ELSEVIER

CONSERVATIVE TREATMENT OF FEMALE URINARY INCONTINENCE WITH FUNCTIONAL MAGNETIC STIMULATION

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ABSTRACT

Objectives. To determine the efficacy and safety of functional magnetic stimulation (FMS) produced by the Pulsegen device compared with placebo in the treatment of women with urinary incontinence.

Methods. Fifty-five women with urinary incontinence were randomly assigned to the active FMS group (30 patients) or the placebo group (22 patients). Each patient in the active group received a Pulsegen device, which produced a pulsating magnetic field of B = 10 μT intensity and a frequency of 10 Hz. Patients were asked to wear the Pulsegen device day and night for 2 months. Clinical and urodynamic data were collected before and after FMS and analyzed using nonparametric statistics.

Results. Compared with the placebo, the number of pads used was significantly lower ($P = 0.0031$) after FMS, as was the pad weight ($P = 0.014$). In patients from the active group, a significant improvement in the power of the pelvic floor muscle contractions ($P = 0.0071$), as well as in the duration of the pelvic floor muscle contractions ($P = 0.038$), was observed. After FMS, a 56.3% improvement in urinary incontinence symptoms was reported by patients in the active group, a significantly greater difference ($P = 0.00012$) compared with the reported 26.3% improvement in symptoms in the placebo group.

Conclusions. We believe that FMS represents a new method in the conservative treatment of urinary incontinence. Magnetic stimulation with the Pulsegen device is efficient and safe. It can be used at home and, because of its small size, wearing the device is not annoying for patients. UROLOGY **61:** 558–561, 2003.

In the past few years, questions have been raised about the place of functional magnetic stimulation (FMS) in the treatment of urinary incontinence (UI). In 1999, Galloway *et al.*[1] published the first results on successful UI treatment with magnetic therapy. After 3 months of FMS, they observed a significant reduction in leak episodes and in pad use. In a study by Yamanishi *et al.*,[2] the inhibition of overactive bladder symptoms was also observed after FMS. The beneficial effect of magnetic therapy on UI was also confirmed by our pilot study in which significant improvement in bladder capacity and the power of the pelvic floor muscle (PFM) contractions was observed.[3] However, the main drawback of this pilot study was the small number of patients and the lack of a placebo group.

The aim of the present study was to estimate the efficacy and safety of FMS produced by the Pulsegen device compared with placebo in the treatment of women with UI.

MATERIAL AND METHODS

The present research was designed as a randomized, double-blind, placebo-controlled study on the effectiveness of magnetic therapy in 55 women with UI. All patients enrolled in the study were older than 18 years, were not pregnant, and were not physically or mentally disabled. All patients with implanted electronic equipment (pacemakers) or with urolithiasis, bladder infection, or tumor were excluded from the study. Patients with recent urethral or continence surgery or those taking anticholinergic drugs, beta-blocking agents, or diuretics were also excluded.

All women with UI were recruited by the same urogynecologist. For each woman, three visits at the outpatient clinic (OPC) were scheduled. At the first visit, her history was taken, she received all necessary information on the study design and procedures, and she signed the informed consent form. Each patient was given a 48-hour volume-voided chart and detailed

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FIGURE 1. *Pulsegen device.*

instructions on how to fill out the form. At the second visit, the standardized pad test was done, and urine loss was registered in grams. Flowmetry (Wiest Urodynamic Equipment) was done, and data on voided volume, maximal urine flow, and postvoid residual urine volume were obtained. A clinical examination and the cotton swab test were performed. The data on frequency, nocturia, average voided urine volume, and number of pads used were collected from the 48-hour volume-voided charts.

PFM contractions were measured with a perineometer (Two Channel Electronic Stimulator with Perineometer, Elecomp). The perineometer consists of a compressible silicone rubber sheath over a skeleton that allows the central section to be pressed radially in response to muscular contractions. It is 80 mm in length and 30 mm in diameter and is connected to a manometer by plastic tubing. For each patient, a clean Latex sleeve was fitted around the silicone rubber sheath and inserted into the vagina. After restoring the 0 point, the women were asked to perform five maximal consecutive PFM contractions, with an interval of 30 seconds between every two contractions. After each contraction, the calibrated 0 point was restored. The power of the PFM contractions was measured as the percentage of the maximum (100% = 45 mm Hg); the time of the PFM contractions was measured in seconds.

Each patient underwent the randomization process and received a numbered Pulsegen device. Neither the investigator nor the patients knew which device was active or sham. The Pulsegen device was put in a small pocket of specially designed underwear that the patients received at the OPC. The stimulator fits this small pocket exactly, putting the stimulator in the correct position. FMS was then carried out day and night for 2 months.

The active Pulsegen device is a generator of pulsating electromagnetic fields of extremely low frequencies. It has a plastic housing and is designed for home use (measurements: 45 mm long, 30 mm wide, and 10 mm thick; weight without battery: 9.5 g). The Pulsegen is powered by a 3-V battery, allowing 8 weeks of continuous FMS. The device is turned on by pressing a small switch located on the front of the device; a green light blinks on the front when the device is active (Fig. 1). The Pulsegen produces a magnetic field at an intensity of B_{max} = 230 μT ± 10% at the housing (maximal electric field strength: *Et = 10 V/cm*; derivative: *dB/dt = 1T/s*) and pulse frequency of 10 Hz (pulse width: t_m = 55 μs ± 5 μs; pulse rise time: t_n = 10 μs ± 1 μs; Certificate of Approval for Use of GS Symbol No. 95 44 083; LGA, Equipment Safety Testing Institute, Nürnberg, Germany, 1995; Test Report No. T231-0087/9; Slovenian Institute of Quality and Metrology, EMC Laboratory, Ljubljana, Slovenia, 1997).

At the third visit, data on frequency, nocturia, average urine volume, and number of pads used were again collected from the volume-voided chart. All examinations done at the second visit at the OPC were repeated. The success of treatment was reported by patients on the basis of a visual analog scale (0%, no change in symptoms after FMS to 100%, no symptoms of UI after FMS).

The data were analyzed using Statistica, version 5.0 (StatSoft) software. Nonparametric descriptive statistics, the Mann-Whitney *U* test, and the Wilcoxon matched pairs test were used for identification of differences in variables between the active and placebo groups. $P < 0.05$ was considered statistically significant. This study was approved by the Ethics Committee at the Ministry of Health of the Republic of Slovenia (No. 59/06/02).

RESULTS

Fifty-five women were enrolled in the study, but 3 patients did not finish it. One patient with an active device withdrew because of lumbar-ischialgic pain in the right leg, and two with sham devices lost them. The average age of the remaining 52 women was 55.8 years (range 34 to 78). UI had been present for an average of 7.1 years (range 1 to 26). Of the 52 patients, 21 were diagnosed with mixed (40.4%), 22 with urge (42.3%), and 9 with stress (17.3%) UI. In 11 patients, hysterectomy had been performed 1 year previously or earlier.

Thirty patients were randomized to the active group and 22 to the placebo group. The two groups did not have significant differences in the clinical and urodynamic parameters, as confirmed by the Mann-Whitney *U* test ($P > 0.05$).

After FMS, the daytime frequency decreased significantly (from 7.8 to 7.2, $P = 0.048$) in the active group, in contrast to nocturia, which decreased significantly in both groups (active group, from 2.2 to 1.6, $P = 0.0057$; placebo group, from 2.2 to 1.5, $P = 0.0035$; Table I). The number of pads used significantly decreased (from 2.9 to 2.1, $P = 0.0031$) in the active group; a significant improvement in pad weight was also observed (from 9.1 to 6.4 g, $P = 0.014$; Table I).

In patients in the active group, a significant improvement in the power of the PFM contractions of 18.3% (from 21.3% to 25.2%, $P = 0.0071$) as well as in the duration of the PFM contractions (from 2.4 to 2.9 s, $P = 0.038$) was observed (Table I, Figs. 2 and 3).

As determined by the visual analog scale, after FMS, a 56.3% improvement in UI symptoms was reported by the active group, significantly greater ($P = 0.00012$) than the 26.3% improvement reported for the placebo group. Although 21 patients (79%) with active stimulation evaluated the success of FMS as excellent or good, the success of treatment was estimated to be significantly lower ($P = 0.0022$) by women in the placebo group (22.7%; Fig. 4).

TABLE I. *Variables that changed significantly after FMS (Wilcoxon matched pairs test)*

	Active Group			Placebo Group		
	Before	After	*P* Value	Before	After	*P* Value
Pads used (n)	2.9	2.1	0.0031*	2.2	1.9	0.24
Pad weight (g)	9.1	6.4	0.014*	7.1	4.8	0.083
Daytime frequency (n)	7.8	7.2	0.048*	7.2	7.0	0.47
Nocturia (n)	2.2	1.6	0.0057*	2.2	1.5	0.0035*
Power of PFM contractions (% of max.)	21.3	25.2	0.0071*	21.4	23.9	0.47
Time of PFM contractions (sec)	2.4	2.9	0.038*	2.7	2.7	0.95

KEY: *FMS = functional magnetic stimulation; PFM = pelvic floor muscle.*
**Statistically significant.*

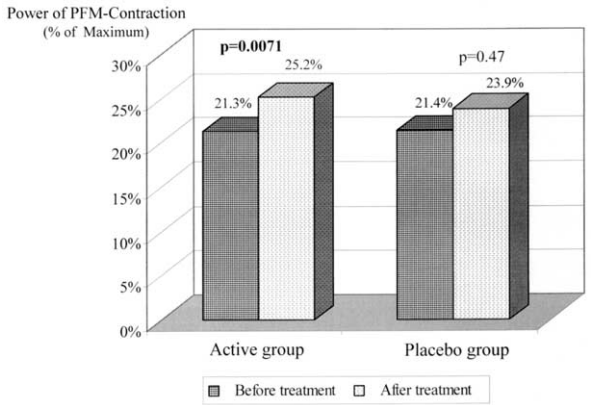

FIGURE 2. *Influence of FMS on power of PFM contractions.*

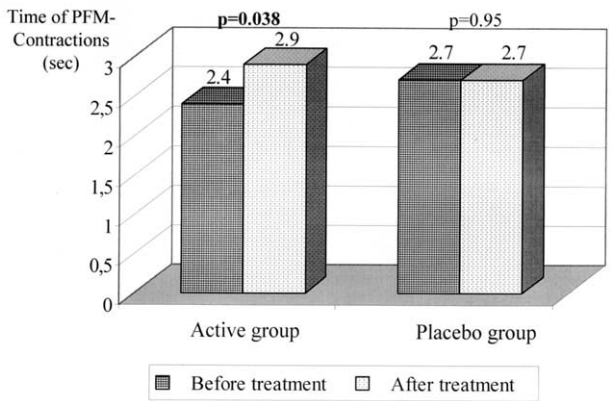

FIGURE 3. *Influence of FMS on duration of PFM contractions.*

COMMENT

According to the International Continence Society definition, UI is the involuntary loss of urine that is a social or hygienic problem. The treatment of UI is gradual and is mainly conservative. Conservative methods include Kegel's exercises, bladder retraining, vaginal cone treatment, functional electrical stimulation, and medication (mainly anticholinergic agents). Of these conservative methods, electrical stimulation of the PFMs seems to be a successful treatment method for UI for which we can expect a success rate of greater than 70%.[4–6]

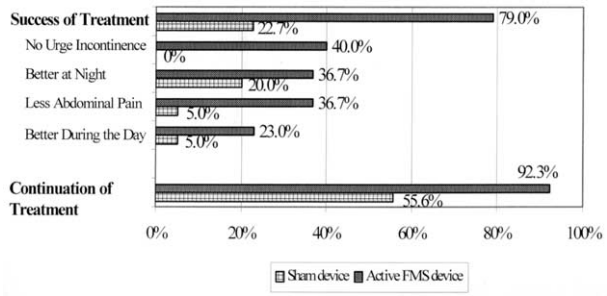

FIGURE 4. *Success of FMS as reported by the patients in the active and placebo groups.*

However, it is poorly tolerated by one half of the patients who reject it because of pain and discomfort.

In June 1998, the U.S. Food and Drug Administration recognized FMS with the NeoControl system as a new method for conservative treatment of stress, urge, and mixed UI in women. Magnetic therapy is based on the theory of Faraday's law on magnetic induction in which magnetic pulses penetrate deeply into the perineum and initiate nerve impulses, causing contractions of the PFMs. The first promising results on FMS were reported by Galloway *et al.*[1] in 1999. Of 50 women with stress UI, 34% were completely dry after 3 months of treatment with magnetic stimulation and 32% were using not more than one pad per day. Pad use was reduced from 2.5 to 1.3 ($P = 0.001$), and the number of leak episodes was reduced from 3.3 to 1.7 ($P = 0.001$).[1] In the same year, Yamanishi *et al.*[7] reported a statistically significant increase ($P = 0.028$) in the maximal urethral closure pressure after magnetic stimulation; compared with the prestimulation level, the maximal closure pressure increased by 16% after FMS.

One of the possible drawbacks of FMS may be that for 6 to 8 weeks the patients have to come to the OPC twice a week to receive FMS—usually 20 minutes in duration. This can represent a rather heavy burden for both the patient and the health service. With that in mind, and also encouraged by favorable results of FMS, a small electromagnetic device (Pulsegen) was created. In 2001, the effi-

cacy of the Pulsegen device was tested on a group of 10 patients with UI. Cystometry revealed a significant improvement in the power of PFM contractions and in bladder capacity after FMS.[3] Because it was not possible to establish the rate of the placebo effect, the present study was designed. Of the 55 women enrolled in this study, 52 completed it; 30 patients were randomized either to the active FMS group and 22 to the placebo group. All women were asked not to change their habits or way of life during the 2 months of treatment. After FMS, we observed a significant decrease in pad weight and in the number of pads used in the active group (Table I). A decrease in the number of used pads, as well as in the amount of urine lost, was also observed in the placebo group, but this decrease was not statistically significant.

The power of PFM contractions in our study increased after FMS in both groups; however, it was significant only in the active group (Table I and Fig. 2). After FMS, the power of the PFM contractions increased by 18.3% in patients from the active group and by 11.7% in patients from the placebo group compared with the prestimulation level. The duration of the PFM contractions also increased significantly after FMS in the active group, as revealed by perineometry (Fig. 3).

In contrast to Galloway *et al.*,[1] who claimed that it was unlikely that changes in pad use were due to the placebo effect, we believe that precisely the data on the objective improvement in the placebo group highlight the necessity of a control group in FMS studies.

The value of FMS in the inhibition of detrusor contractions was reported by Yamanishi *et al.*[2] Compared with the results after electric stimulation, the bladder capacity was found to be significantly greater in the group of patients who underwent magnetic stimulation. Detrusor overactivity was abolished in 3 patients (20%) from the FMS group but not in any patient from the functional electric stimulation group.[2] In our study, it was possible to estimate the bladder function on the basis of the history taken before and after stimulation. In addition to the reported improvement in nocturia and frequency, which was also read from the volume-voided chart, 40% of women no longer leaked during urgency after FMS. However, no such event was observed in the placebo group. Furthermore, the abdominal pain diminished or disappeared in 36.7% of women from the active group but in only 5% of women from the placebo group (Fig. 4).

One side effect was observed during FMS. After 8 hours of FMS, an acute onset of pre-existent lumbar-ischialgia developed. Removal of the Pulsegen device was followed by a gradual disappearance of the pain in the right leg. On the next day, the patient decided to continue with FMS, but the pain reappeared earlier than the day before, after 6 hours of FMS. Two other patients reported a pulsating sensation in the lower abdomen and perineum that was not unpleasant. In addition, 1 woman experienced less pain during her menstrual period (dysmenorrhea) than before FMS.

CONCLUSIONS

On the basis of the results of this study, we believe that FMS with the Pulsegen device represents a new and promising treatment of UI. Compared with functional electric stimulation, the patient reaction to FMS is more positive, because they feel no discomfort or pain at stimulation and they do not need to undress. The mechanism of action of the pulsating magnetic field produced by the Pulsegen device remains unclear; however, on the basis of our results, we can conclude that FMS is efficient and safe, can be used at home, and, because of its small size, wearing it is not annoying for the patients.

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