Sacral nerve stimulation

K.E. Matecă, U. Stadelmaier, M. Bösendorfer
Chirurgische Klinik der Universität Erlangen
Erlangen, Germany

Rezime

The current concept of recruiting residual function of an inadequate pelvic organ by electrical stimulation involves stimulation of the sacral spinal nerves at the level of the sacral canal. The rationale for applying SNS to fecal incontinence was based on clinical observations of its effect on bowel habits and anorectal continence function in urologic patients (increased anorectal angulation and anal canal closure pressure) and on anatomic considerations: dissection demonstrated a dual peripheral nerve supply of the striated pelvic floor muscles that govern these functions. Because the sacral spinal nerve site is the most distal common location of this dual nerve supply, stimulating here can elicit both functions. Since the first application of SNS in fecal incontinence in 1994, this technique has been improved, the patient selection process modified, and the spectrum of indications expanded. At present SNS has been applied in more than 1300 patients with fecal incontinence limited.

METHODS AND PATIENT SELECTION

Technique

The technique for SNS consists of two diagnostic stages, followed by a third therapeutic stage.

Acute Percutaneous Nerve Evaluation (PNE)

Acute PNE aims to determine whether contraction of the striated pelvic floor muscles can be elicited by SNS and to test the individual relevance of each sacral spinal nerve to anal sphincteric contraction and anal canal closure (thus identifying the optimal site of stimulation).

For acute PNE, needle electrodes are inserted into the dorsal sacral foramina of S2, S3 and S4. This positioning aims for placement close to the site where the sacral spinal nerves enter the pelvic cavity through the ventral opening of the sacral foramen and proximal to the sacral plexus. For correct placement, palpable anatomic landmarks and concomitant reactions of the ipsilateral lower extremity are helpful in identifying the sacral foramina and optimizing the position of the needle electrode.

If this acute stimulation successfully elicits contraction of the pelvic floor, subchronic percutaneous stimulation is initiated to evaluate the therapeutic potential of low-frequency stimulation of the identified nerve(s).

Subchronic Percutaneous Nerve Evaluation

The sacral spinal nerve(s) found in acute testing to be most effective with regard to muscular contraction and anal canal closure pressure (most commonly, S3) are stimulated continuously for a period of time sufficient to demonstrate a potential effect on fecal incontinence. Thus, the observation period depends on the frequency of incontinence episodes: bowel habits, such as frequency and degree of involuntary loss of stool, are documented with standardized bowel diaries.

Two technical options are used for subchronic PNE: a temporary, percutaneously placed, test stimulation lead or multiple leads that will be removed at the end of this phase; or operative placement of a quadripolar lead, the so-called "foramen electrode" (usually limited to one nerve site). Both types of leads are connected to an external pulse generator for screening. With both techniques the selected sacral spinal nerve is continuously stimulated (pulse width 210 sec; frequency 15 Hz), except during voiding and defecation. The amplitude of stimulation may require adjustment and is adaptable by the patient within a limited range (1 - 10 V) according to his or her perception of muscle contraction or perianal sensation.

At the end of the screening phase, the percutaneously placed temporary test stimulation lead is removed; the operatively placed foramen electrode is either removed (if unsuccessful) or connected to an implanted pulse generator (so-called "two-stage implant"), offering the advan-
tage of identical positioning of the electrode during screening and therapeutic stimulation.

**Chronic Stimulation with a Permanent Implant**

Permanent stimulation with a fully implantable device aims to make use of the therapeutic effect achieved by subchronic PNE. Patients with a temporary test stimulation lead undergo simultaneous operative implantation of the quadrupolar foramen lead and the pulse generator those with a foramen electrode already in place undergo removal of the percutaneous extension before placement of the pulse generator subcutaneously in the abdomen or gluteal area.

Recently, a less invasive technique that uses a foramen electrode with a modified anchoring device placed through a trochar has gained popularity. This technique can be used either for stage one of the two-stage implant or for electrode placement after successful screening with wire electrodes.

The parameters used for chronic stimulation damage to the nerve: pulse width, 210 sec; frequency, 15 Hz; on-off: 5 sec – 1 sec or continuous stimulation; level of stimulation usually above individual patient’s perception of muscular contraction and adjusted if necessary. The pulse generator is activated by telemetry. Patients are instructed to interrupt stimulation with a hand-held programmer only for defecation and urinary voiding.

**Patients**

Indications, Selection

As the purpose of SNS is to recruit residual function of the continent organ by electrical stimulation of its peripheral nerve supply, the patient selection for the SNS protocol is based on the clinical and physiologic finding of an intact nerve-muscle connection confirmed by reduced voluntary sphincter function or absent voluntary sphincteric function, but existing reflex activity, confirmed by one of the following findings: intact anocutaneous reflex activity, muscular response to pudendal stimulation with the St. Mark’s electrode. In the initial group of patients treated with SNS the causes of incontinence varied, covering a spectrum from postoperative sphincteric weakness consequent to anal and rectal procedures to total lack of voluntary sphincteric control as a sequela of cauda syndrome secondary to lumbar spine fracture.

With the help of PNE and based on physiologic findings during temporary test stimulation (suggesting that the effect of SNS is not limited to the striated sphincter muscle), the indications for permanent SNS were expanded to patients suffering from fecal incontinence owing to a deficiency of the smooth-muscle internal anal sphincter, to limited structural defects, and to functional deficits of the external and internal sphincter.

Subsequently a more pragmatic approach evolved. Further studies based the indication for test stimulation on the existence of an anal sphincter and residual sphincteric or reflex function—regardless of the underlying physiologic condition.

Patients are selected for operative implantation of a permanent neurostimulation device on the basis of clinical improvement during test stimulation. At present no other predictor of functional outcome with chronic stimulation exists. The test stimulation procedure is most commonly considered therapeutically effective if the frequency of episodes of fecal incontinence documented by bowel-habit diary is alleviated by at least 50% and if the improvement is reversible after discontinuation of temporary stimulation.

**RESULTS**

As with indications, outcome assessment has also evolved. Initially the most common measures were the number of incontinent episodes or days with incontinence during a set period of time (based on bowel-habit diary) and incontinence score results (Cleveland Clinic Continence Scoring System). Subsequently, Quality of Life instruments such as SF36 and FIQL Score were added to evaluate the therapeutic effect.

**CLINICAL RESULTS**

In all studies a significant functional benefit-decreased frequency of involuntary loss of stool or improved Cleveland Clinic Continence Score—was achieved with a permanent implant and remained consistent over the course of follow-up, as long as 120 months. The results of the test phase were reproduced or even surpassed by chronic stimulation. The majority of patients—around 90%—experienced an improvement of at least 50% in a single center and multicenter setting 45% – 55% of the patients achieve full continence.

Sacral nerve stimulation not only decreased the frequency of incontinent episodes or improved the Continence Score, but also was shown to have a beneficial effect on the ability to postpone defecation and to empty the bowel.

The rate of complications varied from 0% to 50%. These comprised pain at the site of the electrode or pulse generator, electrode dislodgement or breakage, infection, loss of effect, or deterioration in bowel symptoms. This resulted only in less than 3% in a removal of the neurostimulation device and discontinuation of therapy. The intention-to-treat analysis revealed therapeutic success in 80% - 100% of patients.

**QUALITY OF LIFE**

Sacral nerve stimulation clearly improved quality of life: SF36 revealed positive changes in multiple subscales, reaching statistical significance in some subscales in single-center trials and in social functioning and mental component summary in a multi-center settings. The disease-specific FIQL showed high significant improvement in all four categories—lifestyle, coping/behavior, depression/self-perception, embarrassment—in both single-center and multicenter studies.
DISCUSSION

Sacral nerve stimulation represents a novel treatment in selected patients with fecal incontinence. The technique is therapeutically effective not only in improving continence, but also in improving quality of life.

The spectrum of indications has been expanded by applying a pragmatic approach to patient selection through test stimulation. With the help of the three-stage protocol, patients representing a wide variety of causes of fecal incontinence have been identified and treated successfully. At the moment no other predictor for the outcome of SNS exists. The selection of patients is based on the functional results achieved during temporary test stimulation. The technique of foramen electrode implantation carries limited risk. The complication rate is low, and the need for discontinuation is rare.