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Analysis of the Elective Treatment Process for Critical Limb Ischaemia with Tissue Loss: Diabetic Patients Require Rapid Revascularisation

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WHAT PAPER ADDS

Delay in the treatment of critical limb ischaemia with tissue loss has rarely been investigated, even if the common conception is that these patients require treatment without delay. In this retrospective study, the whole treatment process from referral to revascularisation in all its diversity and complexity is presented. The impact of delay and how rapid revascularisation is essential for diabetic patients is demonstrated.

Objectives: The number of elderly people is increasing; inevitably, the result will be more patients with critical limb ischaemia (CLI) in the future. Tissue loss in CLI is related to a high risk of major amputation. The aim of this study was to analyze the treatment process from referral to revascularisation, to discover possible delays and reasons behind them, and to distinguish patients benefitting the most from early revascularisation.
Methods: A retrospective analysis was performed of 394 consecutive patients with a combined 447 affected limbs, referred to the outpatient clinic during 2010–2011 for tissue loss of suspected ischaemic origin.
Results: For 246 limbs revascularisation was scheduled. After changes in the initial treatment strategy, endovascular treatment (ET) was performed on 221 and open surgery (OS) on 45 limbs. Notably there was crossover after ET in 17.0% of the procedures, and re-revascularisations were required in 40.1% after ET and 31.1% after OS. The median time from referral to revascularisation was 43 days (range 1–657 days) with no significant difference between ET and OS. For 29 (11.8%) patients the ischaemic limb required an emergency operation scheduled at the first visit to the outpatient clinic. For 25 (10.2%) patients the situation worsened while waiting for elective revascularisation and an emergency procedure was performed. Diabetic patients formed the majority of the study population, with 159 diabetic feet undergoing revascularisation. In multivariate analysis, diabetes was associated with poor limb salvage. When revascularisation was achieved within 2 weeks, no difference was seen in limb salvage. However, when the delay from first visit to revascularisation exceeded 2 weeks, limb salvage was significantly poorer in diabetic patients.
Conclusions: Diabetic ulcers always require vascular evaluation, and when ischaemia is suspected the diagnostics should be organised rapidly to ensure revascularisation without delay, according to this study within 2 weeks from the first evaluation.

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INTRODUCTION

Ulcer formation in an ischaemic limb is a sign of critical limb ischaemia (CLI), the most severe form of peripheral artery disease (PAD). The prevalence of CLI and ischaemic ulcers is rising with the aging population and the growing number of diabetic patients. PAD is estimated to affect 9–24%[1–3] of diabetic patients during their lifetime, and analogously 8–25%[1,4] of diabetic patients are estimated to develop a foot ulcer.

Diabetic foot ulcers and their treatment trajectories have been widely investigated, but studies concerning delay in revascularisation are scarce.[5,6] The primary care centres play a vital role in the early detection of inadequate arterial blood supply in a diabetic foot,[7,8] which is crucial for patient prognosis.[9,10] Once PAD is suspected, a vascular surgeon is usually consulted and further investigations are conducted, upon which the revascularisation plan is then based. Specific target times for revascularisation are difficult to establish because of various referral patterns and very heterogeneous ulcers. The guideline for the timing of revascularisation according to previous studies can be encapsulated in the words: "the sooner, the better."

According to the Finnish guidelines, whenever a tissue lesion of suspected ischaemic origin is detected referral for

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vascular evaluation is made, thus commencing the treatment process at the vascular outpatient clinic in Helsinki University Hospital (HUH). The aim has been to organise the first visit within 1 week of the referral for all these patients, including all diabetic patients with an ulcer. After ankle brachial index (ABI) and toe pressure (TP) measurements in the vascular laboratory, vascular imaging, usually magnetic resonance angiography (MRA), is scheduled, after which the decision on treatment is made and revascularisation is scheduled. If ischaemia is detected, the presence of an ulcer is considered to be a sign of CLI and therefore revascularisation is scheduled within 2 weeks from the decision.

This retrospective study was launched in order to determine the success of elective treatment of ischaemic ulcers and to determine guidelines for the treatment process. The main focus was on wound healing, the number of emergency procedures while waiting for an elective procedure, and major amputations and deaths during follow-up. Owing to the growing incidence of diabetes, there was also focus on the treatment trajectories of diabetic foot ulcers.

MATERIALS AND METHODS

The study population for this retrospective study was collected from the 2187 consecutive patients visiting the senior vascular consultant's outpatient clinic between January 1 2010 and December 31 2011 (Fig. 1). The inclusion criterion was a foot ulcer of suspected ischaemic origin including all diabetic ulcers. The ABI was documented and toe pressure (TP) measurements were taken at the first evaluation, but no threshold values were set for inclusion in the study. In addition to the patients assigned for revascularisation, the patients assigned for conservative treatment were included, to gain a comprehensive perspective on the entire elective treatment process.

The whole treatment process was analysed starting from referral, with follow-up continuing until the end of 2013. The time spent on each step of the treatment process from referral to revascularisation was investigated. Cancellations of the intended treatment, and the number as well as the reasons for urgent diagnostics and treatments while waiting for elective treatment were noted. The outcome of the treatment process was analysed separately for endovascular treatment (ET), open surgery (OS), and for patients not receiving revascularisation. Wound healing was analysed during follow-up and healing was regarded as achieved when the wound had healed completely or was so close to being healed that no further follow-up was considered necessary. Limb salvage (LS) and amputation free survival (AFS) were assessed by intention-to-treat (ITT) analysis on the basis of the originally assigned treatment and per treatment (PT) analysis according to the final revascularisation, that is the one that was considered to be the first successful one. For example, when OS was performed after failed ET, the limb belonged to the OS group in the PT analysis, but if a bypass graft undergoing surveillance required ET due to stenosis or occlusion, the limb remained in the OS group. The main focus in this study was the diabetic foot; therefore, their treatment process and outcome during follow-up were analysed separately.

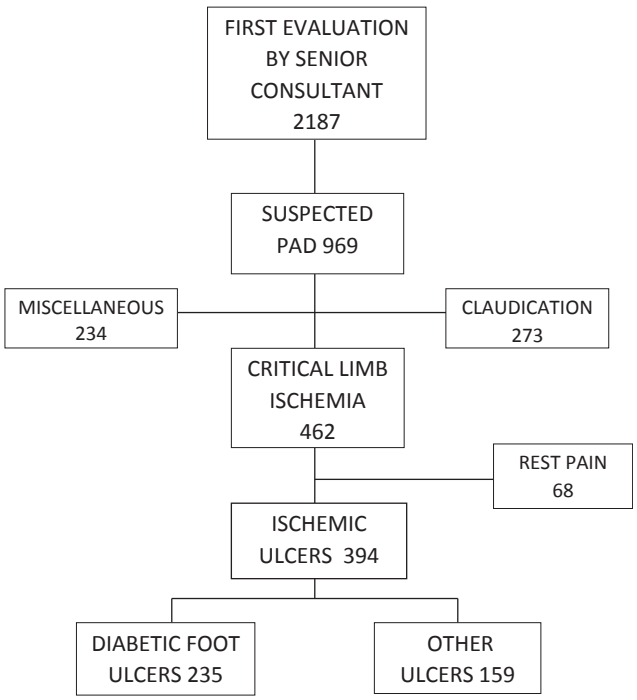

Figure 1. The patients visiting senior consultant at Helsinki University Hospital vascular outpatient clinic in 2010—2011.

The demographic characteristics are expressed as percentages, and the delays in the treatment process as median days with interquartile ranges (IQR). LS and AFS were assessed using the Kaplan—Meier method. To assess the independent risk factors for major amputation, univariate analysis was performed followed by the Cox proportional hazards model consisting of the factors reaching $p < .2$ in the univariate analysis. Using univariate analysis, all the comorbidities, wound location, and delay to treatment were tested. Multivariate analysis was performed for the overall series and separately for diabetic and non-diabetic patients. Statistical analysis was performed with the SPSS 19.0. statistical software (IBM SPSS Inc., Chicago, IL, USA).

RESULTS

Of the 969 first evaluations for suspected PAD at the senior consultant outpatient clinic during 2010—2011, 394 patients with a total of 449 affected limbs had ulcers. The typical patient in the study population lived at home, needed walking assistance, had hypertension and diabetes, and was on either antithrombotic or anticoagulant medication (Table 1). The suspected ischaemic ulcer had normally existed for more than 1 month, was located in the forefoot, and there had been no previous revascularisations (Table 2).

Treatment strategies

Revascularisation was scheduled for 233 patients with a total of 248 affected limbs. The initial treatment strategy, which was ET for 201 and OS for 47 limbs, changed for

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