

Eight-year outcome after invasive treatment of infrainguinal intermittent claudication: A population-based analysis from the Swedish vascular register (Swedvasc)

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Abstract

Objectives: Invasive treatment of infrainguinal intermittent claudication is controversial, and long-term outcomes are scarce. The study aim was to evaluate 8 years results regarding new vascular interventions on index and contralateral limb, hospitalization, mortality, and amputation in 775 patients revascularized for infrainguinal intermittent claudication in 2009.

Methods: Data on new vascular interventions retrieved from the Swedish vascular register (Swedvasc) were linked to the Inpatient Register and Cause of Death Register with information on hospitalizations, primary discharge diagnoses according to the 10th revision of the *International Statistical Classification of Diseases and Related Health Problems (ICD-10)*, deaths, causes of death, and amputations.

Results: During 8 years of follow-up, 486 new vascular interventions were performed. Patients were admitted for a total of 4662 hospitalizations and spent 25,970 days in hospital. Between 79% and 99% of surviving subjects were hospitalized each year. During follow-up, 311 (40.1%) patients died. The most common causes of hospitalization and death were cerebrovascular disease, ischemic heart disease, or other diseases of the circulatory system, causing 47.5% of hospitalizations and 42.4% of deaths. Seventy-seven major lower limb amputations were performed in 52 patients.

Conclusion: As patients undergoing invasive treatment of infrainguinal intermittent claudication have high morbidity and mortality, during 8 years of follow-up, the indication for invasive treatment should be carefully weighed against concomitant comorbidities and the timing of this treatment optimized with regard to the patient's possibilities to enjoy positive treatment effects on quality of life.

Keywords

Surgery, cardiovascular, intermittent claudication, invasive treatment, long-term follow-up

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Introduction

Peripheral arterial disease (PAD) currently affects about 200 million individuals worldwide, and increases in prevalence due to the aging population in Western societies.^{1,2} The Swedish prevalence of intermittent claudication (IC), the most common presentation of PAD, is 6.5% in women and 7.2% in men aged 60–90 years.³

Recommended management of IC consists of risk factor modification and conservative best medical treatment with supervised exercise training.⁴ Invasive treatment of IC is controversial, and even more so if the lesion is infrainguinal, and both international⁴ and Swedish⁵ national guidelines recommend that infrainguinal lesions in most cases should only be considered for revascularization when daily activities are still

compromised after exercise training. In spite of this, in 2009, 25% of patients treated invasively for infrainguinal chronic limb ischemia were due to IC corresponding to a treatment

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incidence of 8.9 per 100,000 inhabitants in Sweden, with a 73.2% improvement rate 1 year after treatment.⁶

Long-term outcomes after invasive infrainguinal IC treatment are scarce or reported in only small series,⁷ but are of specific interest as the indication for intervention is debatable^{4,5} and must be thoroughly weighed against both the high prevalence of cardiovascular and pulmonary comorbidities^{6,8} in this group of patients and the potential risk of limb loss in case of disease progression or treatment failure. Patients registered in the Swedish vascular registry, Swedvasc,⁹ after vascular interventions in the lower limbs have previously been followed for up to 5 years after intervention concerning amputation and death,⁸ but the consumption of hospital care, causes of hospitalization, and causes of death in the subgroup of patients undergoing revascularization of infrainguinal IC have not yet been reported.

The aim of this study was to evaluate the need for new vascular interventions (on the index and the contralateral limb), hospitalizations, mortality, and amputation, during 8 years of follow-up of all 775 patients registered in the Swedvasc registry during 2009 after invasive treatment of infrainguinal IC.

Materials and methods

Study design and study population

An 8-year longitudinal study of new vascular intervention on index and contralateral limb, duration and causes of hospitalization, mortality, causes of death, and major (thigh, lower leg, ankle joint, and Syme) lower limb amputations in the target population, a cohort consisting of all 775 Swedish patients with IC prospectively registered after invasive infrainguinal treatment in 2009.⁶ All patients in the cohort were followed from January 1st 2010 to December 31st 2017 or until death.

Healthcare registers and definitions of outcome

Swedvasc⁹ consecutively collects information on all open vascular and endovascular interventions performed at 28 vascular clinics in Sweden.

To retrieve information regarding lengths of hospitalizations, primary discharge diagnoses classified according to the 10th revision of the *International Statistical Classification of Diseases and Related Health Problems* (ICD-10),¹⁰ mortality, causes of death, and major lower limb amputations data files from Swedvasc were linked to the Inpatient Register (IPR) and Cause of Death Register administered by the National Board of Health and Welfare (<http://socialstyrelsen.se/english>).¹¹ New registration in Swedvasc, hospitalizations, length of hospital stay, mortality, causes of death, and amputation were main outcome measures.

Classification of diagnoses

Diagnoses in the IPR were classified according to the ICD-10 system.¹⁰ Based on the main diagnosis according to

ICD-10, each hospitalization episode or death was attributed to one of the following groups: (1) infectious diseases (ICD-10 A00-B99; J00-J22; N10; N39), (2) malignant (ICD-10 C00-C97) and benign (D00-D89) neoplasms, (3) other medical diseases (ICD-10 D50-D89; E00-E90; L00-L99; G00-G44; G47-G99; H00-H95; J30-J39; J40-J99), (4) mental and behavioral disorders, including drug abuse (ICD-10 F00-F99), (5) cerebrovascular disease (ICD-10 G45-G46; I60-I69) and ischemic heart disease (ICD-10 I120-I125), (6) other diseases of the circulatory system (ICD-10 I10-I14; I26-I49; I51-I52; I70-I99), (7) diseases of the digestive system (ICD-10 K00-K93), (8) diseases of the musculoskeletal system (ICD-10 M00-M99), (9) diseases of the genitourinary system, excluding infectious disease (ICD-10 N00-N99; O00-O99), (10) symptoms and observations (ICD-10 R00-R99; Z00-Z98), and (11) injuries, poisoning, and other external causes (ICD-10 S00-Y98).

Ethics

The Ethics Committee at Lund University (reference nos 2010/549 and 2017/1027) approved the study. The Board of Health and Welfare allowed analysis of data on hospitalizations, diagnoses, deaths, and causes of death only on group level, precluding study of individual patient files.

Statistics

Data are reported as mean values and standard deviation (SD). Student's *t*-test was used to evaluate differences in continuous variables and the χ^2 test was used to evaluate differences in nominal variables between groups. Amputation-free survival was assessed by the Kaplan–Meier survival analysis of time-to-event where the event was the date of first amputation or, in those not amputated, the date of death. Calculations were performed using SPSS 18.0 (SPSS Inc., Chicago, IL, USA).

Results

The 775 included patients (corresponding to a treatment incidence of 8.9 per 100,000 inhabitants per year) had a mean age of 70.4 years (SD 9.6) in 2009 and 304 (39.2%) were women. Baseline characteristics (Table 1), invasive procedures (open surgery 37%, endovascular treatment 58%, and hybrid treatment 5%), and results have previously been described in detail.⁶ Within the 8 years of follow-up, 261 patients underwent 486 new vascular interventions (246 on the index limb and 240 on the contralateral limb). 239 and 226 new vascular interventions were due to IC and critical limb ischemia (CLI), respectively (Table 2). Endovascular treatment was used in 64% of cases and open surgery in 36% of cases (femoral thromboendarterectomy 56%, bypass in 31%, thrombectomy in 9%, and other open surgeries 4%). The yearly incidence of new vascular intervention varied between 7% and 13%. The timing of the new vascular

Table 1. Background variables *n* (%) in all 775 Swedish patients undergoing invasive infrainguinal treatment of intermittent claudication in 2009.

	Open (<i>n</i> =290)	Endovascular (<i>n</i> =447)	Hybrid (<i>n</i> =38)	<i>p</i> value
Gender				0.885
Female	110 (37.9)	179 (40.0)	15 (39.5)	
Male	180 (61.9)	268 (59.9)	23 (60.5)	
Age (SD)	69.6 (10.6)	71.8 (8.8)	69.8 (9.0)	0.007
Hypertension	218 (74.9)	344 (76.8)	29 (76.3)	0.843
Diabetes mellitus	55 (18.9)	116 (25.9)	10 (26.3)	0.081
Cardiac disease	93 (32.0)	156 (34.8)	17 (44.7)	0.273
Renal disease	13 (4.5)	20 (4.5)	2 (5.3)	0.974
Cerebral event	21 (7.2)	50 (11.2)	5 (13.2)	0.163
Current smoking	123 (42.3)	149 (33.3)	18 (47.4)	0.020

SD: standard deviation.

Table 2. New vascular interventions and hospitalization during 8 years (2010–2017) of follow-up in 775 Swedish patients having undergone invasive infrainguinal treatment of intermittent claudication in 2009.

Year	Patients alive (<i>n</i>)	New vascular interventions, <i>n</i> (%)	New vascular intervention CLI, <i>n</i> (%)	New vascular intervention IC, <i>n</i> (%)	New vascular intervention indication not known, <i>n</i> (%)	Patients hospitalized, <i>n</i> (%)	Hospital days (<i>n</i>)	Hospital days per patient, median (range)
2010	764	108 (22)	31 (6)	63 (13)	14 (3)	755 (99)	4196	3.0 (0–80)
2011	736	80 (16)	30 (6)	46 (9)	4 (1)	684 (93)	3830	3.5 (0–62)
2012	696	52 (11)	21 (4)	30 (6)	1 (0.2)	553 (79)	2900	3.0 (0–56)
2013	661	50 (10)	23 (5)	25 (5)	2 (0.4)	619 (94)	3475	3.0 (0–76)
2014	620	43 (9)	25 (5)	18 (4)	–	615 (99)	3392	3.0 (0–48)
2015	542	47 (10)	25 (5)	22 (4)	–	530 (98)	2932	3.0 (0–44)
2016	504	58 (12)	36 (7)	22 (4)	–	468 (93)	2446	3.0 (0–65)
2017	464	48 (10)	35 (7)	13 (3)	–	438 (94)	2799	4.0 (0–74)

IC: intermittent claudication; CLI: critical limb ischemia.

intervention during the observation period is presented in Table 2, showing that the need for new vascular interventions occurred more frequently during the first 2 years of follow-up.

Altogether, there were 4662 episodes of hospitalization during follow-up, and patients spent in total 25,970 days in hospital. The yearly need for hospitalization varied between 79% and 99% in surviving subjects during the observation period (Table 2). The most common causes of hospitalization were cerebrovascular, ischemic heart disease, and other diseases of the circulatory system, together causing 47.5% of the hospitalizations, whereas other medical diseases accounted for 13.0% (Table 3). Whereas most hospitalizations were short (median 3 days), single patients had longer periods in hospital (Table 2).

During follow-up, the cumulative mortality was 10.2% (79 patients), 20.0% (155 patients), and 40.1% (311 patients) at 3, 5, and 8 years, respectively (Table 2). The most common causes of death were cerebrovascular disease, ischemic heart disease, and other diseases of the circulatory system (42.4%), and neoplasms (22.3%). All causes of death after invasive IC treatment in 2009 are presented in Table 3.

Seventy-seven major amputations were performed during follow-up. The cumulative numbers of patients undergoing first major amputation were 21 (2.7%), 30 (3.9%), and 52 (6.7%) at 3, 5, and 8 years, respectively. Amputation-free survival counted on the patients first major amputation (*n*=52) is presented in Figure 1.

Discussion

During 8 years of follow-up of this nationwide total material of patients undergoing infrainguinal vascular interventions of IC in 2009,⁶ about 10% of surviving patients had a new vascular intervention each year, between 79% and 99% spent a median of 3 days in hospital, cumulative mortality rate was 40.1%, and cumulative incidence of amputation was 6.7%. A total of 261 patients (34%) were registered in Swedvasc for 486 new invasive vascular interventions, 49% for IC and 46% for CLI, and 65% of these were performed endovascularly. The number of new vascular interventions in this study is high compared to the previously reported 5-year reintervention rate of 21.8%¹² in patients with IC caused by lesions with different localizations. This difference might reflect that

Table 3. Hospitalization episodes and causes of death during 8 years (2010–2017) of follow-up in 775 Swedish patients having undergone invasive infrainguinal treatment of intermittent claudication in 2009.

Diagnoses according to the ICD-10	Hospitalization		Death	
	n	%	n	%
Infectious diseases	184	3.0	7	2.0
Neoplasms (malignant and benign)	285	4.6	79	22.3
Other medical diseases	806	13.0	41	12.0
Mental and behavioral disorders	62	1.0	7	2.0
Cerebrovascular, ischemic heart disease, and other diseases of the circulatory system	2946	47.5	150	42.4
Diseases of the digestive system	292	4.7	15	4.2
Diseases of the musculoskeletal system	288	4.6	0	0
Diseases of the genitourinary system (excluding infections)	196	3.2	4	1.1
Symptoms and observations	424	6.8	1	0.3
Injuries, poisoning, and other external causes	684	11.1	11	3.1
Missing data	32	0.5	39	11.0

ICD-10: 10th revision of the *International Statistical Classification of Diseases and Related Health Problems*.

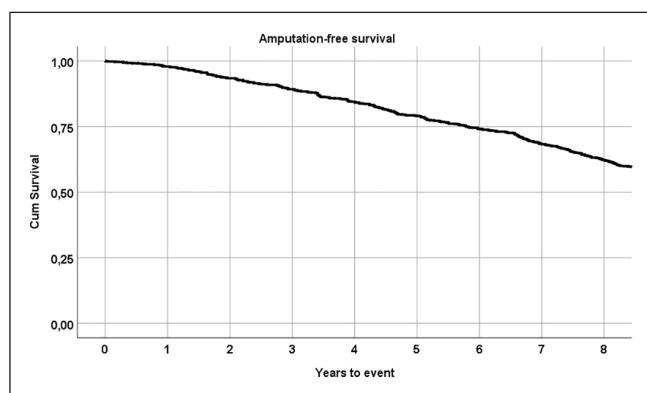


Figure 1. Amputation-free survival during 8 years (2010–2017) of follow-up in 775 Swedish patients having undergone invasive infrainguinal treatment of intermittent claudication in 2009.

patients in this study were treated due to infrainguinal IC, representing a group with more severe PAD than patients with suprainguinal lesions.^{12,13} Furthermore, we report the number of new vascular treatments on both index and contralateral limbs.

Hospitalization due to cardiovascular disease was more frequent in this population than what would be expected and reported in the general population of comparable age. For example, in a middle-aged population with chronic widespread pain, only 6.3% were hospitalized with cardiovascular diagnoses during 10 years of follow-up.¹⁴ This difference reflects the chronic nature of PAD, the palliative nature of its invasive treatment, and the high prevalence of widespread atherosclerosis and concomitant disease. Recent advances in medical, surgical, and endovascular treatment have all helped improve the outcomes in patients with PAD.¹⁵ This patient group still has an increased risk for both death and cardiovascular events,¹⁶ however, and patients with CLI also run a high risk of limb loss.¹⁵

After 3 years, the cumulative mortality in this cohort undergoing invasive intervention for infrainguinal IC was 10.2%, equivalent to the 12% mortality previously reported after 3 years in all Swedish patients invasively treated for IC.¹⁰ A recent meta-analysis of patients with symptomatic PAD¹⁶ reported a 5-year mortality of 13%, but it should be kept in mind that not all patients in this analysis had undergone intervention, and therefore probably had less severe PAD. After further follow-up at 8 years, cumulative mortality in our material was 40.1%, comparable to the 63% mortality shown at 10-year follow-up of patients with different forms of PAD (ranging from asymptomatic PAD to CLI).¹⁷

The increased risk of cardiovascular events in the PAD population despite presumed best medical treatment is highlighted by the causes of death recorded among our patients. Cerebrovascular disease, ischemic heart disease, and other diseases of the circulatory system caused the majority of deaths (42.4%), followed by neoplasms in (22.3%). This finding corroborates the 45% rate of cardiovascular cause among deaths reported during 10 years in a population with different stages of PAD.¹⁷ Furthermore, we do not actually know the quality of the medical treatment in our cohort, as measures of medical therapy such as blood pressures and the percentages of patients using platelet inhibition and statins were not systematically recorded in the Swedvasc registry until 2015. A previous report¹⁵ in which Sigvant et al. used data from the prescribed drug register showed that best medical treatment, defined as both platelet inhibition and statins were prescribed to 65% of patients operated for IC 2008–2013, and that statin use was associated with better prognosis concerning survival.

Malignant and benign neoplasms accounted for only 4.6% of all hospitalizations, but were the second most frequent (22.3%) cause of death in this study. Malignancy and PAD often coexist, which markedly worsen the prognosis. An 11.5% prevalence of associated malignancy was reported

in patients admitted with CLI, and this subgroup had 50% mortality within 6 months compared to 20% in patients with CLI without cancer.¹⁸

The 3-year cumulative incidence of major amputation of 2.7% in this study is higher than the previously reported 1.2% in patients invasively treated for IC caused by both supra- and infrainguinal PADs.⁸ One explanation might be that the subgroup of patients with infrainguinal IC has a more severe form of PAD, with inferior results after invasive treatment than when the IC is caused by suprainguinal lesions.¹³ A randomized study of endovascular treatment of IC caused by lesions in the superficial femoral artery showed, however, favorable effects on quality of life assessments after 1¹⁹ and 2 years²⁰ of follow-up. It would therefore have been interesting to evaluate quality of life in this study. Patients might perhaps have perceived their quality of life as improved despite the many new vascular interventions and hospital stays occurring during the years after intervention (Table 2). Quality of life assessments are currently being added to routine follow-up in Swedvasc, but were unfortunately not available for our patients.

The strength of this study is that it presents long-term follow-up data from validated national inpatient and cause of death registries administered by the National Board of Health and Welfare, on an unselected nationwide cohort of patients treated invasively of infrainguinal IC. Despite the lack of randomization to different treatments, our results should be possible to generalize to long-term outcomes of invasive treatment of infrainguinal IC in Sweden. An unavoidable limitation of all studies including long-term follow-up of a patient material, however, is that it reflects effects of treatment with technologies which might have further improved during follow-up.

Being an observational study on data retrieved from registries, however, its accuracy is dependent on correct data entry into registries. It is therefore important to note that the Swedvasc, inpatient, and cause of death registries are all well-documented with high validity.^{11,21,22} As the Board of Health and Welfare approved only data analysis on un-individualized basis, we were not able to perform follow-up data linkage to individual patient files, which constitutes another study limitation.

Conclusion

As patients undergoing invasive treatment of infrainguinal IC have high morbidity and mortality, during 8 years of follow-up, the indication for invasive treatment should be carefully weighed against concomitant comorbidities and the timing of this treatment optimized with regard to the patient's possibilities to enjoy positive treatment effects on quality of life.

Declaration of conflicting interests

The author(s) declared the following potential conflicts of interest with respect to the research, authorship, and/or publication of this

article: T.G., A.G., S.B. and T.T. have nothing to disclose. H.L. has received compensation according to a proctoring and training agreement with Medtronic AB, Merit Medical AB, and William Cook Europe ApS—companies that had no involvement in any part of the study.

Ethical approval

Ethical approval for this study was obtained from the Ethics Committee at Lund University (reference nos 2010/549 and 2017/1027).

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Informed consent

Informed consent was not sought for this study as all patients registered in Swedvasc are informed about the fact that registration in the registry means that their data might be used for research purposes. This was clearly stated in the application to the Ethics Committee at Lund University which approved the study without the requirement of obtaining written consent from study patients (reference no. 2017/1027).

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