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FIRST STAGE SACRAL NEUROMODULATION: SAFETY OF PROLONGED FOLLOW-UP AND VALUE OF PROGRAMMING SETS TAILORED TO THE UNDERLYING DIAGNOSIS

Hypothesis / aims of study

We report an original work about prolonged first stage Sacral Neuromodulation (SNM) and the use of programming sets tailored to the underlying diagnosis. As stated by the International Neuromodulation Society (INS, Sakas *et al.,* 2007), "for a therapy to be considered Neuromodulation the therapy must be a dynamic, ongoing intervention and not a short and non recurring procedure and the clinical effect is continuously controllable by varying one or more stimulation parameters to satisfy a patient's need" (1). Neuromodulation of central circuits through the sacral nerve (Sacral Neuromodulation, SNM) implies a trial of therapy with a tined quadripolar lead to select patients for permanent implant (staged Interstim® therapy). Suggested duration of first stage evaluation is three weeks. In our Center with 21 years experience with SNM and patients reprogramming, a retrospective review was performed of 94 consecutive patients implanted with a first stage SNM from January 2014 through December 2016. All of the patients had adequate follow-up and were considered eligible for the study. Length of follow-up of first stage SNM implant was up to 12 weeks (6-12 weeks) and weekly follow-up controls were performed. Based on clinical experience of our "sacral neuromodulation goup", programming and reprogramming was correlated with the underlying diagnosis. Aim of the analysis was to evaluate the safety of prolonged follow-up with external cable, and the effectiveness of tailoring reprogramming to the underlying diagnosis.

Study design, materials and methods

A retrospective review of 94 consecutive patients implanted with a first stage SNM from January 2014 through December 2016 was performed. All of the patients had adequate follow-up and were considered eligible for the study. The mean age was 54.1 (22-76 years), 30 males and 64 women. Main underlying diagnosis was urinary retention in 46 patients, painful bladder syndrome in 5, chronic pelvic pain in 5, urge urinary incontinence in 11, urgency frequency in 24, constipation in 1 and fecal incontinence in 2. Fourteen patients were tested on each side in two distinct surgical procedures with a total of 108 first stage procedures performed. Length of follow-up was 6 weeks in 16 patients, 8 weeks in 51 and 12 weeks in 27. Each patient received standard in-office training about management of external cable. Since the introduction of staged procedure in 2002 we've been tunneling the extension cable through the flank to the abdominal wall. Anterior tunneling facilitates management of the external cable to be connected to external power source. It's easier for the patient to handle and dress a cable exiting the abdominal wall than the back. Follow-up controls were performed weekly as standard in-office procedure in 71 patients, as weekly telephone consultation for the first three weeks followed by an in-office procedure at the first month in 23 patients. As regards stimulation programming, Pulse Width (PW) was maintained in a range between 180 and 270 microseconds. Frequency (Pulse Rate, PR) was tailored to the underlying diagnosis: 5 pps in urinary retention due to detrusor underactivity, 40 pps in urinary retention due to dysfunctional voiding, 10 to 21 pps in urge urinary incontinence and urgency/frequency. In pelvic pain and painful bladder syndrome we used 70 to 85 pps. Electrode polarity was chosen based on the lowest stimulation threshold. In all of the patients with weekly in-office follow-up visits PR was changed at each control. The remnant 23 patients started with PR tailored to the underlying diagnosis and it was eventually changed at the first in-office control.

Results

Neither infection nor breaking of external cable was experienced by any patient. Stimulus amplitude varied from 0.3 to 3.3 Volts (mean 0.59-1.59). Frequency tailored for the underlying diagnosis was reprogrammed at the end of follow-up in 82 patients (87.2%) due to better clinical outcome.

Follow-up of the 94 patients closed with a second stage with permanent device implant in 65 patient and with the explant of electrode and external cable in 43.

Interpretation of results

The purpose of this study was to evaluate the consequences of prolonged follow-up of first stage SNM procedure and the value of programming sets tailored to the underlying diagnosis**.**

Prolonged follow-up demonstrated to be a safe choice in informed and trained patients. The absence of complications was observed either in the "weekly controlled" patients or in the "telephone contacted" with monthly in-office controls. A careful selection of stimulation parameters is crucially important to obtain clinical improvement, since the perception of paresthesia is critical to ameliorate clinical outcome (2). In time we developed and used certain programming sets tailored to the underlying diagnosis. Patients were informed about the necessity of reprogramming to optimize therapy and in 87.2% of cases they defined as optimal the "optimized for the underlying diagnosis" set.

Concluding message

In SMN programming and reprogramming is of crucial importance to optimize clinical outcome. We defined different parameters set to be tailored to different underlying diagnosis. Length of first stage follow-up can be safely prolonged up to 12 weeks.

References

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