

Advanced Pelvic Floor Neuromodulation training program Colorectal Surgeons & Urologists

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NEJM Evidence, 2022, 1-11

1.

Systematic Literature Review and Meta-Analysis of Sacral Neuromodulation (SNM) in Patients with Neurogenic Lower Urinary Tract Dysfunction (nLUTD): Over 20 Years' Experience and Future Directions

Authors:

Arndt van Ophoven . Stefan Engelberg . Helen Lilley . Karl-Dietrich Sievert

Source:

Adv Ther (2021) 38:1987–2006

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Received: December 16, 2020 / Accepted: February 3, 2021 / Published online: March 13, 2021 The Author(s) 2021

Abstract:

Introduction: Sacral neuromodulation (SNM) has been used in carefully selected patients with neurogenic lower urinary tract dysfunctions (nLUTD) for over two decades.

Methods: The aim of the current work was to perform a systematic literature review and meta-analysis of studies reporting the safety and effectiveness of SNM in patients with nLUTD (neurogenic detrusor overactivity, non-obstructive urinary retention, or a combination of both). For this purpose a systematic literature research was conducted using Embase (OvidSP), MEDLINE (OvidSP), MEDLINE In-Process Citations & Daily Update (OvidSP), MEDLINE (OvidSP) e-Pub ahead of print, Cochrane Central Register of Controlled Trials (CENTRAL), NIH Clinicaltrials.gov, and WHO International Clinical Trials Registry Platform (ICTRP) between 1998 and March 2020, supplemented by a hand search.

Results: Forty-seven studies were included in the systematic literature review. Twenty-one studies comprising a total of 887 patients were included in the meta-analysis of test SNM. The pooled success rate of SNM test stimulation was 66.2% (95% CI 56.9–74.4). Depending on neurogenic conditions test success rates varied greatly. Twenty-four studies with a total of 428 patients were included in the meta-analysis of permanent SNM. The success rate of pooled permanent SNM was 84.2% (95% CI 77.8–89.0). Among the identified studies, the most common adverse events (AEs) were loss of effectiveness, infection, pain at implant site, and lead migration with AE rates of 4.7%, 3.6%, 3.2%, and 3.2%, respectively. Limitations entail lower level of evidence (Oxford classification 3–4) of included studies, significant risk of bias, small sample sizes in some studies, the inclusion of retrospective case series, substantial between-study heterogeneity, heterogeneous patient populations, insufficient disease classification, and variations in terms of outcome parameters as well as techniques. Furthermore, long-term data are limited.

Conclusion: This meta-analysis supports not only the benefits of permanent SNM for various nLUTDs but also high overall success rates, similar to idiopathic patients. Current data of the analyzed studies showed that SNM is safe for these patients. However, more vigorous studies and/or registries are needed before definitive conclusions can be drawn.

Supplementary Information

The online version contains supplementary material available at <https://doi.org/10.1007/s12325-021-01650-9>.

2.

Sacral Neuromodulation: Standardized Electrode Placement Technique

Authors:

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Source:

Neuromodulation, December 2017, Volume 20, Number 8, Pages 816-824

Abstract:

Introduction: Sacral neuromodulation (SNM) (sacral nerve stimulation SNS) has become an established therapy for functional disorders of the pelvic organs. Despite its overall success, the therapy fails in a proportion of patients. This may be partially due to inadequate electrode placement with suboptimal coupling of the electrode and nerve. Based on these assumptions the technique of sacral spinal neuromodulation has been redefined. All descriptions relate to the only currently available system licensed for all pelvic indications (Medtronic InterstimVR).

Method: An international multidisciplinary working party of ten individuals highly experienced in performing SNM convened two meetings (including live operating) to standardize the implant procedure. This report addresses the main steps to optimal electrode lead placement in temporal sequence.

Results: Key elements of the electrode placement are radiological marking, the use of a curved stylet, the entry of the electrode into the sacral foramen and its progression through the foramen, its placement guided by a combination of a typical appearance in fluoroscopy and achieving specific motor/sensory responses with stimulation. The report describes quadripolar electrode placement and then either insertion of a connecting percutaneous extension lead or permanent implantation of the programmable device.

Conclusion: Standardization of electrode placement may ensure close electrode proximity to the target nerve providing a higher likelihood for optimal effect with less energy consumption (better battery longevity), more programming options with more electrode contacts close to the nerve and reduced likelihood of side-effects. The potentially better clinical outcome needs to be demonstrated.

3.

Reprogramming Sacral Neuromodulation for Sub-Optimal Outcomes: Evidence and Recommendations for Clinical Practice

Authors:

Thomas C. Dudding, MD1 ; Paul A. Lehur, MD, PhD2 ; Michael S. Rensen, MD3; Stefan Engelberg, PhD4 ; Maria Paola Bertapelle, MD5; Emmanuel Chartier-Kastler, MD, PhD6; Karel Everaert, MD, PhD7 ; Philip Van Kerrebroeck, MD, PhD8; Charles H. Knowles, BChir, MA, PhD9; Lilli Lundby, MD, PhD10; Klaus E. Matzel, MD, PhD11; Arantxa Muñoz-Duyos, MD, PhD12; Mona B. Rydningen, PhD13; Stefan de Wachter, MD, PhD14

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Abstract

Objectives: In some patients treated for urinary or fecal incontinence with sacral neuromodulation (SNM) persistence of symptoms, a reduction in efficacy or adverse effects of stimulation can occur. In such situations, further programming of the SNM device can help resolve problems. Infrequently hardware failure is detected. This article aims to provide practical guidance to solve sub-optimal outcomes (troubleshooting) occurring in the course of SNM therapy.

Materials and Methods: A systematic literature review was performed. Collective clinical experience from an expert multidisciplinary group was used to form opinion where evidence was lacking.

Results: Circumstances in which reprogramming is required are described. Actions to undertake include changes of electrode configuration, stimulation amplitude, pulse frequency, and pulse width. Guidance in case of loss of efficacy and adverse effects of stimulation, developed by a group of European experts, is presented. In addition, various hardware failure scenarios and their management are described.

Conclusions: Reprogramming aims to further improve patient symptoms or ensure a comfortable delivery of the therapy. Initial changes of electrode configuration and adjustment of stimulation parameters can be performed at home to avoid unnecessary hospital visits. A logical and stepwise approach to reprogramming can improve the outcome of therapy and restore patient satisfaction.

4.

New Technologies and Applications in Sacral Neuromodulation: An Update

Authors:

Stefan De Wachter . Charles H. Knowles . Dean S. Elterman . Michael J. Kennelly . Paul A. Lehur . Klaus E. Matzel .
Stefan Engelberg . Philip E. V. Van Kerrebroeck

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Adv Ther

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Abstract

Recently rechargeable devices have been introduced for sacral neuromodulation (SNM) with conditional safety for full-body magnetic resonance imaging (MRI). Currently a recharge-free SNM device represents the standard implant; however, it is only approved for MRI head scans. As further new technologies with broader MRI capabilities are emerging, the advantages as well as disadvantages of both rechargeable versus recharge-free devices will be briefly discussed in this commentary from the perspective of patients, healthcare professionals, and providers.

Enhanced Digital Features

To view enhanced digital features for this article go to <https://doi.org/10.6084/m9.figshare.11359523>.

5.

Programming Algorithms for Sacral Neuromodulation: Clinical Practice and Evidence— Recommendations for Day-to-Day Practice

Authors:

Paul A. Lehur, MD, PhD* ; Michael S. Rensen, MD†; Thomas C. Dudding, MD‡; Charles H. Knowles, BChir, MA, PhD ; Stefan de Wachter, MD, PhD **; Stefan Engelberg, PhD†† ; Klaus E. Matzel, MD, PhD,‡‡ On behalf of the European SNM Expert Group

Source:

Neuromodulation: Technology at the Neural Interface

Received: October 14, 2019 Revised: December 3, 2019 Accepted: January 14, 2020 (onlinelibrary.wiley.com) DOI: 10.1111/ner.13117

Abstract

Background: In sacral neuromodulation (SNM), stimulation programming plays a key role to achieve success of the therapy. However to date, little attention has been given to the best ways to set and optimize SNM programming during the test and chronic stimulation phases of the procedure.

Objective: Standardize and make SNM programming easier and more efficient for the several conditions for which SNM is proposed.

Methods: Systematic literature review and collective clinical experience report.

Results: The basic principles of SNM programming are described. It covers choice of electrode configuration, stimulation amplitude, pulse frequency and pulse widths, while use of cycling is also briefly discussed. Step-by-step practical flow charts developed by a group of 13 European experts are presented.

Conclusions: Programming of SNM therapy is not complex. There are few programming settings that seem beneficial or significantly impact patient outcomes. Only four basic electrode configurations could be identified according to four different options to define the cathode. In a majority of patients, the proposed stimulation parameters will allow a satisfactory improvement for long periods of time. A regular follow-up is, however, necessary to assess and eventually optimize results, as well as to reassure patients.

6.

Systematic review of the clinical effectiveness of neuromodulation in the treatment of faecal incontinence

Authors:

N N Thin 1, E J Horrocks, A Hotouras, S Palit, M A Thaha, C L H Chan, K E Matzel, C H Knowles

Source:

Br J Surg. 2013 Oct;100(11):1430-47. doi: 10.1002/bjs.9226.

Affiliations expand

PMID: 24037562 DOI: 10.1002/bjs.9226

7.

The AUA/SUFU Guideline on Adult Neurogenic Lower Urinary Tract Dysfunction: Treatment and Follow-up

Authors:

David A. Ginsberg,^{1,*} Timothy B. Boone,² Anne P. Cameron,³ Angelo Gousse,⁴ Melissa R. Kaufman,⁵ Erick Keays,⁶ Michael J. Kennelly,⁷ Gary E. Lemack,⁸ Eric S. Rovner,⁹ Lesley H. Souter,¹⁰ Claire C. Yang¹¹ and Stephen R. Kraus¹²

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The Journal of Urology 2021, vol. 206, 1106-1113

www.auajournals.org/journal/juro

<https://doi.org/10.1097/JU.0000000000002239>

Abstract

Purpose: The clinician treating patients with neurogenic lower urinary tract dysfunction (NLUTD) needs to balance a variety of factors when making treatment decisions. In addition to the patient's urologic symptoms and urodynamic findings, other issues that may influence management options of the lower urinary tract include cognition, hand function, type of neurologic disease, mobility, bowel function/management, and social and caregiver support. This Guideline allows the clinician to understand the options available to treat patients, understand the findings that can be seen in NLUTD, and appreciate which options are best for each individual patient. This allows for decisions to be made with the patient, in a shared decision-making manner, such that the patient's quality of life can be optimized with respect to their bladder management.

Materials and Methods: A comprehensive search for studies assessing patients undergoing evaluation, surveillance, management, or follow-up for NLUTD was conducted from January 2001 through October 2017 and was rerun in February 2021 to capture newer literature. The primary search returned 20,496 unique citations. Following a title and abstract screen, full texts were obtained for 3,036 studies. During full-text review, studies were primarily excluded for not meeting the PICO criteria. One hundred eight-four primary literature studies met the inclusion criteria and were included in the evidence base.

Results: This guideline was developed to inform clinicians on the proper evaluation, diagnosis, and risk stratification of adult patients with NLUTD and the non-surgical and surgical treatment options available. Additional statements on urinary tract infection and autonomic dysreflexia were developed to guide the clinician.

Conclusions: NLUTD patients may undergo non-surgical and surgical treatment options depending on their level of risk, symptoms, and urodynamic findings. Appropriate follow-up, primarily based on their risk stratification, must be maintained after treatment.

8.

Is sacral neuromodulation effective in patients with Parkinson's disease? A retrospective review

Authors:

Sarah Martin DO | Jacqueline Zillioux MD | Howard B. Goldman MD

Source:

Neurourol Urodyn, 2022; 1-7

Abstract

Introduction and Objective: Parkinson's disease (PD) is the second-most common degenerative neurologic disease worldwide. Overactive bladder (OAB) is prevalent in this population but can be challenging to treat. Sacral neuromodulation (SNM) is an attractive option but remains understudied. We have utilized SNM in PD patients and herein describe our outcomes.

Methods: We performed a retrospective chart review of PD patients who underwent peripheral nerve evaluation (PNE) or Stage 1 SNM from 2000 to 2020. The primary outcome was progression to a permanent implant. The impact of PD stage and preprocedural urodynamic (UDS) parameters on testphase outcome were investigated. Long-term efficacy was assessed using Wilcoxon matched-pairs test looking at a change in urinary symptoms (frequency, nocturia, incontinence episodes, and pad use) documented at follow-up visits and further need for treatment.

Results: Thirty-four patients underwent test phase SNM (7 PNE and 27 Stage 1). Median follow-up was 11 (interquartile range 5.8–29.8) months. Indications included refractory OAB (30/34) and nonobstructive urinary retention (4/34). Overall, 82% (28/34) of patients proceeded to a permanent implant. 71% (5/7) of PNEs were successful. Test-phase success did not differ based on PD disease severity or UDS parameters. In patients with OAB/urgency incontinence who progressed to the permanent implant, there was a statistically significant improvement in their urinary symptoms from baseline. Most (68%) patients were able to discontinue OAB medications post-implant. The overall lead revision rate was 14% (4/28) and 3 devices required removal.

Conclusions: SNM is an efficacious treatment option for PD patients with a high percentage of patients having improvement in their urinary symptoms.

9.

Neuromodulation for lower urinary tract symptoms in special populations

Authors:

Connie N. Wang MD | Doreen E. Chung MD

Source:

Neurourol Urodyn, 2022; 1-10

Abstract

Aims: Discuss the efficacy, safety, and future directions of neuromodulation in special populations of patients with neurological conditions.

Methods: A literature review was done to find meta-analyses, review articles, studies, and case reports of the use of neuromodulation, either sacral neuromodulation or percutaneous tibial nerve stimulation, in patients with various neurological conditions of interest.

Results: Sacral neuromodulation (SNM) and posterior tibial nerve stimulation (PTNS) appear to be safe and effective in special neurological populations of patients with multiple sclerosis (MS), Parkinson's disease (PD), and spinal cord injury (SCI). The majority of publications are smaller retrospective case series. Outcomes appear similar to those seen in nonneurogenic patients but also partly depend on disability progression. Magnetic resonance imaging (MRI) compatibility has helped to improve eligibility for SNM in these special populations.

Conclusions: In a small number of studies, SNM and PTNS appear to be safe and effective in special neurological populations of patients with MS, PD, and SCI. MRI compatibility has helped to improve eligibility for SNM in these special populations. Studies looking at SNM are limited by a small number of subjects, lack of prospective trials, and selection bias. Larger, randomized studies with long-term follow up are needed to better predict response to SNM and PTNS in these populations

DOI: 10.1002/nau.24954

10.

Sacral Neuromodulation for Neurogenic Lower Urinary Tract Dysfunction

Authors:

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Source:

NEJM Evidence, 2022, 1-11

Abstract

Background: Neurogenic lower urinary tract dysfunction (NLUTD) is a highly prevalent and disabling condition; nevertheless, standard treatments often remain unsatisfactory. Sacral neuromodulation (SNM) is a well-established therapy for non-NLUTD, but there is a lack of randomized controlled trials to show benefit in patients with NLUTD.

Methods: For this sham-controlled, double-blind, multicenter trial, patients with refractory NLUTD (and intended SNM) were recruited at four Swiss SNM referral centers. After lead placement into the sacral foramina S3 (rarely, S4), all participants underwent SNM testing. If successful ($\geq 50\%$ improvement in key bladder diary variables), the neurostimulator was implanted for permanent stimulation. For 2 months, neuromodulation was optimized using subsensory stimulation with individually adjusted parameters. Thereafter, the neurostimulator remained on or was switched off (1:1 random allocation to group SNM ON or SNM OFF, respectively) for 2 months, followed by a neurourologic reevaluation.

The primary outcome was success, as defined above, of SNM compared with baseline.

Results: Of 124 patients undergoing SNM testing, 65 (52%) had successfully improved lower urinary tract function. Of these, 60 patients (median age, 49.5 years; 43 women) were randomly assigned to the intervention. After 2 months of intervention, the SNM ON group demonstrated a success rate of 76%. In the SNM OFF group, 42% of patients showed sustained SNM effects despite their neurostimulator being switched off during the last 2 months (odds ratio, 4.35; 95% confidence interval, 1.43 to 13.21; $P=0.009$). During the entire study period, there were 11 adverse events (6 dropouts; no dropouts during the intervention phase).

Conclusions: SNM effectively corrected refractory NLUTD in the short term in well selected neurologic patients. (Funded by the Swiss National Science Foundation, Vontobel-Stiftung, Gottfried und Julia Bangerter-Rhyner Stiftung, Dr. Urs M€uhlebach, and the Swiss Continence Foundation; ClinicalTrials.gov number, NCT02165774.)

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