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Radiofrequency endometrial ablation with a novel endometrial tip for the management of heavy menstrual bleeding and abnormal uterine bleeding: a prospective study

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ABSTRACT

Aim: To evaluate the safety and efficacy of a radiofrequency ablation system with a novel endometrial tip (RFA-EMT) for the management of heavy menstrual bleeding (HMB) or abnormal uterine bleeding (AUB).

Methods: This is a prospective study including a total of 38 premenopausal women with heavy menstrual bleeding (HMB) or abnormal uterine bleeding (AUB) that failed to respond to medical therapy. Hysteroscopic evaluation and curettage biopsy were performed just before the procedure. The procedure was timed to occur during the early proliferative phase (cycle days 4–10). RFA-EMT procedures were performed by a single surgeon with the patient under general anesthesia with a laryngeal mask airway. Primary outcome was reduction in bleeding, reported as amenorrhea, hypomenorrhea, and eumenorrhea, which were measured via hemoglobin level and pictorial blood assessment chart (PBAC) score. Secondary outcomes were adverse events, dysmenorrhea with numeric rating scale (NRS) score, and endometrial thickening in the early proliferative phase, as assessed by transvaginal ultrasonography.

Results: There were no peri- or post-procedural complications. Combined amenorrhea, hypomenorrhea, and eumenorrhea rates at 3 and 6 months were 97.4% and 100%, respectively. The hemoglobin level was significantly increased, and the PBAC score, NRS score, and endometrial thickening were significantly decreased after 3 months. These trends were maintained for 6 months after the procedure.

Conclusion: RFA-EMT, a new technique, is safe and effective for women with HMB or AUB for which medical therapy has failed.

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Introduction

Heavy menstrual bleeding (HMB) has been estimated to occur in approximately 30% of women of reproductive age [1]. Unacceptably profuse or frequent bleeding interferes with a woman's physical or psychosocial well-being. Some cases of HMB and abnormal uterine bleeding (AUB) become a chronic disease, leading to iron deficiency anemia. Interventions seek to identify and correct underlying causes, control bleeding, ameliorate anemia and improve quality of life.

Medical treatments such as hormonal or non-hormonal medications or levonorgestrel-releasing intrauterine devices are available for first-line treatment. When medical treatment has failed or when women do not desire uterus preservation, hysterectomy is definitively to provide permanent relief. However, hysterectomy is associated with risks related to general anesthesia, short- and long-term postoperative complications and high medical costs [2,3]. Therefore, the demand for less invasive options has increased.

Endometrial ablation is a minimally invasive surgical intervention for HMB or AUB, and it has grown as an alternative to hysterectomy. Recently, a Cochrane review summarized eight randomized controlled trials (RCTs) comparing endometrial ablation versus hysterectomy; endometrial ablation showed significant advantages including fewer adverse events, faster recovery and better perception by women than hysterectomy [4]. Ablation techniques continue to evolve, and many studies have shown corresponding improvements in success rates and clinical outcomes.

Since second-generation devices received FDA approval, endometrial ablation procedures continue to rise with approximately 521,140 cases of endometrial ablation in the United States in 2016 [5]. However, women with large fibroids, large uterine size, or malformations of the uterine cavity are often excluded from endometrial ablation [4,5]. This may be because the instruments were designed to assess uterine cavities of normal size and shape; the endometrial cavity could be twisted or distorted due to compression by myomas or adenomyosis and deformed in cases of uterine

anomaly. Thus, it is difficult to use these devices for patients with distorted uterine cavities [5]. To manage all patients regardless of the shape of endometrial cavity, we used a novel endometrial tip for endometrial ablation, which has not been used before.

In this study, we introduced a radiofrequency (RF) ablation system with a novel endometrial tip (RFA-EMT) and determined its safety and efficacy by applying it to patients with HMB or AUB that failed to respond to medical treatment. Primary outcome was reduction in bleeding without abnormal uterine bleeding.

Methods

Study design and sample size calculation

This represents a prospective, single-arm, non-randomized, non-inferiority study. The primary outcome measure of this study was the rate of bleeding reduction, defined as amenorrhea, hypomenorrhea, or eumenorrhea, without abnormal uterine bleeding. In the literature related to ablation therapy, only amenorrhea rates were reported to be more than 40% [6,7]; based on this, the sample number was calculated. The noninferiority margin was prespecified as a 10% absolute difference. Using a one-sided test with $\alpha = 0.05$ and a power of 80%, 39 patients were needed. PASS 11TM software (NCSS, Kaysville, UT, USA) was used to calculate sample size.

Patient selection

Patients referred to the Department of Obstetrics and Gynecology at the Chung-Ang University Hospital, a tertiary teaching and research institution in Seoul, Korea were invited to participate in the study. The indications for endometrial ablation were HMB or AUB that did not respond to medical therapy and the desire for uterine preservation. Patients had either symptomatic HMB, as evidenced by self-assessment of bleeding patterns and iron deficiency anemia, or AUB, as evidenced by self-assessment of bleeding patterns. This study was approved by the Ethics Committee of Chung-Ang University Hospital, Seoul, Korea (approval ref. number, C2014259[1456]), and informed consent was obtained from all patients enrolled in this study.

Eligibility criteria included HMB or AUB with medication refractory, normal cervical cytology, and appropriate medical status for surgery (American Society of Anesthesiologists Physical Status classification 1 or 2). Women with type 0 or 1 submucosal myoma based on ultrasonogram, premalignant lesions, the desire to retain their fertility, uterine malformation including septate, a history of previous ablation procedure, current or recent infection history of the uterus or postmenopausal status were excluded.

Device description and operative technique

The Endometrial Tip (EMT; <http://www.rfa.co.kr/en>, RF Medical Co., Ltd., Seoul, Korea) is a RF electrode that is designed to optimize RF ablation of the endometrium. The

electrode has a built-in temperature sensor. Impedance and temperature can be monitored in real time *via* the generator connected to the electrode. Various exposure tip lengths are available, and an 8-G (5-mm-diameter) electrode (RF Medical) with a 2-cm exposed tip was used in this study. The RF energy is delivered from the 2-cm distal tip end to the uterine lining to ablate the endometrial tissue. RF can cover 3–4-cm of the endometrial cavity. The RF energy was generated by a V-1000 RF generator (RF Medical).

The procedure was timed to the early proliferative phase (cycle days 4–10). All of the procedures were performed under general anesthesia, and by a single surgeon. Patients received antibiotics pre- and post-procedure and stayed in the hospital for one night. The uterine cavity was evaluated using a rigid 3-mm hysteroscope, and then curettage was done. The EMT was inserted transcervically to touch the fundus, and then the heater was activated, and maintained a temperature of 80–85 °C. The endometrium was vaporized during ablation, and the tip was pulled out about 2–3 cm from the fundus to cervix and remained at one site for 30 s to 1 min to target tissue destruction to a depth of 5–8 mm. This ablation depth was obtained from a previous *ex-vivo* experiment (data not shown). This allowed the complete coverage of the endometrial cavity. All procedures were guided by ultrasonography.

Assessment

Menstrual blood loss was assessed using a pictorial blood assessment chart (PBAC) one month before surgery and 3 and 6 months after surgery [8]. The pretreatment PBAC score was based on the patient records archived in their smartphones or was obtained using the retrospective recall method. The PBAC data at 3 and 6 months were prospectively collected. A PBAC score of greater than 150 per month or iron deficiency anemia were defined as HMB. AUB is defined as bleeding from the uterine corpus that is abnormal in regularity, volume, frequency or duration and occurs in the absence of pregnancy. Treatment success was defined as the elimination of menses (amenorrhea), the reduction of flow to normal (PBAC score <100, eumenorrhea) or less than normal (PBAC score <40, hypomenorrhea) or the absence of AUB. Clinical failure was defined as persistent HMB (PBAC score ≥ 100), iron deficiency anemia or the presence of AUB. Dysmenorrhea was evaluated using NRS score [9]. Endometrial thickening was evaluated in the early proliferative phase using transvaginal ultrasonography.

Statistical analysis

We used an intention-to-treat strategy and missing data were completed using the mean substitution method. The Shapiro–Wilk test was used to test for normality of variables. The hemoglobin (Hgb) and PBAC scores passed the Shapiro–Wilk test. NRS scores and endometrial thickening did not pass the Shapiro–Wilk test and a q-q plot did not show marked deviations from linearity. Therefore, the normal

assumptions were applied for repeated measures analysis of variance (ANOVA) for these variables.

Because Hgb in the analysis of patients with HMB [$\chi^2(2) = 5.503$, $p = .064$, Mauchly's $W = 0.802$], as well as endometrial thickening in the analysis of all patients [$\chi^2(2) = 3.359$, $p = .186$, Mauchly's $W = 0.911$] and patients with HMB [$\chi^2(2) = 1.973$, $p = .373$, Mauchly's $W = 0.924$], passed Mauchly's sphericity test, they were analyzed via repeated measures of ANOVA (RM-ANOVA) with Greenhouse–Geisser correction followed by a paired t -test with Bonferroni's correction ($\alpha = 0.05/3 = 0.0167$).

Because Mauchly's sphericity test indicated that the assumption of sphericity had been violated for Hgb in the analysis of all patients [$\chi^2(2) = 8.806$, $p = .012$, Mauchly's $W = 0.783$], as well as for PBAC score in the analysis of all patients [$\chi^2(2) = 46.121$, $p < .001$, Mauchly's $W = 0.278$] and in the analysis of patients with HMB [$\chi^2(2) = 23.084$, $p < .001$, Mauchly's $W = 0.397$], and for NRS score in the analysis of all patients [$\chi^2(2) = 89.929$, $p < .001$, Mauchly's $W = 0.082$] and in the analysis of patients with HMB [$\chi^2(2) = 64.172$, $p < .001$, Mauchly's $W = 0.077$], Wilks' lambda's multivariate analysis of variance (MANOVA) followed by a paired t -test with Bonferroni's correction ($\alpha = 0.05/3 = 0.0167$) was used.

Statistical analysis included a paired t -test to compare clinical outcomes pre- and post-procedure. For each statistic, an acceptable type 2 (a) error was less than 0.05.

Results

The characteristics of the patients are given in Table 1. The procedure was completed successfully in 39 patients, but

one patient withdrew from the study. Data on 38 patients were available at the 3-month follow-up and 37 patients were followed at 6 months. None of the patients underwent tubal ligation.

The mean duration of RF energy delivery was 3.1 min, and this was dependent on the length of the endometrial cavity, which was measured by uterine sounding. There were no immediate or post-procedure complications. All patients had watery discharge mixed with blood for 1–3 weeks, and this finding was not considered a complication. Most of the patients had preoperatively abnormal ultrasonographic findings, including leiomyoma and adenomyosis, and normal endometrial pathologic findings except for three patients in whom endometrial polyps were determined by pathologic examination. Two patients had type 2 submucosal myomas of 2.2 cm and 3.5 cm. The myomas compressed against the endometrium in three cases and 10 patients presented with myomas of variable size (2.2–12 cm) and number (1–7) localized within the myometrial layer. Twelve of 13 patients had myomas >3 cm in size. A subserosal myoma was detected in 1 patient. Of 20 patients with adenomyosis, 14 presented with diffuse adenomyosis and 6 with focal adenomyosis. The maximum thickness of the junctional zone ranged from 13.5 to 56.7 mm (average, 31.1 ± 11.4 mm). The uteri of 7 patients were palpable in the suprapubic area, suggesting over 12 weeks' gestation in size and their endometrial length was greater than 10 cm. Of them, 5 patients had enlarged nodular uteri due to multiple myomas and 2 patients had an enlarged uterus due to adenomyosis. All patients were taking iron at the time of their first visit. We recommended

Table 1. Characteristics of women who underwent endometrial ablation ($N = 38$).

	Number (%) or mean ($\pm$ SD)	Range
Age, mean ($\pm$ SD), range, years	42.3 (± 4.9)	30–52
BMI, mean ($\pm$ SD), range	24.7 (± 4.8)	17.1–35.8
Parity		
0	8 (21.1)	
1	15 (39.5)	
2	14 (36.8)	
3	1 (2.6)	
Menstrual cycle		
Regular	31 (81.6)	
Irregular	7 (18.4)	
Clinical presentation		
HMB	22 (57.9)	
AUB	16 (42.1)	
Pre-procedure Hgb, g/dL	10.4 (± 1.8)	5.7–13.9
PBAC score	331.7 (± 158.8)	27–645
Dysmenorrhea (NRS score)	4.7 (± 2.7)	0–9.0
Endometrial thickening before curettage, mm	9.5 (± 5.2)	2.1–30.0
Length of endometrial cavity, cm	8.5 (± 1.9)	7.0–14.0
Ablation time, min	3.1 (± 0.8)	1.25–6.0
Findings of pre-procedure ultrasound		
Normal	2 (5.3)	
Leiomyoma	16 (42.1)	
Type 2 submucosal	2	
Intramural	13	
Subserosal	1	
Adenomyosis	20 (52.6)	
Diffuse	14	
Focal	6	
Endometrial pathological results		
Normal	35 (92.1)	
Polyp	3 (7.9)	

SD: standard deviation; BMI: body mass index; AUB: abnormal uterine bleeding; Hgb: hemoglobin; PBAC: pictorial blood assessment chart; NRS: numeric rating scale.

discontinuing iron supplementation for patients with normal Hgb and ferritin levels and continued iron supplementation for patients with abnormal Hgb or ferritin levels for a duration of 3 months. Six patients with Hgb level <8.5 g/dL underwent blood transfusions before the procedure by the request of an anesthesiologist as general anesthesia was to be administered during the procedure. Pre-procedure PBAC scores were measured in 22 patients with HMB and six patients with AUB. Ten patients with AUB had irregular small amounts and frequent bleeding; thus, their PBAC scores were not reliable. All 22 patients with HMB had PBAC scores with a mean of 369.6 and range of 188-645, and all had iron deficiency anemia except for one patient.

The primary outcome measure in this study was 97.4% at 3 months following the procedure (Table 2). One patient still had a PBAC score of 240 and 10.0 g/dL of Hgb, whereas there were 590 and 8.3 g/dL, respectively, before the procedure. She had a 12-week-gestation-sized uterus due to adenomyosis and an endometrial cavity 14 cm in length. The ablation time was 6 min. However, at 6 months postoperatively, her PBAC score continued to be reduced to 99 and the Hgb level recovered to normal level of 11.8 g/dL.

Table 2. Post-procedure bleeding pattern.

Bleeding description	No. (%) of patients at		
	Pretreatment	3 months	6 months
Amenorrhea	0	4 (10.5)	5 (13.2)
Hypomenorrhea	2 (5.3)	16 (42.1)	14 (36.8)
Eumenorrhea	14 (36.8)	17 (44.7)	18 (47.4)
Menorrhagia	22 (57.9)	1 (2.6)	0
Follow-up loss	—	0	1 (2.6)
Total	38 (100)	38 (100)	38 (100)

Table 3. Clinical outcomes of the procedure in all women ($N = 38$).

Outcome	Mean ($\pm$ SD)			p Value
	Pre-procedure ^a	3 months	6 months	
Hemoglobin	10.4 ($\pm$ 1.7)	12.3 ($\pm$ 1.4)*	12.6 ($\pm$ 1.2)*	$<.001$
PBAC score	331.7 ($\pm$ 158.8)	73.4 ($\pm$ 44.6)*	64.1 ($\pm$ 34.8)*	$<.001$
Dysmenorrhea (NRS score)	4.7 ($\pm$ 2.7)	0.7 ($\pm$ 1.0)*	0.7 ($\pm$ 1.0)*	$<.001$
Endometrial thickening, mm	11.1 ($\pm$ 4.1)	7.1 ($\pm$ 3.5)*	6.5 ($\pm$ 2.3)*	$<.001$

^aPreprocedural hemoglobin levels for the patients who received blood transfusions are the hemoglobin levels measured before blood transfusion; * $p < .05$ compared with pre-procedure; SD: standard deviation; PBAC: pictorial blood assessment chart; NRS: numeric rating scale.

Table 4. Clinical outcomes of the procedure in women with heavy menstrual bleeding ($N = 22$).

Outcome	Mean ($\pm$ SD)			p Value
	Pre-procedure ^a	3 months	6 months	
Hemoglobin	9.9 ($\pm$ 1.5)	12.0 ($\pm$ 1.4)*	12.2 ($\pm$ 1.1)*	$<.001$
PBAC score	369.6 ($\pm$ 119.9)	83.3 ($\pm$ 44.8)*	72.4 ($\pm$ 30.9)*	$<.001$
Dysmenorrhea (NRS score)	5.4 ($\pm$ 2.5)	0.7 ($\pm$ 1.1)*	0.7 ($\pm$ 1.0)*	$<.001$
Endometrial thickening, mm	12.0 ($\pm$ 4.5)	7.6 ($\pm$ 3.9)*	6.5 ($\pm$ 2.4)*	$<.001$

^aPreprocedural hemoglobin levels for the patients who received blood transfusions are the hemoglobin levels measured before blood transfusion; * $p < .05$ compared with pre-procedure; SD: standard deviation; PBAC: pictorial blood assessment chart; NRS: numeric rating scale.

The clinical outcomes of all patients and of the patients with HMB are shown in Tables 3 and 4, respectively. The MANOVA and RM-ANOVA showed a statistically significant difference among the three-time points (pre-procedure and 3 and 6 months after the procedure). Additionally, there were significant differences between pre-procedure and 3 months post-procedure and between pre-procedure and 6 months post-procedure for all four indicators. Therefore, all parameters were significantly improved at 3 months after the procedure, and this improved status was maintained for 6 months after the procedure.

Discussion

In this study, the rate of bleeding reduction of RFA-EMT was 97.4% at 3 months and 100% at 6 months after surgery. Specifically, PBAC and NRS scores decreased significantly, and the recovery of Hgb and endometrial thinning followed. There were no complications related to RFA-EMT and no subsequent gynecological procedures during the 6 months after this procedure. These results indicate that a novel endometrial ablation system, RFA-EMT could be a promising alternative method in patients with HMB or AUB that fails to respond to medication.

Radiofrequency is used in RFA-EMT in a manner similar to that in bipolar RF global endometrial ablation system (GEA). EMT has some different characteristics than GEA. GEA involves the entire endometrium and led to a high amenorrhea rate, which was 88.9% of women had amenorrhea after GEA [10]. However, RFA-EMT may control the ablation area by adjusting the ablation depth and length. It is thereby able to control the menstruation amount. With this differentiation, 84.2% in this study presented with hypo- or eumenorrhea 6 months after the procedure, and only 13.2% had amenorrhea. The fundamental intention of treatment is to return to the normal condition, and amenorrhea is not normal, but another abnormal condition. Based on this viewpoint, controlling the menstruation amount is a strong point for RFA-EMT. Another important aspect of EMT is the expected potential to apply it in uterine anomalies, such as septate or bicornuate uteri or other congenital malformations. Although we excluded uterine anomalies in this study, EMT was successfully applied in the cases in which the endometrial cavity was twisted or distorted due to myoma or adenomyosis. Further studies are needed to prove these merits over GEA.

Several findings in this study were notable. First, most of the patients had myoma or adenomyosis. This suggests that RFA-EMT could be not only a simple treatment method for AUB-E, which is bleeding presumed to be secondary to endometrial hemostatic dysfunction, but that it could also be effective for AUB-L and AUB-A if there is an absence of organic lesions in the endometrial cavity [11]. This is noteworthy, because many women tend to choose a less invasive option to avoid major surgery [12,13], and women with leiomyoma or adenomyosis are not exceptions. Second, the expected bleeding pattern after the procedure in this study was not amenorrhea, but hypo- or eumenorrhea. For this purpose, with an experienced surgeon and unique

instrument, RFA-EMT contributed to excellent control of endometrial ablation depending on age, endometrial length, endometrial thickening, and bleeding patterns such as HMB or AUB. As mentioned above, inducing hypo- or eumenorrhea might be better to obtain the compliance and satisfaction of patients rather than amenorrhea. Third, this study included 33 patients (84.6%) who complained of dysmenorrhea; 28 of these patients had moderate to severe dysmenorrhea, which was defined as an NRS score greater than 4 that required analgesics. Pre-procedure dysmenorrhea is a factor known to predict ablation failure with odd ratio 2.42 [14]. Nevertheless, the successful rate of this study reached 100% at 6 months, and all patients experienced reduced dysmenorrhea after the procedure. This finding suggests that RFA-EMT could effectively manage dysmenorrhea. Fourth, no limitation on the size of the uterus were included in this study. While previous prospective studies excluded uterus sizes greater than 12 weeks of gestation [15–17], this study included them if there were no pathologic conditions of the endometrial cavity. Therefore, RFA-EMT could increase the upper limitation of endometrial ablation technologies.

There were no complications in this study, and several factors contributed to this. We defended against possible complications including pregnancy after endometrial ablation, obstructed menstruation (hematometra and post-ablation tubal sterilization syndrome), risks related to preexisting endometrial neoplasia and infection [18]. Before the procedure, we recommended barrier contraception to all patients and obtained endometrial tissues for pathological examination. We used prophylactic antibiotics, because we did hysteroscopy and endometrial biopsy just before ablation and believed that this increases infection risk in comparison to performing endometrial ablation alone. We also used ultrasound guidance.

Our study has drawbacks that must be considered. A major limitation of this study is its single-arm and non-comparative nature. The follow-up period was short, so late-onset endometrial ablation failure was not evaluated. Additionally, no measures of satisfaction were surveyed. Other limitations of the study include evaluation by a single surgeon in a single center and lack of an appropriate protocol to determine the ablation depth and length. Based on this study, comparative longer-term follow-up studies should be conducted.

In summary, we reported a novel endometrial ablation method, RFA-EMT, and demonstrated the safety and efficacy of RFA-EMT for the treatment of HMB and AUB when medical therapy has failed. RFA-EMT could be an innovative approach to manage women with HMB or AUB.

Disclosure statement

No potential conflict of interest was reported by the author(s).

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