10.2478/abm-2010-0115

Asian Biomedicine Vol. 4 No. 6 December 2010; 877-884

Original article

Thai version of the Minnesota Living with Heart Failure Questionnaire: psychometric testing using a longitudinal design

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Background: The Minnesota Living with Heart Failure Questionnaire (MLHFQ) is the most widely used disease-specific instrument for heart failure (HF). However, a Thai version of the MLHFQ has not been available yet.

Objective: Test the psychometric properties of the Thai version of the MLHFQ in terms of practicality, reliability, validity, and responsiveness, using a longitudinal design.

Methods: One hundred eighty HF outpatients (mean age: 65±12 years; 58% male) were interviewed at Phramongkutklao Hospital, Bangkok between December 2008 and August 2009. Practicality was assessed with interview-times. Reliability was evaluated using Cronbach's α and intraclass correlation coefficients (ICCs). Validity was tested with correlations between the MLHFQ scores and the SF-36 scores, confirmatory factor analysis, and known-groups validity. Responsiveness was observed with effect sizes (ES) and minimal clinically important differences (MCID).

Results: The averaged interview-time was approximately five minutes. The Cronbach's α and ICCs of the MLHFQ were 0.86-0.93 and 0.84-0.88, respectively. The MLHFQ scores were moderately correlated with the Short Form-36 Health Survey (SF-36) scores, and discriminated the patients with different classes by New York Heart Association. The average ES were medium, ranging from 0.2 to 0.5. The MCID ranged from 1.4 to 14.5 for improved patients and from -1.4 to -12.7 for worsened patients.

Conclusion: The Thai version of the MLHFQ showed acceptable psychometric properties. It can be used as a disease-specific instrument to measure health-related quality of life of Thai patients with HF.

Keywords: Disease-specific measure, health-related quality of life, heart failure, psychometrics, reliability, responsiveness, Thailand, validity

Heart failure (HF) is one of the health care problems worldwide [1]. Since the number of Thai patients with cardiovascular diseases has been increasing in the past decade [2], HF is now an important health problem in Thailand as well. Heart failure symptoms, such as dyspnea and fatigue, may be associated with limitations in patients' daily activities and psychological distress, worsening their health-related quality of life (HRQoL) [3]. Since HRQoL is a predictor of HF patients' later mortality and morbidity [4], it is an outcome measure for intervention evaluations and the prediction of hospital readmission and mortality in HF [5-8].

HRQoL consists of multi-dimensional patient-reported concepts. These include general health, physical functioning, symptoms, emotional functioning, role functioning, and social functioning. In general, HRQoL can be measured using two approaches by generic and specific instruments. Generic instruments are broadly applicable, detecting unanticipated effects, but they are not relevant for specific populations like disease-specific instruments because it is not responsive to change in health [9]. On the other hand, there are specific instruments including the Minnesota Living with Heart Failure Questionnaire (MLHFQ)

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[10, 11], the Chronic Heart Failure Questionnaire (CHQ) [12], and the Kansas City Cardiomyopathy Questionnaire (KCCQ) [13]. The MLHFQ is the most widely used disease-specific instrument for HF clinical trials [14]. In fact, it has been used to comprehensively assess the perceptions of the effects of HF and its treatments on patients' daily lives.

The MLHFQ has good psychometric properties [15-18] and takes short time to administer with less respondent burden. However, a Thai version of the MLHFQ has not been available yet. In this study, we tested the psychometric properties of a Thai version of the MLHFQ in terms of practicality, reliability, validity, and responsiveness, using a longitudinal study design.

Methods

Subjects and procedures

The MLHFQ and the Short Form-36 Health Survey (SF-36) were used to measure the disease-specific and generic HRQoL. One hundred eighty Thai HF outpatients were interviewed at Cardiology and General Medicine Clinics of Phramongkutklao Hospital, Bangkok, between December 2008 and August 2009. The patients having psychiatric problems, severe symptoms, and hearing problems were excluded. The sample size of 180 patients was determined based on the expected minimum correlation coefficient of 0.25 [18]. This study was approved by the Ethics Committee of the Phramongkutklao Hospital.

At the first assessment (baseline), 180 subjects completed the Thai version of the MLHFQ and the Thai standard version 1 of the SF-36 with face-to-face interviews. Each interview took about 30 minutes. At the second assessment, two to three months after the first one, 125 patients were left and interviewed according to the same procedure with the first one. However, prior to each interview, the HF patients were asked to compare their health perceptions between the past and the present visit as follows: 1) much better now than the first visit, 2) somewhat better now than the first visit, 3) about the same as the first visit, 4) somewhat worse now than the first visit, and 5) much worse now than the first visit. These questions were used to evaluate test-retest reliability and responsiveness. If the patients reported no change in health, they were used for the test-retest. Their health perceptions were as follows: 1) n=20, 2) n=46, 3) n=40, 4) n=17, and 5) n=2. For data analyses, we grouped the patients into three subgroups, the patients who felt better about their health (n=66), worse about their health (n=19), and no change about their health (n=40).

In addition to these patients' health reports, we employed the classification of improvement or worsen by New York Heart Association (NYHA) [19] to assess the responsiveness.

Generic HRQoL and MLHFQ

The SF-36 was developed by the Medical Outcome Trust of the USA [20], and was translated into Thai [21]. It consists of 35 questions including eight subscales/dimensions, physical functioning (10 items), role physical (4 items), bodily pain (2 items), general health (5 items), social functioning (2 items), vitality (four items), role emotional (3 items), and mental health (5 items) and another independent question of health transition reported. Therefore, there are 36 items in the questionnaire. Each item has different numbers of response choices between two and six, which are scored from 0 to 100 on each of the dimensions. In addition, eight subscales can be summarized into two components of physical component summary (PCS) and mental component summary (MCS). Higher scores indicate better HRQoL.

The MLHFQ was designed to measure HRQoL of patients with HF [10, 11]. It comprises 21 items. These include two dimensions, physical (eight items: 2-7 and 12-13) and emotional (five items: 17-21). Each item has six-Likert response choices ranging from 0 (no) to 5 (very much). The MLHFQ scores consists of three categories, 1) physical dimension score (range: 0-40), 2) emotional dimension score (range: 0-25), and 3) global score of 21 items (range: 0-105). Fewer scores indicate less dysfunction.

Thai version of MLHFQ

Permission to translate the original MLHFQ into Thai was obtained from the University of Minnesota. Forward translations were prepared by two bilingual experts. After the two translated versions were reconciled into one Thai version, the authors compared it with the original version for conceptual equivalence. Furthermore, backward translations of the Thai version were conducted by other two bilingual translators, which were reconciled into one version and conceptually compared with the original version. The backward translation was accepted by the MAPI Research Trust.

A pretest with 25 HF patients was conducted using cognitive interviews (respondent debriefing with probes) to adjust the words of the Thai version to ensure patient understanding, which was published previously [22].

Data analysis

Since our MLHFQ scores had non-normal distributions, we applied non-parametric statistics for overall statistical analyses.

Practicality was evaluated in terms of time to complete questionnaire. The ceiling (minimum score of dimension-to-scale) and floor effects (maximum score of dimension-to-scale) should fall within 15% [23].

Cronbach's α [24] and intraclass correlation coefficients (ICCs) [25] were used to estimate internal consistency reliability and test-retest reliability, respectively.

Validity was judged with 1) convergent and discriminant validity, 2) confirmatory factor analysis, and 3) known-groups validity. The convergent validity was evaluated using Spearman's rank correlation coefficients (ρ) [18] for assessment of the correlations between the MLHFQ physical/emotional dimensions and the hypothesized SF-36 physical subscales and mental subscales. Correlation levels were described by <0.30 (low correlation), 0.30-0.50 (moderate correlation), and >0.50 (high correlation) [18]. Discriminant validity was assessed with ρ-differences between the MLHFQ physical/emotional dimensions and the SF-36 physical/mental subscales. Student t-tests were used to examine the differences between these correlations [26]. Using a confirmatory factor analysis (CFA) [27], we explored whether the MLHFQ items of the Thai version fit in physical/ emotional dimensions of the original version. Furthermore, we evaluated known-groups validity using Kruskal-Wallis tests and Mann-Whitney U tests for determination of the median differences in the MLHFQ scores among NYHA classes.

Responsiveness was performed based on data from the three subgroups classified by patients health report and NYHA. An effect sizes (ES) was employed as a responsiveness index. The ES was calculated by the mean change scores between the baseline and the second assessment divided by standard deviation (SD) at baseline [28]. Wilcoxon signed ranks tests were used to detect the median differences between two assessments. The mean change scores of each dimension also revealed the minimal clinically-important difference (MCID) of the improved or worsened subgroups.

All data were analyzed using SPSS version 17.0 (SPSS Co., Bangkok, Thailand) and LISREL version 8.8 (student version). P-values less than 0.05 were considered statistically significant.

Results

Table 1 shows baseline sample characteristics of 180 patients enrolled in this study. The mean age was 64.7±12.0 years and 58.3% were male.

Table 2 shows physical, emotional dimensions, and global scores by 180 patients. The distributions of emotional dimension and global score were skewed positively. The highest ceiling effect appeared in the emotional dimension, which was greater than the limit of 15% [23]. There was no floor effect in any dimension and global scores. The averaged interview-times at the first and the second assessment were 5.6±2.1 minutes and 4.5±1.7 minutes, respectively.

The reliability of the Thai version of the MLHFQ is shown **in Table 3**. The α-values were higher than the acceptable level (0.70) for group comparisons, and equal to or higher than the acceptable level (0.90) for individual comparisons [24]. Regarding the test-retest reliability, the observed ICCs in physical/emotional dimensions and global scores were higher than the level of high agreement (0.75) [25].

Correlations between the Thai version and the SF-36 scores are shown in **Table 4.** The MLHFQ emotional dimension showed a strong inverse correlation with the two SF-36 mental subscales and the MCS. This result supports the convergent validity to indicate that the same health concepts should be correlated with each other. In addition, the MLHFQ physical dimension had higher correlations with the two SF-36 physical subscales and the PCS compared to the MLHFQ emotional dimension. Similarly, the MLHFQ emotional dimension provided higher correlation values with the two SF-36 mental subscales and the MCS than the MLHFQ physical dimension. There was a statistically significant difference in correlation coefficients ($p = 0.04$) between the MLHFQ physical and emotional dimensions and the SF-36 physical functioning. These results show the discriminant validity that the different health concepts should be less correlated with each other.

Table 1. Baseline sociodemographic and clinical characteristics (N =180).

Age (years; mean ± SD)	64.7±12.0
Gender; number (%)	
Male	105 (58.3)
Female	75 (41.7)
Education; number (%)	
No formal education	15 (8.3)
Elementary school	65 (36.1)
Secondary school	55 (30.6)
Vocational certificate	13 (7.2)
Diploma	6 (3.3)
University/College	26 (14.5)
Employment status; number (%)	
Employed	45 (25.2)
Unemployed	87 (48.3)
Retired	48 (26.5)
Marital status; number (%)	
Married	120 (66.6)
Single	12 (6.7)
Widowed	43 (23.9)
Divorced	5 (2.8)
Living situation; number (%)	
Living alone	10 (5.6)
Living with other persons	170 (94.4)
NYHA classes; number (%)	
I	67 (37.3)
II	71 (39.4)
III	42 (23.3)
LVEF; number (%)	
< 40	62 (34.4)
≥ 40	118 (65.6)
Etiology of HF; number (%)	
Hypertensive heart disease	6 (3.3)
Coronary artery disease	80 (44.4)
Heart valve disease	32 (17.8)
Dilated cardiomyopathy	28 (15.6)
Alcoholic cardiomyopathy	5 (2.8)
Atrial fibrillation	22 (12.2)
Chronic kidney disease	7 (3.9)
Co-morbidities; number (%)	
Hypertension	129 (71.7)
Coronary artery disease	70 (38.9)
Dyslipidemia	126 (70.0)
Diabetes mellitus	63 (35.0)
Atrial fibrillation	45 (25.0)
Valvular heart disease	35 (19.4)
Chronic kidney disease	34 (18.9)
COPD	3 (1.7)
HF medications; number (%)	
ACE-inhibitors	93 (51.7)
ARBs	42 (23.3)
Aldosterone antagonists	49 (27.2)
Beta blockers	128 (71.1)
Digoxin	57 (31.7)
Loop diuretics	102 (56.7)
Thiazide diuretics	14 (7.8)

ACE-inhibitors = angiotensin converting enzyme inhibitors, ARBs = angiotensin receptor blockers, COPD = chronic obstructive pulmonary disease, HF = heart failure, LVEF = left ventricular ejection fraction.

Table 2. Score distribution of the Thai version of the MLHFQ.

MLHFQ	Mean ± SD	Median	Range	%Floor	%Ceiling	Skewness	Kurtosis
Physical (8 items)	9.4 ± 9.5	6.0	0-35	0	18.3	0.98	-0.15
Emotional (5 items)	4.8 ± 5.6	3.0	0-23	0	27.2	1.49	1.72
Global (21 items)	19.5 ± 19.6	12.0	0-84	0	11.1	1.14	0.38

Table 3. Reliability of the Thai version of the MLHFQ.

MLHFQ	Number of items	Internal consistency (n = 180) Cronbach's α	Test-retest reliability (n = 40) ICC
Physical	8	0.90	0.84
Emotional	5	0.86	0.84
Global	21	0.93	0.88

ICC = Intraclass correlation coefficient.

Table 4. Correlations between the Thai version of the MLHFQ and the SF-36 scores.

SF-36	MLHFQ Physical dimension	MLHFQ Emotional dimension	MLHFQ Global score	P-value[a]
Physical subscales				
Physical functioning	-0.49	-0.39	-0.48	0.04
Role physical	-0.51	-0.48	-0.55	0.52
Physical component summary	-0.53	-0.47	-0.55	0.20
Mental subscales				
Role emotional	-0.53	-0.56	-0.56	0.50
Mental health	-0.47	-0.51	-0.51	0.38
Mental component summary	-0.46	-0.53	-0.50	0.12

Overall values are presented with Spearman's rank correlation coefficient ($p < 0.05$). [a]Difference in correlation coefficient between the MLHFQ physical/emotional dimension and the hypothesized SF-36 physical/mental subscale were tested using t-test.

The confirmatory factor analysis (CFA) revealed that none of the goodness-of-fit indices were close to acceptable model fit (Chi-square = 1,193, $p < 0.00001$, root mean square error of approximation = 0.31, normalized fit index = 0.65, comparative fit index = 0.67, goodness-of-fit index = 0.49, and goodness-of-fit index = 0.30). These results indicate that the CFA did not support the two-factor original model.

Table 5 depicts the MLHFQ scores between three NYHA classes (I, II, and III). There were statistically significant differences in three MLHFQ scores between the three NYHA classes (Kruskal-Wallis tests, all $p < 0.001$). The lowest MLHFQ scores (better HRQoL) appeared in the patients with NYHA class I and the highest scores (lower HRQoL) in those with NYHA class III (Mann-Whitney U tests, all pairs, $p < 0.001$).

According to changes of patients' health perception for improved and worsened groups, the ES was highest on the physical dimension, followed by the MLHFQ global score and the emotional dimension. Similarly, the ES based on change in NYHA classes for the improved group was largest on the physical dimension, followed by the global score and the emotional dimension. Based on Cohen's criteria [29], these ES levels were considered as moderate. However, for the worsened group, the ES based on change in NYHA classes was highest on the emotional dimension, followed by the global score and the physical dimension. These ES were considered large.

Table 5. Known-groups validity of the Thai version of the MLHFQ.

MLHFQ	NYHA Class I (n = 67) Mean ± SD	NYHA Class II (n = 71) Mean ± SD	NYHA Class III (n = 42) Mean ± SD	Pairwise comparisons I & II	P-value	I & III	P-value	II & III	P-value
Physical	4.3 ± 6.2	8.7 ± 7.5	18.5 ± 10.5	I < II	< 0.001	I < III	< 0.001	II < III	< 0.001
Emotional	2.6 ± 4.4	4.4 ± 4.3	8.9 ± 6.8	I < II	< 0.001	I < III	< 0.001	II < III	< 0.001
Global	9.4 ± 13.1	17.9 ± 15.1	38.3 ± 21.9	I < II	< 0.001	I < III	< 0.001	II < III	< 0.001

Difference in the MLHFQ score among three NYHA classes was tested using Kruskal-Wallis test. Pairwise comparison was tested using Mann-Whitney U test.

Table 6. Responsiveness of the Thai version of the MLHFQ.

MLHFQ	Self-reported health perception Improved (n=66) Mean change[a] (SD)	ES	Worsened (n=19) Mean change[a] (SD)	ES
Physical	4.9*** (10.1)	0.49	-6.1** (9.0)	-0.68
Emotional	1.4** (6.0)	0.23	-1.4ns (5.5)	-0.25
Global	9.4*** (21.3)	0.44	-9.3** (17.8)	-0.52
MLHFQ	**NYHA classification Improved (n=23) Mean change[a], (SD)**	**ES**	**Worsened (n=6) Mean change[a], (SD)**	**ES**
Physical	6.9** (10.2)	0.68	-5.7* (5.9)	-0.97
Emotional	2.7** (6.5)	0.42	-4.5* (2.6)	-1.73
Global	14.5** (22.6)	0.64	-12.7* (8.5)	-1.49

ES = effect size, ns = not significant, NYHA = New York Heart Association, [a]Mean change = mean score at the baseline – mean score at the second assessment, tested using Wilcoxon signed rank. *p <0.05, **p <0.01, ***p <0.001.

Discussion

This study comprehensively investigated practicality, reliability, validity, and responsiveness of a Thai version of the MLHFQ. It has been demonstrated that the Thai version satisfied all required psychometric properties. For practicality, the averaged interview-time needed to complete the Thai version was approximately five minutes. Thus, the MLHFQ will not impose a burden to interviewees. In addition, the Thai version presented high reliability of internal consistency with the Cronbach's α (0.90 or above) on the physical dimension and global scores. Thus, the MLHFQ can be applied in clinical practice to compare HRQoL both between patient groups (α >0.7) and between individual patients (α >0.9) [24]. The present results are consistent with previous studies [15-18, 30, 31]. The Thai version also showed excellent test-retest reliability with high ICCs (0.88 on the global score and 0.84 on physical/ emotional dimensions).

The validity of the MLHFQ was evaluated in terms of construct-validity as follows. Firstly, it was confirmed with convergent and discriminant validity. The MLHFQ physical and emotional dimensions were significantly correlated with the hypothesized SF-36 physical/mental subscales moderately or highly. These might confirm the convergent validity, but the correlations between the MLHFQ physical/emotional dimensions and the hypothesized SF-36 physical/ mental subscales were not significantly different, except for physical functioning subscale. This result agrees with a previous study by Saccomann et al. [18]. In fact, they indicated the lack of specificity in correlation between some subscales of the SF-36 and the MLHFQ physical/emotional dimensions [18]. A possible explanation for this non-significant difference in correlation may be related to the strong correlation between the MLHFQ physical/emotional dimensions (ρ=0.74; data not shown). For this reason, it will be hard to find a statistically significant correlation

difference between the MLHFQ physical/emotional dimensions and the theoretical SF-36 subscales. However, this does not mean that the discriminant validity of the MLHFQ could not be supported because the correlations between the same dimensions were evidently greater than those between the different dimensions. Secondly, the CFA did not support the two-factor original model. In an exploratory factor analysis, we found four factors in the Thai version of the MLHFQ (data not shown). This might be due to differences in culture and healthcare systems. Finally, the construct validity was supported with known groups validity, which refers to the ability of the MLHFQ to discriminate among three NYHA classes. Our findings are consistent with previous studies [15, 17], demonstrating that the MLHFQ physical/emotional dimensions and the global score were sufficiently sensitive to classify patients with different NYHA classes.

Our study presented both ES (distribution-based) and MCID (anchor-based). The ES using change in self-reported health perceptions was approximately 0.50, especially for the physical dimension and the global score. These ES levels meet the threshold of discrimination for change in HRQoL for chronic diseases to be approximately half a standard deviation [32, 33]. The ES of the emotional dimension was small (~0.24). This might be due to its high ceiling effect, leading to insensitivity to change. The ES of the MLHFQ employing change in NYHA classes were considered medium and large for the improved and worsened groups, respectively. At average, the ES using NYHA classes was higher than those using health perceptions even though the number of patients whose NYHA classes changed was less than those reporting change in their health. Our study shows that NYHA classes could be used to detect sensitivity to change like a global health rating in HF while there was little previous evidence regarding its use.

The MCID of the MLHFQ derived from change in NYHA classes was higher than those from change in health perceptions. The MCID can be applied for the detection of improvement and worsening in treatments or interventions of HF patients in clinical practices. For example, if patients report change in the global score of 14.5 (see MCID in **Table 6**), it can inform physicians that their clinical status like NYHA class improves. If patients' global scores increase or decrease about nine points, they can feel better or worse about their health status before the clinical status is detected. This implies the MLHFQ can be an important outcome measure for patient care monitoring and intervention or treatment evaluations as well as other HF clinical indicators.

In conclusion, the Thai version of the MLHFQ provided acceptable psychometric properties in terms of practicality, reliability, validity, and responsiveness. The Thai version of the MLHFQ can be used to measure HRQoL for patient care and outcomes research of drug therapy or other treatments in Thai outpatients with HF.

Acknowledgements

This study was financially supported from Chulalongkorn University. The authors are grateful to Major General Chumpol Piamsomboon, MD, Colonel Nakarin Sansanayudh, MD, other physicians, and nurse staffs at Cardiology and General Medicine Clinic at Pramongkutklao Hospital for their supports and assistances during the data collection. The authors also thank Dr. Rungpetch Sakulbumrungsil for her helpful comments.

The authors have no conflict of interest to report.

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