

Invasive treatment for intermittent claudication

Clinical outcomes and cost-effectiveness

Akademisk avhandling

som för avläggande av medicine doktorsexamen vid Sahlgrenska akademien,
Göteborgs universitet kommer att offentligens försvaras i hörsal Arvid Carlsson,
Academicum, Medicinaregatan 3.

fredag 24 april klockan 13:00

av Henrik Djerf, leg läkare

Fakultetsopponent:

Jan Holst, Docent

Lunds universitet, Lund, Sverige

Avhandlingen baseras på följande delarbeten

- I. Djerf H, Hellman J, Baubeta Fridh E, Andersson M, Nordanstig J, Falkenberg M. Low risk of procedure-related major amputation following revascularization for intermittent claudication – a population based study. *Eur J Vasc Endovasc Surg. Published online: Dec 19, 2019.*
- II. Djerf H, Falkenberg M, Jivegård L, Lindgren H, Svensson M and Nordanstig J. Cost-effectiveness of revascularization in patients with intermittent claudication. *Br J Surg.* 2018 Dec;105(13):1742-1748.
- III. Djerf H, Millinger J, Falkenberg M, Jivegård L, Svensson M and Nordanstig J. Absence of long-term benefit of revascularization in patients with intermittent claudication: five-year results from the IRONIC randomized controlled trial. *Circ Cardiovasc Interv.* 2020;13:e008450-e008450
- IV. Djerf H, Svensson M, Nordanstig J, Gottsäter A, Falkenberg M, Lindgren H. Cost-effectiveness for primary stenting of the superficial femoral artery in patients with intermittent claudication: 2 years results of a randomized trial. *Manuscript*

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Abstract

Intermittent claudication (IC) is caused by obstructive arterial lesions and is characterized by effort-induced pain in the lower extremity, limiting walking distance, and reduced health-related quality of life (HRQoL). The prevalence of IC is increasing due to the ageing of the population, and the consequences of the economic effects are a global problem. The walking impairment can be reduced by exercise. Despite the paucity of evidence regarding long-term benefit and cost-effectiveness, invasive revascularization is also often performed.

We wanted to investigate whether invasive treatment for IC is safe with regard to procedure-related limb loss, whether it is cost-effective, and whether it has long-term clinical benefit compared to exercise only.

The Swedvasc registry was used to identify all revascularizations performed in Sweden for IC between 2008 and 2012. Amputations were captured using the National Patient Registry (Paper I). Cost-effectiveness was analyzed in two prospective randomized trials, the IRONIC trial and a randomized trial investigating stenting of the superficial femoral artery in IC (papers II, III, and IV). The long-term clinical effect was analyzed in the IRONIC trial (paper III).

We found a low rate of major amputations during the first year after revascularization for IC: 0.2% (Paper I). A liberal invasive treatment strategy was found to be more expensive than exercise advice only after two years of follow-up. Cost-effectiveness results were within the threshold of the Swedish national guidelines regarding willingness to pay (papers II and IV). Both the clinical benefit and the cost-effectiveness of a liberal invasive treatment strategy that were found after two years of follow-up was lost at five years (paper III).

In conclusion, invasive revascularization of patients with IC appears to be safe in terms of limb outcome within the first post-procedural year. A liberal invasive treatment strategy was cost-effective compared to exercise alone after two years of follow-up. No clinical benefit, nor cost-effectiveness compared to exercise remained after five years.

Future studies should aim at identifying IC subgroups that benefit the most from revascularization and exercise, respectively, in order to enhance the overall patient benefit from available treatment options.

Keywords: intermittent claudication, peripheral arterial disease, cost-effectiveness, invasive treatment, health-related quality of life