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Long-term Results of Inframalleolar Bypass for Critical Limb Ischaemia

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WHAT THIS PAPER ADDS

As the population ages and the incidence of diabetes increases, the expected number of patients with critical limb ischaemia requiring ultra-distal revascularizations will remain high or even increase. This retrospective study investigated the long-term results of inframalleolar bypass for critical limb ischaemia. The results of this study demonstrate that inframalleolar bypass yields excellent long-term patency and good limb salvage can be achieved in both non-diabetic and diabetic patients.

Introduction: As the population ages and the incidence of diabetes increases, the expected number of patients with critical limb ischaemia (CLI) requiring distal revascularization will remain high or even increase. The aim of this study was to investigate the long-term results of inframalleolar bypass.

Material and methods: A total of 352 inframalleolar bypasses for CLI performed between 2002 and 2013 were included. Risk factors were evaluated and patency (both clinical and imaging based), leg salvage, survival, and amputation free survival (AFS) assessed.

Results: The median follow up was 30 months (mean 42 months, range 1—186 months). The median age of the study population was 73 years, and 67% of the patients were male. The incidence of diabetes was 69%. In the majority of cases (82%), the indication for bypass was an ulcer or gangrene, and the remaining 18% of the patients had rest pain. Primary, assisted primary, and secondary clinical patency was 71.2%, 76.5%, 81.0%, and 59.7%, 69.3%, and 70.7%, and 49.0%, 58.6%, and 68.4% at 1, 5, and 10 years, respectively. The last imaging based secondary patency at 1, 5, and 10 years was 79.3%, 68.1%, and 62.8%, respectively. The popliteal artery as the inflow artery ($n = 194$) was associated with superior primary ($p = .013$), assisted primary ($p = .028$), and secondary patency ($p = .014$) when compared with bypasses originating from the femoral artery ($n = 158$). The leg salvage rate at 1, 5, and 10 years was 78.6%, 72.0%, and 67.2%, respectively. Leg salvage was equal in patients with and without diabetes ($p = .460$). The respective survival and AFS rates at 1, 5, and 10 years were 70.3%, 37.4%, and 15.9%, and 58.4%, 29.8%, and 12.8%.

Conclusion: Bypass to the foot arteries yielded excellent long-term patency, and good limb salvage can be achieved in both non-diabetic and diabetic patients.

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INTRODUCTION

Severe peripheral artery disease (PAD) affects the crural arteries especially in patients with diabetes and those of advanced age.[1] As the population ages and the incidence of diabetes increases, the expected number of patients with critical limb ischaemia (CLI) requiring extensive revascularization will remain high or even increase in the future. The pattern of atherosclerosis is unique in patients with diabetes; despite excessive occlusive disease in the crural arteries, the foot arteries are often preserved,[2,3] allowing a pedal bypass in cases of limb threatening ischaemia.

Endovascular revascularization procedures have challenged bypass surgery as the first line treatment for CLI. This is mainly due to their less invasive nature and subsequent better short-term survival rates, especially in elderly patients.[4,5] Excellent technical success as well as short- and mid-term outcomes for endovascular revascularization of crural arteries have been reported.[6] A good technical success rate for endovascular revascularization of foot arteries has also been described.[7] However, long-term results for these procedures are lacking in the literature. On the other hand, excellent mid- and long-term results of pedal[8—10] and plantar or tarsal artery bypass[11] had already been reported as early as 20 years ago.

Despite rapidly evolving endovascular techniques, there are still patients with multi-level infrainguinal disease and long calcified occlusions not amenable to endovascular procedures. Unsuccessful endovascular revascularization or

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repeated occlusions of crural arteries after endovascular revascularization are also indications for bypass to the pedal or plantar arteries. Furthermore, even after successful endovascular revascularization, legs with a large soft tissue lesion often tend not to heal. These patients with extensive tissue loss need rapid and maximum reperfusion of the foot and might therefore benefit from surgical revascularization of the foot arteries. Moreover, one special indication for pedal or plantar bypass is simultaneous microvascular flap reconstruction.[12]

At Helsinki University Hospital, the treatment policy for CLI has traditionally been aggressive. Only patients who are bedridden, in permanent institutional care, or who suffer from extensive dementia have been excluded from revascularization. Although endovascular treatment has gained popularity, the threshold for surgical bypass has been low for patients with long occlusions, or when endovascular revascularization fails, or when the leg does not show healing potential after endovascular treatment. The aim of the study was to critically evaluate the recent long-term results of inframalleolar bypass, to compare the results of these bypasses between diabetics and non-diabetics, and to assess the role of the inflow and outflow arteries in these ultra-distal bypasses.

MATERIAL AND METHODS

A total of 352 patients underwent inframalleolar bypass for CLI at Helsinki University Hospital between January 2002 and December 2013. These patients were included in this retrospective study. Demographic data, procedural details, post-operative outcome, and follow up data were collected prospectively into the institutional vascular and endovascular database (Husvasc) and scrutinized retrospectively from the patients' case records. The demographic data included age, sex, comorbid conditions (diabetes, coronary artery disease, hypertension, dyslipidaemia, cerebrovascular disease, renal insufficiency), and smoking history. The procedural data contained the indications for and details of the bypass, such as the inflow and outflow vessels as well as graft materials. The post-operative data included complications and outcome at discharge. The follow up data comprised limb status, graft patency, and the dates of any graft revisions (surgical or endovascular) or graft occlusion as well as the dates of possible major amputation and/or death. The dates of death and amputations were cross-checked and, if missing, retrieved from the Population Register Centre, and the amputation registry, respectively.

Pre-operative assessments and details of the procedure

Only bypasses to the arteries below malleolar level (the dorsalis pedis, tarsal, or plantar arteries) were included. Tarsal artery bypasses were analysed in same category as pedal bypasses. The suitability of the inflow and outflow arterial anatomy for bypass was evaluated by means of magnetic resonance angiography (MRA) or conventional digital subtraction angiography (DSA). If there was no visible recipient artery on the MRA or DSA, duplex ultrasound (DUS) was performed to find a potentially open recipient artery in the foot. During the earlier years of the study, a blind exploration of a dorsalis pedis or plantar artery not seen on angiography but thought to be patent on the basis of an audible Doppler signal was occasionally performed.

Autologous vein grafts were used whenever possible. The size and quality of the vein material was evaluated preoperatively with ultrasonography, and the best available vein graft was preferred. Thus, in the absence of the ipsilateral great saphenous vein (GSV), the contralateral GSV was used as a conduit unless the donor limb was obviously ischaemic. Arm veins or the small saphenous vein were used if a usable GSV (ipsilateral or contralateral) was absent. If a single segment vein graft was not available, a spliced vein graft with two or more segments was applied. In most cases, a non-reversed, translocated vein graft was used, but the operating surgeon eventually decided, case by case, whether the vein graft was to be used in a reversed or non-reversed configuration. If a spliced vein graft was applied, reversed or non-reversed vein segments were employed to minimise the size mismatch of the vein to vein and the conduit to artery anastomoses. A prosthetic graft with a vein cuff was used in four cases in the absence of a usable vein graft.

Transit time flow measurement was carried out to ensure adequate graft flow (mL/min) at the end of the procedure. If the graft flow was considered compromised, intraoperative duplex scanning was performed to exclude graft segments of inappropriate quality and technical defects in anastomoses. Angioscopy or intra-operative angiography was used selectively, not routinely. Intra-operative heparin was administered to all patients according to their weight, and the adequacy of the heparinization was controlled using activated clotting time (ACT) assessment. All patients received weight adjusted doses of low molecular-weight heparin twice a day post-operatively until discharge and acetylsalicylic acid (ASA) 100 mg per day indefinitely if there were no contraindications (aspirin allergy). Some patients received clopidogrel instead of aspirin (aspirin allergy, previous coronary balloon angioplasty, etc.). Warfarin was not used routinely unless there was a clear indication for it (atrial fibrillation, thrombophilia, etc.).

The standard surveillance protocol included follow up visits at 1, 6, 12, and 24 months post-operatively. Patients with open wounds or with a graft revision or at risk graft were followed up more frequently. Each follow up visit included an inspection of limb status as well as pulse palpation and the measurement of ankle brachial indices and toe pressures. Duplex scanning of the entire graft and both anastomoses was performed and, if a significant stenosis (velocity ratio $[v_1/v_2] \geq 3$) was suspected, angiography and balloon angioplasty (percutaneous transluminal angioplasty, (PTA)) were scheduled. After a surgical revision or graft PTA, the surveillance protocol was repeated from the beginning. In September 2014, all patients who were alive without an amputation were invited to a late follow up where duplex scanning of the graft was performed to verify graft patency. The patient records of those who underwent a major amputation of the index limb during the study period were checked to evaluate whether the graft was patent or occluded at the time of the amputation. For those patients who died during the study period, the graft patency was assessed using last imaging (DUS, MRA, or DSA) based patency. Clinical patency (last date when graft pulse was detected) was also assessed, because in pedal and plantar bypasses the graft lies superficially and therefore the graft pulse can easily be palpated.

Diabetes was defined as hyperglycaemia requiring a special diet, oral medication, or insulin treatment. Coronary artery disease (CAD) was defined as a previously documented myocardial infarction and/or ongoing angina pectoris, or previous coronary bypass surgery or a percutaneous coronary intervention. Cerebrovascular disease was defined as a previous stroke or transient ischemic attack (TIA). Renal dysfunction was determined if the serum creatinine level was >120 μmol/L.

Statistical analysis

Continuous variables are expressed as median, SD, and range and the prevalence of risk factors as proportions. Survival, leg salvage, and amputation free survival rates with mean standard errors (SE) were calculated with the Kaplan—Meyer method. The Mantel—Cox log rank test was used to compare survival curves. Statistical analysis was performed using SPSS 19.0 statistical software (IBM SPSS Inc., Chicago, IL, USA). The study protocol was approved by the Institutional Review Board of Helsinki University Central Hospital (Department of Surgery).

RESULTS

The median follow up was 30 months (mean 42 months, range 1—186 months). The median age was 73 years, and 67% of the patients were male. The incidence of diabetes was 69%, and 68% of the patients had coronary artery disease. The incidence of renal insufficiency was 26%. In the majority of cases (82%), the indication for bypass surgery was an ulcer or gangrene (Fontaine class IV), but 18% of the patients had rest pain alone (Fontaine class III) (Table 1). All except four bypasses (99%) were performed using a vein graft. All four prosthetic bypasses occluded within 4 months. The majority of the vein grafts (n = 241) were single segment GSV grafts. There were 24 alternative autologous vein grafts (small saphenous vein and cephalic vein), and 82 bypasses were performed using spliced vein grafts (Table 2).

Seventy-nine (22.4%) patients had undergone previous endovascular treatment to the index limb before inframalleolar bypass.

At the end of the study period, 104 patients were alive and 83 of them had not undergone amputation. Of these patients, 42 had attended a recent follow up visit with routine duplex scan and the patency of the grafts was documented in their records. The remaining 41 patients with uncertain graft patency were re-checked. Twenty-five patients attended a late follow up visit and graft patency was assessed with DUS. Sixteen patients were not able to attend the late visit. Of these, five patients had undergone MRA showing a patent graft. The remaining 11 patients were visited by a vascular nurse and the patency of the graft was confirmed by portable ultrasound (Fig. 1).

Table 1. Demographic data of the study population.

Demographics	n	%
Age, mean (median)	37—99 (73)	
Male sex	235	67
Hypertension	285	81
Dyslipidaemia	267	76
CAD	238	68
DM	240	69
Renal insufficiency[a]	90	26
Cerebrovascular disease	84	24
Current smoking	145	41
COPD	59	17
Indication		
Rest pain	64	18
Ulcer	215	61
Gangrene	73	21

CAD = coronary artery disease; COPD = chronic obstructive pulmonary disease; DM = diabetes mellitus.
[a] Serum creatinine >120 μmol/L.

Clinical primary, assisted primary, and secondary patency was 71.2%, 76.5%, and 81.0%, 59.7%, 69.3%, and 70.7%, and 49.0%, 58.6%, and 68.4% at 1, 5, and 10 years, respectively. Imaging based secondary patency was 79.3%, 68.1%, and 62.8% at 1, 5, and 10 years, respectively (Fig. 2A—D, Table 3). The popliteal artery as the inflow artery (n = 194) was associated with superior primary (p = .013), assisted primary (p = .028), and secondary patency (p = .014) compared with bypasses originating from the femoral artery (n = 158) (Fig. 3A—C). Similarly, leg salvage at 1, 5, and 10 years was better in bypasses originating from the popliteal artery (81.1% vs. 75.1%, 79.2% vs. 64.2%, and 71.8% vs. 64.2%, respectively; p = .042). The recipient artery did not affect patency; bypasses to dorsalis pedis artery

Table 2. Operative details of the study population.

Operative details	n	%
Primary/redo	286/66	81/19
Elective/urgent	161/191	46/54
Inflow		
Femoral artery	158	45
Popliteal artery	194	55
Outflow		
DPA	281	80
Plantaris	71	20
Graft material		
Autologous vein		
1 piece	266	76
GSV	241	
SSV	4	
Arm vein (cephalica)	20	
Spliced vein	82	23
Prosthesis (PTFE)	4	1

DPA = dorsalis pedis artery; GSV = great saphenous vein; SSV = small saphenous vein; PTFE = polytetrafluoroethylene.

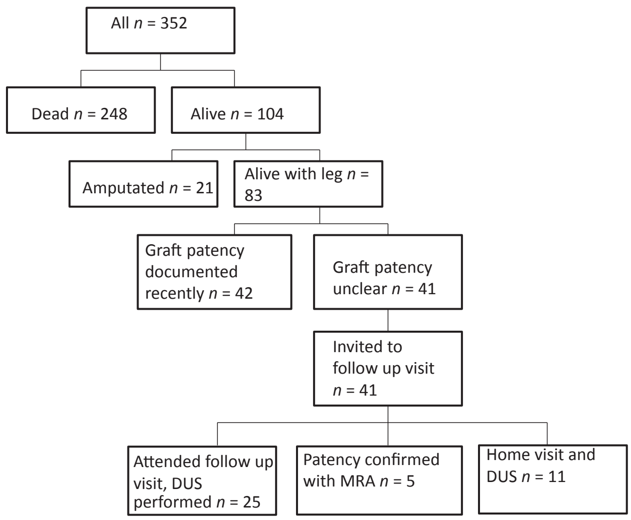

Figure 1. Flowchart of patients undergoing inframalleolar bypass. DUS = duplex ultrasound; MRA = magnetic resonance angiography.

($n = 281$) had the same patency as bypasses to the plantar artery ($n = 71$) ($p = .920$). The leg salvage rate of the overall study population at 1, 5, and 10 years was 78.6%, 72.0%, and 67.2%, respectively. Leg salvage was equal in patients with and without diabetes ($p = .460$; Fig. 4). The respective survival and amputation free survival (AFS) rates at 1, 5 and 10 years were 70.3%, 37.4%, and 15.9%, and 58.4%, 29.8%, and 12.8% (Table 3).

There was no differences between primary (81%) and redo bypasses (19%) regarding primary patency ($p = .611$), assisted primary patency ($p = .344$), secondary patency (0.690), leg salvage ($p = .510$) or survival ($p = .120$). Previous endovascular treatment did not have impact on patency (primary patency $p = .396$; assisted primary patency $p = .491$; secondary patency $p = .132$), or survival ($p = .387$). However, there was a trend towards better leg salvage in patients without previous endovascular treatment (at 1 year 80.4% vs. 69.9%, at 5 years 72% vs. 61.4%, at 10 years 64.8 vs. 53.7%), but the difference was not statistically significant ($p = .069$).

The peri-operative (30 day) mortality rate was 6.5%. Early (30 day) graft failure rate was 4.3%. Cardiac complication (post-operative myocardial infarction or unstable angina) occurred in 16 (4.5%) patients. Eight patients (2.3%) had post-operative pneumonia and one patient (0.2%) had post-operative sepsis. Post-operative renal failure (serum creatinine rise $>$50% from the pre-operative level) occurred in two patients (0.6%).

DISCUSSION

This study demonstrates that good long-term patency and leg salvage can be achieved with distal bypasses to the foot arteries. The patency was not inferior in diabetic patients compared with non-diabetics. Furthermore, it was found that the patency was significantly higher if the inflow was taken from the popliteal artery as opposed to groin level.

The limitations of this study are the lack of a control group as well as its retrospective nature. Other flaws are the lack of data regarding wound healing, relief of rest pain and functional outcome (return to mobility, etc.). The standard duplex surveillance lasted only 2 years. However, those patients who were alive with a leg were invited to a late follow up visit and the graft patency was assessed with duplex scanning. For those patients who had died during the study period, both last imaging based and clinical patency were assessed. Comprehensive data on amputations and deaths were also available as they were extracted from national registries. As regards these outcome measures, no patients were lost to follow up.

The results in terms of patency and leg salvage are similar to those published by Pomposelli et al.,[9] whereas survival in the present series was less good. A probable reason for the inferior survival is the higher median age of the patients and the high incidence of coronary artery disease in this study. This reflects the fact that there were two types of patients undergoing inframalleolar bypass, younger diabetics with distal PAD and elderly patients with multi-level PAD. The latter group has several comorbid conditions and can be considered as high risk.

One interesting finding was the patency—leg salvage gap. At 1 year, the secondary patency was better than the leg salvage rate, indicating that there were amputations performed with a patent graft. This phenomenon has been documented in other series mostly including diabetic patients. In the series of Carsten et al.,[13] persistent infection despite a patent bypass was the reason for early amputations in 4.4% of the patients. Similarly, Virkkunen et al.[14] reported that, after bypass for CLI, significantly more diabetic than non-diabetic patients underwent an amputation despite successful revascularization. On the other hand, at 5 and 10 years, the leg salvage was better than secondary patency, indicating that once the ischaemic lesion has healed, later graft occlusion does not necessarily lead to limb loss. A similar finding has been published by others.[15]

In this series, the patency and leg salvage rate of bypasses originating from the popliteal artery was superior to those originating from the femoral artery. The leg salvage rate of these bypasses remained over 70% at 10 years. The patients undergoing a femoral to pedal/plantar bypass are probably those suffering from the most serious form of PAD, whereas those undergoing a popliteo-pedal/plantar bypass have more restricted PAD. A shorter bypass enables the use of an optimal size and quality of vein graft. Moreover, the incidence of post-operative wound infections is probably lower when a groin incision can be avoided. In contrast to this finding, Brochado Neto et al.[15] found no significant difference in the patency of short versus long grafts in their series of inframalleolar bypasses.

In the current study, the cumulative leg salvage rate in diabetic patients was equal to that of non-diabetic patients. Similarly, there are studies suggesting that diabetics with CLI could achieve an equal outcome to non-diabetics after infrainguinal bypass with an aggressive, multidisciplinary approach, including experience in extremely distal revascularization as well as aggressive treatment of infections, frequent debridement, biomechanical off-loading, blood

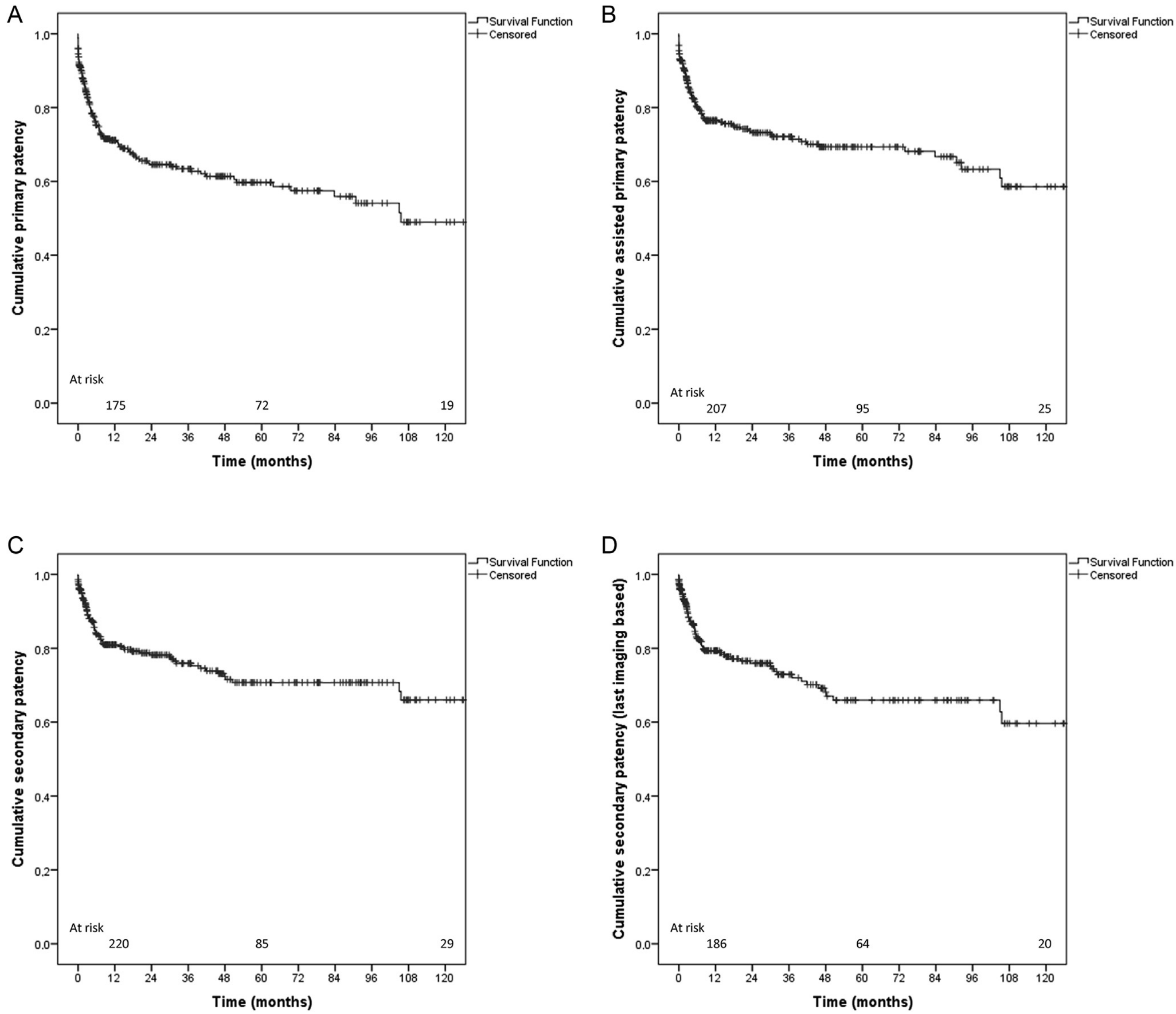

Figure 2. Cumulative (A) primary, (B) assisted primary, (C) secondary patency, and (D) last imaging based secondary patency of inframalleolar bypasses.

glucose control, and treatment of comorbidities.[10,16,17] Actually, in the present study, there even seems to be a slight trend (though not statistically significant) towards better leg salvage in diabetic versus non-diabetic patients. A probable reason for this finding is that, because of the more distal location of PAD, diabetics undergo more popliteo-pedal/plantar bypasses, and the leg salvage rate for these bypasses was superior.

Table 3. Outcome with standard error of all pedal bypasses.

	1 year (%)	5 year (%)	10 year (%)
Primary patency	71.2 ± 2.6	59.7 ± 3.2	49.0 ± 5.0
Assisted primary patency	76.5 ± 2.4	69.3 ± 2.9	58.6 ± 4.9
Secondary patency	81.1 ± 2.2	70.7 ± 3.1	68.4 ± 3.8
Secondary patency (last imaging based)	79.3 ± 2.4	68.1 ± 3.5	62.8 ± 3.8
Leg salvage	78.6 ± 2.6	72.0 ± 2.8	67.2 ± 4.0
Survival	70.3 ± 2.4	37.4 ± 2.8	15.9 ± 2.5
Amputation free survival	58.4 ± 2.6	29.8 ± 2.6	12.8 ± 2.2

Inframalleolar bypass is often the last option for limb salvage. Therefore, it is of paramount importance to focus on the technical aspects, such as the ultrasound assisted vein graft and distal anastomotic site marking to optimize incisions in order to avoid wound problems. With a dedicated vein mapping policy it was possible to find an autologous graft in 348 out of 352 (99%) patients. A meticulous surgical technique is also necessary. We use translocated, non-reversed vein grafts for several reasons. The in situ technique limits the possibility to choose the best segment of the vein for the bypass and for a common femoral artery anastomosis there might be tension on the proximal segment of the graft. The wound complication risk may be increased at the pedal anastomosis due to the need for parallel skin incisions. Moreover, translocated grafts can

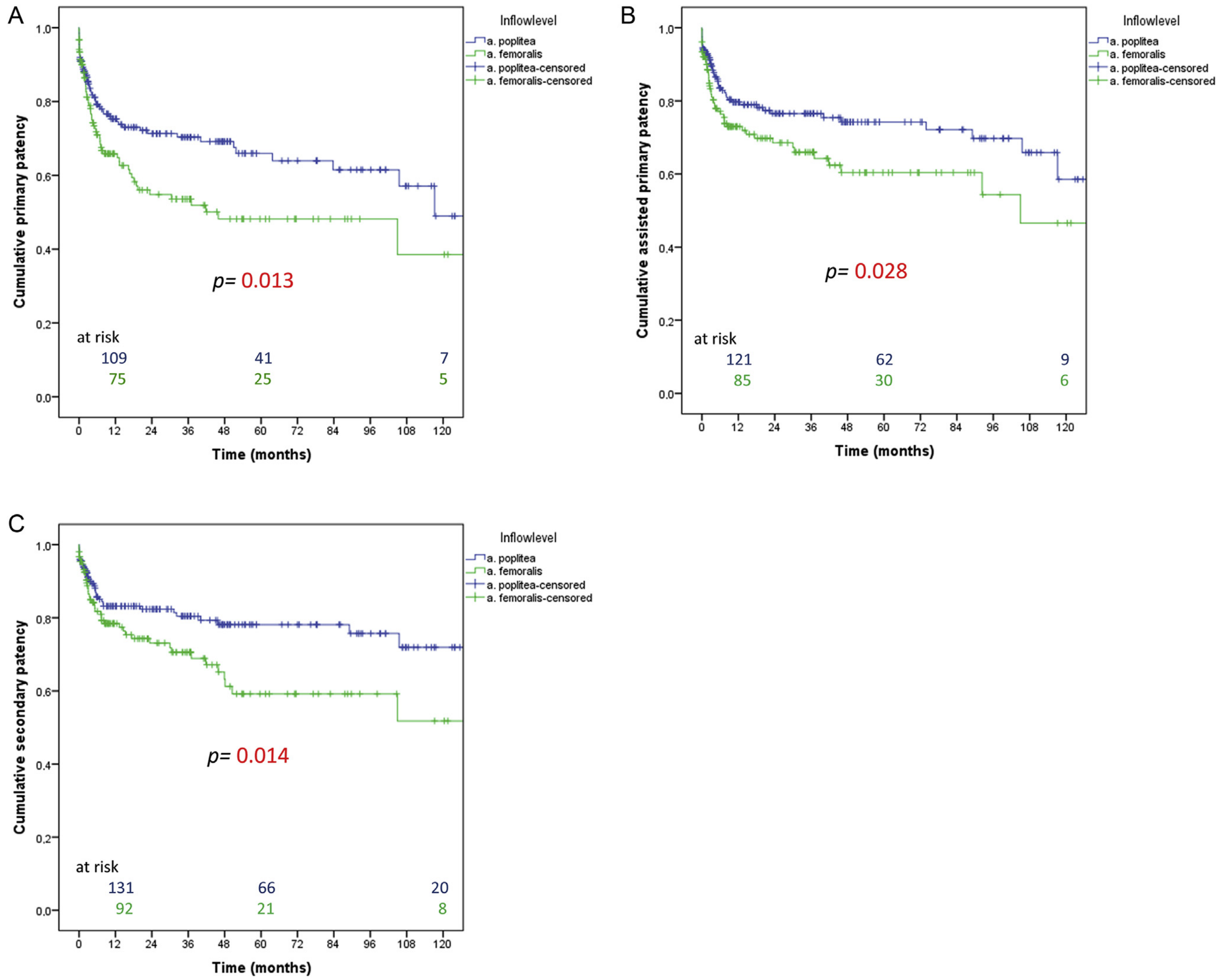

Figure 3. Cumulative (A) primary, (B) assisted primary, and (C) secondary patency of bypasses originating from popliteal artery versus bypasses originating from femoral artery.

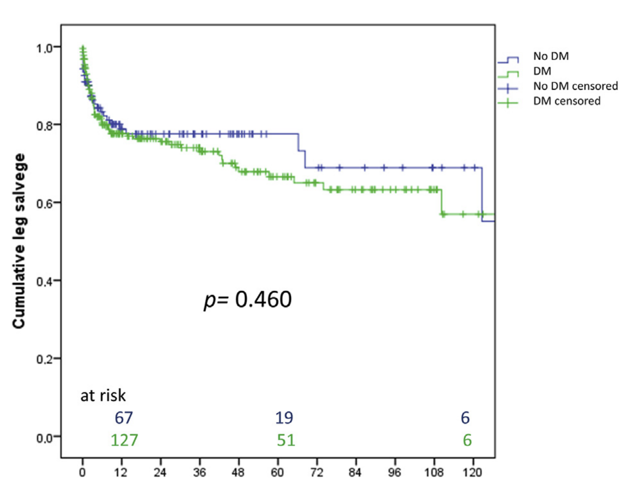

Figure 4. Cumulative leg salvage of diabetic versus non-diabetic patients. DM = diabetes mellitus.

be tunnelled deeply to avoid problems in case of wound infection and/or dehiscence. It is strongly believed that duplex surveillance of these grafts is crucial for the timely detection and treatment of vein graft stenosis as failed grafts have poor long-term patency and only moderate limb salvage rates.[18] Endovascular techniques and inframalleolar bypass are not competing but rather complementary options for limb salvage. As long as there are no data on the long-term results of endovascular revascularization of foot arteries, inframalleolar bypass is a durable option if a good quality vein graft is available and the patient has a good life expectancy. Inframalleolar bypass should also be offered after failed or inadequate endovascular revascularization; there are data suggesting that a prior endovascular intervention to crural occlusions does not have a negative impact on the outcome of a subsequent pedal bypass as long as destruction of the target vessel is avoided and the bypass is performed without excessive delay.[19] Similarly, results of this study demonstrated that previous endovascular treatment did not affect the outcome of subsequent bypass. Furthermore, there was no difference in outcome between primary and redo bypasses. Therefore an active revascularization policy also seems to be worthwhile in patients with a history of previous bypass if there is a good quality vein graft available.

Only one randomized study on the treatment of CLI comparing surgical and endovascular treatment has been published.[20] Differences between the treatment methods were not found. There was a trend towards a better outcome in the surgical group when the patient's life expectancy was more than 2 years.[21] In a propensity score analysis from this institution,[22] with 1023 patients treated for infrapopliteal CLI with either endovascular or surgical revascularization procedures to the crural or pedal arteries, PTA and bypass surgery achieved similar 5 year leg salvage (75.3% vs. 76.0%) and amputation free survival (37.7% vs. 37.3%) rates, whereas freedom from surgical revascularization was higher after bypass surgery (94.3% vs. 86.2%, $p < .001$). The study included all infrapopliteal revascularizations, not only those with a patent outflow vessel at the inframalleolar level. In patients who undergo inframalleolar bypass, treatment by endovascular means is often difficult due to long occlusions of the crural arteries. However, it would be interesting to perform a similar propensity score analysis with these patients.

CONCLUSION

Bypass to the inframalleolar arteries yields excellent long-term patency, and good limb salvage can be achieved in both non-diabetic and diabetic patients.

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CONFLICT OF INTEREST

None.

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None.

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COUP D'OEIL

Tracheo-innominate Artery Fistula

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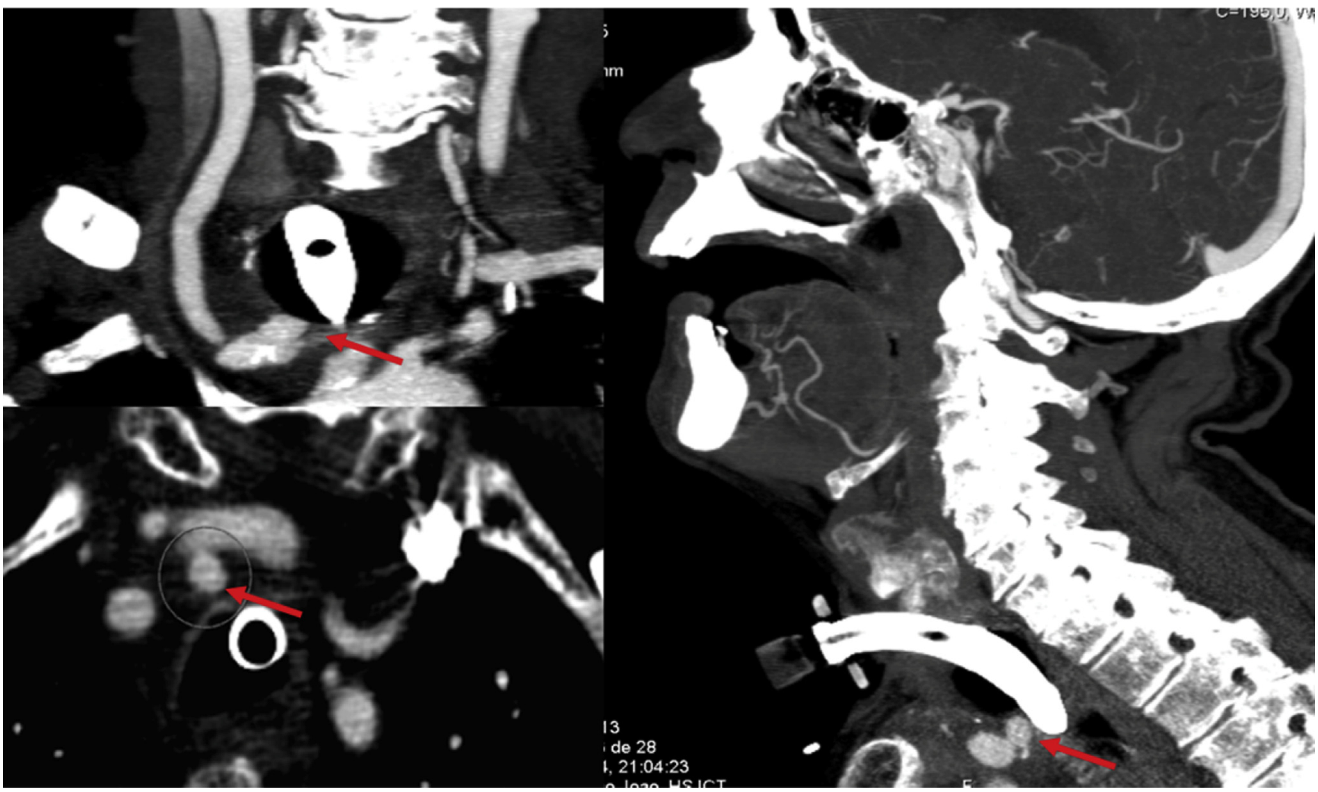

The authors present a case of a 76-year-old man seen at the Emergency Department with a self-limiting bleed from a tracheostomy, 2 weeks after open tracheostomy. A subsequent computed tomography scan revealed an innominate artery pseudoaneurysm in contact with the anterior aspect of the trachea. The patient underwent surgical correction of the pseudoaneurysm with a bifurcated bypass from the ascending aorta to the right common carotid and right subclavian arteries. Fistula formation between the trachea and the innominate artery is a rare complication of tracheostomy, almost always fatal without surgical treatment, and such herald bleeds are an important warning sign.

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