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The Comparison between Axillofemoral Bypass and Endovascular Treatment for Patients with Challenging Aortoiliac Occlusive Disease as Alternative Treatment to Aortofemoral Bypass

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Objective: Although aortofemoral bypass (AoFB) is the standard treatment for challenging aortoiliac occlusive disease (AIOD), less-invasive treatments, such as axillofemoral bypass (AxFB) or endovascular treatment (EVT) have been conducted for patients with severe comorbidities. In this study, we compared the clinical outcomes between AxFB and EVT for AIOD.
Materials and Methods: We retrospectively reviewed 9 patients with AxFB and 10 with EVT for challenging AIOD. The patients' information and operative results were evaluated. The rates of patency and limb salvage were analyzed according to the Kaplan–Meier method.
Results: In the EVT group, 5 of 10 (50%) patients had aortic stenting alone, 3 (30%) received aorto-uniiliac stenting, and 2 (20%) received aorto-biiliac stenting. In the AxFB group, 2 cases (22.2%) showed acute graft thrombosis; however, in the EVT group, no acute thrombotic complications were seen. The primary patency rates in the AxFB and EVT groups at 5 years were 53.6% and 81.2%, respectively (log rank P=0.225), and the assisted primary patency rates at 5 years were 53.6% and 100%, respectively (log rank P=0.012).
Conclusion: EVT exhibited a more durable, better long-term patency rate than AxFB. EVT may, therefore, be a viable treatment alternative to AoFB for challenging AIOD.

Introduction

Aortoiliac occlusive disease (AIOD) is a challenging disease that should be treated by open bypass surgery, especially aortofemoral bypass (AoFB), according to the Trans-Atlantic Inter-society Consensus document (TASC II).[1] The 2017 ESC guidelines[2] stated that for patients with AIOD categorized as TASC II D lesions who are suitable for surgery, AoFB should be considered. However, although extra-anatomical bypass, such as axillofemoral bypass (AxFB), may be indicated for those patients as well, AxFB has shown a lower primary patency rate (67.7% at 5 years) than AoFB (88.5% at 5 years).[3] While AxFB has proven suitable for complex, challenging cases with severe comorbidities, the patients treated by AxFB have shown a lower overall survival rate (67.0% at 1 year) than those who undergo AoFB.[4] Therefore, it might be difficult for AxFB to be considered as a viable alternative treatment to AoFB.

Recently, endovascular treatment (EVT) has improved and been used to manage challenging, complex AIOD cases with low rates of postoperative complications (13.4%) compared with open bypass surgery with AoFB (18.0%, P<0.001).[5] However, the primary patency rates at 1, 3, and 5 years have remained lower in patients who undergo EVT than in those who undergo open bypass surgery (86.0% vs. 94.8%, 80.0% vs. 86.0% and 71.4% vs. 82.7%, respectively; all P<0.001).[2] Therefore, AoFB has become accepted as the standard treatment for AIOD, especially TASC II D lesions, because of its high patency rates. However, the relatively high rates of peri- and postoperative morbidities and mortalities, especially for older and/or high-risk patients, with AoFB remain a concern.[6]

We have treated patients with complex AIOD who had severe comorbidities using AxFB or EVT to prevent post-

operative complications. Recently, Samson et al.[7] reported a high primary patency rate in patients treated by AxFB (83.7% at 5 years), representing what are to our knowledge the best results of AxFB treatments to date.

Therefore, in the present study, we retrospectively reviewed our patients with challenging AIOD treated by AxFB or EVT and evaluated the clinical outcomes, including the peri- and postoperative results and the long-term patency outcomes.

Patients and Methods

We reviewed the data obtained from consecutive patients with complex AIOD treated by AxFB or EVT from April 2008 to December 2018. All surveys and consent forms were approved by the Institutional Review Board (IRB No. M2019-044) of Tokyo Medical and Dental University Hospital. Nine AxFB procedures for 9 patients and 10 EVT procedures for 10 patients were performed during this study period. We also performed 21 AoFB during the same period; however, in this study, we excluded AoFB cases.

Patients

All patients in this study were diagnosed with complex AIOD (defined as TASC II D lesions). We usually diagnose AIOD by computed tomography angiography (CTA); however, patients who were contraindicated for the usage of contrast medium for CTA had complex AIOD diagnosed by duplex ultrasonography (DUS) and/or magnetic resonance angiography (MRA). We excluded the patients with AIOD due to acute aortic occlusion, Buerger disease, and other kinds of systemic diseases except for atherosclerotic disease. The data correlated with the treated patients were retrospectively reviewed from our dedicated database that included the demographic data, perioperative status of the patients, and follow-up outcomes.[8] Furthermore, for the evaluation of the clinical ischemic condition, we assessed the ankle–brachial pressure index (ABI) and the Rutherford classification.[8] We also preoperatively evaluated the outflow vessels classified by TASC II femoropopliteal lesions.[1]

Surgical techniques

We conducted revascularization procedures for the patients with symptoms more severe than Rutherford category 2. The technique for revascularization procedures mainly depended on the patients' systemic conditions. In brief, we preferentially performed AoFB surgery instead of AxFB or EVT procedures for the patients without systemic severe comorbidities. However, patients with severe comorbidities were mainly treated by AxFB or EVT. AxFB or EVT was selected based on physicians' preferences. Because we had no specific, strict criteria for selecting sur-

gical methods between AxFB and EVT, we discussed the surgical techniques for each case preoperatively.

We performed all AxFB procedures except for 1 case under general anesthesia. The other case was treated under local anesthesia with sedation. In all AxFB procedures, we implanted the externally supported 10 mm diameter main limb of a Dacron graft with 8 mm diameter externally supported bilateral femoral components of Dacron grafts. All bypass grafts were positioned subcutaneously, and proximal anastomoses usually originated from the right side of the axillary artery in an end-to-side manner. The distal anastomosis site of AxFB was positioned to the common or deep femoral arteries, depending on the pattern of the atherosclerotic lesions at the groin, in an end-to-side fashion with or without endarterectomy.

Percutaneous EVT approaches were conducted under local anesthesia, and cut-down EVT approaches, which were simultaneously performed with open surgical revascularization, were performed under general anesthesia. In both the percutaneous and cut-down approaches, we usually retrogradely inserted 6-Fr or 7-Fr introducer sheaths into the bilateral common femoral arteries. The occlusive lesions in the aortic and/or iliac segments were passed, and balloon-expandable and/or self-expandable bare-metal stents were positioned in the affected lesions. We are now able to use covered-balloon-expandable stents in the affected iliac arteries following approval by the Japanese insurance system; however, during this study period, we were only able to insert bare-metal stents in these affected lesions. After reconstruction of the inflow arteries, including aortic and iliac lesions, we sometimes added further revascularization procedures, such as ilio-femoral bypass, endarterectomy for common and/or deep femoral arteries, and EVT procedures for femoropopliteal lesions.

Postoperative management and the follow-up protocol

After the operation, we administrated antiplatelet medication to all patients except for those who were contraindicated for such medications. We identified postoperative complications that occurred within 30 days after the operation and reviewed in terms of morbidity and mortality. We reviewed the postoperative course based on clinical examinations, including ABI measurements and categorization by the Rutherford category. We checked each patient every 3 months for the first year and every 3–6 months subsequently during the follow-up period.

We usually checked the graft and treated limbs' patency by palpation of the pulse on the groin. When we suspected stenosis or occlusion of the treated vessels due to weak or no palpation on the groin, CTA and/or MRA and/or DUS were performed for a further examination. Primary patency was defined as no interrupted flow without intervention

to treat disease progression in the adjacent native vessel or any additional procedure performed. Assisted primary patency was defined as patency of the treated lesions with additional procedures required to maintain the patency of the treated lesions before implanted graft or stent occlusion. Secondary patency was defined as restored graft or stent patency with additional treatment after implanted graft or stent occlusion. Limb salvage was defined as the freedom from major amputation above or below the knee level. Those patency and salvage rates were calculated by the Kaplan–Meier method.

Statistical analyses

We performed statistical analyses using the SPSS software program, version 22 (SPSS Inc., Chicago, IL, USA). Continuous variables were presented as the median and interquartile range (IQR) and compared with the Mann–Whitney U test. The categorical variables were presented as frequencies and percentages and assessed using the chi-squared test. Statistical significance was considered at P values of <0.05. The patency and limb salvage rates were calculated by the Kaplan–Meier life-table analysis

with log-rank tests to compare the groups. We reviewed the data obtained from consecutive patients with complex AIOD treated by AxFB or EVT from April 2008 to December 2018. All surveys and consent forms were approved by the Institutional Review Board (IRB No. M2019-044) of Tokyo Medical and Dental University Hospital. Nine AxFB procedures for 9 patients and 10 EVT procedures for 10 patients were performed during this study period. We have also performed 21 AoFB during the same period; however, in this study, we excluded AoFB cases.

Results

Patient demographics

AxFB grafting was performed more frequently (7, 77.8%) than EVT (3, 30.0%) for male patients (P=0.037). In terms of preoperative comorbidities, no significant differences were found between the AxFB and EVT groups. Regarding patients' preoperative clinical hemodynamical status, the patients treated by AxFB showed lower preoperative ABI values (0.31) than the EVT group (0.45); however, the difference was not statistically significant (P=0.053) (**Table 1**).

Table 1 Patient demographics

Variables	AxFB (n=9)	EVT (n=10)	P value
Age (years)	78.0 (66.0–84.0)	69.5 (65.0–77.0)	0.368
Gender (Male)	7 (77.8%)	3 (30.0%)	0.037
BMI (kg/m²)	19.5 (18.5–20.0)	20.6 (18.9–22.7)	0.288
Comorbidities			
Hypertension	8 (88.9%)	7 (70.0%)	0.596
Diabetes mellitus	2 (22.2%)	6 (60.0%)	0.096
Dyslipidemia	2 (22.2%)	6 (60.0%)	0.096
Coronary artery disease	2 (22.2%)	1 (10.0%)	0.466
Cerebrovascular disease	4 (44.4%)	3 (30.0%)	0.876
Chronic obstructive pulmonary disease	1 (11.1%)	1 (10.0%)	0.937
Smoking habit	6 (66.7%)	7 (70.0%)	0.876
Laboratory test			
Hemoglobin (g/dl)	12.4 (10.6–13.1)	11.8 (10.9–12.7)	0.624
Albumin (g/dl)	4.0 (3.5–4.1)	4.1 (3.8–4.3)	0.390
Creatinine (mg/dl)	0.82 (0.70–0.92)	0.77 (0.64–1.19)	0.744
Preoperative clinical status	n=18	n=19	
Ankle brachial pressure index	0.31 (0.20–0.39)	0.45 (0.25–0.68)	0.053
Rutherford classification			0.483
0	0 (0%)	0 (0%)	
1–3	7 (38.9%)	11 (57.9%)	
4	5 (27.8%)	3 (15.8%)	
5–6	6 (33.3%)	5 (26.3%)	
Femoropopliteal lesion			0.264
TASC II 0	10 (55.5%)	6 (31.6%)	
TASC II A, B	3 (16.7%)	7 (36.8%)	
TASC II C, D	5 (27.8%)	6 (31.6%)	

AxFB: axillofemoral bypass; EVT: endovascular treatment; BMI: body mass index; TASC II: Trans-Atlantic Inter-society Consensus document

Surgical details

We had usually conducted AxFB grafting from the right axillary artery to both sides of femoral arteries. In 9 patients with AxFB grafting, 7 (77.8%) proximal anastomosis sites were at the right axillary artery, whereas the other 2 were at the left axillary artery. Among these 2 patients, 1 showed severe calcified lesion in the right axillary artery, and the other had a history of previous revascularization procedure in the right side of axillary artery; therefore, we conducted bypass grafting from the left side of axillary artery to both sides of femoral arteries. Fourteen of 18 limbs (77.8%) were anastomosed to common femoral arteries, and the other 4 limbs (22.2%) were to deep femoral arteries, all of which received additional profundoplasty. In the EVT group, 2 of 10 patients (20.0%) showed aortic occlusion in the infra-renal level; however, they were not in the juxta-renal level. Five of 10 patients (50.0%) started aortic occlusion from the level of inferior mesenteric ar-

tery, and the other 3 patients (30.0%) did the occlusion from the level of terminal aorta. Among 10 patients, 4 (40.0%) showed segmental aortic occlusion, and the other 6 (60.0%) extended occluded lesion to both sides of iliac arteries. Five of 10 patients (50.0%) were treated under local anesthesia by percutaneous endovascular procedures. The other 5 patients (50.0%) received simultaneous EVT and open revascularization under general anesthesia. Among these patients treated by hybrid procedures, 3 of 5 patients (60.0%) performed endarterectomy for common or deep femoral arteries, 2 (40.0%) received ilio-femoral bypass grafting, and 1 (20.0%) received endovascular procedures for infrainguinal lesions. We achieved technical success with EVT (defined as less than 30% of residual stenosis for treated lesions) for all patients (100%).

We implanted only an aortic stent for 5 of 10 patients (50.0%), aorto-uniiliac stent for 3 patients (30.0%), and aorto-biiliac stent for 2 patients (20.0%). Therefore, we

Table 2 Operative details and postoperative outcomes

Variables	AxFB (n=9)	EVT (n=10)	P value
Operative details			
Operative time (min)	195 (174–233)	206 (84–314)	0.935
Intraoperative blood transfusion	1 (11.1%)	5 (50.0%)	0.069
Technical aspects			
Inflow	n=9		
Right axillary	7 (77.8%)		
Left axillary	2 (22.2%)		
Outflow	n=18		
CIA	0 (0%)		
EIA	0 (0%)		
CFA	14 (77.8%)		
DFA	4 (22.2%)		
Aortic stent alone		5 (50.0%)	
Aortic stent with unilateral iliac stent		3 (30.0%)	
Aortic stent with bilateral iliac stent		2 (20.0%)	
Number of stents placed		1.5 (1–2)	
Additional open hybrid procedure		5 (50.0%)	
Postoperative outcomes			
Postoperative hospital stay (days)	20 (18–32)	11.5 (3–19.8)	0.034
Postoperative complications	2 (22.2%)	0 (0%)	0.115
Thrombosis	2 (22.2%)		
Postoperative clinical status	n=18	n=19	
ABI value	0.78 (0.68–0.88)	0.90 (0.67–0.95)	0.214
Increase value of ABI	0.46 (0.37–0.61)	0.33 (0.19–0.49)	0.277
Rutherford classification			0.810
0	4 (22.2%)	6 (31.6%)	
1–3	11 (61.1%)	10 (52.6%)	
4	0 (0%)	0 (0%)	
5–6	3 (16.7%)	3 (15.8%)	
Improvement level of Rutherford grade	1 (1–2)	2 (1–3)	0.673

AxFB: axillofemoral bypass; EVT: endovascular treatment; CIA: common iliac artery; EIA: external iliac artery; CFA: common femoral artery; DFA: deep femoral artery; ABI: ankle brachial pressure index

implanted a median number of 1.5 stents in each patient for EVT. In the EVT group, intraoperative blood transfusion was required for 5 patients (50.0%), all of whom received simultaneous EVT and open revascularization procedures; however, we rarely required intraoperative blood transfusion for patients with AxFB (11.1%), although the difference was not statistically significant (P=0.069). Also, the difference in operating time between AxFB group and EVT group was not statistically significant (195 min vs. 206 min, P=0.935). Because we contained simultaneous EVT and open revascularization procedures in the EVT group. For 5 patients with simple EVT procedures, we conducted EVT operation in the median time of 81 min (77.3–84.0 min) (**Table 2**).

Postoperative outcomes

The duration of the postoperative hospital stay was significantly shorter in the EVT group (11.5 days) than in the AxFB group (20 days) (P=0.034). In the AxFB group, 2 patients had postoperative complications (22.2%), both of whom had acute graft thrombosis graft (1 unilateral and 1 bilateral). We treated the unilateral thrombosed graft with thrombectomy; however, the treated graft became occluded again, and no further treatment was conducted. The other case showed severe systemic comorbidities, and the patient did not desire any further treatment, so the bilateral grafts remained occluded. In contrast, no postoperative complications were seen in the EVT group.

We compared the patients' clinical hemodynamic condition between the AxFB and EVT groups. No statistically significant differences were seen in the postoperative ABI value or a marked increase in the ABI value between the AxFB and EVT groups (0.78 vs. 0.90, P=0.214 and 0.46 vs. 0.33, P=0.277, respectively). Concerning the Rutherford classification, no statistically significant differences were seen in the postoperative Rutherford category or the improvement in the Rutherford grade between the AxFB and EVT groups (**Table 2**).

Follow-up outcomes

During this follow-up period (AxFB group: median 7 months, IQR 3–80 months; EVT group: median 21 months, IQR 11.5–43.5 months), we reviewed the patency rates and limb salvage rate. In the AxFB group, 13 of 18 limbs (72.2%) maintained primary patency and 2 others (11.1%) maintained secondary patency; however, the remaining 3 limbs became occluded. One of 18 limbs (5.6%) had to be amputated due to the onset of gangrene and we were unable to improve the ischemic condition even after performing AxFB grafting, and therefore, 17 of 18 limbs (94.4%) were ultimately salvaged. In the EVT group, 16 of 19 limbs (84.2%) retained their primary patency, and the other 3 showed assisted primary patency (15.8%). No limbs with
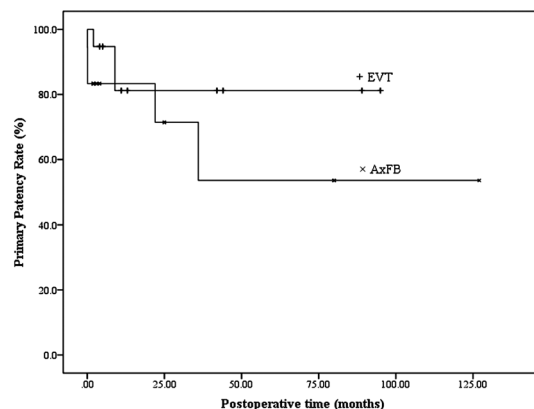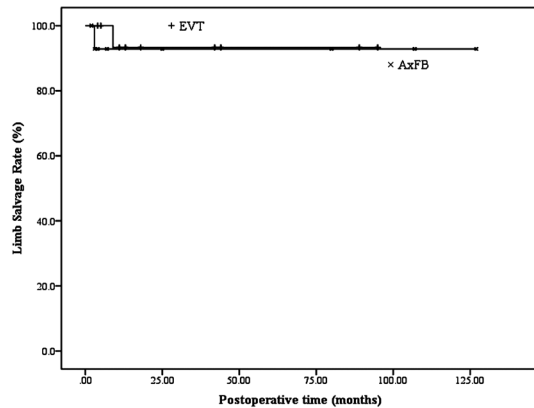

Fig. 1 Kaplan–Meier estimate of primary patency rate after 9 axillofemoral bypass (AxFB) surgeries and 10 patients with endovascular treatment (EVT).
The 5 year primary patency rate was relatively higher in EVT than AxFB (81.2% and 53.6%, respectively, log rank P=0.225).
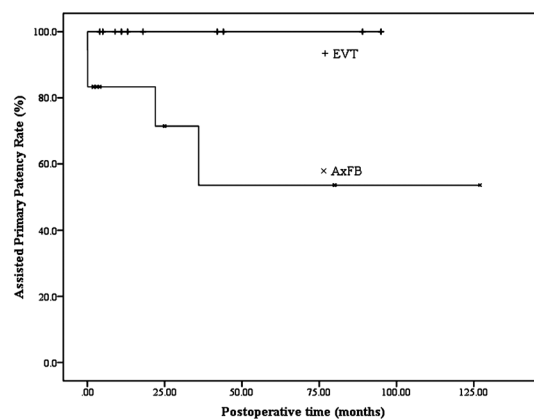
Fig. 2 Kaplan–Meier estimate of assisted primary patency rate after 9 axillofemoral bypass (AxFB) surgeries and 10 patients with endovascular treatment (EVT).
The 5 year assisted primary patency rate was significantly higher in the EVT group than the AxFB group (100% and 53.6%, respectively, log rank P=0.012).

secondary patency or occlusion were seen in the EVT group. However, amputation was required for 1 limb after the revascularization procedure due to the progression of infrainguinal ischemia and infection. Therefore, we salvaged 18 of 19 limbs (94.7%). One death (10.0%) occurred in the EVT group due to unknown causes but none in the AxFB group.

According to the Kaplan–Meier analysis, the primary patency rates in the AxFB and EVT groups were 83.3% and 81.2% at 1 year, 71.4% and 81.2% at 2 years, and 53.6% and 81.2% at 5 years, respectively (log rank P=0.225) (**Fig. 1**). The assisted primary patency rates in the AxFB and EVT groups were 83.3% and 100% at 1 year, 71.4% and 100% at 2 years, and 53.6% and 100% at 5 years, respectively, which showed statistical significance (log rank P=0.012) (**Fig. 2**). The secondary patency

Fig. 3 Kaplan–Meier estimate of limb salvage rate after 9 axillofemoral bypass (AxFB) surgeries and 10 patients with endovascular treatment (EVT).
The 5 year limb salvage rate was almost the same between AxFB group and EVT group (92.9% and 93.3%, respectively, log rank P=0.740).

rate in the EVT group was higher (100%) than in the AxFB group (83.3%) at 5 years, although not to a significant degree (log rank P=0.063). The limb salvage rates in the AxFB and EVT groups were 92.9% and 93.3% at 5 years, respectively (log rank P=0.740) (**Fig. 3**).

Discussion

In the present study, we evaluated the surgical outcomes of patients with complex AIOD treated by AxFB or EVT, as these patients were assumed to be unsuitable for AoFB grafting due to their preoperative systemic condition. Although we showed relatively similar intra- and perioperative results as well as postoperative follow-up outcomes, EVT procedure presented relatively better outcomes, including long-term patency rate. Compared with open bypass surgeries for patients with AIOD, EVT has shown less invasiveness and a better postoperative morbidity and mortality.[6,9] In previous reports, the results of EVT have been compared with those of AoFB grafting, with no reports comparing the results directly between AxFB and EVT procedures. Therefore, to our knowledge, this study is the first to report the direct comparison of the results between AxFB and EVT. On comparing the results between AxFB and EVT in this study, the EVT group showed a significantly shorter hospital stay (11.5 days) than the AxFB group (20 days, P=0.034). Furthermore, both groups showed similar low invasiveness (low rate of postoperative complications, including mortality), graft or treated lesion patency rate and limb salvage rate. Therefore, we successfully demonstrated the durability of the EVT procedure for patients with complex AIOD.

For AxFB surgeries, we used the externally supported 10-mm-diameter main limb of a Dacron graft with 8-mm-diameter externally supported bilateral femoral components of a Dacron graft. However, Samson et al.[7] reported that they implanted ring-reinforced 8-mm-diameter expanded polytetrafluoroethylene (ePTFE) grafts with or without heparin bonding. They found that these materials contributed to better outcomes, including better graft patency rates. Our materials and theirs share one similar point (externally reinforced graft) with two different points (Dacron vs. ePTFE, and non-heparin-bonded vs. heparin-bonded). We also implanted supported prosthetic grafts, as these kinds of supported grafts, including ring-reinforced ones, showed better patency rates than non-supported prosthetic grafts.[10,11] Regarding our preference for Dacron grafts over ePTFE grafts, even though ePTFE grafts are widely used nowadays, no statistically significant difference in superiority has been cited to support better patency rates for Dacron or ePTFE grafts.[12] When performing femoropopliteal bypass surgeries, heparin-bonded ePTFE grafts showed significantly better graft patency rates than non-heparin-bonded ePTFE grafts.[13] However, no report has compared the graft patency rates between heparin-bonded and non-heparin-bonded ePTFE grafts in AxFB. Furthermore, Samson et al.[7] reported that 2 of 34 (5.9%) non-heparin-bonded ePTFE grafts and 3 of 42 (7.1%) heparin-bonded ePTFE grafts were thrombosed; therefore, they concluded that they could not demonstrate the superiority of heparin-bonded ePTFE grafts for AxFB. Based on these comparisons (Dacron vs. ePTFE, extra-supported vs. non-supported, and heparin-bonded vs. non-heparin-bonded), some materials might affect patency rates in AxFB grafting, though not always positively.

In the AxFB group, 2 patients (22.2%) showed an early thrombosed bypass graft; however, no severe postoperative complications, such as mortalities, were observed. In the EVT group, no early graft thromboses or any kind of postoperative complications were seen. Compared with less-invasive AxFB grafting, EVT showed better safety (no postoperative complications), a shorter hospital stay and better early patency (no early thrombosis); therefore, the EVT procedure may be a viable alternative to AxFB for treating complicated patients with challenging AIOD.

In the present study, we implanted not covered stents but bare-metal stents in the aortoiliac lesions because the usage of covered stents for these lesions was not permitted during this study period in Japan. Recent reports have shown promising patency rates with covered-stent implantation compared with bare-metal stents.[14,15] Therefore, we might be able to achieve even better patency rates by implanting covered stents.

Several limitations associated with the present study warrant mention. The sample size of our study was small; therefore, our statistics might have been affected by the small sample size. By collecting a larger sample number,

we can examine the affecting factors for the outcomes, such as graft patency and limb salvage. Furthermore, we are now able to implant covered stents in patients with AIOD, which might further improve the outcomes of our EVT procedures. Therefore, we should collect more data in order to confirm the efficacy and safety of not only AxFB but also EVT in future studies.

Conclusion

We showed that EVT achieved a durable, better long-term patency rate for complex AIOD cases than AxFB. The safety and low invasiveness during the perioperative period were confirmed in both the AxFB and EVT groups. Therefore, our strategy for complex AIOD, in which we do not perform AoFB grafting for patients with preoperative comorbidities, is considered to be an effective and appropriate treatment modality. We should accumulate more samples in order to identify the factors most strongly influencing the outcomes of AxFB and EVT for challenging AIOD situations.

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Disclosure Statement

The authors have no conflicts of interest to declare.

Author Contributions

Study conception: MN, KI, TK
Data collection and analysis: MN, KI, SK
Investigation: KI
Writing: MN, KI
Review and revision: all authors
Final approval: all authors
Accountability for all aspects of the work: all authors

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