Drug-eluting balloon angioplasty versus bare-metal stent in treating chronic total occlusion of femoropopliteal arterial segment: a review of 1-year outcome of 90 patients with TASC C and D lesions

Ahmed K. Allam[a], Mohamed Ismail[b]

[a]Department of General Surgery, Vascular Surgery Unit, Benha University, Benha, [b]Department of Vascular Surgery, Ain Shams University, Cairo, Egypt

Correspondence to Ahmed K. Allam, MD, Mohammed Atteiyia Mansour, Khairy Allam Building, Benha, Kalubeiyia, 13512, Egypt. Tel: +20 122 338 3639/+20 101 332 6487; e-mail: ahmed.allam01@fmed.bu.edu.eg

Received 18 August 2018
Accepted 30 September 2018

The Egyptian Journal of Surgery 2019, 38:204–213

Background
Bare-metal stent (BMS) scaffolding of superficial femoral artery occlusive lesions has been associated with high rates of late clinical failure. Maintaining the patency of recanalized arterial segments was the main issue behind the concept of leaving nothing behind to be evolved and percutaneous balloon angioplasty becomes the preferred option for endovascular therapy. Drug-eluting balloons (DEBs) have shown to be an effective alternative to BMS for patients with de novo complex superficial femoral occlusive disease.
Aims
The aim was to compare the outcome of DEB versus BMS in treating complex chronic total occlusion of superficial femoral and proximal popliteal artery in patients with disabling claudication and critical limb ischemia regarding technical success, primary patency, clinically driven target lesion revascularization (cd-TLR), and limb salvage rate.
Materials and methods
The current study is a multicenter, prospective, randomized study. Ninety patients (110 limbs) complaining of disabling and critical limb ischemia due to complex femoropopliteal occlusive lesions were randomly allocated into two groups according to the intervention method performed. Group A included 48 patients (57 limbs) who were submitted for treatment with paclitaxel DEBs and group B included 42 patients (53 limbs) submitted for treatment with BMS. The follow-up period was for 1, 6, and 12 months. Statistical analysis was performed by using the IBM SPSS Statistics version 22 for Windows Program Package (SPSS Inc., Chicago, IL, USA).
Results
BMSs seem to have lower patency and higher cd-TLR rates compared with patients who received paclitaxel drug-coated balloons but was not statistically significant. The primary patency rates were 100, 96, and 86.2% at 1, 6, and 12 months' respectively' in the DEB group versus 100, 89.8, and 77.6% at 1, 6, and 12 months, respectively, in the BMS group. Clinically driven TLR rates were 2 and 7.8% at 6 and 12 months, respectively, in the DEB group versus 6.1 and 14.2% at 6 and 12 months, respectively, in the BMS group.
Conclusion
Percutaneous therapy for Trans atlantic inter-societies consensus (TASC) C and D femoropopliteal lesion using DEB or BMS is safe and effective with a high patency rate of 1 year. Paclitaxel drug-eluting balloons seem to have a promising role in the prevention of restenosis and recurrence of peripheral arterial occlusive disease. However, stents are still playing important bailout role in the treatment of residual stenosis and dissection. Further follow-up is essential to obtain and document long-term outcome of different percutaneous therapy for complex and long superficial femoral artery (SFA) lesions.

Keywords:
Bare-metal Stent, chronic total occlusion, drug-eluting balloon, target lesion revascularization

Egyptian J Surgery 38:204–213

1110-1121

Introduction

Femoropopliteal arterial segment atherosclerosis is considered the most common malady of disabling claudication. An isolated occlusion of the superficial femoral artery (SFA) often results in demand-related and reversible ischemic pain localized to the calf. Critical limb ischemia (CLI) is not an uncommon outcome of isolated SFA disease and becomes commonly noticed when SFA occlusion is associated

with crural vessels disease [1]. Over the last decades, percutaneous endovascular therapy for SFA disease has been established as a safe and efficient therapy with high initial technical success rates and minimal risk of complications. However, late clinical failure and restenosis remain an important concern [2]. With continuous evolving devices and technologies, percutaneous recanalization of complex long lesions [Trans Atlantic inter-societies consensus (TASC) II classes C and D] becomes technically feasible in a large percentage of patients, but the long-term patency of these complex lesions remains the Achilles' heel of endovascular interventions [3]. The desired long-term success of endovascular therapy in complex SFA lesions is curbed by extensive plaque burden as well as numerous external mechanical stressors (e.g. elongation, flexion, torsion, and compressive forces) resulting in frequent reocclusion [4]. Recent studies have shown that nitinol stents scaffolding after plain old balloon angioplasty (POBA) avoids the problems of early elastic recoil, residual stenosis, and flow-limiting dissection improving vessel patency rates in comparison to POBA alone for moderate-length lesions [5,6]. Unfortunately, with increase in the demand for utilizing of stenting technology in the femoropopliteal system, its outcome is complicated by the frequent occurrence of in-stent restenosis (ISR). Recently, balloons coated with anti-proliferative drugs such as paclitaxel have been utilized with the purpose of reducing ISR in peripheral vessels by inhibiting neointimal growth and thus reducing restenosis after percutaneous SFA interventions [7,8]. From a theoretical point of view, drug-eluting balloon (DEB) angioplasty has potential benefits over standard angioplasty and stent technologies. There is a potential for homogeneous drug transmission to the vessel wall, which is not achieved with the concentration gradients produced by drug-eluting stents. There is immediate drug release without the use of a polymer that can induce chronic inflammation and late thrombosis as observed with some drug-eluting stents; therefore, no metal object is left behind. Finally, with the absence of a polymer-coated stent, there is potential for reducing antiplatelet therapy [9].

Materials and methods

Study design

The current study is a multicenter, prospective, randomized study conducted from June 2015 to December 2017 in three tertiary hospitals at the Department of Surgery, Vascular Unit, Benha University/Department of vascular Surgery, Ain Shams University and Department of Vascular Surgery, Nile Insurance Hospital. Our institutional review board had approved the study protocol. Before enrollment, the patients were informed about the risks and benefits of participating in the study and given written informed consent for all to sign. The first patient was enrolled in June 2015 and the last patient was enrolled in December 2016, to allow a 12-month follow-up period from the last case operated upon.

Patient population

Our study included 90 patients (110 limbs) who were complaining of disabling claudication and critical limb ischemia due to de novo femoropopliteal atherosclerotic lesions with age over 50 years. The patients belonged to the Rutherford category 3–6. The de novo lesions were chronic total occlusion with length greater than or equal to 15 cm. These lesions were involving the superficial femoral artery with/without proximal popliteal artery. The target lesion had to be located in the native femoropopliteal artery, with its most distal point maximally 6 cm proximal to the knee joint, with at least one patent below-the-knee artery with uninterrupted flow to the pedal arch. Patients excluded from this study were those suffering from lesions extending below the proximal popliteal segment. Previous intervention either surgical treatment or percutaneous revascularization of the target superficial femoral artery, associated aortoiliac lesions, arteritic lesions, thrombophilia, patients unable to tolerate continuous antiplatelet therapy, life expectancy less than 1 year, and those unable to comply with the follow-up schedule (as mental disability). On the other hand, patients with severe renal failure (estimated glomerular filtration rate <30 ml/min/1.73 m^2) or known allergy to contrast agents were also excluded. Demographic measures, risk factors, and comorbidities are summarized in Table 1.

The investigational devices

The investigational device used in our study was DEB (IN.PACT Admiral paclitaxel-eluting balloon; Medtronic, Minneapolis, Minnesota, USA) coated with a mixture consisting of urea and paclitaxel (FreePac coating; paclitaxel dose, 3.5 μg/mm^2). It was available in nominal diameters of 5 and 6 mm with a length of 150 mm and diameter of 7 mm. A length of 120 mm and self-expandable stents (Protégé, ev3; EverFlex, Plymouth, Minnesota, USA) were used. Stents used in our study are indicated for use in patients with atherosclerotic disease of peripheral arteries and ranged from 5 to 7 mm in diameter and 100 to 200 mm in length.

Table 1 Patient characteristics

Patients characteristics	DCB (*n*=48 patients; nl=57 limbs) [*n* (%)]	Primary BMS (*n*=42 patients; nl=53 limbs) [*n* (%)]	χ^2 test	*P* value
Age [mean±SD (range)] (years)	61.67±5.04 (52–70)	59.95±4.31 (50–67)	1.72#	0.09
Sex				
Male, female	31 (64.6), 17 (35.4)	29 (69), 13 (31)	0.20	0.65
Bilateral lesion	9 (18.75)	11 (26.2)	0.72	0.40
Diabetes mellitus	36 (75)	33 (78.5)	0.16	0.69
Hypertension	33 (68.7)	26 (61.9)	0.47	0.50
Hyperlipidemia	40 (83.3)	34 (80.9)	0.09	0.77
Current smoker	29 (60.4)	25 (59.5)	0.007	0.93
Coronary artery disease	23 (47.9)	27 (64.2)	2.43	0.12
Carotid artery disease	18 (37.5)	14 (33.3)	0.17	0.68
Rutherford class				
3	20 (41.7)	15 (35.7)		
4	8 (16.7)	7 (16.7)	0.49	0.79
5	13 (27)	12 (28.6)		
6	7 (14.6)	8 (19)		
Angiographic characteristics [nl (%)]				
CTO TASC C, D	27 (47.4), 30 (52.6)	24 (45.3), 29 (54.7)	0.05	0.83
Flush SFA lesion	31 (54.4)	27 (50.9)	0.13	0.72
Proximal popliteal involvement	26 (45.6)	26 (49.1)	0.13	0.72
Number of patent runoff vessels [nl (%)]				
1	14/57 (24.6)	11/53 (20.7)		
2	23/57 (40.3)	26/53 (49.1)	0.84	0.66
3	20/57 (35.1)	16/53 (30.2)		
Lesion length (mean±SD) (cm)	15–25, 19.47±5.06	15–35, 23.81±8.59	3.25#	0.002**
15 to ≤20 cm [nl (%)]	27/57 (47.4)	24/53 (45.3)		
>20 to ≤30 cm [nl (%)]	30/57 (52.6)	29/53 (54.7)	0.05	0.83
Calcification [nl (%)]				
Mild	28/57 (49.1)	19/53 (35.9)		
Moderate	18/57 (31.6)	22/53 (41.5)	2.02	0.36
Heavy	11/57 (19.3)	12/53 (22.6)		

BMS, bare-metal stent; CTO, chronic total occlusion; DCB, drug coated balloon; SFA, superficial femoral artery; TASC, Trans Atlantic inter-societies consensus. #Student's *t*-test. ^Fischer's exact test.

Methods

The patients were randomly allocated into two groups: Group A included 48 patients (57 limbs) who were submitted for treatment with paclitaxel DEBs and group B; included 42 patients (53 limbs) submitted for treatment with primary bare-metal stents (BMSs) after successful wire navigation through the lesion and after initial angioplasty. All patients before the procedure underwent evaluation by complete history taking, full clinical examination for blood pressure in both upper limbs, peripheral pulsations, and carotid pulsation. Preprocedural investigations included laboratory investigation, duplex scanning and computed tomography angiography. Patients were premedicated with acetylsalicylic acid (100 mg/day) and clopidogrel (75 mg/day). Patients not on this regimen were given a loading dose of 300 mg clopidogrel orally before or immediately after the intervention. After the procedure, patients received aspirin 100 mg/day indefinitely plus clopidogrel 75 mg/day for at least 6 months. The SFA was accessed through either antegrade ipsilateral common femoral artery puncture which was the most utilized access in the DEB group using 6F sheaths while contralateral femoral puncture and performing a crossover technique using 8F sheaths was the most utilized access in the BMS group. Retrograde ipsilateral puncture of the popliteal artery (in cases of failure of antegrade access). Accessory transbrachial access was utilized in patients with bilateral lower extremity lesions to maintain healthy common femoral artery or patients with flush SFA lesions. After gaining access, angiography was done to confirm the data obtained by preoperative investigations. Once SFA lesions were identified and decision made to proceed, systemic anticoagulation with intravenous heparin (80–100 IU/kg) is considered. Crossing the lesion was achieved by 0.035 hydrophilic stiff type (ev3; AqWire, Plymouth, Minnesota, USA) (ZIP Wire; Boston Scientific, Natick, Massachusetts, USA) supported

Table 2 Patients and procedural characteristics

Procedural characteristics	DCB (n=48 patients; nl=57 limbs) [nl (%)]	Primary BMS (n=42 patients; nl=53 limbs) [nl (%)]	χ^2 test	P value
Access type				
Transbrachial	12/57 (21.1)	14/53 (26.4)		
Retrograde femoral	18/57 (31.6)	19/53 (35.8)	0.86	0.84
Antegrade femoral	20/57 (35.1)	18/53 (34)		
Retrograde popliteal	7/57 (12.3)	8/53 (15.1)		
Predilatation	57/57 (100)	53/53 (100)	–	–
Second dilatation	17/57 (29.8)	53/53 (100) poststenting	58.45	<0.001**
First treatment balloon maximum pressure (atm)	25/57 (43.9)	20/53 (37.7)	0.43	0.51
Dissections				
Flow-limiting dissection	3/57 (5.3)	6/53 (11.3)	0.21^	0.52
Non-flow-limiting dissection	6/57 (10.5)	8/53 (15.1)	0.51	0.47

DCB, drug coated balloon. P value considered significant if less than 0.005 and highly significant if less than 0.001.

with an angled-tip 5F, 125-cm multipurpose catheter (MPA; Cordis Corp., Miami, Florida, USA). Once the lesion had been crossed, and confirming that the wire was within the lumen, a high-pressure balloon catheter (Dorado PTA balloon dilatator catheter; Bard Peripheral Vascular, Tempe, Arizona, USA), Mustang PTA (Boston Scientific) was selected for an appropriate diameter of 1 mm less than that of the reference vessel diameter and to exceed target lesion length by 5 mm at the proximal and the distal end. The balloon was inflated until any waist on the balloon has been abolished. The inflation time was standardized. Inflation times were 90 s twice with saline injection before, in between the two times, and after. Angiography was performed to assess the result; there should be rapid forward flow through the treated segment with no residual stenosis greater than 30%. If there were residual stenosis, the balloon catheter should be reinserted and reinflated at the site of stenosis. Procedure characteristics are summarized in Table 2.

Drug-eluting balloons group

In patients randomized to DEBA, predilatation of the target lesion with a standard balloon was done to ensure that the DEB coating remains intact during lesion passage. The nominal diameter of the predilatation balloon had to be at least 1 mm smaller than the reference vessel diameter. The duration of dilatation had to be at least 180 s. The nominal balloon diameter had to match the reference vessel diameter and to exceed target lesion length by 10 mm at the proximal and distal end to avoid geographical miss (Fig. 1).

The bare-metal stent group

In patients randomized to primary BMS deployment, stents were deployed with 5–10 mm proximal and distal overlap with healthy arterial segment. The overlap zone was at least 10 mm if greater than 1 stent was used per lesion. The stent should not be oversized relative to the diameter of the SFA. Poststenting, balloon dilatation was done for 30 s with a noncompliant balloon (Fig. 2).

Both treatment groups

Auxiliary procedures like tibial plain balloon angioplasty were performed when needed to enhance and augment the outflow vessels (patients are being treated for critical ischemia).

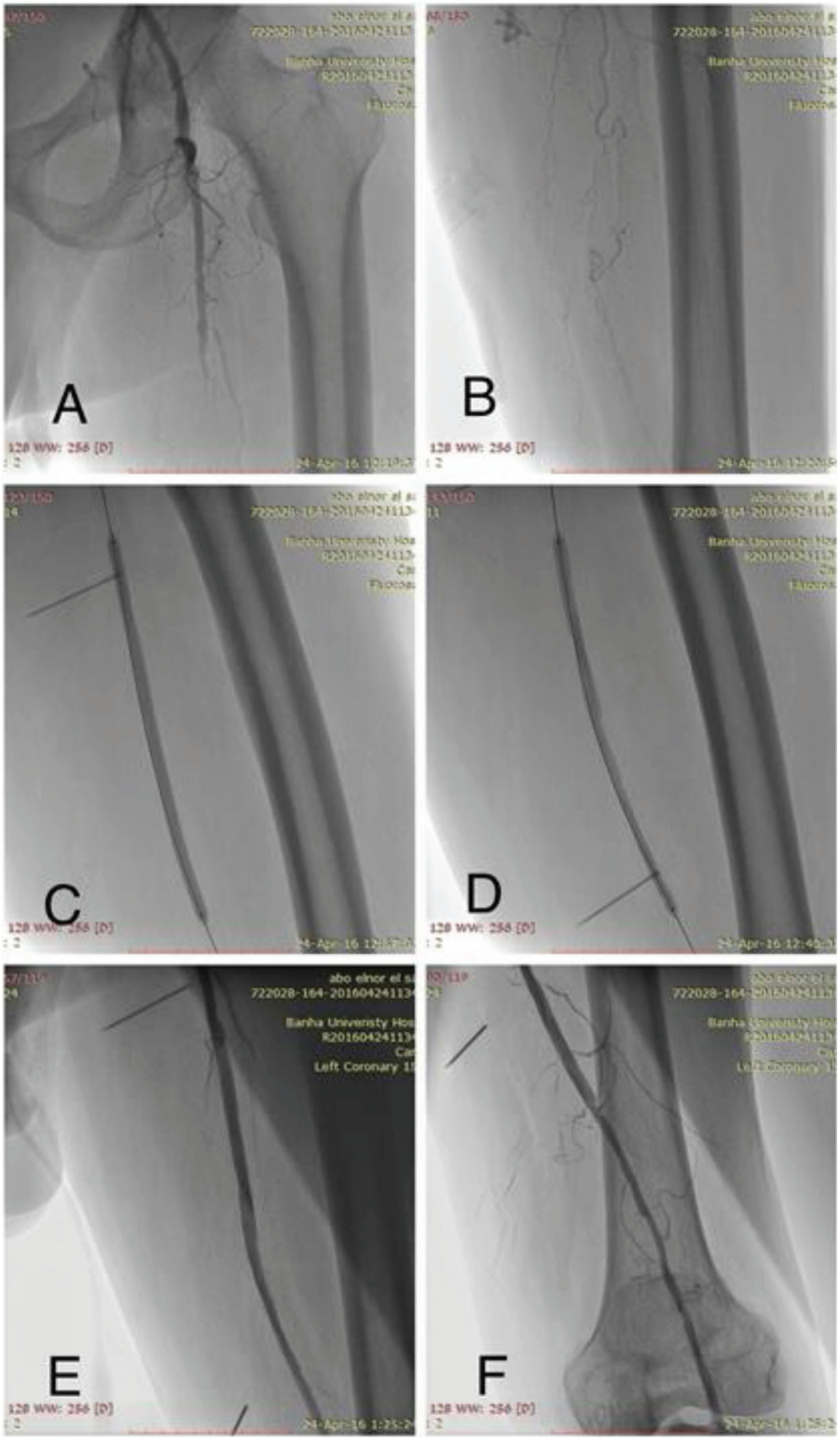
Postprocedure care

The patients were discharged on aspirin 75–150 mg/day for 12 months, Clopidogrel 75 mg/day for 6 months for the stented group and 3 months for the DEB group. The patients received foot care consisting of wound dressing, minor debridement, limited amputations (up to transmetatarsal amputation) and infection control before discharge. All patients were followed up for 12 months with regular visits at 1, 6, and 12 months or when new complaints arise. The follow-up consisted of clinical examination±imaging study (duplex ultrasound every 3 months) or if needed in cases of absent or diminished pulse or recurrence of symptoms.

Study endpoints

The primary endpoint was primary patency at 12 months following the index procedure, defined as freedom from clinically driven target lesion revascularization (cd-TLR) and binary restenosis as determined by a duplex ultrasonography-derived peak systolic velocity ratio of greater than or equal to 2.5, suggesting a greater than or equal to 50% reduction in luminal diameter. The reintervention was due to the clinically recurred symptoms.

Fig. 1



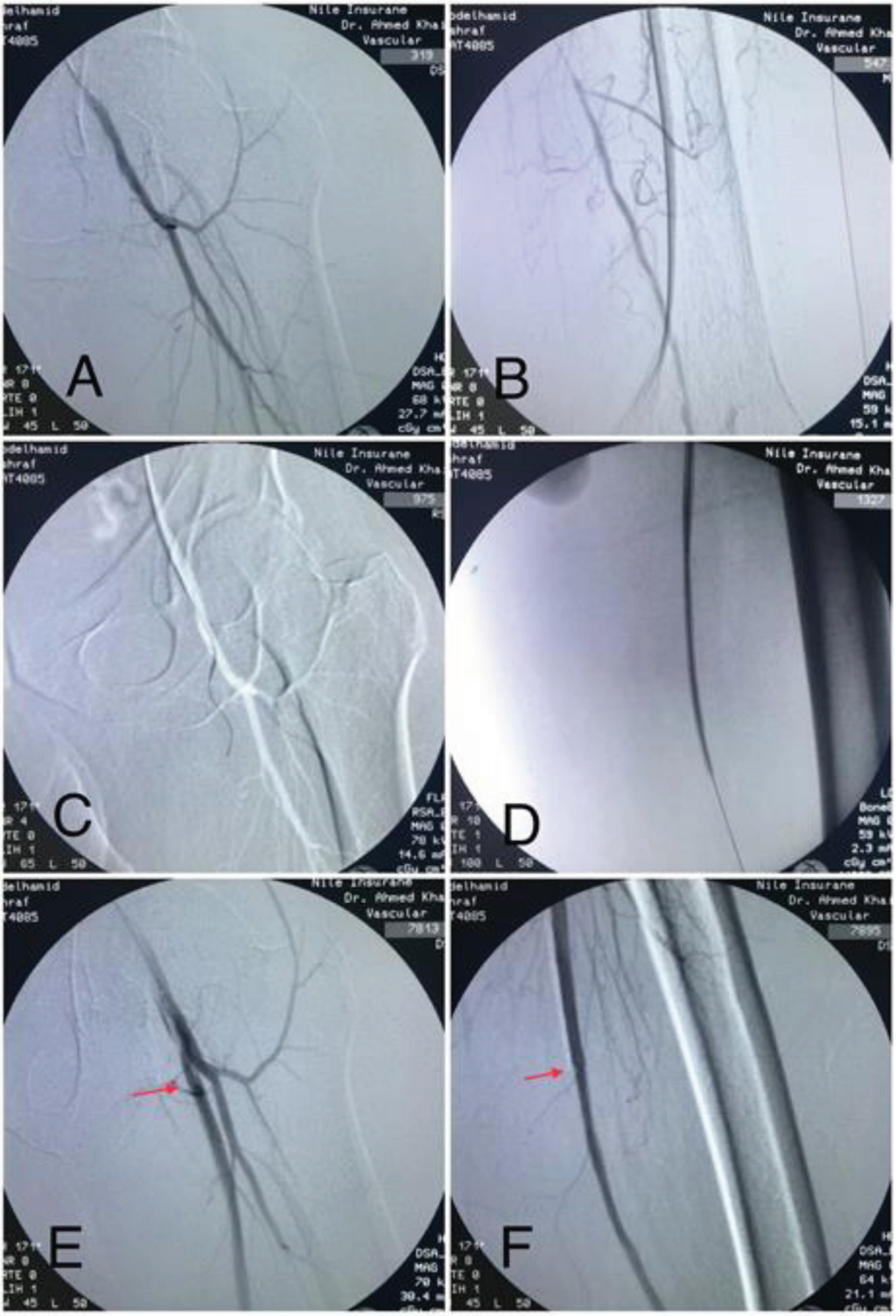
DCB angioplasty (a and b) CTO of distal two-third of SFA (c and d) DCB angioplasty with 10 mm extended beyond proximal and distal end (e and f) angiogram with no residual stenosis or dissection. CTO, chronic total occlusion.

The secondary endpoint was the cd-TLR rate at 12 months.

Our study safety endpoints were a 30-day procedure related death and major target limb amputation.

Additional efficacy endpoints included acute procedural success, device success, and primary clinical improvement (defined as freedom from target limb amputation and increase in Rutherford class at 12 months).

Fig. 2



BMS scaffolding of proximal two-thirds of SFA. (a) flush CTO of SFA, (b) reconstitution of distal SFA and popliteal through DFA collaterals, (c) successful wire engagement of SFA, (d) balloon dilatation of SFA, (e and f) angiogram with uninterrupted flow through the stented SFA (red arrows point to proximal and distal stent struts. BMS, bare-metal stent; CTO, chronic total occlusion.

Statistical analysis

Statistical analysis was performed using IBM SPSS Statistics version 22 for Windows program package (SPSS Inc., Chicago, Illinois, USA). Distribution of continuous variables is tested for normality by using the one-sample Kolmogorov–Smirnov test. Continuous variables with normal distribution are expressed as mean ±SD and compared with the independent-samples *t*-test.

Results

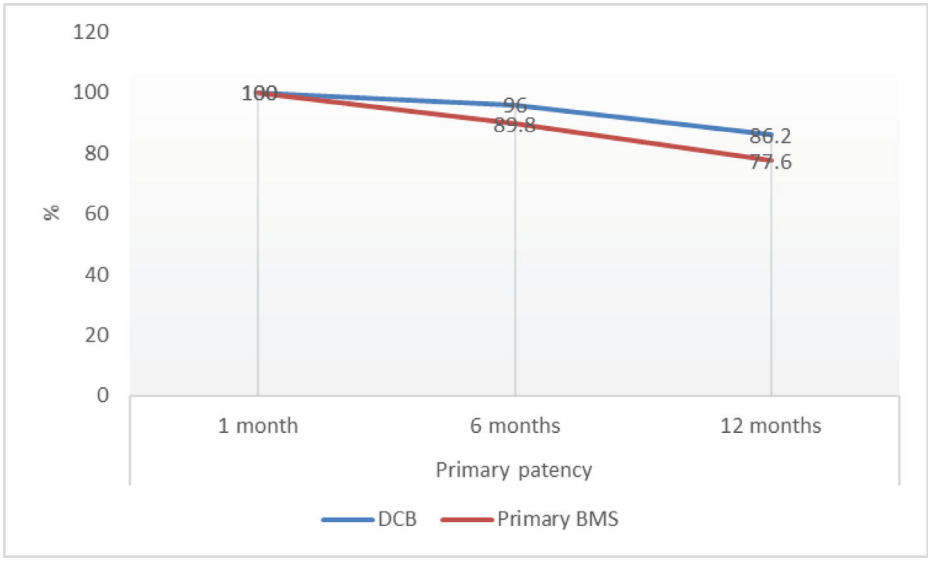
From June 2015 to December 2016, 90 patients (110 limbs) complaining of disabling claudication and CLI due to TASC C and D femoropopliteal atherosclerotic lesions underwent endovascular recanalization either with DEB (N-48; mean length 194.7±50.06 mm) or BMS (N-42; mean length 238.1±85.9 mm). The median DEB size was 5.94 mm±0.69 mm, whereas the median stent size was 5.83±0.81 mm. The clinical and safety outcomes are summarized in Table 3. The device success was 89.5% (51/57) in the DEB group and 92.5% (49/53) in the BMS (P=0.041). In four DEB patients (five limbs=8.75%) bailout stent deployment was necessary due to flow-limiting dissection (3/5), residual stenosis greater than 50% due to highly calcific lesion (1/5) and vessel perforation (1/5). In one BMS patient improper stent deployment with crumbled stent occurred causing acute thrombosis that was treated by great saphenous bypass. Acute thrombosis happened in three BMS patients (5.6%) and in one DEB patients (1.75%); in BMS patients, one patient due to improper stent deployment causing stent crumbling and vessel thrombosis and other two patients due to inadequate heparinization. Two patients were treated with great saphenous bypass and one patient with catheter direct thrombolysis and the DEB patient was also treated with catheter direct thrombolysis. Vessel perforation and extravasation due highly calcified lesions occurred in two patients, one patient belonged to the drug coated balloon (DCB) group and was treated with balloon inflation followed by stenting, and the other one belonged to the BMS group. A 30-day procedure-related mortality was one (2.1%)

Table 3 Clinical and safety results

Clinical and safety results	DCB (n=43 patients; nl=51 limbs) [nl (%)]	Primary BMS (n=38 patients; nl=49 limbs) [nl (%)]	χ^2 test	P value
Device success[a]	51/57 (89.5)	49/53 (92.5)		
Bailout stenting	5/57 (8.75)	0		
Improper stent deployment (crumble)	0	1/53 (1.9)		
Acute thrombosis	1/57 (1.75)	3/53 (5.6)	6.64[b]	0.041*
Procedure success[c]	55/57 (96.5)	48/53 (90.5)		
Death	1/48 (2.1)	2/42 (4.7)		
TVR (bypass surgery)	0	2/53 (3.8)	2.6[b]	0.77
Procedure-related major limb amputation	0	0		
Vessel perforation	1/57 (1.75)	1/53 (1.9)		
ABI index				
Before procedure	0.43±0.03 (0.44)	0.43±0.04 (0.44)		
After procedure	0.86±0.07 (0.84)	0.88±0.06 (0.88)		0.050
The primary efficacy endpoint				
Primary patency				
1 month	51 (100)	49 (100)		
6 months	49/51 (96)	44/49 (89.8)	0.35	0.84
12 months	44/51 (86.2)	38/49 (77.6)		
The secondary endpoint				
Target lesion revascularization				
1 month	0	0		
6 months	1/51 (2)	3/49 (6.1)	0.0[b]	1.0
12 months	4/51 (7.8)	7/49 (14.2)		
12-month clinical improvement				
Freedom from target limb amputation	51 (100)	47/49 (95.9)	0.02	0.89
Increase at Rutherford classification	47/51 (92.2)	47/49 (95.9)		
12-month safety outcomes				
30-day procedure-related death	1/48 (2.1)	2/42 (4.7)	0.0[b]	1.0
Target limb amputation	0	2/49 (4.1)		

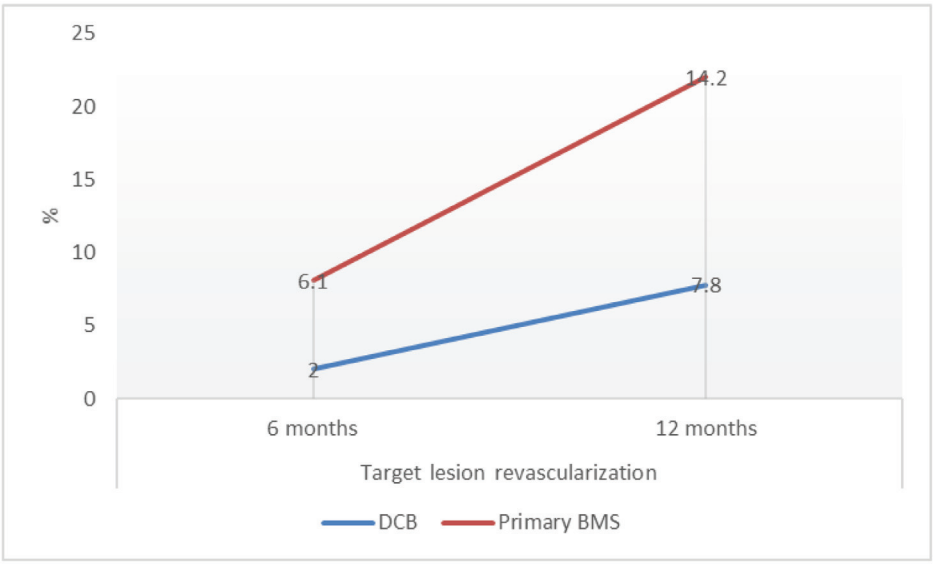
DCB, drug coated balloon; TVR, target vessel revascularization. [#]Student's t-test. [a]Free from residual diameter stenosis greater than 30% or any indication for provisional stenting in DEB patients, or free from residual stenosis less than or equal to 30%, improper stent deployment or acute stent thrombosis in the stented group and distal embolization for both groups. [b]Fischer's exact test. [c]No procedural complications (death, major target limb amputation, thrombosis of target lesion, or target vessel revascularization TVR) before discharge.

Fig. 3



Primary patency of DCB and BMS. BMS, bare-metal stent.

Fig. 4



TLR in DCB and BMS. BMS, bare-metal stent; TLR, target lesion revascularization.

patient in the DCB group and two (4.7%) patients in the BMS all causes of death were due to myocardial infarction. The primary endpoint of our study was primary patency rate at 1 year, in the DEB group there was restenosis and vessel occlusion in six patients (86.2% patency) with freedom of TLR (92.2%) while ISR and occlusion were in 11 BMS patients (77.6% patency) with freedom of TLR (85.8%) which was statistically insignificant for patency (P=0.84) (Fig. 3). This 18 high-grade restenosis was documented by clinical follow-up, duplex ultrasound, and repeat angiography was performed after diagnosis. Repeated angioplasty was performed in four DCB patients (cd-TLR 7.8%) and in seven BMS patients (cd-TLR 14.2%) due to recurrent symptoms; all patients were treated by plain balloon angioplasty (Fig. 4). The clinical improvement with one level upgrade Rutherford classification was 92.2% with freedom of target limb amputation (100%) in DEB and 95.9% for both in the BMS group (P=0.89). A significant increase in the ABI in both groups after intervention demonstrated hemodynamic success. The postmeasurement of ABI in the BMS group was slightly higher compared with the DEB group (BMS group 0.43±0.04 and DEB group 0.43±0.03).

Discussion

According to TASC II consensus, complex long femoropopliteal occlusive lesions were categorized as TASC C and D lesions and according to its recommendations should be managed primarily with a bypass graft. However, due to the associated comorbidities and high risk of those patients and continuous evolving percutaneous therapeutic options, endovascular therapy become the preferred choice for treating these patterns of disease that were previously deemed unsuitable for endovascular repair. Maintaining the patency of recanalized vessels remain the Achilles' heel of endovascular therapy and the main goal of newly introduced endovascular devices and techniques. Stent scaffolding of recanalized vessels and drug-eluting devices are one of these techniques. Our study is one of the first studies to investigate the efficacy of DEB angioplasty versus self-expanding nitinol stent deployment in patients with complex femoropopliteal lesions. Despite BMS has improved the procedure outcome in comparison to balloon angioplasty, its wider use is limited by stent fracture and the high incidence of ISR for complex femoropopliteal lesions [10]. In our study, there were no stent fractures with primary patency (77.6%) with freedom of TLR (85.8%) for lesions with a mean length of 238.1 mm. This result was better in comparison to the Durability-200 study by Bosiers *et al.* (10) that reported a 12-month primary patency rate of 64.8% with a stent fracture of 6%. This might be explained due to more distal popliteal artery stent deployment in durability trial. Teymen *et al.* [11] reported 84.8% patency rate with the supera interwoven nitinol stent (SUS) group. This better result might be due to the associated prestenting use of the atherectomy device. The goal of use of DEB may be the concept of any technology with leaving nothing in the vessel might be preferable to the long-term persistence of a foreign body for the improvement of long-term patency. This makes DEB an effective alternative to stent deployment. Our DEB group showed a primary patency of 86.2% with freedom of TLR (92.2%) which is comparable to the IN-PACT and Pacifier study [12,13] in spite of severe calcification, total occlusion percentage, and mean lesion length are higher in our study. Both of these two studies showed primary patency rates of more than 90% at 1 year. This might be due to vessel preparation with high-pressure balloon before DEB in our patients. Due to long length of the treated lesions we use more than one DEB and stent in all studied patients that was associated with increase procedure coast especially DCB group in comparison to BMS group. this might make BMS our option for longer lesions. Regarding the 1-year patency rate of our study, in spite of it being better in DEB, it was statistically nonsignificant; this may be due to the small number of patients and short duration follow-up in both groups. However, there is a significant difference in acute thrombosis between DEB (1.75%) and BMS (5.6%) (P=0.041). The significant difference in lesion length (P=0.002) with the presence of metal foreign body and induced inflammatory reaction by it may stand behind this result. The lack of data from studies comparing both treatment modalities directly and for the treatment of complex femoropopliteal lesions should invite multiple trials to investigate and establish the best endovascular modality. One important advantage of DEB other than its patency rate that was established for short lesions and still under investigation for complex lesions is leaving the door open to a wider range of endovascular options for further treatment. In turn, this may translate into a potentially superior effect on long-term secondary patency. Limitations of the data presented in our study include inadequate number of patients to allow statistically significant differences to be detected between the two groups, and the most important one is the preference of stent therapy since flow-limiting dissection was seen after predilatation only in three DEB patients and six BMS patients. Another important issue is the short follow-up period of 1 year.

Conclusion

The treatment of long and complex femoropopliteal lesions with DCB or self-expanding BMS is not only associated with impressive 1-year patency results comparing favorably with historical use, but also is safe and effective in patients with high risk. Our findings definitely warrant further follow-up to detect procedure durability and investigation, preferably by means of randomized trials to determine a definitive comparison between DCB and modern, stent-based treatment modalities, especially adding a group of patients with drug-eluting stents would have provided an additional important message about which therapy should be tailored to the specific lesion.

Financial support and sponsorship

Nil.

Conflicts of interest

There are no conflicts of interest.

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