Effect of HIFU on endometrial receptivity and sex hormone level in uterine fibroid patients and analysis of influencing factors for its treatment rate

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Abstract. Effect of high intensity focused ultrasound (HIFU) uterine fibroid ablation on the endometrial receptivity and sex hormone level in uterine fibroid patients and the influencing factors for treatment rate were investigated. A retrospective analysis of 266 uterine fibroid patients admitted to the Department of Gynaecology in the Jining Maternity and Child Care Hospital from October 2013 to October 2016 was performed. Among them, observation group was treated with HIFU ablation (n=143), control group with myomectomy (n=123). The pulsatility index (PI) and the resistance index (RI) of the uterine arterial blood flow were measured during the luteal phase of menstruation by transvaginal ultrasonography. The serum luteinizing hormone (LH), follicle stimulating hormone (FSH) and estradiol (E_2) were detected by chemical immunofluorescence. The relationship between HIFU treatment rate and clinical pathology of uterine fibroid patients was analyzed, and univariate/multivariate regression analysis was used to analyze the influencing factors for HIFU treatment rate. There was no significant difference in preoperative and postoperative PI and RI between the two groups (P>0.05); no significant difference between preoperative and postoperative PI/RI in the same group (P>0.05). There was no significant difference in preoperative and postoperative LH, FSH and E_2 between the two groups (P>0.05); no significant difference between preoperative LH and postoperative LH in the same group (P>0.05), neither FSH or E_2 (P>0.05). Results of multivariate analysis showed that fibroid location and ultrasound contrast intensity were independent influencing factors for HIFU treatment rate (P<0.05). Treatment of uterine fibroid with HIFU has no effect on the patient's endometrial receptivity and sex hormone level. Fibroid location and ultrasound contrast intensity are independent risk factors for HIFU treatment rate. This study provides guidance for the clinical optimization of treatment methods and is more conducive to the promotion of HIFU ablation therapy.

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Introduction

Uterine fibroid is a common gynecological benign tumor, in which the age of most patients is more than 35 years (1). According to reports in the literature, uterine fibroid can cause increased menstrual blood volume, prolonged menstruation, pelvic distention, soreness of waist or even infertility, due to differences in the size and location of fibroid, severely affecting the quality of lives (2,3). With the development of society, more attention has been paid by women to the quality of life, physical integrity, uterine physiological function and abdominal beauty (4). According to reports in the literature, the endometrial receptivity can be evaluated by a good congestive state of endometrium that is the basic condition for embryo implantation and reflects the capacity of an embryo to be accepted (5). The indicator for assessing the congestive state of endometrium is usually the uterine arterial blood flow parameter, mainly pulsatility index (PI) and resistance index (RI), and the smaller the value is, the more favorable the embryo implantation is (6). Testing the function of sex hormone to assess ovarian can indirectly reflect the health of the uterus. Sex hormone mainly includes follicle stimulating hormone (FSH), luteinizing hormone (LH) and estradiol (E_2). When ovarian failure occurs, concentrations of FSH and LH will increase (7). Therefore, the clinical use of minimally invasive

Table I. General information (n, %).

Factors	Groups		t/χ^2	P-value
	Observation	Control		
Age (years)	36.25±7.13 (n=143)	35.75±6.42 (n=123)	0.597	0.551
Tumor diameter (cm)	(n=163)	(n=140)	0.212	0.729
<4	80 (49.08)	65 (46.43)		
≥4	83 (50.92)	75 (53.57)		
Tumor volume (cm^3)	(n=163)	(n=140)	0.196	0.730
<54	81 (49.69)	66 (47.14)		
≥54	82 (50.31)	74 (52.86)		
Fibroid location	(n=163)	(n=140)	0.158	0.722
Anterior wall/Posterior wall	100 (61.35)	89 (63.57)		
Uterine fundus	63 (38.65)	51 (36.43)		
Fibroid target skin distance (cm)	(n=163)	(n=140)	0.198	0.729
<7	88 (53.99)	72 (51.43)		
≥7	75 (46.01)	68 (48.57)		
Fibroid type	(n=163)	(n=140)	0.073	0.795
Muscle wall	121 (74.23)	102 (72.86)		
Non-muscle wall	42 (25.77)	38 (27.14)		

technique in the treatment of uterine fibroid is increasing and requirements are also gradually increasing.

High intensity focused ultrasound (HIFU) technology is new for the treatment of tumors with non-invasiveness (8). The main principle is to use ultrasonic waves with characteristics such as tissue penetrating and focusability to concentrate the low-intensity ultrasonic waves on the lesions in the body, so that the focus area rapidly warms up to 60-100˚C, resulting in coagulation necrosis of the target tissues, but at the same time, it does not damage the tissues outside the target area. Detection of pathology and related enzymes in the tissues around the target area is strong evidence, and no significant changes have been found (9,10). The advantage of HIFU is that it has the same effect as myomectomy and can cause necrosis of fibroid tissues, but it can avoid the damage of ultrasonic waves to normal tissues, so as to achieve the effect of minimally invasive treatment. This has been confirmed by clinical manifestations of patients and imaging (11,12). At the same time, HIFU has played a safe and effective role in patients with a willingness to have pregnancy, not only to allow uterine cavity a good recovery, but also to retain pregnancy ability (13).

This study investigated the effect of HIFU uterine fibroid ablation on the endometrial receptivity and sex hormone level in uterine fibroid patients and the analysis of influencing factors for treatment rate, to provide the decision-making basis for selection of HIFU ablation in the treatment of uterine fibroid indications, and optimization and standardization of treatment schemes.

The study was approved by the Ethics Committee of Jining Maternity and Child Care Hospital (Jining, China). Patients who participated in this research had complete clinical data. The signed informed consents were obtained from the patients or the guardians.

Materials and methods

General information. A retrospective analysis of 266 uterine fibroid patients, who meet the symptoms of uterine fibroid, confirmed clinically and by imaging in the Jining Maternity and Child Care Hospital from October 2013 to October 2016, was performed. The observation group was treated with HIFU ablation, a total of 143 cases, 163 fibroids, with an average age of 36.25±7.13 years. The control group was treated with myomectomy, a total of 123 cases, 140 fibroids, with an average age of 35.75±6.42 years. There was no significant difference in general information between the two groups (P>0.05). All patients in pregnancy and lactation, suffering from other gynecological diseases, heart disease, malignant tumors and coagulation dysfunction were excluded, and patients who had not taken hormone drugs within 6 months were included (Table I).

Treatment methods. JC-200 type HIFU (Chongqing Haifu Medical Technology Co., Ltd., Chongqing, China) was used for ablation therapy within one week after menstruation in observation group. The treatment diameter was 195 mm, and the treatment power was 160-420 W. Ultrasound scanning located the extent of fibroid lesions, captured dynamic images and located planar areas. Ultrasound probes were used to determine the number, size and location of fibroids, and lesion target areas were differentiated into different treatment levels. Patients were placed in a supine position and a dot-line-surface ablation treatment was performed through the focus area according to the treatment plan. At the same time, routine ultrasound examination, ultrasound contrast and MRI examination were performed at 1 month before and within 6 months after treatment to determine the therapeutic effect.

Table II. Modified RECIST criteria for evaluating the curative effect of cancer therapy.

Ablation rate	Evaluation of effect
Ablation rate <50%	Effective
>0 ablation rate ≤50%	Marked effective
Ablation rate =0	Invalid

Table III. Comparison of preoperative and postoperative PI and RI between the two groups.

Indicators	Time	Groups: Observation (n=143)	Groups: Control (n=123)	t value	P-value
PI	Preoperative	1.81±0.13	1.83±0.15	1.165	0.245
	Postoperative	1.83±0.16	1.86±0.17	1.919	0.056
	t value	1.160	1.957		
	P-value	0.247	0.052		
RI	Preoperative	0.92±0.14	0.89±0.12	1.860	0.064
	Postoperative	0.94±0.12	0.91±0.13	1.956	0.051
	t value	1.297	1.254		
	P-value	0.196	0.211		

PI, pulsatility index; RI, resistance index.

The control group was treated with myomectomy, including transabdominal, laparoscope and transvaginal myomectomy.

Observation indicators. The PI and RI of the uterine arterial blood flow were measured during the luteal phase of menstruation by transvaginal ultrasonography at 1 month before and within 6 months after operation. At the same time, the sex hormone level was measured, and 4 ml of fasting cubital venous blood were extracted. Serum LH, FSH and E_2 were detected by chemical immunofluorescence.

Evaluation of curative effect. The ablation rate of fibroid was calculated according to the following formula and evaluation criteria, and the curative effect was evaluated (14) (Table II):

Preoperative uterine fibroid volume =1/6x π x long diameter x wide diameter x thick diameter.

Ablation rate = fibroid volume after ablation/preoperative uterine fibroid volume x100%.

Statistical analysis. SPSS20.0 statistical software (IBM Corp., Armonk, NY, USA) was used for data analysis. Chi-square test was used for count data, t-test for measurement data, paired t-test for comparison between before and after treatment in the group, and logistic, univariate and multivariate regression analyses for the influencing factors for HIFU treatment rate. ANOVA was used for comparison beween multiple groups with LSD test. P<0.05 was considered to indicate a statistically significant difference.

Results

Comparison of preoperative and postoperative PI and RI between the two groups. There was no significant difference in preoperative and postoperative PI and RI between the two groups (P>0.05); no significant difference between preoperative PI and postoperative PI in the same group (P>0.05), neither RI (P>0.05) (Fig. 1; Table III).

Comparison of preoperative and postoperative sex hormone level between the two groups. There was no significant difference in preoperative and postoperative LH, FSH and E_2 between the two groups (P>0.05); no significant difference between preoperative LH and postoperative LH in the same group (P>0.05), neither FSH or E_2 (P>0.05) (Fig. 2; Table IV).

Relationship between HIFU treatment rate and clinical pathology of uterine fibroid. There was no significant

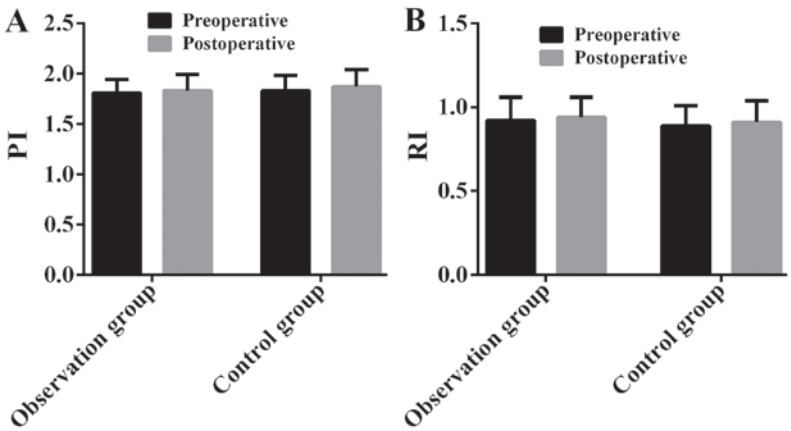

Figure 1. Comparison of preoperative and postoperative PI and RI between the two groups. Results of chemical immunofluorescence showed that: (A) There was no significant difference concerning preoperative PI and postoperative PI between the two groups (P>0.05); no significant difference was observed between preoperative PI and postoperative PI in the same group (P>0.05). (B) There was no significant difference concerning preoperative RI and postoperative RI between the two groups (P>0.05); no significant difference was observed between preoperative RI and postoperative RI in the same group (P>0.05). PI, pulsatility index; RI, resistance index.

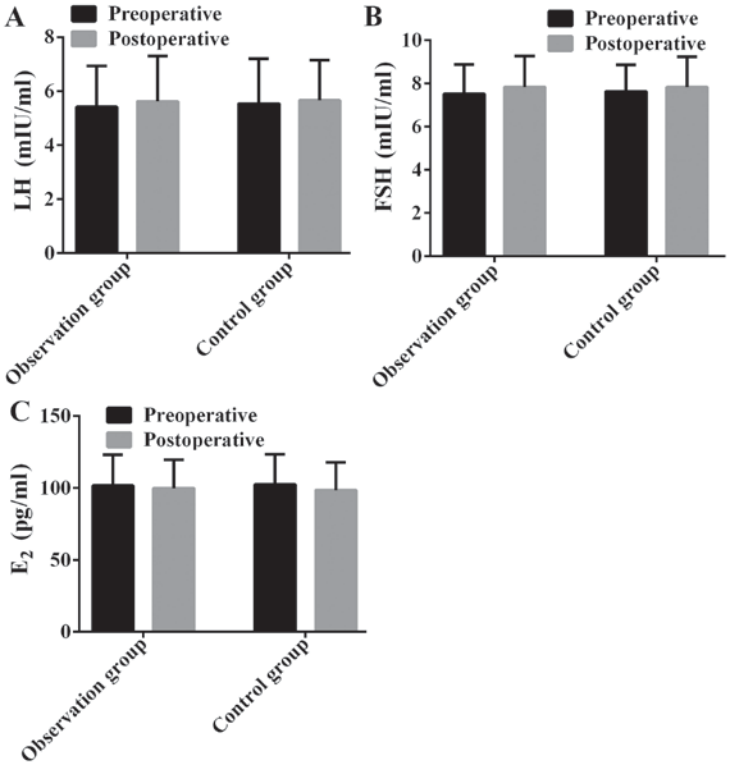

Figure 2. Comparison of preoperative and postoperative sex hormone level between the two groups. Results of chemical immunofluorescence showed that: (A) There was no significant difference in preoperative LH and postoperative LH between the two groups (P>0.05); no significant difference was observed between preoperative LH and postoperative LH in the same group (P>0.05). (B) There was no significant difference in preoperative FSH and postoperative FSH between the two groups (P>0.05); no significant difference was observed between preoperative FSH and postoperative FSH in the same group (P>0.05). (C) There was no significant difference in preoperative E_2 and postoperative E_2 between the two groups (P>0.05); no significant difference was observed between preoperative E_2 and postoperative E_2 in the same group (P>0.05). LH, luteinizing hormone; FSH, follicle stimulating hormone; E_2, estradiol.

Table IV. Comparison of preoperative and postoperative sex hormone level between the two groups.

		Groups			
Items	Time	Observation (n=143)	Control (n=123)	t value	P-value
LH (mIU/ml)	Preoperative	5.41±1.52	5.53±1.67	0.613	0.540
	Postoperative	5.62±1.68	5.66±1.48	0.205	0.838
	t value	1.108	0.646		
	P-value	0.269	0.519		
FSH (mIU/ml)	Preoperative	7.51±1.36	7.62±1.32	0.667	0.506
	Postoperative	7.83±1.45	7.82±1.42	0.057	0.955
	t value	1.925	1.177		
	P-value	0.055	0.241		
E_2 (pg/ml)	Preoperative	101.56±21.43	102.34±20.95	0.299	0.765
	Postoperative	99.82±19.64	98.42±19.13	0.587	0.558
	t value	0.716	1.532		
	P-value	0.475	0.127		

LH, luteinizing hormone; FSH, follicle stimulating hormone; E_2, estradiol.

association between HIFU treatment rate and age, tumor diameter, tumor volume, fibroid type and ultrasonic echo intensity (P>0.05); but an association between HIFU treatment rate and fibroid location, fibroid target skin distance and ultrasound contrast intensity (P<0.05) (Table V).

Analysis of influencing factors for HIFU treatment rate. Statistically different factors in Table V were used as independent variables for univariate/multivariate regression analysis. Results of univariate analysis showed that HIFU treatment rate was associated with fibroid location, fibroid target skin

Table V. Relationship between HIFU treatment rate and clinical pathology of uterine fibroid (n, %).

Factors	Effective (n=123)	Marked effective (n=40)	χ^2	P-value
Age (years)			0.623	0.469
<35	58 (47.15)	16 (40.00)		
≥35	65 (52.85)	24 (60.00)		
Tumor diameter (cm)			0.918	0.367
<4	63 (51.22)	17 (42.50)		
≥4	60 (48.78)	23 (57.50)		
Tumor volume (cm^3)			1.097	0.363
<54	64 (52.03)	17 (42.50)		
≥54	59 (47.97)	23 (57.50)		
Fibroid location			4.478	0.036
Anterior wall/ Posterior wall	76 (61.79)	32 (80.00)		
Uterine fundus	47 (38.21)	8 (20.00)		
Fibroid target skin distance (cm)			8.223	0.006
<7	69 (56.10)	12 (30.00)		
≥7	54 (43.90)	28 (70.00)		
Fibroid type			0.505	0.553
Muscle wall	85 (69.11)	30 (75.00)		
Non-muscle wall	38 (30.89)	10 (25.00)		
Ultrasound contrast intensity			14.466	0.001
Low intensity	24 (19.51)	19 (47.50)		
Equal intensity	41 (33.33)	13 (32.50)		
High intensity	58 (47.15)	8 (20.00)		
Ultrasonic echo intensity			0.180	0.914
Low echo	54 (43.90)	18 (45.00)		
Equal echo	47 (38.21)	16 (40.00)		
High echo	22 (17.89)	6 (15.00)		

distance and ultrasound contrast intensity (P<0.05), but it was not associated with age, tumor diameter, tumor volume, fibroid type and ultrasonic echo intensity (P>0.05). Results of multivariate analysis showed that fibroid location and ultrasound contrast intensity were independent influencing factors for HIFU treatment rate, and the difference was statistically significant (P<0.05) (Tables VI and VII).

Discussion

Uterine fibroid is a gynecological disease with a high incidence, prevalent in menopausal women and lacking typical clinical symptoms. Only a small proportion of patients of childbearing age will consult a doctor because of increased menstrual blood volume (15). For the treatment of uterine fibroid, myomectomy, interventional therapy and drug therapy may not be accepted by the majority of patients, due to risks such as large wound area, long recovery period, metabolic disorder, decreased immune function, decreased

Table VI. Univariate analysis of influencing factors for HIFU treatment rate.

Items	OR	95% CI	P-value
Fibroid location	6.453	3.562-10.245	0.026
Fibroid target skin distance (cm)	3.012	2.033-11.859	0.035
Ultrasound contrast intensity	7.965	1.754-9.523	0.019
Age (years)	5.168	3.468-16.255	0.216
Tumor diameter (cm)	8.629	4.256-12.856	0.082
Tumor volume (cm^3)	8.236	5.826-16.544	0.071
Fibroid type	6.102	3.719-18.408	0.104
Ultrasonic echo intensity	7.338	2.913-15.742	0.069

HIFU, high intensity focused ultrasound.

Table VII. Multivariate analysis of influencing factors for HIFU treatment rate.

Items	OR	95% CI	P-value
Fibroid location	7.216	3.456-9.541	0.032
Ultrasound contrast intensity	8.015	3.568-12.482	0.015

HIFU, high intensity focused ultrasound.

sexual desire, and easy to reduce the ovarian function (16-18). Therefore, in clinical practice, the treatment of retaining the uterus has become the norm.

Results of this study showed that there was no significant difference in preoperative and postoperative PI and RI between the two groups (P>0.05); no significant difference between preoperative PI and postoperative PI in the two groups (P>0.05), neither RI (P>0.05). It suggests that HIFU treatment has no effect on endometrial receptivity and it is safe and effective. There was no significant difference in preoperative and postoperative LH, FSH and E_2 between the two groups (P>0.05); no significant difference between preoperative LH and postoperative LH in the same group (P>0.05), or FSH and E_2 (P>0.05). The study results of Fu *et al* (19) are different from ours. HIFU was effective in the treatment of uterine fibroid and can significantly improve its clinical symptoms. Serum LH level after treatment was significantly higher than that before treatment (P<0.05), and serum E_2 and FSH levels after treatment were significantly lower than those before treatment (P<0.05). It may be due to the large difference in the sample size, and the control group set up in this study was treated with myomectomy. However, study of Yang *et al* only compared HIFU between before and after treatment (16). Study of Rueff *et al* (20) showed that there was no significant difference in serum FSH level between before and after treatment with HIFU in uterine fibroid patients. This is basically consistent with the results of this study that both LH and FSH slightly improved. The observation group was grouped through

imaging examination according to the ablation rate after treatment. Results of logistic univariate analysis showed that HIFU treatment rate was associated with fibroid location, fibroid target skin distance and ultrasound contrast intensity ($P<0.05$), but it was not associated with age, tumor diameter, tumor volume, fibroid type and ultrasonic echo intensity ($P>0.05$). Results of multivariate analysis showed that fibroid location and ultrasound contrast intensity were independent influencing factors for HIFU treatment rate, and the difference was statistically significant ($P<0.05$). This is basically consistent with the findings of Donnez *et al* (21), which showed that the treatment rate was related to fibroid location. According to reports in the literature (22), the fibroid is located on the anterior wall and the anterior uterine fundus can be better focused on in the lesion, due to the proximity of the bladder and the short target skin distance; at the same time, it is far away from the intestinal tract, sacral bone and peripheral nerves. Therefore, the safety and the tolerance of patients with anterior wall and anterior uterine fundus are better, and HIFU treatment rate is also higher. The study results of Chen *et al* (23) showed that the higher the ultrasound contrast intensity was, the richer the perfusion of uterine fibroid was, resulting in a lower HIFU treatment rate. The reason may be that after the absorption of ultrasound energy, the blood flow will leave the focus area of the lesion as the circulation moves, leading to a decrease in heat accumulation that is the key of the treatment of uterine fibroid with HIFU (24).

In conclusion, treatment of uterine fibroid with HIFU has no effect on the patient's endometrial receptivity and sex hormone level. Fibroid location and ultrasound contrast intensity are independent risk factors for HIFU treatment. This study provides guidance for the clinical optimization of treatment methods and is more conducive to the promotion of HIFU ablation therapy.

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Availability of data and materials

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

Authors' contributions

YC and BG conceived and designed the study. YD, XG and DS collected and analyzed the data. YC, YD and BG wrote the manuscript and revised it critically. CX was responsible for observation indicators analysis. All authors read and approved the final manuscript.

Ethics approval and consent to participate

The study was approved by the Ethics Committee of Jining Maternity and Child Care Hospital (Jining, China). Patients who participated in this research had complete clinical data. The signed informed consents were obtained from the patients or the guardians.

Patient consent for publication

Not applicable.

Competing interests

The authors declare that they have no competing interests.

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