

# The Impact of High-Intensity Focused Ultrasound Ablation and Laparoscopic Myomectomy on Ovarian Function in Patients with Uterine Fibroids

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**Purpose:** To explore the value of high-intensity focused ultrasound (HIFU) ablation and laparoscopic myomectomy (LM) in the treatment of uterine fibroids.

**Methods:** One hundred and twenty patients with uterine fibroids admitted to our hospital from October 2020 to September 2022 and were conducted a randomized controlled trial and randomly assigned to two groups, with 60 cases each. The uterine fibroid surgery group is divided into LM group and HIFU ablation group. The healthy control group consisted of 60 cases. Ovarian function evaluations were conducted at four time points before surgery, 6 months after surgery, 1 year, and 2 years. The final follow-up assessment was conducted in September 2024. The ovarian function changes and complication in HIFU and LM groups were compared.

**Results:** The AMH levels and AFC counts of the HIFU group at 6 months after surgery were (2.39±0.35) ng/mL and (6.85±1.06), which were higher than those of the LM group (2.15±0.27) ng/mL and (6.02±0.87), respectively, with statistical differences ( $P<0.05$ ). The incidence of HIFU complications was lower than that of the LM group, with statistical differences ( $P<0.05$ ). Upon further statistical analysis of relevant indicators at 1 and 2 years post-surgery for the two surgical methods, no statistical differences were observed between AMH and AFC.

**Conclusion:** After HIFU ablation for uterine fibroids in women aged 35–40, ovarian function was not significantly affected in the short term (6 months after surgery) and the long term (2 years after surgery). Compared to LM, HIFU ablation is more effective in treating uterine fibroids, reducing the impact on patients' ovarian function with fewer complications, and improving their quality of life.

**Keywords:** high intensity focused ultrasound, laparoscopic myomectomy, uterine fibroids, anti-Mullerian hormone, ovarian function

## Introduction

Uterine fibroids are the most common benign tumors in the reproductive system of women of childbearing age, mostly occurring between the ages of 30 and 50, with an incidence rate of 20% to 50%.<sup>1</sup> At present, there are various treatment methods for uterine fibroids in clinical practice, among which high-intensity focused ultrasound (HIFU) ablation and laparoscopic myomectomy (LM) are commonly used. LM is a minimally invasive surgery that involves making several small incisions in the abdomen, inserting laparoscopy and related surgical instruments, and allowing doctors to accurately remove fibroids from the uterus through laparoscopic visualization.<sup>2</sup> However, LM has disadvantages such as post-operative recurrence and pelvic adhesions. In recent years, with the continuous development of minimally invasive technology, HIFU has been widely used in the treatment of uterine fibroids due to its advantages of non invasiveness and fast postoperative recovery.<sup>3–6</sup> Studies have shown that this method can effectively alleviate clinical symptoms and preserve the integrity of pelvic floor reproductive organs and ovarian blood supply. After 3 months of surgery, pregnancy preparation can be restored.<sup>7</sup> The safety and effectiveness of HIFU ablation for uterine fibroids in pregnant women have



been widely recognized,<sup>5,8</sup> and its non damaging effect on the endocrine function of the uterus and ovaries provides a new option for patients with uterine fibroids. However, further evidence is needed to accumulate regarding the impact on fertility, including ovarian function. From the perspective of its impact on ovarian function, HIFU ablation of uterine fibroid does not require extensive anatomical operations in the pelvic cavity like LM, which avoids direct damage to pelvic blood vessels, nerves, etc. caused by surgical operations and can better maintain the blood supply and nerve innervation status of the ovaries. Both methods are widely used in clinical practice, but further clarification is needed on which surgical approach can achieve ideal therapeutic effects while having less impact on ovarian function, in order to better safeguard women's physical and mental health.

Ovarian function is not only related to fertility but also plays a crucial regulatory role in women's overall health through the periodic secretion of estrogen and progesterone.<sup>9</sup> Its function maintains bone density, cardiovascular health, nervous system function, as well as skin elasticity and metabolic balance. The rate of ovarian function decline and the time of final menopause are influenced by multiple factors such as genetics and environment. Premature menopause (before the age of 40) significantly increases the long-term health risks of cardiovascular disease, osteoporosis, and cognitive decline.<sup>10</sup>

The aim of this study is to explore the differences in the effects of HIFU ablation and laparoscopic myomectomy on ovarian function changes and complication in patients with uterine fibroids. The results will provide new options for the treatment of uterine fibroids.

## Materials and Methods

### Patient Selection

This study was a randomized controlled trial conducted at Lianyungang Maternal and Child Health Hospital, and approved for implementation by the Ethics Committee of Lianyungang Maternal and Child Health Hospital. All patients were informed and consented and random sized into two groups with 60 cases each. The study was performed in compliance with the Declaration of Helsinki.

HIFU and LM group: patients with uterine fibroids aged 35 to 40 years old, who (1) have no fertility needs; (2) Based on clinical symptoms and pelvic ultrasound/MRI examination, the diagnosis of uterine fibroids is confirmed, which meets the indications for HIFU ablation and laparoscopic myomectomy surgery, with no surgical contraindications;

Healthy control group: normal females aged 35 to 40, without underlying diseases, recruited voluntarily. The enrolled subjects signed an informed consent form, voluntarily participated in this study, actively cooperated with the follow-up examination, and completed clinical observation.

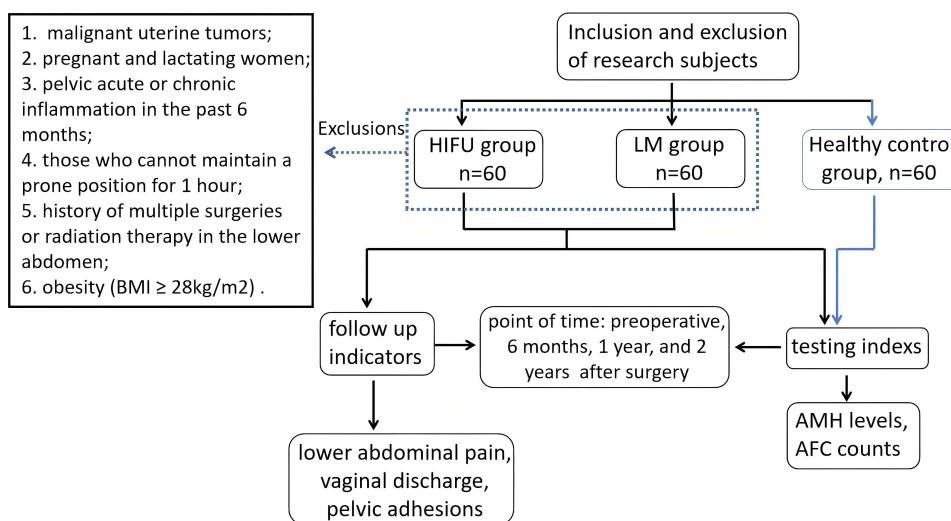
Exclusion criteria (1) patients with malignant uterine tumors; (2) pregnant and lactating women; (3) patients with pelvic acute or chronic inflammation in the past 6 months; (4) those who cannot maintain a prone position for 1 hour; (5) history of multiple surgeries or radiation therapy in the lower abdomen; (6) obesity ( $BMI \geq 28\text{kg/m}^2$ ) affects ultrasound channels. See [Figure 1](#) for details.

The HIFU treatment group uses the JC200D1 focused ultrasound tumor treatment system, managed by the HIFU treatment center; The LM group underwent laparoscopic lesion resection with a monopolar electric knife to partially remove the lesion, ensuring the integrity of the endometrium while completely removing the lesion, which was managed by the gynecology department.

Healthy control group: the purpose of voluntary recruitment is to observe changes in ovarian function, meet the needs of women in this age group, be non-invasive, and ensure the source of healthy control group subjects.

### Test Method

- (1) Ovarian function: 3mL of fasting venous blood was collected at four time points: preoperative, 6 months, 1 year, and 2 years postoperatively. Serum AMH (ng/mL) was measured using chemiluminescence; Between the 2nd and 4th days of the menstrual cycle, count the number of AFC (follicles with a diameter of 2mm to 9mm) using transvaginal ultrasound (HITACHI, F31); (2) Complications: Lower abdominal pain, vaginal discharge, pelvic adhesions, etc.; (3) The healthy control group patients were monitored for serum AMH levels and AFC counts at the first enrollment, 6 months after enrollment, 1 year and 2 years after enrollment.



**Figure 1** Research roadmap of the study.

## Statistical Analysis

We estimated the sample size using PASS 15 software. This calculation indicated that a minimum of  $n$  participants per group was required. Accounting for an anticipated dropout rate of 10%, we aimed to recruit 66 participants per group, for a total of 60 participants. The Cox proportional risk model was used to identify independent risk factors and calculate hazard ratios and 95% confidence intervals. Quantitative data were expressed as mean  $\pm$  standard deviation. Use paired sample  $t$ -test (intra group comparison) and independent sample  $t$ -test (inter group comparison), and  $P < 0.05$  indicated a statistically significant difference. The Bonferroni correction was used to all post-hoc pairwise comparisons following the significant omnibus repeated-measures ANOVA. Statistical analysis was performed using SPSS software (version 24.0, IBM Corp., Armonk, NY, USA).

## Results

The LM group was aged 35–40 years, with an average age of (36.60 $\pm$ 1.56) years; Types of fibroids: 38 cases were single, 22 cases were multiple; The duration of uterine fibroids is 1–15 years, with an average of (5.28 $\pm$ 3.09) years; Body mass index (BMI) is 18–27 kg/m<sup>2</sup>, with an average BMI of (23.0 $\pm$ 2.07) kg/m<sup>2</sup>. The HIFU group was aged 35–40 years, with an average age of (36.90 $\pm$ 2.32) years; Types of fibroids: 40 cases single, 20 cases multiple; The duration of uterine fibroids is 1–15 years, with an average of (5.68 $\pm$ 3.69) years; BMI 18–27kg/m<sup>2</sup>, the average BMI was (22.6 $\pm$ 2.00) kg/m<sup>2</sup>. The healthy control group was aged 35–40 years, with an average age of (36.71 $\pm$ 1.68) years; BMI 18–27 kg/m<sup>2</sup>, the average BMI was (22.8 $\pm$ 2.54) kg/m<sup>2</sup>. There was no significant difference among the three groups of general data ( $P > 0.05$ ). See [Table 1](#) for details.

There was no statistically significant difference ( $P > 0.05$ ) in the serum AMH (ng/mL) level and AFC quantity (counts) of the healthy control group at three time points before and after enrollment. See [Table 2](#) for details. This result indicates that the ovarian function of normal women does not change significantly between the ages of 35 and 40.

**Table 1** Comparison of General Information Among Three Groups of Patients ( $\bar{x} \pm s$ )

	Cases	Age (years)	BMI (kg/m <sup>2</sup> )	Disease Duration (Months)
Healthy control group	60	36.71 $\pm$ 1.68	22.8 $\pm$ 2.54	
HIFU group	60	36.90 $\pm$ 2.32	22.6 $\pm$ 2.00	5.68 $\pm$ 3.69
LM group	60	36.60 $\pm$ 1.56	23.0 $\pm$ 2.07	5.28 $\pm$ 3.09
<i>P</i>		0.323	0.145	0.232

**Note:** \*Indicates statistically significant difference at  $p < 0.05$ .

**Table 2** Comparison of Ovarian Function Indicators at Different Time Points Before and After Enrollment in the Healthy Control Group ( $\bar{x} \pm s$ )

	Before Grouping	6 Months After Grouping	1 Year After Grouping	2 Years After Grouping
AMH (ng/mL)	2.35±1.65	2.32±1.71	2.30±1.59	2.29±1.62
t		1.25	1.76	1.94
P		0.215	0.083	0.057
AFC	7.15±1.32	6.92±1.14	6.98±1.09	6.93±1.21
t		1.95	1.66	1.98
P		0.056	0.124	0.052

Notes: \*Indicates statistically significant difference at  $p < 0.05$ .

Through further comparative analysis, we found that the preoperative AMH levels and AFC numbers in the HIFU group and LM group were higher than those in the healthy control group.

There was no statistically significant difference in serum AMH levels and AFC quantities between the HIFU group before surgery and 6 months, 1 year, and 2 years after surgery, as shown in Table 3.

The AMH level ( $P=0.038$ ) and AFC number ( $P=0.017$ ) in the LM group decreased significantly after 6 months compared to preoperative levels, but ovarian function returned to preoperative levels 1 year after surgery, as shown in Table 4.

Therefore, we further compared the ovarian function of the HIFU group and the LM group at 6 months and 1 year after surgery, and found that the LM group had a decrease in ovarian function at 6 months after surgery compared to the HIFU group ( $P<0.05$ ), but there was no difference at 1 year and 2 years after surgery, as shown in Table 5.

Six months after surgery, the endometrial thickness and volume in the HIFU group were higher than those in the LM group, with statistical significance ( $P<0.05$ ). See Table 6

The HIFU group had fewer complications than the LM group, with a statistically significant difference ( $P<0.05$ ), as shown in Table 7.

**Table 3** Comparison of Ovarian Function Indicators Between HIFU Group at Different Time Points Before and After Surgery ( $\bar{x} \pm s$ )

	Before Surgery	6 Months After Surgery	1 Year After Surgery	2 Years After Surgery
AMH (ng/mL)	2.48±0.39	2.39±0.35	2.40±0.65	2.36±0.56
t		1.97	1.96	0.29
P		0.053	0.054	0.774
AFC	7.19±1.15	6.85±1.06	7.27±1.43	7.10±1.48
t		1.47	0.94	1.11
P		0.145	0.352	0.271

Notes: \*Indicates statistically significant difference at  $p < 0.05$ .

**Table 4** Comparison of Ovarian Function Indicators Between the Laparoscopic Group at Different Time Points Before and After Surgery ( $\bar{x} \pm s$ )

	Before Surgery	6 Months After Surgery	1 Year After Surgery	2 Years After Surgery
AMH (ng/mL)	2.51±0.41	2.15±0.27	2.56±0.50	2.49±1.55
t		2.12	0.24	0.64
P		0.038*	0.808	0.526
AFC	7.22±1.17	6.02±0.87	7.07±0.76	7.01±0.95
t		2.45	0.20	0.63
P		0.017*	0.842	0.529

Notes: \*Indicates statistically significant difference at  $p < 0.05$ .

**Table 5** Comparison of ovarian function between two groups ( $\bar{x} \pm s$ )

	AMH (ng/mL)			AFC (counts)		
	6 Months After Surgery	1 Year After Surgery	2 Year After Surgery	6 Months After Surgery	1 Year After Surgery	2 Year After Surgery
HIFU (n=60)	2.48±0.39	2.50±0.65	2.43±0.73	6.85±1.06	7.27±0.73	7.17±0.53
LM (n=60)	2.15±0.41	2.46±0.50	2.36±0.45	6.02±0.87	7.12±0.76	7.23±0.46
t	4.206	0.456	0.746	4.688	0.687	0.885
P	0.000*	0.623	0.122	0.000*	0.725	0.223

Notes: \*Indicates statistically significant difference at  $p < 0.05$ .

**Table 6** Comparison of Endometrial Thickness and Volume Between Two Groups ( $\bar{x} \pm s$ )

	Endometrial Thickness (mm)		Volume (mL)	
	Before Surgery	6 Months After Surgery	Before Surgery	6 Months After Surgery
HIFU (n=60)	5.8±1.02	8.25±1.15	2.8±0.34	4.78±0.45
LM (n=60)	5.9±1.05	7.23±1.08	2.8±0.36	4.13±0.42
t	0.159	5.008	0.313	8.180
P	0.874	0.000*	0.755	0.000*

Notes: \*Indicates statistically significant difference at  $p < 0.05$ .

**Table 7** Comparison of Complications Between Two Groups (%)

	Lower Abdominal Pain	Vaginal Discharge	Pelvic Adhesions	Incidence Rate
HIFU (n=60)	2(3.33)	1(1.67)	0	3(5.00)
LM (n=60)	7(11.67)	3(5.00)	1(1.67)	11(18.33)
$\chi^2$				5.175
P				0.023*

Notes: \*Indicates statistically significant difference at  $p < 0.05$ .

The above results indicate that after HIFU ablation and laparoscopic surgery for uterine fibroids in women aged 35–40, ovarian function was not significantly affected in the long term (2 years after surgery). However, laparoscopic surgery resulted in a slight decline in ovarian function within 6 months after surgery, but it recovered after 1 year. The HIFU ablation had fewer complications than the laparoscopic surgery. This suggests that HIFU has better short-term efficacy and safety in protecting ovarian function compared to laparoscopic surgery.

## Discussion

As age increases, the cumulative incidence of uterine fibroids significantly increases, and the incidence of fibroids is higher in infertile patients. Common factors causing infertility due to uterine fibroids include anatomical changes related to uterine muscle fibers, high estrogen levels, uterine contractions, ovulation disorders, and reduced endometrial receptivity,<sup>11</sup> seriously hindering women's fertility plans and bringing heavy psychological and physiological burdens. After pregnancy, the probability of miscarriage increases in patients with uterine fibroids. According to reports, 20–30% of women with uterine fibroids have a chance of miscarriage, which is 2–3 times higher than women without fibroids.<sup>12</sup> About 55% of uterine fibroids will show significant enlargement after pregnancy, which can lead to a series of adverse effects such as natural miscarriage, fetal malformation, placenta previa, premature birth, cesarean section, and increased risk of perinatal bleeding.<sup>13</sup> With the increasing awareness of modern people's health, the impact of uterine fibroids on fertility and the treatment of preserving fertility function have received more and more attention. Therefore, patients with uterine fibroids have higher requirements for uterine preservation.<sup>13</sup> Traditional open surgery causes significant trauma to

the ovaries and uterus, and some patients even need to have their uterus removed, greatly reducing their postoperative quality of life. Patients find it difficult to accept and can no longer meet clinical needs. With the change of women's attitudes towards marriage and childbirth, the number of elderly pregnant women has been increasing year by year, and the demand for fertility among elderly patients with uterine fibroids is also extremely urgent. There are various treatment methods for uterine fibroids, and the safety and effectiveness of HIFU ablation for uterine fibroids have been widely recognized,<sup>8,14–16</sup> but further evidence on its impact on fertility, including ovarian function, needs to be accumulated. From the perspective of its impact on ovarian function, HIFU ablation does not require extensive anatomical procedures in the pelvic cavity like LM, which avoids direct damage to pelvic blood vessels, nerves, etc. caused by surgical procedures and can better maintain the blood supply and nerve innervation status of the ovaries.

The anti Mullerian hormone AMH is mainly secreted by granulosa cells of pre antral follicles and antral follicles with a diameter of 2–6mm. The difference between each menstrual cycle is small, and it reflects the number of follicles in the primordial follicle pool earlier than FSH, LH, E2, etc.<sup>17</sup> AMH, as a non cycle dependent hormone, can reflect ovarian function status earlier and more accurately. There is a close relationship between the number of antral follicles (AFC) and non growing follicles, which is a reliable indicator commonly used in clinical practice to evaluate ovarian function. If the total number of AFC in both ovaries is less than 4–6, it indicates a decrease in ovarian reserve function.<sup>18</sup> Patients with uterine fibroids should not only consider the impact of treatment methods on their health and quality of life but also pay attention to the possible effects on ovarian function, pregnancy, and childbirth when choosing a treatment plan. Studies have shown that evaluating the changes in AMH levels in patients with uterine fibroids and adenomyosis after 6 months of ablation using HIFU therapy indicates that HIFU ablation is effective and does not affect ovarian reserve.<sup>19</sup> Other studies have shown that HIFU treatment for uterine fibroids has little effect on ovarian function and does not increase the risk of infertility and adverse pregnancy.<sup>20,21</sup> However, there is currently little research at home and abroad on whether HIFU treatment for uterine fibroids will affect ovarian function in women of childbearing age, and studies related to HIFU and AMH are limited to self control.

Although HIFU technology has non-invasive advantages, its limitations cannot be ignored. In terms of equipment popularity, due to its expensive equipment and high requirements for operators, it is mostly concentrated in large hospitals, and accessibility is limited. The high cost of treatment and incomplete medical insurance coverage bring significant economic burden to patients. In terms of key long-term reproductive health, although it is generally safe, the impact of uterine scars formed by treatment on long-term pregnancy, childbirth (such as theoretically low risk of uterine rupture), and placenta still requires more long-term data validation. In addition, this technique has strict case selection and is not applicable to all patients, and there is a risk of residual lesions and recurrence.

The lack of blinding of participants and personnel may have introduced performance bias and detection bias. The absence of an a priori power calculation means that the study might have been under powered to detect smaller, yet clinically significant, effects, especially for secondary outcomes. Due to the small sample size, large number of variables, single-center study and lack of diversity in patient demographics, we need to interpret these results with caution.

## Conclusions

In summary, our findings suggest that HIFU ablation treatment for uterine fibroids does not damage the short-term or even long-term endocrine function of the ovaries. HIFU ablation may provide a potential benefit in treating uterine fibroids than LM, reducing damage to ovarian function and lowering the risk of complications, providing a new option for elderly patients with uterine fibroids, especially those with fertility needs.

## Ethics Approval

This study was conducted in accordance with the ethical principles of the Declaration of Helsinki and approved by the Ethics Committee of Lianyungang Maternal and Child Health Hospital (Ethics Review Number: LYG-ME202024).

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## Disclosure

The authors report no conflicts of interest in this work.

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