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Psychometric Validation of the 14 items ChronIc Venous Insufficiency Quality of Life Questionnaire (CIVIQ-14): Confirmatory Factor Analysis

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WHAT THIS PAPER ADDS

This article provides a new insight regarding the factorial structure of the 14 items Chronic Venous Insufficiency Quality of Life Questionnaire, a disease specific tool designed for chronic venous disease. It applies a methodology that, to date has not been used to confirm the factorial structure of a CVD specific QoL questionnaire. This article confirms the three dimensional structure of CIVIQ-14.

Objectives: The study aim was to confirm the factorial structure of the short (14 item) version of the ChronIc Venous Insufficiency quality of life Questionnaire (CIVIQ-14) using the Vein Consult Program (VCP) results.
Methods: The international VCP study sought to evaluate the impact of chronic venous disease (CVD) on health care costs and quality of life (QoL). The factorial structure of the CIVIQ-14 was evaluated using two methods: exploratory factor analysis (EFA) to calculate the probabilities of items and dimensions remaining stable and to study the dimensionality of the scale using explained variance criteria, followed by confirmatory factor analysis (CFA) to confirm the original three dimensional structure and investigate alternative models that may have arisen from the dimensionality analysis. We also used the VCP results to evaluate the psychometric properties of the questionnaire and conducted subgroup analyses on countries with validated translations.
Results: A total of 47,149 questionnaires from 17 countries were available in the VCP. EFA revealed both items and dimensions as 100% stable. Dimensionality analysis showed that a two factor approach could be considered. CFA revealed the CIVIQ-14 three dimensional structure to be acceptable while rejecting the two dimensional model. Psychometric analysis confirmed the construct validity, internal consistency, and known groups validity of the CIVIQ-14. The results of subgroup analyses were consistent with those of the primary analysis.
Conclusions: CFA of VCP data supported the factorial structure of the CIVIQ-14. The analysis corroborates the wide use of CIVIQ-14 as a valid instrument for reporting QoL in CVD patients.

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INTRODUCTION

Chronic venous insufficiency (CVI) is a common circulatory disorder that impairs the return of blood to the heart. It mainly affects the legs, causing varicose veins, thrombosis, edema, and ulceration. Although the associated management costs make it a major public health issue, CVI remains a non-lethal condition with a quality of life (QoL) impact that is often underestimated.

The 20 item ChronIc Venous Insufficiency quality of life Questionnaire (CIVIQ-20) was developed to estimate QoL.[1] The subsequent series of psychometric evaluations[2,3] and international linguistic validations[4] have made it the most widely used scale for assessing chronic venous disease (CVD).

The CIVIQ-14 was designed to improve the factorial stability of its predecessor and facilitate its use. Its construction has been described previously.[5] Briefly the 14 item version was built using an iterative process removing all items contributing to the factorial instability of the CIVIQ 20 questionnaire. During the process, six items and one dimension were removed. The 14 remaining items covered three dimensions: "Pain", "Physical", and "Psychological". Structural validity was evaluated using exploratory factor analysis (EFA) on data from one randomized controlled trial (306 Study) and two observational studies (Reflux assEssment and quaLity of lIfe improvEment with micronized purified Flavonoid fraction [RELIEF],[6] and

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ALFIS/THALES,[7] a study by a French drug industry consortium [ALFIS] working with an epidemiological surveillance network of 230 primary care practitioners [THALES]).[8] Although the results helped to extend the routine use of the CIVIQ-14 (translations are now available in 28 countries), it remained important to provide the shortened questionnaire with added methodological consolidation.

The purpose of the present study was to further the validation process initiated by Launois et al.[5] and to address recent concerns about the questionnaire's factorial structure,[9] by conducting a confirmatory factor analysis (CFA). While traditional EFA offers a numerical approach to item clustering, CFA is the necessary next methodological step in terms of statistical rigor for assessing the CIVIQ-14 model for goodness of fit: it is the only method that can compare a given factorial structure to other possible model options on the basis of goodness of fit to the observed data.

Until now, the only QoL scale in CVI to have benefitted from factorial validation has been the CIVIQ-20.[10] The present study had the potential to credit the CIVIQ-14 as the first CFA validated questionnaire in the field. The Vein Consult Program (VCP), a recent international cross sectional study, was therefore mobilized to provide data from a large population of CVD patients.

MATERIALS AND METHODS

Vein consult program

Approval confirming compliance with the ethical standards laid down in the Helsinki Declaration amended in October 2008 was obtained from the ethics committees of the countries in which the program was implemented. Males or females over 18 years were eligible after providing written informed consent to participation in the Vein Consult Program.

The two stage VCP sought to describe and analyze CVD management across 21 countries. Stage 1 consisted of opportunistic CVD screening of patients attending primary care. Physicians were asked to enroll patients consecutively in a brief procedure within the normal visit framework. Those receiving a positive CVD diagnosis were asked to complete the CIVIQ-14. In Stage 2, patients could be referred to a specialist. This generated two case report forms (CRFs), one for the generalist and one for the specialist visit. These complemented use of the CIVIQ-14 and led to the constitution of three databases: one dedicated to GP visits, a second to specialist visits, and a third to the QoL questionnaire.

VCP data were collected over 3 years (March 2009 through March 2012). The CIVIQ-14 database included 47,149 patients from 17 countries, the GP database 138,732 patients from 21 countries, and the specialist database 11,088 patients from 11 countries. Patients answering fewer than 50% of the CIVIQ-14 were excluded from the analysis. The analysis was conducted on a final total of 42,799 patients (Supplementary Table 1).

Prior to analysis, missing questionnaire responses were treated using Rubin's multiple imputation method:[11] conditional distributions of missing values were based on the observed answers to draw plausible imputations in replacement of non-response. Five datasets were created accordingly and averaged for analysis.

Non-parametric bootstrap re-sampling was also applied to account for extraneous country effect:[5] QoL is assumed to differ among countries so that two patients from a given country are likely to have a closer perception of QoL than two patients from different countries. Thus 500 bootstrap samples were constructed and used in factor analyses and psychometric validation.

Exploratory factor analysis

Following construction of the CIVIQ-14, Launois et al.[5] showed that it relied on a three dimensional (3D) structure ("Pain", "Physical", and "Psychological"). Hence the scale's factorial stability using EFA was analyzed. Briefly, EFA states that an item can be described as a linear combination of k dimensions. The coefficients from this linear equation are called factor loadings and their analysis allows identifying to which dimension the item belongs, each item being allocated to the dimension with the largest factor loading for that item. The following two rotations were considered: varimax, a widely used orthogonal rotation that makes results easier to interpret, and an oblique promax rotation that does not assume independence between factors. The dimensionality of the scale was evaluated using the explained variance criterion with a 100% threshold to assess the suitability of alternative models. These could then be corroborated by confirmatory factor analysis (CFA).

Confirmatory factor analysis

CFA was performed to test the validity of the original 3D structure and identify the model with the best fit among all the alternative models emerging from the EFA. A battery of seven common indices was used to evaluate goodness of fit: root mean square approximation (RMSEA), goodness of fit index (GFI), adjusted goodness of fit index (AGFI), standardized root mean square residual (SRMR), normed fit index (NFI), non-normed fit index (NNFI), and comparative fit index (CFI). A general increase in the GFI, AGFI, NFI, NNFI, and CFI denoted improvement in goodness of fit. A 0.90 threshold was used for the AGFI,[12] GFI,[13] NFI,[14] and NNFI,[14] and a 0.95 threshold for the CFI.[14] Conversely, lower SRMR or RMSEA values indicated improved goodness of fit. The thresholds for SRMR and RMSEA were .08[14] and .07.[15] While sometimes reported in this type of analysis, the chi-square test was not considered as it is known to lead to model rejection if used on large samples.[16,17] In addition, the root mean square residual was also not considered since there is no recommended threshold to ease its interpretation, and given that the standardized version of the index was calculated.

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Psychometric validation

The purpose of psychometric validation is to investigate the reliability, validity, and sensitivity of a questionnaire.[18] Given the cross sectional design of the VCP, the validation was limited to the analysis of internal consistency, construct validity, and known group validity.

Internal consistency[19] was used, measured using Cronbach's alpha (α) coefficient ($0 \leq \alpha \leq 1$), to check that items contained in a dimension addressed the same concept. An α value $\geq .7$ indicated good internal consistency.[20,21] To evaluate construct validity, multi-trait/multi-item (MTMI) analysis was used, developed to test correlations between items and their specified dimension scores. Guided by recommendations from Ware et al.,[22] the following acceptability criteria to assess construct validity were used: at least 90% of correlations between an item and its dimension should exceed −0.40 (convergent validity) and at least 80% of the items should be better correlated with their respective dimensions (discriminant validity). A negative correlation between an item and its dimension was expected since they are scored inversely. The ability of the CIVIQ-14 to discriminate between clinical severities (i.e. known group validity) using analysis of variance (ANOVA) was assessed. Disease severity was evaluated using the Clinical, Etiological, Anatomical and Pathophysiological (CEAP) classification for the following four symptoms: heavy legs, sensation of swelling, sensation of burning, and night cramps, and the numbers of symptoms.

Subgroup analysis

A subgroup analysis for countries with available CIVIQ-14 translations (France, Hungary, Russia, Singapore, and Slovakia) was conducted as part of the CFA and the psychometric validation. While there are no recommended thresholds regarding the number of observations required to conduct such analyses, 10 observations per parameter ratio is sometimes considered. Therefore, due to the limited number of observations for Singapore ($n = 105$), results with regards to that country may not be reliable and were not presented.

All statistical analyses were performed with SAS® 9.3 (SAS Institute Inc., Cary, NC, USA).

RESULTS

Overall, 86.53% of the 42,799 patients answered all 14 items in the CIVIQ-14; 3.30% answered six or fewer items (Supplementary Table 2). Georgia had the highest proportion of missing data, with 51.78% of patients completing the entire questionnaire and nearly 25% answering six or fewer items.

Exploratory factor analysis

EFA of factorial stability in both the varimax and promax rotations showed a 100% probability of being stable with most items (Table 1), making it likely that the items were correctly associated with the dimension from which they originated. In one of the 500 bootstrap samples (0.20%), two items were associated with the incorrect dimension ("Climb several floors" and "Feeling nervous"). Similar results were observed with the promax rotation: in respectively 18 (3.60%) and four samples (0.8%), items "Climbing several floors" and "Feeling nervous" were mistakenly associated with the pain dimension.

Dimensionality analysis using the explained variance criteria concluded that items could be distributed within two dimensions; when the dimensionality analysis resulted in a 2D model, as in 75% of the samples (377/500), the "Pain" and "Physical" dimensions were merged. In the remaining 25% (123/500), the analysis favored the original 3D model.

Given that the purpose of an EFA is to identify how the items could be distributed in dimensions but not to compare these possible models, a confirmatory factor analysis was conducted.

Table 1. Factorial stability of the CIVIQ-14 questionnaire using 500 bootstrap samples ($n = 42,799$).

Dimension	Item	Probability for the item to be stable	
		Varimax rotation (%)	Promax rotation (%)
Pain	Pain in the legs	100	100
	Impairment at work	100	100
	Sleeping poorly	100	100
Physical	Climb several floors	99.80	96.40
	Squat/kneel	100	100
	Walk at a good pace	100	100
	Going to parties	100	100
	Perform athletic activity	100	100
Psychological	Feeling nervous	99.80	99.20
	Impression of being a burden	100	100
	Embarrassed to show legs	100	100
	Easily becomes irritable	100	100
	Impression of being disabled	100	100
	Having no desire to go out	100	100

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Table 2. Confirmatory factor analysis results (n = 42,799).

Goodness of fit index	Threshold	Three dimensional model	Two dimensional model
RMSEA	$\leq$ .07	.08	.11
GFI	$\geq$ .95	.93	.88
AGFI	$\geq$ .90	**.90**	.83
SRMR	$\leq$ .08	**.03**	**.05**
NFI	$\geq$ .95	**.95**	.91
NNFI	$\geq$ .95	.94	.89
CFI	$\geq$ .95	**.95**	.91

AGFI = adjusted goodness of fit index; CFI = comparative fit index; GFI = goodness of fit index; NFI = normed fit index; NNFI = non-normed fit index; RMSEA = root mean square approximation; SRMR = standardized root mean square residual.
Values in bold indicate a good model fit.

Confirmatory factor analysis (Table 2)

CFA was performed to test the plausibility of the model structures previously identified by EFA. According to the pre-established AGFI, SRMR, NFI, and CFI thresholds, the original 3D model could be considered acceptable. Conversely, using the RMSEA, GFI and NNFI thresholds, the three dimensionality of the questionnaire could not be demonstrated.

CFA was mobilized in order to test the two dimensionality of the questionnaire. This led to the conclusion that a 2D factorial structure was unacceptable provided that only one of the seven indicators (SRMR) satisfied the threshold criteria. Moreover, results from the RMSEA, GFI, AGFI, NFI, NNFI, and CFI determined that the postulated 2D model did not represent a good fit for the observed data.

According to the subgroup CFA results (Table 3), five indices revealed that the 3D model was well adjusted to the data in the case of Hungary and Russia. In the French subgroup, three indices confirmed CIVIQ-14's three dimensionality.

In contrast, the results from the Slovakian subgroup tended to support rejection of the 3D model, as SRMR was the only indicator showing good model adjustment.

Psychometric validation

The cross sectional design of the VCP limited analysis of the psychometric properties of the CIVIQ-14 to three validation aspects: internal consistency, construct validity, and know group validity. Table 4 presents the Cronbach's α results for each dimension and per country. Overall, each of the three dimensions had Cronbach's α coefficients that were superior to 0.8 (Pain 0.85; Physical 0.92 and Psychological 0.88) indicating very good internal consistency (20, 21).

Subgroup analyses for France, Hungary, Russia, and Slovakia led to a similar conclusion as it was revealed that all the α coefficients were superior or equal to 0.84.

Multi-trait/multi-item analysis was used to assess the convergent and discriminant validity of the questionnaire (Table 5). When evaluating convergent validity, only the correlation of an item and its supposed dimension is relevant, other dimension should not be considered. Symmetrically, when evaluating discriminant validity, the −0.4 threshold is irrelevant. Correlation coefficients from MTMI analysis exposed the convergent validity of the CIVIQ-14 given that, overall, the correlations between each item and its dimension score were superior to 0.4. Furthermore, MTMI showed that items were more correlated to their originating dimension than to the remaining two, which demonstrated the discriminant validity of the questionnaire.

Results for the MTMI subgroup analysis (Table 6) were consistent with those from the primary analysis: across five distinct subgroups, the 14 items of the questionnaire were found to be more correlated with their own dimension. All correlation coefficients were superior to 0.4 in absolute value.

Known groups validity investigates the ability of CIVIQ-14 to discriminate patients according to their clinical severity. Results from the ANOVA showed significant comparisons of CIVIQ14 scores according to the CEAP classification (Table 7). Similar results were observed when comparing CIVIQ-14 scores according to the presence or absence of each of the four clinical symptoms and to the number of symptoms.

Table 4. Cronbach's alpha (α) coefficients for each dimension, in primary and subgroup analyses.

	Pain	Physical	Psychological
Overall (n = 42,799)	.85	.92	.88
France (n = 18,625)	.85	.92	.88
Hungary (n = 3,087)	.86	.93	.90
Russia (n = 4,317)	.84	.92	.87
Slovakia (n = 2,408)	.86	.92	.90

Table 3. Confirmatory factor analysis on subgroups.

Goodness of fit index	Threshold	France (n = 18,625)	Hungary (n = 3,087)	Russia (n = 4,317)	Slovakia (n = 2,408)
RMSEA	$\leq$ .07	.08	.08	**.07**	.09
GFI	$\geq$ .95	.93	.93	.94	.91
AGFI	$\geq$ .90	.89	**.90**	**.92**	.87
SRMR	$\leq$ .08	**.04**	**.04**	**.04**	**.05**
NFI	$\geq$ .95	**.95**	**.95**	**.95**	.94
NNFI	$\geq$ .95	.93	**.95**	.94	.92
CFI	$\geq$ .95	**.95**	**.96**	**.95**	.94

AGFI = adjusted goodness of fit index; CFI = comparative fit index; GFI = goodness of fit index; NFI = normed fit index; NNFI = non-normed fit index; RMSEA = root mean square approximation; SRMR = standardized root mean square residual.
Values in bold indicate a good model fit.

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Table 5. Correlations and (95% CI) between items and dimensions from the MTMI analysis on the 500 bootstrap samples (n = 42,799).

Items	Pain	Physical	Psychological
Pain in the legs	**−0.74 (−0.74; −0.74)**	−0.62 (−0.62; −0.62)	−0.52 (−0.52; −0.52)
Impairment at work	**−0.74 (−0.74; −0.74)**	−0.67 (−0.67; −0.67)	−0.57 (−0.57; −0.57)
Sleeping poorly	**−0.65 (−0.65; −0.65)**	−0.58 (−0.58; −0.58)	−0.53 (−0.54; −0.53)
Climb several floors	−0.66 (−0.66; −0.66)	**−0.77 (−0.78; −0.77)**	−0.57 (−0.57; −0.57)
Squat/kneel	−0.64 (−0.64; −0.64)	**−0.77 (−0.77; −0.77)**	−0.57 (−0.57; −0.57)
Walk at a good pace	−0.63 (−0.64; −0.63)	**−0.83 (−0.83; −0.83)**	−0.58 (−0.59; −0.58)
Going to parties	−0.60 (−0.60; −0.60)	**−0.75 (−0.75; −0.75)**	−0.57 (−0.57; −0.57)
Perform athletic activity	−0.58 (−0.58; −0.58)	**−0.79 (−0.79; −0.79)**	−0.55 (−0.55; −0.55)
Feeling nervous	−0.56 (−0.56; −0.55)	−0.55 (−0.55; −0.55)	**−0.68 (−0.68; −0.67)**
Impression of being a burden	−0.49 (−0.49; −0.48)	−0.54 (−0.54; −0.54)	**−0.72 (−0.72; −0.71)**
Embarrassed to show legs	−0.43 (−0.43; −0.43)	−0.43 (−0.43; −0.43)	**−0.56 (−0.57; −0.56)**
Easily becomes irritable	−0.49 (−0.49; −0.49)	−0.50 (−0.50; −0.50)	**−0.72 (−0.72; −0.72)**
Impression of being disabled	−0.49 (−0.49; −0.49)	−0.54 (−0.55; −0.54)	**−0.73 (−0.73; −0.73)**
Having no desire to go out	−0.49 (−0.49; −0.49)	−0.56 (−0.57; −0.56)	**−0.71 (−0.71; −0.71)**

Table 6. Results of the MTMI subgroup analysis.

	Range of correlation between items and dimensions score without the item		
	Pain	Physical	Psychological
France (n = 18,625)	(−0.77; −0.66)	(−0.81; −0.72)	(−0.74; −0.55)
Hungary (n = 3,087)	(−0.77; −0.67)	(−0.84; −0.79)	(−0.76; −0.59)
Russia (n = 4,317)	(−0.71; −0.65)	(−0.84; −0.76)	(−0.72; −0.53)
Slovakia (n = 2,408)	(−0.80; −0.63)	(−0.85; −0.77)	(−0.79; −0.67)

Table 7. Known groups validity of the CIVIQ-14 questionnaire (n = 42,799).

Clinical assessment	Mean CIVIQ-14 score (SD)	Overall p
Heaviness		< .0001
No	83.3 (17.7)	
Yes	69.8 (19.4)	
Swollen		< .0001
No	81.3 (17.4)	
Yes	68.6 (19.7)	
Burn		< .0001
No	78.2 (17.9)	
Yes	66.1 (20.3)	
Night cramps		< .0001
No	78.5 (18.0)	
Yes	68.5 (20.2)	
Number of symptoms		< .0001*
0	88.8 (15.2)	
1	81.0 (16.5)	
2	74.8 (16.8)	
3	67.6 (18.5)	
4	64.3 (20.6)	
CEAP		< .0001*
C0w	90.4 (15.1)	
C0s	83.3 (16.6)	
C1	80.5 (16.6)	
C2	74.8 (18.3)	
C3	69.7 (18.7)	
C4	63.2 (20.5)	
C5	55.8 (22.5)	
C6	52.3 (25.7)	

*A Bonferroni correction was carried out for multiple comparison. All were found to be significant.

DISCUSSION

This study revealed the factorial stability of the CIVIQ-14 questionnaire on a multi-country CVD population that included data from over 40,000 patients. The questionnaire's psychometric property was also validated employing a battery of statistical analyses that assessed its internal consistency, construct validity, and known groups validity.

The dimensionality analysis provided two suitable factorial structures: the original 3D and the alternative 2D structure. The validity of each structure was further scrutinized using CFA, whereby it was demonstrated that the 3D model was preferred. Subgroup analysis led to a similar conclusion: the 3D structure was favored in three out of four countries examined, but not in Slovakia. Congruent results regarding the number of dimensions were observed in an earlier validation of the questionnaire[5] that assessed a Spanish subgroup of CVD patients. Conversely, a study that sought to evaluate the psychometric properties of the CIVIQ-14 on the Serbian population,[9] qualified its factorial structure as "sub-optimal". However, no further investigation was conducted to justify the assertion. The CFA clearly addresses this concern, advocating the original 3D model instead of the alternative two factor model.

The present study had as principal objective to address contemporary concerns regarding the factorial structure of the CIVIQ-14 questionnaire. Taking into account the widespread use of the CIVIQ-14 as an essential tool for assessing QoL in CVD patients, it was considered relevant to gather evidence that could confirm and validate its factorial structure vis-à-vis emerging claims. Recent data extracted from the Vein Consult Program, a large multicenter

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observational study, were made use of in order to examine the factorial structure of the questionnaire thoroughly. Highly rigorous statistical methods informing current best practices in scale validation were used. As far as known, this is the first study to apply CFA to a QoL scale in CVD.[23] This methodology is widely used throughout numerous generic[24–26] and specific scale validation studies.[27–29] As such, the present work has the potential to progress the field of peripheral vascular disease, and CVD in particular, by improving the tools required for assessing QoL.

The present findings should be interpreted in the light of the following limitations. CFA revealed opposing findings, brought about by the Slovakian subgroups analyzed. Slovakia was only able to show good adjustment of the 3D structure with SRMR. While the sample size was similar to those of other countries studied, the possibility of an inadequate Slovak translation cannot be excluded. Furthermore, Slovakian CVD patient priorities and expectations regarding QoL may be conceived within a sociocultural context that is particular to the country, which the CIVIQ-14's Slovak translation is not yet able to capture. As suggested in the linguistic validation literature, a culture free or universal instrument is a rarity, making the validation process a necessarily iterative task for QoL researchers.[4]

The analysis showed the internal consistency of the CIVIQ-14 questionnaire. However, neither test—retest reliability nor inter-rater reliability could have been investigated in the absence of longitudinal data. Hence, its reliability could not be demonstrated, as internal consistency is a necessary but not sufficient condition of reliability.[19] For the same reason, sensitivity was not investigated either. Furthermore, given that the VEIN CONSULT Program was performed by GPs in the framework of ordinary consultations in the primary care setting, additional severity assessments were not consistently used and only CEAP data was available for known groups validity. These are judged to be minor limitations.

The present study aims to demonstrate the factorial stability of the CIVIQ-14 questionnaire. The factorial stability of the 3D structure can be considered acceptable and is a better option than the 2D model. Additional findings regarding the psychometric properties of the CIVIQ-14 demonstrate its internal consistency, and both its construct and clinical validity. There is, however, a need for longitudinal data to investigate the test-retest reliability and sensitivity of the CIVIQ-14 questionnaire.

CONFLICT OF INTEREST

None.

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APPENDIX A. SUPPLEMENTARY DATA

Supplementary data related to this article can be found at http://dx.doi.org/10.1016/j.ejvs.2015.08.020

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