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Impact of Prolonged Inflation Times During Plain Balloon Angioplasty on Angiographic Dissection in Femoropopliteal Lesions

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Abstract

Purpose: To investigate if balloon angioplasty with a prolonged inflation time (>3 minutes) can prevent postdilation dissection in femoropopliteal lesions. **Methods:** A retrospective single-center analysis examined 294 consecutive patients (mean age 74.1±8.7 years; 215 men) with de novo femoropopliteal lesions treated with balloon angioplasty between 2013 and 2018. The patients were classified into 2 groups to compare angiographic dissection patterns: 175 patients treated with balloon angioplasty for 3 minutes (3-minute group) and 119 treated for >3 minutes (>3-minute group). **Results:** Mean balloon inflation time was 7.8±2.7 minutes in the >3-minute group. Severe dissections (type C or higher) were observed less frequently after balloon dilation in the >3-minute group (22.7% vs 50.9%, p<0.001); therefore, significantly more patients in the >3-minute group had successful endovascular treatment after initial balloon angioplasty (57.1% vs 38.3%, p=0.001). Additional balloon dilation was attempted more frequently in the 3-minute group (30.9% vs 14.3%, p=0.001); as a result, there were more patients in whom additional balloon dilation repaired severe dissection that occurred after the initial dilation (25.1% vs 10.9%, p=0.001). Multivariate analysis revealed that chronic total occlusion (p<0.001) and longer lesion (p<0.001) were independent predictors of severe dissection, and prolonged dilation time was independently related to preventing severe dissection (p<0.001). Among 171 patients undergoing successful balloon angioplasty without stent implantation, the Kaplan-Meier estimates of primary patency within 1 year did not differ significantly according to inflation time. **Conclusion:** Balloon dilation with prolonged inflation time (>3 minutes) may be effective as an initial strategy to prevent severe dissection in femoropopliteal lesions compared to inflation for 3 minutes.

Keywords

balloon angioplasty, balloon inflation time, dissection, endovascular therapy, femoropopliteal segment, peripheral artery disease, stent

Introduction

Endovascular therapy (EVT) represents an established practice in the treatment of lower limb peripheral artery disease (PAD), and several reports have confirmed its efficacy in the femoropopliteal segment.[1,2] Standard percutaneous transluminal angioplasty using noncoated balloons in femoropopliteal lesions is associated with lower patency compared with stent implantation.[3] However, in femoropopliteal lesions, the primary patency after self-expanding nitinol stent implantation remains unsatisfactory.[4-6] Although current investigations have proven the efficacy of a paclitaxel-coated balloon (PCB) in long femoropopliteal lesions as newly established treatment,[7-9] the rate of bailout stenting is not low because of flow-limiting dissection after angioplasty. To resolve the concern, balloon angioplasty needs to be optimized to complete PCB treatment.

Balloon inflation time is considered to be one of the most important factors to achieve successful angioplasty, in

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Table 1. Baseline Patient and Lesion Characteristics.[a]

Variables	Overall (n=294)	Initial Dilation Time, min		p
		3 (n=175)	4–10 (n=119)	
Age, y	74.1±8.7	74.7±9.1	73.3±8.1	0.189
Men	215 (73.1)	132 (75.4)	83 (69.8)	0.283
Body mass index, kg/m^2	22.8±0.2	22.6±3.3	23.0±3.8	0.330
Hypertension	247 (84.0)	144 (82.3)	103 (86.6)	0.323
Dyslipidemia	159 (54.1)	93 (53.1)	66 (55.5)	0.695
Diabetes mellitus	174 (59.2)	108 (61.7)	66 (55.5)	0.285
Current smoker	83 (28.2)	48 (27.4)	35 (29.4)	0.711
Chronic renal disease	141 (48.0)	91 (52.0)	50 (42.0)	0.092
Hemodialysis	85 (28.9)	55 (31.4)	30 (25.2)	0.246
Previous myocardial infarction	30 (10.2)	18 (10.3)	12 (10.1)	0.955
Previous CV disease	53 (18.0)	28 (16.0)	25 (21.0)	0.276
Aspirin	256 (87.1)	156 (89.1)	100 (84.0)	0.203
Thienopyridine	235 (80.0)	136 (77.7)	99 (83.2)	0.246
Cilostazol	84 (28.6)	51 (29.1)	33 (27.7)	0.792
Anticoagulation	48 (16.3)	30 (17.1)	18 (15.1)	0.645
Rutherford category				0.028
2–3	228 (77.6)	128 (73.1)	100 (84.0)	
4–5	66 (22.4)	47 (26.9)	19 (16.0)	
Baseline ankle-brachial index	0.61±0.16	0.61±0.16	0.61±0.16	0.910
TASC II classification				0.075
A	109 (37.1)	69 (39.4)	40 (33.6)	
B	56 (19.0)	31 (17.8)	25 (21.0)	
C	88 (30.0)	45 (25.7)	43 (36.1)	
D	41 (13.9)	30 (17.1)	11 (9.3)	
Reference vessel diameter, mm	5.36±0.69	5.39±0.73	5.35±0.62	0.809
Lesion length, mm	133.0±80.5	122.5±80.1	148.5±79.0	0.007
Chronic total occlusion	110 (37.4)	67 (38.3)	43 (36.1)	0.384
PACSS grade				0.801
0–1	187 (63.6)	108 (61.7)	77 (64.7)	
2	21 (7.1)	12 (6.9)	10 (8.4)	
3	29 (9.9)	20 (11.4)	10 (8.4)	
4	57 (19.4)	35 (20.0)	22 (18.5)	
Tibial runoff ≤1	122 (41.5)	82 (46.9)	40 (33.6)	0.024
Involvement of popliteal lesions	58 (19.7)	32 (18.3)	26 (21.9)	0.453

Abbreviations: CV, cerebrovascular; PACSS, Proposed Peripheral Arterial Calcium Scoring System; TASC, TransAtlantic Inter-Society Consensus.
[a]Continuous data are presented as the means ± standard deviation; categorical data are given as the counts (percentage).

addition to inflation pressure[10] and balloon length,[11] because prolonged inflation time appears to prevent plaque disruption, neointimal tears, and intramural hematoma. Previous reports demonstrated that balloon dilation for 3 minutes was more effective in preventing severe postdilation dissection compared with 1 minute.[11,12] However, there are no studies that have investigated whether inflation time longer than 3 minutes is beneficial in reducing postprocedural dissection.

Most femoropopliteal lesions can be dilated fully for many minutes at one time because long balloons (eg, 220 or 300 cm) have recently become available in daily clinical practice. Based on the hypothesis that longer balloon inflation times might be feasible in preventing postdilation dissection, this study investigated the efficacy of angioplasty with long balloons using a prolonged inflation time >3 minutes in femoropopliteal lesions to reduce the incidence of severe angiographic dissection.

Methods

Study Design and Participants

This retrospective, single-center, nonrandomized study was performed to evaluate the difference in arterial dissection patterns after balloon angioplasty according to inflation

Table 2. Procedure Characteristics and Outcomes.[a]

Variables	Overall (n=294)	Initial Dilation Time, min 3 (n=175)	4–10 (n=119)	p
Initial dilation parameters				
Balloon diameter, mm	4.8±0.7	4.8±0.8	4.9±0.6	0.438
Balloon to artery diameter ratio	0.91±0.16	0.90±0.13	0.92±0.11	0.261
Balloon length, mm	151.9±93.8	129.6±86.1	184.8±95.4	<0.001
Inflation pressure, atm	10.2±3.3	10.2±3.3	10.1±3.3	0.723
Inflation time, min	4.9±2.9	3.0±0.0	7.8±2.7	<0.001
3	—	175 (100.0)	—	—
4–6	—	—	38 (31.9)	—
7–9	—	—	20 (16.8)	—
10	—	—	61 (51.3)	—
Use of scoring balloon	53 (18.0)	31 (17.7)	22 (18.5)	0.303
Use of IVUS	110 (37.4)	52 (29.7)	58 (48.7)	0.003
Initial dilation outcomes				
Dissection type				
None	47 (16.0)	17 (9.7)	30 (25.2)	<0.001
A / B	131 (44.6)	69 (39.4)	62 (62.1)	0.032
C	40 (13.6)	33 (18.9)	7 (5.9)	<0.001
D	59 (20.1)	43 (24.6)	16 (13.5)	0.019
E	10 (3.4)	9 (5.1)	1 (0.8)	0.053
F	7 (2.4)	4 (2.3)	3 (2.5)	1.000
Severe (C-F)	116 (39.5)	89 (50.9)	27 (22.7)	<0.001
Success with initial balloon	135 (45.9)	67 (38.3)	68 (57.1)	0.001
Additional balloon dilation	71 (24.1)	54 (30.9)	17 (14.3)	0.001
Stenting after initial dilation	88 (29.9)	54 (30.9)	34 (28.6)	0.674

Abbreviation: IVUS, intravascular ultrasound.
[a]Continuous data are presented as the means ± standard deviation; categorical data are given as the counts (percentage).

time. From May 2013 to February 2018, 294 consecutive Asian patients (mean age 74.1±8.7 years; 215 men) with symptomatic PAD underwent balloon angioplasty for de novo steno-obstructive femoropopliteal lesions. Patients with in-stent restenosis and acute limb ischemia were excluded; there were no patients treated with PCBs or atherectomy because these devices were not commercially available in Japan during the study period. The study was approved by the institutional review board of the Sendai Kousei Hospital (approval number 27-33), and written informed consent was obtained from all the patients.

The incidences of severe dissection and primary patency after angioplasty were compared between 175 patients (mean age 74.7±9.1 years; 132 men) treated with balloon angioplasty for 3 minutes (3-minute group) and 119 (mean age 73.3±8.1 years; 83 men) treated for >3 minutes (>3-minute group). Table 1 summarizes the baseline patient and lesion characteristics. The mean lesion length of the entire cohort was 133.0±80.5 mm; more than a third of lesions (110, 37.4%) were chronic total occlusions (CTOs). The rate of critical limb ischemia (CLI) was significantly higher in the 3-minute group; however, other variables were not significantly different between the groups. Because the 3-minute group included more CLI patients, the rate of patients with distal runoff ⩽1 was significantly higher. Patients in the >3-minute group had longer lesions.

Procedures

After local anesthesia with 2.0% xylocaine, a 4.5- or 6.0-F guiding sheath was inserted via the ipsi- or contralateral common femoral artery. Unfractionated heparin (5000 units) was injected via the sheath and an additional 2000 units was given intravenously every hour. Entire lesions were dilated routinely for at least 3 minutes using long balloons with 3- to 7-mm diameters. Scoring balloons were used before long-balloon dilation if lesions with calcification appeared not to be fully dilated by the standard balloons. If there was residual stenosis and/or flow-limiting dissection after long-balloon dilation, additional balloon dilation and/or self-expanding stent placement was performed at the discretion of the operator.

Study Definitions and Follow-up

All the lesions within the femoropopliteal segment were characterized according to the TransAtlantic Inter-Society Consensus II classification.[1] The dissection was classified

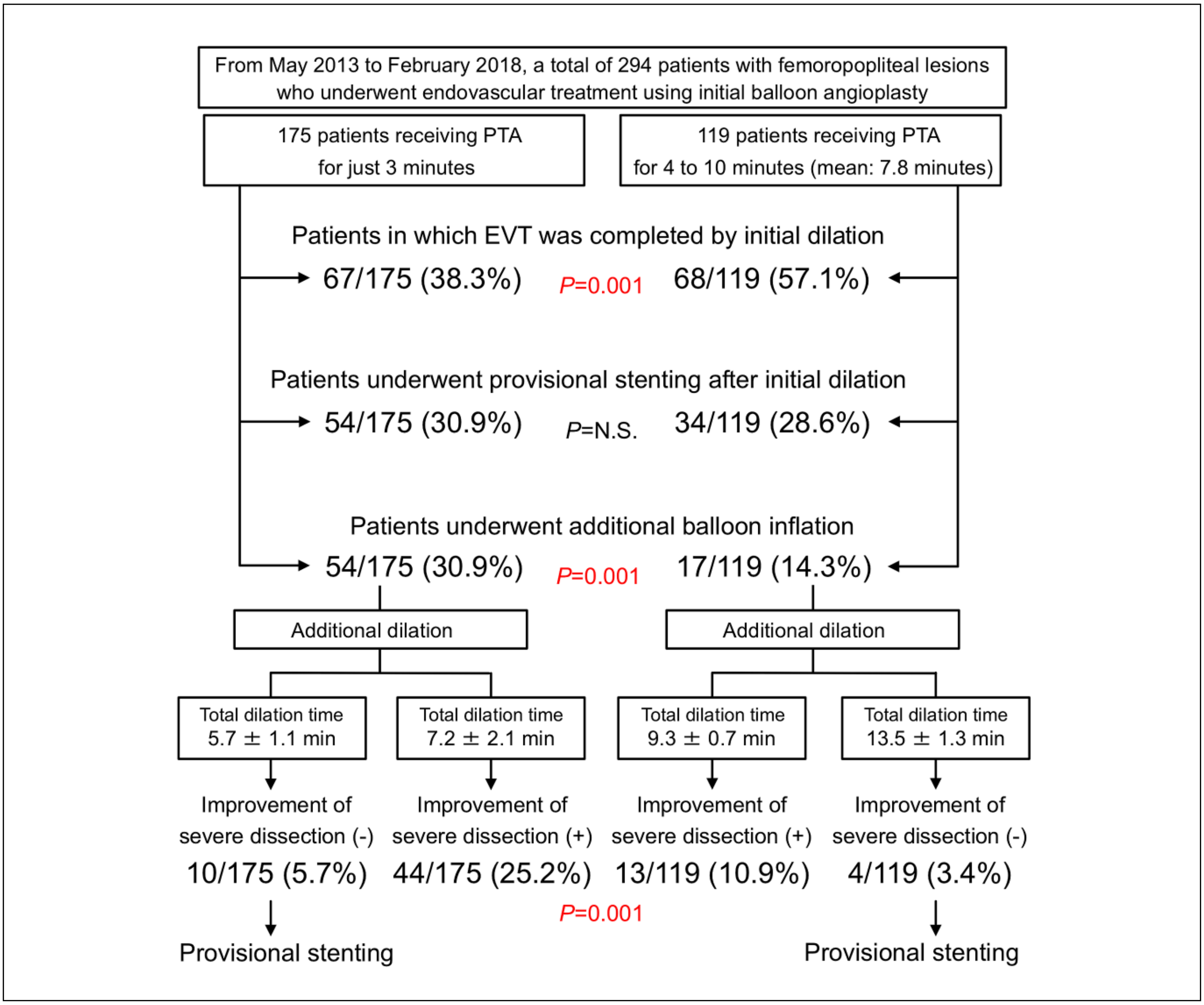


Figure 1. Comparison of results of initial balloon angioplasty between 3-minute and >3-minute groups. The >3-minute group had a significantly higher success rate and less need for additional balloon dilation. In the 3-minute group, there were significantly more patients needing additional balloon dilation to repair severe dissection that occurred after initial dilation. PTA, percutaneous transluminal angioplasty.

as types A to F, and severe dissection was defined as type C (contrast outside the lumen) or higher, as demonstrated previously.[13] When multiple dissections were detected in a single lesion, the worst pattern was adopted for analysis. The Proposed Peripheral Arterial Calcium Scoring System (PACSS) was used to categorize the degree of lesion calcification.[14] All angiograms were evaluated independently by 2 experienced operators for baseline lesion morphology, dissection classification, and procedure success. Immediate success of balloon angioplasty was defined as a residual stenosis of <30% of the reference diameter. Duplex ultrasound assessment was performed routinely at 1, 6, and 12 months after EVT to evaluate patency of the vessel. Restenosis was defined as a peak systolic velocity ratio of 2.4 on duplex ultrasonography, which was considered to indicate >50% narrowing.[15]

Data Analysis and Statistical Methods

Categorical variables are reported as the counts (percentage) and were compared using the chi-square or Fisher exact test. Continuous variables are reported as means ± standard deviation and were compared using the *t* test. Receiver operating characteristics (ROC) curve analysis was used to assess the ability of prolonged balloon inflation to prevent severe dissection. The area under the ROC curve (AUC) was calculated for inflation times. All baseline values and procedure characteristics were prescreened using a univariate logistic regression

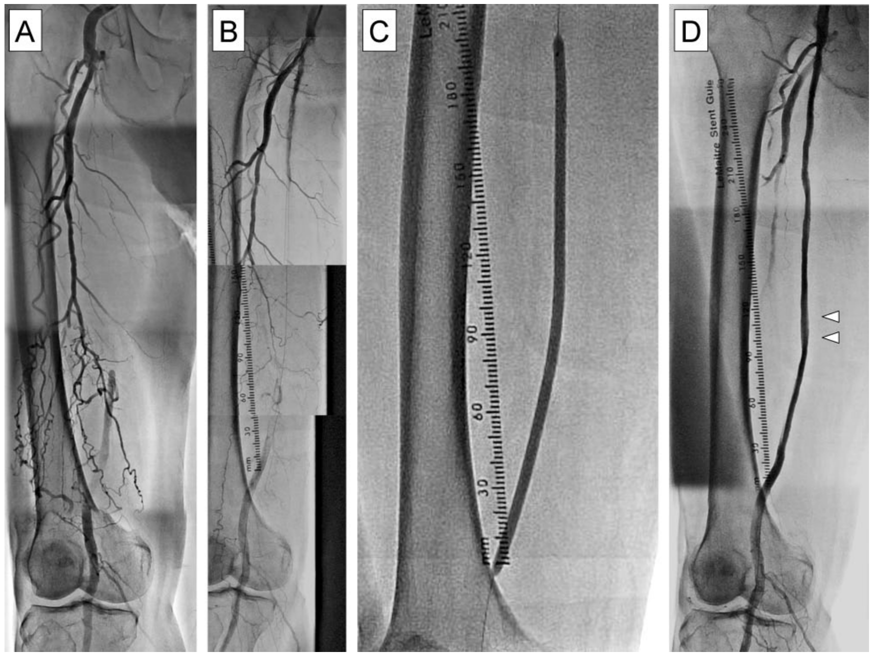


Figure 2. These images are from a representative case in which additional balloon dilation improved a severe dissection that occurred after 3-minute inflation. (A) An 83-year-old man with intermittent claudication (Rutherford category 3) in the right limb owing to a TransAtlantic Inter-Society Consensus D occlusion. (B) Angiography after balloon dilation for 3 minutes revealed type F dissection without distal antegrade flow. (C) Additional balloon dilation for 10 minutes was performed. (D) Angiography after additional dilation revealed that the dissection improved from type F to A (white arrow).

analysis to identify independent predictors of severe dissection. Univariate predictors achieving $p<0.20$ were entered into a multivariate logistic regression analysis with stepwise procedures; the results are presented as the odds ratios (ORs) and 95% confidence intervals (CIs). A subsequent multivariate model, including all the significant variables, was established to estimate the ORs and 95% CIs. Time-dependent outcomes were analyzed using the Kaplan-Meier method and were compared using the log-rank test; $p<0.05$ was considered statistically significant. The JMP statistical software (version 11; SAS Institute, Cary, NC, USA) was used to perform all the statistical analyses.

Results

EVT was technically successful in all patients. Mean initial balloon inflation time was 7.8±2.7 minutes in the >3-minute group. Balloon diameters and inflation pressures were not different (Table 2); however, balloon length was significantly longer in the >3-minute group. Severe dissection occurred less frequently in the >3-minute group (22.7% vs 50.9%, $p<0.001$); therefore, EVT was successful after initial balloon dilation in significantly more patients in the >3-minute group (57.1% vs 38.3%, p=0.001; Table 2). Although the rate of provisional stenting after initial balloon dilation was not different between groups, additional balloon dilation was attempted less frequently in the >3-minute group (14.3% vs 30.9%, p=0.001). In the 3-minute group, there were significantly more patients in whom additional balloon dilation repaired severe dissection that occurred after the initial dilation (25.1% vs 10.9%, p=0.001; Figure 1). Figure 2 shows a representative case in which additional balloon dilation was effective in repairing dissection that occurred after the initial 3-minute balloon inflation.

Predictors of Severe Dissection

The multivariate regression analysis (Table 3) showed that longer inflation time (per minute) was protective against severe dissection (OR 0.76, 95% CI 0.65 to 0.87, $p<0.001$). CTO (OR 3.83, 95% CI 2.03 to 7.34, $p<0.001$) and longer lesions (per 10.0 mm; OR 1.10, 95% CI 1.05 to 1.15, $p<0.001$) were independent predictors of severe dissection. The ROC curve analysis for inflation time showed an AUC of 0.613 (Figure 3), with 5 minutes as the optimal inflation time to prevent severe dissection after initial balloon angioplasty ($p<0.001$). The screening analysis (Figure 4) identified male sex, age ≤75 years, no hemodialysis, reference vessel diameter ≥5.0 mm, lesion length >150 mm, CTO, PACSS grade 0–3, and no scoring balloon application as factors more favorable for >5-minute balloon inflation to prevent severe dissection.

Table 3. Indicators of Severe Dissection After Initial Balloon Dilation.[a]

	Univariate	Multivariate
Age, per 10 years	1.24 (0.59 to 1.09), p=0.315	
Body mass index, per kg/m^2	0.92 (0.84 to 0.99), p=0.020	0.93 (0.84 to 1.02), p=0.142
Female sex	1.49 (0.84 to 2.42), p=0.175	
Hypertension	1.85 (0.86 to 4.45), p=0.118	
Diabetes mellitus	0.70 (0.41 to 1.18), p=0.179	
Current smoking	1.14 (0.64 to 2.01), p=0.984	
Chronic kidney disease	1.12 (0.66 to 1.89), p=0.679	
Hemodialysis	0.64 (0.34 to 1.15), p=0.137	
Critical limb ischemia	0.82 (0.42 to 1.54), p=0.547	
Use of cilostazol	1.03 (0.57 to 1.81), p=0.933	
Chronic total occlusion	5.84 (3.34 to 10.45), p<0.001	3.83 (2.03 to 7.34), p<0.001
TASC D	6.19 (3.11 to 12.66), p<0.001	
Popliteal lesion	0.54 (0.24 to 1.08), p=0.084	
Reference vessel diameter, per mm	0.80 (0.85 to 1.84), p=0.251	
Lesion length, per 10.0 mm	1.12 (1.08 to 1.16), p<0.001	1.10 (1.05 to 1.15), p<0.001
PACSS grade 4	1.28 (0.66 to 2.40), p=0.451	
Tibial runoff ≤1	1.03 (0.61 to 1.76), p=0.901	
Use of IVUS	2.35 (1.38 to 4.02), p=0.002	
Balloon-artery ratio, per 0.1	0.92 (0.75 to 1.09), p=0.443	
Inflation pressure, per atm	0.91 (0.83 to 0.99), p=0.028	
Balloon length ≥220 mm	1.58 (0.93 to 2.69), p=0.089	
Use of scoring balloon	0.19 (0.06 to 0.49), p<0.001	0.36 (0.10 to 1.05), p=0.084
Inflation time, per min	0.82 (0.72 to 0.91), p<0.001	0.76 (0.65 to 0.87), p<0.001
Inflation time >5.0 min	0.43 (0.23 to 0.76), p=0.003	

Abbreviations: IVUS, intravascular ultrasound; PACSS, Proposed Peripheral Arterial Calcium Scoring System; TASC, TransAtlantic Inter-Society Consensus.
[a]Data are presented as the odds ratio (95% confidence interval), p value.

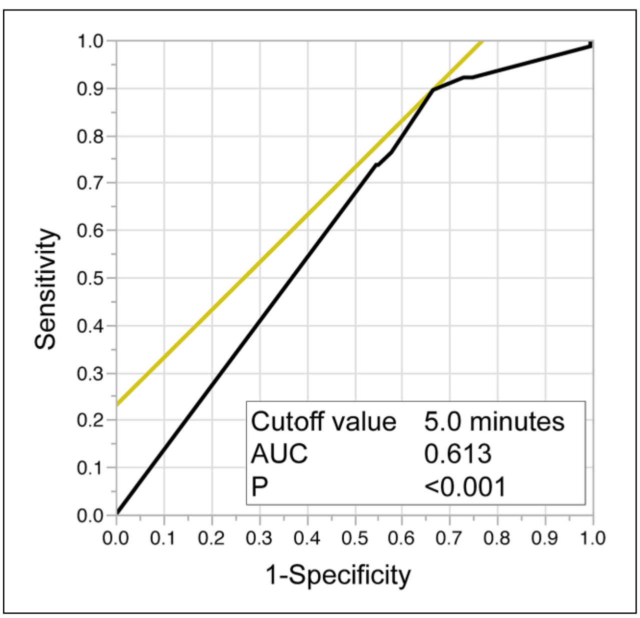


Figure 3. The receiver operating characteristic curve analysis for inflation time showed an area under the curve (AUC) of 0.613, with a 5-minute optimal cutoff value for inflation time to prevent severe dissection after initial balloon angioplasty.

Follow-up Outcomes

After the procedure, the ankle-brachial index rose from 0.61±0.16 to 0.84±0.15; the Rutherford category likewise improved (Figure 5). Primary patency within 1 year was compared according to the total inflation times of the initial and additional balloon dilation among the 171 patients who had successful angioplasty and no stent implantation. The Kaplan-Meier estimates of primary patency did not differ significantly according to total inflation time (Figure 6).

Discussion

Self-expanding nitinol stents have improved the durability of revascularization in the femoropopliteal segment. Recent studies have reported superior results of stents over balloon angioplasty for short to intermediate-length lesions in the superficial femoral artery, with 1-year patency rates ranging from 63% to 83%[3,4] and long-term patency rates of 49% to 60%.[5,6] Despite the benefits of stents, there are concerns regarding in-stent restenosis, stent fractures, and other stent-related complications that negatively affect the patient's clinical progress over the long term.[16,17]

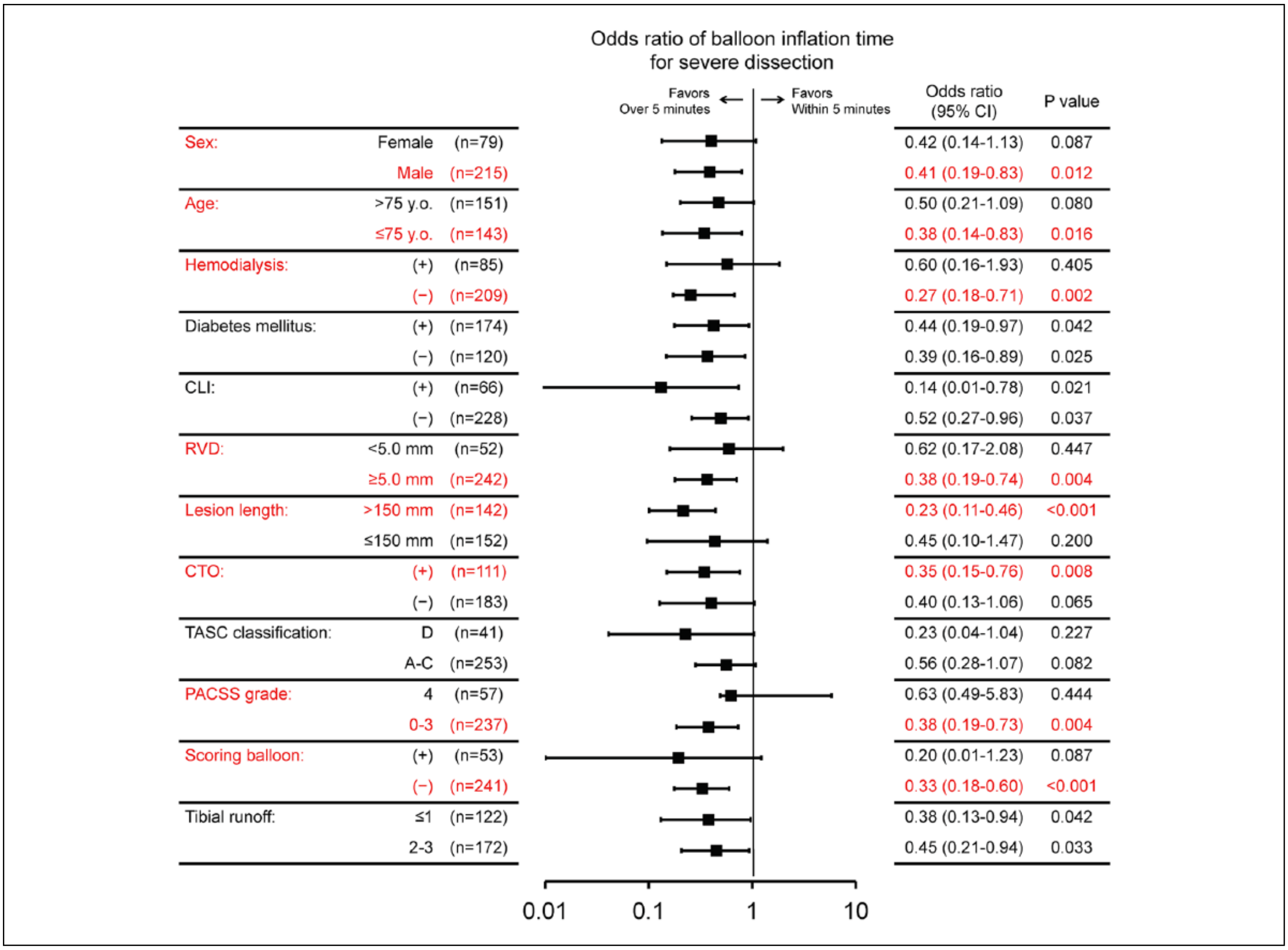


Figure 4. The plot shows the odds ratios for inflation time ≤5 vs >5 minutes for preventing severe dissection. The error bars are the 95% confidence intervals. CLI, critical limb ischemia; CTO, chronic total occlusion; PACSS, Proposed Peripheral Arterial Calcium Scoring System; RVD, reference vessel diameter; TASC, TransAtlantic Inter-Society Consensus.

In recent years, the development of PCBs has resulted in favorable outcomes and has made a substantial contribution to revascularization without stent implantation. Tepe et al[9] demonstrated that the PCB was associated with higher primary patency at 12 months compared with conventional balloon angioplasty in a randomized controlled trial (82.2% vs 52.4%, $p<0.001$). However, 7% to 12% of patients required provisional stent implantation; therefore, the PCB strategy is essential to obtain enough lumen area using uncoated balloon dilation as well as to prevent flow-limiting dissection. To achieve successful EVT using the PCB strategy, balloon angioplasty must be optimized.

This study found that more effective balloon angioplasty resulted when using a prolonged inflation time including both additional and initial dilation. One reason for fewer severe dissections using prolonged inflation time may be reduced arterial trauma, which has been observed angioscopically in other studies.[18] Prolonged inflation time probably enables the balloon to fix the dissection flap on the vessel wall and prevent intramural hematoma. A longer inflation time also can help avoid early elastic recoil by increasing pressure injury to the media.[19,20]

Niels et al[12] demonstrated that a prolonged inflation time of 3 minutes improves the immediate angioplasty result of femoropopliteal lesions compared with a short dilation strategy. However, to the best of our knowledge, no other study has yet investigated the angiographic outcomes of balloon angioplasty with inflation times >3 minutes and demonstrated the higher success rate achieved by preventing severe dissection. Balloon angioplasty with prolonged inflation time does not require special additional devices and is conducted in daily practice easily and safely; therefore, this strategy is appropriate as an initial angioplasty treatment to achieve higher procedure success.

Fujihara et al[13] reported that severe dissection (type C or higher) was detected in 42% of patients who underwent

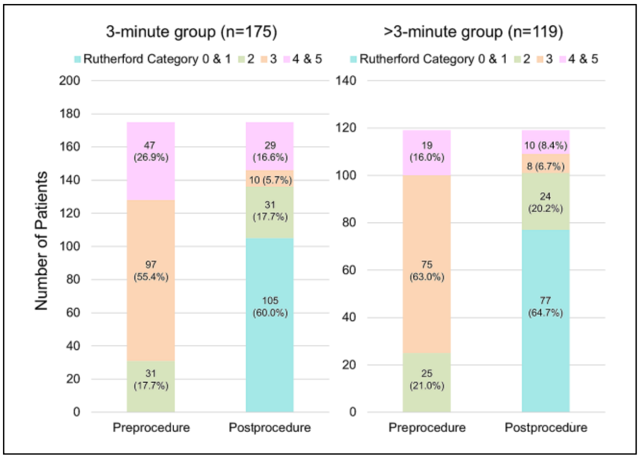
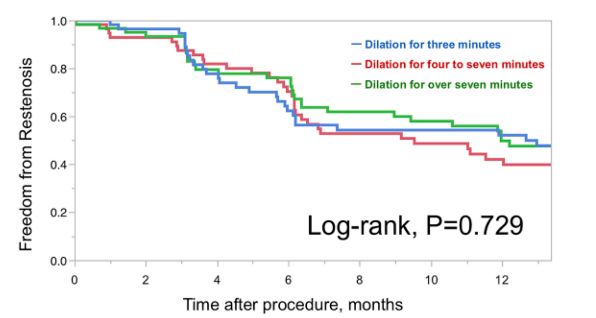


Figure 5. Change in Rutherford category in follow-up.



Months		0	3	6	12
At risk	Three minutes	55	42	28	22
	Four to seven minutes	56	45	29	20
	Over seven minutes	60	47	33	22
Rate (%)	Three minutes	100.0	79.2	54.9	44.9
	Four to seven minutes	100.0	84.9	55.8	39.2
	Over seven minutes	100.0	81.0	61.1	46.8

Figure 6. Primary patency in patients treated without provisional stenting shows no significant difference in patients undergoing successful balloon angioplasty according to total inflation time.

balloon angioplasty; independent predictors were a reference vessel diameter <5.0 mm, lesion length >150 mm, and total occlusion. In their study, lesion length was 148.1±92.4 mm and the rate of total occlusion was 40.2%. The lesion characteristics in our study were similar; however, the incidence of severe dissection was remarkably low at 22.7% in patients who underwent prolonged balloon inflation. Our subanalysis suggested that CTO and lesion length ⩾150 mm were favorable factors for >5-minute balloon inflation.

Prolonged balloon inflation might provide a way to prevent elastic recoil and fix an intimal flap throughout the entire segment of long and/or occlusive lesions, although simple stenosis could be managed using a standard balloon technique. On the other hand, our subanalysis did not show the effectiveness of prolonged balloon inflation in lesions with PACSS grade 4, even though dilation >5 minutes was a favorable factor to prevent dissection in PACSS grades 0–3 lesions. Fanelli et al[15] reported that a highly calcified lesion was significantly associated with dissection and the need for provisional stenting after angioplasty. Moreover, it also reduced the primary patency after PCB treatment.[15] Our study found that prolonged inflation time had limited utility in PACSS-4 lesions. Apparently, it is difficult to concurrently restore a large lumen and prevent a dissection in calcified lesions using only balloon dilation. Although atherectomy devices were not used in our study, debulking may be a solution to reducing calcium burden and improving the immediate angioplasty result in femoropopliteal lesions.[21]

Our study demonstrated that the longer inflation time did not improve primary patency after balloon angioplasty. There is a possible reason for this finding. Primary patency was investigated among patients with few severe dissections after balloon angioplasty. It is likely that prolongation of inflation time was effective in improving immediate procedure success but was not associated with keeping arteries open if severe dissection was absent.

Limitations

Several limitations should be mentioned. First, this was a nonrandomized, retrospective, single-center analysis with a small sample size. In particular, selection bias regarding balloon profiles, inflation times, and stent deployment could not be ruled out. Second, though the dissection grade was adjudicated by independent observers, it was not verified by an external core laboratory. Third, as mentioned above, PCB and atherectomy devices were not used.

Conclusion

Balloon angioplasty with a prolonged inflation time >3 minutes may be effective as an initial angioplasty strategy to prevent severe dissection in femoropopliteal lesions. Although longer inflation time did not improve primary patency within 1 year, it might result in better immediate angioplasty success.

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Declaration of Conflicting Interests

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