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ORIGINAL RESEARCH

Evaluating the Efficacy of High-Intensity Focused Electromagnetic (HIFEM) Therapy for Postprostatectomy Incontinence in Men

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Purpose: Urinary incontinence (UI) is a common complication after radical prostatectomy (RP), adversely affecting patients' quality of life. This study aimed to evaluate the efficacy and safety of high-intensity focused electromagnetic (HIFEM) therapy as a non-invasive treatment for post-prostatectomy UI.

Patients and Methods: Twenty-seven men (mean age ± SD: 67.9 ± 3.4 years) with persistent UI after RP underwent six HIFEM sessions (28 min, twice weekly) using the BTL EMSELLA® chair. Outcomes were assessed after the sixth session and at one-month follow-up. Primary endpoints were changes in International Consultation on Incontinence Questionnaire–Short Form (ICIQ-SF) scores and daily pad use.

Results: Baseline mean ICIQ-SF score was 10.58 ± 4.15. This decreased to 5.43 ± 3.85 after treatment and to 4.16 ± 3.97 at one month, representing improvements of 53.1% and 60.6%, respectively (both $p < 0.005$). Daily pad use declined from baseline to 1.45 ± 1.54 after treatment and 1.13 ± 1.81 at follow-up (both $p < 0.001$). No adverse events were reported.

Conclusion: HIFEM therapy significantly improved UI severity and reduced pad dependence in men with post-prostatectomy incontinence, with effects sustained for at least one month and no observed side effects. These findings support HIFEM as a safe, non-invasive treatment option warranting further study in larger, long-term trials.

Keywords: urinary incontinence, HIFEM, pelvic floor muscles

Introduction

Radical prostatectomy (RP) is widely recognized as the standard intervention for managing localized prostate cancer.[1] Despite notable advancements in both surgical methods and adjunctive therapeutic strategies—including the advent of robotic-assisted RP—post-prostatectomy incontinence (PPI) persists as a commonly reported complication, with prevalence rates reaching as high as 60%.[2] Urinary incontinence (UI) following RP is regarded as one of the most distressing postoperative sequelae, largely due to its profound adverse effects on patients' quality of life.[3] During RP, removal of the prostatic urethral segment may inadvertently damage the intrinsic and striated urethral sphincters and impair detrusor muscle function, thereby precipitating PPI. Prior research has demonstrated that PPI shares pathophysiological features with stress urinary incontinence (SUI).[4] Among urodynamic assessments, sphincteric dysfunction emerges as the predominant abnormality.[5] Several risk factors are known to increase vulnerability to PPI, including pre-existing bladder dysfunction, elevated body mass index, and older age.[6] Given the shared underlying mechanisms between PPI and SUI, conservative interventions aimed at enhancing pelvic floor muscle (PFM) strength represent a promising strategy for regaining continence and boosting patient confidence.

Current conservative approaches for PPI, such as pelvic floor muscle training (PFMT), biofeedback, and electrical stimulation, have demonstrated varying degrees of efficacy but are often limited by factors including patient adherence,

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difficulty in selectively targeting PFMs, and inadequate contraction intensity.[7,8] Moreover, surgical interventions—such as male slings or artificial urinary sphincters—are effective in selected cases but are invasive, costly, and carry the risk of device-related complications.[9] Additionally, conservative therapies may require prolonged treatment durations before measurable improvement is achieved, and patient motivation often declines over time. Electrical stimulation can be uncomfortable and may fail to engage deeper muscle fibers effectively, while surgical solutions, although effective for some, are associated with perioperative risks, potential need for revision surgery, and long-term device-related complications. Consequently, there remains a clear need for non-invasive, well-tolerated, and effective therapies that can bridge the gap between conservative and surgical options.

Urinary continence in men is largely dependent on the active function of the urethral muscles, which play a critical role in maintaining closure during episodes of elevated intra-abdominal pressure. To enhance muscle control and mitigate UI, pelvic floor muscle training (PFMT) is commonly recommended, as it focuses on teaching patients to perform precise and timely voluntary contractions of the pelvic floor muscles in response to pressure changes.[7] Nevertheless, conventional PFMT often faces limitations, particularly in its ability to selectively target the pelvic floor muscles (PFM), and patients may struggle to sustain sufficient contraction intensity.

In recent years, high-intensity focused electromagnetic stimulation (HIFEM) has emerged as a novel modality specifically aimed at reinforcing PFM strength. This non-invasive approach uses electromagnetic fields that penetrate neuromuscular tissues, generating electric currents that depolarize neurons and trigger action potentials. The rapid succession of these action potentials induces supramaximal contractions in the targeted muscles, enhancing strength and endurance. Prior investigations have shown that HIFEM can activate both pelvic and abdominal musculature, suggesting its potential utility in addressing the multifactorial muscle dysfunction underlying PPI.[10] However, despite growing evidence for its efficacy in female SUI and mixed urinary incontinence, research specifically evaluating HIFEM in men with PPI remains scarce. This paucity of data underscores the novelty and clinical relevance of the present study, which systematically evaluates the therapeutic efficacy and safety of HIFEM therapy in male patients following RP, aiming to expand treatment options for this challenging condition.

Materials and Methods

This study enrolled twenty-seven male patients who had previously undergone radical prostatectomy, presenting with persistent urinary incontinence, with a mean age of 67.90 ± 3.40 years. The research protocol received ethical approval from the Clinical Research Ethics Committee of Erciyes University Faculty of Medicine (Decision No: 2024/7) and was conducted in accordance with the ethical principles set forth in the Declaration of Helsinki. Written informed consent was obtained from all participants prior to enrollment. During the consent process, patients were informed in detail about the study's purpose, procedures, potential benefits, and possible risks, and were given the opportunity to ask questions. Participation was entirely voluntary, and patients were informed of their right to withdraw at any time without any impact on their medical care. No personally identifiable information was included in the statistical analyses or reported in the publication. Data collection points included baseline (prior to treatment), immediately following the intervention, and at a one-month follow-up.

Each participant completed six treatment sessions, each lasting 28 minutes, administered twice weekly using the BT EMSELLA® electromagnetic chair. Importantly, patients remained fully clothed throughout the entire procedure. The stimulation protocol was delivered at a frequency of 10–50 Hz, with the intensity gradually increased to the maximum tolerated level for each individual. The initial intensity was set at approximately 60–70% of device output and progressively raised until 100% tolerance was reached. Intensity was monitored in real time via the device's control interface, and the operator adjusted it dynamically based on patient feedback to ensure both maximal muscle activation and comfort. To achieve optimal pelvic floor muscle (PFM) engagement, the operator continuously monitored the participant's posture and adjusted the seating position as needed. Accurate positioning was critical to enhance therapeutic outcomes, and the device's built-in positioning system was used alongside the therapist's observation to ensure effective PFM activation. To minimize potential sources of bias inherent in the retrospective design, all participants were selected according to the same predefined inclusion and exclusion criteria, and no subjects were excluded after enrollment. Inclusion criteria were: male patients aged 18 years or older; history of radical prostatectomy performed at least 6 months

prior to enrollment; persistent urinary incontinence symptoms, defined as leakage occurring at least once daily despite prior conservative management (eg, pelvic floor muscle exercises); and ability to provide informed consent and comply with the treatment and follow-up schedule. Exclusion criteria were: presence of circulatory disorders, cardiac pacemaker, implanted defibrillator, spinal cord metal implants, or other contraindicated metallic/electronic implants; active urinary tract infection, hematuria of unknown origin, or untreated bladder outlet obstruction; history of pelvic radiotherapy within the last 6 months; active malignancy in the pelvic region; neurological conditions affecting bladder function (eg, multiple sclerosis, Parkinson's disease, spinal cord injury); active fever or systemic inflammatory condition at the time of screening; and participation in another clinical trial within the past 30 days. The HIFEM protocol, including device frequency, intensity adjustment procedure, and session duration, was standardized across all treatments. All outcome measures were obtained using validated tools (ICIQ-SF and pad usage questionnaire) at consistent, predetermined time points by the same clinical team. Data collection and analysis procedures were applied uniformly to all participants to ensure methodological consistency and reproducibility.

Patient continence was evaluated using the International Consultation on Incontinence Questionnaire–Short Form (ICIQ-SF), which consists of three key items assessing the frequency and volume of urinary leakage, as well as the associated impact on daily life. The total score ranges from 0 (indicating no impairment) to 21 (reflecting severe incontinence with significant effects on quality of life). An improvement threshold of at least 50% in the total score was anticipated.[10] Participants selected the responses most accurately representing their condition, and longitudinal changes in their answers were analyzed. To further assess quality of life, the study also tracked the number of absorbent pads used over a 24-hour period, utilizing a dedicated questionnaire designed for this purpose. Primary outcome measures were gathered at three time points: baseline (before the initial treatment), after completion of the sixth session, and at the one-month follow-up. Adverse events were systematically monitored throughout the study period, with evaluations focusing on temporary muscle spasms, joint or tendon discomfort, muscle soreness, skin irritation, and localized redness in the treatment area.

Statistical analyses were conducted to assess the significance of observed changes. The null hypothesis (H_0) stated that no significant alterations would occur in patient scores as a result of the treatment. To test for statistically significant effects (alternative hypothesis), both Student's paired *t*-test and the Wilcoxon signed-rank test were employed, particularly suited for the study's small sample size. The inclusion of 27 participants was based on prior pilot data and effect size estimates from similar interventions, indicating that this sample size would provide >80% statistical power to detect a moderate effect (Cohen's $d \geq 0.5$) at a significance level of $p < 0.05$ in within-subject comparisons. Additionally, correlations between measured variables were explored using the Pearson correlation coefficient, with significance also determined at $p = 0.05$.

Results

The average age of the study participants was 67.90 ± 3.40 years, and all individuals successfully completed the full course of six treatment sessions. Among the cohort, hypertension was identified in 8 patients (29.6%), while diabetes mellitus was present in 5 patients (18.5%). Detailed demographic characteristics are summarized in Table 1. Following

Table 1 Demographic and Clinical Characteristics

Variable	Mean ± SD or n (%)
Age (years)	67.9 ± 3.4
Body mass index (BMI, kg/m²)	26.4 ± 2.8
Duration of urinary incontinence (months)	4.8 ± 1.2
Type of radical prostatectomy	Open: 15 (55.6%) Robotic-assisted: 12 (44.4%)
Diabetes mellitus	5 (18.5%)
Hypertension	8 (29.6%)

Abbreviation: BMI, body mass index.

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Table 2 Summarization of ICIQ-SF Score and Pad Usage Data

Parameter	ICIQ-SF Score	*p* value*	Absorbent Pads	*p* value*
Number of evaluated subjects	n=27		n=23	
Baseline score	10.58 ± 4.15		2.57±2.15	
After 6th session	5.43 ± 3.85		1.45±1.54	
Average improvement (%)	53.06%	<0.001	42.70%	<0.001
One month follow-up	4.16 ± 3.97		1.13±1.81	
Average improvement (%)	60.06%	<0.005	53.68%	<0.001

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

completion of the sixth session, 21 out of the 27 participants (77.7%) reported notable symptomatic improvement. At baseline, the mean ICIQ-SF score was recorded as 10.58 ± 4.15 (range: 2–18), which decreased to 5.43 ± 3.85 after six sessions and further declined to 4.16 ± 3.97 at the one-month follow-up. These changes represented an average improvement of 53.06% post-treatment and 60.6% at follow-up, both reaching statistical significance ($p < 0.005$). Beyond statistical significance, these reductions in ICIQ-SF scores reflect a shift from moderate-to-severe incontinence at baseline to mild or no incontinence in the majority of patients, indicating a clinically meaningful restoration of urinary control. An ICIQ-SF score of zero, indicating complete continence, was documented in 6 patients (22.7%) after the sixth session and in 9 patients (33.3%) at the one-month reassessment. By the conclusion of the follow-up period, 13 patients (48.1%; $p = 0.028$) demonstrated further improvement relative to their immediate post-treatment status. Initially, most patients reported experiencing urinary leakage multiple times per day; however, by the one-month follow-up, the majority indicated that leakage occurred only once per week or less. Such improvements represent a substantial enhancement in daily function, reducing the social embarrassment and lifestyle restrictions often associated with PPI. Comparable gains were also observed regarding the self-reported impact of UI on daily life activities.

At the outset, 23 participants reported using at least one absorbent pad daily, with a mean usage of 2.57 ± 2.15 pads per day. Following completion of the sixth HIFEM session, a statistically significant reduction of 42.7% ($p < 0.001$) was observed, lowering the average daily pad count to 1.45 ± 1.54. Furthermore, at the one-month follow-up, the mean daily pad use decreased further to 1.13 ± 1.81, culminating in an overall reduction of 53.68% ($p < 0.001$). From a clinical perspective, this decline in pad use not only reduces the financial burden of incontinence management but also minimizes the inconvenience and skin-related complications associated with prolonged pad dependency. Notably, a subset of patients discontinued pad use entirely; after six sessions, 9 individuals (33.3%) reported no longer requiring pads, a figure that rose to 13 patients (48.1%) by the one-month reassessment. In total, 15 of the 27 patients (55.5%) demonstrated reduced pad use following treatment, increasing to 18 out of 27 (66.6%) at follow-up. A moderate yet significant positive correlation was identified between improvements in ICIQ-SF scores and the reduction in daily pad use after the sixth session ($r = 0.27$, $p < 0.01$), with this relationship strengthening further during the follow-up period ($r = 0.27$, $p < 0.001$). An overview of the ICIQ-SF outcomes and pad usage statistics is detailed in Table 2.

Participants expressed satisfaction with both the convenience of the treatment sessions and the clinical outcomes obtained. Throughout the treatment and follow-up periods, no major adverse effects were noted; only mild, transient symptoms such as muscle discomfort were reported. These findings suggest that HIFEM therapy not only produces statistically and clinically meaningful improvements in continence but also does so with a favorable safety and tolerability profile, directly enhancing patient quality of life.

Discussion

UI following prostatectomy has a substantial negative impact on men's overall quality of life. Given that health-related quality of life is a multifaceted concept, it encompasses not only physical functioning but also psychological well-being

and social engagement.[11] As a result, many affected individuals actively seek effective therapeutic interventions to regain bladder control and improve their daily functioning. In the present study, we demonstrated that high-intensity focused electromagnetic (HIFEM) therapy represents a viable and effective treatment option for managing PPI. Our findings revealed a clinically meaningful decline in ICIQ-SF scores following six treatment sessions, with further improvements observed at the one-month follow-up. These improvements were paralleled by a reduction in the use of absorbent pads. Additionally, the HIFEM intervention was well tolerated, as it allowed patients to undergo therapy fully clothed, and no significant adverse events were identified. Previous research has similarly shown that PPI symptoms can be alleviated through PFM strengthening exercises, such as Kegels, or through electromagnetic stimulation.[4,12]

PPI is a multifactorial condition associated with impaired function of several key muscle groups, including the urethral sphincter, bulbocavernosus, pubovisceralis, and levator ani muscles. Following prostate removal, these muscles are unable to fully compensate for the loss of structural support, leading to insufficient urethral closure and an inability to counteract increases in intra-abdominal pressure.[13] Consequently, an optimal therapeutic approach is presumed to focus on strengthening this critical group of PFMs.[14] High-intensity focused electromagnetic (HIFEM) therapy provides non-invasive and painless electromagnetic stimulation targeted at the pelvic floor, selectively activating the motor neurons responsible for controlling striated muscle fibers.[15] The rapid and repeated stimulation produces robust supramaximal muscle contractions, enhancing muscle strength, endurance, and adaptive training responses.[16] Given its ability to penetrate deeply, cover a broad treatment area, and avoid attenuation within biological tissues, HIFEM effectively stimulates the muscular components involved in the pathophysiology of PPI.[17] This differs from conventional PFMT, which relies on voluntary contractions and often suffers from suboptimal intensity and patient adherence, and from standard electrical stimulation, which generally activates a more limited volume of muscle tissue and may be less effective in reaching deeper muscle fibers. The supramaximal contractions induced by HIFEM can recruit a higher percentage of both fast-twitch and slow-twitch fibers simultaneously, potentially leading to greater functional gains.

In alignment with our findings, Azparren J and Brandeis J conducted a study in which they administered six sessions of electromagnetic chair therapy, each lasting 28 minutes, to a cohort of 10 patients experiencing urinary incontinence (UI) following radical prostatectomy.[11] Patient-reported outcomes on quality of life were assessed using the standardized King's Health Questionnaire (KHQ Parts I and II), alongside a 24-hour pad usage questionnaire, both administered prior to and following the treatment series. Their results indicated that both KHQ scores and pad usage demonstrated significant improvements after six sessions, with further benefits observed at the three-month follow-up compared to baseline. Additionally, in 2019, Samuels et al[9] evaluated electromagnetic chair (HIFEM) therapy in a group of 75 female patients diagnosed with stress urinary incontinence (SUI) or mixed urinary incontinence (MUI). Consistent with our study, they reported statistically significant reductions in ICIQ-SF scores following six treatment sessions, which were sustained at the three-month post-treatment evaluation ($p < 0.001$). Moreover, a 2023 investigation by Guerette et al[18] compared the effectiveness of HIFEM therapy with pelvic floor muscle exercises in a sample of 38 women. Over a follow-up period extending up to one year, the group receiving HIFEM therapy exhibited significantly superior outcomes in terms of ICIQ-LUTS scores, ICIQ-BD scores, and daily pad usage compared to the exercise-only group ($p < 0.001$).

Silantyeva et al[19] conducted a comparative study evaluating the efficacy of HIFEM therapy versus electrostimulation in a cohort of 75 patients presenting with incontinence complaints (HIFEM group I: $n = 50$; electrostimulation group II: $n = 25$). Notably, significant improvements in pelvic floor muscle integrity were observed exclusively within the HIFEM-treated group ($p < 0.05$). Furthermore, participants in group I demonstrated a markedly higher degree of improvement on the Pelvic Floor Disability Index-20 compared to those in group II, with reported improvement rates of 52% versus 18%, respectively ($p < 0.001$). These comparative data, together with our results, indicate that HIFEM may provide greater benefits in symptom reduction, functional recovery, and patient satisfaction compared to both PFMT and conventional electrical stimulation. By incorporating such comparative evidence, our study positions HIFEM not only as an effective stand-alone therapy but also as a potentially superior alternative within the spectrum of non-invasive treatment options for PPI. This broader context underscores the clinical relevance of our findings and supports the integration of HIFEM into individualized patient management strategies.

The outcomes of our study are in line with prior reports on alternative treatment modalities, including pelvic floor exercises and electrical stimulation,[18,19] which have generally demonstrated improvement rates between 50% and 90%.

Consistent with the existing body of literature, the intervention was well tolerated by participants, who expressed favorable opinions regarding its noninvasive application and minimal risk profile.[20] In our cohort, the overall recovery rate was 66.6%, a result that corresponds closely with earlier investigations assessing the role of electromagnetic stimulation in enhancing PFM strength.

A notable strength of our study lies in the comprehensive evaluation of the ICIQ-SF, a well-established and validated instrument for assessing urinary incontinence symptoms among patients following prostatectomy. Nevertheless, several limitations should be acknowledged. Primarily, the investigation focused solely on the short-term outcomes of electromagnetic chair therapy, without capturing long-term data on efficacy or treatment sustainability. Future research should incorporate extended follow-up periods to better understand the durability of therapeutic effects. Additionally, the relatively small sample size of 27 participants restricts the depth of statistical analyses that can be performed. Subsequent studies should aim to include larger patient populations and examine the long-term impact of HIFEM therapy on quality of life, similar to the longitudinal approach employed by Yamanishi et al.[21] Moreover, direct head-to-head comparisons between HIFEM, PFMT, and electrical stimulation in well-designed randomized controlled trials would provide more robust evidence on relative efficacy, cost-effectiveness, and patient selection criteria. Such studies would help determine the optimal role of HIFEM within the broader framework of post-prostatectomy incontinence management.

Conclusions

This study demonstrated that HIFEM technology can be safely and effectively used to prevent PPI by strengthening the PFM in a varied patient population. After six treatment sessions, patients experienced a reduction in the severity of urinary incontinence symptoms and decreased use of absorbent pads, leading to a positive impact on their quality of life. While these findings support the efficacy and safety of HIFEM therapy, it is important to acknowledge the study's limitations, including the relatively small sample size and the short-term follow-up period, which restrict the ability to assess the long-term durability of the treatment effect. In addition, although our results are consistent with the benefits reported in previous studies on PFMT and electrical stimulation, direct comparative trials are needed to determine the relative advantages, cost-effectiveness, and optimal patient selection for HIFEM versus other non-invasive interventions. Although patient motivation and tolerance to the treatment sessions were good in our study, future research should include longer follow-up periods, larger patient populations, and head-to-head comparisons with alternative therapies to further validate these findings.

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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