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Dual Vascular Access for Critical Limb Ischemia: Immediate and follow-up results

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Purpose: To describe a procedural technique involving a combined antegrade femoral and retrograde tibial approach for treatment of complex popliteal and infrapopliteal occlusions, and to determine the safety and efficacy of this technique. Materials and Methods: From May 2008 to March 2010, seven patients presenting with critical limb ischemia received dual vascular access intervention in this institution. Five legs were treated via the retrograde tibial approach after failure of antegrade intervention. A dual access approach was planned and adopted in another two legs. The target vessels were located at popliteal or infrapopliteal arteries. Results: We successfully gained all retrograde tibial access sites and achieved 100% procedural success and immediate hemodynamic improvement. Five legs required stent implantation to optimize the procedural results. No major complication occurred at the tibial access site. During the follow-up period (11.3 ± 7.2, range 3–23 months), no patients required any major amputation; only one patient underwent a mid-foot amputation. The target vessel revascularization rate at 3 and 6 months was 0 and 28.6%, respectively. Conclusion: Dual vascular access was successfully used in a small number of selected patients and this technique may hold promise in improving the success rates in the treatment of complex popliteal and infrapopliteal occlusions.

Key words: critical limb ischemia; antegrade and retrograde revascularization; transtibial access

INTRODUCTION

Critical limb ischemia (CLI) remains a major socioeconomic problem despite advances in medical and interventional management. Patients with CLI are usually elderly, chronically debilitated, and have multiple comorbidities; this makes them poor candidates for crual or pedal bypass surgery. Limb salvage and avoidance of amputation is the treatment goal. Longer survival and better quality of life are achieved in CLI patients who undergo revascularization than in amputees [1]. Although there has been progress in intervention treatment, failure rates ranging from 20 to 40% have been noted with recanalization for infrapopliteal occlusion [2–4] via either the crossover or ipsilateral antegrade femoral approach. Few reports exist on intervention via the retrograde pedal or tibial approach for below-the-knee (BTK) occlusions [5–8]; however, there is a lack of follow-up reports. In this article, we reported the immediate and follow-up results of dual vascular access intervention for complex popliteal and infrapopliteal occlusions.

MATERIALS AND METHODS

From May 2008 to March 2010, seven patients presenting with critical limb ischemia received dual vascular access intervention in this institution. The clinical presentations in these patients were as follows: two, rest pains; three, ulcers; and two, gangrene. Computed tomographic angiography (CTA) was performed for all patients for procedural planning. A retrograde approach was adopted to obtain transtibial access if any evidence of distal reconstruction of the anterior tibial artery (ATA) or posterior tibial artery (PTA) was noted on CTA or conventional angiography. Patients without

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Conflicts of interest: Nothing to declare.

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visible pedal vessels were not eligible for treatment via this technique.

Hemodynamic Evaluation

Ankle brachial pressure index (ABI) and duplex ultrasonography (DUS) measurements were obtained before intervention. The size and depth of distal tibial vessels were assessed before and during the intervention. Doppler spectral waveforms and peak systolic velocity (PSV) were also measured in each arterial segment after angioplasty. Postprocedural hemodynamic assessment was conducted 1 week, 1 month, and then every 3 months after the index intervention.

Angiographic Evaluation

Angiograms were acquired in at least two orthogonal views at baseline and after the final intervention. A radiopaque ruler was used for calibration of angiographic measurements. Target lesion length, target lesion minimum lumen diameter (MLD), and mean proximal and distal reference vessel diameter (RVD) were measured at baseline and after the final intervention. The percent diameter stenosis (%DS) was calculated [%DS = (1 − MLD/RVD) × 100] at baseline and after the final intervention. In addition to quantitative measurement of the treatment site, the distal run-off vessels were assessed on the completion of angiograms to evaluate the evidence of distal embolization.

Interventions

The interventional procedure was conducted via the ipsilateral antegrade femoral approach. All patients received 100 mg aspirin and 75 mg clopidogrel per day, 3 days before the intervention. Aspirin was administered continuously after the intervention and clopidogrel was used for 3 months if the bare-metal stent (BMS) was implanted or 12 months if the drug-eluting stent (DES) was implanted. Unfractionated heparin (5,000–10,000 U) was administered during the endovascular procedure to maintain the activated coagulation time ≥250 sec. A retrograde tibial access was adopted after failure of antegrade recanalization (Fig. 1) or a dual vascular access was planned after diagnostic angiography. The selected vessel was punctured under road mapping or DUS guidance with a 20-G radial needle (Merit Medical, UT), the 0.025-in wire was inserted through the needle over which the 4-French (F) or 5-F introducer sheath (Radifocus Introducer II; Terumo, Tokyo, Japan) was positioned. After gaining the tibial access, a routine 200 μg of nitroglycerin was administrated via retrograde sheath to prevent vasospasm. The initial guidewire using in retrograde intervention was a 300-cm long 0.014-in. hydrophilic guidewire (PT2, Boston Scientific, Natick, MA) that was supported by a 0.014-in. over-the-wire (OTW) coronary balloon (Maverick 2, Boston Scientific, Natick, MA or Ryujin plus, Terumo, Tokyo, Japan). If the crossing of occlusion failed, we used a wire for coronary chronic total occlusion (CTO), such as Miracle 6 or 12 g or Conquest pro (Asahi Intec, Aichi, Japan) via the OTW balloon catheter. Once the wire crossed the occluded segment, the retrograde wire and balloon catheter were guided into the distal tip of the antegrade multipurpose catheter (Fig. 2). Therefore, they were pushed out of the introducer port of the sheath. To rearrange the antegrade position, the retrograde balloon catheter was withdrawn from the distal tibial artery and reinserted over the antegrade introducer distal to the target lesion. The guidewire was reinserted into the distal foot area and a 0.018-in. low-profile long balloon (Submarine plus or Pacific Extreme, Invatec, Roncadelle, Italy) was pushed forward from the femoral access site to the target lesion with balloon inflation up to 3–5 min. Stenting was adopted for flow-limiting dissection or residual stenosis ≥30% after balloon angioplasty. The distal introducer sheath was removed first after completion of the procedure, and hemostasis was maintained at the tibial puncture site by gently manual compression. The patency of the vessel located distal to the tibial access site was checked by physical examination, DUS, and final angiography after the procedure. Finally, antegrade sheath was removed if the tibial access site was patent.

Definitions

Procedural success was defined as <30% residual stenosis after intervention and successful recanalization at least one of tibioperoneal vessels to the distal pedal arch. Immediate hemodynamic success was defined as a >0.2 improvement in the preprocedural ABIs immediately after the procedure (at discharge). Chronic renal failure was defined as a serum creatinine level of >1.5 mg dl^{-1} or if the patients received regular dialysis due to end-stage renal disease. Restenosis was defined as PSV ratio of the stenotic area to the adjacent normal artery ≥2.5 by DUS. Target vessel revascularization was defined as any repeat percutaneous intervention of the target vessel because of clinical recurrence of ischemic symptoms, decrease in ABI of >0.2, and DUS-

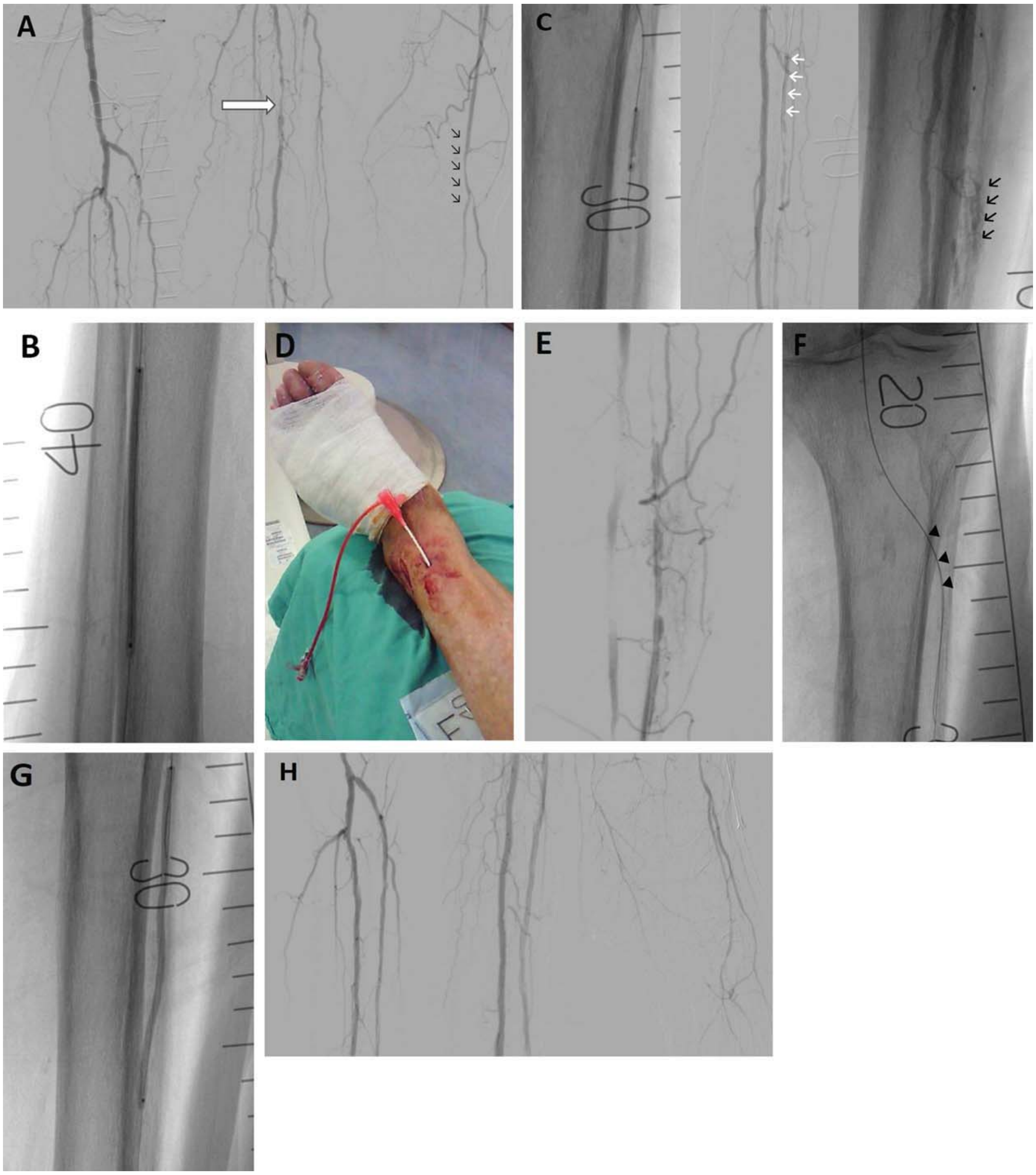

Fig. 1. **(A) The baseline angiogram revealed an occluded anterior tibial artery (ATA) and posterior tibial artery (PTA) and segmental stenosis at the peroneal artery (open arrows) with collateral filling of distal ATA (closed arrows). (B) Balloon angioplasty for peroneal artery stenosis. (C) Antegrade approach for occluded ATA with the over-the-wire (OTW) balloon and Miracle coronary wire (white arrows) with vessel perforation (black arrows). (D) Puncture of ATA under fluoroscope guidance with insertion of 4-French (F) introducer sheath. (E) Cineangiogram from distal introducer sheath. (F) Retrograde PT2 guidewire (arrowheads) crossed the occlusion and advanced into the proximal popliteal artery. (G) A 0.018-long balloon dilatation via retrograde approach. (H) After balloon angioplasty, no significant residual stenosis was noted and good distal run-off vessels were observed.**

detected restenosis. Major adverse events were defined as death, myocardial infarction, unplanned tibial/pedal bypass, contrast-induced nephropathy requiring dialysis, compartment syndrome requiring fasciotomy, and minor complications were defined as vessel perforation caused by the guidewire and access site hematoma.

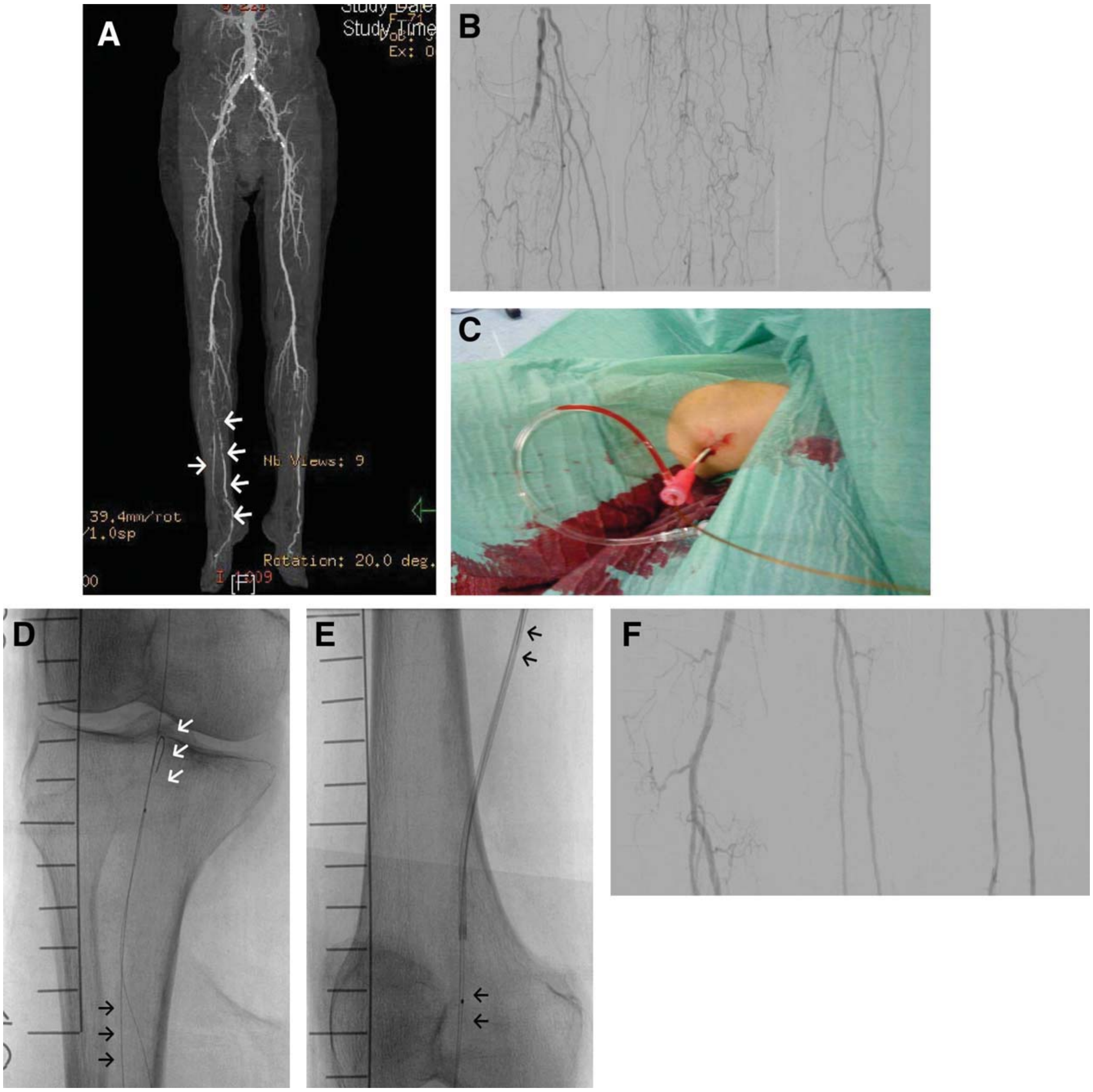

Fig. 2. (A) Computed tomographic angiography (CTA) of the lower extremity showing the occluded distal popliteal artery with collaterals to the distal posterior tibial and peroneal artery of the right leg (white arrows). (B) CTA was consistent with the baseline angiography and showed refilling of the distal PTA and peroneal artery via collaterals. (C) Retrograde access punctures of the distal PTA. (D) After crossing the occlusion, the antegrade guidewire (black arrows) was pushed forward into the peroneal artery and the retrograde wire, into the popliteal artery (white arrows). (E) The retrograde wire and supported OTW balloon were guided into the tip of the antegrade multipurpose guiding catheter (arrows). (F) Lack of flow-limiting dissection and restoration of blood flow in the PTA and peroneal artery after intervention.

RESULTS

Baseline Demographics

The study population consisted of three male and four female patients with a mean age of 74 $\pm$ 9 years. All patients suffered from diabetic foot and more than half of the study population had hypertension, coronary artery disease, and end-stage renal disease under regular dialysis. Only two patients were active smokers or ex-smokers. The clinical presentations of critical limb ischemia were rest pain (two patients), ulcers (three patients), and gangrene (two patients). The ABI of the target limb and contralateral limb were 0.43 $\pm$ 0.07 and 0.78 $\pm$ 0.13, respectively. All infrapopliteal arteries were occluded at the proximal end with collaterals filling into distal tibial artery in four of seven limbs. (Table I).

TABLE I. Patient Demographic Characteristics

Patient number: 7
Sex
Male, 3 (33%),
Female, 4 (67%)
Age: 74 ± 9 (range, 57–83)
Underlying medical comorbidities
Diabetes mellitus: 7 (100%)
Hypertension: 6 (86%)
Coronary artery disease: 4 (57%)
Chronic renal failure or ESRD: 5 (71%)
Smoking: 2 (29%)
Clinical presentations
Rest pain: 2 (29%)
Ulcer: 3 (42%)
Gangrene: 2 (29%)
Target limb ABI: 0.43 ±0.07
Contralateral limb ABI: 0.78 ±0.13
Run-off vessel: 0 vessel, 4 (57.1%)
1 vessel, 2 (28.6%)
3 vessels, 1 (14.3%)

Abbreviations: ESRD, end stage renal disease; ABI, Ankle brachial pressure index.

TABLE II. Preprocedural Results and Lesion Characteristics

Antegrade failure followed by a retrograde approach: 5
Planned double access approach: 2
Target vessel
3 anterior tibial arteries
2 popliteal arteries
1 tibioperoneal trunk
1 posterior tibial artery
Introducer Sheath: 4-F sheath, 6; 5-F sheath, 1
Puncture site success: 100%
Before intervention
Proximal reference vessel diameter (mm): 3.31 ± 1.27
Distal puncture site vessel diameter (mm): 2.86 ± 0.49
Diameter stenosis (%): 100%
Minimal lumen diameter (mm): 0
Occluded lesion length (cm): 11.8 ± 5.2

Abbreviation: F, French.

Procedural Results

Retrograde tibial intervention was adopted after the failure of five antegrade attempts, and dual access intervention was adopted in two cases. Six 4-F and one 5-F introducer sheaths were inserted into tibial access site after successful puncture. The target vessels were three ATA, two popliteal arteries (one in the proximal part and the other in distal part), one PTA, and one tibioperoneal trunk (TPT). All occluded vessel segments were successfully recanalized via dual access intervention. The mean occluded length was 11.8 ± 5.2 cm (5.6–18.3 cm). The %DS was reduced to 16.5% and the minimum lumen diameter increased to 2.85 ± 1.05 mm after endovascular intervention. Before treatment, the proximal and distal vessel diameters were 3.31 ± 1.27 mm and 2.86 ±0.49 mm, respectively, which were not significantly different from the proximal and distal vessel diameters postintervention (3.34 ± 1.20 mm and 2.88 ± 0.52 mm, respectively). Adjuvant stents were implanted in the case of five of seven endovascular treatments owing to suboptimal result. Two overlapping *X*pert nitinol stents (Abbott Vascular, Beringen, Switzerland) were implanted from distal superficial femoral artery to the proximal popliteal artery, two overlapping coronary DES (Endeavor Resolute, Medtronic, Minneapolis, MN) in the proximal PTA, one coronary DES (Cypher, Cordis, USA) in TPT, one Chromis deep stent (Invatec) in the middle ATA, and one Multilink (Abbott Vascular, Santa Clara, LA) in the proximal-middle ATA. Endovascular treatment resulted in 100% procedural success and immediate hemodynamic improvement. No patients suffered from any major complication during or after the intervention. One patient developed a hematoma at the distal puncture site because of the first attempted puncture into the posterior tibial vein, and there was oozing noted from the puncture hole. The hematoma resolved 1 week later by use of an elastic bandage along with leg elevation. The mean ABI increased to 0.88 ± 0.09 after the intervention (Tables II and III).

During a follow-up period of 11.3 ± 7.2 months, none of the patients required major amputation. Only one patient received a mid-foot amputation owing to persistent wound infection despite successful revascularization. The ABI at 1, 3, and 6 months after endovascular intervention was 0.97 ± 0.05, 0.92 ± 0.17, and 0.9 ± 0.23. The restenosis rates of the target lesion were 14.3 and 42.8% at 3 and 6 months, respectively, as determined with DUS. A lack of complete wound healing was noted in two limbs, and restenosis developed during follow-up. In one case, high-grade restenosis developed at the previous proximal ATA angioplasty site; in the

TABLE III. Postprocedural Lesion Characteristics and Immediate Treatment Effectiveness

After intervention
Proximal reference vessel diameter (mm): 3.34 ± 1.20
Distal puncture site vessel diameter (mm) 2.88 ± 0.52
Diameter stenosis (%): 16.5 ± 4.3
Minimal lumen diameter (mm): 2.85 ± 1.05
Adjunctive stenting: 5/7 (50%)
2 Nitinol stents in popliteal artery
2 Coronary drug eluting stents in proximal PTA
1 Cobalt-Chromium stent in middle ATA
1 Coronary drug eluting stent in TPT
1 Bare-metal coronary stent in ATA
Procedural success: 100%
Immediate hemodynamic success: 100%
Distal puncture complications: 1
Ankle brachial index: 0.88 ± 0.09

Abbreviations: ATA, anterior tibial artery; PTA, posterior tibial artery; TPT, tibioperoneal trunk.

TABLE IV. Follow-Up Results

Mean follow-up time: 11.3 ± 7.2, range 3–23 months
Major amputations: 0
Minor amputations: 1 (mid-foot)
ABI after intervention:
1 month: 0.97 ± 0.05
3 months: 0.92 ± 0.17
6 months: 0.9 ± 0.23
DUS-detected restenosis (PSV ratio >2.5)
3 months: 1/7 (14.3%),
6 months: 3/7 (42.9%)
Target vessel revascularization
3 months: 0
6 months: 2/7 (28.6%)

Abbreviations: PSV, peak systolic velocity; ABI, Ankle brachial pressure index; DUS, Duplex ultrasonography.

other case, reocclusion from proximal ATA stented site to middle ATA was noted. A new DES Xience V (Abbott Vascular, Santa Clara, LA) was implanted in this restenosis segment and plain old balloon angioplasty (POBA) was adopted for another long reoccluded lesion. The revascularization rate of the target vessel at 6 months was 28.6% (Table IV).

DISCUSSION

Critical limb ischemia (CLI) is a major health concern in an aging population. In the prerevascularization stage, most patients with CLI were treated by primary amputation because limb salvage rates with conservative treatment are as low as 5% [9]. Poor long-term results have been reported in patients undergoing amputation with up to 35% mortality within 15 months following the surgery [10]. Surgical bypass for popliteal or infrapopliteal occlusion is an alternative treatment for patients with CLI. Unfortunately, patients with CLI often have no suitable saphenous vein graft due to prior bypass grafting of coronary or femoral vessels, and an increasing number of patients are at a high surgical risk because of severe medical comorbidities [11,12]. Although endovascular intervention for CLI has been considered as first-choice therapy for limb salvage [13], the failure of popliteal or infrapopliteal CTO via the crossover or antegrade approach remains significant [3,4].

Few reports exist on dual vascular access intervention for chronic popliteal and infrapopliteal occlusions. From the high success rate of coronary CTO intervention via a retrograde approach, dual vascular access should be considered when angiography showed unfavorable signs for antegrade approach such as flush occlusion without tapered stump, large side branch at occlusion area or abundant bridging collaterals [14]. It was assumed that the distal part of an occlusive vessel is less fibrotic or has less calcified tissue and allows easier passage of a guidewire into the occlusion. In addition, several coronary CTO intervention techniques such as "just landmark," "controlled antegrade and retrograde subintimal tracking," and "proximal true lumen puncture" can be applied for treatment of popliteal and infrapopliteal occlusion via the dual access approach [15]. In this study, we adopted this method and reported a 100% success rate, which was similar that obtained in previous reports with a small series of patients [5–7], but these results were better than the results of Montero-baker et al [8].

Gaining the tibial access is technically challenging and usually has a learning period because of weak pulse and small vessel size. Roadmap or contrast angiography is most frequently used to guide the needle puncture. DUS is helpful to determine the orientation and depth of tibial vessel, it should be considered for obtaining the tibial access if fluoroscope guidance is not feasible.

The tibial access vessel occlusion with subsequent pedal bypass was introduced by Montero-Baker et al [8], and thereafter, they adopted the sheathless approach to minimize the profile of device using in the tibial access. In this study, we did not use this method because the lumen diameter at the puncture site was 2.86 ± 0.49 mm, which was safe for the use of a 4-F introducer sheath (outer lumen, 1.45 mm). In addition, using an introducer sheath, stepwise arterial dilatation can be performed in case the wire and/or balloon encounters friction within the long occlusion. The inflated balloon has a larger diameter than an unused balloon, potentially increasing the trauma to the tibial artery during retrieval. By using a small sized introducer sheath, we can avoid this potential vessel injury. There is a potential of tibial access occlusion after sheath removal, which may result in urgent surgery or even leg loss. Thus, sheathless approach is favored if vessel size of access site is less than 1.5 mm (1.45 mm for outer lumen of 4-F sheath) and check of vessel patency by DUS and final angiography is important. In this study, we did not use the snare-kit to extract the retrograde guidewire. We maneuvered the guidewire easily into the tip of the 5- or 6-F guiding catheter inserted antegrade until the guidewire tip appeared outside of the proximal sheath, as described by Spinosa et al [4].

The immediate results of retrograde tibial intervention have been published in some reports [7,8], but follow-up results for these investigations are not available. Clearly, the restenosis rate for a long occluded infrapopliteal segment is high, but this may be of little consequence, as the high metabolic demand of healing reduces subsequently and existing collaterals then maintain the continued clinical success described by Faglia et al [16]. However, the inadequate blood flow by restenosis or reocclusion may hamper tissue granulation in the ischemic wound, especially in patients with only single run-off vessel. In this study, we found that the restenosis rate was higher 3–6 months after the index procedure in the case of these complex lesions treated by POBA or BMS; the overall vessel patency and TVR rates at 6 months were 57.1 and 28.6%, respectively; these results are similar to those of a previous report [17]. Siablis et al. reported the 1-year results after implantation of a sirolimus-eluting stent in infrapopliteal lesions with an 86% vessel patency rate and 36.7% binary restenosis rate [18]. In our small group, no restenosis was found in occlusion treated by DES at 6 months. Recent advances in drug-coated balloons have resulted in a significant reduction in angiographic late lumen loss and the need for repeated target lesion revascularization (TLR) in the management of femopopliteal disease [19]. This new device holds promise for the improvement of vessel patency and it may eliminate the need for long-length stenting implantation in complex infrapopliteal lesions [20].

The limitation of this study is that it is retrospective observational study. The sample size is small and the follow-up period is relatively short. A larger series should be examined and a longer follow-up should be conducted to clarify the safety and effectiveness of this technique over a long term. In conclusion, Dual vascular access intervention was successfully used in a small number of selected patients and this technique may hold promise in improving the success rates in the treatment of complex popliteal and infrapopliteal occlusions.

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