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A retrospective comparison of microwave ablation and high intensity focused ultrasound for treating symptomatic uterine fibroids

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ABSTRACT

Objectives: To retrospectively compare the effectiveness and safety of percutaneous microwave ablation (PMWA) and ultrasound-guided high-intensity focused ultrasound (USgHIFU) for treating symptomatic uterine fibroids.

Methods: Seventy-three women with symptomatic uterine fibroids who met the inclusion criteria were enrolled in our study from September 2012 to December 2013. Thirty-one patients with forty uterine fibroids underwent PMWA, and forty-two patients with fifty-one uterine fibroids underwent USgHIFU. A contrast-enhanced MRI was performed before and after treatment, and all patients were followed up for 6 months. Assessment endpoints included symptom severity scores (SSS), treatment time, ablation rate, fibroid regression rate and adverse events.

Results: The mean age of the patients in our study was 35.4 ± 6.2 years (range, 21–49 years), and the median volume of uterine fibroids was 95.7 cm^3 (60.3–131.5 cm^3). The ablation rate of uterine fibroids was 79.8 ± 18.2% and 77.1 ± 14.9% in the PMWA group and the USgHIFU group, respectively, and showed no significant difference between the groups. Changes in SSS after PMWA were similar in the PMWA group (47.7 pre-treatment vs. 29.9 post-treatment) and USgHIFU group (42.1 pre-treatment vs. 24.6 post-treatment). The regression rate of uterine fibroids also showed no marked difference between the two groups (PMWA, 50.3%; USgHIFU, 52.4%). The median treatment time of the PMWA group was 46.2 min, which was demonstrably superior to USgHIFU. Finally, the occurrence rate of adverse events was the same in the two groups.

Conclusions: The safety and effectiveness of PMWA and USgHIFU in the treatment of uterine fibroids were similar; however, the median treatment time of PMWA was shorter than that of USgHIFU.

1. Introduction

Uterine fibroids, which are frequently encountered benign tumors in women of reproductive age, have typically been treated by hysterectomy in past years. However, in recent years, there is an increasing appreciation that diseases that cause harm require therapies that are harmless. Many women with uterine fibroids are choosing minimally invasive treatments, such as high-intensity focused ultrasound (HIFU) and percutaneous microwave ablation (PMWA). HIFU, a non-invasive thermal ablation technique that uses a focused ultrasound beam to ablate fibroid tissue, which has been widely used in the treatment of uterine fibroids and has proved to be extremely safe and effective [1–4]. PMWA is a minimally invasive thermal ablation technique for treating uterine fibroids by inducing coagulation necrosis of the target fibroids. Previous studies have demonstrated that PMWA has a higher potential for the conservative treatment of uterine fibroids [5–7].

Both HIFU and PMWA are thermal ablation techniques, and they are both safe and reliable alternative treatment methods for uterine fibroids. However, until now, there have been no clinical trials to compare the therapeutic effects of HIFU and PMWA, so whether there are obvious differences in symptom improvement, treatment time, ablation rate, regression rate and adverse events between these two approaches remains unknown. In this research, we retrospectively compare the results of these two treatment methods.

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2. Materials and methods

2.1. Patients and enrollment

This retrospective study was approved by the Ethics Committees at Chinese PLA General Hospital, and all enrolled patients signed informed consent for the treatment and for the future use of the data collected.

Seventy-three women with symptomatic fibroids were enrolled in the study between September 2012 and December 2013. Uterine fibroids were confirmed by contrast enhanced magnetic-resonance imaging (CE-MRI) before treatment. Before choosing treatment, the patient was informed of the possible efficacy and side effects of both treatments to allow her to come to a rational decision. Thirty-one women with forty uterine fibroids underwent PMWA, and forty-two women with fifty-one uterine fibroids underwent USgHIFU.

The selection criteria for this study were as follows: presence of a clinical syndrome, such as menorrhagia, dysmenorrhea, lower abdominal pain, urinary frequency; age older than 18 years but premenopausal; diameter of uterine fibroids $\geq$4 cm and $\leq$10 cm; and no previous surgical treatment or other minimally invasive treatment (such as UAE, cryoablation, radiofrequency). Patients with active menstruation, pregnancy, pelvic infection, severe heart disease, severe cerebrovascular disease, mental disorder, or malignant tumors were excluded from the study.

2.2. PMWA and USgHIFU procedure

2.2.1. PMWA procedure

We used a KV2100 Microwave tumor treatment device (Nanjing Kangyou Microwave Energy Sources Institute; frequency, 2450 MHz; needle type, internal water-cooling; electrode diameter, 15 G; electrode length, 180 mm; power, 0–100 W; distance from the aperture of the MW emission to the needle tip, 11 mm). The principle of microwave treatment is to cause tumor necrosis by heating tissue via the thermal energy produced by the agitation of water molecules. For the PMWA procedure, the patient laid on her back on the operating table. After intravenous anesthesia (flurbiprofen ester 2 mg/kg, propofol 4 mg/kg/h; intravenous anesthesia for this surgical treatment method is easy, simple, and has a rapid effect) was established, PMWA procedures were performed by the same experienced doctor. First, the percutaneous microwave electrode was placed into the fibroids under the guidance of ultrasound. Based on the dose–effect relation of microwave ablation, the output power was set at 50 W. A single microwave electrode was used for uterine fibroids with diameters of 4–5 cm, and a double microwave electrode with a distance of approximately 1.5 cm between electrodes was used for uterine fibroids larger than 5 cm. The distance between the electrode tip and the pseudocapsules was greater than 5 mm. During MW emission, the ablation area was monitored by ultrasound in real time. MW emission was stopped when the entire lesion was covered with hyperechoic microbubbles. Finally, contrast-enhanced ultrasound (SonoVue, Bracco Sine Pharm) was performed immediately after the procedure for preliminary evaluation of ablation efficacy, and if blood stream perfusion was detected in the fibroid, a supplementary treatment was performed.

2.2.2. USgHIFU procedure

The USgHIFU ablation procedure was performed by using a JC USgHIFU tumor therapeutic system (Chongqing Haifu Technology, Chongqing, China; transducer diameter, 20 cm; focal length, 15 cm; frequency, 0.8 MHz; power, 0–400 W). All patients were given preoperative intestinal preparation, mandatory enema and skin preparation, and patients were placed in the prone position. During the operation, an intravenous sedative (midazolam, 1–4 mg) and analgesic (fentanyl, 50–400 μg) were given to maintain conscious sedation. A water balloon compressor was used to push away the bowel in the acoustic pathway and to avoid intestinal damage. Patients were requested to report any discomfort, and their vital signs were monitored. Treatment began by placing the focus into the uterine fibroid at least 1 cm away from the pseudomembrane of the fibroid and 1.5 cm from the endometrium to prevent injury to the normal myometrium and endometrium. Targeted lesions were fractionally ablated, slice by slice, from the deep to the shallow regions of the tumor.

2.3. Study endpoints

The study's primary endpoints were symptom severity scores (SSS, containing 8 questions regarding the severity of symptoms, scale of scores was 5–40), treatment time (time from sonication emission to the completion of ultrasonic emission), ablation rate (the percentage of non-perfused fibroid volume after treatment compared to before treatment measured by enhanced images), regression rate of uterine fibroids (fibroid volume changes using volumes determined before treatment and after 6 months by T2-weighted MRI; fibroid volumes by MRI were calculated according to the formula $4/3\pi \times (d/2)^3$, where d = (length + width + height)/3 and adverse events (according to updated the standards established by the Society of Interventional Radiology [8]).

2.4. Statistical analysis

Normal distribution tests were conducted for the variables, and non-normal distribution data were analyzed after normal transformation. The NPV ratio, treatment time, ablation rate, SSS, regression rate, and rate of adverse effects were statistically analyzed using one-way ANOVA and the Mann–Whitney U test and chi-square test. Statistical significance was set at a P-value less than 0.05, and statistical analysis was performed by using SPSS19.0 software (SPSS, IBM Company, Chicago, USA).

3. Results

3.1. Baseline information

A total of 73 women with symptomatic fibroids in the period from September 2012 to December 2013 underwent either PMWA (31 women) or USgHIFU (42 women) therapy in a single session at our institution. The average age of the patient was 35.4 ± 6.2 years (range, 24–50 years), the mean fibroid diameter was 66.2 ± 11.2 mm (range, 40.3–100.0 mm), and the mean fibroid-related SSS was 31.2 ± 7.2 (19–38) before treatment. The baseline demographic data of the two groups are given in Table 1, which shows no significant differences in the baseline data between the PMWA group and the USgHIFU group.

3.2. Post-procedure evaluation of PMWA

The PMWA procedure was successfully performed for all 31 patients in this group. The median treatment time was 46.2 min (range, 35.4–60.7 min) for patients, the immediate mean ablation rate after treatment was 79.8 ± 14.9% (range, 70.9–99.1%), the average regression rate was 52.4% (range, 43.1–68.7%) at 6 months after the procedure, and the mean SSS decreased from 32.6 to 21.3, falling by an average of approximately 10.2 points (range, 5.4–16.7) (Fig. 1, Table 2). The common adverse events after treatment were lower abdomen pain, vaginal discharge and low-grade fever; these symptoms were generally mild, were classified as grade A or B according to the unified standardized Society of Interventional Radiology (SIR) grading system, did not require medical attention, and lasted