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# Impact of ultrasound-guided high-intensity focused ultrasound for the treatment of uterine fibroids on ovarian reserve and quality of life: a single-center prospective cohort study

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## Abstract

**Background** We aimed to evaluate changes in ovarian reserve and quality of life in women treated with ultrasound-guided high-intensity focused ultrasound (USgHIFU) for uterine fibroids.

**Methods** In this single-center prospective study, a total of 69 patients with uterine fibroids treated with USgHIFU from October 2018 to November 2021 were enrolled. Fibroid volume, anti-Müllerian hormone (AMH) levels, uterine fibroid symptom scores, and uterine fibroid symptoms and quality of life (UFS-QOL) questionnaire scores before and 1, 3, and 6 months after USgHIFU treatment were analyzed. Correlations between AMH levels and age, fibroid type, and fibroid location were assessed.

**Results** Data from 54 of the 69 patients included in the present study were analyzed. The UFS-QOL scores at baseline and at 1 month and 6 months after USgHIFU treatment were 70 (50.75–87.50), 57 (44.75–80.00), and 52 (40.75–69.00) points, respectively ( $p < 0.001$ ). The rate of fibroid volume reduction increased significantly at the 3-month follow-up compared with the 1-month follow-up ( $p < 0.001$ ), and no significant change was observed between the 3-month and 6-month follow-ups ( $p > 0.99$ ). The median AMH levels before and at 1, 3 and 6 months after treatment were 1.22 (0.16–3.28) ng/ml, 1.12 (0.18–2.52) ng/ml, 1.15 (0.19–2.08) ng/ml and 1.18 (0.36–2.43) ng/ml, respectively ( $p = 0.2$ ). Multivariate linear regression analyses revealed that age was independently associated with AMH levels.

**Conclusions** USgHIFU treatment for uterine fibroids can significantly improve quality of life with minimal adverse effects on ovarian function.

**Keywords** AMH, Ovarian reserve, Quality of life, USgHIFU, Uterine fibroid

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## Introduction

Uterine fibroids are the most common gynecologic neoplasms in women of reproductive age, affecting up to 70% of women worldwide [1]. Although benign, approximately 30% of uterine fibroids can cause severe symptoms, including menorrhagia, pelvic pain, frequent urination, miscarriage, or infertility [2, 3]. Evidence suggests that women with uterine fibroids are at greater risk of experiencing emotional distress, depression, and anxiety, which can affect their health and quality of life [4].

Common treatment options for symptomatic uterine fibroids include medical treatments (hormonal medications and progesterone receptor modulators), surgical procedures to remove uterine masses (myomectomy and hysterectomy), and nonsurgical treatments (uterine artery embolization and high-frequency focused ultrasound [HIFU]) [5]. Notably, a differential diagnosis for uterine sarcoma, an aggressive and rare type of uterine neoplasm with a poor prognosis, must be conducted prior to initiating non-surgical treatment. Gold-standard surgical treatment of uterine sarcoma typically involves hysterectomy with bilateral salpingo-oophorectomy, and a fertility-sparing approach is only appropriate for carefully selected patients with strong desire to preserve fertility [6]. With the American College of Obstetricians and Gynecologists recommending the most minimally invasive approach whenever possible, clinicians have been utilizing less invasive treatments for uterine fibroids [7]. HIFU is a noninvasive treatment technique performed under the guidance of diagnostic ultrasound or magnetic resonance imaging that uses multiple high-intensity ultrasound waves to induce focal thermocoagulation to ablate fibroid vascularity. This procedure has been widely used in recent decades and has achieved favorable clinical efficacy in the treatment of uterine fibroids [8–10]. In addition, studies have shown that HIFU treatment is associated with shorter hospital stays, fewer adverse effects, and fewer complications than traditional surgery [11, 12]. However, there are still limited data on whether HIFU affects women's health-related quality of life or causes ovarian dysfunction in the short or long term.

Anti-Müllerian hormone (AMH), a hormone produced by small developing, mostly antral follicles, is not affected by changes in the menstrual cycle. Compared with follicle stimulating hormone (FSH) or inhibin B, AMH is generally considered a good indicator of the ovarian reserve [13–15]. Therefore, this study was designed to evaluate changes in ovarian function and quality of life in women after USgHIFU treatment for uterine fibroids.

## Materials and methods

### Patients

This single-center prospective study was carried out after approval was obtained from the Ethics Committee of the

International Peace Maternity and Child Health Hospital. Written informed consent was obtained from all participating patients.

A total of 69 patients with symptomatic uterine fibroids were enrolled between October 23, 2018, and November 27, 2021. The inclusion criteria for patients were as follows: (1) were >18 years of age; (2) had imaging-confirmed uterine fibroids 3–8 cm in diameter; (3) were premenopausal; and (4) had symptoms such as abdominal pain, constipation, abnormal uterine bleeding and frequent urination. The exclusion criteria for patients were as follows: (1) had a history of pelvic inflammatory disease, gynecologic malignancy, or endocrine disorders; (2) had contraindications to magnetic resonance imaging, such as metallic implants; (3) had severe fibroid calcifications or abdominal skin scarring along the acoustic pathway; (4) were unable to tolerate USgHIFU or were lost to follow-up; and (5) were suspected of having extensive abdominal adhesions.

### Preprocedural preparation and evaluation

Bowel preparation was performed with semiliquid food 3 days before the scheduled procedure. The lower abdominal skin in the acoustic pathway was shaved and degreased to avoid skin burns. HIFU treatment was performed via a system (SUA-I, Shanghai Zhonghui Medical Equipment Co. Ltd., Shanghai, China) with an ultrasound imaging device (Voluson 730, GE Healthcare, IL, USA) for guidance. Preprocedural evaluation included conventional ultrasound, noncontrast T1-weighted and T2-weighted imaging, and contrast-enhanced T1-weighted imaging. Magnetic resonance images were acquired in the axial and sagittal planes with a slice thickness of 5 mm and an interslice distance of 1 mm via a 1.5 T MRI scanner (MAGNETOM Aera, SIEMENS, Erlangen, Germany). The fibroid volume was calculated on contrast-enhanced T1-weighted images according to the ellipsoid calculation formula:  $V = 0.523 \times D1 \times D2 \times D3$ , where V is the fibroid volume and D1, D2, and D3 are the fibroid diameters in the longitudinal, anteroposterior, and axial planes, respectively [16]. Preoperative information, including patient age, height, weight, fibroid location, type, size, and blood supply, was recorded.

### USgHIFU

The patients were placed in the supine position. After identifying the location of the targeted fibroids, USgHIFU treatment was initiated under the guidance of real-time ultrasound via a 3.5 MHz convex US imaging probe (OPEN 580, Jiangsu Sinoways Medical Technology Co. Ltd., Yangzhou, China). The default acoustic power and periods of pulse-on and pulse-off were 126 W, 500 ms and 1000 ms, respectively. A pulse count of 6 was used for the sonication of each spot. During the procedure,

the patients were conscious and able to inform the physician of any pain or discomfort; USgHIFU was stopped in the presence of unbearable pain or successful ablation, as blood flow could not be detected by color Doppler flow imaging and power Doppler imaging. The procedure was performed by the same operator for all patients, and the duration of treatment was carefully recorded and documented. For patients with multiple fibroids, only the largest fibroid was ablated.

### Patient quality of life

We used the Uterine Fibroid Symptom and Quality of Life (UFS-QOL) questionnaire, which is a fibroid-specific health and symptom-related questionnaire, to measure the patients' quality of life before USgHIFU treatment and at the 1- and 6-month follow-ups after treatment. The original English version of the UFS-QOL questionnaire has been extensively validated and was translated into Chinese for ease of use. This questionnaire consists of 8 items on fibroid-related symptoms and 29 items on health-related quality of life, and the final score is obtained by summing the scores of these 2 domains [17].

### Follow-up evaluation

Complications, such as skin burns, abdominal pain, fever, nausea, vomiting, skin blisters and hematuria, were observed and recorded during and after the USgHIFU procedure. The follow-up evaluation included assessments of hemoglobin levels, AMH levels, and fibroid volume before and at 1, 3, and 6 months after USgHIFU treatment and nonperfused fibroid volume at 1 and 6 months after USgHIFU treatment. The blood samples were subsequently centrifuged at 2000 r/min for 20 min, after which the serum was extracted and stored at -20 °C. AMH levels were measured via an enzyme-linked immunosorbent assay kit (Beckman Coulter Inc., Brea, CA). The magnetic resonance imaging protocol and imaging parameters were the same as those used before USgHIFU. The fibroid volume reduction rate and nonperfused volume ratio were calculated as the ratio of fibroid volume post-USgHIFU/pre-USgHIFU treatment and the nonperfused volume/fibroid volume immediately after USgHIFU treatment, respectively. AMH measurements were performed via an enzyme-linked immunosorbent assay in centrifuged serum from enrolled patients stored at -20 °C.

### Statistical analyses

Statistical analyses and figure generation were performed via SPSS version 22.0 and GraphPad Prism software, respectively. Continuous variables were first tested for normality via the Kolmogorov-Smirnov test. Data are presented as medians (interquartile ranges) for nonnormally distributed data. Comparisons between pre-USgHIFU and post-USgHIFU parameters were performed via the nonparametric Friedman test with post hoc analysis. Multivariate linear regression analysis was used to explore factors influencing AMH levels at different follow-up time points. A two-tailed P value < 0.05 indicated statistical significance.

## Results

### Patient demographics

A total of 69 patients were enrolled, and data from 54 patients were ultimately analyzed. Data from the other 15 patients were excluded from the final analysis because no measurements of pre- or post-USgHIFU AMH levels ( $n=12$ ) and no post-USgHIFU hemoglobin assessments ( $n=3$ ) were performed. The mean age and median height, weight, and body mass index for the 54 included patients were  $41.04 \pm 5.26$  years, 160 (158–164) cm, 56.8 (52.0–61.3) kg and  $21.99$  (20.28–23.88)  $\text{kg/m}^2$ , respectively. Regarding fibroid type, 37 were anterior fibroids, 8 were posterior fibroids, 7 were lateral fibroids and 2 were fundus fibroids. A total of 21 and 33 patients had subserosal and intramural fibroids, respectively. The median baseline fibroid volumes, as assessed by sonography and magnetic resonance imaging, were  $52.03$  (35.90–93.78)  $\text{cm}^3$  and  $56.30$  (25.89–82.76)  $\text{cm}^3$ , respectively. The median USgHIFU treatment time was 100 (70–140) minutes.

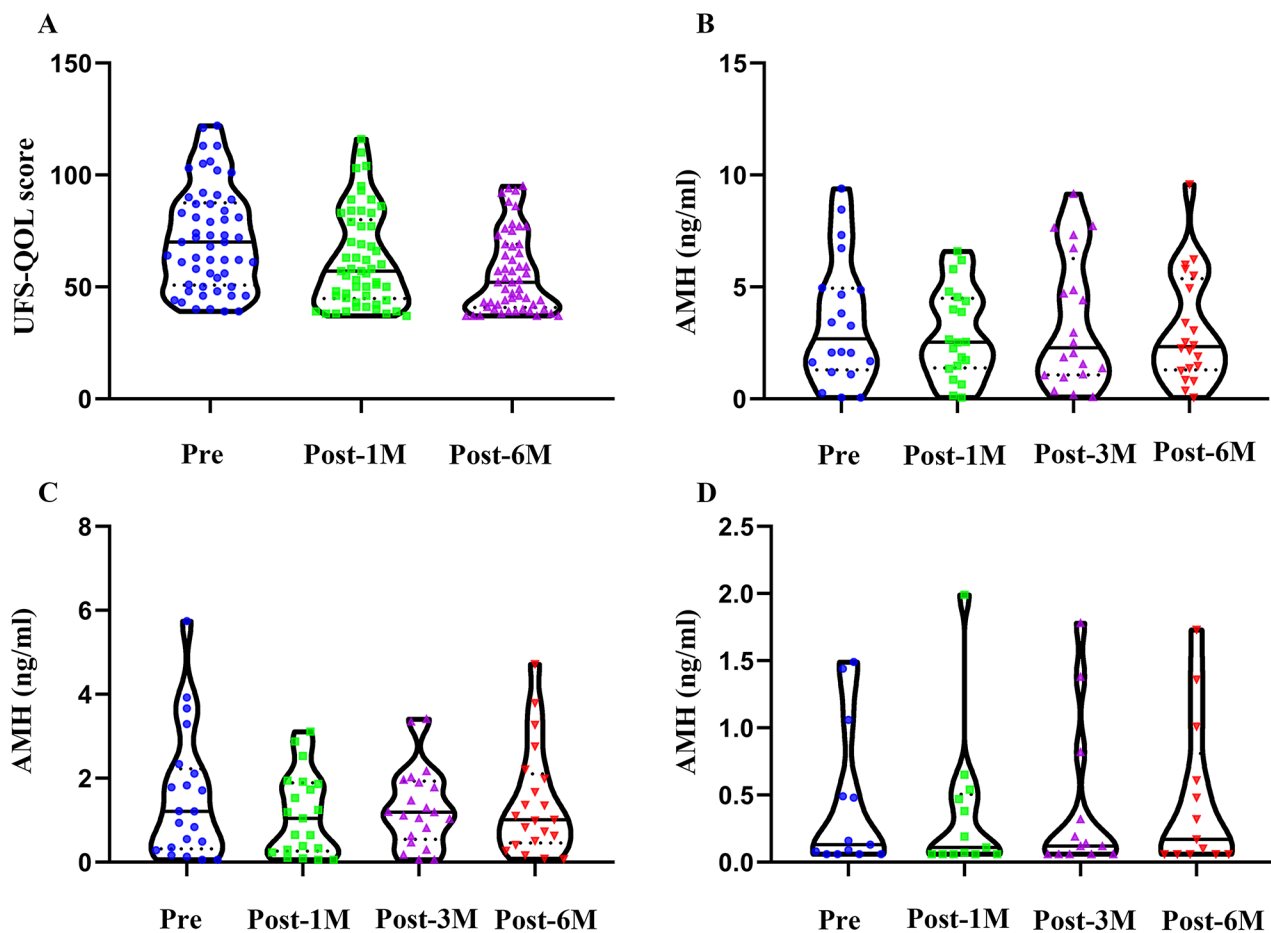
### Changes in quality of life, nonperfused volume ratio, and reductions in the treated volume and hemoglobin level over time

As shown in Table 1; Fig. 1 (A), the median pretreatment UFS-QOL score was 70 points (50.75–87.50). At 1 month and 6 months after HIFU ablation, the UFS-QOL scores decreased to 57 (44.75–80.00) and 52 (40.75–69.00) points, respectively, and a significant difference in the QOL score after USgHIFU treatment between the 1-month and 6-month follow-ups was observed ( $p < 0.001$ ). The rate of fibroid volume reduction was significantly greater at the 3-month follow-up than at

**Table 1** Comparisons of parameters at different time points

Parameters	Pre-HIFU	1 M Post-HIFU	3 M Post-HIFU	6 M Post-HIFU	P
UFS-QOL questionnaire score	70 (50.75–87.50)	57 (44.75–80.00)	/	52 (40.75–69.00)	< 0.001
Rate of volume reduction (%)	/	20.03 (7.42–33.82)	45.58 (28.24–56.08)	45.37 (32.05–61.56)	< 0.001
Hemoglobin level (g/L)	130 (121.75–137)	130 (122.75–137)	132 (121–139)	132 (123–138)	0.72

Data are presented as median (interquartile range). Abbreviations: P<sub>12</sub>, post hoc comparisons between Pre-HIFU and 1 M Post-HIFU; P, comparisons among all the different time points by the nonparametric Friedman test



**Fig. 1** Violin plots of the USF-QOL score and AMH level before and after USgHIFU treatment. **(A)**, USF-QOL score before and at 1-month and 6-month after treatment showed significant difference ( $p < 0.001$ ). **(B–D)**, Violin plots comparing AMH at time points in patients stratified by age. **(B)**, AMH at different time points for patients aged  $< 40$ ; **(C)**, AMH at different time points for patients aged 40 to 44; **(D)**, AMH at different time points for patients aged  $\geq 45$ . No significant change was seen among the three age groups ( $p > 0.05$ ). Abbreviations: Pre, before HIFU; Post-1 M, 1 month after HIFU; Post-3 M, 3 months after HIFU; Post-6 M, 6 months after HIFU

**Table 2** Comparison of AMH levels at different time points and subgroup analysis

Parameter	Pre-HIFU (ng/ml)	1 month after HIFU (ng/ml)	3 months after HIFU (ng/ml)	6 months after HIFU (ng/ml)	P
AMH	1.22 (0.16–3.28)	1.12 (0.18–2.52)	1.15 (0.19–2.08)	1.18 (0.36–2.43)	0.20
Age (years)					
$< 40$ ( $N=20$ )	2.68 (1.30–4.94)	2.54 (1.38–4.50)	2.28 (1.07–6.26)	2.33 (1.29–5.37)	0.588
40–44 ( $N=21$ )	1.21 (0.32–2.23)	1.04 (0.27–1.89)	1.19 (0.55–1.93)	1.01 (0.46–2.10)	0.168
$< 45$ ( $N=41$ )	1.78 (0.52–3.74)	1.73 (0.51–2.77)	1.47 (0.89–3.16)	1.47 (0.76–3.17)	0.16
$\geq 45$ ( $N=13$ )	0.13 (0.06–0.78)	0.11 (0.06–0.51)	0.12 (0.06–0.57)	0.17 (0.06–0.81)	0.892

Data are presented as median (interquartile range)

the 1-month follow-up, and no significant change was observed between the 3-month and 6-month follow-ups ( $p > 0.99$ ). The median nonperfused volume ratio at the 6-month follow-up was lower than that at the 1-month follow-up (82.21% [6.52–100.00%] vs. 91.80% [24.84–100.00%],  $p = 0.001$ ). Notably, the hemoglobin levels at the 1-, 3- and 6-month follow-ups were not significantly different from those before USgHIFU treatment ( $p > 0.05$ ).

#### AMH level assessment

The median AMH levels before and 1 month, 3 months, and 6 months after treatment were 1.22 (0.16–3.28), 1.12 (0.18–2.52), 1.15 (0.19–2.08) and 1.18 (0.36–2.43) ng/ml, respectively, and the pre-USgHIFU and post-USgHIFU AMH levels were stable without statistically significant changes (Table 2). We then explored whether age had an effect on AMH levels. Thus, patients were grouped into the  $< 45$  years group ( $n = 41$ ) [ $< 40$  years subgroup ( $n = 20$ ),

40–44-year subgroup ( $n=21$ ) and  $\geq 45$  years group ( $n=13$ ). As presented in Table 2; Fig. 1(B, C, D), the AMH levels pre-USgHIFU, 1-month post-USgHIFU, 3-month post-USgHIFU and 6-month post-USgHIFU in all the 3 subgroups were statistically insignificant ( $p>0.05$ ).

#### Factors influencing AMH levels at the 1-, 3-, and 6-month follow-ups

Multivariate linear regression analyses were used to determine the relationships between AMH levels and other variables, which included patient age, treatment time, body mass index, fibroid location, and fibroid type. The results revealed that age was independently associated with AMH levels at the 1-, 3-, and 6-month follow-ups (Table 3).

#### Discussion

USgHIFU is a safe and reliable noninvasive treatment for uterine fibroids [18–20]. It has been shown to be effective in reducing the size and symptoms of uterine fibroids, such as heavy menstrual bleeding, pelvic pain, and urinary symptoms. Previous studies reported that the fibroid volume reduction rates at 3, 6, and 12 months after treatment were 58.08%, 66.18%, and 77.59%, respectively [21]. Others reported that the mean fibroid volume reduction in 36 patients was 17.3% at 1 month, 33.3% at 3 months, and 45.1% at 5 months after HIFU treatment [22]. The nonperfused volume rate evaluated by magnetic resonance imaging has been used as an important indicator of the success of HIFU ablation for uterine fibroids [23]. Our study revealed that the 1-month and 6-month

nonperfused volume rates were 91.80% and 82.21%, respectively. Even when the nonperfused volume rate was reduced, the fibroids still shrunk: the fibroid volume reduction rates compared with the initial fibroid volume at 1, 3, and 6 months after treatment were 20.03%, 45.58%, and 45.37%, respectively.

The UFS-QOL questionnaire is a validated questionnaire designed to assess the impact of uterine fibroid symptoms on women's health-related quality of life [24, 25]. It assesses the physical, social, and emotional impacts on patients with uterine fibroids, including symptoms such as pelvic pain, bleeding, and urinary problems, as well as the impact on daily activities, emotional well-being, and sexuality. The UFS-QOL questionnaire consists of 31 questions that patients are required to complete before and at 1 and 6 months after USgHIFU treatment. A raw score of 1~5 points, representing symptoms from mild to severe, is assigned to each of the items, and the final score is obtained by summing the raw scores of related items [17]. Our results convincingly show that, compared with the initial UFS-QOL score, the UFS-QOL score decreased by 18.57% at 1 month and 25.71% at 6 months after treatment.

As women age, the number and quality of primordial follicles decline, and the ovarian reserve decreases. AMH is a member of the transforming growth factor beta protein family. It is produced by the granulosa cells of the ovarian follicles, and its expression increases as the follicles grow from the primary to the small antral stage [26]. AMH levels are not affected by the menstrual cycle and are more accurate at reflecting the ovarian reserve than follicle stimulating hormone levels and the antral follicle count are. It is a good indicator of the number of small antral follicles remaining in the ovaries, which is directly related to the ovarian reserve [13, 27].

Uterine artery embolization is recommended as another nonsurgical treatment for uterine fibroids in patients who desire uterine conservation. During uterine artery embolization, an embolic agent is delivered through the catheterization of both uterine arteries, blocking blood flow to the fibroids and causing involution. Most studies have shown that women who undergo uterine artery embolization for uterine fibroids have an increased risk of decreased ovarian reserve or premature menopause, depending on factors such as the size and location of the fibroids and the type of particles used in the embolization procedure [28, 29]. In contrast, a more recent meta-analysis of 6 studies and 353 participants revealed no effect on ovarian reserve, as measured by AMH and FSH levels at 12 months after the procedure [30]. The small number of available studies makes it difficult to draw accurate conclusions about ovarian reserve with uterine artery embolization [7]. During HIFU treatment, high-intensity ultrasound waves are directed to

**Table 3** Multivariate linear regression analysis of factors influencing AMH levels at 1 month, 3 months, and 6 months post-HIFU

Parameters	B	95% CI	$\beta$	t	P
1 month post-HIFU; adjusted $R^2=0.286$					
Age (years)	-0.196	-0.275--0.118	-0.599	-5.026	<0.001
Treatment time (minutes) /	-0.003	-0.003	-0.006	-0.052	0.959
BMI(kg/m <sup>2</sup> )	-0.015	-0.170-0.140	-0.023	-0.194	0.847
Myoma location	0.151	-0.484-0.786	0.058	0.478	0.635
Myoma type	-0.312	-1.078-0.455	-0.103	-0.817	0.418
3 months post-HIFU; adjusted $R^2=0.220$					
Age (years)	-0.233	-0.340--0.126	-0.546	-4.384	<0.001
Treatment time (minutes)	0.000	-0.004-0.005	0.011	0.090	0.929
BMI(kg/m <sup>2</sup> )	-0.032	-0.243-0.179	-0.038	-0.305	0.762
Myoma location	0.178	-0.685-1.041	0.052	0.414	0.681
Myoma type	-0.176	-1.219-0.867	-0.045	-0.340	0.736
6 months post-HIFU; adjusted $R^2=0.252$					
Age (years)	-0.215	-0.308--0.121	-0.563	-4.615	<0.001
Treatment time (minutes)	0.001	-0.003-0.005	0.087	0.699	0.488
BMI (kg/m <sup>2</sup> )	0.007	-0.177-0.192	0.010	0.079	0.938
Myoma location	0.106	-0.650-0.861	0.035	0.281	0.780
Myoma type	-0.142	-1.055-0.771	-0.040	-0.313	0.755

the precise location of the fibroid, causing ablation of the fibroid vascularity. This may be an advantage of HIFU over uterine artery embolization because it does not interfere with ovarian perfusion by blocking the uterine arteries.

In our study, all 69 patients were successfully treated with USgHIFU, and no complications occurred in any of the patients. As shown in Table 2, there was no change in AMH levels in women who underwent USgHIFU before or six months after treatment. Similarly, several studies have shown that USgHIFU has no effect on the ovarian reserve [9, 31, 32].

AMH levels are known to decrease with age, and the main strength of our prospective study is that we examined possible changes in AMH levels in different age subgroups. The results revealed that there was no change in AMH levels regardless of age (less than 40 years, 40 to 45 years, or 45 years and older). Higher total treatment energy and longer treatment times may be required for larger fibroids, and ovarian function after HIFU treatment may be correlated with the location of fibroids. However, our study revealed that HIFU treatment has no effect on AMH levels regardless of fibroid location, type or treatment time.

The present study has several implications for clinical practice and future research. First, we demonstrated that USgHIFU is safe and effective in improving quality of life. Second, this study also showed that USgHIFU treatment did not have a significant impact on ovarian reserve. This is particularly reassuring for counseling patients, especially relatively young women who are concerned about future pregnancies. Finally, based on our results, future research would be focused on directly assessing whether USgHIFU treatment has a negative impact on maternal and neonatal outcomes.

Compared to previous studies on similar topics [31], the strength of our study lies in the sequential measurement of AMH at multiple time points after USgHIFU, providing a more nuanced understanding of AMH changes. Although this prospective study may have successfully demonstrated the efficacy and safety of USgHIFU in the treatment of uterine fibroids, there are several limitations to this study. The main limitation of the study is the small sample size. In addition, the follow-up period was only six months. Multicenter, large sample, and randomized controlled trials with more ovarian reserve biomarkers, such as serum follicle-stimulating hormone and serum estradiol, are expected to be conducted in the future. Importantly, USgHIFU does not affect ovarian function; therefore, further research is needed to fully understand the impact of USgHIFU treatment on pregnancy outcomes. At last, comparison of USgHIFU with other fibroid treatment modalities,

such as uterine artery embolization, would provide more information on the impact of ovarian reserve.

## Conclusions

In conclusion, USgHIFU is an effective and noninvasive procedure for the treatment of uterine fibroids. It has been shown to improve quality of life and has no adverse effects on the ovarian reserve in the short or long term.

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None.

## Author contributions

YDW was involved in planning and designing the study, interpretation, and manuscript revision and has the final responsibility for the manuscript. WG was involved in planning and designing the study, generating the dataset, manuscript writing, and statistical analyses. JJY was involved in conceiving and designing the study and writing and revising the manuscript; YZ was involved in performing the USgHIFU procedure, data analysis and interpretation. YHL was involved in planning and performing the literature review and editing the manuscript. All authors reviewed the manuscript.

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## Data availability

The data are not publicly available due to privacy or ethical restrictions.

## Declarations

### Ethics approval and consent to participate

This study was approved by the Ethics Committee of the International Peace Maternity and Child Health Hospital (GJEC-A-2017-08-1). All methods were performed in accordance with the relevant guidelines and regulations. All participants provided written consent before participation.

### Consent for publication

Not applicable.

### Competing interests

The authors declare no competing interests.

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