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Original Article

Predictors of immediate residual stenosis after standardized balloon angioplasty for superficial femoral artery lesions

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Abstract

Aim: Residual stenosis after superficial femoral artery (SFA) balloon angioplasty may adversely affect immediate procedural success and long-term patency. This study aimed to identify clinical, angiographic, and procedural factors associated with immediate residual stenosis following SFA balloon angioplasty performed according to a standardized balloon inflation protocol.

Material and Methods: This retrospective single-center observational cohort study included 167 consecutive patients who underwent primary SFA balloon angioplasty between January 2024 and April 2026. All procedures were performed using routine predilatation followed by a standardized 2-minute balloon inflation protocol. Residual stenosis ≥ 30% on postprocedural digital subtraction angiography (DSA) was defined as a suboptimal immediate angiographic outcome. Clinical, angiographic, and procedural variables were evaluated, and independent predictors were identified using multivariable logistic regression analysis. Only Trans-Atlantic Inter-Society Consensus II (TASC II) A and B lesions were included.

Results: Residual stenosis ≥ 30% was observed in 70 patients (41.9%). Compared with patients who achieved an optimal angiographic result, those with residual stenosis were older, had a higher prevalence of diabetes mellitus, and exhibited more severe preprocedural stenosis. Lesion length did not differ significantly between patients with residual stenosis < 30% and ≥ 30% (91.3 ± 21.8 mm vs 88.1 ± 20.4 mm; p = 0.333). Multivariable logistic regression demonstrated that increasing age (odds ratio (OR), 1.05; 95% confidence interval (CI), 1.01 – 1.09; p = 0.026), diabetes mellitus (OR, 2.67; 95% CI, 1.27 – 5.59; p = 0.009), and greater preprocedural stenosis severity (OR, 1.11; 95% CI, 1.06 – 1.15; p<0.001) were independently associated with residual stenosis. Lesion length was not an independent predictor (p = 0.344). The final prediction model demonstrated good discriminatory performance (area under the receiver operating characteristic curve (AUC) = 0.80).

Conclusion: Advancing age, diabetes mellitus, and greater preprocedural stenosis severity were independent predictors of residual stenosis after standardized balloon angioplasty for TASC II A-B SFA lesions, whereas lesion length was not. Early identification of patients at increased risk of residual stenosis may facilitate individualized procedural planning and optimize immediate angiographic outcomes.

Keywords: Peripheral arterial disease; angioplasty; stenosis; treatment outcome

INTRODUCTION

Peripheral artery disease (PAD) is a prevalent manifestation of systemic atherosclerosis and is associated with substantial cardiovascular morbidity, functional impairment, and reduced quality of life, particularly in older adults [1]. The femoropopliteal segment is one of the most frequently affected arterial territories in lower-extremity PAD, and endovascular revascularization has become the preferred treatment strategy for appropriately selected superficial femoral artery (SFA) lesions [2].

Plain balloon angioplasty remains an important endovascular treatment option for femoropopliteal disease because of its technical simplicity, widespread availability, and broad applicability. However, residual stenosis after balloon angioplasty remains a clinically important concern, as incomplete acute luminal gain has been associated with restenosis, target lesion revascularization, and reduced long-term vessel patency [3,4].

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Several clinical and lesion-related characteristics have been linked to suboptimal outcomes following femoropopliteal intervention, including advanced age, diabetes mellitus, lesion morphology, arterial calcification, lesion length, and baseline stenosis severity [5]. Additionally, procedural factors, such as lesion preparation techniques and balloon inflation duration, can substantially influence immediate angiographic outcomes in infrainguinal endovascular interventions [6-9]. Recently, our group demonstrated that prolonged balloon inflation improved immediate angiographic outcomes in infrainguinal atherosclerotic lesions, supporting the use of a standardized 2-minute balloon inflation protocol in the present study [5]. Nevertheless, the independent contribution of baseline patient and lesion characteristics remains difficult to establish because procedural variability often confounds the interpretation of angiographic outcomes.

Therefore, the present study aimed to identify the independent clinical and angiographic predictors of immediate residual stenosis following superficial femoral artery balloon angioplasty performed using a standardized procedural protocol. We hypothesized that minimizing procedural variability through routine predilatation and a fixed balloon inflation duration would enable a more accurate assessment of the baseline patient- and lesion-related factors associated with suboptimal immediate angiographic outcomes.

MATERIAL AND METHODS

Study Design and Patient Population

This retrospective, single-center observational cohort study was conducted at Bakırçay University Çiğli Training and Research Hospital between January 2024 and April 2026. A non-probability consecutive sampling strategy was employed, whereby all consecutive eligible patients who underwent primary superficial femoral artery balloon angioplasty for symptomatic peripheral artery disease during the study period were screened for inclusion. The study was conducted and reported in accordance with the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) Statement.

Inclusion Criteria

Patients were eligible for inclusion if they met all of the following criteria:

- Age between 18 and 90 years
- Symptomatic peripheral artery disease involving the superficial femoral artery
- Undergoing isolated primary balloon angioplasty
- Trans-Atlantic Inter-Society Consensus II (TASC II) class A or B lesions
- Availability of complete clinical and angiographic data.

Exclusion criteria

Patients were excluded if they met any of the following criteria:

- Previous endovascular or surgical intervention involving the target lesion
- Acute thrombotic occlusion
- Concomitant stent implantation
- Hybrid revascularization procedures
- Inadequate postprocedural angiographic imaging for residual stenosis assessment
- TASC II class C or D lesions

The study was conducted in accordance with the principles of the Declaration of Helsinki and was approved by the İzmir Bakırçay University Non-Interventional Clinical Research Ethics Committee (Approval No. 3014; Research No. 3002; Approval date: June 3, 2026). Because of the retrospective study design and the use of anonymized clinical data, the Ethics Committee waived the requirement for informed consent.

Endovascular Procedure

Experienced cardiovascular surgeons performed all procedures in a dedicated angiography suite under standard sterile conditions. Vascular access was routinely obtained via ultrasound-guided retrograde popliteal artery puncture using a percutaneous technique, followed by the placement of a 7-F vascular sheath in all patients. This retrograde approach represents the standard institutional strategy for superficial femoral artery interventions at our center. After vascular access was established, systemic anticoagulation was achieved with an intravenous bolus of 5,000 IU of unfractionated heparin.

Lesions were crossed using a 0.035-inch hydrophilic guidewire in combination with a support catheter. Routine predilatation was performed in all lesions to facilitate adequate lesion preparation and optimize subsequent balloon expansion. Balloon diameter was selected according to the reference vessel diameter, whereas balloon length was chosen to ensure complete coverage of the target lesion based on lesion morphology. Balloon inflation was standardized to a duration of 2 minutes for all procedures.

Procedural success was assessed angiographically using digital subtraction angiography (DSA) obtained in at least two orthogonal projections. No planned or bailout stent implantation was performed in any patient included in the study.

Following the procedure, all patients received dual antiplatelet therapy consisting of aspirin (100 mg once daily) and clopidogrel (75 mg once daily) in accordance with our institutional treatment protocol. In the absence of contraindications, dual antiplatelet therapy was continued for at least 12 months. The duration of

treatment could subsequently be individualized at the treating physician's discretion, based on each patient's clinical condition and bleeding risk.

Lesion Assessment and Residual Stenosis Measurement

Residual stenosis was assessed using a North American Symptomatic Carotid Endarterectomy Trial (NASCET)-based angiographic measurement method. The percentage of residual stenosis was calculated by comparing the minimal luminal diameter at the target lesion with the diameter of the adjacent angiographically normal reference vessel on postprocedural DSA obtained in at least two orthogonal projections [10].

All angiographic measurements were performed by a single experienced cardiovascular surgeon who was blinded to the patients' clinical characteristics and procedural outcomes at the time of image analysis. Although a single observer performed measurements, blinding was implemented to minimize the risk of systematic measurement bias.

Residual stenosis ≥ 30% on postprocedural DSA was predefined as the primary study endpoint and was considered to represent a suboptimal immediate angiographic outcome. The < 30% residual stenosis threshold was prespecified for this study to define an optimal immediate angiographic outcome and is more stringent than the < 50% threshold proposed by PARC for angioplasty [11]. Furthermore, previous studies have demonstrated that inadequate postprocedural lumen gain is associated with impaired long-term vessel patency and an increased risk of restenosis [11–13].

For comparative analyses, patients were classified into two groups according to the degree of postprocedural residual stenosis. An optimal angiographic outcome was defined as residual stenosis < 30%, whereas a suboptimal angiographic outcome was defined as residual stenosis ≥ 30%. Because of the retrospective observational design of the study, no randomization or treatment allocation was performed. Instead, patients were categorized according to the predefined primary endpoint based on the degree of residual stenosis measured on postprocedural DSA.

Data Collection

Clinical data were retrospectively extracted from the institutional electronic medical record system, whereas angiographic measurements were obtained from the institutional Picture Archiving and Communication System (PACS). The following variables were collected: age, sex, diabetes mellitus, hypertension, hyperlipidemia, chronic kidney disease, coronary artery disease, smoking status, antiplatelet therapy, anticoagulant therapy, cilostazol use, TASC II lesion classification, lesion length, balloon diameter, balloon length, balloon inflation pressure, preprocedural stenosis severity, and postprocedural residual stenosis.

Because arterial calcification was not routinely or systematically quantified in the institutional database, this variable could not be incorporated into the statistical analyses.

Statistical Analysis

Statistical analyses were performed using IBM SPSS Statistics for Windows, version 26.0 (IBM Corp., Armonk, NY, USA). The distribution of continuous variables was assessed using the Shapiro – Wilk test. Normally distributed continuous variables are presented as mean ± standard deviation (SD) and were compared using the Student's t-test. When the assumption of homogeneity of variances was violated, Welch's t-test was applied. Categorical variables are presented as frequencies and percentages and were compared using the chi-square test.

Univariable logistic regression analysis was initially performed to evaluate the association between each prespecified clinical, angiographic, and procedural variable and the presence of residual stenosis. Variables that were statistically significant in the univariable analysis, together with those considered clinically relevant based on prior evidence, were entered into the multivariable logistic regression model. Given its established clinical relevance in femoropopliteal interventions, lesion length was additionally evaluated in an exploratory multivariable model regardless of its significance in the univariable analysis.

No missing data were identified for the variables included in the regression analyses; therefore, a complete-case analysis was performed. Odds ratios (ORs) with 95% confidence intervals (CIs) were calculated. Model discrimination was evaluated using receiver operating characteristic (ROC) curve analysis, whereas model calibration was assessed using the Hosmer – Lemeshow goodness-of-fit test.

Because this was a retrospective observational study, no a priori sample size calculation was performed. Instead, all consecutive eligible patients who met the predefined inclusion criteria during the study period were included in the analysis. All statistical tests were two-sided, and a p-value <0.05 was considered statistically significant.

RESULTS

A total of 167 patients met the predefined inclusion criteria and were included in the final analysis. Residual stenosis ≥ 30% following balloon angioplasty was observed in 70 patients (41.9%), whereas 97 patients (58.1%) achieved an optimal immediate angiographic outcome. The baseline clinical, angiographic, and procedural characteristics of the study population are summarized in Table 1. The distribution of TASC II lesion classifications was comparable between the two groups (p = 0.281).

Patients with residual stenosis ≥ 30% were significantly older than those with residual stenosis < 30% (67.6 ± 8.7 vs. 64.5 ± 10.0 years, p = 0.037). Diabetes mellitus was also more prevalent in the residual stenosis ≥ 30% group (54.3% vs. 34.0%, p = 0.016). In addition, baseline stenosis severity was significantly greater among patients with residual stenosis ≥ 30% (84.4 ± 7.3% vs. 71.4 ± 15.3%, p < 0.001). In contrast, lesion length did not differ significantly between the two groups (88.1 ± 20.4 mm vs. 91.3 ± 21.8 mm, p = 0.333). Likewise, no significant between-group differences were observed in balloon diameter, balloon length, or inflation pressure (Table 1).

In the univariable logistic regression analysis, increasing age, diabetes mellitus, and greater preprocedural stenosis severity were significantly associated with residual stenosis (Table 2). By contrast, lesion length was not associated with residual stenosis (OR, 0.99; 95% CI, 0.98 – 1.01; p = 0.336). In the multivariable logistic regression model, increasing age, diabetes mellitus, and greater preprocedural stenosis severity remained independent predictors of residual stenosis (Table 3).

To further explore the potential effect of lesion length, this variable was additionally entered into an expanded multivariable model. Lesion length remained non-significant (OR, 0.99; 95% CI, 0.97 – 1.01; p = 0.344) and did not improve the model's discriminatory performance (area under the ROC curve (AUC) = 0.80). The final multivariable model demonstrated good discrimination performance (AUC = 0.80) and adequate calibration, as confirmed by the Hosmer – Lemeshow goodness-of-fit test (p = 0.353).

Table 1. Baseline clinical, angiographic, and procedural characteristics according to residual stenosis status

Variable	Residual stenosis < 30% (n = 97)	Residual stenosis ≥ 30% (n = 70)	p value
Clinical characteristics			
Age, years	64.5 ± 10.0	67.6 ± 8.7	0.037
Male sex, n (%)	81 (83.5)	56 (80.0)	0.705
Diabetes mellitus, n (%)	33 (34.0)	38 (54.3)	0.016
Hypertension, n (%)	44 (45.4)	41 (58.6)	0.126
Hyperlipidemia, n (%)	37 (38.1)	34 (48.6)	0.236
Chronic kidney disease, n (%)	9 (9.3)	5 (7.1)	0.835
Coronary artery disease, n (%)	36 (37.1)	33 (47.1)	0.254
Smoking history, n (%)	76 (78.4)	47 (67.1)	0.149
Preoperative antiplatelet therapy, n (%)	54 (55.7)	47 (67.1)	0.182
Preoperative anticoagulant therapy, n (%)	9 (9.3)	10 (14.3)	0.448
Preoperative cilostazol use, n (%)	13 (13.4)	17 (24.3)	0.123
Angiographic characteristics			
TASC II A lesion, n (%)	45 (46.4)	26 (37.1)	0.281
TASC II B lesion, n (%)	52 (53.6)	44 (62.9)	0.281
Lesion length, mm	91.3 ± 21.8	88.1 ± 20.4	0.333
Preprocedural stenosis severity, %	71.4 ± 15.3	84.4 ± 7.3	< 0.001
Procedural characteristics			
Balloon diameter, mm	5.7 ± 0.6	5.6 ± 0.9	0.498
Balloon length, mm	114.4 ± 24.0	112.4 ± 21.0	0.567
Inflation pressure, atm	9.1 ± 1.0	8.9 ± 1.0	0.392

Abbreviations: TASC, Trans-Atlantic Inter-Society Consensus.

Table 2. Univariate logistic regression analysis for predictors of residual stenosis

Variable	Odds ratio (OR)	95% confidence interval	p value
Age (per year)	1.04	1.00 – 1.07	0.043
Male sex	0.79	0.36 – 1.75	0.561
Diabetes mellitus	2.30	1.23 – 4.33	0.010
Hypertension	1.70	0.91 – 3.17	0.093
Hyperlipidemia	1.53	0.82 – 2.85	0.180
Chronic kidney disease	0.75	0.24 – 2.35	0.624
Coronary artery disease	1.51	0.81 – 2.82	0.195
Smoking history	0.56	0.28 – 1.13	0.107
Preoperative antiplatelet therapy	1.63	0.86 – 3.09	0.136
Preoperative anticoagulant therapy	1.63	0.62 – 4.25	0.318
Preoperative cilostazol use	2.07	0.93 – 4.61	0.074
Lesion length (per mm)	0.99	0.98 – 1.01	0.336
Preprocedural stenosis severity (per 1%)	1.10	1.06 – 1.14	<0.001
Balloon diameter (per mm)	0.86	0.57 – 1.30	0.467
Balloon length (per mm)	1.00	0.98 – 1.01	0.573
Inflation pressure (per atm)	0.87	0.63 – 1.20	0.389

Table 3. Multivariable logistic regression analysis for predictors of residual stenosis

Variable	Odds ratio (OR)	95% confidence interval	p value
Age (per year)	1.05	1.01 – 1.09	0.026
Diabetes mellitus	2.67	1.27 – 5.59	0.009
Preprocedural stenosis severity (per 1%)	1.11	1.06 – 1.15	< 0.001

AUC = 0.80; Hosmer-Lemeshow goodness-of-fit p-value = 0.353.

DISCUSSION

The present study evaluated the clinical and angiographic predictors of residual stenosis following superficial femoral artery balloon angioplasty performed under a highly standardized procedural protocol that incorporated routine predilatation and a fixed 2-minute balloon inflation duration. The principal findings were threefold. First, advancing age, diabetes mellitus, and greater preprocedural stenosis severity were independently associated with residual stenosis. Second, lesion length was not independently associated with the immediate angiographic outcome. Third, by minimizing procedural variability and restricting the analysis to TASC II A – B lesions, the present study provides a more reliable assessment of baseline patient- and lesion-related factors influencing immediate procedural success. Importantly, these findings should be interpreted as determinants of the immediate angiographic outcome rather than predictors of long-term vessel patency or clinical durability.

Residual stenosis remains clinically relevant because inadequate acute luminal gain has been associated with restenosis, target lesion revascularization, and reduced long-term vessel patency. Secemsky et al. demonstrated that suboptimal angiographic results following femoropopliteal intervention were associated with less favorable clinical outcomes, underscoring the importance of achieving optimal luminal expansion during the index procedure [3]. Consequently, identifying patients at increased risk of residual stenosis before intervention may facilitate procedural planning and improve immediate technical success.

Advancing age was independently associated with residual stenosis. Age-related arterial stiffening, progressive vascular remodeling, and reduced arterial compliance may limit acute vessel expansion during balloon angioplasty. Previous studies have reported similar associations between increasing age and less favorable outcomes following femoropopliteal endovascular intervention [4], supporting the biological plausibility of our findings.

Diabetes mellitus was independently associated with residual stenosis, increasing the likelihood of a suboptimal angiographic outcome by nearly threefold. Diabetes is associated with diffuse atherosclerosis, medial arterial calcification, endothelial dysfunction, and impaired vascular compliance, all of which may reduce the mechanical response of the arterial wall to balloon dilation. Previous studies have consistently demonstrated inferior endovascular outcomes among patients with diabetes undergoing femoropopliteal interventions [4]. Our findings extend these observations by suggesting that diabetes adversely affects not only long-term vessel patency but also the immediate angiographic response to balloon angioplasty.

Among all evaluated variables, preprocedural stenosis severity showed the strongest independent association with residual stenosis. Greater baseline stenosis severity was associated with a significantly higher likelihood of a suboptimal angiographic outcome. This observation suggests that more severe baseline luminal narrowing may limit the degree of acute luminal expansion achievable with balloon angioplasty alone, even when procedural factors are carefully standardized. These findings are consistent with contemporary evidence emphasizing the importance of procedural lumen gain. Horie et al. demonstrated that a larger postprocedural minimum lumen area was independently associated with a lower risk of restenosis following drug-coated balloon treatment [13]. Likewise, Shima et al. reported that greater postprocedural luminal expansion predicted superior primary patency after femoropopliteal intervention [14]. Collectively, these findings support the concept that optimal immediate procedural results are important determinants of long-term vascular durability.

Lesion length was not independently associated with residual stenosis despite its well-established relationship with restenosis and long-term patency. This finding suggests that lesion length may have a greater influence on biological healing and late vessel remodeling than on the immediate mechanical response to balloon inflation. These findings suggest that baseline lesion severity and intrinsic plaque characteristics may be more important determinants of acute luminal gain than lesion extent itself.

The present findings should also be interpreted in the context of advances in intravascular imaging. Rutten et al. demonstrated that intravascular ultrasound (IVUS) and optical coherence tomography (OCT) frequently identify calcification, residual stenosis, dissections, and vessel dimensions that may be underestimated by angiography alone [15]. Consequently, angiography-based assessment may not fully characterize the anatomical factors contributing to suboptimal balloon expansion. Future studies integrating systematic calcification grading with intravascular imaging are warranted to provide a more comprehensive understanding of the mechanisms underlying residual stenosis.

From a clinical perspective, the present findings may facilitate preprocedural risk stratification. Older patients, those with diabetes mellitus, or those presenting with more severe baseline stenosis may be less likely to achieve optimal angiographic results with plain balloon angioplasty alone. In such patients, adjunctive lesion-preparation techniques, plaque-modifying technologies, or intravascular imaging-guided strategies may be considered to optimize acute procedural success [15,16].

The good discriminatory performance of the multivariable model (AUC = 0.80) suggests that these readily available clinical and angiographic variables may have practical value for procedural risk assessment. Nevertheless, prospective multicenter studies incorporating systematic calcification grading, intravascular imaging, and long-term follow-up are needed to validate these findings and determine whether individualized procedural strategies based on these predictors translate into improved long-term clinical outcomes [15,16].

Limitations

Several limitations of this study should be acknowledged. First, the retrospective, single-center design may have introduced selection bias and limits the generalizability of the findings. Second, no a priori sample size calculation was performed because of the retrospective nature of the study. Although the study population was adequate for the planned multivariable analysis, smaller associations may have remained undetected.

Third, residual stenosis was assessed using a NASCET-based angiographic method rather than intravascular imaging modalities such as IVUS or OCT. Furthermore, angiographic measurements were performed by a single blinded observer, precluding assessment of interobserver variability.

Arterial calcification, an important determinant of balloon expansion and a factor closely associated with diabetes mellitus and advancing age, was not routinely or systematically quantified and therefore could not be incorporated into the regression analyses. In addition, angiography may underestimate calcification burden compared with intravascular imaging techniques such as IVUS and OCT [15]. Consequently, the influence of calcific plaque characteristics on residual stenosis could not be fully evaluated.

Furthermore, detailed information regarding the clinical presentation of peripheral artery disease, including intermittent

claudication, rest pain, and chronic limb-threatening ischemia, was not consistently available because of the retrospective nature of the study. As a result, symptom-based subgroup analyses could not be performed. Although all patients had symptomatic peripheral artery disease requiring endovascular intervention, the lack of standardized symptom classification should be considered when interpreting the findings.

Finally, long-term outcomes, including restenosis, target lesion revascularization, primary patency, and limb-related events, were not available. Consequently, the prognostic significance of residual stenosis beyond the immediate postprocedural period could not be determined. In addition, all procedures were performed using a retrograde popliteal approach, and only TASC II A – B lesions were included. Therefore, the findings may not be generalizable to more complex femoropopliteal lesions or to alternative endovascular access strategies.

CONCLUSION

Advancing age, diabetes mellitus, and greater preprocedural stenosis severity were independently associated with immediate residual stenosis following standardized balloon angioplasty for TASC II A – B superficial femoral artery lesions, whereas lesion length was not. These findings suggest that patient- and lesion-related biological characteristics may exert a greater influence on immediate angiographic success than lesion extent when procedural variability is minimized through a standardized treatment protocol.

Early identification of patients at increased risk of a suboptimal angiographic result may facilitate individualized procedural planning, optimize lesion-preparation strategies, and potentially improve immediate procedural success. Because long-term follow-up was beyond the scope of the present study, these findings should not be extrapolated to long-term vessel patency or clinical outcomes. Prospective multicenter studies incorporating systematic assessment of calcification, intravascular imaging, and long-term follow-up are warranted to validate these findings and further define their clinical implications.

Ethics Committee Approval: The study was approved by the İzmir Bakırçay University Non-Interventional Clinical Research Ethics Committee (Approval No: 3014, Research No: 3002, Date: 03 June 2026).

Patient Consent for Publication: The requirement for informed consent was waived by the Ethics Committee because of the retrospective study design and the use of anonymized data. No identifiable individual patient information is reported in this article.

Data Sharing Statement: The data that support the findings of this study are available from the corresponding author upon reasonable request.

Author Contributions: All authors contributed equally to the article.

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