Original article

The Severe Heart Failure Questionnaire: Italian translation and linguistic validation

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Key words

Severe Heart Failure Questionnaire • Heart failure • Quality of Life

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Summary

Introduction. *The quality of life (QoL) is an important outcome indicator for heart failure management. As the use of a validate questionnaire in a different cultural context can affect data interpretation our main objective is the Italian translation and linguistic validation of the Severe Heart Failure Questionnaire (SHF) and its comparison with the MLHF (Minnesota Living with Heart Failure) Questionnaire.*
Methods. *The SHF and "The Minnesota Living with Heart Failure Questionnaire" were translated. A consensus involving parallel back-translations was established among a group of*

cardiologists, psychologists and biostatisticians. SHF and MLHF were both administrated to a sample of 50 patients
Results. *The patients' median age was 63 years. Ace inhibitors therapy was administered in 88% of cases and betablockers in 56% of cases. Finally the Italian version of SHF correlates well with MLHF for all domains, except life satisfaction SHF domain.*
Discussion: The Italian version of the SHF correlates well with MLHF for almost all domains and it represents a valid alternative for quality of life assessment in heart failure patients.

Introduction

The prevalence of symptomatic heart failure in the general European population ranges from 0.4% to 2.0% [1]. Heart failure in Italy is one of the most frequent causes of hospitalization (second medical DRG in Italy in 2001). Patients affected by heart failure have a compromised quality of life (QoL) [2-4]. Although decreasing mortality and improving the prognosis are major end points of the treatment, QoL is an important outcome indicator for heart failure management indeed, the "health related quality of life" could be considered one of the most important outcomes for the evaluation of treatments and improvement of the strategies [5, 6] in such patients.

In literature there is a substantial agreement in considering QoL a multidimensional phenomenon which could be analyzed through different perspectives: the physical, the psychological, the social and the economic well being or status of patients.

Health related QoL assessment could be done using generic or disease specific measures: the specific questionnaires allow the measurement of the clinical relevant domains, and are sensitive in identifying clinical changes.

Several generic and specific disease questionnaires have been established to measure treatment effects but the assessment of QoL using a developed and validated instrument in a different cultural context can affect data interpretation [7].

The main objective of this study was the Italian translation and linguistic validation of the Severe Heart Failure Questionnaire (SHF).

Methods

The questionnaires

SHF is a quite old and widely used [8], 26 items, disease specific health status measure for patients with congestive heart failure which covers somatic, psychological, life dissatisfaction and physical limitations. Higher scores indicate lower heart related QoL [9].

"The Minnesota Living with Heart Failure Questionnaire" (MLHF) is a questionnaire which has been applied in most of the researches on heart failure patients: it is a 21 items questionnaire which using a 6 point response scale assess patient's Emotional and Physical dimensions, and a General Total Score [10]. The Italian version of the MLHF has been produced by the MAPI Research Institute (www.mapi-research.fr) and it is available by them upon request.

The translation

The linguistic adaptation was performed following a standardized protocol. The linguistic validation is a linguistically validated translation which allows the assessment in the relevant target countries: it is conceptu-

ally equivalent to the original questionnaire ensuring the cross-cultural equivalence across translations.

The 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 patients, 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 other and with the original one, was done to ensure conceptual agreement. The quality control was done by the IRCAB Foundation (Udine, Italy).

THE SAMPLE

The final version of the SHF was administered with MLHF [10] to a sample of 50 consecutive patients belonging to the heart failure outpatient clinic.

This is a tertiary care clinic and patients belong to all socioeconomic and cultural background.

Tab. I. Patients' descriptive statistics.	
Patients characteristics	
Age	63 (56; 69)*
Gender:	
Males	80% (N = 40)
Females	20% (N = 10)
NYHA:**	
I	8% (N = 4)
II	52% (N = 26)
III	40% (N = 20)
EF	30 (23; 35)*
Etiology:	
Ischemic	40% (N = 20)
Valvular	24% (N = 12)
Dilatative	36% (N = 18)
Previous hospitalizations	77% (N = 37)
Therapy:	
Ace inhibitors	88% (N = 44)
Beta blockers	56% (N = 28)

N = number of patients per category of variables; * = median [II quartile, III quartile]

** New York Heart Association Classification
A functional and therapeutic classification for prescription of physical activity for cardiac patients.
Class I: patients with no limitation of activities; they suffer no symptoms from ordinary activities.
Class II: patients with slight, mild limitation of activity; they are comfortable with rest or with mild exertion.
Class III: patients with marked limitation of activity; they are comfortable only at rest.
Class IV: patients who should be at complete rest, confined to bed or chair, any physical activity brings on discomfort and symptoms occur at rest.

STATISTICAL ANALYSIS

Data for both SHF and MLHF variables has been transformed to have same range and interpretation, as indicated in Guyatt et al. [11].

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 correlation between SHF Overall Summary Score and MLHF has been computed for several subgroups, according to major clinical variables. Difference in SHF and MLHF domains with respect to New York Heart Association Classification (NYHA) levels has been evaluated using a K-independent samples non-parametric median test. Spearman's correlation between each pair of MLHF and SHF domains has been computed.

Significance has been computed at 0.01, 0.05 level. All calculations have been performed using SPSS 7.0.

Results

See appendix 1 for the Italian version of the SHF.

Patients characteristic are summarized in Table I. The median age was 63 years. There were 40 men (80%) and 10 women (20%). Only 8% of the patients was in NYHA class I whereas 52% of the patients were in NYHA class II (26 pts) and 40% in NYHA class III (20 pts). The median EF (left ventricular ejection fraction) was 30%. The etiology was ischemic in 40% of cases, dilatative in 36% of cases, and valvular in 24%. The majority of patients had a previous hospitalization in the last year (77%). Ace inhibitors therapy was administered in 88% of cases and betablockers in 56% of cases.

The Italian version of SHF correlates well with MLHF for all domains, except life satisfaction SHF domain (Tab. II).

Moreover SHF takes into account the changes in different NYHA class. The distribution of SHF "life satisfaction" and "single item" domains are the only equal regarding to the NYHA I-II and NYHA III variables, as shown in Table III.

Finally, Table IV highlights the negative correlation between SHF "life satisfaction" domain and MLHF domains, being positive otherwise.

Discussion

This study reports the Italian translation and validation of the SHF that is a specific disease health related quality-of-life instrument with a well documented validity, reliability and responsiveness [12]. The questionnaire quantifies symptoms, physical limitations, social functioning, patient's sense of self efficacy and quality of life. The main characteristic of the SHF with respect to other instruments to evaluate QoL is the usage of the semantic differential to quantify patients' responses. Each patient has to tick on a line his/her position between two extreme situations (worse, optimal). In the

Tab. II. Spearman's correlation between SHF overall summary score and MLHF, with respect to the major clinical variables.

Comparison between standardized score*

		MLHF[1]	SHF[2] Somatic Symptoms	Correlation	SHF[2] Emotions	Correlation	SHF[2] Life Satisfaction	Correlation
Ejection Fraction	≤ 30	81 (51, 90)	73 (47, 88)	0.795	77 (55, 91)	0.644	49 (40, 54)	-0.328
	> 30	87 (64, 91)	73 (46, 93)	0.802	73 (47, 93)	0.758	44 (38, 56)	0.165
NYHA	I-II	90 (70, 92)	85 (56, 94)	0.621	81 (62, 92)	0.628	47 (38, 64)	-0.316
	III	73 (47, 81)	73 (47, 92)	0.688	67 (38, 71)	0.499	47 (42, 50)	0.194
Etiology	Ischemic	84 (60, 90)	75 (47, 90)	0.739	81 (63, 95)	0.645	49 (42, 54)	-0.277
	Valvular	82 (43, 92)	73 (51, 92)	0.845	70 (30, 95)	0.778	50 (25, 64)	0.017
	Dilatative	85 (60, 90)	73 (46, 94)	0.810	72 (55, 87)	0.688	46 (39, 50)	-0.132
Gender	Male	82 (48, 90)	73 (47, 92)	0.804	73 (54, 90)	0.825	46 (38, 50)	-0.065
	Female	87 (78, 92)	76 (44, 82)	0.696	78 (42, 90)	0.000	77 (51, 100)	-0.709
Ace inhibitors	Yes	87 (64, 91)	77 (54, 93)	0.748	74 (56, 91)	0.663	47 (38, 54)	-0.055
	No	38 (31, 78)	39 (20, 66)	1.000	20 (9, 79)	0.500	50 (39, 78)	-0.500
Beta blockers	Yes	87 (60, 90)	77 (47, 93)	0.722	80 (65, 92)	0.628	48 (42, 78)	-0.357
	No	81 (47, 91)	71 (46, 86)	0.854	68 (45, 83)	0.816	44 (29, 50)	0.183
Previous hospitalizations	No	87 (47, 91)	73 (56, 86)	0.727	76 (53, 89)	0.677	42 (33, 54)	-0.117
	≥ 1	71 (56, 83)	73 (46, 94)	0.794	72 (55, 92)	0.773	48 (40, 54)	0.161
Overall		85 (51, 90)	73 (47, 92)	0.783	74 (54, 90)	0.703	47 (39, 54)	-0.117

[1]Minnesota Living with Heart Failure; [2]Severe Heart Failure Questionnaire (Italian translation); * = median II quartile, III quartile]

Comparison between standardized score*

		MLHF[1]	SHF[2] Physical Symptoms	Correlation	SHF[2] Single Item	Correlation
Ejection Fraction	≤ 30	81 (51, 90)	57 (46, 71)	0.500	60 (40, 80)	0.405
	> 30	87 (64, 91)	69 (57, 77)	0.871	60 (40, 80)	0.605
NYHA	I-II	90 (70, 92)	71 (57, 77)	0.551	60 (40, 80)	0.397
	III	73 (47, 81)	49 (40, 60)	0.534	40 (40, 60)	0.550
Etiology	Ischemic	84 (60, 90)	69 (46, 77)	0.607	60 (40, 80)	0.365
	Valvular	82 (43, 92)	63 (46, 71)	0.896	80 (20, 80)	0.643
	Dilatative	85 (60, 90)	69 (46, 77)	0.689	60 (40, 60)	0.524
Gender	Male	82 (48, 90)	69 (46, 76)	0.812	60 (40, 80)	0.647
	Female	87 (78, 92)	59 (40, 77)	0.139	70 (40, 80)	-0.086
Ace inhibitors	Yes	87 (64, 91)	69 (46, 77)	0.620	40 (20, 60)	0.417
	No	38 (31, 78)	43 (26, 57)	0.600	60 (40, 80)	0.638
Beta blockers	Yes	87 (60, 90)	69 (49, 77)	0.623	60 (40, 80)	0.575
	No	81 (47, 91)	57 (43, 71)	0.667	60 (40, 80)	0.415
Previous hospitalizations	No	87 (47, 91)	70 (60, 77)	0.709	60 (40, 80)	0.474
	≥ 1	71 (56, 83)	69 (46, 74)	0.208	60 (40, 80)	0.127
Overall		85 (51, 90)	69 (46, 76)	0.673	60 (40, 80)	0.501

[1]Minnesota Living with Heart Failure; [2]Severe Heart Failure Questionnaire; * = mediana II quartile, III quartile]

Tab. III. Domains' distribution of MLHF and SHF questionnaires regarding to the NYHA class.

	NYHA I-II (N = 30)	NYHA III * (N = 19)	Overall * (N = 49)	P-value
Minnesota Living with Heart Failure				
Minnesota Emotional Score	92 (72, 100)	76 (68, 92)	88 (72, 96)	0.037
Minnesota Physical Score	92 (70, 97)	67 (35, 75)	82 (47, 95)	0.004
Minnesota Total Score	90 (70, 92)	73 (47, 81)	85 (51, 90)	< 0.001
Severe Heart Failure Questionnaire				
SHF Somatic Symptoms	85 (56, 94)	57 (30, 69)	73 (47, 92)	0.002
SHF Emotions	81 (62, 92)	67 (38, 71)	73 (54, 90)	0.002
SHF Life Satisfaction	47 (38, 64)	47 (42, 50)	47 (39, 54)	0.910
SHF Physical Symptoms	71 (57, 77)	49 (40, 60)	69 (46, 76)	0.002
SHF Single Item	60 (40, 80)	60 (40, 80)	60 (40, 80)	0.178

N = number of patients per category of variables; * = median [I quartile, III quartile]

Tab. IV. Spearman's correlation between each pair of MLHF and SHF questionnaires' domains.

		Minnesota Living with Heart Failure		
		Minnesota Emotional Score	Minnesota Physical Score	Minnesota Total Score
Severe Heart Failure	SHF Somatic Symptoms	0.551*	0.641*	0.587*
	SHF Emotions	0.569*	0.559*	0.509*
	SHF Life Satisfaction	-0.155	-0.110	-0.085
	SHF Physical Symptoms	0.384*	0.578*	0.547*
	SHF Single Item	0.450*	0.418*	0.416*

* = Correlation is significant at the 0.01 level (1-tailed)

original work the SHF is more sensitive to the important clinical change in the responsiveness cohort of patients than the MLHF or the SF-36 (Short-Form - 36 questions). The increased sensitivity to clinical change is summarized by the responsiveness statistics: the SHF physical limitation scale's responsiveness is three times larger that the corresponding domains of the MLHF and SF-36. Some authors have noted that MLHF is sensitive to differentiates in symptom severity except in the most compromised patients group.

As reported by Green et al. [13], problems of meaning and interpretation could occur when respondents answer items of questionnaire. Respondents might fail to understand a concept and thus give widely different interpretations to it. In particular, problem can arise with items that contain questions separated by the word 'or' and items that are considered not applicable to the respondent's circumstances. Furthermore, the translation from English to other languages may result in a certain loss of concision, making questionnaire items more complex to understand. In spite of these potential drawbacks, the Italian version of the SHF correlates well with MLHF for almost all domains. The two questionnaires also correlate well for EF, NYHA class, etiology, therapy and hospitalization.

Both the SHF and MLHF appear to be valid and reliable, however the SHF has the important advantage to avoid the patient to constrains his/her evaluation of the perceived quality of life into a 5 or 7 point Likert Scale. In this sense, the semantic differential used in the SHF is most appealing to limit cognitive biases in the patients' indications.

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Appendix 1: SHF Italian version

La preghiamo di indicare con una X il punto nella scala sottostante che indica il suo stato di salute durante l'ultima settimana.

Esempio: molto ⊢————————×—⊣ per niente

Il dolore al torace ha limitato le sue attività giornaliere?
Le è mancato il respiro durante la notte?
Si è sentito affaticato?
Si è sentito esausto?
Si è sentito debole?
Si è sentito pigro?
Nel complesso, come le è sembrato il suo stato di salute nell'ultima settimana?
Ha avuto delle difficoltà nel prendere delle decisioni?
Si è sentito nervoso o preoccupato?
Si è sentito depresso?
Si è sentito agitato?
Ha avuto difficoltà a rilassarsi?
Si è sentito suscettibile?
Si è sentito più sensibile ai rumori (o alla confusione)?
Si è sentito soddisfatto della sua vita?
Si è sentito pessimista?
Ha trovato che la sua esistenza ha un significato?
Si è sentito di buon umore?
Si è sentito soddisfatto?

Di seguito troverà una serie di domande relative alle attività quotidiane. La preghiamo di indicare con una crocetta la risposta che corrisponde alla Sua situazione. Può scegliere solo una delle possibili risposte. La preghiamo di risondere a tutte le domande.

Esempio: senza difficoltà   ×
             quasi senza difficoltà   _
             con qualche difficoltà   _
             con parecchia difficoltà   _
             è stato impossibile   _

È stato in grado di uscire durante l'ultima settimana?
Durante l'ultima settimana, è stato in grado di scendere e salire le scale (circa 8 gradini)?
È stato in grado di camminare in salita ed in discesa durante l'ultima settimana?
È stato in grado di muoversi in casa durante l'ultima settimana?
È stato in grado di uscire per fare una passeggiata (meno di 1 km) durante l'ultima settimana?
È stato in grado di stare all'aperto durante l'ultima settimana?
È stato in grado di fare le faccende di casa (spolverare, cucinare, cambiare le lampadine ecc.) durante l'ultima settimana?
Con quante difficoltà il suo stato di salute è migliorato dopo aver iniziato la terapia?

Minnesota Living with Heart Failure® Questionnaire

The following questions ask how much your heart failure (heart condition) affected your life during the past month (4 weeks). After each question, circle the 0, 1, 2, 3, 4 or 5 to show how much your life was affected. If a question does not apply to you, circle the 0 after that question.

Did your heart failure prevent you from living as you wanted during the pat month (4 weeks) by:	No	Very little				Very much
1. causing swelling in your ankles or legs?	0	1	2	3	4	5
2. making you sit or lie down to rest during the day?	0	1	2	3	4	5
3. making your walking about or climbing stairs difficult?	0	1	2	3	4	5
4. making your working around the house or yard difficult?	0	1	2	3	4	5
5. making your going places away from home difficult?	0	1	2	3	4	5
6. making your sleeping well at night difficult?	0	1	2	3	4	5
7. making your relating to or doing things with your friends or family difficult?	0	1	2	3	4	5
8. making your working to earn a living difficult?	0	1	2	3	4	5
9. making your recreational pastimes, sports or hobbies difficult?	0	1	2	3	4	5
10. making your sexual activities difficult?	0	1	2	3	4	5
11. making you eat less of the foods you like?	0	1	2	3	4	5
12. making you short of breath?	0	1	2	3	4	5
13. making you tired, fatigued, or low on energy?	0	1	2	3	4	5
14. making you stay in a hospital?	0	1	2	3	4	5
15. costing you money for medical care?	0	1	2	3	4	5
16. giving you side effects from treatments?	0	1	2	3	4	5
17. making you feel you are a burden to your family or friends?	0	1	2	3	4	5
18. making you feel a loss of self-control in your life?	0	1	2	3	4	5
19. making you worry?	0	1	2	3	4	5
20. making it difficult for you to concentrate or remember things?	0	1	2	3	4	5
21. making you feel depressed?	0	1	2	3	4	5

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