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ORIGINAL RESEARCH

**Strategy-based revascularization for complex femoropopliteal disease:
endovascular-first versus surgical bypass in contemporary practice**

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ABSTRACT

Aim: To compare the outcomes of endovascular treatment (EVT) and surgical bypass (BP) for the management of complex femoropopliteal (FP) artery disease.

Methods: This retrospective single-centre cohort study included patients with Trans-Atlantic Inter-Society Consensus (TASC II) C–D lesions in the FP segment treated between 2018 and 2023. The patients were categorized into two groups according to treatment strategy: EVT and surgical BP. The primary outcome was primary patency at 12 and 24 months. Secondary outcomes included target lesion revascularization, amputation-free survival, major amputation, and procedural complications.

Results: A total of 168 patients were included, with 98 patients in the EVT group and 70 patients in the BP group. Patients in the BP group had significantly longer lesion lengths and a higher prevalence of chronic total occlusions. Kaplan–Meier analysis demonstrated significantly higher primary patency in the BP group compared with the EVT group at 12 months (86.9% vs 71.4%, log-rank $p=0.018$) and 24 months (78.1% vs 58.2%, log-rank $p=0.009$). Target lesion revascularization occurred in 7 patients (7.1%) in the EVT group and 4 patients (5.7%) in the BP group (RR=1.25; 95% CI 0.38–4.07). Major amputation occurred in 9 patients (9.2%) in the EVT group and 7 patients (10.0%) in the BP group (RR=0.92; 95% CI 0.36–2.35). In multivariable analysis, BP was independently associated with reduced risk of primary patency loss (HR=0.58; 95% CI 0.35–0.94; $p = 0.028$).

Conclusion: In patients with complex FP disease, BP was associated with higher mid-term primary patency compared with EVT, while limb-related outcomes remained comparable between strategies.

Keywords: angioplasty, disease progression, limb salvage, peripheral arterial disease, prostheses and implants

INTRODUCTION

Peripheral artery disease (PAD), which represents one of the major manifestations of systemic atherosclerosis, is associated with significant morbidity, disability, and high cardiovascular mortality rates (1, 2). Of the various segments of the arterial tree, the femoropopliteal (FP) segment is one of the most frequently involved and plays a central role in the pathogenesis of lifestyle-limiting claudication and chronic limb-threatening ischemia. Advanced FP PAD, including Trans-Atlantic Inter-Society Consensus (TASC) II C–D lesions, is characterized by long lesion length, chronic total occlusions, and diminished runoff. These factors contribute to the difficulty and negatively impact the success of revascularization (3). Current international guidelines recognize the importance of considering the patient-related factors, life expectancy, and conduit availability in the selection of the revascularization strategy in addition to the effect of the anatomical characteristics of the lesion (4).

Surgical FP bypass, especially with autologous great saphenous vein grafts, has traditionally shown superior long-term patency and longevity in patients with advanced infrainguinal disease (5). However, recent improvements in endovascular techniques have significantly expanded the scope of endovascular treatment (EVT) in managing complex FP disease (6). Current randomized trials and clinical studies have shown that both modalities have a place in the treatment of complex FP disease, and treatment modality selection can be based more on patient- and lesion-specific rather than modality-specific considerations (7,8). In clinical practice, treatment selection is not based on a single parameter. A multidisciplinary approach to patient selection for vascular reconstruction in complex FP disease, considering disease severity, lesion complexity, and patient comorbidity, among other factors, has been recommended. Recent reviews have shown that BP surgery has a role in the endovascular era, especially in anatomically complex lesions and selected patient populations. Despite the

changing strategy-based framework, actual comparative data regarding the outcomes of endovascular first and BP-based strategies in the context of complex TASC II C-D FP disease are limited in the mid-term.

The aim of this study was to compare the outcomes of EVT first and BP-based strategies for the revascularization of complex FP artery disease.

METHODS

Study design and patients

This retrospective single-centre cohort study included consecutive patients that underwent revascularization procedures for symptomatic FP artery disease from January 2018 to December 2023. Patients were categorized into two groups according to treatment strategy: endovascular treatment (EVT) and surgical bypass (BP) group.

The study included patients presenting with TASC II C to D lesions of the FP artery, along with Rutherford class 3 to 6 symptoms. The exclusion criteria encompassed patients with acute limb ischemia, non-atherosclerotic vascular diseases, prior ipsilateral major amputation, life expectancy of less than one year, and insufficient follow-up data. Given the strategy-based nature of the study, differences in clinical and anatomical characteristics between the groups were expected. Decision-making in such cases is usually a multidisciplinary approach.

Methods

The allocation of treatments was decided by a multidisciplinary vascular team depending on clinical presentation, anatomical complexity, co-morbidity, procedural risk, and conduit availability. Anatomical characteristics considered included length of the lesion, presence of chronic total occlusion, and TASC II classification. Clinical severity was assessed according to the Rutherford classification, which categorizes disease severity from class 0 (asymptomatic) to class 6 (ischemic ulceration or gangrene). Patients were grouped as Rutherford class 3 (claudication) and class 4–6 (chronic limb-threatening ischemia).

Outcome results were analysed with respect to baseline clinical severity and anatomical complexity; however, subgroup analyses of outcome results were not performed due to small numbers in subgroups.

The endovascular first approach included lesion crossing using conventional endovascular techniques, followed by balloon pre-dilation and angioplasty using a drug-coated balloon (DCB). Bailout stenting was performed when indicated, including cases of flow-limiting dissections and cases with a residual stenosis of 30% or greater on completion angiography.

The technical success was indicated by a restored flow with an acceptable angiographic outcome at procedure termination. In cases where bailout stenting was indicated, self-expanding nitinol bare-metal stents (BMS) were used, and drug-eluting stents were not used. All the patients who underwent endovascular procedures were on dual antiplatelet therapy with aspirin 100 mg/day and clopidogrel 75 mg/day for at least 3 months, followed by aspirin monotherapy indefinitely unless contraindicated.

Surgical FP bypass operations were carried out using autogenous great saphenous vein grafts whenever possible. Prosthetic grafts made of expanded polytetrafluoroethylene (PTFE) were used when the availability of suitable venous tissue was not possible. Prosthetic grafts were not used for below knee distal anastomosis. The distal anastomosis was performed above or below the knee depending on imaging findings and intraoperative assessment.

The postprocedural follow-up was in accordance with the institution's protocol and included clinical evaluation and non-invasive imaging, when available. The decision to re-intervene was based on clinical symptoms, hemodynamic deterioration, and restenosis detected by imaging.

The main endpoint is primary patency at 12 and 24 months, which is the absence of restenosis greater than or equal to 50%, and the absence of clinically indicated target lesion revascularization. Secondary endpoints include secondary patency, target lesion

revascularization, amputation-free survival (AFS), major amputation, periprocedural complications, length of stay, wound complications, and all-cause mortality.

Secondary endpoints were considered to be exploratory and were to be interpreted with caution without adjusting for multiplicity.

Statistical Analysis

Categorical variables were expressed as counts (N) and percentages (%). Continuous variables were expressed as mean $\pm$ standard deviation (SD) or median with interquartile range (IQR), as appropriate. The normality of distribution was assessed using the Shapiro–Wilk test. Comparisons between the two groups for continuous variables were performed using the student’s t-test for normally distributed variables and the Mann–Whitney U test for non-normally distributed variables, while categorical variables were compared using the chi-square test or Fisher’s exact test.

Time-to-event outcomes were estimated according to the Kaplan–Meier method, while between-group comparison was performed with the log-rank test. Multivariable Cox proportional hazards regression analyses were performed to determine the predictors for the occurrence of primary patency loss. The covariates used in the multivariable analyses included age, gender, diabetes mellitus, chronic kidney disease, smoking status, Rutherford classification, strategy, lesion length, chronic total occlusion, and TASC II classification. As lesion length, chronic total occlusion, and TASC II classification are anatomically related, the issue of potential collinearity was taken into consideration during the multivariable analyses. In such instances, variables with strong anatomical correlation, including lesion length, presence of chronic total occlusion, and TASC II classification, were not simultaneously included in the multivariable model to avoid multicollinearity. The proportionality assumption was also tested with the log-minus-log survival plots. The probability value was set at <0.05 , indicating statistical significance. Kaplan–Meier survival analyses were

performed using IBM SPSS Statistics software (Version 26.0, IBM Corp., Armonk, NY, USA).

RESULTS

A total of 168 patients were included in the study, of whom 98 (58.3%) underwent EVT and 70 (41.7%) underwent BP surgery. Baseline demographic and clinical characteristics were comparable between the groups (Table 1). The mean age was 67.4 ± 9.1 years in the endovascular-first group and 68.9 ± 8.7 years in the bypass group ($p=0.280$), and the majority of patients were male (73.5% vs. 74.3%, $p=0.910$). Diabetes mellitus was present in 52 patients (53.1%) in the EVT group and 39 patients (55.7%) in the BP group ($p = 0.740$), while hypertension was observed in 71 patients (72.4%) and 53 patients (75.7%), respectively ($p = 0.640$). Regarding clinical severity, Rutherford class 3 disease was observed in 48 patients (49.0%) in the EVT group and 26 patients (37.1%) in the BP group, whereas advanced Rutherford class 4–6 disease was present in 50 patients (51.0%) and 44 patients (62.9%), respectively ($p = 0.210$) (Table 1). The median follow-up duration was 18 months (IQR: 12 - 24).

Conversion to surgical BP after EVT was needed in 2 (2.0%) patients. The distal anastomosis was performed above the knee in 49 (70.0%) patients and below the knee in 21 (30.0%) patients. The periprocedural complications occurred in 15 patients (15.3%) in the EVT group and 11 patients (15.7%) in the BP group (Table 2).

At 12 months, primary patency was 86.9% (95% CI 78.5–93.1) in the BP group versus 71.4% (95% CI 61.8–79.3) in the EVT group (log-rank $p = 0.018$; Figure 1). At 24 months, primary patency remained significantly higher in the BP group with 78.1% (95% CI: 68.4–85.3) versus 58.2% (95% CI: 47.6–67.4) (log-rank $p = 0.009$; Figure 1). In multivariable Cox regression analysis, BP was independently associated with a reduced risk of primary patency loss (HR=0.58, 95% CI: 0.35 - 0.94; $p = 0.028$).

Target lesion revascularization occurred in 7 patients (7.1%) in the EVT group and 4 patients (5.7%) in the BP group (RR=1.25; 95% CI 0.38–4.07).

Major amputation occurred in 9 patients (9.2%) in the EVT group and 7 patients (10.0%) in the BP group (RR=0.92; 95% CI 0.36–2.35) (Figure 2).

When outcomes were stratified according to the Rutherford classification, primary patency at 12 months was observed in 61 patients (82.4%) with Rutherford class 3 and in 70 patients (74.5%) with Rutherford class 4–6 ($p=0.180$). Target lesion revascularization occurred in 5 patients (6.8%) in Rutherford class 3 and 6 patients (6.4%) in Rutherford class 4–6 ($p=0.920$). Major amputation occurred significantly less frequently in Rutherford class 3 compared with Rutherford class 4–6 (2.7% vs 14.9%; $p=0.006$). AFS was significantly higher in Rutherford class 3 patients (95.9% vs 84.0%; $p=0.011$). The periprocedural complications occurred in 15 patients (15.3%) in the EVT group and 11 patients (15.7%) in the BP group ($p=0.948$) (Table 2).

During the period of follow-up, mortality occurred in 1 case (1.0%) among the patients of the EVT group and in 1 case (1.4%) among the patients of the BP group.

DISCUSSION

In this study, both EVT and BP-based revascularization strategies demonstrated acceptable mid-term outcomes in patients with complex FP artery disease. Overall, BP-based treatment was associated with numerically higher primary patency and AFS rates compared with endovascular-first therapy, although both strategies provided satisfactory limb preservation. These findings suggest that while EVT approaches remain a feasible and less invasive option, BP surgery continues to offer durable outcomes in appropriately selected patients with advanced FP disease. In patients with complex FP artery disease, BP surgery was associated with significantly better mid-term primary patency, while limb-related outcomes were comparable between the treatment strategies.

In the current cohort, the BP group had superior primary patency rates at 12 and 24 months. These data support previous reports on the long-term success of revascularization techniques and recent endovascular studies evaluating the efficacy of drug-coated balloon-based therapies for the treatment of FP disease (9,10). It is important to note, however, that treatment selection in the current investigation was dictated by anatomical factors, with longer and more severe disease being addressed with BP surgery. As such, baseline anatomical factors may have contributed to the patency disparities between the groups. It should be noted that the patency results vary, but the limb-related clinical results, such as major amputation and AFS, were comparable among the different strategies. Anatomical factors, such as lesion calcification and degree of occlusion, remain important predictors of procedural success and patency in FP interventions (11,12).

BP has been independently related to a decreased risk of primary patency loss in multivariable Cox regression analysis. The clinical implications of limb preservation can also be emphasized by the well-known relationship between major lower extremity amputation and increased risk of death (13).

Another methodological consideration is the potential effect of competing risks, particularly mortality, on limb-related outcomes such as major amputation and amputation-free survival. Previous large revascularization trials have highlighted that mortality may preclude the occurrence of limb-related events and should be considered when interpreting limb outcomes (5,7,8). In the present cohort, mortality was low and comparable between the treatment groups, with one death observed in each group. Therefore, the influence of competing risk bias is likely limited. However, competing risk modelling was not performed, and this should be acknowledged when interpreting limb-related outcomes.

Interpretation of the present findings should also consider the evaluation of multiple secondary outcomes without formal adjustment for multiplicity. Although the primary

endpoint was prespecified, secondary outcomes should be interpreted cautiously. In addition, subgroup evaluation according to the Rutherford classification demonstrated clinically relevant differences in limb-related outcomes, with major amputation occurring more frequently in patients with Rutherford class 4–6 compared with class 3 disease (14.9% vs 2.7%, $p = 0.006$).

The present results are consistent with findings from major contemporary revascularization trials, such as the BASIL and BEST-CLI studies, which reported that bypass-based strategies generally demonstrate superior patency durability, whereas limb-related outcomes, including amputation, may remain comparable between treatment strategies depending on disease severity and patient characteristics (5,7,8). Similarly, contemporary clinical practice guidelines emphasize individualized, multidisciplinary decision-making based on anatomical complexity and patient comorbidity.

BP-first strategies demonstrated improved long-term patency compared with angioplasty, particularly beyond two years of follow-up (5). Similarly, the BEST-CLI trial reported superior limb-event outcomes in patients treated with surgical BP using suitable vein conduit, while endovascular therapy remained an acceptable alternative in selected patients (7). In the present cohort, primary patency at 24 months was higher in the BP group compared with the EVT group (78.1% vs 58.2%), supporting the concept that BP-based strategies may provide more durable patency in anatomically complex FP disease.

The study also recognizes several limitations. The study design is retrospective and monocentric and may be susceptible to confounding variables due to selection bias. This is particularly pertinent because the decision to treat patients was based on anatomical and clinical complexities. Secondly, the inherent anatomical differences between the two groups may have played a role in the patency results despite adjustment for confounding variables. Propensity score matching was not performed due to sample size limitations, and

multivariable adjustment was applied instead, which may have resulted in residual confounding. A competing risk analysis was not undertaken despite low and comparable mortality rates. Finally, multiple secondary outcomes were assessed without adjustment for multiple testing and interaction analysis for subgroups based on the Rutherford classification due to sample size constraints.

CONCLUSION

In this retrospective cohort of patients with complex FP arterial disease, surgical BP was associated with higher mid-term primary patency compared with an EVT approach. However, limb-related outcomes, including major amputation and amputation-free survival, were comparable between the treatment strategies. These findings support individualized, strategy-based decision-making that considers anatomical complexity, clinical severity, comorbidity, and conduit availability.

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Author contributions (CRediT):

Conceptualization—E.K. Methodology—E.K., B.Y. Software—E.K. Validation—E.K., B.Y. Formal analysis—E.K. Investigation—E.K. Resources—E.K., B.Y. Data curation—E.K. Writing – original draft—E.K. Writing – review & editing—E.K., B.Y.

Visualization—E.K. Supervision—B.Y.

Project administration—E.K.

Funding acquisition—None.

Ethics statement: The study protocol was reviewed and approved by the Ethical Committee of Ordu University Research and Education Hospital (approval number: 2021/205).

Data availability statement: The datasets generated and/or analysed during the current study are available from the corresponding author on reasonable request.

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TABLES AND FIGURES

Table 1. Baseline demographic and clinical characteristics

Variable	EVT (N=98)	BP (N=70)	p
	Mean ± SD		
Age, years	67.4 ± 9.1	68.9 ± 8.7	0.280
	N (%)		
Male sex	72 (73.5%)	52 (74.3%)	0.910
Diabetes mellitus	52 (53.1%)	39 (55.7%)	0.740
Hypertension	71 (72.4%)	53 (75.7%)	0.640
Coronary artery disease	36 (36.7%)	29 (41.4%)	0.550
Chronic kidney disease	18 (18.4%)	16 (22.9%)	0.470
Smoking history	61 (62.2%)	45 (64.3%)	0.780
Rutherford classification			
Class 3	48 (49.0%)	26 (37.1%)	0.210
Class 4–6	50 (51.0%)	44 (62.9%)	

EVT, endovascular treatment; SD, standard deviation; N, frequency; BP, bypass;

Table 2. Lesion, procedural, and complication characteristics

Variable	EVT (N=98)	BP (N=70)	p
Lesion characteristics			
Lesion length (cm), Mean $\pm$ SD	18.9 $\pm$ 6.2	25.6 $\pm$ 7.5	<0.001
Chronic total occlusion, N (%)	52 (53.1)	48 (68.6)	0.041
Procedural characteristics, N (%)			
Technical success	94 (95.9)	68 (97.1)	0.690
DCB-only use	72 (73.5)	0	N/A
Bailout stenting	26 (26.5)	0	N/A
Autologous vein graft use	0	52 (74.3)	N/A
PTFE graft use	0	18 (25.7)	N/A
Distal anastomosis level			
Above-knee	0	49 (70.0)	N/A
Below-knee	0	21 (30.0)	N/A
Conversion to bypass	2 (2.0)	0	N/A
Periprocedural complications, N (%)			
Hematoma	5 (5.1)	0	N/A
Wound infection	0	3 (4.3)	N/A
Thrombosis	2 (2.0)	0	N/A
Graft thrombosis	0	3 (4.3)	N/A
Reintervention	7 (7.1)	4 (5.7)	N/A
Periprocedural Mortality	1 (1.0)	1 (1.4)	N/A
Any periprocedural complication	15 (15.3)	11 (15.7)	N/A

EVT, endovascular treatment; BP, bypass; DCB, drug-coated balloon; PTFE, expanded polytetrafluoroethylene; N, number; N/A, not applicable:

Table 3. Clinical outcomes stratified by Rutherford classification

Outcome	Rutherford 3 (N=74)	Rutherford 4–6 (N=94)	p
	N (%)		
Primary patency at 12 months	61 (82.4)	70 (74.5)	0.180
Target lesion revascularization	5 (6.8)	6 (6.4)	0.920
Major amputation	2 (2.7)	14 (14.9)	0.006
Amputation-free survival	71 (95.9)	79 (84.0)	0.011

N, frequency;

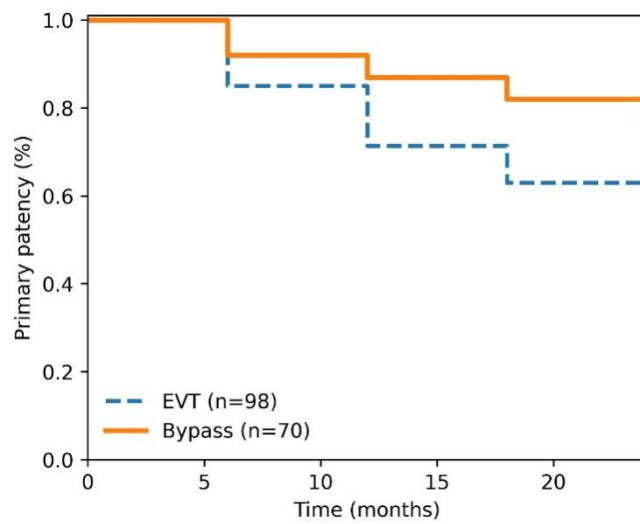


Figure 1. Kaplan–Meier estimates of primary patency according to endovascular (EVT) and surgical bypass (BP) treatment strategy

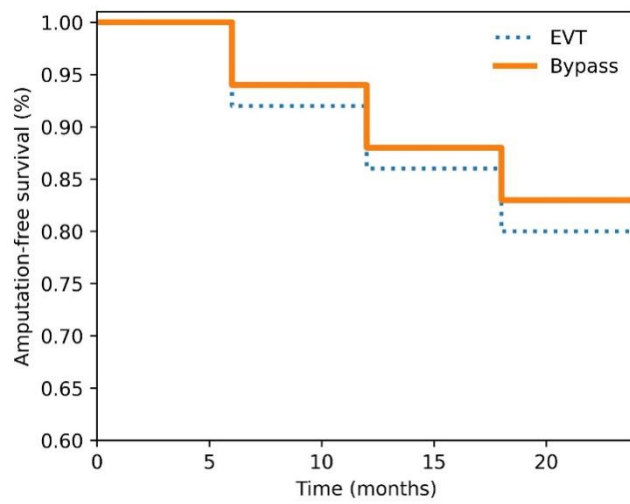


Figure 2. Kaplan–Meier estimates of amputation-free survival (AFS) according to endovascular (EVT) and surgical bypass (BP) treatment strategy