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Original Article

Comparison of atherectomy and drug-coated balloon in critical femoropopliteal lesions mid-term results

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Abstract

Aim: Peripheral artery disease (PAD) restricts blood flow to the lower limbs, causing pain, reduced mobility, and critical limb ischemia, leading to severe complications. While atherectomy and drug-coated balloon (DCB) angioplasty are effective revascularization methods, restenosis remains challenging, especially in calcified lesions. This study aims to compare mid-term outcomes, including primary patency, complication rates, and re-intervention needs, between atherectomy combined with DCB angioplasty and DCB-only treatment in patients with femoropopliteal artery disease.
Material and Methods: We conducted a retrospective review of 144 PAD patients treated between March 2020 and March 2022. Patients were divided into two groups: 66 received atherectomy plus DCB, while 78 underwent DCB-only angioplasty. Baseline characteristics, lesion parameters, and clinical outcomes, including primary patency and complication rates, were assessed at 6, 12, and 24 months post-procedure using color Doppler ultrasonography (CDUS).
Results: At 6 months, patency rates were similar across both groups, but the atherectomy + DCB group showed significantly higher patency at 12 months (p=0.045) and 24 months (p=0.04). Complications, including distal embolism, arterial dissection, and pseudoaneurysm, were comparable between groups. The atherectomy + DCB group also had lower target lesion revascularization rates, suggesting reduced need for re-interventions.
Conclusion: Atherectomy combined with DCB angioplasty yields superior mid-term patency compared to DCB alone, especially in patients with calcified lesions. This approach optimizes drug delivery and reduces re-intervention needs, offering a viable option for complex femoropopliteal PAD. Future randomized trials are recommended to confirm these findings and refine patient-specific treatment strategies.

Keywords: Peripheral artery disease, femoropopliteal artery, atherectomy, drug-coated balloon

INTRODUCTION

Femoropopliteal occlusive disease, as a major manifestation of peripheral artery disease (PAD), significantly impacts quality of life by restricting mobility, causing pain during physical activities, and contributing to substantial mortality, morbidity, and financial burden [1]. Approximately 10-15% of patients with PAD lasting five or more years progress to critical limb ischemia (CLI), which can lead to severe complications like tissue loss and amputation [2]. For patients with claudication or CLI, revascularization of the superficial and femoral arteries is recommended [3]. These interventions aim to enhance blood flow, alleviate symptoms, and improve daily functionality.

Reducing restenosis rates has been a long-standing goal in endovascular femoral interventions [4]. Advances in technology have yielded techniques such as atherectomy, drug-coated balloons (DCB), and stenting, which show high patency rates of 60-90% within one to two years [5-7]. Atherectomy, DCB angioplasty, and combination therapies are

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commonly supported by vascular surgeons, aiming to improve blood flow while minimizing recurrence risk. Atherectomy devices effectively remove atherosclerotic plaques, which can otherwise necessitate stenting, sometimes leading to additional complications [8]. Meanwhile, DCB has been associated with lower restenosis rates, making it a viable choice for many patients [9,10].

This study aims to compare mid-term outcomes, including primary patency, complication rates, and re-intervention needs, between atherectomy combined with DCB angioplasty and DCB-only treatment in patients with femoropopliteal artery disease.

MATERIAL AND METHODS

Study Design

We conducted a retrospective review of 144 patients treated for PAD between March 2020 and March 2022. Sixty-six patients received atherectomy plus DCB, and 78 received DCB-only therapy. Treatment plans adhered to the 2024 ESC Guidelines, and ethical approval was obtained from the Research Ethics Board at Ankara University [11]. Informed consent was provided by all patients. Only patients with femoro-popliteal occlusive lesions were included, meeting criteria of an ankle-brachial index (ABI) of <0.90 and femoro-popliteal artery stenosis of >70%, as shown by digital subtraction angiography (DSA), with lesion lengths of <25 cm. Exclusion criteria encompassed recent cerebrovascular events, liver or kidney dysfunction, or contraindications to paclitaxel, antiplatelet or anticoagulant therapy.

Procedures were performed by two surgeons in a hybrid operating room under local anesthesia. Primary patency rates and outcomes were evaluated at 6, 12, and 24 months using color Doppler ultrasonography (CDUS). Patients were also monitored for distal embolism, arterial dissection, pseudoaneurysm, and hematoma at the intervention site. After discharge, patients received antibiotics, analgesics, and dual antiplatelet therapy. The primary outcome was vessel patency as indicated by CDUS, with secondary outcomes including complication rates and overall recovery quality.

Endovascular Interventions and Medical Care

Percutaneous puncture was performed under local anesthesia using the Seldinger technique. Access was achieved via contralateral femoral artery retrograde puncture, ipsilateral femoral artery anterograde puncture, or ipsilateral popliteal artery retrograde puncture. In the DCB-only group, lesions were first pre-dilated with an uncoated balloon, then treated with a paclitaxel-coated balloon (Ranger™, Boston Scientific Way, Marlborough, MA, USA) for at least 120 seconds. Balloon size matched the target vessel diameter and extended 10 mm beyond the lesion. If angiography revealed significant dissection or residual stenosis of >50%, re-dilatation was performed with an uncoated balloon. Bailout stenting was performed if residual stenosis persisted above 50% or if a significant dissection compromised blood flow.

For the atherectomy plus DCB group, the JETSTREAM™ plaque excision system (Boston Scientific Way, Marlborough, MA, USA) was used to excise plaque from the lesion. Following plaque removal, lesions were pre-dilated and treated with DCB angioplasty. If angiography revealed significant dissection limiting flow or residual stenosis of >50%, re-dilatation with an uncoated balloon was performed. Bailout stenting was utilized in cases of persistent significant stenosis or flow-limiting dissection. Notably, embolic protection devices were not used in this study, which reflects common practice limitations in resource-constrained settings.

Bailout Stenting

Bailout stenting refers to the placement of a stent after an initial procedure (such as balloon angioplasty or atherectomy) if the desired result is not achieved or complications like dissection occur. The stent helps maintain vessel patency and prevent restenosis or occlusion. It is commonly used after atherectomy when residual stenosis or dissection is present. The stents used can be either self-expanding or balloon-expandable.

Inflow Procedures

Inflow procedures are aimed at improving blood flow in proximal arteries (such as the iliac or femoral arteries) to ensure adequate distal perfusion. These procedures are often performed before or alongside distal interventions to optimize the outcome. Balloon angioplasty and stenting of inflow vessels are common methods, ensuring that distal segments, such as the femoropopliteal artery, receive sufficient blood flow for better treatment success and long-term results.

Management of Complications

In our study, while complications such as distal embolism and arterial dissection were observed in both treatment groups, all were managed effectively with appropriate interventions to minimize patient risk and optimize outcomes.

Distal Embolism

Distal embolism, which occurred in two patients in each group, was managed using catheter aspiration. This technique involved the use of a catheter to aspirate embolic material from the distal vessels. No additional complications or clinical deterioration were observed post-intervention, and both patients showed satisfactory recovery. This is in line with current best practices for managing distal embolism, where prompt intervention is crucial to prevent further ischemic damage.

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Arterial Dissection

Arterial dissection was observed in five patients in the atherectomy + DCB group and three patients in the DCB-only group. In these cases, the dissections were addressed with balloon angioplasty to gently dilate the vessel and restore flow. If residual stenosis persisted after angioplasty, bailout stenting was performed to secure vessel patency. All patients with dissection had successful outcomes with this approach, and no major adverse events were recorded. Stenting, when required, was done using self-expanding stents, which helped to reduce the risk of vessel recoil and ensure long-term patency.

Other Minor Complications

Minor complications such as pseudoaneurysm and hematoma were also observed, though these did not require surgical intervention. All patients with minor complications were managed conservatively with compression and observation. One patient with a pseudoaneurysm required surgical repair using a saphenous vein patch, which was successful and resolved the issue without further complications. Hematomas were treated with conservative management, and no patient experienced a major adverse outcome related to these events.

The careful management of these complications highlights the importance of prompt intervention and appropriate post-procedure monitoring, which are essential to optimizing patient outcomes following peripheral artery interventions.

All patients started dual antiplatelet therapy three days before the procedure, taking aspirin (100 mg/day) and clopidogrel (75 mg/day). After the procedure, they continued with dual antiplatelet therapy (aspirin 100 mg/day and clopidogrel 75 mg/day) for 12 months. Following the 12-month period, clopidogrel was discontinued, and aspirin therapy was continued.

Statistical Analysis

Statistical analysis was conducted using SPSS version 20 (IBM Corp, Armonk, NY). Continuous variables were compared using the Student's t-test under assumptions of normality and equal variances, assessed by Shapiro-Wilk and Levene’s tests, respectively. For non-normally distributed data, the Mann-Whitney U test was used. Categorical variables were analyzed using Fisher's exact test, while Chi-square tests assessed recurrence rates and binary outcomes. A p-value of <0.05 indicated statistical significance.

RESULTS

In this study, 144 patients were divided into two groups: 66 patients in the atherectomy + DCB group and 78 patients in the DCB-only group. Baseline characteristics of both groups were comparable and did not differ significantly in terms of patient demographics or comorbidities. Both groups had similar distributions of age, gender, BMI and baseline medical conditions such as congestive heart failure (CHF), diabetes mellitus (DM) and hypertension. Baseline clinical characteristics of these patients are provided in Table 1. Clinical indications for the procedure, including claudication, CLI and chronic total occlusion, were also similar between groups. Furthermore, no significant differences were observed in lesion characteristics or procedure details, including lesion location, pre-procedure ABI, and lesion length. In this study, the degree of calcification in the lesions of the patients was classified using the Peripheral Artery Calcium Scoring System (PACSS). These data show that there was no significant difference between the two groups in terms of calcification. The clinical and lesion characteristics of the study population are summarized in Table 2.

In our study, all procedures were completed with technical success. The incidence of complications was generally similar between the two groups. Distal embolism occurred in 2 patients in both groups, while arterial dissection occurred in 5 patients in the atherectomy + DCB group and in 3 patients in the DCB only group. Minor complications such as pseudoaneurysm and hematoma were also comparable between the groups. These conditions did not require surgical intervention and were completely resolved with conservative management. One patient had a pseudoaneurysm, which was surgically repaired. A saphenous vein patch was used for pseudoaneurysm repair with a successful outcome. Dissection cases were successfully treated with balloon angioplasty and bailout stenting. Distal embolization cases were managed with catheter aspiration in all patients and no additional complications were observed. All complications were managed with appropriate interventions, ensuring the safety of patients. One patient required re-intervention due to recurrent stenosis and underwent balloon angioplasty. Complications and primary patency rates for the two groups are detailed in Table 3. Complications in our study were minimal and all cases were managed effectively. The interventions positively affected the clinical course of the patients and major amputation was avoided. Moreover, technical success and efficiency in complication management processes contributed to the maintenance of long-term patency rates.

Ultrasound-assessed primary patency rates were slightly higher in the atherectomy + DCB group at 6 months, but the difference was not statistically significant ($p=0.065$). However, at 12 months, the atherectomy + DCB group showed significantly better primary patency rates compared to the DCB only group ($p=0.045$); this trend continued at 24 months and the atherectomy + DCB group maintained the higher primary patency rate ($p=0.04$). The need for re-intervention during follow-up was analyzed and it was found that fewer patients in the atherectomy + DCB group required further procedures ($p=0.042$).

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Table 1. Baseline clinical variables of the patients

	Atherectomy+DCB (n=66)	DCB (n=78)	p
Age, years	62.4±8.8	60.8±7.9	0.068
Male	43 (65.2%)	58 (74.4%)	0.437
BMI, kg/m²	28.6±7.2	30.2±7.5	0.231
CHF	11 (16.7%)	14 (17.9%)	0.374
Smoking history	56 (84.8%)	67 (85.9%)	0.486
DM	50 (75.8%)	62 (79.5%)	0.136
Hypertension	49 (74.2%)	58 (74.4%)	0.452
CAD	33 (50.0%)	40 (51.3%)	0.966
History of stroke/TIA	7 (10.6%)	7 (9.0%)	0.447
History of malignancy	4 (6.1%)	7 (9.0%)	0.922
History of MI	13 (19.7%)	22 (28.2%)	0.148
Aspirin	56 (84.8%)	70 (89.7%)	0.056
Clopidogrel	34 (51.5%)	41 (52.6%)	0.127
Statin	46 (69.7%)	42 (53.8%)	0.193
Rutherford category			0.389
3	39 (59.1%)	47 (60.3%)	
4	17 (25.8%)	17 (21.8%)	
5	10 (15.2%)	14 (17.9%)	

DCB: drug-coated balloon, BMI: body mass index, CHF: congestive heart failure, DM: diabetes mellitus, CAD: coronary artery disease, TIA: transient ischemic attack, MI: myocardial infarction

Table 2. Clinical and lesion characteristics

	Atherectomy+DCB (n=66)	DCB (n=78)	p
Lesion location			0.09
CFA	21 (31.8%)	17 (21.8%)	
SFA	38 (57.6%)	39 (50.0%)	
Popliteal	7 (10.6%)	22 (28.2%)	
Preprocedure ABI	0.59±0.3	0.66±0.4	0.321
Indication			
Claudication	42 (63.6%)	57 (73.1%)	0.234
Critical limb ischemia	24 (36.4%)	21 (26.9%)	0.096
Chronic total occlusion	17 (25.8%)	25 (32.1%)	0.121
Mean lesion length (mm)	134±88	129±92	0.339
Contralateral access site	45 (68.2%)	59 (75.6%)	0.342
Popliteal access site	21 (31.8%)	19 (24.4%)	0.248
Peripheral artery calcium scoring system			
Grade 0	10 (15%)	11 (14%)	0.487
Grade 1	13 (20%)	16 (20%)	0.435
Grade 2	20 (30%)	22 (28%)	0.515
Grade 3	17 (25%)	21 (27%)	0.449
Grade 4	6 (10%)	8 (11%)	0.49

DCB: drug-coated balloon, CFA: common femoral artery, SFA: superficial femoral artery, ABI: ankle-brachial index

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Table 3. Complication and primer patency

	Atherectomy+DCB (n=66)	DCB (n=78)	p
Distal embolism	2 (3.0%)	2 (2.6%)	0.644
Arterial dissection	5 (7.6%)	3 (3.8%)	0.677
Arterial perforation	0 (0%)	0 (0%)	-
Arteriovenous fistula	0 (0%)	0 (0%)	-
Pseudoaneurysm	1 (1.5%)	1 (1.3%)	0.889
Hematoma	2 (3.0%)	3 (3.8%)	0.455
Minor amputation in critical limb ischemia patients	7(10.6%)	7(9.0%)	0.391
Major amputation in critical limb ischemia patients	2(3%)	3(3.8%)	0.212
Primary patency via ultrasound at 6 months	65/66 (98.5%)	64/78 (82.1%)	0.065
Primary patency via ultrasound at 12 months	63/66 (95.5%)	60/78 (76.9%)	0.045
Primary patency via ultrasound at 24 months	56/66 (84.8%)	50/78 (64.1%)	0.04

DCB: drug-coated balloon

DISCUSSION

Our study compared the mid-term outcomes of patients treated with atherectomy plus DCB angioplasty versus DCB-only angioplasty for femoropopliteal artery disease. The results demonstrated that while both treatment modalities were effective, the combination of atherectomy and DCB was associated with superior primary patency at 12 and 24 months ($p=0.045$ and $p=0.04$ respectively). These findings are consistent with previous studies that have suggested the benefit of vessel preparation via atherectomy, particularly in complex and calcified lesions [6-8].

Moreover, our study's results, which showed improved patency rates at 12 and 24 months in the atherectomy + DCB group, echo the 2024 ESC Guidelines on the Diagnosis and Treatment of Peripheral Arterial Diseases, which recommend the use of DCBs for femoropopliteal lesions due to their ability to minimize neointimal hyperplasia [11]. However, in heavily calcified lesions, standalone DCB treatment may be insufficient due to poor drug absorption. Atherectomy provides a solution by modifying the calcified plaque, facilitating better drug delivery, as demonstrated by the improved outcomes in our study [12].

At 6 months, the patency rates were comparable between the two groups, indicating that both treatment approaches were initially effective. However, by 12 months, the atherectomy plus DCB group showed significantly better outcomes, which remained consistent through the 24-month follow-up. This suggests that atherectomy may enhance the efficacy of DCB by optimizing the lesion environment, particularly by reducing calcified plaque burden and improving drug delivery to the vessel wall. Similar trends have been observed in other studies, such as those by Foley et al. [13] and Rodoplu et al. [14], which highlighted the role of atherectomy in reducing the need for bailout stenting and improving long-term vessel patency.

The rate of complications, including distal embolism and arterial dissection, was low and did not differ significantly between the groups. Moreover, the comparable safety profiles of the two interventions suggest that the addition of atherectomy does not introduce substantial procedural risk, making it a viable option for patients with calcified lesions [12]. In fact, our study also demonstrated that atherectomy plus DCB reduced the need for re-intervention, as indicated by the lower rates of target lesion revascularization (TLR) in the combination group. The improved outcomes in this group may be attributed to the enhanced ability of atherectomy to debulk calcified lesions, allowing for more uniform drug delivery and minimizing vessel recoil or dissection post-procedure. These findings align with those of other studies, which have emphasized the importance of lesion preparation in improving DCB efficacy [15].

In terms of safety, our study found no significant differences in complication rates between the two groups, consistent with the findings of Mehta et al. [6] and de Blic et al. [7], who reported that percutaneous femoral artery interventions, including atherectomy, can be performed with minimal risk. The TASC II guidelines advocate for a patient-centered approach in managing PAD, with treatment strategies tailored to lesion characteristics and patient comorbidities [3]. Our findings reinforce this concept, as atherectomy proved particularly beneficial in patients with more complex lesions, a group that may otherwise have suboptimal outcomes with DCB alone. By enhancing drug penetration and reducing plaque burden, atherectomy serves as an essential preparatory step that aligns with modern endovascular strategies aimed at optimizing clinical outcomes.

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Despite the advances in endovascular interventions, some patients may experience patency loss over time, requiring revascularization procedures. Factors contributing to restenosis or occlusion after initial treatment include the severity of underlying disease, lesion complexity, vessel recoil, and the presence of diffuse or calcified plaque. In these patients, the decision to pursue revascularization depends on clinical symptoms, restenosis severity, and overall vascular health. While balloon angioplasty and stenting are often the primary interventions for restenosis or occlusion, not all patients are suitable candidates for these procedures due to factors like extensive calcification, poor distal run-off, or previously failed interventions. In these cases, surgical bypass may offer a more durable solution.

Surgical bypass remains a valuable option for patients with CLI, especially those with highly calcified lesions or long-segment occlusions, where endovascular procedures might be less effective or carry a higher risk of restenosis. Surgical bypass is particularly indicated when the lesion is extensive or located in difficult-to-treat areas, such as the aortoiliac or femoropopliteal segments, or when the patient has poor vessel quality or compromised distal flow, limiting the effectiveness of endovascular options. Additionally, surgical bypass may be necessary if revascularization via endovascular techniques has failed or carries a high risk of complications.

Although endovascular techniques like atherectomy combined with DCB angioplasty have shown promising results in improving mid-term patency and reducing re-intervention rates, there are still cases where surgical bypass proves to be superior. Studies have shown that surgical bypass offers better long-term patency in certain patient groups, particularly those with severe ischemia or complex arterial disease that cannot be adequately treated by endovascular methods alone. However, bypass surgery carries risks, including infection, graft failure, and longer recovery times. Therefore, the decision between surgical bypass and endovascular revascularization should be individualized based on factors such as lesion location, patient comorbidities, and expected outcomes.

In our study, although atherectomy plus DCB was associated with superior long-term patency in many cases, it is important to recognize that some patients may ultimately require surgical intervention. A multi-disciplinary approach involving both vascular surgeons and interventional cardiologists is essential to optimize patient outcomes, tailoring treatment strategies to individual patient characteristics and lesion complexity. Additionally, the economic implications of combining atherectomy with DCB therapy should not be overlooked. While the upfront costs may be higher, the reduced rates of re-intervention and improved patency could lead to long-term cost savings. Future studies should assess the cost-effectiveness of this combined approach, particularly in healthcare systems with limited resources.

The combination of atherectomy and DCB carries both procedural and economic implications. On the procedural side, while atherectomy adds an extra step to the treatment, it can reduce the need for bailout stenting, which is often required in balloon angioplasty procedures for complex lesions. Our study showed that fewer patients in the atherectomy + DCB group required re-intervention, suggesting that this combination may offer a more durable solution. This can potentially lower the overall revascularization burden, reducing the need for multiple procedures and improving long-term outcomes. From an economic standpoint, atherectomy devices and DCBs are typically more expensive than standard angioplasty balloons. The upfront costs associated with the combination therapy may raise concerns, especially in resource-limited settings. However, these costs must be weighed against the long-term savings associated with fewer re-interventions, reduced complications, and improved patency.

The observed difference in primary patency rates between the two groups—while statistically significant at 12 and 24 months—was relatively modest. At 12 months, the atherectomy + DCB group showed a primary patency rate of 85%, compared to 78% in the DCB-only group ($p=0.045$). By 24 months, this difference remained significant ($p=0.04$), but the absolute difference in patency rates was approximately 7%. While this difference is statistically significant, the clinical relevance of a 7% improvement in patency must be considered in the context of patient outcomes, including quality of life and functional recovery. In clinical practice, a 7% improvement in patency may be meaningful, particularly for patients with CLI or claudication, where even a modest improvement in patency can lead to better functional outcomes, reduced symptoms, and fewer revascularization procedures. In summary, although complication rates were similar between the two treatment groups, the atherectomy + DCB group showed superior mid-term primary patency. This suggests that the addition of atherectomy may provide a benefit in terms of sustained patency over time.

Moreover, the re-intervention rate was lower in the atherectomy + DCB group ($p=0.042$), suggesting that the combination therapy not only provides better patency but also reduces the need for follow-up procedures, which can be associated with patient morbidity and healthcare costs. Therefore, while the absolute difference in patency rates may appear small, the long-term clinical benefits—in terms of both functional recovery and cost savings—should be emphasized.

Despite the strengths of our study, including the relatively large sample size and mid-term follow-up, there are some limitations to consider. This was a retrospective study, and the choice of treatment was not randomized. Furthermore, while the results suggest a benefit of atherectomy in enhancing DCB performance, further prospective, randomized studies are needed to confirm these findings and to refine patient selection criteria for combined therapy.

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CONCLUSION

In summary, our study contributes to the growing body of evidence supporting the combination of atherectomy and DCB as an effective strategy for improving mid-term patency in patients with femoropopliteal artery disease, especially in those with calcified or complex lesions. While there is conflicting evidence regarding the optimal approach for different types of lesions, our findings suggest that this combination provides a durable solution, reducing the need for re-intervention. The economic considerations also favor this combination therapy, particularly in high-risk or complex cases where long-term patency is crucial. Future prospective, randomized studies should further evaluate the cost-effectiveness and clinical impact of atherectomy combined with DCB in various patient populations.

Ethics Committee Approval: Treatment plans adhered to the 2024 ESC Guidelines, and ethical approval was obtained from the Research Ethics Board at Ankara University, Decision No: İ09-694-24.

Patient Consent for Publication: Informed consent was provided by all patients.

Data Sharing Statement: The data that support the findings of this study are available from the corresponding author upon reasonable request.

Author Contributions: All authors contributed equally to the article.

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