

IDIOPATHIC DETRUSOR INSTABILITY – A DOUBLE-BLIND, RANDOMISED CONTROLLED TRIAL OF ELECTROMAGNETIC STIMULATION THERAPY VERSUS SHAM THERAPY

Aims of Study

Treatment of detrusor overactivity remains problematic despite the introduction of new anticholinergic drugs. Neuromodulation via direct S3 stimulation shows promise but is invasive and expensive. Electromagnetic stimulation of the pelvic floor has been shown to be effective in treating GSI (1) and preliminary studies indicate benefit in the treatment of urge incontinence using different frequencies (10Hz as opposed to 50Hz) (2).

However, prior to the introduction of any new treatment, a placebo or sham controlled study should be undertaken. We aimed to assess the effect of electro-stimulation versus sham therapy using the Neotonus Chair.

Methods

Consecutive patients with systolic detrusor contractions noted at urodynamics but no evidence of outflow obstruction / neuropathy were invited to participate. Exclusion criteria were genuine stress incontinence, a cardiac pacemaker / metallic hip implant, pelvic neoplasia, pelvic surgery within last two months or living > 25km from the Unit.

Randomisation was conducted by an individual with no involvement in the study using a random number table (Arcus Quickstat).

The primary outcome was the 24hr pad test. Secondary outcomes included assessment of 3- day frequency-volume charts (including leaks/urges/24hr) and Quality of Life questionnaires (SF12, IIQ, UDI, 20-point Incontinence Score).

A Therapeutic Listening Category (TLC) score was implemented, recording the exact time in minutes spent listening to any issues raised by the patient during each treatment. This was to determine if the overall therapeutic effect of either treatment was influenced by the emotional support given by the researcher as a considerable placebo effect occurs when treating in detrusor overactivity.

Treatment comprised of thrice weekly visits to the Unit to a total of 20. Each treatment lasts 26 minutes and consists of 2 phases. Both phases involve stimulation at 10Hz for 12 minutes, separated by a 2-minute rest period. Each patient has a preset card, tallying the accumulated number of treatments. The patient is seated in an upright position with back and buttocks to the centre of the chair. Power of the real stimulus is adjusted to the patient's maximum tolerated before discomfort is felt. Following completion of 20 treatments, outcome measures were repeated at 6 weeks and 6 months.

Statistical Analysis

To achieve 90% power to detect a 50% improvement over sham therapy (ie 20% better than the expected 30% placebo effect), we need to recruit 23 pairs (n= 46 subjects). For this report the two groups were coded by an independent individual as Treatments 1 and 2 thereby allowing the research team to remain blinded as to the identity of these treatments until completion of the trial.

Results

25 consecutive patients with systolic detrusor overactivity have been screened. 4 (16%) were excluded (1 pacemaker, 1 total hip replacement, 2 for geographical inconvenience). Of the 21 participants, 1 withdrew due to adverse events, 3 were non-compliant with treatment and 5 are currently on going. To date, 16 (64%) patients have completed treatment.

Table 1 shows similar baseline statistics for the two groups indicating adequate randomisation. Table 2 indicates post treatment outcome measures though this remains a preliminary analysis.

Table 1: Baseline Parameters (Median Values / IQR)

Outcome Measures	Treatment 1 N= 8	Treatment 2 N=8	Mann-Whitney Test P value	U
Age median	68.5 (58.3-75.8)	68 (51.5-79)	1	
BMI median	27.7 (23-31.3)	27.2 (23.1-36.1)	0.94	
24 hour pad test	112.8 (34.3-248.5)	73 (25-126.6)	0.33	
Urges p/day	5 (0-8)	6.3 (3.5-7)	0.64	
Leak p/day	2 (1-7.5)	1.3 (1-5)	0.54	
Mental Component of SF-12	46.6 (33.07-56.7)	47.8 (37.5-56.3)	0.8	
Physical Component of SF-12	50.7 (24.8-57.6)	50.8 (43.8-52.2)	0.78	
IIQ	47.5 (11.9-65.4)	41.2 (25-55.8)	0.9	
UDI	38.8 (29-49.9)	47.2 (29.1-54.6)	0.66	
20 point score	12 (9.5-13)	9 (7-13)	0.29	

Table 2: Post Treatment Outcome Measures. (Median Values / IQR)

Outcome Measures	Treatment 1 N=8	Treatment 2 N=8	Mann-Whitney Test P value	U
24 hour pad test	93.1 (24.1-306.2)	25.4 (2.5-99.9)	0.24	
Urges p/day	4 (0.8-7.4)	1 (0-1)	0.07	
Leaks p/day	2 (0.8-5)	1.3 (0.3-2)	0.3	
Mental Component of SF-12	41.1 (38.4-57.5)	53.4 (38.4-56)	0.9	
Physical Component of SF-12	46.2 (18.4-55)	49.4 (36.6-55.1)	0.56	
IIQ	16.6 (9.5-80.8)	21.4 (6-51)	0.7	
UDI	29.7 (19-33.3)	33.2 (8.3-54.1)	0.98	
20 point score	9 (8.2-14.8)	8.5 (5.2-14)	0.57	

Conclusions

The identity of treatment 1 and 2 is not yet known. Though no outcomes reached statistical significance, patients receiving treatment 2 show a trend toward improvement in urgency and daily leakage. Treatment is well tolerated though compliance with the thrice weekly visits is problematic.

References

1. A double blind randomised trial comparing magnetic stimulation of the pelvic floor to sham treatment for women with stress urinary incontinence (abstract only). Urological Society Meeting, Queensland Australia, March 25-29, 2001, p.83.
2. Extracorporeal magnetic innervation therapy for stress urinary incontinence (1999) Urology, Vol 53, pp 1108-1111.