The Kansas City Cardiomyopathy Questionnaire: Italian translation and validation

Daniela Miani, Patrizia Rozbowsky*, Dario Gregori*, Laura Pilotto**, Maria Cecilia Albanese, Claudio Fresco, Paolo Maria Fioretti

*Department of Cardiovascular Sciences, S. Maria della Misericordia Hospital, *Research Foundation IRCAB, **Health Promotion/Health Education, Azienda per i Servizi Sanitari "Medio Friuli", Udine, Italy*

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Heart failure; Quality of life.

Background. **Several studies have demonstrated that patients affected by heart failure have a compromised quality of life and, in the last few years, "health-related quality of life" has become an important outcome indicator for the evaluation of heart failure treatment and a basis for the improvement of its strategies.**

Methods. **The translation into Italian of the Kansas City Cardiomyopathy Questionnaire (KCCQ), a new, 23 item, disease-specific health status instrument for patients with congestive heart failure, and its subsequent validation by asking 50 consecutive patients in our heart failure outpatient clinic to answer it. The KCCQ was compared to the "Minnesota Living with Heart Failure Questionnaire" (MLHF).**

Results. **The Italian version of the KCCQ correlates well with the MLHF for all domains with the exclusion of symptom stability score and MLHF emotional domain. However, the KCCQ, due to its multiple domains, provided more detailed information about the patients' status, and identified the more compromised ones.**

Conclusions. **The KCCQ appears to be a valid and reliable instrument for the assessment of a patient's quality of life and the degree of limitations imposed upon him/her by the disease. When compared to the MLHF, the KCCQ, however, is somewhat more sensitive in identifying more compromised patients. This capacity could be advantageously used for the identification of clinical changes in future trials and lead to a better planning of new therapeutic interventions.**

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Address:

Dr.ssa Daniela Miani

Dipartimento di Scienze Cardiovascolari
A.O. S. Maria della Misericordia
Piazzale S. Maria della Misericordia, 11
33100 Udine
E-mail: miani.daniela@aoud.sanita.fvg.it

Introduction

The prevalence of symptomatic heart failure in the European population ranges from 0.4 to 2.0%[1]. Heart failure is one of the most frequent causes of hospitalization in Italy being the second medical DRG in 2000 (www.ministerosalute.it). Although decreasing the mortality and improving the prognosis are generally considered major endpoints of treatment, in the last few years "health-related quality of life" has become an important outcome indicator for the evaluation of heart failure treatment and a basis for the improvement of its strategies[2,3]. In fact, several studies have demonstrated that patients affected by heart failure have a compromised quality of life[4-6].

There is substantial agreement in considering quality of life a multidimensional phenomenon, which can be analyzed through different perspectives: the physical, the psychological, the social, and the economic well being or status of patients.

Health-related quality of life assessments are conducted using generic or disease-specific instruments: the specific questionnaires allow the measurement of the significant clinical domains, and are sensitive in identifying clinical changes. However, because these tests evaluate domains that also reflect a patient's cultural and ethnic background and are generally worded using idiomatic expressions typical of one's own language and environment, it may be that their application to another culture affects the results and, in particular, the interpretation of data.

Therefore, the main objective of this study was the translation into Italian and the subsequent validation of the Kansas City Cardiomyopathy Questionnaire (KCCQ)[7].

Methods

The KCCQ is a new, 23 item, disease-specific health status instrument for pa-

tients with congestive heart failure, which measures symptoms (frequency, severity and recent change over time), physical limitations, social functioning, a patient's sense of self-efficacy and quality of life[7].

The symptom dimension measures how many times the symptoms of heart failure, such as shortness of breath, fatigue, swelling of the extremities, etc., occurred in the preceding 2-week period and whether they have undergone any changes.

The physical limitation dimension measures how much the heart failure symptoms have limited some of the patient's daily activities in that same period of time.

The social functioning dimension aims to analyze how much heart failure affects his/her lifestyle.

Self-efficacy and knowledge measure the capacity of the patient to understand how to prevent worsening of the symptoms and what to do if this happens.

Finally, the quality of life dimension assesses a patient's perception about his/her enjoyment of life or the discouragement due to the disease.

The linguistic adaptation was performed in collaboration with the MAPI Research Institute (www.mapi-research-inst.com) following a standardized protocol. The linguistic validation is a linguistically validated translation, which allows its assessment in the pertinent target countries: it is conceptually equivalent to the original questionnaire, ensuring the cross-cultural equivalence across translations.

This linguistic validation follows several steps. In our process, after the production of two independent translations by two professional translators, native speakers in the target language, a professional English native translator produced the backward translation. Then, the original version, the developed Italian version and the back translation were compared discussing any discrepancy with expert cardiologists and psychologists. A cognitive debriefing, consisting in interviews with the patients conducted by trained psychologists, was done to test the interpretability of the resulting version. Finally, an international harmonization, consisting in a comparison of the target language version with the others and with the original one, was done to ensure conceptual agreement. The MAPI Research Institute was responsible for quality control.

The Minnesota Living with Heart Failure Questionnaire (MLHF) is a 21-item instrument, which uses a 6-point response scale to assess a patient's emotional and physical dimensions, and produces a general total score[8]. Since its inception in 1987, it has become one of the most frequently used questionnaires to evaluate a heart failure patient's well being. For this reason, in the validation process, the final Italian version of the KCCQ was administered along with the MLHF questionnaire to a sample of 50 consecutive patients attending the heart failure clinic at our institution. This is a tertiary care outpatient clinic and patients belong to all socio-economic and cultural backgrounds. Patients had to be able to understand and fill up the questionnaire.

Statistical analysis. Data for both the KCCQ and MLHF variables were transformed in order to obtain the same range and interpretation[9]. The scores were standardized on a scale of 0-100, 100 indicating a higher level of functioning, and the direction was redefined to guarantee a homogeneous interpretation. Specifically, with regard to the KCCQ, the stability score is a redefinition of item no. 7 of the questionnaire, according to the following scale: 0 = much worse; 50 = no change; 100 = much better. The symptom frequency score is a function of the mean of items 8, 10, 12, and 14. The symptom burden score is a mean of items 9, 11, and 13. The total symptom score represents the combination of the symptom frequency and symptom burden scores. The quality of life score is a mean of items 17, 18, and 19. The social limitation score is a mean of items 20, 21, 22, and 23. The self-efficacy domain is a mean of items 15 and 16. The summary score is a mean of the physical and symptom scores.

The scoring system is available upon request at the IRCAB Foundation (www.insiel.net/ircab).

Correlations between the two scales were computed using a non-parametric Spearman's ρ. Data have been described using appropriate summary statistics (median, first and third quartile for continuous variables and percentages and counts for discrete variables). Spearman's correlations between the Kansas overall summary score and MLHF were computed for several subgroups, according to major clinical variables. Differences in Kansas and Minnesota domains with respect to NYHA levels were evaluated using a K-independent sample non-parametric median test. The Spearman's correlations between each pair of Minnesota and Kansas domains were also computed.

Significance was set at the 0.01 and 0.05 levels. All calculations were performed using the SPSS 7.0 statistical package.

Results

See Appendix for the Italian version of the KCCQ.

The patients' characteristics are summarized in table I. The study sample included 50 patients, 40 men (80%) and 10 women (20%) with a mean age of 63 years. Only 8% of the patients were in NYHA class I, whereas 52% were in NYHA class II (26 patients), and 40% in NYHA class III (20 patients). The median ejection fraction was 30%. The etiology was ischemic in 40% of cases, dilated in 36%, and valvular in 24%. The majority of patients had been hospitalized during the previous year (77%). ACE-inhibitor therapy was administered in 88% of cases and beta-blockers in 56%.

A comparison between the standardized total scores is summarized in table II.

The Italian version of the KCCQ demonstrates clear changes in the patients' quality of life for the different NYHA classes. It correlates well with MLHF for the

Table I. Patient characteristics.

Age (years)	63 (56; 69)*
Gender	
Male	80% (n=40)
Female	20% (n=10)
NYHA class	
I	8% (n=4)
II	52% (n=26)
III	40% (n=20)
Ejection fraction	30% (23; 35)*
Etiology	
Ischemic	40% (n=20)
Valvular	24% (n=12)
Dilated	36% (n=18)
Previous hospitalizations	77% (n=37)
Therapy	
ACE-inhibitors	88% (n=44)
Beta-blockers	56% (n=28)

n = number of subjects with valid data for the variable. * median (I quartile, III quartile).

Table II. Comparison between standardized total scores*.

	MLHF	KCCQ	Correlation
Ejection fraction			
≤ 30%	81 (51; 90)	60 (43; 79)	0.728
> 30%	87 (64; 91)	70 (46; 78)	0.848
NYHA class			
I-II	90 (70; 92)	72 (54; 87)	0.732
III	73 (47; 81)	46 (34; 58)	0.588
Etiology			
Ischemic	84 (60; 90)	57 (41; 81)	0.755
Valvular	82 (43; 92)	68 (42; 90)	0.812
Dilated	85 (60; 90)	70 (45; 73)	0.787
Gender			
Male	82 (48; 90)	63 (44; 81)	0.848
Female	87 (78; 92)	60 (42; 78)	0.471
ACE-inhibitors			
Yes	87 (64; 91)	67 (45; 83)	0.740
No	38 (31; 78)	41 (24; 72)	0.886
Beta-blockers			
Yes	87 (60; 90)	70 (42; 78)	0.716
No	81 (47; 91)	57 (44; 83)	0.778
Previous hospitalizations			
No	87 (47; 91)	71 (56; 83)	0.739
≥ 1	71 (56; 83)	57 (40; 78)	0.680
Overall	85 (51, 90)	63 (44; 78)	0.770

KCCQ = Kansas City Cardiomyopathy Questionnaire; MLHF = Minnesota Living with Heart Failure Questionnaire. * median (I quartile, III quartile).

ejection fraction, NYHA class I, II and III, for the etiology, the therapy and previous hospitalization parameters. The correlation is lower for women. The KCCQ correlates better with MLHF for NYHA class I and II than for NYHA class III. MLHF seems to overestimate the quality of life as seen by the high total scores (Table II). Table III shows how the higher the NHYA class, the lower is the score for quality of life. The symptom stability score and self-efficacy scores do not change significantly for the various NYHA classes. The total symptom scores (frequency and burden) are statistically significant for the different NYHA classes. The social limitation domain has the lowest score (35), pointing out that the sickest patients are the ones more socially limited. In table IV all domains for Kansas and Minnesota correlate with each other except for the Kansas symptom stability scores, which do not correlate with the MLHF emotional domain. This means that the emotional status is not strictly dependent on the symptoms' stability. Finally, there is a high correlation between the two total scores for the different NYHA classes (Table III).

Discussion

This study reports on the translation into Italian and the subsequent validation of the KCCQ, a new, disease-specific, health-related quality of life instrument with a well-documented and already published, validity, reliability and responsiveness[7]. The questionnaire quantifies symptoms, physical limitations, social functioning, a patient's sense of self-efficacy and overall quality of life. In the original work[7] the KCCQ was found to be more sensitive in detecting clinical changes than the MLHF or the Short Form-36[10]. 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 ability to differentiate in symptom severity was good except in the most compromised patients[11].

In this study, the patients with the worst health status (NYHA class III) had the lowest correlation between KCCQ and MLHF. As reported in the literature[12,13], women generally have a worse quality of life than men, and this may account for the lack of correlation. The symptom stability score remains the same across the different NYHA classes and this could probably be due to how long the patient has been in that particular NYHA class.

According to the questionnaire's authors[14], the KCCQ summary score predicted, in a multivariate model, death and hospitalization for congestive heart failure patients with scores < 50 at 3 months and at 1 year. As can be seen in table II we also obtained similar scores for the more compromised patients such as those in NYHA class III.

As stated before, the Italian version of KCCQ correlates well with MLHF for all domains with the exception of symptom stability score and MLHF emotional domain. The two questionnaires also correlated well for ejection fraction, NYHA class, etiology, therapy, and hospitalization. However, KCCQ has more domains than MLHF; this is important because it can pro-

Table III. Correlation between NYHA classes and the Minnesota Living with Heart Failure Questionnaire and the Kansas City Cardiomyopathy Questionnaire domains.

	NYHA class I-II (n=30)	NYHA class III (n=19)*	Overall (n=49)*	p
Minnesota Living with Heart Failure				
Emotional score	92 (72; 100)	76 (68; 92)	88 (72; 96)	0.037
Physical score	92 (70; 97)	67 (35; 75)	82 (47; 95)	0.004
Total score	90 (70; 92)	73 (47; 81)	85 (51; 90)	0.000
Kansas City Cardiomyopathy Questionnaire				
Physical function domain	71 (54; 92)	50 (21; 70)	67 (46; 83)	0.057
Symptom stability score	50 (50; 75)	50 (25; 75)	50 (50; 75)	0.711
Symptom frequency score	92 (71; 100)	67 (29; 79)	79 (62; 96)	0.001
Symptom burden score	83 (67; 100)	67 (33; 93)	75 (58; 92)	0.037
Combined symptom score	85 (69; 98)	62 (32; 77)	77 (62; 94)	0.004
Quality of life score	75 (50; 92)	50 (50; 67)	67 (42; 92)	0.008
Social limitation domain	62 (31; 84)	35 (19; 50)	38 (31; 75)	0.029
Self-efficacy domain	75 (62; 100)	69 (50; 88)	75 (63; 100)	0.195
Clinical summary score	82 (67; 90)	55 (35; 65)	69 (53; 85)	0.002
Overall summary score	72 (54; 87)	46 (34; 58)	63 (44; 78)	0.000

n = number of subjects with valid data for the variable. * median (I quartile, III quartile).

Table IV. Correlation between the Minnesota Living with Heart Failure Questionnaire and the Kansas City Cardiomyopathy Questionnaire domains.

Kansas City Cardiomyopathy Questionnaire	Minnesota Living with Heart Failure		
	Emotional score	Physical score	Total score
Physical function domain	0.290*	0.472*	0.415*
Symptom stability score	0.185	0.363*	0.322*
Symptom frequency score	0.523*	0.593*	0.612*
Symptom burden score	0.531*	0.587*	0.606*
Combined symptom score	0.536*	0.605*	0.628*
Quality of life score	0.480*	0.493*	0.491*
Social limitation domain	0.319*	0.385*	0.442*
Self-efficacy domain	0.301*	0.202**	0.201**
Clinical summary score	0.430*	0.599*	0.578*
Overall summary score	0.471*	0.596*	0.609*

* correlation is significant at the 0.01 level (one-tailed); ** correlation is significant at the 0.05 level (one-tailed).

vide us with more detailed information about the status of our patients. In our present series, the patients had stable symptoms and they were self-sufficient and living in the community. A limitation in our study is that, since they were all outpatients, there were no patients in NYHA class IV. Another important difference between the two questionnaires is their time frame reference. KCCQ, in fact, asks about the patient's status during the last 2 weeks, whereas MLHF relies on a 1-month span. This last is longer than some authors have recommended, while others[15] even point out that asking about the last few days is better than asking about the past few weeks.

In conclusion, the KCCQ appears to be a valid and reliable instrument for the assessment of a patient's quality of life and the degree of limitations imposed upon him/her by the disease. The Italian version of KCCQ applied to our series has scores that correlate well with those of MLHF that now represents the actual gold standard. The KCCQ, however, is somewhat more sensitive to clinical changes. This capacity could be advantageously used for the identification of clinical changes in future trials and lead to a better planning of new therapeutic interventions.

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Appendix

Italian version of the Kansas City Cardiomyopathy Questionnaire
Questionario sullo scompenso cardiaco

Le seguenti domande si riferiscono al suo *scompenso cardiaco* e a come esso influisce sulla sua vita. Per cortesia legga e completi le seguenti domande. Non ci sono risposte giuste o sbagliate. Faccia una crocetta sulla risposta che meglio descrive la sua situazione.

1. Lo scompenso cardiaco influisce su persone diverse in modo diverso. Alcuni hanno difficoltà a respirare mentre altri si sentono stanchi. Per cortesia indichi quanto lo scompenso cardiaco (difficoltà a respirare o stanchezza) ha limitato la sua capacità di fare le seguenti attività nelle ultime 2 settimane.

Faccia una X su una casella per ciascuna riga

Attività	Estremamente limitato	Molto limitato	Moderatamente limitato	Poco limitato	Per niente limitato	Limitato per altre ragioni o non ho svolto l'attività
Vestirsi	☐	☐	☐	☐	☐	☐
Fare il bagno o la doccia	☐	☐	☐	☐	☐	☐
Camminare in piano per circa 100 metri	☐	☐	☐	☐	☐	☐
Fare piccoli lavori di giardinaggio o intorno alla casa, lavori domestici, portare la spesa	☐	☐	☐	☐	☐	☐
Fare una decina di scalini a piedi senza fermarsi	☐	☐	☐	☐	☐	☐
Affrettarsi o correre (come per prendere l'autobus)	☐	☐	☐	☐	☐	☐

2. Rispetto a 2 settimane fa i suoi sintomi di scompenso cardiaco (difficoltà a respirare, stanchezza o gonfiore alle caviglie) sono cambiati?
I miei sintomi dovuti allo scompenso cardiaco sono ...

Molto peggiorati	Un po' peggiorati	Non sono cambiati	Un po' migliorati	Molto migliorati	Nessun sintomo nelle ultime 2 settimane
☐	☐	☐	☐	☐	☐

3. Nelle ultime 2 settimane, quante volte si è alzato/a la mattina con i piedi, le caviglie o le gambe gonfie?

Ogni mattina	3 o più volte alla settimana ma non ogni giorno	1 o 2 volte alla settimana	Meno di 1 volta alla settimana	Mai nelle ultime 2 settimane
☐	☐	☐	☐	☐

4. Nelle ultime 2 settimane, quanto le ha dato fastidio il gonfiore ai piedi, alle caviglie o alle gambe?
Mi ha dato ...

Estremamente fastidio	Molto fastidio	Moderatamente fastidio	Poco fastidio	Per niente fastidio	Non ho avuto gonfiore
☐	☐	☐	☐	☐	☐

5. Nelle ultime 2 settimane, quante volte in media la stanchezza ha limitato la sua capacità di fare quello che desiderava?

Sempre	Parecchie volte al giorno	Almeno 1 volta al giorno	3 o più volte alla settimana	1 o 2 volte alla settimana	Meno di 1 volta alla settimana	Mai nelle ultime 2 settimane
☐	☐	☐	☐	☐	☐	☐

6. Nelle ultime 2 settimane, quanto le ha dato fastidio sentirsi stanco/a?
   Mi ha dato ...

Estremamente fastidio	Molto fastidio	Moderatamente fastidio	Poco fastidio	Per niente fastidio	Non mi sono sentito/a stanco/a
☐	☐	☐	☐	☐	☐

7. Nelle ultime 2 settimane, quante volte in media la difficoltà a respirare ha limitato la sua capacità di fare quello che desiderava?

Sempre	Parecchie volte al giorno	Almeno 1 volta al giorno	3 o più volte alla settimana	1 o 2 volte alla settimana	Meno di 1 volta alla settimana	Mai nelle ultime 2 settimane
☐	☐	☐	☐	☐	☐	☐

8. Nelle ultime 2 settimane, quanto le ha dato fastidio la difficoltà a respirare?
   Mi ha dato ...

Estremamente fastidio	Molto fastidio	Moderatamente fastidio	Poco fastidio	Per niente fastidio	Non ho avuto difficoltà a respirare
☐	☐	☐	☐	☐	☐

9. Nelle ultime 2 settimane, quante volte in media è stato/a costretto/a a dormire su una sedia o con almeno tre cuscini dietro la schiena a causa della difficoltà a respirare?

Ogni notte	3 o più volte alla settimana ma non ogni giorno	1 o 2 volte alla settimana	Meno di 1 volta alla settimana	Mai nelle ultime 2 settimane
☐	☐	☐	☐	☐

10. I sintomi di scompenso cardiaco possono peggiorare per varie ragioni. In che misura è sicuro/a di sapere cosa fare o chi chiamare, se i suoi sintomi peggiorano?

Per niente sicuro/a	Non molto sicuro/a	Abbastanza sicuro/a	Quasi del tutto sicuro/a	Completamente sicuro/a
☐	☐	☐	☐	☐

11. Quanto le è chiaro cosa può fare affinché i suoi sintomi di scompenso cardiaco non peggiorino (per esempio: pesarsi, mangiare con poco sale nella dieta, ecc.)?

Per niente chiaro	Non molto chiaro	Abbastanza chiaro	Quasi del tutto chiaro	Completamente chiaro
☐	☐	☐	☐	☐

12. Nelle ultime 2 settimane, quanto lo scompenso cardiaco ha limitato il suo piacere di vivere?

Ha limitato estremamente il mio piacere di vivere	Ha limitato molto il mio piacere di vivere	Ha limitato moderatamente il mio piacere di vivere	Ha limitato poco il mio piacere di vivere	Non ha limitato per niente il mio piacere di vivere
☐	☐	☐	☐	☐

13. Come si sentirebbe se sapesse di dover passare il resto della sua vita con lo scompenso cardiaco al livello in cui è adesso?

Per niente soddisfatto/a	Per lo più soddisfatto/a	Abbastanza soddisfatto/a	Quasi del tutto soddisfatto/a	Completamente soddisfatto/a
☐	☐	☐	☐	☐

14. Nelle ultime 2 settimane, quanto spesso si è sentito/a scoraggiato/a o giù di morale a causa dello scompenso cardiaco?

Mi sono sempre sentito/a così	Mi sono sentito/a così spesso	Mi sono sentito/a così qualche volta	Mi sono sentito/a così raramente	Non mi sono mai sentito/a così
☐	☐	☐	☐	☐

15. In che misura lo scompenso cardiaco influisce sul suo stile di vita? Per cortesia, indichi quanto lo scompenso cardiaco può aver limitato la sua partecipazione alle seguenti attività nelle ultime 2 settimane.

Faccia una X su una casella per ciascuna riga

Attività	Estremamente limitato	Molto limitato	Moderatamente limitato	Poco limitato	Per niente limitato	Non è il mio caso o non l'ho fatto per altre ragioni
Passatempi, attività di svago	☐	☐	☐	☐	☐	☐
Lavorare o fare dei lavori in casa	☐	☐	☐	☐	☐	☐
Andare a trovare amici o familiari	☐	☐	☐	☐	☐	☐
Relazioni intime con la persona amata	☐	☐	☐	☐	☐	☐

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