Original Article

Open and Endovascular Treatment of Trans-Atlantic Inter-Society Consensus II D Aortoiliac Occlusive Lesions: What Determines the Rate of Restenosis?

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Abstract

Background: Open surgery is the preferred approach for the treatment of type D lesions according to the Trans-Atlantic Inter-Society Consensus (TASC) II guideline, but endovascular solutions also appear to be a valid option in selected patients. The study aimed to identify the risk factors of restenosis after open and endovascular reconstruction of symptomatic TASC II D aortoiliac occlusive lesions (AIOLs).
Methods: Fifty-six patients (82 limbs) who underwent open repair and endovascular treatment (ET) for symptomatic TASC II D AIOLs between March 2005 and December 2012 were retrospectively reviewed. Baseline characteristics, preoperative and postoperative imaging, and operation procedure reports were reviewed and analyzed. Restenosis after revascularization was assessed by duplex ultrasound or computed tomography angiogram. Kaplan-Meier survival analysis, Log-rank test, and multivariate Cox regression were used to evaluate the relevance between risk factors and patency.
Results: The mean duration of follow-up was 42.8 ± 23.5 months (ranging from 3 to 90 months). Primary patency rates at 1-, 3-, 5-, and 7-year were 93.6%, 89.3%, 87.0%, and 70.3%, respectively. Restenosis after revascularization occurred in 11 limbs. Kaplan-Meier survival analysis and the Log-rank test revealed that diabetes, Rutherford classification ≥5th and concurrent femoropopliteal TASC II type C/D lesions were significantly related to the duration of primary patency. According to the result of Cox regression, diabetes and femoropopliteal TASC II type C/D lesions were identified as the risk factors for restenosis after revascularization.
Conclusion: This study demonstrated that diabetes and femoropopliteal TASC II type C/D lesions are risk factors associated with restenosis after open and ET of TASC II D AIOLs.

Key words: Aortoiliac Occlusive Lesions; Reconstruction; Restenosis; Risk Factor; Trans-Atlantic Inter-Society Consensus II

Introduction

There has been a dramatic improvement in the treatment of symptomatic aortoiliac occlusive lesions (AIOLs) since the revision of Trans-Atlantic Inter-Society Consensus (TASC) II classification in 2007.[1] Although open surgery is the preferred approach for treatment of type D lesions according to the TASC II guideline, endovascular solutions also appear to be a valid option in selected patients, with similar success rate but less mortality and complications. Patient selection based on risk factors of restenosis is important for vascular reconstruction.[2-4] Here we reported an analysis of the predictive risk factors of restenosis according to the experience of 56 consecutive patients (82 limbs) who underwent open and endovascular repair of TASC II D AIOLs at Department of Vascular Surgery, Peking University People's Hospital.

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Methods

Patients and treatment

This retrospective study was approved by Ethics Committee of Peking University People's Hospital. From March 2005 to December 2012, 56 patients (82 limbs) successfully underwent primary vascular reconstruction for symptomatic aortoiliac TASC II D atherosclerotic occlusive disease at Department of Vascular Surgery, Peking University People's Hospital. The diagnosis and the TASC classification were confirmed by computed tomography angiogram (CTA) or digital subtraction angiography (DSA). For patients treated before 2007, the classification was performed retrospectively by another vascular surgeon who was blinded to outcomes.

The population consisted of 47 male and 9 female patients; all of them suffered from chronic limb ischemia with Rutherford classification of 3–6. Patients who had acute limb ischemia, including acute embolism or thrombosis, dissection, aneurysm, arteritis, pseudoaneurysm, or repeat procedures for similar aortoiliac lesions, were excluded from this analysis.

Patient demographics, symptomatology, Rutherford classification, preoperative medication, existing comorbid conditions, smoking history, and other risk factors for atherosclerosis were reviewed. Preoperative CTA or DSA, operative report, and postoperative duplex ultrasound or CTA were evaluated to describe the lesion by length, degree of calcification and limb patency. Lesions of all 6 subclassifications of type D lesions were present, namely type a, b, c, d, e, and f [Figure 1].

Treatment of the 82 limbs included 60 endovascular procedures and 22 open repairs. The type of procedures depended firstly on the patients' conditions. Age, comorbidities, contraindication to open surgery, and patient's preference were taken into consideration. Beyond that, the physician's preference, expertise, the technical level on endovascular treatment (ET) also determined the operative program.

All patients received vasodilator and antiplatelet therapy before and after ET. For patients that underwent endovascular therapy, planning according to the angiographic characteristics of the lesions was performed. The treatment option in all cases included plain old balloon angioplasty (POBA), and then stent deployments in total 74 stents were deployed in 60 iliac arteries. POBA was performed before and after stents deployment in most cases ($n = 56$), POBA were not performed first in other 4 cases because of highly suspected aneurysm or secondary thrombosis. All stents were self-expandable. Covered stents ($n = 17$) were chosen according to long occlusive lesions or iliac aneurysm which was more potent to hemorrhage or precarious secondary thrombosis. Bare stents were performed in more cases ($n = 43$) for the sake of internal iliac artery with low risk of hemorrhage and thromboembolism.

Twenty-two limbs were treated with open repair and insertion of a vascular prosthetic graft, including 7 aortic-bilateral femoral grafts (14 limbs), 5 femoral-femoral grafts (5 limbs), 1 common iliac-femoral graft (1 limb), and 1 axillary-bilateral femoral graft (2 limbs). All bypass material were polytetrafluoroethylene grafts, no autogenous saphenous veins were used.

Surveillance and definitions

Surveillance was performed by ultrasound at 1, 3, 6, and 12 months after treatment. CTA or DSA was used only if the ultrasound was inconclusive or suggested restenosis requiring reintervention. Technical success was defined by a patent bypass or stent with a residual lumen >70% and patient alive without major complications within 30 days. Restenosis was defined as the diameter of vessel or stent lumen <50% or a peak systolic velocity ratio >2.5 in the ultrasound scan.

Statistical analysis

Continuous data were presented as mean ± standard deviation (SD); categorical data were given as counts and percentages. Patency and limb salvage rates were estimated using Kaplan-Meier analysis; the curves were compared using the Log-rank test. Association among categorical variables was tested using the Cox regression. Variables consisted of sex, age, comorbidities, Rutherford classification, lesions in femoropopliteal arteries, subclassifications of type D lesions, and procedural factors. Limbs were censored for their primary endpoint in patency, limb salvage, survival, and restenosis. Values of $P < 0.05$ were considered to be statistically significant. The analysis was performed using SPSS 20.0 (SPSS Inc., Chicago, IL, USA).

Results

The number of endovascular therapy cases were slightly higher than that of open surgery from 2005 to 2009 in our center, however, the proportion of ET grew up obviously along with the increased endovascular technical level and experience after 2009 [Figure 2].

The mean duration of follow-up was 42.8 ± 23.5 months (ranging from 3 to 90 months). None of the patients was lost to follow-up. Four patients (with 6 limbs) died due to cancer

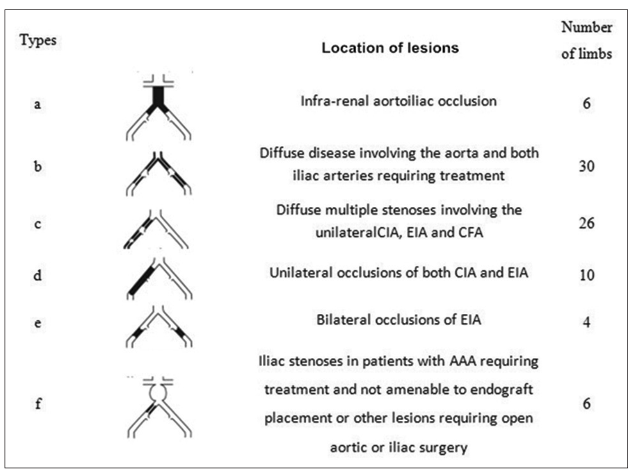

Figure 1: Summary of subclassifications of type D lesions.

(1 patient with 2 limbs), ischemic heart disease (2 patients with 3 limbs), and stroke, none of them was directly related to the limbs treated.

For all the patients in this study, the rates of primary patency were 93.6%, 89.3%, 87.0%, and 70.3% at 1-, 3-, 5-, and 7-year, respectively. The rates of secondary patency were 96.1%, 93.2%, 91.0%, and 75.1% at 1-, 3-, 5-, and 7-year, respectively [Figure 3].

Univariate analysis

The risk factors of all patients for atherosclerosis were reviewed, the summary and univariate analysis of the risk factors were listed as following. The risk factors were analyzed successively by three groups: The baseline characteristics, symptoms and lesions, and procedures and stents.

Baseline characteristics

Hypertension (n = 27, 48.2%), diabetes (n = 16, 28.6%), hypercholesterolemia (n = 17, 30.4%), coronary artery disease (n = 13, 23.2%), and smoking (n = 38, 67.9%) were estimated individually using Kaplan–Meier analysis, finally only the diabetes was identified to be associated with decreased patency rate. The analysis of hypertension (P = 0.293), hypercholesterolemia (P = 0.395), coronary artery disease (P = 0.559), and smoking (P = 0.629) was negative [Figure 4].

The rates of primary patency for all patients with diabetes (25 limbs) were 77.3%, 53.1%, and 53.1% at 1-, 3-, and 5-year,

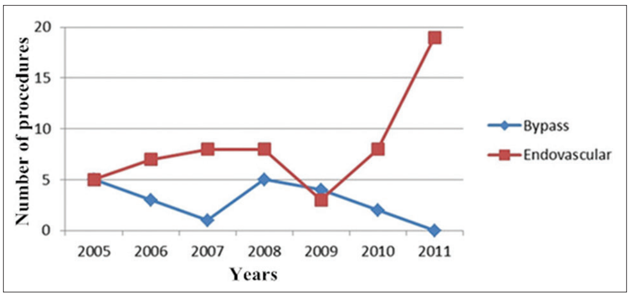

Figure 2: The number of the bypass and endovascular procedures during 2005–2011 in this study: A shift from bypasses toward endovascular treatment.

respectively; and in patients without diabetes (57 limbs), the rates of primary patency were 94.4%, 94.4%, 80.9% at 1-, 3-, 5-year, respectively (χ^2 = 6.418, P = 0.011) [Figure 5].

Symptoms and lesions

The symptoms were indicated by Rutherford classification, the risk factors of the lesions included the TASC II D subclassifications of the AIOLs and the runoff of the AIOLs which was evaluated by the TASC II classification of the lesions in the femoropopliteal segment.

Subclassifications of type D lesions

Subclassifications of TASC II D lesion were not prognostic for primary patency rate by univariate analysis [Table 1 and Figure 6a].

Rutherford classification

Univariate analysis of Rutherford classification indicated that class ≥5th (n = 13, 45.1%) were significantly associated with worse outcomes compared to class 2 (n = 14, 17.0%), 3 (n = 35, 42.6%), and 4 (n = 20, 24.4%) [Table 2 and Figure 6b].

Lesions in femoropopliteal segment

According to the TASC type of the lesions in femoropopliteal segment, patients were divided into three groups: No lesions (n = 37, 45.1%), type A/B (n = 8, 9.8%), and type C/D (n = 37, 45.1%). The rates of primary patency of 37 limbs with TASC type C/D lesions in the femoropopliteal segment were 82.6%, 72.2%, and 72.2% at 1-, 3-, and 5-year, respectively. It was 97.3%, 97.3%, 83.4% at 1-, 3-, 5-year for 37 limbs without lesion in the femoropopliteal segment (χ^2 = 5.028, P = 0.025) [Figure 6c].

Procedures and stents

Sixty (73.2%) limbs were treated by endovascular therapy, of which 43 (71.6%) were revascularized by bare stents, and the rest 17 (28.4%) were by covered stents. Twenty-two limbs were treated by artificial vessel bypasses.

Procedure

Three restenoses occurred in bypasses and 8 in stents. The occlusions of 3 bypasses and 4 stents were caused by thrombosis and were treated with catheter-directed thrombolysis (2 stents) and transfemoral embolectomy

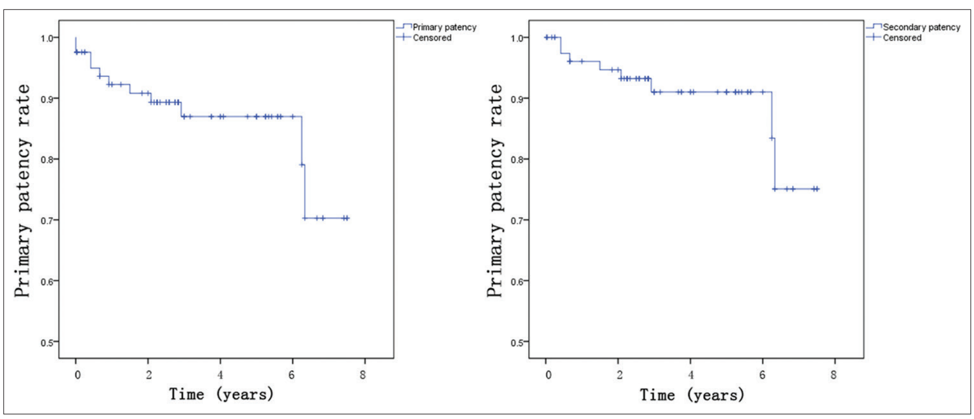

Figure 3: Primary patency and secondary patency rates of all the limbs treated.

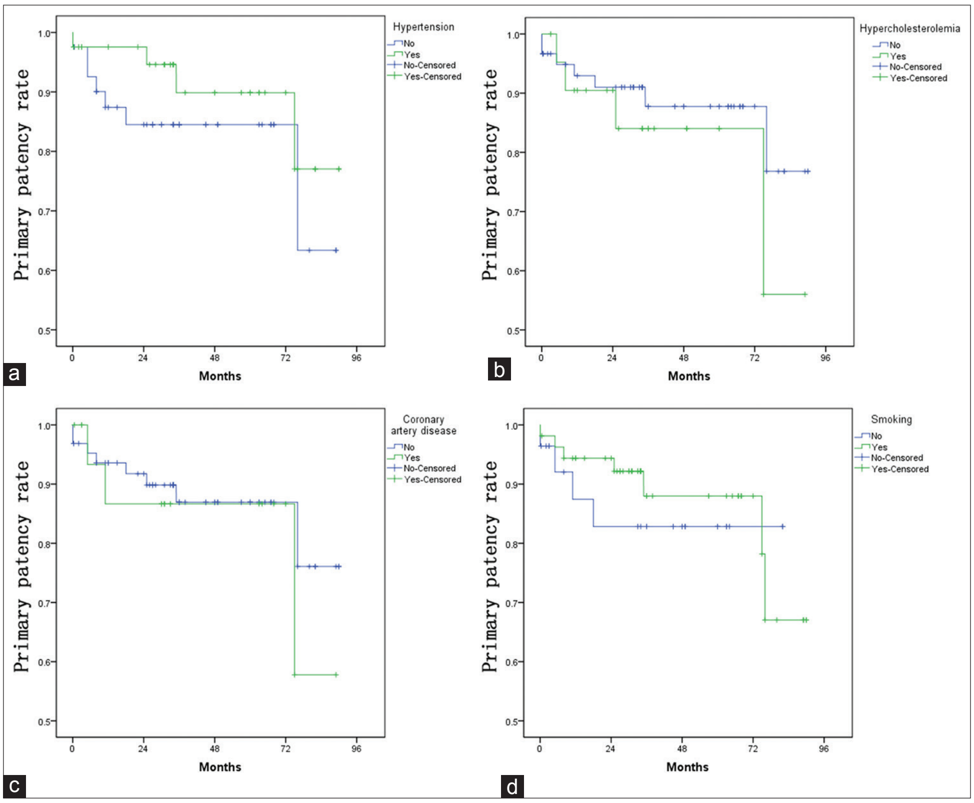

Figure 4: The univariate analysis of hypertension (a, $P = 0.293$), hypercholesterolemia (b, $P = 0.395$), coronary artery disease (c, $P = 0.559$) and smoking (d, $P = 0.629$), no positive differences were identified.

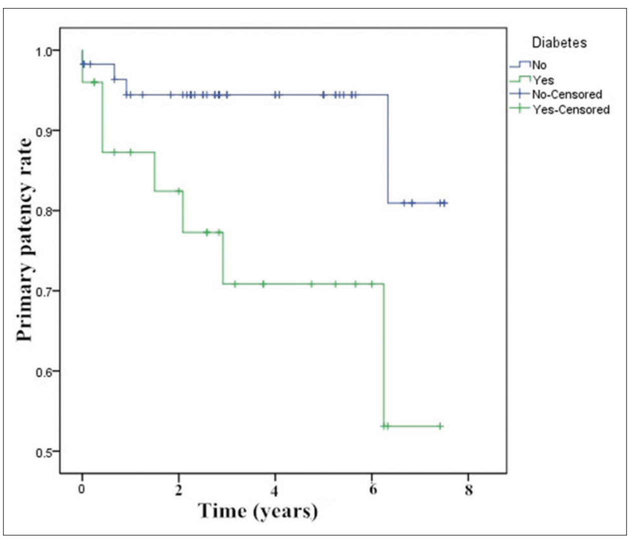

Figure 5: Diabetes was identified to be a risk factor for the primary patency by univariate analysis ($P = 0.011$).

(3 bypasses and 2 stents). The other 4 restenoses in stents were caused by intimal hyperplasia and be treated by balloon angioplasty (3 cases) and femoral-femoral bypass (1 case). The primary patency rates of the bypasses were 94.7%, 94.7%, and 63.2% at 1-, 5-, and 7-year, respectively, and those of stents were 91.2%, 83.4%, and 83.4%, respectively. There was no significant difference in primary patency rates between patients managed with ET versus bypass ($\chi^2 = 0.235$, $P = 0.321$) [Figure 7].

Table 1: Log-rank analysis of primary patency rates according to TASC II D subclassifications

Subclassifications	a	b	c	d	e	f
a	–	0.160	0.441	0.480	0.221	0.136
b	0.160	–	0.102	0.261	0.991	0.204
c	0.441	0.102	–	0.811	0.348	0.381
d	0.480	0.261	0.811	–	0.114	0.317
e	0.221	0.991	0.348	0.114	–	0.221

TASC: Trans-Atlantic Inter-Society Consensus. "– " represented not applicable.

Table 2: Log-rank analysis of primary patency rate according to Rutherford classification

Rutherford classification	Number of limbs	Primary patency rate (%)		Log-rank test versus class ≥5th	
		1-year	3-year	χ^2	*P*
Class 2	14	100	100	4.990	0.025
Class 3	35	94.3	89.6	5.101	0.024
Class 4	20	94.7	89.6	4.152	0.042
Class ≥5th	13	76.2	58.0	–	–

"-" represented not applicable.

Stents

Eight restenoses occurred in stents after endovascular reconstruction, of which 6 occurred in 43 bare stents and 2 in 17 covered stents. No significant difference was

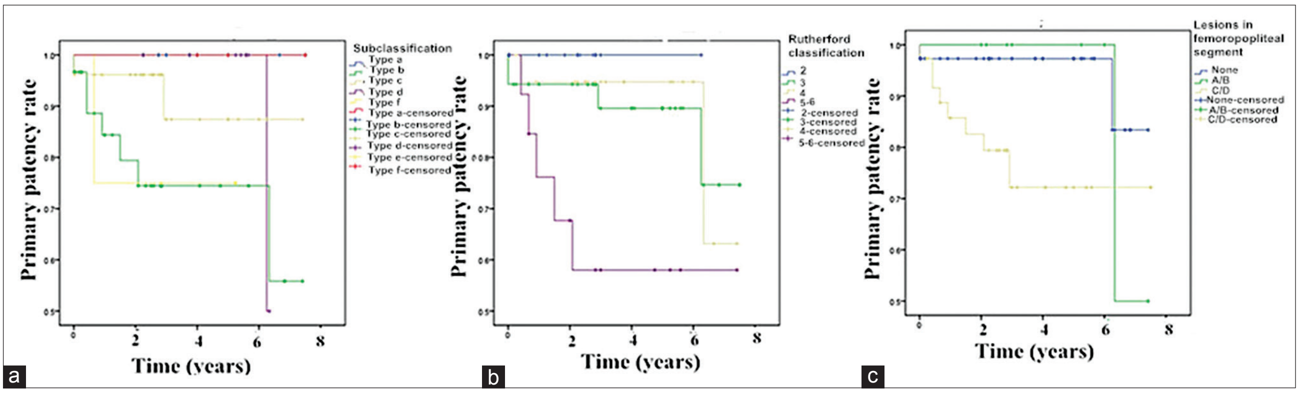

Figure 6: Primary patency according to subclassification (a), symptoms (b) and lesions (c).

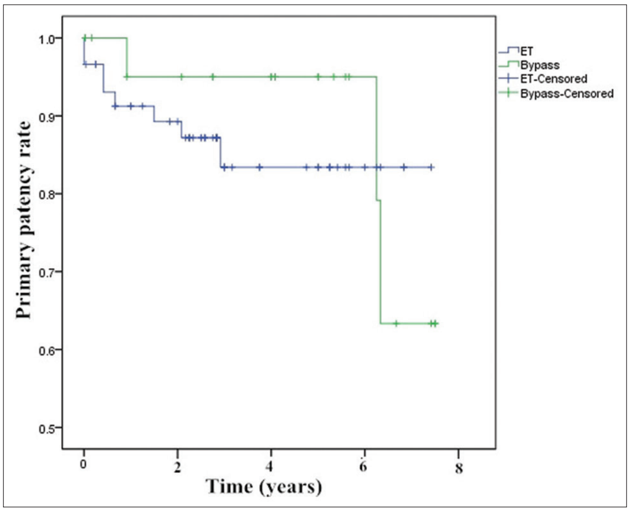

Figure 7: There was no significant difference between the primary patency of endovascular treatment group and bypass group ($P = 0.321$).

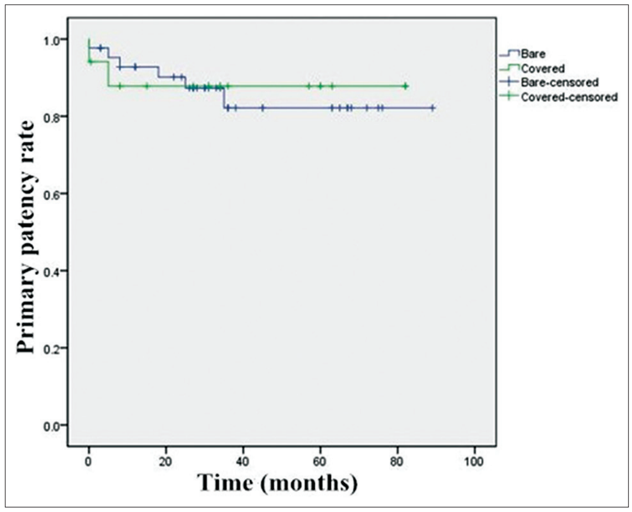

Figure 8: There was no significant difference between the primary patency of bare and covered stents ($P = 0.876$).

identified in primary patency rates between these two types of stent ($\chi^2 = 0.024$, $P = 0.876$) [Figure 8].

Cox regression analysis

Cox regression analysis of these three factors, which were identified by univariate analysis to be associated with decreased primary patency rate, only suggested that diabetes and TASC II C/D lesions were the risk factors for restenosis [Table 3]. Rutherford class ≥5th did not appear to be significantly associated with worse outcomes ($\chi^2 = 2.753$, $P = 0.150$).

Table 3: Multivariate Cox regression of primary patency according to the risk factors

Factors	β	χ^2	P	Exp(B)	95% *CI*
Diabetes	−1.350	4.030	0.005	6.789	1.771–26.019
Type C/D lesions in femoral-popliteal arteries	−2.425	6.428	0.011	1.593	1.014–4.927

Exp(B): Relative risk; *CI*: Confidence interval.

Discussion

In this study, the risk factors of restenosis after vascular reconstruction of symptomatic TASC II D AIOLs are concerned with patients' demographics, Rutherford classification, the severity of lesions and surgical procedures. The factors for patients included demographics, symptomatology, Rutherford classification, preoperative medication, existing comorbid conditions, smoking history, and other risk factors of atherosclerosis. Factors for lesions included the subclassifications of type D lesions and runoff (lesions in the femoropopliteal segment), and those for procedure included the operative program and the different stents used. We will discuss the positive results and some negative results of the analysis as following.

Diabetes has been demonstrated consistently as a risk factor of restenosis, both for endovascular stents and bypass surgery.[5-7] Some reports also verified that the control of diabetes after the procedure was associated with better patency.[5,8,9] This was confirmed in our study again. The proposed underlying mechanisms included: The change of blood viscosity and the enhance of platelet activation by atherosclerotic or implants can lead vascular smooth muscle cell to further proliferation, differentiation and migration which can give rise to intimal hyperplasia.[10,11] Second, the abnormity of hemodynamic slows down the velocity of blood flow, the thrombogenesis brings about vascular restenosis or occlusion.[10-12] Thirdly, for patients with diabetes, their infrapopliteal arteries are generally worse than an aortoiliac artery, the high resistance of runoff can lead to restenosis of proximal arteries.[10,13]

Poor runoff was confirmed to be an independent predictor of restenosis after iliac artery reconstruction surgery.[14-17] Kudo *et al.*[18] reported that the stenotic superficial femoral artery was the risk factor to increase the failure of revascularition. In fact, it is a common challenge for the vascular surgeon when faces to peripheral artery occlusive disease because of its systematicness. The benefit from reconstruction surgery of the femoropopliteal segment in the same session was controversial.[19-22] Some reports indicated positively management of lesions in the femoropopliteal segment was necessary to increase the long-term patency of reconstructed aortoiliac segment. Taurino *et al.*[23] suggested that hybrid treatment is an effective method to improve the runoff. In TASC II C–D iliac lesions, a specific overview of each axis is necessary in order to select the most appropriate treatment. But earlier, some vascular surgeons considered SFA is less important than profundafemoris artery. When SFA is occluded, the diffuse branches of profunda femoris artery can be the bridge between the aortoiliac artery and infrapopliteal arteries when collateral circulation is developed. Because of the insufficient population in our study, we compared type C/D lesions in the femoropopliteal segment to type A/B lesions and no lesions. While our data suggested type C/D lesions are associated with worse outcomes, studies from Nypaver *et al*.[24] and Dalman *et al*.[25] found multilevel procedures may cause longer operation time and more trauma, which lead to increased mortality and complication. So treatment strategy needs to be individualized for each patient.

For those patients with Rutherford class 5 or 6, atherosclerotic lesions in the aortoiliac artery is likely to coexist with diffused calcified atherosclerosis in infrapopliteal arteries.[5,6,26,27] Dosluoglu *et al*.[28] reported that the primary patency of group with class ≥5th lesions was 66%, while the results were 93% and 80% respectively, in groups with class 1–3 and class 4. The meta-analysis including 3314 patients by Jens *et al*.[29] showed beneficial effect on intermittent claudication and much worse prognosis on critical limb ischemia, and suggested more studies for recommending an optimal treatment strategy. Our results suggested class ≥5th as a risk factor for restenosis. Consistent with our findings, Rutherford classification has been reported to be associated with restenosis after vascular reconstruction surgery of TASC II D AIOLs. Notably, this was not confirmed by the Cox regression, likely due to a relatively small number of lesions studied. This warrants further study.

TASC II type D disease comprises a heterogeneous group of diseases, from simple stenosis lesions to occlusive and complex lesions.[2,8,10,14,19] Some studies regarded that long occlusive lesions had a worse prognosis than simple stenosis.[4,30] However, comparison studies of all 6 subclasses of TASC II type D disease are still scant. Our series comprised of patients with different lesions and treatment modalities. The result of an analysis indicated no significant differences between each subclassification of type D lesions, so we suggested that subclassifications were not prognostic for patency. But due to the limited number of samples, this viewpoint need further study to testify.

The endovascular therapy for the atherosclerotic aortoiliac disease has been developing rapidly in last decade, and the trend will continue in the next decade. Open or endovascular therapy always had been controversial. In this study, no significant difference in patency between patients managed with ET versus bypass. Within the period of this study, although the technical experience increased over with time, there were no significant changes in surgeons and operative materials in our institution. These may minimize the sampling bias.

The rates of primary patency of bypasses in our study were 94.7%, 94.7%, and 63.2% at 1-, 5-, and 7-year, respectively. The patency rates at 1- and 5-year are close to the rates reported by some other studies. Several reports indicated the primary patency rates of aortic-bilateral femoral bypasses are over 90% at 1-year, and 85–90% and 75–80% at 5- and 10-year.[31,32] Marrocco-Trischitta *et al*.[33] suggested the best treatment of juxtarenal aortic occlusion, which is a variant of TASC type D lesions, is and will be open surgery. However, they approved the much higher perioperative mortality risk of surgery. Lipsitz *et al*.[34] suggested that surgery should be preferred to be the alternate choice for failure in ET. The guideline suggested that the design and quality of devices, as well as the easy and accuracy of performing these procedures, have improved over the last decades, leading to the preferential treatment of aortoiliac steno-obstructive disease via endovascular means, often as first-line therapy, with high technical success rate and low morbidity.[35]

Gandini *et al*.[4] studied 138 patients who underwent revascularization of an occluded iliac artery with subsequent stenting, the results showed primary patency rates of stents were 90%, 85%, 80%, and 68% at 3-, 5-, 7-, and 10-year, respectively, which was similar to ours. Jongkind *et al*.[3] reviewed 1711 endovascular cases, 4- or 5-year primary patency rates ranged from 60% to 86%. They admitted primary patency rates of stents were lower than those reported for surgical revascularization, but they also emphasized reinterventions can often be performed percutaneously, with secondary patency comparable to surgical repair. Nevertheless, a meta-analysis of 937 patients and 1532 limbs indicated the risk of severe complications and mortality in secondary intervention for restenosis in stents was much higher than the previous stenting. Furthermore, the improvement in clinical symptom and limb function was also significantly worse.

We suggested that even though surgery can be preferred the alternate choice for failure in ET, but not all patients are necessary for a trial on ET; surgery should be chosen decisively for the patient with appropriate condition.

A prospective, multicenter, randomized controlled trial involving 168 iliac arteries in 125 patients with severe aortoiliac occlusive disease indicated that covered stents were significantly more likely to remain free from restenosis than those that were treated with a bare-metal stent ($P = 0.02$). Freedom from occlusion was also higher in lesions treated with covered stents than in those treated with bare-metal stents. However, this did not reach statistical significance ($P = 0.07$).[36] However, another study by Humphries *et al*.[37] which concluded 254 procedures performed in 162 patients suggested that for treatment of distal aorta or common iliac artery stenosis, primary patency, assisted patency, and secondary patency were significantly better in the bare-metal stents group. Tewksbury *et al*.[38] reviewed 30 patients who underwent aortoiliac covered expandable stenting which the primary patency was 79% at 2 years, four cases of in-stent stenosis were reported. There was no significant difference between bare and covered stents in our study, we speculated the reason which caused the divergence was that covered stents in our study were usually used for long occlusive lesions or complex lesions with aneurysm or secondary thrombosis which may lower the patency. We expect to analysis the difference again in more patients in the future.

Our study was retrospective, which was inherently associated with selection bias, and the number was relatively small. In addition, there might be different biology of vascular stenosis between Chinese population and patients from Western countries, either influenced by genetics and environmental factors, including diet and access to medications, and surgical techniques. Despite of this, our observation established 5-year outcomes of endovascular therapy for patients with atherosclerotic iliac artery stenosis in China, which may inform the design of new trials in the setting of a rapid changing landscape of managing the disease.

In conclusion, diabetes and femoropopliteal TASC II type C/D occlusive disease were the risk factors of restenosis after vascular reconstruction surgery for TASC II D AIOLs. The influence of Rutherford classification needs to be further studied.

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Conflicts of interest

There are no conflicts of interest.

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