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High-power Magnetotherapy: A New Weapon in Urinary Incontinence?

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Objective: Urinary incontinence (UI) is one of the most common urinary system diseases that mostly affects women but also men. We evaluated the therapeutic efficacy of functional magnetic stimulation (FMS) as potential UI treatment with improvements in the pelvic floor musculature, urodynamic tests and quality of life.

Methods: A total of 20 UI patients (10 females and 10 men, mean age 64, 14 years), including 10 with stress UI, four with urgency UI and six with mixed UI, were treated with FMS (20 min/session) twice a week for 3 weeks. The patients' impressions, records in urinary diaries, and scores of three life stress questionnaires (overactive bladder symptom questionnaire [OAB-q], urogenital distress inventory questionnaire-short form [UDI-6], incontinence impact questionnaire-short form [IIQ-7]) were performed pre- and post-treatment.

Results: Significant reductions ($P < 0.01$) of micturition number and nocturia after magnetic treatment were evidenced. The urodynamic tests recorded a significant increase in cystometric capacity ($147 \pm 51.3\%$), in maximum urethral closure pressure ($110 \pm 34\%$), in urethral functional length ($99.8 \pm 51.8\%$), and in pressure transmission ratio ($147 \pm 51.3\%$) values compared with the baseline values.

Conclusions: These preliminary findings suggest that FMS with Magneto STYM (twice weekly for 3 weeks) improves the UI and may be an effective treatment for this urogenital disease.

Key words frequency, magnetic stimulation, pressure, stress, urinary incontinence

1. INTRODUCTION

Urinary incontinence (UI) is a common urogenital disease, defined as the involuntary leakage of urine in the absence of a detrusor contraction, usually due to the weakness of the urethral sphincter and pelvic floor.[1] The main symptoms are: reduced ''warning time'' of the need to void with consequently increased frequency and reduced volume voided per micturition, with the potential to result in nocturia.[2] According to the International Continence Society (ICS), the UI affects more than 200 million people worldwide, and mainly women (55%) rather than men.[3] This number may be an underestimate, because up to half of women may fail to report UI probably due to embarrassment, lack of knowledge about treatment options, or a conviction that UI is a normal inevitable part of aging.[4]

This pathological condition has a negative impact on the quality of life of patients and can also affect men and is primarily caused by urethral sphincteric deficiency after radical prostatectomy.[5]

UI can be categorized in: (i) urethral underactivity (stress UI) that accounted from 29 to 75% of the women;[6,7] (ii) bladder overactivity (urgency UI), that accounted for 7–33% of the total population (22% of women vs 2.6% of men);[8–11] (iii) a combination of the two previous types (mixed UI), that accounted from 14 to 61% of the population.[2,12]

The management of UI includes restoration of continence, reduction of the number of UI episodes, and prevention of complications (e.g. pressure ulcers).

New and emerging therapies aim to improve the overall efficacy compared with existing therapies (behavioral, pharmacological, surgical therapies), while minimizing adverse effects/complications, improving tolerability, and reducing invasiveness (Table 1).

Several clinical studies have focused on developing novel, non-invasive techniques to treat the UI, including magnetic stimulation and there have been reported improvements of the urinary symptoms (e.g. reduction

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TABLE 1. Treatment types of UI

	Behavioral therapy	Pharmacologic therapy	Physical therapy	Surgical therapy
Stress UI	Pelvic floor muscle training (PFMT)	Injectable bulking agents		Mid-urethral slings, autologous pubovaginal slings, retropubic suspensions (for women); sling, artificial urethral sphincter (for men)
Urge UI	Lifestyle modifications, timed voiding, bladder retraining	Antimuscarinics agents; Beta-3 agonists	Posterior tibial nerve stimulation (PTNS); sacral neuromodulation	
Mixed UI	PFMT	Alpha blockers; 5-alpha reductase inhibitors (for men)	Sacral neuromodulation	Bladder outlet procedures (e.g. transurethral resection of prostate)

in frequency of leakage, urodynamic improvement, maximum bladder capacity) with no side-effects.[13–20]

There are several types of magnetic stimulation, including extracorporeal magnetic stimulation (ExMS) mainly used for urgency UI, functional magnetic stimulation (FMS) for stress and mixed UI. The action mechanism is the same for both types: the magnetic therapy stimulates both central and peripheral nerve pathways in the pelvis;[21]and induces a flow of ions, at the tissue level, establishing electrical eddy currents that can lead to membrane depolarization, consequently causing the pelvic floor muscles to contract and reducing UI.[22]

The aim of this study has been to investigate the effectiveness of FMS as potential UI treatment with improvements in the pelvic floor musculature, urodynamic tests and quality of life of patients who consulted our ''Second Opinion Medical Network'' (Modena, Italy) for the evaluation of their urinary symptoms.

The ''Second Opinion Medical Network'' is a consultation referral web and Medical Office System recruiting each time a wide panel of real time available specialists, to whom any patient affected by different diseases not adequately satisfied in terms of diagnosis and treatment can apply for an individual clinical audit.[23] Most of the patients, in fact, often wander around the web jumping into the medical Web-sites, looking for proper answers to their health problems, but this screening becomes often obsessive and compulsive, and frequently misleading, ending into the ''Web Babel Syndrome (a doctor-patient communication gap that especially dealing with multiple synchronous pathologies, copes with heterogeneous and misleading information/advice, with the impending risk of confused, contradictory statements and prescriptions).[24,25] To face this problem, the ''Second Opinion Network'' aims to be a useful problem-solving support revisiting each diagnostic and therapeutic step and properly re-addressing tailored treatments and prognosis, but also to avoid un-necessary investigational procedures, undue unhelpful and expensive medical and surgical treatments.[26]

2. METHODS

The anecdotic an retrospective observational study enrolled 20 patients (10 males and 10 females, age 38–82 years) who visited the ''Second Opinion Medical Network'' (Modena, Italy) as new patients for their UI: 10 patients (50%) with stress UI, 4 (20%) with urgency UI, 6 (30%) with mixed UI (Table 2).

TABLE 2. Clinical characteristics of patients

Number patients	20
Mean age (years)	64.14
Menopause	6
SUI	10
Urgency UI	4
Mixed UI	6
Mean duration of symptoms (years)	2.9

Fig. 1 Patient (women, 66 aa) with Urge Urinary Incontinence in treatment (first session) with Functional Magnetic Stimulator-Magneto STYM. [Colour figure can be viewed at wileyonlinelibrary.com].

The specific inclusion criteria are: (i) clinical urinary signs reported by participant and confirmed further by its medical record; (ii) UI history of at least 6 months, (iii) no history of surgery or hormone replacement therapy for UI treatment. All the patients provided written informed consent before participation and detailed personal history, age, previous diseases, urinary diary (number of leaks per day, frequency of micturition, nocturia), physical examination, urinalysis and urodynamic evaluation, including cystometric capacity (intravesical volume at which the patient has a normal, strong desire to void), maximum urethral closure pressure -MUCP- (pressure in

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the urethra keeping the urethra closed over the baseline bladder pressure), functional urethral length (length of the urethra over which the urethral pressure exceeds baseline bladder pressure), pressure transmission ratio-PTR- (ratio between urethral pressure spikes and bladder pressure spikes); in order to define the UI type. The study excluded the patients wearing a cardiac pacemaker or other implanted metallic pacemaker, or implanted metallic instrument such as urethral stent, and women who were pregnant or suspected of being pregnant.

The device used was a functional magnetic stimulator -Magneto STYM- (Iskra Medical [Stegne 23, 1000 Ljubljana, Slovenia]) including the magnetic coil that was positioned beneath the sitting bottom of the chair. During the treatment, each patient was instructed to sit on the seat so that the perineum was positioned at the centre of the coil and so that the patient would feel the muscle contraction (contraction of the pelvic floor and sphincter muscles) during stimulation (Fig. 1).

The patients underwent 20 min/session, twice a week for 3 weeks (six sessions total).

Stimulation intensity (max 2 Tesla) was gradually increased, by the clinician, up to the limit of tolerability as indicated by the patient (average 15–30% of the maximum). While stimulation frequency was fixed at 10 Hz for 10 min, and at 35 Hz for another 10 min, with a rest period (active time and pause time) of 6 sec, respectively. The control unit displayed the status, the pulse generation and the possibility for external communication via a modem.

The efficacy of the FMS was evaluated by the patients' impressions, records in urinary diaries, urodynamic tests (performed in the same manner before and after treatment) and scores of three life stress questionnaires administered pre and post-treatment: (i) Overactive bladder symptom questionnaire (OAB-q): comprises 33 items divided into coping, concern, sleep, social interaction, and total health-related quality of life subscales, during the past week, and it is scored on a five-point scale (0 for ''not at all'', 1 for ''a little bit'', 2 for ''some what'', 3 for ''quite a bit'', 4 for ''a great deal'', 5 for ''a very great deal'');[27] (ii) Urogenital distress inventory questionnaire-short form (UDI-6): comprises seven questions on urine leakage and urgency symptoms over the last 3 months, with a scale of 0–3 (0 for ''not at all'', 1 for ''slightly'', 2 for ''moderately'', and 3 for ''greatly'');[28]and (iii) Incontinence impact questionnaire-short form (IIQ-7): comprises seven questions to assess the adverse effects of UI in terms of physical activities, household chores, recreation, travelling, social activities, emotional health and the feeling of frustration. The average, which ranges from 0 to 3 (0 for ''not at all'', 1 for ''slightly'', 2 for ''moderately'', and 3 for ''greatly'') is multiplied by $33 \times 1/3$ to put scores on a scale of 0–100.[29]

The statistical analysis was evaluated using Mann–Whitney test (continuous variables not normally distributed) and χ^2 test (categorical variables). A commonly-used measure of linear correlation, the Pearson correlation coefficient, denoted by r, was reported. Statistical significance was set at *P*-value less than 0.05, and all data and graphics were analyzed using the R software, version 3.1.2.[30]

3. RESULTS

The mean age of the patients was 64.14 ± 13.61 years. The changes in UI status were evaluated by comparing urodynamic tests and life stress scores before FMS and at 3 weeks after treatment (Tables 2–4).The patients noticed significant reductions of micturition number and nocturia after FMS ($P < 0.01$).

The urodynamic tests recorded a significant increase in cystometric capacity ($147 \pm 51.3\%$), in MUCP ($110 \pm 34\%$), in urethral functional length ($99.8 \pm 51.8\%$), and in PTR ($147 \pm 51.3\%$) values compared with the baseline values (Fig. 2).

The urodynamic testing values that decreased with bladder filling or when the UI patients assuming an upright posture, were increased after 3 weeks of treatment: maximum urethral closure pressure increased in all the stress UI patients, bladder capacity at first desire to void and maximum cystometric capacity significantly increased in four urgency UI patients after stimulation ($P < 0.01$).

4. DISCUSSION

Several studies have evidenced that FMS affects UI through the large fiber somatic nerve and afferent neural pathway: it induces a magnetic current in the autonomic and somatic nervous systems, innervating the lower urinary tract in a manner similar to that of electrical stimulation, and improves bladder hyperreflexia by desensitizing C-afferent fibers and reducing *c-fos* gene expression.[31] Indeed, Yamanishi and co-workers studied the urodynamic effects of FMS on urethral closure in healthy volunteers and concluded that this technique significantly increased the maximum intraurethral and urethral closure pressure after stimulation: pulsed electromagnetic fields (PEMFs) generated by a coil penetrate deep into the pelvic floor, to reach the relevant conductive tissues, and induce a flow of ions to propagate electromagnetic currents.[16] Voltage gradient ensues, and membrane depolarization occurs in the pelvic floor that leads to pelvic floor nerve stimulation (stimulation of motor end plates) and to pelvic floor muscle contraction.[32] Further, Galloway et al.[13] developed a pulsed magnetic device for pelvic floor muscle strengthening in the UI treatment and confirmed a significant reduction in the frequency of leakage episodes and detrusor instability.

Several reports confirmed also the long-term post-treatment duration of therapeutic effect.[17,33] For instance, Yokoyama and co-workers reported that 17/20 patients with urgency UI reduced their urinary symptoms with FMS, and that 9 of 17 patients (53%) maintained improvements until 24 weeks after the last treatment.[17] In the present study, all of the patients who did not need to undress for the treatment underwent a six-session FMS protocol, showing a significant improvement in symptom scales compared with the baseline values and this effect

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TABLE 3. Urodynamic testing results (median values) pre and post-treatment

Urodynamic exams	Pre-treatment	Post-treatment	*P*-value
Cystometric capacity (normal values 300–600 mL)	200 (IQR [145.75–239.25])	419 (IQR [383–429])	<0.01
Maximum urethral closure pressure (MUCP) (normal values ≥30 cm H_2O)	21 (IQR [16.75–22.25])	41 (IQR [38.75–42.25])	<0.01
Urethral functional length (normal values 3.5–5.25 cm)	2.25 (IQR [1.9–2.5])	4.4 (IQR [3.68–4.93])	<0.01
Pressure transmission ratio (PTR) (normal values ≥100%)	48 (IQR [40–56])	118 (IQR [109–125])	<0.01

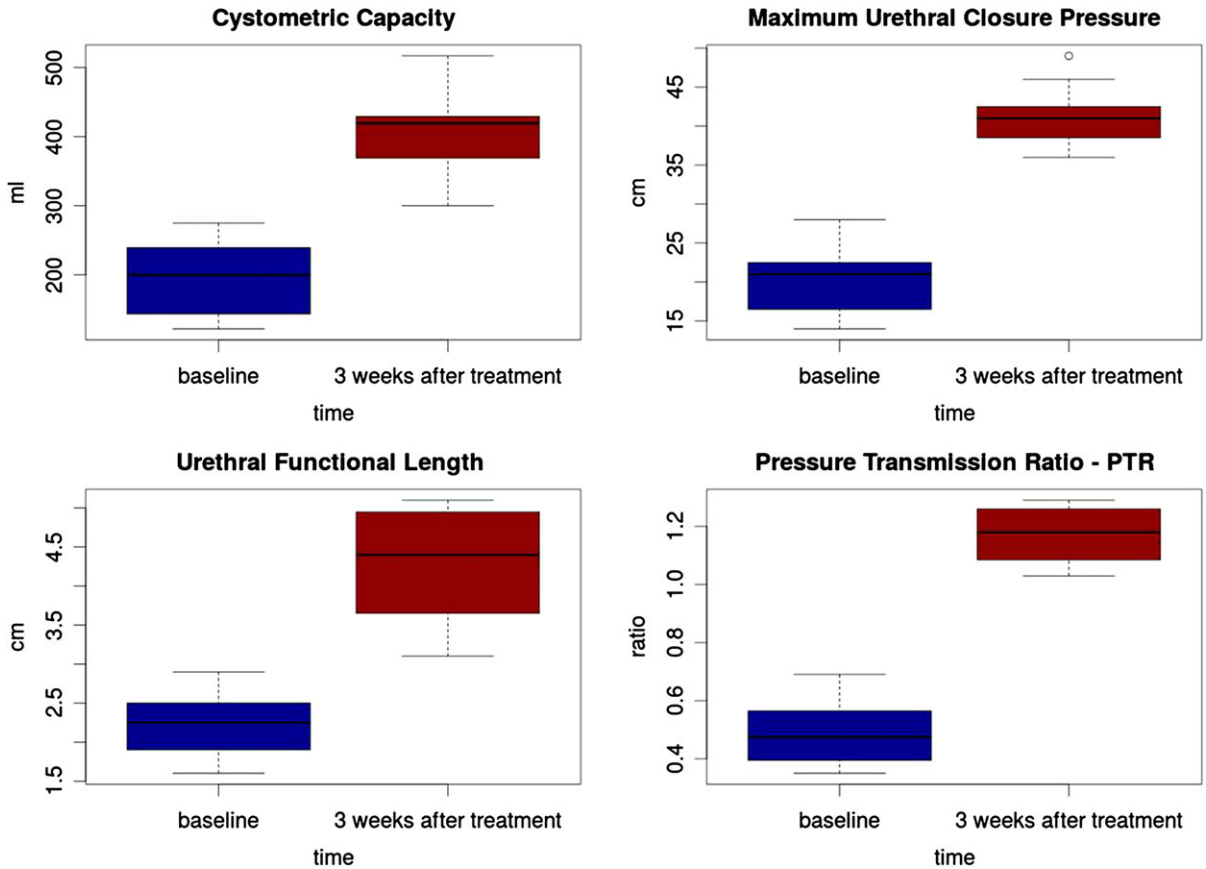

Fig. 2 Graphic illustration of Urodynamic testing results (median values and *P*-value), including cystometric capacity, maximum urethral closure pressure (MUCP), urethral functional length, and pressure transmission rate (PTR), of all the patients pre-and post-functional magnetic treatment. [Colour figure can be viewed at wileyonlinelibrary.com].

TABLE 4. Life stress questionnaires scores (median values) pre and post-treatment

Questionnaire type	Baseline (pre-treatment)	3 weeks (post-treatment)	*P*-value
OAB-q	4 (IQR [3–4.25])	1 (IQR [0.75–2])	<0.01
UDI-6	3 (IQR [2–3])	0 (IQR [0–0.25])	<0.01
IIQ-7	22 (IQR [22–33])	5.5 (IQR [0–11])	<0.01

persisted until the follow-up visit at week 6. However, the therapeutic effect could be maintained for a considerably long time after discontinuation of treatment, as confirmed by the follow-up questionnaire (by post) which revealed that urodynamic improvement and maximum bladder capacity was maintained in all of the patients without any additional pharmacological therapy. This may show a ''re-education effect'' of FMS, as showed by Suzuki et al.,[33] but it could be necessary to perform a longer follow-up study in a greater number of patients in order to verify the therapeutic efficacy of FMS, including the duration of its re-education effect. Regarding the safety of the treatment, no adverse effects due to FMS were noted in this study, as confirmed by Yamanishi and co-workers in the recent multicenter, randomized, sham-controlled study; they did record severe adverse events and observed that the number of leaks/week in bladder diary, as well as the voided volume and in the number of urgency/24 h, were all significantly reduced in 101 women with urgency UI.[34]

However, these data confirm the safety, non-invasiveness and painlessness of FMS compared to electrical stimulation which has side-effects, such as abdominal cramp, diarrhea, pain, and bleeding.[35]

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5. CONCLUSION

Our preliminary study suggests that FMS with MagnetoSTYM (twice weekly for 3 weeks) has significant advantages (no reported adverse effects, unnecessary to undress, automatic contractions and no pain), improves the UI and may be an effective treatment for this urogenital disease.

Nevertheless, further investigation of the optimal stimulation parameters, and standardization protocol is required to optimize therapeutic treatment.

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DISCLOSURE

No competing financial interests exist.

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