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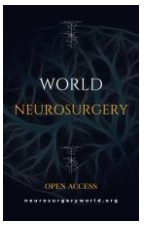


## Case Series

# Paddle Lead Spinal Cord Stimulation for Chronic Pain in Octogenarians: A Case Series

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ABSTRACT

**Background:** Spinal cord stimulation (SCS) is a surgical technique for chronic pain which involves the placement of percutaneous, or paddle leads into the spinal epidural for pain treatment. Paddle lead SCS is a more invasive procedure due to the requirement of bone removal (laminotomy/laminectomy) and may therefore be less commonly offered to older patients.

**Methods:** A retrospective review was conducted of a database of all paddle lead spinal cord stimulators implanted from January 1st, 2019, to July 1st, 2024, by a single surgeon. Octogenarian patients were identified within this cohort and their data analyzed, including demographics and treatment history. Post-operative pain was subjectively measured during follow-up visits. Descriptive statistics were compiled, and a one-way ANOVA test was used to measure the mean post-operative pain levels.

**Results:** Fifty-seven patients were included in our cohort with a median age of 83 (IQR 81-85). Over half (n = 31, 54%) of patients had concurrent back and leg pain. There was no statistically significant difference in regard to location of presenting pain and improvement of pain. Moreover, there was no statistically significant difference in trial improvement with post-operative pain outcomes in our cohort. Two (3.5%) patients suffered post-operative infections, and three (5.3%) had the device removed. There were no neurologic deficits nor mortality.

**Conclusion:** Paddle lead SCS may be performed safely in octogenarians with no obvious increase in complications or less efficacy and should not be precluded in these patients with chronic pain and may have a favorable risk/benefit profile compared to more invasive spinal surgeries.

## 1. Introduction

Chronic pain is a condition that affects over 50 million Americans per year and is responsible for significant morbidity and mortality due to narcotic use [1]. Treatments for chronic neuropathic pain often include non-pharmacological, pharmacological, and surgical treatments. Spinal cord stimulation (SCS) is a well-established, evidence-based treatment for chronic pain that involves placing percutaneous or paddle leads into the epidural space on top of the dorsal column of the cervical or thoracic spine [2-5]. SCS provides an attractive option as a less invasive means of treating chronic neuropathic pain, particularly in those who would like to avoid spine decompression, fusion, or have already failed prior instrumentation [2-5].

While SCS has been studied broadly within the population there has been little attention paid to age as a specific variable of interest. Herein, we present a large retrospective case series of patients over the age of 80 years old to assess their outcomes to identify if SCS is both safe and efficacious in this population.

## 2. Methods

A retrospective chart review was conducted of a single-surgeon database of all paddle lead spinal cord stimulators implanted at two institutions from January 1st, 2019, to July 1st, 2024. Octogenarian patients were identified within this cohort and analyzed. Data gathered included patient demographics, pain history, pain characteristics, medications, imaging, operative reports, complications, and length of stay. Post-

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operative pain was measured using subjective data collected from patient interviews (Numeric Analog Scale). Descriptive statistics were completed, and a one-way ANOVA test was used to measure the mean post-operative pain levels. All statistics were performed using GraphPad Prism (V.10). This study was approved by our Institutional Review Board.

## 3. Results

Within our 57-patient cohort, the median age was 83 years (IQR 81-85) with nearly equivalent proportions of men and women (Table 1). The most common site of laminectomy for SCS implantation was T9 for 43 (75%) patients (Table 2). Forty-seven (82%) patients had non-rechargeable generators placed, 7 (12%) of patients had rechargeable generators placed and three patients did not have information available. Thirty-one (54%) patients had concurrent back and leg pain. There was no statistically significant difference in pain improvement based on presenting location of pain in our cohort. There was also no statistically significant difference in mean frequency of pain improvement across patients with variable improvement in pain from the initial SCS trial. Two (4%) patients suffered post-operative infections, and three (5%) patients had the device removed. There were minimal complications within our cohort and notably, there were no neurologic deficits nor mortality (Table 2).

**Table. 1.** Baseline demographics of all 57 patients included in study cohort.

| | **Median (IQR)** |
|---|---|
| Age (years) | 83 (81–85) |
| BMI (kg/m$^2$) | 27 (23–32) |
| | **n (%)** |
| Gender | |
| Male | 29 (51) |
| Female | 28 (49) |
| Ethnicity | |
| White | 57 (100) |
| Disease and medication history | |
| Hypertension | 46 (81) |
| Diabetes | 18 (32) |
| Coronary Artery Disease | 20 (35) |
| Cancer | 12 (21) |
| Anticoagulants | 17 (30) |
| Aspirin | 23 (40) |
| Depression | 17 (30) |
| Smoking history | |
| Non-smoker | 33 (58) |
| Former | 23 (40) |
| Current | 1 (2) |
| Current Alcohol Use | 17 (30) |

**Table. 2.** Spine surgery history of all 57 patients included in study cohort.

| | **n (%)** |
|---|---|
| **Surgical history** | |
| Anterior Cervical Fusion | 0 (0) |
| Posterior Cervical Fusion | 0 (0) |
| Thoracic Decompression | 1 (2) |
| Lumbar Decompression | 34 (60) |
| Lumbar Fusion | 13 (23) |
| Prior spinal cord stimulator | 6 (11) |
| Pain Pump | 0 (0) |
| **Spinal level of laminectomy** | |
| C3 | 1 (2) |
| T5 | 1 (2) |
| T8 | 4 (7) |
| T9 | 43 (75) |
| T10 | 2 (4) |
| T11 | 1 (2) |
| T12 | 1 (2) |
| Missing | 4 (7) |
| **Paddle brand** | |

| | |
|---|---|
| Abbott Penta | 39 (68) |
| St. Jude Penta | 10 (18) |
| Boston Scientific 32 Contact | 4 (7) |
| Medtronic 565 | 4 (7) |
| **Generator brand** | |
| Non-Rechargeable St. Jude | 6 (11) |
| Non-Rechargeable Proclaim | 15 (26) |
| Non-Rechargeable Proclaim XR | 21 (37) |
| Non-Rechargeable Boston Scientific | 4 (7) |
| Non-Rechargeable Medtronic | 1 (2) |
| *Subtotal non-rechargeable* | *47 (82)* |
| Medtronic Rechargeable | 3 (5) |
| Abbott Eterna Rechargeable | 3 (5) |
| St. Jude Rechargeable | 1 (2) |
| *Subtotal rechargeable* | *7 (12)* |
| Missing | 3 (5) |
| **Presenting symptoms** | |
| Isolated leg pain | 8 (14) |
| Isolated back pain | 18 (32) |
| Concurrent back and leg pain | 31 (54) |
| **Post-operative complications** | |
| Infection | 2 (4) |
| Superficial Wound Dehiscence | 3 (5) |
| Return to Operating Room | 4 (7) |
| Permanent Neurologic Deficit | 0 (0) |
| Device Removal | 3 (5) |

**Table. 3.** Results from a one-way ANOVA comparing mean pain improvement (FPI) across three different symptomatic presentation patterns.

| **Variable** | **Isolated Leg Pain, n = 6** (mean ± SD) | **Isolated Back Pain, n = 16** (mean ± SD) | **Concurrent Back and Leg pain, n = 27** (mean ± SD) | **ANOVA (F)** | ***p*-value** |
|---|---|---|---|---|---|
| FPI after spinal cord stimulator implantation | 78 (± 17) | 74 (±18) | 74 (± 17) | 0.1065 | 0.8992 |

**Table. 4.** Comparison of frequency of pain reduction related to anatomical localization of pain on initial presentation following spinal cord stimulator implantation.

| **Categorization of Pain Response** | **Isolated Leg, n = 8 n (%)** | **Isolated Back, n = 16 n (%)** | **Concurrent Leg and Back, n = 29 n (%)** | **Fisher's Exact *p*-value** |
|---|---|---|---|---|
| Significant Improvement | 1 (13) | 4 (25) | 9 (31) | 0.2695 |
| Moderate Improvement | 4 (50) | 11 (69) | 15 (52) | |
| Mild Improvement | 0 (0) | 0 (0) | 3 (10) | |
| No Improvement | 3 (37) | 1 (6) | 2 (7) | |

## 4. Discussion

Within our cohort, our study demonstrated that SCS is a safe and effective method of treatment of back and leg pain in patients greater than 80 years of age with minimal complications. To date, the majority of research on surgical outcomes for elderly patients greater than 80 years of age has focused on spine surgery (decompression and/or instrumentation) and not on neuromodulation for pain. While this is a different modality for treating underlying pain, important lessons can be gleaned from this literature in terms of stratifying perioperative risks in elderly patients undergoing spine surgery. Deyo *et al.* [6] analyzed approximately 32,000 Medicare recipients from 2002-2007 who had surgery for lumbar stenosis. They determined that patients 80 years old and above had a 1.1% higher risk of cardiopulmonary complications or strokes, 0.1% higher risk of wound complications and 0.3% higher risk of 30-day mortality compared to the 66-70-year-old cohort [6].

While our study did not match patients of ages less than 80 years old, our cohort had significant cardiac comorbidities in the form of hypertension and coronary artery disease. We did not find any instances of perioperative cardiac events such as myocardial infarctions nor a need for cardiac catheterization post-operatively. Epstein *et al.* [7] attempted to distinguish whether age is an independent risk factor for spine surgery complications in geriatric patients and noted that medical comorbidities

were more correlative with perioperative complication risks than age. Older patients tended to have more comorbidities like circulatory, pulmonary, and renal diseases, and it was the presence of the commodities that better predicted outcomes [7]. Our data suggested that while a large portion of our cohort did have medical comorbidities, the overall complication rate remained low.

While operative time was unable to be collected due to inconsistencies in medical record documentation, most of the SCS surgeries in our cohort were performed in under two hours which likely would reduce perioperative complications as well. We do not compare outcomes based on age in our analysis however, the minimal complications encountered in our cohort suggest that the surgery is well tolerated and provides significant pain improvement. For example, while octogenarians do have a higher risk of surgical complications compared to the general population < 65 years of age, due to reduced immune function, our data demonstrated an overall infection risk of approximately 3%, which is in line with the reported incidence of infections within the general population [7-9].

SCS efficacy has been studied in middle aged patients. Notably, Bondoc *et al.* [10] demonstrated no statistically significant difference between patients above or below the age of 65 in regard to their improvement with SCS. While our study only included patients greater than 80 years of age, our outcomes appear to be consistent with those of younger patients which has been studied. Moreover, we found the implantation of paddle lead SCS is just as effective as what has been reported in younger patients.

Interestingly, within our cohort, 60% of patients had prior lumbar decompression and 23% of patients had prior lumbar fusion. This finding demonstrates that SCS was offered commonly as a primary less invasive means to address patients with leg, back or combined symptoms in patients rather than as a salvage therapy for patients with previous decompression or fusion. Another notable trend within our data was the discrepancy between patients receiving rechargeable versus non-rechargeable generators, where 47 (82%) of the generators implanted were non-rechargeable. Our institutional experience has demonstrated that most elderly patients would prefer non-rechargeable generators due to a simpler user interface and not needing to recharge the device. Using non-rechargeable generators will likely require additional future surgeries for generator exchange; however, this is a short and well tolerated procedure and can be done under sedation without general anesthesia to minimize any perioperative risks of anesthesia induction on older patients.

## 5. Conclusion

Paddle lead SCS may be performed safely in octogenarians with no obvious increase in complications or less efficacy. Paddle lead SCS implantation should not be precluded in octogenarian patients with chronic pain.

## Limitations

Our study does have limitations insofar as all surgeries were completed by a single surgeon at a single institution and therefore our cohort may not be generalizable to the general patient population. Additionally, the follow-up period was variable in our patient population due to the retrospective analysis which may skew complication data in patients with surgeries performed approximately one year ago. Lastly, all data were collected from the electronic medical record and therefore were subject to the quality of patient charting. Future studies may include prospective data collection with in-time questionnaires regarding pain improvement and prospective tracking of perioperative outcomes.

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## Ethical Approval

This retrospective review has been approved by our internal IRB with the IRB#2021-165.

## Author Contribution

Stephen Jaffee: Study coneption, data collection, analysis, manuscript writing. Griffin White: Data interpretation and manuscript writing. Trent Kite: Data interpretation and manuscript writing. Matthew Perry: Data collection, analysis, manuscript writing. Jenna Li: Data analysis, statistical analysis. Nestor Tomycz: Study conception, manuscript writing, review.

## Abbreviations

**SCS:** Spinal Cord Stimulation

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