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## Title (type in CAPITAL LETTERS, leave one blank line before the text) ELECTROACUPUNCTURE FOR REFRACTORY IDIOPATHIC INSTABILITY OR SENSORY URGENCY

**AIMS OF STUDY** Electroacupuncture is a recently introduced technique that appears to modulate afferent impulses to the bladder (known as SANS, Stoller Afferent Nerve Stimulator). It was designed for the treatment of urgency, frequency and urgency incontinence, as well as suprapubic pain of vesical origin. The therapeutic rationale derives from previous work showing that traditional acupuncture is effective in patients with urgency and frequency of micturition [1]. Recent animal evidence shows that c-fos expression is upregulated when noxious stimuli are transmitted from the bladder[2], and that electroacupuncture alters c-fos expression[3]. Our aim was to undertake a pilot study of the efficacy of SANS treatment, as judged by objective outcome data, in order to determine whether a sham-controlled study is indicated and the sample size that would be needed.

**METHODS:** Women and men with troublesome refractory frequency, urgency, nocturia, urge incontinence were recruited, after failed response to anticholinergic therapy. Patients who complained of suprapubic pain relating to bladder dysfunction were also able to enrol. A 3 day frequency volume chart (FVC) was performed at baseline and post treatment, to record the average time between voids ("voiding interval") and nocturia. The 5 point International Prostate Symptom Score for urgency, and a standardized 22 point Likert scale quality of life instrument regarding incontinence impact, were given at baseline and post treatment. The majority of patients underwent urodynamic tests but this was not an essential entry criterion for the pilot study. Informed consent was given in accordance with local ethical committee guidelines.

Ten consecutive weekly visits were undertaken, at which a disposable 0.22mm acupuncture needle was inserted by sterile technique, three finger breadths (5c) cephalad to the medial malleollus of the ankle, a traditional Chinese acupuncture site which affects afferent transmission from the bladder Insertion was at 60° with respect to the foot, to a depth of 40 mm A connector cable from the 9 volt battery operated stimulator (0-10 mA adjustable current pulse, fixed 200 usec pulse width, @ fixed 20Hz repetition rate, 500-4000 ohm load) was attached to the top of the acupuncture needle, and a branched connector leading to a ground pad was attached above the sole of the foot. The SANS stimulator was turned on and amplitude increased until the great toe curled or the toes fanned out laterally, a tingling sensation is often felt.

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RESULTS: At present 16 patients (3 men, 13 women) have completed the ten week programme, median age 63 5 y, range 22-77 All but two have undergone urodynamic studies indicating idiopathic detrusor instability or sensory urgency, the remainder having simple urgency, frequency, nocturia in the absence of infection or bladder neoplasia. A further 14 are in recruitment or in progress.

The voiding interval improved from a baseline mean value of 1.9 hours (median 2, range 1-3), to a post treatment mean of 3.3 hours (median 3, range 2-5 hours, p < 0.0001), representing a 74% benefit (1.4/1.9 hours)

The number of episodes of nocturia improved from a baseline mean of 4 2/night(median 4 1, range 2-6) to a post treatment mean of 1 7/ night (median 1.8, range 1-3, p< 0 0001), representing a 59% benefit (2.5/4 2 episodes) The IPSS measure of urgency improved from a baseline mean of 3 8 (total possible 5) (median 4, range 2-5) to a post treatment score of 2 0 (median 2, range 0 – 4), representing a 48% benefit

The baseline QOL score for incontinence impact improved from a mean of 19.6 (median 19.3, range 12-28) to a post treatment mean of 15.7 (median 15.8, range 10-21, p = 0.0006), representing a 19.8% benefit

**CONCLUSIONS:** Although a small sample has completed the ten week course of treatment, and a further series of patients are in progress, we believe that this treatment for refractory urgency/ frequency/ nocturia holds promise A sham-controlled study appears to be indicated despite the attendant patient inconvenience. Collection of voids per day, rather than voiding interval, may allow greater precision of the data. Based upon present results, and allowing a 30% placebo response to emerge, our present sample size would be adequate to demonstrate real improvement for nocturia in a sham-controlled study.

- 1 J Urol, 140, 563<sup>.</sup> 1988
- 2 Nature, 328 632 1987
- 3 J Urol, 160, 2274 1998

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