

Original Article

Clinical efficacy of ultrasound-guided radiofrequency ablation and lauromacrogol sclerotherapy for uterine fibroids

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Abstract: Objective: To explore the efficacy of ultrasound (US)-guided radiofrequency ablation (RFA) and lauromacrogol sclerotherapy for women with uterine fibroids. Methods: This study was a prospective single-center randomized controlled clinical trial. A total of 84 patients with uterine fibroids were randomly divided into two groups (the study group and the control group) with 42 cases in each group. Patients in the control group received US-guided transabdominal RFA, while patients in the study group were treated with US-guided transabdominal RFA plus lauromacrogol sclerotherapy. The total rate of effective treatment was then compared between the two groups. Color Doppler ultrasound of the uterus was performed to evaluate changes in uterine fibroid volumes, and ovarian hemodynamic parameters including resistance index (RI), pulsation index (PI), peak systolic blood flow velocity (V_{max}) and minimum end-diastolic blood flow velocity (V_{min}). Levels of follicle stimulating hormone (FSH), luteinizing hormone (LH), and estradiol (E_2), and scores for symptom severity before and after treatment were also compared between the two groups. Results: The study group had significantly higher total rate of effective treatment than the control group (95.24% vs. 78.57%, $P < 0.05$). Both groups showed significant reduction in fibroid volumes (both $P < 0.05$), and improvement in symptom severity (both $P < 0.05$) after treatment. The changes were more noticeable for the study group (both $P < 0.05$). Both groups experienced significantly reduced PI and RI (all $P < 0.05$), and increased V_{max} and V_{min} (all $P < 0.05$) after treatment. The changes were also more marked for the study group (all $P < 0.05$). There was no statistically significant difference in levels of FSH, LH and E_2 between the two groups before and after treatment (all $P > 0.05$). Conclusion: US-guided RFA and lauromacrogol sclerotherapy can significantly reduce uterine fibroid volumes, and improve the ovarian hemodynamics with minimal impact on ovarian endocrine function for patients with uterine fibroids. It is worth being popularized in clinical practice.

Keywords: Uterine fibroid, ultrasound-guided radiofrequency ablation, lauromacrogol sclerotherapy, ovarian hemodynamics

Introduction

Uterine fibroids are a common reproductive system disease found in women of childbearing age. Women aged 30-50 are more likely to develop such conditions, accounting for about 30% of all cases of uterine fibroids [1]. Research shows that the incidence of uterine fibroids in China was 11.21% in 2011, and it becomes more common as women age, especially during a woman's 40s [2]. Typical symptoms of uterine fibroids are lower abdominal masses, pain, heavy menstrual bleeding and irregular periods. Without timely treatment, the fibroid volume will continue to increase, and result in very large fibroids, which can be difficult to remove,

compromising patients' fertility and decreasing their quality of life [3].

In the past, hysterectomy, myomectomy and oral medications were commonly used for the treatment of uterine fibroids. Hysterectomy involves the surgical removal of the uterus, which makes pregnancy nearly impossible. Therefore, it can only be applied to patients who do not wish to get pregnant in the future. In addition, hysterectomy risks damaging abdominal organs, and has a high rate of postoperative complications such as incision infection, intestinal adhesion and intestinal obstruction. Myomectomy removes only the symptom-causing fibroids and leaves the uterus intact, but it is often

ineffective in taking out very large fibroids. The traumatic nature of this surgical procedure makes it unsuitable for some patients [4, 5].

Medications such as gonadotropin-releasing hormone agonists can block the function of gonadal axis, inhibit the secretion of ovarian hormones and shrink fibroids. However, drug therapy often has a long course of treatment, and fibroid size tends to increase after the discontinuation of medications. Therefore, drugs are often used for the preparation of surgeries, and are not preferred for the treatment of uterine fibroids [6].

In recent years, radio frequency ablation (RFA), a minimally invasive technique, has been widely used for the treatment of uterine fibroids. It can specifically target the desired fibroid tissue without significant collateral damages, and is effective in destroying small fibroids, as well as improves the prognosis of patients [7]. However, some studies have found that RFA is limited in its effects on very large fibroids (diameter >5 cm) with less common locations [8]. It cannot ablate large fibroids thoroughly, and is associated with complications such as fever, vaginal bleeding and discharge, menorrhagia and dyspnea [9]. Lauromacrogol, as a new foamy sclerosing agent, can act as a local anesthetic and provide effective pain relief [10]. Ultrasound (US)-guided injection of lauromacrogol into the center of fibroids can induce aseptic inflammation around the fibroid tissues, and reduce their blood supply, so as to reduce their size [11].

Our study aimed to explore the efficacy of ultrasound-guided RFA combined with lauromacrogol sclerotherapy for women with uterine fibroids.

Materials and methods

Patients

A total of 84 patients with uterine fibroids treated in The Second Clinical Hospital Affiliated to Changjiang University, Jingzhou Central Hospital were selected as subjects and were divided into two groups (42 cases in each group) according to random number tables. Patients in the control group received US-guided transabdominal RFA, while patients in the study group were treated with US-guided transabdominal RFA plus lauromacrogol sclerotherapy. All

patients took part in this study of their own free will and signed the informed consent. This study was approved by the Ethics Committee of The Second Clinical Hospital Affiliated to Changjiang University, Jingzhou Central Hospital.

Inclusion criteria: Patients met the diagnostic criteria for uterine fibroids according to "Consensus for diagnosis and treatment of uterine fibroids among Chinese experts" published in 2017 [12]; patients with fibroids measuring ≤ 6 cm in diameter, or intramural fibroids measuring ≤ 4 cm in diameter or less than 4 submucosal fibroids measuring ≤ 5 cm in diameter; patients aged 18-60; patients had no hormone medications previously; patients had no endometrial abnormality as confirmed by histopathological examination of endometrial biopsy; patients refused hysterectomy or myomectomy.

Exclusion criteria: Patients were pregnant or lactating; patients with plans to have children and had multiple fibroids; patients with severe heart, liver or kidney diseases; patients were allergic or had contraindications to lauromacrogol; patients with coagulation disorder and severe anemia.

Methods

All patients received examinations including routine blood work, blood sugar, blood pressure, electrocardiogram, liver and kidney function, and coagulation function. RFA was performed 3-7 days after menstruation when all parameters of the above tests were within the normal range.

Patients in the control group received US-guided transabdominal RFA. Before the operation, the patient was required to keep her bladder moderately full.

The patient was then placed in a bladder lithotomy position, and had the electrode plates placed in the lumbosacral region. The power was set at 25-60 W according to the size of the fibroid. Pubic hair was removed, and the vulva was routinely disinfected. Sterile surgery drapes were put into place. The cervix was fully exposed by a vaginal speculum, and then sterilized. Philips IU Elite color ultrasound system (Philips Medical Systems, Japan) was used to observe the location, size and blood flow of

Radiofrequency ablation and lauromacrogol sclerotherapy

the uterine fibroids, and determine the depth of the uterine cavity. The Cool-tip™ RF ablation system (Valley Lab, USA) was then applied for the ablation of tumors. First the radio frequency probe was slowly placed into the center of a fibroid through the uterine cavity. Then, radiofrequency thermal effect was used to ablate the fibroid tissues layer by layer until complete coagulative necrosis was achieved.

Patients in the control group were treated with US-guided transabdominal RFA plus lauromacrogol sclerotherapy (Shenxi Tianyu Pharmaceutical Ltd.). RFA was performed in the same way as the control group. A 18G PTC needle (Tianjin Wego Molecular Diagnosis Technology Co., Ltd., China) was used to puncture through the posterior vaginal fornix and enter the center of a uterine fibroid after the ablation procedure. Lauromacrogol was then injected into the fibroid, and the needle was rotated during injection to allow lauromacrogol to fully fill the contrast medium perfusion area of the fibroid.

Observation indexes

Clinical efficacy: The efficacy of treatment was divided into three categories: marked effect, effective and ineffective. Marked effect: symptoms including lower abdominal masses, pain, menorrhagia, and irregular periods disappeared or improved significantly, with completely removed fibroids or at least 60% reduction in fibroid volume; effective treatment: symptoms abated, and fibroid volume reduced by more than 20%; ineffective treatment: the above criteria were not met. Total rate of effective treatment = number of patients who had effective treatment or for whom treatment effect was marked/total number of patients *100%.

Fibroid volumes: Philips IU Elite color ultrasound system was used to measure and compare fibroid volumes between the two groups before treatment and 3 months after treatment.

Ovarian hemodynamic parameters: Ovarian hemodynamic parameters including resistance index (RI), pulsation index (PI), peak systolic blood flow velocity (V_{max}) and minimum end-diastolic blood flow velocity (V_{min}) were measured and compared between the two groups before treatment and 3 months after treatment.

Endocrine function: On the 3rd day of menstruation, venous blood sample (drawn from veins

near the elbow, 4 mL) was collected from patients on an empty stomach to compare the ovarian endocrine function between the two groups before treatment and 3 months after treatment. Levels of follicle stimulating hormone (FSH), luteinizing hormone (LH), estradiol (E_2) were detected by chemiluminescent immunoassay.

Severity of clinical symptoms: The Uterine Fibroid Symptom and Quality of Life (UFS-QOL) Symptom Severity subscale was used to assess symptom severity of the two groups before treatment and 3 months after treatment. The scale consists of 8 items: heavy menstrual bleeding, blood clots, irregular menstrual cycle, irregular menstrual duration, lower abdominal fullness and pain, frequent urination during daytime, frequent urination at night, and fatigue. All items are scored on a 5-point Likert scale, ranging from “not at all” (1 point) to “a very great deal” (5 points). Symptom severity score = (sum of individual item score-8)/32*100.

Statistical methods

The SPSS 22.0 statistical software was used to analyze data. The measurement data were expressed as mean \pm standard deviation ($\bar{x} \pm s$). Paired t-test was used for comparison within groups before and after treatment. Independent t-test was used for comparison between groups. Enumeration data were expressed as n (%), and were compared with χ^2 test. Rank variables were compared with Mann-Whitney U test. $P < 0.05$ meant the difference was statistically significant.

Results

Comparison of clinical data between the two groups

There was no statistically significant difference in age, course of disease, and diameter, number and types of fibroids between the two groups before treatment (all $P > 0.05$). See **Table 1**.

Comparison of efficacy of treatment between the two groups

The study group had significantly higher total rate of effective treatment than the control gr-

Radiofrequency ablation and lauromacrogol sclerotherapy

Table 1. Comparison of clinical data between the two groups

Group	Control group (n=42)	Study group (n=42)	t/ χ^2	P
Age (years)	41.3±4.3	41.9±4.7	0.630	0.530
Course of disease (years)	1.76±0.58	1.89±0.65	0.967	0.336
Diameter of fibroids (cm)	3.57±1.21	3.12±1.14	1.754	0.083
Number of fibroids			0.053	0.819
Single	28	27		
Multiple	14	15		
Types of fibroids			0.068	0.785
Subserosal	24	26		
Intramural	9	10		
Submucosal	9	6		

Table 2. Comparison of efficacy of treatment between the two groups (n, %)

Group	Marked effect	Effective	Ineffective	Total rate of effective treatment
Control group (n=42)	19 (45.24)	14 (33.33)	9 (21.43)	33 (78.57)
Study group (n=42)	23 (54.76)	17 (40.48)	2 (4.76)	40 (95.24)*

Note: compared with the control group, *P<0.05.

Table 3. Comparison of fibroid volumes between the two groups before and after treatment ($\bar{x} \pm sd$) (cm³)

Group	Before treatment	After treatment	t	P
Control group (n=42)	45.86±3.85	31.92±2.46	19.774	<0.001
Study group (n=42)	46.12±4.02	23.89±3.18	28.107	<0.001
t	0.303	12.944		
P	0.763	<0.001		

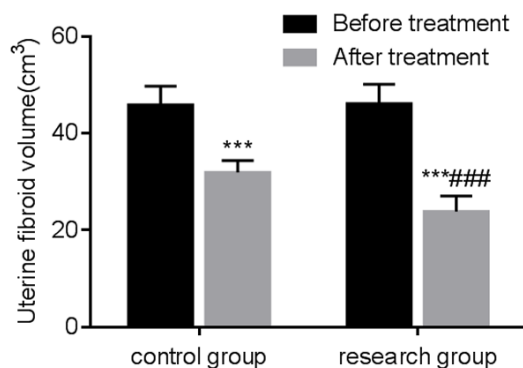


Figure 1. Comparison of fibroid volumes between the two groups before and after treatment. Compared with before treatment, ***P<0.001; compared with control group, ###P<0.001.

oup (95.24% vs. 78.57%, P<0.05), proving the superior efficacy of US-guided RFA and lau-

romacrogol sclerotherapy. See **Table 2**.

Comparison of fibroid volumes between the two groups before and after treatment

There was no statistically significant difference in fibroid volumes between the two groups before treatment (P>0.05). Fibroid volumes decreased in both groups after treatment (both P<0.05), and the decrease was more significant for the study group (P<0.05), suggesting that US-guided RFA and lauromacrogol sclerotherapy can significantly reduce the size of fibroids. See **Table 3** and **Figure 1**.

Comparison of ovarian hemodynamic parameters between the two groups before and after treatment

There was no statistically significant difference in RI, PI, V_{max} and V_{min} between the two groups before treatment (all P>0.05). Both groups experienced significantly reduced PI and RI, and significantly increased V_{max} and V_{min} after treatment (all P<0.05). The changes were more clear for the study group (all P<0.05), showing that US-guided RFA and lauromacrogol sclerotherapy can significantly improve blood supplies to the ovaries. See **Table 4** and **Figure 2**.

Comparison of ovarian endocrine function between the two groups before and after treatment

There was no statistically significant difference in levels of FSH, LH and E₂ between the two groups before and after treatment (all P>0.05), indicating that US-guided RFA and lauromacrogol sclerotherapy did not affect levels of ovarian hormones. See **Table 5** and **Figure 3**.

Radiofrequency ablation and lauromacrogol sclerotherapy

Table 4. Comparison of ovarian hemodynamic parameters between the two groups before and after treatment ($\bar{x} \pm \text{sd}$)

Group	Control group (n=42)	Study group (n=42)	t	P
PI				
Before treatment	1.87±0.45	1.85±0.48	0.197	0.844
After treatment	1.62±0.42*	1.41±0.37**	2.431	0.017
RI				
Before treatment	0.91±0.12	0.93±0.13	0.733	0.466
After treatment	0.82±0.11***	0.71±0.12***	4.379	0.000
V_{max} (m/s)				
Before treatment	0.39±0.19	0.42±0.24	0.635	0.527
After treatment	0.51±0.18***	0.62±0.15***	3.043	0.003
V_{min} (m/s)				
Before treatment	0.16±0.15	0.15±0.13	0.327	0.745
After treatment	0.25±0.12***	0.32±0.11***	2.787	0.007

Note: RI, including resistance index; PI, pulsation index; V_{max}, peak systolic blood flow velocity, V_{min}, minimum end-diastolic blood flow velocity. Compared with before treatment, *P<0.05, **P<0.01, ***P<0.001.

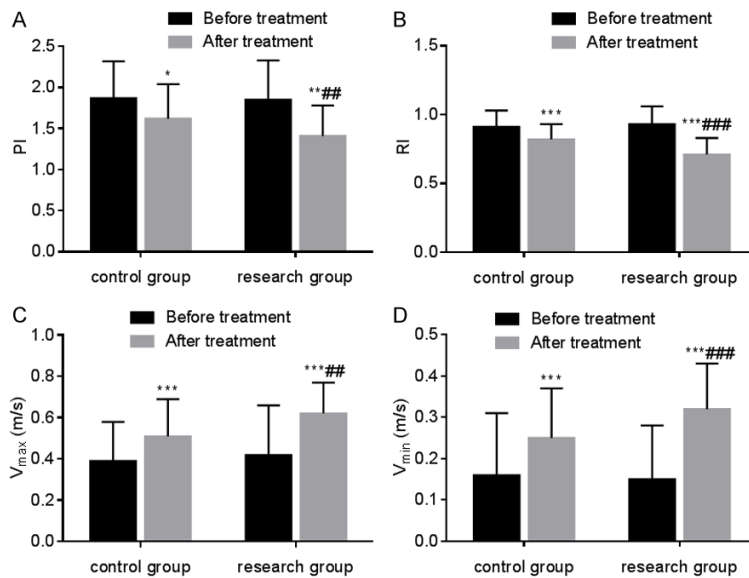


Figure 2. Comparison of ovarian hemodynamic parameters between the two groups before and after treatment. A. Comparison of PI between the two groups before and after treatment; B. Comparison of RI between the two groups before and after treatment; C. Comparison of V_{max} between the two groups before and after treatment; D. Comparison of V_{min} between the two groups before and after treatment. Compared with before treatment, *P<0.05, **P<0.01, ***P<0.001; compared with control group, ##P<0.01, ###P<0.001. PI, pulsation index; RI, including resistance index; V_{max}, peak systolic blood flow velocity; V_{min}, minimum end-diastolic blood flow velocity.

Comparison of symptom severity scores between the two groups before and after treatment

There was no statistically significant difference in symptom severity scores between the two

groups before treatment (P>0.05). Symptom severity scores decreased significantly for both groups after treatment (both P<0.05), and the drop was more noticeable for the study group (P<0.05), revealing that US-guided RFA and lauromacrogol sclerotherapy is more effective in improving fibroid-related symptoms than US-guided RFA alone. See **Table 6**.

Discussion

In recent years, the application of RFA in the treatment of uterine fibroids has caught the attention of my researchers. It uses a high-frequency electric current created by radio waves to heat up targeted tissues and destroy them [14]. However, with its extensive use, doctors found that RFA has limited efficacy in ablating fibroids larger than 5 cm in diameter, and has a high rate of postoperative complications including vaginal bleeding, fever and increased vaginal discharge. In addition, incorrect choice of ablation probes and insufficient ablation time can result in incomplete ablation of lesions, necessitating a second surgery for some patients [15]. Therefore, new treatment methods are needed to overcome RFA's limitations in treating patients with large fibroids.

Lauromacrogol (chemical name: polyethylene glycol monododecyl ether), is a foamy sclerosing agent, and when injected into the vein, it does not mix with blood but rather displaces it, resulting in great

surface contact with the vascular endothelial cells. It has been widely used in treatment of varicose veins, vascular malformations and organ bleeding. Recent studies have shown that the injection of lauromacrogol into cysts can induce aseptic inflammation of the endothelial

Radiofrequency ablation and lauromacrogol sclerotherapy

Table 5. Comparison of endocrine function between the two groups before and after treatment ($\bar{x} \pm sd$)

Group	Control group (n=42)	Study group (n=42)	t	P
FSH ($\mu\text{g/L}$)				
Before treatment	34.25 \pm 2.22	33.97 \pm 2.61	0.530	0.598
After treatment	33.18 \pm 2.85	32.20 \pm 2.18	1.872	0.064
LH (U/L)				
Before treatment	26.36 \pm 4.02	26.58 \pm 3.78	0.258	0.797
After treatment	25.67 \pm 3.56	26.08 \pm 2.45	0.650	0.517
E_2 (nmol/L)				
Before treatment	278.56 \pm 35.25	275.12 \pm 32.96	0.462	0.645
After treatment	268.78 \pm 35.41	269.21 \pm 33.54	0.060	0.952

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

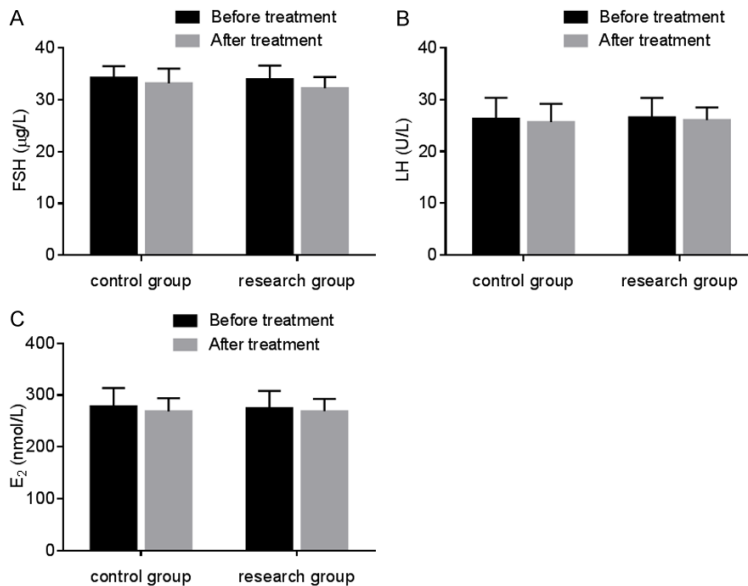


Figure 3. Comparison of ovarian endocrine function between the two groups before and after treatment. A. Comparison of FSH levels between the two groups before and after treatment; B. Comparison of LH levels between the two groups before and after treatment; C. Comparison of E_2 levels between the two groups before and after treatment. FSH, follicle stimulating hormone; LH, luteinizing hormone; E_2 , estradiol.

Table 6. Comparison of symptom severity scores between the two groups before and after treatment

Group	Before treatment	After treatment
Control group (n=42)	28.09 (6.71-54.11)	11.47 (3.46-38.21) ^{***}
Study group (n=42)	29.74 (7.22-55.32)	3.29 (0-13.25) ^{***,###}

Note: compared with before treatment, ^{***}P<0.001; compared with control group, ^{***,###}P<0.001.

cells in the cyst wall, and destroy the normal structure of cyst cavity, eventually cause the cysts to harden, close up, and being absorbed

by local tissue [16]. Li Qing et al. used lauromacrogol as the sclerosing agent for the treatment of renal cysts and injected it via a 16G central venous catheter. The results showed that compared with conventional methods, sclerotherapy with lauromacrogol had the advantages of significant clinical efficacy, no residual cystic fluids, and favorable safety [17].

At the same time, some scholars began to apply it to the treatment of uterine fibroids.

Research by Ni Xuejun et al. found that the average percentage of fibroid volume reduction was 21.07% 3 months after RFA combined with US-guided foam lauromacrogol sclerotherapy for the treatment of uterine fibroids. Color Doppler ultrasound showed that blood flow in the fibroids decreased significantly [18].

Zhou Xia et al. used US-guided lauromacrogol sclerotherapy for the treatment of uterine fibroids, and found that the mean percentage of fibroid volume reduction at 1-, 3-, 6- and 12-month follow-up was 40%, 47%, 58% and 70%, respectively. They also found that scores of symptom severity decreased significantly after treatment, and no serious complications occurred during and after operation [19]. These results confirmed that lauromacrogol sclerotherapy was a safe and effective minimally invasive procedure, and had the potential to complement RFA for the treatment of uterine fibroids.

The results of our study showed that the study group had considerably higher rate of effective treatment than the control group. The study

group also had more noticeable fibroid volume reduction and clinical symptom improvement. These results were consistent with the findings reported by Zhang Yingzhong et al., proving the superior efficacy of US-guided RFA and lauromacrogol sclerotherapy in treating patients with uterine fibroids [20].

The reasons could be that development in medical imaging technology makes possible the precise placement of radiofrequency probe into the fibroids, allowing effective removal of residual lesions with minimal damage to nearby tissues [21-24]. Secondly, lauromacrogol is an ether compound, and it can damage the endothelial cells that line the blood vessels of fibroids, result in clots that block blood flow to the fibroids, and produce inflammation and fibrosis. The result is permanent occlusion of pathological blood vessels, coagulative necrosis of fibroids, and fibroid volume reduction [25-27].

The effects of different therapies for uterine fibroids on ovarian endocrine function and blood supply have been widely researched [28, 29]. Our study found that the study group had significantly lower PI and RI, and higher V_{max} and V_{min} than the control group after treatment. However, there was no statistically significant difference in levels of FSH, LH and E_2 between the two groups before and after treatment. Li Ling et al. found that microwave ablation and RFA were effective in the treating uterine fibroids, and did not affect the production of hormones by ovaries, which was consistent with the results of our study [30].

However, studies by Wang Xiaotao et al. showed that US-guided RFA and lauromacrogol sclerotherapy could significantly reduce fibroid volume, and lower levels of E_2 , FSH and LH. They further speculated that the decrease in E_2 , FSH and LH levels was caused by RFA, as lauromacrogol had no effects on the level of sex hormones [31]. This speculation was inconsistent with the results of our study and studies by other scholars. In our effort to explain this inconsistency, we found that patients recruited in their study had much larger fibroids (mean fibroid diameter: 4.02 cm) than those in our study. Therefore, we believed that this large size of uterine fibroids could explain the discrepancy.

This study was limited by its small sample size of only 84 women, and the relatively short follow-up period of just 3 months. A large-sample study with a longer follow-up period and further grouping of patients according to fibroid size is needed to verify the efficacy of US-guided RFA and lauromacrogol sclerotherapy for the treatment of uterine fibroids.

In conclusion, US-guided RFA and lauromacrogol sclerotherapy are effective in treating patients with uterine fibroids, which can significantly reduce uterine fibroid volumes, improve ovarian hemodynamics and alleviate clinical symptoms.

Disclosure of conflict of interest

None.

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Radiofrequency ablation and lauromacrogol sclerotherapy

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Radiofrequency ablation and lauromacrogol sclerotherapy

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