A Prospective Study of the Intra- and Postoperative Efficacy of Intraoperative Neuromonitoring in Spinal Cord Stimulation

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Key Words

Chronic pain · Electromyography · Intraoperative neurophysiological monitoring · Somatosensory-evoked potentials · Spinal cord stimulation

Abstract

Background: Accurate lead placement is critical for spinal cord stimulation (SCS) efficacy. The traditional gold standard of awake placement is often technically difficult. While there is retrospective evidence supporting the use of intraoperative neurophysiological monitoring (IOM) as an alternative, a prospective assessment has not yet been performed. **Objective:** To prospectively evaluate pain and functionality outcomes for IOM-guided SCS, validate two IOM modalities as a means to lateralize lead placement and assess whether IOM can be useful for postoperative programming. **Methods:** A total of 73 patients were implanted with SCS using electromyography (EMG) and somatosensory-evoked potential collision studies (SSEP-CS) to verify lead placement. Patient pain and function were assessed through serial administration of several validated questionnaires. Stimulation parameters at 6 months were documented. **Results:** Statistically significant ($p < 0.05$) improvements were observed in the McGill Pain

Questionnaire, Oswestry Disability Index, Pain Catastrophizing Scale, and Visual Analog Scale. EMG and SSEP-CS appropriately lateralized leads in 65/73 (89.0%) and 40/58 (69.0%) cases, respectively. EMG predicted active contacts in use at follow-up with 82.7% sensitivity. **Conclusions:** We provide prospective evidence that IOM can be used to verify SCS placement. Additionally, EMG may help to streamline device programming and thereby improve outcomes by predicting the ideal stimulation contacts in many cases.

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Introduction

Spinal cord stimulation (SCS) is a validated and cost-effective means of managing medically refractory chronic pain that is well supported in the literature [1–9]. The most common indications for SCS are failed back surgery syndrome and complex regional pain syndrome [10–12]. As is true with all forms of neuromodulation, accurate placement of the epidural lead is critical for efficacy.

The traditional gold standard for lead placement involves the consciously sedated patient providing confirmation that the system is eliciting satisfactory paresthesia

coverage in their painful region [13]. This technique can be hindered by sedation-related agitation or disorientation, hearing deficits and assorted language barriers [14, 15]. Secondly, this technique may cause high stress levels for the patient and the operative team, predisposes to patient movement and limits airway protection in prone position [14–17]. Retrospective data suggest that intraoperative neurophysiological monitoring (IOM) may provide sufficient feedback to ensure optimal lead placement [14–19]. In addition, it may improve patient safety by appraising the integrity of critical neurological structures [20, 21]. The literature reports the use of both free-run electromyography (EMG) and somatosensory-evoked potential collision studies (SSEP-CS).

Here, we are the first to present prospective data on the utility of IOM for SCS. Further, we compare the utility of EMG and SSEP-CS for lateralization. Lastly, we assess whether the active contacts used in IOM may be used to streamline postoperative programming.

Materials and Methods

Study Design

All candidates for SCS were offered participation in this IRB-approved study. After obtaining informed consent, the subjects were asked to complete a battery of self-assessment questionnaires, including the Beck Depression Inventory (BDI) [22], McGill Pain Questionnaire (MPQ) [23, 24], Oswestry Disability Index (ODI) [25, 26], Pain Catastrophizing Scale (PCS) [27, 28], and Visual Analog Scale (VAS) [29–31]. These outcomes were assessed preoperatively and at 3, 6 and 12 months postoperatively.

Prior to proceeding, secondary gain issues were identified and independent psychological testing was performed. Preoperative imaging and a 3- to 5-day stimulation trial under the care of a pain management specialist followed successful psychological evaluation. Patients reporting $\geq 50\%$ improvement in pain levels during the trial were eligible to proceed with permanent implantation.

Between November 2012 and February 2014, a total of 73 patients received IOM-guided SCS – 2 subjects received separate cervical and thoracic SCS devices, bringing us to our target of 75 procedures. Of these, 72 were first-time implantations and 3 were revisions of devices implanted by a different provider. Demographics are summarized in table 1. At 6 months, systems were interrogated for stimulation parameters and usage data. Specific attention was given to active contacts providing the greatest pain relief.

Implantation and Electrophysiological Testing Protocol

IOM was performed by a neurophysiology team using Cadwell Cascade Pro IOM systems (Cadwell Inc., Kennewick, Wash., USA). IOM modalities included SSEP, EMG and transcranial motor-evoked potentials [20].

Implants were placed in either the cervical/cervicomedullary ($n = 23$) or thoracic/thoracolumbar ($n = 51$) region and included 1-column ($n = 9$), 2-column ($n = 38$), 3-column ($n = 25$), and 5-column ($n = 2$) leads. Laminotomy or percutaneous insertion was

Table 1. Patient demographics

Characteristic	
Total, n	72
Age, years	49.1 $\pm$ 12.6
Range	20–86
Gender, n (%)	
Male	27 (37.5)
Female	45 (62.5)
Pain duration, n (%)	
<2 years	26 (36.1)
2–5 years	22 (30.6)
≥ 5 years	24 (33.3)
Pain etiology, n (%)	
Postlaminectomy syndrome	32 (44.4)
Complex regional pain syndrome	16 (22.2)
Neuritis, neuropathy, radiculitis, or transverse myelitis	24 (33.3)
Length of follow-up, months	9.6 $\pm$ 3.3
Lead type, n (%)	
Paddle	56 (75.7)
Percutaneous	18 (24.3)

performed using standard techniques. Placement was based on imaging obtained during the stimulation trial with an effort made to center the lead over the noted ‘sweet spot’. Serial fluoroscopic imaging was used for preliminary placement.

For IOM testing, the lead was connected to a manufacturer-specific testing device. A contact of interest (COI) was selected as the active contact based on the predicted ‘sweet spot’. The testing device was set to a frequency of 60 Hz, a pulse duration of 300 μ S and an intensity of 0.5 units (milliamperes or volts). Intensity was increased to a maximum of 10.0 units while EMG was concurrently monitored. EMG was considered lateralizing if ipsilateral compound muscle action potential (CMAP) amplitudes were at least double those of the contralateral side.

The testing device was turned off and baseline SSEP waveforms were collected from the extremity of interest. The testing device was activated with an intensity of 0.5 units and a second set of traces collected. Testing was deemed positive if the with-modulation traces exhibited $\geq 40\%$ amplitude reduction in cortical waveforms. If lateralization was not observed, the intensity was increased by 0.5 units (to a maximum of 10.0 units) and the test repeated.

The lead was either kept in place or repositioned based on IOM. Figure 1 contains an example of electrophysiological testing results indicative of appropriate positioning. The process on average added 5 min (range 2–15 min), with the total operative time ranging from 45 to 90 min.

Data Analysis

Mean 6- and 12-month outcome data were compared to baseline values using two-tailed paired-samples t tests with Bonferroni correction. Lead type and pain syndrome subgroups were compared using repeated measures ANOVA. The pain syndrome subgroups were as follows: (1) postlaminectomy syndrome, which included failed neck surgery syndrome, (2) complex regional pain

Fig. 1. Results of electrophysiological testing for a thoracic lead implanted for right lower extremity pain. **a** EMG activity demonstrates clear asymmetry with CMAPs present in muscle groups throughout the right lower extremity. **b** Baseline and with-modulation (unmarked) right tibial nerve SSEP traces. BL = Baseline. The SSEP-CS demonstrates $\geq 40\%$ reduction of cortical waveform amplitude from baseline.

Fig. 2. An intraoperative anterior-posterior fluoroscopic image of a 16-contact paddle lead in the thoracic cord region. In this instance, contact 4 was selected for electrophysiological testing. Using our accuracy schema, contacts 3, 5 and 12 are defined as adjacent.

syndrome and (3) neuritis, which included neuropathy, radiculopathy and transverse myelitis. Significance was determined using a cutoff of $\alpha = 0.05$. Analysis was performed using IBM SPSS Statistics 22.0 (IBM, Armonk, N.Y., USA).

Lateralization rates were calculated for EMG and SSEP-CS. All instances of repositioning as a result of electrophysiological testing were identified. For each final COI, EMG responses were examined for the presence of CMAPs correlating to target painful areas. Also, all adjacent contacts to the COI were identified on the basis of individual lead geometry. An example of this schema is seen in figure 2. In the setting of revision for lead migration or new-onset pain, IOM data from the reoperation were used for analysis.

Results of the retrospective EMG analysis were compared to 6-month device interrogation data. Each COI was placed into one of four categories depending on the following: (1) whether EMG elicited by the COI demonstrated coverage of all target areas and (2) whether the COI or adjacent contact was in use at follow-up. Sensitivity, specificity, positive predictive value, and negative predictive value were calculated.

Results

Clinical Outcomes

At the 6-month follow-up, statistically significant reductions from baseline were present in mean MPQ, ODI, PCS, and VAS scores for 51 complete data sets. At 12

Table 2. Summary of outcome measures

	Baseline	6 months	12 months	6 months vs. baseline, p value	12 months vs. baseline, p value
BDI, mean (SE)	n = 43 12.8 (1.31)	n = 43 10.9 (1.27)	n = 28 11.3 (1.64)	0.38	0.95
MPQ, mean (SE)	n = 44	n = 44	n = 30		
Affective	0.68 (0.13)	0.36 (0.09)	0.27 (0.08)	0.09	0.07
Sensory	4.98 (0.31)	4.02 (0.36)	3.73 (0.44)	0.03	0.12
Total	5.66 (0.38)	4.39 (0.40)	4.00 (0.48)	0.02	0.05
ODI, mean (SE)	n = 44 49.8 (2.37)	n = 44 42.2 (2.92)	n = 30 43.0 (3.84)	0.01	0.02
PCS, mean (SE)	n = 41	n = 41	n = 28		
Helplessness	9.85 (0.88)	6.15 (0.86)	6.04 (0.98)	<0.001	0.01
Magnification	3.76 (0.42)	2.63 (0.44)	2.46 (0.45)	0.09	0.03
Rumination	9.00 (0.69)	5.88 (0.78)	5.36 (0.89)	<0.001	<0.001
Total	22.6 (1.86)	14.7 (1.98)	13.6 (1.99)	<0.001	<0.001
VAS, mean (SE)	n = 51 6.89 (0.21)	n = 51 4.63 (0.40)	n = 36 5.00 (0.46)	<0.001	<0.001

SE = Standard error. p value: comparison by paired-samples t tests with Bonferroni correction for 5 statistical tests.

months, significant reductions were also present in MPQ, ODI, PCS, and VAS for 36 complete data sets. In many instances, subjects incorrectly completed or omitted portions of outcome questionnaires. These were subsequently excluded from analysis. Results are summarized in table 2. No statistically significant differences were observed in either lead type or pain syndrome subgroups, which could be a limitation of small sample sizes.

A total of 14 subjects were excluded from outcome analysis – 1 withdrew consent, 3 were explanted within 1 month, 1 was removed for psychiatric concerns, and 9 did not attend follow-up. Of these 9 subjects ‘lost to follow-up’, 6 responded to correspondence containing simple questionnaires. For this group, the average self-reported reduction in VAS was 3.5 points and 4 subjects (66.7%) reported that they were satisfied with SCS and would undergo the procedure again.

A total of 17 reoperations, consisting of 12 revisions and 5 explantations, were performed for an all-cause reoperation rate of 22.7%. Revisions were for inadequate coverage (n = 1), new-onset pain (n = 2), lead migration (n = 5), implantable pulse generator discomfort (n = 3), and premature battery failure (n = 1). Explantations were for inadequate coverage (n = 1), new-onset pain (n = 1),

implantable pulse generator discomfort (n = 1), and post-operative infection (n = 2).

Electrophysiological Testing

Using EMG, the lead was successfully lateralized in 65/73 (89.0%) cases. Additionally, CMAPs were elicited in 90/106 (84.9%) target painful areas. Using SSEP-CS, the lead was successfully lateralized in 40/58 (69.0%) cases. Of the 18 SSEP-CS failures, 13 had insufficient amplitude reduction and 5 were contaminated with artifact. The lead was repositioned as a result of electrophysiological IOM in 22/73 (30.1%) cases, including twice or more in 7/73 (9.6%).

EMG as a Predictor of Stimulation Contacts

COI-eliciting CMAPs corresponding to target painful areas were found to predict stimulation contacts in use at the 6-month follow-up with regularity. Results are shown in table 3. A sensitivity of 82.7% (95% CI, 71.8–90.1), specificity of 18.2% (95% CI, 3.21–52.2), positive predictive value of 87.3% (95% CI, 76.8–93.7), and negative predictive value of 13.3% (95% CI, 2.52–43.9) were calculated.

An important caveat: this analysis assumes that each COI is independent. However, this is not true in subjects

Table 3. EMG activity in painful areas as a predictor of ideal contacts

EMG response elicited by COI	Active contact at follow-up	
	COI or adjacent, n	distant, n
Complete coverage of noted painful area	62	9
Incomplete coverage of noted painful area	13	2

with bilateral pain syndromes where two contacts from a single lead are used to cover discrete areas. Additionally, any instances where multiple contacts are used to augment the site of stimulation (device settings are not strictly bipolar) act as confounders.

Discussion

This is the first prospective study to present data suggesting that across a number of outcome measures, the results of IOM-guided SCS are similar to those of the awake method at the 6- and 12-month follow-up [3, 13]. We demonstrate that free-run EMG provides more intra-operative benefit than SSEP-CS in our hands, though SSEP-CS was sometimes useful when EMG lateralization failed. Further, we show that active contacts used successfully for lateralization were often predictive of active contacts used at the 6-month follow-up. This suggests that IOM may reduce time spent programming postoperatively and thus results in less health care utilization associated with the therapy.

Electromyography

The use of free-run EMG to evaluate mediolateral lead positioning has been described by several groups, with retrospective data supporting its efficacy for SCS implantation [14, 15, 17, 18]. Stimulation of the dorsal columns by the epidural lead elicits EMG activity in corresponding muscle groups through two proposed mechanisms – direct ventral root activation or indirect synaptic activation of the anterior horn [15, 32]. Regardless of origin, EMG activity can be visually evaluated for symmetry and used to make an accurate prediction of laterality [15].

In our series, we lateralized with 89.0% success using EMG with a 30.1% repositioning rate, similar to the 91.3% lateralization and 15.9% repositioning rates published by

Shils and Arle [17]. Of note, a single patient in our series experienced inadequate coverage due to improper mediolateral positioning. We were unable to appropriately lateralize using IOM during this case.

In an effort to further improve patient outcomes and to streamline device programming, we also used EMG to predict paresthesia coverage. We hypothesized that, in many cases, optimally placed epidural leads would produce motor responses over targeted painful areas. Therefore, in addition to predicting laterality, free-run EMG was also used to monitor the presence or absence of CMAPs in these locations. This was achieved with 84.9% success and found to have high sensitivity (82.7%) and positive predictive value (87.3%) but low specificity (18.2%) for predicting stimulation contacts in use at the 6-month follow-up. It should be noted that the ‘sweet spot’ was chosen with significant preoperative information. Thus, IOM and verbal feedback may have both been predictive of the 6-month settings.

Somatosensory-Evoked Potential Collision Studies

We found SSEP-CS, which has also been described for evaluation of mediolateral positioning, to be overall less reliable than EMG for lateralization [16, 19, 33]. The theorized mechanism of SSEP-CS involves antidromic conduction of sensory responses from the epidural lead and orthodromic conduction of sensory responses from peripheral nerve stimulation [16, 34–36]. These responses travel along the same pathway in opposing directions and result in negative interference or a ‘collision’ manifested in ipsilateral SSEP waveforms as an amplitude reduction [16, 36].

As our results indicate, we were less successful at predicting laterality with SSEP-CS. Our 69.0% success rate was lower than the rates of 100 and 83.3% published by Balzer et al. [16] and Urasaki et al. [19], respectively. Despite this, we noted instances where SSEP-CS provided useful information, while EMG responses were inconclusive. This led us to consider SSEP-CS as a backup lateralization modality and to not perform SSEP-CS in instances when EMG provided convincing data. One readily identifiable reason for SSEP-CS failure was the presence of muscle artifact in the tracings. Muscle artifact can be eliminated by the application of a neuromuscular blocker. However, this would temporarily preclude the use of EMG and transcranial motor-evoked potentials.

Reoperation

An additional end point of our study was to determine the incidence of reoperation. The literature contains re-

ports of all-cause reoperation rates for SCS ranging from 14.94 to 31% [3, 15, 18]. Over the course of our experience, surgeon preference shifted to favor a percutaneous approach over laminectomy with paddle leads for cervical SCS. As 4 of our 5 instances of lead migration occurred in subjects with percutaneous cervical devices, we theorize that the learning curve associated with this new technique inflated our reoperation rate. As expected, the frequency of cervical lead migrations and subsequent reoperation normalized toward the end of our data collection period. Despite the presence of this confounding factor, our calculated all-cause reoperation rate of 22.7% was still comparable to others found in the literature [3, 15, 18].

Utility and Cost-Effectiveness

Despite its minimally invasive and reversible nature, SCS still carries a risk of neurological injury. IOM can be employed to reduce the incidence of adverse events by rapidly assessing the integrity of critical neural elements [20, 21]. However, as noted by Lall et al. [37], evidence-based guidelines for IOM usage are generally lacking, and use is largely driven by surgeon preference. Nuwer et al. [38] estimated that the savings secondary to a reduction in spinal cord injuries during deformity correction is far greater than the cost of routine IOM. However, it is impossible to extrapolate this assertion to SCS without data on injury reduction rates.

Despite our inability to determine the cost-effectiveness of IOM for preventing injury during SCS, it remains a powerful instrument for improving outcomes. As evidenced by our results, IOM has added utility as a means of verifying lead laterality and mitigating concerns associated with conscious sedation. Further, our data show that EMG is predictive of optimal stimulation contacts. Streamlining the programming process may reduce the number of necessary visits and more rapidly improve patient quality of life following surgery.

It has been proposed that wider leads such as the CoverEdge 4-column (Boston Scientific, Marlborough, Mass., USA) and the Penta 5-column (St. Jude Medical, Inc., St. Paul, Minn., USA) may reduce the need for precise mediolateral placement. We feel that while these leads do allow for less precision, exact centering about the physiological midline maximizes programming flexibility and thus remains critical to success. IOM confirmation remains beneficial, particularly in the case of abnormal anatomy or when bilateral coverage is indicated, as there is often a disparity between the radiographic and physiological midline. Additionally, larger leads increase the

likelihood of inadvertent nerve root compression if improperly positioned.

Limitations

With IOM there is a learning curve for the surgeon and anesthesia team. During this period, procedure length may increase and inappropriate anesthesia depth may interfere with IOM data collection. Further, certain patients (e.g. those with spinal cord injury, neuropathy or morbid obesity) make this technique more difficult. Spinal anesthesia is another option for these situations [39, 40]. Lastly, our series possess certain limitations, including heterogeneity of lead locations, lead types and diagnoses. We suspect, however, that this patient group is likely to be representative of other surgeon populations and thus may provide real-life information.

Conclusions

Our prospective data support the use of IOM-guided SCS placement based on outcomes at 6 and 12 months postoperatively. Free-run EMG demonstrates high lateralization success rates and offers the added benefit of streamlining device programming by predicting ideal stimulation contacts in many cases. SSEP-CS has utility as a backup lateralization technique.

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