ScienceFrontier

Review Article

International Journal of Public Health Research and Epidemiology

ISSN Online: 3071-2653 | **OPEN ACCESS**

Adolescent Idiopathic Scoliosis: the use of Outcomes Instruments

Saccomanni Bernardino *

Ambulatorio di ortopedia.

***Corresponding Author**: Saccomanni Bernardino, Ambulatorio di ortopedia

Received Date: February 25, 2026; **Accepted Date: March 03, 2026**; **Published Date: March 16, 2026**

Citation: Saccomanni Bernardino (2026). Adolescent Idiopathic Scoliosis: the use of Outcomes Instruments, J *International Journal of Public Health Research and Epidemiology*. 2(2) 07, **DOI:** IJPHRE-RW-26-07.

Abstract

Clinical outcomes research is characterized by a focus on the outcomes of care from the perspective of patients, as opposed to evolutions of care by providers based on more objective measurements.

Evaulating patient measures as opposed to process measures has had a significant impact on the formulation of treatment guideless. This chapter briefly reviews outcomes research, including pertinent

definitions that illustrate the need for outcomes studies and the mechanisms by which outcomes research is conducted.IN this article there are not outcomes, figures and tables.

Key words: idiopathic scoliosis; use; outcomes instruments

Introduction:

The Rationale for Outcomes Research

Health care costs have increased from 14% of the gross domestic product in 1993 to 20% of the GDP In 2000 and continue to rise. Because clinical science is not exact, uncertainties exist in medical care,Often because solid evidence of therapeutic efficacy is lacking.
Secondary treatments or extended stays resulting from complications of treatment contribute significantly to cost of care. Reproducibility of technique can ensure that repeat or additional treatments are not required. However, because treatments are patient specific, universal application of any one treatment option may not be a practical approach. Selection of treatment modalities must be based on efficacy, which is determined using standardized parameters designed to evaluate which treatment options produce the best patient outcomes.

The goal of outcomes research

Outcomes research yields imformation on overall efficacy related to the current standard of care.More specifically, the goal of outcomes research is to provide the information required to develop Accurate and meningiful clinical practice guidelines. This information includes scientific validation of the efficacy and cost effectiveness of orthopaedic treatments and identification and documentation of ineffective or flawed treatments (6, 7)
Outcomes research generates 1. information to define the research priorities in the field; 2. accurate, high-quality process and outcomes data that will be standardized and be comparable across the specialty; 3. information that will guide orthopaedists and their patients in choosing the best treatment (11); and 4. data and imformation that will scientifically document the effectiveness of orthopaedic care.
Outcomes research aids in the assessment of new operation, new technologies, and new procedures.
It provides a view of end results that measure technical success, patient' s ability to function physically,emotionally, and socially. It is used for a systematic study of cohorts to evaluate the clinical course of patients treated by non-surgical and surgical approaches.
Outcomes research on effectiveness and efficacy, and it is a means through which practive guidelines can be developed.

Measures of Success:

Clinical research data are usually based on process measures or objective assessments such as range of motion and radiograph results. Patient measures are subjective assessments that quantify the results of care as they are perceived by the patient.

These measures may include the severity of pain, daily function, quality of life, satisfaction and more relevant to patients. Patient measures may not reflect all the benefits of surgery, yet they measure the results of care as perceived by the patient.

Long term benefits such as preservation of pulmonary function in the child with scoliosis or the prevertion of osteoarthritis in the lumbar curves can be overlooked.
Methologies used in outcomes research include analysis of databases; structured reviews of the literature (meta-analysis); prospective, patient-oriented clinical trials; cost effectiveness studies; and decision analysis.

The first step in the development of clinical outcomes research is the creation of a hypothesis. Then data for a sufficient number of cases are collected using strict statistical and research methods.
outcomes are assessed using data collected from patient-completed (questionnaires) and other patient outcome data. These data are compared among and between practices and databases. Although the conclusions derived from the data may not reach statistical significance, they should provide credible evidence of the quality and appropriateness of care.

An instrument is a tool used to collect information from patients. Most often the instruments is a high-quality questionnaire that has been tested and validated so that it will provide a source of standardized and comparable data that can be used for useful and valid comparisons of different treatment methods.

Types of instruments:

Patient specific:

Patient specific outcome measurements prioritize the reasons why a patient sought medical treatment.
After a particular procedure, the patient is reassessed, and the efficacy of a given treatment is determined for each of the parameters listed. An example includes the MacMaster Toronto Arthritis scale in which patients are asked to prioritize the primary reasons they are undergoing a particular procedure.

Global instruments:

Health care providers are interested not only in desease-specific and patient-specific outcome measures but also in the overall health of a patient following a medical or surgical intervention. The provider wants to know which patients are most disabled and which form of medical treatment is the most efficacious in restoring normal health. A number of global outcome measurements have emerged. These measurements provide standards by which the severity of patients' morbility before and after treatment can be compared. They also allow for comparisions of different disease states as well as comparisions of the results following treatment of each of these.

Disease Specific:

Desease-specific outcome measurements assess the results of treating a specific using a specific procedure.The Harris, Iowa, and Mayo Hip Scores are examples of these measurements, as is the Scoliosis Research Society (SRS) instruments, the SRS-22 Patient Questionnaire, which is used to Evaluate outcomes following surgery in adolescent idiopathic scoliosis (AIS).

Quality of the instrument:

The strength of the psychometric attributes-reliability, validity, and sensitivity- determine the overall Quality, and sensitivity- determine the overall quality of the instrument. Outcome data are considered reliable when the measurement is reproducible with low levels of random error. It is considered valid only if the instrument measures what it is intended to measure, and it is sensitive if it has the ability to measure change over time.
A domain is a subscale used to measure a specific aspect of a patient' s state or quality of life. Domains May include function, health stutus, pain, patient satisfaction, and include expectations. Questions are Evaluated by factor analysis to assign the appropriate domain for that question.

The Scoliosis research society instrument:

The SRS-22 Patient Questionnaire was designed as a disease-specific questionnaire. The purpose of the instrument is to assess and discriminate outcomes among patients with idiopathic scoliosis. The instrument consists of 22 to 24 validated questions divided into seven equally weighted domains as determined by factor analysis. The domains are pain, general self-image, post-operative self-image,
general function, and satisfaction. Using this set of questions, an estimate of the reliability based on internal consistency for the items making up each domain was done using Cronbach' s alpha (1, 2)
In general, assessments of pain, function, and range of motion form the basis of these tools. Statistically significant improvement in scores (from preoperative to postoperative) is also measured. Many scoring systems are not sensitive enough to distinguish whether one procedure is superior to another because the long-term effect of a given treatment goes unrecognized. The SRS-22 Patient Questionnaire is an exception to address this issue. The instrument is able to gauge changes in patients' postoperative status compared with their preoperative condition. To assess change over time, the postoperative section of the instrument contains questions about current self-image, function, and pain compared with the status of these items before the scoliosis correction surgery. Furthermore, the SRS-22 is administered throughout the life of the patient, thereby providing a data flow that can assess time-dipendent changes.Cosmesis is also considered because

it is an important factor in the quality of life of the adolescent with idiopathic scoliosis (5)

Clinical Application of the SRS-22 Patient Questionnaire:

The SRS-22 is a simple and practical disease-specific questionnaire that provides valid and reliable measures of pain, self-images function, and satisfaction in patients with scoliosis. This information can be used in clinical practice to improve the quality of the patient care, and it offers individual assessment of patient status. Satisfaction and outcome data from various centers also can be compared based on the population standard. In addition, the questionnaire attempts to address the magnitude of longitudinal change, thereby allowing adolescents with scoliosis to be monitored as they become adults.

The instrument is easily administered in the office setting, with a minimum disruption of patient and office flow. The questionnaire is concise enough to provide for a high degree of complicance. Patients are able to fully understand and answer all questions, with a minimum of time required to complete the form.

The SRS-22 may be scored by hand or device. Each question has a specific value within a domain. Each question has a specific within a domain. The scores are added for that domain and may then be compared between and among groups. Scores may be compared before and after treatment or used to compare different treatment modalities either for the same surgeon, among surgeons, or between centers. Postoperative follow-up evaluations are a direct measure of the clinical outcome, whereas patient questionnaires are an indirect assessment of patient satisfaction resulting from the surgical procedure. With respect to the latter, a direct assessment is not possible because, in theory, each patient may define satisfaction based on unique and personal quality of life elements.

Background:

Outcomes instruments provide insight into both the efficacy and patient satisfaction associated with current treatment modalities. It is assumed that there are multiple levels of treatment with resulting characteristic outcomes. While this is simple in concept, in reality the additional data elements associated with the instruments, such as cosmesis, patient satisfaction, achieved correction, and functionality, are manifested as factorial interactions, interposed between the surgical treatment and resulting outcomes. To differentiate between these interactions, outcomes instruments have identified several distinct elements of inquiry and reporting. Thus, the resulting success of a treatment modality is measured not only by its ability to correct the deformity but also by the degree to which the patient can perform the tasks of daily living.

The geometric parameters that constitute a deformity must be established. Changes in those parameters as a result of treatment should result in an improvement in the patient' s quality of life. It is important to note that although such a result is both achievable and constitutes a successful clinical outcome, patient satisfaction may not achieve. Although rigid guidelines for bracing or surgery have been established, several studies have reported that both clinical success and patient satisfaction may be archived with either method.

While correction and stabilization are important regardless of procedure, these are process measures,not patient measures. Danielson et al (6) used outcomes instruments to evaluate patients with AIS who had undergone treatment prior to age 21 years. A total of 147 patients treated with distraction followed by fusion with Harrington instrumentation were compared to a second group of 116 patients who had undergone brace treatment. All patients were fellowed for a minimum of 20 years after completion of their respective treatment. As a control group, 100 age and sex-matched subjects were included and subjected to the identical evaluation criteria.

Patients were evaluated using the SF-36, the Psychological General Well-Being index, the Oswestry Disability Back Pain Questionnaire. These instruments included study-specific questions concerning the treatment. A follow-up examination that included radiographic and clinical evaluations was also performed.

The groups were similar with respect to social and demographic data. Compared to controls, both treatment groups experienced a significant reduction in physical functionality as reported on both the SF-36 and the Oswestry Disability Back Pain Questionnaire. These differences were statistically significant, but the absolute reduction was only slight. Although Statistical differences were detected clinically, the functional outcome was comparable. Significant differences were detected between the two treatment groups with respect to physical activities (49% and 34%, respectively, for the surgical and brace groups). No differences were detected between the treatment groups. The geometric parameters associated with the scoliotic curve such as size and type were not correlated to the outcome scores. Neither the total treatment time nor the patient's age at completion of treatment displayed a significant correlation with outcomes scores.

Hather et al (8) applied the SRS-24 Patient Questionnaire (precursor of the SRS-22) to a cohort of 244 subjects and reported an internally reliable measure for each domain (Cronbach' s alpha > 0.6). A comparison between patients and normal controls revealed consistent differences in the domains ($p < 0.003$). The largest differences were noted in pain and general level of activity. A significant correlation was obtained between pain and patient satisfaction ($r = -0{,}511$; $P < 0{,}001$) as well as self-image ($r = 0{,}412$; $P < 0{,}001$).

In this study, the SRS-24 was validated in a large patient population, resulting in a statistical analysis of sufficient power. The patient cohort was not subdivided, thereby reducing the number of subjects in each group. The investigators examined the effects on outcome as related to pain, a physical baseline common to all patients. Such as a parameter is a good measure of outcome. Although it may possible to perform physical activities, doing so under painful conditions would not be considered a satisfactory result. It would be expected that both activity and satisfaction would exhibit some level of correlation with respect of pain. While these correlations were significant, the absolute values associated with correlation coefficients would suggest that although the trends may be generally linear in nature, inclusion of additional parameters may improve the predictive nature of the model.

In an attempt to improve the assessment of quality-of-life issues, Asher et al (2) devised the SRS-22 Patient Questionnaire. The SF-36 was used as a comparison or control outcomes instrument. Based on 51 patients with postoperative idiopathic scoliosis, the results showed that internal consistencies for the two instruments, as measured by Cronbach' s alpha, were 0,92 to 0,75 and 0,91 to 0,36 for the SRS-22 and SF-36, respectively. In addition, the intra-class correlation coefficient, an indicator of reproducibility between the two instruments was 0,96 to 0,85 for the SRS-22 to 0,61 for the SF-36.

In comparing the two instruments, 17 domains were deemed valid and resulted in a Pearson Correlation Coefficient of 0,7 ($P< 0{,}001$)

between the SRS-22 and SF-36. These data indicate that the two instruments are comparable with respect to both internal consistency and reproducibility. A comparison of the two instruments also illustrated that both the SRS-22 and SF-36 were comparable.

Asher et al (1) also prospectively investigated the discriminative power of the same instrument (SRS-22) with respect to curve pattern and curve size in the context of the health-related quality of life parameters. The patient cohort consisted of three groups ranging in age from 10 to 16 years. A control group was used and consisted of 19 subjects. The control group was characterized by a diagnosis of suspected but unconfirmed scoliosis. A second group consisted of 68 subjects and was classified as a nonsurgical treatment group. The identifying features associated with this group included a mean Cobb angle of 30°, and the group was subdivided into untreated and braced. A third group consisted of 32 patients with a mean Cobb angle of 61°, and was classified as a presurgical group. The author also grouped patients according to curve type and size. An analysis of variance revealed that the differences between the control and nonsurgical groups were not statistically significant, whereas the presurgical group displayed significantly reduced scores in the pain and self-image domains compared with the control or nonsurgical groups. When examining the nonsurgical and presurgical groups by curve geometry, the nonsurgical patients had significantly better self-image scores. There were no significant correlations between the SRS-22 instrument scores and curve pattern. For subjects diagnosed with scoliosis, curve size correlated with pain, self-image, and function.

The SRS-22 was able to differentiate between small, moderate, and large curves. However, the limitations of the instrument were revealed with respect to identification of curve geometry and classification. Several issues should be considered regarding the lack of sensitivity to curve characteristics. The use of Pearson Correlation Coefficients assumes a linear relationship that may not a completely valid assumption over small sample sizes.

One of greatest advantages associated with outcomes research is that the methodology can be used not only as a measure of outcome but also as a way to illustrate natural longitudinal progression of either the disease or the treatment. Such longitudinal studies also can be used for predictive diagnoses given the initial manifestation of the deformity and treatment option (7). In a longitudinal study involving 82 subjects treated for idiopathic scoliosis with Harrington instrumentation, Gotze et al (7) investigated the resulting quality of life using the SF-36 outcomes instrument. The investigators correlated demographic data with King' s classification, Cobb angle, rib deformity, fusion length, and site. The data were compared with data for an age-matched control subject cohort.

No significant differences between the patient and control populations could be detected on the physical aspect of the SF-36 ($p < 0,05$). However, in the phychological of the SF-36 instrument, the patient group had significantly reduced scores compared to baseline ($p<0,01$). It is not surprising that statistical differences occurred in the treatment group, specifically vitality ($p< 0,001$) and general mental health ($p < 0,005$). Again, patient age preoperatively, time of follow-up, type of scoliosis,and fusion extension were not significantly correlated with either quality of life or pain.

In addition, the data from the SF-36 and Roland Morris Questionnaire were not correlated to pre and postoperative curves and rib deformity ($P> 0,06$ to 0,7). The author established relationships between Outcomes parameters and the deformity using a linear approach to modeling. Similar correlations between pain and self-image were detected by Wilson et al (16) in a multicenter study of 265 patients. Radiographic data were correlated to outcomes measures in an attempt to establish a predictive quality of life for patients undergoing idiopathic scoliosis treatment. The author used the Harms Study Group Deformity scores (total, sagittal, coronal), the SRS outcome domains (total pain, general self-image, general function, activity, postoperative function, and satisfaction), and the SRS outcomes instrument total score in conjunction with a developed radiographic measure. A stepwise linear regression using the radiographic measures significantly correlated with outcomes scores.

Conoral measures of the thoracic and lumbar curve magnitude were significantly correlated with total pain, general self-image, and total SRS scores ($P< 0,0001$), and the thoracic curve magnitudes also correlated with general function ($P< 0,002$). The total score of the Harms Study Group radiographic system was significantly correlated with the SRS domain and total scores. Although the stepwise regression analysis involving the radiographic data as predictors of outcomes scores resulted in significant ($p< 0,0001$) r^2 values, low r^2 magnitudes may be indicate that other factors also play a role in the outcome.

Conclusions:

Outcomes instruments attempt to address the rather large strata of elements encompassing patient satisfaction. However, it is unlikely that any one instrument will ever address all issues associated with patient satisfication. Despite these limitations, outcomes questionnaires provide a cost-effective and meaningful window into the efficacy of treatment and resulting quality of life.

Although surgeons must continue to emphasize spinal balance and the prevention of both progressive pulmonary deterioration and osteoarthritis in the later years of their patients (3, 9,13), patients' perceptions of the effectiveness of treatment remain a critical factor, especially for the adolescent, and this factor must be overlooked (5, 15).

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