

Amputation Rates, Mortality, and Pre-operative Comorbidities in Patients Revascularised for Intermittent Claudication or Critical Limb Ischaemia: A Population Based Study

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WHAT THIS PAPER ADDS

This population based observational cohort study provides mid- to long-term follow-up data on the risk of amputation and mortality in a large and unselected nationwide cohort with lower limb peripheral arterial disease who underwent revascularisation during a 5 year period. Amputations and the cumulative incidence of death or amputation are presented separately for patients with intermittent claudication (IC) and critical limb ischaemia (CLI). Pre-operative comorbidities are compared for IC versus CLI patients.

Objectives: The aims of this population based study were to describe mid- to long-term amputation risk, cumulative incidence of death or amputation, and differences in pre-operative comorbidities in patients revascularised for lower limb peripheral artery disease (PAD).

Methods: This was an observational cohort study. Data from the Swedish National Quality Registry for Vascular Surgery (Swedvasc) were combined with mandatory national health care registries and patient medical records. All patients who underwent revascularisation in Sweden between May 2008 and May 2013 for intermittent claudication (IC) or critical limb ischaemia (CLI), aged 50 years and older, were identified through the Swedvasc database. The mandatory national health care registries and medical records provided data on comorbidities, mortality, and major amputations.

Results: A total of 16,889 patients with PAD (IC, $n = 6272$; CLI, $n = 10,617$) were studied. The incidence of amputations in IC patients was 0.4% (range 0.3%–0.5%) per year. Among CLI patients, the amputation rate during the first 6 months following revascularisation was 12.0% (95% CI 11.3–12.6). Thereafter, the incidence declined to approximately 2% per year. The cumulative combined incidence of death or amputation 3 years after revascularisation was 12.9% (95% CI 12.0–13.9) in IC patients and 48.8% (95% CI 47.7–49.8) in CLI patients. Among CLI patients, compared with IC patients, the prevalence of diabetes, ischaemic stroke, heart failure, and atrial fibrillation was approximately doubled and renal failure was nearly tripled, even after age standardisation.

Conclusion: The risk of amputation is particularly high during the first 6 months following revascularisation for CLI. IC patients have a benign course in terms of limb loss. Mortality in both IC and CLI patients is substantial. Revascularised CLI patients have different comorbidities from IC patients.

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INTRODUCTION

Peripheral artery disease (PAD) is one of the most common atherosclerotic morbidities worldwide, surpassed only by coronary artery and cerebrovascular disease.^{1,2} Moreover, PAD prevalence has increased substantially during the last decades, attributable mainly to an increased life expectancy.¹ In Sweden, the estimated current prevalence is as high as 20% among individuals older than 60 years, and, thus, PAD constitutes one of the major health problems.³

Symptomatic PAD in the lower limb presents as either intermittent claudication (IC) or critical limb ischaemia (CLI). It is well established that CLI, compared with IC, confers a substantially worse prognosis with regard to both limb salvage and overall survival.⁴ The limb prognosis in IC is generally benign; only a small percentage develop CLI over time.⁵ Conversely, many CLI patients report a history of IC, often with quite rapid progress to CLI, suggesting that this particular category of patients is not representative of most patients with IC.⁶ However, it is less well understood, at the outset, why symptomatic PAD in some patients is limited to walking pain (IC) while others suffer from constant pain, tissue loss, and risk of amputation (CLI).

Modern management strategies offered to patients with PAD include more active secondary preventive pharmacological treatment and an increasing use of endovascular techniques, which may influence limb outcomes for both IC and CLI patients.^{4,7,8} There is, however, a paucity of studies investigating the contemporary mid- to long-term prognosis for revascularised IC and CLI patients in the setting of modern management algorithms.

This national audit aimed to elucidate the incidence of death and/or amputation among a large cohort of revascularised patients with PAD. Another objective was to describe differences in pre-operative comorbidities for IC and CLI patients.

MATERIALS AND METHODS

Materials

Swedvasc. The Swedish National Quality Register for Vascular Surgery (Swedvasc)^{9,10} was launched in 1987 and reached full coverage of all Swedish centres performing vascular surgery in 1994. Some 12,000 procedures are registered in the Swedvasc Register annually, of which about 3000 represent primary procedures for PAD. In total, the registry contains information about more than 250,000 procedures. The data quality of the Swedvasc Register has repeatedly been validated, confirming high accuracy.^{11,12} The data retrieved included basic characteristics, smoking habits, and peri- and post-procedural details regarding the revascularisation procedure.

The Swedish National Patient Register. The Swedish National Patient Register (NPR) was founded in 1964 and is supervised by the National Board of Health and Welfare. Participation in the register is mandatory for all county council caregivers in Sweden. The coverage of hospital discharges is > 99% and it is updated once a year.¹³ All

primary and secondary diagnoses and operation codes recorded within Swedish hospitals regarding inpatient care and hospital based outpatient care are included.

Cause of Death Register. All deaths in Sweden have been registered in the Cause of Death Register since 1961. The register is supervised by the National Board of Health and Welfare. The combination of the Cause of Death Register and the NPR has previously been demonstrated to provide highly accurate data in other patient populations with cardiovascular disease.¹⁴

Medical records. To ensure accurate data on amputations, the patients' medical records, kept at the treating hospital, were reviewed.

Methods

In this observational cohort study, prospectively collected data from mandatory national health care registers in Sweden were retrieved, merged and analysed. For lower limb outcomes, the combined database was completed by auditing individual medical records to ensure accuracy regarding amputation data. Data in the national registries are protected by confidentiality and a strict juridical and ethical control. Owing to a backlog in the registries, data from 2013 were received in early 2015 and the nationwide review of medical records was completed in mid-2016 (Fig. 1).

Data extraction

Swedvasc. The study cohort was identified and retrieved from Swedvasc and included all patients with established PAD who underwent a revascularisation (by open or endovascular technique) in Sweden between May 12, 2008, and May 1, 2013. The date of the first recorded lower limb revascularisation procedure during the study period was defined as the index date. The inclusion criteria were age \geq 50 years at index date in a patient who underwent lower limb revascularisation for IC (exercise induced ischaemic lower limb pain, i.e., Rutherford 1–3 or Fontaine IIA and B) or CLI (ischaemic rest pain, ischaemic wounds and/or gangrene, i.e., Rutherford 4–6 or Fontaine III or IV). Data on smoking status were also collected from this register.

The Swedish National Patient Register. Information regarding dates of admission and discharge, diagnoses, and operation codes, including amputation codes, was extracted

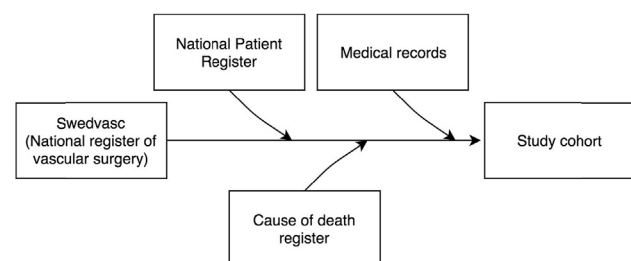


Figure 1. Flow chart of study design.

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