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Efficacy and Safety of HIFU in Improving Bladder Control in Women with Urinary Incontinence

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ABSTRACT

Introduction: Urinary incontinence is a common gynecological issue, affecting millions of women worldwide due to the weakening of pelvic floor muscles.

Aims & Objectives: To evaluate the efficacy and safety of High-Intensity Focused Ultrasound (HIFU) for strengthening pelvic floor muscles and improving bladder control in women with urinary incontinence.

Place and Duration of Study: The study was conducted at CMH Multan from April 2023 to May 2024 in collaboration with the gynecology and urology departments.

Material & Methods: The current non-randomized trial included 100 females diagnosed with urinary incontinence and aged ≥35 years through non-probability convenience sampling. This study adopted a unique HIFU treatment consisting of weekly 20-minute sessions over 8 consecutive weeks. The primary outcome was a change in urinary incontinence symptoms measured by the International Consultation on Incontinence Questionnaire-Urinary Incontinence Short Form (ICIQ-UI SF) score. Secondary outcomes included a reduction in incontinence episodes, bladder control parameters (maximum bladder capacity and detrusor pressure), strengthening pelvic floor (perineometry, digital palpation), life quality (I-QOL and PFDI-20), and adverse events. Descriptive statistics were expressed using SPSS version 23.0, as mean ± SD or frequency/percentages to check the mean difference across the two groups, t-test was applied. A p-value of <0.05 was considered statistically significant.

Results: The HIFU group showed a significant decrease in ICIQ-UI SF scores (-6 ± 2) compared to the non-HIFU group (-2 ± 1, $p < 0.001$). HIFU participants experienced a greater decrease in incontinence episodes (10 ± 3 vs. 4 ± 2, $p< 0.001$) and improvements in bladder control and muscle strength. Participants undergoing HIFU demonstrated a significant rise in the I-QOL score ($p < 0.01$), with 80% reporting subjective improvement. The HIFU group also experienced minimal adverse effects and the results were significant. P<0.05.

Conclusion: HIFU is an effective, safe, and non-invasive treatment for urinary incontinence, significantly improving symptoms, bladder control, muscle strength, and life quality while offering minimum to no adverse effects.

Keywords: Pelvic Floor Training, High-Intensity Focused Ultrasound, Urinary Incontinence

INTRODUCTION

Urinary incontinence (UI) is a common gynecological issue affecting millions of women worldwide. It significantly impacts their quality of life and emotional health. UI is mainly present in pregnant females and is linked with vaginal deliveries[1]. Various invasive and non-invasive methods of management or treatment are currently being practiced with varying degrees of success and limitations. These include behavioral therapy, pelvic floor strengthening exercises, pharmacological interventions, and surgical repairs[2]. Still, there is an increased demand for innovative, non-invasive procedures that can effectively manage UI with minimal possible side effects. Amongst non-invasive methods, a newly developed, High-intensity focused ultrasound (HIFU) represents promising results[6]. HIFU is well known for its medical applications, such as in tumor ablation, and benign prostatic hyperplasia, along with cosmetic treatment and aesthetic gynecology[7]. HIFU delivers focused thermal energy to target tissue via harnessing high-frequency sound waves. The ability of HIFU for a focused target induces controlled tissue damage. HIFU can also stimulate collagen production thus promoting tissue strength, leading to its cosmetic and medical application for tissue tightening[8]. Recent international studies have proposed the beneficial effects of HIFU in improving bladder control, but very little evidence-based national data is available. A critical review of

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the existing literature reveals a significant gap in addressing key clinical outcomes such as patient satisfaction, adverse effects, and bladder capacity following interventions for all types of urinary incontinence. So, this study aims to set a new HIFU treatment session with significant efficacy and minimal adverse effects in improving bladder control in females with any type of UI. By targeting clinical outcomes, patient satisfaction, and potential side effects, this study may provide a robust evidence-based integration of HIFU in routine gynecological and urological setup to treat UI that may also avoid the hassle of prolonged sessions of HIFU and improve patients' compliance and its accessibility to the major population. The rationale of this study is to provide a less time-consuming but effective technique of HIFU on pelvic floor muscle strength and bladder control that may lead to a paradigm shift in the treatment of urinary incontinence, offering a novel, effective, and non-invasive procedure.

MATERIAL AND METHODS

A non-randomized control trial was conducted in the Department of Gynecology and Urology at CMH Hospital in collaboration with clinics of aesthetic gynecology from April 2023 to May 2024. After approval from the institutional review board (ERC No.49/2024), this study was conducted following CONSORT guidelines, and 100 participants were recruited via non-probability convenient sampling. This study included females aged ≥ 35 years and diagnosed with any type of urinary incontinence but no prior surgical interventions for urinary incontinence within the last year. This study excluded females who were pregnant, having pelvic organ prolapse beyond grade II, active urinary tract infection, or other acute pelvic infections and significant comorbid conditions that might interfere with the treatment or evaluation. The minimum calculated sample size for each group was 48 participants per group with the help of the following formula, but we recruited 50 subjects per group. So, n=10

$$n = 2 \cdot (\sigma^2) \cdot \left(Z_{\frac{\alpha}{2}} + Z_{\beta}\right)^2 \div \Delta^2$$

Where, n= sample size, σ^2 =estimated variance (3 for ICIQ-UI), Zα = 5%significance, Zβ=90%, Δ^2= difference between 2 groups. The study adhered to the Declaration of Helsinki for ethical standards, and written informed consent was obtained from all research participants. Descriptive parameters were documented using a standardized proforma. The participants were divided into two equal groups (n=50 each). Group A included 50 participants who underwent HIFU treatment (HIFU group), while Group B consisted of 50 age-matched participants who did not receive HIFU treatment (control group). Demographic data, medical history, baseline ICIQ-UI SF scores, and urodynamic parameters were collected at the initial visit. Primary and secondary outcomes were assessed at baseline, immediately following the 8-week intervention, and at a follow-up 3-month post-intervention, addressing a gap in prior studies that predominantly focused on the 3-month mark. Participants also maintained diaries to log episodes of incontinence and any side effects experienced during the study. The HIFU treatment was administered using a commercially available device specifically designed for pelvic floor therapy. Participants received the treatment in a clinical setting, with sessions lasting 20 minutes each, conducted once a week for 8 consecutive weeks. This protocol distinguishes the study methodology from prior research. The HIFU parameters included a frequency of 1 MHz, an intensity of 3 W/cm², and a pulse duration of 100 ms. In contrast, the control group did not receive HIFU treatment but continued with their usual care, which included pelvic floor muscle training (PFMT) and lifestyle modifications as recommended by their healthcare providers. The study's primary outcome was the reduction in urinary incontinence, measured by the change in International Consultation on Incontinence Questionnaire-Urinary Incontinence Short Form (ICIQ-UI SF) scores from baseline to 8 weeks. Secondary outcomes included a decrease in the weekly number of incontinence episodes, improved bladder control assessed through urodynamic studies (such as maximum bladder capacity and detrusor pressure), and enhanced pelvic floor muscle strength evaluated using perineometry (pressure readings in cmH2O) and digital palpation (graded scale). Additionally, quality of life was measured using the I-QOL and PFDI-20 questionnaires. Patient satisfaction and subjective improvement were gauged through surveys and interviews. Safety was a critical component, with adverse events and complications monitored and recorded during and after the HIFU treatment. Pain and discomfort levels were also assessed using visual analog scales (VAS).

Data Analysis:

Data was analyzed with SPSS version 23.0. The normality of data was determined with the Shapiro-Wilk test. Quantitative variables were expressed as mean±S.D while categorical variables were

expressed as frequency percentages. An independent sample t-test or chi-square test was applied to see the statistical difference between the two groups.

RESULTS

Both groups had an average age in their mid-fifties and comparable body mass index (BMI). The parity, or number of deliveries, was also similar between the groups, indicating a homogeneous sample in terms of childbirth history. A mix of pre-menopausal and post-menopausal women participated, with slightly more post-menopausal women in both groups. The presence of comorbid conditions and previous treatments for urinary incontinence were fairly balanced, suggesting that both groups had a similar baseline health status. (Table 1)

Table 1: Baseline characteristics of the study population (n=100)

Variable	HIFU group	Non-HIFU group
Age (years, mean ± SD)	55 ± 10	54 ± 9
BMI (kg/m², mean ± SD)	28 ± 3	27 ± 4
Pre-menopausal N (%)	20 (40%)	22 (44%)
Post-menopausal N (%)	30 (60%)	28 (56%)
Comorbid Conditions N (%)	15 (30%)	14 (28%)
Previous Treatments N (%)	10 (20%)	12 (24%)
Baseline ICIQ-UI SF Score n (%)	15 ± 3	15 ± 4

Body Mass Index, Incontinence Questionnaire-Urinary Incontinence Short Form

Women who received HIFU treatment experienced a significant reduction in urinary incontinence symptoms. ($p<0.05$) These participants reported feeling considerable relief in the frequency and severity of incontinence episodes, enhanced capacity, and reduced bladder filling, highlighting the effectiveness of HIFU in managing this condition. ($p<0.05$) In contrast, the control group, which did not receive HIFU, showed only minimal improvement, indicating that standard care was less effective in alleviating symptoms. Subjects undergoing HIFU reported subjective feedback of significant strengthening of pelvic floor muscles, further augmented by clinical examination. ($p<0.05$) This can be the possible cause of enhanced bladder control and prevention of UI. The HIFU group also reported a significant improvement in quality of life as compared to the control group as pelvic floor exercises were tiring to many and didn't affect bladder control significantly. (Tables 2 and 4)

Table 2: Primary and secondary outcome measures in the study population at 3 months post-management (n=50 for each group)

Parameter	HIFU	Control	P value
Improvement in Urinary Incontinence Symptoms (Change in ICIQ-UI SF Score)	-6 ± 2	-2 ± 1	0.001
Reduction in Incontinence (Episodes per Week)	-10 ± 3	-4 ± 2	0.001
Bladder Control: Maximum Bladder Capacity (mL) Detrusor Pressure cm H_2O	450 ± 50 20 ± 5	400 ± 45 25 ± 6	0.0001 0.0008
Pelvic Floor Muscle Strength: Perineometry (cm H_2O Digital Palpation (scale 0-5):	50 ± 10 4 ± 1	40 ± 8 3 ± 1	0.00005 0.0002
Quality of Life: I-QOL Score (mean ± SD): PFDI-20 Score (mean ± SD):	90 ± 10 60 ± 10	70 ± 15 80 ± 12	0.001 0.001
Patient Satisfaction: Subjective Improvement (n %): Satisfaction with Treatment (mean ± SD, scale 0-10)	40 (80%) 8 ± 1	20 (40%) 5 ± 2	0.001* 0.0001

An Independent sample t-test was applied and p value of <0.05 was considered significant.

Table 3: ANOVA for measuring the statistical difference of each parameter at baseline, 8 weeks, and 3 months in the HIFU group

Parameter	Baseline	8 weeks	3 months	P value
Improvement in Urinary Incontinence Symptoms (Change in ICIQ-UI SF Score)	3±3	-4±2	-6 ± 2	0.0025
Reduction in Incontinence (Episodes per Week)	14±5	-8±3	-10 ± 3	0.001
Bladder Control: Maximum Bladder Capacity (mL) **Detrusor Pressure cm H_2O**	360±50 28±8	400±45 24±6	450 ± 50 20 ± 5	0.0019 0.0028
Pelvic Floor Muscle Strength: Perineometry (cm H_2O **Digital Palpation (scale 0-5):**	32±10 2.5±1	40±7 3±1	50 ± 10 4 ± 1	0.0027 0.0032
Quality of Life: I-QOL Score (mean ± SD): **PFDI-20 Score (mean ± SD):**	52±18 95±10	75±8 75±15	90 ± 10 60 ± 10	0.001 0.00191
Patient Satisfaction: Subjective Improvement (n %): **Satisfaction with Treatment (mean ± SD, scale 0-10)**	0(0) 2±2	20(40) 6±3	40 (80%) 8 ± 1	0.00001 0.00027

P value of <0.05 was statistically significant. *A chi-square test was applied for adverse effects and an independent sample t-test for pain and discomfort. Significant at 0.05. On the mean t-test was applied.

In the HIFU group, primary and secondary outcomes were compared at baseline, 8 weeks, and 3 months post-HIFU, and significant differences across the readings were observed. (Table-3)

Table 4: Adverse effects in HIFU and non-HIFU group

Parameter	HIFU	Control	p
Adverse Events n (%)	5 (10%)	2 (4%)	0.05*
Pain and Discomfort (VAS, mean ± SD)	2 ± 1	1 ± 1	0.0002

* Chi-squared test was applied

Incontinence Questionnaire-Urinary Incontinence Short Form (ICIQ-UI SF), Incontinence Quality of Life Instrument (I-QOL), and the Pelvic Floor Distress Inventory (PFDI-20).

DISCUSSION

The current study included 100 age-matched females and evaluated the efficacy of high-intensity focused ultrasound HIFU in managing UI among women, comparing its outcomes with a control group that did not receive HIFU treatment. The findings suggest that HIFU significantly improves urinary incontinence symptoms, bladder control, pelvic floor muscle strength, and overall quality of life, with greater patient satisfaction compared to standard care. The current study has shown significant improvement in urinary incontinence symptoms in the HIFU group (-6 ± 2 change in ICIQ-UI SF score) compared to the control group (-2 ± 1, p=0.001). A study involving 28 women reported a significant decrease in UI severity, with 43% of participants experiencing complete resolution of symptoms after HIFU treatment[5]. Another study on HIFU found a significant reduction in incontinence episodes per week, paralleling the -10 ± 3 episode reduction in our study[6]. These improvements can be attributed to the ability of HIFU to stimulate collagen remodeling and tissue regeneration in the urethral and pelvic support structures. The observed increase in perineometry readings (50 ± 10 cm H_2O vs 40 ± 8 cm H_2O in the control, p=0.00005) suggests improved pelvic floor muscle strength, a key factor in continence maintenance.

Bladder function improvements in the HIFU group were reflected by increased maximum bladder capacity (450 ± 50 mL vs 400 ± 45 mL, p=0.0001) and decreased detrusor pressure (20 ± 5 cm H_2O vs. 25 ± 6 cm H_2O, p=0.0008). These findings support the previous literature on patients undergoing non-invasive interventions, including high-intensity electromagnetic-focused ultrasound therapy, exhibiting improved bladder compliance and reduced urgency symptoms, supporting the findings of the present study. (Table 3)

The current study highlights a significant improvement in pelvic floor muscle strength, as measured by perineometry and digital palpation in the HIFU group (p<0.05). A systematic review suggested that thermal and electromagnetic stimulation exhibited significant results among all physical exercises and methods of improving pelvic floor strength in females with UI[7]. Additionally, the increase in digital palpation scores (from baseline 2.5 ± 1 to 4 ± 1 at 3 months) mirrors findings from another study that observed a gradual but consistent strengthening of pelvic floor muscles after HIFU therapy[8].

Patients in the HIFU group reported significantly higher quality of life improvements (I-QOL: 90 ± 10 vs 70 ± 15 in controls, p=0.001) and greater satisfaction with treatment (8 ± 1 vs 5 ± 2, p=0.0001). These findings align with previous literature that women receiving HIFU for UI experienced substantial improvements in social and emotional well-being[9]. A study found that adherence to pelvic floor muscle training is often low due to physical discomfort and lack of motivation[10]. This could explain why patients in our study found HIFU to be a more acceptable and sustainable intervention.

CONCLUSION

The present study reports the significant role of HIFU in pelvic floor strengthening and hence management of urinary incontinence. HIFU proves to be a reliable non-invasive method for the treatment of UI owing to its minimal side effects and patient satisfaction. These findings provide an emerging way forward for managing UI regardless of the type of UI.

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