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# Combined use of atherectomy and drug-coated balloon for endovascular treatment of femoropopliteal artery disease

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**ABSTRACT**

**Objectives:** In this study, we aimed to evaluate the results of the combined use of atherectomy and drug-coated balloon (DCB) treatment in femoropopliteal artery disease.

**Patients and methods:** Between June 2016 and September 2018, a total of 45 patients (32 males, 13 females; mean age 66.2±11.9 years; range, 36 to 87 years) who underwent combined atherectomy and DCB treatment for femoropopliteal artery disease in our clinic were retrospectively analyzed. The demographic data, Rutherford Category, Ankle-Brachial Index, and lesion characteristics were recorded. Stent implantation was allowed only in case of flow-limiting dissection or recoil after prolonged balloon inflation.

**Results:** Procedural and clinical success were achieved in all cases. Flow-limiting dissection was seen in six patients (13.3%) after atherectomy. Provisional stent was performed to these patients. Additional DCB was performed in 39 patients. Mean follow-up was 12.7±7.5 (range, 0.5 to 28.1) months. Two minor amputations were performed to achieve complete wound healing. There was no major amputation and no mortality. Re-occlusion was seen in six patients (13.3%) and target lesion revascularization (TLR) was performed to these patients. The rate of freedom from TLR was 86.7%.

**Conclusion:** Our study results suggest that combined use of atherectomy and DCB may be a potential alternative strategy for the treatment of femoropopliteal artery disease. Atherectomy before balloon angioplasty may reduce the rate of significant dissection and, therefore, may be a valuable option for minimizing the need for bailout stenting.

***Keywords:*** Atherectomy, drug-coated balloon, peripheral artery disease.

Endovascular treatment is the most frequently recommended option in patients with peripheral artery disease refractory to maximal medical and exercise therapy.[1] The first-generation methods of endovascular treatment of peripheral artery disease include percutaneous transluminal angioplasty (PTA) and provisional bare metal stent placement.[2] However, standalone PTA treatment may cause plaque fractures and dissections.[3] Stent placement may also result in a reduction in the future treatment options due to the metal burden and early occlusion due to stent fracture.[4] Several studies have shown that local paclitaxel application with drug-coated balloon (DCB) to the vessel wall significantly reduces restenosis, compared to PTA.[5,6] However, higher provisional stent rates in calcific and long lesions with DCB is still a challenging problem.[7]

Atherectomy improves the luminal gain by removing plaque from the vessel wall and provides plaque modification. As a result, it reduces rates of bailout stenting and dissection.[8] It can also improve drug absorption by reducing the plaque volume.[9] Although patency rates are not too high in the use of atherectomy alone,[10] a limited number of studies has reported promising results regarding the combined use of atherectomy and DCB.[9,11]

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In this study, we aimed to evaluate the results of patients who underwent combined atherectomy and DCB treatment for femoropopliteal artery disease.

## PATIENTS AND METHODS

### Study design

Between June 2016 and September 2018, 70 patients who underwent peripheral intervention for femoropopliteal artery disease in our clinic were screened. In patients with femoropopliteal artery disease, endovascular intervention was performed primarily in patients with a lesion length of ≤25 cm. In patients with a lesion length of more than 25 cm, endovascular intervention was performed to the native femoropopliteal artery in those who had previous femoropopliteal bypass and whose graft was obstructed. In 25 patients, atherectomy was unable to be performed due to the lack of reimbursement criteria and these patients were excluded from the study.

Finally, a total of 45 patients (32 males, 13 females; mean age 66.2±11.9 years; range, 36 to 87 years) who underwent combined atherectomy and DCB treatment were included. A retrospective analysis was performed and data including demographic characteristics and previous vascular interventions were recorded. The Rutherford Category, preoperative imaging results, and Ankle-Brachial Index (ABI) were noted. Angiographic assessment of the lesion length and degree of stenosis were also recorded. A written informed consent was obtained from each patient. The study protocol was approved by the Acibadem Mehmet Ali Aydinlar University Clinical Research Ethics Committee (Date: 08.11.2018-No.2018/17/13). The study was conducted in accordance with the principles of the Declaration of Helsinki.

### Procedure

Procedures were performed in an endovascular suite under local anesthesia and conscious sedation. Access was gained via retrograde contralateral femoral artery puncture in 39 patients (86.7%), antegrade ipsilateral femoral artery puncture in three patients (6.7%), and retrograde ipsilateral popliteal artery puncture in three patients (6.7%) with a 6-Fr sheath. In addition, two patients had additional retrograde ipsilateral popliteal artery and one patient had additional retrograde ipsilateral posterior tibial artery puncture due to inability to pass the lesion. Heparin (5,000 Unit) was routinely administered from the sheath at the beginning of the procedure. Additional doses were administered per hour. Carbon dioxide was used rather than a contrast media in three patients with chronic renal failure, but no dialysis. Contralateral procedures were performed over a 7-Fr long sheath, after the short sheath was replaced with long sheath (Destination® peripheral guiding sheath, Terumo Medical Corporation, Tokyo, Japan). The V-14™ and V-18™ controlwires, Victory™ 14, 18 guidewires, Rubicon™ support catheter (Boston Scientific, Marlborough, MA, USA), and Navicross® support catheter (Terumo Medical Corporation, Tokyo, Japan) were used to penetrate the steno-occlusive lesions by intraluminal wiring. Plain angioplasty with low-profile balloons was applied prior to debulking only when atherectomy device was unable to be advanced through the lesion. Atherectomy was performed according to the protocol for the respective device. In patients with eccentric lesions or short total occlusion, directional atherectomy was used, if there was a distance to use the filter distal to the lesion. Rotational atherectomy was used in all other patients. The majority of lesions (31 lesions; 66.6%) were treated by the JetStream™ rotational atherectomy system (Boston Scientific, Marlborough, MA, USA) (Figure 1). In two of these patients, the EmboShield® NAV6 embolic protection system (Abbott Vascular, Illinois, USA) was located at the distal part of the lesion due to a suspected thrombus in the lesion. Six lesions (13.3%) were treated by the TurboHawk directional

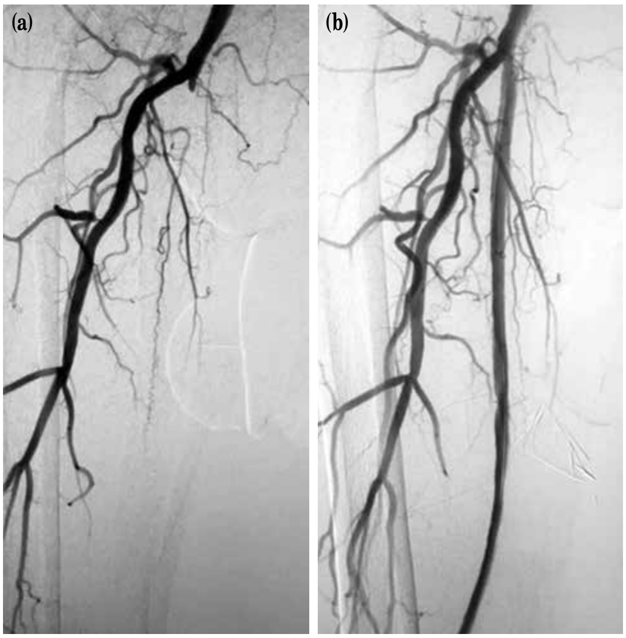



**Figure 1.** **(a)** A digital subtraction angiography image of long segment superficial femoral artery occlusion before procedure. **(b)** A digital subtraction angiography image of superficial femoral artery after combined Jetstream atherectomy and drug-coated balloon treatment.

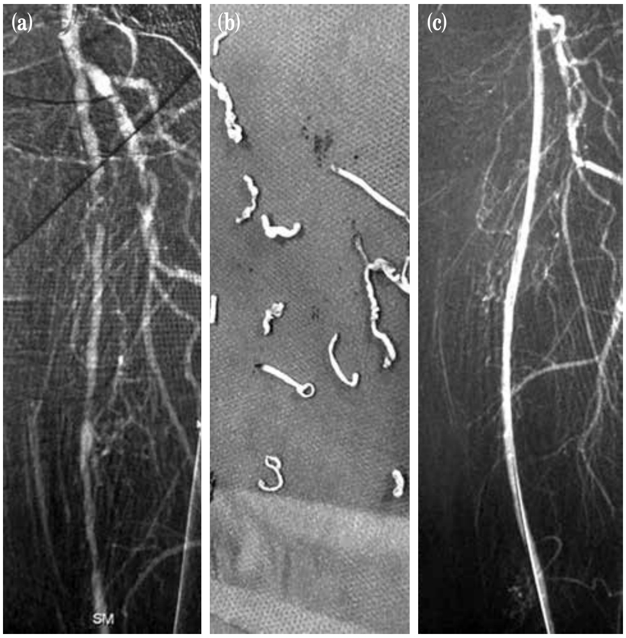



**Figure 2.** (**a**) A carbon dioxide digital subtraction angiography image of superficial femoral artery with multiple occlusions before procedure. (**b**) Atheroma plaques debulked from superficial femoral artery by Hawkone directional atherectomy system. (**c**) A carbon dioxide digital subtraction angiography image of superficial femoral artery after combined Hawkone atherectomy and drug-coated balloon treatment.

atherectomy system (Medtronic, Minneapolis, MN, USA) and six lesions (13.3%) were treated by the HawkOne directional atherectomy system (Medtronic, Minneapolis, MN, USA) (Figure 2). In all of these 12 patients, the SpiderFX embolic protection device (Medtronic, Minneapolis, MN, USA) was located at the distal part of the lesion due to the risk for distal embolism. The remaining two lesions (4.5%) were treated by the Phoenix rotational atherectomy system (Volcano Corp., San Diego, CA, USA). Using an appropriate balloon size, PTA was performed. After performing over two-min balloon inflation, digital subtraction angiography was performed to make the next treatment strategy. Indication for stent implantation was the presence of flow-limiting recoil or dissection after the prolonged balloon inflation. Additional DCB was performed in all patients without a flow-limiting lesion.

### Statistical analysis

Statistical analysis was performed using the Number Cruncher Statistical Software 2007 (NCSS LLC, Kaysville, Utah, USA) (License number: 1675948377483). Descriptive data were expressed in mean and standard deviation (SD), median (min-max), and number and frequency. The Wilcoxon signed-Rank test was used to compare the data before and after the procedure. Kaplan-Meier plot was used to evaluate the freedom from target lesion revascularization (TLR). A $p$ value of <0.05 was considered statistically significant.

## RESULTS

Of the patients, 17 had critical limb ischemia and 28 had lifestyle-limiting claudication. According to the Rutherford Category, 28 patients were classified as the Category 3, nine as the Category 4, and eight patients as Category 5. The mean preoperative ABI was 0.7±0.1. Baseline demographic and clinical characteristics of the patients are shown in Table 1.

Pathologies were total occlusion in 38 limbs and critical stenosis in seven limbs. The lesions were located in the superficial femoral artery (SFA) in 31 patients, in the popliteal artery in three patients, and in both femoral and popliteal arteries in 11 patients. Six patients previously underwent endovascular intervention or surgery. Of these, two had in-stent occlusion, three had previous femoropopliteal graft occlusion, and one patient had stenosis of previous iliofemoral graft distal anastomosis. The mean total occlusion length was 164.3±109.6 (range, 20 to 350) mm in patients with chronic total occlusion. There was an additional iliac artery pathology in 14 and below the knee pathology in 20 patients (Table 2).

Atherectomy was possible in all cases. Flow-limiting dissection was seen in six patients (13.3%). Provisional stent was performed to these patients. Of these, three patients had previous femoropopliteal graft and one patient had previous long SFA in-stent occlusion. Following atherectomy, 39 patients underwent DCB. Adequate vascular lumen (less than 30% stenosis) was provided in all patients and the symptoms regressed. There were two cases of embolization (4.4%) successfully treated with suction embolectomy and thrombolytic infusion treatment for 24 hours. There was one case of arteriovenous fistula (AVF) (2.2%) after popliteal artery puncture. This patient was given thrombolytic treatment after the initial procedure due to embolization. In the second procedure, the fistula was successfully treated with the stent graft (Table 3).

The mean follow-up was 12.7±7.5 (range, 0.5 to 28.1) months. Re-occlusion was seen in six patients (13.3%) (n=2 at one month, n=1 at three months, n=1 at four months, and n=2 at six months). Of these patients,

| Table 1. Baseline demographic and clinical characteristics of patients | | | | | |
|---|---|---|---|---|---|
| | n | % | Mean±SD | Median | Min-Max |
| Age (year) | | | 66.2±11.9 | 67 | 36-87 |
| Gender | | | | | |
| Female | 13 | 28.9 | | | |
| Male | 32 | 71.1 | | | |
| Smokers | | | | | |
| Not smoking | 13 | 28.9 | | | |
| Active | 19 | 42.2 | | | |
| Previous | 13 | 28.9 | | | |
| Rutherford Category (n=45) | | | 3.6±0.8 | 3 | 3-5 |
| 0 Asymptomatic | 0 | 0 | | | |
| 1 Mild claudication | 0 | 0 | | | |
| 2 Moderate claudication | 0 | 0 | | | |
| 3 Severe claudication | 28 | 62.2 | | | |
| 4 Ischemic rest pain | 9 | 20.0 | | | |
| 5 Minor tissue loss | 8 | 17.8 | | | |
| 6 Major tissue loss | 0 | 0 | | | |
| Diabetes mellitus | 21 | 46.7 | | | |
| Hypertension | 25 | 55.6 | | | |
| Dyslipidemia | 26 | 57.8 | | | |
| Coronary artery disease | 15 | 33.3 | | | |
| Chronic obstructive pulmonary disease | 9 | 20.0 | | | |
| Chronic kidney disease | 7 | 15.6 | | | |
| Dialysis-dependent | 4 | - | | | |
| Cerebrovascular disease | 2 | 4.4 | | | |

SD: Standard deviation; Min: Minimum; Max: Maximum.

| Table 2. Lesion characteristics | | | | | |
|---|---|---|---|---|---|
| | n | % | Mean±SD | Median | Min-Max |
| Chronic total occlusion | 38 | 84.4 | | | |
| Total occlusion length (mm) | | | 164.3±109.6 | 145 | 20-350 |
| Superficial femoral artery disease | 31 | 68.9 | | | |
| Popliteal artery disease | 3 | 6.7 | | | |
| Both femoral and popliteal arteries | 11 | 24.4 | | | |
| Additional arterial pathology | | | | | |
| Iliac artery | 14 | 31.1 | | | |
| Below the knee | 20 | 44.4 | | | |

SD: Standard deviation; Min: Minimum; Max: Maximum.

| Table 3. Procedural and follow-up results | | |
|---|---|---|
| | n | % |
| Flow-limiting dissection | 6 | 13.3 |
| Provisional stent | 6 | 13.3 |
| Distal embolisation | 2 | 4.4 |
| Arteriovenous fistula | 1 | 2.2 |
| Minor amputation in critical limb ischemia patients | 2/17 | 11.7 |
| Major amputation in critical limb ischemia patients | 0 | 0 |
| Limb salvage rate in critical limb ischemia patients | 17/17 | 100 |
| Re-occlusion | 6 | 13.3 |
| Target lesion revascularization | 6 | 13.3 |
| Freedom from target lesion revascularization | 39/45 | 86.7 |

SD: Standard deviation; Min: Minimum; Max: Maximum.

two had previous femoropopliteal graft occlusion and two had previous stent occlusion before the initial procedure. One patient previously underwent endovascular therapy two times for a single lesion. The last patient was treated due to long SFA occlusion. Three patients required re-intervention with either atherectomy or stenting over the course of the follow-up period. Two patients required open revascularization via a femoropopliteal bypass graft and one patient required common and superficial femoral endarterectomy and patchplasty. Two minor foot finger amputations (4.4%) were performed to reach complete wound healing in the critical limb

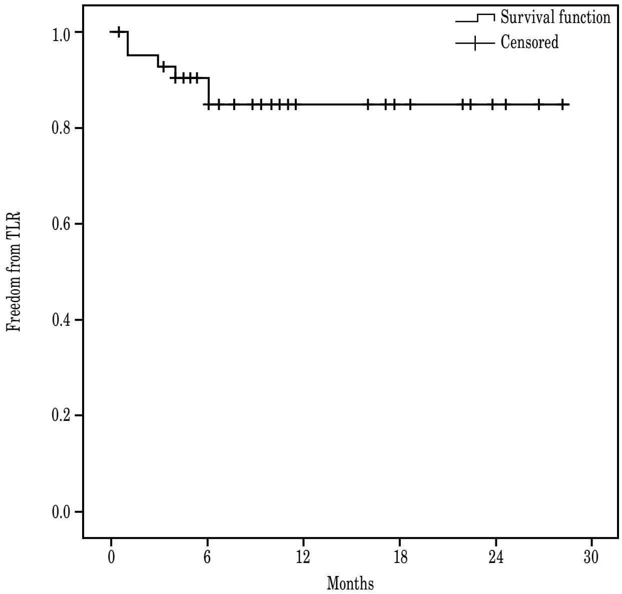
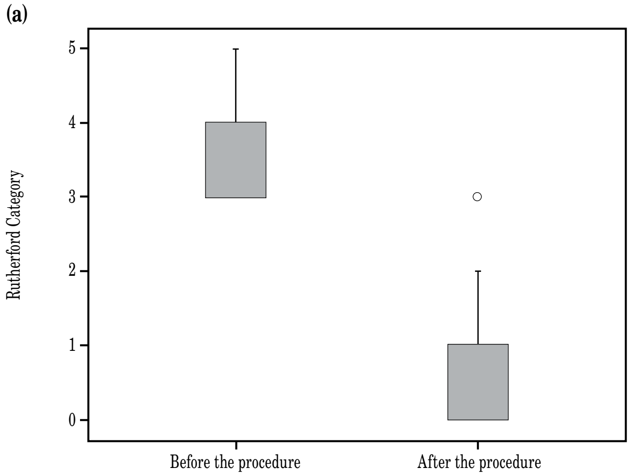



**Figure 3.** Kaplan-Meier plot according to freedom from target lesion revascularization. TLR: Target lesion revascularization.

**(a)**




**(b)**

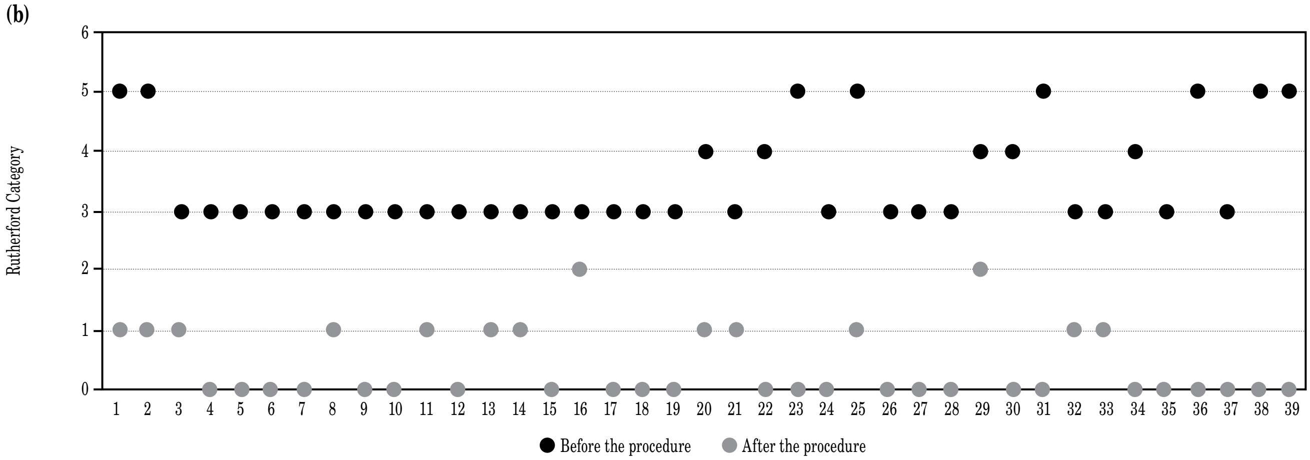



**Figure 4. (a, b)** Distribution of Rutherford Categories before and after procedure.

ischemia patients. There was no major amputation and no mortality. The rate of freedom from TLR was 86.7% (Table 3 and Figure 3). The Rutherford Categories and ABI of patients who underwent TLR were not considered and were excluded from the statistical evaluation. According to the Rutherford Category, 25 patients were classified as Category 0, 12 patients as Category 1, and two patients as Category 2 at the end of follow-up. The decrease in the Rutherford levels after the procedure was found to be statistically significant in 39 patients ($p=0.001$; $p<0.01$) (Figure 4). The mean postoperative ABI was 1.1±0.1. The increase in the ABI indicis after the procedure was found to be statistically significant in 39 patients ($p=0.010$; $p<0.05$) (Table 4).

## DISCUSSION

In this study, we present the early and midterm results of combined atherectomy and DCB treatment. The postoperative clinical improvement was significant with low complication rates and acceptable TLR rates.

Randomized trials showed that the patency improved with the use of self-expanding stents in the SFA. In the Randomized Study Comparing the Edwards Self-ExpandIng Lifestent versus Angio- plasty Alone In LEsions INvolving The SFA and/or Proximal Popliteal Artery (RESILIENT), primary patency (81.3% vs. 36.7%; $p<0.0001$) and freedom from TLR (87.3% vs. 45.1%; $p<0.0001$) were better in the stent group, compared with the angioplasty group.[12] Although stenting seems more feasible for many endovascular specialists, as it can be easily performed with higher speed and predictable

**Table 4. Evaluation of Rutherford Categories and Ankle-Brachial Index measurements before and after the procedure**

| | Before the procedure | | | | | Before the procedure | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | n | % | Mean±SD | Median | Min-Max | n | % | Mean±SD | Median | Min-Max | *p* |
| Rutherford Category (n=39) | | | 3.5±0.8 | 3 | 3-5 | | | 0.4±0.6 | 0 | 0-3 | 0.001* |
| 0 Asymptomatic | 0 | 0 | | | | 25 | 64.1 | | | | |
| 1 Mild claudication | 0 | 0 | | | | 12 | 30.8 | | | | |
| 2 Moderate claudication | 0 | 0 | | | | 2 | 5.1 | | | | |
| 3 Severe claudication | 26 | 66.7 | | | | 0 | 0 | | | | |
| 4 Ischemic rest pain | 5 | 12.8 | | | | 0 | 0 | | | | |
| 5 Minor tissue loss | 8 | 20.5 | | | | 0 | 0 | | | | |
| 6 Major tissue loss | 0 | 0 | | | | 0 | 0 | | | | |
| Ankle-brachial index | | | 0.7±0.1 | 0.68 | | | | 1.1±0.1 | 1.16 | | 0.010** |

SD: Standard deviation; Min: Minimum; Max: Maximum; Wilcoxon Signed-Rank Test; * $p<0.01$; ** $p<0.05$.

excellent angiographic results; however, the long-term outcome remains a problem with a high rate of stenosis, need for repeat TLR, and stent fracture.[4]

The concept of an optimal approach for infrainguinal interventions using a no-stent strategy has been recently propelled with the advent of DCB. Several large-scale, randomized trials have demonstrated improved primary patency and reduced rates of TLR with the use of DCB for the femoropopliteal artery disease.[5,6] In the Drug-Coated Balloon versus Standard Percutaneous Transluminal Angioplasty for the Treatment of Superficial Femoral and Popliteal Peripheral Artery Disease (IN.PACT SFA) trial, DCB angioplasty was associated with significantly improved primary patency (82.2% vs. 52.4%; p<0.001).[5] Similarly, The Trial of a Paclitaxel-Coated Balloon for Femoropopliteal Artery Disease (LEVANT II) demonstrated significantly improved patency rates (65.2% vs. 52.6%; p=0.02) among lesions treated with DCB angioplasty, compared to PTA alone.[6] Of note, both studies included patients with moderate length lesions (<15 cm); however, DCB remains a form of balloon angioplasty which leads to dissection and bailout stenting, particularly in complex diseases such as long lesions, heavy calcifications, or chronic total occlusion.[13] In addition, vascular calcium has been shown to negatively affect the outcomes of DCB. Fanelli et al.[7] showed that calcium distribution and severity affected late lumen loss and primary patency. They also demonstrated that calcium represented a barrier to optimal drug absorption.

Atherectomy offers a way to modify complex disease by improving vessel compliance. Therefore, it reduces the need for high pressure balloon dilatation and barotrauma, leading to low incidence of flow-limiting dissection and bailout stenting.[14] Also, preclinical studies have shown that atherectomy modifies the complex plaque by allowing better drug penetration and diffusion into the vessel wall.[15] In clinical studies, combined use of atherectomy and DCB seems to improve patency and freedom from TLR rates.[11,16,17] Cioppa et al.[11] reported 90% primary patency and 90% freedom from TLR rate in 30 calcified femoropopliteal lesions treated with directional atherectomy and DCB at one year. Foley et al.[16] demonstrated similar TLR and primary patency rate in patients treated with and without adjunctive orbital atherectomy to DCB (77% vs. 82%; p=0.8) at one year, despite the higher lesion complexity among those receiving combined orbital atherectomy and DCB therapy. In a pivotal randomized Directional Atherectomy Followed by a Paclitaxel-Coated Balloon to Inhibit Restenosis and Maintain Vessel Patency (DEFINITIVE AR) study, acute technical success was significantly higher with directional atherectomy and DCB versus DCB alone (89.6% vs. 64.2%; p=0.004), the rate of flow- limiting dissection was significantly lower in the DA+DCB group (2% vs. 19%; p=0.01), and the primary patency rate with combination therapy was 84.6%.[17] In addition, Shammas et al.[18] demonstrated significantly higher freedom from TLR rates with rotational atherectomy and adjunctive DCB, compared to rotational atherectomy with adjunctive PTA at 16 months (94.4% vs. 54%; p=0.002) in 75 patients with femoropopliteal lesions. In our study, the freedom from TLR rate was 86.7%, consistent with previous findings.

The main limitations of the present study include small sample size, retrospective design, and lack of control group. In addition, further long-term studies are needed to confirm our findings.

In conclusion, combined atherectomy and DCB therapy is effective and safe in femoropopliteal lesions with low complication and TLR rates. In particular, in patients with complex femoropopliteal lesions, combination therapy reduces the rates of bailout stenting and flow-limiting dissection during the procedure and leaves nothing behind for the next intervention.

**Declaration of conflicting interests**

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