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Journal of Physical Medicine and Rehabilitation

Spanish validation of Italian Spine Youth Quality of Life (ISYQOL) Questionnaire

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Abstract

Study design: *Cross-sectional study*

Objective: *To develop and validate the Spanish version of the Rasch compatible ISYQOL questionnaire aimed to measure HRQOL in adolescents with scoliosis and kyphosis.*

Background: *Spinal deformity is able to impact the HRQOL, but its treatment can affect the HRQOL too. For this reason, HRQOL is a very important outcome measure in medicine. Previous used questionnaires showed some problems in detecting HRQOL. With the aim of improving the quality of the available tools, ISYQOL questionnaire was developed in a Rasch statistical environment. Rasch analysis is a statistical procedure that allows to develop a HRQOL continuous measure which is additive, generalizable and unidimensional.*

Methods: *The validation process of the trans-cultural adaptation included two phases. The first phase involved two translations and two back translations. A final agreement was obtained by a committee of experts for the ISYQOL Spanish version. In the second phase, psychometric characteristics, reliability (internal consistency) and validity were assessed.*

Results: *The sample consisted of 93 adolescents (7 boys), with a mean age of 14.1 (SD 2.0). Patients with idiopathic scoliosis were 87% and presented a mean major curve 35.7° Cobb Angle (SD 9.9). Patients with idiopathic kyphosis had a mean kyphosis of 51.8° (SD 8.9). Half of the all patients were treated with braces.*

Floor and ceiling effects of ISYQOL were 1.1% for both health conditions. Ceiling effect of SRS-22 was present in the items Functioning, Pain and Mental Health. The distribution of the ISYQOL measurements was symmetrical, even if the average result was around 60%; SRS-22 results were above 4 for total and all sub-scales apart Self Image. Patients treated with orthopaedic braces showed a lower quality of life compared to untreated patients. ISYQOL had a good internal consistency (α =0.77 from Cronbach) comparable to SRS-22. Convergent validity with the criterion standard SRS-22 questionnaire was low and the highest correlation was found for Self-Image (r=.4, p<0.01). No relationship was found for the Cobb angle in either patients with scoliosis or kyphosis.

Conclusions: *The Spanish version of ISYQOL, the first HRQOL questionnaire developed according to the Rasch analysis, worked well. It showed no floor/ceiling effect and obtained good reliability. Convergent validity with SRS-22 was medium.*

Keywords: *health related quality of life; spinal deformities; adolescent idiopathic scoliosis; kyphosis; brace; psychometric properties; transcultural adaptation*

Introduction

Bio-psychosocial (BPS) model was elaborated by the American internist and psychiatrist Dr. G. Engel in 1977 in its landmark paper in Science [1]. The model proposed that biological, psychological and social processes operate in a matrix of inseparably interconnected sub-systems that influence all aspects of mental and physical health. The integration of these systems is critical in terms of understanding the patient's bio-psychosocial story [2]. The present BPS model may complement and include the exploration of disease (biomedical) as well as of the illness (patient's perspective).

Framed by BPS model, the concept of Health-Related Quality of Life (HRQOL) is a very important outcome measure in physical and rehabilitation medicine. In the field of scoliosis conservative treatment, the deformity itself is able to impact the HRQOL, but the treatment is able to affect the HRQOL too [3-5]. Therefore, the currently published SOSORT Guidelines promote the HRQOL as an important aim of treatment [6].

Some instruments to measure HRQOL in adolescents with spine deformities were developed; among them, the SRS (Scoliosis Research Society)-22, the QLPSD (Quality of Life Adolescents with Spine Deformities), the BrQ (Brace Questionnaire) specific for braced patients [7].

However, the most widely used and translated tool is the SRS-22: its original version [8], has been translated and validated in various languages, included Spanish [9]. Despite its diffusion, this questionnaire has shown a high ceiling effect [10]. The SRS-22 was tested also into the Rasch framework, highlighting a severe ceiling effect and multidimensionality. In the attempt to improve the SRS-22, a Rasch-consistent 7-items questionnaire (SRS-7) was prepared, showing unidimensionality by rearranging single items from the original SRS-22 [11].

However, SRS-7 metric properties remain unsatisfactory and therefore a new questionnaire for measuring HRQOL in adolescents with AIS was developed in the Rasch analysis framework. This questionnaire was called ISYQOL (Italian Spine Youth Quality of Life) and was first created in Italian and showed to be Rasch consistent, being unidimensional, additive and reliable [12].

This new questionnaire was translated into Spanish and the present study aims to test the transcultural Spanish adaptation of the ISYQOL and its psychometric properties.

Materials and Methods

The design of the study followed the validation process of trans-cultural adaptation. It included two phases: first, a translation and a back translation were used to create the Spanish version; second, the psychometric characteristics, reliability and validity, were calculated.

The method for the validation is currently used by the American Association of Orthopedic Surgeons (AAOS) [13] and consisted of 5 phases: two Spanish native translators produced two independent translations (Phase 1). A synthesis of the two translations was realized (Phase 2). An Italian native translated this Spanish version into Italian (back translation), assessing that the translated consensus version reflected the same original content (Phase 3). A committee of experts, made by a surgeon and two psychologists, reviewed all the translations and reached a consensus on the discrepancies (Phase 4). The new questionnaire in this pre-final version was passed to a limited number of patients (Test of the pre-final version). Each person completed the questionnaire, and, thanks to his/her comments, some items were changed to improve their meaning (Phase 5).

The number of subjects who must participate for the validation of the questionnaire must be between 2 and 10 times the number of items the instrument has (20). Hence, to carry out the study 93 participants have been included [14].

Two self-administered questionnaires were used:

- The SRS (Scoliosis Research Society)-22. In its current version, SRS-22 measures the HRQOL in patients with scoliosis and presents 22 items and a structure of 5 factors: function/ activity (5 items), pain (5 items), self-image (5 items), mental health (5 items) and satisfaction with the treatment (2 items). Higher scores indicate a better patient HRQOL. Satisfaction with the treatment was not included.
- The Spanish version of ISYQOL consists of 20 items related to two domains: spine health and brace. The questionnaire is composed of two parts: the first part of 13 questions for all the patients and the other 7 specific ones only for patients treated with brace. So, the full version of questionnaire (20 items) is administered for braced patients. For ISYQOL scoring, a first score is obtained by the indication the lower QOL the highest is the score; while for the final score, two tables (4 and 5) from the original article [12] (related to the two versions) have to be consulted. The final score ranges from 0 to 100%. The highest is the score, the better is the HRQOL.

Participants

As inclusion criteria, patients who met the following criteria were eligible for the study: 1. Patients with Idiopathic Scoliosis (IS) or Kyphosis (IK). For IS, the magnitude of the largest Cobb Angle was > 20º. For IK, the magnitude of the largest Kyphotic Angle was ≥45º; 2. Age between 10 and 18 years old; 3. Not received previous surgical treatment; 4. Informed consent to participate to the study; 5. Available Posterior-Anterior Radiographies.

Ninety-three patients were recruited. Mean age of all the sample was 14 (SD= 2), range from 10 to 18 years old. Ninety-three per cent were girls (only 7 boys). They were all patients with idiopathic spine deformity (Table 1). Forty-seven patients, corresponding to 50% of the sample, wore brace in part/full time modality (6 of them treated also by physiotherapy), while the rest did not follow any treatment.

All they agreed to participate to the research as volunteers and they or their parents (if minor) signed an informed consent. All patients underwent frontal and sagittal radiographs.

Pathology	**IS**	81 (87%)	**IK**	12 (13%)
	Cobb	36.5º (SD=9)	**Cobb**	52º (SD=8.9)
	Range	25º- 64º	**Range**	45º-70º

Table 1. *Descriptive analysis for radiological data*

Analysis

A descriptive analysis was carried out of the features of the total sample.
ISYQOL mean and standard deviation (SD) were determined as well as the floor and ceiling effects (percentage of patients with maximum and minimum score). As psychometric properties of ISYQOL, internal consistency, convergent, discriminant validity were assessed.
Internal consistency analyzes the homogeneity of the questionnaire. It measures the degree of correlation among each item of ISYQOL through the Cronbach's α coefficient. The validity ensures the instrument measures what it is meant to measure. Convergent validity was achieved by correlating ISYQOL with SRS-22 as well as its subscales, while discriminant validity was assessed using Cobb Angle.
T-Test was used to check the difference between braced patients and the non-treated ones. SRS-22 mean and SD were calculated as well as means and SD of its subscales. SPSS.16.0 program was used for the statistical analysis.

Results

The ISYQOL score was 60.5% (SD+-10.1) for patients with IS and 59.3% (SD+-12.5) for patients with IK. Floor and ceiling effects were 1.1% for both clinical conditions. The distribution of the ISYQOL measurement was approximately symmetrical (asymmetry: 0.5). ISYQOL presented a leptocurtic distribution (Table 2) although it had a normal distribution (p>0.05) (Table 3).

The values for SRS-22 are reported in Table 4. For SRS-22 we found a ceiling effect in 19.4%, 24.7% and 10.8% for the items Function, Pain and Mental Health, respectively. SRS-22 results were always in the highest range, with an average above 4 for total and all sub-scales apart Self Image.

In terms of psychometric properties, ISYQOL had an acceptable internal consistency (α =0.77 from Cronbach) similar to the SRS-22 values [15]. Convergent validity with SRS-22 was low: the highest correlation evaluated for Self-Image obtained a mean value (r=.4, p<0.01) (Table 5). No relationship was found between ISYQOL and the Cobb angle in patients with either scoliosis or kyphosis. Patients treated with braces showed a lower HRQoL (measured by ISYQOL) compared to untreated patients 58.1 (SD 7.8; CI95% 55.8-60.5) vs 62.5 (SD 12.1; CI95% 58.9-65.9) respectively (p value 0.04). The relationship between treatment with brace and the result of the questionnaire was significant.

On the opposite, the SRS-22 questionnaire showed a negatively significant relationship between Cobb's angle and the total score of the questionnaire but did not show significant relationships with types of treatment (Table 6).

Questionnaires	ISYQOL
Mean	60.36
SD	10.41
Minimum	34.54
Maximum	100.00
Skewness	.48
Kurtosis	1.67

Table 2. *Descriptive statistics for ISYQOL*

Statistical test	ISYQOL.es
Kolmogorov-Smirnov Z	.79
Asymp. Sig. (2-tailed)	.57

Table 3. *Descriptive statistics for ISYQOL*

SRS-22					
	Function	**Pain**	**Body Image**	**Mental Health**	**Total**
Mean	4.52	4.33	3.72	4.10	4.21
SD	.51	.62	.49	.59	.38
Minimum	2.20	2.40	2.80	2.60	3.00
Maximum	5.00	5.00	4.80	5.00	4.90

Table 4. *Descriptive analysis for SRS-22 questionnaire*

ISYQOL	SRS-Function	SRS-Pain	SRS-Body Image	SRS-Mental Health	SRS-Total
Pearson'r	.9	.21	.39**	.33**	.31
p	.39	.04*	.001	.002	.003

Table 5. *Correlation matrix among ISYQOL and SRS-22 (subscales and total)*

	Cobb	Brace
ISYQOL	-.057	.208*
SRS-22	-2.47*	-.058

Table 6. *Correlation matrix between ISYQOL and SRS-22 (Cobb and type of treatment)*

Discussion

This study presents the validation of the Spanish version of ISYQOL, a new measure of quality of life in adolescents with spinal deformities (including both scoliosis and hyperkyphosis). For this study, a classical psychometric analysis was performed to validate this new version of ISYQOL, in order to test its validity with the methodology of classical test theory.

Patients with scoliosis and kyphosis presented a HRQoL of around 60%. Above all, they presented a normal distribution, with almost no ceiling or floor effect. This was not true for the SRS-22, that presented a frequent ceiling effect, with average results on the highest levels of the scale.

ISYQOL presented a good internal consistency (r>0.7), comparable to that found in the same sample with SRS-22. To assess the convergent validity, SRS-22 was used while for discriminant validity correlations with Cobb angles were performed. Although convergent validity was low, for all the subscales it was positive, that means that higher score in ISYQOL correlated with higher score in SRS-22. The lack of correlation could be explained with the reference to the structure of the tools: SRS-22 is a multidimensional questionnaire (with its 5 domains), while ISYQOL is unidimensional. SRS-22 already showed a low compatibility with Rasch analysis [11] and since ISYQOL has been developed with Rasch, this result is in line with the previous one. A lack of correlation with Cobb angles for discriminatory validity was also found: probably due to the fact that ISYQOL focuses primarily on measuring adolescents' ideas, concerns, and fears about their spinal problems, i.e., the patient's perspective on the disease, which need not be directly related to Cobb grade. On the other hand, ISYQOL is able to perceive that HRQoL is affected in patients treated with orthopedic appliances.

We believe that the application of this tool could have an important practical clinical impact if health professionals used it as an opportunity to discuss with the patient about their disease in order to support them, clarify common myths and fears associated with the deformity or help with respect to the brace experience. As a limitation, Spanish version of the ISYQOL lacks of an assessed temporal reliability, presented an inferior sample in comparison to the Italian sample (402 Italian patients versus 93 Spanish) and was tested in the classical test theory methodology instead of in the Rasch analysis.

In the future, we are planning a test of the Spanish version of the ISYQOL in the Rasch framework, and furthermore, a comparison between different phases of treatment and different types of treatments in order to test the discriminative validity of the ISYQOL questionnaire.

In conclusions,

- ISYQOL seems to be a reliable and valid tool to measure HRQOL addressed to Spanish adolescent population with deformity, with conservative treatment or not.

- ISYQOL can offer an insight of the brace impact on HRQOL.
- Its practical characters led professionals to inquire about patients' ideas, concerns, expectations and effects related to the diagnosis or to the brace and to promote their HRQOL.

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Rec: Feb 15, 2020; Acc: Feb 27, 2020; Pub: Feb 29, 2019

J Phys Med Rehabil. 2020;2(1):08
DOI: gsl.jpmr.2020.00008