Outcome instruments to assess scoliosis surgery

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Received: 16 February 2012 / Revised: 19 April 2012 / Accepted: 22 April 2012 / Published online: 11 May 2012
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Abstract

Purpose To review and summarize the current knowledge regarding the outcome measures used to evaluate scoliosis surgery.

Methods Literature review.

Results Outcome instruments should be tested to ensure that they have adequate metric characteristics: content and construct validity, reliability, and responsiveness. In the evaluation of scoliosis, generic instruments to assess health-related quality of life (HRQL) have been used, such as the SF-36 questionnaire and the EuroQol5D instrument. Nonetheless, it is preferable to use disease-specific instruments for this purpose, such as the SRS-22 Patient Questionnaire and the quality of life profile for spinal deformities (QLPSD). More recently, these generic and disease-specific instruments have been complemented with the use of super-specific instruments; i.e., those assessing a single aspect of the condition or specific populations with the condition. The patients' perception of their trunk deformity and body image has received particular attention, and several instruments are available to evaluate these aspects, such as the Walter-Reed Visual Assessment Scale (WRVAS), the Spinal Appearance Questionnaire (SAQ), and the Trunk

Appearance Perception Scale (TAPS). The impacts of brace use can also be measured with specific scales, including the Bad Sobernheim Stress Questionnaire (BSSQ) and the Brace Questionnaire (BrQ). The available instruments to evaluate the treatment for non-idiopathic scoliosis have not been sufficiently validated and analyzed.

Conclusions Evaluation of scoliosis treatment should include the patient's perspective, which can be obtained with the use of patient-reported outcome measures.

Keywords Scoliosis · Outcome instruments

Introduction

The outcome of surgical treatment for idiopathic scoliosis is usually evaluated by process measures, such as the change in the radiologic magnitude of the curve. Nonetheless, it is currently accepted that it should also include the patient's perspective, which can be obtained with the use of patient-reported outcome measures (PROMs). There is evidence that PROMs enable the clinician to better judge patients' problems, because they provide a means to gain insight into the way patients perceive their health and the impact treatments have on their quality of life, and this will help in choosing the most suitable management for their condition [1].

Measurement methods

Health-related quality of life (HRQL) is measured with instruments designed and validated for this purpose. They usually take the form of questionnaires containing a series of questions about which patients express their

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perception of health by marking their choices among several possible responses.

Instruments to measure HRQL usually have a multi-dimensional structure and assess various factors that correspond (in one way or another) to the physical, psychological, and social factors that define HRQL. The metric quality of the instrument depends on whether information is available on the following characteristics [2–4].

Content validity

This property refers to the extent to which the instrument measures the concept it is intended to measure. The content validity is evaluated through pilot studies, investigating whether the instrument's items and domains are appropriate for the concept being evaluated. Thus, the process of generating the items included is crucial, as is the choice of response options, which must be adjusted to the variables the questionnaire is meant to measure. The most commonly used response types are visual analogue scales (VAS), Likert-type scales, checklists, and pictorial scales. The language used in the responses should be easily understood and the distinction between the various possible responses should be clear. Ideally, the difference between consecutive responses to a question should represent a similar interval. For example, on a frequency answer scale, the intended interval between “never” and “rarely” should theoretically be the same as the interval between “rarely” and “sometimes”. A relevant characteristic of the scaling of an instrument is the percentage of patients who mark the minimum response choice (floor effect) and the maximum response choice (ceiling effect) for each item and each dimension. The floor and ceiling effects provide an estimation of the capacity of an instrument to detect a change in the disease that is being evaluated. For the scaling to be considered adequate, the floor and ceiling effects should be below 20 %. Each possible response to an item is assigned a score. These are added up to obtain a total score for the domain or the total scale. Ideally, the scores for each item should be equally weighted.

Reliability

Reliability refers to two properties of the instrument: its stability over time and the accuracy with which it estimates the true effect of a treatment. Stability (or reproducibility) is analyzed by a study of test–retest reliability. The scores obtained on an HRQL instrument administered twice in a short interval of time, during which the patient's health condition cannot have substantially changed, should be quite similar. Reliability is determined by calculating the intraclass correlation coefficient (ICC). The internal

consistency of an instrument expresses the degree of agreement between individual items and the total score, and is determined by calculating Cronbach's alpha coefficient. It is generally expected that a valid scale should have a coefficient ≥ 0.70 .

Construct validity

The extent to which a particular question or domain relates to other theoretical or logical references supporting the existence of the construct being measured is the construct validity. In the case of spinal deformity, it is expected that HRQL questionnaires will evaluate dimensions that are considered significant in this condition. The construct validity can be evaluated by analyzing the relationship of the questionnaire under study with other instruments that have already been assessed (convergent validity) or by determining the capability of the instrument to discriminate between different severity levels of the condition (discriminant validity).

Responsiveness or ability to detect change

The metric quality *responsiveness* is essential for an HRQL questionnaire to be used in longitudinal studies evaluating the results of therapy. In scoliosis, sensitivity to change enables the determination of the effect of a therapeutic intervention, such as bracing or spinal fusion. If an instrument does not have responsiveness, then the expected benefits of a therapeutic intervention cannot be identified and this could lead to the false conclusion that the intervention is not effective. Nonetheless, a favourable impression regarding an intervention based on a statistically significant score change in the HRQL instrument should be taken with caution. In most cases, statistical significance is evaluated by an analysis comparing the mean values obtained; therefore, it is influenced by the size of the sample. For this reason, when using an HRQL outcome instrument, it is of interest to investigate what score change “would be considered meaningful and worthwhile by the patient such that he/she would consider repeating the intervention if it were his/her choice to make again” [5]. This change is known as the minimum clinically important difference (MCID) of the instrument.

Outcome instruments and questionnaires

In scoliosis surgery, outcome measurement has been recently incorporated in the evaluation of the effectiveness of the surgical techniques used. For many years, the results of surgery were assessed mainly by analyzing the radiologic correction of the deformity. Some authors attempted

to assess the clinical outcome of scoliosis surgery by gathering information on spinal pain, and social and work-related factors [6–8]. However, the questionnaires used in these surveys were ad hoc designed for the studies in question. Thus, they were not validated instruments possessing the metric characteristics indicated above.

Three types of questionnaires have been used in studies on spinal deformity: generic, specific, and super-specific. Generic instruments are those designed to evaluate HRQL in the general population. The main ones used in spinal disease are the 36-question Short Form Survey or SF-36 [9] and the EQ-5D [10]. The SF-36 is very useful for studying long-term follow-up when pre-treatment clinical data are not available. In this case, the patients' status is compared with the average population values. Using this method, the efficacy of an intervention cannot be evaluated, but it can estimate the patients' situation with respect to a population that has not undergone treatment [11–15]. The EQ-5D questionnaire has mainly been used in studies on cost-effectiveness in spine surgery [16, 17].

Specific questionnaires

Specific questionnaires are based on the same theoretical model, but they are designed for specific diseases or groups of diseases. They maintain the structure in dimensions, but they are based on the clinical profiles inherent to each disease; that is, they attempt to highlight the impact or specific effect caused by the disease or deformity. For example, a generic questionnaire will ask about pain, but a scoliosis-specific questionnaire will ask about back pain. A generic questionnaire will not be concerned about the patients' body image, but one designed for scoliosis should necessarily ask about the patients' perception of their body.

Quality of life profile for spinal deformities

The first specific questionnaire to evaluate HRQL in idiopathic scoliosis was developed in Spain under the name Calidad de Vida en Deformidades del Raquis (CAVIDRA) or quality of life profile for spinal deformities (QLPSD) [18]. The questionnaire contains 21 items grouped in 5 dimensions: psychosocial functioning (7 items), sleep disturbances (4 items), back pain (3 items), body image (4 items), and back flexibility (3 items). Responses are designed as a 5-point Likert scale and scored 1–5. The total overall score ranges from 21 to 105, and the higher the score, the poorer is the patient's quality of life. The instrument has been evaluated, and its metric properties (validity, reliability, and responsiveness) conform to accepted norms. The original instrument was conceived in

Spanish, and later, English [19] and French [20] versions became available.

The questionnaire was designed for the study of adolescents with spinal disease, and it has not been evaluated in adults. It has been used to analyze the effect of orthotic bracing on quality of life [21] and the changes in quality of life occurring after surgical treatment for idiopathic scoliosis [19].

Scoliosis Research Society: 22 Questionnaire

In 1999, a working group of the Scoliosis Research Society presented an instrument to evaluate the clinical outcome of surgery for idiopathic scoliosis [22]. The original version was not conceived according to standardized methods for designing quality of life instruments. Hence, Asher et al. [23–25] modified the instrument following standardized methods and created the SRS-22 questionnaire. The SRS-22 proved to be a valid and reliable instrument for assessing patients with adolescent idiopathic scoliosis that is sensitive to changes following surgery. Its metric properties were also found to be appropriate for evaluating adults with spinal deformities [26]. Nonetheless, shortly after its introduction, the Function subscale was found to have unacceptably low internal consistency in individuals younger than 18 years of age. Factor analysis indicated that the problem originated in question number 18 [27]. The response scaling was then modified, and the internal consistency of the Function subscale improved. This new version of the questionnaire was named SRS-22r [28], and it is the one posted on the Scoliosis Research Society's web site (http://www.srs.org/professionals/SRS_outcomes/srs-22.pdf).

The questionnaire contains 20 questions distributed in 4 dimensions (function/activity, pain, self-perceived image, and mental health) and 2 additional questions about the patient's satisfaction with the treatment received. Each dimension has five items, except for *satisfaction*, which has two items. Each item is scored from 1 (worst possible) to 5 (best possible). Each dimension has a total sum score ranging from 5 to 25, except *satisfaction*, whose sum score ranges from 2 to 10. Results are expressed as the mean of each dimension. A subtotal sum score of the 4 scales with a range of 20–100 can be obtained, but the usual practice is to calculate the mean. With addition of the 2 questions on satisfaction, the overall score ranges from 22 to 110.

The SRS-22 has been translated, culturally adapted, and validated in several languages [29–41] and has been widely distributed worldwide. It should be noted, however, that some adaptations have been made with the SRS-22 version, whereas others have used the SRS-22r. Therefore, researchers performing studies in this field should be aware of which version they are using. As was mentioned above,

the SRS-22r is the most metrically solid one. The values obtained with SRS-22 can be transformed to SRS-22r using the formulas provided by Lai et al. [42].

We should like to mention another widely used version of this instrument that is also available on the Scoliosis Research Society's website, the SRS-30 (http://www.srs.org/professionals/SRS_outcomes/srs-30.pdf). This instrument has not been specifically validated. It contains the same 22 questions as the SRS-22 (not the SRS-22r) and another question (number 23) asking patients to score their self-image on a numerical rating scale. The seven remaining items are "perceived-effect" questions, in which patients are asked to score how their treatment has changed some aspect of the disease. It is not clear whether the responses to these questions significantly correlate with the true pre/post-treatment score change on the main scale (SRS-22) or whether the same information could be obtained using a conventionally global perceived-effect scale.

The SRS-22 questionnaire enables the analysis of the effects of operative and non-operative treatments on the perceived quality of life of patients with idiopathic scoliosis. Data are available on the MCIDs of the questionnaire following surgical treatment of idiopathic scoliosis [43, 44], as well as reference values for both the adolescent [45] and adult [46] populations without scoliosis.

Super-specific questionnaires

Super-specific instruments have been developed for in-depth evaluation of a specific dimension of scoliosis and to assess HRQL in special populations of patients with scoliosis. Among the first, there are two groups of particular interest: instruments to evaluate body image and those that assess the psychological impact of bracing.

Instruments to evaluate body image

Walter-Reed Visual Assessment Scale (WRVAS) and Spinal Appearance Questionnaire (SAQ)

In 2003, Sanders et al. [47] from the Spine Deformities Study Group devised a pictorial scale that patients could use to express how they perceive their deformity. The scale, known as the Walter-Reed Visual Assessment Scale (WRVAS), includes seven items that deal with various aspects of the deformity: spinal deformity, rib prominence, lumbar prominence, thoracic deformity, trunk imbalance, shoulder asymmetry, and scapular asymmetry. Each item has a set of five standardized drawings that represent degrees of severity of the aspect in question. The patients' responses to WRVAS correlate well with those of their

parents, and the scores correlate with the magnitude of the scoliotic curve.

Later, the same group proposed a new instrument with a similar purpose: the Spinal Appearance Questionnaire [48]. The first version included 20 items (8 pictorial items related to the deformity and 12 questions on the patient's expectations regarding treatment) and showed satisfactory internal consistency (Cronbach's alpha >0.7) and the capacity to discriminate between different curve magnitudes. A second version (SAQ v 1.1) was then created [49] with 33 items: 11 pictorial items and 22 questions on the expectations regarding treatment. However, factor analysis demonstrated that only 15 items aggregated in 2 factors: 10 drawings on the pictorial scale and 5 questions on the treatment expectations. The final instrument shows satisfactory internal consistency and test-retest reliability. The SAQ appears to be a valid scale for evaluating patients' subjective perception of the appearance of their trunk deformity and their expectations regarding treatment. In the case of the WRVAS, however, there are some doubts about the validity of the drawings, since the scores for some deformity-related items do not correlate with their radiologic counterparts [50]. Furthermore, its face validity has been questioned because the drawings are unrealistic. A recent study by Mulcahey et al. [51] has indicated that adolescents have problems in understanding the questionnaire, and report difficulty in comprehending the drawings and reading the questions.

Trunk Appearance Perception Scale

The design of the Trunk Appearance Perception Scale (TAPS) [52] was based on the strengths of the WRVAS: simplicity, and ease of completion and scoring. The scale includes only three sets of drawings corresponding to three views of the torso: looking towards the back, looking towards the head with the patient bending forward (Adam's test), and looking towards the front. There are two sets of drawings for the last item, one for women and another for men. Each drawing is scored from 1 (greatest deformity) to 5 (smallest deformity), and a mean value is obtained for the scale (sum score of drawings 1, 2 and 3, divided by 3). Among the drawings presented for each item, patients must choose the one that is closest to their perception of their body appearance. The TAPS includes the two WRVAS items that have shown the best correlation with the magnitude of the scoliosis: the posterior view and the view in the forward bending position. In addition, it includes a new frontal view, which is what the patient actually sees when looking in a mirror. The drawings are more natural than those used in the WRVAS. The TAPS has shown adequate score distribution and internal consistency. It is a reliable instrument with satisfactorily discrimination according to

the severity of the deformity. Currently, there are no available data on its sensitivity to change.

Instruments to assess the impact of bracing

Super-specific instruments have also been developed to assess the patient's perception of the effects of brace use.

Bad Sobernheim Stress Questionnaire

The Bad Sobernheim Stress Questionnaire (BSSQ) has two parts: the first, BSSQ Deformity, evaluates the stress associated with the deformity, and the second, BSSQ Brace, measures the stress produced by the use of a brace. BSSQ Deformity contains eight questions that are similar to some of the questions on the SRS-22r. BSSQ Brace, which also contains eight unique questions not used in any other instrument. Each item has 4 responses that score from 0 to 3. The sum of all the responses yields the overall score for the questionnaire, which ranges from 0 to 24. The higher the score, the less stress is indicated. The authors [53] suggest a grading of 0–8 for intense stress, 9–16 for moderate stress, and 17–24 for low stress. The questionnaire was originally designed in German, and an adapted version is available in English [53], Polish [54], Italian [55], and Spanish [56]. The instrument has shown excellent internal consistency and reliability. Two factors were demonstrated in the factor analysis [56]: social discomfort caused by the brace and adaptation to the brace.

Brace Questionnaire

The original language of the Brace Questionnaire (BrQ) is Greek [57]. Incompletely validated versions are available in English [58] and Italian [55]. The instrument has 34 questions that measure 8 dimensions: general health, physical functioning, emotional functioning, self-esteem, vitality, school activity, body pain, and social functioning. It is valid for children and adolescents 9–18 years of age. Items are scored from 1 to 5 (or 5–1, depending on the formulation of the question). Each item is multiplied by 20 and the total score is divided by 34 to yield an overall score ranging from 20 to 100. The higher the score, the better is the quality of life. The instrument's dimensions are similar to those of SRS-22, although a number of questions refer specifically to the brace; hence, it can only be used in patients who receive this treatment. Nonetheless, a significant correlation between the two questionnaires has been reported [55].

Outcomes in non-idiopathic scoliosis

All the instruments mentioned have been validated and used in patients with idiopathic scoliosis. Furthermore,

because they are self-report questionnaires, they have only been applied in patients older than 10 years. Thus, in a large number of patients with spinal deformities, the use of these instruments is questionable. This group of patients younger than 10 is heterogeneous and it includes patients with infantile or juvenile idiopathic scoliosis, and those with congenital deformities, syndromic scoliosis, neuromuscular scoliosis, and other etiologies. For these patients, Corona et al. [59] have proposed an instrument called the *Early-Onset Scoliosis Questionnaire* (EOSQ). It comprises 33 items corresponding to 13 domains: general health, pain, physical function, pulmonary function, daily living, fatigue, emotion, surgical concerns, satisfaction, transfer, financial burden, parental burden, and treatment outcome. One interesting characteristic of the instrument is that the list of items was generated from the findings obtained in semi-structured interviews with the patients' parents. The validation study included patients younger than 10 years with congenital scoliosis, neuromuscular scoliosis, scoliosis secondary to spinal cord abnormalities, and idiopathic scoliosis. The instrument is unique in that it includes dimensions that are not usually measured, such as the economic burden of the condition and the parents'/caregivers' burden. The EOSQ can also be used in patients older than 10 with non-idiopathic scoliosis. The questionnaire is answered by proxies (parents and caregivers) rather than by the patients, so it could also be useful in patients with cognitive disorders or the mentally challenged. The factor structure of the EOSQ suggests that it can be used in patients with motor deficits resulting from neuromuscular scoliosis (either spastic or flaccid). To date, however, there are no validity data available for this instrument.

Several authors have evaluated the outcome of surgery in the paediatric population with neuromuscular scoliosis using non-validated questionnaires [60–62] or generic paediatric outcome measurement instruments [63, 64]. It would be of benefit for future work if the related scientific societies would agree to define the most appropriate instruments for evaluating non-idiopathic scoliosis.

How to choose an outcome instrument?

Any of the instruments mentioned in the previous sections with metric properties confirmed to be suitable according to theoretical norms can be used as an outcome measure to evaluate the effect of an intervention in patients with spinal deformities.

The most widespread one available is the SRS-22 questionnaire and its recommended revised version, SRS-22r (http://www.srs.org/professionals/SRS_outcomes/srs-22.pdf). This instrument evaluates four dimensions: pain, mental health, physical function, and body image. The

aesthetic compromise associated with the deformity is a predominant concern in adolescents and young adults. Hence, it would be desirable to apply a pictorial scale to classify the patients' perception of their trunk deformity, such as the WRVAS or TAPS, in addition to the SRS-22. The SAQ could be an alternative to these instruments, if the most recent version were confirmed to be the definitive one. Furthermore, transcultural adaptation to other versions from the original English would be required, a step that is not necessary for pictorial scales. If researchers are interested in assessing the perception of trunk flexibility following a therapeutic intervention (whether bracing or vertebral fusion), the QLPSD, which includes a dimension on spinal mobility, could be used.

In longitudinal studies, in which the interest lies in the changes occurring in HRQL following an operative or non-operative treatment, it is advisable to assess the patients' satisfaction with the treatment received and the outcome of treatment. To this end, the SRS-22 contains contains questions related to satisfaction. In addition, a global perceived-effect scale [65] can be used or perceived effect questions on particular aspects, such as pain, cosmesis, etc. The SRS-30 perceived-effect questions (http://www.srs.org/professionals/SRS_outcomes/srs-30.pdf) could also be useful for this purpose.

In cross-sectional studies, the HRQL of the study population could be compared with that of the general population. The SF-36 would be an optimal instrument for this task. Nonetheless, normative data for the SF-36 are only available for the population older than 18 years; hence, its use in younger populations is not recommendable. As mentioned above, this type of study is especially useful when no data are available on the patients' clinical status before the intervention.

When assessing the outcomes of scoliosis surgery in adults, the SRS-22r would be the instrument of choice or its "extended" version, the SRS-30, if researchers would also know about patient's perceived effect of surgery. In this population, in which pain and disability are two predominating aspects, some researchers [66] suggest using the Oswestry Disability Index and numeral rating scales on back and leg pain in addition to the SRS-22.

In studies on brace outcomes, the SRS-22 questionnaire and the BrQ are equally effective. However, the SRS-22 is available in a large number of languages, and this enables easy comparison between the results of series from different countries. The available data on the BSSQ BrQ seem to confirm its usefulness for measuring the stress related to brace use, although the repercussions of this factor on treatment outcome remain uncertain.

Conflict of interest None of the authors has any potential conflict of interest.

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