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ITALIAN EXPERIENCE IN SACRAL PERCUTANEOUS IMPLANT (SPI) TECHNIQUE FOR SACRAL NEUROMODULATION

Aims of Study

Aim of this report is to present preliminary experience on a new percutaneous technique for placement of permanent lead.

<u>Methods</u>

The traditional procedure for sacral nerve stimulation involved the use of a percutaneous test stimulation 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 resulted in inconclusive results, because test leads would migrate.

From December '99 67 consecutive patients (45 female, 22 male, mean age 44, range 19-64), underwent percutaneous staged implant of permanent lead for sacral neuromodulation. Twenty-one skipping the PNE phase. The procedure was performed in local anaesthesia in 58 pts. Indications for sacral neuromodulation were: voiding difficulties in 28 pts (neurogenic 13), urge incontinence 26 pts (neurogenic 6), urgency/frequency (4), fecal incontinence (6), and pelvic pain (3).

The average time necessary to complete the procedure was 45 minute (range 25-90).

The foramen needle is inserted into the foramen to a desired location (S3 usually), then the technique consist of using two dilator successively inserted over a metal stylet inserted through the needle, the lead is inserted through the plastic dilator. To verify the stimulation lead's position, an electrical signal is applied to the lead to evoke a patient motor or sensory response. The position and depth of the lead is adjusted to obtain the best sensory and motor response.

In 4 pts the lead was not fix to the fascia (3 early displacement), in the remaining 63 pts the lead has been fix to the fascia (2 early displacement).

<u>Results</u>

40 pts underwent second stage (implant of IPG), 12 that report an improvement lower than 50% were not selected for IPG implant and 15 pts are currently in screening phase. The mean follow-up aftere IPG implant is 10 months (1-22), 38 experienced an improvement by more than 90% and 1 have an improvement within 50%-90% while in 1 patient the system has been explanted.

The overall number of displacement is 5, 3 in the group of 4 pts in whom no fixation method were used, 3 in the remanining 63 patients in whom a fascial fixation has been used.

Conclusions

Sacral neuromodulation continues to evolve. The development of minimally invasive implant methods is of great interest to physicians who use sacral neuromodulation in treating their patients. A less invasive approach to implantation has a number of benefits.

- Our experience showed that the staged, percutaneous approach with local anesthesia is feasible, is 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 response to stimuli as an aid in accurately placing the stimulation lead.
- Patients are more willing to undergo the test stimulation.
- Fascial fixation of the lead seems to be a good option to avoid early displacement
- The percutaneous lead placement method may reduce adverse events associated with the surgical procedure required to implant the lead.