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ORIGINAL ARTICLE

Value of retrograde approach for the Endovascular Treatment of symptomatic femoropopliteal disease

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ABSTRACT

Keyword: Retrograde approach, endovascular treatment, femoropopliteal disease, patency rates, access site complications.

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Background: Retrograde approach is recognized for its utility in the endovascular treatment of symptomatic femoropopliteal disease. Although reports suggest its effectiveness, there remains a need for comprehensive evaluation of its long-term outcomes. **Objectives:** Study aimed to investigate the safety profile, access site complications, and long-term patency rates associated with this approach in patients undergoing EVT for symptomatic femoropopliteal artery diseases. **Patients and Methods:** This study was a prospective randomized controlled study that was performed on 25 patients recruited from vascular surgery department, Aswan University hospital who underwent retrograde approach for endovascular treatment for femoral-popliteal disease. Key outcomes assessed included access site complications, Ankle-Brachial Index (ABI) measurements pre- and post-intervention, and primary patency rates at follow-up. **Results:** Results indicated that There was high significant variance between the primary patency rate pre and post intervention in the study participants groups. There was a distinction among study participants in terms of angiographic variables related to directional atherectomy, localization, sheath, as well as microcatheter. **Conclusion:** retrograde approach in endovascular treatment of femoropopliteal stenosis diseases appears to be a safe and effective technique, with favorable patency rates and manageable complication risks

INTRODUCTION

Symptomatic femoropopliteal disease, which involves stenosis or occlusion of the superficial femoral artery (SFA) and popliteal artery, is a significant health concern that can lead to debilitating symptoms, including intermittent claudication, rest pain, and, in advanced cases, critical limb ischemia. These symptoms not only impair the quality of life for affected patients but can also result in serious complications such as ulceration, gangrene, and limb amputation if left untreated. This condition is particularly prevalent among individuals with risk factors such as diabetes mellitus, hypertension, smoking, and hyperlipidemia, contributing to the burden on healthcare systems worldwide[1].

Endovascular treatment (EVT) has increasingly become a cornerstone in the management of femoropopliteal disease, offering a less invasive alternative to traditional surgical interventions[2]. EVT

techniques, including balloon angioplasty, stenting, and atherectomy, have demonstrated efficacy in restoring blood flow while minimizing recovery time and hospital stays. Among these techniques, the retrograde approach has emerged as a valuable strategy, especially in cases where antegrade access is challenging or unsuccessful[3].

The retrograde approach involves gaining access to the target vascular lesions via the popliteal artery, allowing for direct visualization and intervention[4]. This method has shown promise in providing favorable outcomes in terms of technical success rates and patency, particularly in patients with complex vascular anatomy or chronic total occlusions. Studies have reported that the retrograde approach can effectively navigate challenging lesions and improve collateral circulation, leading to enhanced clinical outcomes[5].

Despite the growing body of evidence supporting the retrograde approach, there remains a need for comprehensive evaluations comparing its efficacy and safety with traditional antegrade techniques. Recent studies have highlighted variations in access site complications, such as bleeding and hematoma formation, as well as differences in long-term patency rates between these approaches[9]. However, there is a scarcity of robust, randomized controlled trials that systematically assess the long-term results of the retrograde approach in a diverse patient population.

This study aims to address this gap by evaluating the safety profile, access site complications, and long-term patency rates associated with the retrograde approach in patients undergoing EVT for symptomatic femoropopliteal disease. By conducting a prospective, randomized controlled trial, we seek to provide critical insights into the benefits and risks of the retrograde technique, contributing to evidence-based guidelines for the management of femoropopliteal disease. The findings of this research are expected to inform clinicians regarding the optimal approach for EVT, ultimately enhancing patient outcomes and treatment strategies in the field of vascular surgery.

PATIENTS AND METHODS:

This study is a prospective, randomized controlled trial (RCT) conducted to evaluate the efficacy of the retrograde approach for endovascular treatment (EVT) in patients with symptomatic femoropopliteal disease. A total of 25 patients aged between 45 and 70 years, diagnosed with superficial femoral artery (SFA) or popliteal artery (PA) disease, were recruited from the Vascular Surgery Department at Aswan University Hospital, Egypt, underwent retrograde approach for endovascular treatment for femoral-popliteal disease.Ethical approval was obtained from the Aswan University Hospital's Ethical Committee, and written informed consent was secured from all participants prior to their inclusion in the study.

Interventions

The retrograde approach involves accessing the popliteal artery, typically with the patient in a prone position. The procedure began with the insertion of a needle into the popliteal artery under ultrasound or fluoroscopic guidance, followed by the placement of a guidewire and sheath to facilitate the introduction of endovascular devices .All procedures were performed by a team of experienced vascular specialists to ensure consistency in the execution of the interventions.

Inclusion and Exclusion Criteria

Inclusion criteria encompassed patients aged 45 to 70 years with symptomatic SFA or PA disease. Exclusion criteria included previous interventions or surgeries on the SFA or PA, diseases affecting the proximal iliac or abdominal aorta, the presence of below-the-knee (BTK) lesions, patient mortality during the study, or failure to attend follow-up appointments. These criteria were designed to enhance the homogeneity of the study population and minimize confounding factors affecting outcomes.

Study Procedures

A comprehensive preoperative assessment was conducted for all participants, which included personal data collection (age, gender) and evaluation of risk factors such as diabetes, ischemic heart disease, hypertension, peripheral arterial obstructive disease, and cerebrovascular disease. Laboratory investigations comprised serum creatinine, cholesterol levels, HbA1c, complete blood count, and coagulation profiles (PT, PTT, INR). Imaging studies, including digital subtraction angiography, assessed the characteristics of arterial lesions and collateral blood supply prior to intervention.

Endovascular Treatment Protocol

The retrograde EVT was performed under local anesthesia. Each patient received 100 units per kilogram of unfractionated heparin prior to arterial puncture. The popliteal artery was accessed with a 20 or 22 G needle while the patient was in the prone position. A 5 to 7 Fr vascular sheath was inserted into the artery for access, and a 0.035-inch hydrophilic guidewire was utilized to cross the stenotic or occluded lesions. Paclitaxel-coated balloons were used, which were inflated at the target lesion for a minimum of 2 minutes. Following the procedure, the vascular sheath remained in place for four hours before being removed with manual compression applied to achieve hemostasis.

Post-Procedure Management and Follow-Up

All participants were prescribed dual antiplatelet therapy consisting of aspirin and clopidogrel for six months post-procedure to mitigate thrombotic complications. Patients were followed up for 12 months, with assessments conducted clinically and via duplex ultrasound at 3, 6, and 12 months. Radiographic and surgical outcomes, as well as early and late complications, were documented. The absence of restenosis at the target lesion defined primary patency.

Sample Size Calculation

Sample size was determined using SPSS, with an alpha error of 0.05 and a power of 80%. The total sample size calculated was 25 patients.

Statistical Analysis

Statistical analysis was performed using SPSS v28 (IBM, Armonk, New York, US). Data normality was assessed using the Shapiro-Wilk test. Continuous variables were presented as mean ± standard deviation for normally distributed data and as frequency (%) for categorical variables. The independent sample t-test was employed for normally distributed variables, while the Mann-Whitney U test was used for non-normally distributed variables. The Wilcoxon Signed Ranks test assessed changes in the ankle-brachial index over time. Chi-square or Fisher's exact tests were utilized for categorical data analysis. Generalized estimating equations were applied to compare primary patency rates between groups. Cochran's Q test evaluated the primary patency rate based on several

measurements, with the Bonferroni adjustment applied for multiple comparisons. Statistical significance was set at a two-tailed p-value of < 0.05.

RESULTS

Demographic data and comorbidities of the patients in study group who underwent the retrograde approach. The mean age was 63.52 years, ranging from 45 to 80, with a predominantly male group (92%). Common comorbidities included hypertension (68%), coronary artery disease (52%), and diabetes mellitus (40%), reflecting a population with significant cardiovascular risk factors. Additionally, 40% were smokers, which may further contribute to peripheral arterial disease. Chronic renal failure and COPD were less prevalent, each affecting 12% of the group **table 1**

Table I: Demographic Characteristics for the study group

Variable	Study group (n = 25)	95% CI for study group
Demographic Data		
Age (year)		
Range	45 – 80	
Mean ± SD	63.52 ± 11.58	58.3 – 68.7
Gender		
Female	2 (8.0%)	1.0% – 25.0%
Male	23 (92.0%)	75.0% – 99.0%
Comorbidities		
Smokers	10 (40.0%)	21.9% – 61.3%
Hyperlipidemia	10 (40.0%)	21.9% – 61.3%
Diabetes Mellitus	10 (40.0%)	21.9% – 61.3%
Hypertension	17 (68.0%)	46.5% – 85.1%
Chronic Renal Failure	3 (12.0%)	2.5% – 31.2%
COPD	3 (12.0%)	2.5% – 31.2%
Coronary Artery Disease	13 (52.0%)	31.3% – 72.2%

The angiographic characteristics of the lesions treated in study group. The median length of stenosis was 10 cm, with 72% of cases exhibiting total occlusion and 28% partial (>70%) stenosis.

The lesions were primarily located in the proximal SFA (60%) or involved both the SFA and popliteal artery (32%). Balloon lengths varied, with the majority using 80 mm and 100 mm balloons (each at 36%), and the preferred balloon diameter was 5 mm (56%). Additionally, directional atherectomy was performed in 40% of cases, and sheath sizes of 6F and 7F were used in nearly equal proportions. The data highlights a tailored approach based on lesion length, severity, and location **table II**

TableII: Angiographic Characteristics for the study Group

Variable Angiographic Characteristics	Study group (n = 25)	95% CI for study group
Length of Stenosis (cm)		
Median (IQR)	10 (7 – 26)	
Directional Atherectomy	10 (40.0%)	21.9% – 61.3%
Lesion Characteristic (Occlusion)		
Partial (>70% stenosis)	7 (28.0%)	12.1% – 49.4%
Total occlusion	18 (72.0%)	50.6% – 87.9%
Localization		
Distal SFA	0 (0.0%)	0.0% – 13.7%
Mid SFA	0 (0.0%)	0.0% – 13.7%
Proximal SFA	15 (60.0%)	40.8% – 76.9%
SFA	2 (8.0%)	2.2% – 25.0%
SFA + POPL	8 (32.0%)	17.9% – 50.9%
Length of Balloon (mm)		
40.0	0 (0.0%)	0.0% – 13.7%
60.0	0 (0.0%)	0.0% – 13.7%
80.0	9 (36.0%)	20.2% – 55.5%
100.0	9 (36.0%)	20.2% – 55.5%
150.0	7 (28.0%)	14.1% – 47.6%
Diameter of Balloon (mm)		
≤ 4	5 (20.0%)	8.6% – 39.1%

5	14 (56.0%)	37.9% – 73.0%
≥ 6	6 (24.0%)	11.0% – 44.5%
Sheath		
6F	13 (52.0%)	32.9% – 70.1%
7F	12 (48.0%)	29.9% – 67.1%
Microcatheter alone	10 (40.0%)	21.9% – 61.3%

the complications observed in the retrograde approach. Complications such as bleeding, embolism, and hematoma occurred at relatively low rates, with only one case of bleeding (4%) and embolism (4%), and two cases of hematoma (8%). The confidence intervals indicate a low likelihood of severe complications associated with this approach, suggesting that the retrograde technique is relatively safe for patient's **table III**

Table III: post operative Complications of the study group

Complication	No. of Cases	%	95% CI
Bleeding	**1**	**4.0**	**0.0–13.7%**
Embolism	**1**	**4.0**	**0.1–20.4%**
Hematoma	**2**	**8.0**	**0.1–20.4%**

demonstrates the improvement in the Ankle-Brachial Index (ABI) pre- and post-intervention in study group. The mean ABI increased from 0.74 pre-intervention to 0.84 post-intervention, with a significant p-value (<0.001) for the improvement. This increase in ABI reflects an enhanced blood flow and suggests that the retrograde approach effectively addresses ischemic symptoms in these patients. The broad range and confidence intervals indicate variability in patient response, but the overall improvement underscores the retrograde approach's effectiveness in improving vascular outcomes. **Table IV**

Table IV: Ankle-Brachial Index of the study group

Ankle-Brachial Index	Range	Mean ± SD	95% CI for Mean	p (Pre-intervention)
Pre-intervention	**0.3 – 1.1**	**0.74 ± 0.24**	**0.60–0.88**	**<0.001***
Post-intervention	**0.4 – 1.3**	**0.84 ± 0.26**	**0.70–0.98**	

DISCUSSION

The retrograde popliteal approach for endovascular therapy (EVT) in the treatment of superficial femoral artery (SFA) and popliteal artery occlusions has been increasingly recognized for its safety and reliability. However, there remains a lack of substantial evidence comparing long-term outcomes specifically for retrograde EVT procedures in this patient population. This study contributes valuable insights by evaluating the retrograde approach's efficacy and associated outcomes.

In our study, demographic characteristics, including gender and age, as well as comorbidities like diabetes, hyperlipidemia, coronary artery disease (CAD), and smoking status, showed no significant differences within the retrograde group, supporting the generalizability of these findings to a broader patient population. Khalil and Ozcan, 6 similarly found no significant variation in demographics or comorbidities, highlighting consistency across studies in terms of baseline patient characteristics in the retrograde technique. Giusca et al. 8 also reported that age, gender, and prevalence of comorbid conditions did not significantly differ in retrograde cases, further supporting our findings. Also, Farhan et al.14 analyzed of individual patient data from all randomized controlled trials comparing EVT vs BSx and found that baseline characteristics were comparable between groups.

In the current study, common comorbidities included hypertension (68%), coronary artery disease (52%), and diabetes mellitus (40%), reflecting a population with significant cardiovascular risk factors. Additionally, 40% were smokers, which may further contribute to peripheral arterial disease. Chronic renal failure and COPD were less prevalent, each affecting 12%. This was in accordance with Soga et al.12 who detected hypertension in 90% of patients, Dislipidemia in 46%, and Diabetes in 55%, and 15% were current smoker; which is lower than us.

Angiographic characteristics associated with the retrograde approach, particularly regarding lesion characteristics, localization, and intervention techniques. Patients undergoing retrograde EVT were more likely to require directional atherectomy and presented with a higher incidence of mid-to-distal SFA lesions. Consistent with our findings, Khalil and Ozcan observed that patients in the retrograde group exhibited more complete occlusions and were more likely to have mid and distal lesions, suggesting that the retrograde approach is particularly suitable for more complex and distal lesions. Donbaloglu et al.7 similar results, with the retrograde group showing a significant prevalence of SFA and femoropopliteal artery occlusions compared to popliteal artery lesions.

Angiographic approach was further supported by Iida et al.,13 who demonstrated that a novel angiographic score for 12-month restenosis after femoro-popliteal endovascular therapy in a real-world clinical practice.

Regarding procedural our study demonstrated that the primary patency rates post-intervention was robust within the retrograde group, with no significant difference in pre- and post-intervention Ankle-Brachial Index (ABI), reflecting the retrograde approach's efficacy in restoring blood flow and maintaining patency. Khalil and Ozcan.6 similarly found improved ABI values in the retrograde group, underscoring its effectiveness in enhancing limb perfusion. Donbaloglu et al. 7 also reported CABI improvements and patency rates at one year, affirming the retrograde approach's utility in achieving favorable vascular outcomes.

Complication rates in our study, such as embolism, and hematoma, did not differ significantly, which aligns with the findings of Khalil and Ozcan, who reported similar incidence rates of these complications in the retrograde group. Additionally, Donbaloglu et al.7 observed low complies, with minimal occurrences of hematoma and distal embolization, supporting the retrograde approach's safety profile. Giusca et al. 8 further noted a low rate of complications retrograde puncture, with any complications (such as hematoma or pseudoaneurysm) being conservatively managed, suggesting a relatively low risk of adverse events when using the retrograde route. Farhan et al.14 found no significant differences between patients who received EVT and those who received bypass surgery regarding major adverse limb events.

Additionally, Lam et al.10 case highlights that popliteal retrograde approach is effective and safe for total occlusion of superficial femoral artery. Other study confirmed our study aim and results and concluded that Initial and long-term outcomes of endovascular therapy for chronic total occlusion in iliac and femoropopliteal arteries using the microcatheter-based retrograde approach are promising11.

RECOMMENDATIONS AND LIMITATIONS

It's important to note that these findings are based on the information provided and the specific statistical tests conducted. Additional context and details about the study design, sample size, statistical methods used, and other relevant factors would be necessary to fully interpret the results. Further studies in multiple centers with larger sample size will be important to emphasize our conclusion.

CONCLUSIONS

The retrograde approach in endovascular treatment (EVT) of femoropopliteal stenosis and occlusion appears to be a safe and effective technique, with favorable patency rates and manageable complication risks. However, while the retrograde route provides promising results, definitive conclusions on its superiority are limited due to patient and lesion variability. Further randomized, prospective studies focused specifically on retrograde EVT are needed to establish clearer guidelines and optimize treatment strategies for femoropopliteal disease.

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