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| NONINVASIVE ANTIDROMIC SACRAL NEUROSTIMULATION TO ENHANCE BLADDER STORAGE |

AIMS OF STUDY: Modulation of sacral nerve activity is an effective treatment option for chronic bladder storage dysfunction, but requires invasive neurostimulator implantation. We studied the effect of noninvasive antidromic sacral neurostimulation on bladder filling activity.

METHODS: 71 patients with chronic sensory urge incontinence, detrusor instability or detrusor hyperreflexia were studied. All underwent filling cystometry at 50ml/min. fill rate. In the study group (n=35), transcutaneous antidromic neurostimulation was then applied bilaterally via the third sacral dermatomes. Current (10mA) was set at 10Hz frequency, 200ms pulse width in continuous mode at the maximum tolerable level. Neurostimulation continued throughout a second filling cystometry. The control group (n=36) underwent second fill without neurostimulation.

RESULTS: There were no significant urodynamic differences between study and control groups during the first bladder fill (when no patients received neurostimulation). For second fill, with neurostimulation applied to the study group, bladder volumes (ml) and detrusor pressures (cmH₂O) were as follows:

| CYSTOMETRY | CONTROL | NEUROSTIMULATION | p value |
|--------------|-------------|------------------|---------|
| FDV | 120 ± 1.8 | 184 ± 2.9 | 0.008 |
| PDet at FDV | 12.1 ± 0.5 | 5.3 ± 0.2 | 0.01 |
| Cmax | 298.4 ± 4.7 | 479.3 ± 4.8 | 0.007 |
| PDet at CMax | 40.1 ± 2.3 | 22.3 ± 0.7 | 0.008 |

(Results represent the mean ± standard error; statistical analysis by Mann-Whitney U nonparametric testing.)

CONCLUSIONS: Antidromic transcutaneous sacral neurostimulation significantly improves bladder filling activity in patients with chronic bladder storage dysfunction. Cystometric volumes are increased with a concomitant reduction in detrusor pressures. This may be an effective noninvasive, ambulatory treatment option for such patients.

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PERCUTANEOUS PERIPHERAL NERVE STIMULATION FOR URGENCY/
FREQUENCY SYNDROME

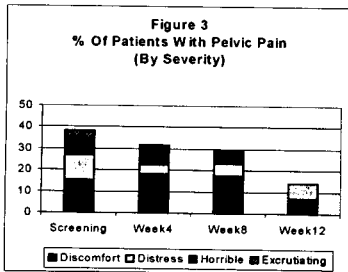
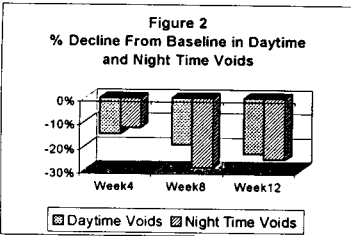
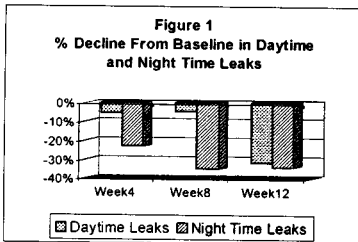
Aims of Study: Urgency/frequency syndrome may result from abnormal detrusor contractions, or be secondary to a hypersensitive bladder without documented detrusor instability.

Electrical stimulation of sacral afferents at S2 and S3 has been shown to modulate bladder function. Peripheral nerve stimulation has previously been studied (~90 patients) under a treatment protocol at the University of California at San Francisco (UCSF), with a subjective success rate of 80%. A prospective multi-center study is underway to further determine the efficacy and safety of percutaneous peripheral afferent nerve stimulation for the treatment of urgency/frequency syndrome. The device, Percutaneous SANS, is manufactured by UroSurge, Inc. of Coralville, IA, USA.

Methods: Thus far 45 patients with urgency/frequency have undergone 12 weekly outpatient treatment sessions, each lasting 30 minutes. Responders then continue according to patient specific tapering protocols. Treatment consists of percutaneous insertion of a 34-gauge solid stainless steel needle at a point (SP6) 5 cm cephalad from the medial malleolus, and just posterior to the margin of the tibia. It is advanced to the medial edge of the fibula. Electrical stimulation is applied to the needle with a low-voltage, adjustable current, external pulse generator, and to the medial surface of the calcaneus.

Results: To date, approximately 75% of patients have seen improvement in their symptoms of pelvic floor dysfunction (Figures 1-3). No study related adverse side effects were reported. Clinical results (urodynamic, voiding diary) from the prospective study to be updated and reported.

Conclusion: Percutaneous peripheral afferent nerve stimulation with the PercSANS treatment presents a minimally invasive and potentially therapeutic alternative to other current treatment options (open-surgery or pharmaceutical intervention, and the associated risks) for patients diagnosed with documented urgency/frequency due to pelvic floor dysfunction.



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FLEXIBLE DOSE STUDY WITH TOLTERODINE IN PATIENTS WITH OVERACTIVE BLADDER CONFIRMS EFFICACY AND SAFETY OF TOLTERODINE (DETROL®)

Aims of Study: Overactive bladder is a debilitating medical condition that affects millions of people worldwide. Although pharmacotherapy is the mainstay of treatment for overactive bladder, many of the established treatments are associated with side effects and poor compliance. Tolterodine is a potent,