

REVIEW

Evidence on the measurement properties of health-related quality of life instruments is largely missing in patients with low back pain: A systematic review

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Abstract

Objective: To synthesize the measurement properties of six health-related quality of life instruments (Short Form 36 [SF-36], Short Form 12 [SF-12], EuroQol 5D-3L [EQ-5D-3L], EuroQol 5D-5L [EQ-5D-5L], Nottingham Health Profile (NHP), and Patient-Reported Outcome Measurement Information System Global Health [PROMIS-GH-10]) in patients with low back pain (LBP).

Study Design and Setting: Six electronic databases (MEDLINE, EMBASE, CINAHL, PsycINFO, SportDiscus, and Google Scholar) were searched (July 2017). Studies assessing any measurement property in nonspecific LBP patients were included. Two reviewers independently screened the articles and assessed the risk of bias (COSMIN checklist). Consensus-based criteria were used to rate measurement properties results as sufficient, insufficient, or inconsistent; a modified GRADE approach was adopted for evidence synthesis.

Results: High quality evidence was found for insufficient construct validity of SF-36 summary scores, and EQ-5D-3L utility and visual analogue scale scores. Moderate evidence was found for sufficient construct validity of SF-12 physical summary score and inconsistent responsiveness of EQ-5D-3L utility score. Very low quality evidence was found on each instrument's content validity; very low to low evidence underpinned the other assessed measurement properties. EQ-5D-5L, NHP and PROMIS Global Health-10 were not evaluated in LBP patients.

Conclusion: Documentation of the measurement properties of health-related quality of life instruments in LBP is incomplete. Future clinimetric studies should prioritize content validity. © 2018 Published by Elsevier Inc.

Keywords: Health-related quality of life; Measurement instruments; Measurement properties; Low back pain; COSMIN

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1. Introduction

Low back pain (LBP) represents one of the most burdensome and costly health conditions [1,2]. This condition has important impacts on the patients' health-related quality of life (HRQoL) [3,4]. HRQoL (defined as "physical, psychological, and social domains of health, seen as distinct areas that are influenced by a person's experiences, beliefs, expectations, and perceptions") was also selected by an interdisciplinary group of stakeholders as a core outcome domain for clinical trials in LBP [5]. However, it is unclear which measurement instrument is best to measure this domain.

What is new?

Key findings

- High quality evidence indicates that the construct validity of the summary scores of the SF-36 and of the utility and visual analogue scores of the EQ-5D-3L is inadequate in patients with low back pain (LBP).
- The quality of evidence on the content validity of six instruments widely used to measure HRQoL (i.e., SF-36, SF-12, EQ-5D-3L, EQ-5D-5L, NHP, PROMIS Global Health-10) is very low in patients with LBP.

What this adds to what is known?

- The measurement properties of HRQoL instruments have been only marginally investigated in patients with LBP.
- Caution should be used in assuming the validity of the SF-36 and EQ-5D-3L scores in patients with LBP, as there is high quality evidence suggesting that correlations of these scores with other instruments are not as expected.

What is the implication and what should change now?

- More research on the measurement properties of HRQoL instruments is needed in patients with LBP, and priority should be given to head-to-head comparison studies focusing on content validity.
- Future head-to-head comparisons should also assess structural validity, reliability, construct validity and responsiveness, and they should also include other recently developed instruments (e.g., LBP Core Set Self-Report Checklist, Musculoskeletal Health Questionnaire).

The selection of an instrument should be based on its measurement properties and feasibility in the target population [6,7]. Previous recommendations on HRQoL measurement in LBP have advocated the use of the Short Form 36 (SF-36), the Short Form 12 (SF-12) and/or the EuroQol 5D (EQ-5D) [8–12]. The SF-36 is most frequently used to measure HRQoL in LBP clinical trials, followed by the Nottingham Health Profile (NHP), the SF-12, the Sickness Impact Profile, and the EQ-5D [13]. The measurement properties of these instruments have been investigated in the general population and in various clinical samples [14]. However, it remains unclear how valid, reliable, and responsive these instruments are in patients with LBP.

Three reviews have attempted to summarize the measurement properties of HRQoL instruments in patients with LBP [15–17]. Two were narrative reviews [16,17], two focused on utility scores [15,17], and all had significant and important methodological weaknesses, such as failure to account for risk of bias in the evidence synthesis [18,19]. The Consensus-based Standards for the selection of health Measurement Instruments (COSMIN) initiative has developed tools to guide systematic reviews on measurement properties of patient-reported outcome measures [20]; these include a taxonomy defining each measurement property [21], a search filter to identify studies on measurement properties [22], a risk of bias assessment checklist [23], and evidence synthesis methods [24,25].

An international consortium developing a core outcome measurement set for LBP clinical trials selected five instruments as potential core outcome measurement instruments for HRQoL in LBP [26]. Four of these instruments (SF-36, SF-12, NHP and EQ-5D) were also among the five most frequently used in LBP trials; the Sickness Impact Profile was not selected because its length (136 items) rendered it unfeasible for inclusion in a core set [26]. Although it has not been broadly used, the 10-item Patient-Reported Outcome Measurement Information System (PROMIS) Global Health short form (PROMIS-GH-10) [27] was also chosen because it demonstrated face validity similar to the other instruments [26] and because it was recommended by another recent core set initiative [28].

This systematic review summarizes the evidence on the measurement properties of SF-36, SF-12, EQ-5D, NHP, and PROMIS-GH-10 in patients with LBP. The results of this review informed a Delphi survey to reach consensus on which instrument(s) to recommend for core outcome measurement of HRQoL in patients with LBP [26]. The original version of the EQ-5D includes three response options for each item (EQ-5D-3L) [29], and it has probably been the most used in LBP; however, because a version with five response options (EQ-5D-5L) was more recently developed [30], this newer EQ-5D version was also assessed in this review.

2. Methods

Conduct and report of this systematic review follows the COSMIN guidance [24] and the Preferred Reporting Items for Systematic Reviews and meta-Analysis statement [31]. The protocol was registered a priori in PROSPERO (<https://www.crd.york.ac.uk/prospero/>), number CRD42015020021.

2.1. Measurement instruments

2.1.1. Short Form 36

The SF-36 consists of 36 items measuring HRQoL subdivided in eight domains (Table 1). The number of response options varies from three (physical functioning subscale) to six (vitality and mental health subscales); originally, 0–100

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