



CORRELATION BETWEEN THE SHORT-FORM 36 (SF-36) HEALTH SURVEY AND THE CHRONIC LIVER DISEASE QUESTIONNAIRE (CLDQ) IN CHRONIC LIVER DISEASE PATIENTS

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ABSTRACT

Background/Aims: Patients with chronic liver disease (CLD) had a variety of symptoms which influenced their life activities and health-related quality of life (HR-QOL). However, evaluated methodology HR-QOL of CLD patients has not been fully established. In this study, we evaluated the relationships between the Short Form-36 (SF-36) and the Chronic Liver Disease Questionnaire (CLDQ).

Materials and Methods: HR-QOL was assessed using SF-36 and CLDQ in 130 CLD without hepatocellular carcinoma (HCC) patients and 51 healthy volunteers (Controls). Correlation was determined by comparing both the physical and emotional component summary scores (physical and emotional QOL) of SF-36 and mean CLDQ scores for physical QOL (abdominal symptoms, fatigue, systemic symptoms and activity) and emotional QOL (emotional function and worry).

Results: In the healthy group (Controls), no correlation with either item was identified. In the overall chronic liver disease group, a correlation was seen in between both the physical and emotional QOL of SF-36 and mean CLDQ. In particular, nonalcoholic fatty liver disease (NAFLD) and hepatitis C virus (HCV) related CLD are correlated between both the physical and emotional QOL of SF-36 and mean CLDQ.

Conclusion: CLDQ appears to offer a useful instrument for assessing QOL among liver disease patients. However, as partial discrepancies with SF-36 have been reported, measurement with both tools may be necessary. Continuous assessment of additional accumulated cases is needed to examine correlation. In the future, the generic HR-QOL tool of the SF-36 and the liver disease-specific CLDQ should be used concurrently to determine the significance of HR-QOL in addressing chronic liver diseases.

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INTRODUCTION

The progression to cirrhosis and the development of hepatocellular carcinoma are major concerns faced by the aging population of patients with chronic liver disease in Japan (1).

Incorporating the subjective perspective of the patient on quality of life (QOL) into medical treatment is becoming more imperative, particularly in terms of addressing health-related quality of life (HR-QOL), as liver disease treatment requires long-term antiviral therapies along with repeated treatments

once hepatocellular carcinoma develops(2). Generic and disease-specific HR-QOL tools are used to measure HR-QOL. The short-form 36 (SF-36) is a questionnaire used to measure general health status. The SF-36 health survey, developed in the United States (3), is a well-validated, widely used, generic HR-QOL assessment tool. The Japanese version of SF-36 was already established and has been validated (4, 5). We previously reported that the importance of HR-QOL evaluation used SF-36 of chronic hepatitis C patients undergoing treatment with IFN based direct-acting antiviral (DAA)therapy and IFN-free DAA therapy (6, 7). However, some items in generic HR-QOL tools are influenced by variables such as age that are unrelated to the disease. The original CLDQ is a well-developed and validated disease specific questionnaire for measuring QOL in CLD (8). However, the correlations between SF-36 and CLDQ have not been examined sufficiently. The aim of this study to investigate the correlation between SF-36 and CLDQ in assessing QOL that was determined along with the validity of both assessment tools.

MATERIALS AND METHODS

We used questionnaires to interview at 130 chronic liver disease (CLD) patients without hepatocellular carcinoma (HCC) in our hospital. Chronic liver disease (CLD) comprised 130 patients who completed both SF-36 and CLDQ and had the following conditions: 25 patients with hepatitis B virus (HBV) chronic liver disease; 59 patients with hepatitis C virus (HCV) chronic liver disease; 8 patients with alcoholic liver disease; 22 patients with non-alcoholic fatty liver disease (NAFLD), 11 patients with primary biliary cholangitis (PBC), 5 patients with autoimmune hepatitis (AIH). The questionnaire was also administered to 51 healthy volunteers as controls. Written informed consent was obtained from all patients, and the Ethical Committee of Saiseikai Niigata Daini Hospital (Niigata, Japan) approved this study, which was conducted in accordance with the Declaration of Helsinki. Correlation was determined by comparing both the physical and emotional component summary scores (physical and emotional QOL) of SF-36 with mean CLDQ scores for physical QOL (abdominal symptoms, fatigue, systemic symptoms and activity) and emotional QOL (emotional function and worry). In the SF-36, one item is designed to assess the perceived change in health status, and each of the remaining 35 items contributes to a score on one of eight scales: physical functioning; role-physical; bodily pain; general health perception; vitality; social functioning; roleemotional; and mental health (3). The 29 items of CLDQ were separated into six domains: abdominal symptoms (AS), fatigue (FA), systemic symptoms (SS), activity (AC), emotional function (EF) and worry (WO). The mean score for the 29 items was taken as the total CLDQ score. Total scores for each of the items in the same domain were then divided by the number of items to obtain the individual domain score.

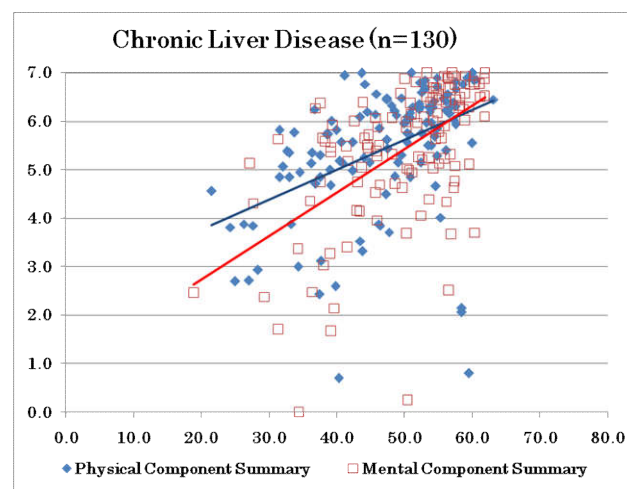
RESULTS

Characteristics of patients with chronic liver disease and controls are shown in Table 1. In the overall chronic liver disease group (n=130), a correlation was seen in between both the physical and emotional QOL of SF-36 and CLDQ (Physical Component Summary $r=0.5$, $p<0.001$; Mental Component Summary $r=0.4$, $p<0.001$) (Fig 1A). In the healthy group (Controls), no correlation with either item was identified (Physical Component Summary $r=0.1$, $p=0.39$; Mental

Component Summary $r=0.1$, $p=0.45$) (Fig 1B). In the correlation comparison by disease, correlation was established with physical QOL in HBV-related CLD, but no correlation with emotional QOL was evident in HBV-related CLD (Physical Component Summary $r=0.5$, $p=0.013$; Mental Component Summary $r=0.2$, $p=0.27$) (Fig 2A).

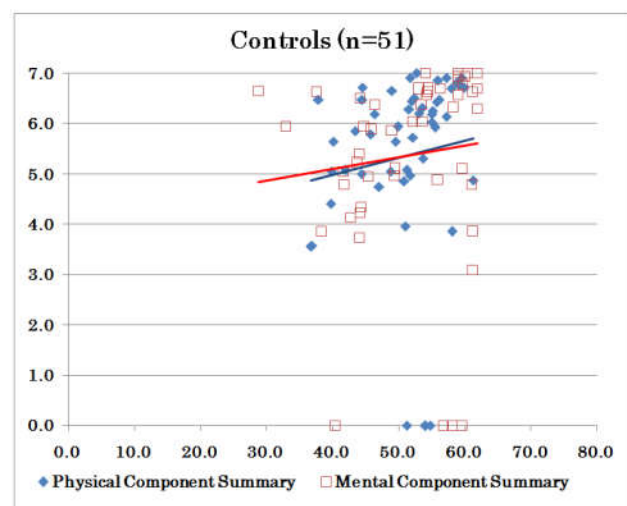
Table 1. Characteristics of patients with chronic liver disease (A) and controls (B)

	Cases (%)	Male	Female	Age (years)
HBV	25 (19.2%)	17	8	65.8 ±7.0
HCV	59 (45.4%)	18	41	73.8 ±9.1
Alcohol	8 (6.2%)	8	0	70.7 ±11.3
NAFLD	22 (16.9%)	12	10	68.2 ±10.4
PBC	11 (8.4%)	5	6	75.0 ±8.9
AIH	5 (3.9%)	1	4	71.0 ±5.5
Total	130 (100%)	61	69	71.3 ±9.6



Physical component summary vs CLDQ; $p<0.001$
Mental Component summary vs CLDQ; $p<0.001$

(A)



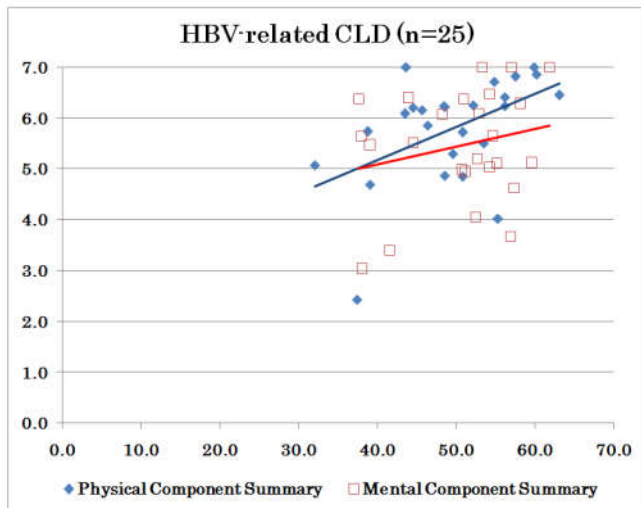
Mental Component summary vs CLDQ; $p<0.001$
Mental Component summary vs CLDQ; $p<0.001$

(B)

Figure 1. Correlation between CLDQ and SF-36 in patients with chronic liver disease (A) and controls (B)

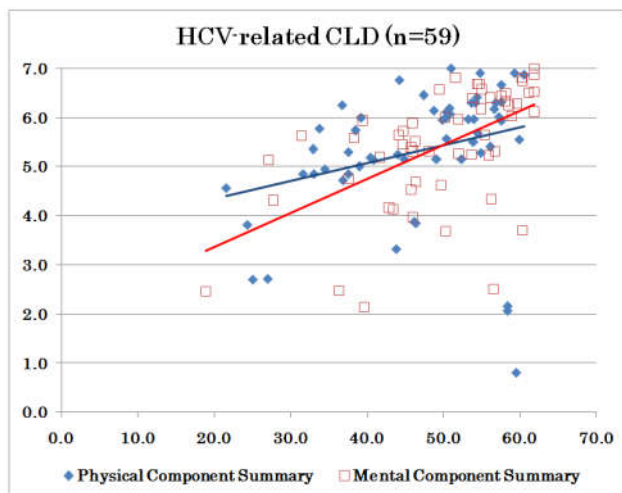
In HCV-related CLD, a slight correlation with physical QOL and a high correlation with emotional QOL (Physical Component Summary $r=0.5$, $p=0.028$; Mental Component Summary $r=0.5$, $p<0.001$) (physical QOL $r=0.3$, $p=0.003$;

emotional QOL $r=0.5$, $p=0.001$) was seen (Fig 2B). In the NAFLD group, a high correlation was found with both physical QOL and emotional QOL (Physical Component Summary $r=0.7$, $p<0.001$; Mental Component Summary $r=0.7$, $p<0.001$) (Fig 3A). No correlation was found in the PBC group (Physical Component Summary $r=0.2$, $p=0.23$; Mental Component Summary $r=0.2$, $p=0.14$) (Fig. 3B).



Physical component summary vs CLDQ; $p<0.013$
Mental Component summary vs CLDQ; $p<0.27$

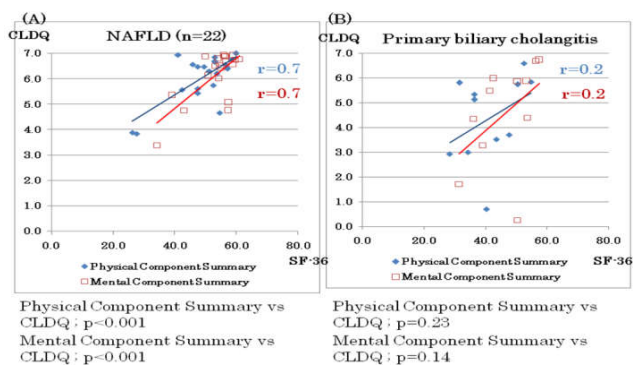
(A)



Physical component summary vs CLDQ; $p<0.028$
Mental Component summary vs CLDQ; $p<0.001$

(B)

Figure 2. Correlation between CLDQ and SF-36 in patients with HBV-related CLD (A) and HCV-related CLD (B)



Physical Component Summary vs CLDQ : $p<0.001$
Mental Component Summary vs CLDQ : $p<0.001$

Physical Component Summary vs CLDQ : $p=0.23$
Mental Component Summary vs CLDQ : $p=0.14$

Figure 2. Correlation between CLDQ and SF-36 in patients with HBV-related CLD (A) and HCV-related CLD (B)

DISCUSSION

Chronic liver disease (CLD) is a serious illness which not only causes high mortality and morbidity but also affects negatively the quality of life (2, 9). Disease-specific instruments for CLD have been recently developed. Chronic Liver Disease Questionnaire (CLDQ) (8) is the most widely used disease-specific questionnaire concerning patients with different etiology of chronic liver disease. It has been translated and validated in many countries (10, 11, 12) and findings have shown that the questionnaire has high reliability and validity results as well as good acceptability from the patients. It consists of 29 items which are a suitable number for exploring QOL in patients who have a brief visit to a clinic (8). Chronic liver diseases greatly impacted QOL, which was confirmed by both generic and disease-specific questionnaires. However, generic and specific instruments have also been used to measure HR-QOL. Generic instruments, such as the widely used Medical Outcomes Study 36-Item Short Form Health Survey (SF-36) (3), provide a global assessment of a given disease and allow comparisons with the general population and other diseases. In our study, no correlation with either item was identified in the healthy group (Controls). The correlation was seen in the relationship between the average CLDQ score and the general health domain of SF-36 in HCV-related CLD and NAFLD. However, PBC group are not correlated SF-36 and CLDQ scores. Moreover, emotional QOL are not correlated between SF-36 and CLDQ in HBV-related CLD. As described above, the correlation between SF-36 and CLDQ is different for each background liver disease, so it is an important task to decide which QOL to use. In conclusion, CLDQ appears to offer a useful instrument for assessing QOL among liver disease patients. However, as partial discrepancies with SF-36 have been reported, measurement with both tools may be necessary. Continuous assessment of additional accumulated cases is needed to examine correlation. In the future, the generic HR-QOL tool of the SF-36 and the liver disease-specific CLDQ should be used concurrently to determine the significance of HR-QOL in addressing chronic liver diseases.

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