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Efficacy and safety of adjunctive drug-coated balloon therapy in endovascular treatment of common femoral artery disease☆,☆☆,★,★★

Hafiz M. Imran [a,*], Omar N. Hyder [a,b], Peter A. Soukas [b]

[a] Department of Medicine, Division of Cardiology, Rhode Island Hospital/Warren Alpert Medical School of Brown University, Providence, RI, United States of America
[b] Department of Medicine, Division of Cardiology, The Miriam Hospital/Warren Alpert Medical School of Brown University, Providence, RI, United States of America

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ABSTRACT

Background: Surgical endarterectomy with or without patch angioplasty has been considered the gold standard for treatment of symptomatic common femoral artery (CFA) disease. Surgical risks include wound infection, hematoma and lymph leak in approximately 17% of patients. Endovascular therapy has less procedure-related morbidity and mortality. Endovascular approaches achieve patency rates of 60% to 90% at 1 and 2 years utilizing atherectomy and balloon angioplasty. CFA stenting has been limited due to concerns of stent kinking, thrombosis and restenosis. Combined directional atherectomy with drug-coated balloon to treat CFA disease in patients with Rutherford II/III patients has been studied recently. We sought to study the safety and outcomes of adjunct drug-coated balloon (DCB) therapy in symptomatic CFA disease patients, including critical limb ischemia (Rutherford IV), after achieving procedural success.
Objective: To evaluate the additive efficacy of drug coated balloon in treating CFA disease.
Methods: Using retrospective single center data, we analyzed the outcomes of patients who underwent CFA interventions. In this non-randomized study, all patients from December 2010 to December 2014 with CFA disease underwent atherectomy (orbital, plaque excision or both) with adjunctive scoring balloon angioplasty (Ath/PTA). After December 2014, patients treated with combination atherectomy and DCB, (Ath/DCB), underwent final drug delivery to the vessel wall with drug-coated balloon. Distal embolic protection devices were used in the majority of patients. Primary efficacy endpoint was 1-year primary patency and freedom from clinically driven target lesion revascularization (CD-TLR). Patency of vessels was assessed at 12-month interval using duplex ultrasound.
Results: Seventy de novo common femoral artery stenotic lesions were treated in both groups. Mean age was 69 in (Ath/PTA) group and 72 in Ath/DCB group. Patients in each group had similar risk factor profiles including diabetes mellitus, hypertension, smoking, coronary artery disease, myocardial infarction, prior coronary revascularization, congestive heart failure, cerebrovascular accidents and chronic kidney disease. The Ath/DCB group had more advanced disease presentation by Rutherford classification (intermittent claudication in 61% and critical limb ischemia in 39% versus intermittent claudication in 76% and chronic limb ischemia in 24%) when compared with the Ath/PTA group. Primary efficacy endpoint was met in 85% and 94% ($p = 0.26$) in the Ath/PTA and Ath/DCB groups respectively. All patients had run-off angiography at the end of procedure to ensure patency.
Conclusion: Adjunctive drug-coated balloon therapy does not increase the primary patency rate when compared with atherectomy and scoring balloon angioplasty alone at 1-year in common femoral artery disease treatment.

1. Background and rationale

Surgical endarterectomy with or without patch angioplasty is considered the gold standard for treatment of symptomatic CFA disease with 5-year patency rates >90%. Surgical intervention, however, entails risks of wound infection, hematoma and lymph leak of approximately 17% [1–8]. Endovascular treatment offers relatively low procedure-related morbidity and mortality with shorter length of hospital stay. Endovascular approaches have patency rates of 60% to 90% at 1 and 2 years with atherectomy and stenting [9–18]. CFA stenting has good short-term patency results, but predisposes patients to the added risks

☆ Key point: Adjunctive Drug-Coated balloon therapy to CFA lesions after atherectomy does not achieve significantly higher 1-year patency rate when compared with atherectomy and focused force balloon angioplasty alone.
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* Corresponding author at: Rhode Island Hospital, Division of Cardiology, 539 Eddy Street, Providence, RI 02903, United States of America.
E-mail address: hafiz_imran@brown.edu (H.M. Imran).

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of stent kinking, fracture, and thrombosis due to flexion and torsion at the hip joint and potentially jeopardizes patency of non-intervened arteries at femoral tripod by jailing them [6, 19]. Moreover, stenting may limit future surgical bypass and endarterectomy options [1, 9]. Orbital or plaque excision atherectomy has been used as an alternative to surgery in high-risk surgical patients. Drug delivery to vessel wall by drug-coated balloon achieved improved patency rates in the IN.PACT SFA and LEVANT2 trials in treatment of superficial femoral and popliteal arterial disease [17, 20–23]. Two recent studies have published data on the role of drug-coated balloons to treat CFA disease [24, 25]. The purpose of this study is to evaluate the efficacy and safety of adjunctive drug-coated balloon in treatment of CFA lesions after achieving technical success with atherectomy.

2. Method

In this non-randomized single center retrospective observational study, patients were divided into 2 groups i.e. Ath/PTA and Ath/DCB. A total 80 CFA stenotic lesions in 80 limbs were treated between December 2010 and September 2016. Ten lesions with CFA re-interventions were excluded. The devices utilized included orbital atherectomy using the 1.5 and/or 2.0 mm Diamondback crown (Cardiovascular Systems Inc. (CSI), Sunnyvale, CA), the Silver Hawk and Hawk One plaque excision catheter (Medtronic, St. Paul, MN) and drug coated balloons, Admiral (Medtronic Inc., Santa Rosa, CA, USA) or Lutonix DCB (Bard Peripheral Vascular Inc., NJ, USA). Data on baseline characteristics including age, gender, hypertension, diabetes mellitus, dyslipidemia, smoking, coronary artery disease, myocardial infarction, congestive heart failure, prior coronary revascularization, stroke or transient ischemic attack, chronic kidney disease and Rutherford classification was collected.

Between December 2010 and December 2014, patients in the Ath/PTA group received orbital, plaque excision atherectomy or both followed by scoring balloon angioplasty only, while after December 2014 patients in the Ath/DCB group received additional treatment with drug-coated balloon after achieving technical success by initial atherectomy and scoring balloon angioplasty. Atherectomy was chosen in all cases for vessel preparation prior to scoring balloon angioplasty to debulk and avoid vessel dissection and need for bailout stenting. Technical success was defined by achievement of final stenosis diameter of <30% by angiography. Based on Lopez classification, Type I, II and III lesions were treated in both groups which also included heavily calcified lesions, while type IV lesions were excluded. The majority of patients were elective out-patients brought from home to vascular suite, observed overnight after interventions, and discharged home following the next morning. The remainder underwent revascularization from the inpatient service. We used embolic protection devices, Emboshield NAV-6 (Abbott Laboratories Inc., Worcester, MA) and SpiderFX (Medtronic, Plymouth, MN) particularly in patients with compromised run-off to decrease distal embolization. Repeat run-off angiography was performed after retrieval of embolic protection device to document patency of distal vessels. Patients in both groups frequently received interventions to inflow or outflow vessels or both. Primary efficacy endpoint was 1-year primary patency assessed by Duplex ultrasound (PSVR > 2.4) and freedom from clinically driven target lesion revascularization (fCD-TLR). Primary safety endpoint was 1-month freedom from death, target limb major amputation or clinically driven target vessel revascularization (CD-TVR) at 12 months.

Student *t*-test was used to compare 1-year primary patency rate between 2 groups and p-value of <0.05 was considered significant.

3. Results

Both groups had patients with similar baseline characteristics as outlined in Table 1. The majority of patients had hypertension, dyslipidemia or history of tobacco use with a small proportion of diabetics in each group. During the study period, 80 CFA lesions were treated in both the Ath/PTA and the Ath/DCB groups. Only 70 de novo lesions were included in study as 10 lesions previously intervened were excluded (Fig. 1). Procedural success was achieved in all patients. The Ath/PTA group had relatively higher number of males and all of them had dyslipidemia (Table 1). Patients were followed up at 1, 6 and 12 months and evaluated for patency and major adverse limb events. One patient in the Ath/DCB group had fracture of EPD delivery catheter during deployment at the distal superficial femoral artery level. Failed EPD retrieval by endovascular techniques requiring retrieval by open surgery followed by surgical endarterectomy to CFA. He was excluded in the final calculation of primary patency. The primary efficacy endpoint was met in 85% patients in the Ath/PTA group and 94% patients in the Ath/DCB group (p-value = 0.26) (Fig. 2). Three patients were lost to follow-up in the Ath/DCB group. In all, 5 patients in the Ath/PTA group required target lesion revascularization after 6 months, while 1 patient in the Ath/DCB group required re-intervention within 6 months and a second patient underwent revascularization after 6 months. All patients underwent multiple interventions to non-target vessel (inflow, outflow or both) lesions during the index procedure Table 2. One patient in the Ath/PTA group underwent planned minor amputation (toe). During the index procedure, 4 vessel dissections (non-CFA) occurred in each group, successfully treated with angioplasty and stenting without any major limb event on follow up.

Sheath size use was similar in both groups, but 5 patients in the Ath/PTA group required 8F sheath for device delivery. Device related complications occurred in 2 patients in the Ath/PTA group. In one patient, orbital atherectomy device wire broke but the crown was retrieved without any complication. In a second patient, the EPD wire broke and was retrieved successfully by endovascular techniques resulting in branch vessel dissection, which was treated with angioplasty. In the Ath/DCB group, 2 patients developed device related complications. In one patient, the orbital atherectomy device suddenly stopped spinning resulting in superficial femoral artery dissection, which was treated with angioplasty and stent. In a second patient, the EPD delivery catheter broke during traversal through a heavily calcified subtotal occlusion of SFA. Failure to retrieve EPD by endovascular techniques resulted in conversion to surgical retrieval and endarterectomy (Table 3).

One patient in the Ath/PTA developed thrombus in the TP trunk, which recanalised on repeat angiography after passing distal wire. Distal athermanous embolization was noted in one Ath/PTA patient, requiring angioplasty in the posterior tibial artery with excellent

Table 1
Baseline characteristics.

Variables	Ath/PTA (n = 34)	Ath/DCB (n = 36)	p-Value
Age (mean, SD), years	69.85 ± 8.64	72.02 ± 7.24	0.80
Male n (%)	27 (79.41)	19 (52.77)	0.01
Smoking history n (%)	27 (79.41)	30 (83.33)	0.67
Diabetes mellitus n (%)	14 (41.17)	14 (38.88)	0.84
Hypertension n (%)	32 (94.11)	35 (97.22)	0.84
Dyslipidemia n (%)	34 (100.00)	32 (88.88)	0.04
Coronary artery disease n (%)	19 (55.88)	23 (63.88)	0.50
Myocardial infarction n (%)	8 (23.52)	8 (22.22)	0.89
Prior coronary revascularization n (%)	18 (52.94)	18 (50)	0.80
Heart failure n (%)	7 (20.58)	10 (27.77)	0.48
Stroke/TIA n (%)	7 (20.58)	8 (22.22)	0.86
Chronic kidney disease n (%)	41 (54.11)	13 (36.11)	0.50
Intermittent claudication n (%)	26 (76.47)	22 (61.11)	0.16
Chronic limb ischemia n (%)	8 (23.53)	14 (38.89)	0.16
Resting pain	6 (17.64)	10 (27.77)	0.31
Tissue loss	2 (5.88)	4 (11.12)	0.43
Lopez classification n (%)			0.70
Type I lesions	6 (17.65)	4 (11.11)	
Type II lesions	7 (20.59)	7 (19.44)	
Type III lesions	21 (61.76)	25 (69.45)	

Ath; atherectomy, PTA; percutaneous transluminal angioplasty, DCB; Drug-coated balloon, SD; standard deviation, TIA; transient ischemic attack.

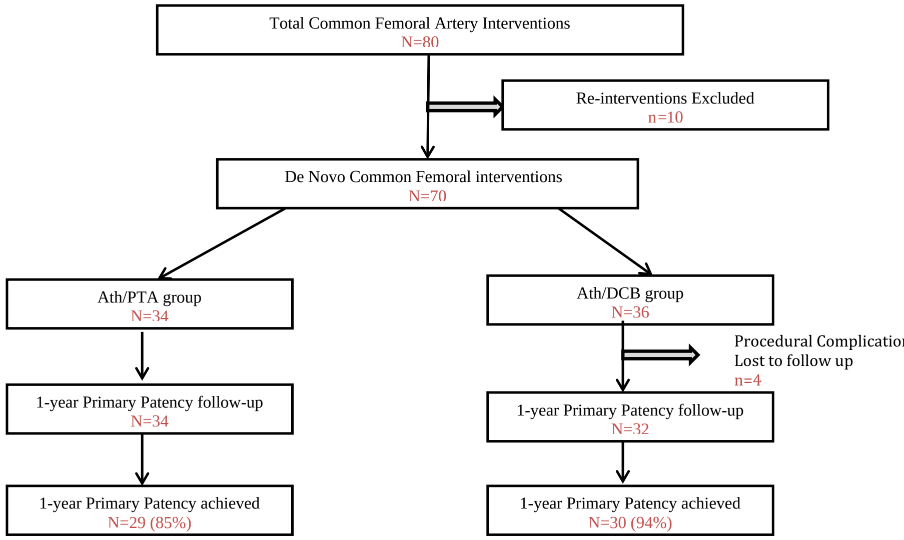

Fig. 1. Consort diagram for study design.

run-off angiographic results. None of these patients developed any major adverse limb event during the study period.

4. Discussion

Our study shows excellent short-term primary patency rate and freedom form clinically driven TLR with endovascular treatment of common femoral disease in patients who received adjunct DCB therapy after atherectomy and scoring balloon angioplasty. Patients had short length of stay without any major adverse limb events at one month. Reflecting extensive disease burden, all patients received additional treatment to inflow, and/or outflow vessels during index procedure. We successfully intervened on the femoral tripod without primary or bailout stenting or jeopardizing patency of non-target vessels. Our study demonstrates that endovascular treatment of symptomatic CFA disease may be an effective alternative to surgical endarterectomy in high surgical risk patients with comparable 1-year primary patency rate.

Antiproliferative therapy reduces restenosis in femoropopliteal disease [17, 20–23]. We hypothesize that both debulking atherectomy and angioplasty decreased elastic recoil leading to decrease in late luminal loss. In our study, the 1-year primary patency rate of 94% in patients treated with DCB is comparable to surgical endarterectomy and results previously published by Cioppa et al. [24] Furthermore, the majority of our population had adjunct treatment to either inflow or outflow vessels or both. Even with a higher proportion of Rutherford Class IV/V patients in the Ath/PTA and Ath/DCB groups in our study (23% and 38% respectively), technical success rate and 1-year primary patency rate were superior compared to the study (95% technical success and 88% 12-month primary patency in directional atherectomy with DCB arm) published by Stavroulakis et al. [25].

In our study, more than two-third of patients received successful treatment to outflow vessels involving the common femoral artery bifurcation. Yamawaki et al. treated common femoral bifurcation disease with 72.5% primary patency at 1-year with distal CFA stenting by jailing the profunda femoral artery and 52% with ostial superficial femoral artery stenting [26]. In a randomized controlled trial, Linni et al. showed comparable primary patency rates in bioabsorbable stent implantation and endarterectomy groups (80% in BASI and 84% in surgical endarterectomy at end of 1 year) [27]. Azema et al. studied 36 patients with clinical improvement in Rutherford classification in 80% and freedom from TLR in 85% at 1 year [9]. In our study, the Ath/PTA group achieved a similar 1-year primary patency rate. With adjunctive DCB therapy, we achieved improved 1-year primary patency rate in Ath/DCB group without primary or bailout stenting eliminating the risk of stent fracture or restenosis, although the difference between the two study groups was not statistically significant.

Surgical endarterectomy has been considered the 'gold standard' in treatment of CFA disease with excellent long-term patency rates. Although it has been considered a relatively safe procedure, recent

Table 2
Device use and successful non-target vessel revascularization.

Variables	Ath/PTA	Ath/DCB	p-Value
Sheath size n (%)			0.05
6F	3 (9)	5 (14)	
7F	24 (71)	31 (86)	
8F	7 (20)	0	
Diameter of balloons used n (%)			0.13
5 mm	5 (15)	2 (6)	
6 mm	14 (41)	23 (64)	
7 mm	15 (44)	11 (30)	
Length of balloons used			<0.01
2 cm	26	13	
4 cm	7	11	
>4 cm	1	12	
Embolic protection device n (%)	19 (56)	30 (83)	<0.01
Number of non-target vessel interventions (number)	96	93	0.40
Non-target vessel interventions n (%)			0.95
Inflow	4 (12)	6 (17)	
Outflow	16 (47)	16 (44)	
Combined	14 (41)	14 (39)	

Ath; atherectomy, PTA; percutaneous transluminal angioplasty, DCB; Drug-coated balloon.

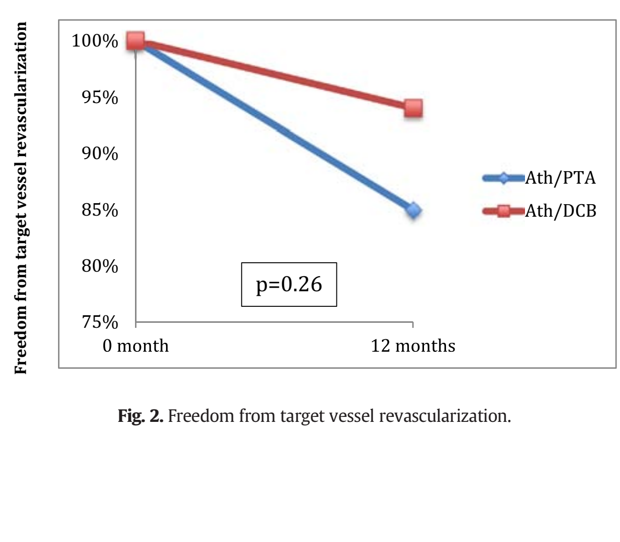

Fig. 2. Freedom from target vessel revascularization.

Table 3
Complications.

	Ath/PTA	Ath/DCB
Non-target vessel dissections (%)	4 (12)	4 (12)
Device related (%)	2 (6)	2 (6)
Distal thrombus (%)	1 (3)	0

Ath; Atherectomy, PTA; Percutaneous transluminal angioplasty, DCB; drug-coated balloon.

data demonstrates significant complications, including local infection, nerve injury and lymph leak. In our study, both groups achieved excellent 1-year primary patency, with the Ath/DCB group achieving a 1-year patency rate of 94% which is comparable to surgical endarterectomy studies. Mukherjee at el. published data on 29 patients who underwent endarterectomy to CFA and additional vessel i.e. superficial or profunda femoral artery, with 94% patency rate at 5 years [1]. Cardon et al. reported on 101 patients with 3 year primary patency of 95% with 21% local complications including wound infection, lymph leak and nerve injury [3]. Our study results are similar to data by Kang et al. who published data on 58 patients followed for 27-months. Primary patency of 93% was achieved at 1 year with 5% major and 9% minor complications [4]. Ballota et al. studied 117 patients, who underwent isolated CFE with <1 cm PFA or SFA interventions with 8% complication rate [2]. Both groups in our study had short length of hospital stay with home discharge within 24 h.

Endovascular treatment has been considered an alternative in high surgical risk patients due to low complication rates and short length of hospital stay. In the TECCO trial, Gouffec et al. reported morbidity and mortality data within 30 days of CFA intervention in endovascular and surgical endarterectomy groups. Primary outcome events occurred in 16 of 61 patients (26%) in the surgery group and 7 of 56 patients (12.5%) in the stenting group [13]. In our study groups, we avoided local hematoma with use of ultrasound to gain vascular access and angiographic confirmation of proper sheath placement. Complications occurred in treatment of non-target vessels, which were treated without any sequelae during the follow up period. Only one patient in Ath/DCB group was converted to open surgical endarterectomy due to EPD device failure. None of the patients in our study group developed wound infection, as compared with Siracuse et al. report of isolated CFA endarterectomy from the National Surgical Quality Improvement Program that showed superficial surgical site infection rate of 6.3% [28].

With excellent 1-year primary patency in the Ath/DCB group, our study still has multiple limitations. First, it is non-randomized single center hypothesis generating retrospective study with small population size. Second, there is no statistically significant difference between the study groups, but there is trend towards higher patency rate in patients who received adjunctive DCB therapy. Third, our study did not include any patients with major tissue loss. It still remains to be explored, if similar results can be achieved in this group by endovascular approach. Fourth, the study population was followed up for one year, thus intermediate and long-term patency rates have not been evaluated.

5. Conclusion

Adjunctive drug-coated balloon treatment of CFA disease can achieve excellent 1-year primary patency rates with very low rate of complications. Intermediate and long-term follow up is needed to assess the efficacy of this approach. Multicenter randomized studies are needed to establish the added benefit of DCB to treat CFA disease in clinical practice.

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