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# Ultrasound-guided transvaginal radiofrequency myolysis for symptomatic uterine myomas

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ABSTRACT

*Objective:* To investigate the feasibility, efficacy and safety of ultrasound-guided transvaginal radiofrequency myolysis for symptomatic uterine myomas.
*Study design:* Forty-six premenopausal women with symptomatic uterine myomas received ultrasound-guided transvaginal radiofrequency myolysis as an outpatient procedure. Outcomes were assessed by measuring myoma volume at baseline and at 3-, 6- and 12-month follow-up; and by calculating the myoma volume reduction rate. Clinical improvement was assessed by calculating the menorrhagia score, the symptom severity score and the health-related quality-of-life score (Uterine Fibroids Symptom and Health-related Quality-of-life Questionnaire) before and after myolysis.
*Results:* The mean age of patients was 40.8 [standard deviation (SD) 6.5] years. The mean diameter of the dominant myoma at baseline was 4.8 (SD 1.1) cm and the mean volume of the dominant myoma at baseline was 67.4 (SD 51.1) $cm^3$. The size of the myoma decreased gradually and an overall volume reduction rate of 83.0% was achieved at 12-month follow-up. The mean symptom severity score decreased and mean health-related quality-of-life score increased; the Uterine Fibroids Symptom and Health-related Quality-of-life Questionnaire showed a significant clinical improvement after myolysis compared with baseline ($p < 0.001$). The menorrhagia score decreased significantly from baseline ($p < 0.05$), showing an improvement in menorrhagia at 3-, 6- and 12-month follow-up. No major complications were observed or reported. The re-operation rate was 8.7%. Fifteen and eighteen months after myolysis, two patients delivered infants with no complications during or after delivery.
*Conclusion:* Ultrasound-guided transvaginal radiofrequency myolysis may be a safe, effective and minimally invasive outpatient procedure for the treatment of symptomatic uterine myomas.


## 1. Introduction

Uterine myomas are the most common benign tumours in women of reproductive age. Most women with myomas remain asymptomatic, but approximately 25% of women experience symptoms including menorrhagia, pressure symptoms, dyspareunia, secondary dysmenorrhoea, pelvic pain, and reproductive problems such as infertility and miscarriage.

Current treatment methods include medical and surgical approaches. Medical treatment [e.g. gonadotrophin-releasing hormone agonist (GnRH)] has shown a significant reduction in uterine size and volume within 3 months of therapy. However, there is rapid resumption of pretreatment uterine values after discontinuation of therapy and associated side effects when used for an extended period of time. Surgical approaches include myomectomy and hysterectomy. Myomectomy is often performed to preserve reproductive potential. However, the tumour recurrence rate is 40–50% following this approach. Hysterectomy is indicated in patients with uterine myomas who do not wish to retain their reproductive potential. As with any surgery, both myomectomy and hysterectomy have significant morbidity rates [1].

In recent years, there has been an increasing need for safe and efficient options to treat symptomatic uterine myomas while conserving the uterus in women who wish to retain their reproductive potential. Therefore, several conservative treatments such as uterine artery embolization, cryomyolysis, high-intensity focused ultrasound and radiofrequency myolysis have been suggested.

Myolysis was introduced in the late 1980s in Europe as a conservative treatment for uterine myomas. Myolysis refers to the destruction of uterine myomas by focused energy. Initially, neodymium:yttrium–aluminium–garnet lasers were used for coagulative necrosis of myomas and destruction of vascularity by thermomyolysis [2]. Subsequently, bipolar electrodes, monopolar

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electrodes and cryoprobes have been used as energy sources [3–5]. Bergamini et al. [6] reported that laparoscopic radiofrequency thermal ablation of symptomatic myomas reduced symptoms and the myoma volume. Efficacy and safety of the various myolysis techniques have since been reported [7].

Transvaginal radiofrequency myolysis can be performed as an outpatient procedure and does not require general anaesthesia, additional laparoscopic procedures or hospital admission. Patients can usually resume their normal activities within a few hours of surgery. Therefore, the present study was performed to evaluate the safety and feasibility of ultrasound-guided transvaginal radiofrequency myolysis for the treatment of symptomatic uterine myomas.

## 2. Materials and methods

This study was approved by the Ethics Committee of the Chinese Ministry of Health and Chinese Medical Association in China.

Premenopausal women with symptomatic uterine myomas were enrolled into this study from January 2009 to January 2012. The main symptoms were menorrhagia (47.8%), bulk-like symptoms (e.g. frequent urination and constipation, 30.4%) and pelvic pain (17.4%). Six patients (13.0%) desired future pregnancy. All patients were counselled extensively on the potential risks and benefits of the procedure, and on possible alternative treatments before giving their written informed consent. The inclusion criteria were: premenopausal women with symptomatic uterine myoma who declined hysterectomy or myomectomy; desire for future pregnancy; not responsive to medical therapies such as GnRH agonists for a period of 3 months; non-pedunculated subserosal myomas; normal endometrial biopsy findings; normal Pap test and normal coagulation test. The exclusion criteria were: presence of more than three myomas; pelvic inflammatory disease; current pregnancy; abnormal coagulation test; abnormal endometrial biopsy findings; abnormal Pap test; history of severe chronic disease or unstable cardiac status; severe anaemia and pedunculated subserosal myomas. Myoma size was not considered as an exclusion criterion.

The radiofrequency generator used in this study (BBT-RF-B Q/XBT01-2002 2003 B2 166; Ban Bian Tian Medical Apparatus and Instruments Company, Xi An City, China) operates at 50 Hz with a transmitting power of 300 W and temperatures ranging from 80 °C to 85 °C. The tissue impedance characteristics, power and ablation time are displayed. The needle electrode used (Ban Bian Tian Medical Apparatus and Instruments Company, Xi An City, China) was 35 cm long with an exposed distal tip.

Pretreatment evaluation included both transabdominal and transvaginal ultrasound to determine the number, dimensions and locations of the myomas. Radiofrequency myolysis of uterine myomas was performed as an outpatient procedure under mild sedation. The procedure was performed between 3 and 7 days after menstruation to reduce the risk of extensive haemorrhage during myolysis. The patients were placed in the lithotomy position, and the dispersive electrode pad was placed on the anterior thigh of the patient. The power of the generator during the procedure was set at 20 W. The urinary bladder of the patients was moderately full, and a radiofrequency needle was introduced transcervically under transabdominal ultrasound guidance. The needle was positioned and penetrated through the endometrium, and the targeted myoma was punctured. During ablation, a single needle deployment or two to three needle deployments were performed to treat the myoma. The tip of the needle electrode was maintained 10–15 mm from the serosal layer of the myoma to prevent uterine perforation. Throughout the procedure, ultrasound was performed transabdominally and the ultrasound probe was kept parallel to the direction of the needle electrode. The vital signs of all patients were monitored carefully. The procedure stopped automatically with an alarm when the myoma coagulated with optimal power. The targeted myoma was ablated when the area of echogenecity reached 80–90% of the cross-sectional view of the myoma on real-time ultrasound (Fig. 1). To avoid haemorrhagic complications, the needle track was cauterized at the end of the procedure by application of a radiofrequency current and by setting the power of the generator to 10 W while the needle was withdrawn.

Ultrasound and symptom assessment were performed just before the radiofrequency myolysis (baseline) and at 3-, 6- and 12-month follow-up (Figs. 1 and 2, and Table 2). When more than one myoma was treated in a single patient, the characteristics of the dominant myoma were considered for statistical analysis, although myolysis was performed in all myomas. During follow-up, the treated myomas were evaluated by tracking the echo-enhanced round zones and the secondary cystic changes.

The volume of each myoma was calculated by the following formula:

$$\text{Volume} = 0.5233 \times \text{D1} \times \text{D2} \times \text{D3}$$

where D1 is the longitudinal dimension, D2 is the anteroposterior dimension and D3 is the transverse dimension.

All patients underwent a thorough clinical evaluation, which included symptom severity and quality of life [Uterine Fibroids Symptom and Quality of Life (UFS-QOL) questionnaire], and menorrhagia score.

The UFS-QOL questionnaire consists of eight questions on the severity of symptoms and 29 questions on health-related quality of life (HR-QOL). Two distinct scores were calculated for symptom severity and quality of life. Raw scores were converted to a transformed score using the following formula:

$$\text{Transformed symptom severity scale score} = \frac{\text{actual raw score} - 8}{32} \times 100$$

$$\text{Transformed HR-QOL score} = \frac{145 - (\text{actual raw score})}{116} \times 100$$

Higher symptom severity scores are indicative of greater symptom severity, while higher quality-of-life scores indicate better health-related quality of life.

The menorrhagia score was evaluated by assessing the patients for menorrhagia before and after myolysis. The patients were instructed as required and asked to use 240-mm sanitary pads for every menstrual period. In accordance with Heath et al. [8] in combination with the pictorial blood analysis chart, the degree of soiling of pads used by the patients was given a score: one point was given for each light bleed, two points were given for each medium bleed and three points were given for each heavy bleed that occurred during the menstrual period (Fig. 3). The patients were asked to count the number of soiled pads used over a 24-h period and to note the score of each pad every day. A score was calculated for each day and summed at the end of the month.

The menorrhagia score was evaluated by the following formula:

$$\begin{aligned}\text{Menorrhagia score} = {} & (\text{number of days of heavy bleeding} \\ & \times \text{score for the degree of soiled pads} \\ & \times \text{total number of pads used during these days}) \\ & + (\text{number of days of medium bleeding} \\ & \times \text{score for the degree of soiled pads} \\ & \times \text{total number of pads used during these days}) \\ & + (\text{number of days of light bleeding} \\ & \times \text{score for the degree of soiled pads} \\ & \times \text{total number of pads used during these days})\end{aligned}$$