

*Brief communication*

## **Evaluative and discriminative properties of the Portuguese MacNew Heart Disease Health-related Quality of Life questionnaire**

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### **Abstract**

The aim of this study was to validate the Portuguese version of the self-administered MacNew Heart Disease Health-related Quality of Life (MacNew) questionnaire in patients after diagnosis of acute coronary syndrome. The MacNew, with a Global score and physical, emotional and social subscales, the Short Form SF-36 (SF-36) and the Hospital Anxiety and Depression Scale (HADS) were completed at baseline by 150 patients and again by 48 clinically stable patients 2–3 weeks later. A cohort of 50 different patients completed the same questionnaires before and after a cardiac rehabilitation program in order to examine responsiveness. Acceptance of the MacNew by the patients was good and the three factor model was substantiated and explained 52.2% of the variance. Internal consistency, intra-class-correlation, and test–retest reliability each exceeded 0.72. The predicted construct validity hypotheses were partially confirmed. The discriminative validity of the MacNew was confirmed with significantly higher MacNew scores for patients with normal left ventricular function, with improved health status, and who were not anxious or depressed. Even though MacNew scores improved significantly following cardiac rehabilitation, the evaluative validity of the MacNew was less robust with small responsiveness statistics. The Portuguese version of the MacNew HRQL questionnaire appears to be a reliable, valid, and moderately responsive instrument to evaluate health-related quality of life after diagnosis of acute coronary syndrome.

**Key words:** Acute coronary syndrome, Cardiac rehabilitation, Health-related quality of life

### **Introduction**

One of the more important developments in health care in the past decade may be the recognition that the patient's perspective is as legitimate as the clinician's in monitoring health care outcomes [1, 2]. As a measure of the patient's perspective, the MacNew Heart Disease Health-related Quality of Life questionnaire (MacNew) is a self-adminis-

tered health-related quality of life (HRQL) questionnaire, validated and used with patients with myocardial infarction (MI) and patients with angina [3]. Acute coronary syndrome (ACS) refers to a range of acute myocardial ischemia states comprising a spectrum of conditions that includes unstable angina and acute MI and characterized by the common pathophysiologic process of a disrupted atherosclerotic plaque [4, 5]. As the

MacNew has not yet been validated in Portuguese, the purpose of this study was to examine the evaluative and discriminative properties of the Portuguese version of the MacNew in patients with a diagnosis of ACS.

## Material and methods

Following approval from the Ethics Committee, we recruited 200 patients with an ACS diagnosis 2 months after their initial treatment. The study was conducted between 2000 and 2003 in the Cardiac Rehabilitation Unit of the Cardiology Service of Hospital Geral de Santo António in collaboration with the Community Health Department of Instituto de Ciências Biomédicas Abel Salazar, Porto, Portugal.

### Instruments

We administered three questionnaires to 150 patients within two months of their initial diagnosis: the MacNew, the Short Form SF-36, and the Hospital Anxiety and Depression Scale. Responsiveness was examined in a cohort of 50 patients recruited into the cardiac rehabilitation programme.

#### *MacNew heart disease health-related quality of life*

The self-administered MacNew HRQL questionnaire has been validated in patients with MI in English [6, 7], Spanish [8], German [9], and Dutch [10] and also in German for patients with angina [11]. The MacNew questionnaire contains 27 items which are scored from 1 (poor) to 7 (high) and provides a global HRQL score, a physical limitations scale, an emotional function scale, and a social function scale [6, 7]. The psychometric properties of the MacNew have been detailed elsewhere [3]. The MacNew was translated into Portuguese using accepted linguistic translation techniques [12].

#### *Medical Outcomes Study Short Form-36 (SF-36)*

The SF-36 is a widely used generic questionnaire that gives valuable information on health status [13] and has been validated in Portuguese [14, 15]. It contains 36 items, combined in eight scales and summarized in a physical component summary

(PCS) and a mental component summary (MCS) measure [13].

#### *Hospital Anxiety and Depression Scale (HADS)*

The HADS is a self-administered questionnaire designed to screen for anxiety and depression states [16]. It consists of 14 items scored from 0 to 21 with values of  $>10$  as cut-off points for anxiety and depression [16] and is being validated in Portuguese.

### Statistical analysis

Frequencies, means and standard deviations (SD) were used to describe patient clinical and sociodemographic as well as item and scale characteristics.

Face and content validity of the MacNew have been established previously [3]. Principal component factor analysis, with varimax rotation and a three-factor solution (factor loading of  $\geq 0.40$  used to allocate an item to a scale), was used to replicate the factor structure.

#### *Discriminative properties:*

We assessed internal consistency reliability of the MacNew with Cronbach's  $\alpha$  and reproducibility 2–3 weeks later with intra-class correlation coefficients (ICC); values greater than 0.70 are considered sufficient for group comparisons [12].

With a priori predictions, construct validity of the MacNew was tested against the SF-36 component scores using Pearson correlation coefficients ( $<0.10$  = absent,  $0.10$ – $0.29$  = weak,  $0.30$ – $0.49$  = moderate and  $\geq 0.50$  = strong). The 'known-groups' approach tests for expected relationships [17] (e.g., more severe and less severe disease will have significantly different HRQL scores) and was examined with left ventricular impairment, the SF-36 health transition item, and anxiety and depression to test for concurrent validity.

#### *Evaluative properties:*

The change scores of the MacNew Global and subscales and the SF-36 component summary measures were used to assess longitudinal validity (*t*-test) in those referred to cardiac rehabilitation. Responsiveness of the MacNew was assessed by calculating the effect size ( $ES = (M1 - M2)/SD1$ ) and

**Table 1.** Baseline sociodemographic and clinical characteristics of the 150 patients with acute coronary syndrome

Patient characteristics	Mean ( $\pm$ SD*) or %
Age (years; range 29–82)	58.8 $\pm$ 11.6
Gender	
Male	84.7%
Female	15.3%
Family status	
Married	95.3%
Other	4.7%
Employment	
Working	28%
Retired	43.3%
Unemployed	2.7%
Unknown	26%
Years of Education	5.6 $\pm$ 4.1
$\leq 4$	52.7%
5–11	18.7%
$\geq 12$	12%
Unknown	16.7%
Smoking	
Never smoked	31.9%
Present smoker	47.4%
Ex-smoker	20.7%
Body mass index (range 18.2–38.6)	26.5 $\pm$ 3.5
$\leq 25\%$	46.3%
26–30%	44.2%
$\geq 31\%$	11.5%
Anxious (HADS 11+)	36%
Depressed (HADS 11+)	24.7%
Primary diagnosis	
MI	70.7%
Angina	17.3%
Other	12%
Left ventricular function	
Normal	48.7%
Mild impairment	21.3%
Moderate impairment	17.3%
Severe impairment	3.3%

\*Standard deviation.

the standardized response mean (SRM = (M1–M2)/SD <sub>$\Delta$ 12</sub>) [18].

## Results

### *Patient characteristics and response rates*

Baseline data were collected on 150 patients with ACS (70% with MI, 17.3% with angina and 12% with other diagnoses) whose sociodemographic and clinical characteristics are presented in Table 1.

The MacNew took less than 10 min to complete. The full response range was used for each item and the highest missing item rate was less than 8.6% except for item #27 (sexual activity, 11.3%, Table 2). On the subscales, no patient scored at the floor but two patients scored at the ceiling (Table 3).

### *Psychometric analysis*

#### *Principal component analysis*

The original three factor structure was confirmed although four items in the Portuguese version (with loadings  $\geq 0.40$ , i.e., #9, 11, 16, 19) did not load in the same way as they did in the English version and two items (#14, chest pain and #22, overprotective family) items failed marginally to reach the standard threshold of 0.40 (loadings for both = 0.39) used for the allocation of the original MacNew items [7]. The physical, emotional, and social subscales explained 52.2% of the total variance (Table 4).

#### *Discriminative properties*

Both of the reliability statistics, Cronbach's  $\alpha$  and the ICC, exceeded 0.84 for all MacNew scales (Table 3). Corresponding values for the MacNew from previously published work are also provided in Table 3.

Construct validity was partially confirmed with strong correlations as predicted between the MacNew Global and SF-36 PCS ( $r=0.70$ ) and MCS ( $r=0.77$ ) scales, the MacNew physical and SF-36 PCS scales ( $r=0.72$ ), MacNew emotional and SF-36 MCS scales ( $r=0.78$ ), and the MacNew social and the SF-36 role-social scales ( $r=0.58$ ). Although the correlations between the MacNew physical and SF-36 MCS and MacNew emotional and SF-36 PCS were higher than predicted, the correlations between the physical MacNew scale and the SF-36 MCS ( $r=0.68$ ) and between the emotional MacNew scale and the SF-36 PCS ( $r=0.61$ ) were lower than those between the matching physical and emotional scales on the two instruments.

Discriminative validity of the MacNew was confirmed (Table 5). Patients with normal left ventricular function, patients whose health status improved, and those who were not anxious or depressed consistently had significantly higher MacNew scores on all scales.

**Table 2.** MacNew heart disease health-related quality of life questionnaire item characteristics

Item	Missing (%)	Mean	Standard deviation
1. Frustrated	0.0	4.67	1.59
2. Worthless	0.67	5.54	1.60
3. Confident	0.0	4.67	1.97
4. Down in the dumps	0.0	4.91	1.79
5. Relaxed	0.0	4.47	1.71
6. Worn out	0.0	4.68	1.66
7. Happy with personal life	0.0	4.21	1.38
8. Restless	0.67	5.14	1.57
9. Shortness of breath	0.67	5.60	1.66
10. Tearful	0.67	5.92	1.61
11. More dependent	1.33	4.99	1.71
12. Social activities	0.67	5.58	1.69
13. Others less confidence in you	0.67	5.73	1.70
14. Chest pain	0.67	5.70	1.45
15. Lack self-confidence	1.33	5.47	1.63
16. Aching legs	0.67	4.57	1.97
17. Sports/exercise limited	8.67	3.91	1.92
18. Frightened	0.67	5.40	1.78
19. Dizzy or lightheaded	0.67	5.93	1.43
20. Restricted or limited	0.67	4.97	1.69
21. Unsure about exercise	6.00	4.28	1.99
22. Overprotective family	1.33	3.27	2.17
23. Burden on others	0.67	5.84	1.66
24. Excluded	0.67	5.95	1.63
25. Unable to socialise	2.67	6.17	1.42
26. Physically restricted	3.33	4.46	1.76
27. Sexual activity	11.33	4.87	2.18

### Evaluative properties

Longitudinal validity of the MacNew was confirmed with significant changes in the MacNew Global score and each subscale in the 50 patients who completed the cardiac rehabilitation program (Table 6).

The responsiveness statistics for the MacNew, measured with both the ES and the SRM, were small ( $<0.50$ ) for the MacNew Global score and each subscale (Table 6).

### Discussion

The psychometric properties of the MacNew Heart Disease Health-related Quality of Life questionnaire have been reported for five languages in patients with angina and MI [3]. The Scientific Advisory Committee of the Medical Outcomes Trust has identified eight attributes for instrument assessment including concept and measurement models, reliability, validity, responsiveness, interpretability, respondent and administrative burden, alternate forms, and cultural and language adaptations [12].

The Portuguese version of the MacNew satisfies the criteria for reliability with Cronbach's  $\alpha$  and the ICC exceeded 0.80 with minimal respondent burden although the Portuguese MacNew responsiveness statistics are lower than those previously reported for the MacNew [3]. This latter observation may be related to the effectiveness of the rehabilitation intervention as delivered and is supported by the fact that the SF-36 mean change scores never exceeded 4.0 and that the mean improvement in the MacNew scale scores was never more than 0.50, the score change suggested as the minimal important difference for the MacNew [19, 20].

There is relatively consistent evidence for the Portuguese MacNew's validity with construct

**Table 3.** Portuguese MacNew global and subscale characteristics; internal consistency (Cronbach's  $\alpha$ ;  $n = 150$ ) and intra-class correlations (ICC;  $n = 150$ )

	% Missing	Mean (SD*)	% Floor	% Ceiling	Cronbach's $\alpha$		ICC	
					Portuguese MacNew	Previous MacNew**	Portuguese MacNew	Previous MacNew**
Global	0	5.08 (1.0)	0	0	0.93	0.92–0.97	0.88	0.76–0.95
Physical	0	5.20 (1.1)	0	0.7	0.86	0.86–0.93	0.88	0.73–0.93
Emotional	0	5.16 (1.2)	0	0	0.92	0.91–0.97	0.84	0.77–0.92
Social	0	5.10 (1.1)	0	1.1	0.87	0.84–0.95	0.84	0.75–0.93

\*Standard deviation.

\*\*Value ranges from previously published data [4].

**Table 4.** Principal Component Analysis: Factor loadings (loadings  $\geq 0.40$  bolded) for each MacNew Item in the Portuguese version together with the factor loadings from the original factor analysis (items in boxes load as in the original scheme)

	Emotional	<i>Original MacNew</i>	Physical	<i>Original MacNew</i>	Social	<i>Original MacNew</i>
1. Frustrated	<b>0.79</b>	<b>0.79</b>	0.25	0.25	-0.06	0.15
2. Worthless	<b>0.68</b>	<b>0.74</b>	-0.07	0.16	0.25	<b>0.42</b>
3. Confident	<b>0.73</b>	<b>0.61</b>	0.13	0.26	0.13	0.37
4. Down in the dumps	<b>0.74</b>	<b>0.86</b>	0.25	0.22	0.17	0.23
5. Relaxed	<b>0.71</b>	<b>0.79</b>	0.01	0.26	0.14	0.21
6. Worn out	<b>0.75</b>	<b>0.59</b>	0.38	<b>0.52</b>	0.10	0.17
7. Happy with personal life	<b>0.59</b>	<b>0.73</b>	<b>0.41</b>	0.21	0.11	0.28
8. Restless	<b>0.71</b>	<b>0.81</b>	0.36	0.29	0.06	0.21
9. Shortness of breath*	<b>0.47</b>	0.24	0.22	<b>0.73</b>	0.20	0.32
10. Tearful	<b>0.65</b>	<b>0.72</b>	<b>0.46</b>	0.17	-0.03	0.20
11. More dependent*	<b>0.43</b>	0.39	<b>0.45</b>	0.20	0.36	<b>0.62</b>
12. Social activities	<b>0.40</b>	<b>0.40</b>	0.39	<b>0.46</b>	<b>0.51</b>	<b>0.52</b>
13. Others less confidence in you	0.29	<b>0.45</b>	0.36	0.08	<b>0.44</b>	<b>0.66</b>
14. Chest pain*†	0.39	0.17	0.22	<b>0.72</b>	0.12	0.17
15. Lack self-confidence	<b>0.68</b>	<b>0.67</b>	<b>0.44</b>	0.19	0.22	<b>0.47</b>
16. Aching legs*	<b>0.51</b>	0.39	0.18	<b>0.44</b>	0.28	0.05
17. Sports/exercise limited	0.18	0.23	<b>0.71</b>	<b>0.60</b>	0.30	<b>0.61</b>
18. Frightened	<b>0.48</b>	<b>0.63</b>	<b>0.44</b>	0.25	0.27	0.36
19. Dizzy or lightheaded	<b>0.56</b>	0.39	-0.06	<b>0.61</b>	0.28	0.07
20. Restricted or limited	0.30	0.21	<b>0.62</b>	<b>0.64</b>	0.38	<b>0.62</b>
21. Unsure about exercise	0.19	0.34	<b>0.71</b>	<b>0.47</b>	0.06	<b>0.48</b>
22. Overprotective family*†	0.11	0.18	0.17	0.00	0.39	<b>0.69</b>
23. Burden on others	0.15	<b>0.44</b>	0.13	0.20	<b>0.64</b>	<b>0.66</b>
24. Excluded	0.02	0.19	0.10	<b>0.43</b>	<b>0.82</b>	<b>0.74</b>
25. Unable to socialise	0.03	0.23	0.13	<b>0.46</b>	<b>0.79</b>	<b>0.68</b>
26. Physically restricted	0.09	0.17	<b>0.80</b>	<b>0.60</b>	0.28	<b>0.65</b>
27. Sexual activity	0.18		0.10		<b>0.42</b>	
Variance explained	25.1%	28.1%	14.4%	17.2%	12.7%	21.4%

\*Items that do not load in the Portuguese version as in the original factor analysis.

†Items that do not load on a scale in the Portuguese version.

validity confirmed in part with strong correlations as predicted between similar MacNew and SF-36 constructs. However, as previously observed, the correlations between dissimilar constructs, e.g., MacNew physical and SF-36 MCS scales, were higher than expected which may be related to the way the MacNew probes were originally developed with the focus on the patient's perceptions of the difficulties with physical activities rather than performance per se as in the SF-36 [9]. Patients with normal left ventricular function, patients with an improved health status, and those who were neither anxious nor depressed consistently had higher MacNew scores, i.e., better HRQL, on all scales providing evidence of the discriminative properties of the Portuguese version of the MacNew. Once again, this observation is consistent with previous reports of the psychometric properties of the MacNew [3].

In conclusion, the Portuguese version of the MacNew Heart Disease Health-related Quality of Life questionnaire appears to be reliable and valid demonstrating strong discriminative although less impressive evaluative properties in this study. The MacNew can be recommended as a specific HRQL instrument in Portuguese patients with a diagnosis of ACS who may or may not be referred to cardiac rehabilitation.

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**Table 5.** Mean scores ( $\pm$  standard deviation) for the MacNew health-related quality of life scores by left ventricular (LV) impairment, health status transition, and anxiety and depression

	MacNew			
	Global	Physical	Emotional	Social
LV impairment				
Normal (n = 73)	5.07 (1.00)	5.19 (1.05)	5.10 (1.13)	5.12 (1.05)
Mild (n = 32)	5.37 (1.04)	5.32 (1.09)	5.56 (1.15)	5.40 (1.05)
Moderate (n = 26)	5.00 (0.80)	5.04 (0.90)	5.12 (0.89)	4.92 (0.97)
Severe (n = 5)	3.57 (1.42)	3.82 (1.50)	3.47 (1.83)	3.46 (1.32)
p-value	0.001	0.001	0.001	0.001
Comparisons*	a, b, c**	a, b**	a, b, c**	a, b**
SF-36 health transition				
Improve (n = 34)	5.56 (0.83)	5.59 (0.94)	5.70 (0.87)	5.53 (0.89)
No change (n = 26)	5.69 (0.73)	5.83 (0.82)	5.77 (0.77)	5.73 (0.75)
Deteriorate (n = 82)	4.63 (1.01)	4.70 (1.01)	4.69 (1.21)	4.65 (1.11)
p-value	0.003	0.029	0.002	0.002
Comparisons*	d, e**	d, e**	d, e**	d, e**
Anxiety (HADS <sup>¶</sup> )				
Not anxious (n = 96)	5.43 (0.81)	5.43 (0.95)	5.59 (0.86)	5.43 (0.92)
Anxious (n = 54)	4.45 (1.08)	4.64 (1.10)	4.39 (1.24)	4.51 (1.16)
p-value	0.001	0.001	0.001	0.001
Depression (HADS <sup>¶</sup> )				
Not depressed (n = 113)	5.31 (0.84)	5.34 (0.97)	5.45 (0.89)	5.34 (0.95)
Depressed (n = 37)	4.35 (1.21)	4.57 (1.17)	4.28 (1.44)	4.34 (1.18)
p-value	0.001	0.001	0.001	0.001

\*Comparisons:

a: severe vs. normal

b: severe vs. mild

c: severe vs. moderate

d: improve vs. deteriorate

e: no change vs. deteriorate

\*\*  $p < 0.05$ <sup>¶</sup> Hospital Anxiety and Depression Scale**Table 6.** Mean change (standard deviation, SD) over 2-months of cardiac rehabilitation, effect size (ES), and standardized response mean (SRM) for the MacNew, the SF-36 component summary scale scores, and anxiety and depression

MacNew	Mean ( $\pm$ SD)		p-value	ES	SRM
	Baseline	2-months			
Global	5.09 (0.92)	5.43 (0.88)	0.003	0.37	0.43
Physical	5.15 (0.99)	5.49 (0.95)	0.016	0.34	0.36
Emotional	5.12 (0.97)	5.47 (0.94)	0.006	0.36	0.41
Social	5.07 (1.12)	5.53 (0.97)	0.001	0.41	0.49
SF-36					
Physical component	39.09 (6.74)	42.65 (7.14)	0.001	0.53	0.53
Mental component	40.43 (9.15)	42.05 (9.44)	0.075	0.18	0.20
HADS*					
Anxiety	6.42 (3.55)	7.32 (3.64)	0.058	0.25	0.29
Depression	5.38 (3.25)	5.70 (3.39)	0.50	0.10	0.10

\*Hospital Anxiety and Depression Scale.

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