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≋ *Original Article* ≋

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Objective: The aim of this study was to evaluate outcomes of combined popliteal-to-distal bypass and endovascular treatment (EVT) for femoropopliteal lesions in patients with critical limb ischemia (CLI).

Patients and Methods: We reviewed data of 14 CLI patients who were treated by popliteal-to-distal bypass combined with femoropopliteal EVT. The femoropopliteal lesions included 3 TASC II-A, 8 TASC II-B, and 3 TASC II-C but no TASC II-D, and balloon dilatation was performed in 9 cases and a stent was placed in 5 cases. The saphenous vein graft was used in all bypasses, and the target arteries were the dorsalis pedis artery in 12 cases and the posterior tibial artery in 2 cases.

Results: At 12 and 24 months, primary patency rates were both 79%, primary assisted and secondary patency rates were both 93%, limb salvage rates were both 93%, and survival rates were 92% and 84%, respectively. Restenosis after femoropopliteal EVT occurred in 2 cases, and both were successfully revised by additional endovascular balloon dilatation.

Conclusion: Combined popliteal-to-distal bypass and femoropopliteal EVT might be a useful therapeutic option for appropriately selected CLI patients. Intensive follow-up for endovascular treated lesions and vein graft is mandatory.

Keywords: critical limb ischemia, popliteal-to-distal bypass, femoropopliteal artery endovascular treatment

Introduction

In cases of distal vein bypass for critical limb ischemia (CLI), the common femoral artery (CFA) has generally been selected as a preferable site for proximal anastomo-

sis. The superficial femoral artery (SFA) and the popliteal artery (PA) have not been considered good candidates for inflow sites because they are at a risk for atherosclerotic occlusive changes.

In 1981, the first report was published suggesting that bypass grafts originating distal to the CFA may be as effective as traditional CFA-originated distal bypass.[1] Clinical reports supporting the effectiveness and safety of this short distal bypass have appeared in succession, and the SFA and PA are now regarded as preferential inflow sites for distal bypass in select patients with a palpable popliteal pulse.[2–16] Although the popliteal-to-distal bypass has an unstable inflow, it has many merits, such as shortening the operating time, minimization of the surgical wound on the ischemic limb, and preservation of the saphenous vein.

With instrumental and technical advances of endovascular treatment (EVT), the concept of popliteal-to-distal bypass with preceding percutaneous transluminal angioplasty (PTA) for femoropopliteal lesions was first reported in 1992; subsequently, clinical experience of popliteal-to-distal bypass concomitant with intraoperative femoropopliteal PTA was reported in 2001.[7–17] Satisfactory outcomes of this combination therapy have been subsequently reported; however, there are few cases to date and further investigations are necessary for accurate evaluation.[18–20] Furthermore, clinical outcomes of femoropopliteal EVT has been improved remarkably with the development of new devices, such as the drug-eluting stent and heparin-bonded stent-graft, and the indication of femoropopliteal EVT has been expanding.[21–27]

The aim of this study was to evaluate clinical outcomes of combined popliteal-to-distal bypass and femoropopliteal EVT in patients with CLI.

Patients and Methods

Patient enrollment and groups

Between January 2005 and December 2015, we treated 324 critical ischemic limbs with gangrene. Of these limbs, 138 of them were treated by infrainguinal bypass including 88 cases of distal bypass, and the remainder were

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Table 1 Preoperative patients' data

	N＝14
Patients	
Age (y)	72 (58–81)
Male	10 (71%)
Preoperative ADL	10：4
(ambulatory：wheel chair)	
Rutherford 5：6	8：6
BMI (kg/m²)	21 (15–27)
Risk factors	
Hypertension	14 (100%)
Diabetes mellitus	14 (100%)
Hemodialysis	6 (43%)
History of coronary intervention	5 (36%)
History of cerebral attack	2 (14%)
Laboratory data	
WBC (/mm³)	8014 (5500–12600)
Hemoglobin (g/dl)	10.8 (8.9–12.4)
Albumin (g/dl)	3.1 (2.3–4.4)
CRP (mg/dl)	4.6 (0.3–14)
EF on cardiac US (%)	67 (52–75)

ADL: activities of daily living; BMI: body mass index; WBC: white blood cell; CRP: C-reactive protein; EF: ejection fraction; US: ultrasonogram

Table 2 Revascularization procedures

	N＝14
Femoropopliteal EVT	
Femoropopliteal lesions	
TASC II-A	3 (21%)
TASC II-B	8 (57%)
TASC II-C	3 (21%)
TASC II-D	0 (0%)
Endovascular procedures	
Balloon dilatation	9 (64%)
Self-expandable stent	5 (36%)
Popliteal-to-distal bypass	
Inflow	
Above-knee popliteal artery	6 (43%)
Below-knee popliteal artery	8 (57%)
Outflow	
Dorsalis pedis artery	12 (86%)
Posterior tibial artery	2 (14%)
Bypass conduit	
Reversed SVG	4 (29%)
Nonreversed SVG	10 (71%)
Saphenous vein graft diameter on US	
Minimum (mm)	2.4 (1.0–3.6)
Maximum (mm)	3.5 (1.9–5.1)

SVG: saphenous vein grafts; US: ultrasonogram

treated by EVT or conservative wound management. The inflow sites of 88 distal bypass cases were CFA in 43 (49%) and above-knee or below-knee PA in 45 (51%).

In this study, we retrospectively reviewed 14 cases of treatment by popliteal-to-distal bypass combined with EVT for femoropopliteal lesions with the intention of hybrid treatment that were followed up until October 2016. This hybrid treatment was adopted in consideration with the morphological severity of femoropopliteal lesions and the quality of saphenous vein grafts (SVG). The patients were 10 men and 4 women, and the mean age was 72 years (range 58–81 years). All patients had ischemic forefoot or toe gangrene (Rutherford 5: 10 cases, Rutherford 6: 4 cases). All patients had hypertension and diabetes mellitus, and 6 (43%) of them received hemodialysis. Hypertension was defined as arterial blood pressure ＞140 mmHg (systolic) or ＞90 mmHg (diastolic), or if the patient was receiving antihypertensive medication. Diabetes mellitus was defined as a fasting blood sugar level ＞120 mg/dl or a hemoglobin A_{1c} level ＞6%, or if the patient was receiving hypoglycemic medication or insulin injection. Preoperative patient characteristics and laboratory data are summarized in **Table 1**.

Revascularization procedures
All endovascular procedures for femoropopliteal lesions were performed by interventionists with assistance from vascular surgeons. Angiographic evaluation revealed

that the femoropopliteal lesions of 14 patients included 3 TransAtlantic Inter-Society Consensus (TASC) II-A, 8 TASC II-B, and 3 TASC II-C but no TASC II-D (**Table 2**). After systemic heparinization (3000 units/body), a guide-wire was passed through the lesion, and the lesion was expanded for 60 s using an optimally sized balloon. A self-expandable nitinol stent was deployed only when flow-limiting dissection or recoil occurred and never implanted in the bending zone. As a result, a self-expandable stent was placed additionally in 5.

All popliteal-to-distal bypasses were performed under general anesthesia after confirmed success of femoropopliteal EVT (**Table 2**). An autologous SVG, harvested by reversed or nonreversed maneuvers, was used in all cases. The inflow sites of the distal bypass were determined based on the degree of occlusive changes in the PA and the length of the harvested SVG and were above-knee PA in 6 and below-knee PA in 8. The target arteries were the dorsalis pedis artery in 12 and the posterior tibial artery in 2. The SVG diameters were measured preoperatively by ultrasonography in a standing or sitting position.

After revascularization, all patients received antiplatelet regimens, such as aspirin (81 mg/day), cilostazol (100 mg/day), or clopidogrel bisulfate (75 mg/day), throughout the follow-up period.

Follow-up and assessments

Follow-up included clinical evaluation, duplex ultrasonography, and skin perfusion pressure (SPP) measurement at discharge and every 3 to 4 months postoperatively. Grafts and femoropopliteal lesions were surveilled with duplex ultrasonography. Revisions were considered for severe stenosis of more than 75% on duplex, defined as a velocity ratio of greater than 3.5 (velocity ratio = peak systolic velocity at the lesion/peak systolic velocity proximal to the lesion) or peak systolic velocity of greater than 300 cm/s. SPP was measured using a laser Doppler scanner (LaserDopp PV2000, Vasamedics, St. Paul, MN, USA). Computed tomography angiography or conventional arteriography was performed before reintervention.

Primary, primary-assisted, and secondary patency as well as limb salvage, and survival after revascularization procedures were the endpoints of the study. Major amputation was defined as limb loss above the ankle level, and limb salvage was defined as freedom from major amputation.

Statistical methods

All analyses were conducted using Statcel 2 (OMS Publishing, Saitama, Japan) as an add-on to Excel 2016 (Microsoft Corp., Redmond, WA, USA). Categorical variables were analyzed by Chi-square test or Fisher exact test. Differences between continuous variables were assessed by paired t-test if normally distributed and by Mann–Whitney U test if asymmetrically distributed. Kaplan–Meier curves were prepared for patency, limb salvage, and survival, and a log-rank test was used to assess differences in these curves between groups. $P < 0.05$ was considered to indicate statistical significance.

Results

Initial revascularization success was obtained in all cases. SPP was significantly elevated from 21 mmHg (range 10–27 mmHg) to 56 mmHg (range 21–95 mmHg) on average. At 12 and 24 months, primary patency rates were both 79% (**Fig. 1A**), primary-assisted and secondary patency rates were both 93% (**Fig. 1B**), limb salvage rates were both 93% (**Fig. 2A**), and survival rates were 92% and 84%, respectively (**Fig. 2B**). Four of them died during the follow-up period (8, 14, 27, and 59 months after revascularization), and the causes of death were acute
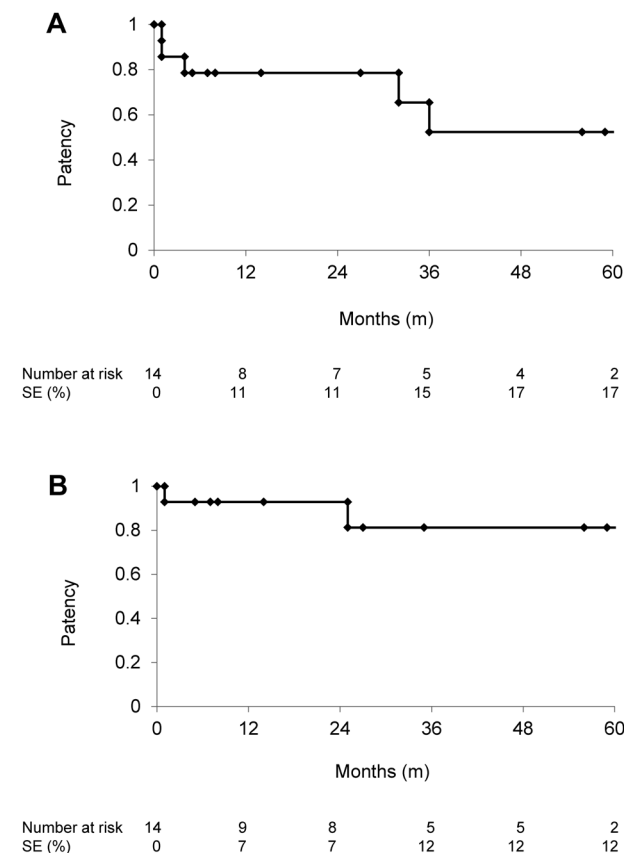

Number at risk	14	8	7	5	4	2
SE (%)	0	11	11	15	17	17

Number at risk	14	9	8	5	5	2
SE (%)	0	7	7	12	12	12

Fig. 1 Patency rates of popliteal-to-distal bypass and femoropopliteal EVT. (**A**) Primary patency. (**B**) Primary assisted/secondary patency.

Number at risk	14	10	9	6	6	2
SE (%)	0	7	7	14	14	14

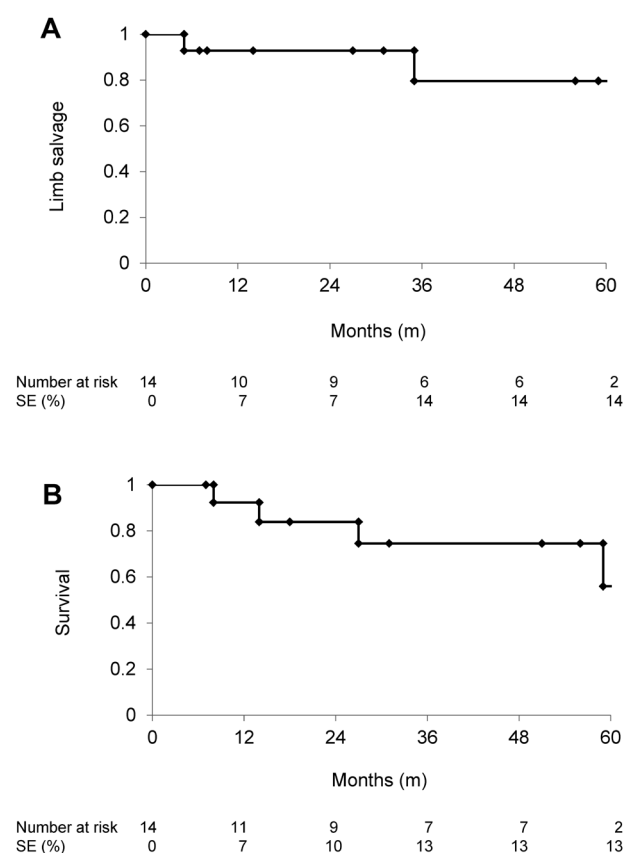|					
Number at risk	14	11	9	7	7	2
SE (%)	0	7	10	13	13	13

Fig. 2 Limb salvage and survival rates of popliteal-to-distal bypass and femoropopliteal EVT. (**A**) Limb salvage. (**B**) Survival.

Fig. 3 Balloon dilatation for restenoses 36 months after EVT for the femoropopliteal lesions. White arrows show the restenoses in the femoropopliteal artery, and the black arrow shows popliteal-to-distal bypass.

myocardial infarction, intestinal bleeding, lung cancer, and unknown for each.

Restenosis after EVT for femoropopliteal lesions occurred in 2 cases (32 and 36 months after surgery, **Fig. 3**), and both were successfully revised by additional endovascular balloon dilatation. Preoperative angiographic classification of these femoropopliteal lesions were TASC II-B and -C in each. Vein graft stenosis was recognized in 2 cases. In one case, proximal anastomotic stenosis occurred 4 months after surgery and was successfully revised by endovascular balloon dilatation. In another case, stenosis of vein–vein anastomosis in the spliced graft occurred one month after surgery and was successfully revised by endovascular balloon dilatation. However, the graft finally occluded 25 months later after repetition of EVT for restenosis.

Discussion

Historically, the CFA has been considered the optimal site for proximal anastomosis of distal vein bypass, and the SFA and PA have been regarded as poor candidates for inflow sites because they have a propensity for atherosclerotic occlusive changes.

In 1981, Veith et al. first reported the clinical outcomes of distal bypass grafts originating from the SFA and PA. Only 1 of 32 failures in 139 bypasses with distal origin was caused by proximal progression of atherosclerotic disease, and they concluded that preferential use of the SFA and the PA as inflow sites for distal bypass is recommended in appropriately selected patients.[1] Since this report, many investigations have supported the preferential use of the SFA and the PA as inflow sites of distal vein bypass for patients with a palpable popliteal pulse.[2–16] Albers et al. conducted a meta-analysis of 12,320 popliteal-to-distal bypasses.[15] The 5-year primary patency rate was 63.1%, secondary patency rate was 70.7%, and foot preservation rate was 77.7%, and they concluded that the popliteal-to-distal vein bypass is highly efficient in CLI treatment. At present, popliteal-to-distal bypass has become widely accepted, especially for diabetic CLI patients whose occlusive lesions mainly appear in the infrapopliteal arteries.

In 1992, Wengerter et al. investigated 153 popliteal-to-distal bypasses, and 19 of them were performed after PTA for femoropopliteal lesions less than 3 cm in length and with luminal narrowing ranging from 24% to 85%.[7] The 2-year primary graft patency of this cohort was 68%, not significantly lower than that of popliteal-to-distal bypass without PTA for 35% or less proximal stenosis. In 2001, Schneider et al. reported 12 cases of popliteal-to-distal bypass concomitant with intraoperative PTA for SFA lesions in the treatment of diabetic gangrene.[17] The 2-year primary patency rate was not inferior to that of either CFA-to-distal bypass or popliteal-to-distal bypass without PTA for SFA lesions. In the follow-up period, the PTA sites in the SFA developed recurrent stenosis in 2 patients, both were successfully treated by additional PTA. In 2007, Schanzer et al. reported 23 popliteal-to-distal bypasses performed after EVT for SFA lesions.[18] The SFA lesions were 11 TASC II-A, 7 TASC II-B, 5 TASC II-C, and 0 TASC II-D, and they were treated by PTA alone in 20 cases and PTA with stenting in 3 cases. Only one patient who presented target lesion restenosis required additional EVT to maintain patency, and none of the graft failures could be specifically attributed to disease progression of the SFA. Some clinical studies including these reports suggested that femoropopliteal EVT in preparation for popliteal-to-distal bypass is a useful and effective option for CLI patients in the setting of both atherosclerotic SFA disease that requires intervention and limited autologous saphenous vein conduit.[19,20]

On choosing this revascularization strategy, it is important to ascertain the reliability of the SFA as an inflow of popliteal-to-distal bypass, that is, the durability of EVT for SFA lesions. Iida et al. reported clinical outcomes of 861 cases nitinol stenting of the femoropopliteal segment. At 1, 3, and 6 years, the primary patency rates were 77%,

67%, and 63%, respectively, and the secondary patency rates were 91%, 87%, and 87%, respectively. They also noted that female gender, ankle-brachial index < 0.6, TASC II-C/D lesion, stent fracture, and absence of cilostazol administration were significant independent factors associated with target lesion restenosis.[21] Dohi et al. reported the outcome of 2447 femoropopliteal lesions treated with nitinol stent-based EVT. In-stent restenosis occurred in 5.2%, 11.2%, and 16.4% at 1, 3, and 5 years, respectively, and female gender, critical limb ischemia, and TASC II-C/D lesion were independent predictors of in-stent occlusion.[22] Based on these reports, we now consider that combined popliteal-to-distal bypass and femoropopliteal EVT might be acceptable for CLI patients with TASC II-A/B femoropopliteal lesions, especially for patients who have inadequate saphenous vein. In cases of TASC II-C/D femoropopliteal lesions, this strategy should be limited for challenging cases.

However, the indication of this strategy could be reconsidered with the appearance of new devices, such as a more flexible stent, drug-eluting stent, drug-eluting balloon catheter, or stent-graft.[23–27] Ohki et al. reported clinical outcomes of the Misago stent (a nickel–titanium bare-metal stent featuring a linkless structure that may reduce the rate of fracture) for the treatment of SFA disease.[23] The stent was implanted in 261 TASC II-A or -B SFA lesions, and overall 12-month primary patency rate and freedom from target lesion revascularization were 82.9% and 87.0%, respectively. Dake et al. reported 5-year results of the Paclitaxel eluting stents (Zilver PTX) in the femoropopliteal artery.[24] Freedom from persistent or worsening symptoms of ischemia was 79.8%, patency was 66.4%, and freedom from target lesion revascularization was 83.1%. Lammer et al. reported the clinical results of heparin-bonded covered stents (Viabahn) versus bare-metal stents for complex femoropopliteal artery lesions.[25] The 12-month patency rate was 71.3% in the Viabahn group, which was significantly better than 36.8% in the bare-metal stent group. Zeller et al. reported the outcome of heparin-bonded stent-graft for the treatment of TASC II-C/D femoropopliteal lesions (Viabahn-25 cm trial).[26] One-year primary and secondary patency rates were 67.0% and 96.9%, and these are satisfying and comparable to historical prosthetic bypass graft outcomes. Ohki et al. reported outcomes of the Japanese multicenter Viabahn trial of endovascular stent grafting for SFA lesions.[27] One hundred SFA lesions of 21.8 cm in length, including 65.7% of total occlusion, were treated with Viabahn, and primary assisted patency rate was 94.1% and freedom from target lesion revascularization was 93.1% at 12 months. After the confirmation of excellent long-term patency of these new devices for femoropopliteal lesions, the application of combination therapy with popliteal-to-distal bypass and femoropopliteal EVT might be expanded in CLI patients with TASC II-C/D femoropopliteal lesions.

We are still convinced that the gold standard of bypass for CLI patients with femoropopliteal and infrapopliteal arterial occlusive diseases is CFA-to-distal bypass, and the indication of combination therapy with popliteal-to-distal bypass and femoropopliteal EVT is limited for patients with inadequate saphenous vein graft. Most patients in this series did not have adequate length, diameter, or quality of SVG, and this might be the reason for the high occurrence rate of SVG stenosis. In addition to 2 cases of SVG stenosis, we encountered 2 cases of target lesion restenosis of femoropopliteal EVT during the follow-up period. All of them were successfully treated by additional PTA, and we are convinced that it is important to survey SFA lesions and vein grafts closely using duplex ultrasonography and to perform reintervention before thrombotic occlusion.

This study has some limitations. This was a retrospective, nonrandomized study with patient-centered criteria and the patient cohort was small. From this preliminary report, we strongly suggest that restenosis of endovascular treated lesions and SVG stenosis are not infrequent, and careful follow-up is mandatory in patients who undergo popliteal-to-distal bypass with femoropopliteal EVT.

Conclusion

Combined popliteal-to-distal bypass and EVT for femoropopliteal lesions might be a useful therapeutic option for appropriately selected patients with CLI. Intensive follow-up for endovascular treated lesions and vein graft is mandatory.

Disclosure Statement

The authors have no conflicts of interest.

Additional Note

Part of this study was presented as Prize Poster Presentation at the 17th Congress of the Asian Society for Vascular Surgery (October 20–23, 2016, Singapore).

Author Contributions

Study conception: YT
Data collection: all authors
Analysis: YT
Investigation: YT
Writing: YT
Funding acquisition: none
Critical review and revision: all authors

Final approval of the article: all authors
Accountability for all aspects of the work: all authors

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