Reliability and validity of Simplified Chinese version of the Italian Spine Youth Quality of Life questionnaire in adolescents with idiopathic scoliosis

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Abstract

Background: The Italian Spine Youth Quality of Life (ISYQOL) questionnaire is a tool used to evaluate health-related quality of life in adolescents with Idiopathic Scoliosis. The study aimed to undertake the process of cultural adaptation of the ISYQOL questionnaire into Simplified Chinese.

Methods: The translation from Italian into Simplified Chinese was performed. It involved 138 adolescents whose Cobb angle ranged between 20-40 degrees, 50 wearing the brace and 88 not wearing the brace. Statistical analysis calculated the reliability, floor and ceiling effects of the ISYQOL. After that, construct validity was measured by analyzing the ISYQOL relationship Scoliosis Research Society-22 patient Questionnaire (SRS-22).

Results: There were no floor or ceiling effects in ISYQOL questionnaire. Cronbach's alpha coefficient evaluated for Internal consistency was 0.75 without the brace and 0.88 with the brace. Intraclass correlation coefficients assessed with the use of the test-retest method was 0.72 without the brace and 0.80 with the brace. A strong relationship exists between the ISYQOL measure and SRS-22 scores (rho=0.63; $p< 0.01$), reflecting the high validity of the questionnaires. Both ISYQOL and SRS-22 scores showed no statistical difference between groups with and without the brace ($p>0.05$).

Conclusions: Trans-cultural validation in Chinses language showed the reliability and validity of the ISYQOL

Keywords: Quality of life, Adolescent idiopathic scoliosis, Cultural adaptation, Italian Spine Youth Quality of Life

Background

Adolescent Idiopathic Scoliosis (AIS) is a frequent pathology among adolescents, the prevalence of which is 1-2% [1]. Scoliosis itself and its treatment may have a severe impact on patients' health-related quality of life (HRQOL), although few patients are associated with severe complications.[2]. The need for a specific HRQOL measure in AIS has been recognized for a long time, which seems as important as radiologic measurements in evaluating treatment effect.[3] As a way of measuring HRQOL, self-administered questionnaires have become the most commonly used means to assess the patients' perspective of health. In 2017 Caronni et al. [4]proposed the ISYQOL questionnaire, showed high measurement properties in Rasch analysis. Further research has found this questionnaire of adolescents with spinal deformities better than SRS-22 questionnaire[5], which seems to be the most widely used as reference standard in the past[6]. ISYQOL was developed and validated in the Italian language. In order to be used in a different language speaking population, it has to be subject to a process called trans-cultural validation[7]. Reliability and validity of self-administered questionnaires must be evaluated In order to make it suitable for research and clinical practice[8]. Simplified Chinese is the contemporary Chinese primarily used in mainland China, Singapore, and Malaysia. The study was aimed to evaluate the reliability and validity of Simplified Chinese version of the ISYQOL (SC-ISYQOL) in adolescents with idiopathic scoliosis.

Methods

Questionnaire

ISYQOL Questionnaire is a 20 Likert scale items questionnaire and consisted of two domains (13 items of the spine health and 7 of the brace domains). The first version was designed to be administered to patients wearing the brace and consisted of both the spine health and brace domains (full questionnaire). The second version was designed to be administered to patients not wearing the brace and consisted of the spine health domain only. Scoring of the ISYQOL was planned as follows: Items investigating the presence of spine-related problems are coded 0, 1, or 2 (0, never; 1, sometimes; 2, often). Items investigating the presence of positive thoughts are coded 2, 1, or 0 (2, never; 1, sometimes; 0, often). The ISYQOL total score is obtained by adding up all single items, and the lower the category, the better quality of life. Using Rasch analysis, the ordinal ISYQOL total score is converted to an interval measure (i.e. ISYQOL measure), which is expressed on a 0%–100% scale (with 100% indicating great quality of life). ISYQOL measure can be used to compare the HRQOL of patients with or without the brace, who filled in different versions of the questionnaire. SRS-22 comprises 5 domains (Function, Pain, Mental Health, Self-Image, Management Satisfaction/Dissatisfaction) up to a total of 22 items. The score ranges from 1 to 5 points for each item, with a summary score between 22 and 110[6]. Higher scores are better quality of life. In our study, we used Simplified Chinese validated version of SRS-22 (SC-SRS-22)[9, 10].

Translation

We followed widely accepted guidelines described by Guillemin for translation and cross-cultural adaptation of ISYQOL questionnaires[6, 7]. In the first stage, two independent

translators converted the original Italian text into Simplified Chinese. One of the translators, who had a medical background, was instructed on the whole process of adaptation. The other translator had no medical background and received no information on the project. The second stage consisted of a comparison of the original and two translated versions. During that stage, the two translators and the authors identified differences in translations and produced a combined version. In the third stage—the so-called reversed translation— two independent translators, who were native in Italy, translated the Simplified Chinese version into the language of the original document (Italian). The translators were not familiar with the original version. The objective of this stage was to assure the equivalence of the two versions and to identify possible mistranslations. At the last fourth stage, a commission composed of a specialist in orthopedics, translators, a statistician, and a psychologist reviewed the translations. As a result of consensus, the so-called pre-final version SC-ISYQOL was drafted.

Sample
The study took place from February 2019 to November 2019 with approval of the local Hospital Ethics Committee. After obtaining patients and their guardians ' consent, we administered the SC-ISYQOL and SC-SRS-22 questionnaire to Chinese adolescents age 10-18 years with idiopathic scoliosis at the end of the clinical visit. The study included 138 consecutive patients whose Cobb angle ranged between 20-40 degrees and without a history of spine surgery. A dedicated research assistant was responsible for ascertaining the on-site completion of all questionnaire items by the participants during their office visits. We randomly selected 70 patients for the test-retest, with 12-16 days in interval. Among them, fifty patients wearing the brace who were treated with the same kind of brace for at least 4 months, at least 10 h per day filled out the full questionnaire, while 88 patients not wearing the brace filled out the spine health domain only.

Statistical analysis
Statistical analysis was performed using Statistics 26.0 software. Firstly, descriptive statistics were used to calculate mean scores and standard deviations for a given question and a domain. The second level was comparative, concerning reliability and validity. The two most important properties of reliability are consistency and stability. Internal consistency was assessed using Cronbach's alpha coefficient. Test-retest design was used to measure the temporal stability of the questionnaire with intraclass correlation coefficient (ICC). Construct validity assessed by comparing ISYQOL measure with SRS-22 through Spearman rank correlation coefficient (r). The independent sample t test was used to compare the differences in quality of life scores between the two groups with or without braces.
For all tests, statistical significance was set at $p < 0.05$.

Results

The sample included 113 girls and 25 boys, whose mean age at the time of questionnaire administration was 13.7 years (±2.3 years). Because patients with or without braces filled out different versions of the ISYQOL questionnaire, they were divided into two groups, brace group and no brace group. The Cobb angle ranged between 21.1-38.5 degrees, and for demographic and clinical characteristics details, see Table 1.

There are 16 (0.6%) missing values in all questionnaires, and we use mean to fill in missing values in this study. A dedicated research assistant ensures better questionnaire quality. Mean, median, minimal, maximal score, standard deviation and interquartile range of ISYQOL are presented in Table 2. The mean score for ISYQOL was 8.5 (ranged between 1-20) without the brace and 14.2 (ranged between 2-33) with the brace. Because first version has more questions than second version, the scores of the two groups are not comparable. There are no floor and ceiling effects in ISYQOL questionnaire in both versions.

Mean, standard deviation, number of options for each ISYQOL question are presented in Table 3. Mean values for individual ISYQOL items ranged from 0.3 (Item 6 and 13) to 1.1 (Item 1, 9 and 20). More than 70% of patients selected "often" in Item 6 and 13. They are "Despite your back problem, is your life normal?" and "Despite your back problem, do you live a happy life?"

The value of Cronbach's alpha is presented in Table 4. In no brace version, Cronbach's α coefficient was 0.75 in the spine health domain. In brace version, Cronbach's α coefficient was 0.88，with 0.85 in spine health domain and 0.86 in brace domain. All of them indicated excellent internal consistency reliability.

Fifty percent of patients or more retested both versions of the questionnaire. ICC assessed was 0.72 in no brace version and 0.80 in brace version. Both versions indicated excellent temporal stability[11].

ISYQOL measure is possible to compare patients not wearing the brace (who fill 13 out of 20 items only) with wearing the brace (who fill the full questionnaire). Mean, standard deviation for ISYQOL measure and SRS22 scores are presented in Table 5. The Spearman rho between ISYQOL measure and SRS-22 scores was 0.63 with highly significative value (p<0.001) Moreover, we used the ISYQOL measure (p=0.425) and SRS-22 scores (p=0.229) to compare the difference in HRQOL between brace group and no brace group. Both scores showed no statistical difference between groups with and without braces.

Discussion

HRQOL in patients with a spine deformity can be decreased for several reasons, especially in adolescents[12, 13]. For example, AIS can lead to physical, psychological, and social impairments that eventually have an impact on HRQOL[12]. Besides, conservative treatment of scoliosis with a rigid brace can be negative to affect their QOL. [14]

In this study, patients wearing the brace would take X-rays with and without the brace. We measured Cobb angle from X-rays without the brace, and strictly chose patients with Cobb angle ranging between 20-40 degrees, making the sample included in the study fitted the indications for braces for AIS. When evaluating the effect of brace treatment, not only the changes in the degree of scoliosis in radiologic measurements, but also the changes in QOL must be considered[14]. In turn, QOL is closely related to patients' compliance with brace treatment and depends on the conservative treatment effect[15, 16].

ISYQOL questionnaire was designed to evaluate the HRQOL of adolescents with idiopathic scoliosis. Some papers perceived the need to use disease specific questionnaires Instead of generic questionnaire[17-19]. From the total questionnaire score, 0% of patients scored at floor and 0% scored at ceiling, showing no floor and ceiling effects.

Cronbach's alpha is the most commonly applied statistical parameter for showing the internal consistency of an instrument [20]. The SC-ISYQOL had a high value of Cronbach's alpha coefficient (0.88 and 0.75), whether wearing brace or not, exceeding the minimum recommended value of 0.70 and indicating satisfactory internal consistency as a factor of satisfactory reliability of the SC-ISYQOL.

Intraclass correlation coefficients（ICC）of the SC-ISYQOL assessed with the use of test–retest method was 0.72 without brace and 0.80 with brace, showing a good temporal stability.

There are some questions designed for wearing the brace in ISYQOL questionnaire. ISYQOL measure can convert scores of with and without the brace to standard measurement, so that is used to compare the total score of the two versions. It is good for evaluating the changes of HRQOL before and after brace treatment.

Criterion validity is the correlation of a scale with a valid, accepted universally acknowledged measure of the trait or disorder under study. The outcome measures for construct validity were adopted SRS-22, most widely used as reference standard in the past, in order to evaluate the relationship with another patient-oriented questionnaire not focused on brace therapy. The results of the current study showed that a strong relationship exists between the ISYQOL measure and SRS-22 scores (rho=0.63; p< 0.01), reflecting the high validity of the questionnaires. This relationship was also found in the study by Caronni al.[5], with rho= 0.71 and p<0 .01.

There is no difference in HRQOL between brace group and no brace group, whether through ISYQOL or SRS-22. Earlier reports reported that braces have impacted HRQOL may due to factors such as stiffness of brace[14], but it did not appear in this study. This may be related to the 3D printing brace applied in the hospital. This brace fits the patient's body design and is custom-made by 3D printing, having good fit and comfort. However, this is a cross-sectional study, with different sample of the 2 groups. This view needs to be followed up and compared by the same person's QOL score before and after brace treatment.

In our study, there are limitations such as cross-sectional design and the single clinical center available in the cross-cultural adaptation process. The ISYQOL questionnaire needs to be promoted and applied in clinical and research, and multi-center cooperation has been obtained for further confirmation.

Conclusion

To conclude, the culturally adapted Chinese version of the ISYQOL showed excellent reliability, high internal consistency and satisfactory concurrent validity. This instrument is therefore useful as a clinical evaluation tool for Chinese scoliosis patients.

Table 1 Participants' demographics and clinical data

	No brace	Brace	Total
N	88	50	138
Males vs. females, N	21 vs 67	4 vs 46	25 vs 113
Mean age (SD), years	13.6 (2.3)	13.9 (2.3)	13.7 (2.3)
Mean body weight (SD), kg	47.5 (12.9)	46.4 (9.0)	47.1 (11.7)
Mean height (SD), cm	160.3 (11.5)	160.5 (13.5)	160.4 (12.2)
Cobb angle, Min-Max	21.1-38.5	26.9-33.7	21.1-38.5
Test-retest, N	44	26	70

N: number of participants; SD: standard deviation; Min: minimal; Max: maximal

Table 2 Mean, median, minimal, maximal score, standard deviation and interquartile range of ISYQOL

Questionnaire	Mean	SD	Min	Max	Median	IQR
No brace	8.5	4.2	1	20	9	6
Brace	14.2	7.4	2	33	13.5	11

SD: standard deviation; Min: minimal; Max: maximal; IQR: interquartile range

Table 3 Mean, standard deviation, number of options for each ISYQOL item

Item	No brace Mean	SD	number% 0	1	2	Brace Mean	SD	number% 0	1	2
1	1.1	0.6	11	68	20	1.1	0.5	8	74	18
2	0.8	0.6	30	59	11	0.5	0.6	54	40	6
3	0.6	0.6	50	43	7	0.6	0.7	52	38	10
4	0.9	0.6	26	63	11	0.8	0.7	34	50	16
5	0.5	0.7	59	31	10	0.6	0.7	54	34	12
6	0.4	0.6	74	17	9	0.3	0.6	72	22	6
7	0.5	0.6	55	40	6	0.5	0.6	54	40	6
8	0.8	0.7	34	50	16	0.8	0.6	26	66	8
9	1.1	0.6	18	58	24	1.1	0.6	12	64	24
10	1.0	0.6	22	61	17	0.8	0.7	32	52	16
11	0.6	0.8	56	28	16	0.6	0.8	60	24	16
12	0.8	0.8	39	41	20	0.9	0.8	42	30	28
13	0.4	0.6	66	27	7	0.3	0.6	76	16	8
14						0.7	0.7	46	38	16
15						0.9	0.8	34	40	26
16						0.8	0.6	30	62	8
17						0.8	0.7	34	50	16
18						0.4	0.6	64	28	8
19						0.4	0.6	64	28	8
20						1.1	0.7	16	56	28

Table 4 The value of Cronbach's alpha

Questionnaire	Cronbach's alpha
No brace	0.75
Brace	0.88
spine health domain	0.85
brace domain	0.86

Table 5 The mean and standard deviation for ISYQOL measure and SRS22 scores

	ISYQOL measure (%)	SRS22 scores
Total	56.7 (11.0)	90.9 (9.3)
No Brace	56.2 (11.0)	91.6 (8.5)
Brace	57.7 (11.1)	89.6 (10.5)

Mean (Standard deviation)

List of abbreviations

ISYQOL	Italian Spine Youth Quality of Life
SRS-22	Scoliosis Research Society-22 patient Questionnaire
AIS	Adolescent Idiopathic Scoliosis
HRQOL	Health-related quality of life
SC-ISYQOL	Simplified Chinese version of the ISYQOL
SC-SRS-22	Simplified Chinese validated version of SRS-22
ICC	Intraclass correlation coefficient

Declarations

Ethics approval and consent to participate
Permission to perform the study was obtained from the Clinical Research Ethics Committee of the Peking University Third Hosiptal.

Consent for publication
Not applicable.

Availability of data and materials
Data can be shared upon contact with the correspondence author.

Competing interests
The authors declare that they have no competing interests.

Authors' contributions
Shanshan Liu, Junyang Liang, Nanfang Xu, Miao Yu, Yan Zeng and Zhongjun Liu participated in the conception and design of the study. Nanfang Xu, Shuo Mai, Qi Wang, Chaojun Du and Yaoxu Du participated in the acquisition of data. Shanshan Liu, Junyang Liang, Nanfang Xu and Lin Zeng participated in the analysis and interpretation of data. Shanshan Liu and Junyang Liang wrote the draft of the manuscript. All authors critically revised the manuscript for important intellectual content and approved the final version to be published.

Authors' information
Not applicable.

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