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Special article

A review of quality of life instruments used in liver transplantation☆

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With improvements in patient and graft survival after liver transplantation, recipient quality of life (QOL) has become an important focus of patient care and clinical outcomes research. To provide a better understanding of the instruments used to assess QOL in the adult liver transplant population, we conducted a systematic review of the MEDLINE database and Cochrane library. Our review identified 128 relevant articles utilizing more than 50 different QOL instruments. Generic health status instruments are the most commonly used, and among them the Medical Outcomes Study Short Form-36 (SF-36), the Hospital Anxiety and Depression Scale (HADS), and the Beck Depression Inventory (BDI) are the most prevalent. Few studies (16%) included targeted, disease-specific instruments. The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) Quality of Life questionnaire, the Liver Disease Quality of Life questionnaire, and the Chronic Liver Disease questionnaire are the most frequently employed targeted instruments; however, these instruments have been designed to assess QOL in patients with chronic liver disease rather than patients after liver transplantation. The present review focuses on the psychometric properties of the existing QOL instruments and discusses their individual strengths and limitations in evaluating liver transplantation recipients. The lack of a gold-standard QOL instrument for liver transplant recipients is an impediment to cross-study comparisons. We conclude that the development of a QOL instrument specifically for liver transplant recipients will improve QOL assessment in this population leading to a more nuanced understanding of the factors that influence transplant recipients' well-being.

***Keywords*: Liver transplantation; Quality of life; Psychometrics; SF-36; LDQOL; Systematic review**

1. Background

Liver transplantation is a life-saving intervention for an increasing number of patients with end-stage liver disease [1]. Steady improvements in graft and patient survival have been achieved over the past two decades. One year adjusted patient and graft survival rates were 87.9% and 82.3%, respectively, for deceased donor liver transplants in 2005 [1]. This represents an increase of approximately 25% for both patient and graft survival since 1987. With significant improvements in survival and a more recent plateau of these gains [1], the focus on outcomes measures has shifted towards inclusion of patient-reported quality of life (QOL). The concept of

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Abbreviations: QOL, quality of life; SF-36, short form-36; HADS, hospital anxiety and depression scale; BDI, beck depression inventory; NIDDK, National Institute of Diabetes and Digestive and Kidney Diseases; WHO, World Health Organization; MeSH, medical subject headings; HRQL/HRQOL, health-related quality of life; MELD, model for end-stage liver disease; EQ-5D, EuroQOL-5D; VAS, visual analog scale; SIP, sickness impact profile; LDQOL, liver disease quality of life questionnaire; CLDQ, chronic liver disease questionnaire; QALY, quality-adjusted life year.

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QOL complements the World Health Organization (WHO) definition of health as "a state of complete physical, mental and social well-being and not merely the absence of disease and infirmity" [2]. Hence, patient-reported outcomes are being increasingly emphasized in recent years and have become an integral component of many ongoing clinical trials [3,4]. However, meaningful assessment of patient QOL relies on the ability to reliably and accurately assess well-being using psychometrically robust instruments.

Multiple studies have reported on QOL in patients with chronic liver disease, liver transplant candidates, and transplant recipients. However, the differences between the various QOL instruments in use and the degree to which these instruments capture the true impact of liver transplantation on QOL have not been rigorously assessed. In order to evaluate the currently available instruments, we have conducted a systematic review of the literature focusing on patient-reported QOL assessment in the context of liver transplantation. We critically evaluated the psychometric properties of these instruments and their ability to measure concerns specific to the liver transplant population. To date, more than 50 instruments have been used to assess QOL in liver transplant candidates or recipients. This is the first review to discuss the relevant merit of the most frequently-used instruments.

2. Materials and methods

A systematic search of the MEDLINE database (1969–2008) and the Cochrane library was performed to identify liver transplant articles that included a patient-reported QOL assessment. To capture any relevant articles, a search using the Medical Subject Headings (MeSH) terms "liver transplantation" and "quality of life" was constructed. Citations associated with the keywords "QOL", "HRQL", or "HRQOL" (health-related quality of life) were also included. The search was limited to original articles relevant to humans and available in English. Publications were included if they used a patient-reported QOL assessment in liver transplant candidates or recipients. Articles using ad hoc instruments or instruments that could not be identified were excluded. Studies were also excluded if they focused exclusively on pediatric patients or living donors. The full text was reviewed prior to exclusion. Furthermore, the bibliographies of review articles on this topic were reviewed for any relevant publications to verify the completeness of our search. This search was performed by a single reviewer (CJ). We reviewed the QOL instruments identified through this search according to psychometric criteria adapted from the Scientific Advisory Committee of the Medical Outcomes Trust criteria [5,6] (Table 1).

3. Results

3.1. Identified studies

We identified 468 citations in our original search. A total of 340 articles were eliminated after applying the exclusion criteria outlined above. One hundred and twenty-eight articles met final inclusion criteria. (Fig. 1 and Appendix A) The first assessment of QOL outcomes in liver transplantation was published in 1988, more than 20 years after the first successful liver transplant performed by Starzl [7]. In the last decade, interest in this area has increased significantly. This is illustrated by the fact that MEDLINE identified more publications using the terms of "liver transplantation" and "quality of life" since 2000 than in the preceding two decades.

This review evaluates both generic and targeted QOL instruments that have been utilized in liver

Table 1
Psychometric properties of QOL instruments.

Criteria[a]	Description
Conceptual and measurement model	Such a model describes the rationale for and operationalization of the concepts to be measured.
Reliability	Reliability is an index describing the degree to which the instrument is free from random error. Two common types of reliability that are reported include: *a. Internal consistency* is the degree to which items on a scale measure the same concept, reported in terms of Cronbach alpha coefficients (minimum suggested $\alpha = 0.5$–0.7 for group comparisons and $\geqslant 0.85$ for individual) [6,76] *b. Test–retest reliability* is the extent to which similar scores are obtained from the same individuals over short time periods, expressed as correlation coefficients (coefficients $\geqslant 0.6$ have been suggested as a measure of "good" or "substantial" reliability) [77,78]
Validity	Validity is an index of the extent to which an instrument measures what it purports to measure. Two common types of validity include: *a. Criterion-related validity* is demonstrated when an instrument is effective in predicting scores on another indicator of the concept. *b. Construct-related validity* is the degree to which an instrument is predictive of a theoretical trait or concept [6].
Responsiveness	This criterion assesses the ability to detect changes over time corresponding to changes in patients' health status
Burden	The time and effort demanded to complete the survey is a measure of the instrument's burden
Cultural/language adaptations	Information about translational process and evidence regarding conceptual and linguistic equivalence enable assessment of the quality of these adaptations

[a] Adapted from review criteria developed by the Scientific Advisory Committee of the Medical Outcomes Trust [5,6].