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e

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Article

Flat Magnetic Stimulation for Stress Urinary Incontinence: A Prospective Comparison Study

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Abstract: Background: Flat Magnetic Stimulation (FMS) is characterized by a stimulation generated by electromagnetic fields with a homogenous profile. One possible application is the treatment of stress urinary incontinence (SUI). We aimed to compare the objective, subjective, quality of life, and instrumental outcomes in women with SUI not eligible for surgery undergoing either FMS or pelvic floor muscle training (PFMT). Methods: This was a prospective interventional study. After proper counseling, patients with isolated SUI were divided according to their treatment of choice into FMS and PFMT groups. At baseline and after treatment, patients completed the International Consultation on Incontinence Questionnaire-Short Form, the Female Sexual Function Index, and the Incontinence Impact Questionnaire, and volumetric measurement of the urethral rhabdosphincter (RS) was performed. The Patient Global Impression of Improvement questionnaire and stress test defined subjective and objective cure rates, respectively. Results: We observed improvements in urinary-related quality of life scores and an increase in RS volume after FMS compared to baseline. All these outcomes were significantly better compared to women who underwent PFMT. Conclusion: Our study demonstrated that FMS is a safe and effective conservative option for SUI management in terms of objective and subjective cure rates.

Keywords: magnetic stimulation; stress urinary incontinence; pelvic floor; quality of life; ultrasound

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1. Introduction

Pelvic floor disorders (PFDs) represent a series of conditions—including prolapse, bowel, sexual, and bladder dysfunction—related to pelvic floor weakening and/or tears, usually related to obstetric trauma [1,2]. Additionally, changes in connective tissue composition and metalloproteinases can be observed in patients with pelvic floor disorders [3]. Pelvic floor disorders share the same factors and may frequently coexist or recur [4,5]. Moreover, the treatment of one of these disorders can improve, worsen, or even predispose to another. For example, prolapse repair has been shown to improve overactive bladder symptoms, but worsening has been demonstrated when a concomitant sling procedure is performed at the time of surgery [6]. Among pelvic floor disorders, stress urinary incontinence is considered one of the most bothering conditions. Stress urinary incontinence (SUI) is defined as involuntary leakage of urine during effort, coughing, or sneezing which generally occurs when the intra-abdominal pressure exceeds the urethral closure pressure [7]. This can occur as a consequence of the damage to the connective support of the urethra and bladder due to vaginal delivery, leading to insufficient urethral support [8]. In addition, the changes in collagen composition of the endopelvic fascia and the impairment of the urethral sphincter, related to the menopausal decrease in estrogen, can lead to a reduction in the urethral closure pressure [9]. Moreover, SUI can occur or persist as a consequence of pelvic floor surgery [10,11]. Globally, SUI is estimated to affect up to 50% of women

in developed countries and has a lifetime risk of requiring surgery of about 4% [12,13]. Moreover, this condition negatively affects social, occupational, domestic, and psychophysical well-being [14]. Diagnostic confirmation may involve urodynamic evaluation due to the well-established poor correlation between clinics and instrumental findings in bladder dysfunctions [15,16]. However, the role of urodynamics is currently under debate due to different definitions and inconstant performance [17,18]. Management can vary from conservative to surgical treatment according to the severity of symptoms, their impact on quality of life, and the patient's medical history and comorbidities. Surgical treatment is indicated when conservative management fails. Many types of surgery have been proposed over the years, including bladder neck suspension, anterior vaginal wall repair, autologous sling, stem cell injection, urethral bulking agents, and suburethral tapes [19–23]. However, each surgical approach has its own drawbacks, including visceral injuries (such as bladder perforation) and chronic neurological pain [24,25].

Consequently, conservative treatments should represent the first therapeutic approach. These include lifestyle modification, pelvic floor muscle training (PFMT), biofeedback/electrical stimulation, and vaginal laser [26]. Additionally, magnetic stimulation (MS) is considered a conservative treatment option for SUI. MS is a non-invasive therapeutic device that interacts with the neuromuscular tissue through a specific electromagnetic field, inducing intense contractions (involuntary and otherwise unachievable regular gym training or superficial electrical stimulation) that stimulate pelvic floor muscles deep down and restoring neuromuscular control. Various clinical trials have evaluated the efficacy of MS in ameliorating female SUI with positive outcomes [27]. However, due to heterogeneous results and weak evidence of the short-term and long-term effects, current European Urology Association recommendations advise against treating urinary with magnetic stimulation [28].

Recently, technological progress has provided advancements in magnetic stimulation equipment. In particular, Flat Magnetic Stimulation (FMS) is characterized by a stimulation generated by electromagnetic fields with a homogenous profile, which can be optimized for the treatment of the pelvic area. The homogeneity of magnetic field distribution does not generate areas of variable stimulation intensity, so the muscle works at the same intensity in all the fields. An advantage of this technology—due to the greater homogeneity of magnetic field distribution in a broader area—is that it allows greater recruitment of muscle fibers without creating areas of variable stimulation intensity. This is thought to be associated with greater treatment efficacy compared with standard MS. The interaction with the tissue involves muscular contraction, depolarization of neuronal cells, and enhancement of the blood circulatory system. Electric currents depolarize the nerve fibers, thus causing concentric contractions that lift all the pelvic muscles. The main effectiveness comes from electromagnetic energy, deep penetration, and stimulation of the entire pelvic floor area. This directly modifies muscle structure, inducing more efficient growth of myofibrils (muscle fiber hypertrophy) and the creation of new protein strands and muscle fibers (fiber hyperplasia muscle). While this new technology may enhance the outcomes of MS, up-to-date data on its efficacy on SUI are scarce. We hypothesize that new FMS may provide results comparable to other conservative treatments in the management of SUI.

As a consequence, with this study, we primarily aimed to compare the objective, subjective, quality of life, and instrumental outcomes in women suffering from stress urinary incontinence not eligible for surgery undergoing either FMS or PFMT. As a secondary outcome, we wanted to evaluate the effects on sexual function.

2. Materials and Methods

This was a prospective interventional study. Recruitment occurred from gynecologic outpatients in San Gerardo Hospital in Monza from August 2022 to September 2022. In the period of interest, all patients underwent a clinical interview to investigate the presence of lower urinary tract symptoms, including stress urinary incontinence (SUI), overactive bladder (OAB), urge urinary incontinence (UUI), voiding symptoms (VS), bulging symp-

toms or fecal incontinence. All definitions conformed to International UroGynacology Association/International Continence Society terminology [7]. In addition, a urogenital examination was carried out and descensus staged according to the Pelvic Organ Prolapse Quantification (POP-Q) system.

To be considered eligible for the study, patients should have isolated SUI without surgical indication, confirmed with a standard 300 mL stress test [29]. Exclusion criteria were women <18 years old, with insufficient Italian language proficiency, in a state of pregnancy, with an implanted pacemaker, defibrillator, neurostimulation, or ferromagnetic prostheses, weighing >160 kg, with recent deep venous thrombosis, fever, acute inflammatory diseases or recent fractures in the area of treatment, neoplasia, arrhythmia, and congestive heart failure. At the baseline, all patients completed the International Consultation on Incontinence Questionnaire-Short Form questionnaire (ICIQ-SF), the Female Sexual Function Index (FSFI-19) questionnaire, and the Incontinence Impact Questionnaire (IIQ-7) [30–32]. The ICIQ-SF is a robust tool to measure the frequency, severity, and impact of incontinence on quality of life among all patient types [30]. The questionnaire comprises four major questions, with the first three adding up to yield the total score: the frequency of leakage, the perceived quantity of leakage, and the degree of interference with life [30]. The fourth item, which is not considered in the scoring system, is a self-diagnostic item to identify the specific type of incontinence [30]. This tool has been demonstrated to have high levels of validity, reliability, and sensitivity, estimated according to standard psychometric methods [30]. The FSFI-19 is a 5-point Likert scale self-reported questionnaire with 19 items covering six domains of sexual function (sexual desire, lubrication, arousal, orgasm, pain, and satisfaction). FSFI-19 is one of the most popular, powerful, and useful diagnostic tools for investigating female sexual dysfunction and monitoring the efficacy of the treatment [31]. The scale has been tested to evaluate the impact of diverse clinical conditions and treatments on sexual dysfunction and has consistently demonstrated excellent psychometric properties [31]. An FSFI total score of 26.5 has been found to be the optimal cut-off for differentiating women with and without sexual dysfunction [31]. The IIQ-7 was developed to assess the impact on life of urinary incontinence among women [32]. This consists of seven items referring to the individual's perceived impact of urinary incontinence on daily activities, relationships, and feelings [32]. Each item has a four-point response scale where individuals rate the extent to which urine leakage affects their daily functioning in four domains: physical activity (items 1 and 2), travel (items 3 and 4), social activities (item 5), and emotional health (items 6 and 7) [32]. Over time, this tool demonstrated an excellent degree of acceptability, reliability, and validity across different countries and cultures [32].

In addition to the quality-of-life tools, a volumetric assessment of the urethral rhabdosphincter (RS) was performed using a BK Flex Focus 400 sonographic machine equipped with a 9052 transducer by vaginal approach (BK Medical, Melegnano, Italy). This is a mechanical, single-element, multifrequency transducer with a built-in 3D acquisition system providing a 360° field of view over a longitudinal distance of 60 mm. Obtained volumes were assessed offline using the BK 3D Viewer 7.1 software in cubic mode. In this mode, the operator is able to perform volume measurements by delineating the margin of the RS on successive planes to achieve volume values (Figure 1).

After proper counseling, patients were divided according to their treatment of choice into a Magnetic Stimulation (MS) group and Pelvic Floor Muscles Training (PFMT) group. Magnetic stimulation treatment was carried out twice a week for one month involving 8 sessions of 25 min each with Dr. Arnold (DEKA, Calenzano, Italy). The following FMS protocol was applied. Sessions 1 to 4 followed the Hypotonus/Weakness 1 protocol. Sessions 5 to 8 followed the Hypotonus/Weakness 2 protocol.

Hypotonus/Weakness 1 protocol consists of a Warm-up and muscle activation phase, a Muscle work aimed at recovering tropism and muscle tone phase (20-30Hz) in a Trapezoidal shape for a total time of 25 minutes. Hypotonus/Weakness 2 protocol consists of a Warm-up and muscle activation phase, a Muscle work aimed at increasing tropism (volume) and muscle strength phase (40-50Hz) in a Trapezoidal shape for a total time of 25 minutes.

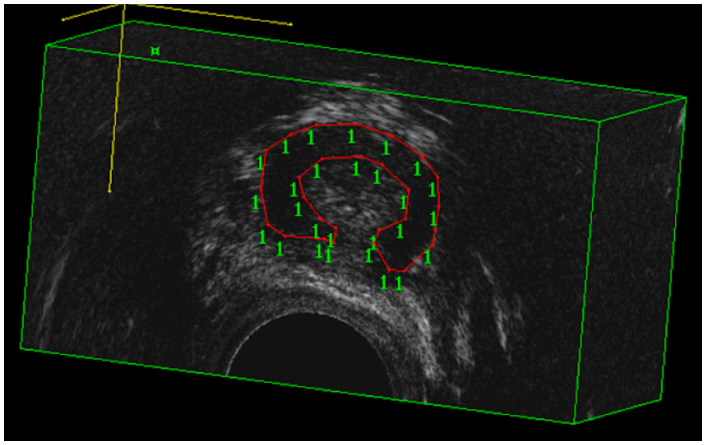

Figure 1. Volumetric assessment of the urethral rhabdosphincter (RS) using a BK Flex Focus 400 sonographic machine equipped with a 9052 transducer by vaginal approach.

Pelvic floor muscle training was performed for one month autonomously at home by patients following the Italian version of the International Urogynecological Association (IUGA) dedicated leaflets [33].

At the end of the treatment, the objective cure rate was assessed with a 300 mL stress test. The ICIQ-SF, FSFI-19, and IIQ-7 questionnaires were collected again, and quality of life outcomes were determined as the difference between preoperative and postoperative questionnaire scores. The subjective cure rate was determined by the Patient Global Impression of Improvement (PGI-I) questionnaire [34], and subjective success was defined as an improvement in the PGI-I score ($\leq$3). The sonographic evaluation was repeated, and the instrumental outcome was determined as the difference between preoperative and postoperative RS volumes.

The study obtained local Ethics Committee approval (protocol code PF-MAGCHAIR). Statistical analysis was performed using JMP software version 9 (SAS Institute, Cary, NC, USA). Outcomes are reported as mean $\pm$ standard deviation for continuous variables and as number (percentage) for noncontinuous variables. Differences were tested using paired T-test for continuous parametric data, Wilcoxon test for continuous non-parametric data, and Fisher's test for non-continuous data. A p-value < 0.05 was considered statistically significant.

3. Results

A total of 50 patients were enrolled. Overall, 25 patients underwent magnetic stimulation, whereas the remaining 25 women underwent pelvic floor muscle training at home following the IUGA leaflet. The patients' characteristics are shown in Table 1. No differences were found in terms of age, parity, or BMI. Baseline (T0) urogenital symptoms severity according to IIQ-7, ICIQ-SF, and FSFI-19 scores were similar. Moreover, baseline 3D ultrasound evaluation demonstrated similar urethral rhabdosphincter volumes between the MS and PFMT groups (p = 0.848). During the treatment, no adverse effects were reported. Post-treatment (T1) objective, quality of life, and ultrasound outcomes are reported in Table 2. Rates of urinary leakage during stress tests recorded a 40% decrease for FMS (p < 0.001), whereas no improvement was observed for PFMT compared to baseline. An improvement in IIQ-7 (20.7 vs. 33.7; p < 0.001) and ICIQ-SF (8.3 vs. 11.2; p = 0.003) scores was observed after FMS compared to baseline, whereas non-significant changes were observed in PFMT patients. Sexual function, according to FSFI-19 was not affected by either FMS or PFMT. The instrumental evaluation demonstrated a significant increase in urethral RS (2.5 cm^3 VS 2.9 cm^3; p < 0.001) after FMS, but this parameter was not affected by PFMT (2.5 cm^3 VS 2.6 cm^3; p = 0.248). The comparison between post-treatment outcomes of FMS and PFMT (Table 3) showed a significative superiority of the former in terms of

objective (40% vs. 0%; $p < 0.001$) and subjective cure rate (72% vs. 20%; $p < 0.001$), IIQ-7 ($p = 0.002$) and ICIQ-SF ($p = 0.024$) scores, and RS volume (2.6 cm^3 vs. 2.9 cm^3; $p < 0.001$).

Table 1. Population characteristics and baseline (T0) findings. FMS = magnetic stimulation. PFMT = pelvic floor muscle training. Continuous data as mean ± standard deviation. Non-continuous data as absolute (relative) frequency.

	FMS	**PFMT**	***p* Value**
Age (years)	60.9 ± 12.7	60.2 ± 12.7	0.851
Parity (n)	1.9 ± 0.7	2.1 ± 0.7	0.327
BMI (kg/m^2)	25.4 ± 3.0	25.6 ± 2.9	0.964
T0 IIQ-7 score	33.7 ± 22.6	38.1 ± 14.8	0.318
T0 ICIQ-SF score	11.2 ± 3.6	11.0 ± 3.1	0.814
T0 FSFI-19 score	12.5 ± 11.2	10.9 ± 10.6	0.622
T0 Urethral rhabdosphincter volume (cm^3)	2.5 ± 0.9	2.5 ± 0.6	0.848

Table 2. Pre- and post-treatment comparisons. FMS = magnetic stimulation. PFMT = pelvic floor muscle training. Continuous data as mean ± standard deviation. Non-continuous data as absolute (relative) frequency. T0 = baseline; T1 = after treatment.

	FMS			**PFMT**		
	T0	**T1**	***p* Value**	**T0**	**T1**	***p* Value**
Negative stress test	0 (0%)	10 (40%)	**<0.001**	0 (0%)	0 (0%)	1.000
IIQ-7 score	33.7 ± 22.6	20.7 ± 18.7	**<0.001**	38.1 ± 14.8	36.3 ± 14.9	0.119
ICIQ-SF score	11.2 ± 3.6	8.3 ± 4.1	**0.003**	11.0 ± 3.1	10.7 ± 3.2	0.129
FSFI-19 score	12.5 ± 11.2	13.2 ± 11.5	0.463	10.9 ± 10.6	10.0 ± 9.0	0.416
URS volume (cm^3)	2.5 ± 0.9	2.9 ± 1.1	**<0.001**	2.5 ± 0.6	2.6 ± 0.6	0.248

Table 3. Post-treatment outcomes. FMS = magnetic stimulation. PFMT = pelvic floor muscle training. Continuous data as mean ± standard deviation. Non-continuous data as absolute (relative) frequency.

	FMS	**PFMT**	***p* Value**
Negative stress test	10 (40%)	0 (0%)	**<0.001**
PGI-I ≤ 3	18 (72%)	5 (20%)	**<0.001**
T1 IIQ-7 score.	20.7 ± 18.7	36.3 ± 14.9	**0.002**
T1 ICIQ-SF score	8.3 ± 4.1	10.7 ± 3.2	**0.024**
T1 FSFI-19 score	13.2 ± 11.5	10.0 ± 9.0	**0.308**
T1 Urethral rhabdosphincter volume (cm^3)	2.9 ± 1.1	2.6 ± 0.6	**<0.001**

4. Discussion

Our study demonstrated that FMS is a safe and effective conservative option for SUI management, in terms of objective and subjective cure rate. Moreover, we observed

improvements in urinary-related quality-of-life scores and an increase in RS volume after FMS compared to baseline. Lastly, all these outcomes were significantly better compared to women who underwent PFMT.

Recently, the necessity to offer high efficacy–low morbidity treatment options for the management of SUI has become more and more important. From a surgical point of view, this contributed to the development and widespread adoption of new minimally invasive techniques, such as urethral bulking agents and single-incision slings. The first procedure consists of injections of an agent (such as polyacrylamide hydrogel) into the submucosal tissues of the urethra to increase the coaptation of the urethral walls, leading to increased urethral resistance and improved continence. The principal advantages of this surgical strategy are the reduced rate of adverse events and the chance of proposing these procedures to patients with severe comorbidities. Single-incision slings (SISs) are characterized by shorter tape length and consequently, a limited intracorporeal dissection and lack of full passage of the introducers through the obturator foramen, adductor tendons, and skin. This results in a lower risk of complications, including visceral injury, major bleeding, infection, and neurological pain, shorter recovery time, and a negligible learning curve [35,36]. While excellent short-term efficacy rates unaffected by age, BMI, obstetrical history, and proper bilateral anchoring on obturator membranes have been demonstrated, long-term data is scarce [37,38]. However, despite surgical innovations, surgical strategies always involve a certain—even if minimal—risk of complications.

Consequently, most guidelines recommend conservative management as the first-line treatment for SUI. Different options include PFMT, biofeedback, functional electrical stimulation, and MS but the evidence, including comparative studies, is scarce. Among all conservative treatment options, MS offers some advantages. Patients with pelvic floor disorders may have difficulty performing isolated voluntary pelvic floor muscle contractions. Consequently, the effectiveness of PFMT may be impaired because the patient is not performing it correctly and consistently over time [39]. Moreover, PFMT has the disadvantage of slow progression, patients' low compliance, and low adherence rates [40]. Both biofeedback and functional electrical stimulation involve the use of an endocavitary probe, which can greatly reduce compliance. Moreover, with electrical stimulation, half of the patients report various degrees of side effects with treatment, the majority of which are related to local discomfort, and 12% of the patients discontinued treatment [41]. Lastly, vaginal habitability may be impaired by a series of conditions, such as previous radiation therapy, previous pelvic surgery, or lichen sclerosus. MS has the advantages of being a passive rehabilitation that does not require the use of vaginal probes, patients do not need to undress, and no adverse effects are expected. Moreover, unlike the electrical current, the conduction of magnetic energy is unaffected by tissue impedance. Consequently, it can be considered a safe, non-invasive, and painless alternative option for the treatment of stress urinary incontinence.

Over the years, many studies demonstrated the role of MS in treating urinary incontinence. However, the differences among them in terms of stimulus intensities, frequencies, locations, and durations and the lack of standardization of the protocols caused the EUA to advise against MS for urinary incontinence treatment. However, reports show encouraging results in terms of MS efficacy for SUI treatment. For example, a randomized controlled trial conducted by Weber-Rajek et al. assessed the physical and psychosocial functioning of 128 women with stress urinary incontinence following MS or PFMT. In this study, the authors concluded that pelvic floor muscle training and extracorporeal magnetic innervation proved to be effective treatment methods for stress urinary incontinence in women [42]. Another randomized study conducted on 120 patients with SUI suggested that active MS treatment significantly improved limitations in physical activities and feelings of depression both immediately after and at 1-year post-treatment, compared with the sham group [43].

Our study confirmed that FMS is safe and effective in the short term in treating SUI, in terms of objective and subjective cure rates. Moreover, we observed improvements in urinary-related quality of life scores and an increase in RS volume after FMS compared

to baseline. Lastly, all these outcomes were significantly better compared to women who underwent PFMT. FMS technology represents the latest innovation in magnetic stimulation technology. FMS triggers intense muscular contractions inducing electric stimulus by targeting the neuromuscular tissue in the pelvic floor area. This is expected to change the muscular structure, inducing hypertrophy and hyperplasia. Initial evidence of this kind of device seems to be very promising for the treatment of SUI, overactive bladder, and mixed urinary incontinence. For example, Lopopolo et al. reported a significant improvement in quality of life and patients awareness of the pelvic floor area in 50 women with mixed urinary incontinence treated with six sessions of FMS even at the end of the treatment and at three months follow-up. In addition, at the baseline evaluation, patients most frequently experienced leakage several times a day, whereas after six sessions, the leakage occurred only about once a week or less [44]. Biondo et al. evaluated the effectiveness and safety of flat magnetic stimulation in eighty-one female patients (35 patients who reported SUI symptoms and 46 patients who reported UUI symptoms) after eight 28 min treatment sessions (twice a week for 4 weeks). Two questionnaires were used to evaluate the urinary improvements: Incontinence Questionnaire Overactive Bladder Module (ICIQ-OAB) for patients with UUI, and Incontinence Impact Questionnaire—Short Form (IIQ-7) for patients with SUI. According to questionnaire results, both improvements in UUI and SUI symptoms were observed; in particular, IIQ-7′s average score significantly decreased ($p < 0.05$) from 15.53 ± 5.62 at baseline to 6.76 ± 3.10 at 3-month follow-up [45]. Literature suggests that successful treatment of SUI can improve overall female sexual function scores. However, we did not observe improvement in sexual function according to FSFI-19 scores. These may be explained by the low prevalence of sexually active patients in our population, as well as by an underpowered sample for this outcome.

Ultrasound evaluation of RS volume as a marker of MS efficacy represents an original contribution of our study. Previous experiences demonstrated the feasibility and reproducibility of this measure [46,47]. Moreover, this volume has been demonstrated to be greater in continent women than women with genuine stress incontinence and may also play a prognostic role in anti-incontinence surgery outcomes [48,49]. Our study demonstrated significant RS hypertrophy as an effect of FMS, resulting in a 15.4% increase in muscular volume. FMS technology was previously reported to have a similar effect on other skeletal muscles. The efficacy of Schwarzy (DEKA MELA) has been evaluated on the abdomen of 15 patients in a study conducted by Leone et al. This paper demonstrated hypertrophy in terms of abdominal muscle tissue thickness 1 month after the last treatment in all treated areas: upper abdomen (11 ± 1 mm vs. 9 ± 2 mm), lower abdomen (13 ± 2 mm vs. 10 ± 2 mm vs.), lateral abdomen (13 ± 3 mm vs. 11 ± 2 mm vs.), and rectus abdominis diastasis (25 ± 4 mm vs. 22 ± 4 mm), which are consistent with our findings on urethral RS volumes [50].

To the best of our knowledge, this is the first study evaluating the outcomes in patients with isolated SUI treated with FMS. Strengths include the PFMT comparison group, the high adherence rate with no loss at follow-up, and the multimodal evaluation of outcomes. In addition, ultrasound evaluation of urethral rhabdosphincter represents an original evaluation of FMS efficacy, which can be potentially used to evaluate the efficacy of the other conservative option for SUI treatment. Limitations involve the short-term follow-up, the likely underpowered sample for sexual outcomes, and the lack of randomization. A medium-term follow-up study is currently ongoing at our Institution.

5. Conclusions

Our study demonstrated that FMS is a safe and effective conservative option for SUI management in terms of objective and subjective cure rate. Moreover, we observed improvements in urinary-related quality of life scores and an increase in RS volume after FMS compared to baseline. Lastly, all these outcomes were significantly better compared to women who underwent PFMT.

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Informed Consent Statement: Informed consent was obtained from all subjects involved in the study.

Data Availability Statement: The data presented in this study are available on request from the corresponding author.

Conflicts of Interest: The authors declare no conflict of interest.

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Effects of magnetic stimulation in the treatment of pelvic floor dysfunction

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Abstract

OBJECTIVE

To correlate, in a pilot study, the clinical results of extracorporeal magnetic innervation therapy (ExMI) of the pelvic floor muscles with functional changes in the pelvic floor musculature, urodynamics and quality of life.

PATIENTS AND METHODS

In all, 74 patients (65 women and nine men) with urge incontinence, urgency/frequency, stress incontinence, mixed incontinence and defecation problems were included in a prospective study of ExMI using a ‘electromagnetic chair’. All patients were treated twice weekly for 8 weeks. Digital palpation and biofeedback with a vaginal or anal probe were used for registration of the pelvic floor musculature. A urodynamic evaluation, a voiding diary, a pad-test, the King's Health Questionnaire (KHQ) and a visual analogue scale (VAS) were completed by the patient at baseline and at the end of the study.

RESULTS

In the group as a whole, there were no significant differences in the voiding diary, pad-test, quality of life, VAS score, biofeedback registration and urodynamics before and after treatment. Additional stratification was applied to the total patient group, related to the pretreatment rest tone of the pelvic floor, the basal amplitude registered on electromyography, to age and to previous treatments. However, there were no significant differences in the data before and after treatment within all subgroups (stress incontinence, urge incontinence, urgency/frequency, defecation problems, overactive pelvic floor, age, previous treatments), except for the KHQ domain of ‘role limitations’, where there was a significant improvement in all groups.

CONCLUSION

ExMI did not change pelvic floor function in the present patients. The varying outcomes of several studies on ExMI stress the need for critical studies on the effect and the mode of action of electrostimulation and magnetic stimulation. In our opinion ‘the chair’ is suitable to train awareness of the location of the pelvic floor. However, active pelvic floor muscle exercises remain essential.

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ORIGINAL ARTICLE

Effects of magnetic stimulation on urodynamic stress incontinence refractory to pelvic floor muscle training in a randomized sham-controlled study

Tomonori Yamanishi, Tsuneki Suzuki, Ryo Sato, Kanya Kaga, Mayuko Kaga, Miki Fuse

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Abstract

Objective

The aim of the present study was to evaluate the effect of magnetic stimulation on urodynamic stress incontinence refractory to pelvic floor muscle training in a randomized sham-controlled study.

Methods

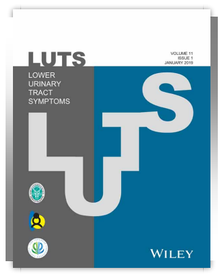
Female patients with urodynamic stress incontinence who had not been cured by pelvic floor muscle training were randomly assigned at a ratio of 2:1 to either active treatment or sham treatment for 10 weeks. The randomization was made using magnetic cards for individuals indicating active or sham stimulation. The primary endpoint was changes in the number of incontinence episodes/week, with secondary endpoints of the degree of incontinence (in g/day; determined using the pad test), the total score on the International Consultation on Incontinence Questionnaire – Short Form (ICIQ-SF), the ICIQ quality of life (QOL) score, and the abdominal leak point pressure (ALPP) on urodynamic study.

Results

Although 39 patients were enrolled in the study, 9 dropped out, leaving a total patients for analysis (18 in the active treatment group, 12 in the sham treatment group). The number of incontinence episodes/week, the degree of incontinence, total ICIQ-SF score, ICIQ-QOL score, and ALPP were significantly improved after active treatment compared with baseline (all $P < .05$), but did not change significantly after sham treatment. There was a significant intergroup difference with regard to changes from baseline in the ICIQ-SF and ALPP in favor of the active treatment group ($P < .05$). There were no significant differences in any other parameters between the 2 groups. Treatment-related adverse events were not found in both groups.

Conclusion

Magnetic stimulation was effective in treating urodynamic stress incontinence.



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Article

Flat Magnetic Stimulation for Stress Urinary Incontinence: A 3-Month Follow-Up Study

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Article

Flat Magnetic Stimulation for Stress Urinary Incontinence: A 3-Month Follow-Up Study

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Abstract: Background: flat magnetic stimulation is based on a stimulation produced by electromagnetic fields with a homogenous profile. Patients with stress urinary incontinence (SUI) can take advantage of this treatment. We aimed to evaluate medium-term subjective, objective, and quality-of-life outcomes in patients with stress urinary incontinence to evaluate possible maintenance schedules. Methods: a prospective evaluation through the administration of the International Consultation on Incontinence Questionnaire-Short Form (ICIQ-SF), the Incontinence Impact Questionnaire (IIQ7), and the Female Sexual Function Index (FSFI) was performed at three different time points: at the baseline (T0), at the end of treatment (T1), and at 3-month follow-up (T2). The stress test and the Patient Global Impression of Improvement questionnaire (PGI-I) defined objective and subjective outcomes, respectively. Results: 25 consecutive patients were enrolled. A statistically significant reduction in the IIQ7 and ICIQ-SF scores was noticed at T1 returned to levels comparable to the baseline at T2. However, objective improvement remained significant even at a 3-month follow-up. Moreover, the PGI-I scores at T1 and T2 were comparable, demonstrating stable subjective satisfaction. Conclusion: despite a certain persistence of the objective and subjective continence improvement, the urinary-related quality of life decreases and returns to baseline values three months after the end of flat magnetic stimulation. These findings indicate that a further cycle of treatment is probably indicated after 3 months since benefits are only partially maintained after this timespan.

Keywords: quality of life; stress urinary incontinence; magnetic stimulation; pelvic floor disorders

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1. Introduction

Pelvic floor disorders include a series of diseases associated with pelvic floor weakening, which involve bowel, urinary, supports, and sexual dysfunctions [1]. Obstetric trauma is considered the primary damage to the pelvic floor giving the predisposition to develop pelvic floor disorders [2]. However, changes in the composition and enzymatic activity in the connective tissue play a role in the genesis of pelvic floor disorders [3]. Some of these changes in the collagenic patterns have been related to the menopausal decrease in estrogen [4]. Since pelvic floor disorders share risk factors, specific conditions may coexist, recur, or evolve into others as a consequence of treatment, such as surgery [5,6]. For instance, overactive bladder symptoms tend to improve after prolapse repair but may worsen if a suburethral tape is positioned at the time of surgery [7].

Stress urinary incontinence (SUI) represents one of the most common and bothersome pelvic floor disorders. Almost 50% of women in developed countries are estimated to be affected, and the lifetime risk of undergoing surgery is about 4% [8,9]. SUI is characterized by involuntary leakage of urine when the intra-abdominal pressure increases more than the urethral closure pressure such as during coughing, effort, or sneezing [10]. Pathogenetic

mechanisms involve injuries to the connective tissue of the urethra, leading to urethral hypermobility and intrinsic urethral deficiency [11]. In addition, stress urinary incontinence may also occur (or persist) after pelvic floor surgery [12,13]. Stress urinary incontinence negatively affects women's quality of life in terms of social, domestic, and psychophysical well-being, with a negative effect on sexual function [14]. Urinary incontinence can reduce the opportunity to be part of intimate relationships, socialize, or the ability to perform daily activities [15]. SUI diagnosis and management need great expertise to approach the intimate sphere of patients who are unable to express themselves autonomously. During the visit, the gynecologist must be able to discuss any concerns and assess any problems related to the quality of life and sexual well-being [16].

Urodynamics may be useful to confirm the diagnosis since clinical and instrumental findings poorly agree in the evaluation of bladder dysfunction [17,18]. However, its diagnostic importance in the work-up of urinary incontinence is currently debated due to differences in performance and adopted definitions [19,20]. Stress urinary incontinence management involves both surgical and conservative treatments based on the patient's will, comorbidities, and quality-of-life impairment. According to the guidelines, conservative measures are considered the first-line choice, while surgical treatment is usually considered after the failure of conservative management. Different surgical options can be proposed for the treatment of SUI, such as anterior compartment repairs, bladder neck suspensions, midurethral slings, and injections [21–25]. To date, midurethral slings are considered the first option because of their high efficacy rates [26]. Retropubic tapes were introduced in 1995 and became the gold standard for SUI treatment [27]. To reduce the complications associated with the blind passage of needles in the retropubic space, the transobturator approach was developed in 2001 [28]. Finally, single-incision slings (SISs) were introduced in 2006. Their novelties were the shorter tape length and the limited intracorporeal dissection, avoiding the passage of tape and trocars through the obturator foramen, adductor tendons, and skin [24]. However, all surgical procedures have pitfalls, including visceral injuries, chronic pelvic pain, de novo bladder voiding dysfunctions, and overactive bladder symptoms [29,30]. As a consequence, conservative strategies should be preferred when possible. Options are represented by lifestyle modifications, pelvic floor exercises, electrical stimulations, biofeedback, and energy-based treatments [31].

An optional treatment for the treatment of stress urinary incontinence is represented by magnetic stimulation. Magnetic stimulators are extracorporeal devices that generate a specific electromagnetic field that interacts with pelvic floor neuromuscular tissue inducing intense muscular contractions and regulating neuromuscular control. Previous studies investigating magnetic stimulation for the treatment of female SUIs demonstrated a certain efficacy [32]. Specifically, systematic reviews and meta-analyses show significant improvements in quality-of-life questionnaires related to urinary incontinence [32,33]. In recent years, technological advancements have improved magnetic stimulator devices. One of them is represented by flat magnetic stimulation. This is characterized by homogeneous electromagnetic fields able to treat the entire pelvic area. In fact, this new magnetic field generates an equal distribution and intensity of stimulation. Consequently, flat magnetic stimulation allows for a large activation of muscle fibers without leaving areas of inconstant/suboptimal recruitment. This is thought to be associated with enhanced efficacy compared with standard magnetic stimulation treatment. The efficacy of this conservative treatment comes from the use of electromagnetic energy, the deep penetration of the waves, and the global stimulation of the pelvic floor. The magnetic field, through electrical tissue currents, induces changes in muscular contraction and allows neurons depolarization and blood supply enhancement. These modifications induce muscle fiber hypertrophy and hyperplasia due to more efficient stimulation. A previous experience has demonstrated the muscle hypertrophy of the urethral rhabdosphincter after flat magnetic stimulation, which has an established role in maintaining stress urinary continence. Similarly, preliminary reports of this new treatment option demonstrate exciting results in terms of quality-of-life

improvements, but medium-term data, as well as optimal maintenance treatment schedules, are still unknown [34].

Consequently, the aim of our study is to analyze medium-term outcomes in patients with stress urinary incontinence undergoing flat magnetic stimulation in terms of objective and subjective cure rate and quality-of-life improvement and evaluate possible maintenance schedules.

2. Materials and Methods

This was a prospective interventional study. Recruitment occurred from August 2022 to September 2022 in the gynecologic outpatients at IRCCS San Gerardo dei Tintori Foundation in Monza, Italy. During the period of the study, a patient clinical interview to investigate the presence of lower urinary tract symptoms, such as urge urinary incontinence (UUI), stress urinary incontinence (SUI), overactive bladder (OAB), voiding symptoms (VS), or prolapse symptoms or anal incontinence was performed. All definitions conformed to IUGA/ICS terminology [10]. A gynecological examination was performed and, in case of prolapse, it was staged according to the POP-Q system.

Non-pregnant patients older than 18 years were included in the study if they had isolated SUI without surgical indication, confirmed with a standard 300 mL positive stress test. Exclusion criteria were a history of neoplasia, arrhythmia, congestive heart failure, recent deep venous thrombosis, fever, acute inflammatory diseases, or fractures in the area of treatment. Moreover, women with insufficient Italian language proficiency, a weight of more than 160 kg, neurostimulators, pacemakers, defibrillators, or ferromagnetic prostheses were excluded, as previously stated [J]. At the baseline (T0), the International Consultation on Incontinence Questionnaire-Short Form questionnaire (ICIQ-SF), the Female Sexual Function Index (FSFI-19) questionnaire, and the Incontinence Impact Questionnaire (IIQ-7) [35–37] were submitted and completed by all patients.

The ICIQ-SF questionnaire has been validated to measure the severity, frequency, and impact of urinary incontinence on quality of life [35]. The tool includes four questions, with the first three determining the total score: the leakage frequency, the perceived amount of leakage, and the level of impact on daily life [35]. The last item does not concur with the total score and is aimed to self-define the sub-type of incontinence [35]. This questionnaire showed high levels of validity, reliability, and sensitivity, and these parameters were evaluated through the use of standard psychometric tests [35]. The FSFI-19 questionnaire is a self-reported tool consisting of 19 items with a 5-point Likert scale addressing 6 domains of sexual function, including desire, lubrication, arousal, orgasm, pain, and satisfaction [36]. This instrument has consistently demonstrated satisfactory psychometric properties in evaluating the impact of several conditions on sexual well-being and the efficacy of different treatments [36]. Consequently, to investigate female sexual dysfunction at the baseline and after therapies, FSFI-19 represents one of the most valid, useful, popular, and powerful diagnostic tools [36]. For differentiating patients with and without sexual disorders, a cut-off of 26.5 points has been proposed to be the optimal [36]. The IIQ-7 questionnaire was introduced to investigate the impact of urinary incontinence on women's daily life [37]. The questionnaire consists of seven items with the aim to evaluate the perceived feelings and impact of urinary incontinence on daily life and relationships [37]. Each item has four answers that participants use to individually self-evaluate the impact of urine leakage on daily activities in four domains: physical activity (items #1 and #2), travel (items #3 and #4), social activities (item #5), and emotional health (items #6 and #7) [37]. Based on psychometric tests, across different countries and cultures, this tool was associated with an excellent level of validity, acceptability, and reliability [37].

After proper counseling, patients underwent flat magnetic stimulation with Dr. Arnold (DEKA, Calenzano, Italy) according to the following protocol: eight sessions (twice a week) of 25 min each, using the "Weakness 1" protocol from sessions 1 to 4 and the "Weakness 2" protocol from sessions 5 to 8. The "Weakness 1" protocol involves a primary warm-up phase and muscle activation and a second phase of muscle work based on recovering

tropism and muscle tone (20–30 Hz) in a trapezoidal shape. The "Weakness 2" protocol involves a warm-up and muscle activation phase followed by muscle work with the aim of increasing tropism (volume), and a muscle strength phase (40–50 Hz) in a trapezoidal shape.

At the end of the treatment (T1), a 300 mL stress test was required to assess the objective cure rate, and patients compiled again the ICIQ-SF, IIQ-7, and FSFI-19 questionnaires. The subjective cure rate was evaluated through the results from the Patient Global Impression of Improvement (PGI-I) questionnaire [38]. The PGI-I questionnaire is a 7-point scale that ensures the clinician can assess how much the patient's disease has improved or worsened compared to a baseline state collected at the beginning of the treatment. This scale is described as follows: 1, very much improved; 2, much improved; 3, minimally improved; 4, no change; 5, minimally worse; 6, much worse; and 7, very much worse [38]. Subjective success was defined as an improvement in the PGI-I score ($\leq$3). Three months after the end of the treatment (T2), the ICIQ-SF, IIQ-7, FSFI-19, and PGI-I questionnaires were resubmitted to the patients, and the stress test was repeated.

The local Ethics Committee approval was obtained (protocol code PF-MAGCHAIR). The scores obtained from the questionnaires were described as the median and interquartile range (IQR) after the failure of the normality check and were performed by using the Shapiro–Wilk test. Friedman's non-parametric test [39] for repeated measures was then used to compare the IIQ-7, ICIQ-SF, and FSFI-19 questionnaire scores, as the small sample size did not allow obtaining normally distributed continuous variables, even after data transformation according to Blom's method [40]. Durbin–Conover pairwise comparisons were used to check for significant differences between the three moments of data collection; this method was preferred over the classic Durbin test to maximize statistical power [41]. Prior to comparing the scores obtained throughout the study, we used the Mann–Whitney U test to check if relevant covariates such as body mass index, number of deliveries, and age produced any statistically significant differences in baseline scores. Confidence intervals for binomial proportions were calculated according to the methods suggested by Ross [42]. Significant differences between proportions were checked by using McNemar's test, as the data came from repeated measures [43]. The significance threshold was established at 0.05 for all calculations; the analysis was conducted with R 4.1 (the R Core Team, Vienna, Austria, 2021) for MacOS®.

3. Results

Our study enrolled a total of 25 consecutive patients. Population characteristics are shown in Table 1. Baseline IIQ7 and ICIQ-SF scores were comparable by age, body mass index, and the number of deliveries ($p > 0.05$ for all calculations) as most women had normal weight (Me = 25.2, IQR = 3.10, eleven overweight and one obese with BMI = 31.8 kg/m^2), and there was only one nulliparous in the sample. Baseline FSFI-19 scores showed a significant, albeit weak, correlation with age (rho = -0.411, $p = 0.041$) and BMI (rho = -0.473, $p = 0.017$). These two variables were, therefore, considered as covariates in the analyses regarding sexual function scores, while all other analyses were unadjusted. No women reported adverse effects during the treatment. Outcome measures of objective, subjective, and quality-of-life questionnaires at the baseline (T0), end of treatment (T1), and 3-month follow-up (T2) are summarized in Table 2. After the treatment, the decrease in the IIQ7 scores (bothersome level of leakages) was statistically significant compared to the baseline ($p < 0.001$), thus supporting the clinical usefulness of this treatment. However, at the three-months follow-up evaluation, the IIQ7 scores showed a statistically significant increase ($p = 0.005$), thus returning to levels comparable to the baseline condition of the patients ($p = 0.135$). Similarly, at the end of the treatment, we observed a statistically significant decrease in the ICIQ-SF scores compared to the baseline ($p = 0.002$). However, the ICIQ-SF values also increased significantly after three months from the end of the sessions, becoming comparable to bothersome baseline levels. Regarding sexual function, the differences observed in the conditions reported by the patients through the FSFI-19 questionnaire did not reach statistical significance, neither between the scores before treatment and at the end

of the sessions nor between the latter and those obtained three months after the end of the rehabilitation program. Regarding the overall perception of improvement reported by the women, the PGI-I scores reported no statistically significant differences ($p = 0.564$) three months after the end of treatment (T2) compared to those obtained at the end of the sessions (T1) even after adjusting the analysis for overweight or obesity and the number of deliveries. With respect to objective outcomes, at the end of the rehabilitation program (T1), the number of women with negative stress tests was 10 out of 25 (40.0%). After three months (T2) 5 out of 25 (20.0%) patients maintained this result (proportion difference = −0.200, 95%CI = [−0.4225; 0.0533]), as shown in Tables 2 and 3, and this decrease was statistically significant ($p = 0.025$).

Table 1. Population characteristics and baseline (T0) findings. Continuous data as mean ± standard deviation. ICIQ-SF: International Consultation on Incontinence Questionnaire-Short Form questionnaire; FSFI-19: Female Sexual Function Index questionnaire; IIQ-7: Incontinence Impact Questionnaire.

Age (years)	60.9 ± 12.7
Parity (n)	1.9 ± 0.7
BMI (kg/m^2)	25.4 ± 3.0
IIQ-7 score (T0)	33.7 ± 22.6
ICIQ-SF score (T0)	11.2 ± 3.6
FSFI-19 score (T0)	12.5 ± 11.2

Table 2. Outcome measures of objective, subjective, and quality-of-life questionnaires at the baseline (T0), end of treatment (T1), and 3-month follow-up (T2). Data are reported as median and interquartile range except for stress test proportion expressed as absolute (relative) frequencies. ICIQ-SF: International Consultation on Incontinence Questionnaire-Short Form questionnaire; FSFI-19: Female Sexual Function Index questionnaire; IIQ-7: Incontinence Impact Questionnaire; PGI-I: Patient Global Impression of Improvement questionnaire.

Questionnaire	**Baseline**	**End of Treatment**	**3-Month Follow-Up**
IIQ-7	33.00 (38.50)	16.50 (11.00)	22.00 (22.00)
ICIQ-SF	12.00 (4.00)	8.00 (6.00)	10.00 (5.00)
FSFI-19	7.80 (22.80)	6.70 (22.30)	6.00 (22.20)
PGI-I	N/a	3.00 (2.00)	3.00 (2.00)
Positive stress test	25 (100%)	15 (60%)	20 (80%)

Table 3. IIQ-7, ICIQ-SF, FSFI-19, and PGI-I scores and positive stress test rates comparisons among the endpoints of the study: the baseline (T0), end of treatment (T1), and 3-month follow-up (T2). *P*-values are provided. Durbin–Conover pairwise comparisons were performed to check for significant differences between the three moments of data collection. ICIQ-SF: International Consultation on Incontinence Questionnaire-Short Form questionnaire; FSFI-19: Female Sexual Function Index questionnaire; IIQ-7: Incontinence Impact Questionnaire; PGI-I: Patient Global Impression of Improvement questionnaire. N/A. not applicable. In bold statistically significant results.

	T0 vs. T1	**T1 vs. T2**	**T0 vs. T2**
IIQ-7	**<0.001**	**0.005**	0.135
ICIQ-SF	**0.002**	**0.034**	0.247

Table 3. *Cont.*

	T0 vs. T1	T1 vs. T2	T0 vs. T2
FSFI-19	0.394	0.495	0.864
PGI-I	N/A	0.564	N/A
Positive stress test	**0.001**	**0.025**	**0.025**

4. Discussion

International guidelines recommend, as the first-line treatment for SUI, conservative management. Among all conservative treatment options including PFMT, functional electrical stimulation, and biofeedback, MS offers some advantages. Concerning PFMT, patients may not be able to recruit, contract, and adequately train the pelvic floor muscle thus reducing its effectiveness and consistency over time [44]. As a consequence, patients who underwent PFMT may show reduced compliance and adherence rates and notice a slow progression of the improvements [45]. Due to the use of endocavitary devices, both functional electrical stimulation and biofeedback can be badly tolerated or even not possible due to impaired vaginal habitability, such as in the case of lichen sclerosis, previous surgery, or radiation. Moreover, mild local discomfort and side effects may cause treatment discontinuation in up to 12% of patients [46]. On the contrary, MS is a type of passive rehabilitation with no adverse effects described, which does not involve endocavitary probes, and patients stay dressed. Moreover, unlike the electrical current, tissue impedance does not affect the conduction of electromagnetic energy. With all these aspects, MS can be defined as a non-invasive, standardizable, and safe conservative treatment option for urinary incontinence management. In particular, the latest innovation in magnetic stimulation technology is represented by flat magnetic stimulation technology. Flat magnetic stimulation induces strong muscle contractions through the induction of electrical currents in the context of pelvic floor neuromuscular tissue. This, consequently, induces more efficient muscle fiber hypertrophy and hyperplasia, changing the muscle's structure. The hypertrophic effect of this technology on the skeletal muscles has been previously demonstrated. Leone et al. evaluated the impact of flat magnetic stimulation on the abdomens of 15 patients, demonstrating 1 month after the last treatment an increase in the abdominal muscle tissue thickness in the treated areas (lateral, upper, and lower abdomen) ranging from +14% to +23% [47]. Similarly, a significant (+15.4%) hypertrophy of the external urethral sphincter has been demonstrated in female patients with stress urinary incontinence [34]. However, the duration of this benefit and the optimal maintenance treatment schedule are still unknown.

For the first time, our study prospectively compared short- and medium-term outcomes of flat magnetic stimulation in patients with stress urinary incontinence. We found that, despite a certain persistence of the objective and subjective continence improvement, urinary-related quality-of-life tends to return to baseline values three months after treatment. Among the quality-of-life outcomes, a statistically significant reduction in the IIQ7 scores (a bothersome number of leakages) was observed after the treatment compared to the baseline but the IIQ7 scores significantly increased ($p = 0.005$), returning to levels comparable to the baseline condition at three months follow-up. Similarly, a statistically significant reduction in the ICIQ-SF scores at the end of the treatment compared to the baseline was followed by a significant increase in the ICIQ-SF values after three months from the end of the sessions, becoming comparable to the baseline. The subjective outcome evaluated by the PGI-I score showed no statistically significant differences ($p = 0.564$) three months after the end of treatment (T2) compared to the end of the sessions (T1), even after adjusting the analysis for overweight or obesity and the number of deliveries. In addition, after three months (T2), 5 out of 25 (20.0%) patients maintained a negative stress test compared to 10 out of 25 (40%) at the end of the rehabilitation program (T1). These findings indicate that a further eight-session cycle of treatment is probably indicated after 3 months since benefits are only partially still present at this time point.

To date, few pieces of evidence are available about the role of flat magnetic stimulation in the treatment of SUI, and there are none about the maintenance schedule. Lopopolo et al. evaluated improvement in the quality of life in 50 female patients with mixed urinary incontinence [48]. All patients underwent six sessions (twice a week) of 28 min each of Dr. ARNOLD magnetic stimulation. The first two minutes of warm-up were followed by the two protocols, Hypotonus/Weakness 1 and Hypotonus/Weakness 2. The ICIQ-UI-SF questionnaire, the Incontinence Questionnaire Overactive Bladder Module (ICIQ-OAB), and the IIQ-7 questionnaire were compiled at the baseline, during the treatment, and after three months. Quality of life improved from the second treatment session to the last one by 91%, 86%, and 98% according to the ICIQ-UI-SF, ICIQ-OAB, and IIQ-7 respectively. After three months, a small increase in scores was noticed, and the scores were better compared to the baseline; this can be probably explained by the return to a physiological hypotonus in the absence of long-term exercise.

Another study by Biondo et al. analyzed eighty-one female patients with urinary incontinence to evaluate the safety and the effectiveness of flat magnetic stimulation [49]. Women were divided into two groups: group A included 35 female patients who met the criteria for stress urinary incontinence, while group B enrolled 46 women with urge urinary incontinence. All patients underwent eight sessions of treatment for 28 min each twice a week for 4 straight weeks with the DR. ARNOLD system. Firstly, all patients started with a short warm-up phase followed by four sessions with the Hypotonus/Weakness 1 protocol and four sessions with the Hypotonus/Weakness 2 protocol for group A. There were eight sessions with the Overtone/Pain protocol (muscle work aimed at muscle inhibition) for group B.

Two questionnaires were completed before each treatment and at 3 months follow-up. The ICIQ-OAB questionnaire was compiled by the patients in group B, while the IIQ-7 questionnaire was assigned and filled out by the patients of group A. According to questionnaire results, there was an improvement in urge and stress urinary incontinence symptoms at the baseline and after treatment sessions at 3 months follow-up [49].

While specific data about the loss of hypertrophy on pelvic floor muscles due to detraining are not available, some studies have examined the effects of detraining on other muscles. In athletes' hearts, the regression of the physiological left ventricular hypertrophy seems to occur already during the first month of detraining, with no further reduction between 1 and 3 months [50]. Regarding skeletal muscles, Narici et al. found a decrease of 4% in the muscle cross-sectional area (CSA) after a period of 40 days of detraining in the quadriceps muscles [51]. Similarly, Psillander et al. aimed to determine if a previously strength-trained leg would respond better to a period of strength training than a previously untrained leg, hypothesizing that the trained leg would have an enhanced hypertrophic response and an increased number of myonuclei compared with the untrained leg. Using muscle biopsies and ultrasounds, they showed that the increase in muscle thickness seen during the training period was completely lost after a 20-week period of detraining, but a relatively large increase in muscle thickness was observed during retraining in both the trained leg and the untrained leg (~10%) [52]. These findings are consistent with our study, which enlightens the necessity of performing retraining after a few months from the first stimulation to maintain the benefits in the long term. From the point of view of physiology, as reported by Terzoni et al., in a previous study on magnetic innervation, the lack of persistence of the results obtained with this rehabilitation method can be explained by the fact that, if no maintenance exercises are performed after the end of the stimulation program, muscular performance can rapidly decrease due to lack of exercise [53].

To date, this is the first study on women with stress urinary incontinence comparing short- and medium-term data about flat magnetic stimulation treatment to try to define an optimal maintenance schedule. Other strengths involve the prospective design and the multimodal evaluation of benefits, including objective cure rate, subjective impression of improvements, and multiple validated quality-of-life questionnaires. A limitation is the small sample size analyzed. Future research can include the evaluation of flat magnetic

stimulation benefits in a larger population study compared to a control group. Another reasonable purpose would be to collect data after a prolonged period of observation, maybe after further sessions of treatment.

5. Conclusions

Our analysis concluded that flat magnetic stimulation represents a safe and effective stress urinary incontinence's conservative treatment in terms of incontinence cure rate and quality-of-life improvement. However, despite a certain persistence of the objective and subjective continence improvement, the benefit in terms of quality of life tends to return to baseline values three months after the end of the treatment. These findings indicate that probably, after 3 months, a further cycle of treatment is indicated since benefits are only partially maintained after this timespan.

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Pelvic Floor Muscle Training for Urinary Incontinence with or without Biofeedback or Electrostimulation in Women: A Systematic Review

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Abstract: To determine the effectiveness of pelvic floor muscle training (PFMT) with or without biofeedback or electrostimulation in reducing urinary incontinence and pelvic floor muscle contraction in non-pregnant women with urinary incontinence. Methods: The following electronic databases were searched: PubMed, Cochrane Central, ClinicalTrials.gov, EU Clinical Trials Register, and sources from NICE, FDA, EMA, and SMC (articles only in English, 2000–2021). Search terms were: urinary incontinence, pelvic floor muscle training or exercises, biofeedback, electrostimulation. We used the PRISMA statement (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) for this systematic review. Relevant articles were selected, data were extracted, and quality was assessed. Data were extracted in predesigned form, followed by narrative synthesis. Results: Following the search, 15 RCTs were retrieved using the strict inclusion and exclusion criteria, assessing 2441 non-pregnant women with urinary incontinence. Of the 15 studies, 7 were low risk, 5 were medium risk, and 3 were high-risk studies. Of the 2441 patients, 970 were in PFMT, 69 were in extracorporeal magnetic innervation (ExMi) or with PFMT + BF, 30 were in electrostimulation (ES), 21 were in whole body vibration training (WBVT), 23 were in pelvic floor muscle + abdominal muscle therapy (PFM + AMT), 326 were in PFMT + biofeedback, 93 were in vaginal cones (VC), 362 were in PFMT + education, 318 were in education, and 229 were in control groups. The most often measures employed were pad tests, bladder diary, and questionnaire on the quality of life. Stress, urge and mixed urinary incontinence were studied. In all RCT, PFMT significantly reduced urinary incontinence, essentially SIU and MUI, when compared with the control group before and after treatment. Overall, out of 997 PFMT or PFMT + education patients, 504 patients (50.5%) showed improvement in urinary incontinence, and 218 became continent (21.8%) (negative pad test). In total, 62% of patients significantly reduced their urinary incontinence or cured it and improved their pelvic floor muscle contraction. All other physiotherapist techniques also significantly reduced urinary leakages, e.g., vaginal cones, biofeedback, ExMI, and WBVT when compared with the control group. There were no significant differences between these methods in reducing the severity of urinary incontinence. Conclusion: PFMT alone or with bio-feedback or electrostimulation was effective in reducing urinary incontinence and improving pelvic floor muscle contraction. PFMT when compared with other interventions such as bio-feedback, VC, and WBVT did not show significant differences but was superior to the control group. RCT studies with similar parameters used for measuring the outcomes need to be included.

Keywords: pelvic floor muscle training; urinary incontinence; non-pregnant; biofeedback; electrostimulation; extracorporeal magnetic innervation; vaginal cones; whole body vibration training; stress urinary incontinence; mixed urinary incontinence

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1. Introduction

Urinary incontinence (UI) is defined as involuntary leakage of urine through the urethra by the International Continence Society (ICS) [1]. It is considered to be a health, social, and hygienic concern. UI affects 6–10% of the population [1]. UI maybe divided into three subtypes: stress urinary incontinence (SUI), urge urinary incontinence (UUI), and mixed urinary incontinence (MUI) based on behavioral symptoms and pathophysiology [1,2]. Stress urinary incontinence (SIU) is the common type of UI among women. SUI occurs during efforts such as sneezing, coughing, or exertion. It is found in either pure or mixed form in one-third of women [3]. SUI is caused due to a lack of strength in the urethral sphincter muscles, pelvic floor muscles, connective tissues, and fasciae [4].

Urge incontinence is defined by urinary leakage following a sudden and strong desire to urinate [3]. The combination of SIU and UUI is referred to as mixed urinary incontinence. Around 25–45% of all women suffer from involuntary urine loss at some stage in their lives, thus making UI one of the most frequent complaints in this population [5]. Non-pregnant or prepartum women were less likely to suffer from UI compared with postpartum women. However, in the last few decades, there has been an increase in the number of women experiencing incontinence among non-pregnant or prepartum women. Currently, the importance of prevention and treatment of UI has grown. Hence, increased attention has been given to conservative treatments for UI.

Conservative management of UI has been recognized as the first-line management, which includes physical therapies, behavior modification, and pharmacological intervention, specifically for SUI [2]. Some examples of conservative treatments that are used in the management of UI are physical therapies and pelvic floor muscle training (PFMT) alone or combined with other treatments—for example, electrical stimulation, biofeedback, and vaginal cones. These are the standard management procedures [3]. Pelvic floor muscle training (PFMT) is considered as the first-line treatment, as suggested by the International Continence Society (ICS), and it has been proven to guarantee results for UI. Guided PFMT also improves adherence positively and promotes self-efficacy behavior among the participants [4]. PFMT provides support to the pelvic organs and helps in the closure of the urethral sphincter muscles, thus resulting in improvement in incontinence. Hence, it is prescribed for increasing strength, endurance, and muscle coordination [6,7]. Previously, many authors have performed various reviews regarding the implications, causes, and treatments for UI, but no systematic review has been performed in measuring the efficacy of PFMT among non-pregnant women.

This review focused on analyzing the efficacy of pelvic floor muscle training in the treatment of UI and its effect on the improvement in muscle strength and endurance among non-pregnant women.

2. Material and Method

This systematic review was carried out according to the pre-specified PRISMA protocol that was implemented before initiation of the study. The protocol was followed throughout the process of study selection, data extraction, quality assessment, and data synthesis.

2.1. Search Strategy

The following databases (PubMed, Cochrane Central, ClinicalTrials.gov, EU Clinical Trials Register), grey literature sources (NICE, FDA, EMA, SMC), and snowballing search were conducted by using Boolean operators and limiting the search strategy to only articles published in English from the 1 January 2000 to the 1 March 2021. The search strategy used was as follows: (pelvic floor muscle therapy) OR (pelvic floor muscle physiotherapy) OR (pelvic floor muscle exercise) OR (pelvic muscle physiotherapy) OR (pelvic muscle therapy) OR (pelvic muscle exercise) OR (pelvic muscle physical therapy) OR (pelvic floor muscle physical therapy) OR (pelvic floor muscle training) OR (PFMT) OR (pelvic muscle training) OR (pelvic floor muscle electrostimulation) OR (pelvic muscle electrostimulation) OR (pelvic floor muscle electrical stimulation) OR (pelvic muscle electrical stimulation)

OR (pelvic floor muscle training) OR (PFMT) OR (pelvic muscle training) OR (pelvic floor muscle electrostimulation) OR (pelvic muscle electrostimulation) OR (pelvic floor muscle electrical stimulation) OR ("pelvic floor training" OR "pelvic floor muscle therapy" OR "PFMT") AND (urinary incontinence) OR AND (women OR female). The equivalent search keywords or the syntonic terms were used in other databases.

2.2. Study Selection and Criteria

Selection of studies was based on predesigned inclusion and exclusion criteria following the searches in relevant databases. Initially studies were identified based on screening of title and abstract, followed by full-text screening and including the final studies. Screening of the articles was conducted by two reviewers. The inclusion and exclusion criteria were based on the PICOS format (Table 1). The population criteria included only non-pregnant women patients suffering from UI. Post-surgical patients were excluded from the study. Intervention criteria included pelvic floor muscle training with or without biofeedback therapy with the exclusion of pharmacological interventions. The outcome of our interest included muscle strength, the endurance of PFM, UI and urinary leakage, and exclusion of another outcome. RCT studies were included, while the rest of all other types of experimental or analytical studies were excluded. A limitation was placed by including only English language studies published from the 1 January 2000 to 31 March 2021.

Table 1. Inclusion and exclusion criteria of the study.

Criteria	Inclusion	Exclusion
Population	Women/Female Mixed population Pre- and post-menopause women Postpartum women	Post-surgical patients Pregnant women Animal Male
Intervention	Physiotherapy Pelvic floor muscle training (PFMT) PFMT with electrostimulation	Other interventions Pharmacological interventions
Comparator	Any comparator Placebo	Pharmacological PFMT with pharmacological Pharmacological with electrostimulation
Outcome	Muscle strength Endurance Urinary incontinence Urinary leakage	Any other clinical or biochemical outcome
Study	RCT	Analytical study Non-randomized study Qualitative study Narrative review Laboratory study
Language	English	Non-English
Year	2000–Present	Before 2000

2.3. Data Extraction, Quality Assessment, Data Synthesis

Data extraction was performed in Microsoft Excel after reviewing all the final included studies. The data that were extracted from all the studies were the studies' first author, year of publication, study design, inclusion criteria, intervention groups sample size, drop out, study duration, study outcome. During data extraction, no authors were contacted. Quality assessment of the studies was carried out using, "The Cochrane risk of bias 2 tool". The quality of the studies was based on the following questions: randomization, deviation from interventions, missing outcome reporting, measuring the outcomes, and selective reporting

of outcomes. Based on the following questions, studies were marked as low, medium, or high risk of bias. Following the data extraction, narrative synthesis was performed. Heterogeneity tests and meta-analysis of the studies were not performed.

3. Results

Study Selection

After systematic retrieval, 264 articles were selected from 4411 citations after duplication removal, proper title, and abstract screening. Following this, full-text screening of 264 articles was performed, out of which 15 were finally included, as shown in Figure 1. Finally, 15 articles consisting of 2441 non-pregnant women who had UI were selected for analysis.

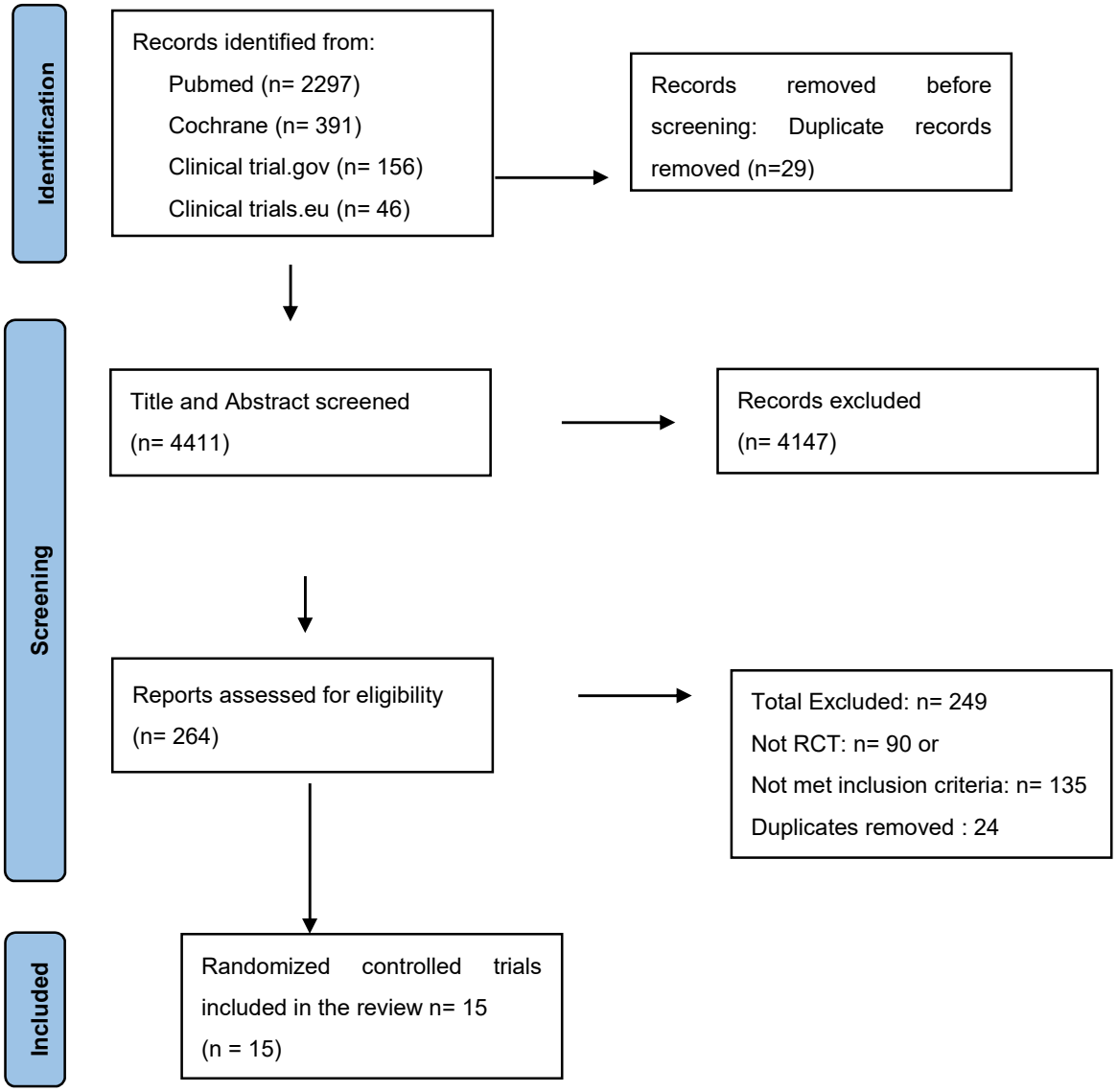

Figure 1. Study selection, flow diagram.

4. Narrative Synthesis

4.1. Study and Population Characteristics

In terms of study and participants characteristics, there was a lot of homogeneity across all the studies [1–16], as shown in Table 2. Among the 15 RCTs selected, 3 were performed in Brazil [3,5,8], 3 were performed in Canada [10,13,15], and 2 in Iran [7,9] while

the rest were performed in Poland [1], UK [11], Sweden [4], Bangladesh [14], Norway [12], Hong Kong [2], and Turkey [16].

Table 2. Study and population characteristic.

Study Name Authors	Country	Study Type	Inclusion Criteria	Sample Randomized	Intervention Groups (Sample Size)	Duration of Study	Study Outcome	Drop out
Gumussoy et al. [16] 20	Turkey	RCT	Women with SIU.	51	26 EMG-BF 25 EMG-BF + ExMI.	8 weeks	1 h pad test (grams of urine loss) 3-day bladder diary I Qol pelvic floor muscle contraction force measured via a perineometer and Modified Oxford Scale (MOS).	23
Dumoulin et al. [15] 2020	Canada	RCT	Stress or mixed UI in older women.	362	Group PFMT (178) vs. individual PFMT (184)	12 weeks 1-year follow-up	%reduction in UI episodes in 1 year I Qol	43
Weber-Razek et al. [1] 2020 [1]	Poland	RCT	Women patients with urinary incontinence.	128	PFMT (44) ExMI (44) Control (40)	4 weeks	Urinary incontinence, severity, QoL	17
Farzinmehr et al. [9] 2015	Iran	RCT	Women patients with 4.5-year history of urinary incontinence.	46	WBVT (24) PFMT (22)	3 months (13 weeks)	Urinary incontinence, severity, PFM strength	3
Chantale et al. 2004 [10]	Canada	RCT	Women patients exhibiting symptoms of stress urinary incontinence at least once per week for 3 months or more after their last delivery.	64	PFMT (21) PFM + AMT (23) Control (20)	8 weeks	PFM function, muscle strength, endurance, rapidity of contraction, urine leakage incontinence	2
Hagen et al. [11] 2020	UK	RCT	Women patients aged 18 years or older and newly presenting with clinically diagnosed stress or mixed urinary incontinence and urine leakage.	600	PFMT + Biofeedback (300) PFMT (300)	24 months (104 weeks)	Incontinence, severity, symptoms, QoL, endurance, PFM strength	7
Ahlund et al. [4]. 2013.	Sweden	RCT	Women patients having urinary incontinence after 10–16 weeks postpartum.	98	PFMT (49) Control (49)	6 months (26 weeks)	PFM strength, endurance, incontinence, symptoms, vaginal squeeze pressure	16
Castro et al. [3] 2008	Brazil	RCT	Women patients having had urodynamic stress incontinence of at least 3 stress incontinence episodes in a week.	118	PFMT (31) ES (30) VC (27) Control (30)	6 months (26 weeks)	QoL, urine leakage, urodynamic test	17
Jahromi et al. 2013 [7]	Iran	RCT	Women having Quid score for incontinence type (stress score $\geq$ 4, clinical symptoms of urinary incontinence within the last 6 months).	50	PFMT (25) Control (25)	2 months (8.5 weeks)	Urinary incontinency, urine leakage, self-esteem, QoL, self-esteem	2
Gameiro et al. [8] 2010	Brazil	RCT	Women patients having symptoms of SUI and urge incontinence.	103	VC (51) PFMT (51)	12 weeks	Urinary leakage, PFM contraction	0
Wagg et al. [14] 2019	Bangladesh	RCT	Women patients having current urinary incontinence, with a positive response of urinary leakage with urgency, stress, or drops of urine loss.	625	PFMT + Education (335) Education (290)	24 weeks	Urinary leakage	46
Bo et al. [12] 2000	Norway	RCT	Women patients having history of stress urinary incontinence and >4 g of urine leakage.	59	PFMT (29) Control (30)	6 months (26 weeks)	Incontinence, symptoms, QOL	6

Table 2. *Cont.*

Study Name Authors	Country	Study Type	Inclusion Criteria	Sample Randomized	Intervention Groups (Sample Size)	Duration of Study	Study Outcome	Drop out
McLean et al. [13] 2013	Canada	RCT	Women patients having symptoms of SUI with or without urge incontinence.	40	PFMT (20) Control (20)	12 weeks	Incontinence, urinary flow	5
Pereira et al. [5] 2013	Brazil	RCT	12-month post-menopausal women patients having at least one episode of SUI symptom.	45	PFMT (15) VC (15) Control (15)	12 months (52 weeks)	Urinary leakage, PFM strength, QoL	4
Leong et al. [2] 2015	Hong Kong	RCT	Women patients having a clinical diagnosis of SUI, UUI, or MUI.	55	PFMT + BT + Education (27) Education (28)	12 weeks	QoL incontinence episodes	0

(ExMi, extracorporeal magnetic innervation; WBVT, whole body vibration training; PFM + AMT, pelvic floor muscle + abdominal muscle therapy; PFMT, pelvic floor muscle therapy; ES, electrical stimulation; VC, vaginal cones).

Patients randomized across all the studies were 2441, of which dropout was 227, and 2214 patients completed the studies. The lowest drop-out rate was 2 in Dumoulin et al. [10], and the highest was in Wagg et al. [14]

Intervention groups across all the studies were PFMT, extracorporeal magnetic innervation (ExMi), whole body vibration training (WBVT), pelvic floor muscle + abdominal muscle therapy (PFM + AMT), PFMT + biofeedback, pelvic floor muscle therapy + electrical stimulation (PFMT + ES), vaginal cones (VC), PFMT + education, education, and control. Out of the 15 studies, 11 studies [2,4,7,9–11,13,15,16] comprised two intervention groups, while 3 studies [1,5,10] comprised three interventions groups, and 1 study [3] comprised 4 intervention groups. The total number of patients in the PFMT group was 970 [1,2,5,7,13,17,18], ExMi was 69 [1,16], WBVT was 21, PFM + AMT was 23, PFMT + biofeedback was 326 [11,18], VC was 93 [3,8], PFMT+ education was 318 [14], education was 290 [14], and control was 229 [1,3–5,7,10,12,13].

The most important inclusion criterion across all the studies was aged above 18 years suffering from UI. Pregnant women or women in the early postpartum period (before 10 weeks after delivery) were excluded from the study. Study duration among all the studies ranged from 4 weeks to 104 weeks. A total of 3 studies [3,4,12] had a study duration of 26 weeks, 4 studies [2,8,13,17] had a duration of 12 weeks, and 3 studies lasted 8 weeks [7,10,18]. The remaining 5 studies had a duration of 52 weeks [5], 24 weeks [14], 104 weeks [11], 13 weeks [9], and 4 weeks [1]. The most common outcomes collected across the 15 studies were UI, PFM strength, endurance, urinary leakage, QoL, symptoms, PFM activity or function, vaginal squeeze pressure, self-esteem, and urodynamic test.

4.2. Overall Quality and Risk of Bias Assessing of Studies

Quality assessment of the studies was conducted using the "Cochrane ROB2" tool, as shown in Figures 2 and 3 and Table 3. The studies were classified as at low risk of bias, some concerns, or high risk of bias. Overall, 7 studies [1,3–5,8,9,17] reported a low risk of bias, 3 studies [12,13] reported a high risk of bias, while the remaining 5 studies reported medium [2,10,11,14,18], or some risk of bias, as represented in Figure 3. Almost half of the studies had a low risk of bias in terms of the randomization process, missing outcome data, and selection of reported result, as shown in Figure 2. Around 76.9%, 69.2%, 84.6%, 61.5%, and 76.9% across all the studies reported low risk of bias in terms of the randomization process, deviation of intended interventions, missing outcome data, measurement of the outcome, and selection of the reported result, respectively. Only 20% across all the studies reported a high risk of bias in terms of measurement of the outcome.

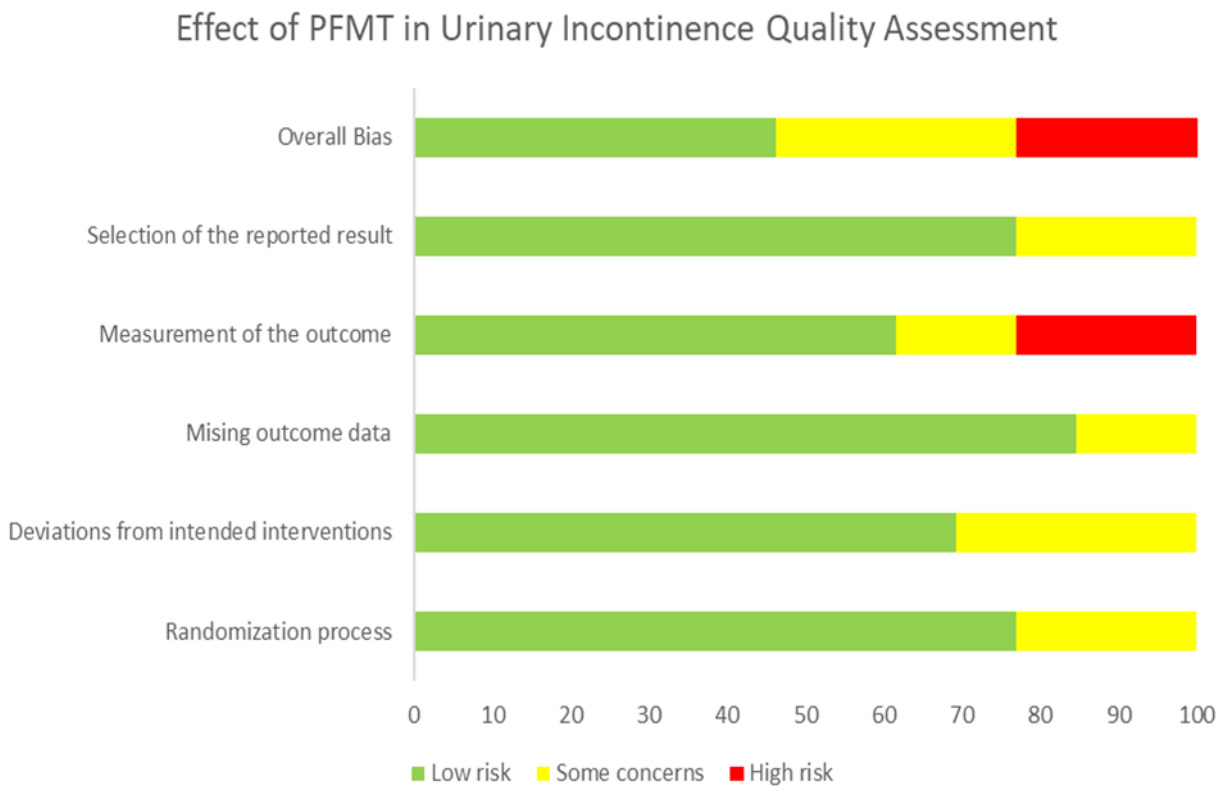

Figure 2. Risk of bias for studies as percentage.

Table 3. Study outcome.

Study Name	Scales Used for Measuring Outcomes	Risk of Bias	Age (Years)	Result for Muscle Contraction	Result for Endurance	Result for Urinary Incontinence
Gumussoy et al. [16] 2021	Pad test, 3-day bladder diary I Qol PFMC with a perineometer and Modified Oxford Scale	Some concern.	50.92 years (SD 8.88).	Pelvic floor muscle contraction force significantly increased in both groups.		Both groups achieved reductions in urine loss during treatment. -The rate of decrease in pad test values of the EMG-BF + ExMI group was higher. - Significant differences in the number of urinations on a daily basis (9 vs. 8 for the EMG-BF and 9 vs. 7 in the EMG − BF + ExMI group.
Dumoulin et al. [15] 2020	%reduction in UI episodes in 1 year, 7-day bladder diary Qol	Low risk.	Age, 67.9 [5.8] years			Significant reduction in leakage episode frequency at 12 weeks and 1 year for both groups' median percentage reduction in urinary incontinence episodes at 1 year of 70% in individual PFMT compared with a 74% reduction in group-based PFMT.
Weber-Razek et al. [1]	RUIS, KHQ	Low risk.	Mean (Range): 68.77 (45 to 78)			Statistical improvement in urinary incontinence severity in PFMT

Table 3. *Cont.*

Study Name	Scales Used for Measuring Outcomes	Risk of Bias	Age (Years)	Result for Muscle Contraction	Result for Endurance	Result for Urinary Incontinence
Farzinmehr et al. [9]	VAS, I-QOL	Low risk.	Range: 36 to 48	WBVT was effective in PFM strength similar to PFMT.		WBVT was effective in reducing the severity of incontinence similar to PFMT. Increasing I-QOL questionnaire score. No significant difference was observed between the WBVT and PFMT groups.
Dumoulin et al. [10]	Pad test, VAS, UDI, IIQ, pelvic floor muscle dynamometer	Some concern.	<45	No significant improvement was observed between the PFMT, PFM + AT, and control group.		Significant improvement was observed in the PFMT and PFM + AT group compared with control.
Hagen et al. [11]	ICIQ-UI SF, PGII	Some concern. No objective measure of urinary leakage.	Mean (SD) PFMT + Biofeedback: 48.2(11.6) PFMT: 47.3(11.4)	No significant difference was found between the PFMT + biofeedback (8.5%) and PFMT group (6%) at 6 months.		No clinical or significant difference was observed between PFMT + biofeedback and PFMT groups. 60% in the PFMT + biofeedback and 62.6% in the PFMT group reported improvement in symptoms at 24 months.
Ahlund et al. [4]	BFLUT Symptoms Module ICIQ FLUTS Perineometer OGS	Low risk both groups received instructions on how to contract PFM and, vaginal palpation.	Mean (SD) 33 (3.6)	Muscle strength: No statistically significant difference was observed between PFMT and Control group. However, a significant increase was observed from baseline in both groups.	No significant difference was observed between PFMT and Control groups. However, there was an increase in endurance from baseline in both groups.	Significant improvement was observed in both PFMT and control group from baseline.
Castro et al. [3]	Pad test I-QOL OGS	Low risk.	Mean ± SD PFMT: 56.2 ± 12.5 ES: 55.2 ± 12.8 VC: 52.6 ± 11.2 Control: 52.6 ± 11.2	Significant improvement was observed in the PFMT compared with the ES and VC groups.		Significant decrease in pad weight or improvement in urinary leakage in PFMT, ES, and VC group compared with control. However, no significant difference between ES, VC, and PFMT.
Jahromi et al. [7]	QUID ICIQ Self-esteem questionnaires	High risk.	60–74 years			Significant difference was observed between the PFMT and the control group for frequency of urine leakage.
Gameiro et al. [8]	VAS Pad test Perineometer	Low risk.	Mean VWC: 49 PFMT 48	No statistical difference Was observed between the VWC and PFMT group.		Significant improvement was observed from baseline in both the groups at 6 months but not at 12 months. NS difference between the VWC and PFMT group.
Wagg et al. [14]	EuroQoL Questionnaire EQ5D	Some concern.	Mean (SD) PFMT + Education: 64.5 (4.2) Education: 64.7 (4.1)			A significant decrease in leakage was observed in the PFMT + education group compared with the only education group.

Table 3. *Cont.*

Study Name	Scales Used for Measuring Outcomes	Risk of Bias	Age (Years)	Result for Muscle Contraction	Result for Endurance	Result for Urinary Incontinence
Bo et al. [12]	QoLS-N B-FLUTS	High risk.	Mean (SD) PFMT: 49.6 (10.0) Control: 51.7 (8.8)			Significant improvement in sex-life, social life, and physical activity in PFMT group. NS difference between the groups.
McLean et al. [13]	Pad test UDI-6 IIQ-7 3-day bladder diary	High risk.	Mean ± SD PFMT: 49.5 ± 8.2 Control: 54.0 ± 8.4			Significant improvements in in PFMT group on the impact of SUI compared with the control group. Pad test NS difference between the PFMT group and the control group.
Pereira et al. [5]	Pad test Perina Stim device	Low risk.	Median (min, max) PFMT: 62 (51, 85) VC: 64 (52, 83) Control: 62(51, 80)			Significant decrease in urinary leakage in PFMT and VC group from baseline compared with the control group.
Leong et al. [2]	IIQ-SF-7 UI7	Some concern.	Mean (± SD) 74.3 ± 4.6			Significant reduction in urinary leakage (>90%) in the PFMT + BT + education group compared with the education group (7.2%).

(VAS, Visual Analogue Scale; UI-7, Urinary Incontinence; IIQ-SF-7, Incontinence Impact Questionnaire-Short form; UDI-6, Urogenital Distress Inventory; QoLS-N, Norwegian version of the Quality of Life Scale; B-FLUTS, Bristol Female Lower Urinary Tract Symptoms Module; EQ5D-; ICIQ, International Consultation on Incontinence Questionnaire-urinary incontinence; QUID, Questionnaire for urinary incontinence diagnoses; OGS, Oxford Grading Scale; I-QOL, Incontinence quality of life; RUIS, Revised Urinary Incontinence Scale; KHQ, King's Health Questionnaire).

4.3. Study Outcome

Regarding outcome reporting, there was a lot of heterogeneity among the studies in terms of scales used for measuring the outcomes, reporting age, and other outcomes, as shown in Table 2. The most used scales for measuring muscle contraction, incontinence, and leakage were the pad test, VAS, I-QOL, Perineometer, ICIQ-UI SF, IIQ, and B-FLUTS. The age of women with incontinence ranged from 29.4 to 85 years across all the studies. In terms of reporting the outcome, there was a lot of dissimilarity across the studies.

Outcome on muscle contraction or muscle strength was reported by eight studies [3,5,8,11,16], urinary incontinence was reported by all the studies, and endurance was reported by one study [4].

In terms of muscle contraction, four studies [3,5,9,16] showed significant improvement between the groups; however, the instruments used for measuring the outcome for muscle contraction were different in all these studies. In four studies, improvements in muscle contraction were observed at the end of the study from baseline. In Hagen et al. [11], 8.5% of the patients in the PFMT + biofeedback and 6% in the PFMT group reported improvement in muscle contraction at 6 months. Ahlund et al. [4] showed a significant increase in PFM contraction from baseline in both groups at 26 weeks. Gameiro et al. [8] showed significant improvement from baseline in both the groups at 6 months but not at 12 months. For Gumussoy et al. [16], PFMC increased in both groups (PFMT with and without ExMI). However, there are few studies on ExMi and WBVT, and other studies are necessary to evaluate the use of these methods.

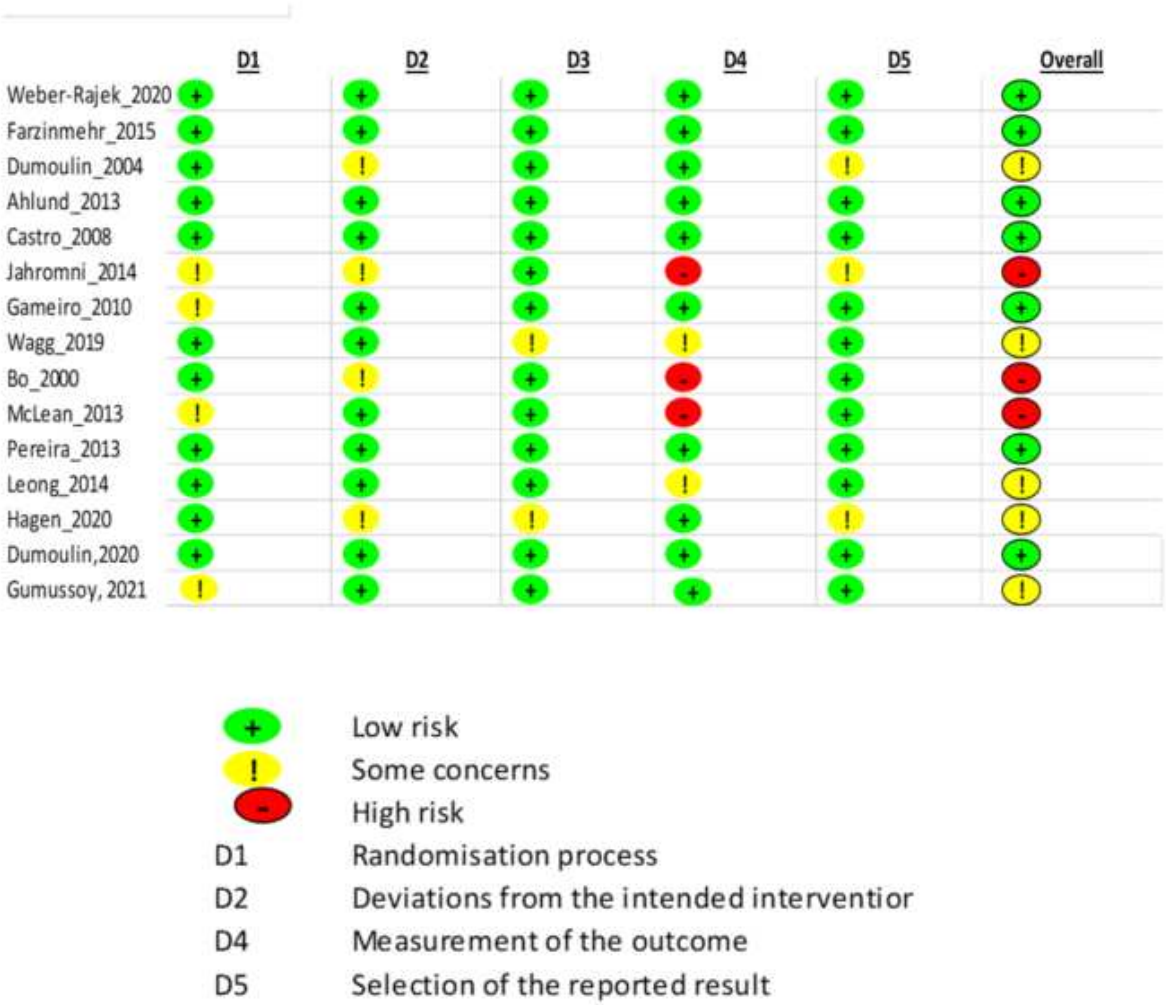

Figure 3. Cochrane risk of bias for each component across all the studies.

On the other hand, there were no significant results found for the endurance outcome across the studies. However, in one study by Ahlund et al. [4] at 26 weeks, improvement in endurance was observed from baseline.

All RCT studies showed significant reduction in severity of urinary incontinence from baseline after PFMT. However, the scale used for measuring the outcomes varied across the studies. For Dumoulin et al. [15], 70% of patients in individual PFMT group and 74% in group-based PFMT had a significant reduction in urinary incontinence at one year. For Gumussoy et al. [16], PFMT with BF with and without ExMI allowed the reduction in urinary loss. In Hagen et al. [11], 60% of patients in the PFMT + biofeedback and 62.6% in the PFMT group reported an improvement in symptoms at 24 months. In Ahlund et al. [4], a significant improvement was observed in both PFMT and control group at 26 weeks. In Jahromi et al. [7], a significant improvement from baseline was observed in both PFMT and control group for incontinence quality of life at 8.5 weeks, and in Leong et al. [2], more than 90% reduction was observed in PFMT group compared with control (7.2%) at 12 weeks.

Eight studies [2,3,5,7,10,14–16], used a similar outcome, i.e., the pad test method for measuring the outcome of urinary leakage, while the remaining three studies used different methods. In four studies, individual improvement was observed in the intervention groups from baseline. In Castro et al. [3], improvement in urinary leakage using the pad test was observed in 46% in PFMT, 48% in ES, 46% in VC, and 8% in the control at 26 weeks. In Jahromi et al. [7], a significant improvement from baseline was observed in both PFMT and control group for frequency of urine leakage and amount of urine leakage at 8.5 weeks.

In Gameiro et al. [8], a significant improvement was observed from baseline in both the groups at 6 months but not at 12 months. Pereira et al. [5] reported significant decrease in urinary leakage in PFMT and VC group from baseline as compared with the control group at 52 weeks.

4.4. Sensitivity and Subgroup Synthesis

Overall, out of 997 PFMT or PFMT + education patients, 504 patients (50.5%) showed improvement in urinary incontinence, and 218 became continent (21.8%) (negative pad test). In total, 62% of patients significantly reduced their urinary incontinence or cured it and improved their pelvic floor muscle contraction.

On the other hand, significant improvements in endurance, muscle contraction, and urinary leakage were observed in 49 patients (23%), 168 patients (79.2%), and 97 patients (46%), respectively. However, the results across the outcome cannot be compared between the intervention groups, as the scales used for measuring the outcome varied across studies, except for urinary leakage.

5. Discussion

This systematic review demonstrated that PFMT is effective in reducing UI and improving muscle contraction.

Although previously, many systematic reviews have been published that assessed the efficacy of PFMT on pregnant and non-pregnant women, this review specifically focused on non-pregnant women [17–21]. Apart from UI, this is the first review that also focused on PMFT efficacy on endurance, muscle contraction, and urinary leakage. Moreover, in this review, only RCT studies were included, followed by quality assessment using the Cochrane risk of bias tool.

It focused on finding the clinical effectiveness of PFMT on non-pregnant women suffering from UI. Indeed, PFM dysfunction is associated with UI [22–25].

Overall, PFMT has almost proven to be effective in all the studies conducted. Some have used PFMT with biofeedback, which also has shown efficacious result [12,26]. It improved not only the physical but also the psychosocial aspects of women. Significant decline in depressive symptoms, with an improvement in UI severity and quality of life, was observed following the treatment [1]. There was also a significant decrease in incontinence among the groups treated with PFMT. Other observational studies also found a significant improvement in urinary continence after PFMT [26–30]. In almost every study, by increasing the pelvic muscle strength in women, it improved the quality of life index as well. Hence, it could be hypothesized that PFMT is a successful method for the treatment of incontinence and is recommended as first-line treatment [31].

Our study demonstrated that PFMT was effective in reducing UI. The duration of analyzed studies varied between 4 weeks and 52 weeks. A long-term follow-up was not evaluated, as our study was not focused on the recurrence of UI. The question of the duration of benefit effects of PFMT is important. However, as it is a conservative and minimally invasive treatment, other PFMT could be prescribed in case of recurrence of UI.

Another significant finding is that most of the studies, which used interventions such as ES, VC, WBVT, ExMi innervation, etc. along with PFMT, concluded that all these interventions were proven to be equally effective in treating UI. All these interventions also helped in the significant decrease in incontinence and improvement in quality of life [32–34]. No such significant difference was seen among the interventions [1–3,5,9]. In this review, in terms of study characteristics, the studies were similar, and in terms of reporting of outcomes, the studies were dissimilar. After conducting the sensitivity synthesis by vote-counting of the studies, all the good quality studies either showed significant improvement from baseline or significant improvement between the intervention groups. The majority of the patients had improvement in UI and in urinary leakage. However, improvement in muscle contraction and endurance could not be well established, as the scales used were

different across the studies, but the pad test was used for measuring urinary leakage across the good-quality studies [3,5,8].

Strengths and Limitations of the Study

This study also has some important strengths and weaknesses. First, the search strategy used in this review was very robust, as it looked for citations on five databases and from four international grey literature sources (NICE, EMA, FDA, SMC). Throughout the review, the screening of the articles was based on the predesigned protocol, which was unchanged throughout the study. The quality of the studies was assessed and was taken into consideration while assessing the efficacy. No authors were contacted for gathering the missing data. Our systematic review was limited to articles written in English, which could constitute some bias. However, the majority of RCTs are written in English to reach an international scientific audience. We limited our study to the period 2000–2021; as methods and machine of physiotherapy changed, we did not extend our review before the year 2000. Meta-analysis was also not possible, as the scales used for measuring the outcomes and the measures of parameters were different across the studies.

However, better-quality RCT studies need to be included with similar parameters used for measuring the outcomes. Thus, this narrative sensitive synthesis showed enough evidence about the efficacy of PFMT in reducing UI and improving pelvic floor muscle contraction. Therefore, PFMT should be proposed before invasive surgical treatment for management of urinary incontinence.

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Pelvic Floor Muscle Training versus Functional Magnetic Stimulation for Stress Urinary Incontinence in Women: A Randomized Controlled Trial

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Abstract: Background: There is strong evidence that specific pelvic floor muscle training (PFMT) reduces stress urinary incontinence (SUI), but the application of functional magnetic stimulation (FMS) is still under discussion. Objective: To evaluate and compare the effects of FMS and PFMT on pelvic floor muscle function, urinary incontinence symptoms and quality of life (QoL) in women with SUI. Methods: A randomized controlled, parallel-group trial was executed in an outpatient physical medicine and rehabilitation centre. The study included 68 women and was fully completed by 48 women (n = 24 in each group) aged 29–49 years, with SUI, who were randomly assigned to PFMT and FMS groups. The symptoms of urinary incontinence and their impact on quality of life were assessed with two questionnaires: the International Consultation on Incontinence Questionnaire–Short Form (ICIQ-SF) and the Incontinence Impact Questionnaire–Short Form (IIQ-7). Perineometer (Pelvexiser) was used to measure the resting vaginal pressure, pelvic floor muscle (PFM) strength and endurance. All outcome measures were taken at baseline and after 6 weeks of interventions. Cohen's effect size (d) was calculated. Results: A significant improvement ($p < 0.05$) of ICIQ-SF and IIQ-7 was observed in both groups with a high effect size in the PFMT group (d = 1.56 and d = 1.17, respectively) and the FMS group (d = 1.33 and d = 1.45, respectively). ICIQ-SF and IIQ-7 scores did not differ significantly between groups after the 6-week treatment period. Resting vaginal pressure, PFM strength and endurance increased ($p < 0.05$) in both groups with a medium (d = 0.52) to large (d = 1.56) effect size. Conclusion: No significant difference between groups was found in any measurement of perineometry. PFMT and FMS significantly improved SUI symptoms and the quality of life of the study participants. None of the applied interventions was superior to the other in the short-term effect.

Keywords: stress incontinence; pelvic floor muscles; functional magnetic stimulation; exercise

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1. Introduction

Urinary incontinence (UI) is a common health problem that negatively affects the physical and social quality of life [1] and economic and psychological well-being [2] both in women and men [3]. The main subtypes of UI are stress urinary incontinence (SUI), urgency and mixed. The prevalence of UI varies depending on different incontinence definitions and assessment methodologies used [4]. SUI is characterized by an involuntary loss of urine on physical effort or exertion or when coughing or sneezing [5]. SUI is the predominant UI type among adult women [6]. Major risk factors for SUI include female

gender, older age, overweight or obesity, multiple births, menopause, dystocia, urinary tract infections, diabetes mellitus, chronic respiratory problems, lifestyle or high-intensity exercise [3,6–8]. Although vaginal delivery is considered a physiological way of delivery, it can also be associated with urinary and even faecal incontinence, because during prolonged vaginal delivery, the pelvic floor muscles can be pressed and get overstretched [9,10]. Barca et al. [11] state that vaginal delivery is directly related to the appearance of pelvic floor disorders, mainly UI, pelvic organ prolapse and anal incontinence.

Many women with SUI symptoms report frustration, anxiety, depression, reduction of self-esteem, feeling of shame and problems in sexual function [3,12,13]. Studies demonstrate that even mild urinary leakage significantly reduces the quality of life QoL [14,15]. A systematic review and meta-analysis including 23 studies and 24,983 participants showed that the presence of UI was significantly associated with poor QoL [16].

Treatment interventions for SUI can include non-surgical options, such as pelvic floor muscle training (PFMT), electrostimulation, magnetic stimulation, vibration and biofeedback [3,12] and radiofrequency or laser therapy [17]. However surgical treatment aims to support the urethra or increase bladder capacity [12]; PFMT is considered the first-line approach to treating SUI [18,19]. Fitz et al. [20] and Felicíssimo et al. [21] reported equal benefits of supervised (outpatient) and unsupervised (home programs) PFMT for improving female SUI, and this may be considered an option for self-management strategy [22]. Specific PFMT exercises, called Kegels, are proven to be effective for female UI and pelvic organ prolapse and have been recommended as the initial therapeutic option [23], but the training needs proper instructions and close follow-up to be effective [24].

Despite the strong evidence of the effectiveness of PFMT for the treatment of SUI [25] there seems to be increasing interest in using functional magnetic stimulation (FMS) [26]. Magnetic stimulation, sometimes called extracorporeal magnetic innervation, is described as a pulsed magnetic technology developed for the transmission of nerve impulses. The aim of FMS is to cause pelvic floor muscle (PFM) contractions by producing pulsing magnetic fields [27]. FMS is a non-invasive and safe treatment for SUI [28]. The setting (patient sitting on a chair with clothes) and the lack of direct activation of skin sensory receptors and C-fibers make this procedure comfortable and painless [17]. Magnetic stimulation procedures have been observed to reduce SUI symptoms without any side effects [29] by stimulating both peripheral and central nerves and resulting in sacral S2-S4 roots neuromodulation [30], thus causing muscle contraction [31].

The efficacy of incontinence treatment is frequently evaluated by patient-reported outcomes using questionnaires. The most frequently used subjective measure is ICIQ-SF [32] and it should be sensitive enough to detect the smallest change that is considered clinically important [33].

There have been many articles published in 5 recent years [17,23,26,28,29,31] discussing the benefits of using FMS in the management of UI. Peng et al. [34] state that "magnetic stimulation leads to an improvement in SUI without any reported safety concerns and an improvement in patient quality of life", but the authors agree on the uncertainty of the long-term effect of this technique. The aim of this research was to evaluate the effect of pelvic floor muscle training and functional magnetic stimulation performed with Magneto STYM device on pelvic floor muscle strength, endurance, resting vaginal pressure, SUI symptoms and quality of life in women.

2. Materials and Methods

2.1. Ethical Approval

The study protocol was approved by the Bioethics Committee (No. MNL-KIN(M)-2021-404) of the Lithuanian Sports University and registered at ClinicalTrials.gov (Identifier: NCT05721807; accessed on 19 January 2023). All participants were informed in detail of the purpose and procedures of the study, and they signed an informed consent form. The study was conducted in accordance with the Declaration of Helsinki Ethical Principles and Good Clinical Practices.

2.2. Study Design

This parallel-designed trial was conducted in an outpatient Rehabilitation clinic in Vilnius, Lithuania. Women who were diagnosed with SUI by a urogynecologist were invited to participate in the study. Those women who agreed to participate in the study were evaluated by a urogynecologist who performed the interview and physical examination. As recommended by the 6th International Consultation on Incontinence [35], the urogynecological examination included abdominal, pelvic and perineal examinations; women were asked to perform a "stress test" (cough and strain to detect leakage). After evaluation, the patients were randomly assigned into the two groups using a list of previously generated blinded intervention codes and an automatic assignment system (random.org, accessed on 7 July 2021) to conceal the allocation. After that, women were prescribed physiotherapy interventions. Physiotherapists were blinded to patients' pre- and post-assessment results. The urogynecologist did not know which group the women were assigned to. Patients who agreed to participate in the study were aware of the physiotherapy they received. This randomized controlled trial allocated women with SUI to either a 6-week supervised outpatient pelvic floor muscle training (PFMT) group or a functional magnetic stimulation (FMS) group. Sample size calculation was performed using statistical software G*Power 3.1.9.2 with a power of 80%, a significance level of 0.05 and an effect size of 0.50. The estimated desired sample size was 34.

The study protocol was prepared following the CONSORT guidelines (Figure 1).

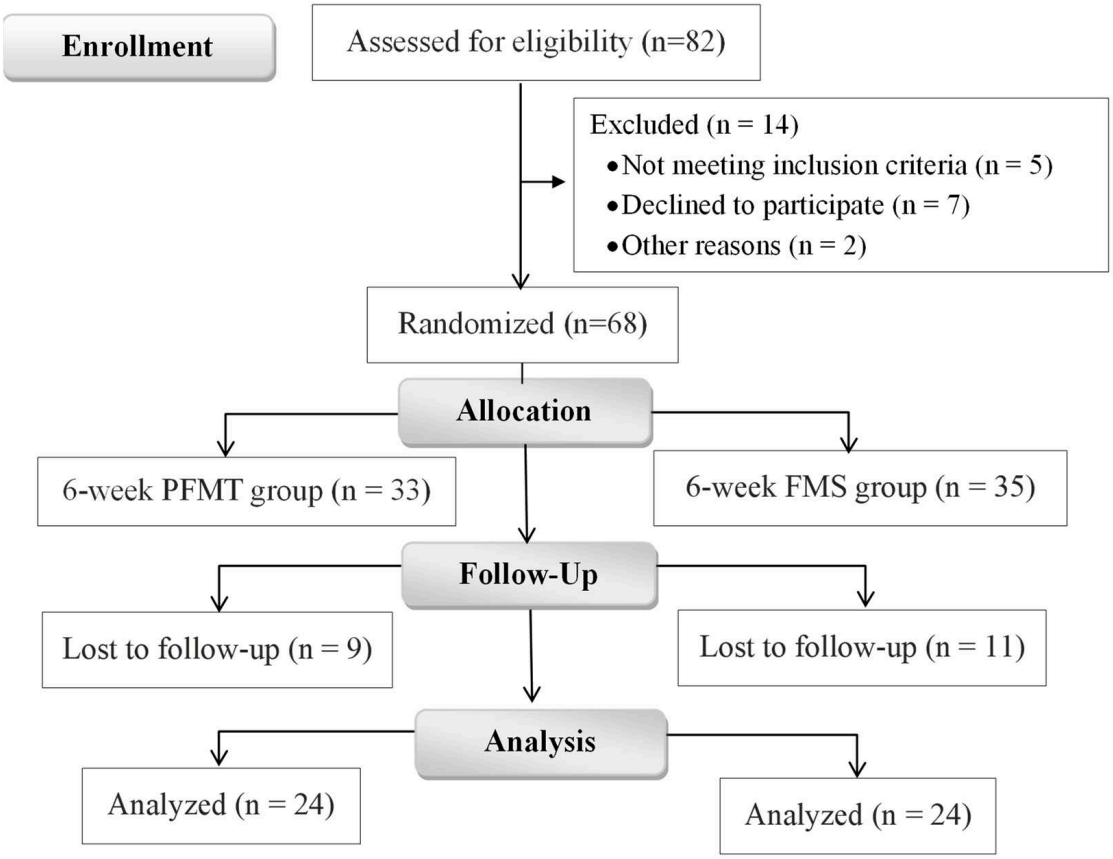

Figure 1. CONSORT flow chart.

2.3. Participants

Women with only SUI participated in the study. The inclusion criteria were having an age between 29 and 49 years, complaints of episodes of SUI for at least 4 weeks and women who had at least one vaginal delivery. Subjects were excluded if they were pregnant or were diagnosed with vaginismus, urinary tract infections, cancer, epilepsy, pelvic organ prolapse greater than stage I, skin diseases, had undergone previous pelvic floor surgeries

or had a heart stimulator or a metal implant and were unable to contract the PFM. After the gynecological evaluation, 82 participants with SUI were selected, but 14 were excluded because they did not meet the inclusion criteria. Sixty-eight women (in group PFMT n = 35, and in group FMS—n = 33) agreed to participate in the study and only forty-eight (70.6%) fully completed the interventions.

At baseline, there were no significant differences between the groups in terms of age, weight, height, body mass index and physical activity (Table 1).

Table 1. Characteristics of the participants.

	PFMT Group (n = 24) Mean ± SD	**FMS Group (n = 24) Mean ± SD**	**p between Groups (Student's t Test)**
Age (years)	37.58 ± 5.86	40.25 ± 6.49	0.142
Weight (kg)	69.79 ± 8.14	74.25 ± 10.64	0.062
Height (cm)	168.00 ± 4.00	168.50 ± 5.23	0.712
Body mass index (kg/m^2)	23.44 ± 3.01	26.13 ± 3.43	0.371
Physically active (%)	66.67%	75%	0.535
Frequency of physical activity (days/week)	2.17 ± 2.28	2.50 ± 2.02	0.594

Note: PFMT—pelvic floor muscle training; FMS—functional magnetic stimulation.

2.4. Outcome Measures

ICIQ–SF—International Consultation on Incontinence Questionnaire–Short Form. This questionnaire is short and easy to use in a clinical setting, assessing the severity of UI and its impact on QoL [36]. The questionnaire consists of four items and the overall score ranges from 0 to 21, with greater values indicating increased symptom severity: 0—no symptoms of UI, 1–5 scores—mild symptoms of UI, 6–12 scores—moderate symptoms of UI, 13–18 scores—severe symptoms of UI and 19–21 scores—very severe symptoms of UI [37].

IIQ-7—Incontinence Impact Questionnaire. The Incontinence Impact Questionnaire short version (IIQ-7) is useful to quickly quantify the UI-related life impact [38]. It consists of seven items and the total score ranges from 0 to 100 [39].

Perineometry. This was conducted with the pressure perineometer Pelvexiser, which consists of an air-filled vaginal balloon (75 mm length and 28 mm in diameter) connected to a high-precision pressure transducer (Wolfram Haboeck Co., Vienna, Austria). Perineometry is a simple, minimally invasive, low cost and reliable quantitative method [10]. Women were tested in a supine position with the knees bent and legs slightly apart and were instructed to perform PFM contraction without any movement of the pelvis or visible contraction of the gluteal, hip or abdominal muscles [40]. The testing procedure was explained to all patients individually, and they were asked to show their best results but were not motivated during testing. Three measurements were performed with 2 min rest between them.

1. The resting vaginal pressure (mmHg) was registered when a perineometer was inserted into the vagina without contracting PFM.
2. PFM strength was calculated as the mean of three isolated maximal voluntary contractions (mmHg). The patient was asked to contract their pelvic floor muscles to a maximum without holding their breath three times with a 5 s rest between trials.
3. PFM endurance was calculated as the mean of three endurance trials (s). Participants were asked to hold an isolated maximal voluntary PFM contraction for as long as they could without holding their breath. The trial was stopped when the squeeze pressure dropped by 2 mm. There was a 10 s rest between the three trials.

2.5. Interventions

Subjects of both groups completed 12 individual training sessions lasting for 6 weeks (two times a week). During the first session subjects were explained the anatomy and function of PFM and how to correctly perform contraction.

Pelvic floor muscle training. Women in the PFMT group received 12 sessions (30-minute duration) that followed a specific exercise program. The PFMT program consisted of two parts (Table 1). The exercise sessions were organised individually under the supervision of an experienced physiotherapist. From sessions 1 to 6, six exercises were performed focusing on slow- and fast-twitch fibers of the pelvic floor muscles (strength, endurance, power and relaxation), diaphragmatic breathing, transversus abdominis contraction and strengthening of thighs, buttocks and core muscles. From sessions 7 to 12, another five exercises were added. These exercises included progression from gravity-eliminated body positions to antigravity, exercise "elevator", and lumbo-pelvic stability training. The exercises were performed in 2 sets of 10 repetitions each with 30–60 s rest intervals in between. While exercising, attention was paid to correct breathing patterns. Body positions were changed progressively from supine to side-lying, sitting, and quadruped [41]. The intensity level was customized for each participant and based on their functional capacity.

Functional magnetic stimulation. FMS was performed with the Magneto STYM device (Iskra Medical d.o.o. Stegne 23, 1000 Ljubijana, Slovenia). It is a chair developed for the treatment of UI. The magnetic coil was positioned at the bottom of the chair. During the treatment, each subject was instructed to sit on a chair so that the perineum was in the centre of the coil to feel the contraction of PFM (Figure 2).

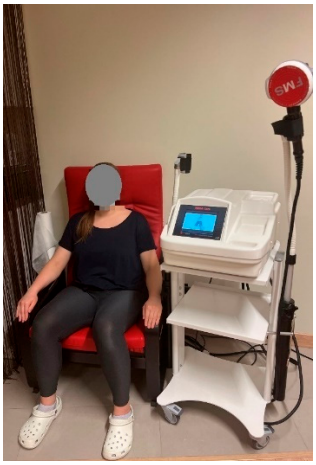

Figure 2. FMS procedure with the Magneto STYM device.

When applying FMS, the SUI program "P2 stress" was chosen. Stimulation frequency for the first 20 min was set at 35 Hz (modulation—rising amplitude from 0 to maximum per second; total wave duration 12 s, active time 6 s, pause time 6 s) [31]. For the last 10 min, stimulation frequency was changed to 5 Hz (modulation and wave duration remained the same) (Table 2). The total duration of the procedure was 30 min.

Table 2. Description of the interventions.

Functional Magnetic Stimulation	**Frequency of Stimulation**	**Time**	**Active Time**	**Pause Time**	**Duration of Session**	**Number of Sessions**
	35 Hz 5 Hz	12 s 12 s	6 s 6 s	6 s 6 s	20 min. 10 min	12 sessions
Pelvic Floor Muscle Training	**Step 1**		**Step 2**		**Duration**	**Number of Sessions**
	Session 1–6 6 exercises		Session 7–12 6 + 5 exercises		30 min.	12 sessions

2.6. Statistical Analysis

The data were tested for normal distribution using the Shapiro–Wilk test; all data were found to be normally distributed. The two groups were compared at baseline with the Student's *t*-test for continuous variables and the chi-square test for categorical variables. Values are reported as mean and standard deviation. A mixed design analysis of variance (ANOVA) was used to determine the effects of treatments on selected outcome measures. Values are reported as mean, standard deviation and percentage. The level of significance was set at $p < 0.05$. Data were analyzed with Cohen's d effect sizes to examine the magnitude of change in outcomes following the intervention, and the effect size was interpreted as follows: 0.0–0.2 small effect, 0.5–0.7 medium and 0.8–2.0 large effect. The data obtained were analyzed using IBM SPSS Statistics (version 26.0, IBM Corp., Armonk, NY, USA).

3. Results

Sixty-eight participants were randomized and forty-eight completed the study (dropout rate 29.41%). There were no adverse effects reported by patients post interventions. The results of the severity of involuntary urine loss measured by ICIQ-SF and IIQ-7 are presented in Table 3. In both groups, the severity of UI symptoms was indicated as moderate to severe before the interventions. A significant decrease in the total ICIQ-SF score was observed both in the PFMT group ($p < 0.001$; Cohen's $d = 1.56$) and in the FMS group ($p < 0.001$; Cohen's $d = 1.33$). Herewith, the total IIQ-7 score significantly decreased after the PFMT ($p < 0.001$; Cohen's $d = 1.17$) and FMS ($p < 0.001$; Cohen's $d = 1.45$) interventions. However, ICIQ-SF and IIQ-7 scores did not differ significantly between groups after the 6-week treatment period.

Table 3. Comparison of outcome measures between groups in pre- and post-intervention assessments.

Measurement	Group	Pre Mean ± SD	Post Mean ± SD	Mean Difference	*p* Inter-Group
Total ICIQ-SF score	PFMT	11.00 ± 3.68	6.33 ± 3.07	4.67 ± 2.99 **	0.509
	FMS	9.17 ± 3.33	5.08 ± 2.45	4.08 ± 3.08 **	
Total IIQ-7 score	PFMT	33.25 ± 23.25	10.75 ± 11.54	22.50 ± 19.26 **	0.699
	FMS	30.42 ± 14.36	9.33 ± 3.62	20.58 ± 14.57 **	
Resting vaginal pressure (mmHg)	PFMT	4.67 ± 1.79	6.67 ± 1.27	2.00 ± 1.67 **	0.089
	FMS	5.58 ± 2.19	6.92 ± 1.74	1.33 ± 0.87 **	
PFM strength (mmHg)	PFMT	11.59 ± 5.72	15.36 ± 5.88	3.77 ± 4.43 **	0.458
	FMS	15.08 ± 7.59	17.94 ± 8.32	2.86 ± 3.96 *	
PFM endurance (s)	PFMT	10.54 ± 9.28	18.97 ± 15.60	8.43 ± 13.55 *	0.661
	FMS	11.03 ± 11.52	17.79 ± 22.33	6.76 ± 12.69 *	

Note: *—$p < 0.05$ between pre- and post-interventions within groups. **—$p < 0.001$ between pre- and post-interventions within groups. Abbreviations: PFM, pelvic floor muscle; PFMT, pelvic floor muscle training; FMS, functional magnetic stimulation.

Data for the perineometry are presented in Table 3. The resting vaginal pressure significantly improved in both the PFMT group ($p < 0.001$; Cohen's $d = 1.20$) and the FMS group ($p < 0.001$; Cohen's $d = 1.54$). Moreover, the PFM strength significantly increased in both the PFMT group ($p < 0.001$; Cohen's $d = 0.85$) and in the FMS group ($p < 0.05$; Cohen's $d = 0.72$). The significant improvement in the PFM endurance was observed after the PFMT ($p < 0.05$; Cohen's $d = 0.62$) and FMS interventions ($p < 0.05$; Cohen's $d = 0.52$). No significant difference between the groups was found in any measurement of perineometry.

The results of ICIQ-SF items are presented in Figure 3. Before the interventions, 100% of women complained of UI with sneezing or coughing and physical exertion. The number of participants with SUI reduced after the interventions—8.3% of study participants in both groups reported that symptoms of UI were eliminated after treatments (Figure 3).

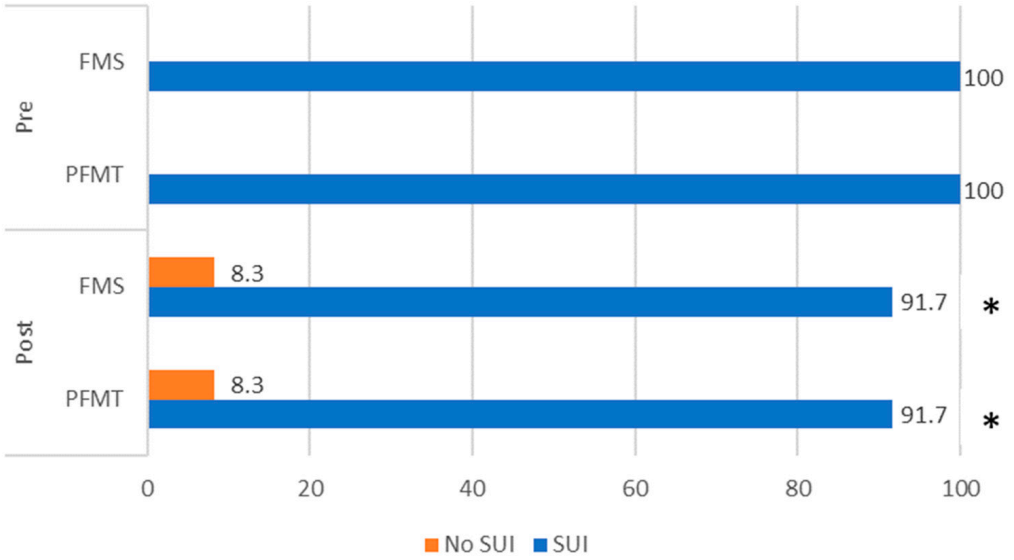

Figure 3. Distribution of study participants according to complaints of SUI pre- and post-interventions. Note: *—$p < 0.05$ between pre- and post-interventions within groups. PFM, pelvic floor muscle; PFMT, pelvic floor muscle training; FMS, functional magnetic stimulation.

As shown in Figure 4 the effect sizes of both interventions on outcome measures were similar. The large effect size was determined with total ICQ-SF and IIQ-7 scores and resting vaginal pressure in both groups and on PFM strength in the PFMT group. The medium effect size was determined with PFM endurance in both groups and on PFM strength in the FMS group.

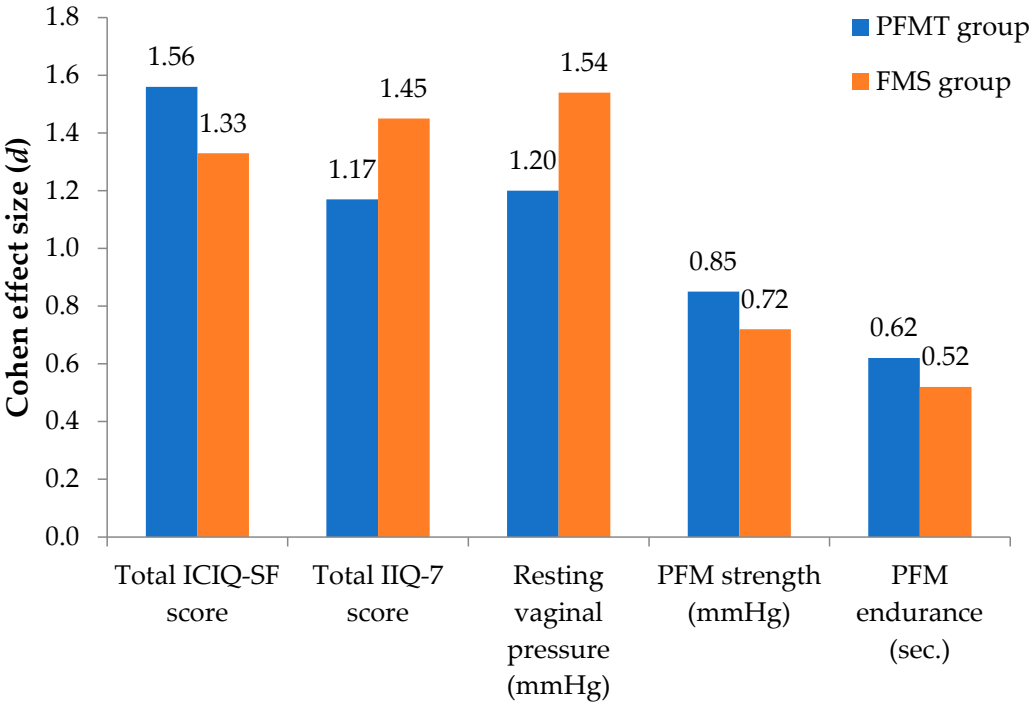

Figure 4. Comparison of Cohen's d effect size values between the groups. Note: ICIQ-SF, International Consultation on Incontinence Questionnaire–Short Form; IIQ-7, Incontinence Impact Questionnaire; PFM, pelvic floor muscle; PFMT, pelvic floor muscle training; FMS, functional magnetic stimulation.

4. Discussion

This preliminary experimental study aimed to investigate the effectiveness of FMS and PFMT on pelvic floor muscle function, urinary incontinence symptoms and the quality of life in women with SUI. Our results showed that both groups significantly improved all these outcomes, with high effect sizes and no superiority for any group.

UI is recognized as a major health problem especially among women [42], negatively affecting their quality of life [1,3,12,13]. Although older age and obesity or being overweight are considered risk factors for UI, our study participants were relatively young (mean age 38.92 ± 6.49 years) and non-obese (mean BMI 24.78 ± 3.43 kg/m^2) but had given at least one birth vaginally. The improvement in the severity of involuntary urine loss measured by ICIQ–SF and IIQ-7 was the primary outcome measure showing the effect of interventions used in our study. QoL scores are considered to be the most important indicator when evaluating treatment [42]. After both interventions used in our study QoL in women with SUI greatly improved with a high effect size. All the females in this study complained of involuntary urine loss during coughing, sneezing or physical exertion before interventions. Results of our study showed that interventions lasting for 6 weeks eliminated SUI symptoms only in 8.3% of women, nevertheless, the quality of life of all subjects improved significantly. From this, we could suggest prolonging the treatment duration. Ongoing research not only should last longer but evaluate the effects of different magnetic stimulation protocols, i.e., different stimulation frequencies, modulation and wave duration.

As recommended in the scientific literature [20,21], we applied supervised interventions to our patients. The resting vaginal pressure as well as PFM strength and endurance improved significantly after both interventions. PFMT programs are proven to be effective in treating SUI [18,19,25,43] with and even without biofeedback [44]. The effectiveness of interventions depends on the improvement in QoL and PFM strength [44]. García-Sánchez with co-authors [45] showed, in the meta-analysis conducted in 2019, that PFMT did not depend on the protocol used in the study and was effective regardless of the women's age (under 53 and over 53 years old). Different training protocols resulted in decreased urine loss in females diagnosed with SUI. The authors suggested intervention programs to last 6–12 weeks. To reach a large effect size, more than 3 sessions per week with a length of one session lasting more than 45 min are recommended [45].

Pulsed magnetic stimulation is a non-invasive treatment in which patients can undergo a procedure while fully clothed [46]. The changing magnetic field leads to pelvic floor nerve stimulation and repetitive PFM contractions [47] similar to PFMT. Lim et al. [28] found that pulsed magnetic stimulation applied for SUI in 35 women involved in 2 sessions per week for 2 months (16 sessions, 20 min each with 50 Hz in an 8 s on 4 s off pulsing manner) improved physical, social and psychological aspects of QoL [28]. In our study, patients received 12 physiotherapy sessions applied two times a week for 6 weeks, but the duration of every session was longer—30 min—and the stimulation frequency in our study was lower. Yamanishi et al. [29] used the stimulation of 50 Hz in 5 s on/5 s off cycles for 10 weeks with one session lasting 20 min and found magnetic stimulation to be effective and safe in the treatment of SUI in 18 women. Weber-Rajek et al. [48] found that even a 4-week duration PFMT, as well as magnetic innervation, were effective treatment methods for SUI in women. In addition, Sun et al. [49] demonstrated that the IIQ-7 scores were statistically significantly reduced even after 8 sessions of extracorporeal magnetic innervation. For women undergoing nonsurgical treatments for incontinence, a reduction of 4 points in ICIQ-SF is perceived as clinically meaningful [30]. In our study, the reduction of ICIQ-SF scores was higher than 4 points and can be considered as clinically important. Furthermore, Vadala et al. [31] concluded that FMS with the Magneto STYM device used twice weekly for 3 weeks had significant advantages on 20 patients with SUI aged 38–82 years without any adverse effects.

A high percentage of females can not voluntarily control PFM [20]; therefore, physiotherapists working in clinical practice must find ways how to educate women to contract

their PFM or to search for other effective and evidence-based treatment methods. Some researchers [50] recommend conservative UI treatment with FMS for patients who are not motivated to perform regular PFM exercises.

Even though magnetic stimulation is widely used in the treatment of UI [23,28–31,34,46–50], it is necessary to evaluate the indications and contraindications of this technique [51].

The main limitations of our study were a relatively small sample size and a lack of follow-up to assess the long-term effects of the interventions. On the other hand, the topic is very sensitive and intimate; many women uncover that they have problems and refuse to participate in research. The age range of the subjects in this study was quite wide (20 years), which could have influenced the results negatively. Another weakness of our study is that the data analysis did not consider the level of physical activity of women, which is presented in the characteristics of the subjects. In addition, the time period after childbirth, the number of deliveries and the satisfaction with treatment should be considered. In the future, larger studies involving long-term outcomes and sham FMS interventions should be planned, and a control group with no interventions could be involved. The strengths of our study are that both groups were homogeneous. The interventions were conducted in parallel and lasted for 6 weeks; therefore, the weather and other environmental factors were the same for the subjects and had the same influence on UI symptoms. Furthermore, our study was double-blinded, as the urogynecologist was not provided with the groups that patients were assigned to, and physiotherapists were not introduced to the results of patients' assessment pre-interventions.

Results of our study showed that physiotherapists working in clinical settings can prescribe PFMT programs as well as FMS interventions, because of the high and similar effect sizes and the safety of the treatments.

5. Conclusions

A six-week PFMT program, as well as low-frequency FMS intervention performed with a Magneto STYM device, improved pelvic floor muscle strength, endurance, resting vaginal pressure, UI symptoms and the quality of life in relatively young women with SUI. None of the applied programs were superior to the other in the short-term effect. Both interventions were safe and well tolerated by the study participants. Further research is needed to investigate the long-term effects of FMS.

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Informed Consent Statement: Written informed consent was obtained before the testing procedures.

Data Availability Statement: Not applicable.

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Conflicts of Interest: The authors declare no conflict of interest.

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Special Issue

Female Stress Urinary Incontinence Treatment: Do We Know Enough?

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A Qualitative and Quantitative Study to Evaluate the Effectiveness and Safety of Magnetic Stimulation in Women with Urinary Incontinence Symptoms and Pelvic Floor Disorders

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Abstract: *Background and objectives*: Involuntary loss of urine owed to dysfunction of the detrusor muscle or muscles of the pelvic floor is known as urinary incontinence (UI). In this study, ultrasound monitoring was employed for the first time to measure the usefulness and safety of electromagnetic stimulation for women with Stress or Urge UI. *Materials and Methods*: A total of 62 women were enrolled, with a mean age of 55.1 (±14.5); 60% of them were menopausal and presented with urinary incontinence (UI). Eight validated questionnaires were used to evaluate Stress UI, prolapse, overactive bladder urge, faecal incontinence, and quality of life, and the whole study population was tested with ultrasounds at the beginning and at the end of the treatment cycle. The device used was a non-invasive electromagnetic therapeutic system composed of a main unit and an adjustable chair applicator shaped for deep pelvic floor area stimulation. *Results*: Ultrasound measurements and validated questionnaires revealed a consistent and statistically significant ($p < 0.01$) improvement of the mean scores when pre- and post-treatment data were considered. *Conclusions*: Study results showed that the proposed treatment strategy led to a significant improvement in Pelvic Floor Muscle (PFM) tone and strength in patients with UI and pelvic floor disorders, without discomfort or side effects. The demonstration was qualitatively carried out with validated questionnaires and quantitatively with ultrasounds exams. Thus, the "chair" device we used represents valuable and effective support that could be widely employed in the gynaecological field for patients affected by different pathologies.

Keywords: magnetic stimulation; women's health; urinary incontinence; pelvic floor disorders; ultrasounds; validated questionnaires

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1. Introduction

Loss of urine subject to dysfunction of the detrusor muscle is known as urinary incontinence (UI). It stems from a problem with the pelvic floor and might be related to urethral muscle weakness [1]. Changes that affect the pelvic floor during pregnancy, postpartum and as a result of ageing diminish pelvic support and weaken Pelvic Floor Muscles (PFMs), culminating in UI.

There are many types of UI; however, stress- and urgency-related types are the most common. Stress Urinary Incontinence (SUI) derives from the weakness of urethral and pelvic floor muscles resulting from various factors or traumas, such as damage associated with childbirth, congenital weakness of supporting structures or loss of elasticity with hormone deficiency. In this situation, urine leaks may occur during exercise, coughing, sneezing or lifting weights. Differently, Urge Urinary Incontinence (UUI) derives from

involuntary contractions of bladder muscles that start to be overactivated (Overactive Bladder, OAB), clinically resulting in a compelling and sudden need to urinate. When SUI and UUI symptoms coexist, it is known as Mixed Urinary Incontinence (MUI) [2]. UI can seriously influence people's physical, psychological and social wellbeing and, based on age, it affects 10–20% of all women and up to 70% of elderly women [3]. The prevalence ranges from 17% in women in their 20s to 38% in their 60s [4]; however, only 25% of patients seek specific medical treatment [5]. For this reason, in the last decade, many strategies have been investigated for treating UI [6,7]. They are surgical procedures, physical/conservative therapies (pessaries or vaginal cones, timing urination and restricting fluid intake), pharmacological approaches (anticholinergic drugs, urethral bulking agents, vaginal oestrogens and peripheral nerve stimulation), and behavioural therapies (Kegel exercises, vaginal weight training, biofeedback and electrical stimulation of pelvic floor) [8].

About 90% of patients experience an improvement in incontinence with surgical intervention, through the use of urethral slings or periurethral injections of bulking agents [9]. However, because these treatment options are invasive and may have risks and complications [10], patients are hesitant when considering them. Indeed, some subjects with SUI prefer methods such as electrical stimulation, PFM training, and biofeedback. However, despite the fact that there exist documented advantages of physical therapy, its drawbacks include a slow rate of improvement, low compliance and overall low patient attendance rates [11]. Patients frequently do not practise Kegel exercises correctly or consistently over time, which can reduce their effectiveness (women frequently need to be pushed to conduct Kegel exercises regularly) [12]. Interestingly, it has also been noticed that more than 30% of SUI patients cannot contract their pelvic floor muscles on their first attempt [13].

In this scenario, since 1998, magnetic stimulation, including extracorporeal magnetic stimulation, has been described mainly for UUI, and functional magnetic stimulation for both SUI and MUI have been authorized by the FDA. They are relevant alternatives that have the benefit of allowing people to stay comfortably clothed during a treatment. Recently published studies have proven that TOP Flat Magnetic Stimulation (TOP FMS) technology reduced urge, mixed, and stress incontinence issues, yielding positive effects and enhancing patients' quality of life (QOL) without risk [6,14]. Indeed, FMS technology, with a homogenous profile and creating no areas of uneven stimulation intensity, enables the strengthening of muscle mass through neuromuscular stimulation because it depolarizes motor neurons, causing large and deep muscle contractions. It is used for muscle rehabilitation as well as for muscular training to build muscle strength.

Due to the minimal impact of the magnetic stimulation on cutaneous receptors, the perceptual pain associated with electrostimulation is also avoided.

Until recently, magnetic resonance (MRI) was the only imaging method capable of assessing in vivo the anatomic changes and differences of PFMs in normal [15] or traumatic [16,17] conditions. However, MRI is not currently used in clinical settings because of excessive costs and access problems. In contrast, the advent of three-dimensional (3D) ultrasound (US) for the pelvic floor now allows for the evaluation of the patient's condition with much lower cost for the healthcare system and minimal discomfort to the patient [18–20]. Even if the spatial resolution may be poorer, US enables some dynamic multiplanar imaging, which is nearly impossible with MRI technology.

With this study, and for the first time in the scientific scenario, we have empirically evaluated, with the use of US, the effectiveness and safety of FMS to treat women with SUI/UUI symptoms.

2. Materials and Methods

2.1. Study Population

For this study, 62 women were enrolled, with a mean age of 55.1 (±14.5); 60% of them were menopausal and presented with urinary incontinence (UI). The UI status of the patients was initially evaluated by a gynaecologist, and after an interview addressing symptoms of dysfunction of the pelvic floor and family history of such symptoms and/or

surgical procedures, every participant was classified as SUI or UUI based on specific questionnaires according to the UI classification of the International Continence Society [21]. Stress UI was found in 80% of the patients, while 48% showed urgency UI. Moreover, 42.8% presented with pelvic organ prolapse of different grades (I, 53%; II, 47%) (see Table 1).

Table 1. General data describing the study population characteristics. Some patients showed coexisting SUI and UUI symptoms, known as Mixed Urinary Incontinence (MUI).

Number of patients	62	
Average age (mean ± SD)	55.1 ± 14.5	
Menopausal patients (%)	60%	
UI type (%)	SUI	UUI
	80%	48%
Prolapse (%)	42.8%	
	GRADE (% PATIENTS) I (53%) II (47%)	

Eight questionnaires were used to evaluate SUI, prolapse, OAB-urge, faecal incontinence and quality of life at different points in time (see Figure 1). Finally, validated consent and informative papers were submitted to the patients before the treatment began.

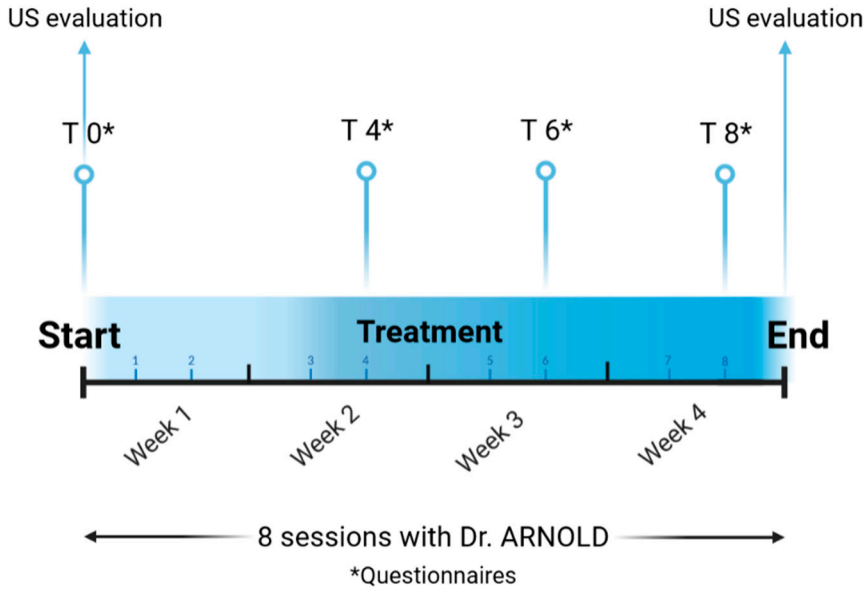

Figure 1. Study Timeline. Every subject was treated for a total of 8 sessions, with two sessions per week. Eight questionnaires (*) were provided at different time points (baseline T0, 4th session T4, 6th session T6, and 8th session T8). The US measurements were performed at baseline and at the end of the treatment course.

Exclusion criteria included, Using the International Continence Society's Pelvic Organ Prolapse Quantification System (POP-Q) (grade 3), the prolapse of the pelvic organ beyond the hymen; active urinary tract infection with either herpes virus (HSV) or human papillomavirus (HPV); use of diuretics or vaginal oestrogen therapy within the previous 6 months; irregular vaginal bleeding; prior pelvic radiotherapy or surgical procedure for SUI; patients with cardiac pacemakers, implanted defibrillators/neurostimulators, metallic and electronic implants, cardiac disorders, pulmonary insufficiency, malignancy, severe neurological diseases, pregnancy and obesity. Side effects such as temporary muscle spasms,

muscular pain, temporary tendon or joint pain, or localized redness or erythema of the skin were assessed before and after the treatment.

2.2. Qualitative Evaluation with Validated Questionnaires

Different questionnaires were completed by the patients to evaluate urinary improvement and pelvic floor dysfunction at the beginning, at the fourth session, the sixth session and at the end of the treatment cycle (after 8 sessions). The questionnaires were completed right before every treatment, within the treatment period (until the 8th session). To assess SUI, the Urinary Incontinence Short Form (ICIQ-UI-SF), [6,22] was used to assess the severity of urinary leakage, the clinical manifestations of urinary incontinence, and the impact on quality of life. Moreover, the seven-question Incontinence Impact Questionnaire-Short Form (IIQ-7) [23] was helpful to evaluate the negative impacts of urinary incontinence on health-related quality of life in terms of physical activities, recreation, domestic tasks, social activities, travelling, emotional health and the sensation of frustration [24]. The same questionnaire was used for the OAB condition investigation. In addition, the Incontinence Questionnaire Overactive Bladder Module (ICIQ-OAB) [25] was administered to evaluate overactive bladder and its related impact on quality of life (QoL). Furthermore, the Pelvic Floor Distress Inventory—20 (PFDI-20) questionnaire was considered to assess pelvic organ prolapse distress as well as urinary and anorectal symptoms using three subscales, the Pelvic Organ Prolapse Distress Inventory (POPDI-6), Urinary Distress Inventory (UDI-6) and Colorectal-Anal Distress Inventory (CRADI-8), respectively, [26,27]. Lastly, a questionnaire evaluating the quality of life (I-QoL) [28] of the patients, with 22 questions concerning various aspects of their life, was used. Table 2 shows the details of the questionnaires that were used for every treated patient.

Table 2. Details of the questionnaires used for the study population. They are sorted by medical indication (Pelvic organ Prolapse, Stress Urinary Incontinence, Quality of Life and Overactive Bladder Urge), and the specific name, score range, aim, and administration time is reported for each.

Indication	Questionnaire Name	Score Range	Aim	Administration Time
SUI	ICIQ-UI-SF	0–21	Evaluation of clinical manifestations of urinary incontinence, everity of urinary loss, and impact on quality of life	T0, T4, T6, T8
	UDI-6	0–100	Urogenital Distress Inventory in daily life	
	IIQ-7 (SUI)	0–100	Evaluation of the impact of urinary incontinence on activities, relationships and emotional states	
Pelvic Organ Prolapse	PFDI-SF20	0–300	Evaluation of the intensity of distress caused by the presence of PFD symptoms	
	POPDI-6	0–100		
	CRADI 8	0–100		
Overactive Bladder Urge/UUI	ICIQ-OAB	0–16	For overactive bladder, evaluation of urgency, frequency, nocturia and urgency leakage	
	IIQ-7 (OAB)	0–100	Evaluation of the impact of urinary incontinence on activities, relationships and emotional states	
Quality of Life	IQoL	0–110	Evaluation of the impact of urinary/pelvic floor disorder on the everyday quality of life, including socializing, sexuality and emotional states	T0, T8

2.3. Quantitative Evaluation with Ultrasounds

The whole study population was tested with US by a single clinician before and at the end of the treatment course (8 sessions). A 3D transperineal-translabial ultrasound was carried out while the woman was in a supine position (Figures 2–4), using as markers the hyperechoic anterior border of the puborectalis muscle, just posterior to the anorectal muscle and the hyperechogenic posterior surface of the pubic symphysis. A Samsung HERA W9 and WS80 ultrasound (Samsung Healthcare products, South Corea) with a 1–8 MHz 3D volumetric ultrasound transducer (CV1-8A) was used. The core transducer axis was positioned in the mid-sagittal plane, between the two labia majora at the level of the rear fork, with the legs bent at the hips and knees. The maximum transducer 120° angle was chosen as the acquisition angle. Transperineal ultrasound can detect the decrease in anteroposterior (AP) diameter and hiatus area induced by PFM contraction. Within the deep layer, changes in hiatus size and anorectal angle are thought to be caused by relaxation and contraction of the puborectalis muscle. Bladder neck displacement, anorectal angle excursions, levator plate, and hiatus narrowing regarding the inferior border of the pubic symphysis have been widely used in women with pelvic organ prolapse and incontinence as markers of pelvic floor muscle strength. These observations were made right before the image acquisition. It has been discovered that the approach for evaluating pelvic organ descent during the Valsalva manoeuvre well correlates with clinical measurements of descent [29].

Figure 2. Ultrasound technique for measurements. The patient lays in a dorsal lithotomy position with hips abducted and flexed. A small urine volume in the bladder should be present (100–150 mL) to enable the best view of bladder morphology. No pre-procedure preparation or vaginal/rectal contrast agents are needed. The transducer should be placed with the patient in a neutral posture to prevent undue pressure on surrounding structures and avoid anatomical distortion.

2.4. Study Device

After the gynaecologist's clinical picture evaluation, the treatment was performed using the Dr. ARNOLD (DEKA M.e.l.a, Florence, Italy) device. This is a non-invasive therapeutic system CE used since July 2020 and made of a main unit and an adjustable chair applicator shaped for deep pelvic floor area stimulation. The chair is designed for the patient to assume the correct therapeutic posture to maximize the interaction with the electromagnetic stimulation and ensure the best comfort during the treatment session. The patient can keep her clothes on and should sit in the centre of the chair with her spine in an upright position (extension position) and with thighs parallel to the floor, legs perpendicularly flexed and feet flat on the ground (forming an angle of 90° at the knee), avoiding the use of heeled shoes. This way, the perineum of the patient is at the seat centre, which makes it easier for the subject to feel the contraction of the sphincter and pelvic

floor muscles during electromagnetic stimulation [30]. The device activity is carried out by selectively stimulating the PFMs with homogeneous-profile (TOP FMS) electromagnetic fields. The recruitment of muscle fibres is made possible by the remarkable uniformity of the magnetic field distribution over a broader area, which prevents the creation of stimulation zones with different intensities. This type of stimulation also provides optimal effects on the blood circulatory system.

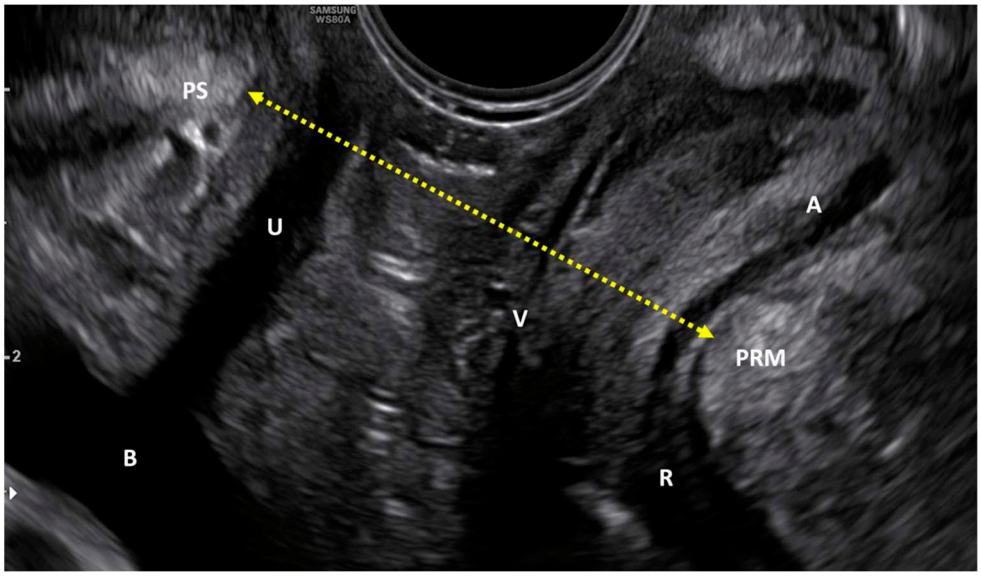

Figure 3. Sample US image of levator ani hiatus. The distance between the inferior border of the pubic symphysis to the medial border of the levator ani (puborectalis muscle) was used to compare pre- and post-treatment improvements. U = Urethra; B = Bladder; PS = Pubic Symphysis; V = Vagina; R = Rectus; A = Anus; PRM = Puborectalis Muscle.

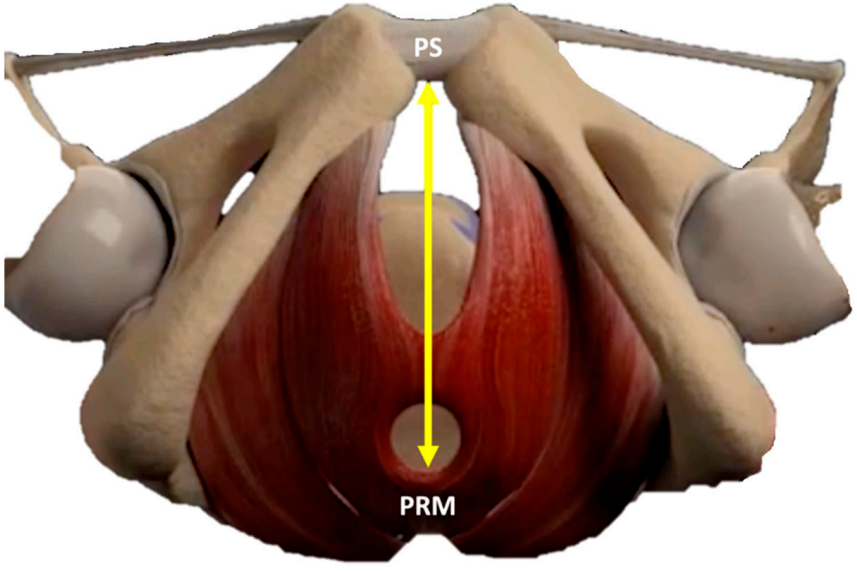

Figure 4. The anatomical distance between the medial edge of the levator ani (puborectalis muscle—PRM) and the lower edge of the pubic symphysis (PS).

2.5. Dr. ARNOLD Protocols and Assessments

For this study, two protocols were selected: "Hypotonus/Weakness 1", where muscles work to improve tone and trophism; and "Hypotonus/Weakness 2", for stimulating the muscles to increase in volume and strength. Every subject underwent eight sessions, each

lasting 30 min and occurring twice a week [31]. According to manufacturer instructions, the first four sessions were performed with an intensity level so that the ideal muscle contraction was reached. Then, if patients showed no discomfort and good tolerance to the treatment, the intensity was raised. At the end of the 8 sessions, all patients were clinically re-evaluated by the study staff, and the questionnaires were re-administered [30].

2.6. Statistical Analysis

Student's *t*-test and SPSS (IBM Corp., New York, NY, USA) were performed to analyse the qualitative and quantitative data obtained. Data were shown as mean ± standard deviation (SD). A p-value < 0.01 was considered statistically significant.

3. Results

No side effects, such as temporary muscle spasms, muscular pain, temporary tendon or joint pain or localized erythema or reddening of the skin, were reported by the study population before or after the treatment.

3.1. Quantitative Evaluation: Ultrasound Measurements

For the quantitative evaluation of the study device effectiveness, all patients in the study were monitored with US before treatment and at the end of the treatment cycle (Figure 5). The distance between the echogenic posterior surface of the inferior border of the pubic symphysis and the echogenic medial-anterior border of the puborectalis muscle of the levator ani was employed to compare pre-and post-treatment improvement. The results showed a statistically significant ($p < 0.01$) distance reduction both at rest (from 59.74 mm ± 7.05 to 56.37 mm ± 8.14) and in a stress (contraction) condition (53.31 mm ± 8.47 to 49.44 mm ± 8.98) (see Table 3).

Table 3. Ultrasound quantitative results. Patients were monitored before and at the end of the treatment cycle. The distance (mm) between the echogenic posterior surface of the inferior border of the pubic symphysis and the echogenic medial-anterior border of the puborectalis muscle of the levator ani was employed to compare pre- and post-treatment improvement. General improvement is shown when both the before/after and rest/contraction conditions are compared.

	Rest (mm)	**Contraction (mm)**
Before treatment	59.74 ± 7.05	53.31 ± 8.47
After treatment	56.37 ± 8.14	49.44 ± 8.98

3.2. Qualitative Evaluation: Questionnaire Findings

SUI

Questionnaires regarding the SUI revealed a consistent and statistically significant ($p < 0.01$) reduction of the mean scores when the pre- and post-treatment data are compared, suggesting a progressive improvement in the medical condition. Specifically, the ICIQ-UI-SF questionnaire (score range 0–21) reported a mean score of 12.44 (±5.30) at baseline, decreasing to 6.75 (±6.22) right after the last treatment session. Similarly, the UDI-6 survey (score range 0–100) decreased from a baseline mean score of 49.26 (±20.84) to 20.83 (±24.60) after the 8th session. Even with the IIQ-7 (SUI) inquiry, the mean scores went down from baseline 46.91 (±26.57) to 27.88 (±27.69) at the end of the treatment course (see Table 4).

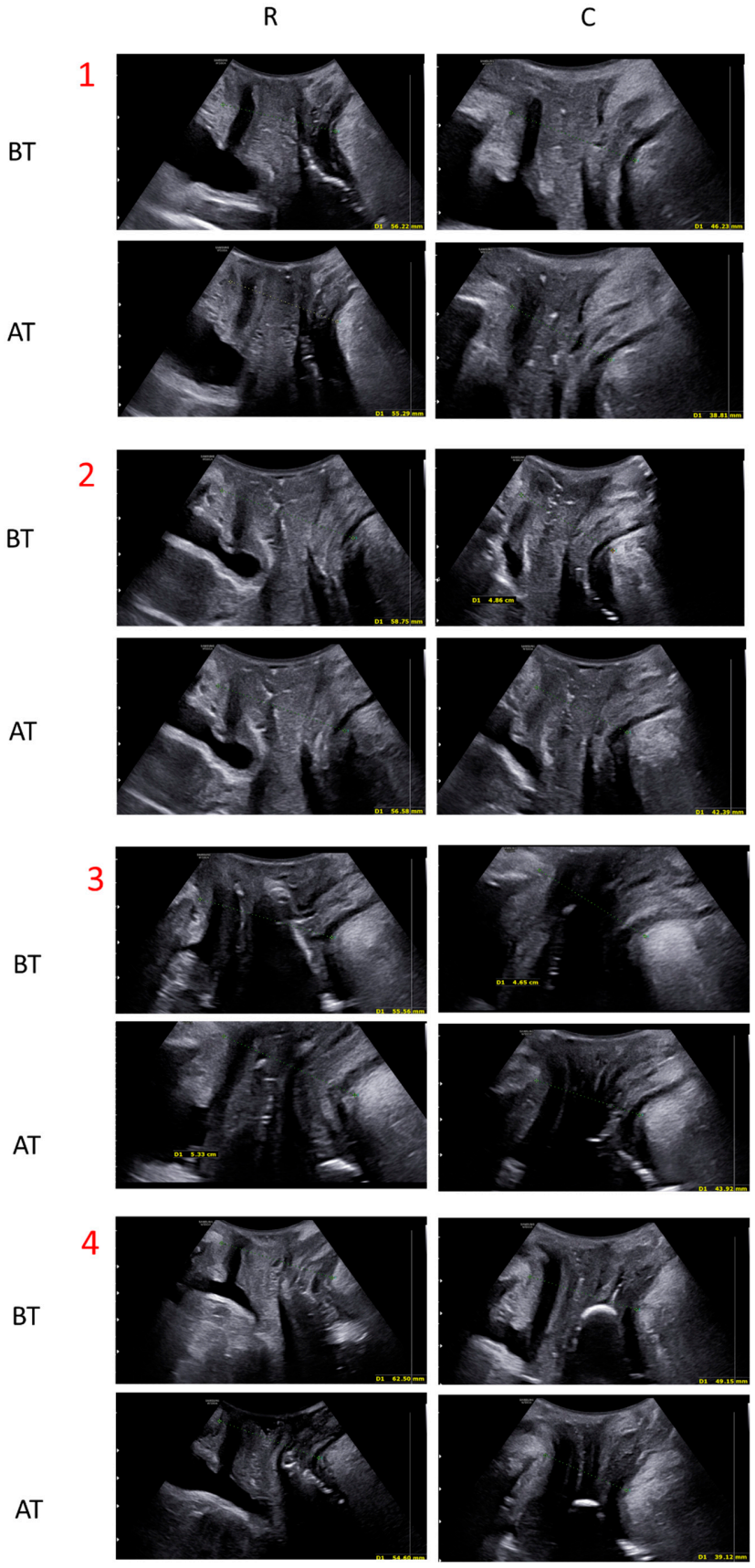

Figure 5. Ultrasound evaluation of four patients before (BT) and after (AT) the treatment with electromagnetic stimulation. For every subject, four pictures were taken. A comparison of a rest (R) condition and under stress/contraction (C) was made.

Table 4. Questionnaire results cumulative table. Data with standard deviation are reported for every questionnaire at different points in time (baseline and at sessions 4, 6 and 8). ICIQ-UI-SF, IIQ-7 (SUI) and UDI-6 were used for evaluating Stress Urinary Incontinence; PFDI-SF20, POPDI-6 and CRADI 8 for pelvic organ prolapse; ICIQ-OAB and IIQ-7 (OAB) for overactive bladder urge and urge urinary incontinence; and IQoL for the quality-of-life improvement.

	Time Points			
Questionnaires	**T0**	**T4**	**T6**	**T8**
ICIQ-UI-SF	12.44 ± 5.30	9.57 ± 6.05	7.93 ± 6.11	6.75 ± 6.22
IIQ-7 (SUI)	46.91 ± 26.57	37.39 ± 28.13	28.80 ± 27.80	27.88 ± 27.69
UDI-6	49.26 ± 20.84	32.84 ± 19.31	25.73 ± 22.64	20.83 ± 24.60
PFDI-SF20	115.62 ± 23.28	104.77 ± 23.15	99.56 ± 19.43	88.45 ± 12.18
POPDI-6	25.69 ± 13.51	18.40 ± 13.58	11.11 ± 10.85	11.45 ± 13.66
CRADI 8	24.55 ± 11.03	18.75 ± 11.41	15.17 ± 10.58	13.39 ± 8.59
ICIQ-OAB	7.2 ± 3.73	6.24 ± 2.96	5.48 ± 3.02	4.76 ± 3.12
IIQ-7 (OAB)	50.16 ± 31.79	45.40 ± 31.72	38.92 ± 35.96	38.92 ± 33.89
IQoL	72.05 ± 21.03	-	-	89.21 ± 20.54

3.3. Pelvic Organ Prolapse

An overall improvement was measured when the pelvic organ prolapse was considered pre- versus post-treatment. The cumulative PFDI-SF20 q. has a score range of 0–300, and it showed a baseline mean value of 115.62 (±23.28), lowered to 88.45 (±12.18) ($p < 0.01$) at the end of the treatment course. Indeed, when subscale results from the CRADI 8 and POPDI-6 questionnaires were analysed, values were more than halved at the end of the study: from 24.55 (±11.03) (pre-treatment) to 13.39 (±8.59) ($p < 0.05$) (post-treatment); and from 25.69 (±13.51) to 11.45 (±13.66) ($p < 0.01$), respectively (see Table 4).

3.4. Overactive Bladder Urge/UUI

For Overactive Bladder Urge evaluation, two questionnaires were used at different points in time. First, the ICIQ-OAB (score range 0–16) reported mean values going from 7.2 (±3.73) at T0 to 4.76 (±3.12) at T8. Similarly, a decrease in IIQ-7 (OAB) (score range 0–100) values from 50.16 (±31.79) at baseline to 38.92 (±33.89) after the last treatment session was registered (see Table 4).

3.5. Quality of Life

The I-QoL questionnaire (score range 0–110) investigated different aspects concerning changes in patients' life and affecting their everyday routines. The sociality, sexuality and emotional sphere were considered to provide a better understanding and a deeper look into the consequences of having a urinary or pelvic muscle disorder. After the electromagnetic stimulation treatment, patients reported a significant improvement in their quality of life, from a mean score of 72.05 (±21.03) at T0 up to 89.21 (±20.54) ($p < 0.01$) at T8 (see Table 4).

4. Discussion

Many non-invasive techniques are available for treating urinary incontinence and pelvic floor disorders. Physiotherapy has been widely used, but it has the disadvantage of having a slow progression and low patient adherence and compliance to the treatment [10]. The same thing can be said for Kegel exercises, whose effectiveness is reduced because they are frequently performed inconsistently or incorrectly over time by the patients. According to the evidence in the literature [32–34], TOP FMS is an alternative method that

is effective for urinary incontinence in all its forms (SUI, UUI, MUI) [31]. By concentrating electric currents on neuromuscular tissue and depolarizing neurons, this technology causes powerful PFM contractions. The primary somatic and autonomic innervation of the pelvic floor muscles, vaginal wall and rectum, and urinary bladder and urethra originates from the S2–S4 roots of the sacral nerves. Stimulating these roots is an effective way to control the pelvic organs and modulate the pelvic floor [35].

A fundamental aspect that distinguishes Dr. ARNOLD from other devices is the spatial profile of the electromagnetic stimulation. It is homogenously distributed up to the top borders, it covers a wider area, and the lateral profiles are better expressed. This conformation allows for a deep, symmetrical and homogenous distribution of electromagnetic energy, reaching deep neuronal structures inside the pelvis without superficial dispersion. This physical characteristic of the electric current makes it possible to intercept and stimulate bilaterally, in a very selective way, the point of confluence of the sacral branches of the pudendal nerve (S2–S4), the area of maximum response of the pudendal nerve to detrusor inhibition (Figure 6).

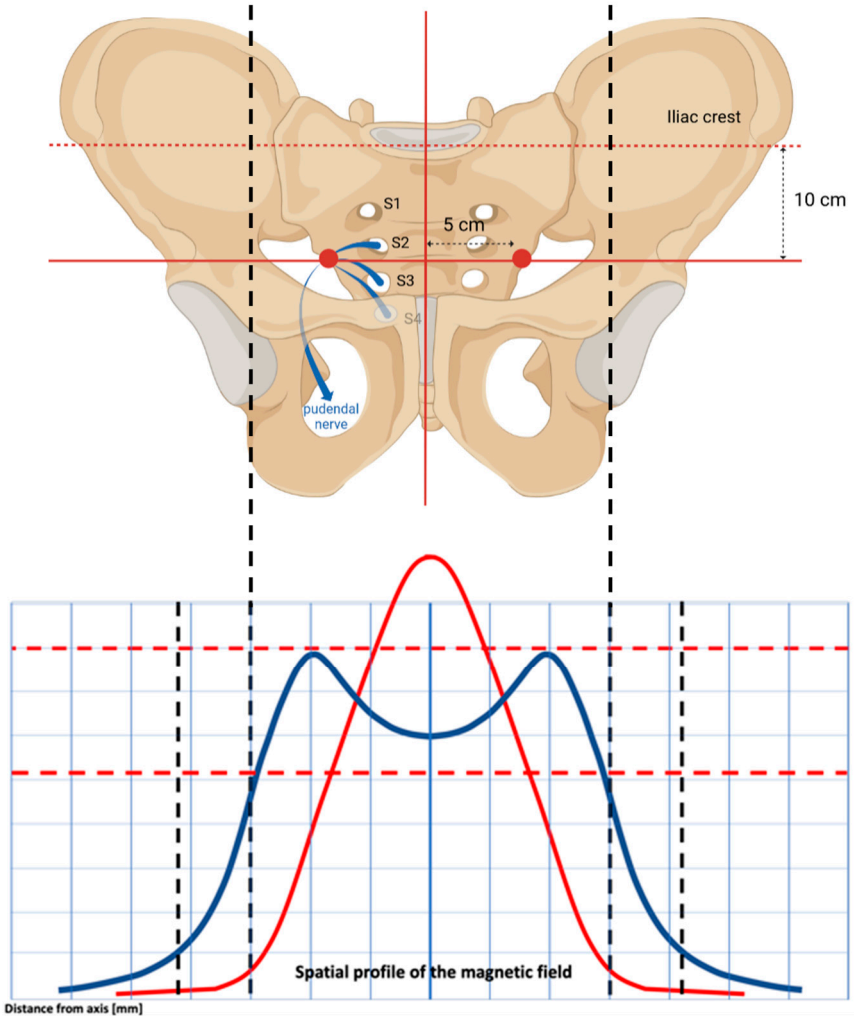

Figure 6. Spatial profile of magnetic field, which allows for a double dome distribution of electromagnetic energy. It intercepts the pudendal nerve at its exit point from the S2–S4 sacral roots. This way, the pudendal nerve is stimulated (as it is shown with red dots, around 10 cm below the iliac crests and 5 cm laterally shifted from the pelvis barycenter) thanks to the homogenous electromagnetic field characterized by a top-flat structure with a diameter of around 16 cm.

Electrical neuromodulation of the sacral and pudendal nerves has been reported to be effective for the treatment of overactive bladder (OAB) with or without stress urinary

incontinence (SUI) and urge incontinence (UUI), [36,37]. Superficial stimulation of the perineal, intravaginal or intrarectal area or direct stimulation of the pudendal nerve is effective for bladder inhibition [38–41].

Additionally, myofibril growth, as well as the development of new protein filaments and muscle fibres, directly result in muscle hyperplasia and hence in an increase in muscle strength and endurance [42]. Electromagnetic energy, stimulation and deep penetration of the whole pelvic floor area are the basis of this treatment's effectiveness. Strengthening pelvic floor muscles with the Dr. ARNOLD system has been demonstrated to be effective in the current study. Our findings on the improvement of the patient's UI symptoms and quality of life align with Isaza et al. [7], Dominguez et al. [30], Lopopolo et al. [6] and Biondo et al. [14].

Indeed, several studies that have used a control group obtained results comparable to ours. This supports our findings, despite the limitations of the study (reported below). Frigerio et al. (2023) [31] demonstrated that urinary-related quality of life scores improved in women who practiced FMS compared to those obtained by women who practiced Pelvic Floor Muscle Training (such as Kegel exercises). Gonzalez Isaza et al. (2022) [7] showed promising improvement in SUI in magnetic stimulation-treated patients compared to the simulated group (sham). In general, these findings underline that magnetic stimulation is a safe and non-invasive alternative for patients who prefer non-surgical treatments. In this study, amelioration in UI, Pelvic Organ Prolapse and OAB symptomatology and quality of life were examined qualitatively by validated questionnaires and quantitatively with US monitoring. Based on the qualitative assessment, there was an improvement in SUI and UUI symptoms after eight sessions of treatment as demonstrated by the reduction of ICIQ-UI-SF, IIQ-7, ICIQ-OAB and UDI-6 questionnaire mean scores (see Table 4). This implied a positive impact on the patient's quality of life as well. Indeed, increased sexual satisfaction and better control of urination were also reported. This is the first time that Dr. ARNOLD effectiveness has been quantitatively evaluated with echography. From our results, US demonstrated to be a useful tool, and PFM showed significant improvement both at rest and in a stress condition.

In conclusion, the TOP FMS has significant advantages over other pelvic floor treatment strategies. This technology can be used in combination with pharmacological and non-pharmacological modalities [43]. Additionally, it does not require a probe to stimulate the muscles. The regular emission of the gradually supplied energy allows patients to stay dressed and in an ergonomic seat. Subjects who feel that the muscles are relaxing become more self-aware and resume their normal daily activities right away. Additionally, the device's ability to work with various protocols makes it useful for treating a variety of pathological disorders linked to UI [14].

Study Limitations and Future Perspectives

Our future goal is to include a control group for comparison purposes. Moreover, it would be interesting to look into the treatment's long- and very-long-term effects by extending the study period with follow-ups (months or even years). Indeed, the therapeutic efficacy of the treatment hereby presented can only be assessed after a proper follow-up and comparing the obtained results with a control group.

5. Conclusions

Study results show that the treatment strategy led, without discomfort or side effects, to a significant improvement in PFM tone and strength in patients with UI and pelvic floor disorders. The demonstration was qualitatively carried out with validated questionnaires and quantitatively with US exams. Thus, the "chair" device we used represents valuable and effective support that could be widely employed in the gynaecologic field for patients with different pathologies.

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Article

Flat Magnetic Stimulation for Urge Urinary Incontinence

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Abstract: *Background and Objectives*: Strategies for overactive bladder syndrome (OAB) management involve, among others, strengthening the bladder outlet to suppress urgency and neuromodulating the sacral roots. Magnetic stimulation (MS) is a technology that involves an extracorporeal device that is able to provide an electromagnetic field specifically designed to interact with pelvic floor neuromuscular tissue. The resulting tissue electrical activity induces contraction of the pelvic muscle and neuromodulation of the S2–S4 sacral roots. Flat Magnetic Stimulation (FMS) is a relevant advancement involving homogeneous electromagnetic fields, which are able to optimize the effect on the entire pelvic area. However, the benefits of this new technology for OAB syndrome are poorly known. Consequently, the aim of our study is to analyze the outcomes and quality of life (QoL) impact of FMS with Dr. Arnold (DEKA, Calenzano, Italy) in women suffering from OAB syndrome associated with urinary incontinence. *Materials and Methods*: This prospective study included patients with OAB, urge urinary incontinence, and no ongoing OAB treatments. At baseline (T0), the Incontinence Impact Questionnaire (IIQ-7), the Female Sexual Function Index (FSFI-19), and the International Consultation on Incontinence Questionnaire–Urinary Incontinence Short Form (ICIQ-UI SF) were collected. Patients underwent 8 FMS sessions of 25 min each in one month. At the termination of the therapy (T1), women repeated the ICIQ-UI SF, FSFI-19, and IIQ-7 tools. Moreover, the Patient Global Impression of Improvement (PGI-I) questionnaire was collected to evaluate the cure rate. *Results*: Our study enrolled a total of 57 consecutive patients. Most women had at least one second- or third-line treatment before FMS, while the remaining naive patients had contraindications to pharmacological treatments. No women reported adverse effects during the treatment. After the treatment, we observed a decrease in the IIQ-7 ($p < 0.001$) and ICIQ-UI SF scores ($p < 0.001$) and an improvement in sexual function ($p < 0.001$) evaluated with FSFI-19. According to PGI-I scores, 42 (73.7%) women referred to some kind of improvement, scoring ≤ 3 points. Specifically, 8.7% of patients considered themselves very much improved, 29.8% much improved, 35.1% minimally improved, and 26.3% found no changes. FMS was effective in treating OAB symptoms without any adverse effects. The mechanism is supposed to be related to suppressing the initiation of micturition. This makes FMS a promising device for treating naive and refractory urge urinary incontinence. *Conclusions*: The new FMS represents a promising non-pharmacological option for the treatment of naive and refractory OAB.

Keywords: overactive bladder; quality of life; urinary incontinence; pelvic floor disorders; magnetic stimulation

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1. Introduction

Pelvic floor disorders are conditions affecting the proper function of a woman's pelvic organs, thus encompassing bowel, urinary, support, and sexual dysfunctions [1,2]. Vaginal delivery and associated trauma are considered the primary etiopathogenetic mechanisms

predisposing to pelvic floor damage [3–5]. Specific obstetric factors, such as fetal macrosomia and instrumental delivery, may be associated with greater pelvic floor injuries [6–9]. Moreover, menopause-related hormonal changes and connective tissue histological features have been related to the development of pelvic floor symptoms [10–14]. Due to shared risk factors, pelvic floor disorders may coexist, and worsening or de novo onset may occur after treatment such as surgery [15–17]. Overactive bladder syndrome, for instance, usually improves after prolapse repair but tends to worsen if a concomitant anti-incontinence procedure is performed at the time of surgery [18,19].

Overactive bladder syndrome (OAB) is defined by the International Continence Society (ICS) as "urgency, with or without urge incontinence, usually with frequency and nocturia" [20]. It is a common pelvic floor disorder, affecting a sixth of women in the United States [21]. Urinary incontinence has a negative impact on women's quality of life (QoL) in terms of interpersonal, household, sexual, and mental-physical well-being [22,23]. OAB can be categorized, based on the presence or absence of neurologic conditions such as Parkinson's disease, multiple sclerosis, and/or a spinal cord injury, into a neurogenic or idiopathic (nonneurogenic) form. However, the etiology of OAB is still unclear, but it has been related to bladder hypersensitivity, low bladder compliance, detrusor overactivity, or pelvic floor surgery [22,24]. Detrusor overactivity (DO) represents the most common finding in OAB patients and can be identified in 64% of patients during urodynamic evaluation [25,26]. However, urodynamics globally shows poor agreement between clinical symptoms and instrumental findings in the evaluation of bladder dysfunction [27–29]. Moreover, the importance of urodynamics for urinary incontinence diagnostic work-up is currently under debate due to inconsistent performance and a lack of consensus on definitions [30,31]. In addition, both OAB and DO have been found in concomitance with underactive bladder syndrome and detrusor underactivity, making proper patients' condition classification and subsequently clinical management challenging [32,33]. ICS has recognized that symptoms of OAB may stem from diverse forms of dysfunction in the urethra and bladder [20]. Recent research has posited the existence of several subcategories within OAB [34,35], suggesting that various underlying mechanisms can elicit the sensation of urinary urgency. An increasing body of evidence in recent years has linked OAB with conditions such as subclinical dysfunction in the autonomic nervous system [36,37], metabolic syndrome [38–40], deficiencies in sex hormones [41], affective disorders [42], gastrointestinal functional issues [43,44], and alterations in urinary microbiota [45,46]. These factors could contribute to OAB and indicate that it might have a distinct pathophysiological basis within these diverse frameworks. Although the available data are limited, several emerging studies point to the potential benefits of categorizing OAB into these different phenotypes, which could lead to more informed treatment decisions and potentially better outcomes. These subtypes of OAB could not be necessarily exclusive as they might often overlap, and this fact could provide a strong rationale for considering combination therapy, which could target multiple underlying mechanisms and enhance the likelihood of achieving successful treatment [47].

Currently, the first-line treatment for idiopathic OAB is behavioral treatment, which involves three approaches: (1) lifestyle modification such as fluid management, a decrease in the intake of caffeine, alcohol, and acidic and spicy foods, and weight loss; (2) modification of bladder function induced by changing voiding habits, such as applying bladder training and delayed voiding; and (3) pelvic floor muscle training (PFMT) to strengthen the bladder outlet and suppress urgency, which may include active exercises for pelvic floor muscles, biofeedback, electrical stimulation, and magnetic stimulation (MS) [48–50]. Second-line treatment involves pharmacological therapy with antimuscarinics, beta-3 adrenergic receptor agonists, or the combination of both of these medications. Combination therapy with an anti-muscarinic and beta-3 adrenergic receptor agonist may be considered for patients refractory to monotherapy [50–53]. The third line is represented by onabotulinumtoxinA therapy, PTNS, or neuromodulation, and may be offered—after careful patient selection and appropriate patient counseling—in patients in whom previous line treatments have

failed or are contraindicated [51,54,55]. However, since all second- and third-line treatments have side effects, drawbacks, and complications, behavioral therapies should be offered at first to all patients with OAB.

Despite most guidelines not recognizing the role of magnetic stimulation, its hypertrophic effect on the urethral rhabdosphincter may be useful in suppressing the initiation of micturition, similar to other forms of pelvic muscle strengthening treatments [56]. This technology involves an extracorporeal device that is able to produce a distinct electromagnetic field that engages with neuromuscular tissue located in the pelvic floor. The resulting electrical activity induces controlled depolarization of the nerves, resulting in pelvic muscle contraction and sacral S2–S4 root neuromodulation [57]. Although the Food and Drug Administration has approved magnetic stimulation for the treatment of urinary incontinence since 1998, limited research in the existing literature has evaluated the safety and effectiveness of this practice [58]. A recent systematic review of the effectiveness of magnetic stimulation for the treatment of urinary incontinence demonstrated a certain efficacy in terms of cure rate and improvement in QoL [59]. However, only 12 studies published between 2010 and 2020 were eligible, and most of them considered patients with stress urinary incontinence.

Recently, magnetic stimulator technology witnessed relevant advancements, which include Flat Magnetic Stimulation (FMS). This involves homogeneous rather than curved electromagnetic fields, which are able to optimize the effect on the entire pelvic area. Due to the equal distribution and intensity of stimulation, FMS allows large recruitment of muscle fibers without leaving areas of inconstant/suboptimal stimulation, leading to substantial advantages compared with standard magnetic stimulation treatment. The interaction between the magnetic field and the neuromuscular tissue induces electrical currents, which initiate neuronal cell depolarization, trigger muscle contractions, and improve blood circulation [60]. Depending on the frequencies of magnetic fields, either sacral S2–S4 root neuromodulation or urethral rhabdosphincter muscle fiber hypertrophy may be evoked, which represent two milestones in the treatment of overactive bladder syndrome. Specifically, a previous sonographic study has demonstrated significant urethral rhabdosphincter muscle hypertrophy consequent to FMS [56]. However, the benefits of this new technology for OAB syndrome are poorly known.

Consequently, the aim of our study is to analyze the outcomes and QoL impact of FMS in women suffering from overactive bladder syndrome associated with urinary incontinence.

2. Materials and Methods

This prospective study was carried out at "Fondazione IRCCS San Gerardo dei Tintori" (Monza, Italy) from August 2022 to March 2023. In the gynecological outpatients, women underwent a clinical interview to evaluate the presence and severity of pelvic floor symptoms, such as bulging symptoms, lower urinary tract symptoms, pelvic pain, or fecal incontinence. All definitions conformed to IUGA/ICS terminology [20]. For each patient, a clinical urogenital examination was performed, and genital prolapse was staged in accordance with the Pelvic Organ Prolapse Quantification (POP-Q) system. Patients were included in the study if they had an overactive bladder with urge urinary incontinence and no active treatments at the moment of enrollment. Among the exclusion criteria we considered were pregnancy, age < 18 years old, weight > 160 kg, deficient Italian language knowledge, defibrillator or implanted pacemaker carriers, patients with ferromagnetic prostheses or neurostimulators, recent diagnosis of malignant tumors, deep venous thrombosis, acute inflammatory conditions, fever, recent fractures involving the body area to be treated, arrhythmia, or congestive cardiac failure, as previously stated [56]. At baseline (T0), all the patients received and completed the Incontinence Impact Questionnaire (IIQ-7), the Female Sexual Function Index (FSFI-19), and the International Consultation on Incontinence Questionnaire–Urinary Incontinence Short Form (ICIQ-UI SF) [61–63]. The IIQ-7 questionnaire is aimed at exploring the effect of urinary incontinence on patients' everyday lives and relationships. It is made of seven items—with four options of answers each—to

individually self-esteem the effect of urine leaking on quotidian activities in four areas: physical exercise (points #1 and #2), traveling (points #3 and #4), social interactions (points #5), and psychological well-being (points #6 and #7). This tool has been associated with an excellent level of acceptability, reliability, and validity based on standard psychometric tests and validated across different countries and cultures [63]. The ICIQ-UI SF questionnaire includes four questions dealing with the urine leaking frequency, the subjective amount of urine leaking, and its impact on everyday life. Only the first three items determine the total score, while the last one is designed to self-define the subcategory of urinary incontinence. The above-mentioned tool demonstrated significant rates of validity, accuracy, and sensitivity through the use of standard psychometric tests, and its validation has allowed the evaluation of the frequency, severity, and effect of urinary incontinence on QoL [61]. The FSFI-19 questionnaire is a self-reported tool aimed at investigating female sexual dysfunction. It consists of 19 questions, divided into six domains, exploring sexual function, which includes arousal, desire, lubrication, orgasm, satisfaction, and pain, with 5-point Likert answer scales. A cut-off of 26.5 points identifies patients with and without sexual disorders. This tool has systematically proven satisfying assessment characteristics in evaluating the impact of multiple conditions on sexual health and the efficiency of various therapies, representing one of the most appropriate, helpful, well-known, and powerful diagnostic tools in this field [62].

After obtaining written informed consent, patients underwent FMS according to the following schedule: eight sessions of 25 min each, two times a week for thirty days, of FMS treatment with Dr. Arnold (DEKA, Calenzano, Italy). The Dr. Arnold device is made of a comfortable and ergonomic chair with a built-in electromagnetic device controlled by an external main unit designed for deep pelvic floor area therapy and has been CE-marked since July 2020. The electromagnetic coil is located under the seat. The patient is seated in a manner that centers the perineum on the chair, ensuring that stimulation and muscle contraction are directed toward the pelvic floor. Before each session of FMS, an operator adjusted the patient's position to both ensure appropriate electromagnetic stimulation and individual wellbeing throughout the entire treatment period. According to the standard position, the patients should have their legs bent at a 90-degree angle, with thighs parallel to the ground and feet resting flat on the floor; if necessary, the seat height could be adjusted. During sessions 1 to 4, the Hypotonia/Weakness 1 protocol was followed; this consisted of a primary phase of warm-up and gentle muscle activation, then a subsequent stage of muscular activity focused on restoring tropism and enhancing muscle tone within a trapezoidal pattern, involving frequencies in the range of 20–30 Hz, requiring a total time of 25 min.

During sessions 5 to 8, the Hypotonia/Weakness 2 protocol was followed; this included an initial phase for warming up and activating muscles, followed by a muscle-focused segment aimed at enhancing tropism (volume), and subsequently, a muscle strengthening phase (40–50 Hz) characterized by a trapezoidal pattern, requiring a total time of 25 min.

As treatment was fully completed (T1), women repeated all three questionnaires, the IIQ-7, ICIQ-UI SF, and FSFI-19 questionnaires, and the results were compared to the T0 to determine the impact on QoL. The Patient Global Impression of Improvement (PGI-I) questionnaire allowed researchers to investigate the subjective cure rate. This tool is a 7-point scale that provides a self-evaluation of how much the patient's condition has improved or aggravated after the treatment, compared to the baseline status. This scale is rated as 1, very much improved; 2, much improved; 3, minimally improved; 4, no change; 5, minimally worse; 6, much worse; or 7, very much worse [64]. An improvement compared to the baseline (PGI-I score ≤ 3) was considered a success.

This study protocol (protocol code PF-MAGCHAIR) was approved by the local Ethics Committee. After the failure of the normality check, which was conducted with Shapiro–Wilk's test, the questionnaire scores were presented as median values along with the interquartile range (IQR). Before comparing the results extracted throughout the analysis, we used the Mann–Whitney's U test to verify if pertinent covariates such as patients' age,

number of deliveries, and body mass index could provide any statistically significant differences in the baseline scores. The scores were compared using Wilcoxon's signed-rank test. We set the significance threshold at 0.05 for all calculations. The analysis was performed with R 4.1 (the R Core Team, Vienna, Austria, 2021) for MacOS®.

3. Results

Our study recruited 58 patients in total. One of them (1.7%) was lost at follow-up. The remaining 57 women were analyzed. Population characteristics are shown in Table 1. Most women had at least one second- or third-line treatment before FMS, while the remaining naive patients had contraindications to pharmacological treatments. The median age was 65 years, IQR [65;75], with 77.2% of the women having given birth to one (n = 15, 26.3%) or two (n = 29, 50.9%) children. A total of 14.0% were nulliparous (n = 8); the remaining five had three children (n = 3, 5.3%) or more children (n = 2, 3.6%).

Table 1. Baseline population characteristics. ICIQ-UI SF: International Consultation on Incontinence Questionnaire–Urinary Incontinence Short Form; FSFI-19: Female Sexual Function Index; IIQ-7: Incontinence Impact Questionnaire. Continuous data as mean ± standard deviation. Non-continuous data as absolute (relative) frequency.

Age (years)	64.6 ± 11.5
Parity (n)	1.6 ± 1.0
Previous second-line treatments (n)	0.7 ± 1.0
Previous third-line treatments (n)	0.1 ± 0.3
Total previous second- and third-line treatments (n)	0.8 ± 1.0
ICIQ-UI SF score (T0)	11.7 ± 4.9
IIQ-7 score (T0)	41.7 ± 23.0
FSFI-19 score (T0)	9.2 ± 10.4

No adverse effects have been documented by any of the patients during the whole procedure. A summary of outcome assessments from subjective and quality of life surveys is presented in Table 2, both at baseline (T0) and upon completion of the treatment (T1).

Table 2. Baseline (T0) versus end-of-treatment (T1) comparison. Data are reported as medians and interquartile ranges. ICIQ-UI SF: International Consultation on Incontinence Questionnaire–Urinary Incontinence Short Form; FSFI-19: Female Sexual Function Index; IIQ-7: Incontinence Impact Questionnaire; PGI-I: Patient Global Impression of Improvement. n/A: not applicable.

Questionnaire	**Baseline (T0)**	**End of Treatment (T1)**	***p*-Value**
IIQ-7	33 [27.5–55.0]	27.5 [11.0–44.0]	<0.001
ICIQ-UI SF	13 [8–16]	8 [6–13]	<0.001
FSFI-19	1.2 [1.2–18.5]	2.7 [1.2–21.4]	<0.001
PGI-I	n/A	3 [2–4]	n/A

The reduction in the IIQ7 scores (leakage severity) at T1, compared to T0, was statistically significant ($p < 0.001$) with a mean difference of 13.2 points, 95%CI [8.7;17.3] and an effect size of 0.802, 95%CI [0.500–1.098], thus supporting the clinical usefulness of this treatment. Moreover, at T1, we observed a statistically significant reduction in the ICIQ-UI SF scores compared to T0 ($p < 0.001$) with a mean difference of 2.46 points, 95%CI [1.54; 3.37], and an effect size of 0.71, 95%CI [0.42–0.99]. Sexual function also improved significantly ($p < 0.001$) with a mean difference of −1.69, 95%CI [−2.59; −0.80], and an effect size of 0.504, 95%CI [0.23–0.78]. Considering sexually active women only, a significant improvement was observed in the IIQ scores ($p < 0.001$, mean difference 14.63 points, 95%CI [7.567–21.69], effect size 0.86, 95%CI [0.39–1.31]), ICIQ-UI SF ($p = 0.003$, mean difference

2.16 points, 95%CI [0.80–3.52], effect size 0.66, 95%CI [0.22–1.01]), and FSFI scores ($p = 0.001$, mean difference −3.30, 95%CI [−5.19; −1.42], effect size 0.72, 95%CI [0.28–1.16]).

According to PGI-I scores, 42 (73.7%) women referred to some kind of improvement, scoring ≤ 3 points. Specifically, 8.7% of patients considered themselves very much improved (1), 29.8% much improved (2), 35.1% minimally improved (3), and 26.3% found no changes (4) (Figure 1).

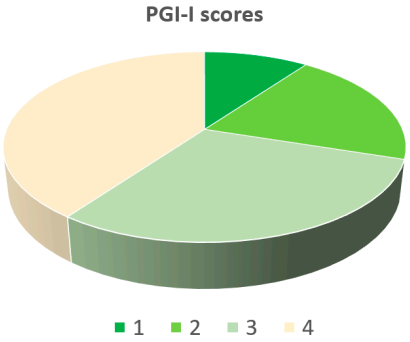

Figure 1. PGI-I scores.

4. Discussion

According to multinational guidelines, behavioral treatment should represent frontline therapy in the case of OAB. Magnetic stimulation offers some theoretical advantages over all other behavioral treatment options, including PFMT, functional electrical stimulation, and biofeedback. Compared to electrical stimulation and biofeedback, MS is a type of passive rehabilitation that is performed passively and with no need for vaginal probes, which may cause discomfort among patients due to potentially compromised vaginal habitability. Moreover, there is no need for the patient to get undressed during treatment [65]. In fact, patients sit in an ergonomic chair, as it is equipped with a height-adjustable backrest, so it is possible to enjoy complete comfort and relaxation during every session. Other negative aspects related to electrical stimulation and biofeedback involve low adherence to therapy and the documented affection caused by tissue impedance to electrical current, which instead does not impact the conduction of electromagnetic energy. Low compliance with first-line treatments concerns even PFMT, as many patients may not be able to perform correct and consistent contractions and training of pelvic floor muscles, leading to poor results in terms of symptom improvement [66].

On the contrary, MS is a first-line non-invasive, standardizable, and with no adverse effects treatment for OAB [67]. Specifically, FMS is the newest innovation in MS technology. This novel device works by inducing an electric current and provoking passive, vigorous contractions of pelvic floor muscle (PFM), targeting neuromuscular tissue. Magnetic stimulation-related electric currents cause neuron depolarization, inducing concentric contractions and lifting all PFMs, which result in being deeply stimulated as well as neuromuscular control being regenerated [68,69]. Moreover, the entire process leads to a modification of the muscular structure as fibers tend to become hypertrophic and hyperplasic. Leone et al. have previously documented this modification on abdominal muscles in 15 patients who underwent FMS, reporting an augmented muscular thickness 1 month after treatment in the four areas that had been targeted by therapy: upper, lower, lateral abdomen, and rectus abdominis diastasis [70]. Moreover, as a consequence of FMS, Frigerio et al. have reported substantial rhabdosphincter muscle hypertrophy, consisting of a 15.4% augmentation in muscular total volume [56]. This is particularly relevant, considering that strengthening the bladder outlet muscles is supposed to be effective in suppressing urgency. This makes FMS a promising device to treat urge urinary incontinence that can eventually be used as exclusive therapy or together with other pharmacological or physical procedures.

Our experience aimed to prospectively compare the short-term outcomes of FMS in patients with urge urinary incontinence and no other ongoing treatments, evaluating urinary symptoms at baseline and at the end of treatment. According to PGI-I scores, 42 (73.7%) women referred to some kind of improvement in their OAB symptoms after 8 sessions of FMS. Considering QoL outcomes, after the MS sessions, we reported a statistically significant decrease in the IIQ7 scores (a troubling amount of leakages) compared to baseline. In the same way, a statistically significant decrease in the ICIQ-UI SF scores was observed. Patients' sexual function was assessed by the FSFI-19 questionnaire, and this study results demonstrate an improvement related to the impact of urge incontinence on patients' sexual lives.

The effectiveness of FMS for mixed/stress and urge incontinence was previously highlighted by other studies; Lopopolo et al. investigated the impact of FMS on mixed urinary incontinence in 50 patients. Women underwent 6 sessions of treatment with the Dr. ARNOLD system (DEKA M.E.L.A. Calenzano, Italy), divided into two of them per week for 3 weeks, for approximately 30 min. Multiple questionnaires were used for the assessment of the urinary symptoms before, within, and 3 months after the treatment period: ICIQ-UI-SF, Incontinence Questionnaire Overactive Bladder Module (ICIQ-OAB), and IIQ-7. Data suggested that FMS technology could reduce mixed urinary incontinence symptoms for all the patients in this study, reflecting an improvement in their QoL [71]. Biondo et al. analyzed 46 female patients reporting urge urinary incontinence who underwent a total of 8 treatment sessions performed twice a week for 4 consecutive weeks for 28 min. Immediately before each treatment and up to 3 months of follow-up, two questionnaires, IIQ-7 and ICIQ-OAB, were used. They concluded that the protocol used led to a decrease in urge incontinence complaints, achieving good results and improving patients' QoL without risk [72]. In a prospective study, Doğanay et al. documented the long-term effects induced by extracorporeal magnetic stimulation on 69 patients with urge incontinence who performed 16 sessions of treatment. At 6-month follow-up, patients in both groups had a significant improvement in QoL, related to a significant decrease in leakage episodes and daily pad use [73].

Strengths of our study involve the prospective design in which a clinical urogynecological evaluation was offered to each patient, the exhaustive assessment of benefits—in particular, subjective and objective curative rate and several validated QoL questionnaires—and the low percentage of lost patients at follow-up (1.7%, 1 out of 58). Limitations are represented by the lack of a control group and a small sample size.

5. Conclusions

Our experience demonstrated that FMS constitutes a safe and effective option for treating naive and refractory urge urinary incontinence in terms of objective and subjective cure rate, with no adverse effects described as well as a high level of acceptance for the patients.

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Informed Consent Statement: All participants in this study provided their informed consent.

Data Availability Statement: The data described in the current study are accessible on demand from the corresponding author.

Conflicts of Interest: The authors declare no conflict of interest.

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Changes in Pelvic Floor Ultrasonographic Features after Flat Magnetic Stimulation in Women with Chronic Pelvic Pain and Levator Ani Muscle Hypertonicity

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Abstract: *Background and Objectives:* Chronic pelvic pain (CPP) represents a major public health problem for women with a significant impact on their quality of life. In many cases of CPP, due to gynecological causes—such as endometriosis and vulvodynia—improper pelvic floor muscle relaxation can be identified. Treatment of CPP with pelvic floor hypertonicity (PFH) usually involves a multimodal approach. Traditional magnetic stimulation has been proposed as medical technology to manage muscle hypertonicity and pelvic pain conditions through nerve stimulation, neuromodulation, and muscle relaxation. New Flat Magnetic Stimulation (FMS)—which involves homogeneous rather than curved electromagnetic fields—has the potential to induce sacral S2–S4 roots neuromodulation, muscle decontraction, and blood circulation improvement. However, the benefits of this new technology on chronic pelvic pain symptoms and biometrical muscular parameters are poorly known. In this study, we want to evaluate the modification of the sonographic aspect of the levator ani muscle before and after treatment with Flat Magnetic Stimulation in women with chronic pelvic pain and levator ani hypertonicity, along with symptoms evolution. *Materials and Methods:* A prospective observational study was carried out in a tertiary-level Urogynaecology department and included women with CPP and PFH. Approval from the local Ethics Committee was obtained before the start of the study (protocol code: MAGCHAIR). At the baseline, the intensity of pelvic pain was measured using a 10 cm visual analog scale (VAS), and patients were asked to evaluate their pelvic floor symptoms severity by answering the question, "How much do your pelvic floor symptoms bother you?" on a 5-answer Likert scale. Transperineal ultrasound (TPU) was performed to assess anorectal angle (ARA) and levator ani muscle minimal plane distance (LAMD). Treatment involved Flat Magnetic Stimulation alone or with concomitant local or systemic pharmacological therapy, depending on the patient's preferences. FMS was delivered with the DR ARNOLD system (DEKA M.E.L.A. Calenzano, Italy). After the treatment, patients were asked again to score the intensity of pelvic pain using the 10 cm visual analog scale (VAS) and to evaluate the severity of their pelvic floor symptoms on the 5-answer Likert scale. Patients underwent TPU to assess anorectal angle (ARA) and levator ani muscle minimal plane distance (LAMD). *Results:* In total, 11 patients completed baseline evaluation, treatment, and postoperative evaluation in the period of interest. All patients underwent eight sessions of Flat Magnetic Stimulation according to the protocol. Adjuvant pharmacological treatment was used in five (45.5%) patients. Specifically, we observed a significant increase in both ARA and LAMD comparing baseline and post-treatment measurements ($p < 0.001$). Quality of life scale scores at baseline and after treatment demonstrated a significant improvement in

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both tools ($p < 0.0001$). *Conclusions:* Flat Magnetic Stimulation, with or without adjuvant pharmacological treatment, demonstrated safety and efficacy in reducing pelvic floor hypertonicity, resulting in improvement in symptoms' severity and sonographic parameters of muscular spasm.

Keywords: flat magnetic stimulation; chronic pelvic pain; vulvodynia; pelvic floor hypertonicity; ultrasound

1. Introduction

Chronic pelvic pain (CPP) represents a major public health problem for women with a significant impact on their quality of life [1]. It is defined as pain originating from the pelvis, typically with a duration of more than 6 months, and is often associated with urinary, sexual, and bowel symptoms or with gynecologic dysfunction, which can have negative cognitive, behavioral, sexual, and emotional consequences [2]. It is estimated to affect 26% of the world's female population, with estimated costs in the USA of USD 5.8 billion in 2020.

CPP is a multifactorial disorder, and pain may originate from gynecological, gastrointestinal, pelvic, musculoskeletal, or nervous systems [3]. Chronic pelvic pain syndrome (CPPS) is a diagnosis of exclusion based on the presence of CPP in the absence of a confirmed infection or a local pathology accounting for the pain [4]. In the absence of well-defined pathology, CPPS is classified according to symptoms, signs, and, where possible, investigations. However, in many cases, chronic pain may continue even after the initial cause has been cured. Gynecological causes of chronic pelvic pain can be divided into two groups: disorders of the external genitals (e.g., vulvodynia, primary vestibular pain syndrome, primary clitoral pain syndrome) and internal pelvic pain syndromes (e.g., endometriosis-associated pain syndrome and primary dysmenorrhoea) [5]. Among all, the most common chronic gynecologic pain syndromes are endometriosis and vulvodynia.

Interestingly, women with endometriosis and vulvodynia are more likely to have improper pelvic floor muscle relaxation [6]. Painful or chronic muscular overload can cause the growth of hyperirritable areas called myofascial trigger points (MTrPs) within the pelvic floor and adjacent (abdominal, gluteal, and iliopsoas) muscles. An active MTrP is clinically associated with spontaneous pain in the surrounding tissue and/or to distant sites in specific referred pain patterns [7]. Pain is aggravated by trigger point pressure or sustained/repeated pelvic floor muscle contraction, such as pain related to voiding, defecation, or sexual intercourse. [4]. This condition has also been defined as pelvic floor hypertonicity (PFH). Several terms are used for PFH in the literature, such as pelvic floor spasm, nonrelaxing pelvic floor, and overactivity. Currently, the International Urogynecological Association (IUGA)/International Continence Society (ICS) defines the term "non-neurogenic hypertonicity" as an increase in muscle tone related to the contractile or viscoelastic components that can be associated with either elevated contractile activity and/or passive stiffness in the muscle.

PFH can be primary or secondary to peripheral and central sensitization resulting from other pain conditions, such as acute or chronic injury to one or more musculoskeletal components in the pelvic floor and surrounding structures. Pelvic surgery, traumatic vaginal delivery, traumatic injury of the back or pelvis, gait disturbances, pelvic pain, experienced threat, and (chronic) stress are found to be associated with PFH [8–10]. PFH is also assumed to be related to wrong behaviors, for example, voluntary holding to inhibit micturition or defecation or to avoid incontinence. This might be related to habit, lifestyle, and/or stressful occupation. Laan et al. conceptualized PFH as a symptom of chronic activation of the defensive stress system and should thus be regarded as a physical manifestation of emotional dysregulation [11].

Given the multifactorial nature of chronic pelvic pain, diagnosis should include a biopsychosocial approach [12]. The evaluation should start with a detailed history collection

of the pain onset and progression, location, frequency, distribution, quality, the severity of all painful sites, coexisting pelvic and non-pelvic pain conditions [12,13]; a complete review of medical diagnoses, past surgeries, pain triggers (activity, menstruation, intercourse, and stress); and urological, gastroenterological, gynecologic, and myofascial symptoms [13]. Screening for bladder pain syndrome or interstitial cystitis and irritable bowel syndrome is specifically recommended by international guidelines [12,13].

Clinically, there is no consensus on diagnostic criteria for PFH. Vaginal examination is easy to perform and is considered the reference test to assess PFH [14,15]. Tenderness on examination should be considered an uncommon finding in asymptomatic individuals [16]. The vaginal examination represents the first level examination to be able to evaluate pelvic floor pathologies with good inter- and intra-rater reliability [17–19]. During the gynecological examination, muscle tone in response to pressure and/or voluntary contractility of the muscle and strength, resistance, repeatability, co-contraction, and relaxation capacity can be assessed [20,21]. There is no single accepted or standardized method to objectively assess muscle tone; furthermore, there are no normative values [20]. In some cases, instrumental tests such as surface electromyography (s-EMG) and dynamometry are associated with a gynecological examination to make a more objective assessment of the pelvic floor muscles [22,23].

A recent systematic review analyzed different clinical and instrumental diagnostic tools [24]. For example, a digital technique for pelvic floor muscle assessment—the PERFECT scheme—has been described. PERFECT is an acronym with P representing power (or pressure measured by a manometric perineometer), E = endurance, R = repetitions, F = fast contractions, and, finally, ECT = every contraction timed, which has demonstrated great reliability and validity as a pelvic floor assessment tool [25]. Dynamometry has been used to evaluate the endurance and strength of the pelvic floor muscles [26,27], but its use is still limited by the difficulty of accessing the device outside of a research context and by the limited experience of clinicians. Vaginal manometry is a second-level diagnostic tool that allows objective assessment of muscle pressure/resistance [28,29] compared to digital examination [29]. To make a subjective assessment of PFH, it is possible to use different types of questionnaires such as the Pelvic Floor Distress Inventory [30–32], the Pelvic Floor Impact Questionnaire [30,32], the Pelvic Pain, Urgency and Frequency [32], Central Sensitization Inventory [33], and the McGill Pain Questionnaire [34]. The modified Oxford scale, through a digital visit, [26,27] allows the muscular strength of the pelvic floor to be quantified as 0, no contraction; 1, flickering; 2, weak; 3, moderate; 4, good; and 5, strong [35]. Electromyography (EMG) has also been used to evaluate nerve transmission to the muscle [36–38]. The limitations to the use of this equipment are mainly the limited experience in its use and the lack of a suitable vaginal probe [38]. Both ultrasound (both transperineal and transvaginal) [39–41] and magnetic resonance imaging (MRI) [41] are emerging imaging modalities for evaluating pelvic floor muscle morphometry.

Both MRI and transvaginal/transperineal ultrasound allow the evaluation of pelvic floor disorders, but ultrasound is more accessible and easier to perform. In particular, pelvic floor ultrasound by transperineal route offers some advantages. Transperineal ultrasound (TPU) is a non-invasive, easy-to-use, and safe technique that dynamically evaluates the pelvic floor area. It is also a reproducible tool for assessing pelvic floor muscle integrity, contraction, and relaxation [42]. Transperineal sonographic equipment includes a B-mode compatible two-dimensional (2D) ultrasound system with a cine-loop function, a convex transducer with a frequency of 3.5–7.5 MHz, and a video transmission system. In order to perform a correct perineal ultrasound, a lithotomy position with the hips flexed and slightly abducted and the heels close to the buttocks with the lumbar spine in neutral may be preferable. The gel is applied directly to the probe, which is covered with a condom, a medical glove, or a probe cover. Only then will the examination be carried out. The midsagittal view of the pelvic cavity is obtained by positioning the probe orthogonally and vertically on the centrum of the perineum. The examination is usually painless, and there is no discomfort after placing the probe over the perineum and pubic symphysis. The

standard mid-sagittal view shows, from left to right of the monitor, the pubic symphysis, urethra and bladder neck, vagina, and anorectal junction. Moreover, this scan allows direct and indirect evaluation of levator ani complex contractility status.

Different sonographic markers have been proposed to evaluate levator ani contractility status on 2D-transperineal ultrasound. The distance between the inferior border of the pubic symphysis to the medial border of the levator ani (puborectalis muscle) has been previously evaluated. In order to measure the levator ani muscle minimal plane distance (LAMD), a line from the inferior limit of the pubic symphysis to the anorectal junction should be drawn, representing a standardized antero-posterior dimension of the pelvic hiatus on 2D imaging. On the same scan, the anorectal angle can be estimated. The more the levator ani is contracted (such as during Valsalva or in case of hypertonicity), the more the anorectal angle is expected to be accentuated [42].

Once the diagnosis of pelvic floor hypertonicity is established, treatment usually requires a staged and multimodal approach and may comprehend pelvic floor rehabilitation (e.g., biofeedback, electrical stimulation, magnetic stimulation, pelvic muscle relaxation, and general relaxation training), first-line pharmacological treatment (e.g., Gabapentin, tricyclic antidepressants, muscle relaxant, vaginal estrogen, and NSAIDS); second-line pharmacological treatment (e.g., pregabalin, serotonin–norepinephrine reuptake inhibitors, and vaginal diazepam); third-line pharmacological treatment (e.g., opioids, topical anesthetic, cannabis); neuromodulation (sacral neuromodulation; S2–S4 roots magnetic modulation); local injections (local anesthetics/glucocorticoids or botulinum toxin).

Magnetic stimulation (MS) may successfully manage muscle hypertonicity conditions and related chronic pelvic pain. It generates an electrical field, resulting in nerve stimulation, neuromodulation, and muscle relaxation. Recently, magnetic stimulator technology witnessed big advancements, including Flat Magnetic Stimulation (FMS). In recent years, technological progress has led to improvements in scientific equipment. In particular, Flat Magnetic Stimulation (FMS) allows the generation of electromagnetic fields with a homogeneous profile, which is useful for the treatment of the pelvic area. The innovative feature of the FMS is the homogeneous distribution of the magnetic field. This homogeneous stimulation generates areas of uniform intensity, and, therefore, the muscle works with the same intensity in all fields. It also allows for greater recruitment of muscle fibers without creating unstimulated/recruited areas. This is believed to be associated with greater treatment efficacy compared to standard MS. This involves homogeneous, rather than curved, electromagnetic fields, which are able to standardize the effect on the entire pelvic area [43]. Due to the equal distribution and intensity of stimulation, FMS allows greater recruitment of muscle fibers without leaving areas of inconstant/suboptimal stimulation, leading to substantial advantages compared with standard magnetic stimulation treatment [44]. The interaction between the magnetic field and the neuromuscular tissue induces electrical currents, which may induce sacral S2–S4 roots neuromodulation, muscle decontraction, and blood circulation improvement. However, the benefits of this new technology on chronic pelvic pain related to pelvic floor hypertonicity are poorly known.

In this study, we want to evaluate the modification of the sonographic aspect of the levator ani muscle before and after treatment with Flat Magnetic Stimulation in women with chronic pelvic pain and levator ani hypertonicity, along with symptoms evolution.

2. Materials and Methods

A prospective observational study was carried out in a tertiary-level Urogynaecology department and included women with CPPS. Approval from the local Ethics Committee was obtained before the start of the study (protocol code: MAGCHAIR). Recruitment occurred from September 2023 to November 2023 in the gynecologic outpatients in Fondazione IRCCS San Gerardo dei Tintori, Monza, Italy.

During the study period, patients with chronic pelvic pain underwent a clinical interview to investigate the concomitant presence of lower urinary tract symptoms, bowel symptoms, or sexual dysfunction. All definitions conformed to IUGA/ICS terminology [20].

A gynecological evaluation was performed, and hypertonicity of the pelvic floor muscles was described. Patients who were younger than 18 years of age, pregnant, had congestive heart failure, arrhythmia, a history of malignancy, recent deep vein thrombosis, fever, acute inflammatory disease, or fractures in the treatment area were excluded from the study. Furthermore, as previously stated, women with insufficient knowledge of the Italian language, weighing more than 160 kg, or with neurostimulators, pacemakers, defibrillators, or ferromagnetic prostheses were excluded.

At baseline, pelvic pain intensity was assessed using a 10 cm visual analog scale (VAS), where the left end of the scale (score = 0) indicated "no symptoms" and the right end indicated "very severe symptoms" it could be (score = 100) [45]. Additionally, patients were asked to rate the intensity of their pelvic floor symptoms by answering the question "How much do your pelvic floor symptoms bother you?" on a 5-response Likert scale with the following choice of answers: "1, not at all"; "2, a little"; "3, moderate"; "4, a lot"; and "5, very much" [46].

From an instrumental point of view, patients underwent TPU to assess anorectal angle (ARA) and levator ani muscle minimal plane distance (LAMD). The measurements were taken in the midsagittal plane, after bladder emptying, at rest (Figure 1) [47].

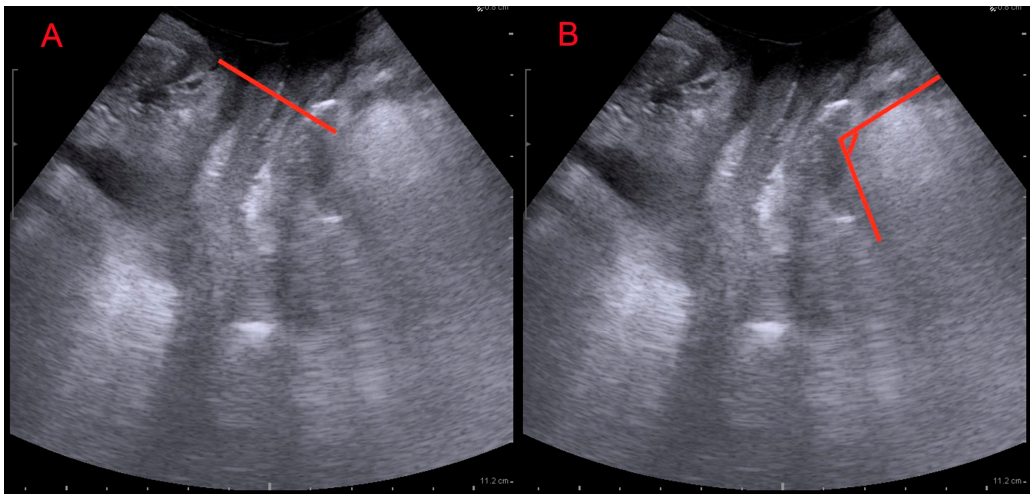

Figure 1. Translabial ultrasound: midsagittal view. (**A**): levator ani muscle minimal plane distance (LAMD) defined as the minimal distance between the hyperechogenic posterior aspect of the symphysis pubis and the hyperechogenic anterior border of the levator ani muscle just posterior to the anorectal angle; (**B**): anorectal angle (ARA) measured as the angle between the posterior edge of the rectum and the posterior edge of the anal canal.

Treatment involved Flat Magnetic Stimulation alone or with concomitant local or systemic pharmacological therapy, depending on the patient's preferences. Flat Magnetic Stimulation was delivered with the DR ARNOLD system (DEKA M.E.L.A. Calenzano, Italy). Treatment was applied for a total of 8 treatments on all patients. Sessions were conducted twice weekly for four consecutive weeks; depending on the patient's muscular condition, each session lasted 28 min. The overtone/pain protocol (muscle work aimed at muscle inhibition and reduction of pain) was selected after the first two minutes of warm-up for all patients. Any adverse effect was registered and classified according to the Clavien–Dindo classification [A]. The Clavien–Dindo classification is easy to use and has been clinically validated.

One month after the treatment, patients were asked again to score the intensity of pelvic pain using the 10 cm visual analog scale (VAS) and to evaluate their pelvic floor symptoms severity by answering the question, "How much do your pelvic floor symptoms bother you?" on the 5-answer Likert scale. Patients repeated TPU to assess anorectal angle

(ARA) and levator ani muscle minimal plane distance (LAMD). The measurements were taken in the midsagittal plane, after bladder emptying, at rest.

The anonymized data were entered into the database by the Authors. Statistical analysis was performed using JMP version 9 software (SAS Institute, Cary, NC, USA). Results were reported as mean ± standard deviation for continuous variables and as number (percentage) for non-continuous variables. Pre- and post-treatment data were compared to obtain objective and subjective results and tested for statistical significance. Differences were tested using a paired *t*-test for continuous data and Fisher's exact test for non-continuous data. A p value < 0.05 was considered statistically significant.

3. Results

In total, 11 patients completed baseline evaluation, treatment, and postoperative evaluation in the period of interest. Population characteristics are shown in Table 1. All patients underwent eight sessions of Flat Magnetic Stimulation according to the described protocol. Adjuvant pharmacological treatment was used in five (45.5%) patients. Baseline and post-treatment sonographic findings are reported in Table 2. Specifically, we observed a significant increase in both ARA and LAMD, comparing baseline and post-treatment measurements. Quality of life scale scores at baseline and after treatment are reported in Table 3. A significant improvement in both tools was demonstrated after the treatment. Improvements in quality of life (VAS $p > 0.001$; Likert $p = 0.001$) and sonographic parameters (ARA $p < 0.001$; LAMD $p = 0.001$) remained significant even in patients who received only FMS without adjuvant pharmacological treatment.

Table 1. Population baseline characteristics. Continuous data are reported as mean (SD). Non-continuous data are reported as absolute (relative) frequency.

Age (years)	52.6 ± 12.6
Parity (n)	1.1 ± 1.0
Menopausal status	7 (63.6%)
Chronic pelvic pain	11 (100%)
Obstructed defecation	6 (54.5%)
Dyspareunia	6 (54.5%)
Bladder pain syndrome	5 (45.5%)
Bladder voiding symptoms	4 (36.4%)

Table 2. Baseline and post-treatment sonographic findings. ARA: anorectal angle; LAMD: levator ani muscle minimal plane distance.

	Baseline	**Post-Treatment**	***p*-Value**
ARA (°)	84.8 ± 7.7	111.3 ± 5.9	<0.001
LAMD (mm)	39.4 ± 2.9	50.3 ± 3.1	<0.001

Table 3. Baseline and post-treatment quality of life findings.

	Baseline	**Post-Treatment**	***p*-Value**
Likert scale	4.4 ± 0.5	1.6 ± 0.7	<0.001
VAS score	75.5 ± 9.3	30.9 ± 19.2	<0.001

4. Discussion

Pelvic floor hypertonicity is a complex disorder that, as previously mentioned, can be caused by multiple triggering events that often coexist with each other. It is, therefore, necessary to evaluate possible causes of traumatic, iatrogenic, postural, and/or antalgic origin. This condition could also be attributed to incorrect pelvic floor activities or poor activities acquired during life, such as continuous voluntary retention of urine or feces [48]. Over the years, some works have appeared in the literature focusing on the diagnosis and

treatment of CPPS, increasing the awareness of the complex, multifactorial nature of chronic pelvic pain. So, chronic pelvic pain syndromes could be managed by a multidisciplinary team with the appropriate skills and understanding to address the variety of factors that maintain its condition [1]. Generally, the goals of treatments are reduction of local inflammation, regularization of nerve transmission to decrease pain, and relaxation of contracted muscles. In the case of pelvic floor muscle hypertonic dysfunction, many non-invasive techniques are available. Physiotherapy is the first-line conservative therapy but has the disadvantage of having slow progression and low patient adherence and compliance with treatment [49,50]. The same thing can be said for Kegel exercises, whose effectiveness is reduced because they are often performed inconsistently or incorrectly over time by patients.

According to the evidence in the literature, magnetic stimulation can be considered an alternative method for the treatment of pelvic floor dysfunctions. Since 1998, it has been described as an alternative conservative approach in women with stress and mixed urinary incontinence [43,44,51,52]. Recently published studies have shown that the new TOP Flat Magnetic Stimulation (TOP FMS) technology reduced the symptoms of urge, mixed, and stress incontinence, improving patients' quality of life without the risk of side effects. [53] (Figure 2).

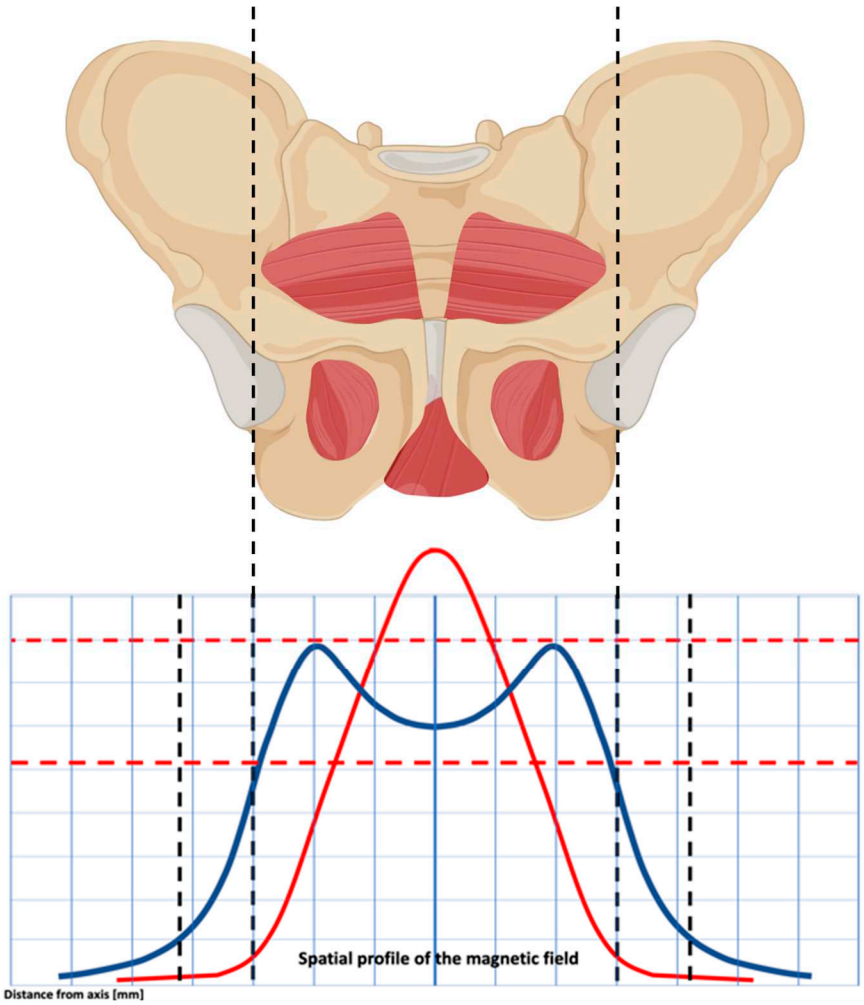

Figure 2. The spatial profile of the magnetic field's electromagnetic energy results in a double-dome distribution. This allows you to uniformly stimulate the pelvic floor muscles, obtaining a homogeneous effect on the pelvic floor muscles.

A fundamental aspect that distinguishes Dr. ARNOLD from other devices is the spatial profile of the electromagnetic stimulation. It is homogeneously distributed up to the top borders, it covers a wider area, and the lateral profiles are better expressed. This conformation allows for a deep, symmetrical, and homogenous distribution of electromagnetic energy, reaching deep neuronal structures inside the pelvis without superficial dispersion. During the procedures, a non-invasive electromagnetic therapeutic device with a main unit and a chair applicator was used. The coil of the chair applicator, which is located in the center of the seat, is intended for therapy of the deep pelvic floor area. The patient is seated on the chair with their perineum in the center of the seat, which helps them feel the stimulation of their pelvic floor and sphincter muscles during stimulation therapy. In order to stimulate the pelvic area, "the chair" can produce an electromagnetic field with a homogenous profile (TOP FMS-TOP Flat Magnetic Stimulation). The beneficial effect of the device in question is due to a greater uniformity of distribution of the magnetic field over a larger area, which allows greater recruitment of muscle fibers without generating different areas in terms of stimulation intensity. Furthermore, the electromagnetic field determines the deep and uniform stimulation of the nerve roots of the sacral nerves (S2–S4) and the pudendal nerve, physiologically responsible for the sensitivity of the perineal region. Electromagnetic energy, stimulation, and deep penetration of the entire pelvic floor are the basis of the effectiveness of this treatment. In the present study, it was shown that relaxing the pelvic floor muscles with the Dr. ARNOLD system is effective. The strengths of this innovative technology are the homogenous profile of stimulation with no differences in intensity between pelvic floor areas, the ergonomic seat, and the opportunity for the patients to stay dressed and not use a vaginal probe. Regarding FMS in PFH, a few studies have reported the use of this device in this peculiar population. Biondo et al. described the use of the device in the treatment of muscle hypertonicity in women with vulvodynia. In these cases, the overtone/pain protocol is based on lower frequencies (around 10 Hz) and low-level electric currents on neuromuscular tissue, bringing to depolarize neurons and PFM decontractions. The homogeneous distribution of the electromagnetic field avoids overstimulation of the already hypersensitive receptors and sensory nerves typical of vulvodynia conditions. In their study, the authors found a significant decrease in PISQ-12 (Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire short form) score and an improvement in vulvodynia symptoms with no side effects [54].

In our study, we aimed to evaluate the effect of Flat Magnetic Stimulation in women with chronic pelvic pain and levator ani hypertonicity on the evolution of symptoms and on the sonographic aspect of the levator ani muscle before and after treatment. After eight sessions of FMS overtone pain protocol, our patients reported an improvement in pain perception and in quality of life, as shown by the significant reduction of VAS and Likert scale scores. Notably, less than half of the patients in our series used adjuvant pharmacological treatment. In addition, we decided to evaluate the effect of magnetic stimulation on the morphological aspect of the levator ani muscle. Through translabial ultrasound, the change of levator ani muscle and anorectal angle in women before and after FMS were collected, and a significant increase in both ARA and LAMD comparing baseline and post-treatment measurements was observed.

The use of pelvic floor ultrasound to assess pelvic floor muscles is well-established. In fact, it has been shown to be more specific than clinical palpation for measurement of the action of the pelvic floor muscles on the anterior compartment; for these reasons, rehabilitative ultrasound imaging has provided novel access to the structure and behavior of the levator ani muscle and their influence on associated structures [55,56]. It can also provide real-time information as a possible source of biofeedback that can be valuable during re-education of the pelvic floor muscles in patients with pelvic floor dysfunction [57]. In particular, it is well reported that transperineal ultrasound is a feasible and reproducible tool in the assessment of pelvic floor muscle thickness at rest and during contraction as an indirect index of hypertone [42]. On the contrary, there is less data on the relationship between pelvic floor hypertonicity and sonographic muscular measurements. Recent

studies have demonstrated how women with chronic pelvic pain were found to have pelvic floor muscle hypertonicity, with a smaller levator hiatal area (LHA) at rest and reduced ability to increase the LHA area on Valsalva maneuver, showing inadequate pelvic floor relaxation [48,58]. With this study, we demonstrated for the first time that magnetic stimulation is able to induce sonographic measurable modifications of pelvic floor muscles consistent with symptom relief. As a consequence, we do think that in the management of pelvic floor hypertonicity, ultrasound imaging can be considered a valid and useful tool to provide important information about the function of the pelvic floor muscles and to monitor the efficacy of the treatment during subsequent observations.

Strengths of our study include the originality, the prospective design, and the multimodal panel of treatment outcomes evaluation. The most relevant limitation is related to the limited population, which is consistent with the still limited—despite emerging—prevalence of this condition.

5. Conclusions

Our study demonstrated that this innovative type of treatment led to a significant improvement in the hypertonicity of the pelvic floor muscles in patients with chronic pelvic pain in terms of symptoms and ultrasound parameters, without discomfort or side effects. Therefore, flat magnetic stimulation represents promising support for the management of chronic pelvic pain related to pelvic floor hypertonicity.

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Original Article

Efficacy of optimized pelvic floor training of YUN combined with pelvic floor magnetic stimulation on female moderate stress urinary incontinence and sexual function: a retrospective cohort study

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[#]These authors contributed equally to this work and should be considered as co-first authors.

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Background: Owing to its tediousness and monotony, traditional pelvic floor muscle training (PFMT) is difficult to ensure the correctness of exercise, and it is difficult for patients to adhere to treatment. We designed this study to evaluate and analyze the efficacy of optimized pelvic floor training of YUN combined with pelvic floor magnetic stimulation on female moderate stress urinary incontinence (SUI) and sexual function.

Methods: This is a retrospective cohort study. This study was carried out in 95 female patients with moderate SUI. The inclusion criteria were as follows: premenopausal women aged 25–45; moderate SUI; over 3 months of disease duration; informed consent and cooperation with treatment and follow-up. The participants in group 1 (control group, n=46) were treated with pelvic floor magnetic stimulation, while those in group 2 (trial group, n=49) were treated with pelvic floor magnetic stimulation combined with optimized pelvic floor training of YUN. Evaluations were scheduled before the treatment (0 week), after 6 weeks of treatment (6 weeks), and after 12 weeks of treatment (12 weeks). And compare the differences between the two groups.

Results: There was no significant difference in age, body mass index (BMI), duration of disease, and abdominal leak point pressure (ALPP) between the two groups (P>0.05). The total effective rate of the trial group was higher than that of the control group (89.80%, 44/49 *vs.* 78.26%, 36/46) (P<0.05). The electromyographic values, the International Consultation on Incontinence Questionnaire Short Form (ICI-Q-SF) score, Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire-12 (PISQ-12) score, physiological factors, and emotional factors were all improved significantly in both groups after active treatment, and the improvement of the trial group was more obvious (P<0.05).

Conclusions: Optimized pelvic floor training of YUN combined with pelvic floor magnetic are more effective for the treatment of female moderate SUI and sexual function. It has become a safe, effective, and well tolerated new type of pelvic floor functional reconstruction training method with good patient compliance.

Keywords: Stress urinary incontinence (SUI); sexual function; magnetic stimulation; optimized pelvic floor training of YUN; combined treatment

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Introduction

Stress urinary incontinence (SUI) is a common disease among middle-aged and elderly women. It has been reported that about half of middle-aged and elderly women have different degrees of SUI (1). In the United States, 25–50% of women experience SUI and spend more than $12 billion annually on its treatment (2). Although SUI is not immediately life-threatening, it has a serious impact on patients' quality of life and sex life. Research shows that 19–50% of SUI patients also experience/present with sexual dysfunction, which is a much higher rate than that of women with normal urinary control (3).

Treatment modalities range from surgical management and drug therapy to physical therapy such as lifestyle intervention, pelvic floor muscle training (PFMT), electrical stimulation, biofeedback, and magnetic stimulation. A study has shown that the incidence of adverse events in magnetic stimulation therapy is low, with a high degree of treatment satisfaction, and fewer patients withdraw from the treatment (4). A randomized clinical trial in 2015 showed that the cure rate in moderate cases of SUI using pelvic floor magnetic stimulation therapy was as high as 75% (5). Some studies have shown that pelvic floor magnetic stimulation therapy can not only improve the short- and long-term overall health condition of female SUI patients, but also affect their quality of life from physical, social, and psychological aspects (6,7). The International Urinary Incontinence Consultation (ICI) suggests that research of female SUI should evaluate the effect of treatment on sexual function. A study of magnetic stimulation therapy suggested that with the improvement of urinary incontinence symptoms in female SUI patients, their sexual function also improved from both physiological and psychological aspects (8).

Besides lifestyle improvement, PFMT is the most important non-invasive treatment for SUI. The National Institute for Health and Clinical Excellence (NICE) recommends PFMT as the first-line treatment for SUI patients. The total short-term effective rate of PFMT can reach 50–75% (8). There was a systematic review of records, which demonstrated that most of the studies indicated that PFMT can improve the sexual function of female SUI patients and pelvic organ prolapse patients (9). However, in traditional PFMT it is difficult to ensure the correctness of exercise, owing to its tediousness and monotony, and it is difficult for patients to adhere to treatment. Optimized pelvic floor training of YUN is a method to integrate professional and scientific PFMT into a fashionable dance, and it has become a safe, effective, and well tolerated new type of pelvic floor functional reconstruction training method with notably good patient compliance (10). A study showed that the inefficiency rate of PFMT group after treatment (44.8%) was higher than that of functional magnetic stimulation group (9.4%) and combined treatment group (4.77%) (11). The current authors found themselves questioning whether it could be more effective to improve the symptoms, quality of life, and compliance of patients with moderate SUI by amalgamating optimized pelvic floor training of YUN to magnetic stimulation. No relevant study had previously been conducted to investigate this topic. Our goal was therefore to conduct research to explore the clinical effect of pelvic floor magnetic stimulation combined with optimized pelvic floor training of YUN on moderate SUI in women. We present the following article in accordance with the STROBE reporting checklist (available at https://tau.amegroups.com/article/view/10.21037/tau-22-222/rc).

Methods

Study design

This is a retrospective cohort study. The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). The study was approved by ethics board of The Fifth People's Hospital of Shanghai (No. 20180801-1). Informed consent was taken from all the patients. The inclusion criteria were as follows: premenopausal women aged 25–45; moderate SUI; over 3 months of disease duration; informed consent and cooperation with treatment and follow-up. Patients were excluded if the following conditions applied: pregnancy, urinary tract infections, other forms of urinary incontinence, neurological diseases, cardiovascular and cerebrovascular diseases, metal pelvic implants, and cardiac pacemakers.

They received either pelvic floor magnetic stimulation therapy alone or combined with optimized pelvic floor training of YUN between June 2017 and June 2018. Group 1 (the control group) included 46 participants who only received pelvic floor magnetic stimulation therapy. Group 2 (the trial group) included 49 participants who not only received the magnetic stimulation treatment, but also engaged in the optimized pelvic floor training of YUN.

Treatment method

The pelvic floor magnetic stimulation therapy was conducted as follows: the device utilized was the

Magneuro30F magnetic stimulation instrument (Nanjing Vishee Medical Technology Co., Ltd., Nanjing, China). After micturition, the patient sat on the treatment chair and started the treatment protocol for SUI. The magnetic stimulation therapy lasted for 20 min/session, twice a week, to a total of 24 sessions.

The optimized pelvic floor training of YUN is a new type of training method combining PFMT with belly dance movements. The pectineus muscles are exercised indirectly, and the pelvic floor muscles are exercised directly and precisely, with both the fast and slow twitch muscles of the pelvic floor being trained with different rhythm designs. The participants were trained once a day, wearing a metal waist chain weighing 0.8±0.1 kg. The course included 15 min basic warm-up exercises of belly dancing; 25 min contracting the vagina and anus under different conditions, such as hips rolling, dropping, performing figure-8s and shimmy; and 15 min pelvic floor muscle strengthening and systemic relaxation exercises with soothing music.

Therapeutic evaluation

Evaluations were scheduled before the treatment (0 week), after 6 weeks of treatment (6 weeks), and after 12 weeks of treatment (12 weeks). If a participant achieved complete resolution of their urinary incontinence, they were evaluated as cured; a reduction in the occurrence level of SUI but incomplete resolution of urinary incontinence was classified as an improvement; no change indicated invalidity of the treatment; and aggravation was used to describe a worsening of moderate urinary incontinence.

Observation indicators

The clinical efficacy of the two groups at 12 weeks of treatment was compared.

(I) Incontinence related indicators: at 0, 6, and 12 weeks, the improvement of symptoms before and after treatment and between the two groups was compared by recording the number of urine leakages per day, and results of the cough test, and 1 hour pad test.

(II) Urodynamic studies were conducted, including maximum urinary flow rate (Qmax), maximum bladder capacity (MBC), post-void residual volume (PVR), and abdominal leak point pressure (ALPP). After filling the bladder with 300 mL of water, participants were raised to a standing position and the ALPP was recorded by straining (Valsalva maneuver).

(III) The Glazer protocol was used to evaluate the electromyography (EMG) of pelvic floor muscles, and signals were detected using the RAYEE-A Vaginal Probe intravaginal electrode (Nanjing Vishee Medical Ltd., Nanjing, China) and collected with 14-bit accuracy at sampling rate of 2048 Hz using the two-channel EMG device, MyoTrac Infiniti (Thought Technology Ltd., Montreal, QC, Canada). There are five steps to the Glazer protocol: (i) pre-baseline rest; (ii) phasic contraction; (iii) tonic contraction; (iv) endurance contraction; (v) post-baseline rest. The participant was instructed to contract and relax their pelvic floor muscles according to the instructions without contracting the abdominal muscles, adductor muscles, or hip muscles and the EMG value was obtained after the test. The measurement was average peak amplitude (μV) for the phasic contraction and average mean amplitude (μV) for the tonic contraction.

(IV) Questionnaires: the results of International Consultation on Incontinence Questionnaire Short Form (ICI-Q-SF) and Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire-12 (PISQ-12) questionnaires were collected at 0, 6, and 12 weeks. The ICI-Q-SF questionnaire recommended by the ICS allows patients to carefully recall the symptoms of the past 4 weeks, and was designed to assess the level of patients' urinary incontinence. The PISQ-12 questionnaire, designed by Rogers *et al.* in 2001, was used to assess the quality of patients' sexual lives (12). The questionnaire included emotional factors, physiological factors, and sexual partner factors. There are three dimensions and 12 sub-items. The participants filled out the questionnaires themselves.

Statistical methods

Statistical analyses were performed using the software SPSS version 20 (IBM Corp., Armonk, NY, USA). The measurement data were analyzed by *t*-test before and after treatment and were used to compare the differences between the two groups. The statistical description of the counting data was expressed by percentage, and the

Table 1 Participant characteristics at baseline

Characteristics	Group 1 (n=46)	Group 2 (n=49)
Age (years), mean (SD)	37.3 (4.4)	35.8 (5.2)
BMI (Kg/m^2), mean (SD)	25.7 (2.4)	25.2 (2.5)
Duration of disease (months), mean (SD)	27.7 (16.6)	22.2 (13.9)
ALPP, mean (SD)	74.3 (9.3)	74.9 (11.7)

BMI, body mass index; SD, standard deviation; ALPP, abdominal leak point pressure.

Table 2 Comparison of symptoms improvement between the two groups

Follow-up time	0 week			6 weeks			12 weeks		
	Group 1	Group 2	P value	Group 1	Group 2	P value	Group 1	Group 2	P value
Number of urine leakage incidents	3.6 (1.2)	3.9 (1.2)	0.14	1.5 (1.7)[a]	1.3 (1.6)[a]	0.49	1.4 (1.8)[a]	1.1 (1.6)[a]	0.35
1 hour urine pad test (g)	6.6 (1.9)	6.4 (1.9)	0.53	2.6 (2.9)[a]	1.8 (2.7)[a]	0.17	2.3 (3.0)[a]	1.6 (2.7)[a]	0.22
Cough test (participants)	46	49	–	15[a]	20[a]	0.41	18[a]	23[a]	0.44

[a], in the upper right corner represents this data as compared with that before treatment in this group, P<0.05.

χ^2 test was used. If test variables are normally distributed, Statistical significance was considered at P<0.05 (two-tailed test).

Results

Baseline characteristics of the 95 randomized participants were balanced across treatment assignment (*Table 1*). There was no significant difference in age, body mass index (BMI), duration of disease, and ALPP between the two groups (P>0.05).

At 12 weeks of treatment, among the 46 cases in the control group, 18 were cured, 18 were improved, 8 were deemed ineffective, and 2 cases were aggravated. The total effective rate was 78.26%. Among the 49 participants in the trial group, 23 cases were cured, 21 were improved, 4 were deemed ineffective, and 1 case was aggravated. The total effective rate was 89.80%, which was higher than that of the control group.

To compare the improvement of symptoms between the two groups, the number of urine leakages per day, 1 hour urine pad test, and cough test were recorded. It was shown that (*Table 2*) at 6- and 12-week follow up, the number of urine leakages per day, 1 hour urine pad test, and cough test were significantly improved in both groups (P<0.05), while there were no significant intergroup differences at 0, 6, and 12 weeks of treatment (P>0.05).

All participants underwent pelvic floor testing via surface electromyography. *Table 3* shows the pelvic floor EMG values between the trial group and the control group. At 6- and 12-week follow up, phasic contraction EMG values and tonic contraction values were significantly improved in both groups (P<0.05). There were significant differences at each step between the two groups at 6 and 12 weeks after treatment (P<0.05).

Table 4 shows a summary of results of the assessment based on the ICI-Q-SF and PISQ-12 questionnaires. After 6- and 12-week of treatment, the total score of ICI-Q-SF and PISQ-12 in both groups were significantly increased (P<0.05), and the improvement in the trial group was more obvious (P<0.05).

The scores of physiological factors in both groups were significantly increased, while at the level of emotional factors, only the trial group increased after 6 and 12 weeks of treatment (P<0.05). There was no improvement in partner factors in both groups of patients.

Discussion

The findings of this study support that, compared with pelvic floor magnetic stimulation alone, pelvic floor magnetic stimulation combined with optimized pelvic floor training of YUN can further improve the clinical efficiency of female patients with moderate SUI, their pelvic floor

Table 3 Comparison of electromyographic values of the phasic contraction and tonic contraction between the two groups

Follow up	0 week			6 weeks			12 weeks		
	Group 1	Group 2	P value	Group 1	Group 2	P value	Group 1	Group 2	P value
Phasic contraction (μV)	24.1 (2.2)	24.3 (2.4)	0.65	33.5 (5.7)[a]	38.9 (5.4)[a]	0.00	36.6 (5.9)[a]	41.2 (6.2)[a]	0.00
Tonic contraction (μV)	19.0 (2.3)	19.2 (2.5)	0.71	32.7 (6.8)[a]	36.8 (5.2)[a]	0.01	36.0 (6.7)[a]	38.9 (5.5)[a]	0.02

[a], in the upper right corner represents this data as compared with that before treatment in this group, P<0.05.

Table 4 Results of ICI-Q-SF and PISQ-12 scores in two groups

Follow up	0 week			6 weeks			12 weeks		
	Group 1	Group 2	P value	Group 1	Group 2	P value	Group 1	Group 2	P value
ICI-Q-SF score	12.85 (1.619)	13.24 (1.702)	0. 248	5.20 (5.093)[a]	4.43 (4.946)[a]	0. 458	5.93 (5.733)[a]	3.39 (4.873)[a]	0.022
PISQ-12 score	28.83 (3.335)	28.61 (2.745)	0.733	30.63 (3.466)[a]	31.65 (2.955)[a]	0.124	30.24 (3.420)[a]	32.47 (3.076)[a]	0.001
Emotional factors	7.61 (2.038)	7.82 (1.954)	0.613	7.83 (1.877)	8.55 (1.569)[a]	0.043	7.83 (1.877)	8.78 (1.571)[a]	0.009
Physiological factors	14.41 (2.257)	14.37 (2.089)	0.919	15.70 (2.096)[a]	16.84 (2.055)[a]	0.009	15.70 (2.096)[a]	17.24 (2.097)[a]	0.001
Partner factors	6.67 (1.194)	6.43 (1.208)	0.322	6.67 (1.194)	6.27 (1.151)	0.093	6.67 (1.212)	6.45 (1.174)	0.361

[a], in the upper right corner represents this data as compared with that before treatment in this group, P<0.05. ICI-Q-SF, International Consultation on Incontinence Questionnaire Short Form; PISQ-12, Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire-12.

EMG values, and sexual function. The reasons we consider are as follows: (I) by incorporating belly dance into PFMT, optimized pelvic floor training of YUN can significantly improve patient compliance and facilitate a good doctor-patient relationship. Simultaneously, the doctor's careful guidance also fosters patient attention to the ideology of PFMT, and increases the time of home-training between two magnetic stimulation therapies, thereby enhancing the effectiveness of pelvic floor magnetic stimulation therapy. (II) Belly dancing can effectively improve vaginal pressure and adductor muscle strength, thereby improving the symptoms of urinary incontinence (13). Optimized pelvic floor training of YUN was designed to train pelvic floor muscles by incorporating different postures, contracting the pelvic floor muscles rhythmically, improving the motor function and blood circulation of the pelvic floor muscles, promoting the muscle metabolic ability, and then restoring the muscles to the normal dynamic range, thus reducing the occurrence of urinary incontinence. By enhancing pelvic floor muscle strength, vaginal tightness can be improved, while reducing the adverse effects of urinary incontinence on sexual life, thus improving overall sexual function. (III) It has been reported that BMI is an important factor affecting the quality of life of SUI patients (14), with a larger BMI indicating a worse the quality of life. Through general movements, professional and scientific tools can be integrated into a trendy and sexy belly dance to form the innovative method of optimized pelvic floor training of YUN. It can not only exercise the pelvic floor muscle, but also exercise the cross-section, perineum, waist, abdomen, chest, and arms. It can reduce the increase in abdominal pressure caused by obesity through whole-body exercise, thereby improving SUI symptoms and the psychological state of patients.

A recent study showed that treatment of female SUI with pelvic floor magnetic stimulation resulted in significant improvements in multiple sexual dimensions for both partners from both physiological and psychological aspects (15). In the physiological aspect, the sexual function of female SUI patients can be improved by raising pelvic floor muscle strength and SUI symptoms. Psychologically, reducing the fear of urinary incontinence may increase sexual desire, improve vaginal lubrication, and reducing pelvic floor spasm may reduce the incidence of sexual pain. The improvement of urinary incontinence symptoms and sexual function in female SUI patients may engender an improvement of their spouses' sexual function, such as erectile dysfunction and premature ejaculation. This experiment was the first time that pelvic floor magnetic stimulation combined with optimized pelvic floor training of YUN was used to

improve SUI. It has been confirmed again that magnetic stimulation can improve pelvic floor muscle strength, urinary incontinence symptoms, and sexual function of female SUI patients. However, this study did not reach the same conclusion that after combined optimized pelvic floor training of YUN with pelvic floor magnetic stimulation, there were improvements in the sexual function of patients at the psychological level and their spouses' sexual function. As observed in our study, the sexual function of female moderate SUI was further improved by progressively ameliorating the level of physiological factors and emotional factors. However, this study still had its limitations. Due to the short observation time, the long-term efficacy of combined treatment is still unknown and needs further observation and research.

Conclusions

This study found that pelvic floor magnetic stimulation alone or combined with optimized pelvic floor training of YUN are both effective methods for the treatment of female moderate SUI and sexual function, and that their combined use is even more effective. These intervention methods can be effective treatments to decrease SUI symptoms, and have a great impact on physiological and emotional factors in women with SUI.

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Footnote

Reporting Checklist: The authors have completed the STROBE reporting checklist. Available at https://tau.amegroups.com/article/view/10.21037/tau-22-222/rc

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Ethical Statement: The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). The study was approved by ethics board of The Fifth People's Hospital of Shanghai (No. 20180801-1). Informed consent was taken from all the patients.

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射频联合磁刺激治疗对轻中度盆腔器官脱垂的疗效

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[摘 要] 目的：单一的盆底电刺激或磁刺激治疗盆底功能障碍性疾病疗效有限，本研究拟探讨磁刺激联合射频治疗对轻中度盆腔器官脱垂(pelvic organ prolapse，POP)的疗效。**方法：**筛选中南大学湘雅三医院诊断为POP并完成治疗的患者，依据治疗方案不同分为2组：磁刺激治疗组(n=28)为完成磁刺激治疗的患者，联合治疗组(n=21)为完成磁刺激联合射频治疗的患者。比较2组治疗前后的盆腔器官脱垂定量分期法(pelvic organ prolapse quantitation，POP-Q)结果、盆底肌肌力和盆底超声结果，治疗结束后3个月，采用POP-Q评价治疗方式的维持效果。**结果：**2组治疗后Aa、Ap、C点的POP-Q结果均优于治疗前，差异均有统计学意义(均P<0.05)；治疗后联合治疗组Aa点POP-Q结果优于磁刺激治疗组，差异有统计学意义(P<0.05)；联合治疗组在valsalva动作下盆底超声评估膀胱颈的位置高于磁刺激治疗组，差异有统计学意义(P<0.05)；治疗结束后3个月，联合治疗组疗效持续性好于磁刺激治疗组，差异有统计学意义(P<0.01)。**结论：**磁刺激联合射频治疗的疗效优于单一的磁刺激治疗，且疗效更持久。

[关键词] 盆底超声；射频治疗；磁刺激；盆腔器官脱垂

Effect of radiofrequency combined with magnetic stimulation on mild and moderate pelvic organ prolapse

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ABSTRACT

Objective: The efficacy of using a single electrical or magnetic stimulation for treating pelvic floor dysfunction is limited. This study aims to investigate the efficacy of radiofrequency combined with magnetic stimulation treatment for mild to moderate pelvic organ prolapse.

Methods: Patients who completed the treatment in the Third Xiangya Hospital, Central South University were screened, and were divided into 2 groups based on different treatment plans. There were 28 patients who completed magnetic stimulation therapy (the

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magnetic stimulation therapy group) and 21 patients who completed radiofrequency combined with magnetic stimulation therapy (the combined treatment group). The pelvic organ prolapse quantitation (POP-Q), pelvic floor muscle strength, and pelvic floor ultrasound results were analyzed to assess the efficacy before and after the treatment in both groups, and the POP-Q results of 3 months after the treatment were used to evaluate the maintenance effect of the treatment mode.

Results: The POP-Q evaluation results of Aa, Ap, and C points after the treatment in both groups were better than those before the treatment, with statistical significance (all $P<0.05$). The Aa point POP-Q result of the combined treatment group was better than that of the magnetic stimulation therapy group, with statistical significance ($P<0.05$). Pelvic floor ultrasound evaluation showed that the bladder neck position during the valsalva maneuver in the combined treatment group was higher than that in the magnetic stimulation treatment group, with statistical significance ($P<0.05$). The persistence effect of the combined treatment group was long better than that of the magnetic stimulation treatment group, with significant statistical significance ($P<0.01$).

Conclusion: The combined treatment is more effective and has a longer lasting effect than single magnetic stimulation treatment.

KEY WORDS pelvic floor ultrasound; radiofrequency therapy; magnetic stimulation; pelvic organ prolapse

盆腔器官脱垂(pelvic organ prolapse，POP)是由于盆底肌肉和筋膜组织异常造成的盆腔器官下降而引发的器官位置异常及功能障碍，是中老年妇女的常见疾病[1]。一项中国的基于全国性横断面研究[2]显示中国女性有症状的POP患病率为9.6%。近年来成年妇女的POP发生率不断上升，且随着年龄的增长而升高，绝经妇女的发病率高达50%[3]。虽然POP不是一种致命性疾病，但严重影响患者的身心健康和生活质量。

POP的发病机制尚无定论，目前认为主要是年龄、腹压、分娩、妊娠、基因等因素引起的，与盆底结缔组织、盆底神经、盆底肌等盆底支持组织减弱有关[3-4]。

目前临床上主流的治疗盆底功能障碍性疾病的方法为电刺激生物反馈。电刺激和磁刺激的机制类似，都是通过电流在细胞水平起作用。但相比电刺激，磁刺激对盆底刺激的范围更广、深度更深，且无需内置电极，无需穿脱衣物，操作简便[5]，更受患者及工作人员喜欢。

然而单一磁刺激对POP的疗效有限，仅能在盆底肌肉及神经方面改善盆底结构，对盆底结缔组织疗效不佳，而盆底温控射频治疗作为近年来的新技术，通过高频交流电使阴道黏膜上皮深层的胶原变性、再生，组织重构，可有效增加盆底肌肉中结缔组织的厚度和弹性，增强盆底肌肌力，改善盆底稳定性[6]，弥补单一治疗的不足。

本研究拟探讨盆底磁刺激联合射频治疗对POP的疗效，为临床选择更优的治疗方案提供依据。

1 对象与方法

1.1 对象

筛选2020年1月至2022年12月在中南大学湘雅三医院康复医学科盆底中心进行盆底康复治疗的产后女性，纳入标准：1)超过18岁的产后女性；2)所有患者的症状、体查评估及盆底B型超声等结果均符合POP诊断标准[依据POP的中国诊治指南(2020年版)[1]]；3)盆腔器官脱垂定量分期法(pelvic organ prolapse quantitation，POP-Q)检查结果为I~II度；4)规律且按时完成10次磁刺激治疗和/或完成3次射频治疗；5)治疗前后完成盆底评估；6)治疗结束后3个月进行复诊。

排除标准：1)无法完成或未按时规律完成盆底治疗者；2)盆腔手术史；3)POP-Q分度为III或以上者；4)妊娠及产后40 d以内女性；5)临床资料不完整；6)合并精神类疾病无法配合者。本研究为回顾性临床研究，获得中南大学湘雅三医院伦理委员会批准(审批号：快23102)。

1.2 方法

盆底中心值班治疗师(此治疗师对患者治疗方案不知情)首先在评估室对患者进行盆底检查、评估与记录，然后对盆底正确收缩方法进行教学，在超声科或盆底诊断室进行盆底超声评估，评估完成后患者结合首诊医生建议及个人经济条件和意愿选择盆底治疗方案，转至盆底治疗室进行治疗(同种治疗的操作者为同一治疗师)。

依据治疗方案不同将患者分为磁刺激治疗组和联合治疗组，磁刺激治疗组进行盆底磁刺激治疗，联合治疗组进行温控射频联合磁刺激治疗(由于符合标准的进行单一射频治疗患者人数过少，故未被纳入本研究当中)。对患者的基本资料及治疗前后评估结果进行分析。

1.2.1 收集人口学信息

人口学信息包括年龄、身高、体重、孕产次，生产日期、分娩方式、新生儿体重、孕期增重等。

1.2.2 治疗方法

盆底磁刺激使用Magneuro60F磁刺激治疗仪(南京伟思医疗科技股份有限公司产品)进行治疗。患者坐在磁刺激治疗椅上，刺激频率为50 Hz，刺激时间为5 s，休息时间为5 s，刺激强度以患者有明显收缩感并且无过度不适为宜，30 min/次，2~3次/周，为期4周，共进行10次治疗。

射频治疗使用VaginaLove薇吉娜矩阵射频治疗仪(武汉半边天医疗技术发展有限公司产品)进行治疗，阴道探头为单人专用，探头涂抹无菌耦合剂，将阴道探头置入阴道内，设置温度在42~48 ℃，额定最大输出功率为45 W，单极治疗40 min(截石位9点至3点进行25 min，3点至9点进行15 min)，每10天1次，共做3次。

联合治疗组在4周内完成10次磁刺激治疗和3次温控射频治疗。

1.3 评价指标

1.3.1 POP-Q评估

对患者治疗前、治疗结束后1周内及治疗结束后3个月进行以下各点的POP-Q评估：Aa点为阴道前壁中线距处女膜缘3 cm处，Ba点为阴道前穹窿的反褶或阴道残端(子宫切除者)距离Aa点最远处，Ap点为阴道后壁中线距处女膜缘3 cm处，Bp为阴道后穹窿的反褶或阴道残端(子宫切除者)距离Ap点最远处，C点为宫颈外口最远处，D点为阴道后穹窿或直肠子宫陷凹的位置，tvl是当C、D点在正常位置时阴道顶部至处女膜缘的总长度，gh为尿道外口到阴唇后联合中点的距离，pb为阴唇后联合到肛门开口中点的距离。均在valsalva动作下测量，各点脱垂的最远端<−1 cm为I度，−1~1 cm为II度，>1~(tvl−2) cm为III度，>(tvl−2) cm为IV度。

治疗结束后3个月POP-Q评估结果与治疗结束后1周内评估结果比较，存在Aa、Ba、Ap、Bp点位置下降超过0.5 cm，C、D点位置下降或tvl减少超过1 cm视为疗效持续性不佳，位置不变或有所上升视为疗效持续性良好。

1.3.2 盆底肌肌力

治疗前、治疗结束后1周内及治疗结束后3个月，采用国际盆底肌功能测评量表中的改良牛津肌力分级法测定盆底肌肌力，4级或以上表明盆底肌收缩力良好。

1.3.3 盆底超声评估

评估治疗前及治疗后结束后1周内盆底三维超声；记录静息状态下及valsalva动作下膀胱颈、子宫颈、直肠壶腹部位置，通过解剖结构评估三腔室位置水平，以耻骨联合后下缘延长线为参考线，线上为负值，线下为正值，负值越大表明盆腔器官位置越高，移动度越小，病情越轻。

1.4 统计学处理

采用SPSS 27.0统计学软件进行数据分析。计量资料以均数±标准差($\bar{x}\pm s$)表示，采用Shapiro-Wilk方法进行正态分布检验，符合正态分布的变量采用t检验进行比较，非正态分布的变量采用Mann-Whitney U检验进行比较；计数资料采用χ^2检验进行比较。P<0.05为差异有统计学意义。

2 结 果

共有1 921名患者进行盆底治疗，其中597名完成全部治疗。符合纳入标准的女性共49名，其中完成盆底磁刺激治疗患者28例，为磁刺激治疗组，完成联合治疗患者21例，为联合治疗组。

2.1 基线比较

2组年龄、BMI、生产次数、新生儿出生体重、生产方式、治疗前POP-Q分度、治疗前盆底肌肌力等差异均无统计学意义(均P>0.05，表1)。

2.2 盆底肌肌力比较

2组治疗后盆底肌肌力分级优于治疗前，联合治疗组在治疗结束后1周内及治疗结束后3个月肌力4级及以上者人数均多于磁刺激治疗组，但差异均无统计学意义(均P>0.05，表2)。

表1　2组患者一般资料比较

Table 1　Comparison of general information between the 2 groups

组别	n	年龄/年	BMI/(kg·m^{-2})	生产次数/[例(%)]			新生儿出生体重/kg
				1次	2次	≥3次	
磁刺激治疗组	28	33.96±6.69	22.24±2.89	14(50)	14(50)	0(0)	3.37±0.59
联合治疗组	21	35.71±7.20	22.32±2.43	11(52.38)	9(38.09)	1(4.76)	3.08±0.41
t/χ^2		−0.877	−0.094		1.477		1.77
P		0.385	0.925		0.478		0.084

组别	生产方式/[例(%)]		治疗前POP-Q分度/[例(%)]		治疗前盆底肌肌力/[例(%)]	
	顺产	剖宫产	Ⅰ度	Ⅱ度	2级	3级
磁刺激治疗组	16(57.14)	12(42.86)	14(50)	14(50)	7(25)	21(75)
联合治疗组	17(80.95)	4(19.05)	9(42.86)	12(57.14)	9(42.86)	12(57.14)
t/χ^2	3.093		0.246		1.740	
P	0.079		0.620		0.187	

BMI：体重指数；POP-Q：盆腔器官脱垂定量分期法。

表2　2组治疗后盆底肌肌力分级比较

Table 2　Comparison of pelvic floor muscle strength grading after treatment between the 2 groups

组别	n	治疗结束后1周内/例		治疗结束后3个月/例	
		≥4级	<4级	≥4级	<4级
磁刺激治疗组	28	15	13	11	17
联合治疗组	21	15	6	15	6
χ^2		2.216		5.495	
P		0.137		0.190	

2.3 POP-Q评估结果比较

POP-Q评估结果显示：治疗前2组Aa、Ap、C点位置的POP-Q差异均无统计学意义(均P>0.05)；治疗结束后1周内，联合治疗组Aa点位置的POP-Q高于磁刺激治疗组，差异具有统计学意义(P<0.05)；联合治疗组治疗结束后1个月内Ap、C点位置的POP-Q均小于磁刺激治疗组，但差异无统计学意义(均P>0.05，表3)。

表3　治疗前后2组POP-Q评估结果比较($\bar{x}\pm s$)

Table 3　Comparison of POP-Q between the 2 groups before and after treatment ($\bar{x}\pm s$)

组别	Aa点					
	治疗前位置/cm	t	P	治疗结束后1周内位置/cm	t	P
磁刺激治疗组	−0.90±0.57	0.725	0.473	−1.71±0.64*	2.038	0.049
联合治疗组	−1.06±0.80			−2.09±0.47*		
组别	Ap点					
	治疗前位置/cm	t	P	治疗结束后1周内位置/cm	t	P
磁刺激治疗组	−1.83±0.53	0.934	0.356	−2.40±0.47*	1.450	0.155
联合治疗组	−1.98±0.46			−2.58±0.31*		
组别	C点					
	治疗前位置/cm	t	P	治疗结束后1周内位置/cm	t	P
磁刺激治疗组	−4.43±0.86	0.046	0.964	−5.26±0.72*	1.458	0.153
联合治疗组	−4.44±0.83			−5.58±0.65*		

与同组治疗前比较，*P<0.05。POP-Q：盆腔器官脱垂定量分期法；Aa点：阴道前壁中线距处女膜缘3 cm处；Ap点：阴道后壁中线距处女膜缘3 cm处；C点：宫颈外口最远处。

2.4 盆底超声评估结果比较

治疗结束后1周内，联合治疗组在valsalva动作下膀胱颈位置优于磁刺激治疗组，差异具有统计学意义(P<0.05)；联合治疗组在静息状态下膀胱颈、子宫颈、直肠壶腹部位置，valsalva动作下子宫颈、直肠壶腹部位置虽均优于磁刺激治疗组，但差异均无统计学意义(均P>0.05，表4)。

2.5 2组治疗结束后3个月疗效持续性比较

对比治疗结束后3个月的POP-Q评估结果，联合治疗组疗效持续性好于磁刺激治疗组，差异具有统计学意义(P<0.01，表5)。

表4 治疗后2组超声评估结果比较

Table 4 Comparison of ultrasound evaluation results after treatment between the 2 groups

组别	膀胱颈位置/cm		子宫颈位置/cm		直肠壶腹部位置/cm		肛提肌裂孔面积/cm^2
	静息状态	Valsalva动作	静息状态	Valsalva动作	静息状态	Valsalva动作	
磁刺激治疗组	−2.74±0.30	−1.01±0.83	−3.83±0.81	−2.33±1.07	−2.35±0.49	−1.04±0.67	20.55±2.14
联合治疗组	−2.90±0.55	−1.50±0.72	−3.90±0.80	−2.70±1.22	−2.70±0.6	−1.40±0.77	20.40±2.19
t	0.894	2.111	0.381	0.968	2.069	1.745	0.191
P	0.377	0.041	0.705	0.339	0.045	0.089	0.849

表5 2组治疗结束后3个月疗效持续性对比

Table 5 Comparison of efficacy persistence after 3 months of treatment between the 2 groups

组别	有效/例	无效/例	合计/例	有效率/%
磁刺激治疗组	10	18	28	35.71
联合治疗组	20	1	21	95.24**

与磁刺激治疗组比较，**P<0.01。

3 讨 论

POP病因复杂，目前盆底理论倾向于将盆底器官和组织视为一个整体，女性在整个孕期和生产过程中，盆底纤维承受巨大压力，韧带、筋膜等被牵拉变形导致弹性下降，盆底肌肌力下降，同时也会对盆底肌肉和神经造成器质性损伤，导致盆底疾病的发生[7]。目前电刺激、磁刺激是辅助盆底肌训练，治疗POP的常用方法[1]。

磁刺激技术最早应用并普及于神经脑科学领域，近年来，磁刺激技术逐渐被引入盆底疾病治疗领域，在国外已广泛应用于盆底肌训练及尿失禁等盆底疾病的治疗。磁刺激机制与电刺激类似，均是利用法拉第电磁感应机制及神经电生理学机制，使磁场穿透骨骼、脂肪等组织，到达深处刺激深部神经，使神经细胞膜电位发生改变产生感应电流，引起相应的神经电生理活动，诱发盆底肌肉收缩，继而提高盆底肌肌力，改善POP症状[8-9]。此外，盆底磁刺激可直接刺激深层及浅层神经、肌肉，增加Ⅰ、Ⅱ类肌纤维肌力，改善本体感觉。亦有研究[7]发现：较单纯盆底功能训练，磁刺激可以引发更强的收缩力，提高收缩功能。

本研究治疗后2组患者脱垂程度均较治疗前明显改善，盆底肌肌力增强，表明无论有无射频治疗，单一磁刺激对POP均有良好的疗效，可以认为磁刺激能够有效改善盆底肌肉力量，使得盆底支持结构较前稳固有力，进而改善POP患者的组织结构。

本研究发现产后POP女性普遍存在盆底肌肌力减弱现象，盆底肌肌力减弱可能因怀孕及分娩导致的肌肉结构改变、肌肉损伤及去神经化所致[4]，经治疗后2组盆底肌肌力均明显提高，绝大多数患者治疗后自我感觉盆底肌肌力有明显增强，可能由于磁刺激提高了神经肌肉兴奋性，改善了盆底本体感觉，增强了盆底肌收缩力。研究[10]表明：磁刺激在盆底神经组织建立脉冲磁场，可通过不断的磁刺激来修复受损的神经，刺激会阴周围运动神经，调动盆底肌肉收缩。盆底肌肌力的好转及POP的改善亦可能有盆底神经在一定程度上被修复的原因。

盆底组织主要是由疏松结缔组织构成，结缔组织的改变会导致盆底的结构性损伤。盆底结缔组织由胶原蛋白、弹性蛋白和平滑肌细胞组成，胶原是支持盆底稳定性和可塑性的细胞外基质的重要组成部分。研究[11-12]表明：POP患者胶原纤维的超微结构和生化特性发生了改变，结缔组织的破坏导致支撑结构(韧带、筋膜等)松弛，最终导致POP的发生。阴

道壁中成纤维细胞是细胞外基质合成、分泌的重要来源，有研究[13]证实，POP患者阴道壁组织胶原总含量降低且胶原蛋白比例失衡。目前电刺激及磁刺激均很难从韧带、筋膜层面去改善盆底组织结构，而射频治疗可以弥补这一缺陷。

射频最初获批应用于皮肤领域，近年来应用于女性盆底功能修复。射频治疗的机制为组织热重塑，通过高频交流电产生的热量刺激胶原蛋白、弹性蛋白等的组织基质，导致胶原蛋白的螺旋结构发生变化，成纤维细胞随之激活，进而促进胶原蛋白和弹性蛋白分泌；此外，热量激活热休克蛋白并启动炎症级联反应，激活成纤维细胞，导致组织重塑。射频还可以使外阴阴道细胞产生雌激素，这在恢复和刺激阴道组织和胶原蛋白方面起重要作用。近年来，其由于非侵入性、无不良事件和快速见效而广受欢迎[14-16]。

本研究联合治疗组阴道前壁Aa点位置及valsalva动作下膀胱颈位置改善明显大于磁刺激治疗组，考虑是联合治疗除能够增强盆底的肌肉力量外，还重塑了盆底结缔组织，增加了结缔组织厚度和韧性，能够更好地帮助盆底支持结构撑托起盆腔器官。联合治疗对阴道前壁疗效更加明显，可能是阴道前壁本身组织结构特性相对于其他部位对射频治疗反应更好，亦可能是本研究中心射频治疗方案中探头作用于阴道前壁时间更长所致，后续还需要更多研究进一步证实。

此外，本研究磁刺激治疗组在治疗结束后3个月部分患者出现盆腔器官位置下降现象，而联合治疗组大部分患者盆腔结构位置与之前相同，部分患者甚至出现较治疗后1周内评估结果稍有提升现象，几乎没有出现疗效持续性不佳现象。这可能是由于联合治疗组能够在神经、肌肉、结缔组织多方面对盆底支持结构进行改善，盆底支持结构更稳固，结缔组织变厚更加持久，使得盆底支持结构能够在相对较长时间内保持稳固状态，因此，可以认为射频治疗在提高疗效的同时，还能使疗效更持久。

研究[15, 17-18]表明：射频热效应使血管扩张、毛细血管开放、静脉丛循环改善，从而改善整个盆腔血液循环，促进阴道壁糖原分泌，改善阴道壁营养、氧合、细胞代谢和润滑，进一步改善女性性功能障碍性疾病，如阴道干涩、性欲减退等。本研究缺乏对性功能进行评估的问卷信息，后续有待更多前瞻性研究来弥补。此外，本研究的随访时间较短，未来期待有更长时间的随访研究来证实射频治疗的长期疗效。

综上，磁刺激和射频治疗均为十分安全的治疗手段，两者联合为产后POP患者提供了更优的选择。

作者贡献声明：童瑶　数据采集，统计分析和论文撰写；李旭红　论文选题和研究设计；严文广、曾小玲、谢芬、黎晶晶　数据收集，资料分析与解释；周艳华　研究实施，数据收集，统计分析，论文修改。所有作者阅读并同意最终的文本。

利益冲突声明：作者声称无任何利益冲突。

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REVIEW ARTICLE

The effectiveness of magnetic stimulation for patients with pelvic floor dysfunction: A systematic review and meta-analysis

Hong Pan, Yong Bao, Honghao Cao, Rongjiang Jin, Pu Wang, Junmei Zhang

First published: 17 September 2018 | https://doi.org/10.1002/nau.23797 | Citations: 6

Limin Liao led the peer-review process as the Associate Editor responsible for the paper.
Hong Pan and Yong Bao contributed equally to this work.

Abstract

Aims

To evaluate the value of magnetic stimulation (MS) in patients with pelvic floor dysfunction (PFD).

Methods

The Preferred Reporting Items for Systematic Review and Meta-analysis (PRISMA) statement was followed. We searched five databases for articles published until November 2017. Included studies investigated the effects of MS on PFD. Meta-analysis of RCTs was performed using a random effects model, and narrative analysis was undertaken where meta-analysis was not possible.

Results

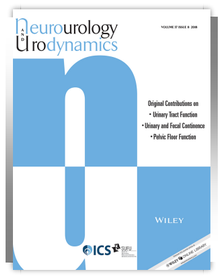
A total of 20 studies including 1019 patients were eligible for inclusion whose level of evidence for the included studies was low. Meta-analysis of four trials comparing MS with sham intervention showed that MS was not associated with significant improvement in ICIQ-SF score (–0.52, 95%CI –1.05, 0.01; $P = 0.06$, $I^2 = 16\%$), QOL score (–0.27, 95%CI –0.57, 0.04; $P = 0.09$, $I^2 = 0\%$), number of leakages (–0.16, 95%CI –0.62, 0.29; $P = 0.48$, $I^2 = 52\%$), and pad test (–1.36, 95%CI –2.64, –0.08; $P = 0.04$, $I^2 = 94\%$). Narrative review showed that there were no convincing evidences that MS was effective for chronic pelvic floor pain, detrusor overactivity, overactive bladder, and the included RCTs had controversial results. MS may have some benefits for nocturnal enuresis and erectile dysfunction according to the trials.

Conclusions

There is no convinced evidence to support the benefits of using MS in the management of PFD. The applicability of MS in the treatment of PFD remains uncertain, so larger, well-designed trials with longer follow-up periods adopted relevant and comparable outcomes are needed to be further explored to provide a definitive conclusion.

CONFLICTS OF INTEREST

The authors declare that there are no conflicts of interest regarding the publication of this paper.



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Review Obstet Gynecol Surv. 2000 Nov;55(11):715-20.
doi: 10.1097/00006254-200011000-00024.

Electromagnetic pelvic floor stimulation: applications for the gynecologist

R P Goldberg [1], P K Sand

Affiliations + expand

PMID: 11075736 DOI: 10.1097/00006254-200011000-00024

Abstract

The therapeutic potential of magnetic energy has been a subject of long-standing interest within both conventional and alternative medical practice. Numerous devices using magnetic fields, ranging from the dubious to truly innovative, have claimed a wide variety of clinical benefits. For gynecologists involved with the diagnosis and treatment of pelvic floor and bladder dysfunction, magnetic stimulation of the sacral nerve roots and peripheral nerves continues to evolve as a noninvasive treatment alternative. The conduction characteristics of magnetic energy confer several practical advantages for its use. This article reviews the use of electromagnetic stimulation for treatment of common urogynecologic conditions, and provides an historical overview of the therapeutic application of electromagnetic energy.

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Publication types

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MeSH terms

> Electric Stimulation / methods*
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Review. Int Urogynecol J. 2012 Jun;23(6):687-97. doi: 10.1007/s00192-011-1651-5. Epub 2012 Jan 14.

Pelvic floor muscle training for urgency urinary incontinence in women: a systematic review

Joy A Greer [1], Ariana L Smith, Lily A Arya

Affiliations + expand

PMID: 22246576 DOI: 10.1007/s00192-011-1651-5

Abstract

The objective of this study is to evaluate the effectiveness of existing physiotherapy modalities for the treatment of urge urinary incontinence (UUI). A systematic review was performed for primary studies of physiotherapy techniques for UUI published in English between 1996 and August 2010 in major electronic databases. Only randomized clinical trials that reported outcomes separately for women with UUI were included. Outcomes assessed were reduction in UUI, urinary frequency, and nocturia. Data from 13 full-text trials including the modalities of pelvic floor muscles exercises with or without biofeedback, vaginal electrical stimulation, magnetic stimulation, and vaginal cones were analyzed. The methodologic quality of these trials was fair. Significant improvement in UUI was reported for all physiotherapy techniques except vaginal cone therapy. There are insufficient data to determine if pelvic physiotherapy improves urinary frequency or nocturia. Evidence suggests that physiotherapy techniques may be beneficial for the treatment of UUI.

Comment in

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Publication types

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Dis Colon Rectum. 2005 Oct;48(10):1945-50. doi: 10.1007/s10350-005-0145-2.

Extracorporeal magnetic stimulation of the pelvic floor: impact on anorectal function and physiology. A pilot study

M J Thornton [1], M L Kennedy, D Z Lubowski

Affiliations + expand

PMID: 16132478 DOI: 10.1007/s10350-005-0145-2

Abstract

Purpose: This study was designed to investigate the effect of extracorporeal magnetic stimulation on anorectal function and physiology.

Methods: A pilot study comparing the physiology of ten incontinent (9 females) and five continent (4 females) patients with and without perineal magnetic stimulation (10 Hz and 50 Hz) was performed. The ten incontinent patients were treated with two sessions weekly for five weeks of perineal magnetic stimulation. At treatment completion, precontinent and postcontinent scores and resting and squeeze anal pressure were compared. Patients also reported symptom improvement and satisfaction on a linear analog scale.

Results: The patients' mean age was 57 years. Sitting resting and squeeze anal pressures were significantly greater than lying pressures (P = 0.007, 0.047). Both 10-Hz and 50-Hz stimulation effected a significant increase in anal pressures compared with the baseline resting pressure (P = 0.005). The baseline squeeze pressures were significantly higher than the stimulated pressures compared with 50-Hz pressures (P = 0.022). After six weeks of treatment, there was a statistically significant increase in resting and squeeze anal pressures and a significant decrease in continence scores (P = 0.007, P = 0.008, P = 0.017). The mean percentage subjective improvement was 16 percent, and the mean patient satisfaction score was 3.3, positively correlating with an improvement in the continence score.

Conclusions: Extracorporeal magnetic stimulation results in a significant increase in anal resting pressure irrespective of pretreatment continence. Although the subjective improvement in continence after treatment is small, there is a significant improvement in both resting pressures and patient continence scores.

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Observational Study World J Urol. 2023 Jan;41(1):173-177.
doi: 10.1007/s00345-022-04233-7. Epub 2022 Dec 14.

Role of top flat magnetic stimulation for urinary incontinence as a debilitating condition of pelvic floor dysfunction: an observational evaluation of Latin American population

Antonio Posada Dominguez [1], Pablo Gonzalez Isaza [2], Sarai Niño Pantoja [1], Irene Fusco [3]

Affiliations + expand

PMID: 36513890 DOI: 10.1007/s00345-022-04233-7

Abstract

Background: Urinary incontinence (UI) is a common dysfunction of the pelvic floor, affecting 10-20% of all women, and up to 70% in the elderly general prevalence of 17% 20-year-old women and 38% in women over 60 years. It is estimated that only 25% of patients seek treatment for this debilitating condition.

Aim: The aim of this study was to evaluate the efficacy of a device based on top flat magnetic stimulation to treat pelvic floor disorders especially female urinary incontinence.

Methods: A total of 33 volunteer patients were divided into 5 groups according to the type of complaint. Subjects received 8 treatment sessions, with a frequency of twice a week with two different settings. Pelvic Floor Bother Questionnaire (PFBQ), Pelvic Organ Prolapse/Urinary Incontinence Sexual Function Questionnaire (PISQ-12) and Urinary Incontinence Short Form (ICIQ-UI-SF) were compiled by all patients at the beginning and after 3 months from the end of the last treatment (3MFU).

Results: The patient's scores from validated Questionnaires significantly decreased ($p < 0.01$) from baseline up to 3MFU inside most of the groups.

Conclusions: The noninvasiveness and safety of device make this approach an interesting tool as alternative approach for pelvic floor dysfunctions .

Keywords: Pelvic floor dysfunction; Quality of life; Stress urinary incontinence; Top flat magnetic stimulation; Urge urinary incontinence.

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Zhong Nan Da Xue Xue Bao Yi Xue Ban. 2023 Nov 28;48(11):1696-1702.
doi: 10.11817/j.issn.1672-7347.2023.230070.

Effect of radiofrequency combined with magnetic stimulation on mild and moderate pelvic organ prolapse

[Article in English, Chinese]

Yao Tong [1], Xuhong Li [2], Wenguang Yan [2], Xiaoling Zeng [2], Fen Xie [2], Jingjing Li [2], Yanhua Zhou [3]

Affiliations + expand

PMID: 38432860 PMCID: PMC10929959 DOI: 10.11817/j.issn.1672-7347.2023.230070

Abstract in English, Chinese

Objectives: The efficacy of using a single electrical or magnetic stimulation for treating pelvic floor dysfunction is limited. This study aims to investigate the efficacy of radiofrequency combined with magnetic stimulation treatment for mild to moderate pelvic organ prolapse.

Methods: Patients who completed the treatment in the Third Xiangya Hospital, Central South University were screened, and were divided into 2 groups based on different treatment plans. There were 28 patients who completed magnetic stimulation therapy (the magnetic stimulation therapy group) and 21 patients who completed radiofrequency combined with magnetic stimulation therapy (the combined treatment group). The pelvic organ prolapse quantitation (POP-Q), pelvic floor muscle strength, and pelvic floor ultrasound results were analyzed to assess the efficacy before and after the treatment in both groups, and the POP-Q results of 3 months after the treatment were used to evaluate the maintenance effect of the treatment mode.

Results: The POP-Q evaluation results of Aa, Ap, and C points after the treatment in both groups were better than those before the treatment, with statistical significance (all $P<0.05$). The Aa point POP-Q result of the combined treatment group was better than that of the magnetic stimulation therapy group, with statistical significance ($P<0.05$). Pelvic floor ultrasound evaluation showed that the bladder neck position during the valsalva maneuver in the combined treatment group was higher than that in the magnetic stimulation treatment group, with statistical significance ($P<0.05$). The persistence effect of the combined treatment group was long better than that of the magnetic stimulation treatment group, with significant statistical significance ($P<0.01$).

Conclusions: The combined treatment is more effective and has a longer lasting effect than single magnetic stimulation treatment.

Keywords: magnetic stimulation; pelvic floor ultrasound; pelvic organ prolapse; radiofrequency therapy.

Conflict of interest statement

作者声称无任何利益冲突。

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