

Neuromodulation

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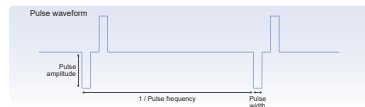
Review Articles



Editor's Choice

1 A Definition of Neuromodulation and Classification of Implantable Electrical Modulation for Chronic Pain

Eellan Sivanesan, MD; Richard B. North, MD; Marc A. Russo, MBBS; Robert M. Levy, MD, PhD; Bengt Linderöth, MD, PhD; Salim M. Hayek, MD; Sam Eldabe, MD; Scott F. Lempka, PhD



To improve clinical care and facilitate dissemination amongst the public, payors, research groups, and regulatory bodies, there is a clear need for a standardization of terms in neuromodulation for chronic pain. We formed an international group of basic scientists, anesthesiologists, neurosurgeons, and engineers with expertise in neuromodulation. We first present a consensus definition of neuromodulation. We then describe a classification scheme based on the: 1) intended use (the site of modulation and its indications), and 2) physical properties (waveforms and dose) of a neuromodulation therapy.

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Editor's Choice

70 Factors Predicting Clinically Relevant Pain Relief After Spinal Cord Stimulation for Patients With Chronic Low Back and/or Leg Pain: A Systematic Review With Meta-Analysis and Meta-Regression

Ferdinand Bastiaens, MSc; Ilse H. van de Wijgert, MSc; Ewald M. Bronkhorst, PhD; Bert-Kristian W.P. van Roosendaal, MD; Esther P.Z. van Heteren, MD; Christopher Gilligan, MD; Peter Staats, MD; Jessica T. Wegener, MD; Miranda L. van Hooff, PhD; Kris C.P. Vissers, MD, PhD

To evaluate predictive factors of clinically relevant pain relief following SCS for patients with CLBP and/or radicular leg pain, including PSPS, PubMed, Cinahl, Cochrane and EMBASE were searched to identify studies published between January 2010 and August 2023. Studies reporting the percentage of patients with $\geq 50\%$ pain relief after SCS in patients with CLBP and leg pain, including PSPS at 12 or 24 months were included. Meta-analysis was conducted to pool results for back, leg, and general pain relief. Predictive factors for pain relief after 12 months were examined using univariable and multivariable meta-regression.

Included for analysis were 27 studies (2,220 patients). The mean percentage of patients with substantial pain relief were 68% for leg pain, 63% for back pain, and 73% for general pain at 12 months follow-up, and 63% for leg pain, 59% for back pain, and 71% for general pain at 24 months follow-up assessment. Implantation method and baseline ODI made the multivariable meta-regression model for $\geq 50\%$ back pain relief. Sex and pain duration made the final model for $\geq 50\%$ leg pain relief. Variable stimulation and implantation method made the final model for general pain relief. Models were developed to predict substantial back and leg pain relief.

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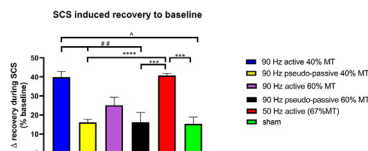
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Basic Science

★ Editor's Choice

95 Ninety-Hz Spinal Cord Stimulation–Induced Analgesia Is Dependent on Active Charge Balance and Is Nonlinearly Related to Amplitude: A Sham-Controlled Behavioral Study in a Rodent Model of Chronic Neuropathic Pain

Lonne Heijmans, PhD; Tianhe C. Zhang, PhD; Rosana Esteller, PhD; Elbert A. Joosten, PhD



This preclinical study investigates the behavioral effect of multiple 90 Hz SCS variants in a rodent model of neuropathic pain, focusing on charge balance and the relationship between 90 Hz efficacy and stimulation intensity. Rats ($n = 24$) received a unilateral partial sciatic nerve ligation to induce neuropathic pain and were implanted with a quadripolar lead at T13. Mechanical hypersensitivity was assessed prior to, during and after 60 minutes of SCS. After a pre-screen with 50 Hz SCS 67% MT, the positive control), rats underwent a randomized-crossover study including sham SCS and several 90 Hz SCS paradigms (at 40% MT or 60% MT, either using active or pseudo-passive recharge) (experiment 1, $n = 16$). A second, identical experiment (experiment 2) was performed to supplement data with 90 Hz SCS at 20% and 80% MT (experiment 2, $n = 8$). In experiment 1, 90 Hz active recharge SCS at 40% MT produced a significantly larger recovery to baseline as compared to 90 Hz pseudo-passive SCS at both tested intensities and sham SCS. In experiment 2, only the 90 Hz SCS active recharge at 40% MT and 50 Hz SCS positive control resulted in mean recovery to baseline that was statistically better as compared to sham SCS.

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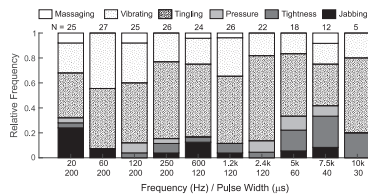
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John Hatheway, MD; Michael Yang, MD; Michael Fishman, MD; Michael Verdolin, MD; Tory McJunkin, MD; Steven Rosen, MD; Sean Slee, PhD; Andrew Kibler, PhD; Kasra Amirdelfan, MD



The boundaries of sensory perception of spinal cord stimulation are not well defined. The BENEFIT-01 study aimed to create a map of perceptual threshold responses across a broad range of SCS parameters and programming to inform sub-perception therapy design. This multicenter study was conducted at 7 US sites. A total of 43 patients with low back and/or leg pain who completed a percutaneous commercial SCS trial were enrolled. Test stimulation was delivered via trial leads for ~90 minutes before removal. SCS parameters, including amplitude, frequency, pulse width (PW), electrode configuration, cycling, and multi-frequency stimulation were varied during testing. Perception threshold (PT), comfort level (CL), perceptual coverage area and paresthesia quality (via patient selection of keywords) were collected. Differences were evaluated with ANOVA followed by post hoc multiple comparisons using t-tests with Bonferroni correction.

PT was primarily determined by PW and was insensitive to frequency for constant frequency stimulation (range: 20 Hz–10 kHz; $F(1,284) = 69.58$, $p < 0.0001$). For all tests, CL was ~25% higher than PT. The dominant variable that influenced perception quality was frequency. Sensations described as comfortable and tingling were most common for frequencies between 60 Hz–2.4 kHz; unpleasant sensations were generally more common outside this range. Increasing distance between active electrodes from 7 mm to 14 mm, or cycling the SCS waveform at 1 Hz, decreased PT ($p < 0.0001$). Finally, PT for a low-frequency stimulus (ie, 60 Hz) was unaffected by mixing with a sub-PT high-frequency stimulus.

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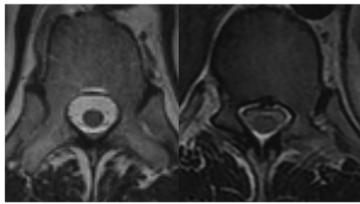
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During initial SCS paddle led placement, a second laminotomy or laminectomy, termed a “skip” laminotomy, may be necessary to pass the lead to the appropriate midline position. Patient and radiographic factors that predict the need for a skip laminotomy have yet to be identified. Participants who underwent SCS paddle placement at Albany Medical Center between 2016 and 2017 were identified. Operative reports were reviewed to identify the paddle type, level of initial laminotomy, target level, and skip laminotomy level. Preoperative thoracic Magnetic Resonance Images (MRIs) were reviewed and spinal canal diameter, interpedicular distance, and dorsal cerebral spinal fluid thickness were measured for each participant when available.

A total of 106 participants underwent thoracic SCS placement. Of these, 97 had thoracic MRIs available for review. Thirty-eight participants required a skip laminotomy for placement of the paddle compared to 68 participants that did not. There was no significant difference in demographic features including age, sex, BMI, and prior surgical history. Univariate analyses that suggested trends were selected for further analysis using binary logistic regression. Level of initial laminotomy (OR = 1.51, $p = 0.028$), spinal canal diameter (OR = 0.71, $p = 0.015$), and dorsal CSF thickness (OR = 0.61, $p = 0.011$) were correlated with skip laminotomy. Target level (OR = 1.27, $p = 0.138$) and time from trial (1.01, $p = 0.117$) suggested potential association. The multivariate regression was statistically significant, $X^2(10) = 28.02$, $p = 0.002$. The model explained 38.3% of the variance (Nagelkerke R^2) and predicted skip laminectomy correctly in 73.3% of cases. However, for the multivariate regression, only a decrease in spinal canal diameter (OR = 0.59, $p = 0.041$) was associated with a greater odds of skip laminotomy.

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