

The future of the Sacral Nerve Stimulation

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Summary: Over the last ten years sacral nerve stimulation has shown great potential in the treatment of pelvic dysfunction. Initially used to treat urinary symptoms it has recently also been used to treat fecal incontinence and constipation. The technique has been refined, by introducing a minimally invasive percutaneous two stage implantation, so that patients can undergo a prolonged test stimulation using a permanent lead. Accurate neurophysiological evaluation can now be performed before, during, and after implantation and this has confirmed improved treatment success rates. Current studies are investigating the efficacy of new treatment systems, based on both direct and indirect sacral root stimulation, and in the future other systems modulating the central control mechanisms and directly stimulating the sacral nerve roots on demand.

Key words: Sacral neurostimulation; Permanent lead; Incontinence; Direct and indirect stimulation; Functional assessment.

RECENT HISTORY.

EVOLUTION OF IMPLANT TECHNIQUE

Sacral Neuromodulation (SNM) is the most innovative treatment modality developed in recent years for the management of pelvi-perineal dysfunction. An intense international scientific debate has been and is taking place, to define indications, rationale, implantation techniques, and long-term results.

In the "Materials and Methods" section of several published studies on SNM the importance of having a test to select patients for treatment is emphasised. The ability to test a patient prior to permanent implantation has characterized SNM from its beginning.

Percutaneous Nerve Evaluation (PNE) enables assessment of response with a temporary lead but these leads have a tendency to displacement due to patient activity, resulting in decreased efficacy because factors such as distance of the lead from the nerve and polarity affect nerve depolarisation.

The original indications for SNM were urinary incontinence and urinary retention. In conditions such as faecal incontinence and constipation the PNE test is unsuitable as a prolonged test is needed to evaluate efficacy. Results of other studies in patients with interstitial cystitis and neurological bladder may also have been inaccurate due to the inadequacy of the PNE test.

Patients with lower urinary tract dysfunction, who have failed to respond to functional electrical stimulation (FES), and for whom reconstructive surgery is too invasive and non-physiological may be suitable for SNM. Patients with a long history of problems who are judged to be suitable for a PNE test but unsuitable for permanent implantation under general anaesthesia may be lost to treatment with SNM.

Psychometric evaluation and Quality of Life assessment has contributed to better patient selection but evaluation techniques still need to be improved.

From the personal experience in performing PNE tests, as well as from a progressively better understanding of the anatomy of the posterior surface of sacrum, acquired by implanting direct extradural stimulators via a sacral laminectomy, the author developed a minimally invasive technique to implant a permanent quadripolar lead. At first this was done with disposable devices used for percutaneous nephrostomy.

In 1999 the author introduced a new technique for positioning the sacral stimulation lead through the S3 sacral foramen under local anaesthesia. This innovation led to the current percutaneous system method in 2001.

A simple method of permanent implantation was devised without any dissection of the tissue planes superficial to the sacral foramen, thus maintaining tissue integrity around the lead.

Between December 1999 and March 2002 forty-three patients had percutaneous implantation of a quadripolar permanent sacral neuromodulation lead. In this technique two 8 Fr. dilators are passed along a guidewire. The first metal dilator is used to pass through the fascial layer, without reaching the sacral foramen, then a plastic dilator is used to pass the lead into the chosen sacral foramen.¹

All lead implants have been performed using local anaesthetic (Ropivacaine), with fluoroscopic guidance.

Since 2002, two staged percutaneous implantation of a quadripolar lead for electrical stimulation (Model 3889 Medtronic, USA) under local anaesthetic has enabled an extended stimulation test using a permanent lead. This system has dramatically improved the technique, offering a truly minimally invasive approach to implant only one lead.²

BEFORE AND AFTER THE IMPLANT: PATIENT SELECTION AND CORRECT PROGRAMMING

In the 90's, in a "pre-neuromodulation era", Clare Fowler³ claimed the existence of an organic cause for retention, in patients with signs of secondary neuro-endocrinological disturbances. The observation of patients that for many years were in urinary retention, and that after a simple test of sacral roots chronic stimulation regained a spontaneous bladder voiding, led to a major reconsideration of the concept of "idiopathic retention".

In the middle of the 90's, there was enormous enthusiasm for the results of sacral neuromodulation, but poor longterm results in some patients led researchers to question the indications for treatment with SNM, and raised doubts about the aetiology of this condition.

Variable results with this group of patients have led to renewed efforts to identify predictive factors for success and improving patient selection. Psychometric assessment has enabled identification of patients with a conversion-histrionic disturbance who typically show an excellent immediate result, followed by failure in the short to medium term. Excluding this group has improved the long term results of treatment with SNM.

In sacral neuromodulation, modulating the nervous system of patients referred to as "idiopathic", and of obtaining favourable results in a number of different, and often contradictory, clinical situations is a paradox.

Neurogenic dysfunction is now seen as a complex spectrum of dysfunction with variable expression. Dysfunctions previously thought to be "idiopathic" are now regarded as "non-overt neurogenic". Combinations of symptoms localised to the perineum, such as constipation, urinary retention, sexual dysfunctions, or, the association of urinary and faecal incontinence in the same patient that improve with the same therapy, has led to the realisation that the indication for SNM is localised sacral symptoms.

The sacral area can be regarded as the crossroads of vesical-sphincteric, anorectal, and sexual function. In recent years, the studies of Holstege and Blok have given us an insight into the areas of the brain responsible for control of these functions.

Afferent fibres lead to areas that are referred to as "emotional" in the central nervous system. Neuromodulation of these afferent fibres leads to identification of specific cortical and sub-cortical areas whose expression is modified during SNM. This enables us to postulate the mechanism of action of this treatment.

Clinical issues should be discussed with the patient ethically and honestly. This means informing patients of the true potential and limitations of this therapy as a possible tool to restore the physiological mechanisms of micturition and defecation, rather than as just another treatment option to be offered, after the failure of previous treatments.

The neurophysiological assessment is a new tool to help us predict the response of an individual patient to SNM. It has also been helpful as a research tool in developing a standardised implant technique and defining the best stimulation parameters. Clinical neurophysiology, applied to pelvic floor dysfunction, has progressed both as a diagnostic tool, to improve patient selection, and as a possible tool for a better understanding of the mechanisms of action of sacral stimulation and modulation treatment modalities.

FUTURE PERSPECTIVES

Direct Stimulation

The early history of sacral nerve root stimulation was made with patients with a neurogenic bladder due to a complete spinal injury. The implant of stimulation leads directly on the sacral roots, either intra or extra-dural, was the first technique in humans to evoke a response to a specific electrical stimulation to cause bladder and bowel emptying or an erection in males.

Indirect stimulation

Implanting leads for sacral neuromodulation results in a modulatory effect on control of the sacral area, as shown by neurophysiological and neuroradiological studies. This indirect stimulation is referred to as "neuromodulation".

Based on our experience with both methods, and trying to optimize our results with patients with incomplete spinal injury, since 2003 we have described an original technique for stimulating the pudendal nerve using the same lead used for sacral neuromodulation. The pudendal nerve rises from S2, S3, S4 roots, and its terminal fibers function in the sacral area so Pudendal Nerve Stimulation (PNS) has been proposed for incomplete neurogenic lesions, and for patients who have failed to respond to sacral neuromodulation⁴.

The observations carried on the first group of implanted patients have made it possible to recognize two different actions of the pudendal stimulation: a modulatory effect (indirect stimulation), and an acute inhibitory effect (direct stimulation).

This approach is a new minimally invasive option that can show good results when treating all dysfunctions of the sacral area. These results correlate well with the stimulation parameters.

A new era is coming, in which the main goal is to understand which are the best indications for the three modalities available - Direct Nerve stimulation, Sacral Neuromodulation and Pudendal Nerve Stimulation. In the future adjustable stimulation based on the specific dysfunction could replace continuous or on-demand stimulation. Several authors are investigating "intelligent" stimulation, able to monitor, assess and then take action to correct the dysfunction proactively. At present, a number of experimental models exist, but none have yet been realized as an implantable technology.⁵

Currently, investigators are re-evaluating previous implantation sites, with new technologies. For example, in direct sacral root stimulation the aim is to avoid a selective posterior rhizotomy, by providing a stimulation to both anterior and posterior roots, thus ensuring a mixed modulatory and excitatory effect. Similarly the use of appropriate currents should be able to avoid the dissynergic effect deriving from the simultaneous stimulation of all the components (anodal block).⁶

In order to achieve better results in the future a multidisciplinary approach is essential. Recent advances in the use of sacral neuromodulation have shown that a treatment modality can lead to a favourable outcome despite the mechanism of action being poorly understood.

A deeper knowledge of the sacral area from the neurophysiological perspective, the urological and colorectal approach to pelvic dysfunctions, and the introduction of new technologies are all contributing to change our interpretation of pelvic dysfunction from an "anatomic" interpretation to a more "functional" one.

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