

ABSTRACT

Background: Drug-coated balloons (DCBs) have shown promise in improving the outcomes of patients with peripheral arterial disease. Several trials have shown that DCB angioplasty has superior antirestenotic efficacy in the femoropopliteal artery (FPA) disease..

Methods: 84 consecutive adult patients with type 1 and 2 diabetes had been enrolled. Overall, 42 patients were treated with DCB angioplasty and 42 were treated with plain old balloon angioplasty (POBA) in a 1 : 1 randomization pattern. The primary end point of the study was the primary patency, mean diameter restenosis, and binary restenosis of the treated sites at 12 months without reintervention in the interim

Results: The 12-month mean diameter restenosis was significantly lower in the DCB arm than in the POBA group (27.9±35.1 vs. 44.8±33.9%, P=0.034). Furthermore, analysis showed that the binary (≥50% diameter stenosis) restenosis rates were significantly lower in DCB patients as compared with the POBA patients (28 vs. 47%, P=0.029). The primary patency was significantly better in DCB group (71 vs. 49%, P=0.028). On the contrary, we noted that the rate of clinically driven target lesion revascularization was slightly higher in the POBA patients, though not statistically significant as compared with the paclitaxel-coated balloon group (28 vs. 20%, P=0.13).

Conclusions: The treatment of diabetic peripheral arterial disease of FPA disease with IN.PACT paclitaxel-coated balloon angioplasty is associated with superior antirestenotic efficacy that provides a better primary patency rate compared with POBA at 12 months.

BACKGROUND

EVT of symptomatic atherosclerotic (PAD) has gained a widespread acceptance & is now recommended as the primary revascularization strategy in many clinical and anatomical scenarios. (PTA) remains highly effective for reducing symptomatic stenosis and PTA of SFA and/or popliteal artery has a high initial success rate, however, restenosis occurs in up to 60% of cases.

PURPOSE

This controlled, prospective study was designed to compare the efficacy of DCB vs POBA as regard to angiographic outcomes and restenosis rate of the atherosclerotic FPAs in diabetic patients with a 12-month follow-up period.

METHODS

Between January 2016 through December 2017, 84 consecutive adult diabetic patients with type 1 and 2 DM had been enrolled with de novo SFA stenosis ≥ 50% with a length of ≤15 cm or ≤10 cm occlusion of the SFA, ≥ 50% de novo lesions or occlusion of the popliteal artery (PA) and till the tibioperoneal trunk (TPT) with a length of ≤10 cm.

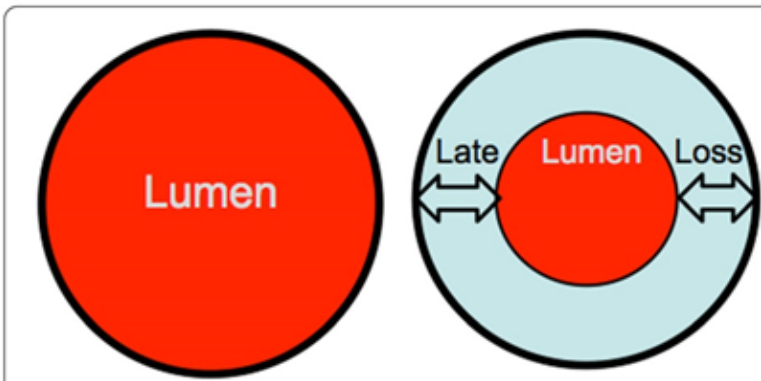
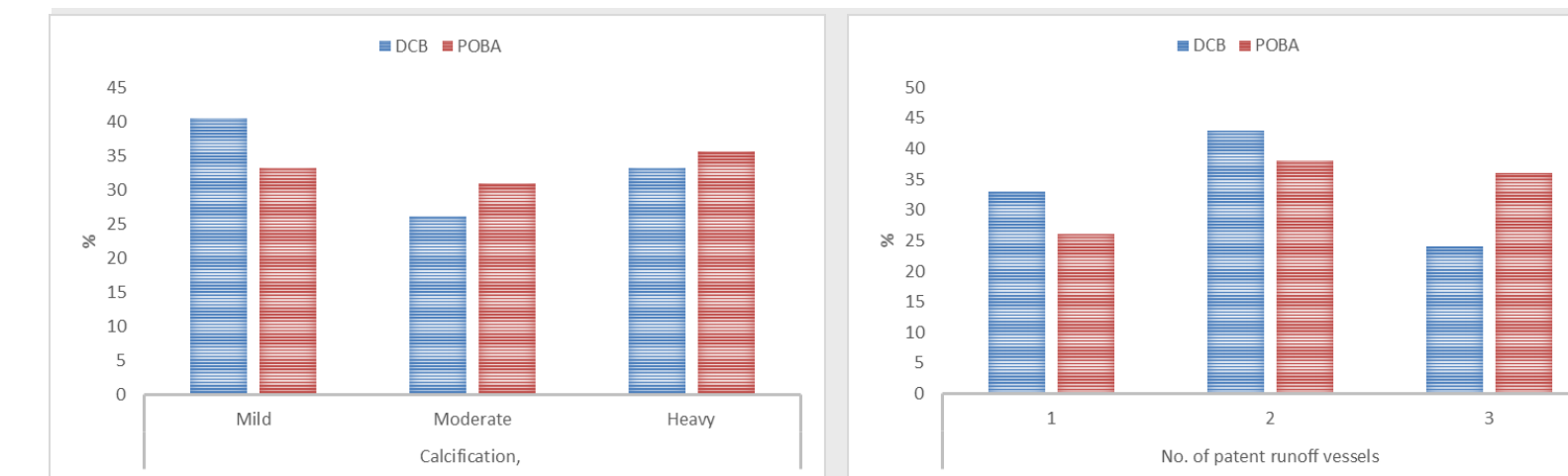


Figure 1: Late lumen loss (LLL) is defined as the angiographic minimum lumen diameter (MLD) immediately after percutaneous transluminal angioplasty (PTA) minus the minimum lumen diameter (MLD) at angiographic follow-up.

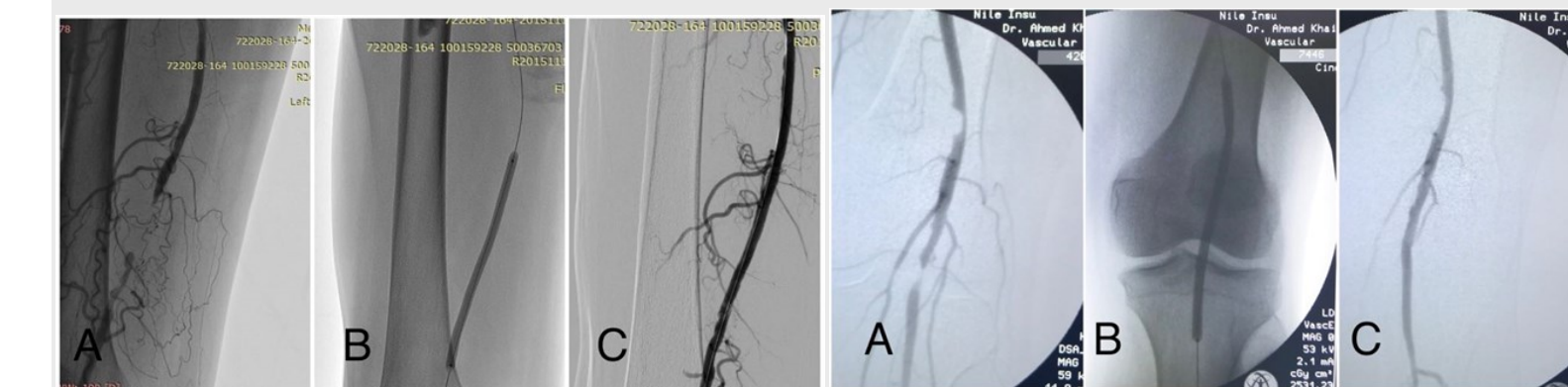
RESULTS

	POBA (N.=42)	DBC (N.=42)	P value
Age, years	68±10	69±10	0.754
Male	27 (64%)	29 (69%)	0.537
Diabetes			0.371
Oral	21 (50%)	20 (49%)	
Insulin	21 (50%)	22 (51)	
Hypertension	37 (88%)	38 (90%)	0.921
Dyslipidemia	29 (69%)	34 (81%)	0.593
Smoking	25 (59.5%)	24 (57%)	0.949
CAD	20 (47.6%)	24 (57%)	0.852
CVD	7 (17%)	3 (7%)	0.037*
CKD	15 (36%)	19 (45%)	0.258
BMI	22±4	28±4	0.781
Rutherford Stage			0.836
3= Severe claudication	21 (50%)	23 (55%)	
4= Ischemic rest pain	2 (5%)	3 (7%)	
5= Minor tissue loss	19 (45%)	16 (38%)	

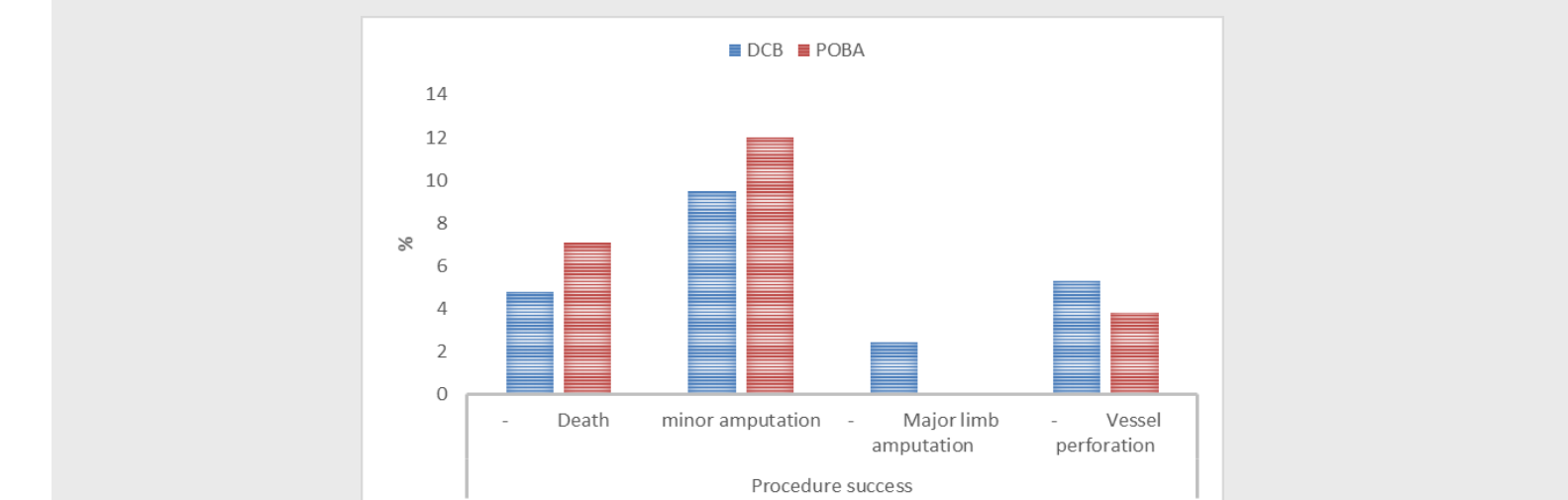
RESULTS



	POBA (N.=42)	DBC (N.=42)	P value
De novo lesions	42(100%)	42 (100%)	
Arteries			
SFA	31 (74%)	29 (69%)	0.783
PA	11 (26%)	13 (31%)	0.779
Avg lesion length (cm)	8.4±5.2	7.9±5.8	0.87
Avg vessel diameter (mm)	4.9±3.1	5.2±2.8	0.399
Lesion calcification			0.906
Mild	14 (33.3%)	17 (40.5%)	
Moderate	13 (31%)	11 (26.2%)	
Severe	15 (35.7%)	14 (33.3%)	
Diameter stenosis (%)	88.4	89.6	0.699
stenosis	29 (69%)	32 (76%)	0.712
Occlusions	13 (31%)	10 (24%)	0.296
Patent BTK arteries			0.893
1	11 (26%)	14 (33%)	
2	16 (38%)	18 (43%)	
3	15 (36%)	10 (24%)	



Angiographic outcome of DCB vs POBA



RESULTS

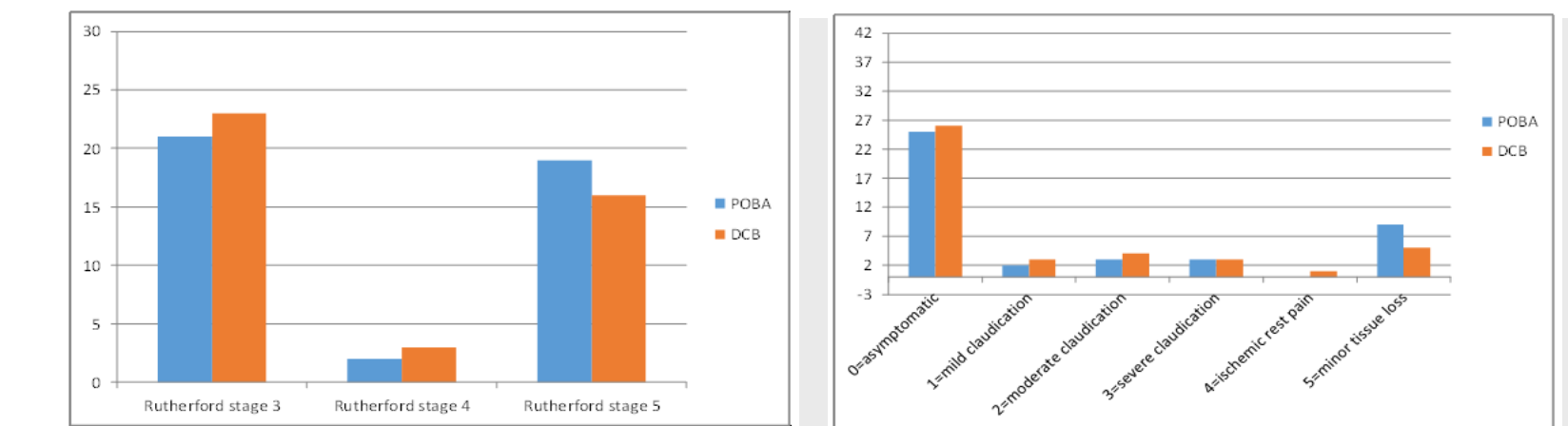
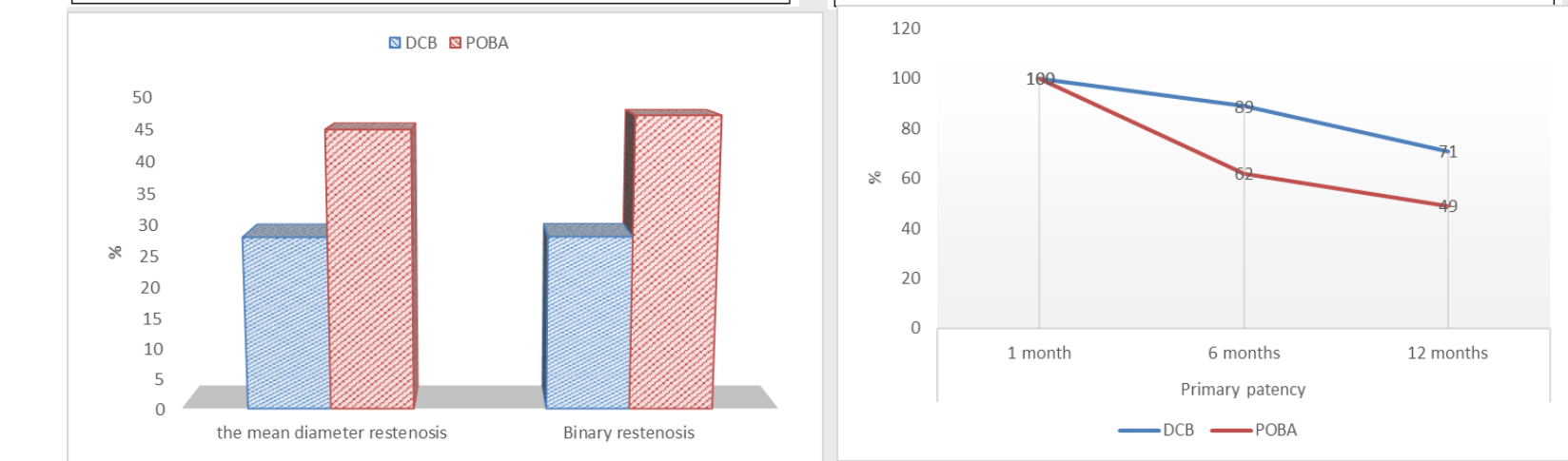


Figure 7: Distribution of Rutherford stage between the both study arms before angioplasty. Figure 8: Distribution of Rutherford stage between the both study arms at 12-month follow-up.



The 12-month mean diameter restenosis was significantly lower in the DCB arm than in the POBA group (27.9±35.1% vs. 44.8±33.9%, P=0.034). Furthermore, analysis showed that the binary (≥50% diameter stenosis) restenosis rates was significantly lower in DCB patients as compared with the POBA's (28% vs. 47%, P=0.029). The primary patency was significantly better in the paclitaxel-coated balloon group (71% vs. 49%, P=0.028)

CONCLUSION

- The treatment of diabetic peripheral arterial disease of FPA disease with IN.PACT paclitaxel-coated balloon angioplasty is associated with superior antirestenotic efficacy that provides a better primary patency rate compared with POBA at 12 months. The number of major adverse clinical events was comparable between DCB and POBA groups of patients

DISCLOSURES

I don't have disclosure