

Functional extracorporeal magnetic stimulation as a treatment for female urinary incontinence: 'the chair'

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Accepted for publication 4 November 2003

OBJECTIVE

To evaluate, in a prospective study, the efficiency and applicability of functional magnetic stimulation (FMS) of the pelvic floor for treating urinary incontinence in women.

PATIENTS AND METHODS

FMS was provided by a 'magnetic chair'; 24 patients were treated twice weekly for 8 weeks (12 with urge incontinence and 12

with a mixture of urge and stress incontinence). The outcome was assessed urodynamically, by a pad test, and by patient satisfaction.

RESULTS

In 58% of the patients there was an objective improvement in incontinence; three patients were completely dry and 71% reported a subjective improvement ($P < 0.001$).

CONCLUSION

FMS is a safe, noninvasive and painless treatment for urinary incontinence; it is effective and easy to administer as an outpatient treatment.

KEYWORDS

functional magnetic stimulation, electrical, stress incontinence, urge

INTRODUCTION

The treatment of urinary incontinence (urge and stress) consists of conservative and operative techniques. Besides drug therapies and behavioural training, conservative treatment also includes a variety of neurostimulating methods for treating detrusor instability. Several different techniques of neuromodulation are in use, including anogenital electrical stimulation, neurostimulation of the sacral nerves, and Stoller afferent nerve stimulation (SANS) [1]. Pulsatile functional magnetic stimulation (FMS) is a recent technique approved by the USA Food and Drug Administration in 1998. Recently FMS was compared with functional electrical stimulation (FES); FMS has many unique advantages [2,3], e.g. it is possible to modulate the sacral nerves without invasive anal or vaginal devices, and thus FMS is much more comfortable than FES.

We investigated the effect of FMS in 24 women with urge and mixed (urge and stress) incontinence using FMS built into a chair, evaluating the effectiveness of FMS and any urodynamic changes.

PATIENTS AND METHODS

Since January 2001, 24 patients with urge incontinence (12) and mixed (stress and urge,

12) incontinence were included in a prospective study of the electromagnetic chair (Neocontrol®, Neotonus, Marietta, GA, USA; Fig. 1). Women with a history of radiotherapy, neurological diseases, pacemaker, arrhythmia or metal implants, or pregnant, were excluded. A voiding diary was completed at baseline and at the end of the study to evaluate voiding patterns and any possible changes. The UD-2000 (Medical Measurement Systems, Enschede, the Netherlands) and MMS Unitip catheter with one urethral and one bladder sensor was used for the urodynamic evaluation, at baseline and after completing the study. The medical history and any previous treatment were noted (drugs, physiotherapy, electrotherapy, SANS or a combination of therapies). The effect of the treatment was evaluated after 8 weeks by the voiding diary, a pad test, a subjectivity score and the stress leak-point pressure (SLPP) during cystometry in patients with stress incontinence.

During treatment the patients sat on the Neocontrol chair; the stimulation is provided by an electromagnetic generator in the seat, controlled by an external unit. The generator creates pulses of 275 μ s; the clinician can change the frequency and amplitude, and thereby control the magnitude and strength of the magnetic field. The effect is greatest in the centre of the field and therefore the perineum must be in the middle of the seat.

After studying previous publications we treated patients with urge incontinence using a monophasic frequency of 10 Hz for two episodes of 10 min, with a pause of 1 min, instead of the 'standard' 10/50 Hz as used by most other investigators. Patients with mixed incontinence were treated with 10 min at 10 Hz and 10 min at 50 Hz. All patients were treated twice weekly for 8 weeks. The patients' satisfaction was estimated by a subjectivity score, consisting of a visual analogue scale (0–6) in which patients could specify whether they appreciated the quality of their life as 'happy' (0) or 'terrible' (6). Therapy was considered successful if incontinent episodes decreased by half or more, or if voiding frequency had diminished by more than half. A cure was defined as < 3 g of urine loss in the 24 h pad test. The results were analysed statistically using the Wilcoxon matched-pairs test.

RESULTS

All patients were ambulant and used pads for protection; their mean (SD, range) age was 50 (10, 35–68) years. The results of the statistical analysis are shown in Table 1. In 14 of the 24 patients (58%) incontinence improved; three were completely dry. After treatment the voiding frequency decreased significantly from that before treatment. The treatment was effective in six of the 12

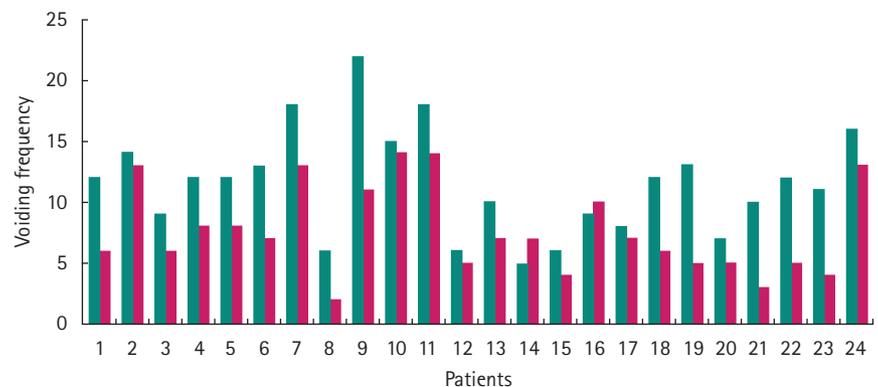
patients with urge incontinence and in eight of the 12 with mixed incontinence. The pad test before and after therapy for all patients showed an improvement in the loss of urine; in those with mixed incontinence this loss did not improve significantly but in those urge incontinence it did. Most patients were satisfied with the treatment; the subjectivity score for all patients improved significantly and most (70%) of all patients reported an improvement, while 30% did not, or reported a deterioration (one).

The urodynamic evaluation for patients with urge incontinence showed a mean (range) first sensation of fullness (FSF) of 166 (30–403) mL before treatment; five patients had detrusor instability and four urethral instability. The mean maximum bladder capacity (MBC) was 358 (30–900) mL before treatment for all patients with urge incontinence; filling cystometry data, available for seven of the 12 with urge incontinence at the follow-up, showed no significant changes after FMS, with a mean FSF of 223 (93–457) mL and mean MBC of 462 mL. One of the six patients with urodynamic data available had urethral instability when detrusor instability was present. For the 12 patients with mixed incontinence the mean FSF was 131 (46–228) mL and mean MBC 444 (155–800) mL before FMS. In seven of the 12 patients there was urethral instability and six had an unstable detrusor. After treatment filling cystometry was available for eight patients, with a mean FSF of 95 (2–161) mL and a mean MBC of 355 (202–534) mL. Five of the eight patients had urethral instability and four detrusor instability. The SLPP improved in seven of 12 patients with stress incontinence and in one there was no second measurement of SLPP.

DISCUSSION

The treatment of incontinence by electrostimulation can consist of FES or FMS. In FES a greater electrical current is needed to modulate the nerves because of the high impedance of the tissues and bones than with FMS. Therefore FES requires a greater intensity, which can lead to unpleasant sensations and even pain in the skin, vagina and/or anus. The magnetic field in FMS penetrates all tissues and therefore a lower intensity can be used, causing fewer complaints.

FIG. 1. Urinary diary (1–12: urge, 13–24: mixed incontinence). Before, green; after, red.



Median (range)	Before therapy	After therapy	P	TABLE 1 Statistical analyses using the Wilcoxon matched-pair test
Voiding frequency:				
total	12 (5–22)	7 (2–14)	<0.001	
urge	12.5 (6–22)	8 (2–14)	<0.005	
mixed	10 (5–16)	5 (3–13)	<0.01	
Pad-test, g				
total	67 (10–313)	31 (0–215)	<0.05	
urge	94 (11–313)	62 (0–215)	<0.05	
mixed	49 (10–305)	32 (9–151)	NS	
Subjectivity score:				
total	5 (3–6)	3 (0–6)	<0.001	
urge	5 (3–6)	3 (0–6)	<0.01	
mixed	4 (3–6)	3 (2–5)	P = 0.01	

The mode of action of neuromodulation is not yet fully understood. There are many reflexes known that may inhibit the micturition reflex [1,4]. Increased activity of the urethral sphincter as a response to filling of the bladder induces relaxation of the detrusor muscle; afferent anorectal nerve branches prohibit voiding during defecation; nerve branches of the pudendal nerve to the clitoris prohibit voiding during copulation; afferent branches of the nerves of the muscles of the limbs prohibit voiding during 'flight or fight' reactions; there is increased activity of the sympathetic nervous system as a response to filling of the bladder (Edvardsen's reflex).

McFarlane *et al.* [5] investigated the influence of magnetic stimulation of the root of S3 in humans; stimulation led to contraction of the urethral sphincter. Unstable contractions of the detrusor muscle, during cystometry, disappeared immediately after stimulation. Sheriff *et al.* [6] stimulated S2–S4 and found a diminished instability of the detrusor muscle after FMS.

Several studies using different frequencies for stimulation have been reported. Sympathetic inhibiting reflexes of the bladder are stimulated by low frequencies from 5 to 10 Hz; these frequencies also cause central inhibition of the bladder. Most low frequencies cause unpleasant sensations and hence 10 Hz is used for treating urge incontinence. High frequencies of 50–100 Hz are needed for good stimulation of the pudendal nerve and therefore for contraction of the urethral sphincter. They are used for treating stress incontinence [4,7].

The motor innervation of the bladder and the urethra are regulated by the same root (S2–4), which could explain the common finding of instability in the urethra related to detrusor instability. That there were no significant changes after FMS in the urge group but changes in the mixed group could be a result of the frequencies used (10 Hz urge and 10 or 50 Hz mixed) but more data are needed for valid conclusions.

Compared with FES only a few studies have been published measuring the effect of FMS for treating urinary incontinence; only one investigated whether FMS is a better therapy for incontinence than FES [3]. Fujishiro *et al.* [8] studied 75 patients with stress incontinence treated with FMS. The pressure needed to close the urethra increased ($P < 0.001$) and there was a significant increase in bladder capacity after stimulation ($P < 0.05$) by modulation with 15 Hz. Yamanishi *et al.* [9,10] investigated the effect of FMS on the pressure needed to close the urethra and the inhibition of the detrusor muscle by stimulation with 20 Hz. They reported a significant increase in closure pressure of the urethra and inhibition of the bladder; 86% of patients with stress incontinence and 75% with urge incontinence improved after therapy [10].

Sand *et al.* [14] reported a significant improvement with transvaginal electrostimulation (FES) in a group of 17 patients. Luber and Wolde-Tsadik [12] investigated the efficacy of FES in patients with stress incontinence, compared with a placebo treatment; there were no significant differences between the groups. Yamanishi *et al.* [11] reported a clear improvement in incontinence by FES in patients with stress incontinence, but they also assessed the difference in the urodynamic effects of FMS and FES on the inhibition of an unstable detrusor muscle [3]. The inhibition was better with FMS ($P < 0.05$) during stimulation with 10 Hz. Gilling *et al.* [13], in a placebo-controlled study with FMS in patients with stress incontinence, evaluated the outcome with the pad test after 8 weeks. In the FMS group the pad test showed a significant improvement in the urinary loss, from 36 mL to 13.7 mL, while there was no significant difference in the placebo study (48 vs 39 mL). We also considered a placebo-controlled study, although we had practical difficulties in developing a good sham device which could be used in a double-blind randomized study.

The present study included patients with urge and mixed (urge and stress) incontinence because there were few patients with only stress incontinence. FMS seems to clearly improve urinary frequency and the satisfaction of the patient when analysed in all patients. The pad test shows an improvement in all patients and in the group with only urge incontinence, but there was no significant improvement in those with mixed

incontinence. Although good results are reported for FMS therapy in patients with stress incontinence we could not confirm this in the mixed group.

For patients with mixed incontinence we used a frequency of 10 Hz to treat the urge component and 50 Hz for the stress component, according to earlier studies [2,7]. These authors reported good results in treating stress incontinence using low frequencies (15–20 Hz). This might explain the differences between the results. However, Galloway *et al.* [2] reported a significant improvement in the pad test in the total group, and used 10 and 50 Hz in all patients, as in the present patients with mixed incontinence. Assessing only those with stress incontinence and using different frequencies could be provide meaningful results in future studies.

Values of filling cystometry variables after treatment did not change significantly from those beforehand. Unfortunately, cystometry data were not available for all patients after treatment. Unlike in most other forms of neuromodulation, there was no increase in FSF and MBC in the present series, but filling cystometry data were not regarded as a primary study objective and there were few patients.

FES can also be used at home because the equipment is portable. It is a safe method but invasive, and therefore it is not very comfortable. Not every device is successful and the results depend on good instruction and compliance of the patient. FMS is an expensive method; the chair and 20 cards cost about 40 000 Euro. A single card (20 treatments) costs 400 Euro. The long-term effects remain to be evaluated, and because of the exclusion criteria not every patient can be treated. FMS seems to be a safe and painless treatment with good compliance by the patient. Patients do not have to undress and the method is easy to use in the clinic. Treatment with FMS is useful for patients with different voiding disorders. Follow-up studies are needed to evaluate the long-term efficacy and to determine if continuous treatments are necessary.

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Abbreviations: SANS, Stoller afferent nerve stimulation; FMS, functional magnetic stimulation; FES, functional electrical stimulation; FSF, first sensation of fullness; MBC, maximum bladder capacity; SLPP, stress leak-point pressure.