



SRS-22R Minimum Clinically Important Difference and Substantial Clinical Benefit After Adult Lumbar Scoliosis Surgery

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Abstract

Study Design: Longitudinal cohort.

Objectives: To determine if the minimum clinically important difference (MCID) and substantial clinical benefit (SCB) thresholds for the Scoliosis Research Society–22R (SRS22R) domains in patients with degenerative lumbar scoliosis are similar to those in patients with adult spinal deformity (ASD) with fusions extending into the thoracic spine.

Summary of Background Data: The MCID and SCB thresholds for the SRS22R domains in patients with ASD and adolescent idiopathic scoliosis have been reported.

Methods: Patients enrolled in the NIH-sponsored Adult Symptomatic Lumbar Scoliosis (ASLS) trial who underwent surgery and completed the SRS22R preoperative and the SRS30 one-year postoperative were identified. One-year postoperative answers to the last eight questions of the SRS30 were used as anchors to determine the MCID and SCB for the Pain, Appearance, and Activity domains, and the Subscore and Total score using receiver operating characteristic (ROC) curve analysis.

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Results: The sample population consisted of 147 patients. A total of 132 (89%) were females with a mean age of 59.4 years. There was a statistically significant improvement in all SRS22R scores from preoperative to one-year postoperative. There was also a statistically significant difference in domain scores among the different responses to the anchors. According to the ROC analysis, MCID was 1.17 for Appearance, 0.40 for Activity, 0.60 for Pain, 0.53 for Subscore, and 0.77 for Total; and SCB was 1.67 for Appearance, 0.60 for Activity, 0.62 for Subscore, and 1.11 for Total score. These are similar to previous reports of MCID and SCB thresholds for ASD patients who underwent fusion to the thoracic spine.

Conclusion: The MCID and SCB thresholds for the SRS22R domains in patients with adult symptomatic lumbar scoliosis are very similar to the threshold values previously reported for adult deformity patients.

Level of Evidence: Level II.

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Keywords: Adult lumbar spine deformity; SRS-22R; Minimum clinically important difference

Introduction

Although the Scoliosis Research Society–22R instrument (SRS-22R) [1] was initially designed as a disease-specific instrument to measure health-related quality of life (HRQOL) in patients with adolescent idiopathic scoliosis [1–4], its use has been extended to patients with adult spinal deformity. Studies have shown that it is reliable, valid, and responsive to change in patients with adult spinal deformity (ASD) [5–7]. However, patients with ASD are a heterogeneous group and may present with varying degrees and types of curvatures.

Most spine surgeons consider patients with lumbar degenerative scoliosis (LDS) as a unique subgroup as these patients include those with asymmetric disc collapse, facet arthritis, and stenosis. Surgical planning for LDS patients usually involves decompression with or without fusion that does not extend into the thoracic spine and may not require complex maneuvers to correct the deformity.

The minimum clinically important difference (MCID) [8,9] and substantial clinical benefit (SCB) [10] thresholds for the SRS22R domains in patients with ASD who underwent surgical fusion extending into the thoracic spine have been reported [11,12]. It is unknown if the same thresholds hold true for patients with primarily degenerative lumbar scoliosis. The purpose of the current study is to determine if these thresholds reported for adult spinal deformity applies to patients with LDS.

Methods

Deidentified data from subjects enrolled in a National Institutes of Health–sponsored trial for adult symptomatic lumbar scoliosis who underwent surgery and completed the SRS22R preoperatively and the SRS30 one year postoperatively were identified. One-year postoperative answers to the last 8 questions of the SRS-30 (Table 1) were used as anchors for the Appearance (Items 23, 24, 28, 29, and 30), Activity (Items 25 and 26), and Pain (Item 27) domains as well as the Total score (Items 23 to 30). Responses to the items that comprise the Satisfaction domain (Items 21 and 22) were used as anchors for the Subscore.

Answers to Questions 23, 24, 28, 29, and 30 were summed to produce an Appearance Anchor score, with a range of scores from 5 to 25. The Appearance Anchor scores were then classified as 1–5 “much worse,” 6–10 “worse,” 11–15 “unchanged,” 16–20 “better,” and 21–25 “much better.” Answers to questions 25 and 26 were summed as the Activity Anchor score, with a range of scores from 2 to 6. These scores were then classified as 2 “decreased,” 3–4 “same,” 5 “increased,” and 6 “much increased.” Question 27 was used as the Pain Anchor with three possible responses: 1 “increased,” 2 “same,” and 3 “decreased.”

Responses to the items that comprise Satisfaction (Items 21 and 22) were used as anchors for the Subscore. The Subscore is the average score from Items 1 to 20, that is, all items minus the items for Satisfaction. Responses were classified as 1–4 “unsatisfied,” 5–10 “neither satisfied or unsatisfied,” 11–13 “satisfied,” and 14–15 “very satisfied.” Responses for all the eight additional items of the SRS-30 were used as the anchor for Total Score: 1–10 “not improved,” 11–25 “neither improved or not improved,” 26–29 “improved,” and 30–34 “much improved.”

One-way analysis of variance with Bonferroni post hoc tests were used to compare change in domain scores between groups classified according to responses to the anchor question.

The receiver operating characteristic (ROC) curve–derived MCID for Appearance is the change score with equal sensitivity and specificity to distinguish the unchanged from the better patients; for Activity, it is the change score with equal sensitivity and specificity to distinguish same and increased patients; for Pain, it is the change score with equal sensitivity and specificity to distinguish same and decreased patients; for Subscore, it is the change score with equal sensitivity and specificity to distinguish between neither satisfied or unsatisfied and satisfied patients; for Total, it is the change score with equal sensitivity and specificity to distinguish between neither improved or not improved and improved patients.

The ROC curve–derived SCB for Appearance is the change score with optimal sensitivity and specificity to distinguish the better from the much better patients, for Activity, it is the change score with optimal sensitivity and

Table 1
Items on SRS-30 completed post-op and not included in SRS-22.

23. On a scale of 1 to 9, with 1 being very low and 9 being extremely high, how would you rate your self-image	1 2 3 4 5 6 7 8 9	Low —○—○—○—○—○—○—○—○—○— High	
24. Compared with before treatment, how do you feel you now look?	<input type="radio"/> Much better	<input type="radio"/> Worse	
	<input type="radio"/> Better	<input type="radio"/> Much worse	
	<input type="radio"/> Same		
25. Has your back treatment changed your function and daily activity?	<input type="radio"/> Increased	<input type="radio"/> Not changed	<input type="radio"/> Decreased
26. Has your back treatment changed your ability to enjoy sports/hobbies?	<input type="radio"/> Increased	<input type="radio"/> Not changed	<input type="radio"/> Decreased
27. Has your back treatment _____ your back pain?	<input type="radio"/> Increased	<input type="radio"/> Not changed	<input type="radio"/> Decreased
28. Has your treatment changed your confidence in personal relationships with others	<input type="radio"/> Increased	<input type="radio"/> Not changed	<input type="radio"/> Decreased
29. Has your treatment changes the way others view you?	<input type="radio"/> Much better	<input type="radio"/> Worse	
	<input type="radio"/> Better	<input type="radio"/> Much worse	
	<input type="radio"/> Same		
30. Has your treatment changed your self-image?	<input type="radio"/> Increased	<input type="radio"/> Not changed	<input type="radio"/> Decreased

SRS, Scoliosis Research Society patient questionnaire.

specificity to distinguish increased and much increased patients; for Subscore, it is the change in score with optimal sensitivity and specificity to distinguish satisfied and very satisfied patients; for the Total score it is the change score with optimal sensitivity and specificity to distinguish improved and much improved. SCB for the Pain domain could not be determined as the anchor question for the Pain domain (Item 27) had only three possible choices, such that delineation of patients who responded that their pain had markedly decreased from those that decreased could not be made.

The accuracy of ROC curve is evaluated using the calculated area under the curve (AUC). A ROC curve with AUC equal to 0.80 implies that 80% of the time a patient who reports being much better will have a higher outcome score than a patient who reports being about the same. AUC between 0.90 and 1.00 is considered excellent, 0.80–0.89 good, 0.70–0.79 fair, 0.60–0.69 poor, and 0.50–0.59 failed [13]. All statistical analyses were performed using PASW GradPack V17.0 (SPSS, Chicago, IL) with a threshold p value set at .01 for statistical significance.

The primary NIH-funded study received institutional review board approval from all five centers prior to enrolling patients. Institutional review board approval was received prior to conducting the current secondary analysis.

Results

The sample population consisted of 147 patients. Among them, 132 (89%) were females, with a mean age of 59.4 ± 8.8 years. There was a statistically significant improvement in all SRS22R scores from preoperative to one year postoperation (Table 2). Mean preoperative SRS22R Appearance score was 2.70, improving to 3.95 at

one year postoperation. Mean preoperative SRS22R Activity score was 3.12, improving to 3.51 at one year postoperation. Mean preoperative SRS22R Pain score was 2.78, improving to 3.72 at one year postoperation. Mean preoperative SRS22R Subscore was 3.1, improving to 3.8 at one year postoperation. There was also statistically significant improvement in the lumbar coronal Cobb angle, from 55.19° preoperation to 24.50° postoperation, and improvement in the sagittal vertical axis from 34.23 mm preoperation to 16.07 mm postoperation.

There was also a statistically significant difference in domain scores among the different responses to the anchors (Table 3). According to the ROC curve analysis (Table 4), MCID was 1.17 (AUC = 0.706) for Appearance, 0.40 (AUC = 0.779) for Activity, 0.60 (AUC = 0.780) for Pain, 0.53 (AUC = 0.698) for Subscore, and 0.77 (AUC =

Table 2
Paired comparison of preoperative and postoperative scores.

Variable	Preoperative scores, mean (SD)	Postoperative scores, mean (SD)	p value
Scoliosis Research Society Domain			
Pain	2.78 (0.79)	3.72 (0.84)	<.0001
Activity	3.12 (0.72)	3.51 (0.77)	<.0001
Self-image	2.70 (0.68)	3.95 (0.77)	<.0001
Mental	3.68 (0.79)	4.01 (0.77)	<.0001
Subtotal	3.07 (0.58)	3.79 (0.66)	<.0001
Satisfaction	NA	4.26 (0.97)	NA
Total	3.02 (0.55)	3.8 (0.66)	<.0001
Radiographic measures			
Lumbar coronal Cobb angle, °	55.19 (15.05)	24.50 (12.35)	<.0001
Sagittal vertical axis, mm	34.23 (42.85)	16.07 (37.39)	<.0001

Table 3
Mean domain scores classified according to summed response to anchor questions.

Response to pain anchor	n	Change in appearance score, mean (SD)
Increased back pain	20	0.11 (0.80)
No change	19	0.39 (0.98)
Decreased back pain	108	1.18 (0.83)
Response to appearance anchor		Change in appearance score, mean (SD)
Much worse	0	
Worse	8	-0.10 (0.48)
Same	39	0.83 (0.66)
Better	91	1.47 (0.70)
Much better	9	2.19 (0.88)
Response to activity anchor	N	Change in activity score, mean (SD)
Decreased activity	43	-0.09 (0.65)
No change	47	0.28 (0.56)
Increased activity	28	0.49 (0.51)
Much increased activity	29	1.04 (0.72)
Response to subtotal anchor		Change in subtotal score, mean (SD)
Very unsatisfied	4	0.07 (1.17)
Unsatisfied	11	0.02 (0.52)
Neither	14	0.39 (0.50)
Satisfied	51	0.55 (0.46)
Very satisfied	67	1.08 (0.44)
Response to total anchor		Change in total score, mean (SD)
Not improved	14	0.36 (0.81)
Neither	27	0.32 (0.45)
Improved	85	0.92 (0.50)
Much improved	21	1.31 (0.44)

p < .001 for one-way analysis of variance for the different responses to the summed Anchor responses.

0.614) for Total score. SCB was 1.67 (AUC = 0.789) for Appearance, 0.60 (AUC = 0.834) for Activity, 0.62 (AUC = 0.649) for Subscore, and 1.11 (AUC = 0.767) for Total score. These are similar to previous reports of MCID thresholds of 1.23 for Appearance, 0.6 for Activity, and 0.4 for Pain and SCB thresholds of 1.60 for Appearance and 0.87 for Activity.

Single-sample *t* test showed that patients with ASD who underwent surgical fusion extending into the thoracic spine

Table 4
MCID and SCB based on ROC curve analysis of domain scores.

Domain	ROC MCID	AUC	ROC SCB	AUC
Appearance	1.17	0.706 (0.612-0.800)	1.67	0.789 (0.621-0.956)
Activity	0.40	0.779 (0.702-0.855)	0.60	0.834 (0.752-0.917)
Pain	0.60	0.780 (0.689-0.871)	NA	NA
Subscore	0.53	0.698 (0.560-0.837)	0.62	0.649 (0.559-0.739)
Total	0.77	0.614 (0.517-0.710)	1.11	0.767 (0.676-0.858)

AUC, area under the curve; MCID, minimum clinically important difference; NA, not available; ROC, receiver operating characteristic; SCB, substantial clinical difference.

Table 5
Comparison of demographics and pre-operative Scoliosis Research Society domain scores between current cohort and previously published data on patients with adult spinal deformity fused to the thoracic spine [11,12].

Variable	Adult lumbar scoliosis, mean (SD)	Adult spinal deformity, mean (SD)	p value*
Age	59.4 (8.8)	53.12	< .000
Females	132	1,185	.045
Domain			
Pain	2.78 (0.79)	2.73 (0.92)	.356
Activity	3.12 (0.72)	2.96 (0.59)	.005
Self-image	2.70 (0.68)	2.50 (0.73)	.599
Mental	3.68 (0.79)	3.51 (0.83)	.014
Total	3.02 (0.55)	2.93 (0.64)	.047

* p value is from a single-sample *t* test comparing variables from the current cohort to the published mean values from Crawford et al. [11,12].

[11,12] were younger and had similar preoperative SRS22R domain scores compared to the current cohort (Table 5).

Discussion

Although clinical studies typically aggregate all ASD patients, patients with LDS differ from those with a thoracic deformity in etiology and indication for treatment. Patients with LDS are older and may present with symptoms, including low back pain, radiculopathy, and limited walking ability that is similar to those in patients with lumbar degenerative conditions such as spondylolisthesis or stenosis. However, comparison of baseline SRS22R Pain and Activity scores were similar between the two groups. It is unknown if baseline back pain or low back disability specific scores as measured by the Oswestry Disability Index [14] are different between these two cohorts. In addition, patients with LDS may also have concerns with how their condition affects their appearance, similar to patients with ASD. This is evidenced by the similarity in baseline SRS22R Appearance scores between patients with LDS and ASD.

However, patients with LDS rarely require fusion into the thoracic spine or complex surgical maneuvers and techniques to correct their deformity. Thus, previously published psychometric data on the SRS-22R as it applies to ASD patients may not be applicable to patients with LDS.

In the current study of patients with LDS, the MCID and SCB thresholds for the Appearance domain were the largest among the different domains and were similar to published thresholds for ASD [12]. In the current study as well as in Crawford's study of ASD patients, larger score changes in the Appearance domain are needed in order for patients to detect a clinically meaningful change, suggesting that improvement in the other domains are more clinically important to the patient than improvement in Appearance.

Interestingly, the MCID threshold for Activity (0.40) is lower than that reported in a study using data from the Adult Deformity Outcomes Study from the Spine Deformity Study group (0.60) [12]. The Activity Domain SCB threshold in LDS was similar to the MCID threshold in ASD [12]. This may suggest that patients with LDS consider smaller improvements in Activity more clinically relevant than patients with ASD or that patients with ASD value other aspects of HRQOL improvement more than activity. This is further demonstrated by the results that show the reverse finding in MCID thresholds for Pain, where the MCID threshold for Pain in patients with ASD (0.4) was lower than that for LDS (0.6). A substantial portion of the symptoms in patients with LDS may be due to their limited walking ability due to stenosis, while in patients with ASD, pain may be a more predominant symptom because of sagittal imbalance.

Both the MCID and SCB for the Subscore and Total Scores were greater in the LDS population compared with those reported for ASD patients. There may be other factors, such as improvement in Mental domain score and the differential additive effect of changes in the other domains that account for this.

There are limitations to the current study. The last eight items of the SRS-30 were not specifically designed to be used as anchors for determining MCID thresholds for each of the domains. SCB for the Pain domain could not be calculated because of a lack of an appropriate anchor. As the pain anchor question has only three levels, it is not possible to differentiate between "improved" and "much improved." The sample size is smaller than in previous studies, although statistically significant changes in preoperative and one-year postoperative scores were seen. Comparisons between the current cohort and previously published cohorts in terms of curve magnitude, extent of sagittal imbalance, need for decompression, combined surgical approaches, or fusion to the pelvis could not be performed as these data were not published.

Further studies are needed to define clinically relevant outcomes in patients with spine deformity. Differences in the MCID and SCB values between patients with adult spinal deformity and lumbar degenerative scoliosis show that these patients value various aspects of the HRQOLs differently.

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