Validation in Brazil of a Questionnaire on Quality of Life in Chronic Venous Disease (Aberdeen Varicose Veins Questionnaire for Brazil/AVVQ-Brazil)

Validação no Brasil de Questionário de Qualidade de Vida na Doença Venosa Crônica (Questionário Aberdeen para Veias Varicosas no Brasil/AVVQ-Brasil)

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Abstract

Background: There is growing global interest in validated health assessment instruments. In order to use these instruments in different countries, it is necessary to conduct translation, cultural adaptation and validation in the target language. In Brazil, there are few instruments for assessment of the impact of chronic venous disease (CVD) on the quality of life (QoL) of patients. **Objective:** To validate the AVVQ-Brazil. **Method:** This was an analytical, observational study to validate the AVVQ questionnaire with 107 individuals with CVD. The version of the AVVQ adapted for Brazilian Portuguese was administered three times. The first two administrations were successive, with a 30-minute interval (interobserver reproducibility) and the third administration took place 7 to 15 days later (intraobserver reproducibility). Internal consistency and validity were also assessed. **Results:** A total of 107 people took part, 87.9% were female, mean age was 50.1 years ± 14.7; the majority had spent long periods standing up (57.0%) throughout their lives and did not engage in physical exercise (96.3%). Many had not completed primary education (25.2%); were members of economic class C2 (36.4%); and had disease severity class C4 (22.4%) or C6 (23.3%) on the CEAP scale. Interobserver and intraobserver reliability of the AVVQ were excellent. Internal consistency was excellent to moderate for the majority of domains. Spearman correlations showed that total AVVQ score and its Pain and Dysfunction domains were negatively correlated with all SF-36 domains. The Mann-Whitney test showed that patients with CEAP 1, 2 or 3 exhibited differences that were statistically significant from those with CEAP 4, 5 or 6 for total AVVQ scores and for Complications domain scores. **Conclusions:** The AVVQ has been validated for Brazil and can now be used.

Keywords: venous insufficiency; quality of life; validation studies.

Resumo

Contexto: Há crescente interesse por instrumentos de avaliação em saúde produzidos e validados no mundo. Para sua utilização, é necessário realizar a tradução, a adaptação cultural e a validação ao idioma-alvo. No Brasil, existem poucos instrumentos que avaliem o impacto da doença venosa crônica (DVC) na qualidade de vida (QV) do indivíduo. **Objetivo:** Validar o AVVQ-Brasil. **Método:** Estudo observacional, analítico, para validação de questionário, em que 107 indivíduos com DVC responderam três vezes à versão adaptada do AVVQ para o português brasileiro. As duas primeiras aplicações foram sucessivas, com intervalo de 30 minutos (reprodutibilidade interobservador), e a terceira, após 7 a 15 dias (reprodutibilidade intraobservador). Foram avaliadas também consistência interna e validade. **Resultados:** Dos 107 participantes, 87,9% foram do sexo feminino, com idade média de 50,1 anos ± 14,7; assumiram postura em ortostatismo prolongado (57,0%) ao longo da vida e não realizam exercício físico (96,3%); observou-se Ensino Fundamental incompleto (25,2%) e pertencem à classe econômica C2 (36,4%); apresentam gravidade da doença C4 (22,4%) e C6 (23,3%) do CEAP. As reprodutibilidades inter e intraobservador do AVVQ mostraram-se excelentes. Sua consistência interna mostrou-se de excelente a moderada para a maioria dos seus domínios. As correlações de Spearman mostraram pontuação total do AVVQ, com domínio Dor e Disfunção se correlacionando negativamente com todos os domínios do SF-36. O teste de Mann-Whitney mostrou diferença estatística significante para a pontuação total do AVVQ e domínio Complicações entre o CEAP 1, 2, 3 e o CEAP 4, 5, 6. **Conclusão:** O AVVQ está validado no Brasil e pode ser utilizado.

Palavras-chave: insuficiência venosa; qualidade de vida; estudos de validação.

INTRODUCTION

Use of health assessment measures, such as quality of life (QoL) assessments, originally published in other languages is becoming increasingly relevant in the international context.[1] However, in order for use of these measures to be appropriate and trustworthy, it is necessary to ensure cross-cultural equivalence, which consists of translation, cultural adaptation and validation of the proposed instrument.[1,2]

Translation and cultural adaptation are not simple procedures[3] and the objective is to preserve the sense of the original version (meaning, ideas, format and values) in the new context.[4,5] In turn, validation assesses and measures specific (clinimetric) criteria, such as internal consistency (the capacity to measure a single concept using several items), reproducibility (the capacity to produce concordant results when the instrument is administered to a stable individual at different points in time, by the same observer – intraobserver reproducibility – or different observers – interobserver reproducibility) and validity, among others,[3,6,7] which correlate with the scores of another instrument, considered the gold standard, or with other conceptual instruments in the absence of a gold standard.[3]

Hand-in-hand with the technological advances related to chronic venous disease (CVD), the current tendency is to include investigation of QoL in clinical assessments, in order to capture the true reach and impact of these advances on patients' lives.[6] However, few studies have assessed the impact of CVD on QoL,[8,9] and it has been perceived that there is a growing need for promotion of this aspect in the lives of people who are affected[8] and for in-depth analyses of the magnitude of this impact, since a more comprehensive view of this influence enables a better directed and more effective treatment approach.[10]

In general, instruments for assessment of QoL in CVD are written in English, as is the case of the CIVIQ (Chronic Venous Insufficiency Questionnaire), of the VEINES-QOL/Sym (Venous Insufficiency Epidemiological and Economic Study), of the AVVQ (Aberdeen Varicose Veins Questionnaire) and of the CCVUQ (Charing Cross Venous Ulcer Questionnaire).[9,11] The first two of these have already been validated for Brazil and they assess CVD as a whole, whereas the AVVQ observes people's perceptions of specific aspects of the disease and the CCVUQ is focused on venous ulcers, the most important complication of CVD.[12]

The Aberdeen Varicose Veins Questionnaire (AVVQ) is a specific measure for assessment of QoL and severity of CVD that is sensitive to aspects inherent to the disease and focuses on signs and symptoms, evaluating dimensions that significantly compromise QoL.[9] Its clinimetric properties have been shown to be good in its country of origin,[13-15] and it has been used in several different studies.[16]

No published or ongoing studies were identified in the literature that report on validation of the AVVQ for the Brazilian population.[9] The nonexistence of a reliable and reproducible instrument validated for Brazil designed to assess QoL in CVD and which offers an overview of its details[6] is the motive for validating the AVVQ, in order to enable assessment of aspects affected by the disease and to make it possible to detect changes provoked by specific interventions, from the patients' perspective.

METHOD

This study was approved by the Research Ethics Committee at the Universidade Federal de São Paulo (UNIFESP), under protocol n.º 1108/10, and is an observational analytical study for validation of a questionnaire.

Participants were selected non-probabilistically at publicly-funded CVD treatment centers and a private center providing care and dressings, after direct approach by the researcher.

The sample size was based on internationally defined and recommended criteria for the processes of translation, cultural adaptation and validation of health-related questionnaires.[5,17]

Recruitment of participants comprised two distinct stages: stage 1- Translation and Cultural Adaptation, for which 10 people were recruited, and stage 2- Validation, for which 107 people were recruited. The final data resulting from stage one have already been published in the Jornal Vascular Brasileiro, in an article entitled "Translation and cultural adaptation of Aberdeen Varicose Veins Questionnaire",[18] and this article will only describe data relating to Validation of the AVVQ – stage 2.

For the Validation stage, participants of both sexes were recruited, with CVD confirmed by a vascular surgeon using the CEAP classification (clinical 1-6), by clinical examination of the lower limbs, considering the patient's class as that of the limb with the higher classification. Those classified as 4a (pigmentation or eczema) or 4b (lipodermatosclerosis or atrophy blanche) were grouped together under the heading Class 4. The CEAP system classifies clinical presentation of CVD and measures changes in its severity,[19,20] as follows: C_1- telangiectasias and/or reticular veins; C_2- varicose veins; C_3- edema; C_4- hyperpigmentation and lipodermatosclerosis; C_5- healed ulcer; C_6- active ulcer.[10,20,21]

Candidates were excluded if they were aged < 18 or ≥ 60 years; had cognitive disorders (Mini mental state examination); had associated conditions (arterial and lymphatic); were diabetic; had neuropathies; had erysipelas, lymphangitis, acute deep vein thrombosis or ulcers of a non-venous origin; had psychiatric disorders and/or dementia (physician diagnosed); could not speak or understand Portuguese, or if they exhibited factors that changed clinical stability during the period of investigation: taking antibiotic and/or phlebotropic medication; sclerotherapy of the lower limbs; surgical debridement and/or other surgical procedures; changes to dressing methods, such as adoption of an Unna boot, multi layered dressings or dressings with topical medications.

Patients who qualified according to the inclusion and exclusion criteria were invited to take part during first contact at the healthcare service and, after signature of a free and informed consent form, were interviewed.

The primary variable was validation of the AVVQ questionnaire by testing its clinimetric properties, and secondary variables were CEAP clinical classification and the domains of the AVVQ and of the SF-36. Complementary data investigated were age, sex, educational level and economic class. The statistical methods employed were Cronbach's Alpha (internal consistency), Intraclass Correlation Coefficient (ICC, reproducibility), Spearman's correlation coefficients and the Mann-Whitney test (validity) and the significance level was p< 0.05.

Validation method

Validation was conducted using three administration times (T1, T2 and T3) with 107 individuals with CVD who were invited to complete the questionnaires as follows:

1st Administration (T1) – data collection form, Mini Mental questionnaire, Brazilian Economic Classification Criteria, SF-36 questionnaire and Portuguese version of the AVVQ (AVVQ-Brazil), administered by observer 1.

2nd Administration (T2) – second administration of the Portuguese version of the AVVQ (AVVQ-Brazil), 30 minutes after the first, by observer 2.

3rd Administration (T3) – another administration of the Portuguese version of the AVVQ (AVVQ-Brazil), 7 to 15 days after the first, by observer 1. After this administration, patients were given instructions on CVD, prevention of exacerbation and exercises to do at home, in the form of a lecture and an educational pamphlet.

Responses were collected either by interview or by self-administration. For illiterate patients, the AVVQ-Brazil questionnaire was read out loud by the researcher, strictly adhering to the instructions prepared by the author of the original instrument and following a pre-established interview script, which was restricted to an exact reading of the instructions, of the questions and of the response options, with repetition of any of these elements when necessary, but without interference in the response process.

■ RESULTS

The sample comprised 165 patients with CVD. Ten of them only took part in the Translation and Cultural adaptation of the AVVQ, 107 of them only took part in the Validation of the AVVQ and 48 of them were excluded, because they did not complete the second or third administrations of the AVVQ-Brazil or did not meet the minimum cutoff on the Mini Mental State Examination.

Age varied from 18 to 82, with a mean age of 50.1 ± 14.7 years. The majority of respondents were female (87.9%); had spent long periods in an orthostatic position throughout their lives (57.0%); and did not engage in physical exercise (96.3%). Many had not completed primary education (25.2%); were members of economic class C2 (36.4%); and had disease severity class C6 (23.3%).

Excellent interobserver reproducibility and excellent to regular intraobserver reproducibility were observed for the domains of the AVVQ (Table 1).

Table 1. Intraclass Correlation Coefficients (ICC), 95% confidence intervals (95%CI) and *p* values for the AVVQ domains for the first administration (T1) against the second (T2), 30 minutes after the first, and for the first (T1) against the third (T3), 7 to 15 days after the first (n=107).

DOMAINS	T1 – T2		T1 – T3		p
	ICC	95%CI	ICC	95%CI	
Overall AVVQ score	0.953	[0.931-0.968]	0.857	[0.790-0.902]	0.000*
Pain and Dysfunction	0.923	[0.887-0.947]	0.893	[0.843-0.927]	0.000*
Esthetic Appearance	0.905	[0.861-0.936]	0.857	[0.791-0.903]	0.000*
Extent of Varicosities	0.927	[0.893-0.950]	0.675	[0.523-0.778]	0.000*
Complications	0.946	[0.921-0.963]	0.893	[0.844-0.927]	0.000*

*p<0.0001; ICC > 0.75 (excellent). ICC = 0.40-0.75 (regular to good). ICC < 0.40 (poor).

Internal consistency varied from excellent (α=0.767), through moderate (α=0.544/0.294) to weak (α=0.064) (Table 2).

Assessment of QoL in CVD showed that total AVVQ score and the domains Pain and Dysfunction of the AVVQ exhibited a negative correlation with all SF-36 domains. The domain Esthetic Appearance was negatively correlated with the SF-36 domains Pain, Vitality, Social Functioning and Mental Health. The domain Extent of Varicosities was only correlated with the SF-36 domain (Table 3).

Analysis of CVD severity showed that there was a gradual increase in total score on the AVVQ as CEAP changed, with the exception of C4. There were statistically significant differences between different CEAP groups for total AVVQ score and the domain Complications (p<0.05), but there were no differences for other domains (Table 4).

Table 2. Cronbach's Alpha values for AVVQ domains (n=107).

Domains	Cronbach's Alpha
Overall AVVQ score (13 items)	0.544
Pain and Dysfunction (4 items)	0.767
Esthetic Appearance (2 items)	0.733
Extent of Varicosities (3 items)	0.064
Complications (4 items)	0.294

Significant values: at least 0.70.

DISCUSSION

It cannot be assumed that the properties revealed by the validation tests of the original version of an instrument will be applicable to adapted versions.[3] Such an instrument, which would not be reproducible or valid for the target-population,[3] will lack scientific recognition, indicating that the instrument is not precise and does not measure what it is intended to measure.[22] This study tested the reproducibility and validity of the AVVQ to enable its administration to the Brazilian population.

According to Meneses-Gaya et al.,[23] an appropriate interval of time between T1 and T2 is of fundamental importance in studies of reproducibility because if the interval is too short it will increase the influence of memory and if it is too long it allows time for individual changes in terms of what is being measured. In the present study a 30-minute interval was used to assess interobserver reproducibility and intervals of 7 to 15 days were used for intraobserver reproducibility, as recommended by Terwee et al.,[7] with the aim of ensuring the clinical stability of participants during the periods between administrations of the AVVQ.

Maher et al.[3] state that tests of reproducibility verify the instrument on different occasions and with

Table 3. Correlations between SF-36 domains and AVVQ domains.

AVVQ DOMAINS (n=107)

SF-36 DOMAINS	AVVQ score	Pain and Dysfunction	Esthetic Appearance	Extent of Varicosities	Complications
Functional Capacity	-0.506**	-0.583**	-0.087	0.052	-0.423**
Role - Physical	-0.521**	-0.485**	-0.153	-0.089	-0.415**
Pain	-0.547**	-0.485**	-0.378**	-0.246*	-0.298**
General Health Status	-0.316**	-0.395**	-0.13	0.086	-0.267**
Vitality	-0.282**	-0.447**	-0.305**	0.047	-0.148
Social Functioning	-0.476**	-0.511**	-0.345**	-0.089	-0.336**
Role - Emotional	-0.494**	-0.467**	-0.189	-0.119	-0.370**
Mental Health	-0.278**	-0.315**	-0.307**	-0.059	-0.111

*significant to 5%. **significant to 1%. Spearman's correlation coefficients: 0.75-1.00 (+ or −) – very good to excellent; 0.50-0.75 (+ or −) – moderate to good; 0.25-0.50 (+ or −) – regular.

Table 4. Mean scores for domains and total score of AVVQ by CEAP and means and standard deviations for total AVVQ score and domains Pain and Dysfunction, Esthetic Appearance, Extent of Varicosities and Complications by CEAP class (n=107).

Domains	CEAP						CEAP 1, 2 and 3 (n=47)		CEAP 4, 5 and 6 (n=60)		p
	C1	C2	C3	C4	C5	C6	Mean	SD	Mean	SD	
AVVQ score	23.86	28.92	31.26	27.42	37.70	43.11	28.1	10.6	35.8	16.3	0.012
Pain and Dysfunction	19.71	40.33	57.74	39.14	52.76	58.01	40.0	29.6	49.5	34.0	0.159
Esthetic Appearance	75.95	71.72	82.12	73.03	72.85	50.33	76.8	25.1	63.5	38.0	0.167
Extent of Varicosities	24.84	23.84	23.26	19.40	31.08	24.73	23.9	14.4	23.8	15.5	0.725
Complications	11.88	18.74	15.77	19.30	29.39	53.19	15.5	12.5	35.3	25.4	0.000*

*p<0.0001; p<0.05.

different examiners and that it is of fundamental importance that these administrations result in similar responses.[24] Following this guidance, two different observers were used (observers 1 and 2) and, after training, they administered the AVVQ at different points in time.

A study of seropositive people observed no significant differences between scores of QoL instruments administered in interviews and by self-administration.[25] The AVVQ is self-administrable according to Garrat et al.,[14] but in view of the considerable illiteracy rates in the Brazilian population it was administered during interviews, after prior discussions with the author of the original, and was only self-administered by literate people.

There is no CVD-specific QoL questionnaire that has previously been validated for use in Brazil and so for the test of validity the AVVQ was compared with the SF-36, as was done by Soárez et al.[26] when validating a QoL questionnaire in Brazil, and also by Garrat et al.,[14] during the process of construction and validation of the original AVVQ.

Also as part of the tests of validity, the AVVQ, as a measure of CVD severity, was compared with the CEAP classification (clinical scale), which, according to Vasquez & Munschauer,[27] consists of a description of information relating to diagnosis, indicating a reflection of the patients' perceptions of the severity of CVD.[19]

According to Hora et al.[28] in order to apply Cronbach's Alpha, the questionnaire must be made up of dimensions, must have been validated in at least one other language and must have been administered to a significant and heterogeneous sample. Cronbach's Alpha was therefore used to verify internal consistency, since they AVVQ is divided across four domains, has been validated in English and Dutch and was being administered to a significant and heterogeneous sample.

The results indicated excellent interobserver and intraobserver reproducibility, with a high degree of response agreement between different administrations, suggesting that the items are clear and reduce possible biases on the part of the observers, as demonstrated by Leon et al.[24] The lower intraobserver agreement for the domain Extent of Varicosities, at regular to good, was probably the result of random errors, such as the reactive effects of repeat administrations of the instrument, sensitizing patients and making them more aware of their condition, or of the effects of the time elapsed between administrations, during which time events that modified patients' clinical condition occurred, changing the questionnaire's scores, which

facts were confirmed by Freitas[29] when validating an index for assessment of osteoarthritis.

The correlations between the AVVQ and the SF-36 indicate the validity of the total score of the AVVQ and its Pain and Dysfunction domain, with a significant negative relationship between these values and all SF-36 domains, considered of reasonable to good magnitude, and with their largest correlations with the SF-36 domains Functional Capacity (r=-0506, p<0.01), Role - Physical (r=-0.521; p<0.01) and Pain (r= -0.547; p<0.01), in common with results reported by Klem et al.[30] and confirmed by Garrat et al.[14] in a study of the original version. These correlations suggest that the AVVQ captures the adverse effects of CVD in all SF-36 domains.

The domain Esthetic Appearance only had a significant correlation with the SF-36 domains Pain (r=-0.378; p<0.01); Vitality (r=-0.305; p<0.01); Social Functioning (r=-0.345; p<0.01), and Mental health (r=-0.307; p<0.01), in contrast with what was observed by Garrat et al.,[15] where the greatest correlation was with the Mental Health domain of the SF-36. According to Rosanova et al.,[31] the absence or reduction of the correlation between this domain and other SF-36 domains may have occurred because the SF-36 is not a specific questionnaire for conditions that affect body esthetics, which is relevant in CVD-related QoL assessments.

The domain Extent of Varicosities only had a significant correlation with the SF-36 domain Pain (r=-0.246; p<0.05), in contrast with Garrat et al.[15] who reported the largest correlation with the SF-36 domain Role - Physical. This may have occurred because of the influence of factors such as age and educational level on the results, in view of the difficulty of understanding the questions in this domain. However, the domain Complications was correlated with almost all of the SF-36 domains, exhibiting its strongest correlation with the domain Functional Capacity (r=-0.423; p<0.01), the same as was reported by Garrat et al.[15]

The correlations between the AVVQ and CEAP classes (clinical scale) revealed individual increases in the total score of the AVVQ as CEAP class increased, demonstrating measurement of the severity of CVD, and declining QoL, with exacerbation of the disease, and the capacity to discriminate between individuals, with the exception of C4. This possibly occurred because the participants were not classified separately by C4 subcategory (C4a and C4b), in order to reproduce the procedure used in validation of the original, and also because of the static nature of the CEAP in classes C4 and C5, interfering with assessment and complicating follow-up over time, as

stated by Vasquez & Munschauer.[27] Dezotti et al.[32] consider class C4 individuals to have intermediate skin lesions and this class denotes a transition phase from absence to presence of skin changes, which may have interfered with discrimination of the QoL of these patients.

Scores in the Complications domain were highest for classes C5 and C6, indicating lower QoL among individuals most affected clinically, in common with data reported by Moura et al.[10] who compared the SF-36 with the CEAP classification.

The total AVVQ score exhibited internal consistency with a lower result (α=0.544) than those reported in the validation studies for the English (α= 0.76) and Dutch (α=0.72) versions,[14,30] but nonetheless indicating that the Brazilian AVVQ has moderate internal consistency, is reliable and has uniform items. It should be pointed out that the samples assessed in those studies were much larger, increasing the likelihood of a higher Cronbach's Alpha score, as was also observed by Gasparin et al.,[33] in a study validating a different international questionnaire.

The results for the domains of the AVVQ indicated excellent internal consistency for the domains Pain and Dysfunction, and Esthetic Appearance, moderate for Complications and weak for Extent of Varicosities, all with Cronbach's Alpha values greater than 0.2; indicating that is not necessary to remove any domains or items, according to Garrat et al.,[14] since the Cronbach's Alpha values recommended in the literature by several different authors serve as a guide and not as a definitive criterion for classification.[34]

Some authors state that the negative impact of CVD on QoL is primarily related to the domains Pain, Physical Function and Mobility.[10] In agreement with this, it was observed that all patients exhibited compromised general and specific QoL, with the greatest correlations between the AVVQ and the SF-36 occurring in the SF-36 domains Pain, Role - Physical and Functional Capacity, confirming what was reported by Garrat et al.,[14] during construction of the AVVQ, and by Klem et al.[30] in a later study of the clinimetric properties of their Dutch version. This provides strong evidence of its validity as a measure of QoL.

Implications for research and for clinical practice

The design of this study followed the guidelines proposed in the "magic sextet", in terms of correct planning, execution and publication of research.[35] It has indicated certain avenues for further investigations in presenting a valid and trustworthy scale for use in vascular research and the AVVQ-Brazil (AVVQ-Br)

should contribute to use of data expressed as a reference in future research to review the clinimetric properties of the AVVQ and to elucidate the correlations between QoL and C4 severity of CVD, in view of its relevance to researchers in the area and to society in general.

The AVVQ-Br offers diagnostic support to assessments of CVD by providing measurable data on patients, identifying problems, facilitating therapeutic intervention and enabling new strategies for investigation of the disease. It will be possible to use it as a reference to record changes in the QoL of people with CVD, using it in the future as part of the assessment of CVD, raising QoL to the level of the essential principle for healthcare systems.

CONCLUSIONS

The AVVQ questionnaire is now validated for Brazil as a measure for assessment of QoL and the severity of CVD.

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