

Outcome for Endovascular and Open Procedures in Infrapopliteal Lesions for Critical Limb Ischemia: Registry Based Single Center Study

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WHAT THIS PAPER ADDS

There is a lack of robust contemporary data from randomized controlled trials regarding differences in the outcome of patients with below knee critical limb ischemia treated by endovascular or open repair. This large, single center series of 549 patients shows a similar risk factor profile, distribution of concomitant diseases, and outcome between the two treatment groups, even if wound complications were more common in the open group. This single center, real world experience in a large number of patients encourages the continued search for refined measures to select the best treatment modality for each patient.

Objective/Background: To describe the risk factor distribution and outcome for patients with critical limb ischemia (CLI) due to infrapopliteal arterial lesions treated by endovascular or open procedures, with special consideration of diabetic patients.

Methods: Data were collected from the Swedish Vascular Registry, Swedvasc, covering all procedures performed on 549 consecutive patients between May 2008 and January 2014 at the Karolinska University Hospital. Diagnosis of ischemic rest pain and/or tissue loss and treatment of infrapopliteal arterial occlusive disease were considered. Analysis was performed on the first procedure during the observation period, “endo” or “open”. Amputation rate and death from any cause were recorded as the primary outcome measures. Subgroup analysis was performed on diabetic patients.

Results: Patient demographics did not differ between the endo ($n = 430$) and open ($n = 114$) cohorts. Wound complications requiring treatment within 30 days were more common in patients treated with open procedures (32% vs. 1% for endo; $p < .001$), as well as stroke and myocardial infarction. Amputation rates were higher at 30 days in the open group (7% vs. 2%; $p = .012$) but similar at 1 year (10% vs. 7%; $p = .206$). Mortality was similar at 30 days ($p = .400$) and 1 year ($p = .860$). Median survival at the end of the observation period was 43 months for endo and 56 months for open patients ($p = .055$). Patients with diabetes treated with open procedures had more complications at 30 days and a higher rate of transfemoral amputations at 1 year compared with non-diabetic patients.

Conclusion: This non-randomized registry based study shows similar outcomes regarding amputation and survival rate in a large group of patients treated for infrapopliteal CLI with endovascular or open procedures, although more post-operative complications were reported in the open group. These findings support the continued use of both treatments while stressing the importance of minimizing surgical trauma to reduce wound complications.

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INTRODUCTION

Critical limb ischemia (CLI) is, in the majority of patients, caused by multi-segmental or extensive infrapopliteal

arterial disease. Below knee arterial lesions are particularly common in patients with diabetes, often involving all three infrapopliteal vessels, with a high prevalence of long occlusions.^{1,2} In these patients, CLI is reported to be more aggressive with a major amputation rate 5–10 times higher than in non-diabetic patients.³

Historically, bypass surgery to crural or foot arteries has been the treatment of choice in patients with CLI in need of revascularization.⁴ A considerable shift towards an endovascular approach has occurred since the 2007 Inter-Society

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Consensus for the Management of Peripheral Arterial Disease (TASC) report. Contradictory results have been presented for open procedures, with excellent as well as poorer outcomes reported.^{5–9} In diabetic patients, an elevated incidence of ipsilateral amputation and death has been reported after bypass surgery compared with non-diabetics.⁶ The poor outcomes reported in the literature have possibly also promoted an increased use of endovascular techniques.¹⁰ The rapid development of dedicated endovascular equipment, for example guidewires, balloons, stents, and the option to deliver drugs locally, has also contributed. Endovascular treatment is reported to be a safe, effective option in some patients with a high surgical risk compared with open surgery, but most series are small.^{9,11,12} Few reports exclusively covering infrapopliteal disease are available, and long-term follow up is largely missing.¹³ To date, the BASIL (“Bypass versus Angioplasty in Severe Ischaemia of the Limb”) trial is the only larger multicenter randomized controlled trial (RCT) comparing open and endovascular interventions in patients with severe limb ischemia (SLI).¹⁴ Two factors in the BASIL cohort make interpretation in a contemporary setting difficult: first, few patients were treated for infrapopliteal lesions (<10%) and, second, endovascular techniques have evolved.

The absence of contemporary level I evidence from an RCT has resulted in a continuing debate on how patients with CLI and infrapopliteal occlusive disease are best treated while awaiting long-term data.^{15,16}

It has been reported that patients treated first with endovascular procedures, followed by bypass surgery have a poorer outcome.¹⁷ An individualized selection of the first vascular procedure, “endo” or “open”, would probably enhance therapeutic results.¹⁵ There is a specific need to investigate infrapopliteal procedures in order to improve outcomes.

The primary aim of this study was to describe the outcome in patients with CLI and infrapopliteal arterial disease treated by endovascular (endo) or open surgery (open). The secondary aim was to investigate the distribution of comorbidity in the two treatment groups.

METHODS

Swedvasc

The Swedish Vascular Registry (Swedvasc) is a population based vascular registry covering > 95% of all arterial vascular procedures—endovascular and open—performed in the Swedish population.^{18–20} Data are collected prospectively on indications, risk factors, and details of surgical procedures for each individual. All variables and definitions can be found on the registry website.¹⁹ The registry defines right and left limbs. Outcome variables are registered at 30 days and 1 year. Post-operative complications are defined in Swedvasc as follows: operation for bleeding; fasciotomy; need for treatment of wound (pharmacological or operation); occlusion; acute myocardial infarction (AMI); stroke (hemorrhagic or ischemic). Date of death is updated continuously for all patients in the registry; hence, long-

term survival data are highly valid for this cohort. Earlier validation of the Swedvasc database, in 2008, of infrainguinal data including amputation and procedure, has shown >90% accuracy of registered variables, including both amputation and mortality data, and international validity has also been tested for the registry in general.^{6,18–21}

Study cohort

The patient cohort was extracted from the local database within the Swedvasc registry at Karolinska University Hospital, which performs 50–60% of the total procedures for limb ischemia in the Stockholm County (2.2 million inhabitants). Data were extracted on patients having their first infrapopliteal procedure (open or endovascular) for CLI from 12 May 2008 to 31 January 2014. The study cohort was extracted by choosing from the registry (i) infrainguinal procedure; (ii) select indication (rest pain/gangrene); (iii) exclusion of acute/popliteal aneurysm; and (iv) selection of distal anastomosis (truncus, anterior tibial, posterior tibial, fibular arteries, or pedal arteries). Patients with a diagnosis of popliteal aneurysm, acute thrombosis, or acute embolus were excluded.

Definitions and procedure

Patient demographics collected from the Swedvasc registry included age, sex, smoking status (current, previous, never), and creatinine level. Comorbidities included registered patient history of hypertension (pharmacologically treated), chronic pulmonary disease (emphysema and others), diabetes mellitus, stroke or transient ischemic attack, cardiovascular disease (AMI, atrial fibrillation, angina pectoris, coronary artery bypass graft, percutaneous coronary intervention), all defined accordingly in the registry. All included patients had a diagnosis of CLI (rest pain and or gangrene or tissue loss). The majority of patients with CLI were treated either by a scheduled endovascular attempt based on a computed tomography (CT) or magnetic resonance (MR) angiography, or alternatively during a conventional diagnostic angiogram, and then treated endovascularly *en suite*. A smaller number of patients were scheduled for an open first distal bypass procedure based on a MR or CT angiogram, without endovascular attempts.

The observation period began on the index date, that is, the procedure date, and continued until the primary outcome event or measure—amputation, amputation free survival, or death—occurred or until 1 March 2015. To study *amputation free survival*, the first amputation above the ankle (i.e., major amputation) in the ipsilateral limb was recorded or death from any cause at 1 year. Secondary outcomes were death from any cause during follow up.

Post-operative complications and secondary interventions occurring at 1 year were considered in the analysis, as registered within the requirements of the Swedvasc.

However, death is consecutively recorded on a daily basis for all patients ever registered in Swedvasc. Mortality data were extracted until 1 March 2015, allowing a median follow up of 48 months for this variable (range 14–83 months).

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