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Authors: R.O'Sullivan, P.Dunkley, W.Allen, K.Moore
Institution: St. George Hospital
Title: EXTRACORPOREAL MAGNETIC INNERVATION TREATMENT FOR PATIENTS WITH IDIOPATHIC DETRUSOR INSTABILITY- AN OPEN STUDY OF CLINICAL EFFICACY

Aim of the Study:

Electrostimulation via vaginal probes has been used to treat both genuine stress incontinence and detrusor instability(DI) for many years (1).The frequency of stimulation determines the effect on striated and smooth muscle with frequency settings of 10Hz inhibit unstable detrusor contractions(2). Extracorporeal magnetic innervation (ExMI) is a new technique that evokes physiological effects similar to electrical stimulation, but the stimulus is delivered from an energy source in the baseplate of an ordinary chair, thus patients do not need to disrobe. This makes the treatment attractive for use in the frail elderly, in whom idiopathic DI is common (3). Whilst our pilot study (4) has indicated that application of ExMI evoked a reduction in maximum detrusor pressure and an increase in maximum cystometric capacity, the clinical efficacy in terms of incontinence benefit remains unknown. We aimed to employ objective outcome measures to determining whether this new treatment is efficacious in reducing incontinence and improving quality of life in patients with urge incontinence arising from idiopathic DI.

Methods:

Patients with pure urodynamically proven idiopathic DI were recruited. Exclusion criteria were: metallic implants, cardiac pace makers, clinically significant prolapse or residual volumes and current bacterial cystitis. Patients were consented and underwent baseline measures, i.e. 24-hour pad test, 20 point incontinence score (5), frequency of micturition, incontinence episodes and daily pad usage from 72-hour frequency volume charts (FVC), with generic (SF-12) and short form disease specific (Incontinence Impact Questionnaire,IIQ-6, Urogenital Distress Inventory,UDI-7) Quality of Life tests. All patients underwent thrice weekly treatments over 6 weeks (duration 22 minutes/ treatment,2 minute break after 10 minutes), with a frequency of 10Hz with intensity determined by maximum patient tolerance. All baseline measures were repeated 6 weeks after completion of treatment.

Results:

Nineteen women have been recruited, with 14 completing treatment and follow-up. Recruitment is on-going. Median age was 68.5 years (IQR 55.5-76.25), all had symptoms for a median of 5.9 years (IQR 2.5-8.3). The Table below summarises pre and post-treatment parameters on FVC, pad tests, quality of life instruments and incontinence score. Using a definition of 5.5g to define ‘dry’ on the 24-hour pad test (4) we found 9/14 (14%) of patients were dry on baseline testing, despite disabling urgency. This increased to 9/14 (64%) at the 6 week follow-up post treatment .

Table: Pre and Post-treatment Outcome Measures

Median (IQR)	Baseline	Post-treatment	Sig.
Frequency	10 (9-10)	7 (7-8)	P<0.0001
Nocturia	2(1-2)	1 (0.75-1)	P<0.0001
Max.Voided Volume	250 (200-500)	300 (300-425)	P=0.065
Min.Void Interval	30 (30-52.5)	60 (52.5-60)	P=0.008

Leakage episodes	7 (2.5-14)	4 (0.5-7)	P=0.016
24-hour pad test	10 (8-12)	2 (2-12)	P<0.0001
Pads/day	2 (1-3)	0 (0-1)	P<0.0001
SF-12 (PCS)*	43.13 (38.93-51.35)	45.6 (42.88-51.61)	P=0.082
SF-12 (MCS)*	51.91 (49.09-56.45)	54.06 (49.3-56.15)	P=0.3
S-IIQ	67 (48.25-75.75)	59 (35.75-75.25)	P=0.065
S-UDI	67.5 (46-75.75)	58.5 (30.25-74.75)	P=0.055
20-point incontinence score	10 (7.25-12.5)	6.5 (3.25-8.75)	P=0.0001

Table 1.

*PCS = Physical component score *MCS = mental component score

IIQ-6 and UDI-7 scores revealed a trend toward improvement although not statistically significant. SF-12 physical component scores were more obviously improved than the MCS, but did not achieve significance for the sample size. Nevertheless 7 of the 8 continence measures showed significant benefit.

Conclusion:

In this open study of ExMI for proven IDI, the majority of outcome measures demonstrated significant improvement. However the final judgement regarding efficacy of this new treatment must rest upon a sham controlled study. The promising results shown in the current study indicate a definite need and ethical justification for the conduct of a sham controlled trial, which is now commencing..

References:

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Authors: R.O'Sullivan, P.Dunkley,W.Allen,K.Moore
Institution: St. George Hospital
Title: URODYNAMIC MONITORING DURING EXTRACORPOREAL MAGNETIC STIMULATION IN PATIENTS WITH IDIOPATHIC DETRUSOR INSTABILITY

Aim of the study Electrical stimulation has been employed to treat detrusor instability (DI) since the 1960's (1) with variable success. Nevertheless, mechanical or electrical stimulation of pudendal afferent nerves in the penis are known to suppress unstable detrusor contractions (2,3,4). Detrusor activity can be virtually abolished if stimulation is given either before or at the onset of the contraction . More recently magnetic stimulation of the S2-4 nerve root has been used with limited success (5).

Extracorporeal Magnetic Innervation (ExMI) is a new technology used for the treatment of neuromuscular disorders. ExMI has a physiological mode of action similar to that of electrical stimulation, but is non-invasive (i.e.) the patient sits on a chair containing ExMI energy source in the base of the unit. This treatment has been used with some objectively proven benefit in GSI (6) .

We questioned whether could alter the stimulation parameters in the same way as has been done for electrical stimulation therapy, to achieve reduction in the magnitude of unstable detrusor contractions and perhaps improve bladder capacity as well. Our aim was to perform cystometry before and during the application of ExMI and to measure the change in cystometric parameters that may occur in patients with DI.

Methods Eight neurologically normal patients with urodynamically proven DI (provoked by filling alone) were recruited. They were refractory to behavioural and pharmacologic therapies over the previous 1-6 years. None were currently using anticholinergic medication and nor had previous urologic surgery. Patients initially were seated on the ExMI device and their maximal tolerable intensity of stimulation was determined. The stimulation frequency utilised was 10Hz with a duty cycle of 15 seconds on and 2 seconds off.

Patients underwent dual channel subtracted cystometry with a 6F intravesical catheter, a medium fill rate of 50mls/min with normal (0.9%) saline at 25^0C. Maximum capacity, volume at first detrusor contraction, maximum amplitude and duration of contraction were recorded along with patient symptoms. The bladder was then emptied fom the catheter and second fill was then undertaken. The chair was activated (at the predetermined intensity setting) during the height of the first detrusor contraction. The acute effect upon detrusor contractility was observed (i.e. change in P_{det}). Having emptied the bladder again by gravity, a third fill was undertaken with the chair activated form the beginning of the filling phase. All cystometric parameters were again recorded. The subjects then voided following removal of the catheters.

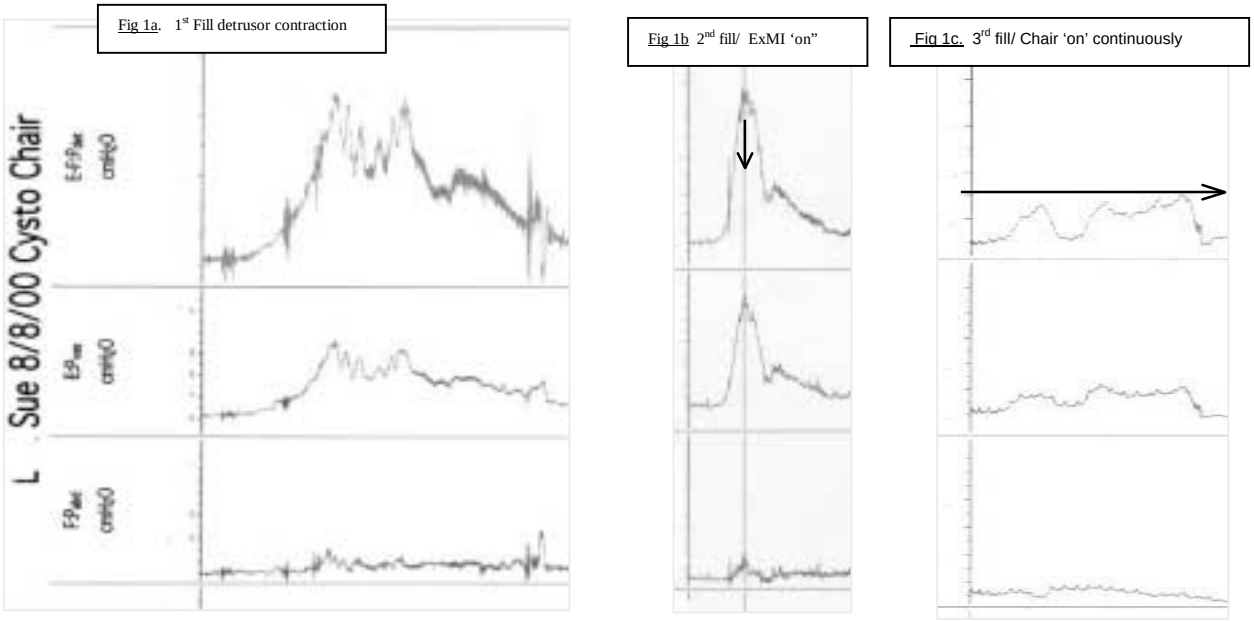
Results. All 8 of the patients tolerated the complete procedure (3 fill phases).Their median age was 56.3 years (IQR 44-72) and had been attending the unit for a mean of 13.4 months(SD 9.6). Cystometric parameters at baseline are shown in the table. The commencement of ExMI stimulation completely abolished the detrusor contraction in 4 (50%) patients and the amplitude of the contraction was suppressed in 3 by ≥50% with the eight patient non-responsive. Patients also described reduction in urgency symptoms on activation of the chair with 4 remaining continent.

During the 3rd fill, with ExMI stimulation throughout the fill phase, significant improvement was observed in

cystometric parameters (table)

Median	Initial Cystometry	ExMI Cystometry	Sig. (Wilcoxon's SRT)
Max.Cap ,(IQR)	290(236.3-321.3)ml	330(290-430)ml	P=0.007
Vol.1st Contraction (IQR)	285(225-330)ml	325(290-422.5)ml	P=0.008
Vol.1st Sensation(IQR)	110 (110-141.47)ml	117.5(102.5-143.75)ml	P=0.031
Max.Amplitude (IQR)	41(42.75-61)cmH_2O	37.5(27-44.25)cmH_2O	P=0.007
Duration Contract. (IQR)	67.5(45-92.75)sec	64.75(40-80)sec	P=0.055

In all subjects, maximum bladder capacity ,volume at first detrusor contraction and volume of first sensation of filling increased.The duration of the observed contractions before and during ExMI treatment were not significantly altered (p=0.055) but the maximum amplitude was significantly decreased (p=0.007).



Conclusion

This study demonstrates that extracorporeal magnetic innervation (ExMI) significantly modified urodynamic variables when activated during the fill phase of cystometry in patients with DI. Detrusor contractions were abolished in 50% of patients on activation of the chair (fig 1b).With ExMI active from the onset of bladder filling, maximum capacity, P_{det} amplitude were significantly improved (fig 1c) and table. Thus ExMI may have therapeutic potential for patients with IDI. A trial regarding longer-term clinical efficacy is now underway.

References

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