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Measuring Outcomes in Spinal Deformity

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Historically, spinal deformity treatment assessment has been performed using process measures, such as curve correction and achievement and maintenance of coronal and sagittal balance. Over the past 2 decades, the discipline of spinal deformity surgery, as with other surgical specialties, has come to recognize the importance of the patient's perception of the outcome of his or her surgery. The attempt to equate patient measures with process measures led to the development of health-related quality-of-life (HRQL) questionnaires to measure these outcomes. HRQL questionnaires are typically divided into "domains," which are groups of questions aimed at one particular patient attribute, such as pain or function. One of the most widely used HRQLs is the Short Form-36 (SF-36) [1], which is a nondisease-specific assessment tool. The desire for a disease-specific HRQL led the Scoliosis Research Society (SRS) to develop a questionnaire specific for spinal deformity useful in adolescents as well as in adults [2].

This article reviews the science of psychometrics, the development history of the SRS outcomes instrument, and the measurement of outcomes in adult and pediatric patients.

Science of psychometrics

Psychometrics is the use of standardized measures to quantitate the qualitative attributes of an individual's existence. This discipline was largely developed by the 1980s [1]. The important psychometric attributes of an HRQL questionnaire are reliability, validity, responsiveness, and score distribution.

Reliability means that a questionnaire is free from random error. It is measured by two attributes: internal consistency and reproducibility. Internal consistency is a measure that determines whether the questions in an individual domain, such as "pain" or "physical function," represent that particular domain. The statistical measure to evaluate internal consistency is the Cronbach α. Reproducibility is determined by the test-retest assessment and is evaluated statistically using the intraclass correlation coefficient (ICC) [3].

Validity is the ability of an instrument to measure what it is attempting to measure. The measures of validity are criterion, concurrent, and discriminant validity. Criterion validity compares the outcome with a similar variable, perhaps a process variable. Concurrent validity compares it against a different already validated instrument. Discriminant validity is the ability to distinguish between differing severities of disease, such as a 20° curve versus a 100° curve. The statistical analysis of validity uses ANOVA and the Pearson correlation coefficients [3].

Responsiveness refers to the instrument's ability to detect change over time or after an intervention. It is measured with the paired *t* test. Score distribution refers to the instrument's ability to assess the full range of severities within a disease state [3].

History of the development of the Scoliosis Research Society outcomes instrument

In 1995, Haher and colleagues [4] published a meta-analysis of surgical outcomes in adolescent idiopathic scoliosis (AIS) surgery. The results of this study, along with the desires of the membership of the SRS, led to an effort to develop a disease-specific HRQL for idiopathic scoliosis. Haher and colleagues [2] published the results of

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this effort in 1999, developing a disease-specific instrument they named the SRS-24. This instrument was divided into seven general domains of pain, general and postoperative self-image, postoperative function, function from back condition, general level of activity, and satisfaction. Internal consistency was assessed with patients with AIS and found to be good in all domains. Reliability was assessed with normal controls and found to be good also. Discriminant validity was assessed by comparing the normal controls with the patient population. Using Mann-Whitney nonparametric tests, the normal controls were found to have better scores than the patients with AIS.

Further studies of this instrument have shown it to be useful in pediatric patients with AIS [5] as well as in adult patients with AIS [6]. It has been studied in Finnish patients with spondylolisthesis [7] and in Japanese patients with AIS [8,9].

With further use, it was thought that the SRS-24 could be improved, with concerns regarding unknown test-retest reliability, criterion validity, and responsiveness to change [10]. The initial work was the SRS-23, which included 11 unchanged questions, 6 refined questions, and 6 new questions. Additionally, the domains were changed to five: pain, function, self-image, mental health (a new domain with questions taken, with permission, from the SF-36), and satisfaction with management [10].

Additional work was needed, and with the elimination of one question because of low internal consistency and the movement of another to a different domain, the SRS-22 emerged. A larger study was undertaken to assess each relevant psychometric property of the SRS-22 and to develop a relatively finished product. A series of studies on a mixed adolescent and adult population with idiopathic scoliosis assessed and verified the reliability and concurrent validity [3], responsiveness to change [11], and discrimination validity [12] of the SRS-22.

It has been successfully translated into Turkish [13] and Spanish [14,15], and based on the results and suggestions of those authors, minor refinements have been made in the function domain of the English version, improving the internal consistency, with the final version called the SRS-22r [16].

Validating outcomes in pediatric and adult spinal deformity

The SRS outcomes instrument was initially designed for pediatric patients with idiopathic scoliosis. Because scoliosis is a lifelong condition, many of the initial validation studies were performed on a mixed age range population [10–16], although all had been treated as adolescents. The SRS-22r [16] is currently under study to assess whether its psychometric properties remain valid when studied in a purely pediatric (ages 8–18 years) population.

A recent study [17] from the authors' center has analyzed the reliability and concurrent validity of the SRS-22r compared with the Child Health Questionnaire (CHQ) child form (CF-87) in 70 patients with spinal deformity aged 8 to 18 years. The SRS-22r was found to be reliable, with good concurrent validity between the relevant domains of pain, function, and mental health. As has been found in the adult population when comparing the SF-36 with the SRS-22r, self-image and satisfaction with management domains do not translate well from the disease-specific instrument (SRS-22r) to the generic instrument (SF-36 or CHQ) [17].

Similar studies have sought to validate the SRS-22 in an adult deformity population. Bridwell and colleagues [18] compared the SRS-22 with the Oswestry Disability Index and SF-12 and evaluated score distribution, concurrent validity, internal consistency, and reliability. They found that the SRS-22 did as well or better in score distribution compared with the other instruments. Looking at the domains of pain, function, and mental health, concurrent validity was high between the SRS-22 and the SF-12. Reliability was excellent in all domains, and internal consistencies were high in all domains except pain, where it was 0.67, which is still acceptable but lower than the other domains.

Berven and colleagues [19] analyzed the SRS-22 alongside the SF-36 to evaluate validity, reliability, and discrimination in an adult population. Similar to Bridwell and colleagues [18], they found the SRS-22 to have excellent psychometric properties in the adult population.

Neither study assessed responsiveness to change, which remains an important area of study. Bridwell and colleagues [20] recently reported their early findings in analyzing this important attribute and found that the SRS-22 was responsive in an adult population, particularly in the self-image domain.

An even more interesting, and important, concept is "minimal clinically important difference" (ie, not just statistically significant but clinically significant) [21]. Work in this area is preliminary but encouraging.

Summary

The development of validated HRQL instruments that are generic (SF-36) or disease-specific (SRS-22) allows physicians and researchers to measure the qualitative impact of spinal deformity and its treatment on their patients quantitatively. Although some further research may be needed in the area of the responsiveness of the SRS-22r, it should be considered a validated instrument that is useful in the research and treatment of pediatric and adult patients with spinal deformity.

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