

# Vascular Quality of Life Questionnaire-6 facilitates health-related quality of life assessment in peripheral arterial disease

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**Background:** Most commonly used outcome measures in peripheral arterial disease (PAD) provide scarce information about achieved patient benefit. Therefore, patient-reported outcome measures have become increasingly important as complementary outcome measures. The abundance of items in most health-related quality of life instruments makes everyday clinical use difficult. This study aimed to develop a short version of the 25-item Vascular Quality of Life Questionnaire (VasculoL-25), a PAD-specific health-related quality of life instrument.

**Methods:** The study recruited 129 individuals with intermittent claudication and 71 with critical limb ischemia from two university hospitals. Participants were a mean age of  $70 \pm 9$  years, and 57% were men. All patients completed the original VasculoL when evaluated for treatment, and 127 also completed the questionnaire 6 months after a vascular procedure. The VasculoL-25 was reduced based on cognitive interviews and psychometric testing. The short instrument, the VasculoL-6, was tested using item-response theory, exploring structure, precision, item fit, and targeting. A subgroup of 21 individuals with intermittent claudication was also tested correlating the results of VasculoL-6 to the actual walking capacity, as measured using global positioning system technology.

**Results:** On the basis of structured psychometric testing, the six most informative items were selected (VasculoL-6) and tested vs the original VasculoL-25. The correlation between VasculoL-25 and VasculoL-6 was  $r = 0.88$  before intervention,  $r = 0.96$  after intervention, and the difference was  $r = 0.91$  ( $P < .001$ ). The Cronbach  $\alpha$  for the VasculoL-6 was .85 before and .94 after intervention. Cognitive interviews indicated that the responders considered all six items to be relevant and comprehensible. Rasch analysis was used to reduce response options from seven (VasculoL-25) to four (VasculoL-6). VasculoL-6 was shown to have high precision and discriminative properties. Item fit was excellent, with both “infit” and “outfit” between 0.7 and 1.3 for all six items. The standardized response mean after intervention was 1.15, indicating good responsiveness to clinical change. VasculoL-6 results correlated strongly ( $r = 0.72$ ;  $P < .001$ ) with the actual measured walking ability ( $n = 21$ ).

**Conclusions:** VasculoL-6 is a valid and responsive instrument for the assessment of health-related quality of life in PAD. The main advantage is the compact format that offers a possibility for routine use in busy clinical settings. (*J Vasc Surg* 2014;59:700-7.)

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The main goal of vascular surgical treatment efforts in peripheral arterial disease (PAD) is limb salvage in critical limb ischemia<sup>1</sup> and improvement of walking ability in intermittent claudication. Commonly used clinical tools for the assessment of disease impact and results of invasive interventions in PAD include amputation-free survival, walking performance during treadmill testing, patency of revascularized arterial segments, and a variety of physiologic measurements. However, these outcomes do not address the PAD patient's own perception about his or her actual functional walking capacity, pain discomfort, or the social and emotional implications of living with PAD.<sup>2</sup>

Therefore, it has been suggested that objective outcome measures should be complemented with patient-reported outcome measures.<sup>3,4</sup> Such measures can provide clinically useful additional decision-basis and also important information about the results of different medical interventions, with the potential to be integrated in everyday clinical practice. In this context, most authors recommend the use of disease-specific health-related quality of life (HRQoL) instruments because they

concentrate on the specific limitations experienced by PAD patients,<sup>5</sup> making them more sensitive to detect clinically relevant changes in health status in response to treatment.

The Vascular Quality of Life (VascuQoL) questionnaire, a PAD-specific HRQoL instrument, was developed by Morgan et al<sup>6</sup> and first published in 2001. The VascuQoL questionnaire has been translated to several languages,<sup>7</sup> has been validated in the United Kingdom,<sup>8</sup> and was first used in the Bypass vs Angioplasty in Severe Ischemia of the Leg (BASIL) trial.<sup>9</sup> The instrument has been recommended as the preferred questionnaire for outcome measurement in patients with peripheral vascular disease.<sup>5,8</sup> The VascuQoL was also validated among Swedish PAD patients by our research group.<sup>10</sup> This work was a necessary first step to confirm the validity of the translated original VascuQoL instrument in a Swedish context.

As with most HRQoL instruments, the VascuQoL contains a relative abundance of items, making patient completion of the instrument potentially too arduous and time-consuming for routine use in busy clinics. A recent review article looking at available measures for functional and QoL status in intermittent claudication clearly links brevity and ease of use in the clinical setting.<sup>2</sup>

In the last few decades, a system of national quality registries has been established in the Swedish health and medical services. These contain individualized data about patient medical history, including medical and surgical interventions and outcomes after treatment, for all health care services.<sup>11</sup> In this context, use of patient-reported outcome measures is seen as essential, but the PAD-specific HRQoL instruments currently available are too cumbersome for robust and sustainable data collection.

The main aim of this study was therefore to develop a short, yet efficient, version of the VascuQoL for use in everyday clinical practice among PAD patients.

## METHODS

This study was approved by the Regional Ethical Review Boards at the University of Lund (No. 315/2008) and Gothenburg (No. 501/2009).

**Study population.** The study recruited 200 consecutive patients with an established diagnosis of PAD from two academic vascular centers in Sweden. A senior vascular surgeon established the diagnosis, and all patients were considered as having symptoms of critical limb ischemia ( $n = 71$ ) or claudication ( $n = 129$ ) attributable to peripheral vascular disease. All participants unaided completed the Swedish VascuQoL questionnaire while being evaluated for treatment in the outpatient clinic. In one of the participating hospitals, 127 of the enrolled patients also completed the questionnaire 6 months after a vascular procedure. A subset of 21 patients also participated in an outdoor test walk monitored by a global positioning system (GPS). Prospectively defined cardiovascular risk factors were collected from the medical records.

Solely for cognitive interviews, as described below, 15 more patients with moderate intermittent claudication (Rutherford stage 3) were consecutively recruited from the vascular surgical outpatient clinic at one of the two participating centers.

**The VascuQoL.** The VascuQoL aims to assess QoL in PAD regardless of disease severity (ie, in intermittent claudication and in critical limb ischemia). The questionnaire comprises 25 items, divided into five subscales (domains): pain (4 items), symptoms (4 items), activities (8 items), social (2 items), and emotional (7 items). Every item has a 7-point response scale. When summarizing item responses, an overall score and five different domain scores are generated, ranging from 1 (worst HRQoL) to 7 (best HRQoL).

**Psychometric item selection and reduction strategy.** For item selection and reduction from VascuQoL-25 we applied the following criteria:

1. *Correlation analysis criteria* (item score vs total score): choosing the items that correlate most strongly with the total score of VascuQoL-25.
2. *Exploratory factor analysis criteria*: choosing the items with the strongest factor loading in a single factor model for all 25 variables.
3. *Disease burden criteria*: choosing the items where respondents report most problems or limitations.
4. *Responsiveness criteria*: choosing items that change most after treatment.
5. *Content criteria*: selecting at least one item from every domain of VascuQoL-25.

After applying these criteria, we decided to choose one item from every domain of VascuQoL, except for the “activity” domain, from which two items were chosen, because limitations in activities are a central consequence of PAD. Two items (item 9 “During the past two weeks, the distance I can walk has improved. . .” and item 24 “During the past two weeks, the distance I can walk became less. . .”) were excluded because of suboptimal item construction. We then tested the correlation (Pearson correlation coefficient) of the short instrument (VascuQoL-6) vs VascuQoL-25, aiming for  $r \geq 0.90$ .

For reliability assessment, we calculated the Cronbach  $\alpha$  for the short version. The Cronbach  $\alpha$  measures internal consistency, which refers to the extent to which the items within a scale are inter-related. Cronbach  $\alpha$  coefficients  $>.7$  are generally regarded as acceptable for psychometric scales, although .9 is recommended for individual patient assessment.<sup>12</sup> We assessed sensitivity by exploring the capacity of VascuQoL-6 to discriminate between patients with intermittent claudication and critical limb ischemia by using nonparametric statistical testing (Mann-Whitney  $U$  test).

**Cognitive interviews.** Fifteen patients (seven women and eight men) with moderate-to-severe intermittent claudication (Rutherford stage 3) were consecutively recruited for cognitive interviews.<sup>13</sup> The individual interviews took place at the vascular surgical outpatient clinic and lasted

between 20 and 40 minutes. The patients were a mean age of 69 years (range, 54-80 years). Every participant read the original VasuQoL version and was asked the following questions for all 25 items:

- Do you consider this question relevant in relation to your disease?
- Do you think this question is comprehensible?

Every participant thoroughly read every question of the instrument and was asked for additional comments and suggestions for improving the questions and the response options.

**Rasch analysis.** Rasch models<sup>14</sup> analyze valuation data about capabilities, attitudes, and personalities. The models can give information about how well items function to describe capability or personalities. The psychometric qualities tested by the Rasch analysis are:

- **Rating scale.** This test explores the category thresholds. VasuQoL-25 has seven response options, which mean that there are six thresholds between the response options.
- **Discrimination.** This test explores how many levels of person-ability that the questionnaire can discriminate. The test results in two measures: person separation and a separation reliability coefficient. The latter is a measure of precision.<sup>15</sup> Precision is a fundamental characteristic of a measurement instrument.
- **Item fit statistics.** This test produces two measures: infit and outfit mean square. The test explores if each item contributes to the respondent's capability in a predictable way. Both measures should have a value of 1.0. Accepted limits are from 0.7 to 1.3.<sup>16</sup>
- **Targeting.** This test explores if the difficulty of the items and the ability of the respondents have about the same mean. There should be easy items for poorly performing patients and difficult items for the able patients.<sup>17</sup>
- **Unidimensionality.** The items should measure the same underlying trait and no other dimensions. If the questionnaire does not fulfill this criterion, no summary score can be calculated.<sup>18</sup>
- **Differential item functioning.** Differential item functioning (DIF) means that a particular group of patients responds otherwise to a specific item although the same amounts of the latent trait are measured. A large DIF may cause poor fitting of data to the Rasch model. In our analysis, we tested DIF between groups with different age and sex.<sup>15</sup>

The standardized response mean, based on the calculated Rasch person scores, was used for responsiveness testing and was calculated as the mean difference in score after a vascular surgery procedure compared with baseline, divided by the standard deviation of the difference. We used the Cohen criteria<sup>19</sup> for grouping the effect size (small, 0.2-0.5; moderate, 0.5-0.8; large, >0.8). In our

**Table I.** Demographics and risk factors in the patient population

Variables	Mean $\pm$ SD or No. (%) (n = 200)
Demographics	
Age, years	70 $\pm$ 9
Sex	
Male	114 (57)
Female	86 (43)
Risk factors	
Regular smoking (current or in last 5 years)	97 (49)
Previous TIA or stroke	20 (10)
Diabetes	57 (29)
Hyperlipidemia	22 (11)
Angina pectoris/previous MI	85 (43)
Chronic pulmonary disease	25 (13)
Kidney disease <sup>a</sup>	19 (10)
Ankle-brachial index	0.70 $\pm$ 0.18

MI, Myocardial infarction; SD, standard deviation; TIA, transient ischemic attack.

<sup>a</sup>Defined as serum creatinine >150 mmol/L.

study questionnaire, responses (six items) were arranged into a Rasch measurement model. The aim was to create a latent variable of disability caused by peripheral vascular disease on a single linear scale. Our analysis used a polytomous Andrich rating scale model with joint maximum-likelihood estimation. The calculations were made by the Winsteps 3.70.2 program (Chicago, Ill).

**GPS-monitored outdoor test walk.** As an additional test of criterion validity of the proposed new instrument, and as an adjunct to the criterion validity established by the baseline correlation between the VasuQoL-25 and VasuQoL-6 in 200 patients and the postintervention correlation in 127 patients, a test of everyday walking ability was performed in a subgroup of 21 patients (10 women, 11 men) with mild to moderate intermittent claudication (Rutherford stage 2 and 3). Patients were a mean age of 69 years (range, 55-80 years).

This test walk was situated in a flat park area with no disturbing motorized vehicles or traffic lights. The patients were instructed to walk for 40 minutes at their leisure walking pace and to stop when required by their claudication pain. The test was performed individually and was monitored by a research nurse. We used an iPhone4 (Apple Corp, Cupertino, Calif) equipped with the Walkmeter walking performance application (Abvio Inc, San Francisco, Calif),<sup>20</sup> which uses GPS technology to continually record walking time, location, distance, elevation, and speed. Spearman rank correlation coefficients were used to correlate the results from the test walks to the participants' individual total scores for VasuQoL-25 and the proposed VasuQoL-6 instrument.

## RESULTS

**Study population and missing data.** In the studied population, mean age was 70  $\pm$  9 years, and 57% were

**Table II.** Item selection for the six-item Vascular Quality of Life (*VasquQoL-6*) assessment<sup>a</sup>

<i>Item-total correlation analysis</i>		<i>Exploratory factor analysis</i>		<i>Disease burden</i>		<i>Responsiveness</i>	
<i>Pearson correlations (r) between the 25 items and the total VasquQoL-25 score (corrected for overlap).<sup>b</sup></i>		<i>Factor correlations are presented. Results of a single factor model including all 25 items.<sup>c</sup></i>		<i>Mean item score before treatment. A lower mean value indicates more health problems/limitations (range 1-7).</i>		<i>Change in item score after treatment. A larger mean change indicates greater improvement.</i>	
Activity 16	0.74	Activity 16	76	Activity 4	2.15	<b>Activity 18</b>	<b>1.92</b>
Social 6	0.72	Activity 22	76	Pain 1	2.20	Pain 1	1.91
Activity 22	0.71	Social 6	72	<b>Activity 18</b>	<b>2.58</b>	<b>Emotional 12</b>	<b>1.91</b>
Emotional 25	0.69	Activity 14	72	<b>Emotional 12</b>	<b>2.69</b>	<b>Pain 20</b>	<b>1.76</b>
Activity 14	0.69	<b>Activity 18</b>	<b>71</b>	<b>Symptoms 5</b>	<b>2.74</b>	Activity 4	1.74
<b>Emotional 12</b>	<b>0.68</b>	<b>Social 15</b>	<b>71</b>	<b>Pain 20</b>	<b>2.79</b>	<b>Activity 10</b>	<b>1.60</b>
Emotional 11	0.67	<b>Emotional 12</b>	<b>70</b>	<b>Activity 10</b>	<b>3.10</b>	<b>Symptoms 5</b>	<b>1.59</b>
<b>Social 15</b>	<b>0.66</b>	Emotional 11	70	<b>Social 15</b>	3.32	Symptoms 8	1.50
<b>Pain 20</b>	<b>0.66</b>	Emotional 25	69	Activity 14	3.33	Emotional 19	1.48
<b>Symptoms 5</b>	<b>0.66</b>	<b>Pain 20</b>	<b>68</b>	Activity 22	3.37	Pain 7	1.46
<b>Activity 18</b>	<b>0.65</b>	<b>Symptoms 5</b>	<b>67</b>	Symptoms 8	3.53	<b>Social 15</b>	<b>1.40</b>
Emotional 21	0.65	Emotional 19	67	Emotional 19	3.71	Activity 22	1.34
Emotional 19	0.65	<b>Activity 10</b>	<b>65</b>	Pain 7	3.93	Emotional 25	1.31
Pain 13	0.63	Emotional 21	65	Emotional 25	4.03	Symptoms 3	1.17
Pain 7	0.63	Symptoms 8	62	Symptoms 3	4.20	Activity 14	1.17
Symptoms 8	0.62	Pain 7	61	Activity 16	4.20	Activity 16	1.17
<b>Activity 10</b>	<b>0.62</b>	Activity 4	61	Pain 13	4.35	Emotional 11	1.03
Emotional 2	0.60	Pain 13	61	Emotional 11	4.37	Emotional 23	0.99
Emotional 23	0.60	Emotional 2	59	Social 6	4.58	Social 6	0.94
Activity 4	0.57	Emotional 23	58	Emotional 2	4.61	Pain 13	0.94
Pain 1	0.51	Pain 1	53	Emotional 21	4.92	Symptoms 17	0.93
Symptoms 17	0.49	Symptoms 17	48	Emotional 23	4.74	Emotional 2	0.83
Symptoms 3	0.42	Symptoms 3	41	Symptoms 17	5.21	Emotional 21	0.82
Activity 9 <sup>d</sup>	0.16	Activity 9	24	Activity 9	1.73	Activity 9	1.60
Activity 24 <sup>d</sup>	0.57	Activity 24	58	Activity 24	4.71	Activity 24	1.26

*VasquQoL-25*, 25-item Vascular Quality of Life.

<sup>a</sup>Summary of psychometric analysis of the *VasquQoL-25* items according to four criteria: item-total correlation analysis, exploratory factor analysis, disease burden and responsiveness. Items are labeled according to the health domain they represent in *VasquQoL-25*. Item numbers correspond to the placement in *VasquQoL-25*.<sup>b</sup> The six items selected for the *VasquQoL-6* are in bold type.

<sup>b</sup>Corrected for overlap means that the value of the test item is subtracted from the total *VasquQoL-25* score.

<sup>c</sup>One factor accounted for 74.4% of the variance.

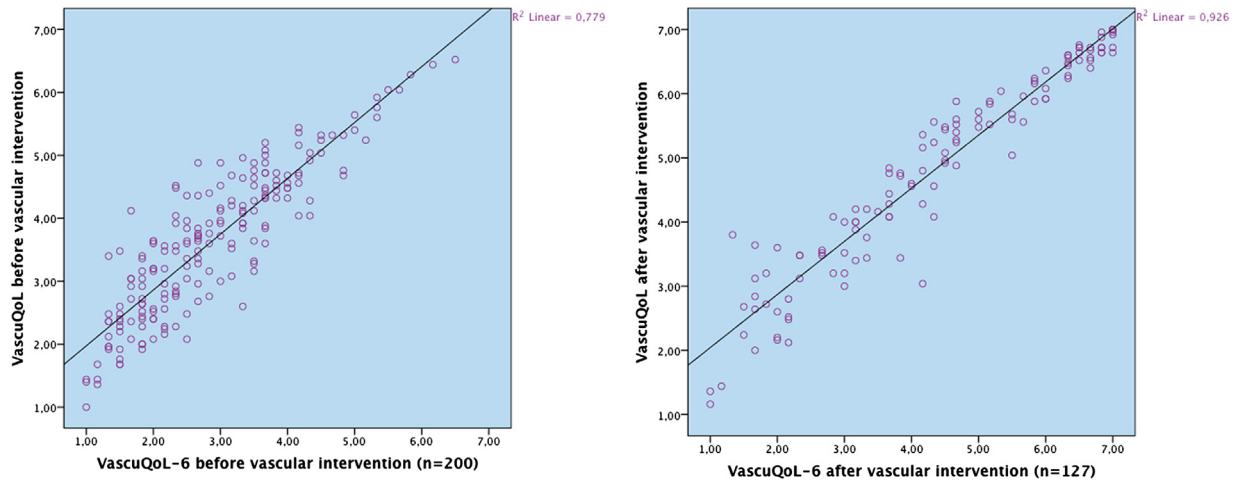
<sup>d</sup>Items 9 and 24 were excluded because of suboptimal item construction.

men. Almost half of the patients (49%) had a history of smoking (previous or current), 29% had a diagnosis of diabetes, and 43% had coronary heart disease (Table I). Missing data were negligible (0%-3%) for all items, because 183 of the 200 patients (92%) had complete *VasquQoL* registrations, and every participant had a computable scale (using the half-scale method). The mean time taken to complete the *VasquQoL-6* was significantly less than that of the *VasquQoL-25* (1.4 vs 9.6 minutes;  $P < .001$ ).

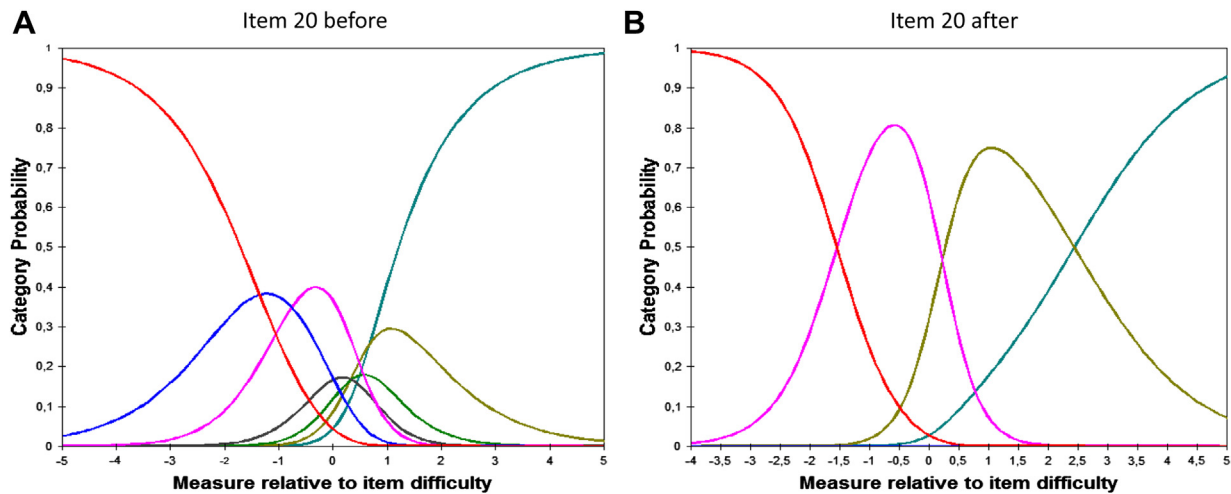
**Psychometric item selection strategy.** The results of the psychometric analysis are summarized in Table II. The item-total correlation analysis shows the strength of association between each of the 25 *VasquQoL* items and the total *VasquQoL-25* score. Items with strong correlation are regarded as the best indicators of the total *VasquQoL-25*. Results of exploratory factor analysis indicate which of the 25 items best represents the latent variable, QoL in this case, in PAD patients. The outcome of the item-total correlation analysis was similar to the item-factor pattern obtained from factor analysis. However, a somewhat different item structure was uncovered when the disease burden and responsiveness

criteria were applied (Table II). The analysis of disease burden pointed out which areas (items) the respondents reported the most problems or limitations in QoL. The evaluation of responsiveness indicated which items were most sensitive to change in QoL after treatment. Our intention was to select items that performed well according to all selection criteria.

However, because the aim was to construct a short-form instrument that would perform well for the description of disease severity and also as an outcome measure after a vascular intervention, we attached greater importance to items that were most effective according to disease burden and responsiveness criteria. Also, because walking limitations are of great concern for most PAD patients, we chose two items from the activity domain and one item from the remaining four domains (symptoms, pain, social, and emotional subscales), resulting in six items for the short version of the instrument, *VasquQoL-6* (Appendix, online only). The selection of two items from the activity domain was supported by factor analysis, which revealed that four of the five highest loading items were from the activity domain (Table II).



**Fig 1.** Scatterplots show the correlation between the original 25-item Vascular Quality of Life (*VascuQoL-25*) assessment and six-item version (*VascuQoL-6*) (left) before and (right) after vascular surgical intervention.



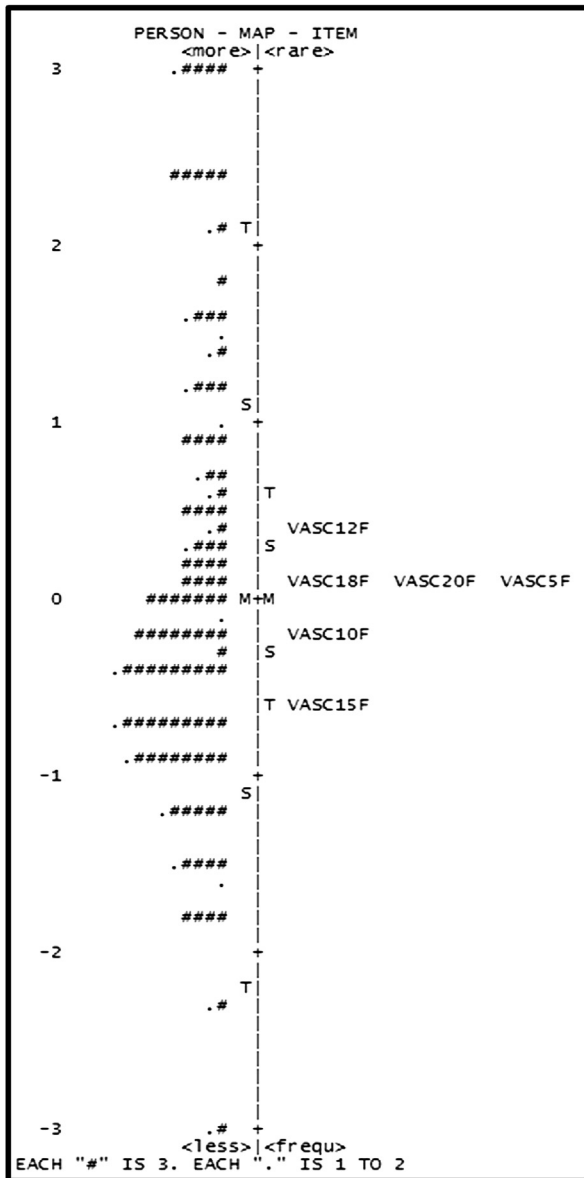
**Fig 2.** Category thresholds for item 20 in the (A) original 25-item Vascular Quality of Life (*VascuQoL-25*) assessment before categories were collapsed and (B) for the same item in the six-item version (*VascuQoL-6*) after categories were collapsed.

The correlation between *VascuQoL-25* and *VascuQoL-6* was  $r = 0.88$  before intervention,  $r = 0.96$  after intervention, and the difference was  $r = 0.91$  ( $P < .001$ ; Fig 1). Adding more items to *VascuQoL-6* improved the correlations only marginally. The Cronbach  $\alpha$  for the *VascuQoL-6* was .85 before and .94 after intervention, indicating good internal consistency. The *VascuQoL-6* significantly differentiated intermittent claudication patients from critical limb ischemia patients ( $P < .001$ ).

**Cognitive interviews.** Every item of *VascuQoL-25* was considered comprehensible by the responders. Items 2, 11, 17, 21, and 23 were considered least relevant in relation to the disease. Most responders (14 of 15) commented on the abundance of response options, and suggested that three to four response options should be used.

Of the suggested items for the short version, the participants considered all of the selected items as highly relevant for PAD disease.

**Rasch analysis.** Rasch analysis demonstrated disordered category thresholds in the original *VascuQoL-25*. The categories for the six items were collapsed from 7 (*VascuQoL-25*) to 4 (*VascuQoL-6*), which gave ordered thresholds (Fig 2). Person separation for *VascuQoL-6* was 2.23, and the separation reliability coefficient was 0.83, indicating high precision. Item fit was good with “infit” between 0.85 and 1.23 and “outfit” between 0.79 and 1.12. Targeting showed that the degree of difficulty of the items matched the ability of the responders (Fig 3). Item mean was 0 logits, and person mean was 0.09 logits. Evidence of unidimensionality was shown by residual



**Fig 3.** Person-item map for the six-item version of the Vascular Quality of Life (VascuQoL-6) assessment shows the ability of the patients to the *left* and the difficulty of the items to the *right* of a linear scale. The measure of the linear scale is logits, which is the logarithm of the odds ratio for being able to perform an item activity successfully. The distance between a respondent and an item on the scale shows the probability of the respondent to perform successfully the item activity. Ideally, person and item mean should center on the same mean value. #, Persons; M, mean; S, 1 standard deviation; T, 2 standard deviations; VASC 12F, item 12 from original VascuQoL-25.

analysis, demonstrating that variance explained by the measures was comparable for empirical calculation (62.7%) and by the model (62.5%). The VascuQoL-6 was free of DIF (<0.5 logits) by sex and age. The standardized response mean, calculated on the person scores achieved from Rasch

analysis, was 1.15 for the short version, which indicates excellent responsiveness.

For the final selection of response options, we analyzed the utilization frequencies of the different item response options before and after vascular intervention. We chose the response options that were most frequently used by the responders, taking into account the need for equidistance between the different response options.

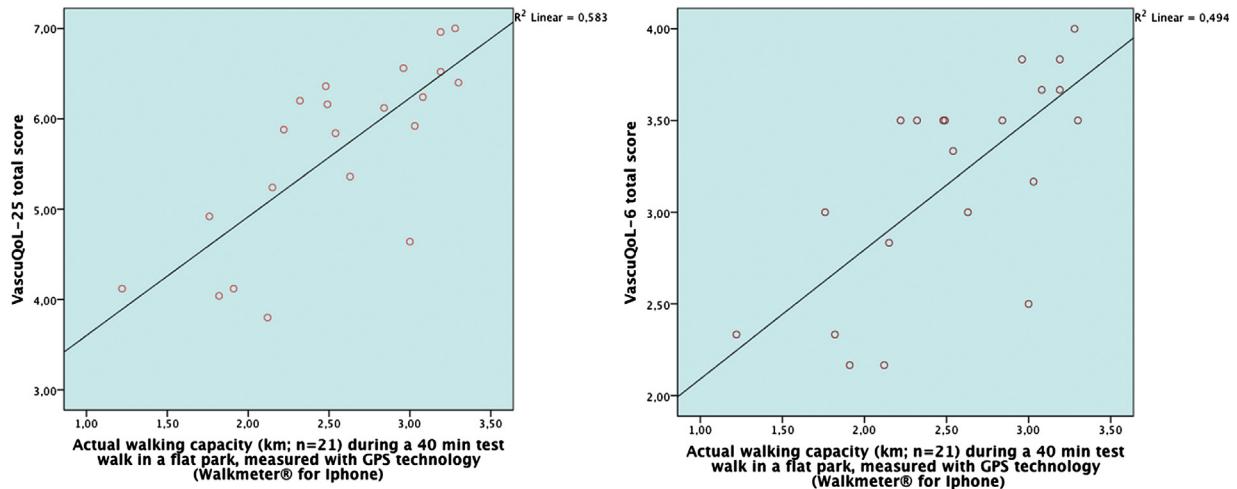
**GPS-monitored outdoor test walk.** VascuQoL-25 and VascuQoL-6 both correlated strongly with the measured total walking distance (km) during the test walk. The Spearman rank correlation coefficient was  $r = 0.78$  ( $P < .01$ ) for VascuQoL-25 and  $r = 0.72$  ( $P < .01$ ) for VascuQoL-6 (Fig 4).

### DISCUSSION

Our main clinically important finding is that the VascuQoL-6, a short version of the PAD-specific HRQoL instrument VascuQoL, seems to be a valid and responsive instrument for the measurement of HRQoL in PAD. Using structured psychometric testing, we were able to select the most efficient items from the original instrument and demonstrated a strong correlation between the scores from the original and the short version of the instrument. Rasch analysis confirmed the validity of the new instrument (VascuQoL-6) by demonstrating a high precision, item fit, and targeting in the studied sample. Moreover, the Rasch analysis confirmed the unidimensionality (ie, the instrument measures only one underlying latent trait) of the instrument and showed no signs of DIF as a consequence of age or sex. Cognitive interviews with a subgroup of PAD patients confirmed that the selected items were considered relevant from the patient perspective.

The validity of a shortened instrument can be established by showing close correlation with the original longer version, and this premise was used in creating shorter versions of the Medical Outcome Study Short-Form 36 Health Survey.<sup>21-23</sup> We have established “criterion validity” of the VascuQoL-6 showing excellent correlation with the VascuQoL-25 not only at baseline but also after intervention. Moreover, further criterion validity was established because VascuQoL-6 scores also adequately reflected objective walking capacity during a GPS-measured outdoor test walk that approached a real-life scenario. This approach to assess community-based outdoor walking limitations has previously been shown to provide valid estimates of walking ability in PAD patients.<sup>24</sup> The combination of traditional psychometric testing and Rasch analysis, as used in this study, has been used for the development of HRQoL instruments within other areas of medicine.<sup>25</sup>

One crucial component of a measurement scale is the number of response options. To differentiate between individuals with different disease severity and divergent functional limitations, it seems rational to offer several response options. At the same time, the responders have to be able to firmly differentiate between the response alternatives.<sup>26</sup> In our data set, we found that a reduction



**Fig 4.** Scatterplots show the correlations between (left) the 25-item original Vascular Quality of Life (*VascuQoL-25*) assessment and (right) the six-item version (*VascuQoL-6*) vs the total covered distance during the 40-minute test walk as determined by a global positioning system (GPS) using the iPhone4 (Apple Corp, Cupertino, Calif) equipped with the Walkmeter walking performance application (Abvio Inc, San Francisco, Calif).

to four response options was required to get ordered category thresholds according to the Rasch analysis, and adding more options gave disordered and random answer patterns.

Limitations of our study include that our calculations are based on a theoretic model and we do not know how the presence of the other items of the *VascuQoL* affect our data regarding the selected items for the short version. This highlights the need for further validation and testing of the new instrument in a different patient sample. Also, we included only individuals with intermittent claudication for the cognitive interviews and cannot exclude that interviewing patients with critical limb ischemia would have given a somewhat different result.

## CONCLUSIONS

We would stress the importance of integrating patient-reported outcome measures in daily vascular practice.<sup>27</sup> These assessments provide important and useful data about the vascular patient, adding a decision-base when evaluating different treatment regimens. Another possibility is to use such measurements as assessment tools for case selection to invasive treatment and in clinical follow-up programs.<sup>2</sup> In PAD, the rapid and continuous developments of medical management and minimally invasive treatment options underscore the need for valid patient-reported outcome measures.<sup>3</sup> Patient-based outcome measures are also consequently recommended in the TransAtlantic Inter-Society Consensus (TASC) II document (recommendation 13) for determining success of treatment in intermittent claudication.<sup>28</sup> However, to be useful in busy routine clinical scenarios, the instruments ought to contain only a limited number of items in order to be easy and rapid to complete. Instruments like that are generally uncommon and mostly generic in nature, making their use as an outcome measure in PAD

problematic because of the lack of focus on the PAD patient's specific limitations.<sup>5</sup>

HRQoL is often a difficult concept to measure, and ease of use for any instrument is vital if broader use in an everyday clinical setting is to become a reality. The ideal QoL instrument, in addition to being valid and reliable (and responsive) should be brief, have high response and completion rates, and be easy for health professionals to administer, score, and analyze. We believe that the *VascuQoL-6* meets these ideals, and this has been the driving force behind the development of the instrument.<sup>29</sup> Potential use of *VascuQoL-6* includes integration in clinical routine, as a follow-up tool for outpatient programs, and also as an assessment of results after vascular surgical interventions. Further testing and validation is now required, and is already ongoing, as the *VascuQoL-6* is being used as a complementary outcome measure in all patients entered into the National Swedish Vascular Registry.

## AUTHOR CONTRIBUTIONS

Conception and design: JN, CW

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Data collection: JN, CW

Writing the article: JN, CW, JK, ML, MP, MM

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Overall responsibility: JN

## REFERENCES

1. Egorova NN, Guillermo S, Gelijns A, Morrissey N, Dayal R, McKinsey JF, et al. An analysis of the outcomes of a decade of

- experience with lower extremity revascularization including limb salvage, lengths of stay, and safety. *J Vasc Surg* 2010;51:878-85. 85 e1.
2. Mays RJ, Casserly IP, Kohrt WM, Ho PM, Hiatt WR, Nehler MR, et al. Assessment of functional status and quality of life in claudication. *J Vasc Surg* 2011;53:1410-21.
  3. Mazari FA, Carradice D, Rahman MN, Khan JA, Mockford K, Mehta T, et al. An analysis of relationship between quality of life indices and clinical improvement following intervention in patients with intermittent claudication due to femoropopliteal disease. *J Vasc Surg* 2010;52:77-84.
  4. Patient-Centered Outcomes Research Institute. Preliminary draft methodology report: our questions, our decisions: standards for patient-centered outcomes research. June 4, 2013. Available at: <http://www.pcori.org/assets/Preliminary-Draft-Methodology-Report.pdf>. Accessed August 17, 2012.
  5. de Vries M, Ouwendijk R, Kessels AG, de Haan MW, Flobbe K, Hunink MG, et al. Comparison of generic and disease-specific questionnaires for the assessment of quality of life in patients with peripheral arterial disease. *J Vasc Surg* 2005;41:261-8.
  6. Morgan MB, Crayford T, Murrin B, Fraser SC. Developing the Vascular Quality of Life Questionnaire: a new disease-specific quality of life measure for use in lower limb ischemia. *J Vasc Surg* 2001;33:679-87.
  7. Mapi Group. Linguistic validation. Available at: <http://www.mapi-institute.com/linguistic-validation/methodology>. Accessed August 17, 2012.
  8. Mehta T, Venkata Subramaniam A, Chetter I, McCollum P. Assessing the validity and responsiveness of disease-specific quality of life instruments in intermittent claudication. *Eur J Vasc Endovasc Surg* 2006;31:46-52.
  9. Forbes JF, Adam DJ, Bell J, Fowkes FG, Gillespie I, Raab GM, et al. Bypass versus Angioplasty in Severe Ischaemia of the Leg (BASIL) trial: Health-related quality of life outcomes, resource utilization, and cost-effectiveness analysis. *J Vasc Surg* 2010;51(5 Suppl):43-51S.
  10. Nordanstig J, Karlsson J, Pettersson ME, Wann-Hansson C. Psychometric properties of the disease-specific health-related quality of life instrument VasuQoL in a Swedish setting. *Health Qual Life Outcomes* 2012;10:45.
  11. Nationella Kvalitetsregister. Quality registries. Available at: [http://www.kvalitetsregister.se/om\\_kvalitetsregister/quality\\_registries](http://www.kvalitetsregister.se/om_kvalitetsregister/quality_registries). Accessed August 17, 2012.
  12. Fayters P. Quality of life. The assessment, analysis and interpretation of patient-reported outcomes. 2nd ed. Chichester: Wiley; 2007. p. 123.
  13. Collins D. Pretesting survey instruments: an overview of cognitive methods. *Qual Life Res* 2003;12:229-38.
  14. Rasch G. Probabilistic models for some intelligence and attainment tests. Expanded ed. Chicago: University of Chicago Press; 1980. xxiii, p. 199.
  15. Lundstrom M, Pesudovs K. Catquest-9SF patient outcomes questionnaire: nine-item short-form Rasch-scaled revision of the Catquest questionnaire. *J Cataract Refract Surg* 2009;35:504-13.
  16. Smith RM. Person Fit in the Rasch Model. *Educ Psychol Meas* 1986;46:359-72.
  17. Pesudovs K, Garamendi E, Elliott DB. The Quality of Life Impact of Refractive Correction (QIRC) Questionnaire: development and validation. *Optom Vis Sci* 2004;81:769-77.
  18. Smith RM. Assessing unidimensionality for Rasch measurement. In: Wilson M, editor. Objective measurement: theory into practice. Vol 2. Norwood, NJ: Ablex; 1994. p. 316-28.
  19. Fayters P. Quality of life. The assessment, analysis and interpretation of patient-reported outcomes. 2nd ed. Chichester: Wiley; 2007:446-7.
  20. Abvio Walkmeter. Available at: <http://www.abvio.com/walkmeter/>. Accessed August 17, 2012.
  21. Patient Reported Outcome Measurement Group, UHCE, University of Oxford. Available at: [http://phi.uhce.ox.ac.uk/inst\\_selcrit.php](http://phi.uhce.ox.ac.uk/inst_selcrit.php). Accessed August 17, 2012.
  22. Streiner DL, Norman GR. Health measurement scales: a practical guide to their development and use. 3rd ed. Oxford, UK: Oxford University Press; 2003. p. 5-15.
  23. Ware J Jr, Kosinski M, Keller SD. A 12-Item Short-Form Health Survey: construction of scales and preliminary tests of reliability and validity. *Med Care* 1996;34:220-33.
  24. Le Faucheur A, Abraham P, Jaquinandi V, Bouye P, Saumet JL, Noury-Desvaux B. Measurement of walking distance and speed in patients with peripheral arterial disease: a novel method using a global positioning system. *Circulation* 2008;117:897-904.
  25. Badia X, Arribas F, Ormaetxe JM, Peinado R, de Los Terreros MS. Development of a questionnaire to measure health-related quality of life (HRQoL) in patients with atrial fibrillation (AF-QoL). *Health Qual Life Outcomes* 2007;5:37.
  26. Knutsson I, Rydstrom H, Reimer J, Nyberg P, Hagell P. Interpretation of response categories in patient-reported rating scales: a controlled study among people with Parkinson's disease. *Health Qual Life Outcomes* 2010;8:61.
  27. Kolh P. Improving quality of life in patients with peripheral arterial disease: an important goal. *Eur J Vasc Endovasc Surg* 2010;40:626-7.
  28. Norgren L, Hiatt WR, Dormandy JA, Nehler MR, Harris KA, Fowkes FG. Inter-Society Consensus for the Management of Peripheral Arterial Disease (TASC II). *J Vasc Surg* 2007;45(Suppl S):S5-67.
  29. Gulati S, Coughlin PA, Hatfield J, Chetter IC. Quality of life in patients with lower limb ischemia; revised suggestions for analysis. *J Vasc Surg* 2009;49:122-6.
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**APPENDIX (online only).****The six-item Vascular Quality of Life (*VascuQoL-6*) health-related quality of life (HRQoL) instrument**

1. Because of the poor circulation in my legs, the range of activities that I would have liked to do in the past two weeks has been...
  1. Severely limited—most activities not done
  2. Very limited
  3. Very slightly limited
  4. Not limited at all—have done all the activities that I wanted to
2. During the past two weeks, my legs felt tired or weak...
  1. All of the time
  2. Some of the time
  3. A little of the time
  4. None of the time
3. During the past two weeks, because of the poor circulation in my legs, my ability to walk has been...
  1. Totally limited, couldn't walk at all
  2. Very limited
  3. A little limited
  4. Not at all limited
4. During the past two weeks, I have been concerned about having poor circulation in my legs...
  1. All of the time
  2. Some of the time
  3. A little of the time
  4. None of the time
5. During the past two weeks, because of the poor circulation in my legs, my ability to participate in social activities has been...
  1. Totally limited, couldn't socialize at all
  2. Very limited
  3. A little limited
  4. Not at all limited
6. During the past two weeks, when I have had pain in the leg (or foot) it has given me...
  1. A great deal of discomfort or distress
  2. A moderate amount of discomfort or distress
  3. Very little discomfort or distress
  4. No discomfort or distress

Each question is scored 1-4. The total score is achieved by summarizing the score on each question, resulting in a score between 6 and 24. Higher value indicates better health status.

If you wish to use the *VascuQoL-6* instrument for any clinical or research purpose, please first contact Dr Mark B.F. Morgan regarding permission for use, stating your intended purpose. Contact details for Dr Morgan are: [mark.morgan@bopdhb.govt.nz](mailto:mark.morgan@bopdhb.govt.nz).