Adjunctive drug-coated balloon vs percutaneous transluminal angioplasty after atherectomy in common femoral artery diseases: a comparative study

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Received: 12 May 2020
Accepted: 22 June 2020
Published: 24 December 2020

The Egyptian Journal of Surgery 2020, 39:979–984

Purpose
Recent reports examined the efficacy of adjuvant techniques, such as drug-eluting balloon (DEB) inflation and percutaneous plain balloon angioplasty (POBA), in improving the long-term patency rate after atherectomy for common femoral artery (CFA) disease. The authors conducted the present comparative trial to compare the 6-month patency rate of adjuvant DEB inflation vs POBA after atherectomy of CFA disease.

Materials and methods
The authors conducted a retrospective comparative study on 80 patients with CFA disease who presented to the operating theaters of Vascular Surgery Department of Aswan University Hospital during the period from February 2016 to February 2018. Patients were allocated in equal ratio to one of the following groups: group DEB and group POBA.

Results
There were no statistically significant differences between studied groups in terms of procedure characteristics ($P>0.05$). Regarding the primary outcome of the present study, the DEB ad POBA groups had comparable rate of patency at 1 month (92.5 vs 100%, respectively), 6 months (87.5 vs 95%, respectively), and 12 months (72.5 vs 75%, respectively; $P>0.05$). There were no statistically significant differences between studied groups in terms of complications ($P>0.05$).

Conclusion
Both adjuvant DEB and POBA are effective modalities in improving the long-term patency rate in patients undergoing atherectomy for CFA lesions. This study demonstrated that both techniques achieved high success rate, with low incidence of procedure-related complications. Nonetheless, larger studies are still needed to confirm the findings.

Keywords:
common femoral artery disease, drug-coated balloon, percutaneous transluminal angioplasty

Egyptian J Surgery 39:979–984

1110-1121

Introduction

Peripheral arterial disease has become one of the main causes of cardiovascular-related mortality and morbidity in the past few decades; it is a chronic disease that is characterized by atherosclerotic occlusion of the lower extremities arteries, leading to peripheral hypoperfusion and ischemia [1,2]. According to previous epidemiological figures, almost 13–16% of elderly population (≥60 years old) experience peripheral arterial disease, with progressive increase in its incidence with age to reach almost 30% in patients aged more than 80 years [3,4]. Old age, male sex, genetic predisposition, smoking, obesity, and comorbidities such as diabetes and hypertension are established risk factors for peripheral arterial disease [5,6]. The current body of evidence shows that patients with peripheral arterial disease are at notable increased risk of mortality and cardiovascular [7]. Peripheral arterial disease of the common femoral artery (CFA) is a serious presentation, as it may reflect broader involvement of aortoiliac or femoropopliteal territories [8]; patients with CFA disease may present with calf pain, claudication, and even critical limb ischemia [9].

Although endovascular treatment has been established as the first-line revascularization option in patients with wide range of peripheral arterial disease, surgical endarterectomy is still the gold-standard technique for CFA diseases [10]. Factors such as easy accessibility, high success rate, favorable medium and long-term outcomes, low mortality rate, and challenges with stent placement in that location have favored surgical atherectomy for the management of CFA disease [11]. Nonetheless, the

 DOI: 10.4103/ejs.ejs_136_20

past two decades have witnessed a major advances in atherectomy technologies, which in return encouraged many centers to utilize atherectomy as promising approach for CFA disease without stenting [12,13]. Previous reports showed high success rates and low rate of complications following atherectomy of CFA diseases [14,15]. Unfortunately, this high success rate was not met with satisfactory long-term patency rate [16].

Therefore, recent reports examined the efficacy of adjuvant techniques, such as drug-eluting balloon (DEB) inflation and plain balloon angioplasty (POBA), in improving the long-term patency rate after atherectomy for CFA disease [17,18]. However, limited data are available about the superiority of one technique over the other as an adjuvant to atherectomy. Therefore, we conducted the present comparative trial to compare the 6-month patency rate of adjuvant DEB inflation vs POBA after atherectomy of CFA disease.

Materials and methods

Study design and patients

We conducted a retrospective comparative study on 80 patients with CFA disease who presented to the operating theaters of Vascular Surgery Department of Aswan University Hospital during the period from February 2016 to February 2018. The study was approved by the Ethical Committee of the Faculty of Medicine, Aswan University. Patients were included if they were adults (aged >18 years old), had atherosclerotic CFA disease, and agreed to sign the written informed consents. We excluded patients with non-atherosclerotic disease and patients with complicated CFA such as bleeding. All eligible patients underwent atherectomy. In addition, patients were allocated in equal ratio to one of the following groups:

(1) Group DEB: this included 40 patients who underwent DEB inflation.
(2) Group POBA: this included 40 patients who underwent POBA.

Endovascular techniques

A contralateral retrograde access was used to achieve revascularization. In POBA group, all patients received orbital or plaque excision atherectomy or both followed by scoring balloon angioplasty only, whereas in the DEB group, patients received additional treatment with DEB. We used embolic protection devices, Emboshield NAV-6 (Abbott Laboratories Inc., Worcester, Massachusetts, USA) and SpiderFX (Medtronic, Plymouth, Minnesota, USA), particularly in patients with compromised run-off to decrease distal embolization. The choice of sheath size was based on extent of the lesion.

Data collection

The following data were retrieved from patients' records: demographic characteristics, history of comorbidities, prior coronary revascularization, presentation, technical success, procedure-related complications, and patency rate through the follow-up period. The patency of CFA lesion was examined using duplex ultrasound and defined as less than 50% restenosis (defined as stenotic peak velocity ratio <2.4) or absence of target lesion revascularization within 12 months after the procedure. The follow-up visits were done at 1, 6, and 12 months after the procedure.

Statistical analysis

The data were analyzed using IBM SPSS Statistics 24.0 program (SPSS Inc., Chicago, Illinois, USA). Screening for extreme values in quantitative variables was done using independent *t*-test. Discrete and categorical variables were screened using frequency distribution, χ^2 test, and Fisher exact test. A *P* value of less than 5% was considered statistically significant.

Results

In the present report, the majority of the included patients in POBA were males (67.5%) compared with 50% in the DEB groups. The vast majority of patients in both groups were older than 50 years old. Major risk factors for peripheral arterial disease in both groups were smoking, diabetes, hypertension, and dyslipidemia. Overall, 30% of the patients in POBA group had prior coronary revascularization compared with 15% in DEB group. In addition, 42.5 and 30% of patients in POBA and DEB groups had critical limb, respectively. There were no statistically significant differences between studied groups in terms of sex, age, risk factors, history of myocardial infarction, history of prior coronary revascularization, history of heart failure or stroke, history of chronic kidney disease, and presentation ($P>0.05$) (Table 1).

In terms of procedure characteristics, most of patients in both groups had a sheath size of 7 F. In addition, the vast majority of patients in both groups had a balloon diameter of 6 mm and length of

Table 1 Preoperative data of the studied groups

Variables	POBA group (*n*=40) [*n* (%)]	DEB (*n*=40) [*n* (%)]	*P* value
Male	27 (67.5)	20 (50)	0.71
Age			
>40	5 (12.5)	2 (5)	
40–45	2 (5)	4 (10)	
45–50	4 (10)	5 (12.5)	0.74
50–55	9 (22.5)	5 (12.5)	
55–60	10 (25)	12 (30)	
60–65	5 (12.5)	6 (15)	
65–70	3 (7.5)	5 (12.5)	
<70	2 (5)	1 (2.5)	
Risk factor			
Smoking	30 (75)	35 (87.5)	0.15
DM	19 (47.5)	25 (62.5)	0.65
Hypertension	37 (92.5)	40 (100)	0.08
Dyslipidemia	34 (85)	27 (67.5)	0.07
CAD	23 (57.5)	19 (47.5)	0.65
Myocardial infarction	3 (7.5)	5 (12.5)	0.45
Prior coronary revascularization	12 (30)	6 (15)	0.11
Heart failure	2 (5)	8 (20)	0.07
Stroke/TIA	5 (12.5)	12 (30)	0.06
Chronic kidney disease	8 (20)	13 (32.5)	0.21
Intermittent claudication	23 (57.5)	26 (65)	0.49
Critical limb	17 (42.5)	14 (35)	0.49
Ischemia	9 (22.5)	10 (25)	0.79
Rest pain	8 (20)	4 (10)	0.21

CAD, coronary artery disease; DEB, drug-eluting balloon; DM, diabetes mellitus; POBA, percutaneous plain balloon angioplasty; TIA, transient ischemic attack.

Table 2 Procedure characteristics of the included patients

Variables	POBA group (*n*=40) [*n* (%)]	DEB (*n*=40) [*n* (%)]	*P* value
Sheath size			
6 F	12 (30)	6 (15)	0.22
7 F	24 (60)	31 (77.5)	
8 F	4 (10)	3 (7.5)	
Balloon diameters			
5 mm	8 (20)	6 (15)	0.41
6 mm	17 (42.5)	23 (57.5)	
7 mm	15 (37.5)	11 (27.5)	
	Length of balloons		
2 cm	20 (50)	18 (45)	0.58
4 cm	12 (30)	10 (25)	
<4 cm	8 (20)	12 (30)	
Embolic protection devices	15 (37.5)	19 (47.5)	0.36

DEB, drug-eluting balloon; POBA, percutaneous plain balloon angioplasty.

2 cm. Less than half of the patients in both groups had embolic protection devices. There were no statistically significant differences between studied groups in terms of procedure characteristics ($P>0.05$) (Table 2).

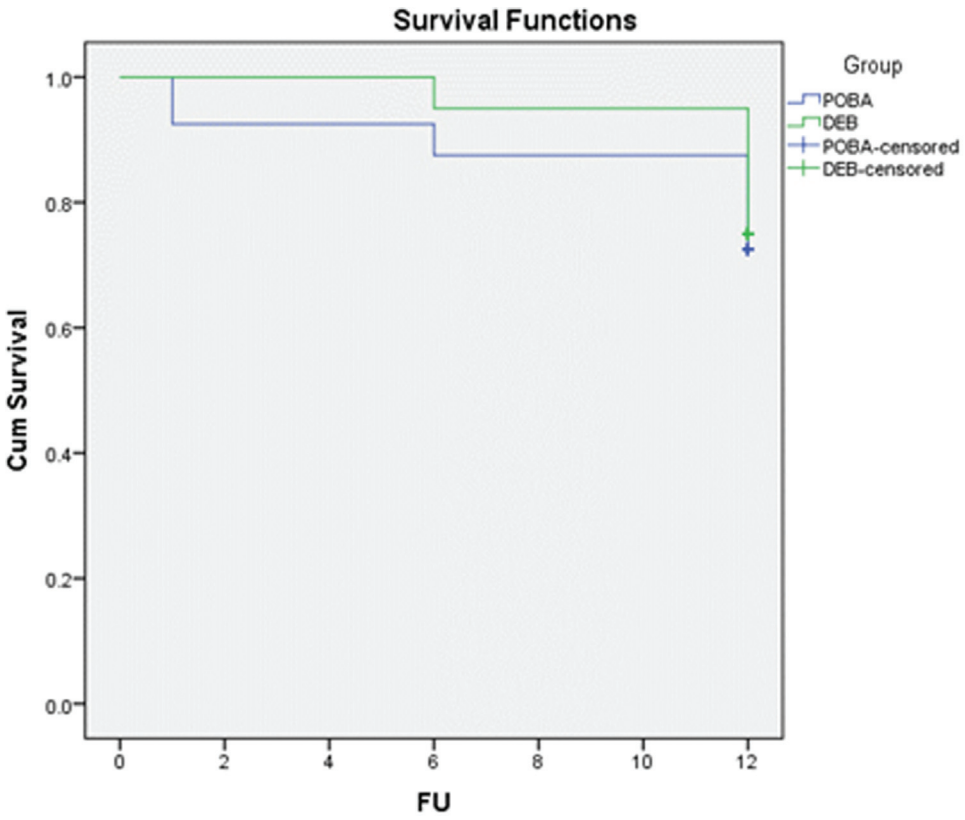
Regarding the primary outcome of the present study, the DEB and POBA groups had comparable rate of patency at 1 month (92.5 vs 100%, respectively), 6 months (87.5 vs 95%, respectively), and 12 months (72.5 vs 75%, respectively; $P>0.05$; Figs 1 and 2).

There were no statistically significant differences between POBA and DEB groups in terms of device-related complications (7.5 vs 5%), distal embolization (5 vs 2.5%), non-targeted vessel dissection (2.5 vs 0%), and conversion to open surgery (2.5 vs 0%; $P>0.05$; Fig. 3).

Discussion

The use of atherectomy for the management of CFA disease has emerged recently owing to its promising

Figure 1



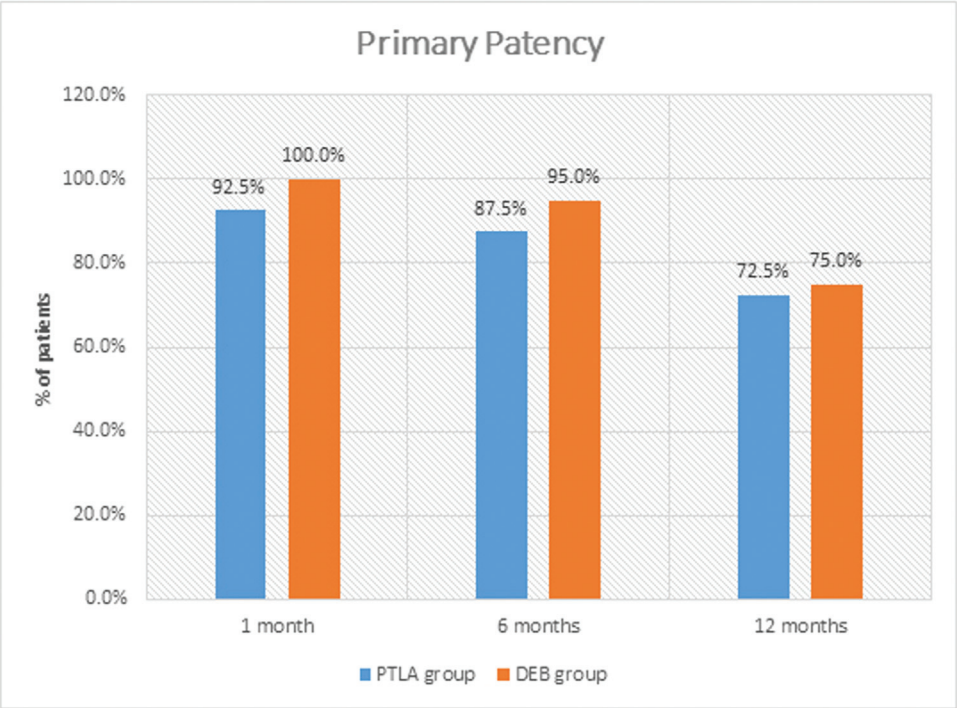
Kaplan–Meier curve of primary patency rate.

results; nonetheless, the long-term patency rate remains problematic. In the present trials, we demonstrated that both adjuvant DEB and POBA achieved acceptable patency rate at 12 months after the procedure, with no statistically significant difference. In addition, our results showed that the DEB and POBA had well-acceptable safety profile, with low rate of postoperative procedure-related complications.

Endovascular interventions for CFA disease are challenging owing to the critical location of the vessels and possible need to implant stent in this area owing to heavily calcified CFA lesions; previous reports demonstrated low rates of technical success and high complications rates when endovascular interventions are used to treat CFA disease [19]. Other concerns with endovascular management of CFA disease include the possibility of flow-limiting dissections and immediate vessel recoil [20]. However, the dramatic evolution in the endovascular techniques in recent years has encouraged many centers to re-assess the use of endovascular treatment in the setting of CFA disease [12,13]. A cumulative body of evidence demonstrated that atherectomy of CFA diseases is an effective treatment modality with high success rates and well-tolerable safety profile [14,15]. Nevertheless, poor long-term patency is a limiting factor for the use of endovascular interventions in the setting of CFA disease; this poor rate was attributed to the presence of severe calcification of the atherosclerotic lesion [21]. Thus, the combination of directional atherectomy with DEB was proposed to optimize the rate of technical success, through debulking the fibrocalcific portion of the atherosclerotic plaque, and improve the long-term [22]. However, limited data are available about the superiority of BED over POBA as an adjuvant to atherectomy. In the present study, we found that both adjuvant DEB and POBA achieved acceptable patency rate at 12 months after the procedure, with no statistically significant difference.In concordance with our findings, Imran and colleagues reported no survival benefit of DEB over POBA in term of primary patency rate, when used as adjuvant to atherectomy in patients with CFA. These findings were further supported by other reports [23,24]. On the contrary, Sixt *et al.* [25] reported that the atherectomy plus DEB was more effective than POBA in improving the 12-month patency rate in patients with femoropopliteal disease. More recent reports demonstrated similar findings [26].

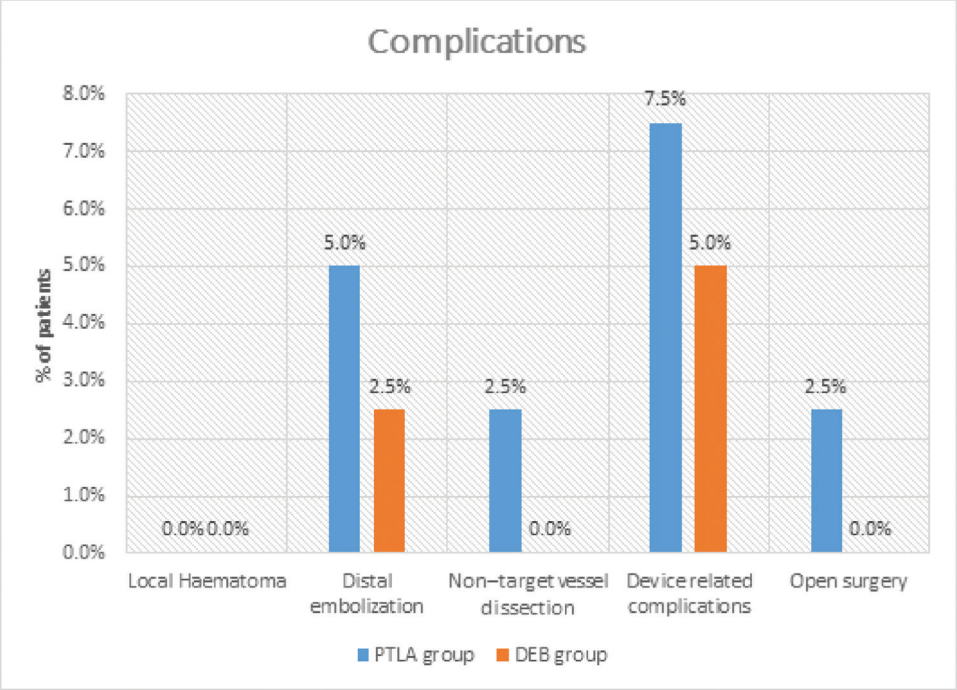
Endovascular interventions are known for their low rate of mortality and morbidity; previous reports

Figure 2



Primary patency rate.

Figure 3



Postoperative complications.

showed that CFA percutaneous interventions are associated with high success and low complication rates (1.4% major and 5.0% minor complications) [27]. In the present study, we found that the DEB and POBA had well-acceptable safety profile with low rate of procedure-related complications.

Conclusion

In conclusion, both adjuvant DEB and POBA are effective modalities in improving the long-term patency rate in patients undergoing atherectomy for CFA lesions. Our study demonstrated that both

techniques achieved high success rate, with low incidence of procedure-related complications. Nonetheless, larger studies are still needed to confirm our findings.

Financial support and sponsorship
Nill.

Conflicts of interest
There are no conflicts of interest.

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