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Comparison of the endovascular therapy with drug-coated balloon and bypass surgery for Trans-Atlantic Inter-Society Consensus II C and D femoropopliteal lesions

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Abstract
Aim: The optimal revascularization strategy with the greatest durability and the lowest morbidity in femoropopliteal artery occlusions still remains debated. This study aimed to compare 2-year follow up after endovascular therapy (EVT) and femoropopliteal bypass in subjects with TASC II C and D femoropopliteal artery occlusions.
Material and Methods: This study included 92 patients with extensive (TASC II C and D) de novo femoropopliteal occlusion who underwent EVT or femoropopliteal bypass surgery. Drug coated balloons competent with target vessel diameter were used for PTA interventions.
Results: A total of 92 subjects with 92 limbs treated were included in the study. Fifty-one of the study subjects received EVT and 41 underwent femoropopliteal bypass surgery. The primary patency rate was higher in the femoropopliteal bypass group compared to the PTA group at 6th, 12th, and 24th -month follow-up studies.
Discusion: We compared the early and mid-term clinical outcomes of EVT and femoropopliteal bypass for TASC II C and D lesions of the femoropopliteal artery. We hypothesized that, given the superiority of drug-coated balloons compared to uncoated balloons in terms of postoperative outcomes, EVT with drug-coated balloons would provide superior primary patency compared to femoropopliteal bypass in subjects with complex femoropopliteal artery disease. However, our findings failed to demonstrate the superiority of EVT with drug-coated balloons over femoropopliteal bypass. This result supports the evidence derived from previous studies comparing the two treatment strategies for TASC II C and D lesions of the femoropopliteal artery. Our results indicate that postoperative ABI is also higher in subjects undergoing femoropopliteal bypass than those receiving EVT. Femoropopliteal bypass surgery provides a higher primary patency rate and a more significant improvement in ABI in subjects with TASC II C and D femoropopliteal artery occlusions with similar complication rates for the two treatment strategies.

Keywords
Femoropopliteal bypass; Endovascular; TASC

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Introduction

Peripheral arterial disease (PAD) constitutes a significant healthcare problem [1]. About 25% of patients with symptoms of PAD require intervention and 5% progress to critical limb ischemia [2]. The risk of limb amputation and all-cause mortality has been shown to be increased in patients with critical limb ischemia [3]. Revascularization is critical in reducing mortality and morbidity [3].

The femoropopliteal region, which harbors the superficial femoral artery (SFA) and the popliteal artery, is particularly prone to atherosclerotic vascular disease due to the exposure to high dynamic forces of flexion, extension, shortening and torsion [4]. Vascular injury stemming from the cyclic deformation, strain caused by external forces, and cellular proliferation is considered to be responsible for the increased prevalence of PAD in the femoropopliteal region. Femoropopliteal bypass is the traditional first-line revascularization strategy for TASC II class D femoropopliteal disease, due to the lower patency rate with percutaneous transluminal angioplasty (PTA) in SFA stenosis compared to surgical revascularization [5]. On the other hand, recent advances in endovascular device technology, including hydrophilic guidewires, drug-coated balloons, and drug-eluting stents contain high success rates (exceeding 80–90%) with endovascular therapy (EVT) in TASC II C/D lesions [6]. However, past studies comparing EVT with femoropopliteal bypass for TASC II C and D lesions have provided inconsistent results. Moreover, there are only a few studies comparing EVT with femoropopliteal bypass in the treatment of femoropopliteal disease. In general, the outcome achieved with bypass surgery is still better than that of PTA [7]. We hypothesized that EVT with drug-coated balloons could provide a primary patency rate comparable to femoropopliteal bypass surgery.

The purpose of this study was to compare the 2-year clinical outcomes of EVT and femoropopliteal bypass in subjects with TASC II C and D femoropopliteal artery occlusions.

Material and Methods

Study Group

This retrospective study included 92 patients with extensive (TASC II C and D) de novo femoropopliteal disease who underwent EVT or femoropopliteal bypass in Ordu University, Education and Research Hospital between March 2016 and March 2018. The ethic approval of the present the study was obtained from Ethical Committee of Ordu University, School of Medicine (Approval number: 2020/186). The indications for revascularization included intermittent claudication, resting pain, critical limb ischemia, wound infection, and tissue loss. All subjects were evaluated with duplex ultrasound and CT angiography subsequent to physical examination and ankle-brachial index (ABI) calculation. Limbs with significant stenosis requiring endarterectomy, limbs without at least one patent vessel up to the distal third of the leg, patients with occlusion of the tibioperoneal trunk, and subjects receiving hybrid therapy were excluded from the study. Data regarding demographic features, lesion characteristics and complications were collected and retrospectively evaluated. All participants provided written informed consent for the use of their data in this research.

Intervention

The optimal treatment strategy for each patient was chosen by the consensus of the cardiovascular team consisting of a cardiovascular surgeon, a cardiologist and a radiologist.

All femoropopliteal bypass surgeries were carried out under general anesthesia. Polytetrafluoroethylene (PTFE) grafts or saphenous vein grafts were used for femoropopliteal bypass surgeries. Autologous veins were the first choice for bypass grafting. The proximal anastomotic region was the common femoral artery or superficial femoral artery, and the distal anastomosis was located on the above-knee popliteal artery or below-knee popliteal artery.

All EVT interventions were performed in a standard manner by the same team. Following the local anesthesia of the groin, a 6 or 7F introducer was inserted into the ipsilateral common femoral artery. UF heparin bolus of 100U/kg was administered to all subjects undergoing PTA. An angled, tapered catheter and a hydrophilic guidewire were used to pass through the lesions. A wire escalation technique was used for crossing total occlusions. The subintimal technique was used only in cases where other techniques failed to pass through the lesion. DCBs matching the target vessel diameter were used for PTA interventions. Bail-out stenting was reserved for residual stenosis >30% and for flow-limiting dissections. A loading dose of 300 mg of clopidogrel was administered, followed by 75 mg daily for twelve weeks, in combination with aspirin and statin therapy on a long-term basis.

Follow-up was conducted by means of a clinical assessment, including ABI, and a duplex scan at 1, 6, 12, and 24 months. Primary patency, which was defined as a treated vessel that remained patent without restenosis or revascularization during follow-up, was recorded for each patient. A more-detailed medical examination and imaging were employed for any suspected complications. All complications including hematomas, pseudoaneurysm formation, wound infections, bleeding, and distal embolism were recorded during follow-up.

The difference in primary patency rate between subjects undergoing EVT or femoropopliteal bypass was the primary outcome measure of the study. The differences in complication rate, ABI, and length of hospital stay between the groups were the secondary outcome measure.

Statistical analysis

All analyses were performed on Statistical Package for the Social Sciences (SPSS v21 Inc., Chicago, IL, USA). Data are given as mean ± standard deviation or median (minimum - maximum) for continuous variables according to the normality of distribution, and as frequency (percentage) for categorical variables. Categorical variables were evaluated using the Chi-square or Fisher's exact tests. The Shapiro-Wilk test was used to determine whether variables were normally distributed. The independent samples t-test was used to analyze normally distributed variables, and the Mann-Whitney U test was used to analyze non-normally distributed variables. The change in ABI was analyzed with the Wilcoxon Signed Ranks test for repeated measurements. Between-groups comparison of the ankle-brachial index was performed by analyzing the differences between the repeated measurements, using the Mann-Whitney U test. Generalized estimating equations were used to

compare primary patency rates between the groups. Repeated measurements of primary patency rate were analyzed with the Cochran's Q test. Pairwise comparisons were performed with the Bonferroni correction method. Two tailed p-values of less than 0.05 were considered statistically significant.

Results

Patient and lesion characteristics

A total of 92 subjects with 92 limbs treated were included (mean age 65.87 ± 13.17 years, 87% males). Fifty-one of the study subjects received EVT and 41 underwent Femoropopliteal bypass surgery. Comparison of the demographic features of the study groups is presented in Table 1. Subjects receiving EVT were more likely to have Rutherford class 4 and 5 lesions, whereas subjects undergoing femoropopliteal bypass were more likely to have Rutherford class 3 and 4 lesions. The frequencies of TASC II C and D lesions were similar in the two groups. Diabetes was more frequent among subjects undergoing femoropopliteal bypass than in those receiving PTA (53.66% vs. 21.57%, p = 0.003). In contrast to diabetes, hypertension was more frequent among subjects receiving PTA than in those undergoing femoropopliteal bypass (58.82% vs. 24.39%, p = 0.002). Table 2 demonstrates the lesion characteristics. Lesion length was longer in subjects receiving PTA compared to those undergoing femoropopliteal bypass surgery (16 [4 - 50] cm vs. 12 [5 - 50] cm, p=0.022).

Surgery characteristics

Surgical features of the subjects undergoing femoropopliteal bypass are given in Table 3. Distal anastomosis point was above-knee in 25 subjects (60.98%) and below-knee in 16 subjects (39.02%). Autologous vein grafts were used in 75.61% of these subjects, while PTFE grafts were implemented in only 24.39% of the subjects undergoing surgery. Drug-coated balloons were used in all subjects. Bail-out stenting was employed in only 5 subjects (9.8%).

Outcomes

The primary patency rate was higher in the femoropopliteal bypass group compared to the PTA group at 6th, 12th, and 24th month follow-up (Figure 1). All groups displayed significant improvements in ABI in the post-procedural first month. However, the improvement in ABI was higher in the femoropopliteal bypass group compared to the PTA group (p = 0.008) (Figure 2). The median length of hospital stay in the PTA group was shorter compared to the femoropopliteal bypass group (2 [1 - 10] days vs. 5 [3 - 20] days, p < 0.001) (Figure 3). Four subjects receiving PTA (7.84%) and 2 subjects undergoing femoropopliteal bypass (4.88%) required amputation (p=0.689). No mortality was recorded during the follow-up.

Table 1. Summary of patient characteristics

	Groups		
	EVT (n=51)	By-pass (n=41)	p
Age (years)	65.00 ± 13.06	66.95 ± 13.38	0.483
Gender (Male)	47 (92.16%)	33 (80.49%)	0.180
Rutherford Classification			
3	6 (11.76%)	13 (31.71%)	
4	26 (50.98%)	21 (51.22%)	**0.022**
5	19 (37.25%)	7 (17.07%)	
TASC II			
C	27 (52.94%)	24 (58.54%)	0.745
D	24 (47.06%)	17 (41.46%)	
Smoking Status			
Never	29 (56.86%)	21 (51.22%)	
Ex-smoker	3 (5.88%)	1 (2.44%)	0.547
Smoker	19 (37.25%)	19 (46.34%)	
Diabetes Mellitus	21 (41.18%)	18 (43.90%)	0.960
Coronary Artery Disease	11 (21.57%)	22 (53.66%)	**0.003**
Hypertension	30 (58.82%)	10 (24.39%)	**0.002**
Chronic Renal Failure	2 (3.92%)	1 (2.44%)	1.000
Hyperlipidemia	14 (27.45%)	8 (19.51%)	0.521
Drug Usage	43 (84.31%)	29 (70.73%)	0.188
Clopidogrel	16 (31.37%)	7 (17.07%)	0.183
ASA	13 (25.49%)	18 (43.90%)	0.102
Cilostazol	9 (17.65%)	0 (0.00%)	0.004
Warfarin	1 (1.96%)	1 (2.44%)	1.000
Antihypertensive	12 (23.53%)	3 (7.32%)	0.071
Statin	11 (21.57%)	9 (21.95%)	1.000
Indication			
Rest Pain	21 (41.18%)	18 (43.90%)	
Claudication	16 (31.37%)	9 (21.95%)	
CLI	8 (15.69%)	13 (31.71%)	0.197
Wound Infection	1 (1.96%)	0 (0.00%)	
TissueLoss	5 (9.80%)	1 (2.44%)	

Data are given as mean ± standardd eviation and as frequency (percentage) for categorical variables

Table 2. Summary of lesion characteristics

	Groups		
	EVT (n=51)	By-pass (n=41)	p
Length of Stenosis (cm)	16 (4 - 50)	12 (5 - 50)	**0.0**
Lesion Characteristic (Occlusion)			
60% - 89%	13 (25.49%)	14 (34.15%)	
90% - 99%	12 (23.53%)	13 (31.71%)	0.2
Total occlusion	26 (50.98%)	14 (34.15%)	
Localization			
Proximal SFA	4 (7.84%)	4 (9.75%)	
Mid SFA	8 (15.69%)	9 (21.95%)	0.7
Distal SFA	10 (19.61%)	7 (17.07%)	
SFA + POPL	29 (56.86%)	21 (52.21%)	

Data are given as median (minimum - maximum) for continuous variables and as frequency (percent for categorical variables.

Table 3. Characteristics of by-pass operation

Surgery	n, %
Fem-Pop By-pass (AboveKnee)	25 (60.98%)
Fem-Pop By-pass (BelowKnee)	16 (39.02%)
Graft	
PTFE	10 (24.39%)
Vein	31 (75.61%)

Data are given as frequency (percentage) for categorical variables.

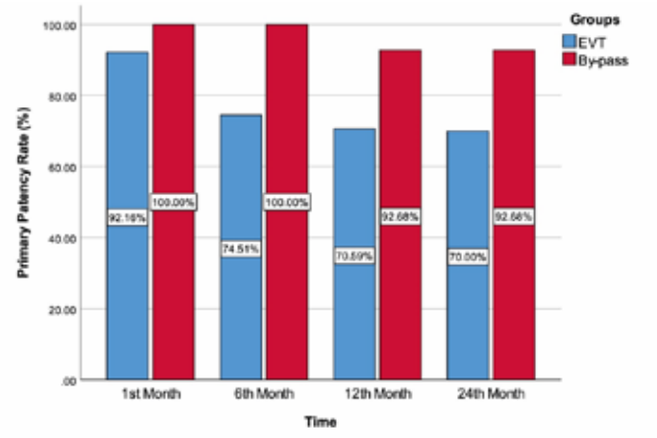

Figure 1. Primary patency rates with regard to groups

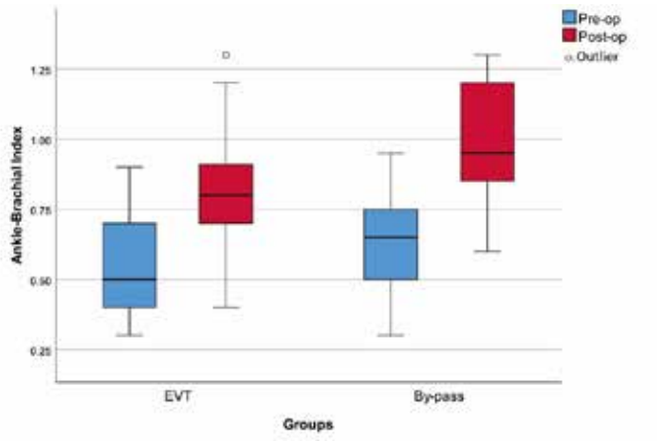

Figure 2. Ankle-brachial index with regard to groups

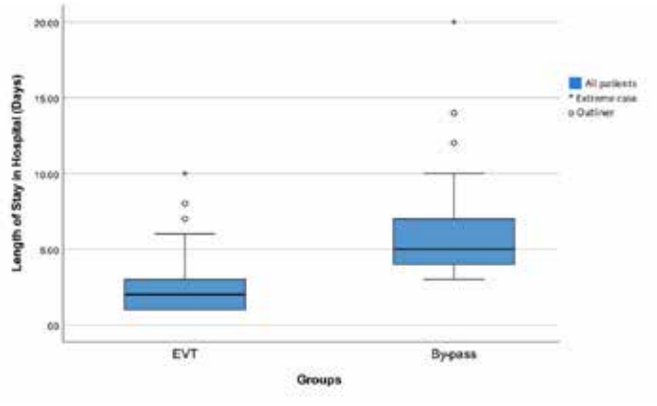

Figure 3. Length of stay in hospital (days9 with regard to groups

Discussion

In this study, we compared the early and mid-term clinical outcomes of EVT and femoropopliteal bypass for TASC II C and D lesions of the femoropopliteal artery. Findings of the present study demonstrate that femoropopliteal bypass surgery provides a higher primary patency rate at early and mid-term follow-up in subjects with TASC II C and D femoropopliteal artery occlusions. The femoropopliteal bypass also leads to a more significant improvement in ABI compared to that achieved with EVT. Complication rates are similar in both treatment approaches. However, the length of hospital stay is significantly shorter in subjects receiving EVT compared to those undergoing femoropopliteal bypass surgery.

Management of the occlusive lower extremity PAD is generally guided by the severity of the symptoms reported by the patients. Patients with mild to moderate symptoms are often assigned to conservative treatment, including smoking cessation, regular exercise, and regulation of cardiovascular risk factors [8, 9]. However, patients with critical limb ischemia are definite candidates for revascularization, since the timely restoration of adequate blood flow to the ischemic area is often critical for the salvation of the limb [10, 11]. Nevertheless, the optimal revascularization strategy with the greatest durability and the lowest morbidity still remains debated.

Recent developments in endovascular approach, supported by advanced endovascular technology and improved operator skills, have significantly extended the range of EVT use. Currently, an 'endo-first' strategy is considered the standard of care, particularly, for elderly and critically ill patients in many centers, even though the presence of comorbidities such as diabetes and chronic renal failure often complicates the success of EVT [12]. The European Society of Vascular Surgery (ESVS) guidelines recommend the use of the endovascular approach in the management of TASC II A and B PAD [3, 13]. Recent evidence has revealed that the clinical outcomes achieved with EVT under such anatomical conditions are comparable to those achieved with the surgical bypass. Moreover, EVT is more advantageous compared to surgical bypass in terms of healthcare costs and length of hospital stay [14]. However, whether EVT or surgical bypass provides better clinical outcomes in more complex arterial disease (TASC II C and D) is still controversial. In a retrospective analysis conducted by Gur and colleagues, EVT was shown to fail more frequently and alter the site of subsequent open treatment in TASC II C and D lesions compared to TASC A or B lesions [15].

There are limited studies comparing the endovascular and bypass surgery approaches in patients with TASC II C and D femoropopliteal occlusive disease. The majority of these studies indicate that the rates of primary patency are similar for the two approaches; however, perioperative complications are reported to be lower with EVT compared to femoropopliteal bypass [16, 17]. Some of the largest randomized clinical trials comparing the outcomes of bypass surgery and balloon angioplasty in patients with critical limb ischemia (among whom the majority of the target lesions were in the femoropopliteal artery), reported similar amputation- free survival and all-cause mortality for the two approaches [18]. Aihara et al. have shown in 1156 patients presenting with intermittent claudication that bypass surgery provides a higher primary patency rate than EVT in TASC II C and D femoropopliteal lesions [19]. However, the reported complication rate in that study was significantly lower in the EVT group than that of the bypass group. Recently, Okuno et al. have compared femoropopliteal bypass and the endovascular approach with self-expandable nitinol stents for TASC II C and D femoropopliteal lesions and found that a 3-year primary patency rate was significantly higher for femoropopliteal bypass than EVT [20]. The superiority of bypass surgery over EVT in complex femoropopliteal disease

has been supported by other studies. Veraldi et al., in their retrospective study which included 80 limbs with TASC II D femoropopliteal lesions, showed that femoropopliteal bypass with polytetrafluoroethylene graft + Linton patch was superior to PTA ± bare metal stents in terms of primary patency at 6, 12 and 24 months [21]. However, PTA procedures included regular balloons in the aforementioned trials, and DCBs were not used in these studies. The present study is therefore unique in terms of using drug-coated balloons instead of regular balloons. Previous evidence with drug-coated balloons in femoropopliteal disease has shown promising efficacy of drug coated balloons, particularly with regard to late lumen loss and target lesion revascularization rates compared to angioplasty alone [22-25]. We hypothesized that, given the superiority of drug-coated balloons over uncoated balloons in terms of postoperative outcomes, EVT with drug-coated balloons would provide superior primary patency compared to femoropopliteal bypass in subjects with complex femoropopliteal artery disease. However, our findings failed to demonstrate the superiority of EVT with drug-coated balloons when over femoropopliteal bypass. This result supports the evidence derived from previous studies comparing the two treatment strategies for TASC II C and D lesions of the femoropopliteal artery. Our results indicate that postoperative ABI is also higher in subjects undergoing femoropopliteal bypass than those receiving EVT. The complication rate of the bypass group in this study was comparable to that of the EVT group. The only advantage of EVT over bypass surgery was the shorter length of hospital stay in subjects receiving EVT compared to those undergoing femoropopliteal bypass surgery.

With this in mind, we suggest that femoropopliteal bypass surgery is likely superior in the treatment of TASC II C and D lesions of the femoropopliteal artery, even if the EVT is performed with drug-coated balloons. In this context, we consider that EVT, even with drug-coated balloons, should be reserved for patients with significant comorbidities; whereas a bypass surgery should be offered for subjects who are more likely to have longer-term survival.

This study has some limitations that should be mentioned. Relatively small sample size and the retrospective, non-randomized study design are the major drawbacks. In addition, this study demonstrates single-center data. Lack of data concerning the healthcare costs for the two treatment strategies is also another limitation. However, implementation of autologous vein grafts in the majority of subjects undergoing femoropopliteal bypass, and utilization of drug-coated balloons rather than uncoated balloons in subjects receiving EVT are the strengths of the study.

Conclusion

Femoropopliteal bypass surgery provides a higher primary patency rate and a more significant improvement in ABI in subjects with TASC II C and D femoropopliteal artery occlusions. Complication rates are similar between the two treatment approaches. However, EVT provides shorter hospital stay compared to femoropopliteal bypass surgery. These findings suggest that femoropopliteal bypass surgery is likely in the treatment of TASC II C and D lesions of the femoropopliteal artery, even when DCBs are used in the EVT procedure.

Scientific Responsibility Statement

The authors declare that they are responsible for the article's scientific content including study design, data collection, analysis and interpretation, writing, some of the main line, or all of the preparation and scientific review of the contents and approval of the final version of the article.

Animal and human rights statement

All procedures performed in this study were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. No animal or human studies were carried out by the authors for this article.

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Conflict of interest

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