



Validity and Reliability of the MacNew Heart Disease Health-Related Quality of Life Questionnaire in Patients with Heart Failure: The Persian Version

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ABSTRACT

Background: Heart failure due to changes in the lungs, circulation, and skeletal muscle adversely influences the quality of life.

Objectives: The objective of the present study is to assess the reliability and validity of the Persian version of the MacNew in patients with heart failure.

Patients and Methods: The 200 Iranian patients who referred to Shahid Beheshti hospital in Qom were recruited by convenience sampling. All the patients filled out the MacNew HRQL questionnaire, the hospital anxiety and depression scale (HADS), the Short Form-36 and socio-demographic and clinical characteristics. The reliability of the MacNew was assessed by internal consistency and test-retest reliability. Construct validity was assessed by factor analysis, convergent validity and discriminant validity. Discriminant validity of MacNew was assessed by the known-groups approach. All analyses were done through SPSS, version 20, and level of significance was considered at $P < 0.05$.

Results: The mean MacNew Global score was 3.6 ± 0.82 . Our results demonstrated that internal consistency ($\alpha = 0.94$) and reproducibility ($ICC = 0.84$) of the Persian version of the MacNew were confirmed. The Factor analysis confirmed three factors as the original MacNew. Convergent and divergent validity of the MacNew was confirmed by its correlation pattern with physical and mental components of the SF-36. Discriminative validity was confirmed statistically and clinically for the differences in the MacNew scores on the Global scale and each subscale between Iranian patients with and without anxiety and depression.

Conclusions: The Persian version of the MacNew HRQL questionnaire can be applied as a reliable and valid tool in the clinical research for Iranian patients with heart failure.

1. Background

Heart failure is the chronic cardiac disease in the elderly people (1). Prevalence of this disease is increasing in the developed and developing countries (2). It is a major burden to populations and health services in low-and middle-income countries (3). The most concern in all diseases that affects many aspects of health status is the health-related quality of life (HRQL) (4). Heart failure due to changes in the lungs, circulation, and skeletal muscle adversely influences the

quality of life (5). Medical treatments in diseases with poor prognosis and complex treatments evaluate the efficiency of the interventions by estimation of the patients' health status (6). For evaluation of HRQL, there are generic and disease-specific questionnaires. The generic questionnaires assess a broad range of aspects of life in a variety of health states, but specific questionnaires focus on relevant issues of specific diseases and are sensitive to identify clinical changes (7). For heart failure, 32 HRQL instruments of the generic and disease-specific have been used in different studies (1). The Short Form-36 (SF-36), the Minnesota Living with Heart Failure Questionnaire (MLWHFQ) and Kansas City Cardiomyopathy Questionnaire (KCCQ)

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have been the most frequently used ones (8). However, the Kansas City Cardiomyopathy Questionnaire measure the HRQoL better compared to the Minnesota Living with Heart Failure Questionnaire in patients with heart failure (5). The self-administered MacNew HRQL questionnaire (MacNew) is specific to coronary artery disease that has been used widely in the literature. It was translated and validated in many languages in patients with myocardial infarction, angina and ischaemic heart failure worldwide (7, 9-19). The MacNew questionnaire has been validated in Iranian patients with MI (6), but it has not been validated in patients with heart failure.

2. Objectives

Thus, the objective of the present study was to assess reliability and validity of the Persian version of the MacNew in patients with heart failure.

3. Patients and Methods

3.1. Participants and Procedure

200 Iranian patients referring to Shahid Beheshti hospital in Qom were recruited by convenience sampling. The patients were aged over 18 years, had no psychiatric disorders, and were able to complete the self-administered questionnaires. Also, the patients were eligible if they were being treated for ischaemic heart failure (New York Heart Association [NYHA] class II, III, IV) with evidence of left ventricular dysfunction (EF² 40% by invasive or non-invasive testing). Interviewers were trained to administer the data collection questionnaire. The study protocol was approved by local Ethics of Qom University of Medical Sciences.

3.2. Measurements

The questionnaires included the MacNew HRQL, the hospital anxiety and depression scale (HADS), the Short Form-36 and socio-demographic and clinical Characteristics. The MacNew HRQL was re-completed for some patients (N = 20) two weeks after the baseline.

1- The MacNew HRQL questionnaire is designed to evaluate the patients' feelings about how heart disease affects their daily functions (20, 21). The questionnaire contains 27 items with three subscales of physical limitation, emotional and social function and Global HRQL. The physical, emotional and social subscales contain 12 items, 14 items and 13 items, respectively, in accordance with the recommended practice and a Global score. The items are scored from 1 (low HRQL) to 7 (high HRQL) and minimal important difference is a value of 0.5 on the seven-point scale (22). The MacNew questionnaire has been validated in the Persian version in patients with MI (6).

2- The hospital anxiety and depression questionnaire is designed to evaluate depressive and anxiety symptoms (23). The HADS contains 14 items, each being scored from 0 to 3. The Persian version of the HADS has been validated with scores 7, identifying patients with symptoms of depression or anxiety (24).

3- The SF-36 questionnaire is designed to assess the general health status (25). It contains 36 items with eight subscales summarized into physical components summary (PCS) and mental component summary (MCS). The SF-36

questionnaire has been validated in Persian version (26).

3.3. Data Analysis

1- Socio-demographic and clinical characteristics of the patients were summarized by frequency, means and standard deviations. Distribution of responses to minimum item (1) as the floor effect and to maximum item (7) as the ceiling effect was examined. The abundance of floor and ceiling effects in the target population could recommend that an item should be reviewed and even deleted (27).

2- The reliability of the MacNew was assessed by internal consistency and test-retest reliability (14-day). Internal consistency was evaluated by Cronbach's alpha and test-retest reliability by intra-class correlation coefficient (ICC). For alpha and ICC, the criterion values of > 0.9 and > 0.7 were considered as evidence of satisfactory, respectively (19, 28).

3- Construct validity was assessed by factor analysis, convergent validity and discriminant validity. Factor analysis was performed by exploratory factor analysis with PCA method for extraction factor and varimax rotation. The factor loadings ≥ 0.4 was used to allocate the items to subscales. Therefore, the cross-loadings were allowed as in the original validation of the MacNew (21).

Convergent and divergent validity of the MacNew was assessed through the correlation between subscales of MacNew and SF-36 component scales. If the Pearson correlation coefficients between similar components of SF-36 and MacNew were strong ($r \geq 0.5$), then convergent validity of MacNew was confirmed. If the Pearson correlation coefficients between dissimilar components of SF-36 and MacNew were weak ($r^2 < 0.3$) or moderate ($0.3 < r < 0.5$), then the divergent validity of MacNew was confirmed.

Discriminant validity of MacNew was assessed by the known-groups approach (29). Groups were presence or absence of anxiety and depression ($HADS \geq 7$), the New York Heart Association classification (NYHA) and the SF-36 health transition item consisting of three groups: deteriorated, no change, and improved. Moreover, the differences of the MacNew scores were assessed by age, Hypertension, Hyper-cholesterolemia and diabetes variables. T-test and ANOVA were applied to assess the differences in the MacNew HRQL scores between groups. All analyses were done through SPSS, version 20, and the level of significance was considered at $P < 0.05$.

4. Results

4.1. Patient Characteristics

The socio-demographic and clinical characteristics on 200 heart failure patients who referred to one center in Iran during the years 2015-2016 are shown in Table 1. The mean left ventricular ejection fraction (EF) was 34.6 ± 5.8 with a range of 20 to 40 percent. The mean of scores, MacNew subscales, and SF-36 component scales are presented in Table 2. The scores of MacNew subscales ranged from 1.38 to 6.69 and those of SF-36 component scales ranged from 0 to 100. There were no floor or ceiling effects for the mean Global and subscale of the MacNew in Iranian patients with heart failure.

Table 1. Socio-demographic and Clinical Characteristics of the Patients (n = 200)

Item	(Mean ± SD) n (%)
Age	62.3 ± 14.3
Body mass index	25.8 ± 5.2
Left ventricular ejection fraction (%)	34.6 ± 5.8
NYHA Function Class	
Class II	81 (41.1)
Class III	99 (50.3)
Class IV	17 (8.6)
Gender	
Female	88 (44.7)
Male	109 (55.3)
Family status	
Single/Widow	42 (22.3)
Married	146 (77.7)
Education	
< High school	144 (74.6)
High school	43 (22.3)
> High school	6 (3.1)
Smoker	64 (32.7)
Hypertension	94 (48)
Diabetes	96 (49.2)
Hyper cholesterolemia	122 (62.2)

Discrepancies in the totals are due to missing covariate values

Table 2. Summary of Mac New, Short Form -36 Health Survey and Hospital Anxiety and Depression Questionnaire in Patients

MacNew	Mean	SD
Global	3.6	0.82
Physical	3.4	0.93
Emotional	3.7	0.82
Social	3.5	0.82
SF-36		
PCS	39.6	20
MCS	46.1	16
HADS		
Anxiety	9.3	4.06
Depression	10.2	4.8

4.2. Reliability

Internal consistency is reported for Global and subscale of MacNew in Table 3. Cronbach alpha for Global scale was 0.94. Test-retest reliability is also reported in Table 3. ICC value ranged from 0.72 to 0.84 and exceeded the criteria of ≥ 0.70 on the Global and each subscale.

4.3. Exploratory Factor Analysis

Table 4 shows the results of the PCA with varimax rotation. A decision rule for allocating a question to a domain was taken based on factor loading ≥ 0.4 . The three

factor solutions for the MacNew, with social, physical and emotional scales, explained 43.3%, 7.8% and 4.8% of the variance respectively and 55.8% of the total variance overall. Factor analysis of the Persian version of the MacNew in heart failure patients was similar to that of Persian version in MI patients and both were consistent with the factor structure of the original MacNew. Of all the factor loadings at ≥ 0.4 , 51.8% were fully similar with the original MacNew factor structure, 37.03% were moderately similar and 7.4% (number 15 and number 19) did not match with the original.

4.4. Convergent and Divergent Validity

Correlation between MacNew domains and SF-36 dimensions is presented in Table 3. Range of correlation coefficients was 0.48 to 0.64 and all were statistically significant. As expected, the correlation between similar MacNew domains and SF-36 component scales was strong (MacNew physical and SF-36 PCS ($r = 0.64$, $P < 0.001$) and MacNew emotional and SF-36 MCS ($r = 0.6$, $P < 0.001$) scales), but the correlation between dissimilar scales in the two instruments was moderate (MacNew physical and SF-36 MCS ($r = 0.48$, $P < 0.001$) and MacNew emotional and SF-36 PCS ($r = 0.49$, $P < 0.001$) scales).

4.5. Discriminative Validity

Discriminative validity was confirmed statistically and clinically for differences in the MacNew scores on the Global scale and each subscale between Iranian patients with and without anxiety (3.2 ± 0.6 vs. 4.2 ± 0.6 , all $P < 0.001$), and depression (3.1 ± 0.7 vs. 4.3 ± 0.8 , all $P < 0.001$). However, discriminative validity was confirmed partially for the variables including the New York Heart Association classification (NYHA) and the SF-36 health transition item. The differences in MacNew scores between patients with and without Hypertension, Hyper-cholesterolemia and diabetes were not clinically significant for the Global and each subscale (Table 5).

5. Discussion

Heart failure is an increasing public health problem all over the world (4). Almost heart failure will be developed to about one in every three individuals over fifty-five years. Symptoms of heart failure such as dyspnea, fatigue, pain, orthopnea, edema, loss of appetite, anxiety and depression diminish their quality of life (5). Using a HF-specific HRQL questionnaire, such as the Minnesota Living with Heart Failure Questionnaire (MLWHFQ) and Kansas City Cardiomyopathy Questionnaire (KCCQ), the effectiveness of interventions, cardiac rehabilitation and quality of cares on the heart failure patients can be determined. Therefore, the HRQL outcome is the important measure in the health

Table 3. Reliability and Convergent Validity of the MacNew Domain Scales and Global Score

MacNew	% Floor	% Ceiling	Cronbach's alpha	Test-retest (ICC)	Correlation coefficients	
					MCS	PCS
Global	0	0	0.94	0.84	0.58 *	0.61 *
Physical	0	0	0.91	0.72	0.48 *	0.64 *
Emotional	0	0	0.89	0.75	0.6 *	0.49 *
Social	0	0	0.92	0.81	0.53 *	0.61*

* $P < 0.001$

Table 4. Principal Component Analysis: Factor Loadings for Items of Mac New in Persian Version and Original Version. (Loadings < 0.40 Are Not Displayed)

	Emotional	Physical	Social	Original MacNew (Emotional)	Original MacNew (Physical)	Original MacNew (Social)
1- Frustrated	0.67			0.79		
2- Worthless	0.83		0.45	0.74		0.42
3- Con dent	0.74			0.61		
4- Down in the dumps	0.63			0.86		
5- Relaxed	0.51			0.79		
6- Worn out	0.57			0.59	0.52	
7- Personal life	0.56			0.73		
8- Restless	0.42			0.81		
9- Shortness of breath		0.7			0.73	
10- Tearful	0.46		0.44	0.72		
11- More dependent		0.55	0.50			0.62
12- Social activities			0.68	0.4	0.46	0.52
13- Others Less con dence			0.43	0.45		0.66
14- Chest pain		0.61			0.72	
15- Lack self-confidence		0.68		0.67		0.47
16- Aching legs		0.53			0.44	
17- Sports/exercise limited			0.58		0.60	0.61
18- Frightened	0.48			0.63		
19- Dizzy or lightheaded	0.42				0.61	
20- Restricted or limited			0.58		0.64	0.62
21- Unsure about exercise		0.69	0.42		0.47	0.48
22- Overprotective family			0.78			0.69
23- Burden on others	0.63		0.4	0.44		0.66
24- Excluded			0.79		0.43	0.74
25- Unable to socialize			0.78		0.46	0.68
26- Physically restricted			0.58		0.60	0.65
27- sexual activity		0.63	0.4			
Variance explained (%)	4.8	7.8	43.3			

services research and clinical trials (7). The MacNew HRQL questionnaire has been designed to measure the quality of life in patients with coronary artery disease (CAD) (30). The Persian version of the MacNew has been validated in MI patients (6); however, its psychometric properties have not been validated in the heart failure patients. The MacNew has been validated in the heart failure patients in some languages including German, Italian, French, Chinese, Dutch, Danish, Norwegian, and Swedish (1, 7, 13, 17, 19, 31, 32). Our findings show that the Persian version of the MacNew HRQL Questionnaire in patients with heart failure has good psychometric properties for reliability and validity. The MacNew in Iranian patients with heart failure as well as those with MI in our previous study was reliable. The high internal consistency reliability was demonstrated in this study. Cronbach's alpha in the Global and subscale of the MacNew ranged between 0.89 - 0.94 that exceeded the recommended criterion of 0.9 approximately. The Persian version had an adequate reproducibility. The ICC values ($r = 0.72 - 0.84$) exceeded the criterion of 0.7. The internal consistency and ICC values estimates observed in this study were similar with the previous study in different languages in the heart failure patients (13, 19, 31).

The three-factor (physical, emotional and social) with cross-loadings for the structure of MacNew was confirmed in the Persian version in the present study; this is also consistent with previous reports (13, 17, 19, 31). However, since most of the items were loaded on the first one of

three factors using PCA as the method of the extraction factor, the varimax rotation was applied to the results of the 3-factor solution as the original MacNew analysis. Two items of the MacNew (item #15, Lack self-confidence and item #19, Dizzy or lightheaded) in the Persian version were not loaded as in the original factor analysis. Also, in the previous study on Iranian MI patients, three out of 26 items were not loaded as the recommended scoring system. These differences are most likely due to small sample size, distributional misspecifications and cultural reasons. Item 27 was not included in the original version, but in the present study, it was loaded to both the physical and social subscales as previous studies (8, 13, 14, 17, 19, 31). Convergent and divergent validity of the MacNew physical and emotional subscales was confirmed by its correlation pattern with the SF-36 PCS and MCS, as observed in other studies (1, 8, 12, 32). However, the discriminative validity was confirmed partially. Using the known groups approach, the MacNew Global and subscale scores of the patients who had NYHA class IV, those who met the HADS criteria for symptoms of anxiety or depression, and the patients whose health was deteriorated were reported statistically and clinically lower than the patients who had NYHA class II, those who were neither showing symptoms of anxiety nor depression, and the patients whose health had improved. However, there were no clinically significant difference between MacNew Questionnaire HRQL scores of those patients with NYHA class II and with NYHA

Table 5. Discriminate Validity of the MacNew Domain Scales and Global Score

Item	MacNew			
	Global	Physical	Emotional	Social
Gender				
Female	3.56 ± 0.7	3.35 ± 0.8	3.73 ± 0.7	3.48 ± 0.7
Male	3.57 ± 0.8	3.36 ± 1.01	3.74 ± 0.8	3.46 ± 0.9
P value	0.83	0.99	0.84	0.92
Age				
< 65 years	3.7 ± 0.7	3.6 ± 0.8	3.9 ± 0.7	3.7 ± 0.8
65 years	3.2 ± 0.8	2.9 ± 0.9	3.5 ± 0.8	3.1 ± 0.8
P value	< 0.0001	< 0.0001	0.001	< 0.0001
Hypertension				
Yes	3.3 ± 0.7	3.2 ± 0.9	3.5 ± 0.7	3.3 ± 0.8
No	3.7 ± 0.8	3.5 ± 0.9	3.9 ± 0.8	3.7 ± 0.8
P value	0.001	0.001	0.003	0.001
Hyper Cholesteroaemia				
Yes	3.4 ± 0.7	3.2 ± 0.8	3.6 ± 0.7	3.3 ± 0.8
No	3.7 ± 0.8	3.6 ± 0.9	3.9 ± 0.8	3.6 ± 0.9
P value	0.006	0.015	0.003	0.01
Diabetes				
Yes	3.4 ± 0.6	3.2 ± 0.7	3.6 ± 0.7	3.4 ± 0.7
No	3.6 ± 0.9	3.4 ± 1.05	3.8 ± 0.8	3.6 ± 1.02
P value	0.07	0.14	0.053	0.07
NYHA Function Class				
Class II	3.8 ± 0.6	3.7 ± 0.7	4.02 ± 0.7	3.7 ± 0.7
Class III	3.3 ± 0.7	3.1 ± 0.8	3.6 ± 0.7	3.2 ± 0.7
Class IV	3.06 ± 1.4	2.7 ± 1.5	3.2 ± 1.3	3.03 ± 1.5
P value	< 0.0001	< 0.0001	< 0.0001	< 0.0001
Anxiety				
Yes	3.2 ± 0.6	2.9 ± 0.7	3.4 ± 0.7	3.09 ± 0.7
No	4.2 ± 0.6	4.1 ± 0.7	4.4 ± 0.6	4.2 ± 0.7
P value	< 0.0001	< 0.0001	< 0.0001	< 0.0001
Depression				
Yes	3.1 ± 0.7	2.9 ± 0.9	3.3 ± 0.7	3.03 ± 0.9
No	4.3 ± 0.8	4.1 ± 0.9	4.5 ± 0.8	4.2 ± 0.9
P value	< 0.0001	< 0.0001	< 0.0001	< 0.0001
SF-36 health transition				
Improve	3.6 ± 0.6	3.5 ± 0.7	3.8 ± 0.7	3.6 ± 0.7
No change	3.8 ± 0.7	3.7 ± 0.8	3.9 ± 0.7	3.7 ± 0.8
Deteriorate	3.1 ± 0.8	2.7 ± 0.9	3.1 ± 0.9	2.8 ± 0.9
P value	< 0.0001	< 0.0001	< 0.0001	< 0.0001

class III, for those patients whose health had not changed, and those whose health was deteriorated. In some studies, discriminant validity was largely confirmed (1) and in some other studies it was partially confirmed, as in our study (7).

The scores of the MacNew in Iranian patients were reported poorer than previous studies in different populations. This might be due to the fact that the patients did not find self-administering the MacNew questionnaire acceptable.

A major limitation of our study was that prospective data were not available for this project. On the other hand, psychometric property of responsiveness of the MacNew was not assessed. In conclusion, our results showed the Persian version of the MacNew HRQL questionnaire could be applied as an appropriate tool in the clinical research for Iranian patients with heart failure.

5.1. Compliance with Ethical Standards

The study protocol was approved by Ethics Committee of

Qom University of Medical Sciences. An informed written consent was obtained from the patients.

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Authors' Contribution

Mohammad Abbasi: conceived the idea. Somayeh Momenyan: designed the study. Fatemeh Sarvi: wrote the draft of manuscript. Fariba Eslamimoghadam: Gathering data. Imaneh Khaki: reviewed draft of the manuscript.

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