**Validation of the Korean version of the MacNew heart disease health-related quality of life questionnaire**

Running head: VALIDATION OF THE KOREAN VERSION OF THE MACNEW

Kyoungrim Kang, MSN, BSN, RN

PhD Candidate, University of Technology Sydney, NSW, Australia

Leila Gholizadeh, PhD, RN, MSc, BSc

Lecturer, University of Technology Sydney, NSW, Australia

Sally C Inglis, PhD, RN, BN, BHSc(Hons)

Associate Professor, University of Technology Sydney, NSW, Australia

Hae-Ra Han, PhD, RN, MSN, BSN, FAAN

Professor, The Johns Hopkins University, Baltimore, MD, USA

\*Corresponding Author: Kyoungrim Kang

E-mail: Kyoungrim.Kang@student.uts.edu.au, Mobile: +61 452 622 171

Postal address: HDR space (03.300), Level 3, UTS Building 10, 235 Jones St, Ultimo NSW 2007, Australia

Acknowledgement: Not applicable.

Funding sources: All authors have no funding source to declare.

Conflict of Interest: The authors declare that they have no competing interests.

# Abstract

Background: Health-related quality of life (HRQoL) is an important measure in patients with cardiac disease including myocardial infarction (MI). The disease-specific tools can better reflect the impact of the disease on different aspects of the patient’s life.

Purpose: The aim of the study was to assess the psychometric properties of the Korean version of the MacNew Heart Disease HRQoL Questionnaire

Methods: A total of 136 patients who had experienced MI about three months earlier were recruited from two tertiary hospitals in South Korea. The internal consistency and various types of validity of the Korean MacNew were assessed. Partial confirmatory factor analysis (PCFA) with direct oblimin rotation (Maximum likelihood) was performed to determine if the items in the Korean version corresponded to the theoretical three-factor structure in the original version.

Results: The internal consistency of the Korean MacNew was excellent as indicated by high Cronbach’s alpha coefficients, ranging from 0.86 to 0.93. Face validity and construct validity (both discriminant and concurrent) of the Korean MacNew were established. There were strong positive correlations between the total Korean MacNew and the single-item global QoL scale (r=0.73, P<0.001). As expected, the emotional and the physical domains of the Korean MacNew had strong negative correlations with the DASS 21 (r=-.80, *p*<.001), and the single-item fatigue scale (r=-.54, *p*<.001). Factor analysis fairly supported the original three-dimensional structure of the scale, but not the factor-loading pattern.

Conclusion: The Korean version of the MacNew showed consistently acceptable psychometric properties of reliability and validity in patients with MI. Therefore, this instrument can be recommended for assessing HRQoL of MI patients among the Korean population. However, caution should be made in using the sub-scale scores.

Keywords: Health-related quality of life; MacNew; myocardial infarction; Korean; validation.

# Introduction

Health-related quality of life (HRQoL) is an important and relevant measure in patients with cardiac disease, allowing for a more comprehensive assessment of health status as perceived by the patient. HRQoL presents the patient’s individual perspective of the burden and trajectory of their illness as well as their overall health (Rumsfeld et al., 2013). Thus, careful assessment of this concept can provide valuable information about the patient and help guide clinical decisions and treatment. Several generic and disease-specific measurements have been used to assess HRQoL in cardiac patients and they are useful; however, the disease-specific tools can reflect better the impact of the disease on various aspects of the patient’s life (Pavy et al., 2015). Further, disease-specific tools are more sensitive to changes during recovery from cardiac events such as myocardial infarction (MI) and treatments (Nakajima, Rodrigues, Gallani, Alexandre, & Oldridge, 2009).

Despite significant improvements in intervention and treatment, MI remains one of the leading causes of mortality and morbidity in South Korea (Kook et al., 2014). Increasing attention is being paid to improving patients’ experience with MI and the impact that such a life threatening event can have on the patients’ wellbeing and quality of life (Rumsfeld et al., 2013). In Korea, the 36-Item Short Form Health Survey is the most commonly used generic tool for assessing HRQoL in cardiac patients, followed by the Seattle Angina Questionnaire, the Quality of Life Index-Cardiac, and the Padilla and Grant’s Quality of Life Index (Lee, Tak, & Song, 2005). However, the MacNew Heart Disease Health-related Quality of Life (MacNew) is more likely to comprehensively reflect the experiences of patients with cardiac diseases. This measurement requires patients to answer the items about their ‘heart problem’ and the impact of these experiences on different aspects of their life, while the Seattle Angina Questionnaire and the Minnesota Living with Heart Failure Questionnaire refer to ‘chest pain, chest tightness or angina’ and ‘your heart failure’, respectively, in the questions that may be hard to cover a wide range of cardiac events, such as heart attacks (Stefan Höfer et al., 2012; Pavy et al., 2015).

The MacNew is the modified version of the Quality of Life after Myocardial Infarction Questionnaire (QLMI), developed by Hiller et al. (1994), and the QLMI questionnaire (QLMI-2) developed by Valenti, Lim, Heller, & Knapp (1996). It is a valid and reliable questionnaire for assessing HRQoL in patients with a broad range of cardiac diseases including angina, heart failure and MI (Stefan Höfer, Lim, Guyatt, & Oldridge, 2004). The MacNew has been translated into a wide range of languages and is available in more than 50 countries. The psychometric properties of the tool have been validated in patients with MI and other cardiac conditions in 20 languages (MacNew.org, 2016). However, the Korean version of the MacNew has not been validated. The aim of the study was to translate the MacNew into Korean, and assess the reliability and validity, and factor structure of the tool to measure HRQoL in Korean patients with MI.

# Methods

## Settings and subjects

The study was implemented as part of a larger observational longitudinal study, which aimed to examine changes in HRQoL after MI and to identify factors affecting HRQoL in this patient population. The study was conducted at the cardiovascular centres of two major tertiary referral hospitals in the southern part of South Korea. Patients admitted to these centres were consecutively recruited from August 2015 to February 2016, and were followed up for three months after discharge. Inclusion criteria of the study included patients: 1) admitted to a cardiac department with a diagnosis of MI (either STEMI or NSTEMI); 2) able to understand and speak Korean; 3) living in Korea; and 4) able to understand the study and provide an informed consent.

A total of 215 patients were screened in accordance with the inclusion criteria. One hundred and fifty patients (69.8%) gave informed consent to participate and completed the study questionnaires at baseline and after three months. Of the screened patients, 65 patients were not recruited due to poor health condition (n=23), declined without any reason (n=19), inadequate hearing (n=17), discharged before enrolment (n=5) or being unconscious (n=1). Poor health condition was mentioned as experiencing dyspnoea, pain on the site of intervention, severe tremor, or tiredness. By the time of the follow-up, four out of 150 participants were deceased and ten were lost to the follow-up. As a result, 136 participants completed the study questionnaires at the three-month follow-up, including the Korean version of the MacNew.

## Study procedure

Before recruitment of participants, the ethics approval of each Institutional Review Board was obtained. Once participants signed the consent form, they were asked to complete the self-report questionnaires in the Korean language. Clinical data of the participants were retrieved from medical records. Nursing staff and cardiologists collaborated and provided counselling in recruitment of the study participants and collecting medical records. At three months after discharge from hospital, a follow-up interview was carried out with each participant by telephone, or participants were asked to complete the follow-up questionnaires in a face-to-face session when they attended the outpatient department as part of their routine care.

## Measurements

The study questionnaires included key socio-demographic questions such as age, gender, marital status and self-evaluated income (excellent, good, only fair, and poor); and questions about clinical characteristics contained recurrent MI (yes/ no) and physical activity (active/ relatively active/ not active).

This study used the Korean version of the MacNew. The MacNew consists of 27 items, which assess cardiac patients’ perceived emotional (14 items), physical (13 items), and social functioning (13 items) over the previous two weeks. A single item can be part of more than one subscale. Each item is scored on a seven-point Likert scale ranging from 1 to 7. A higher score on the scale indicates better HRQoL. The total score of the MacNew is the sum of the 27 items ranging from 26 to 189, and the total score for each physical, emotional and social HRQoL subscales ranges from 14 to 98, 13 to 98 and 13 to 91, respectively (Dixon, Lim, & Oldridge, 2002).

For the purpose of this study, the tool was translated into Korean following the guidelines suggested by Guillemin et al. (1993). To obtain a quality translation, the principal researcher, who has vast experience in the translation of English texts into Korean, first translated the instrument into Korean. Then, the back-translation was carried out by two bilingual experts who had not seen the questionnaire previously. Differences in the translations were discussed and agreement was reached on the final version. The Korean version of the MacNew was next reviewed by three Korean native health professionals in the field of cardiovascular disease and five laypersons for face validity.

We used the Depression Anxiety and Stress Scale (DASS 21), the single-item fatigue scale, and the single-item global quality of life scale to assess the concurrent construct validity of the Korean MacNew. We hypothesised that the MacNew emotional scale would correlate significantly and closely with the DASS 21 (McDonnell, Mackintosh, Hillier, & Bryan, 2014). DASS 21 is the short form of the DASS 42, designed to measure the severity of the core symptoms of depression, anxiety and stress. It consists of 21 items and each item is scored from 0 (did not apply to me at all) to 3 (applied to me very much or most of the time). Higher total scores on the DASS 21 represent greater emotional distress. Past research shows strong positive relationships between experience of depression and poorer HRQoL in patients with MI (McDonnell et al., 2014; Moryś, Bellwon, Höfer, Rynkiewicz, & Gruchała, 2016). DASS 21 has been widely used in Asian countries and the Korean version is available (Cha, 2014). We also hypothesised that the MacNew’s physical scale would correlate significantly and closely with the single-item fatigue scale (Alsén & Brink, 2013; Casillas, Damak, Chauvet-Gelinier, Deley, & Ornetti, 2006; Hwang, Liao, & Huang, 2014). The single-item fatigue scale is a valid tool with response options ranging from 0 (no fatigue) to 10 (greatest possible fatigue) (H.-J. Kim & Abraham, 2017).

Additionally, we expected to find a significant correlation between the MacNew’s global scale with the single-item quality of life scale (De Boer et al., 2004), as they both measure the same construct. The single-item quality of life scale has proved to be a valid tool with response options ranging from 0 (the worst it has ever been) to 10 (the best it has ever been) (De Boer et al., 2004). Based on past literature, we hypothesised that the MacNew scores would correlate negatively with the DASS (McDonnell et al., 2014; Moryś et al., 2016) and the fatigue scores (P. Alsén & E. Brink, 2013; Casillas, Damak, Chauvet-Gelinier, Deley, & Ornetti, 2006; Hwang, Liao, & Huang, 2014), but positively with the single-item quality of life score (Alsén & Brink, 2013; De Boer et al., 2004; W. Wang, Thompson, Ski, & Liu, 2014).

## Ethical considerations

Ethical approvals were obtained from the relevant research ethics committees prior to commencement of the study (PNUH-IRB No. H-1505-008-029, PNUYH IRB No. 05-2015-072, UTS HREC Approval Number: 2015000254). The researcher provided verbal and written information about the study and its objective to the participants and assured them of their voluntary participation, confidentiality and privacy. Informed consent was obtained from all participants.

## Statistical analyses

The follow-up data of 136 participants were analysed for the present validation study, using IBM SPSS Statistics 24. Characteristics of the participants were described using frequencies, means, and standard deviations (SD) (Table 1). The psychometric properties of the Korean version of the MacNew were assessed in accordance with the recommendations of the Scientific Advisory Committee of Medical Outcomes Trust (2002). Specifically, partial confirmatory factor analysis (PCFA) with direct oblimin rotation (Maximum likelihood) was performed to determine if the items loaded similarly to the theoretically clear structure in three factors of the original version (Valenti et al., 1996).

The Cronbach's α coefficient was used to examine the internal consistency of each dimension and of the overall tool. The concurrent construct validity of the Korean MacNew was assessed by calculating the Pearson correlation coefficients of the emotional score of the MacNew with the DASS, the physical score with the single-item fatigue scale, and the total score with the a single-item of global quality of life scale. The strength of the correlations was considered weak when r=0.10 to 0.29, medium when r=0.30 to 0.49 and strong when r=0.50 to 1.0 (Pallant, 2016). Discriminant validity was determined via assessment of the ability of the Korean MacNew to discriminate between males and females, different age groups, and levels of physical activity. We hypothesised that HRQoL of the participants would be poorer if they were female, aged older and less active. Gender (Lim et al., 1993; Valenti et al., 1996) and age (H. M. Kim, Kim, & Hwang, 2015; Ogińska-Bulik, 2014; Valenti et al., 1996) have been used in previous studies for assessment of discriminate construct validity of the MacNew. There is also evidence in the fact that patients who are less physically active tend to have poorer quality of life than those who are more active (Hawkes et al., 2013).

# Results

Socio-demographic and clinical characteristics of the study participants are demonstrated in Table 1. The sample consisted of mainly male patients (73.5%) with mean (SD) age of 64.35 ± 11.61 who were married (87.5%) and evaluated their income as only fair (60.3%). The majority of the participants had experienced MI for the first time (78.0%) and were physically not active or only relatively active (71.3%).

## Table 1. Socio-demographic and clinical characteristics of the study participants (N=136)

|  |  |
| --- | --- |
| Participant characteristics | N (%) |
| Age  Mean ± SD years  Range  ≥65 | 64.35 ± 11.61  21- 86  69 (50.7) |
| Gender  Female  Male | 36 (26.5)  100 (73.5) |
| Marital Status  Married  Never married, separated, divorced, widowed | 119 (87.5)  17 (12.5) |
| Physical activity  Active  Relatively active  Not active | 39 (28.7)  29 (21.3)  68 (50.0) |
| Self-evaluated income  Excellent  Good  Only fair  Poor | 3 (2.2)  15 (11.0)  82 (60.3)  36 (26.5) |
| Recurrent MI  Yes  No | 30 (22.1)  106 (77.9) |

To examine the factor structure of the Korean MacNew Questionnaire, data on all 27 items of the questionnaire were subjected to PCFA with direct oblimin rotation. The suitability of data for factor analysis was assessed; the inspection of the correlation matrix revealed the presence of many coefficients of 0.30 and above; the Kaiser-Meyer-Oklin value was 0.89, exceeding the recommended value of 0.60; and the Bartlett’s Test of Sphericity reached significance (*p*<.001) supporting factorability of the data.

The PCFA with the direct oblimin rotation solution was applied to help interoperate factor loading of each of 27 items of the MacNew on the three factors, explaining 49.2% of the total variance. The emotional factor explained 38.7% of variance, the physical factor 6.6%, and the social factor 4.0% of variance (see Table 2). The majority of the items loaded to the similar factor of the original study at more than 4.0, although five of them loaded at between 0.3 and 0.4. Specifically, three of the 27 items in the Korean MacNew loaded on unexpected factors. Item 16 (aching legs) loaded on the social factor instead of the physical factor, item 21 (unsure about exercise) and item 22 (overprotective family) loaded on the emotional factor rather than the physical or the social factor. Table 3 showed figures of normed fit index (NFI), comparative fit index (CFI), Tucker-Lewis index (TLI), root mean square error of approximation (RMSEA), and standardised root mean square residual (SRMR) for evaluating confirmatory factor analysis model fit at three-, five- and one-factor structures. In the three-factor model, NFI (0.776), CFI (0.877) and TLI (0.842) were calculated slightly under the need of the model fit (higher than .95), while RMSEA (<.08) and SRMR (<.06) met the model fit requirements.

The internal consistency of the global scale and subscales of emotional functioning, physical functioning, and social functioning were excellent as indicated by the Cronbach’s alpha coefficients of 0.93, 0.91, 0.86, and 0.90 respectively.

## Table 2: Partial Confirmatory Factor Analysis (PCFA) with direct oblimin rotation (Maximum likelihood) of the Korean MacNew (N=136)

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
|  |  | **The MacNew domains** | | | | | |
|  |  | **Emotional** | | **Physical** | | **Social** | |
|  | **MacNew items** | **Korean** | **Original** | **Korean** | **Original** | **Korean** | **Original** |
| 1 | Frustrated | 0.78 | **0.79** |  |  |  |  |
| 2 | Worthless | 0.45 | **0.74** |  |  | 0.51 | **0.42** |
| 3 | Confident | 0.38 | **0.61** |  |  |  |  |
| 4 | Down in the dumps | 0.70 | **0.86** |  |  | 0.33 |  |
| 5 | Relaxed | 0.55 | **0.79** |  |  |  |  |
| 6 | Worn out |  | **0.59** | 0.32 | **0.52** |  |  |
| 7 | Happy with personal life | 0.46 | **0.73** |  |  |  |  |
| 8 | Restless | 0.69 | **0.81** |  |  |  |  |
| 9 | Short of breath |  |  | 0.44 | **0.73** |  |  |
| 10 | Tearful | 0.34 | **0.72** |  |  | 0.42 |  |
| 11 | More dependent |  |  |  |  | 0.64 | **0.62** |
| 12 | Social activities |  | **0.40** |  | **0.46** | 0.44 | **0.52** |
| 13 | Others/less confident in you | 0.59 | **0.45** |  |  |  | **0.66** |
| 14 | Chest pain |  |  | 0.39 | **0.72** |  |  |
| 15 | Lack of self-confident |  | **0.67** |  |  | 0.70 | **0.47** |
| 16 | Aching legs |  |  |  | **0.44** | 0.44 |  |
| 17 | Sports/exercise limited |  |  | 0.78 | **0.60** |  | **0.61** |
| 18 | Frightened | 0.52 | **0.63** |  |  |  |  |
| 19 | Dizzy/ light-headed |  |  | 0.42 | **0.61** |  |  |
| 20 | Restricted or limited |  |  | 0.80 | **0.64** |  | **0.62** |
| 21 | Unsure about exercise | 0.41 |  |  | **0.47** |  | **0.48** |
| 22 | Overprotective family | 0.35 |  |  |  |  | **0.69** |
| 23 | Burden on others |  | **0.44** |  |  | 0.90 | **0.66** |
| 24 | Excluded | 0.36 |  |  | **0.43** | 0.32 | **0.74** |
| 25 | Unable to socialize | 0.32 |  | 0.41 | **0.46** |  | **0.68** |
| 26 | Physically restricted |  |  | 0.89 | **0.60** |  | **0.65** |
| 27 | Sexual activities |  |  |  | N/R | 0.39 |  |
| Variance explained | | 38.7% | **28.1%** | 6.6% | **17.2%** | 4.0% | **21.4%** |

Concurrent construct validity of the Korean MacNew was supported by demonstrating strong negative correlations between the emotional dimension of the MacNew and DASS 21 (r=-.80, *p*<.001), and between the physical dimension and the single-item fatigue scale (r=-.54, *p*<.001). There were significant positive correlations between the total MacNew score and the single-item global quality of life scale (r=.73, *p*<.001).

Discriminant validity of the Korean MacNew was also supported by examining the discriminant function of the tool across different age groups, gender, and physical activity. Patients ≥65 years old showed lower HRQoL than those <65 years old (144.19 vs. 155.07 respectively, p=.002). The Korean MacNew also discriminated well between female and male, with female patients showing poorer HRQoL than male patients (140.50 vs. 152.80 respectively, p=.002). The difference in the MacNew scores among patients who had been more active, relatively active and who had not been active (157.14, 156.89 vs 140.05 respectively, p<.001) was statistically significant, indicating that the discriminant concurrent validity on the Korean MacNew was well confirmed.

# Discussion

Patients’ evaluation of the impact of the disease on their daily functionality and quality of life is important to facilitate patient centred care and improve disease and patient outcomes. HRQoL has been an important patient-reported health outcome in consideration of its prediction of mortality, recurrence of cardiovascular events and re-hospitalisation among patients with cardiovascular disease, particularly in MI (Anker et al., 2014). The MacNew questionnaire is one of the most popular disease-specific questionnaires for assessing HRQoL in cardiac patients (MacNew.org, 2016). The current study demonstrated that the Korean MacNew is also reliable and valid for measuring HRQoL in patients with MI.

The Cronbach’s alpha coefficients of the Korean MacNew in the current study were high with 0.93 for the overall score and 0.91, 0.86 and 0.90 for the emotional, physical and social subscales, respectively. The results were consistent with prior internal consistency reports, with the average internal consistency reliability coefficients for the total, emotional, physical and social domains being 0.93, 0.92, 0.86 and 0.88, respectively, throughout the 23 validation studies conducted in different languages (Stefan Höfer et al., 2004; Stefan Höfer et al., 2012; Pavy et al., 2015; Wenru Wang, Lau, Palham, Chow, & He, 2015). The concurrent construct validity and discriminate construct validity of the Korean MacNew were also supported. Therefore, the Korean version of the MacNew demonstrated high reliability and validity for assessing HRQoL in patients with MI.

All the 27 items on the Korean MacNew met the threshold standard for item retainment and most loaded on the expected factors consistent with the original version. The results supported the original three-factor structure of the tool; however, a few items loaded on a different factor compared to the original validation study, as seen in Table 2. Loading of item 16 (aching legs) was skewed to the social factor rather than the physical factor. A potential explanation for this finding is that this item culturally affects the patient’s social health rather than only their physical aspect. Korean people may think of enduring the recovery phase of MI as interfering more with their social status and activities rather their emotional or physical health. On the other hand, loadings of item 21 (unsure about exercise) and item 22 (overprotective family) were on the emotional dimension rather than the physical or the social ones. Pogosova, Kursakov, and Boycharov (2015) and Seneviwickrama et al. (2016), who used the Russian and the Sinhalese versions respectively, also found that item 21 loaded on the emotional domain. Item 22 loading on the emotional domain was consistently found in a study of the German version of the MacNew, conducted by Stefan Höfer et al. (2008). These findings may suggest that the Korean patients who have experienced MI three months earlier are still affected emotionally regarding their certainty regarding exercise and feeling they have an overprotective family. In the previous validation studies, item 27 mostly loaded on either the social domain (Stefan Höfer et al., 2012; Leal et al., 2005) or the physical domain (Nakajima et al., 2009; Pavy et al., 2015; Yu, Thompson, Yu, & Oldridge, 2008), while the original study (Valenti et al., 1996) and a few other versions did not include this item in the factor analysis (Seneviwickrama et al., 2016; Wenru Wang et al., 2015). However, item 27 (sexual activities) in the Korean version fell into the social dimension at 0.39 consistent with studies in other languages including Portuguese (Leal et al., 2005), German (S Höfer et al., 2005), and Russian (Geulayov et al., 2013). These results suggest that sexual activities in Korean patients after MI are related to their social aspect of HRQoL.

In general, the results of previous validation studies on both English (Dempster, Donnelly, & O’Loughlin, 2004) and non-English patients with cardiac disease fail to support the item loading pattern (Gramm, Farin, & Jaeckel, 2012) as reported in the original study. For example, Dempster et al. (2004) established a five-factor solution, including factors of emotion, restriction, symptoms, perception of others and social on a population of cardiac patients in Ireland (Dempster et al., 2004). The results of the model fit evaluation in the present study also showed slightly improvement at the five-factor structure. Therefore, it implies that the factor structure of the MacNew may need to be further reviewed.

Overall, the results of the current validation study suggest that the Korean MacNew is a valid and reliable tool for assessing HRQoL in patients with MI. However, we recommend that only the total score for the Korean MacNew to be used at this stage, unless future studies with bigger sample sizes provide more consistent results on the pattern of item loadings on the individual subscales. Our study sample size of 136 may not be large enough to produce reliable results. Although, some authors suggest that five cases for each item are adequate for factor analysis in most cases, the recommendation generally is the larger sample size, the better (Tabachnick & Fidell, 2013).

# Conclusion

The Korean version of the MacNew showed consistently acceptable psychometric properties of reliability and validity in patients with MI. The instrument can therefore be used for assessing HRQoL of Korean MI patients to develop a better understanding of patients’ health conditions after MI and evaluation of interventions or related treatments from patients’ experiences. However, caution should be made in using the sub-scale scores.

Conflict of Interest: The authors declare that they have no competing interests.

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