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Endovascular treatment versus femoropopliteal bypass surgery for TASC II type C lesions of the superficial femoral artery

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ABSTRACT

Objectives: In this study, we aimed to compare the outcomes of endovascular treatment (ET) and femoropopliteal artery bypass (FPB) in patients with Trans-Atlantic Inter-Society Consensus (TASC) II type C femoropopliteal lesions.

Patients and methods: A total of 149 patients with symptomatic TASC II type C femoropopliteal lesions who underwent invasive treatment between January 2012 and January 2017 were retrospectively analyzed. The patients were divided into two groups as the ET group (n=46; 34 males, 12 females; mean age: 64.3±10.3 years) and the FPB group (n=103; 82 males, 21 females; mean age: 62.9±8.2 years). Primary and secondary patency rates at 6, 12, and 24 months were evaluated.

Results: The primary success rates for ET and FPB were 100%. Primary patency at 6, 12, and 24 months were 93.5%, 89.0%, 69.5%, respectively for ET and 86.4%, 81.5%, 72.8%, respectively for FPB (p>0.05). Secondary patency rates at 6, 12, and 24 months were 97.8%, 93.5%, %84.8, respectively for ET and 96.1%, 90.3%, 79.6%, respectively for FPB group (p=0.41). The length of hospital stay was significantly longer in the FPB group (p<0.001). The cost of treatment was significantly higher in the FBP group (p=0.02).

Conclusion: In TASC II type C patients, ET is a safe therapeutic option with lower in-hospital stay and treatment expenses and similar primary and secondary patency rates to FPB.

Keywords: Atherosclerosis, balloon angioplasty, endovascular procedures, femoropopliteal bypass, peripheral artery disease.

Peripheral arterial disease (PAD) is a common health condition that affects nearly 10% of the population.[1] Approximately 50% of PAD consists of femoropopliteal lesions.[1] Therefore, femoropopliteal lesions accompanying severe claudication (SC) or chronic limb-threatening ischemia (CLI) should be treated. Femoropopliteal lesions and suggested treatments have been classified in the Trans-Atlantic Inter-Society Consensus II (TASC II) guidelines. Currently, TASC II type A and B lesions frequently receive endovascular treatment (ET), while low-risk patients with TASC II type D lesions are usually treated with open surgery (OS). However, inconclusive debates on the TASC type C lesions are still ongoing.[2]

Improvements in endovascular devices and the growing experience of physicians have led to an upward trend in the use of ET for patients with TASC II type C femoropopliteal lesions.[3] Although femoropopliteal bypass (FPB) remains the gold standard in the treatment of complex femoropopliteal lesions, endovascular first strategy has been advocated by the European Society of Cardiology (ESC) in patients with femoropopliteal lesions up to 25 cm in length.[4,5] Still, particularly in TASC II C femoropopliteal lesions, there is still a lack

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of evidence to evaluate the outcomes of ET with FPB. In the present study, we, therefore, aimed to compare the outcomes of ET and FPB in patients with TASC II C femoropopliteal lesions.

PATIENTS AND METHODS

This single-center, retrospective study was conducted at Tepecik Training and Research Hospital, Department of Cardiovascular Surgery between January 2012 and January 2017. During the study period, invasive femoropopliteal lesion treatment was performed in 318 patients. Patients with femoropopliteal lesions other than TASC II C were excluded. Finally, a total of 149 patients with symptomatic TASC II type C femoropopliteal lesions were included. The patients were divided into two groups as the ET group (n=46; 34 males, 12 females; mean age: 64.3±10.3 years) and the FPB group (n=103; 82 males, 21 females; mean age: 62.9±8.2 years). Inclusion criteria were as follows: age over 18 years old, having symptomatic, complex femoropopliteal lesion (TASC II C). The TASC II C lesions were identified as multiple stenoses or occlusions having a total length of more than 15 cm with or without severe calcification. We used the Peripheral Academic Research Consortium (PARC) scoring system to quantitate vascular calcification.[6] Recurrent stenoses or chronic occlusions, which still needed an intervention after two ET, were also classified as TASC II C.[7] All of the patients were classified according to the first attempt of treatment for their lesions. The patients who underwent ET after FPB or FPB after ET were considered readmissions. All patients had at least one intact tibial run-off vessel. Patients without any run-off vessels were excluded. Asymptomatic patients and patients with mild or moderate claudication (Rutherford classification Stage 0-2) were also excluded. A written informed consent was obtained from each patient. The study protocol was approved by the Institutional Review Board of the Tepecik Training and Research Hospital (No: 2018/13-8). The study was conducted in accordance with the principles of the Declaration of Helsinki.

Patients with Stage ≥3 according to the Rutherford classification or unsuccessful conservative treatment were scheduled for invasive treatment. Femoropopliteal disease was suspected in patients with PAD symptoms such as hair loss on the feet and legs, claudication, rest pain, or ischemic foot ulcers, when ipsilateral distal pulses were undetectable. Color Doppler ultrasound (CDUS) was used as the initial tool to diagnose femoropopliteal lesions (Philips EPIQ; Philips Healthcare, Amsterdam, Netherlands). At rest, the typical Doppler waveform of the lower extremities arteries was characterized by a triphasic flow pattern and was classified as a high pulsatility waveform. If the waveform was monophasic, damped, or absent in the target vessel, the CDUS result was considered abnormal.

For the patients with abnormal CDUS results and scheduled for invasive treatment, computed tomography angiography (CTA) or magnetic resonance angiography (MRA) was performed. For complex femoropopliteal lesions, we considered ET as a preferred option, particularly in high-risk patients; i.e., patients having comorbidities that pose a high risk for general anesthesia, having a history of recent coronary stenting, dialysis-dependent renal failure, history of stroke or transient ischemic attack, severe chronic obstructive pulmonary disease (forced expiratory volume in 1 sec <50% predicted), pulmonary hypertension, and severe liver disease.

Patients with severe chronic kidney disease (estimated glomerular filtration rate <30 mL/min/1.73 m^2), superficial femoral artery (SFA) occlusion from its origin, or a previous unsuccessful attempt of ET were scheduled for FPB. The procedure was performed in sterile conditions under general anesthesia. Graft failure was defined as total thrombosis of graft material or restenosis greater than 50%.

Ultrasound guidance was used for arterial access in all ET. Whenever possible, the antegrade femoral access was chosen. An additional pedal or contralateral puncture with the crossover technique was used, when an antegrade puncture was not possible. The lesions were crossed with different sized wires and a NaviCross® support catheter (Terumo Medical Corp., NJ, USA).

The intimal recanalization approach was usually adopted and, in case of an unsuccessful attempt, the subintimal recanalization approach was chosen. In all cases, predilatation was performed for at least 1 min with a plain old balloon catheter (POBA) Mustang® (Boston Scientific, MA, USA) that was 1-mm smaller than the mean diameter of the intact artery. Percutaneous transluminal balloon angioplasty (PTA) was preferred for target lesion revascularization. The balloon was inflated for at least 3 min at nominal pressure (8-10 atmospheres). The Luminor® (iVascular, Sant Vicenc¸ dels Horts, Barcelona, Spain) was used as

a drug-coated balloon. The balloons had the same size as the mean arterial diameter. The Supera™ Self-expandable nitinol stent grafts (Abbott Vascular, CA, USA) were used in cases with flow-limiting dissection and residual stenosis greater than 30%. The Angio-Seal™ VIP Vascular Closure Device (Terumo Medical Corp., NJ, USA) was deployed at the end of the procedure.

Primary success was defined as the completion of the revascularization without any residual stenosis greater than 30% or flow-limiting stenosis at the final angiography.

After treatment, follow-up was carried out with all the patients at the first week and also at 1, 6, 12, and 24 months with CDUS. For patients with symptoms, additional follow-up sessions were scheduled. All patients in both groups received dual antiplatelet therapy with acetylsalicylic acid 100 mg and clopidogrel 75 mg for at least six months after the intervention. Statin was also prescribed to all patients, unless contraindicated.

When the stenosis of the target lesion was higher than 50% in CDUS and CTA, the restenosis was considered significant. Reintervention was planned in all patients with a significant symptomatic stenosis. As the first option, ET was chosen for these patients.

The primary outcome measure was the 24-month primary patency rate, which was defined as the duration of patent revascularization without evidence of stenosis/occlusion. The primary outcome measure of the study was restenosis greater than 50% or total thrombosis of the target lesion or graft. Secondary patency was defined as the duration of patent revascularization after a new intervention for occlusion.

The total cost included all the costs in the hospital for the pre-, peri-, and postoperative follow-up procedures and screening. In addition, reintervention costs were included to this amount. To avoid being affected by inflation and to create homogenous groups, the costs were converted to USA Dollar at daily exchange rate.

Statistical analysis

Statistical analysis was performed using the IBM SPSS for Mac version 20.0 software (IBM Corp., Armonk, NY, USA). Continuous variables were expressed in mean ± standard deviation (SD) or median (min-max), while categorical variables were expressed in number and frequency. Correlation analysis for continuous variables was performed using the Pearson correlation test. The Mann-Whitney U test was used for non-normally distributed data, whereas the Student t-test was used for normally distributed data on a continuous/interval scale. In terms of primary and secondary patency rates, the Kaplan-Meier curves were used to compare the results of the ET and FPB groups. The Cox regression was used to examine the impact of factors at different time points. A p value of <0.05 was considered statistically significant.

RESULTS

Table 1 shows the demographics and comorbidities of the patients. Among The indications for treatment

Table 1. Demographic characteristics and comorbidities of patients

	Endovascular treatment (n=46)			Femoropopliteal bypass (n=103)			
	n	%	Mean±SD	n	%	Mean±SD	p
Age (year)			64.3±10.3			62.9±8.2	NS
Sex							
Male	34	73.9		82	79.6		NS
Body mass index (kg/m^2)			23.7±2.5			24.4±2.7	NS
Hypertension	35	81.4		68	66.0		NS
Hyperlipidemia	32	69.5		68	66.0		NS
Coronary artery disease							
Percutaneous coronary intervention	20	43.4		36	34.9		NS
Coronary artery bypass graft surgery	4	8.7		15	14.6		NS
Insulin-dependent diabetes mellitus	29	63.0		87	84.5		=0.001
Chronic obstructive pulmonary disease	11	23.9		27	26.2		NS
End-stage renal failure	4	8.7		18	17.5		NS
Current smoker	34	73.9		76	73.8		NS

SD: Standard deviation; NS: Non-significant.

Table 2. Clinical variables

	Endovascular treatment (n=46)			Femoropopliteal bypass (n=103)			
	n	%	Mean±SD	n	%	Mean±SD	*p*
Indication for treatment							NS
Claudication	33	71.7		85	82.5		
Critical limb ischemia	13	28.3		18	17.5		
Runoff vessels							NS
Three/two vessels	39	84.8			78	75.7	
Single vessel	7	15.2			25	24.3	
Mean lesion length (cm)			23.9±5.3			25.5±4.6	NS
Severe vessel calcification	7	15.2		18	17.5		NS

SD: Standard deviation; NS: Non-significant.

and clinical assessments of both groups are shown in Table 2.

Compared to the FPB group, the mean procedural time was significantly shorter in the ET group (46.1±22.9 min *vs.* 51.5±5.9 min, respectively; p=0.03). The mean follow-up was 24.1±5.1 (range, 1 to 38) months. The primary success rate for ET was 100%, and early revascularization was not necessary for any patient. Target lesion revascularization was performed by POBA and/or drug-eluting balloon (DEB) angioplasty in 37 patients. In addition, implantation of a self-expandable nitinol stent was necessary for nine patients. During follow-up, no structural damages were observed in any of the patients.

There was no perioperative mortality. In the FPB group, the acute technical success rate was also 100%. In terms of complication rates, there were no statistically significant differences between the ET and FPB groups (p=0.42) (Tables 3).

Primary and secondary patency rates are shown in Table 4. There were no significant differences between the groups regarding primary and secondary patency rates (p=0.85 and p=0.41, respectively) (Figures 1 and 2). Subgroup analysis revealed that, in both groups, the patients with three distal run-off arteries had better primary patency rates at 24 months (ET 79%, FPB 89%) than patients with only one distal run-off artery (ET 25%, FPB 54%) (p=0.04 and p=0.01, respectively). Intimal recanalization was unable to be achieved in nine patients and subintimal recanalization was performed. The primary patency rate in patients who had intimal

Table 3. Peri- and post-procedural outcomes

	Endovascular treatment (n=46)			Femoropopliteal bypass (n=103)			
	n	%	Mean±SD	n	%	Mean±SD	*p*
Mean procedural duration (min)			46.1±22.9			51.5±5.9	=0.03
Type of graft							
PTFE				73			
SVG				16			
CVG				14			
Type of balloon							
POBA	13						
POBA+DEB	24						
POBA+Stent implantation	9						
Mean in-hospital stay (days)			1.4±0.7			7.2±4.8	<0.001
Complication	6	15.2		11	10.7		NS
Reintervention	15	32.6		28	27.2		NS
Cost (US Dollars)			1,346±560.4			1,544.2±184.1	=0.02
Major amputation	2	4.3			11	10.7	NS
All-cause mortality	0	0			2	0	NS

SD: Standard deviation; PTFE: Polytetrafluorethylene grafts; SVG: Saphenous vein graft; CVG: Collagen vascular graft; POBA: Plain old balloon angioplasty; DEB: Drug eluting angioplasty; NS: Non-significant.

Table 4. Kaplan-Meier estimates of early and late outcome in overall series

	6 months	12 months	18 months	24 months	
	%	%	%	%	*p*
Primary patency					NS
Endovascular treatment	93.5	89.0	70.1	69.5	
Femoropopliteal bypass	86.4	81.5	76.7	72.8	
Secondary patency					NS
Endovascular treatment	97.8	93.5	87	84.8	
Femoropopliteal bypass	96.1	90.3	81.6	79.6	
Limb salvage					NS
Endovascular treatment				91.3	
Femoropopliteal bypass				85.4	

NS: Non-significant.

recanalization was 86% and it was 33% in patients who had subintimal recanalization (p<0.001).

Although the subgroup analysis for primary patency in the ET group was not significant, there was a slightly better primary patency outcomes for patients treated with DEB. The primary patency rates were 88.9%, 77.8%, 69.5%, and 66.7% for patients treated with POBA, and 94.6%, 91.9%, 75.7%, and 70.3% for patients treated with DEB, at 6, 12, 18, and 24 months, respectively (p=0.42). The primary patency at 24 months was not significantly different between the groups of patients treated with or without stent implantation (65% and 73%, respectively; p>0.05). In the FPB group, the primary patency rates at 24 months were 75% for saphenous vein grafts (SVGs), 71% for collagen vascular grafts (CVGs), and 68% for polytetrafluoroethylene (PTFE), indicating no significant differences (p=0.15).

During follow-up, 15 patients (32.6%) in the ET group and 28 (27.2%) patients in the FPB group were readmitted to the hospital with a significant lesion that needed reintervention (p>0.05). In the ET group, all patients who were readmitted to the hospital were treated with ET. Among 28 patients in the FPB group readmitted to the hospital, 13 were successfully treated with ET 13 surgical graft embolectomy procedures and two redo FPB operation with popliteal artery patch plasty. Complete revascularization was established in all 28 patients.

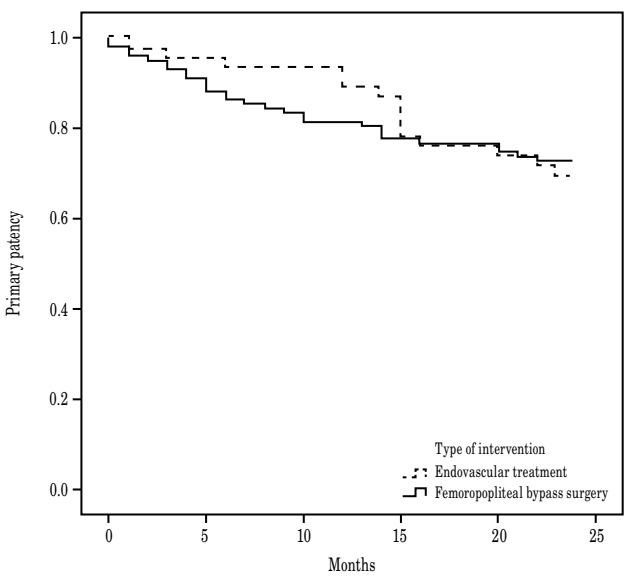

Figure 1. Kaplan-Meier estimates of primary patency rate of endovascular treatment and femoropopliteal bypass (95% confidence interval).

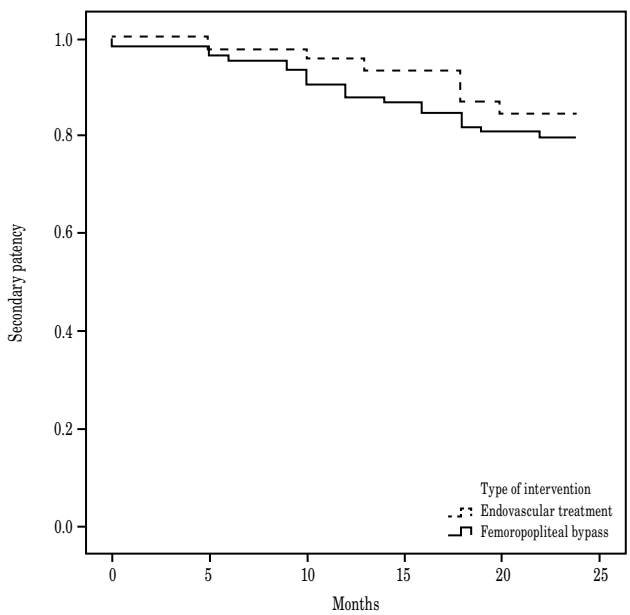

Figure 2. Kaplan-Meier method estimates of secondary patency rate of endovascular treatment and femoropopliteal bypass surgery (95% confidence interval).

All patients who underwent minor or major amputations had a CLI on admission. There was no clinical worsening in either group. Limb salvage after a 24-month follow-up was 91.3% in the ET group and 85.4% in the FPB group. All patients received dual antiplatelet therapy for at least six months.

DISCUSSION

In the present study, we found that ET was as safe and effective as FPB to treat TASC II C femoropopliteal lesions. Also, ET showed similar primary and secondary patency rates to FPB. However, ET was associated with a shorter procedural time, shorter hospital stay, and lower cost than FPB.

Scali et al.[8] concluded a primary patency rate of 43% for ET and 67% for FPB at three years. Similar to our study, most of their cohort consisted of patients who underwent FPB with prosthetic grafts. AbuRahma et al.[9] also found a similar primary patency rate (68%) for FPB with PTFE grafts at three years. Vossen et al.[10] performed a retrospective study comparing ET with FPB and reported a primary patency rate of 53% with ET, compared to 78% with FPB, at three years. It is noteworthy that their whole PAD cohort consisted of patients with all types of TASC II B and C, in contrast to our cohort, in which all patients had TASC II C lesions.

Insulin-dependent diabetes mellitus (DM) is a well-known factor that may affect the success rates of all intervention or surgical based procedures.[11] However, İnan et al.[12] found no significant differences in the long-term patency rates between DM and non-DM patients. In our study, the number of insulin-dependent DM patients was significantly higher in the FPB group, although there was no significant difference between the groups. Also, Cox regression analysis showed no significant differences in the patency rates for insulin-dependent DM. This result can be explained by the fact that there is no significant difference between the groups in terms of DM.

In the present study, our immediate primary success rate was 100% in both groups. Successful recanalization was performed in all patients with ET. There are also studies showing similar success rates for ET.[8,9] Despite our results, the Bypass versus Angioplasty in Severe Ischaemia of the Leg (BASIL) trial compared angioplasty first with bypass-first patients and reported an immediate primary success rate of 75% for ET.[13] We could partly explain this high success rate by using an additional pedal or contralateral puncture with the crossover technique (4.3%) and provisional stenting, if indicated. There is a clear benefit in routine stent placement, particularly in iliac diseases.[14] However, there is still controversy for femoropopliteal lesions due to frequent stent-related failures.[15] Currently, in our daily practice, we mostly use self-expanding nitinol stents for femoropopliteal lesions, and these are designed to overcome severe stresses faced in the SFA. However, there is still a risk of stent fracture, which may lead to in-stent stenosis or occlusion.[16] Although our study did not use stent placement as the first-line therapy, stent placement was performed in cases of flow-limiting dissection or residual stenosis greater than 30%. In our study, nine (19.6%) patients needed self-expandable nitinol stent placement. Our study showed similar primary patency rates at the 24-month follow-up between patient groups treated with and without stent implantation. However, studies have shown superior primary and secondary patency rates for routine stent placements.[17,18]

Similar to our study, Giannopoulos et al.[19] also found similar primary patency rates for POBA and DEB at 12 months. Thus, it is not surprising to explore that, in our practice, primary patency results are better in patients with intact distal run-off arteries than patients with one-patent vessel. Our study found 79% and 89% primary patency at two years in the ET and FPB groups, respectively, when all the outflow vessels were patent, and 25% and 54%, respectively, when there was only one patent distal vessel. According to Lazaris et al.,[20] the one-year primary patency rate for ET patients with one patent outflow vessel was 25%, and 85% when all outflow vessels were patent. Our study findings are consistent with the literature. Therefore, in patients with CLI and one run-off artery, intervention to the pathological infra-popliteal artery may be considered without compromising the running run-off artery.

Our FPB group included a heterogenous patient population including PTFE, vein graft, and collagen vascular graft groups. The subgroup analysis in the FPB group showed no significant differences between the PTFE (68%), SVG (75%), and CVG (71%) in terms of 24-month primary patency rates (p=0.15). There are also randomized-controlled and retrospective studies which showed similar results to our study and found no significant differences between graft types in terms of patency rates.[21-23] However, Rahman and Azak[24] reported better patency rates for SVG compared PTFE in FPB. Also, a meta-analysis of randomized-controlled trials

conducted by Sharrock et al.[25] showed the SVG in above-knee FPB grafting due to its superiority in primary, primary assisted, and secondary patency rates and less need for reintervention compared to prosthetic grafts. Of note, the limitation of this analysis is that not all prosthetic grafts were made of the same material (Dacron and PTFE).

Although surgery is the treatment approach for TASC II C patients in some centers, it is a reasonably priced procedure, when all the costs are considered together. In our study, cost-analysis revealed significant differences between the ET and FPB groups. The mean cost for the ET group was $1,346.5±560.4, whereas it was $1,544.2±184.1) for the FPB group (p=0.02). The prolonged hospitalization partly explains these results in the FPB group in which the PTFE grafts were used in nearly 70% of cases. The study's generalizability is further restricted by its single-center, retrospective, and non-randomized design with a relatively small sample size.

In conclusion, ET as the first-line therapy for symptomatic TASC II C patients offers promising results. It is a safe treatment choice with lower in-hospital costs and similar primary and secondary patency rates to FPB in TASC II C patients. However, FPB treatment is still the gold standard for complex femoropopliteal lesions, and further randomized controlled trials are needed for ET to become the standard treatment for TASC II C femoropopliteal lesions.

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