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# Long term outcomes of diabetic haemodialysis patients with critical limb ischemia and foot ulcer <sup>☆</sup>

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## ABSTRACT

**Aim:** To evaluate the outcomes of diabetic dialysis patients with critical limb ischemia and foot ulcer.

**Methods:** The study group included 599 diabetic, 99 dialyzed (Ds) (16.5%) and 500 not dialyzed (NDs) (83%) patients with critical limb ischemia and foot ulcers identified as stage C (ischemia) or D (ischemia plus infection) of Texas Wound Classification.

All patients were treated by endovascular revascularization. Outcomes were expressed as healing, major amputation, death and non healing after 12 months. The mean follow-up was 15 ± 13 months.

**Results:** The outcomes of the whole population were: 48.9% healing, 11.3% major amputation, 12.7% death, 27.1 non healing. At the multivariate analysis dialysis was a negative predictor of healing and a positive predictor of major amputation. Outcomes for Ds and NDs were respectively: healing (30.3 vs 52.6%), major amputation (14.4 vs 10.8%), death (21.1 vs 11%) and non-healing (34.2 vs 25.6%) ( $X = 0.0004$ ). Amputation occurred earlier in Ds than in NDs. According to the multivariate analysis in Ds ischemic heart disease and lower  $\Delta TcPO_2$  were negative predictors for healing. Successful revascularization was a negative predictor for major amputation. HDL and carotid artery disease were predictive factors of death among NDs. Among Ds high blood pressure values were the only predictor of amputation while no variable resulted predictive of healing or death.

**Conclusions:** Our study shows that our limb salvage protocol ensures a good rate of limb salvage in Ds even if they have a higher risk of amputation and death compared to NDs.

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## 1. Introduction

Diabetes and renal disease are two recognized independent risk factors for peripheral arterial disease (PAD) [1]. The presence of both diabetes and dialysis significantly increases PAD risk. In diabetic patients on dialysis the PAD prevalence reaches values of about 80% [2]. Furthermore, dialysis is an

independent risk factor for foot ulcer (FU), non-healing ulcer and amputation in diabetic subjects [3–6]. A primary amputation rate of 44% has been reported in dialyzed diabetic patients with ischemic foot lesions [5].

Revascularization of lower limbs might be the first line treatment in case of critical limb ischemia (CLI) also in dialysis diabetic patients [7]. However, although good results have

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been reached in the treatment of diabetic patients with CLI [8], unsatisfactory outcomes are reported for CLI diabetic patients on dialysis [7].

In our institution we apply a limb salvage protocol to all diabetic patients with CLI including those on dialysis [9,10], and it may be interesting to analyze them as a specific cohort.

Therefore, the aim of this study is to evaluate the outcomes of diabetic patients with CLI and FU treated according to a limb salvage protocol comparing subjects under dialysis treatment and not.

## 2. Subjects and methods

The study group included 599 diabetic patients, 99 dialyzed (Ds) (16.5%) and 500 not dialyzed (NDs) (83.5%) with CLI and foot ulcers (FUs) identified as stage C (ischemia) or D (ischemia plus infection) of Texas Wound Classification (TWC) [11] consecutively recruited at the Diabetic Foot Unit of University of Tor Vergata Rome. Subjects on dialysis were treated exclusively by haemodialysis. All patients included in this analysis were managed according to a defined limb salvage protocol that includes: early and aggressive surgical debridement, revascularization performed by endovascular technique, antibiotic therapy in case of infection (starting with empirical broad-spectrum therapy and after driven by swabs culture results). Patients general health was optimized with the close control of comorbidities, heart disease, renal function, glycemic levels, electrolyte balance, anemia, pain. To better define the other macrovascular complications a standard electrocardiogram was routinely performed and in case of clinical or instrumental abnormalities an echocardiogram or a myocardial scintigraphy was performed. In case of significant coronary heart disease, cardiac revascularization was performed and CLI was treated only after haemodynamic stabilization. Carotid arteries were studied by standard doppler ultrasound and in selected cases by computed tomography (CT). In case of stenosis >70% or ulcerated plaque, angioplasty of carotid vessels or thromboendarterectomy was performed before lower limbs angioplasty. Vascular assessment of lower limbs arteries was usually performed by doppler ultrasound and in some cases by magnetic resonance or CT to detect arterial stenosis and/or obstruction and to allow our interventional radiologists in defining the treatment road map. Transcutaneous oxygen pressure (TcPO<sub>2</sub>) was measured on different areas of the foot according to the ulcer localization and angiosome theory before PTA, immediately after, after 1 month and then every 6 months. TcPO<sub>2</sub> is a non invasive tool used to evaluate the foot perfusion and nowadays it is considered a validated criteria to define CLI [1]. After PTA and during the follow-up it allows to monitor lower limb perfusion and to identify promptly a relapse of limb ischemia.  $\Delta$ TcPO<sub>2</sub> was considered as the difference in terms of TcPO<sub>2</sub> between the values recorded before the PTA and one-month after. Among the different variables recorded at baseline carotid artery disease was considered present in case of occlusion or stenosis >50% or in case of previous carotid revascularization (by open surgery or by endovascular approach). According to American Diabetes Association patients were considered to have target levels of glycemia, blood pressure (BP) and low density

lipoproteins (LDL) in presence of respectively HbA<sub>1c</sub> < 7.0% (48 mmol/mol), BP < 130/80 mmHg and LDL < 70 mg/dl [12].

### 2.1. Revascularization

All revascularization procedures were performed by endovascular approach. According to Italian Guidelines, PTA was indicated in case of significant arterial stenosis (>50%) or complete obstruction [8]. After a local anesthesia and a bolus injection of sodium heparin in the artery (usually 4000–6000 IU) a preliminary angiographic study is performed. Then guidewires are inserted to cross arterial obstruction followed by a balloon catheter to allow the required dilatation. Rarely stents are placed because of the risk of thrombosis in low-flow vessels mainly in the below-the-knee arteries. In some cases sub-intimal approach is adopted. All patients were treated by both aspirin (100 mg/die) and clopidogrel (75 mg/die) before the procedure and for one month after. Afterwards clopidogrel was discontinued. In case of intolerance to aspirin or clopidogrel, ticlopidine was administered.

### 2.2. Surgical debridement

Surgical debridement was routinely performed at each examination and repeated in a more or less aggressive way during the follow-up according to the progression of the ulcer. Aggressive surgery was applied in case of abscess, compartment syndrome, extended gangrene, infected tissues, open fistulas. In those cases of extended infection early debridement was performed, even before revascularization, to limit the progression of infection and completed after adequate perfusion was ensured.

### 2.3. Antibiotic therapy

Broad spectrum antibiotic therapy was administered in case of infected ulcer and adapted to culture results, if required, during the follow-up [13].

### 2.4. Post-operative offloading

Adequate post-operative shoes were prescribed during the acute phase according to ulcer localization and the amount of tissue lost.

### 2.5. Outcomes

The followed outcomes were recorded: healing, non healing, major amputations and death. The outcomes were considered for the whole population and separately for patients on dialysis and not. The first outcome achieved at the follow-up was the only considered and the time to event was recorded. Healing was considered in case of epithelial viable tissue covering completely all previous open wounds. Non-healing was defined as unhealed ulcer after at least one year of follow-up with no interference on deambulation, without signs of infection and limb ischemia not requiring both new revascularization or major amputation. Major amputation was defined as amputation above the ankle.

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