Evaluation of versatility of drug-coated balloons in prevention of restenosis after angioplasty of superficial femoral artery occlusive lesions: a 2-year surveillance study

El-Sayed A. Abd El-Mabood[a,b], Waleed A. Sorour[c], Mohamed A. Elbegawy[a]

[a]Department of General Surgery, Benha University, [b]Department of Vascular Surgery, Benha Insurance Hospitals, Banha, [c]Department of Vascular Surgery, Zagazig University, Zagazig, Egypt

Correspondence to El-Sayed A. Abd El-Mabood, MD, Department of General Surgery, Benha University Hospitals, Borg, Tiba Misr Beside Elfath School Elfell, Benha 13516, Kaliobia, Egypt. Tel: 01065351802; fax: 0552358540; e-mail: elsayedafifi@yahoo.com

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Purpose
To assess superiority of paclitaxel drug-coated balloons (DCB) in prevention of neointimal hyperplasia and restenosis after treatment of symptomatic superficial femoral artery (SFA) occlusive lesions.

Background
Endovascular treatment (ET) has become the first choice for SFA atherosclerotic lesions. Despite enhanced immediate technical success, neointimal hyperplasia and restenosis remain the Achilles heel of ET.

Patients and methods
This prospective randomized controlled two-arm blind interventional study was conducted on 134 patients with symptomatic SFA atherosclerotic lesions. Patients were randomly allocated by using simple random allocation method, where 134 cards were used for allotment of cases into two groups (67 patients were assigned to group A, in which patients were subjected to treatment with paclitaxel DCB and other 67 were assigned to group B, where patients were subjected to treatment with plain old balloon angioplasty). Follow-up was for 2 years.

Results
Primary patency and limb salvage after 1 and 6 months were statistically insignificant in both groups (P=0.21 and 0.19 and 0.049 and 0.051, respectively), but after 12 and 24 months, primary patency and limb salvage were statistically highly significant in group A (P=0.0018 and 0.0011 and 0.0019 and 0.0023, respectively).

Conclusion
ET with DCB has equal risks but higher antirestenotic efficacy than plain old balloon angioplasty in femoropopliteal artery disease. The use of DCB increases patency and limb salvage. Stenting still has a rising role in bail-out in the treatment of SFA occlusive disease and is associated with better acute angiographic results.

Keywords:
drug-coated balloon, plain old balloon angioplasty, superficial femoral artery restenosis

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Introduction

There are challenges after endovascular treatment (ET) of superficial femoral artery (SFA) occlusive lesions in keeping its patency owing to compression and torsion forces acting on SFA; moreover, continuity with both popliteal and common femoral arteries (CFAs) exposes SFA to elongation with ambulation [1].

A wide range of factors affect short-term, medium-term, and long-term success of infra-inguinal endovascular management of patients presenting with disabling intermittent claudication and critical limb ischemia (CLI) [2]. Characteristics of the lesion are very important determinant of patency after SFA stenting. Angioplasty alone seems to provide good results for stenotic SFA lesions especially if focal [3].

ET is increasingly used to treat SFA occlusive disease. This could be explained by less peri-procedural morbidity and mortality, with the fact that, in many countries, peripheral arterial disease (PAD) is increasingly treated by physicians who cannot offer surgical intervention [4–10].

At the present time, the role of infra-inguinal ET and which type of it is most appropriate, in the management of intermittent claudication and CLI, remains uncertain and controversial, with a very wide range of views being expressed at scientific meetings and in the literature [11].

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Neointimal hyperplasia is the principal cause of restenosis after angioplasty. Bare-metal stents (BMS) do not prevent neointimal hyperplasia. The risk for in-stent restenosis grows with lesion length [12–14].

Recently, development of a balloon able to deliver a drug (paclitaxel) to prevent inflammation and intimal hyperplasia has been achieved. The method of delivery depends on balloon design and drug kinetics (coating vs. adsorption). Although the duration of contact with vessel wall may be short (1–3 min), the effect of retained drug continues over weeks. Better outcomes after drug-coated balloons (DCBs) were shown when compared with plain old balloon angioplasty (POBA) [15–19].

The use of paclitaxil DCB for SFA percutaneous revascularization lowers the risk of reinterventions by inhibiting neointimal growth and thus reducing restenosis [20–22].

Patients and methods

This study was conducted after approval from Local Ethical Committee of Benha and Zagazig Universities and Benha Insurance Hospitals and obtaining written fully informed consent from the patients. Patients undergoing treatment for symptomatic SFA atherosclerotic lesions, at the Vascular Surgery Department, Zagazig and Benha Universities Hospitals and Benha Insurance Hospitals, were included in this study from June 2015 till May 2019. The expected study duration is 4 years. The enrollment period is 2 years, and follow-up period is 2 years.

This prospective randomized controlled two-arm blind interventional study was conducted on 134 patients with symptomatic SFA atherosclerotic lesions. Patients were randomly allocated by using simple random allocation method, where 134 cards (67 were assigned to group A, in which patients were subjected to treatment with paclitaxel DCB and other 67 were assigned to group B, in which patients were subjected to treatment with POBA) were prepared by the principal investigator and were put in closed envelops and mixed together. Each patient chose an envelope after providing approval for participation. Double-blind technique was applied, where patients and care providers were blind about to which group the patients were allocated. The randomization sequence was generated by an independent statistician. MedCalc software version 16.1 (1993–2016; MedCalc Software) was used to calculate the required sample size [level of significance (type I error)=0.05, type II error (1-level of power)=0.1, percentage of the aware patients=84.4%, and null hypothesis percentage=50%].

Patients included in this study had symptomatic SFA occlusive lesions, with resting ankle brachial index less than 0.9 and Rutherford class category 3–6. Target lesions have a preprocedure percent diameter stenosis of at least 60% or chronic total occlusion (CTO) with length (≤14 cm). SFA lesions included in this study did not extend to involve the proximal 1 cm of SFA or the proximal 3 cm of popliteal artery. CTA should show at least 1 patent runoff vessel (<50% diameter stenosis throughout its course) with uninterrupted flow to pedal arch, reference vessel diameter 4–7 mm determined by computed tomography (CT) scan (reference vessel diameter obtained from averaging 5-mm segments proximal and distal to the lesions). Lesion is eligible for treatment with a maximum of two stents per lesion (treatment of both legs is not permitted).

Patients were excluded from this study who had lesions of at least 14 cm, extending below proximal popliteal segment or lies within or adjacent to an aneurysm, restenosis of the target SFA, failed lesion crossing, untreated more than 60% diameter stenosis of the inflow tract, artertic lesions, thrompophilia, life expectancy less than 1 year, cerebral vascular disease, who require interventional management first, inability to comply with the follow-up schedule (as mental disability) or if there were contraindications to contrast, contraindication to aspirin or clopidogrel (patient must be able to receive dual antiplatelet treatment for 2 months after the procedure), or patients had prior major amputation, bypass surgery, endarterectomy, or other vascular surgery on any vessel of the ipsilateral (target) extremity.

All patients underwent evaluation by complete history taking and full clinical examination for blood pressure in both upper limbs, and peripheral and carotid pulsations. Preprocedural investigations included laboratory investigation: duplex scanning and CT angiography.

Procedure

Patients of both groups were given 300 mg loading dose of oral clopidogrel at least 1 day before ET or during the procedure. Under local anesthesia, access to the target SFA lesion was done by (antegrade ipsilateral CFA puncture) or (contralateral femoral puncture, and performing a crossover technique) or (transbrachial puncture with using long sheath) or

(retrograde ipsilateral transpopliteal access (in cases of failure of antegrade access) in prone or lateral decubitus position).

Angiography was done to confirm data obtained preoperatively using nonionic low osmolar dye diluted to 50% with normal saline. SFA lesions were identified. A guidewire was positioned through the lesion: a 0.035 hydrophilic guide wire [standard type (Terumo, Tokyo, Japan)] for stenosis and stiff type (Terumo) for CTO supported by an angled-tip angiographic catheter (Bernstein 4 or 5 F) (Merit Medical, South Jordan, Utah, USA).

Then a balloon catheter [Admiral xtreme; Invatec S.p. A, Roncadelle (BS), Italy] of suitable diameter (5 or 6 mm) and length was introduced over the wire to the distal extent of the lesion. The balloon was inflated till any waist has been abolished then deflated and should be re-inflated with overlaps until the whole lesion had been dilated. The inflation time was standardized: 3 min with heparinized saline injection after deflation. The balloon was withdrawn completely. Angiography was done to assess the result (Fig. 1).

Then in patients of group A, paclitaxel DCB (In.Pact Admiral 5 or 6 mm) (Medtronic, Minneapolis, Minnesota, USA) was inserted. This balloon was inflated once for 1 min. DCB should cover the lesion and 5–10 mm of normal artery proximal and distal to the lesion (Fig. 2).

However, in the patients of group B, POBA was done only (Fig. 1). In both groups, indications for stenting in both groups were elastic recoil (if the balloon was inflated fully, but the stenosis persists), a flow-limiting dissection (if prolonged balloon inflation was performed but the dissection persists).

So stent (Protégé Everflex self-expanding stent 5 or 6 mm) (ev3, Plymouth, Minnesota, USA) insertion was done selectively as a bailout in the patients of both groups; the stent diameter and length were selected according to baseline CT scan estimate. The stent should cover the lesion and 2–5 mm of the normal artery proximal and distal to the lesion. Stents were deployed at least 1 cm below origin of profunda femoral artery and 3 cm above proximal margin of the intercondylar fossa of femur. Maximum of 1 cm overlap was allowed in cases of two stents (Fig. 3).

Associated inflow or outflow lesions were also treated. The technical result was assessed by digital subtraction angiography. Manual compression was applied for number of sheath multiplied by 3 min (e.g. 6 F×3 min = 18 min), and mobilization was delayed for 6–12 h (Fig. 4).

Postintervention follow-up

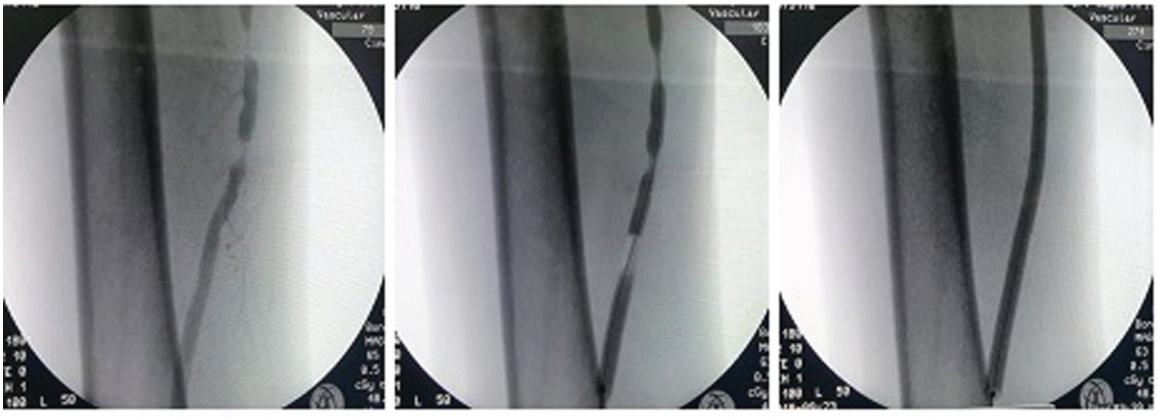
Medications

All patients were maintained on dual antiplatelet agents (acetyl salicylic acid 75 mg forever and clopidogrel 75 mg for≥2 months). If patients were in need for oral anticoagulant, aspirin only was added. The patients received foot care consisting of wound dressing, minor debridement, limited amputations (up to transmetatarsal amputation), and appropriate footwear.

Outcomes

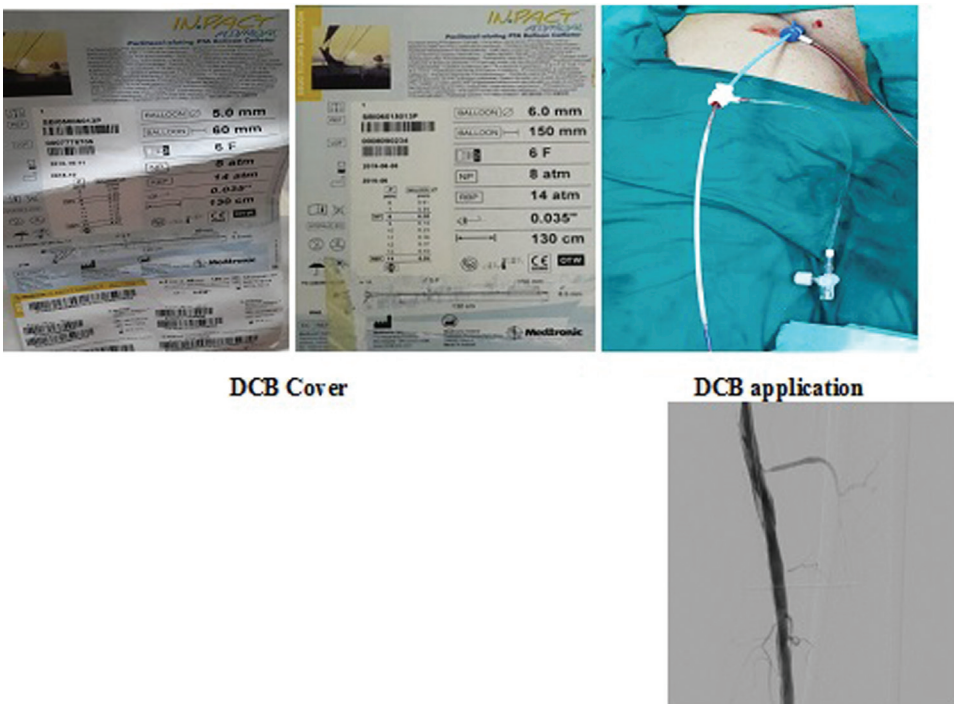
Success of the procedure depends on angiographic success; hemodynamic success; such as increase in

Figure 1



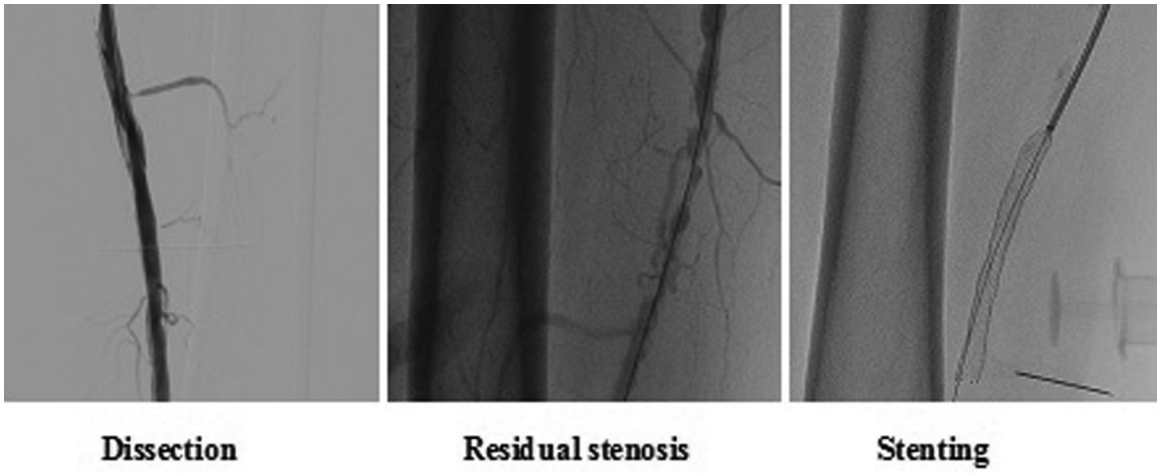
Balloon inflation till any waist has been abolished.

Figure 2



Paclitaxel drug-coated balloon cover and application.

Figure 3



Indications for stenting in both groups.

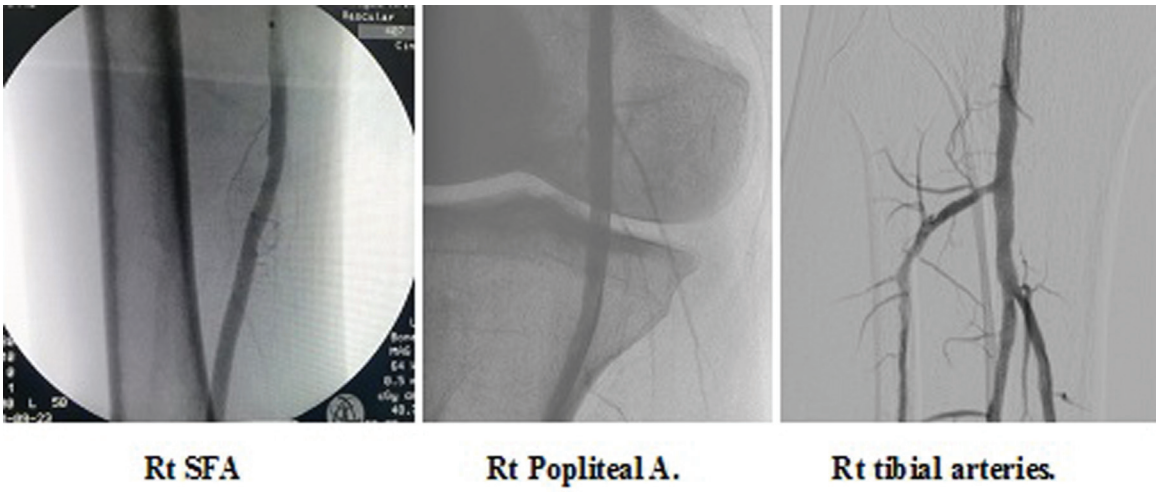
ankle brachial index by at least 0.1 and demonstration of biphasic or triphasic waveforms; and clinical success, such as absence of symptoms or improvement by at least one (claudication) or two (tissue loss) categories according to Rutherford classification.

(1) Objective end points: patency (primary or secondary), limb salvage, and patient survival (procedure related 1 month mortality).
(2) Subjective end points: healed wound and independent living status (continued ambulation).

Schedule

Clinical follow-up consisted of pulse examination and evaluation of ulcer or amputation site healing or resolution of infection. Clinical outcomes, patency rates, and complications following the procedure were reported. All patients were re-examined after 1 week to check for access site complications and to confirm patency. All patients were followed for 2 years with regular visits at 1, 6, 12, and 24 months. Follow-up was in the form of clinical examination and duplex US±CT angiography if needed in cases of

Figure 4



Post angioplasty angiogram to assess technical result.

Table 1 Patients' characteristics

Variables	Group A (*N*=65) (50%)	Group B (*N*=65) (50%)	Test of significance	*P* value
Age (years)	58.3±2.9	56.4±5.6	t=1.71	0.09 (NS)
Sex				
Female	16 (24.6)	18 (27.7)	χ^2=0.016	0.78 (NS)
Male	49 (75.4)	47 (72.3)		
Duration of symptoms (months)	5.7±1.43	6.2±3.01	Z_{MWU}=1.07	0.23 (NS)
Risk factors and comorbidities				
Diabetics	31 (47.7)	27 (41.5)	χ^2=3.52	0.51 (NS)
Hypertensive	27 (41.5)	26 (40)		
Smokers	43 (66.2)	41 (63.1)		
Hyperlipidemia	15 (23.1)	16 (24.6)		

Data were presented as numbers; percentages and ranges are in parenthesis. χ^2, χ^2 and *P* values for χ^2-test for comparison.

absent or diminished pulse or recurrence of symptoms.

Statistical analysis

Collected data were tabulated and analyzed using SPSS version 16 software (SPSS Inc., Chicago, Illinois, USA) and Microstat W software (India, CNET Download.com). Categorical data were presented as number and percentages and analyzed using χ^2-test or *Z*-test of two proportions. Continuous data were expressed as mean±SD. Data were tested for normality using Shapiro–Wilks test, assuming normality at *P* value more than 0.05. Differences between groups were tested using Student '*t*' for normally distributed variables or Mann–Whitney *U* (Z_{MWU}) test for nonparametric ones.

Results

This study was conducted on 134 patients with symptomatic SFA atherosclerotic lesions. Four patients were lost during follow-up (two patients of each group). So the data were available only for 130 patients distributed equally in both groups: group A had 65 patients who were subjected to treatment with paclitaxel DCB and group B had 65 patients who were subjected to treatment with POBA. There were no significant differences between both groups in patients characteristics, with *P* value more than 0.05 (Table 1).

On reviewing the presenting symptoms, the commonest was foot ulceration or minor tissue loss (R_5), in 28 (43.1%) patients in group A and 27 (41.5%) patients in group B. There were no significant differences between both groups regarding Rutherford category, with *P* value more than 0.05 (Table 2).

Regarding lesion characteristics, most patients in both groups were TASC II B. Stenosis was more than CTO in 47 (81.4%) patients in group A and 46 (79.1%) patients in group B. Two tibial vessels were patent in nearly half of the patients. There were no significant

Table 2 Clinical presentation (Rutherford category) in both groups

Rutherford (R)	Group A (*N*=65) (50%)	Group B (*N*=65) (50%)	Test of significance	*P* value
R_3	7 (10.7)	6 (9.3)	χ^2=0.017	0.89 (NS)
R_4	17 (26.2)	18 (27.7)		
R_5	28 (43.1)	27 (41.5)		
R_6	13 (20)	14 (21.5)		

χ^2, χ^2 and *P* values for χ^2-test for comparison.

Table 3 Lesion characteristic of both groups

Variables	Group A (*N*=65) (50%)	Group B (*N*=65) (50%)	Test of significance	*P* value
Lesion type				
Stenosis	47 (72.3)	46 (70.8)	χ^2=0.019	0.98 (NS)
Chronic total occlusion	18 (27.7)	19 (29.2)		
Runoff vessels				
Single vessel	17 (26.2)	16 (24.6)	χ^2=3.411	0.41 (NS)
Two vessels	28 (43.1)	27 (41.5)		
Three vessels	20 (30.7)	22 (33.9)		

χ^2, χ^2 and *P* values for χ^2-test for comparison.

Table 4 Access site used in both groups

Access type	Group A (*N*=65) (50%)	Group B (*N*=65) (50%)	Test of significance	*P* value
Crossover femoral	23 (35.4)	22 (33.9)	χ^2=0.625	0.69 (NS)
Ipsilateral femoral	30 (46.2)	31 (47.7)		
Retrograde popliteal	2 (3.07)	1 (1.54)		
Transbrachial (left)	10 (15.4)	11 (16.9)		

χ^2, χ^2 and *P* values for χ^2-test for comparison.

Table 5 Bailout stenting in both groups

Selective stenting	Group A (*N*=65) (50%)	Group B (*N*=65) (50%)	Test of significance	*P* value
Stenosis	3 (4.6)	4 (6.2)	χ^2=0.128	0.79 (NS)
Chronic total occlusion	10 (15.4)	11 (16.9)		
Total bare-metal stent	13 (20)	15 (23.1)		

χ^2, χ^2 and *P* values for χ^2-test for comparing between the two groups.

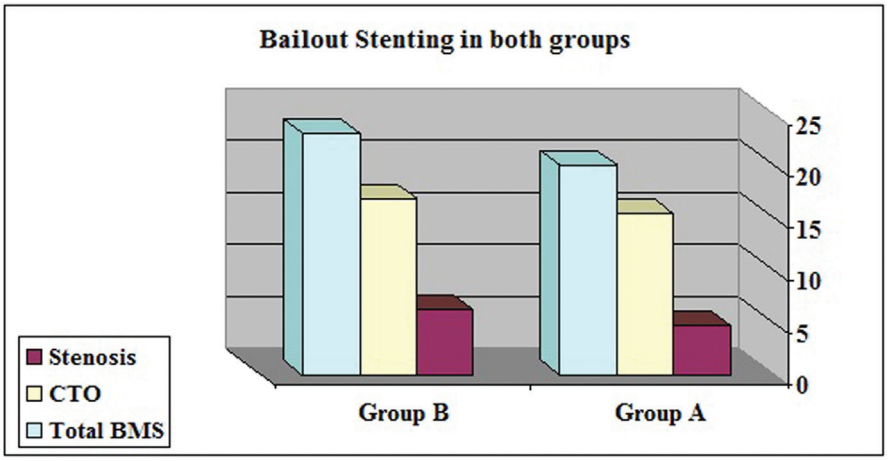
differences between both groups regarding lesion characteristics, with *P* value more than 0.05 (Table 3).

There were many access used in this study especially in CTO; the most used access was ipsilateral femoral. There was no significant difference between both groups regarding access site, with *P* value more than 0.05 (Table 4).

Regarding selective stenting in both groups as a bailout for elastic recoil or a flow-limiting dissection, there was no statistical significance between both groups (Table 5 and Graph 1).

There was no procedure-related mortality during the first month of both groups. After the first month, primary patency was reported in 63 (96.9%) patients in group A and 62 (95.4%) patients in group B; this failure was owing to acute thrombosis with trash foot in five patients (two patients of group A and three patients of group B) who were treated using thrombolytic therapy; three of them were successfully treated, where intervention was done on the second day, and the other two cases needed urgent bypass. Of the technically successful patients, three cases (one patient of group A and two patients of group B) had above-knee amputations owing to spreading infection despite successful revascularization, thus decreasing the overall success rate. Limb salvage was achieved in 127 (97.7%) patients, distributed as 64 (97.7%) patients in group A and 63 (96.9%) patients in group B. Debridement procedures were done in the form of foot-sparing amputations (debridement±Toe and Ray amputation, or transmetatarsal amputation). After 6-month follow-up, primary patency was reported in 59 (90.8%) patients of group A and 54 (83.1%) patients of group B. Successful surgical bypass was done in three patients of group A and three patients of group B, and other patients

Graph 1



Bailout stenting in both groups.

Table 6 Objective end points of both groups at first and sixth month

Objective endpoints	Group A (*N*=65) (50%)	Group B (*N*=65) (50%)	Test of significance	*P* value
After 1 month				
Primary patency	63 (96.9)	62 (95.4)	Z_{PROP}=0.81	0.21 (NS)
Limb salvage	64 (97.7)	63 (96.9)	Z_{PROP}=0.89	0.19 (NS)
After 6 months				
Primary patency	59 (90.8)	54 (83.1)	Z_{PROP}=1.69	0.049 (NS)
Limb salvage	62 (95.4)	57 (87.7)	Z_{PROP}=1.79	0.051 (NS)

Z_{PROP}, *Z*-test of two proportions.

Table 7 Objective end points of both groups at 12 and 24 months

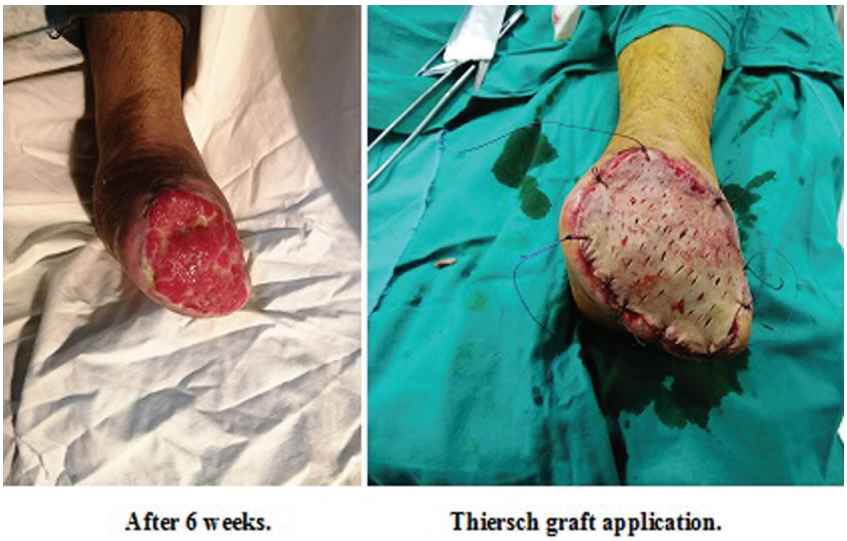
Objective endpoints	Group A (*N*=65) (50%)	Group B (*N*=65) (50%)	Test of significance	*P* value
After 12 months				
Primary patency	55 (84.6)	34 (52.3)	Z_{PROP}=3.27	0.0018 (HS)
Secondary patency	7 (10.8)	23 (35.4)	Z_{PROP}=3.15	0.0021 (S)
Limb salvage	60 (92.3)	44 (67.7)	Z_{PROP}=3.21	0.0011 (HS)
After 24 months				
Primary patency	46 (70.8)	26 (40)	Z_{PROP}=3.28	0.0019 (HS)
Secondary patency	14 (21.6)	18 (27.7)	Z_{PROP}=1.89	0.059 (NS)
Limb salvage	53 (81.5)	36 (55.4)	Z_{PROP}=3.11	0.0023 (S)

Data are presented as numbers and mean±SD; percentages and ranges are in parenthesis. HS, highly significant; S, significant; Z_{PROP}, *Z*-test of two proportions.

underwent major amputation owing to unsalvageable limb (Table 6).

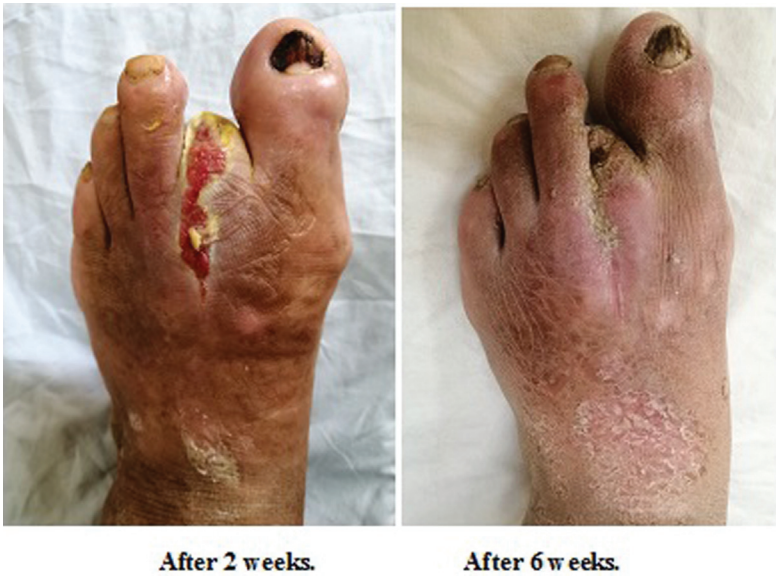
After 12-month follow-up, primary patency and limb salvage were statistically highly significant in group A, with *P* values of 0.0018 and 0.0011, respectively. Moreover, secondary patency was statistically significant in group A, with *P* value of 0.0021. Secondary patency was obtained in group A by DCB angioplasty in three patients, and surgical bypass was done in two patients, but in group B by POBA angioplasty in two patients, and surgical bypass was done in eight patients; other patients underwent major amputation owing to extensive infection or unsalvageable limb. After 24-month follow-up, primary patency and limb salvage were statistically highly significant in group A, with *P* values of 0.0019 and 0.0023, respectively, and secondary patency was statistically nonsignificant, with *P* value of 0.059. Secondary patency was obtained in group A by DCB angioplasty in four patients and surgical bypass was done in three patients, but in group B by POBA angioplasty in one patient and surgical bypass was done in seven patients; other patients underwent major amputation owing to unsalvageable limb (Table 7 and Figs 5 and 6).

Figure 5



Foot wound of the same case of group A of paclitaxel drug-coated balloon.

Figure 6



Foot wound of the same case of group B of plain old balloon angioplasty.

Discussion

ET has become a preferable line of management of SFA atherosclerotic lesions, but intimal hyperplasia hinders its durability [11,23]. Evolving endovascular strategies embrace new technologies, that is, DCBs, in an attempt to improve the outcomes of revascularization procedures for lower extremity arterial occlusive disease [23,24].

This study included 130 patients complaining of lower limb symptomatic SFA atherosclerotic lesions; all were managed by endovascular intervention according to a strategy of endovascular-first for femoropopliteal occlusive lesions. It is also reported that the incidence of PAD is 3.1% in the ages between 45 and 65 years. Aging is a very strong risk factors for PAD [11,25,26]. Our patients aged over 45 years.

In this study, ~75.4% of patients in group A and 72.3% of patients in group B were males. Popa *et al.* [27] examined sex in 2623 patients with CLI and found similar result, with 75% of patients are males.

By giving concern to presenting symptoms, it was found that they were comparable to a study on 109 patients done by Ihnat *et al.* [28] who reported in his

study, tissue loss in 26 (24%) patients, claudication in 71 (65%) patients, and rest pain in 12 (11%) patients. Near similar patients were reported in a study done by Vierthaler *et al.* [29] who reviewed 1244 patients who underwent 1414 interventions, and rest pain was seen in ~29%, but there were more patients with tissue loss (71%).

Patients involved in this study have multiple risk factors. Smoking is by far the most important risk factor for developing PAD and the main cause of progression to CLI and more likely to require amputation or vascular intervention. This was comparable to a study done by Lu *et al.* [30] and Jude *et al.* [31].

The access used in this study was ipsilateral CFA in ~47% of the patients, but contralateral CFA with crossover was used in ~34.5% of patients when ipsilateral CFA access was not ideal for proximal SFA occlusions. Moreover, retrograde popliteal access was used after the failure of the previous accesses especially in CTO lesions of the SFA; this access was fluoroscopic or duplex guided, as mentioned by Dumantepe [32].

On review of primary patency and limb salvage in this study after 1 and 6 months, primary patency and limb salvage were statistically insignificant in both groups, but at 12 and 24-month follow-up, primary and secondary patency and limb salvage were statistically significant in group A, with *P* values of 0.0018 and 0.0011, respectively, at 12 months, and 0.0019 and 0.0023, respectively, at 24 months.

Promising efficacy of DCB of group A is approved by many studies; THUNDER trial (Local Taxane with Short Exposure for Reduction of Restenosis in Distal Arteries) that reported that 12-month restenosis rate is significantly lower in patients treated with paclitaxel-coated balloons than patients of the control group (17 vs. 44%, *P*=0.01) [33]. The IN.PACT SFA Trial confirmed the benefits of the IN.PACT Admiral DCB and reported that 12-month primary patency is excellent on the first 655 patients [34] and more recently reported that 24-month patency results are excellent [35].

However, in the patients of group B, POBA was done only, and stent insertion was done selectively as a bailout in the patients of both groups. The limitation of BMS is evidenced by many studies. Vienna Absolute trial (Balloon Angioplasty Versus Stenting With Nitinol Stents in the SFA) included 104 patients, and binary restenosis rate of the stent group at 6, 12, and 24 months was 24, 37, and 45.7%, respectively [36]. The SUPER study reported 12-month rates of binary restenosis rates of 47.2% in the primary stenting group of 74 patients [37]. More recently, the Femoral Artery Instent Restenosis trial randomized patients to primary stenting in 123 patients, and the investigators found 12-month binary restenosis rates of 31.7% [38].These bad results of BMS can be explained by the forces of compression and torsion, exerted by the muscles on SFA, which can lead to metal fatigue and stent fracture. Moreover, SFA responds to stenting by a stronger reaction than any vessel which may be due to stent micro-movements within SFA that can lead to intimal hyperplasia especially in the area of two stents overlap that act as a hinge point. So meta-analysis of randomized studies does not support the use of stents in femoropopliteal segments [1].

There are many systematic reviews and meta-analysis of randomized clinical trials that reported significant inhibition of re-restenosis after treatment of SFA occlusive lesions by DCB [39]. The results of this study are quietly comparable to other mentioned studies. The differences between studies are probably related to technical experience and selection criteria of patients and differences in the quality of the runoff.

Conclusion

ET with DCB has equal risks but higher antirestenotic efficacy than POBA in femoropopliteal artery disease. The use of DCB increases patency and limb salvage. Stenting still has an increasing role in bail-out in the treatment of SFA occlusive disease and is associated with better acute angiographic results.

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Conflicts of interest

There are no conflicts of interest.

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