

## UNILATERAL SACRAL NEUROMODULATION IN PATIENTS WITH PAINFUL BLADDER SYNDROME/INTERSTITIAL CYSTITIS: 5 YEARS FOLLOW UP.

### Hypothesis and Aim of Study:

Painful Bladder Syndrome/Interstitial Cystitis (PBS/IC) is a disabling nonmalignant clinical condition of multifactorial etiology, characterized by suprapubic pain related to bladder filling, accompanied by other symptoms such as increased day time frequency and night-time frequency, in the absence of proven urinary infection or other obvious pathology.

Sacral nerve root stimulation (SNS) has been proven clinically as a treatment of urinary frequency and urgency, urge incontinence and non-obstructive urinary retention.

The aim of this study is to evaluate the response after 5 years follow up in patients who received unilateral sacral stimulator as a treatment for refractory PBS/IC and had initial good response. The latter was defined as 50% improvement in one or more of the voiding parameters as documented by the voiding diary.

### Study design, materials and methods:

A retrospective chart review was performed of patients who received permanent unilateral S3 stimulator (Interstim® Medtronic Neurological, Minneapolis, Mn) as treatment for refractory PBS/IC between January 2002 and December 2003, and had a good response at the 1<sup>st</sup> year follow up, and were off any previous treatment for PBS/IC.

All patients were qualified for permanent Interstim® if a 50% improvement in their voiding symptoms was achieved after peripheral nerve evaluation. All patients completed pre-treatment, one-year and five-year post-treatment voiding diaries.

Urgency and bladder pain were rated on a 4-point scale (0-non, 1-mild, 2-moderate, 3-severe).

Analysis of variances (ANOVA) was used to compare paired values. Urgency, bladder pain, nocturia, day time frequency and average voided volume were compared at base line, 1-year and 5-year follow up with  $p \leq 0.05$  considered statistically significant.

### Results:

13 female patients (mean age =  $45.7 \pm 10.8$  years) received successful InterStim® therapy for their refractory PBS/ IC. Average duration of symptoms was  $3.7 \pm 1.7$  years. The site of stimulation was on the left S3 in 9 patients (69%) and on the right S3 in 4 patients (31%). The average follow up was  $5.2 \pm 1.1$  years. Two patients removed their InterStim® in the 1<sup>st</sup> year due to lack of efficacy and were not included in the statistical analysis. Table (1) shows the response of patients at 1<sup>st</sup> year and Table (2) shows the response at 5- year follow up.

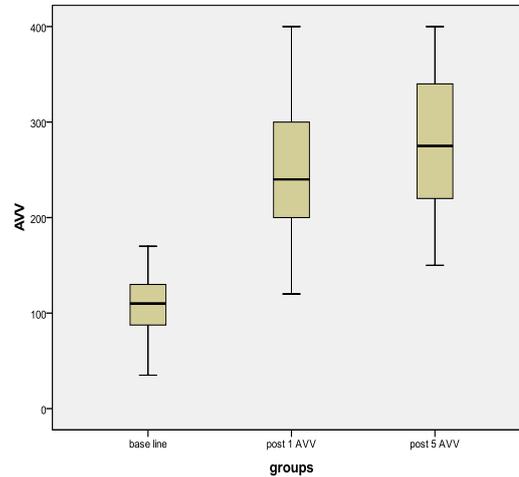
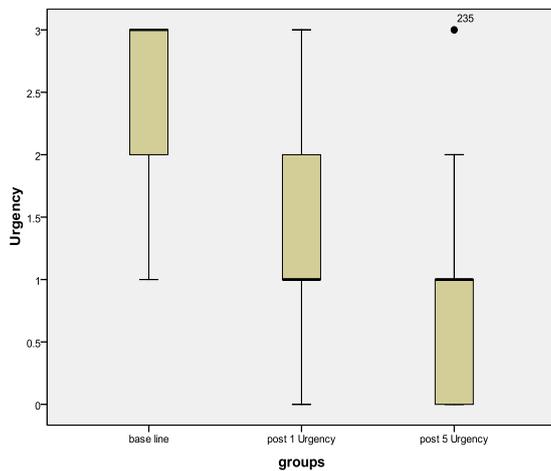
Table (1): Response at 1<sup>st</sup> year follow-up

Period	n	Urgency	Day time frequency	Nocturia	Avg. Void Volume(mL)	Bladder pain
Base line	11	$2.6 \pm 0.56$	$12.75 \pm 5$	$6.45 \pm 2.1$	$108 \pm 31.6$	$2.5 \pm 0.55$
1-year follow up	11	$1.2 \pm 0.68$	$6.09 \pm 2.1$	$3.75 \pm 1.5$	$242 \pm 62.7$	$0.98 \pm 0.73$
P value		0.0001	0.001	0.001	0.0001	0.001

Table (2): Response at 5-year year follow-up

Period	n	Urgency	Day time frequency	Nocturia	Avg. Void Volume (mL)	Bladder pain
Base line	11	$2.6 \pm 0.56$	$12.75 \pm 5$	$6.45 \pm 2.1$	$108 \pm 31.6$	$2.5 \pm 0.55$
5-year follow up	11	$0.98 \pm 0.72$	$5.7 \pm 1.6$	$3.23 \pm 1.9$	$276 \pm 64.7$	$0.80 \pm 0.70$
P value		0.0001	0.001	0.0001	0.0001	0.0001

In addition to maintaining good response at the 5-years follow up, there was a significant difference between urgency and average voided volume between 1 and 5-years follow up ( $p = 0.0001$ ). There was a sustained reduction in urgency score ( $1.2 \pm 0.68$ ) to ( $0.98 \pm 0.72$ ) ( $p = 0.02$ ), and an incremental increase in the average voided volume ( $242 \pm 62.7$ ) to ( $276 \pm 64.7$ ) ( $p = 0.014$ ).



AVV= average voided volume

**Interpretation of results:**

Unfortunately, no therapy has been shown to be consistently effective in treating severe PBS/ IC and many patients remain refractory to pharmacologic or behavioural therapies. Several investigators have recently studied the use of sacral neuromodulation in patients with PBS/IC and established the effectiveness of this modality of the treatment of urgency, frequency, nocturia and pain associated with PBS/IC [1, 2].

Unfortunately long term follow up for patients who showed good response to sacral neuromodulation is lacking. The results obtained in this study confirmed that patients who showed good response in the first year continue to maintain a good response. All patients who showed a persistent favourable response to Intrestim therapy had discontinued other treatment for PBS/IC. Our data also showed that there is continuous improvement in the degree of urgency and in the average voided volume.

**Concluding message**

Sacral nerve modulation is effective in treating symptoms of PBS/IC refractory to standard therapies. Patients who had good initial response maintained their response to treatment at the 5-year follow up.

**References**

- Whitmore KE, Payne CK, Diokno AC, Lukban JC
- Steinberg AC, Oyama IA, Whitmore KE

<b>Specify source of funding or grant</b>	Canadian Institute of Health Research (CIHR). Department of Surgery, Devison of Urology,Toronto Western Hospital
<b>Is this a clinical trial?</b>	Yes
<b>Is this study registered in a public clinical trials registry?</b>	No
<b>What were the subjects in the study?</b>	HUMAN
<b>Was this study approved by an ethics committee?</b>	Yes
<b>Specify Name of Ethics Committee</b>	University Health network (UHN) Research Ethics Board, Toronto, Canada
<b>Was the Declaration of Helsinki followed?</b>	Yes
<b>Was informed consent obtained from the patients?</b>	Yes