Spinelli M¹, Malaguti S¹, Giardiello G², Lazzeri M³, Van den Hombergh U⁴, Gerber M⁵
1. Magenta Hospital, 2. Medtronic Italia, 3. Clin. S. Chiara Firenze, 4. Medtronic Europe, 5. Medtronic Inc. Mineapolis

CHRONIC PUDENDAL NERVE ELECTROSTIMULATION: FIRST EXPERIENCE OF THE NEW PERCUTANEOUS IMPLANT WITH NEUROPHYSIOLOGICAL GUIDANCE

Aims of Study

As pudendal nerve is a one of the major nerves which innervates the pelvic floor muscles, the external urethral and anal sphincters and the pelvic organs with the anatomical possibilities to reach the nerve, one could postulate that the stimulation of this nerve could have a beneficial effect to multiple impaired functions. We decided to attempt to stimulate pudendal nerve in a chronic setting and record clinical changes. This preliminary work presents the original method for new therapeutical stimulation and minimally invasive approach to treat neurogenic patients.

Methods

Pudendal nerve stimulation and the electrode placement is done during the neurophysicological monitoring using the lead and the introducer kit available for minimally invasive implant of sacral neuromodulation.

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 (constituted by maximal amplitude, regular shape, shorter latency) is identified, recorded and memorized: this will be the reference potential response (RPR).

The patient is placed in lithotomic position. The surgical procedure is done under local anaesthesia. An insulated needle is inserted perpendicular to the skin for about 4 cm to reach the ischial tuberosity. The needle is tilt laterally and dorsally to reach the recto-ischial fossa until it is located below and behind the ischial spine in Alcock's channel.

Once the needle is in this correct position, it is possible to place either a temporary stimulation lead (PNE) or a definitive quadripolar tined lead along the pudendal nerve in the Alcock's channel.

In each of the following steps the neurophysiological monitoring is repeated in order to confirm the consistency between the recorded trace and the RPR.

A stylet is inserted in the needle. The introducer assembly is inserted over the stylet, the inner part of the introducer assembly is removed, the lead is inserted through the plastic sheat, the sheath is removed after the stimulation of the lead confirming the correct placement.

The lead is connected to an external stimulator. An implantable pulse generator can be subcutaneously implant in case of positive results.

From May 2002, 10 patients (6 male, 4 female, mean age 45, range 21-66) underwent pudendal nerve stimulation. All patients were submitted to a complete neurophysiological evaluation at baseline and were asked to fill out a bowel and voiding diary for 7 days. Baseline urodynamic assessment was performed as part of the baseline workup. All patients were neurogenic: 4 non traumatic (2 vascular myelopathy, 1 transverse myelitis, 1 syringomelia) 4 had trauma (incomplete lesion at cervical level in 2, at level D12-L1 in 1), 1 patient had peripheral lesion after pelvic surgery and 1 patient had central lesion due to cerebellum neoplasia. Main reported symptoms were: Urge incontinence in 9 and urinary retention in 1 patient. Seven patients with urge incontinence had constipation and one patient suffered from combined fecal incontinence.

All patients failed conservative, 5 pts underwent SNS test stimulation (PNE) but had unsatisfactory results, 2 pts were implanted with neurostimulator (1 pt had worsening of symptoms after 6 yrs, and the other patient pts was implanted 12 months ago with only 30% of improvement). 3 pts didn't undergo neuromodulation before pudendal stimulation. Nine out of 10 patients, were screened with a temporary stimulation (PNE) lead left in situ for at least 7 days (range 7-10). One was screened with the definitive quadripolar tined lead.

Results

Four out of 9 pts with urge incontinence became continent during screening phase, 1 pt improved by more 88% (from 9 to 1 daily incontinence episodes), 1 pt is still in screening phase, 3 didn't improve.

Out of the 7 patients with constipation at baseline, 5 pts reported normalization of bowel habits, 1 pt is in screening phase, 1 didn't improve. One patient with chronic urinary retention is in screening phase.

Out of 9 patients who underwent temporary pudendal nerve stimulation, 6 were selected for permanent implant and 3 pts are in currently in the screening phase. One pt who received a permanent implant was explanted one month later because of erosion of the skin at the level of the connection between lead and extension cable.

Conclusions

Chronic pudendal nerve stimulation is feasible, the implant of the lead is easy to perform using percutaneous technique originally developed for sacral neurostimulation. Neurophysiological guidance allows reproducible and reliable guide to place the lead. This technique could wide the field of application of electrical stimulation for treating functional disorders in neurogenic patients. Further study must carried out to identify the best selection criteria, the best stimulation parameter and to verify the long term results.