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Neuromodulation: Indication-Approach-Complications-Outcomes

Tuesday, January 3, 2023

7-8:30 pm ET

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Neuromodulation: Indications

Alexander Bautista, MD, MBA, FASA
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Disclosure

None

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Objectives

- To discuss different indications for neuromodulation
- Review some landmark papers for each indication
- Look at what insurance is trying to look for prior to approval.

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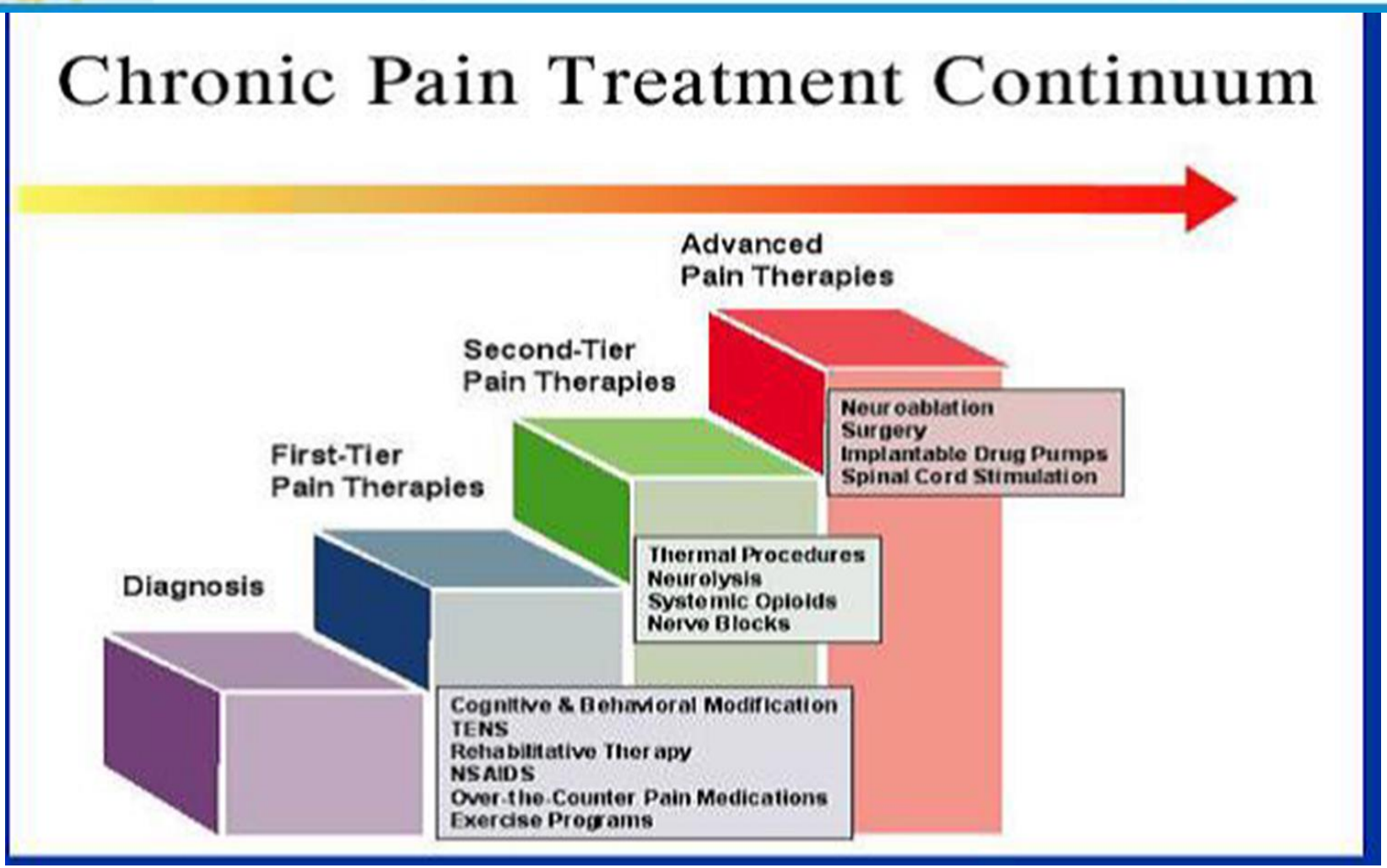
Chronic Pain Treatment Continuum



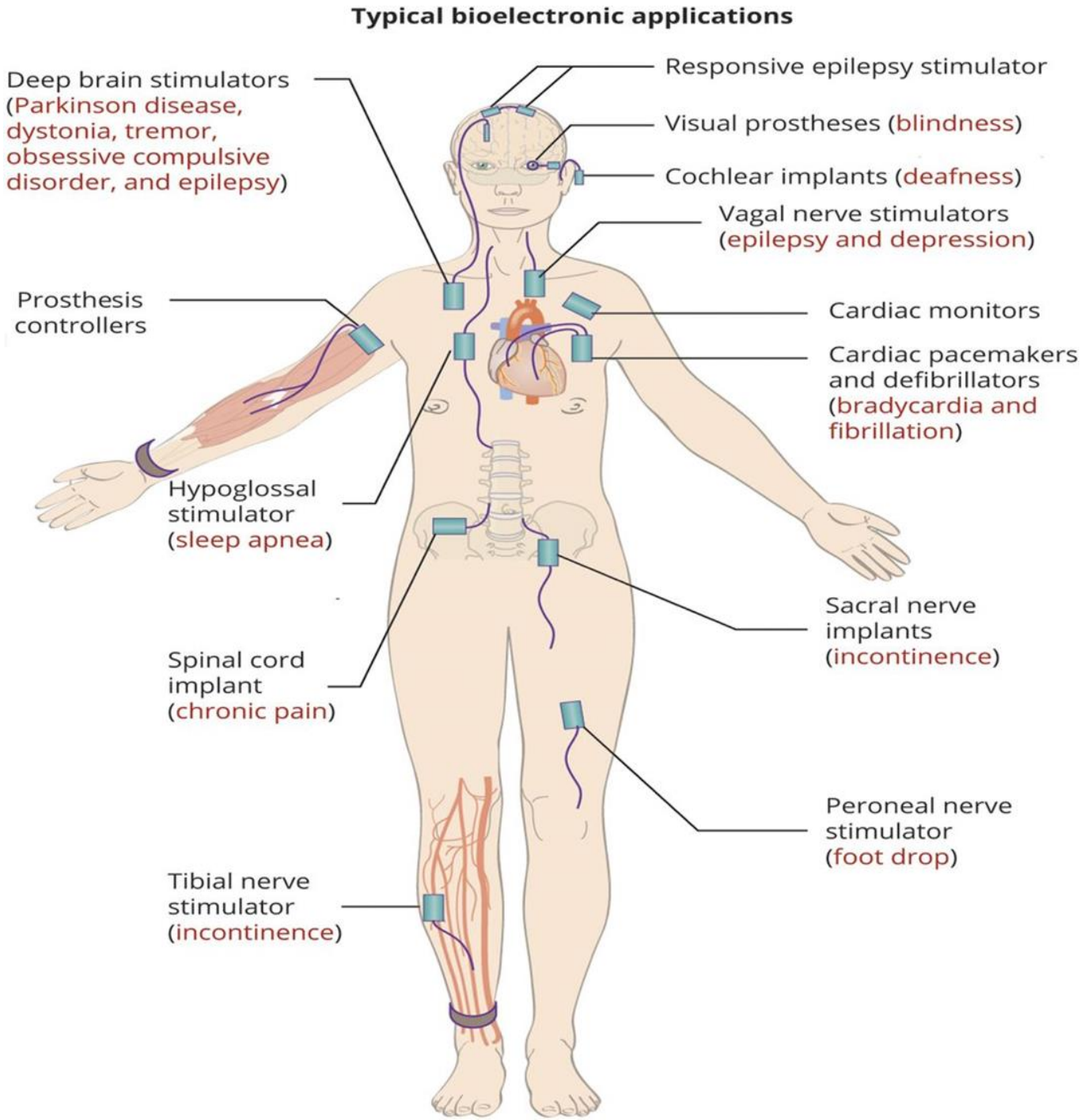
Neuromodulation : Definition

- " Alteration of nerve activity through targeted delivery of a stimulus, such as electrical stimulation or chemical agents to specific neurologic sites in the body"

- International Neuromodulation Society

Neuromodulation

- Relief of Pain
- Restoration of function
- Normal- bowel and bladder function
- Tremor
- Reversible
- Minimally invasive



Neuromodulation in 2035
The Neurology Future Forecasting Series
Tim Denison, Martha J. Morrell
Neurology Jan 2022, 98 (2) 65-72; DOI: 10.1212/WNL.0000000000013061

Table Examples of Food and Drug Administration–Approved and Investigational Use Neuromodulation Devices

	Disorder	Device/target
FDA-approved indication for use	Tremor in Parkinson disease, essential tremor, dystonia	DBS of STN, GPi, Vim
	Focal onset seizures	DBS of ANT, responsive cortical stimulation, vagus nerve stimulation
	OCD	DBS anterior limb internal target
	Pain	Spinal cord stimulation
	Depression	Vagus nerve stimulation, TMS
Investigational Use Exemption	Focal epilepsies	tDCS, TMS
	Generalized onset epilepsy, Lennox-Gastaut syndromes[1]	DBS: anterior and centromedian nucleus of the thalamus
	Restoration of function: motor, sensory, memory[2,3]	Cortical stimulation, assistive technologies, spinal cord stimulation
	Psychiatric: depression, PTSD, impulse control including substance use disorders[4]	DBS targets: cingulate, dorsal lateral frontal lobe, nucleus accumbens, amygdala
	Traumatic brain or spinal cord injury[5]	Multiple cortical and deep brain targets; spinal cord
	Vegetative state and other disorders of consciousness[6]	DBS of thalamic reticular nucleus, tDCS, TMS
	Alzheimer disease[7]	TMS, DBS: multiple cortical and subcortical targets

Abbreviations: ANT = anterior nucleus of thalamus; DBS = deep brain stimulation; FDA = Food and Drug Administration; GPi = internal globus pallidus; PTSD = posttraumatic stress disorder; STN = subthalamic nucleus; tDCS = transcranial direct current stimulation; TMS = transcranial magnetic stimulation; Vim = ventral intermediate nucleus.

Current Pain Indications

- Failed low back and neck surgery
- CRPS
- Ischemic Disease – Refractory Angina, Peripheral Vaso occlusive Disease
- Pelvic Pain/Incontinence
- Malignancy
- Spasticity (spinal cord injury/ spastic diplegia)

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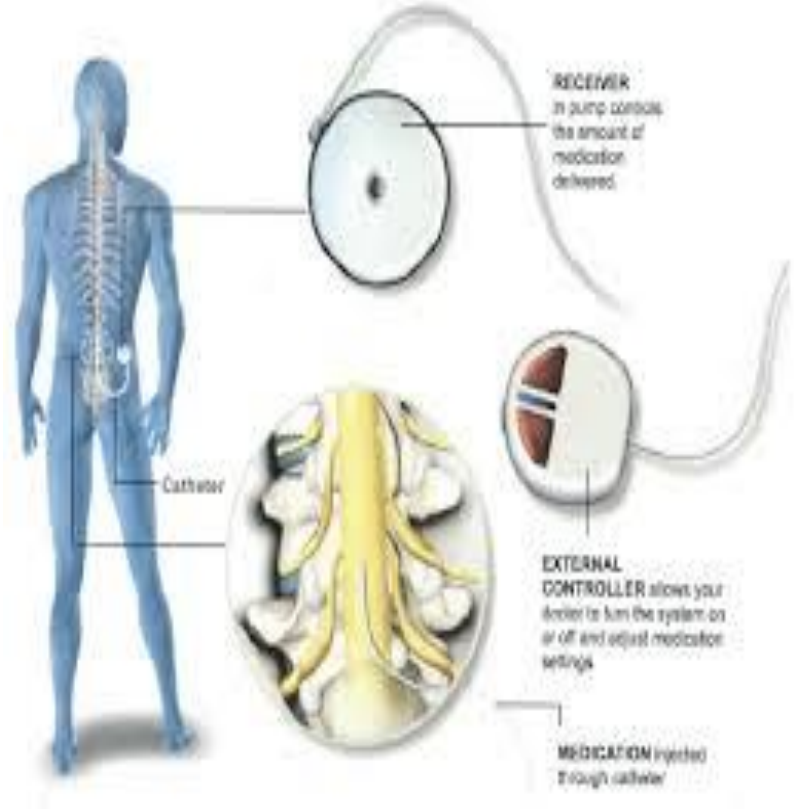
Intrathecal Pain Pump



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Intrathecal Pain Pump: Indications

- Cancer pain
- Non-malignant pain
  - Neuropathic pain – Ziconotide
  - Spasticity – Baclofen
  - Chronic pain – Opioids, Local anesthetics, clonidine

Intrathecal Pain Pump: Indications

- Pain Diagnosis : Neuropathic, Nociceptive, or Mixed.
- Cancer; Chronic and Progressive
- Failed to achieve analgesia with conservative nonpharmacologic modalities
- Refractory or intolerant to orally administered analgesics
- Corrective treatment addressing the pain generator is not warranted.
- Absence of surgical contraindications to implanting prosthetic hardware and intrathecal space access

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Spinal Cord Stimulation

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Intractable Back and Radicular Pain

- Radicular Pain
  - Failed Back Surgery Syndrome
- Axial back pain

RESEARCH PAPERS

Spinal cord stimulation versus conventional medical management for neuropathic pain: A multicentre randomised controlled trial in patients with failed back surgery syndrome

Kumar, Krishna[a,*]; Taylor, Rod S.[b]; Jacques, Line[c]; Eldabe, Sam[d]; Meglio, Mario[e]; Molet, Joan[f]; Thomson, Simon[g]; O'Callaghan, Jim[h]; Eisenberg, Elon[i]; Milbouw, Germain[j]; Buchser, Eric[k]; Fortini, Gianpaolo[l]; Richardson, Jonathan[m]; North, Richard B.[n]

Author Information

Pain: November 2007 - Volume 132 - Issue 1 - p 179-188
doi: 10.1016/j.pain.2007.07.028

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Effective Relief of Pain and Associated Symptoms With Closed-Loop Spinal Cord Stimulation System: Preliminary Results of the Avalon Study

Marc Russo, MBBS FFPMANZCA*; Michael J. Cousins, MD, DSc†; Charles Brooker, MBBS‡§; Nathan Taylor, BSc(Med), MBBS¶; Tillman Boesel, MBBS, BMedSc (hons); Richard Sullivan, MBChB††; Lawrence Poree, MD, PhD‡‡; Nastaran Hesam Shariati, PhD§§; Erin Hanson, MPH§§; John Parker, PhD§§¶¶**

Objectives: Conventional spinal cord stimulation (SCS) delivers a fixed-input of energy into the dorsal column. Physiologic effects such as heartbeat, respiration, spinal cord movement, and history of stimulation can cause both the perceived intensity and recruitment of stimulation to increase or decrease, with clinical consequences. A new SCS system controls stimulation dose by measuring the recruitment of fibers in the dorsal column and by using the amplitude of the evoked compound action potentials (ECAPs) to maintain stimulation within an individualized therapeutic range. Safety and efficacy of this closed-loop system was evaluated through six-month postimplantation.

Materials and Methods: Chronic pain subjects with back and/or leg pain who were successfully trialed received a permanent system (Evoke; Saluda Medical, Sydney, Australia). Ratings of pain (100-mm visual analogue scale [VAS] and Brief Pain Instrument [BPI]), quality of life (EuroQol instrument [EQ-5D-5L]), function (Oswestry Disability Index [ODI]), and sleep (Pittsburgh Sleep Quality Index [PSQI]) were collected at baseline and repeated three and six months after implantation.

Results: Fifty-one subjects underwent a trial procedure; permanent implants were placed in 36 subjects. The proportion of subjects with $\geq$50% relief was 92.6% (back) and 91.3% (leg) at three months, and 85.7% (back) and 82.6% (leg) at six months. The proportion with $\geq$80% pain relief was 70.4% (back) and 56.5% (leg) at three months, and 64.3% (back) and 60.9% (leg) at six months. Statistically significant improvements in mean BPI, EQ-5D-5L, ODI, and PSQI were also observed at both time points.

Conclusions: The majority of subjects experienced profound pain relief at three and six months, providing preliminary evidence for the effectiveness of the closed-loop SCS system. The exact mechanism of action for these outcomes is still being explored, although one likely hypothesis holds that ECAP feedback control may minimize recruitment of Aβ nociceptors and Aδ fibers during daily use of SCS.

Keywords: back pain, closed loop, closed-loop, dose, Evoked Compound Action Potential (ECAP), feedback, feedback stimulation, leg pain, neuromodulation, Spinal cord stimulation

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Novel 10-kHz High-frequency Therapy (HF10 Therapy) Is Superior to Traditional Low-frequency Spinal Cord Stimulation for the Treatment of Chronic Back and Leg Pain

The SENZA-RCT Randomized Controlled Trial

Leonardo Kapural, M.D., Ph.D., Cong Yu, M.D., Matthew W. Doust, M.D., Bradford E. Gliner, M.S., Ricardo Vallejo, M.D., Ph.D., B. Todd Sitzman, M.D., M.P.H., Kasra Amirdelfan, M.D., Donna M. Morgan, M.D., Lora L. Brown, M.D., Thomas L. Yearwood, M.D., Ph.D., Richard Bundschu, M.D., Allen W. Burton, M.D., Thomas Yang, M.D., Ramsin Benyamin, M.D., Abram H. Burgher, M.D.

ABSTRACT

Background: Current treatments for chronic pain have limited effectiveness and commonly known side effects. Given the prevalence and burden of intractable pain, additional therapeutic approaches are desired. Spinal cord stimulation (SCS) delivered at 10 kHz (as in HF10 therapy) may provide pain relief without the paresthesias typical of traditional low-frequency SCS. The objective of this randomized, parallel-arm, noninferiority study was to compare long-term safety and efficacy of SCS therapies in patients with back and leg pain.

Methods: A total of 198 subjects with both back and leg pain were randomized in a 1:1 ratio to a treatment group across 10 comprehensive pain treatment centers. Of these, 171 passed a temporary trial and were implanted with an SCS system. Responders (the primary outcome) were defined as having 50% or greater back pain reduction with no stimulation-related neurological deficit.

Results: At 3 months, 84.5% of implanted HF10 therapy subjects were responders for back pain and 83.1% for leg pain, and 43.8% of traditional SCS subjects were responders for back pain and 55.5% for leg pain ($P < 0.001$ for both back and leg pain comparisons). The relative ratio for responders was 1.9 (95% CI, 1.4 to 2.5) for back pain and 1.5 (95% CI, 1.2 to 1.9) for leg pain. The superiority of HF10 therapy over traditional SCS for leg and back pain was sustained through 12 months ($P < 0.001$). HF10 therapy subjects did not experience paresthesias.

Conclusion: HF10 therapy promises to substantially impact the management of back and leg pain with broad applicability to patients, physicians, and payers. (ANESTHESIOLOGY 2015; 123:851-60)

ORIGINAL ARTICLE

Prospective, Multicenter Feasibility Study to Evaluate Differential Target Multiplexed Spinal Cord Stimulation Programming in Subjects With Chronic Intractable Back Pain With or Without Leg Pain

Michael A. Fishman, MD, MBA*; Aaron Calodney, MD†; Philip Kim, MD*; Jan Slezak, MD‡; Ramsin Benyamin, MD§; Atiq Rehman, MD¶; Eliezer Soto, MD**; Thomas Yang, MD††; Asteghik Hacobian, MD‡; Lee Griffith, MD†; Cong Yu,MD††; Ricardo Vallejo, MD, PhD§

*Center for Interventional Pain and Spine, Exton, Pennsylvania; †Precision Spine Care, Tyler, Texas; ‡Interventional Spine Medicine, Barrington, New Hampshire; §Millennium Pain Center, Bloomington, Illinois; ¶Decatur Memorial Hospital, Decatur, Illinois; **Millennium Pain Center —Libertyville, Libertyville, Illinois; ††Swedish Medical Center, Seattle, Washington U.S.A.

Original Research Article

Long-Term Improvements in Chronic Axial Low Back Pain Patients Without Previous Spinal Surgery: A Cohort Analysis of 10-kHz High-Frequency Spinal Cord Stimulation over 36 Months

Adnan Al-Kaisy, MB, ChB, FRCA, FPMRCA, FIPP,* Stefano Palmisani, MD,* Thomas E. Smith, MBBS, MD, FRCA, FPMRCA,* Roy Carganillo, RN, MSc,* Russell Houghton, MB, ChB, MRCP, FRCR,* David Pang, MB, ChB, FRCA, FPMRCA,* William Burgoyne, MB, BS,† Khai Lam, FRCS (Orth),* and Jonathan Lucas, MBBS, FRCS (Eng), FRCS (Tr&Orth)*

*Guy's and St Thomas' NHS Trust, London, UK;
†Epsom and St Helier University Hospitals NHS Trust, UK

Correspondence to: Adnan Al-Kaisy, Pain Management and Neuromodulation Centre, Guy's and St Thomas' Hospital, Westminster Bridge Road, London SE1 7EH, UK. Tel: 02071883237; Email: adnan.al-kaisy@gstt.nhs.uk.

Funding sources: This study was sponsored by Nevro Corp. (Nevro Corp., Redwood City, CA, USA).

Conflicts of interest: A.A. received travel sponsorship and speaker fees from Medtronic and Nevro Corp., he is the principal investigator in studies sponsored by Medtronic and Nevro Corp., and he has a financial interest in Micron Device, LLC. S.P. received speaker fees and/or sponsorships to attend professional meetings from Medtronic and Nevro Corp. D.P. received sponsorship to attend professional meetings from Medtronic and Nevro Corp. T.S. received consultancy fees and sponsorship to attend professional meetings from Nevro Corp.

Ethical committee approval: NRES Committee North East – Northern & Yorkshire (REC ref: 11/NE/0047).

ISRCTN registration: 9642 4062.

Abstract

Objective. To evaluate the long-term safety and effectiveness of 10-kHz high-frequency spinal cord stimulation (SCS) in the treatment of chronic axial low back pain with no history of spinal surgery.

Methods. Patients with chronic low back pain without previous spinal surgery underwent assessment by a multidisciplinary pain and surgical team to confirm eligibility. After a successful temporary trial of 10-kHz HF-SCS therapy, defined by ≥50% back pain reduction, enrolled subjects underwent permanent system implantation and were followed up for 36 months. Outcome measures consisted of a 100-mm visual analog scale (VAS) for pain intensity, the Oswestry Disability Index (ODI), and a standard measure of health-related quality of life.

Results. Twenty-one patients satisfied the inclusion/exclusion criteria. Following a temporary trial, 20 of 21 (95%) subjects were implanted with a pulse generator, and 17 of 20 reached the 36-month time point. From baseline to 36 months, the average VAS pain intensity decreased from 79 ± 12 mm to 10 ± 12 mm, the average ODI score decreased from 53 ± 13 to 19.8 ± 13, and use of opioids decreased from 18 subjects to two subjects. One subject was deceased, unrelated to the study, one subject was explanted due to loss of effectiveness, and one subject was lost to follow-up.

Conclusions. These results suggest that 10-kHz high-frequency SCS may provide significant, long-term back pain relief, improvement in disability and quality of life, and reduction in opioids for nonsurgical refractory back pain.

What insurance is looking for ? –Medically Necessary

- Prior lumbar surgery
- ≥ 6 months of pain, refractory to treatment and impaired ADLs.
- Not a candidate for additional surgery
- Failure of > 6 months of conventional multidisciplinary medical therapy
  - Chiropractic, PT, Home exercise program
  - NSAIDS (unless contraindicated or not tolerated)
  - Activity modification
- Cognitive ability to manage stimulator
- Passed psychological evaluation
- NO untreated, existing drug or alcohol dependency for a minimum of 60 days as confirmed by lab testing.

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Peripheral Diabetic Neuropathy

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JAMA Neurology | Original Investigation

Effect of High-frequency (10-kHz) Spinal Cord Stimulation in Patients With Painful Diabetic Neuropathy

A Randomized Clinical Trial

Erika A. Petersen, MD; Thomas G. Stauss, MD; James A. Scowcroft, MD; Elizabeth S. Brooks, PhD; Judith L. White, MD; Shawn M. Sills, MD; Kasra Amirdelfan, MD; Maged N. Guirguis, MD; Jijun Xu, MD, PhD; Cong Yu, MD; Ali Nairizi, MD; Denis G. Patterson, DO; Kostandinos C. Tsoulfas, MD; Michael J. Creamer, DO; Vincent Galan, MD; Richard H. Bundschu, MD; Christopher A. Paul, MD; Neel D. Mehta, MD; Heejung Choi, MD; Dawood Sayed, MD; Shivanand P. Lad, MD, PhD; David J. DiBenedetto, MD; Khalid A. Sethi, MD; Johnathan H. Goree, MD; Matthew T. Bennett, MD; Nathan J. Harrison, MD; Atef F. Israel, MD; Paul Chang, MD; Paul W. Wu, MD; Gennady Gekht, MD; Charles E. Argoff, MD; Christian E. Nasr, MD; Rod S. Taylor, PhD; Jeyakumar Subbaroyan, PhD; Bradford E. Gliner, MS; David L. Caraway, MD, PhD; Nagy A. Mekhail, MD, PhD

IMPORTANCE Many patients with diabetic peripheral neuropathy experience chronic pain and inadequate relief despite best available medical treatments.

OBJECTIVE To determine whether 10-kHz spinal cord stimulation (SCS) improves outcomes for patients with refractory painful diabetic neuropathy (PDN).

DESIGN, SETTING, AND PARTICIPANTS The prospective, multicenter, open-label SENZA-PDN randomized clinical trial compared conventional medical management (CMM) with 10-kHz SCS plus CMM. Participants with PDN for 1 year or more refractory to gabapentinoids and at least 1 other analgesic class, lower limb pain intensity of 5 cm or more on a 10-cm visual analogue scale (VAS), body mass index (calculated as weight in kilograms divided by height in meters squared) of 45 or less, hemoglobin A_{1c} (HbA_{1c}) of 10% or less, daily morphine equivalents of 120 mg or less, and medically appropriate for the procedure were recruited from clinic patient populations and digital advertising. Participants were enrolled from multiple sites across the US, including academic centers and community pain clinics, between August 2017 and August 2019 with 6-month follow-up and optional crossover at 6 months. Screening 430 patients resulted in 214 who were excluded or declined participation and 216 who were randomized. At 6-month follow-up, 187 patients were evaluated.

INTERVENTIONS Implanted medical device delivering 10-kHz SCS.

MAIN OUTCOMES AND MEASURES The prespecified primary end point was percentage of participants with 50% pain relief or more on VAS without worsening of baseline neurological deficits at 3 months. Secondary end points were tested hierarchically, as prespecified in the analysis plan. Measures included pain VAS, neurological examination, health-related quality of life (EuroQol Five-Dimension questionnaire), and HbA_{1c} over 6 months.

RESULTS Of 216 randomized patients, 136 (63.0%) were male, and the mean (SD) age was 60.8 (10.7) years. Additionally, the median (interquartile range) duration of diabetes and peripheral neuropathy were 10.9 (6.3-16.4) years and 5.6 (3.0-10.1) years, respectively. The primary end point assessed in the intention-to-treat population was met by 5 of 94 patients in the CMM group (5%) and 75 of 95 patients in the 10-kHz SCS plus CMM group (79%; difference, 73.6%; 95% CI, 64.2-83.0; $P < .001$). Infections requiring device explant occurred in 2 patients in the 10-kHz SCS plus CMM group (2%). For the CMM group, the mean pain VAS score was 7.0 cm (95% CI, 6.7-7.3) at baseline and 6.9 cm (95% CI, 6.5-7.3) at 6 months. For the 10-kHz SCS plus CMM group, the mean pain VAS score was 7.6 cm (95% CI, 7.3-7.9) at baseline and 1.7 cm (95% CI, 1.3-2.1) at 6 months. Investigators observed neurological examination improvements for 3 of 92 patients in the CMM group (3%) and 52 of 84 in the 10-kHz SCS plus CMM group (62%) at 6 months (difference, 58.6%; 95% CI, 47.6-69.6; $P < .001$).

CONCLUSIONS AND RELEVANCE Substantial pain relief and improved health-related quality of life sustained over 6 months demonstrates 10-kHz SCS can safely and effectively treat patients with refractory PDN.

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What insurance is looking for ? –Medically Necessary

- Right/appropriate diagnosis – Diabetic Neuropathy
- Failed conservative management or tried at least three classes of medications
  - Anticonvulsants (gabapentinoids)
  - Antidepressants
  - Opioids
  - Pharmacological agents

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Chronic Regional Pain Syndrome

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SPINAL CORD STIMULATION IN PATIENTS WITH CHRONIC REFLEX SYMPATHETIC DYSTROPHY

MARIUS A. KEMLER, M.D., GERARD A.M. BARENDSE, M.D., MAARTEN VAN KLEEF, M.D., PH.D., HENRICA C.W. DE VET, PH.D., COEN P.M. RIJKS, P.T., CARINA A. FURNÉE, PH.D., AND FRANS A.J.M. VAN DEN WILDENBERG, M.D., PH.D.

BACKGROUND Chronic reflex sympathetic dystrophy (also called the complex regional pain syndrome) is a painful, disabling disorder for which there is no proven treatment. In observational studies, spinal cord stimulation has reduced the pain associated with the disorder.

METHODS We performed a randomized trial involving patients who had had reflex sympathetic dystrophy for at least six months. Thirty-six patients were assigned to receive treatment with spinal cord stimulation plus physical therapy, and 18 were assigned to receive physical therapy alone. The spinal cord stimulator was implanted only if a test stimulation was successful. We assessed the intensity of pain (on a visual-analogue scale from 0 cm [no pain]to 10 cm [very severe pain]), the global perceived effect (on a scale from 1 [worst ever]to 7 [best ever]), functional status, and the health-related quality of life.

RESULTS The test stimulation of the spinal cord was successful in 24 patients; the other 12 patients did not receive implanted stimulators. In an intention-to-treat analysis, the group assigned to receive spinal cord stimulation plus physical therapy had a mean reduction of 2.4 cm in the intensity of pain at six months, as compared with an increase of 0.2 cm in the group assigned to receive physical therapy alone ($P<0.001$ for the comparison between the two groups). In addition, the proportion of patients with a score of 6 ("much improved") for the global perceived effect was much higher in the spinal cord stimulation group than in the control group (39 percent vs. 6 percent, $P=0.01$). There was no clinically important improvement in functional status. The health-related quality of life improved only in the 24 patients who actually underwent implantation of a spinal cord stimulator. Six of the 24 patients had complications that required additional procedures, including removal of the device in 1 patient.

CONCLUSIONS In carefully selected patients with chronic reflex sympathetic dystrophy, electrical stimulation of the spinal cord can reduce pain and improve the health-related quality of life.

N Engl J Med. 2000;343(9):618.

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ORIGINAL ARTICLES

The Effect of Spinal Cord Stimulation in Patients with Chronic Reflex Sympathetic Dystrophy: Two Years' Follow-up of the Randomized Controlled Trial

Marius A. Kemler, MD, PhD,[1] Henrica C. W. De Vet, PhD,[2] Gerard A. M. Barendse, MD,[3] Frans A. J. M. Van Den Wildenberg, MD, PhD,[1] and Maarten Van Kleef, MD, PhD[3]

Chronic reflex sympathetic dystrophy is a painful, disabling disorder for which no treatment with proven effect is available. We performed a randomized trial in a 2 to 1 ratio of patients, in which 36 patients were treated with spinal cord stimulation and physical therapy (SCS+PT), and 18 patients received solely PT. Twenty-four SCS+PT patients were given a permanent spinal cord stimulation system after successful test stimulation; the remaining 12 patients received no permanent system. We assessed pain intensity, global perceived effect, functional status, and health-related quality of life. Patients were examined before randomization, before implantation, and also at 1, 3, 6, 12, and 24 months thereafter. At 2 years, three patients were excluded from the analysis. The intention-to-treat analysis showed improvements in the SCS+PT group concerning pain intensity (−2.1 vs 0.0cm; $p < 0.001$) and global perceived effect (43% vs 6% "much improved"; $p = 0.001$). There was no clinically important improvement of functional status. Health-related quality of life improved only in the group receiving spinal cord stimulation. After careful selection and successful test stimulation, spinal cord stimulation results in a long-term pain reduction and health-related quality of life improvement in chronic reflex sympathetic dystrophy.

Ann Neurol 2004;55:13–18

Direct Peripheral Nerve Stimulation for the Treatment of Complex Regional Pain Syndrome: A 30-Year Review

Mark A. Chmiela, MD[1]; Mark Hendrickson, MD[2]; Jason Hale, MD[3]; Chen Liang, MS[4]; Phillip Telefus, MD[1]; Afrin Sagir, MD[3]; Michael Stanton-Hicks, MD[1]

ABSTRACT

Introduction: Complex regional pain syndrome (CRPS), formerly known as reflex sympathetic dystrophy (RSD), is a difficult to treat condition characterized by debilitating pain and limitations in functional ability. Neuromodulation, in the form of spinal cord stimulation (SCS) and peripheral nerve stimulation (PNS), have been traditionally used as a treatment for CRPS with variable success.

Objective: This chart review describes the use of implantable PNS systems in the treatment of CRPS of the upper and lower extremities spanning nearly three decades.

Materials and Methods: A retrospective chart review was performed on 240 patients with PNS implanted between 1990 and 2017 at our institution. Of these, 165 patients were identified who had PNS systems implanted for a diagnosis of CRPS. Patient profile, including baseline characteristics, comorbidities, past/current interventions/medications and targeted nerves, was descriptively summarized through standard summary statistics. Patients' pain scores and opioid consumptions at baseline (pre-implant), 1 month, 6 months, and 12 months were collected and compared. Device revisions and explants were summarized, and patient functional outcomes were described.

Results: Pain scores at baseline and at 12-month follow-up were decreased from a mean of 7.4 ± 1.6 to 5.5 ± 2.4 and estimated to be 1.87 (95% CI: [1.29, 2.46], paired *t*-test *p*-value <0.001) lower at 12 months. At baseline, 62% of patients were on chronic opioid therapy, compared with 41% at 12 months. Of 126 patients who reported changes in functional status, 64 (51%) reported improvement, 27 (21%) reported worsening, and 35 (28%) did not report any meaningful change. Excluding end-of-life battery replacements, surgical revision occurred in 56 (34%) of patients. Thirteen patients (8%) underwent implantation of a second PNS because of symptomatic expansion outside of the original painful region. Device explant was performed in 32 (19%) of patients. Median length of follow-up was 74 [14, 147] months. Of the 36 patients who continue to follow-up at our institution, 29 (81%) continue to use their PNS.

Conclusions: We can conclude that PNS is a useful modality to improve function and reduce long-term pain in selected patients suffering from CRPS type I and type II.

Keywords: Complex regional pain syndrome, CRPS, peripheral nerve stimulation, reflex sympathetic dystrophy, RSD

Conflict of Interest: The authors reported no conflict of interest.

What insurance is looking for ? –Medically Necessary

- Pain management specialist > 6 months
- ≥ 2 of the following symptoms limited to one extremity
  - Allodynia/Hyperalgesia
  - Swelling/tenderness
  - Cyanotic/red/pale digit/extremity
  - Increased sweating
  - Altered temperature
  - Persistent loss of of motion
  - Trophic changes or contractures
- Pain is refractory, chronic and interferes with ADLs
- Failure of ≥ 6 months of conventional multidisciplinary medical therapy
  - Chiropractic, PT, Home exercise program
  - NSAIDS (unless contraindicated or not tolerated)
  - Activity modification
- Cognitive ability to manage stimulator
- Passed psychological evaluation
- NO untreated, existing drug or alcohol dependency for a minimum of 60 days as confirmed by lab testing.

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Visceral Pain

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JOURNAL ARTICLE

Spinal Cord Stimulation for Chronic Visceral Abdominal Pain

FREE

Leonardo Kapural, MD, PhD ✉, Hassan Nagem, MD, Heather Tlucek, MD, Daniel I. Sessler, MD

Pain Medicine, Volume 11, Issue 3, March 2010, Pages 347–355, https://doi.org/10.1111/j.1526-4637.2009.00785.x
Published: 02 March 2010

Background. Spinal cord stimulation (SCS) may reduce pain scores and improve function in patients with chronic visceral abdominal pain. We thus present our large clinical experience in SCS for visceral abdominal pain.
Methods. We trialed spinal cord stimulation in 35 patients, each of whom was shown by retrograde differential epidural block to have either visceral pain (n = 32) or mixed visceral and central pain (n = 3). SCS trials lasted 4 to 14 days (median 9 days). SCS lead tips were mostly positioned at T5 (n = 11) or T6 (n = 10).
Results. Thirty patients (86%) reported at least 50% pain relief upon completion of the trial. Among these, pretrial visual analog scale (VAS) pain scores averaged 8.2 ± 1.6 (SD) and opioid use averaged 110 ± 119 mg morphine sulfate equivalents. During the trial, VAS pain scores decreased to 3.1 ± 1.6 cm ($P < 0.001$, Mann–Whitney Rank Sum Test) and opioid use decreased to 70 ± 68 mg morphine equivalent a day ($P = 0.212$). Five patients failed the trial, one was lost to follow-up, and 19 were followed for the whole year. Seven patients were either followed for less than a year (n = 3) or the SCS system was removed due to infection or lead migration (n = 4). One patient despite the successful trial felt no improvements at 6 months after the implant and requested an explant of the SCS device. Among the 28 patients who received permanent implant, 19 were followed at least a year. Their VAS pain scores remained low (3.8 ± 1.9 cm; $P < 0.001$) at 1 year, as did opioid use (38 ± 48 mg morphine equivalents; $P = 0.089$).
Conclusions. Spinal cord stimulation may be a useful therapeutic option for patients with severe visceral pain.

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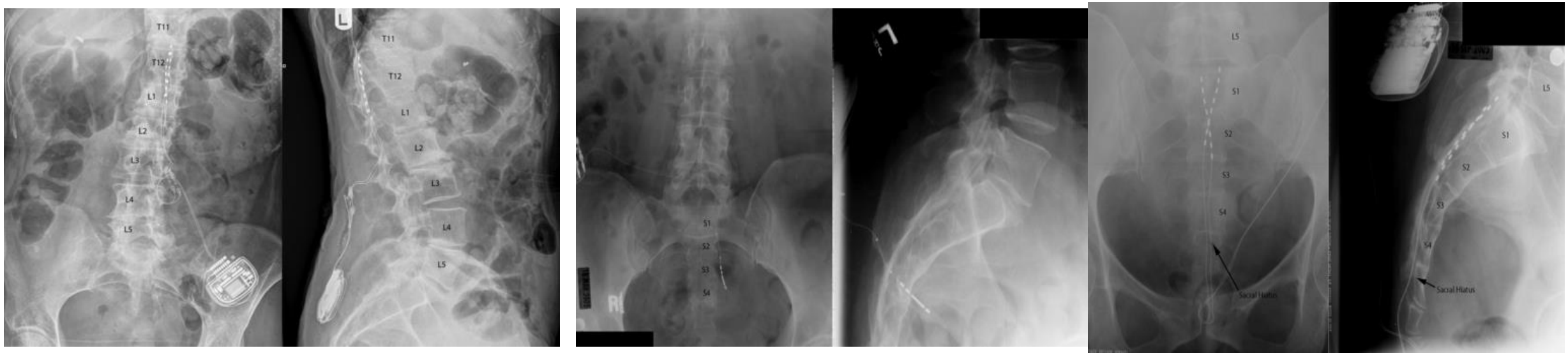
Neuromodulation of Pelvic Visceral Pain: Review of the Literature and Case Series of Potential Novel Targets for Treatment

Corey Hunter MD, Nimish Davé MD, MPH, Sudhir Diwan MD, Timothy Deer MD

First published: 23 April 2012 | https://doi.org/10.1111/j.1533-2500.2012.00558.x | Citations: 42



What insurance is looking for ? –Medically Necessary

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Dorsal Root Ganglion Stimulation

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Dorsal Root Ganglion Stimulation: Indication

- Trunk and Limbs : (Deer, Neuromodulation 2013;161:67-72).
- Foot (Liem, Neuromodulation 2015) and Groin (Liem, Pain Practice 2016)
- Axial low back pain and Discogenic Pain (Huygen, Pain Practice 2018)
- Phantom limb pain (Hunter, Neuromodulation 2018)
- Post-herpetic Neuralgia (Lynch, Neuromodulation, 2017)
- CRPS (Deer, Pain 2017)
- Salvage treatment for SCS (Yang, Neuromodulation, 2017)
- Perineal Pain

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Dorsal root ganglion stimulation yielded higher treatment success rate for complex regional pain syndrome and causalgia at 3 and 12 months: a randomized comparative trial

Timothy R. Deer[a,*], Robert M. Levy[b], Jeffery Kramer[c], Lawrence Poree[d], Kasra Amirdelfan[e], Eric Grigsby[f], Peter Staats[g], Allen W. Burton[h], Abram H. Burgher[i], Jon Obray[j], James Scowcroft[k], Stan Golovac[l], Leonardo Kapural[m], Richard Paicius[n], Christopher Kim[a], Jason Pope[a], Thomas Yearwood[o], Sam Samuel[p], W. Porter McRoberts[q], Hazmer Cassim[r], Mark Netherton[s], Nathan Miller[t], Michael Schaufele[u], Edward Tavel[v], Timothy Davis[w], Kristina Davis[c], Linda Johnson[c], Nagy Mekhail[p]

Abstract

Animal and human studies indicate that electrical stimulation of dorsal root ganglion (DRG) neurons may modulate neuropathic pain signals. ACCURATE, a pivotal, prospective, multicenter, randomized comparative effectiveness trial, was conducted in 152 subjects diagnosed with complex regional pain syndrome or causalgia in the lower extremities. Subjects received neurostimulation of the DRG or dorsal column (spinal cord stimulation, SCS). The primary end point was a composite of safety and efficacy at 3 months, and subjects were assessed through 12 months for long-term outcomes and adverse events. The predefined primary composite end point of treatment success was met for subjects with a permanent implant who reported 50% or greater decrease in visual analog scale score from preimplant baseline and who did not report any stimulation-related neurological deficits. No subjects reported stimulation-related neurological deficits. The percentage of subjects receiving ≥50% pain relief and treatment success was greater in the DRG arm (81.2%) than in the SCS arm (55.7%, $P < 0.001$) at 3 months. Device-related and serious adverse events were not different between the 2 groups. Dorsal root ganglion stimulation also demonstrated greater improvements in quality of life and psychological disposition. Finally, subjects using DRG stimulation reported less postural variation in paresthesia ($P < 0.001$) and reduced extraneous stimulation in nonpainful areas ($P = 0.014$), indicating DRG stimulation provided more targeted therapy to painful parts of the lower extremities. As the largest prospective, randomized comparative effectiveness trial to date, the results show that DRG stimulation provided a higher rate of treatment success with less postural variation in paresthesia intensity compared to SCS.

Keywords: Chronic pain, Neurostimulation, Complex regional pain syndrome, Causalgia, Dorsal root ganglion stimulation

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Peripheral Nerve Stimulation

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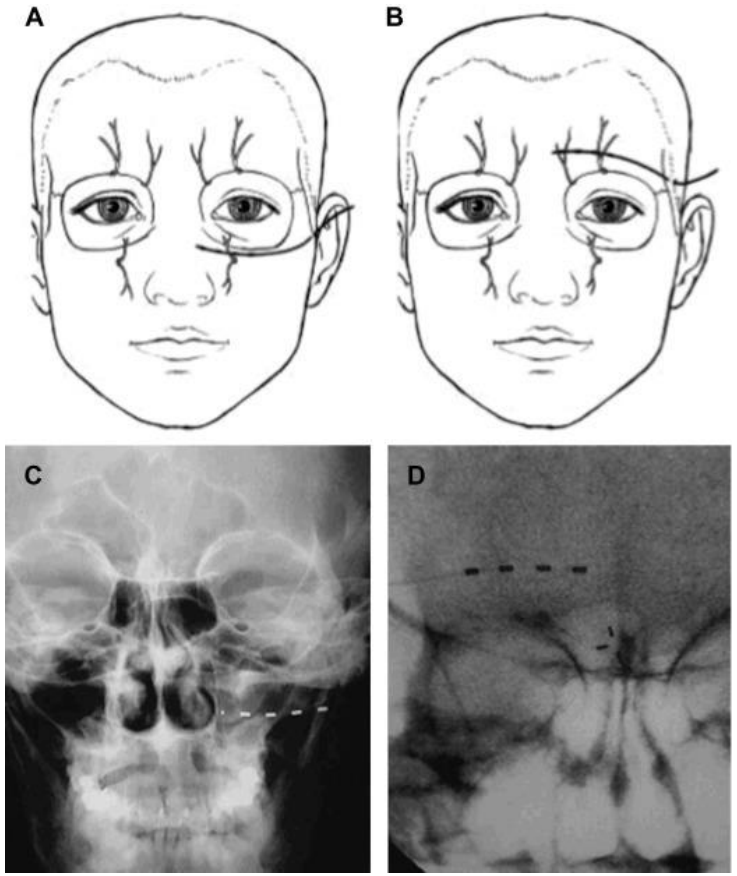
Peripheral Nerve Stimulation

- Stimulation outside the neuraxis
- Targeted peripheral nerve
- Neuropathic, musculoskeletal, visceral
- Uses in isolation or concomitant with SCS

Peripheral Nerve Stimulation

- Facial Pain



Slavin KV, Wess C. Trigeminal branch stimulation for intractable neuropathic pain: technical note. Neuromodulation 2005;8(1):8–11

Percutaneous Peripheral Nerve Stimulation of the Medial Branch Nerves for the Treatment of Chronic Axial Back Pain in Patients After Radiofrequency Ablation

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Funding: These results were collected as part of an ongoing Institutional Review Board–approved study sponsored by SPR Therapeutics.

Conflicts of interest: Drs. Deer, Gilmore, Desai, Li, DePalma, Hopkins, and Burgher are investigators with research funded by SPR Therapeutics. Drs. Deer, Gilmore, Desai, Spinner, and Cohen are consultants to SPR. Drs. Deer and Desai have equity ownership in SPR. Drs. McGee and Boggs are employees of SPR with equity ownership and inventors on patents relating to the peripheral nerve stimulation technology.

Trial registration: ClinicalTrials.gov Id: NCT03179202.

Abstract

Objective. Lumbar radiofrequency ablation is a commonly used intervention for chronic back pain. However, the pain typically returns, and though retreatment may be successful, the procedure involves destruction of the medial branch nerves, which denervates the multifidus. Repeated procedures typically have diminishing returns, which can lead to opioid use, surgery, or implantation of permanent neuromodulation systems. The objective of this report is to demonstrate the potential use of percutaneous peripheral nerve stimulation (PNS) as a minimally invasive, nondestructive, motor-sparing alternative to repeat radiofrequency ablation and more invasive surgical procedures. **Design.** Prospective, multicenter trial. **Methods.** Individuals with a return of chronic axial pain after radiofrequency ablation underwent implantation of percutaneous PNS leads targeting the medial branch nerves. Stimulation was delivered for up to 60 days, after which the leads were removed. Participants were followed up to 5 months after the start of PNS. Outcomes included pain intensity, disability, and pain interference. **Results.** Highly clinically significant ($\geq$50%) reductions in average pain intensity were reported by a majority of participants (67%, n = 10/15) after 2 months with PNS, and a majority experienced clinically significant improvements in functional outcomes, as measured by disability (87%, n = 13/15) and pain interference (80%, n = 12/15). Five months after PNS, 93% (n = 14/15) reported clinically meaningful improvement in one or more outcome measures, and a majority experienced clinically meaningful improvements in all three outcomes (i.e., pain intensity, disability, and pain interference). **Conclusions.** Percutaneous PNS has the potential to shift the pain management paradigm by providing an effective, nondestructive, motor-sparing neuromodulation treatment.

Future of Neuromodulation

- Smaller
- Easily implanted and removed
- Highly targeted
- A continued growth in scientific understanding of neural circuitry
- Advances in biomedical engineering

Conclusion

- Disease specific criteria for SCS
- Documented trial of ≥ 3days.
- Documented pain reduction of > 50% from the trial with functional improvement
- The same device used for the trial.

Thank You For Listening!

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