

Evolution and Advancement of Adult Spinal Deformity Research and Clinical Care: An Overview of the Scoli-RISK-1 Study

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Abstract

Study Design: Narrative review.

Objective: The prevalence of adult spinal deformity (ASD) has been cited anywhere between 2-32%, while the prevalence in the elderly population has been estimated at 68%. Neurologic complications following ASD surgery remains a concern. Previous literature reported incidence of neurologic complications varied between 1-10%, while non-neurologic complications reported were as high as 50%. To assess the incidence of neurologic deficits, complications, and outcomes following ASD surgery, an international group of spine deformity surgeons initiated a prospective, multicenter, international, observational study: Scoli-RISK-1.

Methods: Two hundred seventy-two patients were enrolled from 15 centers with ASD having primary or revision surgery with a major Cobb \geq 80°, revision including an osteotomy, and/or a complex 3-column osteotomy. Patients had lower extremity muscle strength (LEMS) exams performed preoperatively and at specific time points through 2-year follow-up.

Results: Preoperatively, 203 patients (74.9%) had no LEMS impairment (normal) and 68 (25.1%) had a LEMS of <50 (abnormal). Compared with baseline, 23.0% of all patients experienced a LEMS decline at discharge, with this rate decreasing to 17.1% at 6 weeks and to 9.9% at 6-months and remaining stable at 10.0% at 2-years.

Conclusion: This study revealed that a decline in LEMS after complex ASD surgery is common and more frequent than previously reported. We identified such a decline in 23.0% of patients at discharge, with neurologic function recovering over time to a decline of 10.0% at 2-years postoperatively. The Scoli-RISK-1 study revealed valuable information regarding the incidence, natural history, and prognosis of neurologic and non-neurologic complications following ASD surgery and provides useful information for patient counseling.

Keywords

scoliosis, deformity, neuro, fusion, revision surgery

Introduction

The demographics of the global population are expected to shift dramatically as the world's population ages rapidly, creating a significant impact on health care and health systems.¹ In today's aging society, the prevalence of adult spinal deformity (ASD) has been cited anywhere between 2% and 32%, while the prevalence in the elderly population has been estimated at 68% ²⁻⁴ ASD has consistently been shown to have a significant negative impact on health-related quality of life (HRQoL) and often requires operative or nonoperative management.^{5,6} Operative management of ASD may consist of complex, technically advanced reconstructive surgery to treat these deformities.

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Advancements in medical technology have faciled improvements in surgical correction for ASD, although intricate procedures are associated with a vast array of pot complications during and following surgery. Neurologic plications following ASD surgery remains one of the mount concerns for both patient and surgeon. In pre literature, the reported incidence of neurologic complications. was inconsistent, varying between 1% and 10% , while neurologic complications reported were as high as 50. 7-9 These fluctuating rates were primarily derived from retrospective studies with heterogeneous populations and incons definitions of complications, which likely underestimate true incidence of complications following ASD surgery.

For appropriate preoperative planning and patient co ing, risk factors and possible complications must be considered ered, thus creating a complication profile for each patient. address the inconsistencies in the current literature and to assess the incidence of neurologic deficits, complication outcomes following ASD surgery, an international gro spine deformity surgeons decided to initiate a prospective ticenter, international, observational study: Scoli-RI Before Scoli-RISK-1 began enrollment, the study protocol developed to ensure homogeneity of the population with precise inclusion/exclusion criteria requirements, ensure an objecttive and consistent approach to quantify and collect data determine all primary and secondary research question study would assess.

Materials and Methods

This prospective, observational, international, multic study evaluated neurologic complications associated with surgical correction of complex ASD; defined as: major angle of $\geq 80^\circ$ in the coronal and/or sagittal plane; corrective osteotomies for congenital spinal deformity or for any ty deformity revision; 3-column osteotomy (ie, pedicle subtion osteotomy (PSO), vertebral column resection (between $C7-L5$ inclusive); reconstruction for defor induced myelopathy; or deformity reconstruction with c mitant spinal cord decompression with ossification of the ligamentum flavum or posterior longitudinal ligament.

The study was conducted in 15 spinal deformity centers worldwide: North America (9), Europe (3), and Asia (3). A total of 272 consecutive patients were enrolled between September 2011 and October 2012 by 43 board-certified surgeons. The ethics committees/institutional review boards granted approval at all sites and patients signed informed consent prior to enrollment. The study is registered with clinicaltrials.gov, NCT01305343. Each participant's operating surgeon decided on surgical approach, instrumentation, corrective maneuvers, and use of bone grafts/substitutes. Patients were between 18 and 80 years old and had ASD with the major deformity apex in the cervicothoracic or thoracolumbar region (Table 1).

An American Spinal Injury Association (ASIA) neurologic examination¹⁰ was performed by an ASIA-certified examiner within 6 weeks preoperative, at hospital discharge, and Table 1. Study Inclusion and Exclusion Criteria.

6 weeks, 6 months, and 2 years postoperative. The primary outcome measure was the change in the ASIA lower extremity motor score (LEMS) at each time point. The LEMS evaluates motor function on a scale of 0 (no motor function) to 5 (full motor function) for 5 lower extremity muscle groups with a 50-point maximum (25 per side). Neurological recovery was defined as any recovery of LEMS points at any time point through the follow-up period in comparison with LEMS at discharge. Recovery was categorized into 3 groups: full (back to baseline status or better), partial, and no recovery.

Further neurologic outcomes subanalysis categorized postoperative neurological decline into "major" (loss of 5 points or more) and "minor" decline (loss of less than 5 points). Based on previous literature, a 5-point change in the LEMS has been reported to be the minimal clinically important difference in spinal cord injury patients. 11 A second subanalysis assessed unilateral LEMS decline, defined as patients with decline in LEMS by at least 1 point with no new weakness on the contralateral extremity, and bilateral LEMS decline, defined as patients with a decline in LEMS in both legs following surgery.

Standing coronal/sagittal x-rays, patient-reported outcomes, and adverse events were collected at each visit. Adverse events were classified as perioperative (intraoperative and those occurring within the first 6 weeks after surgery) and late (those occurring after 6 weeks). These adverse events were also categorized into major or minor according to Glassman et al.¹² All nonneurologic adverse events recorded by the participating spine surgeons were included. The study used the Web-based online data capture system (eCRF) OpenClinica. Additionally, a clinical endpoint committee (CEC) evaluated all neurologic and nonneurologic complications. These were assessed and adjudicated to ensure their accuracy.

Differences in demographic and surgical characteristics between the groups were analyzed using the Fisher exact test for categorical variables and the t test for continuous variables. Changes in the LEMS were analyzed using a mixed model for repeated measures with an unstructured covariance to handle missing data points. The statistical analysis was performed using SAS software, version 9.2 (SAS Institute).

Results

A total of 272 consecutive patients were enrolled between September 2011 and October 2012. One patient lacked a preoperative LEMS and was excluded, therefore only 271 patients could be included in the analyses. The study population included 182 women and 89 men. The mean age $(\pm$ standard deviation) was 56.9 (+15.3) years. A total of 169 (62.1%) patients had previous spine surgeries, and 212 (77.9%) patients had 1 or more nonneurologic comorbidities.

The average number of levels operated on was 11.7 (range 3-23 levels). The mean total operative time was 448.5 (± 164.4) minutes, with an estimated total blood loss of 2639.0 (\pm 2008.8) mL. Procedures included primary or revision surgery for ASD with a major Cobb angle of $>80^\circ$ in the coronal or sagittal plane in 29.0% of the patients, revision surgery including an osteotomy in 60.7%, and/or a 3-column osteotomy in 75.7%, emphasizing the complex nature of these patients' conditions and their surgical treatments.

Neurologic

Seven patients did not have LEMS completed at discharge and 1 patient also lacked preoperative LEMS, resulting in 265 patients included in the group analyses. Thirteen patients (4.8%) missed their 6-week assessment; 19 patients (7.0%) missed their 6-month assessment and 62 patients (22.9%) did not attend the 24-month visit.

Preoperatively, 203 patients (74.9%) had no lower extremity motor impairment (LEMS of 50; normal group) and 68 (25.1%) had a LEMS of <50 (abnormal group). The normal group included a higher percentage of women than the abnormal group (70.4% and 57.4%, $P = .053$) and a lower percentage with previous spine surgery (57.6% and 76.5%, $P = .006$). Patients with a postoperative LEMS decline were similar in both groups at each time point. The decline was most pronounced at discharge, with gradual improvement over time (Table 2). Compared with baseline, 23.0% of all patients experienced a LEMS decline at discharge, with this rate decreasing to 17.1% at 6 weeks and to 9.9% at 6 months and remaining stable at 10.0% at 2 years.

Compared with baseline, the LEMS declined for 22.1% of the patients in the normal group and 25.8% in the abnormal group at discharge; 11.1% and 6.5% , respectively, at 6 months; and 9.2% and 13.0%, respectively, at 2 years. There was a small significant decline in the mean LEMS at all follow-up assessments as compared with baseline ($P = .001$ up to 6 months and $P = .002$ at 2 years) in the normal group, whereas the abnormal group had a significant improvement at 6 months $(P < .001)$ and 2 years $(P = .003)$ (Table 3). Importantly, no patient in this study experienced permanent postoperative paraplegia following their index surgical procedure.^{13,14}

Of the 61 patients (23%) who experienced a decline in LEMS at discharge, major neurological decline (5 LEMS points loss) occurred in 20 patients (33%), whereas 41 (67%) experienced a minor decline. For 20 patients with a major decline of 5 or more LEMS points loss at discharge, full recovery was seen in 4 patients (24%) at 6 weeks, increasing to 65% at 6 months and 67% at 24 months, while the rest remaining with some neurologic decline. Four patients (24%) showed no recovery at 6 weeks, but only one patient showed no recovery at 6 months (5%) . In contrast, 20 of 41 patients (49%) with a minor decline of less than 5 LEMS points loss at discharge showed full recovery at 6 weeks, increasing to 70% at 6 months and 74% at 24 months, with some decline persisting in the rest. No recovery was observed in 18 of 41 patients (44%) at 6 weeks, with the rate decreasing to 20% at 6 months and 18% at 24 months.¹⁵

Furthermore, of the 23% of patients that had a decline in LEMS a unilateral decline was seen in 32 patients (12%), while the other 29 (11%) had bilateral symptoms. The unilateral cohort did include more women 26 (81.3%) than the bilateral cohort 14 (48%) ($P = .007$). The study population mean age was 56.9 \pm 15.3 years compared with 63.1 \pm 10.5 years in the unilateral group and 60.7 \pm 10.1 in the bilateral group. Patients were otherwise similar in both groups at every time point, with the majority having only minor neurologic LEMS decline (unilateral $n = 25$, 78%; bilateral $n = 19, 66\%$). The patients with unilateral motor decline were more likely to have undergone a combined anterior-posterior approach, 11 patients (34.4%) versus 2 patients (6.9%) with bilateral deficits ($P = .009$) (Table 2). The median number of levels involved in surgery was also higher in the unilateral group compared with the bilateral group, that is, 13.0 (interquartile range [IQR] 11.0-17.5) and 10.0 (IQR 9.0-13.0) ($P = .005$), respectively. There was no statistically significant difference in other operative variables between the 2 groups. Unilateral versus bilateral motor decline did not significantly affect the length of stay in the hospital or disposition on discharge. 16

^a Presented as median (interquartile range).

Table 3. Change in Lower Extremity Motor Score (LEMS) Compared With Baseline by Group.

^a Chi-square test.

b Fisher's exact test.

Nonneurologic

A total of 184 patients (67.6%, 95% CI 61.7%-73.2%) experienced 515 nonneurologic events. Overall, 63 patients (23.2%) had 1 nonneurologic adverse event, and 121 (44.5%) had 2 or more adverse events (AEs). There were 300 (58.3%) perioperative and 215 (41.7%) late adverse events. There were 234 AEs classified as major (in 121 patients, 44.5%) and 281 as minor (in 142 patients, 52.2%).

Overall, the most frequently encountered nonneurologic AEs were surgery related (27.6% of all nonneurologic AEs, occurring in 39.7% of the patients), implant failure (9.1% of all nonneurologic AEs, occurring in 14.7% of the patients) and dural tear (8.3% of all nonneurologic AEs, occurring in 15.8% of the patients).

For perioperative adverse events, surgery-related complications accounted for 27.3% of all the nonneurologic AEs, followed by urinary tract infections (9.0%) and wound-related problems (6.7%). The perioperative AEs occurred in 25.7%, 9.2%, and 7.4% ofthe patients, respectively. Forlate adverse events, implant failure (20.9%), wound-related problems (6.5%), and loss of correction (6.0%) were most commonly reported and affected 14.3%, 4.0% and 4.8% of the patients, respectively (Table 4).¹⁷

Discussion

This prospective study analyzed lower extremity motor neurologic function and nonneurologic outcomes after complex spinal reconstruction in patients with severe ASD. To our knowledge, this is the largest series of adult patients with severe deformities whose neurologic function was documented prospectively using a validated outcome instrument. Loss of neurologic function is one of the most important complications following complex ASD surgery. The decreased mobility directly affects the patient's quality of life and may lead to additional adverse events.

The primary analysis found that the LEMS at hospital discharge, compared with preoperative LEMS, was 23.0% of the

Table 4. Nonneurological Adverse Events.

Nonneurological Adverse Events	n	% (95% CI)
Any of the nonneurological adverse events specified below	184	67.6 (61.7-73.2)
Stroke	0	$0.0 (0.0 - 1.3)$
Cardiac arrest	L	$0.4(0.0-2.0)$
Surgery related	108	39.7 (33.8-45.8)
Cerebrospinal fluid leak	2	$0.7(0.1-2.6)$
Dural tear	43	15.8 (11.7-20.7)
Screw malposition	7	2.6 (1.0-5.2)
Loss of correction	18	6.6 $(4.0 - 10.3)$
Implant failure	40	14.7 (10.7-19.5)
Pedicle fracture	L	$0.4(0.0-2.0)$
Laminar fracture	0	$0.0 (0.0 - 1.3)$
Visceral injury	6	$2.2(0.8-4.7)$
Vascular injury	L	$0.4(0.0-2.0)$
Excessive bleeding	14	$5.1(2.8-8.5)$
Graft dislodgement	L	$0.4(0.0-2.0)$
Graft donor site pain	ı	$0.4(0.0-2.0)$
Intraoperative coagulopathy	3	$1.1(0.2-3.2)$
Visual field deficits/loss	0	$0.0 (0.0 - 1.3)$
Malignant hyperthermia	0	$0.0 (0.0 - 1.3)$
Anesthetic complication	4	$1.5(0.4-3.7)$
Wound infection	26	$9.6(6.3-13.7)$
Deep infection	$\overline{2}$	$4.4(2.3-7.6)$
Superficial infection	8	2.9 (1.3-5.7)
Graft site infection	$\overline{2}$	$0.7(0.1-2.6)$
Wound dehiscence/Stitch abscess	7	2.6 (1.0-5.2)
Gastrointestinal	П	$4.0(2.0-7.1)$
Superior mesenteric artery syndrome	0	$0.0 (0.0 - 1.3)$
lleus	П	$4.0(2.0-7.1)$
Deep vein thrombosis	8	2.9 (1.3-5.7)
Pulmonary embolism	3	$1.1(0.2-3.2)$
Respiratory	14	$5.1(2.8-8.5)$
Pneumonia	10	$3.7(1.8-6.7)$
Atelectasis	6	$2.2(0.8-4.7)$
Urogenital	37	13.6 (9.8-18.3)
Urinary retention	10	$3.7(1.8-6.7)$
Retrograde ejaculation	0	$0.0 (0.0 - 1.3)$
Urinary tract infection	30	$11.0(7.6-15.4)$
Other	119	43.8 (37.8-49.9)

patients who underwent surgical correction for ASD. As motor function recovered over time, this rate decreased to 17.1% at 6 weeks and then to 9.9% at 6 months, and then remained stable at 10.0% at 2 years.¹⁴ These rates of perioperative motor decline are the highest reported to date, which is attributed to the prospective nature of the study with a homogenous patient population, predefining data collection points, and standardized neurological assessments. Previous retrospective studies with heterogeneous patient populations, surgical procedures, and inclusion/exclusion criteria have cited new postoperative neurologic deficits at 0%, 4.7%, 7%, 11.1%, and 17.9%, respectively.18-22 To further elucidate the extent that a retrospective study may underreport neurologic deficits, a comparative retrospective cohort with 5 of the participating centers in the Scoli-RISK-1 study using identical inclusion and exclusion criteria was performed. For the retrospective data collection, case report forms mirroring those of the prospective arm were distributed to the participating sites and the medical records of eligible patients between June 2009 and June 2011 were reviewed. A total of 207 patients were included in the retrospective analysis, and only 9% were reported to have had a new neurologic deficit postoperatively, compared with the 23% found in the prospective study.²³ This represents how paramount prospective data collection is for analyses of neurologic deficits, which may be subtle and/or transient and remain undetected in retrospective studies.

In addition to comparing new postoperative neurologic deficits, we were able to dissect various forms of deficits, including unilateral, bilateral, minor, and major deficits. When comparing major versus minor postoperative neurologic decline of those who experienced postoperative weakness, we found that one-third experienced a major decline, while the remainder had a minor decline. Furthermore, while the majority of recovery occurred in the first 6 months, onethird of the postoperative neurological deficits showed some persistence through long-term follow-up. Interestingly, although a quicker full recovery was seen in the patients with a minor decline than in those with a major decline, patients with minor deficits showed full recovery less frequently than those with major deficits. 15

Focusing on the incidence of unilateral versus bilateral neurologic deficits, we identified that new weakness affected either one or both legs at a similar rate. In both groups at 2-year follow-up, approximately two-thirds recover to at least their preoperative baseline level of lower extremity strength. The prognosis for neurologic recovery of new motor deficits following complex ASD is similar with both unilateral and bilateral weaknesses. Although both groups had similar neurologic function, patients who initially had bilateral deficits have worse patient reported outcomes at 2 years postoperative.¹⁶ Understanding the risk of such deficits is fundamental to patients' ability to provide informed consent and to clinical decision making, which we are now able to provide more accurately.

Postoperative complications, neurologic and nonneurologic, are critical data points to assess following ASD surgery, as it is vital for preoperative patient counseling. Patients need to be adequately informed of the potential postoperative risks and complications they may experience after their surgery. Similar to postoperative neurologic outcomes, the majority of literature on nonneurologic outcomes following ASD surgery contains an inconsistent array of findings derived from retrospective studies, thus subject to underreporting and bias. Therefore, an accurate and thorough knowledge base of the true incidence, types of, and risk factors for nonneurologic AEs after complex ASD surgeries are crucial to surgeons and patients.

This analysis presents an overall incidence of patients with at least 1 nonneurologic AE at 67.6%, with a slightly higher rate during the perioperative than late period (53.7% vs 42.3%). The most frequent nonneurologic AEs were surgically related (27.6% of the AEs occurring in 39.7% of the patients), of which implant failure and dural tear were most common. A recent

comprehensive review of the literature on complication rates after surgery for ASD found an overall complication rate of 55%. ²⁴ However, these series suffered from methodological limitations, including retrospective nature, single-centered, heterogeneous inclusion criteria, nonstandardized reporting, lack of data monitoring, and loss to follow-up.¹⁷ These constant inconsistencies further illustrate the need for prospective studies in accurately assessing the true incidences of postoperative outcomes following ASD surgery.

Once the incidence of postoperative complications is truly understood, we can do further work to identify the specific risk factors associated with individual and/or groups of complications. Identifying preoperative risk factors can aid physicians in mitigating risk for complications preoperatively and optimize patients for surgery to reduce the chances of postoperative complications. Not only does the Scoli-RISK-1 study add valuable insights to neurologic and nonneurologic outcomes data, but we can also use this to identify risk factors that are associated with specific complications. For example, when analyzing predictive risk factors for neurologic decline univariate analysis found that age, lumber level osteotomy, 3-column osteotomy, and blood loss were found to differ significantly between the patients with and without neurologic decline. After using a multivariate logistic regression model, there were three significant predictors of neurologic decline: older age, larger coronal deformity angular ratio, and lumbar osteotomy.²⁵ A similar univariate analysis of the Scoli-RISK-1 data done for nonneurologic outcomes revealed age, previous spine surgery, and ASA (American Society of Anesthesiologists) grade as risk factors for developing a nonneurologic AE. However, a multivariate logistic regression analysis only identified previous spine surgery as an independent risk factor. Interestingly, previously reported risk factors in the literature, including body mass index, number of documented nonneurologic comorbidities, operative duration, blood loss, and preoperative neurologic status were not significant according to this analysis.¹⁷ With the proper understanding of the incidence profiles of the outcomes following ASD surgery, we can more accurately understand preoperative risks that can be modified.

Conclusion

This landmark study revealed that a decline in lower extremity motor function after complex ASD surgery is common and more frequent than previously reported. We identified such a decline in 23.0% of patients at discharge, with neurologic function recovering over time to a decline (compared with preoperatively) of 10.0% at 2 years postoperatively. The Scoli-RISK-1 study revealed valuable information regarding the incidence, natural history, and prognosis of neurologic and nonneurologic complications following adult deformity surgery and provides useful information for patient counseling. To date, the Scoli-RISK-1 study has a multitude of manuscript publications, abstract presentations, and poster presentations worldwide. The field of medicine is constantly evolving and through this expansion, we have the opportunity to advance the care that we provide. Through the unique collaboration of 2 leading spine deformity societies, SRS and AOSpine, along with dedicated spine deformity surgeons around the world, the Scoli-RISK-1 study was made possible and adult spine deformity care will forever benefit.

Declaration of Conflicting Interests

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

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