

One Year Health Status Benefits Following Treatment for New Onset or Exacerbation of Peripheral Arterial Disease Symptoms: The Importance of Patients' Baseline Health Status[☆]

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WHAT THIS PAPER ADDS

This study evaluated 1 year changes in health status in patients with new onset or an exacerbation of peripheral arterial disease (PAD) symptoms. Thirty-nine per cent were referred for invasive treatment. Invasive treatment was offered across the whole spectrum of pre-procedural health status scores. Patients within the lowest quartile of pre-procedural health status scores had the greatest improvements, whereas those in highest quartiles did not improve substantially. One year invasive treatment and lower pre-procedural health status scores were independent associates for greater 1 year health status gains. This information may help to facilitate the discussion between patients and PAD specialists about which treatments should be considered for the patients' PAD.

Objective/Background: Limited information is available on expected health status gains following invasive treatment in peripheral arterial disease (PAD). One year health status outcomes following invasive treatment for PAD were compared, and whether pre-procedural health status was indicative of 1 year health status gains was evaluated.

Methods: Pre-procedural and 1 year health status (Short Form-12, Physical Component Score [PCS]) was prospectively assessed in a cohort of 474 patients, enrolled from 2 Dutch vascular clinics (March 2006–August 2011), with new or exacerbation of PAD symptoms. One year treatment strategy (invasive vs. non-invasive) and clinical information was abstracted. Quartiles of baseline health status scores and mean 1 year health status change scores were compared by invasive treatment for PAD. The numbers needed to treat (NNT) to obtain clinically relevant changes in 1 year health status were calculated. A propensity weight adjusted linear regression analysis was constructed to predict 1 year PCS scores.

Results: Invasive treatment was performed in 39% of patients. Patients with baseline health status scores in the lowest quartile undergoing invasive treatment had the greatest improvement (mean invasive 11.3 ± 10.3 vs. mean non-invasive 5.3 ± 8.5 [$p = .001$, NNT = 3]), whereas those in the highest quartile improved less ($.8 \pm 6.3$ vs. -3.0 ± 8.2 [$p = .025$, NNT = 90]). Undergoing invasive treatment ($p < .0001$) and lower baseline health status scores ($p < .0001$) were independently associated with greater 1 year health status gains.

Conclusion: Substantial improvements were found in patients presenting with lower pre-procedural health status scores, whereas patients with higher starting health status levels had less to gain by an invasive strategy.

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INTRODUCTION

The goals of treatment in symptomatic lower extremity peripheral arterial disease (PAD; Fontaine 2, mild to moderate symptoms of claudication) are to alleviate patients' symptoms and to improve their health status.^{1–5} Despite these objectives, patients' health status may not always be

a decisive factor in referring patients for invasive treatment.⁶ In addition, in large clinical trials, outcomes of interest were often focused on hemodynamic success rates,^{7–9} as opposed to clinically meaningful improvements in patients' health status.

It is also unclear whether invasive treatment is being applied in patients for whom the greatest health status benefit can be expected. One of the factors that may predict health status outcomes following invasive treatment is pre-procedural health status. In coronary disease, patients with lower health status scores undergoing percutaneous coronary intervention had the most to gain from this treatment when comparing their health status improvements with those having high pre-procedural health status scores.¹⁰ This has never been evaluated for invasive treatments. It is also unknown whether invasive treatments are offered to patients with PAD across the whole spectrum of pre-procedural health status scores in daily practice.

Given these gaps in knowledge and the rapid increase in use of endovascular procedures and its associated costs,^{11–13} it seems desirable to quantify and predict expected health status benefits by treatment strategy based on pre-procedural, measurable characteristics such as patients' health status. This study documented invasive treatment rates as a function of patients' pre-procedural health status, and quantifies the magnitude of 1 year benefits in patients' self reported health status across the range of pre-procedural health status scores.

METHODS

Study population and design

In this prospective observational study, 474 consecutive patients with new onset symptomatic lower extremity PAD or worsening of existing exertional PAD symptoms requiring new clinical work (Fontaine 2, mild to moderate symptoms of claudication) were enrolled in the period March 2006–August 2011 from two vascular surgery outpatient clinics (St. Elisabeth Hospital and TweeSteden Hospital, Tilburg, the Netherlands) (Appendix I). Patients were eligible for inclusion if they presented with exertional leg symptoms and if their resting ankle brachial index (ABI) was abnormal (≤ 0.90) or decreased $\geq 15\%$ from the resting ABI following a distance limited treadmill test. Exclusion criteria were a non-compressible ABI (≥ 1.30), critical limb ischemia, severe cognitive impairment or severe somatic or psychiatric comorbidities, insufficient knowledge of the Dutch language, or other reasons (e.g., participation in another study, treatment started before study inclusion). Patients were additionally excluded if: (i) patients had $>25\%$ missing values on their health status assessments; (ii) patients died during the first year of follow up; or if (iii) no pre-procedural duplex ultrasound examination was available in the patients' medical charts 3 months prior to or after inclusion.

All patients underwent a vascular diagnostic work up on enrollment, including a clinical evaluation by their treating vascular surgeon (Appendix II).

The local ethics committee of each participating institution approved the study, which was designed in line with the Declaration of Helsinki. All participants provided written informed consent. Study participation did not influence the type of treatment patients received because the study was observational in nature.

Measures

Assessment of health status. The Dutch version of the Short Form 12 (SF-12), a generic health status instrument,^{2,14} was used to assess patients' self reported pre-procedural (i.e., prior to treatment), and 1 year physical and mental health status (Physical Component Summary [PCS] score and Mental Component Summary (MCS) score). PCS and MCS scores (range 0–100, mean \pm SD score 50 ± 10) were standardized against the Dutch general population norms.¹⁵ Higher scores were indicative of better physical and mental functioning.¹⁵ Based on ranges of scores to expect following invasive treatment in PAD in similar populations,^{4,16–18} clinically relevant changes based on a 1 year change score (1 year health status score minus pre-procedural health status score) falling within the range of 0.5 SD (≥ 5 points) and 1.0 SD (≥ 10 points) were calculated. All treating vascular specialists were blinded to the initial SF-12 score, as this could have had the potential to influence the decision making process.

One year treatment strategies. A variety of treatment strategies were available at both enrolling centers, including non-invasive strategies: a formal supervised exercise therapy program supported by a regional network of certified physiotherapists; smoking cessation counseling; and optimal medical care (e.g., aspirin, anticoagulants, and statins).⁶ Treatments were categorized for analytical purposes: if no hospital admissions for vascular reasons were documented within the first year following diagnosis, patients were considered to have had *non-invasive treatment* options only. Patients were assigned to the *invasive treatment* category if any invasive lower extremity procedure was documented in their medical records.⁶ Patients received care for their PAD at the vascular surgery department. In any case, medical management of cardiovascular risk factors was initiated or sustained for all patients, and exercise therapy was also made available, regardless of whether patients were referred for invasive therapy for their PAD symptoms.

Disease severity. A handheld Doppler instrument (Imexlab 9000; Imex Medical Systems Inc., Golden, CO, USA) was used by trained vascular technicians to confirm the PAD diagnosis by measuring patients' resting and post-exercise ABI following a distance limited treadmill test.

Duplex ultrasound examination protocol. Based on his/her clinical evaluation during the diagnostic work up, a duplex ultrasound examination of the lower extremities was ordered by the treating vascular surgeon. Trained vascular technicians performed the ultrasounds with the Toshiba

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