

# Measures and determinants of outcome in conservative intermittent claudication treatment

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# **CHAPTER 9**

## **Impact**

## RESEARCH AIMS

This dissertation aimed to contribute to various aspects of the management of intermittent claudication (IC). In the two-part thesis it was investigated how treatment outcomes are measured and how various patient characteristics determine the outcome of conservative treatment.

In the first part, measures of outcome were investigated to improve their use in both clinical and research practice. It was shown what improvement or deterioration in walking performance on a treadmill after supervised exercise therapy (SET) is perceived as a meaningful change by the IC patient. Furthermore, a study revealed that patients generally overestimate their maximal walking ability. Treadmill-measured impairment of walking capacity does not necessarily correspond to the impairment patients experience during outside walking. Then does the ability to walk further without claudication pain on a treadmill, leads to the behavioural change of becoming more active in daily life? This was assessed by aggregating all available evidence from randomized trials on the benefits of SET, home-based exercise therapy (HBET) and endovascular revascularization (ER). Results showed that SET, and probably HBET, lead to substantial increases in daily physical activity levels in patients with IC in the short term.

In the second part, the efficiency of the stepped care treatment strategy in IC was investigated by assessing the cost-effectiveness of SET as primary treatment, and determinants of its outcomes. First, the impact on costs and quality of life of a SET-first strategy (with ER in the event of SET failure) was compared with an ER-first strategy. Analyses showed that over the 5 years after start of treatment, a mean of €6500 could be saved per patient if SET would be employed as first treatment. These savings could be achieved without detrimental effects on quality of life, secondary intervention rate (ER, open revascularization or amputations) or mortality. Thus, for the general IC population, SET should be employed first. In daily practice however, clinicians tailor treatment decisions to the individual patient. For instance, an important practice-based reason for early revascularization rather than await the efficacy of SET is location and extent of the atherosclerotic lesions. The results of the ELECT Registry revealed that patients with aortoiliac, femoropopliteal, and multilevel disease show meaningful improvements in walking performance and health-related quality of life, with no between-group differences. All IC patients should receive a trial of SET before invasive treatment is considered, regardless of the location or extent of the stenosis.

## IMPACT

The main beneficiaries of all research performed as part of this thesis are patients with IC (peripheral arterial disease Fontaine stage 2, Rutherford I-III). The principal conclusions have likely resulted in a more efficient management of the IC population in the Netherlands. For instance, SET was universally reimbursed for all IC patients per 2017. In addition, referral to SET as primary treatment increased to 87%, with freedom from intervention rates of up to 80% for the first five years after SET. Extrapolating these referral rates to the worldwide population, where SET is largely unavailable, carries great potential. Especially given the high prevalence of IC combined with the mean cost savings per patient referred to SET as exhibited in this thesis. To realize this potential, further dissemination of the Dutch real-world results and their underlying evidence (to which this thesis contributed) to policy makers in other healthcare systems is required. This dissertation has shown that the initial investment required to develop the necessary infrastructure for a SET program will be compensated for by the economic benefits SET yields. More importantly, IC patients can be spared unnecessary vascular interventions and its complications, and substantially increase their daily physical activity, which is an important prognostic factor in cardiovascular health. Expanding the knowledge of vascular specialists and general practitioners on these important benefits should increase referral rates, thus greatly impacting the prognosis of the global IC population.

On a smaller scale, the results of the ELECT Registry have confirmed it is not necessary to obtain imaging (computed tomography angiography, magnetic resonance angiography or duplex) of the lower extremity arteries prior to referral to SET. While this is already recommended in current guidelines, it is not widespread standard practice. Omitting these diagnostics from the standard work-up saves patients time and harmful radiation (in case of computed tomography angiography), as well as avoids costs.

Finally, the results of this thesis are of interest to healthcare professionals responsible for administering exercise therapy in their community. They have regular in-person contact with the patient, thus have the ability to directly impact treatment. In the Netherlands, these mainly consists of physical therapist affiliated with ClaudicatioNet, a Dutch network of physical therapists specialized in SET with lifestyle guidance. ClaudicatioNet's conditions for participation mandate regular schooling and attendance to a yearly symposium, allowing up-to-date research insights to be incorporated on the short-term. This way, most of the presented research in this thesis was disseminated quickly after its conception, directly changing the way outcome is measured in all Dutch IC patients. For instance, the choice of treadmill test (graded instead of non-graded), or the increased use of measures of physical activity.