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### **Health and Quality of Life Outcomes**



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# Adaptation of the MacNew quality of life questionnaire after myocardial infarction in an Iranian population

Mohsen Asadi-Lari\*<sup>1</sup>, Hamid R Javadi<sup>2</sup>, Martin Melville<sup>1</sup>, Neil B Oldridge<sup>3</sup> and David Gray<sup>1</sup>

Address: <sup>1</sup>Division of Cardiovascular Medicine, Queen's Medical Centre, University of Nottingham, Nottingham, UK, <sup>2</sup>Department of Cardiology, Qazvin University of Medical Sciences, Qazvin, Iran and <sup>3</sup>Centre for Urban Population Health, University of Wisconsin-Milwaukee, Milwaukee, USA

Email: Mohsen Asadi-Lari\* - msxma@nottingham.ac.uk; Hamid R Javadi - hrj679@yahoo.com; Martin Melville - martin.melville@mail.qmcuhtr.trent.nhs.uk; Neil B Oldridge - neilb@uwm.edu; David Gray - d.gray@nottingham.ac.uk

\* Corresponding author

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#### **Abstract**

**Background:** Health-related quality of life (HRQL) assessment is an important measure of the impact of a wide range of disease process on an individual. To date, no HRQL tool has been evaluated in an Iranian population with cardiovascular disorders, specifically myocardial infarction, a major cause of mortality and morbidity. The MacNew Heart Disease Health-related Quality of Life instrument is a disease-specific HRQL questionnaire with satisfactory validity and reliability when applied cross-culturally.

**Method:** A Persian version of MacNew was prepared by both forward and backward translation by bilinguals after which a feasibility test was performed. Consecutive patients (n = 51) admitted to a coronary care unit with acute myocardial infarction were recruited for measurement of their HRQL with retest one month after discharge in the follow-up clinic. Principal components analysis, intra-class correlation reliability, internal consistency, and test-retest reliability were assessed.

**Results:** Trivial rates of missing data confirmed the acceptability of the tool. Principal component analysis revealed that the three domains, emotional, social and physical, performed as well as in the original studies. Internal consistency was high and comparable to other studies, ranging from 0.92 for the emotional and physical domains, to 0.94 for the social domain, and to 0.95 for the Global score. Domain means of 5, 5.3 and 4.9 for emotional, physical and social respectively indicate that our Iranian population has similar emotional and physical but worse social HRQL scores. Testretest analysis showed significant correlation in emotional and physical domains (P < 0.05).

**Conclusion:** The Persian version of the MacNew questionnaire is comparable to the English version. It has high internal consistency and reasonable reproducibility, making it an appropriate specific quality of life tool for population-based studies and clinical practice in Iran in patients who have survived an acute myocardial infraction. Further studies are needed to confirm its validity in larger populations with cardiovascular disease.

#### Introduction

The World Health Organisation (WHO) defines health as "a state of complete physical, mental, and social well being, not merely the absence of disease or infirmity" (WHO, 1958). As providers of health care attempt to evaluate the effectiveness of interventions aimed at controlling or reducing the sequelae of diseases such as cardiovascular conditions, morbidity and mortality indices are too crude and insensitive. [1] Measurement of health, the effects of disease and the impact of health care ought to include not only an indication of changes in disease frequency and severity but also an estimate of patients' perception of health status before and after treatment.

Health-related quality of life (HRQL) refers to a multitude of subjective and objective experiences among which health, well-being and the ability to function in day-to-day activities are essential. [2] HRQL instruments provide a valuable tool to assess the impact of disease, effect of treatment and other variables affecting people's lives. Outcome measures used to evaluate HRQL among cardiac patients have been introduced [3,4] and numerous generic and disease-specific questionnaires have been developed but there is no general consensus on their relative merits. [5,6]

Population-based studies confirm that the prevalence of coronary artery disease (CAD) is higher among Iranian population even than in western countries; [7] its high mortality rate [8] makes CAD the principal cause of death in recent decades [9] In the absence of an appropriate tool for measuring HRQL in an Iranian population, the MacNew Heart Disease Health-related Quality of Life (MacNew), a disease-specific HRQL instrument, was translated into Farsi and administered to a Farsi (Persian)-speaking population with myocardial infarction (MI). This study aimed to measure HRQL in a group of Iranian patients with CAD and documented MI.

#### Method

#### Translation process

The MacNew questionnaire consists of 27 questions in three domains, emotional, physical, and social, and uses a 7-point scale with higher scores indicating better HRQL perception.[10] The tool is valid, reliable and responsive to clinical change,[3,11–13] has been favourably reviewed against a selection of other disease-specific HRQL instruments [12,14] and reference data are available.[15] With rehabilitation, the time course of recovery of HRQL, using the original QLMI, is more rapid than that of exercise tolerance. [16] Predictors of HRQL have been identified, [17,18] and poor HRQL on the MacNew is an independent predictor of later mortality and morbidity.[19] A change score of 0.5 has been identified as the

minimal important difference (MID) [20] which is the smallest score where significant change is clinically identifiable.

The first step comprised forward translations from English to Farsi by two independent bilingual translators who were not health professionals; minor differences were accommodated. Next, a 'backward translation' was carried out, in which a third bilingual translator converted the document back into English and this process was repeated until differences on all items had been accommodated. [21] For religious and cultural reasons, the question relating to sexual activity was omitted. The Farsi version of the MacNew therefore consists of 26 items. The newly translated tool was administered to five hospitalised patients to ascertain any difficulties with regard to language or conceptual issues. Finally a member of medical staff conducted face-to-face interviews with patients admitted to a coronary care unit in Qazvin in western Iran and the questionnaire was administered to establish the validity and reliability of the Persian/Farsi translation. To ascertain test-retest reliability, all patients recruited were invited to take part in a similar interview one month after discharge.

#### Setting

Consecutive patients with a diagnosis of a definite MI, according to the European Society of Cardiology/American College of Cardiology guidelines [22] were recruited in a three-week time period. Patients with severe mental disorders or other disabilities that prevented participation in the survey were excluded. The University Research Council's Ethics Committee approved the study.

#### **Data Analysis**

The contribution of each item in the questionnaire to the three domains of 'physical', 'emotional', and 'social' was evaluated. The maximum possible score for each item was 7 (good health-related quality of life) and the minimum 1 (poor health-related quality of life). The emotional score was calculated as the average of responses to 14 items contributing to the emotional domain; the Physical Score was the average of 12 items contributing to the physical domain, and the social score the average of 13 items contributing to the social domain. The scoring of the items in the three domains was in accordance with the recommended practice and a global score also was calculated. [10]

Analysis was carried out using SPSS version 11. The Mann-Whitney test was used to detect differences in scores between age groups and sexes; Principal Component Analysis (PCA) was used to test for the best allocation of the items in the Persian/Farsi questionnaire to each of the original three domains described by Valenti and colleagues [10]; Cronbach's alpha was used to assess internal

Table 1: Patients' characteristics

Item		Number (%)	
Gender	Male	45 (88%)	
	female	6 (12%))	
Age	<65	32 (63%)	
	>65	198 (37%)	
Working status	Working	29 (59%)	
	Unemployed	5 (10%)	
	Retired	IS (3I)	
Admission to CCU	First	33 (72)	
	2 <sup>nd</sup>	7 (15)	
	>2	6 (13)	
Education level	Illiterate	25 (51)	
	Left school @14	19 (39)	
	College/university	5 (lo)	
Comorbidity	Yes	15 (29)	
•	No	36 (71)	
Duration of stay at hospital	≤ 8 days	29 (58)	
,	>8 days	21 (42)	

reliability; and Wilcoxon 2-sample test for test-retest reproducibility. Intra-class correlations were calculated to examine the reproducibility of the tool over the follow-up period.

#### Results

We recruited 51 patients (age range 36–81 years; mean 60 y, SD = 11.7) whose major demographic features are documented in Table 1. Six patients omitted answering one question, equating to a data loss of less than 1%. Although responses skewed towards higher scores, 70% of responses covered the entire 7-point range. At the domain-level, one patient scored at the floor on each domain while two patients scored at the ceiling level on both the physical and emotional domains. Median response was 5-7 for 77% of items (20 out of total 26 items), comparable to the original MacNew results. [11] Younger patients had better physical, social and global but not emotional scores ( $P \le 0.05$ ); no significant difference was found in the emotional domain. Duration of hospital stay, literacy and occupational status did not influence any of the HRQL scores.

#### Principal component analysis

Table 2 shows factor weights for each domain at the baseline test with 63% of variation explained. The 'social domain' accounted for 47% of variation and the 'emotional domain' for more than 10% (Table 2). Results in the Farsi version of the MacNew are similar to the contribution of the items to the three different domains in the recommended scoring system [10] except for three of the 26 items: numbers 3 (confident), 18 (frightened) and 22 (over-protective family). Item number 3 (confident) was statistically allocated to the social domain in the Farsi version rather than to the emotional domain as in the English version [10]. Item number 18 (frightened) had more relevance statistically to the social and physical domains in the Farsi version, while in the original report it was allocated to the emotional domain. Similarly, item number 22 (over-protective family) was allocated to the social domain while in our Farsi-speaking sample none of the correlation coefficients gained enough significance (>0.40) to contribute to any domain. These minor differences could be explained by the small population sample.

#### Psychometric properties

Table 3 describes the major psychometric results of the Farsi version at baseline and 4-week following discharge after acute myocardial infarction. Baseline domain means were 5, 5.3 and 4.9 for emotional, physical and social domains (at baseline) respectively. The 4-week follow-up clinic was attended by 27 patients as two patients died during the month following discharge and 22 (43%) missed the second visit. No significant differences were detected between follow-up clinic attendees and nonattendees when controlling for age, gender, level of education and duration of hospital stay. There was no significant difference in global score or in any of the three domains (Table 3) among patients with baseline and follow-up assessments (Z value: -0.33 to -1.66, non-significant). The lowest item-level score was higher one month after discharge compared with baseline (Fig. 1). Physical and global scores improved in men with no change in social and emotional scores.

Table 2: MacNew components mean rank in age and sex groups

	Emotional		Physical	Physical		Social		Global	
	Mean rank	Z score	Mean rank	Z score	Mean rank	Z score	Mean rank	Z score	
<65	27.7	98	29.6	-2.1*	30	-2.3*	29.3	-1.9*	
> = 65	23.6		20.8		20.2		21.2		
Male	27.2	-1.7	27.7	-2.2*	27.3	-1.7	27.5	-1.9*	
Female	16.5		13.2		16.3		14.8		

P < 0.05 is marked with an asterisk

Table 3: Adjusted factor weights in principal component analysis

	Social	Emotional	Physical	
I. Frustrated	.600	<u>.463</u>	.171	
2. Worthless	.757	<u>.546</u>	.180	
3. Confident	. <u>451</u>	.204	711	
4. Down in the dumps	.771	<u>.678</u>	0	
5. Relaxed	.687	<u>.797</u>	185	
6. Worn out	.724	<u>.713</u>	.140	
7. personal life	.592	.851	141	
8. Restless	.414	<u>.726</u>	0	
9. Short of breath	.545	229	<u>.753</u>	
10. Tearful	.560	<u>.553</u>	.109	
II. More dependent	<u>.722</u>	154	232	
12. Social activities	<u>.828</u>	227	0	
13. Others less confidence	<u>.811</u>	377	103	
14. Chest pain	.676	.396	<u>.554</u>	
15. Lack self-confidence	<u>.855</u>	<u>.350</u>	.135	
16. Aching legs	.652	125	<u>.712</u>	
17. Sport/exercise limited	.741	217	<u>.545</u>	
18. Frightened	<u>.660</u>	0	.663	
19. Dizzy/lightheaded	.296	158	<u>.367</u>	
20. Restricted/limited	.832	170	.360	
21. Unsure about exercise	.835	344	<u>.364</u>	
22. Overprotective family	143	295	.239	
23. Burden on others	<u>.806</u>	323	19 <del>6</del>	
24. Excluded	<u>.810</u>	379	375	
25. Unable to socialise	<u>.900</u>	.339	0	
26. Physically restricted	.872	.412	<u>.391</u>	
Total variance explained	47%	10.2%	5.8%	

Weight is shown in bold if greater than 0.40 and underlined with reference to the original weighting.[10]

All domains had excellent agreement (Intra-class correlation varied between 0.92-0.95) at p < 0.001 (Table 3). The corrected total-item correlation at baseline ranged from 0.32-0.87 in different domains. Question 22 (overprotected family) was omitted in the analysis of social and global item correlation as an outlier (Spearman rho = 0.07 and 0.17 for social and global scale respectively) and this variable may need to be the subject of modification for the Farsi version of the MacNew. Internal consistency for each domain was supported with Cronbach's alpha = 0.92

for the emotional and physical domains, 0.94 for the social domain, and 0.95 for the Global score. Test-retest analysis in those attending the follow-up clinic showed significant correlations in emotional and physical domains ( $P \le 0.05$ ) and the global scores (P < 0.01). Table (3)

#### Discussion

A common critique of quality of life tools in clinical research is that data are 'soft' and less reliable than

Table 4: Baseline data psychometric analysis

	Mean score at baseline (SD)	Mean score at retest (SD)	Z value: Mean change (P value)	Corrected total- item correlation	Baseline Cronbach's alpha	Baseline Intra-class correlation	Test-retest correlation
Emotional	4.99 (1.35)	5.21 (1)	-0.33 (0.74)	0.54–0.85	0.92	0.92 (P < 0.001)	0.42 (P < 0.05)
Physical	5.29 (1.27)	5.22 (0.99)	-1.66 (0.09)	0.44-0.84	0.92	0.92 (P < 0.001)	0.38 (P < 0.05)
Social	4.91 (1.31)	5.11 (0.98)	-0.47 (0.64)	0.66-0.87	0.94	0.93 (P < 0.001)	031 (P = 0.11)
Global	5 (1.26)	5.18 (0.95)	-0.65 (0.51)	0.32-0.86	0.95	0.95 (P < 0.001)	0.50 (P < 0.01)

traditional clinical assessment or physiological measurement. Nevertheless, both generic and disease-specific tools can detect subtle clinical changes quite precisely [23], especially in cardiac disease. [24] English language-based quality of life tools have been tested in a wide range of diseases; overall in clinical practice and in health service research, they have proven so useful that both generic and disease-specific tools have been translated into a variety of other languages for wider application.

Coronary disease is at least as prevalent in Iran as in most Western nations but population studies have been restricted by the lack of culturally-sensitive investigational tools in Farsi to assess, inter alia, quality of life. This survey reflects the first administration of such a health-related quality of life questionnaire among Iranian cardiac patients and provides an interesting insight into the quality of life of survivors of a myocardial infarction in this patient group.

Accomplishing the recommended approach to translation to achieve language equivalence was fairly straightforward but administration of the tool revealed several unexpected problems. First, the literacy rate of this population at 50% was considerably lower than the Iranian mean, which made MacNew difficult to administer. Second, this study was a reminder that cultural barriers do exist among populations with strong religious beliefs; for example, questions relating to sexual activity are particularly difficult. Third, self-administered tools are a novel experience for Iranians; as an alternative, training for and conducting interviews is costly and cannot be integrated into routine assessments until validity has been demonstrated in larger samples.

The large variety of generic and disease specific instruments can confuse researchers contemplating the most appropriate tools for quality of life investigation. We thought that the specificity of the MacNew for cardiac patients might be the most appropriate tool to assess HRQL in our patients. Its acceptability and reliability are proven, which favours its application in population studies, and several domains can predict adverse outcome [3], providing confounders such as disease severity and concurrent medications are taken into account. The latest ver-

sion of MacNew applied in this study is considerably different from its predecessor and this perhaps explains the unexpectedly improved reproducibility compared with the original application. [25] As a general rule, however, the combination of generic and disease-specific QOL questionnaires provide complimentary information. [26–28]

We were pleased with the Farsi version of MacNew. There was minimal loss of data, internal consistency exceeded that recommended [21] and was comparable with previous studies [10,11,13] and, overall, reproducibility was satisfactory. We did observe both similarities and differences between Iranian and Western populations. For example, emotional and physical scores were comparable but our Iranian patient group reported poorer social quality of life.[10]

Surprisingly, our patients found an interview-administered questionnaire acceptable and this has encouraged us to test MacNew in larger populations, to investigate the feasibility of a self-completed tool, exploring the actual weight of item 22, comparing generic and other specific questionnaires, and specifically to examine the validity of the MacNew (Farsi) by applying a standard cardiovascular classification scale concomitantly. Provided that larger studies confirm that MacNew (Farsi) is acceptable to our patients, we foresee quality of life assessment being widely adopted as an adjuvant to clinical assessment and physiological measurement in routine clinical practice Iran. This approach will facilitate patient management, allow international comparisons and direct medical services to meet patients' needs.

#### **Authors' contribution**

MAL, HRJ, MM and DG designed the study, HRJ admitted patients and conducted the interviews, MAL analysed data and wrote the first draft, NBO and DG commented on analysis and discussion and all authors approved the final manuscript.

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