Severity of Demographic and Clinical Characteristics, Revascularization Feasibility, Major Amputation, and Mortality Rate in Diabetic Patients Admitted to a Tertiary Diabetic Foot Center for Critical Limb Ischemia: Comparison of 2 Cohorts Recruited at a 10-year Distance

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Background: To compare demographic and clinical characteristics, revascularization, major amputation, and mortality among patients admitted to a diabetic foot center because of critical limb ischemia (CLI) during 1999−2003 (cohort 1) and 2009 (cohort 2).
Methods: During 1999−2003, 564 diabetic patients with CLI (cohort 1) were admitted to our center, and 344 patients (360 affected limbs) were admitted during 2009 (cohort 2). Data on demographic and clinical characteristics, revascularization by peripheral angioplasty (PTA) or bypass graft (BPG), major amputation, and mortality were recorded.
Results: Patients belonging to cohort 2 were older than patients of cohort 1 ($P = 0.001$). In cohort 2, there were more subjects requiring insulin ($P = 0.008$) and duration of diabetes was longer ($P = 0.001$); moreover, there were more patients requiring dialysis ($P = 0.001$), patients with history of stroke ($P = 0.004$), or foot ulcer ($P = 0.001$). No significant difference between the 2 groups was found concerning gender, metabolic control, hypertension, lipid values, neuropathy, and retinopathy. Occlusion was more frequent than stenosis in the posterior tibial ($P < 0.001$) and peroneal ($P = 0.016$) arteries. However, the revascularization rate did not differ ($P = 0.318$) between the 2 groups. Restenosis after PTA was not significantly different ($P = 0.627$), whereas BPG failure was significantly more frequent ($P = 0.010$) in cohort 2 (2009). Major amputation ($P = 0.222$) and mortality rate ($P = 0.727$) did not differ between the 2 groups.
Conclusions: The severity of either foot lesions or patients comorbidities should be concomitantly assessed and taken into proper consideration when evaluating changes in the amputation rate among different studies or in different temporal settings.

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INTRODUCTION

One of the primary objectives of diabetes care is to reduce the need for major amputation in diabetic patients. The St. Vincent declaration signed in 1989, within the 5-year targets for health improvement in diabetic subjects, included the recommendation to adopt interventions to "reduce the rate of limb amputations for diabetic gangrene by half".[1] There is a vast amount of articles in the literature on this topic. However, the reported incidence of limb amputation varied enormously between published studies.[2,3] In many reports the amputation rate significantly dropped,[4–17] in others seemed to remain unchanged, and whereas in some cases, there was even an increase of the amputation rate.[18–24]

In our diabetic foot center, a substantial reduction in the amputation rate was achieved at the beginning of the nineties. In particular, around year 2000 there was a substantial decrease of the amputation rate because of the increasing revascularization rate.[25,26] However, it remained virtually unchanged since then[27] Therefore, questions arose concerning the correct data evaluation and the possible reasons behind observed results.

The aim of this study was to evaluate any significant difference in demographic and clinical characteristics, revascularization rate, and prevalence of major amputation and mortality between 2 series of diabetic patients admitted to our foot center with critical limb ischemia (CLI). In particular, the cohort recruited during 1999–2003 (cohort 1) was compared with a cohort recruited during 2009 (cohort 2).

METHODS

Between January 1999 and December 2003, 564 diabetic patients were consecutively admitted to our foot center because of CLI; the follow-up of this group of patients (cohort 1) lasted until the 31 December 2006.[26] During 2009, 344 consecutive diabetic patients with CLI (a total of 360 affected limbs) were admitted to our foot center. This group of patients (cohort 2) was followed up until 31 December 2012.[27]

In particular, we examined the databases that were created for these 2 quoted studies for the comparison of demographic and clinical characteristics. Only identical sets of variables from the 2 databases were taken into account and compared.

Comparable Data Recorded in the 2 Study Periods

Database records included the followings: age, gender, diabetes treatment and duration, finger-stick blood glucose levels measured at patient admission and discharge, glycosylated hemoglobin (HbA$_1$c, Hb% measured by high-pressure liquid chromatography, normal value: 4–6.4), sensorimotor neuropathy (vibration perception threshold >25V, insensitivity in >5/9 foot points with a Semmes–Weinstein 10 g filament, and absent Achilles reflex), serum creatinine value (mg/dL; Jaffe; Roche, Milan, Italy), retinopathy (history), arterial hypertension (ongoing antihypertensive treatment), total cholesterol (measured by colorimetric assay, Boehringer Mannheim, Monza, Italy), high-density lipoprotein cholesterol (measured using the Polyethylene Glycol 6,000 method, with a reagent made in laboratory), triglycerides (measured by colorimetric assay, Bayer, Milan, Italy), previous history of cardiac disease, stroke, and prior major amputation.

The severity of lesions in cohort 1 was classified using the Wagner classification system, whereas the Rutherford grade and category classification was used to classify lesions in cohort 2. Therefore, a direct comparison of diabetic foot lesions between the 2 groups of patients is difficult except for comparing the rates of patients admitted because of pain at rest without foot ulcers (Wagner grade 0 and Rutherford grade and category 0). However, it is possible to venture a comparison between patients with the Wagner grades 2 + 3 + 4 and Rutherford grades 5 + 6.

CLI was diagnosed according to the Trans-Atlantic Inter-Society Consensus (TASC) 2000 and TASC II ankle-pressure values, which did not differ in the 2 TASC editions.[28,29] According to the 2000 TASC, transcutaneous oxygen pressure (TcPO$_2$) values <50 mm Hg were required for CLI diagnosis, while TcPO$_2$ values <30 mm Hg were required according to the 2007 TASC edition; however, as the mean TcPO$_2$ values reported in the 2 studies did not differ too much, we considered the oximetric data appropriate for comparison.

Follow-up

The follow-up period was similar in the 2 groups of patients: 3.4 ± 1.3 years in cohort 1 and 3.7 ± 0.9 years in cohort 2. Therefore, the rates of major amputation, CLI recurrence (peripheral angioplasty [PTA] restenosis or by-pass graft [BPG] failure), and mortality during the follow-up between the 2 groups were also compared.