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Mid-term Outcomes of Physician-Modified Fenestrated or Branched Endovascular Repair for Post-dissection Thoracoabdominal Aortic Aneurysms

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Abstract
Purpose To report the early experience and mid-term outcomes of physician-modified fenestrated or branched endovascular repair (PM-F/BEVAR) for patients with post-dissection thoracoabdominal aortic aneurysm (PD-TAAA).
Methods PD-TAAA patients treated with PM-F/BEVAR between December 2014 and September 2020 in our institution were retrospectively analyzed.
Results Out of the 39 patients, technical success defined as successful deployment of all stent grafts with patent target vessels (TVs) and exclusion of the lesion without type I or III endoleak was achieved in 35 patients (89.7%). A total of 126 TVs were successfully reconstructed. Thirty-day mortality was 0%. Seven major adverse events occurred including one acute kidney injury, four renal infarctions, one retroperitoneal hematoma and one left renal artery occlusion. Seven type II endoleak and three type III endoleak were detected. During a mean 29.4 ± 15.5 months follow-up period, the mortality was zero. Three renal arteries and one external iliac artery occluded in four patients. No other new onset major adverse event occurred. No patient required reintervention. One type II endoleak spontaneously resolved, while the remaining six remained stable. One early type III endoleak diminished, and one new type III endoleak occurred at 2 months. The primary patency of TV was 96.8% (120/124). Shrinkage or stability of aneurysm diameter can be observed in 38 patients (97.4%). The false lumen thrombosis rate was 89.7% (35/39).
Conclusions The present study showed encouraging results of PM-F/BEVAR for treatment of PD-TAAAs.
Level of Evidence Level 4, Case Series.

Keywords Aortic dissection · Endovascular repair · Physician-modified stent grafts · Fenestrated or branched stent grafts · Post-dissection aneurysm

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Introduction

About 20–40% of patients who survive the acute phase of aortic dissection will develop aneurysmal dilatation of the descending thoracic or thoracoabdominal aorta [1, 2]. Once the aorta is greater than 6 cm, the risk of aortic rupture is estimated to be 30% [2]. About 20–24% of patients require intervention after aortic dissection despite initial repair [3, 4].

Post-dissection aneurysms can be addressed by open surgery, which was technically demanding with considerable mortality and morbidity [5–7]. Endovascular techniques represent a less invasive alternative. Parallel stents techniques have been introduced with encouraging results to extend landing zone and preserve sidebranches [8]. However, the theoretical high risk of type Ia endoleak remains an inherent drawback. Fenestrated and branched endovascular aneurysm repair (F/BEVAR) have played a growing role in the management of post-dissection thoraco-abdominal aortic aneurysm (PD-TAAA) [9]. However, the custom made devices (CMDs) are limited by manufacturing delay and high cost, while the off-the-shelf devices failed to fit all anatomies [10]. Physician-modified fenestrated or branched stent graft (PMSG) represents an alternative option [11–13]. However, the relevant literature was limited [14–16].

The aim of this study was to present the initial experience and mid-term outcomes of F/BEVAR with PMSGs for patients with PD-TAAA in our center.

Materials and Methods

Patient Population

The present study is a single-center, retrospective, observational cohort study. Prospectively maintained database in our center was reviewed, and patients receiving PM-F/BEVAR for PD-TAAA between December 2014 and September 2020 were identified.

Inclusion criteria were as follows:

(I) Patients with TAAAs following aortic dissection extending through the visceral segment receiving endovascular treatment. Indications included (a) large aneurysms diameter ($\geq$ 5 cm) or rapid growth of maximum aortic diameter ($\geq$ 5 mm/6 months); (b) sidebranch malperfusion; (c) uncontrollable hypertension or repeated pain; (d) rupture or impending rupture;
(II) Patients who underwent F/BEVAR with PMSGs.

Exclusion criteria were as follows:

(I) Patients who underwent PM-F/BEVAR for treatment of degenerative TAAAs, penetrate ulcer, pseudoaneurysm and other aortic pathologies;
(II) Patients treated with open surgery, hybrid operation and parallel stent graft technique.

The study was conducted in accordance with the Declaration of Helsinki. The study was approved by institutional ethics committee of our hospital and individual consent for this retrospective analysis was waived. We present the following article in accordance with the STROBE reporting guidelines.

Physician-Modified Fenestrated/Branched Endovascular Repair Procedure

The PMSGs were prepared based on Ankura (Lifetech. Shenzhen, China) platform, as shown in Supplementary Fig. 1. The main steps were as follows:

(I) One femoral access was prepared for PMSG deployment, while the contralateral femoral access and bilateral brachial arteries accesses for TVs reconstruction;
(II) fourfranch catheters were placed into all TVs;
(III) the PMSG was introduced and semi-deployed at the appropriate level and clock position;
(IV) the TVs were cannulated across the fenestrations/branches and secured with Flexor sheaths (Cook, Bloomington, IN, USA);
(V) once the bridging stent grafts were introduced into the TVs, trigger wires were removed to release the posterior reducing wires to fully deploy the PMSG;
(VI) the Viabahn (W.L. Gore Associates, Inc, Flagstaff, AZ, USA) self-expandable covered stents or bare metal stents were deployed as bridging stents between the TVs and fenestrations or branches. Additional bare stent was not routinely used unless compression or kinking of the primary branch stent was detected.

One representative case of PM-F/BEVAR procedure is shown in Fig. 1.

A 2 cm length of normal aortic segment above the dissected aorta or previous existed proximal endograft or elephant trunk was considered as the proximal landing zone. For patients with high risk of spinal cord ischemia (SCI), the aortic segment 2 cm above the celiac trunk was also considered as the proximal landing zone to reduce the length of aortic coverage. Although involved by dissection, the aortic segment may be strong enough in chronic phase. The oversize rate of PMSG was set on 5–10% based on the diameter of proximal landing zones. The stent grafting often extended distally to common iliac artery or even

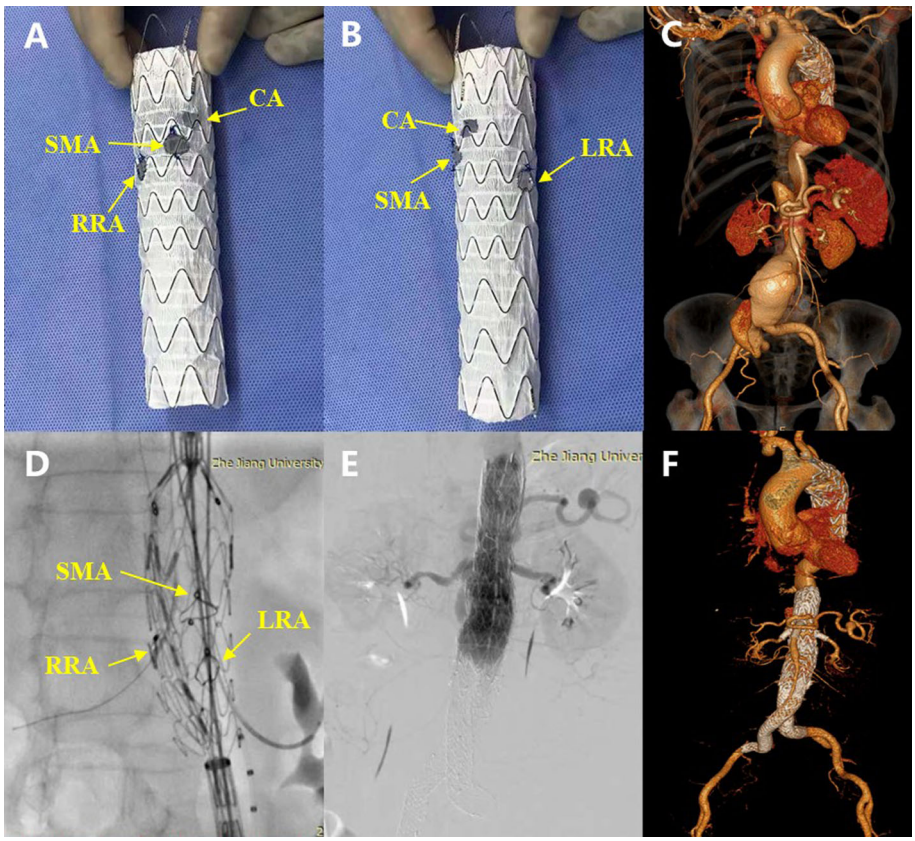

Fig. 1 Physician-modified fenestrated endovascular repair procedure for a post-dissection thoracoabdominal aortic aneurysm. **A**, **B** Prepared physician-modified stent-graft with four fenestrations for revascularization of celiac, superior mesenteric, right renal and left renal artery. **C** Preoperative computed tomography angiography scan showing a 72-year-old woman presenting with post-dissection thoracoabdominal aortic aneurysms after initial TEVAR for type B aortic dissection 5 years ago. **D** Intraoperative DSA showing catheterization of the superior mesenteric, right renal and left renal artery. **E** completion DSA showing successful deployment of physician-modified stent-graft with 4 patent target vessels. **F** Follow-up reconstruction computed tomography angiography scan showing successful aneurysm exclusion and good perfusion of all targeted vessels

external iliac artery to cover the distal tear (Fig. 2). The LSA and at least one-side internal iliac artery (IIA) were intended to be preserved to decrease the risk of SCI. Needle-assisted in situ fenestration (ISF) was applied to reconstruct LSA for patients who received previous TEVAR covering the LSA. Physician-modified iliac branched device (IBD) or chimney technique was applied to preserve at least one-side IIA when bilateral IIAs should be covered with stent graft for distal extension of landing zone or distal tear exclusion, or when ipsilateral IIA should be covered with contralateral IIA occlusion or severe stenosis. In case of brisk retrograde flow into the false lumen (FL), adjunctive embolization of the FL with coils, glues and/or plugs was performed (Fig. 3).

Follow-Up

Demographic, anatomical, intra-operative, and postoperative data were recorded. All patients underwent computerized tomography (CT) scan preoperatively and before discharge. The follow-up protocol included CT scan at 1, 3, 6, and 12 months and yearly thereafter. The follow-up clinical data were obtained during patient visits to the hospital, other hospital stays, or by telephone interview.

Outcome and Definition

The results were presented according to the guidelines for reporting standards in TEVAR [17, 18]. Technical success was defined as successful deployment of all stent grafts with patent TVs and exclusion of the lesion without type I or III endoleak in the completion angiogram. Major adverse events (MAEs) included all-cause mortality, myocardial infarction, respiratory failure, renal function decline or new-onset dialysis, bowel ischemia, major stroke, paraplegia and other major complications. Renal infarction was defined as lack of perfusion in the kidney parenchyma using contrast angiography, CTA, or MRA. Acute kidney injury was defined as that serum creatinine increased to $\geq$ 150% from baseline. Target vessel stenosis

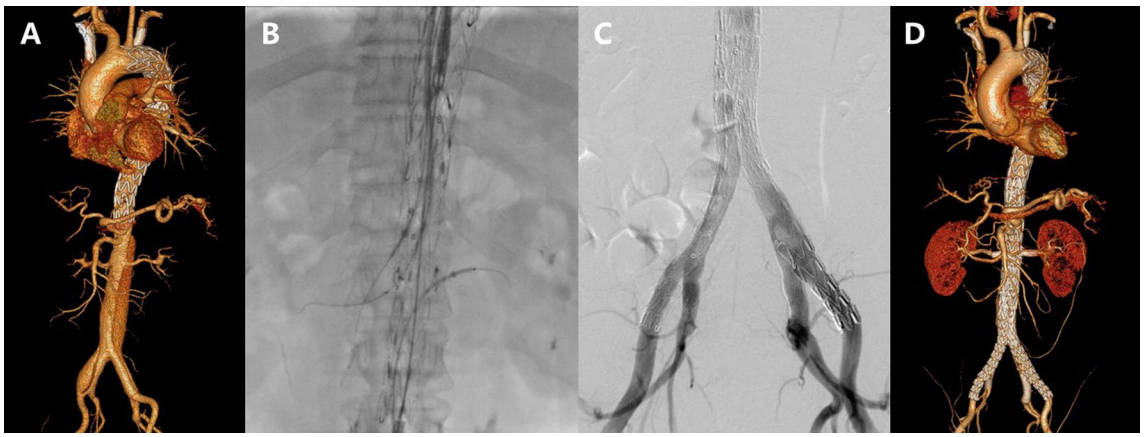

Fig. 2 Physician-modified fenestrated endovascular repair combined with distal extension and internal iliac arteries preservation. A 51-year-old man with type B aortic dissection presented with distal aortic aneurysm after proximal thoracic endovascular aortic repair six months ago (**A**). Physician-modified fenestrated endovascular repair was provided to exclude the aneurysm preserving all reno-visceral arteries (**B**). Stent grafts were extended to bilateral external iliac arteries and internal iliac arteries were reconstructed with physician-modified branched grafts to prevent spinal cord injury (**C**). Follow-up computed tomography angiography showed patent side branches and well excluded aneurysm (**D**)

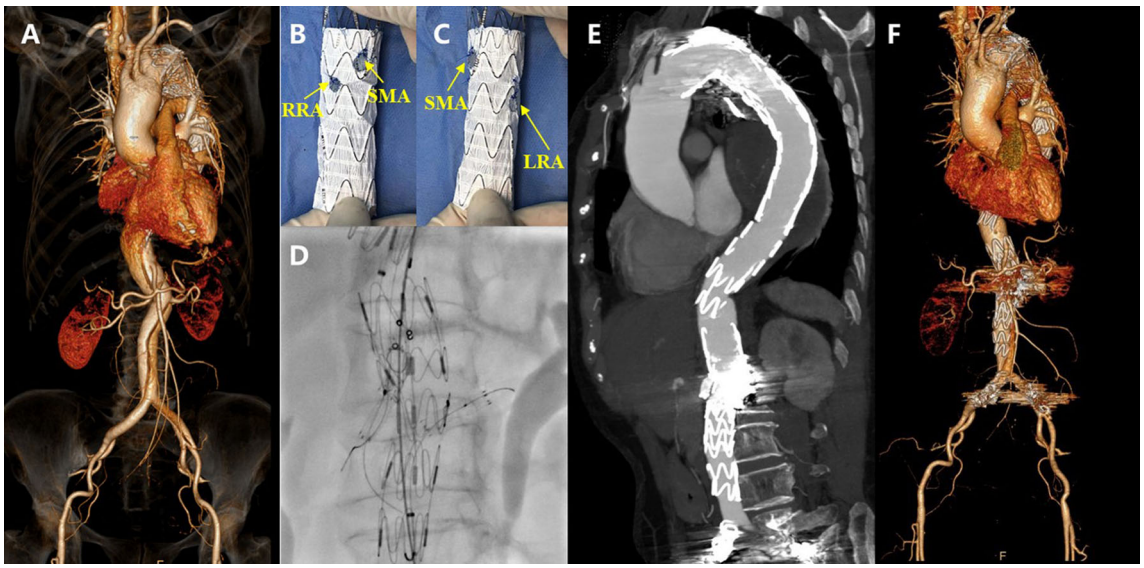

Fig. 3 Physician-modified fenestrated endovascular repair combined with false lumen embolization technique. A 66-year-old woman presented with post-dissection thoracoabdominal aortic aneurysm after proximal stent grafting (**A**). A physician-modified stent graft was prepared with 3 fenestrations for superior mesenteric and bilateral renal arteries (**B**, **C**). The fenestrated endograft was accurately deployed with successful revascularization of the target vessels (**D**). Embolization with coils was performed in the false lumen near the origin of the left renal artery and in the bilateral common iliac arteries to block the retrograde blood flow into false lumen (**E**). Follow-up computed tomography angiography showed favorable aortic remodeling with patent reno-visceral arteries

less than 50% was defined as patency. Short term was defined as the first 30 postoperative days. The follow-up index was defined as the ratio between the investigated follow-up period and the theoretically possible follow-up period up to the pre-specified study end date [19]. Aorta status was classified as enlargement (maximum aortic diameter increasing greater than 5 mm at follow-up compared with baseline measurement), stable (changing < 5 mm) and shrinkage (decreasing > 5 mm).

Statistical Analysis

Statistical analysis was performed using SPSS software (version 19.0; SPSS, Inc., Chicago, IL, USA). Continuous variables were summarized as means ± standard

deviations if normally distributed, and as median, and range if not. Categorical variables were expressed as count and percentage. Time-dependent outcomes were reported using Kaplan–Meier estimates.

Results

Between December 2014 and September 2020, 39 patients (74.4% male with mean age of 51.3 ± 12.5 years) were treated with PMSGs for PD-TAAA. Demographic characteristics and baseline clinical data are detailed in Table 1.

A total of 126 consecutive target vessels (TVs) were intended to be preserved by fenestration (n = 119, 94.4%) and branched stent grafts (n = 7, 5.6%). Grafts incorporated four TVs in 14 (35.9%) patients, three TVs in 20 (51.3%) patients, and two TVs in five patients (12.8%). The technical success was 89.7% (35/39) with no perioperative mortality. The reason for technical failure was failed renal arteries revascularization in two patients for hostile anatomy and severe stenosis leading to renal infarction and type III endoleaks found in completion aortography in three patients. FL embolization with coils with/without glue was used in 15 (38.5%) patients, while distal tear exclusion by plug and coils were simultaneously conducted in two (16.7%) patients. In four patients, a proximal stent graft was placed to partially expand the narrow true lumen before PMSG deployment. Six patients received previous Z2 TEVAR with (n = 4) or without (n = 2) LSA preservation. For the two patients, concomitant LSA reconstruction with needle-assisted ISF was conducted during PM-F/BEVAR procedure for repair of PD-TAAA. Six patients received internal iliac artery (IIA) reconstruction with physician-modified IBD (n = 4) or chimney technique (n = 2). The indications included stent grafting extension to bilateral IIAs in five patients and stent grafting extension to ipsilateral IIA with contralateral IIA occlusion in one patient. In all patients, the procedures were performed in one stage. A total of 124 TVs were successfully preserved with (n = 115) or without bridging stents placement (n = 9). Out of the 115 stented TVs, 104 were revascularized with one self-expandable covered stent (Viabahn) for each, eight with one bare metal stent for each, two with two bare metal stents for each, and one with a covered stent and a bare metal stent. Procedure details are presented in Table 2.

The thirty-day mortality was 0%. Seven major adverse events in five patients occurred within 30 days including one acute kidney injury, four renal infarctions, one retroperitoneal hematoma and one left renal artery occlusion. There were no stroke or SCI. No type I endoleak was observed via 30-day follow-up CTA, while seven type II endoleak and three type III endoleak were detected. These patients were left close follow-up without intervention considering the endoleak flow was mild. The patient suffering from retroperitoneal hematoma received reintervention 4 days after operation (Table 3).

The mean follow-up was 29.4 ± 15.5 months (12–69 months). All patients were followed up and the mean follow-up index was 1.0 ± 0.0. During follow-up period, no death occurred. The cumulative survival rate was 100.0% at one, three and five years according to Kaplan–Meier curves (Fig. 4A). Four new onset major adverse events occurred including one right external iliac artery occlusion at 3 months and three renal arteries occlusion at 3 months, 12 months, and 18 months, respectively. No stroke or SCI occurred in this series during follow-up. No patient received reintervention. The freedom from reintervention was 94.9% at one, three and five years (Fig. 4B). No type I endoleak occurred during follow-up. Out of the seven early type II endoleak, one spontaneously resolved while the remaining six remained stable. Out of three early type III endoleak, one diminished at 54 months, while the remaining two remained stable. One new type III endoleak occurred at 2 months. The freedom from type I or III endoleak was 89.7% at one, three and five years (Fig. 4C). Out of the 124 successfully revascularized TVs, 120 remained patent resulting in a follow-up primary patency rate of 96.8% (120/124). Of note, all 14 reconstructed TVs from FL were patent. The cumulative primary patency of TV was 97.6% at one, 96.4% at three and 96.4% at five years (Fig. 4D). No significant stenosis, kink, fracture and migration of stent was observed (Table 3).

The mean aneurysm diameters were 52.7 ± 16.7 mm preoperatively and 50.7 ± 18.0 mm at last follow-up (p = 0.001). As for the maximum aortic diameter, shrinkage (n = 15) or stable status (n = 23) was seen in 38 (97.5%) cases and enlargement was observed in one (2.6%) case (Table 3). The FL thrombosis rates were 89.7% (35/39) at last follow-up.

Discussion

F/BEVAR has now been increasingly used for patients with complex aortic disease [20, 21]. CMDs, off the shelf devices and PMSGs were the currently available options. Off the shelf devices cannot accommodate all the aortic anatomy, while CMDs were limited by manufacturing delay. Hence, PM-F/BEVAR can be considered as an option. Sénémaud and his colleges [22] revealed that the rates of intraoperative adverse events, mortality, complications, and reinterventions were in an acceptable range in the PMSG group based on their short-term results of 69 CMDs and 28 PMSGs for complex aortic aneurysm repair.

Table 1 Demographics and baseline clinical characteristics (n = 39)

Variable	*n* (%) or Mean ± SD
Age (years, mean ± SD)	51.3 ± 12.5
Sex	
Male	29 (74.4%)
Female	10 (25.6%)
Smoker	18 (46.2%)
Comorbidities	
Hypertension	15 (38.5%)
Diabetes	5 (12.8%)
Hyperlipidemia	5 (12.8%)
Coronary artery disease	4 (10.3%)
Myocardial infraction	0
Congestive heart failure	2 (5.1%)
Cerebrovascular disease	0
Renal function insufficiency	4 (10.3%)
Renal failure	1 (2.6%)
COPD	5 (12.8%)
Peripheral artery disease	2 (5.1%)
Hepatitis	2 (5.1%)
History of tumor	1 (2.6%)
ASA classification	
II	8 (20.5%)
III	29 (74.4%)
IV	2 (5.1%)
Pathology	
Type A dissection	9(23.1%)
Type B dissection	30 (76.9%)
Time from primary event, (months, mean ± SD)	37.4 ± 24.2
Type of TAAA at the time of F/B-EVAR	
I	3 (7.7%)
II	9 (23.1%)
III	17 (43.6%)
IV	8 (20.5%)
V	2 (5.1%)
Previous aortic operation	30 (76.9%)
Open	9(23.1%)
TEVAR	21 (53.8%)
Presentation	
Asymptomatic	20 (51.3%)
Pain	19 (48.7%)
Rupture	0

COPD Chronic obstructive pulmonary disease, *TAAA* thoracoabdominal aortic aneurysm, *F/B-EVAR* fenestrated/branched-endovascular aneurysm repair, *TEVAR* thoracic endovascular aortic repair

However, the published data about F/BEVAR for PD-TAAA using PMSGs were scarce. Yang et al. [16] has recently reported their short outcomes of 62 post-dissection aortic aneurysms patients treated with PMSGs demonstrating high technical success (98.3%), low 30-day mortality (1.6%), favorable 1-year follow-up FL thrombosis (91.8%) and survival rate (96.8%). Our results were also favorable and comparable, with a technical success rate of 89.7%, mortality of zero, major adverse event rate of 17.9%.

During the PM-F/BEVAR procedure, several assistant techniques were used in the present cohort to improve

Table 2 Procedure details

Variable	*n* (%) or Mean ± SD
Indication	
Refractory hypertension	1 (2.6%)
Intractable pain	8 (20.5%)
Visceral malperfusion	0
Leg ischemia	1 (2.6%)
Aneurysmal dilation	20 (51.3%)
Rapid enlargement	11 (28.2%)
Rupture/impending rupture	1 (2.6%)
Preoperative maximum aneurysm diameter, mm	52.7 ± 16.7
Technical success	35 (89.7%)
Procedure time, minutes	310.3 ± 119.3
Volume of contrast material, mL	246.7 ± 75.3
Total target vessel	126
Celiac trunk	15
Superior mesenteric artery	35
Renal artery	76
Accessory Renal Artery	0
No. of bridging stents per patient	3.0 ± 0.6
TV take off from lumen	
True lumen	94
False lumen	14
True and false lumen	18
Adjunctive procedure	
False lumen embolization	15 (38.5%)
Tear exclusion by plug or coiling	2 (5.1%)
Celiac trunk embolization	17 (43.6%)
Access vessel injury	1 (2.6%)
Length of stay (days, mean ± SD)	12.0 ± 5.1
Length of ICU stay (days, mean ± SD)	0.3 ± 0.7

TEVAR Thoracic endovascular aortic repair, *TV* target vessel, *LSA* left subclavian artery, *ICU* intensive care unit

results. In chronic post-dissection aneurysms, the most specific feature is the narrow true lumen. A proximal tube graft was deployed first above the celiac trunk to expand the true lumen slightly, making full deployment of the main body of PMSG possible [14, 15]. Another feature is that visceral branches can originate from the FL. To enable successful catheterization of TVs originating from the FL, the dissection flap sometimes has to be perforated with a stiffer tip of a wire or a steerable needle (Lifetech, Shenzhen, China) supported by a guiding sheath [14]. Then, long covered stents were used to connect the fenestrations or directional branches to the TVs across the flap and FL.

SCI is a devastating complication, which often occurred after extensive endovascular repair [23]. Perioperative blood loss, lack of CSF drainage, hypotension, as well as procedure time and patient comorbidities may be associated with SCI [23–25]. To reduce risk of SCI, the LSA and at least one-side internal iliac artery was preserved as far as possible with fenestration, chimney or IBD technique. Further, prophylactic CSF drainage was applied in a proportion of patients. These measures may contribute to the relative low occurrence of SCI in this study.

The FL thrombosis of PD-TAAAs is another concern which was associated with aortic remodeling and long-term

Table 3 Early and follow-up outcomes

Variable	*n* (%) or Mean ± SD
30-day mortality	0
30-day MAE	7 (17.9%)
Death	0
Myocardial infarction	0
Respiratory failure	0
Spinal cord injury	0
Acute kidney injury	1 (2.6%)
Renal infarction	4 (10.3%)[#]
Major stroke	0
Bowel ischemia	0
Lower limb ischemia	0
Other	2 (5.1%)*
30-day endoleak	10 (25.6%)
Type I	0
Type II	7 (17.9%)
Type III	3 (7.7%)
30-day Re-intervention	2 (5.1%)
30-day TV instability†	2 (5.1%)
Branch vessels	
Branch occlusion, stenosis	1 (2.6%)
Bridging stent migration	0
Follow-up (months)	29.4 ± 15.5
FU mortality	0
FU MAE	9 (23.1%)
FU endoleak	9 (23.1%)
Type I	0
Type II	6 (15.4%)
Type III	3 (7.7%)
FU Re-intervention	0
FU TV instability†	4 (10.3%)
Branch vessels	
Branch occlusion, stenosis	4 (10.3%)
Bridging stent migration	0
FU maximum aneurysm diameter, mm	50.7 ± 18.0
Change of maximum aortic diameters at last FU	
Shrinkage	15 (38.5%)
Stability	23 (59.0%)
Enlargement	1 (2.6%)

MAE Major adverse event, *TV* target vessel, *FU* follow-up

[#]Two renal infarctions resulted from intended overstenting of small accessary renal arteries in one patient and renal arteries in a dialysis patient. And another two infarctions resulted from failure of target vessels reconstruction

*Other MAEs include one retroperitoneal hematoma resulting from access artery injury and one left renal artery occlusion detected on 1-month CTA resulting from in-stent thrombosis

[†]TV instability means composite end point used to define any death or rupture related to side branch complication (e.g., endoleak, rupture) or any secondary intervention indicated to treat a branch-related complication, including endoleak, disconnection, kink, stenosis, occlusion, or rupture

outcomes. To promote FL thrombosis, embolization of aneurysmal false lumen with coils or glues and distal residual tear exclusion with plug, coils or distal endograft was applied to block the persist retrograde blood flow from distal tears into FL [26]. In 17 patients with large FL or multiple distal tears, the FL or the distal tear was well dealt with the techniques mentioned before resulting in a FL thrombosis rate of 89.7%.

The high rates of endoleak and consequent reinterventions also raise some concerns. Type III endoleaks often occurred following FEVAR due to short junction between the main body stent graft and the bridging covered stent leading to a higher reintervention rate [27]. Therefore, branches were preferred rather than fenestration in patients with appropriate anatomy to reduce type III endoleaks. In the present case series, post-balloon dilation was employed to strengthen the junction between bridging stents and fenestrations/directional branches. The Viabahn used as bridging stents in this study have enough flexibility to well fit TVs' anatomy, physiological movement and remodeling may also help reducing the risk of endoleaks [28].

In our study, the primary patency rate of TVs was 96.8% (120/124) with four renal arteries occlusion. According to the current literature, visceral branch patency remains high (> 98%), while renal branch patency varied. A number of factors was supposed to affect long-term branch patency, including anatomy of the TVs, the length and curvature of the branch component, and the type of bridging stents based on clinical observations [29]. There was a trend toward greater occlusion rates with cranially directed as opposed to caudally directed branches, and the length of the renal artery was slightly longer in the group with renal artery occlusions [30].

Limitations

There are some limitations of this study. This is a single-center, retrospective observational study with a relatively small sample size and short follow-up. In addition, it lacks comparison groups between CMDs and PMSGs. Further, the learning curve and surgeon experience may impact the results of the procedure.

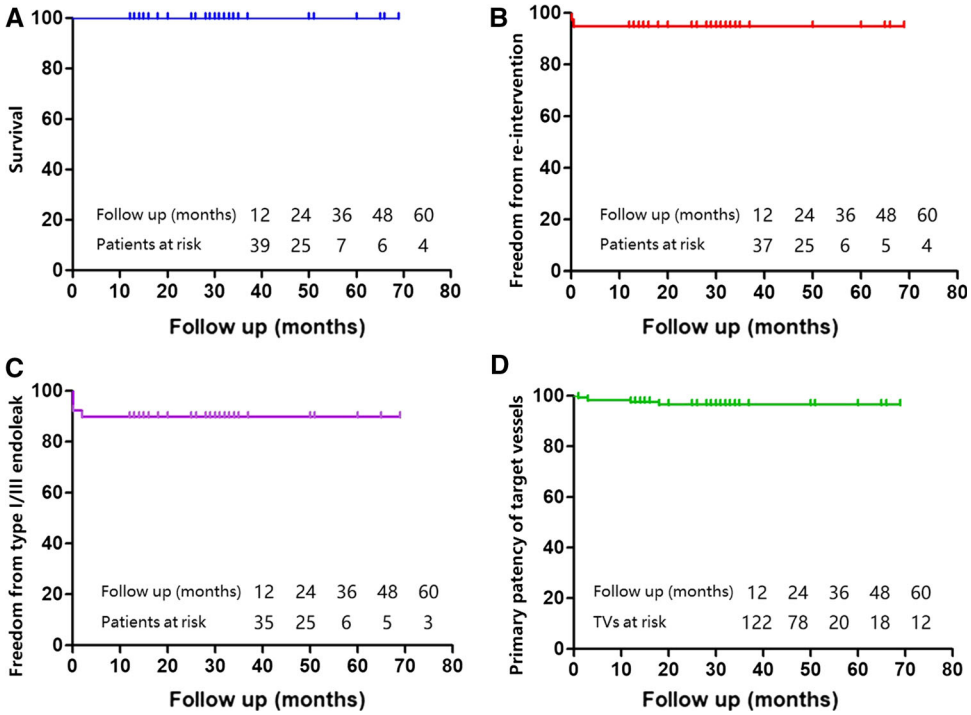

Fig. 4 Cumulative Kaplan–Meier curves of survival, freedom from re-intervention, freedom from type I or III endoleak and target vessel primary patency of patients treated for PD-TAAAs by PM-F/BEVAR. **A** The cumulative survival rate was 100.0% at one, three and five years. **B** The freedom from re-intervention was 94.9% at one, three and five years. **C** The freedom from type I or III endoleak was 89.7% at one, three and five years. **D** The cumulative primary patency of target vessel was 97.6% at one, 96.4% at three and 96.4% at five years

Conclusion

The present study showed encouraging results of PM-F/BEVAR for treatment of PD-TAAAs. Favorable aortic remodeling with false lumen thrombosis and aneurysm regression can be observed with acceptable rates of target vessel occlusion, endoleak and reintervention. Nevertheless, more studies with longer follow-up and larger sample size are required to confirm the efficacy and durability of this procedure.

Supplementary Information The online version contains supplementary material available at https://doi.org/10.1007/s00270-022-03232-w.

Author's Contribution Seven authors have contributed significantly to the submitted work. The contribution of each author is as follows: Hongkun Zhang, Zhenjiang Li contributed to conception and design; Xiaohui Wang, Zhenjiang Li, Yangyan He, Yilang Xiang, and Tao Shang contributed to analysis and interpretation of data; Xiaohui Wang, Zhenjiang Li and Qianqian Zhu contributed to writing the article; Donglin Li, Lu Tian, and Hongkun Zhang contributed to critical revision of the article; Qianqian Zhu, Qinglong Zeng, and Ziheng Wu contributed to statistical analysis; Zhenjiang Li, Hongkun Zhang and Donglin Li obtained funding.

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Declarations

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

Ethical Approval All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Informed Consent For this type of study, formal consent is not required. The study was approved by institutional ethics committee of our hospital.

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

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