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
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).

Table 1: Characteristics of LDQOL 1.0.

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

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.

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

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<tr>
<td>Sleep</td>
<td>5</td>
<td>5 point</td>
<td>14a-14e</td>
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<tr>
<td>Loneliness</td>
<td>5</td>
<td>5 point</td>
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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.

<table>
<thead>
<tr>
<th>Units</th>
<th>1 Point</th>
<th>2 Point</th>
<th>3 Point</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hepatic encephalopathy</td>
<td>Absent</td>
<td>Mild</td>
<td>Advanced (coma)</td>
</tr>
<tr>
<td>Ascites</td>
<td>Absent</td>
<td>Controlled</td>
<td>Refractory</td>
</tr>
<tr>
<td>Total serum bilirubin (mg/dL)</td>
<td>0-2.0</td>
<td>2.0-3.0</td>
<td>&gt;3.0</td>
</tr>
<tr>
<td>Serum albumin (g/L)</td>
<td>&gt;3.5</td>
<td>2.8-3.5</td>
<td>&lt;2.8</td>
</tr>
<tr>
<td>Protrombin time (INR)</td>
<td>&lt;1.70</td>
<td>1.71-2.20</td>
<td>&lt;2.20</td>
</tr>
<tr>
<td>seconds prolongation</td>
<td>(0-4)</td>
<td>(4-6)</td>
<td>(&gt;6)</td>
</tr>
</tbody>
</table>

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.

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(%)  
Ages(years)  
18-36  29  17.1  
37-55  109  64.1  
56-74  32  18.8  
Gender  
Men  71  41.8  
Women  
Marital status  
Married  152  89.4  
Single  9  5.3  
Widowed  5  2.9  
Divorced  4  2.4  
Educational Status  
Elementary school  70  41.2  
High school  49  28.8  
University  51  30.0  
Etiologies  
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  
CTP classification  
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.

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.

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].

Table 5

<table>
<thead>
<tr>
<th>Subscales of LDQOL 1.0</th>
<th>N</th>
<th>Mean (SD) Scores</th>
<th>ICC</th>
<th>Cronbach’s α</th>
</tr>
</thead>
<tbody>
<tr>
<td>Symptoms of liver disease</td>
<td>170</td>
<td>81.16 (16.88)</td>
<td>0.79*</td>
<td>0.83*</td>
</tr>
<tr>
<td>Effects of liver disease</td>
<td>170</td>
<td>74.73 (18.17)</td>
<td>0.92*</td>
<td>0.86*</td>
</tr>
<tr>
<td>Concentration</td>
<td>170</td>
<td>76.93 (24.45)</td>
<td>0.91*</td>
<td>0.93*</td>
</tr>
<tr>
<td>Memory</td>
<td>170</td>
<td>70.29 (26.62)</td>
<td>0.87*</td>
<td>0.92*</td>
</tr>
<tr>
<td>Quality of social interaction</td>
<td>170</td>
<td>70.64 (19.47)</td>
<td>0.85*</td>
<td>0.97*</td>
</tr>
<tr>
<td>Health distress</td>
<td>170</td>
<td>68.46 (28.46)</td>
<td>0.89*</td>
<td>0.89*</td>
</tr>
<tr>
<td>Sleep</td>
<td>170</td>
<td>66.52 (20.52)</td>
<td>0.76*</td>
<td>0.67*</td>
</tr>
<tr>
<td>Loneliness</td>
<td>170</td>
<td>83.00 (18.99)</td>
<td>0.93*</td>
<td>0.71*</td>
</tr>
<tr>
<td>Hopelessness</td>
<td>170</td>
<td>70.59 (26.53)</td>
<td>0.80*</td>
<td>0.71*</td>
</tr>
<tr>
<td>Stigma of Liver disease</td>
<td>170</td>
<td>79.49 (27.13)</td>
<td>0.84*</td>
<td>0.68*</td>
</tr>
<tr>
<td>Sexual function</td>
<td>170</td>
<td>74.94 (29.65)</td>
<td>0.91*</td>
<td>0.81*</td>
</tr>
<tr>
<td>Sexual problems</td>
<td>100**</td>
<td>85.70 (25.83)</td>
<td>0.71**</td>
<td>0.94**</td>
</tr>
<tr>
<td>Total</td>
<td>170</td>
<td>816.76 (169.73)</td>
<td>0.94*</td>
<td>0.80*</td>
</tr>
</tbody>
</table>

* p<0.01 ; ** Sexual problems subscale was evaluated in itself, p<0.05
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.

Acknowledgements

This study was carried out at Ege University Medicine Faculty, Izmir, Turkey. We thank to all those who supported us in conducting the study.

References