Gynecology and Minimally Invasive Therapy 4 (2015) 76–80

Contents lists available at ScienceDirect

Gynecology and Minimally Invasive Therapy

journal homepage: www.e-gmit.com

Original article

Clinical practice and short-term efficacy of 2.45-GHz microwave endometrial ablation to treat menorrhagia

Naoki Matsumoto*, Nobuyuki Ikeda, Toshifumi Takenaka, Satoshi Yazaki, Yuichi Sato

Department of Obstetrics and Gynecology, Tatedebari Sato Hospital, 96 Wakamatsucho, Takasaki City, Gunma, Japan

ARTICLE INFO

Article history:
Received 10 November 2014
Received in revised form
22 February 2015
Accepted 13 March 2015
Available online 9 May 2015

Keywords:
dysmenorrhea
endometrial ablation
menorrhagia
microwave
minimally invasive surgery

ABSTRACT

Objective: To evaluate the clinical practice and short-term efficacy of microwave endometrial ablation (MEA) to treat menorrhagia, and to identify prognostic factors for optimal outcomes.
Methods: We performed MEA in 22 women with menorrhagia between October 2012 and December 2013. To evaluate efficacy, objective and subjective variables were measured using medical records and patients' pre- and postoperative responses to a written questionnaire with a visual analog scale (VAS) scored from 0 to 10 for each symptom. MEA outcome was evaluated 6 months after treatment. Patients with amelioration of menorrhagia and no anemia were defined as the effective group, and the others were defined as the noneffective group. Effective patients requiring no hormonal therapy were defined as the highly effective group. To identify prognostic factors, background factors were compared between the highly effective group and the other groups.
Results: Uterine fibroids and adenomyosis were diagnosed in 68% and 32% of patients, respectively. The median VAS score of postoperative pain was 1.0, and that of satisfaction was 8.1. Hemoglobin concentration, menstrual bleeding volume, menstrual duration, menstrual pain, vaginal discharge, and fatigue were ameliorated in the postoperative period. The effective group, the highly effective group, and the noneffective group included 95%, 84%, and 5% of patients, respectively. The uterine corpus cavity was significantly shorter in the highly effective group than in the other groups.
Conclusion: MEA was safe and effective. The short-term efficacy rate of MEA for alleviating menorrhagia symptoms was 95%. Optimal outcomes were correlated with a shorter uterine corpus cavity.

Introduction

Endometrial ablation is considered an important surgical option for the treatment of menorrhagia.[1] In Japan, microwave endometrial ablation (MEA) using a frequency of 2.45 GHz was described and developed as an original applicator for use by Kanaoka et al[2] in 2001. After the Japanese Ministry of Health, Labour, and Welfare authorized the use of MEA as an advanced medical therapy in 2009, MEA has been offered in a few approved institutions and facilities. In April 2012, MEA was approved by the national health insurance system in Japan as a covered treatment for menorrhagia. At that time, we began providing MEA in our hospital. Several researchers evaluated the efficacy of MEA based on the condition during 3–24 months after operations. Ishikawa et al[3] showed that no patient experienced recurrent menorrhagia for > 6 months after MEA. Therefore, the short-term postoperative condition was evaluated in 6 months in this research. The purposes of this research were to evaluate the clinical practice and short-term efficacy of 2.45-GHz MEA to treat menorrhagia and to identify the prognostic factors associated with optimal MEA outcomes.

Materials and methods

Patient selection

Patients with symptoms of menorrhagia who were no longer bearing children and with no uterine malignancy were initially

Conflicts of interest: The authors have no conflicts of interest relevant to this article.

A summary of this report was presented at the 66th Academic Conference of the Japan Society of Obstetrics and Gynecology, Tokyo, Japan, 2014.

* Corresponding author. Tatedebari Sato Hospital, 96 Wakamatsucho, Takasaki City, Gunma 370-0836, Japan.
E-mail address: research@matsumotoc.org (N. Matsumoto).

http://dx.doi.org/10.1016/j.gmit.2015.03.002

deemed eligible to receive MEA. After initial screening, eligibility to receive MEA was individually decided on the basis of preoperative assessment using ultrasonography and/or magnetic resonance imaging. In principle, patients whose menorrhagia was not easy to control by conservative therapy were deemed to be good candidates. Patients whose uterine cavity was too large or too complex in shape to appropriately and safely provide MEA were excluded. Patients who preferred hysterectomy, which would furnish a perfect effect for menorrhagia in exchange for the invasiveness, were excluded as well. Before undergoing MEA, patients received an iron supplement, pseudomenopausal therapy (subcutaneous leuprolide acetate), and an oral hormonal medication (dienogest or an estrogen–progestin combination) if necessary.

Ablation procedure

The microwave system used in this research was composed of a Microtaze device and a Sounding Applicator (Alfresa Pharma, Osaka, Japan). The former is a power generator of 2.45-GHz microwaves, and the latter is an intrauterine applicator that irradiates microwaves from its tip. The applicator is 4 mm in diameter and curved to access the endometrium easily, and it reaches to a maximum distance of 18 cm. MEA was performed according to the procedure guidelines described previously.[4] The microwave generator's output was set to 70 watts for 50 seconds for each irradiation. Transabdominal ultrasonography was used for intraoperative monitoring. Immediately before and after the procedure, as well as during the procedure if necessary, hysteroscopy was used to visualize the ablated area. Microwave irradiation was repeated until a sufficient area of the uterine corpus endometrium had been ablated. General anesthesia was used, and a nonsteroidal anti-inflammatory drug was administered intraoperatively.

Research design

We performed MEA in 22 women with menorrhagia between October 2012 and December 2013. To evaluate MEA efficacy, subjective and objective variables were measured. Objective variable data were drawn from patients' medical records, including their laboratory test results, and subjective variables were measured using patients' responses to a written questionnaire survey. Pre- and postoperative subjective symptom ratings of each patient were obtained using a questionnaire with a visual analog scale (VAS) scored from 0 to 10 for each symptom. The questionnaire survey was performed and MEA outcome was evaluated by each patient 6 months after treatment. At that time, patients with amelioration of menorrhagia and no anemia were defined as the effective group, and the others were defined as the noneffective group. Amelioration of menorrhagia was defined by self-report as mentioned in the patient's medical record 6 months after MEA, or by a subjective estimate of postoperative menstrual bleeding volume that was decreased to half or less than the preoperative volume in the patient. Moreover, the effective group was subdivided into two groups: those whose postoperative symptoms required no hormonal therapy comprised the highly effective group, whereas those who continued to use additional hormonal therapy in the postoperative period were classified as the fairly effective group.

To evaluate MEA efficacy in detail, each patient's pre- and postoperative variables were compared. To identify the prognostic factors associated with the optimal outcomes, background factors were compared between the highly effective group and the other groups. Correlation was measured between the length of the uterine corpus cavity (from the anatomical internal os to the upper edge of the endometrium) and the number of microwave irradiation sessions required.

This research was planned and performed on the basis of the approval of the research ethics committee in our hospital. Each patient's written informed consent to the research was obtained along with the responses to the questionnaire.

Data were analyzed using JMP version 8.0 (SAS Institute, Cary, NC, USA) and R version 2.13. Two-tailed p values were calculated using univariate methods including the Mann–Whitney U test, Wilcoxon signed rank test, McNemar test, Chi-square test, and Pearson product-moment correlation coefficient. A p value < 0.05 was considered significant.

Results

The characteristics of the 22 patients who received MEA are shown in Table 1. No patients received a diagnosis of functional menorrhagia; all patients had either uterine fibroids or adenomyosis. Summarized data concerning the MEA procedures are shown in Table 2. On the whole, MEA yielded high levels of patient satisfaction with minimal postoperative pain. The only clinically problematic adverse event occurred in a patient with a single intramural fibroid of 55 mm in diameter. The patient had a fever with purulent vaginal discharge 1 week after MEA. The condition was diagnosed as bacterial endometrisis, and she had to be briefly admitted to our hospital for intravenous antibiotics.

To evaluate MEA efficacy in detail, pre- and postoperative variables of each patient were compared. An iron supplement was administered to 81.8% and 5.3% of patients ($p < 0.001$ by McNemar test), pseudomenopausal therapy was administered to 68.2% and 10.5% ($p < 0.001$), and oral hormonal medication was administered to 5.3% and 10.5% ($p = 1.0$) of the 22 women in the pre- and postoperative periods, respectively. Changes in hemoglobin concentration and patients' subjective symptom ratings are presented in Figure 1. Hemoglobin concentration (median preoperative score, median postoperative score, and median variation were 8.6, 13.5, and +5.3, respectively), menstrual bleeding volume (10, 1.0, and −8.0, respectively), menstrual duration (7.0, 2.5, and −3.5, respectively), menstrual pain (7.5, 0.5, and −4.0, respectively), vaginal discharge (4.8, 1.6, and −2.4, respectively), and fatigue (7.5, 2.0, and −5.0, respectively) ameliorated in the postoperative period.

Table 1
Characteristics of the 22 patients who received microwave endometrial ablation to treat menorrhagia.

Factors	Median	Range	*n*	%
Age (y)	46.5	39–54		
Parity	2	0–4		
Previous cesarean delivery			6	27.3
Obesity (BMI ≥ 25)			4	18.2
Initial anemia[a]			18	81.8
Initial hemoglobin concentration (g/dL)	8.6	4.0–13.6		
Organic diagnosis causing menorrhagia				
Uterine fibroids			15	68.2
Multiple fibroids			9	60.0
Submucosal fibroids			8	53.3
Adenomyosis			7	31.8
Functional menorrhagia			0	0
Patient complaints				
Heavy menstrual bleeding			22	100
Prolonged menstruation			10	45.5
Painful menstruation			11	50.0
Uterine corpus cavity length (cm)	5.5	3.4–7.5		
Preoperative use of iron supplement			18	81.8
Preoperative pseudomenopausal therapy			15	68.2
Preoperative oral hormonal medication			1	4.5

BMI = body mass index.
[a] Initial hemoglobin concentration < 12.0 g/dL.