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## Clinical Research

# A Comparison of Health Status and Quality of Life in Patients with Intermittent Claudication

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**Background:** Patient reported outcome measures (PROMs) such as health status (HS) and quality of life (QOL) are frequently used interchangeably while they represent different outcomes. Whether a discrepancy exists in patients with intermittent claudication (IC) in changes over time between HS and QOL is unclear. This study aimed to investigate the strength and the direction of the association between HS and QOL over time in patients with IC that underwent supervised exercise therapy (SET).

**Material and Methods:** Patients were part of the ELECT multi-center prospective cohort study. One goal of this study was to obtain data on HS and QOL at different time intervals of patients with IC that underwent SET. HS (VascuQOL-6) and QOL (WHOQOL-BREF) were completed at baseline, 3 months, and 6 months follow up. Pearson's correlation coefficients and the associated common variances ( $R^2$ ) were calculated to measure the strength and the direction of the association between HS and QOL in changes between baseline and follow-up moments.

**Results:** In total, 177 patients were included in data analyses. Only changes in physical QOL and overall QOL had a small correlation with changes over time in HS, at both 3- and 6 months follow up (respectively  $R^2 = .14$ ;  $P < 0.001$  and  $R^2 = 0.12$ ;  $P < 0.001$  for physical QOL and  $R^2 = 0.18$ ;  $P < 0.001$  and  $R^2 = 0.13$ ;  $P < 0.001$  for overall QOL).

**Conclusions:** This study showed that HS and QOL provide different outcomes in patients with IC that underwent SET. Future studies should be aware of these differences before PROMs are being incorporated as an outcome measure in clinical studies.

## INTRODUCTION

Intermittent claudication (IC) is a common manifestation of peripheral arterial disease (PAD). It is characterized by pain or discomfort in the leg muscles, exacerbated by walking. These symptoms result in a diminished health status (HS).<sup>1,2</sup>

The use of outcomes that assess the success of treatment by means of technical measures or

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symptomatology is widespread. However, Patient Reported Outcome Measures (PROMs) are gaining in general importance. PROMs serve to evaluate a patient's subjective perception of their health and well-being. Examples of PROMs are health status (HS) and quality of life (QOL).

Whereas HS and QOL share an overlap in properties, there are some important differences. HS uses a strictly functional approach to measure physical, psychological and social functioning.<sup>3</sup> An example of a question that assesses HS is: 'Are you able to walk?'. Hereby, no evaluation about the patient's feelings about functioning is made. QOL is a broader concept and encompasses a patient's subjective appraisal of well-being.<sup>4</sup> QOL may be assessed by questions as: 'How satisfied are you about your ability to walk?'.

Remarkably, while HS and QOL represent different outcomes, they are frequently used interchangeably.<sup>5,6</sup> Not surprisingly, a discrepancy between HS and QOL was observed in patients with IC and also in patients with chronic limb-threatening ischemia.<sup>5,7</sup> In vascular surgery literature, no gold standard PROM has been identified to measure HS or QOL.

The VasuQOL-6 questionnaire is a disease-specific PROM that measures HS. It has been specifically designed for patients with PAD.<sup>8</sup> The VasuQOL-6 assesses a patients' physical, psychological and social functioning related to the existence of PAD symptoms. All the questions are aimed to relate the effect of impaired circulation in the legs to functional abilities.

In contrast, the World Health Organization Quality of Life-BREF (WHOQOL-BREF) questionnaire measures QOL. The WHOQOL-BREF assesses a patient's subjective appraisal of their satisfaction with various domains of well-being.<sup>9</sup> Hereby, the emphasis is laid upon the patient rather than on the disease.

Whether discrepancies in outcomes exist in the WHOQOL-BREF and the disease specific VasuQOL-6 in patients with IC that undergo SET is unclear. This study aimed to investigate the strength and the direction of the association between HS (VasuQOL-6) and QOL (WHOQOL-BREF) over time in patients with intermittent claudication that underwent supervised exercise therapy (SET).

## MATERIAL AND METHODS

### Patient Population

The patients in this study cohort were part of a multi-center prospective cohort study (ELECT

(Netherlands Trial Register registration number: NTR732). Patients with IC due to PAD that were candidates for SET were recruited in 10 Dutch hospitals (academic and nonacademic) between October 2017 and October 2018. In brief, patients with IC underwent a supervised exercise therapy programme, data on various outcomes such as maximum walking distance, 6-minute walk test, health status and quality of life were collected at different time intervals. Patients with rest pain and patients with ischemic rest pain, ischemic ulcers or gangrene in 1 or both legs (Fontaine III and IV) were not eligible for inclusion. Patients with a history of SET less than 12 months before study inclusion were excluded. Additional methodological information as well as a description of the SET program was extensively described in the study protocol.<sup>10</sup>

Data on HS (VasuQOL-6) and QOL (WHOQOL-BREF) at different time intervals of patients with IC that underwent SET was obtained. The first 36 study participants did not receive the WHOQOL-BREF questionnaire since this was added to the study protocol only after the inclusion had begun. All patients that were part of the ELECT registry and that were sent the both the WHOQOL-BREF and VasuQOL-6 questionnaires were eligible for inclusion in this study.

Informed consent was obtained and signed by each individual patient. A formal written waiver for ethical approval was not required as was confirmed by the Medical Research Ethics Committees United 'MEC-U' (reference number W17.071).

### Data Collection

Data on age, gender, smoking status, medical history, ankle brachial index (ABI) or toe brachial index (TBI) and prior vascular surgery were obtained from the medical charts. Medical history was put into the following categories: history of cardiac disease (myocardial infarction, atrial fibrillation, history of heart failure, valvular disease, coronary artery bypass graft, or percutaneous coronary intervention), history of pulmonary disease (chronic obstructive pulmonary disease (COPD), asthma, obstructive sleep apnea syndrome [OSAS]), history of renal impairment (eGFR < 60 mL/min/1.73m<sup>2</sup>), history of cerebrovascular disease (cerebrovascular incident or transient ischemic attack) and a history of diabetes mellitus, hypercholesterolemia, and hypertension.

In case of an unreliable ABI (e.g. in diabetic patients with noncompressible arteries), the toe ankle index was used. Prior vascular surgery was categorized as: history of percutaneous transluminal

angioplasty (PTA), PTA with stent, bypass surgery (central, peripheral and extra-anatomical), femoral endarterectomy, patch angioplasty, thrombolysis, thrombectomy, and a history of SET more than 12 months before study inclusion.

The Dutch version of the VascuQOL-6 questionnaire was used to measure HS at baseline, 3 months and 6 months.<sup>8</sup> The VascuQOL-6 was specifically designed and validated for patients with PAD and showed to have good psychometric properties.<sup>11</sup> It consists of 6 questions that regard the patient's activities, symptoms, pain and emotional and social well-being. Answers are scored on a 4-item Likert scale. The total score is calculated by summing the scores of the individual items and ranges from 6 to 24. A higher score is indicative of a better health status.

The WHOQOL-BREF questionnaire has good to excellent psychometric properties and was used to measure QOL at baseline, 3 months, and 6 months.<sup>9,12</sup> This questionnaire consists of 26 items with a 5-point Likert type response scale. Questions are divided into 4 domains: physical health (7 questions), psychological health (6 questions), social relationships (3 questions), and environment (8 questions). Domain scores are calculated by summing the scores of the items measuring each domain and range from 5–20. Additionally, answers to 2 questions ('*how would you rate your quality of life?*' and '*how satisfied are you with your health?*') are summed to retrieve an overall QOL score, ranging from 1–5. A higher score corresponds with higher QOL.

### Outcome Measure

The primary endpoint was HS and QOL scores and baseline, 3 months and 6 months. The strength and the direction of the association between HS and QOL was subsequently calculated at each time interval.

### Statistical Analysis

Categorical variables were presented as numbers with percentages. Continuous variables as means with standard deviation (SD; normally distributed variables) or as medians with range (nonnormally distributed variables).

In order to calculate the QOL domain scores for the WHOQOL-BREF patients had to have at least 5 answers in the physical domain, 4 answers in the psychological domain, 2 answers in the social relationship's domain, 6 answers in the environment domain and 2 answers in the

overall domain. Mean-imputation was used for the WHOQOL-BREF in case of missing answers.

Nonresponders to the questionnaires at baseline were excluded from data analysis, patients that did not respond at both 3 months, and 6 months were also excluded from analysis.

Linear mixed models were used to assess whether there were any changes in means between time points in HS (VascuQOL-6) and QOL (WHOQOL-BREF). Comparisons between baseline and specific follow-up measurements were conducted using a custom hypothesis test in the SPSS mixed model syntax. The full information maximum likelihood procedure incorporated in SPSS mixed models allows for optimal use of the available participant data, thereby preventing listwise deletion of all participants without complete data. Pearson's correlation coefficients were computed to analyze the strength and the direction of the association between HS and QOL. The strength of the relationship between QOL and HS was expressed as the square of the correlation coefficient ( $R^2$ ) which corresponds with the common variance.  $R^2$  is reported on a scale from 0 to 1, where 0 indicates no correlation and 1 indicates a perfect correlation.

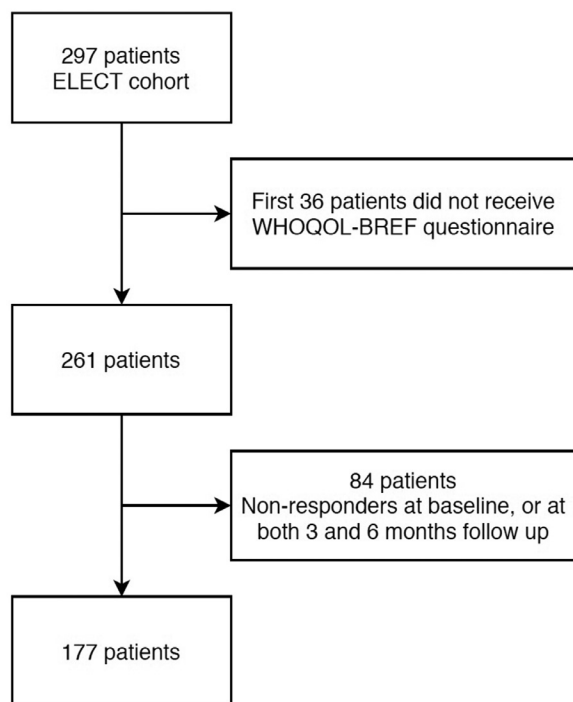
A Bonferroni correction was used for the linear mixed model analyses and the Pearson's correlation analyses, to adjusted for the fact that the WHOQOL-BREF involves 5 statistical tests (1 test for each domain). In these analyses,  $P$ -values  $<0.01$  were considered statistically significant. In all other analyses,  $P$ -values  $<0.05$  were considered statistically significant. Statistical analyses were performed using SPSS version 25.

## RESULTS

Data analyses were conducted with 177 patients, after the exclusion of 84 patients that were nonresponders to the questionnaires at baseline or at both 3 and 6 months follow up (Fig. 1). Table I presents an overview of the patient's baseline characteristics.

For each time interval, the mean scores (and standard deviations) of the VascuQOL-6 and WHOQOL-BREF questionnaires are presented in Table II. On average, the absolute scores of physical QOL improved at each time interval, whereas psychological QOL did not show any change in absolute scores throughout follow-up. The VascuQOL-6 showed a subsequent improvement at each time interval.

Linear mixed models were used to determine whether any of the observed changes over time were statistically significant. Regression



**Fig. 1.** Patient flowchart.

coefficients that represent changes over time for the 2 questionnaires at each time interval are presented in [Table III](#). The physical domain of the WHOQOL-BREF showed the greatest absolute improvement at all time intervals in comparison to the other WHOQOL-BREF domains. There were no statistically significant changes over time in the psychological, social relationships, and environment domains at any time interval. The overall domain significantly improved at baseline to 3 months follow up, however, there was no statistically significant improvement from baseline to 6 months follow up. The VascuQOL-6 had statistically significant changes over time at all time intervals.

The Pearson correlation coefficients represent the strength and the direction of the association in changes over time between the 2 questionnaires ([Table IV](#)). The change in the WHOQOL-BREF physical and overall domains had a positive correlation with changes over time in the VascuQOL-6, at both 3- and 6 months follow up (respectively  $R^2=.140$ ;  $P < 0.001$  and  $R^2=.123$ ;  $P < 0.001$  for the physical domain and  $R^2 = 0.176$ ;  $P < 0.001$  and  $R^2 = 0.130$ ;  $P < 0.001$  for the overall domain). No statistically significant association

**Table I.** Baseline characteristics of the study cohort.

Variable	<i>n</i> = 177
Age, y (SD)	70 (8.8)
BMI, kg/m <sup>2</sup> (range)	27.1 (18–42)
Gender, male (%)	105 (59.3)
Active smoker (%)	67 (42.1)
Diabetes (%)	51 (29)
Hypercholesterolemia (%)	99 (56.3)
Hypertension (%)	107 (61.1)
Renal impairment (%)	19 (10.9)
Cerebrovascular history (%)	21 (11.9)
Cardiac history (%)	41 (23.2)
Pulmonary history (%)	47 (26.6)
Ankle brachial index at rest (range) <sup>a</sup>	0.62 (1.18–0.28)
Ankle brachial index post-exercise (range) <sup>a</sup>	0.33 (0.88–0.1)
History of PTA (%)	24 (14.3)
History of PTA with stent (%)	26 (15.5)
History of bypass surgery (%)	7 (4.2)
History of femoral endarterectomy (%)	7 (4.2)
History of patch angioplasty (%)	1 (.6)
History of thrombolysis (%)	0
History of thrombectomy (%)	0
History of SET (%) <sup>b</sup>	24 (14)

SD, standard deviation; BMI, body mass index; PTA, percutaneous transluminal angioplasty; SET, supervised exercise therapy.

<sup>a</sup>Value corresponds with either ankle brachial index or toe brachial index.

<sup>b</sup>History of SET more than 12 months before study inclusion.

**Table II.** Mean scores (and standard deviations) of the WHOQOL-BREF domains and VascuQOL-6 questionnaire at the individual time intervals.

WHOQOL-BREF	Baseline ( <i>n</i> = 177)	3 months ( <i>n</i> = 172)	6 months ( <i>n</i> = 142)
Physical domain	13.5 (2.5)	14.0 (2.5)	14.6 (2.7)
Psychological domain	15.0 (2.5)	15.0 (2.6)	15.0 (2.4)
Social relationships domain	15.2 (2.8)	15.2 (3.1)	15.5 (2.8)
Environment domain	16.0 (2.5)	15.9 (2.5)	16.2 (2.4)
Overall domain	3.5 (0.7)	3.5 (0.7)	3.6 (0.6)

VascuQOL-6	Baseline ( <i>n</i> = 175)	3 months ( <i>n</i> = 169)	6 months ( <i>n</i> = 141)
Total score	15.7 (3.8)	17.8 (3.8)	19.1 (4.0)

**Table III.** Regression coefficients with standard errors from the linear mixed model analyses, comparing baseline QOL with specific follow-up measurements.

Questionnaire	Baseline versus 3 months	<i>P</i> -value
<i>WHOQOL-BREF</i>		
Physical domain	0.53 (0.15)	<0.001 <sup>a</sup>
Psychological domain	0.04 (0.12)	0.742
Social relationships domain	-0.03 (0.17)	0.845
Environment domain	-0.13 (0.12)	0.306
Overall domain	0.13 (0.05)	0.008 <sup>a</sup>
<i>VascuQOL-6</i>	2.13 (0.31)	<0.001 <sup>a</sup>

Questionnaire	Baseline versus 6 months	<i>P</i> -value
<i>WHOQOL-BREF</i>		
Physical domain	0.97 (0.18)	<0.001 <sup>a</sup>
Psychological domain	-0.02 (0.14)	0.892
Social relationships domain	0.34 (0.2)	0.086
Environment domain	0.15 (0.14)	0.286
Overall domain	0.07 (0.04)	0.077
<i>VascuQOL-6</i>	3.16 (0.35)	<0.001 <sup>a</sup>

Questionnaire	Baseline versus entire follow-up	<i>P</i> -value
<i>WHOQOL-BREF</i>		
Physical domain	0.75 (0.14)	<0.001 <sup>a</sup>
Psychological domain	0.01 (0.12)	0.923
Social relationships domain	0.15 (0.16)	0.334
Environment domain	0.01 (0.11)	0.910
Overall domain	0.1 (0.04)	0.008 <sup>a</sup>
<i>VascuQOL-6</i>	2.65 (0.29)	<0.001 <sup>a</sup>

<sup>a</sup>Statistically significant ( $p < 0.05$ ) after a Bonferroni correction for multiple testing.

was present between the psychological domain of the WHOQOL-BREF and the VascuQOL-6 at 3 months ( $R^2 = 0.010$ ;  $P = 0.206$ ). However, there was a statistically significant association at 6 months follow up ( $R^2 = 0.102$ ,  $P < 0.001$ ). The social relationships and environment domains did not show any association with the VascuQOL-6 questionnaire in their change scores at all time intervals.

## DISCUSSION

This study observed a clear discrepancy in changes over time in HS (VascuQOL-6) and QOL (WHOQOL-BREF) in patients with IC. The VascuQOL-6 had an association at both 3 and 6 months with the physical and overall domain of the WHOQOL-BREF. However, despite its statistical significance, the strength of this positive association was only small.

**Table IV.** Squares of Pearson correlation coefficients ( $R^2$ ) representing the strength of the association between changes over time in each of the WHOQOL-BREF domains and the VascuQOL-6.

Baseline – 3 months	VascuQOL-6	P-value	N
<i>WHOQOL-BREF</i>			
Physical domain	0.140	<0.001 <sup>a</sup>	167
Psychological domain	0.010	0.206	167
Social relationships domain	0.004	0.477	166
Environment domain	0.004	0.419	167
Overall domain	0.176	<0.001 <sup>a</sup>	167
Baseline – 6 months	VascuQOL-6	P-value	N
<i>WHOQOL-BREF</i>			
Physical domain	0.123	<0.001 <sup>a</sup>	138
Psychological domain	0.102	<0.001 <sup>a</sup>	137
Social relationships domain	0.026	0.856	138
Environment domain	0.01	0.179	137
Overall domain	0.130	<0.001 <sup>a</sup>	138

<sup>a</sup>Statistically significant ( $P < 0.05$ ) after a Bonferroni correction for multiple testing.

While the VascuQOL-6 did improve in a statistically significant manner at both time intervals, the psychological domain of the WHOQOL-BREF did not show any absolute improvement at both 3 and 6 months (Table II and III). This discrepancy may be explained by the fact that only 1 question of the VascuQOL-6 addresses psychological well-being, compared to 6 questions in WHOQOL-BREF. Additionally, the VascuQOL-6 merely reports a total score, and does not provide insight in sub-domains (e.g. physical or psychological). Hereby, the total score can increase when psychological well-being remains unaffected.

Altogether, the results of this study showed that HS is predominantly associated with physical and overall QOL. The strength of this association was however only small. An even less powerful association was observed with HS and psychological QOL. No association was present in changes over time between HS and the social relationships and environment domains of QOL. Similar results were observed in a study by Breek et al.<sup>5</sup>

The observations made in this study are likely explained by the different designs of the 2 questionnaires. The WHOQOL-BREF assesses QOL in a patient-centered manner and asks about the subjective appraisal of physical, psychological, and social functioning. Patients are asked about how they feel about themselves and their capability of performing daily activities rather than on the possibility of performing these activities alone. As a result, an increase in objective physical functioning

may not automatically result in an increase of physical QOL.

The WHOQOL-BREF measures QOL in 4 distinct domains. Hereby, the domain of QOL that is susceptible for improvement will be more easily revealed. As a result, treatment may be adapted in order to benefit the specific domains of QOL that are the most susceptible for improvement.

In contrary, the VascuQOL-6 is considered to be a valid instrument to measure HS specifically in patients with PAD.<sup>8,13,14</sup> It should be noted that the VascuQOL-6 measures functioning in an objective manner and does not address the subjective appraisal of functioning. Therefore we argue that it measures HS instead of QOL. Additionally, the VascuQOL-6 is a disease specific questionnaire. All questions in the VascuQOL-6 are posed in such way that they directly relate to the symptoms of PAD. The questions are designed in a way to illustrate the effect of the symptoms of PAD on HS. As a consequence, factors that impair QOL that are not directly related to the symptoms of PAD are not being addressed.

All patients in this study participated in a SET program. This program is predominantly aimed to improve the walking performance of a patient. However, it is a multi-component program that also aims to enhance intrinsic motivation and to initiate lifestyle modifications. Improvements after SET were predominantly observed in HS and in the physical and overall domains of QOL (Table III). This indicates that patients who undergo SET improve in both functioning and in their subjective appraisal

of their physical activity and overall functioning. No significant improvement in the psychological domain of QOL was observed after SET. In contrast, the VascuQOL-6 statistically significantly improved but does not make a distinction between objective functioning and psychological functioning. This indicates that the WHOQOL-BREF, in contrast to the VascuQOL-6, provides information about different aspects of QOL.

Clear differences in the PROMs HS and QOL were observed in this study. Unfortunately, PROMs such as HS and QOL are used interchangeably.<sup>5,6,15,16</sup> Consequently, outcomes of these studies are being misinterpreted, and wrongfully compared. As a result incorrect conclusions may be drawn.

What PROM is the most accurate for patients with IC remains unclear. The current ESC guideline has not proposed a PROM of choice for patients with PAD.<sup>17</sup> We argue that selecting the most accurate PROM may be of guidance in shared decision making. This study does not serve to make preferences about what PROM to use in patients with IC. It does serve however to reveal the existence of differences in the PROM's HS and QOL. A PROM should be chosen based on the characteristics of a study population and on the clinical concepts of interest of the study.<sup>3</sup> Future studies should be aware of this before PROMs are being incorporated as an outcome measure.

## LIMITATIONS

The changes over time in HS and QOL may not be applicable for the entire study cohort since nonresponders were excluded from analyses. It should be noted however that the goal of this study was to investigate whether a discrepancy exists in changes over time between HS and QOL. We did not aim to investigate the effect of SET itself on changes over time in HS and QOL. These results can be found in the paper by van Houten et al.<sup>18</sup> Hence, the results and conclusions of this study were unlikely affected by excluding nonresponders. Nevertheless, due to the absence of a control group, the effect of SET on changes over time in HS and QOL should be interpreted with care.

## CONCLUSIONS

This study observed a clear discrepancy in changes over time in HS (VascuQOL-6) and QOL (WHOQOL-BREF) in patients with IC that underwent SET. Future studies should be aware of these differences before PROMs are being

incorporated as an OUTCOME MEASURE IN CLINICAL STUDIES.

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## CONFLICT OF INTEREST STATEMENT

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

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