Original Article

Long-term results of endovascular reconstruction for aortoiliac occlusive disease

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Background: Open surgery is the gold standard for the treatment of aortoiliac occlusive disease (AIOD). Endovascular therapy has emerged as an attractive alternative for AIOD due to its minimal invasiveness. The aims of the present study were to investigate the long-term patency of endovascular treatment and to compare the outcomes of Transatlantic Inter-Society Consensus II (TASC II) A/B and C/D lesions.

Methods: Patients with AIOD (n=156) were enrolled in this retrospective cohort study. Patency rates were assessed at 12, 36, and 60 months after the procedure. Parameters for comparisons between TASC II A/B and C/D lesions included primary patency, secondary patency, freedom from target lesion revascularization (TLR), the technical success rate, the rate of complications, and risk factors for in-stent restenosis.

Results: For all patients, the technical success rate was 98.7%, the complication rate was 4.5%, and the mean follow-up period was 35.7 months. At 12, 36, and 60 months after the procedure, the primary patency rates were 96.5%, 88.3%, and 80.4%, respectively. The secondary patency rates were 99%, 96.4%, and 88%, respectively. The rates of freedom from TLR were 97.5%, 91.6%, and 89.6%. No significant differences were observed between A/B and C/D lesions in terms of primary patency (P=0.443), secondary patency (P=0.393), or freedom from TLR (P=0.481).

Conclusions: Endovascular reconstruction is effective and safe for AIOD, and should be the first-line treatment option for patients with TASC II A–D aortoiliac lesions.

Keywords: Aortoiliac occlusive disease (AIOD); endovascular procedures; Transatlantic Inter-Society Consensus II (TASC II)

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Introduction

Chronic arterial occlusive disease of the lower extremities is mainly caused by atherosclerosis, with symptoms ranging from intermittent claudication to critical limb ischemia (1). The disease is more prevalent among older people, affecting 16.9% of men and 20.5% of women aged ≥55 years (2,3). Approximately 30% of arterial lesions affect the aortoiliac segment, leading to aortoiliac occlusive disease (AIOD) (4).

According to the Transatlantic Inter-Society Consensus II (TASC II), which was published in 2007 (5), the first-line therapy for A/B lesions is endovascular therapy, while for C/D lesions, open surgery is still the preferred approach. However, endovascular devices and techniques have advanced considerably since 2007, and endovascular therapy currently has high rates of success and few complications, even for C/D lesions (6-12). Nevertheless, a consensus regarding the use of endovascular therapy for AIOD in C/D lesions has not been reached (13).

In the present study, we reviewed the 13-year experience

of the Department of Interventional Radiology and Vascular Surgery in Peking University First Hospital, in the use of endovascular reconstruction to treat AIOD. The long-term patency rates of the procedure were investigated and the outcomes of patients with TASC II A/B and C/D lesions were compared.

Methods

Patient population

This study was approved by the institutional human investigations committee of Peking University First Hospital (no. 2018043), and informed consent was obtained from all patients prior to participation. AIOD patients admitted to our department between November 2004 and May 2017 were enrolled. Patient baseline characteristics included age, sex, cardiovascular risk factors, and clinical status (14). Peripheral pulse status, ankle-brachial index (ABI) measurements, and duplex sonography results were collected. In all patients, AIOD was diagnosed by angiography or computed tomographic angiography (CTA). Lesions were classified as types A–D based on the TASC II criteria (5). Patients with stenosis ≥70% or total occlusion in the distal aorta, common iliac artery (CIA), or external iliac artery (EIA) were considered for endovascular treatment. All patients with AIOD in the present study received systematic stenting.

Endovascular procedures

Stents were primarily implanted in all lesions. Procedures were conducted under local anesthesia with supplemented intravenous sedation when required, and 6–7 F sheaths were chosen for artery access. Occlusions or stenoses were crossed by a 0.035- or 0.018-inch hydrophilic guidewire intraluminally or subintimally with a catheter. For chronic total occlusions (CTOs), antegrade recanalization was performed. In occlusive lesions of the ipsilateral CIA or EIA, the contralateral common femoral artery (CFA) was punctured using the crossover technique for an antegrade approach. For CTO of the abdominal aorta or bilateral iliac artery, left brachial arteries were also punctured to achieve antegrade recanalization. For aortic bifurcation lesions, a tri-directional approach (bilateral CFA and left brachial artery) was adopted with the pull-through technique.

In lesions involving the distal aorta and bilateral/ipsilateral CIA, kissing balloon inflation and stenting were performed with self-expandable stents (SESs), as they are flexible and widely available in China. Balloons with a diameter of 4–6 mm were chosen for pre-dilatation. For distal aortic occlusions, stents were implanted below the renal artery origins. Post-dilation was performed if residual stenosis was ≥30% after stent deployment. Bare metal stents (BMS) ranging in diameter from 7–10 mm and in length from 40–200 mm were used in the endovascular procedures. Covered stents were used as a bailout method for ruptured vessels. Concomitant CFA lesions (n=2) were treated with drug-coated balloon, introduced from the contralateral CFA at the same time; CFA endarterectomy was not performed.

During the procedure, heparin (60–80 U/kg) was used for anticoagulation. All patients were prescribed dual antiplatelet therapy (aspirin 100 mg/day and clopidogrel 75 mg/day) for at least 3 days before and 6 months following the procedure. After 6 months, either aspirin (100 mg/day) or clopidogrel (75 mg) was prescribed, depending on the patient. For patients with cardiovascular comorbidities, the strategy for antiplatelet therapy was at the doctors' discretion. Statin was prescribed for patients with dyslipidemia.

Follow-up

Follow-ups were scheduled at 1, 3, 6, and 12 months after discharge, and annually thereafter. During the visit, symptom enquiries, physical examinations, duplex ultrasound scanning, and ABI measurements were conducted. When the ABI decreased by >20%, duplex ultrasound scanning showed significant stenosis (>50%), or the patient had severe symptoms, CTA or angiography was performed.

Outcome measures and definitions

The main outcome measure of the present study was the cumulative primary patency rates at the 12-, 36-, and 60-month follow-ups. The secondary outcome measures were secondary patency rates, freedom from target lesion revascularization (TLR), the technical success rate, the rate of complications, and risk factors for in-stent restenosis.

Patency was defined as <50% restenosis on CTA/angiography or duplex ultrasound scanning. Primary patency was defined as uninterrupted patency without procedures, performed on or at the margin of the treated segment. TLR was defined as any intervention for treating restenosis or another complication of the

culprit vessels. Complications included local infection, dissection, thromboembolism, fistulas, hematoma, acute occlusion, renal failure, stroke, and myocardial infarction. Complications were considered to be major when death, a life-threatening condition, disability, or prolonged hospitalization occurred. Other complications were defined as minor complications. Symptom improvement was defined as a decline in Rutherford category of at least 1 grade.

Statistical analysis

Statistical analyses were performed using SPSS version 20.0 (SPSS, Chicago, IL, USA) software. Continuous data are shown as means ± standard deviations, and categorical data as counts and percentages. The baseline and immediate postoperative or follow-up measurements were compared using a paired *t*-test. The χ^2-test and unpaired *t*-test were applied for comparisons between A/B and C/D lesions. Kaplan-Meier survival analysis was used to estimate primary patency, secondary patency, and freedom from TLR, and comparisons between TASC II groups were examined with the log-rank test.

Cox regression analysis was used to identify independent predictors of restenosis. Variables associated with restenosis in the univariate analysis were entered into a multivariable model (P<0.10). Outcomes were depicted as hazard ratios and 95% confidence intervals. For all analyses, P<0.05 was considered to show statistical significance.

Results

Patient and limb characteristics

In total, 156 patients were included in the present study (age, 63.68±9.41 years), of whom 134 (85.9%) were male (*Table 1*). Fifty-two (33.3%), 30 (19.2%), 20 (12.8%), and 54 (34.6%) patients conformed to the TASC II lesion classifications of A, B, C, and D, respectively. The study cohort according to TASC II classification is shown in *Figure 1*. Overall, 124 (79.5%) patients had intermittent claudication and 32 (20.5%) had critical limb ischemia, corresponding to Rutherford categories 1–3 and 4–6, respectively (*Table 2*).

Cardiovascular diseases and risk factors were comparable between the TASC II A/B and C/D groups; however, the former group had a lower percentage of Rutherford category 4 cases (P=0.005), a higher baseline ABI value (P<0.001) (*Table 3*), and fewer superficial femoral artery (SFA) lesions (P=0.01). The rate of severe calcification was similar in both groups.

Acute outcomes

The overall technical success rate of aortoiliac lesion recanalization was 98.7%, with rates of 100% and 97.3% for A/B and C/D lesions, respectively (P=0.43). Technical failure in two cases was due to an inability to cross the CTO lesions. In 154 patients, 249 stents were deployed, including 238 SESs (200 GPS & Everflex, Medtronic, Plymouth, MN, USA; 15 Innova, Boston Scientific, San Jose, CA, USA; 10 Lifestent, Bard, Tempe, AZ, USA; 5 SmartControl, Cordis Santa Clara, CA, USA; 4 MARIS, Invatec, Torbole Casaglia BS, Italy; 4 Astron, Biotronik, Berlin, Germany), 8 balloon-expandable stents (BESs) (4 Scuba, Invatec, Torbole Casaglia BS, Italy; 4 Express LD, Boston Scientific, San Jose, CA, USA), and 3 covered stents (2 Viabahn Endoprosthesis, Gore Newark, DE, USA; 1 FluencyPlus Endovascular stent graft, Bard, Tempe, AZ, USA). Of these patients, 94 received 1 stent, 33 received 2 stents, and the rest received ≥3 stents.

The average number of stents used in the TASC A/B group was 1.18±0.59, compared with 2.05±1.25 in the C/D group (P<0.001). After the procedure, symptoms improved immediately in 94.9% (148/156) of patients, with no significant difference between the A/B (97.6%) and C/D (91.9%) groups (P=0.215). In both groups, the ABI improved significantly after the procedure (both P<0.001; *Table 3*).

Complications occurred in seven patients (4.5%, major complications in four patients and minor complications in three patients), of whom one patient was in the A/B group, and six were in the C/D group (P=0.091; *Table 4*). Three developed arterial rupture, and groin hematoma, thrombus formation at the site of treatment, myocardial infarction, and intracranial hemorrhage affected one patient each. All three arterial ruptures occurred in the C/D group; however, the difference in rupture rate between the two groups was not significant (P=0.104). There were two procedure-related deaths, both of which occurred in the C/D group, with one resulting from arterial rupture and subsequent hemorrhagic shock, and the other caused by intracranial hemorrhage. The procedure-related mortality rate was 2.7% in the C/D group and 0% in the A/B group (P=0.223), equating to an overall procedure-related mortality rate of 1.3%.

Follow-up outcomes

The overall follow-up rate was 81.2% (125/154), and the

Table 1 Clinical characteristics and lesion classifications of the entire cohort and patients in the TASC II A/B or C/D group

Variables	Total	TASC A/B	TASC C/D	P value*
Patients, n	156	82	74	–
Age (years)	63.68±9.41	63.82±9.40	63.51±9.49	0.835
Male	134 (85.9)	68 (82.9)	66 (89.2)	0.357
Hypertension	111 (71.2)	60 (73.2)	51 (68.9)	0.598
Dyslipidemia	111 (71.2)	54 (65.9)	57 (77.0)	0.157
Diabetes	58 (37.2)	34 (41.5)	24 (32.4)	0.252
Nicotine	124 (79.5)	62 (75.6)	62 (83.8)	0.237
Coronary artery disease	51 (32.7)	27 (32.9)	24 (32.4)	1.000
Ischemic stroke	44 (28.2)	19 (23.2)	25 (33.8)	0.157
Renal artery stenosis	31 (19.9)	15 (18.3)	16 (21.6)	0.689
SA stenosis/occlusion	28 (18.0)	16 (19.5)	12 (16.2)	0.678
CA or VA stenosis/occlusion	37 (23.7)	24 (29.3)	13 (17.6)	0.094
Rutherford category				
1	2 (1.3)	1 (1.2)	1 (1.3)	1.000
2	17 (10.9)	12 (14.6)	5 (6.8)	0.130
3	105 (67.3)	61 (74.4)	44 (56.5)	0.060
4	21 (13.5)	5 (6.1)	16 (21.6)	0.005
5	9 (5.8)	2 (2.4)	7 (9.5)	0.125
6	2 (1.3)	1 (1.2)	1 (1.3)	1.000
CFA lesion	2 (1.3)	0 (0.0)	2 (2.7)	0.13
SFA lesion	40 (25.6)	14 (17.1)	26 (35.1)	0.01
Severe calcification	83 (53.2)	43 (52.4)	40 (54.1)	0.84

Continuous data are presented as means ± standard deviations; categorical data are given as n (%); *, P value indicates significance of difference between A/B and C/D groups. TASC II, Transatlantic Inter-Society Consensus II; SA, subclavian artery; CA, carotid artery; VA, vertebral artery; CFA, common femoral artery; SFA, superficial femoral artery.

mean follow-up time was 35.7±29.1 [5–144] months. Five patients (4%) died during follow-up (one due to cancer, one due to chronic kidney disease, and three due to unknown reasons). The cumulative primary patency rates at 12, 36, and 60 months post treatment were 96.5%, 88.3%, and 80.4%, respectively (*Figure 2*). During follow-up, 6 patients (7.31%) in the A/B group and 10 patients (13.5%) in the C/D group developed restenosis at the site of treatment. A total of eight patients received TLR during follow-up; of them, five patients received angioplasty, two received additional stents, and one received percutaneous mechanical thrombectomy. The cumulative rates of freedom from TLR at 12, 36, and 60 months were 97.5%, 91.6%, and 89.6%, respectively (*Figure 2*). The cumulative secondary patency rates at 12, 36, and 60 months after treatment were 99%, 96.4%, and 88%, respectively (*Figure 2*).

For A/B lesions, the primary patency rates at 12, 36, and 60 months were 98.6%, 90.1%, and 83.5%, respectively (Kaplan-Meier survival analysis) (*Figure 3*). For C/D lesions, the primary patency rates at 12, 36, and 60 months were 93.6%, 85.8%, and 73.5%, respectively. The difference between the two groups was not significant (P=0.443). The rates of secondary patency and freedom from TLR were also not significantly different between the A/B and C/D groups (P=0.393 and P=0.481, respectively).

The symptoms of 90.4% (114/125) of patients improved

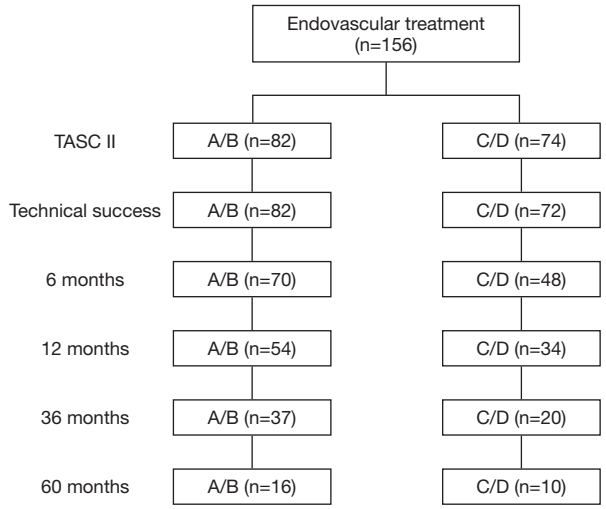


Figure 1 Flow diagram of the study cohort according to the TASC II classification. TASC II, Transatlantic Inter-Society Consensus II.

Table 2 Lesion characteristics of the cohort

Variables	Value
Lesion length (cm)	6.8±1.8
Bilateral lesions	71 (45.5)
Aortic lesions (with or without iliac lesions)	16 (10.3)
CTO lesions	82 (52.6)
Solitary CIA lesions	98 (50.5)
Solitary EIA lesions	48 (24.7)
Lesions of both CIA and EIA	48 (24.7)

Continuous data are presented as means ± standard deviations; categorical data are given as n (%). CTO, chronic total occlusion; CIA, common iliac artery; EIA, external iliac artery.

Table 3 ABI improvement after the procedure or at follow-up compared with baseline

ABI	Total	TASC II A/B	TASC II C/D	P*
Baseline	0.56±0.23	0.67±0.21	0.47±0.20	<0.001
Post-procedure	0.92±0.27**	0.98±0.22**	0.87±0.30**	0.055
Follow-up	0.96±0.29**	0.97±0.27**	0.96±0.31**	0.916

*, P value indicates significance of difference between the A/B and C/D groups; **, P<0.001 of baseline value. ABI, ankle-brachial index; TASC II, Transatlantic Inter-Society Consensus II.

Table 4 Intraoperative performance of patients in the TASC II A/B and C/D groups

Variables	TASC II A/B	TASC II C/D	P value*
Patients, n	82	74	
Technical failure, n (%)	0 (0.0)	2 (2.7)	0.43
Complications			
Total, n (%)	1 (1.2)	6 (8.1)	0.091
Rupture, n	0	3	
Groin hematoma, n	0	1	
Thrombus at the treatment site, n	0	1	
Myocardial infarction, n	1	0	
Intracranial hemorrhage, n	0	1	

*, P value indicates significance of difference between the A/B and C/D groups. TASC II, Transatlantic Inter-Society Consensus II.

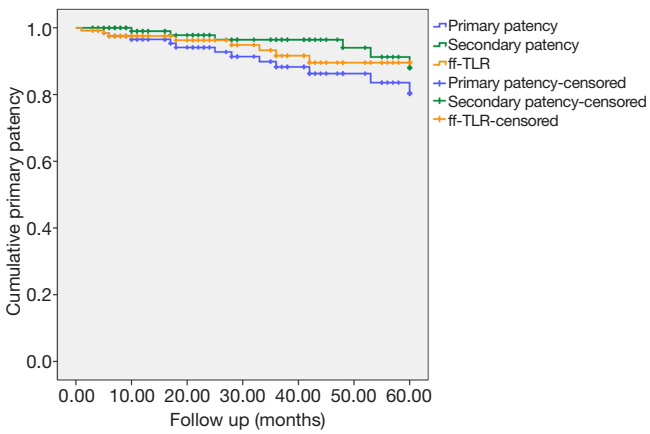
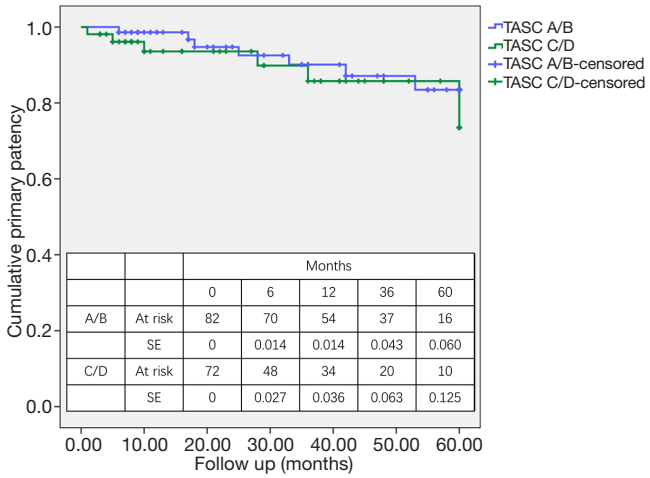


Figure 2 Kaplan-Meier analysis showing the cumulative primary patency, secondary patency, and freedom from TLR of the cohort at different follow-up times. TLR, target lesion revascularization.

during follow-up, with no significant difference between the two groups (P=0.457). In both the A/B and C/D groups, the ABI values showed a significant increase relative to baseline (P<0.001 for both) (*Table 3*).

Univariate analysis determined that none of the included variables were risk factors for in-stent restenosis (all P>0.10) (*Table 5*). Therefore, no factors were entered in the Cox multivariate analysis.



		Months				
		0	6	12	36	60
A/B	At risk	82	70	54	37	16
	SE	0	0.014	0.014	0.043	0.060
C/D	At risk	72	48	34	20	10
	SE	0	0.027	0.036	0.063	0.125

Figure 3 Kaplan-Meier analysis showing the cumulative primary patency of TASC II A/B and C/D groups at different follow-up times. For A/B lesions, the primary patency rates at 12, 36, and 60 months were 98.6%, 90.1%, and 83.5%, respectively. For C/D lesions, the primary patency rates at 12, 36, and 60 months were 93.6%, 85.8%, and 73.5%, respectively (P=0.443). TASC II, Transatlantic Inter-Society Consensus II.

Discussion

In the present study, data of 156 AIOD patients treated with an endovascular approach were reviewed. The mean follow-up period was 35.7 [5–144] months. The overall primary patency rates at 12, 36, and 60 months after the procedure were 96.5%, 88.3%, and 80.4%, respectively, and the cumulative freedom from TLR rates were 97.5%, 91.6%, and 89.6%, respectively. At the 60-month follow-up, no significant differences were found between the A/B and C/D groups in terms of the rates of primary patency, secondary patency, or freedom from TLR. The technical success rate for all patients was 98.7%, while the complication rate was 4.5%.

In recent years, endovascular therapy has been widely applied for AIOD. A large-scale meta-analysis of AIOD treatments determined that hospital stay, complication risk, and mortality were significantly lower for patients undergoing endovascular therapy, although those who underwent open bypass achieved higher primary patency rates (15). Similarly, a study of 4,119 AIOD patients showed that endovascular procedures resulted in lower

Table 5 Univariable analysis of risk factors for restenosis

Factors	Standard error	χ^2-test	Hazards ratio	95% confidence limit for hazards ratio
Sex (male *vs.* female)	0.659	0.392	1.757	0.48–6.39
Age (≥65 *vs.* <65)	0.573	0.834	1.127	0.37–3.47
Stroke (yes *vs.* no)	0.602	0.858	0.898	0.28–2.93
Coronary heart disease (yes *vs.* no)	0.571	0.777	1.175	0.38–3.60
Diabetes (yes *vs.* no)	0.557	0.308	1.765	0.59–5.26
Hypertension (yes *vs.* no)	0.659	0.984	0.987	0.27–3.59
Smoking (yes *vs.* no)	0.659	0.715	0.786	0.22–2.86
Dyslipidemia (yes *vs.* no)	0.574	0.295	0.548	0.18–1.69
Renal artery stenosis (yes *vs.* no)	0.770	0.746	0.780	0.17–3.52
TASC II category (C/D *vs.* A/B)	0.560	0.447	1.531	0.51–4.59
SFA lesion (yes *vs.* no)	0.770	0.471	0.574	0.13–2.60
Leriche syndrome (yes *vs.* no)	0.769	0.854	1.152	0.26–5.20
Covered stents (yes *vs.* no)	12.395	0.807	0.049	0.00–1732843285.35
Kissing stents (yes *vs.* no)	0.659	0.425	1.692	0.47–6.16
Multiple stents (yes *vs.* no)	0.573	0.834	1.127	0.37–3.47
Rutherford (4–6 *vs.* 1–3)	1.042	0.456	0.460	0.06–3.55

TASC II, Transatlantic Inter-Society Consensus II; SFA, superficial femoral artery.

complication rates, reduced cost, and shorter hospitalization compared with open surgery (16). Another study reported that plain old balloon angioplasty (POBA) achieved primary patency rates of only 54% and 50% at 5 and 10 years after treatment, respectively, whereas those of stenting after suboptimal POBA were 82% and 75%, respectively (17). In the present study, the cumulative primary patency rates were 96.5%, 88.3%, and 80.4% at 12, 36, and 60 months after the procedure, respectively. Further, the mean ABI and Rutherford's category were significantly improved, suggesting a satisfactory outcome.

Endovascular therapy for C/D lesions is not the preferred choice, according to TASC II (5). However, recent studies have provided evidence in recommending endovascular treatment in AIOD (7-9,17,18). The Cardiovascular and Interventional Radiological Society of Europe guidelines state that endovascular therapy is the first-line option for treating type A, B, and C lesions, and in experienced centers, D (19). Furthermore, a comparison between A/B and C/D lesions showed that the technical success and long-term cumulative primary patency rates were not significantly different (8). Sixt *et al.* demonstrated that the first-line therapy strategy for AIOD should be an endovascular approach, independent of the TASC II classification (9). A novel endovascular technique, the covered endovascular reconstruction of the aortic bifurcation technique, has been applied for AIOD lesions, with reported primary patency rates of 86%, 84%, and 82% at the 1- 2-, and 3-year follow-ups, respectively (20). In the present study, the difference in primary patency rates was not significant (P=0.443), and the Rutherford category and ABI improvements were similar between the A/B and C/D groups.

In the present cohort, Cox analysis showed that none of the considered risk factors were related to long-term primary patency, which differed from a previously published study that indicated that female sex and residual stenosis were independent predictors of restenosis in aortoiliac bifurcation lesions (21). Another single-center study reported that the absence of anti-platelet medication was the only independent risk factor (10). The BRAVISSIMO study determined that only kissing stent configuration and obesity were predictors of restenosis (22). There is currently no consensus on the risk factors for AIOD restenosis after endovascular therapy.

In the current study, a primary stenting strategy was applied. The advantages of stent deployment over percutaneous transluminal angioplasty in terms of technical success and clinical outcomes have already been demonstrated in a previously published meta-analysis (23). However, there are also controversial reports. In the Dutch Iliac Stent Trial, 279 patients were randomly assigned to receive either direct stent placement or primary angioplasty with subsequent stent placement. No significant differences were found in technical success, or short- or long-term clinical outcomes (24,25). Another study showed that selective stenting was associated with a higher clinical success rate but inferior long-term clinical success compared with primary stenting (26).

In the endovascular management of AIOD, covered stents appear to be superior compared with BMS (27-29). However, the relatively high cost of covered stents is a limiting factor for their widespread application. BESs are seemingly preferred to SESs for treating AIOD, especially in patients with lesions with severe calcification or greater recoil, due to their precise deployment and greater radial strength (30). However, there is limited evidence to support the superiority of BESs. In the only randomized controlled trial to compare BESs with SESs, the latter were found to have lower binary restenosis and lower rates of TLR compared with BESs (31). In the present study, most patients were treated with SESs, and we obtained a satisfactory outcome in both technical success and long-term patency.

Our overall complication rate was 4.5%, which is in accordance with the 3–45% reported in a previous systematic review (32). The procedure-related mortality rate was 1.3%, which is also within the 1.2–6.7% range reported previously (32). Furthermore, in our study, the complication rates in patients with A/B and C/D lesions were similar. This finding differs from that of Ichihashi *et al.*, who found C/D lesions (8.8%) to have a higher complication rate than A/B lesions (3.1%, P=0.014) (8).

The present study has two limitations. First, it was a single-center review of only endovascular treatment. Comparisons with open surgery could not be performed. Second, bias related to the sample size and loss to follow-up may limit the generalizability of the results.

Conclusions

Endovascular reconstruction for AIOD achieves good long-term primary patency, secondary patency, and freedom from TLR, with high rates of technical success and low rates of complications for both A/B and C/D lesions. Therefore, an endovascular-first treatment strategy should be considered

in patients with aortoiliac disease, regardless of the current TASC classification.

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Footnote

Conflicts of Interest: All authors have completed the ICMJE uniform disclosure form (available at http://dx.doi.org/10.21037/qims-20-599). The authors have no conflicts of interest to declare.

Ethical Statement: The study was approved by institutional ethics/ committee of Peking University First Hospital (No. 2018043) and informed consent was taken from all the patients.

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