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Benelux
Neuromodulation
Society

BNS NEWSLETTER

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PREFACE BY THE PRESIDENT

MAARTEN MOENS

Dear BNS-members,
Dear friends of Neuromodulation,

With the ending of this year in sight, the BNS board is reaching out to all of our members with this second newsletter.

Many of us were surprised by the reactions of colleagues, some hospital management strategies and the public opinion after the publication in JAMA of Hara et al., where a non-optimized burst-SCS paradigm was compared head-to-head to placebo-SCS. In this edition, you will find a letter from Marc Russo, president of INS, with a call to action.

In this newsletter, we will also give you an updated overview of multicenter research in the Benelux. Let us start 2023 with a big "Bang" and a lot of stimuli!

BNS
NEWSLETTER

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LETTER FROM MARC RUSSO

Response to the recent JAMA article on Spinal Cord Stimulation (Hara et al. 2022)

I am writing to you today because both myself and the International Neuromodulation Society (INS) Executive Officers have been flooded with calls from members who, like us, are concerned about the methodological flaws in a recent study on SCS published in the prestigious journal JAMA (Journal of American Medical Association) and the likelihood for a range of patients, doctors and healthcare delivery systems to reach erroneous conclusions on the evidence base for spinal cord stimulation (SCS) based on this one study.

The flaws are so manifold and the statements of the authors so disparaging of the whole field that I feel it is important that all members of the INS have the facts available to them to help dispel this misinformation. In particular I would urge each and everyone of you to use your social media and networking channels to educate those around you as to the true nature of how this study was conducted as I've enumerated in the points below. Together in a concerted effort we can ensure that this vital information is delivered where it is needed before payers use this flawed study as justification to cease covering SCS.

A formal letter to the Editor of JAMA will be forthcoming from signatories of multiple medical societies including the INS but INDIVIDUAL activity will have more effect in the court of public opinion. Patient access to neuromodulation, including pain relief, must be a first and last priority of both practitioners and the societies that represent them.

The study, in short, purported to be a randomised blinded "placebo-controlled" study of clinical SCS on disability in patients with leg pain after spine surgery. It found no difference between the two groups at 90 days on Oswestry Disability Index (ODI). The authors have subsequently made multiple media statements that SCS "doesn't work".

Here are the major flaws that make any conclusions from the study inapplicable to how we conduct spinal cord stimulation around the world.

1. The subjects were trialled with tonic waveform SCS when the actual study was run with burst SCS. There is no data and no reason to assume that a response to tonic SCS means that the patient has been shown to be a responder to burst SCS to gain entry into the study.

2. Only a 30% pain reduction was required to enter study yet we know SCS delivers 60-100% pain relief; HENCE many placebo responders would have been included in the initial cohort. 30% reduction in pain should never be allowed as entry criteria for a SCS study.

3. The trial was conducted with pain reduction as the measure to gain entry but then the primary outcome measure for the study was switched to Oswestry Disability Index change at 90 days. Disability reduction follows (not leads) pain reduction so, if pain relief was not allowed to be optimised (as we will see), then the investigators will have manufactured a placebo outcome.

4. Manufacturer guidelines on therapy delivery were NOT followed. Simple burst waveform at 50-70% of paresthesia threshold was deployed, not the manufacturer's algorithm. The patient controller was REMOVED from the patients so they could do no adjustments themselves to optimise their therapy, nor turn off the device if they experienced discomfort. This however is mandatory, to ensure that no overstimulation occurs under any circumstances. Patients were not given the opportunity to have any optimisation of pain relief within the 90 day period. It seems to have not been recognised by the investigators that SCS is a titrated therapy not a fixed therapy.

5. Researchers should be experienced in the field and highly experienced in the specifics of the therapy under investigation. The implanters had no prior experience of managing paresthesia free SCS. The study nurse who did all the programming had never programmed patients prior to this study. This raises the question of whether sufficient experience was present to run a study of this kind.

6. There were no washout periods at all during the study when crossing over to the other group, hence carryover effects bleed into the next treatment group and wash results to a single common level. Carry over effects are proven to be real in SCS. 2

7. Only 90 day results were chosen as a primary endpoint when the purpose of SCS studies is to assess BEYOND the possible placebo response time of 3 months and assess outcomes at one, two and five years. The primary endpoint was chosen within the possible placebo response period of 90 days. 3

8. Subjects were told in the informed consent document that they would receive "stimulation". It is reasonable to assume that subjects believed they were to receive standard clinical care SCS. However they were not remotely allowed to have an optimised algorithm that was individually titrated to their needs and which they could control and optimise themselves with the patient remote programmer. They were given a version of the therapy that is not actually practised by clinicians anywhere in the world currently. This raises the issue of proper informed consent and whether the study has breached ethical guidelines on subject information and consent.

What can be gleaned from the above is that the study has major methodological flaws that call into question whether any conclusion at all can be relied upon. Certainly it would seem prudent to rely on multi year outcome studies, meta-analyses and registry data of true clinical care SCS to guide patients, clinicians and healthcare systems.

I urge you to communicate your own critique of this study to your social and medical networks so that information is accessible to those who need it.

The INS will continue to demand high quality research in the field of neuromodulation including not only efficacy but cost-effectiveness and quality of life outcomes across the board.

Best wishes,

Marc A. Russo, MBBS DA (UK) FANZCA FFPMANZCA
President, International Neuromodulation Society

For those who want to read this paper:

VOICE OF THE NURSE

My name is Tanja Hamm, and I am a Nurse Practitioner in the Department of Pain Medicine at the Albert Schweitzer Hospital in the Netherlands.
I trained as in nurse in 1984 and had the resouces to advance in the different areas of my work field. Eventually, I achieved a Master of Arts in Advanced Nursing Practice in 2005.
For 20 years, I have been involved in the field of neuromodulation therapy. In November 2018, I started my PhD at the Radboud U.M.C. in Nijmegen.
In my daily work, I consider it is essential to communicate with the patient in a shared decision model. Moreover, I hope to stimulate the patient to be self-supportive in their physical, social, and emotional challenges.
Shared decision-making in patients with chronic pain and neuromodulation therapy will be a main theme in my manuscript. My first article is titled: Views of patients suffering from failed Back Surgery Syndrome on their health and their ability to adapt to daily life and self-management: A qualitative Exploration, (Hamm et al., PlosOne.2020 Dec7; 15(12): e0243329)
My second study is a multicenter feasibility investigation of physical activity in FBSS patients. We compiled objective data from an Intellis AS and a smartwatch, as well as gathering the experiences of patients' personal goals and needs.
Combining my research work with a full-time job at the hospital requires some organizational skills.
Therefore, I am very grateful for the support I have experienced, and I hope to finish my PhD in time.

Read this article:

BNS MEMBERSHIP

The BNS Board encourages all members of the large neuromodulation family to get their BNS membership. Only by standing together, shoulder to shoulder, based on good practice and scientific sound evidence, new indications, new innovations and more awareness around neuromodulation will be achieved.
The BNS stands for being a trusty partner in the regulatory framework for the authorization and for increased focus on research with joint research projects and shared registries.

New members may contact us at:
BNS.scientific@gmail.com
170 euro/year

GOOD TO KNOW

BNS MEMBERSCHIP

Neuromodulation nurses, students and young researchers in neuromodulation can be a BNS member and therefore also an INS member for only 50 euro/year.

The BNS board believes that treating patients with neuromodulation is a multidisciplinary team effort and strongly encourages nurses and researchers to join the big BNS family!

Mail to: BNS.scientific@gmail.com

BNS MEMBERSHIP

WHAT IS IN FOR YOU?

Acces to the journal 'Neuromodulation'

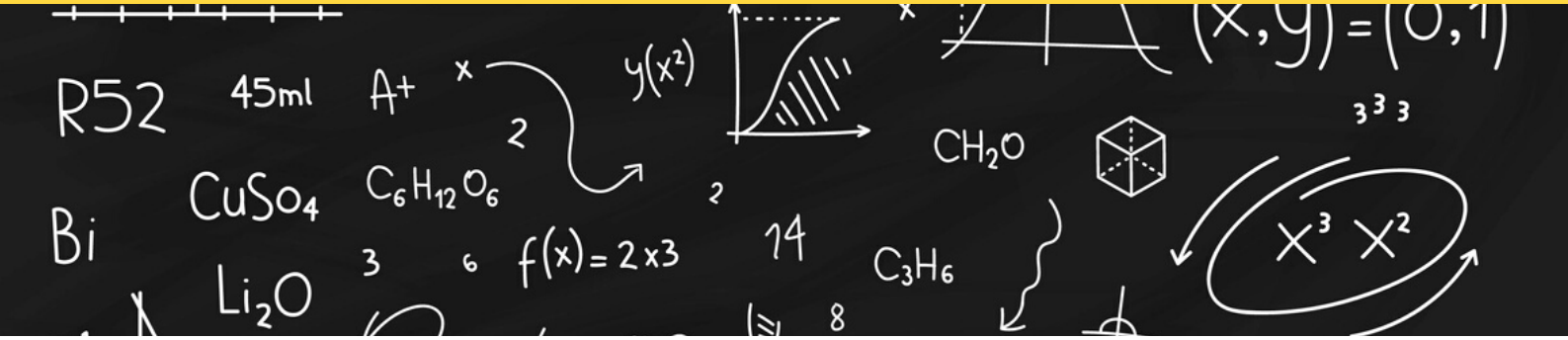
Access to webinars & journal clubs

Mentorship program

Access to fact sheets and educational video's

and so much more...

RESEARCH IN THE BENELUX



EXISTING RESEARCH NETWORKS

MULTICENTER STUDIES

After the call in the previous newsletter, we hereby provide an overview of the ongoing multicenter studies that are conducted by BNS members. Please feel free to provide us with a summary of your ongoing multicentric studies so that we can include them in the next newsletter.

DETECT (DTM SCS)

- Conducted by STIMULUS research group (Maarten Moens & Lisa Goudman, VUB/ UZ Brussel)
- In this prospective, multicenter cohort study, the aim is to evaluate the effectiveness, safety and feasibility of differential target multiplexed spinal cord stimulation for the treatment of chronic low back and leg pain. In total, 200 patients with chronic low back and leg pain due to Persistent Spinal Pain Syndrome Type II will be included with a follow-up period until 12 months after IPG implantation. Recruitment for this study is ongoing, whereby the consortium has included the 61th patient this weekend.
- DETECT consortium (coorporating centra): AZ Delta, AZ Groeninge, AZ Sint-Jan Bugge-Oostende, AZ Sint-Lucas Brugge, AZ Sint-Maarten, AZ Turnhout, CHR de la Citadelle, GZA, Heilig Hart Algemeen Ziekenhuis Lier, Jessa Ziekenhuis, La Clinique Notre Dame de Grâce (recruitment not yet started), UZ Brussel, UZ Leuven, Vitaz and ZNA.

SCS for Endometriose

- Conducted by Jan Willem Kallewaard (Rijnstate Ziekenhuis and Amsterdam UMC), Velja Mijatovic (Amsterdam UMC) and Annemiek Nap (Radboud UMC).
- Spinal Cord Stimulation for intractable chronic lower abdominal neuropathic pain caused by endometriosis.

PROSTIM study (profiling SCS patients)

- Conducted by Mark Plazier and Vincent Raymaekers (Jessa ziekenhuis).
- In this study we are developping patient profiles based on patient reported outcome measurements for spinal cord stimulation on a big data set. With the profiling we hope to adress questions as: Which stimulation suits which patient, which paradigm is most likely to yield profound clinical results, which multidisciplinary approach of treatment forms would benefit my patient.....
- The study protocol has been submitted and is under review, we hope to start inclusions spring 2023.

TRADITION (BMT versus subthreshold SCS)

- STIMULUS research group (Maarten Moens & Lisa Goudman)
- A two-arm multicentre randomised controlled trial will be conducted whereby 114 patients will be randomised (1:1) to (a) BMT or (b) paresthesia-free SCS. After a follow-up period of 6 months (primary time endpoint), patients receive the opportunity to cross over towards the other treatment group. The primary outcome is the proportion of clinical holistic responders at 6 months (i.e. a composite measure of pain intensity, medication, disability, health-related quality of life and patient satisfaction). The secondary outcomes are work status, self-management, anxiety, depression and healthcare expenditure.
- Recruiting centra: AZ Delta, AZ Turnhout, AZ Sint-Maarten, Jessa Ziekenhuis and UZ Brussel.
- Funding by Fonds Wetenschappelijk Onderzoek Vlaanderen.

OPERA (Return to work after SCS)

- STIMULUS research group (Maarten Moens & Lisa Goudman), together with Lode Godderis (KU Leuven), Dominique Van de Velde (UGent) and Koen Putman (VUB).
- A two-arm, parallel-group multicentre randomised controlled trial will be conducted including 112 patients who will be randomised (1:1) to either (a) a personalised biopsychosocial RTW rehabilitation programme of 14 weeks or (b) a usual care arm, both with a follow-up period until 12 months after the intervention. The primary outcome is work ability.
- Recruiting centra: AZ Turnhout, Jessa Ziekenhuis, UZ Brussel, UZ Gent, UZ Leuven and Vitaz.
- Full protocol available through the QR code.
- Funding by Fonds Wetenschappelijk Onderzoek Vlaanderen.

In line with the call of Marc Russo as president of INS, we are firmly convinced that the BeNeLux neuromodulation network with experienced implanters is very valuable and necessary to create methodologically sound, high standard scientific evidence, whereby neuromodulation is applied according to worldwide standards and practices. The need to prove the efficacy of SCS is urgent. We fully believe in the strength of the different research networks within the BNS and in the value of performing multicenter clinical research together.

BNS members who aim to take part in ongoing studies or strive to create a new study with members who are working on the same topic within neuromodulation can always contact the BNS at BNS.scientific@gmail.com.

2021 Clarivate Analytics Impact Factor

On 29th of June 2022, the impact factors for 2021 became public.

The Impact Factor (or journal impact factor) is an index provided by an analytics company named "Clarivate". It is frequently used an an indicator of the relative importance of a specific journal in respect to its field and it presents the frequency with which the '*average article in a specific journal* ' has been cited in a particular time period.

The impact factor is calculated by dividing the number of times the articles are cited in the last two years by the total number of publications in those two years. Neuromodulation currenlty has an impact factor of 3.025. Compared to the previous years, the impact factor has decreased this year.

Within each field, journals are ranked according to their impact factor whereby the journal with the highest impact factor receives place 1 and the journal with the lowest impact factor the lowest place. Based on this ranking, journals are categorised within quartiles. Q1 is occupied by the top 25% of journals in a specific field; Q2 is occupied by journals in the 25 to 50% group; Q3 is occupied by journals in the 50 to 75% group and Q4 is occupied by journals in the 75 to 100% group.

For clinicians who are active in academics, impact factors are taken into account when pursuing an academic carrier (e.g. criteria for the degree of PhD are related to the amount of articles published in Q1 or Q2 journals, grants for funding etc.).

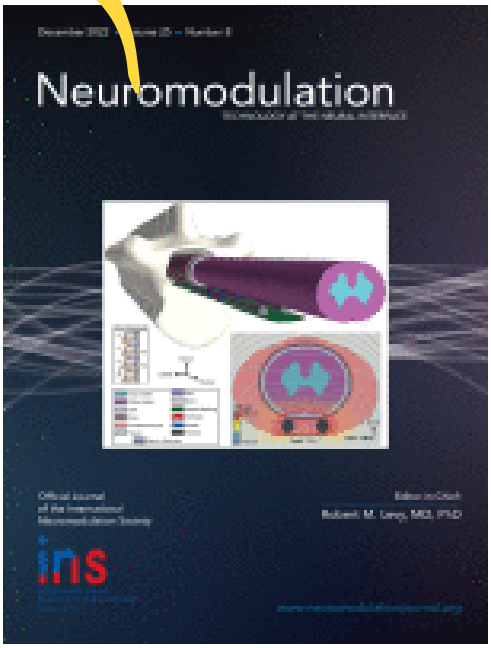
Neuromodulation is now ranked as Q3 journal in the field of 'clinical neurology' and in the field of 'medicine, research & experimental'.

Calculation

Journal Impact Factor ™ is calculated using the following metrics:

$$\frac{\text{Citations in 2021 to items published in 2019 (422) + 2020 (664)}}{\text{Number of citable items in 2019 (116) + 2020 (243)}} = \frac{1{,}086}{359} = 3.025$$

A letter to the editor concerning the use, significance and limitation of Journal Impact Factors can be found here:



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