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SACRAL PERCUTANEOUS IMPLANT (SPI) LONG TERM FOLLOW UP: SINGLE CENTER, SINGLE OPERATOR, SINGLE PROTOCOL IN PREDICTIVE FACTORS.

Hypothesis / aims of study

Aim of this report is to present single center and single operator results using staged percutaneous implant (SPI) for sacral nereuromodulation (SNM) with tined lead.

Study design, materials and methods

The traditional procedure for sacral nerve stimulation involved the use of a percutaneous test stimulation (PNE) prior to implantation of a chronic system. The implant occurred after obtaining positive results, and the procedure was typically performed as a single-stage implant. The test stimulation sometimes results in inconclusive results, because test leads would migrate. The introduction of sacral percutaneous implant with tined lead with staged procedure, is now a codified and innovative approach

From September 2001 to December 2003, 55 consecutive patients (41 female, 14 male, mean age 39, range 19-57), underwent percutaneous implant of tined lead for SNM skipping the PNE phase.The procedure was performed in local anaesthesia. Indications for SNM were: urge incontinence in 23 pts (10 pts of neurogenic origin), retention in 32 pts (neurogenic urinary retention in 6 pts).

The average time to complete the procedure was 35 minutes (range 25-60 minutes).

The foramen needle is inserted into the foramen to a desired location (S3 usually); then the device consists of a percutaneous system for the introduction of the lead with coaxial metal and plastic dilator; the lead is then inserted through the plastic dilator.

To verify the correct lead's position, electrical stimulation is applied to the lead to evoked motor and sensory responses, which in our protocol are recorded with intraoperative neurophysiologic monitoring of afferent and efferent pathways.

Finally the position and depth of the lead is adjusted to obtain the best sensory and motor evoked responses.

Results

Out of 55 patients, 32 (58%) were submitted to the second stage of implant after a first stage mean time of 40 days. Twenty-three patients were submitted to the explant of the lead after the first stage due to an improvement of symptoms lower than 50%. Prevalence in this group is in neurogenic patients, five retention due to incomplete lower motor neuron lesion, six patients with neurogenic overactive bladder.

At a mean follow up of 16 months (average 4-27 months) a stability of results was obtained in 29 patients implanted (92%): 18 resulted cured, while in 11 pts an improvement within 50-90% was observed. In all patients to set the parameters of stimulation was used a neurophysiological evaluation and monitoring. Only three patients didn't maintain long term results after the implant of the Internal Pulse Generator (IPG).

By analizing different groups, in codified indications (idiopathic overactive bladder and voiding difficulties) with SPI the success rate is 91 %, while in neurogenic bladder worst results are obtained. For this reasono in six patients with neurogenic overactive bladder we decided to converte SNM in pudendal nerve percutaneous implant.

Interpretation of results

By the means of staged tined lead implant, with an alghorithm of intraoperative neurophysiological guidance, long evaluation between first stage and the implant of IPG, setting parameters under neurophysiological guidance, an increase of success rate is achieved in codified indications for SNM. Poor results are obtained in neurogenic overactive bladder, where a different site of modulation – pudendal nerve – seems to be the future target.

Concluding message

Sacral neuromodulation continues to evolve. The development of minimally invasive implant methods is of great interest to physicians who use SNM in treating their patients. Our

experience showed that the staged percutaneous approach with local anesthesia is feasible, quicker than the traditional implant and may reduce adverse events associated with the surgical procedure required to implant the lead. The use of local anesthesia lets the implanting physician use the patient's conscious sensory responses to stimuli as an aid in accurately placing the stimulation lead. The displacement rate is low and lower than reported with surgical implant. The success rate of patients underwent a PNE with positive results is slightly lower than the success rate of patients screened with quadripolar lead. This could show the relative low value of PNE as predictive factor, this could be explained with inconsistent position of the PNE lead and the early displacement of PNE lead.