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Title: SACRAL NEUROMODULATION IN PATIENTS WITH INTERSTITIAL CYSTITIS: A MULTI-CENTER CLINICAL TRIAL

Aims of Study:

This study investigates the clinical use of sacral neuromodulation for patients with interstitial cystitis (IC).

Methods:

A prospective, observational, pilot study enrolled IC patients at three clinical sites. Entry criteria were typical urinary urgency, frequency and bladder pain coupled with cystoscopic findings of IC seen on bladder distention within the past three years. Demographic and baseline symptom data were collected. The primary endpoint was frequency reduction as measured by a three-day voiding diary. The secondary endpoints were the O'Leary-Sant symptom and problem indices (ICSI/ICPI) and other diary variables. Percutaneous nerve evaluation (PNE) was performed under local anesthesia with temporary wires placed at S₃ or S₄ nerve roots, often bilaterally. An external stimulator was worn for seven days to test the effect of subacute stimulation.

Results:

Thirty-one female patients were recruited. Mean age was 44.4 ± 15.9 years (range 23.2 – 81.4). All patients had urinary frequency and urgency; 30/31 had significant pelvic pain. Past treatments included, but were not limited to, oral pentosanpolysulfate (83%), hydroxyzine (64%), amitriptyline (92%), and intravesical dimethyl sulfoxide (68%). No patient had undergone bladder reconstructive surgery for IC. Despite extensive prior therapy the patients were highly symptomatic with 20.5 voids/day, ICSI = 16.4, and ICPI 13.8 at baseline. The results of subacute stimulation were good with highly statistically significant differences between baseline and treatment values seen in voids per day, ICSI, ICPI, average and maximum volume voided. (See table) The differences were clinically significant as 21/28 (75%) had at least a 50% improvement in one of their major symptoms, 10 (32%) reduced the ICSI by >50%, and 6 (19%) increased the maximum void volume by at least 100%.

Voiding Diary Variables	n*	Baseline Average	Test Average	p-value
Number of voids per day	28	20.5 ± 9.9	12.7 ± 4.7	<0.01
Urgency (0 _{none} -3 _{severe})	27	1.8 ± 0.8	1.6 ± 0.7	0.11
Bladder discomfort (0 _{none} -3 _{severe})	20	2.2 ± 0.7	1.6 ± 0.8	0.01
Avg. volume voided (ml)	28	83 ± 52	121 ± 77	<0.01
Max volume voided (ml)	28	217 ± 133	301 ± 212	0.02
O'Leary-Sant ICSI	27	16.4 ± 3.1	10.7 ± 5.4	<0.01
O'Leary-Sant ICPI	27	13.8 ± 2.4	9.0 ± 5.2	<0.01

*number of patients responding

A total of 20 patients (64%) were candidates for a permanent implant and 15 patients (48%) have gone on

to implantation. Success and implantation rates varied widely between the three sites.

Conclusions:

Subacute sacral nerve root stimulation was shown to provide benefit in IC patients with a significant decrease in all symptom measures. These results should be tempered with the understanding that response to test stimulation does not, at present, necessarily predict short or long-term response to a permanent implant in IC patients. Continued examination of this promising technology is warranted.