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Test–retest Reliability and Measurement Error Are Excellent for the Dutch Version of the VascuQol Questionnaire in Patients with Intermittent Claudication

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WHAT THIS PAPER ADDS

Reliability parameters indicate the robustness of a measurement instrument, and measurement error pertains to its precision. To date, both have hardly been studied for the VascuQol. This study demonstrates that test–retest reliability and measurement error of the Dutch version of the VascuQol are excellent, which strengthens all findings based on this instrument.

Objectives: Although the Vascular Quality of Life Questionnaire (VascuQol) is a widely used instrument to assess quality of life in patients with peripheral arterial disease (PAD), data on its reliability are scarce and its measurement error is unknown. The aim of this study was to determine test–retest reliability and measurement error of the Dutch version of the VascuQol in patients with intermittent claudication (IC).

Methods: Patients with intermittent claudication due to PAD presenting between October 2013 and April 2014 completed the VascuQol twice, with a 1 week interval. Test–retest reliability was expressed as the intraclass correlation coefficient (ICC) with 95% confidence interval (CI), and measurement error as a standard error of measurement (SEM).

Results: Sixty-one patients completed two VascuQol questionnaires sufficiently. The ICC for the VascuQol sumscore was 0.91 (95% CI 0.86–0.95). The ICC for the different VascuQol domains ranged between 0.77 (95% CI 0.64–0.86) and 0.87 (95% CI 0.79–0.92). The SEM of the sumscore was 0.34 and ranged between 0.44 and 0.76 for the different VascuQol domains.

Conclusions: The test–retest reliability of the Dutch version of the VascuQol is excellent, both for the sumscore and for its different domains. The VascuQol has a measurement error that is sufficiently small to allow detection of clinically relevant changes.

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INTRODUCTION

Intermittent claudication (IC) due to peripheral arterial disease (PAD) is a chronic condition. Exercise induced pain in the legs results in limited walking capacity for patients, which affects their health related quality of life (HRQL).[1] The disease-specific vascular quality of life questionnaire (VascuQol) was designed to measure HRQL in patients with symptomatic PAD, and has been translated into several languages including Dutch. The VascuQol is one of the most frequently used HRQL instruments in PAD research.[2] In a recent systematic review on measurement properties of all disease-specific HRQL questionnaires for patients with IC deficiencies relating to the evaluation of reliability and measurement error of the VascuQol were identified.[3]

Reliability parameters reflect the robustness of a measurement instrument, which is particularly relevant in diagnostic and prognostic research.[4] In other words, reliability indicates whether two or more measurements in a patient with an unchanged health status provide more or less similar scores on a questionnaire. Measurement error pertains to the precision of the measurement instrument, that is, the measurement error indicates the magnitude of the uncertainty around an observed score. Only a precise measurement instrument can accurately determine changes in quality of life, both in evaluation research, as in individual patients.[4]

Reliability for the English and Dutch VascuQol has been examined in just two studies, with 17 and 20 patients,

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respectively.[2,5] Although the VascuQol has been widely used in several languages for many years, its measurement error was never studied in any language.[3] The COnsensus based Standards for the selection of health Measurement INstruments (COSMIN) checklist, which was compiled in a Delphi study among international experts in the field of patient reported outcome measures (PROMS), indicates that at least 50 patients are necessary for good quality studies on reliability and measurement error.[6] Therefore, the aim of the study was to determine the test–retest reliability and measurement error of the VascuQol in patients with IC in a sufficient sample size.

MATERIAL AND METHODS

Patients

The Academic Medical Center Institutional Review Board exempted the study from complete ethics approval. Consecutive patients with symptomatic IC due to PAD were prospectively recruited from the outpatient clinic or vascular laboratory between October 2013 and April 2014. Inclusion criteria were ankle brachial pressure index (ABPI) of $\leq$0.90 at rest or a decrease of ABPI after treadmill testing (speed 3.2 km/h, 10% incline) by $\geq$0.15. As reliability indicates whether repeated measurements provide similar results in patients with an unchanged health status, only patients who were not scheduled for an intervention within 2 weeks were selected. Baseline data were collected from patients' medical charts.

VascuQol

The VascuQol was developed by Morgan et al.[2] in 2001. It consists of 25 items in five domains (pain, symptoms, activities, emotional, and social). Each item is rated on a seven point scale, with 1 representing the worst and 7 the best score. A sumscore, also ranging from 1 to 7 (worst to best) is calculated by adding up the score of all items and then dividing the total by 25. A score per domain can be calculated similarly. The VascuQol was originally developed in the English language. A recent review provides an overview of the few validation studies available.[3]

All patients completed the first VascuQol questionnaire at the hospital. The second VascuQol questionnaire was to be completed at home by all patients 1 week later, and returned by mail. This timeframe was chosen since, due to the chronic nature of IC, it is unlikely that a patients' health status has changed within 1 week. The questionnaire was self-administered on both occasions. Non-responders were reminded by telephone after 8 days. As a means to verify that patients kept to the 1 week interval between completing the questionnaires, these were checked for completely identical pairs once they were returned by mail.

Imputation of missing items

Since missing items were anticipated and as many VascuQol questionnaires as possible were to be included, missing items per domain were imputed if at least 50% of the items in that domain were filled in, with the mean value of the filled items in that particular domain.

Analysis

Baseline data and VascuQol scores on the first questionnaire were compared for included and excluded patients using an unpaired *t* test or Mann–Whitney U test for continuous variables and a Fisher exact test or chi-square test for categorical variables where appropriate. A p value $< .05$ indicated statistical significance.

Test–retest reliability was determined on the VascuQol scores of the two measurements. It was expressed as the intra-class correlation coefficient (ICC) of absolute agreement based on a two way mixed model with 95% confidence interval (CI). An ICC $\geq .70$ indicates excellent test-retest reliability.[4]

Measurement error was expressed as a standard error of measurement (SEM) and was calculated as follows: $SD_{difference}/\sqrt{2}$, where $SD_{difference}$ is the standard deviation of the mean change score between the two time points; $\sqrt{2}$ was used since the questionnaires were filled in at two different time points.[4]

All analyses were done with SPPS 20.0 (IBM Corporation, New York, NY, USA).

RESULTS

Demographics and risk factors

Seventy-seven patients consented to participate. Four patients did not meet the inclusion criterion of an ABPI $\leq$ 0.90. Of the remaining 73 patients, 61 sufficiently completed the VascuQol twice and 12 patients had to be excluded for only returning the first questionnaire. None of the included patients returned two questionnaires with identical responses. The demographics and baseline VascuQol scores of all 73 patients are summarized in Table 1. There were no significant differences in demographics and VascuQol scores between included and excluded patients.

Missing items

Fifty-three of 3,050 items (25 items $\times$ 61 questionnaires $\times$ 2 time points) were missing in all returned questionnaires. The number of usable questionnaires after imputation is shown in Table 2. The social domain was never imputed since it contains only two items and therefore the criterion of $\geq$50% of the scale filled can never be met.

Reliability

Mean scores and ICC for the imputed and not imputed VascuQol scores are shown in Table 2. The ICC of the imputed sumscore was 0.91 (95% CI 0.86–0.95), and the ICC ranged between 0.77 (95% CI 0.64–0.86) and 0.87 (95% CI 0.79–0.92) for the different domains, reflecting excellent reliability. Moreover, the ICCs for both the imputed and the not imputed questionnaires were always in the same range, diverging no more than 0.02 points.