Randomised Clinical Trial

Patient Related Outcomes After Receiving a Person Centred Nurse Led Follow Up Programme Among Patients Undergoing Revascularisation for Intermittent Claudication: A Secondary Analysis of a Randomised Clinical Trial

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What This Paper Adds
This secondary analysis describes patient reported outcomes in a randomised controlled clinical trial, the FASTIC study, testing a person centred, nurse led follow up programme vs. standard follow up for patients undergoing revascularisation with open or endovascular surgery for intermittent claudication. In unadjusted analyses, no significant differences between the programmes could be identified regarding health related quality of life, comprehensive health literacy, or general self efficacy. However, the intervention was associated with higher health related quality of life at one year after surgery when adjusting for baseline values, age, and health literacy (unplanned analysis). As high as 43% prevalence of insufficient health literacy was observed among all participants in this study.

Objective: The aim was to evaluate the effect of a person centred nurse led follow up programme on health related quality of life (HRQoL), health literacy, and general self efficacy compared with standard care for patients undergoing revascularisation for intermittent claudication (IC), and to describe factors associated with HRQoL one year after revascularisation.

Methods: This was a secondary analysis of a randomised controlled trial. Patients with IC scheduled for revascularisation at two vascular surgery centres in Sweden between 2016 and 2018 were randomised to intervention or control. During the first year after surgery, the intervention group received a person centred follow up programme with three visits and two telephone calls with a vascular nurse, while the control group received standard follow up with two visits to a vascular surgeon or vascular nurse. Outcomes were HRQoL measured by VascuQol-6, health literacy, and general self efficacy measured by validated questionnaires.

Results: Overall, 214 patients were included in the trial; this secondary analysis comprised 183 patients who completed the questionnaires. One year after revascularisation, HRQoL had improved with a mean increase in VascuQol-6 of 7.0 scale steps (95% CI 5.9 – 8.0) for the intervention and 6.0 scale steps (95% CI 4.9 – 7.0) for the control group; the difference between the groups was not significant ($p = .18$). In an adjusted regression analysis, the intervention was associated with higher VascuQol-6 (2.0 scale steps, 95% CI 0.08 – 3.93). There was no significant difference between the groups regarding health literacy or general self efficacy. The prevalence of insufficient health literacy among all participants was 38.7% (46/119) at baseline and 43.2% (51/118) at one year.

Conclusion: In this study, a person centred, nurse led follow up programme had no significant impact on HRQoL, health literacy, or general self efficacy among patients undergoing revascularisation for IC. The prevalence of insufficient health literacy was high and should be addressed by healthcare givers and researchers.
INTRODUCTION

Intermittent claudication (IC) affects 7% of all adult individuals aged older than 60 years. One of the main goals of surgical treatment of IC is symptom relief and to increase the health related quality of life (HRQoL), which decreases due to long term pain, impaired walking ability, restricted mobility, social isolation, and a sense of dependency. Surgical revascularisation has been shown to increase HRQoL, though the improvement is not sustained in the long term and patients with peripheral arterial disease have lower HRQoL than those without IC, even after revascularisation. Assessing HRQoL as a patient reported outcome in addition to objective measures like treadmill measured walking ability can provide insight into treatment effects on the patient. In order to be able to adapt to and live with long term illness, patients with IC need to get clear, consistent disease specific information and mental support to enable behavioural changes. There is a deficit in knowledge and understanding about their illness, treatment, risk factors, and secondary prevention measures among patients with peripheral arterial disease. The capacity to comprehend and use information about health does not depend only on the capabilities of the individual, but rather on how, why, and which health information is provided. A cross sectional study reported a prevalence of inadequate health literacy of 76.7% among patients with peripheral arterial diseases. Health literacy is defined as knowledge, motivation and competences to access, understand, appraise, and apply health information. A low level of health literacy is associated with low medication adherence, poor illness management, and lower health status. Self efficacy is significantly associated with adherence and even with life satisfaction. The concept of self efficacy apprehends patients’ beliefs in their capability to amend the incidents that affect their lives. Improving self efficacy has an important role in empowering patients to achieve treatment goals, health promoting behaviour changes and an effective self management of illness.

A person centred care approach added to the usual care has shown to improve self efficacy among patients with acute coronary syndrome. Person centred care means involvement of the patients as partners in their care and has an approach that lets the patient and care giver acquire a common understanding and a good basis for discussing, planning care and for a shared decision making. Studies about person centred care for patients with IC are limited.

This study aimed to evaluate the effect of a person centred, nurse led follow up programme on HRQoL, health literacy, and self efficacy compared with standard care for patients undergoing revascularisation for IC. It was also the aim to describe and analyse factors associated with HRQoL one year after revascularisation.

MATERIALS AND METHODS

Study design and participants

The study was conducted as a secondary analysis of a randomised controlled clinical trial, the Follow up After Surgical Treatment for Intermittent Claudication (FASTIC) trial, comparing a person centred, nurse led follow up intervention programme with standard follow up care. The study protocol and main results have been published previously. Recruitment of study participants took place at the two large hospitals conducting vascular surgery in Stockholm, Sweden, between June 2016 and October 2018 (centre 1) and between September 2017 and November 2018 (centre 2). Patients 18 years or older, able to speak and understand the Swedish language, who were diagnosed with IC (International Classification of Disease (ICD)-10 codes I70.2 or I739B), scheduled for vascular surgery, and had no signs of critical limb ischaemia were screened for eligibility. Exclusion criteria were dementia, planned discharge to a nursing home, not being accountable for administering their medications, or a survival expectancy of less than one year. All eligible patients were invited to participate, and written informed consent was obtained from all participants.

Randomisation

Participants were randomised to either a person centred, nurse led follow up programme (intervention group), or a standard care follow up programme (control group). Randomisation was performed by a study nurse using secure computer generated sequence random numbers. The study nurse had no awareness of the sequence generation process. No blinding was applied in this study. Participants were withdrawn from the study if a planned endovascular procedure did not result in revascularisation and no further surgical treatment was planned. Figure 1 shows an enrolment and allocation flow of the study.

Intervention and standard care programmes

The intervention programme consisted of three visits (at four to eight weeks, six months, and one year) and two telephone calls (at two weeks and nine months) with a specially trained vascular nurse during the first year after revascularisation. The person centred care model comprised (1) the establishment of a partnership between the professional healthcare worker and the patient; (2) patient narratives; and (3) a documented self care plan containing goals, self care activities, and a plan for future follow up and revision. The standard care programme included two visits during the first year after revascularisation, one to a vascular surgeon four to eight weeks after surgery and another to either a vascular surgeon or a vascular nurse at one year. The published study protocol contains thorough information on the study design.
procedure, the content of the person centred, nurse led programme, and standard care.²⁶

Sample size
The sample size for this study was based on a power analysis performed for the primary outcome (adherence to medication) in the FASTIC trial and resulted in a required sample size of 186 patients. With an expected drop out rate of 10%, the plan was to recruit 210 patients to the FASTIC trial.²⁷ No complementary sample size calculation for the secondary endpoints reported in this study was performed.

Data collection
All participants in the FASTIC trial were asked to fill out a set of questionnaires measuring HRQoL, health literacy, and general self efficacy at baseline and one year after revascularisation. Baseline data were collected directly after inclusion and before revascularisation. For the one year follow up, the questionnaires were posted to the patient enclosed with a pre-paid envelope and the letter of invitation to the follow up visit. The questionnaires were anonymised and could only be identified with study identity number.

Outcome measures
Health related quality of life. Vascular Quality of Life Questionnaire (VascuQol-6) was used as the main measure of HRQoL. It is a peripheral vascular disease specific instrument consisting of six items (symptom, pain, social life, emotional, and two items in activity). Each item has a four point response scale from 1 (severe problems) to 4 (no problems). VascuQol-6 is
vali-

dated and tested for reliability and has been shown
to have high internal consistency and significant
correlations with comparable dimensions in non-disease
specific instruments.28,29

As a complement, the Swedish version of EQ-5D 5L was
used.30,31 It is a generic instrument for measuring HRQoL,
developed by the Euro Qol Group,32 and measures health in
five dimensions (mobility, self care, usual activities, pain or
discomfort, and anxiety or depression). The questionnaire
also includes EQ-5D-5L visual analogue scale (VAS) where
the participants grade their own perceived health state on a
visual analogue thermometer scale with endpoints of 0 —
100 (0 = the worst health imaginable and 100 = the best
health imaginable).33 In this study, only the results from EQ-
5D-5L VAS are reported.

Health literacy. To measure health literacy, the Swedish
version of the European Health Literacy Scale, HLS-EU-Q1633
was used. The HLS-EU-Q16 contains 16 items measuring
comprehensive health literacy by focusing on four health
literacy dimensions, reflecting a perceived ease or difficulty
in an individual’s ability to accessing or obtaining health in-
formation, understanding health information (not only in writ-
ten form), processing or appraising health information, and
applying or using health information. Response choices are
very easy, easy, difficult, very difficult, and don’t know.
Following recommendations on how to analyse, the re-
sponses very easy and easy were put together and given the
value of 1, while difficult and very difficult were given the
value 0 and don’t know was regarded as missing.33 Patients
with maximum of two missing values were included in
further analysis. After addition of the response values, a
minimum of 0 and a maximum of 16 score points were
generated and lastly categorised in to three categories of
comprehensive health literacy: 0 — 8 points = inadequate, 9
— 12 points = problematic, or 13 — 16 points = sufficient.33

General self efficacy. General self efficacy was measured
using the General Self-Efficacy (GSE) scale, which measures
people’s beliefs in their capabilities to cope with day to day
difficulties and the ability to adapt to diverse demanding
events in life.34 The GSE scale consists of 10 items and is rated
on a four point Likert scale (1 = not true at all, 2 = hardly true,
3 = moderately true, and 4 = exactly true), yielding a total
score between 10 (lowest self efficacy) and 40 (highest self
efficacy). The total sum was then divided by the number of
items and considered as the patient’s GSE score. Response to
a minimum of seven items was required to be included in the
analysis. The GSE scale was originally developed in Germany34
and has been validated in Swedish.35

Statistical analysis

Normally distributed continuous data are presented as mean ±
standard deviation (SD), whereas skewed data and ordinal
data are presented as median (interquartile range [IQR]).
Categorical data are presented as frequencies (percentage).
Dependent on the data, either Pearson chi-squared test,
Fisher’s exact test, Mann—Whitney U test, or the
independent samples t test was used to compare differences
between the groups. General linear models for repeated
measures were used to test change over time in VascuQoL-6
between baseline and one year and are reported as mean
differences with 95% confidence interval (CI).

Uni- and multivariable generalised linear regression an-
alyses were performed to analyse the impact on HRQoL
on background factors (gender, age, and highest level of
education) and study specific factors (randomisation group,
baseline VascuQoL-6 general health literacy, and self effi-
cacy). The one year measurement of VascuQoL-6 was used as
dependent variable. We categorised age into three
groups (< 69 years, 70 — 79 years, and ≥ 80 years), and
highest level of education into three groups (college or
university, high school or upper secondary school, and
elementary school). Variables that were statistically signifi-
cant at p < .20 in the univariable analyses were included in
the multivariable analyses. All statistical analyses were
performed using IBM Statistical Package for the Social Sci-
ences (SPSS), version 28 (IBM Corp., Armonk, NY, USA). Two
tailed p values of < .050 were considered statistically sig-
nificant in the final analyses.

Ethics

The study was approved by the Regional Ethical Review
Board in Stockholm (registration number: 2015/2346-31/2)
and registered with the ClinicalTrials.gov database
(NCT03283358). Written and oral informed consent was
obtained from all participants. The trial was conducted in
compliance with the Helsinki Declaration36 and reported in
adherence to the Consolidated Standards of Reporting Trials
(CONSORT) statement.37

RESULTS

A total of 318 patients were assessed for eligibility (Fig. 1).
Ninety patients declined to participate. The most common
stated reason for declining was a long travel distance from
the hospital. Fourteen patients were excluded because no
revascularisation was performed (n = 11) or because of
other exclusion criteria (n = 3). A total of 214 patients who
consented to participate were randomised and allocated to
either the intervention group (n = 107) or the control group
(n = 107). After randomisation, two patients in the control
group were excluded due to screening error (not meeting
inclusion criteria), and eight patients in the intervention
group were excluded due to withdrawal of consent (n = 3)
or screening error (not meeting inclusion criteria (n = 5).
A total of 204 patients remained, of which 176 were treated
at centre 1 and 28 at centre 2. A total of five patients (two
vs. three) did not fulfill the study protocol and 92/103 (89%)
vs. 91/96 (95%) respectively in the control and intervention
group completed the questionnaires at one year (Fig. 1). At
baseline, the groups were comparable and did not differ
significantly in characteristics (Table 1). Seventeen of 91
patients (19%) and 21 of 92 patients (23%) respectively for
the intervention and the control group had a bilateral
revascularisation. A total of 20 patients (10 patients in each
group) underwent an ipsilateral repeated revascularisation during the study year. None of the repeated re-interventions was bilateral.

All patients in the intervention group received the three key components of person centred care: they had a written health plan documented in their medical record, updated after every follow up visit, and the health plan included documentation of the patient’s narrative and the establishment of a partnership with the vascular nurse.

At follow up one year after revascularisation, HRQoL had improved in total score as well as in all five domains of VascuQoL-6 in both the intervention and control groups. The mean improvement in VascuQoL-6 total score between baseline and follow up was 7.0 scale steps (95% CI 5.9 − 8.0) in the intervention group and 6.0 scale steps (95% CI 4.9 − 7.0) in the control group. The greatest change was observed among the intervention group in the domains of activity and pain, each with a mean increase of 1.3 scale steps (95% CI 1.0 − 1.5). Although the intervention group tended to improve to a greater extent, there were no significant differences between the groups, either at one year follow up or in change over time between the groups (Table 2). Self reported health state according to EQ-5D-5L VAS showed similar results among the groups, with a general improvement over time but no significant differences between the groups at one year, with a mean health state of 69.4 ± SD 19.9 for the intervention group vs. 66.0 ± SD 17.9 for the control group (Table 2, Fig. 2A).

The groups did not differ (p = .16) in change over time in self efficacy score with a median change of 0 (95% CI −0.10 − 0.10) and 0 (95% CI 0.00 − 0.16) respectively for the intervention and control groups. The median general self efficacy score at baseline was 3.1 (IQR 2.8, 3.4) for the intervention group and 3.0 (IQR 2.7, 3.3) for the control group, and the corresponding value at one year follow up was 3.0 (IQR 2.7, 3.4) for both groups (Fig. 2B).

Regarding change over time in comprehensive health literacy, there was no difference (p = .72) between the groups with a median difference of 0 (95% CI 0 − 2) in the intervention group and 0 (95% CI 0 − 1) in the control group. The prevalence of insufficient (inadequate and problematic) health literacy among all study participants was 38.7% (46/119) at baseline and 43.2% (51/118) at one year. The categories of levels of comprehensive health literacy were similarly distributed among the two groups both at baseline and one year (Table 3).

In the multivariable regression analyses, the intervention was associated with higher VascuQoL-6 (2.0 scale points).
steps, 95% CI 0.08 – 3.93) when adjusted for baseline HRQoL and other study specific or background factors. See Supplementary Table S1 for univariable and multivariable analyses.

**DISCUSSION**

Results from this study have shown that person centred, nurse led follow up after surgery did not have a significant effect on the improvement of HRQoL achieved at one year follow up after surgery. In addition to the five domains of HRQoL measured through VasucuQol-6, financial impact and process of care are suggested as dimensions that can impact HRQoL among patients with peripheral arterial diseases. The impact of those dimensions on the result of HRQoL in this study remains unknown since the dimensions are not included in the generic or disease specific measures employed. The mean improvement in total HRQoL score one year after revascularisation was higher among both the

### Table 2. Health related quality of life and self reported health state at one year follow up and change overtime, among 183 randomised patients undergoing revascularisation for intermittent claudication

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EQ-5D-VAS = visual analogue scale on health state included in the EQ-5D-VS questionnaire; CI = confidence interval.

* Number included in the analysis. Person centred, nurse led care: VascuQol-6, n = 81; EQ-5D VAS, n = 85; Standard care: VascuQol-6, n = 83; EQ-5D VAS, n = 87.

† Number included in the analysis. Person centred, nurse led care: VascuQol-6, n = 90; EQ-5D VAS, n = 88; Standard care: VascuQol-6, n = 91; EQ-5D VAS, n = 89.

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**Figure 2.** (A) Self reported health state (median) measured by EQ-5D-5L visual analogue scale (from 0 = the worst health imaginable to 100 = the best health imaginable) at baseline and follow up at one year, among 183 patients undergoing revascularisation for intermittent claudication and randomised. Number of patients: 88 and 89 in the person centred, nurse led care group and 85 and 87 in the standard care group respectively at baseline and one year. An outlier is defined as any point of data that lies over 1.5 times the interquartile range (IQR) below the first quartile (Q1). (B) General self efficacy score (median) was measured by the GSE Scale at baseline and one year, among 183 patients undergoing revascularisation for intermittent claudication and randomised. Number of patients: 89 and 85 in the person centred, nurse led care group and 90 and 90 in the standard care group respectively at baseline and one year. An outlier is defined as any point of data that lies over 1.5 times the IQR below the first quartile (Q1).
intervention and control groups than the previously determined minimum important difference (1.7 – 2.2 scale steps) and substantial clinical benefit (3.5 scale steps) in HRQoL measured with VascuQol-6 for patients with IC. Although the regression analyses showed an association with higher HRQoL in the intervention group, the difference of two scale steps between the groups might not be of clinical importance. However, this association raises questions such as whether the intervention might have been more effective for people with poorer health literacy or a particular age group, which may be a topic for future studies.

The improved HRQoL in both groups is probably mainly the result of the surgical revascularisation, which has been stated previously in other studies. The design of this study did not allow an evaluation on the effect of the intervention programme alone (without revascularisation) on HRQoL. Therefore, testing the intervention as sole treatment or in addition to best medical treatment among patients with IC who are not offered revascularisation or supervised exercise therapy could be of interest for future research. The prevalence of insufficient health literacy among the participants in this study was lower (38.7%, 46/119, at baseline, and 43.2%, 51/118, at one year) than in a previous study (76.6%) that investigated prevalence of health literacy in patients with peripheral arterial disease. However, the measuring instruments used in the studies are different and therefore the results are difficult to compare. The results did not show an association between inadequate health literacy and low HRQoL. This contrasts with previous research among patients with other long term diseases, and an association between inadequate health literacy and worsening HRQoL has been described among patients with type 2 diabetes. In a meta-analysis that reviewed the relationship between health literacy and general quality of life, and not only HRQoL, a moderate correlation between quality of life and health literacy was reported.

**Strengths and limitations**

The design of the study as a prospective randomised clinical trial, the use of validated questionnaires, and the high response rate at both baseline and follow up are strengths of the study. However, the valid number of patients included in the analysis regarding health literacy is a limitation. A vast number of patients (35%) who completed the questionnaires were excluded from the analysis due to missing values, either because they responded didn’t know or did not respond in more than two of the 16 items of the questionnaire.

Another strength of the study is that the intervention could be implemented as planned with no major divergence from protocol which was not standardised except for the dose aspect. Tailoring complex interventions to local circumstances may contribute to better results than completely standardised interventions. Though the partnership between the patient and the healthcare giver was not studied, the other two components of person centred care (an initial assessment based on the patient’s narrative and a healthcare plan which was reviewed during all attended visits) were present in the medical records of all patients in the intervention group. An overview of attended visits per protocol for both the intervention and control groups is shown in [Supplementary Table S2](#). The telephone call nine months after surgery was the least (87%) attended visit. The assessment is that nurse led follow up of patients revascularised for IC can be delivered safely by similarly trained nurses and at similar settings as in this study.

No blinding could be applied in the study since the participants needed to get information on the content of the intervention before consent. Thus, the possibility of the standard care being influenced cannot be excluded.

**Conclusion**

In this study, a person centred, nurse led follow up programme had no significant impact on HRQoL or health literacy or general self efficacy among patients undergoing revascularisation for IC. The prevalence of insufficient health literacy among the study population was high and needs to be addressed by healthcare givers and researchers.

**CONFLICTS OF INTEREST**

None.
ACKNOWLEDGMENT

We sincerely thank all the patients who participated in the study.

APPENDIX A. SUPPLEMENTARY DATA

Supplementary data to this article can be found online at https://doi.org/10.1016/j.ejvs.2023.06.030

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Pseudoaneurysm After Endovascular Repair of Aortic Transection

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A 78 year old patient underwent thoracic endovascular repair with a Valiant (Medtronic, Santa Rosa, CA, USA) stent graft 13 years ago for traumatic aortic transection following blunt injury to the chest wall. Surveillance computed tomography angiography (CTA) imaging performed consecutively for the first five years showed a stable appearance of the implanted stent graft. A recent CTA scan done due to dilated aortic root seen on echocardiography revealed new mid thoracic aortic aneurysmal dilatation to 55 mm with type 1B endoleak at the distal end (A, arrow). (B, arrow, 3D reconstruction). It is hypothesised that the stent graft straightened over time causing a distal aortic tear.

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