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Technical Report

ISYQOL: a Rasch-consistent questionnaire for measuring health-related quality of life in adolescents with spinal deformities

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Abstract

BACKGROUND CONTEXT: Spinal deformities are commonly associated with poor health-related quality of life (HRQOL). Several questionnaires (eg, Scoliosis Research Society-24 [SRS-24] and Scoliosis Research Society-22 [SRS-22]) have been developed to evaluate HRQOL in these conditions. In adults as well as during growth, the HRQOL is considered one of the most relevant outcomes of both conservative and surgical treatments. Rasch analysis is a powerful statistical technique for developing high-quality and valid questionnaires. The SRS-24 and SRS-22 have been evaluated using the Rasch analysis but showed poor measurement properties. Thus, a proper measure of HRQOL in people with a spine condition is still missing.

PURPOSE: This study aimed to develop a new questionnaire that is totally Rasch consistent for measuring the HRQOL in young people with a spine condition.

STUDY DESIGN: This is a cross-sectional study for developing a new HRQOL measure.

PATIENT SAMPLE: A total of 402 participants with adolescent idiopathic scoliosis or Scheuermann juvenile kyphosis were included in the study.

OUTCOME MEASURE: The outcome measure used was the Italian Spine Youth Quality of Life (ISYQOL) questionnaire.

MATERIALS AND METHODS: The study consisted of different stages: a conventional approach content analysis, an opinion poll among clinicians trained in spine deformities, and the Rasch analysis (partial credit model).

RESULTS: The Rasch analysis showed that all items of the ISYQOL questionnaire had ordered thresholds and a good fit to the model. Differential item functioning was present for Item 1, with bracing only, and was solved with a conventional items splitting procedure. The ISYQOL item map spans an adequate range of HRQOL. The principal component analysis for Rasch residuals showed, in practical terms, the ISYQOL unidimensionality. The reliability of ISYQOL was high enough so that approximately three significantly different levels of HRQOL could be discerned. Two questionnaire versions were provided for patients with and without the brace, respectively.

FDA device/drug status: Not applicable.

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CONCLUSIONS: ISYQOL is the first HRQOL questionnaire developed according to the Rasch analysis. It was developed in a conservative treatment setting for all types of spinal deformities, including also patients with surgical curves. Validation in many languages is already under way.

Keywords: Adolescent idiopathic scoliosis; Brace; Content analysis; Health-related quality of life; Interval measurement; Ordinal measurement; Psychometrics; Rasch analysis; Scheuermann juvenile kyphosis; Spinal deformities

Introduction

Spinal deformities such as adolescent idiopathic scoliosis (AIS) and Scheuermann juvenile kyphosis (SJK) are common among adolescents [1,2]. Adolescent idiopathic scoliosis and SJK and their treatments may have a serious impact on patients' health-related quality of life (HRQOL [3]). For example, bracing can be a stressful experience, and an impact of bracing on patients' well-being has been observed [4,5]. In adults as well as during growth, the HRQOL is considered one of the most relevant outcomes of both conservative and surgical treatments [6].

The Scoliosis Research Society-22 [7] (SRS-22) questionnaire is the most commonly used instrument for measuring HRQOL in patients with scoliosis [8]. It is a five-domain questionnaire developed according to the classical test theory (CTT) and, in this framework, showed satisfactory properties such as concurrent validity and reliability [9].

In a previous work [10], the Rasch analysis has been used to test SRS-22 in the item response theory framework. Authoritative explanations of what Rasch analysis is can be found elsewhere [11]. Briefly, Rasch analysis is a statistical procedure to construct questionnaires and scales that eventually allow measurement in accordance with the principles of the modern psychometric [12]. Being additive, generalizable, and unidimensional, a Rasch-consistent measure has the attributes of a proper measure [13].

Rasch analysis showed that the SRS-22 suffers poor metric properties, thus preventing a proper measure of HRQOL. As a provisional solution, a Rasch-consistent 7-item questionnaire (Scoliosis Research Society-7 [SRS-7]) was prepared by rearranging single items from the original SRS-22 [10]. However, SRS-7 metric properties remain unsatisfactory, and thus, a proper questionnaire for measuring HRQOL in adolescents with spinal deformities is still missing. The introduction of a better questionnaire able to offer an HRQOL measure that complies with the requirement of a proper measure [12,13] will have a high clinical impact and will provide an advance in care.

The current work presents the development of a new patient-reported outcome measure for measuring HRQOL in adolescents with AIS or SJK of various degrees (from conservative to surgical).

Materials and methods

The questionnaire development was articulated into three phases: Phase 1 consisted of a content analysis, Phase 2 consisted of an opinion poll, and Phase 3 consisted of a Rasch analysis. The content analysis and the opinion poll are described in Supplementary Appendix A. Briefly, in Phase 1, a conventional approach content analysis was used to identify the self-reported problems affecting the HRQOL of patients with a spine deformity. A pool of 147 items was arranged according to the content analysis results and, in Phase 2, 23 clinicians with expertise in spine deformities rated the items' appropriateness for measuring the patients' HRQOL. The first version of the Italian Spine Youth Quality of Life (ISYQOL-1) questionnaire was eventually arranged based on the results of the survey. In Phase 3, a Rasch analysis was run on ISYQOL-1 and on the second version of the Italian Spine Youth Quality of Life (ISYQOL-2) questionnaire; the latter was developed based on the Rasch analysis of the former. Because of the setting of development, the questionnaire has been called Italian Spine Youth Quality of Life (ISYQOL).

Patient population

The current study involved 402 participants attending two outpatient clinics that specialized in the conservative treatment of spinal deformities. The participants themselves filled out one of the two versions of the questionnaire before the medical evaluation. Data from the ISYQOL-1 were collected from June to July 2014, and ISYQOL-2 data were collected from January to March 2015.

Inclusion criteria were as follows: (1) AIS diagnosis according to the criteria of the Scoliosis Research Society [14] or SJK diagnosis according to the Sorensen criteria [15], and (2) age less than 18 years at the time the ISYQOL questionnaire was completed. Exclusion criteria included the following: (1) history of spine surgery; (2) combined spinal deformities (eg, scoliosis plus spondylolysis); and (3) a history of relevant diseases, surgery, or trauma, including a positive neurologic examination.

All of the participants signed an informed consent form before recruitment and agreed to complete the questionnaires; the local ethical committee was informed about the study.

Rasch analysis of the questionnaire

Details on the Rasch analysis used in the current work are provided elsewhere [10,11]. Briefly, the Rasch analysis consists of an iterative process in which questionnaire characteristics are summarized according to analysis parameters and thus easily refer to commonly accepted values. In the current work, the Rasch analysis parameters were checked using the following steps: (1) threshold order, (2) fit to the model, (3)