Original Article

The Results of the Endovascular Management of Femoropopliteal Arterial Occlusive Disease: A Prospective Study on 65 Consecutive Patients

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ABSTRACT

Background: We report the angioplasty results of patients suffering from chronic lower extremity ischemia with the involvement of femoropopliteal arteries.

Methods: Sixty-five patients were studied. All patients with lower extremity chronic ischemia resulting from femoropopliteal arterial lesions at Sina Hospital, Tehran University of Medical Sciences, Tehran, Iran, from September 22, 2013, through March 21, 2015, were included in the study. The success of angioplasty and stenting was defined as the diminishing of the stenosis to less than 30%. A follow-up Doppler ultrasound was conducted to evaluate restenosis and reocclusion. Additionally, healing of ulcers and recovery of claudication were assessed at follow-up visits.

Results: The mean age of the study participants was 64.5±9.7 years. Forty-four patients (67.7%) were male, and 21 patients (32.3%) were female. In follow-up Doppler ultrasounds, 7 patients (10.8%) had stenosis, while 9 patients (13.8%) had occlusion, and 49 patients (75.4%) had a normal patent arterial flow. On follow-up, 53 patients (81.5%) did not report claudication. The success rate of the procedures was 98.46%. The presence of preprocedural tissue gangrene was a potential predictor of restenosis and reocclusion (P<0.05).

Conclusions: It seems that endovascular management is a feasible and effective technique in lower extremity arterial ischemia due to lesions in femoropopliteal arteries, even in subtypes TASC C and D. ***(Iranian Heart Journal 2021; 22(4): 34-44)***

KEYWORDS: Femoropopliteal, Angioplasty, Chronic limb ischemia

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Endovascular therapy is one of the accepted interventions for the treatment of chronic limb ischemia resulting from aortoiliac and femoropopliteal arterial involvements.[1,2] It has been reported that angioplasty and stenting are more successful in the Trans-Atlantic Inter-Society Consensus on the management of peripheral arterial disease (TASC) types A and B.[3,4] However, a number of reports suggest the

potential benefits of endovascular therapy in all the classes of TASC.[5,6] Thus, endovascular therapy is an effective modality to manage chronic arterial ischemia in the lower extremities. It has been reported that endovascular interventions for TASC B and C femoropopliteal lesions are associated with restenosis or reocclusion rates comparable with those of open bypass surgery.[7] Moreover, endovascular or hybrid approaches have been successfully used for the treatment of the TASC C and D lesions of iliac arteries.[8] Angioplasty has also been used in the TASC lesions of A to D of femoropopliteal involvement in patients with vascular risk factors. It has been reported that diabetes, no stent use, chronic total occlusion, and poor below-the-knee runoff are the potential predictors of restenosis.[9] Herein, we report the angioplasty results of patients with femoropopliteal occlusive disease. The patients were prospectively followed up, and their clinical and sonographic outcomes are presented. Patients with TASC classifications of A to D were included in this study, and endovascular therapy was applied in all the patients. The outcomes are from the Department of Vascular and Endovascular Surgery, Sina Hospital, Tehran University of Medical Sciences, Tehran, Iran. Sina Hospital is a high-volume vascular surgery center in Tehran, Iran, and the report is of potential use and clinical interest.

METHODS

Study Sample

We studied the results of angioplasty with or without stenting in patients with femoropopliteal occlusive disease prospectively. Sixty-five prospective patients were studied. All patients with lower extremity arterial chronic ischemia at the Department of Vascular and Endovascular Surgery, Sina Hospital, Tehran University of Medical Sciences, Tehran, Iran, from September 22, 2013, through March 21, 2015, were assessed for eligibility to enter the study. The diagnosis of chronic arterial ischemia in lower extremities was made by clinical evaluation and color Doppler studies with or without computed tomography (CT) angiography or digital subtraction angiography (DSA). The classification of arterial ischemia was done based on TASC. The indications for endovascular intervention were intermittent claudication with an impact on the quality of life, rest pain, and tissue loss.

Inclusion and Exclusion Criteria

The inclusion criteria were composed of normal serum creatinine clearance levels, having patent lumens at the common femoral artery and the proximal superficial femoral artery, and femoropopliteal involvement. The exclusion criteria consisted of chronic kidney disease, elevated serum creatinine levels, history of previous endovascular interventions, history of bypass surgery for chronic lower extremity arterial disease, aortoiliac involvement, and history of previous below-the-knee or above-the-knee amputations. Eighty patients met the inclusion and exclusion criteria of the study. Nonetheless, 10 patients refused to give consent to endovascular treatment. Out of the 70 patients, 5 patients were missed in the follow-up. Finally, 65 patients were followed up and were analyzed for the study purpose (Fig. 1).

Variables

Background variables were recorded for the patients. These included age, sex, cigarette smoking, hypertension, diabetes mellitus, hyperlipidemia, heart failure, dialysis, and past drug history.

In addition, a complete history was taken, and a physical examination was conducted. The patients were evaluated for claudication, rest pain, tissue gangrene, and ulcers. Minor and major tissue losses were assessed and recorded. The patients had femoropopliteal involvement. The TASC classification was

done. The presence of preprocedural stenosis or occlusion was also recorded. Admission days and follow-up duration were also recorded. The success of angioplasty and stenting was defined as the diminishing of the stenosis to less than 30%. A follow-up Doppler ultrasound was conducted to evaluate restenosis and reocclusion. In addition, healing of ulcers and recovery of claudication were assessed at follow-up visits.

Hypercholesterolemia was defined as a cholesterol level of more than 200 mg/dL. Hypertension was defined as minimum systolic and diastolic blood pressures 140/90 mm Hg. Chronic kidney disease was considered to be creatinine values greater than 1.5 mg/dL.

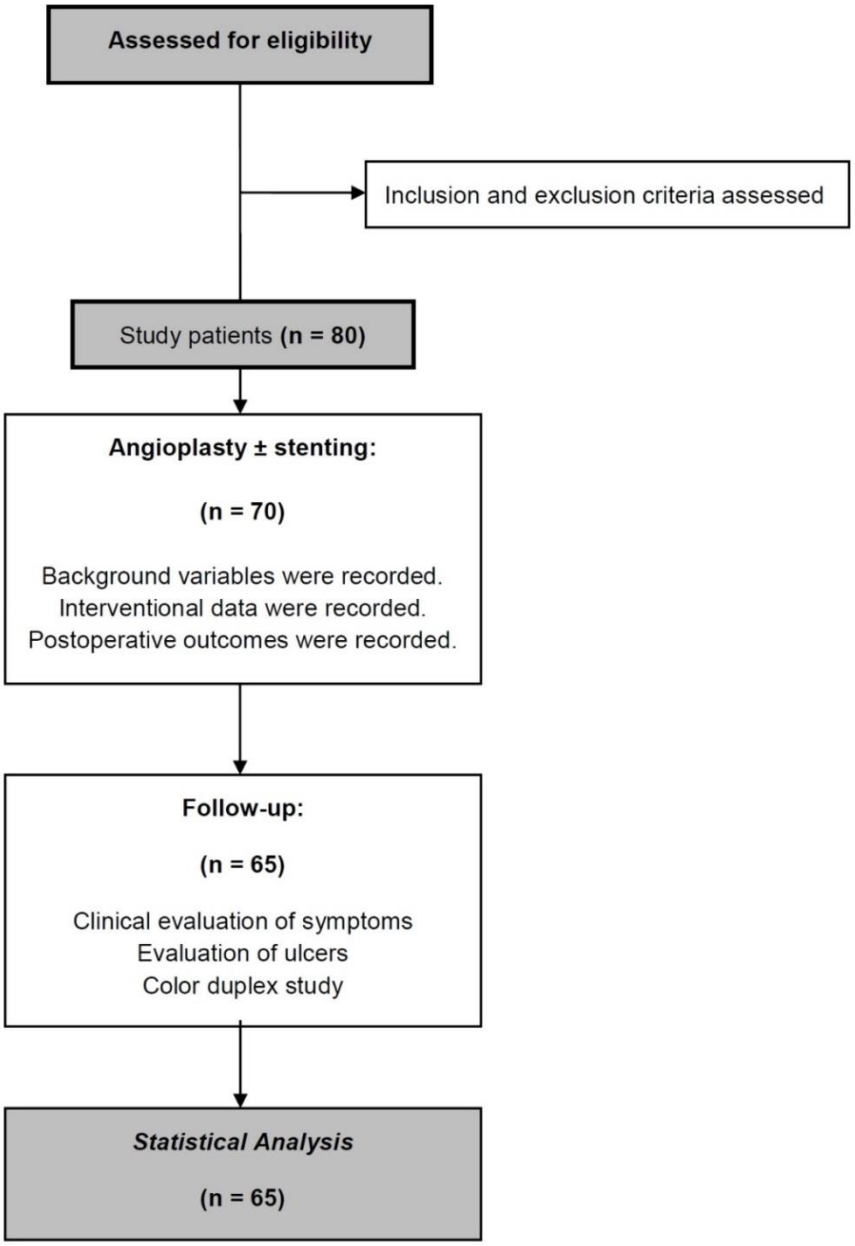

Figure 1. The flowchart of the study patients is presented herein.

Endovascular Procedure

All the patients had common femoral or superficial femoral artery stump to introduce angiography sheaths. A loading dose of 300 mg of clopidogrel was administered to the patients prior to angiography and angioplasty. The sheaths were inserted through ipsilateral common or superficial femoral arteries in antegrade fashion to have access to femoropopliteal arteries. The sheaths were placed through the contralateral common femoral artery in a retrograde fashion when a more proximal site of the femoral artery was necessary. Brachial artery access was also used in some cases. The size of the sheaths was 6 to 7 French (F). After sheath introduction, 80 international units per kilogram of body weight of unfractionated heparin was administered.

Standard and hydrophilic guidewires with a diameter of 0.014, 0.018, and 0.035 inches were used. Additionally, 4F and 5F vertebral and JR and MPA1 catheters were used to reach the stenosis or occlusion. After the lesion was crossed, balloon angioplasty was conducted by optimal nominal pressures. If more than 30% stenosis or flow-limiting intimal flap was present after angioplasty or in the long length of the lesion, the stenting of the angioplasty site was conducted.

Follow-up

All the patients received oral aspirin (80 mg daily), clopidogrel (75 mg daily), and atorvastatin (40 mg daily) for 1 month. Then, aspirin, atorvastatin, and cilostazol (or pentoxifylline) were continued based on indications. All the patients were followed up after 2 to 3 weeks. Then, the patients were followed up every 2 to 3 months, and then every 6 months. Color Doppler ultrasound was conducted 6 months and 1 year after angioplasty. Stenosis less than 50% was considered to be patent. In the cases of restenosis and reocclusion, the patients were evaluated for signs and symptoms, and repeat angiography and angioplasty were conducted in select cases. All the follow-up visits were conducted by the same vascular surgeon. The Doppler ultrasound studies were also done by a single radiologist, who was an expert in arterial sonography. The endovascular interventions were conducted by the vascular surgeons of Sina Hospital, the Department of Vascular and Endovascular Surgery, Tehran University of Medical Sciences, Tehran, Iran.

Statistical Analysis

The statistical analyses were conducted using the SPSS 21.0 software. Variables were described as the mean ± the standard variation (SD) and frequencies (%). For quantitative variables, the Student *t* test and the one-way ANOVA test for normally distributed data and the Mann–Whitney *U* test for non-normally distributed data were utilized. The associations between qualitative variables were studied using the χ^2 test or the Fisher exact test. The association between restenosis or reocclusion follow-up color Doppler and background variables was assessed via multivariate analysis using a logistic regression test. The assessment of the patterns of restenosis or reocclusion during the follow-up times regarding the TASC classification was done using the Kaplan–Meier survival analysis. A *P*-value of less than 0.05 was considered statistically significant. Informed consent was obtained from all the study patients.

Informed Consent

The protocol of the present study was approved by the Research Deputyship of the Faculty of Medicine and the Research Vice-Chancellorship of Tehran University of Medical Sciences, Tehran, Iran (IR.TUMS.REC.1395.2763). All consent

forms were obtained by vascular surgery fellows and attending physicians.

RESULTS

The data of 65 patients were analyzed during the study period. The mean age of the study participants was 64.5±9.7 years. Forty-four patients (67.7%) were male, and 21 patients (32.3%) were female. Twenty-six patients (40.0%) were smokers. The mean cigarette smoking amount was 37.2±16.4 pack-years among the smokers. Table 1 illustrates past disease and drug histories among the study participants. In 1 patient (1.5%), the stenotic lesion was bilateral. The lesions were treated in 33 patients (50.8%) on the right side and 31 patients (47.7%) on the left side.

Table 1. Past disease and drug histories among the study participants

Past Medical History	
Disease	
Hypertension	25 (38.5%)
Diabetes mellitus	44 (67.7%)
Hyperlipidemia	6 (9.2%)
Heart failure	9 (13.8%)
Heart disease	5 (7.7%)
Past Drug History	
Drug	
Aspirin	39 (60.0%)
Warfarin	5 (7.7%)
β-blocker	10 (15.4%)
Clopidogrel	12 (18.5%)
Statins	25 (38.5%)

The clinical presentations of the study patients prior to endovascular intervention were recorded. Claudication, rest pain, gangrene, and foot ulcers were present in 17 (26.2%), 11 (16.9%), 17 (26.2%), and 20 (30.8%) patients respectively. In addition, the TASC classification of the study patients was as follows: TASC A, 28 patients (43.1%); TASC B, 10 patients (15.4%); TASC C, 11 patients (16.9%); and TASC D, 16 patients (24.6%). The patients were followed up for 24 months. The mean follow-up period was 13.8±5.9 months. The mean preprocedural stenosis rate was 83.6%±6.2%, and the mean postprocedural stenosis rate was 10.9%±4.7% (P=0.000; the paired-sample t test). A single procedure was done in 32 patients (49.2%), and multiple procedures were done in 33 patients (50.8%). Fifteen angioplasty procedures were performed without stenting (23.1%). Angioplasty and stenting were done in 54 procedures (83.1%). Overall, 55 stents were used.

Table 2 shows the numbers of angioplasty and stenting in the study patients together with the diameter and length of the stents used in the study patients. The mean admission duration was 9.6±8.4 days, with a minimum and a maximum of 2 and 46 days, respectively. Two main reasons for the prolonged admission were long waiting lists of angioplasty and repeated debridement of the infected and necrotic tissues of the lower extremities after angioplasty.

Table 3 illustrates the clinical and ultrasound findings of the study patients at follow-up visits. Moreover, Table 4 tabulates the association between background pre-interventional variables and follow-up Doppler ultrasound results. These associations were analyzed twice by univariate and multivariate analyses. As is shown in Table 4, only the presence of preprocedural tissue gangrene was a potential predictor of restenosis and reocclusion (P<0.05). However, hypertension was a predictive factor (P<0.05). The association between restenosis and reocclusion and the preprocedural TASC classification during the follow-up time was analyzed by Kaplan–Meier survival analysis (Fig. 2).

Table 2. Numbers of angioplasty and stenting in the study patients together with the diameter and length of the stents used

Variables	Frequency	Number of Stents	Diameter	Length
Single procedure	32 (49.2%)	First stent	6.85±7.38	102.11±46.20
Multiple procedures	33 (50.8%)	Second stent	6.09±0.53	85.00±45.33
Number of stents used	1.15±0.92	Third stent	6.40±0.55	84.46±36.29
Angioplasty alone	15 (23.1%)	Fourth stent	6.00±0.00	150.00±0.00
Angioplasty and stenting	54 (83.1%)			
Self-expandable stents	52 (80.0%)			
Balloon-expandable stents	1 (1.5%)			

Table 3. Clinical and ultrasound findings of the study patients at follow-up visits

Variables	Frequency
Ulcers	36 patients
Complete healing of the ulcer	34 patients (94.4%)
Incomplete healing of the ulcer (at least 50%)	0 patients (0.0%)
Ulcers without healing	2 patients (5.6%)
Claudication	43 patients
Recovery of claudication	31 patients (72.1%)
Persistence of claudication	12 patients (27.9%)
Doppler ultrasound	65 patients
Without stenosis or occlusion	49 patients (75.4%)
Stenosis	6 patients (9.2%)
Occlusion	10 patients (15.4%)

Table 4. Association between background pre-interventional variables and follow-up Doppler ultrasound results

Variables	Doppler Ultrasound Results			*P-value**	*P-value***
	Open 49 patients	Stenosis 7 patients	Occlusion 9 patients		
Smoking	16 patients (32.7%)	4 patients (57.1%)	6 patients (66.7%)	*0.099*	*0.067*
Hypertension	23 patients (46.9%)	0 patients	2 patients (22.2%)	*0.032*	*0.016*
Diabetes mellitus	35 patients (71.4%)	4 patients (57.1%)	5 patients (55.6%)	*0.529*	*0.559*
Hyperlipidemia	5 patients (10.2%)	0 patient	1 patient (11.1%)	*0.669*	*0.492*
Heart failure	7 patients (14.3%)	0 patient	2 patients (22.2%)	*0.436*	*0.556*
Heart disease	3 patients (6.1%)	1 patient (14.3%)	1 patient (11.1%)	*0.688*	*0.180*
Claudication	14 patients (28.6%)	3 patients (42.9%)	2 patients (22.2%)	*0.653*	*0.196*
Gangrene	10 patients (20.4%)	2 patients (28.6%)	5 patients (55.6%)	*0.278*	*0.030*
Chronic total occlusion***	31 patients (63.3%)	5 patients (71.4%)	8 patients (88.9%)	*0.311*	*0.178*
Stenosis***	83.82±6.50%	83.33±5.77%	80.00±0.00%	*0.845*	-

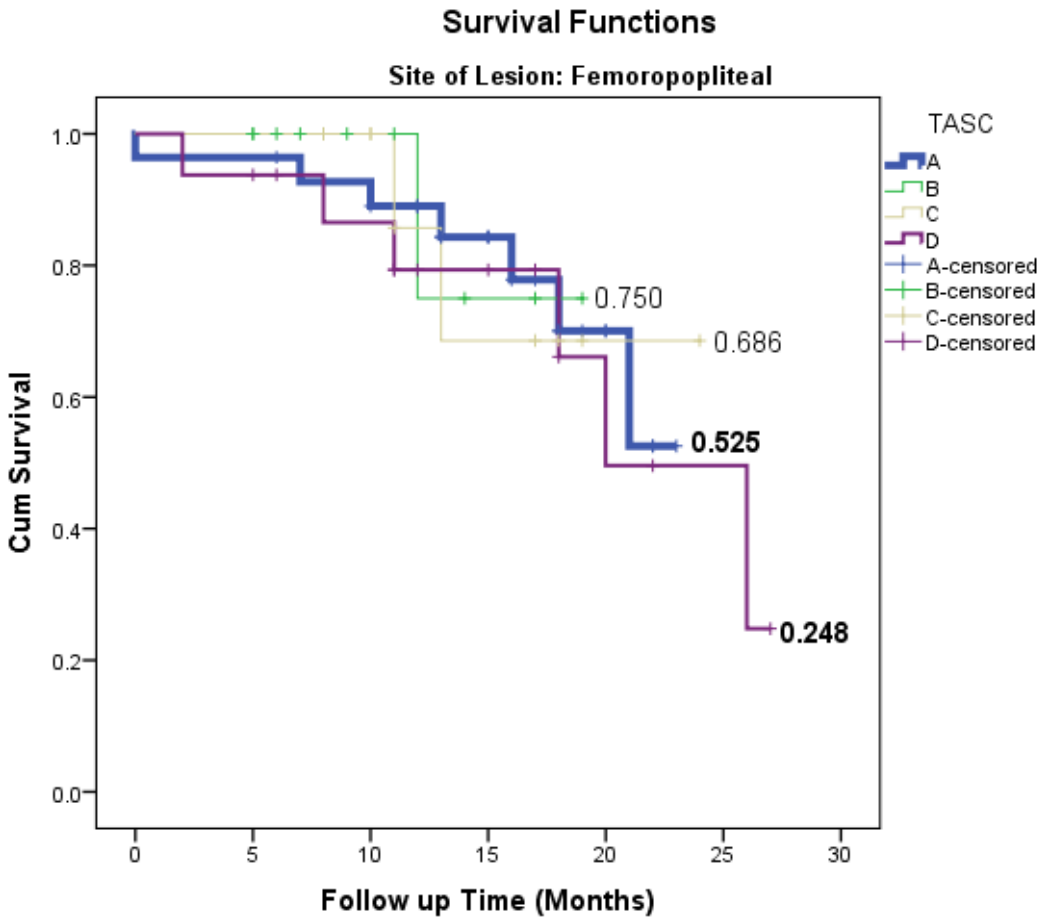

Figure 2. The image depicts the Kaplan-Meier analysis for the illustration of the patterns of restenosis or reocclusion in the follow-up period based on the TASC classification of the patients.
TASC, Trans-Atlantic Inter-Society Consensus on the management of peripheral arterial disease

DISCUSSION

The patients were followed up for 13.8±5.9 months. The preprocedural stenosis and postprocedural stenosis rates were 83.6%±6.2% and 10.9%±4.7%, respectively (P<0.05). Healing of ulcers was seen in 94.4% of the patients. The recovery of claudication was seen in 72.1% of the study population. Follow-up Doppler ultrasound revealed open vasculature in 75.4% of the study participants. Our multivariate analysis showed that preprocedural tissue gangrene was a potent predictor of restenosis or reocclusion following angioplasty for lower extremity chronic arterial ischemia involving the femoropopliteal arterial vasculature (P<0.05). Hypertension was more common in patients with open vasculature than in patients with restenosis or reocclusion (P<0.05). Nonetheless, it could have been due to selection bias, or it might have resulted from the effects of hypertension on maintaining patency following angioplasty and stenting. In a study by Yin et al,[10] the endovascular treatment of the TASC C and D lesions of femoropopliteal arteries had a high technical success rate and a favorable patency rate. Giles et al[11] reported that infrainguinal angioplasty was a potential treatment for patients with chronic lower extremity ischemia with TASC A, B, and C lesions. Nevertheless, restenosis, re-intervention, or

amputation necessitates careful follow-up. Ratnam et al[1] also reported good technical results and low complication rates in lower limb endovascular interventions, including lesions of aortoiliac, femoropopliteal, and infrapopliteal regions. Favorable outcomes were obtained in 4 groups of TASC A, B, C, and D. We also performed angioplasty in all TASC classification groups, and the results were as good as those reported by other studies. Our study revealed that tissue gangrene was a potent predictor of restenosis or reocclusion in follow-up Doppler studies. Still, complete total occlusion, hyperlipidemia, diabetes, and claudication were not related to sonographic outcomes. Iida et al[9] reported diabetes, no stent use, chronic total occlusion, and poor below-the-knee runoff as potent predictors of poor outcomes after femoropopliteal angioplasty in TASC A to C lesions. Some other studies have also reported the successful use of angioplasty and stenting in femoropopliteal arterial lesions.[12-14]

Symptomatic common and external iliac artery stenosis and occlusion are potential indications for angioplasty and stenting. Park et al[15] reported successful results of iliac artery stenting in a retrospective analysis of 218 patients. They concluded that the TASC classification did not have an impact on outcomes. Their technical success rate was 99%. Leville et al[16] also reported successful endovascular management of iliac artery occlusions in TASC C and D lesions. Their results were comparable with those of open reconstructions. It is suggested that patients with TASC types C and D iliac lesions, a stenotic ipsilateral superficial femoral artery, ulcers or gangrene, smoking history, and chronic renal failure with hemodialysis be followed carefully after endovascular iliac artery intervention.[2] Our study also indicated that gangrene was a potent predictor of angioplasty failure.

Schönefeld et al[17] reported the successful use of endovascular first-line treatment in femoropopliteal arterial lesions even in long segment cases. They used nitinol stents with acceptable long-term patency rates. However, the superiority of bypass surgery over angioplasty has been reported in some studies. In addition, the recurrence of symptoms in superficial femoral artery occlusive disease has been related to TASC D lesions and endovascular therapy. Postoperative statin use has also been a protective factor.[18] We administered aspirin and statin postoperatively for all our patients. A report from Darling et al[19] showed higher wound healing, higher freedom from restenosis, improved patency rates, fewer re-interventions, and higher survival by open surgery than with endovascular interventions in patients with lower extremity chronic limb-threatening ischemia.

Be that as it may, although bypass surgery is feasible and effective, endovascular therapy is also a good option because of its lower complication rate and favorable patency rate among patients in poor condition for bypass.[20] Malas et al[21] compared the results of percutaneous transluminal angioplasty with or without stenting of the superficial femoral artery or femoral-popliteal bypass after the failure of medical management. They reported higher re-intervention rates for femoral-popliteal bypass than with angioplasty and stenting. Nevertheless, this could have been due to selection bias because more severe diseases underwent surgical bypass. The endovascular treatment of the arterial lesions of iliac arteries in TASC groups of A, B, C, and D is technically feasible even in patients with complete total occlusion.[22] Nonetheless, our results revealed that only tissue gangrene was a potent predictor of recurrence and poor sonographic outcomes at follow-up visits. Although nitinol stents have been

accompanied by favorable results,[17] paclitaxel-eluting stents may not prevent in-stent restenosis for TASC C and D lesions.[23] It is worthy of note that stent placement is an effective, safe, and feasible method for the management of long-segment iliac artery complete total occlusions. [24] While based on the mentioned studies, the patency rate in iliac artery angioplasty is good, our study showed that the patency rate in femoropopliteal disease is not as good as that in the iliac artery but is acceptable. Despite the fact that the patency rate in TASC D is low, especially in high-risk patients for surgery, it is deemed an acceptable procedure. In a recent study by Hassani et al[25] in Tehran University of Medical Sciences, Tehran, Iran, a 2-year primary patency rate of aortoiliac occlusive disease was assessed following endovascular treatment. They reported that the endovascular management of different TASC subtypes was associated with a considerable technical success rate and a primary patency rate even in TASC D lesions. These subtypes were previously treated by open bypass surgery. In the present study, the technical, radiological, and clinical success of the endovascular management of femoropopliteal arterial lesions was also confirmed. We also performed endovascular treatment in all TASC groups, even in TASC D patients. Our results are also from the same institution.

The patency of the endovascular procedure was lower in TASC C and D groups during the follow-up. The outcomes were also suboptimal when compared with the results of the previous study by Hassani et al[25] in patients with aortoiliac involvement. The weakness of this study was the low number of patients. A more comprehensive review requires further research on more patients.

In conclusion, endovascular management is a feasible and effective technique in lower extremity arterial ischemia resulting from lesions in femoropopliteal arteries. Although a number of reports are in favor of open bypass surgery, patient selection should consider all risk factors. Either open surgery or endovascular therapy should be selected based on precise indications. We revealed that tissue gangrene and complete total occlusion were potent predictors of recurrence and poor outcomes. In addition, TASC lesions C and D were related to poor sonographic outcomes during the follow-up period. Further studies with precise sample sizes and subgroup classifications are necessary to reach firm conclusions.

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Conflict of Interest

The authors do not have any conflicts of interest. The selection of endovascular equipment was based on procedure indications and was not limited to any specific brands.

Authors' Contributions

MM, MRZ, JS, and MH designed the study. MH collected the data, which SZ and PB analyzed. SZ drafted the manuscript. MM, MRZ, JS, and MH critically reviewed the manuscript. All the authors read and accepted the final version of the manuscript.

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Ethical Statement

The protocol of this study was approved by the Ethics Committee of Tehran University of Medical Sciences, Tehran, Iran (IR.TUMS.REC.1395.2763).

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