

ASSESSING THE EFFICACY OF HIGH INTENSITY FOCUSED ELECTROMAGNETIC (HIFEM) STIMULATION IN ALLEVIATING URINARY INCONTINENCE SYMPTOMS:INDONESIAN-BASED COMMUNITY

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ABSTRACT

Introduction: Urinary incontinence (UI) is common in women and may impair quality of life. Pelvic floor muscle dysfunction contributes to stress and mixed urinary incontinence. High-Intensity Focused Electromagnetic (HIFEM) therapy is a promising non-invasive modality for improving pelvic floor muscle function. **Objective:** This study aims to evaluate whether HIFEM can offer a more effective alternative for managing urinary incontinence. **Material & Methods:** 31 women were enrolled in this cohort study. Patients are assessed before and after intervention using the International Consultation on Incontinence Questionnaire Urinary Incontinence—Short Form (ICIQ-UI-SF). The intervention is a 28-minute HIFEM stimulation with 33 sequences and intensities between 50 to 100% and sequential amplitude modulation, once a week within 4 weeks. **Results:** 26 participants (83.8%), dominated by mixed-type UI (17 patients), followed by 7 stress-type and 2 urge-type, have experienced an improvement in UI symptoms and showed improvement in ICIQ scores, while the other 5 participants (16.2%) showed insignificant progress after the intervention. The enhanced group reported a transition from moderate-severe symptoms to mild symptoms or complete recovery, and statistical analysis showed a significance value of $p = 0.001$ ($p < 0.05$). **Conclusion:** The HIFEM stimulation procedure significantly alleviates urinary incontinence patients, particularly the mixed-type.

Keywords: HIFEM, urinary incontinence, pelvic floor muscles training.

ABSTRAK

Pendahuluan: Inkontinensia urin (UI) merupakan kondisi yang umum terjadi pada perempuan dan dapat menurunkan kualitas hidup. Disfungsi otot dasar panggul berperan dalam terjadinya inkontinensia urin tipe stres dan campuran. Terapi High-Intensity Focused Electromagnetic (HIFEM) merupakan modalitas non invasif yang menjanjikan untuk meningkatkan fungsi otot dasar panggul. **Tujuan:** Penelitian ini bertujuan untuk mengevaluasi apakah HIFEM dapat menawarkan alternatif yang lebih efektif untuk mengelola inkontinensia urin. **Bahan & Cara:** 31 wanita dimasukkan dalam studi kohort ini. Pasien dinilai sebelum dan setelah intervensi menggunakan Kuesioner International Consultation on Incontinence Questionnaire Urinary Incontinence Short Form (ICIQ-UI-SF). Intervensi yang diberikan adalah stimulasi HIFEM selama 28 menit dengan 33 sekuensi dan intensitas antara 50 hingga 100% dan modulasi amplitudo berurutan, seminggu sekali dalam waktu 4 minggu. **Hasil:** 26 peserta (83,8%) didominasi oleh UI tipe campuran (17 pasien), diikuti oleh 7 tipe stres dan 2 tipe urgensi, telah mengalami perbaikan gejala UI dan menunjukkan perbaikan skor ICIQ, sedangkan 5 pesertalainnya (16,2%) menunjukkan kemajuan yang tidak signifikan setelah intervensi. Kelompok yang ditingkatkan melaporkan adanya transisi dari gejala sedang-berat ke gejala ringan atau pemulihan total, dan analisis statistik menunjukkan nilai signifikan $p=0,001$ ($p < 0,05$). **Simpulan:** Prosedur stimulasi HIFEM secara signifikan meringankan inkontinensia urin pada seluruh pasien khususnya tipe campuran.

Kata kunci: HIFEM, inkontinensia urin, latihan otot dasar panggul.

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INTRODUCTION

Urinary incontinence (UI) refers to a condition where unwanted urine leakage occurs. UI

is a common problem that spreads throughout the world, affecting women from various culture, age, and backgrounds. Overall, approximately 25-45 percent of women report experiencing varying

degrees of UI, with approximately one in every five women reporting that UI has affected their daily life.¹ In women, weakening of pelvic structures such as fascia, ligaments, and pelvic floor muscles, as well as impaired blood supply to the area, often trigger symptoms of stress or mixed urinary incontinence. Stress urinary incontinence (SUI) occurs when urine leaks unexpectedly during physical activity or even when sneezing or coughing. This mainly occurs during general physical activity such as sneezing, laughing, and exercise, and is related to damage to the urethral closure mechanism in the absence of detrusor contraction. This SUI may be associated with hypermobility and decreased urethral support, or even neuromuscular disorders of the urethra itself.² Meanwhile, mixed urinary incontinence (MUI) is the main cause of UI problems both in the community and in hospitals. This term refers to a combination of symptoms, where the patient exhibits features of both stress urinary incontinence (SUI) and urge urinary incontinence (UUI).^{3,4} Urge urinary incontinence (UUI) is characterized by the involuntary loss of urine which begins with a sudden and strong urge to urinate. Sufferers cannot hold urine at the same time, which causes bedwetting. The primary cause of this type can be non-neurogenic or neurogenic. In non-neurogenic type of UUI, the cause can come from stones or tumours in the bladder, which cause irritation and increase the contraction activity of the bladder. Meanwhile, in the neurogenic type UUI, these symptoms are related to abnormalities in the nerves that regulate bladder function.^{1,5} In some cases, this term also includes a combination of SUI symptoms related to urodynamics and detrusor hyperactivity. According to guidelines from the International Continence Society, MUI is currently defined as complaints of unwanted urine leakage during physical activity, sneezing, or coughing, as well as leakage associated with a sense of urgency. The overall prevalence of UI is estimated at 51.7 percent. The prevalence rates for SUI and MUI are 5.4 percent and 33 percent, respectively.

The Pelvic Floor Muscles (PFMs) have a very complex role in the urination process. PFMs has an important function in providing stability and support to muscles, aponeurotic elements, and ligaments involved in the dynamics of micturition and digestion. Furthermore, the primary role of the perineal membrane in urinary continence should not be overlooked. Located in the urogenital triangle, the perineal membrane has a vital responsibility in

stabilizing and compressing the external urethral sphincter. This group of structures is known as the urogenital diaphragm, which is a continuation of the lower fascia of the levator ani muscle, an important component of the pelvic diaphragm. Finding the underlying root cause of UI has tremendous significance in directing appropriate treatment strategies.^{5,6} The variety of treatment techniques available makes it important to choose an approach that suits the patient's condition and the type of incontinence they are experiencing. Treatment options include conservative measures, pharmacological use, as well as surgical intervention. One conservative approach that is quite popular is the Pelvic Floor Muscle Training (PFMT). Among the various physical therapy methods available, High Intensity Focused Electromagnetic (HIFEM) is one that is promising. The positive effects of HIFEM on peripheral nerve stimulation, muscle activation, and improvement of collagen structure composition and blood circulation are proven in existing studies.^{7,8}

OBJECTIVE

This human-trial prospective study aims to investigate the efficacy of High-Focused Electromagnetic Stimulation-Induced Pelvic Floor Muscles (HIFEM) for the treatment of urinary incontinence in the Indonesian-based community.

MATERIAL & METHODS

It was a cohort prospective study with a one-group pre-test and post-test design, 31 women were enrolled in this study. Patients were screened according to the inclusion and exclusion criteria to determine their eligibility for the study. The study is carried out at the urology clinic at Fatmawati Hospital. Patients are assessed before and after intervention using the International Consultation on Incontinence Questionnaire Urinary Incontinence Short Form (ICIQ-UI-SF). Patients were explained about the HIFEM device and procedures. The intervention we are using is the U1 protocol (Incontinence Protocol) consist of 28 minutes of HIFEM stimulation by 33 sequences and intensities between 50 to 100 percent with sequential amplitude modulation, once a week within 4 weeks.

To begin the procedures, we made sure the patient had no metal objects on them prior to the treatment starting. The patient should tilt their pelvic

area closest to the center of the seat; they may need to tilt forward or backward to achieve the proper angle. The patient should be sitting comfortably with their feet flat on the floor, shoulder-width apart. The patient should also place their knee exactly above the ankle at a 90-degree angle with a slight outward rotation. After each session, the assessor take notes about the HIFEM intensity, the number of HIFEM sessions, and the complaint after each session. 1 week after the last session, a questionnaire was presented to the patient in order to gauge changes in complaints and scores.

The study was approved by the Ethical Committee of Fatmawati Hospital (PP.08.02/D.XXI.18/112/2023). Informed consent was obtained from all participants involved in the study. Participants were fully informed about the study's purpose, procedures, potential risks, and benefits, and written consent was obtained prior to their participation.

The data analysis software was used to examine the gathered data. To evaluate changes between the pre-test and post-test, the data were subjected to a Wilcoxon test for differences.

RESULTS

The 26 participants (83.8%), dominated by MUI type, followed by SUI type, around 7 women and 2 women with the UII type, experienced an improvement in UI symptoms and showed improvement in ICIQ-UI-SF scores, while the other 5 participants (16.2%) showed insignificant progress after the intervention. The enhanced group reported a transition from moderate-severe symptoms to mild symptoms or complete recovery, and statistical analysis showed a significance value of $p = 0.001$ ($p < 0.05$).

Demographic data showed the largest distribution of UI patients was in the group of 51-60 years old, consisting of 13 patients (41.9%), followed by a group of 11 patients aged 41-50 years old (35.5%) and 6 patients over >60 years old (19.4%) and 1 patient in age range 31-40 years old (3.2%). From these data, it is known that the majority of patients with BMI categories were normal and obese by 13 people in each group (41.9%), followed by 5 people in the overweight category (16.1%) and no patients were in the underweight category. The majority of patients said they had been pregnant and had children, with the highest frequency of 20 women (64.6%) in the category of having multiple child born with vaginal birth method, followed by 8

Table 1. Demographic sample urinary incontinence.

Variable	N	%
Gender		
Women	31	100
Age		
30-40 years old	1	3.2
41-50 years old	11	35.5
51-60 years old	13	41.9
>60 years old	6	19.4
BMI (Body Mass Index)		
Underweight	0	0
Normal	13	41.9
Overweight	5	16.1
Obese	13	41.9
History of pregnancy		
Never been pregnant	1	3.2
History of having a child born with vaginal birth method	2	6.5
History of having a child born with caesarean section surgery method	0	0
History of having multiple child born with vaginal birth method	20	64.6
History of having multiple child born with caesarean section surgery method	8	25.8
History of surgery in the pelvic area		
No	14	45.2
Yes	17	54.8
History of treatment before HIFEM		
No	18	58.1
Yes	13	41.9
Urinary Incontinence Subtype		
SUI	7	22.6
UII	3	9.7
MUI	21	67.7

women (25.8%) in the category of having multiple child with a history of caesarean section surgery method and 2 women (6.5%) having a child born with vaginal birth method and only 1 woman who had never been pregnant.

Based on this table, it was found that 17 patients had a history of surgery in the pelvic area (54.8%) compared to 14 patients without a history of surgery in the pelvic area (45.2%). More than 50% of patients also said there was no history of treatment for complaints of urinary incontinence before this therapy, 18 people (58.1%) compared to 13 patients who had taken other treatments (41.9%) and the most common subtype of UI in this study was MUI type with 21 people (67.7%) followed by SUI type with 7 people (22.6%) and UII with 3 people (9.7%).

Based on the table above, because the value 0.0001 is smaller than 0.05, H_a is accepted. This means that there is a significant difference between the pre-test and post-test scores in all urinary

incontinence patients after HIFEM stimulation therapy. Apart from that, there were more significant results in the MUI subtype compared to the SUI and UUI subtypes.

There is an improvement in the symptoms of urinary incontinence which can be seen in the reduction of the ICIQ-UI-SF score in the patients. The dominant subtype in this study was MUI (Mixed Urinary Incontinence), the highest distribution of urinary incontinence occurs in mothers with a history of multiparity, The highest UI incidence is in the group of 51-60 years old. There is an effect of giving HIFEM stimulation therapy on changes in the frequency of urinary incontinence in women at Fatmawati Hospital.

Table 2. Wilcoxon test outcomes.

Group of Patients (Before and After intervention)	Outcome (P Value)
All UI patients	0.0001
MUI subtype	0.0001
SUI subtype	0.015
UUI subtype	0.157

DISCUSSION

Regardless of the volume or frequency, urinary incontinence (UI) is the involuntary leakage of pee, which can lead to issues with quality of life, behaviour, emotions, and health.⁹ The International Continence Society (ICS) defines UI as a complaint of inadvertent urine discharge that results in negative social and/or health consequences. Non-invasive techniques are quickly gaining popularity across the globe and have emerged as a crucial area of aesthetic medicine. The benefits of this therapy include the ability to improve physical appearance, particularly in terms of body contouring, and the ability to avoid the risks connected with surgical procedures. High-Intensity Focused Electromagnetic (HIFEM) technology is one such example. One of the most used non-invasive techniques is HIFEM technology. The issue of body shaping has been successfully resolved by this technique. The US Food and Drug Administration has given it approval for the purpose of toning and strengthening muscles.¹⁰

HIFEM can decrease fat layers and enhance muscle mass, according to clinical research conducted in 2018.¹¹ High-Intensity Focused Electromagnetic Therapy (HIFEM) operates in accordance with Faraday's law by employing

electromagnetic induction and a rapidly generated, inverted magnetic field created by a coil of wire to depolarize motor nerves. This allows HIFEM therapy to initiate the biochemical cascade that leads to fat breakdown and can strengthen and stimulate muscle growth (hypertrophy) as well as reduce fat in areas with excess adipose tissue.

Because adipose tissue often serves as a source of energy for muscular activity, increasing muscle volume increases the energy required to produce contractions, which in turn encourages the body to carry out catabolic processes that occur in lipolysis. According to the aforementioned mechanism, HIFEM therapy can enhance a patient's physical appearance and assist in their efforts to boost their self-confidence. Based on a clinical study done in 2021, it was shown that within one to three months, body image and skin appearance, particularly in the buttocks and belly, may be improved by combining the continuous use of TPE and RF with HIFEM. In a number of trials, therapy sessions are held twice a week for two weeks, and the HIFEM technology must be utilized consistently. Sessions typically last 30 minutes and operate in the extremely low frequency range (3 to 30 kHz).^{10,11}

High-intensity focused electromagnetic therapy (HIFEM) can assist in inducing an electric current by forcing the pelvic floor muscles to contract, hence forcing the neuromuscular network to be anchored. This technique is useful in treating urine incontinence. All of the pelvic floor muscles can be activated and concentric contractions produced by electrical currents that depolarize the nerves.¹²

CONCLUSION

The HIFEM stimulation procedure significantly alleviates urinary incontinence patients, particularly the mixed-type by strengthening the pelvic floor muscles. The research procedure we conducted revealed that roughly once a week for four sessions can have a significant impact. Since the assessment includes improvements in quality of life, fewer sessions are thought to be more effective in reducing the patient's need to visit the hospital, which feels more comfortable.

It is hoped that future researchers can develop this research by adding factors that influence complaints of urinary incontinence, including the amount of fluid ingested and the

condition of the pelvic floor muscles before and after the intervention which is described via other supporting examinations.

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