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Comparison of Paclitaxel Eluting Balloon Angioplasty Combined with Directional Atherectomy and Self Expandable Nitinol Stent Implantation in Treatment of Calcified Stenotic Superficial Femoral Artery Lesions

Kalsifiye Stenotik Süperfisyal Femoral Arter Lezyonlarının Tedavisinde Direksiyonel Aterektomi ile Kombine Edilmiş Paklitaksel Salınımlı Balon Anjioplasti ve Kendiliğinden Açılan Nitinol Stent Uygulamasının Karşılaştırılması

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ABSTRACT

Aim: The frequency and variety of endovascular interventions have increased with the rise in peripheral arterial occlusive disease incidence and to lessen undesirable outcomes after peripheral vascular surgery. Extensive calcific stenotic lesions affect patency rates of endovascular interventions and enhance complication rates. In this study we aimed to compare paclitaxel eluting balloon angioplasty (PEBA) combined with directional atherectomy (DA) with self expandable nitinol stent (SENS) implantation in terms of patency rates.
Material and Methods: Fifty-six patients (28 patients in each group) underwent endovascular interventions for calcific stenotic superficial femoral artery lesions between March 2013 and May 2014 at Cardiovascular Surgery clinic in Namık Kemal University Hospital were included in the study. Mean age was 65.4±7.6 and male to female ratio was 46/10. Patients were followed up with ankle brachial index (ABI), Rutherford score (RS) and Doppler ultrasonography (DUSG) from the pre-intervention period to sixth month after intervention.
Results: Mean lesion length in DA and PEBA group was 66.4±24.8 mm and 65.0±20.6 mm in SENS group. Primary and secondary patency rates were 85.7% and 92.9% in DA and PEBA group, and 57.1% and 71.4% in SENS group in six months follow up. There was a statistically significant difference between groups. Significant improvement was detected in terms of ABI and RS in both groups.
Conclusion: We conclude from this study results that PEBA combined with DA is better than SENS implantation, because of its successful early-term results, no intravascular foreign bodies, and continues the chance of surgery without affecting the anastomosis field.
Keywords: Calcification; atherectomy; stent.

ÖZ

Amaç: Periferik arter hastalığı insidansının artması ve periferik vasküler cerrahi sonrası istenmeyen sonuçları azaltmak için endovasküler girişimlerin sıklığı ve çeşitliliği artmıştır. Yaygın kalsifik stenotik lezyonlar, endovasküler prosedürlerin açık kalma oranlarını etkilemekte ve komplikasyon sıklığını artırmaktadır. Bu çalışmada direksiyonel aterektomi (DA) ile kombine edilmiş paklitaksel salınımlı balon anjioplasti (PEBA) ve kendiliğinden açılan nitinol stent (SENS) uygulamalarının açık kalma oranları bakımından karşılaştırılması amaçlandı.
Gereç ve Yöntemler: Namık Kemal Üniversitesi Hastanesi Kalp Damar Cerrahisi kliniğinde Mart 2013 ile Mayıs 2014 tarihleri arasında kalsifik stenotik süperfisyal femoral arter lezyonları sebebiyle endovasküler prosedür uygulanmış 56 hasta (her grupta 28 olgu) çalışmaya alındı. Olguların yaş ortalaması 65,4±7,6 olup, 10'u kadın 46'sı erkek idi. Olgular işlem öncesi ve işlem sonrası 6. aya kadar Ayak bileği-kol indeksi (ABI), Rutherford skoru (RS) ve Doppler ultrasonografi (DUSG) ile takip edildi.
Bulgular: DA ve PEBA grubunda ortalama lezyon uzunluğu 66,4±24,8 mm olup SENS grubunda ise 65,0±20,6 mm olarak tespit edildi. Olguların 6 aylık takibinde primer ve sekonder açık kalma oranları DA ve PEBA grubunda %85,7 ve %92,9 olarak saptanırken SENS grubunda ise %57,1 ve %71,4 olarak saptandı. Gruplar arasında istatistiksel olarak anlamlı bir fark mevcuttu. Her iki grupta da ABI ve RS açısından anlamlı derecede düzelme olduğu gözlendi.
Sonuç: Bu çalışmadan elde edilen sonuçlardan, DA ile kombine edilmiş PEBA'nın, başarılı erken dönem sonuçları olması, intravasküler yabancı cisim içermemesi ve cerrahi şansını anastomoz sahasını etkilemeden devam ettirmesi sebepleriyle SENS uygulamasına göre daha üstün olduğunu düşünmekteyiz.
Anahtar kelimeler: Kalsifikasyon; aterektomi; stent.

INTRODUCTION

Atherosclerosis is a systemic disease affecting all vascular system. Although risk factors inducing atherosclerosis such as smoking, hyperlipidemia, diabetes mellitus and hypertension are well known, the incidences of atherosclerosis and peripheral occlusive arterial disease are increasing (1,2). Surgical revascularization was the gold standard treatment for infrainguinal arterial stenotic lesions for years (3). Despite good long term results after surgery, complications such as graft thrombosis, graft infections and wound infections resulted in progress in endovascular treatment procedures. Among the advantages of endovascular procedures; patients can return to normal daily activities earlier, morbidity rates are lower, shorter stay in the hospital, lower rates of complications may be underlined (3). Especially after publishment of the Trans Athlantic Inter Society Consensus-2 (TASC) report percutaneous endovascular procedures are used more often for treatment of peripheral arterial occlusive diseases. Among the endovascular procedures, balloon angioplasty and stent implantation are the most commonly preferred endovascular treatment methods. Also atherectomy procedure is becoming an alternative method in the last years in treatment of calcific stenotic lesions.

In this study, we aimed to compare the results of self expandable nitinol stent implantation (SENS) with paclitaxel eluting balloon angioplasty (PEBA) combined with directional atherectomy (DA) in patients with calcified stenotic superficial femoral artery lesions.

MATERIAL AND METHODS

Endovascular interventions for calcific stenotic superficial femoral artery lesions were performed to 56 patients between March 2013 and May 2014 at Cardiovascular Surgery clinic in Namık Kemal University Hospital and included in the study. We performed PEBA combined with DA to 28 patients with Turbohawk catheter (Covidien Mansfield, MA, USA) (Figure 1) and SENS (Protégé-Everflex EV3, MN, USA) implantation to 28 patients. The study was approved by the local Ethics Committee of Namık Kemal University Medical Faculty (2014/34/04/07).

Turbohawk DA catheter has a rotatable cutter unit at its distal lateral part and a flexible and smooth shaft. Catheter may be directed via control unit proximally and is suitable for vascular structures with a 3-7 mm width lumen. SENS is made of nickel and titanium unlike bare metal stents and is suitable for calcific lesions because of its high resistance feature.

We included the patients in the study with age ≥18, TASC A-C superficial femoral artery lesion, RS between II-IV and vascular diameter between 3-7 mm. We excluded the patients with TASC-D lesions at the superficial femoral artery.

Demographic and clinical variables of the patients are summarized at Table 1. All patients were evaluated with computed tomography angiography (CTA). Preoperatively the medications of the patients were not cessated. All endovascular interventions were performed at cardiac angiography unit with Siemens Artis zee floor interventional angiography (Siemens Medical Solutions, Erlangen, Germany). The endovascular procedure to be performed; DA and PEBA or SENS technique, decided to each patient randomly and just prior to procedure. Lesion length and vascular diameter were measured by using Osirix programme (Pixmeo SARL, Bernex, Switzerland). 2% lidocain (Jetmonal, Adeka Ilac, Istanbul, Turkey) were used for local anesthesia prior to the procedure. Based on the procedure to be performed, 7-9 F sheath (Terumo, Tokyo, Japan) was placed under Doppler ultrasonography guidance (MicroMaxx, SonoSite tech, Washington-USA) from retrograde popliteal artery (n=18), antergrade ipsilateral femoral artery (n=12) or contralateral femoral artery (n=26) and intra-arterial 100 IU/kg heparin was administered. The procedures were performed by passing through the lesions with 0.035 inch hydrophilic (Terumo, Tokyo, Japan), 0.018 inch (Boston scientific, MA, USA) and 0.014 inch (Abboth Vascular, IL, USA) guidewires. A distal embolization protection device (SpiderFX, EV3, MN, USA) was placed to all patients before DA prior to procedure 2-3 cm distal to lesion site to prevent atherosclerotic debris embolization. SENS was implanted via 0.035 inch guidewire, while Turbohawk DA and PEBA procedures were performed via 0.014 inch guidewire. DA was performed to 360 ºC of the stenotic lesion including all 4 quadrants. PEBA was performed to all patients after DA application. After the procedures, 300 mg of clopidogrel was given to all patients and low molecular weight heparin was administered at first 48 hours. Patients received double antiplatelet therapy (75 mg clopidogrel and 100 mg aspirin) at first month and only 100 mg aspirin from the second month on.

The procedure was accepted as successful if lesions are below 30% with angiography during DA or SENS (Figure 2). Patients were followed up with ankle brachial index (ABI), Rutherford score (RS) and Doppler ultrasonography (DUSG) on a monthly control basis from the pre-intervention period to sixth month after intervention. All endovascular procedures were performed by cardiovascular surgery staff.

Statistical Analysis

Distribution of continuous data were examined by Shapiro-Wilk test, and Student t test was used to compare

Figure 1. Turbohawk atherectomy catheter during the procedure

Table 1. Comparison of demographic and clinical characteristics

	DA+PEBA (n=28)	SENS (n=28)	p
Age	66.1±6.7	64.6±8.4	0.444
Sex			
Male	22 (78.6%)	24 (85.7%)	0.485
Female	6 (21.4%)	4 (14.3%)	
Smoking	14 (50.0%)	8 (28.6%)	0.101
Diabetes mellitus	4 (14.3%)	8 (28.6%)	0.193
Hyperlipidemia	10 (35.7%)	6 (21.4%)	0.237
Hypertension	6 (21.4%)	4 (14.3%)	0.485
Coronary artery disease	6 (21.4%)	8 (28.6%)	0.537
Lesion length (mm)	66.4±24.8	65.00±20.6	0.816
ABI at baseline	0.55±0.15	0.58±0.13	0.461
RS at baseline	3.5 (2-5)	3.0 (2-5)	0.156
TASC Score			
TASC B	12 (42.9%)	10 (35.7%)	0.584
TASC C	16 (57.1%)	18 (64.3%)	
Intervention site			
Retrograde popliteal artery	8 (28.6%)	10 (35.7%)	
Contralateral femoral artery	14 (50.0%)	12 (42.9%)	0.829
Antegrade ipsilateral femoral artery	6 (21.4%)	6 (21.4%)	

DA: Directional Atherectomy, PEBA: Paclitaxel Eluting Balloon Angioplasty, SENS: Self Expandable Nitinol Stent, ABI: Ankle-Brachial Index, RS: Rutherford Score, TASC: Trans Athlantic Inter Society Consensus

Figure 2. (A) Superficial femoral artery stenotic lesion prior to atherectomy, (B) Angiographic view of superficial femoral artery after paclitaxel eluting balloon angioplasty combined with directional atherectomy

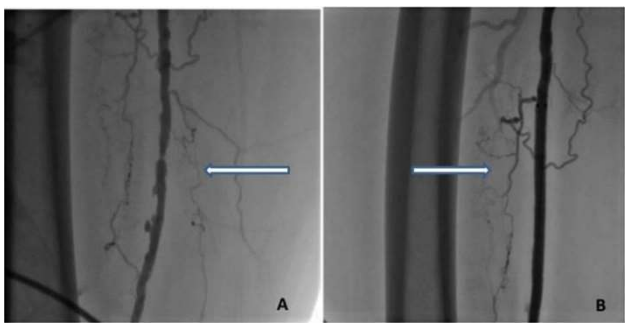

Figure 3. (A) Superficial femoral artery stenotic lesion prior to intervention, (B) Computed tomography angiography view of pseudoaneurysm after atherectomy

groups for data with normal distribution, while Mann-Whitney U test was used for data with non-normal distribution. Descriptives are expressed as mean±standard deviation or as median (minimum-maximum), as appropriate. Categorical data were analyzed with Chi-square test and summarized as numbers and percentages. A p value of <0.05 was considered significant. All statistical calculations were performed using the SPSS version 20.0 (SPSS Inc., Chicago, IL, USA) software.

RESULTS

Primary and secondary patency rates were 85.7% and 92.9% in DA and PEBA performed group and 57.1% and 71.4% in SENS performed group in six months follow up. We found a statistically significant difference between groups in terms of primary and secondary patency rates (p=0.018, p=0.036). Acute arterial occlusion occurred due to thrombus formation in 4 patients in DA group and 12 patients had stent thrombosis in SENS group. Thrombus material was aspirated via percutaneous aspiration systems in these patients. A popliteal artery pseudoaneurysm was detected in one patient at postoperative 1st month in DA and PEBA performed group and no complication was observed in SENS group. This pseudoaneurysm was repaired surgically (Figure 3).

In the follow up of the patients in DA and PEBA group, mean ABI value was 0.55±0.15 prior to procedure and 0.90±0.11 six months after the procedure. Also median RS value was 3.5 (2-5) prior to procedure and 0.5 (0-3) six months after the procedure. There was a statistically significant difference in both ABI and RS values prior to procedure and sixth month control (p<0.001). In the follow up of the patients in SENS group mean ABI value was 0.58±0.13 prior to procedure and 0.81±0.13 six months after the procedure. Also median RS value was 3.0 (2-5) prior to procedure and 1.0 (0-4) six months after the procedure. There was a statistically significant difference in both ABI and RS values prior to procedure and sixth month control (p<0.001). ABI and RS values in both groups are detailed in Table 2.

DISCUSSION

High restenosis rates after percutaneous angioplasty for calcified lesions contributed to an increase in stent implantation in interventional procedures, but together other complications appeared in front of endovascular procedures such as stent stenosis, inadequate opening of the stent and dehiscence due to calcified lesion, infection, stent migration and stent fracture (4-8).

Table 2. Comparison of follow up results

	DA+PEBA (n=28)	SENS (n=28)	p
Primary patency rate	24 (85.7%)	16 (57.1%)	***0.018***
Secondary patency rate	26 (92.9%)	20 (71.4%)	***0.036***
ABI			
at 6th month	0.90±0.11	0.81±0.13	***0.005***
improvement	0.35±0.11	0.23±0.12	***<0.001***
RS			
at 6th month	0.5 (0-3)	1.0 (0-4)	***0.021***
improvement	3.0 (0-5)	2.0 (0-5)	***0.014***

DA: Directional Atherectomy, PEBA: Paclitaxel Eluting Balloon Angioplasty, SENS: Self Expandable Nitinol Stent, ABI: Ankle-Brachial Index, RS: Rutherford Score, Rutherford scores were given as median (minimum-maximum)

Atherectomy was first performed percutaneously in 1985 for removal of the calcified plaques (9). Although promising primary and secondary patency rates were reported after atherectomy, long term results aren't still widely accepted. Atherectomy procedure may be used alone in severely calcific lesions, stent stenosis or together with stent implantation (10). Zeller et al. (11) reported primary patency rates after DA as 84% at 12 months and 73% at 18 months, while Keeling et al. (12) reported a 61.7% patency rate at 12 months follow up and concluded that there's no significant difference in patency rates between DA and other endovascular procedures. This is due to high restenosis rates after DA and thrombotic complications because of intimal injury and some authors recommend drug eluting balloon application to avoid this complication (13).

The drug eluting balloon application inhibits platelet derived growth factor release, prevents smooth muscle cell migration to intimal area and blocking smooth muscle cell proliferation. Also inhibits extracellular matrix release and reduces restenosis development due to intimal hyperplasia (13). In a study that combined DA and PEBA was performed, primary patency rate at 12 months was reported to be 90% and secondary patency was 100% (14). In our study, primary patency rate after combined DA and PEBA is 85.7% and secondary patency is 92.9%. In stent implanted patients, patency rates may vary due to length of the lesion, anatomic localization and degree of calcification. In a study on superficial femoral artery stent implanted patients, Lenti et al. (15) reported 64%, 59% and 59% patency rates at 12, 24 and 36 months follow up respectively. It was shown that SENS procedure performed patients have better patency rates compared to bare metal stents. Mevissen (16) reported a 76% 1 year patency rate. Although SENS procedure is reported have advantageous results compared to bare metal stent implantation, in our study 6 months primary patency rate was 57.1% and secondary patency rate was 71.4%. We found a statistically significant difference between groups in terms of primary and secondary patency rates.

Another advantage of DA that it does not include foreign body and the chance of surgery in terms of restenosis or occlusion continues without affecting possible surgical anastomotic areas. After SENS procedure, the chance of surgical treatment may become inconvenient because of the intravascular foreign structures (17). Atherectomy may have some complications such as bleeding, hematoma formation, pseodoaneurysm, arterial rupture, dissection and distal atherosclerotic debris embolization. There is no consensus on placing distal debris embolization preventing device on the distal portion of the lesion during endovascular interventions. Some authors propose distal embolization devices are unnecessary since distal embolization is rare, but some authors strongly recommend its routine usage (18,19). The risk of distal embolization is high during DA. Distal embolization prolongs the processing time, increases the radiation dose received by the operator and the patient, also the contrast volume used (20). Karnabaitis et al. (21) reported that distal embolization occurrence rate for <1 mm atherosclerotic plaques and thrombus during endovascular interventions was 58% and <3 mm was 12%. Shammas et al. (20) stated that the incidence of clinically significant <2 mm macrodebris embolus formation after endovascular interventions was 27.6%, while during atherectomy this incidence was 90.9% and propose the use of distal embolization device during atherectomy applications routinely. In our study group, only one patient developed a popliteal artery pseudoaneurysm, none of the patients developed distal embolization.

In conclusion, we consider that DA and PEBA procedure is superior to SENS application in calcified stenotic superficial femoral artery lesions because of its high primary and secondary patency rates, low restenosis risk, also it does not include intravascular foreign body and the chance of surgery in terms of restenosis or occlusion without affecting possible surgical anastomotic areas. Long term follow up results of larger series are required to propose more precise conclusions.

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