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COMPARATIVE STUDY BETWEEN DRUG ELUTING BALLOON VERSUS UNCOATED BALLOON ANGIOPLASTY IN MANAGEMENT OF FEMORAL ARTERY DISEASE IN CRITICAL LOWER LIMB ISCHEMIA AND ITS PRELIMINARY RESULTS

By

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ABSTRACT

Background: Critical Limb Ischemia (CLI) often causes disabling symptoms of pain and can lead to loss of the affected limb. It is also associated with increased risk of myocardial infarction, stroke and death from cardiovascular disease.

Objective: To compare between drug coated balloons (DCB) and standard percutaneous transluminal angioplasty (PTA) for management of femoral artery disease in critical lower limb ischemia and its preliminary results.

Patients and methods: A prospective single blinded randomized study conducted on 40 patients with femoro-popliteal arterial occlusive disease between May 2017 and May 2019 at the Department of Vascular Surgery in Al-Azhar University and Military Armed Forces Hospitals.

Results: No major adverse events were reported in either arm apart from the minimal occurrence of puncture site haematoma (1 case in either arm which resolves spontaneously necessitating no surgical intervention), allergic reactions (1 case in the PTA group) and transient increase in renal function (2 cases in PTA group and 1 case in DCB group).

During the 12-month follow-up period, 1 patient in the drug coated balloon group died because of multiple organ failure due to severe sepsis, another patient in the uncoated balloon group died due to heart failure. One case in the DCB group ended with above knee amputation compared with two cases in the PTA group.The 12-month primary patency rate was 85% in the DCB arm versus 55% in the PTA arm (P<0.001). The DCB-treated patients demonstrated lower rates of clinically driven target lesion revascularization versus PTA-treated patients through 12 months (5% versus 25%; P<0.001). A significantly higher primary sustained clinical improvement (85%) was observed in the DCB arm in comparison with the PTA arm (60%) (P<0.001).

Conclusion: The DCB demonstrated impressive patency rates with low repeat revascularization rates in comparison with other conventional balloons.

Key words: drug eluting balloon; uncoated balloon; angioplasty; ischemia.

INTRODUCTION

Critical limb ischemia (CLI) is a severe form of peripheral arterial disease (PAD). CLI often causes disabling symptoms of pain and can lead to loss of the affected limb. It is also associated with increased risk of myocardial infarction, stroke and death from cardiovascular disease. The aims of management in patients with CLI are to relieve ischemic pain, heal ulcers, prevent limb loss, improve function and quality of life, and prolong survival *(Belch and Lambert, 2013).*

Over the last decades, endovascular repair has become the preferred treatment for femoropopliteal arterial obstructive disease. However, even with stenting restenosis rates were between 35% and 45% after one- and two-years follow-up respectively often requiring repeat percutaneous or surgical intervention *(Karimi et al., 2013).*

The new Trans-Atlantic Inter-Society Consensus (TASC) femoro-popliteal criteria reflect the fact that increasingly complex disease can be managed using endovascular techniques. TASC type A lesions are suitable candidates for endovascular techniques; TASC type D lesions necessitate surgery, owing to endovascular technique's prohibitive failure rate; and TASC types B and C lesions can be treated using either endovascular or surgical revascularization, depending on the clinical scenario. There is some evidence that in patients with high-grade disease (e.g., TASC type C or D) who are facing imminent limb loss but are not candidates for surgical reconstruction, endovascular reconstruction may be beneficial *(Sadek and Peter , 2010).*

Treatment modalities have included risk factor optimization through life-style modifications and medications, or operative approaches using both open and minimally invasive techniques, such as balloon angioplasty. Drug-eluting balloon (DEB) angioplasty has emerged as a promising alternative to uncoated balloon angioplasty for the treatment of this difficult disease process *(Kayssi et al., 2016).*

The use of drug-eluting balloons for treatment of femoro-popliteal artery obstructions has become widespread in recent years. Drug-coated balloons promise to reduce the rates of restenosis by effective delivery of antiproliferative agent (paclitaxel) directly to vessel wall without the need for a permanent implant *(Mehrotra et al., 2017).*

The challenging idea behind the drug-coated balloon (DCB) concept is the biological modification of the injury response after balloon dilatation. Major advantages of the DCBs are the rapid delivery of drug at uniform concentrations with a single dose, their efficacy in areas where in stents have been contraindicated until now (ie, bifurcation, ostial lesions), and in leaving no stent scaffold behind. Reinterventions are easier to perform because DCBs leave no metal behind *(Herten et al., 2016).*

The present study aimed to compare between drugs coated balloons (DCB) and standard percutaneous transluminal angioplasty (PTA) for management of femoral artery disease in critical lower limb ischemia and its preliminary results.

PATIENTS AND METHODS

Study design: a prospective single blinded randomized study. Study population: 40 patients with critical lower limb ischemia due to femoro-popliteal arterial occlusive disease. They were divided into two equal groups. Group A was treated with drug eluting balloon and Group B treated with conventional balloon angioplasty. Study duration: between May 2017 and May 2019 at the Department of Vascular Surgery in Al-Azhar University and Military Armed Forces Hospitals.

Inclusion criteria: Adults (Age over 18), Symptomatic atherosclerotic lesions of the femoropopliteal artery, Rutherford class 4 to 6, De novo lesions, At least one patent below-the-knee artery with uninterrupted flow to the pedal arch, resting ankle-brachial index (ABI) < 0.5 in the study limb prior to procedure and Signed informed consent.

Exclusion criteria: Acute thrombus or aneurysm in the target vessel, Previous endovascular or surgical treatment of the target femoro-popliteal artery, Inflow lesions that cannot be successfully pretreated, Failure to cross the target lesion with a guidewire, Significant disease of all 3 infrapopliteal vessels, Concomitant (intentional or accidental) use of alternative therapies in the target vessel, including atherectomy, excimer laser, or cutting balloon during the index procedure, Renal failure (serum creatinine >2.0 mg/dL), Known allergy to iodinated contrast agents, Non-salvageable foot or Contraindication to anticoagulation or antiplatelet therapy.

Pre-procedure Workup: A written medical history including: A history of the presenting symptoms, Indications for the procedure, Patient medical and surgical history, A list of current medications, Allergic history, and Vascular risk factors. Physical examination including: A detailed vascular examination, Skin lesions, Ankle-brachial indexes, Measurement of segmental pressures, Pulse volume recordings, General examination of sufficient depth to exclude significant concurrent illnesses. Laboratory and radiological assessment were done preoperatively for all patients. Patients were evaluated through follow up clinic visits at 1-, 3-, 6-, and 12-months post-procedure regarding clinical improvement, Hemodynamic state, and Limb salvage rate.

Statistical analysis: Data were collected throughout history, basic clinical examination; laboratory investigations and outcome measures coded, entered and analyzed using Microsoft Excel software. Data were then imported into Statistical Package for the Social Sciences (SPSS version 20.0) (Statistical Package for the Social Sciences) software for analysis.

Qualitative data were described using number and percentage. Quantitative data were described using mean and standard deviation (SD).

The following tests were used to test differences for significance. Chi square test (X2) was used for difference and association of qualitative variable. The t test was used to compare between quantitative parametric groups. P value was set at <0.05 for significant results .

RESULTS

A total of 40 patients were enrolled in the study from May 2017 and May 2019 and followed up for up to 12 months. Patients presenting with critical lower limb ischemia were randomly assigned to treatment with drug coated balloon (DCB) angioplasty versus the standard percutaneous transluminal angioplasty (PTA). The mean age of the study population was 60.1 years for angioplasty with uncoated balloons (range 49-70) and 59.8 years for angioplasty with drug eluting balloons (range 45-72) **(Table 1)**.

Table (1): Demographic and clinical characteristics

Characters / Parameters	PTA	DEB	Total
Number	20	20	40
Mean Age (Y)	60.1	59.8	59.95
Sex-no (%)			
Male	16 (80%)	15 (75%)	31 (77.5%)
Female	4 (20%)	5 (25%)	9 (22.5%)
Diabetes (%)	14 (70%)	15 (75%)	29 (72.5 %)
Hypertension (%)	14 (70%)	13 (65%)	27 (67.5%)
Current smoker (%)	11 (55%)	10 (50%)	21 (52.5%)
IHD (%)	12 (60%)	11 (55%)	23 (57.5%)
ABBI (mean)	0.37	0.39	0.38
Rutherford category			
3	1 (5%)	2 (10%)	3 (7.5%)
4	4 (20%)	7 (35%)	11 (27.5%)
5	10 (50%)	9 (45%)	19 (47.5%)
6	5 (25%)	2 (10%)	7 (17.5%)

Men were included in 80% and 75% of PTA and DCB arms respectively. Slight differences were present in the following characteristics: 55% of patients in the uncoated balloon group versus 50% in the coated balloon group were smokers; diabetes was slightly more frequent in the coated balloon group (75%) than in the uncoated balloon group (70%); hypertension was reported more often in the uncoated balloon group (70 % versus 65%); and history of coronary artery disease was also more frequent in the uncoated balloon group (60 % versus 55%) **(Figure 1)**.

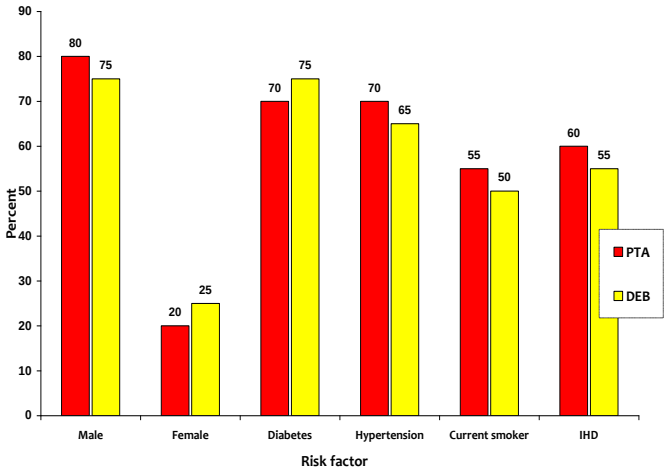

Figure (1): Risk factors of uncoated balloon angioplasty versus drug eluting balloon angioplasty

Patients in the DEB and PTA arms presented predominantly with Rutherford Category 5 (50% and 45%, respectively) when compared with Rutherford Category 4 (20% and 35%, respectively), 6 (25% and 10%, respectively) and 3 (5% and 10%, respectively) The mean peri-interventional ABBI was 0.38. **Figure 2)**.

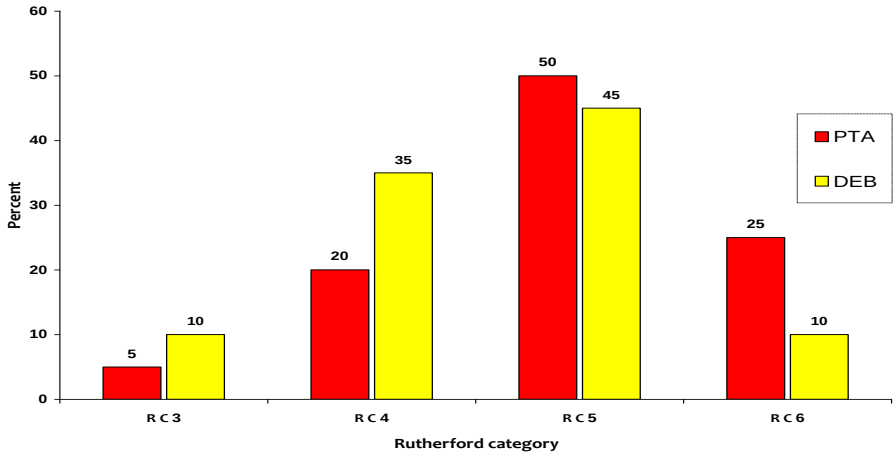

Figure (2): Rutherford category of the involved patients

The majority of lesions were located in the superficial femoral artery (SFA) predominantly in the middle and distal SFA (75% and 80% of PTA and DCB lesions were in the SFA). Isolated popliteal artery lesions were present in 15% of PTA treated lesions and 10% of DCB treated lesions. Combined lesions of SFA and popliteal artery were treated in 10% of PTA and DCB arms.

The majority of lesions were total arterial occlusion. Occlusions were treated in 70% and 75% (P=0.22) of patients in the DCB and PTA arms, respectively. The mean lesion length was 8.94±4.89 in the DCB arm and 8.81±5.12 cm in the PTA arm (P=0.82). The majority of lesions were more than 10 cm in length (45% of PTA lesions versus 40% of DCB lesions). No significant differences across the 2 arms were observed, with the exception of a lower number of patent infra-popliteal runoff vessels in the DCB group (15% of DCB treated patients has poor distal run off in comparison to 10% in the PTA group) (P=0.04) **(Table 2)**.

Table (2): Baseline Angiographic Characteristics

Characters / Parameters	PTA	DEB	Total
N	20	20	40
Location of the lesion			
Femoral	15 (75%)	16 (80%)	31 (77.5%)
Popliteal	3 (15%)	2 (10%)	5 (12.5%)
Femoral &popliteal	2 (10%)	2 (10%)	4 (10%)
Type of lesion			
Stenosis	5 (25%)	6 (30%)	11 (27.5%)
Occlusion	15 (75%)	14 (70%)	29 (72.5%)
Length of lesion			
< 5 cm	7 (35%)	4 (20%)	11 (27.5%)
5-10	4 (20%)	8 (40%)	12 (30%)
>10	9 (45%)	8 (40%)	17 (42.5%)
Runoff status			
Good (2-3 vessels)	18 (90%)	17 (85%)	35 (87.5%)
Poor (0-1 vessel)	2 (10%)	3 (15%)	5 (12.5%)

All procedural data, including balloon size and required additional stents, were similar in both treatment groups. Crossover access was chosen in 35% of patients treated with PTA and 25% of patients treated with DCB. Lesion crossing was mainly subintimal (65% of PTA treated lesions and 70% of DCB treated lesions were crossed sub-intimally).

As a result of recoil or dissection, stents were implanted in 5 of 20 patients treated with PTA and 4 of 20 patients treated with DCB. 15% of stents in the PTA group were implanted because of flow limiting dissection and 10% because of persistent stenosis (>50%). In the DCB arm 15% of stents were implanted because of flow limiting dissection and 5% because of persistent stenosis (>50%).

Pre-dilation was performed more often in DCB than PTA patients (95% vs. 85%, p=0.010), and post-dilatation was performed in 20% and 25% in DCB and PTA arms respectively. Procedural success, defined as a residual diameter stenosis of ≤50% for non-stented patients or ≤30% for stented patients, was achieved in 99 % of subjects in the DCB arm and 98 % of subjects in the PTA arm **(Table 3)**.

Table (3): Baseline Procedural Characteristics

Characters / Parameters	PTA	DEB	Total
Number	20	20	40
Vascular access			
Contralateral	7 (35%)	5 (25%)	12 (30%)
Ipsilateral	10 (50%)	14 (70%)	24(60%)
Retrograde	3 (15%)	1 (5%)	4 (10%)
Successful guidewire crossing	100%	100%	100%
Lesion crossing			
True lumen	7 (35%)	6 (30%)	13 (32.5%)
Subintimal	13 (65%)	14 (70%)	27 (67.5%)
Pre-dilatation (%)	17 (85%)	19 (95%)	36 (90%)
Post-dilatation (%)	5 (25%)	4 (20%)	9 (22.5%)
Provisional stenting	5 (25%)	4 (20%)	9 (22.5%)
Flow limiting dissection	3 (15%)	3 (15%)	6 (15%)
Persistent stenosis (>50%)	2 (10%)	1 (5%)	3 (7.5%)
Device success (%)*	100%	100%	100%
Procedural success (%)*	98%	99%	98.75%
Clinical success (%)*	97%	99%	98%

* Device success: Successful delivery, inflation, deflation, and retrieval of the intact study balloon without burst

* Procedural success: Residual DS ≤ 50% for non-stented subjects or ≤ 30% for stented subjects

* Clinical success: Procedural success without procedural complications (death, major target limb amputation, thrombosis of target lesion, or target vessel restenosis) prior to discharge

During and shortly after the intervention, no major adverse events were reported in either arm apart from the minimal occurrence of puncture site haematoma (1 case in either arm which resolves spontaneously necessitating no surgical intervention), allergic reactions (1 case in the PTA group) and transient increase in renal function (2 cases in PTA group and 1 case in DCB group).

During the 12-month follow-up period, 1 patient in the drug coated balloon group died as a result of multiple organ failure due to severe sepsis, another patient in the uncoated balloon group died due to heart failure **(Table 4)**.

During the 12-month follow-up period, one case in the DCB group ended with above knee amputation compared with two cases in the PTA group **(Table 4)**.

The 12-month primary patency rate was 85% in the DCB arm versus 55% in the PTA arm (P<0.001). During the first six months follow up, the primary patency rate of DCB and PTA were closely related but after 6 months the curves start to diverge in favour of the drug-coated balloon **(Table 4 & Figure 3)**.

Table (4): Follow-up at 12 months

Characters / Parameters	PTA	DEB	Total
N	20	20	40
Rutherford stage			
–Improved	13 (55%)	16 (85%)	29 (72.5%)
–Worsened	4 (25%)	2 (5%)	6 (15%)
–Equal	2 (15%)	1 (5%)	3 (7.5%)
ABBI (mean)	0.6	0.84	
Primary patency rate*	55%	85%	
Clinically driven TLR*	25%	5%	
All-cause deaths	5%	5%	
Target limb major amputation	10%	5%	
Clinical improvement*	70%	90%	
Complete wound healing	50%	80%	

–Primary patency is defined as the absence of target-lesion restenosis (as assessed by means of duplex ultrasonography) and freedom from target-lesion revascularization (adjudicated by the clinical-events committee).
–Clinically-driven TLR adjudicated by an independent Clinical Events Committee, blinded to the assigned treatment based on any re-intervention at the target lesion due to symptoms or drop of ABI of ≥20% or >0.15 when compared to post-procedure baseline ABI.
–Clinical improvement = reduction in size and/or depth of ulceration or improvement of rest-pain

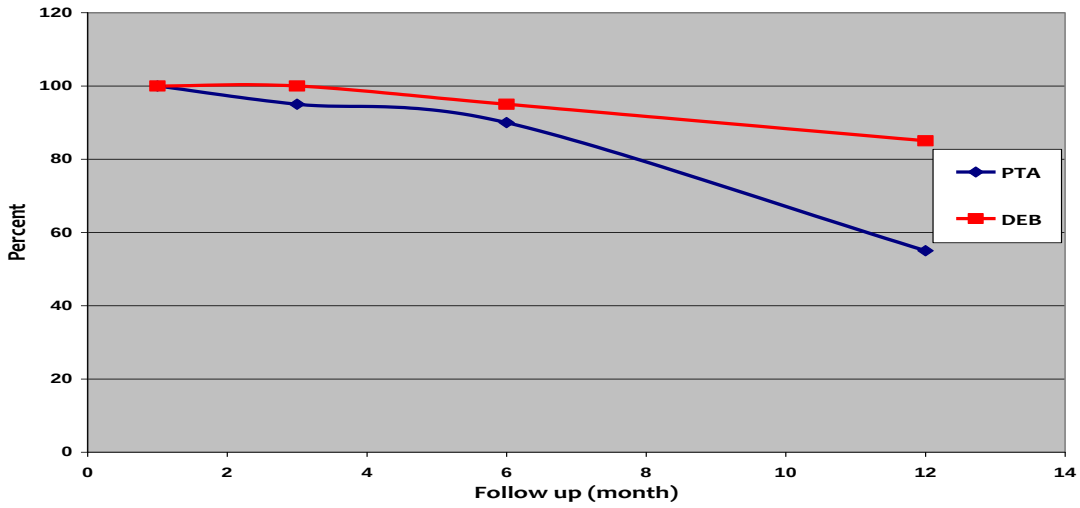

Figure (3): 12–month primary patency rate

The DCB-treated patients demonstrated lower rates of clinically driven target lesion revascularization versus PTA-treated patients through 12 months (5% versus 25%; P<0.001). A significantly higher primary sustained clinical improvement (85%) was observed in the DCB arm in comparison with the PTA arm (60%; P<0.001).

No statistically significant difference between treatment groups was seen in the change in ankle brachial index during the

period from shortly after intervention to 6 months but after 6 months the curves start to diverge in favor of the drug-coated balloon. The ankle-brachial index (ABI) was significantly higher in the DCB arm at 12 months. The ABI was in the normal range at follow-up and was 0.9±0.2 for the DCB group and 1.0±0.2 for the PTA group at the 6- and 12-month intervals

Compared with before the intervention, Rutherford category improved in both treatment groups, but the improvement was larger in the patients treated with the coated balloons (P<0.045). Improvement of at least one Rutherford category was seen in 72.0% of the DCB patients vs. 65.2% of the PTA patients (p=0.846) **(Figure 4)**.

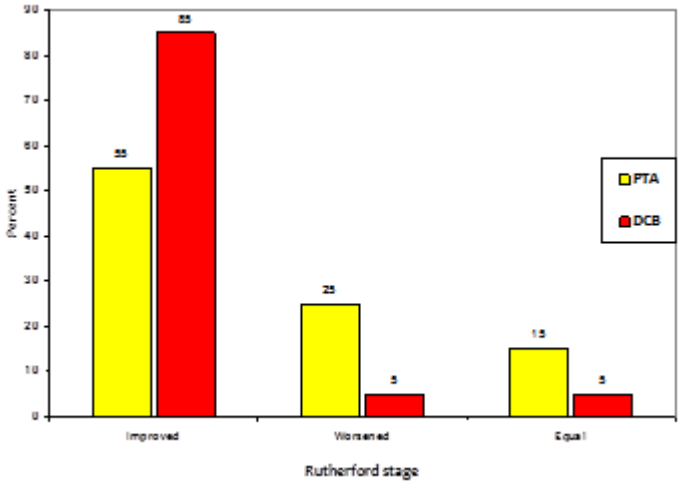

Figure (4): Rutherford stage at 12 months follow up

DISCUSSION

Critical limb ischemia (CLI) is the most common cause for major amputation and indication for peripheral revascularization. Most cases of CLI are diabetic patients; and CLI in this group of patients is likely to be complicated by infected non healing ulcers *(Uccioli et al., 2014).*

In the present work, the mean age was 60.1 years for angioplasty with uncoated balloons (range 49-70) and 59.8 years for angioplasty with drug eluting balloons (range 45-72). Men were included in 80% and 75% of PTA and DCB arms respectively. This matched with *Gunnar et al. (2015)* who showed that the mean age was 68 years in the PTA arm and 67.5 years in the DCB arm. Also, men were more in this study by 67.6% and 65% for PTA and DCB arms.

It was noticed in our study that the majority of lesions were located in the superficial femoral artery (SFA) predominantly in the middle and distal SFA (75% and 80% of PTA and DCB lesions were in the SFA). Our results were in line with *Fanelli et al. (2014).*

In this work, during the 12-month follow-up period, 1 patient in the drug coated balloon group died as a result of multiple organ failure due to severe sepsis, another patient in the uncoated balloon group died due to heart failure. This agreed with *0* who found that the overall mortality rate in the DCB group

was 8.1% versus 0.9% in the PTA group. However, there were no device or procedure related deaths. This also agreed with *Rosenfield et al. (2015)* and *Tepe et al (2015).*

In our study, the 12-month primary patency rate was 85% in the DCB arm versus 55% in the PTA arm. This went with *Laird et al. (2015)* in patients treated with DCB and showed significantly higher primary patency when compared with PTA (78.9% vs. 50.1%).

In this work, the drug-coated balloon resulted in superior efficacy in comparison with a plain angioplasty balloon for the treatment of patients with symptomatic superficial femoral and proximal popliteal PAD. There was significantly better primary patency rate. Also, there was a marked reduction in the need for target lesion revascularization at 12 months following treatment with the DCB. Our results were in line with *Gunnar et al. (2015).*

This current study showed that clinically driven target lesion revascularization rate was 5% for DCB versus 25% for PTA. Our results were similar to *Osamu et al. (2019)* who showed that the clinically driven target lesion revascularization rate was 9.1% for DCB versus 20.7% for PTA.

Our results were also similar to *Salvatore et al. (2012)* who reported that the revascularization with DCB is associated with lower TLR risk when compared with uncoated ballon angioplasty (UCB). DCB significantly reduces LLL and restenosis at 6-month angiographic follow-up.

In the present work, Rutherford category improved in both treatment groups, but the improvement was larger in the patients treated with the coated balloons. This went with *Fanelli et al. (2014)* who showed that the fontaine stage improved in both groups but more so in patients treated with DEBs.

The efficacy of paclitaxel in reducing restenosis in the femoropopliteal artery has been previously reported using different DCB technologies in various trials. Although paclitaxel was the most used antiproliferative drug in these preceding trials, each DCB was unique with respect to the paclitaxel dose (varying from 2 to 3.5 μg/mm2), the carrier molecule (excipient), the balloon material, and the balloon and coating technology used *(Tepe et al., 2015).*

Numerous modalities are available for the treatment of superficial femoral and popliteal artery disease, including implant-based technologies such as bare metal stents, covered stents, and drug-eluting stents, and implant-free technology, as well, such as atherectomy devices. DCB is an attractive alternative because it offers the promise of improved patency in comparison with PTA and a reduction in the need for stents. This is particularly important in the dynamic environment of the superficial femoral and popliteal arteries, where mechanical fatigue may lead to stent fracture and increased risk of in-stent restenosis *(Tepe et al., 2015).*

CONCLUSION

PTA with DCB was superior to PTA with plain conventional balloons, and had a favorable safety profile for the treatment of patients with symptomatic superficial

femoral and proximal popliteal artery. The DCB demonstrated impressive patency rates with low repeat revascularization rates in comparison with other conventional balloons. DCB stands to become an important treatment option for patients with superficial femoral and popliteal artery disease.

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مقارنة دراسيه بين البالونه المغطاه بالدواء مقابل البالونه الغير مغطاه في التدخل الجوفوعائئ لعلاج الشريان الفخذي في حالات القصور الشريانى الحرج ونتائجه الأولية

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خلفيـــة البحـــث: يســـبب قصـــور الشـــرايين الطرفيـــة آلام محـــددة للحركـــة، ويمكـــن أن يـؤدي الـى فقـدان الطـرف المصـاب، كمـا انـه يـرتبط بزيـادة مخـاطر الإصـابة باحتشـاء عضلة القلب والسكتة الدماغية والوفاة بسبب أمراض القلب والأوعية الدموية.

الهـدف مـن البحـث: دراسـه مقارنـه نتـائج التعامـل مـع انسـداد الشـريان الفخـذي عـن طريـق التوسـيع بالبـالون المغطـاه بالـدواء مقابـل البـالون الغيـر مغطـاة فـي حـالات القصور الحرج بالشرايين الطرفيه.

المرضـى وطـرق البحـث: دراسـة مقارنـة مسـتقبلية أجريـت علـى اربعـين مريضـا تـرددوا علـي مستشـفيات جامعـة الأزهـر والمستشـفيات العسـكرية فـي الفتـرة مـن مـايو 2017 حتـي مـايو 2019، وكـانوا يعـانون مـن قصـور حـرج بالـدورة الدمويـة فـي الشـريان الفخـذي، وتـم علاجهـم بالتوسـيع البـالوني باسـتخدام البالونـة المغطـاة بالـدواء والغير مغطاة.

نتـائج البحـث: لـم توجـد أي أحـداث سـلبية كبيـرة فـي أي مـن الـذراعين بصـرف النظـر عـن الحـد الأدنـى مـن حـدوث ورم دمـوي فـي موقـع البـذل (حالـة واحـدة فـي أي مـن الـذراعين والتـي شـفيت تلقائيًـا دون تـدخل جراحـي)، وردود فعـل تحسسـية (حالـة واحـدة فـي مجموعـة البالونـه الغيـر مغطـاه), وزيـادة مؤقتـة فـي وظـائف الكلـى (حالتـان فـي مجموعـة البالونـه الغيـر مغطـاه وحالـة واحـدة فـي مجموعـة البالونـه المغطـاه بالدواء).

وخـلال فتـرة المتابعـة التـي اسـتمرت 12 شـهرًا، تـوفي مـريض واحـد فـي مجموعـة البالونـات المغطـاة بالـدواء بسـبب فشـل أعضـاء متعـددة بسـبب تسـمم الـدم

الشديد، وتوفي مريض آخر في مجموعة البالونات غير المغطاة بسبب قصور في القلب، وانتهت حالة واحدة في مجموعة البالونات المغطاه بالدواء ببتر أعلى الركبة مقارنةً بحالتين في مجموعة البالونات الغير مغطاه، وكان معدل النجاح الفني لمدة 12 شهرًا 85٪ في ذراع البالونات المغطاه بالدواء مقابل 55٪ في ذراع البالونات غير المغطاة (P<0.001). أظهر المرضى الذين عولجوا بالبالونات المغطاة بالدواء معدلات أقل لإعادة تكوين الأوعية الدموية للآفة المستهدفة المدفوعة سريريًا مقابل المرضى المعالجين بالبالونات الغير مغطاه خلال 12 شهرًا (5٪ مقابل 25٪؛ P<0.001). لوحظ تحسن سريري مستدام أولي أعلى بشكل ملحوظ (85٪) في ذراع البالونات المغطاة بالدواء مقارنة بذراع البالونات الغير مغطاه (60٪) (P<0.001).

الاستنتاج: أظهر العلاج بالتوسيع البالوني باستخدام البالونه المغطاه بالدواء معدلات مبهرة رائعة مع معدلات إعادة تكوين الأوعية الدموية المتكررة مقارنةً بالبالونات التقليدية الأخرى.

الكلمات الدالة: البالونة المغطاة بالدواء، البالونة الغير مغطاة، التوسيع البالوني للوعاء، قصور الشرايين الطرفية.