THE EFFECT OF HIGH-INTENSITY FOCUSED ELECTROMAGNETIC (HIFEM) THERAPY ON PATIENTS WITH URGE URINARY INCONTINENCE

[1]Besut Daryanto, [1]Taufiq Nur Budaya, [1]Hikmat Satria.

[1] Department of Urology, Faculty of Medicine/University of Brawijaya, Saiful Anwar General Hospital, Malang.

ABSTRACT

Objective: *This study aims to determine the effect of HIFEM on OABSS and pad usage through the Voiding Diary.* ***Material & Methods:*** *An experimental study with pre and post-test. Patients will be given a questionnaire before and after undergoing HIFEM therapy for six sessions, and be followed for one month. Data analysis was carried out using SPSS software. Paired T-test was used for data with normal distribution, while the Wilcoxon Non-parametric test was used for data which is not normally distributed. Data are considered statistically significant if the p-value <0.05.* ***Results:*** *Twenty-eight patients completed the study. After six HIFEM sessions, the mean OABSS significantly decreased from 12.89 ± 1.03 to 11.61 ± 1.59 (p < 0.001), and pad usage reduced from 8.39 ± 1.20 to 2.82 ± 1.56 (p < 0.001).* ***Conclusion:*** *Six sessions of HIFEM therapy were associated with a decrease in OABSS and pad use in patients with urinary incontinence. But OABSS did not significantly reduce in patient with DM and HT.*

Keywords: *HIFEM, urinary incontinence, OABSS.*

ABSTRAK

Tujuan: *Penelitian ini bertujuan untuk mengetahui pengaruh HIFEM terhadap OABSS dan penggunaan pembalut melalui Catatan Harian Buang Air Kecil.* ***Bahan & Cara:*** *Sebuah studi eksperimental dengan pra dan pasca-uji. Pasien akan diberikan kuesioner sebelum dan sesudah menjalani terapi HIFEM selama enam sesi, dan akan dipantau selama satu bulan. Analisis data dilakukan menggunakan perangkat lunak SPSS. Uji T berpasangan digunakan untuk data dengan distribusi normal, sedangkan uji non-parametrik Wilcoxon digunakan untuk data yang tidak berdistribusi normal. Data dianggap signifikan secara statistik jika nilai p < 0,05.* ***Hasil:*** *Dua puluh delapan pasien menyelesaikan penelitian ini. Setelah enam sesi HIFEM, rata-rata OABSS menurun secara signifikan dari 12,89 ± 1,03 menjadi 11,61 ± 1,59 (p < 0,001), dan penggunaan pembalut berkurang dari 8,39 ± 1,20 menjadi 2,82 ± 1,56 (p < 0,001).* ***Simpulan:*** *Enam sesi terapi HIFEM dikaitkan dengan penurunan OABSS dan penggunaan pembalut pada pasien dengan inkontinensia urin. Namun, OABSS tidak berkurang secara signifikan pada pasien dengan DM dan HT.*

Kata kunci: *HIFEM, inkontinensia urin, OABSS.*

Correspondence: Besut Daryanto; c/o: Department of Urology, Faculty of Medicine, Universitas Brawijaya, Saiful Anwar General Hospital. Jl. Jaksa Agung Suprapto No.2, Klojen, Kec. Klojen, Malang, Jawa Timur 65112, Indonesia. Phone: +6282233678283.Fax: +62341333030. Email: urobes.fk@ub.ac.id.

INTRODUCTION

Urinary incontinence (UI) refers to the involuntary loss of urine, regardless of the amount or frequency, leading to physical, emotional, social problems and a decrease in an individual's quality of life.[1] According to the Asia Pacific Continence Board (APCB), the prevalence of urinary incontinence ranges from 20.9% to 35% among adults in the region.[2] In 2017, the Ministry of Health of the Republic of Indonesia reported that 5,052 men in Asian countries, including Indonesia, suffered from UI. It is estimated that 15% to 30% of individuals experiencing UI are aged over 60 years.[3]

UI can be categorized into several types, including stress urinary incontinence, urge urinary incontinence, functional incontinence, mixed incontinence, and overflow incontinence. Urge urinary incontinence is characterized by the involuntary loss of urine preceded by a sudden urge to urinate. The causes can be non-neurogenic (presence of stones, tumors, bladder infections) or neurogenic (related to nerve disorders). It is also considered one of the symptoms of a clinical syndrome known as Overactive Bladder (OAB).[4]

Treatment is adjusted to the type of urinary incontinence experienced by the patient. For urge

urinary incontinence, antimuscarinics are the primary medical therapy, working by blocking muscarinic receptors in the detrusor muscle of the bladder. Another therapeutic approach for strengthening pelvic floor muscles in patients with urinary incontinence is High-Intensity Focused Electro-Magnetic (HIFEM) therapy. HIFEM technology induces deep pelvic floor muscle contractions through focused electromagnetic stimulation, enhancing muscle strength and neuromuscular control. Previous studies have demonstrated that HIFEM therapy can improve continence outcomes more effectively than traditional Kegel exercises.[3] Research using electromagnetics with the HIFEM method has been recommended because the impact of the electromagnetic field produced is very useful in the therapy of urge urinary incontinence, so that it has better outcomes than conservative treatment.

OBJECTIVE

This study aims to determine the effect of HIFEM on OABSS and pad usage through the Voiding Diary.

MATERIAL & METHODS

This was a pre–post interventional study (single-arm experimental design) using purposive sampling. Patients with a diagnosis of urge urinary incontinence based on urodynamic examination, and patients who underwent urodynamics before and after HIFEM but failed medication, were included in the study. However, patients dropping out, patients with bone implants, pacemaker or heart ring installation, patients whose OAB is due to neuropathy complications, patients with OAB secondary to bladder outlet obstruction and patients with PFUI were excluded from the study. Direct sampling was carried out under the supervision of researchers, including age, sex, and diabetes mellitus (DM) and hypertension (HT) risk factors.

Patients were followed for one month, starting from the first diagnosis and finished after completing the HIFEM therapy. Patients were given questionnaires before and after undergoing six sessions of HIFEM therapy. The questionnaires mainly covered the Overactive Bladder Symptom Score (OABSS) and voiding diary. OABSS is the scoring system used to evaluate the severity of OAB. The OABSS questionnaire consists of 4 questions regarding OAB symptoms with a maximum score ranging from 2 to 5: daytime frequency (2 points), nighttime frequency (3 points), urgency (5 points), and UUI (5 points). OABSS is divided into 3 categories: mild (OABSS <5), moderate (OABSS 6-11), and severe (OABSS >12).6 The voiding diary questionnaire includes the number of pads used during the OAB period.

The data collected was assigned to several categories before data analysis: male or female, with DM risk factor or Non-DM, and with HT risk factor or Non-HT, to see if sex, DM and HT risk factors affect the effectivity of the HIFEM therapy. The overall pre- and post-test data were also analysed to see if the HIFEM therapy had a significant effect on the overall OABSS and voiding diary. Data analysis was carried out using SPSS software. Normality test was conducted to see the normality of data distribution. A p-value of >0.05 indicates normally distributed data, while <0.05 indicates not normally distributed data. Paired T-test was used for data with normal distribution, while the Wilcoxon Non-parametric test was used for data which is not normally distributed. A p-value of <0.05 in the Paired T-test result shows a significant effect of HIFEM compared to the pre-HIFEM therapy, while a p-value of <0.05 shows a significant effect of HIFEM compared to the pre-HIFEM therapy.

RESULTS

A total of 28 patients were included in this study. There were 22 female and 6 male patients, ranging from 15-70 years old. Laboratory data was compiled on set on day the patients come to the urology polyclinic. Diabetes mellitus comorbidity was found in 6 patients, and HT comorbidity was found in 5 patients. All patients underwent 6 sessions of HIFEM therapy.

The OABSS score is divided into 3 criteria: mild, moderate, and severe. In this study, no mild criteria were found. Four patients were having moderate OAB, while 24 patients were in severe criteria. Table 1 showed a decrease in the overall OABSS mean, from 12.89 1.03 before treatment, to 11.61 1.59 after HIFEM therapy, from severe to moderate category. Statistical analysis also showed a significant effect of HIFEM therapy on patients with OAB, with a p-value of <0.001. The mean OABSS decreased significantly following HIFEM therapy, indicating improvement in overactive bladder symptoms.

Both gender (male and female) showed a significant correlation and improvement of OABSS and voiding diary after 6 sessions of HIFEM therapy. However, comorbidities such as diabetes mellitus and HT showed to affect the effectivity of HIFEM therapy. The OABSS of patients with DM and or HT showed insignificant HIFEM therapy result, with a p-value >0.05. However, DM and HT comorbidities showed to still effectively decrease the pad used by the OAB patients after the HIFEM therapy. Patients without comorbidities showed to have a significant effect, both of the OABSS and number of pads used after receiving HIFEM therapy. These details appeared in Table 1.

A significant decrease in number of pads used after the HIFEM therapy was obtained, from 8.39 1.20 to 2.82 1.56. Statistical analysis also showed a significant decrease of number of pads used, with a p-value of <0.001. Different sexes and comorbidities showed to not have a significant effect on the effectivity of HIFEM therapy. Either male and female, and patients with DM and or HT and not, showed to have a significant effect of pad used after HIFEM therapy as mentioned in Table 2.

Table 1. OABSS Pre and Post HIFEM.

Variable	Count	Pre-HIFEM	Post-HIFEM	p-value
OABSS	28	12.89 ± 1.03	11.61 ± 1.59	<0.001**
Sexes				
Male	6	13.00 ± 1.09	12.17 ± 1.60	0.042*
Female	22	12.86 ± 1.04	11.45 ± 1.60	<0.001**
Age				
≥ 60 years old	4	12.75 ± 1.26	11.75 ± 1.89	-
< 60 years old	24	12.92 ± 1.02	11.58 ± 1.59	
Diabetes Mellitus				
+	7	13.00 ± 0.58	12.14 ± 0.90	0.078*
-	21	12.86 ± 1.15	11.43 ± 1.75	<0.001**
Hypertension				
+	5	13.40 ± 0.55	12.40 ± 0.89	0.059**
-	23	12.78 ± 1.09	11.43 ± 1.67	<0.001*

Values expressed as mean ± standard deviation. p < 0.05 considered significant.
* Paired T-Test
** Wilcoxon

Table 2. Pad Usage Pre and Post HIFEM.

Variable	Count	Pre-HIFEM	Post-HIFEM	p-value
Pad Usage	28	8.39 ± 1.20	2.82 ± 1.56	<0.001**
Sexes				
Male	6	8.17 ± 1.33	4.00 ± 2.45	0.005*
Female	22	8.45 ± 1.18	2.50 ± 1.10	<0.001**
Age				
≥ 60 years old	4	8.25 ± 1.50	3.00 ± 2.45	-
< 60 years old	24	8.42 ± 1.18	2.79 ± 1.44	
Diabetes Mellitus				
+	7	8.71 ± 0.76	3.86 ± 1.46	0.014**
-	21	8.29 ± 1.31	2.48 ± 1.47	<0.001**
Hypertension				
+	5	8.60 ± 0.89	4.20 ± 1.64	0.039**
-	23	8.35 ± 1.27	2.52 ± 1.41	<0.001*

* Paired T-Test
** Wilcoxon

Overall, HIFEM therapy significantly reduced both OABSS and pad usage across sexes. However, improvement in OABSS was not significant in patients with diabetes or hypertension, although pad usage still decreased in these subgroups.

DISCUSSION

This study demonstrated that both male and female patients experienced significant improvement in OAB symptoms after HIFEM therapy. Among the participants, 21.4% were male and 78.6% were female. Women have anatomically different urinary tract systems compared to men. Women's urethra is shorter and wider than men's. This makes the woman's urethra more susceptible to pressure from the bladder and decreased pelvic muscle tone. Previous research suggests that the process of pregnancy and childbirth can weaken the pelvic muscles and structures that support the bladder and urethra. Over time, this condition can cause urinary incontinence. Difficult labour or multiple deliveries can also increase a woman's risk of incontinence. The process of pregnancy and childbirth is the main factor that causes stress on the pelvic floor muscles. During pregnancy, the expanding uterus can put pressure on the pelvic muscles. Childbirth, especially vaginal delivery, can cause stretching, trauma, or injury to the pelvic muscles and supporting structures of the bladder and urethra. This condition can result in weakness of the pelvic floor muscles.[4,5]

In addition, hormonal changes associated with menopause, such as a decrease in estrogen, can affect pelvic tissue and cause a decrease in the elasticity and strength of the muscles around the bladder and urethra. Menopause can affect the tissue around the bladder and urethra, and can reduce the sensitivity of the urethra to changes in the volume of urine in the bladder. Estrogen has a positive effect on the elasticity and strength of the pelvic muscles, as well as the tissues that support the bladder and urethra. When estrogen levels are low, especially during menopause, these muscles can weaken, and connective tissue can become thinner and less elastic. This can cause a decrease in pelvic muscle tone, which can result in urinary incontinence. Estrogen also affects the sensitivity of the urethra. Decreased estrogen levels can reduce the sensitivity of the urethra to changes in the volume of urine in the bladder. As a result, the patient may not feel the urge to urinate as quickly when the bladder is full which can result in urge incontinence. The estrogen hormone also affects the urinary tract mucosa. As estrogen levels decrease, the urinary tract mucosa may become thinner and more susceptible to irritation, which may affect bladder control.[6] Meanwhile in men, BPH is a common cause of UI. When the prostate enlarges, it can put pressure on the urethra and bladder, which can disrupt urine flow and cause incontinence.[7] In this study we found that there were no difference in effectivity in patients after HIFEM therapy in both gender based on OABSS score and pad usage.

In this study, non-DM patients were found to have a greater impact on UI than DM patients, both based on OABSS scores and diaper use after HIFEM therapy. In DM patients, OABSS scores were not found to decrease significantly after HIFEM therapy, but diaper use was still found to decrease. UI in patients with DM can be caused by various pathophysiological mechanisms related to metabolic disorders and the impact of disease on the urinary system. Diabetic neuropathy is nerve damage that often occurs in DM sufferers. Diabetic neuropathy can affect the nerves that control contractions of the pelvic and bladder muscles. As a result, the signals that regulate bladder emptying may be disrupted. Patients with diabetic neuropathy may experience urinary incontinence because the bladder cannot control urination properly. Management of urinary incontinence in patients with DM involves good blood sugar control, therapy for diabetic neuropathy, pelvic muscle exercises, lifestyle changes, and in some cases, medications aimed at reducing incontinence symptoms.[8]

In this study, HIFEM found affective in reduced UI in non-HT patient that analysed on OABSS and pad usage post therapy. In non-HT patient, it found decreased in pad usage but not decreased in OABSS score. HT can lead to frequent sudden and repeated intra-abdominal pressure increase, which over time may lead to pelvic floor muscles exhaustion that contributing to UI. Moreover, individuals with HT often require long-term use of antihypertensive medications as diuretics, calcium channel blockers, and beta blockers that can exacerbate OAB symptoms.[9,10]

Previous research states that the main treatment options for OAB conditions are bladder training, drug therapy, electrical stimulation and pelvic floor muscle training with or without electrical stimulation. Currently, HIFEM is the most

commonly used intervention in physical therapy for patients with OAB who exhibit symptoms of incontinence. Several previous studies stated that pelvic floor muscle strengthening therapy through HIFEM can be used to improve OAB symptoms.[11,12] The rationale for using pelvic floor muscle strengthening therapy for incontinence in general is to establish structural support of the pelvic floor by closing the levator hiatus and increasing maximum urethral closure pressure to prevent leakage during increased intra-abdominal pressure. However, the rationale behind using pelvic floor muscle strengthening therapy to treat OAB symptoms is based on the initial observation of voluntary contractions of the pelvic floor muscles during ultrasound assessment of the pelvic floor muscles which must be observed before taking action. Pelvic floor muscle contraction causes a decrease in detrusor pressure, an increase in urethral pressure and suppression of the voiding reflex, so these results encourage the use of HIFEM therapy in the treatment of OAB.[13] However, in this study, ultrasound measurements of the pelvic muscles were not carried out so that initial observations of voluntary contractions of the pelvic floor muscles could not be observed in the patients involved in this study.

This research is in line with previous research which stated that the group that was given HIFEM therapy for 10 times with each therapy lasting 28 minutes, resulted in a significant reduction in incontinence symptoms compared to the group that was not treated with HIFEM. For pelvic floor muscle strengthening, strong contractions with rest periods in between should be involved to provide sufficient load. If muscles are appropriately stimulated, both endurance and strength can be restored. Better results after HIFEM therapy in previous studies were influenced by strengthening the deep penetration of high-intensity electromagnetic fields into the pelvic area resulting in even activation of the PFM. Previous research also states that the effect of reducing incontinence symptoms is not only felt in young people, but also in women who have experienced menopause.[14-15]

CONCLUSION

After carrying out HIFEM for 6 times, it can reduce the number of OABSS and pads usage in both gender. Diabetes and hypertension can be reducing factor of successful rate of HIFEM therapy in urinary incontinence patient.

REFERENCES

1. Lopopolo G, Salsi B, Banfi A, Isaza PG, Fusco I. Is It Possible to Improve Urinary Incontinence and Quality of Life in Female Patients? A Clinical Evaluation of the Efficacy of Top Flat Magnetic Stimulation Technology. Bioengineering (Basel). 2022;9(4):140.
2. Zhang Y, Wang XD, Song Y, Peng R, Tang T, Li M, Yu Z, Ji Y, Niu J. Epidemiology of Frequent/Urgent Urination in Older Adults in China: A Multicenter, Cross-Sectional Study. Front Public Health. 2021 Sep 7;9:669070.
3. Rahardjo, H.E. Panduan Tata Laksana Inkontinensia Urine Pada Dewasa Edisi Kedua. Edisi ke-2. Ikatan Ahli Urologi Indonesia. Jakarta. 2018.
4. Hu, J. S. and Pierre, E. F. Urinary Incontinence in Women: Evaluation and Management. American family physician. United States. 2019. 100(6). pp. 339–348.
5. Samuels, Julene B., Pezzella, Andrea., Berenholz, Joseph., Alinsod, Red. et al. Safety and Efficacy of a Non-Invasive High-Intensity Focused Electromagnetic Field (HIFEM) Device for Treatment of Urinary Incontinence and Enhancement of Quality of Life. Lasers in surgery and medicine. United States. 2019. 51(9). pp. 760–766.
6. Homma Y, Yoshida M, Seki N, Yokoyama O, Kakizaki H, Gotoh M, et al. Symptom assessment tool for overactive bladder syndrome--overactive bladder symptom score. Urology. 2006;68:318-23
7. Pang D, Gao Y, Liao L. Functional brain imaging and central control of the bladder in health and disease. Front Physiol. 2022;13:914963.
8. Hakim S, Santoso BI, Rahardjo HE, Setiati S, Kusumaningsih W, Prihartono J. The Risk Factor Associated with Stress Urinary Incontinence (SUI) Severity: a Cross-Sectional Multi-centered Study. Bali Medical Journal. 2023; 12(1): 631-635.
9. S. Almutairi, O. Alobaid, M.A. Al-Zahrani, et al. Urinary incontinence among Saudi women: prevalence, risk factors, and impact on quality of life. Eur Rev Med Pharmacol Sci. 2021; 25(20): 6311-6318.
10. Patel M, Vellanki K, Leehey DJ, et al. Balasubramanian N, Sandhu J, Kramer H. Urinary incontinence and diuretic avoidance among adults with chronic kidney disease. Int Urol Nephrol. 2016; 48(8): 1321-1326.
11. Bai J, Tian Y, Wang Y, Zhang X, Wang P. Physical and Rehabilitation Therapy for Overactive Bladder in Women: A Systematic Review and Meta-Analysis. International Journal of Clinical Practice. 2023; 4: 6758454.
12. Daryanto B, Purnomo A, Patriawan Y, Purnomo B. The Effect of Long-Term Tamsulosin Monotherapy and Tamsulosin – Dutasteride Combination Therapy

on PKC-α Enzyme Expression in Prostate Stromal Tissue. Medical Archives. 2023 .
13. Bo K, Fernandes ACNL, Duarte TB, Brito LGO, Ferreira CHJ. Is pelvic floor muscle training effective for symptoms of overactive bladder in women? A systematic review. Physiotherapy. 2020;106:65-76.
14. Castro RA, Arruda RM, Zanetti MR, Santos PD, Sartori MG, Girão MJ. Single-blind, randomized, controlled trial of pelvic floor muscle training, electrical stimulation, vaginal cones, and no active treatment in the management of stress urinary incontinence. Clinics (Sao Paulo). 2008.
15. Silantyeva E, Zarkovic D, Astafeva E, et al. A Comparative Study on the Effects of High-Intensity Focused Electromagnetic Technology and Electrostimulation for the Treatment of Pelvic Floor Muscles and Urinary Incontinence in Parous Women: Analysis of Posttreatment Data. Female Pelvic Med Reconstr Surg. 2021;27(4):269-273.