Pedal bypass surgery after crural endovascular intervention

Christian Uhl, MD, Carolin Hock, Thomas Betz, MD, Ingolf Töpel, MD, and **Markus Steinbauer, MD,**
Regensburg, Germany

Background: **Many centers choose endovascular intervention as their first-line treatment for crural occlusions in patients with critical limb ischemia (Rutherford 4-6). However, unsuccessful interventions often result in major amputation. Therefore, pedal bypass surgery should be considered as an alternative first-line treatment. We reviewed the impact of a prior endovascular intervention on the outcome of our patients' pedal bypass procedures.**
Methods: **A retrospective analysis was conducted for all patients who had undergone pedal bypass surgery in our department from February 2008 to October 2012. We performed 75 pedal bypass operations in 71 patients (male, 54; female, 17; median age, 72 years; range, 29-90 years). In 36 of those cases, patients had undergone a prior infrapopliteal endovascular intervention (PEI group). In 39 cases, patients underwent bypass surgery as first-line treatment because their prior angiography had resulted in either unsuccessful endovascular intervention, or intervention had been deemed 'not feasible' (BSF group). Only autologous vein grafts were used, and no retrograde intervention was done via the pedal arteries. Endpoints of the analysis were primary and secondary patency rates, mortality, and limb salvage at 1 year postoperatively.**
Results: **Overall primary patency at 1 year was 58.3%, and secondary patency was 61.3%. Limb salvage was 76.8% and survival was 80.4%. Graft occlusion within 30 days was 18.7%. Revision in those cases was futile and 78.6% of patients had to undergo major amputation. Primary patency at 1 year was 67.0% in PEI group vs 48.3% in BSF group ($P = .409$) and secondary patency was 73.5% vs 48.6% ($P = .100$). Prior endovascular intervention had no significant impact on either limb salvage (82.3% vs 71.6% at 1 year; $P = .515$) or graft occlusions within 30 days (19.4% vs 17.9%; $P = .547$). Survival rate at 1 year was 79.5% in PEI group and 81.3% in BSF group ($P = .765$). Risk factors and indications were similar in both groups.**
Conclusions: **Crural endovascular intervention does not seem to have a negative impact on the outcome of subsequent pedal bypass surgery. Requirements are avoiding a destruction of the target vessel and opting for timely bypass surgery whenever endovascular treatment does not achieve a sufficient perfusion for wounds to heal. Early graft occlusions are associated with a higher risk for major amputation. (J Vasc Surg 2014;59:1583-7.)**

An aging population, unhealthy lifestyles, and diseases of affluence, such as diabetes, all are risk factors for peripheral arterial occlusive disease. Every 20 seconds, somewhere in the world, a leg is lost to diabetes.[1,2] Atherosclerotic lesions frequently involve the crural vessels, and the prevalence of long and multilevel lesions is high.[3] This process is known as critical limb ischemia (CLI), and patients frequently present with rest pain, ulcers, and gangrene (Rutherford 4-6). Their substantial comorbidities put them at risk for complications related to open bypass surgery, and morbidity and mortality rates are high. At the same time endovascular treatment (ET) techniques have improved tremendously. Therefore, many centers have adopted an endovascular-first strategy. However, the Bypass vs Angioplasty in Severe Ischaemia of the Leg (BASIL) trial showed that patients who had undergone bypass surgery after a previously unsuccessful ET demonstrated worse amputation-free survival rates than those who had undergone primary surgical treatment without prior ET.[4-6] Various studies present good patency rates for pedal bypasses.[7-10] However, they all lack sufficient information on whether the underlying first-line treatment was surgery or endovascular intervention. The purpose of this study was to evaluate the outcome of pedal bypass operations in a center where ET is the first-line treatment. We assessed the impact of a prior crural angioplasty on the outcome of pedal bypass surgery in patients with CLI. Then we compared their outcome with the outcome of patients who underwent bypass surgery as their primary treatment.

METHODS

This is a retrospective analysis of 75 pedal bypasses between February 2008 and October 2012. During this time, we did 326 cural endovascular interventions as first-line treatment for occlusions. The indication was CLI with rest pain, ulcers, or gangrene (Rutherford 4-6). After an initial postinterventional improvement, 36 cases (prior endovascular intervention [PEI group]) went on to require pedal bypass surgery (with a median of 3 months after the intervention) due to increasing necroses. Their

From the Department of Vascular Surgery, Krankenhaus Barmherzige Brüder Regensburg.
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Reprint requests: Christian Uhl, MD, Krankenhaus Barmherzige Brüder Regensburg, Prüfeningerstraße 86, 93049 Regensburg, Germany (e-mail: christian.uhl@barmherzige-regensburg.de).
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Table I. Endovascular procedures

	All	*Stenosis*	*Long segment occlusion*	*Percutaneous transluminal angioplasty/ atherectomy*
Distal popliteal artery (below knee)	5	2	3	4/1
Tibial-fibular trunk	5	3	2	5/0
Anterior tibial artery	12	1	11	12/0
Posterior tibial artery	7	1	6	7/0
Peroneal artery	11	2	9	11/0

endovascular intervention sites and further details are shown in Table I. In 39 cases, patients underwent pedal bypass surgery first as their primary treatment without prior successful endovascular intervention (BSF group). We compared primary and secondary patency, limb salvage rates, and survival between the groups. Primary patency was defined as the period between bypass surgery and first occlusion of the bypass. Secondary patency was defined as the period between bypass surgery and second occlusion of the bypass.

A limb was deemed salvageable if perfusion could be improved. Necrosis and ulcer of toes and heels were deemed salvageable, as well as multiple locations of necrosis on the foot. Gangrene of the entire foot was deemed not salvageable. Three patients underwent minor amputation before receiving any kind of revascularization treatment because there appeared to be sufficient perfusion for the amputation wounds to heal. However, this turned out not to be the case, and all three patients (PEI group, n = 1; BSF group, n = 2) had to undergo subsequent treatment for revascularization (with a median of 2 weeks after the minor amputation). Four patients in the PEI group underwent minor amputation after their endovascular revascularization but before their bypass operation. In 40% of all patients (PEI group, 47.2%; BSF group, 33.3%; $P = .161$), planned minor amputations were performed in concert with their bypass operations. The demographics, risk factors, and indications are shown in Table II, and the bypass characteristics are shown in Table III. There was no retrograde intervention via the pedal arteries. Only autologous vein grafts were used, and all bypasses were controlled by angiography to exclude any technical failure. Postoperatively, 74% of patients were managed with statins, and all of patients were put on anticoagulant medication. All received the vitamin K antagonist Phenprocoumon for their anticoagulation therapy. Postoperative graft surveillance follow-ups (at discharge, and at 6, 12, 24, and 36 months postoperation) included pulse examination and duplex ultrasound imaging. Patients whose last duplex scan had been more than 6 months ago were called in for another follow-up in January 2013 to compile the most up-to-date data. Follow-up was complete with no patients lost during the period of our study. Wound healing and pulsatile bypass perfusion were evaluated. The bypass was considered occluded when no duplex signal could be detected.

Statistical analysis was done using SPSS 15 (SPSS Inc, Chicago, Ill). Kaplan-Meier life table method evaluated graft patency, limb salvage, and patient survival. Nonparametric Mantel-Cox log-rank test was used to compare the survival curves between the groups. The variables subjected to nonparametric testing were survival, primary patency, secondary patency, and limb salvage. χ^2 test and Fisher exact test were used to compare patients' risk factors, indications, bypass characteristics, and morbidity and mortality between the PEI group and BSF group. $P < .05$ was deemed statistically significant.

RESULTS

Morbidity and mortality rates. Comparative morbidity and mortality information is shown in Table IV. The overall 30-day mortality was 4.0% (PEI group, 2.8%; BSF group, 5.1%; $P = .525$). There were no procedure-related deaths (one myocardial infarction, one renal failure, one pulmonary failure). There were no significant differences in major complications between both groups. The overall survival rate was 80.4% at 1 year (PEI group, 79.5%; BSF group, 81.3%; $P = .765$; Fig 1).

Graft patency and limb salvage rates. Overall primary patency at 1 year was 58.3% (PEI group, 67.0%; BSF group, 48.3%; $P = .409$; Fig 2). Overall 1-year secondary patency was 61.3%, without reaching statistical significance (PEI group, 73.5%; BSF group, 48.6%; $P = .100$; Fig 3). There was a cumulative of 14 graft occlusions within the first 30 postoperative days (18.7%). Again, there was no significant difference between the groups (PEI group, 19.4%; BSF group, 17.9%; $P = .551$).

Limb salvage at 1 year (Fig 4) was 82.3% in PEI group and 71.6% in BSF group ($P = .515$) with an overall limb salvage of 76.8%. Out of the 14 patients with early graft occlusions, 78.6% underwent major amputation. We did not attempt any further ETs in any of the patients with early graft occlusions before major amputation. A total of 11.1% of patients in the PEI group and 7.7% of patients in the BSF group underwent minor amputation at some point after their bypass surgery ($P = .454$).

Secondary interventions and operations. We performed five graft thrombectomies in five of the 14 patients with early graft occlusions. Unfortunately, none of them were successful, and four of them had to undergo major amputation. Furthermore, five patients successfully underwent ET for graft stenosis. One acute graft occlusion was successfully treated with lytic therapy. Lytic therapy failed in two other patients. Out of the successfully treated patients, three went on to require another intervention. Two of them received ET, and one underwent thrombectomy surgery. All of those interventions were successful.

DISCUSSION

The purpose of this study was to assess whether an endovascular-first approach to crural occlusions has a negative impact on the outcome of subsequent pedal bypass surgery. Our study shows that a prior endovascular intervention does not affect the outcome of pedal bypass