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Phlebology 2014 29: 484 originally published online 3 May 2013

DOI: 10.1177/0268355513479582

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Linguistic validation of the 20 item-chronic venous disease quality-of-life questionnaire (CIVIQ-20)

R Launois¹, A Mansilha² and F Lozano³

Abstract

Our objective was to review the linguistic validation of the 20 item-Chronic Venous disease quality-of-life Questionnaire (CIVIQ-20) in the countries that have used it since its publication in 1996. Seventeen linguistic versions of CIVIQ-20 were validated using forward/backward methodology in patients presenting with chronic venous disease, stages C0s to C4 of the CEAP (clinical, aetiological, anatomical and pathological) classification (patients with venous ulcers were excluded). Most obstacles in the cross-cultural validation of CIVIQ-20 related to content and semantic equivalence. Confirmation of cultural relevance by experts with the native language as their mother tongue and the use of forward/backward translation methodology partly resolved these difficulties. CIVIQ-20 is valid for the assessment of treatment effects in multinational studies.

Keywords

Chronic venous disease, CIVIQ, languages, linguistic validation, quality of life

Introduction

Chronic venous disease (CVD) is a considerable burden for society worldwide. The Chronic Venous disease quality-of-life Questionnaire (CIVIQ-20) was created and validated in France in 1996¹ as a sensitive instrument to capture the key dimensions of quality of life impaired by CVD and to assess changes with treatment. The four quality-of-life dimensions identified in CIVIQ-20 are physical (4 items), psychological (9 items), social (3 items) and pain (4 items). Details of the phases of its development and international psychometric validation are described elsewhere and summarized in Table 1.^{1,2} In the original French version¹ as well as in the international version,² the five conditions required for validation (relevance, acceptability, reliability, construct validity and sensitivity) were met. Extensive use of CIVIQ-20 has been made in recent years to compare the effect of invasive procedures (open or intraluminal) for varicose veins, or after venous stenting, or to assess the efficacy of non-invasive therapies (more details available from: www.CIVIQ-20.com). Most of these trials were conducted in CEAP (clinical, aetiological, anatomical and pathological) C2–C5 patients. The source questionnaire for CIVIQ-20 was validated in French. Spanish, Dutch and Greek versions have since been prepared,^{3–5} but no other language versions

have been published. Our objective was to review the linguistic validation of CIVIQ-20 in the many national versions of the questionnaire that have been developed since 1996.

Methods

Linguistic validation was achieved using internationally accepted translation methodology as summarized in Table 2. For each national version, the cultural relevance of the questionnaire was confirmed, forward and backward translations were produced, and finally a pilot test was performed to ensure the quality and sharpness of the questioning.

Equivalence in *content*, as well as *semantic* and *technical* equivalence was verified in order to meet the demands of the cross-cultural equivalence in each country of research.

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Table 1. Design steps for CIVIQ-20.

Step	Year	No. of patients	Aim
Item generation	1991	20	Item collection in 5 dimensions (signs and symptoms, functional impact, psychological effect, social consequences and perception of general health)
Item reduction	1992	150	Checklist of the most important items based on patient preference
Scale construction of CIVIQ-20	1992	1001	Construction of a questionnaire with 20 equally weighted items split into 4 dimensions ('pain', 'physical', 'psychological', 'social')
Psychometric validation of CIVIQ-20	1993	1001	Verification of content, face validity, reliability, reproducibility and construct validity
	1993	60 (for reproducibility)	
Clinical validation of CIVIQ-20	1994	934	Assessment of responsiveness and sensitivity to changes
Use of CIVIQ-20 in real life	1996–2002	5052	Assessment of reliability, construct and clinical validity, and responsiveness to assess patient response to therapy using the RELIEF ⁴ database
International validation of CIVIQ-20	2010	3956	Validation of consistency, reliability, reproducibility and responsiveness using databases from 18 countries
Construction of CIVIQ-14	2011	Five databases from Poland, Czech Republic, Spain and France with 1334, 506, 476, 291 and 397 CVD patients, respectively	Construction of a questionnaire with 14 equally weighted items split into 3 dimensions (pain, physical, psychological)
Use of CIVIQ-14 in real life	2009–2011	6232	Assessment of reliability, construct and clinical validity, and responsiveness to assess patient response to therapy using the Vein Consult Program database
Linguistic validation	1994–2012	International surveys	Forward–backward validation in 17 languages

CIVIQ-20, Chronic Venous Disease quality-of-life Questionnaire; RELIEF, Reflux assessment and quality of life improvement with micronized purified flavonoid fraction; CVD, chronic venous disease.

Results

For equivalence in *content*, we endeavored to confirm that each item of the questionnaire was relevant to the culture studied. Some items had to be adapted to cultural differences in certain countries. For instance, in countries where travel by car is limited to a small section of the population, such as Eastern Europe, the question 'how much difficulty did you have in traveling by car' was supplemented by 'traveling by bus, train, or plane'. In the question 'How much trouble have you experienced performing household tasks such as standing around the kitchen, carrying a child in arms, ironing, cleaning the floor, or DIY', some of the tasks required modification. For example, in Austria, gardening was added, as many Austrians have gardens even in cities. In Italy, 'carrying a child in arms' was removed

because the Italian 'Mamma' image is no longer relevant and was replaced by 'doing the shopping' to better recognize the involvement of men who often go shopping with their wives. In Spain and Poland, men also accompany their wives when shopping and this task was also added. There were also some cultural differences in social activities. The item 'go out to bars, restaurants, events' is very popular in Spain and replaced 'go out for the evening', while it was added in the Italian questionnaire. 'Go to balls' was added to the Austrian version where waltzes are very popular and 'cooking a meal for friends' was added in the Polish version.

Semantic equivalence, which verifies that the meaning of each item remains the same after translation, must be respected. This was not without difficulty as

Table 2. Methodology for the linguistic validation of CIVIQ-20.**Confirmation of cultural relevance of CIVIQ-20 prior to translation**

Recruitment of experts

Selection of experts: required to speak the language of the country as their mother tongue and to be fluent in French, to have lived in the country concerned up to the last 2 years, and to have personal experience of problems related to chronic venous disorders (CVD)

Interview of three experts per country (1 man and 2 women)

Interviews with experts

Experts were requested to confirm whether the questions chosen in the French version appeared to them to be suitable for the cultural setting in their country

They were asked to describe their own troubles related to CVD, to retrace its history, how and when it began, to describe their symptoms and to list the problems which troubled them most in their daily lives

They were then asked to complete CIVIQ-20 and report their general impressions

We then reviewed the items one by one with each expert, recording his or her comments on the expression and comprehension of each question. If an item did not appear to be representative, although the area in which it applied was relevant, replacement items were proposed. Possible additions due to specific cultural factors could be suggested by experts

Forward-backward translation procedure

Consultation with developers of the questionnaire for clear understanding of the basic concepts and medical problems to be evaluated

Briefing of both teams conducting the forward translation in each language to provide translators with a clear and uniform understanding of the basic concepts and medical problems to be evaluated

Forward translations in each language performed by two teams working independently to reduce the bias of one translator

Development of a consensus forward translation by comparing the two forward translations to ensure that the two teams were in agreement on the appropriate translation

Backward translations in each language performed by two teams working independently to verify that concepts, language and response descriptions as translated were equivalent to the original meanings in the original version

Comparison of backward translations with each other and the original version to identify semantic problems and possible alternative translations

Administration of the questionnaire to patients in the target population to simulate a clinical trial setting on a pilot basis

Interviews with each patient in the pilot administration group to identify questions that were difficult to understand and measure the time required to complete the questionnaire. Modification of forward translations if necessary

Production of the translated questionnaire

Pilot test

Recruitment of 12 patients per country who were representative of the population and were suffering from CVD at stages of severity ranging from the C0s to C4 clinical classes of the CEAP classification

Evaluation of the overall acceptability of the questionnaire, understanding of the questions, exhaustiveness of the questionnaire and relevance of the questions with regard to the cultural context of the country

CIVIQ-20, Chronic Venous Disease quality-of-life Questionnaire; CEAP, clinical, aetiological, anatomical and pathological.

many words in the source language did not have equivalents in other languages. For instance, French words such as 'gêne' (trouble, discomfort), 'piétiner' (to stand about) and 'bricoler' (do it yourself [DIY]) have no equivalent in other languages. The term 'gêne' is not appropriate in Canadian French where it means 'embarrassment', and so the equivalent 'sensation of discomfort' was used. In the US Spanish version, the equivalent of 'bother, troubles' was used. The word 'piétiner' was replaced with 'standing and moving around' in Canadian English, UK English and US English versions. 'DIY' is not a commonly used term in the USA, while in Canadian French it means 'doing arts and crafts'. It was therefore replaced with 'house projects' in the USA, and 'doing small repairs' in Canada. In Canadian French, the term 'cocktail

party' was replaced with '5 à 7', an idiomatic expression for cocktail parties, which generally take place between 17:00 and 19:00. Other items, such as 'to travel (car, bus, plane)', 'to do the housework' and 'must take precautions' created specific translation problems.

The *technical* dimension did not raise particular difficulties as data collection methods using pencil and paper were appropriate for the cultures approached and the scoring using the 5-point Likert scale was correctly used.

Seventeen linguistic versions of CIVIQ-20 have been validated. Eleven additional versions were simply translated without using the internationally accepted translation methodology. It should be noted that translating a questionnaire literally is the most common method of preparing instruments for cross-cultural research and

Table 3. Summary of the available linguistic versions of CIVIQ-20.

The 17 validated linguistic versions according to forward-backward methodology			The 11 translated linguistic versions (without formal methodology)	
Target country	Language	Date of validation	Target country	Language
Austria	German	1996	Brazil	Portuguese
Canada	French	2002	China	Chinese
Canada	English	2002	Czech Republic	Czech
The Netherlands	Dutch	2009	Egypt	Arabic
France	French (source questionnaire)	1995	Hungary	Hungarian
Greece	Greek	2004	India	English
Italy	Italian	1996	Japan	Japanese
Poland	Polish	1996	Russia	Russian
Portugal	Portuguese	1996	Slovakia	Slovak
Romania	Romanian	2013	Switzerland	French
Singapore	English	1996	Turkey	Turkish
Slovenia	Slovenian	2013		
Spain	Spanish	1996		
UK	English	2002		
USA	English	2002		
USA	Spanish	2002		
Vietnam	Vietnamese	2013		

CIVIQ-20, Chronic Venous Disease quality-of-life Questionnaire.

may be helpful. However, clinicians who adopt this solution must be aware that literal translation has pitfalls that are difficult to detect and may threaten the validity of the research results. Researchers must ensure that simply translated items are culturally relevant and comprehensible, while maintaining the meaning and intent of the original form.

All the available linguistic versions of CIVIQ-20 are displayed in Table 3.

Conclusion

While it is accepted that a culture-free or universal instrument is a rarity, the use of independent and qualified bilingual translators and back-translators, as well as feedback from a bilingual committee during each step of the validation process, has allowed the main dimensions of cross-cultural equivalence to be respected in CIVIQ-20. The rigorous methods applied to the cross-cultural adaptation of CIVIQ-20 make the instrument suitable for multicenter, multinational studies.

Funding

This research received no specific grant from any funding agency in the public, commercial, or not-for-profit sectors.

Conflict of interest statement

The authors have no conflicts of interest to declare.

References

1. Launois R, Reboul-Marty J and Henry B. Construction and validation of a quality of life questionnaire in chronic lower limb venous insufficiency (CIVIQ). *Qual Life Res* 1996; 5: 539–54.
2. Launois R, Mansilha A and Jantet G. International psychometric validation of the chronic venous disease quality of life questionnaire CIVIQ-20. *Eur J Vasc Endovasc Surg* 2010; 40: 783–9.
3. Erevnidou K, Launois R, Katsamouris A and Lionis C. Translation and validation of a quality of life questionnaire for chronic lower limb venous insufficiency into Greek. *Int Angiol* 2004; 23: 394–9.
4. Lozano FS and Launois R. Reflux Assessment and Quality of Life Improvement with Micronized Flavonoids (RELIEF) Spanish group. Quality of life (Spain and France): validation of the chronic venous insufficiency questionnaire (CIVIQ). *Methods Find Exp Clin Pharmacol* 2002; 24: 425–9.
5. Biemans AA, van der Velden SK, Bruijninx CM, Buth J and Nijsten T. Validation of the Chronic Venous Insufficiency Quality of Life Questionnaire in Dutch patients treated for varicose veins. *Eur J Vasc Endovasc Surg* 2011; 42: 246–53.