PROGRAMME d'e-learning
Collège des Enseignants en Neurochirurgie

Prise en charge Neurochirurgicale de la Douleur

Responsable de l'e-module « Douleur » :
Philippe RIGOARD

Responsables scientifiques du projet :
Jean-Luc BARAT & Philippe RIGOARD

Partie A : Douleur

Partie B : Neurochirurgie lésionnelle de la douleur

Partie C : Neuromodulation de la douleur

Partie D: « Camp de base »

Module 11 : « Evidence-Based Medicine » en neuromodulation

Dr Jimmy VOIRIN

Société Française de Neurochirurgie

En partenariat avec:

SFCR Société Française de Chirurgie rachidienne

SFETD

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Liens d'intérêts

Financiers:

Medtronic

Boston Scientific

dooloo
mieux vivre avec ma douleur

Non Financiers:

Medtronic

Abbott

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vexim
REBALANCING SPINE

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Douleurs Évaluation - Diagnostic - Traitement (2020) 21, 11—19

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FAITES LE POINT

Stimulation médullaire : une thérapie efficace face à certaines douleurs chroniques mais ignorée

Spinal cord stimulation: An efficient but ignored therapy for chronic pain

Jimmy Voirin[a,b,*], Philippe Rigoard[c], Denys Fontaine[d]

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Section 1 : Introduction

Module 11 : « Evidence-Based Medicine » en neuromodulation

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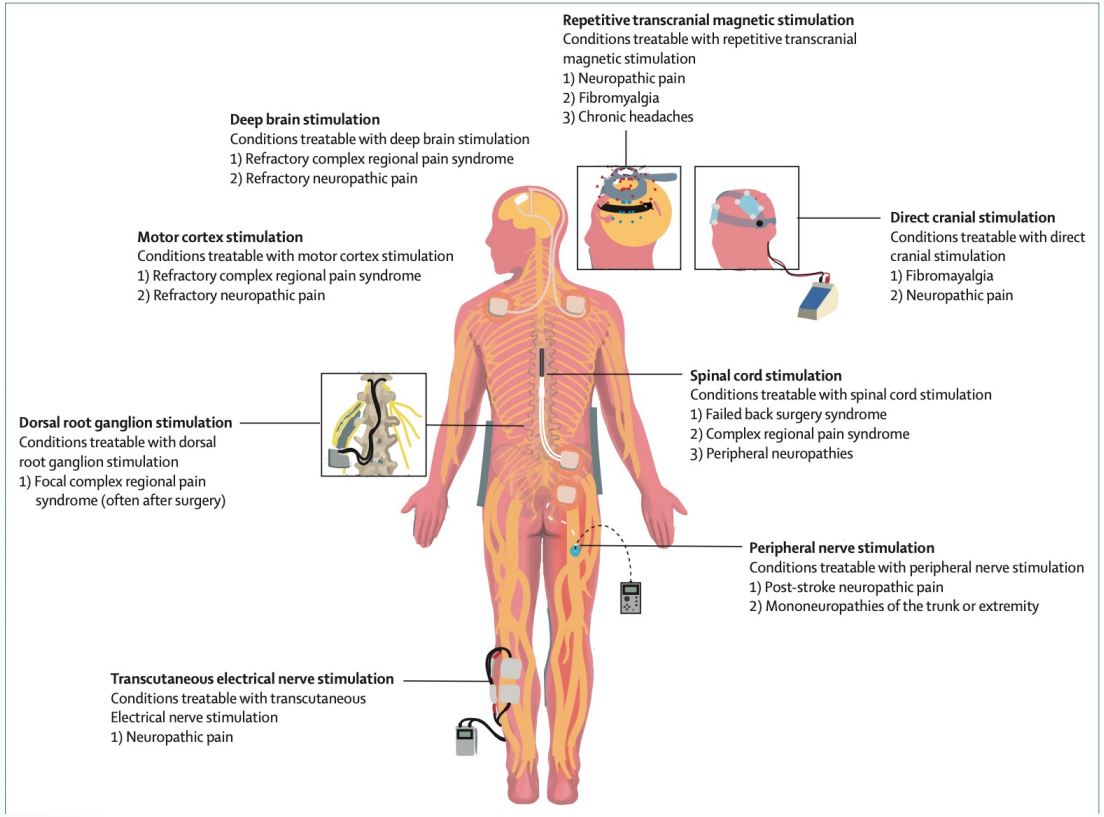
Neuromodulation

- Définition :
- INS =

- Non lésionnelle (non destructrice)
- Réversible
- Modulable (effet thérapeutique / effets secondaires)

- Peut être :
- Interne (SCS, DBS, MCS, DRG, PNS…) ou externe (TENS, rTMS, TdCS, eVNS…)
- Electrique / magnétique / pharmacologique / optogénétique…..

De la lésion à la neuromodulation



Neuromodulation for chronic pain

Helena Knotkova, Clement Hamani*, Eellan Sivanesan*, María Francisca Elgueta Le Beuffe, Jee Youn Moon, Steven P Cohen, Marc A Huntoon*

Neuromodulation is an expanding area of pain medicine that incorporates an array of non-invasive, minimally

Lancet 2021; 397: 2111–24


ALAN MOORE
DAVE GIBBONS
WATCHMEN
ÉDITION LIMITÉE
COMMENTÉE PAR
LESLIE S. KLINGER
URBAN COMICS
DC

Electrical Inhibition of Pain by Stimulation of the Dorsal Columns:

Preliminary Clinical Report

Dr. Shealy

C. NORMAN SHEALY, M.D.*
J. THOMAS MORTIMER, M.S.†
JAMES B. RESWICK, D.Sc.†

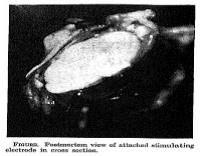
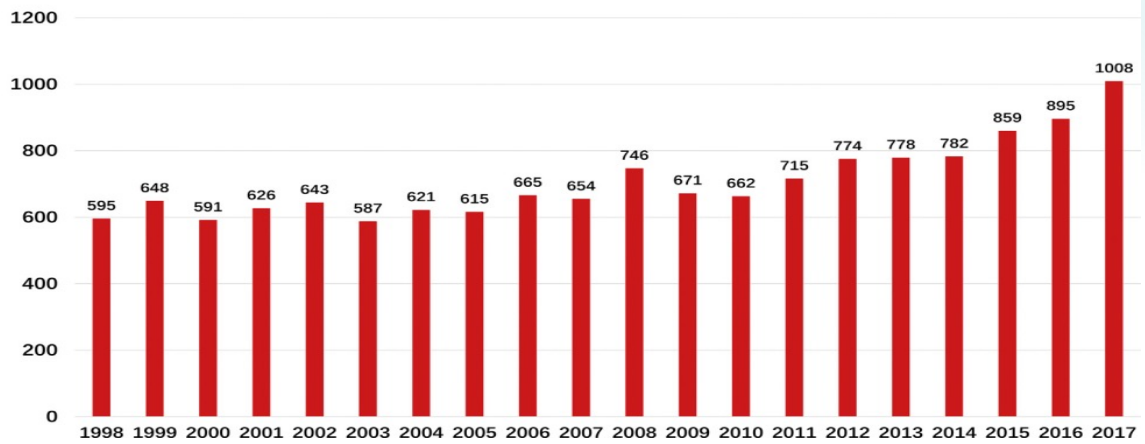


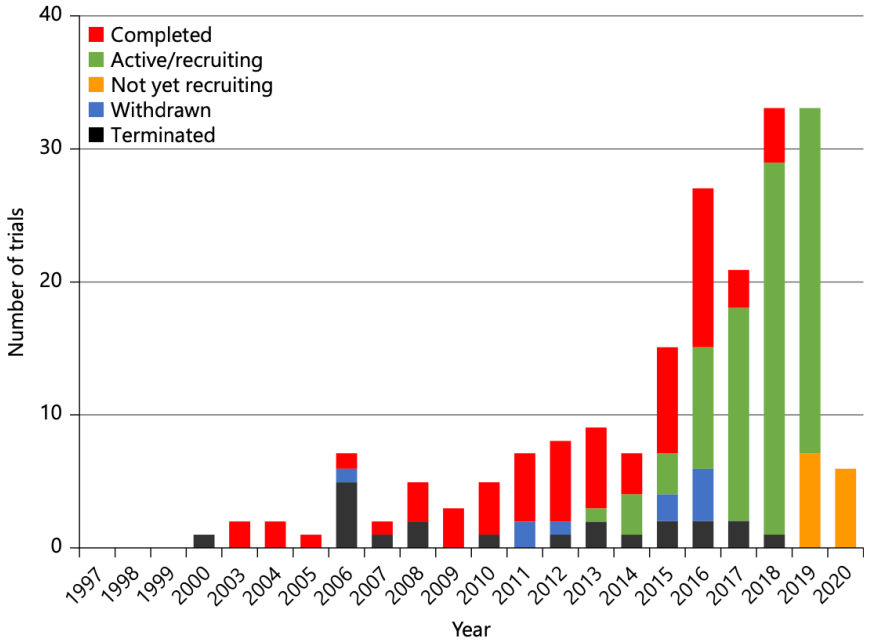
FIGURE. Posterolateral view of attached stimulating electrode in cross section.

Number of articles

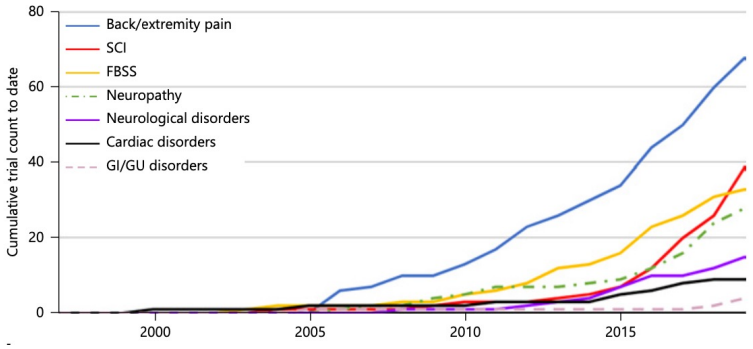


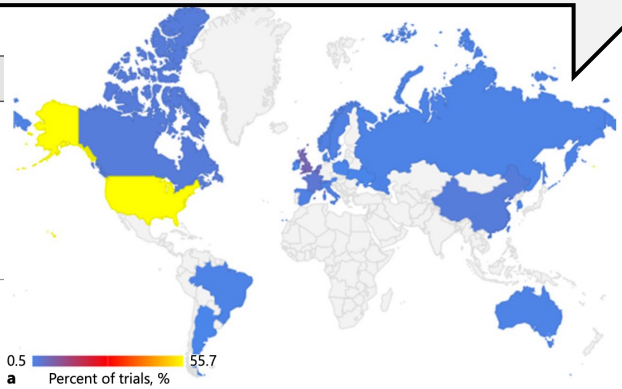
Xie et al. World Neurosurg 2019; ??????

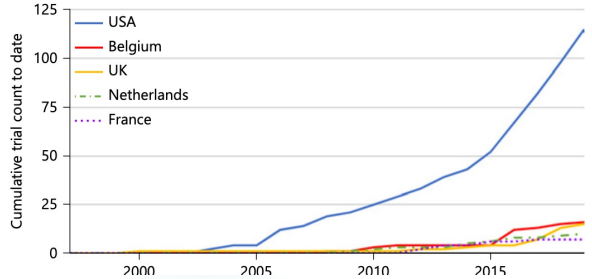
Harmsen et al. Stereotactic Func Neurosurg 2021; 99: 123-134



Stimulation intervention	Studies, *n*
Epidural spinal cord stimulation (eSCS)	174
Intradural spinal cord stimulation (iSCS)	1
Transcutaneous spinal cord stimulation (tcSCS)	28
Trans-spinal direct current stimulation (tsDCS)	6
Spinal transcutaneous electrical nerve stimulation (TENS)	1
Spinal magnetic stimulation (SMS)	2
Subtotal	212







Biais et critiques

- Financements
- Manque description méthode randomisation
- Follow-up court
- Multiplicité des indications et traitements
- Effectifs faibles : >2 EVA → 2 bras de 42 patients chacun ou 24 en crossover
- Rapidité de l'innovation technologique
- Effet de report de la thérapie précédente sur la nouvelle en crossover (Washout)
- Placebo vs sham :
  - Placebo = IPG éteint → risque de levée d'aveugle par augmentation délai recharge
  - Sham = IPG ON + intensité nulle → comportement peu modifié vis-à-vis recharge

Anaesthesia 2020, 75, 775–784 doi:10.1111/anae.15036

Original Article

10 kHz spinal cord stimulation for the treatment of non-surgical refractory back pain: subanalysis of pooled data from two prospective studies

A. Al-Kaisy,[1] **J. P. Van Buyten,**[2] **L. Kapural,**[3] **K. Amirdelfan**[4] **B. Gliner,**[5,6] **D. Caraway,**[6,7] **J. Subbaroyan**[6,8] **D. Edgar**[9] and **A. Rotte**[10]

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Sources of bias and measurement error in randomized controlled trials and their mitigation.

Source of error	Description	Mitigation options
Allocation bias	Investigators choose which subjects go in which groups	Randomization[132] Concealment of assignments before patient selection
Expectation bias	Subjects report the response they expect (eg, pain relief) Research staff expectation is transmitted to patients consciously or unconsciously	Double-blinding[133] Placebo controls Neutral expectation training of researchers and subjects[165] Balanced information in all groups[76]
Unbalanced randomization*	Treatment groups differ by prognostic factors or treatment effect modifiers	Stratified randomization[82] Adjust analyses for potential confounding factors
Observer bias	Those who observe the treatment effect report their desired outcome	Double-blinding Neutral expectation training of observers[58]
Unbalanced ancillary treatment	Patients in 1 group get more attention, supplemental treatments, visits, psychological support, etc.	Double-blinding Standardized and documented ancillary treatment and interactions (eg, programming)
Patient selection or characterization		
Inaccurate diagnosis	Patient does not have the disease being studied	Central review of diagnostic assessment[86,97] Investigator training[97]
Inaccurate pain reporters	Patients might not be able to report pain accurately Inaccurate pain reporters are also placebo responders	Accurate pain reporting training[149,150] Exclude patients with excess variability of clinical or experimental pain[31,32,42,61,145,148]
Placebo responders	Preferential placebo responders have higher than average responses to placebo but not to active treatment	Select internally focused patients[31,32,148] Neutralize expectation[92,160,165]
Baseline score inflation	Subjects/investigators might inflate baseline scores to meet enrollment criteria	Mask entry requirements Use different measures for the primary endpoint and for inclusion Statistical surveillance[31,86]
Unstable or resolving pain conditions	Pain that is highly variable or destined to resolve during the study decreases assay sensitivity	Enroll patients with a history of at least 12 months of moderate to severe chronic pain Minimum pain intensity of 4-5/10 Prerandomization period long enough to establish stable baseline
Psychological comorbidities and substance abuse	Patients with psychological comorbidities or substance abuse report pain less reliably and might be less compliant with study procedures	Exclude such patients based on established validated assessments (including urine drug screens) unless specifically studying these populations[31,32]
Studying heterogeneous phenotypes	Studying mixed phenotypes might result in failed studies when the treatment is effective in a specific phenotype	Phenotype all subjects at baseline and evaluate efficacy by phenotype[53,119]
Duplicate subjects	Patients often deceitfully enroll in the same study at multiple sites or in multiple studies, putting themselves and the study at risk	Use a duplicate subject detection service in every study[31,122,139]
Medical and treatment history	Patients are often unable to supply all relevant information about past or current medical history and pharmacologic and nonpharmacologic treatments	Consider methods to import prescription monitoring data and electronic medical records data for enrolled subjects Try to obtain medical records
Outcome assessment		
Insensitive outcome measures	Measures must not only be valid and reliable, but also responsive to treatment differences	Choose the most responsive measure that is valid for the target concept Prioritize disease-specific over generic measures Consider developing a new measure if no suitable measures are available or if there is reason to believe that a new measure would be substantially more responsive than available measures[29,49,120]
Noncompliance with outcome assessments, eg, e-diaries	E-diary compliance is poor in many studies Missing data in general must be minimized	Automated reminders; alerts to coordinators for missed entries; calls from coordinators to subjects after missed entries; and real-time central monitoring Back-up in-clinic assessments of the primary endpoint Avoid paper diaries[142]

Table 2 (continued)

Source of error	Description	Mitigation options
Adherence to study treatments		
Failing to measure adherence (to study or rescue treatment) accurately or to achieve adherence	Variable and poorly documented adherence to SCS regimen or rescue medications	Document prescribed SCS regimen and adherence to it Standardize and provide rescue meds; measure adherence electronically Real-time central monitoring of adherence Adherence promotion strategy[6,8]
Confounding by subject		
Subjects failing to follow protocol	Subjects need to follow the protocol, particularly medication adherence, diary compliance, accurate symptom reporting, and stable regimens of nonstudy treatment (eg, physical therapy)	Perform a training needs assessment based on risks to data quality[99] Follow principles of validated training (Katz N, unpublished, 2020)
Physical and psychological treatments	No new physical or psychological interventions should begin during studies. Patients should maintain unchanged physical and psychological regimens	Provide structured guidance to subjects about physical and psychological therapeutics; consider structured support Capture changes in physical and psychological regimens using questionnaires; consider objective measures such as actigraphy[153]
Site selection and management		
Overly heterogeneous sites or regions	Heterogeneity in health care systems, language, culture, availability of treatment, etc. introduces error	Minimize the number of sites; invest in prestudy recruitment activities to maximize the number of patients/site[124] Minimize heterogeneity in sites and regions
Variability in study conduct by sites	Sites implement protocols in varying ways that might be difficult to predict, describe, or understand	Perform a training needs assessment based on risks to data quality[99] Follow principles of validated training (Katz N, unpublished, 2020) Central statistical monitoring and intervention[49,70] (and Katz N, unpublished, 2020)

* Can produce a positive or negative bias.
SCS, spinal cord stimulation.

Recommendations for randomized controlled trials of spinal cord stimulation for chronic pain: outcome measures and reporting.

Outcome evaluation		
Endpoint model	Describe the endpoint model in the protocol; have clear and aligned objectives, assessments, and endpoints	161
Primary endpoint	Must be prespecified Adjust for multiplicity Specify missing data imputation method	25,56,155
Secondary endpoints	Key secondary endpoints will more likely show differentiation between treatments if they also meet minimum baseline severity criteria	
Adverse events (AEs)	Prespecify the method for ascertaining AEs (eg, open-ended, spontaneous, checklists, scripts)	80,141
Outcome measures		
Core domains/measures*	Pain intensity 0-10 numerical rating scale†	27,31
	Physical function Brief Pain Inventory Interference Items Oswestry Disability Inventory Roland–Morris Disability Questionnaire WOMAC function subscale	28,156
	Emotional functioning Beck depression inventory Hospital anxiety and depression Scale Profile of mood states	28,156
	Global improvement or satisfaction Patient global impression of change Patient satisfaction scale Would you do this again?	28
	Concomitant and rescue medications Careful capture in-clinic of concomitant analgesic medication including dose, frequency, and reason for use (ie, index or nonindex pain) Rescue medication use by electronic methods Opioid consumption	6,28
	Patient Disposition Adherence to treatment regimen: SCS and any additional treatments Reason for early termination	154
	Sleep and fatigue MOS Sleep Scale Pittsburgh Sleep Quality Index Multidimensional Fatigue Inventory	28,156
	Health-related quality of life EQ5-D SF-36 Quality-adjusted life years (QALYs)	28,156
	Cost-effectiveness Dollars per QALY	126
	Health care costs Country-specific health and social care costs	126
	Work status Work Productivity and Activity Impairment Questionnaire Workplace Activity Limitations Scale Work Limitations Questionnaire	156
	Patient preference (for crossover studies) Preference scale	63
	Abuse-related events MADDERS	152
	Opioid side effects Opioid Side Effects Scale	40
	SCS-specific measures Device survival/revision-free survival Durability of analgesia Adherence to SCS regimen (eg, hours use/day) Recharging burden (recharge interval, time required for recharge) Programming parameters (see below)	102
Safety and complications‡	Prospective monitoring for Infection (superficial, deep) Cerebrospinal fluid leak Hematoma Stimulator pocket fluid collection Wound dehiscence Skin erosion Allergic reaction Lead migration/breakage Hardware malfunction Battery failure Loose connection Implantable pulse generator migration/discomfort Dysesthesia Device explantation (and reason) New device-related pain syndrome	62
Reporting§		
Methods	Patient characteristics and eligibility Neuropathic pain assessment Sensory phenotyping Literacy and numeracy Ability to report pain accurately Level of expectation	
	Blinding How it is maintained and documented Patient access to controllers and recharging	
	Expectation How balanced expectations are created and monitored Information provided to subjects and staff	
	Adherence Prescribed SCS regimen, allowed concomitant and rescue medication How adherence will be measured and documented	
	Analysis Primary estimand Complete primary endpoint including primary analysis cohort, clinical outcome assessment, analysis method, and handling of missing data All secondary endpoints (secondary endpoints can be considered for claims if appropriate procedures for handling multiple endpoints are implemented) Confidence intervals with interpretation Handling of multiplicity for studies with multiple primary endpoints Sample size calculation and supporting assumptions	56
Results	Follow applicable reporting guidelines CONSORT statement Pain-specific supplement to CONSORT Recommendations for reporting crossover studies Recommendations for describing complex interventions Recommendations for reporting cost-effectiveness studies	106 52 54 66 132
	SCS-specific reporting recommendations Programming details Position of cathode, method of placement (eg, paresthesia mapping), and details of trial stimulation Description of risk-based quality management activity	

Recommendations are not meant to be prescriptive; measures are provided as examples and should be evaluated based on the study context. Not all domains or measures will be appropriate for all studies. Review of the psychometric properties of all measures should be performed for each study.
Location should be specified, eg, index vs nonindex pain location.
Note that some complications are associated with AEs and others are not. Ascertainment of specified complications should be prospective whether associated with AEs or not.
Reporting recommendations are not exhaustive but highlight areas of special importance in reporting SCS studies.
CS, spinal cord stimulation.

Narrative Review

PAIN®

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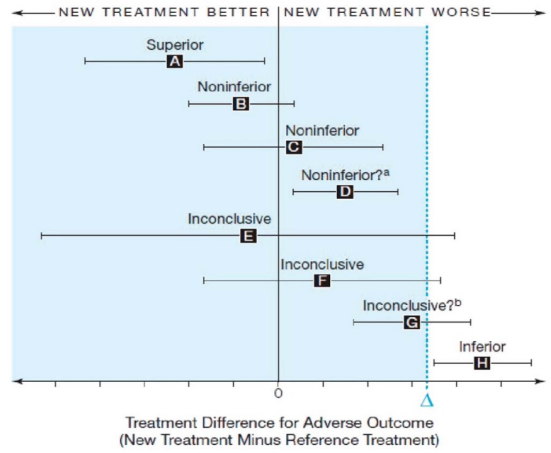
Research design considerations for randomized controlled trials of spinal cord stimulation for pain: Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials/Institute of Neuromodulation/International Neuromodulation Society recommendations

Nathaniel Katz*, Robert H. Dworkin, Richard North, Simon Thomson, Sam Eldabe, Salim M. Hayek, Brian H. Kopell, John Markman, Ali Rezai, Rod S. Taylor, Dennis C. Turk, Eric Buchser, Howard Fields, Gregory Fiore, McKenzie Ferguson, Jennifer Gewandter, Chris Hilker, Roshini Jain, Angela Leitner, John Loeser, Ewan McNicol, Turo Nurmikko, Jane Shipley, Rahul Singh, Andrea Trescot, Robert van Dongen, Lalit Venkatesan



Impact of Spinal Cord Stimulation on Opioid Dose Reduction: A Nationwide Analysis

Syed M. Adil, BS[‡•] **Lefko T. Charalambous, BS**[‡•] **Charis A. Spears, BA**[‡] **Musa Kiyani, MD**[‡] **Sarah E. Hodges, BA**[‡] **Zidanyue Yang, MB**[§] **Hui-Jie Lee, PhD**[§] **Shervin Rahimpour, MD**[‡] **Beth Parente, PA-C**[‡] **Kathryn A. Greene, MPP**[¶] **Mark McClellan, MD, PhD**[‖] **Shivanand P. Lad, MD, PhD**[‡]

[‡]Department of Neurosurgery, Duke University Medical Center, Durham, North Carolina; [§]Department of Biostatistics and Bioinformatics, Duke University Medical Center, Durham, North Carolina; [¶]Duke-Robert J. Margolis Center for Health Policy, Duke University, Durham, North Carolina

*Syed M. Adil and Lefko T. Charalambous contributed equally to this work.

BACKGROUND: Opioid misuse in the USA is an epidemic. Utilization of neuromodulation for refractory chronic pain may reduce opioid-related morbidity and mortality, and associated economic costs.
OBJECTIVE: To assess the impact of spinal cord stimulation (SCS) on opioid dose reduction.
METHODS: The IBM MarketScan® database was retrospectively queried for all US patients with a chronic pain diagnosis undergoing SCS between 2010 and 2015. Opioid usage before and after the procedure was quantified as morphine milligram equivalents (MME).
RESULTS: A total of 8497 adult patients undergoing SCS were included. Within 1 yr of the procedure, 60.4% had some reduction in their opioid use, 34.2% moved to a clinically important lower dosage group, and 17.0% weaned off opioids entirely. The proportion of patients who completely weaned off opioids increased with decreasing preprocedure dose, ranging from 5.1% in the >90 MME group to 34.2% in the ≤20 MME group. The following variables were associated with reduced odds of weaning off opioids post procedure: long-term opioid use (odds ratio [OR]: 0.26; 95% CI: 0.21-0.30; $P < .001$), use of other pain medications (OR: 0.75; 95% CI: 0.65-0.87; $P < .001$), and obesity (OR: 0.75; 95% CI: 0.60-0.94; $P = .01$).
CONCLUSION: Patients undergoing SCS were able to reduce opioid usage. Given the potential to reduce the risks of long-term opioid therapy, this study lays the groundwork for efforts that may ultimately push stakeholders to reduce payment and policy barriers to SCS as part of an evidence-based, patient-centered approach to nonopioid solutions for chronic pain.

KEY WORDS: Chronic pain, Morphine milligram equivalent, Opioid epidemic, Opioid misuse, Spinal cord stimulation

Neurosurgery 88:193–201, 2021 DOI:10.1093/neuros/nyaa353 www.neurosurgery-online.com

Table 7. Reporting Recommendations for RCTs of SCS for Pain

Reporting recommendations for randomized clinical trials of spinal cord stimulation for treatment of pain

The following information should be clearly reported

Reporting
- Source of funding and specific role of funder in compensation, study design and analysis

Study design
- Parallel group, cross-over, other
- Posting of a protocol detailing a priori inclusion criteria, outcomes assessed (with clear delineation of primary and secondary endpoints, and if multiple endpoints are primary, methods for multiplicity adjustment) and statistical methods employed on a website such as www.clinicaltrials.gov.

Study methodology
- Clinical eligibility criteria
- Duration of washout in cross-over trials
- Extent and methodology of blinding
- Methods of randomization and its concealment
- Role of screening phase in enrollment of participants
- Initial settings and adjustment parameters for SCS units
- Allowance of concurrent treatments
- Methods to ensure balanced expectation of benefit of both researchers and patients (equipoise) between groups, and also balance of non-intervention treatment between groups (eg, programming time, psychological support, physical activity, rescue meds, etc.)

Outcomes
- Primary and secondary outcomes
- Assessment of adverse events, including what and how these were assessed

Statistical analysis
- Number of participants and reasons for withdrawing
- Similarity of groups at baseline and methods for accommodating differences
- Type of analysis (superiority, noninferiority, etc.)
- Sample size calculations, power analyses, and assumed effect size
- Methods for dealing with missing data

Interpretation
- Clinical significance of any statistically significant difference

USASP US ASSOCIATION FOR THE STUDY OF PAIN
PUBLISHED BY ELSEVIER
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Available online at www.jpain.org and www.sciencedirect.com

Systematic Review of Research Methods and Reporting Quality of Randomized Clinical Trials of Spinal Cord Stimulation for Pain

Ewan McNicol,[*] McKenzie Ferguson,[†] Kathleen Bungay,[‡] Emily L. Rowe,[§] Sam Eldabe,[¶,**] Jennifer S. Gewandter,[††] Salim M. Hayek,[‡‡] Nathaniel Katz,[§§,‡] Brian H. Kopell,[¶¶] John Markman,[***] Ali Rezai,[†††] Rod S. Taylor,[‡‡‡,§§§] Dennis C. Turk,[¶¶¶] Robert H. Dworkin,[††] Richard B. North,[****] and Simon Thomson[††††]

Study/Article ID	Design	Treatment Group	Control Group	Follow-up Time	Pain Area	NNT for ITT Treatment Group vs. ITT Control Group (95% CI)	NNT for PP Treatment Group vs. PP Control Group (95% CI)
North 2005 [32]	RCT (open-label)	t-SCS	Reoperation	2.9 Yr	Comb. pain	5.00 (2.53, 250.00)	2.79 (1.63, 9.77)
PROCESS: Kumar 2007 [30]	RCT (open-label)	t-SCS	CMM	3 Mo	Leg pain	2.20 (1.64, 3.35)	2.13 (1.59, 3.25)
PROCESS: Kumar 2007 [30]	RCT (open-label)	t-SCS	CMM	6 Mo	Leg pain	2.64 (1.87, 4.51)	2.57 (1.81, 4.41)
PROCESS: Kumar 2007 [30]	RCT (open-label)	t-SCS	CMM	12 Mo	Leg pain	4.08 (2.58, 9.78)	3.74 (2.36, 9.09)
PROCESS: Kumar 2008 [33]	RCT (open-label)	t-SCS	CMM	24 Mo	Leg pain	3.27 (2.27, 5.80)	2.90 (2.03, 5.05)
Turner 2010 [42]	Controlled cohort (open-label)	t-SCS	PCM	6 Mo	Leg pain	7.99 (−3732.39, 3.99) †	8.08 (−384.11, 4.00) †
Turner 2010 [42]	Controlled cohort (open-label)	t-SCS	PCM	12 Mo	Leg pain	16.58 (−15.19, 5.36) †	15.24 (−14.19, 4.96) †
Turner 2010 [42]	Controlled cohort (open-label)	t-SCS	PCM	24 Mo	Leg pain	110.50 (−7.57, 6.66) †	63.57 (−6.82, 5.62) †
SENZA-RCT: Kapural 2015 [34]	RCT (open-label)	10 kHz SCS	t-SCS	3 Mo	Back pain	2.62 (1.96, 3.95)	2.47 (1.86, 3.67)
SENZA-RCT: Kapural 2015 [34]	RCT (open-label)	10 kHz SCS	t-SCS	3 Mo	Leg pain	3.58 (2.44, 6.77)	3.55 (2.41, 6.78)
SENZA-RCT: Kapural 2015 [34]	RCT (open-label)	10 kHz SCS	t-SCS	6 Mo	Back pain	4.08 (2.63, 9.02)	4.08 (2.59, 9.57)
SENZA-RCT: Kapural 2015 [34]	RCT (open-label)	10 kHz SCS	t-SCS	6 Mo	Leg pain	3.78 (2.52, 7.60)	3.77 (2.49, 7.77)
SENZA-RCT: Kapural 2015 [34]	RCT (open-label)	10 kHz SCS	t-SCS	12 Mo	Back pain	3.70 (2.48, 7.31)	3.66 (2.43, 7.42)
SENZA-RCT: Kapural 2015 [34]	RCT (open-label)	10 kHz SCS	t-SCS	12 Mo	Leg pain	3.70 (2.48, 7.31)	3.66 (2.43, 7.42)
SENZA-RCT: Kapural 2016 [35]	RCT (open-label)	10 kHz SCS	t-SCS	24 Mo	Back pain	3.54 (2.40, 6.71)	3.68 (2.39, 8.03)
SENZA-RCT: Kapural 2016 [35]	RCT (open-label)	10 kHz SCS	t-SCS	24 Mo	Leg pain	3.95 (2.58, 8.45)	4.23 (2.59, 11.54)
SUNBURST: Deer 2018 [40]	RCOT (open-label)	Burst stim.	t-SCS	3 Mo	Comb. pain	14.29 (−16.06, 4.94) †	13.71 (−15.81, 4.78)
SURF: Bolash 2019 [36]	RCT (open-label)	Externally powered 10 kHz SCS	10–1500 Hz SCS	6 Mo	Back pain	7.78 (−16.83, 3.16) †	10.25 (−17.65, 3.97)
PROMISE: Rigoard 2019 [37]	RCT (open-label)	t-SCS + OMM	OMM	6 Mo	Back pain	11.10 (6.04, 68.13)	8.70 (4.98, 34.47)
PROMISE: Rigoard 2019 [37]	RCT (open-label)	t-SCS + OMM	OMM	6 Mo	Leg pain	4.62 (3.16, 8.59)	3.67 (2.60, 6.24)
WHISPER: North 2019 [41]	RCOT (open-label)	≤1.2 kHz subperc. SCS	t-SCS	3 Mo	Comb. pain	10.00 (−17.99, 3.91) †	- *
EVOKE: Mekhail 2019 [38]	RCT (double-blind)	Closed-loop SCS	t-SCS	3 Mo	Comb. pain	5.15 (2.85, 26.66)	6.16 (3.23, 67.14)
EVOKE: Mekhail 2019 [38]	RCT (double-blind)	Closed-loop SCS	t-SCS	3 Mo	Back pain	4.79 (2.72, 19.81)	5.47 (2.97, 34.51)
EVOKE: Mekhail 2019 [38]	RCT (double-blind)	Closed-loop SCS	t-SCS	3 Mo	Leg pain	9.57 (−19.78, 3.85) †	19.71 (−11.50, 5.31) †
EVOKE: Mekhail 2019 [38]	RCT (double-blind)	Closed-loop SCS	t-SCS	12 Mo	Comb. pain	5.15 (2.83, 29.17)	7.10 (−148.78, 3.47) †
EVOKE: Mekhail 2019 [38]	RCT (double-blind)	Closed-loop SCS	t-SCS	12 Mo	Back pain	5.15 (2.81, 31.50)	6.84 (−79.46, 3.28) †
EVOKE: Mekhail 2019 [38]	RCT (double-blind)	Closed-loop SCS	t-SCS	12 Mo	Leg pain	5.15 (2.83, 29.17)	7.10 (−148.78, 3.47) †
Fishman 2021 [39]	RCT (open-label)	DTM SCS	t-SCS	12 Mo	Back pain	6.24 (−98.36, 3.02) †	4.25 (2.36, 21.37)

biomedicines

MDPI

Review

Concept of the Number Needed to Treat for the Analysis of Pain Relief Outcomes in Patients Treated with Spinal Cord Stimulation

Ashley Bailey-Classen [1], Amar Parikh [2], Nima Adimi [3], Deborah Edgar [4], Alice Yan [5], Anand Rotte [5] and David Caraway [5,*]

PROGRAMME d'e-learning

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Partie D: « Camp de base »

Section 2 : Neuromodulations non invasives

Module 11 : « Evidence-Based Medicine » en neuromodulation

Dr Jimmy VOIRIN

Société Française de Neurochirurgie

En partenariat avec:

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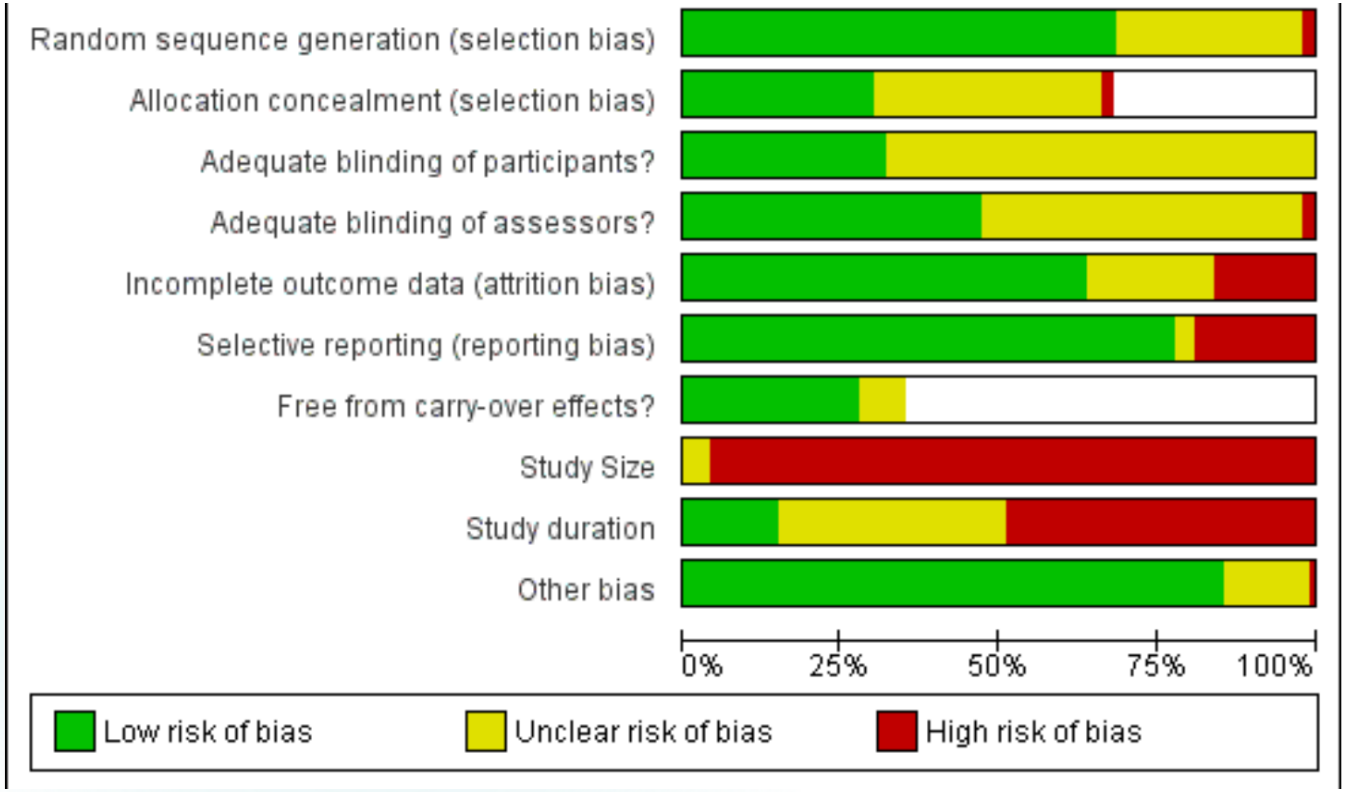
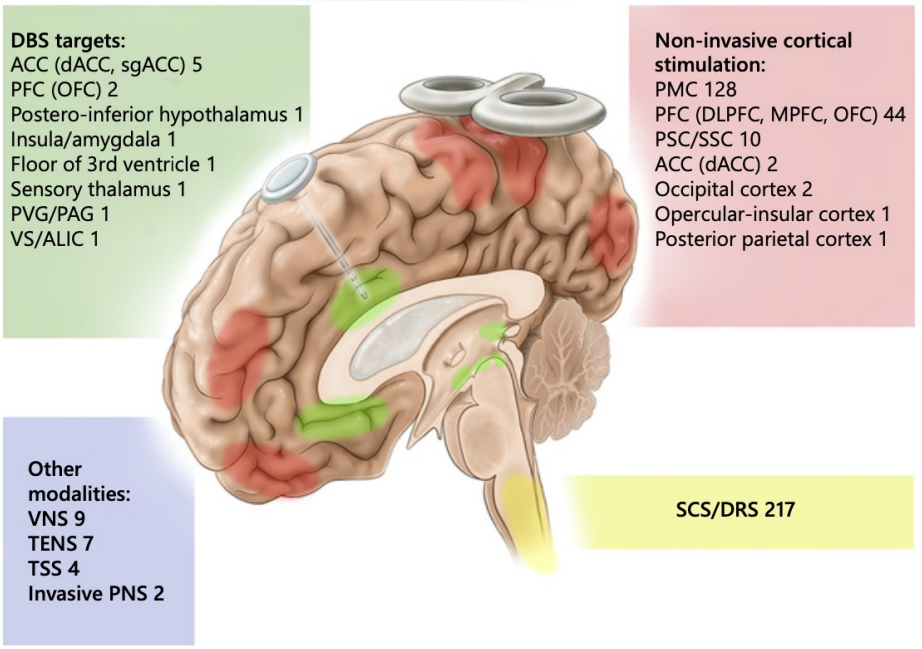




Stereotactic and Functional Neurosurgery

Clinical Study

Stereotact Funct Neurosurg 2022;100:14–25
DOI: 10.1159/000517873

Received: Apri
Accepted: May
Published onli

Neuromodulation for Pain: A Comprehensive Survey and Systematic Review of Clinical Trials and Connectomic Analysis of Brain Targets

Kazuaki Yamamoto[a] Gavin J.B. Elias[a] Michelle E. Beyn[a] Ajmal Zemmar[a, b]
Aaron Loh[a] Can Sarica[a] Jürgen Germann[a] Roohie Parmar[a] Emily H.Y. Wong[a]
Alexandre Boutet[a, c] Suneil Kalia[a] Mojgan Hodaie[a] Andres M. Lozano[a]

TENS

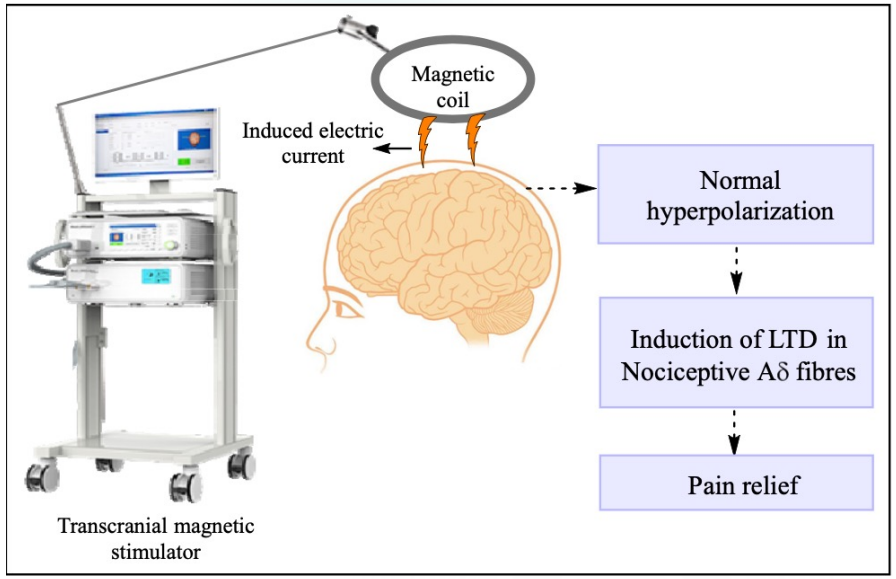
TENS vs sham	Boldt 2014	Limited data, not calculable	Not calculated	40 (1 study)	⊕⊖⊖⊖ Very low	Limited data, pooled analysis not performed
	Brosseau 2003	Limited data, not calculable	Not calculated	78 (3 studies)	⊕⊖⊖⊖ Very low	Limited data, pooled analysis not performed
	Gibson 2017	(0 to 10 VAS) −1.58 (95% CI −2.08 to −1.09)	Not calculated	728 (15 studies) Pooled analysis: 207 (5 studies)	⊕⊖⊖⊖ Very low	Significant methodological limitations across the five pooled trials as well as small sample size of trials and issues with participant blinding in trials
	Hurlow 2012	Limited data, not calculable	Not calculated	88 (3 studies)	⊕⊖⊖⊖ Very low	Limited data, pooled analysis not performed
	Johnson 2015	No data	Not calculable	0 (no studies)	n/a	No studies identified
	Johnson 2017	Not calculable	Not calculated	315 (8 studies)	⊕⊖⊖⊖ Very low	Pooled analysis not performed
	Khadilkar 2008	Not calculable	Not calculated	485 (4 studies)	⊕⊖⊖⊖ Very low	Pooled analysis not performed
	Kroeling 2013	Not calculable	Not calculated	472 (6 studies)	⊕⊖⊖⊖ Very low	Pooled analysis not performed
	Rutjes 2009	Not calculable	Not calculated	465 (12 studies)	⊕⊖⊖⊖ Very low	Pooled analysis was performed but the analysis combined sham and no treatment studies and compared these against active TENS. For this overview, the result is therefore severely compromised. The estimate of the effect is deemed 'not calculable'

- 8 reviews / 51 RCT / 2985 pts

Gibson W, Wand BM, Meads C, Catley MJ, O'Connell NE.
Transcutaneous electrical nerve stimulation (TENS) for chronic pain - an overview of Cochrane Reviews.
Cochrane Database of Systematic Reviews 2019, Issue 4. Art. No.: CD011890.
DOI: 10.1002/14651858.CD011890.pub3.

We are unable to confidently state whether TENS is effective in relieving pain in people with chronic pain. This is due to the very low quality of the evidence, and the overall small numbers of participants included in studies in the reviews. Issues with quality, study size and lack of data meant we were unable to draw any conclusion on TENS-associated harms or side-effects or the effect of TENS on disability, health-related quality of life, use of pain-relieving medicines or people's impression of how much TENS changed their condition.

rTMS



- 42 RCT
- Target :
  - M1: 31/ DLPFC : 7 / S2 : 2 / Ant Cing : 1/ S1: 1
- Frequency (5Hz) : 12 low / 30 high
- Sham : angled coil, electric scalp stimulation, coils (2 types, 2-sided blinded….
- Méta-analysis : 27 RCT -627 pts
- QOL

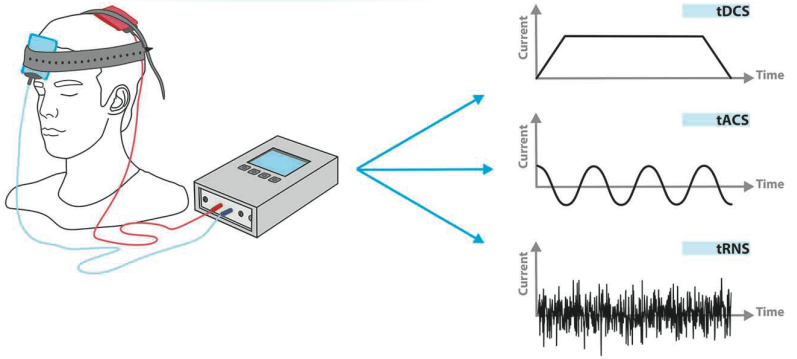
rTMS compared with sham for chronic pain

Patient or population: adults with chronic pain
Settings: laboratory/ clinic
Intervention: active rTMS
Comparison: sham rTMS

Outcomes	Effect size	Relative and absolute effect (average % improvement (reduction) in pain (95% CIs) in relation to post-treatment score from sham group)* *Where 95%CIs do not cross the line of no effect.	No of participants (studies)	Quality of the evidence (GRADE)
Pain intensity (0 to < 1 week postintervention) measured using visual analogue scales or numerical rating scales	SMD -0.22 (-0.29 to -0.16)	This equates to a 7% (95% CI 5% to 9%) reduction in pain intensity, or a 0.40 (95% CI 0.53 to 0.32) point reduction on a 0 to 10 pain intensity scale	655 (27)	⊕⊕◯◯ **low**[1]
Disability (0 to < 1 week postintervention) measured using self-reported disability/pain interference scales	SMD -0.29, 95% CI -0.87 to 0.29	-	119 (5)	⊕◯◯◯ **very low**[2]
Quality of life (0 to < 1 week postintervention) measured using Fibromyalgia Impact Questionnaire	MD -10.80, 95% CI -15.04 to -6.55	-	105 (4)	⊕⊕◯◯ **low**[3]

O'Connell NE, Marston L, Spencer S, DeSouza LH, Wand BM.
Non-invasive brain stimulation techniques for chronic pain.
Cochrane Database of Systematic Reviews 2018, Issue 3. Art. No.: CD008208.
DOI: 10.1002/14651858.CD008208.pub4.

TdCS



- 38 RCT
- Type : 26 parallel / 10 crossover
- Target : M1 : 34 / DLPFC : 4
- I : 2mA (18), 1mA (6), unspecified (14)

tDCS compared with sham for chronic pain

Patient or population: adults with chronic pain
Settings: laboratory/ clinic
Intervention: active tDCS
Comparison: sham tDCS

Outcomes	Effect size	Relative effect (average % improvement (reduction) in pain (95% CIs) in relation to post-treatment score from sham group)* *Where 95%CIs do not cross the line of no effect.	No of participants (studies)	Quality of the evidence (GRADE)
Pain intensity (0 to < 1 week postintervention) measured using visual analogue scales or numerical rating scales	SMD -0.43 (-0.63 to -0.22)	This equates to a 17% (95% CI 9% to 25%) reduction in pain intensity or a 0.82 (95% CI 0.42 to 1.2) point reduction on a 0 to 10 pain intensity scale	747 (27)	⊕◯◯◯ **very low**[1]
Disability (0 to < 1 week postintervention) measured using self-reported disability/pain interference scales	SMD -0.01, (95% CI -0.28 to 0.26)	-	212 (4)	⊕⊕◯◯ **low**[2]
Quality of life (0 to < 1 week postintervention) measured using different scales across studies	SMD 0.66, 95% CI 0.21 to 1.11	-	82 (4)	⊕⊕◯◯ **low**[2]

O'Connell NE, Marston L, Spencer S, DeSouza LH, Wand BM.
Non-invasive brain stimulation techniques for chronic pain.
Cochrane Database of Systematic Reviews 2018, Issue 3. Art. No.: CD008208.
DOI: 10.1002/14651858.CD008208.pub4.

Autres techniques

- CES (Cranial Electrotherapy Stimulation) : 5 studies non significant for pain but one for QOL.
- RINCE (Reduced Impedance Non-Invasive Cortical Electro-stimulation) : 1 small RCT in fibromyalgia, non significant
- tRNS (transcraniual random noise stimulation): No RCT
- Non invasive VNS:
- Case series in trigeminal neuralgia, fibromyalgie, chronic pelvic pain, headache
  - Left Ear Auricular : 1 RCT vs Sham (46pts) (significant only for headache days
  - Transcutaneous Magnetic : none

Straube A, Ellrich J, Eren O, Blum B, Ruscheweyh R. Treatment of chronic migraine with transcutaneous stimulation of the auricular branch of the vagal nerve (auricular t-VNS): a randomized, monocentric clinical trial. J Headache Pain. 2015;16(1):543.

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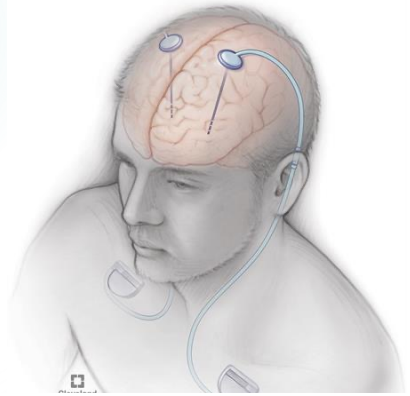
DBS



PAIN MEDICINE
Volume 2 • Number 3 • 2001

RESEARCH ARTICLES

Deep Brain Stimulation for Chronic Pain: Results of Two Multicenter Trials and a Structured Review

Robert J. Coffey, MD

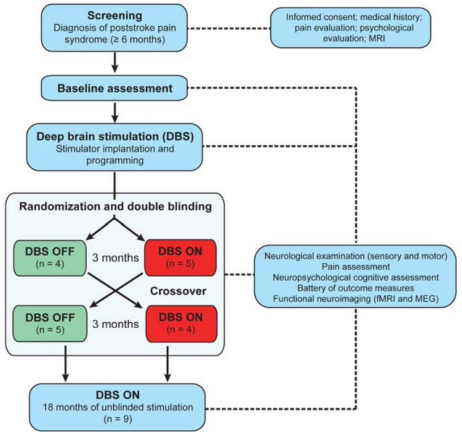
Medtronic Drug Delivery, Bronxville, New York

Galafassi et al (2020)[52]	11 studies; one RCT and ten case series or retrospective reviews (n=304) with peripheral neuropathic pain, central pain, phantom pain, CRPS, facial pain, FBSS, brachial plexopathy, etc	Intervention: deep brain stimulation; control: one study used sham stimulation, most had no comparator; primary outcome: pain improvement (inferred)	Only three studies reported negative results including the only sham-controlled study; effectiveness generally varied between 50% and 60%; follow-up periods ranged from 12 to 78 months (two did not note follow-up); only neuropathic pain consensus was for SCI (poor results)	Very low-quality evidence for effectiveness; most studies were uncontrolled; the only sham-controlled study was negative for the primary endpoint but reported improvement for affective component of pain; AMSTAR-2 rating: low

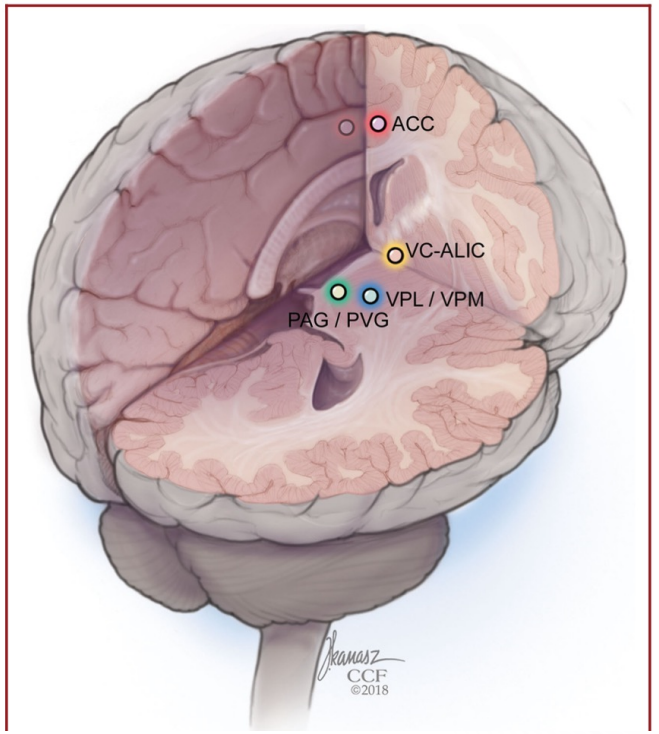
Measure	Baseline Mean	DBS ON Mean or %[a]	DBS OFF Mean or %[a]	Difference, DBS OFF vs DBS ON Estimate[b]	95% Confidence Interval		p
PDI							
Score	54.56	47.79	47.95	0.16	−2.97	3.29	0.920
≥50% improvement	N/A	11%	12%	1.05	0.96	1.15	0.270
MADRS							
Score	11.22	9.02	10.87	1.85	−1.15	4.86	0.230
≥50% improvement	N/A	44%	19%	0.30	0.11	0.83	0.020[c]
BDI							
Score	10.89	8.86	10.54	1.68	−0.71	4.08	0.170
≥50% improvement	N/A	45%	27%	0.44	0.26	0.77	0.004[c]
Short-Form McGill Pain Questionnaire							
S-PRI							
Score	11.89	12.77	12.39	−0.38	−2.05	1.29	0.660
≥50% improvement	N/A	10%	6%	0.55	0.04	6.73	0.640
A-PRI							
Score	4.56	3.48	4.34	0.86	−0.20	1.91	0.111
≥50% improvement	N/A	39%	18%	0.35	0.17	0.73	0.005[c]
T-PRI							
Score	16.44	16.25	16.73	0.48	−1.87	2.82	0.690
≥50% improvement	N/A	14%	10%	0.65	0.12	3.52	0.620
VAS							
Score	69.89	76.25	79.43	3.18	−0.61	6.98	0.100
≥50% improvement	N/A	11%	12%	1.05	0.96	1.15	0.270
PPI							
Score	3.78	3.65	3.78	0.13	−0.18	0.45	0.400
≥50% improvement	N/A	10%	3%	0.27	0.11	0.63	0.002[c]

Randomized Clinical Trial of Deep Brain Stimulation for Poststroke Pain

Scott F. Lempka, PhD,[1,2] Donald A. Malone, Jr, MD,[3] Bo Hu, PhD,[4] Kenneth B. Baker, PhD,[5] Alexandria Wyant, BA,[1] John G. Ozinga, IV, MSPAS, PA-C,[1] Ela B. Plow, PhD,[1,6,7] Mayur Pandya, DO,[1] Cynthia S. Kubu, PhD,[1,3] Paul J. Ford, PhD,[8] and Andre G. Machado, MD, PhD[1,5]



DBS



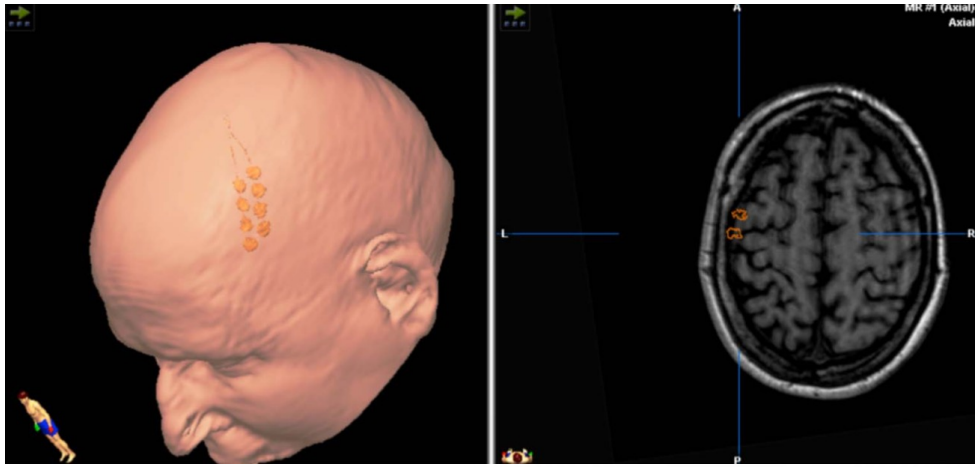
REVIEW

Deep Brain Stimulation for Pain in the Modern Era: A Systematic Review

Leonardo A. Frizon, MD*‡

BACKGROUND: Deep brain stimulation (DBS) has been considered for patients with

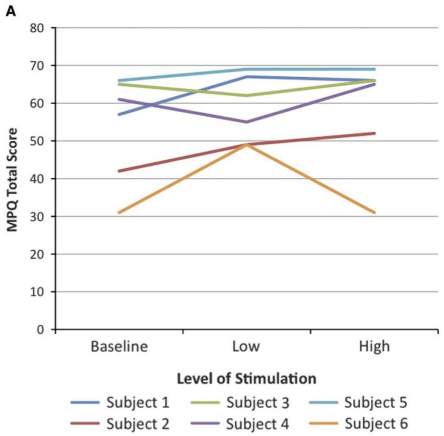
MCS



MCS

Motor Cortex Stimulation for Neuropathic Pain: A Randomized Cross-over Trial

Julia A.E. Radic, Ian Beauprie, Paula Chiasson, Zelma H.T. Kiss, Robert M. Brownstone



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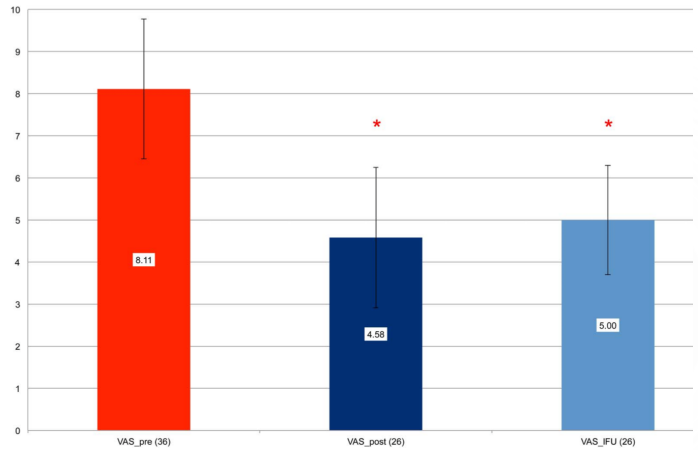
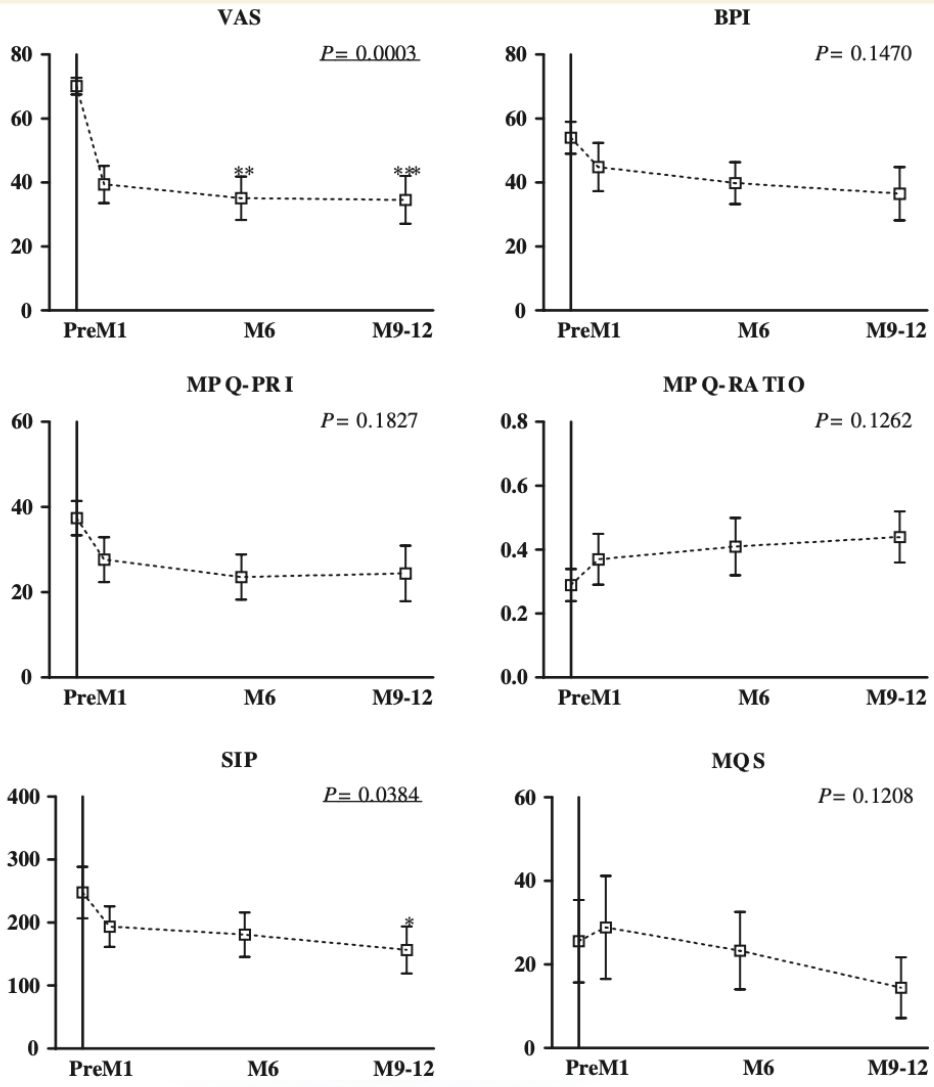


Clinical Significance of Invasive Motor Cortex Stimulation for Trigeminal Facial Neuropathic Pain Syndromes

Dirk Rasche, MD
Volker M. Tronnier, MD, PhD

BACKGROUND: Invasive neuromodulation of the cortical surface for various chronic pain syndromes has been performed for >20 years. The significance of motor cortex stimulation (MCS) in chronic trigeminal neuropathic pain (TNP) syndromes remains

MCS

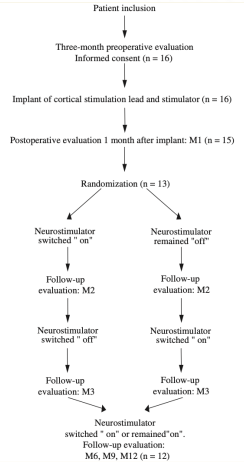


doi:10.1093/brain/awp035 Brain 2009: 132; 1463–1471 | 1463

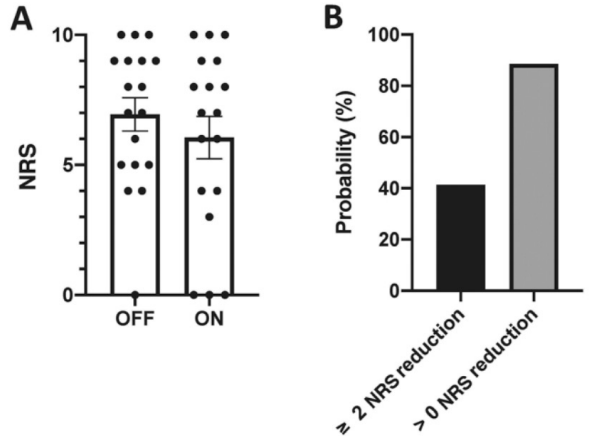
BRAIN
A JOURNAL OF NEUROLOGY

Motor cortex stimulation for the treatment of refractory peripheral neuropathic pain

Jean-Pascal Lefaucheur,[1] Xavier Drouot,[1] Patrick Cunin,[2] Rémy Bruckert,[2] Hélène Lepetit,[2] Alain Créange,[3] Pierre Wolkenstein,[4] Patrick Maison,[2] Yves Keravel[5] and Jean-Paul Nguyen[5]



MCS

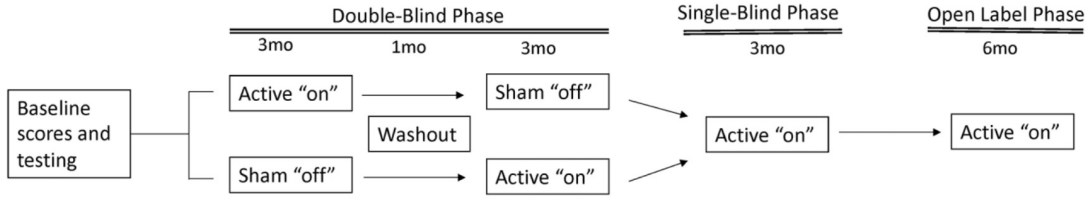


doi:10.1093/brain/awab189

BRAIN
CLINICAL TRIAL

Motor cortex stimulation for chronic neuropathic pain: results of a double-blind randomized study

Clement Hamani,[1,2,†] Erich T. Fonoff,[1,†] Daniella C. Parravano,[1] Valquiria A. Silva,[3] Ricardo Galhardoni,[3] Bernardo A. Monaco,[1] Jessie Navarro,[1] Lin T. Yeng,[3] Manoel J. Teixeira[1,3] and Daniel Ciampi de Andrade[1,3]



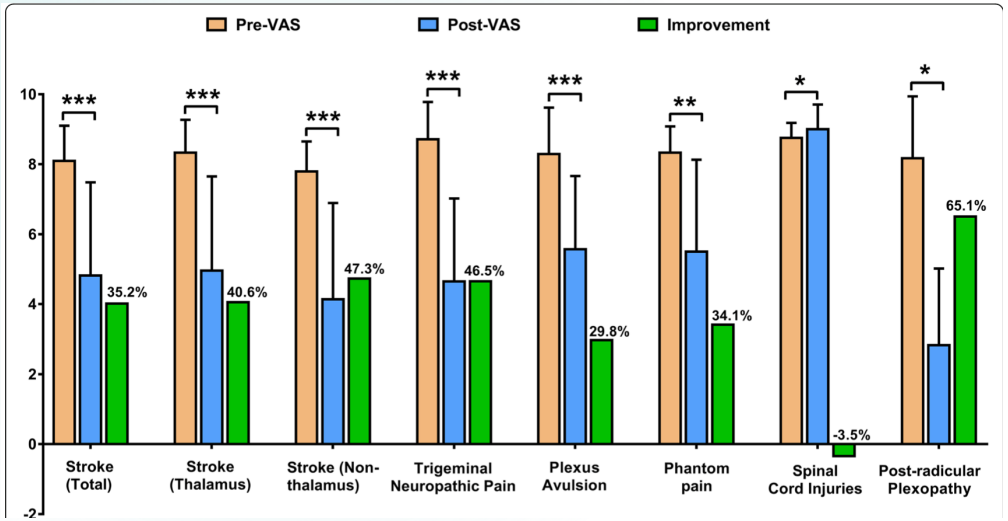
Mo *et al. BMC Neurology* (2019) 19:48
https://doi.org/10.1186/s12883-019-1273-y

BMC Neurology

RESEARCH ARTICLE Open Access

Motor cortex stimulation: a systematic literature-based analysis of effectiveness and case series experience

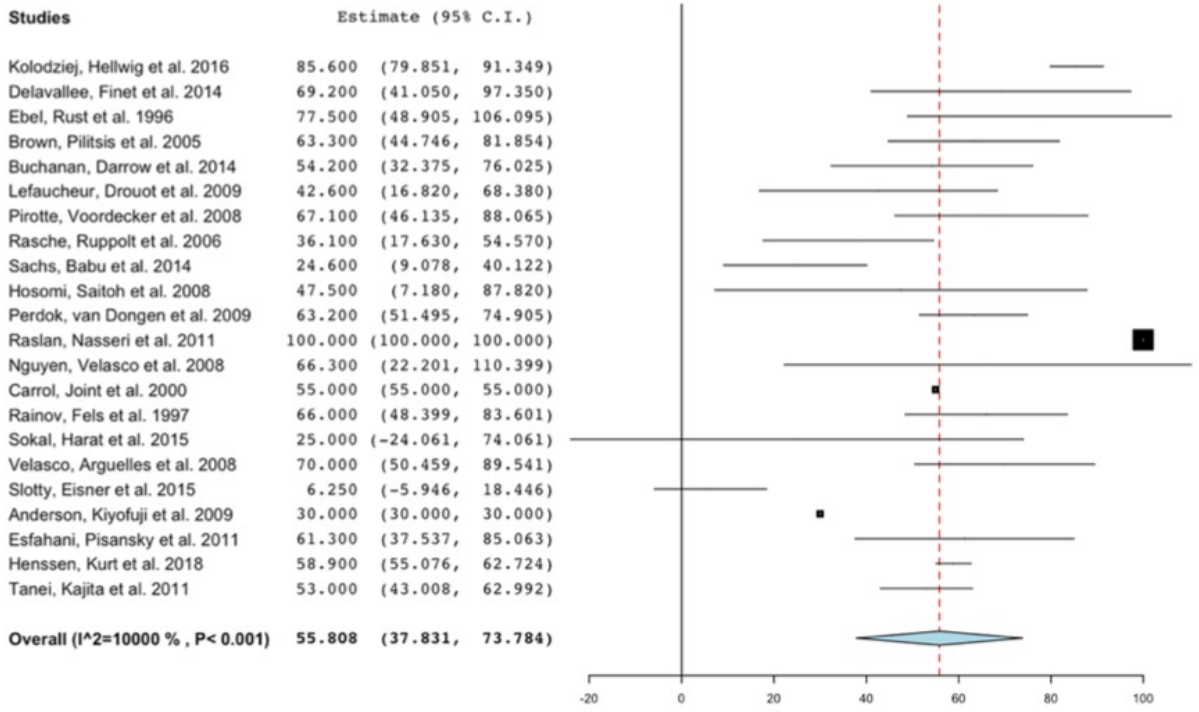
Jia-Jie Mo, Wen-Han Hu, Chao Zhang, Xiu Wang, Chang Liu, Bao-Tian Zhao, Jun-Jian Zhou and Kai Zhang*



SCIENTIFIC REPORTS
nature research

Motor cortex stimulation in chronic neuropathic orofacial pain syndromes: a systematic review and meta-analysis

Dylan Henssen[1,2,3], Erkan Kurt[2,3], Anne-Marie Van Cappellen van Walsum[1], Tamas Kozicz[1], Robert van Dongen[4] & Ronald Bartels[2]



Autres cibles

- ONS
- SPG
- PNS

. Saper JR, Dodick DW, Silberstein SD, et al, ON-STIM Investigators. Occipital nerve stimulation for the treatment of intractable chronic migraine: ON-STIM feasibility study. Cephalalgia 2011;31: 271–85.

. Lipton RB, Goadsby PJ, Cady RK, et al. PRISM study: occipital nerve stimulation for treatment-refractory migraine. Cephalalgia 2009;29(Suppl 1):30.

. Silberstein SD, Dodick DW, Saper J, et al. Safety and efficacy of peripheral nerve stimulation of the occipital nerves for the management of chronic migraine: results from a randomized, multicenter, double-blinded, controlled study. Cephalalgia 2012;32: 1165–79.

THE LANCET
Neurology

ARTICLES | VOLUME 18, ISSUE 12, P1081-1090, DECEMBER 01, 2019

Safety and efficacy of sphenopalatine ganglion stimulation for chronic cluster headache: a double-blind, randomised controlled trial

Prof Peter J Goadsby, MD • Soma Sahai-Srivastava, MD • Eric J Kezirian, MD • Anne H Calhoun, MD • David C Matthews, MD • Peter J McAllister, MD • et al. Show all authors

Between July 9, 2014, and Feb 14, 2017, 93 patients were enrolled and randomly assigned, 45 to the sphenopalatine ganglion stimulation group and 48 to the control group. 36 patients in the sphenopalatine ganglion stimulation group and 40 in the control group had at least one attack during the experimental phase and were included in efficacy analyses. The proportion of attacks for which pain relief was experienced at 15 min was 62·46% (95% CI 49·15–74·12) in the sphenopalatine ganglion stimulation group versus 38·87% (28·60–50·25) in the control group (odds ratio 2·62 [95% CI 1·28–5·34]; p=0·008). Nine serious adverse events were reported by the end of the open-label phase. Three of these serious adverse events were related to the implantation procedure (aspiration during intubation, nausea and vomiting, and venous injury or compromise). A fourth serious adverse event was an infection that was attributed to both the stimulation device and the implantation procedure. The other five serious adverse events were unrelated. There were no unanticipated serious adverse events.

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Société Française de Neurochirurgie

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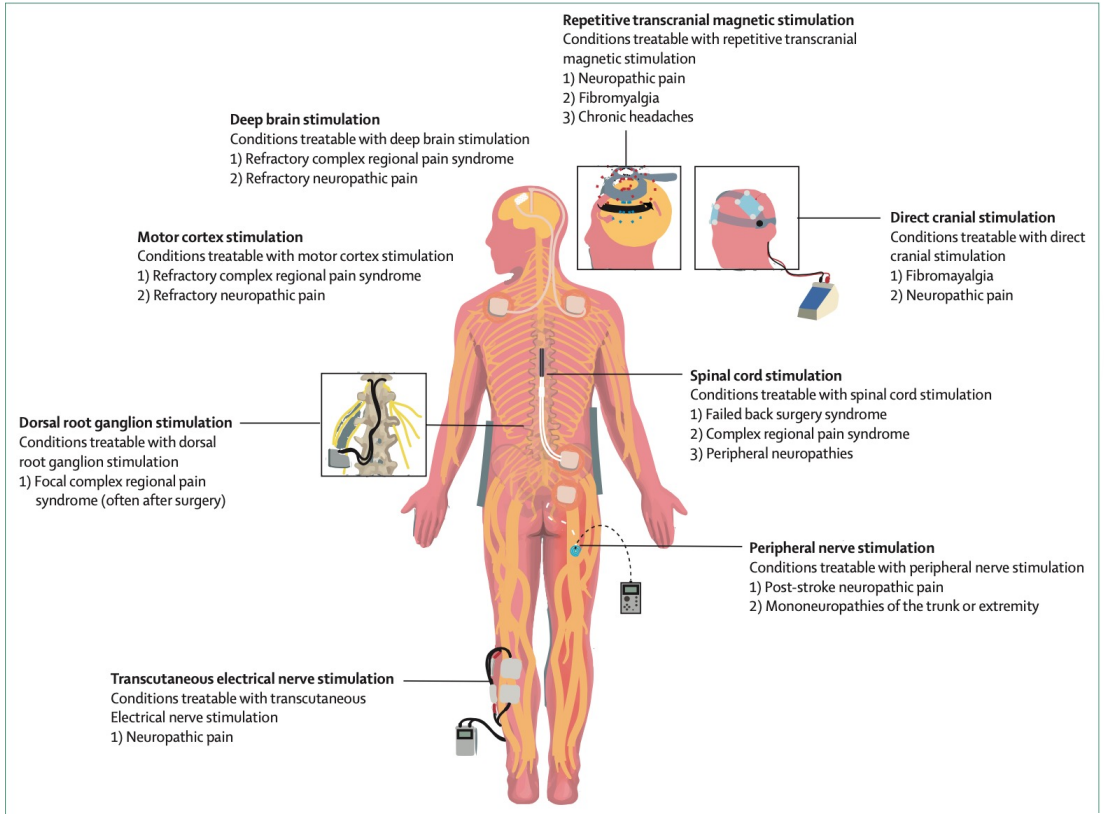
De la lésion à la neuromodulation



Neuromodulation for chronic pain

Helena Knotkova, Clement Hamani*, Eellan Sivanesan*, María Francisca Elgueta Le Beuffe, Jee Youn Moon, Steven P Cohen, Marc A Huntoon*

Neuromodulation is an expanding area of pain medicine that incorporates an array of non-invasive, minimally

Lancet 2021; 397: 2111–24

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Annals of Oncology 16: 825–833, 2005
doi:10.1093/annonc/mdi156
Published online 7 April 2005

An implantable drug delivery system (IDDS) for refractory cancer pain provides sustained pain control, less drug-related toxicity, and possibly better survival compared with comprehensive medical management (CMM)

T. J. Smith[1*], P. J. Coyne[1], P. S. Staats[2], T. Deer[3], L. J. Stearns[4], R. L. Rauck[5], R. L. Boortz-Marx[6], E. Buchser[7], E. Català[8], D. A. Bryce[9], M. Cousins[10] & G. E. Pool[6] for the Implantable Drug Delivery Systems Study Group

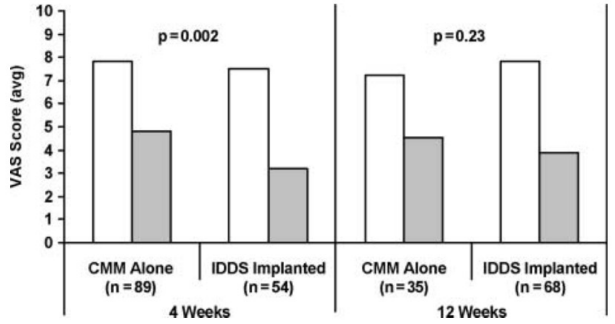


Figure 2. Reduction in VAS pain scores from baseline at 4 and 12 weeks (as treated). The difference between 'non-IDDS' and 'IDDS' is significant ($P = 0.002$) at 4 weeks, but the difference narrows at 12 weeks, as CMM patients cross over to IDDS and obtain relief of pain, and the number of patients diminishes ($P = 0.23$).

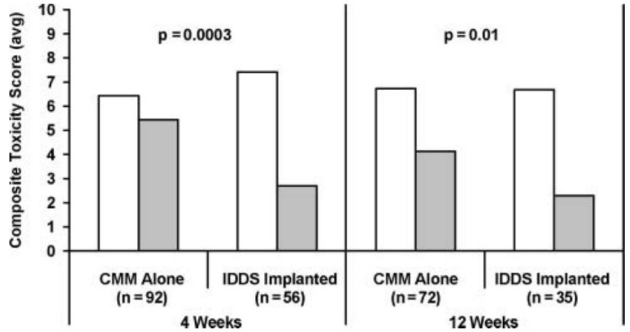
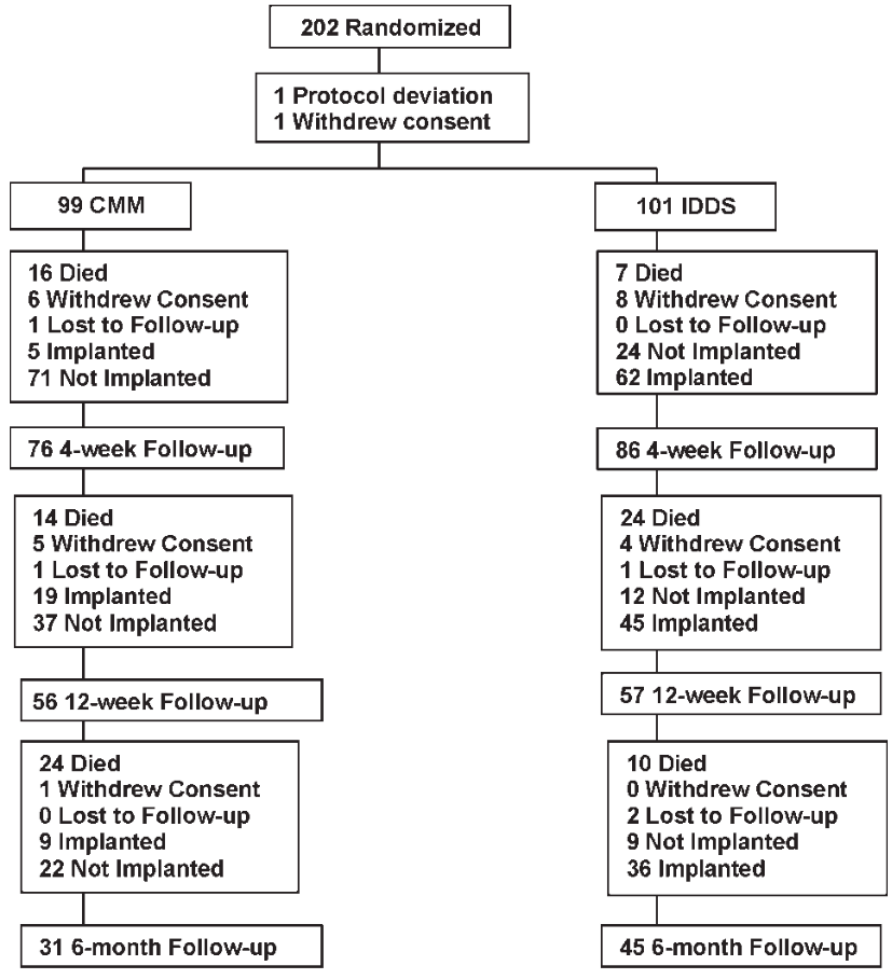


Figure 3. Reduction in toxicity from baseline to 4 weeks (as treated). The difference between 'non-implanted' and 'implanted' is significant ($P = 0.0003$) at 4 weeks and at 12 weeks ($P = 0.01$).



Ziconotide for treatment of severe chronic pain

Achim Schmidtko, Jörn Lötsch, Rainer Freynhagen, Gerd Geisslinger

Pharmacological management of severe chronic pain is difficult to achieve with currently available analgesic drugs, *Lancet* 2010; 375: 1569–77

	Staats et al (2004)[6]	Wallace et al (2006)[32]	Rauck et al (2006)[33]
Titration schedule	Fast*	Fast*	Slow†
Treatment duration	10–11 days	6–11 days	21 days
Population	Patients with pain (VASPI score ≥50 mm) associated with cancer or AIDS	Patients with severe chronic pain (VASPI score ≥50 mm) of non-malignant cause	Patients with severe chronic pain (VASPI score ≥50 mm) of any cause
Number of patients given Z/P	71/40	169/86	112/108
Pain reported			
Neuropathic (Z/P)	NR	75·7%/ 76·7%	75·9%/71·3%
Non-neuropathic (Z/P)	NR	13·0%/12·8%	35·7%/32·4%
Mean baseline VASPI score for Z/P group (mm)	74/78	80/77	81/81
Mean decrease in VASPI scores after Z/P	51·4%/18·1% (p<0·001)	31·2%/6·0% (p<0·001)	14·7%/7·2% (p=0·036)
Adverse events			
Nervous system‡	Dizziness (50·0%)§; nystagmus (45·8%); somnolence (23·6%)§; confusion (20·8%)§; abnormal gait (12·5%)§	Dizziness (53·5%)§; nystagmus (40·0%)§; abnormal gait (27·1%)§; somnolence (12·4%); confusion (11·8%); amblyopia (10·6%)§	Dizziness (47·3%)§; somnolence (22·3%); confusion (17·9%)§; ataxia (16·1%)§; abnormal gait (15·2%)§; memory impairment (11·6%)§
Digestive system‡	Nausea (29·2%)§; vomiting (18·1%)§; constipation (12·5%)	Nausea (48·8%)§; constipation (18·2%); vomiting (14·1%)§	Nausea (41·1%); diarrhoea (18·8%); vomiting (15·2%)
Other systems‡	Fever (25·0%)§; postural hypotension (23·6%)§; urinary retention (18·1%)§; headache (15·3%)	Pain (16·5%)§; headache (16·5%); urinary retention (15·3%)§; postural hypotension (11·8%)	Asthenia (22·3%); headache (15·2%); pain (10·7%)

Z=ziconotide, P=placebo, NR=not reported. *Fast titration: initial dose 9·6 μg per day, a dose increase 7–14 times per week, maximum dose per protocol 57·6 μg per day, time to maximum dose 5–6 days. †Slow titration: initial dose 2·4 μg per day, a dose increase 2–3 times per week, maximum dose per protocol 21·6 μg per day, time to maximum dose 21 days. ‡Adverse events reported in >10% of patients treated with ziconotide. §Occurred with significantly greater frequency with ziconotide than with placebo (p<0·05).

Table: **Overview of randomised placebo-controlled clinical studies with ziconotide**

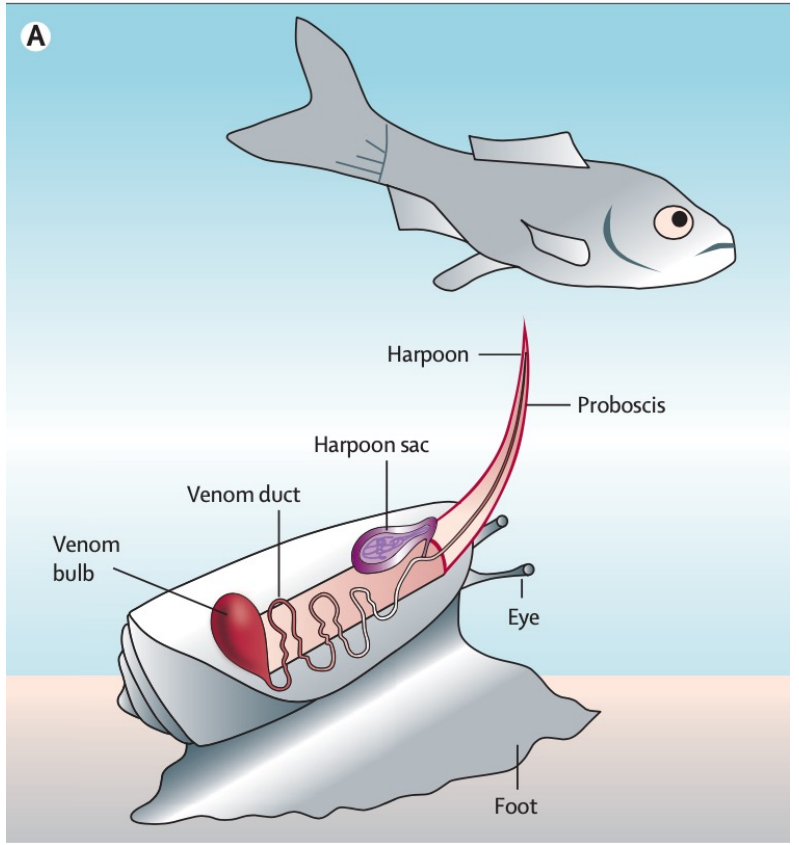


Figure 1: Conus magus

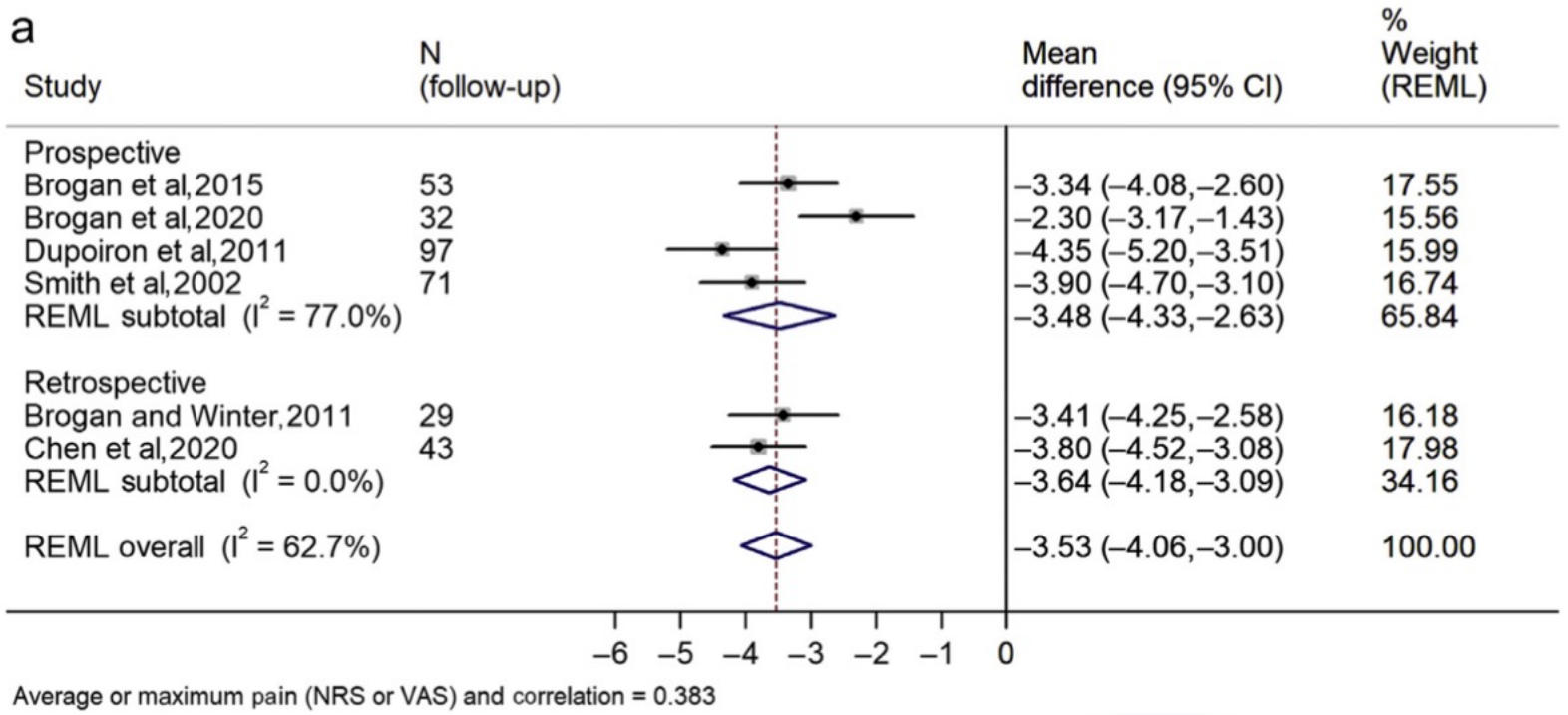
Neuromodulation: Technology at the Neural Interface

Received: January 19, 2022 Revised: March 2, 2022 Accepted: March 6, 2022

https://doi.org/10.1016/j.neurom.2022.03.003

Effectiveness and Safety of Intrathecal Drug Delivery Systems for the Management of Cancer Pain: A Systematic Review and Meta-Analysis

Rui Duarte, PhD[1]; Sue Copley, MSc[2]; Sarah Nevitt, PhD[1]; Michelle Maden, PhD[1]; Ali Mohammed Al-Ali, MD[2,3]; Denis Dupoiron, MD[4]; Sam Eldabe, MD[2]



PROGRAMME d'e-learning

Collège des Enseignants en Neurochirurgie

Prise en charge Neurochirurgicale de la Douleur

Responsable de l'e-module « Douleur » :
Philippe RIGOARD

Responsables scientifiques du projet :
Jean-Luc BARAT & Philippe RIGOARD

Partie A : Douleur

Partie B : Neurochirurgie lésionnelle de la douleur

Partie C : Neuromodulation de la douleur

Partie D: « Camp de base »

Section 4b : Stimulation médullaire

Module 11 : « Evidence-Based Medicine » en neuromodulation

Dr Jimmy VOIRIN

Société Française de Neurochirurgie

En partenariat avec:

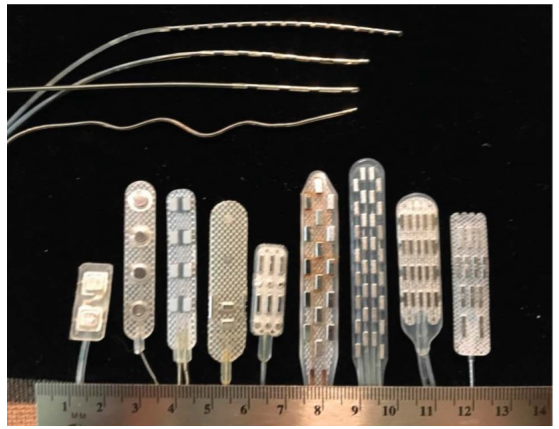
SFCR Société Française de Chirurgie rachidienne

SFETD

SFNM

Principes SCS

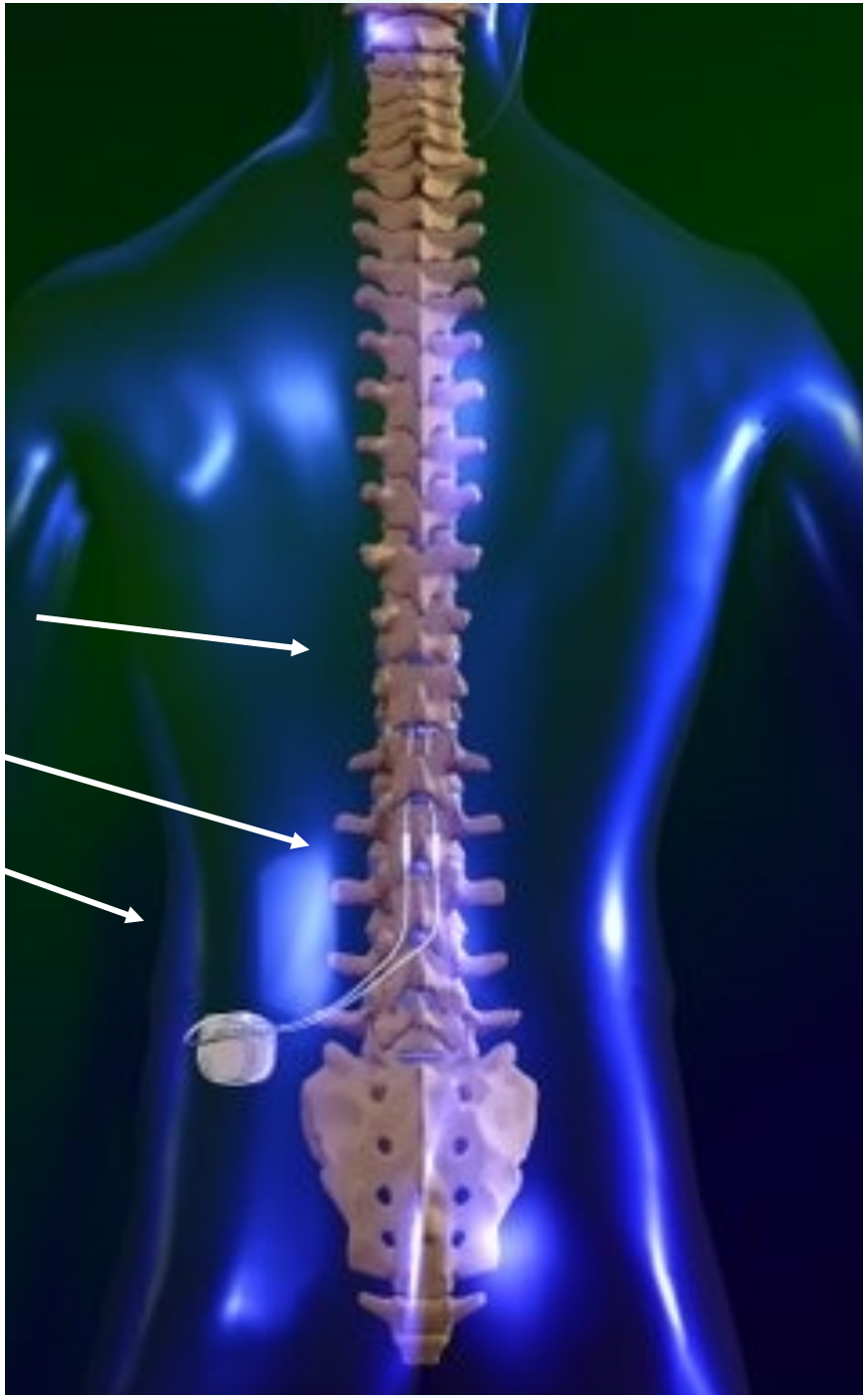
Intervention	Manufacturer	Studies, *n*	Total studies, %
eSCS	Medtronic	41	19.1
	Boston Scientific	36	16.7
	Abbott	18	8.4
	Nevro	10	4.7
	Nuvectra	5	2.3
	Stimwave Technologies	3	1.4
	Saluda Medical Pty Ltd	2	0.9
	Biotronik	1	0.5
	Finetech/Ardiem Medical	1	0.5
	GiMer Medical	1	0.5
	Meagan Medical	1	0.5
	PINS	1	0.5
	Not specified	57	26.5
tcSCS	NeuroEnabling Technologies	2	0.9
	Anatomical Concepts	1	0.5
	BioMedical Life Systems	1	0.5
	DJO Global	1	0.5
	neuroConn GmbH	1	0.5
	Restorative Technologies	1	0.5
	Not specified	21	9.8
tsDCS	neuroConn GmbH	1	0.5
	Soterix Medical	1	0.5
	Not specified	4	1.9
TENS	Enraf-Nonius	1	0.5
iSCS	Not specified	1	0.5
SMS	Not specified	2	0.9
Total[a]		215	100



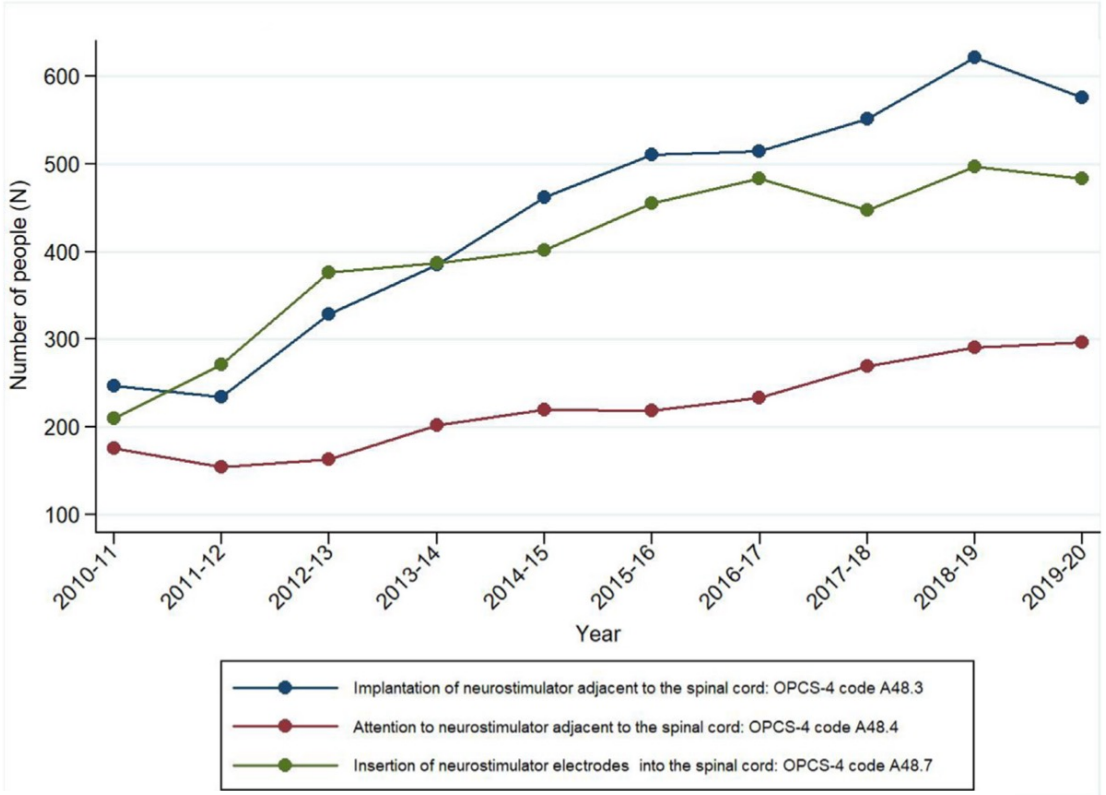
Électrode de stimulation épidurale

Câble de connexion ?

Neuro-stimulateur interne

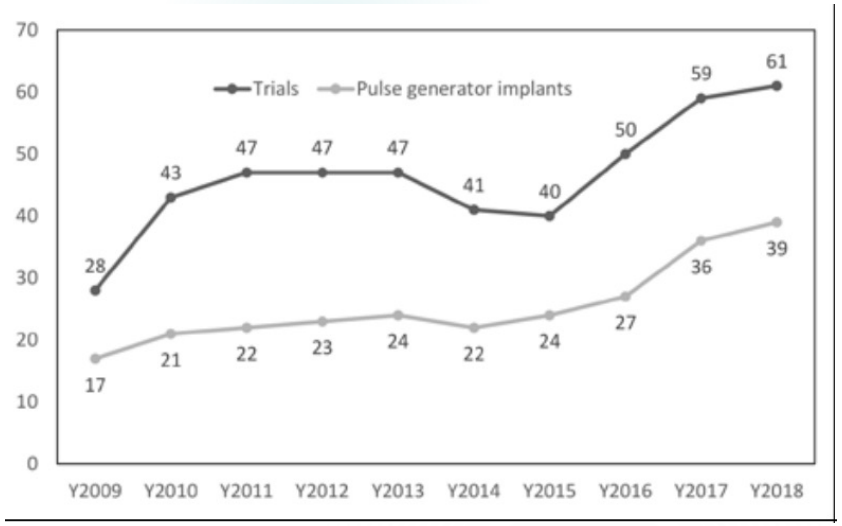


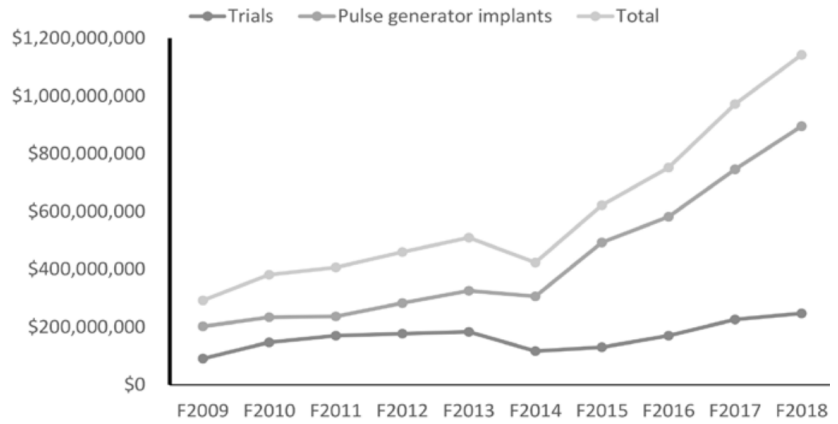
NACC Janvier 2022



Spinal Cord Stimulation for Neuropathic Pain in England From 2010 to 2020: A Hospital Episode Statistics Analysis

Rui V. Duarte, PhD[1]; Sarah Nevitt, PhD[1]; Rachel Houten, MSc[1]; Morag Brookes, MSc[2]; Jill Bell, BEd[3]; Jenny Earle, BA[3]; Rod S. Taylor, PhD[4,5]; Sam Eldabe, MD[2]





Pain Physician 2021; 24:293-308 • ISSN 1533-3159

Expenditure Analysis

Spinal Cord Stimulation Trends of Utilization and Expenditures in Fee-For-Service (FFS) Medicare Population from 2009 to 2018

Laxmaiah Manchikanti, MD[1], Vidyasagar Pampati, MSc[1], Bramha Prasad Vangala, MBBS[2], Amol Soin, MD[3], Mahendra R. Sanapati, MD[1], Srinivasa Thota, MD[1], and Joshua A. Hirsch, MD[4]

Méthodologie

Table 4. Levels of Evidence for Therapeutic Studies*

Level	Type of Evidence
1a	Systematic review (with homogeneity) of RCTs
1b	Individual RCT (with narrow confidence intervals)
1c	All-or-none study
2a	Systematic review (with homogeneity) of cohort studies
2b	Individual cohort study, including low-quality RCTs (e.g., <80% follow-up)
2c	"Outcomes" research; ecological studies
3a	Systematic review (with homogeneity) of case-control studies
3b	Individual case-control study
4	Case series (and poor quality cohort and case-control study)
5	Expert opinion without explicit critical appraisal or based on physiology, bench research, or "first principles"

RCT, randomized controlled trial.
*From the Centre for Evidence-Based Medicine (Web site). Available at: http://www.cebm.net. Accessed December 17, 2010.

The Levels of Evidence and Their Role in Evidence-Based Medicine

Patricia B. Burns, M.P.H.
Rod J. Rohrich, M.D.
Kevin C. Chung, M.D., M.S.
Ann Arbor, Mich.; and Dallas, Texas

Plastic and Reconstructive Surgery • July 2011

Moher *et al. Systematic Reviews* 2015, 4:1
http://www.systematicreviewsjournal.com/content/4/1/1

SYSTEMATIC REVIEWS

RESEARCH Open Access

Preferred reporting items for systematic review and meta-analysis protocols (PRISMA-P) 2015 statement

David Moher[1*], Larissa Shamseer[1], Mike Clarke[2], Davina Ghersi[3], Alessandro Liberati[^], Mark Petticrew[4], Paul Shekelle[5], Lesley A Stewart[6] and PRISMA-P Group

- Littérature : 1/1/2012-1/7/2022
- Meta-analyses/ Randomised Controlled Trials (RCT) / etudes de cohortes prospectives
- Inclusion : douleur
- Exclusion :
  - Rééducation marche
  - Instabilité posturale d'origine neurologique
  - Etat neurovegetatif
  - Modulation débit sanguin cérébral
- <u>2 considérations importantes</u> :
  - **Paresthésies induites empêchent la réalisation d'un double-aveugle avec groupe placebo ou sham**
  - **« absence de preuve ne signifie pas absence d'efficacité »**

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Section 4b2 : Indications

Module 11 : « Evidence-Based Medicine » en neuromodulation

Dr Jimmy VOIRIN

Société Française de Neurochirurgie

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SFETD

SFNM

HAS
HAUTE AUTORITÉ DE SANTÉ

BON USAGE DES TECHNOLOGIES DE SANTÉ

Neurostimulateurs médullaires implantables :
une technique de dernier recours

Les neurostimulateurs médullaires implantables sont des dispositifs médicaux conçus pour délivrer une stimulation électrique à visée antalgique par l'intermédiaire d'électrodes implantées en regard des cordons postérieurs de la moelle épinière. Ils sont utilisés dans les douleurs chroniques, notamment dans des situations où la prise en charge médicamenteuse ou les techniques non interventionnelles ont échoué. Le courant émis substitue à la douleur des paresthésies locales.

La HAS a récemment revu l'ensemble de la gamme des dispositifs existants pour mieux préciser leurs indications. Celles-ci apparaissent limitées aux échecs des autres méthodes de contrôle de la douleur, faisant des neurostimulateurs médullaires des dispositifs de dernier recours.

Compte tenu du faible niveau de preuve disponible pour les systèmes implantables de neurostimulation médullaire, aucune des données cliniques retenues ne permet de distinguer les indications des systèmes en fonction de leurs caractéristiques techniques. Il apparaît seulement préférable de réserver les systèmes rechargeables aux patients forts consommateurs en énergie.

HAS

Ce document a été élaboré à partir du rapport d'évaluation technologique de la Commission nationale d'évaluation des dispositifs médicaux et des technologies de santé (CNEDiMTS) : « Évaluation des systèmes implantables de neurostimulation médullaire (mars 2014). »

Ce rapport, comme l'ensemble des publications de la HAS, est disponible sur **www.has-sante.fr**

Mars 2014

Indications actuelles

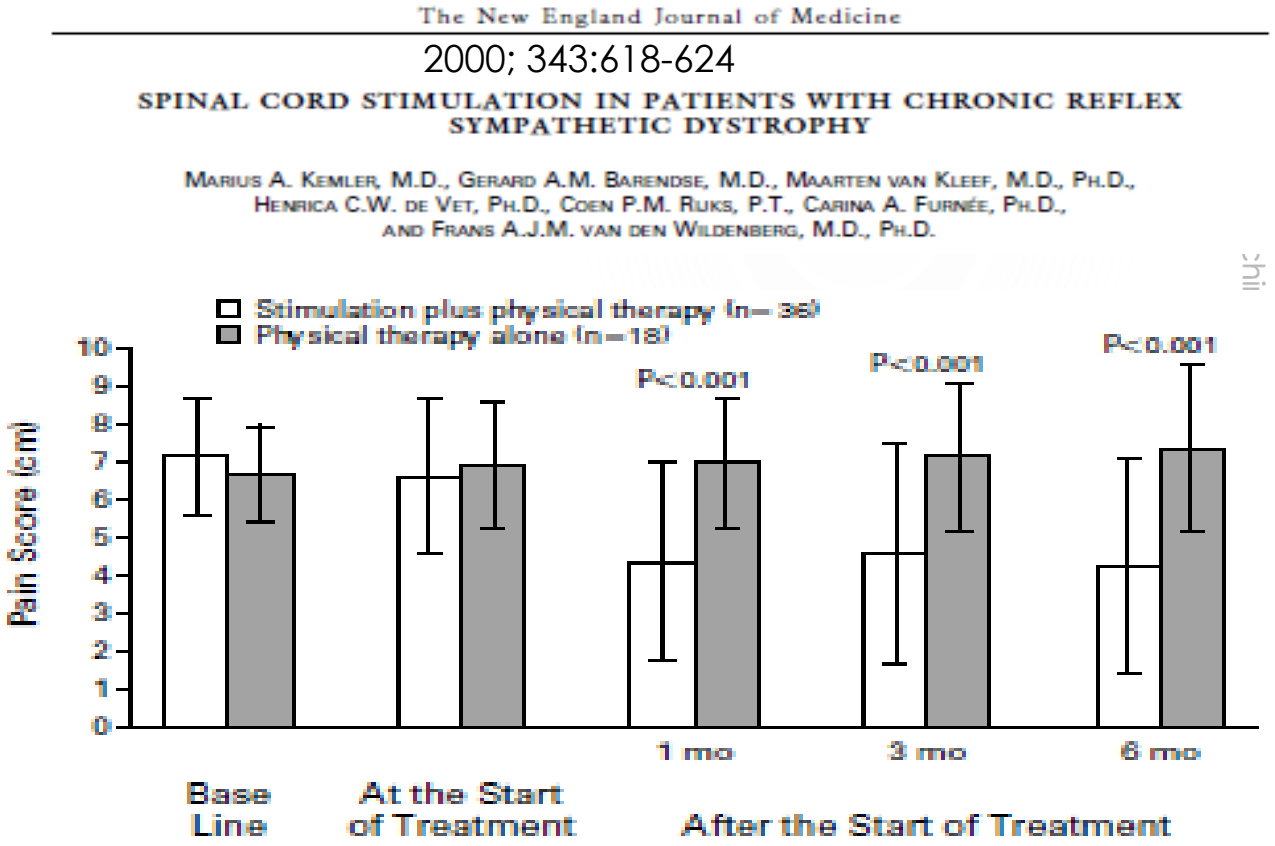
Neurostimulateurs médullaires implantables : une technique de dernier recours

Des indications relativement limitées

- **Les indications des systèmes implantables de neurostimulation médullaire** retenues par la HAS sont les suivantes :
  - **Douleurs chroniques d'origine neuropathique, après échec des alternatives thérapeutiques,** secondaires à :
    - un syndrome douloureux chronique radiculaire ou tronculaire d'origine diabétique, zostérienne, traumatique ou chirurgicale, persistant depuis au moins un an ;
    - un syndrome douloureux régional complexe (anciennement algodystrophie) de type I ou II persistant depuis au moins six mois.
  - Douleurs chroniques d'origine ischémique, après échec des alternatives thérapeutiques, secondaires à une **maladie de Buerger** (thrombo-angéite oblitérante touchant d'abord les artères des membres inférieurs).
- Les douleurs d'origine ischémique secondaires à l'artériopathie chronique oblitérante des membres inférieurs ne sont **pas retenues** comme indications de la neurostimulation médullaire, compte tenu de l'insuffisance des preuves cliniques.

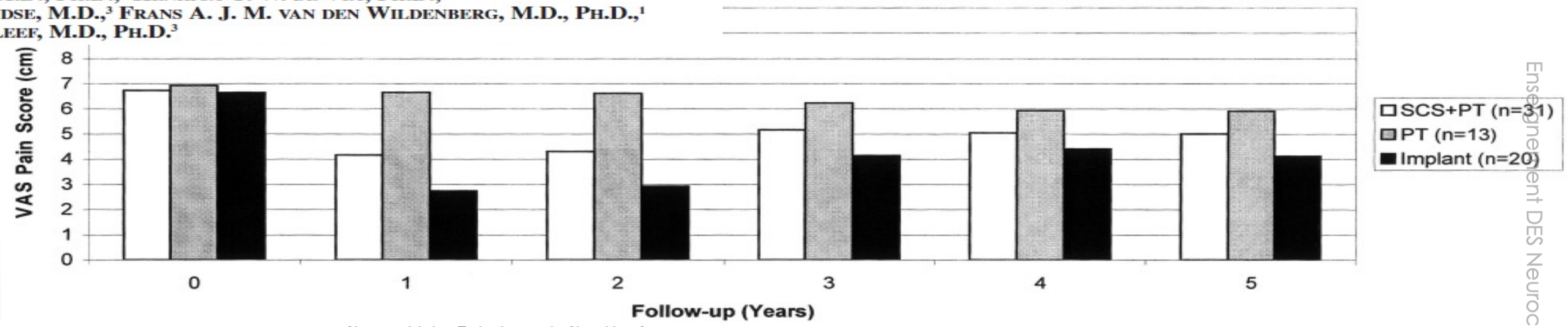
Algodystrophie / Syndrome Douloureux Complexe Régional (SDRC)

- RCT (2/1 : 54 patients 1997-98)
- SCS + rééducation Vs rééducation
- Objectif Principale: Réduction moyenne EVA à 6 mois
- Pas de placebo
- Financement : Dutch Health Insurance Council



Effect of spinal cord stimulation for chronic complex regional pain syndrome Type I: five-year final follow-up of patients in a randomized controlled trial

MARIUS A. KEMLER, M.D., PH.D.,[1] HENRICA C. W. DE VET, PH.D.,[2]
GERARD A. M. BARENDSE, M.D.,[3] FRANS A. J. M. VAN DEN WILDENBERG, M.D., PH.D.,[1]
AND MAARTEN VAN KLEEF, M.D., PH.D.[3]



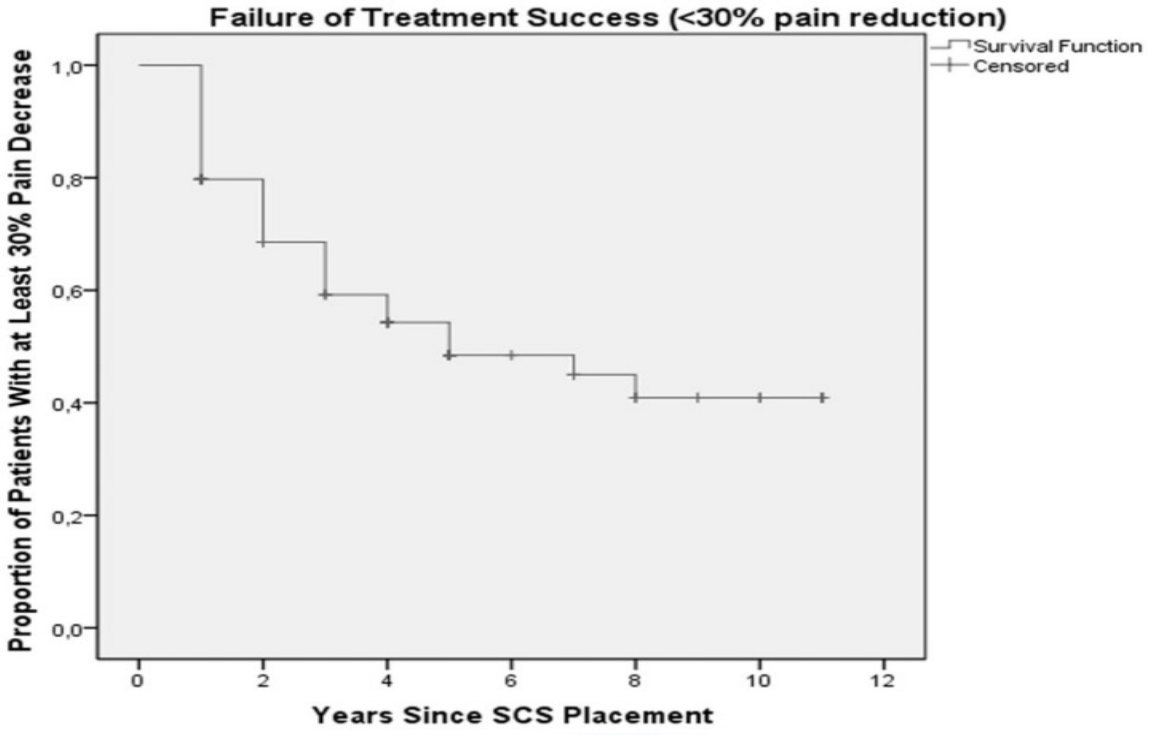
Neuromodulation: Technology at the Neural Interface

Received: June 25, 2012 Revised: December 10, 2012 Accepted: December 17, 2012

(onlinelibrary.wiley.com) DOI: 10.1111/ner.12024

Spinal Cord Stimulation for Complex Regional Pain Syndrome Type I: A Prospective Cohort Study With Long-Term Follow-Up

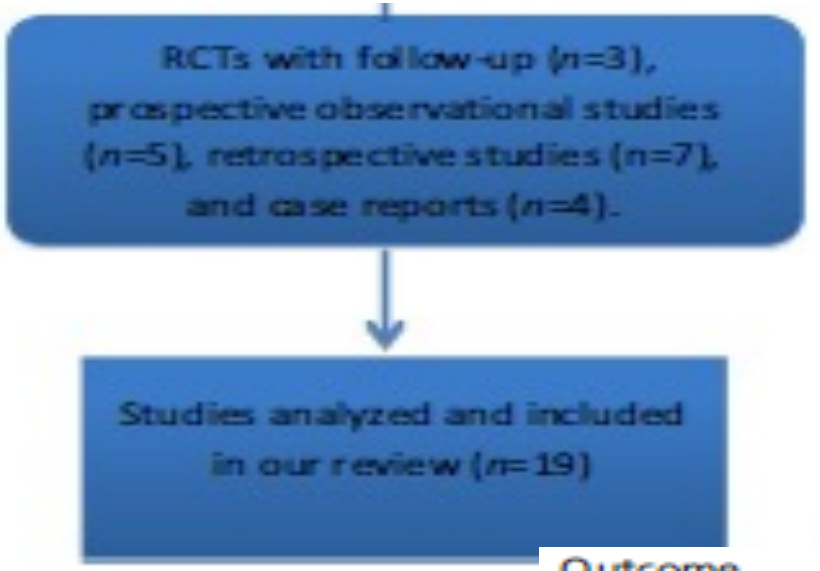
José W. Geurts MSc*, Helwin Smits MD PhD*, Marius A. Kemler MD PhD*, Florian Brunner MD PhD†, Alfons G. H. Kessels MD Msc‡, Maarten van Kleef MD PhD*



A Comprehensive Outcome-Specific Review of the Use of Spinal Cord Stimulation for Complex Regional Pain Syndrome

Pain Practice, Volume ●●, Issue ●, 2016 ●●–●●

Ognjen Visnjevac, MD*; Shrif Costandi, MD†; Bimal A. Patel, DO*; Girgis Azer, MD†; Priya Agarwal, MD*; Robert Bolash, MD†; Nagy A. Mekhail, MD, PhD†



Score	Description	Implication
1A+	Effectiveness demonstrated in various RCTs of good quality. The benefits clearly outweigh risks and burdens	Positive recommendation
1B+	One RCT, or more RCTs with methodological weaknesses, demonstrate effectiveness. The benefits clearly outweigh risks and burdens	
2B+	One RCT, or more RCTs with methodological weaknesses, demonstrate effectiveness. Benefits closely balanced with risks and burdens	
2B±	One or more RCTs with/without methodological weaknesses yielding contradictory results, leading to an uncertainty in estimating benefits, risks, or burdens	Consider, preferably for study-related application
2C+	Effectiveness only demonstrated in prospective observational studies, or well-designed retrospective studies. There is no conclusive evidence to the effect, but benefits appear to closely match risks and burdens	
0	There is either no literature, or there are only case reports available, or the date is of low quality and retrospective, but these are insufficient to prove effectiveness and/or safety	Study-related application only
1A–	Lack of effectiveness is demonstrated in various RCTs of good quality. The risks and burdens clearly outweigh the benefits	Negative recommendation
1B–	One RCT, or more RCTs with methodological weaknesses, demonstrate a lack of effectiveness. The risks and burdens clearly outweigh the benefits	
2B–	One RCT, or more RCTs with methodological weaknesses, demonstrate no superiority over control treatment. The risks and burdens outweigh the benefits	
2C–	Observational studies indicate no or too short-lived effectiveness. The risks and burdens outweigh the benefits	

Outcome	Score	Implication
Perceived pain relief	1B+	Recommended
Pain score improvement	1B+	Recommended
Resolution of CRPS signs	0	Study-related application
Functional status improvements	2B±	Considered, study related
Quality of life	1B+	Recommended
Psychological effects	2B±	Considered, study related
Sleep hygiene	0	Study-related application
Analgesic requirements	2C+	Considered, study related
Satisfaction with SCS	1B+	Recommended

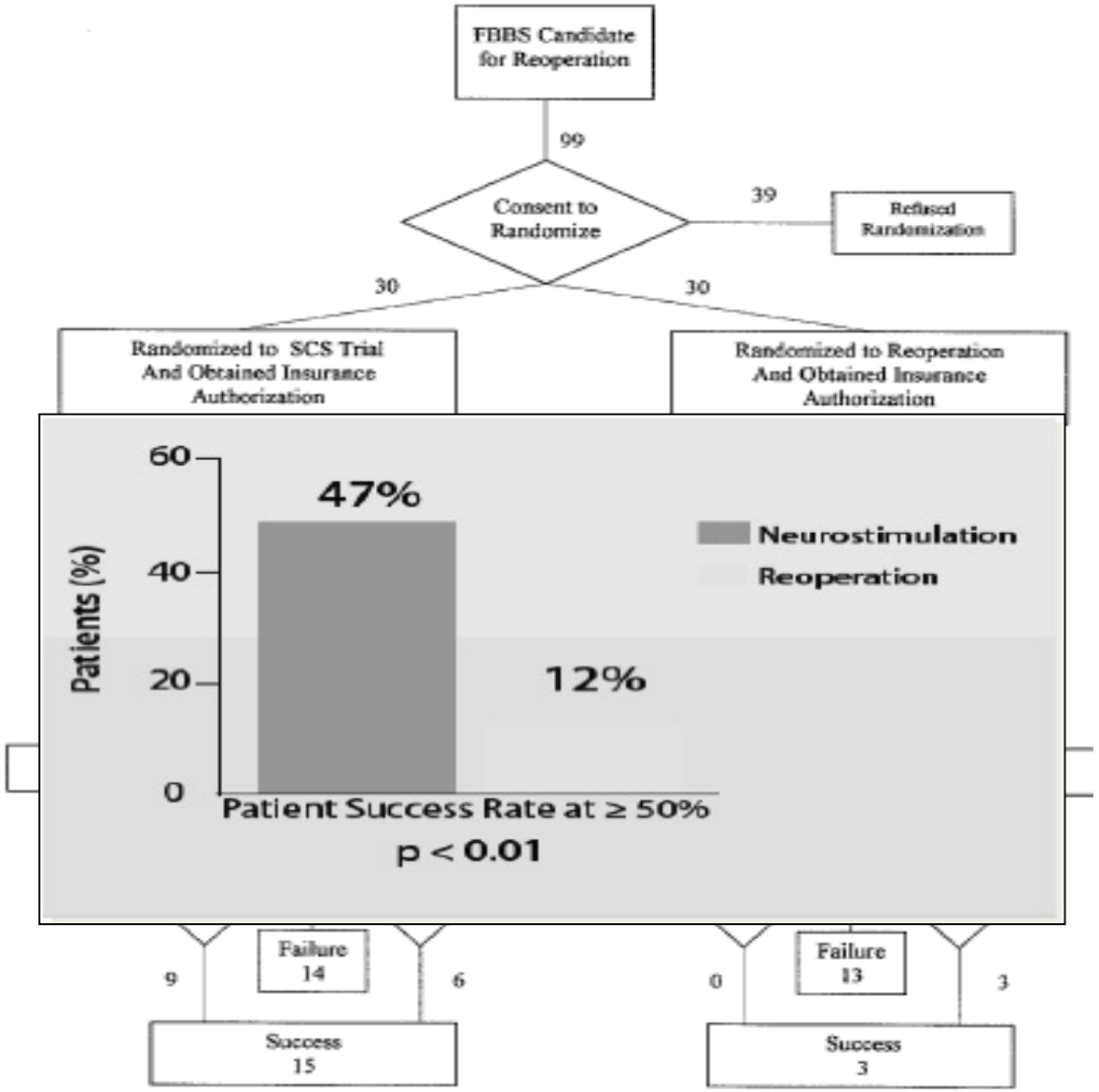
FBSS (2 RCT)

Medtronic

Richard B. North, M.D.
David H. Kidd, M.A.
Farrokh Farrokhi, M.D.
Steven A. Piantadosi, M.D., Ph.D.

Neurosurgery 56:98-107, 2005

Spinal Cord Stimulation versus Repeated Lumbosacral Spine Surgery for Chronic Pain: A Randomized, Controlled Trial

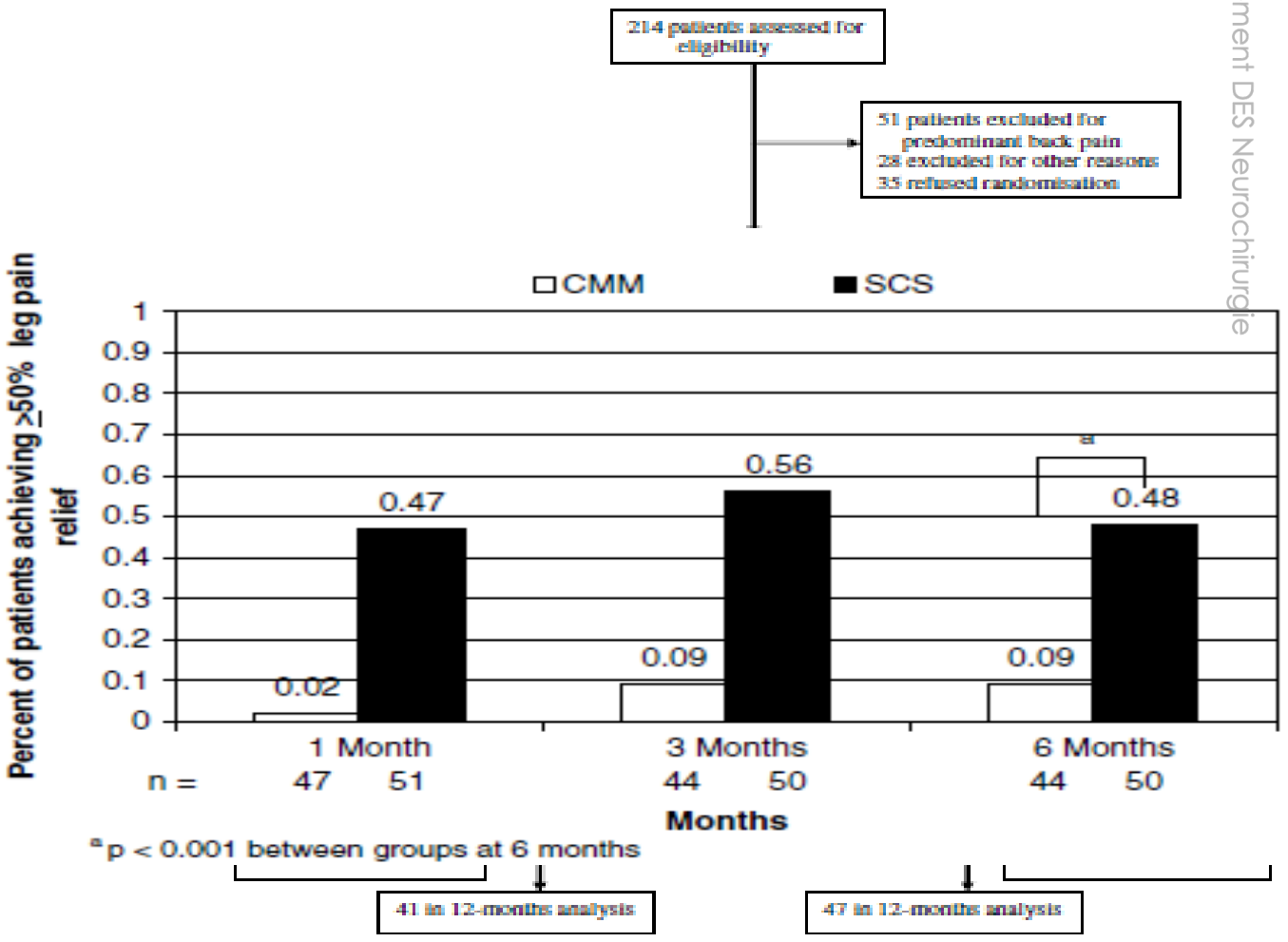


Medtronic

Pain 132 (2007) 179–188
www.elsevier.com/locate/p

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

Krishna Kumar [a,*], Rod S. Taylor [b], Line Jacques [c], Sam Eldabe [d], Mario Meglio [e], Joan Molet [f], Simon Thomson [g], Jim O'Callaghan [h], Elon Eisenberg [i],



PAIN

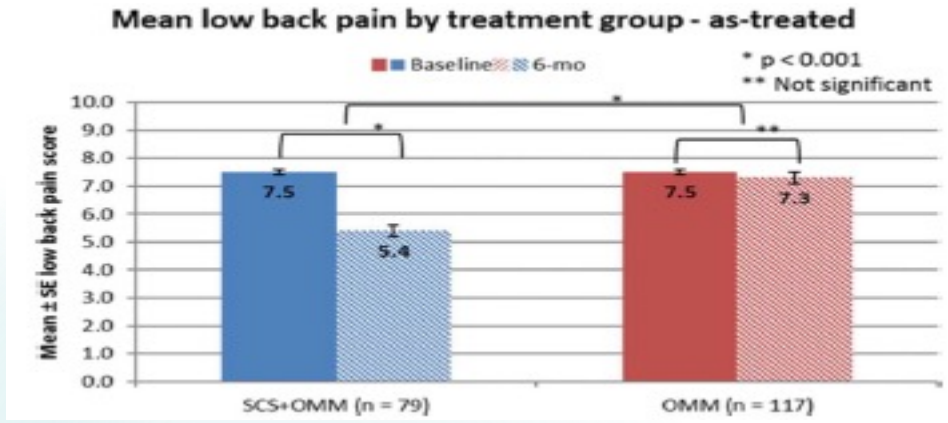
OPEN

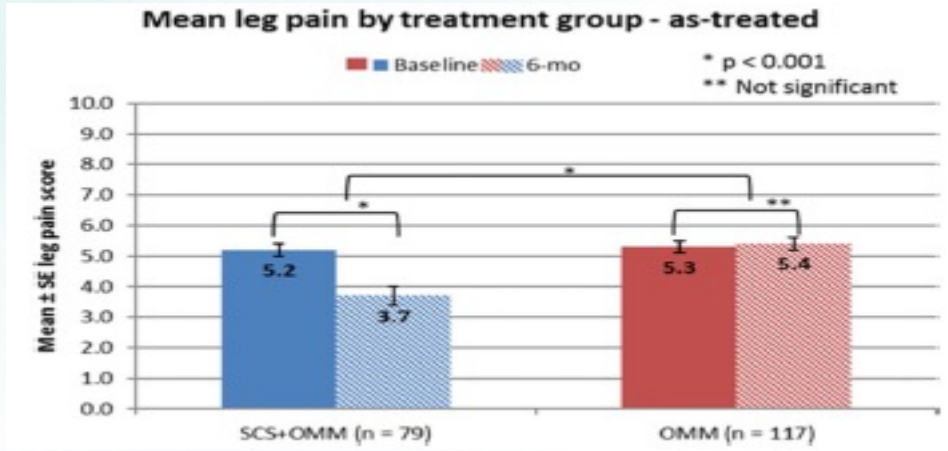
Medtronic

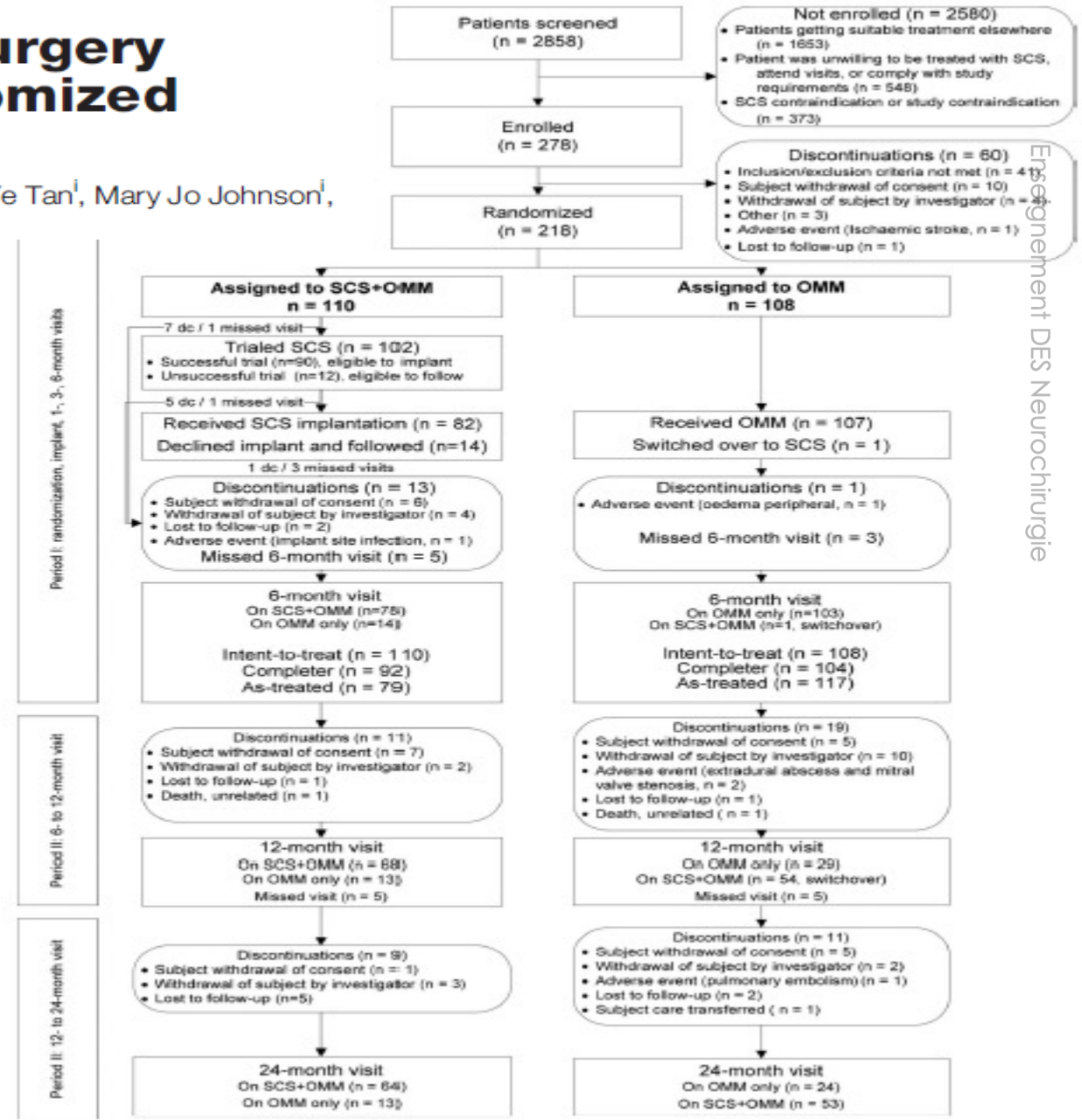
Multicolumn spinal cord stimulation for predominant back pain in failed back surgery syndrome patients: a multicenter randomized controlled trial

160 (2019) 1410–1420

Philippe Rigoard[a,b,c,*], Surajit Basu[d], Mehul Desai[e,f], Rod Taylor[g], Lieven Annemans[h], Ye Tan[i], Mary Jo Johnson[i], Carine Van den Abeele[j], PROMISE Study Group, Richard North[k,l]







- RCT (1:1 , 103 patients 2012-2015)
- Paramètres multicolonnes vs Mono
- OP: Réduction moyenne EVA à 6 mois
- Pas de placebo
- Financement : STIC 2011 (NCT01628237)

Neuromodulation: Technology at the Neural Interface

Received: February 21, 2020 Revised: June 5, 2020 Accepted: June 15, 2020

(onlinelibrary.wiley.com) DOI: 10.1111/ner.13251

How Should we Use Multicolumn Spinal Cord Stimulation to Optimize Back Pain Spatial Neural Targeting? A Prospective, Multicenter, Randomized, Double-Blind, Controlled Trial (ESTIMET Study)

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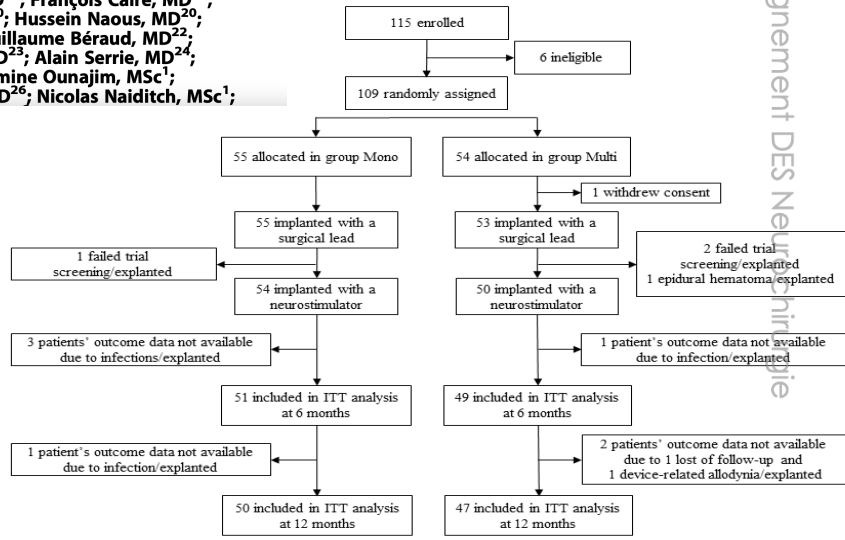
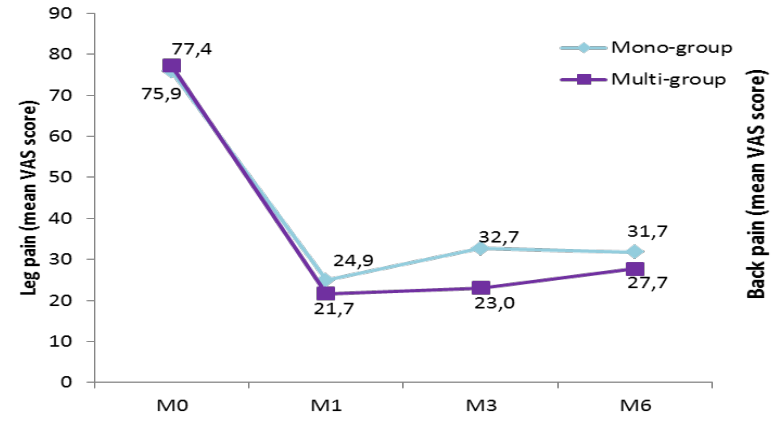
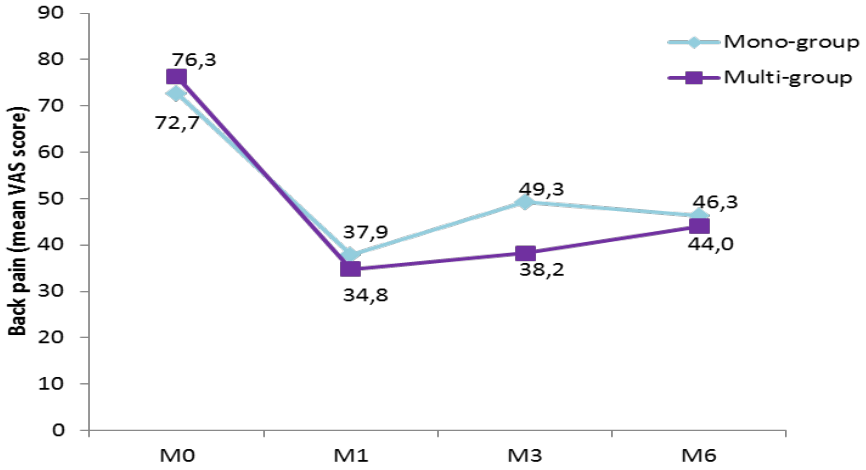
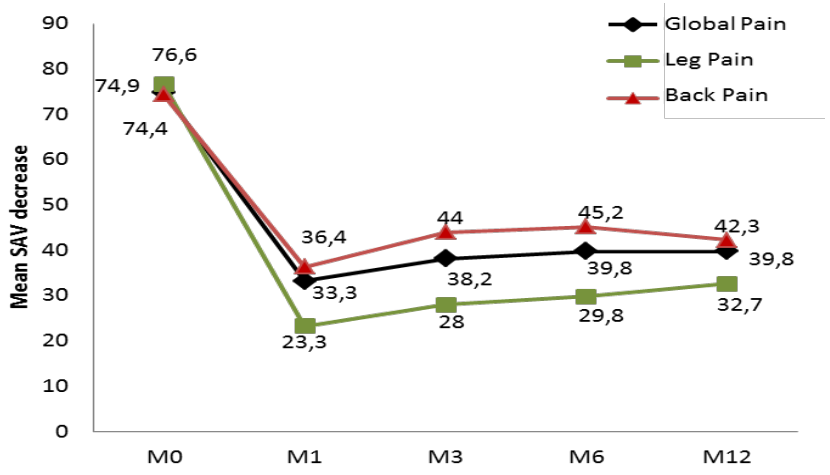








Meta-analysis / Review

Articles	M / R	CRPS	FBSS
Grabow et al., Clin J Pain 2003	R	B/C	NA
Cameron et al., JNS 2004	R	84%	62%
Turner et al., Pain 2004	R	NNT = 3	NA
Taylor et al., Spine 2005	M	NA	62% (3222pts)
Taylor et al., Eur J Pain 2006	M	A (I) / D (II)	NA
Cruccu et al., Eur J neurol 2007	R	B	B
Frey et al., Pain phy 2009	R	NA	1B
Atkinson et al., J Clin Neurosci 2011	R	Intermediate	Strong
Cruccu et al. Eur j Neurol 2016	R	Weak	Weak

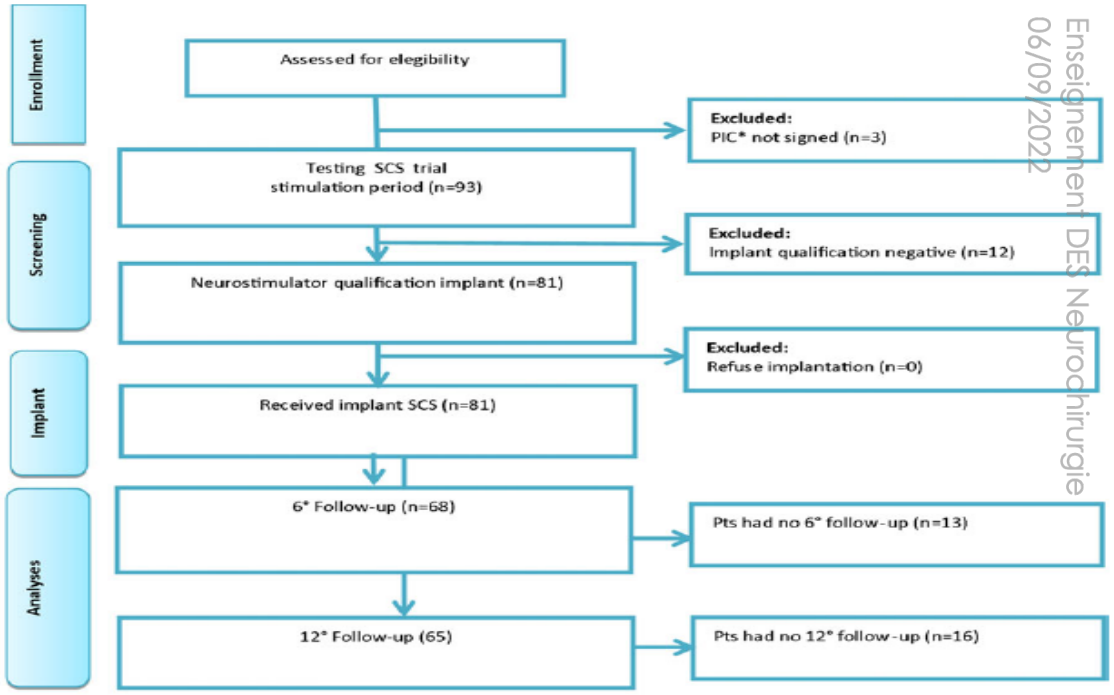
Cohortes Prospectives / Registres

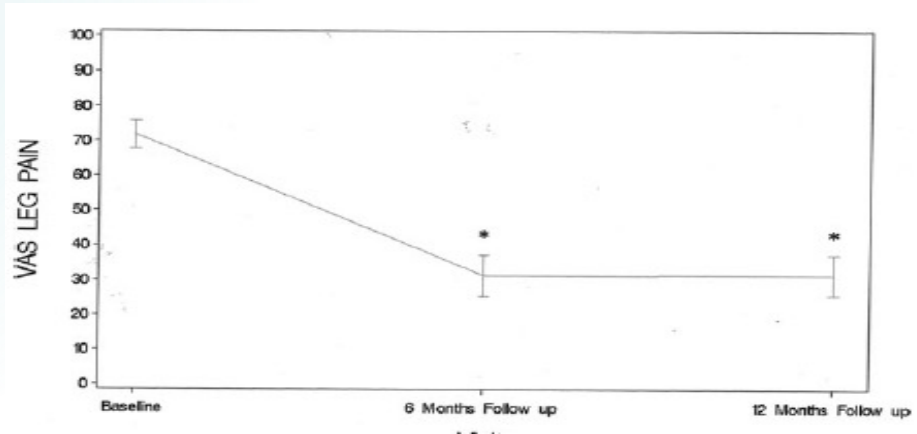
Evaluation of the Effectiveness of Percutaneous Octapolar Leads in Pain Treatment with Spinal Cord Stimulation of Patients with Failed Back Surgery Syndrome During a 1-Year Follow-Up: A Prospective Multicenter International Study

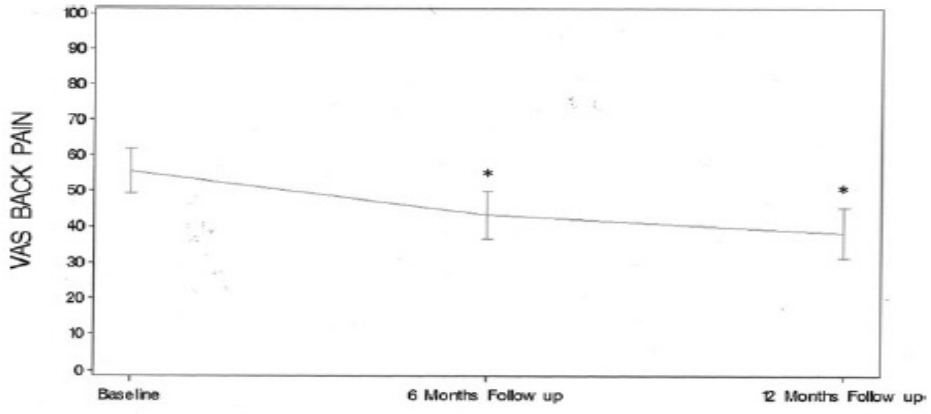
Pain Practice, Volume 17, Issue 4, 2017 428–437

Kliment Gatzinsky, MD, PhD*; Roald Baardsen, MD†; Hendrik P. Buschman, PhD‡

- International Multi center
- 93 patients (2009-2013)
- Single 8 contacts perctuaneous electrode
- No sham stimulation







Received: 5 April 2018 | Revised: 10 December 2018 | Accepted: 21 December 2018

DOI: 10.1002/ejp.1355

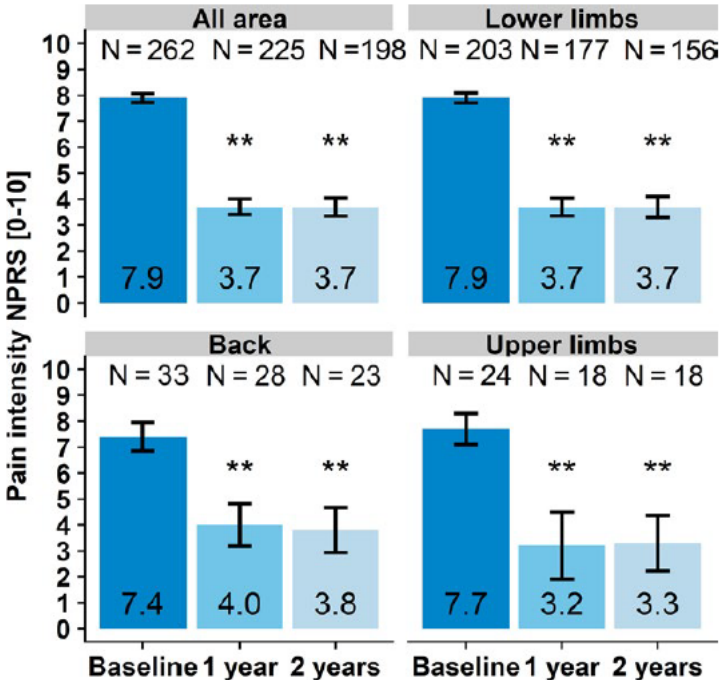
ORIGINAL ARTICLE

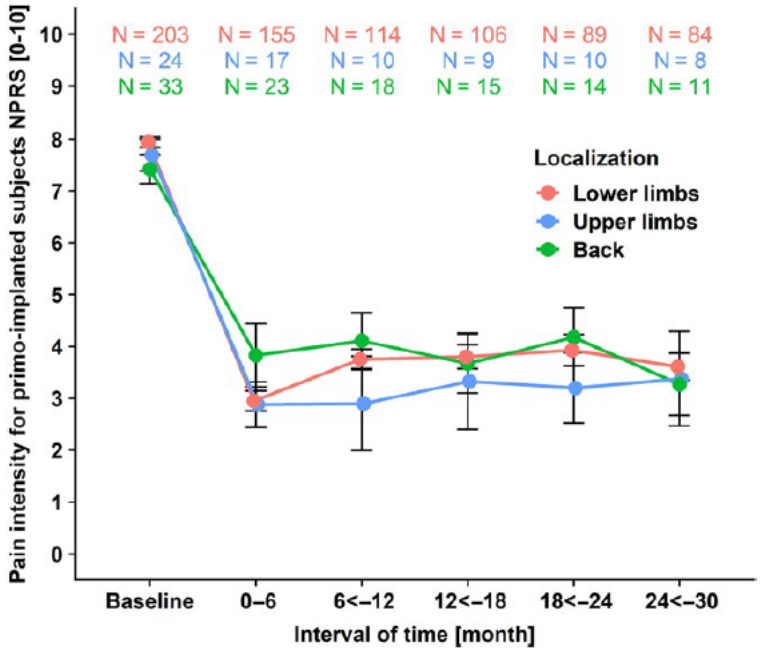
WILEY EJP European Journal of Pain

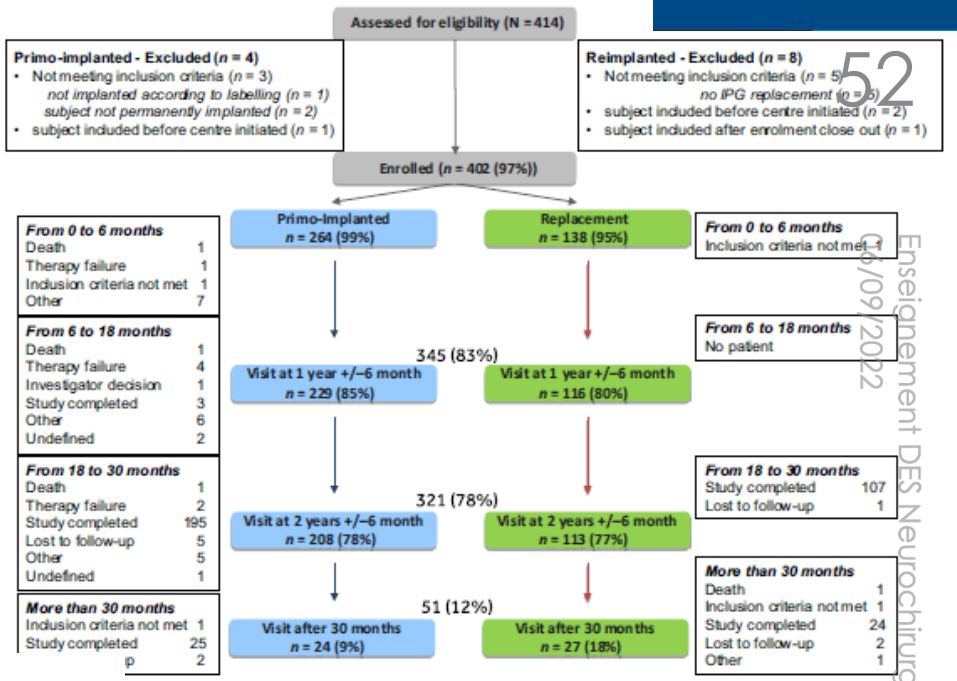
Spinal cord stimulation for chronic refractory pain: Long-term effectiveness and safety data from a multicentre registry

Andrei Brinzeu[1] | Emmanuel Cuny[2] | Denys Fontaine[3,4] | Patrick Mertens[1] | Pierre-Philippe Luyet[5] | Carine Van den Abeele[5] | Marie-Christine Djian[6] |

on behalf of the French SCS Study Group

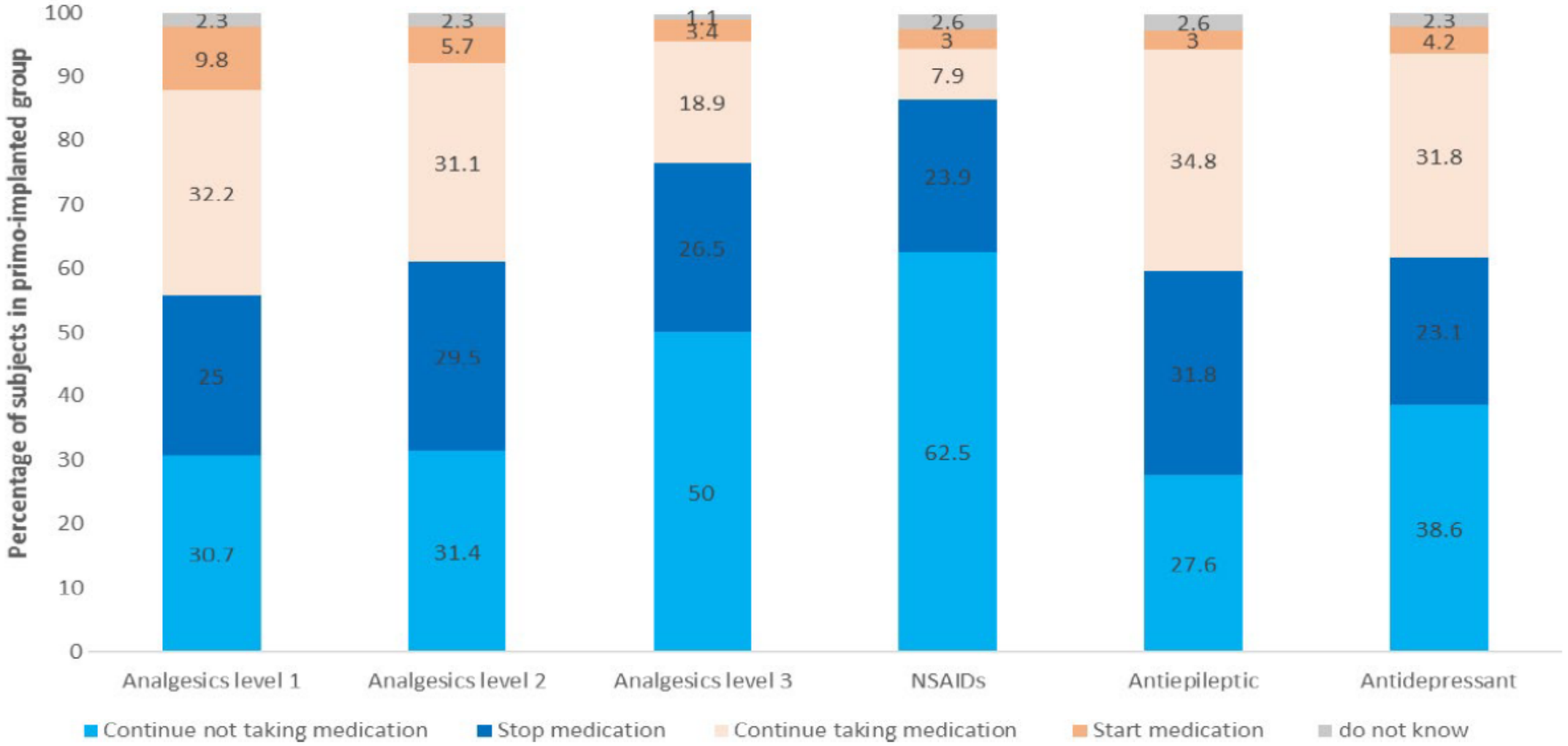






Patient population set	Primo-implanted N (%)	Replacement N (%)
Enrolled patients	268 (100)	146 (100)
Excluded subjects	4 (1.5)	8 (5.5)
Full analysis set (FAS):	264 (98.5)	138 (94.5)
Intended-to-treat set – (ITT) imputation [a]:	264 (98.5)	- -
Intended-to-treat set – (ITT) completer [b]:	198 (73.9)	- -

Evolution of pain medication between baseline and last follow-up



Acta Neurochir
DOI 10.1007/s00701-015-2352-5

CLINICAL ARTICLE - FUNCTIONAL

Epidural spinal cord stimulation for neuropathic pain: a neurosurgical multicentric Italian data collection and analysis

Elena Virginia Colombo · Carlo Mandelli · Pietro Mortini · Giuseppe Messina · Nicola De Marco · Roberto Donati · Claudio Irace · Andrea Landi · Angelo Lavano · Massimo Mearini · Stefano Podetta · Domenico Servello · Edvin Zekaj · Carlo Valtulina · Ivano Dones

Parameters	Baseline	12 months	Primary outcome	*P* value
No-Trial				
Axial VAS	30	20	0 % (one patient)	–
Lower limbs VAS	90 (80–90)	30 (20–50)	68.8 %	<0.001
Prevalent VAS	90 (80–90)	30 (20–50)	71.4 %	<0.001
Trial				
Axial VAS	80 (55–90)	40 (10–65)	56.3 %	0.003
Lower limbs VAS	80 (70–90)	30 (10–60)	60 %	<0.001
Prevalent VAS	80 (70–90)	30 (10–60)	59.5 %	<0.001

Table 4 Quality of life outcomes

Parameter	Baseline	12 months	*P* value
No-Trial			
EQ5D Index	0.38±0.36	0.66±0.10	0.044
EQ5D VAS	53.3±27.4	78.9±10.5	0.025
ODI	47.0±14.1	19.8±10.4	<0.001
SF-36 PCS	28.4±4.6	43.1±7.3	<0.001
SF-36 MCS	35.6±8.1	40.3±6.1	0.245
Trial			
EQ5D Index	0.26±0.33	0.65±0.28	<0.001
EQ5D VAS	41.4±20.4	68.3±17.9	<0.001
ODI	47.7±13.9	24.9±19.0	<0.001
SF-36 PCS	29.9±5.8	42.5±10.9	<0.001
SF-36 MCS	38.9±10.1	44.2±10.0	0.164

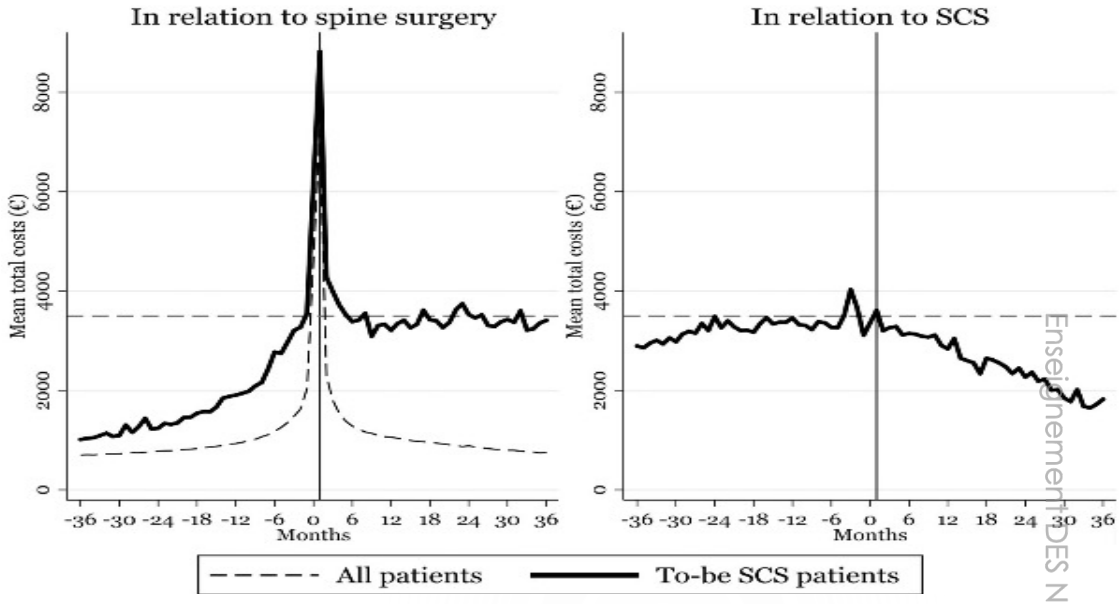
Neuromodulation: Technology at the Neural Interf
Received: March 18, 2019 Revised: August 13, 2019 Accepted: August 19, 2019
(onlinelibrary.wiley.com) DOI: 10.1111/ner.13056

Cost and Health Outcomes Patterns in Patients Treated With Spinal Cord Stimulation Following Spine Surgery—A Register-Based Study

Emma Jonsson, MSc*; Amanda Hansson-Hedblom, MSc*; Terje Kirketeig, MD†‡; Peter Fritzell, MD, PhD§¶; Olle Hägg, MD, PhD; Fredrik Borgström, PhD*††**

CONCLUSIONS

In summary, the initial spine surgery appeared not to have any effect on pain, QoL, or costs in patients who were eventually treated for SCS. It is expected that patients who are treated with SCS after spine surgery would have worse outcomes of the spine surgery compared with the total spine surgery group, as it is highly probable that they have received SCS for persisting pain. However, the to-be SCS patients were notably worse off in terms of pain intensity and quality of life already at the baseline spine surgery. This may warrant for investigating the possibility of identifying these patients for SCS treatment even before the spine surgery. There might be a proportion of patients who could benefit from SCS treatment, but who in fact were not treated with SCS, potentially due to restricted access. In this study, it was not possible to identify these patients as we did not have data on, for example, patient history and clinical examinations. Future research may investigate whether there are potential improvements in health outcomes and cost-savings if more patients with persistent pain following spine surgery could be identified and treated with SCS, as well as patients could be ruled out for spine surgery based on baseline data.



In this study, more than 70,000 patients who underwent lumbar spine surgery were identified, whereof 239 patients (0.3%) were identified to have subsequently received permanent SCS. The

Authors	Cost/intervention/yr CMM	Cost/intervention/yr SCS	QALYs/intervention/yr CMM	QALYs/intervention/yr SCS	Incremental Cost/QALY
Farber et al[15]	$10 103.9	$9611	N/P	N/P	N/P
Zucco et al[16]	€6567	€13 216	N/P	0.173*	€3222
Annemans et al[17]	€5374	€5761	0.221	0.343	€3153
Kumar and Rizvi[18]	$CDN 7676	$CDN 8322	0.173	0.242	$CDN 9293
Hollingworth et al[19]	$19 151	$18 195	N/P	N/P	$USD 335 000
Taylor et al[20]	€5466	€5934	0.271	0.354	€5622

Special Issue Article

AO SPINE North America

Global Spine Journal
2021, Vol. 11(1S) 66S-72S

DOI: 10.1177/2192568220970163
journals.sagepub.com/home/gsj
SAGE

A Systematic Review of the Cost-Utility of Spinal Cord Stimulation for Persistent Low Back Pain in Patients With Failed Back Surgery Syndrome

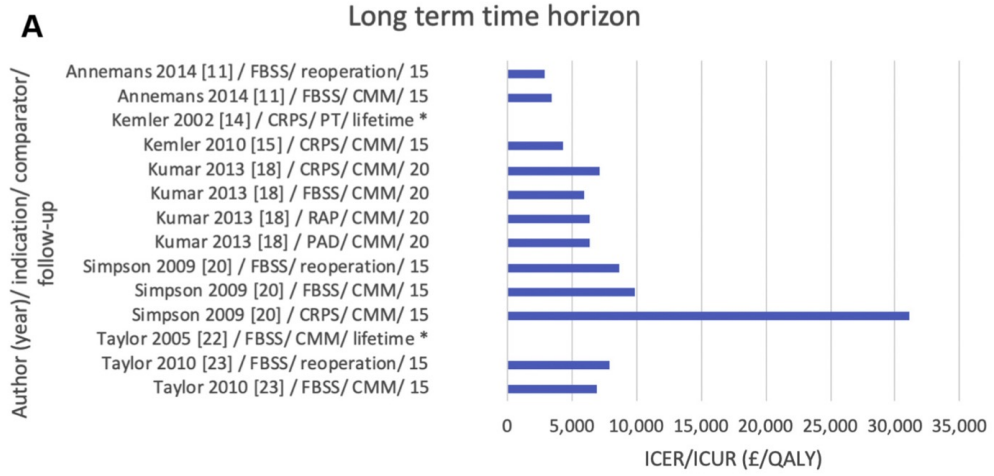
Jesse J. McClure, PharmD, PhD[1], Bhargav D. Desai, MD[1], Leonel Ampie, MD[1,2], Wen You, PhD[1], Justin S. Smith, MD, PhD[1], and Avery L. Buchholz, MD, MPH[1]

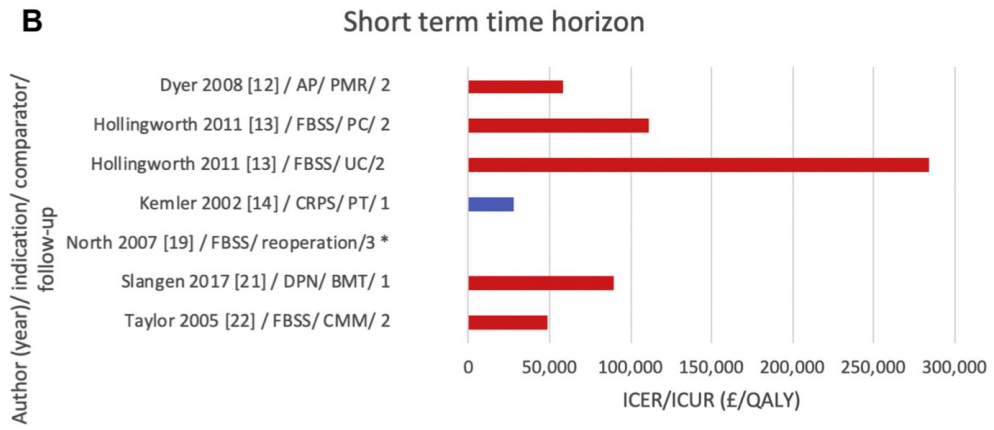
ScienceDirect
Contents lists available at sciencedirect.com
Journal homepage: www.elsevier.com/locate/jval

Systematic Literature Review

A Systematic Review of Economic Evaluations Reporting the Cost-Effectiveness of Spinal Cord Stimulation

Siwaporn Niyomsri, MSc,[1,2] Rui V. Duarte, PhD,[1,*] Sam Eldabe, MD,[3] Gregory Fiore, MD,[4] Brian H. Kopell, MD,[5] Ewan McNicol, PharmaD,[6,7] Rod S. Taylor, PhD[8,9]





PAIN® 155 (2014) 2426–2431

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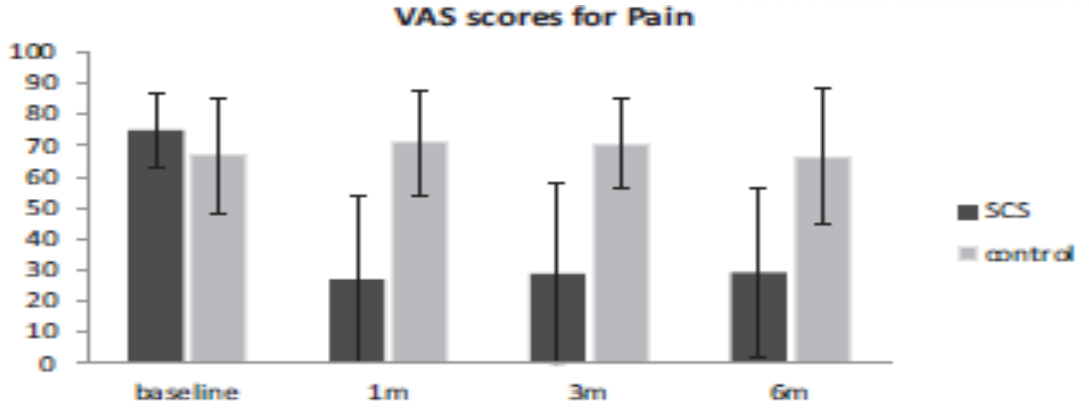
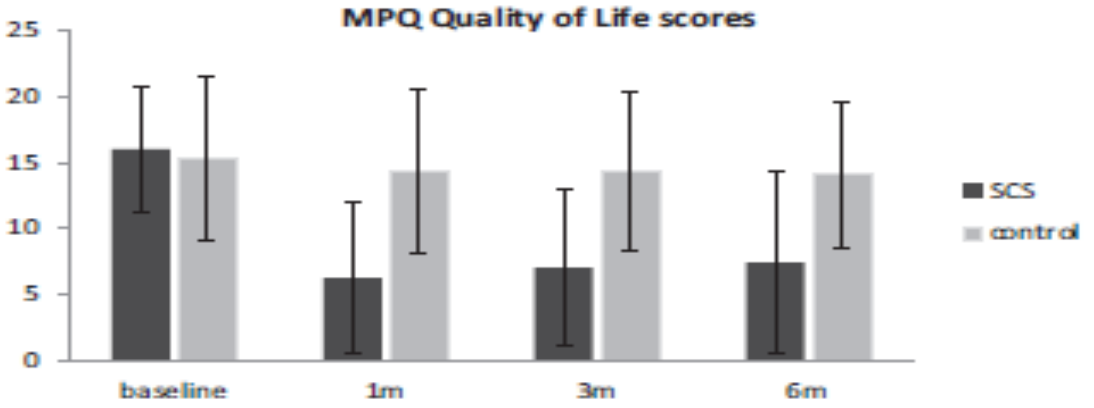
Clinical note

Spinal cord stimulation in patients with painful diabetic neuropathy: A multicentre randomized clinical trial

Cecile C. de Vos [a,b,c,*], Kaare Meier [d], Paul Brocades Zaalberg [e], Harold J.A. Nijhuis [f], Wim Duyvendak [g], Jan Vesper [h], Thomas P. Enggaard [i], Mathieu W.P.M. Lenders [a,c]

- RCT : 7 centers international
- 60 pts (2:1 2008-2012)
- SCS vs OMM
- OP: %patients with >50% decrease VAS
- Pas de placebo





Spinal Cord Stimulation and Pain Relief in Painful Diabetic Peripheral Neuropathy: A Prospective Two-Center Randomized Controlled Trial

Rachel Slangen,[1] Nicolaas C. Schaper,[2] Catharina G. Faber,[3] Elbert A. Joosten,[1] Carmen D. Dirksen,[4,5] Robert T. van Dongen,[6] Alfons G. Kessels,[4] and Maarten van Kleef[1,7]

Diabetes Care 2014;37:3016–3024 | DOI: 10.2337/dc14-0684

Medtronic

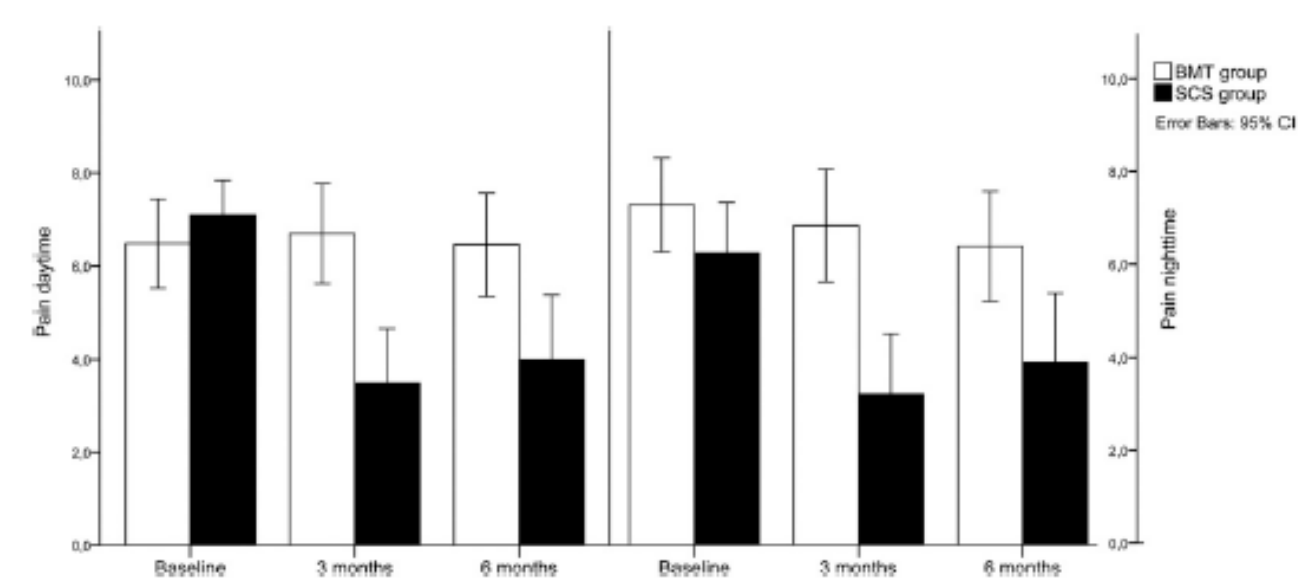
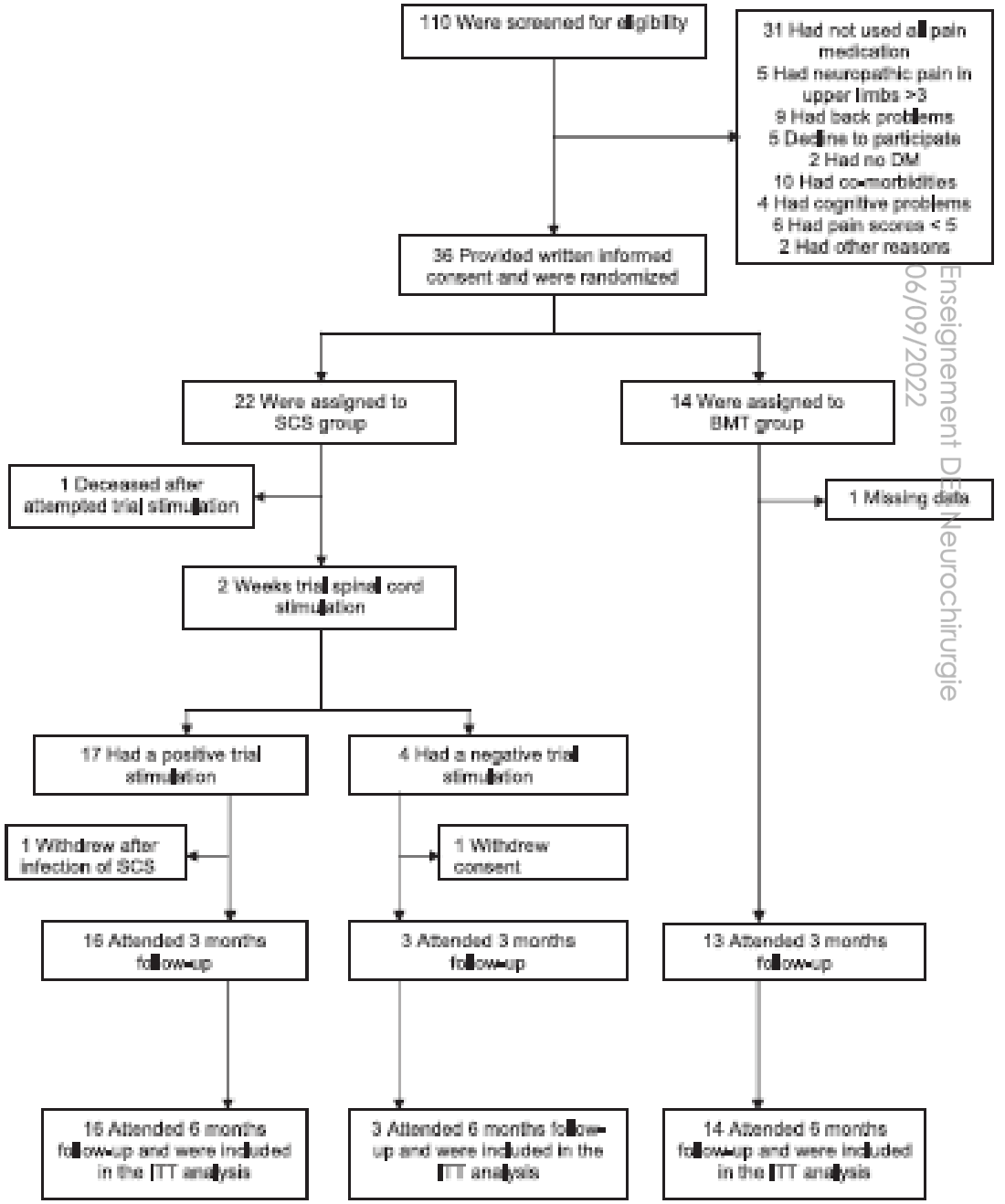


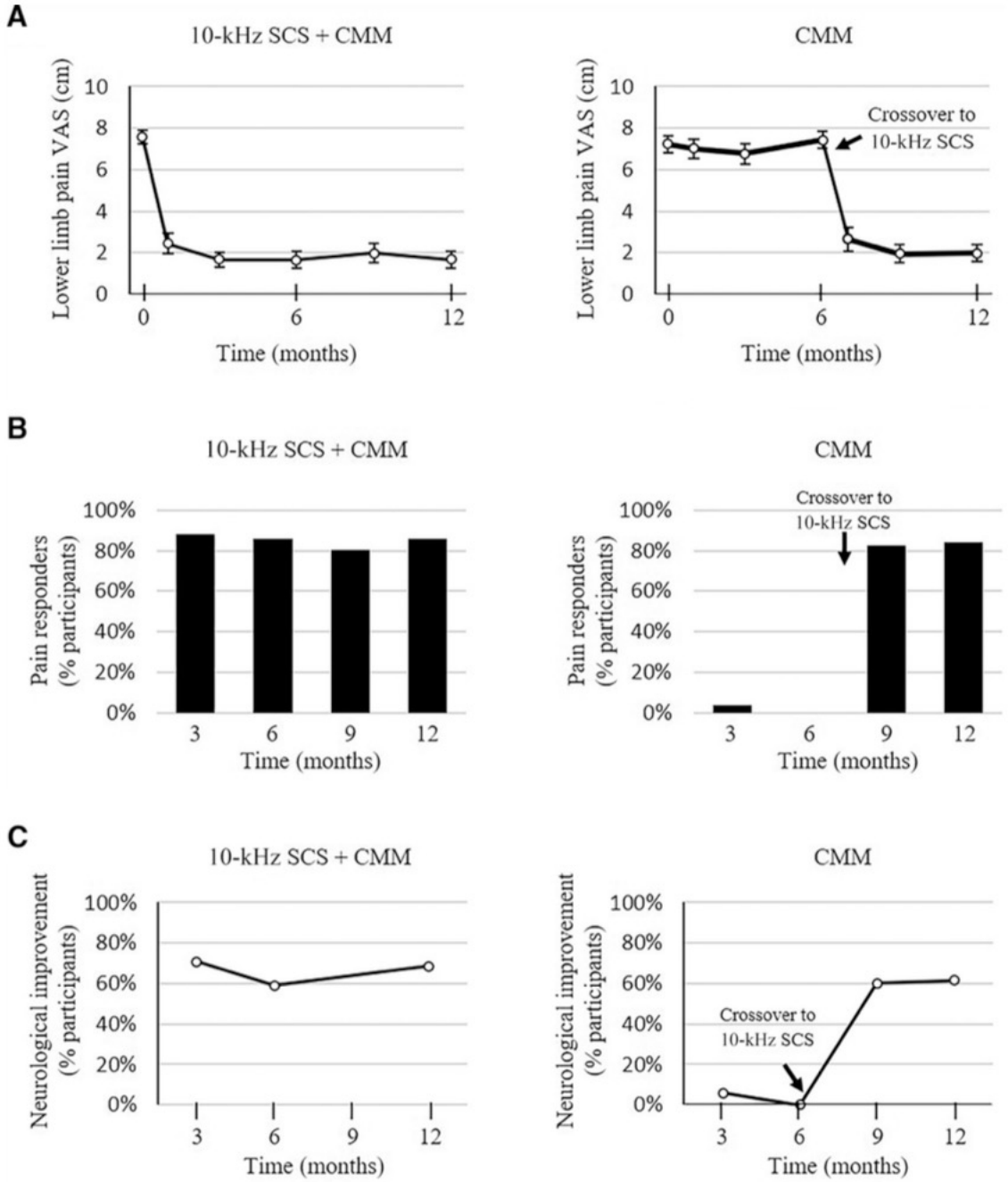
Figure 2—Mean pain scores at daytime and nighttime. ITT analysis.



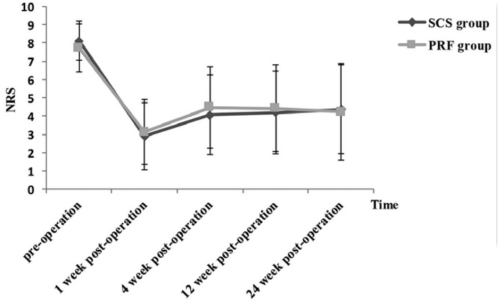
Durability of High-Frequency 10-kHz Spinal Cord Stimulation for Patients With Painful Diabetic Neuropathy Refractory to Conventional Treatments: 12-Month Results From a Randomized Controlled Trial

Diabetes Care 2022;45:e3–e6 | https://doi.org/10.2337/dc21-1813

Erika A. Petersen,[1] Thomas G. Stauss,[2] James A. Scowcroft,[3] Elizabeth S. Brooks,[4] Judith L. White,[5] Shawn M. Sills,[6] Kasra Amirdelfan,[7] Maged N. Guirguis,[8] Jijun Xu,[9] Cong Yu,[10] Ali Nairizi,[11] Denis G. Patterson,[11] Kostandinos C. Tsoulfas,[2] Michael J. Creamer,[12] Vincent Galan,[13] Richard H. Bundschu,[14] Neel D. Mehta,[15] Dawood Sayed,[16] Shivanand P. Lad,[17] David J. DiBenedetto,[18] Khalid A. Sethi,[19] Johnathan H. Goree,[20] Matthew T. Bennett,[19] Nathan J. Harrison,[8] Atef F. Israel,[3] Paul Chang,[13] Paul W. Wu,[21] Charles E. Argoff,[22] Christian E. Nasr,[23] Rod S. Taylor,[24] David L. Caraway,[4] and Nagy A. Mekhail[9]



Autres douleurs neuropathiques



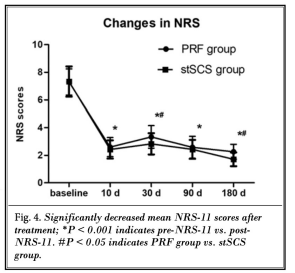


Fig. 4. *Significantly decreased mean NRS-11 scores after treatment; *P < 0.001 indicates pre-NRS-11 vs. post-NRS-11. #P < 0.05 indicates PRF group vs. stSCS group.*

- **Post-Zostériennes :**
  - 10 CS – 245 patients
  - Mean VAS reduction = 64.4% (Texakalidis et al., Stereo Funct neurosurg 2019;97:55–65)
  - 1 RBP : 2C+ (recherche) (Van Wijck et al., Pain Pract 2011; 11(1):88-97)
  - 2 RCT : SCS vs PRF (Liu et al., Pain Physician 2020: 23:263-270, Wan et AL. Pain Phy 2022:24:215-222)
  - 1 méta analyse (Xue Medicine 2022, in press)
- **HIV :**
  - 2 CS : Knezevic et al. Pain Physician. 2015 Jul-Aug;18(4):E643-50 / Abd-Elsayed et al. J Clin Anaesth 2016 28:74-7
- **Lyme** :
  - 1 CS : Shui et al. pain Phy 2012 15:511-4
- **Toxiques :**
  - Post-chimiothérapie : 4 CS
- **Cancer :**
  - 4 CS + 7 case
  - 1 review Cochrane : Peng et al. Cochrane Database Syst Rev. 2015 Jun 29;(6):CD009389
- **Postopératoires :**
  - Herniorapphie: 2 CS : Elias, M. Neuromodulation 2000, 3, 155–157; Lepski, Neuromodulation 2013, 16, 84–88.
  - Post-Thoracotomie : Graybill et al. Pain Phy 2011 14:441-5

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(onlinelibrary.wiley.com) DOI: 10.1111/ner.12208

The Appropriate Use of Neurostimulation of the Spinal Cord and Peripheral Nervous System for the Treatment of Chronic Pain and Ischemic Diseases: The Neuromodulation Appropriateness Consensus Committee

Timothy R. Deer, MD[1]; Nagy Mekhail, MD, PhD[2]; David Provenzano, MD[3]; Jason Pope, MD[1]; Elliot Krames, MD[4]; Michael Leong, MD[5]; Robert M. Levy, MD, PhD[6]; David Abejon, MD[7]; Eric Buchser, MD[8,9]; Allen Burton, MD[10]; Asokumar Buvanendran, MD[11]; Kenneth Candido, MD[12]; David Caraway, MD, PhD[13]; Michael Cousins, MD[14];

Table 9. Recommendations for Disease-Specific Indications and Considerations Made by the Neuromodulation Appropriateness Consensus Committee of the International Neuromodulation Society Using U.S. Preventive Services Task Force Criteria.

Disease-specific indications	USPSTF evidence strength (9)	USPSTF recommendation strength (9)
The use of SCS early in the treatment algorithm for failed back surgery syndrome in the absence of neurological progression requiring surgical intervention with persistent axial and radicular complaints (121,125–127)	I	A
The use of SCS should be either conventional SCS or DRG stimulation when the pain is dominantly radicular in nature	II-2	B
The use of cervical SCS for the treatment of upper extremity pain of neuropathic pain syndromes affecting the upper extremities, including, but not limited to, radiculopathy	II-2	A
The use of SCS for the treatment of CRPS-I and CRPS-II	I	A
The use of SCS with pacemakers appears to be safe in most settings (128)	III	C
The use of neurostimulation has been shown to have a better outcome if used early in the course of the disease process; SCS and PNS would be considered earlier, when possible, and recommended to be trialed within the first two years of chronic pain (129,130)	II-3	B
High-frequency stimulation or burst stimulation may be helpful in treating axial back pain and those with tonic stimulation resistance	III	I, consensus panel strong
DRG stimulation should be trialed for discrete areas of neuropathic pain	II-1	B
The NACC recommends SCS as an early intervention in patients with Raynaud's syndrome and other painful ischemic vascular disorders; if ischemic symptoms persist despite initial surgical or reasonable medical treatment, SCS should be trialed (131)	II-3	C

SCS Study Quality Analysis: Complex Regional Pain Syndrome

- USPSTF: Level 1 evidence based upon one randomized trial with SCS + PT vs PT alone for CRPS.
- mIMP-QRB: The one randomized trial was judged to be of high quality and would be classified as Level 1 evidence. The lack of other randomized trials in this category limits the generalization of the results, as at least two randomized trials are required for classification as Level 1.
- Cochrane criteria: Supports the findings of mIMP-QRB, as the Cochrane evaluation for the Kemler et al. study [17] demonstrated low to moderate risk of bias.

SCS Study Quality Analysis: Axial Back and Radicular Pain

- USPSTF: Level 1 evidence based upon five RCTs for SCS in the treatment of low back pain with and without radicular pain, neuropathic pain, and neuropathic pain of other origin.
- mIMP-QRB: Level 1 evidence based upon five studies of high-quality design consistent with construction using the CONSORT methods.
- Cochrane criteria: Supports the findings of the mIMP-QRB criteria as the five studies meet criteria for low to moderate risk of bias.

Pain Medicine, 21(7), 2020, 1421–1432
doi: 10.1093/pm/pnz353
Advance Access Publication Date: 29 May 2020
Review Article
OXFORD

A Systematic Literature Review of Spine Neurostimulation Therapies for the Treatment of Pain

Timothy R. Deer, MD,* Jay S. Grider, DO, PhD, MBA,† Tim J. Lamer, MD,‡ Jason E. Pope, MD,§ Steven Falowski, MD,¶ Corey W. Hunter, MD,‖ David A. Provenzano, MD,‖ Konstantin V. Slavin, MD,** Marc Russo, MD,†† Alexios Carayannopoulos, DO, MPH,‡‡,§§ Jay M. Shah, MD,¶¶ Michael E. Harned, MD,† Jonathan M. Hagedorn, MD,‡ Robert B. Bolash, MD,*** Jeff E. Arle, MD, PhD,††† Leo Kapural, MD,‡‡‡ Kasra Amirdelfan, MD,§§§ Sameer Jain, MD,¶¶¶ Liong Liem, MD,**** Jonathan D. Carlson, MD,†††† Mark N. Malinowski, DO,‡‡‡‡ Markus Bendel, MD,‡ Ajax Yang, MD,§§§§ Rohit Aiyer, MD,¶¶¶¶ Ali Valimahomed, MD, FAAPMR,***** Ajay Antony, MD,††††† Justin Craig, MD,† Michael A. Fishman, MD,‡‡‡‡‡ Adnan A. Al-Kaisy, MD,§§§§§ Nick Christelis, MD,¶¶¶¶¶ Richard W. Rosenquist, MD,*** Robert M. Levy, MD, PhD,****** and Nagy Mekhail, MD, PhD***

Et ailleurs?

Haute Autorité de Santé. Evaluation des systèmes implantables de neurostimulation médullaire. Service d'évaluation des dispositifs. Saint-Denis La Plaine : HAS ; 2014.

	France	Belgique	Allemagne	Pays Bas	Royaume Uni
Choix de l'implant	Inscrit sur la LPPR Implantation d'un neurostimulateur rechargeable si : - la durée de vie du dispositif non rechargeable primo implanté < 30 mois, ou - seuil de stimulation > 3,5 V ou 4,5 mA à l'issue de la période de stimulation test. Implantation d'un neurostimulateur non rechargeable à pile à haute capacité d'énergie pour les douleurs bilatérales ou étendues.	Inscrit sur une liste limitative. Implantation d'un neurostimulateur rechargeable si la durée de vie du dispositif non rechargeable primo implanté < 2 ans.	Implantation d'un neurostimulateur rechargeable après négociation entre l'hôpital et l'Assurance maladie.	Décision d'implantation suite à négociation entre le centre implanteur et les assureurs.	Décision prise au vue de la complexité de la douleur et du seuil de stimulation requis. Dans le cas où plusieurs dispositifs sont éligibles, le moins cher doit être choisi.
Indications pour les douleurs d'origine neuropathique	Douleurs chroniques neuropathiques irréductibles, après échec des autres moyens thérapeutiques, secondaires à : - des radiculalgies chroniques (sciatalgies, cruralgies, cervico-brachialgies) ; - une lésion nerveuse périphérique, post traumatique ou post chirurgicale ; - une amputation (algo-hallucinose) ; - un syndrome douloureux régional complexe (dystrophies sympathiques réflexes, causalgies périphériques).	Douleur chronique après échec des traitements conventionnels. Les étiologies de la douleur neuropathique ne sont pas définies formellement mais : - syndrome d'échec de chirurgie du rachis → accepté ; - syndrome douloureux régional complexe → exclu ; - autre → sur accord du médecin conseil.	Douleurs chroniques neuropathiques irréductibles après échec des traitements conventionnels secondaires à : - syndrome d'échec de chirurgie du rachis ; - syndrome douloureux régional complexe ; - douleur du membre fantôme ; - lésion du plexus brachial ; - polyneuropathie diabétique ; - névralgie postherpétique.	Douleurs chroniques neuropathiques irréductibles après échec des traitements conventionnels secondaires à : - syndrome d'échec de chirurgie du rachis ; - syndrome douloureux régional complexe ; - douleur du membre fantôme ; - lésion nerveuse périphérique ; - lésion médullaire ; - lésion traumatique du plexus brachial.	Douleurs neuropathiques chroniques.
Indications pour les douleurs d'origine ischémique	AOMI.	- Maladie de Buerger ; - AOMI.	- Angine de poitrine réfractaire ; - AOMI.	Angine de poitrine réfractaire.	Absence de prise en charge. Accepté uniquement dans le cadre de la recherche.
Autres indications	-	Pancréatite chronique.	-	-	-

Artériopathie Oblitérante Membres Inférieurs / Buerger

Cochrane Library

Cochrane Database of Systematic Reviews

Ubbink DT, Vermeulen H.
Spinal cord stimulation for non-reconstructable chronic critical leg ischaemia.
Cochrane Database of Systematic Reviews 2013, Issue 2. Art. No.: CD004001.
DOI: 10.1002/14651858.CD004001.pub3.

Limb salvage after 12 months was significantly higher in the SCS group (risk ratio (RR) 0.71, 95% confidence interval (CI) 0.56 to 0.90; risk difference (RD) -0.11, 95% CI -0.20 to -0.02). Significant pain relief occurred in both treatment groups, but was more prominent in the SCS group where the patients required significantly less analgesics. In the SCS group, significantly more patients reached Fontaine stage II than in the conservative group (RR 4.9, 95% CI 2.0 to 11.9; RD 0.33, 95% CI 0.19 to 0.47). Overall, no significantly different effect on ulcer healing was observed with the two treatments.

Analysis 1.1. Comparison 1 Limb survival, Outcome 1 Amputations (12 months).

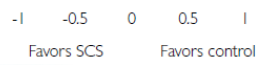
Review: Spinal cord stimulation for non-reconstructable chronic critical leg ischaemia

Comparison: 1 Limb survival

Outcome: 1 Amputations (12 months)

Study or subgroup	SCS n/N	Conservative n/N	Risk Difference M-H,Fixed,95% CI	Weight	Risk Difference M-H,Fixed,95% CI
Amann 2003	21/73	18/39		24.1 %	-0.17 [-0.36, 0.01]
Claeys 1996	7/45	8/41		20.4 %	-0.04 [-0.20, 0.12]
ESES	24/60	29/60		28.5 %	-0.08 [-0.26, 0.09]
Jivegard 1995	9/25	13/26		12.1 %	-0.14 [-0.41, 0.13]
Spincemaille 2000a	6/19	9/18		8.8 %	-0.18 [-0.50, 0.13]
Suy 1994	5/16	4/11		6.2 %	-0.05 [-0.41, 0.31]
Total (95% CI)	**238**	**195**		**100.0 %**	**-0.11 [-0.20, -0.02]**

Total events: 72 (SCS), 81 (Conservative)
Heterogeneity: Chi² = 1.63, df = 5 (P = 0.90); I² =0.0%
Test for overall effect: Z = 2.41 (P = 0.016)
Test for subgroup differences: Not applicable



Analysis 3.1. Comparison 3 Clinical improvement, Outcome 1 Reaching Fontaine stage II.

Review: Spinal cord stimulation for non-reconstructable chronic critical leg ischaemia

Comparison: 3 Clinical improvement

Outcome: 1 Reaching Fontaine stage II

Study or subgroup	SCS n/N	Control n/N	Risk Difference M-H,Fixed,95% CI	Weight	Risk Difference M-H,Fixed,95% CI
Claeys 1996	18/45	4/41		69.4 %	0.30 [0.13, 0.47]
Suy 1994	9/20	1/18		30.6 %	0.39 [0.15, 0.64]
Total (95% CI)	**65**	**59**		**100.0 %**	**0.33 [0.19, 0.47]**

Total events: 27 (SCS), 5 (Control)
Heterogeneity: Chi² = 0.37, df = 1 (P = 0.54); I² =0.0%
Test for overall effect: Z = 4.66 (P < 0.00001)
Test for subgroup differences: Not applicable

Angor réfractaire

Study	Design	Pat pop	Lost to follow-up	Intervention	Follow-up	Results	Complications
de Jongste et al. [5]	RCT	24	1	SCS vs placebo	2 months + 1 year	1 year: -QoL ⇑ -Ischemia ⇓ (n.s)	Six electrode dislocations
de Jongste et al. [4]	RCT	17	3	SCS vs waiting list (8 w) and then all SCS	8 weeks + 1 year	8 weeks: -Working capacity ⇑ -Ischemia ⇓ -Symptoms ⇓ -QoL⇑ 1 year: -Working capacity ⇑ -QoL ⇑	Two electrode dislocations
Mannheimer et al. [23]	RCT (ESBY-study)	104 (21 women/ 83men)	8 deaths (1 SCS/ 7 CABG)	SCS vs CABG(51/53)	6 months	-Symptoms ⇓ (same both groups) -Working capacity ⇑ (more in CABG) -Mortality (1.9% SCS vs 13.7% CABG)	0
Hautvast et al. [13]	RCT	25	0	SCS + standard treatment vs standard treatment	6 weeks	SCS + standard treatment: -Working capacity ⇑ -Symptoms ⇓ -QoL ⇑	?
Ekre [8]	RCT* (ESBY follow up)	104	29 deaths (13 SCS/16 CABG)	SCS vs CABG	5 years	6 months: -QoL ⇑ in both groups (n.s) 5 years: -QoL ⇑ in both (n.s) -Mortality 28% (n.s)	SCS: 1 sc infection and 3 electrode dislocations
Andrell [1]	RCT* (ESBY follow up)	104	17 deaths (5 SCS/10 CABG, other: 0/2)	SCS vs CABG	2 years	SCS group: -Hospitalisation ⇓ -Cardiac morbidity ⇓ -Total costs ⇓	SCS: 1 sc infection and 3 electrode dislocations
McNab [24]	RCT	68	7 (3 SCS/4 PMR) deaths: 1/0	SCS vs PMR (34/34)	12 months	-Exercise time ⇑ -Symptoms ⇓ -QoL ⇓ (no difference between groups) -Time to angina ⇑ in SCS	0 infections, electrode dislocation 1, generator dislocation 2 (SCS)
Eddicks [7]	RCT (cross-over design)	12		SCS at 3 stimulation regimes vs placebo stimulation	4 months (4 weeks × 4)	-Symptoms ⇓ -Walking distance ⇑ with all regimes vs placebo stimulation	0
Jessurun [17]	CT (retrospective)	57	?	SCS vs external control group	?	SCS: mortality 6.5%(similar to external control group)	Unipolar electrode: 83% reop.; Quadripolar electrodes: 33% reop.
Jessurun [16]	CT	24	?	SCS vs controls	4 weeks	Symptoms similar after 4 weeks of non-stimulation	?

Pain 140 (2008) 501–508

PAIN

www.elsevier.com/locate/pain

Spinal cord stimulation in severe angina pectoris – A systematic review based on the Swedish Council on Technology assessment in health care report on long-standing pain

Mats Börjesson [a,*], Paulin Andrell [a,*], Dag Lundberg [b], Clas Mannheimer [a,*]

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[b] Lunds University, Lund, Sweden

Spinal Cord Stimulation for Refractory Angina Pectoris

A Systematic Review and Meta-analysis

Xiaoxiao Pan, MS, Hongguang Bao, MD,† Yanna Si, MD,† Chenjie Xu, MS,† Hao Chen, MS,† Xianzhong Gao, MS,† Xinyi Xie, MS,† Yajie Xu, MS,* Fan Sun, MS,* and Lingqing Zeng, MS**

(*Clin J Pain* 2017;33:543–551)

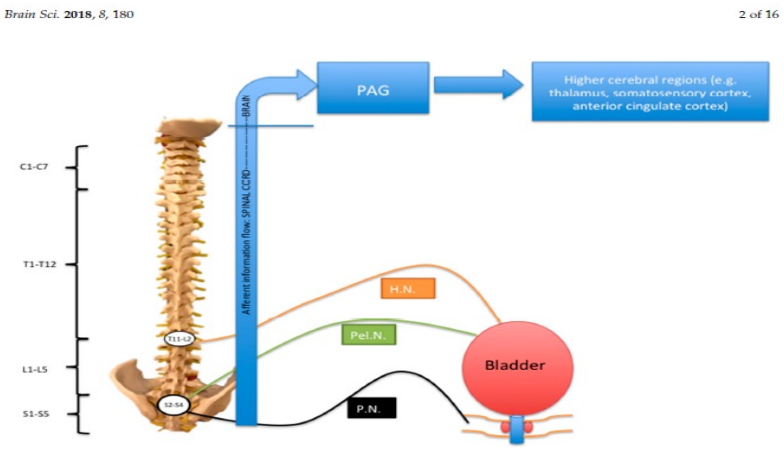
References	Group (No. Patients)	Follow-up Time	Outcome Parameters
Bondesson et al[11]	SCS (78) Control (43)	6 and 12 mo	Exercise time, changes in CCS
De Jongste et al[15]	SCS (8) Control (9)	12 mo	Exercise time, VAS score, SAQ, nitroglycerin use
Dyer et al[16]	SCS (10) Control (10)	3, 12, and 24 mo	Exercise time, changes in CCS
Eddicks et al[17]	SCS (12) Control (12)	13 mo	Nitroglycerin use, VAS score, SAQ
Greco et al[18]	SCS (23) Control (23)	3 and 24 mo	Exercise time
Hautvast et al[19]	SCS (13) Control (12)	6 wk	Exercise time, nitroglycerin use, VAS score, angina attacks
Jessurun et al[20]	SCS (12) Control (12)	2 and 4 wk	Nitroglycerin use, angina attacks
Lanza et al[21]	SCS (10) Control (15)	3, 6, and 12 mo	Exercise time, VAS score, SAQ, nitroglycerin use
Mannheimer et al[22]	SCS (10) Control (10)	6 mo	Exercise time, time to angina
McNab et al[23]	SCS (34) Control (34)	12 mo	Exercise time, changes in CCS, SAQ
Vulink et al[24]	SCS (20) Control (20)	3 and 12 mo	VAS score, nitroglycerin use
Zipes et al[25]	SCS (23) Control (23)	6 mo	Exercise time, VAS score, SAQ, nitroglycerin use

Outcomes	No. Patients	No. RCTs	Estimated Benefit (95% CI)	*P*
Exercise time after intervention	286	8	MD = 0.49 (0.13, 0.85)	0.008
Changes in CCS classes	229	3	OR = 2.12 (1.19, 3.76)	0.01
VAS score	177	6	MD = −0.50 (−0.81, −0.20)	0.001
Physical limitation	171	4	MD = −2.69 (−8.75, 3.38)	0.39
Angina stability	173	4	MD = −1.94 (−7.55, 3.67)	0.50
Angina frequency	174	4	MD = −9.03 (−15.70, −2.36)	0.008
Treatment satisfaction	174	4	MD = 6.87 (2.07, 11.66)	0.005
Disease perception	174	4	MD = −8.34 (−14.45, −2.23)	0.007
Nitroglycerin use	204	7	MD = −0.64 (−0.84, −0.45)	< 0.00001

Pain intensity was scored with VAS score.
CI indicates confidence interval; MD, mean difference; OR, odds ratio; VAS, visual analog scale scores of pain.

NOUVELLES INDICATIONS

Douleurs Neuropathiques Périnéales



- 3 études de cas :
  - Reichart et al. Schmerz 2009;23:640–644.
  - Rigoard et al. Neurosurgery 2012, 71: E757-63
  - Buffenoir et al. Neurourol Urodyn. 2015, 34, 177–182.
- 1 RCT : PHRC CHU Nantes
  - 6 centers
  - SCS vs OMM
  - Postoperative neuropathic pain after Alcock nerve decompression
  - Under recruitement (until 2022)

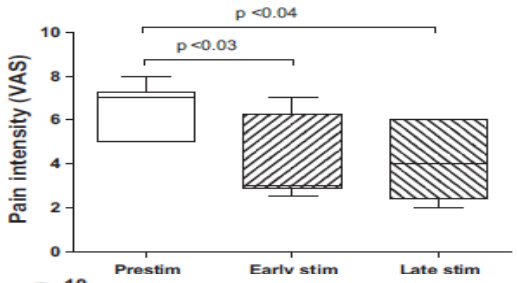
Douleurs Viscérales

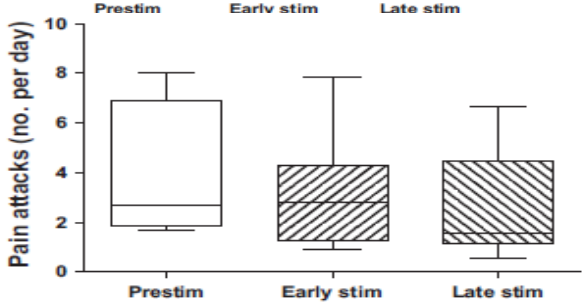
Am J Physiol Regul Integr Comp Physiol 308: R887–R894, 2015.
First published March 18, 2015; doi:10.1152/ajpregu.00022.2015.

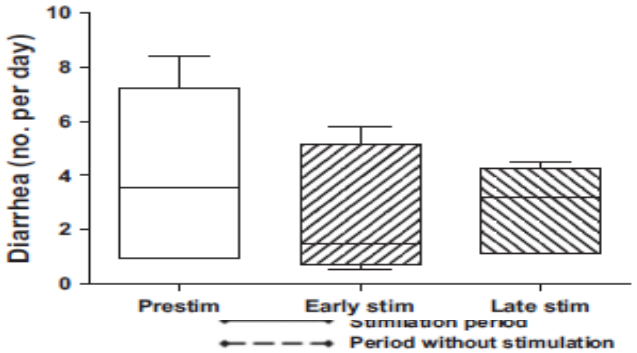
- Colon irritable :

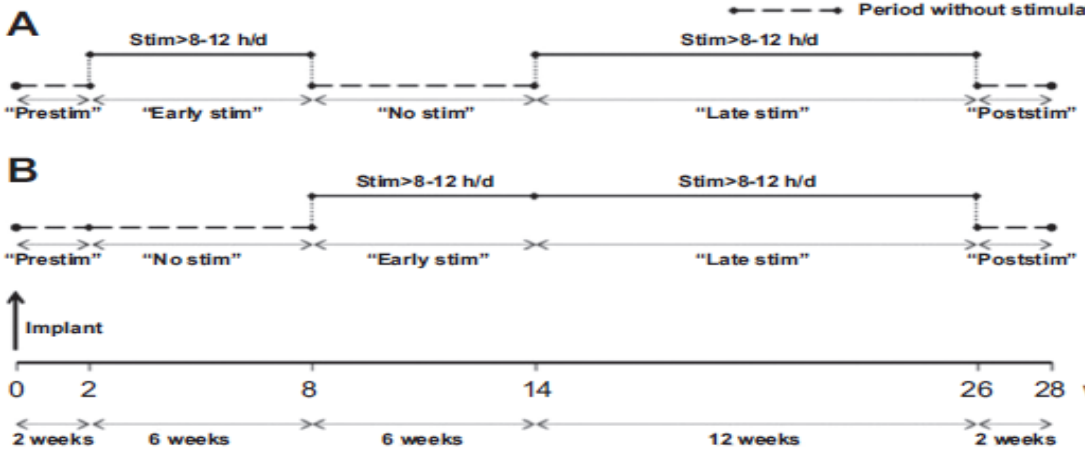
Therapeutic value of spinal cord stimulation in irritable bowel syndrome: a randomized crossover pilot study

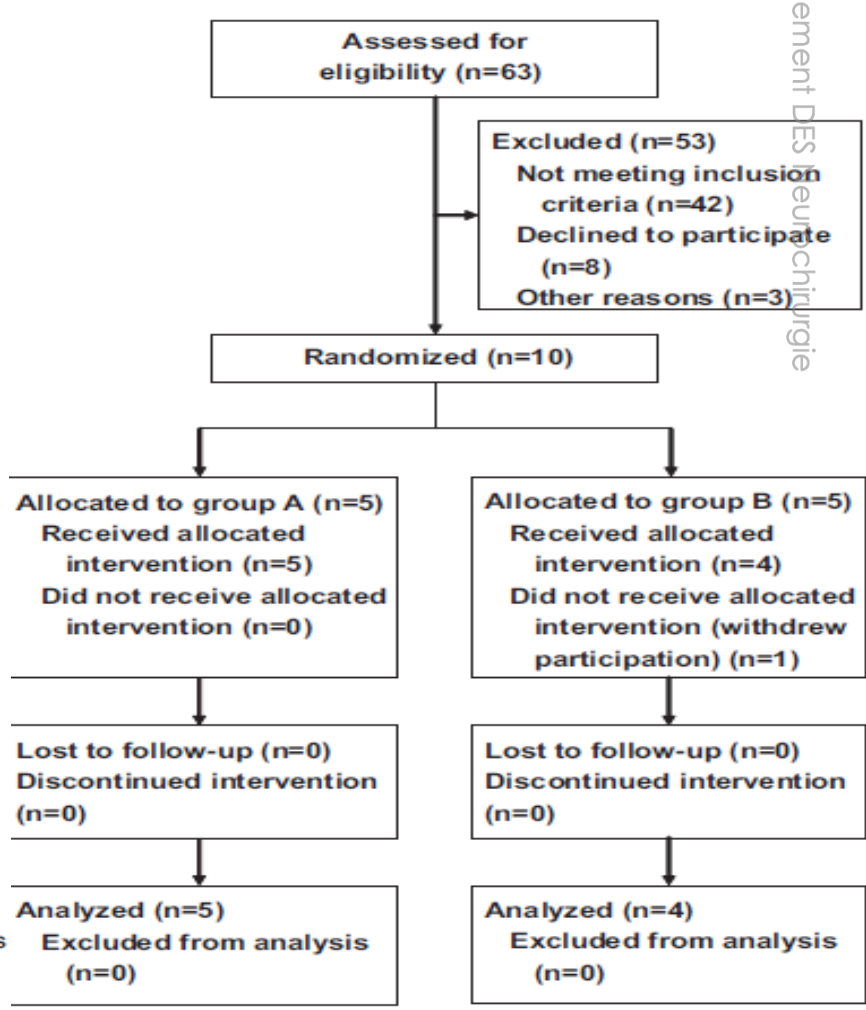
Göran Lind,[1] Jaleh Winter,[1] Bengt Linderoth,[1] and Per M. Hellström[2]











Douleurs Viscérales

Neuromodulation: Technology at the Neu

Received: June 8, 2019 Revised: August 11, 2019 Accepted: August 20, 2019

(onlinelibrary.wiley.com) DOI: 10.1111/ner.13051

Spinal Cord Stimulation for Management of Pain in Chronic Pancreatitis: A Systematic Review of Efficacy and Complications

Chathura Bathiya Ratnayake, MBChB*†; Amanda Bunn, BHSc(Physio), MBChB*†; Sanjay Pandanaboyana, MBBS, MS, MPhil‡; John Albert Windsor, BSc, MBChB, DipObst, MD*†§

- Pancréatite chronique:

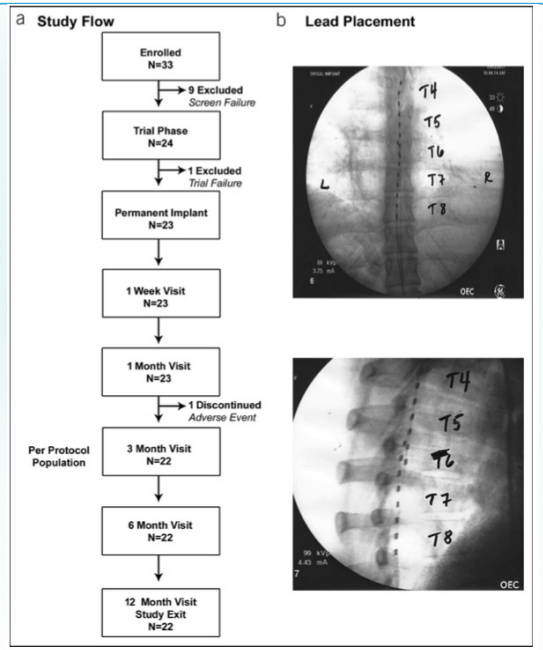
Author	Year	Study type	Pain scales	SCS trial period (days)	Overall follow-up (months)	Overall patients in study (*N*)	Patients included in the review (*N*)
Segura et al. (21)	2019	Case report	VAS	7	6	1	1
Vergani et al. (12)	2014	Case series	VAS	7	48-120	2	2
Al-Mahrouqi et al. (20)	2012	Case report	VAS	7	16	1	1
Kapural et al. (19)	2011	Retrospective cohort study	VAS	7-14	12	30	20
Kim et al. (22)	2009	Case report	VAS, PRO, PPI, KBPI	-	14	1	1
Kapural et al. (10)	2008	Case report	VAS, PDI	14	3	1	1
Khan et al. (11)	2005	Case series	VAS	5-7	6-8	9	5

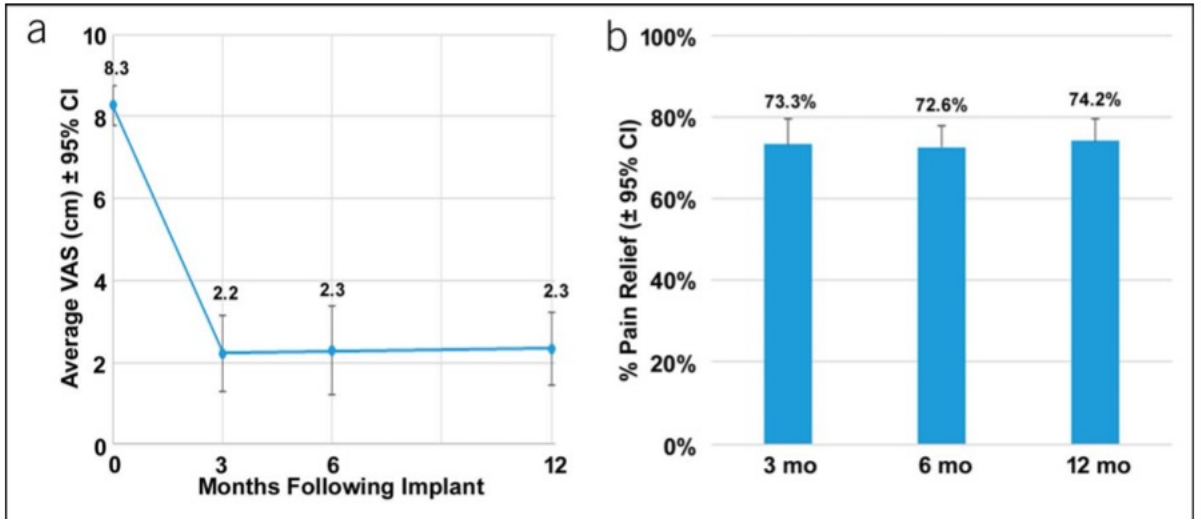
- Sphincter Oddi dysfunction: 1 case : Kang Hun Lee et al. Korean J Pain Vol. 28, No. 1, 2015
- Loin Pain Hematuria Syndrome: CS : Richter et al. Pain Pract 2019 19:440-3/ Kim et al. Pain Phy 2011 14:55-9
- Bannayan-Riley-Ruvalcaba syndrome: 1 case ; Yakovlev, WMJ 2009, 108, 323–326.

Chronic Abdominal PAin

Treatment of Chronic Abdominal Pain With 10-kHz Spinal Cord Stimulation: Safety and Efficacy Results From a 12-Month Prospective, Multicenter, Feasibility Study

Leonardo Kapural, MD, PhD[1,2], Mayank Gupta, MD[3], Richard Paicius, MD[4], Wyndam Strodtbeck, MD[5], Kevin E. Vorenkamp, MD[5], Christopher Gilmore, MD[1], Bradford Gliner, MS[6], Anand Rotte, PhD[6], Jeyakumar Subbaroyan, PhD[6] and Rose Province-Azalde, MS[6]





Miscellanées (Séries de cas)

- Post-AVC : 5 CS – 125 pts : success rate (6.7%-60.6%)
- Moelle attachée: 2 CS : Novik et al. World Neurosurg 2019 122:278-28, Tyagi JNS 2016 18(1):105-10
- Syndrome jambes sans repos (2 CS) : Adil et al., Stereo Funct neurosurg 2019;97:31–36), Byrne et al. AAPract 2019; 13:110-3
- Arthrose épaule : 1 case Susa et al. Surg Neurol Int. 20181;9:54
- Neuropathie petites fibres: 1 case : Eckmann et al. Case Rep Med. 2017; doi: 0.1155/2017/6969285.
- Melorheostosis : 1 case : zaveri et al. Neuromodulation 2014 17(3):286-8
- Erythromélalgie : 1 case : Matzke et al. Reg Anesth Pain Med. 2016 Sep-Oct;41(5):619-20
- Lèpre : 1 case: Brandmeir et al. Neuromodulation Dec;18(8):762-4
- Migraine : 1 cohort prospective HF cervical 17 pts (Level4): Arcioni et al. Eur J Pain. 2016 Jan;20(1):70-8.

PROGRAMME d'e-learning

Collège des Enseignants en Neurochirurgie

Prise en charge Neurochirurgicale de la Douleur

Responsable de l'e-module « Douleur » :
Philippe RIGOARD

Responsables scientifiques du projet :
Jean-Luc BARAT & Philippe RIGOARD

Partie A : Douleur

Partie B : Neurochirurgie lésionnelle de la douleur

Partie C : Neuromodulation de la douleur

Partie D: « Camp de base »

Section 4b3 : Techniques et modalités de stimulation

Module 11 : « Evidence-Based Medicine » en neuromodulation

Dr Jimmy VOIRIN

Société Française de Neurochirurgie

En partenariat avec:

SFCR Société Française de Chirurgie rachidienne

SFETD

SFNM

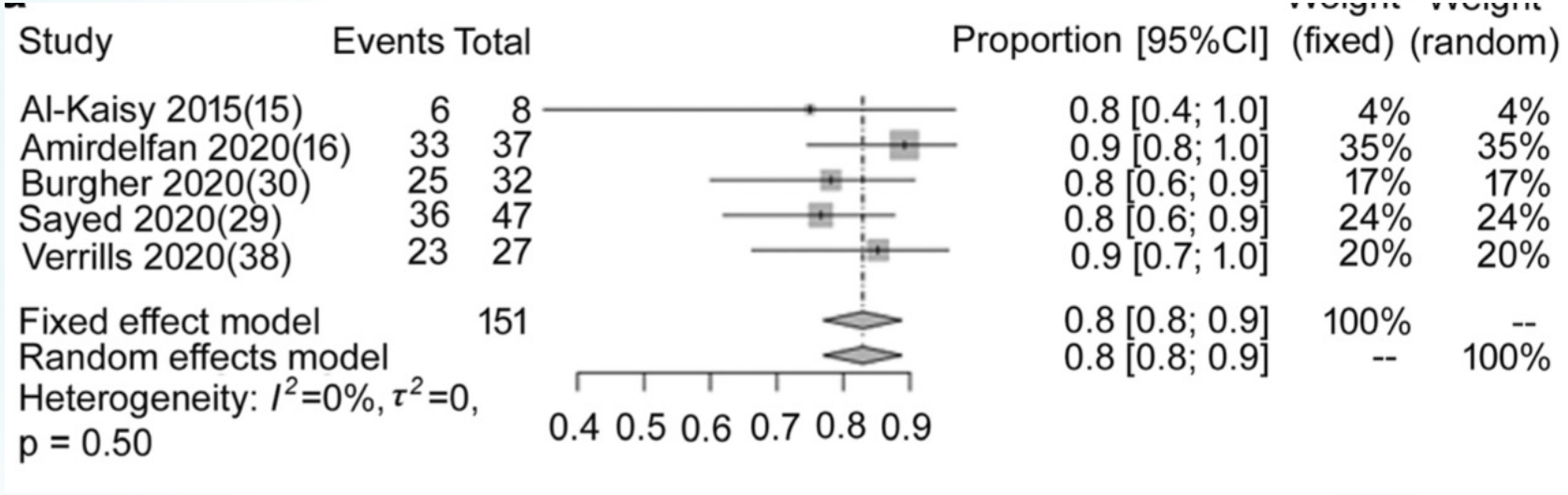
Implantation

Pain Ther (2021) 10:849–874
https://doi.org/10.1007/s40122-021-00269-6

REVIEW

Pain Relief and Safety Outcomes with Cervical 10 kHz Spinal Cord Stimulation: Systematic Literature Review and Meta-analysis

Ganesan Baranidharan · Beatrice Bretherton · Craig Montgomery · John Titterington · Tracey Crowther · Christopher Vannabouathong · Jason A. Inzana · Anand Rotte



Implantation

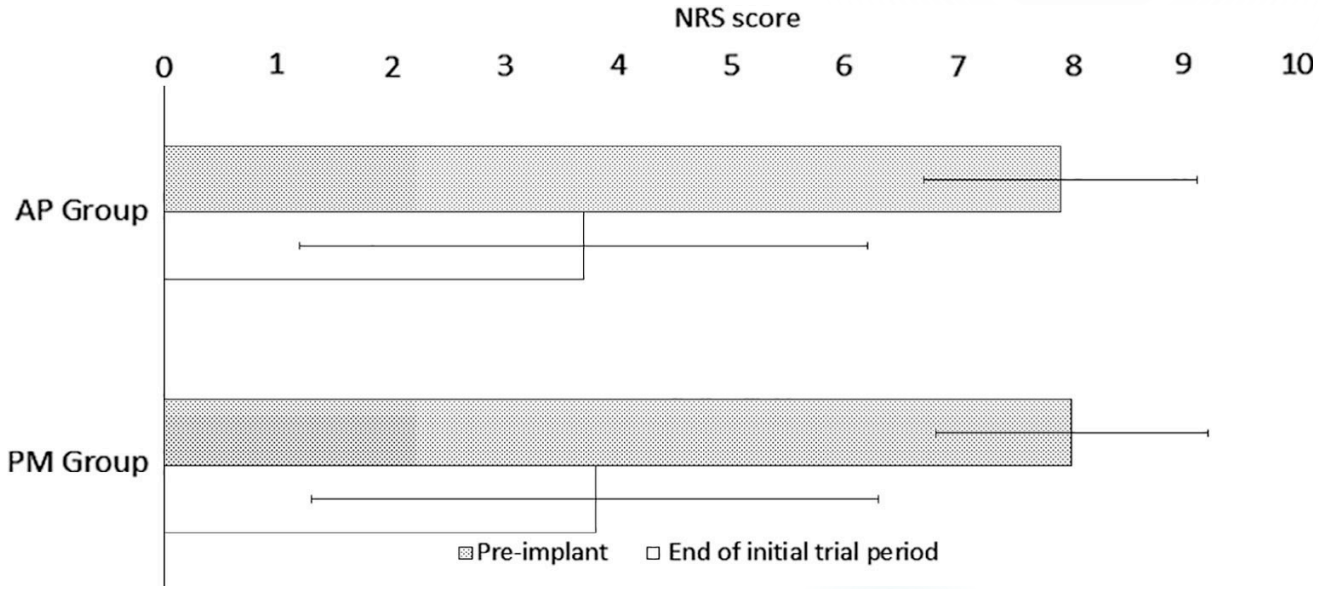
Neuromodulation: Technology at the Neural Interface

Received: March 29, 2019 Revised: May 15, 2019 Accepted: June 6, 2019

(onlinelibrary.wiley.com) DOI: 10.1111/ner.13019

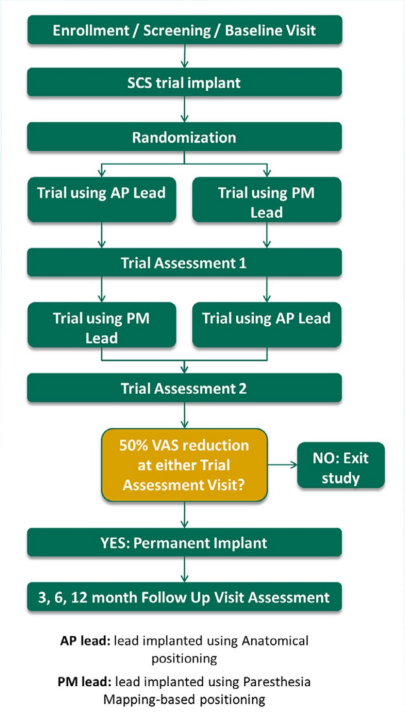
Anatomic Lead Placement Without Paresthesia Mapping Provides Effective and Predictable Therapy During the Trial Evaluation Period: Results From the Prospective, Multicenter, Randomized, DELIVERY Study

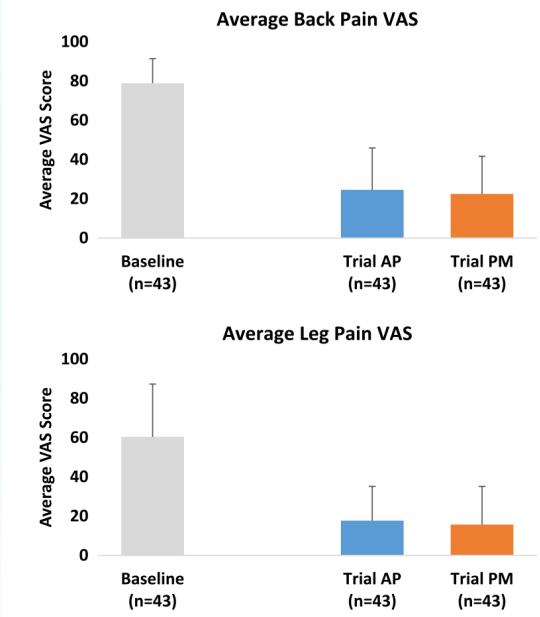
Jason E. Pope, MD*; Stefan Schu, MD†; Dawood Sayed, MD‡; Ahmed M. Raslan, MD§; Ganesan Baranidharan, MD¶; Robert D. Heros, MD**; Bram Blomme, PhD††; Robyn A. Capobianco, PhD††; Timothy R. Deer, MD‡‡



Comparison of Paresthesia Mapping to Anatomical Placement in Burst Spinal Cord Stimulation: Initial Trial Results of the Prospective, Multicenter, Randomized, Double-Blinded, Crossover, CRISP Study

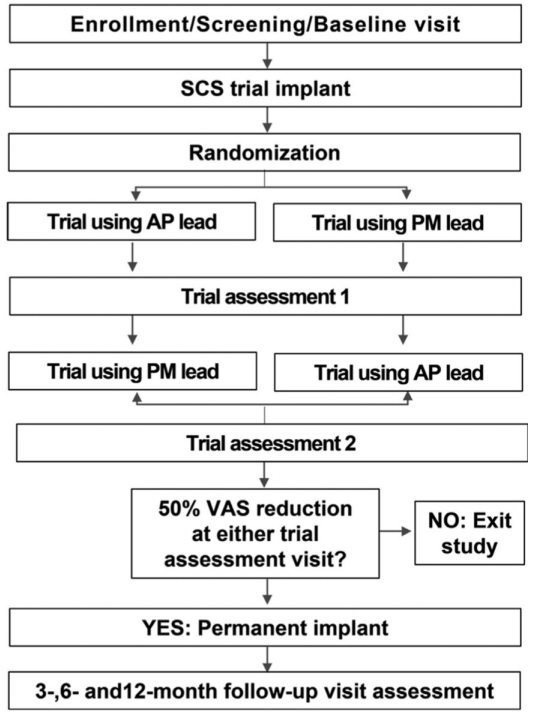
Adnan Al-Kaisy, MD*; Ganesan Baranidharan, MD†; Stefano Palmisani, MD*; David Pang, MD*; Onita Will, BSc Hons*; Samuel Wesley, BSc Hons*; Tracey Crowther, RN†; Karl Ward, RN†; Paul Castino†; Adil Raza, MPH‡; Filippo Agnesi, PhD‡

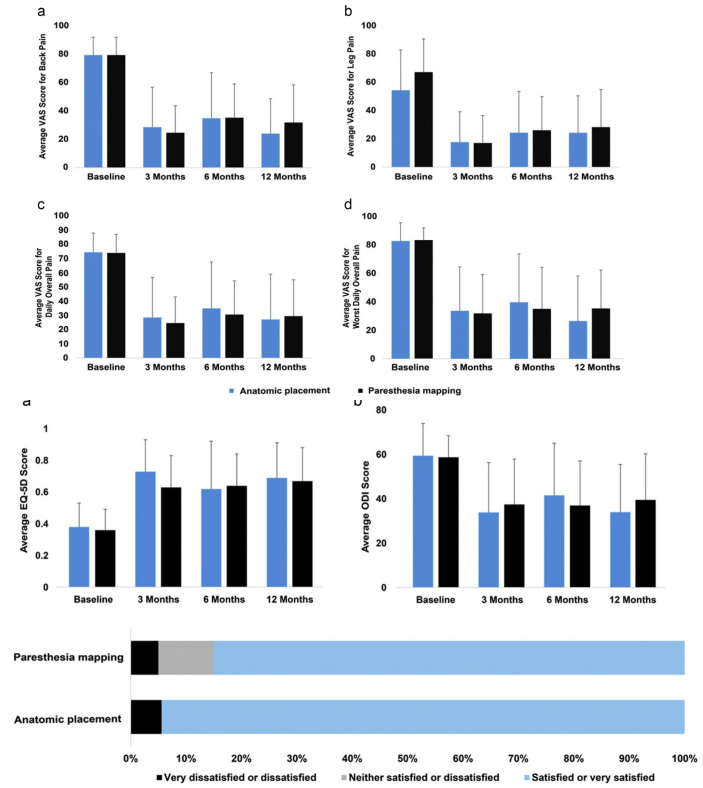




Comparison of Paresthesia Mapping With Anatomic Placement in Burst Spinal Cord Stimulation: Long-Term Results of the Prospective, Multicenter, Randomized, Double-Blind, Crossover CRISP Study

Adnan Al-Kaisy, MBChB[1]; Ganesan Baranidharan, MD[2]; Haggai Sharon, MD, PhD[1,3,4]; Stefano Palmisani, MD[1]; David Pang, MD[1]; Onita Will, BSc Hons[1]; Samuel Wesley, BSc Hons[1]; Tracey Crowther, RN[2]; Karl Ward, RN[2]; Paul Castino[2]; Adil Raza, MPH[5]; Yagna J. Pathak, PhD[5]; Filippo Agnesi, PhD[5]; Thomas Yearwood, MD, PhD[1]



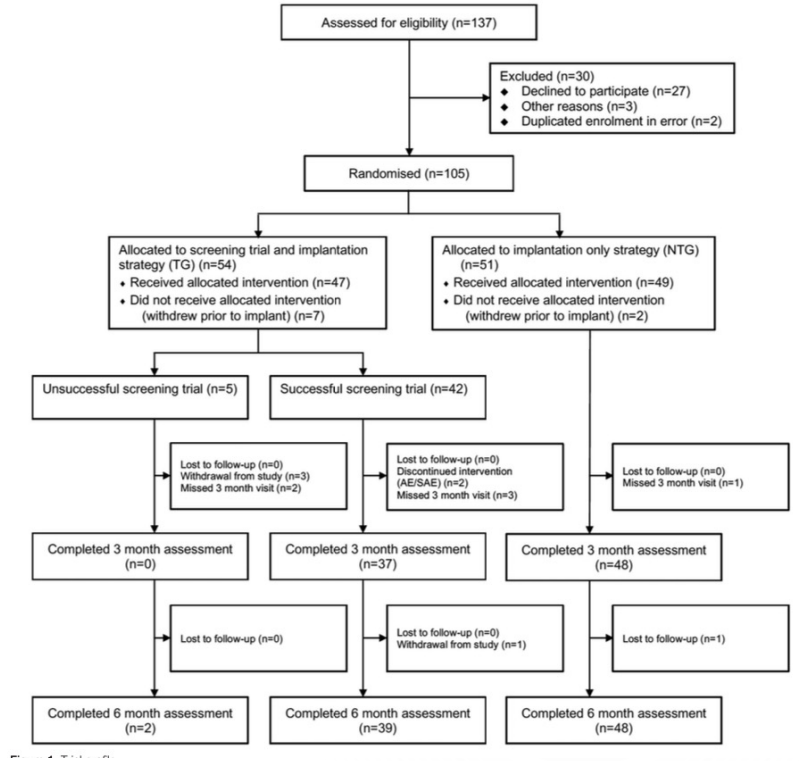


PAIN

OPEN

Does a screening trial for spinal cord stimulation in patients with chronic pain of neuropathic origin have clinical utility and cost-effectiveness (TRIAL-STIM)? A randomised controlled trial

Sam Eldabe[a,*], Rui V. Duarte[b], Ashish Gulve[a], Simon Thomson[c], Ganesan Baranidharan[d], Rachel Houten[b], Susan Jowett[e], Harbinder Sandhu[f], Raymond Chadwick[g], Morag Brookes[a], Anu Kansal[a], Jenny Earle[h], Jill Bell[h], Jennifer Robinson[a], Sarah Walker[i], Shelley Rhodes[i], Rod S. Taylor[i,j]



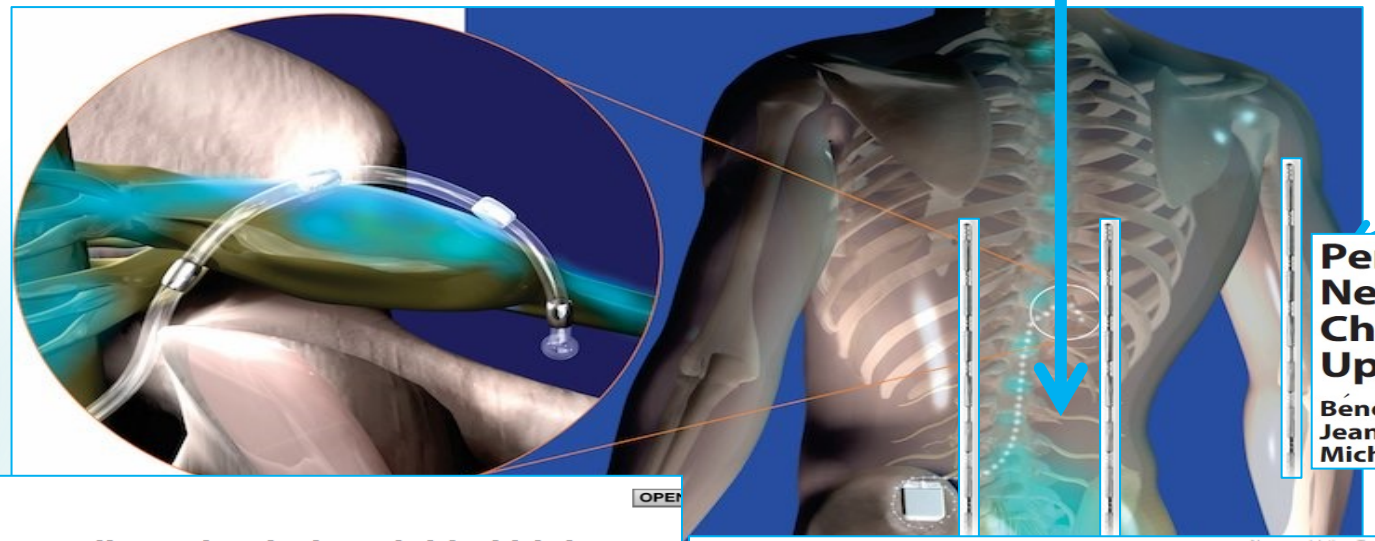
Clinical effectiveness—primary complete case analysis of primary and secondary outcomes at 6-month follow-up.

	TG (n = 41)		NTG (n = 48)		Between-group difference	
	Baseline mean (SD) or n/N	Follow-up mean (SD) or n/N	Baseline mean (SD) or n/N	Follow-up mean (SD) or n/N	Mean difference or odds ratio (95% CI)	*P*
Primary outcome						
Pain NRS: Clinic	7.5 (1.1)	4.3 (2.4)	7.5 (1.1)	4.5 (2.5)	0.2 (−1.2 to 0.9)	0.74
Secondary outcomes						
Pain NRS: 4 d	7.3 (1.1)	4.1 (2.4)	7.4 (0.9)	4.8 (2.6)	0.3 (−0.8 to 1.4)	0.60
Pain relief ≥50%	—	15/41 (37%)	—	19/48 (40%)	1.2 (0.4 to 1.7)	0.73
Pain relief ≥30%	—	23/41 (56%)	—	28/48 (58%)	1.3 (0.5 to 3.2)	0.55
EQ-5D-5L	0.32 (0.22)	0.57 (0.24)	0.30 (0.24)	0.53 (0.27)	−0.06 (−0.16 to 0.04)	0.23
PGIC	—	38/39 (97%)	—	41/47 (87%)	0.2 (0.0 to 2.6)	0.20
ODI	56.1 (13.6)	36.2 (18.4)	57.6 (14.9)	41.4 (23.4)	1.7 (−5.8 to 9.2)	0.65

Autres cibles

Subcutaneous Stimulation ou PNfS

Dorsal Root ganglia Stimulation



PAIN

OPEN

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[b]

Abbott

Peripheral Nerve Stimulation

Peripheral Nerve Stimulation of Brachial Plexus Nerve Roots and Supra-Scapular Nerve for Chronic Refractory Neuropathic Pain of the Upper Limb

Bénédicte Bouche, MD*; Marie Manfiotto, MD†; Philippe Rigoard, MD, PhD‡§; Jean Lemarie, MD¶; Véronique Dix-Neuf, MD¶; Michel Lanteri-Minet, MD**††‡‡; Denys Fontaine, MD, PhD†††

Neuromodulation: Technology at the Neural Interface

Received: November 6, 2012 Revised: January 15, 2013 Accepted: February 19, 2013

(onlinelibrary.wiley.com) DOI: 10.1111/ner.12055

Peripheral Nerve Field Stimulation for the Management of Localized Chronic Intractable Back Pain: Results From a Randomized Controlled Study

W. Porter McRoberts, MD*; Richard Wolkowitz, MD†; D Joseph Meyer, MD†; Eugene Lipov, MD‡; Jay Joshi, MD§; Bennet Davis, MD¶; Kevin D. Cairns, MD, MPH**; Giancarlo Barolat, MD††

Abbott

Neuromodulation: Technology at the Neural Interface

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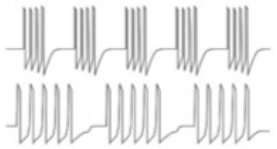
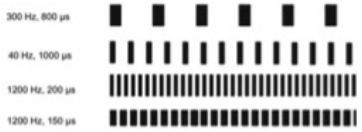
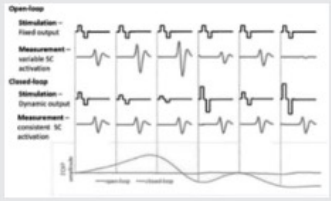
(onlinelibrary.wiley.com) DOI: 10.1111/ner.12784

A Randomized Controlled Trial of Subcutaneous Nerve Stimulation for Back Pain Due to Failed Back Surgery Syndrome: The SubQStim Study

Sam S. Eldabe, MB, ChB, FRCA*; Rod S. Taylor, PhD†; Stefaan Goossens, MD‡; Benedicte Bouche, MD§; Ismail Gültuna, MD¶; Colin Green, PhD†; Jennifer Tinsley, MBA**; Pierre-Philippe Luyet, PhD**; Eric Buchser, MD, DEAA††

Medtronic

Différentes modalités de stimulation

Name	Frequency	Pulse width	Amplitude	Waveform	Comment
Low frequency	10-100 Hz	100-1000 μs	1-10 mA		Traditionally paresthesia-based, manually adjustable output. Also called "tonic," although this technically describes any waveform with constant evenly spaced pulses.
Burst	Passive charge recovery: 40-Hz intrabursts of 5 pulses at 500-Hz interbursts Active charge recovery: Up to 8 0-Hz intrabursts of 3-7 pulses at 2- to 1200-Hz interbursts	500 μs 20-1000 μs	1-5 mA 1-5 mA		Several types of burst stimulation, some with passive, others active charge recovery Fixed output, typically below paresthesia threshold
High frequency	1-10 kHz	30 to 150 μs	1-5 mA		Fixed output, typically below paresthesia threshold.
High charge	300-1200 Hz	150-800 μs	1-5 mA		Fixed output, typically below paresthesia threshold. Minimal time between pulses (high duty cycle).
ECAP-controlled closed loop	10-100 Hz	100-450 μs	Automatically adjusted for every pulse (usually within 1-10 mA).		Stimulation amplitude adjusted based on physiologic response to stimulation, eg, evoked compound action potentials (ECAPs), to maintain a target physiologic response amplitude.
Multiple contact calibrated field shape	10-1000 Hz	100-350 μs	1-5 mA		Stimulation amplitude on each contact adjusted to preferentially modulate different areas of the spinal cord

PAIN

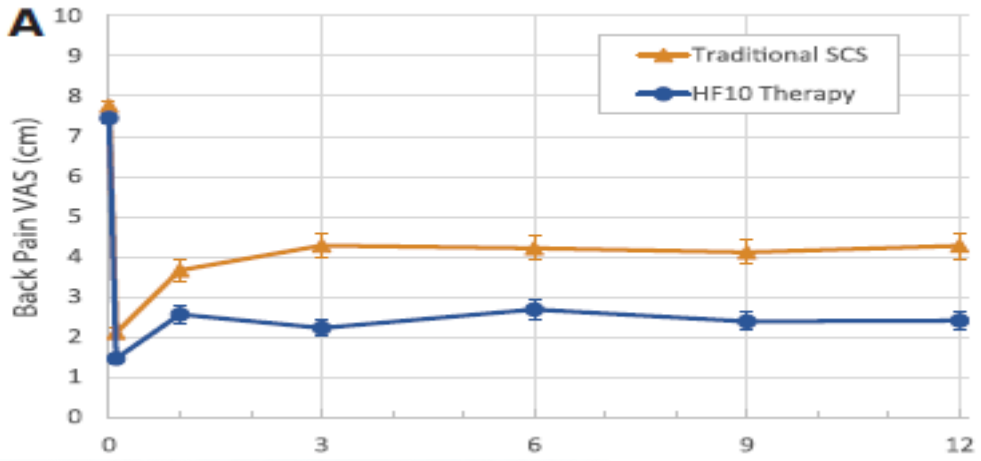
PAIN 162 (2021) 1935–1956

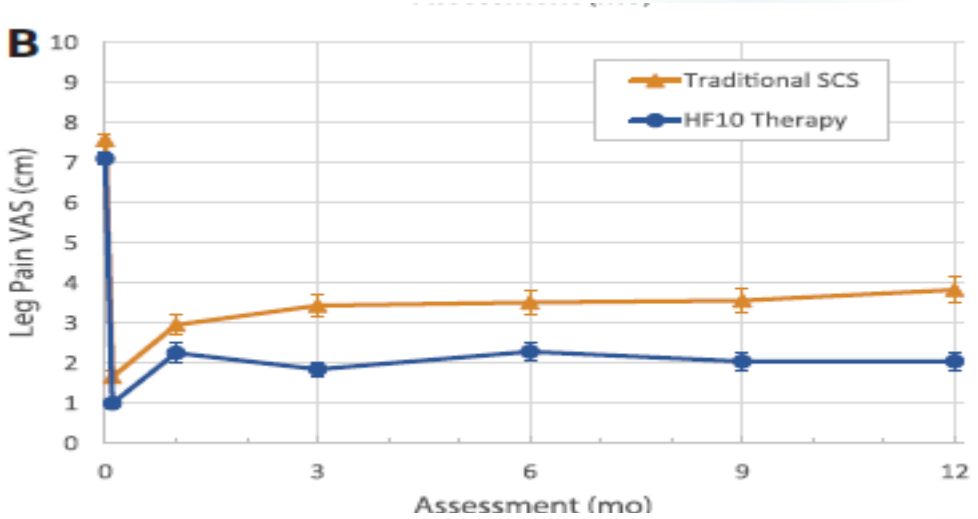
OPEN

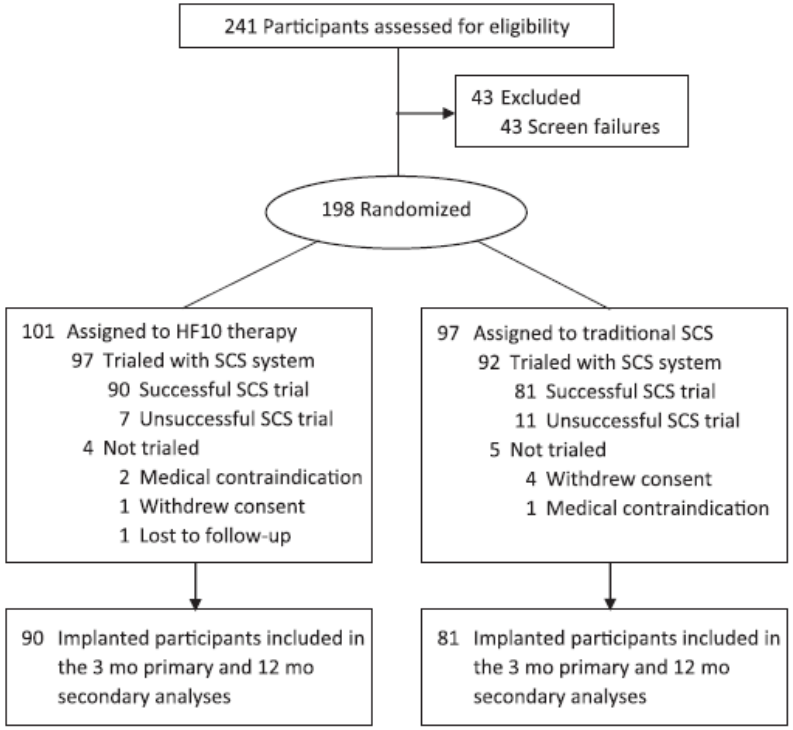
Research design considerations for randomized controlled trials of spinal cord stimulation for pain: Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials/Institute of Neuromodulation/International Neuromodulation Society recommendations

Nathaniel Katz*, Robert H. Dworkin, Richard North, Simon Thomson, Sam Eldabe, Salim M. Hayek, Brian H. Kopell, John Markman, Ali Rezai, Rod S. Taylor, Dennis C. Turk, Eric Buchser, Howard Fields, Gregory Fiore, McKenzie Ferguson, Jennifer Gewandter, Chris Hilker, Roshini Jain, Angela Leitner, John Loeser, Ewan McNicol, Turo Nurmikko, Jane Shipley, Rahul Singh, Andrea Trescot, Robert van Dongen, Lalit Venkatesan

Haute fréquence







	Month 3	Month 6	Month 12
Back pain responders			
HF10 therapy, %	**84.3**	76.4	78.7
Traditional SCS, %	**43.8**	51.9	51.3
Relative ratio (95% CI)	**1.9 (1.4–2.5)**	1.5 (1.2–1.9)	1.5 (1.2–1.9)
Back pain remitters			
HF10 therapy, %	65.2	59.6	68.5
Traditional SCS, %	31.3	36.7	36.3
Relative ratio (95% CI)	2.1 (1.4–3.0)	1.6 (1.1–2.3)	1.9 (1.3–2.7)
Leg pain responders			
HF10 therapy	83.1	80.9	78.7
Traditional SCS, %	55.0	54.4	51.3
Relative ratio (95% CI)	1.5 (1.2–1.9)	1.5 (1.2–1.9)	1.5 (1.2–2.0)
Leg pain remitters			
HF10 therapy, %	76.4	68.6	67.4
Traditional SCS, %	37.5	44.3	42.5
Relative ratio (95% CI)	2.0 (1.5–2.8)	1.5 (1.2–2.0)	1.6 (1.2–2.1)

Responder: ≥50% reduction in pain from baseline. Remitter: pain score of ≤2.5. Relative ratio (95% CI): ratio of responder or remitter rates for HF10 therapy to traditional SCS with 95% CIs. Rates in bold represent the primary endpoint comparison. 10% noninferiority *P* value <0.001 at all endpoints. Between-group *P* value <0.001 at all endpoints.

Vol. 123 No. 4 October 2015

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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.

Haute Fréquence

Pain Medicine 2017; 18: 2401–2421
doi: 10.1093/pm/pnx241

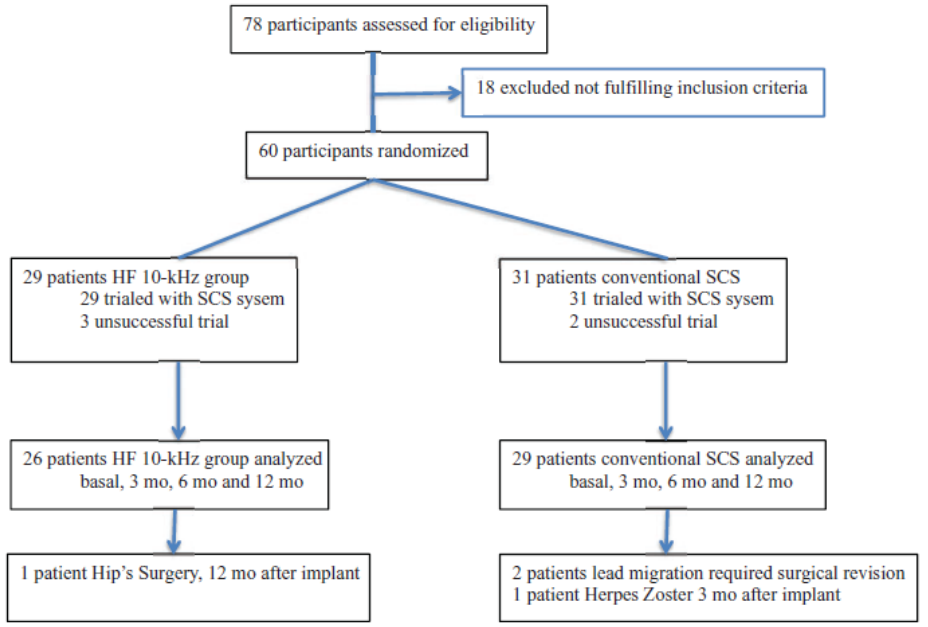
OXFORD

NEUROMODULATION & INTERVENTION SECTION

Original Research Article

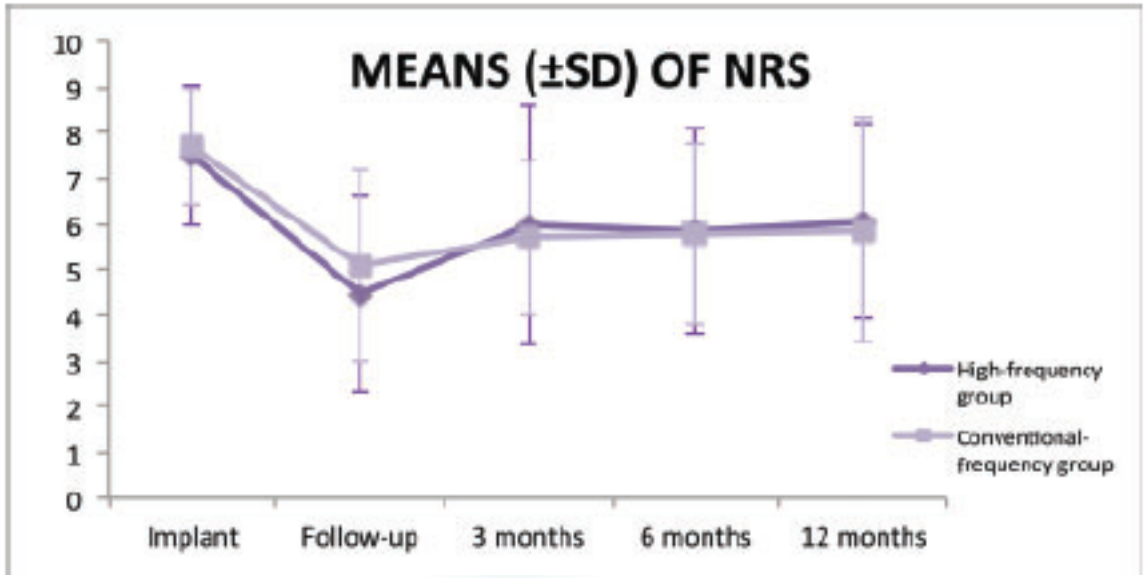
Prospective, Randomized Blind Effect-on-Outcome Study of Conventional vs High-Frequency Spinal Cord Stimulation in Patients with Pain and Disability Due to Failed Back Surgery Syndrome

Jose De Andres, MD, PhD, FIPP, EDRA,*,† Vicente Monsalve-Dolz, PhD,* Gustavo Fabregat-Cid, MD, PhD,* Vicente Villanueva-Perez, MD, PhD,* Anushik Harutyunyan,*,‡ Juan Marcos Asensio-Samper, MD,* and Nerea Sanchis-Lopez, MD*



	Conventional SCS group (N = 29)	HF 10 kHz SCS group (N = 26)	Difference*
Age, mean (SD), y	53.79 (11.46)	51.62 (9.31)	0.446
Male/female, %	37.9/62.1	57.7/42.3	0.116
Pain diagnosis, %			
Failed back surgery syndrome	100	100	
Previous back surgery, %	100	100	
Baseline NRS, mean (SD)	7.60 (1.06)	7.69 (1.17)	0.33
Baseline pain detect, mean (SD)	18.86 (7.17)	16.23 (6.85)	0.329
Baseline ODI, mean (SD)	27.18 (5.21)	26.96 (5.18)	0.33

HF = high frequency; NRS = numeric rating scale; ODI = Oswestry Disability Index; PD-Q = Pain Detect Questionnaire; SCS = spinal cord stimulation.



Haute Fréquence

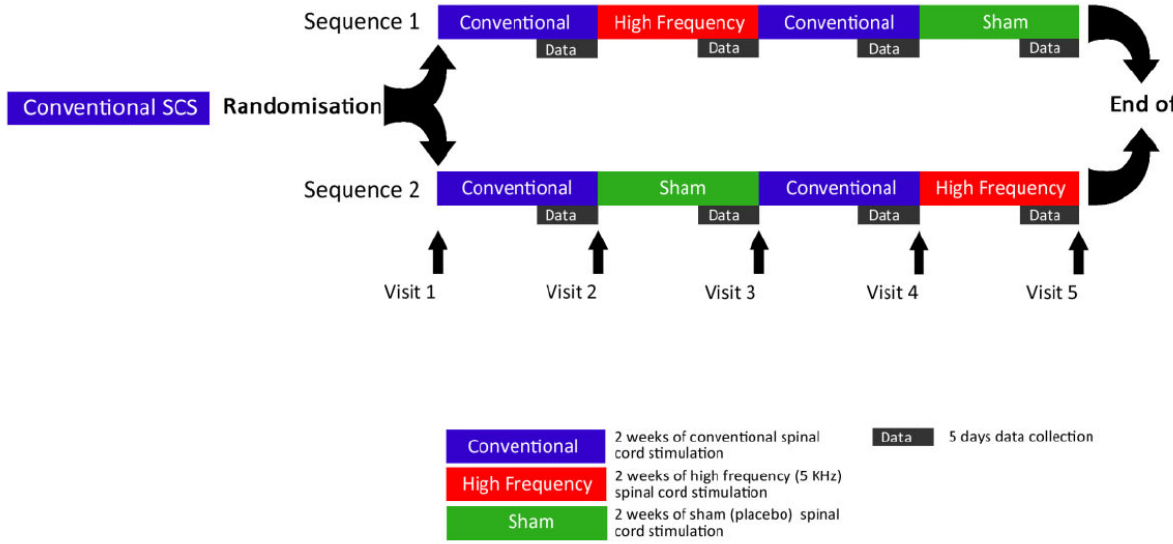
Neuromodulation: Technology at the Neural Interface

Received: November 15, 2012 Accepted: December 21, 2012

(onlinelibrary.wiley.com) DOI: 10.1111/ner.12027

Analgesic Efficacy of High-Frequency Spinal Cord Stimulation: A Randomized Double-Blind Placebo-Controlled Study

Christophe Perruchoud, MD*; Sam Eldabe, MBChB, FRCA, FFPMRCA†; Alan M. Batterham, PhD‡; Grace Madzinga, RN, Dip HE Adult, BSc (Hons)†; Morag Brookes, RGN, BSc (Hons), PG Dip Health Research†; Anne Durrer, RN*; Marilu Rosato, RN*; Nora Bovet, RN*; Samantha West, RN, BSc (Hons)†; Michèle Bovy, MD*; Blaise Rutschmann, MD*; Ash Gulve, MD†; Fay Garner, RGN, Dip (Pain Management)†; Eric Buchser, MD DEAA*



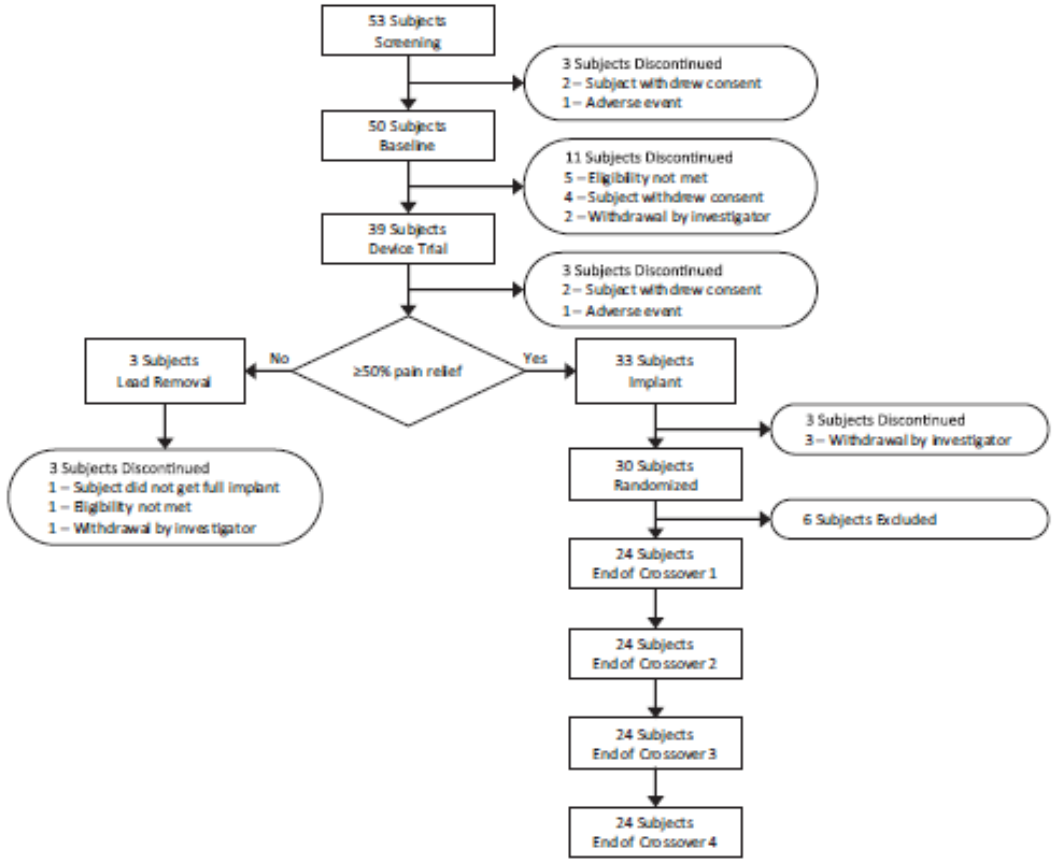
The overall proportion of patients responding to HF stimulation was 42.4% (14/33 patients) vs. 30.3% (10/33 patients) in the sham condition (Table 2). There was a statistically significant "period effect," whereby 51.5% (17/33) of patients improved at visit 3 and only 21.2% (7/33) at visit 5, irrespective of treatment received (mean difference in proportions = 30.3%; 9–51%; $p = 0.006$).

In sequence 1 (HFSCS first), 9/17 patients responded to HFSCS vs. 2/17 to sham. The difference in the proportions of responding patients (HFSCS 52.9% minus sham 11.7%) is 41.2%. In sequence 2 (sham first), 5/16 patients responded to HFSCS vs. 8/16 to sham. The difference in proportions (HFSCS 0.325 minus sham 0.5) is –0.188, i.e. 18.8% in favor of sham. The mean benefit of HFSCS vs. sham is given by the average of these two values that is a proportion of 0.112% or 11.2% (95% CI, –10.1% to 32.5%; $p = 0.30$).

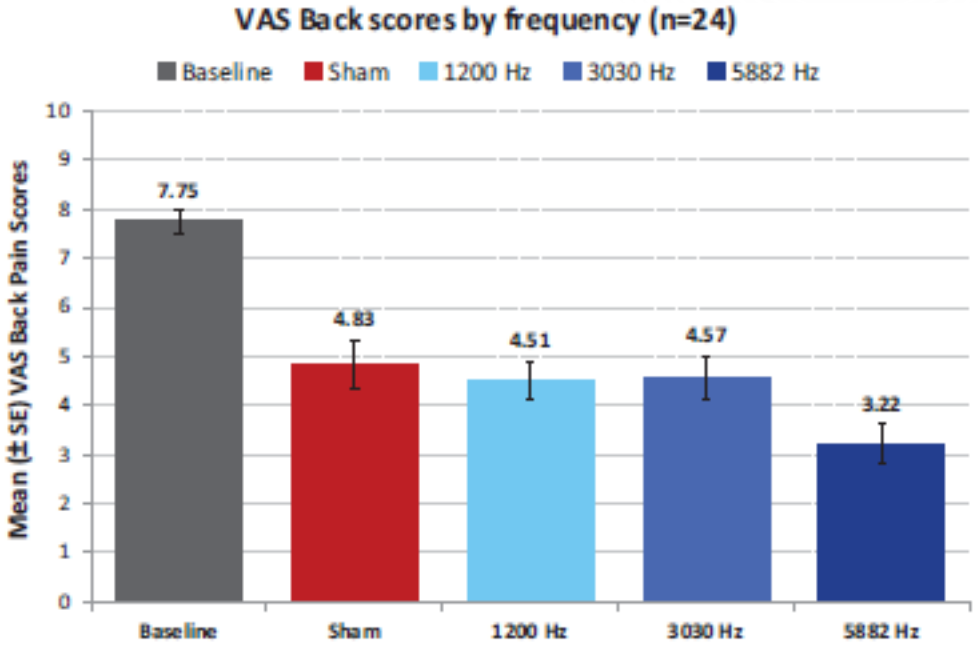
Haute Fréquence

Prospective, Randomized, Sham-Control, Double Blind, Crossover Trial of Subthreshold Spinal Cord Stimulation at Various Kilohertz Frequencies in Subjects Suffering From Failed Back Surgery Syndrome (SCS Frequency Study)

Adnan Al-Kaisy, MD*; Stefano Palmisani, MD*; David Pang, MD*; Karen Sanderson, RN*; Samuel Wesley*; Ye Tan, MS†; Sheryl McCammon†; Andrea Trescott, MD‡



1. CONSORT flowchart for this study.

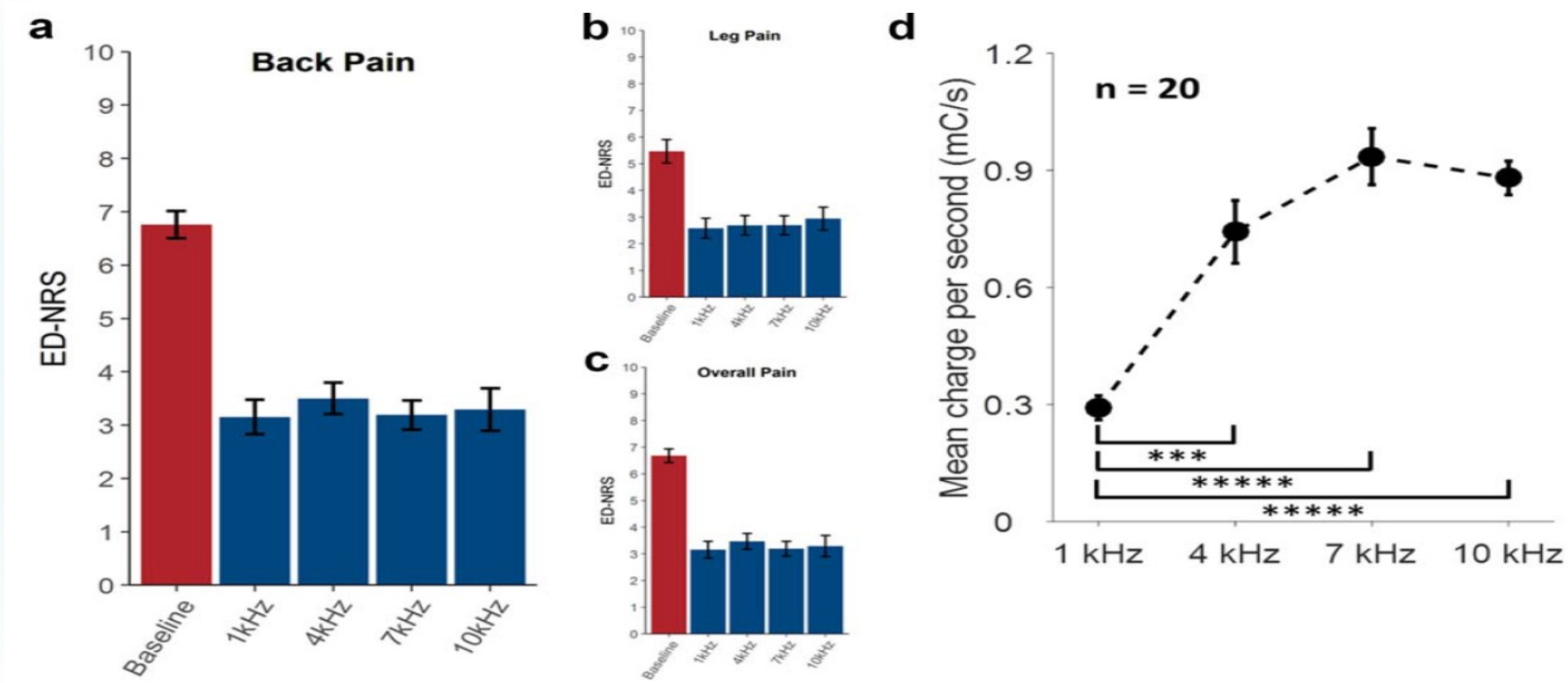


Haute fréquence

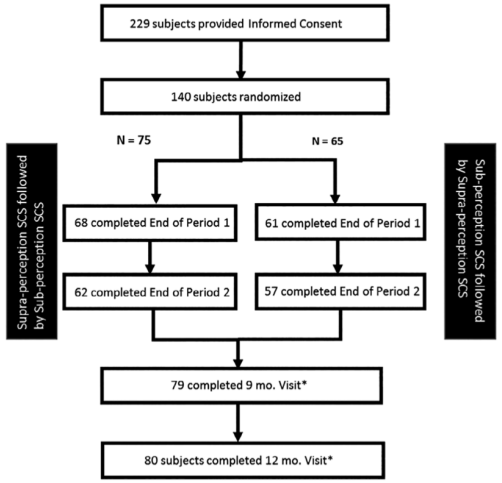
Received: October 22, 2017 Revised: November 13, 2017 Accepted: November 13, 2017
(onlinelibrary.wiley.com) DOI: 10.1111/ner.12746

Effects of Rate on Analgesia in Kilohertz Frequency Spinal Cord Stimulation: Results of the PROCO Randomized Controlled Trial

Simon J. Thomson, MBBS*; Moein Tavakkolizadeh, MD†; Sarah Love-Jones, MBBS‡; Nikunj K. Patel, MD§; Jianwen Wendy Gu, PhD¶; Amarpreet Bains, PhD**; Que Doan, BS¶; Michael Moffitt, PhD¶



Haute Fréquence



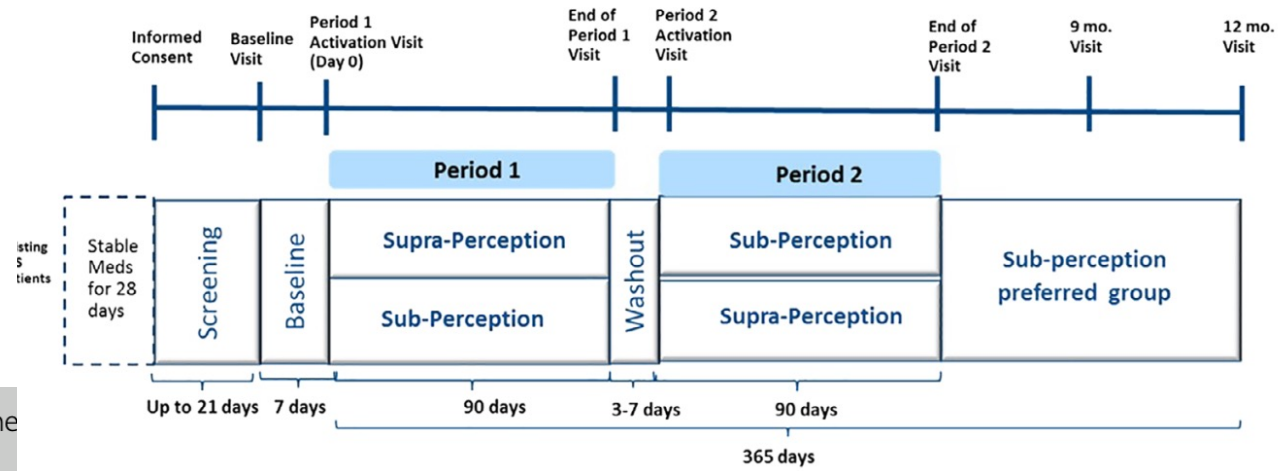


Table 2. Pain Scores in All Randomized Subjects (*N* = 140) Based on The Treatment Assignment.

Outcome	Baseline mean (SD) *N*	Subperception SCS mean (SD) *N*	Supraperception SCS Mean (SD) *N*
Mean overall pain (VRS)	7.3 (1.1) 131	4.7 (1.9) 123	5.1 (1.9) 124
Mean low back pain (VRS)	6.9 (1.6) 131	4.2 (1.9) 123	4.8 (1.8) 124
Mean leg pain (VRS)	6.1 (2.3) 131	3.9 (2.2) 123	4.3 (2.2) 124
Mean overall pain (PPR)	NA	57.4 (24.0) 119	54.9 (25.6) 124
Mean low back pain (PPR)	NA	56.1 (24.1) 118	51.9 (27.7) 122
Mean leg pain (PPR)	NA	55.0 (26.4) 112	52.7 (28.5) 119

Outcomes of a Multicenter, Prospective, Crossover, Randomized Controlled Trial Evaluating Subperception Spinal Cord Stimulation at ≤1.2 kHz in Previously Implanted Subjects

James North, MD*; Eric Loudermilk, MD†; Albert Lee, MD‡; Harsh Sachdeva, MD§; Demetrios Kaiafas, MD¶; Edward Washabaugh, MD**; Samir Sheth, MD††; James Scowcroft, MD‡‡; Nagy Mekhail, MD, PhD§§; Benjamin Lampert, MD¶¶; Thomas Yearwood, MD, PhD***; Erik Shaw, DO†††; Joseph Atallah, MD‡‡‡; Carroll McLeod, MD§§§; John Han, MD¶¶¶; Cong Yu, MD****; Mark Sedrak, MD††††; Rene Lucas, MD‡‡‡‡; Andrew Trobridge, MD§§§§; Joseph Hegarty, MD¶¶¶¶; Nathan Miller, MD*****; Lilly Chen, MD†††††; Roshini Jain, MS†††††

« Super » Haute-Fréquence 30-150KHz

Journal of Pain Research

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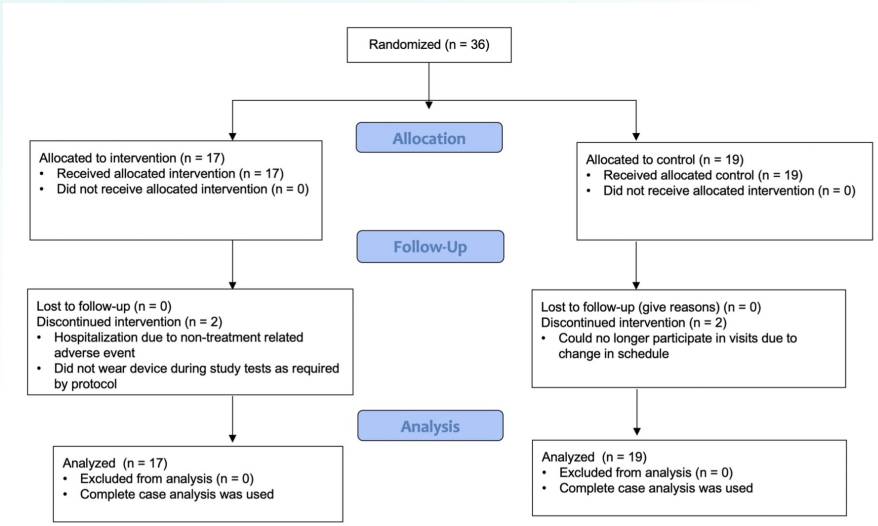
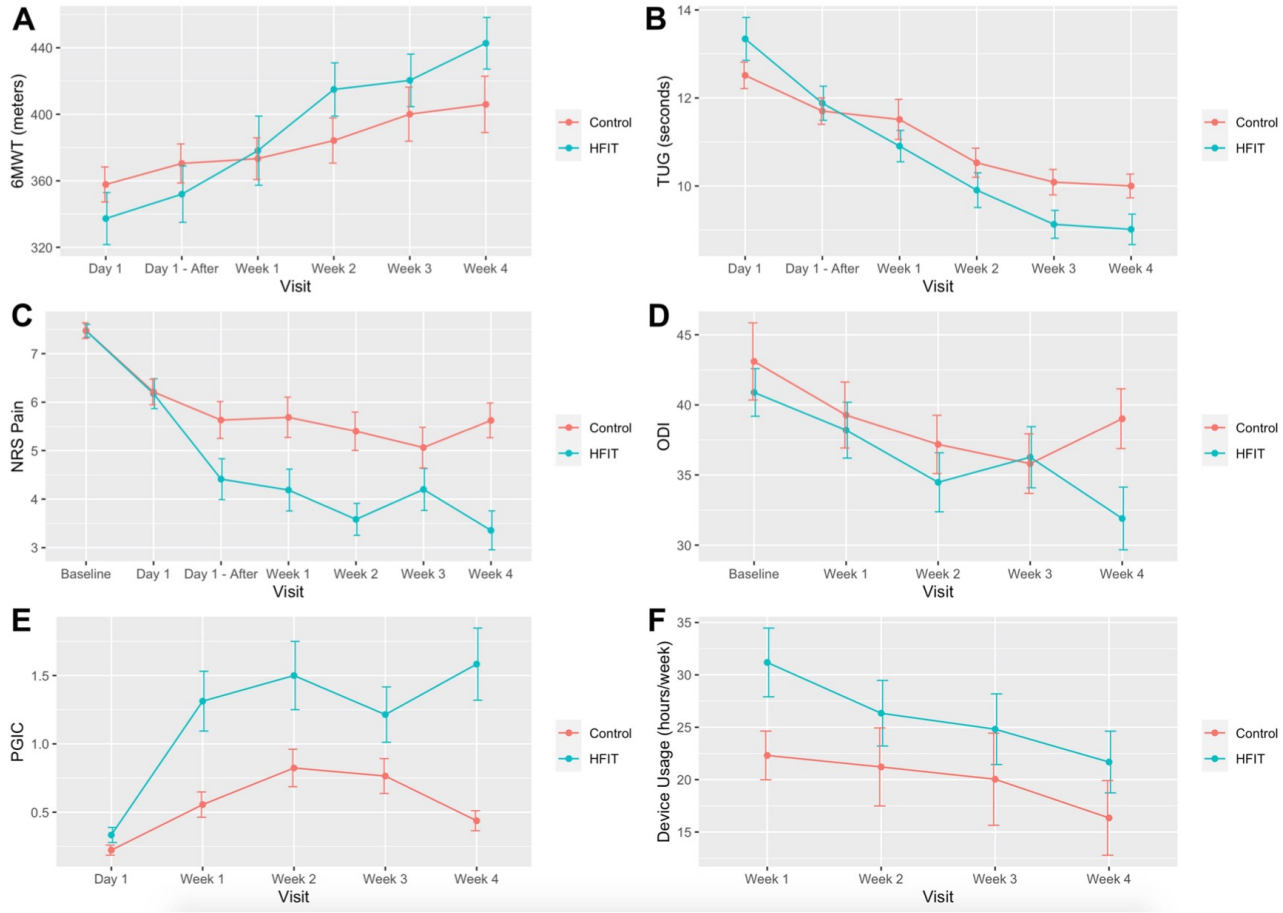
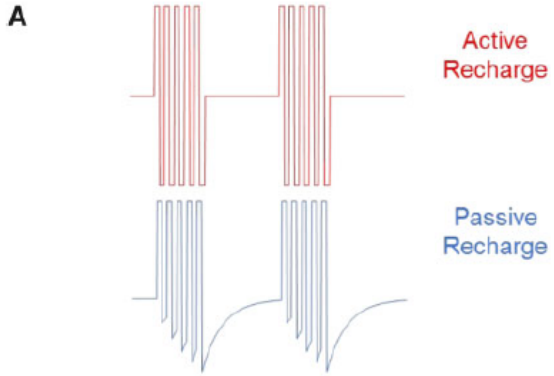
CLINICAL TRIAL REPORT

High-Frequency Impulse Therapy for Treatment of Chronic Back Pain: A Multicenter Randomized Controlled Pilot Study





Stimulation burst



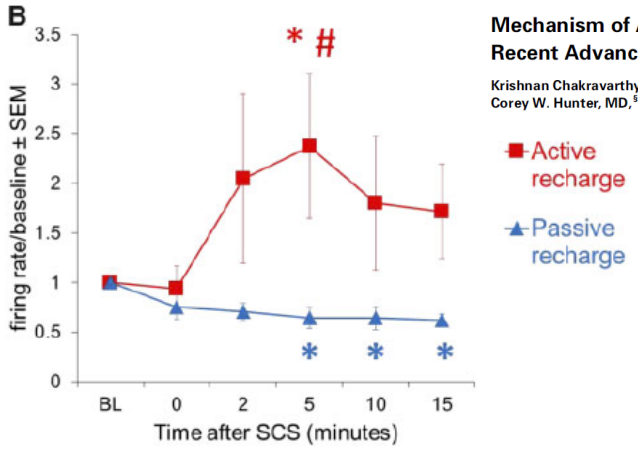
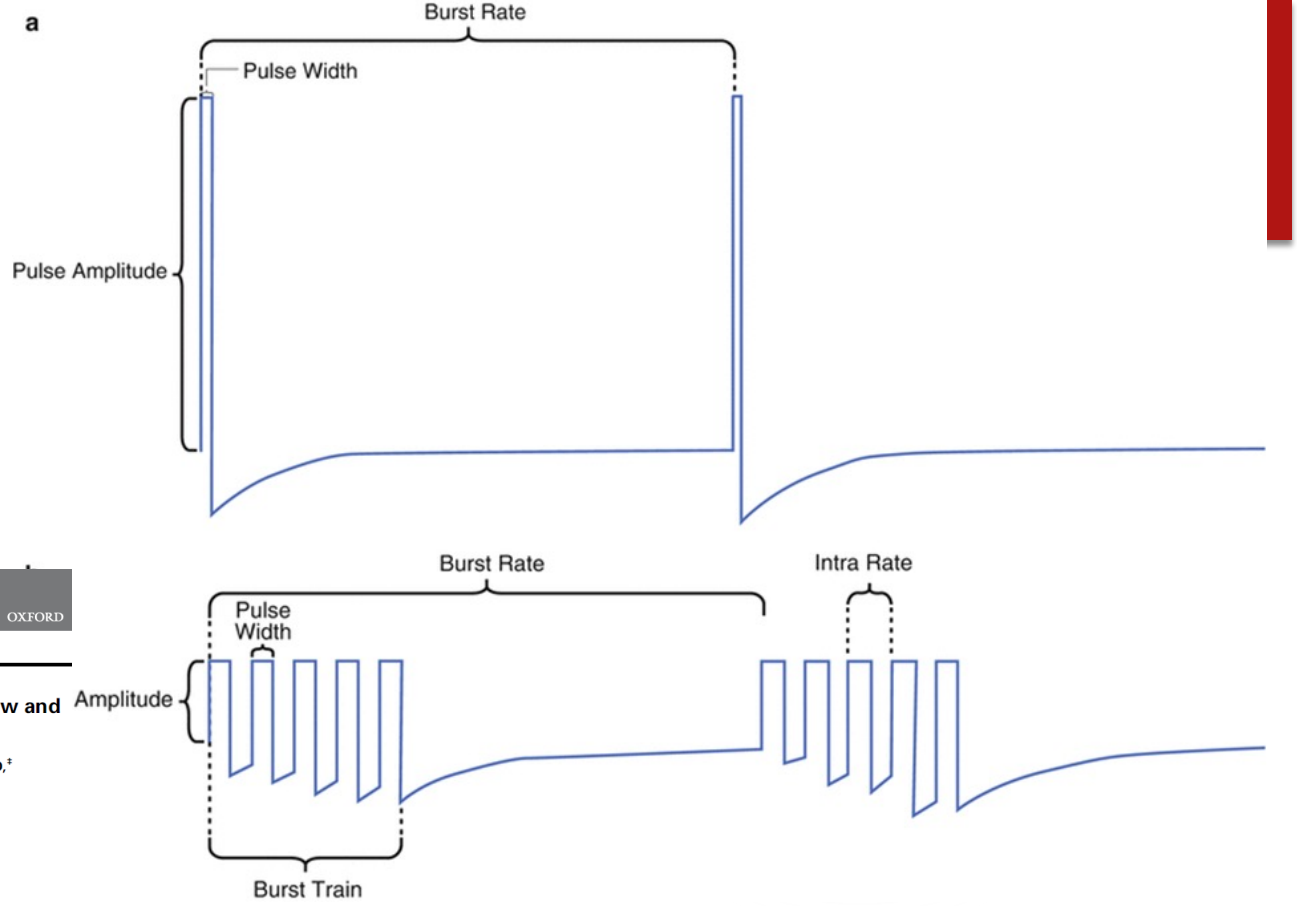


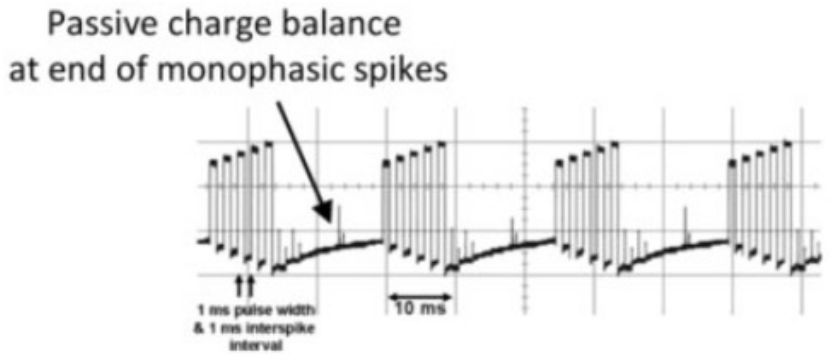
Figure 4. A) Illustration of burst waveforms with active recharge or passive recharge. B) Changes in spinal neuron firing rate from baseline after burst with active recharge or passive. Following burst spinal cord stimulation (SCS) with passive recharge, the normalized firing rate was significantly lower overall ($P = 0.019$) and at five, 10, and 15 minutes relative to baseline (blue $^{*}P < 0.04$). Conversely, five minutes after burst SCS with active recharge, the normalized firing rate was increased relative to baseline ($^{\#}P < 0.006$) and zero minutes (red $^{*}P < 0.003$). Figures used with permission from Weisshaar et al. [83].

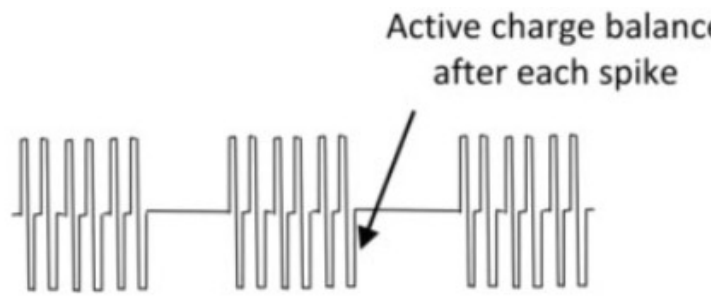
Pain Medicine, 20, 2019, S13–S22
doi: 10.1093/pm/pnz073
Review Article

Mechanism of Action in Burst Spinal Cord Stimulation: Review and Recent Advances

Krishnan Chakravarthy, MD, PhD,* Michael A. Fishman, MD,† Xander Zuidema, MD, PharmD,‡ Corey W. Hunter, MD,§ and Robert Levy, MD, PhD¶







Burst stimulation

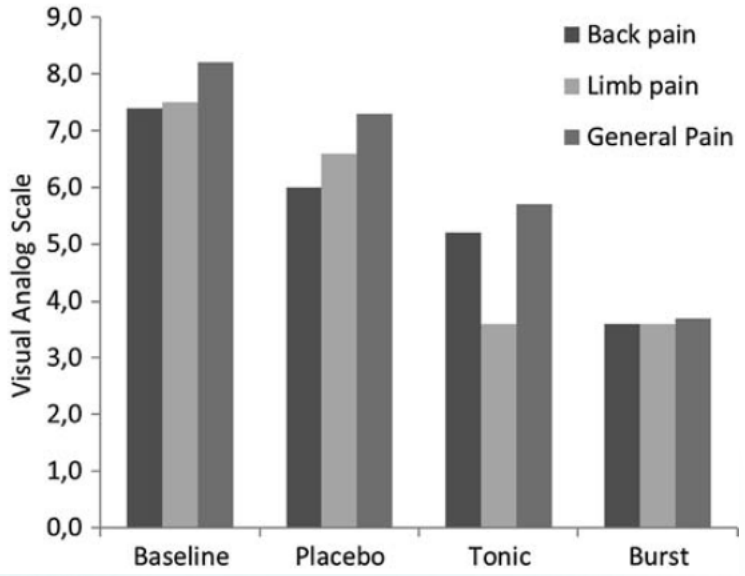
Clustered Tonic stimulation

Burst DR

Burst Spinal Cord Stimulation for Limb and Back Pain

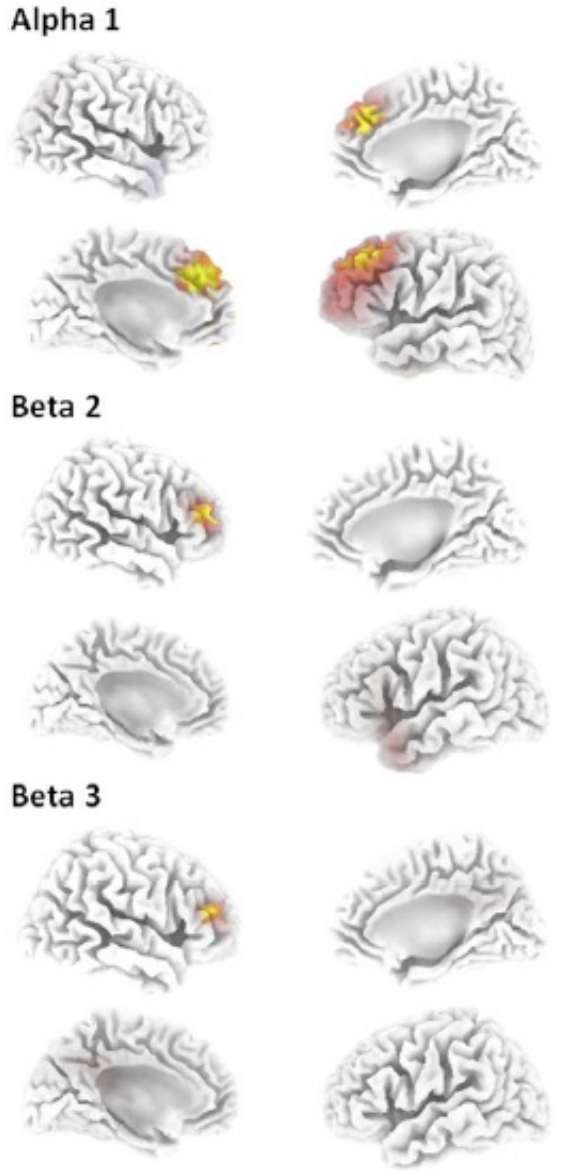
World Neurosurg. (2013) 80, 5:642 649.

Dirk De Ridder[1,2], Mark Plazier[3], Niels Kamerling[3], Tomas Menovsky[3], Sven Vanneste[4]



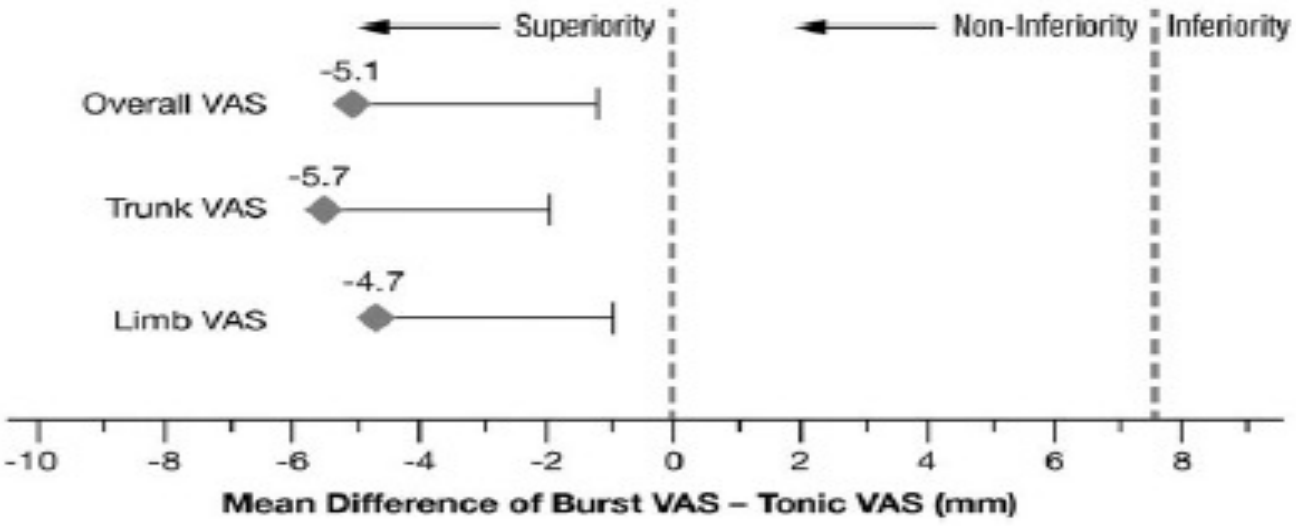
	Placebo		Tonic		Burst		
	RD	%	RD	%	RD	%	*F* Value
PVAQ							
Attention to pain	0.5[a]	3.3	0.8[a]	5.0	1.2[b]	7.6	6.57*
Attention to changes in pain	0.6[a]	3.2	0.7[a]	3.9	1.9[b]	10.0	4.93*
VAS scales							
Pain now	0.9[a]	12.8	1.9[b]	26.0	3.6[b]	49.8	6.36*
Least pain (last 7 days)	1.1[a]	21.7	2.4[b]	45.8	3.8[c]	73.2	6.02*
Worst pain (last 7 days)	0.05[a]	0.6	1[a]	12.6	2.8[b]	36.0	4.63*

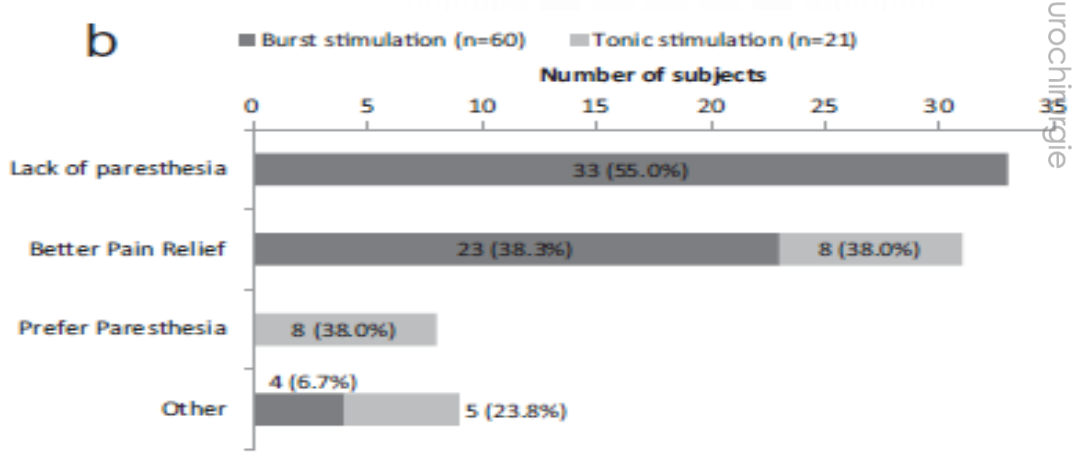
	Placebo		Tonic		Burst		
	RD	%	RD	%	RD	%	*F* Value
Back pain	1.4a	18.9	2.2a,b	30.3	3.8b	51.3	6.20*
Limb pain	0.9a	11.7	3.9b	51.5	3.9b	52.7	4.66†
General pain	0.9a	10.9	2.5b	30.9	4.5c	55.0	7.44*

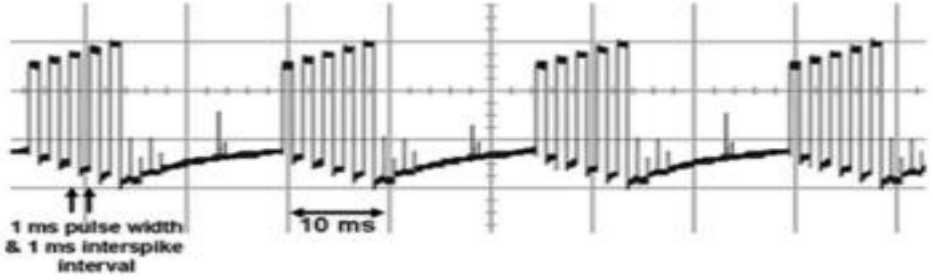


Success Using Neuromodulation With BURST (SUNBURST) Study: Results From a Prospective, Randomized Controlled Trial Using a Novel Burst Waveform

Timothy Deer, MD*; Konstantin V. Slavin, MD †; Kasra Amirdelfan, MD‡; Richard B. North, MD§; Allen W. Burton, MD¶; Thomas L. Yearwood, MD, PhD**; Ed Tavel, MD††; Peter Staats, MD‡‡; Steven Falowski, MD§§; Jason Pope, MD¶¶; Rafael Justiz, MD***; Alain Y. Fabi, MD†††; Alexander Taghva, MD ‡‡‡; Richard Paicius, MD‡‡‡; Timothy Houden, MD§§§; Derron Wilson, MD¶¶¶



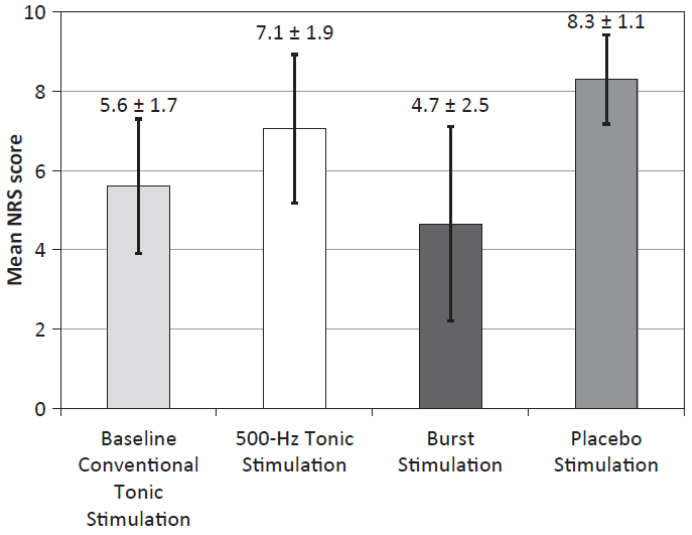


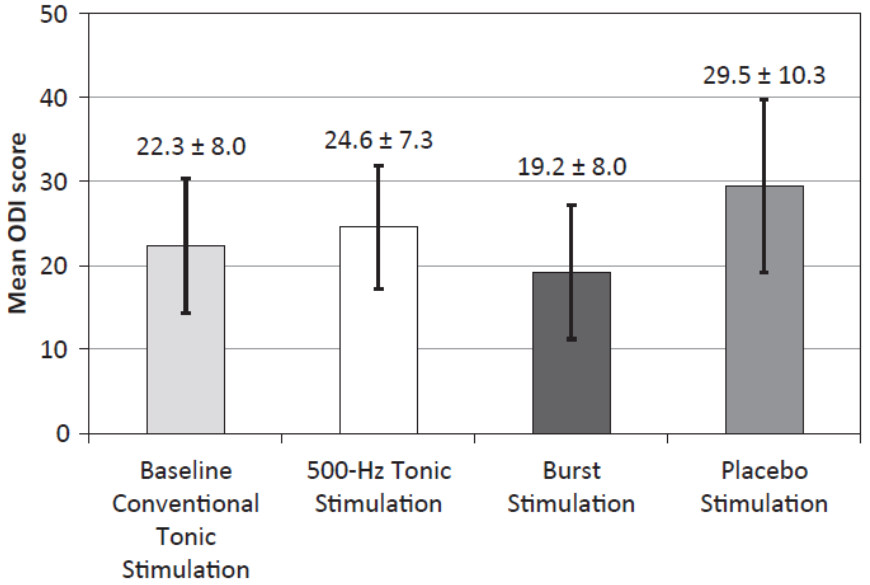


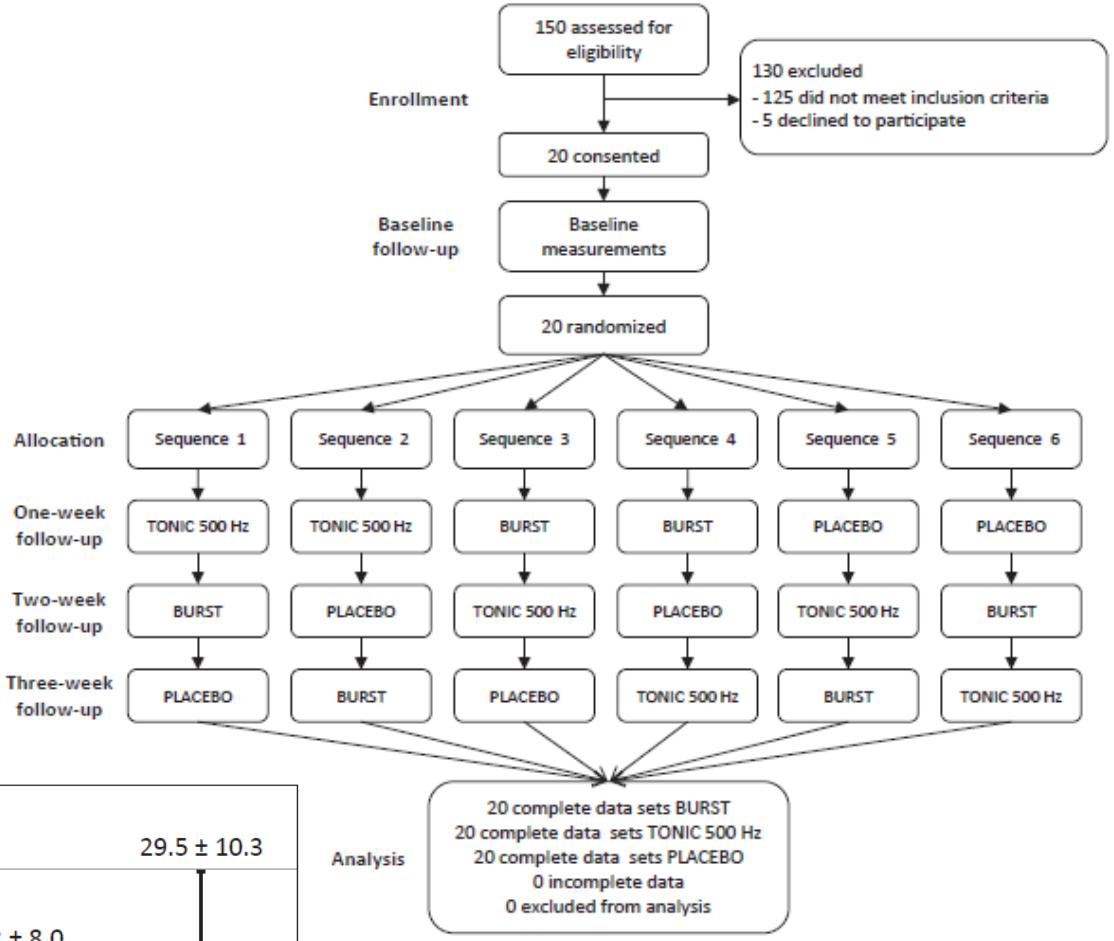
Stimulation Tonique Cluster

A Prospective, Randomised, Double-blind, Placebo-controlled Study to Examine the Effectiveness of Burst Spinal Cord Stimulation Patterns for the Treatment of Failed Back Surgery Syndrome

Stefan Schu, MD, PhD*; Philipp J. Slotty, MD*; Gregor Bara, MD*; Monika von Knop*; Deborah Edgar, PhD†; Jan Vesper, MD, PhD*







EJP
European Journal of Pain

ORIGINAL ARTICLE

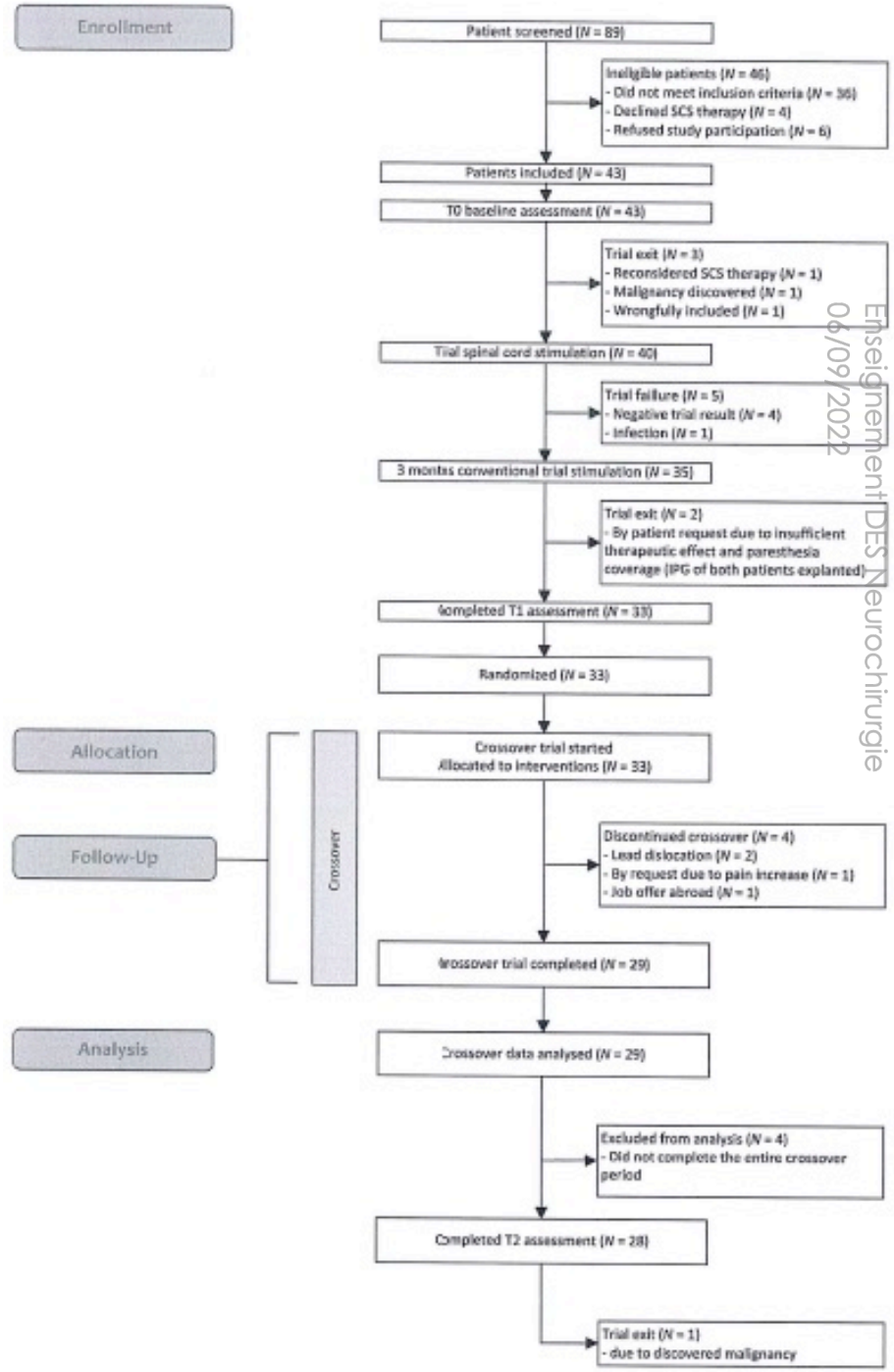
Preferred frequencies and waveforms for spinal cord stimulation in patients with complex regional pain syndrome: A multicentre, double-blind, randomized and placebo-controlled crossover trial

N. Kriek[1], J.G. Groeneweg[1], D.L. Stronks[1], D. de Ridder[2], F.J.P.M. Huygen[1]

1 Center for Pain Medicine, Erasmus MC – University Medical Center Rotterdam, The Netherlands
2 Department of Surgical Sciences, Section of Neurosurgery, Dunedin School of Medicine, University of Otago, Dunedin, New Zealand

Primary outcome parameters (n = 29)	Standard	500 Hz	1200 Hz	Burst	Placebo	Overall statistical outcome*
Visual analogue scale, mean (SE) [95% CI]	39.83 (4.7)^{A} [30.19–49.47]	40.13 (4.94)^{B} [30.02–50.24]	42.89 (4.79)^{C} [33.09–52.70]	47.98 (5.26)^{D} [37.22–58.75]	63.74 (3.51)$^{A–D}$ [56.56–70.91]	$F_{(1,4)} = 7.834$; $p < 0.001$
McGill pain scores, mean (SE) [95% CI]						
Average pain	4.70 (0.40)^{A} [3.89–5.50]	5.10 (0.45)^{B} [4.18–6.03]	5.31 (0.46)^{C} [4.36–6.26]	5.66 (0.49)^{D} [4.65–6.66]	7.07 (0.28)$^{A–D}$ [6.50–7.63]	$F_{(1,4)} = 11.370$; $p < 0.001$

Distribution of stimulation preferences	Standard	500 Hz	1200 Hz	Burst	Placebo	Total
Preferred stimulation, n (%)	14 (48.3)	6 (20.7)	4 (13.8)	4 (13.8)	1 (3.4)	29 (100)
Best user-friendliness, n (%)	14 (48.3)	8 (27.6)	1 (3.4)	6 (20.7)	0 (0)	29 (100)
Comfortable, n (%)	14 (48.3)	7 (24.1)	4 (13.8)	4 (13.8)	0 (0)	29 (100)



Journal of Clinical Medicine

MDPI

Article

Sub-Perception and Supra-Perception Spinal Cord Stimulation in Chronic Pain Syndrome: A Randomized, Semi-Double-Blind, Crossover, Placebo-Controlled Trial

Paweł Sokal [1,2,*], Agnieszka Malukiewicz [1], Sara Kierońska [1], Joanna Murawska [3], Cezary Guzowski [3], Marcin Rudaś [1], Dariusz Paczkowski [1], Marcin Rusinek [1] and Mateusz Krakowiak [1]

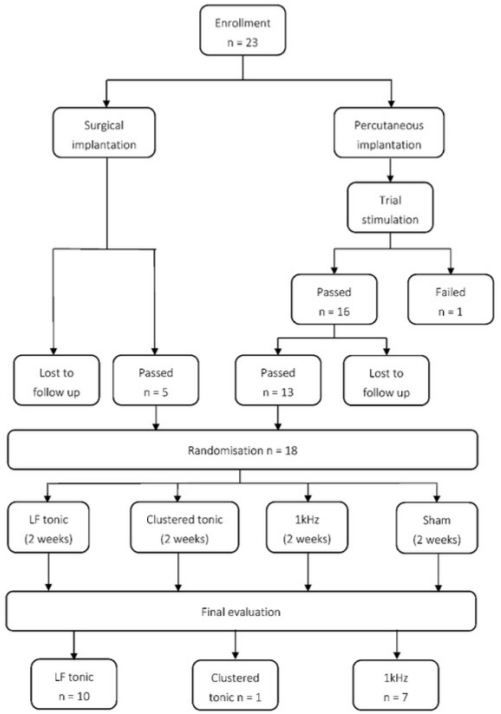
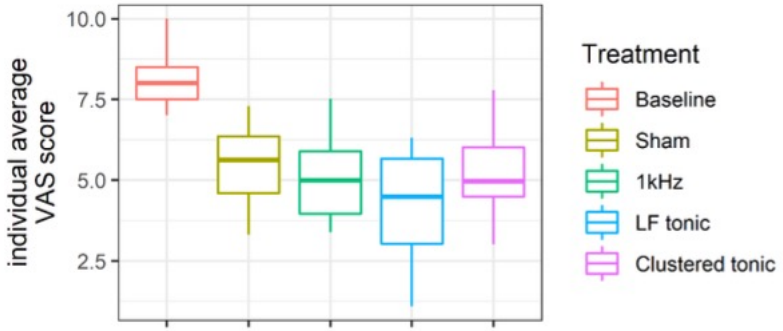


Figure 1. Consort flowchart.

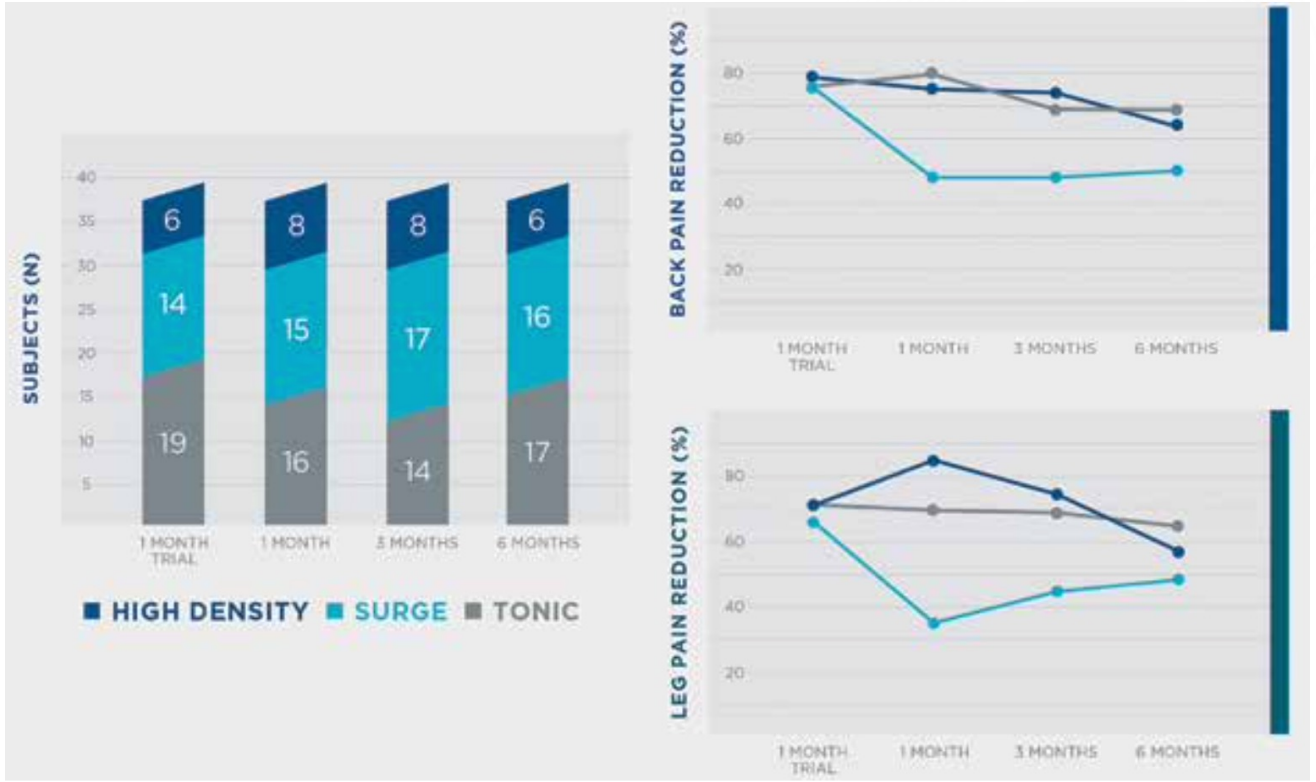


Pain Physician 2022; 25:67-76 • ISSN 1533-3159

Prospective Study

Multi-waveform Spinal Cord Stimulation with High Frequency Electromagnetic Coupled (HF-EMC) Powered Implanted Electrode Array and Receiver for the Treatment of Chronic Back and Leg Pain (SURF Study)

Robert Bolash, MD[1], Michael Creamer, DO[2], Richard Rauck, MD[3], Payam Vahedifar, MD[4], Aaron Calodney, MD[5], Ira Fox, MD[6], Cuneyt Özaktay, MD[6], and Niek Vanquathem, BA[7]



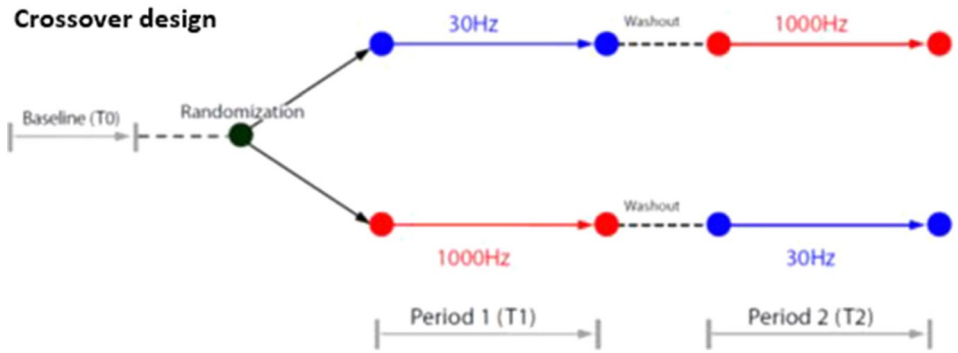
Pain Ther (2021) 10:1189–1202
https://doi.org/10.1007/s40122-021-00268-7

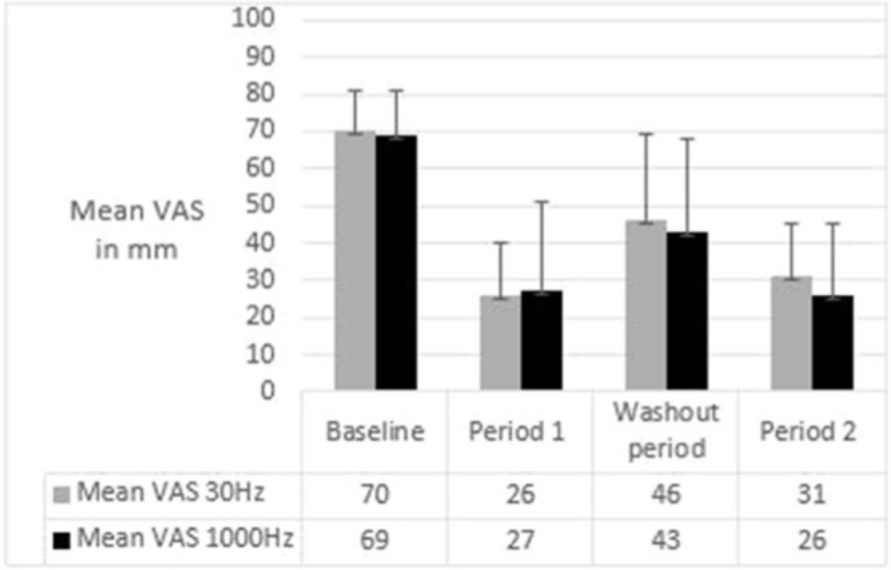
Medtronic

ORIGINAL RESEARCH

A Comparison of 1000 Hz to 30 Hz Spinal Cord Stimulation Strategies in Patients with Unilateral Neuropathic Leg Pain Due to Failed Back Surgery Syndrome: A Multicenter, Randomized, Double-Blinded, Crossover Clinical Study (HALO)

Jennifer Breel · Frank Wille · Agnes G. C. L. Wensing · Jan Willem Kallewaard · Harmen Pelleboer · Xander Zuidema · Katja Bürger · Stijn de Graaf · Markus W. Hollmann



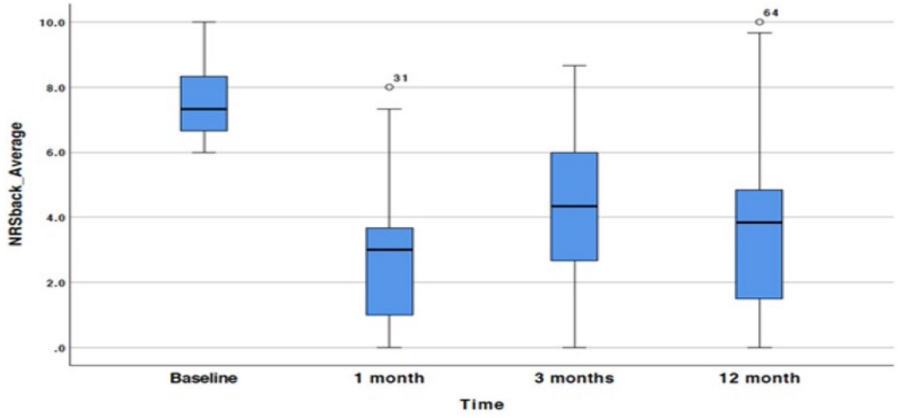


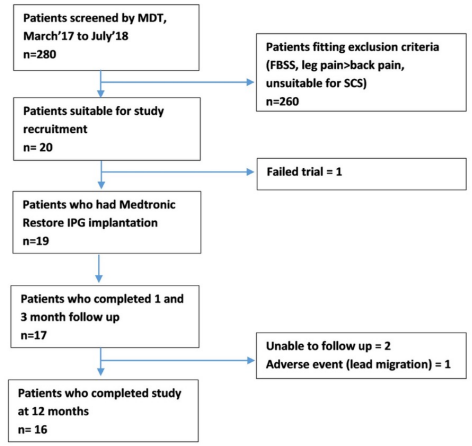
Autres formes d’ondes??

High Density

Effectiveness of high dose spinal cord stimulation for non-surgical intractable lumbar radiculopathy - HIDENS Study

Vivek Mehta MBBS, MD, FRCA, FFPMRCA[1,2] | Kavita Poply FRCA, FCARCSI, FFPMRCA, PhD[1,2] | Alia Ahmad MSc, BSc[1] | Joanne Lascelles RN, MSc, Bsc[1,2] | Amin Elyas MBBS, FRCS, FRCS (SN)[2,3] | Sanskriti Sharma MSc, BSc[1] | Balaji Ganeshan PhD, BEng[4] | Habib Ellamushi MBBS, FRCS (SN)[2,3] | Serge Nikolic MD FRCA FFPMRCA[1,2]





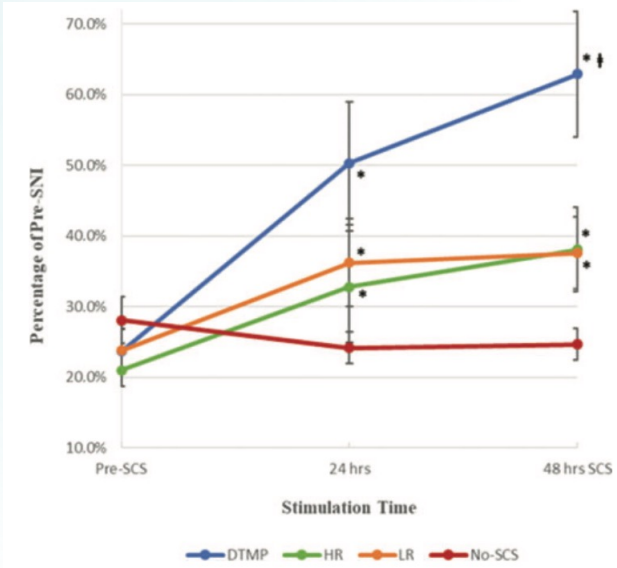
Differential Target Multiplexed (DTM)

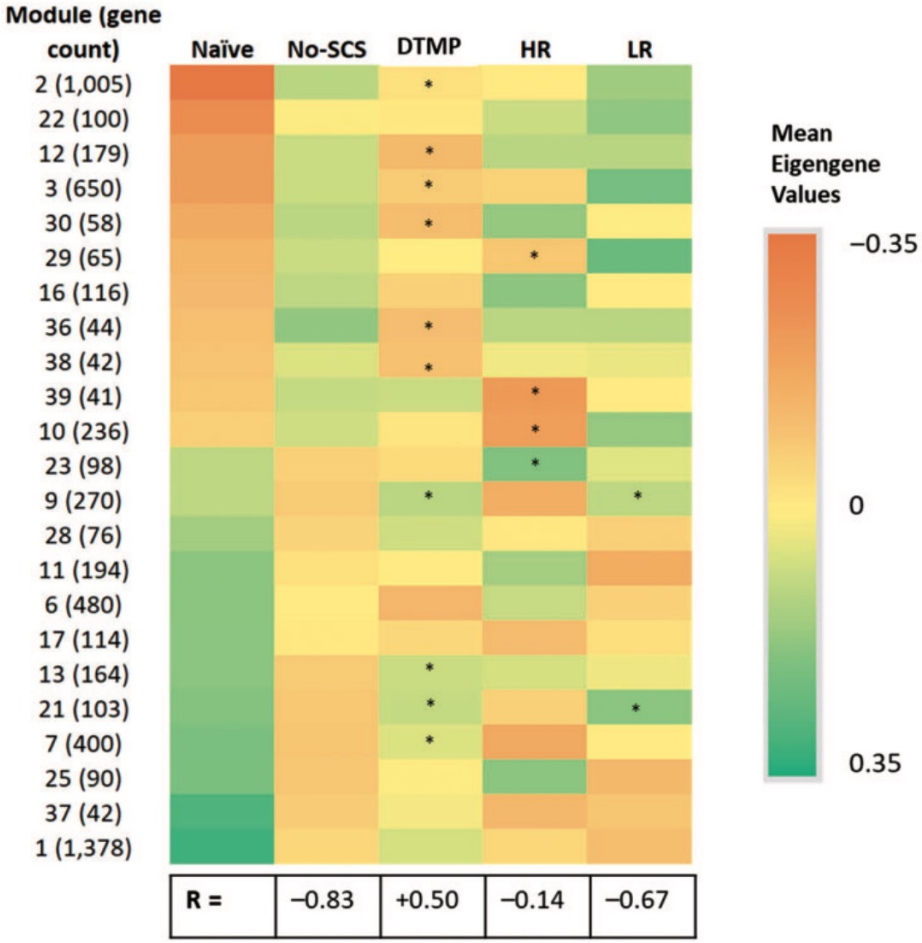
Modulation of neuroglial interactions using differential target multiplexed spinal cord stimulation in an animal model of neuropathic pain

Ricardo Vallejo[1,2], Courtney A Kelley[1,2], Ashim Gupta[1,2,3], William J Smith[1,4], Alejandro Vallejo[1], and David L Cedeño[1,2]

Molecular Pain
Volume 16: 1–13

DOI: 10.1177/1744806920918057
journals.sagepub.com/home/m
SAGE



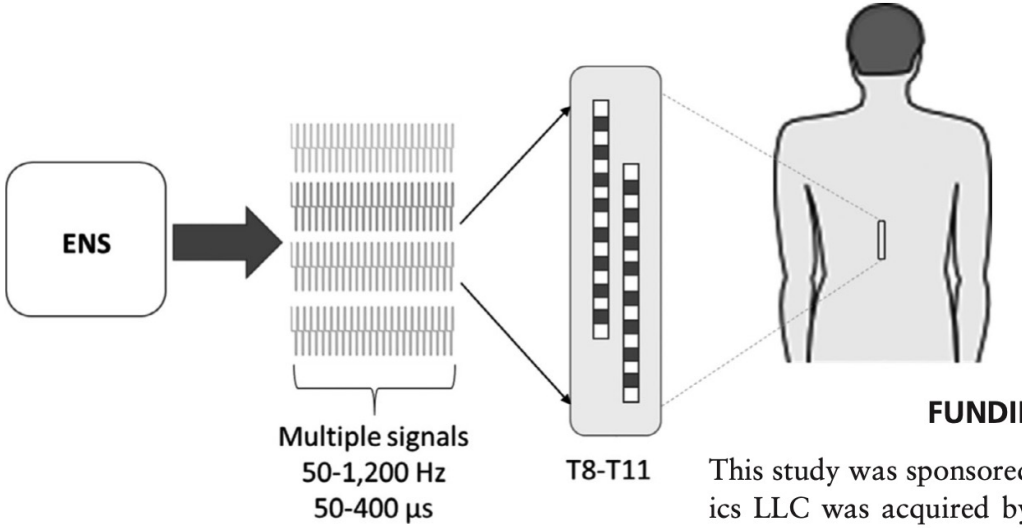


Differential Target Multiplexed (DTM)

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

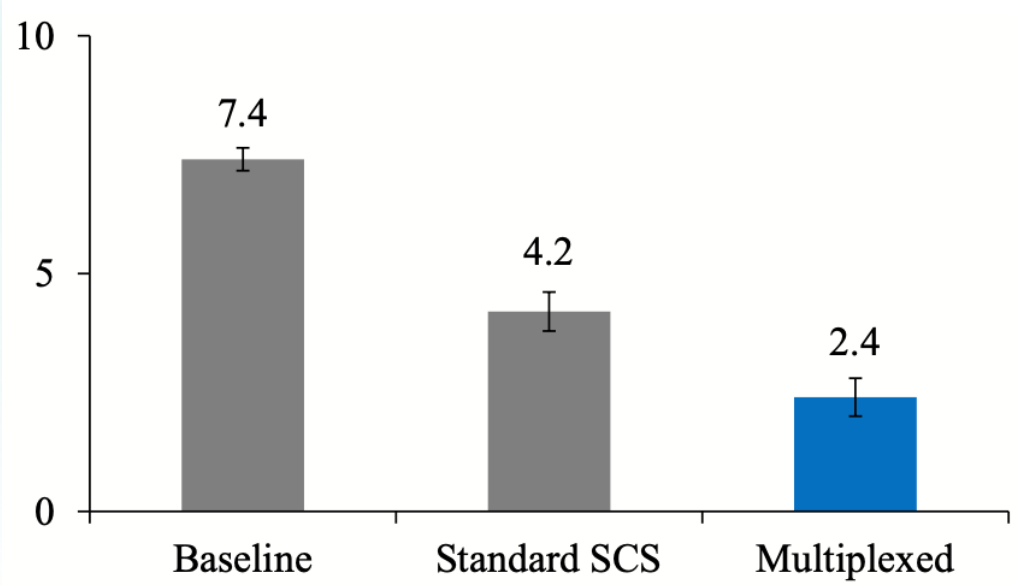
Pain Practice, Volume 20, Issue 7, 2020 761–768

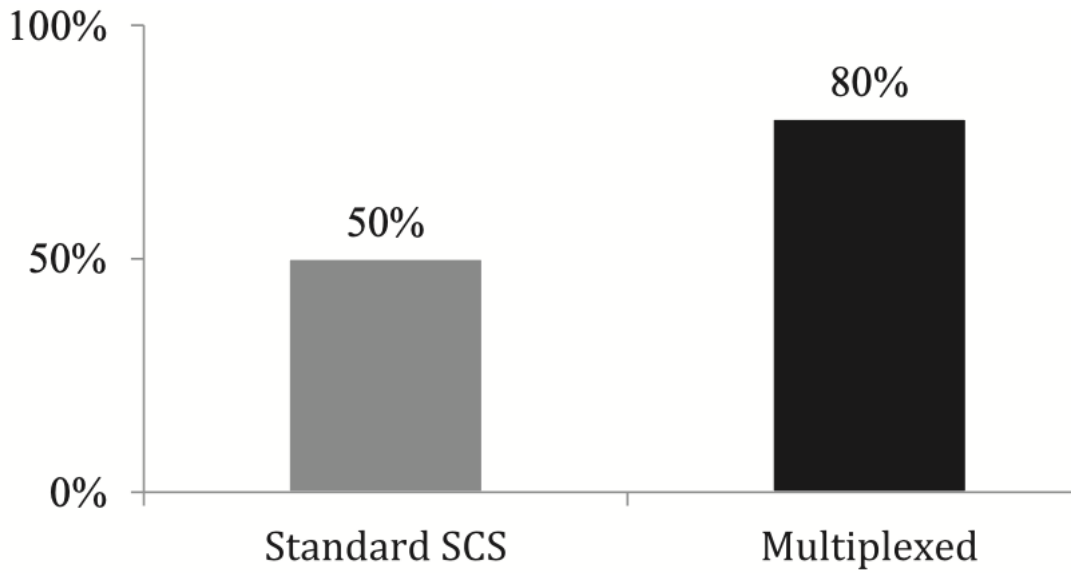
Michael A. Fishman, MD, MBA*; Aaron Calodney, MD†; Philip Kim, MD*; Jan Slezak, MD‡; Ramsin Benyamin, MD§; Atiq Rehman, MD¶; Eliezer Soto, MD**; Thomas Yang, MD††; Asteghik Hacobian, MD‡; Lee Griffith, MD†; Cong Yu,MD††; Ricardo Vallejo, MD, PhD§



FUNDING SOURCE

This study was sponsored by Stimgenics LLC. Stimgenics LLC was acquired by Medtronic in January 2020. Differential Target Multiplexed SCS (DTM) is a trademark of Medtronic.





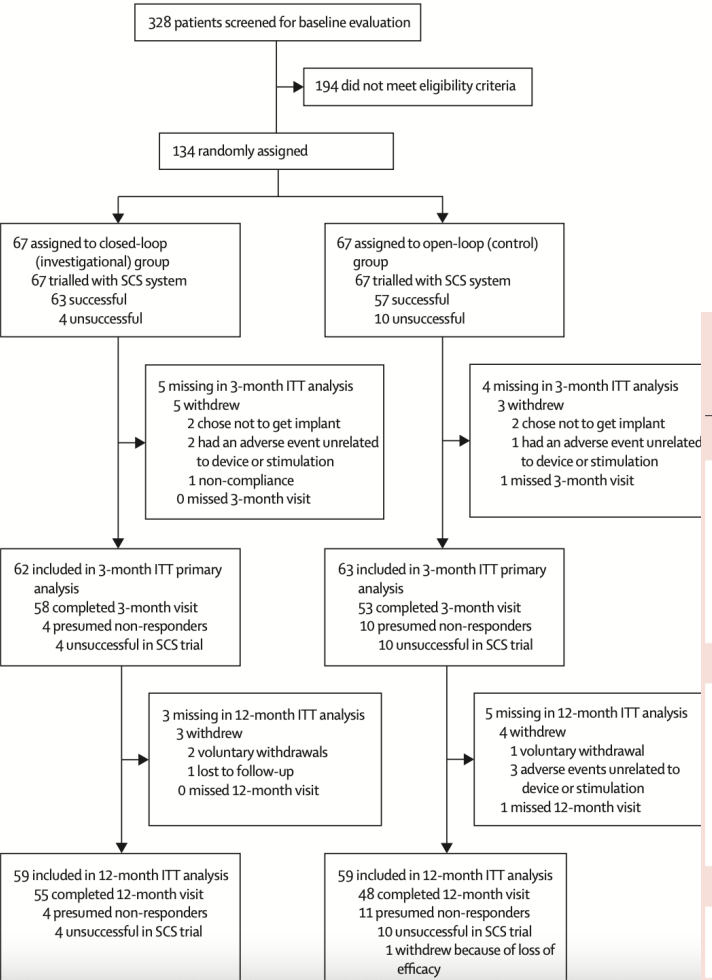
Long-term safety and efficacy of closed-loop spinal cord stimulation to treat chronic back and leg pain (Evoke): a double-blind, randomised, controlled trial

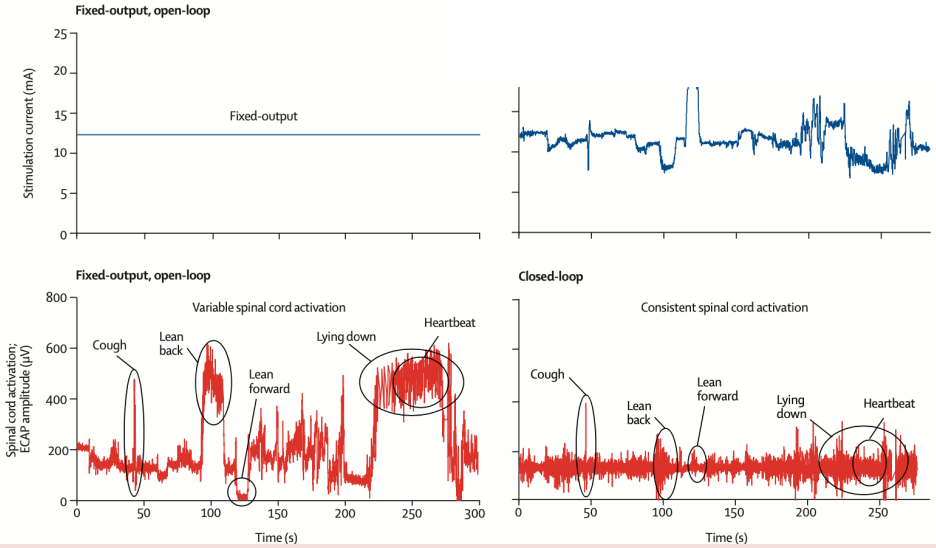
*Nagy Mekhail, Robert M Levy, Timothy R Deer, Leonardo Kapural, Sean Li, Kasra Amirdelfan, Corey W Hunter, Steven M Rosen, Shrif J Costandi, Steven M Falowski, Abram H Burgher, Jason E Pope, Christopher A Gilmore, Farooq A Qureshi, Peter S Staats, James Scowcroft, Jonathan Carlson, Christopher K Kim, Michael I Yang, Thomas Stauss, Lawrence Poree, on behalf of the Evoke Study Group**

Lancet Neurol 2019

Summary

Background Spinal cord stimulation has been an established treatment for chronic back and leg pain for more than





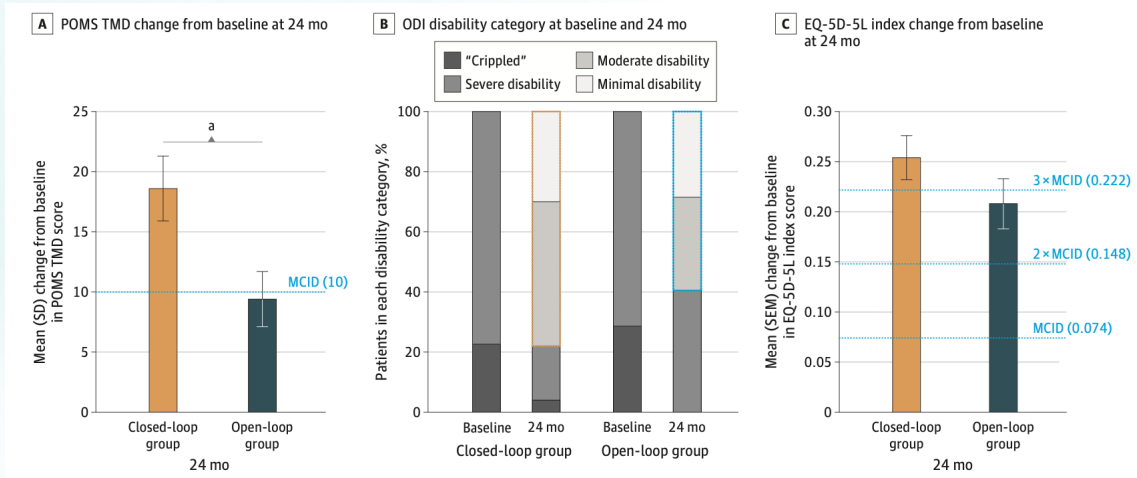
	3 months				12 months			
	Closed-loop group	Open-loop group	Difference (95% CI)	p value	Closed-loop group	Open-loop group	Difference (95% CI)	p value
VAS percentage change from baseline*†‡								
Overall pain	73·8% (28·0)	59·4% (35·8)	14·4% (3·0 to 25·8)	0·013	72·3% (29·0)	56·2% (38·5)	16·0% (3·6 to 28·5)	0·012
Back pain (hierarchical secondary outcome)	72·1% (29·4)	57·5% (36·4)	14·6% (2·9 to 26·3)	0·015§	69·4% (30·6)	54·0% (39·5)	15·4% (2·5 to 28·3)	0·020§
Leg pain (hierarchical secondary outcome)	76·8% (28·3)	67·8% (35·5)	9·0 (−2·4 to 20·4)	0·0006¶	72·9% (31·0)	62·1% (37·5)	10·7% (−1·8 to 23·3)	0·0007¶
VAS responder rates*‖								
Overall pain ≥50% reduction (primary outcome)	51/62 (82%)	38/63 (60%)	21·9% (6·6 to 37·3)	0·0052§	49/59 (83%)	36/59 (61%)	22·0% (6·3 to 37·7)	0·0060§
Back pain ≥50% reduction (hierarchical secondary outcome)	50/62 (81%)	36/63 (57%)	23·5% (7·8 to 39·2)	0·0033§	47/59 (80%)	34/59 (58%)	22·0% (5·8 to 38·3)	0·0079§
Leg pain ≥50% reduction	50/62 (81%)	43/63 (68%)	12·4% (−2·7 to 27·5)	0·0020¶	49/59 (83%)	36/59 (61%)	22·0% (6·3 to 37·7)	0·0060§
VAS high responder rates*‖								
Overall back and leg pain ≥80% reduction (hierarchical secondary outcome)	36/62 (58%)	27/63 (43%)	15·2% (−2·1 to 32·5)	0·0023¶	33/59 (56%)	22/59 (37%)	18·6% (1·0 to 36·3)	0·039§

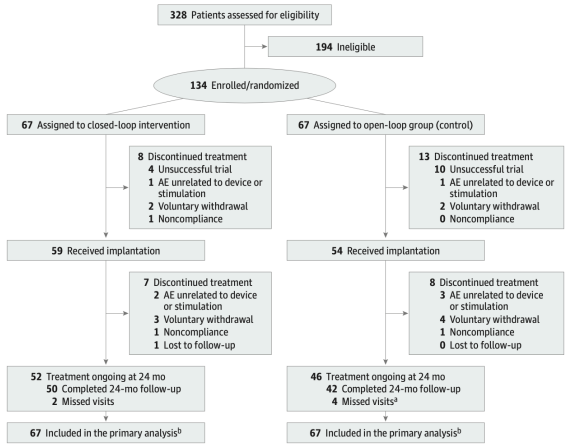
JAMA Neurology | Original Investigation

Durability of Clinical and Quality-of-Life Outcomes of Closed-Loop Spinal Cord Stimulation for Chronic Back and Leg Pain

A Secondary Analysis of the Evoke Randomized Clinical Trial

Nagy Mekhail, MD, PhD; Robert M. Levy, MD, PhD; Timothy R. Deer, MD; Leonardo Kapural, MD, PhD; Sean Li, MD; Kasra Amirdelfan, MD; Corey W. Hunter, MD; Steven M. Rosen, MD; Shrif J. Costandi, MD; Steven M. Falowski, MD; Abram H. Burgher, MD; Jason E. Pope, MD; Christopher A. Gilmore, MD; Farooq A. Qureshi, MD; Peter S. Staats, MD; James Scowcroft, MD; Tory McJunkin, MD; Jonathan Carlson, MD; Christopher K. Kim, MD; Michael I. Yang, MD; Thomas Stauss, MD; Julie Pilitsis, MD; Lawrence Poree, MD, MPH, PhD; and the Evoke Study Group





Marc Russo, MBBS, DA*
Charles Brooker, MBChB‡§
Michael J. Cousins, MD, DSc‡§
Nathan Taylor, MBBS‡§
Tillman Boesel, MBBS¶
Richard Sullivan, MBChB‖
Lewis Holford, MBChB‡§
Erin Hanson, MPH#
Gerrit Eduard Gmel, PhD#
Nastaran Hesam Shariati, PhD#
Lawrence Poree, MD, PhD**
John Parker, PhD#‡‡

*Hunter Pain Clinic, Broadmeadow

Sustained Long-Term Outcomes With Closed-Loop Spinal Cord Stimulation: 12-Month Results of the Prospective, Multicenter, Open-Label Avalon Study

BACKGROUND: Spinal cord stimulation (SCS) activates the dorsal column fibers using electrical stimuli. Current SCS systems function in fixed-output mode, delivering the same stimulus regardless of spinal cord (SC) activation.

OBJECTIVE: To present long-term outcomes of a novel closed-loop SCS system that aims to maintain the SC activation near a set target level and within a therapeutic window for each patient. SC activation is measured through the evoked compound action potential

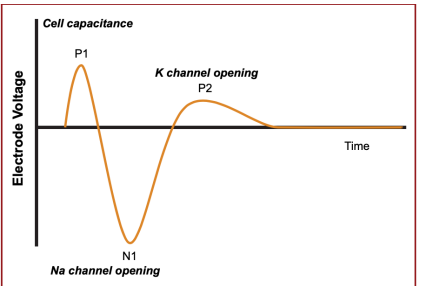


FIGURE 1. *Schematic representation of an ECAP. ECAPs have a well-defined shape with 3 peaks: 2 positive and 1 negative, labeled P1, N1, and P2, in order of appearance. In simple terms, they are the combined electrical field generated by the action potentials of stimulated fibers at the recording site. The first P1 peak stems from capacitive coupling between the inside and outside of the fibers and is caused by the incoming action potential. The N1 and P2 peaks result from ionic flow (sodium [Na+] and potassium [K+]) in and out of the fibers that form the well-known action potential. As the measurement is done outside of the fibers, the polarity of the peaks is reversed compared with intracellular recordings often depicted in textbooks. ECAP, evoked compound action potential.*

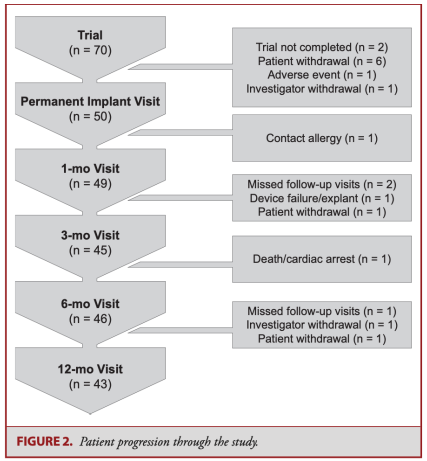


FIGURE 2. *Patient progression through the study.*

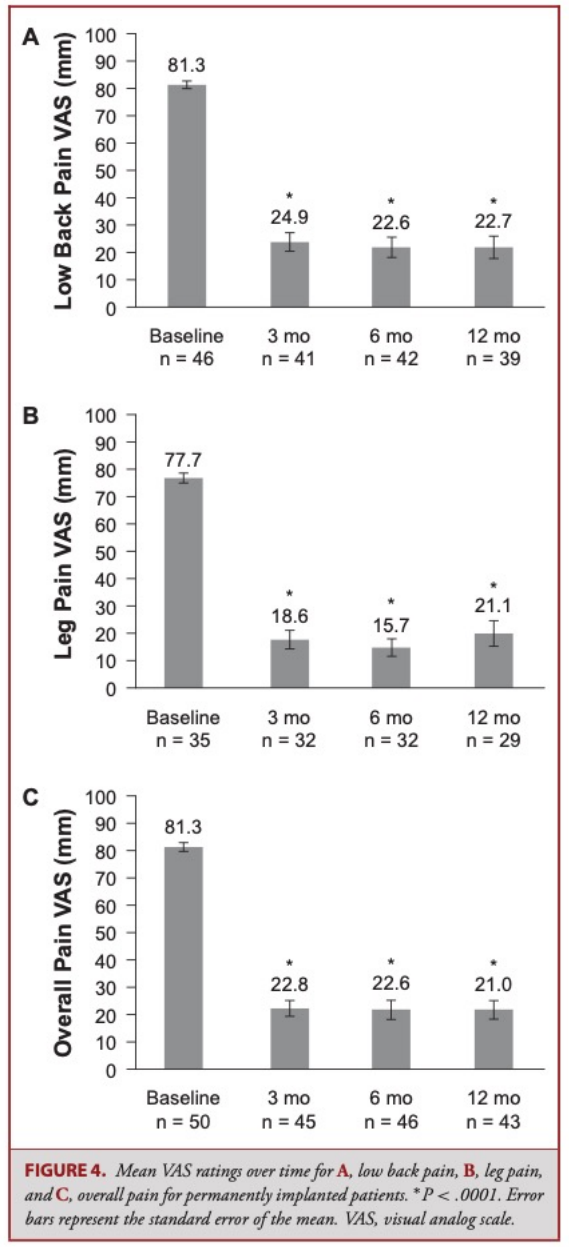
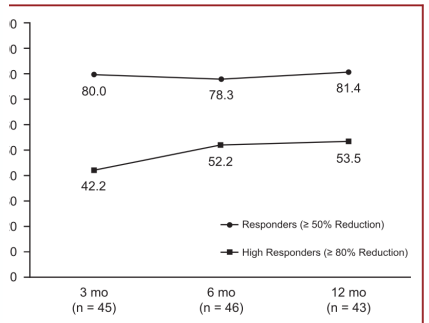


FIGURE 4. *Mean VAS ratings over time for A, low back pain, B, leg pain, and C, overall pain for permanently implanted patients. * $P < .0001$. Error bars represent the standard error of the mean. VAS, visual analog scale.*



RE 5. *Responder and high responder rates for overall pain over time.*

ECAP-Controlled Closed-Loop Spinal Cord Stimulation Efficacy and Opioid Reduction Over 24-Months: Final Results of the Prospective, Multicenter, Open-Label Avalon Study

Charles Brooker, MBBS*,†; Marc Russo, MBBS, DA‡; Michael J. Cousins, MD, DSc*,†; Nathan Taylor, MBBS*,†; Lewis Holford, MBChB*,†; Rebecca Martin, MBBS*; Tillman Boesel, MBBS§; Richard Sullivan, MBChB¶; Erin Hanson, MPH**; Gerrit Eduard Gmel, PhD**; Nastaran Hesam Shariati, PhD**; Lawrence Poree, MD, PhD††; John Parker, PhD**,‡‡

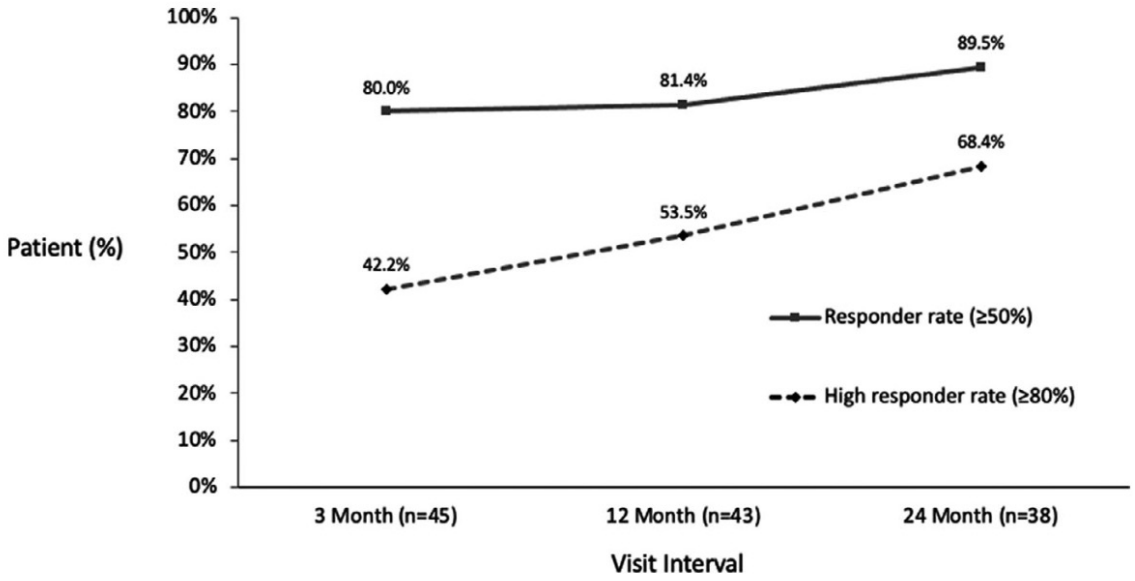
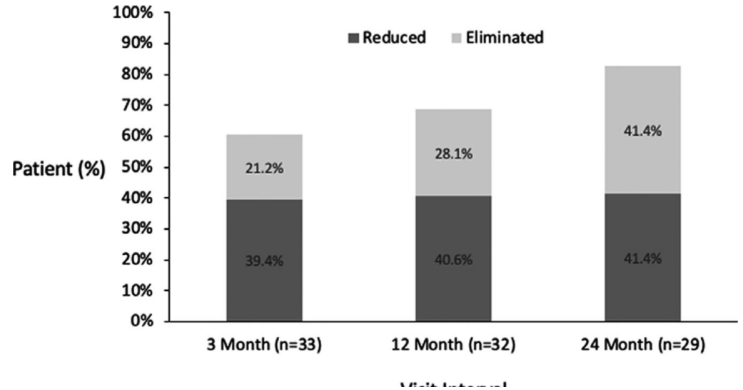
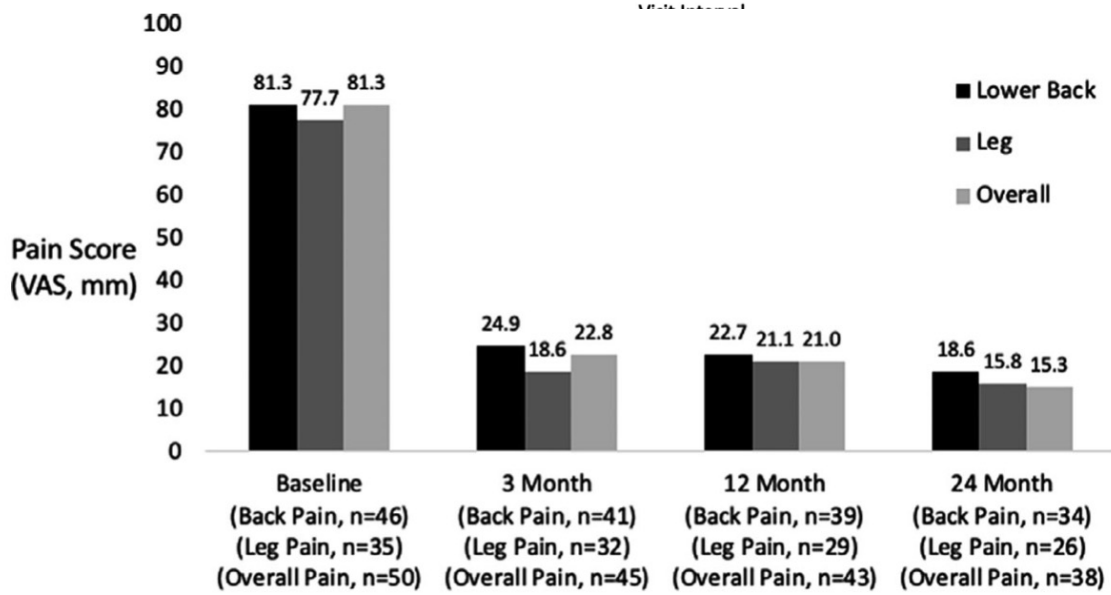


FIGURE 6. Average morphine milligram equivalent (MME) per day for the permanently implanted patients over time. MME, Morphine Milligram Equivalent.





Anaesthesia 2020, 75, 775–784 doi:10.1111/anae.15036

Original Article

10 kHz spinal cord stimulation for the treatment of non-surgical refractory back pain: subanalysis of pooled data from two prospective studies

A. Al-Kaisy,[1] **J. P. Van Buyten,**[2] **L. Kapural,**[3] **K. Amirdelfan**[4] **B. Gliner,**[5,6] **D. Caraway,**[6,7] **J. Subbaroyan**[6,8] **D. Edgar**[9] and **A. Rotte**[10]

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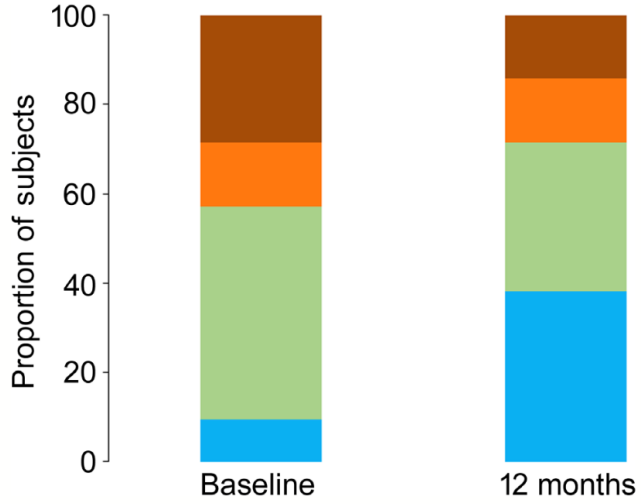

Figure 4 Opioid use categorised in morphine milligram equivalents (MME) at baseline and 12 months following 10 kHz spinal cord stimulation treatment. 0 MME (blue) 1–49 MME (green) 59–90 MME (orange) > 90 MME (brown).

Impact of Spinal Cord Stimulation on Opioid Dose Reduction: A Nationwide Analysis

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BACKGROUND: Opioid misuse in the USA is an epidemic. Utilization of neuromodulation for refractory chronic pain may reduce opioid-related morbidity and mortality, and associated economic costs.
OBJECTIVE: To assess the impact of spinal cord stimulation (SCS) on opioid dose reduction.
METHODS: The IBM MarketScan® database was retrospectively queried for all US patients with a chronic pain diagnosis undergoing SCS between 2010 and 2015. Opioid usage before and after the procedure was quantified as morphine milligram equivalents (MME).
RESULTS: A total of 8497 adult patients undergoing SCS were included. Within 1 yr of the procedure, 60.4% had some reduction in their opioid use, 34.2% moved to a clinically important lower dosage group, and 17.0% weaned off opioids entirely. The proportion of patients who completely weaned off opioids increased with decreasing preprocedure dose, ranging from 5.1% in the >90 MME group to 34.2% in the ≤20 MME group. The following variables were associated with reduced odds of weaning off opioids post procedure: long-term opioid use (odds ratio [OR]: 0.26; 95% CI: 0.21-0.30; $P < .001$), use of other pain medications (OR: 0.75; 95% CI: 0.65-0.87; $P < .001$), and obesity (OR: 0.75; 95% CI: 0.60-0.94; $P = .01$).
CONCLUSION: Patients undergoing SCS were able to reduce opioid usage. Given the potential to reduce the risks of long-term opioid therapy, this study lays the groundwork for efforts that may ultimately push stakeholders to reduce payment and policy barriers to SCS as part of an evidence-based, patient-centered approach to nonopioid solutions for chronic pain.

KEY WORDS: Chronic pain, Morphine milligram equivalent, Opioid epidemic, Opioid misuse, Spinal cord stimulation

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TABLE 3. Significant Factors Associated With Completely Weaning Off Opioids for All Patients Taking Opioids During the Last Quarter Before SCS, as Determined by Multivariate Logistic Modeling

	Adjusted OR (95% CI)	*P* value
Pre-SCS trial MME dose group		
≤20 MME	4.85 (3.76, 6.25)	<.001
20-50 MME	2.50 (1.93, 3.23)	<.001
50-90 MME	1.34 (0.97, 1.85)	.08
>90 MME	Reference	–
Long-term use of opioids		
Yes	0.26 (0.21, 0.30)	<.001
No	Reference	–
Use of other pain medications		
Yes	0.75 (0.65, 0.87)	<.001
No	Reference	–
Obesity		
Yes	0.75 (0.60, 0.94)	0.01
No	Reference	–

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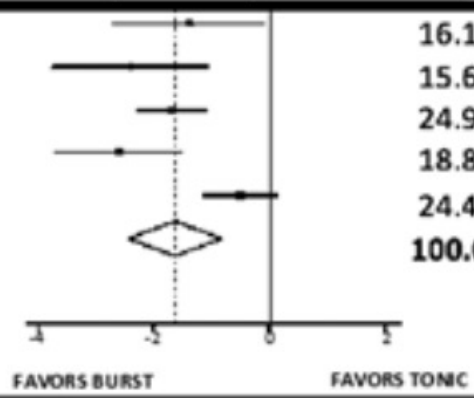
Systematic Review

Comparison of Spinal Cord Stimulation Waveforms for Treating Chronic Low Back Pain: Systematic Review and Meta-Analysis

Jay Karri, MD[1], Vwaire Orhurhu, MD[2], Sayed Wahezi, MD[3], Tuan Tang, MD[4], Timothy Deer, MD[5], and Alaa Abd-Elsayed, MD[6]

	BURST WAVEFORM			TONIC WAVEFORM					
Author, Year	Mean Pain Score	SD	Total	Mean Pain Score	SD	Total	Weighted Mean Difference D+L, Random, 95% CI	Weighted Mean Difference D+L, Random, 95% CI	Weight
Devos, 2014	3.5	2.2	24	4.9	2.5	24	-1.40 (-2.73, -0.07)		16.15
Schu, 2014	4.7	2.5	20	7.1	1.9	20	-2.40 (-3.78, -1.02)		15.68
DeRidder, 2015	3.2	2.3	102	4.9	2.3	102	-1.69 (-2.31, -1.07)		24.95
Courtney, 2015	2.8	1.7	22	5.4	2.0	22	-2.60 (-3.71, -1.50)		18.80
Deer, 2017	4.4	2.5	100	4.9	2.3	100	-0.50 (-1.17, 0.17)		24.42
Total (95% CI)			**268**			**268**	**-1.64 (-2.43, -0.84)**		**100.00**

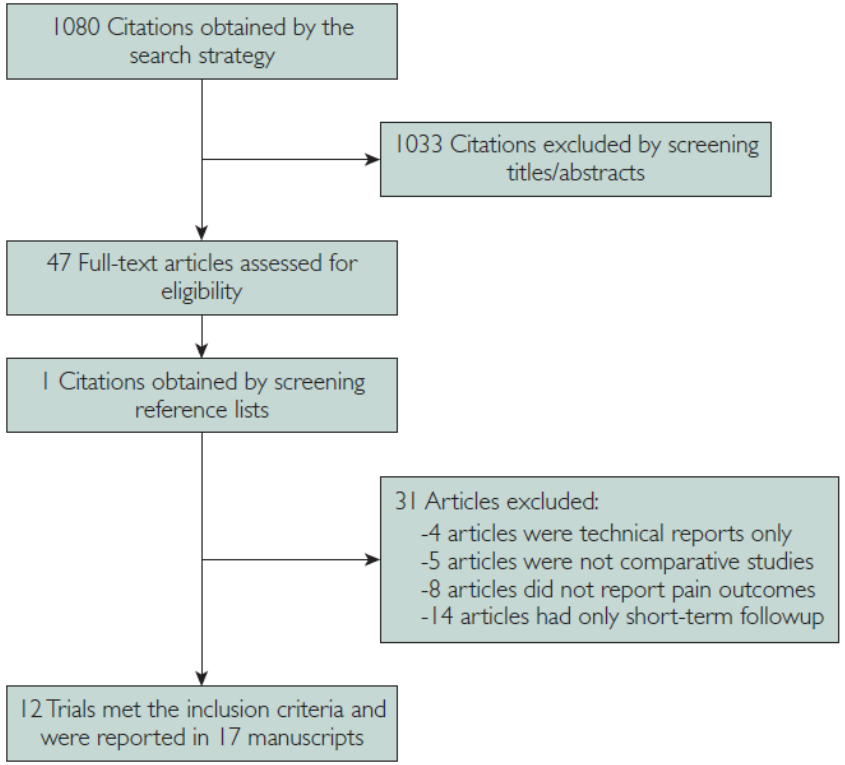
Heterogeneity: Tau^2=0.56, Chi^2 =14.38, df=4 (P=0.006): I^2=72.2%
Test of Overall effect: Z =4.02, P<0.0001

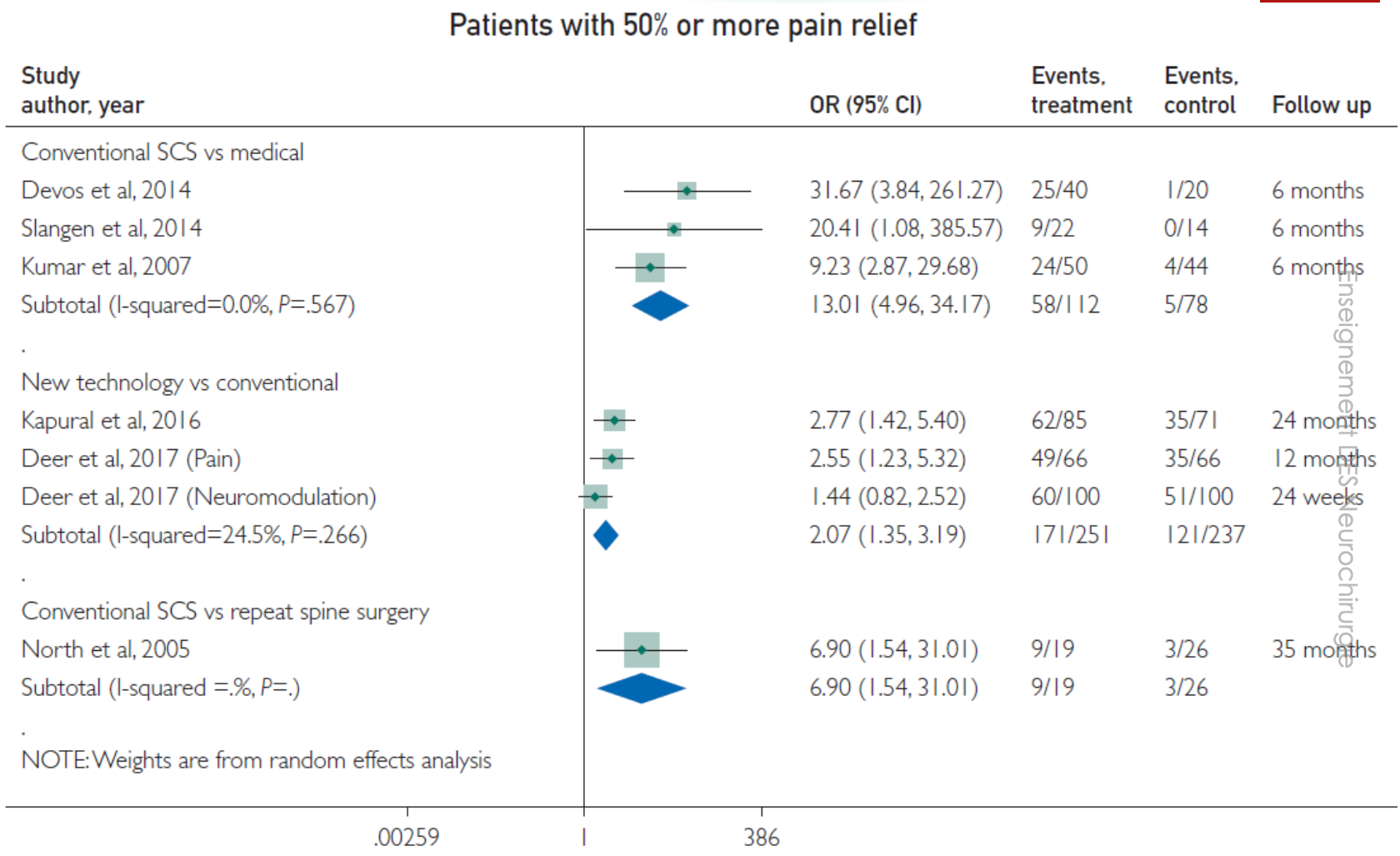


MAYO CLINIC

Spinal Stimulation for the Treatment of Intractable Spine and Limb Pain: A Systematic Review of RCTs and Meta-Analysis

Tim J. Lamer, MD; Susan M. Moeschler, MD; Halena M. Gazelka, MD; W. Michael Hooten, MD; Markus A. Bendel, MD; and M. Hassan Murad, MD





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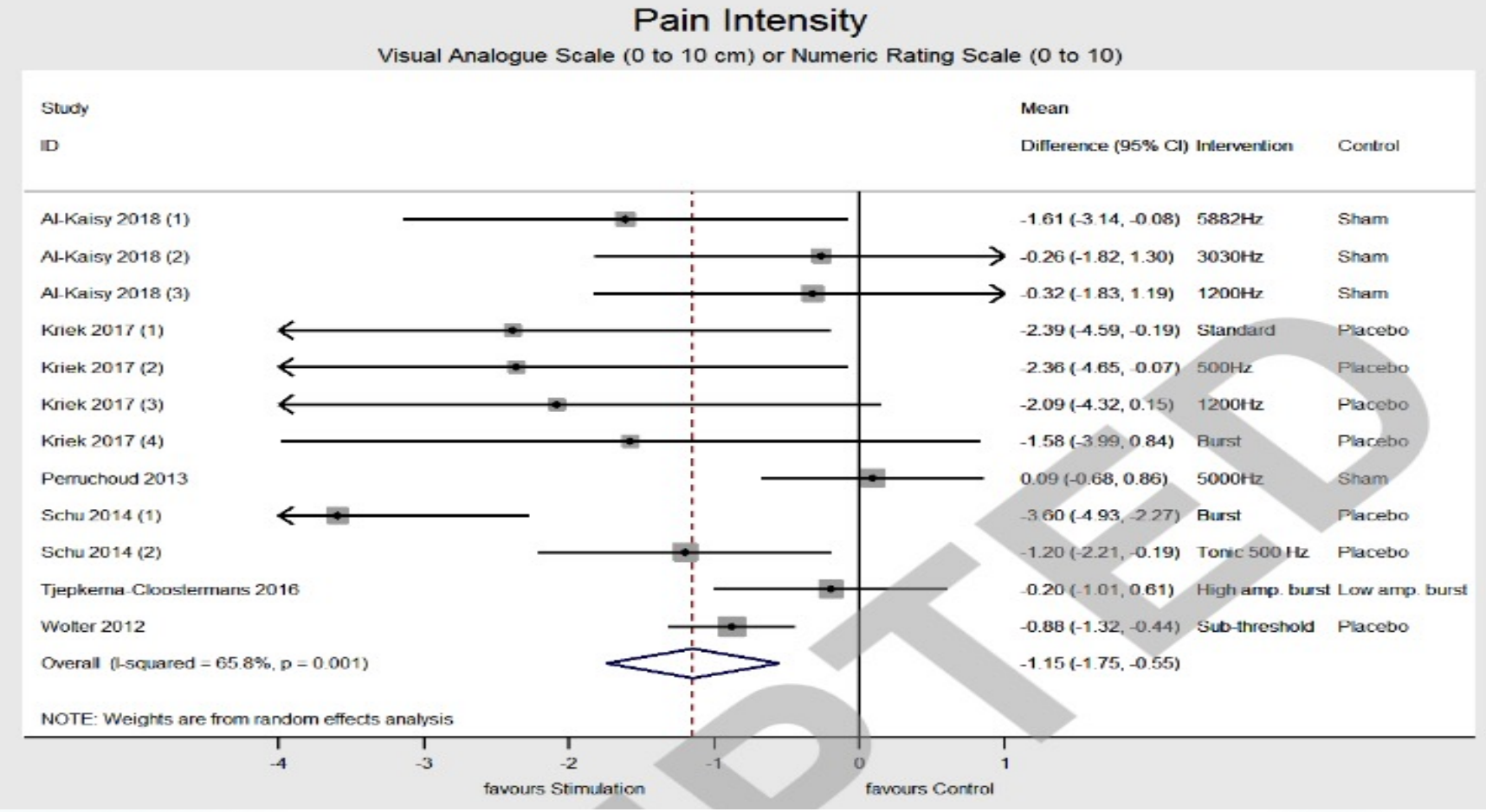
Systematic review and meta-analysis of placebo/sham controlled randomised trials of spinal cord stimulation for neuropathic pain

Rui V Duarte, PhD[1] Sarah Nevitt, PhD[1] Ewan McNicol, PharmD[2,3] Rod S Taylor, PhD[4,5] Eric Buchser, MD[6] Richard B North, MD[7] Sam Eldabe, MD[8]



Conclusion

- Peut-on réfléchir en 2021 comme en 2013 pour la SCS?
- De quoi disposons-nous maintenant ?
  - 1 recommandation société savante 1A
  - 18 RCT dont 8 avec placebo ou sham
  - 2 méta-analyses
- Combien d'entre vous propose ou envisage une SCS pour un patient avec lombo-radiculalgie majoritairement neuropathique (DN4) postopératoire répondant à la TENS?
- Combien d'entre vous propose ou envisage une SCS pour des douleurs neuropathiques d'origine diabétique, post-zostérienne, ou d'une maladie de Buerger?
- Peu de patients proposes en pratique et delai CETD long
- Frein = meconnaissance

Quiz : question

1. Par principe, une technique de neuromodulation est uniquement et seulement :

- ☐ Implantée
- ☐ Électrique
- ☐ Réversible
- ☐ Non lésionnelle
- ☐ Au niveau du système nerveux central

Quiz : réponses

1. Par principe, une technique de neuromodulation est uniquement et seulement :

- ☐ Implantée
- ☐ Électrique
- ☐ Réversible
- ☐ Non lésionnelle
- ☐ Au niveau du système nerveux central

Quiz : question

2. Les indications reconnues en France par l'HAS de la stimulation médullaire sont :

- ☐ Douleurs neuropathiques du diabète de type I
- ☐ Syndrome douloureux complexe régional de type II
- ☐ Douleurs neuropathiques trigéminales postopératoires
- ☐ Artériopathie Oblitérante des membres inférieurs de tout type
- ☐ Douleurs neuropathiques post-zostériennes

Quiz : réponses

2. Les indications reconnues en France par l'HAS de la stimulation médullaire sont :

- [x] Douleurs neuropathiques du diabète de type I
- [x] Syndrome douloureux complexe régional de type II
- [ ] Douleurs neuropathiques trigéminales postopératoires
- [ ] Artériopathie Oblitérante des membres inférieurs de tout type
- [x] Douleurs neuropathiques post-zostériennes

Quiz : question

3. Les Indications de stimulation médullaire dont les résultats antalgiques sont reconnus comme significativement supérieurs au traitement médical optimal par RCT sont :

- ☐ Syndrome douloureux complexe régional
- ☐ Lomboradiculalgies postopératoires
- ☐ Angor réfractaire
- ☐ Douleur neuropathique diabétique
- ☐ Douleurs neuropathiques post-zostériennes

Quiz : réponses

3. Les Indications de stimulation médullaire dont les résultats antalgiques sont reconnus comme significativement supérieurs au traitement médical optimal par RCT sont :

- [x] Syndrome douloureux complexe régional
- [x] Lomboradiculalgies postopératoires
- [x] Angor réfractaire
- [x] Douleur neuropathique diabétique
- [ ] Douleurs neuropathiques post-zostériennes

Quiz : question

4. Quelle(s) modalité(s) de stimulation ont-elles démontré leur supériorité antalgique significativement sur une autre modalité par essai randomisé contrôlé ?

- ☐ Stimulation paresthésiante
- ☐ BurstDR®
- ☐ Stimulation tonique en cluster
- ☐ DTM®
- ☐ Closed-loop stimulation (ECAP)
- ☐ Aucune des 5 propositions

Quiz : réponses

4. Quelle(s) modalité(s) de stimulation ont-elles démontré leur supériorité antalgique significativement sur une autre modalité par essai randomisé contrôlé ?

- ☐ Stimulation paresthésiante
- ☐ BurstDR®
- ☐ Stimulation tonique en cluster
- ☐ DTM®
- ☐ Closed-loop stimulation (ECAP)
- ☐ Aucune des 5 propositions

Quiz : question

5. Quels sont les points pouvant remettre en question la solidité méthodologique d'une RCT en neuromodulation de la douleur ?

- ☐ 2 bras spécifiques groupe placebo et groupe sham
- ☐ Populations étudiées hétérogènes dans les indications
- ☐ Objectif principal fondé uniquement sur l'EVA
- ☐ Financement non-institutionnel
- ☐ Résultats à 6 semaines

Quiz : réponses

5. Quels sont les points pouvant remettre en question la solidité méthodologique d'une RCT en neuromodulation de la douleur ?

- ☐ 2 bras spécifiques groupe placebo et groupe sham
- ☑ Populations étudiées hétérogènes dans les indications
- ☐ Objectif principal fondé uniquement sur l'EVA
- ☑ Financement non-institutionnel
- ☑ Résultats à 6 semaines