

## Not All Patients with Critical Limb Ischaemia Require Revascularisation<sup>☆</sup>

T.B. Santema<sup>\*</sup>, R.M. Stoekenbroek, J. van Loon, M.J.W. Koelemay, D.T. Ubbink

Department of Surgery, Academic Medical Centre, Amsterdam, The Netherlands

### WHAT THIS PAPER ADDS

Most contemporary research focuses on the outcome of invasive procedures for critical limb ischaemia (CLI), but little is known about the outcome of patients managed conservatively. The aim of this study was to investigate amputation free survival and overall survival in patients with CLI who did or did not undergo revascularisation, and to explore clinical characteristics associated with clinical outcomes in these patients. Conservative management for some of the CLI patients appears warranted. Hence, surgeons and interventional radiologists should reconsider their current practice. Better patient selection would save unnecessary revascularisation and pre-operative diagnostic procedures.

**Objectives:** International guidelines recommend revascularisation as the preferred treatment for patients with critical limb ischaemia (CLI). Most contemporary research focuses on the outcome of invasive procedures for CLI, but little is known about the outcome of conservative management. Amputation free survival (AFS) and overall survival (OS) was investigated in patients with CLI who did or did not receive revascularisation, and characteristics associated with clinical outcomes were explored.

**Methods:** This was a retrospective cohort study of consecutive patients with chronic CLI between 2010 and 2014 in a Dutch university hospital. CLI was defined as the presence of ischaemic rest pain or tissue loss in conjunction with an absolute systolic ankle pressure < 50 mmHg or a toe pressure < 30 mmHg. Patients were divided into invasive (revascularisation within 6 weeks), deferred invasive (revascularisation after 6 weeks), or permanently conservative treatment groups. Univariable and multivariable survival analyses were used to identify factors associated with AFS and OS.

**Results:** The majority (66.7%;  $N = 96$ ) of the identified 144 patients with CLI (mean age 71.2 years; median follow-up 99 weeks) underwent revascularisation within 6 weeks of diagnosis. Deferred invasive treatment was provided in 18.1% ( $N = 26$ ) patients and 22 patients (15.3%) were treated permanently conservatively. AFS and OS did not differ significantly between the three groups (Breslow–Wilcoxon  $p = .16$  for AFS and  $p = .09$  for OS). Age, chronic obstructive pulmonary disease (COPD), and heart disease were significant independent predictors of AFS. Age, COPD, and hypertension were significant independent predictors of OS. Treatment was not a significant predictor of either AFS or OS.

**Conclusions:** Not all patients with CLI require revascularisation to achieve an AFS that is similar to patients undergoing revascularisation, although the efficacy of conservative versus invasive treatment in CLI patients is still unclear. Further prospective studies should determine subgroups of patients in whom revascularisation may be omitted.

© 2016 European Society for Vascular Surgery. Published by Elsevier Ltd. All rights reserved.

Article history: Received 7 June 2016, Accepted 22 October 2016, Available online XXX

**Keywords:** Critical limb ischaemia, Peripheral vascular disease, Revascularisation, Conservative management, Amputation free survival, Major amputation

<sup>☆</sup> Parts of this manuscript were presented during an abstracts session at the Charing Cross International Symposium. (London, United Kingdom, April 26–29, 2016). <http://www.cxsymposium.com/cx-events-2016/?set=3.0700>.

<sup>\*</sup> Corresponding author. Department of Surgery, Room G4-132, Academic Medical Centre, PO Box 22660, 1100 DD Amsterdam, The Netherlands.

E-mail address: [t.b.santema@amc.uva.nl](mailto:t.b.santema@amc.uva.nl) (T.B. Santema).

1078-5884/© 2016 European Society for Vascular Surgery. Published by Elsevier Ltd. All rights reserved.

<http://dx.doi.org/10.1016/j.ejvs.2016.10.018>

### INTRODUCTION

Chronic critical limb ischaemia (CLI) is associated with a high risk of lower limb amputation, diminished quality of life, and substantial mortality.<sup>1,2</sup> The Inter-Society Consensus for the Management of Peripheral Arterial Disease (TASC II) guidelines<sup>3</sup> recommend diagnostic staging and revascularisation for all patients with CLI. The main goals of endovascular and open revascularisation are pain relief and the prevention of lower limb amputation.

Revascularisation is not always possible because patients with CLI often have severe comorbidities or because it is not

technically feasible. In this case patients are treated conservatively with analgesics and optimal wound care or with primary amputation. Two systematic reviews reported 1 year AFS rates of 55% and 57 in patients with CLI without options for revascularisation.<sup>4,5</sup> Although patients with CLI have a poor prognosis in terms of amputation free survival (AFS), there is evidence to suggest that some patients who are not suitable candidates for revascularisation carry on well.<sup>6–9</sup>

Despite optimal diagnostics and technical success, not all revascularisation procedures are successful and additional interventions may be necessary to maintain patency or achieve wound healing. Furthermore, complications such as graft occlusion and wound infection are relatively common after bypass surgery.<sup>10,11</sup> Even if technically successful, revascularisation procedures do not always outperform non-interventional treatment. In some patients amputation is necessary despite adequate revascularisation,<sup>12</sup> and in other patients wounds heal despite a failed, or even without, revascularisation.<sup>9</sup>

Most contemporary research focuses on outcomes of invasive procedures for CLI, but few data are available on the outcome of patients managed conservatively. The aim of this study was to investigate AFS and overall survival (OS) in patients with CLI who did or did not receive revascularisation, and to explore clinical characteristics associated with clinical outcome in these patients. By gaining insight into the outcome after conservative management, improved patient selection for costly revascularisation procedures may follow.

## METHODS

This study was conducted and reported in accordance with the STrengthening the Reporting of OBservational studies in Epidemiology (STROBE) statement.<sup>13</sup> Ethical approval of the local Institutional Review Board was waived since this was a retrospective observational study.

### Patient selection

All consecutive patients with chronic CLI presenting between January 2010 and January 2014 were selected for this retrospective study by evaluating vascular laboratory data and medical charts. Only patients with clinical symptoms of ischaemic rest pain or tissue loss and a systolic ankle pressure below 50 mmHg or a systolic toe pressure below 30 mmHg were eligible. If only one of these two parameters was present (e.g., low ankle pressure but no rest pain or tissue loss) the patient was not included. Other exclusion criteria were acute limb ischaemia, Buerger's disease, or vasculitis. Patients who were treated elsewhere and visited the hospital for a second opinion were also excluded. When CLI was demonstrated during an earlier examination (i.e., before January 2010) and the pressure measurement (showing CLI) was for follow-up purposes, the date of diagnosis was set at the date of the first clinical manifestation of CLI.

### Data collection and outcome measures

Patient characteristics including age, gender, smoking habits, body mass index (BMI), comorbidities diabetes mellitus, cerebrovascular disease, end stage renal disease (ESRD), chronic obstructive pulmonary disease (COPD), heart disease, hypertension, presence of ischaemic rest pain (Fontaine stage III) or presence of ulceration or gangrene (Fontaine Stage IV) and prior revascularisation procedures were obtained from clinical charts and operation records. "Cerebrovascular disease" was defined as a previous transient ischaemic attack (TIA) or stroke, and "heart disease" as a previous myocardial infarction, angina pectoris, congestive heart failure, or prior coronary intervention. "ESRD" was defined as current haemodialysis, peritoneal dialysis, or previous kidney transplantation. Follow-up data included information about the revascularisation procedures performed, limb salvage and survival.

Patients were divided into one of the following three groups: "invasive" if the revascularisation took place within 6 weeks of presentation, "deferred invasive" if the revascularisation was conducted after more than 6 weeks of conservative management, and "permanently conservative" when no revascularisation was done between diagnosis and death or the last follow-up. The 6 week period was chosen as it was assumed that primary invasive treatment would have been completed within that period. Patients who immediately underwent a primary major amputation were excluded from the analysis.

Data of the included patients were collected until the patient's last follow-up visit or date of death. When there were no follow-up data available in the clinical charts, the patient's family physician was contacted to obtain additional information about any revascularisation procedures performed elsewhere, limb salvage, and survival.

The primary outcome of this study was AFS, defined as the time the patient remained alive without major amputation (i.e., proximal to the ankle joint) of the affected limb after they were diagnosed with CLI. Furthermore, OS was assessed.

### Statistical analyses

Statistical analysis was performed using Statistical Package for the Social Sciences version 21 (SPSS Inc., Armonk, NY, USA). Descriptive statistics were expressed as means and standard deviations, or medians and interquartile ranges (IQR), whenever appropriate. One-way analysis of variance (ANOVA) was used to analyse differences between the three groups with normally distributed continuous variables and Kruskal–Wallis was used for non-normally distributed continuous variables. The chi-square and Fisher exact tests were used to compare categorical variables where appropriate. A  $p$  value  $< .05$  was taken to be significant. AFS and OS were estimated using Kaplan–Meier survival curves, and differences between groups were analysed using the Breslow–Wilcoxon method. A Cox proportional hazards regression analysis was performed to detect factors that

Download English Version:

<https://daneshyari.com/en/article/5602298>

Download Persian Version:

<https://daneshyari.com/article/5602298>

[Daneshyari.com](https://daneshyari.com)