ORIGINAL ARTICLE

Atherectomy followed by drug-coated balloon angioplasty for below knee lesions in diabetic patients

Aterectomía seguida de angioplastia con balón recubierto de fármaco para lesiones debajo de la rodilla en pacientes diabéticos

Orhan Rodoplu[1], Zafer Er[2], Ibrahim Erdinc[3], and Cuneyd Ozturk[4]*

[1]Cardiovascular Surgery Clinic, Atasehir Florence Nightingale Hospital, Istanbul; [2]Department of Cardiovascular Surgery, Bozok University Medical Faculty, Yozgat; [3]Cardiovascular Surgery Clinic, Izmir Bozyaka Training and Research Hospital, Izmir; [4]Cardiovascular Surgery Clinic, Kadikoy Florence Nightingale Hospital, Istanbul. Turkey

Abstract

Objective: *The aim of this study was to compare the long-term outcomes of below the knee revascularization with percutaneous atherectomy followed by drug-coated balloon and revascularization with drug-coated balloon alone for symptomatic diabetic patients with peripheral arterial disease.* **Patients and methods:** *Between April 2015 and January 2020, total of 128 patients and 228 below the knee procedures were enrolled into this retrospective study. Sixty-five patients were treated with atherectomy followed by drug-coated balloon and 63 patients were treated solely with drug-coated balloon.* **Results:** *Technical success rates were similar in the AT+DCB group and DCB group. Target lesion revascularization (TLR) was found similar in both groups at 6-month follow-up. Clinically, driven repeat endovascular and surgical limb revascularization rates were also significantly lower at 12 and 24 months.* **Conclusion:** *Combined usage of rotational atherectomy and drug-coated balloons for the treatment of diabetic patients with below-the knee arterial lesions and critical limb ischemia is associated with reduced long-term TLR rates and improved the long-term outcomes.*

Keywords: *Atherectomy. Below the knee peripheral artery disease. Chronic limb-threatening ischemia.*

Resumen

Objetivo: *El objetivo de este estudio fue comparar los resultados a largo plazo de la revascularización por debajo de la rodilla con aterectomía percutánea seguida de balón recubierto de fármaco y revascularización con balón recubierto de fármaco solo en pacientes diabéticos sintomáticos con arteriopatía periférica.* **Métodos:** *Entre abril de 2015 y enero de 2020, un total de 128 pacientes y 228 procedimientos por debajo de la rodilla se inscribieron en este estudio retrospectivo. Sesenta y cinco pacientes fueron tratados con aterectomía seguida de balón recubierto de fármaco y 63 pacientes fueron tratados únicamente con balón recubierto de fármaco.* **Resultados:** *Las tasas de éxito técnico fueron similares en el grupo AT+DCB y DCB. La revascularización de la lesión diana fue similar en ambos grupos a los 6 meses de seguimiento. Las tasas de revascularización endovascular y quirúrgica de las extremidades también fueron significativamente más bajas a los 12 y 24 meses.* **Conclusión:** *El uso combinado de aterectomía rotacional y balones recubiertos de fármaco para el tratamiento de pacientes diabéticos con lesiones arteriales por debajo de la rodilla e isquemia crítica de las extremidades se asocia con tasas reducidas de revascularización de la lesión diana a largo plazo y mejores resultados a largo plazo.*

Palabras clave: *Aterectomía. Enfermedad arterial periférica debajo de la rodilla. Isquemia crónica que amenaza las extremidades.*

***Correspondence:**
Orhan Rodoplu
E-mail: orhanrodoplu34@gmail.com

Date of reception: 26-02-2022
Date of acceptance: 02-07-2022
DOI: 10.24875/CIRU.22000131

Cir Cir. 2022;90(S2):29-35
Contents available at PubMed
www.cirugiaycirujanos.com

Introduction

Infra-popliteal (or below-the-knee [BTK]) atherosclerosis is the most common cause of critical limb ischemia (CLI). The pathology is associated with increased morbidity, mortality, and amputation rates[1]. The mortality rates of patients with peripheral arterial disease (PAD), especially in the presence of CLI, are approximately 20% in 6 months and may be more than 50% within 5 years from the first diagnosis[2,3]. Endovascular interventions are more frequently preferred in the current era with respect to the low success rates of open surgical revascularization in the infra-popliteal lesions[1]. However, despite advances in endovascular procedures, the restenosis and revascularization necessities are still challenging[4,5].

Percutaneous transluminal angioplasty (PTA) alone is widely used for the treatment of infra-popliteal atherosclerosis. It may be performed with standard or drug-coated balloons. However, the long-term patency of the technique is suboptimal[6]. The calcification, which frequently persists in tibial arteries, limits the efficacy of PTA leading to vessel recoil, dissection, and increased target lesion revascularization (TLR)[7,8].

At present, there is no approved stent available for the treatment of infra-popliteal revascularization. On the other hand, atherectomy provides atherosclerotic plaque removal from the arterial wall and may be used as a sole therapy or applied in combination with balloon angioplasty[9].

The symptomatic PAD is seen in approximately 21% of the patients with diabetes mellitus[10]. The infra-popliteal lesions generally consist of heavy and circumferential calcifications. These characteristic features of the BTK lesions complicate revascularization and cause endovascular interventions to become more challenging[11]. Diabetes mellitus may lead to chronic kidney disease which in combination significantly increases incidence of PAD[12]. Percutanous transluminal angioplasty of complex and calcified lesions may result in the early recoiling and dissections in patients with diabetes mellitus and end-stage renal disease. Furthermore, the primary and secondary patency rates are lower in these cases and bailout stenting may be required in up to 50% of the cases[13].

Patients with CLI generally have transatlantic intersociety consensus D lesions, total occlusions, and/or advanced calcified lesions, and these lesions are not fully suitable for interventional therapies. Surgical treatment is superior to PTA (with or without stenting) in the presence of a suitable ipsilateral saphenous vein and an appropriate non-calcified artery[6]. However, the patients with CLI, especially those with infra-popliteal lesions, sometimes do not have an appropriate saphenous vein as a graft or a non-calcified bypass-able patent artery. Besides, these patients may have multiple comorbidities, that the open surgical treatment may have higher risk for the occurrence of major adverse events[6].

Preparation of the vessels before PTA in complex lesions increases the success rates of PTA. For instance, the increased lumen diameter before angioplasty could enable lesion crossing and provide higher long-term patency rates[13]. The atherectomy prepares vessels by debulking the plaque burden and requires lower pressures of PTA for revascularization; presenting decreased risk of intimal hyperplasia and dissection[14].

The aim of the present study was to compare the long-term results of rotational atherectomy followed by drug-coated balloon angioplasty (AT+DCB) with sole drug-coated angioplasty (DCB) for the treatment of infra-popliteal PAD in patients with diabetes mellitus.

Patients and methods

This retrospective study included 128 diabetic patients with symptomatic PAD patients secondary to infra-popliteal lesions who underwent endovascular interventions with drug-coated balloon alone or in combination with atherectomy between April 2015 and January 2020. Due to the retrospective nature of the study, the ethical approval was not required. The patients older than 18 years of age, who had severe claudication (Rutherford 3) or CLI (Rutherford 4-6) were investigated retrospectively if they had at least 70% stenosis in a lower extremity, confirmed by angiography. Patients with concomitant femoropopliteal disease and in-stent restenosis were excluded from the study. The 128 patients and a total of 218 BTK interventions were categorized into two groups according to use of rotational atherectomy followed by drug-coated balloon (AT+DCB) or drug-coated balloon (DCB) alone.

All of the patients had diabetes mellitus with the mean HbA1c levels of 8.9. Mean age of the patients were 66.4 ± 10.7 years and 67.1% (n = 86) of the patients were male. About 76.5% (n = 98) of patients consisted of past and current smokers. Hypertension and hyperlipidemia were the most frequently seen comorbidities in our cohort, found in 75.8% (n = 97) and 73.4% (n = 94),

respectively; followed by 71.1% (n = 91) of the patients with coronary artery disease. About 29.2% (n = 19) of patients had a history of myocardial infarction, while 32% (n = 41) of the patient population had coronary artery revascularization either percutaneously or with coronary artery bypass surgery. About 11.7% (n = 15) of the patients had prior amputations.

Percutaneous interventions were performed with standard techniques as femoral ante- and retrograde approach. Dual antiplatelet therapy including 300 mg aspirin and 300 mg or 600 mg clopidogrel were initiated in all patients before the procedures. Heparin (100 units/kg) was administered for periprocedural anticoagulation. Drug-coated balloon was applied with (Bio-Path™ 035 paclitaxel-eluting balloon dilatation catheter) balloon diameters of 80-90% of reference vessel with low pressure and 60 s inflation time. Additional inflations were not hesitated if necessary. Phoenix rotational atherectomy device (Volcano Corporation, San Diego, California) was utilized in this study. Distal protection systems were not used. The interventions with a result of postprocedural TIMI 3 flow, without dissection, and residual stenosis were defined as successful intervention.

The primary endpoints of this study were determined as primary patency rates, clinically driven repeat endovascular and surgical limb revascularization (CD-TLR). The change in ankle brachial index (ABI) and Rutherford classification at 1 and 2 years were also evaluated. The secondary endpoints included 1-year all-cause mortality, major and minor amputations, and peri-procedural complications such as perforation, dissection, and distal embolization.

All the patients were prescribed 40 mg/day atorvastatin and dual antiplatelet therapy with clopidogrel (75 mg) and acetylsalicylic acid (100 mg) once a day. Dual antiplatelet therapy was used to prevent the risk of acute or subacute thrombosis originating from the intima-media exposure of reticulocytes after atherectomy[15].

Statistical analysis

All the statistical analysis was performed with SPSS 18.0 software (Statistical Package for the Social Sciences Inc., Chicago, Ill, US). Data are expressed as mean ± SD for continuous variables and as counts for categorical variables. Categorical variables are presented as percentages. Comparisons of clinical, angiographic, and procedural characteristics were performed with the Fisher exact test for categorical variables and Mann–Whitney U-test for non-parametric continuous variables. Odds ratio and 95% confidence interval were calculated with univariate logistic regression. Variables with $p \leq 0.2$ in the univariate model or known to be significantly associated were entered into a multivariate logistic regression model. The target vessel revascularization, primary, and secondary patency rates during the follow-up were presented with Kaplan–Meier event-free survival curves. A value of $p < 0.05$ was described statistically significant.

Results

The features of patients and characteristics of the lesions are described in Table 1. A total of 228 BTK procedures were performed in 128 patients. The AT+DCB group consisted 50.7% (n = 65) of the interventions and 49.3% (n = 63) of the patients were treated only with DCB. Clinical characteristics of the patients were similar in both groups. An indication for the treatment of CLI was present in 74.2% (n = 95) of the patients.

The characteristics of the lesions such as the location and the morphology of the segments and the number of total chronic occlusions were similar in both groups. The pre-operative ABI and Rutherford classification data did not significantly differ between the two groups (p = 0.28). The mean lengths of the lesions were also similar (47.12 ± 24.03 mm in AT+DCB vs. 42.26 ± 26.5 mm in DCB, p = 0.47). Vessel calcifications (75.4% in AT+DCB vs. 69.1% in DCB) were comparable between two groups.

The location of the lesion was primarily the anterior tibial artery both in AT+DCB and DCB alone group (43.2%, n = 51 vs. 42.7%, n = 47). The mean time of inflation duration, length, and diameter of balloon angioplasty among two intervention groups were similar ([2.8±1.3 min vs. 3.1±1.5 min [p = 0.63], 3.2±0.9 mm vs. 3.4±1.1 mm [p = 0.33], and 12.3±8.2 cm vs. 11.9±6.7 cm (p = 0.47]). However, inflation pressures required for sufficient arterial patency were higher in DCB alone group (6.2±3.9 vs. 8.9±4.1 atmospheres [p = 0.001]).

Technical success rates were similar in the AT+DCB group (Fig. 1) and DCB alone group (98.4% vs. 96.8%, p = 0.228). The adverse events did not differ between two groups; however, bailout stenting was more common in the PTA alone group (DCB, 11.1% [n = 7] vs. AT+DCB, 1.5% [n = 1], p < 0.001) as a result of flow-limiting dissection. The periprocedural complications are presented in Table 2.

Table 1. Baseline characteristics and risk factors

Variables	Total (n = 128)	RA-DCB (n = 65)	DCB (n = 63)	p-value
Mean age, years	66.4 ± 10.7	68.6 ± 12.4	63.2 ± 11.3	0.528
Male, gender	67.1% (86/128)	67.6% (44/65)	67.8% (42/63)	0.423
Diabetes Mellitus	100% (128/128)	100% (65/65)	100% (63/63)	1.000
HbA1c (SD)	8.9 (1.6)	9.2 (1.3)	8.7 (1.8)	0.758
Hypertension	75.8% (97/128)	87.5% (48/65)	77.8% (49/63)	0.856
Hyperlipidemia	73.4% (94/128)	73.5% (49/65)	71.4% (45/63)	0.793
Smoking				
Current smoker	46.1% (59/128)	46.1% (30/65)	46.0% (29/63)	0.563
Past smoker	30.4% (39/128)	32.3% (21/65)	25.6% (18/63)	0.647
Never smoker	21.7% (30/128)	27.7% (18/65)	19.0% (12/63)	0.452
BMI (kg/m^2)	32.3 ± 6.7	32.7 ± 6.8	31.7 ± 6.4	0.482
CAD	71.1% (91/128)	78.5% (51/65)	63.4% (40/63)	0.453
History of stroke	10.1% (13/128)	12.3% (8/65)	7.9% (5/63)	0.352
History of MI	29.2% (19/128)	18.4% (12/65)	11.1% (9/63)	0.567
CHF	14.1% (18/128)	16.9% (11/65)	11.1% (7/63)	0.752
CABG or PCI	32.0% (41/128)	33.8% (22/65)	30.1% (19/63)	0.468
CRD	20.3% (26/128)	21.5% (14/65)	19% (12/63)	0.355
ESRD	21% (21/128)	20% (13/65)	12.6% (8/63)	0.582
COPD	28.2% (36/128)	32.3% (21/65)	23.8% (15/39)	0.498
Aspirin	94.45% (121/128)	95.3% (62/65)	93.6% (59/63)	0.454
Clopidogrel	96.1% (123/128)	96.9% (63/65)	95.2% (60/63)	0.328
Statin	85.9% (110/128)	83.1% (54/65)	88.8% (56/63)	0.256
Prior amputation	11.7% (15/128)	13.8% (9/65)	9.5% (6/63)	0.228

TLR at 6 months was not different in both groups (DCB, 6.3% [n = 4] vs. AT+DCB, 3.1% [n = 2], p = 0.224). However, it was more frequent in the DCB only group at 12 months follow-up (DCB, 17.4% [n = 11] vs. AT+DCB, 6.1% [n = 4], p = 0.001) and 24 months follow-up (DCB, 30.1% [n = 7] vs. AT+DCB, 10.7% [n = 7], p < 0.001) (Fig. 2). CD-TLR rate was detected significantly lower at 1 and 2 years with the use of AT+DCB when compared with DCB (6.1% vs. 17.4%; p < 0.001) in Kaplan-Meier analysis. The rate of CD-TLR decreased by 64% at 1 year and 65% in 2 years with AT+DCB when compared with DCB only group in the adjusted Cox proportional hazard model (HR 0.23, 95% CI 0.32-0.78; p < 0.01; HR 0.23, 95% CI 0.27-0.76; p < 0.01). The values are presented in Figure 2.

The minor amputation rates at 6-12- and 24-months follow-ups were lower in AT+DCB compared to DCB only group (3.1%, n = 2 vs. 9.5%, n = 6, p = 0.08; 6.1%, n = 4 vs. 12.6%, n = 8, p = 0.07; 7.6%, n = 5 vs. 15.8%, n = 10, p = 0.58), while the major amputation rates were similar between groups. At 6 months follow-up,

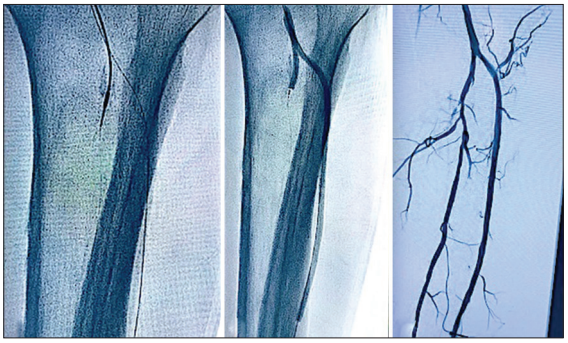

Figure 1. *Atherectomy followed by drug-coated balloon angioplasty.*

Table 2. Peri-procedural complications

Complication	RA + DCB	DCB only	p-value
Distal embolism (clinically significant)	1.5% (1/65)	9.5% (6/63)	0.05
Dissection-grade C/D or greater	1.5% (1/65)	11.1% (7/63)	< 0.001
Vessel recoil	1.5% (1/65)	4.7% (3/63)	< 0.001
Arterial perforation	1.5% (1/65)	3.1% (2/63)	0.638
Arteriovenous fistula	0	1.6% (1/63)	0.623
Pseudoaneursysm	0	0	1.000
Hematoma	3% (2/65)	3.1% (2/63)	0.476
Total number of events	5	18	< 0.001

there were two patients (3.1%) with below the knee + Syme amputations in DCB group and one patient (1.5%) with Syme amputation in RA+DCB (p = 0.57). At 12-month follow-up, three patients (4.7%) treated with DCB alone had above the knee amputation and two of the patients (3.1%) in AT+DCB group had Syme amputations (p = 0.64). At 24-month follow-up, four patients (6.3%) in DCB only group and two patients (3.1%) in AT+DCB group required below the knee amputations (p = 0.58) (Fig. 2). The all-cause mortality rates at 6, 12, and 24 months were also similar (Fig. 3). At 6-month follow-up, two patients (3.1%) in DCB alone group and one patient in (1.5%) AT+DCB group; at 12 months follow-up, three patients (4.7%) in DCB alone group and two patients (3.1%) in AT+DCB group; and at 24 months follow-up, four patients (6.3%) in DCB alone and two patients (3.1%) in AT+DCB group were deceased (p = 0.25; p = 0.23; p = 0.44). Finally, distal embolization rates were significantly lower in the AT+DCB group when compared with DCB only group (1.5%, n = 1 vs. 9.5%; n = 6, p = 0.05). The amputation free survival and all-cause mortality are presented in Figures 3 and 4.

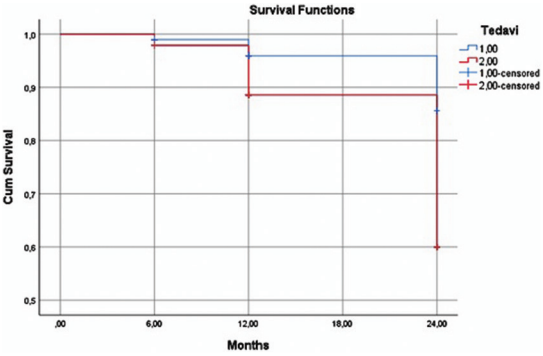

Figure 2. *Target lesion revascularization.*

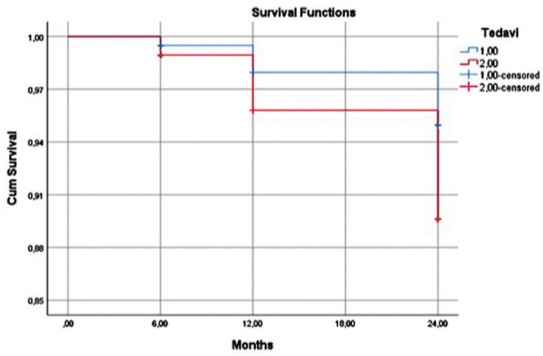

Figure 3. *Major amputation-free survival.*

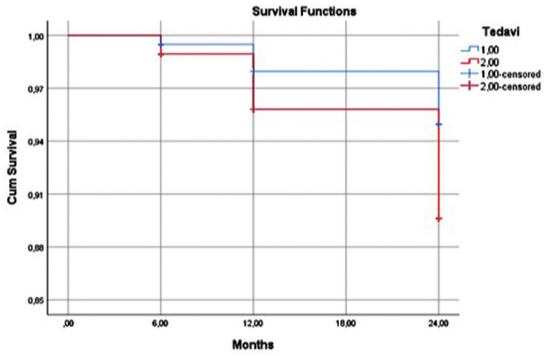

Figure 4. *All-cause mortality-free survival.*

Discussion

Patients with diabetes mellitus often experience atherosclerotic peripheral arterial lesions in the course of the disease. Advanced infra-popliteal atherosclerosis is associated with severe lower extremity ischemia[16]. The comorbidities such as older age, diabetes mellitus, and end-stage renal disease are associated with high risk of complex and highly calcified lesions which increase the risk of amputation and mortality. Even at a rate as high as 67% amputation is performed as an initial therapy without diagnostic angiography or further vascular interventions in this particular patient population with CLI[17].

Atherectomy has been shown to be a useful adjunctive therapy in the long term, especially in the long and calcified lesions. While directional atherectomy

devices are generally used in short or chronic totally occluded lesions, rotational atherectomy devices are more effective in long, highly calcified lesions. The improved luminal gain and decreased requirement for stenting are the main advantages of atherectomy when compared with PTA. These advantages allow inflation of the balloon at lower pressures providing lower dissection rates[18-20].

Atherectomy provides a reduction in plaque burden and facilitates PTA. Such an advantage has proven superior to PTA alone treatment in patients with CLI due to complex infra-popliteal diseases[21]. The patency rates and patient outcomes have been improved parallelly with increased clinical experience for the use of atherectomy as an alternative or additive technique for the treatment of PAD[22].

According to the randomized trial in 2005, amputation-free survival at 6 months was similar between the infra-inguinal saphenous vein bypass and PTA at the above-knee or below-knee segments (BASIL). Since then, endovascular interventions decreased morbidity, lowered the costs, and provided sufficient quality of life outcomes for the patients equal to the surgery[23].

The DEBATE-BTK trial included 132 diabetic patients with CLI. The study compared drug-eluting balloon (In. Pact Amphirion, Medtronic Cardiovascular) and PTA in 158 infra-popliteal lesions. The mean length of lesion was 129 ± 83 mm and this was longer than other randomized trials with drug-eluting stents for the treatment of the infra-popliteal lesions. The restenosis rate and target vessel occlusion were higher in PTA group at 1 year, and major adverse events were less often in the drug-eluting balloon group. However, amputation, limb salvage, and mortality rates were similar between the two groups[24].

In another study, the results of atherectomy were compared on patients with diabetes mellitus and non-diabetic patients with PAD. The TLR, amputation, or death rates were not significantly different between the groups. In addition, there was no statistically significant difference in the time to TLR, amputation or death in Kaplan–Mayer analysis in this particular research[25].

Stavroulakis et al.[25] compared drug-coated balloon angioplasty with directional atherectomy with anti-restenotic therapy in popliteal artery lesions. The freedom from TLR was similar between two groups (82% vs. 94%, p = 0.072), while the primary patency rates were found significantly higher in the DAART group (p = 0.021) at 12-month follow-up. Secondary patency rates were similar (96% vs. 96%) between two groups at 12 months. Bailout stenting was more often following DCB angioplasty (p = 0.13) and aneurysmal degeneration was more common after DAART (p = 0.25)[26].

In another recent meta-analysis, there was no significant benefit associated with single use of atherectomy compared to balloon angioplasty[27]. Atherectomy was typically used for highly calcified lesions that were challenging for stent or balloon expansion, or in the regions that are risky for stent fracture (common femoral and popliteal arteries). Despite more often occurrence of distal embolization in the registry data, it was found lower in the contemporary non-randomized DEFINITIVE-LE study[28]. Literature lacks information about the use of distal protection for atherectomy; however, it is generally applied in the existence of poor or single-vessel distal run-off[29].

Severity of illness, amputation level, gender, and comorbidities may influence the amputation rates. The amputation rates were higher in male and diabetic patients in the reported analysis and the procedure types (DCB or PTA alone vs. atherectomy-PTA or atherectomy-DCB) were not found superior to one another in terms of amputation rates in the multivariate analysis[30]. Among the included studies, all-cause mortality rates did not differ between both groups at 12 and 24 months. The patients with more advanced diseases had higher mortality rates[22,31].

In our study, although the major amputation rates were similar between two groups, minor amputation rates were lower in the AT+DCB group. CD-TLR rate was significantly lower in AT+DCB group and the rate of CD-TLR was decreased by 64% at 1-year and 65% at 2-year with AT+DCB when compared with DCB alone, in the adjusted Cox proportional hazard model. The all-cause mortality rates and adverse events did not differ significantly between two groups; however, bailout stenting and distal embolization rates were lower in AT+DCB group.

Conclusion

Combined usage of rotational atherectomy and drug-coated balloons reduce the long-term TLR rates and improve the long-term outcomes, especially in diabetic patients with heavily calcified below-the knee lesions and CLI.

Funding

The authors declare that no funding was received.

Conflicts of interest

The authors declare no conflicts of interest.

Ethical disclosures

Protection of human and animal subjects. The authors declare that no experiments were performed on humans or animals for this study.

Confidentiality of data. The authors declare that they have followed the protocols of their work center on the publication of patient data.

Right to privacy and informed consent. The authors have obtained the written informed consent of the patients or subjects mentioned in the article. The corresponding author is in possession of this document.

References

1. Fowkes FG, Rudan D, Rudan I, Aboyans V, Denenberg JO, McDermott MM, et al. Comparison of global estimates of prevalence and risk factors for peripheral artery disease in 2000 and 2010: a systematic review and analysis. Lancet. 2013;382:1329-40.
2. Stoyioglou A, Jaff MR. Medical treatment of peripheral arterial disease: a comprehensive review. J Vasc Interv Radiol. 2004;15:1197-207.
3. Abu Dabrh AM, Steffen MW, Undavalli C, Asi N, Wang Z, Elamin MB, et al. The natural history of untreated severe or critical limb ischemia. J Vasc Surg. 2015;62:1642-51.e3.
4. Egorova NN, Guillerme S, Gelijns A, Morrissey N, Dayal R, McKinsey JF, et al. An analysis of the outcomes of a decade of experience with lower extremity revascularization including limb salvage, lengths of stay, and safety. J Vasc Surg. 2010;51:878-85.e1.
5. Mustapha JA, Finton SM, Diaz-Sandoval LJ, Saab FA, Miller LE. Percutaneous transluminal angioplasty in patients with infrapopliteal arterial disease: systematic review and meta-analysis. Circ Cardiovasc Interv. 2016;9:e003468.
6. Rocha-Singh KJ, Zeller T, Jaff MR. Peripheral arterial calcification: prevalence, mechanism, detection, and clinical implications. Catheter Cardiovasc Interv. 2014;83:E212-20.
7. Razavi MK, Mustapha JA, Miller LE. Contemporary systematic review and meta-analysis of early outcomes with percutaneous treatment for infrapopliteal atherosclerotic disease. J Vasc Interv Radiol. 2014;25:1489-96.e1-3.
8. Kuntz RE, Safian RD, Carrozza JP, Fishman RF, Mansour M, Baim DS. The importance of acute luminal diameter in determining restenosis after coronary atherectomy or stenting. Circulation. 1992;86:1827-35.
9. Criqui MH. Peripheral arterial disease--epidemiological aspects. Vasc Med. 2001;6:3-7.
10. O'Hare AM, Glidden DV, Fox CS, Hsu CY. High prevalence of peripheral arterial disease in persons with renal insufficiency: results from the National Health and Nutrition Examination Survey 1999-2000. Circulation. 2004;109:320-3.
11. Conrad MF, Kang J, Cambria RP, Brewster DC, Watkins MT, Kwolek CJ, et al. Infrapopliteal balloon angioplasty for the treatment of chronic occlusive disease. J Vasc Surg. 2009;50:799-805.e4.
12. Criado FJ. Below-the-knee Intervention: promises and Reality. Vascular Disease Management. Vol. 3. 2006. Available from: http://www.vasculardiseasemanagement.com/content/below-knee-intervention-promises-and-reality [Last accessed on 2018 Feb 05].
13. Arora N, Garcia LA. Treating infrapopliteal PAD in CLI patients. Endovasc Today. [cited January 18th, 2022] Available from: https://evtoday.com/articles/2010-sept/treating-infrapopliteal-pad-in-cli-patients
14. Writing Committee Members, Gerhard-Herman MD, Gornik HL, Barshes NR, Corriere MA, Drachman DE, Fleisher LA, et al. 2016 AHA/ACC guideline on the management of patients with lower extremity peripheral artery disease: executive summary. Vasc Med. 2017;22:NP1-43.
15. Mishkel G, Goswami NJ. A practical approach to endovascular therapy for infrapopliteal disease and the treatment of critical leg ischemia: savage or salvage angioplasty? J Invasive Cardiol. 2005;17:45-51.
16. Mustapha JA, Igyarto Z, O'Connor D, Armstrong EJ, Iorio AR, Driver VR, et al. One-year outcomes of peripheral endovascular device intervention in critical limb ischemia patients: sub-analysis of the LIBERTY 360 study. Vasc Health Risk Manag. 2020;16:57-66.
17. Mustapha JA, Fisher BT Sr., Rizzo JA, Chen J, Martinsen BJ, Kotlarz H, et al. Explaining racial disparities in amputation rates for the treatment of peripheral artery disease (PAD) using decomposition methods. J Racial Ethn Health Disparities. 2017;4:784-95.
18. Shammas NW, Coiner D, Shammas GA, Dippel EJ, Christensen L, Jerin M. Percutaneous lower-extremity arterial interventions with primary balloon angioplasty versus Silverhawk atherectomy and adjunctive balloon angioplasty: randomized trial. J Vasc Interv Radiol. 2011;22:1223-8.
19. Dattilo R, Himmelstein SI, Cuff RF. The COMPLIANCE 360 degrees trial: a randomized, prospective, multicenter, pilot study comparing acute and long-term results of orbital atherectomy to balloon angioplasty for calcified femoropopliteal disease. J Invasive Cardiol. 2014;26:355-60.
20. Adam DJ, Beard JD, Cleveland T, Bell J, Bradbury AW, Forbes JF, et al. Bypass versus angioplasty in severe ischaemia of the leg (BASIL): multicentre, randomised controlled trial. Lancet 2005;366:1925-34.
21. Rundback JH, Herman KC. Optimal use of atherectomy in critical limb ischemia. Tech Vasc Interv Radiol. 2014;17:211-8.
22. Todd KE Jr., Ahanchi SS, Maurer CA, Kim JH, Chipman CR, Panneton JM. Atherectomy offers no benefits over balloon angioplasty in tibial interventions for critical limb ischemia. J Vasc Surg. 2013;58:941-8.
23. Liistro F, Porto I, Angioli P, Grotti S, Ricci L, Ducci K, et al. Drug-eluting balloon in peripheral intervention for below the knee angioplasty evaluation (DEBATE-BTK): a randomized trial in diabetic patients with critical limb ischemia. Circulation. 2013;128:615-21.
24. Zeller T, Baumgartner I, Scheinert D, Brodmann M, Bosiers M, Micari A, et al. Drug-eluting balloon versus standard balloon angioplasty for infrapopliteal arterial revascularization in critical limb ischemia: 12-month results from the IN.PACT DEEP randomized trial. J Am Coll Cardiol. 2014;64:1568-76.
25. Stavroulakis K, Schwindt A, Torsello G, Stachmann A, Hericks C, Bosiers MJ, et al. Directional atherectomy with antirestenotic therapy vs drug-coated balloon angioplasty alone for isolated popliteal artery lesions. J Endovasc Ther. 2017;24:181-8.
26. Janas AJ, Milewski KP, Buszman PP, Trendel W, Kolarczyk-Haczyk A, Hochuł M, et al. Long term outcomes in diabetic patients treated with atherectomy for peripheral artery disease. Cardiol J. 2020;27:600-7.
27. Ambler GK, Radwan R, Hayes PD, Twine CP. Atherectomy for peripheral arterial disease. Cochrane Database Syst Rev. 2014;3:CD006680.
28. McKinsey JF, Zeller T, Rocha-Singh KJ, Jaff MR, Garcia LA, DEFINITIVE LE Investigators. Lower extremity revascularization using directional atherectomy: 12-month prospective results of the DEFINITIVE LE study. JACC Cardiovasc Interv. 2014;7:923-33.
29. Shammas NW, Dippel EJ, Coiner D, Shammas GA, Jerin M, Kumar A. Preventing lower extremity distal embolization using embolic filter protection: results of the PROTECT registry. J Endovasc Ther. 2008;15:270-6.
30. Reynolds S, Galiñanes EL, Dombrovskiy VY, Vogel TR. Longitudinal outcomes after tibioperoneal angioplasty alone compared to tibial stenting and atherectomy for critical limb ischemia. Vasc Endovasc Surg. 2013;47:507-12.
31. Zeller T, Sixt S, Schwarzwälder U, Schwarz T, Frank U, Bürgelin K, et al. Two-year results after directional atherectomy of infrapopliteal arteries with the SilverHawk device. J Endovasc Ther. 2007;14:232-40.