

Translation and Cross-Cultural Adaptation, Reliability and Validation Study of the Persian Version of Kansas City Cardiomyopathy Questionnaire

Hassan Tamartash¹, Behrouz Attarbashi Moghadam², Kianoosh Hosseini³, Shiva Musavi²

¹ Department of Physiotherapy, School of Medical Sciences, Tarbiat Modares University, Tehran, Iran

² Department of Physiotherapy, School of Rehabilitation, Tehran University of Medical Sciences, Tehran, Iran

³ Shariati Hospital, Tehran University of Medical Sciences, Tehran, Iran

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Abstract- The Kansas City Cardiomyopathy Questionnaire (KCCQ) has been developed to measure the health status of Congestive heart failure (CHF) patients. This study aimed to translate KCCQ into a Persian version and assess its validity and reliability. We used a forward-backward procedure to translate the questionnaire. In a cross-sectional study, 150 CHF patients and 50 healthy subjects over 30 years old were selected to assess the reliability and construct validity of the instrument. The face and content validity were used for the questionnaire's validity. The validity was examined on a population of patients with CHF using the Persian version of the Minnesota Living Heart Failure Questionnaire (MLHF) health survey. Calculation of the Intraclass correlation coefficient (ICC) and Cronbach's alpha was done to evaluate the questionnaire's reliability. Test-retest reliability was examined by re-administering the KCCQ after 2 weeks. Test-retest results demonstrated that the Persian version has excellent reliability (ICC for all domains was higher than 0.93, $P \leq 0.000$). Internal consistency was found by Cronbach's alpha to be 0.86 for the clinical summary and 0.87 for the overall summary, respectively. Also, the correlation between the components of KCCQ and MLHQ showed satisfactory construct validity. Good Pearson's Correlation Coefficient was seen between KCCQ and MLHF ($r = -0.44$, $P \leq 0.000$ for the clinical summary; $r = -0.45$, $P \leq 0.000$ for the overall summary). Analysing the data from 50 healthy persons and 150 patients were shown that the Persian version of KCCQ has acceptable discriminate validity for all domains except self-efficacy. The Persian version of the KCCQ had satisfactory reliability and validity for assessing health-related quality of life status for Iranian CHF patients.

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Introduction

Heart failure (HF) is a clinical syndrome caused by a structural and/or functional cardiac abnormality that is characterized by signs and symptoms such as breathlessness, ankle swelling, and fatigue (1). HF is a public health concern worldwide, with a prevalence of 1-4% in most European countries (2), the prevalence and incidence increasing progressively with age. In the US, the incidence of HF is reported to be 10 per 1000 after 65 years of age (3). Congestive heart failure (CHF) is a

congestive disease that affects the health-related quality of life (HRQoL) of people with the disease. The concept of "quality of life" includes the physical, psychological, and social dimensions of a patient's life and feelings. Studies have shown that CHF affects the quality of life for patients to varying degrees (4).

To diagnose and control Congestive Heart Failure (CHF), functional activities and Activities of Daily Living (ADL) should be examined (5). Recent studies on HRQoL provide important information about the assessment of heart failure patients and how to improve

Corresponding Author: B. Attarbashi Moghadam

Department of Physiotherapy, School of Rehabilitation, Tehran University of Medical Sciences, Tehran, Iran
Tel: +98 9121883095, E-mail address: attarbashi@tums.ac.ir

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treatment strategies (6). HRQoL assessments examine patients' situations using Generic and specific tools. Generic tools for General information and Specific tools to closely examine changes in different domains (7). Researchers are increasingly interested in patient-based assessments. Because methods such as electrocardiographic signal, echocardiography, measuring heart rate, and genetic evaluation of family members due to lack of patient information, cost, and unavailability are less considered (4,8-10). The most authoritative specific tools for assessing the quality of life of patients with CHF include the MLHF (Minnesota Living with Heart Failure Questionnaire) and KCCQ (Kansas City Cardiomyopathy Questionnaire) questionnaires. Has also been reviewed and approved (11). The purpose of this study was to translate cultural adaption and calculate the validity and reliability of the Persian version of the KCCQ to assess the quality of life of Iranian patients with CHF.

Materials and Methods

This is a cross-sectional study. Patients with CHF have been involved in the study, which was confirmed by a cardiologist. Also, those who were less than 30 years old or had mental disorders or had a malignant disease or did not know the Persian language, or had undergone changes in their treatment plan, were excluded from the study.

Quality of life assessment tools

The MLHF is a valid self-governing questionnaire. In this study, the Persian version of the MLHF questionnaire, including 21 items, was used in the physical, emotional, social, and mental fields (11). This questionnaire examines the effects of heart failure on physical and social functioning, including walking, climbing stairs, housekeeping, need to rest, working, socializing with family and friends, sex, eating, and mental functioning. Emotions such as memory, disturbing behavior, and disturbing others are also assessed. Scores between 0 (without affecting the quality of life) to 5 (with maximum impact on the quality of life) are chosen by patients to show how much each of the 21 areas mentioned in the questionnaire affects their quality of life (11-17).

The KCCQ is a self-administered HRQL questionnaire specific to patients with CHF. It comprises 23 items in seven domains: physical limitation (Question 1); symptoms, with domains for change over time (question 2), frequency (Questions 3,5,7,9), and severity

(Questions 4,6,8); self-efficacy and knowledge (Questions 10,11); quality of life (question 12,13,14) and social interference (question 15). A Likert-type scale ranging from 1 to 5, 6, or 7 points is used for the responses. Each domain score ranges from 0 to 100 (100 is the best, and 0 is the worse quality of life). There are two summary scores: the score, which is derivative by summing the individual scores on the physical limitation and symptoms domains (i.e., total symptom score) with the modification of symptoms over time excluded as the clinical summary, and the overall summary score which is calculated by summing the clinical summary score and the quality of life and social interference scores (18).

Translation procedure

The MAPI protocol (www.mapi-research-inst.com) was used as a procedure for translation of the KCCQ questionnaire.

First stage: Initial translation of the questionnaire

In the first stage, two translators who were fluent in English and Persian translated the questionnaire into Persian. In this phase, each translator independently translated the questions of the source questionnaire. The translators and researchers then discussed the content of the translation, and a compound version was obtained. In this stage, the goal was to get a literal translation of the source questionnaire in a simple, conversational way. The researcher was also contacted by the author of the source questionnaire to eliminate lexical errors. In this stage, the initial translation or forward translation of the questionnaire was the result.

Second stage: Secondary translation of the questionnaire

In the second stage, the last version of the Persian questionnaire was translated based on the source language for the secondary translation. Two translators who were fluent in Persian and English were assigned to re-translate the combined questionnaire, and by comparing them, a secondary translation or backward translation of the questionnaire was the result. In this stage, the translators did not have access to the source questionnaire. Meetings were also held between researchers and translators to find ambiguous statements and errors in the inventive type of the questionnaire. Finally, by comparing the version that was translated based on the source language with the source questionnaire and eliminating the problems in it, a secondary translation into Persian was the result.

Third stage: Preparing the final version of the questionnaire

In this stage, face validity was used to indicate whether the questionnaire could achieve its goals. The main purpose of this stage was to measure the validity of the questionnaire's questions by the patients to determine the conceptual level of the questions and to correct the ambiguous words in the questionnaire. The secondary version of this questionnaire was completed with 30 individuals suffering from congestive heart failure in Iran. In the third stage, the interview was conducted in a face-to-face manner with patients. Here the researcher assessed the problems that the patient faced in understanding the questions. The researcher also used suggestions made by translators and patients to correct ambiguous questions in the questionnaire. In the third stage, a final version of the questionnaire was prepared.

Reliability

Reliability is defined as the ability of a test to "yield the same results on repeated trials under the same conditions" (19). To determine the test-retest reliability, a KCCQ was given to a random sample of 30 patients from 150 patients who were percipients in the study. They were asked to complete the questionnaires at 2-week intervals and return them immediately after completion. Test-retest reliability was assessed by the intra-class coefficient (ICC) (20).

Validity

Validity relates to the ability of a questionnaire to measure the outcome parameter of interest. Criterion validity refers to the comparison of the new test with the "gold standard." The scores of the 4 domains of the MLHF were used to assess the convergent and divergent validity of the 23-item KCCQ. Construct validity was evaluated using Pearson correlation coefficients between the 23-item KCCQ and the 21-item MLHF. To conclude

the validity of the KCCQ questionnaire structurally, the relationship between the results of the Persian version of the questionnaire and the results of the MLHF questionnaire was evaluated. Then to determine test-retest reliability, the KCCQ questionnaire was completed by 30 patients twice in two weeks. To assess discrimination validity, 50 healthy persons also completed the KCCQ questionnaire.

Also, to define the validity of the Persian questionnaire in terms of content, the views of cardiologists about the capability of this Persian questionnaire in relation to determining the disability of Iranian patients with CHF were collected.

Statistical analysis

Cronbach's alpha test was used to determine the Internal Consistency, Intraclass-Correlation Coefficient test was used for test-retest reliability, Pearson's Correlation Coefficient test was used to determine the construct validity, and an independent t-test was used to evaluate the discrimination validity of the Persian version of the questionnaire. It should be noted that all statistical analyses of the present study were performed using SPSS software version 16, and also, the P for all tests was less than 0.05.

Results

In a cross-sectional study, 150 CHF patients and 50 healthy subjects over 30 years old were nominated to evaluate the reliability and construct validity of the questionnaire. The face and construct validity were used for the questionnaire validity. The patients' features are summarized in table 1. The study sample included 150 patients: 53 men and 52 women, with a mean age of 60.57 years.

Table 1. Demographic data of participants

Age		Min =36y	Max =75 y	Mean (SD)=55.38(±8.60)
Gender	Men	N =83	55.33%	--
	Women	N =67	4.66%	--
Education	High school	N =25	16.66%	--
	Diploma	N =31	20.66%	--
	Diploma to bachelor	N=47	31.33%	--
	Masters and higher	N =47	31.33%	--

SD= Standard Deviation

Acceptability

After the participants answered all the questions of

the KCCQ questionnaire, the surveys were conducted to correct the questions whose meaning was unclear. Each

question was appraised separately, and in cases where more than 15% of individuals voted for the intangible rewrite of a certain question, that question was reevaluated. For this reason, changes were made in the translation of question 14 of the KCCQ to better understand the meaning of the phrase "felt discouraged or down."

Internal consistency

After the evaluation of Cronbach's alpha in various domains of the KCCQ, the results showed that the internal consistency level of KCCQ was at a high level. These results can be seen in table 2.

Table 2. Internal consistency using cronbach's alpha

KCCQ Domain	Cronbach's alpha
Physical Limitation	0.80
Symptoms	0.88
Self-Efficacy	0.66
Quality of Life	0.76
Social Interference	0.75
Clinical Summary	0.86
Overall Summary	0.87

Test-retest reliability

After two weeks, the Intraclass correlation coefficient (ICC) test for the KCCQ had to 0.95, which

indicates the high repeatability of the Persian version of KCCQ. The results can be seen in Table 3.

Table 3. Intraclass correlation coefficient (ICC) test results after two weeks

ICC	95% confidence interval	
	Lower Bound	Upper Bound
0.95	0.93	0.97

Construct validity

The results of Pearson's correlation coefficient test can be seen in Table 4. In the KCCQ, the total score of question 1 in the domain of physical limitation, questions 2, 3, 4, 5, 6, 7, 8, and 9 in the domain of symptoms, questions 10 and 11 in the domain of self-efficacy, questions 12, 13 and 14 are in the domain of quality of life and question 15 is in the domain of social

interference. Also, the total score of the questionnaire is reported in two domains: Clinical Summary (total scores of Physical Limitation and Symptoms) and Overall Summary (total scores of Clinical Summary, Quality of life, and Social Interference). The degree of correlation obtained from the results of these tests:

$0.81 \leq r \leq 1$: Excellent correlation, $0.61 \leq r \leq 0.80$: Very good correlation, $0.41 \leq r \leq 0.60$: Good correlation.

Table 4. Coefficient of correlation (r) in MLHF and KCCQ questionnaires

KCCQ	MLHF		
	Emotional	Physical	total
Physical Limitation	-0.383	-0.448*	-0.448
Sig.	0.000	0.000	0.000
Symptoms	-0.325	-0.456*	-0.411
Sig.	0.000	0.000	0.000
Self-Efficacy	-0.302	-0.347	-0.309
Sig.	0.000	0.000	0.000
Quality of life	-0.320	-0.384	-0.354
Sig.	0.000	0.000	0.000
Social Interference	-0.385	-0.426*	-0.411
Sig.	0.000	0.000	0.000
Clinical Summary	-0.367	-0.475*	-0.448
Sig.	0.000	0.000	0.000
Overall Summary	-0.387	-0.482*	-0.455
Sig.	0.000	0.000	0.000

Discriminate validity

Comparing the scores of the MLHF questionnaire of 50 healthy subjects and CHF patients, the independent t-test was used. The results represent a high discriminate

validity of the MLHF questionnaire to distinguish between a healthy subject and a CHF patient, and no significant correlation has been shown between groups (Table 5).

Table 5. Independent T-test results between the healthy group and patient group

Domain	Correlation	T	P
Physical Limit	-0.05	15.57	0.731
Symptoms	0.02	23.27	0.857
Self-Efficacy	-0.15	-7.159	0.060
Quality of life	0.23	9.137	0.105
Social Interference	0.71	17.586	0.288
Clinical Summary	0.03	21.370	0.802
Overall Summary	0.30	20.220	0.060

Factor analysis

The results of the exploratory factor analysis

categorized the questions into four groups (Table 6).

Table 6. Factor analysis results for KCCQ questionnaire questions

Question	Component			
	1	2	3	4
1a	0.468	0.350	0.010	0.489*
1b	0.460	.4730	.0860	0.545*
1c	0.698*	0.214	0.011	0.362
1d	0.698*	0.229	0.101	-0.019
1e	0.719*	0.114	0.245	0.247
1f	0.085	0.215	0.186	0.807*
Q2	0.527*	0.344	0.319	0.094
Q3	0.610*	-0.051	0.475	0.333
Q4	0.551*	0.497	0.080	-0.013
Q5	0.323	0.518*	0.282	0.319
Q6	0.645*	0.204	0.137	0.153
Q7	0.616*	0.423	0.351	0.089
Q8	0.634*	0.050	0.339	0.207
Q9	0.582*	0.345	0.286	0.132
Q10	0.132	0.096	0.811*	0.270
Q11	0.310	0.483	0.512*	0.230
Q12	0.567*	0.302	0.420	0.103
Q13	0.273	0.286	0.701*	-0.196
Q14	0.279	0.502	0.548*	0.156
15a	0.682*	0.346	0.316	-0.088
15b	0.357	0.573*	0.419	0.231
15c	0.066	0.742*	0.156	0.164
15d	0.281	0.689*	0.133	0.107

Discussion

The Persian version of the KCCQ questionnaire is an accurate, specific tool for measuring the quality of life of patients with CHF. This questionnaire has been translated into other languages (6,21). The Persian version of the KCCQ questionnaire was translated and equated using systematic methods. In the following, the

studied factors, such as Validity and Reliability, reported very good results and because very few changes were made in the Face Validity stage to make the questions more understandable. The Persian version of KCCQ showed very high feasibility. The questionnaire quantifies symptoms, physical limitations, social functioning, a patient's sense of self-efficacy, and overall quality of life. In the original work, the KCCQ (7) was

found to be more sensitive in detecting clinical changes than the MLHF or the Short Form-36 (22). In fact, in that study, the increased sensitivity to clinical change was summarized by the results: the KCCQ physical limitation scale's responsiveness was 3 times higher than the corresponding domains of the MLHF and Short Form-36. Other authors have also found that the MLHF's ability to differentiate in symptom severity was good except in the most compromised patients (23).

According to the calculation of Cronbach's alpha in different areas of the Persian version of the KCCQ, the values obtained 0.86 for Clinical Summary, and 0.87 for the overall summary indicated the high reliability of the Persian version of the KCCQ questionnaire. It should be noted that Cronbach's alpha for the original version of the questionnaire was 0.93 for the clinical summary and 0.95 for the overall summary (5). Also, the value of 0.95 Intraclass correlation coefficient indicates the high test-retest reliability of the Persian version of KCCQ after two weeks of follow-up. Except in the domain of self-efficacy, where the questions in this domain are generally stated and have little to do with the individual's illness, and most of the person's general information about the disease is examined.

The results of the analysis factor, unlike the main questionnaire, categorized the questions into four subgroups. The high value of the correlation coefficient between different domains of the Persian version of the KCCQ questionnaire indicates its appropriate construct validity. Also, this value is good between the related domains of KCCQ and MLHF. It was reported that this indicates that both questionnaires examine the same subject. In all domains between KCCQ and MLHF, a good correlation coefficient was obtained except in the areas of Self efficacy and quality of life, which resulted in less-than-good results. It seems that the duality of the MLHF questionnaire and its focus on the physical and emotional domains can justify this issue because this questionnaire, unlike the KCCQ questionnaire, does not have a specific domain to assess the quality of life and self-efficacy. Self-efficacy separately by KCCQ can be considered an advantage over MLHF.

It should be noted that one of the limitations of this study is the lack of a standard and appropriate reference to check the validity of some domains in KCCQ. Another limitation of this study was the difference in the time frame of the two questionnaires. The KCCQ questionnaire asks the patient to answer questions according to his condition in the past two weeks, while the MLHF asks the patient to consider his condition in the last month. Most researchers believe that it is better

to ask the patient to answer questions based on the circumstances of the last few days rather than the circumstances of the past few weeks (18).

The assessment features of the Persian version of the KCCQ are consistent with the innovative form of the questionnaire. The Persian version of KCCQ is a useful tool in assessing the quality of life of CHF patients in daily clinical work and research work due to its shortness and simplicity in implementation. This study showed that the Persian version of KCCQ is reliable and valid tool, and in accordance with Iranian culture in assessing the quality of life of patients with CHF.

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