ACTA MÉDICA PORTUGUESA
A Revista Científica da Ordem dos Médicos

Contributions for the Validation of the European Portuguese Version of the Vascular Quality of Life-6 Questionnaire for Peripheral Artery Disease

Contribuições para a Validação da Versão em Português Europeu do Questionário Vascular Quality Of Life-6 para Doença Arterial Periférica

Rafaela OLIVEIRA✉[1,2], Susana PEDRAS[1], Rui PIMENTA[3,4,5], Ivone SILVA[1,6,7]
Acta Med Port 2024 Jun;37(6):436-444 ▪ https://doi.org/10.20344/amp.20760

ABSTRACT

Introduction: Peripheral arterial disease (PAD) is an occlusive atherosclerotic disease of the arteries of the extremities of the body that affects more than 230 million people worldwide. The most common symptom is intermittent claudication, described as leg pain which occurs mainly while walking. The symptoms impair the ambulation and functional capacity of patients, leading to loss of mobility, disease deterioration, increased risk of other cardiovascular diseases, and lower quality of life (QoL). Therefore, the aim of this study was to perform a cross-cultural adaptation and validation of the VascuQol-6 questionnaire for the Portuguese population to obtain a quick, sensitive, and easy-to-use way to assess the QoL of Portuguese patients diagnosed with PAD.

Methods: The Vascular Quality of Life-6 Questionnaire (VascuQoL-6) was adapted and translated into European Portuguese using standard validation methodology, including 115 patients with a mean age of 64.67 (7.23) years, with PAD with IC stable for more than three months; and ABI < 0.9 at rest. VascuQoL-6, SF-36, International Physical Activity Questionnaire (IPAQ), and the PAD Knowledge Questionnaire (PADKQ) were used. Reliability, construct validity analysis through convergent and discriminant validity, known-group validity, and responsiveness analysis were tested.

Results: The Cronbach's alpha was 0.64 and the average inter-item correlation was 0.27, indicating acceptable internal consistency. VascuQoL-6 was positively associated with SF-36 Physical Component Summary and Mental Component Summary scores (r = 0.64, $p < 0.01$ and r = 0.42, $p < 0.01$, respectively). In turn, there was no significant correlation between VascuQoL-6 scores and the PADKQ or IPAQ. A statistically significant difference between groups according to IC severity [$F(2.47) = 8.35$, $p < 0.001$] was found. A paired samples *t*-test showed differences between VascuQol-6 scores before a walking program (M = 15.65, SD = 3.09), and after a walking program (M = 17.41, SD = 2.71), $t(67) = 3.94$, $p \leq 0.001$.

Conclusion: The VascuQoL-6 is a six-item instrument to assess the QoL associated with PAD with good psychometric properties, convergent and discriminant validity with SF-36, PADKQ and IPAQ. The instrument proved to have known group validity and responsiveness.

Keywords: Peripheral Arterial Disease; Portugal; Quality of Life; Reproducibility of Results; Surveys and Questionnaires; Translating

RESUMO

Introdução: A doença arterial periférica (DAP) é uma doença aterosclerótica oclusiva das artérias das extremidades do corpo que afeta mais de 230 milhões de pessoas em todo o mundo. O sintoma mais comum é a claudicação intermitente (CI), descrita como dor nas pernas que ocorre principalmente durante a marcha. Os sintomas prejudicam a deambulação e a capacidade funcional dos doentes, levando à perda de mobilidade, deterioração da doença, aumento do risco de outras doenças cardiovasculares e diminuição da qualidade de vida (QV). Assim, este estudo teve como objetivo realizar uma adaptação e validação transcultural do questionário *Vascular Quality Of Life-6* (VascuQol-6) para a população portuguesa, de forma a obter uma forma rápida, sensível e de fácil utilização para avaliar a QV dos doentes portugueses com diagnóstico de DAP.

Métodos: O VascuQoL-6 foi adaptado e traduzido para o português europeu através de metodologia de validação *standard*, incluindo 115 doentes com idade média de 64,67 (7,23) anos, com DAP com CI estável há mais de três meses; e ITB < 0,9 em repouso. Foram utilizados o VascuQoL-6, o SF-36, o Questionário Internacional de Atividade Física (IPAQ) e o Questionário de Conhecimento sobre DAP (PADKQ). Foram testadas a fiabilidade, a análise da validade através da validade convergente e discriminante, a validade do grupo-conhecido (*known-group validity*) e a análise da capacidade de resposta (*responsiveness*).

Resultados: O alfa de Cronbach foi de 0,64 e a correlação média inter-itens foi de 0,27, indicando uma consistência interna aceitável. O VascuQoL-6 foi positivamente associado aos *scores* da Componente Física e da Componente Mental do SF-36 (r = 0,64, $p < 0,01$ e r = 0,42, $p < 0,01$, respetivamente). Por outro lado, não houve correlação significativa entre os *scores* do VascuQoL-6 e o PADKQ ou IPAQ. Foi encontrada uma diferença estatisticamente significativa entre grupos de acordo com a gravidade da CI [$F(2,47) = 8,35$, $p < 0,001$]. Um teste *t* para amostras emparelhadas mostrou diferenças estatisticamente significativas entre os *scores* do VascuQol-6 antes de um programa de caminhada (M = 15,65, DP = 3,09) e depois de um programa de caminhada (M = 17,41, DP = 2,71), $t(67) = 3,94$, $p \leq 0,001$.

Conclusão: O VascuQoL-6 é um instrumento de seis itens para avaliar a QV associada à DAP com boas propriedades psicométricas, validade convergente e discriminante com o SF-36, PADKQ e IPAQ. O instrumento demonstrou ter validade de grupo-conhecido e responsividade.

Palavras-chave: Doença Arterial Periférica; Inquéritos e Questionários; Portugal; Reprodutibilidade dos Resultados; Tradução

1. Angiology & Vascular Surgery Department. Unidade Local de Saúde de Santo António. Porto. Portugal.
2. Health School. Instituto Politécnico de Porto. Porto. Portugal.
3. Center for Health Studies and Research (CEIS). Faculdade de Economia. Universidade de Coimbra. Coimbra. Portugal.
4. Centre for Innovative Biomedicine and Biotechnology (CiBB). Coimbra. Portugal.
5. Associated Laboratory for Green Chemistry of the Network of Chemistry and Technology (LAQV@REQUIMTE). Escola Superior de Saúde. Instituto Politécnico do Porto. Porto. Portugal.
6. Unit for Multidisciplinary Research in Biomedicine (UMIB). Institute of Biomedical Sciences Abel Salazar. Universidade do Porto. Porto. Portugal.
7. Laboratory for Integrative and Translational Research in Population Health (ITR). Universidade do Porto. Porto. Portugal.

✉ **Autor correspondente:** Rafaela Oliveira. rafaela.oliveira.37@outlook.pt

Recebido/*Received*: 30/09/2023 - **Aceite/*Accepted*:** 10/04/2024 - **Publicado/*Published*:** 03/06/2024

INTRODUCTION

Peripheral arterial disease (PAD) is an occlusive atherosclerotic disease of the arteries of the extremities of the body that affects more than 230 million people worldwide.[1,2] Intermittent claudication (IC) is the most common symptom of PAD and is described as leg pain that occurs mainly while walking.[3] The symptoms impair the ambulation and functional capacity of patients, leading to loss of mobility, disease deterioration, increased risk of other cardiovascular diseases, and lower quality of life (QoL).[4]

Disease severity and functional impairment in patients with IC are usually quantified by the ankle-brachial index (ABI) at rest and after exercise and walking distance by standardized walking tests.[5,6] However, the exclusive use of these parameters requires specialized equipment and professionals, is costly, time-consuming, and does not adequately reflect the patient's day-to-day walking ability and perception of their functional impairment.[7] In addition, these parameters do not assess the impact of the disease concerning the social and emotional consequences of living with PAD. Therefore, it has been suggested that traditional measures should be complemented with patient-reported outcome measures, such as health-related QoL instruments.[8]

Health-Related Quality of Life (HRQoL) questionnaires have been used as an essential tool in the evaluation of clinical outcomes and are aimed at assessing the impact of the disease and treatment on the biopsychosocial scope of the patient. In addition, they are of great relevance in improving knowledge about different conditions and in analyzing the economic cost of an intervention.[9]

In a systematic review by Poku *et al*,[10] different tools used for psychometric evaluation were analyzed and the Vascular Quality of Life Questionnaire (VascuQol) was recommended as the preferred questionnaire to measure HRQoL outcomes in patients with PAD.[9,11]

The VascuQoL is a 25-item specific measure of HRQoL for patients with PAD. A shorter version, VascuQoL-6, was developed to facilitate the use of the instrument, consisting of six items with different response scales, and is now widely used to assess QoL in patients with PAD.[12,13] The validation study by Larsen *et al*[13] demonstrated improved accuracy and discriminating power for measuring QoL compared to the original 25-item questionnaire in a group of 21 patients with IC.

This instrument was translated and validated in different countries, including in the Portuguese language for the Brazilian population.[9,11,13,14] The Brazilian version of the VascuQoL-6 showed adequate valid and reliable indicators, allowing its use in patients with PAD and with IC symptoms.[14]

Although the VascuQol-6 questionnaire has already been translated into Portuguese, it has only been validated in the Brazilian population, making its application in the Portuguese population difficult due to their sociocultural differences. Thus, the aim of study was to perform a cross-cultural adaptation and validation of the VascuQol-6 questionnaire for the Portuguese population in order to develop a fast, sensitive, and easily applicable way to assess QoL in Portuguese patients diagnosed with PAD.

METHODS

A cross-sectional study of cultural adaptation and validation of the European-Portuguese version of the VascuQoL-6 questionnaire was conducted. All the patients provided written informed consent to participate in the study. This study was approved by the Department of Education, Training, and Research of Centro Hospitalar Universitário Santo António, on October 22nd, 2019 (reference no. 184/2020, of May 7th, 2020, and reference 069-DEFI/068-CES, respectively).

The first phase of the study concerned the translation, cultural adaptation, and assessment of the semantic equivalence of the questionnaire following the principles of good practice for the translation and cultural adaptation process of patient-reported outcomes.[15,16]

The questionnaire was originally provided by the author in the target language (European Portuguese). As such, a direct translation of the questionnaire was not necessary. Instead, the focus was on cultural adaptation, which involved ensuring that the items of the questionnaire were clear, relevant, and appropriate for the study population. To this end, an expert committee including vascular surgeons and nurses was set up to assess and evaluate the content of the items, i.e., if the items were adequate and adjusted to the population, to identify any potential cultural differences or ambiguities that could affect the interpretation of the questions.[17] After the revision of each item, the expert committee concluded that no modifications were necessary, as the questionnaire items were deemed clear and relevant for the study population.

The second phase of the study concerned evaluation of reliability and validity of the translated version of the scale. This included the internal consistency analysis, construct validity analysis through convergent and discriminant validity, known-group validity, and responsiveness analysis.

Participants

The VascuQoL-6 questionnaire was applied to voluntary participants whose native language was European Portuguese. These participants were PAD patients followed in an Angiology and Vascular Surgery Department of a Central Hospital. Inclusion criteria were (a) Symptomatic PAD; (b)

IC stable for more than three months; (c) Ankle-brachial index (ABI) < 0.9 at rest; and (d) age between 50 and 80 years old. Patients with cognitive impairment (evaluated with the Mini Mental State Examination), and asymptomatic PAD were excluded from the study.

Data collection and procedures

All data collection was performed during 2021 at Centro Hospitalar Universitário Santo António and was divided in two different evaluation sessions. The sessions were performed by a multidisciplinary team comprising a vascular surgeon, a psychologist, a physical exercise technician and a clinical physiologist. The assessment was performed face-to-face in an interview format. In an initial session, the ABI was measured using a handheld Doppler device [LifeDop 150 Doppler (8 MHz), USA], according to the AHA/ACC guidelines.[18]

A treadmill test was conducted to provide an objective assessment of performance since it is an accepted method used in patients with IC to evaluate walking ability. Severity is generally described in terms of claudication distance, and it can be objectively measured by a treadmill test with the assessment of pain-free walking distance (PFWD).[19,20] This way, the modified Gardner-Skinner Treadmill Protocol was used, where participants begin to walk on the treadmill at 1 km/h with a 0% slope. After two minutes, the speed is increased to 1.6 km/h, at 0% slope. Then, the speed is increased by 0.8 km/h every two minutes until reaching 3.2 km/h. After reaching 3.2 km/h, the speed is kept constant, and the slope is increased by 2% every two minutes.[21] The PFWD was recorded as the first sign of claudication pain.

To assess reliability and validity of the scale, patients were asked to answer the VascuQoL-6, Short-Form Health Survey (SF-36), International Physical Activity Questionnaire for elderly-Short Form (IPAQ), and the Peripheral Arterial Disease Knowledge Questionnaire (PADKQ) questionnaires.

Participants that met the inclusion criteria received a prescription of a physical exercise program, that included walking three times a week for a minimum of 30 minutes for the duration of three months, which is the first-line therapeutic measure recommended by clinical practice guidelines.[18]

In a second session, after three months, the participants completed the VascuQoL-6 questionnaire again to enable the assessment of the degree to which the VascuQoL-6 questionnaire was sensitive to change in response to an intervention (physical exercise program).

Questionnaires

Sociodemographic and clinical data questionnaire

The sociodemographic questionnaire included questions on sex, age, employment status, and education level, and the clinical data questionnaire included information about risk factors and lifestyle habits.

VascuQoL-6 questionnaire

The VascuQol-6 questionnaire is composed of six items that reflect the five dimensions of the original VascuQoL and assess the QoL of patients with PAD. These six items relate to limitations in performing activities (activity), tiredness in the legs (symptom), walking ability (activity), concern about poor circulation in the legs (emotional aspect), ability to participate in social activities (social aspect), and discomfort from pain in the legs (pain).[11] Each item has a four-point response scale ranging from 1 (worst patient-perceived QoL) to 4 (best patient-perceived QoL). The responses to the items are added to generate an overall score ranging from 6 to 24 points. Higher values indicate a better health status.[14]

Short-Form Health Survey

The Short-Form Health Survey (SF-36) is a widely used generic HRQoL measure that encompasses multiple dimensions of physical and mental health. This instrument consists of 36 items with different response scales assessing eight health concepts: bodily pain, physical functioning, role limitations due to physical problems, mental health, vitality, social functioning, role limitations due to emotional problems and general health. Two summary components can be calculated: physical component score (PSC) and mental component score (MCS). The scores for each domain were converted into a 0 - 100 scale, with higher scores indicating better HRQoL.[8,22] In this sample, Cronbach alpha for PSC was 0.73 and for MCS was 0.84.

International Physical Activity Questionnaire for elderly-Short Form

The International Physical Activity Questionnaire for elderly-Short Form (IPAQ) version adapted for the elderly was used. This version consists of four self-reported moderate-to-vigorous physical activity and sedentary behavior (sitting) items. The items encompass the following behaviors, in the last seven days: the time spent sitting, the days and time spent walking, the days and time spent in moderate-intensity activities, and the days and time spent in vigorous-intensity activities. Scores range from 0 to indefinite minutes of physical activity per week and higher results correspond to a greater amount of physical activity performed. Results are reported in categories (low, moderate, or high activity levels).[23]

Peripheral Arterial Disease Knowledge Questionnaire

The Peripheral Arterial Disease Knowledge Questionnaire (PADKQ) is a 16-item questionnaire that assesses patients' level of knowledge about PAD risk factors, symptoms, treatment options, and self-management strategies. The total score ranges from 0 to 16 with higher scores on the PADKQ indicating greater knowledge about PAD.[24] In this sample, Cronbach alpha was 0.77.

Statistical analysis

Descriptive statistics were used for the sociodemographic characterization of the sample and summarization of the VascuQoL-6, SF-36, IPAQ, and PADKQ scores. The distribution analysis of the quantitative variables was performed using the Shapiro-Wilk test, and all variables had a normal distribution. This way, parametric tests were used for the statistical analysis. The statistical analysis was performed with SPSS Version 28.0.

In terms of reliability, internal consistency reflects the extent to which the questionnaire items are inter correlated, or whether they are consistent in the measurement of the same construct.[17] Internal consistency of the VascuQol-6 items was assessed using the Cronbach's alpha, which is the most used internal consistency measure.[25] Values above 0.60 can indicate an acceptable level of internal consistency, but 0.70 is the most commonly used threshold for questionnaires intended for clinical use.[26,27]

McDonald's omega and average inter-item correlation were also calculated since these are alternative measures to Cronbach's alpha. McDonald's omega is based on a factor analytic approach and some authors defend that it has been proven to be more robust that Cronbach's alpha. Values of 0.70 or higher are considered acceptable.[28] Average inter-item correlation involves calculating the correlation coefficients between each pair of items within the questionnaire and then computing the average of these correlations. Some authors defend that this measure is better for scales that have a small number of items (less than 10) which may invoke low Cronbach's alpha values. Optimal average inter-item correlation values range from 0.20 to 0.40.[29]

Convergent and discriminant validity are integral aspects of assessing the construct validity of a questionnaire, ensuring that it accurately measures what it is intended to measure.[17,30] Pearson correlation coefficients were computed to evaluate (a) the relationship between the score obtained in the VascuQoL-6 questionnaire and the SF-36 questionnaire to assess convergent validity and (b) evaluate the relationship between the score obtained in the VascuQoL-6 questionnaire and the IPAQ and PADKQ to assess discriminant validity.

Known-groups validity is another way of assessing the validity of an instrument.[31] For this, one-way analysis of variance (ANOVA) was conducted to compare the mean VascuQoL-6 scores among the PAD clinical presentation of participants. Patient treadmill PFWD was categorized based on the Fontaine classification where patients with PFWD ≥ 200 m were classified with Mild IC (stage IIa), 50 - 200 with Moderate IC (stage IIb) and < 50 with Severe IC (stage III).[32]

The Tukey's Post-hoc test was performed to identify specific group differences. A *p*-value of < 0.05 was considered statistically significant. The known-group validity of the VascuQoL-6 questionnaire was determined based on the ability of the questionnaire to differentiate between different clinical presentations of PAD (Mild IC, Moderate IC, and Severe IC) as indicated by significant differences in mean scores across Treadmill PFWD categories.

Responsiveness is considered the longitudinal aspect of validity.[33] To assess the responsiveness of the VascuQoL-6 questionnaire, change scores were calculated by subtracting the baseline scores from the scores obtained after the three-month physical exercise program. The statistical analysis included paired *t*-tests to determine the significance of changes in VascuQoL-6 scores following the intervention consisting in a physical exercise prescription. A *p*-value of < 0.05 was considered statistically significant. Effect sizes (Cohen's criteria) were also calculated to quantify the

Table 1 – Demographic and risk factor characteristics in the patient population (n = 115)

Variables		Mean (SD) or n (%)
Sociodemographic		
Sex	Male	98 (85.2)
	Female	17 (14.8)
Age (years)		64.67 (7.23)
Education level (years)		6.41 (3.77)
Risk factors		
Hypertension	No	16 (13.9)
	Yes	99 (86.1)
High cholesterol	No	14 (12.2)
	Yes	101 (87.8)
Obesity (BMI > 30)	No	85 (73.9)
	Yes	30 (26.1)
Type 2 diabetes *mellitus*	No	65 (56.5)
	Yes	50 (43.5)
Smoking history (active or former)	No	10 (8.7)
	Yes	105 (91.3)
Ankle-brachial index (ABI)		
Right ABI		0.71 (0.19)
Left ABI		0.71 (0.18)

magnitude of change. These effect sizes were evaluated based on established benchmarks: a small effect size was indicated by d = 0.2, medium by d = 0.5, and a large by d ≥ 0.8.[34] The responsiveness of the VascuQoL-6 questionnaire to the physical exercise program was evaluated based on the magnitude and significance of changes in scores over time.

RESULTS

From the 115 participants that answered the VascuQoL-6, 85.2% were male and the mean age was 64.67 (7.23) years. Most the patients had hypertension (86.1%), dyslipidemia (87.8%), and were current or previous smokers (91.3%). Detailed demographic and risk factor characteristics can be found in Table 1. Table 2 provides a comprehensive characterization of the evaluation instruments employed in our study.

To gain a deeper understanding of the QoL within this cohort, an analysis examining potential differences related to sex, age, and education in relation to the VascuQoL-6 total scores was conducted. Our analysis did not reveal significant differences in VascuQoL-6 scores among different demographic subgroups. The results of this analysis are presented in Table 3.

Table 2 – Characterization of evaluation instruments (n = 115)

Variables		Mean (SD) or n (%)
Treadmill test[a]		
Pain free walking distance (PFWD) (meters)		125.31 (118.31)
Fontaine classification based on PFWD	Mild claudication - stage IIa (≥ 200 m)	26 (24.3)
	Moderate claudication - stage IIb (50 - 200 m)	45 (42.1)
	Severe claudication- stage III (< 50 m)	36 (33.6)
VascuQoL-6		
Item 1: Activity		3.17 (0.89)
Item 2: Symptoms		2.25 (1.22)
Item 3: Activity (walking)		2.59 (0.67)
Item 4: Emotional		1.96 (1.05)
Item 5: Social activities		3.50 (0.82)
Item 6: Pain		1.81 (0.70)
Total Score		15.28 (3.28)
SF-36[b]		
Physical functioning		18.69 (5.48)
Physical role limitations		11.55 (5.80)
Emotional role limitations		12.06 (3.84)
Mental health		17.57 (4.92)
Social functioning		7.98 (2.37)
Energy/vitality		14.29 (3.74)
General health perceptions		14.70 (3.50)
Bodily pain		5.75 (2.42)
Physical component score (PCS)		50.70 (13.43)
Mental component score (MCS)		51.90 (12.56)
IPAQ		
IPAQ categories	Insufficiently active	80 (69.6)
	Moderately active	29 (25.2)
	Vigorously active	6 (5.2)
Disease knowledge (PADKQ)[c]		11.07 (3.26)

[a]: n = 107; [b]: n = 49; [c]: n = 111

Table 3 – Quality of life differences among demographic subgroups

	n	Mean (SD)	*p*-value
Male	98	15.50 (3.325)	0.082
Female	17	14.00 (2.784)	
Age ≤ 65	64	15.11 (3.019)	0.539
Age < 65	51	15.49 (3.608)	
Education level ≤ 4 years	63	15.09 (3.627)	0.513
Education level > 4 years	52	15.50 (2.832)	

Table 4 – Correlation coefficients (r) for physical and mental components of SF-36, IPAQ, and PADKQ scores and individual items of VascuQoL-6 at baseline

		Item 1: Activity	Item 2: Symptoms	Item 3: Walking activity	Item 4: Emotional	Item 5: Social activities	Item 6: Pain	Total score
SF-36	Physical component score (PCS)	0.380*	0.274	0.441*	0.366*	0.303*	0.518**	**0.635****
	Mental component score (MCS)	0.255	0.180	0.272	0.288*	0.106	0.397*	**0.419***
IPAQ		0.067	0.306	0.083	-0.144	-0.109	-0.073	**0.065**
PADKQ		-0.172	0.199	0.062	-0.369	0.014	0.022	**-0.078**

* $p < 0.05$; ** $p < 0.01$

Internal consistency

The value obtained for the Cronbach's alpha was 0.64, indicating an acceptable internal consistency.[35] McDonald's Omega was also measured, and the value obtained was 0.64.

Analyzing the internal consistency coefficients of Cronbach's alpha and McDonald's Omega presented above, it is possible to see that this scale is below the value of 0.70, a particularly commonly used threshold for questionnaires intended for clinical use.[36-38] In this sense, the average inter-item correlation was calculated and revealed an average inter-item correlation of 0.27, suggesting an acceptable level of inter-item correlation, reflecting a reasonable degree of homogeneity among the items.[29,39]

Construct validity

Convergent validity

To assess the convergent validity, the correlation between the VascuQoL-6 questionnaire and the SF-36 questionnaire was examined. The sample comprised 49 participants with PAD who completed both questionnaires. Pearson correlation coefficients were computed between the two measures. The Physical Component Summary (PCS) and Mental Component Summary (MCS) scores of the SF-36 correlated with the VascuQoL-6 scores (r = 0.64, $p < 0.01$ and r = 0.42, $p < 0.01$, respectively). Table 4 shows the correlation between the VascuQoL-6 score and SF-36 domains.

Discriminant validity

To assess discriminant validity, the correlation between VascuQoL-6 scores and two other measures (PADKQ and the IPAQ questionnaire) was examined. Results indicated that there was no significant correlation between VascuQoL-6 scores and scores on either the PADKQ questionnaire or the IPAQ questionnaire. Table 4 shows the correlation between VascuQoL-6 score and PADKQ and IPAQ.

Known-group validity

To assess Known-group validity, a one-way ANOVA was conducted to compare the mean VascuQoL-6 scores among the patients with PAD (Mild IC, Moderate IC, and Severe IC). There was a statistically significant difference between groups [$F(2.47) = 8.35$, $p < 0.001$].

A Tukey post hoc test showed that the Mild IC group was able to walk without pain further than the Moderate IC group ($p = 0.005$) and Severe IC group ($p < 0.001$) and these differences were statistically significantly. There was no statistically significant difference between the Moderate IC and Severe IC groups ($p = 0.691$).

Responsiveness

A paired samples *t*-test was performed to evaluate whether there was a difference between VascuQol-6 scores before the walking program and after the walking program. The results indicated that the VascuQoL-6 summary score after the physical exercise program (M = 17.41, SD = 2.71) was significantly higher than the VascuQoL-6 summary score before the physical exercise program (M = 15.65, SD = 3.09), $t(67) = 3.94$, $p = < 0.001$. There was also a statistically significant improvement in the symptoms, walking ability and pain items (item 2, 3 and 6).

Effect sizes of SF-36 domains and component summary scores and all items and summary score of VascuQoL-6 are shown in Table 5. According to Cohen's criteria, there was a

Table 5 – Responsiveness to change. Effect size of SF-36, domains and component summary scores, and VQ6, all items and summary score.

		Effect Score
VascuQoL-6	Activity	0.1
	Symptoms	0.5
	Walking activity	1.6
	Emotional aspects	0.1
	Social aspects	0.2
	Pain	0.3
	VascuQoL-6 summary score	0.5
SF-36	Physical functioning	1.0
	Physical role limitations	0.5
	Emotional role limitations	0.3
	Mental health	0.8
	Social functioning	0.3
	Energy/vitality	0.7
	General health perceptions	0.2
	Bodily pain	1.1
	Physical component summary score (PCS)	0.9
	Mental component summary score (MCS)	0.7

small effect size for Activity, Emotional, and Social aspects, a small to moderate effect size for Pain, a moderate effect size for Symptoms, and a large effect size for Walking activity. The VascuQoL-6 summary score showed a moderate effect size (d = 0.5).[34]

DISCUSSION

In this study of the psychometric properties of the HRQoL questionnaire VascuQoL-6 revealed an acceptable internal consistency, suggesting that the items within the questionnaire are sufficiently interrelated in measuring the construct of interest.[35] The observed internal consistency, while deemed satisfactory, also revealed that other validation studies conducted on the VascuQoL-6 reported higher alpha values, indicating stronger inter-item reliability in those investigations.[9,11,13,14] One plausible explanation for the differences might be the variations in the study populations across different validation studies. In our study, we deliberately excluded patients with critical ischemia, which represents the most severe form of PAD. By excluding this subset of patients, who often face unique challenges and significant impact on their QoL, we may have inadvertently influenced the internal consistency results of the VascuQoL-6.

In this sense, the average inter-item correlation was calculated and revealed a moderate level of inter-item correlation, reflecting a reasonable degree of homogeneity among the items. The average inter-item correlation provides valuable insights into the internal consistency of the VascuQoL-6 questionnaire, indicating that the items collectively contribute to a coherent measurement of peripheral artery disease-specific QoL.[29,39]

A good correlation between the physical domains and the PCS of the SF-36 and the VascuQoL-6 score was found, providing evidence of convergent validity, although the correlation between the VascuQoL-6 and the MCS was low (0.42), which may be due to the fact that VascuQoL-6 includes only one item that assesses emotional aspects. These results suggest that the VascuQoL-6 questionnaire is measuring a construct similar to the SF-36 and that it is a valid measure of QoL in individuals with vascular disease. Similar results were demonstrated in previous validation studies of the VascuQoL-6 instrument, where correlations between the dimensions of SF-36 and the items in the VascuQol-6 were somewhat stronger for the items representing physical components.[9,11,13]

No significant correlation between VascuQoL-6 scores and scores on either the PADKQ questionnaire or the IPAQ questionnaire was found. These findings suggest that the VascuQoL-6 is measuring a distinct construct from disease knowledge and physical activity, providing evidence for discriminant validity of the questionnaire.

In the present study, we aimed to assess the known-group validity of the VascuQoL-6 questionnaire by comparing its scores among three groups of patients with varying degrees of IC severity: mild, moderate, and severe. Our findings revealed that the VascuQoL-6 questionnaire demonstrated significant discriminative ability in distinguishing between patients with mild and moderate IC, as well as between those with mild and severe IC. These results suggest that the questionnaire is effective in capturing meaningful differences in vascular-related QoL between these two pairs of groups, indicating its sensitivity to varying degrees of disease impact on patients' daily lives.

When comparing patients with moderate and severe claudication, the known-group validity analysis did not yield significant differences in VascuQoL-6 scores between these two groups. This unexpected finding warrants further exploration and consideration. One possible explanation could be the overlapping symptomatology and functional limitations experienced by patients in the moderate and severe claudication groups. It is plausible that patients in both groups may experience comparable levels of impairment, leading to similar VascuQoL-6 scores. Additionally, the VascuQoL-6 questionnaire may have limitations in distinguishing the subtle differences in QoL experienced by patients with moderate versus severe claudication, particularly if the impact of the disease becomes more profound in both groups.

Despite the non-significant result in the comparison between moderate and severe IC groups, the overall findings provide valuable insights into the known-group validity of the VascuQoL-6 questionnaire. The significant differences observed between mild and moderate IC, as well as between mild and severe IC, indicate that the questionnaire is capable of capturing clinically meaningful distinctions in QoL in relation to disease severity. As such, the VascuQoL-6 remains a valuable tool for assessing the impact of PAD on patients' QoL, particularly in distinguishing between patients with mild disease and those with more pronounced impairment.

In the present study, we aimed to evaluate the responsiveness of the VascuQoL-6 questionnaire to an intervention involving the prescription of physical exercise for patients with PAD. Our results demonstrated promising evidence of the questionnaire's sensitivity to changes in vascular-related QoL following the physical exercise program.

Specifically, the overall responsiveness analysis revealed a moderate effect size for the VascuQoL-6 summary score, indicating a meaningful and noticeable improvement in patients' overall QoL after engaging in the prescribed physical exercise program. This finding suggests that the VascuQoL-6 can detect clinically important changes in vascular-related QoL, highlighting its relevance as a valuable outcome measure in the context of interventions targeting PAD. Larsen *et al*, and Soria-Juan *et al*, also had similar findings where excellent responsiveness to change was demonstrated.[9,13]

Some limitations were found with this study. The fact that the sample was collected in only one hospital in the north of the country does not allow us to generalize the results to other geographic areas. Moreover, the study cohort consisted primarily of male participants, potentially introducing a sex-related bias that may impact the generalizability of results. Another limitation is the variation in sample size, particularly the fact that only 49 patients completed the SF-36 questionnaire.

One significant limitation to acknowledge is the absence of a test-retest analysis. Ideally, such an analysis would have been valuable to assess the stability of responses over time. However, due to the three-month interval between assessments and the concurrent implementation of a physical exercise intervention, conducting a reliable test-retest analysis was not feasible within the constraints of the study. This extended interval and intervention may have introduced variability in participants' responses, potentially affecting the reliability of the instrument.

Additionally, the exclusion of patients with critical ischemia from the sample limits the generalizability of the results to this specific subgroup of individuals with PAD.

To address these limitations in future research, it is recommended that studies aim to recruit a more diverse and larger sample to enhance the external validity of the findings. While conducting a traditional test-retest analysis may not have been feasible in our study contexts, researchers can explore this method to assess the stability of responses over time. Additionally, investigating the instrument's performance in a broader range of PAD severity levels, including patients with critical ischemia, will provide a more comprehensive understanding of its utility in clinical practice.

CONCLUSION

This study presents the Portuguese version of the VascuQoL-6 questionnaire and contributes to its validation as an instrument to assess the QoL of Portuguese patients with PAD. This tool can be especially valuable in follow-up evaluations, to measure the result of the physical exercise prescription, more invasive surgical interventions, as well as to compare the results with the international literature.

ACKNOWLEDGMENTS

We appreciate the participation of all patients because without them this study would not have been possible.

AUTHOR CONTRIBUTIONS

RO, SP: Study design, data acquisition, analysis, and interpretation, writing of the manuscript.

RP: Data acquisition, analysis, and interpretation, writing and critical review of the manuscript.

IS: Study design, writing and critical review of the manuscript.

All authors approved the final version to be published.

PROTECTION OF HUMANS AND ANIMALS

The authors declare that the procedures were followed according to the regulations established by the Clinical Research and Ethics Committee and to the Helsinki Declaration of the World Medical Association updated in 2013.

DATA CONFIDENTIALITY

The authors declare having followed the protocols in use at their working center regarding patients' data publication.

COMPETING INTERESTS

The authors have declared that no competing interests exist.

FUNDING SOURCES

This study was financed by the FEDER – European Regional Development Fund through NORTE 2020 – Northern Regional Operational Program, under PORTUGAL 2020 and by national funds, through the FCT – Foundation for

Science and Technology, within the scope of the project with the reference NORTE-01-0145-FEDER-031161-PTDC / MEC-VAS/31161/2017.

REFERENCES

1. Shu J, Santulli G. Update on peripheral artery disease: epidemiology and evidence-based facts. Atherosclerosis. 2018;275:379-81.
2. Aday AW, Matsushita K. Epidemiology of peripheral artery disease and polyvascular disease. Circ Res. 2021;128:1818-32.
3. Conte SM, Vale PR. Peripheral arterial disease. Heart Lung Circ. 2018;27:427-32.
4. Van Den Houten MM, Gommans LN, Van Der Wees PJ, Teijink JA. Minimally important difference of the absolute and functional claudication distance in patients with intermittent claudication. Eur J Vasc Endovasc Surg. 2016;51:404-9.
5. Henni S, Ammi M, Semporé Y, Hersant J, Zegar G, Gourdier A, et al. Treadmill measured vs. questionnaire estimated changes in walking ability in patients with peripheral artery disease. Eur J Vasc Endovasc Surg. 2019;57:676-84.
6. Frans FA, Van Wijngaarden SE, Met R, Koelemay MJ. Validation of the Dutch version of the VascuQol questionnaire and the Amsterdam linear disability score in patients with intermittent claudication. Qual Life Res. 2012;21:1487-93.
7. Nicolaï SP, Kruidenier LM, Rouwet EV, Graffius K, Prins MH, Teijink JA. The walking impairment questionnaire: an effective tool to assess the effect of treatment in patients with intermittent claudication. J Vasc Surg. 2009;50:89-94.
8. Nordanstig J, Karlsson J, Pettersson M, Wann-Hansson C. Psychometric properties of the disease-specific health-related quality of life instrument VascuQoL in a Swedish setting. Health Qual Life Out. 2012;10:1-8.
9. Soria-juan B, Llanos L, Moral LR, Aparicio C, Gonzalez A, Shaw O, et al. Cross cultural adaptation and validation of a Spanish version of vascuqol-6 questionnaire. Res Sq. 2021:1-17.
10. Poku E, Duncan R, Keetharuth A, Essat M, Phillips P, Woods H, et al. Patient-reported outcome measures in patients with peripheral arterial disease: a systematic review of psychometric properties. Health Qual Life Outcomes. 2016;14:161.
11. Kumlien C, Nordanstig J, Lundström M, Pettersson M. Validity and test retest reliability of the vascular quality of life questionnaire-6: A short form of a disease-specific health-related quality of life instrument for patients with peripheral arterial disease. Health Qual Life Outcomes. 2017;15:1-12.
12. Nordanstig J, Wann-Hansson C, Karlsson J, Lundström M, Pettersson M, Morgan MB. Vascular quality of life questionnaire-6 facilitates health-related quality of life assessment in peripheral arterial disease. J Vasc Surg. 2014;59:700-7.
13. Larsen AS, Reiersen AT, Jacobsen MB, Kløw NE, Nordanstig J, Morgan M, et al. Validation of the vascular quality of life questionnaire-6 for clinical use in patients with lower limb peripheral arterial disease. Health Qual Life Outcomes. 2017;15:184.
14. Correia M, Andrade-Lima A, Oliveira PL, Domiciano RM, Domingues WJ, Wolosker N, et al. Translation and validation of the Brazilian-Portuguese short version of vascular quality of life questionnaire in peripheral artery disease patients with intermittent claudication symptoms. Ann Vasc Surg. 2018;51:48-54.
15. Gjersing L, Caplehorn JR, Clausen T. Cross-cultural adaptation of research instruments: Language, setting, time and statistical considerations. BMC Med Res Methodol. 2010;10:13.
16. Wild D, Grove A, Eremenco S, McElroy S, Verjee-Lorenz A, Erikson P. Principles of good practice for the translation and cultural adaptation process for patient-reported outcomes (PRO) measures: report of the ISPOR task force for translation and cultural adaptation. Value Health. 2005;8:94-104.
17. Tsang S, Royse CF, Terkawi AS. Guidelines for developing, translating, and validating a questionnaire in perioperative and pain medicine. Saudi J Anaesth. 2017;11:S80-9.
18. Gerhard-Herman MD, Gornik HL, Barrett C, Barshes NR, Corriere MA, Drachman DE, et al. 2016 AHA/ACC Guideline on the management of patients with lower extremity peripheral artery disease: executive summary: a report of the american college of cardiology/american heart association task force on clinical practice guidelines. Circulation. 2017;135:e686-75.
19. Kruidenier LM, Nicolaï SP, Willigendael EM, de Bie RA, Prins MH, Teijink JA. Functional claudication distance: a reliable and valid measurement to assess functional limitation in patients with intermittent claudication. BMC Cardiovasc Disord. 2009;9:1-7.
20. Treat-Jacobson D, McDermott MM, Bronas UG, Campia U, Collins TC, Criqui MH, et al. Optimal exercise programs for patients with peripheral artery disease. Circulation. 2019;139:10-33.
21. Gardner A, Skiner J. Progressive vs single-stage treadmill tests for evaluation of claudication. Med Sci Sports Exerc. 1991;23:402-8.
22. Ferreira PL. Development of the portuguese version of MOS SF-36. Part II - Validation tests. Acta Med Port. 2000;13:119-27.
23. Hurtig-Wennlf A, Hagstrmer M, Olsson LA. The international physical activity questionnaire modified for the elderly: aspects of validity and feasibility. Public Health Nutr. 2010;13:1847-54.
24. Pedras S, Oliveira R, Veiga C, Silva I. What do patients know about peripheral arterial disease? a knowledge questionnaire. Rev Port Cir Cardiotorac Vasc. 2023;29:31-41.
25. Hamed Taherdoost A, Lumpur K. Validity and reliability of the research instrument; how to test the validation of a questionnaire/survey in a research. Int J Academ Res Manag. 2016;5:28-36.
26. DeVellis RF. Scale development: theory and applications. Vol 26. 5th ed. Newbury Park: SAGE Publications; 1991.
27. Maroco J, Garcia-Marques T. Qual a fiabilidade do alfa de Cronbach? Questões antigas e soluções modernas? Laboratório de Psicologia. 2006;4:65-90.
28. Stensen K, Lydersen S. Internal consistency: from alpha to omega? Tidsskr Nor Laegeforen. 2022;142.
29. Pallant J. SPSS survival manual: a step by step guide to data analysis using SPSS Program. 6th edition. London: McGraw-Hill Education; 2016.
30. Rattray J, Jones MC. Essential elements of questionnaire design and development. J Clin Nurs. 2007;16:234-43.
31. Davidson M. Known-groups validity. In: Michalos AC, editor. Encyclopedia of quality of life and well-being research. Dordrecht: Springer; 2014. p.3481-2.
32. Hardman RL, Jazaeri O, Yi J, Smith M, Gupta R. Overview of classification systems in peripheral artery disease. Semin Intervent Radiol. 2014;31:378-88.
33. Mokkink L, Terwee C, de Vet H. Key concepts in clinical epidemiology: responsiveness, the longitudinal aspect of validity. J Clin Epidemiol. 2021;140:159-62.
34. Sullivan GM, Feinn R. Using effect size—or why the p value is not enough. J Grad Med Educ. 2012;4:279-82.
35. McHorney C, Ware J, Lu J, Sherbourne C. The MOS 36-item short-form healthy survey (sf-36): iii. test of data quality, scaling assumptions and reliability across diverse patient groups. Med Care. 1994;32:40-66.
36. Hair J, Back W, Aderson R. Multivariate data analysis. 7th ed. London: Pearson Prentice Hall; 2010.
37. Bland JM, Altman D. Statistics notes: Cronbach's alpha. BJM. 1997;314:572.
38. Streiner DL. Starting at the beginning: an introduction to coefficient alpha and internal consistency. J Pers Assess. 2003;80:99-103.
39. Piedmont R. Encyclopedia of quality of life and well-being research. 1st ed. Dordrecht: Springer; 2014.