Original Article
Effectiveness of intra-arterial manometry in guiding femoral popliteal stent implantation: a prospective randomized controlled trial

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Abstract: Background: Femoropopliteal artery occlusion is a prevalent peripheral arterial disease, and endovascular therapy has become the preferred treatment. Accurate assessment of balloon dilation efficacy is crucial for determining the necessity for subsequent stent implantation. This study aims to investigate the use of interlesion arterial pressure gradients as a novel approach to assess balloon dilation efficacy and guide stent implantation decisions. Methods: A prospective, randomized, controlled trial was conducted on 100 patients with femoropopliteal artery occlusion. Patients were randomized into a control group (n=50) and an experimental group (n=50). Stent implantation was performed in the control group according to standard indications, while the experimental group underwent stent implantation only if the mean arterial pressure gradient exceeded 10 mmHg or fractional flow reserve (FFR) fell below 0.85. Post-intervention, pressure measurements and angiography were used to evaluate residual stenosis, dissection, and pressure gradients. Results: Lesions were categorized into stent-indicated and non-indicated groups. In the non-stent-indicated lesions, the experimental group demonstrated significantly higher patency rates for lesions with pFFR < 0.85 or ΔP > 10 mmHg compared to the control group (92.9% vs. 50.0%, P=0.039). There was no significant difference in patency rates between the experimental and control groups for stent-indicated lesions. Conclusion: Combining pressure measurement with angiography provides a more precise evaluation of balloon dilation efficacy and stent implantation indicators in femoropopliteal artery occlusive disease. Further research is needed to establish optimal pressure threshold values and refine treatment guidelines.

Keywords: Femoropopliteal artery occlusion, peripheral arterial disease, endovascular therapy, balloon dilation efficacy, stent implantation, interlesion arterial pressure gradients

Introduction

Peripheral arterial disease (PAD) is a condition characterized by atherosclerotic disease affecting the arteries of the lower extremities [1]. Among PAD patients, femoropopliteal artery occlusion is the most prevalent site, leading to clinical symptoms such as intermittent claudication, rest pain, and limb ulcers [2]. In recent years, endovascular therapy has become the preferred treatment modality for femoropopliteal lesions, surpassing traditional surgical interventions [3]. This approach involves balloon angioplasty and stent implantation [4-6].

Balloon angioplasty, also known as percutaneous transluminal angioplasty (PTA), aims to re-

store blood flow by mechanically rupturing the arterial intima, reshaping the vessel, and compressing atherosclerotic plaques into the arterial wall. However, it has limitations, including early vessel closure, plaque dislodgment, vascular recoil, and constriction-induced remodeling, leading to the potential for late re-stenosis [4]. Stent implantation has emerged as a solution to overcome these limitations by addressing early vascular elastic recoil, residual stenosis, and dissection incurred during balloon dilation [4-6].

One of the main challenges in femoropopliteal stent implantation is the complex morphologic changes that the artery undergoes during lower limb motion, leading to stent fractures and nar-

rowing. These changes are caused by axial shortening, bending, and torsion resulting from positional changes [7, 8]. Current guidelines recommend selective stent placement for non-long-segment femoropopliteal lesions [9-11]. However, ongoing debates persist regarding the optimal selection criteria.

The evaluation of plain balloon dilation efficacy typically relies on two-dimensional imaging post-angiography, which assesses the degree of restriction, residual stenosis, and dissection classification [12]. However, this approach may result in assessment errors, particularly for critical lesions, and the results can vary due to differences in individual technique and experience. In contrast, direct arterial pressure measurement stands as the gold standard for determining the hemodynamic significance of lesions [13]. Some medical centers use an interlesion pressure gradient threshold of > 10 mmHg as an indicator of poor hemodynamics following revascularization [14], while others employ peripheral flow reserve scores for evaluation [15].

Several previous studies have explored the use of pressure measurement for assessing treatment efficacy in endovascular interventions for femoropopliteal artery occlusion. For instance, Tepe et al. conducted a study evaluating the correlation between intraoperative pressure measurements and clinical outcomes, unveiling a significant association between pressure gradients and long-term patency rates [16]. Similarly, Antusevas et al. conducted a prospective study comparing pressure measurements with angiographic parameters in patients undergoing stent implantation and reported that pressure gradients provided additional information regarding the hemodynamic significance of lesions beyond angiography alone [17]. Despite the advantages of pressure measurement, there is still a lack of consensus on the optimal pressure thresholds for determining the necessity for stent implantation. Moreover, there is a need for larger-scale studies to validate the findings and establish standardized evaluation criteria. These limitations highlight the need for further research to overcome these challenges and establish more robust and standardized approaches for pressure measurement in femoropopliteal artery intervention.

Therefore, the present study aims to address the limitations of previous research and investigate the effectiveness of intra-arterial manometry in guiding femoral-popliteal stent implantation through a prospective randomized controlled trial. By comparing the clinical outcomes of endovascular treatment assessment based on arterial angiography with those based on arterial pressure measurements, this study seeks to provide a more accurate evaluation of treatment outcome and refine the selection criteria for stent implantation. The novelty of this study lies in its comprehensive evaluation of treatment outcomes by incorporating arterial pressure measurement as an adjunct to angiography. This approach should enhance the precision and objectivity of treatment evaluation, particularly in determining stent implantation indications. By elucidating the correlation between residual stenosis rates and arterial pressure, this study endeavors to augment to the existing body of knowledge in the field of endovascular therapy for femoropopliteal artery occlusion.

Data and methods

Study design

This study was conducted at the Second Affiliated Hospital of Wenzhou Medical University from January 2021 to December 2022. A total of 100 patients diagnosed with femoropopliteal artery atherosclerotic occlusion underwent endovascular treatment as part of a prospective, randomized, controlled trial. The trial is still ongoing. Patients meeting the criteria were randomly allocated into a control group (n=50) and an experimental group (n=50). All patients underwent balloon angioplasty and subsequently had repeat angiography post-surgery. Catheter measurements of proximal and distal pressures at the lesion site were taken, recording residual stenosis rates, dissection, and pressure gradients for each lesion.

Based on angiography results, cases with residual stenosis rates > 30% or exhibiting flow-limiting dissections were deemed suitable for stent implantation. Patients in the control group meeting the criteria underwent immediate stent placement, whereas those in the experimental group only received stent implanta-

tion when the average arterial pressure gradient was > 10 mmHg or FFR was < 0.85. Randomization was generated by a computer-generated list, with results disclosed only post-conventional balloon angioplasty by an assistant, informing the operating surgeon and the patient or their family.

The study was approved by the hospital ethics committee. Prior to participating in the study, all patients provided written informed consent. The informed consent process included a clear explanation of the study purpose, procedures, potential risks and benefits, confidentiality, and the voluntary nature of participation. Patients were given adequate time to review the consent form, ask questions, and make an informed decision about their participation. To ensure allocation concealment, the study employed a centralized randomization process. A computer-generated randomization system assigned participants to their respective treatment groups. The allocation sequence was concealed from the investigators involved in patient recruitment and assessment, thereby preventing potential selection bias.

Inclusion and exclusion criteria

Inclusion criteria: (1) Age between 18 and 85 years. (2) Confirmed diagnosis of lower limb arterial occlusive disease, TASC grade A-C. (TASC Grade A: Minimal or early-stage occlusive disease in the lower limb arteries, typically involving a single or few short-segment stenoses (narrowing) or occlusions (blockages) in the arteries. Blood flow to the affected area is mildly affected, with minimal or absent symptoms. TASC Grade B: Moderate disease in the lower limb arteries characterized by longer segment stenoses or occlusions, affecting multiple arteries or branches. Blood flow to the affected area is moderately compromised, resulting in intermittent claudication (pain or cramping during physical activity) or other symptoms. TASC Grade C: Severe or extensive disease in the lower limb arteries, involving long-segment stenoses or occlusions, often affecting multiple major arteries. Blood flow to the affected area is significantly reduced, leading to severe symptoms such as rest pain, non-healing wounds or ulcers, and even tissue loss (gangrene)). (3) Severe stenosis (≥70%) or occlusion in the superficial femoral artery and/

or popliteal artery P1 segment. (4) Signed informed consent.

Exclusion criteria: (1) Plasma creatinine level > 150 umol/L. (2) Thrombotic lesions requiring thrombolysis or thrombectomy. (3) More than two target lesions requiring treatment in the target vessel. (4) Lower limb arterial surgery or thrombolytic therapy within the past six weeks. (5) Less than one viable outflow vessel. (6) Pregnancy or lactation. (7) Participation in other clinical trials. (8) Expected lifespan of less than 12 months. (9) Other conditions deemed unsuitable for trial participation by the investigators.

The study flowchart is shown in **Figure 1**.

Endovascular treatment procedure

Upon admission, all patients underwent medical history collection, physical examination, routine blood tests, and relevant auxiliary examinations. Lower limb color Doppler ultrasound and lower limb arterial CTA examinations were conducted to evaluate the extent of arterial occlusion. The Rutherford classification was employed to grade the severity of ischemic symptoms. All patients underwent interventional angiography or treatment. A standard femoral puncture was performed to establish vascular access, identifying luminal lesions and determining the TASC classification. Balloon angioplasty was carried out at the lesion site, followed by repeat angiography to record residual stenosis rates and dissection and measure pressures at the lesion's proximal and distal ends. Treatment plans were selected according to the trial design. The specific intraluminal pressure measurement method was as follows: After identifying the target lesion, a guidewire was first passed through the lesion, positioned in the distal portion, and the catheter was then replaced with a 5F single-curve catheter, and the wire was withdrawn. The single-curve catheter was adjusted to position its tip at the distal target location of the lesion. After flushing with heparin saline to remove air, pressure measurement was conducted by connecting a pressure gauge. Three readings were taken after stabilization of values. Pressure measurement was initially performed at the distal end of the lesion, followed by withdrawing the catheter tip to the proximal
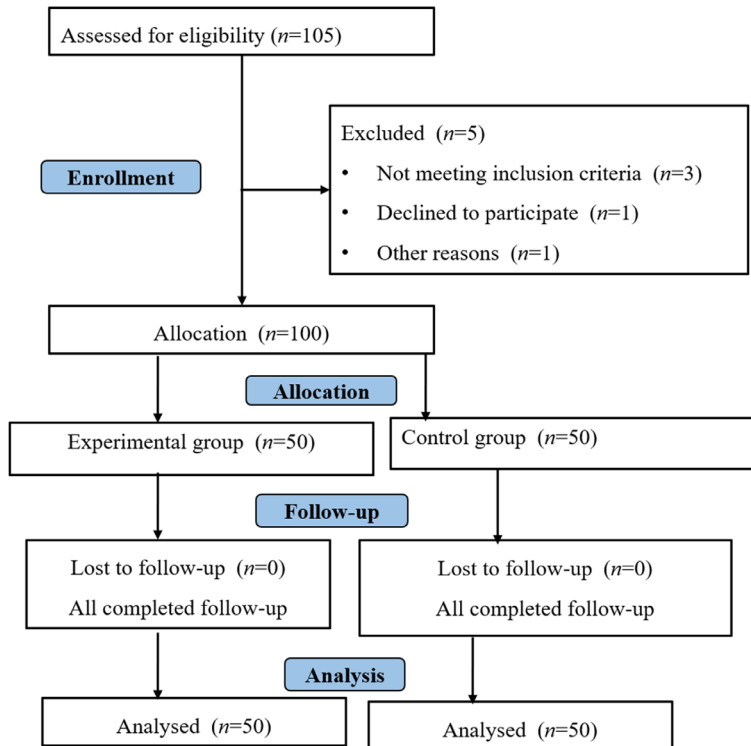
Figure 1. Study flowchart.

target position for proximal pressure measurement. The pressure gradient calculation formula: Pressure Gradient = Proximal Pressure - Distal Pressure (measured in mmHg). Postoperatively, patients received standard care for endovascular treatment. Subsequent lower limb CTA examinations were performed to assess lesion treatment efficacy and vascular patency [18].

Outcome measures

Primary outcome: The primary outcome measure for this study was the 1-year patency rate of the target lesions. Patients were classified into two groups based on the need for stent placement: the No-Stent Group and the Stent Group. In the No-Stent Group, the primary outcome was assessed in two scenarios: lesions with pFFR > 0.85 and/or ΔP < 10 mmHg, and lesions with pFFR < 0.85 and/or ΔP > 10 mmHg. The primary patency rates were compared between the control and experimental groups within each scenario.

Secondary outcome: The secondary outcome measure was the correlation analysis between residual stenosis and pFFR. A linear fit analysis

was performed to evaluate the linear relationship between these two variables. The correlation analysis aimed to determine the strength and significance of the correlation between residual stenosis and pFFR.

Statistical methods

Sample size was pre-calculated with the alpha level set at 0.05, an anticipated effect size (Cohen's *d*) of 0.5 and a desired statistical power level of 0.8. The required sample size per group was determined to be 50. Shapiro-Wilk test was used to test the normality of the distribution of the quantitative variables. For normally distributed variables, the data were presented as mean ± standard deviation (x ± sd); For non-normally distributed variables, the data were presented in the form of median and interquartile range, the Mann-Whitney U rank sum test was used to compare continuous variables between the control cohort and the experimental cohort. The classification variables between the two queues were compared using the Pearson chi-square test or the Fisher exact test, as appropriate. The Kaplan Meier product was used to calculate and compare 1-year patency rates between subgroups in the control and experimental groups. Differences between unadjusted curves were tested by the log-rank test. All statistical analyzes were performed using SPSS25.0, with a significance level set at P < 0.05.

Results

Baseline clinical characteristics

Following the inclusion criteria, 100 elderly patients, predominantly male, were enrolled. Both groups exhibited a normal range of body mass index (BMI), with some having hypertension (84%), diabetes (31%), or a history of smoking (32%). Upon admission, Rutherford and TASC classifications were conducted, showing similar distributions in both groups (**Table 1**).

Table 1. Comparison of basic characteristics between the two groups

	Control group (n=50)	Experimental group (n=50)	p-value
Age (y), median (IQR)	75 (70, 79)	71 (67, 76)	0.198
Men	36 (72.0%)	40 (80.0%)	0.349
BMI (kg/m^2), median (IQR)	22.4 (20.4, 24.2)	22.9 (19.9, 25.1)	0.440
Hypertension, n (%)	40 (80.0%)	44 (88.0%)	0.275
Diabetes mellitus, n (%)	14 (28.0%)	17 (34.0%)	0.517
Hyperlipidemia, n (%)	4 (8.0%)	4 (8.0%)	1.000
Cerebrovascular disease, n (%)	10 (20.0%)	12 (24.0%)	0.629
Coronary artery disease, n (%)	4 (8.0%)	6 (12.0%)	0.505
Current Smoker, n (%)	20 (40.0%)	12 (24.0%)	0.086
Rutherford classification, n (%)			0.825
I (1-3)	18 (36.0%)	20 (40.0%)	
II (4)	14 (28.0%)	10 (20.0%)	
III (5)	5 (10.0%)	6 (12.0%)	
IV (6)	13 (26.0%)	14 (28.0%)	
TASC category, n (%)			0.404
A	6 (12.0%)	11 (22.0%)	
B	25 (50.0%)	23 (46.0%)	
C	19 (38.0%)	16 (32.0%)	
Lesion length	99.9±41.0	96.6±41.5	0.321
Residual stenosis (post-PTA) (%), mean (± SD)	83.0±12.0	82.5±12.8	0.981
Pressure gradient, mean (± SD)	43.62±10.21	42.83±10.95	0.782
Resting pressure ratio	0.64±0.12	0.67±0.14	0.211

Treatment outcomes

Based on angiographic assessments (residual stenosis > 30% and/or dissections classified as C-type or above), the patients were categorized into a No-Stent Group, consisting of patients who did not require stent placement, and a Stent Group, including patients who required stent placement.

In the No-Stent Group, the Control Group had 10 cases (10/18) of lesions with pFFR > 0.85 and/or ΔP < 10 mmHg, while the Experimental Group had 12 cases (12/26). The 1-year patency rates of Control and Experimental groups were 70.0% and 83.3%, respectively, with no significant difference observed (P= 0.624). However, for lesions with pFFR < 0.85 and/or ΔP > 10 mmHg, the Experimental Group demonstrated a significantly better 1-year patency rate compared to the Control Group (50.0% vs. 92.9%, P=0.039).

In the Stent Group, the Control Group had 17 cases (17/32) of lesions with pFFR > 0.85 and/or ΔP < 10 mmHg, while the Experimental Group had 15 cases (15/24). The 1-year paten-

cy rates for these groups were 94.1% and 80.0%, respectively, without a significant difference (P=0.319). Similarly, for lesions with pFFR < 0.85 and/or ΔP > 10 mmHg, there was no significant difference in the 1-year patency rate between the Experimental and Control groups (86.7% vs. 100%, P=0.511). These findings are summarized in **Table 2** and **Figure 2**.

The surgical success rate was 100%, with only one case of groin hematoma observed in the Control Group.

Correlation analysis

A linear fit analysis was performed between residual stenosis and pFFR, revealing a strong linear correlation when residual stenosis exceeded 40% (R=0.72, P=0.00017). Further correlation analysis and results can be found in **Figure 3**.

Discussion

Femoropopliteal artery (FPA) interventions pose a significant challenge due to the high risk of restenosis or re-occlusion, stemming from the

Table 2. Outcome

No indication for stent placement						
	Control group (n)	1-year patency, n (%)	Experimental group (n)	1-year patency, n (%)	p-value	
	18	11 (61.1%)	26	23 (88.5%)	0.033	
	No stent placement (n)		No stent placement (n)			
FFR > 0.85 and/or ΔP < 10 mmHg	10	7 (70.0%)	12	10 (83.3%)	0.624	
	No stent placement (n)		No stent placement (n)			
FFR < 0.85 and/or ΔP > 10 mmHg	8	4 (50.0%)	14	13 (92.9%)	0.039	
Stent-appropriate						
	Control group (n)	1-year patency, n (%)	Experimental group (n)	1-year patency, n (%)	p-value	
	32	29 (90.6%)	24	21 (87.5%)	1.000	
	Stent placement (n)		Stent placement (n)			
FFR > 0.85 and/or ΔP < 10 mmHg	17	16 (94.1%)	15	12 (80.0%)	0.319	
	Stent placement (n)		Stent placement (n)			
FFR < 0.85 and/or ΔP > 10 mmHg	15	13 (86.7%)	9	9 (100.0%)	0.511	

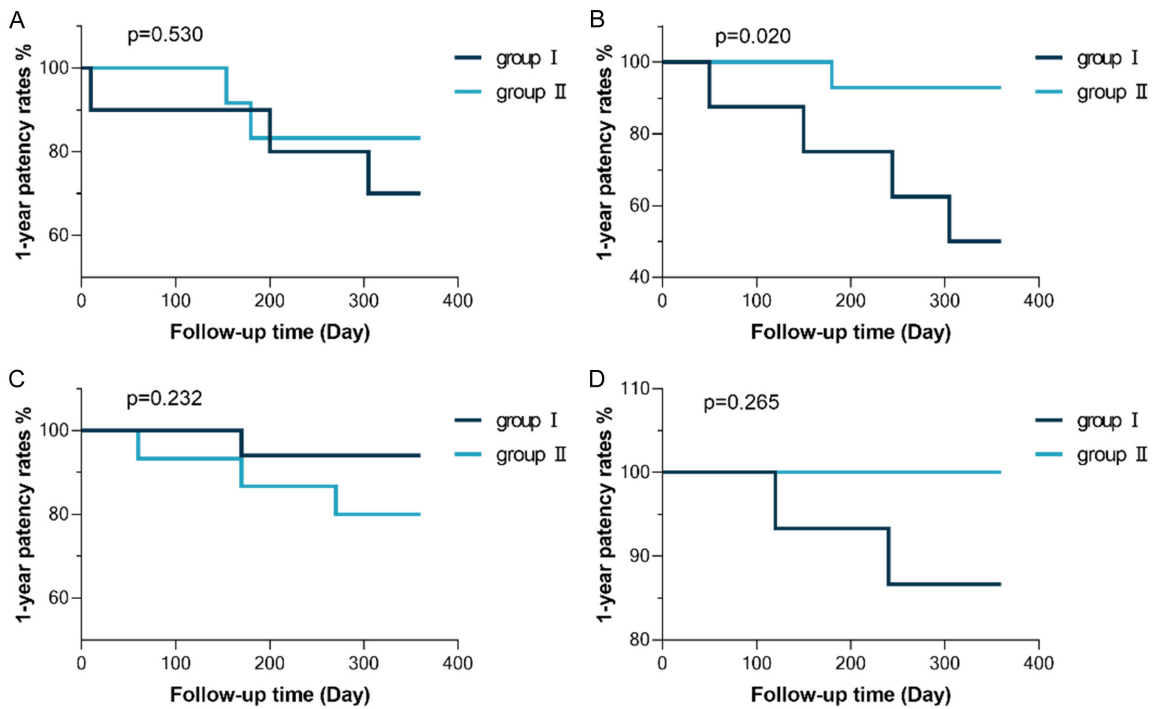**Figure 2.** Kaplan-Meier curve demonstrating the 1-year primary patency rates. A. No-Stent Group with pFFR > 0.85 and/or ΔP < 10 mmHg. B. No-Stent Group with pFFR < 0.85 and/or ΔP > 10 mmHg. C. Stent Group with pFFR > 0.85 and/or ΔP < 10 mmHg. D. pFFR < 0.85 and/or ΔP > 10 mmHg.

unique anatomic structure and complex disease characteristics of this artery. The selection between simple balloon angioplasty and stent placement as the optimal endovascular treatment for femoropopliteal occlusive disease remains uncertain, emphasizing the necessity of identifying the most durable and cost-effective approach.

In this study, both angiography and pressure measurements were conducted on the control and experimental cohorts, with one cohort randomly assigned as the indication for stent implantation. Among the subgroup that did not require stents, lesions with a peripheral fractional flow reserve (pFFR) of > 0.85 and/or a pressure gradient (Δp) of < 10 mmHg demonstrated high patency rates in both the Control and Experimental groups (70.0% vs. 88.5%, P=0.624). Importantly, these rates were significantly higher than those reported in other randomized trials with similar cohorts [16, 17],
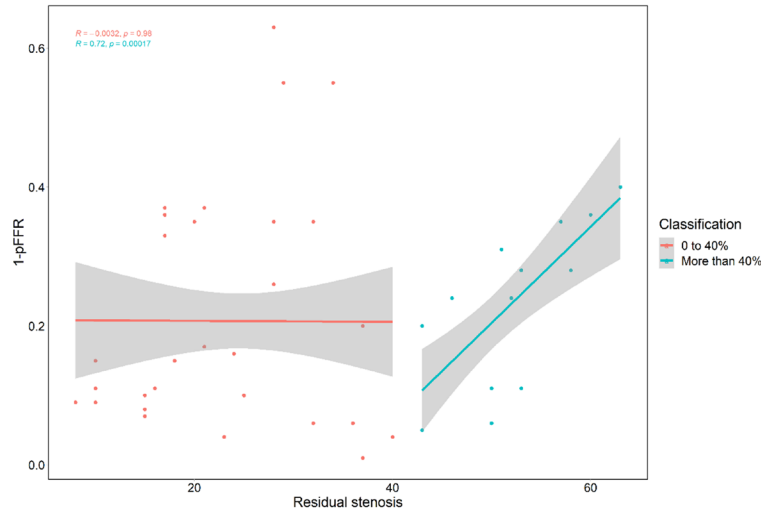
Figure 3. Linear fit graph of residual stenosis and 1-pFFR, indicating a strong linear correlation when residual stenosis is > 40% (R=0.72, P=0.00017).

where the 1-year patency rates following balloon angioplasty ranged from 42% to 52.4%. Conversely, lesions with a pFFR of < 0.85 and/or a Δp of > 10 mmHg exhibited poorer patency in the Control Group compared to the Experimental Group (50.0% vs. 92.9%, P=0.039). This suggests that relying solely on angiography-guided assessments may result in inadequate treatment, while the inclusion of pressure measurements helps to avoid missed stent placements.

Within the subgroup that required stents, lesions in the Experimental Group with a pFFR of > 0.85 and/or a Δp of < 10 mmHg showed patency rates comparable to the Control Group with stent implantation (80.0% vs. 94.1%, P=0.319). This finding aligns closely with the reported stent patency of 72.6% and aids in identifying cases where stent placement was initially overlooked (54%) or where unnecessary stenting occurred (60%). These results highlight the role of pressure measurements in predicting post-angioplasty restenosis, which aligns with the development trend of adopting an "As Less As Reasonably Achievable Stenting" (ALARAS) strategy in femoropopliteal endovascular treatment.

Although the conventional reliance on angiographic images to evaluate post-endovascular treatment vascular hemodynamics is prevalent, this study identified 44 lesions (44/100) with residual stenosis < 30% or no dissections above the C-type on angiography, yet pressure measurements revealed hemodynamic complications in 22 lesions (22/44). Two-dimensional angiography provides evidence of vessel diameter narrowing; however, in complex narrowing (e.g., spirals), angiography offers limited morphological information and lacks quantitative evaluation [18]. By incorporating residual stenosis and pFFR, it was observed that the correlation between residual stenosis and pFFR was not consistently strict, particularly when residual stenosis was ≤ 40%, indicating varying hemodynamic changes in different lesions. A linear relationship between stenosis and pFFR was evident only when residual stenosis was > 40%. Thus, the concept of critical stenosis emerges following femoropopliteal arterial revascularization. Previous studies [19, 20] have established a relationship between critical hemodynamic changes in iliac arteries and 50% luminal narrowing. Subsequent research [21] utilizing single-sensor 5F or 4F catheters measured pressure gradients in 20 arterial narrowings, including renal, iliac, subclavian, and aortic arteries, predicting a pressure gradient of 10 mmHg with catheter measurements correlating to 50% arterial diameter narrowing. The Dutch Iliac Stent Trial (DIST) [22-24] also employed 5F dual-sensor catheters to measure a pressure gradient > 10 mmHg as an indicator for stent placement in iliac artery stenosis. However, some studies [18, 25] suggest a pressure gradient > 20 mmHg under congested conditions as a marker for significant hemodynamic change.

The variation in critical values of arterial pressure measurement can be attributed to factors such as sensor variations, catheter sizes, utilization of vasodilators, and arterial diameters. Another assessment index derived from pressure measurements is the fractional flow reserve (FFR), which is extensively used in guiding percutaneous coronary intervention (PCI) treatments for coronary artery disease [26-28]. However, the application of peripheral fractional flow reserve (pFFR) for evaluating peripheral

arterial disease lacks comprehensive data. A study [29] employed a 0.014-inch guidewire to inject adenosine into the superficial femoral artery, measuring pFFR in patients with femoropopliteal lesions. The results demonstrated that pFFR can effectively identify hemodynamically significant stenoses and improve the accuracy of treatment selection. This finding is consistent with our observations, which suggest that pFFR and pressure gradient measurements can provide valuable insight into the hemodynamic significance of lesions in femoropopliteal occlusive disease.

The study acknowledges several limitations. One limitation is possible inaccuracies introduced by the selected 5F catheter used for pressure measurements. The physical volume of the catheter could affect the accuracy of pressure measurements. Additionally, there are temporal discrepancies in measuring distal and proximal pressures, which could be addressed by employing dual-sensor catheters. The study also emphasizes that the evaluation of patency using pressure data is limited to one-year follow-up, and longer follow-ups are necessary to assess potential risks associated with extended stent use. Furthermore, the external applicability of the pressure thresholds set in this study may be limited to specific measurement tools and individual cases. Therefore, determining critical pressure thresholds requires larger-scale studies, more precise sample groups, and refined pressure measurement tools.

In conclusion, this study highlights the importance of pressure measurements in guiding the treatment of femoropopliteal occlusive disease. It demonstrates that pressure measurements can help identify missed stent placements and avoid inadequate treatment guided solely by angiography. The study also suggests the existence of a concept of critical stenosis in femoropopliteal arterial revascularization. However, further research is needed to establish consensus on critical pressure thresholds and address the limitations of the study, such as the accuracy of pressure measurement tools and longer-term follow-up.

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Disclosure of conflict of interest

None.

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