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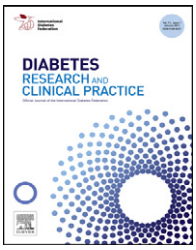

Limb revascularization feasibility in diabetic patients with critical limb ischemia: Results from a cohort of 344 consecutive unselected diabetic patients evaluated in 2009

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ABSTRACT

Aims: To evaluate the feasibility of peripheral revascularization by angioplasty (PTA) or bypass grafting (BPG) in diabetic patients with critical limb ischemia (CLI).
Methods: All diabetic patients referred to our Diabetic Foot Centre for foot lesion or rest pain were assessed for the presence of CLI as assessed by the TASC criteria. All patients underwent angiography that was evaluated jointly by an interventional radiologist, a vascular surgeon and a diabetologist of the diabetic foot care team.
Results: During 2009, 344 diabetics were admitted because of CLI in a total of 360 limbs. PTA was performed in 308 (85.6%) limbs, and BPG was performed in 40 (11.1%) limbs in which PTA was not feasible. Revascularization could not be carried out in 12 (3.3%) limbs due to the lack of target vessel (9 limbs) or high surgical risk (3 limbs).

According to the judgement of the vascular surgeon, BPG was anatomically feasible in 180 (58.4%) of the 308 limbs that underwent PTA. Therefore, considering also the 40 limbs that underwent BPG, surgical revascularization was judged anatomically possible in a total of 220 (61.1%) limbs.

At 30 days, 19 (5.3%) above-the-ankle amputations were performed: 8 (66.7%) amputations were performed in the 12 non-revascularized limbs, 8 (2.6%) amputations were performed in the 308 limbs treated with PTA and 3 (7.5%) amputations were performed in the 40 limbs treated with BPG.
Conclusions: Revascularization by PTA is highly feasible in diabetics with CLI. The feasibility of revascularization by BPG is lower but nonetheless consistent. In centres where both revascularization procedures are available, it is possible to revascularize more than 96% of diabetics with CLI.

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Abbreviations: CLI, critical limb ischemia; PTA, peripheral angioplasty; BPG, bypass graft; $TcPO_2$, transcutaneous oxygen tension.

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1. Introduction

In diabetic patients with critical limb ischemia (CLI), increased revascularization has been shown to decrease above-the-ankle amputations [1,2]. Many trials have only reported the outcomes of revascularized patients [3,4], while only few studies have described the revascularization feasibility and outcomes of both revascularized and non-revascularized diabetic patients with CLI [5,6], and only a few of them have specifically focused on diabetic population [7,8].

The purpose of this prospective study was to evaluate the feasibility of revascularization either by peripheral transluminal angioplasty (PTA) or peripheral bypass grafting (BPG), as well as the rate of limb salvage at 30 days in a consecutive series of diabetic patients hospitalized for CLI in 2009 in a specialized and multidisciplinary Diabetic Foot Centre.

2. Methods

2.1. Study design

The present prospective study reports the revascularization feasibility with endoluminal or surgical revascularization in a series of consecutive unselected diabetic patients admitted to our foot centre during 2009 because of CLI according to the Trans-Atlantic Inter-Society Consensus II (TASC II) criteria [9]. The study was approved by the ethical committee of our institution and registered at ClinicalTrials.gov (NCT01297387).

2.2. Protocol

CLI was detected if transcutaneous oxygen tension ($TcPO_2$) at the dorsum of the foot was <30 mmHg and ankle pressure was <70 mmHg when measurable (non-palpable foot pulses or non-compressible foot arteries because of medial calcifications). All patients with these parameters underwent an arteriography. At the end of the arteriography study, the anatomical and clinical revascularization feasibility was evaluated jointly by an interventional radiologist, a vascular surgeon and a diabetologist. In patients at low surgical risk who presented a long femoral occlusion with at least one infrapopliteal artery patent down to the foot, a bypass graft (in accordance with AHA guidelines) was scheduled [10]. In patients with significant comorbidities, PTA was attempted in the same session of the angiographic study, even in case of long calcified femoral occlusions.

A nephroprotection protocol was used in all nondialyzed patients: 1500 ml saline was infused intravenously the day before and the day of the procedure and the day after the procedure. In patients with an ejection fraction <40%, 20 mg of furosemide were injected intravenously at the beginning and the end of the daily hydration. Bun and creatinine values were determined the day before and after the PTA.

2.3. PTA procedure

PTA was indicated for angiographically documented obstructions in >50% of the vessel lumen. The procedures were performed under local anesthesia. The first choice approach for lower limb intervention was ipsilateral antegrade puncture of the common femoral artery. Brachial or contralateral femoral approach was chosen if at least one of the following pre-specified conditions was found: duplex scan evidence of iliac or common femoral artery stenosis >50%, severe obesity, high femoral bifurcation, previous stenting of the common femoral artery, recent intervention at the ipsilateral femoral groin with hematoma, or suspect skin infection at the target groin. Thereafter, a bolus of 70 UI/kg of unfractionated heparin was administered, eventually incremented in order to maintain an activated clotting time (ACT) >250 s. A 0.014–0.018-inch guide wire was inserted over arterial obstructions and balloon catheters used for the dilatation of 2–8-mm diameter arteries. The occurrence of thrombi was managed by mechanical aspiration and/or alteplase and heparin infusion. Stents were used based on the opinion of the interventional radiologist, particularly if dissection or suboptimal results persisted despite repeated, prolonged balloon inflations. Vessel recanalization was considered successful when direct flow was obtained in the treated vessel with no residual stenosis >30% of vessel diameter along the artery.

2.4. BPG procedure

The choice of proximal and distal BPG anastomosis depended on the angiographic picture and aimed at obtaining at least one patent foot artery. The inflow was optimized, when possible, by combining femoral-popliteal bypass and PTA of the iliac trunk. Moreover, also in view of a following distal angioplasty, the distal anastomosis was performed on the most suitable popliteal or tibial artery segment by using intraluminal clamping and microsurgical technique. The autogenous saphena vein was employed if present and in good condition. If venous conduit could not be used, alloplastic prosthetic material (polytetrafluoroethylene: PTFE) was employed and the peripheral anastomosis consisted of a venous cuff using the Miller's technique, or ''composite'' bypass with interposition of distal venous segments. The absence of an available saphena and an angiographic score of run off >7 on the Rutherford scale [11] did not exclude any patient, who otherwise could be eligible only for a major amputation, from a revascularization with distal bypass.

All the patients were prescribed ticlopidine 500 mg/day plus acetyl salicylic acid 100 mg/day indefinitely. In patients with previous anticoagulant or clopidrogel therapy the therapy was confirmed.

2.5. Comorbidity evaluation

All patients were assessed using the PREVENT III CLI risk score [12]. The following data were recorded: ulcer grade according to the Rutherford's categories [11], clinical signs of ulcer infection (local cellulitis, erythema, or purulence with a positive swab culture), diabetes treatment and duration, history of diabetic retinopathy, sensorimotor neuropathy (vibration perception threshold >25 V, insensitivity in >5 of 9 foot points with Semmes-Weinstein 10 g filament, absent Achilles' reflex), renal insufficiency