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Impact of balloon inflation duration on angiographic outcomes in infrainguinal atherosclerotic lesions

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ABSTRACT

Objectives: This study aimed to evaluate the effect of short versus prolonged balloon inflation times on the degree of residual stenosis following peripheral balloon angioplasty.

Patients and methods: In this retrospective cohort study, 239 balloon angioplasty procedures performed on 192 patients (158 males, 34 females; mean age: 66±9.7 years; range, 42 to 94 years) between April 1, 2020, and September 1, 2020, were analyzed. Patients were categorized into two groups based on balloon inflation time: ≤1 min (n=138) and >2 min (n=101). Preoperative and postoperative angiographic images were compared to assess the degree of stenosis.

Results: No statistically significant differences were observed between the groups in terms of age or comorbid conditions (hypertension, diabetes mellitus, coronary artery disease, chronic renal failure, hyperlipidemia, and obesity; p>0.05 for all). Preoperative stenosis levels were similar between groups (p=0.738); however, residual stenosis was significantly lower in the prolonged inflation group (p<0.001). The incidence of arterial dissection was also reduced in this group. No significant differences were found between the groups regarding thrombosis or vascular perforation.

Conclusion: This study demonstrated that balloon inflation times exceeding 2 min reduced residual stenosis and complications such as dissection.

Keywords: Angioplasty, balloon inflation time, drug-eluting balloon, peripheral artery disease, residual stenosis.

Percutaneous transluminal angioplasty (PTA) is an established minimally invasive treatment for peripheral artery disease (PAD).[1] While peripheral bypass surgery is reserved for select cases of advanced atherosclerotic disease, angioplasty is commonly preferred as the first-line intervention due to its lower invasiveness and faster recovery time.[2]

The main objective of angioplasty is to mechanically dilate the vessel lumen by remodeling and compressing the atherosclerotic plaque. In recent years, drug-coated balloons have been introduced to improve clinical outcomes in PAD, drawing from experience in coronary interventions.[3] These drug-coated balloons deliver antiproliferative agents, such as paclitaxel, directly to the vessel wall, minimizing the risk of restenosis without requiring a permanent vascular implant.[4,5] Paclitaxel inhibits vascular smooth muscle cell proliferation and migration by inducing cell cycle arrest and apoptosis, thus preventing neointimal hyperplasia.[6]

While numerous strategies have been proposed to reduce restenosis rates after angioplasty, many have not been rigorously evaluated in randomized clinical trials. One such procedural factor is balloon inflation time. Prolonged inflation may reduce dissection and vasospasm by inducing transient smooth muscle dysfunction, potentially resulting in less residual stenosis.[7]

This study aimed to compare the immediate angiographic outcomes of two different balloon

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inflation durations, short (≤1 min) and prolonged (>2 min), in patients undergoing infrainguinal balloon angioplasty for PAD.

PATIENTS AND METHODS

This retrospective single-center study was conducted on 401 patients who underwent peripheral angiography between April 1, 2020, and September 1, 2020. Patients undergoing endovascular revascularization were identified using the guidelines of the European Society of Cardiology, American College of Cardiology/ American Heart Association, and European Society for Vascular Surgery and national guidelines for the management of PAD.[5,8-10] Data were retrospectively collected from patients' electronic medical records in a standardized form that included demographic and clinical characteristics and radiologic images (computed tomography angiography, as well as preoperative and postoperative angiography images). Adults (aged 18 years or older) who underwent angioplasty for infrainguinal atherosclerotic vascular disease (nonobstructive) were enrolled in the study. Exclusion criteria were suprainguinal occlusions, previous surgery for peripheral arterial disease, last peripheral balloon angioplasties at the same site, iliac arterial lesions, failed interventions, and venous interventions. Angioplasty was performed in both legs in 47 patients. A total of 192 patients (158 males, 34 females; mean age: 66±9.7 years; range, 42 to 94 years) with 239 consecutive balloon angioplasties were included in the study. Written informed consent was obtained from all participants. The study protocol was approved by the Bakırçay University School of Medicine Ethics Committee (Date: 12.10.2020, No: 81/51). The study was conducted in accordance with the principles of the Declaration of Helsinki.

There were two surgical procedures in which two different balloon inflation times were used in the study. In one of the two procedures, the balloon inflation time was ≤1 min; in the other, it was >2 min. Lesions of the superficial femoral artery, popliteal artery, and infrapopliteal artery were intervened. Balloon angioplasties were classified into two groups to compare balloon inflation times: 138 balloon angioplasties were performed for ≤1 min, and 101 procedures for >2 min. Waiting times after the nominal pressure was reached were evaluated. Carotid stenosis was measured according to a previous formula described in the North American Symptomatic Carotid Endarterectomy Trial and adapted for patients with PAD. Preoperative and postoperative angiographic images were compared to determine the degree of stenosis. The narrowest diameter observed in any plane of the lumen and the proportion of normal segment diameter in the proximal or distal part of that segment were calculated according to the following formula: (% stenosis = [1- (minimal residual lumen diameter / distal or proximal normal lumen diameter)] ×100).[11]

Residual stenosis was assessed immediately after angioplasty with a postoperative angiogram. After angioplasty, residual stenosis was graded as mild, moderate, and severe between 0-25%, 25-50%, and 50-75%, respectively. We recorded complications of the angiographic procedures, such as arterial dissection, vascular perforation, and acute occlusion (thrombosis).

Procedure

After local anesthesia with 20 mg/mL lidocaine, a 7.0- to 8.0-F guide sheath was inserted via the ipsilateral or contralateral common femoral artery. Unfractionated heparin (5000 IU) was injected via the sheath. Drug-eluting balloon angioplasty (Extender; Invamed, Ankara, Türkiye) was performed in all patients, and calcification density was reduced by atherectomy (Temren atherectomy device; Invamed, Ankara, Türkiye) before angioplasty. The entire lesions were routinely dilated with long balloons of 2- to 7-mm in diameter. If flow-restricting dissection occurred after dilation with long balloons, additional balloon dilation was performed at the surgeon's discretion.

Statistical analysis

Statistical analyses were performed using IBM SPSS version 25.0 software (IBM Corp., Armonk, NY, USA). Mean, median, first quartile, and third quartile were used to express continuous variables, whereas numbers and percentages were used to express categorical variables. Missing data were excluded from statistical analysis. Differences between the two groups were analyzed using the t-test. Categorical variables were compared using the chi-square test and the exact test. The Wilcoxon test was applied for dependent variables that were

Table 1
Demographic and clinical characteristics of the patients

	Total (n=192)				Balloon inflation time (min) ≤1 min (n=105)				Balloon inflation time (min) >2 min (n=87)				
Characteristics	n	%	Mean±SD	Range	n	%	Mean±SD	Range	n	%	Mean±SD	Range	*p*
Age (year)			66.1±9.7	42-94			66.6±9.7	46-94			65.6±9.8	42-83	0.499 t=0.678
Sex													0.040
Male	158	82.3			81	77.1			77	88.5			
Female	34	17.7			24	22.9			10	11.5			
Body mass index (kg/m^2)													<0.001
18.5-24.9	123	64			88	83.8			35	40.2			
25-29.9	52	27.1			14	13.3			38	43.7			
30-34.9	14	7.3			2	1.9			12	13.8			
35-39.9	1	0.5			0.0	0.0			1.0	1.1			
≥40	2	1.0			1	1.0			1.0	1.1			
Hypertension	103	53.6			58	55.2			45	51.7			0.627
Diabetes mellitus	84	43.8			45	42.9			39	44.8			0.784
Hyperlipidemia	77	40.1			47	44.8			30	34.5			0.148
Chronic renal disease	18	9.4			7	6.7			11	12.6			0.157
Coronary artery disease	75	39.1			40	38.1			35	40.2			0.763
Smoker	139	72.4			73	69.5			66	75.9			0.128

SD: Standard deviation.

nonnormally distributed. A p-value <0.05 was considered statistically significant.

RESULTS

The mean age was 66±9.7 (range, 42-94) years, which meant no statistical difference between the groups (p=0.499; Table 1). One hundred fifty-eight (82.3%) patients were male; 88.5% had prolonged balloon inflation times, and 77.1% had shortened balloon inflation times (p=0.040). Patients' body mass indices (BMIs) were examined; 121 (63%) patients had normal BMI. When comparing BMIs between the groups, 88 (83.8%) patients with shortened balloon inflation times had normal BMIs; in contrast, 35 (40.2%) patients with prolonged balloon inflation times had normal BMIs (p<0.001). A total of 103 (53.6%) patients had hypertension, 84 (43.8%) had diabetes, 77 (40.1%) had hyperlipidemia, 18 (9.4%) had chronic renal failure, and 75 (39.1%) patients had coronary artery disease. The distribution of comorbidities did not differ between the groups (all p>0.005; Table 1). One hundred thirty-nine (72.4%) patients were smokers. Medication history was evaluated, and 141 (59%) patients had used antiplatelet therapy (acetylsalicylic acid, clopidogrel, or a combination), 29 (12.1%) patients had used anticoagulant therapy (warfarin sodium or direct oral anticoagulants), and 37 (15.5%) had used cilostazol therapy.

The superficial femoral artery was the most commonly processed artery, with 167 (69.9%) patients (Table 2). The median lesion length was 80 (interquartile range [IQR], 70-90) mm. The median balloon diameter was 6 (IQR, 4-6) mm, and the median balloon length was 120 (IQR, 100-120) mm. The median inflation pressure was 9 (IQR, 8-10) atmospheres. There was no statistical difference between the prolonged and shortened balloon inflation time groups for median balloon diameters, lesion lengths, and inflation pressures (p>0.05; Table 2).

It was observed that the preoperative angiograms of most patients showed moderate and severe stenosis (Table 2). There was no statistical difference between the groups regarding balloon inflation time for preoperative stenosis (p=0.738). Postoperative residual stenosis was milder in the group with prolonged balloon inflation times than in the group with shortened balloon inflation times, with predominantly moderate stenosis (p<0.001). Severe residual stenosis was observed postoperatively in eight patients with shortened balloon inflation times. The Wilcoxon test was applied to assess the preoperative and postoperative stenosis levels in patients, and results revealed a statistically significant difference (p<0.001) All of these patients had a history of smoking; no severe residual stenosis was observed in nonsmokers (p=0.109).

Complications that occurred after angioplasty were dissection in 16 patients, thrombosis in two patients, and perforation in one patient. Five of these patients were in the group with prolonged balloon inflation times. The result was insignificant when comparing complications according to two different balloon inflation times, but insufficient numbers may have affected this (p=0.257). One patient who developed thrombosis was treated with mechanical aspiration, and another patient with perforation was treated with a covered stent, resulting in no morbidity or mortality.

DISCUSSION

Endovascular techniques, including drug-eluting balloons and bailout stenting, have become effective alternatives for treating infrainguinal PAD.[12] Among the critical factors in angioplasty, balloon inflation time is potentially significant yet underinvestigated. The use of standard balloons (semicompliant/noncompliant) in preparing lesions and using prolonged inflations (>180 sec) increased procedural success rates and long-term patency. Furthermore, it reduces the risk of arterial dissection.[13] In another study, harvested porcine carotid arteries were used in an *ex vivo* pulsatile flow bioreactor system. Using drug-coated balloons, balloon inflation times and transit times were used to calculate the amount of drug passing into the vein. As a result, it was observed that the drug passing into the vein was better when the balloon inflation time was increased and the transit time was decreased.[14]

Although several studies have examined the optimal duration of balloon inflation, the evidence remains inconclusive, and clinical practice continues to vary based on individual surgeon preference.[7] Thus, this study aimed to evaluate the impact of short versus prolonged balloon inflation times on angiographic outcomes, using standardized procedural techniques across all patients.

Table 2
The characteristics of procedure and lesion

					Balloon inflation time (min)								
	Total (n=239)				<1 min (n=138)				>2 min (n=101)				
Characteristics	n	%	Median	IQR	n	%	Median	IQR	n	%	Median	IQR	*p*
Balloon diameter (mm)			60	40-60			60	40-60			50	35-60	0.785
Balloon length (mm)			120	100-120			100	100-120			120	100-150	<0.001
Inflation pressure (atm)			9	8-10			9	8-10			9	8-10	0,476
Lesion length (mm)			80	70-90			80	70-90			80	70-90	0.294
Location of the lesion													0.290
Superficial femoral artery	167	69.9			101	73.2			66	65.3			
Popliteal artery	22	9.2			13	9.4			9	8.9			
Infrapopliteal artery	50	20.9			24	17.4			26	25.7			
Preoperative stenosis													0.738
50	37	15.5			23	16.7			14	13.9			
50-75	105	43.9			58	42			47	46.5			
75-100	97	40.6			57	41.3			40	39.6			
Postoperative residual stenosis													<0.001
0-25	147	61.5			59	42.8			88	87.1			
25-50	84	35.1			71	51.4			13	12.8			
50-75	8	3.3			8	5.8			-	-			
Complications													0.257
Dissection	16	6.6			11	8			5	5			
Thrombosis	2	0.8			2	1.4			-	-			
Perforation	1	0.4			1	0.7			-	-			

IQR; Interquartile range.

Historically, when balloon angioplasty was first introduced, early randomized trials supported the immediate benefits of prolonged inflation, though these advantages were not always maintained over time.[15-17] In early methods, a 1-min inflation duration was common, yet often used without a clearly defined rationale.[18] More recent work by Zorger et al.[17] demonstrated improved early angiographic results and reduced dissection rates with balloon inflation times exceeding 3 min in femoropopliteal lesions. Similarly, Elens et al.[18] reported that inflation times of 3 to 5 min produced superior angiographic outcomes and minimized the need for additional interventions.[15]

Our study aligns with these findings, demonstrating that prolonged inflation (>2 min) significantly reduces residual stenosis and arterial dissection compared to inflation durations ≤1 min. Importantly, these benefits were observed without increased procedure-related complications such as thrombosis or perforation.

However, concerns have been raised about the potential risks of extended balloon inflation. In animal studies, durations longer than 60 sec were associated with endothelial injury, inflammation, and subsequent intimal hyperplasia, raising questions about long-term vascular healing.[19-21] Although our findings suggest promising immediate angiographic outcomes, the long-term impact of prolonged balloon inflation on restenosis and vessel integrity remains uncertain.

Prolonged balloon inflation has several advantages: it is easily implemented in routine practice, requires no additional devices, and may reduce the need for bailout stenting. Additionally, adequate dilation and prolonged contact time may facilitate better drug delivery in drug-eluting balloons, enhancing the antiproliferative effect of agents such as paclitaxel.[22-24]

Our study also supports the hypothesis that prolonged inflation may reduce the risk of severe dissection, as suggested by Fujihara et al.,[25] who found that longer inflation times significantly lowered dissection rates in similar lesion types.[21] However, it is also possible that extended inflation may temporarily mask dissections, which could later result in acute occlusion if not adequately addressed intraoperatively. Therefore, careful post-dilation imaging and clinical monitoring remain essential.

Moreover, while our findings demonstrate significant short-term advantages of prolonged inflation, persistent risk factors, such as smoking, diabetes, and hyperlipidemia, may continue to influence mid- and long-term outcomes. Interestingly, all cases of severe residual stenosis in our cohort occurred in smokers, although the association was not statistically significant.

This study had several limitations. First, its retrospective design inherently limited the ability to establish causality. Second, the relatively small sample size may have restricted the generalizability of the findings and reduced the power to detect specific differences between groups. Additionally, balloon inflation time was not strictly standardized and may have varied based on individual surgeon discretion, introducing a potential source of bias. Although all procedures were performed at a single center using standardized protocols, not all interventions were conducted by the same operator, which may have influenced angioplasty outcomes. Furthermore, not all procedures recorded actual inflation pressure and balloon deflation velocity, limiting further procedural comparisons. Lastly, this study focused solely on immediate postprocedural outcomes; long-term follow-up data were unavailable, including restenosis rates and target lesion revascularization.

In conclusion, while many studies attribute improved patency to using drug-eluting balloons, it is worth reconsidering the role of balloon inflation time as a potentially critical factor in optimizing outcomes. The improved patency associated with drug-eluting balloons may partly depend on sufficient drug transfer, which, in turn, is influenced by the duration of balloon contact with the vessel wall. This study demonstrated that balloon inflation times exceeding 2 min reduce residual stenosis and complications such as dissection. Nonetheless, well-designed, prospective randomized controlled trials are needed to validate these findings and determine the optimal balloon inflation duration for different lesion types and patient subgroups.

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

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