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The impact of diabetes on rotational atherectomy and drug-coated balloon outcomes in lower extremity chronic total occlusions

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ABSTRACT

Aims: This study aimed to evaluate the effect of combining rotational atherectomy (RA) and drug-coated balloon (DCB) angioplasty on clinical outcomes in diabetic (DMG) and non-diabetic (NDMG) patients with chronic total occlusions (CTOs) in the lower extremity arteries (LEAs).

Methods: A total of 151 patients treated between 2018 and 2022 were retrospectively analyzed. Patients were categorized as DMG (n=77) and NDMG (n=74). Outcomes such as technical success, vessel patency, re-occlusion, and ankle-brachial index (ABI) were compared between the groups.

Results: Technical success was achieved in all patients, with a stent usage rate below 8%. At 12 months, re-occlusion occurred in 13.0% of DMG and 5.4% of NDMG patients. Both groups showed a significant increase in ABI: from 0.60 to 1.10 in DMG and from 0.60 to 1.20 in NDMG. The 12-month re-occlusion-free survival rate was 87.0% in DMG and 94.6% in NDMG.

Conclusion: RA combined with DCB angioplasty appears to be a safe and effective treatment strategy for CTOs in LEAs. The approach offers high technical success and favorable mid-term outcomes in both diabetic and non-diabetic patients, supporting its use in high-risk populations.

Keywords: Ankle-Brachial Index, chronic total occlusion, diabetes, drug-coated balloon, peripheral artery disease, rotational atherectomy

INTRODUCTION

Lower extremity arterial diseases (LEAD), especially in the presence of chronic total occlusions (CTOs), represent a significant clinical challenge in terms of both technical success and long-term vessel patency. This challenge becomes even more pronounced in patients with diabetes mellitus (DM), as they typically present with more distal, diffuse, and calcified lesions that limit the effectiveness of revascularization.[1,2] Moreover, DM is considered one of the most important risk factors for poor outcomes in LEAD, as it is associated with higher rates of restenosis, limb loss, and early mortality, especially in insulin-dependent patients.[3]

Drug-coated balloons (DCBs) have emerged as promising tools in LEAD due to their ability to reduce restenosis rates. However, in long and calcified CTO lesions, debulking strategies that prepare the vessel beforehand are increasingly preferred to enhance the efficacy of DCBs.[4,5] Rotational atherectomy (RA) offers a potential advantage by mechanically removing plaque, thereby improving balloon penetration and reducing the need for stenting.[6,7]

Previous studies have demonstrated that in heavily calcified or complex femoropopliteal and infrapopliteal lesions, combining vessel preparation with atherectomy prior to DCB use may significantly improve technical and clinical outcomes. For example, higher patency rates and reduced dissection rates have been reported with the use of directional atherectomy followed by DCB angioplasty, particularly in no-stenting zones such as the popliteal artery (PA).[8,9] However, these studies either lacked diabetes-specific subgroup analyses or were confined to isolated anatomical regions.

Although successful outcomes with the RA and DCB angioplasty have recently been reported, particularly in the popliteal and infrainguinal segments, comprehensive data comparing its performance in DM and non-DM patients remain limited in the literature.[10-13] In contrast, our study offers a more comprehensive evaluation by comparing diabetic and non-diabetic patients across multiple arterial territories using RA and DCB.

This study aims to evaluate the effect of RA and DCB angioplasty on technical success, vessel patency, and re-occlusion rates in patients with CTOs in LEAD, with a particular focus on DM and non-DM subgroups. Based on a large sample size, the study seeks to objectively reveal the impact of DM on endovascular treatment outcomes.

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METHODS

Study Design

This study was planned as a retrospective, single-center observational study. A total of 151 patients who underwent elective RA and DCB percutaneous transluminal angioplasty (PTA) for chronic lower extremity ischemia (CLEI) between October 2018 and October 2022 were retrospectively evaluated. Patients were categorized into two groups; diabetic group (DMG, n=77) and non-diabetic group (NDMG, n=74). The study was conducted in accordance with the principles of the Declaration of Helsinki and was approved by the Hitit University Faculty of Medicine Clinical Researches Ethics Committee (Date: 03.10.2023, Decision No: 2023/124). Patient data were obtained from hospital records and patient files. Written informed consent was obtained from all patients prior to treatment.

Patient Selection

Patients aged 18 years or older who were diagnosed with peripheral artery disease (PAD) of the lower extremities due to claudication or critical limb ischemia that limited daily activities, and who were scheduled for endovascular intervention, were included in the study.

Importantly, only patients who underwent combined RA and DCB PTA were included. Patients treated with DCB alone, without atherectomy, were excluded from the study. This was done to ensure treatment homogeneity and to directly evaluate the outcomes of RA and DCB in patients with and without DM.

Inclusion criteria:

- Patients undergoing PTA for the first time
- Presence of CLEI classified as Rutherford stage 3 or 4
- Angiographically confirmed total occlusion of femoropopliteal or infrapopliteal arteries
- Undergoing RA and DCB PTA
- Exclusion criteria:
- Intervention involving the aortoiliac segment
- Patients undergoing procedures in more than one segment or lesion
- Concomitant surgical revascularization
- Acute limb ischemia
- Non-salvageable limbs (Rutherford stage 5-6)
- Patients with incomplete data.

Procedural Details

All procedures were performed under local anesthesia by the same interventional cardiovascular surgical team. Preoperatively, all patients underwent computed tomography angiography (CTA) with 0.625 mm slices covering the abdominal and lower extremity arteries (LEA) to evaluate the arterial anatomy in detail. At least one week prior to the procedure, all patients were started on 100 mg of acetylsalicylic acid (ASA), 75 mg of clopidogrel, and 10 mg of atorvastatin.

Vascular access was mostly achieved via an antegrade 7F sheath inserted under sterile conditions using B-mode and color Doppler ultrasonography (CDUS) guidance through the ipsilateral femoral artery (FA). For proximal superficial femoral artery (SFA) lesions that could remain within the sheath, retrograde access from the contralateral common femoral artery (CFA) was used.

All patients received 5,000 IU of intravenous heparin, and the target activated clotting time (ACT) was maintained between 200-250 seconds. Hydrophobic and hydrophilic guidewires (0.014", 0.018", or 0.035") were used to cross the lesion. Lumen creation was achieved using the Temren™ Rotational Atherectomy System (Invamed, Ankara, Turkiye); 7F for FAs and 5F for other vascular structures. To avoid arterial injury, the device was advanced at a rate of 2 mm/sec. The device was paused every 30 seconds to perform contrast injections and assess the vascular structure.

The size of the DCB was determined based on the reference diameter of the healthy arterial segment distal to the lesion. DCB PTA was performed using paclitaxel-coated balloons with diameters ranging from 1.5-6.0 mm, inflated for 120 seconds at a pressure of 6-12 atm. Technical success was defined as residual stenosis of less than 30% following DCB PTA and/or stent implantation. In cases of flow-limiting dissection, residual stenosis greater than 30%, rupture, or acute occlusion, stent implantation was performed as needed. Distal embolic protection devices were not routinely used.

Ankle-Brachial Index (ABI): ABI was calculated using systolic blood pressure measurements obtained from the ankle and the arm. Measurements were performed after the patient had rested in the supine position for 5 minutes.

Primary patency: Maintenance of vessel patency in the treated segment without the need for repeat endovascular or surgical intervention.

Re-occlusion: Development of ≥50% stenosis or complete occlusion in the treated segment.

Follow-Up and Clinical Monitoring

All patients were clinically evaluated at 1-month post-procedure and subsequently at 3, 6, and 12 months, and every 6 months thereafter. Additionally, patients with new or worsening symptoms outside of these follow-up intervals were also reassessed.

During follow-up, ABI measurement, pulse palpation, and handheld Doppler were performed. In patients with symptomatic deterioration (claudication, rest pain, pulse loss), further imaging with CDUS and/or 3D CTA was conducted.

Pharmacological Treatment

Post-procedurally, all patients received 100 mg/day of ASA indefinitely, 75 mg/day of clopidogrel for one year, and 10 mg of atorvastatin for six months. Additionally, risk factors such as hypertension (HT) and DM were managed according to appropriate pharmacologic treatment protocols.

Statistical Analysis

Data analyses were performed using SPSS version 23.0 (IBM Inc., Chicago, IL, USA). The normality of distribution of continuous variables was assessed using the Shapiro-Wilk

test. Continuous variables were presented as mean±standard deviation (SD) for normally distributed data, and as median (IQR: 25%-75%) for non-normally distributed data. Comparisons between DMG and NDMG groups were performed using the Mann-Whitney U test for continuous variables and the Chi-square test or Fisher's exact test for categorical variables, as appropriate.

Changes in the ABI within each group (pre- vs. post-operative) were evaluated using the Wilcoxon signed-rank test. Differences in ABI change between groups were compared using the Mann-Whitney U test.

Re-occlusion-free survival was analyzed using the Kaplan-Meier method, and survival curves between groups were compared using the log-rank test.

A p-value of <0.05 was considered statistically significant.

RESULTS

A total of 151 patients were included and categorized into two groups: diabetic group (DMG, n=77) and non-diabetic group (NDMG, n=74). Preoperative demographic characteristics, procedural data, and postoperative outcomes were evaluated between the two groups.

Preoperative Demographic and Clinical Characteristics

There were no statistically significant differences between the groups in terms of age, sex, smoking status, HT, hyperlipidemia, chronic kidney disease (CKD), and coronary artery disease (CAD) (p>0.05). Additionally, preoperative Rutherford classifications were similar between the groups (p=0.722). Detailed data are presented in Table 1.

Table 1. Baseline demographic and clinical characteristics of the study population

Variables	DMG (n=77)	NDMG (n=74)	p-value
Age (years)	61.00 (54.00-67.00)	64.00 (58.00-72.00)	0.022[a]
Sex (female)	17 (22.1%)	8 (10.8%)	0.080[b]
BMI	28.73 (27.66-31.56)	28.84 (27.80-29.75)	0.297[a]
Smoking	54 (70.1%)	55 (74.3%)	0.590[b]
Hypertension	49 (63.6%)	50 (67.6%)	0.732[b]
Hyperlipidemia	49 (63.6%)	48 (64.9%)	1.000[b]
Chronic kidney disease	4 (5.2%)	5 (6.8%)	0.742[b]
Coronary artery disease	51 (66.2%)	48 (64.9%)	0.866[b]
Rutherford classification			
Stage 3	23 (29.9%)	20 (27.0%)	0.722[b]
Stage 4	54 (70.1%)	54 (73.0%)	

[a]: Mann-Whitney U test, [b]: Fisher's exact test, DMG: Diabetic group, NDMG: Non-diabetic group, BMI: Body-mass index. Values are presented as median (IQR: 25th-75th percentile).

Operative Data

There were no statistically significant differences between the DMG and NDMG groups in terms of lesion length, fluoroscopy time, or amount of contrast used (p>0.05). No significant differences were observed in terms of lesion location (SFA, PA, anterior tibial artery (ATA), posterior tibial artery (PTA) lesions) or procedures performed (use of stent, occurrence of perforation) (p>0.05) (Table 2).

Table 2. Procedural characteristics and operative data

Variables	DMG (n=77)	NDMG (n=74)	p-value
Lesion length (cm)	12.00 (11.00-13.00)	12.00 (11.00-13.00)	0.319[a]
Fluoroscopy time (minutes)	13.00 (12.00-14.00)	13.00 (12.00-13.00)	0.634[a]
Contrast volume (ml)	60.00 (60.00-70.00)	60.00 (52.50-70.00)	0.868[a]
SFA lesions	22 (28.6%)	28 (37.8%)	0.299[b]
PA lesions	22 (28.6%)	21 (28.4%)	1.000[b]
ATA lesions	15 (19.5%)	12 (16.2%)	0.674[b]
PTA lesions	18 (23.4%)	13 (17.6%)	0.424[b]
Stent usage	5 (6.5%)	6 (8.1%)	0.762[b]
Perforation	1 (1.3%)	2 (2.7%)	0.615[b]

DMG: Diabetic group, NDMG: Non-diabetic group, SFA: Superficial femoral artery, PA: Popliteal artery; ATA: Anterior tibial artery; PTA: Posterior tibial artery, [a]: Mann-Whitney U test, [b]: Fisher's exact test. Values are presented as median (IQR: 25th-75th percentile).

Postoperative Outcomes

Re-occlusion occurred in 13.0% (10/77) of patients in the DMG group and 5.4% (4/74) in the NDMG group. Although the re-occlusion rate was numerically higher in the DMG group, the difference was not statistically significant (p=0.160) (Table 3).

Table 3. Postoperative outcomes and complications

Variables	DMG (n=77)	NDMG (n=74)	p-value
Re-occlusion (at 12 months)	10 (13.0%)	4 (5.4%)	0.160[b]
Embolism	0 (0.0%)	1 (1.4%)	0.490[b]
Hematoma	2 (2.6%)	3 (4.1%)	0.677[b]

DMG: Diabetic group, NDMG: Non-diabetic group, [b]: Fisher's exact test

There were also no significant differences between the groups regarding embolism and hematoma rates (p>0.05).

Preoperative and Postoperative ABI Changes

Both DMG and NDMG groups showed a significant increase in ABI values measured at 1-month post-procedure (p<0.001 for both groups, Wilcoxon test). In the DMG group, the median ABI increased from 0.60 (0.50-0.70) preoperatively to 1.10 (1.00-1.20) postoperatively. In the NDMG group, the median ABI increased from 0.60 (0.50-0.70) to 1.20 (1.02-1.20). Although both groups showed significant improvement, the difference in ABI change between the groups was not statistically significant (p=0.143, Mann-Whitney U test) (Table 4, Figure 1).

Table 4. Comparison of preoperative and postoperative ABI values between groups

Variables	DMG (n=77)	NDMG (n=74)	p-value
Preoperative ABI	0.60 (0.50-0.70)	0.60 (0.50-0.70)	0.297[a]
Postoperative ABI	1.10 (1.00-1.20)	1.20 (1.02-1.20)	0.339[a]
ABI Change	<0.001[c]	<0.001[b]	0.143[a]
	Wilcoxon	Wilcoxon	

ABI: Ankle-Brachial Index, DMG: Diabetic group, NDMG: Non-diabetic group, a: Mann-Whitney U test, c: Wilcoxon signed-rank test. Values are presented as median (IQR: 25th-75th percentile).

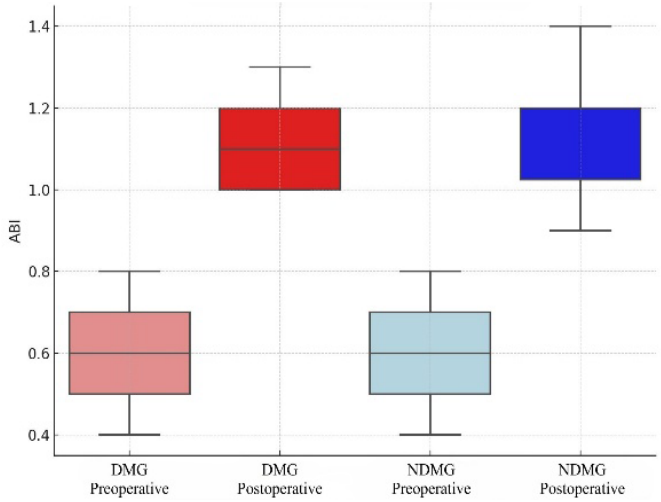

Figure 1. Boxplots illustrating pre- and post-procedural ABI values in DMG and NDMG groups. A significant improvement in ABI was observed in both groups (p<0.001). However, the magnitude of ABI change between groups was not statistically significant (p=0.143)

ABI: Ankle-Brachial Index, DMG: Diabetic group, NDMG: Non-diabetic group

Re-Occlusion-Free Survival Analysis

At 12 months, the re-occlusion-free survival rate was 87.0% in the DMG group and 94.6% in the NDMG group. According to the log-rank test, there was no statistically significant difference in re-occlusion-free survival between the groups (p=0.48) (Figure 2).

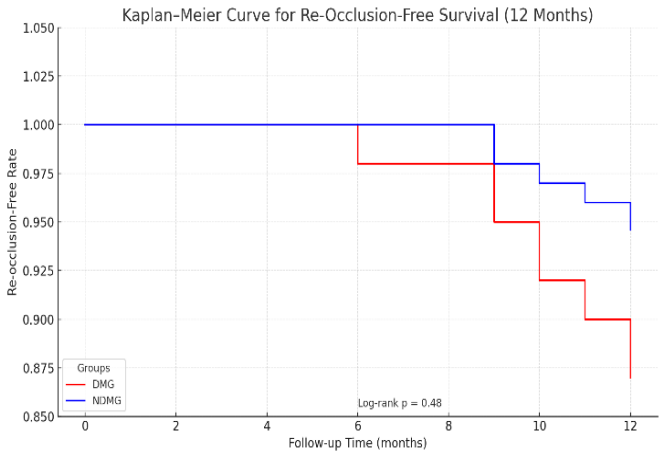

Figure 2. Kaplan-Meier survival curves demonstrating re-occlusion-free survival over a 12-month follow-up period in DMG and NDMG groups. Events occurring during follow-up (e.g., at 8 months) were appropriately incorporated. No statistically significant difference was observed between groups (log-rank p=0.48). Number at risk at 0 and 12 months is indicated below the graph

DMG: Diabetic group, NDMG: Non-diabetic group

DISCUSSION

In this study, we evaluated the 12-month technical and clinical outcomes of the combination of RA and DCB angioplasty in patients with and without DM who had CTO lesions in the LEAD. Our findings demonstrate that the RA and DCB angioplasty is an effective and safe endovascular strategy for both DM and non-DM patients, supported by high technical success, low re-occlusion rates, and a statistically significant increase in ABI.

Patients with DM often present with more distally extended, diffuse, and calcified lesions in PAD, which generally results in lower revascularization success rates.[1,3] In the literature, DCB monotherapy in such patients is frequently insufficient due to risks such as dissection, inadequate balloon penetration, and a high need for stent implantation, which may lead to suboptimal outcomes.[4,5] A large VQI-based registry analysis also showed that diabetic patients experienced higher rates of reintervention and adverse limb events following endovascular procedures, highlighting the challenges of achieving long-term success in this high-risk subgroup.[14]

At this point, vessel preparation with RA enables more effective interaction of the DCB drug with the intima by mechanically removing calcified plaque.[6,7] For example, in the JET-RANGER study by Shammas et al.,[6] the 1-year target lesion revascularization (TLR) rate was reported as 0% in the group treated with Jetstream RA followed by DCB, whereas the same rate reached 56% in the group treated with PTA followed by DCB. Similarly, it has been shown that laser atherectomy combined with DCB results in improved two-year freedom from TLR and reduced restenosis in complex calcified lesions when compared to PTA followed by DCB.[15] In another comparative study, the combination of directional atherectomy and antirestenotic therapy (DAART) achieved higher primary patency rates than DCB alone in isolated popliteal artery lesions (82% vs. 65%), emphasizing the importance of plaque debulking before drug delivery.[9] In line with these findings, our study showed that the re-occlusion rate was 13% in the DMG group and 5.4% in the NDMG group; despite the presence of CTO and a high prevalence of DM, these rates are considerably lower than many series in the literature.[10,11]

Moreover, we achieved 100% technical success in both groups, with a stent implantation rate of less than 8%. These findings are consistent with results from the DEFINITIVE AR study, in which the use of directional atherectomy prior to DCB reduced dissection rates and improved procedural success in calcified lesions.[8] Additionally, orbital atherectomy combined with DCB has been associated with a high safety profile and a low requirement for bailout stenting, even in heavily calcified femoropopliteal lesions.[16] This supports the "leave nothing behind" approach in the popliteal and infrainguinal segments where stent implantation may pose mechanical limitations, affirming the practicality of the RA and DCB angioplasty.[12-17] In other series in the literature, technical success rates have been reported between 90% and 100%.[7,12,17] Our study also achieved a 100% technical success rate. However, this alone is not sufficient for long-term clinical durability. While ABI improvements were similar in the short term, re-occlusion rates varied between groups in the mid-term. This disparity may be explained by the more widespread and distally inclined atherosclerotic burden, degree of calcification, and impaired vascular healing response typically observed in DM patients.[3]

In the study by Gumus et al.,[7] the RA and DCB angioplasty was applied in 28 patients with isolated PA lesions, reporting a 12-month primary patency rate of 92.3% and a TLR rate of 7.1%. In our study, however, similarly favorable patency rates (87.0% and 94.6%) and low re-occlusion rates were observed

in a more complex patient population with CTOs not limited to the popliteal segment. These findings suggest that the RA and DCB angioplasty may achieve comparable success across different anatomical regions.

Furthermore, medial calcification, poor distal runoff, and impaired wound healing are frequently cited in the literature as key factors negatively affecting long-term outcomes, particularly in DM patients.[18] A comprehensive review highlighted that, although long-term randomized data are still limited, the combination of atherectomy with DCB may provide notable benefits in complex lesion subsets, particularly in patients with diabetes.[19] Although our study was limited to ABI and re-occlusion assessment, it demonstrated significant ABI improvement in both patient groups (from 0.60 to 1.10 in DMG and from 0.60 to 1.20 in NDMG, p<0.001). This improvement indicates not only technical success but also a meaningful enhancement in functional perfusion. Similarly, in the study by Ulukan et al.,[11] ABI increased from 0.57 to 0.80 following RA and DCB angioplasty in 34 patients, and this improvement was statistically significant. In the study by Gumus et al.,[7] ABI improved from 0.45 to 0.91. However, both studies included small patient groups with mixed DM status, and subgroup analyses of DM patients were not conducted.[7,11] Our study thus fills an important gap in the literature, providing evidence that vessel preparation with RA can positively influence perfusion outcomes even in DM patients, as objectively demonstrated by ABI. The significant increase in ABI supports not only angiographic patency but also clinical improvement.

In conclusion, this study demonstrates that RA and DCB angioplasty is technically feasible and effective in both the short and mid-term. Although re-occlusion rates were numerically higher in DM patients, the observed improvement in ABI highlights the functional efficacy of the treatment. As one of the few studies directly comparing patients with and without DM, this work provides a valuable foundation for future prospective research.

Limitations

This study, while having certain strengths, also possesses limitations that must be acknowledged. First, its retrospective and single-center design limits generalizability and introduces potential biases in patient selection and data accuracy. Second, although the sample size was relatively large compared to similar previous studies, the inability to reach statistical significance for some intergroup differences might reflect the sample size limitation. Third, ABI measurements were only evaluated pre-procedurally and in the early period (first month), and long-term hemodynamic changes or impacts on quality of life were not assessed. Moreover, restenosis evaluation was limited to symptomatic patients, and systematic control angiography was not performed in all cases. Finally, important clinical variables such as disease progression, lesion morphology, degree of calcification, distal runoff, and operator experience were not included in the analysis. Therefore, to enhance the generalizability of our findings and standardize treatment strategies, well-designed, multicenter, prospective, and randomized controlled trials are warranted.

CONCLUSION

This study demonstrated that the combination of RA and DCB angioplasty is an effective and safe treatment approach for CTOs in LEAD, achieving high technical success, significant ABI improvement, and low re-occlusion rates in both DMG and NDMG patient groups. The comparable success achieved in the DM cohort supports the applicability of this strategy even in high-risk populations. These findings support the use of RA and DCB angioplasty as a viable, vessel-preserving strategy across diverse anatomic segments, even in the presence of diabetes-related arterial complexity. If validated by larger, prospective, and randomized trials, this strategy may become a valuable tool in the treatment of complex peripheral arterial disease.

ETHICAL DECLARATIONS

Ethics Committee Approval

The study was carried out with the permission of the Hitit University Faculty of Medicine Clinical Researches Ethics Committee (Date: 03.10.2023, Decision No: 2023/124).

Informed Consent

Because the study was designed retrospectively, no written informed consent form was obtained from patients.

Referee Evaluation Process

Externally peer-reviewed.

Conflict of Interest Statement

The authors have no conflicts of interest to declare.

Financial Disclosure

The authors declared that this study has received no financial support.

Author Contributions

All of the authors declare that they have all participated in the design, execution, and analysis of the paper, and that they have approved the final version.

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