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***Original Article** / Özgün Makale*

Endovascular balloon angioplasty for infrainguinal arterial occlusive disease: Efficacy analysis

İnfrainguinal arteriyel tıkayıcı hastalıkta endovasküler balon anjiyoplasti: Etkinlik analizi

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ABSTRACT

Background: We present early and mid-term clinical outcomes of endovascular revascularization for femoropopliteal involvement of peripheral arterial disease.

Methods: A total of 128 patients (113 males, 15 females; mean age: 63.4±9.9 years; range, 32 to 87 years) who underwent percutaneous transluminal angioplasty for femoropopliteal lesions between August 2016 and April 2018 were analyzed retrospectively. Treatment with Luminor® paclitaxel-coated drug-eluting balloon catheter or bailout therapy with iVolution® self-expanding nitinol stent were performed. Overall patency rates and freedom from reintervention rates were analyzed using the Kaplan-Meier analysis. The primary patency and freedom from reintervention to target lesion rates at 12 and 24 months were evaluated.

Results: Technical success was achieved in 133 (93%) of the interventions with a median follow-up of 11 (range, 1 to 35) months. At 12 and 24 months, the mean overall patency rates were 85.6±3.7% and 66.8±6.7%, respectively and the mean freedom from reintervention to target lesion rates were 91.6±2.9% and 78.1±6.3%, respectively. The primary patency and freedom from reintervention to target lesion rates were significantly higher in the bailout stenting group than the drug-eluting balloon group at 12 months (97.3±2.7% vs. 94.8±6.1%, respectively, p=0.025 and 97.1±2.9% vs. 84.2±5.5%, respectively, p=0.005) and at 24 months (76.9±7.9% vs. 55.8±13.4%, respectively, p=0.025 and 85.2±7.0% vs. 70.2±13.6%, respectively, p=0.005).

Conclusion: Endovascular procedures including drug-eluting balloon and bailout stenting seem to be effective alternative treatment modalities for treatment of infrainguinal peripheral arterial disease and can be also used in patients with long lesions and/or total occlusion of femoropopliteal arteries.

Keywords: Bail-out therapy, drug-eluting balloon, endovascular procedure, percutaneous transluminal angioplasty, peripheral arterial disease.

ÖZ

Amaç: Bu çalışmada, periferik arter hastalığının femoropopliteal tutulumunda endovasküler revaskülarizasyonun erken ve orta dönem klinik sonuçları sunuldu.

Çalışma planı: Ağustos 2016 - Nisan 2018 tarihleri arasında femoropopliteal lezyonlar nedeniyle perkütan transluminal anjiyoplasti yapılan toplam 128 hasta (113 erkek, 15 kadın; ort. yaş: 63.4±9.9 yıl; dağılım, 32-87 yıl) retrospektif olarak incelendi. Luminor® paklitaksel kaplı ilaç salınımlı balon kateteri veya iVolution® kendiliğinden açılan nitinol stent ile kurtarıcı tedavi yapıldı. Genel açıklık oranları ve tekrar girişim olmaması oranları, Kaplan-Meier analizi kullanılarak analiz edildi. On iki ve 24. ayda primer açıklık ve hedef lezyona tekrar girişim olmaması oranları da değerlendirildi.

Bulgular: Medyan takip süresi 11 (dağılım, 1-35) ay olup, girişimlerin 133'ünde (%93) teknik başarı sağlandı. On iki ve 24. aylarda ortalama genel açıklık oranları sırasıyla %85.6±3.7 ve %66.8±6.7 ve ortalama hedef lezyona tekrar girişim olmaması oranları sırasıyla %91.6±2.9 ve %78.1±6.3 idi. Primer açıklık ve hedef lezyona tekrar girişim olmaması oranları, kurtarıcı stent tedavisi grubunda, ilaç salınımlı balon grubuna kıyasla, 12. ayda (sırasıyla, %97.3±2.7'e kıyasla %94.8±6.1, p=0.025 ve sırasıyla, %97.1±2.9'a kıyasla %84.2±5.5, p=0.005) ve 24. ayda (sırasıyla %76.9±7.9'a kıyasla %55.8±13.4, p=0.025 ve %85.2±7.0'ye kıyasla %70.2±13.6, p=0.005) anlamlı olarak daha yüksek idi.

Sonuç: İlaç salınımlı balon ve kurtarıcı stentleme dahil olmak üzere endovasküler girişimler, infrainguinal periferik arter hastalığında etkili tedavi seçenekleri olarak görünmekte ve femoropopliteal arterlerin uzun lezyonları ve/veya tam tıkanıklığı olan hastalarda da uygulanabilmektedir.

Anahtar sözcükler: Kurtarıcı tedavi, ilaç salımlı balon, endovasküler işlem, perkütan transluminal anjiyoplasti, periferik arter hastalığı.

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Atherosclerotic peripheral arterial disease, which affects about 50 million individuals in the Unites States and Europe, is a major challenging issue that can lead to disabling ischemia, limb loss, and impaired quality of life.[1] Novel interventional modalities such as percutaneous transluminal angioplasty (PTA) with a drug-eluting balloon (DEB) or plain balloon, stent implantation, and atherectomy procedures have dramatically altered the treatment paradigms, particularly for extensive femoropopliteal (FP) lesions. Endovascular strategies have become a well-recognized therapeutic alternative to bypass surgery with the aforementioned technical advancements.[2]

The incidence of restenosis of FP lesions following PTA is significant and cannot be ignored, particularly for complex lesions.[3,4] However, paclitaxel-coated balloons have been shown to be superior, compared to plain balloons, in preventing restenosis.[5-8] Furthermore, durability of endovascular interventions have been reported to be improved using self-expanding nitinol stents.[9]

While the endeavor for effective and durable therapeutic strategies continues, in this study, we aimed to analyze the early and mid-term clinical outcomes of endovascular revascularization for FP involvement of peripheral arterial disease performed by cardiovascular surgeons.

PATIENTS AND METHODS

A total of 128 patients (113 males, 15 females; mean age: 63.4±9.9 years; range, 32 to 87 years) who underwent PTA for FP lesions between August 2016 and April 2018 were analyzed retrospectively and assigned prospectively. All patients underwent PTA with the Luminor® paclitaxel-coated DEB catheter (iVascular, S.L.U., Barcelona, Spain) or bailout therapy with iVolution® self-expanding nitinol stent (iVascular, S.L.U., Barcelona, Spain). The patients whose data could have not been reached and who have not agreed to participate in this study were excluded. A written informed consent was obtained from each patient. The study protocol was approved by the Türkiye Yüksek İhtisas Training and Research Hospital Ethics Committee (No: 29620911-929, Date: 31.01.2016). The study was conducted in accordance with the principles of the Declaration of Helsinki. Demographic and clinical data including age, sex, hypertension, dyslipidemia, chronic obstructive pulmonary disease, the presence of coronary artery disease, chronic kidney disease, coronary artery bypass grafting, cigarette smoking, and previous percutaneous interventions were recorded. Pre- and postoperative ankle-brachial indices (ABIs) and creatinine levels which were measured on Day 3 after the intravenous contrast administration were also noted. The overall patency rates and freedom from reintervention were analyzed using the Kaplan-Meier. The primary patency and freedom from reintervention to target lesion rates at 12 and 24 months were also evaluated.

Operative technique

Prior to PTA, the ABIs of all patients were evaluated using the Duplex ultrasound and, then, were evaluated with the digital subtraction angiography. The PTA was performed under local anesthesia with monitorization by cardiovascular surgeons in the hybrid operating theatre. After placement of a 7-Fr single lumen introducer sheath ipsilaterally or contralaterally to the lesion according to level of the FP lesion, intravenous heparin was administered with an activated clotting time of 180 to 200 sec. None of the lesions were predilated. All lesions were dilated with DEB (vessel/balloon ratio of 1:1 on the basis of visual estimate) for a total inflation time of 3 min at 6 to 14 atmosphere pressure. Balloons were inflated only once. However, when control angiography revealed a residual lesion (>50% stenosis), flow-limiting dissection or atherosclerotic plaque deformation, a second DEB was carried out and dilatation was maintained for a longer period (≥3 min). In these cases in which residual stenosis or flow-limiting dissection persisted following repeated dilatation, self-expanding nitinol stents were implanted as bailout therapy.

Statistical analysis

Statistical analysis was performed using the SPSS version 16.0 (SPSS Inc., Chicago, IL, USA). Distribution of continuous variables were tested using the Shapiro-Wilk test. Descriptive data were presented in mean ± standard deviation (SD) or median (min-max) for continuous variables and in number and percentage for nominal variables. Dependent in-group variables were compared using the Wilcoxon test. A p value of <0.05 was considered statistically significant.

RESULTS

There were 143 FP lesions in a total of 128 patients included in the study. The incidence of hypertension and diabetes was 59.4% and 55.5%, respectively. Most of the patients (63.3%) presented with moderate claudication (Rutherford Class 3),[2] and proximal superficial femoral artery (SFA) was the most

Table 1. Baseline demographic and clinical data of patients

	n	%	Mean±SD	Min-Max
Age (year)			63.4±9.9	32-87
Sex				
Male	113	88.3		
Hypertension	76	59.4		
Coronary artery disease	56	43.8		
Chronic obstructive lung disease	25	19.5		
Coronary artery bypass grafting	18	14.1		
Hyperlipidemia	70	54.7		
Diabetes mellitus	71	55.5		
Chronic renal failure	11	8.6		
Previous intervention for peripheral artery disease	29	22.7		
Current smoking	96	75		
Wound	10	7.8		
Left ventricular ejection fraction (%)			50.5±8.6	20-66
Rutherford Class				
0	0	0		
1	0	0		
2	25	17.5		
3	91	63.6		
4	22	15.4		
5	5	3.5		
6	0	0		

SD: Standard deviation; Min: Minimum; Max: Maximum.

common lesion site in 82.5% of the patients. Baseline demographic and clinical characteristics of the patients are shown in Table 1 and lesion features are presented in Table 2.

The median follow-up was 11 (range, 1 to 34) months. During follow-up, no mortality was seen and none of the patients withdrew his/her consent or lost to follow-up.

Angioplasty was successful in 133 (93%) of the interventions. Bailout stenting was required in 51 (35.7%) of lesions and only nine (6.3%) of the lesions needed percutaneous reintervention. However, eight lesions (5.6%) needed FP bypass during the follow-up. The mean ABIs significantly improved in the post-procedural period, compared to pre-procedural measurements (0.78±0.19 vs. 0.40±0.11, respectively) ($p<0.001$) (Table 3). Clopidogrel was prescribed to all patients, whereas cilostazol was only prescribed for patients with poor distal vasculature (Table 4).

In one patient, an isolated perforation developed at the target lesion site and resolved spontaneously.

Table 2. Lesion characteristics (n=143)

	n	%
TASC classification		
A	55	38.5
B	57	39.9
C	25	17.5
D	6	4.1
Lesion localizations		
Common femoral artery	7	4.9
Superficial femoral artery proximal	118	82.5
Superficial femoral artery distal	56	39.2
Popliteal artery	20	14
Lesion length		
0	5	3.5
1	47	32.9
2	30	21
3	41	28.6
4	15	10.5
5	5	3.5
Infrapopliteal lesion	75	52.4

TASC: Trans-Atlantic Inter-Society Consensus Document; 0: l ≤5 cm, 1: 5 <l ≤10 cm, 2: 10 <l ≤15 cm, 3: 15 <l ≤20 cm, 4: 20 <l ≤25 cm, 5: l >25 cm.

Table 3. Peri-procedural data

	n	%	Mean±SD	Min-Max
Drug-eluting balloon*	132	92.3		
Stenting	51	35.7		
Technical success	133	93.0		
Complication	3	2.1		
Pseudoaneurysm	2	1.4		
Rupture	1	0.7		
Pre-procedural ABI**			0.4±0.1	0.12-0.7
Post-procedural ABI			0.8±0.2	0.12-1.65
Pre-procedural creatinine level			1.2±0.9	0.51-7.2
Post-procedural creatinine level			1.2±1.1	0.51-9.36

SD: Standard deviation; Min: Minimum; Max: Maximum; ABI: Ankle-brachial indices; * Paclitaxel coated-drug eluting balloon angioplasty; ** Ankle-Brachial Index.

Table 4. Post-procedural data

	n	%	Mean±SD	Median	Min-Max
Clopidogrel medication	143	100			
Cilostazol medication	50	35			
Statin medication	94	66.2			
Hospitalization period (day)			1.8±1.6		1-11
Claudication at control (Rutherford Class ≥2)	26	18.2			
Follow-up period (month)			13.2±8.7	11	1-34
Freedom from >50% restenosis	114	79.7			
Decision after control examination					
Medical follow-up	126	88.1			
Surgical intervention	8	5.6			
Percutaneous intervention	9	6.3			

SD: Standard deviation; Min: Minimum; Max: Maximum.

Table 5. Clinical outcomes at Months 12 and 24

	Bail-out stenting		No bail-out stenting		
	n	Mean±SE	n	Mean±SE	*p*
Primary patency					
12 month	50	97.3±2.7	87	94.8±6.1	0.025
24 month	39	76.9±7.9	51	55.8±13.4	0.005
Freedom from reintervention to TL					0.025
12 month	49	97.1±2.9	77	84.2±5.5	0.005
24 month	43	85.2±7.0	65	70.2±13.6	

SE: Standard error; TL: Target lesion.

Two patients developed a pseudoaneurysm following the removal of the introducer sheath and these pseudoaneurysms were repaired surgically. There was a marked increase in creatinine levels post-procedurally (p=0.033) (Table 3).

According to the Kaplan-Meier estimates of 12 and 24 months of follow-up, the mean overall patency rates were 85.6±3.7% and 66.8±6.7%, respectively and the mean freedom from reintervention to target lesion rates were 91.6±2.9% and 78.1±6.3%, respectively (Figures 1 and 2).

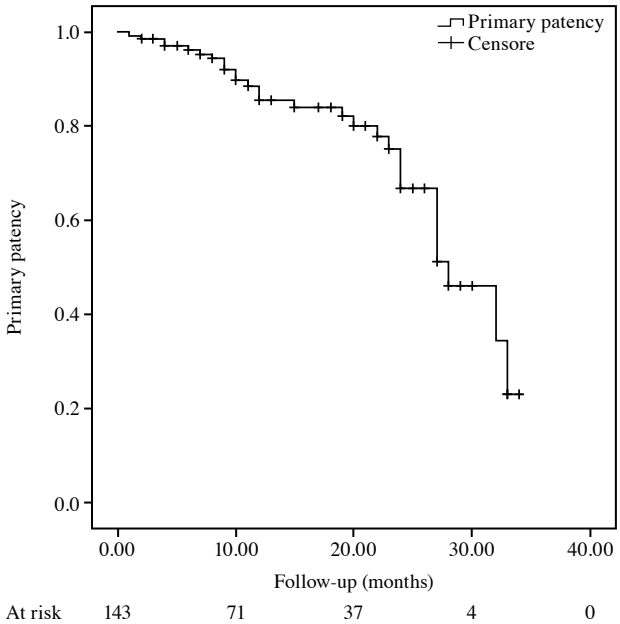

Figure 1. Primary patency rates of all cohort.

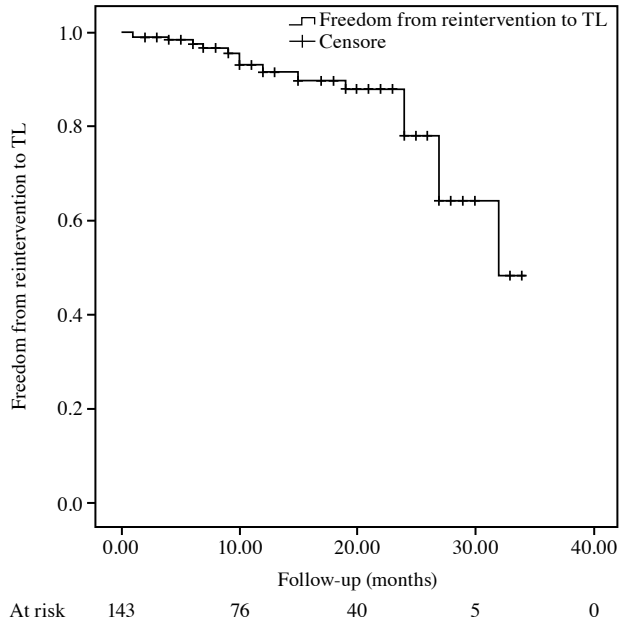

Figure 2. Freedom from reintervention to target lesion rates of all cohort.
TL: Target lesion.

Furthermore, the primary patency and freedom from reintervention to target lesion rates were significantly higher in bailout stenting group, compared to PTA with only DEB group at 12 months (97.3±2.7% vs. 94.8±6.1%, respectively; p=0.025 and 97.1±2.9% vs. 84.2±5.5%, respectively, p=0.005) and at 24 months (76.9±7.9% vs. 55.8±13.4%, respectively, p=0.025 and 85.2±7.0% vs. 70.2±13.6%, respectively, p=0.005) (Table 5). The restenosis rates in FP lesions greater than 15 cm were 20% with bare metal stents (BMSs) and 30% with DEBs.

Although all patients had claudication pre-procedurally, a total of 81.8% of them had mild symptoms or became asymptomatic at the end of the follow-up (p<0.001).

DISCUSSION

In recent years, the treatment of chronic lower extremity ischemia has shifted toward endovascular approach in many centers.[10] In our cardiovascular clinic, the application of percutaneous revascularization procedures has developed over the past five years and all of them have been achieved by cardiovascular surgeons, enabling immediate treatment of intraoperative and acute postoperative complications or failed percutaneous procedures. Hence, these advantages have led us to study the efficacy of the use of DEBs and BMSs.

The last report of Trans-Atlantic Inter-Society Consensus (TASC) has offered the endovascular therapy as treatment of choice for infrainguinal lesions and even for more complex stenosis or occlusions (TASC-C lesions).[11] At the present day, even chronic total occlusions can be cured successfully using endovascular treatment.[12] The current guidelines strongly recommend the use of DEBs among the therapeutic options for FP diseases, particularly for high risk patients.[13,14] In addition, DEBs have been suggested to be cost-effective and safe, particularly in the short term, for the treatment of the FP lesions by large randomized-controlled trials including Global Clinical Study for the Treatment of Comprehensive Superficial Femoral and/or Popliteal Artery Lesions Using the IN.PACT Admiral™ Drug-Eluting Balloon (IN.PACT) and Pilot Study for the Treatment of Subjects With Symptomatic Femoropopliteal Artery Disease (COMPARE) studies.[15-18]

According to our study results, the early outcomes of PTA are favorable and mid-term results are acceptable and in agreement with previous studies. The Effectiveness of Paclitaxel-coated Luminor® Balloon Catheter Versus Uncoated Balloon Catheter in the Arteria Femoralis Superficialis (EffPAC) study similarly reported that Luminor® DEB (iVascular, S.L.U., Barcelona, Spain) demonstrated 90.3% primary patency rate and 98.7% freedom from

reintervention at 12 months and 90.2% and 97.2% at 24 months, respectively.[19,20] Werk et al.[21] and Schroë et al.[22] reported a short-term primary patency rate of 94.3% and 81%, respectively.[21,22] Another multi-center, large-scale, prospective study showed a patency rate of 65.2% at 12 months.[8] Similarly, Tepe et al.[6] found a primary patency rate in 154 patients of 85% at 24 months.

Complex FP lesions are challenging issues for PTA procedures. A two-year, multi-center, prospective study of long FP lesions revealed a primary patency rate of 70.4% and a restenosis rate of up to 50%, following stenting of long superficial femoral artery lesions.[23] A recent clinical trial underlined the long-term restenosis rates in challenging FP lesions: 17% with drug-eluting stents and 20% with DEBs.[24] Similarly, we detected restenosis rates in FP lesions of greater than 15 cm as 20% with BMSs and 30% with DEBs. At 24 months, the overall freedom from reintervention to target lesion rates were significantly higher in the bailout stenting group, compared to PTA with only DEB, (85.2% vs. 70.2%, respectively; p=0.005). In the Efficacy of the Self-Expanding iVolution® nitinol stent for treatment of femoropopliteal lesions (EVOLUTION) study reported that iVolution® self-expanding nitinol stent (iVascular, S.L.U., Barcelona, Spain) had showed 86.3% primary patency rate and 88.0% freedom from revascularization at 12 months and 76.7% and 77.2% at 24 months, respectively.[25,26] However, Deloose[27,28] reported that, in the Clinical Trial Investigating the Combination Therapy With Luminor® DCB and iVolution Stent in TASC C and D Femoropopliteal Lesions (TINTIN), a primary patency of 96.5% and freedom from revascularization rate of 98.9% at six months and these figures were 90.5% and 94.4% at 12 months, respectively.

Consistent with Black et al.,[10] we concluded that PTA procedures did not preclude secondary surgical revascularization to salvage the limb. In their series, five of 95 patients (5.3%) underwent surgical bypass. In our report, eight patients (6.3%) underwent successful FP bypass at the end of the follow-up. In the aforementioned study, one patient (1.1%) developed a femoral hematoma after sheath removal and required open surgical repair of a femoral pseudoaneurysm,[15] while two patients (1.4%) underwent surgical repair for the same reason in our study. Also, we found an isolated perforation in one patient (0.7%) at the target lesion site and it was resolved spontaneously as in the aforementioned study reporting one patient (1.1%) with an arterial rupture.[15]

Improvement in the ABI is essential following treatment of peripheral arterial disease. Similar to the findings of Pastromas et al.[29] and Iida et al.,[30] there was a significant improvement in the ABIs and Rutherford classes in all lesions, including the complex ones (p<0.001) at 12 months. In our study, 81.8% of the patients had mild symptoms of claudication, or became asymptomatic at the end of the follow-up period.

Although many randomized-controlled studies have shown that the use of DEB and BMS is suitable in the treatment of long (greater than 15 cm), complex FP lesions; long-term follow-up with large-scale, prospective, comparative, randomized, protocol-driven device trials would provide more useful outcomes in determining the safety and durability of treatment in the future.[31]

With the advances in PTA technology, surgical experience for endovascular interventions of cardiovascular surgeons have developed rapidly.[32,33] The surgeons should be able to offer patients advice on both percutaneous and surgical approaches used in the treatment of peripheral arterial disease, thus providing the patient with a variety of options catered to their needs. The results of the present study show that endovascular procedures can be performed by cardiovascular surgeons with high success and low complication rates. Cardiovascular surgeons should be encouraged to involve even more in this field, since they possess the understanding of the cardiovascular system and experience in the surgical treatment of arterial disease requiring practice of PTA and in combating pre-, intra-, and post-procedural complications.

Nonetheless, our study has several limitations. Firstly, the numerical stenosis diameter was unable to be established in this study and, therefore, it could not be compared to the findings of other studies. Secondly, the calcification load of the arteries and the reference vessel diameters could not be determined. The guidewire was advanced easily across the lesions in all, including the total occlusions, probably due to the low calcium load; however, we should also consider that there may be thrombosis. Therefore, vessel preparation using plain balloon or atherectomy was not performed, which may be also a limitation to the study. Moreover, the inclusion of patients who previously underwent percutaneous interventions can be deemed as a limitation; however, statistical analysis revealed that there was no significant difference in the primary patency rates at 12 and 24 months between the redo cases and the others (91.1±6.3 vs. 76.9±10.7 and 81.8±4.8 vs. 63.7±8.3 respectively, p=0.488).

Finally, a quality of life survey was unable to be used for the evaluation of quality of life of the patients.

In conclusion, endovascular procedures including drug-eluting balloon and bailout stenting seem to be effective alternative treatment modalities for the treatment of infrainguinal peripheral arterial disease, and also can be used in patients with long lesions and/or total occlusion of femoropopliteal arteries. However, long-term follow-up with a large-scale, prospective, comparative, randomized device trials would be more useful in determining the safety and durability of treatment and its effects on quality of life.

Declaration of conflicting interests

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