Received: October 9, 2020 Revised: December 8, 2020 Accepted: December 8, 2020

(onlinelibrary.wiley.com) DOI: 10.1111/ner.13351

Spinal Cord Stimulation: A Reasonable Alternative Treatment in Patients With Symptomatic Adult Scoliosis for Whom Surgical Therapy Is Not Suitable? A Pilot Study

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ABSTRACT

Introduction: In adult scoliosis, dorsal instrumentation and fusion can provide significant improvement of pain and disability scores (Owestry Index); however, complication rates of up to 39% have been reported. As such, recent attempts have been made at expanding the surgical spectrum to include less invasive techniques in patients such as neuromodulation, specifically spinal cord stimulation (SCS). We therefore aimed to evaluate its use in a larger cohort of adult scoliosis patients in the form of a pilot study.

Materials and Methods: We analyzed prospectively collected data from 18 adult scoliosis patients receiving SCS treatment in our institution between February 2019 and May 2020. Clinical follow-up was performed at 3, 6, and 12 months following implantation of an epidural SCS System. Patients reported numeric rating scale (NRS) values for the categories of lower back pain (LBP) and regional pain (RP) both at rest and in motion. Further, SF-36, ADS-K, PSQI, and ODI forms were completed. The study was approved by the institutional Ethics Committee (EA2/093/13).

Results: Initial preoperative NRS of LBP at rest was significantly reduced following SCS at three (45% reduction, $p = 0.005$) and six (43% reduction, $p = 0.009$) months follow-up. LBP in motion was also reduced at three (27% reduction, $p = 0.002$) and six (33% reduction vs. preoperative, $p = 0.005$) months. RP at rest was reduced at three (38% reduction, $p = 0.003$) and six (37% reduction, $p = 0.007$) and in movement at three (29% reduction, 0.006) and six (32% reduction, $p = 0.011$). Loss of thoracic kyphosis and increased pelvic incidence were associated with worse NRS response to SCS stimulation at six months follow-up.

Discussion: In overweight, older adults for whom the risks of corrective surgery must be carefully considered, neuromodulation can significantly reduce LBP as well as regional pain in the first six months following implantation. These findings may provide a reasonable alternative in patients not willing or eligible to undergo extensive corrective surgery.

Keywords: Adult degenerative scoliosis, depression, quality of life, SCS, sleep quality

Conflict of Interest: Dr. Bayerl reports personal fees and non-financial support from Boston Scientific, outside the submitted work. Dr. Kuckuck reports personal fees from Boston Scientific, outside the submitted work. The remaining authors declare no conflict of interest.

INTRODUCTION

Adult scoliosis is considered a deformity of the matured spine with a Cobb angle of greater than 10° in the frontal plane (1,2). The underlying causes of scoliosis range from degenerative disc disease with facet joint hypertrophy to secondary deformity related to bone disease, pathology of hip joints, and lower extremities or progression of untreated adolescent scoliosis (2). In adult degenerative scoliosis, the asymmetric load of weight-bearing structures promotes progressive degeneration and can manifest with spinal stenosis and segmental instability. Patients with thoracolumbar scoliosis ultimately suffer predominantly from lower back pain, which can be accompanied by claudication symptoms in the legs and regional pain. In many cases, these symptoms can have socioeconomic impacts resulting in work absenteeism and increased health-care costs (3).

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For more information on author guidelines, an explanation of our peer review process, and conflict of interest informed consent policies, please go to http://www.wiley.com/WileyCDA/Section/id-301854.html

Source(s) of financial support: No financial support was received for this study.

Multimodal nonsurgical therapy is generally recommended for initial treatment in patients suffering from mild symptoms. In patients who do not respond to conservative therapy, surgical treatment is considered a well-established method of addressing chronic back pain resulting from scoliotic deformity in adult patients (4). While dorsal instrumentation and fusion can provide significant improvement of pain and disability scores (Oswestry index) in adult degenerative scoliosis patients (5–7), previous studies have reported complication rates of surgical treatment ranging from 13.5 to 39% (8,9). As such, treatment and long-term management of adult degenerative scoliosis patients presents a significant challenge and recent attempts have been made at expanding the surgical spectrum to include less invasive techniques in patients such as neuromodulation, specifically spinal cord stimulation (SCS) (10).

The method of SCS is a minimally invasive procedure involving the percutaneous placement of leads in the epidural space of the spinal column to treat various forms of chronic pain (11). The precise mechanism of action has not been fully elucidated, however one predominant theory proposes stimulation of dorsal column Aβ-Fibers presumed to mediate cortical processing of pain signals (12,13). To date, evidence exists supporting the use of SCS for the treatment of trunk and limb pain resulting from failed back surgery (failed back surgery syndrome, FBSS) or neuropathic pain (14) or complex regional pain syndromes (15,16).

More recently SCS has been implemented in the treatment of chronic lower back pain (17,18). As chronic lower back pain is also a leading symptom in degenerative scoliosis, SCS may provide a potential alternative treatment method for scoliotic patients who may be not good surgical candidates, yet who are also nonresponders to conservative therapy.

Based on initial evidence of efficacy of SCS in one report of a subject with adult degenerative scoliosis without previous surgery (10), we aimed to evaluate its use in a larger cohort of adult scoliosis patients. In particular, we examine the effect of SCS on lower back pain (LBP), regional pain, quality of life, sleep quality, disability, and mood states. We also performed rank order correlation analysis to determine the relationship between radiographic, clinical and demographic characteristics and response to the implantation of SCS in adult degenerative scoliosis.

MATERIALS AND METHODS

We prospectively analyzed 18 patients diagnosed with adult scoliosis patients receiving SCS treatment in the Department of Neurosurgery of the Charité hospital between February 2019 and May 2020. Adult scoliosis was defined as a Cobb angle of >10° in the coronal plane in skeletally mature patients The decision to perform neuromodulation vs. surgical intervention was made after careful consideration of individual risk factors on a case-by-case basis together with the patient. All patients underwent a 7–14 day trial phase using 8 or 16 contact leads (AVISTA/Infinion, Boston Scientific) with percutaneous connection to an external impulse generator. Permanent implantation was performed in those who reported at least a 50% improvement of symptoms over this time period. Three stimulation protocols were used in this study: burst stimulation (four pulses at 40 Hz and amplitude of 70% subthreshold), tonic stimulation (pulse width range 200–500 μsec, frequency approximately 40 Hz, amplitude necessary for acceptable paraesthesia) and contour stimulation (pulse width 200 μsec, 200 Hz, amplitude 50% subthreshold). In some cases, stimulation forms were combined. An impulse generator (Precision Montage/Wavewriter, Boston Scientific) was implanted either gluteally or abdominally. The choice of lead and location of impulse generation implantation were made on a case-by-case basis under consideration of patient-specific complaints and preferences. Of the 18 patients observed, two reported no effect of test stimulation so that the leads were removed and these patients were not considered in further analysis. In addition to preoperative data collection, clinical follow-up was performed during the test phase and at 3, 6, and 12 months following epidural implantation of an SCS System. At each of these time points, patients reported numeric rating scale (NRS) values on an 11 point scale for the categories of LBP and specific regional pain both at rest and in motion, quality of life (short form-36; SF-36) (19), mood states (short form of the Profile of Mood States; ADS-K (20)), sleep quality (Pittsburgh Sleep Quality Index; PSQI) (21) and measures of disability in activities of daily life (Oswestry Disability Index; ODI) (22). Regional pain was defined as either radiating into the lower extremities or affecting the thoracic or thoracolumbar spine. Patients defined their regional pain by illustration and written descriptions.

Statistical analysis was performed using SPSS Version 26 (IBM, Armonk, NY, USA). To examine the effect of SCS treatment at the above mentioned time intervals, *t*-tests for dependent variables was used and significance evaluated for each outcome variable for the difference between time points after implantation versus baseline. Spearman rank order correlation analysis was run to identify any relationship between preoperative demographics and radiological characteristics with the response to SCS in the above-mentioned instruments. The threshold for significance was set at $p < 0.05$.

This study was conducted according to the ethical principles of medical research involving human subjects according to the Declaration of Helsinki. The clinical data were assessed and anonymized for patients' confidentiality. Ethical approval (EA2/093/13) was granted by the institutional ethics board of the Charité Ethics Committee.

RESULTS

Patient Characteristics

Our patients were predominantly female (15/18, 83%) with a median age of 78 years (range 33–85 years) and a median BMI of 29 kg/m^2 (range 22–37 kg/m^2). Six patients presented with scoliotic deformity of the lumbar spine (33%) with the remaining 12 patients displaying involvement of both the thoracic and lumbar spine including the thoracolumbar junction. Fifteen patients (83%) reported both LBP in addition to regional pain consisting of thoracic/thoracolumbar pain and/or radiating pain to the lower extremities. Two patients reported isolated LBP and one patient isolated pain of the foot. The etiology of scoliotic deformity in all but one patient (age 33 years with idiopathic scoliosis) could be classified as degenerative. Ten patients (56%) reported regular use of opioid medication prior to SCS implantation. Two of these patients discontinued opioid use after SCS implantation. Classification of the perioperative risk profile for patients was conducted using the American Society of Anesthesiologists score (ASA). Twelve patients were classified as having mild systemic disease (ASA 2) and six patients had severe systemic disease (ASA 3). Lack of benefit during the trial stage was observed for two subjects, thus leads were removed and 16 subjects were available for examination at the three months follow-up visit after implantation. Thirteen

patients had follow-up for six months following implantation and data was collected for eight patients at 12 months following implantation. Burst stimulation was used in nine of the 16 patients (56%), contour stimulation in four patients (25%) and combined modes in three patients (19%). Table 1 contains a summary of the characteristics for 16 patients included in long-term follow-up. The data reflect the current state of follow-up in our department following implantation, therefore not all patients have the same length of follow-up time.

Response to SCS Stimulation

Pain Relief (NRS)

Prior to SCS implantation patients reported a mean LBP pain intensity score (NRS) of 6.1 points (standard deviation 2.2 points) at rest and 8.8 points (standard deviation 1.2 points) in motion. During the test phase following implantation patients reported a reduction of LBP at rest by 2.7 points, ($p = 0.001$) and in motion by 3.8 points ($p = 0.001$) (Fig. 1a). NRS scores for LBP remained significantly lower than preoperative values at rest at three months (2.2 points lower vs. preoperative, $p = 0.003$) and six months (2.0 points vs. preoperative, $p = 0.009$) (Fig. 1a). LBP in motion was also significantly reduced at three months (2.4 points vs. preoperative, $p = 0.002$) and six months (2.9 points vs. preoperative, $p = 0.005$) (Fig. 1b). At 12 months following implantation patients continued to report a decrease in LBP at rest (0.6 points vs. preoperative) and in motion (1.4 points vs. preoperative); however, these results did not reach statistical significance (Fig. 1a,b).

In regards to regional pain, patients reported a mean NRS score of 5.9 (standard deviation 2.0) at rest and 8.7 (standard deviation 1.2). During the test phase after SCS implantation NRS scores were reduced by 3.1 points at rest ($p = 0.001$) and 3.6 points in motion (0.001) (Fig. 1c). Regional pain at rest was also lower at three months (2.3 points lower vs. preoperative, $p = 0.001$) and six months (2.2 points lower vs. preoperative, $p = 0.007$) after implantation (Fig. 1c). At 12 months following implantation patients continued to report a decrease in regional pain at rest (1.2 points lower vs. preoperative); however, these results did not reach statistical significance (Fig. 1c). Regional pain in motion was reduced at three months (2.0, points lower vs. preoperative, $p = 0.006$) and six months (2.7 points lower vs. preoperative, $p = 0.011$) (Fig. 1d). At 12 months following implantation, regional pain was also reduced by 1.7 points, but this was not statistically significant (Fig. 1d). Figure 3 illustrates an example of NRS response over time.

Effect on Mood and Sleep (ADS-K and PSQI)

Patients reported a significant decrease in depressive symptoms compared to preoperative values at three months following implantation (three points lower vs. preoperative, $p = 0.022$). At six and 12 months following implantation the ADS-K score increased (Fig. 2a). The total Pittsburg Sleep Quality Index score improved significantly in patients three months following SCS implantation (three points improvement vs. preoperative, $p = 0.006$). At 6 and 12 months, the scores increased compared to the three months value and remained lower than the preoperative score, however these differences did not reach statistical significance (Fig. 2b).

Effects on Quality of Life and Disability (SF-36 and ODI)

No significant changes in the physical or mental component summary score of the SF-36 questionnaire were observed at 3, 6, and 12 months following SCS implantation. The tendency toward improvement in health-related quality of life, however, could be observed at three and six months in both the physical and mental component summaries (Supporting Information SI). Patients reported significant improvement in the degree of disability in daily activities as measured by the ODI questionnaire at six months following SCS implantation (9.8 points improvement vs. preoperative, $p = 0.018$).

Predictors of SCS Response

Spearman rank order correlation analysis was run to identify any relationship between preoperative demographics and radiological characteristics with the response to SCS in the above mentioned instruments. Here, we identified a statistically significant strong negative correlation between the degree of thoracic kyphosis and NRS score for regional pain in motion at six months following SCS implantation ($r_s = -0.807$, $p = 0.028$). Furthermore, the degree of pelvic incidence also showed a strong positive correlation with NRS scores for regional pain in motion at six months following implantation ($r_s = -0.823$, $p = 0.012$). There were no further statistically significant associations with other measurements performed (ADS-K, PSQI, ODI, SF-36) (Fig. 3).

Table 1. Clinical and Radiographic Patient Characteristics.

Sex	Age	Cobb-Angle	Scoliosis (location)	SCS-Program
F	56	27°	Lumbar	Contour
F	79	---	Thoracolumbar	Burst
M	79	17°	Thoracolumbar	Burst
F	81	15°	Thoracolumbar	Combined
M	71	18°/22°	Thoracolumbar/Thoracic	Combined (Contour/Tonic)
F	81	18°/22°	Lumbar/Thoracolumbar	Contour
M	72	19°	Lumbar	Burst
F	80	59°	Lumbar	Burst
F	53	22°/20°	Lumbar/Thoracic	Burst
F	85	25°/20°	Lumbar/Thoracolumbar	Burst
F	78	14°	Lumbar	Burst
F	33	35°/21°	Thoracolumbar/Thoracic	Burst
F	78	29°	Thoracolumbar	Burst
F	74	17°	Lumbar	Contour
F	65	15°/22°	Lumbar/Thoracic	Combined (Burst/Tonic)
F	64	36°	Lumbar	Contour

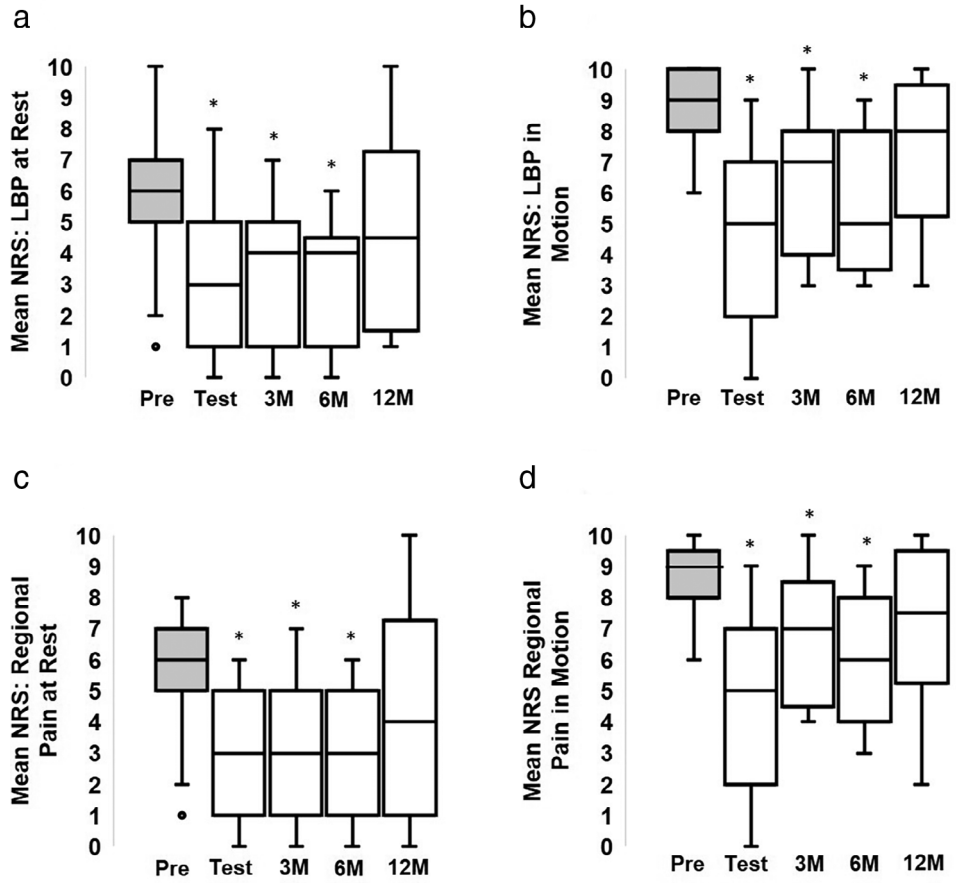


Figure 1. NRS response to SCS. NRS values determined before SCS implantation (gray box plots), during the testing phase and at 3, 6, and 12 months following permanent implantation. Means are represented as horizontal lines within the box plots. Statistical significance was determined by paired *t*-test at each time point compared to the pre-operative NRS score for the categories of (a) lower back pain (LBP) at rest, (b) LBP in motion, (c) regional pain at rest, and (d) regional pain in motion, with $*p < 0.05$.

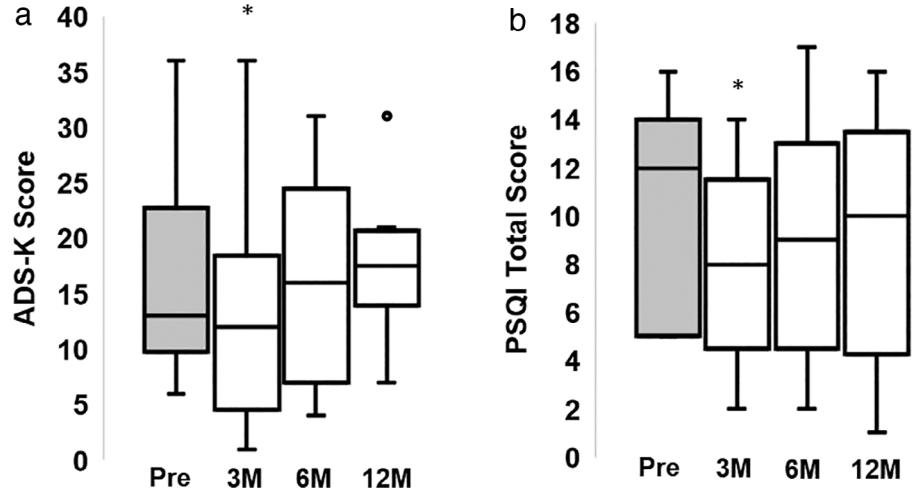
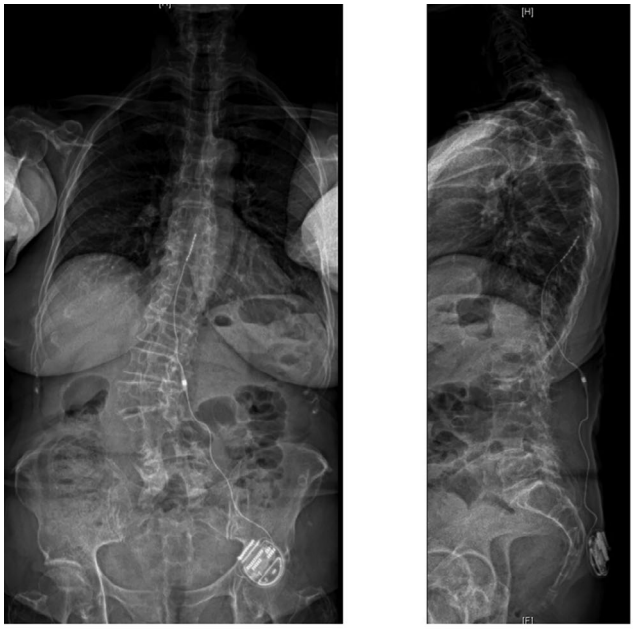


Figure 2. ADS-K and PSQI Response to SCS. Means are represented as horizontal lines within the box plots. Statistical significance was determined by paired *t*-test at each time point compared to the pre-operative score for the categories of (a) mean *Allgemeine Depressionsskala Kurzform* (ADS-K) scores and (b) mean *Pittsburgh Sleep Quality Index* (PSQI). The circle above the 12-months bar represents an outlier. $*p < 0.05$.

DISCUSSION

In our analysis of the response to SCS treatment in adult scoliosis, there was a significant reduction of both back and regional pain in motion and at rest following implantation at three and six months which was attenuated at the 12 months follow-up. In our cohort, we report on patients who are currently undergoing follow-up in our clinic; therefore, follow-up times are heterogenous



	Pre-OP	Test Phase	3 Mo.	6 Mo.	12 Mo.
LBP at Rest	2	1	1	3	1
LBP in motion	7	3	3	1	3
RP at rest	2	1	1	6	1
RP in motion	7	6	6	1	6

Figure 3. Case illustration. A 71-year-old patient after SCS implantation. NRS development of LBP (lower back pain) and RP (regional pain) over time are depicted in the figure.

and do not reflect further drop outs or discontinuation of therapy. Previous retrospective cohort studies of have demonstrated similar temporal dynamics regarding loss of efficacy following SCS treatment beginning at six months after initial implantation in which patients with strong initial improvement in pain scores as measured by VAS were found to experience stronger loss of efficacy over time (23). A prospective analysis in a cohort of patients receiving SCS for chronic neuropathic pain has also shown loss of efficacy in regards to VAS beginning at the six months time point with no statistically significant preoperative clinical or demographic predictors (24). Among patients with complex regional pain syndromes (CRPS) and failed back surgery syndrome (FBSS), attenuation of pain relief has similarly been observed beginning at six months following implantation, and no predictive factors for treatment response could be identified (15,25). Our results for adult scoliosis therefore prove to be in line with the dynamics of loss of efficacy for other diagnoses treated with SCS. Despite the reported data on loss of efficacy, there are however reports of sustained benefit (over one year) in patients receiving SCS (26), so that further exploration regarding the use of novel wave forms and closed-loop may also provide insight into the possible attenuation of therapeutic response in patients with degenerative scoliosis.

In regards to the effect of SCS on psychosocial factors as measured by the ADS-K, we observed similar improvement of depressive symptoms at three months following implantation, which then receded at six months follow-up (without reaching statistical significance), showing even an increase above preoperative levels. One explanation may be associated with the reduction of initial benefit, ultimately causing disappointment and catastrophizing of symptoms. Overall sleep quality as measured by the PSQI responded similarly, showing significant improvement at three months, which then begins to decrease at 6 and 12 months while still remaining lower than the preoperative values. Preoperative ADS-K and mental component summary scores on the SF-36 test did not show any association with the degree of pain relief (as measured by NRS) following SCS. Previous meta-analyses, however, have shown that the presence of psychological factors such as depression and anxiety can negatively affect the therapeutic effect of SCS treatment (27). Along these lines, failure of ODI scores to significantly improve over similar times points as the NRS scores improved may also be due to the multifactorial nature in which chronic pain affects disability in daily activities and is not limited to pain alone, but also includes psychosocial aspects as mentioned above. In our institution patients are invited to regular follow-up visits at 3, 6, and 12 months to optimize any problems with the SCS system and patients are encouraged to present at any time in between visits if concerns arise. Furthermore, we recommend evaluation of possible psychosomatic concerns as needed on an individual basis. A further consideration regarding continuing management of SCS patients with degenerative scoliosis is the use of add-on therapeutic measures such as physical therapy which may extend the benefit of SCS in a chronic degenerative disease.

The explorative analysis of possible predictors of SCS response was conducted to aid the generation of further hypotheses in consecutive studies which can be conducted in larger populations. While we found no significant correlation between presurgical clinical or demographic variables and the degree or length of NRS response to SCS in adult scoliosis patients, the radiographic parameters of thoracic kyphosis and pelvic incidence showed a statistically significant correlation with NRS values at the six months follow-up. Here, we found that decreasing thoracic kyphosis was associated with higher NRS values of regional pain in motion at six months following implantation indicating the possible predictive value in patients who may not significantly profit from SCS. We therefore postulate that pain in the thoracolumbar region may be a more difficult target for SCS in adult degenerative scoliosis. As loss of thoracic kyphosis has been identified as a predictor of back pain intensity in a large cohort of patients with adolescent idiopathic scoliosis, examining a larger patient cohort of adult degenerative scoliosis patients the loss of thoracic kyphosis may also reveal an effect of SCS on LBP as well (28).

Greater pelvic incidence was also positively associated with higher NRS values of regional pain in motion at six months follow-up. Patients with high pelvic incidence and posterior shear forces may therefore suffer more from load-dependent pain which could pose as a difficult target for SCS therapy. Degree of pelvic incidence may serve as an additional parameter in predicting the positive effects of SCS in adult scoliotic patients with higher pelvic incidence possibly indicated lower rates of response. As postulated for thoracic kyphosis, we propose that a larger sample size may reveal a predictive value for pelvic incidence in the dimension of LBP as well. Overall, longitudinal analysis of the development of spinopelvic parameters over time should be performed to better understand the loss of effect of SCS over time.

Furthermore, it should be underscored that the results of our study apply to an elderly cohort with a median age of 78 and BMI of 29 kg/m^2 (overweight), both of which are considered risk factors for perioperative morbidity (29,30). As such, performing corrective spondylodesis in these patients may have not resulted in satisfactory results and the response to SCS as found in this cohort may be considered a reasonable alternative. The findings of this study may therefore be of particular interest when assessing the risk versus benefit of corrective spinal surgery versus SCS in patients for whom the risks of surgery may outweigh its' potential benefit.

Limitations of the current study include the relatively small sample size of 18 patients, for which follow-up until 12 months following implantation is currently only available for eight patients. Increasing sample size and observation time may provide a more robust representation of additional predictive factors for response to SCS treatment.

CONCLUSION

Taken together, our findings were generated in a cohort of patients for whom the risks of corrective surgery must be carefully considered. The results of this study show that in these patients, neuromodulation can significantly reduce LBP as well as regional pain in the first six months following implantation. In addition, radiographic parameters of spinopelvine balance (decreased thoracic kyphosis and increased pelvic incidence) were shown to associate with the degree of pain relief following SCS implantation, therefore providing a possible method of screening for patients which may profit from this treatment. These findings indicate that neuromodulation may provide a reasonable alternative in patients not willing or eligible to undergo extensive corrective surgery, or in those for whom corrective surgery has not adequately addressed LBP or regional pain.

Acknowledgement

Open access funding enabled and organized by Projekt DEAL.

Authorship Statements

Simon Bayerl designed the study, provided intellectual input in data analysis and approved the final manuscript. Stefan Nulis conducted patient examinations and collected clinical data. Peter Vajkoczy co-designed the study, provided intellectual input in data analysis and approved the final manuscript. Dimitri Tkatschenko und Anja Kuckuck provided intellectual input in analyzing the data and approving the final manuscript. Kristin Lucia performed statistical analysis of the data, wrote the manuscript and designed the manuscript figures.

How to Cite this Article:

Lucia K., Nulis S., Tkatschenko D., Kuckuck A., Vajkoczy P., Bayerl S. 2021. Spinal Cord Stimulation: A Reasonable Alternative Treatment in Patients With Symptomatic Adult Scoliosis for Whom Surgical Therapy Is Not Suitable? A Pilot Study.
Neuromodulation 2021; 24: 1370–1376

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SUPPORTING INFORMATION

Additional supporting information may be found online in the supporting information tab for this article.

COMMENTS

This is a small number of case series (18 subjects; 16 implanted) with a short term (13 subjects at 6 months) follow-up. It explores a potential new indication for spinal cord stimulation - an exploratory longitudinal single cohort. No therapeutic conclusions can be drawn from such data. But it can inform future researchers in this population.

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This is a retrospective analysis with small sample size of 16 patients. However, there is no novelty in this case series. The decision-making process and criteria to select patients for SCS is vague. Presenting predictors of SCS response is not valid due to small sample size. The authors should only stick to descriptive analysis.

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