Original Article

Ultrasound-Guided Percutaneous Microwave Ablation for Subserosal Uterine Myomas

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ABSTRACT Study Objective: To prospectively evaluate the clinical effectiveness and safety of ultrasound-guided percutaneous microwave ablation for symptomatic subserosal uterine myomas.

Design: Prospective observational study (Canadian Task Force classification II-1).

Setting: A teaching hospital (Department of Interventional Ultrasound, General Hospital of Chinese PLA, Beijing, China).

Patients: Sixty-nine patients with symptomatic subserosal uterine myomas treated with ultrasound-guided percutaneous microwave ablation.

Interventions: All 69 patients underwent ultrasound-guided percutaneous microwave ablation. The number of patients lost to follow-up was 21 at 3 months, 34 at 6 months, and 35 at 12 months.

Measurements and Main Results: The efficacy of treatment was evaluated based on the mean myoma volume shrinkage rate and changes in Uterine Fibroid Symptom and Quality of Life Questionnaire scores at 3, 6, and 12 months after therapy. Treatment safety was evaluated based on the Society of Interventional Radiology practice guidelines. The mean patient age was 40.3 ± 4.9 years (range, 26–49 years). The mean myoma volume was 221.74 ± 153.18 cm³ before ablation, decreasing to 87.24 ± 45.93 cm³ at 3 months after ablation (p < .001), 46.68 ± 24.7 cm³ at 6 months after ablation (p < .001), and 38.05 ± 24.93 cm³ at 12 months after ablation (p < .001), respectively. Between pretreatment and 3-month follow-up, the mean symptom severity score decreased from 34.53 ± 3.83 to 12.74 ± 3.07 (p < .001), and the mean health-related quality of life score increased from 45.25 ± 10.97 to 78.48 ± 11.39 (p < .001). Both scores remained stable at the 6- and 12-month follow-up time points. No permanent injury or fatal complications were seen in this series.

Conclusion: Ultrasound-guided percutaneous microwave ablation of subserosal uterine myomas is a promising treatment method. Further studies with larger sample sizes and a control group are needed. Journal of Minimally Invasive Gynecology (2019) 26, 544–550. © 2018 Published by Elsevier Inc. on behalf of AAGL.

Keywords: Ablation; Microwave; Subserosal uterine myoma; Ultrasound

Uterine myomas are the most common benign tumors in women of reproductive age [1]. According to the International Federation of Gynecology and Obstetrics (FIGO) classification system, myomas can be classified into 9 types. Among these, type 5 (subserosal, ≥50% intramural), type 6 (subserosal, <50% intramural), and type 7 (subserosal, pedunculated) are subserosal myomas [2–4]. When large, these types of myomas may cause urinary symptoms, constipation, and pelvic pressure [5,6]. In recent years, ultrasound (US)-guided percutaneous microwave ablation (PMA) has been widely used to treat certain symptomatic myomas and has demonstrated satisfactory efficacy with intramural and submucosal myomas [7,8]; however, to date, no systematic study has evaluated its use for subserosal uterine myomas. Some technical difficulties precluded analysis of type 7 myomas, so this type was considered outside the scope of this study. The purpose of this study was...
to evaluate the clinical effects and safety of PMA use for type 5 and 6 subserosal myomas.

Ultrasound-guided PMA has not received US (Food and Drug Administration) approval, but has been approved by the Chinese FDA.

Materials and Methods

Study Participants and Enrollment

Between August 2010 and August 2016, a total of 69 Chinese patients with symptomatic subserosal uterine myomas were enrolled in this study. The mean patient age was 40.3 ± 4.9 years (range, 26–49 years). The patient inclusion criteria were diagnosis of type 5 or 6 subserosal myoma by magnetic resonance imaging (MRI) and ultrasonography, the presence of subserosal uterine myoma-related symptoms (e.g., pelvic pressure, frequent micturition), the desire for uterine preservation, a history of regular periods, a safe abdominal puncture path, and myoma diameter ≥4 cm. Exclusion criteria included pregnancy, the presence of a nodule for which leiomyosarcoma could not be excluded (tumors with an intermediate T2-weighted, high b1000 signal intensity and a low ADC value could not exclude a malignancy), pelvic inflammation, and anesthesia intolerance.

All patients were counseled on the potential risks and benefits of PMA and possible alternative treatments, including laparoscopy, uterine artery embolization, and radiofrequency ablation. All patients provided written informed consent.

Institutional Review Board approval was obtained for this prospective study. The study has been registered at the Chinese Clinical Trial Registry (http://www.chictr.org.cn; registration no. ChiCTR-TRC-10001119; date of trial registration June 1, 2010).

Equipment and Procedures

A KY-2000 microwave (MW) tumor coagulator (Kangyou Medical Instruments, Nanjing, China) with a frequency of 2450 MHz was used (Fig. 1A and B). The microwave antenna was 180 mm long and 15 gauge and had internal water cooling and embedded aperture microwave emission (Fig. 1C). An Acuson Sequoia 512 Computer Color ultrasonography unit (Signature 10.2: Siemens Medical Solutions, Mountain View, CA) with a puncture-guided device and contrast-enhancing function was used in this study.

Before ablation, all patients underwent a contrast-enhanced MRI (ce-MRI) examination to identify the nodule type and distinguish it from leiomyosarcoma. Ultrasonography was used to assess myoma volume [9] and evaluate for pelvic fluid.

Ablation was performed under intravenous conscious sedation (induction: midazolam 1.0 mg, fentanyl 0.05 ng, and propofol 1.0–1.5 mg/kg; maintenance: propofol...

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**Fig. 1**

Working end of the instrument. (A) KY-2000 microwave tumor coagulator. (B) Control panel of the microwave tumor coagulator. (C) Microwave antenna (180 mm long, 15 gauge).
The whole procedure was monitored by real-time ultrasound. The MW tumor coagulator antenna was inserted into the leiomyoma percutaneously. A single antenna was used for myomas with a mean diameter <5 cm and lower perfusion, whereas double antennae were used for myomas with a mean diameter ≥5 cm or those <5 cm with a rich blood supply. The output MW energy was set at 50 or 60 W, which creates a nearly spherical ablated zone [10]. The flowing hyperecho, caused by microbubbles generated during MW emission, can be a rough indicator of the ablated zone [11]. When the hyperecho covered the entire nodule, MW therapy was discontinued [12]. Contrast-enhanced ultrasound (CEUS) was then performed to assess ablation effect. The contrast agent (SonoVue; Bracco, Milan, Italy) was mixed with 5 mL of normal saline, and 2.4 mL of the mixture was administered as a rapid bolus infusion into the median cubital vein, followed immediately by injection of 5 mL of normal saline. If there was no enhancement within the lesion, the treatment was completed [12]. On completion of therapy, the depth of pelvic fluid in the Douglas pouch was recorded.

Guidelines for PMA included the following. Before antenna insertion, the probe was used to slowly push the abdominal wall, moving the intestine away from the puncture path. Bladder catheterization was used to adjust the degree of bladder filling to change the position of the uterus and bring the myoma close to the abdominal wall. The filled bladder also decreased the bladder temperature, helping protect it from thermal injury when the myoma to be ablated was near the bladder. For patients with nonanterior myomas, the antenna was inserted through the uterine fundus to avoid damage to the endometrium. In some cases, the operator had difficulty inserting the antenna into a myoma on the posterior uterine wall without injuring the endometrium. The use of a uterine manipulator to lift and move the uterus and bring the myoma closer to the abdominal wall solved this problem. This technique allowed the antenna to reach the target myoma through the uterine fundus without injuring the endometrium. After insertion of the antenna, the uterine manipulator should be removed. For myomas near the rectum, artificial pelvic fluid was used to protect the rectum from thermal injury. To produce the artificial pelvic fluid, normal saline was injected through the abdominal wall into the peritoneal cavity under ultrasound guidance using an 18-gauge intravenous catheter (Angiocath; BD, Franklin Lakes, NJ). The drip infusion was continued via the catheter during the ablation procedure to maintain separation between the uterus and rectum of at least 0.5 cm [13].

All PMA procedures were performed by 2 doctors, J. Z. and Z.H., each of whom has performed more than 500 PMAs. Antibiotics (tinidazole and levofloxacin hydrochloride) were administered after ablation for infection control.

**Technical Security Assessment**

Each complication was categorized based on the Society of Interventional Radiology (SIR) practice guidelines. The SIR classification system for complications by outcome is as follows: A, no therapy, no consequence; B, nominal therapy, no consequence (includes overnight admission for observation only); C, require therapy, minor hospitalization (<48 hours); D, require major therapy, unplanned increase in level of care, prolonged hospitalization (>48 hours); E, permanent adverse sequelae; F, death [14].

**Effectiveness Assessments**

CE-MRI examination was performed within 3 days of ablation to confirm the ablated zone and check the safety of the surrounding organs. The nonperfused area was defined as necrotic tissue.

Outcomes were evaluated at 3, 6, and 12 months after PMA, including the myoma volume shrinkage rate (measured by ultrasound), patient symptoms, and quality of life. Ultrasonography was performed to determine myoma volume (MV), which was calculated using the maximum extent of 3 vertical lines (for length, width, and height) according to the following formula: MV = 0.523 × length × width × height. The shrinkage rate (%) was equal to 100 × (MVpreablation – MVpostablation)/MVpreablation. Patient symptoms and quality of life were assessed using the Uterine Fibroid Symptom and Quality of Life questionnaire, which consisted of a symptom severity score (SSS) and a health-related quality of life (HRQL) score; the questionnaire was designed for self-administration [15].

Recurrence was both clinical (reappearance of symptoms) and anatomic (increase in leiomyoma size or detection of new leiomyomas) [16].

**Statistical analysis**

All analyses were performed with the SPSS 13.0 software package (SPSS Inc., Chicago, IL, USA). The MV and UFS-QOL scores were presented as means ± SDs because of asymptotic normality. Because of multiple comparisons, the Type I error rate (alpha) was adjusted using the Bonferroni adjustment. A value of p < 0.016 (0.05/3) was considered to indicate statistical significance. Side-effects and complications were statistically described by frequency.

**Results**

A single myoma was treated in each of the 69 patients. Fifty-one myomas were type 5, and 18 were type 6, in anterior (n = 20), posterior (n = 25), fundal (n = 15), and lateral (n = 9) locations. Preablation myoma diameter ranged from 5.7 to 10.9 cm (mean, 7.2 ± 1.5 cm).

Four patients had been treated by laparoscopic myomectomy (LM) at 3 to 5 years before the procedure. Fifty-six
patients (81.2%) had at least 2 subserosal myoma-related symptoms, and the other 13 (18.8%) had only 1 symptom before ablation (Table 1).

No patient requested a second PMA or further treatment for myoma-related symptoms. The ablation time ranged from 520 to 3000 seconds. The nonenhanced volume, representing necrotic areas, was $193.41 \pm 125.35 \text{ cm}^3$ on ce-MRI at 3 days after ablation (Fig. 2B) and $182.37 \pm 110.72 \text{ cm}^3$ on immediate postablation CEUS (Fig. 3D).

Forty-eight patients (69.6%) attended scheduled follow-up at 3 months, 35 (50.7%) did so at 6 months, and 34 (49.3%) did so at 12 months. The remaining patients (20, 33, and 34, respectively) missed their hospital follow-up appointments. Except for 1 patient who could not be reached, we contacted all these patients by telephone. Satisfactory symptom relief and far distance from our hospital were the 2 main reasons given for nonattendance. The average follow-up period for the entire cohort was 6.6 months.

For those women who came for follow-up, clinical symptoms improved. The symptom severity score had decreased and the health-related quality of life had increased significantly at the 3-month follow-up compared with preablation values. The 6- and 12-month follow-up scores were not significantly changed compared with the 3-month values. The follow-up data are presented in Table 2.

On follow-up, 17 of the 51 type 5 myomas (33.3%) had transformed into type 4, and their mean myoma volume decreased from $202.23 \pm 65.66 \text{ cm}^3$ before ablation to $56.59 \pm 28.89 \text{ cm}^3$ at follow-up. In addition, 4 of the 18 type 6 myomas (22.2%) had transformed into type 5, and their mean myoma volume decreased from $212.26 \pm 43.75 \text{ cm}^3$ before ablation to $64.31 \pm 22.56 \text{ cm}^3$ at follow-up.

Two patients gave birth by cesarean section after ablation. To our knowledge, both were unplanned pregnancies and neither involved complications. Owing to the novel nature of this procedure and in accordance with the ethics requirements, initial trials were restricted to patients with no desire for future fertility, and most of the patients were age > 40 years.

Ten of the 69 patients (14.5%) experienced lower abdominal pain immediately after ablation. Four patients (5.8%) who had grade 4 pain on a 5-point scale received pethidine or bucinnazine hydrochloride, and they recovered within 6 days.

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### Table 1

<table>
<thead>
<tr>
<th>Symptom</th>
<th>Number (%)</th>
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<tbody>
<tr>
<td>Frequent urination</td>
<td>44 (63.8)</td>
</tr>
<tr>
<td>Pelvic pain</td>
<td>33 (47.8)</td>
</tr>
<tr>
<td>Constipation</td>
<td>16 (23.2)</td>
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Contrast-enhanced magnetic resonance imaging (ce-MRI) changes preablation and postablation in a 39-year-old woman with a single subserosal myoma. (A) Preablation ce-MRI showing enhancement within the subserosal myoma (arrows). (B) Ce-MRI at 3 days postablation showing nonenhancement within the myoma.
hours (SIR class C). Six patients (8.7%) experienced grade 2 or 3 pain and recovered within 4 hours without any medication (SIR class B). The depth of pelvic fluid in the Douglas pouch before and after ablation did not change significantly.

**Discussion**

PMA is a minimally invasive method of tumor treatment performed under ultrasound guidance. The microwave heated center can reach 65°C to 100°C in seconds and can completely coagulate the tumor tissue [17].

After ablation therapy, myoma volume decreased dramatically, and subserosal myoma-related symptoms improved significantly in the first 3 months and remained stable at late follow-up. These results are in accordance with previous studies [7,8,18].

LM has clear medical, social, and economic advantages [19,20]. However, managing type 5 and 6 subserosal
myomas with LM may be technically challenging [20], especially for large myomas that are deeply embedded in the myometrium [21], and carries increased risks of hemorrhage and conversion to laparotomy [22]. In contrast, PMA is associated with a smaller wound surface that can readily coagulate [23], such that there is minimal bleeding into the peritoneal cavity during the procedure. However, PMA is not suitable for FIGO type 7 tumors, for 2 reasons. First, a pedunculated subserosal myoma is not easy to fix when the microwave antenna is inserted, so the antenna could injure the surrounding tissues. Second, after ablation, fracture of the pedicle could lead to separation of the myoma from the uterus.

Some aspects of subserosal myoma PMA treatment require further study. For example, subserosal myomas may develop a specific feeding artery and obtain their blood supply from other vascular structures [24]. In such cases, thorough ablation may prevent recurrence. Nevertheless, vital organs that surround subserosal myomas, such as the bladder, rectum, and iliac artery, are at greater risk of thermal injury than during treatment of other types of myomas. Therefore, rigorous temperature control is important, even though no method exists to monitor the temperature of every point around the antenna (i.e., temperature mapping). In this study, the operator estimated the ablation area using the flowing hyperechoic signal, which cannot accurately predict the risk of thermal injury to surrounding organs. Finding ways to solve these dilemmas is of paramount importance. Although no recurrence was reported in this study, recurrence has been found with the use of other technologies [16].

In conclusion, US-guided PMA is a promising technique for treating subserosal uterine myomas with good efficacy and some unique advantages. However, additional studies may be needed; for example, studies with longer follow-up periods and larger sample sizes, and trials looking at subsequent fertility rates, methods for accurate temperature monitoring, and how PMA compares with LM or other treatment.

References


