Pedal Arterial Bypass for Limb Salvage in Patients with Diabetes Mellitus

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Objective: to evaluate pedal bypass grafting in patients with diabetes mellitus with critical limb ischaemia.

Patients and Method: from 1994 to 1999, 49 consecutive pedal bypass grafts were performed in 46 patients with a median age of 69 years (range 37–85 years). The incidence of insulin-dependent diabetes mellitus was 87%. The distal anastomosis was located at the dorsalis pedis artery in 36, at the inframalleolar posterior tibial artery in 9 and at the plantar artery in 4 cases, respectively.

Results: one patient died perioperatively. Two bypass occlusions and one major amputation accounted for a primary patency rate of 96% and a limb salvage rate of 98% at 30 days, respectively. During a median follow-up of 28 months (range 1–70 months), 21 patients died of nonrelated causes. Three additional graft occlusions and 4 major amputations were noted resulting in a primary patency rate of 89% and a limb salvage rate of 87% at 48 months, respectively.

Conclusion: Pedal bypass grafting utilising the greater saphenous vein with in-situ technique is a reliable and effective procedure to achieve durable limb salvage in patients with diabetes mellitus.

Introduction

In patients with diabetes mellitus, the prevalence of gangrene is 20–30 times higher when compared to non-diabetic patients and the loss of protective sensation and susceptibility to infection further contribute to a 10 fold increased risk of amputation when compared to non-diabetic patients with peripheral arterial occlusive disease and culminate in the fact that 40–45% of all amputees are diabetic.1 However, as patients with long existing diabetes mellitus exhibit a very distal pattern of arterial occlusive disease, particularly of tibial vessels with cross-sectional occlusions,2 vascular reconstructive procedures remain challenging. In this context, pedal bypass grafting has emerged as a reliable method for durable limb salvage where limb salvage rates of up to 87% can be achieved at 5 years3 and current advances in pedal arterial imaging further facilitate the identification of reliable target vessels even in difficult situations.4

Autologous vein has clearly proven to be the graft of choice for infrainguinal arterial revascularisations in a large recent study of 2650 patients5 and two principal techniques of vein-graft orientation, i.e. translocated (reversed/non-reversed) and in-situ, are available. The purpose of the present study was to evaluate our results of pedal bypass grafting with autologous vein in a series of diabetic patients with impending limb loss due to advanced foot lesions.

Patients and Method

At our institution, all patients receiving infrainguinal reconstructive vascular procedures (bypass grafts) were prospectively entered into a computer-based registry (MS ACCESS) and were scheduled for routine follow-up examinations. In accordance to the purpose of this study, the vascular surgery registry of our institution was reviewed for patients with diabetes mellitus and tissue loss (i.e. gangrene/ulcerations) of the foot that received pedal arterial bypass grafts and the retrieved records were analysed. From March 1994 through March 1999, 46 consecutive patients (10 women, 36 men) with a median age of 69 years (range 37–85 years) were identified that received 49 pedal bypass grafts with greater saphenous vein. Three patients were operated bilaterally in staged procedures. The total number of infrainguinal bypass
procedures performed during that period was 744, the number of pedal revascularisations 76, respectively. Six pedal bypass grafts were performed in non-diabetic patients and 21 patients received a sequential pedal bypass with an additional anastomosis at the tibial/peroneal artery.

Preoperative diagnostic examinations encompassed either digital subtraction angiography (DSA), DSA complemented by a magnetic resonance angiography (MRA) in selected cases or MRA alone. In addition, the quality of the greater saphenous vein was assessed preoperatively by duplex ultrasound examination and the course of the vein was marked (vein-mapping).

The operations were performed under general (n = 27) or regional (peridural) anaesthesia (n = 22) (the technical details of the operations performed are outlined in Table 2). For the construction of in-situ grafts, the greater saphenous vein was prepared and the side-branches were selectively identified by gently distending the vein with heparinised saline while performing stepwise digital occlusion and ligated. The proximal anastomosis was completed and subsequently, destruction of vein valves was performed by a distally inserted catheter mounted valvulotome (LeMaitre, Vascutech, Burlington MA, n = 21 or in situ cath, Braun, Melsungen, Germany, n = 19). After demonstration of unimpeded blood-flow, the distal anastomosis was performed. For the non-reversed grafts (n = 4) and the spliced grafts (n = 2), valve destruction was accomplished using Boehmig-scissors.

Intraoperative flow measurement with an electromagnetic flow probe (CM 4008, Cardiomed, Oslo, Norway) followed by angiography (selective DSA, MRA) or duplex ultrasound in the early postoperative period (day 1–3) served as quality control and clinical and serial duplex ultrasound examinations were routinely performed at 3, 6 and 12 months postoperatively with annual repetitions afterwards.

All patients received intravenous therapeutic anticoagulation (unfractionated heparin) in the perioperative period that was replaced by oral anticoagulation in the majority of cases prior to discharge.

**Results**

According to the selection criteria in this study, all patients had diabetes mellitus with a high proportion being insulin dependent (87%) (Table 1) and all operations were performed for critical limb ischaemia with frank tissue loss (Table 2). In addition, resting pain was present in 19 patients.
of a proximal anastomosis that could be revised successfully. Furthermore, two AV-fistulas were detected that were managed conservatively and occluded spontaneously as confirmed by subsequent duplex examination.

There was one death (myocardial infarction) encountered within 30 days resulting in a perioperative mortality of 2%. Early bypass occlusion occurred in two cases, both in patients with chronic renal failure (CRF). Because no reinterventions (thrombectomy) were undertaken, this resulted in a cumulative patency rate of 96%, respectively. One major amputation had to be performed as a consequence of persistent limb ischaemia after bypass graft thrombosis, accounting for a limb salvage rate of 98% after 30 days. Minor haematomas were noted in two and secondary wound healing in four cases, respectively. Of note, a local advancement flap of full thickness skin was required in four cases for coverage of the distal anastomosis to the dorsalis pedis artery. Secondary orthopedic procedures (minor amputations) were performed in 32 patients with frank tissue loss (gangrene of toes/rays) as operative indication (Table 2), the perioperative major amputation was performed in a patient with ulcers of the distal calf and foot. The median follow-up in this series was 28 months (range 1–70 months) and 21 patients died of non-related cause (cardiac/neoplasm). During that time, four major amputations and three bypass occlusions were noted. None of the occluded grafts underwent any revision (thrombectomy). Two late graft occlusions (6 and 9 months) remained asymptomatic and one major amputation had to be performed as a consequence of bypass occlusion 3 months after surgery. Persistent or recurrent tissue necrosis accounted for the remaining three amputations that had to be performed despite patent bypass graft (out of them one patient with lymphoma and immunosupressive medication and one patient with CRF). The resulting patency and limb salvage rates are depicted in Figure 1.

Serial duplex ultrasound examinations led to the diagnosis of 4 graft stenoses: one significant stenosis \( v_{\text{max}} = 300 \text{ cm/s} \) that was confirmed in a DSA was successfully treated by percutaneous balloon dilatation \( v_{\text{max}} = 70 \text{ cm/s} \). A second significant stenosis \( v_{\text{max}} = 280 \text{ cm/s} \) of a proximal anastomosis was treated by a patch plasty \( v_{\text{max}} = 52 \text{ cm/s} \). In one case, a significant stenosis \( v_{\text{max}} = 216 \text{ cm/s} \) detected by duplex ultrasound turned out to be only of mild degree in a confirmatory DSA. Retrospectively, it was reasoned this phenomenon was due to the diameter mismatch of a wide distal anastomosis to a relatively small recipient vessel with extensive calcification. Lastly, one patient with a distal anastomotic stenosis \( v_{\text{max}} = 325 \text{ cm/s} \) deceased before a confirmatory DSA could be scheduled.

The majority of patients (30) was placed on oral anticoagulation (phenprocoumon).\(^6\) 10 patients received either inhibitors of platelet function (aspirine, \( n = 6 \)) or fractionated heparine (\( n = 4 \)) due to contra-indications for oral anticoagulation or chronic haemodialysis, respectively.

**Discussion**

This study was designed retrospectively to elucidate the performance of our pedal grafts. A primary assisted patency rate of 89% and a limb salvage rate of 87% at 4 years compare favourably with the experiences of other groups.\(^7,8\)

It is noteworthy, that the two early occlusions occurred in patients with CRF. A reduced expectancy for graft survival with a patency of 56.1% and a limb salvage of 73.5% at 3 years was observed in a study with a similar incidence of CRF (13% of patients).\(^9\) Although recent studies have brought a change in the view of long-term patency results in patients with CRF, there is consensus that the risk of amputation despite a patent bypass graft in this group remains high.\(^7,10,11\) In our report, too, one amputation despite patent bypass graft had to be performed in a patient with CRF at 48 months. Wound complications at the site of the distal (pedal) incision have been observed with an incidence of up to 10%, especially in diabetic patients of older age (> 70 years) due to increasing tension after wound closure and the tendency to develop postoperative reperfusion.
oedema. Here, a local advancement flap can be created to provide secure and tension free coverage of the arterial anastomosis while the incision for venous harvest can be used as donor defect and left open for secondary healing. We also took advantage of a local advancement flap (full thickness skin) to cover the distal anastomosis in four cases with and observed an uneventful wound healing and reepithelisation within two weeks.

Due to the selection criteria in this study, a relevant tissue defect was present in all patients preoperatively, therefore, secondary orthopaedic procedures had to be performed to remove the necrotic tissue. About two thirds of the minor amputations were performed in the early postoperative period as soon as demarcation of the necrosis had occurred that in turn enabled a tissue-sparing amputation at the most distal anatomical level. In all cases with gangrene and impending septic complications, an open amputation was performed intraoperatively.

We advocate an all autogenous policy for infrainguinal, especially pedal revascularisations and preoperatively, the availability of venous conduits is examined by duplex ultrasound. Depending on the morphology, the most suitable vein (greater saphenous vein > lesser saphenous vein > cephalic/basilic vein) is selected and marked. Applying this protocol, ipsilateral greater saphenous vein served in 48 cases as conduit, supplemented by lesser saphenous vein in two cases (spliced grafts). Only in one case, contralateral vein had to be harvested. Interestingly, even in patients with prior coronary artery bypass procedures (n = 6), ipsilateral vein was available in this study. Despite contradictory results from two randomised studies investigating the utility of duplex scanning for vein graft surveillance, current recommendations strongly emphasise the duplex surveillance of infrainguinal vein grafts according to a standardised protocol. The outcome of failed grafts is significantly worse and therefore it is our policy to correct a failing graft due to a significant stenosis promptly by a surgical or interventional (balloon angioplasty) procedure and to follow mild to moderate degree stenoses closely. In our study, two out of four stenoses detected by duplex ultrasound were confirmed to be critical (high-grade) in a subsequent angiography and were corrected by a patch/balloon angioplasty.

With regard on the impact of vein graft stenosis, the utilisation of in-situ saphenous vein for pedal bypass grafting offers several advantages: the incidence of a de novo graft stenosis was shown to be significant lower after in-situ grafting. Furthermore, traumatisation of the graft due to dissection and ischaemia can be minimised while providing an optimal diameter match and finally, the subcutaneous course of the graft allows accurate surveillance by means of duplex ultrasound and easy access in case of a surgical intervention.

Although several recent prospective studies of in-situ versus translocated grafts have failed to demonstrate a statistically significant difference in patency and limb salvage of either technique, the above mentioned factors in concert may promote the improved performance of in-situ grafts for pedal revascularisation when compared to translocated grafts.

Therefore, the in-situ saphenous vein represents the conduit of first preference for pedal arterial reconstructive surgery at our Department.

We noticed an extensive increase in patients with diabetes mellitus and foot lesions requiring pedal bypass grafting and two thirds of the 76 pedal bypass procedures performed between 1994 and 1999 dated in the last 2 years. Recent reports revealed that long-term patency, limb salvage and survival rates of diabetic patients are equal or even superior to non-diabetic individuals and based on our results, we also advocate an aggressive attempt to achieve limb salvage in this patient subgroup. Currently, the rate of ankle and pedal revascularisations is approaching 20% of overall infrainguinal bypass procedures. In this study, as in our institution in general, patient selection relies primarily to feasibility of reconstruction and limb salvage, whereas gender, comorbidity and age are of secondary influence and a nonambulatory patient or an advanced tissue defect with non-salvageable foot (advanced heel/forefoot gangrene) are the only true contraindications. This is reflected by the high incidence of patients classified in ASA category IV (33%) and the median age (69 years) in this study. In summary, we provided an encouraging piece of evidence that pedal bypass grafting with in-situ saphenous vein is a reliable and effective method for limb salvage in patients with diabetes mellitus. It is realised that further acquisition of patients and follow-up is necessary to confirm these promising results and to extend our knowledge on the long-term performance of pedal bypass grafting.

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