

Migration of Epidural Leads During Spinal Cord Stimulator Trials

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Objective: Lead migration is the most commonly reported complication of spinal cord stimulation (SCS) procedures and lead migration during trials of SCS can compromise both the success of the trial as well as the efficacy of subsequent implantation. Our objective was to examine the incidence and degree of intra-trial SCS lead migration and our hypothesis was that there would be a higher rate of significant radiographic lead migration during SCS trial than what has been previously published for permanently implanted leads.

Materials and Methods: We retrospectively assessed the radiographic location of SCS leads on final fluoroscopic imaging at the time of trial lead placement compared to thoracic radiographs obtained at the end of the SCS trial to quantify the rate and degree of migration during the trial. Thirty-five patients were included in the study with 69 leads assessed for radiographic degree of migration. The majority of patients were trialed utilizing paresthesia-free systems (57%) and the most common indication was for post-laminectomy syndrome (57%).

Results: In our series of 35 patients, on average there was 28 mm or 1.17 vertebral body levels of migration. No statistically significant correlation was found between fixation technique, physician experience, device manufacturer, patient age, sex, height or BMI and likelihood of significant radiographic migration.

Conclusion: In our study, lead migration appears to be a more significant occurrence during SCS trial than previously reported. Intra-trial migration presents a significant challenge for clinical care and examination of risk factors for migration and techniques for prevention are warranted.

Keywords: lead migration, spinal cord stimulator trial, spinal cord stimulation, stimulator trial, dorsal column stimulator

Plain Language Summary

Spinal cord stimulators are used to treat pain that has not responded to other treatments such as medications and injections. Spinal cord stimulation involves placing small wires into the spine (epidural space) to provide stimulation to the nerves involved in transmitting pain signals from the painful part of the body. A temporary version of these wires is placed during a trial for 7 days to ensure that the device would be helpful. Although a common complication of permanent implantation, it is not known how often these wires move during the trial, which may influence the success of the trial and the placement of the permanent implanted device.

Introduction

Lead migration remains the most commonly reported complication resulting from spinal cord stimulation (SCS), and migration during SCS trials introduces a significant challenge to clinical care.¹ Unfortunately, published information describing the rate and degree of lead migration during SCS trials is limited. Several small case reviews have looked at lead migration while comparing anchoring technique.²⁻⁵ These studies have failed to report the degree of lead migration and the direction of migration. Prior retrospective reviews of SCS trial complications reported rates as low as 0.7% for lead migration, however no radiographic assessment was routinely conducted to assess lead position.⁶

The described rate of epidural lead migration for permanently implanted SCS leads has ranged from 13.2% to 22.6% of case, although incidences of migration requiring surgical revision have been reported to be as low as 2.1%.⁶⁻⁸ Most

studies reporting lead migration have relied on physician reported lead migration, typically detected only after patients self-reported loss of efficacy and/or paresthesia requiring imaging evaluation and reoperation. The common operational definition of meaningful lead migration relies on a loss of the original paresthesia coverage that is not responsive to reprogramming and requires surgical lead revision.¹ Otherwise, lead migration has been used as a general description for any displacement of the lead from its desired location.⁹

There remains no consensus, other than self-reported loss of efficacy from the patient, as to what constitutes a meaningful degree of migration for permanent SCS leads. Furthermore, no consensus has been reached for what constitutes a meaningful degree of trial lead migration. The introduction and popularization of paresthesia-free-based SCS systems has further complicated the detection of lead migration without the routine use of imaging. The application of “need for lead revision” or reprogramming as criteria for meaningful migration during a SCS trial is additionally complicated by the rarity of intra-trial lead revision as well as the brief window typically available for reprogramming. Our hypothesis was that there is a higher rate of significant radiographic lead migration during SCS trial than what has been previously published for permanently implanted leads, roughly 15%.^{6,7}

Materials and Methods

Our academic medical center practice instituted a clinical protocol to assess for lead migration during percutaneous SCS trial by obtaining radiographs on the last day of the trial to evaluate for final lead position and potential migration. This was based on the recommendations of previous authors that radiographs be taken at the completion of every spinal cord stimulator trial for determination of optimal lead position for permanent placement as well as to assess for migration.¹⁰ This study was approved by the Institutional Review Board (IRB) of the University of Utah as well as the IRB of the Salt Lake City Veterans Affairs Medical Center and was conducted in compliance with the current version of the Declaration of Helsinki. Patient consent was not required due to the retrospective nature of the study with de-identified data. All patient data collected were de-identified to preserve confidentiality. We retrospectively examined our first cohort of patients who underwent end-of-trial radiographs and compared these images to the final fluoroscopic images obtained at the time of trial lead placement to quantify the rates of lead migration as well as characterize the direction and the degree of migration. Patients 18 years and older who underwent percutaneous trial of spinal cord stimulator lead placement in the thoracic spine were included in the trial. Exclusion criteria included cervical or lumbar lead placement, cancelled or aborted cases, and patients who did not obtain an end-of-trial thoracic radiograph for any reason. All patients underwent a pre-procedural visit and clearance with a pain psychologist prior to proceeding with SCS trial. All cases were conducted in typical fashion by fellowship-trained and board-certified pain medicine physicians, with epidural access in the thoracolumbar region followed by placement of percutaneous leads in the posterior epidural space under fluoroscopic guidance. Lead fixation method was at the discretion of the attending physician and included adhesive fixation device (Merit StayFIX[®] Fixation Device), wound closure strips (Nexcare Steri-Strip[®]), or placement of sutures, followed by occlusive dressing (3M Medical[®] Tegaderm) and further tape as deemed necessary to secure the leads and external pulse generator in place. Four different device manufacturers were used as determined by the primary physician. All patients were assessed for not only efficacy at the end of their trial period but also for any changes in the position or intensity of their paresthesia for paresthesia-based systems or a change in the degree of analgesia for non-paresthesia-based stimulation patterns. Patients underwent an upright anteroposterior (AP) and lateral thoracic radiograph of the spine on the day of their lead-pull appointment.

Final fluoroscopic imaging from trial lead placement and end of trial radiographs prior to lead pull were compared. Migration was quantified using a radiographic image ruler to decipher the percentage of change over each individual vertebral level. A full vertebral level was defined as the superior endplate of the vertebral body to the bottom of the disc space below the vertebral body for any given vertebrae level (for example the T8 vertebral body would also include the entirety of the T8 - T9 disc space).

Significant radiographic lead migration was defined as greater than or equal to 50% of a full vertebral level. Measurements were taken from final AP and lateral radiographs with the fluoroscopic image from the trial used as a reference for the starting

position of the leads. This 50% of a vertebral level would typically correlate with roughly 1 centimeter of migration assuming an average vertebral body and disc height of 24 mm in the mid- and lower thoracic spine.¹¹ See Figure 1.

Statistical Analysis

Descriptive analyses were performed to summarize the distributions of pain diagnoses, treatment procedure characteristics and clinical outcomes among enrolled patients. We used the Elastic Net regression approach with logistic regression to identify important factors for predicting significant radiographic lead migration, defined as migration of $\geq 50\%$ of a vertebral level.¹² The optimal penalty term was determined based on 10-fold cross-validation approach. The candidate risk factors we considered included age, sex, BMI, height, primary pain diagnosis, length of trial, access level, lead tip location, device manufacturer, physician experience (>5 years versus <5 years), and fixation device to determine odds ratio (OR), 95% confidence interval (CI) and statistical significance. The Elastic Net approach can decrease the coefficients of those unimportant predictors to zero while retain those important ones. Note that a predictor has predictability on an outcome if and only if its coefficient is nonzero. The association between selected predictors and lead migration was estimated using the mixed effect logistic regression approach, where random effect was used to account for the repeated observations from same patient. All statistical analyses were performed using statistical programming software R.

Results

Retrospective review of radiographic imaging was carried out for 35 patients at the University of Utah, Huntsman Cancer Institute, and Salt Lake City Veterans Affairs Medical Center. Eight separate attending physicians performed cases that were included in the study. The primary indication for SCS trial included post-laminectomy syndrome (20 patients, 57%), lumbosacral radiculopathy (6 patients, 17%), chronic back pain (4 patients, 11%), peripheral neuropathy (3 patients, 9%), chronic post-thoracotomy pain (1 patient, 3%), and complex regional pain syndrome (1 patient, 3%). Thirty-one of 35 patients (88.5%) had a successful trial, defined as improvement in pain of at least 50%. The average length of trial was 6.8 days with a median of 7 days and a range of 4–8 days. Thirty-four patients underwent SCS trial utilizing 2 leads and 1 patient underwent a single-lead trial. Demographic and additional procedural information can be found in Tables 1 and 2.

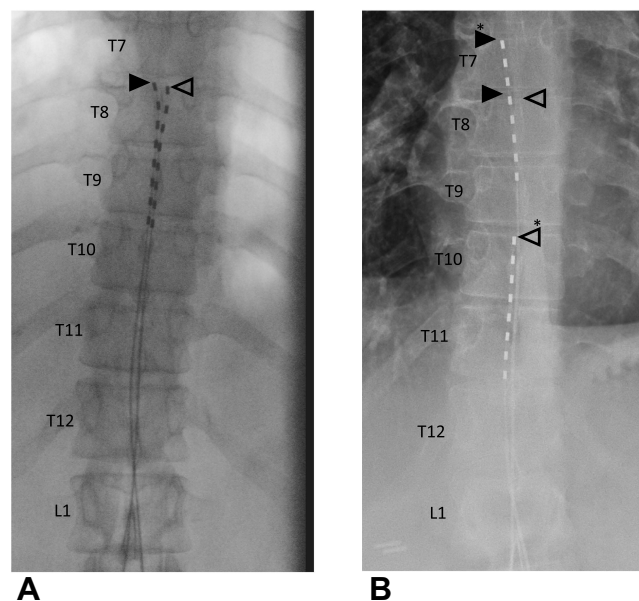


Figure 1 Example of a final AP fluoroscopic image obtained at the time of a trial lead placement (**A**) depicts the positions of the anatomically left and right lead tips at the level of the T8 vertebral body (open arrowhead and closed arrowhead, respectively). Example of an AP radiograph of the thoracic spine acquired seven days after a trial lead placement (**B**) demonstrates interval migration of the leads. From its original position (open arrowhead), the left lead tip has migrated caudally by 2.0 vertebral body heights to a new position at the level of the T10 vertebral body (open arrowhead and asterisk). The right lead tip has migrated from its original position (closed arrowhead) 0.8 vertebral body heights cranial to a new position at the level of the T7 vertebral body (closed arrowhead and asterisk).

Table 1 Patient Demographics

Variable	N=35
Mean Age (SD, Range)	61 (14.9, 25–83)
Sex	
Female	10 (29%)
Male	25 (71%)
Mean BMI (SD, Range)	29.3 (5.9, 25–33)
Mean Height (in) (SD, Range)	68.8 (4.1, 62–78)
Primary Pain Diagnosis	
Post-laminectomy syndrome	20 (57%)
Lumbosacral radiculopathy	6 (17%)
Chronic back pain	4 (11%)
Peripheral neuropathy	3 (9%)
Complex regional pain syndrome	1 (3%)
Post-thoracotomy pain	1 (3%)

Table 2 Procedure Details

Variable	N=35
Mean length of trial in days (SD, Range)	6.8 (1.4, 4–8)
Epidural access level (N=69)	
T12-L1	41 (59%)
Other	28 (41%)
Lead tip location (N=69)	
T8-10	57 (83%)
Other (Range T2-T11)	12 (17%)

Thirty-three of 35 patients (94%) had radiographically significant intra-trial migration of at least one lead. All these migrations were found to be caudad in direction. On an individual basis, 78% of leads were found to have significant radiographic migration. The mean degree of migration was 1.17 vertebral levels (Standard Deviation (SD) 0.88). Further details on lead migration can be found in [Table 3](#).

In assessing risk factors for lead migration, a diagnosis of post-laminectomy syndrome as compared to other diagnoses was associated with increased likelihood of lead migration (OR 1.31, 95% CI 1.07–1.61, $p = 0.014$). No association was found with age, sex, BMI, height, access level or device manufacturer. Variables including trial length of 7 days as compared other lengths, lead tip location at T9 as compared to elsewhere, physician experience of > 5 years as compared to <5 years, and utilization of adhesive strips or sutures as compared to adhesive fixation device had lower rates of lead migration, however because of the small sample size in this study, the p -values for these Elastic Net selected factors from the unpenalized regression model were not statistically significant. See [Table 4](#) for full statistical details.

Table 3 Migration Details

Variable	
Incidence of significant radiographic lead migration left lead (N=35)	27 (77.1%)
Mean degree of left lead migration in vertebral levels (SD, Range)	1.14 (0.89, 0–4.00)
Incidence of significant radiographic lead migration right lead (N=34)	27 (79.4%)
Mean degree of right lead migration in vertebral levels (SD, Range)	1.21 (0.88, 0–3.00)

Note: Significant radiographic migration defined as ≥ 0.5 vertebral levels.

Table 4 Demographics and Factors Relative to Significant Radiographic Lead Migration

Variable	OR (95% CI)	p-value
Right-sided lead	1.022 (0.85–1.229)	0.817
Post-laminectomy syndrome pain diagnosis	1.314 (1.072–1.61)	0.014
7-day trial length	0.945 (0.832–1.074)	0.397
T9 lead tip location	0.818 (0.668–1.001)	0.062
Physician experience >5 years	0.909 (0.726–1.138)	0.413
Fixation method: adhesive strip	0.885 (0.67–1.169)	0.398
Fixation method: suture	0.981 (0.689–1.396)	0.915

Note: Significant radiographic migration defined as ≥ 0.5 vertebral levels.

Discussion

The data from our review indicated that there was a 78% incidence of significant radiographic lead migration during percutaneous SCS trials (54 of 69 leads) with a mean distance of migration of 1.17 (SD 0.88) vertebral levels. Furthermore, 94% of patients (33 of 35) included in this study experienced intra-trial migration of $\geq 50\%$ of a vertebral level of at least one of their leads. The rate of significant radiographic lead migration observed in our study was higher than previously published reports of clinically significant lead migration after permanent implantation. Our radiographic degree of migration also appears higher than previously reported measurements of lead migration during SCS trial (3.05mm to 24.49mm), though this is complicated by the use of millimeters of migration in some prior studies rather than vertebral body levels.^{3,13} Osborne et al examined anchoring with tape versus suture for trial leads and found an average migration of 8.72mm with tape versus 24.49mm for leads anchored with suture.³ Mironer et al reported a 6% to 23% risk of loss of paresthesia coverage during a 4–5 day trial when comparing a traditional epidural placement technique versus a “midline anchoring” technique.¹⁴ Our decision to designate greater than or equal to 50% of a vertebral body level as radiographically significant lead migration was based on physician consensus, clinical experience as well as ease of rapid clinical decision-making compared to radiographic ruler measurement. Loss of paresthesia coverage was also felt to be a poor marker of meaningful migration as 57% of patients (20 of 35) in our study were trialed using a paresthesia-free-based system precluding the use of patient reported loss of stimulation as a universal means of detection.

Our trial shows that significant radiographic lead migration during percutaneous spinal cord stimulator trial affects the vast majority patients (94% in our case) and that the mean degree of migration is over a full vertebral level (mean of 1.17 vertebral levels in a caudal direction). There have been case reports of significant cephalad migration during SCS trials, however this was not our experience during this study.^{15,16} Among patient and procedural variables, only a diagnosis of post-laminectomy syndrome as compared to other diagnoses was found to be associated with a statistically significant increase in the incidence of radiographically meaningful migration. The mechanism for this finding is unclear, but it is notable that post-laminectomy syndrome accounted for 57% of diagnoses in our cohort. Larger studies would be useful in further clarifying risk factors for lead migration.

Radiographic lead migration during SCS trial presents a significant clinical challenge. Migration may compromise not only the success of the trial due to decreased analgesia but may alter the efficacy of subsequent implantation if suboptimal positioning is selected for permanent lead placement that does not reflect intra-trial lead movement and patient response. The popularization of paresthesia-free-based SCS systems further complicates the sole reliance on patient-reported efficacy and/or paresthesia coverage to monitor for the presence of significance of lead movement. Our study was not adequately powered to detect possible correlations between degree of migration and intra-trial analgesia or trial to implant ratio.

No common nomenclature for degree of lead migration has evolved over the last several years. Some articles report degree of migration in distance measured from the electrodes in relation to the vertebral endplate while other studies have examined rates of lead migration utilizing only lead markings at the skin.^{5,13} We chose to report our results in vertebral levels for several reasons. Anatomic correlation of radiographically measured distances when examined for disc and vertebral body height has been poor, often under measuring the anatomic measurement by 50% within the mid and lower thoracic spine, areas most commonly targeted during SCS trial and permanent placement.¹¹ Additional factors included

institutional familiarity with this endpoint as well as vertebral body levels being a more commonly discussed clinical measure of lead movement compared to radiographically derived numeric data or other previously reported markers of lead position. Previous studies have reported no association between degree of SCS lead migration as a result of postural changes and need for adjustment of SCS settings and reported an average degree of migration due to postural change of 3.05 mm.¹³ This would typically correlate with only 12.5% of a vertebral level assuming an average vertebral body and disc height of 24 mm in the mid- and lower thoracic spine.¹¹ The degree of migration thought to correlate with a consistent loss of paresthesia coverage or a loss of efficacy is not known.

The optimal fixation technique during percutaneous SCS trials remains unclear. In our study, multiple different techniques for lead fixation were performed including use of a commercially available adhesive fixation device, wound closure strips and suturing, all in addition to occlusive adhesive dressing. There was no statistically significant difference in incidence of meaningful lead migration between fixation techniques in our study. Paradoxically, some authors have found that a more mechanically rigid form of anchoring to the skin (suturing) resulted in a greater degree of lead migration compared to tape alone.³ Previous authors have postulated that the elimination of an external point of fixation may decrease the risk of lead migration as a suture or anchor may provide a focal point of mechanical stress.¹ Observational reports of subcutaneous loops have corroborated this hypothesis when comparing rates of lead migration utilizing this technique versus suturing.¹⁷

There remain significant areas of ambiguity on the topic of SCS trial lead migration and the significance of intra-trial lead movement. Further areas for consideration include additional examination of anchoring technique, patient activity restrictions or use of abdominal binder, differences between manufacturer and degree of migration, and differences in migration between percutaneous lead versus permanently-anchored lead trials. Additional studies may help define a unified nomenclature surrounding trial lead migration, acceptable degree of lead movement during SCS trial, what degree of migration correlates with a negative trial as well as aid in establishing standards for radiographic imaging during trial which have the potential to change placement practices.

Conclusion

This study aimed to determine the rate and degree of SCS lead migration during SCS trial and found significant radiographic migration regardless of most patient or procedure-related factors. Further studies are needed to corroborate this single group study, to further define risk factors for migration as well as to examine techniques to minimize intra-trial lead movement.

Author Contributions

All authors contributed to data analysis, drafting or revising the article, have agreed on the journal to which the article will be submitted, gave final approval of the version to be published, and agree to be accountable for all aspects of the work.

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Disclosure

Jill Sindt has served as a consultant for Medtronic. The authors report no other conflicts of interest in this work.

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