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Microwave endometrial ablation at a frequency of 2.45 GHz for menorrhagia: analysis of its efficacy, recurrence rate, and complications

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Summary

In late years, microwave endometrial ablation (MEA) has been attracting attention as an effective and minimally invasive treatment alternative to hysterectomy. Microwave irradiation removes whole endometrium including its basal layer and reduces the amount of menstrual bleeding. The authors performed MEA in 103 patients with hypermenorrhea from August 2007 to October 2012. As a note, all patients had no hope of delivering. Among those patients, 72 cases were able to be enrolled for the evaluation. Then, the effectiveness of MEA for the excessive menstruation was evaluated. As a result, the authors have reached the conclusion that MEA is a new effective treatment with safety and good cost performance for excessive menstruation. MEA should be considered as a standard treatment for the conservative therapy-resistant excessive menstruation.

Key words: Hysterectomy; Microwave endometrial ablation; Menorrhagia.

Introduction

Approximately six million women in Japan are said to be suffering from menorrhagia. Currently, we are facing an enormous revolution in how it can be treated. As of April 2014, microwave endometrial ablation (MEA) has been listed for medical insurance coverage under "K863-C 3 Hysteroscopic Endometrial Ablation: 17,810 points". Endometrial ablation was developed as a treatment to replace total hysterectomy. Using microwaves or radiowaves, it induces necrosis of the endometrial tissue and reports on this treatment have been published since the 1980s. MEA using a 2.45-GHz microwave is a novel treatment for menorrhagia that was developed by Kanaoka *et al.* [1]. It was first introduced as minimally invasive treatment in August 2007 at the Department of Obstetrics and Gynecology, School of Medicine, Shimane University. In June 2009, the present authors became the fourth certified institution for advanced medical care in Japan, and have progressively employed this treatment in their practice. In Japan, an estimated 40,000 cases of hysterectomy are conducted every year, and it is speculated that 10,000 hysterectomies are avoided thanks to MEA. In the present department alone, the authors performed 116 cases of MEA surgeries over the past five years and four months, and their institution boasts experience with the largest number of these surgeries in Japan. Until now, they have published reports on the efficacy, safety, and minimal invasiveness of MEA compared to traditional surgery [2-5]. In this study, the authors conducted an investigation of 72 cases that could be evaluated for improvement of menorrhagia after MEA, looking primarily at recurrences or complications, and would like to report their results.

Materials and Methods

MEA was performed in 72 patients with a chief complaint of menorrhagia who had no wish to bear children and who presented to the present gynecology department between August 2007 and April 2012. The 72 cases who were six months or longer post-MEA and in whom the authors could evaluate menorrhagia improvement, were assessed for menstrual interstitial myoma volume, painful periods, and satisfaction with treatment using visual analog scale (VAS) scores. Before MEA was listed for insurance coverage, the Shimane University Institutional Review Board had approved MEA treatments. In addition, written informed consent was obtained after patients were provided with both written and oral explanations of the procedure. After epidural anesthesia and placement in a lithotomy position, the women underwent isodine disinfection of the lower abdomen, genitalia, thighs, and intravaginal area. Using a transabdominal or transrectal ultrasound guide, the entire surface of the endometrium was ablated by MEA, while confirming coagulation of the endometrium throughout the operation. A color Doppler was used with the ultrasound guide, making it easy to confirm which parts of the endometrium had been ablated (Figure 1). Using Microtas output 70W, the energizing time per coagulation was 50 seconds in accordance with the MEA Treatment Guidelines [6].

Results

The 72 women treated with MEA ranged in age from 37 to 53 years with a median age of 46 years. All patients had

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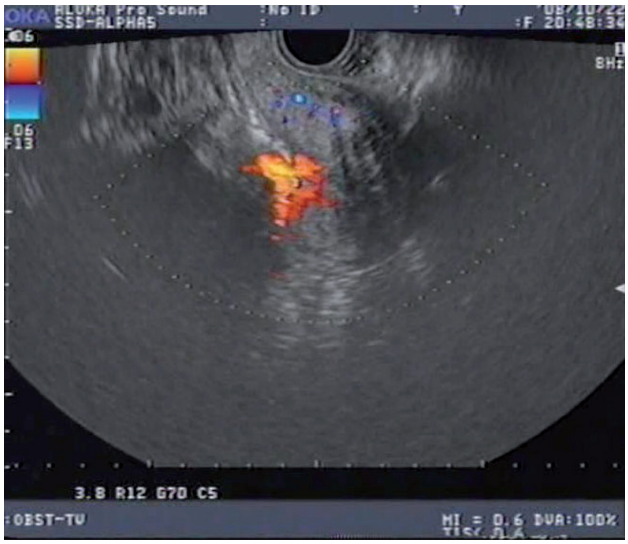

Figure 1. — Ultrasound imaging of endometrium during MEA. Colored area (arrow) indicates an irradiated site during ablation of endometrium.

a chief complaint of menorrhagia. Clinical diagnoses of the 72 cases comprised 47 cases of myoma, 18 cases of uterine adenomyoma (includes four cases of uterine myoma complicated by uterine adenomyoma), nine cases of functional menorrhagia, two cases of intrauterine polyps, and one case of uterine cancer. None of the patients had plans to undergo surgery and presented with massive genital bleeding when they consulted the outpatient clinic, so that emergency MEA was required in 23.6% of these patients. Among these patients, there was one case of uterine cancer, but when the patient presented to the outpatient clinic, she was suffering from uncontrolled genital hemorrhage and so MEA was performed to provide as much hemostasis as possible.

Presurgical Hb values ranged from 6.3-13.9 g/dL, with a mean level of 10.0 g/dL. Surgical times ranges from 14 to 74 minutes with the mean at 37.4 minutes. Hemorrhage volumes ranged from 0 to 300 mL with a mean of 17.0 mL. Hospitalizations ranged from one to 12 days with a mean of 1.5 days. At six months or longer after MEA, menstrual volume, painful menstruation, and satisfaction with treatment were

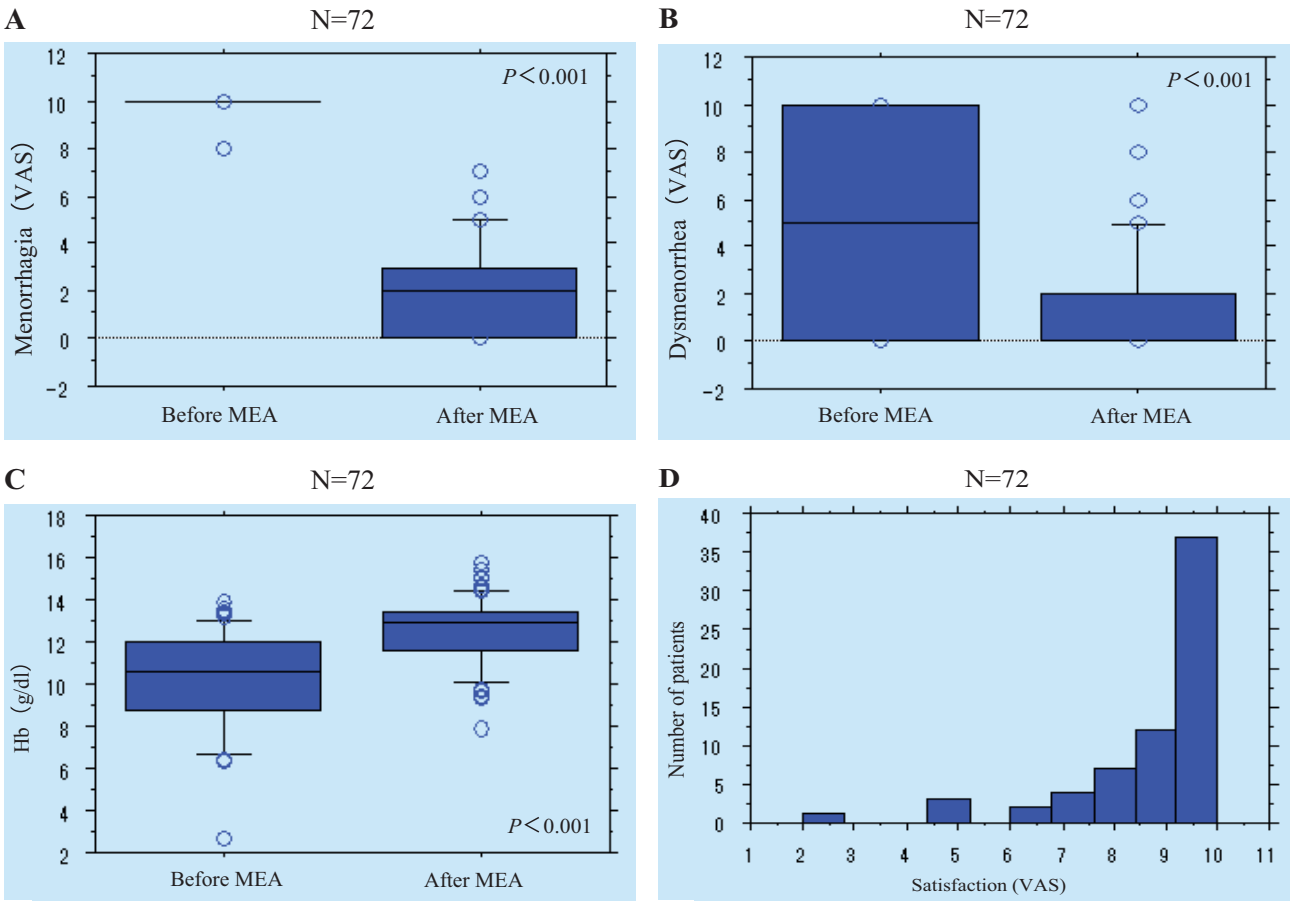

Figure 2. — A: Change in the visual analog scale (VAS) score for menorrhagia prior to and following microwave endometrial ablation (MEA). B: Change in VAS score for dysmenorrhea prior to and following MEA. C: Summary of patient satisfaction for MEA based on VAS score. D: Change in the hemoglobin prior to and following MEA. Revised and cited from references 2, 3, 4, and 5.

Table 1. — *Clinical factors and amenorrhea after MEA.*

Factors	Patients (number)	Amenorrhea Negative	Amenorrhea Positive	*p*-value
Age (years)				
< 45	21	15	6	
≥ 45	51	33	18	0.58
Adenomyosis				
Positive	18	9	9	
Negative	54	39	15	0.08
Myoma: submucosal				
Positive	28	21	7	
Negative	44	27	17	0.23
Myoma: intramural				
Positive	27	25	2	
Negative	45	23	22	0.0003
Myoma diameter > 5 cm				
Positive	19	18	1	
Negative	53	30	23	0.003
Multiple myomata				
Positive	18	15	3	
Negative	54	33	21	0.08
Uterine sounding > 9 cm				
Positive	42	31	11	
Negative	30	17	13	0.13

MEA: microwave endometrial ablation.

evaluated through VAS scoring. VAS scores for menstrual volume improved from an average of 10 before surgery to a mean of 1.8 after surgery ($p < 0.0001$) (Figure 2A). Presurgical VAS scores for painful menstruation improved from a mean of 5.0 to a postoperative mean of 1.4 ($p < 0.0001$) (Figure 2B). At six months post-MEA, Hb values increased from 10.2 before surgery to 12.5 g/dL post-surgery ($p < 0.0001$) (Figure 2C). VAS scores for mean treatment satisfaction were 8.7 (Figure 2D). At six months after surgery, 25 out of the 72 cases became amenorrheic, with a rate of 34.7%. In the 72 patients who could be evaluated for six or more months after surgery, there were five patients in whom treatment was ineffective or menorrhagia recurred (5.3%). The mean duration until recurrence was 9.7 months. Clinical factors that could have been associated with ineffectiveness or recurrence were studied, but the present authors were unable to identify any statistically significant factors (data not shown). In addition, ten out of the 72 cases (13.1%) developed complications such as myometritis/endometritis. In these patients, symptoms were alleviated with oral antibiotic treatment in six cases (60%), while four cases (40%) required i.v. antibiotic infusions. The present authors attempted to identify clinical factors that could have been related to the development of myometritis and endometritis, but nothing proved to be statistically significant (data not shown). In addition, cases with myometrial gliomas and cases free of large interstitial myomas with diameters of five cm or more, were significantly more likely to become amenorrheic after surgery (Table 1). Furthermore, cases from the literature [2-5] were added to the present MEA treatment result data, and some of these cases were added to factor analyses.

Discussion

Although the present data on cases that illustrate the therapeutic efficacy and effectiveness of MEA are limited, the authors have reported their findings in these cases in the past [2-5]. This time, they conducted an investigation in a larger number of cases, and found that the results remained the same. They were again able to confirm MEA's usefulness. Improved VAS scores for menorrhagia and menstrual pain suggest major improvement in the patients' QOL in terms of their menorrhagia. Objective evaluations are often based on Hb values before and after treatment, and the Hb value had improved by 2.3 g/dL at six months after MEA, showing that it had been effective in improving symptoms of anemia. The incidence of menorrhagia recurrence after MEA was 5.5% (4/72), which almost matches the results of Kanaoka *et al.* [7]. In addition, the present authors investigated clinically-related factors that might be associated with the recurrence of menorrhagia, but were unfortunately unable to identify any statistically significant clinical factors that could be linked to this finding. Since they may have failed to find statistically significant clinical factors because there were too few cases, they are currently in the process of collecting cases with Dr. Kanaoka *et al.* for use in a collaborative, large scale, multicenter study.

When the present authors looked at postoperative complications, not even one case of serious complications requiring emergency surgery for situations, such as postsurgical intestinal heat damage was noted. They suspect this was because they adhered to the indications calling for a normal myometrial thickness of one cm or thicker as specified in the MEA guidelines. At the present institution, in order to further ensure patient safety, the authors include color Doppler imaging during transabdominal and transrectal ultrasonography guidance (Figure 1). As a result, it was easy to confirm the ablation points of the sounding applicator, allowing them to perform MEA more safely. The US FDA has also added a condition that the myometrium must be at least 1.0 cm in thickness to approve use of the MEA system. As of that time, the incidence of extrauterine organ damage in the subsequent 5,000 cases performed has been 0 cases [8]. The present authors believe it is important to adhere to these guidelines strictly in order to prevent serious complications, especially since MEA is predicted to spread rapidly throughout Japan hereafter [6]. In addition, as a mild complication of MEA, endometritis and myometritis was observed in 13.8% (10/72). Interestingly, at one week post-MEA, not a single case presented with myometritis/endometritis at the present outpatient clinic, and all cases of myometritis/endometritis developed their dis-

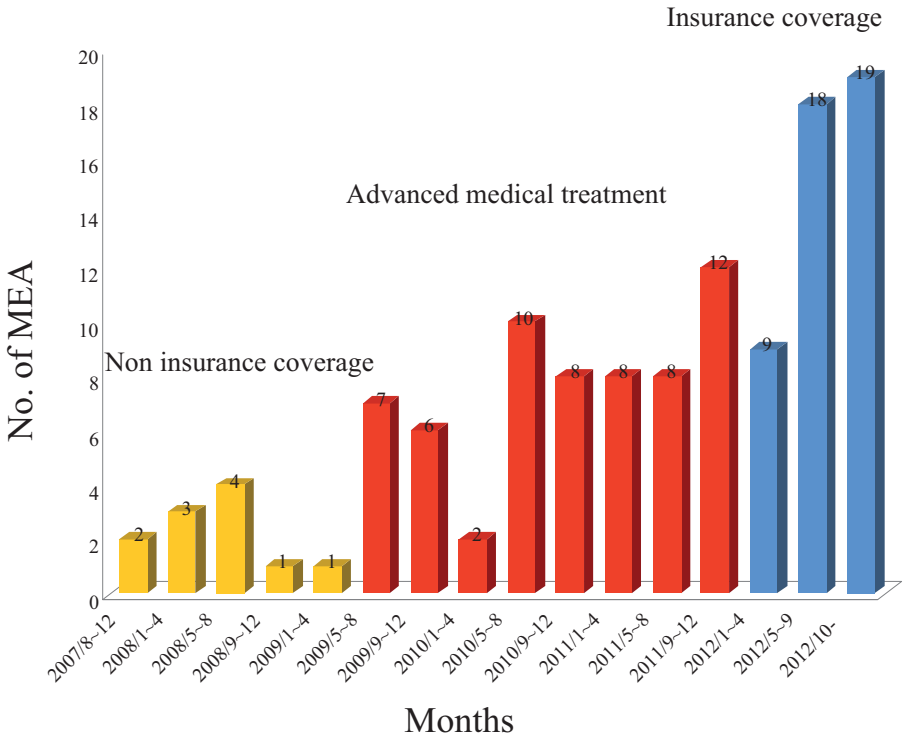

Figure 3. — Number of MEA cases increased from period of non-insurance to period of advanced medical treatment or insurance coverage.

ease two weeks after MEA. Up to April 2012 patients were allowed to take baths one week after MEA. In other words, there is a possibility that transvaginal bacterial infection during bathing after the first week post-MEA could have been the cause of these infections. Therefore, as of June, 2012, bathing was prohibited for two weeks after an MEA procedure. Thereafter, until now (end of December 2012), not a single case of myometritis/endometritis has occurred. We must take into consideration that there is a possibility that for about two weeks after MEA, the area around the external opening of the uterus has compromised contractility. In addition, cases that do not have interstitial myomas, or those without myomas with a larger diameter of five cm or more, were significantly more likely to develop post-surgical amenorrhea (Table 1). Cases that satisfy these conditions suggest that the treatment efficacy of MEA and complete hysterectomy are roughly the same. In other words, patients with menorrhagia that satisfy these conditions should actively avoid radical hysterectomies.

Recently, there have been reports from multiple institutions in Japan on treatment results with MEA [9-12]. All reports show similar data, suggesting the safety and efficacy of MEA has been confirmed. Among these reports, there is one paper that includes the results from an office gynecology [12], and now that insurance coverage will pay for the procedure, it is predicted that MEA will become even more popular in Japan. In the UK where endometrial ablation is already very popular, a meta-analysis reported that bipolar radiofrequency and microwave ablative device use was more effective than thermal balloon or fluid ablation methods [13]. Moreover, patients were equally satisfied with bipolar radio frequency and microwave ablative device use [14]. These reports should help MEA to become more widespread within Japan.

MEA was certified as advanced medical care in December 2008 by the MHLW. Since that time, mixed healthcare (mix of insurance-covered treatment with medical treatment at one's own expense) has become an option, and compared to the previous situation when patients were required to pay all costs themselves, the economic burden on patients has been greatly alleviated. The number of cases undergoing MEA at the present department has increased since June 2009 when it was certified as advanced medical care. Furthermore, since April 2012, it has been listed as a treatment covered by medical insurance under "K863-3 hysteroscopic endometrial ablation surgery: 17,810 points". Alfresa Pharma Corporation and Kanaoka, Asakawa *et al.* held a press seminar in Tokyo, in June 2012, and explained insurance coverage for MEA [15]. Thereafter, many mass media outlets began to cover MEA and this became the trigger that led to laypersons learning about MEA. At the Department of Obstetrics and Gynecology, School of Medicine, Shimane University, the present authors began to see patients come to their clinic for MEA treatment from other prefectures in the Chugoku region (Hiroshima, Okayama, Yamaguchi), and the number of cases with indications for MEA is rapidly increasing. In Figure 3 the authors show the number of pa-

tients treated by MEA at their department, but after MEA was listed for medical insurance coverage, a sudden and dramatic increase in the number of patients has been seen. However, MEA recognition and knowledge has yet to spread to laypersons and gynecologists at private clinics, hence further activities will be necessary to promote dissemination.

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