

## LONG TERM EFFECTS OF SACRAL NERVE STIMULATION IN PATIENTS SUFFERING FROM URINARY RETENTION: A PROSPECTIVE STUDY

### Aims of Study

Sacral neuromodulation is a proven beneficial treatment for non-obstructive urinary retention. The treatment obtained FDA approval for this indication in 1999. The long term results of sacral neuromodulation (Interstim®, Medtronic), for retention are reported for those patients who were transferred to the post approval study by from investigative sites worldwide who participated in the pre approval study.

### Methods

At the time of database closure in October 2001, 59 patients had been implanted with an Interstim device due to urinary retention. Analysis was performed based on patient voiding diaries. 53 Patients had completed at least a 12 months diary. The primary endpoint for analysis was average catheterized volume per catheterization. Other variables that were analyzed included number of catheterizations /day, total catheterized volume /day; number of voids/day total volume voided/day and force of urinary stream.

### Results

Of the 53 patients available for analysis 9 were explanted due to lack of efficacy or adverse events. Average follow-up time was 40 ±17 months. The mean change in number of catheterizations per day went from 5.5 ± 3.4 to 2.6 ± 4.0 (p<0.0001). The catheterized volume per catheterization decreased from 329 ml ± 173 to 103 ml ± 158 (p<0.0001). 53% Of the patients did not catheterize at last follow up, and another 9% perceived a more than 50% reduction in catheterization volume. Voiding variables that changed significantly are listed in table 1.

Diary variables	n	Avg at Baseline	Avg at last FU	p-value
Primary endpoint				
Cath vol per cath (ml)	53	329 ± 173	103 ± 158	<0.0001
# cath per day	53	5.3 ± 3.5	2.6 ± 4.0	<0.0001
Tot cath volume per day (ml)	44	1692 ± 1062	408 ± 828	<0.0001
Max cath volume (ml)	44	577 ± 392	162 ± 62	<0.0001
# voids per day	44	4.1 ± 5.0	6.5 ± 3.8	0.0002
Tot vol voided / day (ml)	44	784 ± 1178	1772 ± 1156	<0.0001
Pelvic / bladder discomfort (0=none – 3=severe)	18	1.6 ± 1.0	0.9 ± 1.0	0.04
Patients who voided at baseline & at last follow up				
% Felt empty	23	44 ± 38	76 ± 35	0.0025
Force of stream (scale 1=strong – 4 = poor)	18	3.5 ± 0.5	2.2 ± 1.0	<0.0001

Table 1. Voiding diary results at last follow up in all implanted retention patients

Apart from the primary endpoint, significant improvements were also seen in the following categories: number of catheterizations / day, total catheterization volume /day; max catheter volume; voids / day, volume voided, pelvic discomfort, perception of bladder emptiness and force of stream. Patients who had retention as well as urinary leakage (n=17) also perceived significant improvement in severity and number of leakages.

### Conclusions

Persistent effectiveness of sacral neuromodulation was seen in this group of patients suffering from urinary retention. Sacral neuromodulation also appears to improve total functioning of the lower urinary tract as other important voiding and storage parameters also showed significant improvement.