

PRACTICE MANAGEMENT: THE ROAD AHEAD

Patient-Reported Outcomes for Patients With Chronic Liver Disease

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Chronic liver disease (CLD) and its complications such as decompensated cirrhosis and hepatocellular carcinoma are major causes of mortality and morbidity worldwide.^{1,2} In addition to its clinical impact, CLD causes impairment of health-related quality of life (HRQL) and other patient-reported outcomes (PROs).¹ Furthermore, patients with CLD use a substantial amount of health care resources, making CLD responsible for tremendous economic burden to the society.^{1,2}

Although CLD encompasses a number of liver diseases, globally, hepatitis B virus (HBV) and hepatitis C virus (HCV), as well as alcoholic and nonalcoholic steatohepatitis (NASH), are the most important causes of liver disease.^{1,2} In this context, recently developed treatment of HBV and HCV are highly effective. In contrast, there is no effective treatment for NASH and treatment of alcoholic steatohepatitis remains suboptimal.³ In the context of the growing burden of obesity and diabetes, the prevalence of NASH and its related complications are expected to grow.⁴

In recent years, a comprehensive approach to assessing the full burden of chronic diseases such as CLD has become increasingly recognized. In this context, it is not only important to evaluate the clinical burden of CLD (survival and mortality) but also its economic burden and its impact on PROs. PROs are defined as reports that come directly from the patient about their health without amendment or interpretation by a clinician or anyone else.^{5,6} Therefore, this commentary focuses on reviewing the assessment and interpretation of PROs in CLD and why they are important in clinical practice.

Assessment of Patient-Reported Outcomes

Although a number of PRO instruments are available, 3 different categories are most relevant for patients with CLD. In this context, PRO instruments can be divided into generic tools, disease-/condition-specific tools, or others instruments that specifically measure outcomes such as work or activity impairment (Table 1). Generic HRQL tools measure overall health and its impact on patients' quality

of life. One of the most commonly used generic HRQL tools in liver disease is the Short Form-36 (SF-36) version 2. The SF-36 version 2 tool measures 8 domains (scores, 0–100; with a higher score indicating less impairment) and provides 2 summary scores: one for physical functioning and one for mental health functioning. The SF-36 has been translated into multiple languages and provides age group- and disease-specific norms to use in comparison analysis.⁷ In addition to the SF-36, the Sickness Impact Profile also has been used to assess a change in behavior as a consequence of illness. The Sickness Impact Profile consists of 136 items/12 categories covering activities of daily living (sleep and rest, eating, work, home management, recreation and pastimes, ambulation, mobility, body care and movement, social interaction, alertness behavior, emotional behavior, and communication). Items are scored on a numeric scale, with higher scores reflecting greater dysfunction as well as providing 2 aggregate scores: the psychosocial score, which is derived from 4 categories, and an aggregate physical score, which is calculated from 3 categories.⁸ Although generic instruments capture patients' HRQL with different disease states (eg, CLD vs congestive heart failure), they may not have sufficient responsiveness to detect clinically important changes that can occur as a result of the natural history of disease or its treatment.⁹

To improve responsiveness of HRQL instruments, disease-specific or condition-specific tools have been developed. These tools assess those aspects of HRQL that are related directly to the underlying disease. For patients with CLD, several tools have been developed and validated.^{10–12} One of the more popular tools is the Chronic Liver Disease Questionnaire (CLDQ), which was developed

Abbreviations used in this paper: CLD, chronic liver disease; CLDQ, Chronic Liver Disease Questionnaire; CLDQ-HCV, hepatitis C virus-specific Chronic Liver Disease Questionnaire; CLDQ-NAFLD/NASH, nonalcoholic fatty liver disease/nonalcoholic steatohepatitis-specific Chronic Liver Disease Questionnaire; HBV, hepatitis B virus; HCV, hepatitis C virus; HRQL, health-related quality of life; NASH, nonalcoholic steatohepatitis; PRO, patient-reported outcome; SF-36, Short-Form 36.

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and validated for patients with CLD.¹⁰ The CLDQ has 29 items and 6 domains covering fatigue, activity, emotional function, abdominal symptoms, systemic symptoms, and worry.¹⁰ More recently, HCV-specific and NASH-specific versions of the CLDQ have been developed and validated (CLDQ-HCV and CLDQ-non-alcoholic fatty liver disease [NAFLD]/NASH). The CLDQ-HCV instrument has some items from the original CLDQ with additional items specific to patients suffering from HCV. The CLDQ-HCV has 29 items that measure 4 domains: activity and energy, emotional, worry, and systemic, with high reliability and validity.¹¹ Finally, the CLDQ-NAFLD/NASH was developed in a similar fashion to the CLDQ and CLDQ-HCV. The CLDQ-NAFLD/NASH has 36 items grouped into 6 domains: abdominal symptoms, activity, emotional, fatigue, systemic symptoms, and worry.¹² All versions of the CLDQ are scored on a Likert scale of 1 to 7 and domain scores are presented in the same manner. In addition, each version of the CLDQ can provide a total score, which also ranges from 1 to 7. In this context, the higher scores represent a better HRQL.¹⁰⁻¹²

In addition to generic and disease-specific instruments, some investigators may elect to include other instruments that are designed specifically to capture fatigue, a very common symptom of CLD. These include the Functional Assessment of Chronic Illness Therapy-Fatigue, Fatigue Symptom Severity, and Fatigue Assessment Inventory.^{13,14}

Finally, work productivity can be influenced profoundly by CLD and can be assessed by self-reports or questionnaires. One of these is the Work Productivity Activity Impairment: Specific Health Problem questionnaire, which evaluates impairment in patients' daily activities and work productivity associated with a specific health problem, and for patients with liver disease, patients are asked to think about how their disease state impacts their life. Higher impairment scores indicate a poorer health status and range from 0 to 1.¹⁵ An important aspect of the PRO assessment that is utilized in economic analysis measure health utilities. Health utilities are measured directly (time-trade off) or indirectly (SF6D, EQ5D, Health Utility Index). These assessment are from 0 (death) to 1 (perfect health). Utility adjustments are used to combine quality of life with quantity of life such as quality adjusted years of life (QALY).¹⁶

Patient-Reported Outcome Results for Patients With Chronic Liver Disease

Over the years, studies using these instruments have shown that patients with CLD suffer significant impairment in their PROs in all domains measured when

compared with the population norms or with individuals without liver disease. Regardless of the cause of their CLD, patients with cirrhosis, especially with decompensated cirrhosis, have the most significant impairments.^{16,17} On the other hand, there is substantial evidence that standard treatment for decompensated cirrhosis (ie, liver transplantation) can significantly improve HRQL and other PROs in patients with advanced cirrhosis.¹⁸

In addition to the data for patients with advanced liver disease, there is significant amount of PRO data that have been generated for patients with early liver disease. In this context, treatment of HCV with the new interferon-free direct antiviral agents results in substantial PRO gains during treatment and after achieving sustained virologic response.¹⁹ In fact, these improvements in PROs have been captured by disease-specific, generic, fatigue-specific, and work productivity instruments.¹⁹

In contrast to HCV, PRO data for patients with HBV are limited. Nevertheless, recent data have suggested that HBV patients who have viral suppression with a nucleoside/nucleotide analogue have a better HRQL.²⁰ Finally, PRO assessments in subjects with NASH are in their early stages. In this context, HRQL data from patients with NASH show significant impairment, which worsens with advanced liver disease.^{21,22} In addition, preliminary data suggest that improvement of fibrosis with medication can lead to improvement of some aspects of PROs in NASH.^{23,24}

Clinical Practice and Patient-Reported Outcomes

The first challenge in the implementation of PRO assessment in clinical practice is the appreciation and understanding of the practicing gastroenterologists and hepatologists about its importance and relevance to clinicians. Generally, clinicians are more focused on the classic markers of disease activity and severity (laboratory tests, and so forth), rather than those that measure patient experiences (PROs). Given that patient experience increasingly has become an important indicator of quality of care, this issue may become increasingly important in clinical practice. In addition, it is important to remember that PROs are the most important outcomes from the patient's perspective. Another challenge in implementation of PROs in clinical practice is to choose the correct validated tool and to implement PRO assessment during an office visit. In fact, completing long questionnaires takes time and resources, which may not be feasible for a busy clinic. Furthermore, these assessments are not reimbursed by payers, which leave the

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