

# Validation of the Portuguese language version of a chronic venous ulcer quality of life questionnaire (Charing Cross Venous Ulcer Questionnaire – CCVUQ-Brazil)

*Validação do questionário de qualidade de vida na úlcera venosa crônica em língua portuguesa (Charing Cross Venous Ulcer Questionnaire – CCVUQ-Brasil)*

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## Abstract

**Background:** The use of quality of life instruments has become widespread over recent years. There is an important questionnaire specifically designed for patients with venous ulcers, the Charing Cross Venous Ulcer Questionnaire (CCVUQ), which has already been translated into Portuguese as part of a recent study, but its psychometric properties still need to be tested to complete its validation for use in Brazil. **Objectives:** To validate the Portuguese version of a venous ulcer quality of life questionnaire, the CCVUQ-Brazil. **Methods:** The translated version of the questionnaire was administered to 50 individuals and its internal consistency was analyzed. It was re-administered (30 minutes and 7 to 15 days after the first administration) in order to test its reproducibility. Results were compared with results for the 36-Item Short Form Health Survey (SF-36) to test validity. **Results:** The Portuguese version is semantically and culturally similar to the original version in English. It has satisfactory internal consistency, it exhibited high correlations in tests of reproducibility and it has significant construct validity. **Conclusions:** The Portuguese version of the CCVUQ-Brazil has been validated for use.

**Keywords:** questionnaire; quality of life; venous ulcer.

## Resumo

**Contexto:** Instrumentos de qualidade de vida vêm sendo usados nos últimos anos. Para a úlcera venosa, há um importante questionário específico, o Charing Cross Venous Ulcer Questionnaire (CCVUQ), já traduzido para português em recente estudo, mas necessitando do teste de suas propriedades psicométricas e da consequente validação para ser utilizado no Brasil. **Objetivos:** Validar o questionário de qualidade de vida na úlcera venosa em língua portuguesa, o CCVUQ-Brasil. **Métodos:** A versão traduzida do questionário foi aplicada em 50 indivíduos. Sua consistência interna foi analisada, sendo posteriormente reaplicado (30 minutos e entre 7 e 15 dias após a primeira aplicação) para testar a reprodutibilidade. Os resultados foram comparados com o 36-Item Short Form Health Survey (SF-36) para testar a validade. **Resultados:** A versão em português é semântica e culturalmente semelhante à versão original em inglês, tendo consistência interna satisfatória, alta correlação na verificação da reprodutibilidade e validade de constructo significativa. **Conclusões:** O CCVUQ-Brasil encontra-se validado na língua portuguesa.

**Palavras-chave:** questionário; qualidade de vida; úlcera venosa.

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The study was carried out at public health centers offering treatment to chronic venous disease in the municipality of Maceió, state of Alagoas, and at a private wound care center (CICATRIZA), Campina Grande, PB, Brazil.

## INTRODUCTION

The validation process verifies whether an adapted instrument has maintained the characteristics of the original version<sup>1</sup> and is performed to ensure that a questionnaire is understandable and relevant in a new cultural context.<sup>2</sup> An adequate validation process must test psychometric properties<sup>3</sup> and analyze internal consistency, interobserver and intraobserver reproducibility<sup>4</sup> and validity.<sup>1</sup>

Internal consistency is the extent to which the items that make up a given scale measure the same unobservable theoretical concept (construct).<sup>5</sup> The reproducibility assessment tests whether a measurement instrument is reproducible on different occasions (intraobserver reproducibility) and with different examiners (interobserver reproducibility).<sup>1</sup> Finally, tests of validity investigate to what extent scores on the instrument being tested are related to scores on another instrument that assesses the same construct or a similar construct.<sup>6</sup>

Over recent years a number of quality of life instruments have been validated for patients with

venous disease,<sup>7</sup> and one such disease is venous ulcers. The Charing Cross Venous Ulcer Questionnaire (CCVUQ) is cited as the only and most important disease-specific quality of life questionnaire for venous ulcers.<sup>8</sup> Its simplicity and sensitivity and the short time required for administration have led to it being recognized as a valuable instrument for assessing progression and response to treatment.<sup>7</sup> It has 21 items that identify four important health domains: social interaction, domestic activities, cosmesis and emotional status.<sup>9</sup> The CCVUQ has already been translated into Portuguese,<sup>10</sup> which resulted in the CCVUQ-Brazil version (Table 1); but despite its great importance, its psychometric properties have not yet been tested. Doing so would make it available for use with the Brazilian population.

This study is relevant because of current understanding of the importance of quality of life studies and because a specific questionnaire for venous ulcers, the CCVUQ-Brazil, already exists in the Portuguese language, but needs to be validated. Once made possible by the validation process, using the CCVUQ in Brazil, should, among other factors, make it possible to:

**Table 1.** Version of the Charing Cross Venous Ulcer Questionnaire (CCVUQ) translated and adapted for use in Brazil.<sup>10</sup>

1- Eu tenho dor por causa da minha úlcera					
Nenhuma parte do tempo	Pouca parte do tempo	De vez em quando	Frequentemente	Sempre	
1	2	3	4	5	
2- Estar com uma úlcera na minha perna me impede de fazer o seguinte					
	Nenhuma parte do tempo	Pouca parte do tempo	De vez em quando	Frequentemente	Sempre
a) Reunir com parentes e amigos	1	2	3	4	5
b) Viajar de férias	1	2	3	4	5
c) Realizar meus passatempos (hobbies)	1	2	3	4	5
d) Usar transporte público	1	2	3	4	5
3- Quanto verdadeiro ou falso são as seguintes informações considerando sua úlcera na perna					
	Definitivamente falso	Na maior parte falso	Não sei	Na maior parte verdadeiro	Definitivamente verdadeiro
a) Minha úlcera geralmente faz com que eu realize minhas atividades de forma mais lenta	1	2	3	4	5
b) Minha úlcera me deixa preocupado em meus relacionamentos pessoais	1	2	3	4	5
c) A secreção da minha úlcera é um problema	1	2	3	4	5
d) Eu gasto muito tempo pensando sobre minha úlcera	1	2	3	4	5
e) Eu fico preocupado que minha úlcera nunca cure	1	2	3	4	5
f) Eu estou cansado de gastar muito tempo tratando da minha úlcera	1	2	3	4	5
4- Eu sou triste por causa da aparência das minhas pernas devido à úlcera e/ou aos curativos					
Não, definitivamente não	De vez em quando	Frequentemente	Toda hora (sempre)		
1	2	3	4		

Table 1. Continued...

5- A úlcera da minha perna me limita de fazer as seguintes tarefas de casa					
	Nenhuma parte do tempo	Pouca parte do tempo	De vez em quando	Frequentemente	Sempre
a) Cozinhar	1	2	3	4	5
b) Limpar	1	2	3	4	5
c) Fazer compras	1	2	3	4	5
d) Cuidar do quintal	1	2	3	4	5
6- Eu me sinto deprimido por causa da minha úlcera na perna					
	Nunca	De vez em quando	Frequentemente	Sempre	
	1	2	3	4	
7- Com relação aos curativos da sua perna, indique o quanto é um problema para você					
	Nenhum problema	Pequeno problema	Problema moderado	Grande problema	Enorme problema
a) O volume deles	1	2	3	4	5
b) A aparência deles	1	2	3	4	5
c) A influência nas roupas que eu uso	1	2	3	4	5
8- Eu tenho dificuldade de andar por causa da úlcera na minha perna					
	Nunca	De vez em quando	Frequentemente	Sempre	
	1	2	3	4	

a) determine the impact of ulcers on daily activities; b) identify specific problems; c) assess the impact of treatments; d) obtain data enabling comparison of different types of treatment; e) enable use of the CCVUQ-Brazil in combination with generic instruments; and f) make an instrument specifically designed for assessment of venous ulcers available. These factors justify conducting this study to determine the validity of the CCVUQ-Brazil in Portuguese.

## METHODS

The voluntary nature of patients' participation was documented on free and informed consent forms. The study was conducted at public and private healthcare centers with venous disease patients.

People were recruited who had chronic lower limb venous ulcers diagnosed by a vascular surgeon. Potential participants were excluded if they had physician diagnoses of psychiatric disorders or dementia, arterial or lymphatic abnormalities, acute deep vein thrombosis, erysipelas, non-venous ulcers, lymphangitis or diabetes. People who did not speak or understand Portuguese or were 60 years or more old and had cognitive problems according to the mini mental state examination (MEEM) were also excluded. Additional exclusion criteria were presence of active ulcer for fewer than 15 days prior to the start of the study, ulcer smaller than 1 cm<sup>2</sup> and clinical instability during the interval between administration and re-administration of the questionnaire. Clinical

instability was assessed on the basis of criteria such as: onset of an infectious process, taking antibiotics and/or phlebotropics, surgical debridement or other surgical procedures, changes to type of dressing (starting to use an Unna boot, multi-layer dressings or dressings with topical medications) and closure of the ulcer.

The sampling technique was non-probabilistic, there was no sample size calculation and the sample was determined on the basis of criteria utilized in similar studies.<sup>11-15</sup> Individuals who met the inclusion criterion were invited to take part in the study while they were waiting to be seen at healthcare centers. After signature of free and informed consent forms, these people began their participation in the study, which extended over three separate contacts with the investigators.

During the first contact, participants were interviewed by an investigator (Examiner 1) and a data collection form was administered. Assuming none of the exclusion criteria were detected, the participants were instructed (or helped) by the same investigator to complete the SF-36 questionnaire, an economic classification scale and finally the CCVUQ-Brazil (Table 1). The questionnaire is self-administrable, but if participants were illiterate or had reading difficulties the questionnaires and other instruments were read to them, in a standardized manner, with no interpretation or interference in the responses. Participants who were aged 60 years or over were also assessed with the MEEM.

During the second contact, after a 30-minute interval, the CCVUQ-Brazil was administered once more, by a second investigator (Examiner 2). The third contact took place from 7 to 15 days later, when the patient returned for another consultation and/or to change dressings, and during which the CCVUQ-Brazil was administered for a third time, once more by the first investigator (Examiner 1).

## RESULTS

The sample of 50 patients had a mean age of 63.02 years (standard deviation [SD] = 11.74), and the majority (66%) had venous ulcers that had been active for more than 1 year. The majority of the sample were female (80%). The predominant educational level category was primary education completed (30%). According to the social class assessment the sample was heterogeneous, but with a higher concentration of the lower social classes, C2 (28%) and D (30%).

Just 14% of the sample was in active employment, the great majority had retired on the basis of age (36%) or because of disease (22%), while 28% were homemakers.

Interobserver reproducibility was excellent (Table 2). The intraobserver reproducibility correlation was also high (Table 3). The internal consistency analysis showed that all items were highly correlated with total score on the questionnaire (Table 4). Analysis of items that comprise the same domain also returned high correlations, demonstrating homogeneity between items measuring the same construct and indicating excellent internal consistency (Table 4).

Validity of the CCVUQ-Brazil was assessed in terms of correlation between its total score and domain scores and the domain scores of the SF36. Correlations were negative for all items assessed and varied from reasonable to moderate and good (within the range of 0.25 to 0.75), as shown in Table 5.

**Table 2.** Interobserver reproducibility: Intraclass Correlation Coefficients (ICC), 95% confidence intervals (95%CI) and p values for total score and domain scores of the Charing Cross Venous Ulcer Questionnaire (CCVUQ) for first administration (T1) against second administration (T2).

Domains	ICC	95%CI	p
Total score	0.951	0.914-0.972	0.000*
Social interaction	0.965	0.938-0.980	0.000*
Domestic activities	0.845	0.728-0.912	0.000*
Cosmesis	0.899	0.823-0.943	0.000*
Emotional status	0.884	0.796-0.934	0.000*

\* p < 0.0001. > 0.75 excellent agreement; from 0.4 to 0.75 regular to good agreement; < 0.4 poor agreement.

**Table 3.** Intraobserver Interobserver reproducibility: Intraclass Correlation Coefficients (ICC), 95% confidence intervals (95%CI) and p values for total score and domain scores of the Charing Cross Venous Ulcer Questionnaire (CCVUQ) for first administration (T1) against third administration (T3).

Domains	ICC	95%CI	p
Total score	0.951	0.914-0.972	0.000*
Social interaction	0.860	0.754-0.921	0.000*
Domestic activities	0.885	0.797-0.935	0.000*
Cosmesis	0.917	0.854-0.953	0.000*
Emotional status	0.915	0.851-0.952	0.000*

\* p < 0.0001. > 0.75 excellent agreement; from 0.4 to 0.75 regular to good agreement; < 0.4 poor agreement.

**Table 4.** Internal consistency: Cronbach's Alphas for total score and domain scores of the Charing Cross Venous Ulcer Questionnaire (CCVUQ).

Domains	Items	Cronbach's alpha
Total score	All	0.917
Social interaction	2A, 2B, 2C, 2D, 3A, 8	0.803
Domestic activities	3A, 5A, 5B, 5C, 5D	0.885
Cosmesis	3C, 3E, 4, 7A, 7B, 7C	0.739
Emotional status	3F, 3B, 6, 3E, 3D	0.734

Acceptable from 0.7 to 0.95.

**Table 5.** Validity: Spearman's correlation coefficients for total score and domain scores of the Charing Cross Venous Ulcer Questionnaire (CCVUQ) against SF-36 domain scores.

Domains (SF-36)	CCVUQ total score and domain scores				
	Total score (CCVUQ)	Social interaction (CCVUQ)	Domestic activities (CCVUQ)	Cosmesis (CCVUQ)	Emotional status (CCVUQ)
Physical functioning	-0.581	-0.437	-0.524	-0.528	-0.551
Role-physical	-0.407	-0.286*	-0.393	-0.398	-0.340*
Pain	-0.602	-0.519	-0.431	-0.625	-0.465
General health	-0.663	-0.545	-0.519	-0.658	-0.540
Vitality	-0.725	-0.659	-0.530	-0.643	-0.561
Social functioning	-0.540	-0.564	-0.351*	-0.484	-0.327*
Role-emotional	-0.418	-0.366	-0.475	-0.291*	-0.291*
Mental health	-0.479	-0.412	-0.353*	-0.420	-0.458

From 0.75 to 1 correlation very good to excellent; from 0.5 to 0.75 moderate to good agreement; from 0.25 to 0.5 reasonable agreement. \*The lowest correlations.

## DISCUSSION

The methodological idea for this study is based on the proposal of the “magic sextet” of research, which prescribes a direct and consecutive relationship between the stages of scientific publications, proposing the correct method for planning, execution and publication of research.<sup>16</sup>

The current recommendation for quality of life assessment is that a disease-specific instrument should be used in combination with a generic instrument.<sup>4</sup> Since no venous ulcer instruments had yet been validated for use in Brazil, the CCVUQ was chosen, because it is a specific instrument that has importance, applicability and good psychometric properties demonstrated in previous studies that have successfully produced satisfactory versions in languages other than the original.<sup>8,9,17-19</sup> A preliminary study was necessary before this study could be conducted, in which the CCVUQ questionnaire was translated into Portuguese and culturally adapted for Brazil.<sup>10</sup>

The sample size of 50 venous ulcer patients was defined in accordance with the “Quality criteria for measurement properties of health status questionnaires”,<sup>20</sup> which state that at least 50 participants are needed for analyses of reproducibility and validity.

The large majority of females (80%) and the predominance of socioeconomic class D are similar to the distributions observed in a previous study of venous disease conducted in the Brazilian state of Alagoas, which analyzed a sample of 66 people, 83.3% of whom were female and in which the same social class predominated.<sup>21</sup> However, a third study stated that male sex was a risk factor for ulceration, since males predominated among their patients.<sup>22</sup>

The initial intention was to analyze reproducibility using self-administration of the questionnaire. However, in the event the examiners had to read the

questions out to people who were illiterate or had reading difficulties, which is a method that was also used during the process of creating the questionnaire.<sup>8</sup>

The interval chosen for re-administration of the questionnaire was from 7 to 15 days, which, according to explanations in previous studies,<sup>6</sup> would not allow for memorization of responses, while also making loss of clinical stability unlikely.

As a precaution to control errors, during validation of the CCVUQ-Brazil people were excluded from the sample if they were not clinically stable over the 7 to 15 day interval before re-administration of the questionnaire. The criteria used were predefined by vascular surgeons and were based on ensuring absence of conditions that could have an influence of magnitude on patients' health status.

Another study has suggested that for analysis of internal consistency the sample should be proportional to the number of questions.<sup>2</sup> With regard to this recommendation, it can be stated that the present study employed a sample comprising more people than the 21 questions contained in the CCVUQ questionnaire, thereby exceeding the minimum level desirable.

Validity was assessed in terms of correlation between total and domain scores of the CCVUQ and the domain scores on the SF-36, which is the same procedure used in validation of the original CCVUQ.<sup>8</sup> It should be pointed out that the correlation with the SF-36 is based on an inverse comparison of scores, i.e. there should be a negative relationship, since the closer the SF-36 scores approach 100, the better the quality of life indicated, whereas the CCVUQ indicates better quality of life the closer the score approaches to zero.<sup>8</sup> The results of these analyses did indeed reveal negative correlations between CCVUQ and SF-36, varying from reasonable to moderate and good, similar to the original version.<sup>8</sup>

According to the original study, the CCVUQ had good internal consistency and reproducibility. This is also similar to the present study, since when administered to a population in Brazil, reproducibility analysis revealed high correlations between the different times of administration and different observers, with Intraclass Correlation Coefficients greater than 0.800 in all domains. Internal consistency results were satisfactory, with Cronbach's alphas ranging from 0.7 to 0.95, which is similar to the original validation study<sup>8</sup> and to the results of validation of the Chinese version.<sup>16</sup>

Overall, the fact that the correlations were reasonable, rather than excellent, has been explained by another study of quality of life in venous disease, which suggested that those factors to which the CCVUQ is sensitive are likely to be different from those to which the SF-36 is sensitive, since the generic instrument is less sensitive for assessing the effects of disease on the quality of life of individuals or populations with a specific pathology,<sup>4</sup> while the CCVUQ is less sensitive to disease in general.

Additionally, working from the assumption that it is recommendable to employ the specific questionnaire as a supplement to a generic one, rather than as a substitute, it is acceptable that the correlations are not particularly high. This has also been justified in the other study,<sup>4</sup> which explains that moderate correlations are to be expected, since if the values were very high (close to one), it could indicate that the questionnaires were redundant. However, if the values were very low, it could indicate that there is no evidence that the scales were measuring similar constructs similar.

The Portuguese language version produced in Brazil is semantically and culturally similar to the original version in English. It has satisfactory internal consistency, it exhibited high correlations in tests of reproducibility and it has significant construct validity. The Portuguese version of the CCVUQ-Brazil has therefore been validated for use.

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