Progress of Applied Research on Patient-reported Outcomes in Adolescent Idiopathic Scoliosis

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Abstract

This paper mainly reviews patient-reported outcome assessment tools for adolescent idiopathic scoliosis at home and abroad and their application status in the field of adolescent idiopathic scoliosis, aiming to provide references for further development of patient-reported outcome assessment tools for adolescent idiopathic scoliosis in China and selection of appropriate assessment tools for clinical staff.

Keywords

Adolescent idiopathic scoliosis (AIS), patient-reported outcomes (PROs), assessment tools, review.

1. Introduction

Adolescent idiopathic scoliosis (AIS) is a three-dimensional spine deformity characterized by coronal, sagittal curvature and rotation of the longitudinal axis of the body that develops in adolescents 10 years of age and older [1]. As the most common type of scoliosis, AIS has no clear etiology or underlying pathology and affects approximately 2%-4% of adolescents, with a higher prevalence in females than males [2, 3, 4]. AIS causes patients to present with abnormal posture, resulting in discomfort or pain, affecting their quality of life, mental health, and social integration, increasing the family and social economic load, and posing major challenges for healthcare [5, 6]. The routine use of patient-reported outcomes (PROs) in clinical care may help identify relevant patient needs, improve patient/family communication, quality management, outcome evaluation, and patient outcomes [7]. Research shows [8] that the number of patient-reported outcomes studies in China has been increasing in recent years but is still in its infancy. Therefore, this study searched for patient-reported outcome measures (PROMs) applicable to AIS patients at home and abroad, analyzed the content, advantages and disadvantages, and clinical applications of the tools in order to provide the basis for the development of AIS patient localization PROM in China, and selected appropriate PROs for clinical decision-makers.

1.1. An Overview of Patient-reported Outcomes in Adolescent Idiopathic Scoliosis

Overseas study shows that adolescent patients over 10 years old with normal cognition have the need and ability to participate in treatment decision-making and also the desire to express their preferences and wishes [9].AIS patients are in this important period of physical and mental development, self-awareness, and independence formation, but due to trunk deformity and other reasons, 32% of the patients have psychological problems, an increased anxiety level, and a risk of suicidal ideation [10-12]. Therefore, the effective management of AIS patients should be holistic care that can address the needs of all aspects of physical, psychological, and social care throughout the treatment stage [13]. PROs can reflect the real experience and feelings of the patients' treatment and express their related needs by collecting information directly from the patients themselves, which can provide information to support the decision-making of healthcare professionals [14, 15].

At present, there are a lot of PROMs available for AIS patients at home and abroad, and each has its own focus. Choosing accurate and comprehensive PROs can better reflect their real experience and feelings during treatment, help clinical healthcare professionals better evaluate health-related quality of life (HRQoL) or other related outcomes, provide evidence support for patients to formulate treatment plans, and improve the quality of medical services.

2. Patient-reported Outcome Measures for Adolescent Idiopathic Scoliosis

PROM is a tool or means of measuring PROs and is divided into universal and specific tools [16].

2.1. Universal Patient-reported Outcome Measures

Universal PROM applies to the general population or patients with different diseases, focusing on common problems and providing a more comprehensive assessment of individual health status on some dimensions, including the patient's symptomatic trouble, psychological trouble, and quality of life [17].

2.1.1. Short Form-36 Health Survey (SF-36)

In 1992, Ware et al [18] released its initial version, which covered both the general assessment of physical health and the general assessment of mental health, including 8 dimensions of physical pain, social functioning, daily mental status, ability to perform daily activities, vitality, mental health, general health, self-assessment of physical function, and 1 self-assessment of health change, with a total of 36 items and a scoring range of 0-100. The higher the score, the better the health status. In 2003, Li et al [19] translated into Chinese and tested the convergent and discriminant validity, which were satisfactory except for the social functioning scale. Cronbach's α coefficient ranges from 0.72 to 0.88, and the retest reliability coefficient ranges from 0.66 to 0.94. As a universal HRQoL scale, it has good validity in AIS-related studies and can be used for themultidimensional overall assessment of patients' HRQoL.With its high universality and cross-cultural applicability, it is often used as a scale to measure new questionnaires and is currently the most widely used quality of life assessment tool in the world. However, this scale has the problems of repeated questions, too long questionnaires, low sensitivity, and a lack of specificity for AIS patients.

2.1.2. European Quality of Life 5 Dimensions (EQ-5D)

In 1990, the EuroQol Group published EQ-5D-3L [20], and in 2011, Herdman et al [21] published EQ-5D-5L, which modified the EQ-5D health description section and increased the number of response options to 5. Both versions consist of a health description system and a visual analog scale,covering five dimensions of mobility, self-care, daily activities, pain/discomfort, and anxiety/depression. Both the Chinese version of EQ-5D-3L and EQ-5D-5L have been validated for equivalence compared to the English version, and have good reliability in the general and diseased population in China [22, 23]. A study by Cheung et al [24] demonstrated that EQ-5D-5L showed satisfactory psychometric properties in Chinese AIS patients. It is universal, convenient, and highly cross-culturally applicable, with a brief questionnaire and high response rate, and can be used to continuously monitor the course of the disease. It has been widely used in the quality of life evaluation of many chronic diseases and geriatric diseases in China. However, it has low sensitivity, lacks specific symptom assessment, and is mainly used to assess the cost and efficacy of spinal surgery in patients with scoliosis, and other application data are still lacking [25].

2.1.3. Oswestry Disability Index (ODI)

ODI was developed by Fairbank to evaluate the function and treatment of patients with chronic low back painin 1976 [26]. ODI 2.0, proposed by the UK Medical Research Council in 1989 [27], is currently the most widely used assessment scheme in the world. The original ODI includes five dimensions: pain level, living ability, daily activity, sleep, and social activity. A total of 10 items are divided into 6 levels and assigned 0 to 5 points. The total score is a percentage of the full score of 50, which is the Oswestry Disability Index, with 0% being normal, and the closer it gets to 100%, the more severe the disability is. In 2002, Zheng et al [28] made a cross-cultural adaptation and tested it. In 2017, Cheng et al [29] improved it further and tested that it has good compliance, reliability, and validity, or can improve the sensitivity of short-term efficacy evaluation and maintain the accuracy of medium and long-term efficacy evaluation, but later follow-up verification is needed.

In addition, some studies have applied the pain Visual Analog Scale (VAS) and the Numerical Rating Scale (NRS) to the assessment of single pain symptoms in AIS patients. Scholars also often use the SDQ-S, SAS and PHQ-9 to assess the psychosocial behaviors of AIS patients, including anxiety and depression.

2.2. Specific Patient-Reported Outcome Measures

Specific disease PROM is used to evaluate the characteristics of a specific disease and a specific population, is more sensitive to the outcome measurement, and has higher responsiveness, which can lay the foundation for the development of targeted intervention strategies.

2.2.1. Scoliosis Research Society (SRS) Questionnaire

Initially, Haher et al [30] developed the SRS-24 in 1999, which covers 7 dimensions of pain, general image, postoperative self-image, general function, overall activity level, postoperative function and satisfaction with a total of 24 items. The first 15 apply to all patients, and the last 9 are only to be answered for patients after treatment. It is simple and easy to answer and has good reliability and validity, but there are some limitations in its survey scope.

Later, Ashe et al [31] compiled the SRS-22 in 2003 and revised it in 2006 [32]. It covers subjective feelings in five dimensions,including pain, functional status, self-image, psychological status, and treatment satisfaction, with a total of 22 items. By using the Likert 5 scale, each item is assigned 1-5 points. The higher the total score, the better the quality of life of patients. In 2008, Li et al [33]conducted cross-cultural adaptation and reliability andbelieved that it was suitable for measuring the quality of life of Chinese AIS patients. The SRS-22 is one of the most widely used PROMs for evaluating the outcomes of AIS patients and as a multidimensional scale for the evaluation of the health-related quality of life of AIS patients. It has been widely used internationally to evaluate the impact of spinal deformity on the patient and the treatment outcome, and it is considered to be the gold standard for the measurement of HRQoL in scoliosis patients.

In 2014, Caronni et al [34] carried out Rasch analysis (RAS) on the SRS-22 and then developed the SRS-7, which better reflects the treatment goals and needs ofAIS patients. Jain et al [35] compared SRS-22 with SRS-7 and concluded that the SRS-7 scale is valid, reliable, and responsive, and is relatively more simple and suitable for the first HRQoL survey of AIS patients, but its indicator characteristics are still not ideal in large-scale surveys.

2.2.2. Quality of Life Profile for Spine Deformities (QLPSD)

QLPSD, developed by Climent et al [36] is the first questionnaire specifically designed to assess the quality of life of adolescents with spinal deformities. It covers 5 dimensions of psychosocial function, sleep disorders, back pain, body imagery, and back flexibility, with a total of 21 items utilizing the 5-point Likert scale, with a score range of 1-5 for each item and a total score range of 21 (i.e., best quality of life) to 105 (i.e., worst quality of life). Hu et al [37] translated and made cross-cultural adaptations, and found that the simplified Chinese version of QLPSD had good internal consistency. Cronbach’s α coefficient was 0.914, and the intra-group correlation coefficient (ICC) was within the range of 0.784 to 0.870, showing good retest consistency and repeatability, and the reliability was generally satisfactory. The main problem with this scale is that there is no significant correlation between its score and bending angle, which has long been regarded as the gold standard for evaluating the severity of lateral bending.

2.2.3. Spinal Appearance Questionnaire (SAQ)

The original 35-item SAQ questionnaire was developed based on the Walter Reed Visual Assessment Scale to specifically assess AIS patients’ opinions of the appearance of the spine [38]. In 2007, Sanders et al [39] simplified and adapted it into two parts: image and text representation, covering a total of 20 project areas, including 9 dimensions: trunk curvature, back bulge, trunk displacement, waist, shoulder level, kyphosis, chest deformity, postoperative scar, and the most concerned problems of patients. In 2012, Wei et al [40]translated the 20-item SAQ into Chinese and made cross-cultural adaptations. Cronbach’s α was 0.933, and the ICC value was 0.965, showing good internal consistency and retest reliability. Mulcahey et al [41] proposed that, compared to the SRS-22, the SAQ can provide more information on appearance and feelings through the combination of images and questions and can more sensitively assess patients’ postoperative quality of life. However, since teenagers may not understand the meaning of some contents, professionals should explain when using SAQ, which may affect patients’ judgment.

2.2.4. The Bad Sobernheim Stress Questionnaire (BSSQ)

In 2006, Weiss et al [42] constructed the BSSQ for assessing the stress levels ofAIS patients, including the assessment of Bad Sobernheim Stress Questionnaire Deformity (BSSQ-Deformity) and Bad Sobernheim Stress Questionnaire Brace (BSSQ-Brace). Each questionnaire contains 8 items,4 optionseach, assigned a score of 0-3, and further divided into three groups based on the total score: 0-8 (high pressure), 9-16 (moderate pressure), and 17-24 (low pressure); that is, the lower the score, the greater the psychological pressure of the patient. Xu et al [43] carried out cross-cultural translation and adjustment of the original BSSQ-Deformity and BSSQ-Brace and tested them. The results showed that the BSSQ adapted to the Chinese background and showed good clinical practicability, reliability, and structural validity. BSSQ-Deformity and BSSQ-Brace have excellent internal consistency, with Cronbach’s α coefficients of 0.85 and 0.80 and repeatability, i.e., intraclass correlation coefficients (ICC) of 0.85 and 0.90, respectively. The scale has the characteristics of strong psychological pressure, short time, simple question, easy return, and so on, which make it suitable for children and adolescents. However, the questionnaire has no relevant entries on the factors that have a great influence on patients’ lives, such as social interaction and family relationships, which is a certain defect.

2.2.5. Brace Questionnaire (BrQ)

BrQ was designed and compiled by Vasiliadis et al [44]in 2006, and its role is to evaluate the impact of brace therapy on the physical and mental health of AIS patients. The scale covers eight dimensions: general health perception, self-esteem and aesthetics, vitality, school activity, emotional functioning, somatic functioning, social functioning, and physical pain. The scale consists of 34 items and utilizes the 5-point Likert scale, where each item is assigned a score of 1-5 out of a possible 100, with lower scores indicating poorer quality of life. Yi et al [45] translated, adapted, and validated the BrQ. The Chinese version of the BrQ showed good internal consistency and excellent retest reliability, with a Cronbach's α coefficient of 0.891 and an ICC of 0.860. This scale has the role of monitoring the changes in the health of AIS patients. Aulisa et al [46] applied the BrQ, BSSQ, and SRS-22 to measure the quality of life of AIS patients treated with brace treatment and found that BrQ is more identifiable and has a clearer role in the assessment and selection of braces for treatment, but this questionnaire can only be used for patients receiving brace treatment.

2.2.6. Trunk Appearance Perception Scale (TAPS)

In 2010, the TAPS developed by Bago et al [47] mainly investigated the AIS patients' cognition of the body. It includes 3 groups of graphics depicting the torso from 3 angles, each group of 5 body appearance graphics; each graphic is assigned 1-5 points. The higher the score, the more mild the spinal deformity. The scale has satisfactory internal consistency, retest reliability, and adequate responsiveness, with a Cronbach's α coefficient of 0.89 and an ICC of 0.92 [48]. Its characteristics make it an effective tool for assessing the subjective perception of trunk deformity in patients with idiopathic scoliosis. It is simple and easy to score. However, it is rarely used in China and needs further study. TAPS is sensitive to changes after specific treatments. TAPS scores are similar in both genders, but there are obvious differences according to age, with younger patients having higher scores than adults.

2.2.7. Body Image Disturbance Questionnaire-Scoliosis (BIDQ-S)

The Body Image Disturbance Questionnaire (BIDQ) is a validated psychometric questionnaire containing seven items to measure body imagedisturbance in the general population. It also asks patients to describe negative experiences in detail. The questionnaire uses a rating scale from 1 to 5, with 1 indicating no concern at all for the patient's body image and 5 indicating very concern for the patient's body image. Auerbach et al [49] first verified the use of BIDQ-S specifically to study body intention disorder in AIS patients. In 2015, Bao et al [50] made cross-cultural adaptation and validated the BIDQ-S and concluded that the Chinese-adapted BIDQ-S's internal consistency was satisfactory, with a Cronbach's α value of 0.877. The results showed a stronger correlational regression relationship with body image disturbance and could better distinguish AIS patients from healthy people. The BIDQ-S can also be used to identify patients who may be at risk of psychosocial problems, thus referring them for mental health assessment and intervention and appropriately adjusting their AIS treatment strategies.

2.2.8. Italian Spine Youth Quality of Life (ISYQOL)

In 2017, Caronni et al [51] proposed the ISYQOL, which showed high measurement properties in Rasch analysis. As a new method to assess HRQoL in AIS patients, the questionnaire used the 3-point Likert scale and covered 20 items and 2 areas, including 13 items in the spinal health area related to scoliosis and 7 items in the stent area related to the impact of wearing a stent. In 2021,Liu et al [52] translated and made cross-cultural adaptations of it to simplified Chinese and evaluated it.In the unprocessed group and the brace treatment group, the Cronbach's α coefficient of internal consistency was 0.75 and 0.88, and the correlation coefficient in the retest method evaluation group was 0.72 and 0.80, respectively. The advantage of using the ISYQOL instead of the SRS-22 or other questionnaires is that the scale is more targeted by including specific questions for patients who use braces. The disadvantage of ISYQOL is that it is limited to different languages and has not been validated in a wide range of populations. Further studies have found that this questionnaire for adolescents with spinal deformities is better than SRS-22, and ISYQOL shows high validity when used to measure HRQOL in adolescents with spinal deformities.

The above commonly used specific patient-reported outcome measures were compared according to their main features, applicable age, assessment dimensions, advantages and limitations, as shown in Table 1.

Table 1: Comparison of the characteristics of commonly used specific patient-reported outcome measures

PROM	Main features	Applicable age	Assessment dimensions	Pros	Cons
SRS-22	Covering 5 dimensions of pain, function, and self-image and so on with 22 items, 5-point Likert scale	10-22 years	Pain, functional status, self-image, psychological status, treatment satisfaction	Widely used with good reliability and validity, it is considered the gold standard for measuring HRQoL in scoliosis patients	Some questions were highly subjective and the scope of investigation is limited
QLPSD	Covering 5 dimensions including psychosocial functioning, with a total of 21 items	Adolescents	Psychosocial functioning, sleep disorders, back pain, body imagery, back flexibility	Good internal consistency, good retest consistency and repeatability	No obvious correlation between score and scoliosis angle
SAQ	Combination of images and text, covering 9 dimensions and 20 items in total	Adolescents	Overall, trunk flexion, back bulge, etc.	Provides more Appearance perception information through the combination of images and questions with good internal consistency and retest reliability	Adolescents may not be able to understand it and need a professional explanation when using it
BSSQ	Contains two questionnaires including assessing deformity and brace treatment pressure, each with 8 items and 4 options for assigning points	Children and adolescents	Deformity pressure, brace treatment pressure	Strong against to psychological pressure, short time, simple questions, easy to call back	Social interaction and family relationship were not involved, which had great influence on patients' life
BrQ	Covering 8 dimensions with a total of 34 items	Adolescents	General health perception, self-esteem and aesthetics, vitality, school activity, emotional function, body function, social function, body pain	Good internal consistency and retest reliability, with a clearer role in the assessment and selection of brace therapy	Use only in patients receiving brace therapy
TAPS	3 groups of graphics, each group of 5 body appearance pictures, each graphics assigned points	Adolescents	Trunk appearance perception	Good internal consistency, retest reliability and responsiveness, simple and easy to complete and score	Rarely used in China and needs further study

BIDQ-S	7 items, 1-5 rating scale	Adolescents	Body image disorder	It can better distinguish between AIS patients and healthy people, and can identify patients who may be at risk for psychosocial problems	
ISYQOL	Covering 2 areasand 20 items	Adolescents	Spine health field, brace field	Specific questions for patients with braces, more targeted	Limited availability in different languages, not yet proven in a wide range of populations

3. Conclusion

Currently, the SRS-22 developed by the Scoliosis Research Society is often regarded as the gold standard for assessing HRQoL in AIS patients and has been used by many scholars as a PROM to assess patient-reported outcomes. Although there are many PROMs available for AIS patients that meet the needs of domestic researchers, the development and application of each PROM are not the same; each has its own unique, focused direction and limitations. And in terms of China, no local evaluation tool has been developed. Given the large cultural and social differences at home and abroad, it is appropriate to develop PROs that meet the needs of AIS patients in our country according to their actual situation and cultural background, deeply examine their performance, and then put them into the clinic.

In order to reduce a series of individual, family, and social problems caused by adolescent idiopathic scoliosis, the overall condition of AIS patients needs to be assessed, detected, and diagnosed as early as possible. Meanwhile, targeted interventions should be implemented based on the results of the assessment. The selection of an accurate and comprehensive PROM can more truly reflect the actual experience and feelings of the patient during the treatment, which is helpful for a better assessment of HRQoL or other related outcomes. According to the results of PROs, medical staff should actively strengthen the health education for AIS patients and their parents, formulate individualized training programs for patients, standardize the training movements, and reduce the burden and anxiety of families. As a bridge for communicating the current situation and needs between children and their families and medical staff, PROs are also key means to eliminate negative emotions. Therefore, researchers should select appropriate and reliable PROs to measure AIS patients according to the different purposes and targets of the study, combined withclinical objective criteria, to provide the basis for the development of personalized treatment plans and to improve the quality of medical service.

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