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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

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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.

Keywords: Implantable neurostimulators; Magnetic resonance imaging; Meta-analysis; Neurogenic lower urinary tract dysfunction; Sacral neuromodulation

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Sacral Neuromodulation: Standardized Electrode Placement Technique

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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.

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

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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.

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New Technologies and Applications in Sacral Neuromodulation: An Update

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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.

Keywords: Fecal incontinence; Magnetic resonance imaging; Overactive bladder;

Rechargeable battery; Sacral neuromodulation; Stimulator; Urology

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

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

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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.

Keywords: Basic programming, electric stimulation, fecal incontinence, pelvic organ dysfunction, sacral neuromodulation, urinary incontinence

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

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