Short-term outcome of management of isolated complex infrapopliteal disease in critical limb ischemia with drug-coated balloon

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Background
However, endovascular intervention provided a great advance in management of peripheral arterial disease, tibial-occlusive disease, especially the complex one, remains a challenging issue regarding not only the management but also the end results even with technical success. In this study, we try to review the outcome of management of cases with complex infrapopliteal disease with drug-coated balloon in patients presented with critical limb ischemia (CLI).
Patients and methods
This is a prospective study of over 50 patients with 50 CLI and isolated tibial-occlusive disease that were managed with angioplasty-first approach with drug-coated balloon in East Jeddah Hospital (Saudi Arabia) in the period from May 2017 to May 2019, with follow-up over 12 months.
Results
The study included 50 patients with a mean age of 64 years and male-to-female ratio 4 : 1, presented with 50 CLI. All patients were classified according to Rutherford classification between category 4 and 6, all lesions were class C and D according to the Inter-Society Consensus for the Management of Peripheral Arterial Disease (TASC II). Technical success was accomplished in 40 (80%) limbs, 18 (36%) limbs showed clinical improvement without amputations, 16 (32%) limbs required minor foot amputation, 16 (32%) limbs ended by major amputation, and two cases required distal bypass (popliteal tibial bypass) after failure of the angioplasty-first approach. As regards complications, one case developed acute myocardial infarction after amputation and died in the ICU, five patients developed groin hematoma that was managed conservatively, and primary patency was 100% after 3 months, 86% after 6 months, and dropped to 76% after 12 months for patients with successful revascularization.
Conclusion
Management of complex infrapopliteal disease in CLI is still challenging with an unfavorable outcome. However, using drug-coated balloon in such cases improved the patency rate.

Keywords:
drug-coated balloon, isolated infrapopliteal disease, tibial TASC II C, tibial TASC II D

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Introduction

Critical limb ischemia (CLI) is a dangerous presentation of peripheral arterial disease (PAD), with high risk of major limb amputation representing less than 10% [1].

Tibial revascularization is almost indicated for patients with multivessel tibial lesion, as single-vessel tibial disease is not expected to cause critical limb symptoms [1].

Complexity of the tibial disease is classified according to the recently added TASC infrapopliteal classification illustrated in Fig. 1 [3].

Endovascular tibial revascularization has been utilized since the 1990s [4]. Since publication of BASIL in 2005 [5], 'endovascular-first' approach is the principle that was utilized in tibial vascularization [2].

With the exception of BASIL trial, still there is no clear data comparing open versus endovascular strategies for several key outcomes in patients with CLI [3].

Hybrid approach may suggest better results with lower complications [6].

Not only the complexity of the arterial disease determines the outcome of CLI, but patient clinical

stage, limb hemodynamics, and wound infection are also important factors [3].

Patients and methods

Patients

This is a prospective study over 50 patients with 50 CLI and isolated tibial-occlusive disease that were managed with angioplasty-first approach in East Jeddah Hospital in the period from May 2017 to May 2019, with follow-up over 12 months.

Approval from ethical committee was obtained, and all patients were consented for interventions and possible risks.

Only patients presented by CLI with isolated infrapopliteal disease were included, however, those with intermittent claudication and those with femopliteal or iliac lesions, or acute ischemia, were not involved in this study.

Preoperative evaluation

All patients were exposed for full clinical, laboratory, and cardiological assessment prior to intervention.

As regards to medical history, all patients were diabetic, 34 patients were hypertensive, and 40 patients were heavy smokers, four patients were end-stage renal disease on regular dialysis.

Clinically, all patients were conscious, alert, mobile with good cognitive functions, and classified between class 4 and class 6 according to Rutherford classification, all patients presented with palpable popliteal pulse and no pedal pulses.

Laboratory assessment involved complete blood picture, liver and renal function and coagulation profile, and all results were favorable.

Cardiological assessment involved referral to the cardiology specialist with performance of ECG and echocardiogram to ensure good cardiac condition.

Diabetes and hypertension were controlled by medical referral.

Operative technique

All patients proceeded for conventional angiogram directly without further preoperative contrast-mediated radiological assessment aiming to decrease the volume of administrated contrast.

Ipsilateral antegrade femoral access with 6-Fr sheath was used for all patients, in addition, retrograde tibial access was used in five procedures with 5-Fr sheath.

After initial diagnostic angiogram, the lesions were classified according to TASC II, and all cases were between class C and D (Fig. 1).

Only patients with runoff to the foot were attempted for revascularization.

Patients that were decided for revascularization, received 5000 IU of heparin thought the sheath initially.

Crossing of the lesion in the target artery was attempted by 0.018- or 0.014-inch wires aided with crossing the catheter (CXI catheter 2.6 Fr), crossing the planter arch was attempted in all cases.

All lesions that crossed transluminally then opened with paclitaxel drug-coated balloon (lutonix balloon of Bard) with diameter ranging between 2.5 and 3 mm and long length ranging between 100 and 120 mm with inflation time of 2–3 min.

Completion angiography at the end of the procedures to ensure success of the angioplasty together with pulse assessment.

Postprocedure period: the patients continued on dual antiplatelets (clopidogrel and low-dose aspirin) for 6 months and then continued on aspirin only with statins.

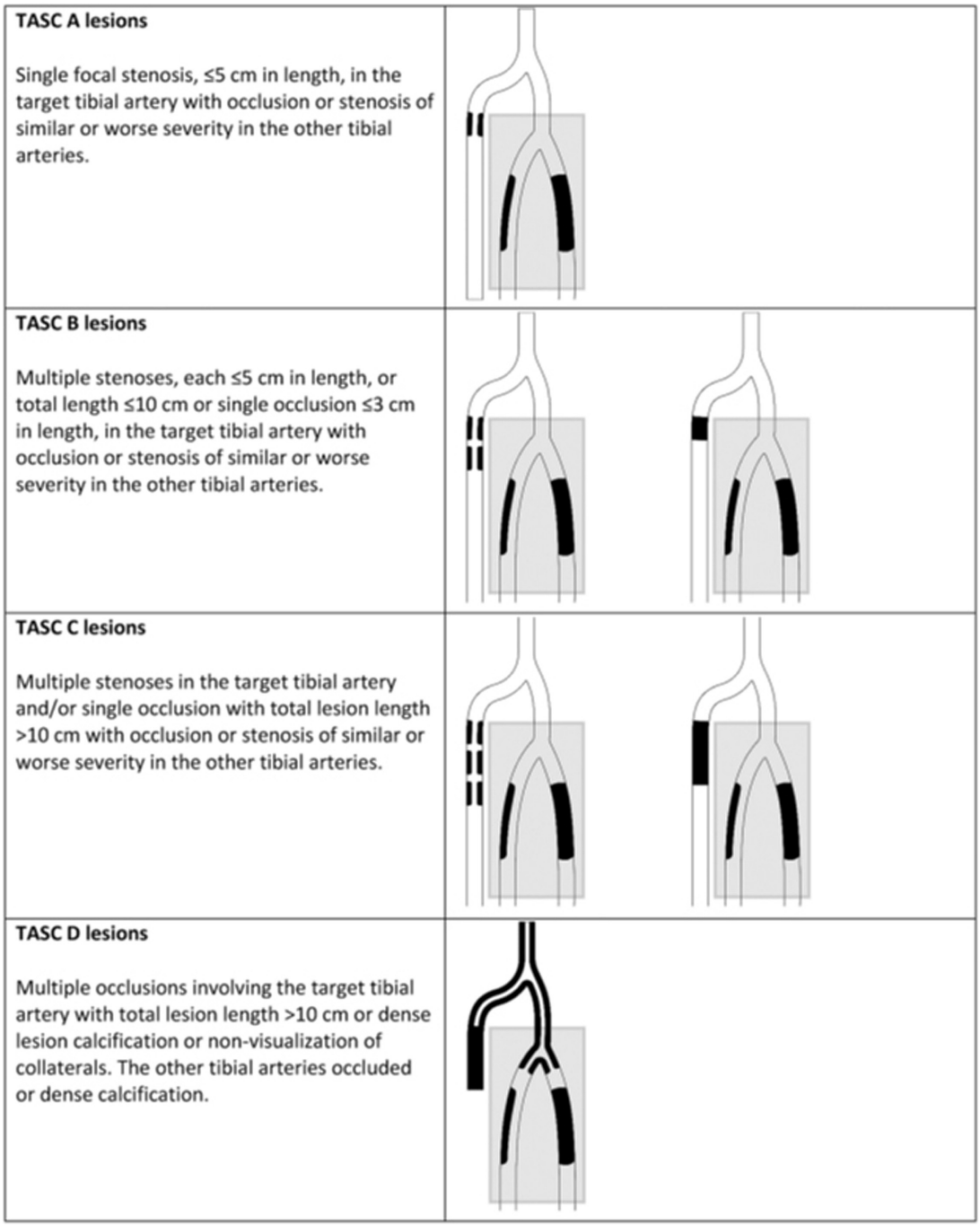
Cases that showed no runoff on catheter-directed angiography proceeded to below-knee amputation (BKA), in two cases, we failed to cross the lesion even after trying posterior tibial artery retrograde access and were managed by popliteoposterior tibial bypass with synthetic tapered graft 7–4 mm (polytetrafloroethylene (PTFE) heparin-coated GORE graft) through medial approach and were discharged after one week on dual antiplatelets for 6 months and then continued on aspirin only.

Patients with infected wounds were managed with wound debridement within 3 days after revascularization.

Follow-up

Revascularized cases were followed up every 3 months for 1 year and were examined clinically for pedal pulses and wound healing.

Figure 1



TASC II classification of infrapopliteal disease [2].

Results

The study included 50 patients with a mean age of 64 years and male-to-female ratio 4 : 1. They presented with 50 CLI.

All limbs were classified according to Rutherford classification between category 4 (eight limbs with rest pain), category 5 (10 limbs with nonhealing ulcer), and category 6 (32 limbs with gangrene), all lesions were class C and D according to the Inter-Society Consensus for the Management of Peripheral Arterial Disease (TASC II).

After diagnostic angiography, eight limbs showed infrapopliteal disease with no runoff, Rutherford category 6 with extensive tissue loss of foot, and were managed with BKA, representing failed revascularization in 16% of cases.

In the remaining patients, technical success was accomplished in 40 (80%) limbs, 32 cases through

antegrade femoral access and eight cases through combined femoral and retrograde pedal access, with failed crossing the lesion in two patients (category 4) that were managed with popliteoposterior tibial bypass with synthetic PTFE-tapered graft, with all successful revascularization in 42 (84%) limbs.

Follow-up

Category 4: eight (16%) limbs with rest pain improved immediately after revascularization.

Category 5: 10 (20%) limbs with nonhealing ulcers showed complete healing over a period between 2 and 6 months.

Category 6: eight (16%) limbs with no runoff were managed with primary BKA, 16 (32%) limbs required minor foot amputation ranging between toes and forefoot amputation and showed complete wound healing over 6 months, while eight (16%) limbs ended by BKA after 3 months, despite continued palpable pedal pulses as the following: three patients had full-thickness heel gangrene, two patients had resistant foot infection not responding to antimicrobial treatment and repeated debridement, and three patients showed repeated dry gangrene of foot stump after repeated foot amputation.

As regards complications, one case developed acute myocardial infarction after amputation and died in the ICU, five patients developed groin hematoma that was managed conservatively.

Endpoints

Primary patency for revascularized cases was 100% after 3 months and dropped to 86% after 6 months and to 76% after 12 months without clinical worsening in cases with disappearing pulse.

Clinical improvement without amputation was obtained in 18 (36%) limbs, limb-saving amputation obtained in 16 (32%) limbs, and major amputation occurred in 16 (32%, eight primary and eight secondary) limbs.

Mortality rate: one (2%) case.

Discussion

CLI is the worst clinical presentation of PAD with a high incidence of morbidity and mortality owing to associated cardiovascular events and functional impairment caused by limb amputation, especially with infrapopliteal disease with mortality and amputation rates of 20 and 25%, respectively, at 1 year [7].

From our point of view, this unfavorable outcome is owing to the smaller diameter of infrapopliteal vessels, multiple-vessel affection, heavy calcification, and paucity of below-knee collateral sets with poor runoff to the foot together with associated comorbidities of the patients like diabetes and ischemic heart disease, making the treatment of such cases difficult with poor outcome.

With advancement of angioplasty procedures, management of infrapopliteal disease became easier with lower morbidities, even with lower patency rate, but with improved survival rate and nearly equal limb-salvage rate compared with bypass procedures, making surgery the next option of intervention when failed angioplasty [8].

In our study, we consider improved primary patency to 76% at 1 year compared with 58% mentioned by Romiti *et al.* [8], and 35% by Söderström *et al.* [9], owing to the usage of drug-coated balloons in all cases. However, there is still no enough literatures about the significance of drug-coated balloon, but our results agreed with the results of DEBELLUM [10] and DEBATE-BTK [11] trials, while did not agree with that of In Pact Deep CLI trial [12] regarding the primary patency that also used drug-coated balloons in their studies.

Lower mortality rate owed to the simplicity of the procedure with lower stress exposure and lower complications coincidental with the results of BASIL in which the mortality rate in the PTA arm was 3% compared with 5.5% to the surgical arm [5].

Lower technical success rate of 80% (despite the usage of low-profile wires 0.014 and 0.018 with crossing CXI catheter that facilitated crossing the long lesions) and lower-limb saving rate of 68% compared with 86% reported by Romiti *et al.* [8], is mainly referred to the complexity of the lesion in our cases, as all cases were TASC C, D in addition to the late clinical presentation, as 32 (64%) limbs were category 6 of Rutherford classification, with extensive tissue loss in some cases like heel gangrene or resistant foot infection, in spite of successful revascularization.

In three patients even after successful revascularization with intact pedal pulse, foot gangrene continued to spread after every debridement or amputation till ended by BKA, we supposed that is due to impaired

microvasculature like Li and Partovi [13] who concluded in their literature that the microvascular disease has a great contribution in the pathogenies of PAD, and greatly affects treatment outcome.

Last, we consider that our results are acceptable, especially when managing complex anatomic lesions with advanced CLI that are not uncommonly present in patients with isolated complex infrapopliteal disease.

Conclusion

Management of complex infrapopliteal disease in CLI is still challenging with an unfavorable outcome. However, using drug-coated balloon in such cases improved the patency rate.

Even after successful revascularization, microvascular circulation remains an obstacle that may worsen the end outcome of CLI.

Infrapopliteal treatment with drug-coated balloon still needs more assessment, especially in comparison with conventional PTA and drug-eluting stents.

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Conflicts of interest

There are no conflicts of interest.

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