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Is the High-Intensity Focused Electromagnetic Energy an Effective Treatment for Urinary Incontinence in Women?

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Purpose: To assess the effectiveness and safety of high-intensity focused electromagnetic technology (HIFEM) used as a therapeutic approach in patients with stress and mixed urinary incontinence.

Patients and Methods: Thirty-five females suffering from stress and mixed urinary incontinence were included in the study. The electromagnetic chair (BTL EMSELLA®) was applied to the patient's pelvic area twice a week for 28 minutes, totaling 6 sessions. The patients' "International Consultation on Incontinence Questionnaire-Short Form" (ICIQ-SF) scores and the number of daily absorbent pad usage were recorded. Results were evaluated after the sixth session and at a first-month follow-up.

Results: The average ICIQ-SF score at baseline was 10.18 ± 4.19 (ranging from 2–18) which declined to 5.33 ± 3.97 after six sessions, and further improved to 4.26 ± 3.94 points at the one-month follow-up. After six sessions, an average improvement of 52.06% in ICIQ-SF score was observed, and after one month of follow-up, an average improvement of 59.6% was detected, which was found to be statistically significant (p=0.038). In addition, the mean number of pads used per day decreased to 1.25 ± 1.54 after treatment, a significant improvement was observed, and the mean daily pad use decreased further to 0.91 ± 1.11 at the first-month follow-up.

Conclusion: HIFEM has demonstrated in our study its ability to safely and effectively treat female patients suffering from stress and mixed urinary incontinence, as evidenced by significant improvements in symptoms and quality of life observed in clinical trials.

Keywords: urinary incontinence, pelvic floor muscle, HIFEM

Introduction

Urinary incontinence (UI) is characterized by the involuntary leakage of urine and represents a chronic condition that can have adverse impacts on an individual's quality of life (QOL).[1] Based on its underlying causes and physiological mechanisms, urinary incontinence is categorized as stress urinary incontinence (SUI), urge urinary incontinence (UUI), or a combination of both, known as mixed urinary incontinence (MUI). Clinical studies involving significant population samples have reported a 25% to 45% prevalence for this condition.[2] The findings from these studies indicated that the severity of UI symptoms tends to escalate primarily with advancing age. Furthermore, the research uncovered associations between the development of urinary incontinence and factors such as increased body mass index, parity, or specific medical comorbidities.[3–5] Broadly, particularly concerning stress urinary incontinence (SUI), the mechanism of continence is primarily linked to the pelvic floor muscles (PFM). The pelvic region's skeletal muscles provide support to the urinary bladder, the urethra, and other pelvic organs.[6] This support helps maintain an optimal urethral closure pressure, preventing unintentional leakage of urine. When the pelvic floor muscles weaken, it disturbs the pressure equilibrium, leading to UI. Due to the discomfort of urinary incontinence, patients often have to change their habits regarding their personal and professional lives. Demoralization, anxiety, sexual reluctance, and decreased work efficiency in the patient are some of the reasons that reduce the QOL.[7] To cope with UI, patients use absorbent pads daily. Yet, this passive approach does not alleviate UI

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symptoms, and despite advancements in pad composition, the risk of incontinence-associated dermatitis (IAD) remains—a condition characterized by skin inflammation due to urine contact with the perineal or perigenital area.[7]

Numerous treatment approaches have been introduced in the past to diminish the severity of UI by targeting the weakened PFM through both voluntary and involuntary stimulation methods, aiming to enhance the quality of life for patients. These include Kegel exercises, surface and intravaginal electrotherapy, PFM exercises with bio-feedback, and vaginal cones.[8–10] However, all these continence techniques have certain limitations. It was estimated that 30–50% of women do not perform PFM exercises properly,[11] and a common issue with electrical stimulation is the discomfort caused by the electrodes and the risk of vaginal infections.[12] Recently, high-intensity focused electromagnetic (HIFEM) stimulation has been introduced specifically for the PFM.[13] The non-invasive electromagnetic field travels through neuromuscular tissue, generating induced electric currents that depolarize neuronal cells and trigger action potentials. Subsequently, the high frequency of action potentials results in specific and supramaximal muscle contractions. Previous studies have documented that HIFEM technology can influence both abdominal and pelvic muscles, suggesting its potential effectiveness and safety as a treatment modality for urinary incontinence.[14] For instance, research has shown that HIFEM can significantly improve PFM strength and UI symptoms, with patients reporting increased satisfaction and quality of life post-treatment.[15] Several studies, including systematic reviews and meta-analyses, support the efficacy of electromagnetic stimulation, showing that it improves PFM function, increases patient satisfaction, and enhances QOL in UI patients.[13–15] For example, a meta-analyses by Qing et al demonstrated significant improvements in PFM strength and UI symptom relief following magnetic stimulation therapy.[16]

This study aimed to objectively evaluate the effectiveness and safety of HIFEM technology in female patients diagnosed with SUI and MUI.

Materials and Methods

35 female patients with SUI and MUI were included in the study which was designed retrospectively. The protocol was approved by the Erciyes University Faculty of Medicine Clinical Research Ethics Committee with decision number 2024/7 and complies with the Declaration of Helsinki. At the beginning of the study, the medical history of the patients was questioned, urological examination was performed, and written informed consent was obtained from all participants. Data was collected pre-treatment, post-treatment, and after first-month follow-up. All patients had a total of 6 sessions lasting 28 minutes, twice a week, sitting on an electromagnetic chair (BTL EMSELLA®). According to the procedure, all patients remained fully clothed throughout the entire process. To ensure adequate PFM stimulation, the operator confirmed the patient's chair posture throughout the treatments and adjusted the intensity of stimulus as high as tolerated by the patient, usually at 100%. Ensuring correct positioning is crucial for maximizing therapy effectiveness; therefore, the therapist supervised the subject's posture and confirmed it using the device's positioning system to attain the best possible PFM contractions. Women with pacemakers, metal implants in the spinal cord, blood circulation disorders, fever, tumors, and pregnancy were excluded from the study.

The International Consultation on Incontinence Questionnaire-Short Form (ICIQ-SF) was employed to evaluate the patient's continence. The questionnaire comprises three inquiries aimed at measuring how often leakage occurs, the volume of urine leaked, and the extent of disruption to daily activities. Scores on the questionnaire range from 0 (indicating no disruption) to 21 (representing significant involuntary urination affecting the individual's quality of life). A minimum of a 50% overall improvement in the total score was anticipated.[17] Participants were requested to mark the provided responses that applied to their situation, and alterations in their responses over time were assessed. Regarding the QOL for the patient, the utilization of absorbent pads (per 24-hour cycle) was tracked using a questionnaire specifically designed for pad usage. Data on the primary outcome were collected before the first therapy, upon completion of the sixth therapy session, and at the first-month follow-up. Adverse events were monitored throughout the entire study. The assessment of observed side effects included the following in the treated area: muscle pain, temporary muscle spasms, temporary joint or tendon pain, and local erythema.

The results were analyzed for statistical significance. H0 (null hypothesis) was formulated as follows: "The treatments did not make any difference in the patients' scores". To evaluate the significance of differences caused by treatments (alternative hypothesis), Student's paired *t*-test and Wilcoxon signed rank test were used if the sample size was small, the

significance level was set at $p < 0.05$. A sample size of 35 individuals was considered sufficient to demonstrate clinically significant improvement for this single-arm prospective study. The potential relationship between the measured variables was confirmed using the Pearson correlation coefficient ($p < 0.05$).

Results

The mean age of the patients was 55.3 ± 9.4 years and all patients had SUI or MUI symptoms. The most frequent procedure reported was a history of hysterectomy in seven women (14.2%). Hypertension was diagnosed in 13 (37.1%) patients and diabetes mellitus in 7 (20%) patients. Demographic data of the patients are shown in Table 1. Overall, after the sixth session, 29 of 35 patients (82.8%) reported significant relief in their symptoms. Their average ICIQ-SF score at baseline was 10.18 ± 4.19 (ranging from 2–18) which declined to 5.33 ± 3.97 after six sessions, and further improved to 4.26 ± 3.94 points at the one-month follow-up. After six sessions, there was an average improvement of 52.06% in the ICIQ-SF score, and after a one-month follow-up, the improvement reached 59.6%, demonstrating statistical significance (p=0.038). An ICIQ-SF score of zero was observed in 9 (25.7%) patients after the sixth session and in 11 (31.4%) patients after the one-month follow-up. A summary of the ICIQ-SF results is shown in Table 2. The results of both the SUI and MUI patient groups were highly statistically significant ($p < 0.001$). Based on baseline assessment, patients most frequently reported leaking only a few times per day. At the one-month follow-up, most of them mentioned that urine leakage occurred only approximately once a week or less.

The questionnaire on 24-hour pad usage indicated that each participant was utilizing absorbent pads at the study's outset, with an average daily usage of 2.5 ± 2.8 pads. After the sixth treatment, a significant improvement was observed as the average number of used pads decreased to 1.25 ± 1.54 per day ($p < 0.001$). At the first-month follow-up, the average daily pad usage was calculated as 0.91 ± 1.11 ($p < 0.001$) (Table 3).

Table 1 Demographic Characteristics

		N=35 (100%)
Age (year)		**55.3 ± 9.4**
BMI* (kg/m^2)		26.2 ± 2.9
Comorbidity	**Diabetes mellitus**	N=7 (20%)
	Hypertension	N=13 (37.1%)
Diagnosis	**SUI**	N=25 (71.4%)
	MUI	N=10 (28.6%)

Note: *body mass index.

Table 2 Summarization of ICIQ-SF Score

Parameter	**ICIQ-SF score**	**P value***
Baseline score	10.18 ± 4.19	
After 6th session	5.33 ± 3.97	p<0.001
-Average improvement	%52,06	p<0.001
-Zero score after 6th session	N=9 (%25.7)	
After 1st month follow up	4.26 ± 3.94	p<0.001
-Average improvement	%59,6	p=0.038
-Zero score after 6th session	N=11 (%31.4)	

Note: *Wilcoxon signed rank test, two-tailed p values.
Abbreviation: ICIQ-SF, International Consultation on Incontinence Questionnaire-Short Form.

Table 3 Summarization of Absorbent Pads

Parameter	Absorbent Pads	p value*
Baseline	2.5±2,8	
After 6th session	1.25 ± 1.54	p<0.001
After 1st month follow-up	0.91 ± 1.11	p<0.001

Note: *Wilcoxon signed rank test, two-tailed p values.

Discussion

Urinary incontinence is an important public health problem that reduces women's quality of life. Health-related quality of life encompasses various dimensions of human well-being, comprising overall health status, physical functioning, mental well-being, and social engagement.[18] That's why many people are looking for effective treatment options, hoping that they will no longer have to worry about not being able to control their bladder during daily activities. This study was planned to investigate whether the HIFEM procedure can be used effectively in the treatment of SUI and MUI in women. To the best of our knowledge, our study is the first study in the literature to evaluate patients before treatment, after the 6th session, and at the first-month follow-up. Our study's findings suggest that using HIFEM stimulation for PFM training was successful in treating a patient cohort exhibiting various forms of urinary incontinence across a spectrum of severity, as indicated by baseline ICIQ-SF scores ranging from 2 to 18. As a result of the treatment, UI interfered less with the person's daily life, and in some cases, these symptoms disappeared completely, helping patients regain their self-confidence. The presence of statistically significant differences in ICIQ-SF scores during the initial one-month follow-up suggests a progressive enhancement in the results over time.

PFM exercise is proposed to increase pelvic muscle tonus, leading to hypertrophy and fortification of the muscle fibers.[19] Hundreds of accurately executed contractions are necessary to effectively accomplish motor and PFM re-education.[20] Nevertheless, when participants undergoing treatment engage in the exercise, they need personalized education regarding the anatomy of the pelvic floor, lower urinary tract, continence mechanism, and oversight from a proficient physiotherapist.[21] The advantage of HIFEM technology over this type of traditional approach is a rapidly changing electromagnetic field mechanism that initiates thousands of supramaximal contractions during a single therapy. In addition magnetic stimulation is recognized in the management of SUI within the context of the European Association of Urology (EAU) guidelines. The EAU positions magnetic stimulation as a non-invasive alternative to traditional PFM training and as an adjunct for patients who may not achieve sufficient results with physical therapy alone.[22]

In the study conducted by Samuels et al in 2019, electromagnetic chair (HIFEM) treatment was applied to 75 female patients diagnosed with SUI and MUI. A statistically significant improvement was observed in ICIQ-SF scores after 6 sessions and at the 3-month post-procedure follow-up ($p<0.001$), similar to our study.[14] Moreover, the proportion of participants showing improvement in absorbent pad usage (59.6%) was consistent with previous findings reported by Jozef.[23] Our findings align with observations from other approaches, such as exercise or electrical stimulation,[24] where reported enhancements typically fell within the range of 50 to 90%. Consistent with the literature, the treatment was well tolerated, and participants expressed favorable feedback regarding the procedure's noninvasive nature and its minimal risk profile.[25]

Patients exhibit a general recovery rate of 59.6%, with 31.4% attaining a cured status (zero score at follow-up), mirroring findings from prior literature that explored the impacts of electromagnetic stimulation on strengthening pelvic floor muscles.[14,26]

While our study presents unique aspects in terms of pre-treatment and post-treatment evaluations, other studies have similarly examined the impact of magnetic stimulation on UI. For instance, the study by Lukanovic et al[15] provided insights into the sustained effects of magnetic stimulation over longer follow-up periods, while our study focuses on a shorter one-month period. Additionally, But et al[27] reported similar positive outcomes, suggesting that HIFEM could serve as a valuable alternative to more invasive interventions for UI. These findings corroborate the improvements in quality of life and reduction of symptoms reported by our patient cohort, with baseline ICIQ-SF scores demonstrating

significant positive changes. Side effects associated with HIFEM and other magnetic stimulation methods have been reported as minimal, but they remain an essential consideration for clinical practice. The study by Pavcnik et al highlights rare but potential adverse effects, including temporary muscle pain, joint discomfort, or localized erythema in the treatment area.[28] In our study, participants experienced mild and transient side effects that resolved without intervention, aligning with these reports and supporting the procedure's favorable safety profile.

The limitation of our study was the absence of a control group. Nonetheless, we are confident that the statistical significance of our results adequately compensates for this limitation. A significant disadvantage was also the relatively brief one-month follow-up interval in this study. The recorded results indicate promise regarding the sustained improvement observed over time. Nevertheless, it would be imperative to conduct a future study tracking patients for 6–12-18 months to determine the necessary re-treatment intervals for maintaining continence outcomes appropriately. Moreover, considering that HIFEM treatment may also have secondary benefits, we believe that a more comprehensive query score can be made on patient satisfaction.

Conclusions

This study demonstrated the safe and effective utilization of HIFEM technology in addressing SUI and MUI through the strengthening of pelvic floor muscles across a diverse range of patients. Patients experienced a relief in the severity of urinary incontinence symptoms and a decrease in the utilization of absorbent pads, thereby positively impacting their quality of life. In our study, patient motivation and tolerability for treatment sessions were very good. However, future studies with longer follow-ups and a larger number of patients are needed.

Data Sharing Statement

Data are available upon request to the corresponding author.

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Author Contributions

All authors made a significant contribution to the work reported, whether that is in the conception, study design, execution, acquisition of data, analysis and interpretation, or in all these areas; took part in drafting, revising or critically reviewing the article; gave final approval of the version to be published; have agreed on the journal to which the article has been submitted; and agree to be accountable for all aspects of the work.

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Disclosure

The authors declare no conflict of interest.

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