Reliability and Validity of Chinese Version of Brace Questionnaire for Adolescent Idiopathic Scoliosis: A Cross-Sectional Study

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Research Article

Abstract

Background: There is an increasing concern about the impact of bracing on the quality of life (QoL) of patients with adolescent idiopathic scoliosis (AIS). However, up to now, few multidimensional questionnaires on this impact are available in China. This **cross-sectional** study aimed to evaluate the reliability and validity of the Chinese version of Brace Questionnaire (C-BrQ).

Methods: The BrQ was translated from Greek into Chinese with proper cross-cultural adaptation.

An observational, cross-sectional study in Chinese patients with AIS was conducted to measure the temporal stability of C-BrQ using the intraclass correlation coefficient (ICC). The effects of ceiling and floor were evaluated and the reliability was verified by examining the internal consistency. The C-BrQ domains were compared with the domains in C-SRS-22 using Pearson's correlation coefficient to assess the concurrent validity.

Results: A total of 208 patients were included in the study. The results of test-retest reliability for each dimension of C-BrQ were desirable. The floor or ceiling effects were not demonstrated in the C-BrQ and C-SRS-22. Satisfactory internal consistency was found in all the C-BrQ domains. Most C-BrQ and C-SRS-22 domains showed satisfactory correlation coefficients, except when vitality and school activity in C-BrQ were compared with self-image, mental health and management satisfaction in C-SRS -22, respectively.

Conclusion: C-BrQ is reliable in evaluating the QoL of AIS patients receiving brace treatment.

Trial registration: This study protocol was registered with the Chinese Clinical Trial Registry (Registration number: ChiCTR1800018310).

1. Background

Adolescent idiopathic scoliosis (AIS), a complicated and progressive deformity, compromises the patients' physical and mental health, as well as their social adaptation.[1] Bracing, as a commonly used conservative therapy to prevent curve progression, often lasts for years and can also produce stress on the patients[2].

According to the consensus reached by the Scoliosis Research Society (SRS) and International Scientific Society on Scoliosis Orthopaedic and Rehabilitation Treatment (SOSORT),[3] a systematical clinical report of conservative treatment should focus on the patient's outcomes (e.g. appearance, disability, pain and quality of life) and predictable ones, like clinical and radiological outcomes. The patients' quality of life (QoL) should be considered when assessing the outcomes of AIS treatment.

However, only three questionnaires (SRS-22,[4] BSSQ-Deformity and BSSQ-Brace[5]) are now being used in China to assess the QoL of AIS patients. The SRS-22, adapted into Chinese to make comprehensive evaluation of health-related QoL for scoliosis patients, has shown good reliability and validity, as well as

desirable score distribution, internal consistency, reproducibility and concurrent validity. Weiss et al.[6] developed two questionnaires to monitor the severity of deformity-induced stress (Bad Sobernheim Stress Questionnaire Deformity, BSSQ-Deformity) and bracing-induced stress (Bad Sobernheim Stress Questionnaire Brace, BSSQ-Brace).[7] Nevertheless, none of these questionnaires involves the assessment of the overall QoL.

Brace Questionnaire (BrQ), originally developed and validated in Greece, has been translated into different languages[8-12] and shown excellent reliability and validity. BrQ contains 34 Likert scale items and covers eight domains to measure QoL of AIS patients receiving bracing treatment. Since BrQ has not been formally adapted into Chinese and there is urgent need to prove its effectiveness in both clinical practice and research, we designed the present study to evaluate the reliability and validity of the Chinese version of BrQ (C-BrQ).

2. Methods

2.1 Study design

A single-center, cross-sectional trial was conducted to evaluate the reliability and validity of the C- BrQ. This study included AIS patients from all over the country. They were recommended by the spine surgery department of the local hospital to come to our clinic because they did not meet the surgical indications. The diagnosis was made by the attending physicians of our institution based on standardized diagnostic assessment results, including history, physical examination and X-ray.

2.2 Participants and sample size

The target population for this study was patients with moderate AIS who met the current indications: age 10 to 17 years, a cobb's angle between 25°and 40°, skeletal immaturity with a 0-3 Risser stage and wearing a brace for at least 3 months. Study exclusion criteria were unwillingness to participate, previous scoliosis fusion surgery, psychiatric disorders, mental retardation and previously received other types of brace. In addition, subjects with incomplete questionnaires were not included.

According to the guidelines of COSMIN Risk of Bias checklist, the sample size should be more than 100 cases. And considering that it should be seven times of 34 items of continuous variable, the sample size was determined to be 250.

2.3 Adaptation of BrQ

BrQ contains 34 Likert scale items and covers eight domains (including general health perception, physical functioning, emotional functioning, self-esteem and aesthetics, vitality, school activity, bodily pain and social functioning). It is specifically designed for children and adolescents between 9 and 18 years old to fulfill by themselves. The scoring of BrQ is as follows:

– For items 4, 5, 6, 12, 14, 15, 16 and 17: "Always", 5 points; "Most of the time", 4 points; "Sometimes", 3 points; "Almost never", 2 points; "Never", 1 point.

– For items 1, 2, 3, 7, 8, 9, 10, 11,13, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27, 28, 29, 30, 31, 32, 33 and 34: "Always", 1 point; "Most of the time", 2 points; "Sometimes", 3 points; "Almost never", 4 points; "Never", 5 points.

The score for each item is multiplied by 20, and the total score of the 34 items is divided by 34. Therefore, the minimum score is 20, and the maximum score is 100. The higher the score is, the better the QoL is. The total score of a domain can be divided by the number of items it comprises to obtain the subscale score of each domain[13].

The BrQ was adapted according to the International Quality of Life Assessment (IQOLA).[15] Two translators independently translated the original version from Greek into Chinese. One translator specializing in medical translation was in charge of the whole adaptation process. The other translator with no medical background was blind to the project. Then, the two translators and the authors of this paper compared the two translated versions and combined them into one. Next, two Greek translators who were unfamiliar with the original version translated the combined Chinese version back into Greek to ensure the two versions were equivalent and pinpoint the mistranslations. Lastly, a committee consisting of orthopedic experts, translators, statisticians and psychologists co-examined the Chinese version. After reaching a consensus, the Chinese version of BrQ (C-BrQ) was established.

2.4 Prefinal version test

A preliminary experiment was carried out before the formal study. During the first pilot study, 28 Chinese-speaking AIS patients (25 girls, 3 boys) aged 10-17 years completed the preliminary version of C- BrQ in the Department of Sports Medicine of Guangzhou Sport University. The patients filled out a standardized feedback form about unclear phrases and understanding difficulties in the C-BrQ. In case of ambiguity, the expert committee rephrased the expressions in the questionnaire based on the comments, and then conducted further investigation and review. All ambiguities were solved in the final version of the questionnaire. After the pilot study, the majority of the subjects understood and completed all questions in the questionnaire within 10 minutes. The expert committee made minor changes in three questions (28,29, 30) based on the results of the interview. The "friends" and "peers" in questions 28/29/30 of the questionnaire were changed into "classmates", because 10-year-old children tended to think that the concepts of friends and classmates in school were similar. A second pilot study among 14 participants showed no further equivocality and so this version emerged as the final one. Subjects in these pre-trials were also included in the final part of the study.

2.5 Measurement of outcomes

A total of 250 AIS patients, who underwent the Chêneau brace treatment from the outpatient clinic of Guangzhou Sport University between June 18, 2019 and August 20, 2020, were surveyed in the study.

Informed consents were obtained from the participants and their parents. All participants were asked to complete C-SRS-22 and C-BrQ independently in the waiting room of the clinic before meeting the orthopedist. During further review, 6 cases were diagnosed with scoliosis of other causes (such as syringomyelia, unequal length of lower extremities, etc.), 9 cases had a Risser sign greater than grade 3, 3 cases were with cobb's angle greater than 40°, and 15 cases were incomplete. Therefore, 217 cases were finally included in the study.

C-SRS-22 is the Chinese version of SRS-22 and its reliability and validity has been proved.[4] It contains 5 dimensions: function activity level, pain, mental health, self-image and management satisfaction. A 5-point scale ranging from "1" to "5" is applied in each item. The total score ranges from 22 to 110 points; lower scores are associated with poorer QoL.[14]

All participants underwent two tests. To avoid the memory effect, the two tests had a 7-day interval. For those who did not complete the second questionnaire, their responses in the first questionnaire were excluded from the test-retest reliability analysis but used for other analyses in the study.

2.5 Statistical analysis of data

Demographics and characteristics of the participants were summarized using frequency and percentage; mean and standard deviation(SD) were used appropriately. A test−retest design was used to measure the temporal stability of each domain with the intraclass correlation coefficient (ICC). ICCs between 0.70 and 0.80, and >0.80 indicated good and excellent reliability, respectively. Then, as for content analysis, data were investigated (mean, SD, and range) and evaluated for outliers. The floor and ceiling effects (>10% of the possible minimum and maximum scores) were calculated. To assess the reliability, Cronbach's alpha was used to evaluate the internal consistency of each domain in C-BrQ and C-SRS-22. Poor internal consistency was suggested if Cronbach's alpha was <0.70; 0.70-0.80 indicated good internal consistency; and >0.80 showed excellent internal consistency. Then, the C-BrQ domains were compared with the C-SRS-22 domains using Pearson's correlation coefficient to assess the concurrent validity. The Pearson's correlation coefficients of less than 0.50, 0.50 -0.70, and more than 0.70 indicated poor, good, and excellent concurrent validity, respectively.

The level of statistical significance was set at 0.05. Statistical Package for the Social Sciences (SPSS) version 20.0 (IBM Corp, Chicago, IL) was applied for statistical analyses.

3. Results

3.1 Sample characteristics

The patient came from the eastern, southern, central, northern, northwest, southwest, and northeastern regions of China. Table 1 displays the patients' clinical characteristics. The mean age (SD) of the participants at the completion of the questionnaire was 11.86 years (2.65 years). 191 (88.0%) were females and 72(33.2%) of them have menarche. The mean(SD) BMI was 15.9(2.81). The mean Cobb's

angle was 32.7(5.35). The mean (SD) duration of wearing the brace was 7.4 (3.15) months and the bracing time was17.5 (3.12) hours per day. The distribution of classification was as follows: 22(10.1%) of Lenke I, 41(18.9%) of Lenke II, 66(30.4%) of Lenke III, 56(25.8) of Lenke IV, 21(9.7%) of Lenke V, and 11(5.1%) of Lenke VI. Among these subjects, 56 cases (25.8%) had Risser grade 0, 82 grade 1 (37.8%), 68 grade 2 (31.3%), and 11 grade 3(5.1%).

No participants had difficulty in comprehension when filling out the questionnaires.183 (84.3%) of the patients completed and submitted the second C-BrQ one week later. In the first test, the mean score (SD) of C-BrQ was 77.8 (9.8) points, while in the second one, it was 79.2(10.5) points. The mean (SD) durations of fulfilling the questionnaire were 8.5 minutes (2.01 minutes) and 8.2 minutes (1.87minutes), respectively.

3.2 Ceiling and floor effects and reliability

As shown in Table 2, the ICC value of C-BrQ was good in Bodily pain domain (0.78) and excellent in other domains (> 0.80). Value of Cronbach's alpha of the C-BrQ calculated using the test–retest method was compared with the Polish, French, Turkish, Korean and Greek versions (Table 3).

The mean value ranges, standard deviations and C-BrQ and C-SRS-22 scores are listed in Table 4. For all the patients, no floor or ceiling effect was demonstrated in the domains of both C-BrQ and C-SRS-22. The internal consistency of the C-BrQ and C-SRS-22 domains that consisted of more than one item is shown in Table 4. Good internal consistency was found in the C-BrQ domains including general health perception, emotional functioning, vitality, school activity, bodily pain and social functioning (Cronbach's alpha from 0.70 to 0.79), and excellent internal consistency in the domains of physical functioning (0.83), self-esteem and aesthetics (0.85). For C-SRS-22 domains, excellent internal consistency was found in domains of function (0.82) and good performance in pain (0.79), self-imageand(0.72) , mental health (0.75) and satisfaction with management (0.74).

3.3 Concurrent validity

Most C-BrQ and C-SRS-22 domains, showing close correlations with the correlation scores ranging between 0.51 and 0.83, all lower than the 0.05 significance level, except for vitality and school activity in C-BrQ and pain, mental health and management satisfaction in C-SRS -22, which exhibited poor correlations (Table 5).

4. Discussion

The impact of scoliosis on health-related QoL has aroused great concern and thus been investigated by several authors.[16, 17] Conservative treatment of adolescent scoliosis using rigid braces could exert severe negative impacts on the patients' QoL and even affect their compliance and rehabilitation. Bracing can be stressful for patients and often takes a long time. Therefore, it is crucial to enhance the patients' compliance and reduce the negative impacts of bracing on patients. Effective evaluation the patients'

QoL is the first step to solve this problem. BrQ is the first multidimensional questionnaire specifically designed and tested to evaluate the QoL of AIS patients treated with braces.

In the current study, the time spent in answering the C-BrQ was acceptable. Statistical analysis revealed that patients *had* good stability at weekly intervals. The questions in C-BrQ were not difficult for patients to understand, which contributed to a satisfactory recovery rate of the questionnaires. C-BrQ showed a favorable reproducibility because the patients had almost no difficulty in recognizing the questions related to bracing. Unlike previous instruments[18,19,20,21,22], C-BrQ subdivides the function/activity domain into sports activities, social activities, and school functions, so that the patients could understand the impact of brace treatment on life more easily.

According to the present study, the total score of C-BrQ had no floor or ceiling effects, suggesting the generally satisfactory reliability of C-BrQ. The high Cronbach's alpha coefficient of C-BrQ (0.83) indicates its consistency and reliability. The original Greek version of BrQ has a Cronbach's alpha coefficient of 0.82. The Polish and Turkish versions have a coefficient of 0.94, and the coefficient of the Korean version is 0.87, which further confirms the reliability of C-BrQ.

With regard to validity, most domains of the C-BrQ were acceptably correlated to the C-SRS-22 and the results were similar to those by Angelo AG [9], and Lim and Gür G et al.[11,12] In our research, all Lenke subtypes were covered in the participants' clinical characteristics. However, the sample size was small and Lenke classification was not used to classify participants in the previous studies, which might explain the Cronbach's alpha coefficient of our study was different from that in those studies. The physical function, school activity and social function, domains in C-BrQ were well correlated with function of C-SRS-22, and the self-esteem and aesthetics domain was well connected with the self-image of C-SRS-22. Although SRS-22 was most commonly used to evaluate scoliosis patients'QoL,[18] specific questions concerning the impacts of conservative bracing on health-related QoL for AIS patients were not included. This may explain why the domains of vitality and school activity in C-BrQ were poorly correlated with domains of self-image, mental health and management satisfaction in SRS-22. Overall, our study demonstrated that C-BrQ was reliable and valid in detecting the QoL of AIS patients, although further longitudinal studies with large and heterogeneous samples are still needed to test its sensitivity.

Although the results have confirmed the validity and reliability of C-BrQ, this study has several limitations. Firstly, some patients with large Cobb's angle were not included in the survey because they were unwilling to receive surgical treatment and had to wear the brace. Secondly, although evidence in the present study supports that C-BrQ is reliable and valid in evaluating QoL of AIS patients treated with bracing, whether C-BrQ could be applied to scoliosis of other causes and other types of braces (e.g., Boston, Milwaukee) requires further verification. Finally, we did not analyze the values of the missing responses, though a relatively small proportion of missing responses would not have produced inordinately biased outcomes. The limitations mentioned above should be considered and a longitudinal study of a longer term should be carried out in the future.

5. Conclusion

C-BrQ, as a new multi-dimensional instrument, provides a reliable and valid means of measuring outcomes in patients with AIS wearing brace, which could potentially benefit the clinical research and practice. A longitudinal follow-up study on the application of C-BrQ in evaluating the QoL of AIS patients should be conducted in the future.

Abbreviations

AIS
adolescent idiopathic scoliosis; BQ = Brace Questionnaire; C-BrQ = Chinese version of Brace Questionnaire; C-SRS-22 = Chinese version of Scoliosis Research Society-22 Outcomes Questionnaire;QoL = quality of life; ICC = intraclass correlation coeffificient.

Declarations

Ethics approval and consent to participate All methods were carried out in accordance with relevant the Declaration of Helsinki. Ethical approval was obtained from human subject review board of Guangzhou Sport University (approval number: 2018LCLL-008) .Informed consent was authorized from each patient or legal guardian prior to recruitment.

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Authors' contributions

All authors have read and approved the manuscript. Conceptualization and methodology: :Bagen Liao.Data curation:Xiaohui Zhang,Dong wang.Investigation: Dong Wang,Mengqi Yao, Rudan Wan.Project administration: Mengqi Yao, Rudan Wan.Statistical analysis:Xiaohui Zhang.Writing-original draft: :Xiaohui Zhang,Bagen Liao.

Competing interests

The authors declare that they have no competing interests.

Availability of data and materials

The datasets generated and/or analyzed during the current study are available from the corresponding author by reasonable request.

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Tables

Table 1

Clinical characteristics of the study subjects

Clinical characteristics	AIS patients (n = 217)
Age (SD)	11.86 (2.65)
Women (%)	191 (88.0)
Postmenarchal (%)	72 (33.2)
BMI (SD)	15.9 (2.81)
Cobb angle (± SD)	32.7 (5.35)
Curve type	
Lenke I (%)	22 (10.1)
Lenke II (%)	41 (18.9)
Lenke ▯(%)	66 (30.4)
Lenke ▯(%)	56 (25.8)
Lenke ▯(%)	21 (9.7)
Lenke ▯(%)	11 (5.1)
Risser stage	
0(%)	56(25.8)
I (%)	82(37.8)
II (%)	68(31.3)
III (%)	11(5.1)
Duration of wearing brace (months, SD)	7.4 (3.15)
Average bracing time per day (hours, SD)	17.5(3.12)

AIS=adolescent idiopathic scoliosis;

n=number of participants;

Data are represented as the mean±standard deviation;

% = percentage;

BMI= body mass index.

Table 2

Test/retest reproducibility of each domain as determined by ICC (n = 183)

C-BrQ domain	ICC
General health perception	0.82
Physical functioning	0.86
Emotional functioning	0.91
Self-esteem and aesthetics	0.83
Vitality	0.81
School activity	0.83
Bodily pain	0.78
Social functioning	0.85

Table 3

Value of Cronbach's α in Chinese version of BrQ compared with other languages

BrQ	Cronbach's α
Chinese	0.83
Polish	0.94
French	0.85
Turkish	0.94
Korean	0.87
Greek (original)	0.82

Table 4. Descriptive statistics and internal consistency of the C-SRS-22 and C-BrQ domains （n=217）

Domains	Minimum	Maximum	Mean	SD	% With floor effect	% With ceiling effect	Cronbach's α
C-BrQ						4	
General health perception	3	10	6.5	1.3	0		0.76
Physical functioning	15	35	22.3	4.6	0	3	0.83
Emotional functioning	6	25	13.2	3.6	0	2	0.79
Self-esteem and aesthetics	4	10	6.2	1.4	0	3	0.85
Vitality	3	10	6.5	1.3	0	1	0.78
School activity	3	15	9.6	2.1	0	4	0.73
Bodily pain	14	29	21.5	3.6	0	0	0.76
Social functioning	8	30	24.5	5.2	0	2	0.70
C-SRS-22						3	0.82
Function	13	25	13.2	2.5	0		
Pain	15	23	17.3	3.6	0	0	0.79
Self-image	14	25	15.9	4.4	0	4	0.72
Mental health	13	20	13.8	2.2	0	4	0.75
Satisfaction with management	4	10	6.5	1.7	0	5	0.74

Table 5

Concurrent validity between the C-BrQ and SRS-22 domains (n = 217)

C-BrQ domains	C-SRS-22 domains				
	Function	Pain	Self-image	Mental health	Satisfaction with management
General health perception	0.57*	0.53*	0.75*	0.74*	0.73*
Physical functioning	0.83*	0.56*	0.68*	0.63*	0.76*
Emotional functioning	0.75*	0.63*	0.73*	0.66*	0.69*
Self-esteem and aesthetics	0.66*	0.69*	0.85*	0.69*	0.71*
Vitality	0.65*	0.56*	0.45	0.31	0.29
School activity	0.82*	0.53*	0.38	0.25	0.35
Bodily pain	0.67*	0.77*	0.74*	0.65*	0.66*
Social functioning	0.85*	0.64*	0.76*	0.72*	0.75*

* Significative value: p < 0.05

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