

A comparative study between microwave endometrial ablation and conventional surgical procedures for treatment of menorrhagia

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Summary

Objective: To compare microwave endometrial ablation (MEA) using a new curved applicator with conventional surgical procedures in 26 patients with menorrhagia. **Study Design:** Ten patients received MEA and 16 patients received conventional surgical procedures. Using a visual analog scale (VAS), MEA patients rated their menorrhagia, dysmenorrhea, and feelings of satisfaction from the procedure. The patients' intraoperative blood loss, operating time, and length of hospital stay were compared. **Results:** Following MEA, the VAS scores were significantly decreased in the MEA patients for menorrhagia ($p < 0.0001$) and dysmenorrhea ($p = 0.0002$). The average VAS score regarding feelings of satisfaction for MEA was 8.9 (full score = 10). Mean blood loss, operating time, and mean length of hospital stay were significantly decreased in the MEA group compared to the conventional surgical procedure group ($p < 0.0001$). **Conclusion:** MEA successfully controlled menorrhagia and achieved a high rate of satisfaction among patients.

Key words: Conventional surgical procedures; Menorrhagia; Microwave Endometrial ablation.

Introduction

Microwave endometrial ablation (MEA) is a second-generation method of endometrial ablation utilizing microwaves at a fixed frequency, which are delivered by inserting a microwave probe into the uterine cavity. The microwaves destroy the basal layer of the endometrium and the glands by heating them to more than 60°C.

Over 70,000 hysterectomies are performed annually in the UK, with more than half being used to treat cases of menorrhagia [1]. Although the rate of effectiveness of hysterectomies for treating menorrhagia is 100%, the rate of complications during the operation can reach 40%, with a death rate of 6-11 per 10,000 [2]. Thus, endometrial ablation, a low-invasive therapy for menorrhagia, has become a widespread alternative to hysterectomy in the past two decades. Conventional ablative techniques are not suitable for enlarged uterine cavities greater than 10-12 cm in length, or those distorted by submucosal or intramural myomas [3]. However, most menorrhagia develops in patients with enlarged distorted uteri with submucosal myomas, intramural myomas, or adenomyosis rather than in those with uteri that do not show pathological findings. Recently, a new curved applicator was developed that is specifically designed for MEA at 2.45GHz for enlarged uteri with distorted cavities [4]. In this study, we compared MEA using the new curved applicator with conventional surgical procedures in 26 patients with menorrhagia.

Patients and Methods

From August 2007 to November 2008, 26 patients aged 33 to 56 years (mean age 46 years) whose chief complaints were menorrhagia, severe anemia, and abnormal uterine bleeding were treated at Shimane University Hospital. Of the 26 patients, 21 were diagnosed with uterine myoma, three with adenomyosis, one with endometrial hyperplasia simple, and one with dysfunctional bleeding. None of the patients intended to become pregnant in the future. Endometrial malignancy was ruled out using diagnostic magnetic resonance imaging (MRI) and transvaginal sonography (TVS), as well as cytological examinations. For surgical treatment of menorrhagia, we discussed different methods of treatment with each patient, including total abdominal hysterectomy (TAH), laparoscopic assisted vaginal hysterectomy (LAVH), myomectomy and MEA, and the patients selected which treatment method they wanted to follow. As a result, ten patients underwent MEA, and 16 patients chose a conventional surgical procedure (TAH, LAVH, or myomectomy). Written informed consent was obtained from all of the patients, and the ethical committee of Shimane University Hospital approved the protocol.

MEA was performed under spinal anesthesia using a device manufactured by Alfresa Pharma (Osaka, Japan). The device consisted of a sounding applicator and a microwave generator. The applicator was 4 mm in diameter and 20 cm in length, and terminated at the tip with a curved microwave applicator. The 2.45 GHz microwaves were supplied by a Microtaze AZM-520 microwave generator (Azwell, Osaka, Japan). This was in contrast to a previous microwave device, which was 8.5 mm in diameter with a non-bending tip, that could generate microwaves at 9.2 GHz [5]. The modified shape of the tip facilitated easier and safer operation of the device, even in a large and distorted uterine cavity [6]. For each irradiation site, microwaves were transmitted at 70 W for approximately 50 sec. To avoid perforating the uterus we opted for MEA under the

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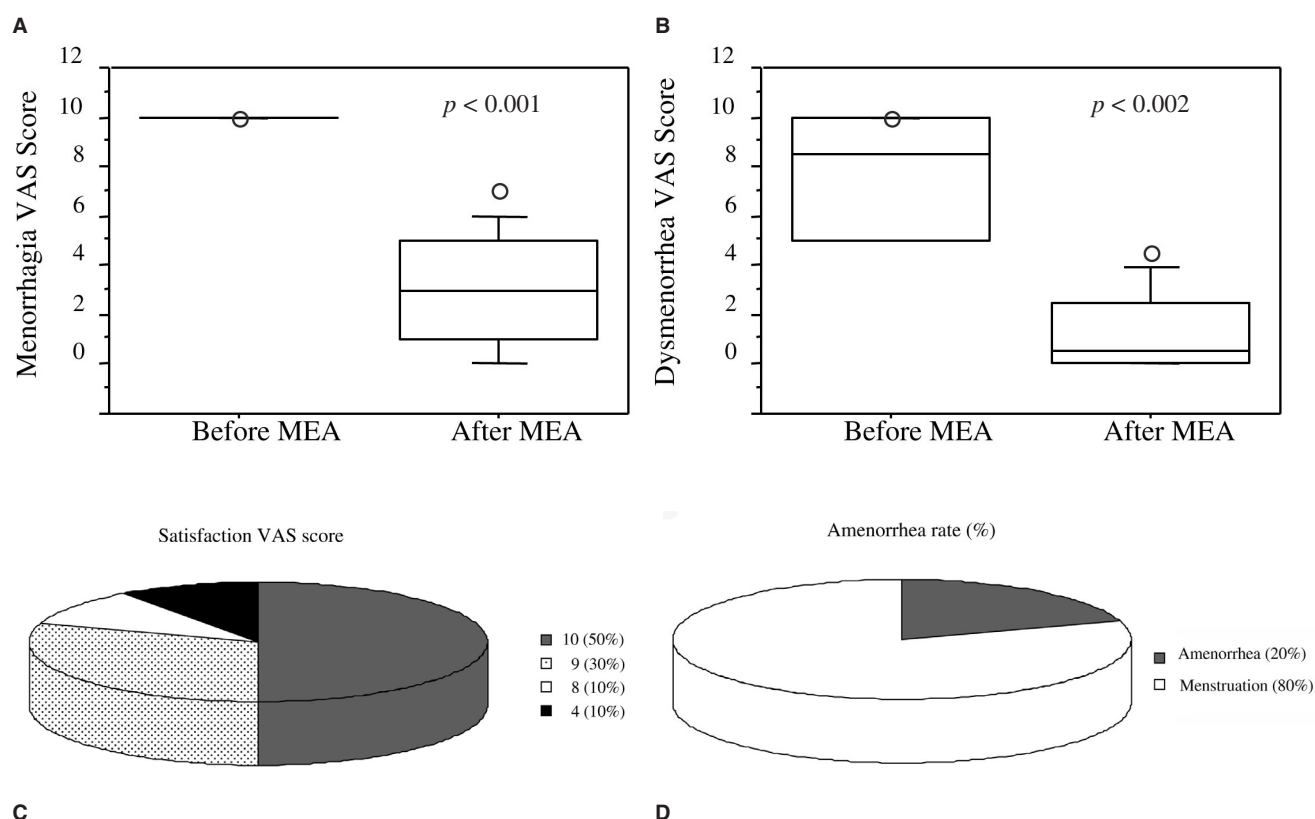


Figure 1. — A) Change in the visual analog scale score for menorrhagia prior to and following microwave endometrial ablation. B) Change in visual analog scale score for dysmenorrhea prior to and following microwave endometrial ablation. C) Summary of patient satisfaction for microwave endometrial ablation based on visual analog scale score. D) Summary of amenorrhea rate (%).

guidance of transrectal ultrasonography (US). None of the patients had any intraoperative or postoperative complications. All of the patients had follow-up visits at one week and at one to six months that included a careful interview regarding uterine bleeding and a clinical examination. MRI images taken after MEA showed a gradual reduction in the size of the myomas and uterus. Gadolinium (Gd)-enhanced MRI revealed the necrotic endometrium as an avascular area [7]. The patients who received MEA were asked to complete a visual analog scale (VAS) regarding their menorrhagia, dysmenorrhea, and feelings of satisfaction regarding MEA. Patients were asked to fill out the VAS form prior to MEA and at approximately four to six months after MEA.

Traditional techniques were used for TAH, LAVH, and trans-abdominal myomectomy. TAH, LAVH, and myomectomy were performed with general anesthesia and epidural anesthesia. We compared intraoperative blood loss, operating time, and length of hospital stay following the operation for the MEA group and the conventional group.

Statistical analysis

The data from the two groups were compared using Student's *t* test; *p* values less than 0.05 were considered statistically significant.

Results

Comparison of menorrhagia and menstrual distress before and after MEA

The characteristics of patients in the MEA group are summarized in Table 1A. As indicated in Figure 1A and 1B, there was a significant decrease in the mean VAS scores for menorrhagia ($p < 0.0001$) and dysmenorrhea ($p = 0.0002$) at the 4-6 month follow-up. The VAS scores for feelings of satisfaction following MEA are summarized in Figure 1C. The average VAS score for satisfaction was 8.9, with a full score equal to 10. The amenorrhea rate four to six months after MEA was 20% (Figure 1D).

Comparison of blood loss, operating time, and length of hospital stay between MEA and conventional surgical procedure

The characteristics of patients in the conventional surgical procedure group are summarized in Table 1B. The level of hemoglobin in the MEA group (7.9 ± 2.0 g/dl) was significantly lower than that in the conventional surgical procedure group (10.7 ± 1.3 g/dl) ($p < 0.0003$). There was no significant difference in the age of the

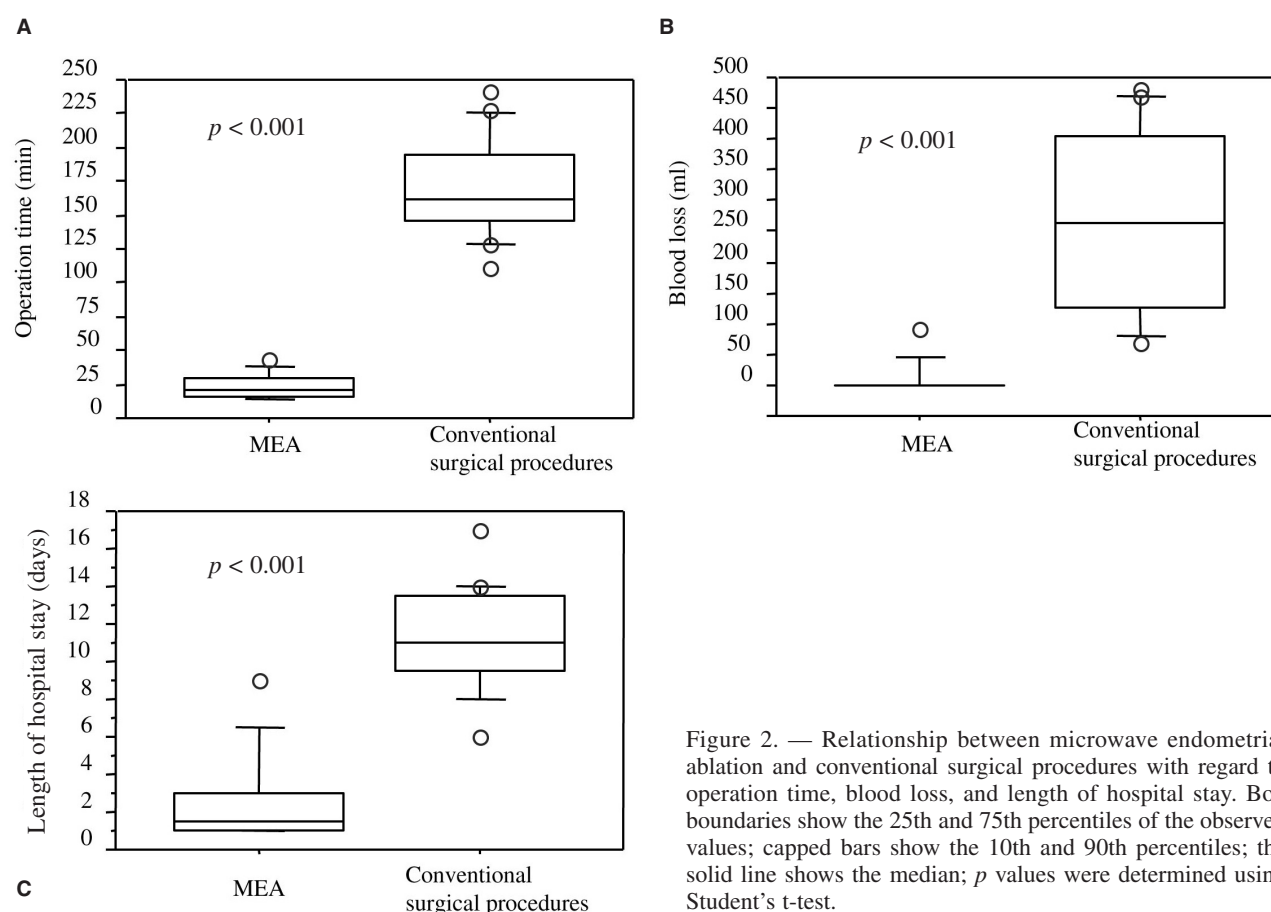


Figure 2. — Relationship between microwave endometrial ablation and conventional surgical procedures with regard to operation time, blood loss, and length of hospital stay. Box boundaries show the 25th and 75th percentiles of the observed values; capped bars show the 10th and 90th percentiles; the solid line shows the median; p values were determined using Student's t -test.

patients between the two groups. The operating time for the MEA group was dependent on the area and depth of the uterine cavity, and ranged from 14 to 44 minutes, with a mean of 24 ± 9 minutes. For the conventional surgical procedure group, the operating time ranged from 111 to 242 minutes, with a mean of 170 ± 24 minutes. The difference in the operating time between the two groups was significant ($p < 0.0001$) (Figure 2A). One patient in the MEA group had a 90 ml blood loss, but the other patients in the MEA groups had no blood loss. The mean amount of blood loss was 9 ± 28 ml (range 0-90 ml) in the MEA group and 265 ± 152 ml (range 80-480 ml) in the conventional surgical procedure group. The difference in the amount of blood loss between the two groups was significant ($p < 0.0001$) (Figure 2B). The mean length of hospital stay after the operation was 2.5 ± 2.5 days (range 1-9 days) for the MEA group and 11.3 ± 2.8 days (range 7-17 days) for the conventional surgical procedure group. The difference in the length of hospital stay between the two groups was significant ($p < 0.0001$) (Figure 2C).

Discussion

Microwave ablation therapy has been extensively utilized in the liver and kidney. The use of microwaves at 9.2 GHz in gynecology was first reported for MEA at the

University of Bath [8]. However, that particular device was unsuitable for treating uterine cavities that were remarkably distorted or enlarged by uterine myomas. Recently, Kanaoka *et al.* developed a special instrument to deliver 2.45 GHz microwaves through a thin curved microwave applicator that conforms to the curvature of the uterine cavity [6]. This applicator may be used in cavities up to 16 cm in length and can treat myomas bigger than 3 cm. [6]. In the current study, we assessed the outcome of MEA using this modified device on patients with menorrhagia, and determined the level of patient satisfaction with the procedure. There were no complications in any of the ten patients who were treated with MEA in this study. At the 4-6 month follow-up, 90% (9/10) of the patients were satisfied with MEA, and gave an average VAS score of 8.9 (full score = 10), which was comparable with those of other studies [1,3,9]. There was also a significant decrease in the VAS score for menorrhagia from ten prior to MEA to 2.3 following MEA. Interestingly, there was also a significant improvement in 100% (8/8) of patients who had dysmenorrhea prior to MEA, and similar results have been reported previously [10]. This may be a secondary effect related to the improvement of menorrhagia. Our amenorrhea rate of 20% (2/10) was lower than that in previous reports [11], which may be due to the thickness of the endometrium

Table 1A. — Patient characteristics, surgical strategy, and outcomes for the MEA group.

Case no.	Age	Chief complaint	Diagnosis	Hb (g/dl)	Surgical procedure	Operation time (min.)	Blood loss (ml)	Length of hospital stay (days)	Menorrhagia (VAS)	Dysmenorrhea (VAS)	Satisfaction (VAS)
1	51	Menorrhagia	Myoma (submucosal)	6.7	MEA	30	90	9	10→4.5	0→0	10
2	42	Menorrhagia	Myoma (submucosal)	11.7	MEA	21	0	4	10→5	7→4.5	10
3	33	Menorrhagia	Endometrial hyperplasia, simplex	5.1	MEA	21	0	3	10→5	1→1	4
4	47	Menorrhagia	Myoma (submucosal)	9.9	MEA	30	0	2	10→0	10→0	10
5	50	Menorrhagia	Myoma (intramural)	8.8	MEA	15	0	1	10→1.5	10→1	9
6	51	Menorrhagia	Adenomyosis	6.4	MEA	44	0	1	10→1	10→2.5	10
7	51	Menorrhagia	Adenomyosis	7.8	MEA	14	0	1	10→0	5→0	10
8	46	Menorrhagia + abnormal uterine bleeding	Functional uterine bleeding	7.5	MEA	14	0	1	10→4	5→0	9
9	50	Menorrhagia	Myoma (submucosal)	9.4	MEA	22	0	1	10→7	10→2.5	8
10	46	Menorrhagia + abnormal uterine bleeding	Myoma (intramural)	5.8	MEA	33	0	2	10→2	5→0	9

MEA: microwave endometrial ablation; VAS: visual analog scale

Table 1B. — Patient characteristics, surgical strategy, and outcomes for conventional treatment group.

Case no.	Age	Chief complaint	Diagnosis	Hb (g/dl)	Surgical procedure	Operation time (min.)	Length of hospital stay (days)
1	41	Menorrhagia	Myoma (intramural)	10.5	Myomectomy	147	12
2	49	Menorrhagia	Myoma (intramural)	11.6	TAH + BS	200	11
3	46	Menorrhagia	Adenomyosis	7.1	TAH + BS + LO	128	8
4	48	Menorrhagia	Myoma (intramural)	10.4	TAH + BS + RO	143	17
5	50	Menorrhagia	Myoma (intramural)	10.6	TAH + BS + LO	181	14
6	36	Menorrhagia	Myoma (intramural)	11.7	TAH + BS	183	9
7	38	Menorrhagia	Myoma (intramural)	11.3	TAH + BS	154	12
8	56	Abnormal uterine bleeding	Myoma (intramural)	11.2	TAH + RSO	228	14
9	50	Menorrhagia	Myoma (intramural)	11.5	TAH + BS	188	14
10	46	Menorrhagia	Myoma (intramural)	10.8	LAVH	242	6
11	50	Anemia	Myoma (intramural)	9.7	TAH + BSO	111	11
12	52	Menorrhagia	Myoma (intramural)	12.2	TAH + BSO	153	8
13	46	Menorrhagia	Myoma (intramural)	9.5	TAH + BS	170	10
14	46	Menorrhagia	Myoma (intramural)	12.8	TAH + BS	152	13
15	49	Anemia	Myoma (intramural)	9.7	TAH + BS	130	11
16	44	Menorrhagia	Myoma (intramural)	11.1	TAH + BS + RO	211	10

TAH: total abdominal hysterectomy; BS: bilateral salpingectomy; LO, RO: left, right oophorectomy; LAVH: laparoscopic assisted vaginal hysterectomy; BSO: bilateral salpingoophorectomy

and the fact that microwaves are not able to easily penetrate the basal layer in some areas of a large and severely distorted uterine cavity. Thus, it is easy to treat incompletely, even when using a device with a modified sounding applicator. Endometrial curettage prior to MEA may be necessary when the endometrium is particularly thick, such as during the luteal menstrual phase. However, the low rate of amenorrhea may also be an advantage in our population. Some Japanese patients wish to avoid amenorrhea because they think of it as sign of aging, even when the biology has been carefully explained to them. Two of our patients expressed concerned about amenorrhea during an outpatient visit. They were satisfied with the resolution of their menorrhagia, but were afraid that they were prematurely entering menopause, despite their hormonal levels being normal. Amenorrhea certainly solves the problem of menorrhagia, but it may create new anxiety for some patients.

Compared to conventional surgical procedures, our study showed that MEA had simpler anesthesia, shorter

operating times, lower blood loss, and a shorter hospital stay. Similar results from another study comparing MEA to total hysterectomy have also been reported [2]. Also, the fact that the level of hemoglobin in the MEA group was significantly lower than that in the conventional surgical procedure group indicated that MEA could be adopted for control of menorrhagia with poor surgical candidates. Taking together our current results and previous reports, MEA appears to be a minimally invasive treatment option for menorrhagia.

Following MEA, postoperative pain is controllable with administration of non-steroidal anti-inflammatory drugs, and patients may be discharged as early as the following day. In a previous report, we successfully performed MEA as an emergent control of uterine bleeding [7]. Previously, Kanaoka *et al.* reported that the use of transabdominal US as a guide was helpful for improving the safety of MEA [4]. However, some patients in the current study were difficult to guide with transabdominal US. For patients who have a fatty abdomen or severe retroversion

of the uterus, guidance under transrectal US could be useful for avoiding perforation of the uterus and/or bowel injury during MEA.

In conclusion, MEA successfully controlled menorrhagia and achieved a high rate of satisfaction among patients. MEA is a minimally invasive procedure, which reduces operation-induced trauma, intraoperative blood loss, and allows for shorter hospital stays. MEA is a promising new method for treating menorrhagia instead of conventional surgical procedures.

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