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# Effectiveness of spinal cord stimulation in refractory chronic pain: An ambispective cohort study

## Efectividad de la estimulación medular en el dolor crónico refractario: Un estudio de cohorte ambispectivo

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**ABSTRACT**

**Introduction:** Chronic pain is a public health issue with an estimated global prevalence ranging from 20.8% to 51.3%, leading to impaired quality of life. Spinal cord stimulation (SCS) has emerged as an effective therapy for pain syndromes refractory to medical management. The aim of this study was to evaluate the analgesic effectiveness and reduction in medication use following SCS in patients with refractory chronic pain. **Methods:** We conducted an observational, longitudinal, ambispective, and analytical study in patients aged ≥ 18 years with CRPS, neuropathic pain, persistent spinal pain syndrome type 2, phantom limb pain, or chronic radicular pain who underwent SCS between May 2016 and August 2024. Pain intensity was assessed using the Numeric Rating Scale (NRS) and analgesic use before implantation, and at 3 and 6 months post-implantation. Responders were defined as patients achieving a ≥ 50% reduction in NRS. Secondary outcomes included reduction in the use of opioids, NSAIDs, and neuromodulators. **Results:** A total of 49 patients were included; 51% were responders. At 6 months, responders showed a significant reduction in pain compared with non-responders (NRS 2.8 ± 1.32 vs. 6.42 ± 1.82; $p < 0.001$). SCS led to a significant decrease in the use of neuromodulators (98% to 67.3%), opioids (87.8% to 42.9%), and NSAIDs (42.9% to 6.1%), all with $p < 0.001$ at 6 months. The NNT was 3.3 for neuromodulators, 2.2 for opioids, and 2.7 for NSAIDs. **Conclusion:** SCS is an effective intervention that significantly reduces pain intensity and analgesic consumption within a 6-month period.

**Keywords:** Chronic pain, complex regional pain syndrome, opioid epidemic, electric stimulation therapy, spinal cord stimulation.

**RESUMEN**

**Introducción:** El dolor crónico es un problema de salud pública con una prevalencia global estimada que varía entre 20,8% y 51,3%, lo que conlleva a un deterioro en la calidad de vida. La estimulación de la médula espinal (SCS, por sus siglas en inglés) ha surgido como una terapia eficaz para los síndromes dolorosos refractarios al manejo médico. El objetivo de este estudio fue evaluar la efectividad analgésica y la reducción en el uso de medicación tras la SCS en pacientes con dolor crónico refractario. **Métodos:** Se realizó un estudio observacional, longitudinal, ambispectivo y analítico en pacientes ≥ 18 años con SDRC, dolor neuropático, síndrome de dolor persistente de columna tipo 2, dolor de miembro fantasma o dolor radicular crónico que fueron sometidos a SCS entre mayo de 2016 y agosto de 2024. La intensidad del dolor se evaluó mediante la Escala Numérica de Valoración (NRS) y el uso de analgésicos antes del implante, y a los 3 y 6 meses posteriores. Se consideraron respondedores aquellos pacientes que alcanzaron una reducción ≥ 50% en la NRS. Los desenlaces secundarios incluyeron la disminución en el uso de opioides, AINEs y neuromoduladores. **Resultados:** Se incluyeron un total de 49 pacientes; 51% fueron respondedores. A los 6 meses, los respondedores mostraron una reducción significativa del dolor en comparación con los no respondedores (NRS 2,8 ± 1,32 vs. 6,42 ± 1,82; $p < 0,001$). La SCS produjo una disminución significativa en el uso de neuromoduladores (98% a 67,3%), opioides (87,8% a 42,9%) y AINEs (42,9% a 6,1%),

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todos con p < 0,001 a los 6 meses. El NNT fue de 3,3 para neuromoduladores, 2,2 para opioides y 2,7 para AINEs. **Conclusión:** La SCS es una intervención eficaz que reduce de manera significativa la intensidad del dolor y el consumo de analgésicos en un periodo de 6 meses.

**Palabras clave:** Dolor crónico, síndrome de dolor regional complejo, epidemia de opioides, terapia de estimulación eléctrica, estimulación medular.

## Introduction

Chronic pain is a public health problem, with an estimated global prevalence ranging from 20.8%[1] to 51.3%[2] in the adult population. It is associated with functional impairment, high healthcare resource utilization, and reduced quality of life[3]. Complex regional pain syndrome (CRPS)[4] and persistent spinal pain syndrome type 2 (PSPS-T2)[5] continue to pose therapeutic challenges due to their limited response to conventional pharmacological treatment. Spinal cord stimulation (SCS) has become a consolidated therapeutic alternative for these syndromes, with growing evidence supporting its analgesic efficacy, reflected in reductions in the use of opioids, nonsteroidal anti-inflammatory drugs (NSAIDs), and neuromodulators[6].

The mechanism of action of SCS is explained by the stimulation of large-diameter afferent fibers in the dorsal columns of the spinal cord, which interferes with nociceptive transmission, based on the gate control theory proposed by Melzack and Wall[7]. However, experimental studies have demonstrated that its action is not limited to the spinal level but also involves supraspinal mechanisms[8], mediated by inhibitory factors such as gamma-aminobutyric acid (GABA) and other systems such as the cholinergic pathway[9], which inhibit wide dynamic range neurons through descending inhibitory mechanisms that may persist even after stimulation is turned off[10]. This has prompted investigations into its effectiveness across various chronic pain syndromes, although results remain inconclusive for many of them.

The aim of the present study was to evaluate the analgesic effectiveness of SCS in patients with different types of chronic pain refractory to medical management, treated at a referral center.

## Methods

This study was approved by the Research Ethics Committee of the Colombian Pain Institute (INCODOL), as documented in the institutional minutes dated June 9, 2023. We conducted an observational, longitudinal, ambispective, and analytical study aimed at assessing the analgesic effectiveness of SCS in patients with chronic pain treated at INCODOL, in Medellín, Colombia. Patients who underwent SCS between May 2016 and August 2024 were included, with clinical follow-up up to six months after neurostimulator implantation.

The study population consisted of patients aged 18 years or older, with a clinical history of CRPS, neuropathic pain, PSPS-T2, phantom limb pain, or chronic radicular pain, with NRS ≥ 7 and refractory to medical management. All patients underwent implantation of a dorsal column neurostimulator (Medtronic, Minneapolis, MN, USA) and had a clinical record documenting at least six months of post-procedural follow-up.

Collected variables included sociodemographic characteristics (age, sex, weight, height, and body mass index), clinical variables (diagnosis, pain location, medication use before and after the procedure, trial stimulation, physical therapy), and outcome variables (mean reduction in pain intensity on the Numeric Rating Scale, NRS) assessed before implantation and at 3 and 6 months post-implantation. The primary outcome was defined as a ≥ 50% reduction in NRS score compared to baseline[11], measured at 3 and 6 months after implantation. Secondary outcomes included reductions in opioid, NSAID, and neuromodulator use after SCS implantation.

Data were collected using a Microsoft Excel® template by four investigators, who extracted the information directly from clinical records. Statistical analysis included descriptive statistics for quantitative variables expressed as measures of central tendency and dispersion (mean or median, standard deviation or interquartile range), according to variable distribution. Categorical variables were reported as absolute and relative frequencies. Normality was assessed using the Shapiro-Wilk test[12].

Patients were classified as responders or non-responders based on the primary outcome. Clinical and treatment characteristics were compared between groups. For categorical variables, chi-square or Fisher's exact test was used, while for continuous variables, Student's t-test was applied in cases of normal distribution or the Mann-Whitney U test[13] otherwise. To evaluate changes in NRS scores across the three measurement points (baseline, 3 months, and 6 months), Friedman's non-parametric test[14] was applied, followed by paired Wilcoxon tests with Bonferroni correction for multiple comparisons. The number needed to treat (NNT) was calculated as the inverse of the absolute risk reduction in analgesic consumption.

Statistical analysis was performed using R language via RStudio® version 4.3.1, with statistical significance set at $p < 0.05$.

## Results

A total of 53 patients were screened for inclusion; after applying the eligibility criteria, 49 patients who underwent dorsal column stimulation for refractory chronic pain were included (Figure 1). Of these, 25 patients (51%) were classified as responders and 24 (49%) as non-responders. Most patients were male (61.2%), with a mean age of 46.9 ± 12.83 years. A significantly higher proportion of non-responders were not receiving any medication compared with responders (p = 0.048) (Table 1).

At baseline, mean NRS was 7.9 (SD ± 1.56). Responders had higher pain scores than non-responders (p = 0.044). This

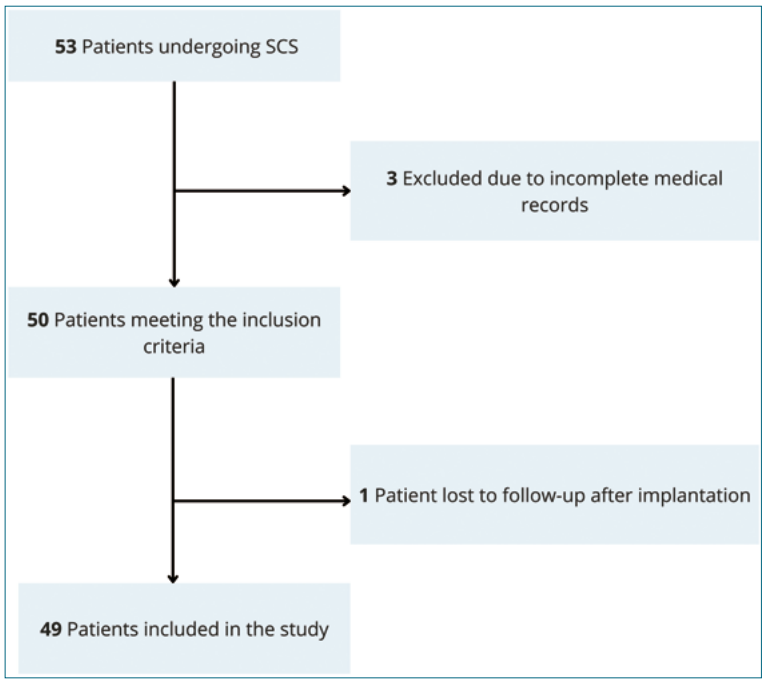


**Figure 1.** CONSORT diagram of patient inclusion, exclusion, and follow-up.

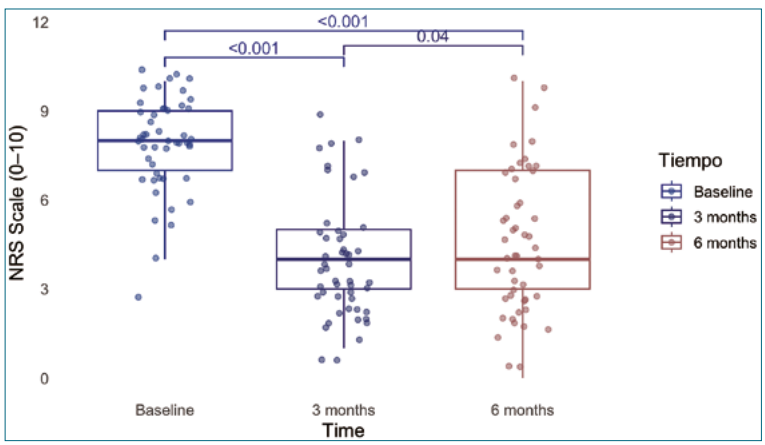


**Figure 2.** Comparison of NRS (0-10) before and after spinal cord stimulation across all patients at baseline, 3 months, and 6 months. Friedman test followed by pairwise Wilcoxon comparisons with Bonferroni correction was used.

difference disappeared at 3 months post-implant (p = 0.143); however, at 6 months, the difference became significant again, with mean NRS 2.8 (SD ± 1.32) in responders vs. 6.42 (SD ± 1.82) in non-responders (p < 0.001). The clinical impact of SCS at 6 months was reflected in NNT values of 3.3 for neuromodulators, 2.2 for opioids, and 2.7 for NSAIDs (Table 2).

There was a significant reduction in pain over time in the overall cohort, reaching significance at both 3 and 6 months (Figure 2). This reduction was associated with decreased neuromodulator use, with greater improvement among responders (52%) compared to non-responders (83.3%) (p = 0.04). Overall, there was a significant reduction in neuromodulator use (98% vs. 67.3%, p < 0.001), opioids (87.8% vs. 42.9%, p < 0.001), and NSAIDs (42.9% vs. 6.1%, p < 0.001) after SCS implantation. No additional significant benefit was observed in patients without prior analgesic use (p = 0.19) (Figure 3).

## Discussion

This ambispective cohort shows that SCS is an effective strategy for managing patients with refractory chronic pain. A total of 51% of patients achieved a clinically meaningful improvement in pain scores (≥ 50% NRS reduction), a success rate comparable to that reported for persistent spinal pain syndrome type 2 (PSPS-2) and diabetic neuropathy, which show success rates of 50%-80%[10],[15]. Pain reduction was sustained up to 6 months (p < 0.001), though longer follow-up is needed to evaluate long-term durability.

The limited efficacy of SCS over time is likely multifactorial. Tolerance is the main explanation for diminishing analgesic benefit[16]. One proposed mechanism is localized macroscopic fibrosis around the electrode tip, interfering with electrical current and ascending nociceptive pathways. Advances such as

| Table 1. Demographic and clinical characteristics of patients | | | | |
|---|---|---|---|---|
| **Variable** | **Total sample n = 49 (%)** | **Responders n = 25 (%)** | **Non-responders n = 24 (%)** | **p-value** |
| Gender | | | | |
| Female | 19 (38.8) | 11 (44) | 8 (33.3) | 0.63* |
| Male | 30 (61.2) | 14 (56) | 16 (66.7) | |
| Age (mean ± SD) | 46.9 ± 12.83 | 46.8 ± 12.17 | 47 ± 13.74 | 0.94‡ |
| Weight (mean ± SD) | 72.95 ± 12.94 | 73.34 ± 14.46 | 72.54 ± 11.4 | 0.83‡ |
| BMI (mean ± SD) | 26.45 ± 4.35 | 26.39 ± 5.1 | 26.51 ± 3.5 | 0.46§ |
| Baseline NRS | | | | |
| Mean ± SD | 7.9 ± 1.56 | 8.4 ± 1.12 | 7.38 ± 1.79 | 0.044§ |
| Median (IQR) | 8 (7-9) | 8 (8-9) | 8 (7- 8) | |
| Diagnosis | | | | |
| CRPS | 5 (10.2) | 4 (16) | 1 (4.2) | 0.21† |
| Peripheral neuropathic pain | 14 (28.6) | 8 (32) | 6 (25) | |
| Persistent spinal pain syndrome type 2 | 14 (28.6) | 7 (28) | 7 (29.2) | |
| Phantom limb pain | 4 (8.2) | 3 (12) | 1 (4.2) | |
| Chronic radicular pain | 12 (24.5) | 3 (12) | 9 (37.5) | |
| Electrode location | | | | |
| Cervical | 14 (28.6) | 6 (24) | 8 (33.3) | 0.24† |
| Thoracic | 28 (57.1) | 17 (68) | 11 (45.8) | |
| Lumbar | 7 (14.3) | 2 (8) | 5 (20.8) | |
| Opioids prior to SCS | 43 (87.8) | 24 (96) | 19 (79.2) | 0.09† |
| NSAIDs prior to SCS | 21 (42.9) | 10 (40) | 11 (45.8) | 0.902* |
| No analgesics prior to SCS | 7 (14.3) | 1 (4) | 6 (25) | 0.048† |
| Neuromodulators prior to SCS | 48 (98) | 25 (100) | 23 (95.8) | 0.49† |
| Physical therapy | 26 (53.1) | 12 (48) | 14 (58.3) | 0.66* |
| Neurostimulation trial | 47 (95.9) | 25 (100) | 22 (91.7) | 0.23† |

Comparison of clinical and therapeutic characteristics between responders and non-responders to spinal cord stimulation (SCS). Values are expressed as n (%) for categorical variables, mean ± SD for normally distributed continuous variables, and median (IQR Q1-Q3) for non-normally distributed variables. *Chi-square test; †Fisher's exact test; ‡Student's t-test; §Mann-Whitney U test. SD: standard deviation; SCS: spinal cord stimulator; CRPS: complex regional pain syndrome; BMI: body mass index; NRS: Numerical Rating Scale; IQR: interquartile range; NSAID: nonsteroidal anti-inflammatory drug.

| Table 2. Outcomes after spinal cord stimulation implant | | | | |
|---|---|---|---|---|
| **Variable** | **Total sample n = 49 (%)** | **Responders n = 25 (%)** | **Non-responders n = 24 (%)** | **p-value** |
| NRS at 3 months | | | | |
| Mean ± SD | 3.94 ± 1.99 | 3.52 ± 1.66 | 4.38 ± 2.24 | 0.143‡ |
| Median (IQR) | 4 (3 - 5) | 3 (2 - 4) | 4 (3 - 5) | |
| NRS at 6 months | | | | |
| Mean ± SD | 4.57 ± 2.41 | 2.8 ± 1.32 | 6.42 ± 1.82 | < 0.001‡ |
| Median (IQR) | 4 (3 - 7) | 3 (2 - 4) | 7 (5 - 7) | |
| Neuromodulators | 33 (67.3) | 13 (52) | 20 (83.3) | 0.04* |
| Opioids | 21 (42.9) | 10 (40) | 11 (45.8) | 0.9* |
| NSAIDs | 3 (6.1) | 2 (8) | 1 (4.2) | 0.99† |
| No analgesics or neuromodulators | 7 (14.3) | 6 (24) | 1 (4.2) | 0.09† |

Values presented for the total cohort, responders, and non-responders. *Chi-square test; †Fisher's exact test; ‡Mann-Whitney U test. SD: standard deviation; SCS: spinal cord stimulator; NRS: Numerical Rating Scale; IQR: interquartile range; NSAID: nonsteroidal anti-inflammatory drug.

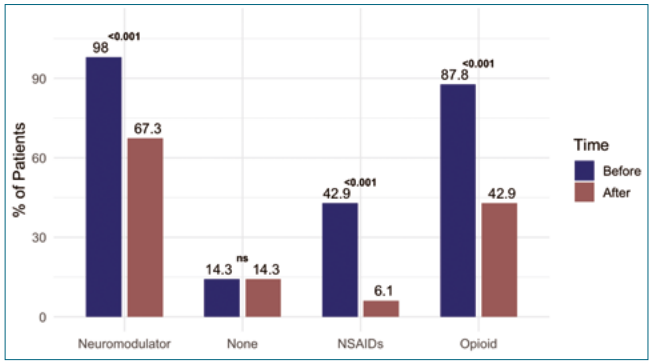


**Figure 3.** Comparison of the proportion of patients using each medication type before and 6 months after spinal cord stimulation. McNemar test was used for paired comparisons of pre- and post-implant medication use. NS: not significant.

high-frequency and burst stimulation may help overcome tolerance[17]. Our study did not include patients with these newer modalities, which may account for limited long-term benefit in pain and medication reduction.

A key goal of SCS is reducing medication use[18]. We observed significant and clinically relevant reductions in opioids ($p < 0.001$), NSAIDs ($p < 0.001$), and neuromodulators ($p < 0.001$) within 6 months. NNT values of 2.2 for opioids, 2.7 for NSAIDs, and 3.3 for neuromodulators highlight the substantial pharmacological burden reduction[19]. Given the global public health crisis of opioid dependence, reducing reliance on medications with significant side effects and dependency risk may improve safety and quality of life in refractory chronic pain patients[20].

Our results reflect the diversity of real-world chronic pain populations. While most evidence focuses on CRPS[21] and PSPS-2[10], our findings suggest SCS may benefit other conditions such as radicular pain and phantom limb pain, though further studies are needed. Real-world data such as ours add value, often better reflecting clinical complexity than highly controlled RCTs[22]. This supports the external validity of current evidence in the Latin American context, with efficacy similar to that reported globally.

## Limitations

This study has several limitations. First, only patients with ≥6 months follow-up were included, potentially biasing responder rates. However, only 7.5% of eligible patients were excluded, mainly due to incomplete records. Second, heterogeneity in diagnoses (CRPS, PSPS-2, radicular pain) reduces condition-specific conclusions, although it reflects real clinical practice. While SCS efficacy in PSPS-2 and CRPS is well established, its benefit in phantom limb pain remains preliminary[23]. Third, the absence of a control group (placebo or standard medical therapy) limits causal attribution. Fourth, follow-up was limited to 6 months, whereas other studies show declining efficacy beyond 3 years[24], leading to explantation[25]. Lastly, as a single-center study, findings may not generalize and could reflect center-specific expertise.

## Future directions

Prospective, multicenter studies with longer follow-up are needed to confirm efficacy in heterogeneous populations, given potential attenuation of pain relief over time[25]. Further research should explore less-studied conditions such as phantom limb pain, where early results are promising. Incorporating patient-centered outcomes such as quality of life, functionality, and return to work will help evaluate the broader impact of SCS and refine patient selection for optimal benefit.

## Conclusion

Spinal cord stimulation shows 51% effectiveness in refractory chronic pain patients, sustained for at least 6 months. This benefit is accompanied by significant reductions in neuromodulator, opioid, and NSAID use, underscoring its potential to reduce pharmacological burden and associated risks. Multicenter, long-term studies are required to confirm sustained efficacy and evaluate broader impacts on quality of life and functionality.

### *Authors' contributions:*

- MABL: Conception and design of the study; data interpretation; critical revision of the manuscript; final approval of the version to be published.
- FALA: Conception and design of the study; scientific analysis; drafting and writing of the manuscript; critical revision of the manuscript; final approval of the version to be published.
- JHAB: Conception and design of the study; data interpretation; critical revision of the manuscript; final approval of the version to be published.
- CMQ: Conception and design of the study; data collection; data interpretation; critical revision of the manuscript; final approval of the version to be published.
- MCJM: Data interpretation; drafting of the manuscript; critical revision of the manuscript; final approval of the version to be published.
- SAA: Data interpretation; drafting of the manuscript; critical revision of the manuscript; final approval of the version to be published.
- AY: Drafting of the manuscript; critical revision of the manuscript; final approval of the version to be published.

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