Combined popliteodistal bypass with inflow angioplasty in treating patients with critical limb ischemia

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Objective
This study evaluated the outcome of combined popliteal-to-distal bypass and angioplasty of inflow lesions in patients with critical limb ischemia (CLI).
Patients and methods
Data of all patients with CLI undergoing infrapopliteal bypasses with inflow originating from the popliteal artery above the knee (Pop-AK) or below the knee (Pop-BK) were analyzed retrospectively. Outcomes assessed were patency rates, amputation-free survival, patient survival, and wound healing rates at 1-year follow-up. A comparative analysis of patency rates and amputation-free survival between Pop-AK and Pop-BK bypasses was done.
Results
A total of 43 bypasses originating from the popliteal artery (19 Pop-AK and 24 Pop-BK) were performed in the period from March 2017 to February 2021 at Vascular Surgery Department, Zagazig University Hospitals, Egypt. Overall, 25 patients necessitated preoperative endovascular treatment of femoropopliteal lesions, where 18 were males, mean age was 72.8±10 years, diabetes mellitus was seen in 88%, hypertension was seen in 80%, and renal impairment was seen in 36%. The Trans-Atlantic Inter-Society Consensus II (TASC II) classification of femoropopliteal lesions was TASC II-B in 21 (84%) patients, TASC II-C in two (8%) patients, and TASC II-D in two (8%) patients. A total of 13 (52%) distal bypasses originated from Pop-AK and 12 (48%) from Pop-BK. The most common outflow artery was the anterior tibial artery (60%). At 1-year follow-up, the primary patency rate was 48%, the assisted-primary patency rate was 84%, and the secondary patency rate was 96%. At 12 months, amputation-free survival and patient survival rates were 100 and 88%, respectively. Wound healing at 12 months reached 96%.
Conclusion
Combined popliteodistal bypass with inflow arterial angioplasty is a useful therapeutic option in treating patients with CLI because of durable patency, acceptable wound healing rates, and good limb salvage. This hybrid approach provides a good solution in cases of combined femoropopliteal lesions with limited autogenous conduit.

Keywords:
critical limb ischemia, distal bypass, endovascular therapy, limb salvage, wound healing

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Introduction

Critical limb ischemia (CLI) is an advanced state of peripheral arterial disease. According to Rutherford classification, it is defined as the presence of lower extremity ischemic rest pain or tissue loss (minor or major) [1]. It is progressively increasing with the ageing population. Distal and ultradistal bypasses are now firmly established as effective techniques for treatment of such cases [2].

Since 1981, bypasses originating from distal to the common femoral artery (CFA) were comparable to the more traditional CFA-originating bypasses regarding effectiveness and safety in patients with popliteal pulse [3–7]. Benefits of distal inflow bypasses include shorter operating time, smaller surgical wound, and shorter autologous vein segment needed. However, long-term inflow stability of the popliteal artery (PA) remains debatable [7,8].

With technical advances of endovascular therapy (EVT), satisfactory outcomes of popliteodistal bypasses preceded by percutaneous transluminal angioplasty for iliac or femoropopliteal (FP) lesions have been reported. However, few studies are reported, and further evaluation is necessary for accurate assessment [9–11].

The aim of this study was to assess clinical outcomes of combined popliteal-to-distal bypass and EVT of inflow lesions in patients with multilevel CLI.

Patients and methods

Study design

Between March 2017 and February 2021, we performed 43 bypasses originating from the PA: 19 from the above knee popliteal artery (Pop-AK) and 24 from the below knee popliteal segment (Pop-BK). Of the 43 bypasses, 25 necessitated preoperative endovascular treatment of FP lesions. This study was conducted at Vascular Surgery Department, Zagazig University Hospitals, Egypt.

We retrospectively analyzed a prospectively collected database, based on the clinical, operative, and outpatient reports.

Patients suitable for hybrid revascularization were selected by vascular surgeons with EVT expertise. Preoperative duplex evaluation of all patients was done. Computed tomography (CT) angiogram was performed in good renal function patients, which is replaced by MRA in cases of renal impairment. Patients' demographics, operative details, and 1-year outcomes were evaluated.

The study protocol was approved by the local ethical committee of Zagazig Faculty of Medicine and all patients gave informed consent before participation in the study.

Inclusion criteria

Inclusion criteria were patients with CLI as defined by Rutherford classification, that is, ischemic rest pain or tissue loss (minor or major). Patients with inflow arterial lesions (iliac or FP) causing more than 50% stenosis or obstruction, lesions of the three tibial vessels more than 5 cm in length, and failed infrapopliteal EVT were also included.

Exclusion criteria

Patients without inflow lesions, patients with no crural vessels disease, those who underwent revascularization procedures other than infrapopliteal bypasses, and patients with unsalvageable limbs are excluded.

Technical procedure

Inflow EVT is performed intraoperatively or within 2 weeks before the bypass in a dedicated surgical theater under fluoroscopic guidance using a mobile C-arm. All EVT procedures were performed by vascular surgeons with EVT expertise via an antegrade approach from ipsilateral CFA access as the CFA was patent with no lesions.

Regarding the infrapopliteal bypasses, the site of the proximal anastomosis was the supragenicular or infragenicular PA depending on the presence of triphasic flow and absence of angiographic lesions. The outflow vessel was chosen respecting the concept of angiosomal distribution of tissue loss provided that straight line flow to the foot is present.

Regarding the conduit used, the ipsilateral great saphenous vein (GSV) was selected as a first choice. All vein grafts were harvested and inverted. In the absence of a suitable GSV segment, a synthetic graft was used instead.

After anesthetic assessment of patient's pre-anesthesia medical comorbidities using American Society of Anesthesiologists physical status classification system, all procedures were performed under spinal anesthesia. Systemic heparinization was administered intraoperatively. After EVT completion, angiography and intraoperative Doppler assessment at the end of the bypass were done. Ulcer debridement or minor amputations were carried out during the same session after finishing the surgical revascularization. Postoperative anticoagulation was given to all patients using low-molecular-weight heparin (Clexane, Sanofi Winthrop Industries, France) at a dose of 1 mg/kg subcutaneously twice daily during the in-hospital admission period. Dual antiplatelets and statin are initiated before intervention and maintained postoperatively for the first 3 months, and then aspirin was continued as a life-long treatment.

Follow-up

Duplex surveillance program was initiated in all patients as well as wound care until complete healing. Follow-up scans were performed during hospital admission and then every 3 months for the first year. Data on inflow artery, proximal anastomosis, in-graft, distal anastomosis, and outflow artery were provided. A threatened graft is picked up when finding a focal peak systolic velocity (PSV) more than 200 cm/s, PSV ratio more than 2.0 (50% stenosis), or global graft PSV less than 35 cm/s. Threatened grafts were offered urgent angiography, and if significant stenosis was confirmed, immediate salvage angioplasty was performed. Corrective surgery was undertaken if angioplasty deemed unsuccessful or if the stenosis recurred. Patients were discharged from the surveillance program after completing an intervention-free follow-up year.

Study end points and outcome measures

Primary end points of this study were the primary, assisted-primary and secondary graft patency. Secondary endpoints included wound healing, amputation-free survival, and patient survival. Major amputation is limb loss above the ankle level.

Statistical analysis

Statistical analysis was performed using the IBM SPSS Statistical Analysis Software, version 19, Armonk – New York – USA. *P* value less than 0.05 was considered statistically significant. Pearson χ^2 test was used to analyze categorical data, whereas independent *t* test was used to analyze numerical data. Primary patency, assisted primary patency, secondary patency, amputation-free survival, and patient survival rates were estimated with the Kaplan–Meier life-table analysis method.

Results

Patient population

During the study period, 43 distal bypasses originating from the PA were performed. Of the 43 distal bypasses, 25 patients (18 males and seven females) necessitated preoperative endovascular treatment of FP inflow lesions.

The mean age was 72.8 years (range, 49–86 years). History of smoking (88%), diabetes mellitus (88%), hypertension (80%), and renal impairment (36%) were recorded. The demographic criteria and risk factors are summarized in Table 1. Rutherford clinical categories 5 and 6 were present in 15 and 10 patients, respectively.

The Trans-Atlantic Inter-Society Consensus II (TASC II) classification of femoro-popliteal lesions was TASC II-B in 21 (84%) patients, TASC II-C in two (8%) patients, and TASC II-D in two (8%) patients.

Table 1 Patient demographics and cardiovascular risk factors

Age (mean±SD)	72.8±10
Male sex	18 (72)
Lower limb affected	
Right	13 (52)
Left	12 (48)
Rutherford classification	
5	15 (60)
6	10 (40)
Diabetes mellitus	22 (88)
Hypertension	20 (80)
Coronary artery disease	5 (20)
Dyslipidemia	14 (56)
Renal impairment	9 (36)
Smoking/ex-smoking	22 (88)

Intervention

A total of 13 (52%) distal bypasses originated from Pop-AK and 12 (48%) from Pop-BK. The outflow artery used for distal anastomosis is the anterior tibial artery (ATA) in 15 (60%) patients, the posterior tibial artery (PTA) in eight (32%) patients, and the peroneal artery (PerA) in two (8%) patients. Autologous GSV is used in all cases except a case in which a synthetic PTFE graft is used owing to suboptimal GSV.

EVT procedures were performed to treat FP inflow stenoses (20 cases) or occlusions (five cases). All inflow lesions were treated with plain old balloon angioplasty (POBA) except one case which necessitated SFA stenting with a nitinol stent.

Salvage angioplasty to rescue threatened grafts was needed in nine (36%) cases. The number of repeated salvage angioplasties was 12/25 (48%). Nine (75%) of the 12 salvage angioplasties were for the preoperatively treated inflow artery and the remaining three (25%) were to treat outflow lesions.

Graft occlusion occurred in four (16%) cases; of which, re-operation was necessitated in three (12%) cases as follows: thrombectomy and redo-distal anastomosis in one case 4 days postoperatively, jump vein graft from CFA to distal graft due to bleeding from ruptured pseudo-aneurysm secondary to wound infection in

Table 2 Procedure characteristics

Characteristic	*n* (%)
TASC classification of FP lesions:	
TASC B	21 (84)
TASC C	2 (8)
TASC D	2 (8)
EVT interventions	
POBA	24 (96)
Stenting	1 (4)
Origin of bypasses	
Pop-AK	13 (52)
Pop-BK	12 (48)
Target outflow vessels	
ATA	15 (60)
PTA	8 (32)
PerA	2 (8)
Conduit used	
GSV	24 (96)
PTFE	1 (4)
Repeated salvage angioplasty	12/25
Inflow	9 (75)
Outflow	3 (25)
Re-operation	3 (12)

ATA, anterior tibial artery; EVT, endovascular therapy; GSV, great saphenous vein; PerA, peroneal artery; POBA, plain only balloon angioplasty; Pop-AK, popliteal above knee; Pop-BK, popliteal below knee; PTA, posterior tibial artery; PTFE, polytetrafloroethylene; TASC, Trans-Atlantic Inter-Society Consensus.

the other, and a third case in which the target outflow vessel was changed from PTA to ATA as the original bypass was complicated by secondary hemorrhage from wound infection. Although the fourth graft got occluded 4 months after the hybrid procedure, no intervention was required as complete wound healing was achieved by the time the bypass got occluded. Procedure characteristics are summarized in Table 2.

Modification of modifiable cardiovascular risk factors, such as smoking, diabetes mellitus, hypertension, sedentary life, and dyslipidemia was done.

Outcome

Technical success was achieved in all cases. At 1-year follow-up, overall primary patency rate was 48%, assisted primary patency was 84%, and secondary patency rate was 96%. No 30-day mortality was recorded. At 12 months, amputation-free survival and patient survival rates were 100 and 88%, respectively. Wound healing at 12 months reached 96%.

Pop-AK and Pop-BK originating bypasses are comparable regarding patency rates and patient survival, with no statistically significant differences (Table 3) (Figs 1–4).

Table 3 Comparative analysis between popliteal above knee and popliteal below knee originating grafts

Outcomes	Pop-AK (%)	Pop-BK (%)
Primary patency rates	53.8	41.7
Assisted primary patency rates	76.9	91.7
Secondary patency rates	92.3	100
Patient survival rates	92.3	83.3

Pop-AK, popliteal above knee; Pop-BK, popliteal below knee.

Three (12%) cases died during the follow-up period. One passed owing to renal failure and cerebral hemorrhage, another patient died from unrelated causes (hepatocellular carcinoma and end-stage cardiac failure), and the third from pneumonia.

TASC II-B lesions (P=0.046) and female sex (P=0.022) were statistically significant independent factors for target inflow lesion restenosis.

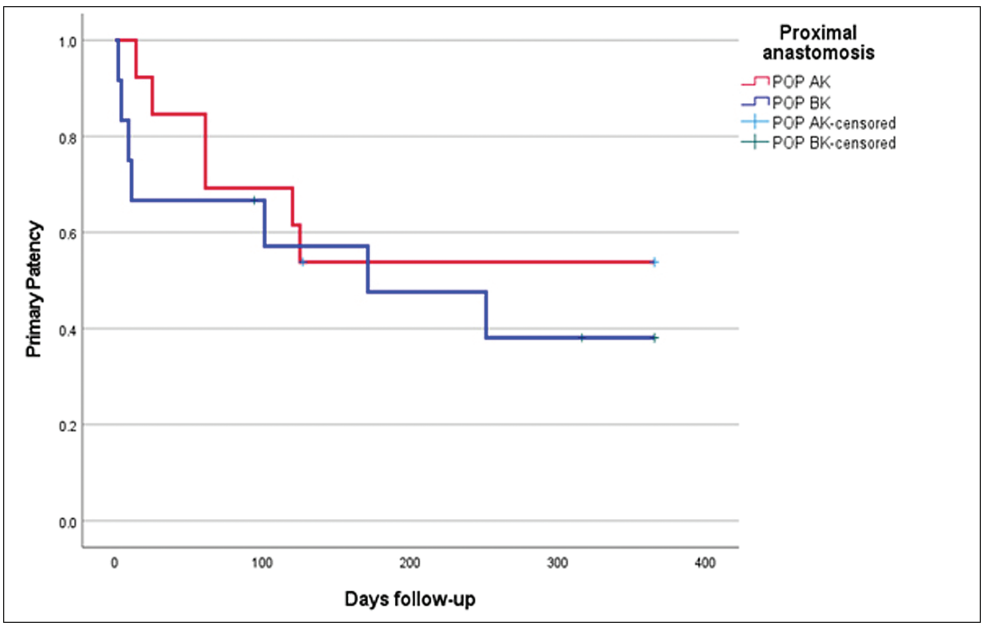
Bypasses with inflow arterial lesions treated with EVT have comparable graft patency and patient survival rates to those without EVT owing to absent proximal lesions (Figs 5 and 6).

Discussion

Historically, the gold standard for lower extremity revascularization involved bypass grafts extending from the groin to a distal patent vessel with straight-line flow to the foot.

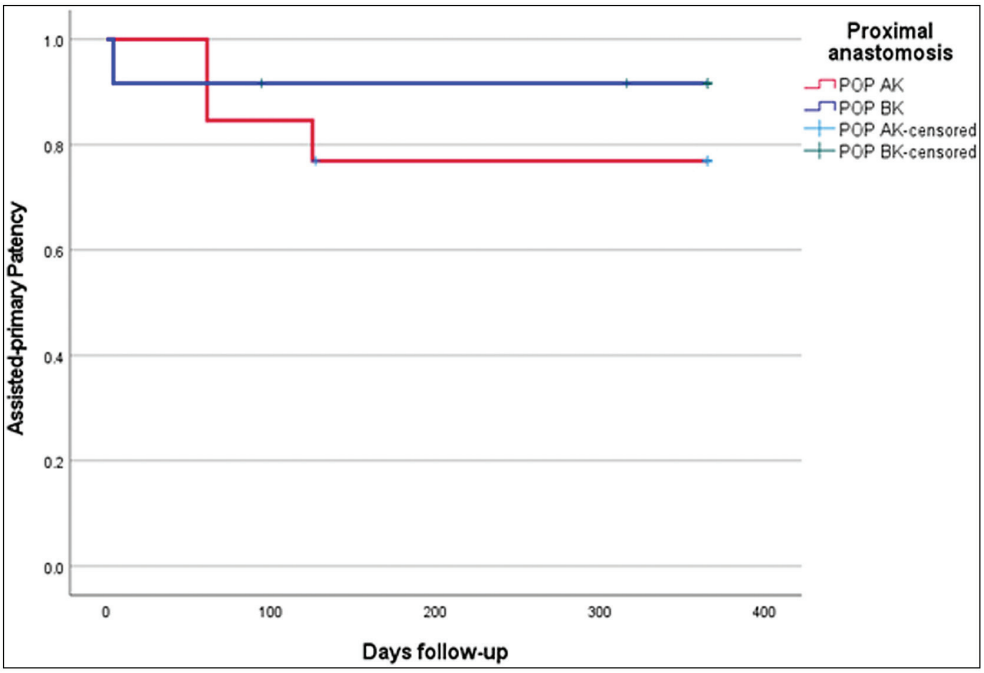
Since 1981 and over time, alternate revascularization methods, including bypass grafts originating from the vascular tree distal to the groin, have been validated. At present, popliteodistal bypasses are widely accepted, especially for diabetic patients whose occlusive lesions tend to involve the infrapopliteal arteries [7].

Figure 1



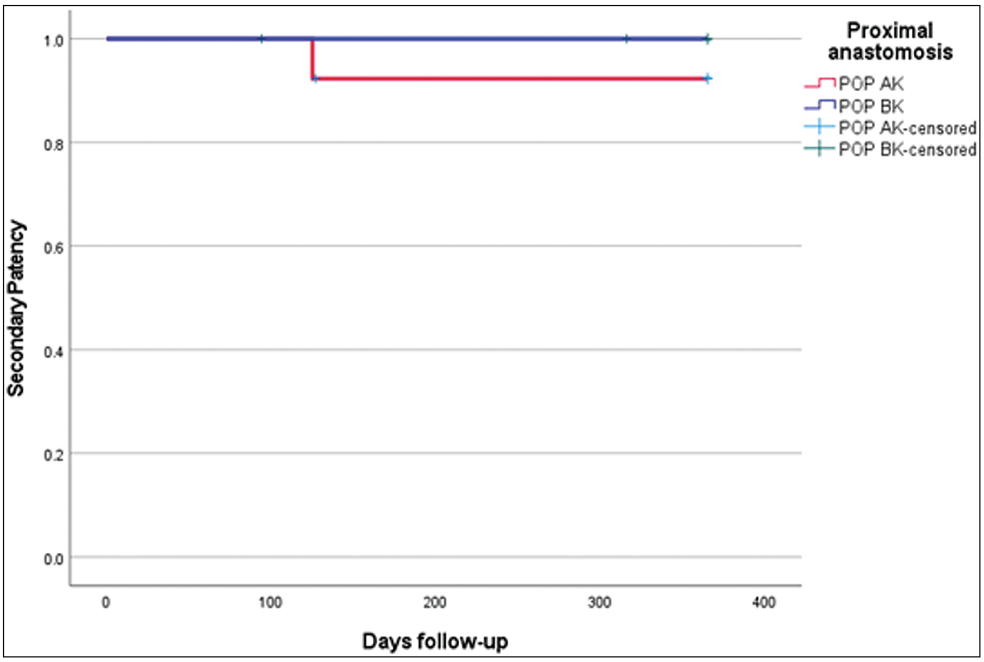
Kaplan–Meier analysis of the primary patency rates of different inflow bypasses.

Figure 2



Kaplan–Meier analysis of the assisted-primary patency rates of different inflow bypasses.

Figure 3

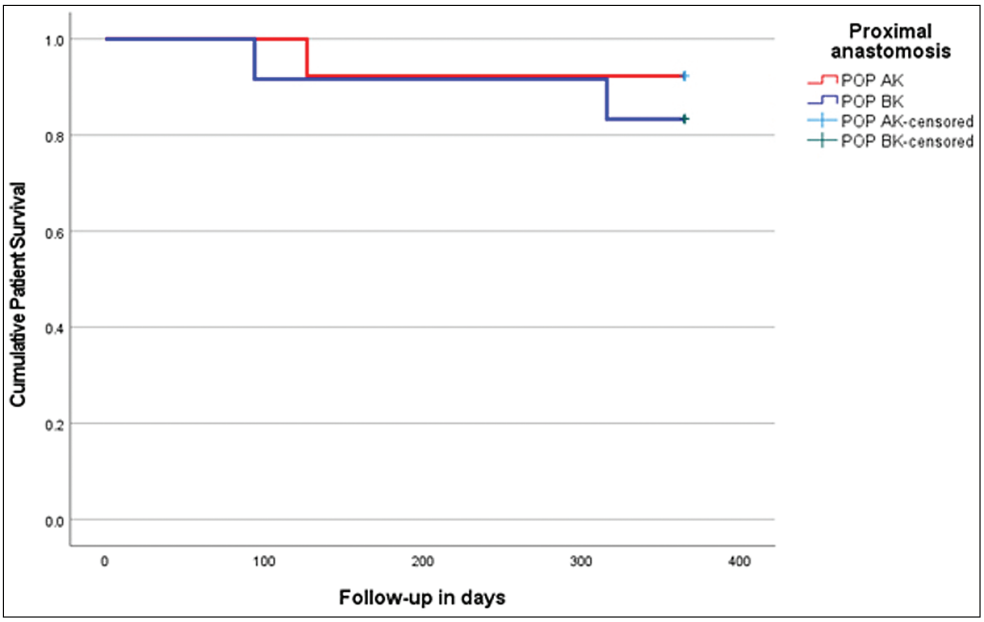


Kaplan–Meier analysis of the secondary patency rates of different inflow bypasses.

Owing to the multilevel nature of the disease especially in diabetics, this bypass type has had limited application because of the impaired inflow from proximal FP segment lesions. Advances in EVT encouraged the use of such endovascular strategies, both independently and in a complementary fashion, to improve results with open surgical techniques.

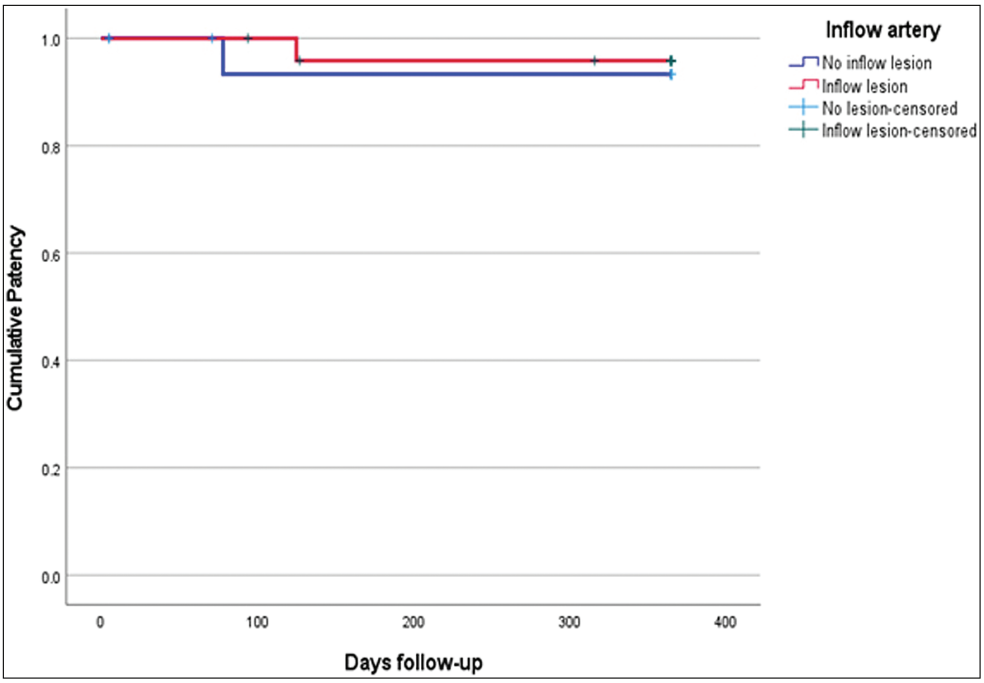
In 2001, Schneider and colleagues were the first to report the use of EVT to treat SFA lesions to facilitate placement of a distal origin bypass graft. They published their results in 12 patients who had simultaneous intraoperative angioplasty for focal SFA TASC A lesions and popliteodistal bypasses. Patency and limb salvage rates were comparable to their CFA–

Figure 4



Kaplan–Meier analysis of the patient survival rates among different inflow bypasses.

Figure 5



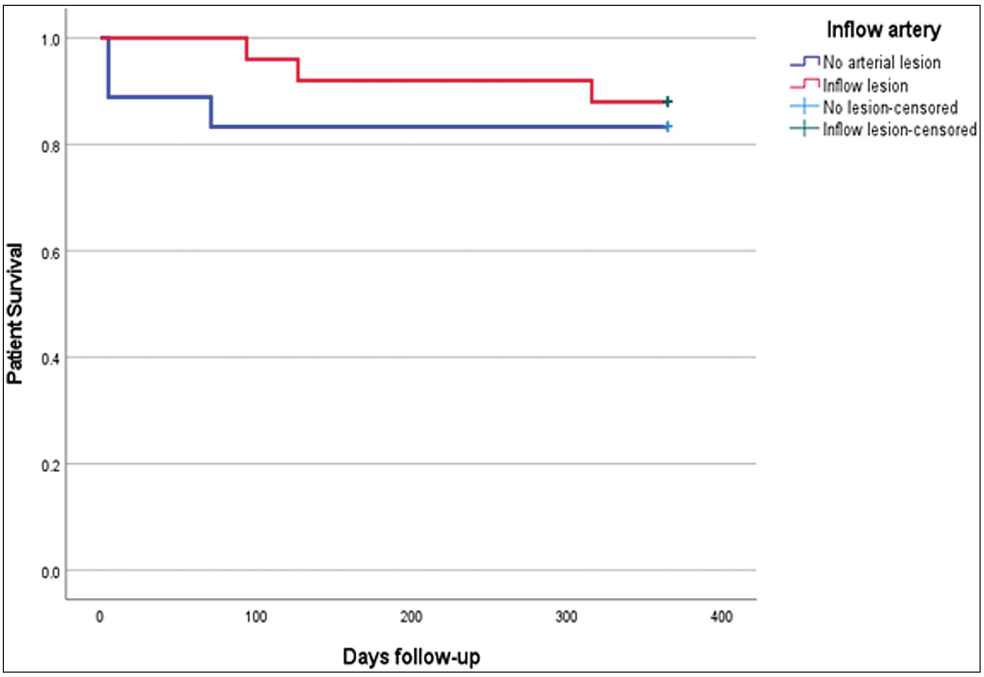
Kaplan–Meier comparison of overall graft patency according to presence/absence of inflow arterial lesions.

distal bypasses or popliteodistal bypasses without SFA angioplasty during the same period [12].

In the current study, we present a group of 25 patients who were candidates for distal bypasses originating from the PA with FP lesions that are treated by EVT. We combined endovascular and open surgical techniques by performing preoperative angioplasty of FP stenosis/occlusion, followed by a distal bypass graft originating from the PA above or below the knee.

In a study by Tsuji *et al.* [7]; advanced age, male sex, hypertension, and tobacco smoking were statistically significant risk factors for CLI. Similarly, in our study, type II diabetes mellitus, hypertension, male sex, and smoking were statistically significant risk factors for CLI.

Figure 6



Kaplan–Meier comparison of patient survival based on presence/absence of inflow arterial lesions.

In 2007, Schanzer and colleagues investigated 23 patients with CLI who had EVT for SFA lesions followed less than or equal to 30 days by distal origin grafts. SFA lesions were 11 (48%) TASC II-A, seven (30%) TASC II-B, five (22%) TASC II-C, and no TASC II-D. These were treated by POBA in 20 (87%) cases, and a self-expanding stent was inserted in three cases. Of the bypasses, five (22%) originated from the distal SFA, five (22%) originated from Pop-AK, and 13 (56%) originated from the Pop-BK. Distal anastomosis was to a pedal vessel in 11 (48%) cases and to a tibial vessel in 12 (52%) cases. Target lesion restenosis was encountered in only one patient necessitating salvage EVT to maintain patency [11].

In 2008, Lantis and colleagues retrospectively reviewed 22 patients with CLI presented with tissue loss in the foot, severe multilevel infrainguinal disease, and inadequate vein for femoro-distal bypass. SFA lesions were categorized as three (14%) TASC II-A, 13 (60%) TASC II-B, and six (27%) TASC II-C with no TASC II-D lesions. A total of 14 (64%) patients had POBA and eight (36%) had self-expandable stents placed for residual stenosis more than 30% or flow limiting dissection. No procedural failures had been recorded. Overall, eight (36%) bypasses originated from Pop-AK and 14 (64%) Pop-BK cases. The target outflow artery was the dorsalis pedis artery in six, the PTA in eight, the PerA in five, and the ATA in three cases. Primary patency was 95% at 3 months. One-year assisted-primary and secondary patency rates were the same at 68%. Patient survival and amputation rates were 76 and 5%, respectively [9].

Lantis *et al.* [13] and Marcucci *et al.* [9] suggested that FP EVT in preparation for popliteal-to-distal bypass is a useful and effective option for patients with CLI with both significant SFA lesion and limited vein conduit.

In 2017, Tsuji and colleagues reported 14 patients with CLI who underwent popliteal-to-distal bypass combined with FP EVT. FP lesions included three (21%) TASC II-A, eight (57%) TASC II-B, three (21%) TASC II-C, and no TASC II-D. POBA was performed in nine (64%) cases, and stent placement was necessitated in five cases. GSV was used in all bypasses. Target outflow arteries were the dorsalis pedis artery in 12 (85%) cases and the PTA in two cases. Technical success was achieved in all cases. At 12-month follow-up, primary patency rate was 79%, and assisted-primary and secondary patency rates were 93% each. Limb salvage rate was 93%, and patient survival rate was 92% [7].

In 2020, Barillà and colleagues analyzed 34 patients with CLI who had undergone hybrid revascularization in the form of SFA EVT plus popliteodistal vein graft bypass. Primary patency rates were 85 and 82% at 30 days and 12 months, respectively. Survival rates at 6 and 12 months were both 96% [14].

In our study, at 1-year follow-up, primary patency rate was 48%, assisted primary patency was 84%, and secondary patency rate was 96%. No 30-day mortality was recorded. At 12 months, no major amputation was

encountered, and patient survival rate was 88%. Wound healing at 12-month follow-up reached 96%.

In the current series, assisted-primary and secondary patency rates were comparable to the aforementioned studies [7,9,14] at 1 year. Our relatively low primary patency rate can be justified by the intensive duplex surveillance program picking up early graft failure (50% stenosis) requiring EVT or surgical intervention. A clearly defined follow-up system with a duplex surveillance program improves graft patency [15].

TASC II-B lesions (P=0.046) and female sex (P=0.022) were statistically significant independent factors for target lesion restenosis necessitating salvage angioplasty, thus meticulous follow-up is needed. Only two TASC II-D lesions were encountered in the current study, necessitating further multicenter studies before validating this hybrid strategy in such challenging patient group.

There were no statistically significant differences between Pop-AK and Pop-BK originating bypasses regarding inflow vessel restenosis, primary patency, assisted primary patency, secondary patency, and patient survival rates. In addition, graft patency and patient survival rates are comparable between distals of EVT treated inflow lesions and distals without EVT due to absent proximal lesions (Figs 5 and 6).

Conclusion

Femoro-popliteal angioplasty in preparation for popliteodistal bypass is effective for patients with CLI, especially those with both significant SFA lesion and limited vein conduit. Such technique is a useful and effective therapeutic option in patients with CLI because of durable patency, acceptable wound healing rates, and good limb salvage. Durability and patient survival of this hybrid approach are comparable to those of distal origin bypasses with no proximal lesions requiring endovascular interventions.

Limitation

This study is limited by the small sample size, being a single-center study, in addition to long duration of patient recruitment, which makes long-term follow-up difficult.

Recommendation

Further multicenter studies on TASC II-D patients with long-term follow-up are needed.

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Conflicts of interest

There are no conflicts of interest.

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