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DEFORMITY

Examination of Adult Spinal Deformity Patients Undergoing Surgery with Implanted Spinal Cord Stimulators and Intrathecal Pumps

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Study Design. Retrospective cohort study of a prospectively collected multi-center database of adult spinal deformity (ASD) patients.

Objective. We hypothesized that patients undergoing ASD surgery with and without previous spinal cord stimulators (SCS)/intrathecal medication pumps (ITP) would exhibit increased complication rates but comparable improvement in health-related quality of life.

Summary of Background Data. ASD patients sometimes seek pain management with SCS or ITP before spinal deformity correction. Few studies have examined outcomes in this patient population.

Methods. Patients undergoing ASD surgery and eligible for 2-year follow-up were included. Preoperative radiographs were reviewed for the presence of SCS/ITP. Outcomes included complications, Oswestry Disability Index (ODI), Short Form-36 Mental Component Score, and SRS-22r. Propensity score matching was utilized.

Results. In total, of 1034 eligible ASD patients, a propensity score-matched cohort of 60 patients (30 with SCS/ITP, 30 controls) was developed. SCS/ITP were removed intraoperatively in most patients (56.7%, n = 17). The overall complication rate was 80.0% *versus* 76.7% for SCS/ITP versus control ($P > 0.2$), with similarly nonsignificant differences for intraoperative and infection complications (all $P > 0.2$). ODI was significantly higher among patients with SCS/ITP at baseline (59.2 *vs.* 47.6, $P = 0.0057$) and at 2-year follow-up (44.4 *vs.* 27.7, $P = 0.0295$). The magnitude of improvement, however, did not significantly differ ($P = 0.45$). Similar results were observed for SRS-22r pain domain. Satisfaction did not differ between groups at either baseline or follow-up ($P > 0.2$). No significant difference was observed in the proportion of patients with SCS/ITP versus control reaching minimal clinically important difference in ODI (47.6% *vs.* 60.9%, $P = 0.38$). Narcotic usage was more common among patients with SCS/ITP at both baseline and follow-up ($P < 0.05$).

Conclusion. ASD patients undergoing surgery with SCS/ITP exhibited worse preoperative and postoperative ODI and SRS-22r pain domain; however, the mean improvement in outcome scores was not significantly different from patients without stimulators or pumps. No significant differences in complications were observed between patients with *versus* without SCS/ITP.

Key words: adult spinal deformity, complications, HRQOL, pain pump, spinal cord stimulator.

Level of Evidence: 3

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Adult spinal deformity (ASD) encompasses a variety of conditions related to deviation in alignment or abnormal curvature of the spine. These deformities can markedly impact health-related quality of life (HRQOL).[1–4] Additionally, progression of ASD occurs at variable rates posing challenges for determining the optimal course of action for alleviating symptoms, thus some patients seek alternative measures for symptom alleviation.[5] ASD is growing in incidence and overall economic impact on the health care system.[6]

Spinal cord stimulation (SCS) was first employed in 1967, and it has since increased in popularity.[7] At a willingness to pay threshold of $30,000 in 2010, SCS was shown to have an 89% probability of being cost effective.[8] In the United States, SCS is most widely used to manage pain related to failed back surgery syndrome (FBSS).[9] In one study among patients with FBSS, patients receiving SCS reported significant pain relief and improvement in HRQOL, and the majority were able to resume daily activities.[10] SCS has also shown efficacy among patients with ASD specifically, though studies among this population are fewer in number.[11,12] The complication rate of SCS is has been estimated at 30% to 40%, although serious complications are rare.[7,13,14] The majority of complications are related to the device and leads, notably lead failure or migration, but biological complications such as infection are also often reported. An additional option for pain treatment is intrathecal opioid infusion via implanted pumps (ITP), which has also shown to be efficacious in the treatment of FBSS.[15–17]

Select studies have shown that SCS offers superior rates of pain relief as compared to repeated surgery and conventional medical management (CMM) in FBSS.[18–21] Less is known, however, regarding outcomes after ASD surgery among patients who have already been treated with either SCS or ITP. We hypothesized that patients undergoing ASD surgery with and without previous SCS/ITP would exhibit increased complication rates but comparable improvement in HRQOL.

METHODS

Data Sources and Patient Selection

This study utilized a prospectively collected, multicenter database of ASD patients. Institutional review board approval was obtained at all participating sites. Inclusion criteria for database enrollment included age $\geq$18 years old with diagnosis of adult degenerative or idiopathic scoliosis. Patients were required to meet at least one of the following radiographic parameters: coronal Cobb angle $\geq$20°, sagittal vertical axis $\geq$5 cm, pelvic tilt $\geq$25°, or thoracic kyphosis $\geq$60°. Patients with spinal deformity secondary to causes other than degenerative or idiopathic, including traumatic, neuromuscular, congenital, infectious, and paralytic, were excluded in an effort to create a more homogenous cohort. Only patients undergoing surgery for ASD and eligible for minimum 2-year follow-up were included.

Outcome Measures

The primary outcomes in this study were Oswestry Disability Index (ODI), SF-36 Mental Component Score (MCS), and Scoliosis Research Society (SRS)-22r Pain and Satisfaction domains. Narcotic use at baseline and 2 years postop-eratively was assessed with SRS-22r question 11. Minimal clinically important difference (MCID) in ODI was set at 12.8.[22] Patient-reported outcome measures (PROMs) were recorded at baseline preoperatively and at 2 years postop-eratively. Additional outcomes included total complications, intraoperative complications (defined as any complication occurring intraoperatively), and infection.

Independent Variables

The primary independent variable in this study was the presence of SCS/ITP on preoperative spine radiographs, as determined by investigator review. Radiographs at 6 weeks postoperatively were also reviewed to determine whether the SCS/ITP was removed or left *in situ*.

Statistical Analysis

Descriptive statistics for all variables were generated both before and following propensity score matching. Propensity score matching was conducted based on age, sex, Charlson Comorbidity Index (CCI), and surgical invasiveness. Notably, of 31 patients with SCS/ITP, 1 patient was unable to be matched, resulting in a cohort of 30SCS/ITP and 30 controls. Bivariable analyses for the presence of a preoperative SCS/ITP against PROMs, radiographic parameters, and complications were conducted using Wilcoxon-Mann-Whitney tests, χ^2 tests, and Fisher exact tests, as appropriate. All statistical analyses were completed using SAS 9.4 (SAS Institute, Cary, NC). Statistical significance was defined as $P < 0.05$.

RESULTS

Descriptive Statistics

In total, 1034 patients were eligible for inclusion in this study. SCS/ITP were observed in 3.0% (n = 31) preoperatively. Of the final matched cohort (30 with SCS/ITP and 30 controls) SCS/ITP were removed intraoperatively in most patients (56.7%, n = 17). (All subsequent statistics refer to the matched cohort.) The mean age was 63.7 years (SD 10.6), and 60.0% (n = 36) of patients were female (Table 1). A case example is provided in Figure 1. No significant differences were observed in T1-pelvic angle or pelvic incidence at either baseline, 2 years postoperatively, or 2-year change from baseline (all $P > 0.05$).

Complications

In total, 78.3% (n = 47) of patients experienced one or more complication, and 33.3% (n = 20) experienced intraoperative complications. Patients with preoperative SCS/ITP *versus* controls did not experience significantly different rates of total complications (80.0% *vs.* 76.7%, $P = 0.75$),

TABLE 1. Descriptive Statistics

Variable	Full Cohort		Matched Cohort	
	N	%	N	%
All patients	1034	–	60	–
Preoperative SCS or ITP				
No	1003	97.0	30	50.0
Yes	31	3.0	30	50.0
Sex				
Male	267	25.9	24	40.0
Female	766	74.2	36	60.0
Frequency missing = 1				
CCI				
0	324	31.4	3	5.0
1	222	21.5	26	43.3
2	215	20.8	14	23.3
≥3	272	26.3	17	28.3
Frequency missing = 1				
Complications				
Total complications	610	59.0	47	78.3
Intraoperative	208	20.1	20	33.3
Deep infection	27	2.6	3	5.0
Superficial infection	24	2.3	2	3.3
2-y MCID in ODI	384	55.8	24	54.6
Frequency missing = 346				
Baseline narcotic usage	556	55.5	41	70.7
Frequency missing = 32				
2-y Narcotic usage	222	32.8	27	64.3
Frequency missing = 357				
	Mean	**SD**	**Mean**	**SD**
Age	59.8	14.7	63.7	10.6
ISSG surgical invasiveness	99.7	39.3	43.3	43.3
ODI				
Baseline	45.1	18.1	53.3	15.4
2 y	27.3	20.5	35.7	23.7
Δ 2Y–BL	−16.4	18.3	−16.4	18.7
SF-36 MCS				
Baseline	45.1	13.9	39.6	14.6
2 y	50.6	12.4	50.2	14.0
Δ 2Y–BL	5.1	12.7	9.8	12.9
SRS-22r Pain Domain				
Baseline	2.3	0.8	2.1	0.8
2 y	3.5	1.1	3.1	1.3
Δ 2Y–BL	1.1	1.1	1.1	1.2
SRS-22r Satisfaction				
Baseline	2.7	1.1	2.8	1.2
2 y	4.1	1.0	4.3	1.0
Δ 2Y–BL	1.4	1.4	1.5	1.6
T1-pelvic angle				
Baseline	23.6	13.3	29.4	13.8
2 y	17.6	10.9	19.2	7.7
Δ 2Y–BL	−5.4	10.5	−9.9	11.6
Pelvic incidence				
Baseline	55.7	12.9	55.7	12.5
2 y	55.2	12.5	56.0	12.2
Δ 2Y–BL	0.1	2.5	−0.3	2.0

BL indicates baseline; CCI, Charlson Comorbidity Index; ISSG, International Spine Study Group; ITP, intrathecal medication pump; MCID, minimal clinically important difference; MCS, Mental Component Score; ODI, Oswestry Disability Index; SCS, spinal cord stimulators; SF-36, Short Form 36; SRS-22r, Scoliosis Research Society-22r.

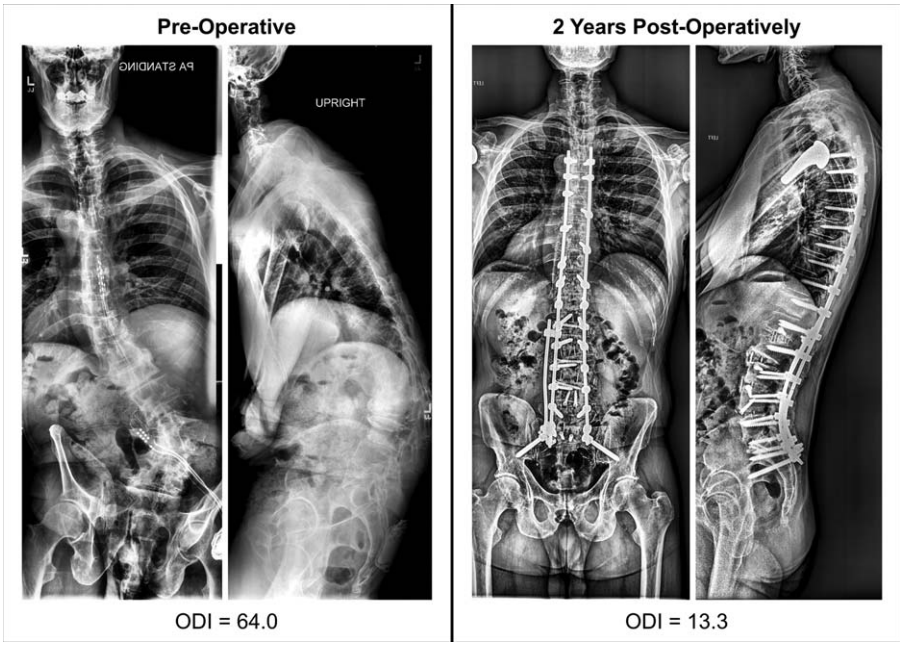

Figure 1. Case example: A 66-year-old male patient with pre-operative implanted spinal cord stimulator and baseline ODI of 64.0, improving to 13.3 at 2 years postoperatively. The spinal cord stimulator was removed intraoperatively. ODI indicates Oswestry Disability Index.

intraoperative complications (30.0% *vs.* 36.7%, $P = 0.58$), deep infection (3.3% *vs.* 6.7%, $P = 1.0$), and superficial infection (80% *vs.* 50%, $P = 1.0$) (Table 2).

PROMs

ODI was higher among patients with SCS/ITP at baseline (59.2 *vs.* 47.6, $P = 0.0057$) and 2 years (44.4 *vs.* 27.7, $P = 0.0295$). MCS was worse among patients with SCS/ ITP at 2 years (44.9 *vs.* 54.1, $P = 0.0489$), but not baseline (37.8 *vs.* 41.3, $P = 0.29$). SRS-22r Pain domain was worse among patients with SCS/ITP at both baseline (1.7 *vs.* 2.4, $P = 0.0004$) and 2years (2.7 *vs.* 3.6, $P = 0.0219$). No significant differences in satisfaction were observed at baseline or 2 years postoperatively ($P > 0.3$ for all comparisons). At minimum 2-year follow-up, 47.6% of patients with SCS/ ITP *versus* 60.9% without had achieved MCID in ODI ($P = 0.3779$) (Table 2).

Narcotic Usage

Patients with SCS/ITP exhibited markedly increased rates of narcotic utilization at both baseline (89.3% *vs.* 53.3%, $P = 0.0026$) and 2years postoperatively (80.0% *vs.* 50.0%, $P = 0.0427$) (Table 2).

DISCUSSION

This retrospective, propensity score-matched cohort study of ASD surgery observed the presence of spinal stimulators or intrathecal pain pumps in 3.0% of patients. Those with *versus* without SCS/ITP exhibited generally poorer ODI, and SRS-22r Pain domain scores, but experienced a comparable magnitude of improvement at 2 years postoperatively. No significant difference was observed in the rates of total complications, intraoperative complications, or deep/superficial infection. Narcotic usage was markedly higher among patients with SCS/ITP at both baseline and 2 years postoperatively.

We observed that patients undergoing ASD surgery with previous SCS/ITP generally had poorer ODI and SRS-22r pain scores at all follow-up points, but that they experienced similar magnitude of improvement as compared to patients without SCS/ITP. In this study, 47.6% of patients with SCS/ ITP experienced at least one MCID in ODI at 2-year follow-up, which was not statistically significantly different from those without SCS/ITP (60.9%, $P > 0.3$). Evidently, despite poorer baseline status, these patients may benefit from surgery.

It is important to underscore that our cohort of patients included only patients with previous SCS/ITP undergoing surgery. As a result, those patients with previous SCS/ITP will likely be those for whom SCS/ITP offered insufficient relief of symptoms. Previous studies of SCS *versus* repeat surgery among patients with FBSS have suggested that SCS may offer superior rates of pain relief. Among a cohort of FBSS patients with persistent radicular pain, North *et al* observed that 47% *versus* 12% of patients treated with SCS *versus* repeat surgery reported $\geq$50% pain relief. Kumar *et al* conducted a randomized trial of SCS *versus* CMM, observing $\geq$50% pain relief among 48% *versus* 9% of patients, respectively. Neither these studies nor the present investigation, however, were designed to assess the relative benefit of surgery among patients who have failed management with SCS or ITP. Future studies may further investigate this topic.

We had hypothesized that patients undergoing ASD surgery with preexisting SCS/ITP would exhibit increased complication rates, particularly intraoperative complications and infection. Although complication rates were directionally higher for patients with SCS/ITP, these differences

TABLE 2. Complications and ODI by Preoperative SCS/ITP Status

Outcome	None (%)	SCS/ITP (%)	*P*
Complications			
Total complications (%)	76.7	80.0	0.7540
Intraoperative (%)	36.7	30.0	0.5839
Deep infection (%)	6.7	3.3	1.0000
Superficial infection (%)	3.3	3.3	1.0000
2 y MCID in ODI (%)	60.9	47.6	0.3779
Baseline narcotic usage (%)	53.3	89.3	0.0026
2-y Narcotic usage (%)	50.0	80.0	0.0427
	None *(Mean)*	**SCS/ITP *(Mean)***	***P***
ODI			
Baseline	47.6	59.2	0.0057
2 y	27.7	44.4	0.0295
Δ 2Y–BL	−17.9	−14.8	0.4588
MCS			
Baseline	41.3	37.8	0.2865
2 y	54.1	44.9	0.0489
Δ 2Y–BL	11.9	7.1	0.1821
SRS-22r Pain Domain			
Baseline	2.4	1.7	0.0004
2 y	3.6	2.7	0.0219
Δ 2Y–BL	1.2	1.0	0.4379
SRS-22r satisfaction			
Baseline	2.8	2.8	0.9807
2 y	4.4	4.1	0.3277
Δ 2Y–BL	1.7	1.3	0.3728
T1-pelvic angle			
Baseline	25.9	32.8	0.0905
2 y	18.6	19.8	0.5750
Δ 2Y–BL	−9.5	−10.3	0.9037
Pelvic incidence			
Baseline	54.9	56.4	0.5395
2 y	56.4	55.6	0.9912
Δ 2Y–BL	−0.4	−0.3	0.6841

BL indicates baseline; ITP, intrathecal medication pump; MCID, minimal clinically important difference; MCS, Mental Component Score; ODI, Oswestry Disability Index; SCS, spinal cord stimulators; SF-36, Short Form 36; SRS-22r, Scoliosis Research Society-22r.

were nonsignificant in multivariable analysis. Given the relatively small number of patients with SCS/ITP in this study, we recognize the possibility that low statistical power may have contributed to these results. In a systematic review, Eldabe *et al* noted reports of lead breakage during removal of SCS.[7] Giberson *et al* reported two cases of epidural hematomas after removal of trial leads.[23] Implantation of SCS/ITP may contribute to local post-surgical changes, potentially impacting future surgery in that area. In a large retrospective database study of 10,912 patients, Diebo *et al* found that patients undergoing revision *versus* primary ASD surgery have elevated complication rates, particularly neurological complications, hematoma/seroma formation, vessel/nerve injury, wound dehiscence, and infection.[24] Other smaller studies, however, have not observed a significant increase in complications for revision surgery.[25,26] Future investigations of complications among SCS/ITP patients undergoing ASD surgery and pain device removal with a larger patient samples should be undertaken.

There are several clinical implications which can be explored based on the results of this investigation. First, among patients with previous thoracic laminectomy to place paddle leads for SCS, the spinal deformity surgeon may choose not to place the upper instrumented vertebra at the level of the thoracic laminectomy to decrease the chance of junctional failure. Additionally, when removing pain pump tubing, repairing the hole in the dura is important to reduce the chance of CSF leak. Another concern is that placing SCS/ITP in patients with debilitating spinal deformity who are candidates for deformity correction may not be effective; however, further studies are needed to explore this topic. Further, some orthopedic surgeons may be less comfortable than neurological surgeons when approaching SCS/ITP

revisions, as training differences exist between the specialties and thus further education for all spine surgeons is needed regarding these patients. Finally, some surgeons may elect for staged removal of leads followed by revision surgery—this approach may be explored in future studies.

This study had several potential limitations. As above, the small sample size of patients with SCS/ITP may have limited our ability to detect small differences in outcomes. Future investigations with larger sample size should be undertaken. Additionally, although we attempted to control for potential confounders via propensity score matching, the possibility of unknown confounding remains. Furthermore, patients with SCS/ITP were identified via review of radiographs. Accordingly, no information regarding the efficacy of SCS/ITP treatment was available. This information would have proved valuable in subanalysis of treatment response, and future studies of this type are necessary. Similarly, although we reviewed postoperative radiographs and determined that most SCS/ITP were removed intraoperatively, the number patients in removed *versus* not removed groups was too small to allow for subanalysis.

CONCLUSION

Although patients with spinal cord stimulators or intrathecal pumps exhibited worse preoperative and post-operative ODI and SRS-22r pain domain scores, the mean improvement was not significantly different from patients without these devices. No significant differences in complications were observed between patients with versus without SCS/ITP. ASD surgery among patients with spinal stimulators or pain pumps is potentially beneficial, with many reaching MCID in ODI scores.

➢ Key Points

- ❑ This study examined outcomes and complications among patients undergoing ASD surgery with *versus* without implanted SCS or ITP.
- ❑ ASD patients undergoing surgery with SCS/ITP exhibited worse preoperative and postoperative ODI and SRS-22r pain domain; however, the mean improvement in outcome scores was not significantly different from patients without stimulators or pumps.
- ❑ No significant differences in complications were observed between patients with *versus* without SCS/ITP.

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