

## Validity and Reliability of the Turkish Version of the Liver Disease Quality of Life (LDQOL 1.0) Instrument

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### Abstract

**Objective:** Chronic liver disease affects physical, psychological, social, economic problems and medical side effects in different levels. Because of these problems, the specific nature of a disease is best evaluated by a specific instrument. Specific instruments provide for nurses to capture the specific status of disease and make specific interventions to client and disease.

**Design:** A cross-sectional and methodological design.

**Methods:** The study data was collected from 170 patients with chronic liver disease. The validity of the instrument was examined with translation procedures, face validity, construct validity and concurrent validity. The reliability of instrument was examined with test-retest reliability and internal consistency.

**Results:** It showed that factor analysis consisted of 3 levels which are Physical Health, Mental Health, and Social/Cognitive health. A negative relation was found between the mean score of CTP and the mean score of instrument ( $r = -0.26$ ,  $p < 0.001$ ). The test-retest reliability of instrument was found as 0.94 (ICC)  $p < 0.01$ . The internal consistency Cronbach Alfa Coefficient of LDQOL 1.0 had good level and it was 0.80.

**Conclusion:** At the end of study "LDQOL 1.0" was found that it is very reliable and a valid instrument for Turkish society in chronic liver disease.

**Keywords:** Quality of life; Chronic liver disease; Reliability; Validity

### Introduction

Chronic liver disease and cirrhosis caused by excessive alcohol consumption, viral hepatitis, or non-alcoholic fatty liver most of which are preventable lead to morbidity and mortality [1]. The prevalence of etiologic causes is closely related to cultural and economic reasons. In Turkey, viral hepatitis is the major cause of chronic liver diseases with a prevalence rate of 50 to 90%. It is followed by alcoholic cirrhosis with a prevalence rate of 10% [2]. According to annual statistics in Turkey, 19,120 patients were treated in hospitals because of cirrhosis. Of them 1,101 died and the others were discharged [3].

The studies in the literature show that physical, mental, social and economic domains of the quality of life are impaired due to chronic liver disease. There are many factors reducing health related quality of life (HRQOL) such as disease symptoms, disease severity and disease type, complications of liver disease, age, female sex, low socioeconomic status, financial burden, and poor health perception of HRQOL [4-9]. Chronic liver disease with various etiologies differs from asymptomatic chronic hepatitis to decompensated cirrhosis. That is why, symptoms, especially the ones affecting the quality of life, vary. Most patients can remain asymptomatic until decomposition occurs. In the previous studies, patients with decompensated cirrhosis reported poorest HRQOL, which is followed by patients with compensated cirrhosis.

Patients with no sign of cirrhosis are capable of performing the daily activities [10-13].

In the past decades, most research on the HRQOL of the chronic liver patients focused on the treatments inducing changes in HRQOL, the variation of HRQOL depending on the disease severity and the comparison of HRQOL between etiologies. However, HRQOL is often defined not only as the impact of disease and/or treatment on a patient's physical, emotional and social function and well-being, but also as an individual's satisfaction from his/her life experience [6,8]. In addition, many studies investigated the HRQOL of patients with chronic liver disease by means of a generic questionnaire. A generic questionnaire is capable of assessing fatigue, pain, energy level, social activities and physical conditions. However, chronic liver disease has some specific characteristics including ascites, hepatic encephalopathy, edema, pruritus, yellow appearance of the skin etc. For this reason, generic instruments cannot reflect the quality of life of the patients thoroughly. The quality of life instrument with the specific characteristics for the liver disease has been recommended because a specific instrument addresses to a specific disease [14,15].

Nursing focuses on a number of areas including health promotion, living with chronic conditions and enhancing quality of life and caring for clients experiencing changes in their health [16]. One way to improve the health is to strengthen the quality assurance systems employed to evaluate nurse-led interventions. In particular, the integration into practice of validated tools to monitor and evaluate

patient-reported outcomes such as the health gain and quality of life benefits of care to patients and their families [17]. However, there is not a validated and reliable instrument to determine the quality of life of the patients with chronic liver disease in Turkey. Therefore, in Turkey, it is unlikely for nurses caring for patients with chronic liver disease to determine the patients' needs and to evaluate the results of nursing activities they apply.

### Aim of the Study

The aim of this study was to establish the psychometric properties including validity, reliability and sensitivity of a Turkish version of the Liver Disease Quality of Life Instrument 1.0 (LDQOL-1.0) to Turkish patients with chronic liver disease.

### Methods

#### Participated settings

A cross-sectional and methodological design was used in the study. The research was took place at out-patient clinic of Hepatology, Department of Gastroenterology, School of Medicine at Ege University in Izmir. This hospital has 1884 bed capacity. The hospital was serviced 716,594 patients receives out-patient care and 55,592 patients receives in-patient care. The selection criteria of this hospital are to being the biggest hospital in Aegean region. In addition, Gastroenterology department has a hepatology out-patient clinic in this hospital.

The research was administered to 170 patients with chronic liver disease in a hepatology out-patient clinic. Normally there is no agreement on adequacy of sample size but one important feature is the ratio of items to the number of participants and, generally, a ratio of 1:10 is advised [18,19]. LDQOL 1.0 consisted of 17 main questions related to quality of life of patients with chronic liver disease. The 170 participants met the criteria for an adequate sample.

**Inclusion criteria:** (1) Voluntary, ambulatory and conscious participants. (2) At least 18 years of age and literate.

**Exclusion criteria:** (1) Secondary chronic disease could decrease quality of life and affect the results. Therefore, patients who had a secondary chronic disease were not included in the research.

(2) The patients in the class Child A and B were out-patient clinic patients. But the patients in the class Child C were treated in hospital which did not take place in the research. The duration of interviews was approximately 20-25 min for each patient.

#### Instruments

A third- part survey was used to collect the data. The survey included:

- Demographic questionnaire and disease information
- The Liver Disease Quality of Life Instrument 1.0
- The Child-Turcotte-Pugh classification

#### Sociodemographic data form

This form consisted of sociodemographic questions about patients' age, sex, marital status, educational status, disease etiologies.

### The Liver Disease Quality of Life Instrument 1.0 (LDQOL 1.0)

The Liver Disease Quality of Life Instrument 1.0 is a comprehensive disease specific instrument. LDQOL 1.0 was developed to measure the effects of chronic liver disease on the quality of life and the daily activities by Gralnek IM et al. [20]. The instrument consists of 17 main questions, 12 subscales which include 75 questions were formed. The 12 subscales in the LDQOL 1.0 are: liver disease-related symptoms, liver disease-related effects on activities in daily life, concentration, memory, sexual function, sexual problems, sleep, loneliness, hopelessness, quality of social interaction, health distress, and self-perceived stigma of liver disease. The LDQOL 1.0 is the likert type scale. To ensure balance among questions, scores were calculated for each scale by summing the scores of their component items and converting the sum to a scale ranging from 0 to 100, higher values indicate better HRQOL (20,21) (Table 1).

Subscales of the LDQOL 1.0	Items	Likert Type	Question Numbers
Symptoms of liver disease	17	6 point	1a-1r
Effects of liver disease	10	6 point, 5 point	2a-2h, 2i-2j
Concentration	7	5 point, 5 point	3a-3c, 4a-4d
Memory	6	5 point, 5 point	5a-5d, 6a, 6b
Quality of social interaction	5	5 point	7a-7e
Health distress	4	5 point	8a-8d
Sexual function	3	4 point, 5 point, 5 point	9, 10, 13
Sexual problems	3	4 point	12
Sleep	5	5 point	14a-14e
Loneliness	5	5 point	15a-15e
Hopelessness	4	5 point	16a-16d
Stigma of Liver disease	6	5 point	17a-17f

**Table 1:** Characteristics of LDQOL 1.0.

### The Child-Turcotte-Pugh classification

Child-Turcotte-Pugh classification (CTP) was developed in 1964 and was revised in 1973. CTP' variable include hepatic encephalopathy, ascites, serum albumin level, total serum bilirubin level, and prothrombin time. Each variable was placed in one of three severity strata. Thereafter, Child-Turcotte-Pugh (CTP) classes A, B, and C was calculated by totaling the sum of individual scores. In 1984, the Copenhagen Study Group for Liver Disease confirmed the value of the CTP to evaluate the prognosis of medically treated patients with cirrhosis. Investigators from Innsbruck University validated its usefulness in 620 patients with chronic liver disease for 15 years. As the CTP score became the preferred method to evaluate the severity and prognosis of the disease worldwide. At present, the CTP classification is by far the most widely applied and reported system as it is easy to use at the bedside [21-23]. The consequences of previous researches show that the patients at the Child A have better quality of life levels than Child C [13,20,21,24,25]. Variables of CTP score was showed in Table 2.

## Procedures

Data collection was by face to face interview with the stroke patients in outpatients in outpatient clinic by the researcher. The questionnaire was used to collect information. The researcher individually approached patients to describe the study and obtain verbally informed consent, before start questionnaire. Researchers informed verbally all patients about the aim of research. To declare their willingness, written permission was taken. They were informed that they were able to withdraw from study at any time.

	Units	1 Point	2 Point	3 Point
Hepatic encephalopathy		Absent	Mild	Advanced (coma)
Ascites		Absent	Controlled	Refractory
Total bilirubin	serum mg/dL	0-2.0	2.0-3.0	>3.0
Serum albumin	g/L	>3.5	2.8-3.5	<2.8
Protrombin time	INR	<1.70	1.71-2.20	<2.20
	seconds prolongation	(0-4)	(4-6)	(>6)
CTP Class A=5 to 6 points; CTP Class B = 7 to 9 points; CTP Class C=10 to 15 points				

**Table 2:** Variables of Child-Turcotte-Pugh classification.

## Statistical analysis

The reliability and validity of the Liver Disease Quality of Life Instrument 1.0 were evaluated as follows language validity, content validity, construct validity, internal consistency reliability of the scale, test-retest reliability.

## Ethical approval

The permission was obtained from the Gralnek IM et al. [20] by e-mail to examine the validity and reliability of instrument in Turkish society. Before the research, permission was obtained from Ege University School of Nursing Ethics Committee and Ege University Medicine Faculty, Department of Gastroenterology.

## Validity and Reliability Studies

### Language validity

The instrument was translated from English into Turkish by a gastroenterologist assistant professor, a university lecturer at the medical nursing department, three transplantation nurses, and two physicians. The translations were compared and harmonized by the researcher. Back translation was performed by an English language expert who had not seen the original version and a specialist on the field of internal medicine who was educated in USA. The last version of instrument was compared with the original version and necessary revisions were made. After the translation process, a pilot study was performed with 10 patients with chronic liver disease. The patients routinely came for outpatient clinic controls. They assessed the LDQOL in terms of readability and comprehensibility of the items.

## Content validity

The Turkish version of the Liver Disease Quality of Life Instrument 1.0 was sent to 8 teaching faculty members for their opinions on content validity. They evaluated every item for its distinctiveness, understandability and appropriateness for the purpose. The faculty members used an index for evaluation on which score of 1-4 is given for each item (1-3: Inappropriate, 4: Changes were made in the statements based on their recommendations and the tool was given its final form).

## Construct validity

An exploratory factor analysis was used to determine the construct validity of the scale. The Kaiser-Meiyer-Olkin (KMO) index, which is criterion for determining whether items are appropriate for basic component analysis, was investigating for the exploratory factor analysis (EFA) sample. Kaiser-Meyer Olkin (KMO) Measure of Sampling Adequacy was calculated 0.89 and Barlett test was calculated 713.54,  $p < 0.001$  [17,26].

## Internal consistency reliability of the scale

To establish the internal consistency of the instrument, Cronbach alpha coefficient was calculated for the total score of the Liver Disease Quality of Life Instrument 1.0.

## Test-retest reliability

Test-retest reliability was evaluated by calculated the Pearson product moment correlation coefficient between pretest and posttest with a 25-30 day interval in a sample of 38 patients. In determining the internal consistency Spearman-Brown and Gutmann split -half reliability coefficients were calculated [13,21,24,27-29].

## Results

### Participant characteristics

One hundred seventy participants completed the LDQOL 1.0. The mean age was 45.85 years (SD  $\pm$  11.34), with 58.2% of the sample being men. The majority of patients were married (89.4%). The patients were mainly graduated from elementary school (41.2%). The most common diagnosis for chronic liver disease was hepatitis B (64.7%), followed by hepatitis C (20.6%), primary biliary cirrhosis (7.0%), autoimmune hepatitis (3.5%), cryptogenic (2.4%), Budd-Chiari (1.2%) and alcoholic liver disease (0.6%). When patients were classified according to CTP it was observed that 91.2% of patients were in the Child A. Table 3 shows socio-demographic characteristics of the participants.

### Validity results

The Turkish LDQOL 1.0 explained three factors.

**Factor 1:** The physical health dimension was mainly defined by the subscales including symptoms of liver disease, effects of liver disease, sexual function and sleep.

**Factor 2:** The mental health dimension of the LDQOL 1.0 was primarily defined by the subscales including hopelessness, health distress, stigma of liver disease, and loneliness.

**Factor 3:** The cognitive/social health dimension was defined by subscales including memory, concentration and quality of social interaction.

Total amount of explained variance for these 3 factors was 63.48%. However the eigenvalue of the Factor 3 was observed 0.91. When it was removed from the instrument the total explained variance of the instrument was reduced to 55.20%. Exploratory factor analysis with promax oblique rotation was conducted to assess the construct validity of instrument. Factor loadings and eigenvalues were described in Table 4.

Characteristics	N	Mean(%)
<b>Ages(years)</b>		
18-36	29	17.1
37-55	109	64.1
56-74	32	18.8
<b>Gender</b>		
Men	71	41.8
Women		
<b>Marital status</b>		
Married	152	89.4
Single	9	5.3
Widowed	5	2.9
Divorced	4	2.4
<b>Educational Status</b>		
Elementary school	70	41.2
High school	49	28.8
University	51	30.0
<b>Etiologies</b>		
HBV	110	64.7
HCV	35	20.6
PBC	12	7.0
Autoimmune	6	3.5
Cryptogenic	4	2.4
Budd-chiari	2	1.2
Alcoholic liver disease	1	0.6
<b>CTP classification</b>		
Child A	155	91.2
Child B	15	8.8

**Table 3:** Participant sociodemographics (n=170).

Kaiser-Meyer Olkin (KMO) measure of sampling adequacy was calculated 0.89 and Barlett test was calculated 713.54,  $p < 0.001$ . The

pearson moment correlation coefficient was calculated between the mean score of the instrument and the mean score of CTP, and negative relation was observed ( $r = -0.26$ ,  $p < 0.001$ ).

### Reliability results

Internal consistency was established by calculating the cronbach alpha coefficient. Coefficients of 0.94 for the LDQOL 1.0 items indicate good internal consistency for the LDQOL 1.0 in chronic liver patients. The item total correlation coefficients are represented Table 5.

	Factor loadings	Eigenvalue
<b>Factor 1: Physical Health</b>		
(21.68% variance, Cronbach's $\alpha = 0.72$ , ICC=0.87)		
Symptoms of liver disease	0.71	2.385
Effects of liver disease	0.73	
Sexual function	0.73	
Sleep	0.57	
<b>Factor 2: Mental Health</b>		
(20.92% variance, Cronbach's $\alpha = 0.74$ , ICC=0.92)		
Health distress	0.68	2.301
Loneliness	0.63	
Hopelessness	0.68	
Stigma of liver disease	0.8	
<b>Factor 3: Cognitive/Social Health</b>		
(20.88% variance, Cronbach's $\alpha = 0.81$ , ICC=0.94)		
Concentration	0.76	2.297
Memory	0.96	
	0.76	
<b>Total:</b> 63.48% of variance explained, $\alpha = 0.86$ , ICC=0.94		

**Table 4:** Factor constructs analysis of the LDQOL 1.0.

The stability of the instrument was established by measuring the test-retest reliability. The questionnaire was re-completed by 38 patients after six weeks. ICC was measured as 0.94 for the instrument. The measured ICC of subscales was ranged from 0.79 to 0.93 ( $p < 0.01$ ). Cronbach's alpha of the instrument was 0.80. Cronbach's alphas of subscales were higher than 0.71 except for the sleep subscale and quality of social interaction subscale.

Cronbach's alpha of the sleep subscale was 0.67 and the quality of social interaction scale was 0.57. The sexual problems subscale was answered by one hundred participants. Because of reducing Cronbach's alpha of all scale, the sexual problems subscale was evaluated itself with one hundred participants. When it was measured together with other subscales in the instrument, Cronbach's alpha was measured below 0.70.

## Discussion

Chronic liver disease affects patients in many ways. Patients have to deal with both the physical problems and psychological, social, economic problems and medical side effects. Generic instruments have a number of limitations, of which the most important is that they do not allow specific aspects of a disease to be studied.

Factor loadings		Eigenvalue		
<b>Factor 1:</b>				
Symptoms of liver disease	0.71	2.385		
Effects of liver disease	0.73			
Sexual function	0.73			
Sleep	0.57			
<b>Factor 2:</b>				
Health distress	0.68	2.301		
Loneliness	0.63			
Hopelessness	0.68			
Stigma of liver disease	0.8			
<b>Factor 3:</b>				
Concentration	0.76	2.297		
Memory	0.96			
	0.76			
Total:63.48% of variance explained, alpha=0.86, ICC=0.94				
Subscales of LDQOL 1.0	N	Mean Scores (SD)	ICC	Cronbach's α
Symptoms of liver disease	170	81.16 (16.88)	0.79*	0.83*
Effects of liver disease	170	74.73 (18.17)	0.92*	0.86*
Concentration	170	76.93 (24.45)	0.91*	0.93*
Memory	170	70.29 (26.62)	0.87*	0.92*
Quality of social interaction	170	70.64 (19.47)	0.85*	0.57*
Health distress	170	68.46 (28.46)	0.89*	0.89*
Sleep	170	66.52 (20.52)	0.76*	0.67*
Loneliness	170	83.00 (18.99)	0.93*	0.71*
Hopelessness	170	70.59 (26.53)	0.80*	0.71*
Stigma of Liver disease	170	79.49 (27.13)	0.84*	0.88*
Sexual function	170	74.94 (29.65)	0.91*	0.81*
Sexual problems	100**	85.70 (25.83)	0.71**	0.94**
<b>Total</b>	170	816.76 (169.73)	0.94*	0.80*
* p<0.01 ; ** Sexual problems subscale was evaluated in itself, p<0.05				

**Table 5:** Reliability of the LDQOL 1.0.

However, specific instruments are more comprehensive and can capture all the possible changes that can occur during the course of a disease. Therefore, we aimed to gain a valid and reliable instrument for Turkish society.

The Turkish LDQOL 1.0 explained three factors. Total amount of explained variance for these 3 factors was 63.48%. However the eigenvalue of the Factor 3 was observed 0.91. When it was removed from the instrument the total explained variance of the instrument was reduced to 55.20%. Because of being of eigenvalue nearly 1.0 and yielding contribution to explain variance, it was accepted. The explained variance of the instrument is consistent with the other studies in the literature. It was showed that the total explained variance was 57% reported by Gralnek [20]. It was observed that the total explained variance was found 68% in the study made up by the use of Chronic Liver Disease Questionnaire [13].

Only the loneliness subscale took place inside Factor 2 and Factor 3. When loneliness subscale was evaluated in the Factor 3 it was calculated 0.28 which was below than acceptable level. As a result, loneliness subscale was accepted inside Factor 2. All of the factor loadings were over 0.40 and none of them was eliminated. The value of KMO Measure of Sampling Adequacy was 0.89 indicating a "very good" level of inter correlation among the subscales of instrument. The result of Barlett's test of sphericity ( $X^2=713.54$ ;  $p<0.001$ ) was sufficient to perform factor analysis.

In this study, 91.2% of patients were into Child A, 8.8% of patients were into Child B. The absence of patients in the Child was the limitation of the study. It was expected that there is a correlation between mean score of LDQOL 1.0 and mean score of CTP. The results were low ( $r=-0.26$ ,  $p<0.001$ ) to show concurrent validity of the instrument even though these were statistically significant [30]. This finding was similar with the previous studies [20,21,31] for either in this study or the studies in the literature, most of the time it is said that there is direct relationship between CTP score and the quality of life score which were taken from the instrument studied in patients with chronic liver disease. This means that those who have been in Child C class have worse quality of life than Child A and B. We need further studies with patients in the Child C to obtain strong correlation between instrument score and CTP score.

After the language adaptation test-retest reliability was examined. Test-retest reliability of the LDQOL 1.0 instrument was 0.94 and for all subscales was over 0.76. Sexual problems subscale rest-retest reliability was studied with 100 patients and measured 0.71. Test-retest reliability in the original study had not been reported by Gralnek et al. [20]. Therefore, the test-retest results were compared with the same instrument which had been validated. The values are in line with that of other studies that LDQOL 1.0 were showed high stability [32,33].

Cronbach's alpha of the instrument was 0.80. Cronbach's alpha of subscales, except the sleep (0.67) and quality of social interaction (0.57), easily met the minimum criterion of 0.70 which indicates a satisfactory degree of internal consistency reliability. The participants into the research were in CTP Class A and B. Besides, these patients were ambulatory and active in their life. Some of them were student and much of them had a job. These subscales were insufficient to reflect correlation among their items. The results were similar to those reported for original study and other versions of LDQOL 1.0 [20,32-34] Gralnek had suggested bolstering the reliability of this particular scale in the further studies [20].

## Conclusion

All results concerned with analysis indicate that the Turkish version of LDQOL 1.0 is a valid and reliable instrument. It can be used for determining the quality of life in patients with chronic liver disease in these kinds of clinic researches. Because of including physical, mental, social, cognitive domains, instrument yields to nurses and health staffs holistically approaches and applications in that way. The instrument will be useful for nurses and health professions to gain special data when assess clients' HRQOL, plan for improving their health and implement nursing interventions. For the future studies, it is possible to determine quality of life in patients with chronic liver disease in a large population. In addition, quality of life in patients with chronic liver disease can be assessed according to disease type or severity. A recommendation that this scale should be further evaluated; with a large sample in different regions in Turkey.

## Limitations of Study

The research was conducted in one region of Turkey with patients registered in a Hepatology Department of Gastroenterology results cannot be generalized. For this reason it is recommended that research be done different sample group.

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