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A STUDY TO DEVELOP A VALID, UNDERSTANDABLE, ACCEPTABLE, AND RELEVANT CHINESE VERSION OF THE CHRONIC LIVER DISEASE QUESTIONNAIRE FOR PATIENTS WITH CHB INFECTION IN HONG KONG

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Abstract

Infection with chronic hepatitis B (CHB) is a major public health problem in China and other Asian countries. This was the first paper to examine the influence of disease and healthcare requirements on the health-related quality of life (HRQOL) of Chinese CHB patients at various stages of illness. Using the Chronic Liver Disease Questionnaire (CLDQ), a liver disease specific HRQOL instrument, and the Chinese (HK) Short Form-36 Health Survey version 2 (SF-36v2), a complete assessment of the HRQOL and health preferences of Chinese patients with various stages of CHB was made. Specifically, researchers looked at how CHB patients' treatment demands and use correlated with HRQOL. Iterative translations, expert panel review, and cognitive debriefing were used to make the Chronic Liver Disease Questionnaire (CLDQ) accessible to the Chinese community in Hong Kong. The validity, reliability, and sensitivity of the test were demonstrated in a small pilot research including 150 CHB patients. Patients with various stages of CHB illness, including asymptomatic liver function and impaired liver function, cirrhosis and hepato cellular carcinoma, were assessed for their HRQOL using the Chinese (HK) CLDQ and the Chinese (HK) SF-36v2, a general HRQOL measure (HCC). HRQOL ratings were considerably lower in AHB carriers than in the general population. These preference values were translated from SF-36v2 to Short Form-6D (SF-6D) and showed a gradual decline from 0.755 in AHB to 0.745 in ILF, 0.720 in HCC and 0.701 in cirrhosis compared to the 0.787 population norm for each group. Taking antiviral medication, higher bilirubin levels, psychiatric co-morbidity, younger age, and female gender were all linked to worse HRQOL despite the fact that CHB disease severity (stage) was not included.

Keywords: HRQOL, CHB, severity, HCC, CLDQ, hepatitis B, co-morbidity.

1. INTRODUCTION

Infection with the hepatitis B virus (HBV) continues to be a global health issue (Maynard 1990; Maddrey 2000; Lai, Ratziu et al. 2003; Lavanchy 2004; Lavanchy 2005; Wright 2006). Every year, an estimated 50 million new cases of human hepatitis B (HBV) are recorded, with 5% to 10% of adults and 90% of infected babies developing chronic HBV infection (Maynard 1990; Maddrey 2000; Lai, Ratziu et al. 2003; Lavanchy 2004; Lavanchy 2005; Wright 2006). Most chronic carriers are Asians, accounting for 75 percent of the

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global population (Maddrey 2000; Merican, Guan et al. 2000; Lai, Ratziu et al. 2003; Custer, Sullivan et al. 2004; Lin, Robinson et al. 2005; Liu and Fan 2007). Liver-related problems, including cirrhosis, hepatic decomposition, and hepatocellular carcinoma, can occur in HBV carriers who have been positive for HBsAg for more than six months (Liaw, Leung et al. 2008).

There are several studies (Merican et al. 2000; Lai et al. 2003; Lavanchy 2004; Lavanchy 2005; Liu and Fan 2007). Chronic hepatitis B (CHB) carriers have a high risk of developing major problems over their lifespan (15-40 percent) (Wright 2006; Lok and McMahon 2007). Hepatitis B (HBV) infection kills 500,000 to 1.2 million people worldwide each year and is the 10th greatest cause of mortality worldwide, responsible for 300,000 to 500,000 fatalities each year (Lavanchy 2004; Lavanchy 2005).

There are three phases to the natural history of the CHB infection: the immune-tolerance phase (positive hepatitis B e antigen (HBeAg) and normal liver function; the immune-clearance phase (positive HBeAg and impaired liver function, typically indicated by an abnormal ALT); and the residual phase (anti-HBe and normal ALT) (Lau, Lai et al. 1997; Fattovich, Bortolotti et al. 2008; McMahon 2008). It is possible for a carrier to remain in the "residual phase" for the rest of its life (McMahon 2008). In the residual phase, however, some individuals with sero-conversion still have a risk of developing cirrhosis and/or hepatocellular carcinoma (McMahon 2008).

According to a carrier rate of HBsAg of 8 percent, nations can be classed as having a high, moderate, or low prevalence of HBV infection, based on the prevalence of HBsAg in their populations (Maddrey 2000; Lavanchy 2004). South East Asia, China, sub-Saharan Africa, and parts of the Amazon Basin have significant HBV prevalence (Maddrey 2000; Lavanchy 2004). However, nations in North America, Europe, and Australia have the lowest rates of chronic illness, with less than 1% of their populations infected (Maddrey 2000; Lavanchy 2004). High and low endemic locations have distinct transmission patterns of HBV infection. In places with a high prevalence of CHB infection, the disease is transmitted during pregnancy or early infancy (Maddrey 2000; Lai, Ratziu et al. 2003; Lavanchy 2004; Lavanchy 2005). Percutaneous or sexual transmission of the virus is the primary mode of infection among adults in locations with low endemic levels of the disease (Maddrey 2000; Lai, Ratziu et al. 2003; Lavanchy 2004; Lavanchy 2005).

2. LITERATURE REVIEW

Research on the epidemiology, quality of life, and treatment of chronic hepatitis B (CHB) was conducted. Medical Subject Headings (MeSH) phrases "chronic hepatitis B" and "quality of life" were used to search for related papers. As part of the citations, we included citations connected with the terms QOL (quality), HRQOL (health-related quality of life), and HRQL (healthy living). Searches were restricted to just include people and English-language sources. Pediatric patients and liver transplant recipients were omitted from the review. Finally, the bibliographies of relevant works were checked to see whether there were any new references.

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This chapter begins by examining the prevalence of hepatitis B virus (HBV) and the suggested treatment for CHB patients. Data from research on HRQOL and CHB is emphasized in order to identify any knowledge gaps. It is then determined which HRQOL measure is the best appropriate for the study.

A primary cause of death worldwide, hepatitis B is one of the most frequent infectious illnesses (Maynard 1990; Lai, Ratziu et al. 2003; Lavanchy 2004; Lavanchy 2005; Wright 2006). Hepatitis B virus (HBV) is present in about 2 billion people, with over 400 million of these persons having a chronic infection (Lai, Ratziu et al. 2003; Fattovich, Bortolotti et al. 2008). Hepatitis B surface antigen (HBsAg) is characterised as those who have been infected for more than six months (Maddrey 2000; Lok and McMahon 2009). Approximately 75% of chronic hepatitis B (CHB) carriers were detected in Asia and the Western Pacific area (Maynard 1990; Gust 1996; Maddrey 2000; Merican, Guan et al. 2000). There are an estimated 500,000 to 1,200,000 fatalities per year due to cirrhosis or liver failure caused by HBV (Lavanchy 2004; Lavanchy 2005). HCC is becoming more common.

The fifth most frequent cancer in the world kills between 300,000 and 500,000 individuals each year. Increasing (Lavanchy 2004). Cirrhosis and hepatocellular carcinoma (HCC) are two of the most common liver diseases in the world, and HBV is responsible for more than half of them (Perz, Armstrong et al. 2006). In Western Pacific areas, HBV infection accounted for more than 50% of HCC (65%) and cirrhosis (57%) (Perz, Armstrong et al. 2006).

3. RESEARCH GAP

In addition to cirrhosis and hepatocellular carcinoma (HCC), other liver-related problems such as cirrhosis and HKSAR (Department of Health HKSAR 1998; European Association for the study of liver 2008; Keeffe, Dieterich et al. 2008; Liaw, Leung et al. 2008; Lok and McMahon 2009) can impair human well-being (HQOL). Patients with chronic hepatitis B (CHB) in China are increasingly demanding that HRQOL be used as an outcome measure of the illness's impact and the efficacy of therapy (Poon, Fan et al. 2001; Wu, Deng et al. 2003; Yi 2006; Ong, Mak et al. 2008). Human Resources for Quality of Life (HRQOL) measures have been developed specifically for people with liver disease. These include the Chronic Liver Disease Questionnaire (CLDQ), the Hepatitis Quality of Life (HQOL) (Bayliss, Gandek et al. 1998), the Liver Disease Quality of Life (Gralnek, Hays et al. 2000), and the Liver Disease Symptom Index (LDSI) (Unal, de Boer et al (CLD-QOL) and Hepatitis B Quality of Life instrument (HBQOL) questionnaires (Spiegel, Bolus et al. 2007) These HRQOL measures were designed in English in the West, where expectations on health and sickness may be considerably different from those of the Chinese (Bayliss, Gandek and Gandek, 1998; Gralnek, Haas and Hays, 2000). If the ideas and substance of an HRQOL measure are not universally applicable, it may be ineffective. The HQLQ, CLDQ, and LDQOL questionnaires have been adapted to additional groups (Bayliss, Gandek et al. 1998; Younossi, Guyatt et al. 1999; Gralnek, Hays et al. 2000). A liver

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disease-specific questionnaire known as the CLDQ has been translated into a variety of different languages (Wu, Deng et al. 2003; Hauser, Schnur et al. 2004; Sobhonslidsuk, Silpakit et al. 2004; Rucci, Taliani et al. 2005; Ferrer, Cordoba et al. 2006; Sumskiene, Sumskas et al. 2006; Schulz, Kroencke et al. 2008). The Chinese are one of the most common ethnic groups to suffer from liver disease, yet the existing HRQOL measures for Chinese CHB patients are restricted in their relevance to this population (Wu, Deng et al. 2003). There were no measurements in use for Cantonese-speaking Southern Chinese before this study. Putonghua-speaking Chinese in Mainland China have tested the CLDQ's Chinese translation.

People's Republic of China (Wu, Deng et al. 2003). Internal consistency was shown in pilot testing.

Infraclass correlation >0.7, test-retest reliability (Cronbach's alpha 0.72-0.89) and acceptable concept validity were found (Wu, Deng et al. 2003). Because of these discrepancies, we cannot simply utilize the Mainland Chinese translation for our Cantonese-speaking Chinese patients in Hong Kong. Our local community in Hong Kong needs a Cantonese-speaking Chinese translation. It is also important to ensure that the translation is accurate and comparable.

In the creation and validation of instruments, content validity is essential (Bowden and Fox-Rushby 2003). Measurement quality relates to how well the thing being tested is reflective of what it is being tested for based on the conceptual description of its scope (McDowell 2006). The results might be deceptive if the material covered by the HRQOL test is not what it is designed to measure. As a result, before using an HRQOL measure in any data collection, it is important to verify its content validity.

For content verification, a two-step process is the most frequent method (Lynn 1986). Scale identification, item production, and instrument construction are all necessary elements in the development process (Lynn 1986). Second, a panel of experts and/or members of the target audience must assess and rate each item on its clarity and relevance to the audience's needs (Lynn 1986). The initial step may only be used for the creation of brand new instruments. A cross-cultural adaptation of a well-established measure can be applied to the second stage (Lynn 1986). As part of the judgment step of content validation, the International Society for Pharma-co-economic and Outcomes Research (ISPOR) Task Force recommends the use of cognitive debriefing (Wild, Grove et al. 2005). For cognitive debriefing, at least five experts or members of the target population are required (Wild, Grove et al. 2005). The findings of cognitive debriefing should be compared to the original version of the test in order to identify any differences (Wild, Grove et al. 2005; Acquadro, Conway et al. 2008).

4. RESEARCH OBJECTIVE & METHODOLOGY

Clinical and health policy settings have increasingly relied on HRQOL to evaluate patients with chronic illnesses, such as chronic hepatitis B (CHB), as it has become an essential outcome metric in the previous two decades (Foster, Goldin et al. 1998; Martin, Sheridan

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et al. 2002; Gutteling, de Man et al. 2007; Ong, Mak et al. 2008). In order to provide a more complete picture of the HRQOL of patients with specific disorders, disease-specific measures are frequently required to supplement general measurements. Chronic Liver Disease Questionnaire (CLDQ), Hepatitis Quality of Life (HQLQ), Liver Disease Quality of Life (Gralnek, Hays et al. 2000), and the Liver Disease Symptom Index (LDSI) (van der Plas, Hansen et al. 2004) are some of the HRQOL measures specific to chronic liver disease (CLD). However, very few of these measures have been validated for use in Asia. In Chapter 3, the CLDQ was translated into Cantonese-speaking Hong Kongers' preferred language.

Kong. Cognitive debriefing findings validated the Chinese (HK) CLDQ's content validity in the majority of cases (Chapter 3). The results of a pilot research on the concept validity and other psychometric features of the instrument on Chinese CHB patients in Hong Kong are presented in this section.

Original research by Younossi et al. demonstrated acceptable reliability, validity and sensitivity, but test-retest reliability was more variable, with ICCs ranging from 0.23 to 0.72 across different scales (Younossi, Guyatt et al. 1999). The ICC estimate for the Systemic Symptoms (SS) scale was the lowest (0.23). (Younossi, Guyatt et al. 1999). CLDQ is more sensitive than a generic measure in detecting changes in patients with CLD, according to previous investigations (Younossi, Guyatt et al. 1999; Ferrer, Cordoba et al. 2006). In subsequent studies, it was found to be valid in a wide range of populations, including the Chinese in Mainland China (Wu, Deng et al. 2003; Hauser, Schnur et al. 2004; Sobhonslidsuk, Silpakit et al. 2004; Rucci, Taliani et al. 2005; Ferrer, Cordoba et al. 2006), indicating its potential as a cross-cultural measure. According to Bayliss, Gandek, et al. (1998) and Gralnek, Hays et al. (2000), the majority of the psychometric data of the CLDQ has come from patients with hepatitis C virus (HCV) and Western populations. Few studies have examined the validity and psychometrics of this test.

Study participants were Cantonese-speaking Southern Chinese CHB patients to see if the Chinese (HK) version of the CLDQ had any psychometric qualities. Additionally, it would help prove the applicability of the liver disease-specific HRQOL measure on the world's biggest group of CHB patients by supplementing data from China's Mainland.

5. DATA ANALYSIS & FINDINGS

The HBV infection is the most widespread in the globe. HBV has infected more than 2 billion individuals globally, 350 of whom are chronically sick, and more than a third of them (120 million) are in China (Liu and Fan 2007). More than 1 billion individuals die each year from hepatitis B-related liver disorders, including cirrhosis and hepatocellular carcinoma (HCC) (Lok and McMahon 2007). Hong Kong's population has a prevalence of chronic hepatitis B (CHB) of more than 10 percent (Chen, Wang et al. 2000). As a result, a large number of people in this region have to deal with the long-term health risks and social stigma associated with having a chronic infection (Lai, Ratziu et al. 2003).

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In the last two decades, health-related quality of life (HRQOL) has emerged as a key measure of chronic illness outcomes. Chronic liver disease (CLD), including viral hepatitis, cirrhosis, cholestatic liver disease, and hepatocellular carcinoma (HCC), has been linked to worse quality of life (HRQOL) in patients (Foster, Goldin et al. 1998; Younossi, Kiwi et al. 2000; Hussain, Fontana et al. 2001; Marchesini, Bianchi et al. 2001; Younossi, Boparai et al. 2001; Van der Plas, Hansen et al. 2003; Sobhonslidsuk, Silpakit et al. 2006; Bondini, Kallman et al. 2007; Kondo, Yoshida et al. 2007; Dan, Kallman et al. 2008; Ong, Mak et al. 2008). Despite the fact that hepatitis C virus (HCV) patients have been studied extensively (Foster, Goldin et al. 1998; Hussain, Fontana et al. 2001; Dan, Kallman et al. 2008), data on the HRQOL of CHB patients is scarce. Previous studies have shown that patients with CHB infection have similar HRQOL as healthy controls, but the research' samples were small and chosen, which reduced the power and generalizability of the results (Foster, Goldin et al. 1998; Bondini, Kallman et al. 2007). Human Resources Quality of Life (HRQOL) in Chinese CHB carriers was equivalent to that of normal controls, whereas patients with cirrhosis and HCC had significantly poorer HRQOL than those with asymptomatic CHB carriers.

HRQOL scores (Ong, Mak et al. 2008). There wasn't enough data in their study to draw conclusions.

Number of HCC patients for distinguishing between cirrhosis and HCC, and the effects of antiviral medication, the length of illness and clinical variables were not accounted for.

Patients with CLD's HRQOL has been found to be strongly correlated with the stage of their disease in previous research (Marchesini, Bianchi et al. 2001; Younossi, Boparai et al. 2001; Gutteling, de Man et al. 2006; Sobhonslidsuk, Silpakit et al. 2006). A correlation between HRQOL and indicators of liver function has been discovered (Kondo, Yoshida et al. 2007). Another study (Gutteling 2006; Younossi 2001; Sobhonsliduk 2006; Hauser 2004) revealed that age, gender, and presence of psychiatric disease had a significant influence on HRQOL, whereas marital status and socioeconomic class were not (Sobhonslidsuk A 2006).

CHB infection's health impact may be assessed using a preference index derived from HRQOL that can also be used to evaluate the cost-effectiveness of treatment options. Health care professionals and patients have been asked to rank their preference for CHB infection using disease-specific metrics (Bennett, Inoue et al. 1997; Kim, Poterucha et al. 1999).

Results may not be valid since health preference should be taken into account in the study (1997).

In accordance with recommendations from the National Institute for Clinical Excellence (NICE), which is situated in the United Kingdom (Guide to the methods of technology appraisal)? The patient's point of view must also be taken into account while measuring HRQOL.

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In Hong Kong (Hong Kong), hepatitis B is one of the most frequent chronic infections (China). According to the Department of Health (1998). Hepatocellular carcinoma (HCC) affects between 15% to 40% of CHB-infected individuals (Lok and McMahon 2007). HCV (chronic hepatitis B) is a substantial health and financial burden on the health care system in the Hong Kong territory (Li, Ong et al. 2004).

Understanding the patterns of health service consumption and identifying factors that influence service utilization are critical to meeting the needs of individuals (Blais 1994). Such data helps policymakers and healthcare professionals plan for the allocation of resources and the provision of healthcare services in the future. Health-related quality of life (HRQOL) has been found to play a significant role in determining care consumption by the general public in Hong Kong and elsewhere (Nelson and McHorney 1998; Matsumura 2000; Ethgen and Kahler 2002; Lam and Fong 2002; Dominick and Ahern 2004; Singh and Nelson 2005; Chen and Li 2009; Lam and Leung 2009). By using SF-36 physical HRQOL, Matsumura et al found that patients with poorer physical HRQOL were more likely to be hospitalized and to use outpatient services (Matsumura 2000). Sick leave was more common among those who reported having poorer levels of physical and psychological HRQOL (Matsumura 2000). According to lam et alsurvey.'s of Hong Kong's general Chinese adult population,

Quality of life and usage of services (Lam and Fong 2002). Health care usage and HRQOL were shown to have an unfavorable association in mainland China, as well, according to a recent study (Chen and Li 2009). Because CHB patients' health-related quality of life is worse, they may place an additional burden on the healthcare system, as detailed in Chapter 5. CHB care is extremely expensive, and many patients are forced to pay for their own diagnostics and treatments out of their own pockets.

Individuals are willing to pay (WTP) what they are willing to pay for an item, service or decrease in the risk of death and sickness (Gold MR, Siegel JE et al. 1996; Breidert, Hahsler et al. 2006). In health care, WTP has become a subject of significant attention (O'Brien and Viramontes 1994; O'Brien and Gafni 1996; Healey and Chisholm 1999; Narbro and Sjostrom 2000; Unutzer, Katon et al. 2003; Marra and Frightetto 2005; Yasunaga, Ide et al. 2006). According to Diener, O'Brien et al. (1998; Guanatilake, Yang et al. 2007), WTP may be calculated via open-ended or binary valuation questions. How much would you be prepared to pay to avoid risk or have access to a certain treatment, test, or preventative programme? (Klose 1999). Each responder is asked to accept or reject an amount of money for a good in a binary valuation inquiry (Klose 1999). WTP is a useful tool for determining how much an individual is willing to pay for various treatments (Healey and Chisholm 1999; Unutzer, Katon et al. 2003). WTP data is critical to policymakers and health care professionals in order to allocate resources in a cost-effective manner (Olsen and Smith 2001). There is no information available.

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6. CONCLUSION

Carbapenem-resistant chronic hepatitis B (CHB) is still a major health issue worldwide including in the United States. If you're suffering from a severe and perhaps fatal sickness, you're going to be affected physically and emotionally. The improvement of people's well-being is an essential objective of health treatment. Improving patient treatment and health policy can be informed by learning about the influence that CHB has on one's well-being. HRQOL can give extra information on antiviral therapy's effectiveness for CHB patients, despite the fact that eradication of the virus is the primary therapeutic aim and the primary metric for antiviral therapy's success. When it comes to the measurement of treatment efficacy in terms of quality-adjusted life years, HRQOL can be transformed to preference values (QALY). Since earlier studies on CHB infection only examined virology, comorbidities, and mortality, a complete picture of the illness was missing. Filling a gap in our knowledge, this research project evaluated the HRQOL of CHB patients in order to better understand their health needs, identify service gaps, and establish CHB patients' preferences (utility) values for future cost-effectiveness analyses of antiviral drug treatments for CHB, which are based on quality adjusted life years (QALYs).

CHB patients' HRQOL can be more accurately assessed using both a disease-specific and a general HRQOL measure. Because Hong Kong does not have a disease-specific HRQOL. The Chronic Liver Disease Questionnaire (CLDQ) was translated for our local Chinese CHB patients from the original Chinese (Hong Kong [HK]) version. CHB patients in Hong Kong were assessed using the Chinese (HK) version of the CLDQ, which was validated, and a general HRQOL measure, the Medical Outcomes Study Short Form 36 Health Survey (SF-36). Hong Kong CHB patients have high service use rates, perceived requirements, and gaps in access to health care, and these factors are associated with HRQOL, according to our findings. Data on CHB patients' willingness to pay was also discovered. An overview of my study findings is presented in this chapter. After that, I'll give some ideas for health policy and service reforms. There is also discussion of the limits of the findings and the need for more study.

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9. Availability of data and materials:

The datasets used and/or analyzed during the present study are available from the corresponding author upon reasonable request.

10. Authors' contributions:

Meng Li were principally responsible for the conception and design of the study. , Faridah Binti Mohd Said and Mohamed Saifulaman Bin Mohamed Said supervised and monitored the project.

11. Ethics approval and consent to participate: NA (Not applicable).

12. Consent Patient for publication: NA (Not applicable).

13. Competing interests: As Corresponding author, I on behalf of co-authors do state that there is no any conflict of interest involved in the paper.

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