

## SACRAL NEUROMODULATION (SNM): CERTITUDES AND ISSUES. FIFTEEN YEARS OF ITALIAN CLINICAL EXPERIENCE

### Hypothesis / aims of study

For 15 years, SNM has become the standardized treatment for voiding dysfunction of the low urinary tract with both motor and sensory aetiology and for bowel dysfunctions.

The literature confirms the long term efficacy for treatment of overactive bladder dry or wet, non obstructive urinary retention, painful bladder and chronic pelvic pain syndromes. ICI guidelines indicate NMS as specialist treatment urge incontinence due to detrusor overactivity with grade A recommendation in women and B in men (1).

Up to now, there are 57 urological sites in Italy doing SNM with around 3500 implants performed.

This study describes the present Italian clinical practice and is focused on the certitudes and issues in patient selection, in implant procedure and in follow up.

### Study design, materials and methods

During May 2010, 27 implanter physicians completed a questionnaire about InterStim therapy.

The questionnaire had 5 sections regarding indications, diagnostic assessments, implant procedure (I stage and II stage), follow up and results evaluation. The questionnaire required the respondent to express the degree of agreement for each statement (AA totally agree, A agree, N neutral, D not agree, DD completely not agree). Results were statically evaluated considering the experience of each physician in term of number of definitive implants and years of work with NMS.

All the answers that were the same for more than 60% of the respondents were considered as a recommendation.

During a meeting held on 28<sup>th</sup> July 2010 with 27 participating physicians, 5 major experts in the therapy presented the results of the survey, integrating them with their clinical experience and the literature, which was done through a PubMed search with the key words "sacral nerve stimulation", "urinary incontinence" and "urinary retention". On this occasion, physicians debated about the results and responded again in case where there was no consensus. Following that a document about certitudes and issues of the therapy was prepared and reviewed on 19<sup>th</sup> Nov 2010 by 11 implanters.

The three steps involved 34 physicians: 25 completed the questionnaire before the deadline, 27 were present at the first meeting and 10 at the second. They performed more than 1800 implants and have more than 8 years of experience in the InterStim therapy (range 1-15 years).

### Results

The data from the questionnaire and the discussion established a list of certitudes about SNM:

- patient selection: the therapy is indicated in cases of idiopathic overactive bladder which are not responding to conservative medical treatment, in preference to detrusor infiltration of botulinum toxin, and in cases of non obstructive urinary retention and in sensory dysfunctions of the low urinary tract (PBS, CCP). Use of bladder diaries and urodynamic evaluation are mandatory.
- implant procedure: the use of tined lead, two phase implant procedure, local anaesthesia and antibiotic prophylaxis are recommended.
- follow up: there is consensus on a range of disease specific stimulation parameters, although not with intermediate or poor results.

Some aspects of the therapy, despite the wide experience, are still unresolved. This situation is confirmed also by few data published in the literature and the difficulty of multicenter study or meta-analysis.

In patient selection the neurophysiological evaluation is not mandatory for the study of the patient; it is a speculative evaluation to measure the progression of an underlying neuropathy. The repetition of neuroradiological and endoscopic assessment depends on the clinical situation and is not applicable in all cases.

The indication for InterStim therapy in cases of symptomatic neuropathy due to a congenital or acquired lesion is not applicable in all cases.

The test phase with the temporary monopolar electrode (PNE) is discussed. It is used for different reasons: for with diagnostic purposes in cases with uncertain results, for reimbursement reasons as it is less expensive than tined leads to facilitate therapy learning or as a "retention tool" in cases of long waiting lists.

The bladder diary is used to measure the success rate of the therapy although in some cases is difficult to chose which variable has to be considered to establish the improvement and how to quantify the patient's subjective judgement.

How to manage sub-optimal results or the failure of the therapy is still under discussion, and a common protocol for the programming is lacking, as is a predictive factor to move to bilateral stimulation.

### Interpretation of results

Sacral neuromodulation is not only a therapy for dysfunction which is unresponsive to other treatments; but is also an instrument to learn the physiopathology of different dysfunctions of the lower urinary tract. Following its introduction, the studies performed to understand the action mechanism have changed the functional urological culture.

Today we can say that sacral neuromodulation is the most effective tool for the treatment of voiding dysfunctions of the low urinary tract, for the entire voiding cycle, with both motor and sensory aetiology.

Sacral neuromodulation has increased national and international interest in the field of functional urology, underlining the role of the complex neurological balance that, both at periferical and central level, maintains the normal function of the lower urinary system.

The evolution of the method, which over time has become less invasive and reversible, has led to a grater diffusion of the therapy in clinical practice and the setting up of more dedicated implanter centres.

Outstanding issues represent the subjects for future research.

#### Concluding message

The therapy is an effective specialist treatment for idiopathic overactive bladder, non obstructive urinary retention and for sensory dysfunctions of the low urinary tract. In the patient selection, bladder diaries and urodynamic exam are the only mandatory evaluations, other specialist assessments have to be reserved to selected patients.

Sacral neuromodulation is the therapeutic option that, compared to all the others, has led to a close correlation between the use of the therapy and the understanding the physiopathology mechanisms. Over the last few years, multicenter analysis has led an evolution in understanding of the therapy, in defining correct indications and in the growth of knowledge in functional urology.

#### References

1. • P. Abrams et al., Fourth International Consultation on Incontinence Recommendations of the International Scientific Committee: Evaluation and Treatment of Urinary Incontinence, Pelvic Organ Prolapse, and Fecal Incontinence, Neurourology and Urodynamics 29:213–240 (2010)

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