

## EFFECTS OF CHRONIC PUDENDAL NERVE STIMULATION ON “SACRAL AREA” DYSFUNCTIONS.

### Hypothesis / aims of study

Starting from June 2002 we introduced an original method for chronic pudendal stimulation (CPNS) using the same system for minimally invasive sacral neuromodulation staged implant with tined lead (SNM), with the possibility to implant a lead, close to pudendal nerve, under neurophysiological guidance. Our technique consists of measuring several Pudendal Nerve Terminal Motor Latency (PNTML) responses and Compound Muscle Action potentials from external anal sphincter. The best evoked response is identified, recorded and memorized: this will be the reference potential response (RPR). With a posterior approach, under fluoroscopy we find the connection between two perpendicular lines, one trasversal passing by the big trochanter and the second, longitudinal passing the ischial tuberosity (1). The point obtained is over ischial spine projection. The surgical procedure is done under local anaesthesia with a staged procedure using the algorithm in fig.1. The second stage consists of implanting the Implantable pulse generator (IPG). In each of the steps in implanting tined lead the neurophysiological monitoring is repeated in order to confirm the consistency between the recorded trace and the RPR.

### Study design, materials and methods

Thirty-six patients (14 male, 22 female – mean age 35, 19-66) underwent CPNS. All patients were neurogenic: 13 dorsal lesion, 10 cervical lesion, 4 transverse myelitis, 4 vascular myelopathy, 2 suprapontin lesion, 1 siringomyelia, 2 spina bifida. Before CPNS, 20 patients underwent SNM: 9 patients had an implant on sacral nerve with worsening of symptoms or suboptimal outcome and 11 patients had no success with 1st stage SNM. Sixteen patients were submitted to CPNS as first option. All patients were submitted to complete neurophysiological and urodynamic evaluation at baseline and follow-up and were asked to fill out a bowel and voiding diary for 7 days. A group of 7 male patients used the International Index of Erectile Function (IIEF5) at baseline and at follow up. After implant all patients were submitted to a weekly evaluation to set best parameters of stimulation

### Results

The average number of urinary incontinent episodes decreased from  $7\pm 3.3$  to  $2.6\pm 3.3$  ( $p<0.02$ , paired t-test) during screening phase. Twenty nine patients with urge incontinence became continent during the screening phase and 2 patients improved by more 88% (from 9 to 1 daily incontinence episodes), 1 patient reduced by 50% the number of incontinence episodes and 4 patients had no results. At a mean follow up of 21 months 17 patients are dry using self catheterization for voiding, 2 patients use catheterization twice a day and fifteen patients void without catheter. In 15 patients with associated constipation at baseline, 11 reported normalization of bowel voiding with an increase in the number of weekly evacuations from 2.5 to 7 together with a decrease in difficulties and straining to achieve bowel emptying and a reduction in laxative use. One patient with associated fecal incontinence became continent (at baseline the bowel diary showed a weekly episode of incontinence to solid stool). Urodynamic evaluation showed an objective improvement and in urge incontinence patients the maximum cystometric capacity increased from  $153.3\pm 49.9$  to  $331.4\pm 110.7$  ml ( $p<0.01$ , paired t-test). The pressure at maximum cystometric capacity decreased from  $66\pm 24.3$  to  $36.8\pm 35.9$  cmH<sub>2</sub>O ( $p=0.059$ , paired t-test). The patient who exhibited symptoms of retention showed no improvement in either urodynamic or clinical values. Seven males reported an increase in mean percentage of IIEF from 32 to 79% reducing use of oral drugs for erection.

### Interpretation of results

In treatment of neurogenic patients, pudendal stimulation approach has been historically the best target of treatment. Our method permits a minimally invasive percutaneous procedure with possibility to check responses during screening phase on all sacral area dysfunctions.

Use of neurophysiology as guidance in implanting the lead but also in checking better stimulation parameters permit to achieve good results even if we are going to improve our understanding in predictive factors and in parameters related on different functions.

### Concluding message

The method of pudendal percutaneous implant under neurophysiological guidance seems to be a new way in treatment of neurogenic overactive bladder. The procedure is safe and reversible. This approach is a good opportunity in neurogenic bowel and sexual dysfunctions. From these preliminary data, a strategic issue is to find best parameters of stimulation and time of application of the therapy. A continuous monitoring of results related on parameters is the way to achieve further information. Parameter setting seems related on neurophysiological baseline situation. A multicentric protocol is going to start to obtain a larger experience.

### References

Schmidt RA. Technique of pudendal nerve localization for block or stimulation. J Urol. 1989 Dec; 142(6):1528-31

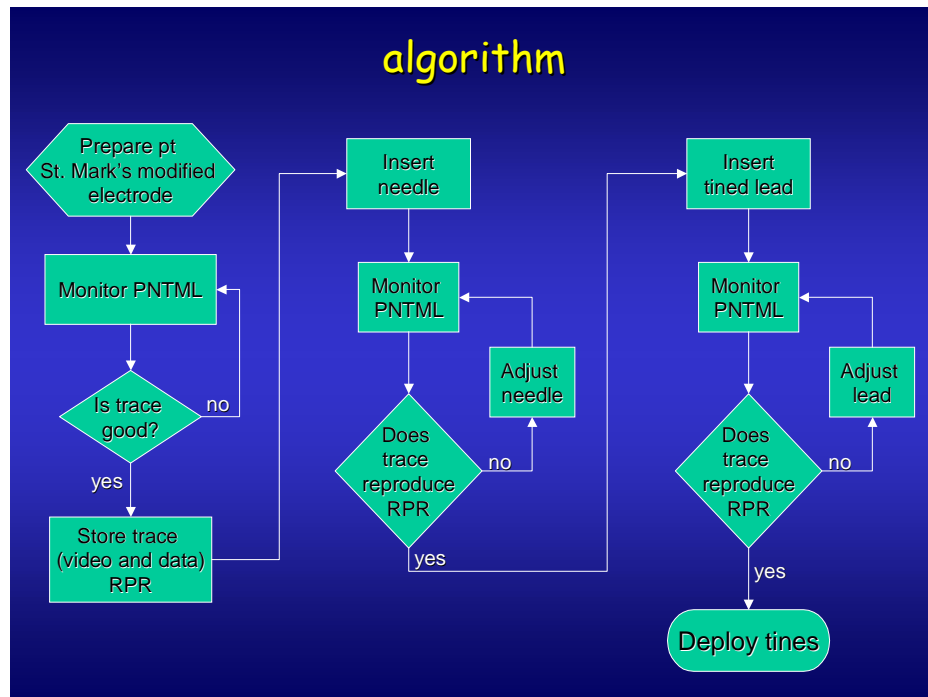


Figure 1: Algorithm during implant of tuned lead on pudendal nerve