

**BENEFICIAL EFFECT ON NOCTURIA OF INTERSTIM™ FOR THE TREATMENT OF REFRACTORY URGENCY/FREQUENCY AND URGE INCONTINENCE.****Aims of Study**

Urge urinary incontinence and urgency frequency syndrome are common voiding dysfunctions that represent important health issues for patients, care givers and clinicians. These disorders have also devastating impact on the quality of life. This is aggravated when these disorders are accompanied by sleep disturbances caused by frequent voiding during the night, which is rather common in those patients. Sacral neuromodulation has shown to be a very effective treatment modality for these disorders but until now no reports have been made on the possible effect in reducing the nighttime voiding frequency. We retrospectively investigated the effect of Neuromodulation therapy on nocturia in these groups of patients.

**Methods**

73 Patients (8 males, 65 females) suffering from the urgency/frequency (UF) syndrome refractory to standard therapy and 122 patients (15 males, 107 females) with refractory urge incontinence (UI) with an InterStim™ implant (Medtronic, Minneapolis, USA) at least had 2 voids per night. These patients were part of the multi center trial where neuromodulation treatment was evaluated for its efficacy and safety. We defined that 2 or more voids per night should be considered as severe enough to bother patient and have an impact on QoL. In both groups more than 50% of the implanted patients who had nocturia, suffered from more than 2 voiding episodes per night. The UF and UI group had a follow-up of 36 and 48 months respectively. The change in the number of nocturnal voiding, defined as the number of voiding between 11 pm and 7 am was analyzed.

**Results**

UF group. The average number of nocturnal voiding was 3 (range 0-9.7). After 6 months this was reduced to only 1.3 and during the 3 years time stayed unchanged. At 36 months follow-up, nocturia was still reduced to 1.6 (range 0-2.9). 42 Patients (58%) voided more than 2 times per night (mean 4.2) at baseline. After 36 months the mean decrease in this group of patients was 2.9. The results are listed in table 1.

Number of voids in UF group				Change for patients with > 2 voids /night		
Time (months)	n	Voids / night	Mean decrease	N	Mean decrease	% of pt's with < 2 voids/night
Baseline	73	3.0 ± 2.0	-	42	4.2 ± 1.8	
6	55	1.8 ± 1.1	1.3 ± 1.9 *	34	2.1 ± 2.0 *	44%
12	50	2.1 ± 1.3	1.3 ± 1.9 *	31	2.2 ± 1.9 *	52%
24	28	2.1 ± 1.2	1.8 ± 2.2 *	23	2.2 ± 2.2 *	43%
36	18	1.6 ± 0.8	2.3 ± 2.6 *	14	2.9 ± 2.7 *	57%

Table 1. Number and change of number of voids in UF group (\* p<0.01)

UI group: The average number of nocturnal voiding at baseline was 2.3 (range 0-6.4). After 48 months this was reduced to 1.8 (range 0.6 – 5.5). 63 Patients (52%) voided more than 2 times per night (mean 3.4). After 48 months, with the data available of 16 patients, the mean decrease was 1.2. The results are listed in table 2.

Number of voids in UI group				Change for patients with > 2 voids /night		
Time (months)	n	Voids / night	Mean decrease	N	Mean decrease	% of pt's with < 2 voids/night
Baseline	122	2.3 ± 1.4	-	63	3.4 ± 1.2	
6	82	1.9 ± 0.9	0.6 ± 1.3 *	44	1.2 ± 1.2 *	43%
12	90	1.7 ± 1.0	0.7 ± 1.3 *	49	1.4 ± 1.2 *	59%
24	60	1.7 ± 0.9	0.8 ± 1.2 *	35	1.3 ± 1.2 *	57%
36	30	1.8 ± 0.9	0.8 ± 1.3 *	30	1.3 ± 1.1 *	50%
48	27	1.8 ± 1.0	0.5 ± 1.5 *(p=0.10)	16	1.2 ± 1.3 *	69%

Table 2. Number and change of number of voids in UI group (\* p<0.01)

#### Conclusions

The long-term effect of sacral neuromodulation on nocturnal voiding in patients suffering from UI and UF is beneficial. We demonstrated the decrease in the number of nocturnal voiding in these difficult to treat groups of patients. These good results may further demonstrate the improved QoL, that has also been reported previously but more specific QoL should be used in order to be able to measure the impact of this change. Since nocturia has a severe impact of quality of life it may be expected that InterStim increases quality of life in these patients.