416

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LONG-TERM EFFECTS OF SACRAL NEUROMODULATION IN PATIENTS SUFFERING FROM URGENCY / FREQUENCY.

Aims of Study
Sacral neuromodulation has shown to be an effective treatment for the urgency / frequency syndrome. For this indication FDA approval was obtained in 1999. We present the long-term data of patients who entered a five-year Post Approval Study from 16 centers who received Interstim (Medtronic, USA) neuromodulation systems.

Methods
74 patients were implanted in the study of whom 47 completed a voiding diary 12 months post implant. 10 Patients were explanted or exited the study due to lack of efficacy or an adverse event. Therefore voiding diaries of 57 patients were available for analysis. The primary endpoints were number of voids per day; degree of urgency per day and the volume voided per void.

Results
The average period of follow up was 35 ± 12 months. A significant change was found in almost all primary endpoints. The number of voids per day decreased from 17 ± 8 to 11±6 ($p<0.0001$); the volume voided per void increased from 117 ± 79 to 204 ± 144 ($p<0.001$), the degree of urgency (scale 0_{none} - 3_{severe}) decreased from 2.2 ± 0.6 to 1.9 ± 0.7 ($p=0.002$). Furthermore, there was a significant decrease of pelvic / bladder discomfort. 72% of the patients ± 36% experienced bladder emptying at follow up versus 41% ± 39% at baseline. The maximum voided volume increased from 315 ml ± 208 to 462 ml ± 246 ($p<0.0001$). The improvement in force of flow as perceived by the patients on a 4-point scale was significant ($p<0.001$).
48% of the patients experienced a reduction of 50% or more in number of voids per day, whereas 53% had an increase of >50% in volume voided per void. This was 47% at 6 months after implant.
Since in this patient population the goal of stimulation is to postpone the sense of urgency to a clinically more appropriate bladder volume clinical success was defined as those patients who have an increased volume voided per void with at least a corresponding degree of urgency. Therefore 41 (73%) of the patients were considered a clinical success. The results are listed in table 1.

Degree of urgency last FU compared to baseline	**Volume voided per void at last FU versus baseline**		
	Increased	Same/less	Explant / lack of efficacy
Increased (>0.5)	2	0	0
Same (+0.5)	29	3	0
Decreased (<0.5)	12	3	0
Explant /lack of efficay	0	0	10
Success / no success	41 success	15 no success	

Table 1. Degree of urgency prior to void related to voided volume

Conclusions
The beneficial effects of sacral neuromodulation for urgency / frequency syndrome is persistent over time. Improvement on voiding variables during urine storage and during voiding suggest that total bladder behavior is improved by sacral nerve stimulation.