Adaptation of MacNew Heart Disease Health-Related **Quality of Life Instrument in Indonesian Myocardial Infarction Patients**

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Abstract

Lack of adapted health-related quality of life measurement in Bahasa Indonesia may create difficulties in concluding the effects of heart disease and its treatment on a patient's health-related quality of life in Indonesia. MacNew heart disease health-related quality of life questionnaire (MacNew) has been proven a valid and reliable health-related quality of life measurement. It also has been adapted in several languages. This study aimed at translating and assessing the Indonesian version of MacNew questionnaire validity evidence based on the relation with other variables on and internal consistency. Validity evidence based on the relation with other variables was assessed by correlating the Indonesian version of the MacNew questionnaire score with cardiac anxiety, gender, age, education level, left ventricular ejection fraction score, and comorbidity. Two hundred thirty-six patients diagnosed with myocardial infarction (MI) filled out the questionnaire at a one-time intake. Results from confirmatory factor analysis revealed three domains of health-related quality of life, namely emotional, physical, and social. The three-domain explained 42.31% of the health-related quality of life total variance. The internal consistency of the questionnaire was good (0.816-0.900). Health-related quality of life was negatively correlated with cardiac anxiety. Male patients had a higher health-related quality of life compare to female patients. However, there was no significant correlation between health-related quality of life and left ventricular ejection fraction and comorbidity. The Indonesian version of MacNew questionnaire demonstrated satisfactory psychometric properties and can be recommended to measure HRQOL in heart patients in Indonesia.

Keywords: Health-related quality of life, MacNew Heart Disease HRQOL instrument, instrument adaptation

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Introduction

In the past decades, health-related quality of life (HRQOL) has been examined extensively. Keywords health-related quality of experience in the Google Scholar engine revealed 1,470,000 results. Although HRQOL has received much attention, the consensus regarding the definition of HRQOL remains afar. There are several definitions of HRQOL. HRQOL can be defined as the effects of health, illness, and its treatment on quality of life (Ferrans, Zerwic, Wilbur, & Larson, 2005). Guyatt, Feeny, & Patrick (1993) distinguish between the quality of life and HRQOL. Quality of life, health status, and functional status can be used interchangeably and infer wide aspects of life. However, HRQOL assumes more limited aspects that are far from medical relations are not included in HRQOL. Cella & Stone (2015) define HRQOL as a general perception of the quality of life affected by the disease, its treatment, and functional limitations. Bowling (2005) stated that as one domain of broader quality of life, HRQOL could be defined as perceptions of goodness in life affected by health.

HRQOL is an important index not only for clinicians but also for patients to measure the impacts of disease and medical interventions (Guyatt et al., 1993). There are two types of HRQOL measurements, namely disease-specific measurement and generic measurement. A generic measurement is not specified for a certain disease; thus, it can be used for patients with any type of disease and healthy people. Disease-specific measurement contains items that are meaningful for a disease. It is concluded that disease-specific measurement is more relevant to the patients and also more responsive to changes caused by the treatment or disease progression. Generic measurement also has its advantages that enable comparison of results across different types of disease, with a healthy population to have a better understanding regarding HRQOL (Cella & Stone, 2015). It is also advisable to use both disease-specific and generic measurements to gather more comprehensive data (Sneed, Paul, Michel, Vanbakel, & Hendrix, 2001).

Mortality and morbidity in Indonesia caused by cardiovascular disease are concerning. It is reported that cardiovascular disease caused more than 30% of death in Indonesia (World

Health Organization, 2014). The increasing number of patients with hypertension and diabetes, cigarette smoking, high level of cholesterol and body weight are considered to be risk factors contributing to premature death caused by cardiovascular disease (Hussain, Peters, Woodward, Huxley& Al Mamun, 2016; Kementrian Kesehatan Republik Indonesia, 2013). Not only death, DALY (disability-adjusted life years) caused by cardiovascular disease ranged from 10-19 years (World Health Organization, 2004). Patients with MI experienced many challenges in their life; hence, MI affected a patient's health-related quality of life. However, to the best of our knowledge, there is none health-related quality of life instruments available to assess the impact of myocardial infarction on Indonesian patients. Therefore, a validated HRQOL instrument will be beneficial to measure the effects of myocardial infarction and its treatments on a patient's HRQL.

MacNewHeart Disease HRQOL instrument (MacNew) is a self-administered disease-specific measurement that consists of 27 items. The MacNewHeart questionnaire was a modification from the Quality of Life after Myocardial Infarction questionnaire (QLMI). There are three domains in the MacNew questionnaire, namely physical limitation, emotional function, and psychological function. The MacNew questionnaire has have been adapted into 28 languages and more appropriate measures for intervention trials and routine clinical care (Höfer et al., 2012). It is also proven to be a valid, reliable and responsive instrument to assess HRQOL in patients with myocardial infarction, heart failure, angina and ischaemic heart disease(Dixon, Lim, & Oldridge, 2002; Höfer et al., 2012). The MacNew questionnairewas correlated with adverse events in patients (Höfer, Lim, Guyatt, & Oldridge, 2004). Currently, no study adapted the MacNew Heart questionnaire in Indonesia. Therefore it needs to examine whether the MacNew Heart questionnaire appropriate for MI patients in Indonesia. This study aimed to adapt MacNew Heart Disease HRQOL into Bahasa Indonesia and examine the factor structure of it in Indonesian MI patients.

Method

Respondents

Respondents were recruited from a national hospital in Jakarta. Before the study was conducted, ethical approval was given from the hospital and university ethical committee. Purposive sampling was employed in the study. The inclusion criteria for the study are patients diagnosed with MI and not diagnosed with mental illness, according to DSM IV. The questionnaire was distributed to the patients after their regular monthly visit, in a closed room to ensure confidentiality. More than 90% of the respondent prefers to do interview administered questionnaire. Two hundred fifty patients filled out the questionnaire. However, 14 patients were not included in the analysis because of the incomplete data. The response rate for the study is 94.4%.

The study sample consisted of 236 respondents with a range of age 41-71. There were 34 female and 197 male respondents in the study. Inclusion criteria for the study were: diagnosed with MI and not suffered from any mental disorder, as mentioned in DSM V. Table I showed respondents characteristic in the study. More than 50% of the respondents were above 56 years of age. There were 14.7% female and 85.3% male respondents of the study. More than 70% of the total respondents had high and higher education. As can be seen in Table I, the two most prevalent secondary diagnoses of the patients were diabetes and hypertension.

Respondent's Demographic and Medical Characteristics				
Variable	n	%		
Age (years)				
41-45	19	8.3		
46-50	26	11.4		
51-55	62	27.2		
56-60	50	21.9		
61-65	56	24.6		
66-70	11	4.8		
>70	4	1.8		
Sex				
Male	197	85.3		
Female	34	14.7		

Tabel 1. Respondent's Demographic and Medical Characteristics

Marital Status	229	99.1
Married	2	0.9
Single		
Educational Level		
Primary	50	21.7
High School	81	35.1
College	98	43.2
Comorbidity		
Diabetes Mellitus	89	41.4
Congestive Heart Failure	34	15.8
Hypertension	91	42.3
Treatment		
Percutaneous Coronary	154	66.7
Intervention		
Coronary Artery Bypass	4	1.7
Grafting		

Tabel 2 showed mean and SD for each of the MacNew questionnaire domains. The emotional domain has the highest mean, followed by a physical and social domain. Thus, it can be concluded that MI patients experienced better emotional responses compare to physical and social responses affected by MI and its treatment.

Table 2.

Descriptive Statistics of MacNew HRQOL Domains of MI Patients

Domain	Mean	SD	Min	Max	
Emotional	5.125	0.871	3.09	6.91	
Physical	4.881	1.089	2.00	7.00	
Social	4.778	1.055	1.60	6.90	

Translation process

The forward translation of the MacNew questionnaire was delivered by two independent bilingual health professionals. Differences between the two translations were resolved to achieve one appropriate MacNew questionnaire translation by the author and also from the MacNew Organization. This MacNew translation was translated again in English by two translators who have not seen the parent language version of the test. The author and MacNew questionnaire developer worked together to select the best translation. This backtranslation was conducted several times until a satisfactory result achieved. The Indonesian MacNew questionnaire consisted of 27 items. Before distributed to the respondent, ten heart patients were given the questionnaire and interviewed to explore any language difficulties.

Measurements

The MacNew questionnaire is an HRQOL instrument that can either be self- administered and interviewer-administered. It has been tested on more than 5,200 heart patients. The instrument consists of 27 items with a seven-point Likert scale. There are three domains in MacNew questionnaire namely physical (e.g., How much shortness of breath have you experienced during the last 2 weeks while doing your day-to-day physical activities?) psychological (e.g. how often in the last two weeks have you felt worthless and inadequate?) and social wellbeing (e.g. how often during the last two weeks have you felt you were unable to do your usual social activities, or social activities with your family?) (Dixon et al., 2002). The score of each item ranges from I (all of the time) to 7 (none of the time) with a higher score means higher HRQOL. For each of the three-domain, averaged response of each domain. The global score derived from the averaging response from all 27 items. (Dixon et al., 2002). If 50% of the response for each domain is missing, the score for that domain is considered missing. Studies show that the MacNew questionnaire has good reliability. It is also predicted adverse cardiac events, responsive and sensitive to changes in HRQOL due to interventions (Höfer et al., 2004). The scoring system of the adapted questionnaire follows the instruction for the originally developed MacNew questionnaire. The maximum score for the questionnaire is 7 (high HRQOL), and the minimum is 1 (low HRQOL). A higher score indicating higher HRQOL. In order to evaluate the three domains, each score from each domain was derived from averaging items that contribute. Average of scores from 13 items will constitute a score for physical limitation. Average of 14 items will make up the score for the emotional function domain, and the mean of 13 items will result in a score for the social function domain. The score for global HRQOL will be derived from averaging scores from 27 items.

Cardiac anxiety was measured by the Cardiac Anxiety Questionnaire (CAQ). CAQ is a Likert type scale consisted of 18 items with five answering options, form 0 (never) to 4

(always). The score for total and subscale obtained from the mean score. A higher score of CAQ indicated higher cardiac anxiety. Factor analytic study revealed three subscales, namely fear regarding heart disease (e.g., I worry that I may have a heart attack), escaping behavior (e.g., I avoid physical exertion), and attention focused (e.g., I pay attention to my heartbeat). CAQ is a valid and reliable instrument and proven to be different from general cardiac anxiety measurement (Van Beek et al., 2012). In this study, the Cronbach $\alpha = 0.808$ for the overall measure, indicating good internal consistency.

Left ventricular ejection fraction (LVEF) is a measurement for the cardiac function to pump blood (DeSilva, 2013). The score for LVEF was gathered from the patient's medical report. The higher percentage of LVEF indicated better cardiac function. For the study, the score of LVEF will be categorized into moderate to severe ($\leq 40\%$) and normal to mild (> 40%). Comorbidity was indicated by the Charlson Comorbidity Index (CCI) score, which summed up the number of comorbidities reported by patients. The CCI obtained by using weighted factors based on disease severity. The CCI is known to measure patients' comorbidity (Charlson, Pompei, Ales, & MacKenzie, 1987; H.-Y. Wang, Chew, Kung, Chung, & Lee, 2007). The higher the CCI score, the more patients have a comorbid condition.

Statistical analysis

The patient's demographic data, internal consistency, and validity evidence based on relations with other variables were calculated using IBM SPSS Statistics 20. For demographic data, mean and SD were used to describe descriptive statistics of the data. To tested the measurement model of the MacNew questionnaire, confirmatory factor analysis with three domains, namely physical limitations, social function, and psychological function, was conducted by using MPlus 7. Internal consistency was examined with Cronbach Alpha. Evidence-based on relations with other variables validity was examined by association between HRQOL and variables that proved to be correlated with HRQOL namely cardiac anxiety(Van Beek et al., 2012), age(Longmore et al., 2011; Muhammad et al., 2014), gender(Ahmad, Muhammad, & Abdullah, 2011; Bergman, Malm, Karlsson, & Berterö, 2009; Hosseini, Ghaemian, Mehdizadeh, & Ashraf, 2014; Norris et al., 2008), left ventricular ejection fraction (LVEF)(Pettersen, Kvan, Rollag, Stavem, & Reikvam, 2008), educational

level (Choo, Burke, & Pyo Hong, 2007; Norekvål et al., 2010) and comorbidity (W. Wang et al., 2014). Mann-Whitney was used to explore the association between HRQOL, gender, age, and educational level. Pearson product-moment analyzed the association between LVEF, CCI, cardiac anxiety, and HRQOL.

Results

Factor analysis

Results from confirmatory factor analysis revealed that the three factors explained 42.31% of HRQOL variance. As can be seen in Table 3, the first factor that consists of the item that describes social issues in heart patients. Explained about 28.85%. The first factor included Item 8, 11, 12, 13, 17, 20, 21, 22, 23, 24, 25, 26, 27 were loaded \geq 0.40. The second factor, which describes emotional issues, explained 7.41% and consisted of the item that was loaded \geq 0.40 were item 1, 2, 4, 5, 7, 8, 10, and 18. The last factor explained physical issues in MI patient's life, explained 6.05% of the total variance. The physical factor comprises item 3, 6, 9, 14, 16, 17, and 19 has factor loading \geq 0.40 in the physical domain. Item 8, 17 were loaded in more than one factor with factor loading \geq 0.40.

Table 3.

Results of Confirmatory Factor Analysis of the Indonesian version of MacNew Questionnaire

ltem		Social	Emotional	Physical	
Ι.	Frustrated		<u>0.583</u>		
2.	Worthless	0.339	<u>0.439</u>		
3.	Confident			<u>0.432</u>	
4.	Down in the dumps		<u>0.788</u>		
5.	Relaxed		<u>0.482</u>	0.343	
6.	Worn Out			<u>0.524</u>	
7.	Happy with Personal Life	0.344	<u>0.443</u>		
8.	Restless	<u>0.405</u>	<u>0.405</u>		
9.	Short of Breath			<u>0.728</u>	
10.	Tearful		<u>0.762</u>		
11.	More Dependent	<u>0.577</u>			
12.	Social Activities	<u>0.587</u>	0.255		
13.	Other/less Confidence in you	<u>0.472</u>	0.371		
14.	Chest Pain			<u>0.668</u>	
15.	Lack Self-Confidence	0.390	0.360	0.349	
16.	Aching Legs			<u>0.501</u>	

17.	Sports/Exercise Limited	<u>0.601</u>		<u>0.429</u>	
18.	Frightened		<u>0.612</u>	0.314	
19.	Dizzy/Lightheaded			<u>0.509</u>	
20.	Restricted or Limited	<u>0.742</u>			
21.	Unsure about Exercise	<u>0.571</u>			
22.	Overprotective Family	<u>0.485</u>			
23.	Burden on Others	<u>0.492</u>	0.340		
24.	Excluded	<u>0.572</u>			
25.	Unable to Socialize	<u>0.612</u>			
26.	Physically Restricted	<u>0.733</u>			
27.	Sexual Activities	<u>0.543</u>			
% va	riance explained	28.85%	7.41%	6.05%	

Only weights \geq 0.30 are shown. The weights in bold and underlined if the item loads \geq 0.40 on a domain

Internal Consistency

Cronbach α coefficients for the global scale were 0.900 for the physical limitation domain was 0.851 for the social function domain was 0.869 and for the psychological function was 0,811. Thus, it can be concluded that Indonesia version of MacNew questionnaire showed acceptable internal consistency (Field, 2009).

Tabel 2.

Cronbach's Alpha Coefficient of Adapted MacNew

Scale	Number o	of	Cronbach's α	Item-Total
	items			Correlation
Emotional	14		0.816	0.237 – 0.607
Physical	13		0.851	0.348 – 0.681
Social	13		0.869	0.324 – 0.697
Total	27		0.900	0.250 - 0.643

Evidence-based on relations with other variables validity

Evidence-based on relations with other variables validity will be explored by correlating HRQOL score with cardiac anxiety, age, gender, LVEF, educational level, and score of Charlson comorbidity index. The total score of HRQOL was negatively correlated with cardiac anxiety r = -0.552, P < 0.000. The higher the cardiac anxiety, the lower the patient's HRQOL. HRQOL in male respondent were significantly higher compare to female

respondent U = 239.5, z = -2.238, P < 0.05. There were no significant differences in HRQOL between respondent age group and educational group. Pearson correlation revealed that there is no significant association between LVEF and CCI and HRQOL score.

Discussion

MI prevalence in Indonesia has increased exponentially. More information regarding MI patient's HRQOL is needed not only to gain insight into the challenges faced by the patients but also to create a suitable intervention to improve HRQOL. Therefore, it is necessary to provide a valid and reliable HRQOL instrument in Bahasa, Indonesia. Statistical analysis conducted in the study revealed that the Indonesian version of the MacNew questionnaire is a valid and reliable instrument. The instrument showed an acceptable internal consistency, for global and also domain score. Several MacNew adaptations such as in Brazilian, Dutch and Norwegian also showed acceptable internal consistency (De Gucht, Van Elderen, Van Der Kamp, & Oldridge, 2004; Hiller, Helvik, Kaasa, & Slørdahl, 2010; Nakajima, Rodrigues, Gallani, Alexandre, & Oldridge, 2009). For evidence-based correlation with other variables' validity, the Indonesian version of the MacNew questionnaire score has a negative correlation with cardiac anxiety. The result of the study was also supported by several studies (Blakemore et al., 2014; Hosseini et al., 2014; Kepka et al., 2013; Van Beek et al., 2012). The study also found that female patients' HRQOL was lower compared to male patients. This result was in line with the results from several studies. Less social support, higher depressive symptom, and delayed referral were considered as contributing factors in gender differences (Martin et al., 2012; Norris et al., 2008).

The result of the study showed a three-domain of the Indonesian version of the MacNew questionnaire, namely emotional, physical, and social domains. Thus, the structure of the Indonesian MacNew questionnaire is equivalent to the parent language version. Similar results also found in several studies (De Gucht et al., 2004; Hiller et al., 2010). The most significant factor loading in the emotional domain was item 4 (down in the dumps) and 10 (tearful). The result of the study was supported by psychometric research conducted in Norwegian (Hiller et al., 2010). As concluded by several studies, feeling depressed and sad are the most common emotions experienced by myocardial infarction patients that

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correlated with HRQOL (Foxwell, Morley, & Frizelle, 2013; Hosseini et al., 2014). Item 20 (restricted and limited) and 26 (physically restricted) were items that have the most significant factor loading in the social domain. Patients with myocardial infarction tend to feel fatigued and have a physical limitation and may result in social isolation (Fredriksson-Larsson, Alsen, & Brink, 2013). Items that have the most significant loading factor in the physical domain were item 9 (short of breath) and 14 (chest pain). Dyspnea and chest pain are the most common physical symptoms in Type I and Type 2 myocardial infarction. Thus, the result of the present study confirms the physical challenges experienced by patients with MI.

Results for factor analysis showed two common problems faced with instrument adaptation. First, several items were loaded in more than one domain. Second, different items were clustered in different domains compared to the original scoring system. These results correspond with the result from several original studies (Asadi-lari, Javadi, Melville, Oldridge, & Gray, 2003; De Gucht et al., 2004; Hiller et al., 2010).

HRQOL was not correlated with LVEF and CCI. The result of the study proved that HRQOL is a subjective assessment regarding one's health. Guyatt et al. highlighted the low correlation between HRQOL and physiologic measures(1993). A meta-analytic study in 12 chronic studies concluded that patients gave more emphasis on mental health than physical functioning. Thus HRQOL is primarily based on psychological functioning and less on physical functioning (Smith et al., 1999).

Although the study has revealed good psychometric properties of the Indonesian version of the MacNew questionnaire, further study is needed to examine the questionnaire reproducibility and its sensitivity to detect clinical improvement. The Indonesian version of the MacNew questionnaire. Should also be explored its divergent and convergent validity.

Even though more than 70% of the respondents have high education, however, they preferred an interview administered questionnaire compare to a self-administered questionnaire. Lacked visual aid for reading and unfamiliarity with research instruments were several reasons behind this behavior.

Conclusion

The Indonesian version of MacNew questionnaire showed satisfactory psychometric properties in the sample of Indonesian MI patients. It also confirmed good internal consistency and evidence-based on correlation with other variables' validity. The study had succeeded in exposing the psychometric properties of the Indonesian version of the MacNew questionnaire, and further exploration is still needed, especially for clinical studies in myocardial infarction patients. To ensure the sensitivity of the questionnaire, the questionnaire should be tested its reproducibility. Varied samples of heart disease patients are also needed to discover more benefits of the Indonesian version of the MacNew questionnaire in assessing heart patient's HRQOL.

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