Surgical treatment of lower limb ischemia in diabetic patients – long-term results

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Abstract

Introduction: Lower limb ischemia may cause nonhealing ulcers, infection, amputation and even mortality in diabetic patients. In this study, we review our data of ischemic lower limb revascularization procedures in diabetic patients and present the early, mid- and long-term results.

Material and methods: From March 2004 to September 2008, 83 patients with lower limb ischemia in Fontaine class III and IV underwent distal arterial bypass procedures. Saphenous vein grafts were used for below-knee arterial bypasses in all patients. In 16 (19%) patients femoropopliteal bypasses were performed with PTFE grafts. Short-term and long-term surgical results were evaluated.

Results: Ulcer recovery was determined in 36% of patients. Graft patency was 95% and 1 death (1%) occurred in short-term follow-up. In long-term follow-up the total effectiveness rate was 74%. Graft patency was 79% and 6 deaths (7%) occurred during the follow-up.

Conclusions: Lower limb ischemia is a serious event in patients with diabetes mellitus. The consequences may include increased mortality and morbidity in this particular patient population. However, distal arterial revascularizations are considerably effective procedures to avoid amputation, to eliminate symptoms, to promote ulcer recovery and to help the patient participate in social life with acceptable short, mid- and long-term follow-up results.

Key words: diabetes mellitus, diabetic food, ischemia, distal arterial bypass.

Introduction

Diabetes mellitus (DM) is a widespread pathology in the world population and the prevalence of diabetes for all age groups was 2.8% in 2000 and is estimated to be 4.4% in 2030. The total number of people with diabetes is projected to rise from 171 million in 2000 to 366 million in 2030. Its complications such as neuropathy, retinopathy, nephropathy and atherosclerosis are the major causes of morbidity and mortality of this multisystemic disease. Peripheral vascular disease in lower extremities varies from asymptomatic to critical limb ischemia in the presence of DM. Vascular disease in diabetic patients provokes ulcers and gangrene, finally leading to amputation or even death. Most authors mention diabetes as an important risk factor in the development of critical and/or chronic limb ischemia and consequent amputation [1]. It is important to perform surgical and medical treatments for diabetic patients with lower limb ischemia [2]. Recovery and increasing the life quality are the targets of these procedures.

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In this study, we review our data of ischemic lower limb revascularization procedures in diabetic patients and present the early, mid- and long-term results.

Material and methods

Between March 2004 and September 2008, 931 peripheral vascular bypass procedures were performed at our institution. Among them 83 patients received lower limb surgical revascularization for critical limb ischemia. Demographic data and risk factors are presented in Table I. Exclusion criteria were emergent operations, redo cases, acute thrombosis and distal embolisation.

Mean age of the patients was 58.61 ±4.80 years. Seventy-two of them were males and 11 were females. Hypertension was present in 72 cases (93%). Incidences of significant atherosclerotic coronary artery disease and congestive heart failure occurred in 18 (21%) and 24 (28%) patients, respectively. Active smoking was present in 55 (66%) cases. There was nephropathy in 15 (18%) patients. Mean glycated haemoglobin (HbA$_{1c}$) was measured to be 7.29 ±0.45%. According to the Fontaine classification 47 (57%) patients had class III disease and 36 (43%) had class IV limb ischemia. Diagnosis modalities were Doppler ultrasonography and angiography. These diagnostic modalities were performed in all patients. The Bollinger scoring system [3] was used to assess the severity of arterial disease. In this system, each arterial segment is assigned a number corresponding with disease severity. The minimum score is 0, indicating a normal segment; the maximum score is 15, indicating total occlusion extending for more than half the length of a segment. The results are presented in Table II.

Medical treatment protocols of patients were organized with antiaggregant/anticoagulant, statin and vasodilator therapies. Blood glucose range was controlled with crystallized insulin. Combined antibiotics according to drug sensitivity testing were used to control infection. Foot wounds were debrided with hydrogen peroxide, 0.9% NaCl solution and collagenase pomade. Hyperbaric oxygen therapy was performed in 16 (19%) patients and iloprost was included in the medical therapy in 18 (21%) patients. Low molecular weight heparin was administered in preoperative and postoperative periods. Severity of patients' symptoms was evaluated by the ankle-brachial index (ABI). Ankle-brachial index was < 0.3 in 46 (55%) patients, 0.3–0.5 in 28 (33%) patients, and > 0.5 in 9 (10%) patients.

Operations were performed under general anesthesia in 5 (6%), epidural anesthesia in 52 (62%) and with regional nerve block in 26 (31%) patients. A summary of the operations performed on patients is presented in Table III. Autologous saphenous vein grafts were used in all patients for distal bypass procedures. A polytetrafluoroethylene (ePTFE) graft with a diameter of 6 mm was used in 16 (19%) patients for femoropopliteal bypass procedures. The proximal site of the popliteal artery with adequate flow, diagnosed with angiography and noninvasive studies, was selected for proximal anastomosis. Proximal anastomosis was performed at the distal segment of the femoropopliteal bypass graft (ePTFE) in 16 patients. Inflow anastomoses were performed with 6.0 monofilament suture and outflow anastomoses were performed with 6.0 or 7.0 monofilament suture. A 100 U/kg of heparin was administered before arterial clamping, and heparin was not reversed after the flow was maintained.

After hospital discharge antithrombotic and antioxidant agents such as acetylsalicylic acid, clopidogrel, cilostazol, and pentoxifylline were used for the treatment and better graft patency.

Table I. Demographic data and risk factors

Parameter	Results
Age, mean ± SD	58.61 ±4.80
Sex (M/F), n (%)	72 (86)/11 (13)
Hypertension, n (%)	78 (93)
ACAD, n (%)	18 (21)
CHF, n (%)	24 (28)
DM, n (%)	83 (100)
COPD, n (%)	14 (16)
Smoking, n (%)	55 (66)
Nephropathy, n (%)	15 (18)
HbA$_{1c}$ (mean ± SD)	7.29 ±0.45

ACAD – atherosclerotic coronary artery disease, CHF – congestive heart failure, DM – diabetes mellitus, COPD – chronic obstructive pulmonary disease

Table II. Surgical procedures

Procedure	Number (percent)
Femoropopliteal (PTFE) + distal popliteal artery (SVG) bypass	16 (19)
Proximal popliteal-tibialis anterior artery (SVG) bypass	30 (36)
Proximal popliteal-tibialis posterior artery (SVG) bypass	11 (13)
Proximal popliteal-distal popliteal artery (SVG) bypass	13 (15)
Proximal popliteal-dorsalis pedis artery (SVG) bypass	5 (6)
Proximal popliteal-posterior tibial artery (SVG) bypass	8 (9)

PTFE – polytetrafluoroethylene, SVG – saphenous vein graft

Table III. Bollinger scoring of arterial segments

Variable	Score (mean ± SD)
Profunda femoris artery	1.06 ±0.7
Superficial femoral artery	6.1 ±3.1
Popliteal artery	7.7 ±2.7
Anterior tibial artery	10.0 ±3.6
Peroneal artery	6.4 ±2.06
Posterior tibial artery	11.4 ±2.2

Table IV. Complications observed in long-term follow-up

Complication	Numbers
Mortality	6
Stroke	1
MI	3
CHF	2
Thrombosed bypass procedures	16
Femoropopliteal-distal popliteal artery bypass	10
Proximal popliteal-tibialis posterior artery bypass	3
Proximal popliteal-dorsalis pedis artery bypass	3
Amputation	13
Major	3
Minor	10
Ulcer recurrence	6

Results

Short-term results of the patients were evaluated in the first 3 months of the postoperative period. Ankle-brachial index above 0.8 was maintained in 44 (53%) patients, and an ABI between 0.8 and 0.6 in 20 (24%) patients, between 0.6 and 0.5 in 17 (20%) patients and less than 0.5 in 2 (2%) patients was measured. Limb salvage was possible in 44 (53%) patients, and there was a mild increase in arterial flow in 37 patients; however, no significant flow increase occurred in 2 patients and ischemic necrosis could not be controlled in these particular cases, which resulted in major amputation. In addition, 8 minor amputations were performed in patients with ABI between 0.6 and 0.5. In the early postoperative period (postoperative day 0) 3 patients required reoperation. Reoperations were performed for graft thrombosis (n:2) and hematoma (n:1) in the distal anastomosis site. Myocardial infarction occurred in 1 patient and cardiac ischemia led to mortality in this case. Ulcer recovery was determined in 30 (36%) patients. Despite surgical interventions and medical treatment, 6 foot ulcers

remained untreated. In the 3-month post-operative period the graft patency rate was 95.1%.

Mean long-term follow-up time was 17.2 ±7.8 months. Complete recovery was maintained in 40 (48%) patients, and there was mild improvement in 22 (26%) cases. The effectiveness was 74%. In the long-term follow-up the graft patency rate was 79%. Graft thrombosis was seen in patients who had undergone femoropopliteal and distal popliteal artery bypass procedures (n:11), proximal popliteal artery to dorsalis pedis artery bypasses (n:3), and proximal popliteal artery to posterior tibial artery (n:3) bypass procedures (Table IV). Endothelial hyperplasia at the distal anastomosis site, inadequate anticoagulant therapy and insufficient proximal or distal arterial runoff were determined as the causes of graft failure. Thrombectomy and new bypass procedures were performed in 10 of these patients. Debridement and medical treatment procedures were performed in 7 patients in the long term. Thirteen patients underwent various amputations (10 minor, 3 major). In total, 5 major amputations were performed and 2 of them were below the knee, 1 was Syme's amputation and 2 were medio-tarsal amputation. Ulcer recurrence was observed in 6 (7%) patients. In long-term follow-up 6 further mortalities occurred; 1 patient died from stroke, 3 died from myocardial infarction, and 2 died from congestive heart failure (Table IV).

Discussion

Distal arterial revascularization in patients with critical limb ischemia is a limb saving procedure. The literature includes reports of higher incidence of peripheral arterial disease and poor prognosis in the diabetic patient population [4, 5]. However, Maharaj et al. [6] reported no difference between diabetic and nondiabetic patients with respect to the lower limb graft patency, morbidity and mortality rates. In addition, favorable results have been obtained supporting distal revascularization in diabetic patients [7–9].

Ischemia of the lower limb is an important social health problem [10, 11]. Limb salvage in patients with extensive tibial and peroneal occlusive disease is feasible with aggressive revascularization of the vessels of the ankle and foot [12, 13]. The main goal of distal arterial revascularization procedures is to eliminate symptoms, achieve recovery of ulcers, obtain high graft patency and return the patients to an active social life [10, 11].

In our study, the limb salvage rate in the long-term follow-up was 74% and graft patency was found to be 79% and the results were consistent with Maharaj et al.'s findings [6]. Poor graft patency with femoropopliteal and distal popliteal artery bypass procedures was observed. These procedures constituted 19% of all bypass procedures and were

the cause of 62% of all graft thromboses (Table IV). The 2-year primary patency rate for above-knee femoropopliteal bypass with PTFE graft was reported as 57%, 55%, and 54% in different series [14–17]. Consequently, above-knee femoropopliteal bypasses with ePTFE grafts were not related to high patency rates. The high incidence of graft thrombosis with this procedure may be related to the quality of inflow and outflow structures [17].

Patency of bypass procedure is related to many factors such as diabetes mellitus, graft material, anastomosis site, and tobacco use. Patency rates are lower in diabetic patients; consequently reversed saphenous vein had higher patency rates than PTFE grafts. A significant difference was reported between RSV and the PTFE grafts below the knee level. However, the only factor other than graft type and distal anastomotic site that consistently correlated with late patency was tobacco use [18]. In this study anastomosis sites were all below the knee level and graft material was reversed saphenous vein for all patients. Furthermore, patency rates of bypass procedures in diabetic and/or tobacco addicted patients were low, as reported by previous studies [10, 11, 19].

There are studies which focused on the effects of endoluminal interventions for the treatment of infrapopliteal arterial stenosis or occlusions. These interventions include angioplasty, angioplasty with stenting, subintimal angioplasty, cutting balloon angioplasty and vibrational angioplasty. However, even the short-term results of these procedures have been reported with poor outcomes when compared to the traditional standards [20–22]. Furthermore, the Bypass versus Angioplasty in Severe Ischaemia of the Leg (BASIL) trial [23] was published in 2010. This study reported that angioplasty was associated with a significantly higher early failure rate than bypass surgery, and bypass surgery with vein offered the best long-term patency. The surgical strategy we followed corresponds to these results [3, 23].

Additional risk factors are former amputation and recurrent ulcers, and treatment with insulin may increase the risk of amputation despite distal revascularization procedures in diabetic patients with critical limb ischemia [24]. In our study, 5 major and 18 minor amputations were performed. Unfortunately, in some circumstances, despite perfusion of the tissues, tissue necrosis may be inevitable [24, 25].

Circulatory diseases are the main causes of mortality in diabetic patients. Cardiac and cerebral disorders are the leading factors among them [26, 27]. In our study, there were 6 deaths in total. Among them, 5 were due to cardiac events and 1 was caused by stroke.

In conclusion, lower limb ischemia is a serious event in patients with diabetes mellitus. It may lead to increased mortality and morbidity in this particular patient population. However, distal arterial revascularizations are considerably effective procedures to avoid amputation, to eliminate symptoms, to promote ulcer recovery and to help the patient participate in social life with acceptable short, mid- and long-term follow-up results. However, further studies are warranted to prevent ischemic feet, improve interventional measures and achieve better graft patency rates in diabetic patients.

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