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Voiding Dysfunction

Extracorporeal Magnetic Stimulation is of Limited Clinical Benefit to Women with Idiopathic Detrusor Overactivity: A Randomized Sham Controlled Trial

Alastair R. Morris [a], *Ray O'Sullivan* [a], *Paula Dunkley* [a], *Kate H. Moore* [b,*]

[a] *The Pelvic Floor Unit, St George Hospital, Kogarah, NSW 2217, Australia*
[b] *First Floor, Pitney Clinical Sciences Building, St George Hospital, Kogarah, NSW 2217, Australia*

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Abstract

Objectives: To observe the effect of both acute and medium-term magnetic stimulation of the pelvic floor on detrusor function amongst women with idiopathic detrusor overactivity (IDO).

Methods: Two separate studies were undertaken amongst women with a sole diagnosis of IDO. The first study assessed the acute effect of magnetic stimulation (provided by Neocontrol®) on detrusor function during the filling phase of standard cystometry. Multiple filling cycles were performed with stimulation at a different key moment in each. This was done to establish that the device could influence the detrusor. Subsequently, a randomized sham control trial was performed to assess clinical efficacy. A total of 20 treatments, each of 20 minutes duration, were administered over six weeks with follow-up six weeks thereafter. Half the patients received therapy from a genuine device, the others receiving fake treatment on an identical looking/sounding sham device. The sham device contained a deflector plate to degrade the magnetic field and was located in a separate room. Outcome measures included changes in a 24 hour fluid volume chart, urine loss (24 hour pad test) and quality of life instruments.

Results: Amongst 10 patients receiving stimulation during cystometry, volume at first involuntary detrusor contraction during filling rose from a median value of 240 ml (Interquartile range (IQR) 210–300) to 285 ml (IQR 231–320), $p = 0.03$ and maximum detrusor pressure decreased from 40 cm water (IQR 34–45) to 33 cm water (IQR 25–41), $p < 0.01$. The RCT was completed by 29 of 44 (66%) recruits. Of these, 15 of 29 (52%) received active treatment and 14 of 29 (48%) sham therapy. Active therapy significantly reduced the number of urge episodes per day, $p < 0.01$. With respect to baseline, actively treated patients experienced significant reduction in voids per day and quality of life but this trend did not reach significance when compared to the sham group, partly due to unexpected difficulty in recruitment which yielded an underpowered sample size for these outcome measures.

Conclusions: Magnetic stimulation reduces detrusor contractility in the acute phase of administration. Although the treatment was well tolerated and urge episodes reduced following prolonged therapy, no statistically significant improvement was observed in quality of life indices or measured 24 hour urinary loss. The treatment cannot be recommended for women with IDO.

* Corresponding author. First Floor, Pitney Clinical Sciences Building, St George Hospital, Kogarah, NSW 2217, Australia. Tel. +61 (02) 9350 2054; Fax: +61 (02) 9350 3951.
E-mail address: k.moore@unsw.edu.au (K.H. Moore).

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1. Introduction

Idiopathic detrusor overactivity (DO) is identified in approximately 20% of women seeking help for incontinence who undergo urodynamic testing [1]. Traditional management comprises bladder training, often in association with anti-cholinergic drugs. Unfortunately, compliance with medication is poor owing to side effects and their overall efficacy is disappointing [2] with up to 50% of patients observing little clinical improvement. Surgical therapy carries significant morbidity and is generally reserved for patients unresponsive to other treatments. Consequently, alternative therapies that are simple to administer and have few side effects have been sought.

Neuromodulation, a term describing a group of therapies, has therefore been explored. All require the passage of electrical current through neuromuscular tissues within the pelvis. Devices are available to deliver current via a variety of routes. Some utilize a vaginal probe while others require cutaneous pads [3–5]. Insertion of an electrode into the third sacral (S3) foramina along with placement of a permanent subcutaneous stimulator appears efficacious in selected cases [6,7] but is expensive and not widely available.

Alternatively, current may be induced in tissues situated within a rapidly changing magnetic field. This is known as extracorporeal magnetic induction therapy (ExMI). The changing magnetic field generates a current that, once of sufficient magnitude, causes depolarisation of neuromuscular tissue. The frequency with which the magnetic field changes determines which tissues are primarily affected. At 10 Hz, the optimal effect is upon detrusor smooth muscle whereas at 50 Hz striated muscle within the pelvic floor is preferentially stimulated [8]. Patients do not need to disrobe to receive ExMI and appear to experience less cutaneous discomfort than with conventional electrostimulation techniques.

The aim of this study was firstly to test whether acute stimulation of the pelvic floor using Neocontrol® can influence the magnitude and duration of detrusor contractions during cystometry or the maximum bladder capacity. Secondly, we assessed the overall clinical benefit by undertaking a randomised, sham controlled trial.

2. Methods

The study was performed in two parts. All patients had a sole diagnosis of idiopathic phasic DO according to the International Continence Society (ICS) [9]. No woman had clinically apparent neurological deficit or was concurrently being treated with anticholinergic/tri-cyclic therapy. Age, parity, duration of symptoms and the number/type of treatments for incontinence previously received by each patient was recorded.

Identical stimulation parameters used in both studies: 10 Hz with a duty cycle of 10 s stimulation followed by 2 s rest. Each pulse lasted 275 μs. General contraindications to ExMI (pregnancy, cardiac pacemaker, metallic femoral implants) were applied.

2.1. *Study 1 – The acute effect of ExMI on unstable detrusor contractions ('on-chair' cystometry)*

An initial sample size of ten patients was chosen to determine whether consistent and clinically important results would be noted across a modest number of patients. All patients undergoing standard cystometry were informed of the study. If, during filling, phasic detrusor contractions were observed and all the above entry criteria were met, recruitment was undertaken. The filling and pressure recording lines were left in situ, the bladder emptied via the catheter and the patient asked to sit on the Neocontrol® device which was adjacent to the urodynamics equipment (Fig. 1). Thereafter, a further two filling cycles were performed. On the first occasion, Neocontrol® was activated (and thus stimulation applied) when the first unstable contraction was observed. Filling ceased at this point and the bladder was drained via the catheter once unstable detrusor activity had ceased. The last cycle was then performed and on this occasion stimulation was applied via Neocontrol® from the onset of filling up until maximum cystometric capacity (MCC). At this point stimulation ceased, the filling line was removed and uroflowmetry performed. During this study the volume at first unstable detrusor contraction, MCC, maximum detrusor pressure and the length of the unstable detrusor contraction were recorded. All women who participated underwent both acute stimulation experiments, but none of these women were enrolled in the sham controlled clinical trial.

Fig. 1 – The Neotonus® Chair with control unit.

2.2. Study 2 – A prospective randomised sham control trial of ExMI in patients with idiopathic DO

A consecutive series of patients meeting the entry criteria were enrolled (from January 2001 to July 2002) in a randomized trial comparing active and sham ExMI. Entry criteria were similar to those for study 1. Patients living over 25 km away were excluded owing to the requirement for twenty visits within six weeks. Patients were informed that two strengths of stimulation were being compared. Written consent was obtained prior to recruitment, in accordance with local ethical committee approval.

2.2.1. The sham chair

This was located in a different room within the department. It was identical in appearance to its authentic counterpart, but was fitted with a removable seat. The sham seat, could be readily substituted and contained a deflector plate that dissipated the magnetic field. It could also deliver standard stimulation. Crucially, when delivering either sham or active stimulation, the device made a similar 'click' with each charge/discharge cycle. Patients never witnessed the sham seat being fitted.

2.2.2. Method of randomization

A commercial computer statistics package ('Arcus Quickstat Biomedical', Research Solutions, Cambridge, United Kingdom) was used to generate a randomized intervention/control list. This list was kept in a locked drawer accessible only to a member of the administrative staff who had no other involvement in the study. This individual allocated treatment in a sequential fashion. A dedicated research nurse gathered outcome data but did not analyze results. The first author was unaware of treatment allocations until the statistical analysis of outcome data was completed.

2.2.3. Outcome measures

The primary outcome was a reduction in daily urge episodes, daily urge leaks and voids per 24 hours as recorded on a 24 hour frequency/volume chart (FVC). Secondary outcomes were changes in measured urine loss on 24 hour pad test [10], and generic, Short Form 12 (SF-12) [11] and disease specific [short versions of the Urogenital Distress Inventory (UDI) and Incontinence Impact Questionnaire (IIQ)] quality of life (QoL)] indices [12]. Data relating to adverse events was also collected. Three 24 hour FVCs, a 24 hour pad test and the QoL instruments were completed prior to and six weeks following treatment. QoL instruments were also repeated immediately after the last treatment cycle. Prior to treatment, those receiving active therapy received a short test stimulation to ascertain their maximum tolerated intensity.

2.2.4. Treatment protocol for magnetic stimulation

The protocol comprised twenty treatment cycles administered over six weeks. Each cycle was separated by a rest period of 36–72 hours to prevent muscular fatigue, although 10 Hz causes minimal stimulation of striated muscle within the pelvic floor. Each treatment cycle comprised two 10 minute periods of stimulation, at that individual's maximum tolerated intensity, separated by 2 minutes rest. The sham chair provided stimulation at a fixed intensity of 25% for two reasons. Firstly, below this level, the device generated no noise and it was felt that a lack of noise may encourage patients to believe that were indeed receiving this therapy. Such questioning of their treatment allocation could bias the results. Secondly, this intensity was below the level required for patient perception even in the absence of the deflector plate (which was nevertheless always in place).

2.2.5. Power calculation and statistical analysis

Daily urge episodes and 24 hour urinary loss were chosen to reflect effects on the afferent and efferent limbs of the micturition reflex respectively. 28 patients (14 pairs) were required to achieve 80% power to detect a reduction in 2 urge episodes/day from baseline ($\alpha = 0.05$). For a 90% power to detect a 40% cure rate ($\alpha = 0.05$) in the 24 hour pad test then 40 patients (20 pairs) were needed. The distribution of data was determined using the Shapiro-Wilk Test. Wilcoxon and Mann-Whitney U Tests were utilized as appropriate. All data are quoted as median values (inter-quartile range).

Local ethical approval was obtained prior to commencement.

3. Results

3.1. Results of study 1

Ten patients participated in this study and all completed the protocol. Demographic data is shown in Table 1. No patient had undergone either Caesarian section or hysterectomy. Cystometric parameters at baseline are shown in Table 2. Commencement of magnetic stimulation during the second fill reduced the duration of the contraction from the time of peak detrusor pressure until its cessation from 38 s (26–74) to 31 s (11–31), Wilcoxon $p = 0.008$. During the third fill, with magnetic stimulation applied throughout, the MCC was 285 ml (235–363) with significant changes observed in other recorded cystometric parameters (Table 2).

3.2. Results of study 2

Following urodynamic assessment alone, 44 consecutive suitable patients were identified. Of these,

Table 1 – Demographic data for patients participating in study 1 ('on-chair' cystometry)

Variable	Value
Age (years)	64 (50–75)
Parity	2.5 (2–3)
Duration of symptoms prior to review in PFU (months)	66 (39–66)
Total number of treatments undertaken by patient	6 (3–7)

Table 2 – Urodynamic data from study 1 ('on-chair' cystometry)

Urodynamic parameter	Standard cystometry ($n = 10$)	Cystometry with ExMI stimulation throughout fill phase ($n = 10$)	Wilcoxon signed rank test p
Volume at first involuntary detrusor contraction during filling (ml)	240 (210–300)	285 (231–320)	0.03
Maximum detrusor pressure (cm H_2O)	40 (34–45)	33 (25–41)	0.004
Duration of detrusor contraction (s)	73 (45–131)	45 (36–76)	0.04

Table 3 – Reasons for non-participation in study 2 (randomized control trial of sham chair)

Reason	Number
Dementia	2
Weight >135 kg	1
Cardiac pacemaker	1
Metallic femoral implants	2
Lived >25 km from location of hospital	4
Total	10

ten (23%) were subsequently deemed ineligible for recruitment (Table 3). The patient weighing >135 kg could not sit comfortably on the chair and her weight exceeded the design tolerance of the device. Three (60%) patients withdrew without notification while one (20%) informed the research nurse of her decision. The final patient believed that treatment precipitated atrial fibrillation, though after un-blinding she was identified as receiving sham therapy.

The two groups were adequately matched for demographic and baseline outcome variables although the patients allocated to sham treatment tended to have greater leakage on 24 hour pad testing (Table 4). As outcome data was not available for those patients withdrawing from the trial they have been eliminated from the remainder of the analysis. Intra-group changes in outcome measures are described in Table 5 as is the significance of inter-group comparisons. Sham therapy did not significantly change any measure. Active treatment did show a trend toward overall improvement of bladder function. A reduction occurred in the number of voids and urge episodes per day however this did not result in an improvement in the overall volume of leakage as the pad test was not significantly improved within either group. A small but non-significant increase in the maximum intervoid interval (median of 20 minutes) and a reduction in the number of urge leaks occurred.

Amongst QoL indices, only the UDI showed significant improvement following active treatment, $p = 0.01$ (Table 5).

4. Discussion

The effect of ExMI on detrusor function has most frequently been described in patients with neurogenic DO. In these studies, various devices and stimulation parameters were used [13–15]. More recently one study reported its effect amongst eight women with phasic DO [16].

In contrast to hand held devices, Neocontrol® can stimulate deep structures of the pelvis and the pelvic floor. The bladder lies within the magnetic field generated by the device, though the posterior sacral roots do not. Magnetic stimulation readily effects depolarisation in larger myelinated and unmyelinated nerve fibers although smaller diameter ones are unaffected. Consequently, when activated, Neocontrol® causes some contraction of the pelvic floor muscle. This is known to cause

Table 4 – Baseline data for patients enrolled into study 2 (randomized control trial of sham chair)

Parameter	Sham group ($n = 17$)	Active group ($n = 17$)	Mann Whitney U test p
Age (years)	67 (51–75.5)	63 (53–73.5)	0.87
Parity	2 (0–3)	2 (1–3)	0.50
Body mass index (kg/m^2)	26.5 (23–28)	29 (24–31)	0.45
24 hour pad test (g)	94 (22–200)	46 (9–94)	0.16
Total voids per 24 hours	8.5 (7–13)	9 (8–13)	0.53
Total fluid intake per 24 hours (ml)	1700 (1420–2000)	1567 (1250–2075)	0.89
Maximum recorded volume for a single void during day (ml)	392 (262–575)	400 (255–475)	0.55
Maximum voiding interval during day (min)	247 (180–290)	210 (132–240)	0.19
Episodes of urgency per 24 hours	5 (2–7)	5 (4–7)	0.54
Urge incontinence episodes per 24 hours	2 (1–5)	2 (1–4)	0.59

Table 5 – Intra- and inter-group changes in pad test and frequency/volume chart from study 2 (randomized control trial of sham chair)

Parameter	Intra-group change						Inter-group change
	Sham group ($n = 14$)			Active group ($n = 15$)			
	Baseline	Post treatment	Wilcoxon signed rank test (p)	Baseline	Post treatment	Wilcoxon signed rank test (p)	Mann-Whitney U test (p)
Pad test (g/24 hours)	95 (27–231)	49 (6–224)	0.43	46 (8.5–91)	44 (0–93)	0.84	0.46
Voids during the day	7 (6–11)	7 (6–9.5)	0.59	9 (7–11)	7 (6–12)	0.03	0.66
Voids during the night	1 (0.75–3)	1 (1–3.5)	0.30	0 (0–1)	0.5 (0–1)	0.84	0.48
Maximum voided volume during day (ml)	437 (287–606)	450 (275–600)	0.91	400 (260–450)	350 (250–400)	0.22	0.58
Maximum voiding interval during day (min)	247 (172–277)	277 (210–450)	0.68	210 (145–240)	230 (200–300)	0.15	0.62
Urge episodes per day	5 (2–7)	4 (1–6)	0.27	5 (4–7)	1 (0–3)	0.006	0.003
Urge incontinence episodes per day	2 (1–5.75)	2 (1–3)	0.20	2 (1–4)	1 (0–2)	0.15	0.68
SF-12 (physical component)	45 (34–58)	50 (32–56)	0.85	48 (40–52)	46 (32–54)	0.93	0.59
SF-12 (mental component)	46 (35–51)	58 (43–61)	0.18	48 (39–58)	52 (37–57)	0.80	0.10
UDI	42 (28–51)	44 (30–47)	0.54	44 (28–61)	19 (10–39)	0.01	0.13
IIQ	48 (13–72)	28 (10–67)	0.28	45 (28–57)	28 (10–38)	<0.001	0.16

relaxation of the detrusor, most likely through reflex inhibition of parasympathetic neurons [17], this may be the principal mode of action of Neocontrol®. As the dorsal clitoral nerve lies in close proximity to the stimulating coil there will be stimulation of afferent sensory fibers which can also cause bladder relaxation.

Some studies suggest short to medium term benefit is achievable [16–20]. However, small numbers of patients were recruited, not all had DO and the stimulation parameters varied. In contrast, the present study included only patients with a sole diagnosis of phasic DO and, uniquely in the current literature, a sham limb was incorporated that participants could not differentiate from active therapy. Thus our protocol is the most stringent of published trial regarding magnetic stimulation therapy for DO. However, recruitment proved problematic. Many eligible individuals lived far from the Department and some unusual exclusion criteria were more common than expected (Table 3). The time consuming nature of the study also caused attrition, thus only 29 of 44 (66%) individuals completed the full protocol. Similarly, Bradshaw reported that 9 of 18 (50%) women withdrew from their six week study, all citing time commitment as the principal reason [16].

The pad test showed that active treatment did not significantly improve overall urine loss but the placebo group tended to have larger leakage on the pad test at baseline. The increased MCC noted during filling cystometry in study 1, combined with the reduction in urge episodes observed in study 2 suggests that afferent input to the brain is mainly altered, thereby reducing sensations associated with increasing distension of the bladder. How this is achieved is unclear. Prolonged magnetic stimulation may cause a sustained increase in pelvic floor tone, thereby stimulating reflex circuits, resulting in detrusor suppression. Alternatively, prolonged stimulation may result in alteration of neural pathways themselves, with formation of new circuits or re-growth of damaged ones. The type or quality of neurotransmitter released in the relevant synapses may also change thus altering afferent input to the central nervous system. However these hypotheses cannot be answered in the intact human and experiments using animal models are more likely to yield significant findings in this regard.

5. Conclusion

Although ExMI has been shown to acutely affect detrusor contractility, clinical efficacy was not

consistently demonstrated. With the exception of a reduced number of urge episodes per day, no other clinically important feature of the disease was improved. These observations are however made on a limited number of patients. Although further refinement of the duration or frequency of stimulation and the characteristics of the magnetic field itself may increase the treatment's efficacy, based upon the results of the randomized study described here, Neocontrol® is of limited clinical value in the treatment of women with idiopathic detrusor overactivity.

Conflicts of interest

None of the authors have a financial interest in the product used in the study or stand to gain in any way from publication of the results of this study.

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References

[1] Hilton P. Urinary incontinence in women. BMJ 1987;295: 426–32.
[2] Herbison P, Hay-Smith J, Ellis G, Moore KH. Effectiveness of anticholinergic drugs compared with placebo in the treatment of overactive bladder: systematic review. BMJ 2003;326:841–4.
[3] Primus G, Kramer G. Maximal electrical stimulation for treatment of neurogenic or non neurogenic urgency and/or urge incontinence. Neurourol Urodynam 1996;15:187–94.
[4] Kulseng-Hanssen S, Kristoffersen M, Larsen E. Evaluation of the subjective and objective effect of maximal electrical stimulation in patients complaining of urge incontinence. Acta Obstetricia et Gynecologica Scandinavica 1998;168: 12–5.
[5] Bower WF, Moore KH, Adams RD, Shepherd R. A urodynamic study of surface neuromodulation versus sham in detrusor instability and sensory urgency. J Urol 1998;160: 2133–6.
[6] Siegel SW, Catanzaro F, Dijkema HE, Elhilali MM, Fowler CJ, Gajewski JB. Long-term results of a multicenter study on sacral nerve stimulation for treatment of urinary urge incontinence, urgency-frequency, and retention. Urology 2000;56:87–91.
[7] Klingler HC, Pycha A, Schmidbauer J, Marberger M. Use of peripheral neuromodulation of the S3 region for treatment of detrusor overactivity: a urodynamic-based study. Urology 2000;56:766–71.
[8] Lindstrom S, Fall M, Carlsson CA, Erlandson BE. The neurophysiological basis of bladder inhibition in response to intravaginal electrical stimulation. J Urol 1983;129: 405–10.
[9] Abrams P, Cardozo L, Fall M, Griffiths D, Rosier P, Ulmsten U. The standardisation of terminology of lower urinary tract function: report from the standardisation subcommittee of the International Continence Society. http://www.icsoffice.org.
[10] Karantanis E, O'Sullivan R, Moore KH. The 24 hour pad test in continent women and men: normal values and cyclical alterations. BJOG 2003;110:567–71.
[11] Ware J, Kosinski M, Keller S. A 12-item short-form health survey: Construction of scales and preliminary test of reliability and validity. Med Care 1996;34:220–7.
[12] Uebersax JS, Wyman JF, Shumaker SA, McClish DK, Fantl JA. Short forms to assess quality of life and symptom distress for urinary incontinence in women: the incontinence impact questionnaire and the urogenital distress inventory. Neurourol Urodynam 1995;14:131–9.
[13] Sheriff MK, Shah PJR, Fowler C, Mundy AR, Craggs MD. Neuromodulation of detrusor hyper-reflexia by functional magnetic stimulation of the sacral roots. Br J Urol 1996;78:39–46.
[14] Yamanishi T, Yasuda K, Suda S, Ishikawa N, Sakakaibara R, Hattori T. Effect of functional continuous magnetic stimulation for urinary incontinence. J Urol 2000;163:456–9.
[15] Shah N, Edhem I, Knight S, Shah J, Craggs M. Acute suppression of provoked detrusor hyperreflexia by electrical stimulation of the dorsal penile nerve. Eur Urol 1999;35:60–4.
[16] Bradshaw HD, Barker AT, Radley SC, Chapple CR. The acute effect of magnetic stimulation of the pelvic floor on involuntary detrusor activity during natural filling and overactive bladder symptoms. BJU Int 2003;91: 810–3.
[17] McFarlane JP, Foley SJ, DeWinter P, Shah PJR, Craggs MD. Acute suppression of idiopathic detrusor instability with magnetic stimulation of the sacral nerve roots. Br J Urol 1997;80:734–41.
[18] Fujishiro T, Takahashi S, Enomoto H, Ugawa Y, Eeno S, Kitamura T. Magnetic stimulation of the sacral roots for the treatment of urinary frequency and urge incontinence: an investigational study and placebo controlled trial. J Urol 2002;168:1036–9.
[19] Almeida FG, Bruschini H, Srough M. Urodynamic and clinical evaluation of 91 female patients with urinary incontinence treated with perineal magnetic stimulation: 1 year follow up. J Urol 2004;171:1571–4.
[20] Unsal A, Saglam R, Cimentepe E. Extracorporeal magnetic stimulation for the treatment of stress and urge incontinence in women. Scand J Urol Nephrol 2003; 37:424–8.

Editorial Comment on: Extracorporeal Magnetic Stimulation is of Limited Clinical Benefit to Women with Idiopathic Detrusor Overactivity: A Randomized Sham Controlled Trial

Massimo Lazzeri
Department of Urology, Casa di Cura Santa Chiara, P.zza Indipendenza 11, Florence, Italy
lazzeri.m@tiscali.it

Overactive bladder (OAB) affects one sixth of Western population aged ≥40 yr and a recent cross-sectional population-based survey of people older than 18 yr showed that is a common condition in men and women across all adult age groups [1]. Today, many of us are disputing formally and systematically how to find an appropriate response to antimuscarinic refractory OAB and which alternative strategies we can use in the management of these patients [2]. In the last two decades neurophysiology gained advantages from basic science research and the experimental results were translated into clinical practice. Electrical stimulation and neuromodulation of sacral nerve roots have been used extensively with some satisfactory outcomes. Recently extracorporeal magnetic stimulation showed that it is able to suppress detrusor overactivity and randomised, controlled studies demonstrated excellent short-term effects in the treatment of OAB [3,4].

In this issue of *European Urology*, Morris and colleagues [5] investigated the acute inhibitory effects of magnetic stimulation and the clinical efficacy using a rigorous sham designed study. They found that the magnetic stimulation may induce inhibitory effects on detrusor function in the acute phase, but it fails to obtain clinical advantages, suggesting that the treatment cannot be recommended for women with idiopathic detrusor overactivity. The authors have to be congratulated for providing a reliable estimate of the likely long-term effects of magnetic stimulation.

We must learn from these results; the way forward is demanding for all of us. First, there is a need to plan and fund more studies in OAB management to provide new and more effective therapies. Second, processes need to be put in place to let patients have direct access to the best diagnostic pathway and the best tailored therapies for each individual. Finally, further basic science and clinical studies need to be done to refine the complementary role of any actual and future therapy to improve outcome and save money.

References

[1] Reilly K, Milson L, Irwin D, et al. Prevalence of incontinence and overactive bladder: European results from the EPIC study. Eur Urol Suppl 2006;5:116.
[2] Lazzeri M, Spinelli M. The challenge of overactive bladder therapy: alternative to antimuscarinic agents. Int Braz J Urol 2006;32:620–30.
[3] Takahashi S, Kitamura T. Overactive bladder: magnetic versus electrical stimulation. Curr Opin Obstet Gynecol 2003;15:429–33.
[4] Chandi DD, Groenendijk PM, Venema PL. Functional extracorporeal magnetic stimulation as a treatment for female urinary incontinence: 'the chair'. BJU Int 2004;93:539–42.
[5] Morris AR, O'Sullivan R, Dunkley P, Moore KH. Extracorporeal magnetic stimulation is of limited clinical benefit to women with idiopathic detrusor overactivity: a randomized sham controlled trial. Eur Urol 2007;52:876–83.

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Editorial Comment on: Extracorporeal Magnetic Stimulation is of Limited Clinical Benefit to Women with Idiopathic Detrusor Overactivity: A Randomized Sham Controlled Trial

Clare J. Fowler
Institute of Neurology, UCL
c.fowler@ion.ucl.ac.uk

It was an ingenious idea—a chair in which you could sit in fully clothed for 20 min/d and it would prevent incontinence by the power of magnetism. Sadly, however, proof of efficacy of the procedure has been found lacking, as shown by the paper from Morris et al from New South Wales [1].

That sacral root stimulation, either electrical or magnetically induced, can reduce detrusor overactivity has been well established over the years in several different laboratories [2–5], probably due to direct stimulation of pelvic afferents, which have an inhibitory effect on abnormal detrusor contraction. Indeed, the data from this study showed a reduction in detrusor contractility in the acute situation, that is, 'on chair' cystometry. However, what could not be shown was a useful reduction in

urgency incontinence when magnetic stimulation was used over a 6-wk period with a 6-wk follow-up. Had the results been otherwise a theory for mechanism of action based on there being a significant ''carryover'' effect would have been needed to be invoked. We know from the evidence of sacral neuromodulation that such carryover does not occur; when the battery runs down urgency incontinence returns, so the result found here is not surprising. It seems likely that for stimulation to be effective long term it must be chronically applied and until miniaturization of magnetic stimulators has been achieved this will not be feasible.

This was a well-designed study, recruiting only women with idiopathic detrusor overactivity and most importantly including sham stimulation. The comparison with results of treatment with those of sham stimulation is unique and although the study became underpowered because of drop-outs, the authors' conclusion that extracorporeal magnetic stimulation is ''of limited clinical value in the treatment of women with idiopathic detrusor overactivity'' seem fully justified.

References

[1] Morris A, O'Sullivan R, Dunkley P, Moore K. Extracorporeal magnetic stimulation is of limited clinical benefit to women with idiopathic detrusor overactivity: a randomized sham controlled trial. Eur Urol 2007;52:876–83.
[2] Eriksen BC, Mjolnerod OK. Changes in urodynamic measurements after successful anal electrostimulation in female urinary incontinence. Br J Urol 1987;59:45–9.
[3] Sheriff MK, Shah PJ, Fowler CJ, Mundy AR, Craggs MD. Neuromodulation of detrusor hyper-reflexia by functional magnetic stimulation of the sacral roots. Br J Urol 1996;78:39–46.
[4] Yamanishi T, Yasuda K, Suda S, Ishikawa N, Sakakibara R, Hattori T. Effect of functional continuous magnetic stimulation for urinary incontinence. J Urol 2000;163:456–9.
[5] Arruda RM, Castro RA, Sartori MG, et al. Clinical and urodynamic evaluation of women with detrusor instability before and after functional pelvic floor electrostimulation. Clin Exp Obstet Gynecol 2003;30:220–2.

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