Acta Clin Croat 2025; 64:301-308
doi: 10.20471/acc.2025.64.02.14

Original Scientific Paper

COMPARISON OF ENDOVASCULAR INTERVENTION AND DISTAL-LEG BYPASS FOR BELOW-THE-KNEE CHRONIC LIMB-THREATENING ISCHEMIA

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SUMMARY – Chronic limb-threatening ischemia (CLTI) is the main cause of major amputation and associated morbidity and mortality. Currently, both endovascular and open surgical methods for below-the-knee (BTK) interventions result in unsatisfactorily short patency rates. The aim of this retrospective single-center study was to evaluate six-month and one-year primary patency and major amputation rate in patients with CLTI treated with distal-leg bypass or BTK endovascular intervention. Overall, 46 patients underwent BTK intervention and 32 were available for follow-up analysis. Nine surgical bypasses and 23 endovascular treatments (balloon angioplasty) were performed. Six-month and one-year primary patency was 5/9 (55%) after bypass and 18/23 (78%) and 16/23 (69%) following endovascular intervention (p=0.20 and p=0.46). Angiography findings, predominantly advanced atherosclerosis, precluded any secondary intervention attempts. At one year post-intervention, the incidence of major amputation was 3/9 (33%) after bypass surgery and 5/23 (22%) following endovascular treatment. Although endovascular intervention for BTK CLTI seems to offer better 12-month patency and lower incidence of major amputation compared to bypass surgery, no statistically significant difference was noted. A randomized trial with more subjects and longer follow-up should be undertaken.

Key words: *Angioplasty; Endovascular treatment; Chronic limb-threatening ischemia; Limb salvage; Peripheral artery disease; Vascular bypass*

Introduction

Lower extremity artery disease (LEAD) is the third leading cause of atherosclerotic cardiovascular morbidity, following coronary artery disease and stroke. LEAD affects nearly one fifth of all adults older than 55 years, with increased prevalence in smokers and patients with diabetes or renal insufficiency[1]. Clinical presentation varies from asymptomatic disease to intermittent claudication, atypical leg pain, chronic limb-threatening ischemia (CLTI), and occasionally acute ischemia. CLTI is the most severe form of LEAD, occurring in less than 10% of all patients. It is defined by rest pain, gangrene, or lower limb ulceration of more than two-week duration associated with one or more abnormal hemodynamic parameters such as ankle-brachial pressure index (ABI) <0.4, systolic ankle pressure <50 mm Hg, toe pressure <30 mm Hg, transcutaneous partial pressure of oxygen <30

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Received March 7, 2023, accepted July 8, 2023

mm Hg, and flat or minimally pulsatile pulse volume recording waveforms[2]. Patients with CLTI have a 1-year mortality rate of approximately 20% to 25%, and 5-year all-cause mortality rates exceed 50%[2,3]. Management strategies include pain control, wound healing, revascularization, and optimizing coexistent cardiovascular risk factors. To prevent limb amputation, revascularization should be attempted. Unfortunately, some patients have no revascularization option, especially long-standing diabetics, dialysis dependent patients, and those with failed previous revascularization attempts. In these circumstances, just as if CLTI is not treated, amputation remains the last option to avoid complications of irreversible ischemia[4]. CLTI caused by below-the-knee (BTK) disease represents a revascularization challenge due to diffuse lesions, small vessel diameter, poor outflow, and calcifications[5]. Few scientific data are available to identify the optimal revascularization strategy in this setting. The aim of this study was to compare the outcomes of endovascular and surgical revascularizations in patients with CLTI due to BTK lesions with the presumption that according to the literature[13], distal-leg bypass has superior results than endovascular intervention regarding primary patency and lack of major amputation (MA).

Patients and Methods

This was a retrospective single-center study which included all patients who underwent distal-leg bypass surgery with distal anastomosis below the third segment of the popliteal artery (P3) or endovascular BTK intervention for CLTI in a two-year period between January 1, 2019 and December 31, 2020.

Data were collected from the hospital central information system and theater reports, and radiological images were retrieved and analyzed from the radiological image computer database. Data on patient demographics (age and sex), comorbidities (diabetes, smoking, anemia, renal insufficiency, and other systemic conditions), MA rate and patency of the bypass/intervention were collected. Amputations were classified as minor (transmetatarsal and toe amputations) and major amputations (above the knee and BTK amputation), according to the severity of functional disability after amputation.

Bypass and intervention patency was assessed by Doppler examination, and if unclear, multi-slice computed tomography angiography (MSCTA) was performed.

The inclusion criteria were CLTI defined as rest pain with ABI <0.4 or tissue loss and Trans-Atlantic Inter-Society Consensus (TASC) D lesion on MSCTA.

The indication for the intervention was made on a case-by-case basis by the multidisciplinary hospital team (MDT) for peripheral arterial occlusive disease consisting of vascular surgeons, cardiologists (angiologists) and interventional radiologists. The decision on the feasibility of intervention was made based on patient medical history, walking distance, ABI, and plethysmography curve analysis, and type of intervention was based on morphological appearance and atherosclerotic plaque distribution on MSCTA.

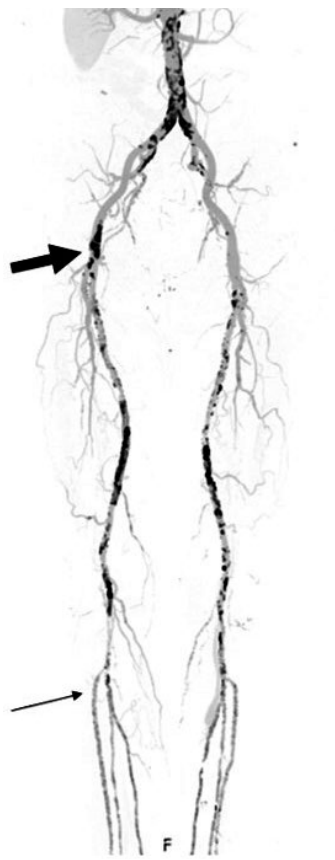

Fig. 1. Preoperative multi-slice computed tomography angiography of a patient selected for bypass surgery. Thick arrow: proximal anastomosis site; thin arrow: distal anastomosis target vessel site.

Surgery was the first choice if the lesion was TASC D with one target vessel (anterior or posterior tibial artery) patent in continuity from the distal leg to the foot (Fig. 1). Otherwise, endovascular procedure was indicated (Fig. 2).

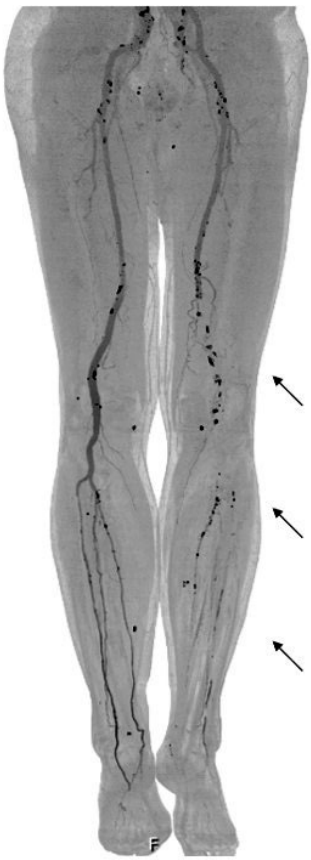

Fig. 2. Preinterventional multi-slice computed tomography angiography of a patient selected for endovascular intervention. Arrows pointing to target vessels for interventions.

All patients received best medical treatment for at least three months before any kind of intervention (maximal walking effort, blood pressure improvement, optimization of glycemia, and statin therapy).

Surgery

Reversed autologous greater saphenous vein graft was used as a conduit in all patients who underwent surgery. Intraoperatively, three minutes before vessel clamping, all bypass patients received intravenously 5000 IU of unfractionated heparin (Heparin Sodium®, Belupo, Croatia). Postoperatively patients received 5000 IU of unfractionated heparin every six hours during the first two postoperative days, followed by low molecular weight heparin once daily until discharge. All patients were discharged with mono antiplatelet therapy (MAPT), dual antiplatelet therapy (DAPT), anticoagulation therapy (warfarin or non-vitamin K antagonist oral anticoagulant (NOAC)) or a combination.

Endovascular intervention

Percutaneous transluminal balloon angioplasty (PTA) was done in all patients and a bare metal stent was placed if intraprocedural dissection of the target vessel was noted (five patients). Bolus of 5000 IU of unfractionated heparin was administered at the end of the procedure, followed by DAPT. All patients were discharged with DAPT or anticoagulant therapy.

The follow-up period was 12 months after the procedure. Follow-up appointments with Doppler examination were scheduled at one, two, four and eight weeks, then at 6 and 12 months after the procedure.

Due to the advanced BTK atherosclerosis, the MDT decided that no secondary procedures would be attempted in case of treatment failure/graft thrombosis. Therefore, only primary patency data were available for analysis. If gangrene or rest pain with no improvement on oral analgesia occurred, amputation was indicated.

Statistical analysis was performed using Microsoft Office Excel and Medcalc Statistical Software (MedCalc Software Ltd., ver. 15.1).

Results

Data on 46 patients who underwent distal-leg bypass or BTK intervention for CLTI in the study period were collected. After exclusion of 14 patients (all from the endovascular group) who were lost to follow-up, data on 32 patients were analyzed, i.e., 23 patients in the endovascular group and nine patients in the bypass group. There was no difference between the two groups in patient age, smoking status, and incidence of comorbidities. Patient data are shown in Table 1.

Table 1. Patient data

N=32		**Distal-leg bypass** (n=9)	**Endovascular intervention** (n=23)
Sex (male/female) Age (yrs), mean (range) Diabetes Renal insufficiency		8/1 66 (52-81) 6 1	18/5 68 (33-86) 10 8
Patency	at 6 months at 1 year	5/9 (55%) 5/9 (55%)	18/23 (78%) 16/23 (69%)
MA rate	at 6 months at 1 year	0 3/9 (33%) (3 of 4 occluded bypasses)	4/23 (17%) 5/23 (22%) (5 of 7 occluded interventions)
Postprocedural therapy	MAPT DAPT	4 (ASA 1 x 100 mg) 2 (ASA 1 x 100 mg + clopidogrel 1 x 75 mg)	1 19 (ASA 1x 100 mg + clopidogrel 300 mg postprocedure, followed by 1x 75 mg)
	warfarin NOAC DAPT + NOAC	1 1 (rivaroxaban 2x2.5 mg) 1 (ASA + clopidogrel + rivaroxaban)	0 2 0
Postprocedural complications	MI In-hospital death Bleeding Early occlusion	1 0 0 1	0 0 1 (resulted in amputation) 0

MI = myocardial infarction; MA = major amputation; ASA = acetylsalicylic acid; MAPT = mono anti-platelet therapy; DAPT = dual anti-platelet therapy; NOAC = non-vitamin K antagonist oral anticoagulants

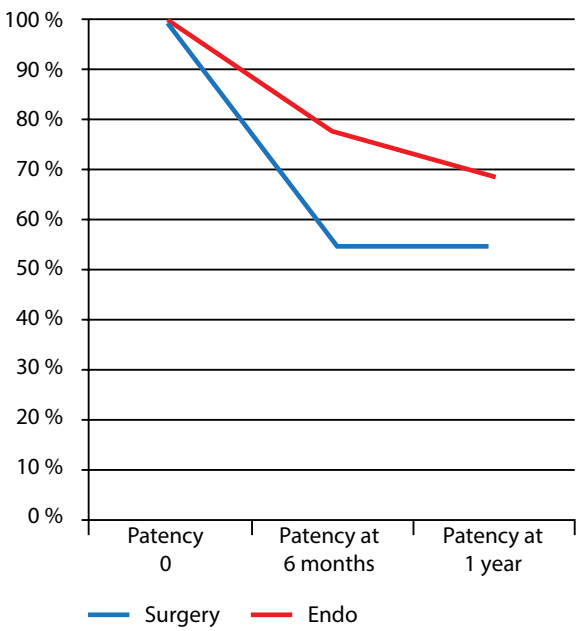

Fig. 3. Six-month and one-year patency after distal leg bypass (surgery) and below-the-knee endovascular intervention (endo).

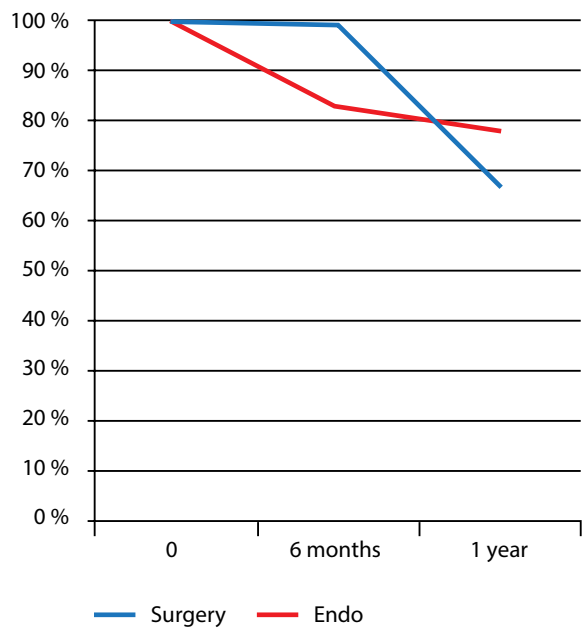

Fig. 4. Percentage of patients with no major amputation during follow-up.

Patency

Patency was analyzed at 6 and 12 months after surgery/intervention. In the bypass group, six-month and one-year patency were the same (5/9 patients, 55%); all the bypasses occluded in the first six months after surgery. In the endovascular group, six-month patency was 18/23 (78%) and one-year patency was 16/23 (69%) patients (Fig. 3). There was no statistically significant difference in six- and 12-month patency between the bypass and endovascular group (six months: 95% CI -9.72 to 54.22, χ^2 1.628, DF 1, p=0.2020; 12 months: 95% CI -18.87 to 46.42, χ^2 0.54, DF 1, p=0.4623).

Major amputation rate

All patients who underwent bypass procedure had their leg saved for at least first six months after the procedure, even though their bypass patency might have last for less than six months. No MA had to be performed in the first six months in this group. Three MAs were performed 6-12 months after surgery. All three amputations were performed in patients with occluded bypasses (4/9 patients). The overall MA rate in the bypass group was 3/9 (33%).

In the endovascular group, all MAs were performed in patients with occlusion after the intervention (7/23 patients). Four MAs were performed during the first six months post-intervention. Among those patients was one in whom a stent was placed during endovascular procedure due to flow-limiting dissection of the target vessel. One MA was performed in the period of 6-12 months after the intervention. The overall MA rate in the endovascular group was 5/23 (22%). There was no statistically significant difference in six- and 12-month incidence of MA between the bypass and endovascular group (95% CI -17.7 to 45.1, χ^2 0.450, DF 1, p=0.5023).

Peri- and postprocedural complications

In the bypass group, two major complications were noted. One patient developed early graft thrombosis on the first postoperative day but he did not require MA during the follow-up period and managed to improve walking distance. The other patient sustained myocardial infarction, underwent percutaneous coronary intervention and had a patent bypass during follow-up.

In the endovascular group, six major complications were noted. Five patients developed dissection of the target vessel during the procedure, which was treated with bare metal stent placement. One patient developed iatrogenic bleeding of the target vessel intra-procedurally, which required leg amputation.

Postprocedural therapy

In the bypass group, all patients were discharged with antiplatelet therapy and/or anticoagulant therapy. Four patients were discharged with MAPT (acetylsalicylic acid (ASA) 1x100 mg/day), two with DAPT (ASA 1x100 mg and clopidogrel 1x75 mg), one with warfarin, one with NOAC (rivaroxaban 2x2.5 mg), and one with DAPT and NOAC because he sustained myocardial infarction during early postoperative period.

Of the four patients with bypass occlusion, MA was performed in three of them, i.e., two patients received only MAPT (ASA) and one received a DAPT and NOAC combination. One patient (bypass occlusion on the first postoperative day) was discharged with ASA and NOAC, and no amputation was performed during follow-up.

In the endovascular group, 22/23 patients were discharged with antiplatelet or anticoagulant therapy. The patient who suffered iatrogenic bleeding of the target vessel during the procedure underwent amputation, and was discharged without DAPT. Of the 22 patients discharged with therapy, 19 were discharged with DAPT (ASA 1x100 mg + clopidogrel 300 mg postprocedure, followed by 1x75 mg/day), one patient with MAPT (ASA 1x100 mg/day) because he refused DAPT, and two with NOAC (rivaroxaban 2x2.5 mg) because it was introduced before the intervention for cardiac reasons.

The patient who refused DAPT underwent MA four months after the procedure. Patients discharged with NOAC did not undergo MA and had patent target vessels during follow-up.

Discussion

This study aimed to compare six-month and one-year primary patency and MA rate in patients with CLTI due to BTK atherosclerotic disease treated with distal-leg bypass and BTK endovascular intervention. No statistically significant difference was found regarding both primary patency and MA rate.

Autologous vein bypass is considered the gold standard for the treatment of CLTI due to TASC-C and TASC-D above-the-knee lesions[13,15]. For BTK lesions, both the bypass surgery and endovascular intervention are employed[13-15].

Several studies analyzed primary patency and incidence of MA after bypass surgery and endovascular intervention for CLTI due to BTK atherosclerotic plaque distribution, with one or more years of follow-up[6,7,9-11,13-16]. Although the studies were retrospective and heterogeneous due to diverse patient selection and intervention methods, similar patency and MA rates have been reported in patients who underwent endovascular intervention or surgery (12-month patency ranging from 50% to 70%, MA rate around 20%).

The study by Hicks *et al.*[16] from 2016 favored endovascular approach for one-year primary patency was 80% (*vs.* 73% in the bypass group), although there was no difference in one-year MA rate (12% *vs.* 14%). Several facts can explain better primary patency in the endovascular group, i.e., there were significantly more smokers, distal target vessel (e.g., 30% of bypasses were done to the dorsal pedal artery *vs.* 0% in the endovascular group, and 44% of endovascular interventions were done on the popliteal artery *vs.* 0% in the bypass group). Large studies such as BASIL trial[17] have shown similar short-term (1-year) results with endovascular or bypass surgery, but better MA rates two years post-procedure in patients who underwent bypass surgery. This is as expected since it is well known that, provided a good target vessel and no disease progression, autologous vein bypass offers better patency than endovascular intervention[2]. On the other hand, BASIL-2[18] study found similar MA rates after endovascular interventions, but with more re-interventions in the endovascular group (19% *vs.* 5%) and significantly higher all-cause mortality in the bypass group. A large BEST-CLI[19] study found a significantly lower incidence of adverse events (such as MA) among patients with CLTI who had an adequate great saphenous vein when compared to the endovascular group. When an autologous vein conduit was not available, outcomes in the two groups were similar.

Based on the available data, optimal strategy for BTK CLTI patients is not clear; instead, it should be decided on a case-to-case basis at MDT meetings[2]. All MDTs should perform regular audits to compare their institution outcomes with data from other centers. Large randomized trials are difficult to conduct mainly because of the heterogeneity among CLTI patients in comorbidities, plaque characteristics and distribution, different natural disease progression and autologous vein availability. Optimal endovascular intervention method is also unclear due to variability among centers, different operator preferences, and the fact that new techniques are often performed before proper comparison to the well-established and standard methods[2].

The CLTI with only BTK arteries as target vessels is challenging and requires MDT approach, preoperative planning and preparation, microvascular technique, hybrid approach due to variability in plaque distribution and distal vessel patency, and postoperative rehabilitation[20].

This analysis showed single medium volume center results that are similar to the data available in the literature. Both bypass surgery and endovascular intervention offer similar results in patients with CLTI due to predominantly BTK atherosclerotic disease.

Concerning study limitations, the small number of patients precluded statistical analysis, and 30% of patients were lost to follow-up.

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Sažetak

USPOREDBA ENDOVASKULARNE INTERVENCIJE I DISTALNOG PREMOŠTENJA KOD POTKOLJENIČNOG TIPA KRONIČNE ISHEMIJE KOJA UGROŽAVA EKSTREMITET

J. Figl, I. Škorak, D. Papeš, I. Romić, S. Figl i *M. Vrkić Kirhmajer*

Kronična kritična ishemija donjih ekstremiteta (*chronic limb-threatening ischemia*, CLTI) glavni je uzrok velikih amputacija i povezanog pobola i smrtnosti. Trenutno endovaskularne i otvorene kirurške metode za intervencije ispod koljena (*below-the-knee*, BTK) rezultiraju nezadovoljavajuće kratkim stopama prohodnosti. Cilj ove retrospektivne studije provedene u jednom centru bio je procijeniti šestomjesečnu i jednogodišnju primarnu prohodnost i stopu velikih amputacija u bolesnika s CLTI liječenih distalnom premosnicom ili endovaskularnom intervencijom ispod koljena. Ukupno je 46 bolesnika bilo podvrgnuto BTK intervenciji, a 32 su bila dostupna za naknadnu analizu. Učinjeno je devet kirurških premosnica i 23 endovaskularna tretmana (balonska angioplastika). Šestomjesečna i jednogodišnja primarna prohodnost bila je 5/9 (55%) nakon premosnice te 18/23 (78%) i 16/23 (69%) nakon endovaskularne intervencije (p=0,20 i p=0,46). Angiografski nalaz, pretežno uznapredovala ateroskleroza, onemogućio je bilo kakve pokušaje sekundarne intervencije. Incidencija velikih amputacija godinu dana nakon intervencije bila je 3/9 (33%) nakon operacije premosnice i 5/23 (22%) nakon endovaskularnog liječenja. Iako se čini da endovaskularna intervencija za BTK CLTI nudi bolju 12-mjesečnu prohodnost i nižu incidenciju velikih amputacija u usporedbi s operacijom premosnice, nije primijećena statistički značajna razlika. Trebalo bi provesti randomizirano ispitivanje s više ispitanika i dužim praćenjem.

Ključne riječi: *Angioplastika; Endovaskularna intervencija; Kronična kritična ishemija nogu; Periferna arterijska bolest; Spašavanje ekstremiteta; Vaskularno premoštenje*