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#### CLINICAL & BASIC RESEARCH

# Development and Validation of a Cross-Cultural Heart Failure-Specific Quality of Life Questionnaire

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# التطوير والتحقق من صحة استبيان نوعية الحياة عبر الثقافات الخاص بالفشل القلبي

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ABSTRACT: Objectives: Heart failure (HF) is a common clinical syndrome with an enormous impact on prognosis and lifestyle. Accordingly, rehabilitation measures need to be patient-specific and consider various sociocultural factors so as to improve the patient's quality of life (QOL). This study aimed to develop and validate a HF-specific QOL (HFQOL) questionnaire within a multicultural setting. Methods: This study took place at the National Heart Institute and Universiti Kebangsaan Malaysia Medical Centre, Kuala Lumpur, Malaysia, between March 2013 and March 2014. A self-administered 75-item HFQOL questionnaire was designed and administrated to 164 multi-ethnic Malaysian HF patients. Exploratory factor analysis was performed to assess the instrument's construct validity. Cronbach's alpha coefficients were used to determine internal consistency. Results: A total of 33 out of 75 items were retained in the final tool. The HFQOL questionnaire had three common factors—psychological, physical-social and spiritual wellbeing—resulting in a cumulative percentage of total variance of 44.3%. The factor loading ranges were 0.450–0.718 for psychological wellbeing (12 items), 0.394–0.740 for physical-social wellbeing (14 items) and 0.449–0.727 for spiritual wellbeing (seven items). The overall Cronbach's alpha coefficient of the questionnaire was 0.82, with coefficients of 0.86, 0.88 and 0.79 for the psychological, physical-social and spiritual wellbeing subdomains, respectively. Conclusion: The HFQOL questionnaire was found to be a valid and reliable measure of QOL among Malaysian HF patients from various ethnic groups. Such tools may facilitate cardiac care management planning among multi-ethnic patients with HF.

Keywords: Heart Failure; Quality of Life; Culturally Competent Care; Ethnic Groups; Questionnaire Design; Reliability and Validity; Malaysia.

الملخص: الهدف: فشل القلب هو متلازمة سريرية شائعة ذات تأثير هائل على التكهن وأنماط الحياة. وبناءً على ذلك، يجب أن تكون تدابير التأهيل محددة للمرضى وأن تراعي العديد من العوامل الاجتماعية والثقافية لتحسين نوعية حياة المريض. تهدف هذه الدراسة للى تطوير والتحقق من صحة استبيان نوعية الحياة لفشل القلب في بيئة متعددة الثقافات. الطريقة: أجريت هذه الدراسة في معهد القلب الوطني والمركز الطبي لجامعة كيبانجسان ماليزيا، كوالا لامبور، ماليزيا، في الفترة ما بين مارس 2013 ومارس 2014. تصميم استبيان نوعية الحياة لفشل القلب نو 75 عنصراً بإدارة ذاتية وتوزيعه على 164 مريضا متعدي الأعراق مصابين بفشل القلب تم إجراء تحليل العوامل الاستقصائية لتقييم أدوات الصلاحية. تم استخدام معاملات ألفا كرونباخ لتحديد الاتساق الداخلي. النتائج: تم الاحتفاظ بما مجموعه 33 من أصل 75 عنصرا في الأداة النهائية. كان لاستبيان نوعية الحياة لفشل القلب ثلاثة عوامل مشتركة—النفسية والبدنية—الاجتماعية والرفاهية الروحية، مما أدى إلى نسبة تراكمية من التباين الكلي من %4.3 كانت نطاقات تحميل العوامل (سبعة عناصر). بلغ معامل ألفا كرونباخ الإجمالي للاستبيان 0.28، مع معاملات بلغت 0.88، و0.77 بالنسبة للنطاقات الفرعية النفسية والبدنية—الاجتماعية والرفاهية الروحية على التوالي. الخلاصة: يعتبر استبيان نوعية الحياة لفشل القلب مقياس ذو مصداقية النفسية والبدنية—الاجتماعية والرفاهية الروحية على التوالي. الخلاصة: يعتبر استبيان نوعية الحياة لفشل القلب مقياس ذو مصداقية وموثوق لنوعية الحياة بين مرضى فشل القلب من مختلف المجموعات العرقية. يمكن لمثل هذه الأدوات أن تسهل تخطيط إدارة الرعاية القلبة بين المرضى متعددى الأعراق المصابين بفشل القلب.

الكلمات المفتاحية، فشل القلب: نوعية الحياة: ثقافة الرعاية المتخصصة: فئات عرقية: تصميم الاستبيان: الموثوقية والمصداقية: ماليزيا.

#### Advances in Knowledge

 This study provides a valid and reliable heart failure (HF)-specific questionnaire to measure quality of life (QOL) in a multi-ethnic population.

#### Application to Patient Care

- The HF-specific QOL questionnaire can be used to assess the QOL of Malaysian HF patients, regardless of ethnic, cultural or religious background.
- Such instruments facilitate patient-specific management by prioritising items with a lower QOL domain, enhancing the effectiveness of care as well as patient satisfaction.

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HE NUMBER OF HEART FAILURE (HF) PATIENTS worldwide is increasing, with the condition affecting an estimated 26 million people globally.1 In Southeast Asia, the population is growing, with the majority younger than 65 years old; however, rapid epidemiological transition has led to high rates of premature death from noncommunicable diseases, particularly cardiovascular disease.2 Southeast Asians also have a high prevalence of HF risk factors, including hypertension, tobacco smoking, physical inactivity, overweight/obesity and raised blood glucose levels. Moreover, Southeast Asian patients with HF tend to be younger and have more severe clinical features, with higher rates of mechanical ventilation and longer hospital stays compared to those in developed countries.2 In Malaysia, ischaemic heart disease is a major cause of death, with the condition contributing to 13.2% of all deaths in 2016.3 Unfortunately, as Malaysia has an ageing population, the prevalence and burden of HF is expected to increase in the future.4

Among patients with HF, quality of life (QOL) is not only affected by the physical symptoms of illness but also by a myriad of social, emotional, sexual and mental factors.<sup>5</sup> In particular, patients may suffer from significant psychological distress due to changes in functional level, work status and family relationships.5 As such, the treatment goal in HF is not only to enhance survival rates, but to improve the patient's QOL (i.e. meaningful survival).67 However, most existing QOL measures for HF patients are based on expert opinions, with only a limited number based on actual patient experiences.8-11 Dunderdale et al. opined that QOL measures based on expert opinions rather than on patients' perceptions might demonstrate lower accuracy and usefulness in real-life settings.10

Furthermore, QOL may vary in the context of the patient's unique culture and value systems and in relation to their specific goals, expectations, standards and concerns.6 Yusuf et al. recommended that cultural and ethnic differences be taken into consideration when designing QOL tools, especially in view of the collectivist nature of Southeast Asian communities.<sup>12</sup> Recently, efforts have been made to maintain cultural sensitivity when developing QOL measures.<sup>13</sup> This study therefore aimed to develop and validate a HF-specific QOL (HFQOL) questionnaire within a multi-ethnic setting in Malaysia.

#### Methods

This study was conducted at the National Heart Institute (IJN) and Universiti Kebangsaan Malaysia Medical Centre (UKMMC), Kuala Lumpur, Malaysia between March 2013 and March 2014. A preliminary version of the HFQOL questionnaire was developed based on qual-

itative findings from in-depth interviews conducted with 19 HF patients. During the interviews, the questions focused on the patients' experiences during HF and the recovery stage; interview guides were developed based on a literature review and feedback from experts in cardiology management. Qualitative data from the interviews were then analysed to identify themes for the questionnaire constructs. 14 The preliminary constructs were physical wellbeing (i.e. restrictions in physical function), social wellbeing (i.e. dependency on social support networks), psychological wellbeing (i.e. the grieving process and negative emotions regarding adapting to the condition) and spiritual wellbeing (i.e. a personal or religious belief system).

Subsequently, the content of the preliminary HFQOL questionnaire was reviewed by seven experienced professionals, including four cardiologists and three cardiac unit nurses, all of whom had experience managing HF patients of various ethnicities. Each reviewer was asked to rate the relevance of each item for the purposes of the tool from 1-10. They were also asked to evaluate each item's agreement with the identified constructs, which resulted in the rephrasing of some items. The final version of the HFQOL questionnaire was administered in either Malay or English, according to the respondent's preference, and consisted of 75 items scored on a four-point Likert scale, with specific definitions tailored to each item [Table 1].15 All of the reviewers rated the final version of the questionnaire to be relevant and adequate to measure the QOL of HF patients. A pilot study of 35 HF patients confirmed the appropriateness of the questionnaire from a patient's point of view. The questionnaire could be completed by the respondents either individually or with assistance from the researchers in 20 minutes.

A minimum sample of 210 patients was deemed necessary based on the sample size calculations, wherein the construct with the highest number of variables (35 variables) was multiplied by five at 80% power. 16 Due to the limited number of patients with HF, a convenience sampling technique was employed to recruit participants. All respondents were either in- or outpatients at the IJN and UKMMC and had HF as identified by cardiologists based on the criteria of reduced left ventricular function (ejection fraction of ≤45%).17 Patients from all three major ethnic groups in Malaysia were eligible to participate in the study; however, only those able to communicate in either Malay or English were included. Patients were assessed by cardiologists for HF severity according to the classifications of the New York Heart Association (NYHA), with class I indicating no HF symptoms and no limitations in ordinary physical activity, class II indicating mild HF symptoms and slight limitations during ordinary activity, class III

Table 1: Example of items in each construct in a cross-cultural heart failure-specific quality of life questionnaire

Item	Likert score			
	1	2	3	4
Psychological wellbeing				
I feel sad whenever thinking about my health condition	Almost every day of the week	At least 4–6 days per week	At least 1–3 days per week	Never
I feel depressed whenever thinking about my health condition	Almost every day of the week	At least 4–6 days per week	At least 1–3 days per week	Never
Physical wellbeing				
Ease of breathing	Difficult even without performing any activity	Difficult even when performing simple activities	Easy when performing simple activities	Easy when performing any activity
Ability to walk	Impossible even with assistance	Impossible without assistance	Possible without assistance, but with limitations	Possible without assistance or limitations
Social wellbeing				
Interactions with family members or friends	Very distant	Distant	The same as before	Strengthened
Support from family members	Not supportive	Less supportive than before	More supportive than before	Very supportive
Spiritual wellbeing				
Level of spiritual beliefs when having heart problems	None	Reduced	The same as before	Strengthened
Involvement in spiritual activities (e.g. prayer, meditation, etc.)	None	Reduced	The same as before	Strengthened

indicating significant limitations in activity due to HF symptoms and class IV indicating severe limitations and HF symptoms which persist even at rest.<sup>18</sup>

All quantitative data were analysed using the Statistical Package for the Social Sciences (SPSS), Version 19.0 (IBM Corp., Armonk, New York, USA). Item-level descriptions were performed to explore the distribution of responses. An exploratory factor analysis (EFA) was performed to assess construct validity using a principal component analysis with varimax rotation. The Kaiser-Meyer-Olkin (KMO) measure of sampling adequacy and Bartlett's test of sphericity was used to assess the adequacy of the sample size for the EFA.<sup>19</sup> Scree plots and Eigen values of >1 were used to guide the number of factors, along with the construct of four domains.20 A correlation coefficient of  $\geq 0.3$  with a *P* value of  $\leq 0.050$ was considered statistically significant. Following the EFA, a reliability analysis was done to assess internal consistency utilising Cronbach's alpha coefficient for each identified factor, with a coefficient of >0.70 considered acceptable.<sup>21,22</sup>

The protocols of this study were approved by the IJN Ethics Committee (#IJNEC/03/2011) and UKMMC Ethics Committee (#FF-390-2011). Informed consent was obtained from all patients following screening by a cardiologist to determine their fitness to participate in the study.

# Results

A total of 164 HF patients participated in the study, with a mean age of 61 years. The majority of patients were Malay (64%), male (68.3%) and married (81.1%). Many participants were unemployed (37.2%) and had not been educated past secondary school level (77.4%). In terms of religious beliefs, the majority were Muslims (65.9%), followed by Buddhists (16.5%), Hindus (12.2%), Christians (4.3%) and atheists (1.2%). More than half of the respondents had a family history of heart disease (52.4%) and were currently non-smokers (90.8%). Most patients were categorised as having NYHA classes I or II HF (92.1%), with only two patients (1.2%) having class IV HF [Table 2].

The KMO measure was 0.81, with significant sphericity (P = 0.001), thus indicating that the sample size was suitable for the EFA. In total, 42 items were eliminated from the HFQOL questionnaire based on poor communality, inter-item correlations and factor loading. The rotated component matrix of the remaining 33 items was loaded into three rather than four common factors, due to the combination of the physical and social wellbeing constructs into a single subdomain. The first common factor, psychological wellbeing, consisted of 12 items with a factor loading range of 0.450-0.718. The second common factor was physical-social wellbeing

**Table 2:** Sociodemographic and clinical characteristics of multi-ethnic Malaysian patients with heart failure (N = 164)

Characteristic	n (%)
Gender	
Male	112 (68.3)
Female	52 (31.7)
Ethnicity	
Malay	105 (64)
Chinese	33 (20.1)
Indian	26 (15.9)
Religion	
Muslim	108 (65.9)
Buddhist	27 (16.5)
Hindu	20 (12.2)
Christian	7 (4.3)
Atheist	2 (1.2)
Marital status	
Single	31 (18.9)
Married	133 (81.1)
Education level	
None	12 (7.3)
Primary school	51 (31.1)
Secondary school	64 (39)
Diploma/college/university	37 (22.6)
<b>Employment status</b>	
Employed	57 (34.8)
Unemployed	61 (37.2)
Retired	46 (28)
Smoking status	
Non-smoker	104 (63.4)
Ex-smoker	45 (27.4)
Current smoker	15 (9.1)
Family history of heart disease	
Yes	86 (52.4)
No	78 (47.6)
NYHA class	
I	67 (40.9)
II	84 (51.2)
III	11 (6.7)
IV	2 (1.2)
NYHA = New York Heart Association	

NYHA = New York Heart Association.

Table 3: Factor loading\* of items in a cross-cultural heart failurespecific quality of life questionnaire

Item	Factor loading			
Psychological wellbeing				
I. I feel sad whenever I think about my health condition	0.718			
2. I feel anxious whenever I think about my health condition	0.702			
3. I feel pressured whenever I think about my health condition	0.695			
4. I worry whenever I think about my health condition	0.692			
5. I feel depressed whenever I think about my health condition	0.660			
6. My mind is troubled whenever I think about my health condition	0.630			
7. I easily feel frustrated	0.619			
8. I feel something is not right with my physical abilities	0.605			
9. I feel inferior	0.548			
10. I blame myself for the effects of my past lifestyle choices	0.485			
11. I feel angry whenever I think about my physical weaknesses	0.480			
12. I often cry	0.450			
Physical-social wellbeing				
13. Ability to climb up stairs	0.740			
14. My family responsibilities have increased	0.672			
15. Ability to walk	0.654			
16. Ability to bend down	0.647			
17. The effects of my heart problem on my health	0.621			
18. Interactions with family members or friends	0.587			
19. Ease of breathing	0.565			
20. Level of tiredness	0.555			
21. Quality of sleep	0.538			
22. Ability to perform simple exercises	0.516			
23. I feel less energetic than I have in the past	0.504			
24. My heart problem causes a burden	0.493			
25. My recent lifestyle is far better than before	0.481			
26. Appetite	0.394			
Spiritual wellbeing				
27. Involvement in spirituality is important to me	0.727			
28. My spirituality is helpful in facing my heart problem	0.725			
29. Level of spiritual beliefs when having heart problems	0.673			
30. During disasters, I increase my level of worship/prayer	0.603			
31. The concept of life and death is decided by God	0.542			
32. Involvement in spiritual activities feels peaceful	0.476			
33. During disasters, I believe God protects me from danger	0.449			
*Using principal axis factoring in which all items with a factor loading of >0.2 were				

\*Using principal axis factoring in which all items with a factor loading of >0.2 were removed from the table.

Table 4: Internal consistency of a cross-cultural heart failure-specific quality of life questionnaire

Subdomain	Number of items	Cronbach's alpha coefficient
Psychological wellbeing	12	0.86
Physical-social wellbeing	14	0.88
Spiritual wellbeing	7	0.79
Total	33	0.82

and consisted of 14 items with a factor loading range of 0.394–0.740. Lastly, the third common factor, spiritual wellbeing, consisted of seven items with a factor loading range of 0.449-0.727 [Table 3].

The cumulative percentage of total variance explained by the three common factors was adequate at 44.3%, with a factor-structure coefficient of 39%. In terms of internal consistency, the first two factors (psychological and physical-social wellbeing) had Cronbach's alpha coefficients of >0.80, whereas factor three (spiritual wellbeing) had a value of 0.79. The overall Cronbach's alpha coefficient for the HFQOL instrument was 0.82 [Table 4].

# Discussion

The current study aimed to design and validate a HFQOL questionnaire in a multi-ethnic population in Malaysia. The preliminary version of the questionnaire was designed based on the qualitative findings of in-depth interviews conducted with HF patients which sought to determine their perspectives on QOL. The four constructs identified from these interviews included physical wellbeing (i.e. restricted functionality), social wellbeing (i.e. dependency on social support), psychological wellbeing (i.e. the emotional processes involved in adapting to their illness) and spiritual wellbeing (i.e. religious belief systems). The overall HFQOL and each of its three subdomains were found to be a reliable measure of QOL among Malaysian HF patients, regardless of differences in ethnicity, social background or religious beliefs.

In the current study, the physical and social wellbeing constructs were later grouped into a single subdomain; this may reflect the idea that physical restrictions are closely related to dependency on social support. Moreover, certain physical disabilities can be observed by others, thus affecting how a patient is treated and how that individual interacts in society.<sup>23</sup> In Malaysia, there is a strong culture of collectivism; as such, patients rely heavily on their family and caregivers for support.24 Therefore, Malaysian HF patients who receive social support may perceive themselves to have a better QOL and improved self-care behaviours.<sup>25</sup> On the other hand,

negative perceptions of physical-social interactions may lead to negative psychological responses.<sup>26</sup>

Psychological wellbeing remained a separate subdomain in the final HFQOL questionnaire, thus highlighting the importance of the psychological impact of HF in determining the QOL of affected patients. Patients with HF may suffer negative psychological effects such as sadness, depression, anger and anxiety—all of which were established in the qualitative phase of the current study—due to functional disability, rehospitalisation and daily variations in symptoms, such as dyspnoea and the need for oxygen therapy.7 Among other factors, the presence of a close protective individual may strengthen the patient's coping skills, leading to fewer psychological problems.14,27

Similarly, spiritual wellbeing also remained a separate subdomain in the final HFQOL questionnaire. This finding is interesting as it indicates that the participants considered spirituality to be a significant part of QOL, despite the multi-ethnic nature of the sample and consequent variations in social norms or religious beliefs. Spiritual peace has been shown to be closely related to mortality risk in HF patients; moreover, reduced spirituality has been associated with decreased psychological and physical wellbeing, thus indirectly contributing to less favourable outcomes as a whole.<sup>28</sup> According to previous research, spiritual factors related to religious beliefs and practices have enabled patients with advanced HF to cope positively with the disease, improving their psychological wellbeing.<sup>29–31</sup>

This study was subject to certain limitations. First, as the patients were recruited from a tertiary referral hospital, the sample may not be representative of the entire HF population in Malaysia. However, the high proportion of Malay patients included in the current study is reflective of the overall demographic structure of the national population.<sup>32</sup> The larger number of male patients also conforms to previous research indicating that heart disease is more prevalent in males.33 Second, most of the patients had less severe forms of HF as it was deemed unethical to ask severely ill patients to answer research questions that might remind them of their disabilities. This limitation also serves to explain the smaller than ideal sample size. Further research is therefore needed to assess the sensitivity of the HFQOL instrument for patients with different stages of HF. Third, the expert panel strongly recommended that two additional items—sexual relationships and interest in having a life partner—be included in the questionnaire; however, these items were excluded as these concepts did not arise during the interviews. This may be due to general reluctance to discuss such topics or conservative cultural or social norms. Alternatively, this may reflect perceptions that

such factors are not important aspects of QOL for those suffering from HF, especially for those with more severe disease. Nevertheless, these factors should not be ignored in a care management plan.

# Conclusion

The HFQOL questionnaire is a valid and reliable tool for measuring QOL among multi-ethnic Malaysian HF patients. Such tools may help cardiac and rehabilitation teams to develop patient-specific management plans.

#### CONFLICT OF INTEREST

The authors declare no conflicts of interest.

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