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Original article

Role of High Intensity Focused Ultrasound (HIFU) in Management of Uterine Fibroids

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Abstract:

Background: Uterine fibroids are common benign gynecological tumors affecting women worldwide. This study aims to assess the effectiveness of High-Intensity Focused Ultrasound (HIFU) on uterine fibroid ablation, regarding fibroid volume at 3- and 6-months post-procedure. **Methods:** A prospective observational study was conducted at the National Hepatology and Tropical Medicine Research Institute. Thirty patients with uterine fibroid-related symptoms were included, and HIFU ablation was performed. Pre- and post-procedure assessments were carried out through comprehensive patient history, laboratory investigations, and post-contrast MRI examinations. Fibroid volume reduction and changes in pain levels and menorrhagia symptoms were analyzed. **Results:** HIFU ablation resulted in a significant reduction in pain levels (median score decreased from 6 to 3.5). No significant changes in hemoglobin levels were observed. Most participants experienced an improvement in menorrhagia symptoms (83.33%). Analysis of non-perfused volume (NPV) indicated successful ablation, with a mean NPV percent of 46.1%. Target fibroid volume significantly decreased at the 3-month and 6-month follow-ups, demonstrating the effectiveness of HIFU ablation in reducing fibroid size. The incidence of adverse events associated with HIFU ablation was low, with minimal complications reported. **Conclusion:** HIFU ablation emerges as a promising non-invasive treatment option for uterine fibroids, providing an effective reduction in fibroid volume, alleviation of symptoms, and minimal adverse events. Further long-term investigations are warranted to validate these findings and establish HIFU as a standard therapeutic approach for uterine fibroids.

Keywords: High-Intensity Focused Ultrasound (HIFU); Uterine fibroids; Ablation; Fibroid volume reduction; Non-invasive treatment.

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Introduction

Uterine fibroids, also known as leiomyomas, are one of the most prevalent benign tumors affecting women worldwide [(1)]. These non-cancerous growths in the uterine muscle can lead to various symptoms, including heavy menstrual bleeding, pelvic pain, and reproductive issues, significantly impacting the quality of life for affected individuals [(2)]. Traditional treatment options such as surgery (hysterectomy or myomectomy) and hormonal therapies have limitations and potential side effects [(3)].

In recent years, there has been growing interest in the use of High-Intensity Focused Ultrasound (HIFU) as a non-invasive and potentially effective alternative for uterine fibroid ablation [(4)]. HIFU utilizes focused ultrasound waves to generate intense heat, precisely targeting and destroying fibroid tissue while preserving the surrounding healthy tissue [(5)]. This innovative technique offers the potential for reduced invasiveness, shorter recovery times, and minimal post-procedural complications compared to surgical interventions [(6)].

This technique employs the transmission of ultrasonic waves deep into the body's tissues, focusing them on a specific target area. By using this external source of focused ultrasonic energy, thermal coagulative necrosis can be induced selectively, effectively treating the target tissue while minimizing damage to surrounding vital structures [(6)]. HIFU has emerged as a non-invasive therapeutic approach for the ablation of uterine fibroids, even those with a diameter smaller than 2 cm. This procedure is guided by magnetic resonance imaging (MRI) or ultrasound, ensuring precise targeting and protecting neighboring structures [(7)]. Notably, due to its high therapeutic efficiency and minimal discomfort, HIFU can often be performed as an outpatient procedure [(8,9)].

In the past 20 years, HIFU has gained popularity as an option for treating adenomyosis and uterine fibroids. Its efficiency and security have been demonstrated. Based on systematic reviews and meta-analyses, the fertility and pregnancy rates following HIFU are encouraging, which makes it a viable option for women pursuing fertility [(10)]. Through this study, we aim to highlight the role of HIFU as a non-invasive treatment for uterine fibroids including assessment of its ablation effect on fibroid volume after 3 and 6 months.

Patients and methods

The current study is a prospective observational study conducted at the National Hepatology and Tropical Medicine Research Institute (NHTMRI) within the Radiology department. The study focuses on patients suffering from uterine fibroid-related symptoms from January 2024 until January 2025.

The target population consisted of thirty patients who either sought help independently or were referred to the HIFU unit by their obstetricians. The study spanned a period of 18 months.

Inclusion criteria encompassed patients with uterine fibroid-related symptoms, a preference for non-surgical treatment, fibroids visible on guiding ultrasound, and a uterine size of ≥10 weeks' gestation (with the largest fibroid diameter <12 cm). Additionally, patients were required to consent to undergo HIFU for fibroid treatment and participate in the study.

Exclusion criteria encompassed pregnant and lactating women, patients with pedunculated myoma, those with acute pelvic inflammation, individuals with foreign bodies or extensive abdominal scars obstructing the ultrasound beam's path, patients with a thick layer of anterior abdominal wall fat (>5 cm), and those unable to lie prone for up to 1 hour.

Ethical considerations were addressed by providing comprehensive explanations of the procedure to each patient, ensuring their understanding of the study's purpose, risks, benefits, and potential discomfort.

Informed consent was obtained from all participants, confirming their voluntary participation and comprehension of the study requirements.

Patient preparation for the HIFU procedure involved obtaining a detailed medical history, including demographic information, symptoms, previous surgeries, and concurrent medical conditions. Laboratory investigations, such as complete blood count, liver function tests, kidney function tests, and coagulation profile, were conducted. Additionally, a post-contrast MRI examination of the pelvis was performed to evaluate the characteristics of the uterine fibroids and their impact on surrounding structures.

The HIFU procedure was performed using the Sonalleve V1 system in conjunction with a 1.5 T MRI machine. Pre-procedure preparations included addressing pelvic infections, removing intrauterine devices, cleansing the skin, and ensuring urinary bladder distension. Patients received medication to manage potential discomfort and were positioned in a prone position on the MRI table. The HIFU transducer was placed in direct contact with the patient's anterior pelvic skin, and the procedure was guided by MRI imaging.

During the procedure, low-power sonication was first utilized to test patient tolerance. Subsequently, high-power sonication waves were applied to heat-specific treatment cells within the fibroid and monitored in real-time using MRI thermometry. The treatment automatically ceased when the desired temperature was reached, signifying complete ablation of the targeted area. Cooling techniques were employed to protect surrounding structures, and multiple treatment cells were ablated sequentially.

Following the procedure, a post-contrast MRI was performed to assess the non-perfused volume (NPV) of the treated fibroid, indicating the necrosed area. Patients were discharged on the same day with appropriate medications and scheduled for follow-up MRI examinations at 3- and 6-month intervals to monitor fibroid volume reduction.

Statistical analysis was performed using STATA software (version 15.1; Stata Corp). Categorical variables were presented as frequencies and percentages. The normality of continuous variables was assessed using the Shapiro-Wilk test. Continuous variables were summarized as mean ± standard deviation (SD) or median (range). The Wilcoxon signed-rank test, Kruskal-Wallis test, and Chi-squared test were utilized to compare different groups.

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Results:

The current study conducted at the National Hepatology and Tropical Medicine Research Institute aimed to evaluate the effects of HIFU ablation on fibroid volume in 30 adult females over a period of 3 and 6 months. The participants had an average age of 40.2 years, with most of them having multiple fibroid lesions located on the anterior wall of the uterus (Table 1).

Before the procedure, the participants reported a median pain score of 6, which significantly decreased to 3.5 after HIFU ablation, indicating a substantial improvement in pain levels. The procedure also resulted in no significant changes in hemoglobin (Hb) levels (Table 2). However, 83.33% of the participants experienced an improvement in menorrhagia symptoms following the HIFU ablation (Table 3).

The study examined the NPV of fibroids after the procedure. The mean NPV percent was 46.1%, indicating successful ablation of fibroid tissue (Table 3). The NPV grade had a mean of 2.4, with higher grades indicating a greater degree of non-perfused volume and successful ablation (Table 3). Most participants had NPV grades of 3, indicating a substantial reduction in perfused volume.

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The target fibroid volume decreased significantly over the 3-month and 6-month follow-ups (p= 0.019, Fig. 1).
In terms of safety, the incidence of adverse events associated with HIFU ablation was low. No cases of lower abdominal pain, local skin burn, rapid myoma enlargement, or risk of claustrophobia were observed. Only one patient reported vaginal discharge and bleeding, while another experienced sciatica.

Table (1): Baseline characteristics of the study cohort.

Parameters	Subjects (**N= 30**)
Age, ***years***	
- ***Mean ± SD***	40.2 ± 5.8
- ***Median (Range)***	41.5 (30-51)
Number of lesions, ***n (%)***	
- **Multiple**	17 (56.7)
- **Solitary**	13 (43.3)
Location, ***n (%)***	
- **Anterior wall**	17 (56.7)
- **Posterior wall**	13 (43.3)
Target Funaki type, ***n (%)***	
- **I**	13 (43.3)
- **II**	12 (40.0)
- **III**	5 (16.6)
Pain score before	
- ***Mean ± SD***	6 ± 2.3
- ***Median (Range)***	6 (0-9)
Hb level before, ***(g/dL)***	
- ***Mean ± SD***	11.05 ± 2.1
- ***Median (Range)***	10.9 (6.6-14.9)
Target fibroid volume before, ***cm^3***	
- ***Mean ± SD***	110.1 ± 64.4
- ***Median (Range)***	116 (8 - 200)

Hb: Hemoglobin

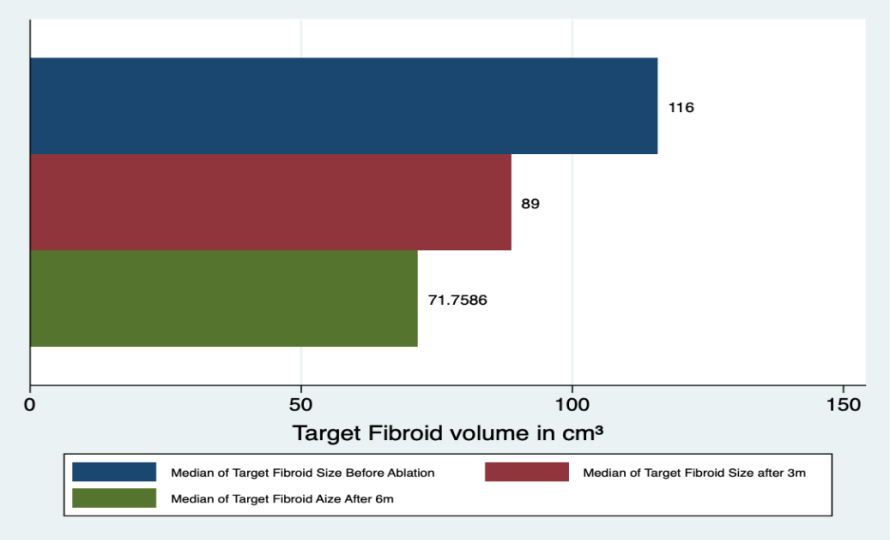

Fig. (1): Comparison of target fibroid volume, before, after 3 months, and 6 months of the procedure.

Table (2): Comparison between pain, and HB level regarding before and after the procedure.

Parameters	Subjects (**N= 30**)		**Test** of significance	**P value**
	Before ablation	**After ablation**		
Pain score, Median (Range)	6 (0-9)	3.5 (0-7)	W= 17.69	0.0001**
Hb level (g/dL), Median (Range)	10.9 (6.6-14.9)	11.1 (8 – 14.4)	W= 0.003	0.9587

*Significantly (p<0.05); ** highly significant (<0.001); Hb: Hemoglobin; W: Wilcoxon rank test.

Table (3): Clinical and radiological outcomes after the procedure.

Parameters	Subjects (**N= 30**)
Improvement of the menorrhagia, *n (%)*	25 (83.33)
NPV percent	
- ***Mean ± SD***	46.1 ± 23.9
- ***Median (Range)***	51 (4 - 90)
NPV grade	
- ***Mean ± SD***	2.4 ± 0.96
- ***Median (Range)***	3 (1 - 4)
NPV grade, *n (%)*	
- **1**	7 (23.3)
- **2**	7 (23.3)
- **3**	13 (43.3)
- **4**	3 (10.0)
Target fibroid volume after 3 months, cm^3	
- ***Mean ± SD***	81.4 ± 48.7
- ***Median (Range)***	9 (5 - 152)
Target fibroid volume after 6 months, cm^3	
- ***Mean ± SD***	70.2 ± 43.3
- ***Median (Range)***	79 (5 - 142)

Discussion

Uterine fibroids are one of the commonest benign pathological conditions of females, especially in childbearing age, and can be detrimental to the affected women's quality of life by causing menorrhagia, dysmenorrhea, infertility, and compression symptoms [(11)].

This prospective observational study was conducted over a span of approximately two years at the HIFU unit within the esteemed NHMRI. The research aimed to evaluate the efficacy of HIFU as a non-invasive treatment option for uterine fibroids. Specifically, the study focused on assessing the ablation effect of HIFU on fibroid volume after 3 and 6 months of treatment. The analysis primarily centered on investigating the changes in fibroid volume observed during these specific post-treatment time points.

The median target fibroid volume before the procedure was 116 cm^3, which decreased to 89 cm^3 after 3 months and further decreased to 79 cm^3 after 6 months. The estimated mean difference percentages were 30.33% and 46.8%, respectively. These results align closely with previous studies by Tomasz Lozinski, Mustafa Z. Mahmoud, and Xiao-Long, who reported reductions in fibroid size ranging from 27% to 31.4% [(12–14)]. Comparatively, studies by Cherng-Jye Jeng and Wang et al. showed better results with reductions of 40.2% and 46.7% in fibroid size, respectively [(15,16)].

Similarly, after 6 months, our study demonstrated better results than those reported by Tomasz Lozinski, Mustafa Z. Mahmoud, and Xiao-Long, with reduction percentages of 34%, 33%, and 44.8%, respectively [(12–14)]. However, Park et al., Wang et al., and Ren et al. achieved superior

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outcomes with reductions of 62.5%, 68.2%, and 47.9% [17–19].

Our study revealed results of significant impact on the quality of life, characterized by symptoms such as menorrhagia, dysmenorrhea, and compression-related issues. These participants underwent MRgHIFU sessions, where the objective was to ablate their fibroids. Subsequently, the volume reduction of the ablated fibroids was assessed using post-contrast MRI studies at the 3-month and 6-month follow-up periods.

Conclusion

HIFU ablation emerges as a promising non-invasive treatment option for uterine fibroids, providing an effective reduction in fibroid volume, alleviation of symptoms, and minimal adverse events. Further long-term investigations are warranted to validate these findings and establish HIFU as a standard therapeutic approach for uterine fibroids.

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