Role of MRI in Assessment of the Response Post High-Intensity Focused Ultrasound (HIFU) Treatment in Uterine Fibroids

Original Article

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ABSTRACT

Background: Fibroids are the most common benign uterine tumors in women of child-bearing period. They cause an array of symptoms as dysmenorrhea, menorrhagia, menometrorrhagia, and even discomfort in the lower abdomen and infertility. Sometimes, these fibroids exert pressure on neighboring organs, leading to disruptions in urination and defecation.

Aim of the Work: To evaluate the role of MRI in assessment of uterine fibroids response post HIFU treatment

Patients and Methods: In this prospective study, thirty adult females with uterine fibroid diagnosed by contrast-enhanced MRI underwent HIFU ablation therapy. The clinical and laboratory outcomes were assessed in correlation with the MRI findings as regards the non-perfused (NPV) percent and volume.

Results: The menstruation and pain score were notably reduced. There was substantial reduction in fibroid volume post-treatment. Reduction in NPV correlated strongly with symptom improvement. The NPV measurement was central to evaluating the procedure's success.

Conclusion: HIFU is a non-invasive, uterus-preserving treatment. The NPV can be used as a crucial metric for assessing treatment outcomes and guiding clinical decisions and hence, serving as a pivotal marker of treatment success.

Key Words: Assessment of the response treatment, High-Intensity Focused Ultrasound (HIFU), MRI, non-perfused volume (NPV), uterine fibroids.

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INTRODUCTION

The most frequent solid benign gynecological uterine tumors are leiomyomas which are benign, encapsulated uterine tumors that are the leading cause of hysterectomy in premenopausal women^[1]. Due to their dependence on hormonal regulation, uterine fibroids predominantly occur during the reproductive years, are exceedingly uncommon prior to menarche, and generally regress after menopause^[2]. Epidemiologic studies that primarily focused on symptomatic women in the past underestimated the prevalence of fibroids, where a large sum of women without symptoms and women who failed to report their symptoms with a prevalence nowadays ranging from as low as 4.5% and reaching up to 68.6% according to the investigation done and racial/ethnic demography [3, 4]. Up to 70% of uterine fibroids have no symptoms and may be encountered coincidentally. Symptomatic fibroids, depending on their size and location within the uterus, can lead to abnormal

uterine bleeding (AUB), dysmenorrhea, and urinary or gastrointestinal disturbances, including increased frequency of urination and constipation. Additionally, fibroids may contribute to sexual dysfunction, infertility, and adverse obstetric outcomes, such as an elevated risk of preterm labor, cesarean delivery, antepartum hemorrhage, mispresented, fetus and restricted fetal growth^[5].

Treatment options improve fibroid-associated symptoms by decreasing the size of the fibroids or definitively eradicating the fibroids. Medical therapies, interventional radiology, and surgical procedures are among the available treatment options. Many international obstetrics and gynecology societies recommend a step-up approach for the management of uterine fibroids, prioritizing pharmacological and minimally invasive treatments as first-line options before considering surgical intervention^[2]. Magnetic resonance-guided focused ultrasound (MRgFUS), also known as high-intensity focused ultrasound (HIFU), utilizes high-intensity

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transabdominal ultrasound waves to induce coagulative necrosis and regression of uterine fibroids. Although available, this fibroid-specific therapy remains limited in widespread use^[6]. High-intensity ultrasound waves are precisely focused on the tumor target and raise the temperature without obstructing the blood vessels, causing the tissue to be destroyed via ablation^[7]. Following MRgHIFU, approximately 71% of women reported symptoms improvement^[8].

The primary physical mechanism of HIFU involves the absorption of ultrasound energy by tissues, resulting in heat generation and the formation of necrotic foci. These necrotic regions, referred to as non-perfused volume (NPV), serve as a key indicator of treatment efficacy, with higher NPV being the strongest predictor of therapeutic success in MR-guided HIFU for uterine fibroids^[9]. While ultrasound is the most commonly used first-line imaging modality for assessing uterine fibroids, with a sensitivity of up to 99%, it has limitations in gauging fibroid viability and vascularity, which are critical for the success of focused ultrasound ablation (FUS) and uterine artery embolization (UAE). In contrast, magnetic resonance imaging (MRI) provides superior accuracy in fibroid mapping, viability assessment, and the detection of coexisting uterine pathologies, such as adenomyosis, which are essential considerations for women opting for conservative surgical management^[2].

PATIENTS AND METHODS

Study population:

This prospective study was conducted at MRI & HIFU units at the National Hepatology & Tropical Medicine Research Institute having a duration of 6 months The study included thirty adult females in the childbearing period complaining of one or more of the following symptoms (menorrhagia, abdominal pain, urinary frequency, and dyspareunia) and diagnosed to have uterine fibroid by contrast-enhanced pelvic MRI. We excluded pregnant and lactating patients and patients with pedunculated serosal fibroids, extensive cutaneous scarring, and thick abdominal wall fat of more than 5 cm in thickness. Patients with uncontrolled bleeding or active malignancies, inability to lie prone, those with renal impairment, gadolinium-based contrast allergy or inserted metallic objects as IUCD were on our exclusion list. The study was approved by the ethical committee of Ain Shams University, Faculty of Medicine, MS 338/2023. All patients were subjected to full clinical and menstrual history taking and medical assessment, routine laboratory assessment. The included patients were treated by HIFU ablation. Contrast enhancement MRI pelvis before and 3 months after the HIFU treatment were also performed.

MRI Acquisition:

Each patient underwent MRI examinations twice: once before the HIFU session and again 20–30 minutes afterward. First, MRI was performed using a 1.5-Tesla magnetic resonance (MR) scanner (Ingenia, Philips Medical System, Eindhoven, Netherlands) equipped with a 12-channel abdominal coil. The following sequences were performed after the patient lying in the supine position and using pelvic coils which were (the posterior table coil and the anterior d stream torso coil 32 channels, and the following images were obtained (Axial T1 & T2 WIs, coronal & sagittal T2/STIRWIs, post gadolinium contrast axial, sagittal & coronal T1 series). Then, MRI with the same positioning and sequences was done 20 minutes post MRI-guided HIFU session by the Sonalleve MR-HIFU system.

MRI interpretation and NPV analysis:

Magnetic resonance (MR) images were independently and blindly reviewed. In case of disagreement, the final decision is made by consensus. Signal intensity on T2WI was categorized as hypointense (lower than or similar to skeletal muscle), isointense (higher than skeletal muscle but lower than myometrium), or hyperintense (similar to or higher than myometrium). The fibroid's location (anterior, posterior, lateral, fundus), uterine position (anteverted, retroverted, mid-position), and type (sub-mucosal, intramural, sub-serosal) were documented. The following data on fibroid characteristics and imaging parameters were also assessed; the distance from the fibroid's anterior/posterior aspect to the skin and sacrum, abdominal wall thickness, and maximal fibroid diameter seen on fat-suppressed T2-weighted sequences. Fibroid enhancement on CE-MRI was classified as slight (lower than myometrium), moderate (similar to myometrium), or significant (higher than myometrium).

MRI done 20 minutes post MRI-guided HIFU session was assessed to evaluate the non-perfused volume. This was done by transferring the former images to the Philips workstation and a tumor tracking software, developed by Phillips Company was used to aid in measuring the volume of the targeted uterine fibroid before the sonication session. After the sonication ended, the necrosed area did not enhance, so axial and craniocaudal measurements were taken. Phillips Intel space tumor tracking software was used to aid in measuring the NPV. The three-dimensional diameters of both the non-perfused area and the leiomyoma were measured on contrast-enhanced MRI (CE-MRI) images along the longitudinal (a), anteroposterior (b), and transverse (c) axes. The volumes of the non-perfused area and the fibroid were calculated using the equation

 $V=0.5233 \times a \times b \times c$. In addition, the non-perfused volume (NPV) ratio, representing the proportion of NPV to total fibroid volume, was determined. NPV ratio = non-perfused volume/perfused volume expressed as a percentage).

Fibroids are classified into three groups (Types I, II, and III) based on their signal intensity relative to skeletal muscle on T2-weighted MRI where the signal in type I was hypointense (signal intensity was lower than that of the skeletal muscle or similar), type II was isointense (signal intensity higher than that of the skeletal muscle but lower than the myometrium) and type III was hyperintense (signal intensity similar to or higher than that of the myometrium).

The NPV grade, which categorizes the extent of non-perfused tissue was used where Grade 1 had 0-25% of the fibroid tissue sonicated, Grade 2 had 25-50%, Grade 3 had 50-75% and Grade 4 had 75-100%.

Technique of High intensity focused ultrasound (HIFU):

The procedure was conducted by Sonalleve system (Profound Medical Inc., Mississauga, Canada) in combination with a 1.5 T MRI machine (Ingenia, Philips medical system, Eindhoven, Netherlands). The procedure should be executed during the non-menstrual period of the patient. The patients were instructed to fast for 6 hours and to remove any metallic objects before entering the MRI room, e.g., jewelry. Subsequently, the anesthesiologist administered an intravenous bolus of fentanyl to achieve pain relief at a tolerable level while ensuring that pain assessment remained accurate for optimizing the heating dose.

Each patient was informed to stay in a prone position on the MRI table with a special MRI coil applied to the pelvis. The patient's anterior pelvic skin was in complete contact with the device's coupling pad with meticulous elimination of any trapped gas bubbles in between. Under the coupling pad, there was an amount of previously prepared degassed water under which, there was the ultrasound transducer emitting the high-intensity focused ultrasound waves (HIFU). At the start of the procedure, first MRI images of 3D sagittal T2 turbo spin echo (T2W-TSE) were obtained to visualize the sagittal view of the fibroid and coronal fast field echo (FFE) to detect any trapped air bubbles on the skin surface as well as to show the site, size, and shape of any skin scars to make sure that they are away from the expected path of the sonication waves. Then another 3D sagittal T2W-TSE was taken for the pelvis "T2 planning sequence" to plan the exact direction and path of the sonication waves.

Then, high-power sonication waves (reaching up to 220 watts) were applied to heat gradually a limited small ellipsoid focus of the fibroid (which was called "the treatment cell"). Following thermal ablation of the selected treatment cell, the system initiates cooling of the degassed water positioned beneath the patient's skin before proceeding to ablate the next treatment cell within the fibroid. The treatment strategy was based on a sequential ablation approach, beginning with the posterior portion of the fibroid, followed by the middle and anterior regions. After finishing the procedure, the urinary bladder was flushed with cold saline to achieve pelvic cooling and prevent thermal damage to the surrounding tissues.

Outcome Measurements and Follow-up

Pain scoring questionnaire to assess the degree of pain reduction by Visual analogue scale (VAS). Pain intensity was assessed using the Visual Analogue Scale (VAS), ranging from 0 to 10, where 0 indicated no pain. Patients were instructed to mark the subjective intensity of their pain along the scale, and the recorded value was then used to provide an objective evaluation of their symptoms. The clinical outcome included the pain score and the menorrhagia, while the laboratory outcome included the Hb level and the RBC count. These outcomes were analyzed in correlation with the radiological outcome regarding the fibroid volume and the NPV grade and percent.

Statistical Analysis

The STATA software (version 15.1; Stata Corp) was used for statistical analysis. Categorical variables were presented as frequency and percentages. The normality of continuous variables was assessed using the Shapiro-Wilk test. These variables were summarized as mean and standard deviation (SD) or median (range). The Wilcoxon signed-rank test and Spearman correlation tests were used to compare the different groups.

RESULTS

The mean age of the study population of 30 adult females was 40.1 ± 5.9 with a median of 42 and age range of 30-51. The lesions were multiple in 16 patients (53.3%) and single in 14 patients (46.7%). Target fibroid Funaki type was I, II and III in 18 patients (60.0%), 5 patients (16.6%) and 7 patients (23.3%). The location of the target lesion in the uterus was anterior wall in 40% and posterior wall in 60%.

Table 1: Efficacy of the procedure on pain, HB level, RBCs count.

	N= 30 Patients			
Parameters	Before Median (Range)	After Median (Range)	Test	P value
Hb level (g/dL)	12 (6.6 – 14.9)	11 (8-14.4)	W = -0.669	0.503
RBCs Count (million cells/µL)	4.5(3.5-5.5)	4.7(3.8-5.6)	W = -2.59	0.009

Hb: hemoglobin; RBC: red blood cell; NPV: non-perfused volume; W: Wilcoxon signed-rank test.

Table 2: Clinical and radiological outcomes after the procedure.

Damanastana	N= 30 Patients			
Parameters	$Mean \pm SD$	Median (Range)		
Improvement of the menorrhagia, n (%)	26 (86.6%)			
NPV percent, %	45.63	44.5 (4 - 90)		
NPV grade, n (%)				
•1	7 Patients (23.3%)			
•2	9 Patients (30.0%)			
•3	9 Patients (30.0%)			
•4	5 Patients (16.7%)			

NPV, non-perfused volume; SD, standard deviation.

Comparisons between pain score, HB level and RBCs count before and after the procedure are summarized in (Table 1). Before the procedure, the included patients reported a median pain score of 5, ranging from 0 to 9 and a mean pain score of 5.2 with a standard deviation of 2.1. After the procedure, the median pain score significantly decreased to 3, ranging from 0 to 7 (Wilcoxon signedrank test, W=4.133, p<0.001). This stipulates a statistically outstanding reduction in pain levels following the procedure. Regarding Hb levels, the median value before the procedure was 12 g/dL, ranging from 6.6 to 14.9 g/ dL and the mean value was 11.25 g/dL with a standard deviation of 2.17 g/dL. After the procedure, the median Hb level was 11 g/dL, ranging from 8 to 14.4 g/dL. However, the difference in Hb levels before and after the procedure was not statistically impactful (Wilcoxon signed-rank test, W=-0.669, p=0.503). In terms of RBC counts, the median count before the procedure was 4.5 million cells/µL, ranging from 3.5 to 5.5 million cells/µL and the mean red blood cell count was 4.51 million cells/µL with a standard deviation of 0.51 million cells/µL. After the procedure, the median count increased to 4.7 million cells/µL, ranging

from 3.8 to 5.6 million cells/ μ L. The change in RBC counts before and after the procedure was statistically noteworthy (Wilcoxon signed-rank test, W=-2.59, p=0.009), indicating an increase in RBC count following the procedure.

Regarding the improvement of menorrhagia (excessive menstrual bleeding), 86.6% of participants (26 out of 30) reported improvement following the procedure (Table 2). The non-perfused volume (NPV) percent, which indicates the amount of necrotic tissue after the procedure, had a mean value of 45.63% of the fibroid volume with a standard deviation (Table 2). The median NPV percent was 44.5%, ranging from 4% to 90%. This suggests a substantial reduction in the volume of the treated fibroids. The NPV grade, which categorizes the extent of nonperfused tissue, was assessed. Among the participants, 7 (23.3%) had NPV grade 1, indicating minimal nonperfused tissue. 9 (30.0%) had NPV grade 2, 9 (30.0%) had NPV grade 3, and 5 (16.7%) had NPV grade 4, which indicates increasingly higher levels of non-perfused tissue (Table 2) (Figures 1-8).

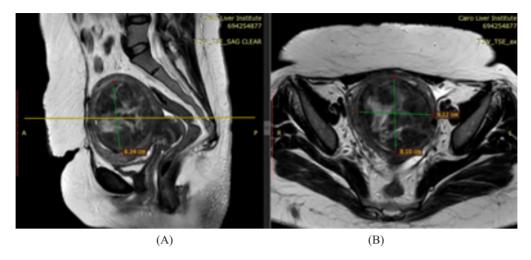


Fig. 1: A 42-year-old female presented with heavy menstruation for 5 years since her last birth. She underwent one MR-HIFU session, and now the patient has reported that blood clots have disappeared. (A) Sagittal & (B) Axial T2 MRI images demonstrate a sizable fundal interstitial myoma, showing intermediate/high signal denoting FUNAKI-type III. Total myoma volume before HIFU = 308 cc

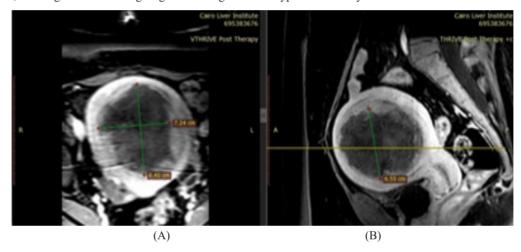


Fig. 2: Post MR-HIFU for patient in figure 1. (A) Axial & (B) Sagittal post-contrast T1 MRI images revealed areas of non-enhancement within the former myoma denoting well ablation. Volume of ablated areas after HIFU = 200 cc, calculated NPV = 65%.

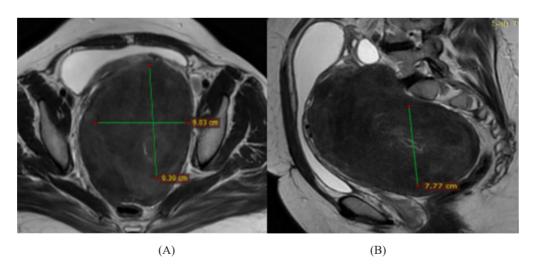


Fig. 3: A 40-year-old female presented with lower back pain, pelvic heaviness, constipation, and frequent urination. She underwent one MR-HIFU session, and now the patient has reported a significant relief of the symptoms. Axial (A) & Sagittal (B) T2 MRI images demonstrate a large posterior wall interstitial myoma, showing dark signal denoting FUNAKI-type I. Total myoma volume before HIFU = 335 cc.

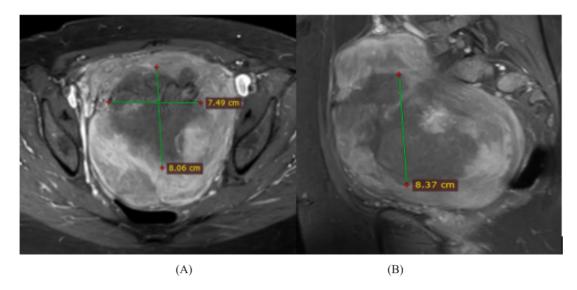


Fig. 4: Post MR-HIFU for patient in figure 3. Axial (A) & Sagittal (B) post-contrast T1 MRI images revealed areas of non-enhancement within the former myoma denoting well ablation. Volume of ablated areas after HIFU = 265 cc, calculated NPV = 79%

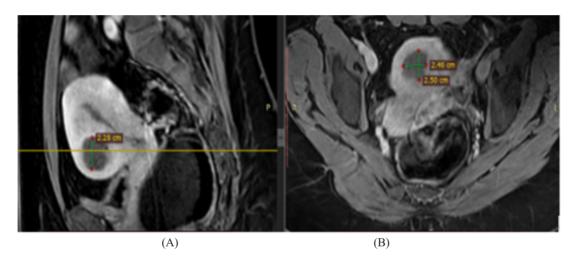


Fig. 5: A 42-year-old female presented with Heavy continuous menstrual bleeding, she underwent one MR-HIFU session, and now the patient reports significant relief in the symptoms. The cycle has returned to normal. Sagittal (A) and Axial (B) T2 MRI image demonstrates an interstitial anterior wall myoma, showing dark signal denoting FUNAKI-type I with homogenous enhancement in T1 post contrast image. Total myoma volume before HIFU = 19 cc.

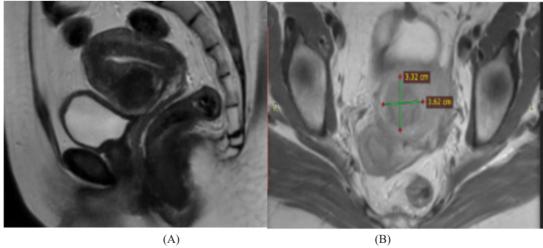


Fig. 6: Post MR-HIFU for patient in figure 5. Sagittal (A) & Axial (B) post-contrast T1 MRI images revealed areas of non-enhancement within the former myoma denoting well ablation. Volume of ablated areas after HIFU = 7 cc, calculated NPV = 53%

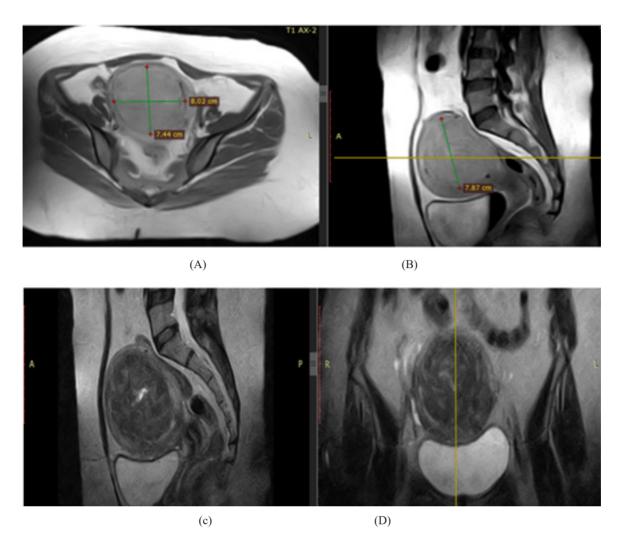


Fig. 7: A 41-year-old female presented with frequent painful heavy menstruation and dyspareunia, she underwent one MR-HIFU session, and now the patient has a tolerable menstrual cycle with an average amount and the dyspareunia was remarkably relieved. T1 axial (A), T1 sagittal (B), T2 sagittal (C) and T2 coronal (D) MRI images demonstrate anterior wall interstitial myoma, showing intermediate/high signal denoting FUNAKI-type III with internal areas of cystic degeneration and iso-intense signal in T1 WIs with peripheral rim of low signal. Total myoma volume before HIFU = 234 cc

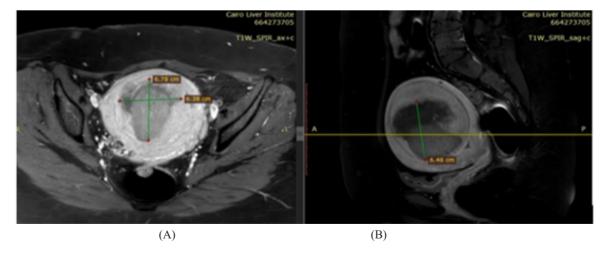


Fig. 8: Post MR-HIFU for patient in figure 7. Axial (A) & Sagittal (B) post-contrast T1 MRI images reveal areas of non-enhancement within the former myoma denoting well ablation. Volume of ablated areas after HIFU = 140 cc, calculated NPV = 40%.

DISCUSSION

This study investigates the effectiveness of evaluating the NPV of MRI-guided High-Intensity Focused Ultrasound (HIFU) for treating symptomatic uterine fibroids, primarily focusing on evaluating non-perfused volume (NPV) as a key marker of treatment efficacy in a cohort of 30 adult females. Three was an improvement in menorrhagia, indicating a positive impact on menstrual bleeding. This finding aligns with those of Wang et al.[10], further substantiating the role of MRI-Guided HIFU as a minimally invasive alternative to more traditional surgical interventions. Additionally, the NPV percent and grade assessments suggest successful ablation of the fibroids, with a significant reduction in their volume and the presence of varying degrees of non-perfused tissue. These findings provide valuable insights into the value of MRI NPV in the evaluation of the efficacy of HIFU ablation as a treatment option for fibroids. A substantial reduction in fibroid volume post-HIFU, as measured by NPV, was observed.

The reduction in NPV was not only indicative of successful tissue ablation but also correlated strongly with clinical symptom improvement, thereby validating the use of NPV as a reliable indicator of therapeutic success. Moreover, the stratification of NPV grades across the study population highlighted varying degrees of non-perfusion, which may reflect differences in fibroid characteristics such as size, location, and vascularity, as well as variations in patient response to MRI-guided HIFU. These findings underline the necessity of individualized treatment planning and suggest that the degree of non-perfusion achieved may be predictive of clinical outcomes. Collectively, the reduction in NPV and associated symptom relief provide compelling evidence for the efficacy of MRI-guided HIFU in the targeted ablation of symptomatic uterine fibroids, with potential implications for improving patient quality of life while minimizing the need for more invasive procedures. Using the Funaki classification method, we were able to classify 60.0% of the target fibroids as Funaki type I, 16.6% as type II, and 23.3% as type III among our patients' fibroids. These results are consistent with earlier research that showed differences in fibroids' kinds according to their vascularity and perfusion properties^[11].

In terms of clinical outcomes, our study showed a significant reduction in pain scores following HIFU ablation. The median pain score decreased from 5 before the procedure to 3 after the procedure. These results agreed with *Lozinski et al.*^[12] who stated a marked fibroid symptom reduction post-HIFU ablation. The analysis of red blood cell (RBC) counts revealed a statistically significant increase in RBC count following the procedure. This finding suggests that HIFU ablation may have a positive effect on improving RBC counts in patients with fibroids. The results of this study are in agreement with a recently published

study by Marinova et al.[13], investigated the potency of ultrasound-guided high-intensity focused ultrasound (USgHIFU) for treating uterine fibroids and adenomyosis. It aligns with the findings by demonstrating the potential of minimally invasive interventions in managing these common gynecological conditions. The study, conducted at a single center, retrospectively analyzed data from 167 patients who underwent USgHIFU between 2018 and 2020. The results showed a significant reduction in fibroid volume, improvement in symptom severity scores, and enhanced health-related quality of life scores following USgHIFU treatment. This non-surgical approach achieved a remarkable reduction in fibroid volume, averaging 68% at 6 months and 75% at 12 months post-treatment. Furthermore, this study highlighted the safety and effectiveness of USgHIFU, with a low re-intervention rate of 7.7% and successful pregnancies reported in 6 patients. This evidence underscores the potential of USgHIFU as a viable alternative for women seeking fertility preservation or who are not suitable candidates for traditional surgical interventions^[13].

Our study had some limitations including a small sample size, the absence of long-term follow-up data restricting the assessment of treatment durability, the bias of being a single center study and the absence of the comparison of HIFU ablation efficacy with other treatments. Despite these limitations, this study has notable strengths that contribute to the existing knowledge. One strength lies in its clinical relevance, as it focuses on important outcomes such as pain relief and improvement in menorrhagia. These outcomes are highly significant for women with symptomatic fibroids, as they significantly impact their quality of life. Additionally, the objective measurement of non-perfused volume (NPV) provides a quantitative measure of treatment effectiveness and helps in evaluating the success of HIFU ablation in ablating fibroid tissue. Multi-center collaborations would allow for a more diverse patient population, accounting for variations in demographics, fibroid characteristics, and treatment protocols. Long-term follow-up assessments are crucial to determine the durability of treatment effects and assess long-term outcomes such as fibroid recurrence. Furthermore, conducting randomized controlled trials (RCTs) with appropriate control groups would provide more robust evidence on the comparative effectiveness and safety of HIFU ablation. These future research endeavors will contribute to a more comprehensive understanding of HIFU ablation in uterine fibroid treatments and guide clinical decision-making.

CONCLUSION

HIFU is a non-invasive, uterus-preserving alternative to traditional surgical options. NPV can be used as a key performance indicator in fibroid treatment as its serves as a pivotal marker of treatment success.

ETHICAL CONSIDERATIONS

This study was performed after ethical approval of research ethics committee of Ain Shams university, Faculty of Medicine, MS 338/2023.

CONFLICT OF INTERESTS

There is no conflicts of interest.

AUTHORS CONTRIBUTION

Equal contribution.

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دور التصوير بالرنين المغناطيسي في تقييم استجابة الأورام الليفية الرحمية بعد علاج الموجات فوق الصوتية المركزة عالية الكثافة

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الخلفية: تُعد الأورام الليفية الرحمية أكثر الأورام الحميدة شيوعًا لدى النساء في سن الإنجاب. تسبب مجموعة متنوعة من الأعراض مثل عسر الطمث، غزارة الطمث، النزيف الرحمي غير المنتظم، وتؤدي إلى الشعور بعدم الراحة في أسفل البطن والعقم. في بعض الحالات، قد تضغط هذه الأورام الليفية على الأعضاء المجاورة، مما يؤدي إلى اضطرابات في التبول والتبرز.

هدف الدراسة: تقييم دور التصوير بالرنين المغناطيسي في تقييم استجابة الأورام الليفية الرحمية بعد علاج الموجات فوق الصوتية المركزة عالية الكثافة.

المنهجية: في هذه الدراسة المستقبلية، خضعت ثلاثون امرأة بالغة مصابة بورم ليفي رحمي، مشخص باستخدام التصوير بالرنين المغناطيسي المحسن بالتباين، لعلاج الاستئصال بالموجات فوق الصوتية المركزة عالية الكثافة. تم تقييم النتائج السريرية والمخبرية وربطها بنتائج التصوير بالرنين المغناطيسي من حيث نسبة وحجم المنطقة غير المروية.

النتائج: لوحظ انخفاض ملحوظ في معدل النزيف وآلام الدورة الشهرية. كما كان هناك انخفاض كبير في حجم الورم الليفي بعد العلاج. وكان انخفاض حجم المنطقة غير المروية عنصرًا محوريًا محوريًا في تقييم نجاح الإجراء العلاجي.

الأستنتاج: يُعد علاج علاجًا غير جراحي يحافظ على الرحم. يمكن استخدام قياس المنطقة غير المروية كمؤشر أساسي لتقييم نتائج العلاج وتوجيه القرارات السريرية، مما يجعله علامة رئيسية على نجاح العلاج.