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Title: Drug-Eluting Balloon Angioplasty for Complex Femoropopliteal Lesions in End Stage Renal Disease Patients

Running Head: DEB Angioplasty, Femoropopliteal Lesions and ESRD

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Abstract/Öz

Introduction: This study is to examine the clinical outcome results of drug eluting balloon (DEB) angioplasty to complex femoropopliteal lesions in patients with end stage renal disease (ESRD).

Methods: A retrospective chart review identified 30 patients who were treated for symptomatic peripheral artery disease with DEB angioplasty in ESRD patients between September 2012 and February 2016. Restenosis or reocclusion at femoropopliteal site after 12 months' follow-up was the primary end point whereas amputations (minor or major) after 12 months' follow-up was the secondary end point.

Results: Thirty ESRD patients underwent endovascular therapy with DEB. The mean lesion length was 135.6±46.0mm. Primary patency was 73.1% and the secondary end point was 10.7 % at 1-year. Mean follow-up of patients were 16.0 ± 5.0 months and all cause mortality rate was 7.1% (n=2). A significant increase in the ankle-brachial index (ABI, 0.45±0.04 preoperative to 0.88±0.05 postoperative) after intervention demonstrated a hemodynamic success where as the decrease in mean Rutherford Becker Class (RBC) demonstrated a clinical success.

Conclusion: DEB angioplasty is efficient and safe even in long and calcified obstructive lesions including the distal superficial femoral and popliteal artery in patients with ESRD.

Keywords: Drug eluting balloon, balloon angioplasty, end stage renal disease, peripheral intervention

Amaç: Bu çalışmada son dönem böbrek yetersizliği ve kompleks femoropopliteal arter lezyona sahip hastaların girişimsel tedavisinde ilaç salımlı balon kullanımının güvenilirliği ve etkinliğini araştırıldı.

Yöntemler: Kabul edilme kriterleri, Rutherford Klas 2 veya üstü semptomu sahip olmak ile birlikte hastalarda femoropopliteal arter'de kritik darlık veya tıkanıklık olması idi. Hedef

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damar tıkanıklığı veya daralması primer sonlanma iken majör ve minör amptütasyon sekonder sonlanım olarak kabul edildi.

Bulgular: Eylül 2012 ve Şubat 2016 tarihleri arasında, diyabetik ve kompleks femoropopliteal lezyonu olan ve girişimsel tedavide ilaç salınımlı balon kullanılmış 36 hasta tanımlandı. 4 hasta takibi bıraktığından dolayı 30 hasta ile devam edildi. Ortalama lezyon uzunluğu 114.6 ± 27.8 mm idi. 12 ay sonunda primer açıklık 73.1 % sekonder sonlanım 10.7 % gözlemlendi. Ortalama 16.0 ± 5.0 aylık takip sonrası tüm sebeplere bağlı mortalite 7.1 % olarak gözlemlendi (n=2). Ayak bileği brakial indeksi operasyon öncesi 0.42 ± 0.04 'den operasyon sonrası 0.88 ± 0.05 'a yükseldi.

Sonuç: Son dönem böbrek yetersizliği ile birlikte uzun kalsifik ve distal yüzeysel femoral ve popliteal darlığı olan hastalarda dahi girişimsel tedavisinde ilaç salınımlı balon kullanımı etkilidir.

Anahtar Kelimeler: ilaç kaplı balon, balon anjiyoplasti, son dönem böbrek yetersizliği, periferik girişim

Introduction

Peripheral arterial disease (PAD) is more common in patients with ESRD who are undergoing hemodialysis than the general population. By-pass surgery is mostly not suitable since most patients with ESRD have multiple comorbidities with distal occlusions (1). Endovascular treatment (EVT) is being preferred method of revascularization in patients with the femoropopliteal lesions. Percutaneous trans luminal angioplasty (PTA) is mostly preferred for revascularization of femoropopliteal disease with relatively low risk. However, results of balloon angioplasty (BA) alone, for the complex femoropopliteal disease have been disappointing (2,3). The possibility for treating superficial femoral artery (SFA) obstruction and maintaining patency rates has dramatically increased because of further device and technique development in recent years (4). Recently DEB has been introduced to reduce femoropopliteal restenosis compared to standard balloon angioplasty (POBA). Therefore we

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analyzed our experiences of 30 femoropopliteal DEB angioplasties in ESRD patients in our study.

Patient population

Our study concerns a retrospective single-center study of 34 ESRD patients (hemodialysis patients, four patients lost to follow up leaving 30 patients) with femoropopliteal arterial disease and life-style-limiting claudication underwent DEB angioplasty between September 2012 and February 2016. The presence of ESRD with Rutherford Becker Class 2 or greater (Fontaine IIB) and femoropopliteal critical lesions were the inclusion criteria for our study. Mean age is 58.4 ± 6.2 years, and 54.5% of patients are men. Hypertension (83.3%) and diabetes (66.7%) are the most common risk factors in this patient cohort. Baseline characteristics are summarized in Table 1.

Methods

The present study complies with the principles outlined in the Declaration of Helsinki and was approved by the local ethics committee and consent was obtained from all patients for participation in the study. Arterial access was obtained by antegrade puncture in 24 patients and contralateral femoral puncture in 4 patients. In 2 patients retrograde popliteal approach was preferred because of failed antegrade approach. Duplex USG and digital subtraction angiography (DSA) were used for evaluation of infra-inguinal vessel calcifications. ABI was measured before and after the intervention.

Intravenous heparin (100IU/kg) was given after diagnostic angiography was performed [Figure 1A, 1B, 1C, 2A, 2B]. Atherectomy was preferred by operator' choice in severely calcified 6 lesions with suitable vessel diameter. We used a support catheter with hydrophilic guide wire for chronic total occlusions. All lesions predilated before treatment with DEB angioplasty (3 minutes inflation time, 4-7mm 20-120mm). The ratio of DEB to vessel diameter was planned to be 1:1. The overlap zone was more than 10 mm if multiple balloons were used per lesion. Another dilation of up to 3 minutes was performed, if flow-limiting dissection or residual stenosis more than 50% was seen. A self-expandable stent was deployed when flow limiting dissection or when there was >50% residual stenosis was seen

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after DEB angioplasty. A completion angiogram concluded the procedure [Figure 2C, 3A, 3B]. Patients with additional below the knee lesions were treated with DEB angioplasty (N=5). Arterial access site was managed with digital pressure. Procedural details are summarized in Table 2. Proper medication for risk factors (coronary artery disease, hypertension, and hyperlipidemia) was given with dual antiplatelet therapy (3 months with aspirin 100mg + Clopidogrel 75mg then with aspirin alone). At each follow-up visit, a duplex ultrasonography of the treated femoropopliteal site was performed (peak systolic velocity ratio 2.5 and >50% decrease in vessel diameter was an angiography indication) and with additional peripheral angiography when indicated.

Statistical analysis

NCSS (Number Cruncher Statistical System) 2007 (Kaysville, Utah, USA) program was used for the statistical analysis. Data were reported as mean, standard deviation, median, frequency, and ratio. Wilcoxon signed ranks test was used to test the difference between preop and postop values. The results were evaluated in 95% confidence interval and at a significance level of $p < 0.05$.

Definitions

Technical success was defined as restoration of straight line of blood flow to the foot with a residual stenosis less than 30%. Restenosis is defined as >50% lesion. Major amputation was defined as limb loss above the ankle, whereas minor amputation referred to below the ankle amputation or removal of more distal parts of the lower extremity.

Results

30 ESRD patients (hemodialysis patients, 4 patients lost to follow-up) underwent EVT with DEB angioplasty for femoropopliteal lesions were enrolled. The mean follow-up time was 16.0 months. The technical success rate was 93.3 %. Procedural details are summarized in Table 2. Stent implantation was needed for 2 patients because of flow limiting dissection. 2 patients died due to acute myocardial infarction (10th, 11th month). These 4 patients were excluded from the primary and secondary endpoints. Seven patients with restenosis and

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reocclusion (N=7 73.1% patency 26 patients, Table 3, >50% at narrowest point) were diagnosed by clinical investigation and duplex USG. Peripheral angiography was performed in these cases after diagnosis. These patients had revascularized with EVT where bailout stent was not needed in any of them. Three amputations involving three patients were seen in this patient cohort (2 minor 1 major). Minor extravasation occurred when crossing a total occlusion with guide-wire in two patients. Obviously these extravasations were not seen after normal treatment protocol with balloon angioplasty. Access related hematoma occurred in three patients, which resolved on manually digital pressure. The mean baseline ABI was increased after the intervention, which demonstrated a hemodynamic success, and a clinical improvement with significant decrease in RBC was seen in the patients (0.43 ± 0.06 p 0.001 Table 4, 5).

Discussion

ESRD is a strong determinant of atherosclerotic vascular disease and is associated with a high incidence of cardiovascular diseases. EVT of infra-inguinal lesions in ESRD patients remains a controversial issue; due to this fact we examined the clinical and procedural outcomes of DEB angioplasty of femoropopliteal lesions in this patient cohort.

ESRD patients on dialysis with DM, frequently have calcific, long and diffuse arteriosclerotic disease in the femoropopliteal site. Therefore these patients are often not suitable for surgery due to other comorbidities and advanced age, making EVT preferable. However, primary patency rate of angioplasty with standard balloons is low in multiple studies compared to DEB (3,5-8). Therefore we have chosen DEB angioplasty for treatment of femoropopliteal lesions in this study.

Nitinol or drug-eluting stents have provided better results compared to standard PTA for femoropopliteal disease, but they change the structure of the vessel and it still carries a relevant risk of restenosis, especially in long and complex lesions where commonly seen in ESRD patients [5,6]. Another important issue is that in-stent restenosis is more difficult to treat than restenosis in non-stented segments. Studies with DEB angioplasty have patency outcomes at least similar to stents but without leaving permanent metallic implants (9-11). Due to these facts we preferred DEB angioplasty instead of stent deployment in our study.

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EVT for peripheral arterial disease in ESRD patients may be technically hard because of calcified nature of very tight stenosis or mostly occlusion, that makes the crossing by a balloon catheter and even with guide wire problematic. Through mostly antegrade femoral approach (80.0 %) with using a support catheter and a hydrophilic guide wire, we crossed the lesions with a high technical success rate of 93.3% in this setting of patients.

Revascularization for peripheral arterial lesions in patients with ESRD has been controversial because of the low rates of limb preservation and short life expectancy and increased risk of dissection in this patient cohort with severe calcification (12-14). EVT, particularly with DEB angioplasty is costly. Although it seemed expensive, in a cost-effectiveness study, it appears to be better compared to local wound care alone, primary amputation or even surgical approach, especially in patients with non-healing foot wounds. (15). A recent analysis came to the conclusion that DEB angioplasty offers the lowest budget impact in the treatment of femoropopliteal lesions (16).

An alternative concept to potentially improve DEB efficacy in lesions with severe calcification (instead of predilatation with a standard balloon) is to combine DEB angioplasty with directional atherectomy. After reducing plaque burden, paclitaxel can potentially inhibit cell proliferation more effectively. The DEFINITIVE AR, which is a pilot study, suggest that there is a benefit with adjuvant directional atherectomy in patients with long and calcified femoropopliteal lesions prior to using a DEB in comparison to the DEB angioplasty alone. However, the study was not sufficiently powered to detect differences in clinical outcomes. In our study, there was only one patient needed reintervention out of 6 patients treated with atherectomy before DEB angioplasty (16.7 %). Studies with larger population are needed to evaluate the efficacy, safety, and cost-effectiveness of atherectomy as an adjuvant therapy in this patient cohort.

There is still no consensus about the duration of dual antiplatelet therapy following DEB angioplasty (ranging from 1 to 3 months or more in different studies (17,18)). We administered a 3-months DAPT in our study. Such duration appeared safe and no acute thrombosis or major bleeding was observed during the follow-up period.

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Limitations

This study has some limitations. First of all it was a retrospective, rather small populated and without a control arm study. Second, we could not perform follow-up angiography in all patients and third, toe brachial index was not measured although it is needed for reliable diagnosis for PAD in this patient group (19).

Conclusion

DEB seems still efficient and safe in the treatment of complex femoropopliteal lesions in ESRD patients. Larger and longer studies are needed to evaluate the efficacy, safety and cost-effectiveness of DEB angioplasty in this patient cohort.

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Table 1. Baseline characteristics

Variable	n=30	
	n (%)	
Age, years	<i>Mean±SD</i>	57.4±6.1
Gender	Male	19 (63.3)
	Female	11 (36.7)
Diabetes mellitus		21 (70.0)
Hypertension		26 (86.7)
Hypercholesterolaemia		15 (50.0)
Coronary artery disease		22 (73.3)
Cerebrovascular disease		1 (3.3)
Congestive heart failure		4 (15.9)
Current smoker		18 (60)

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Table 2. Procedural Details

			n=30
Variable			n (%)
Mean length	<i>Mean±SD</i>		135.56±46.02 ,mm
Total occlusion			11 (36.7)
Atherectomy performed			6 (20.0)
Severe calcification			14 (46.7)
TASC	A		4 (13.3)
	B		11 (36.7)
	C		10 (33.3)
	D		5 (16.7)
Lesion type	De novo		25 (83.3)
	Restenosis		3 (10.0)
	Instant stenosis		2 (6.7)
BTK lesion needed intervention			5 (16.7)
Multiple DEB			16 (53.3)

TASC=The Trans-Atlantic InterSociety Consensus Document on Management of Peripheral Arterial Disease
BTK=below the knee, DEB=drug eluting balloon

Table 3. Clinical Outcomes, 12 months

Variable	n (%)
Primary Endpoint	19 (73.1)
All cause mortality	2 (6.7)
Minor Amputation	2 (7.7)
Major Amputation	1 (3.8)

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Table 4. RBC Pre-Post (12months) Treatment

	n (%)	
Preop RBC	0,1	0 (0)
	2	5 (16.7)
	3	17 (56.7)
	4	5 (16.7)
	5	2 (6.7)
	6	1 (3.3)
	<i>Mean±SD</i>	3.33±0.60
12 months follow up RBC	0	0 (0)
	1	3 (11.5)
	2	20 (77)
	3	3 (11.5)
	<i>Mean±SD</i>	2±0.49
		p 0.001

RBC=Rutherford Becker Classification, * $p<0,01$

Table 5. Change in ABI

ABI	n=30
	Mean±SD
Before procedure	0.45±0.04
After procedure	0.88±0.05
	<i>p 0.001**</i>
Difference	0.43±0.06

** $p<0,01$ ABI=ankle brachial index

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Figure 1. Preinterventional angiogram of Superficial femoral artery with critical osteal stenosis and severe calcification (A). Femoro-popliteal artery with critical stenosis and severe calcification (B) Popliteal artery occlusion (C)

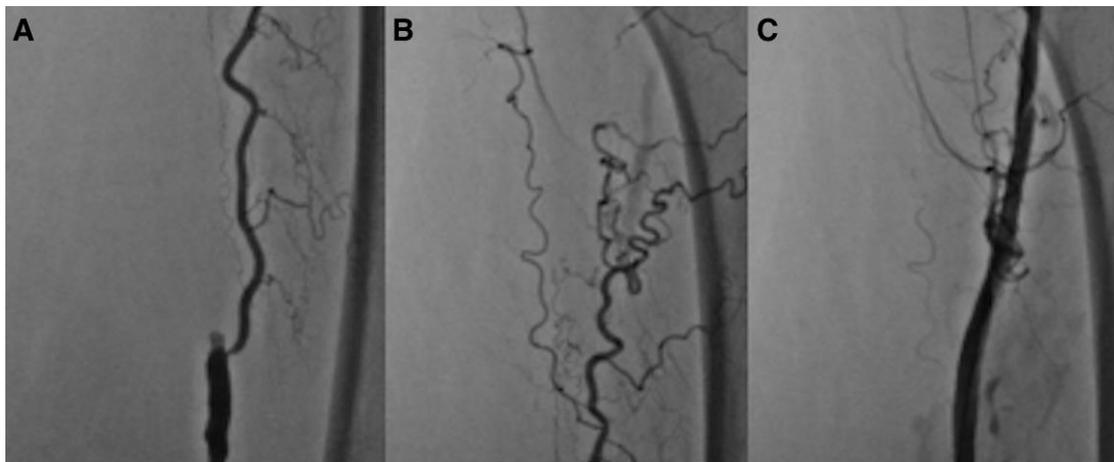


Figure 2. Superficial femoral artery chronic total occlusion (A). Popliteal artery is barely visible with collaterals (B). Superficial femoral artery after intervention (C)

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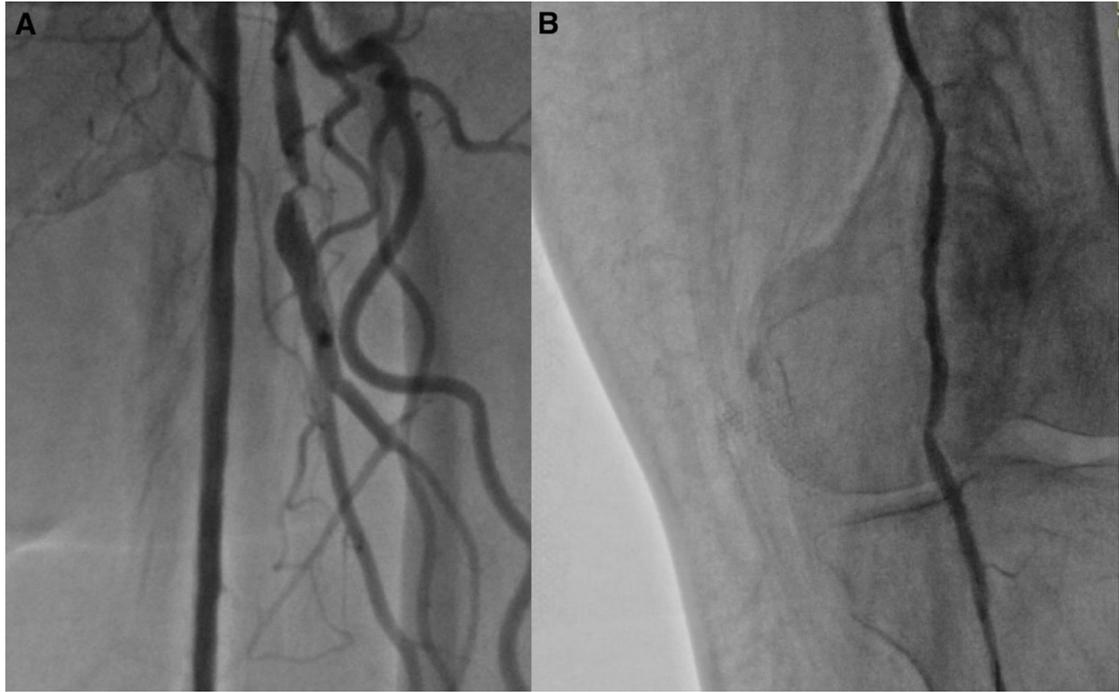


Figure 3. Superficial femoral artery after intervention (A). Popliteal artery after intervention (B)

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