

Chronic liver disease questionnaire: Translation and validation in Thais

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Abstract

AIM: Quality of life (QOL) is a concept that incorporates many aspects of life beyond "health". The chronic liver disease questionnaire (CLDQ) was developed to evaluate the impact of chronic liver diseases (CLD) on QOL. The objectives of this study were to translate and validate a liver specific questionnaire, the CLDQ.

METHODS: The CLDQ was formally translated from the original version to Thai language with permission. The translation process included forward translation, back translation, cross-cultural adaptation and a pretest. Reliability and validity of the translated version was examined in CLD patients. Enrolled subjects included CLD and normal subjects with age- and sex-matched. Collected data were demography, physical findings and biochemical tests. All subjects were asked to complete the translated versions of CLDQ and SF-36, which was previously validated. Cronbach's alpha and test-retest were performed for reliability analysis. One-way Anova or non-parametric method was used to determine discriminant validity. Spearman's rank correlation was used to assess convergent validity. P -value <0.05 was considered statistically significant.

RESULTS: A total of 200 subjects were recruited into the study, with 150 CLD and 50 normal subjects. Mean ages (SD) were 47.3(11.7) and 49.1(8.5) years, respectively. The number of chronic hepatitis: cirrhosis was 76:74, and the ratio of cirrhotic patients classified as Child A:B:C was 37 (50%): 26(35%): 11(15%). Cronbach's alpha of the overall CLDQ scores was 0.96 and of all domains were higher than 0.93. Item-total correlation was >0.45 . Test-retest reliability done at 1 to 4 wk apart was 0.88 for the average CLDQ score and from 0.68 to 0.90 for domain scores. The CLDQ was found to have discriminant validity. The highest scores of CLDQ domains were in the normal group, scores were lower in the compensated group and lowest in the decompensated group. The significant correlation between domains of the CLDQ and SF-36 was found. The average CLDQ score was strongly correlated with the general health domain of SF-36. ($P=0.69$; $P=0.01$).

CONCLUSION: The translated CLDQ is valid and applicable in Thais with CLD. CLDQ reveals that QOL in these patients

is lower than that in normal population. QOL is more impaired in advanced stage of CLD.

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INTRODUCTION

The World Health Organization gave the definition of health as being not only the absence of disease and debility but also the presence of physical, mental and social well-being^[1]. Quality of life (QOL) is a concept that incorporates many aspects of an individual's experience, general well-being, satisfaction, social and physical function^[2]. By definition, QOL is subjective and multi-dimension. It can be influenced by socioeconomic factors, age, gender, presence of disease and treatment^[2]. QOL examines how patients experience and perceive. Its results provide a basis for holistic view of the patient and complements the organic outcomes. QOL has been evaluated in a large number of chronic medical and gastrointestinal conditions, such as dyspepsia, inflammatory bowel diseases, liver diseases, *etc.*^[3-7]. Well-developed and validated questionnaires have been used as instruments for QOL measurement. Generic and disease-specific instruments measure different aspects of QOL. It is encouraged to use both instruments in clinical research to gain substantial information^[5]. Since the development of the first liver-specific questionnaire, the chronic liver disease questionnaire (CLDQ)^[7], the QOL research in chronic liver diseases have been steadily reported^[6,8-12]. Previous studies in Western patients showed that chronic liver disease (CLD) had negative impact on QOL, and QOL worsened as the severity of disease increased^[8,9,12-14]. The study of QOL in gastrointestinal and liver diseases has hardly received attention in Asian population. Our study was aimed to translate and validate a disease specific questionnaire, the CLDQ, to be used in study of QOL in Thai population.

MATERIALS AND METHODS

Ethics

This study received ethics approval from the ethic committee of our hospital. All subjects provided written consent before participation.

Subjects

Between June 1 and September 31, 2003, 150 Thai patients with chronic liver diseases who attended gastroenterological clinic and 50 normal subjects were invited to participate in the study. Chronic liver diseases included chronic hepatitis and cirrhosis. Chronic hepatitis was defined by an elevation of serum transaminases above 1.5 times of upper normal limit for longer than 6 mo and cirrhosis by definition had biochemical and radiological findings consistent with cirrhosis^[15]. The staging of cirrhosis was categorized according to Child-Pugh classification: Child (class) A, B and C^[16]. Causes of chronic

liver disease were divided into viral hepatitis, alcohol, viral hepatitis combining with alcohol, non-alcoholic fatty liver (NAFLD) and others. Chronic liver disease due to alcohol was defined by the regular intake of alcohol (80 g/d in men, and 40 g/d in women)^[7]. History of other medical illness was taken from medical records. Exclusion criteria were concomitant presence of hepatic encephalopathy, other active medical diseases, malignancy, being treated with antiviral agents and those who refused to give consent.

QOL instruments

CLDQ The CLDQ is the first liver specific instrument developed by Younossi *et al.*^[7]. The CLDQ includes 29 items in the following domains: abdominal symptoms, fatigue, systemic symptoms, activity, emotional function and worry. The response of CLDQ results in 1 to 7 scales: ranging from “all of the time” to “none of the time”^[7]. The original CLDQ was shown to have constructed validity from the studies in chronic liver diseases^[7,12].

Translation of CLDQ After the translation permission was granted, the original version of CLDQ was translated into Thai according to the standardized guidelines proposed in 1993^[18]. Forward translation from the original English version was performed independently by two Thai native speakers. Reconciliation of both forward versions was done subsequently. A native English speaker living in Thailand who understood Thai language quite well and did not have knowledge about QOL carried out back translation. The semifinal version derived from reconciliation of the original, back translation and forward translation. A pretest in 10 patients with chronic liver diseases was performed. The final version was obtained after the step of cross-cultural adaptation.

Assessment of translated CLDQ The CLDQ and SF-36 questionnaires were administered in 150 patients with chronic liver diseases and in 50 normal subjects. The permission to use the SF-36, a generic questionnaire, in this study was granted from QualityMetric Inc. The study version of SF-36 was previously tested and validated in Thai population^[19]. CLDQ was repeated in 25 patients in 1-3 wk apart for test-retest analysis. Reliability was determined from Cronbach's alpha (reliability coefficient) and test-retest. One-way Anova or non-parametric method was used to determine discriminant validity of scores among different stages of liver diseases. Spearman's rank correlation was used to assess test-retest and convergent validity. A *P* value <0.05 was considered to be statistically significant.

RESULTS

Clinical and demographic data

One hundred and fifty patients with CLD and 50 normal subjects were enrolled into the study. Mean ages (SD) of CLD and controlled groups were 47.3(11.7) and 49.1(8.5) years (*P*=0.40). Of the 150 patients with CLD, 76(51%) had chronic

hepatitis and the remainder had cirrhosis. Summarized clinical and demographic data are shown in Table 1. Patients with cirrhosis were older, more unemployed and had lower education levels than those with chronic hepatitis. Viral hepatitis and regular alcohol drinking were the most common causes of CLD. Hepatitis B virus was the major cause of chronic viral hepatitis in this study (68.1%).

Table 1 Clinical and demographic data

Characteristics	Normal (n=50)	Chronic hepatitis (n=76)	Cirrhosis (n=74)	<i>P</i> -value
mean±SD, yr	49.1 (8.5)	43.1 (12.6)	51.6 (8.9)	0.00
Men, <i>n</i> (%)	28 (56)	49 (64.5)	47 (63.5)	0.60
Married, <i>n</i> (%)	40 (81.6)	46 (62.2)	52 (81.3)	0.01
Education, <i>n</i> (%) ¹				
≥Bachelor degree	20 (40)	29 (39.2)	10 (15.6)	0.004
Career, <i>n</i> (%) ¹				
- White collar	42 (91.3)	44 (69.8)	28 (50)	0.00
- Blue collar	1 (2.2)	4 (6.3)	9 (16)	
- Unemployed	3 (6.5)	15 (23.8)	19 (34)	
Financial burden (+), <i>n</i> (%) ¹	22 (44)	30 (40.5)	29 (45.3)	0.84
Etiologies, <i>n</i> (%)				
- Viral hepatitis		52 (68.4)	41 (55.4)	
- Alcohol		4 (5.3)	20 (27)	0.00
- Viral hepatitis and alcohol		2 (2.6)	7 (9.5)	
- Non-alcoholic fatty liver disease		11 (14.5)	2 (2.7)	
- Others		7 (9.2)	4 (5.4)	
Child-Pugh Classification, <i>n</i> (%)				
- Child A			37 (50)	
- Child B			26 (35)	
- Child C			11 (15)	

¹Incomplete data.

Reliability

Measurement of internal consistency Cronbach's alpha of overall scores was 0.96, which was above the acceptable level of 0.70 for comparison between groups^[20]. Cronbach's alpha of domains was higher than 0.93. Item-total correlation (omit that item) was above 0.45 (Table 2).

Test-retest Spearman's rank correlation of average CLDQ was 0.88 (*P*=0.00) and domains of CLDQ was higher than 0.67 (*P*=0.00).

Validity

Discriminant validity The various stages of liver diseases in this study were rearranged as normal, compensated (= chronic hepatitis + Child A cirrhosis) and decompensated (= Child B and Child C cirrhosis) groups. A comparison of domain scores in different groups was performed. All domain scores of CLDQ and SF-36 significantly decreased from normal group to

Table 2 Reliability of CLDQ

CLDQ domains	Mean score (SD)	Cronbach's alpha (if item deleted)	Test-retest reliability	
			Correlation coefficient	<i>P</i> -value
Abdominal symptoms	5.3 (1.3)	0.95	0.85	0.00
Fatigue	4.7 (1.2)	0.94	0.90	0.00
Systemic symptoms	5.3 (1.1)	0.94	0.77	0.00
Activity	5.3 (1.3)	0.94	0.68	0.00
Emotional function	5.2 (1.1)	0.94	0.80	0.00
Worry	5.3 (1.4)	0.94	0.78	0.00
Average CLDQ	5.2 (1.1)	0.93	0.88	0.00

Table 3 Discriminant validity among different groups of patients (mean±SD)

CLDQ domains	Normal (n=50)	Compensated group (n=113)	Decompensated group (n=37)	P-value
Abdominal symptoms	5.8 (1.2)	5.3 (1.1)	4.6 (1.6)	0.00
Fatigue	5.4 (1.0)	4.6 (1.1)	4.0 (1.4)	0.00
Systemic symptoms	5.9 (0.9)	5.2 (1.1)	4.7 (1.1)	0.00
Activity	5.9 (1.0)	5.4 (1.1)	4.4 (1.5)	0.00
Emotional function	5.7 (0.9)	5.1 (1.1)	4.8 (1.4)	0.001
Worry	6.3 (0.8)	5.2 (1.4)	4.4 (1.6)	0.00
Average CLDQ	5.8 (0.8)	5.2 (1.0)	4.5 (1.2)	0.00
SF-36 domains				
Physical function	79.4 (14.0)	74.1 (20.2)	59.1 (21.5)	0.00
Role physical	79.5 (34.5)	59.3 (41.1)	34.5 (42.2)	0.00
Bodily pain	76.0 (14.3)	69.4 (22.8)	57.7 (23.8)	0.001
General health	68.6 (19.1)	51.3 (24.2)	42.0 (22.9)	0.00
Vitality	66.1 (14.2)	63.3 (16.3)	57.2 (14.7)	0.03
Social function	85.5 (16.6)	77.5 (20.0)	74.3 (22.0)	0.02
Role emotion	78.0 (36.0)	59.3 (42.9)	39.6 (45.7)	0.00
Mental health	75.2 (15.4)	69.5 (17.7)	65.7 (17.9)	0.03

Table 4 Correlations between CLDQ and SF-36

CLDQ domains	SF-36 domains							
	Physical function	Role physical	Bodily pain	General health	Vitality	Social function	Role emotion	Mental health
Abdominal symptoms	0.28 ¹	0.32 ¹	0.48 ¹	0.49 ¹	0.45 ¹	0.35 ¹	0.38 ¹	0.53 ¹
Fatigue	0.44 ¹	0.52 ¹	0.49 ¹	0.61 ¹	0.58 ¹	0.54 ¹	0.63 ¹	0.59 ¹
Systemic symptoms	0.48 ¹	0.50 ¹	0.63 ¹	0.55 ¹	0.49 ¹	0.48 ¹	0.54 ¹	0.50 ¹
Activity	0.49 ¹	0.45 ¹	0.47 ¹	0.54 ¹	0.47 ¹	0.44 ¹	0.50 ¹	0.50 ¹
Emotional function	0.38 ¹	0.41 ¹	0.46 ¹	0.59 ¹	0.62 ¹	0.59 ¹	0.54 ¹	0.68 ¹
Worry	0.38 ¹	0.48 ¹	0.41 ¹	0.68 ¹	0.53 ¹	0.48 ¹	0.49 ¹	0.63 ¹
Average CLDQ	0.47 ¹	0.52 ¹	0.56 ¹	0.69 ¹	0.61 ¹	0.55 ¹	0.60 ¹	0.67 ¹

¹P=0.01.

compensated and decompensated groups (Table 3). The CLDQ was found to have good discriminant validity.

Convergen validity Each domain of CLDQ correlated with all domains of SF-36 with correlation coefficient (r) >0.27: P=0.01 as shown in Table 4. The average CLDQ score was strongly correlated with the general health domain of SF-36 (P=0.69: P=0.01).

Influence of disease severity on HRQOL

The CLDQ scores in Thai patients with CLD deteriorated as severity of chronic liver disease increased similarly to previous reports in Western patients^[8,9,12-14]. However, we found that average CLDQ, emotional function and activity scores in chronic hepatitis were lower than those in Child A cirrhosis (5.2(1.1) vs 5.7(1.2), 5.0(1.1) vs 5.5(1.0) and 5.0(0.9) vs 5.4(0.9), respectively; P-values were 0.04, 0.02 and 0.03.

DISCUSSION

The original CLDQ is a well-developed and validated disease-specific questionnaire for measuring QOL in CLD^[7]. It consists of 29 items which are a suitable number for exploring QOL in patients who have a brief visit to a clinic^[7]. It has 7 linkert scale type of answers^[7]. To find a standardized disease-specific questionnaire for researches involving QOL in CLD, we translated the CLDQ from the original English to Thai versions by following the proposed guideline^[18]. Simple translation of questionnaire from one language to the other without concerning language difference, culture context and lifestyle, jeopardizes the sensibility of the original version. The translated CLDQ used the language which even poorly educated Thais were able

to understand the questionnaire meaning, and it was aimed for conceptual and semantic equivalences with the original concept. After the translation and cross-cultural adaptation, the reliability and validity of the translated version were proved to be maintained. Reliability of the CLDQ was confirmed from internal consistency and test-retest. Cronbach's alpha of overall CLDQ was higher than 0.70, indicating that the translated version had acceptable reliability^[20]. Chronic liver diseases greatly impacted QOL, which was confirmed by both generic and disease-specific questionnaires. We arranged chronic hepatitis and cirrhosis Child A into "compensated" group, and Child B and C cirrhosis into "decompensated" group according to the reserved function of the liver. The results from generic and disease-specific questionnaires were in agreement with the fact that a markedly decrease of QOL was seen in advanced stages of chronic liver diseases. On the other hand, it showed that the average CLDQ, activity and emotion function domains in chronic hepatitis were significantly lower than those in Child A cirrhosis. This finding may point out that chronic hepatitis had impairment in some parts of QOL more than Child A cirrhosis which may be a more stable condition. We could not compare the QOL between Child B and C cirrhosis due to the small sample size in both groups. The CLDQ domains correlated significantly with every domain of SF-36. The strongest correlation was seen in the relationship between the average CLDQ score and the general health domain of SF-36. The effect of other demographic and clinical factors on QOL of CLD was inconsistently reported. From a previous study, old age was inversely correlated with physical function of SF-36^[8]. However, a subsequent study revealed that younger patients showed more impairment in QOL^[9]. Several studies

revealed that chronic viral hepatitis, especially viral hepatitis C-related decreased QOL greater than cholestatic or alcoholic liver disease^[8,12]. Other socioeconomic factors, e.g. education, career and financial status may affect QOL as well. The validated CLDQ is found to be a satisfactory tool for future research of QOL in Thai population.

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