and postoperative clinical data were recorded.

Results The median patient age was 61 (range 45–81) years, and 9 (90%) patients were men. Ten PMSGs (Medtronic Valiant stent grafts, n = 1; Relay thoracic stent grafts, n = 4; Cook TX2 device, n = 5) were deployed. PMSGs were deployed from Z0 and Z1 in 5 and 5 patients, respectively. Double small fenestrations for the left subclavian artery (LSA) and the left common carotid artery (LCCA), respectively, were created in 3 patients. Triple small fenestrations for the innominate artery (IA), the LCCA and the LSA, respectively, were created in 2 patients. One large fenestration for both the IA and the LCCA combined with one small fenestration for the LSA was created in 3 patients. One large fenestration for the LCCA combined with one small fenestration for the LSA was created in 2 patients. Posterior diameter-reducing ties were added to all the devices except to one Valiant stent graft. All but 2 patients underwent elective procedure. Median duration for stent graft modifications was 105 (range 90–125) min. The technical success rate was 90%. Overall mortality was 10% (1/10). One patient died of sudden cardiac arrest intraoperatively after the deployment of the PMSG and all the supra-aortic branch stents. Mean operative time was 106.0 ± 43.0 min, and fluoroscopy time was 30.6 ± 22.9 min. There were no type I or type III endoleaks, perioperative neurological complications or spinal cord ischemia. Median length of stay was 8 (range 4–35) days. Nine patients survived at mean 13.3 (range 6.0–19.0) months follow-up. Retrograde dissection occurred in one patient of Z0 group 40 days post-f-TEVAR and resolved after open repair. During follow-up, all target vessels remained patent without fenestration-related type I or III endoleaks.

Conclusions f-TEVAR using PMSGs in Z0 and Z1 for the treatment of aortic arch diseases in high-risk patients is feasible in the hands of experienced operators.

Keywords Aortic arch disease · Fenestration · Thoracic endovascular aortic repair

Abbreviations

f-TEVAR	Fenestrated thoracic endovascular aortic repair
PMSG	Physician-modified stent graft
ABAD	Acute type B dissection
CTA	Computed tomography angiography

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IA	Innominate artery
LCCA	Left common carotid artery
LSA	Left subclavian artery
ASA	American Society of Anesthesiologists
RTAD	Retrograde type A aortic dissections
RAO	Right anterior oblique
LAO	Left anterior oblique

Introduction

Aortic arch diseases are challenging for cardiac surgeons and vascular surgeons. Open surgery, which requires cardiopulmonary bypass and deep hypothermic circulatory arrest, has high mortality and morbidity ranging from 4% to 10% [1]. Debranching thoracic endovascular aortic repair (TEVAR) is the most common approach to treat high-risk patients with aortic arch diseases to extend the proximal sealing zone [2]. Alternatively, the chimney technique and graft fenestration in situ have been used to achieve endovascular solutions [3, 4]. In a series of 37 high-risk patients who were treated with semi-custom-made fenestrated endografts for aortic arch diseases, Kurimoto et al. [5] described mortality and stroke rates of 0% and 8%, respectively, which compares favorably to the results after open surgery. Use of custom-made fenestrated/branched stent grafts is associated with high device costs and long manufacturing delays; thus, physician-modified fenestrated stent grafts (PMSGs) are considered to be suitable for high-risk patients in acute/subacute settings or unable to bear the high costs. In this study, we describe our initial experience of fenestrated TEVAR (f-TEVAR) using PMSGs in zone 0 and zone 1 for aortic arch diseases to assess the efficacy and safety of this technique.

Patients and Methods

This study was performed with approval of the Institutional Review Boards of Tianjin Medical University General Hospital and of Yala Medical Center Hospital. Informed consent for the procedure was obtained from all patients.

Technical success was defined as successful deployment of the device at the intended level with successful alignment of fenestrations to the supra-aortic branches and the absence of conversion to open surgery, death within 24 h, and types I or III endoleaks (angiographically detected).

Patient Identification

Between November 2015 and September 2017, a cohort of ten consecutive patients with aortic arch diseases underwent f-TEVAR using PMSGs at Tianjin Medical University General Hospital (n = 9) and Yala Medical Center Hospital (n = 1), and patient demographics, surgical indications, operative and postoperative details, follow-up, and outcomes were retrospectively reviewed. During the same time period, 53 cases with arch aneurysm underwent open arch repair at our center.

Preoperative Evaluation and Imaging

Preoperative imaging was performed with computed tomography angiography (CTA). Imaging measurement was taken using a dedicated 3D vascular software (3mensio Vascular™) with centerline luminal reconstructions. The device sizing, proximal and distal landing zone diameters and fenestration position were planned preoperatively (Fig. 1, Table 1).

Inclusion Criteria

All patients in our study were not suitable for open surgical repair. Reasons for selection of patients for endovascular therapy included advanced age, relevant comorbidities and complex prior open cardiothoracic surgery.

f-TEVAR using PMSGs in zone 0 and zone 1 was performed to extend the proximal landing zone of TEVAR. The inclusion criteria were descending aorta diseases involving the arch, and mid- or proximal arch diseases of the inner arch curvature. The exclusion criteria were mid- or proximal arch pathologies of the greater arch curvature and anatomical features (including the diameter and morphology of the aorta) precluding stent graft opposition to the aortic wall at the level of the target vessels.

Device Preparation

The procedure for endograft modification was described in detail previously [6]. Stent graft modifications were performed on a back table, commencing before the start of general anesthesia. The stent grafts were fully unsheathed. The fenestrations were marked on the fabric according to the preoperative measurements taken from centerline analysis and created using a cautery device. The loop of a snare (Amplatz GooseNeck, ev3, Plymouth, MN, USA) was sewn onto the edge of each fenestration for reinforcement. Small fenestrations were circular, had comparable size to the target vessels and did not have struts crossing them. Large fenestration was rectangular with stent struts going across it. One large fenestration for the

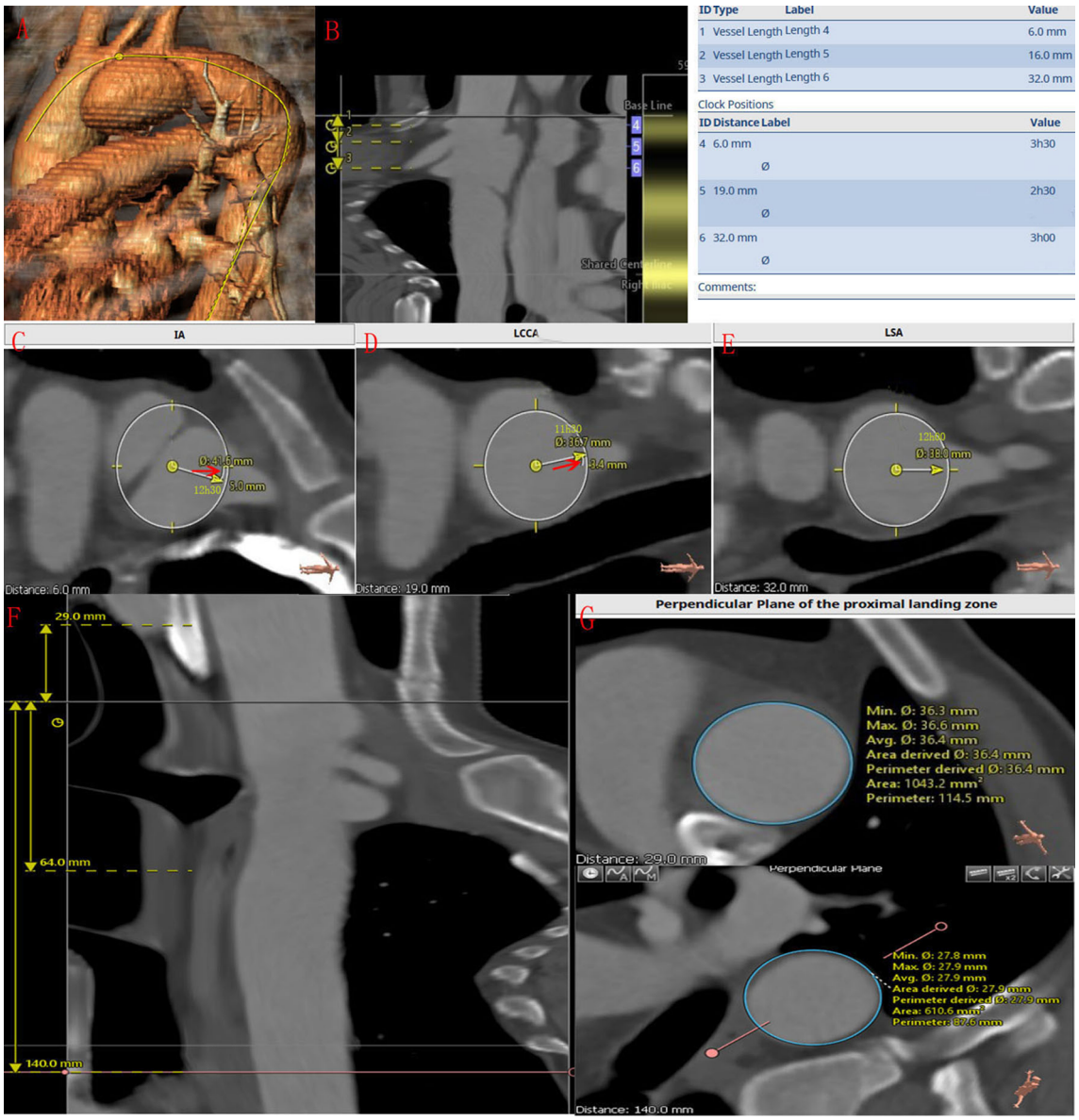

Fig. 1 Preoperative imaging measurements using a dedicated 3D vascular software (3mensio Vascular™). **A** Luminal reconstruction using the greater arch curvature line of the aortic arch. **B** Distances between the baseline (the proximal edge of the IA) to the central point of each of the supra-branches. **C** Clock position and arch length of the IA (red arrow). **D** Clock position and arch length of the LCCA (red arrow). **E** Clock position of the LSA. **F** Distances between the baseline to the proximal and distal landing zones. **G** Aortic diameter of the perpendicular plane of the proximal landing zone. **H** Aortic diameter of the perpendicular plane of the distal landing zone

left common carotid artery (LCCA) combined with one small fenestration for the left subclavian artery (LSA) was created in 2 patients (Fig. 2A). One large fenestration for both the innominate artery (IA) and the LCCA combined with one small fenestration for the LSA was created in 3 patients (Fig. 2B). Double small fenestrations for the LSA and the LCCA, respectively, were created in 3 patients (Fig. 3F). Triple small fenestrations for the IA, the LCCA and the LSA, respectively, were created in 2 patients (Fig. 2C).

Posterior diameter-reducing ties were added to the devices. One of the three proximal trigger Nitinol wires was retrieved from the gray inner cannula and used as the size-reducing wire in Zenith TX2 Cook device [7] (Fig. 2A, D). A 190-cm, 0.014-inch Nitinol guidewire (ASAHI, Nagoya, Aichi, Japan) used as diameter-reducing wire was introduced to pass into the soft sheath through two needle holes made in the outer sheath and inner soft sheath immediately distal to the section bearing the endograft in Relay thoracic stent graft (Fig. 3A–E). Posterior

Table 1 Data from preoperative CT images

Aortic PLZ		Z0 (n = 5)	Z1 (n = 5)
Baseline	–	Proximal edge of IA	Distal margin of IA
Branch distance (mm)	Baseline to IA central point	7.6 ± 0.8	–
	Baseline to LCCA central point	23.3 ± 6.2	9.2 ± 1.6
	Baseline to LSA central point	41.8 ± 7.8	29.8 ± 5.8
Supra-branch diameter (mm)	IA	13.3 ± 1.4	–
	LCCA	9.1 ± 0.2	8.9 ± 0.7
	LSA	10.5 ± 0.4	9.4 ± 0.4
Supra-branch clock	IA	12:24 ± 0:07	–
	LCCA	11:45 ± 0:10	11:54 ± 0:15
	LSA	12:00 ± 0:00	12:09 ± 0:18
Supra-branch arch length (mm)	IA	4.0 ± 0.9	–
	LCCA	2.0 ± 1.3	1.6 ± 1.4
	LSA	0.0 ± 0.0	1.9 ± 1.7
PLZ length (mm)	–	30.0 ± 6.3	23.0 ± 5.1
PLZ diameter (mm)	–	36.4 ± 2.6	34.0 ± 1.5

IA innominate artery, *LCCA* left common carotid artery, *LSA* left subclavian artery, *PLZ* proximal landing zone

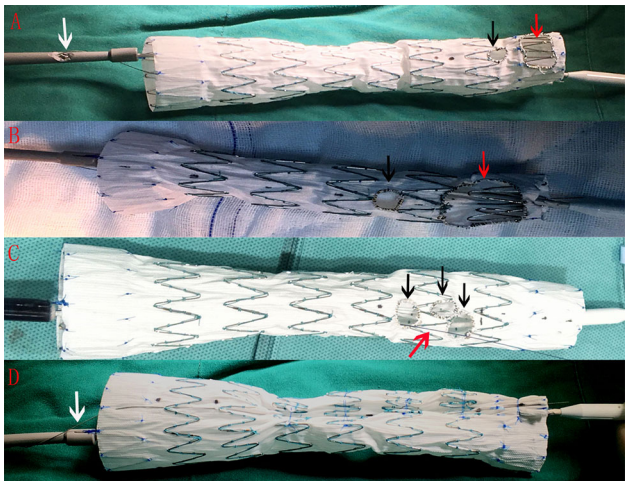

Fig. 2 The Zenith TX2 Cook device was fully unsheathed. **A** A small fenestration for the LSA (black arrow) combined with a large fenestration for the LCCA (red arrow) was created. One of the three proximal trigger Nitinol wires was retrieved from the gray inner cannula and used as the posterior size-reducing tie in the device (white arrow). **B** One large fenestration for both the IA and the LCCA (red arrow) combined with one small fenestration for the LSA (black arrow) was created. **C** Triple small fenestrations for the IA, the LCCA and the LSA, respectively, were created (black arrow), and a 300-cm, 0.014-inch Nitinol guidewire (ASAHI) was preloaded in the LSA fenestration (red arrow). **D** Posterior diameter-reducing wire was added to the device

diameter-reducing wires were added to all the devices except to one Valiant stent graft.

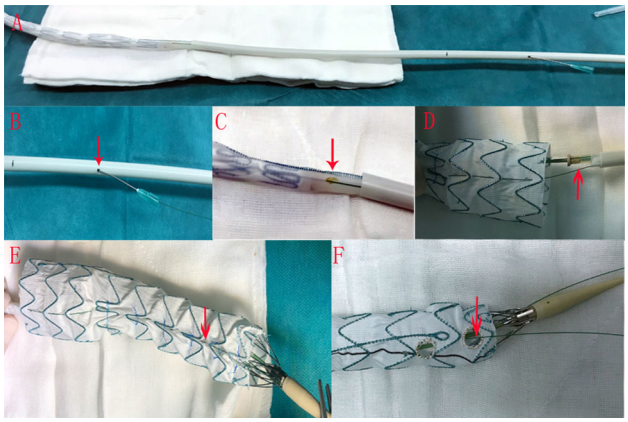

Fig. 3 **A** The outer sheath of Relay thoracic stent graft was fully retrieved. **B**, **C** A 190-cm, 0.014-inch Nitinol guidewire (ASAHI, Nagoya, Aichi, Japan) was introduced to pass into the soft sheath through two needle holes (red arrow) made in the outer sheath and inner soft sheath, respectively. **D**, **E** The posterior diameter-reducing tie was added (red arrow). **F** Double small fenestrations for the LCCA and the LSA, respectively, were created and a 300-cm, 0.014-inch Nitinol guidewire (ASAHI) was preloaded in the LCCA fenestration (red arrow)

Surgical Procedures and Techniques

Three arterial accesses were prepared to deliver the components when the PMSG was deployed from zone 1. The first was a common femoral access to introduce the PMSG over a Lunderquist guidewire positioned in the ascending aorta and to deliver the alignment covered stent [Viabahn (Gore & Associates, Flagstaff, Arizona, USA) or Fluency (C. R. Bard, Murray Hill, NJ)] to the LCCA or the LSA if

needed due to the large-sized sheath. The second one was a left common carotid access to catheterize the LCCA through the fenestration and to insert the alignment uncovered stent to the LCCA. The third one was a left brachial access to catheterize the LSA through the fenestration and to insert the alignment uncovered stent to the LSA. Besides the latter three arterial accesses, an additional right brachial access was needed to catheterize the IA through the fenestration and to insert the alignment stent to the IA when the PMSG was deployed from zone 0. All fenestrated endografts were constructed with a preloaded guidewire running through the LCCA (Fig. 3F) or the LSA fenestration (Fig. 2C), which may facilitate alignment of the fenestration to the target vessel during the procedure.

The PMSG was deployed sequentially, with the diameter-reducing wire allowing precise deployment of the endograft and preservation of the supra-aortic blood supply during the procedure of target vessel catheterization (Fig. 4A–C, E–G). Once Flexor sheaths were separately advanced into the aortic arch through the fenestrations from supra-aortic branch accesses, the posterior diameter-reducing wire was removed to fully deploy the endograft after its precise positioning. Appropriate alignment covered stents [Advanta V12 (Atrium Medical Corp, Hudson, NH)] and uncovered stents were deployed through the access sheaths, and the alignment covered stents (Viabahn or Fluency) were deployed into the LCCA or the LSA from the femoral access. Completion aortography was performed to confirm that the PMSG was at the intended level with target vessel patency and without endoleak (Fig. 4D, H).

Postoperative Follow-Up

CTA was performed prior to discharge and at 3, 6, and 12 months and annually thereafter to assess patency of supra-aortic branches and endoleak (Fig. 2C, F).

Statistical Analysis

Descriptive statistics were used for patient data and outcomes in this cohort.

Results

Patient Demographics and Presentation

The median patient age was 61 years old (range 45–81 years). Patient demographics and clinical features

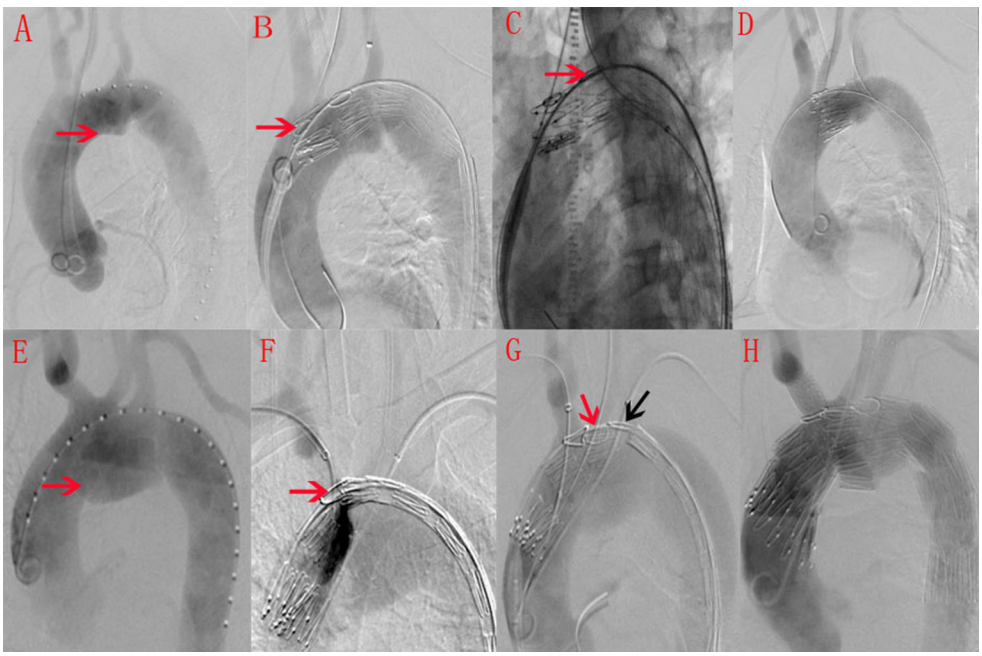

Fig. 4 Procedure of the fenestrated TEVAR using the physician-modified stent graft. **A** Diagnostic angiogram showing the penetrating aortic ulcer located in the mid-arch (red arrow). **B** Successful catheterization of the LCCA through the fenestration from the retrograde access (red arrow). **C** Successful catheterization of the LSA through the fenestration from the left brachial access (red arrow). **D** Final angiogram showing complete exclusion of the penetrating aortic ulcer with patency of the stented LCCA and LSA without endoleak. **E** Diagnostic angiogram showing the aneurysm located in the arch. **F** Successful catheterization of the IA through the fenestration from the right brachial access (red arrow). **G** Successful catheterization of the LCCA (red arrow) and the LSA (black arrow) through their respective fenestrations. **H** Final angiogram showing successful exclusion of the aneurysm with patency of all the supra-aortic stented branches without endoleak

are summarized in Table 2. Indications were ABAD with retrograde dissection involving the mid-arch (n = 1) or distal arch degenerative aneurysms (n = 3), mid-arch pseudo-aneurysms of the inner arch curvature (n = 3) and penetrating aortic ulcer located in the mid- or proximal arch (n = 3). All the patients were classified as ASA (American Society of Anesthesiologists) 3 or 4. Two young people who suffered from post-traumatic arch pseudo-aneurysm with craniocerebral injury were classified as ASA 3.

Stent Graft Configuration and Operative Data

Median duration for stent graft modifications was 105 (range 90–125) min. Ten PMSGs [Valiant stent grafts (Medtronic, Eden Prairie, MN, USA), n = 1; Relay thoracic stent grafts (Bolton Medical, Sunrise, FL, USA), n = 4; and Cook TX2 devices (Cook Medical, Bloomington, Ind), n = 5] were deployed. PMSGs were deployed from Z0 (n = 5) and Z1 (n = 5).

Ten alignment stents for the LSA (covered stent, n = 6; uncovered stent, n = 4) were deployed in all the patients. Eight alignment stents for the LCCA (bare metal stents, n = 7; covered stent, n = 1) were implanted in 8 patients. Two uncovered alignment stents for IA were deployed in 2 patients.

Table 2 Patient demographics

Variables	n = 10
Age (years)	61 (45–81)
Men	9 (90%)
Comorbid conditions	
Hypertension	8 (80%)
Coronary heart disease	4 (40%)
Renal insufficiency	0
Chronic obstructive pulmonary disease	4 (40%)
Diabetes mellitus	3 (30%)
Peripheral arterial disease	3 (30%)
Dyslipidemia	5 (50%)
Marfan syndrome	0
Previous cardiothoracic surgery	1 (10%)
Previous TEVAR	0
Previous AAA repair	2 (20%)
ASA class	
ASA 3	9 (90%)
ASA 4	1 (10%)

Data are shown as mean (range) or n (%)

AAA abdominal aortic aneurysm, *ASA* American Society of Anesthesiologists, *TEVAR* thoracic endovascular aortic repair

Covered stents for the supra-aortic branches ranged in diameter from 10 to 13 mm and in length from 25 to 40 mm. Uncovered stents for supra-aortic branches ranged in diameter from 9 to 14 mm and in length from 37 to 40 mm.

The common femoral artery was accessed to introduce the PMSG in 9 patients, and a left common iliac conduit was used in one patient due to severe stenosis of the left external iliac artery. Mean operative time was 106.0 ± 43.0 min, and fluoroscopy time was 30.6 ± 22.9 min.

Perioperative Outcomes and Complications

Outcomes of f-TEVAR are displayed in Table 3. Technical success rate was 90%, with precise placement of the PMSG, maintenance of supra-aortic branches perfusion and absence of endoleak. The overall in-hospital mortality was 10% (1/10). One patient died of sudden cardiac arrest after deployment of the PMSG and all the supra-aortic branch stents intraoperatively. Median hospital length of stay was 8 (range 4–35) days. There were no type I or type III endoleaks. There were no perioperative neurological complications and spinal cord ischemia.

Follow-Up

Nine patients survived to mean follow-up of 13.3 (range 6.0–19.0) months. Retrograde dissection occurred in one patient of the Z0 group 40 days post-f-TEVAR and resolved after open repair. During follow-up, all target

Table 3 Outcomes of f-TEVAR

Outcomes	n = 10
Operation time (min)	106.0 ± 43.0
Contrast dose usage (mL)	153.0 ± 27.7
Fluoroscopy time (min)	30.6 ± 22.9
Perioperative morbidity	
Endoleaks	0
Neurological complications	0
Spinal cord ischemia	0
Renal deterioration	0
In-hospital mortality	1 (10%)
Late events	
Aorta-related or aorta-unrelated death	0
Retrograde type A dissection	1 (10%)
Endoleaks	0
Target vessel occlusion	0

Data are presented as mean ± SD or n (%)

vessels remained patent. No fenestration-related type I or III endoleaks were observed.

Discussion

Conventional surgical repair of aortic arch pathologies with cardiopulmonary bypass and hypothermic circulatory arrest remains the gold standard for the treatment of aortic arch pathologies, but remains associated with high rates of mortality and morbidity [8, 9]. While less invasive than traditional open repair, hybrid surgical debranching procedure may still have surgery-related complications [10]. Endovascular repair of aortic arch pathologies is a solid treatment option with favorable outcomes [11]. Although chimney technique was a feasible alternative for proximal extension of the stent graft with preservation of supra-aortic branch blood flow, there are concerns on type Ia gutter endoleak. Fenestrated or branched TEVAR may be attractive therapies for aortic arch diseases. Custom-made stent grafts are currently still being investigated, and they are not yet commercially available. Moreover, custom-made devices are not suitable for patients in an emergent setting, or unable to wait for the 8-week manufacturing delays or to afford the high device costs [12]. Early use of PMSGs extends the benefits of aortic arch repair to patients in emergency settings or to high-risk patients unfit for other conventional options. Although there are several publications on small series of patients documenting acceptable short-term outcomes of f-TEVAR from zone 0, data on this issue are still lacking.

Expansion of TEVAR to aortic arch pathologies requires coverage of supra-aortic branches to obtain an adequate proximal landing zone. Fenestrated thoracic endografts were usually used in patients with complex mid- or proximal arch diseases of the inner arch curvature and in cases with descending aortic diseases encroaching the distal arch which is severely angulated and necessitating a longer length of proximal landing zone. Otherwise, branched endograft is more suitable for the treatment of aortic arch disease involving the greater part of the arch [13]. The pathologies of the patients in our study included complicated ABAD with retrograde dissection involving the distal arch, and complex mid- or proximal arch diseases of the inner arch curvature. In these patients, a greater part of the arch was uninvolved, and stent grafts could have apposition to the aortic wall at the level of the target vessels; thus, f-TEVAR was considered suitable.

During the procedure of f-TEVAR using PMSG in zone 0 and zone 1, cannulation and stenting of the supra-aortic branches require a relatively long time. The use of a diameter-reducing wire, which constrains the thoracic stent graft into a smaller diameter, maintains cerebral circulation and reduces cardiac afterload during target vessel catheterization. In our study, the diameter-reducing wire was not added to the first fenestrated stent graft. This patient died of sudden cardiac arrest despite completion of the technical procedure. The definite cause of death is unknown. The patient had serious coronary heart disease and a grade IV ASA score. In our opinion, the sudden cardiac arrest was most likely associated with high afterload for a long time during the catheterization of the supra-aortic branches. Of course, aortic valve damage by device tip is also a possible cause. In addition, partial obstruction of cerebral flow during the procedure might be related to the death.

Nikolaos et al. [14] reported a higher 30-day mortality (20%) for f-TEVAR using custom-made fenestrated endografts in zone 0 and zone 1 for the treatment of aortic arch diseases in 15 patients, which they considered possibly secondary to the learning curve of the complicated procedures. Iwakoshi et al. [15] reported a multicenter experience with 32 high-risk patients who underwent f-TEVAR using Najuta stent grafts and Yokoi HIJ stent (based on the Najuta endograft). Early mortality in this series was 0%, and the rates of stroke, spinal cord ischemia and retrograde type A dissection (RTAD) were 3.1%, 3.1% and 6.3%, respectively. We obtained acceptable short-term outcomes of f-TEVAR using PMSGs for aortic arch diseases, with no perioperative endoleaks, stroke or spinal cord ischemia. The 0% stroke rate could be associated with our strategy for endograft positioning. We positioned the fenestrations and resolved the entanglement of the preloaded wire in the proximal struts in the mid-descending aorta, thereby assuring endograft advancement in the aortic arch only once and minimizing the risk of embolization due to back-and-forth movement of the delivery sheath. Some possible tips may help in fenestration orientation. Firstly, the plane of the aortic arch was confirmed by selecting the precise RAO (right anterior oblique) angulation, under which the parts of the Lunderquist guidewire in the ascending and descending aorta were superimposed [16]. Next, an angiogram was obtained using a retrograde sheath placed earlier in the target vessel. The relationship between the orifice of the target vessel and the Lunderquist guidewire was identified. Finally, the aortic arch was viewed en face in the LAO (left anterior oblique) angulation perpendicular to the RAO angulation. The fenestration marker should be positioned laterally toward the outer curve of the thoracic aorta under this longitudinal view. Advancement of the delivery system from this position into the aortic arch without further rotation can lead the endograft fenestrations to the precise orientation for the target vessels. If the ostium of the target vessel is anterior or posterior to the Lunderquist guidewire in the clocking position, the LAO

angulation should be decreased or added according to the difference angulation.

One potentially devastating complication with f-TEVAR is RTAD. Wire manipulation and pushing forward the endograft may cause injury to the aortic wall, leading to iatrogenic RTAD. Deployment of the stent graft in the aortic arch and especially in zone 0 during aortic debranching may be the risk factor for RTAD [17, 18]. Czerny et al. [19] reported a RTAD incidence of up to 7.5% during zone 0 debranching. Performing f-TEVAR in zone 0 requires much more flexibility and conformability of the stent graft due to the special character of the ascending aorta. Injury of the aortic intima by wire and catheter manipulation can cause perioperative iatrogenic dissection; however, natural disease progression may be related to later presentation. One patient (1 of 10, 10%) with fenestrated endograft in zone 0 suffered from RTAD in our study, which could be secondary to both the conformability of the COOK TX2 endograft in zone 0 and natural disease progression.

Both covered stents and uncovered stents used as bridging stents for supra-aortic branches appeared safe and feasible in our experience. Covered stents are normally used for aortic arch pathologies involving the greater arch curvature, and uncovered stents for arch diseases of the inner arch curvature. In terms of bare metal alignment stents deployed in supra-aortic branches in our study, the main aims were to maintain long-term branch vessel patency and prevent PMSG migration.

There are some limitations in the current study. All technical and clinical data were analyzed retrospectively, the series included a small numbers of patients, and the follow-up interval was short. Another limitation is the absence of bench testing of PMSGs prior to clinical use. Additionally, all f-TEVAR procedure was performed by only 2 operators with extensive experience.

Conclusions

f-TEVAR using PMSGs in Z0 and Z1 is feasible in the hands of experienced operators for the treatment of aortic arch diseases in high-risk patients. Early results based on this study seem to be acceptable. Durability needs to be assessed in large case series studies with long-term follow-up.

Compliance with Ethical Standards

Conflict of interest The authors declare that they have no conflict of interest.

Ethical Approval For this type of study formal consent is not required.

Informed Consent Informed consent was obtained from all individual participants included in the study.

Consent for Publication Consent for publication was obtained for every individual person's data included in the study.

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