Int. J. Curr. Res. Med. Sci. (2019). 5(6): 1-13

International Journal of Current Research in Medical Sciences

ISSN: 2454-5716

P-ISJN: A4372-3064, E -ISJN: A4372-3061

www.ijcrims.com

Original Research Article

Volume 5, Issue 6 -2019

DOI: http://dx.doi.org/10.22192/ijcrms.2019.05.06.001

Management of De novo Long Femoropopliteal Occlusions; Plain Balloon, Drug Coated Balloon, Bare Metal Stent; Comparative Study

Osama A. Ismail,

Vascular Surgery Department, Sohag University, Egypt

E- mail: *oelnahaas@yahoo.com*

Abstract

Aim of work: To compare the results of plain balloon (PB), drug coated balloon (DCB) and bare metal stent in management of de novo long femoropopliteal occlusive lesions.

Methods: This prospective study was carried out from January 2016 to December 2018 at Sohag University Hospitals and 6th October Insurance Hospital, Dokki, Cairo on 70 patients suffered from de novo femoropopliteal occlusions ≥10 cm, Rutherford category 3,4,5 divided in 3 groups. Group (A) consisted of 30 patients (17 males, 13 females) with a mean age of 57 years (ranged from 50 - 64 years) treated by plain balloon angioplasty. Group (B) consisted of 22 patients (12 males, 10 females) with a mean age of 61 years (ranged from 52 - 65 years) treated by DCB and group (C) consisted of 18 patients (10 males, 8 females) with a mean age of 59 years (ranged from 49 - 65 years) treated with long bare metal nitinol stent. Lesion length was 15.1±2.7 cm in group (A), 14.2±3.6 cm in group (B) &15.3±2.8 cm in group (C). There were no significant differences between groups in age, gender and risk factors. Subjects were scheduled to be evaluated and followed up for one year.

Results: In group (A) (plain balloon group), primary patency rate was 53.8% (14/26) patients. 12 patients (46.2%) developed significant stenosis. (4/12) patients continued medically as they were claudicant. (8/12) had critically ischemic limb, 3 cases were treated by DCB angioplasty, one patient by stent, 2 patients by femoropopliteal bypass and 2 cases ended by limb amputation. Bailout stenting was performed in 4/30 (13.3%) lesions due to flow limiting dissection and those patients were shifted from this group to group (C) of stent group. In DCB patients (group B), primary patency rate was 76.4% (13/17) patients. Four patients (23.5%) developed significant stenosis. One patient continued medically, one case was treated by DCB angioplasty and stent, one patient treated by femoropopliteal bypass and the 4th one ended by limb amputation. Bailout stenting was performed in 5/22 cases (22.7%). In group (C) of long bare metal stent, primary patency rate was 63.6%.(14/22) patients. Eight patients (36.4%) developed in-stent stenosis. 2 cases treated conservatively, 4 patients treated by DCB angioplasty, one treated by femoropopliteal bypass and the other one ended by amputation. The clinically driven target lesion revascularization (TLR) rates were 30.8%, 17.6% and 27.3 % respectively. It was statistically significant difference between the study cohorts, (p-value < 0.01).

Conclusions: DCB angioplasty yields better results and comparable outcomes compared to bare metal stents when treating long femoropopliteal occlusions. Because the nature of peripheral occlusive disease is progressive, it is wise to apply DCB angioplasty first and reserve the stent as a future option later on.

Keywords: Plain Balloon, Drug Coated Balloon, Bare Metal Stent, De novo, Long Femoropopliteal lesions.

Introduction

Peripheral arterial disease (PAD) is a progressive pathology affecting quality of life of over 200 million people worldwide.[1] Percutaneous transluminal angioplasty is now validated as the first line of revascularization strategy for patients with symptomatic femoropopliteal disease.[2]

Long femoropopliteal lesions are one of the major challenges. Surgical bypass by autologous vein graft is still considered the golden standard for femoropopliteal Trans Atlantic Inter-Society Consensus (TASC) II class C & D lesions.[3] However, open surgery has its disadvantages especially with unsuitable vein conduit, lack of adequate distal run-off vessels and associated patient comorbidities.[4]

Within the last decades, there has been a competition and various players have already appeared on the ground; however, long-term outcomes are not satisfactory due to limited patency rates and increased incidence of restenosis especially in TASC II C/D lesions.[5] Plain balloon angioplasty remains the initial endovascular therapy for symptomatic patients but primary patency rates was about 55%. Provisional stenting has improved its patency up to 80% at one year.[6]

Drug-coated balloons (DCBs) have been used for limb revascularization since their first use in Europe in 2008 until nowadays because of their initial excellent results. DCB provided a combination of balloon dilatation with local delivery of an antiproliferative agent; paclitaxel, a proof of evidence in decreasing restenosis rate, need for re-intervention, acceptable primary patency and freedom from target lesion revascularization rate (TLR). [7] Drug-eluting techniques, e.g., DCB and DES had shown promising results in TASC II A/B lesions but there were limited data in literature about the performance of DCB in long femoropopliteal lesions.[8] Three-year results demonstrate a durable and superior outcome of DCB with significantly higher primary patency and lower clinically driven target lesion revascularization.[9]

TASC II had announced that endovascular treatment is the preferred method for multiple lesions ≤ 5 cm length or single stenoses/occlusions ≤15 cm not involving the popliteal artery. Longer lesions treated with stents show improved 12-month patency. Primary stenting outcomes have surpassed those of PTA with selective stenting in longer lesions.[10] Femoral Stenting in Obstructions (FESTO) study reported that stent fractures influenced significantly restenosis rates,[11] while Sirolimus Coated Cordis Selfexpandable Stent (SIROCCO) study, and the Femoral Artery Stenting Trial (FAST) did not see a relationship between restenosis and stent fractures.[12] In-stent restenosis (ISR) rates ranged from 19% - 37% at one year by neointimal hyperplasia.[13] Different modalities of interventions were used to treat (ISR) by either repeated balloon angioplasty, stent-in-stent, stent-grafts or drug-eluting stents (DES), cutting balloons, cryoplasty or laser atherectomy with reasonable success rates.[14]

Materials and Methods

This prospective study was carried out from January 2016 to December 2018 at Sohag University Hospitals and 6 th October Insurance Hospital, Dokki, Cairo on 70 patients collected among 120 cases complaining from de novo femoropopliteal diseases. Those patients suffered from long occlusions ≥10 cm, Rutherford category 3,4,5 divided in 3 groups. Group (A) consisted of 30 patients (17 males, 13 females) with a mean age of 57 years (ranged from 50 - 64 years) treated by plain balloon angioplasty, group (B) consisted of 22 patients (12 males, 10 females) with a mean age of 61 years (ranged from 52 - 65 years) treated by DCB and group (C) consisted of 18 patients (10 males, 8 females) with a mean age of 59 years (ranged from 49 - 65 years) treated with long bare metal nitinol stent. Inclusion criteria in this study were; patients with chronic limb ischemia caused by long SFA occlusion Rutherford categories 3,4 or 5, the diseased femoropopliteal segment should be ended at least 3 cm above the knee joint, lesion

length ranged between 10- 18 cm and adequate distal run-off vessels to the foot . Exclusion criteria were; patients with non-salvageable limb or those with life threatening infection, patients with multi-vessels occlusions rather than femoropopliteal segment, total occlusion that cannot be crossed by a wire, previous bypass surgery in the same limb or more than one stent might be needed to cover the lesion.

All patients were admitted and signed a written informed consent. This series was approval by the hospital ethics committee. Patients were assessed clinically including history of risk factors; diabetes mellitus (DM), smoking, hypertension, cardiovascular, cerebrovascular diseases, renal insufficiency, previous endovascular intervention or bypass surgery. All patients were examined carefully including ankle brachial pressure index (ABI) and duplex ultrasound. CT angiography (CTA) was performed in all cases for diagnosis, identification the character of the lesion, distal run-off vessels. All patients were subjected to full laboratory investigations with special concern to renal functions and coagulation profile.

Procedure details: Peri-procedural medications with dual antiplatlet therapy in the form of salicylates 75 mg and clopidogrel 300 mg as a loading dose followed by daily maintenance dose 75 mg clopidogrel continued postoperatively for at least 3 months in all cases. The procedure was done under local anesthesia in all cases either ipsilateral or contralateral femoral access according to the anatomical characteristics and lesion location. 70- 100 U/kg of unfractionated heparin were injected intra-arterially after sheath insertion. Pre-intervention angiography was performed to assess the lesion characteristics; length, stenosis / occlusion and distal run-off vessels. Patients were randomly classified into group (A) (B) and (C). In all patients of both groups, 0.035 Terumo hydrophilic guidewire (Radifocus, Terumo, Japan) was used to cross the lesion either intraluminal or subintimally. Length of the plain balloon, DCB or stent was chosen according to a ruler placed over patient thigh.

Group (A) patients; plain balloon group:

After passing the wire, lesions were dilated using 5 mm low-profile standard balloon for 1-2 minutes in their nominal pressure. In cases of flow-limiting dissection, repeated balloon inflation for 2 min was carried out. Completion angiography was done to assess the results. Bail-out stents were deployed in cases of residual stenosis > 30 % or flow limiting dissection and those patients were discarded from this group and turned to group (C) group.

Group (B) patients; DCB group:

After passing the wire, lesions were dilated using 5 mm low-profile standard balloon for 1-2 minutes in their nominal pressure to decrease the friction between the DCB surface and the diseased segment. This was followed by paclitaxel coated balloon for 3 min (IN. PACT balloon, Medtronic, USA). Paclitaxel dose is 3 ug/mm^2 of balloon surface in a specific matrix consisting of urea. Diameter sizing was 1:1 to the reference vessel. Treatment strategy was covering the whole lesion starting proximally from an apparently healthy segment and ended distal to the lesion in a healthy area. In lesions requiring more than one balloon, 5-mm balloon overlap was allowed to obtain a uniform drug elution and avoid a geographic missed area in the treated vessels. In cases of flow-limiting dissection, prolonged dilation up to 5 min was carried out as advised by Schmidt et al.[15] Completion angiography was done to assess the results. Bail-out stents were deployed in cases of residual stenosis > 30 % or flow limiting dissection and those patients were discarded from the study. (Fig. 1)

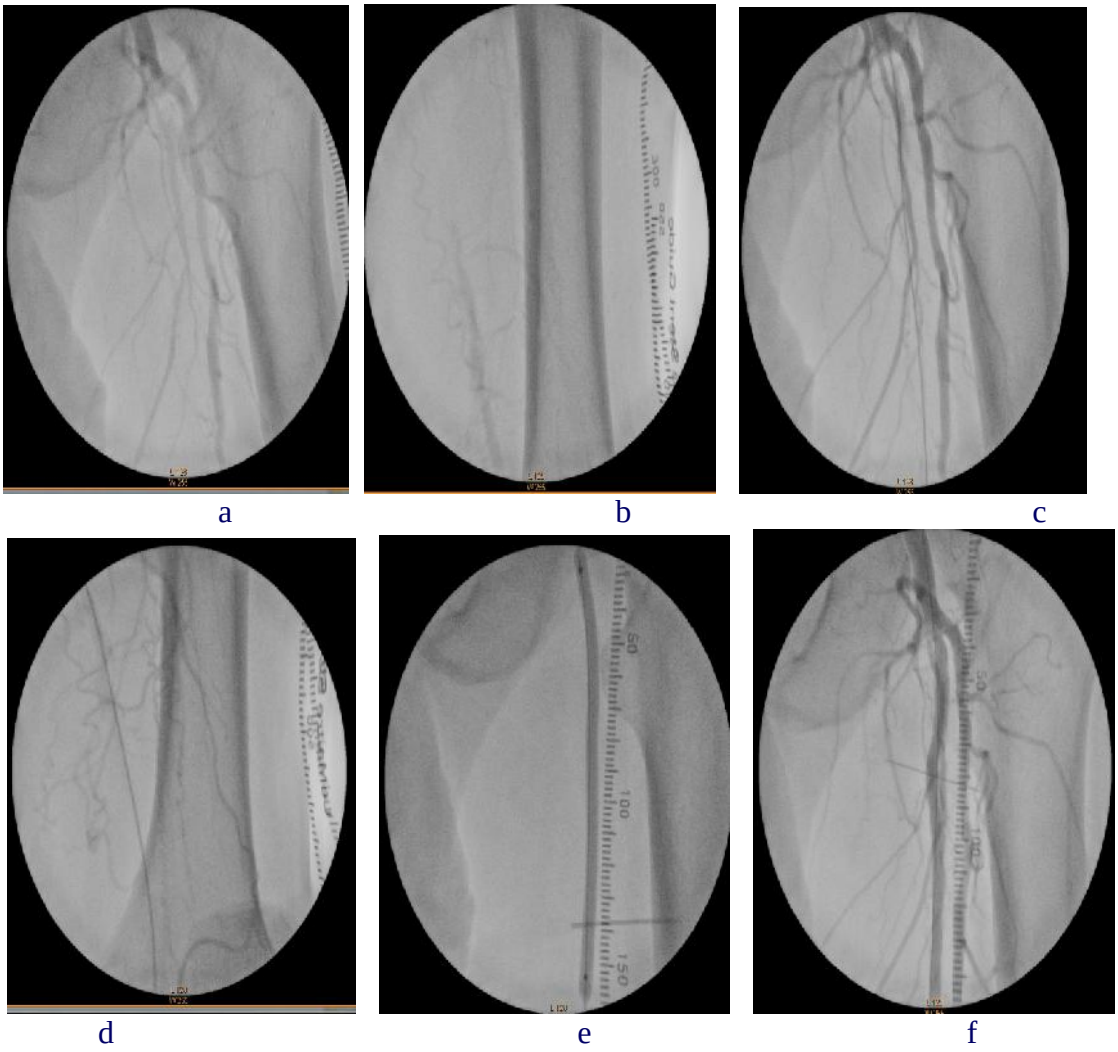

Fig.(1) DCB group: a,b,: flush occluded SFA with distal run-off at popliteal artery, c,d angiography after crossing the lesion by wire, e: DCB infation, f: completion angiography.

Group (C) patients; long bare metal stent group

After wire crossing, the lesion was dilated using a standard 5 mm balloon for 1-2 minutes in their nominal pressure. Self-expandable nitinol stent PROTEGE´ EverFlex (ev3 Inc., USA) was deployed to cover the whole lesion length extending 1 cm proximally and distally. Post stent balloon dilatation was performed. Completion angiography was performed routinely to assess the technical success of the procedure. (Fig. 2)

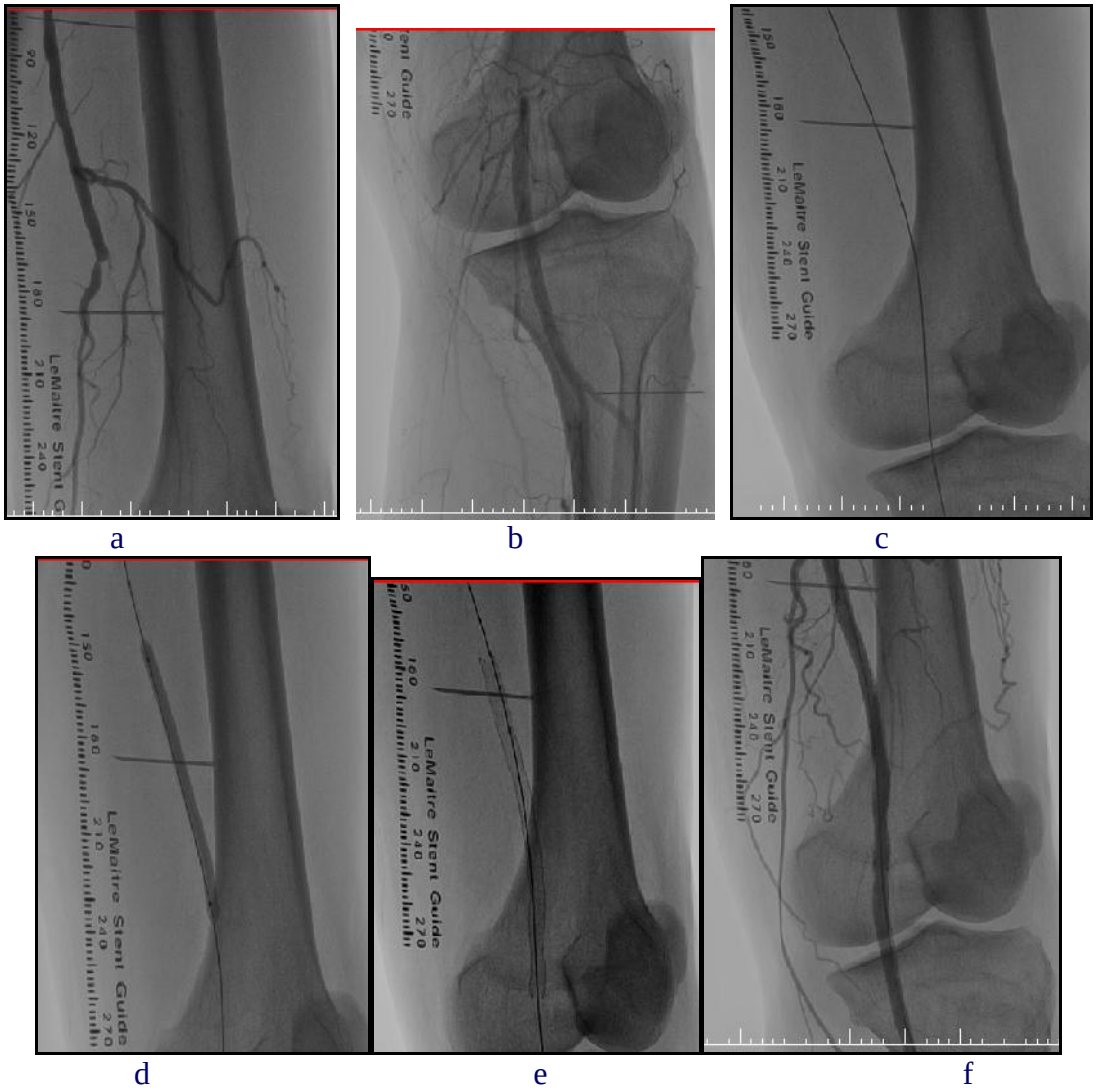

Fig.(2) Stent group: a,: totally occluded distal SFA, b: distal run-off at popliteal artery and crural vessels, c: crossing the lesion by wire d: plain balloon angioplasty prior to stent deployment, e:stent deployment, f: completion angiography.

Follow-up was conducted daily during period of admission and then in vascular surgery outpatient clinic at 3, 6, 9 and 12 months of follow up period. During the hospital stay, patients with ischemic foot ulcers or gangrene received standard wound care, debridement and/or minor amputation. During follow up visits; assessment were done by regaining pulse, ankle brachial index (ABI), disappearance of rest pain, wound healing, target lesion patency by duplex ultrasound and assess procedure related complications.

Definitions:

Technical success: was defined as residual stenosis < 30 % by visual estimation.

Clinical success: healing of foot lesion, improvement in clinical Rutherford category after the procedure and increase in ankle-brachial index (ABI).

Primary patency: absence of hemodynamically significant stenosis at the target lesion (by duplex ultrasound; peak systolic velocity ratio (PSVR) < 2.4).

Target lesion revascularization (TLR): was defined by re-intervention within the target lesion because of recurrence of symptoms or decreased ankle-brachial index (ABI) ≥20% as it was reported by Zeller et al,.([15])

Statistical analysis:

Descriptive statistics were used to present continuous data as mean±SD. Categorical variables were expressed as numbers and percentages. Patency rates and freedom from TLR were described using Kaplan-Meier analysis and log-rank test to compare groups over time on relevant outcome measures.

Results

There were no differences between the three groups in patient age, male / female gender, cardiovascular risk factors, or concomitant diseases, such as renal insufficiency or Rutherford classification. Major risk factors were diabetes and smoking as their incidence were 66.7% & 63.3% in group (A), 63.6% & 59.1% in group (B) and 61.1% & 66.6% in group (C) respectively. Patients' criteria and demographic data were summarized in (Table 1).

Table 1 Demographic data and risk factors:

	Group (A) NO (30)	Group (B) NO (22)	Group (C) NO (18)
Age/years	57(50-64)	61 (52-65)	59 (49-65)
Males/females	17(56.7%)/13(43.3%)	12 (54.5%) / 10 (45.5%)	10 (55.5%) / 8 (44.5%)
Risk factors			
DM	20 (66.7%)	14 (63.6 %)	11 (61.1 %)
Smoking	19 (63.3%)	13 (59.1 %)	12 (66.6 %)
Hypertension	16 (53.3%)	11 (50 %)	10 (55.5 %)
Ischemic heart disease	13 (43.3%)	10 (45.4 %)	8 (44.4 %)
Stroke	6 (20%)	4 (18.2 %)	4 (22.2 %)
Renal insufficiency	7 (23.3%)	5 (22.7 %)	4 (22.2 %)

In patients of group (A), lesion length was 15.1±2.7 cm. 14 patients (46.7%) were Rutherford category "5", 12 patients (40%) Rutherford category "4" and 4 patients (13.3%) Rutherford category "3". In group (B) patients, lesion length was 14.2±3.6 cm. 10 patients (45.5%) were Rutherford category "5", 9 patients (40.9%) Rutherford category "4" and 3 patients (13.6%) Rutherford category"3". In group (C) patients, lesion length was 15.3±2.8 cm. 8 patients (44.4%) were Rutherford category "5", 6 patients (33.3%) Rutherford category "4" and 4 patients (22.2%) Rutherford category "3". Most of patients (89%, 85.4%,83.4%) in both groups respectively had more than one vessel distal run-off to the foot. There were no significant differences between the three groups (Table 2).

Table (2): Lesion criteria and intraoperative data:

	Group (A) NO (30)	Group (B) NO (22)	Group (C) NO (18)
Lesion Length	15.1±2.7	14.2±3.6	15.3±2.8
Rutherford classification			
Rutherford category 3	4 (13.3%)	3 (13.6 %)	4 (22.2 %)
Rutherford category 4	12 (40%)	9 (40.9 %)	6 (33.3 %)
Rutherford category 5	14 (46.7%)	10 (45.5 %)	8 (44.4 %)
Approach			
Crossover	21 (70%)	15 (68.2%)	11 (61.1%)
Antegrade	9 (30%)	7 (31.8%)	7 (38.9%)
Run-off vessels 1 2 3	 3 (10%) 20 (66.7%) 7 (23.3%)	 1 (4.5%) 14 (63.6%) 7 (31.8%)	 3 (16.7%) 10 (55.6%) 5 (27.8%)

Table (3) Complications:

	Group (A) No. (30)	Group (B) No. (22)	Group (C) No. (18)
Puncture site hematoma	3 (10%)	2 (9.1 %)	1 (5.6%)
Acute thrombosis	2 (6.6%)	1 (4.5 %)	2 (11.1%)
Dissection	4 (13.3%)	4 (18.2 %)	_
Contrast induced nephropathy	3 (10%)	2 (9.1 %)	2 (11.1%)

Regarding to procedure related complications, in group (A) patients, 3 patients (10 %) developed groin hematoma which resolved spontaneously and 4/30 patients (13.3%) developed flow limiting dissection so stents were deployed and those patients were added to group (C) stent group. In group (B) patients, two patients developed groin hematoma which resolved spontaneously and 4/22 (18.2%) patients developed flow limiting dissection and bail out stents were deployed .Those patients were discarded from this study. This was due to assess the results of each procedure separately without conflict. In group (C) patients,8 patients (36.4%) developed in-stent stenosis. In this study 5 patients developed acute thrombosis during their procedure; 2 in group (A), one in group (B) and 2 in group (C). Those patients were treated by thrombolytic therapy. There was no procedure related mortality in both groups. (Table: 3)

In group (A) plain balloon patients, 4 patients had flow limiting dissection during the procedure so bail out stents were deployed. Those patients were shifted from this group to group (C) of stent group. Primary patency rate was 53.8% (14/26) patients. 12 patients (46.2%) developed significant stenosis and were diagnosed by duplex imaging (PSVR ≥ 2.4). 4/12 patients were claudicant while 8/12 patients had critical limb ischemia and were treated by DCB in 3 cases & by long stent in one case and bypass surgery in 2 patients. The other 2 cases ended by limb amputation because of poor distal run off and life threatening infection.

In the DCB cohort (group B), bail out stents were performed in 5/22 (22.7%) lesions due to persistent stenosis in 3 patients, flow limiting dissection in 2 patients. Those patients were excluded from this group. Primary patency rate was 76.4% (13/17) patients. Four patients (23.5 %) developed significant stenosis and were diagnosed by duplex imaging. One patient continued medically as the patient was claudicant. (3/4) patients had critical ischemic limb, one case were treated by DCB angioplasty with stents due to flow limiting dissection during angioplasty, the 2nd patient treated by femopropopliteal bypass as the lesion extended to P2 popliteal segment and the 3rd one ended by limb amputation as the lesion was difficult to be crossed by wire and had poor distal run-off that prevent bypass surgery.

In group (C) of long bare metal stent group, primary patency rate was 63.6 %.(14/22) patients. Eight patients (36.4%) developed in-stent stenosis. Two cases treated conservatively, 4 patients treated by DCB angioplasty, 2 patients were difficult to cross their lesions and failed the endovascular intervention. One of them treated by femoropopliteal bypass and the other one developed life threatening infection and amputation was done.

Significant stenosis rates were 46.2% (12/26), 23.5% (4/17) and 36.4% (8/22) in plain balloon group, DCB and long stent groups respectively while the clinically driven TLR rates were 30.8% (8/26), 17.6 % (3/17) and 27.3 % (6/22) respectively (Fig.3&4). It was statistically significant difference between the study cohorts, (p-value: < 0.01).

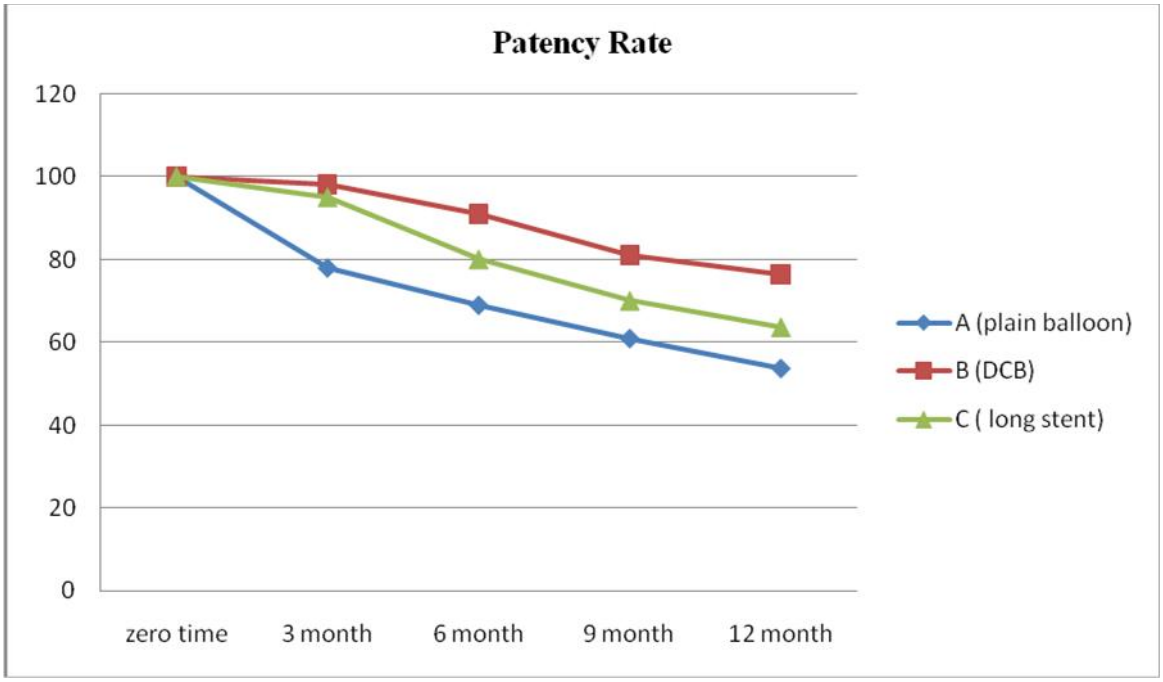

Fig. (3): Patency Rate: One year patency rate of group (B) showed better results (76.4%) with significant (p-value= < 0.01) .

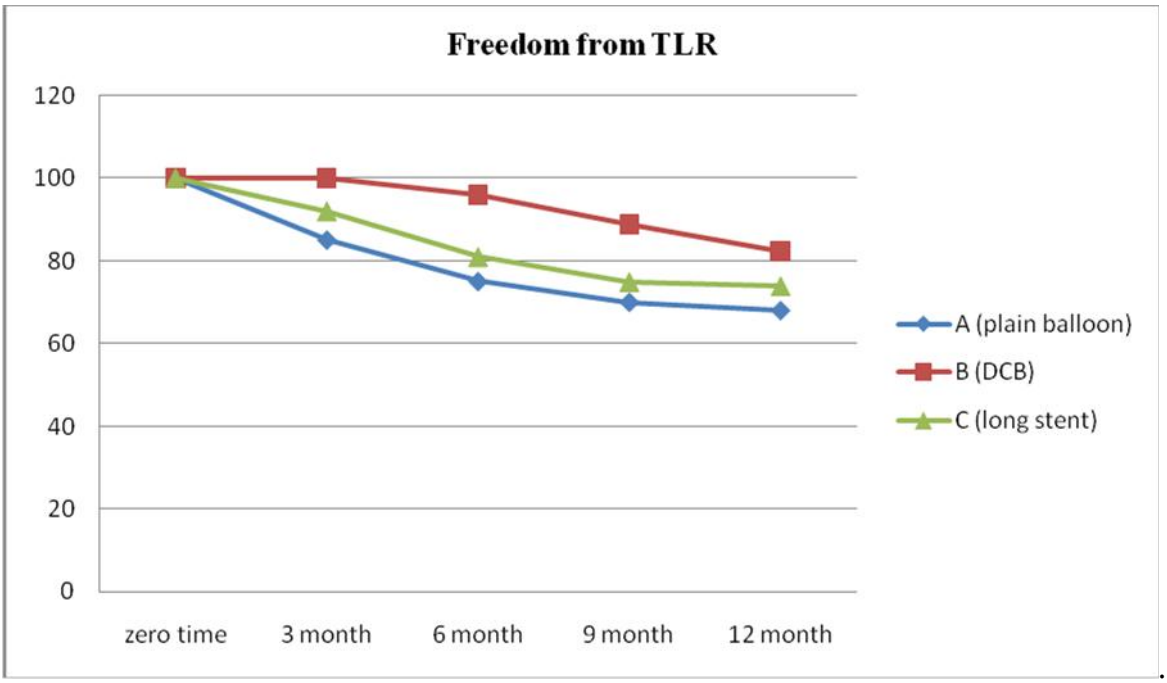

Fig.(4): Freedom from TLR: The clinically driven TLR was the least in DCB group in comparison to standard balloon group and stent group.

Discussion

Within the last few years, there were many advances in endovascular management for TASC II type C and D femoropopliteal lesions with a successful recanalization rate up to 80% but not superior to open surgery especially in lesions ≥ 15 cm length. Although, endovascular therapy provides similar limb salvage to bypass surgery, early postoperative recovery with less morbidity and mortality in comparison to surgery and also not hamper the use of bypass later on, the endovascular interventions still remain a controversy.[16]

Different modalities are available for treatment of (SFA) disease including DCB or implantation technologies such as bare metal stents, covered stents, and drug-eluting stents. [17]

Plain balloon angioplasty has a high rate of technical success and accepted safety profile; however its rate of restenosis is considerable. This can be explained by frequent vessel recoil and flow-limiting dissections, negative remodeling and intimal hyperplasia.[18] DCB is significantly superior to plain balloon in improving patency and decreases the risk of TLR.[19] This was also matched with the results of this series (76.4%, 17.6% versus 53.8%, 30.8% respectively).

DCB is a combination of balloon dilatation with local delivery of antiproliferative agent; paclitaxel drug. Each DCB type is variable in paclitaxel dose (varying from 2 - 3.5 µg/mm2) and carrier molecule (excipient). Not all the DCBs are the same despite the same drug but variable in technical characteristics of each balloon[20] as well as paclitaxel dose (2 : 3.5 mg/mm^2) and excipients.[21] The type of balloon used in this series was IN. PACT balloon, Medtronic, paclitaxel dose was 3 ug/mm^2 and the excipient was urea. In an experimental animal model, the effectiveness of DCB appeared at a dose of 1 mg/mm^2 with increased its antirestenotic effect up to 3 mg/mm^2. Excipients are also important components that regulate paclitaxel elution. It was noted that paclitaxel can persist in the vessel wall for up to 180 days in experimental models.[11]

Liistro et al,.[22] reported that there were anatomical and procedural considerations playing a significant factor in tailoring the decision making in choosing DCB or stenting; lesion length, type of recanalization whatever subintimal or intraluminal, degree of calcification and lesion site. Generally, it is better to avoid stent when unnecessary due to the behavior possibility of stent restenosis which is often difficult to be treated. Stenting is also best avoided when popliteal artery is involved due to well-known risk of stent fracture which remains a significant concern. ISR lesions were classified by Tosaka classification.[23] Class I : focal, ≤ 5 cm length included lesions located in stent body, stent edge, or combination of these sites. Class II: diffuse lesions > 5cm length in stent body or stent edges. Class III: totally occluded stent.

In this series, patency rate at one year was 76.4 % and freedom from TLR was 82.4 % in group (B) patients treated by DCB. Nearly similar results (73.5%) patency rate was obtained in the Moxy DCB in (LEVANT 2) study.[24] Scheinert et al,.[25] in Lutonix trial registered a reasonable short term and midterm outcomes of DCB in the form of primary patency (67%– 91%) and freedom from (TLR) (76%–92%) . Similar outcomes were noticed by Zeller et al,.[26] in his series comparing DCB and DES in long femoropopliteal lesions. Schneider et al,.[27] had reported 3 year follow up data on INPACT SFA trial, primary patency was 69.5 % and a clinically driven TLR was 2.4 % at 1 year, 9.1 % at 2 years and 15.2 % at 3 years.

Bare metal stent implantation primarily for moderate-length lesions was associated with better results versus balloon angioplasty alone.[28] However, their use has its limitations when long term patency is in consideration.[29] The dynamic stresses applied by the superficial femoral and popliteal artery may interpret stent fracture and in-stent restenosis. Restenosis after nitinol stents occurs in up to 30% within one year and 50% at 2 years and became higher in long lesions.[30] This was matched with our results as restenosis had occurred in (36.4%). Thus, these limitations has made in mind the interest in searching upon other options for long patency rate without need for a permanent metal implant.[31] Virga et al,.[32] had reported that diffuse in-stent restenosis or occlusion is a serious problem and suggested improving outcomes by DES.

Primary stenting is proved to be superior when compared to plain angioplasty particularly with long lesions but with concern of leaving a metal behind and its drawbacks.[33] In this series, patency rate at one year and clinically driven TLR were 63.4% & 27.3% in patients of stent group (C) and 53.8 % & 30.8% in patients of group (A) plain balloon. Nearly similar results were obtained by Schneider et al,.[34] who compared DCB and plain balloon in lesion lengths up to 18 cm and reported at 3 years follow up that primary patency remained significantly higher among patients treated with DCB compared with PTA 69.5% versus 45.1%. (p value <0.001) and clinically driven TLR were 15.2% and 31.1% respectively, (p value =0.002) so they concluded the durability and superior treatment effect of DCB versus standard balloon with significantly higher primary patency and lower clinically TLR. Also, in stent group, multiple trials e.g. STELLA study, DURABILITY I study and DURABILITY-200 study had assessed primary patency rates of stents in long lesions and achieved 66%, 72.2 % and 64.8% respectively which had less patency rates compared to DCB .[33,35,36] Patency rate of stent group in this study was 63.6%.

Bosiers et al,.[36] used a covered stent "viabahn stent" for (SFA) in-stent restenosis and achieved one year primary patency rate of 74.8%. and freedom from TLR of 79.9% and concluded that covered stents resulting in better patency rates .

Zeller et al,.[31] reported in his series that DCB and DES perform equally well in femoropopliteal lesions. Also, he compared DCB with provisional stenting and DES and reported that there was no significant outcomes regarding freedom from TLR and event-free survival so he preferred DCB angioplasty with or without provisional stenting over DES implantation.

In this series, assessment of freedom from TLR and one year patency rate of DCB and long bare metal stent showed a trend toward better outcome of the DCB angioplasty over long stents. This was also appreciated by others.[31]

Conclusion

DCB angioplasty yields better results and comparable outcomes compared to bare metal stents when treating long femoropopliteal occlusions. Because the nature of peripheral occlusive disease is progressive, it is wise to apply DCB angioplasty first and reserve the stent as a future option later on.

References

(1) Fowkes FG, Rudan D, Rudan I et al,. Comparison of global estimates of prevalence and risk factors for peripheral artery disease in 2000 and 2010: a systematic review and analysis. Lancet 2013;382:1329

(2) Tendera M, Aboyans V, Bartekink ML, et al. ESC Guidelines on the diagnosis and treatment of peripheral artery diseases: document covering atherosclerotic disease of extracranial carotid and vertebral, mesenteric, renal, upper and lower extremity arteries. Eur Heart J 2011;32:2851–906.

(3) Norgren L, Hiatt WR, Dormandy JA, et al. Inter- Society Consensus for the Management of Peripheral Arterial Disease (TASC II). J Vasc Surg. 2007;45 Suppl S:S5–67.

(4) Rastan A, Krankenberg H, Baumgartner I, et al. Stent placement versus balloon angioplasty for the treatment of obstructive lesions of the popliteal artery: a prospective, multi-centre, randomized trial. Circulation. 2013;127:2535–2541.

(5) Francesco Liistro, Sebastian Sixt, Gary Ansel, et al,. When would you elect to use a DCB versus a DES for SFA interventions, and what guides your decision making?. Endovascular Today, safety in SFA intervention. 2014; 10:89-92.

(6) Anantha-Narayanan M, Shah SM, Jelani QU, et al,. Drug-coated balloon versus plain old balloon angioplasty in femoropopliteal disease: An updated meta-analysis of randomized controlled trials. Catheter Cardiovasc Interv. 2019 Mar 6. doi: 10.1002/ccd.28176.

(7) Micari A, Cioppa A, Vadalà G, Castriota F, Liso A, Marchese A, Grattoni C, Pantaleo P, Cremonesi A, Rubino P, Biamino G. 2-year results of paclitaxel-eluting balloons for femoropopliteal artery disease: evidence from a multicenter registry. JACC Cardiovasc Interv. 2013;6:282-289.

(8) Micari A, Cioppa A, Vadala G, et al. 2-year results of paclitaxel-eluting balloons for femoropopliteal artery disease: evidence from a multicenter registry. JACC Cardiovasc Interv. 2013;6:282–289.

(9) Peter A. Schneider, John R. Laird, Gunnar Tepe, et al,. Treatment Effect of Drug-Coated Balloons Is Durable to 3 Years in the Femoropopliteal Arteries Long-Term Results of the IN.PACT SFA Randomized Trial. Circ Cardiovasc Interv. 2018 Jan;11(1):e005891. doi: 10.1161/CIRCINTERVENTIONS.117.00589.

(10) Marc Bosiers, Giovanni Torsello, Hans-Martin Gißler, et al,. Nitinol Stent Implantation in Long Superficial Femoral Artery Lesions: 12-Month Results of the DURABILITY I Study. J Endovasc Ther. 2009;16:261–269.

(11) Krankenberg H, Schluter M, Steinkamp HJ, et al. Nitinol stent implantation versus percutaneous transluminal angioplasty in superficial femoral artery lesions up to 10 cm in length: the femoral artery stenting trial (FAST). Circulation. 2007;116:285–292.

(12) Duda SH, Bosiers M, Lammer J, et al. Drug eluting and bare nitinol stents for the treatment of atherosclerotic lesions in the superficial femoral artery: long-term results from the SIROCCO trial. J Endovasc Ther. 2006;13:701–710.

(13) Laird JR, Katzen BT, Scheinert D, et al; RESILIENT Investigators. Nitinol stent implantation versus balloon angioplasty for lesions in the superficial femoral artery and proximal popliteal artery: twelve-month results from the RESILIENT randomized trial. Circ Cardiovasc Interv. 2010;3:267–276.

(14) Zeller T, Dake MD, Tepe G, et al. Treatment of femoropopliteal in-stent restenosis with paclitaxel-eluting stents. JACC Cardiovasc Interv. 2013;6:274–281.

(15) Andrej Schmidt, Michael Piorkowski, Henrik Görner, et al,. Drug-Coated Balloons for Complex Femoropopliteal Lesions 2-Year Results of a Real-World Registry. J A C C : Cardiovascular intervention 2016; 9(7): 715-724.

(16) Schmieder GC. Endovascular superficial femoral artery treatment: can it be as good as bypass? Sem Vasc Surg. 2008;21:186–194.

(17) Armstrong EJ, Saeed H, Alvandi B, et al,. Nitinol self-expanding stents vs. balloon angioplasty for very long femoropopliteal lesions. J Endovasc Ther. 2014;21:34-43.

(18) Daniele Giacoppo, Salvatore Cassese, Yukinori Harada et al,. Drug-Coated Balloon Versus Plain Balloon Angioplasty for the Treatment of Femoropopliteal Artery Disease;

An Updated Systematic Review and Meta-Analysis of Randomized Clinical Trials. JACC: Cardiovascular intervention 2016; 9: 1731-42.

(19) Byrne RA, Joner M, Alfonso F, et al. Drug–coated balloon therapy in coronary and peripheral artery disease. Nat Rev Cardiol 2014;11:13–23.

(20) Gongora CA, Shibuya M, Wessler JD, et al. Impact of Paclitaxel Dose on Tissue Pharmacokinetics and Vascular Healing: A Comparative Drug-Coated Balloon Study in the Familial Hypercholesterolemic Swine Model of Superficial Femoral In-Stent Restenosis. JACC Cardiovasc Interv 2015;8(8):1115–23.

(21) Kelsch B, Scheller B, Biedermann M, et al. Dose response to Paclitaxel-coated balloon catheters in the porcine coronary overstretch and stent implantation model. Invest Radiol 2011;46: 255–63.

(22) Francesco Liistro, Sebastian Sixt, Gary Ansel, et al,. When would you elect to use a DCB versus a DES for SFA interventions, and what guides your decision making?. Endovascular Today, safety in SFA intervention. 2014; 10:89-92.

(23) Tosaka A, Soga Y, Iida O, et al. Classification and clinical impact of restenosis after femoropopliteal stenting. J Am Coll Cardiol. 2012;59:16–23.

(24) Rosenfield K, Jaff MR, White CJ, et al. Trial of a Paclitaxel coated balloon for femoropopliteal artery disease. N Engl J Med 2015;373(2):145–53.

(25) Scheinert D, Duda S, Zeller T, et al,. The LEVANT I (Lutonix paclitaxel-coated balloon for the prevention of femoropopliteal restenosis) trial for femoropopliteal revascularization: first-in-human randomized trial of low-dose drug-coated balloon versus uncoated balloon angioplasty. JACC Cardiovasc Interv. 2014;7:10-19.

(26) Zeller T, Rastan A, Macharzina R, et al,. Drug-coated balloons vs. drug-eluting stents for treatment of long femoropopliteal lesions. J Endovasc Ther. 2014; 21:359-368.

(27)Schneider PA, Laird JR, Tepe G, et al.; IN.PACT SFA Trial Investigators. DCB show superior 3-year outcomes vs. PTA: results from In.Pact SFA randomized trial. Circ Cardiovasc Interv. 2018;11(6):e006699. DOI: https://doi.org/10.1161/ Circinterventions. 118.006699.

(28) Laird JR, Katzen BT, Scheinert D, et al. Nitinol stent implantation vs. balloon angioplasty for lesions in the superficial femoral and proximal popliteal arteries of patients with claudication: three-year follow-up from the RESILIENT randomized trial. J Endovasc Ther. 2012;19:1–9.

(29) Lammer J, Zeller T, Hausegger KA, et al. Heparin bonded covered stents versus bare-metal stents for complex femoropopliteal artery lesions: the randomized VIASTAR trial (Viabahn Endoprosthesis With PROPATEN Bioactive Surface [VIA] Versus Bare Nitinol Stent in the Treatment of Long Lesions in Superficial Femoral Artery Occlusive Disease). J Am Coll Cardiol 2013;62:1320–7.

(30) Klein AJ, Chen SJ, Messenger JC, Hansgen AR, Plomondon ME, Carroll JD, Casserly IP Quantitative assessment of the conformational change in the femoropopliteal artery with leg movement. Catheter Cardiovasc Interv. 2009;74:787-798.

(31) Laird JR, Yeo KK. The treatment of femoropopliteal in-stent restenosis: back to the future. J Am Coll Cardiol. 2012; 59:24-25.

(32) Virga V, Stabile E, Biamino G, et al,. Drug-Eluting Balloons for the treatment of the Superficial Femoral Artery in Stent Restenosis: 2-Year Follow-up. JACC Cardiovasc Interv. 2014; 7: 411-415.

(33) Davaine JM, Az´ema L, Guyomarch B, et al. One-year clinical outcome after primary stenting for Trans-Atlantic Inter-Society Consensus (TASC) C and D femoropopliteal lesions (The STELLA ‘‘STEnting Long de

L'Art 'ere f ´emorale superficielle'' Cohort). Eur J Vasc Endovasc Surg. 2012; 44: 432–441.
(34) Peter A. Schneider, John R. Laird, Gunnar Tepe, et al,. Treatment Effect of Drug-Coated Balloons Is Durable to 3 Years in the Femoropopliteal Arteries Long-Term Results of the IN.PACT SFA Randomized Trial. Circ Cardiovasc Interv. 2018; 11: e005891. DOI: 10.1161/ circinterventions. 117.005891.
(35) Bosiers M, Torsello G, Gissler HM, et al. Nitinol stent implantation in long superficial femoral artery lesions: 12-month results of the Durability I study. J Endovasc Ther. 2009;16:261– 269.
(36) Bosiers M, Deloose K, Callaert J, et al. Results of the Prot´eg´e EverFlex 200-mm-long nitinol stent (ev3) in TASC C and D femoropopliteal lesions. J Vasc Surg. 2011; 54: 1042–1050.

Access this Article in Online	
Quick Response Code	Website: www.ijcrims.com
	Subject: Medical Sciences

How to cite this article:
Osama A. Ismail. (2019). Management of De novo Long Femoropopliteal Occlusions; Plain Balloon, Drug Coated Balloon, Bare Metal Stent; Comparative Study. Int. J. Curr. Res. Med. Sci. 5(6): 1-13. DOI: http://dx.doi.org/10.22192/ijcrms.2019.05.06.001