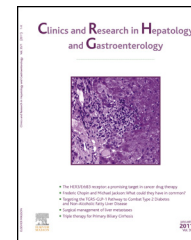




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ORIGINAL ARTICLE



Assessment of health related quality of life in polish patients with primary biliary cirrhosis

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Summary

Background: Most patients with primary biliary cirrhosis (PBC) have impaired health related quality of life (HRQoL), as assessed by PBC-specific HRQoL (PBC-40) and generic (SF-36) questionnaires. Data on the applicability of PBC-27, a shorter version of PBC-40, have been limited. **Aims:** To assess HRQoL in Polish PBC patients, applying PBC-40, PBC-27 and SF-36 and to associate clinical or laboratory parameters with HRQoL factors.

Methods: A total of 205 PBC patients (188 females) were analyzed using PBC-40, PBC-27 and SF-36; 85 disease-free demographically matched (in terms of age, gender, ethnicity) individuals were used as normal controls.

Results: When compared to controls, PBC patients had significantly impaired HRQoL across all the domains of SF-36. HRQoL impairment by PBC-40 and PBC-27 was comparable between cirrhotics and non-cirrhotics, except for significantly worse Itch in cirrhotics (6.5 ± 4.9 vs 5.1 ± 4.3 ; $P=0.03$). In PBC-40/27, alkaline phosphatase (ALP) levels correlated with itch ($P=0.0003$).

Abbreviations: PBC, primary biliary cirrhosis; HRQoL, health-related quality of life; IBD, inflammatory bowel disease; PF, physical functioning; RP, role limitation-physical; BP, bodily pain; GH, general health; VT, vitality; SF, social functioning; RE, role limitation-emotional; MH, mental health; PCS, physical component summary; MCS, mental component summary.

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<http://dx.doi.org/10.1016/j.clinre.2015.10.006>

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Please cite this article in press as: Raszeja-Wyszomirska J, et al. Assessment of health related quality of life in polish patients with primary biliary cirrhosis. Clin Res Hepatol Gastroenterol (2015), <http://dx.doi.org/10.1016/j.clinre.2015.10.006>

Female patients had marginally impaired cognitive function compared to males by PBC-40 ($P=0.06$). Other gender-related differences were not found. Anti-gp210 positive, as well as AMA negative PBC patients, had worse HRQoL features in itch and social/emotional domains of PBC-40/PBC-27 questionnaires. Very strong correlations ($P < 0.0001$) between PBC-40/PBC-27 and SF-36 were seen for several domains.

Conclusions: HRQoL is significantly impaired in Polish patients with PBC, independently of gender and disease severity. PBC-40 and PBC-27 questionnaires are efficient in detecting HRQoL impairment in Polish PBC patients. The striking correlation between PBC-40/PBC-27 and SF-36 confirms the usefulness of the former HRQoL measures in PBC patients from Central-Eastern Europe.

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Introduction

Primary biliary cirrhosis (PBC) is a progressive cholestatic liver disease that affects predominantly middle-aged women, though more recently an increasing number of premenopausal women over the years has been noted [1–5]. Most patients with PBC suffer from various symptoms, which may significantly impair their health-related quality of life (HRQoL), including fatigue, pruritus, jaundice, sleep disturbances, cognitive dysfunction, mood disorders, and depression [2,6–8]. Meticulous evaluation of the quality of life in PBC has reached the conclusion that fatigue is the most cardinal symptom affecting daily activities and individuals' lives, irrespectively of the stage of PBC [6,8–14].

The wealth of data stemming from studies investigating the impact of PBC in HRQoL has led to the development of a PBC-specific HRQoL questionnaire, known as PBC-40 [15], which has been considered the most efficient tool for the assessment of quality of life in a valid and reproducible way [12,16–24]. PBC-40 is comprised of 40 questions assessing six domains including itch, fatigue, other symptoms, cognitive, social and emotional items [15]. The total domain scoring allows proper, quantitative determination of PBC-related factors (including the positive or negative impact of disease treatment) which collectively contribute to the impairment of HRQoL from the patient's perspective. The greater the scores the greater the impact of symptoms in health and functioning, signifying poorer quality of life [15].

More recently, a shorter version of the PBC-40 questionnaire with just 27 questions, the "PBC-27", has been suggested as a more suitable, friendly, robust and simplified HRQoL measure in PBC [25]. As for PBC-40, PBC-27 is readily applicable to clinical routine practice and is designed for self completion, preventing from a biased interpretation of the patient's response from the clinician or anyone else.

These questionnaires have been validated and applied mainly in UK patients, recruited in various ways ranging from single-center and multi-center enrollment to patient-group charitable foundation or national UK registry-based recruitment [15,17–24,26]. Their evaluation outside Britain has been rather limited [16,25,27]. For example, data from North America on PBC-40 derive from a large clinical practice (single center) in Canada [16]. Over the last three decades, quality of life in PBC has been the focus of clinical research in various liver centers in Continental

Europe. Despite that, very few centers have reported their experience on the applicability of PBC-40, and hardly any of those have published data on PBC-27, a noteworthy exception being that of the original study that developed the measure based on an Italian-Japanese PBC study group [25]. To the best of our knowledge, data from Asia originate mainly from Japanese centers [25] and to a lesser extent from small Chinese PBC series [27], as it is revealed through Pubmed search. No data have been reported from Australian cohorts.

Our group has been one of the very first in Continental Europe to systematically apply the PBC-40 and PBC-27 measures in clinical practice over the last five years [28–31]. We have also utilized SF-36, a multi-purpose, short-form health survey with 36 questions, widely used in routine clinical care for HRQoL assessment. As opposed to PBC-40 and PBC-27 that target a specific disease, SF-36 is a generic measure applying to any individual, irrespectively of its health status [32]. Using these questionnaires, we have been able to demonstrate novel associations between HRQoL measurements and clinical, laboratory or immunogenetic features [28]. Also, we recently investigated the extent by which PBC-specific questionnaires can evaluate HRQoL in patients with primary sclerosing cholangitis [29,31].

In the present study, we have assessed HRQoL in a well-defined cohort of 205 PBC patients followed up by one principal investigator (PM) consecutively working in two Polish centers, using PBC-40, PBC-27 and SF-36. In the past, it has become apparent that social, economic, and geographical issues distinctively influence the quality of life in PBC [13,33,34]. Hence, our study is in a unique position to address the effect of this enigmatic disease in patients originated from a country with a historically quite distinct socioeconomic status from other member states such as UK and Italy. Thus, our study is the first to report on a cohort of homogenous Caucasian PBC patients originated from a Central-Eastern European country.

Patients and methods

Study group

Two hundred and five Caucasian patients with PBC (17 males and 188 females, mean age: 58 ± 11 years) who received

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