Received:
3 February 2016

Revised:
23 October 2016

Accepted:
26 October 2016

<https://doi.org/10.1259/bjr.20160119>

Cite this article as:

Hai N, Hou Q, Ding X, Dong X, Jin M. Ultrasound-guided transcervical radiofrequency ablation for symptomatic uterine adenomyosis. *Br J Radiol* 2017; **90**: 20160119.

FULL PAPER

Ultrasound-guided transcervical radiofrequency ablation for symptomatic uterine adenomyosis

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Objective: To retrospectively evaluate the midterm outcomes of transvaginal ultrasound-guided radiofrequency ablation (RFA) for the treatment of symptomatic uterine adenomyosis.

Methods: 87 patients with symptomatic uterine adenomyosis, who met the inclusion criteria, were enrolled in our study from January 2013 to October 2015. All of the patients underwent transvaginal ultrasound-guided RFA and were followed up for 12 months. Assessment end points included uterus volume reduction rate, lesion regression rate, dysmenorrhoeal score, symptom severity score (SSS) and adverse events.

Results: In all 87 patients, 81 patients fulfilled the follow-up evaluations post-ablation. The mean uterine volume

reduction rate was 35.8% at 1 month, 40.8% at 6 months and 41.2% at 12 months post-ablation. Dysmenorrhoea and SSS statistically significantly declined. Reintervention rate was 18.5%. Two patients developed intrauterine adhesion after ablation. No serious complications including penetration or burn injuries of the nearby organs were observed.

Conclusion: Ultrasound-guided RFA might be a safe and effective minimally invasive alternative in the treatment of symptomatic adenomyosis.

Advances in knowledge: This is the first study to evaluate the efficacy and safety of ultrasound-guided RFA for the treatment of adenomyosis to our knowledge. This is also the first study to provide various changes of intrauterine cavity after this treatment.

INTRODUCTION

Adenomyosis or its variance, localized adenomyosis (adenomyoma), is a heterogeneous gynaecological condition. It is caused by the benign invasion of ectopic endometrial glands and stroma in the myometrium. Patients with adenomyosis can have a wide range of clinical presentations. The most common presenting features of adenomyosis include heavy menstrual bleeding, secondary dysmenorrhoea and an enlarged uterus (which may produce pressure symptoms on the bladder or the bowel). However, patients can also be asymptomatic.¹ Hysterectomy is a definite solution, but many females did not want to lose their uterus. There are various conservative treatment options. However, there is still no consensus on the optimal strategy for treating symptomatic adenomyosis.

Radiofrequency ablation (RFA) of tumours results from the heat that is generated from the medium frequency alternating current. The heat causes coagulation necrosis in targeted tumours and obliteration of interstitial vessels. It was first used *via* a laparoscopic approach for treating uterine fibroids and subsequently with ultrasound guidance. Ultrasound-guided RFA can be performed as an outpatient procedure without requiring general anaesthesia and many

studies have reported it as a safe and effective treatment for uterine fibroids.^{2–8} However, there are limited data to support ultrasound-guided RFA for adenomyosis which is like uterine fibroids a benign uterine lesion. Therefore, this study was performed to investigate the efficacy and safety of transvaginal ultrasound-guided RFA for the treatment of symptomatic uterine adenomyosis.

METHODS AND MATERIALS

Participants

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

All the patients were diagnosed with adenomyosis based on ultrasound and MRI apart from some uncertain cases which were confirmed by biopsy. The typical ultrasound findings, including an enlarged uterus, heterogeneous poorly circumscribed areas within the myometrium, increased echotexture of the myometrium and asymmetrical thickening of the myometrial wall, were all considered highly indicative of the presence of adenomyosis.^{9,10}

The selection criteria for this study were as follows: (1) adenomyosis-related symptoms, *e.g.* menorrhagia, dysmenorrhoea or bulk pressure; (2) age between 35 and 50 years; (3) childbearing completed; (4) surgery or other conservative treatments declined; and (5) normal ThinPrep cytology test results.

The exclusion criteria included suspected pelvic endometriosis, pelvic inflammatory disease, concomitant fibroids, any treatment within the 3 months preceding the study and abnormal coagulation test results.

Ultrasound-guided radiofrequency ablation procedure

The radiofrequency (RF) generator used in this study (Ban Bian Tian Medical Apparatus and Instruments Company, Xi'an, China) operates at 50 Hz with a transmitting power of 300 W. The needle electrode used (Ban Bian Tian Medical Apparatus and Instruments Company, Xi'an, China) was 35-cm long with a 1.5-cm exposed distal tip. The output energy was set at 30–50 W. An RF electrode was introduced transcervically under transabdominal ultrasound guidance. The electrode was penetrated through the endometrium and inserted into the lesion. Once the hyperechogenic signal covered nearly 80–90% of the entire lesion on real-time ultrasound, the ablation was discontinued. Technological efficacy of RFA was evaluated by contrast-enhanced ultrasound (CEUS). The non-enhanced regions on CEUS represent necrotic areas. When no focal and/or irregular enhancement is detected within the treated lesion during the dynamic study, we then consider the treatment successful. Treatment is judged as a failure if there is nodular enhancement within the treated region in arterial phase and washout in late vascular phase.¹⁸ A supplementary RFA was immediately performed in the enhanced regions. All patients received oral antibiotic prophylaxis for 3 days after the treatment.

Although MRI has been proved to be accurate in differentiating adenomyosis from uterine fibroid, the image characteristics may overlap.¹⁰ In these cases, a biopsy of the lesion was performed with an 18-gauge core needle for pathological diagnosis. Along the path of the biopsy, the RF electrode was then inserted into the lesion for ablation. The biopsy results confirmed after the procedure helped us determine the future treatment. All the procedures were performed by one experienced doctor who has performed nearly 1000 transvaginal ultrasound-guided RFA for uterine fibroids since 2009.

Study end points ultrasound was performed just before RFA (baseline) and at 1, 6 and 12 months following the treatments. During follow-up, the treated lesions were evaluated by size of the echoenhanced zones and secondary cystic changes (Figure 1). The secondary cystic changes represent liquefaction necrosis of the ablation zone. The mean uterine or lesion diameter and volume were calculated using the following formulas: mean diameter = (length + width + height)/3 and volume = $4/3 \times \pi \times r^3$, where r is the mean radius (mean diameter/2). MR image was not used routinely because the cost was high.

All patients underwent a thorough clinical evaluation before and 12 months after the treatment, which included dysmenorrhoea symptom severity [visual analogue scale (VAS)] and symptom severity score (SSS)¹¹ questionnaires including eight items: heavy bleeding during menstrual periods, passing blood clots during the menstrual period, fluctuation in the duration of the monthly cycle compared with the previous cycle, feeling tightness or pressure in the pelvic area, frequent urination during daytime or night-time and feeling fatigued. Response options for the symptom severity subscale range from “not at all” to “a very great deal”. VAS score ranges from 0 to 10. SSS ranges from 0 to 100 with higher scores indicating more severe symptomatology.

We evaluated minor and major complications during RFA and post-RFA procedure in all patients. Minor complications were defined as temporary and self-limiting symptoms requiring no therapy. Major complications were defined as those requiring further interventions and/or hospitalization.

All the information and data was kept in our RFA treatment data bank.

Statistical analysis

Statistical analysis was performed using SPSS® (v. 22.0; IBM Corp., New York, NY; formerly SPSS Inc., Chicago, IL) for Windows. Mean was compared by *t*-test, and proportions were compared by χ^2 or Fisher's exact tests. Paired *t*-tests were used for changes of each score from baseline. $p < 0.05$ was considered statistically significant.

RESULTS

A total of 87 premenopausal females with symptomatic adenomyosis were enrolled in this study from January 2013 to October 2015. Over the study period, six patients with incomplete data were excluded from this study. The mean age was 40.0 ± 8.5 years, the mean body mass index was 22.5 ± 2.4 kg/m² and the mean pre-operative CA125 was 78.41 ± 57.64 U/ml. Focal thickening of the junction zone (>12 mm) was found in 66 patients (defined as focal adenomyosis) and diffuse thickening of the junction zone was found in 15 patients (defined as diffuse adenomyosis). In the patients with focal adenomyosis, adenomyosis affected the posterior uterine wall in 38 (57.6%) patients, anterior in 20 (30.3%) patients and fundal in 8 (12.1%) patients. To avoid multiple punctures and guarantee a normal uterus wall structure, complete ablation was not performed for the 15 patients in whom adenomyosis was diffuse. The mean ablation time was 25.7 ± 6.2 min (5–40 min). The mean number of punctures ranged from one to three. There were no complications during the procedure.

The mean volume of the focal adenomyosis at baseline was 58.4 ± 35.6 cm³. The mean baseline volume of the uterus was 260.85 ± 149.27 cm³. Compared with the baseline measurement, RFA resulted in a significant decrease in the mean volume of focal adenomyosis change 1, 6 and 12 months after ablation (all $p < 0.001$), and the reduction rate was 31.2, 53.6 and 54.7%, respectively (Table 1). Compared with the mean baseline uterus volume, the volume reduction rate was 35.8% at 1 month, 40.8% at 6 months and 41.2% at 12 months post-procedure (Table 1).

Figure 1. (a) A transvaginal sonographic image before treatment: the adenomyosis affected the posterior uterine wall (arrows = endometrium); (b) 1 month after the procedure (arrows = endometrium, a = needle path); (c) 6 months after the procedure [(i) = the secondary cystic changes; (ii) = the echoenhanced zone]; (d) 12 months after the procedure: the uterus volume reduction is 46%; and (e) evaluation of the volume of the non-perfused region with contrast-enhanced ultrasound guidance (arrows = the non-perfused region).

Of the 81 individuals, 75 individuals suffered from dysmenorrhoea. 11 (14.7%) individuals had dysmenorrhoea with VAS scores of 1–3 points; 43 (57.3%) individuals scored 4–6 points; and 21 (28%) individuals scored 7–10 points. The VAS score declined statistically significantly from 6.9 ± 0.8 before treatment to 1.9 ± 1.2 at 12-month follow-up ($p < 0.001$). Meanwhile, SSS also showed statistically significant improvement by the end of the first year, with scores dropping from a baseline of 44.17 ± 11.31 to 11.85 ± 8.24 at 12-month follow-up ($p < 0.001$). 15 (18.5%) patients (4 patients with focal adenomyosis and 11 patients with diffuse adenomyosis) out of 81 patients showed no improvement and required further treatment. Among them, eight patients refractory to the medical treatment underwent total hysterectomy and four patients received levonorgestrel-releasing intrauterine device therapy, although the remaining three patients with alleviated dysmenorrhoeal received endometrial RFA because they still had persistent heavy menstrual loss.

Two patients developed intrauterine adhesion after ablation. One was a 47-year-old patient who reported hypomenorrhoea at 3-month follow-up. The office hysteroscopic procedure demonstrated endometrial atrophy and a single filmy adhesion on the anterior uterine wall (Figure 2). The second patient was a 43 year old referred back to our hospital with amenorrhoea 6 months after the procedure. We observed a thick intrauterine

adhesion in the central portion of her uterine cavity on hysteroscopic examination (Figure 2). Further treatment was not considered, since the symptom was acceptable to both patients. The characteristics of these two patients are listed in Table 2. 10 patients volunteered to have hysteroscopic evaluation and all of them demonstrated normal uterine cavity (Figure 2). No other post-operative complication was observed.

DISCUSSION

Conservative treatment of adenomyosis is a clinical challenge. Conservative surgery includes excision of focal change and myometrial reduction with electrosurgical myolysis as the option with promising results, but the intraoperative recognition of the lesion is usually difficult and separating normal myometrial tissue from myometrial tissue invaded by adenomyosis can be difficult.^{12–14} Thermal ablation is an established treatment for tumour masses. The merging of developed imaging techniques has allowed precise targeting and accurate evaluation of ablation rate. Currently, the main methods used for evaluating the efficacy of tumour ablation treatment include enhanced CT, enhanced MRI and CEUS. Venous ultrasound contrast agents are able to enter the microcirculation at the blood capillary level and show high sensitivity, specificity and spatial resolution of the perfusion level in target organs.¹⁵ According to previous studies, CEUS allows immediate assessment of the result of ablation and achieves

Table 1. Uterine and focal adenomyosis volume reductions at baseline and follow-up imaging

Time and location of measurement	Number of patients	Volume (cm ³)
Baseline ($n = 81$)		
Uterus	81	260.85 ± 149.27
Focal adenomyosis	66	58.4 ± 35.6
1-month follow-up ($n = 81$)		
Uterus	81	197.75 ± 99.53
Focal adenomyosis	66	47.6 ± 25.5
6-month follow-up ($n = 78$)		
Uterus	75	155.66 ± 97.23
Focal adenomyosis	65	33.3 ± 26.1
12-month follow-up ($n = 75$)		
Uterus	66	153.38 ± 93.65
Focal adenomyosis	60	29.6 ± 16.2

Figure 2. A schematic representation of the various changes of intrauterine cavity after radiofrequency ablation (RFA) by hysteroscopy: (a) 1 month after RFA, hysteroscopic view of a spot (i) was recognized as the puncture point; (b) normal intrauterine cavity 3 months after RFA: the puncture point disappeared; (c) a 47-year-old female developed singular filmy adhesions 3 months post-ablation: the cornual areas were normal; and (d) a 43-year-old female developed a thick intrauterine adhesion from front to back uterine walls in the mid-cavity 6 months after RFA: both tubal ostia are occluded.

similar results to those achieved by enhanced CT and enhanced MRI.^{15–18} In our study, RFA achieved a non-enhanced region of over 70% of the initial lesion size when assessed by CEUS.

There are various thermal ablation techniques such as RFA, cryotherapy, laser ablation and high-intensity focused ultrasound (HIFU). In our study, transvaginal ultrasound-guided RFA effectively relieved the severity of symptoms in females with adenomyosis, as demonstrated by not only the patient pain scores and menorrhagia scales but also the uterine size at the end of the first year. The results in our study revealed that the mean uterine volume and the volume of focal disease change significantly decreased by 41.2% and 54.7%, respectively, at 12 months after RFA, in contrast with those treated with HIFU reported by Ling et al¹⁹ (22% and 30%) and those treated with MRI-guided HIFU reported by Fan²⁰ et al (23.8% and 26.1%). The present improvement in symptoms at 12 months post-procedure was similar to that reported for HIFU.^{21,22} But, the percentage (72%) of serious symptom (defined as VAS score > 3) in our study is higher than that in HIFU studies (15.4% in Zhou et al²¹ and 62% in Lian et al²²). Although HIFU is non-invasive, RFA shares several theoretical advantages over HIFU in that it is relative cheaper, treatment times are shorter and complete ablation rates are better.²³ Furthermore, the effectiveness of HIFU is confined to the location of the lesion. The energy attenuation occurs during transmission of the ultrasonic wave and ultrasonic energy deposition is reduced gradually along its propagation path.²³ If the lesion is too deep, the ultrasound wave may not penetrate deep enough. Moreover, if the lesion is sited on the posterior uterine wall, *i.e.* close to the sacrum, the incidence of heating of the sacral bone will increase and lead to sciatic nerve injury.²⁴ Gong et al²⁵ found that HIFU efficiency was significantly lower in patients with adenomyosis at the posterior

uterine wall in comparison with patients with adenomyosis at the anterior uterine wall. However, the posterior uterine wall is most severely involved in adenomyosis²⁶ and unfortunately, none of the studies above provided the distribution of the predominant area affected by adenomyosis.

There were no major complications such as perforation, peritonitis and sepsis in the present group of patients. Two patients developed intrauterine adhesion after RFA and it is unclear why this occurred. A reasonable explanation would be thermal injury to the endometrium. During the ablation procedure, the endometrium is in close proximity to the ablative field. The present system allows for good targeting of the lesion to be treated, but it is not capable of accurate temperature monitoring. An additional explanation may lie in the actual number of punctures performed during the procedure. Standardization of ablative margin, ablation time and deployment of the RF electrode needle need to be established to optimize the effect of treatment while reducing potential thermal injury. Although several studies reported patients who experienced successful conception and childbirth after transvaginal ultrasound-guided RFA procedure,^{2–8} transcervical insertion of the needle through the endometrium should be avoided in females who want to preserve fertility. Moreover, this method should not be recommended for females with a desire for further pregnancy until effective protective measures for endometrium are warranted.

Limitations inherent to the present study were the lack of a control group, small sample size and its single-centre nature. Therefore, further multicentre and prospective large-sample randomized controlled trials are required before this modality can be widely used in gynaecology field.

Table 2. The information of the lesion and radiofrequency ablation procedure in the females developed IUA post-ablation

Case	Age (years)	Puncture times	Ablation time	Lesion volume (cm ³)	Lesion position	Uterus volume (cm ³)
1	47	2	9 min 28 s	5.3 × 4.7 × 5.1	Posterior wall	8.8 × 8.3 × 7.6
2	43	3	6 min 31 s	5.4 × 5.1 × 3.1	Posterior wall	7.9 × 6.7 × 7.0

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