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Application of high intensity focused ultrasound in the treatment of uterine fibroids in overweight/obese women

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Abstract

Objective To investigate the clinical efficacy and safety of High-Intensity Focused Ultrasound (HIFU) in the treatment of uterine fibroids in overweight/obese women.

Methods A retrospective analysis was conducted on the clinical data of 155 overweight/obese women with uterine fibroids treated at our hospital between January 2022 and January 2024. Among them, 75 patients underwent HIFU treatment (observation group), while 80 patients received conventional laparoscopic myomectomy (control group). Perioperative indicators, symptom improvement (assessed by the Symptom Severity Score, SSS), health-related quality of life (HRQL score), complications, and recurrence rates at 1-year post-treatment were compared between the two groups.

Results All procedures were successfully completed in both groups. No significant differences were observed in baseline characteristics such as age, BMI, number of fibroids, maximum fibroid diameter, and hemoglobin levels between the two groups ($P > 0.05$). At 6 months and 1 year post-treatment, the observation group showed significantly better SSS scores (12.61 ± 1.22 vs. 15.89 ± 1.21; 10.40 ± 1.27 vs. 12.03 ± 1.33) and HRQL scores (89.35 ± 1.90 vs. 84.69 ± 1.24; 94.19 ± 1.16 vs. 91.69 ± 1.32) compared to the control group ($P < 0.05$). The total complication rate in the observation group was significantly lower than that in the control group (9.33% vs. 21.3%, $\chi^2 = 4.34$, $P = 0.04$). No recurrence or fibroid enlargement was observed in the observation group at 1-year follow-up.

Conclusion HIFU is an effective and safe treatment for uterine fibroids in overweight/obese women, offering advantages such as minimal invasiveness, fewer complications, and faster recovery. It represents a superior minimally invasive option for this patient population.

Keywords High-Intensity focused ultrasound, Uterine fibroids, Overweight, Obesity, Women

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Introduction

Uterine fibroids are the most common benign tumors of the female reproductive system, particularly prevalent among middle-aged women [1]. In line with international guidelines and the latest evidence, treatment options for uterine fibroids include pharmacological therapy, minimally invasive procedures, and traditional surgical approaches. Pharmacological therapy mainly involves the use of gonadotropin-releasing hormone agonists (GnRH-a) to shrink the size of fibroids, thereby alleviating symptoms and preparing patients for surgery [2]. Minimally invasive procedures, such as uterine artery embolization (UAE) and radiofrequency ablation (RFA), are also evolving. These techniques relieve symptoms by reducing the blood supply to fibroids or directly destroying fibroid tissue [3].

With societal development and lifestyle changes, the global prevalence of overweight and obesity has been steadily increasing [4], which not only elevates the risk of uterine fibroids [5], but also impacts the selection and efficacy of treatment methods. Traditional treatments, such as laparoscopic myomectomy, are effective but are associated with higher surgical risks, longer recovery periods, and potential adverse effects on fertility in overweight/obese patients [6]. In recent years, High-Intensity Focused Ultrasound (HIFU) has emerged as a promising non-invasive therapeutic technology for uterine fibroids [7–9]. HIFU focuses low-energy ultrasound waves from outside the body onto a target area within the body, creating a high-energy focal point. At this focal point, the energy of the ultrasound waves is converted into thermal energy, which rapidly increases the local tissue temperature and causes coagulative necrosis of the fibroid tissue. This thermal effect can precisely destroy the fibroid tissue while having minimal impact on surrounding normal tissues. This approach offers advantages such as being incision-free, bloodless, and enabling rapid recovery [10–12]. However, there is limited research on the efficacy and safety of HIFU specifically for overweight/obese populations. This study aims to compare the outcomes of HIFU and laparoscopic myomectomy in the treatment of uterine fibroids in overweight/obese women.

Materials and methods

Study design

This study is a retrospective analysis of clinical data from patients with uterine fibroids treated at our hospital between January 2022 and January 2024. The study compares the outcomes of High-Intensity Focused Ultrasound (HIFU) treatment and conventional laparoscopic myomectomy in overweight/obese women.

Selection criteria

Patients were included if they met the following criteria: Diagnosis of uterine fibroids confirmed by clinical and imaging criteria; Categorized according to the International Federation of Gynecology and Obstetrics (FIGO) classification; Premenopausal women aged 18 years or older; Body Mass Index (BMI) calculated as weight (kg) divided by height squared (m^2), with overweight defined as 24 $kg/m^2 \leq$ BMI < 28 kg/m^2 and obesity defined as BMI ≥ 28 kg/m^2, according to the Chinese Health Industry Standard "Criteria for Weight Assessment in Adults" (WS/T 428–2013); Non-pedunculated intramural/serosal fibroids (FIGO classification types 2–5), Maximum fibroid diameter between 2 cm and 10 cm, with the number of fibroids ranging from 1 to 5; No plans for pregnancy within the next 6 months.

Exclusion criteria included: Severe comorbidities or systemic dysfunction affecting major organs. Submucosal pedunculated fibroids. Patients with clinical or imaging findings suggestive of malignant lesions of the uterus or adnexa were excluded. Specific criteria included: Ultrasound findings: Irregular borders, heterogeneous echogenicity, cystic areas, and necrosis within the fibroid. MRI findings: High T2 signal intensity with hemorrhagic and necrotic changes, central non-enhancement on contrast-enhanced MRI, and apparent diffusion coefficient (ADC) values indicative of malignancy. Biochemical markers: Elevated serum lactate dehydrogenase (LDH) levels, particularly when combined with MRI findings. Clinical presentation: Postmenopausal women with uterine fibroids and no history of hormone replacement therapy, presenting with abnormal uterine bleeding or rapid tumor growth.

Study outcomes

The outcomes assessed were perioperative indicators, symptom improvement (assessed by the Symptom Severity Score, SSS), health-related quality of life (HRQL score) [13–16], complications, and recurrence rates at 1-year post-treatment.

Ethical statement

The retrospective medical review was approved by the institutional review board (IRB) of the Fujian Maternity and Child Health Hospital,.And the study was performed in accordance with the principles stated in the Declaration of Helsinki. All patients underwent a detailed pretreatment evaluation to rule out malignancy, including clinical assessment, ultrasound, MRI, and biochemical marker testing. Written informed consent was obtained from all participating patients.All patients were managed with standard of care, and their spouses or authorized representatives were thoroughly informed about the surgical procedure, associated risks, and potential

complications before the surgery.All patient privacy information is protected.

Data collection

Data were collected retrospectively from the medical records of 155 overweight/obese women with uterine fibroids. The data included age, BMI, number of fibroids, maximum fibroid diameter, preoperative hemoglobin levels, and postoperative outcomes. The HIFU treatment group ($n=75$) and the laparoscopic myomectomy group ($n=80$) were compared.

Surgical techniques

HIFU Treatment: Preoperative preparations included bowel preparation, routine skin preparation, and urinary catheterization. The treatment area was degreased and degassed. Patients were positioned supine on the treatment table, and intravenous access was established. Pre-treatment scanning was performed to localize the fibroids, followed by sedation and analgesia as needed. Contrast-enhanced ultrasound was used to visualize blood flow signals in the target area and define the treatment range. The HIFU probe was activated with the following parameters configured: pulse duration of 0.02–0.08 s, interval time of 0.01–0.08 s, 10 pulses per treatment, and a treatment power of 300–340 watts. Parameters were adjusted based on the lesion characteristics. Treatment was terminated when a significant grayscale change was observed in the target area. Post-treatment contrast-enhanced ultrasound was performed to confirm the absence of blood flow signals, indicating effective treatment. Intraoperative fluid management was maintained, and the urinary catheter was removed postoperatively, with patients advised to rest in bed. Patients were advised to refrain from attempting pregnancy for at least 6 months following the procedure to allow for adequate healing and monitoring of potential complications.

Laparoscopic myomectomy Preoperative preparations included bowel preparation, routine skin preparation, and urinary catheterization. Under general anesthesia, patients were placed in the lithotomy position, and a pneumoperitoneum was established. Pitocin was injected into the uterine body, and the fibroids were bluntly dissected and removed for pathological examination. The fibroid cavity and seromuscular layer were sutured intermittently with absorbable sutures. The laparoscopic suture technique used in this study was standardized, employing 2 – 0 Vicryl sutures for all procedures. Postoperative care followed standard protocols.

All surgeries were performed by the same experienced surgical team to ensure consistency in surgical technique. For the control group, conventional laparoscopic myomectomy was performed using a standardized approach. The laparoscopic suture technique involved the use of 2 – 0 Vicryl sutures for intermittent suturing of the fibroid cavity and seromuscular layer. The study was approved by the Startup Fund for scientific research, Fujian Medical University (Approval No: 2021QH1197).

Table 1 Baseline patient characteristics

Group (n)	OG($n=75$)	CG ($n=80$)	t/χ2	P
Age(year)	37.51 ± 5.82	38.48 ± 4.90	-1.12	0.263
overweight(count)	49(65.33%)	52(65%)	0.002	0.965
BMI(kg/m2)	27.11 ± 1.94	27.10 ± 1.85	0.02	0.982
Number of fibroids (count)	2.37 ± 0.98	2.42 ± 0.96	-0.33	0.742
Maximum diameter of uterine fibroid (cm)	4.86 ± 1.96	4.75 ± 1.86	0.35	0.730
Hb value of preoperative (g/L)	96.75 ± 6.38	96.53 ± 6.24	0.22	0.827

OG, Observation Group; CG, Control Group; BMI, Body Mass Index; Hb, Hemoglobin

Statistical analysis

Statistical analysis was conducted using SPSS 22.0 statistical software. For continuous data, the Shapiro-Wilk test was employed to assess normality. If the Shapiro-Wilk test yielded a p-value > 0.05, the data were considered to follow a normal distribution; otherwise, the data were deemed non-normally distributed. For normally distributed data, results were expressed as mean ± standard deviation (x ± s), and between-group comparisons were performed using independent sample t-tests. For non-normally distributed data, results were expressed as median (Q1, Q3), and between-group comparisons were conducted using the Mann-Whitney U test. Categorical data were presented as percentages (%), and between-group comparisons were carried out using the chi-square test. A p-value < 0.05 was considered statistically significant.

Results

Based on their preferences, 75 patients underwent HIFU treatment, designated as the Observation Group (OG), while 80 patients received conventional laparoscopic myomectomy, designated as the Control Group (CG). In the OG, 49 patients were overweight, and 26 were obese. In the CG, 52 patients were overweight, and 28 were obese. Data collected from both groups included age, Body Mass Index (BMI), number of fibroids, maximum fibroid diameter, and preoperative hemoglobin (Hb) levels. Comparative analysis showed no significant differences in baseline characteristics between the two groups ($P>0.05$), indicating comparability (Table 1). A typical case is shown in Fig. 1.

Both the observation group and the control group successfully completed the surgeries. Before treatment, there was no significant difference in the Symptom Severity Score (SSS) between the two groups, with no statistical

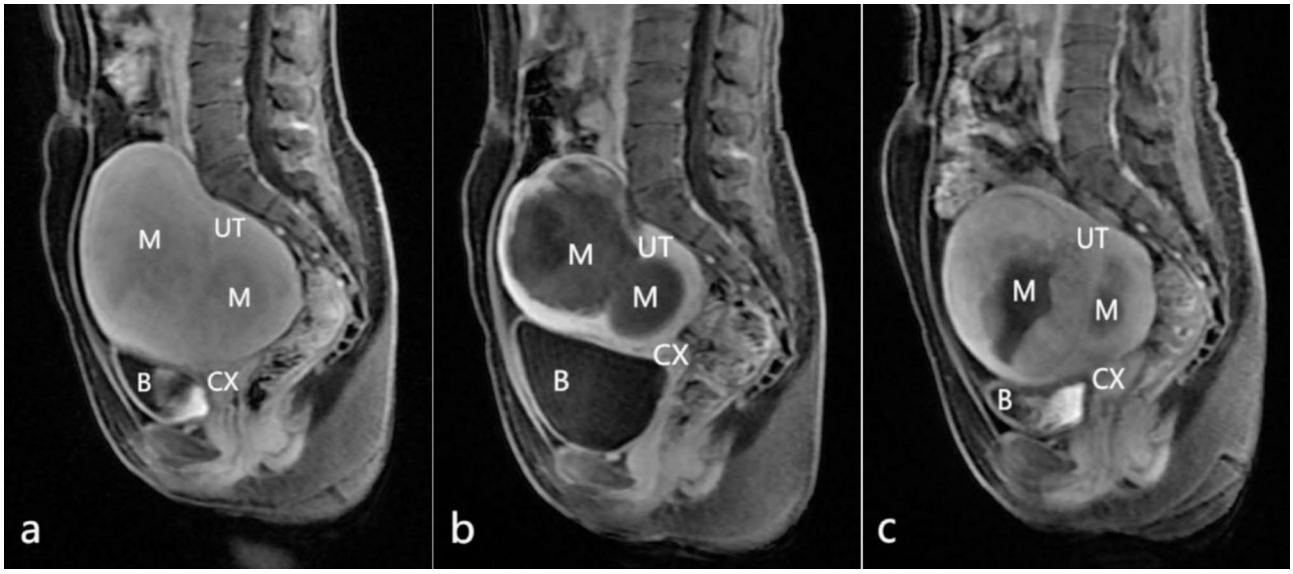

Fig. 1 MR images showing the maximum length plane of the treated fibroid from a 41-year-old woman with menorrhagia. (**a**) Pretreatment image shows the fibroid; (**b**) 6 months after treatment image shows the non-perfusion area and a reduction in the volume of the treated fibroid; (**c**) 1year after treatment image shows further shrinkage of the treated uterine fibroid volume and the persistence of non-perfusion areas. MR, magnetic resonance; B, bladder; CX, cervix; M, myoma; UT, uterine

Table 2 SSS scores of two groups pre- and postoperation(mean ± SD, score)

Group (*n*)	OG(*n* = 75)	CG (*n* = 80)	t	*P*
Preoperative	30.03 ± 1.73	29.56 ± 1.47	1.80	0.074
Six months postoperatively	12.61 ± 1.22	15.89 ± 1.21	-16.77	0.000
One year postoperatively	10.40 ± 1.27	12.03 ± 1.33	-7.76	0.000

OG, Observation Group; CG, Control Group

Table 3 HRQL scores of two groups pre- and postoperation(mean ± SD, score)

Group (*n*)	OG(*n* = 75)	CG (*n* = 80)	t	*P*
Preoperative	81.95 ± 1.38	81.75 ± 1.59	0.82	0.414
Six months postoperatively	89.35 ± 1.90	84.69 ± 1.24	18.20	0.000
One year postoperatively	94.19 ± 1.16	91.69 ± 1.32	12.51	0.000

OG, Observation Group; CG, Control Group

significance observed ($P > 0.05$). At 6 months and 1 year post-treatment, the SSS in the observation group was significantly lower than that in the control group. Meanwhile, the Health-Related Quality of Life (HRQL) subscale scores in the observation group were significantly higher than those in the control group, with statistical significance ($P < 0.05$). These results are comparable between the two groups.(Table 2).

Before treatment, there was no significant difference in the Health-Related Quality of Life (HRQL) scores between the two groups, with no statistical significance observed ($P > 0.05$). At 6 months and 1 year post-treatment, the HRQL subscale scores in the observation group were significantly higher than those in the control group, with statistical significance ($P < 0.05$). These results are comparable between the two groups. (Table 3).

Table 4 Comparison of postoperative complications between the two groups [n(%)]

Group (*n*)	OG(*n* = 75)	CG (*n* = 80)	χ2	*P*
Postoperative Fever	5	7	0.24	0.628
Vaginal Bleeding	2	5	1.15	0.283
Postoperative Intestinal Obstruction	0	3	-	-
Readmission	0	2	-	-
Total Occurrence	7(9.33)	17(21.3)	4.20	0.040

OG, Observation Group; CG, Control Group

Postoperative complications were compared between the two groups. The observation group had a lower total incidence of postoperative complications than the control group, with a statistically significant difference ($P < 0.05$). (Table 4). Both groups were followed up for 1 year postoperatively, and no recurrence or further enlargement of uterine fibroids was observed in either group.

Discussion

Uterine leiomyomas are the most common benign tumors in women of reproductive age, with clinical manifestations including abnormal menstruation, pelvic compression symptoms, and fertility impairment, all of which severely affect patients' quality of life [1, 17]. Current treatment strategies primarily consist of pharmacotherapy, traditional surgery, and minimally invasive techniques [18, 19]. Although pharmacotherapy can temporarily alleviate symptoms, long-term use is prone to inducing side effects associated with hypoestrogenism, and the recurrence rate is high after discontinuation of

medication [20]. Traditional hysterectomy, while curative, is associated with significant trauma, prolonged recovery, and is not suitable for patients who need to preserve fertility [21]. In recent years, minimally invasive techniques such as laparoscopic or hysteroscopic myomectomy have gradually become more prevalent. These techniques reduce tissue damage through small incisions. However, obese patients, due to thick abdominal wall fat and difficult surgical field exposure, still face issues such as increased intraoperative bleeding and increased risk of postoperative infection.

With the rapid development of medical technology, HIFU has achieved remarkable progress in the treatment of uterine fibroids, particularly in its unique therapeutic advantages for overweight and obese patients [8–10]. HIFU is characterized by precise targeting and localized treatment, focusing ultrasound energy directly on fibroid tissue to induce thermal effects that lead to coagulative necrosis of the fibroid tissue, while exerting minimal impact on surrounding normal tissues [22, 23]. This non-invasive approach avoids the surgical trauma and prolonged recovery associated with traditional surgical procedures, reduces the risks of intraoperative bleeding and infection, and alleviates both physical pain and psychological burden for patients. Importantly, HIFU is especially suitable for overweight and obese patients, as it does not rely on surgical incisions and is unaffected by abdominal fat thickness. Furthermore, relevant studies suggest that HIFU may offer benefits for women who wish to preserve their fertility [24]. The short recovery period associated with HIFU treatment allows patients to resume normal life and work activities more quickly [25, 26].Certainly, HIFU also has certain limitations. These include the relatively long treatment duration, which is particularly pronounced in obese patients or those with large fibroids, potentially necessitating fractionated treatment sessions. Additionally, fibroids located in specific anatomical sites, such as the anterior uterine wall, in close proximity to the bladder or bowel, may be challenging to completely ablate due to the obstruction of the ultrasound pathway or the risk of thermal injury to adjacent organs [26, 27].

As a non-invasive therapeutic modality, HIFU has demonstrated significant advantages in the treatment of uterine fibroids in overweight/obese patients, while also presenting certain technical challenges. Based on clinical practice, we summarize the following experiences: First, precise targeting and energy control are crucial. Overweight/obese patients often have thicker abdominal fat layers, which may affect the penetration and focusing of ultrasound waves. Therefore, preoperative magnetic resonance imaging (MRI) is required to precisely assess the location, size, and relationship of the fibroid with surrounding tissues, and to formulate an appropriate treatment plan. During treatment, real-time monitoring of grayscale changes and dynamic adjustment of ultrasound power and energy deposition time are essential to ensure complete coverage of the target area while minimizing damage to surrounding tissues [27]. Second, sedation and analgesia management is important. Patients undergoing HIFU treatment need to maintain a fixed position for an extended period, which may cause discomfort. Therefore, a moderate sedation and analgesia protocol should be employed to enhance patient tolerance and reduce the impact of positional movement on treatment accuracy. Third, skin protection is crucial. Given the thicker abdominal fat layers in overweight/obese patients, skin protection is essential during treatment to prevent burns. This can be achieved by applying coupling gel to the treatment area, using cooling devices, and adjusting the angle of ultrasound wave incidence. Fourth, for fibroids that are deeply located or adjacent to vital organs such as the bowel or bladder, HIFU treatment can be challenging. Filling the bladder or rectum can increase the acoustic window and improve ultrasound penetration. Fifth, for fibroids with a diameter > 10 cm, complete ablation in a single HIFU session may be difficult. A fractionated treatment strategy can be adopted, with the initial session aimed at reducing fibroid volume and alleviating symptoms, followed by subsequent sessions to consolidate the therapeutic effect. Additionally, preoperative use of gonadotropin-releasing hormone agonists (GnRH-a) can reduce fibroid volume and improve treatment success. Finally, common postoperative complications of HIFU include mild skin burns, transient abdominal pain, and pelvic effusion. Close monitoring of vital signs and timely symptomatic management, such as anti-inflammatory and analgesic treatments, are necessary [28]. For patients with pelvic effusion, ultrasound-guided puncture and drainage can be performed to alleviate symptoms.

In this study, all patients in both groups successfully completed their treatments. Before treatment, there were no significant differences in the Symptom Severity Score (SSS) and Health-Related Quality of Life (HRQL) scores between the two groups. However, at 6 months and 1 year post-treatment, the observation group had significantly lower SSS scores and higher HRQL subscale scores compared to the control group. This indicates that patients treated with HIFU had a higher quality of life than those treated with laparoscopic myomectomy. The reasons for this are mainly that HIFU treatment requires only sedation and analgesia, without the need for general anesthesia, resulting in higher patient acceptance and lower psychological stress. Additionally, HIFU is minimally invasive, leaves no surgical wounds, and allows for a faster postoperative recovery, enabling patients to return to daily life and work more quickly and

thus achieve a higher quality of life [25, 26]. In this study, three patients in the control group experienced postoperative intestinal obstruction. One patient improved after conservative outpatient treatment, while the other two patients with more severe symptoms were readmitted for strict fasting, gastrointestinal decompression, and parenteral nutrition. Their intestinal obstruction was successfully resolved, and they were discharged after recovery.

In summary, HIFU provides a safe and effective non-invasive treatment option for overweight/obese patients with uterine fibroids, offering advantages such as rapid recovery, minimal complications, and preservation of uterine function, thereby significantly improving patients' quality of life. Even though the procedural cost of HIFU is higher, the overall cost-effectiveness remains advantageous, with certain economic and social significance. The limitations of this study include the small sample size, short follow-up duration, and single-center, retrospective design. Future research should focus on expanding the sample size, conducting long-term follow-up studies, and participating in multicenter, prospective randomized controlled trials to further validate these conclusions.

Author contributions

L.J.W and L.Y.Z wrote the main manuscript text, Q.Y.Z and L.N.H prepared figures 1, F.N.L and Z.W.C prepared Tables 1, 2, 3 and 4, C.Y.L is the main surgeon of these surgeries. All authors reviewed the manuscript.

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Data availability

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

Declarations

Ethics approval and consent to participate

The retrospective medical review was approved by the institutional review board (IRB) of the Fujian Maternity and Child Health Hospital,.And the study was performed in accordance with the principles stated in the Declaration of Helsinki. All patients underwent a detailed pre-treatment evaluation to rule out malignancy, including clinical assessment, ultrasound, MRI, and biochemical marker testing. Written informed consent was obtained from all participating patients.All patients were managed with standard of care, and their spouses or authorized representatives were thoroughly informed about the surgical procedure, associated risks, and potential complications before the surgery.All patient privacy information is protected.

Consent for publication

All data in this study do not involve patient sensitive information, so this section is not applicable.

Competing interests

The authors declare no competing interests.

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