

Invasive Treatment for Infrainguinal Claudication Has Satisfactory 1 Year Outcome in Three out of Four Patients: A Population-based Analysis from Swedvasc

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WHAT THIS PAPER ADDS

This national survey found that the invasive treatment incidence of infrainguinal intermittent claudication (IC) was 8.9 per 100,000 inhabitants in Sweden in 2009 despite current guidelines recommending no treatment for infrainguinal lesions in patients with IC in most cases. A systematic review of the 12-month follow-up results from the 775 patients (843 procedures) is presented. The identified results of satisfactory outcome in three out of four patients warrants further studies of whether or not invasive treatment of infrainguinal IC is appropriate.

Objectives: In spite of recommendations advocating conservative best medical treatment, many patients with infrainguinal intermittent claudication (IC) are treated by invasive open and endovascular methods. This study aims to evaluate the incidence and 1-year results of all such treatments during 2009 in Sweden.

Methods: The design was a one-year follow-up through the Swedish Vascular Registry (Swedvasc) of all 775 patients from the Swedish population of 10 million inhabitants in whom 843 invasive infrainguinal procedures (796 index procedures and 47 secondary procedures) were performed for IC in 2009. Index procedures were open surgery in 290 (37%) patients, bilateral in nine cases, giving a total of 299 limbs, endovascular treatment in 447 (58%) patients, bilateral in 10, giving a total of 457 limbs, and hybrid treatment in 38 (5%) patients, bilateral in two cases, giving a total of 40 limbs. Data were analysed both with regard to the number of patients (775) and the number of procedures (843). Clinical outcome was calculated from patient-reported leg function (unchanged, improved, deteriorated) and whether amputation had been necessary or death had occurred. Patent reconstruction at 1 year was also counted as improvement.

Results: Improvement at 1 year was seen in 567 (73.2%) patients, (225 [77.6%] in the open surgery group, 320 [71.6%] in the endovascular treatment group, and 22 [57.9%] in the hybrid treatment group). No significant difference was found between the open surgery and endovascular treatment groups comprising 737/775 patients ($p = .350$). Hybrid treatment gave significantly worse results ($p = .046$). Fifty-seven (7.3%) patients reported unchanged limb function and 32 (4.1%) patients reported deterioration. Within 30 days two patients died and one patient underwent amputation. Within 1 year 10 patients underwent 11 amputations: five (1.7%) in the open surgery group, three (0.6%) in the endovascular treatment group, and two (7.5%) in the hybrid treatment group; one underwent bilateral amputation ($p = .07$). Twenty-two patients died: 10 (3.4%) in the open surgery group, 12 (2.7%) in the endovascular treatment group and none in the hybrid treatment group ($p = .465$).

Conclusions: Reported improvement at 1 year was 73.2% in patients invasively treated for infrainguinal IC. Patients reporting an unchanged or deteriorated clinical state are a considerable clinical challenge. Further studies to determine whether or not invasive treatment of infrainguinal IC is appropriate are justified.

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INTRODUCTION

Peripheral arterial disease (PAD) is a common atherosclerotic manifestation occurring in 18% of subjects 60–90 years of age.¹ The prevalence of the different stages of PAD, asymptomatic PAD, intermittent claudication (IC), and

critical limb ischaemia (CLI) vary with age, gender, and geographic region.¹ The prevalence of IC in Sweden has been reported to be 6.5% in women and 7.2% in men aged 60–90 years.¹

The management of IC traditionally consists of risk factor modification and conservative best medical treatment with or without supervised exercise training.²

The role of invasive treatment such as open surgery or endovascular treatment remains controversial in this condition, especially when IC is caused by infrainguinal disease. In general, the restriction of patient quality of life by IC has not been considered great enough to justify the risks of open surgery.³

Whereas the results of inflow procedures such as reconstructions above the inguinal ligament in patients with IC are good with 91% primary patency at 6 years,⁴ the treatment of infrainguinal lesions remains a challenge to both open surgery and endovascular treatment. Bypass surgery is associated with complications (such as wound infection) and prolonged hospital stay.⁵ One main problem with endovascular infrainguinal treatment is restenosis. Follow-up studies have established that restenosis rates are dependent upon both the length of the stented segment, the number of stents placed, and the stent brand used.⁶

The best treatment for IC should provide the best quality of life for the patient as well as the best survival and limb salvage rate.^{2,7} Both international² and Swedish⁷ guidelines recommend that infrainguinal lesions should not be revascularized in most patients with IC. In spite of this, according to the Swedish Vascular Registry (Swedvasc)⁸ 843 of a total of 3,304 invasive infrainguinal procedures (open and endovascular) performed in Sweden in 2009 for PAD, were undertaken on patients with IC. Endovascular treatment was performed in 60% of these.

The aim of this study was to evaluate the one year results of these 843 procedures in Swedish patients treated for infrainguinal IC by invasive methods during 2009.

MATERIALS AND METHODS

Population

We conducted a follow-up study, using the Swedvasc registry,⁸ of all 843 prospectively registered infrainguinal treatments performed on 775 patients for IC in Sweden in 2009. The procedures were analysed in three groups: open surgery, endovascular treatment, and hybrid treatment (defined as registration of open surgery and endovascular treatment of two or more infrainguinal lesions at same date). The Swedvasc registry has an external validity of 93% of infrainguinal procedures.⁹ In Swedvasc, data on preoperative risk factors (Table 1) for patients undergoing vascular treatment at Swedish hospitals are registered together with the type of treatment (open surgery, endovascular treatment, or hybrid treatment) and patients are followed up at 1 and 12 months.⁸

Follow-up data at 1 year regarding improvement, deterioration, amputation, death, complications,

Table 1. Definition of risk factors in Swedvasc 2.0.

Hypertension	Treatment with antihypertensive drug
Diabetes mellitus	Pharmacological treatment of diabetes mellitus
Cardiac risk	Previous myocardial infarction, current angina pectoris, previous heart surgery or endovascular cardiac intervention
Renal risk	Serum creatinine above 150 µmol/L or preoperative haemo- or peritoneal dialysis
Cerebral event	Previous cerebrovascular lesion with residual symptoms and/or radiologically verified brain injury
Current smoking	Ongoing smoking or smoking cessation within last 5 years

occlusion, reoperation, cerebrovascular and cardiovascular events were analysed both with regard to the number of patients (775) and the number of procedures (843; 796 index procedures, i.e. limbs, and 47 secondary procedures). The secondary procedures (23 ipsilateral reinterventions and 24 new interventions on the other side) contribute to the clinical outcome evaluated 1 year after the index procedure.

The index procedures were open surgery in 290 (37%) patients, bilateral in nine cases, giving a total of 299 limbs, endovascular treatment in 447 (58%) patients, bilateral in 10 cases, giving a total of 457 limbs, and hybrid treatment in 38 (5%) patients, bilateral in two cases, giving a total of 40 limbs. The type of procedures and their distal landing zones are described in detail in Table 2. Clinical outcome was evaluated in a composite variable from patient-reported leg function (unchanged, improved, deteriorated) and whether amputation had been necessary or death had occurred. Patent reconstruction at 1 year was also counted as improvement. Ankle–brachial index (ABI) values were not entered into the composite outcome variable list because of inconsistency in their registration: only 82% at baseline and 62% at 12 months.¹⁰

Table 2. Detailed description of 796 index procedures, i.e. limbs, and level of landing zone, *n* (%). in all 775 Swedish patients undergoing invasive infrainguinal treatment of intermittent claudication in 2009.

	Above knee 653 (82)	Below knee 143 (18)
Thromboendarterectomy	128 (16.1)	0 (0)
Bypass (graft)	58 (7.3)	6 (0.8)
Bypass (vein)	35 (4.4)	38 (4.8)
Exploration	15 (1.9)	3 (0.4)
Other open	11 (1.4)	3 (0.4)
Percutaneous angioplasty	187 (23.5)	54 (6.8)
Subintimal recanalization	76 (9.5)	12 (1.5)
Stent implantation	100 (12.6)	24 (3.0)
Other endovascular treatment	1 (0.1)	0 (0)
Thrombectomy	2 (0.2)	0 (0)
Thrombolysis	2 (0.2)	1 (0.1)
Hybrid procedure	38 (4.8)	2 (0.2)

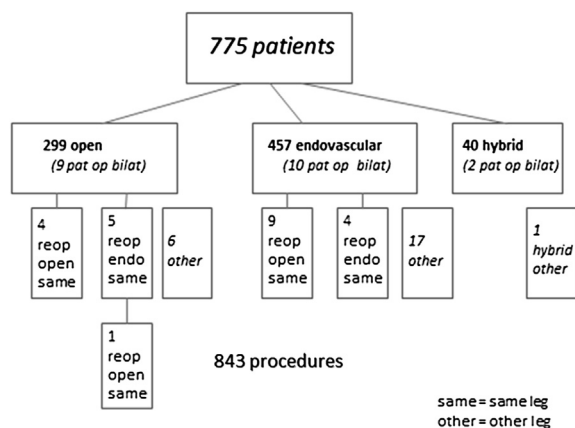


Figure 1. Flow chart of 843 invasive infrainguinal procedures performed in all 775 Swedish patients undergoing invasive infrainguinal treatment of intermittent claudication in 2009.

Ethics

The study was approved by the Ethics Committee at Lund University (Ref. no. 2010/549).

Statistics

Data are reported as mean (SD). The Student *t* test was used to evaluate differences in continuous variables and the chi-square test was used to evaluate differences in nominal variables between groups. Multiple logistic regression analysis was performed, with all factors found to differ between groups in univariate analyses. Calculations were performed using SPSS 18.0 (SPSS Inc., Chicago, IL, USA).

RESULTS

Baseline data

Of a total of 3,304 invasive procedures on patients with chronic PAD performed in Sweden in 2009 and registered in the Swedvasc database, 843 were invasive infrainguinal procedures performed on 775 patients for IC (Fig. 1). This corresponds to a treatment incidence of 8.9 per 100,000 inhabitants per year. During the preceding 10 years, 236 of these patients had been registered as undergoing 370 treatments.

Among the patients 304 (39.2%) were women and 471 (60.8%) men. The mean age was 70.4 (SD 9.6) years, 72.6 (SD 8.4) years in women and 69.7 (SD 10.1) years in men. 591 (76.2%) of patients were on antihypertensive treatment, 181 (23.3%) had diabetes mellitus, 266 (34.3%) had cardiac risk factors, 76 (9.8%) had had a previous cerebrovascular event, 35 (4.5%) had renal impairment, and 290 (37.4%) were current smokers or former smokers within the last 5 years.

The only difference in preoperative risk factor distribution was that patients undergoing endovascular treatment (71.8 [SD 8.8] years) were significantly older than patients treated by open surgery (69.6 [SD 10.6] years) and hybrid treatment (69.8 [SD 9.0] years; *p* = .007); they more often had ABI >0.5 (72.7% vs. 61.7% in the open surgery group

Table 3. Background variables, *n* (%), in all 775 Swedish patients undergoing invasive infrainguinal treatment of intermittent claudication in 2009.

	Open	Endovascular	Hybrid	<i>p</i>
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 risk	93 (32.0)	156 (34.8)	17 (44.7)	0.273
Renal risk	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

and 50.0% in the hybrid treatment group; *p* = .002), and were less often current or former smokers within the last 5 years (33.3% vs. 42.3% in the open surgery group and 47.4% in the hybrid treatment group; *p* = .020) (Table 3).

30-day follow-up data

Within 30 days two patients had died and one patient had undergone amputation. A total of 101 (12.7%) post-operative complications were registered: 62 (20.7%) in the open surgery group, 31 (6.8%) in the endovascular treatment group, and eight (20.0%) in the hybrid treatment group (*p* < .0001, Table 4). The most frequently reported complications at 30 days were wound complications (*n* = 57 [7.1%]) and occlusions (*n* = 26 [3.3%]). One 74-year-old male treated endovascularly, who had suffered a compartment syndrome and was treated by fasciotomy, had continuing IC at 30 days. One 79-year-old male with occluded fibular and tibial posterior arteries was treated by percutaneous angioplasty (PTA) of the anterior tibial artery and had an amputation within 30 days. Seven wound complications occurred after endovascular procedures, five angioplasties and two stent placements in the superficial

Table 4. Thirty-day complications, *n* (%) in all 796 index procedures, i.e. limbs, in all 775 Swedish patients undergoing invasive infrainguinal treatment of intermittent claudication in 2009.

	Open	Endovascular	Hybrid	<i>p</i>
Wound complication	46 (15.3)	7 (1.5)	4 (10)	<.0001
Occlusion	8 (2.7)	17 (3.7)	1 (2.5)	.703
Reoperation due to bleeding	5 (1.7)	3 (0.6)	0 (0)	.317
Compartment syndrome	2 (0.7)	1 (0.2)	0 (0)	.568
Amputation	0 (0)	1 (0.2)	0 (0)	.690
Myocardial infarction	0 (0)	1 (0.2)	2 (5.3)	<.0001
Major stroke	1 (0.3)	1 (0.2)	1 (2.5)	.077
Death	1 (0.3)	1 (0.2)	0 (0)	.904

Note. Myocardial infarction and major stroke counted on 775 patients.

Table 5. Clinical outcome in 737 of 775 patients undergoing invasive infrainguinal treatment of intermittent claudication in 2009.

	Open	Endovascular	Total
Improved	225 (77.6)	320 (71.5)	545 (73.9)
Unchanged	16 (5.5)	37 (8.3)	53 (7.2)
Deteriorated	7 (2.4)	21 (4.9)	28 (3.8)
Living amputated	2 (0.7)	3 (0.7)	5 (0.7)
Dead	8 (2.7)	11 (2.5)	19 (2.6)
Amputated and dead	2 (0.7)	1 (0.2)	3 (0.4)
Missing data	30 (10.3)	54 (12.1)	84 (10.8)

Note. Hybrid procedures were excluded, n (%); $p = .350$.

femoral artery, with improvement at 30 days in all but one. Complications within 30 days were more frequently reported in patients who later underwent amputation than in non-amputated patients (3.5% vs. 1.0%; $p = .02$).

One-year follow-up data

Clinical outcome in 775 patients. Improvement at 1 year was reported by 567 (73.2%) patients (225 [77.6%] in the open surgery group, 320 [71.6%] in the endovascular treatment group, and 22 [57.9%] in the hybrid treatment group; $p = .046$). Fifty-seven (7.3%) patients reported unchanged limb function, and 32 (4.1%) patients reported deterioration. When analysing the 737 individuals in the open surgery and endovascular treatment groups (comprising 95% of the study population) and excluding the small hybrid treatment group (with inferior outcome) from the analysis, there was no significant difference between the groups (Table 5).

The 12-month mortality rate was 22/775 (2.8%): 10 (3.4%) in the open surgery group, 12 (2.7%) in the endovascular treatment group, and none in the hybrid treatment group ($p = .465$).

Clinical outcome in 843 procedures. The 843 procedures consisted of 796 index procedures (i.e. limbs) and 47 secondary procedures. Improvement at 1 year was reported in 579 (72.7%) limbs (234 [78.2%] in the open surgery group, 322 [70.4%] in the endovascular treatment group, and 23 [57.5%] in the hybrid treatment group; $p = .006$). Fifty-four (7.1%) limbs had unchanged function and 30 (4.0%) limbs had deteriorated function (Table 6). When the small hybrid treatment group (40 limbs) was excluded from the analysis

Table 6. Clinical outcome, n (%), in 756 of 796 index procedures of invasive infrainguinal treatment of intermittent claudication in 2009.

	Open	Endovascular	Total
Improved	234 (78.2)	322 (70.6)	556 (73.5)
Unchanged	15 (5.0)	39 (8.5)	54 (7.1)
Deteriorated	7 (2.3)	23 (5.0)	30 (4.0)
Living amputated	2 (0.7)	3 (0.7)	5 (0.7)
Dead	8 (2.7)	11 (2.4)	19 (2.5)
Amputated and dead	2 (0.7)	1 (0.2)	3 (0.4)
Missing data	31 (10.3)	58 (12.7)	89 (11.8)

Note. Hybrid procedures were excluded; $p = .139$.

no significant difference in functional outcome was seen between the open surgery and endovascular treatment groups ($p = .139$, Table 6).

The 12-month amputation rate was 11/796 (1.4%): five (1.7%) in the open surgery group, three (0.6%) in the endovascular treatment group and three amputations (7.5%); one patient had bilateral amputation in the hybrid treatment group ($p = .07$). Three amputated patients died within the 12-month follow-up period (Table 6).

New interventions were performed in 47 (5.9%) cases. Reintervention on the index side was performed in 10 (3.3%) cases in the open surgery group and in 13 (2.8%) cases in the endovascular treatment group ($p = .062$). New contralateral interventions were performed in six (2.0%) cases in the open surgery group, in 17 (3.7%) cases in the endovascular treatment group and one (2.5%) case in the hybrid treatment group ($p = .519$). The ABI was available at baseline for 654/796 (82%) procedures and at 12 months for 496/796 (62%) procedures.

Follow-up data at 1 year was missing in 10.8% of cases, 80% of which were due to a decision by the surgeon at the 30-day visit that the patient did not need further follow-up. None of these patients was reported as deceased within 1 year to the National Population Registry with virtually 100% validity, nor were any amputations reported to the obligatory National In-patient Registry for these individuals. Thus all patients were followed up with respect to amputation and survival.

Treatments were registered as primary successful in all cases except 11/91 (12.1%) subintimal angioplasties, 2/41 (4.9%) hybrid procedures, and 3/253 (1.2%) PTAs.

Neither the type of institution (tertiary centre, or county hospital), nor patient characteristics (age, sex, hypertension, diabetic mellitus, renal impairment, cardiovascular risk, cerebrovascular risk, smoking or distal landing zone) influenced the improvement rate after 1 year in multiple regression analysis (data not shown).

DISCUSSION

In this nationwide study of patients undergoing infrainguinal invasive treatment of IC, the self-reported improvement rate 1 year after treatment was 73.2%. The remaining 26.8% of patients either did not benefit from the treatment or were lost to follow-up at 1 year. When comparing the results of the open surgery and endovascular treatment groups (comprising 95% of the study population) no significant difference in clinical outcome was found but hybrid treatment gave significantly worse results.

When assessing PAD treatment, it is important to recognize that the disease can affect both legs in one individual. This study comprised 775 patients with 796 index procedures (limbs), and the results in both limbs must consequently be taken into account when evaluating the clinical outcome in patients undergoing bilateral treatment.

In a register study like the present one, the responsible clinician has chosen a particular treatment for the individual patient for reasons not entered into the register. As patients

are not randomized into different treatment groups, the register is not designed to compare results between treatment groups. However, it may be relevant for use when searching for underlying risk factors or particular treatment issues influencing treatment results within groups. The present study could not demonstrate such factors in either uni- or multivariate analysis.

Previous randomized trials comparing different treatments for IC have shown varying results. Spronk et al.¹¹ found no difference in walking performance or health-related quality of life (HRQL) at 12 months when comparing hospital-based supervised exercise training with endovascular intervention. Nordanstig et al.¹² reported no significant improvement in maximal walking performance with invasive treatment (open or endovascular) compared with non-invasive treatment in a randomized study of unselected supra- and infrainguinal IC patients, whereas a moderate to large positive effect on HRQL (as a secondary outcome measure) was found in the invasive treatment group. In the light of new data on the efficacy of supervised exercise training,¹³ results from studies of treatment of IC should be evaluated in the context of the natural history of IC: about 50% of patients become symptom free and only 1–3% require an amputation during a 5-year follow-up period.¹⁴

When comparing these results with others, it is important to note that these data are based on a large unselected total nationwide record of invasively treated patients with infrainguinal IC, whereas previously reported clinical trials^{11,12} have included smaller numbers of patients. It is reasonable to believe that these results adequately reflect the efficacy of the current clinical practice of invasive treatment for infrainguinal IC in Sweden.

Furthermore, results of different studies on IC can be hard to compare due to the different inclusion and outcome parameters used. While other studies often involve suprainguinal and infrainguinal cases of IC,^{11,12} this study has selectively chosen *infrainguinal* IC. Which outcome parameters are relevant when studying IC is also open to debate. Whereas mortality and limb salvage are reasonable outcomes to assess after vascular intervention in CLI patients, there is more controversy regarding which parameters are relevant after interventions for IC. Older studies often evaluated maximum walking capacity and ABI, whereas more recent studies have often included HRQL questionnaires. As the Swedvasc registry did not collect information on walking distance or quality of life in 2009, the present study has focused upon the readily available parameters of self-reported improvement, amputation, and death.

International data on the incidence of invasive treatment of infrainguinal IC are sparse and hard to interpret. The Swedish incidence of 8.9 per 100,000/year can be compared with data from Vascunet on 32,084 cases of infrainguinal bypass surgery in nine countries which showed that the incidence per 100,000 individuals varied between 2.3 and 24.6. Of these, the rate for procedures performed on IC patients varied from 15.7% to 40.8%.¹⁵

There are some limitations to this study. Being an observational study it is dependent on correct data entry into the register by the many different responsible clinicians, which might contribute to the rather high likelihood of missing data in the study; in fact, 80% of missing data at 12 months was due to a decision taken by the responsible clinician at the 30-day visit. The Swedvasc register is, however, well documented with high external validity⁹ and has provided background data for many scientific reports.^{16–19}

The register does not give specific information about the lesion anatomy or post-procedure antiplatelet therapy, factors that might have been valuable in evaluating cases of deterioration or lack of improvement. The fact that the small group that underwent hybrid procedures had a worse outcome might, however, reflect the fact that these patients have more extensive underlying disease with at least two distinct lesions.

It is important to include factors contributing to suboptimal results and patient satisfaction. One such factor, missing in the register, might be the severity of the IC. The disease might, in some cases, be mild and not restricting quality of life enough to merit invasive treatment.² On the other hand, in other cases it might be so severe that the need for later amputation rather reflects failure to reverse an already severe ischaemic damage at presentation rather than the loss of patency of the treated segments.²⁰

The potential influence of other medical conditions such as diseases of the spine, hips, or knees and musculoskeletal pain might all affect walking ability and are common causes of reduced HRQL.²¹

The prevalence of IC in Sweden has been reported to be 6.5% in women and 7.2% in men aged 60–90 years.¹ As only invasively treated patients are listed in the Swedvasc registry and there is no registry on conservative treatment of IC in Sweden, we cannot provide data on the quality and efficacy of conservative treatment. This study has clarified, however, that the incidence of invasive treatment for infrainguinal IC in Sweden is 8.9/100,000 inhabitants per year in spite of current recommendations.^{2,7} The fact that 236 of these 775 patients had been registered as undergoing 370 invasive treatments for infrainguinal IC during the 10 preceding years reflects the chronic character of PAD and the palliative character of its treatment.

The results from this study, with 75% of patients reporting improvement and 15% reporting no benefit of treatment, have to be compared with the natural course of the disease.¹⁴ Such a comparison challenges the rationale of treating infrainguinal IC patients invasively at all, and highlights the need for controlled prospective randomized clinical trials assessing outcomes with special focus on HRQL. One such study is currently recruiting Swedish patients with IC with lesions in the SFA, randomizing them to either endovascular stenting or conservative best medical treatment with 2 year follow-up with regard to quality of life.

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None.

CONFLICT OF INTEREST

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