83

Bosch R, Groen J
Erasmus Medical Center Rotterdam

COMPLETE 5-YEAR FOLLOW-UP OF SACRAL (S3) SEGMENTAL NERVE STIMULATION WITH AN IMPLANTABLE ELECTRODE AND PULSE GENERATOR IN 36 CONSECUTIVE PATIENTS WITH REFRACTORY DETRUSOR OVERACTIVITY INCONTINENCE.

Aims of Study

Reports of complete 5-year follow-up of the effects of treatments for detrusor overactivity incontinence (urge incontinence due to idiopathic or neurogenic detrusor instability) are non-existent. The aim of this study was to evaluate the complete 5 year treatment results of unilateral sacral (S3) segmental nerve stimulation (neuromodulation with an implantable electrode and pulse generator: Interstim) in patients who had been refractory to pharmacologic treatment.

Methods

It is assumed that electrical stimulation of sacral somatic nerve afferents carried by the pudendal nerve can induce detrusor inhibition. The S3 spinal nerve carries pudendal nerve afferents and can be used for chronic electrical stimulation in the treatment of detrusor overactivity incontinence in patients who are refractory to conservative management.

Patients who reacted favorably to a 4-6 day test-stimulation (PNE) with a temporary, percutaneously placed wire electrode received a permanent implant: an S3 foramen electrode connected to a subcutaneously placed Itrel pulse generator (Medtronic Interstim). A favorable response is defined as a more than 50% decrease in leaking episodes and pad use. The first 36 consecutive implanted patients (5 men and 31 women with an average age of 45.4 years) who completed a minimum follow-up of 5 years are the subjects of this report. 70 patients (56 women and 14 men) had to undergo a PNE to reach this number of 36 implants for a 51% success rate of the PNE.

The stimulation amplitude had been adjusted to achieve an optimal symptomatic result. The parameters frequency and pulse width were set at 10 Hz and 210 µsec respectively. Follow-up tests included detailed voiding / incontinence diaries which were completed on a 3 to 6 monthly basis. Filling cystometries and pressure-flow studies, have been performed before the implant and at 6 months follow-up with the pulse-generator in the on-mode. The urodynamic tests were performed in the most provocative, that is the standing position.

Results

Of the implanted patients, none were lost to follow-up. During follow-up, one patient developed bladder cancer and 2 and 3 patients, respectively underwent a urinary diversion and an ileocystoplasty. Of these 6 patients who failed before the 5 year follow-up mark, the last available values of the voiding diary parameters were carried forward. At 5 years, the treatment was considered successful in 52.8% (22.2% complete success = decrease of pad use and the number of leakages by > 90% and 30.6% partial success = decrease of pad use and the number of leakages by 50 to 90%). There is a slow but steady decrease of the percentage of patients who are a complete success. Of those who fail, most have failed before two years of follow-up (Table 1).

Table 1: Durability of effects on symptomatic / voiding diary parameters in 36 patients:

Duration of follow-up.	**Fail:** < 50% improvement in pads and leaks. (% of pts)	**Partial success:** 50-90% improvement in pads and leaks. (% of pts)	**Complete success:** >90% improvement in pads and leaks. (% of pts)
1 month	19.4%	33.4%	47.2%
1/2 year	36.1%	27.8%	36.1%
1 year	33.3%	38.9%	27.8%
2 years	38.9%	33.3%	27.8%
3 years	47.2%	27.8%	25.0%
4 years	52.8%	22.2%	25.0%
5 years	47.2%	30.6%	22.2%

With increasing follow-up, the evolution of the effects of unilateral sacral segmental nerve stimulation on the number of incontinence pads used, the number of leaking episodes and the voiding frequency per 24 hrs, as well as the average voided volume is as summarized in table 2 (values are means ± SEM).

Table 2: Durability of effects on symptomatic / voiding diary parameters in 36 patients:

Follow-up (years)	Pads (N/24 hrs)	Leaks (N/24 hrs.)	Voids (N/24 hrs.)	Av. volume per void. (mL)
Pre-implant	6.5±0.6	7.5±0.6	14.0±0.9	133±10
1/2 year	1.9±0.3	2.1±0.4	9.5±0.5	187±13
1 year	2.1±0.4	2.3±0.4	8.6±0.5	195±14
2 years	2.4±0.6	2.7±0.5	9.1±0.5	183±13
3 years	2.5±0.4	2.6±0.5	9.3±0.5	181±13
4 years	2.3±0.4	2.9±0.5	9.4±0.5	170±13
5 years	2.6±0.4	2.8±0.5	9.4±0.6	164±12

In 17 of the 36 patients no instability was detected on follow-up cystometry in the standing position. The correlation between the urodynamic and the symptomatic effect is only moderate: 7 out of 17 patients (41%) without detrusor overactivity at the 6 months post-op cystometry versus 10 out of 19 (53%) with detrusor overactivity, have failed at 5 years.

Conclusions

Neuromodulation is a valuable treatment option in this difficult group of patients with refractory detrusor overactivity incontinence. About 50% of these patients respond favorably to a PNE and are candidates for a permanent implant. Of the implanted patients, about 50% have failed after 3 years of follow-up. Thereafter, the symptomatic effects seem to be durable for at least another 2 years. Three of five men (60%) and 14 of 31 women (45%) have failed. Disappearance of detrusor instability at the 6-month urodynamic study is not predictive of long-term (5-year) symptomatic success.