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Outcome of Unreconstructed Chronic Critical Leg Ischaemia

Mauri Lepäntalo and Sorjo Mätzke

Division of Vascular Surgery, Fourth Department of Surgery, Helsinki University, Helsinki, Finland.

Objective: *To assess the outcome of unreconstructed chronic critical leg ischaemia with a special reference to the definition of CLI.*
Design and Setting: *A retrospective study with 1 year follow-up in an academic referral centre (Fourth Department of Surgery, Helsinki University Central Hospital).*
Material: *105 consecutive unreconstructed patients with 136 critically ischaemic legs as defined by the European Consensus Document on Chronic Critical Leg Ischaemia.*
Main outcome measures: *Major amputations and mortality.*
Results: *81% of the 136 critically ischaemic legs survived 1 month, 70% three months and 54% one year. Of the 105 patients 93%, 77% and 46% were alive at 1, 3 and 12 months, respectively, whereas survival of patients with nonamputated leg was only 71%, 56% and 28%. Patients with bilateral CLI had a worse prognosis in terms of survival and leg salvage. The leg outcome was not worsened by the presence of diabetes nor by the distal extent of arterial changes.*
Conclusion: *Although the selection of the present material is likely to cause some bias, unreconstructed CLI seemed to predict a very poor outcome in terms of survival and limb salvage.*

Key Words: Critical leg ischaemia; Outcome; Mortality; Amputation.

Introduction

One of the main measures of the efficacy of femorodistal bypass surgery in the treatment of chronic critical leg ischaemia (CLI) is the limb salvage rate. An important confounding factor in this assessment is, that there is no reliable way to find out which CLI leads to amputation. It is, if not unethical, very hard to do randomised studies between surgical and non-surgical treatments of CLI, and such studies could be considered only for a limited subset of patients. Therefore the question, how to define true CLI inevitably leading to amputation, is crucial. Both European[1] and American[2] attempts have been made to define CLI. Serious criticism, however, has been raised against these criteria.[3]

The aim of this study was to assess the outcome of CLI in patients unsuitable for reconstructive arterial surgery, in terms of mortality and leg salvage with a special reference to the definition of CLI.

Please address all correspondence to: Mauri Lepäntalo, Division of Vascular Surgery, Fourth Department of Surgery, Helsinki University, Kasarmikatu 11-13, SF-00130 Helsinki, Finland.

Material and Methods

A retrospective 5 year evaluation of 2147 new admissions to the vascular outpatient clinic of the Fourth Department of Surgery, Helsinki University Central Hospital, revealed 658 patients with chronic CLI.[1] In 436 patients (66%) the primary treatment was the revascularisation of the affected leg. 125 (19%) were primarily amputated. 97 (15%) received conservative treatment including anti-smoking counselling, ASA, pain killers, keeping the foot in dependency and local treatment as appropriate. Of the reconstructed legs 41 (9%) were amputated within the first postoperative month.

The patients with unreconstructed chronic CLI were identified retrospectively by evaluating the vascular laboratory data from the years 1988 to 1992 disclosing all patients with CLI and comparing it with operation records. In order to increase the number of patients, the inclusion of the patients was extended for a further 8 months up to August 1993. Patients with an ankle pressure below or equal to 50 mmHg or a toe pressure below or equal to 30 mmHg were identified. By comparing the pressure data to hospital records, all patients having acute or acute on chronic ischaemia,

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Table 1. Characteristics of the patients

	Total	Mean age	Age range	Risk factors								
				No risks	Hypertension	Coronary heart disease	Cerebro vascular disease	Pulmonary disease	Renal disease	Previous vascular operation	Congestive heart failure	Steroid treatment
Nondiabetics	52	75	56–93	1	24	23	16	6	5	10	25	4
Male	24	70	56–86									
Female	28	79	59–93									
Diabetics	53	75	40–96	0	27	29	16	2	2	14	22	1
Male	23	72	40–90									
Female	30	77	61–96									
All	105	75	40–96	1	51	52	32	8	7	24	47	5
Male	47	71	40–90									
Female	58	78	59–96									

undergoing arterial reconstruction, endovascular surgery for chronic critical leg ischaemia or immediate major amputation for any reason could be excluded.

Vascular laboratory data disclosed 160 patients with ankle or toe pressures suggesting critical leg ischaemia. 105 met the clinical and objective pressure criteria for chronic CLI.[1] Altogether 136 legs in these patients had rest pain or ischaemic tissue loss and an ankle pressure below or equal to 50 mmHg or toe pressures below or equal to 30 mmHg. Reconstruction had not been feasible due to technical reasons, mostly the extensive distal nature of the disease alone or in combination with an increased operative risk in 57 (54%), due to an increased operative risk alone in 35 (33%), due to borderline CLI in seven (7%) and due to the patient's refusal in six (6%) patients. The clinical judgment in decision-making was always supplemented by segmental pulse volume recordings and Doppler-derived pressure data, including toe pressure measurements with strain gauge plethysmography, as well as selective femoral angiography in 45 (43%) and Duplex assessment in 16 cases (15%). The majority of the patients were returned either to the primary care physicians, or transferred to other hospitals after the decision not to operate, was made, with an option to readmission at any time in case of deterioration of the ischaemia.

The presence of major risk factors: coronary heart disease and diabetes, was assessed from the patient records. The criteria for coronary heart disease were old myocardial infarction, typical angina pectoris or coronary artery bypass grafting. Coronary heart disease was encountered in 52 patients and one of them had a history of coronary bypass. Fifty-three patients were diabetics requiring either insulin or oral treatment; the diabetic and nondiabetic group did not differ from each other as to risk factors (Table 1). Although there were 34 diabetic patients (60%) in the group whose reconstruction was rejected due to technical reasons, there were no significant differences between them and the others concerning risk factors. The risk factors were defined as follows: hypertension was indicated by treatment with antihypertensive drugs or blood pressure > 160/95, cerebrovascular disease by a history of a transient ischaemic attack or a stroke, renal disease by creatinine serum levels constantly > 150μmol/l or dialysis and pulmonary disease by the recorded diagnosis.

Follow-up data for 1 year was gathered retrospectively. Amputation and death data were traced using the records of our own or other hospitals, or other institutions including homes for the elderly, as well as from the Central Statistical Office of Finland. Patientwise, data was used for life-table analysis of survival and survival without major amputation, whereas legwise data was used for life-table analysis of leg salvage. The effect of risk factors was evaluated by log rank tests. The survival of an age- and sex matched population was calculated with the aid of national statistics.[4]

Results

Although no revascularisation was performed, of all 136 legs with critical ischaemia according to European criteria 81% were saved at 1 month, 70% at 3 months, 58% at 6 months and 54% at 1 year. Five patients were lost to follow-up during the first month and further six were lost up to 1 year. Both mortality and amputation rates were high in the study population (Fig. 1). 72% of the patients died of cardiovascular reasons. Of all 105 patients 93%, 77% and 46% were alive at 1, 3 and 12 months, respectively. The 1 year survival of an age and sex adjusted population would have been 93%. A favourable outcome was observed in 71%, 56% and 28% of the patients who were alive and not amputated at 1, 3 and 12 months (Fig. 1).

The diabetics fared worse than the nondiabetics as to survival ($p < 0.01$) but the limb salvage rate did not show any significant difference between the two groups (Fig. 2). Patients with bilateral CLI had a worse prognosis for survival ($p < 0.01$) and limb salvage ($p < 0.05$) than those with a unilateral CLI at presentation (Fig. 3). If the operation was rejected due to technical reasons, the leg salvage and the patient survival were the same as in patients rejected solely for high operative risk (N.S.). Three of the seven patients with a clinically borderline CLI deceased during the study year although none of them lost their leg. Of the six patients, who refused operative treatment three died and one was amputated in 1 year.

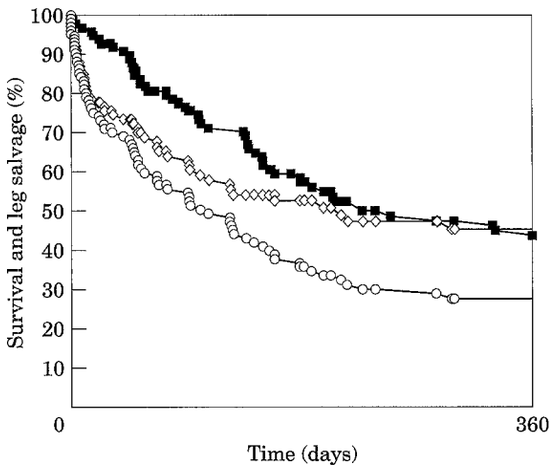

Fig. 1. Patientwise survival and leg salvage in patients with unreconstructed chronic critical leg ischaemia. (-■-) survival, (-◇-) leg salvage, (-○-) survival and leg salvage

Coronary heart disease did not significantly affect the outcome of limb salvage or survival rate.

Discussion

Although there have been previous attempts to define chronic critical leg ischaemia[5] the Second European Consensus Document definition was used in the present study as it is well prepared and discussed.[1] Exact criteria for CLI are mandatory for any comparison between studies and the pressure criteria used are recommended because it has been suggested that they include most patients in whom the rest pain or ischaemic lesions do not improve spontaneously without intervention.[6–10] On the other hand, there are no data available to disclose what would be the natural outcome if CLI would not be treated at all. It has been estimated that only 25% of patients with CLI ever require amputation,[1] but these estimates seem to be based on series in which the majority of the legs have been revascularised either by reconstructive or endovascular surgery.[11,12] The data by Wolfe *et al.* summarises the estimated 1 year outcome of CLI: 25% of the patients will have at least one leg amputated, 55% will have retained both legs and 20% will have died.[11] This scenario is supported by more recent data with a shorter follow-up.[13]

The natural outcome of CLI cannot be assessed without bias. The present material is selected, as only patients who were not considered candidates for revascularisation, were included. However, the revascularisation was rejected in many cases only through clinical judgment, aided solely by vascular laboratory

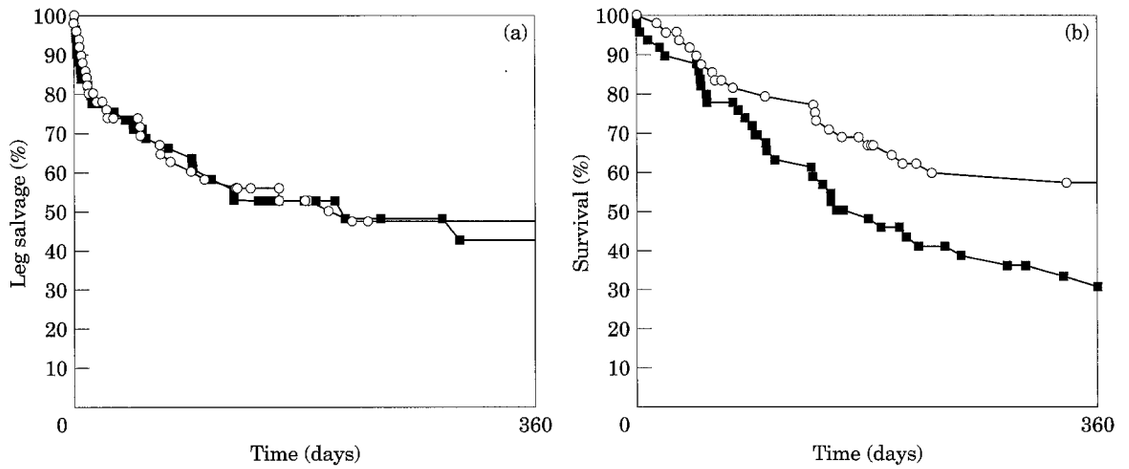

Fig. 2. (a) Effect of diabetes on leg salvage. (-■-) diabetics, (-○-) nondiabetics. (b) Effect of diabetes on patient survival. (-■-) diabetics, (-○-) nondiabetics

data. More frequent use of selective angiography might have increased vascular reconstructions, but the use of that method was started in the later phase of the study. On the other hand, the proportion of the patients treated conservatively in the present study was the same as it was in a large survey from the British Isles.[13] Although the selection of the present material may cause bias, unreconstructed CLI seems to predict a very poor outcome, both in terms of limb salvage and mortality. It is far worse than the estimates which include all patients with CLI irrespective of the treatment chosen.[11,13] This particular study shows, however, that CLI does not inevitably lead to major amputation. Thus, leg salvage rates claimed to be due to a particular treatment in uncontrolled series should be considered cautiously, especially if these rates are low.[14,15]

The value of a clinical assessment by an experienced vascular surgeon was demonstrated in seven patients who, according to the statement of the surgeon had only borderline ischaemia and who therefore were not reconstructed. None of these seven patients were amputated, although the pressure data and the symptoms suggested CLI. An experienced vascular surgeon has been reported to be able to assess arterial insufficiency adequately, even without noninvasive diagnostic measurements.[16] The value of the pressure criteria has been criticised by Thompson *et al.*, who found no difference in the survival and limb salvage rates between those with ankle pressures above 50 mmHg and those below.[3] On the other hand the European consensus criteria might be considered too strict[3,11] as it is unclear whether any pressure data is necessary if there is ischaemic tissue loss.[11]

Roughly 25% of all patients with CLI were alive and nonamputated after 1 year in the present series. The 1 year life expectancy was decreased to half of that of an age and sex matched normal population. The survival data of the present patients should, however, be examined with even greater care than that of the amputation data. The patients whose reconstruction was rejected due to poor condition represented a very high operative risk group and, therefore, their high mortality rate was expected. However, the mortality in that particular group was not higher than that of the rest of the study population. This observation emphasises the importance of CLI as a global risk factor. Indeed, CLI has been shown to be strongly linked to high coronary mortality.[17] This finding is further emphasised by the present results showing that the degree of CLI, i.e. whether manifested as unilateral or bilateral, seemed to be related to the overall outcome. This could be thought to show the involvement of the entire arterial tree, including the heart. The history indicating coronary heart disease did not appear to be a predicting factor for death in the present study, even though more than two-thirds of the deaths during the study, were due to vascular causes. This emphasises the importance of silent ischaemia in this group of patients and patients with impaired mobility, including many diabetics.[18–20]

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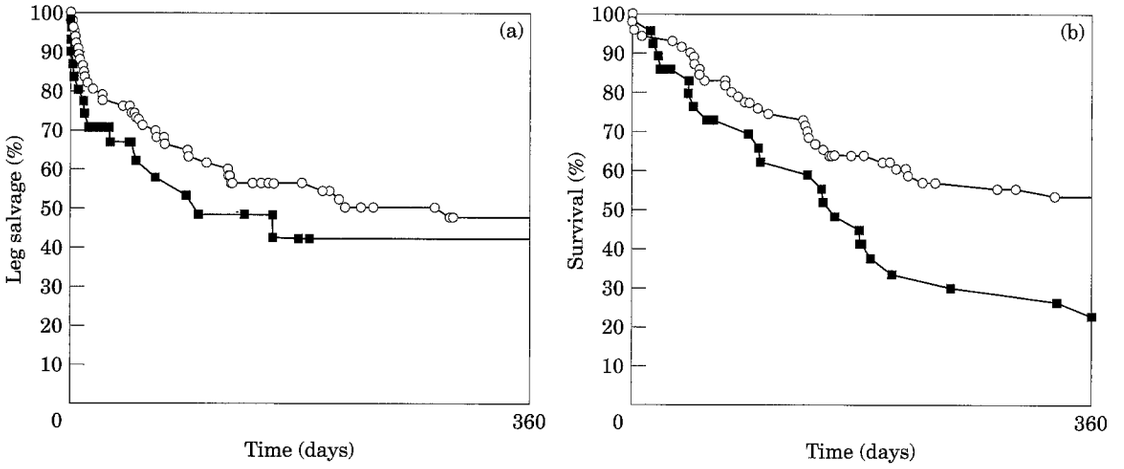

Fig. 3. (a) Effect of bilateral or unilateral CLI on leg salvage. (-■-) bilateral CLI, (-○-) unilateral CLI. (b) Effect of bilateral or unilateral CLI on patient survival. (-■-) bilateral CLI, (-○-) unilateral CLI.

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