

Tibial Bypass Surgery for Treatment of Critical Limb Ischemia Associated with Diabetes Mellitus

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Abstract: Background: Tibial bypass surgery is frequently indicated for critical limb ischemia, especially in patients with diabetes mellitus. Bypass often is difficult in these patients because of extensive tibial artery calcification or diffuse occlusion. Furthermore, chronic renal failure caused by diabetic nephropathy and necessitating hemodialysis increases the risk and difficulty of anastomotic procedures. We analyzed results of tibial bypass operations in our diabetic patients.

Methods: Retrospective review of 101 patients undergoing tibial bypass surgery since 1993 identified 72 (71.3%) as having critical limb ischemia. Results were compared between patients with and without diabetes mellitus. The nondiabetic critical ischemia group included 41 men and 6 women with a mean age of 63.7 years (range; 25 to 81), representing 63.5% of all nondiabetic patients (47/74). The diabetic critical ischemia group included 22 men and 3 women with a mean age of 62.4 years (range; 41 to 81), representing 92.6% of all diabetic patients (25/27). Nine patients in the diabetic group (36%) required hemodialysis because of diabetic nephropathy, also having severe limb ischemia with ulcer or gangrene. All bypass operations were performed with autogenous vein grafts, accomplishing anastomosis using tourniquet occlusion.

Results: Primary patency rates in the nondiabetic and diabetic critical ischemia groups respectively were 87.1% and 80.1% at 1 year after operation, 70.4% and 80.1% at 3 years, and 65.0% and 60.1% at 5 years; secondary patency rates respectively were 92.8% and 87.4% at 1 year, 80.5% and 87.4% at 3 years, and 75.4% and 76.5% at 5 years. Respective survival rates in the nondiabetic and diabetic groups were 88.4% and 70.1% at 1 year, 74.9% and 63.1% at 3 years, and 74.9% and 44.9% at 5 years. Survival in diabetic patients requiring hemodialysis because of chronic renal failure was 33.3% at 1 year.

Conclusions: Diabetic patients, especially those requiring hemodialysis, showed more severe ischemic symptoms, but comparable graft patency rates. Poor life expectancy in diabetic patients dictates strict selection for tibial artery reconstructive surgery, especially in end-stage renal disease. (Jpn. J. Vasc. Surg., 14: 627-631, 2005)

Key words: Diabetes mellitus, Critical limb ischemia, Arterial reconstruction, Tibial bypass surgery

Introduction

Recent reports suggest a steady increase in Japanese patients

with diabetes mellitus. In 2004, more than seven million Japanese were diagnosed with diabetes and treated with medication.¹⁾ Studies also suggest that this number of diabetic patients could double if larger numbers of asymptomatic patients could be identified. As diabetes mellitus is a well-known risk factor for atherosclerosis, these patients often develop critical limb ischemia as a result of arteriosclerosis obliterans, and often show diffuse arterial occlusion extending distally to tibial or pedal arteries. Vascular surgery in these patients is frequently complicated by severe calcification of

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Received: September 30, 2004

Revision accepted: May 25, 2005

第32回日本血管外科学会総会 重症虚血肢国際シンポジウム

affected vessels.²⁾ Diabetic patients also are high-risk operative candidates because of depressed immunity.³⁾ We retrospectively compared results of tibial bypass operations for treatment of critical limb ischemia in diabetic patients with those in others.

Materials and methods

Since 1993, surgeons in our department performed 101 tibial bypass operations to treat limb ischemia. Among limbs operated upon, 72 (71.3%) had critical limb ischemia. Retrospective review of medical records of nondiabetic patients with critical limb ischemia (group N) was conducted in comparison with records of critical ischemia patients with diabetes mellitus (group D). Group N had 47 limbs in 47 patients, accounting for 63.5% of all nondiabetic patients (47/74), including 41 men and 6 women with a mean age of 63.7 years (range; 25 to 81). In this group, ischemic heart disease (IHD) was present in 3 patients (6.4%) and cerebrovascular disease (CVD) in 1 (2.1%). Group D consisted of 25 limbs in 25 patients, accounting for 92.6% of all diabetic patients (25/27), including 22 men and 3 women with a mean age of 62.4 years (range; 41 to 81). Six patients in this group had IHD (24.0%), while 3 patients had a history of CVD (12.0%). Nine patients in group D required maintenance hemodialysis because of diabetic nephropathy; all 9 of these treated limbs showed signs of severe ischemia such as ulceration or gangrene.

Distal anastomoses in group N targeted tibial or peroneal arteries in 37 limbs (78.7%) and pedal arteries in 10 (21.3%). Distal anastomoses in group D targeted tibial or peroneal arteries in 20 limbs (74.1%) and pedal arteries in 7 (25.9%). Tourniquet occlusion was used during the distal anastomotic procedure to obtain a bloodless field. Vascular conduits were reversed autogenous saphenous vein grafts in 70 limbs, and spliced vein grafts in 2 limbs.

Postoperative anticoagulation was initiated immediately after surgery; intravenous heparin was started and then replaced with oral Warfarin after oral intake resumed. Oral anticoagulation continued for at least 3 years after surgery. Graft patency was followed up mainly by the ankle-brachial pressure index (ABPI). When ABPI decreased more than 0.1, duplex scanning or angiography was performed to assess

graft patency and to identify lesions decreasing blood flow.

Results

Two patients died after operation (one from graft infection, one from stroke) in group N (mortality; 4.3%). Three patients developed wound infections (6.4%) in group N. Three patients died from sepsis or malnutrition in group D (mortality; 12.0%), while wound infection occurred in five patients (20.0%). Primary patency rates in groups N and D respectively were 87.1% and 80.1% at 1 year, 70.4% and 80.1% at 3 years, and 65.0% and 60.1% at 5 years (**Fig. 1**). Secondary patency rates in groups N and D were 92.8% and 87.4% at 1 year, 80.5% and 87.4% at 3 years, and 75.4% and 76.5% at 5 years (**Fig. 2**). Limb salvage rates in groups N and D respectively were 97.6% and 78.5% at 1 year, and 97.6% and 68.7% at 5 years (**Fig. 3**). Respective survival rates in groups N and D were 88.4% and 70.1% at 1 year, 74.9% and 63.1% at 3 years, and 74.9% and 44.9% at 5 years (**Fig. 4**). Patients in group D were divided into two subgroups according to need for hemodialysis (HD). Primary and secondary patency rates at 1 year in the non-HD subgroup were 78.7% and 87.5%, respectively, while primary and secondary patency rates in the HD subgroup were 83.3% and 83.3%, respectively. However, survival rates in non-HD and HD subgroups at 1 year were 85.2% and 33.3%.

Discussion

Vascular reconstruction is the treatment of choice for critical limb ischemia. Tibial bypass surgery frequently is necessary in such patients, in contrast to patients who present with ischemic claudication. Considering the increasing numbers of patients with diabetes mellitus, numbers of patients requiring bypasses to the tibial or a pedal artery presumably are increasing as well since diabetic patients, especially those with critical limb ischemia, show diffuse arterial occlusion extending distally in the tibial arteries. However, certain problems occurring in bypass surgery in diabetic patients require careful management to obtain a favorable outcome.

Infection control is a critical issue in the treatment of diabetic patients, since immune defenses are suppressed by diabetes.³⁾ The typical foot lesion in diabetic patients, commonly called "diabetic foot," includes neuropathic ulcer,

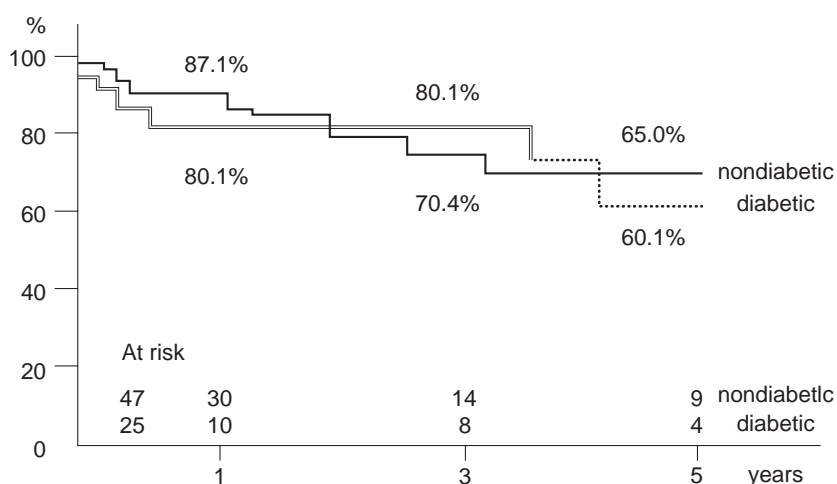


Fig. 1 The primary patency rates of tibial bypass surgical procedures for critical limb ischemia of the nondiabetic and diabetic groups (Kaplan-Meier Method).

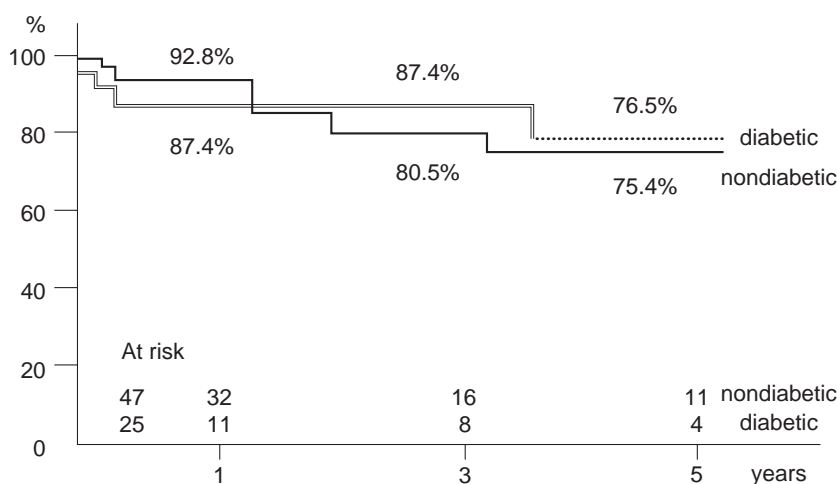


Fig. 2 The secondary patency rates of tibial bypass surgical procedures for critical limb ischemia of the nondiabetic and diabetic groups (Kaplan-Meier Method).

ischemic ulcer, and combinations of these. Usually the foot lesion is infected to varying degrees, and shows wet ulceration or gangrene. Uncontrolled local infection readily progresses to septicemia in diabetic patients, especially those with poor glycemic control. Control of blood sugar and concomitant treatment of the infected foot lesion therefore are the first issues to be addressed.

Aggressive debridement and cleansing is mandatory. Typically an abscess cavity enlarges in the plantar area and extends proximally via the intermetatarsal spaces. Wide dissection

along metatarsal bones, sometimes extending to the heel, therefore is recommended. If osteomyelitis is diagnosed the metatarsal bone should be removed. After wide incision of the plantar lesion, cleansing with warm normal saline is carried out repeatedly; recently vacuum-assisted compression (VAC) therapy has been reported to achieve good results.⁴⁾ At present, VAC systems are not commercially available in Japan, but favorable results have been reported with individually constructed VAC systems. Whether or not VAC is used, infection should be controlled before vascular reconstruction is per-

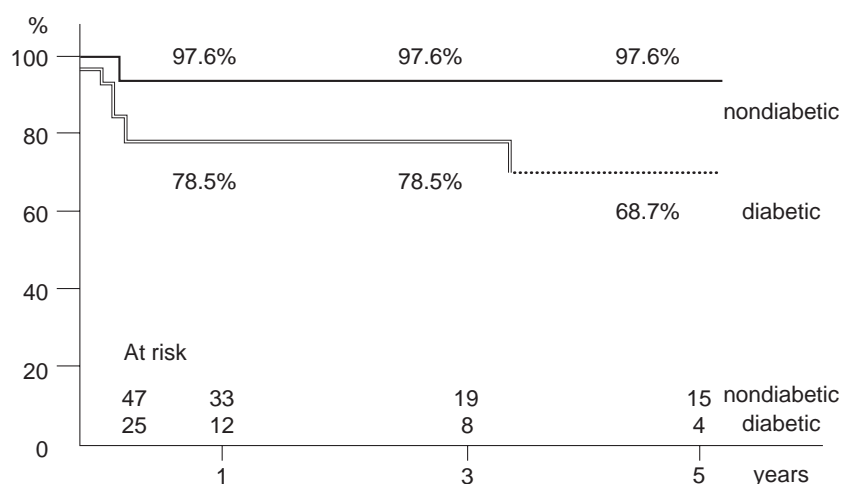


Fig. 3 The limb salvage rates of tibial bypass surgical procedures for critical limb ischemia of the nondiabetic and diabetic groups (Kaplan-Meier Method).

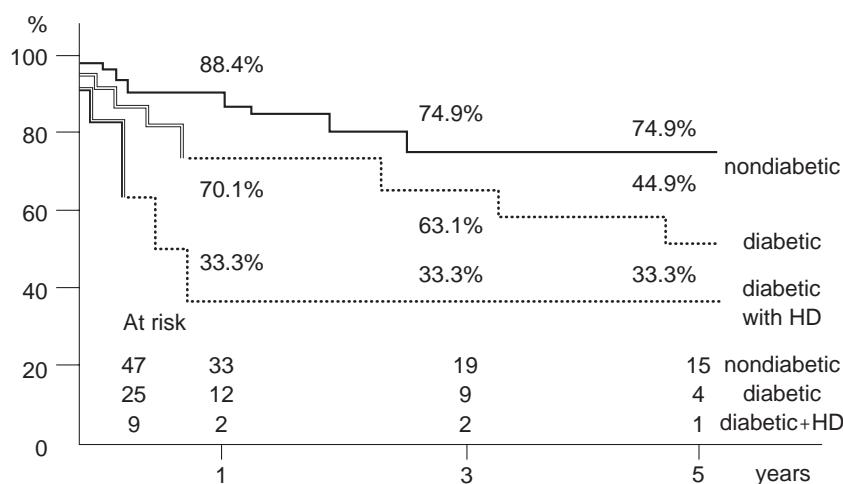


Fig. 4 The survival rates of tibial bypass surgical procedures for critical limb ischemia of the nondiabetic, diabetic and diabetic with hemodialysis groups (Kaplan-Meier Method).

formed.

Severe calcification of arteries can present difficult problems during anastomotic procedures in diabetic patients. Atherosclerosis frequently includes calcification in the intima, usually in a segmental, patchy distribution. However, many patients with atherosclerosis and diabetes mellitus concomitantly show additional medial calcinosis of the Monckeberg type.²⁾ Such calcification of arteries is annular and continuous, especially in patients requiring maintenance hemodialysis because of diabetic nephropathy. Arteriotomy and anastomotic proce-

dures are impeded by such severe calcinosis, and procedures required to remove these easily damage the arterial wall. Preoperative assessment using roentgenography to locate uncalcified areas and angiography to identify appropriate anastomotic sites is critical. We sought sites with relatively little calcification, particularly at anastomosis in the toes. When uninterrupted calcification at the anastomotic site could not be circumvented, the calcified lesion was removed from the media and sutures were applied to the adventitia. Long-term results of this technique need to be analyzed, since anasto-

motric stenosis is related to arterial injury.

Extensive calcification of arteries only rarely precluded their effective clamping with a pneumatic tourniquet. Among 101 limbs in our study, 3 could not be clamped with the pneumatic tourniquet, even though the area of occlusion was shifted several times. Two limbs were managed with a standard vascular clamp, while the other was managed with an internal shunt ordinarily used in off-pump coronary artery bypass operations. Acceptable short-term results were obtained in these 3 limbs, but long-term results remain undetermined, considering the likelihood of arterial injury from the metal clamp or intimal injury from the shunt tube.

Although these specific concerns should be followed up and managed carefully, our graft patency rates in tibial bypass surgery in patients with diabetes mellitus were comparable to those in our patients without diabetes. Previous reports also have described comparable results in tibial artery bypass surgery comparisons between nondiabetic and diabetic patients.^{5,6} This argues for an aggressive approach to critical limb ischemia in diabetic patients. On the other hand, reduced life expectancy and increased postoperative morbidity in diabetic patients may dictate strict patient selection in performing vascular reconstruction, especially in those requiring maintenance hemodialysis. Major risk factors such as ischemic heart disease and cerebrovascular disease should be assessed preoperatively, considering that our diabetic patients presented such risks more frequently than our nondiabetic patients.

Quality of life before onset of ischemic limb manifestations also needs to be evaluated. Yet, overall, our results suggested that tibial or pedal artery bypass surgery is a treatment of choice in well-selected diabetic patients with critical limb ischemia.

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