Eur J Vasc Endovasc Surg (2016) ■, 1—8

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.

Article history: Received 7 December 2015, Accepted 29 August 2016, Available online XXX

Keywords: Inframalleolar bypass, Critical limb ischaemia, Outcome

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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http://dx.doi.org/10.1016/j.ejvs.2016.08.051

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 pre-operatively 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, intra-operative 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