

Radiofrequency endometrial ablation - new possibility of heavy menstrual bleeding conservative treatment

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Summary

Objective: evaluation of radiofrequency endometrial ablation (RFEA) clinical efficacy in patients with heavy menstrual bleeding (HMB).

Design: original article

Setting: Department of Gynecology and Obstetrics, Brno University Hospital and Masaryk University Medical School, Jihlavská 20, 625 00 Brno, Czech Republic

Methods: study included 20 patients with HMB who had failed hormonal therapy and met the study inclusion criteria. All RFEA procedures were performed in the operating theater in general anesthesia by two experienced surgeons according to a standardized protocol. All RFEA were performed using specific disposable electrodes and radio frequency generator M-3004 (RF Medical Co., South Korea).

Study outcomes were evaluated three months post-surgery included percentage of women with amenorrhea or menstrual bleeding persistence measured by the modified Pictorial Blood Assessment Chart (PBAC) score. Furthermore, chronic pelvic pain intensity assessed by visual analogue scale (VAS), patient satisfaction (Patient Global Impression of Improvement, PGI-I score), and the incidence of complications were evaluated.

Results: All RFEAs were performed without operational or technical complications, the average age being operated was 43.0 ± 2.9 years and the operating time did not exceed 10 minutes. In the early postoperative follow-up, patients did not require any analgesics and were all released to outpatient care the following day. Percentage of amenorrhea at three months post-treatment was 35.0%, mean PBAC score for women with menstrual bleeding was 1.8 ± 0.6 . Patient's satisfaction with the treatment was evaluated by 1.6 ± 0.6 on the PGI-I scale and long-term pelvic pain was on average 2.1 ± 0.8 by VAS, which counts an improvement of 31%.

Conclusion: The HMB treatment with RFEA achieves good clinical results in three-month evaluation with objective and also subjective parameters. The technique is suitable for outpatient treatment and is an alternative to hysteroscopy endometrial ablation. Its wider clinical usage is limited by the high cost of the radiofrequency generator and disposable probes.

Key words:

heavy menstrual bleeding; hysteroscopy; radiofrequency endometrial ablation; amenorrhea; complications.

Preface

Strong menstrual bleeding (SMB) is a serious health problem in premenopausal women. It causes chronic anemia and significantly worsens the quality of life of a woman. The first-line treatment for this disease is hormonal therapy, which is often less effective [3]. On the other hand, surgical removal of the uterus (hysterectomy), which may be associated with a number of serious perioperative complications, allows one hundred percent certainty of cure. The technique of uterine endometrial ablation (EA) is a less invasive surgical procedure that allows the uterus to be preserved. However, this procedure is not 100% effective and may require several repetitions. Long-term studies show that EA compared to hysterectomy is not sufficiently cost-effective [6].

In the last decade, new EA techniques, called second generation methods, have been developed. The argument for their introduction into clinical practice was simplicity of implementation and at least the same efficiency and safety. These methods do not require the aseptic environment of the operating room, no direct visualization of the uterine cavity is necessary and can be performed on an outpatient basis only under regional anesthesia. These EA techniques include laser ablation, microwave EA, radiofrequency endometrial ablation (RFEA), thermo-balloon ablation, cryo-ablation, endometrial destruction by hyper-osmolar solution, and all other endometrial destruction techniques. In the treatment of SMB, these second generation EA techniques are considered to be more effective in literature than first generation ablation techniques. In addition to higher efficiency, these techniques are particularly observed to have faster recovery after exercise and fewer surgical complications [10].

The aim of this work was to evaluate the safety of endometrial ablation by radio frequency technology. Furthermore, we evaluated the clinical efficacy of the procedure three months after its performance and the satisfaction of patients with cure of SMB symptoms, which significantly affects their quality of life. The clinical results obtained are further compared with the standard reference method of hysteroscopic electro-coagulation endometrial ablation (HEEA).

Patients and methods

The study was conducted at the Department of Gynecology and Obstetrics, Faculty of Medicine, Masaryk University in Brno (GPK), recruitment of patients and RFEA surgeries were performed in January and February 2018. In total, 20 patients (n = 20) with SMB symptoms were operated on by RFEA. The intensity of menstrual bleeding was assessed using a modified Pictorial Blood Assessment Chart (PBAC) score: 1 - only spotting, 2 - moderate bleeding, 3 - severe bleeding, 4 - very strong bleeding [17]. RFEA performance was performed in patients with SMB Intensity 4 according to PBAC scores for which hormone therapy was unsuccessful and showed a pelvic pain rate of at least 6 rated by Visual Analogue Scale (VAS) range 0-10 (maximum pain) during menstruation [7]. Patients were included in the study within the clinic's indication outpatient clinic on the basis of gynecological examination and vaginal ultrasound according to predetermined input criteria: absence of serious uterine pathology (atypical endometrial hyperplasia, uterine cancer, congenital uterine malformation, uterine adhesion), absence of uterine fibroids in diameter greater than 3 cm and longitudinal uterine size up to 11 cm. They were no longer included in the study patients who have not yet excluded pregnancy have used hormone therapy and patients with a history of uterine surgery (caesarean section, myomectomy) or already performed ablation or endometrial resection. Women under 25 years of age, perimenopausal patients (FSH above 10 mmol / l) and women suspected of gynecological inflammation were also excluded from screening.

All patients signed informed consent before being included in the follow-up. All performances RFEAs were conducted in the clinic operating room according to established workplace standards. The procedures were performed in short-term general anesthesia also according to established clinical

protocol. All the performances were operated by one experienced surgeon with specialized competence in the field. All interventions were further timed to the fourth to tenth days of the patient's menstrual cycle. Prior to RFEA, diagnostic hysteroscopy (HSK) was always performed with endometrial tissue collection for histological examination to exclude pre-tumor or tumor changes in the uterus.

The RFEA performance itself was performed using specific EMT electrodes and radio frequency generator M-3004 (RF Medical Co., Seoul, South Korea). The device was lent to the workplace on the basis of a loan agreement with the exclusive system importer for the Czech Republic by Mivamed s.r.o. (Prague). Consumables (EMT probes and electrodes) were also provided to the clinic by Mivamed as a research project. The radiofrequency EMT electrode was introduced trans-cervically into the uterine fundus under ultrasound control so as to touch its active end of the left uterine horn. Subsequently, a 90-second radiofrequency protocol was performed, according to the system manufacturer's clinical protocol. After moving the active end of the electrode to the right uterine horn, the RFEA procedure was repeated a second time. During the performance we monitored the operating time and technical performance of the procedure evaluated by the surgeon on the 1-5 scale (5 is the worst). Furthermore, the visual effect of endometrial destruction by radiofrequency waves on the same "school" grading scale 1-5 was evaluated by the surgeon during subsequent hysteroscopy.

After the procedure, the patients were monitored at the ward and released for home treatment the next day, or on the day of surgery, at least four hours after the end of anesthesia, if they tolerated the diet well and did not have an emptying problem. If patients felt pain after surgery, they were given an analgesic piritramide 7.5 mg subcutaneously. The pain was evaluated using the VAS visual analogue scale, the pain intensity required for analgesic application was $VAS \geq 4$.

The RFEA clinical performance indicators were evaluated three months after the performance. The main evaluation parameter was the percentage of women with no menstrual bleeding (amenorrhea). When menstrual bleeding was present, its intensity was evaluated similarly as before surgery with the modified PBAC score. Furthermore, the intensity of long-term pelvic pain was evaluated using the VAS 0-10 scale as well as before surgery. The generalized Patient Global Impression of Improvement (PGI-I), was used to evaluate patient satisfaction with cure for SMB symptoms compared to pre-treatment improvement: 1 – significant improvement, 2 - improvement, 3 - same condition, 4 – worsening. In the three months after the RFEA also all early and late surgical complications were noted.

Standard statistical evaluation methods were used for statistical evaluation of results using Microsoft Excel software. For qualitative variables (nominal and ordinal), the method of frequency and median evaluation with percentiles was used, for mean variables the mean and standard deviation were calculated. The study, including written informed consent, was approved by the Ethics Committee of the University Hospital Brno in June 2017.

Results

The mean age of operated patients ($n = 20$) was 43.0 ± 2.9 years. Average parity of women in the group was 2.3 ± 0.5 deliveries. In all cases, the patients were still of reproductive age, the mean value of follicle-stimulating hormone (FSH) was 7.1 ± 1.5 mmol / L. The pelvic pain intensity assessed by the patients prior to procedure varied from 6.6 ± 0.5 points on the VAS scale. The ultrasound longitudinal size of the uterus was 8.3 ± 1.1 cm. The mean duration of surgery was 9.1 ± 2.3 minutes. The technical intensity of the performance was assessed by the operator on average at 1.2 ± 0.3 on

the standard "school" scale. The rate of radiofrequency ablation of the endometrium visually assessed by the surgeon during subsequent hysteroscopy was evaluated by an average score of 1.5 ± 0.6 . Figure 1 illustrates the visual comparison of the endometrium just before and after radiofrequency ablation treatment. No peroperative or early postoperative complications were observed in the study group. The application of analgesics was not necessary in the early postoperative period and the patients were released for home treatment at the latest the day after surgery. Histological examination of the endometrium, performed before the RFEA itself, showed no cancer or pre-tumor changes in the uterus in any patient. The characteristics of the set of patients and the operational characteristics of the radiofrequency endometrial ablation are summarized in Table 1. (Table 1).

Clinical efficacy of RFEA was evaluated three months after the procedure. Percentage of amenorrhoe was 35.0%. The mean PBAC score in women with menstrual bleeding was 1.8 ± 0.6 points, representing an improvement of 45% compared to pre-operative clinical status. Patient satisfaction with SMB symptoms was 2.1 ± 0.8 points on the PGI-I scale from 1-4 (worst). Patients described long-term pelvic pain by an average of 1.6 ± 0.6 according to VAS, which represents an improvement of 31% compared to pre-operative status. There were no serious postoperative complications in the study group. Clinical indicators of radiofrequency endometrial ablation are summarized in Table 2 (Table 2).

Discussion

Second generation EA surgical techniques have been developed over the last twenty years. The gold standard of these ablation techniques are electrosurgical transcervical ablation of the endometrium using a loop or a ball. This technique requires direct visualization of the uterine cavity by hysteroscopy, which only an experienced endoscopic surgeon can perfectly handle. EA ball method using simple electro-surgical equipment was first introduced in 1988. A more modern method of endometrial destruction using resection hysteroscopy (HSK) was developed in 1997. This technique is characterized by endometrial excision rather than mere ablation. [2]. Although it has good clinical results in practice, it is associated with a significant risk of uterine injury. The aforementioned techniques, referred to in the literature as "first generation" techniques, require relatively expensive endoscopic equipment, an aseptic operating theater environment, an experienced surgeon, and often the need for general anesthesia. At most gynecological and obstetric workplaces in the Czech Republic and Western Europe, hysteroscopic electrocoagulation of endometrial ablation (HEAE) is currently the first choice method for conservative SMB surgery in women of childbearing age [9].

The second generation EA methods have developed especially in the last decade. Unlike the first generation ablation methods this technique does not require direct visual inspection of the uterus and experienced surgeon. Of all the available second generation endometrial ablation techniques, RFEA has the best clinical results. From the technical point of view, it is very simple and shows high efficiency and safety for the patient. Another advantage is the reduction of hormonal expression in endometrial cells, which still potentiates long-term good clinical results. Proper placement of the ablation probe in the uterus with ultrasound navigation and generator is sufficient for reliable endometrial ablation radiofrequency current, which is less at risk of destruction of uterine tissue than electrocoagulation devices. Therefore, the procedure is safer for the patient, has less risk of surgical complications, is less painful and requires less burdening the form of anesthesia or analgosedation [11].

RF Medical System M-3004 (Seoul, Korea) was developed as one of the most advanced second generation endometrial ablation systems. Moreover, its generator is very flexible and can be used not only for radiofrequency ablation of endometrium, but also for destruction of uterine fibroids,

ovarian cysts or other gynecological pathologies. To ensure the best clinical results, the system allows the adjustment of the ablation protocol according to the individual needs of the patient (uterine size, phase of the menstrual cycle, menstruation intensity). The multifunctional radiofrequency current generator can also be used in other medical expertise for the destruction of pathological conditions, particularly tumors of the liver, lung, kidney or thyroid [16].

In comparison with the standard HEEAE technique used so far, surgical treatment of SMB by RFEA is, according to our experience, technically very simple and does not require an experienced surgeon. The method is also very fast and does not require significant cervical dilatation. Endometrial destruction rate, evaluated by subsequent hysteroscopy, but significantly depends on the correct placement of the radio frequency electrode and is directly proportional to the duration of the radio frequency current. Based on ex vivo experiments in bovine liver and after the first clinical experience, the ablation protocol accurately described in the study methodology has proven to be the most effective. The ablation effect can also be evaluated in real time by abdominal ultrasound, where hyperechogenic tiny bearings of up to 1 mm (reminiscent of "bubbles") stretching about one quarter of the width of myometrium are visible around the probe. The rate of amenorrhoe in our patient population three months after the RFEA of 35% is lower than that described in some previous work evaluating this technique. Clark et al. in his 2011 work reports the percentage of amenorrhoe for six months at 39% and Penninx et al. even 50% [4]. However, a different system for RFEA (Novasure) was used in both studies and the incidence of post-operative complications in terms of hematometry due to cervical stenosis and worsening of pelvic pain [13] was reported in both studies.

Interestingly, the available literature compares the long-term effectiveness of RFEA with HEEA have demonstrated similar efficacy of both techniques to achieve amenorrhoe (65% hysterectomy was significantly lower in patients after RFEA with a five-fold interval (16% vs. 25%) and ten years (17% vs. 28%) after the procedure [14]. Comparing RFEA with balloon thermoablation, also second generation ablation, the result of the comparison in randomized trials was significantly better in terms of radiofrequency in both objective [8] and subjective evaluation parameters [1].

Our pilot results show that the treatment of patients with SMB by RFEA is safe and technically simple with the possibility of outpatient treatment in analgesedation or regional anesthesia. Clinical efficacy as well as patient satisfaction with symptomatic cure for three months after surgery is relatively high and appears to be at least comparable to or better than standard HEEA treatment, which is the reference treatment technique used in the Czech Republic. So far, the introduction of this method into routine clinical practice is hampered by the relatively high cost of consumables (disposable probes and electrodes) for the future, with full or partial patient reimbursement. The acquisition cost of the radio frequency generator is also in the order of several million crowns. However, the generator is simply portable and can be used in the outpatient operation by renting or lending from the supplier. Investment in a generator can also be more quickly assessed in large inpatient facilities by utilizing other expertise (oncology, radiology, surgery), where there is more realistic reimbursement of performance radiofrequency ablation by healthcare payers [12].

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Tables

Table 1

Characteristics of patients and surgical performance of radiofrequency endometrial ablation

Parameter (Unit)	Average Result (Decisive Deviation)
Age (years)	43,0 ± 2,9
Parity (number of births)	2,3 ± 0,5
FSH before procedure (mmol / l)	7,1 ± 1,5
Pelvic pain intensity (VAS scale 0-10)	6,6 ± 0,5
The longitudinal size of the uterus ultrasonic measurement (cm)	8,3 ± 1,1
Procedure time (min.)	9,1 ± 2,3
The technical difficulty of the procedure (grading scale 1-5)	1,2 ± 0,3
Endometrial ablation rate (1-5 scale)	1,5 ± 0,6
Peroperative complications	-

* VAS- Visual Analogue Scale

Table. 2

Clinical indicators of radiofrequency endometrial ablation efficiency three months after surgery

Parameter (Unit)	Average Result (Decisive Deviation)
Reaching Amenorrhoe (%)	35,0 ± 4,5
PBAC* score (1-4)	1,8 ± 0,6
Pelvic pain intensity (VAS scale 0-10)	2,1 ± 0,8
Patient satisfaction with recovery (* PGI-I score 1-4)	1,6 ± 0,6
Postoperative complications	-

* PBAC - Pictorial Blood Assessment Chart, VAS- Visual Analogue Scale, PGI-I - Patient Global