Outcome and Influence of Age After Infrainguinal Revascularisation in Critical Limb Ischaemia

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Objectives: To evaluate whether revascularisation has any influence on the mortality rate, and the impact of old age in patients with critical limb ischaemia (CLI).

Design: Analysis of Swedish Vascular Registry (Swedvasc) data.

Patients and methods: During 1987-1995, 3730 surgical and 1199 endovascular (PTA) procedures below the groin due to CLI were reported. At 1 year three groups were defined: "occluded, amputated"; "occluded, not amputated" and "patent". Survival was also calculated. Clinical outcome at 1 month and at 1 year was defined as: patient "alive, improved"; "alive, not improved"; "alive, amputated" and "dead". Two age groups: ≤75 years or and ≥76 years were compared.

Results: The mortality rate for the whole group was 5.3% at 1 month and 22.9% at 1 year, with no difference between the Surgery and PTA groups. Significantly more patients were alive and improved after surgery than after PTA at 1 month (82.3% vs. 77.7%) and at 1 year (49.6% vs. 44.3%). The amputation rate was 5.6% at 1 month and 14.4% at 1 year; 17% for diabetics. After surgery, the cumulative mortality rate did not differ between patients with a salvaged limb, irrespectively of patency of the re-construction, but was significantly higher after amputation. After PTA, only a reconstruction reported as patent was linked to the most favourable survival rate. The older patient group had a mortality rate of 6.4% at 1 month and 26.4% at 1 year, significantly higher than the younger group (3.8% and 17.6%, respectively). The amputation rate did not differ according to age. Significantly more patients were alive but not improved in the older group.

Conclusions: The outcome of surgery vs. PTA was similar regarding survival and amputation, but surgery resulted in a greater improvement although this might be due to selection. Older patients and those with an amputation had higher mortality rates.

Key Words: Critical limb ischaemia; PTA; By-pass; Outcome.

Introduction

The prognosis for the patient suffering from CLI is far from satisfying. Studies point to a yearly mortality rate of 20%.

The Joint Vascular Research Group of the U.K. found that 60% of the patients were suitable for a revascularisation, while a further 20% needed an amputation. These figures seem to be very stable, although newer treatment options may save some of the legs which previously were amputated. On the other hand, a considerable number of limbs which are not salvaged by a reconstructive procedure may as the next step require an amputation. Important questions are whether survival rates are influenced by revascularisation and whether old age is associated with inferior results. This paper, based on the Swedish Vascular Registry (Swedvasc) aims at analysing the role of age and survival after revascularisation in patients with critical limb ischaemia.

Materials and Methods

The Swedish Vascular Registry has existed since 1987. At the start it comprised about 20% of the Swedish population and from 1994 covered all of Sweden. Vascular procedures, including both surgery and endovascular interventions, are reported to the registry at the time of treatment at a 30-day follow-up and at an 1-year follow-up. The registry is also connected to the Swedish Population Registry, which means that mortality rates may be calculated beyond the 1-year follow-up.
Patients with critical limb ischaemia are reported with codes for rest pain, ulcers or gangrene, respectively (Fontaine grade III and IV). Initially ankle pressures were reported as an ankle-brachial pressure index only, which means that these data were not easily comparable with the European definition which requires the absolute values of pressure levels. Further details from the registry have been presented elsewhere. An analysis of 4929 patients treated with infringuinal revascularisation due to CLI between 1987-1995 was done. A surgical reconstruction was performed in 3730 cases, 1139 above the knee and 2591 below the knee, and a percutaneous transluminal angioplasty (PTA) was done in 1199 cases, 891 above the knee and 308 below the knee. All procedures were performed either for rest pain (surgery n = 1666, PTA n = 513), ischaemic ulcers (surgery n = 1359, PTA n = 503) or gangrene (surgery n = 705, PTA n = 183).

The influence of revascularisation on survival was investigated as follows: patients were categorised according to whether occlusion or amputation had been reported during the first year after surgery or PTA. Thus three groups were defined: “occluded, amputated”; “occluded, not amputated” and “patent” (Fig. 1). Survival was thereafter calculated utilising data from the Swedish Population Register.

Clinical outcome at 1 month and at 1 year was defined as: “alive, improved”, “alive, not improved”, “alive, amputated” and “dead” (Fig. 1). Furthermore, patients were divided into two age groups, 75 years or younger and 76 years or older. Survival was calculated according to the Cox proportional hazards method controlled for the presence of diabetes, sex and clinical stage. Age and presence of heart disease or hypertension were not included in the model as these variables did not differ significantly between categories. The confidence interval for the relative risk was calculated regarding mortality. The results were evaluated using the Chi-squared test for comparisons between groups. A p value <0.05 was regarded as significant.

The mean age of the patients was 75.6 years with no difference between those treated with surgery and those undergoing PTA. There were 47% men and 53% women, 40% had diabetes and 55% cardiac disease. The 1 month and 1 year mortality rates were 5.3 and 23%, respectively, without differences between the surgical and the PTA groups at 1 month and at 1 year. Significantly more patients were alive and improved after surgery than after PTA at 1 month (82.3% vs. 77.7%) and at 1 year (49.6% vs. 44.3%) (p<0.0001). The proportion of patients alive but not improved at 1 month were 7.5% after surgery and 12.3% after PTA, increasing to 17.4% and 23.0%, respectively, at 1 year (Table 1).

Slightly fewer diabetic patients were alive and improved (73% compared to 76%) and they also had higher amputation rates (17% vs. 12.4%) than non-diabetics. The amputation rates were 5.6% at 1 month and 14.4% at 1 year for all patients. Patients with a gangrene, as the reported indication for surgery or PTA, had significantly more amputations than those with rest pain and ischaemic ulcers both at 1 month and at 1 year (10.8% vs. 4.4% and 24.9% vs. 12.1%, respectively, p<0.0001). There was no difference in 1-year mortality rates for patients with procedures performed above the knee (23.4% for surgery and 22.3% for PTA) compared to below the knee (24.7 and 22.7%, respectively).

Figures 2 and 3 show the cumulative survival for the three groups defined by the state of the reconstruction at 1 year. After bypass surgery the relative risk for mortality was significantly less for the “patent”-category (CI for RR 0.82–0.95) and the non-amputated (CI for RR 0.79–0.98) as compared to those amputated. After PTA only the “patent”-category had a mortality that significantly differed (CI for RR 0.64–0.82) from that of those amputated. The mean age of the patients younger than 76 years was 67.7 and of the older group (76 years and older) 81.7 years. When comparing patients in those two age groups a higher mortality rate was found in the older group at 1 month and at 1 year after surgery as well as after PTA. Tables 2 and 3 display the results of the various procedures. No differences were recorded in amputation rates for the two groups at 1 month and 1 year. On the other
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Table 1. 30 days and one year outcome in 3730 patients treated with surgery and 1199 patients treated with PTA.

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<th>30 days</th>
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<td></td>
<td>Surgery</td>
<td>PTA</td>
<td>Surgery</td>
<td>PTA</td>
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<tr>
<td>Alive, improved</td>
<td>82.3</td>
<td>77.7</td>
<td>49.6</td>
<td>44.3</td>
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<tr>
<td>Alive, not improved</td>
<td>7.5</td>
<td>12.3</td>
<td>17.4</td>
<td>23.0</td>
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<tr>
<td>Alive, amputated</td>
<td>4.8</td>
<td>5.0</td>
<td>10.1</td>
<td>9.8</td>
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<tr>
<td>Dead</td>
<td>5.4</td>
<td>5.0</td>
<td>22.9</td>
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Fig. 2. The cumulative survival of three patient groups (n =3730), treated with bypass for CLI, defined by the state of the reconstruction at 1 year. The relative risk for mortality was significantly less for the "patent"-category and the non-amputated as compared to those amputated. State at 1 year: (——) ocl/amp; (—) ocl/non-amp; (—) "patent".

hand, the older group had a significantly lower rate of patients "alive and improved" than the younger group at 1 month and at 1 year. (Surgery p<0.05 and p<0.0001, PTA p<0.05 and p<0.05, respectively).

Discussion

Most reports on the results of revascularisation for critical limb ischaemia have been from single centres. Myers et al. presented 750 femorodistal procedures, finding that diabetes was an independent prognostic covariate, while the patients' age was not. Less frequently, data are compiled from groups of centres, one example being The Joint Vascular Research Group in the U.K., from which it was learnt that there was a 20% yearly mortality in patients suffering from CLI, a figure which still holds true. The present report compiled data from Swedvasc, which includes vascular centres from both county hospitals and university hospitals.

Long-term survival is infrequently reported. However, it is known that 5 years after a major amputation, the mortality rate is between 50–100%. In a recent study from The Netherlands, Hoofwijk reported the long-term outcome of 289 patients with Fontaine stages III and IV, which compares well with the present material. The 1-year mortality rate was 27.4%. The author used a score to describe the patients' condition preoperatively. This score, but not the age of the patients, or any other parameter, predicted the patients' survival. Our results in terms of the 1-year mortality compare favourably to this single centre report, and most probably this is also true for the long-term mortality (Swedvasc 50–60% at 6 years, The Netherlands study 41% at 3.5 years).

Patency and limb salvage are evidently not always the same. Patent reconstructions without limb salvage are reported, as well as limb salvage with occluded grafts. In a detailed analysis of the Iloprost Bypass...
Study\textsuperscript{10} it was shown that 17\% of patients with a patent bypass remained critically ischaemic, while 13\% improved despite an occluded bypass.\textsuperscript{11} Swedvasc parameters recording improvement do not necessarily imply a patent reconstruction. Although the variable “patency” is reported, it is not always based on objective evidence, such as ABPI or imaging. “Patency” is a difficult parameter to establish, especially after PTA. This study showed that neither the 1-year mortality rate nor the cumulative mortality rate differed significantly between open and occluded reconstructions as long as the limb was saved, albeit with a slight difference between the two treatment groups. There may be various explanations, the most probable one is that the critical ischaemia had been relieved while the reconstruction stayed open, and further deterioration did not appear. Revascularisation apparently reduces mortality compared to amputation. However, the results once again stress that amputation is the main predictor of mortality. The finding that diabetic patients had a higher amputation rate was expected. The worse outcome for diabetic patients, as well as for female patients has been verified in other studies, including a recent Finnish review on distal reconstruction.\textsuperscript{12} The amputation rate was higher in patients with gangrene, compared to those suffering an ischaemic ulcer or rest pain only. Differences in outcome for these various stages of CLI are usually recorded, and it may be reasonable to describe the results of a reconstruction and the true outcome separately for these groups.\textsuperscript{13}

From several reports\textsuperscript{12,14,15} it seems evident that old age should not exclude a patient with CLI from a reconstruction. On the other hand, the older group consumes more hospital costs and has a higher mortality rate.\textsuperscript{16} The age limits vary, but 75 years seems a relevant break point. The results of the reconstructions at 1 month are in line with most reports. The older age group had a significantly higher mortality after surgery. On the other hand, the figures of 6.5\% and 4.0\%, respectively, were both within an acceptable range. The reason that corresponding figures after PTA (6.0\% vs. 3.1\%) did not differ statistically might be the smaller sample. A dramatic decrease of the group “alive and improved” was recorded at 1 year and mortality was significantly higher in the older age group. The total mortality rate at 1 year (23\%) is comparable with previous figures and there was little difference between those patients treated by PTA and those undergoing a surgical reconstruction.

In conclusion, based on the Swedvasc results and when contraindications do not exist, an attempt should be made to save a critically ischaemic leg by balloon angioplasty or surgical reconstruction. This decision should not be based on age alone, accepting that there will be a higher long-term mortality in older patients. In studies to come, quality of life factors should also
be assessed. The functional outcome and quality of life might be of much greater importance to the patient than the technical result.\textsuperscript{11,17-19}

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\textbf{References}


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