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BRIEF ARTICLES

Psychometrics of the chronic liver disease questionnaire for Southern Chinese patients with chronic hepatitis B virus infection

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Abstract

AIM: To test the psychometric properties of a Chinese [(Hong Kong) HK] translation of the chronic liver disease questionnaire (CLDQ).

METHODS: A Chinese (HK) translation of the CLDQ was developed by iterative translation and cognitive debriefing. It was then administered to 72 uncomplicated and 78 complicated chronic hepatitis B (CHB) patients in Hong Kong together with a structured questionnaire on service utilization, and the Chinese (HK) SF-36 Health Survey Version 2 (SF-36v2).

RESULTS: Scaling success was ⩾ 80% for all but three items. A new factor assessing sleep was found and items of two (Fatigue and Systemic Symptoms) subscales tended to load on the same factor. Internal consistency and test-retest reliabilities ranged from 0.58-0.90 for different subscales. Construct validity was confirmed by the expected correlations between the SF-36v2 Health Survey and CLDQ scores. Mean scores of CLDQ were significantly lower in complicated compared with uncomplicated CHB, supporting sensitivity in detecting differences between groups.

CONCLUSION: The Chinese (HK) CLDQ is valid, reliable and sensitive for patients with CHB. Some modifications to the scaling structure might further improve its psychometric properties.

Key words: Chronic liver disease; Health-related quality of life; Hepatitis B; Southern Chinese; Validity

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INTRODUCTION

Chronic hepatitis B (CHB) virus infection remains a major global health problem. It is estimated that 350 million people worldwide are chronically infected, of whom one third (120 million) are Chinese[1]. The prevalence is higher in southern China (> 10%) than Northern China (6%-10%)[2]. Up to 25% of patients may die from CHB complications, such as cirrhosis-related complications or hepatocellular carcinoma (HCC), posing a threat to both mental and physical health, leading to impairment of health-related quality of life (HRQOL).

HRQOL has become an important outcome measure in clinical and health policy settings in the last two decades. Disease-specific measures are often needed to complement generic measures to give a more comprehensive evaluation of the HRQOL of patients with specific diseases. Several HRQOL measures have been developed specifically for chronic liver disease (CLD), such as the Chronic Liver Disease Questionnaire (CLDQ)[3], the Hepatitis Quality of Life (HQLQ)[4], the Liver Disease Quality of Life[5] and the Liver Disease Symptom Index (LDSI)[6]. The CLDQ developed by Younossi *et al*[3] was the first and is the most widely used. The other liver disease-specific HRQOL measures are not commonly used because they are either too long, or the validity data are limited[4-8].

The CLDQ consists of 29 items which are grouped into 6 subscales: abdominal symptoms (AS), fatigue (FA), systemic symptoms (SS), activity (AC), emotional function (EF) and worry (WO). It is applicable to all types of liver diseases including CHB. It has been shown to have adequate internal reliability, validity and sensitivity. Test-retest reliability was more variable with intra-class correlation (ICC) ranging from 0.23 to 0.72 for different subscales[3]. Previous studies showed that the CLDQ is more responsive than a generic measure to detect a change in patients with CLD[3,9]. It has been translated and validated in different languages[9-13], supporting its potential for cross-cultural adaptation. However, most of the psychometric data of the CLDQ have been derived from patients with hepatitis C virus (HCV) infection and Western populations. There are few data on its applicability for Southern Chinese CHB patients despite the fact that China has the world's largest population suffering from CLD.

Recently, the CLDQ has been translated into Mandarin Chinese but this Chinese (Mainland) version may not be applicable to Southern Chinese who speak Cantonese, a dialect that has significant differences in the usage of words and terms from Mandarin. In addition, information on the validity, reliability and other psychometric properties of the Chinese (Mainland) CLDQ version is limited. The aim of this study was to test the psychometric properties of a Chinese [Hong Kong (HK)] translation of the CLDQ for Southern Chinese CHB patients. This would enable the evaluation of the impact of CHB infection and assess the effect of anti-viral drug treatments on HRQOL in the world's largest population of CHB patients.

The objectives of this study were: (1) To develop a Chinese (HK) CLDQ that is semantically equivalent to the original; (2) To test the scaling assumptions and factor structure of the Chinese (HK) CLDQ; (3) To assess the psychometric properties in terms of reliability, construct validity, and sensitivity of the Chinese (HK) CLDQ; (4) To determine whether any modification of the CLDQ can improve its psychometric properties for Southern Chinese CHB patients.

MATERIALS AND METHODS

Ethics

This research project was approved by the Institutional Review Board of the University of Hong Kong/Hospital Authority Hong Kong West Cluster (IRB reference No., UW 06-089 T/1114 and trial registration No., HKC-TR-151).

Development of the Chinese (HK) CLDQ

The Chinese (HK) translation of the CLDQ was developed by iterative translations, expert panel review and cognitive debriefing, as recommended guidelines by experts[14,15]. The original CLDQ was translated into Chinese by two independent professional translators. Reconciliation of the forward translations into a single forward translation was carried out by a bilingual expert in HRQOL measures (Lam CLK) and the translators. The reconciled Chinese translation was back-translated into English by another professional translator. The back translation was reviewed by the original author and the bilingual expert to identify any non-equivalence in the Chinese translation, which was then revised. The first draft of the Chinese (HK) CLDQ was evaluated by cognitive debriefing interviews with six Southern Chinese patients with CHB infection and further revision was made to ensure item clarity and equivalence to become the final Chinese (HK) CLDQ (used in this study on psychometrics properties).

Subjects

Patients with complicated CHB were recruited from outpatient hepatitis clinics of a regional hospital and patients with uncomplicated CHB were randomly selected from the computerized registers of three public primary care clinics serving over 100 000 people in one of five regions in Hong Kong. Patients aged 18 years or older who were hepatitis B surface antigen-positive for more than six months were included in the study. Patients were excluded if they could not communicate in Cantonese; had cognitive impairment shown by the patient's inability to understand the study to give consent; were co-infected with HIV, HCV or hepatitis D virus; had undergone liver transplantation or had end-stage non-hepatitis B-related illnesses; were currently taking excessive alcohol (> 30 U/wk) or illegal drugs; or refused to give consent. Each patient completed the Chinese (HK) CLDQ, the Chinese (HK) SF-36v2 Health Survey and a structured questionnaire on morbidity and socio-demographics, administered by a trained interviewer. Each patient was asked if he/she had ever been diagnosed by a registered practitioner for more than four weeks to have hypertension, diabetes mellitus, heart disease, stroke, chronic lung disease, arthritis, psychological illness (i.e. depression, anxiety, neurasthenia or psychosis) or any other chronic diseases. Chronic co-morbidity was measured by the total number of diseases (summation of positive responses to the questions) and the presence of a specific diagnosis. Clinical data related to the CHB infection including Child's staging for patients with cirrhosis and the biomarkers of liver disease (alanine aminotransferase, aspartate aminotransferase, α-fetoprotein and total bilirubin) in each patient were retrieved from medical records. Socio-demographic data including age, gender, education, marital status, occupation, household income and family history of liver disease were also collected.

The Chinese (HK) CLDQ was re-administered to the 46 subjects with uncomplicated CHB, whose condition was expected to be stable, by telephone two weeks from the first administration, in order to assess the test-retest reliability of the Chinese (HK) CLDQ. Sixty one percent of the repeat interviews were carried out by the same interviewer.

Instruments

The Chinese (HK) CLDQ consists of 29 items measuring six subscales as described above. Each item is rated on a 7-point (1 = all of the time to 7 = none of the time) Likert scale. Scores for each of the six domains are calculated by the mean of the item scores within the subscale. A summary score is calculated by the mean of all subscale scores. The scores range from 1 to 7 with a higher score indicating better HRQOL.

The Chinese (HK) SF-36v2 Health Survey is a generic HRQOL measure that has been translated, validated and normed on the general Chinese population in Hong Kong[16,17]. It measures eight domains of HRQOL on physical functioning (PF), role-physical (RP), bodily pain (BP), general health (GH), vitality (VT), social functioning (SF), role-motional (RE) and mental health (MH). Summations of item scores of the same domain give the domain scores, which are transformed into a range from 0 to 100. A higher score indicates better HRQOL. The eight domain scores are summarized to form the physical component (PCS) and mental component (MCS) summary scores.

Statistical analysis

All data analysis was carried out in SPSS for Windows 15.0. Statistical significant levels were set at *P* values less than 0.05.

Scaling assumptions

The CLDQ item and subscale scores were calculated and tested against the following scaling assumptions: (1) Items should be substantially linearly correlated to the hypothesized subscale score with a coefficient of 0.4 or above by Spearman rank correlation test, to show the item is a significant indicator for the subscale concept. (2) An item should have a stronger correlation with its hypothesized subscale than other subscales indicating scaling success[18]. This is a test of item discriminant validity. The difference between correlations is statistically significant if it is greater than two standard errors (1 divided by the square root of sample size).

Construct validity

Factor analysis: Exploratory factor analysis using principal components with varimax rotation was performed to evaluate the factor structure of the Chinese (HK) CLDQ. The criterion for factor extraction was an eigenvalue greater than one. The highest factor loading was identified for each item. The scree plot was also used to determine the number of factors.

Convergent validity: Construct validity was also tested by convergent validity determined by Spearman correlations between corresponding CLDQ and SF-36v2 Health Survey domain scores. It was hypothesized that moderate ($r = 0.4$ to 0.7) to strong ($r > 0.7$) correlations should exist between CLDQ FA and SF-36v2 VT; between CLDQ SS and SF-36v2 BP; between CLDQ AC and SF-36v2 PF, RP and RE; and between CLDQ EF and SF-36v2 MH scores.

Sensitivity

The mean CLDQ scores were compared between two CHB patient groups, and the difference was tested by independent *t* to evaluate its sensitivity in detecting a difference between patients with complicated and uncomplicated infections. The sensitivity of the CLDQ was also assessed by the effect size (difference between group mean scores/overall standard deviation). According to Cohen[19], effect sizes of 0.3, 0.5 and 0.8 were considered small, medium and large differences, respectively. An effect size of less than 0.3 was considered not significant.

Reliability

Different methods were used to assess reliability, including internal consistency and test-retest reliability. Internal consistency was measured by Cronbach's α, which is a measure of the extent to which items in a questionnaire are homogeneous (correlated) in supporting the same concept[20]. Test-retest reliability refers to the stability of an instrument over time[21], which was measured by the intra-class correlation (ICC) between the two-week test-retest results. Reliability coefficients $\geqslant 0.7$ and 0.9 are usually expected for group comparisons and individual comparisons, respectively[21].

RESULTS

Translational equivalence of the Chinese (HK) CLDQ

All items except item 11 (level of energy) were found to be understood by 6 patients. Three out of six patients did not understand item 11. Five patients (83%) interpreted the meaning of all except four items (11, 13, 19 and 28) correctly. Four out of six patients misinterpreted the meaning of item 11 with three interpreting it as decreased physical strength. Two patients (33.3%) had difficulty in differentiating the meaning of "sleepy" and "drowsy"; and did not seem to have interpreted the words "mood swings" (item 19). Two out of six patients did not include the meaning of "worried about never feeling better" (item 28) in their interpretation. The Chinese (HK) translation was revised based on the results of cognitive debriefing and the revised questionnaire was then field tested on 23 CHB patients before this study. The final Chinese (HK) CLDQ was formed and its back-translation is shown in the appendix.

Subjects

One hundred and eighty four CHB patients were identified; 6 patients were excluded (3 had hepatitis B infection less than 6 mo, 2 had communication problems and 1 had co-infection with HCV) and 28 patients refused to participate in this study. One hundred and fifty Chinese adults consisting of 72 uncomplicated (normal liver function defined as liver enzymes persistently within the normal range and without any history of cirrhosis or HCC) and 78 complicated (cirrhosis or HCC) completed the study, giving a response rate of 84.3% (150/178). Table 1 shows their characteristics, overall and by disease severity groups. There were 8 patients in the complicated CHB group who had HCC without any cirrhosis and had normal liver function. There were no statistical differences in demographics between the uncomplicated and complicated CHB groups, except age and sex ($P < 0.001$). Complicated CHB patients were older and there were more men than those in the uncomplicated group which was expected because CHB complications were more common in men than in women and the median age for the development of complications was 57.2 years[22,23].

Score distribution

Table 2 shows the distribution of the Chinese (HK) CLDQ and SF-36v2 scores. There was practically no

Table 1 Socio-demographic and clinical characteristics of subjects *n* (%)

	Uncomplicated CHB (*n* = 72)	Complicated CHB (*n* = 78)	Overall (*n* = 150)
Age, mean years ± SD[1]	50.2 ± 12.0	55.9 ± 9.5	53.2 ± 11.1
Sex[1]			
Male	42 (58.3)	65 (83.3)	107 (71.3)
Female	30 (41.7)	13 (16.7)	43 (28.7)
Education attainment			
No schooling	2 (2.8)	6 (7.7)	8 (5.3)
Primary	19 (26.4)	14 (17.9)	33 (22.0)
Secondary	35 (48.6)	46 (59.0)	81 (54.0)
Tertiary	16 (22.2)	12 (15.4)	28 (18.7)
Marital status			
Now married, living with spouse	59 (81.9)	67 (85.9)	126 (84.0)
Never married	6 (8.3)	5 (6.4)	11 (7.3)
Widowed	1 (1.4)	1 (1.3)	2 (1.3)
Divorced/separated	6 (8.3)	5 (6.4)	11 (7.3)
Occupation			
Managers, administrators & professional	19 (26.4)	17 (21.8)	36 (24.0)
Clerk, service and shop sales workers	16 (22.2)	19 (24.4)	35 (23.3)
Craft, machine operators & elementary	27 (37.5)	39 (50.0)	66 (44.0)
Others	10 (13.9)	3 (3.8)	13 (8.7)
Health status			
CHB	72 (100)		72 (48.0)
Cirrhosis		30 (38.5)	30 (20.0)
HCC		48 (61.5)	48 (32.0)
Child-Pugh Classification			
No cirrhosis/normal LF	72 (100)	8 (10.3)	80 (53.3)
Child A		47 (60.3)	47 (31.3)
Child B		8 (10.3)	8 (5.3)
Child C		15 (19.2)	15 (10.0)

CHB: Chronic hepatitis B; HCC: Hepatocellular carcinoma; LF: Liver function. Data are no. (%) of patients, unless otherwise indicated. [1]Significant difference between uncomplicated and complicated CHB groups by independent sample *t* or Fisher's exact test, $P < 0.05$. Socio-demographic variables are recoded as binary categorical variables for performing Fisher's exact test: male *vs* female; no schooling *vs* any formal education; living with spouse *vs* other marital status; managers, administrators and professional *vs* other occupations.

floor effect but there were significant ceiling effects in the Chinese (HK) CLDQ AS, AC and WO subscales, more so in the uncomplicated than the complicated group. Significant ceiling effects were also found in most SF-36v2 Health Survey scales. Sub-group analysis showed that the mean Chinese (HK) CLDQ scores were significantly lower in the complicated group than the uncomplicated group in all subscale and overall scores.

Figure 1 compares the distribution of the Chinese (HK) CLDQ scores with those from other countries. The distribution pattern of the Chinese (HK) CLDQ subscale scores was very similar to those of other countries[3,9,11,13], except Italy, supporting cross-cultural conceptual equivalence.

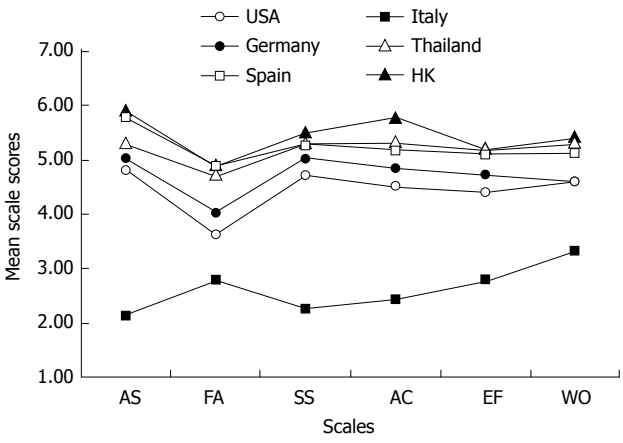

Figure 1 The Chinese (HK) CLDQ scores by countries. AS: Abdominal Symptoms; FA: Fatigue; SS: Systemic Symptoms; AC: Activity; EF: Emotional Function; WO: Worry.

Scaling properties

Table 3 shows the mean item scores and standard deviation of the 29 CLDQ items grouped under their hypothesized subscales. All correlations between items and their hypothesized subscales score exceeded the standard of 0.4.

All but six items had a higher correlation with its hypothesized subscale than other subscales, i.e. 100% scaling success. Four items of the SS subscale and two items of the AC subscale correlated more highly with some other subscales than their own. Scaling success was the lowest in item 3 "bodily pain", which correlated more highly with four other subscales than with the SS subscale, with the highest found for EF, but the differences were not statistically significant. Items 6 "shortness of breath", 23 "dry mouth", 27 "itching", 7 "not able to eat as much as you would like" and 9 "trouble in lifting or carrying heavy objects" correlated higher with one to three other subscales than its own, but the differences in the correlations were not statistically significant.

The overall scaling success rate on discriminant validity was 100% for four scales (AS, FA, EF and WO), but it was 73% for the AC subscale and 64% for the SS subscale.

Factor analysis

Table 4 illustrates the rotated factor loadings between the

Table 2 Distribution of the Chinese (HK) CLDQ and SF-36v2 Health Survey scores[1]

	Uncomplicated CHB[2] (n = 72)				Complicated CHB[2] (n = 78)				Overall (n = 150)				
	Mean	(SD)	% floor[3]	% ceiling[4]	Mean	(SD)	% floor	% ceiling	Mean	(SD)	% floor	% ceiling	ES[5]
CLDQ													
AS	6.3	(1.0)	0.0	47.2	5.6	(1.5)	0.0	28.2	5.9	(1.3)	0.0	37.3	0.5[a]
FA	5.2	(1.1)	0.0	6.9	4.6	(1.5)	0.0	5.1	4.9	(1.4)	0.0	6.0	0.4[a]
SS	5.8	(1.0)	0.0	19.4	5.2	(1.2)	0.0	6.4	5.5	(1.2)	0.0	12.7	0.5[a]
AC	6.2	(1.1)	0.0	48.6	5.4	(1.6)	0.0	28.2	5.8	(1.4)	0.0	38.0	0.6[a]
EF	5.5	(1.0)	0.0	8.3	5.0	(1.4)	0.0	5.1	5.2	(1.3)	0.0	6.7	0.4[a]
WO	5.9	(1.3)	1.4	37.5	5.0	(1.7)	0.0	17.9	5.4	(1.6)	0.7	27.3	0.6[a]
Overall	5.8	(0.8)	0.0	0.0	5.1	(1.2)	0.0	1.3	5.4	(1.1)	0.0	0.7	0.6[a]
SF-36v2 Health survey (HK norm)													
PF (90.6)	89.0	(14.7)	0.0	34.7	80.4[b]	(15.4)	0.0	10.3	84.5	(15.6)	0.0	22.0	0.5[a]
RP (90.2)	83.6[b]	(21.0)	0.0	45.8	63.9[b]	(29.4)	1.3	24.4	73.4	(27.4)	0.7	34.7	0.7[a]
BP (82.6)	72.6[b]	(23.0)	0.0	31.9	70.1[b]	(28.6)	1.3	38.5	71.3	(26.0)	0.7	35.3	0.1
GH (53.2)	53.8	(21.7)	0.0	0.0	46.9[b]	(25.6)	0.0	2.6	50.2	(24.0)	0.0	1.3	0.3
VT (60.2)	63.9	(19.8)	1.4	1.4	58.0	(26.5)	5.1	5.1	60.8	(23.6)	3.3	3.3	0.2
SF (92.4)	86.1[b]	(19.3)	0.0	48.6	71.6[b]	(29.0)	1.3	35.9	78.6	(25.8)	0.7	42.0	0.6[a]
RE (88.5)	80.4[b]	(19.8)	0.0	36.1	75.0[b]	(26.9)	0.0	33.3	77.6	(23.8)	0.0	34.7	0.2
MH (72.0)	73.6	(18.4)	0.0	5.6	70.4	(21.9)	0.0	11.5	72.0	(20.3)	0.0	8.7	0.2
PCS (50)	46.4[b]	(9.9)	0.0	0.0	39.5[b]	(12.2)	0.0	0.0	42.8	(11.6)	0.0	0.0	0.6[a]
MCS (50)	50.1	(10.4)	0.0	0.0	47.8	(13.9)	0.0	0.0	48.9	(12.3)	0.0	0.0	0.2

AS: Abdominal Symptoms; FA: Fatigue; SS: Systemic Symptoms; AC: Activity; EF: Emotional Function; WO: Worry; PF: Physical Functioning; RP: Role Physical; BP: Bodily Pain; GH: General Health; VT: Vitality; SF: Social Functioning; RE: Role Emotional; MH: Mental Health; PCS: Physical Component Summary; MCS: Mental Component Summary; ES: Effect Size. [1]The Chinese (HK) CLDQ score range 1-7 and SF-36v2 score range 0-100; higher scores indicate better health-related quality of life; [2]Uncomplicated CHB are patients who had no cirrhosis or hepatocellular carcinoma (HCC) and normal liver function; Complicated CHB refers to those with cirrhosis or HCC; [3]% floor: Percentage of CHB patients at the lowest possible score; [4]% ceiling: Percentage of CHB patients at the highest possible score; [5]Effect size was calculated as the difference between uncomplicated and complicated mean score, divided by the overall SD. [a]Significant difference between uncomplicated and complicated CHB patients by independent sample t ($P < 0.05$); [b]Significant difference between CHB groups and HK norm by independent sample t ($P < 0.05$).

29 items and 6 factors with eigenvalue > 1. The six factors explained 70.1% of total variance. The factor loadings of the items were not entirely consistent with the scaling hypothesis. Items of the FA and SS subscales, except bodily pain (item 3), decreased strength (item 8) and decreased energy (item 11), seemed to load on the same factor (factor 3). Two FA subscale items (8 "decreased energy" and 11 "decreased strength") loaded more strongly on AC than its hypothesized factor. A new factor (factor 6) was found with the highest loading from two items assessing sleep (items 16 and 20). The items of EF, WO, AS and AC subscales loaded nicely on their hypothesized factors.

Construct validity

Table 5 shows the correlations between the scores of the CLDQ and SF-36v2 Health Survey. As hypothesized, moderate to strong correlations were found between CLDQ FA and SF-36v2 VT scores; and between CLDQ SS and the SF-36v2 BP scores. The CLDQ AC score correlated significantly with all SF-36v2 Health Survey domain scores and the strongest was found with the SF-36v2 RP and SF scores. The CLDQ EF score correlated strongly not only with the SF-36v2 MH score but moderately with the SF-36v2 VT, RE, RP and GH scores.

Sensitivity

As shown in Table 2, the CLDQ overall and subscale mean scores were all significantly higher in the uncomplicated than the complicated CHB group. The effect sizes of the group differences in the CLDQ scores all exceeded 0.4 (range 0.4-0.6). Only three of the eight SF-36v2 domain scores (PF, RP and SF) and the PCS score detected a significant difference between the uncomplicated and the complicated groups. However, the greatest effect size difference between the two groups was found in the SF-36v2 RP score.

Reliability

Across all subscales, the Cronbach's α coefficients of the internal consistency reliability were higher than the recommended value of 0.7 (Table 5). ICC coefficients measuring the two-week test-retest reliability exceeded 0.7 in all but the AS (0.58) and AC (0.66) subscales. The reliability coefficients were comparable to those of the SF-36v2 Health Survey.

Table 5 also shows that the correlations (range 0.50-0.87) between the CLDQ subscales were smaller than the subscale internal reliability coefficients for all subscales, showing that each subscale measures a distinct concept. The overall CLDQ scores correlated strongly with all CLDQ subscale scores.

DISCUSSION

The mean scores of the CLDQ found in our population were generally higher than those found in other countries. This might be the result of a sampling difference, in that over half of our subjects had uncomplicated CHB infection and most of the other studies included patients with more serious diseases and patients with HCV who tend to have more impairment in HRQOL than patients with CHB infection[24]. The other reason for a difference in the absolute HRQOL scores between different populations is a difference in the sociocultural norms. A comparison

Table 3 Item descriptive statistics and item-subscale correlations of the Chinese (HK) CLDQ

Items	Mean	(SD)	Item-subscale correlations[1]						Success[2] (%)
			AS	FA	SS	AC	EF	WO	
AS									
1: Abdominal bloating	5.7	(1.6)	0.57[1]	0.48	0.45	0.44	0.52	0.49	100
5: Abdominal pain	6.1	(1.4)	0.63[1]	0.45	0.47	0.37	0.49	0.39	100
17: Abdominal discomfort	6.0	(1.5)	0.73[1]	0.49	0.52	0.50	0.52	0.50	100
									(100)
FA									
2: Tiredness or fatigue	4.3	(1.6)	0.52	0.79[1]	0.68	0.57	0.61	0.48	100
4: Feel sleepy during the day	4.4	(1.6)	0.35	0.70[1]	0.55	0.45	0.49	0.36	100
8: Decreased strength	5.6	(1.7)	0.53	0.72[1]	0.59	0.70	0.63	0.53	100
11: Decreased energy	5.0	(1.6)	0.40	0.77[1]	0.59	0.61	0.66	0.47	100
13: Drowsiness	5.1	(1.7)	0.40	0.66[1]	0.56	0.46	0.58	0.47	100
									(100)
SS									
3: Bodily pain	5.5	(1.7)	0.51[3]	0.53[3]	0.44[1]	0.44[3]	0.60[3]	0.40	20
6: Shortness of breath	6.0	(1.5)	0.51	0.60[3]	0.57[1]	0.54	0.55	0.50	80
21: Muscle cramps	5.9	(1.4)	0.29	0.47	0.52[1]	0.38	0.37	0.28	100
23: Dry mouth	4.7	(1.8)	0.37	0.47[3]	0.47[1]	0.41	0.51[3]	0.54[3]	40
27: Itching	5.4	(1.7)	0.30	0.49[3]	0.49[1]	0.41	0.42	0.41	80
									(64)
AC									
7: Not able to eat as much as you would like	5.6	(1.9)	0.42	0.59[3]	0.46	0.56[1]	0.48	0.47	80
9: Trouble in lifting or carrying heavy objects	5.8	(1.7)	0.40	0.51[3]	0.55[3]	0.42[1]	0.52[3]	0.40	40
14: Bothered by a limitation of the diet	6.0	(1.6)	0.37	0.47	0.44	0.65[1]	0.50	0.50	100
									(73)
EF									
10: Anxiety	5.1	(1.8)	0.54	0.57	0.53	0.46	0.74[1]	0.61	100
12: Unhappiness	5.2	(1.6)	0.43	0.58	0.52	0.44	0.72[1]	0.52	100
15: Irritability	5.4	(1.5)	0.47	0.54	0.52	0.44	0.73[1]	0.56	100
16: Difficulty in sleeping at night	5.1	(1.7)	0.45	0.46	0.46	0.45	0.59[1]	0.48	100
19: Mood swings	5.5	(1.5)	0.46	0.60	0.57	0.50	0.79[1]	0.54	100
20: Difficulty in falling asleep at night	4.5	(2.0	0.36	0.49	0.50	0.45	0.52[1]	0.41	100
24: Depression	5.5	(1.4)	0.42	0.56	0.52	0.41	0.76[1]	0.60	100
26: Problems with concentration	5.4	(1.6)	0.44	0.69	0.61	0.61	0.69[1]	0.61	100
									(100)
WO									
18: Worries about the impact of the liver disease	5.5	(1.8)	0.56	0.49	0.44	0.50	0.64	0.64[1]	100
22: Worries that symptoms will develop into major problem	5.1	(1.8)	0.43	0.42	0.45	0.37	0.52	0.79[1]	100
25: Worries that the condition is getting worse	5.2	(1.8)	0.44	0.49	0.54	0.49	0.59	0.85[1]	100
28: Worries about never feeling any better	5.6	(1.7)	0.44	0.54	0.57	0.59	0.67	0.83[1]	100
29: Availability of a liver for transplant	5.7	(2.0)	0.36	0.45	0.47	0.55	0.48	0.62[1]	100
									(100)

[1]Spearman correlation between item and its hypothesized subscale corrected for overlap (relevant item removed from its subscale for correlation); [2]Level of scaling success, item-subscale correlation is higher for hypothesized subscale than competing subscale; [3]Item-subscale correlation is lower for hypothesized subscale than for competing subscale, but not statistically significant at the cutoff point of two standard errors (0.16).

with the population norms of generic HRQOL measures such as those of the SF-36 Health Survey will provide a more meaningful interpretation on the impact of CHB on HRQOL between different populations. Our study found that uncomplicated CHB patients had significant impairment in the SF-36v2 RP, BP, SF and RE domains, and complicated CHB patients had significantly lower SF-36v2 scores in six domains (PF, RP, BP, GH, SF and RE) than the norms of the HK population (Table 2)[25,26]. The findings suggested that CHB infection affected HRQOL only modestly unless complications develop. Surprisingly, there was no difference in the MH score between CHB patients and the HK population norm. It was unlikely that a potentially lethal chronic infection had no effect on mental health, the SF-36v2 Health Survey was probably not sensitive enough to detect the difference.

The high ceiling effects in the AS, AC and WO subscales in patients with uncomplicated CHB were expected since they were usually asymptomatic. A pattern that was similar to that found in a Spanish population[9]. A high ceiling effect was also observed among patients with complicated CHB which was unexpected, this was probably because most of our subjects with complicated CHB were under anti-viral treatment that might have improved their HRQOL, or perhaps some patients had adjusted to their illnesses. On the whole, the CLDQ had a lower ceiling effect than the SF-36v2 Health Survey, suggesting that this disease-specific HRQOL measure would be more responsive than the generic measure in detecting improvements with treatment, which needs to be confirmed by prospective studies. The lack of floor effect indicates that the Chinese (HK) CLDQ would be able to capture any deterioration in patients' QOL as the disease progresses.

The item-subscale correlations and factor analysis results supported the scaling structure of the Chinese (HK)

Table 4 Factor loadings of the Chinese (HK) CLDQ

Item	Factor 1 EF	Factor 2 WO	Factor 3 SS + FA	Factor 4 AS	Factor 5 AC	Factor 6 SL
Abdominal symptom (AS)						
1: Abdominal bloating	0.18	0.27	0.16	0.70	0.14	0.15
5: Abdominal pain	0.20	0.06	0.13	0.81	0.08	0.14
17: Abdominal discomfort	0.17	0.23	0.17	0.82	0.20	0.08
Fatigue (FA)						
2: Tiredness or fatigue	0.33	0.03	0.51	0.31	0.45	0.22
4: Feel sleepy during the day	0.28	-0.05	0.47	0.14	0.44	0.14
8: Decreased strength	0.37	0.14	0.37	0.24	0.60	0.24
11: Decreased energy	0.56	0.06	0.37	0.11	0.51	0.12
13: Drowsiness	0.49	0.09	0.47	0.15	0.36	-0.17
Systemic symptoms (SS)						
3: Bodily pain	0.49	0.00	0.18	0.39	0.14	0.22
6: Shortness of breath	0.22	0.22	0.59	0.39	0.18	0.03
21: Muscle cramps	0.09	0.08	0.76	0.17	0.10	0.14
23: Dry mouth	0.24	0.42	0.48	0.16	0.08	-0.02
27: Itching	0.10	0.27	0.65	-0.01	0.02	0.28
Activity (AC)						
7: Not able to eat as much as you would like	0.05	0.29	0.04	0.24	0.81	0.12
9: Trouble in lifting or carrying heavy objects	0.41	0.18	0.37	-0.05	0.35	0.17
14: Bothered by a limitation of the diet	0.11	0.43	0.09	0.10	0.67	0.12
Emotional function (EF)						
10: Anxiety	0.67	0.32	0.15	0.39	0.14	0.04
12: Unhappiness	0.77	0.25	0.15	0.20	0.13	0.01
15: Irritability	0.78	0.27	0.15	0.17	0.06	0.13
16: Difficulty in sleeping at night	0.27	0.17	0.17	0.18	0.14	0.79
19: Mood swings	0.78	0.24	0.10	0.19	0.20	0.21
20: Difficulty in falling asleep at night	0.16	0.14	0.25	0.22	0.25	0.71
24: Depression	0.8	0.31	0.15	0.08	0.03	0.22
26: Problems with concentration	0.52	0.28	0.29	0.18	0.37	0.27
Worry (WO)						
18: Worries about the impact of the liver disease	0.40	0.47	0.03	0.50	0.25	0.07
22: Worries that symptoms will develop into major problem	0.29	0.80	0.11	0.16	0.04	0.05
25: Worries that the condition is getting worse	0.29	0.84	0.13	0.17	0.17	0.09
28: Worries about never feeling any better	0.27	0.77	0.13	0.18	0.26	0.24
29: Availability of a liver for transplant	0.16	0.64	0.26	0.14	0.30	0.10

SL: Sleep.

Table 5 Reliability and correlations of the Chinese (HK) CLDQ and SF-36v2 health survey scores

	AS	FA	SS	AC	EF	WO	Cronbach's α	ICC[1]
CLDQ								
AS							0.84	0.58
FA	0.54						0.88	0.82
SS	0.54	0.72					0.74	0.86
AC	0.5.0	0.67	0.60				0.72	0.66
EF	0.58	0.72	0.68	0.61			0.90	0.86
WO	0.52	0.57	0.60	0.58	0.69		0.90	0.89
Overall	0.72	0.87	0.84	0.80	0.86	0.81	0.90	0.85
SF-36v2 Health Survey								
PF	0.47	0.56	0.65	0.54	0.47	0.46	0.81	0.93
RP	0.56	0.72	0.70	0.67	0.60	0.62	0.91	0.90
BP	0.44	0.44	0.62	0.42	0.48	0.44	0.89	0.77
GH	0.46	0.66	0.56	0.57	0.60	0.62	0.82	0.89
VT	0.51	0.79	0.63	0.58	0.67	0.54	0.86	0.85
SF	0.44	0.56	0.52	0.60	0.58	0.52	0.88	0.54
RE	0.53	0.51	0.52	0.46	0.66	0.50	0.89	0.74
MH	0.41	0.58	0.49	0.49	0.78	0.61	0.84	0.89

[1]All analyses were performed with the total sample of 150 patients, except for the Intra-class Correlation Coefficient (ICC), which was based on the results from 46 uncomplicated CHB patients.

CLDQ in general. However, the scaling success rates of items 3 (bodily pain), 23 (dry mouth) and 9 (trouble in lifting or carrying heavy objects) seemed too low to be acceptable, raising the question whether they should be

Table 6 Psychometric properties of the revised Chinese (HK) CLDQ subscales

Revised subscales	Mean	SD	% floor	% ceiling	Scaling success	Cronbach's α	ICC
AS	5.9	1.3	0.0	37.3	100.0	0.84	0.58
SS + FA	5.2	1.1	0.0	4.7	95.0	0.84	0.88
AC	5.6	1.4	0.0	20.7	88.0	0.84	0.75
EF	5.3	1.3	0.0	12.0	93.3	0.92	0.87
WO	5.4	1.6	0.7	27.3	100.0	0.90	0.89
SL	4.8	1.7	1.3	17.3	100.0	0.78	0.79
Overall Scores	5.4	1.1	0.0	0.7	NA	0.89	0.85

grouped under other subscales than the originally hypothesized. It is interesting to note that bodily pain correlated the most with the EF subscale score and loaded the strongest on the EF factor (Table 4). It is a common observation that emotional state has a strong influence on pain perception and *vice versa*. Although the items on dry mouth or trouble in lifting or carrying heavy objects correlated more strongly with other subscales than their own, they should probably remain in the hypothesized subscale because the differences in the item-subscale correlations were not significant and the item-hypothesized subscale correlations were greater than 0.4. Furthermore, the factor loading results were not consistent with the results of the item-subscale correlations. The item "dry mouth" correlated most strongly with WO subscale score but the loading was the highest on the SS factor (0.48). The item "trouble in lifting or carrying heavy objects" correlated highest with the SS score but factor analysis showed that it loaded most strongly on the factor of EF.

The factor structure of the Chinese (HK) CLDQ version was almost identical to the original CLDQ in four subscales (EF, WO, AS and AC). The new factor of Sleep found in our Chinese population was also found in the Spanish, Italian and German population[9,10,27]. CHB patients may have sleep difficulties due to reasons other than emotional problems, such as pain and other symptoms. The items of the FA and SS subscales, except items 3, 8 and 11, loaded on one single factor since they all measure symptoms. Items 8 and 11 of the FA subscale loaded on the AC factor. Factor analysis with promax rotation was also performed to cross-validate the factor structure obtained by the varimax rotation, and it showed similar results with a new factor assessing sleep and items of the FA subscale loaded mostly on the AC factor instead of a separate factor.

An alternative scaling structure for the Chinese (HK) CLDQ based on the factor loading results could be formed. Items 16 (difficulty in sleeping) and 20 (difficulty in falling asleep at night) were grouped into a new Sleep subscale. Items 8 (decreased strength) and 11 (decreased energy) were grouped into the AC subscale. Items 2, 4 and 13 of the original FA subscale are grouped with items of the SS subscale to form the new SS subscale. Item 3 (bodily pain), although loaded most strongly and correlated the most with EF factor, remains in the SS subscale because this has better face validity. The psychometric properties of the revised Chinese (HK) CLDQ subscales with regrouping of the items are shown in Table 6. It can be seen that the new subscale structure greatly improves the scaling success rates of the SS and AC items, although it reduces the success rate of the EF subscale slightly. The new scaling structure also reduced the ceiling effects of the SS and AC subscales. Further studies are needed to determine whether the revised subscale structure will translate into better sensitivity and responsiveness in clinical applications. Until such data are available, the original subscale structure of the CLDQ is recommended to allow better international comparability.

The expected correlations between the CLDQ and SF-36v2 Health Survey domains were observed confirming convergent construct validity. The correlation with the SF-36v2 RE domain was higher in the CLDQ EF than the AC subscale because conceptually the SF-36v2 RE measures the effect of emotional problems on daily activities.

The CLDQ subscales of AS and WO address domains that are not assessed by the generic measure (SF-36v2 Health Survey) and detected significant differences between the two groups of CHB patients. There were significant differences in the WO and EF subscales of the CLDQ between the CHB groups although this was not found in most of the mental-health related domains (RE, MH and MCS) of the SF-36v2 Health Survey, suggesting that the Chinese (HK) CLDQ was more sensitive than the generic measure in detecting the emotional impact of CHB. It is worth noting that although more domains in the CLDQ showed a significant difference between the complicated and uncomplicated CHB groups, the largest effect size difference was found in the SF-36v2 RP domain indicating that a disease-specific measure may not always be more sensitive than a generic measure. The two types of HRQOL measures should complement each other in the evaluation of the HRQOL of CHB patients.

Internal consistency and test-retest reliability were acceptable for all subscales. Test-retest reliability (ICC) of the AS subscale was relatively low (0.58) probably because these symptoms could fluctuate from day to day and pain intensity might vary noticeably in a relatively short period of time. Reliability of the CLDQ in our study was generally higher than those found in other studies (0.46-0.95)[9,12]. The SS subscale had very good test-retest reliability (ICC 0.86) in our population. The very low ICC (0.23) found in the US study was likely the result of an inappropriately long retest interval of six months[3].

Our study administered the Chinese (HK) CLDQ using an interviewer since our populations had a relatively low literacy level. The performance of the instrument by self-completion will need to be confirmed by further studies. The responsiveness of the Chinese (HK) CLDQ in detecting changes with disease progression or anti-viral treatment will also need to be determined.

The Chinese (HK) CLDQ was validated in content and construct. It had satisfactory psychometric properties in terms of factor structure, scaling assumption, construct validity, reliability and sensitivity in Southern Chinese patients with CHB infection. It was more sensitive than the SF-36v2 Health Survey in detecting the impact of CHB on mental-health and symptom related HRQOL. The Chinese (HK) CLDQ should be applicable to all Cantonese-speaking Chinese in HK and other parts of Southern China. It is also likely to be applicable to the majority of Chinese populations in Australia, North America, and Europe who are mostly emigrants from HK. There was good equivalence in the score distribution pattern across several cultures indicating that it can be used as a cross-cultural HRQOL measure in multiethnic populations or global studies. Some modifications of the scaling structure of the CLDQ may improve its psychometric properties for CHB patients, which need to be explored by further clinical studies.

Appendix: Back-translation of Chinese (HK) CLDQ

Original Wording	Backward Translation
This questionnaire is designed to find out how you have been feeling during the last 2 wk.	The purpose of this questionnaire is to understand how you felt in the past 2 wk.
You will be asked about you symptoms related to your liver disease, how you have been affected in doing activities, and how your mood has been.	The questions are about the symptoms resulting from your liver illness and how these symptoms affect your participation in activities, and your emotions.
Please complete all of questions and select only one response for each question.	Please answer all questions. You can only choose one answer for each question.
1 How much of the time during the last 2 wk have you been troubled by a feeling of abdominal bloating?	1 In the past 2 wk, how much time you have been bothered by your bloating problem?
All of the time	All the time
Most of the time	Most of the time
A good bit of the time	Quite Often
Some of the time	Sometimes
A little of the time	A Short Time
Hardly any of the time	Hardly Any
None of the time	Never
2 How much of the time have you been tired or fatigued during the last 2 wk?	2 In the past 2 wk, how much time did you feel tired or exhausted?
3 How much of the time during the last 2 wk have you experienced bodily pain?	3 In the past 2 wk, how much time did your body ache?
4 How often during the last 2 wk have you felt sleepy during the day?	4 In the past 2 wk, how often did you feel sleepy during the daytime?
5 How much of the time during the last 2 wk have you experienced abdominal pain?	5 In the past 2 wk, how much time did you have abdominal pain?
6 How much of the time during the last 2 wk has shortness of breath been a problem for you in your daily activities?	6 In the past 2 wk, how much time were your daily activities affected by your shortness of breath?
7 How much of the time during the last 2 wk have you not been able to eat as much as you would like?	7 In the past 2 wk, how much time were you unable to eat as much as you want?
8 How much of the time in the last 2 wk have you been bothered by having decreased strength?	8 In the past 2 wk, how much time have you been bothered by the decline in your physical energy?
9 How often during the last 2 wk have you had trouble lifting or carrying heavy objects?	9 In the past 2 wk, how often did you find it difficult when you were lifting or carrying heavy objects?
10 How often during the last 2 wk have you felt anxious?	10 In the past 2 wk, how often did you feel anxious?
11 How often during the last 2 wk have you felt a decreased level of energy?	11 In the past 2 wk, how often did you find your energy level decreasing?
12 How much of the time during the last 2 wk have you felt unhappy?	12 In the past 2 wk, how much time did you feel unhappy?
13 How often during the last 2 wk have you felt drowsy?	13 In the past 2 wk, how often did you feel sleepy?
14 How much of the time during the last 2 wk have you been bothered by a limitation of your diet?	14 In the past 2 wk, how much time have you been bothered by your restricted diet?
15 How often during the last 2 wk have you been irritable?	15 In the past 2 wk, how often did you become irritable?
16 How much of the time during the last 2 wk have you had difficulty sleeping at night?	16 In the past 2 wk, how much time did you find it difficult to sleep at night?
17 How much of the time during the last 2 wk have you been troubled by a feeling of abdominal discomfort?	17 In the past 2 wk, how much time have you been bothered by your abdominal discomfort?
18 How much of the time during the last 2 wk have you been worried about the impact your liver disease has on your family?	18 In the past 2 wk, how much time did you worry that your liver illness will affect your family?
19 How much of the time during the last 2 wk have you had mood swings?	19 In the past 2 wk, how much time did your emotions fluctuate?
20 How much of the time during the last 2 wk have you been unable to fall asleep at night?	20 In the past 2 wk, how much time were you unable to sleep until sunrise?
21 How often during the last 2 wk have you had muscle cramps?	21 In the past 2 wk, how often did your muscle cramp?
22 How much of the time during the last 2 wk have you been worried that your symptoms will develop into major problems?	22 In the past 2 wk, how much time did you worry that your symptoms will become a serious problem?
23 How much of the time during the last 2 wk have you had a dry mouth?	23 In the past 2 wk, how much time did you have dry mouth?
24 How much of the time during the last 2 wk have you felt depressed?	24 In the past 2 wk, how much time did you feel depressed?
25 How much of the time during the last 2 wk have you been worried about your condition getting worse?	25 In the past 2 wk, how much time did you worry that your condition will deteriorate?
26 How much of the time during the last 2 wk have you had problems concentration?	26 In the past 2 wk, how much time did you find it hard to concentrate?
27 How much of the time have you been troubled by itching during the last 2 wk?	27 In the past 2 wk, how much time have you been bothered by itchiness?
28 How much of the time during the last 2 wk have you been worried about never feeling any better?	28 In the past 2 wk, how much time did you worry that your health condition will not improve?
29 How much of the time during the last 2 wk have you been concerned about the availability of a liver if you need a liver transplant?	29 In the past 2 wk, how much time have you worried that you could not get a liver if you have to undergo a liver transplant?

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COMMENTS

Background

Chronic hepatitis B (CHB) virus infection remains a global problem and a public health threat. CHB patients may suffer or die from liver-related complications, posing a threat to both mental and physical health, leading to impairment of quality of life.

Research frontiers

Health-related quality of life (HRQOL) outcomes should supplement traditional clinical outcomes in the evaluation of the impact and the effectiveness of treatment for patients with CHB infection.

Innovations and breakthroughs

The Chronic Liver Disease Questionnaire (CLDQ) had been applied mainly to patients with hepatitis C virus infection in Western countries. This study was the first to show that a Chinese (Hong Kong) translation of the CLDQ was valid, reliable and sensitive for Southern Chinese patients with CHB infection. The CLDQ can be applied to millions of Southern Chinese CHB patients to evaluate their HRQOL. Some modifications might further improve its validity, reliability and sensitivity.

Applications

The Chinese (Hong Kong) CLDQ can be used to evaluate the impact of CHB virus infection and assess the effectiveness of anti-viral drug treatments in Cantonese-speaking Southern Chinese. The CLDQ can be used as a cross-cultural HRQOL measure in international studies that include Southern Chinese.

Terminology

CHB virus infection refers to those who are hepatitis B surface antigen-positive for more than six months. Validity is defined as the extent to which a test measures what it is intended to measure. Reliability refers to the consistency or stability of the measurement process across time, patients or observers.

Peer review

The authors validated and tested the psychometric properties of a Southern Chinese translation of the CLDQ and determined that their questionnaire was valid, reliable, and sensitive for southern Chinese patients with hepatitis B virus infection. The study was well done and used appropriate methodology to validate and test the questionnaire.

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