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Safety and efficacy of non-invasive, high-intensity, focused electromagnetic stimulation to improve quality of life and pelvic floor muscle function in women with pelvic organ prolapse: a pilot study

Abstract

Introduction: Pelvic organ prolapse (POP) results from pelvic floor weakness, making pelvic floor muscle training essential. In this setting, high-intensity focused electromagnetic (HIFEM) treatment offers a minimally invasive option, though its effects on POP remain uncertain. This study aims to evaluate the safety and effectiveness of HIFEM treatment on POP.

Materials and methods: This prospective study involved women with POP at a Portuguese rehabilitation center, excluding those with concurrent conservative treatments, prior pelvic floor surgery, advanced POP, active infection, pregnancy, pelvic floor cancer, certain medications, or implants. Participants underwent six sessions of HIFEM treatment with an electromagnetic chair. Clinical and sociodemographic data were collected, and evaluations were performed one week before and after treatment using the Prolapse Quality-of-Life Questionnaire (P-QoL), the PERFECT scheme, and the Baden-Walker grading system. Participants were also asked to provide their subjective opinion on treatment experience compared to previous treatments (rated on a Likert scale from 1, worse, to 3, better).

Results: Eight women were included in the study. The P-QoL questionnaire revealed statistically significant improvements in quality-of-life perception, vaginal bulge sensation, pressure sensation, defecation interference, sexual interference, feelings of depression, low self-esteem, use of tampons and pads, and total P-QoL score. All participants had previously undergone pelvic floor rehabilitation with biofeedback. Out of the six women who completed the PERFECT evaluation, improvements were noticed in all parameters, although these were not statistically significant. No differences in POP stage were perceived. All patients reported a preference for this treatment due to its non-invasiveness and ease/comfort. No adverse effects were documented.

Conclusion: HIFEM treatment seems safe and effective in enhancing quality of life for women with POP stage 1 and 2 who have undergone conventional treatment. Larger studies are needed to confirm its effectiveness and compare it with other treatments.

Keywords: pelvic organ prolapse, pelvic floor muscles, quality of life, pelvic floor rehabilitation, non-invasive, focused electromagnetic stimulation

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Introduction

Pelvic organ prolapse (POP) is a common condition that is characterized by the herniation of pelvic organs beyond the vaginal walls.[1-3] Accurately determining the prevalence of POP is a complex task due to several factors. First, there is a lack of consistency in the classification systems used for diagnosis. Second, research studies differ in whether they focus on reporting the rate of prolapse among women who show symptoms or those who do not. Finally, there is a lack of information about how many women with POP do not seek medical treatment.[3]

The exact causes of POP are multifactorial and can involve a combination of factors, but weakening of pelvic support structures is one of the primary underlying causes. These structures include the pelvic floor muscles, ligaments, and connective tissues that normally hold the pelvic organs in place. According to research evidence, established risk factors for POP include parity, advanced age, and obesity,[2,4] with additional contributors including menopause,[5] some connective tissue disorders,[6] chronic constipation,[7] and family history.[8]

Although POP can be asymptomatic, it can significantly impact daily activities, social participation, body image, and sexuality when symptoms arise.[3,9] Symptoms of POP can vary, encompassing sensations such as a vaginal bulge, pelvic pressure, or the feeling that something is descending from the vagina. Additionally, affected individuals may experience problems related to urinary, bowel, and sexual function.[3,10] Urinary issues are predominantly associated with stress urinary incontinence in cases of stage I or II prolapse, whereas obstructive symptoms tend to manifest as the prolapse progresses.[2,11]

Common defecatory symptoms include constipation and a sensation of incomplete bowel emptying.[11] Furthermore, women with POP may avoid sexual activity due to discomfort or embarrassment, and they may also report adverse effects on orgasm or sexual satisfaction.[10,12]

Historically, severity of prolapse was graded using a variety of classification systems. However, the Pelvic Organ Prolapse Quantitation system (POP-Q), introduced in 1996, has emerged as the standard classification system.[13] Another frequently used classification for staging POP is the Baden-Walker grading system, in which the degree, or grade, of each prolapsed structure is described individually and is defined as the extent of prolapse for each structure noted on examination while the patient is straining, categorizing stages on a scale ranging from 0 to 4.[14]

Treatment of POP is generally recommended for symptomatic patients and can involve conservative measures such as vaginal pessaries, pelvic floor muscle training, and estrogen therapy, as well as surgical procedures.[2,3] It is well-established that pelvic floor muscles play a pivotal role in providing support to pelvic organs. Consequently, weakening of these muscles contributes to the loss of pelvic floor support, which can ultimately result in POP.[2,3] Therefore, pelvic floor muscle training is essential in POP treatment.

Recently, high-intensity focused electromagnetic (HIFEM) treatment emerged as a non-invasive alternative treatment for pelvic floor muscle training, and is already approved by the United States Food and Drug Administration. Studies have shown positive outcomes in terms of quality of life and pelvic floor muscle function in patients with urinary incontinence.[15]

However, the efficacy of HIFEM in POP treatment is less known, but it may provide non-invasive and enhanced training for pelvic floor muscles, which are a key factor in POP development. The aim of this study was to assess the safety and the efficacy of HIFEM treatment on the quality of life, pelvic floor function, and severity of POP in Portuguese women.

Materials and methods

a. Subjects and study design

A prospective pilot study was conducted on Portuguese women with POP, who were followed via pelvic floor consultation at a Portuguese rehabilitation center. This study was approved by the ethics committee of Unidade Local de Saúde de Vila Nova de Gaia/Espinho, and written informed consent was obtained from all participants.

The inclusion criteria for the study were adult women with POP grade 1 or 2, followed in pelvic floor consultation at our center. The exclusion criteria were as follows: concurrent conservative treatments (to avoid confounding factors), prior pelvic floor surgery, grade 3 and 4 POP (according to the Baden-Walker grading system), active infection, pregnancy, pelvic floor cancer, certain medications (e.g., diuretics, alpha adrenergic antagonists, and bladder activity modulators), metallic implants, and electronic devices.

Clinical and sociodemographic data on the participants were collected through clinical records and interviews, comprising age, body mass index, marital status, academic habilitations, employment status, physical activity level, obstetric history, POP classification, and previous treatments performed for POP. The participants were evaluated at two different time points: T0, which corresponds to the initial assessment conducted one week before commencing the HIFEM protocol, and T1, which corresponds to the assessment conducted one week after the treatment.

At T0 and T1, the following evaluations were performed: first, the participants answered the Portuguese version of the Prolapse Quality-of-Life Questionnaire (P-QoL) to evaluate the impact of POP on their quality of life.[13,16] Then, one of two physiatrists specialized in pelvic floor rehabilitation applied the PERFECT scale to assess pelvic floor muscle function,[17] and also evaluated POP severity by applying the Baden-Walker grading system.

At the end of the study, the participants were asked to provide their subjective opinion on their treatment experience compared to other treatments they had previously undergone (rated on a Likert scale from 1, worse, to 3, better). Those who considered the experience worse or better were asked to provide justification for their answer.

b. Treatment protocol

The participants underwent six sessions of HIFEM treatment (two sessions per week over three weeks) supervised by a physician or physiotherapist familiar with the device and treatment protocol. A magnetic stimulator, with a rapidly changing, high-intensity, focused electromagnetic field was used (BTL EMSELLA™), in which the electromagnetic field is produced by a flat, spiral-shaped coil, reaching intensities of 2.5 T. The magnetic coil was set on an armchair-type seat. The patients were instructed to sit on the seat so that the perineum was positioned at the center of the coil, and so they would feel the highest contraction of the pelvic floor muscles centered on the vaginal walls during the stimulation. The device has two predefined treatment protocols, each comprising 33 sections varying in pulse rate/frequency, intensity, and impulse morphology to maximize the strengthening of the different pelvic floor muscle fibers. Protocol 1 of the chair was implemented in the first two sessions, whereas Protocol 2 was employed in the subsequent sessions. Each therapy consisted of a 28-min treatment session, with the intensity of the stimulus as high as was tolerated by the patient, ranging from 60% (1.5 T) to 100% (2.5 T).

c. Statistical analysis

Continuous variables are expressed as means and standard deviations, represented as mean±SD, or medians with inter quartile ranges (IQR), represented as median [IQR], either in the presence or absence of a normal distribution, respectively. Categorical variables are presented as frequencies and percentages, or n (%). The normality of each distribution was checked using the Shapiro-Wilk test. Considering the sample size (n=8) and variables distribution, all inferential statistical analyses were conducted using non-parametric tests, specifically the Wilcoxon test. Analyses considered both data collection time points (T0 and T1 assessments) for the same group of subjects. All reported p-values are two-tailed, with a p-value of ≤ 0.05 indicating statistical significance. Statistical analysis was conducted using Software Statistical Package for the Social Sciences (SPSS) Version 28 (IBM, Armonk, NY).

Results

Eight women completed the treatment, whose median age was 47.00 (21.00) years. The majority of the women (n=6; 75%) had at least one childbirth, and three (37.5%) underwent episiotomy. Only two patients had no history of pregnancy, but neither had a history of infertility. All had previously undergone treatment involving exercises, pelvic floor rehabilitation with biofeedback, and two (25%) also underwent electrostimulation. Sample characterization is presented in Table 1, and prolapse characteristics (e.g, previous treatments) are shown in Table 2.

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Table 1 Sample characteristics

Baseline characteristics	Median [IQR] or n (%)
Age (years)	47.00 [21.00]
BMI (kg/m2)	68.00 [11.00]
Marital Status	
Single/divorced	1 (12.5)
Married/civil union	7 (87.5)
Academic habilitations	
Elementary education up to 9th grade	4 (50.0)
Bachelor's degree	4 (50.0)
Employment status	
Employed	6 (75.0)
Unemployed	1 (12.5)
Retired	1 (12.5)
Practice of physical exercise	
Active	4 (50.0)
Sedentary	4 (50.0)
Number of pregnancies	
0	2 (25.0)
1	2 (25.0)
2	3 (37.5)
3	1 (12.5)
Number of childbirths	
0	2 (25.0)
1	2 (25.0)
2	4 (50.0)
Number of women who underwent a C-section	
	1 (12.5)
Number of abortions	
0	7 (87.5)
1	1 (12.5)
Previous episiotomy	
Yes	3 (37.5)
No	5 (62.5)

IQR, Interquartile range; BMI, body mass index; C-section, cesarean section; n=frequency; %=percentage.

Table 2 Pelvic organ prolapse characteristics and previous treatments

Baseline characteristics	n (%)
Type of prolapse	
Anterior vaginal wall prolapse	5 (62.5)
Posterior vaginal wall prolapse	1 (12.5)
Apical prolapse	2 (25.0)
Baden-Walker grading system	
1	1 (12.5)
2	7 (87.5)
Previous treatment for POP	
Exercises for PF muscles	8 (100.0)
PF rehabilitation	8 (100.0)
Biofeedback	8 (100.0)
Electrostimulation	2 (25.0)

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The P-QoL questionnaire revealed statistically significant improvements in prolapse impact on quality-of-life, vaginal bulge sensation, pressure sensation, interference with defecation, sexual interference, feelings of depression, low self-esteem, need to use tampons and/or pads, as well as total P-QoL score, as seen in Table 3.

Table 3 P-QoL questionnaire results at time points T0 and T1

P-QoL domains	T0	T1	Z-value	p-value
General health perception	2.25±0.71	3.00 [0.00]	−1.890	0.059
Prolapse impact in QoL*	2.25±0.71	1.00 [1.00]	−2.111	0.035
Prolapse				
Symptoms impact				
Frequent urination	2.25±1.04	1.00 [1.75]	−1.663	0.102
Urgency	2.00±0.76	1.50 [1.75]	−0.816	0.414
Urge incontinence	1.00 [1.50]	1.50 [1.00]	−0.378	0.705
Stress incontinence	2.00 [1.00]	1.00 [1.00]	−1.732	0.083
Vaginal bulge sensation*	2.50 [1.75]	1.00 [1.75]	−2.530	0.011
Pressure sensation*	3.00 [0.75]	1.50 [1.75]	−2.428	0.015
Interference with defecation*	1.50±1.20	1.00 [1.75]	−2.070	0.038
Vaginal discomfort worst when standing	2.88±1.13	3.00 [2.25]	−0.577	0.564
Poor urine stream	2.00±1.20	1.00 [0.75]	−1.604	0.109
Straining/effort to urinate	2.25±1.16	1.00 [1.75]	−1.342	0.18
Post-void dribbling	2.50 [2.00]	1.50 [1.00]	−1.667	0.096
Incomplete emptying sensation	1.50 [1.00]	1.50 [1.00]	−1.000	0.317
Constipation	2.00 [2.25]	1.50 [1.00]	−1.414	0.157
Straining/effort to defecate	2.00 [1.75]	1.00 [1.00]	−1.414	0.157
Vaginal bulge interference in sexual relations	2.25±0.71	2.00 [1.00]	−1.890	0.059
Lower backache worsens by vaginal discomfort	2.13±1.25	1.00 [0.75]	−1.890	0.059
Need to use fingers to facilitate defecation	1.00 [1.50]	1.00 [1.50]	−1.000	0.317
Role limitations				
Household tasks	1.50 [1.75]	1.00 [2.00]	−1.000	0.317
Professional activity	1.13±1.13	0.00 [1.75]	−1.732	0.083
Physical/social limitations				
Physical activity	1.50 [2.50]	1.00 [2.00]	−1.732	0.083
Travels	0.00 [1.75]	0.00 [0.00]	−1.342	0.18
Social life	0.00 [1.50]	0.00 [0.75]	−1.000	0.317
Ability to see/visit friends	0.00 [1.75]	0.00 [1.75]	−0.000	1
Personal relationships				
Impact in intimate relationships	1.50 [1.75]	1.00 [1.75]	−1.414	0.157
Impact in sexual relationships*	2.00 [2.50]	2.00 [1.75]	−2.000	0.046
Impact in family relationships	1.00 [1.00]	1.00 [1.00]	−0.000	1
Emotions				
Feelings of depression*	2.00 [1.50]	1.00 [1.00]	−2.640	0.008
Feelings of anxiety	1.00 [2.25]	1.00 [1.00]	−1.633	0.102
Low self-esteem*	1.00 [1.75]	0.50 [1.00]	−2.070	0.038
Sleep energy				
Impact in sleep	0.00 [0.00]	0.00 [0.00]	−0.000	1
Feelings of tiredness	0.50 [1.75]	0.50 [1.00]	−1.000	0.317
Severity measures				
Need to use tampons/pads*	1.38±1.19	0.00 [0.75]	−2.251	0.024
Need to push up the prolapse	1.00±1.07	0.00 [1.00]	−1.633	0.102
Pain/discomfort due to the prolapse	1.25±1.16	0.00 [1.00]	−1.890	0.059
Prolapse impedes standing	0.00 [1.75]	0.00 [0.00]	−1.633	0.102
TOTAL	57.63±22.03	33.50 [20.00]	−2.521	0.012

QoL, Quality of life

Questions with statistically significant improvements (p≤0.05).

Data at time points T0 and T1 are presented as mean±standard deviation or median [interquartile range]. The Z-value and p-value were calculated using the Wilcoxon signed-rank test for paired samples.

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The answers to each question in the P-QoL questionnaire are assigned numerical values ranging from 0 to 3 or 0 to 4, following the format of the Portuguese version of the questionnaire.[16] However, it is worth noting that the first and second questions do not utilize numerical values for their responses. For the first question, which assesses general health perception, we categorized the responses as follows: 0 (very bad) to 4 (very good). For the second question, which evaluates the impact of prolapse on quality of life, we categorized the responses as follows: 0 (no impact) to 3 (a lot of impact).

Out of the six women who completed the PERFECT evaluation, improvements were observed in power, endurance, fast and total score, although these were not statistically significant, as seen in Table 4. Two women did not complete the PERFECT evaluation at T1. There was no improvement in POP stage according to the Baden-Walker grading system.

Table 4 PERFECT scale results at time points T0 and T1

PERFECT parameters	T0	T1	Z-value	p-value
Power	1.50 [2.00]	2.00 [3.00]	−1.732	0.083
Endurance	1.00 [3.00]	2.50 [4.50]	−0.756	0.45
Repetitions	0.00 [1.50]	0.00 [2.00]	−0.000	1
Fast	2.50 [3.25]	3.00 [5.75]	−1.633	0.102
TOTAL	5.50 [10.25]	9.00 [12.50]	−1.095	0.273

Data at time points T0 and T1 are presented as median [interquartile range]. The Z-value and p-value were calculated using the Wilcoxon signed-rank test for paired samples.

In the subjective evaluation, all women were satisfied with the treatment experience, considering it to be better than the conventional treatment (all rating it as a 3, i.e., better, on the Likert scale) due to its non-invasiveness and ease/comfort. No adverse effects were documented.

Discussion

This study represents a preliminary investigation into the safety and efficacy of HIFEM treatment for POP stages 1 and 2. Some studies have applied HIFEM for the treatment of urinary incontinence, and sexual and pelvic floor disfunction, with the results showing enhancements in pelvic floor muscle function and quality of life in these populations.[15,18-21]

Our study also noted significant enhancements in participants' quality of life perception, symptom relief, and self-esteem. While the evaluation of pelvic floor muscle function using the PERFECT scheme indicated improvements in almost all parameters, these changes were not statistically significant.

It is worth noting that women who participated in this study seemed to prefer this treatment over previous rehabilitation programs due to its non-invasiveness and overall comfort. This preference may be attributed to the fact that other existing procedures (e.g., intravaginal probes for biofeedback and electrostimulation) can potentially cause discomfort, as they require the insertion of disposable vaginal probes. Comparatively, when contrasted with pelvic floor muscle exercises alone (e.g., Kegel exercises), patients may encounter challenges in effectively contracting their pelvic floor muscles and adhering to the recommended routine of performing these exercises frequently throughout the day and on a daily basis to achieve the desired results.

In the literature, minor reported side effects include spotting, muscular pain, temporary muscle spasm, temporary joint or tendon pain, increased sensitivity during intercourse, and local erythema or skin redness. However, in our population, no adverse effects were documented.

For HIFEM treatment, we believe it is crucial to have a physician or physiotherapist present with the patient, at least during the initial sessions, to provide supervision and educate the patient on the proper use of the chair and the gradual increase in intensity as tolerated. After the initial sessions and upon reaching the maximum intensity, continuous supervision throughout the treatment duration is unnecessary. Thus, this technology offers the advantage of allowing physiotherapists to attend to other patients while one patient undergoes a 28-min session in the electromagnetic chair. This ability could alleviate the workload on human resources, thereby increasing the capacity of pelvic floor rehabilitation services to cater to these patients and reducing wait times for the initiation of rehabilitation programs focusing on pelvic floor muscle strengthening.

Additionally, it is noteworthy that all participants in this study had prior experience with conventional rehabilitation programs, including biofeedback, which may have enhanced their awareness of pelvic floor muscle control and contraction. Therefore, prior awareness of the pelvic floor muscles may lead to increased effectiveness of HIFEM treatment in such patients.

The parameters of HIFEM treatment used in this work, as well as the treatment frequency and time duration established for the device, which has standardized protocols, were also used in previous studies.[15,18–20] Nevertheless, further research is required to assess the potential variances in treatment efficacy associated with longer treatment durations and different parameter settings.

In addition, there is a limited body of research that directly compares HIFEM to other conventional treatments,[21,22] and minimal evidence regarding the duration of treatments benefits, with few existing studies reporting follow-ups of three months to one year.[15,18,20]

This gap in the literature highlights the importance of comparison studies to evaluate and compare the effectiveness of different treatments, not only in the context of POP but also in other pelvic floor disorders that rely on the function of pelvic floor muscles.

Although improvements in pelvic floor muscle function were documented, the results were not statistically significant. It is important to note that the PERFECT scheme was conducted by two specialists and, despite its proven reliability,[17] it remains a subjective evaluation, and intraobserver/interobserver variability may occur.

Additionally, there were no observed improvements in the severity of POP as assessed by the Baden-Walker grading system. It is well known that pelvic floor muscle plays a crucial role in pelvic organs support, but ligaments, connective tissue, and other factors may also contribute to POP. Furthermore, the observed improvements in pelvic muscle function did not reach statistical significance, and the Baden-Walker grading system is not the most reproducible or reliable classification system for POP, which could potentially lead to inaccurate assessment of POP severity. Despite the POP-Q system being the preferred choice endorsed by professional societies for its higher precision and reproducibility,[23] we opted for the Baden-Walker system due to its simplicity and practicality, especially within the constraints of clinical research environments where time and resources are often limited. This choice aligned with the practical necessities of our study. Nonetheless, future studies could benefit from using more objective and replicable outcome measures.

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Our study had several limitations. The primary limitations comprise the relatively small sample size, the absence of a control group, and the fact that all patients previously underwent a conventional rehabilitation program, enhancing their awareness of the pelvic floor muscles. In addition, the use of subjective evaluations such as the PERFECT scheme and the Baden-Walker grading system may affect the reliability of the results.

Conclusion

Our study found significant improvements in symptom relief, self-esteem, and perceived quality of life following HIFEM treatment. In the subjective evaluation, all participants reported satisfaction with the treatment experience, appreciating its non-invasive nature and ease of use compared to conventional methods. However, there was no improvement in POP severity according to the Baden-Walker grading system and improvements in pelvic floor muscle function measured by the PERFECT scheme were not statiscally significant. This indicates that, despite the positive perceptions and satisfaction reported by patients, these changes did not result in statistically significant improvements in pelvic floor muscle function.

In conclusion, HIFEM treatment seems safe and effective in enhancing quality of life for women with POP stages 1 and 2, who have undergone previous conventional treatment. Future studies with larger sample sizes, control groups, and more objective measures like the POP-Q system are needed to confirm these findings and further evaluate the effectiveness of HIFEM in pelvic floor muscle function and POP severity, optimize the treatment protocols, and compare the technology with other treatments currently used. Additionally, it is necessary to conduct comparison studies of its efficacy between groups with distinct previous treatment experiences, as well as follow-up studies to ascertain the duration of treatment benefits.

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None.

Conflicts of interest

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Authors' contribution

Ana Filipa Gonçalves, Luís Oliveira, and Marta Torres conceived and designed the experiments. Ana Filipa Gonçalves, Igor Santos Neto, Teresa Oliveira, and Ana João Costa e Marta Torres performed the experiments. Ana Filipa Gonçalves analyzed the data. Ana Filipa Gonçalves wrote the paper. All authors reviewed the manuscript.

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