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# CHRONIC SACRAL (S3) NERVE STIMULATION: THE EFFECTS ON NOCTURIA AND NOCTURNAL BLADDER CAPACITY AND CORRELATES WITH SUPINE URODYNAMICS IN WOMEN WITH REFRACTORY URGE URINARY INCONTINENCE

## Aims of Study

Nocturia can have a significant impact on sleep patterns and quality of life. The aim of this study was to evaluate the effects of chronic sacral (S3) nerve stimulation on nocturia (nocturnal voiding frequency [NVF] > 1) in women with refractory urge urinary incontinence. 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 electrical stimulation in the treatment of detrusor overactivity (DOA). The efficacy of this treatment has been shown in pivotal trials that were conducted in patients with urge incontinence [J Urol 162:352, 1999] and urge-frequency [J Urol 163: 1849, 2000]. However, in these trials, the possible effect of SNS on nocturia and the mechanism responsible for the effect have not been studied.

### Methods

Patients who reacted favorably to percutaneous nerve evaluation (PNE) with a temporary test electrode received a permanent implant: an S3 foramen electrode connected to a pulse generator (Medtronic Interstim). A favorable response is defined as a more than 50% decrease in leaks and pad use. PNE was performed in 114 women with urge urinary incontinence. 54 women responded to the PNE and were implanted. Of these, 26 (50%) had a baseline NVF>1, and a minimum follow-up of 6 months. The stimulation amplitude had been adjusted to achieve an optimal symptomatic result. Filling cystometries, in the supine and in the standing position, and pressure-flow studies have been performed before the implant and at 6 months follow-up with the pulse-generator in the on-mode. Follow-up tests also included bladder diaries (3 to 6 monthly). The nocturnal urine volume derived from the diaries was divided by the maximal cystometric capacity (MCC) during supine filling to calculate the predicted nocturnal voiding frequency (NVFpred). At baseline and after 6 months of follow-up we determined the correlation coefficient between the predicted and the actual nocturnal voiding frequency (NVFact). The nocturnal bladder capacity index (NBCi = NVFact - NVFpred) was calculated at baseline and at 6 months. A higher value of NBCi indicates diminished nocturnal bladder capacity or more severe sensory urgency. Values are expressed as means±SEM.

### Results

Of the 26 patients (age:47 $\pm$ 2 yrs), one was lost to follow-up before the 6 month urodynamic study could be performed and one patient refused urodynamics. The average follow-up of the implanted patients with nocturia was 65 (range:6-120) months. At baseline, 2 women did not have detrusor overactivity (DOA), 7 had DOA during filling cystometry in the standing position only, whereas 17 had DOA in the supine and standing position. Furthermore, 4 women had polyuria; one of these and 3 others had nocturnal polyuria. The NVFact and NVFpred at baseline were 2.9 $\pm$ 0.4 and 1.7 $\pm$ 0.3, respectively.There was no correlation between NVFpred and NVFact:: r = 0.005 (p=0.981) .

At 6 months follow-up a > 50% improvement in the number of incontinence pads and the number of leaks, was demonstrated in 20 (74%) women. Furthermore, no patient had polyuria and only 1 had persistent nocturnal polyuria. The correlation between NVFpred (0.5 $\pm$ 0.1) and NVFact (1.0 $\pm$ 0.2) at 6 months follow-up had increased to r = 0.75 (p=0.0001).

The MCC in the supine position increased from 345 (±31) mL at baseline to 414 (±26) mL at 6 months with IPG in the on-mode (p=0.04).

The NBCi decreased from  $1.4\pm0.5$  at baseline to  $0.4\pm0.1$  at 6 months follow-up. Interestingly, the NBCi at baseline did not differ significantly between those who did have supine DOA and those who did not  $(1.1\pm0.7 \text{ vs } 1.3\pm0.4)$ .

The average NVFact decreased from 2.9 (range 1.3-9.7) times at baseline to 1.1 (range 0-3.7) times at latest follow-up (average 65 months).

The durability of the effect of SNS on NVFact is shown in table 1.

Table 1: Durability of effect of SNS on actual

nocturnal voiding frequency:

Follow-up		N	Nocturia	- a
(years)			frequency	
Pre-implant	26		2.9±0.3	-
1/2 year		26	1.0±0.2	
1 year	24		0.8±0.1	
2 years	19		1.2±0.2	
3 years	19		1.1±0.2	
4 years	17		1.1±0.2	
5 years	15		1.1±0.3	_

# **Conclusions**

SNS has a durable effect on nocturnal voiding frequency in women treated for refractory urge urinary incontinence. The data also give insight in the mechanism of action.

The lack of correlation between NVFact and NVFpred at baseline indicates that the MCC found during supine filling cystometry is a poor determinant of nocturnal voiding frequency. Furthermore, the NBCi at baseline does not seem to depend on the presence or absence of DOA on supine filling. After 6 months of treatment the NBCi has decreased significantly and the correlation between NVFact and NVFpred has become very good (r=0.754). These findings indicate that a "sensory" effect is more important than a "motor" effect in order to achieve a significant improvement of nocturia in this group of patients.