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Efficacy and safety of GnRH-a combined with ultrasound-guided percutaneous microwave ablation in the treatment of uterine fibroids

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Abstract: Uterine fibroids seriously affect patients' physical and mental health and clinical treatment currently faces certain challenges. This study analysed the efficacy and safety of gonadotropin-releasing hormone agonist (GnRH-a) combined with ultrasound-guided percutaneous microwave ablation (UPMA) in the treatment of uterine fibroids. In a retrospective study, 120 patients with uterine fibroids from Zhangye Second People's Hospital between March 2023 and December 2023 were divided into GA and GU groups, both groups were treated with UPMA and GnRH-a treatment was added to the GU group. Fibroid volume, fibroid shrinkage rates (FSR), symptom severity score (SSS), sex hormone levels, serum indicator levels and clinical efficacy were mainly assessed. Secondary outcomes included pain scores, uterine fibroid-relative symptom and health-related qualities of life scores (UFS-HRQL), complication profiles, recurrence rates and adverse reaction incidence. After treatment, both groups had better indicators than pre-treatment (P<0.05). The FSR, serum indicator levels, clinical efficacy and UFS-HRQL scores in the GU group were superior to the GA group and fibroids volume, SSS, sex hormone, pain scores, complication conditions, recurrence rate and adverse reaction incidences were markedly below GA group (P<0.05). This method has remarkable efficacy, can effectively reduce clinical symptoms and is worth promoting its use in clinical practice.

Keywords: Uterine fibroids; gonadotropin-releasing hormone agonists; ultrasound; microwave ablation; clinical efficacy

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INTRODUCTION

Uterine fibroids, the most common benign tumour of the female reproductive system, are formed by abnormal proliferation of uterine smooth muscle tissue and fibrous connective tissue, with a prevalence of 60 to 80 per cent in women between the ages of 30 and 50 years (Zheng *et al.*, 2022). Although fibroids do not cause significant symptoms in most cases, some patients may develop a series of serious complications due to the location and size of the fibroids, as well as alterations in the hormonal environment of the body. The pathogenesis of fibroids is complex, involving oestrogen sensitivity, genetic predisposition and metabolic factors. The development of uterine fibroids is closely related to hormonal regulation in the body (Qiu *et al.*, 2021). Studies have shown that the density of oestrogen receptors in fibroid tissue is markedly superior to normal myometrium and its conversion of oestrogen is less efficient, which leads to high local oestrogen concentration and continuous stimulation of cell proliferation (Tsujikawa *et al.*, 2022). The role of progesterone in the growth of fibroids is more complex. On the one hand, it promotes cell division and accelerates the growth of fibroids; on the other hand, the long-term use of progestogens may reduce the risks of the disease, which demonstrates the subtle influence of hormonal balance on fibroid formation (A Li an d Yajuan, 2020). Genetic factors also have a key part in the development of fibroids. Individuals with a family history of fibroids have a 1.5- to 3.5-fold increased risks of developing the disease. In addition to hormonal and genetic factors, factors such as obesity, hypertension and early menstruation are also strongly associated with fibroid formation (Kuznetsova *et al.*, 2023). Uterine fibroids are divided into uterine body fibroids (90%) and cervical fibroids (10%) according to the location of growth and can be divided into intermural (60%-70%), subplasma (20%) and submucosal (10%-15%) according to their relationship with the muscle wall. The main clinical manifestations are increased menstrual flow, dysmenorrhoea, anaemia and infertility, which not only affect physical and mental health, but may also reduce the quality of life (Yang *et al.*, 2022).

Currently, uterine fibroids treatment modalities include medication and surgery. The medications included gonadotropin-releasing hormone analogue (GnRH-a) and mifepristone, etc. (Faustino *et al.*, 2017). GnRH-a is an endocrine hormone synthesised and secreted by hypothalamic nerve cells, which can inhibit the secretion of gonadotropins by the pituitary gland and reduce the level of oestrogen, resulting in the shrinkage of fibroids. It is commonly used to reduce the size of fibroids before surgery to facilitate surgical operation, or for the treatment of excessive menstruation and anaemia caused by uterine fibroids and to correct the anaemia before surgery (Corrêa *et al.*, 2020). GnRH-a is an analogue of natural gonadotropin-releasing hormone and the more clinically used ones are triptorelin and leuprolide acetate (Capezzuoli *et al.*, 2022). Triptorelin is a synthetic analogue of natural gonadotropin-releasing hormone, a 10-peptide analogue

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and leuprolide is a 9-peptide analogue of gonadotropin-releasing hormone. The structure of the synthetic analogue of this peptide has a greatly increased binding to the receptor, producing competitive inhibition, competition for the GnRH receptor and faster onset of action, while the high degree of similarity gives it a similar effect to natural GnRH and produces like-for-like effects (Veth *et al.*, 2023). In addition, there are other drugs, such as androgens, which counteract oestrogen and cause the endometrium to shrink, reducing the amount of menstruation, but long-term use may cause side effects, etc. (Moroni *et al.*, 2014). Surgical treatment mainly includes myomectomy and hysterectomy. Myomectomy is indicated for patients who wish to retain their reproductive function. Surgery can be performed transabdominally, transvaginally or laparoscopically to remove the fibroid from the uterus. The procedure preserves the uterus, but there is a possibility that the fibroids may recur after surgery. Hysterectomy may be considered for patients with large and numerous fibroids, obvious symptoms and no fertility requirements. This includes total hysterectomy and subtotal hysterectomy. Total hysterectomy involves complete removal of the uterine body and cervix, while subtotal hysterectomy preserves the cervix. After hysterectomy, patients no longer menstruate and lose their fertility (Farris *et al.*, 2019).

For women of reproductive age, fibroids are treated mainly with conservative therapy. Ultrasound-guided percutaneous microwave ablation (UPMA), as a minimally invasive interventional therapy, has been widely used in the clinical treatment of uterine fibroids by virtue of the advantages of precise and reliable ablation effect, minimal trauma, low patient pain and short postoperative recovery cycle (Q Li *et al.*, 2022). Microwave is a kind of high-frequency electromagnetic wave and the principle of microwave ablation for uterine fibroids is that under the guidance of ultrasound, the microwave antenna is placed into the fibroid by percutaneous puncture and the microwave antenna emits microwaves, so that the water molecules and other polar molecules in the fibroid tissues will have high-speed movement and friction heat under the action of the microwave field, which generates a high temperature (60-100°C) and causes the fibroid tissues to undergo coagulation necrosis, so that the therapeutic purpose can be achieved. In the treatment process, no incision is needed and the treatment can be completed only through skin puncture, which is less traumatic to the patient, with quick postoperative recovery and small abdominal incision (Chen *et al.*, 2022). It is able to preserve the integrity and function of the uterus while destroying the fibroids, avoiding damage to the surrounding normal tissues and organs and reducing the risk of surgery. Less impact on the daily life and work of the patient, to quickly return the normal life (H Zhang *et al.*, 2023).

Therefore, this study observed the clinical efficacy of GnRH-a combined with UPMA for the treatment of patients with uterine fibroids, analysed the fibroids volume after treatment, combining the complications and adverse reactions, to clarify the effectiveness and safety of the combined use of the two treatments and to provide more therapeutic options for the clinic.

MATERIALS AND METHODS

Study design and participants

The present study is a systematic evaluation and integration aimed at comparatively analysing the clinical efficacy of GnRH-a combined with UPMA in the treatment of patients with uterine fibroids and further assessing its impact on the patients' fibroids volume profile. This is a retrospective study, 120 patients with uterine fibroids from Zhangye Second People's Hospital between December 2021 and December 2023 and were divided into both groups, GA group and GU group, according to the different interventions. The flow chart of this study is displayed in fig. 1.

Inclusion and exclusion criteria

Inclusion criteria: (1) Diagnosed with uterine fibroids in our hospital by clinical manifestations and pelvic ultrasound (Marsh *et al.*, 2024); (2) Age 30~50 years old; (3) Diameter of the lesion was 3~10 cm; (4) No adenomyoma-related treatment had been performed; (5) Patients with good compliance and willingness to cooperate with the treatment plan developed by the study; (6) The patients' overall mental status is good, they are basically healthy and they can truthfully express their complaints about the symptoms and answer the relevant questions from the healthcare personnel; (7) Those who can tolerate the drugs involved in this study; (8) The patient and his family were inform and consenting, signing an informative consent form.

Exclusion criteria

(1) Patients with any site or type of malignant tumour, severe cardiopulmonary dysfunction; (2) Abnormal uterine bleeding caused by other reasons; (3) Patients with pelvic inflammatory disease, polycystic ovary syndrome and other diseases; (4) Menstruation, pregnancy, lactation and perimenopause; (5) Patients with combined haemorrhagic coagulation dysfunction, or severe liver or renal function defects, severe cardiovascular disease or other more serious diseases; (6) Combined chronic infectious diseases; (7) Combined cerebral, cardiac, hepatic and renal functional abnormalities; (8) Patients who have been involved in clinical drug trials or clinical studies, or have recently used hormonal drugs; (9) Requesting to stop treatment or automatic discharge for personal reasons; (10) Other circumstances that, in the opinion of the study physician, should not be included; (11) Other circumstances affecting the follow-up observation indicators.

Ethical statement

The study was performed in compliance with the Declaration of Helsinki and hospital ethical guideline and was endorsed by the Zhangye Second People's Hospital ethical committees. The IRB number for this study is No. 23JRRG0023.

Interventions

UPMA was performed in both groups. The diagnostic ultrasound instruments were Esaote MyLab Classc and MyLab 90 colour Doppler ultrasound diagnostic machines, CA541 convex array probes with a frequency of 2.0-5.0 MHz, equipped with ultrasonography imaging software. The puncture needle was an 18G interventional puncture needle (PTC needle) with a needle length of 200 mm. The contrast agent was sulfur hexafluoride microbubble injection (SonoVue®, Bracco Company, Italy), which was diluted with 5 mL of saline, shaken well and then 2.4 mL of microbubble suspension was aspirated and then injected through the elbow vein and then the needle was rinsed with 5 mL of saline. The cases were all operated by percutaneous transabdominal puncture route, using a combination of intratumoural and subperitoneal drug injection method, emptying the bladder before operation, taking the lying position, choosing the appropriate puncture route according to the location of fibroids and the characteristics of blood supply and paying attention to the process of needle insertion to avoid the bladder, intestinal tubes, large blood vessels and other important organs, so as to avoid causing adverse consequences. The puncture point was routinely disinfected and taped and the skin, subcutaneous and peritoneum were anaesthetised with 2% lidocaine hydrochloride locally and the 18G PTC needle was used to enter the interior of the tumour. During the injection process, real-time observation of colour Doppler flow and guidance of drug injection was performed until the drug was diffused to the whole myoma area and the intra-tumour blood flow disappeared and the myoma showed a foggy hypoechoic mass. Intraoperative ultrasound monitored the thermal field in real time and the strong echoes covered the whole tumour. The extent of the ablation area was determined by ultrasonography.

In terms of ablation parameters, a single microwave antenna was used for fibroids with a diameter of ≤5 cm or a lack of blood supply and the microwave output power was set at 50 W. For fibroids with a diameter of >5 cm and rich blood supply, 2 microwave antennas were placed and the power was set at 60 W. The duration of ablation depends on the size of the leiomyoma, generally the ablation time for smaller leiomyomas (≤3 cm in diameter) is about 240-600 s, while the ablation time for larger leiomyomas (>3 cm in diameter) is 600-1300 s. During the ablation process, the ultrasound monitors the echo changes in the ablation zone in real time and stops the microwave radiation when the high echo reaches the edge of the intended ablation zone of about 0.3 cm. At the same time, real-time monitoring of echo changes in the uterine cavity was performed and microwave radiation was stopped as soon as flowing hyperecho appeared in the uterine cavity as a means of preventing thermal damage to the endometrium (Zia *et al.*, 2020). These ablation parameters are designed to ensure effective ablation of fibroids with different characteristics and to minimise damage to the surrounding normal tissues, providing a reproducible basis for subsequent studies.

GnRH-a treatment was added to the GU group. Patients were given subcutaneous injections of leuprolide acetate extended-release microspheres (Manufacturer: Beijing Boente Pharmaceutical Co., Ltd; Approval No.: National Drug Code H20093809) and were injected with 1 injection (3.75 mg) on days 1-3 of menstruation and 1 injection was given for 1 course (28 d), with continuous treatment for 3 courses of treatment (Ren, 2018).

Observational indicators

In this study, primary indicators are key indicators used to directly assess the core treatment effects of the study, answer the main questions of the study and play a decisive role in shaping the conclusions of the study. Secondary indicators are those that complement the description of the treatment effect and provide more information about the study from different perspectives, which can further enrich the interpretation of the study results.

Primary indicators

Myoma volume and shrinkage rate

Ultrasonography was performed before and after treatment to determine the long, anterior-posterior and left-right diameters of the fibroids. Fibroids volume (V) = 0.5233 × long diameter × anterior-posterior diameter × right and left diameters. Fibroid volume reduction rate (FSR) = $(V_{preoperatively} - V_{at\ follow\text{-}up}) / V_{preoperatively} \times 100\%$. This indicator directly reflects the impact of treatment on the size of the fibroids and is a key measure of the effectiveness of treatment, visually reflecting whether the treatment has achieved the core goal of reducing the size of the fibroids.

Symptom severity

Clinical improvement was assessed by the Symptom Severity Score (SSS), which consisted of eight items (Elkana *et al.*, 2019). Increased bleeding during menstruation, clots and menstrual cycle irregularity. A higher Symptom Severity Score (SSS) indicates a higher level of symptom severity. SSS = (Raw score - 8)/32 × 100. This indicator quantifies the degree of improvement of patients' symptoms before and after treatment from the patients' actual symptom manifestations, which is directly related to the patients' quality of life and treatment effects and is an important aspect of assessing the effectiveness of treatment.

Sex hormone level

Before and after treatment, fasting peripheral blood was

sampled from 5 mL in both groups on days 5-7 of the menstrual cycle and the supernatant was retained for measurement and serum follicle-stimulating hormone (FSH), luteinising hormone (LH) and oestradiol (E2) levels were determined by radioimmunoassay (Y Zhang and Sun, 2024). Sex hormone levels are closely related to the development of uterine fibroids and by monitoring their changes, it is possible to determine the effect of the treatment on the patient's endocrine system and thus assess the effectiveness of the treatment in regulating hormonal imbalances.

Serum indicators

Patients' serum tumour antigen 125 (CA125) levels were measured by electrochemiluminescence (Pourmadadi *et al.*, 2023). Serum vascular endothelial growth factors (VEGF) level was determined by enzyme-linked immune-sorbent assay, the kit was Human VEGF ELISA kit (Item No.: ml064281, Shanghai Enzyme-linked Biotechnology Co., Ltd.) (Sumner *et al.*, 2019). Haemoglobin (HGB) levels were measured by haematology analyser method (Bhola *et al.*, 2024). These indicators provide a basis for assessing the effectiveness of treatment from a biochemical point of view and are an important reference for determining the effectiveness of treatment.

Clinical efficacy

Clinical efficacy was evaluated in conjunction with immediate postoperative fibroid ablation. Ineffective: no significant improvement in prolonged menstruation, increased menstrual flow, anaemia, etc., fibroid ablation rate <20%. Effective: clinical symptoms improved, ablation rate 20%~80%. Obvious effect: clinical symptoms basically disappeared, fibroid ablation rate >80%. Ablation rate = (volume of non-perfused area after ablation/total volume of fibroids before ablation) × 100%. Total effective rate = (Obvious effect + effective) / total effective × 100%. This indicator combines a number of factors to grade the effectiveness of the treatment and determine whether the study has achieved the desired treatment goals.

Secondary indicators

Pain scoring

Pain visual analogue score (VAS) was used to evaluate dysmenorrhoea as well as abdominal pain before and after treatment (Bielewicz *et al.*, 2022). It was counted as 0 ~ 10 points, 1 ~ 3 points as mild pain, 4 ~ 7 points as moderate pain and 7 ~ 10 points as severe pain. Pain is a common and disruptive symptom in patients with uterine fibroids and this indicator aids in assessing the effectiveness of treatment in relieving painful symptoms and provides more nuanced and complementary information on the effectiveness of treatment.

Uterine fibroid-related symptoms and quality of life scores

The different conditions of the patients were analysed on the base of uterine fibroid related symptom and health related qualities of life score (UFS-HRQL) (Fasciani *et al.*, 2023). UFS score: a minimum score of 8 and a maximum score of 40 were scored according to the severity of fibroid-related symptoms section of the UFS-HRQL questionnaire. HRQL score: scored according to the degree of impact of uterine fibroids on the patient's healthy life section of the UFS-HRQL questionnaire, which involves 6 dimensions, including concerns about the disease, energy/mood, activity limitation, self-concern, loss of control of life and sexual functioning. The scoring format was 0-100, with higher scores resulting in better quality of life. This indicator provides a more comprehensive picture of the impact of treatment on patients' daily lives in terms of both symptoms and quality of life dimensions, further enriching the assessment of treatment effects.

Complications

Postoperative complications were recorded in both groups, including anaemia, infertility and miscarriage and bloating. This indicator assists in assessing the effectiveness of treatment from a safety perspective and provides the information necessary for a comprehensive evaluation of treatment programmes.

Recurrence rate

To record the recurrence of patients in both groups during the follow-up period. The recurrence rate is a key indicator of the long-term effectiveness of treatment and can visually reflect the likelihood of fibroids re-growth after treatment, providing an important basis for evaluating the strengths and weaknesses of treatment options.

Incidence of adverse reactions

To record the occurrence of adverse reactions during treatment in both groups, including nausea/vomiting, hot flashes/sweating and headache. The incidence of adverse reactions reflects the adverse effects of treatment on the patient's body, which is related to the safety of the treatment programme and patient compliance and provides additional information for the comprehensive assessment of the treatment programme.

Follow-up visits

This study was primarily scheduled for a 6-month post-treatment follow-up to assess the durability of the effect and to address any potential adverse reactions or problems.

Sample size calculation

Sample sizes were based on power analyses conducted with G*Power 3.1.9.7 computer software to determine the sample size required to detect statistical significance difference. Sample size was calculated based on FSR as the primary outcome (Dridi *et al.*, 2022; Neumann *et al.*, 2024). Taking into account an α level of 0.05, an efficacy of 85% and an effect value of 0.55 (calculated on the basis of the results of the retrospective data, which were not

included in the subsequent analyses), we calculated that 49 patients were needed in each group. Considering the potential uncertainties, a sample size of 60 cases in each group was chosen for this study and we believe that the sample size of this study allows us to draw reliable conclusions.

STATISTICAL ANALYSIS

SPSS27.0 statistics software was applied for analysis of the data. Measurements that conform to normally distributed value are represented as ($\bar{x}$±s) and comparisons among groups adopts act independently pattern *t* examination and counting data is expressed as rate (%) using x^2 test, with $P<0.05$ indicating a statistical significance of the difference.

RESULTS

Basic information

In this study, 120 patients with uterine fibroids from Zhangye Second People's Hospital between December 2021 and December 2023 were assigned to GA group (n=60) and GU group (n=60) based on different interventions. The baseline demographic and baseline characteristics in the both groups are displayed in table 1, these characteristics demonstrated no remarkable discrepancy among the both groups ($P>0.05$). It means that in the subsequent assessment of the therapeutic effects of different interventions on patients with uterine fibroids, the interfering factors due to individual patient differences can be minimised, so that the results of the study can more truly reflect the differences in the effects of the different interventions themselves. This lays a solid and reliable foundation for subsequent studies.

Primary results

Fibroids volume and shrinkage rate

Fibroids volume and shrinkage rate are important indicators that directly reflect the treatment effect. The results of fibroids volume and shrinkage rate of the both groups of patients are demonstrated in table 2. Before treatment, no remarkable discrepancy was found in the myxoma volume of the both groups ($P>0.05$). Post-treatment, the fibroids volume of patients in both groups was decreased remarkably ($P<0.05$). The fibroids volume in the GU group was 45.76±8.34 cm^3 markedly below in the GA group, which was 58.84±9.69 cm^3 ($P<0.05$). Post-treatment, FSR in GU group was 79.96±5.53 % markedly above in the GA group, which was 64.35±7.17 % ($P<0.05$). It indicated that both treatments could reduce the volume of fibroids and the FSR of GU group was greater.

SSS

The SSS score is an important indicator for assessing the severity of symptoms. The results of the SSS scores of the both groups are demonstrated in table 3. Before treatment, no marked discrepancy was found in the SSS scores of the both groups ($P>0.05$). Post-treatment, the scores of patients in both groups were decreased remarkably ($P<0.05$). The score in GU group was 17.31±2.70 markedly below the score of 20.50±3.64 in GA group ($P<0.05$). It indicated that both treatments could alleviate the severity of fibroids and the GU group had a better alleviation effect.

Sex hormone level

The results of the comparison of sex hormone levels among the both groups of patients are presented in table 4. Before treatment, no marked discrepancies were found in the comparison of sex hormone levels among the both groups of patients ($P>0.05$). Post-treatment, the FSH, LH and E2 levels of patients in the GU group were 4.97±1.12 U/L, 4.14±0.86 U/L and 162.20±22.69 pmol/L and in the GA group were 6.99±0.95 U/L, 7.37±1.30 U/L and 208.13±23.31 pmol/L, respectively, which were markedly below the before treatment and GU group was markedly below the GA group ($P<0.05$). These results indicated that the sex hormone levels of patients in both groups were remarkably reduced post-treatment and the GU group was better in terms of marked improvement in sex hormone levels.

Serum indicators

The results of the comparison of the serum indexes of the both groups are demonstrated in table 5. Before treatment, no remarkable discrepancy was found in the comparison of serum indexes among the both groups ($P>0.05$). Post-treatment, the levels of CA125 and VEGF in patients in the GU group were 54.48±13.63 U/mL and 83.98±9.47 ng/L, respectively and 69.11±11.36 U/mL and 92.97±10.05 ng/L in the GA group, which were markedly reduced versus pre-treatment and were markedly below in the GU group versus the GA group. HGB levels were remarkably increased in both groups, with 116.20±12.08 g/L in patients in the GU group markedly above the 107.41±11.78 g/L in GA group ($P<0.05$). These results indicated that the serum indexes of both groups improved after treatment and the GU group markedly improved better.

Clinical efficacy

Combined with the treatment effect we analysed the clinical efficacy of the both groups of patients and the results of the analysis are presented in table 6. The total efficacy rate of GA group patients was 76.67% (46/60) and GU group was 93.33% (56/60), with a remarkable discrepancy among the groups ($P<0.05$). The results indicated that the efficacy of patients in GU group was better, indicating that the clinical efficacy of combined treatment was better.

Secondary results

Pain scores

VAS score is an important indicator to assess the levels of pain. The results of the VAS scores of the both groups of patients are demonstrated in table 7.

Table1: Patient demographics and baseline disease characteristics ($\bar{x}$±s)

Parameter	GA group (*n*=60)	GU group (*n*=60)	t/x^2	*P*
Age (year)	40.53±6.07	40.75±5.43	0.209	0.835
Height (cm)	158.87±7.23	158.60±8.63	-0.186	0.853
Weight (kg)	58.49±7.26	58.26±5.91	-0.190	0.849
Body mass index (kg/m^2)	23.10±2.14	23.05±1.65	-0.143	0.886
Married/unmarried	58/2	57/3	0.521	0.470
Fertile/non-fertile	55/5	54/6	0.244	0.621
Diameter of fibroid (cm)	2.91±0.53	2.89±0.45	-0.223	0.824
Disease duration (years)	3.01±1.04	3.04±1.04	0.158	0.875
Location (uterine wall/floor)	49/11	50/10	0.035	0.852
Number of fibroids (<3/ ≥3)	45/15	44/16	0.104	0.747
Hypertension (yes/no)	14/46	13/47	0.029	0.866
Diabetes (yes/no)	18/42	17/43	0.097	0.755
Temperature/ (ºC)	36.29±0.29	36.33±0.29	0.755	0.452
Breathing/ (breaths/min)	17.52±2.12	17.27±1.97	-0.669	0.505
Heart rate/ (beat/min)	74.71±6.99	74.85±5.72	0.120	0.905
Systolic blood pressure/ (mmHg)	118.87±5.44	119.11±4.79	0.256	0.798
diastolic blood pressure/ (mmHg)	76.06±5.44	75.99±5.22	-0.072	0.943

Table 2: Fibroids volume and shrinkage rate ($\bar{x}$±s)

norm	time	GA group	GU group	*t*	*P*
Fibroid volume (cm^3)	Pre-treatment	91.19±9.35	90.86±8.89	0.329	0.743
	Post-treatment	58.84±9.69	45.76±8.34	-7.925	<0.001
t		-18.609	-28.659		
P		<0.001	<0.001		
Reduction rate (%)		64.35±7.17*	79.96±5.53*	13.354	<0.001

Note: "*" represents marked discrepancy compared with pre-treatment, *P*<0.05.

Table 3: SSS scores ($\bar{x}$±s, score)

	GA group	GU group	*t*	*P*
Pre-treatment	28.06±3.61	28.03±4.27	-0.042	0.967
Post-treatment	20.50±3.64	17.31±2.70	-5.452	<0.001
t	-11.423	-16.436		
P	<0.001	<0.001		

Table 4: Comparisons of sex hormone levels ($\bar{x}$±s)

norm	time	GA group	GU group	*t*	*P*
FSH (U/L)	Pre-treatment	15.30±1.17	15.04±1.17	-1.217	0.226
	Post-treatment	6.99±0.95*	4.97±1.12*	-10.654	<0.001
LH (U/L)	Pre-treatment	12.06±1.26	11.99±1.71	-0.255	0.799
	Post-treatment	7.37±1.30*	4.14±0.86*	-16.051	<0.001
E2 (pmol/L)	Pre-treatment	290.60±37.19	291.54±36.01	0.141	0.888
	Post-treatment	208.13±23.31*	162.20±22.69*	-10.937	<0.001

Note: "*" represents marked discrepancy compared with pre-treatment, *P*<0.05.

Table 5: Serum indicators ($\bar{x}$±s)

Norm	Time	GA group	GU group	*t*	*P*
CA125 (U/mL)	Pre-treatment	104.32±19.53	103.51±21.44	-0.216	0.829
	Post-treatment	69.11±11.36*	54.48±13.63*	-6.387	<0.001
VEGF (ng/L)	Pre-treatment	120.48±12.04	120.78±12.44	0.134	0.894
	Post-treatment	92.97±10.05*	83.98±9.47*	-5.043	<0.001
HGB (g/L)	Pre-treatment	98.85±8.34	98.44±9.91	-0.245	0.807
	Post-treatment	107.41±11.78*	116.20±12.08*	4.035	<0.001

Note: "*" represents marked discrepancy compared with pre-treatment, $P<0.05$.

Table 6: Clinical efficacy analysis

Group	Obvious effect (*n*)	Effective (*n*)	Ineffective (*n*)	Total effective rate (*n*, %)
GA group	22	24	14	46 (76.67)
GU group	25	31	4	56 (93.33)
x^2			10.039	
P			<0.05	

Note: Total effective rate = (Obvious effect + effective) / total effective × 100%.

Table 7: VAS score ($\bar{x}$±s, score)

Time	GA group	GU group	*t*	*P*
Pre-treatment	6.42±1.04	6.48±0.96	0.328	0.743
Post-treatment	3.06±0.79	1.48±0.43	-13.607	<0.001
t	-19.928	-36.819		
P	<0.001	<0.001		

Table 8: UFS-HRQL score ($\bar{x}$±s, score)

Norm	Time	GA group	GU group	*t*	*P*
UFS	Pre-treatment	22.99±4.40	22.72±3.89	-0.356	0.722
	Post-treatment	17.43±2.70*	10.20±2.11*	-16.343	<0.001
HRQL	Pre-treatment	60.19±12.24	60.74±12.65	0.242	0.809
	Post-treatment	84.42±8.49*	90.58±7.63*	4.180	<0.001

Note: "*" represents marked discrepancy compared with pre-treatment, $P<0.05$.

Table 9: Complications [*n*(%)]

	GA group	GU group	x^2	*P*
Anaemia	1 (1.67)	0 (0.00)	2.020	0.155
Infertility and miscarriage	1 (1.67)	1 (1.67)	0.000	1.000
Abdominal distension	1 (1.67)	0 (0.00)	2.020	0.155
Compression symptoms	1 (1.67)	0 (0.00)	2.020	0.155
Pain	2 (3.33)	1 (1.67)	0.205	0.651
Infection and suppuration	2 (3.33)	1 (1.67)	0.205	0.651
Malignant lesions	1 (1.67)	1 (1.67)	0.000	1.000
Gastrointestinal Diseases	1 (1.67)	0 (0.00)	2.020	0.155
Hypoglycaemia	1 (1.67)	0 (0.00)	2.020	0.155
Total incidence	11 (18.33)	4 (6.67)	5.531	<0.05

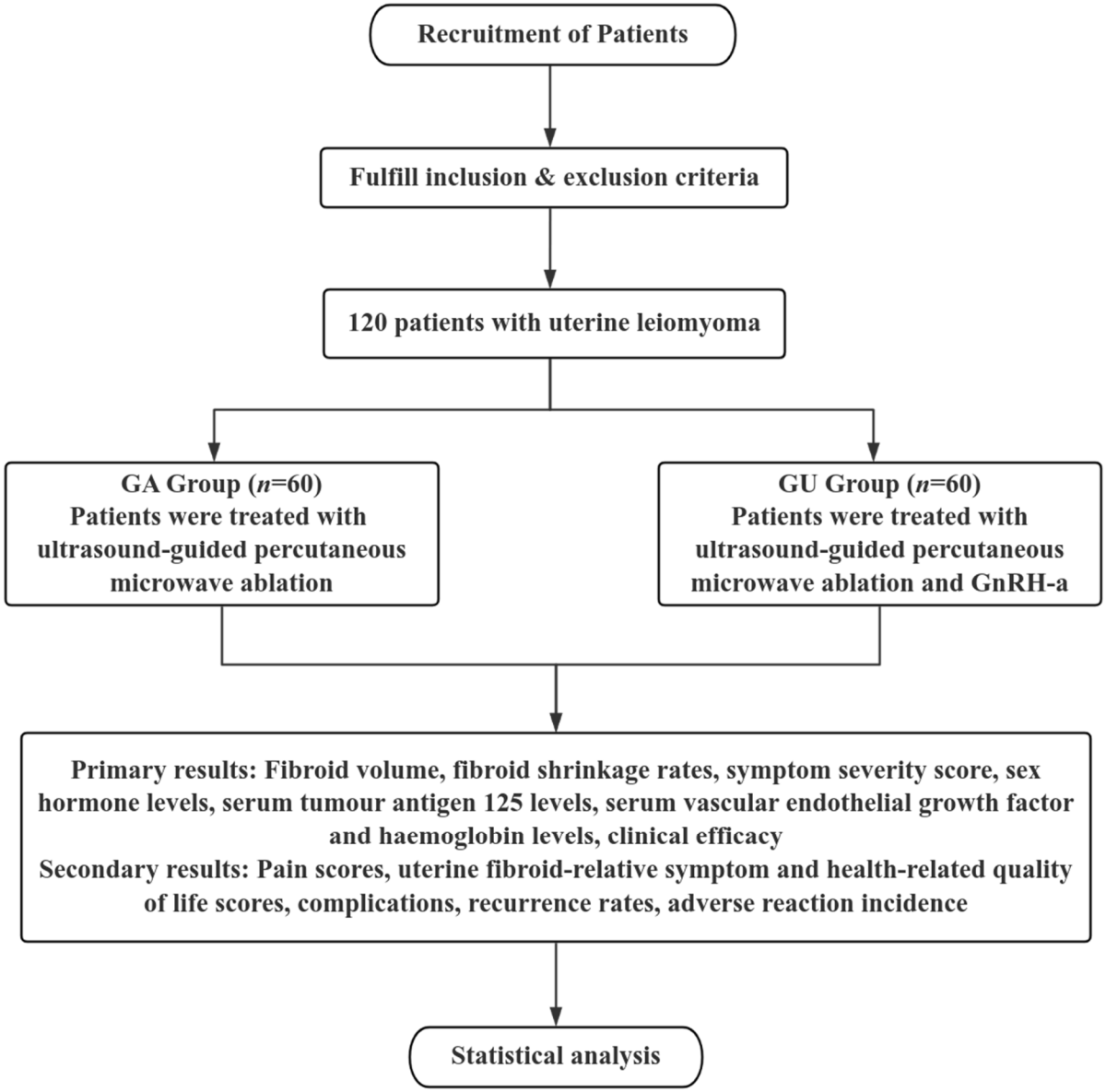

Fig. 1: Flow chart

Before treatment, no obvious discrepancy was found between the VAS scores of the both groups (P>0.05). Post-treatment, the scores in both groups were remarkably reduced (P<0.05). The score in the GU group was 1.48±0.43 markedly below the score of 3.06±0.79 in the GA group (P<0.05). It indicated that both treatments could relieve pain and the GU group had better relief.

UFS-HRQL score

The results of UFS-HRQL scores of the both groups are presented in table 8. Before treatment, no remarkable discrepancy was found among the UFS and HRQL scores of the both groups (P>0.05). Post-treatment, the UFS scores of patients in both groups were remarkably reduced. The score of patients in the GU group was 10.20±2.11 markedly below the score of 17.43±2.70 in the GA group (P<0.05). HRQL scores were markedly increased in both groups. The score of patients in GU group was 90.58±7.63 markedly above the score of 84.42±8.49 in GA group (P<0.05). The results indicated that both treatment modalities could improve the symptoms related to uterine fibroids and improve the life quality and the GU group had a better improvement effect.

Complications

We recorded the occurrence of complications including anaemia, infertility and miscarriage in both the groups and the results are presented in table 9.

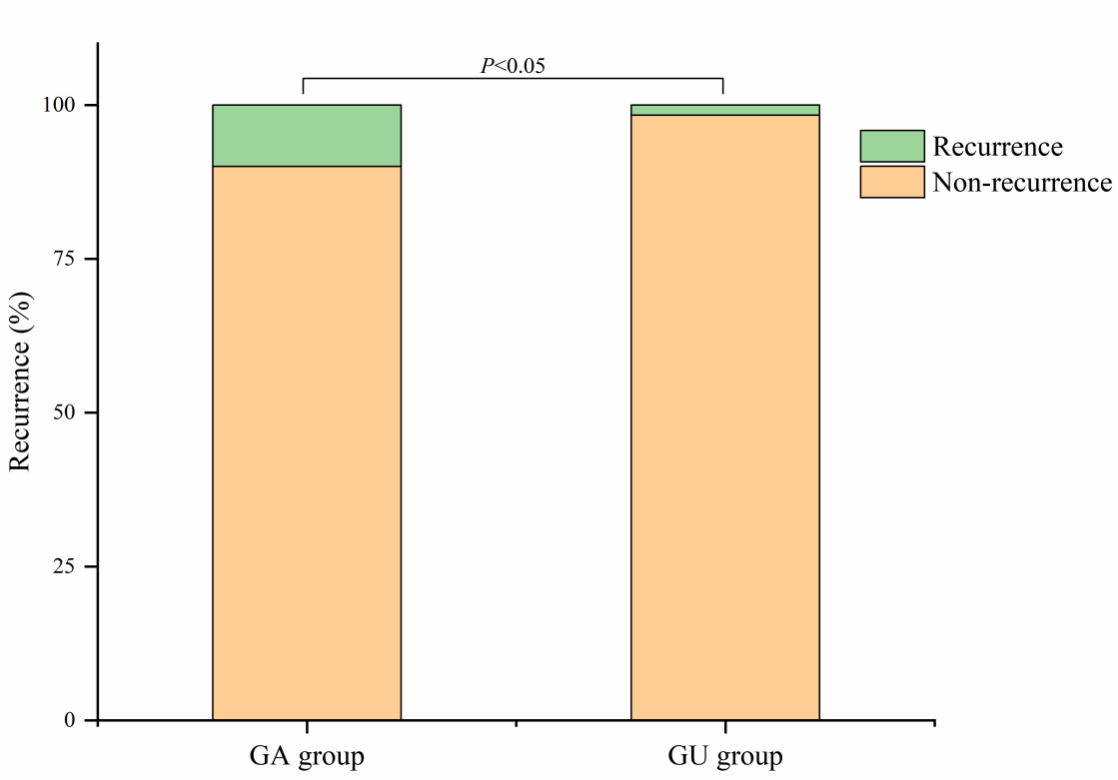

Fig. 2: Recurrence rate

No marked discrepancy was observed among the both groups when compared to the group presenting with complications such as anaemia (P>0.05). The total complication rate in the GU group was 6.67% (4/60) remarkably below the 18.33% (11/60) in the GA group (P<0.05). This indicates that the incidence of complications can be effectively reduced after combined treatment of uterine fibroids.

Recurrence rate

We recorded the recurrence of patients in the both groups during the follow-up period, as demonstrated in fig. 2, the recurrence rate of patients in GA group was 10.00% (6/60) and that of GU group was 1.67% (1/60), which was remarkably different among the both groups (P<0.05). It shows that the combined treatment method used in this study can effectively reduce the recurrence rate after treatment.

Adverse reactions

We followed up the patients to observe the adverse reactions. Adverse reactions such as nausea/vomiting with varying degrees of severity during the treatment period in both groups are presented in table 10. The total adverse reactions incidences in GU group was 6.67% (4/60) markedly below the 16.67% (10/60) in the GA group (P<0.05). It indicated that the combined treatment method was effective in reducing the incidence of adverse reactions.

DISCUSSION

Uterine fibroids are the most common benign tumours in premenopausal women, with a high incidence during the reproductive years, making them an important public health problem. In recent years, the incidence of uterine fibroids is increasing and tends to be younger with the changes in people's living environment and habits (Ahmad *et al.*, 2023). Fibroid tissues are divided into 3 categories according to their relationship with the uterine muscle wall: intermural fibroids, subplasma fibroids and submucosal fibroids. Submucosal fibroids are the most likely type to present with clinical symptoms because they are located in or protrude into the uterine cavity, which increases the endometrial area, affects menstrual blood discharge during menstruation and interferes with the endometrial tolerance, which may lead to symptoms such as excessive menstrual flow, prolonged bleeding during menstruation, vaginal discharge, dysmenorrhea, recurrent miscarriage, infertility and anaemia (Uimari *et al.*, 2022). Submucosal fibroids may cause serious symptoms even if they are small in size and need to be treated aggressively once symptoms appear (McWilliams and Chennathukuzhi, 2017).

Oral medications as well as surgical methods are often used in clinical practice. Pharmacological treatments are effective in the short term and are suitable for those with mild symptoms, near menopausal age, or whose systemic conditions do not favour surgery. Commonly used drugs

include GnRHa and mifepristone (Ali, Ciebiera, Vafaei*, et al.*, 2023). GnRH-a has the characteristics of long duration of a single dose and few adverse reactions, which can improve the local symptoms of patients by regulating their sex hormone levels and can significantly reduce the size of uterine fibroids and at the same time, it can effectively improve the symptoms of excessive menstruation, anaemia, abdominal pain, frequent urination, etc. and improve the quality of life of patients (Filindris *et al.*, 2024). However, adverse reactions such as headache may occur and the fibroid may enlarge again after stopping the drug. Surgery is the main treatment method. For patients with large fibroids, obvious symptoms, ineffective drug treatment or suspected malignancy, myomectomy or hysterectomy can be chosen according to the patient's age, fertility requirements and general condition. However, it is more traumatic for patients and will affect their endocrine function (Metwally *et al.*, 2020). In recent years, UPMA has been widely used in the clinic due to its advantages of less trauma and faster recovery (Cianci *et al.*, 2023). During the procedure, ultrasound guidance can monitor the ablation process in real time and precisely control the positions of the microwave antenna and the ablation range to ensure the accuracy and safety of the treatment (Ali, Ciebiera, Wlodarczyk*, et al.*, 2023). Therefore, this study focuses on the combined treatment of uterine fibroid patients with GnRH-a and UPMA, comparing the clinical efficacy, observing the volume of fibroids and complications after the treatment and analysing the efficacy and safety of the combination of the two treatments with a view to providing more clinical references.

The results of this study indicated that after treatment, the indicators of the both groups of patients were statistical significance comparing with pre-treatment. In the treatment of uterine fibroids, the change in the volume of fibroids as well as the shrinkage rate is a key indicator that directly reflects the effect of treatment. If the fibroids volume is significantly reduced and the shrinkage rate is high, it usually indicates that the treatment plan is effective, which can make the fibroids tissue be inhibited or destroyed and achieve the expected therapeutic purpose (Sohn *et al.*, 2018). The outcomes of this study indicated that the fibroids volume was markedly reduced in both groups post-treatment and the FSR of the GU group was remarkably above the GA group (P<0.05), suggesting that the combined treatment was effective in reducing the fibroids volume. We evaluated the severity of the patients' symptoms and the results indicated that the SSS scores of the patients in the GU group were remarkably below the GA group, indicating that the combined treatment was effective in improving the severity of the patients' fibroids. Changes in sex hormone levels are closely related to the development of uterine fibroids. Detection of sex hormone levels, combined with patients' clinical symptoms, signs and other examination results, can help in the diagnosis and differential diagnosis of uterine fibroids (Navarro *et al.*, 2021). CA125 is a glycoprotein tumour-associated antigen that helps to differentiate uterine fibroids from other gynaecological diseases (Ruma *et al.*, 2025). VEGF is a highly specific pro-vascular endothelial cell growth factor. Angiogenesis in uterine fibroids can be indirectly assessed by measuring VEGF levels. Patients with uterine fibroids often suffer from chronic blood loss due to excessive menstrual flow and prolonged menstrual periods, which in turn causes anaemia. HGB level is an important indicator of the degree of anaemia (Aimagambetova *et al.*, 2024). The findings indicated that the sex hormone levels, CA125 and VEGF levels were markedly below in GA group and the HGB levels were markedly above in GA group (P<0.05). The clinical efficacy of GU group was above GA group (P<0.05). It indicates that the clinical efficacy of GnRH-a combined with UPMA for the treatment of patients with uterine fibroids is remarkable, which can effectively reduce the patients' sex hormone levels and CA125 and VEGF levels and increase the HGB level. Lv et al. reported similar findings in a study on the clinical application of ultrasound-guided percutaneous perforation polyguirol sclerotherapy for symptomatic uterine fibroids (Lv *et al.*, 2021). Similar evaluation was reported by Liu et al. in a study of GnRH-a combined with laparoscopic treatment of giant uterine fibroids (Liu and Zhang, 2023).

We analysed the pain level of the patients and the results demonstrated that the VAS scores of the patients in the GU group were remarkably below the GA group (P<0.05). In uterine fibroid studies, UFS - HRQL scores can assess the severity of symptoms and also evaluate the impact on patients' quality of life (Soliman *et al.*, 2015). The results showed that patients in GU group had markedly lower scores of UFS and higher scores of HRQL than GA group (P<0.05). In addition, the total incidence of complications, recurrence rate and total incidence of adverse reactions of patients in the GU group were markedly below the GA group (P<0.05). This indicates that the combined treatment method can reduce the pain level and improve the quality of life of patients and can effectively reduce the complications and adverse reactions, which is worthy of further promotion and application in the clinic.

This study has some limitations. The sample size was relatively small and failed to cover the different conditions of all patients with uterine fibroids, which may lead to biased findings and affect the extrapolation and reliability of the conclusions. There are differences in the patients' own underlying conditions, which may affect the generalisability of the study results. In addition, the relatively short follow-up period did not allow adequate assessment of the long-term effects and safety of the treatment. Therefore, future studies should further expand the sample size and extend the follow-up time to more comprehensively assess the efficacy and safety of GnRH-a combined with UPMA for the treatment of patients with uterine fibroids.

CONCLUSION

This study analysed the clinical efficacy of GnRH-a combined with UPMA in the treatment of patients with uterine fibroids, in order to provide a new pharmacological pathway for the treatment of this type of disease. The results showed that after treatment, all the indicators of patients in both groups improved. It shows that both groups have certain efficacy in treating uterine fibroids and the efficacy of combined treatment is remarkable, which can better improve the severity of fibroid symptoms and improve the quality of life, providing a new reference method for the clinical treatment of related diseases. However, the present study exists a small sample size and a short course of clinical medication, failing to observe the long-term effectiveness of this method of treatment. Due to the limitation of the conditions, more specific indexes such as others could not be added. Multi-centre, large-sample, high-quality clinical studies can be carried out in the future for verification.

Consent to participate

We secured a signed informed consent form from every participant.

Ethical approval

This experiment was approved by Zhangye Second People's Hospital Ethics Committee. (No. 23JRRG0023)

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Author contribution

[Jie Zhu]: Developed and planned the study, performed experiments and interpreted results. Edited and refined the manuscript with a focus on critical intellectual contributions.

[Mei Li, Fan Yang, Shenglian Cao]: Participated in collecting, assessing and interpreting the date. Made significant contributions to date interpretation and manuscript preparation.

[Haoguo Tang, Qiang Liu, Haisen Xu]: Provided substantial intellectual input during the drafting and revision of the manuscript.

Conflicts of interest

The authors declare that they have no financial conflicts of interest.

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