Research

New insights into validity, reliability, and measurement invariance of the Kansas City Cardiomyopathy Questionnaire 23

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Abstract

Background: People affected by heart failure (HF) often exhibit a poor health status, which places a great deal of burden on the healthcare systems. The Kansas City Cardiomyopathy Questionnaire (KCCQ) 23 is the most used tool to measure the health status in this population; however, its psychometric properties have not been thoroughly established.

Objectives: To evaluate the psychometric properties of the KCCQ-23 in a European cohort of HF patients.

Methods: 510 patients (median age 74 years, IQR=18, 58% males) completed the KCCQ-23 along with clinical and psychosocial measures. Factorial validity was established with confirmatory factor analysis (CFA); omega and model-based internal consistency indexes were computed to examine the internal consistency of the scale. Convergent validity was established by correlating the KCCQ-23 scores with clinical and psychosocial measures. Measurement invariance tests across those with preserved vs reduced ejection fraction were conducted within a multigroup framework.

Results: Two CFA solutions were tested, which confirmed the theoretical and empirical models postulated by the original author. The internal consistency coefficients for the latent dimensions were adequate (Omega range =0.77-0.93; internal consistency coefficient =0.89-96). KCCQ-23 scores were found to be correlated with ejection fraction, NYHA levels, quality of life, self-care confidence, anxiety and depression, and symptom burden, supporting its convergent validity. Finally, the KCCQ-23 was invariant across ejection fraction levels, both in the theoretical and empirical factor solution.
Conclusions: Overall, this study provides evidence of satisfactory psychometric properties of the KCCQ-23, promoting its use in clinical settings and research fields.

Keywords: Psychometric Properties; Validation Study; Quality of Life; Reliability; Instrument; Heart Failure; Health Status.

INTRODUCTION

Heart Failure (HF) has been defined as a global pandemic, with 64 million people estimated to suffer worldwide[1]. Despite the evolving pharmacological therapies, HF prognosis remains inauspicious with mortality reaching 50% at 5 years[2] and rehospitalization rates of almost 30% at one year after discharge[3].

Patients with HF exhibit important physical signs and symptoms, such as dyspnea, chest pain and fatigue[4], which can greatly influence their health status. Indeed, the health status has become an important indicator of HF clinical severity because it is correlated with hospitalizations, prognosis, and overall survival[5,6]. The health status of HF patients (e.g., quality of life) can be promoted with targeted educational strategies, such as physical exercise, diet, and health promoting practices[7]; however, given that the health status is a complex multidimensional construct, a fundamental prerequisite for its improvement is the availability of valid and reliable measures to assess all its domains. One of the most important tools in the HF field is the Kansas City Cardiomyopathy Questionnaire (KCCQ).

Developed in 1996 and published in 2000[8] the KCCQ includes 23 items aimed to map the clinically relevant domains of physical limitations, symptoms (burden, frequency, and stability), social interference, quality of life, and self-efficacy and knowledge. Since its origin, several studies have tested the validity and reliability of the KCCQ. One of the less recent was the study conducted in 2003, where the authors tested and confirmed its construct validity on an Italian sample of 50 individuals referred to outpatient clinics. Other important studies of that decade were conducted in Norway[9] and Germany[10] on HF patients who had previous myocardial infarction. Subsequently, other psychometric investigations were conducted in USA[11,12,13,14], Portugal[15], Spain[16], Sweden[17], Uganda[18], and Japan[19] where their results generally confirmed satisfactory validity and reliability of the KCCQ across different HF populations.

Despite several international psychometric studies declared confirming the validity and reliability of the KCCQ, so far, important methodological issues persist. First, only few researchers[13,14,20] performed the factorial validity of this scale while others approached the analyses with initial testing of construct validity, and then prosecuted with reliability testing[9,13,16,19] or vice versa[18]. Recognized guidelines for the validation of relevant constructs recommend that factorial validity should always precede any other form of validity and reliability testing[21]. In other words, the dimensionality of a measure cannot be exclusively assumed theoretically, but rather it should be tested with some forms of factorial analysis. Only after this step the specific domains can be checked for reliability and construct validity[21,22].

Second, in order to inspect the factorial validity of the KCCQ, a few authors performed Exploratory Factor Analysis (EFA), while others performed Confirmatory Factor Analyses (CFA) when in fact, EFAs were tested[14]. As per guidelines, CFA models are more appropriate than EFA approaches for already theoretically-

defined scales such as the KCCQ[23,24], because the relationship between the items and the number of latent factors underlying the scale has already been defined[8]. As a result of this approach, different factorial structures are present than those originally postulated by Green, et al.[8], which can be attributed to the inherent limitations of EFA models (i.e., subjective judgement and heuristic rules for determining the number of factors and items per factor)[25].

Third, the reliability of the KCCQ was mostly ascertained with Cronbach's alpha, which is not the best choice when the scale is multidimensional and congeneric (i.e., different strengths of association between each item and the latent factors). In the first case, composite reliability coefficient is more appropriate because it accounts for the different loadings, while when the scale is intended to yield single scores derived from more than one construct, multidimensional reliability coefficients should be used, in order to account for the multidimensionality of the scale[21].

Finally, measurement invariance of the KCCQ has never been established across patients with preserved and reduced ejection fraction. Patients who have reduced ejection fraction generally have lower quality of life compared to those with preserved fraction. This situation may result in shifts of internal standards and perceptions of the construct and may respond to the KCCQ items using a different frame of reference toward the different domains of health status. Invariance of a measure means that a questionnaire measures the same construct among groups of respondents; therefore, if this property is confirmed, comparability of the KCCQ scores across these individuals can be possible.

Therefore, the aim of this study was to 1) evaluate the factorial validity of the KCCQ by means of confirmatory factor analytic models; 2) test the convergent validity of the KCCQ by examining its relationship with conceptually related psychosocial measures; 3) test the KCCQ reliability with an appropriate estimate for multidimensional instruments, and 4) test the measurement invariance of the scale across patients with reduced vs those with preserved ejection fraction.

METHODS

Design

The data used for this study were collected for the MOTIVATE-HF study, which was a three-arm, multicenter, randomized controlled trial to evaluate the effect of motivational interviewing for improving self-care and caregiver contribution to self-care in HF. The RCT was approved by the Institutional Review Board of the University of Rome "Tor Vergata", and was registered at ClinicalTrials.gov (Identifier: NCT02894502). For additional information on the study design see Vellone, et al.[26].

Setting and inclusion criteria

Patients were enrolled at three outpatient clinics located in the Lazio region (Italy). Patients were eligible for the study if they: 1) had a diagnosis of HF, according to the guidelines of the European Society of Cardiology[27] and a NYHA class of II, III, and IV; 2) did not have severe cognitive impairment, defined as a score <4 on the Six-Item Screener[28], 3) had not had a coronary event in the preceding three months; 4) were ≥ 18 years old; and 5) were able to understand and speak the Italian language.

Data collection procedures

Enrollment of patients with HF and caregivers was performed by research assistants, who were all registered nurses trained on the research protocol. The research assistants approached the potential participants, explained the objectives of the study and invited them to participate. After the informed consent form was signed, data collection began. Data were collected at baseline and three, six, nine and twelve months from enrollment in all the three study arms, but for this study only data collected at baseline were considered.

Ethical considerations

The MOTIVATE-HF study was approved by the Ethical Committees of the University of Rome Tor Vergata (letter number: 121/13). Patients and caregivers were fully informed about the aim of the study and that their personal data were protected per university protocol.

Instruments

In the MOTIVATE-HF trial, multiple instruments were administered to HF patients and caregivers; however, for this psychometric study, only the following instruments were considered.

Kansas City Cardiomyopathy questionnaire

The KCCQ is a 23-item questionnaire developed by Green, et al.[8] with the aim of measuring patients' perceptions and the impact

of HF symptoms on their health status. The KCCQ scores are standardized on a 0-100 range with higher scores representing better health status. The KCCQ quantifies, in a disease-specific fashion, physical limitation, symptoms (frequency, severity and recent change over time), QoL, social interference and self-efficacy[8]. To facilitate interpretability, four summary scores were developed: (i) the Symptoms score, obtained by combining the domains of Symptom frequency, and symptom burden; (ii) the Functional limitations score, obtained by combining the domains of physical limitations and social limitations; (iii) the Clinical Summary score, obtained by combining the physical limitation and symptom scores (excluding symptom stability), and (iv) the Overall Summary score, calculated by combining the Clinical Summary score with the QoL score[8].

Sociodemographic and clinical questionnaire

Sociodemographic characteristics of HF patients and their caregivers (e.g., gender, age, education, marital status, job, and level of education) were measured with a self-report questionnaire. Clinical variables related to the patients (e.g., etiology of HF, New York Heart Association functional class, ejection fraction, duration of heart failure in months, and comorbidities) were abstracted from the patients' medical records.

New York Heart Association

The New York Heart Association (NYHA) is used to evaluate the severity of functional limitations in patients with HF[29] and is composed of four classes ranging from 1 to 4, where class 1 indicates absence of symptoms, and class 4 indicates symptoms at rest and inability to perform any physical activity without discomfort. Validity and reliability of this tool have broadly been established[29]

Self-Care Confidence Scale

The Self-Care Confidence Scale measures the confidence of the patients affected by HF to perform self-care[30]. This instrument consists of 6 items on a 5-point response rate from 1 (Not at all confident) to 5 (Very confident). Total score is standardized 0-100 where higher scores indicate higher confidence in self-care behaviors. The scale has shown satisfactory validity and reliability on a sample of 659 outpatient individuals[30].

Short Form-12

The Short Form-12 (SF-12) measures the physical (PCS12) and mental (MCS12) self-perceived health components of quality of life. The two scores are computed by using US-derived item weights, according to the indications of the authors of the instrument[31] and standardized 0-100, with higher scores indicating better quality of life. The SF-12 has shown adequate validity and reliability in a large European HF population[32].

Hospital Anxiety and Depression Scale

The Hospital Anxiety and Depression Scale is a 14-item scale developed to measure anxiety and depression symptoms. The instrument has two subscales to measure anxiety and depression symptoms, respectively. The total score for each subscale ranges from 0 to 21, where higher scores indicate worse anxiety or depression. Adequate validity and reliability of the depression subscale has been documented by a recent study on a large European cardiac population[33].

Heart Failure Somatic Perception Scale

The Heart Failure Somatic Perception Scale is a 18-item scale used to quantify the burden of signs and symptoms of HF that have afflicted the patient in the past week [34]. Each item has a Likert scale from 0 to 5, where 0 indicates the absence of symptoms (*"I did not have this symptom"*) and 5 the maximum symptoms (*"Extremely bothersome"*). The total score ranges from 0 to 90, and higher scores indicate worse HF symptoms. The HFSPS has shown adequate validity and reliability in a European HF population[35].

Sample size

For this analysis we used data collected from 510 individuals, as established by the power analysis for the mother study[36]. The adequacy of the sample size for this study was confirmed based on two criteria. First, we conducted an RMSEA-based sample size calculation for the test of close fit; given a power of 0.80, an alpha level of 0.05 (two-tailed test) and 222 degrees of freedom of the less parsimonious model, the minimum sample needed was 105. Second, we conducted a sample size calculation to detect a significant effect size (ρ=0.2) in correlation analyses; given a power of 0.80, an alpha level of 0.05 (two-tailed test) the minimum sample size needed was 193.

Statistical analysis

SPSS v. 25[37] and MPLUS 8.9[38] were used to conduct the analyses. Means, standard deviations, medians, interquartile ranges and frequencies and percentages were used to describe the sample and the items of the KCCQ;

skewness and kurtosis indices were used to investigate the normality distribution of each item.

The factorial structure of the KCCQ was established with confirmatory factor analysis (CFA) since the scale has already been defined theoretically by Green, et al.[8]. First, we specified an initial "theoretical" model in line with the clinically relevant domains postulated by Green, et al.[8] and recently reconfirmed by Spertus, et al.[39]; physical limitations (Q 1a-1f), symptoms (Q 2-9), self-efficacy and knowledge (Q 10,11), social interference (Q 15a-15d), and quality of life (Q 12-14).

According to the second structure postulated by Green to help interpretability (i.e., derive summary scores), we also specified an "empirical" model: a) six first-order factors to reflect the domains of physical limitations (Q 1a-1f), symptom burden (Q 4, 6, 8) and symptom frequency (Q 3, 5, 7, 9), self-efficacy and knowledge (Q 10, 11), quality of life (Q 12-14), and social interference (Q 15a-15d); b) two second-order factors to reflect the domains of functional limitations (physical limitations plus social limitations) and symptoms (symptom burden plus symptom frequency); c) a third-order factor to reflect the domain of clinical summary (symptoms plus functional limitations), and d) an overall summary (clinical summary plus quality of life) and a KCCQ domain (overall summary plus symptom stability item plus self-efficacy and knowledge) as fourth and fifth-level factors, respectively.

A robust estimator (MLR) was used since the KCCQ items were slightly skewed and kurtotic. Consistent with a multifaceted approach to model fit assessment (40), we used the following fit indices: (a) χ^2 test, (b) comparative fit index (CFI): values greater than 0.90 are indicative of good fit, (c) Tucker and Lewis incremental Index (TLI): values greater than 0.90 are indicative of good fit, (d) root mean square error of approximation (RMSEA): values lower than 0.6 are indicative of good fit approximation, and (e) standardized root mean square residual (SRMR): values lower than 0.08 are indicative of good fit.

Internal consistency reliability of the KCCQ monodimensional factors was computed with the model-based omega coefficient (ω). Compared to Cronbach's alpha, Omega takes into account the congeneric nature of the model. Since the KCCQ was intended to yield total scores in addition to the scores of the monodimensional factors, the model-based internal consistency index was also computed. Common recommendations indicate acceptable internal consistency values if greater than 0.70[41].

Convergent validity was investigated with zero-order correlations between the scores of the KCCQ domains and other conceptually related variables that include ejection fraction, NYHA class, self-care confidence, quality of life (mental and physical component scores), and anxiety and depression. According to Cohen's recommendation, effect size correlation coefficients between 0.1 and 0.3 are considered small, 0.3 to 0.5 are considered moderate, and higher than 0.5 are considered large[42].

Measurement invariance was tested by means of multigroup confirmatory factor analysis. We stratified the sample by severity of ejection fraction (preserved ejection fraction = ≥50 percent; reduced = <50 percent)[43]. We verified configural, metric, scalar, and strict invariance using the sequential steps recommended by

Table 1. Demographic and clinical characteristics of the patients (n=510).

Age (years), median (IQR)	74 (18)
Males, n (%)	296 (58)
Partnered, n (%)	316 (62)
Educational level (>=9y), n (%)	168 (33)
Retired, n (%)	387 (75.9)
Do not have enough to make ends meet, n (%)	22 (4.3)
NYHA class II, n (%)	313 (61.4)
NYHA class III, n (%)	160 (31.4)
NYHA class IV, n (%)	33 (6.5)
EF, mean (SD)	44 (9.75)
Live alone, n (%)	78 (15.3)

Legend. NYHA, New York Heart Classification; IQR, interquartile range; EF, ejection fraction.

Table 2. Descriptive statistics of the items of the Kansas City Cardiomyopathy Questionnaire (n=510).

		M	*SD*	Skewness	Kurtosis
1.	Heart failure affects different people in different ways. Some feel shortness of breath while others feel fatigue. Please indicate how much you are limited by heart failure (shortness of breath or fatigue) in your ability to do the following activities over the past 2 weeks.				
	a. Dressing yourself	3.52	1.35	-0.32	-0.95
	b. Showering/Bathing	2.88	1.31	0.16	-1.01
	c. Walking 1 block on level ground	3.21	1.35	-0.12	-1.17
	d. Doing yardwork, housework or carrying groceries	2.92	1.32	0.10	-0.96
	e. Climbing a flight of stairs without stopping	2.69	1.38	0.38	-0.95
	f. Hurrying or jogging (as if to catch a bus)	1.92	1.34	1.63	1.87
2.	Compared with 2 weeks ago, have your symptoms of heart failure (shortness of breath, fatigue or ankle swelling) changed? My symptoms of heart failure have become..	3.20	1.21	0.85	0.61
3.	Over the past 2 weeks, how many times did you have swelling in your feet, ankles or legs when you woke up in the morning?	3.70	1.30	-0.60	-0.78
4.	Over the past 2 weeks, how much has swelling in your feet, ankles or legs bothered you?	4.03	1.63	-0.11	-1.24
5.	Over the past 2 weeks, on average, how many times has fatigue limited your ability to do what you want?	3.95	1.83	0.04	-1.09
6.	Over the past 2 weeks, how much has your fatigue bothered you?	3.01	1.42	0.74	-0.23
7.	Over the past 2 weeks, on average, how many times has shortness of breath limited your ability to do what you wanted?	4.48	1.92	-0.19	-1.19
8.	Over the past 2 weeks, how much has your shortness of breath bothered you?	3.70	1.59	0.20	-1.17
9.	Over the past 2 weeks, on average, how many times have you been forced to sleep sitting up in a chair or with at least 3 pillows to prop you up because of shortness of breath?	3.65	1.44	-0.58	-1.08
10.	Heart failure symptoms can worsen for a number of reasons. How sure are you that you know what to do, or whom to call, if your heart failure gets worse?	3.24	1.08	0.13	-0.64
11.	How well do you understand what things you are able to do to keep your heart failure symptoms from getting worse? (for example, weighing yourself, eating a low salt diet, etc.)	3.11	1.07	0.12	-0.48
12.	Over the past 2 weeks, how much has your heart failure limited your enjoyment of life?	3.18	1.18	-0.04	-0.89
13.	If you had to spend the rest of your life with your heart failure the way it is right now, how would you feel about this?	2.29	1.25	0.64	-0.64
14.	Over the past 2 weeks, how often have you felt discouraged or down in the dumps because of your heart failure?	3.06	1.15	0.16	-0.76
15.	How much does your heart failure affect your lifestyle? Please indicate how your heart failure may have limited your participation in the following activities over the past 2 weeks.				
	a. Hobbies, recreational activities	3.16	1.33	0.18	-0.75
	b. Working or doing household chores	2.91	1.32	0.40	-0.56
	c. Visiting family or friends out of your home	3.30	1.42	-0.05	-1.04
	d. Intimate relationships with loved ones	4.18	1.81	-0.05	-1.22

Legend. SD, standard deviation, M, mean

Meredith[44]. We considered measurement non-invariance if the deterioration in fit was equal or higher to 0.01 in CFI, and 0.015 in RMSEA for the more constrained model compared to the less constrained model.

RESULTS

Characteristics of the sample

Demographic and clinical data of the sample are shown in Table 1. Patients [(mean age = 72.4 (SD=12.29)] were prevalently males (58%), partnered (62%), retired (75.9%), and did not live alone (84.7%). Clinically, individuals were mostly in NYHA class II (61.4%), while a small proportion of the sample was in class IV (6.5%).

Descriptives of the items

The descriptive statistics of the KCCQ scale are reported in Table 2. The highest mean was on item 7 (how many times has shortness of breath limited your ability to do what you wanted) while the lowest mean was on item 1f (activity of

hurrying or jogging). The items did not exceed ±1 and ±3 on skewness and kurtosis indices, respectively, indicating univariate normality. However, Mardia test was significant (p<0.001), indicating multivariate non normality.

Factorial validity

Theoretical model

When the "theoretical" model (8,39) was specified, fit indices were not completely satisfactory: $\chi 2$ (225, N = 510) = 1,087.01, P = < 0.001, CFI = 0.87, TLI = 0.85, RMSEA = 0.087 (90% CI, 0.082–0.092), p = <0.001, and SRMR = 0.050. An excessive covariance between items 3 and 4 emerged from the modification indices, indicating that this was the cause of misfit. Accordingly, we respecified the CFA with this covariance, after which all fit indices became satisfactory: $\chi 2$ (224, N = 510) = 719.72, p = < 0.001, CFI = 0.93, TLI = 0.92, RMSEA = 0.066 (90% CI, 0.061–0.71), p <0.001, and SRMR = 0.043. All the factor loadings were significant (Figure 1).

Empirical model

When the empirical model was specified, fit indices were not completely satisfactory: $\chi 2$ (223, N = 510) = 1,135.04, p = < 0.001, CFI = 0.86, TLI = 0.85, RMSEA = 0.090 (90% CI, 0.084–0.095), p <0.001, and SRMR = 0.053. Similar to the "theoretical" model, the modification indices showed an excessive covariance between items 3 and 4. Accordingly, we respecified the model with this covariance, after which the fit became satisfactory: $\chi 2$ (222, N = 510) = 758.61, p = < 0.001, CFI = 0.92, TLI = 0.91, RMSEA = 0.069 (90% CI, 0.064–0.74), p <0.001, and SRMR = 0.049. All the loadings were significant (Figure 2).

Reliability testing

When we assessed the internal consistency reliability of the theoretical model, the omega coefficients for the single dimensions were adequate, with values ranging from 0.77 to 0.93. The factor score determinacy indexes computed on all dimensions were also adequate, ranging from 0.90 to 0.98. The model-based internal consistency index for the health status domain was adequate at 0.96 (Table 3).

When we assessed the internal consistency reliability of the empirical model, the omega coefficients for the single dimensions were adequate, with values ranging from 0.77 to 0.93. The model-based internal consistency indexes for the health status domain were all adequate ranging from 0.89 to 0.96. The factor score determinacy indexes computed on all dimensions were also adequate, ranging from 0.90 to 0.98 (Table 3).

Convergent validity

Table 4 shows the Pearson correlation coefficients

Table 3. Reliability indexes of the Kansas City Cardiomyopathy Questionnaire

Domains	ω	FSD	MB-ICI
Theoretical model			
Physical limitations	0.93	0.98	-
Symptoms	0.90	0.96	-
Self-efficacy and knowledge	0.78	0.90	-
Quality of life	0.83	0.95	-
Social interference	0.77	0.97	-
Health status	-	0.96	0.96
Empirical model			
Physical limitations	0.93	0.98	-
Symptom frequency	0.80	0.95	-
Symptom burden	0.75	0.95	-
Self-efficacy and knowledge	0.78	0.90	-
Quality of life	0.83	0.95	-
Social interference	0.77	0.97	-
Functional limitations	-	0.96	0.92
Symptoms	-	0.95	0.89
Clinical summary domain	-	0.96	0.95
Overall summary domain	-	0.95	0.96

Legend. FSD, Factor score determinacy; MB-ICI, model-based internal consistency index; ω, model-based Omega coefficient.

Figure 1: Confirmatory factor analysis of the theoretical model of the Kansas City Cardiomyopathy Questionnaire (n=510).

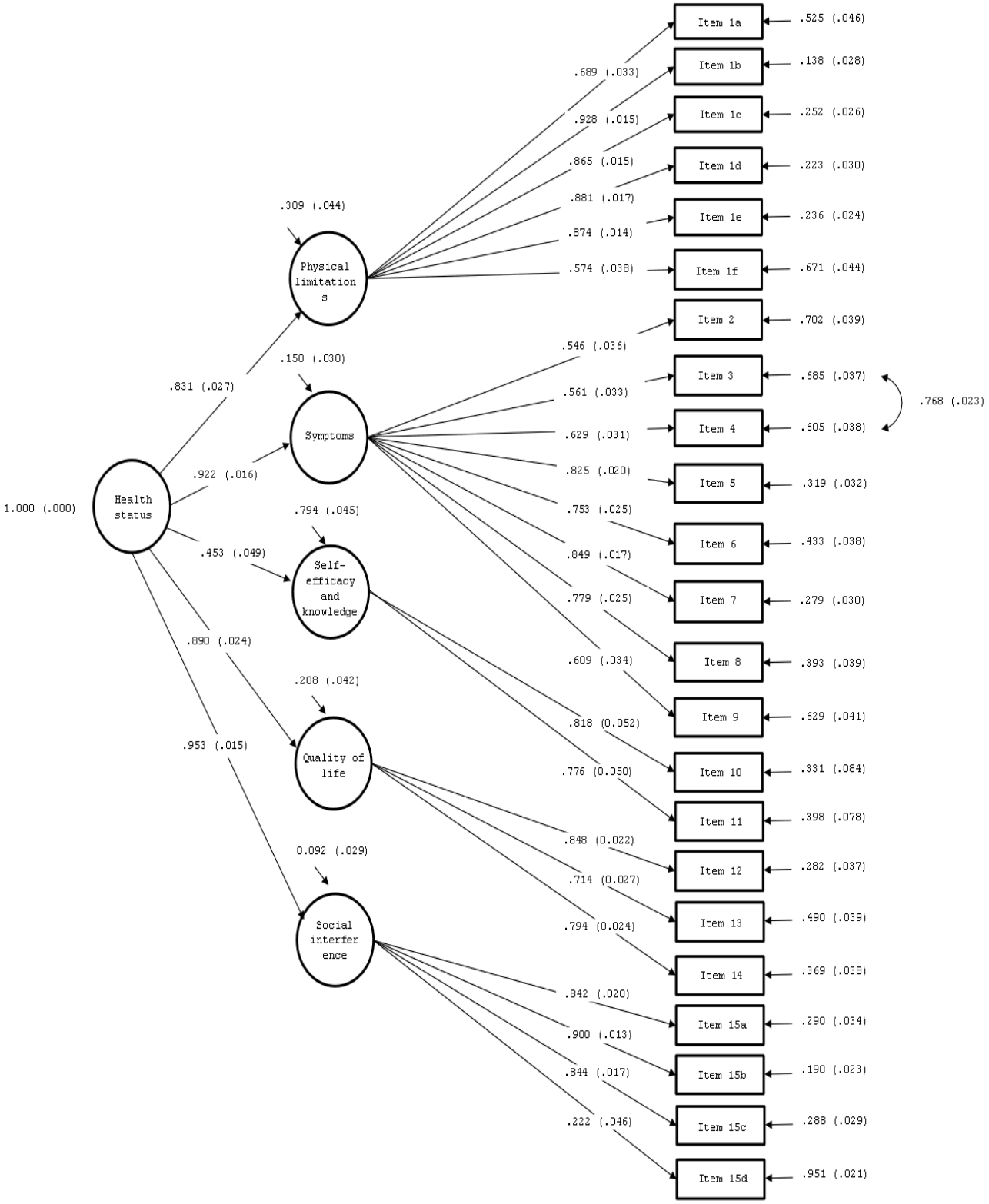
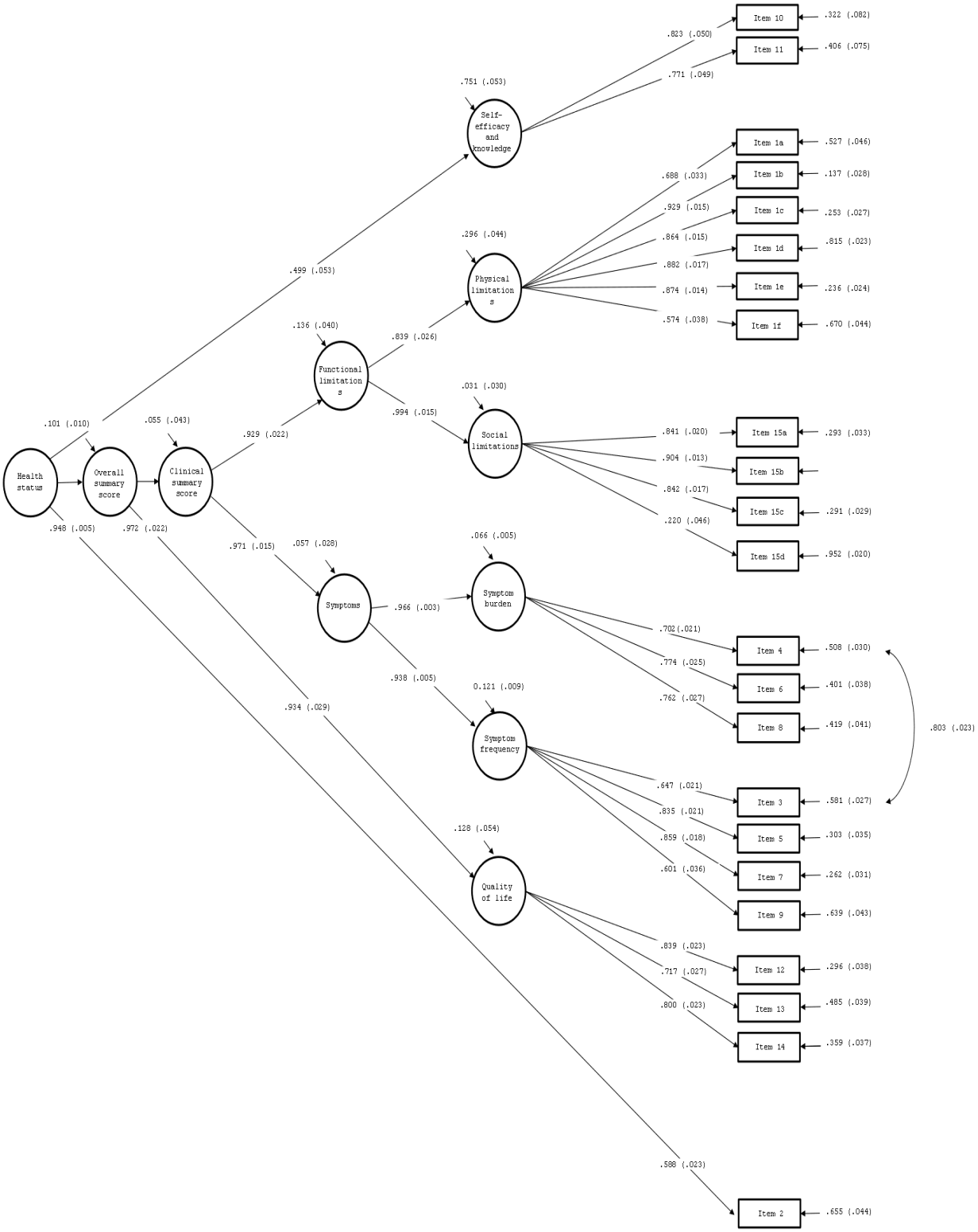


Figure 2: Confirmatory factor analysis of the empirical model of the Kansas City Cardiomyopathy Questionnaire (n=510).



of the relationship between the KCCQ score and the constructs of interest. When the different KCCQ scores were analyzed in relation to EF, NYHA class, SF-12 MCS/PCS, we found significant positive correlations ranging from 0.20 to 0.64 (p = 0.01). When we examined the relationship between the KCCQ domain of self-efficacy and knowledge and the self-care confidence scale, we found a significant positive correlation at 0.51 (p = 0.01).

Measurement invariance

When measurement invariance was tested on the theoretical model, we found that the overall scale was fully invariant across those with preserved vs those with low ejection fraction (Table 5). Invariance testing conducted on the empirical model indicated that full scalar invariance was achieved. Strict invariance could not be tested because the models failed to converge.

Table 4. Correlations between the score of the Kansas City Cardiomyopathy Questionnaire and other variables

KCCQ domains	EF	NYHA	SC confidence	SF-12 MCS	SF-12 PCS	HAD anxiety	HADS depression	HFSPS Total score
Physical limitations	0.257**	-0.478**	-	0.409**	0.605**	-0.368**	-0.448*	-0.572**
Symptom frequency	0.169**	-0.341**	-	0.442**	0.487**	-0.405**	-0.368	-0.672**
Symptom burden	0.291**	-0.421**		0.425**	0.512**	-0.413**	-0.432**	-0.584**
Symptom stability	0.62	-0.269**	-	0.254**	0.300**	-0.300**	-0.300**	-0.514**
Self-efficacy and knowledge	-	-	0.505**	0.441**	0.410**	-0.411**	-0.487**	-0.468**
Quality of life	0.194**	-0.415**	-	0.554**	0.548**	-0.492	-0.531**	-0.619**
Social interference	0.205**	-0.462**	-	0.600**	0.267**	-0.422**	-0.503**	-0.599**
Overall summary domain	0.252**	-0.494	-	0.638**	0.521**	-0.470**	-0.527**	-0.671**
Clinical summary score	0.277*	-0.483**	-	0.468**	0.616**	-0.433**	-0.475**	-0.652**

Legend. EF, ejection fraction; NYHA, New York Heart Association; SC, Self-care; SF-12, short form 12; MCS, mental component summary score; PCS, physical component summary score; HADS, Hospital Anxiety and Depression Scale, HFSPS, Heart Failure Somatic Perception scale. **, correlations are significant at p=0.01.

Table 5. Measurement invariance fit indices of the Kansas City Cardiomyopathy Questionnaire between patients with preserved (n=158) and reduced ejection fraction (n=321).

Theoretical model	Chi2	p	df	RMSEA	RMSEA (95%CI)	CFI	ΔCFI	ΔRMSEA
Configural invariance	1,012.160	<0,001	438	0.074	(0.068 – 0.080)	0,916	-	
Metric invariance	1,041.590	<0,001	461	0.073	(0.067 – 0.078)	0,915	-0,001	-0,001
Scalar invariance	1,098.092	<0,001	484	0.073	(0.067 – 0.078)	0,910	-0,005	0.000
Strict invariance	1,151.243	<0,001	507	0.073	(0.067 – 0.078)	0,906	-0,004	0.000
Empirical model	**Chi2**	**p**	**df**	**RMSEA**	**RMSEA (95%CI)**	**CFI**	**ΔCFI**	**ΔRMSEA**
Configural invariance	1,064.454	<0.001	451	0.075	(0.070 – 0.081)	0.910	-	-
Metric invariance of the indicators	1,061.914	<0.001	460	0.074	(0.068 – 0.080)	0.912	0.000	-0.001
Scalar invariance of the indicators	1,123.436	<0.001	482	0.075	(0.069 – 0.080)	0.906	-0.006	0.001
Strict invariance of the indicators	1,188.826	<0.001	503	0.075	(0.070 – 0.081)	0.899	-0.007	0.000
Metric invariance of the second order factors	1,185.866	<0.001	507	0.075	(0.069 – 0.080)	0.901	0.002	0.000
Metric invariance of the third order factor	1,189.083	<0.001	509	0.075	(0.069 – 0.080)	0.900	-0.001	0.001
Metric invariance of the fourth order factor	1,190.446	<0.001	511	0.075	(0.069 – 0.080)	0.900	0.000	0.000
Metric invariance of the fifth order factor	1,201.508	<0.001	514	0.075	(0.069 – 0.080)	0.899	-0.001	0.000

Legend. $\chi 2$, chi square; CFI, comparative fit index; CI, confidence interval; SRMR, standardized root mean square residual; TLI, Tucker-Lewis Index; RMSEA, root mean square error of approximation; df, degree of freedom; p, p-value. *The means of the factors were released in the group with reduced ejection fraction and were not significant.

Note. To verify the metric invariance of the first indicator, the intercepts of the factors were fixed to zero in the empirical model; thus, scalar invariance of the factors was verified. Strict invariance of the latent factors could not be tested due to convergence problems

DISCUSSION

The aim of this study was to investigate the psychometric properties of the KCCQ-23 in an Italian sample of patients with HF, by gaining new insights into its factorial structure, convergent validity, internal consistency, test-retest reliability, and measurement invariance. The results are noteworthy because, to our knowledge, this is the first time a rigorous psychometric assessment of this scale has been conducted.

In a first step, we examined the factorial validity of the KCCQ-23 by testing both a theoretical and an empirical model, following Green, et al.[8] and Spertus, et al.[39]. We employed a confirmatory factor analytic approach, which allowed us to conclude that both the underlying theoretical and empirical structures of the KCCQ-23 significantly explain the covariation among the items of the scale.

Factorial validity

We initially found not completely satisfactory models, which improved after correlating the error covariances of items 3 and 4. This covariance is plausible because these items are all related to information regarding feet swelling; moreover, a proximity effect may also have occurred given the similar semantic content. Future studies should examine the content of these items and assess the possible presence of conceptual redundancy. We also found that item 15d, measuring the intimate relationships with loved ones, had a factor loading below the standard of 0.30, even though significant. This may indicate either that this item measures social limitation insufficiently, or a broader and complex aspect of this domain[45]. It is likely that this item, which investigates the level of "intimate relationships with loved ones" taps more into mutuality and love aspects rather than social participation per se. We chose not to eliminate it from the scale, but we recommend further psychometric testing. Should this loading be confirmed in other studies, this item could simply be deleted from the scale, which has essentially been done in the short form of the KCCQ[46]. The fact that also the "empirical" model was tenable was somewhat surprisingly; actually, this structure was derived from proper aggregation of specific items and related factors for deriving useful summary scores and help interpretability. This process would not necessarily imply that these domains could accurately explain the covariance of the items, which was instead our case.

Convergent validity

In a second step, we confirmed the convergent validity of the KCCQ-23, by finding significant correlation coefficients with conceptually related constructs. This is in line with the broad available evidence indicating consistent associations between more severe heart failure symptoms and poorer clinical, physical, and psychosocial constructs[47,48,49]. For the first time after Creber, et al. (13), we were able to confirm the convergent validity of the KCCQ with the self-care confidence scale. This correlation is not surprising because consistent with Bandura's definition[50], both these constructs capture the perceived capability to perform a target behavior, or in this case, the management of the heart failure when symptoms get worse.

Internal consistency

In a third step, we confirmed that the items measuring each domain have satisfactory internal consistency. This finding is further corroborated by the findings that the domains of functional limitations, symptoms, clinical summary, and overall summary are multidimensionally reliable, which justifies the use of composite scores. To our knowledge, this approach to multidimensional reliability has never been used so far, which has always raised doubts about the appropriateness to use composite scores for this measure, especially in clinical trials. Moreover, previous validation studies of the KCCQ-23 have always measured its internal consistency with Cronbach's alpha, but this coefficient can be used only when the indicators of the scale equally load onto their domains (i.e., tau equivalence property), which was never the case. Thus, the use of Omega in this study leads to coefficients that are unbiased by the unequal factor loadings of this scale.

Measurement invariance

In the final step of our analysis, we confirmed that the KCCQ-23 is invariant across patients with reduced and preserved ejection fraction. This result was confirmed both for the theoretical and empirical model, indicating that the two groups used an identical cognitive framework when responding to the items, used the Likert scale identically, and responded to them in an identical way. Achievement of measurement invariance, such as in this study, is important because it means the scores derived from the KCCQ-23 can be used to quantitatively compare

the two groups.

Limits and strengths

This study has several limitations: first, the results are from a convenience sample, which was recruited in a single country, and based on the exclusion/inclusion criteria of the MOTIVATE-HF study, which only included symptomatic and not cognitively compromised patients. This may affect generalizability to other cultural contexts and to those who are asymptomatic and more cognitively impaired. Second, temporal stability of the KCCQ cannot be claimed due to the nature of the data; thus, future longitudinal studies may specifically address this aspect of reliability. Third, measurement invariance testing on the empirical model had convergence problems probably due to the limited size determined by sample splitting; this led to the impossibility to test strict invariance of the empirical model. We do not know how this issue may have altered our findings, but it is unlikely that this would significantly alter our conclusions, given that strict invariance regards residual or uniqueness testing, which is not considered part of the measurement model. The strengths of this analysis include the multicenter nature of the data, which helped to compensate for the shortcomings of the convenience sampling, and the rigor of the psychometric tests conducted.

CONCLUSION

The number of patients with HF is steadily increasing worldwide, and promoting their health status is essential for a better patient-centered approach. Consequently, valid and reliable measures are increasingly needed to capture the various facets of HF-specific health. By following a rigorous approach, this study confirms the satisfactory psychometric properties of the KCCQ-23 in the Italian context. Therefore, this tool can be confidently used in clinical practice and research to investigate the health status, quantitatively compare this construct and related domains in patients with reduced and preserved ejection fraction, and ultimately improve health outcomes.

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