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## CLINICAL ARTICLE

## Radiofrequency endometrial ablation for the treatment of heavy menstrual bleeding among women at high surgical risk

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## ABSTRACT

**Objective:** To evaluate quality of life (QoL) after radiofrequency endometrial ablation (RFEA) for heavy menstrual bleeding among women at high surgical risk. **Methods:** An observational study was undertaken among women aged at least 18 years who underwent RFEA at Hanover Medical School, Germany, between June 2010 and November 2012. A validated menorrhagia outcomes questionnaire (MOQ) was used to evaluate QoL and global outcomes among patients at high risk and low risk of complications after major surgery. The high-risk group included women with anemia, coagulopathy, anticoagulation, thromboembolism, transplantation, malignancy, severe cardiovascular or pulmonary disease, and obesity. **Results:** Overall, 235 women underwent RFEA during the study period. Median follow-up was 13 months (range 3–30). Questionnaire responses were received from 202 (86.0%) women, including 132 (65.3%) high-risk patients. The MOQ total outcome (mean difference 2.0;  $P = 0.166$ ) and QoL/satisfaction (mean difference 0.8;  $P = 0.601$ ) scores were similar in the two groups. Success (i.e. symptom relief and no further surgery) was recorded for 119 (90.2%) patients in the high-risk group and 67 (95.7%) patients in the low-risk group ( $P = 0.155$ ). **Conclusion:** RFEA improved QoL and achieved a high rate of satisfaction for both high- and low-risk patients. RFEA offers a less invasive alternative to hysterectomy and its associated perioperative risks, particularly among high-risk patients.

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## 1. Introduction

Heavy menstrual bleeding (HMB) interferes with physical, mental, and socioeconomic well-being, affecting the quality of life (QoL) of approximately 30% of women of reproductive age [1,2]. As a result, many women, especially those with severe comorbidities, ask for a structural solution to their excessive bleeding.

Hysterectomy is a definitive treatment for HMB, but has a high incidence of both major and minor complications [3]. In addition, severe comorbidities can preclude patients from hysterectomy because they are major risk factors for complications, such as genitourinary and gastrointestinal tract injuries, hemorrhage requiring blood transfusion, neuropathy, and thromboembolism [4–6].

As compared with hysterectomy, radiofrequency endometrial ablation (RFEA) is minimally invasive and therefore might be an alternative treatment modality for patients considered too high risk for surgery. So far, most studies reporting outcomes after RFEA have excluded patients

with major surgical risk factors for hysterectomy such as coagulopathy [7,8]; however, both the effectiveness and safety of RFEA for patients in the low-risk category have been demonstrated by a multicenter randomized trial [9].

For patients with severe comorbidities at high surgical risk, general health and QoL after RFEA might be impaired, which in turn might have a negative impact on patients' satisfaction with RFEA. The aim of the present study was to assess QoL and global outcome after RFEA for women at high risk for complications after hysterectomy.

## 2. Materials and methods

The present retrospective, observational, cohort study enrolled women with HMB aged at least 18 years who were referred to Hanover Medical School, Hanover, Germany, for RFEA between June 1, 2010, and November 30, 2012. Women with severe underlying conditions, such as extrauterine malignancy, coagulopathy, or previous transplant, were included in the study. Women with a uterine malignancy confirmed by pathology, with current uterine anomalies, and who would like to retain the option of pregnancy in the future were excluded. Ethical approval was obtained from the Hospital's Local Research Ethics Committee. All women provided informed consent.

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For RFEA, a NovaSure (Hologic, Bedford, MA, USA) device was used. The procedure was performed under general anesthesia and required no specific timing. One dose of perioperative antimicrobial prophylaxis was administered to all patients. Diagnostic hysteroscopy and fractional curettage were carried out immediately before RFEA to confirm a normal uterine cavity and to rule out endometrial malignancy. The RFEA device delivers bipolar radiofrequency energy into the endometrial cavity via a gold-mesh electrode and is controlled for impedance [7]. Histologic results were obtained after RFEA.

All women who underwent RFEA received an invitation to participate by mail, an explanation of the research, and a consent form. Periodic reminder letters and pseudonymization were used to increase response rates [10].

For the present study, comparative improvement in QoL was the primary measure of outcome considering the NICE guideline for HMB [2]. To assess patient-based outcomes with a valid and reliable questionnaire—the Menorrhagia Outcomes Questionnaire (MOQ)—was used and included in the invitation mail. It was developed to evaluate the outcomes of all surgical interventions for the treatment of HMB [11]. Before use of the MOQ in Germany, standard linguistic validation was implemented including forward and back translation of the English questionnaire [12].

The MOQ consists of scored questions covering four domains of symptoms, postoperative complications, QoL, and satisfaction with outcome; and non-scored questions regarding sociodemographic characteristics, treatment characteristics, and evaluation of preoperative symptoms. The total outcome score (TOS) was obtained by summing 17 scored items across all four domains. The QoL/satisfaction score was the sum of 12 scored items covering exclusively QoL and satisfaction with outcome. All scores were calculated by summing standard scores from each question and by converting them to a so-called T score, with a defined mean of  $50 \pm 10$ . Higher scores indicate worse outcomes.

For the subordinate QoL analysis, women who had a hysterectomy after RFEA or ongoing chemotherapy were excluded because their answers to the MOQ [11] would not be able to consider RFEA alone; however, they were considered in the success rate and histologic data.

For the present study, demographic data were collected from medical records. The success rate of RFEA was determined by symptom relief (bleeding and/or pain) reported in the MOQ, and lack of need for further surgery. Patients were categorized into two groups by surgical risk factors for hysterectomy, as documented in previous studies [4–6]. They were classified as high risk if they had at least one major risk factor or two minor risk factors.

Data were analyzed by SPSS version 21 (IBM, Armonk, NY, USA), which was also used to calculate the mean TOS and QoL/satisfaction score. Mean outcome scores were compared by Student *t* test for equality of means. In addition, both Fisher and  $\chi^2$  tests were used for statistical evaluation. Missing values were replaced by the group mean. To evaluate the uncertainty of the results owing to missing values, a sensitivity analysis was conducted among patients with complete data. The reliability of the German version of the MOQ was evaluated by calculating the Cronbach  $\alpha$  coefficient for the TOS and QoL/satisfaction scores. These calculations were based on the responses of patients who fully completed all items for the two summary scores.  $P < 0.05$  was considered to be statistically significant.

### 3. Results

In the study period, 238 women were referred to the study institution for RFEA. The treatment was not completed for 3 (1.3%) women (Fig. 1). The remaining 235 patients who underwent RFEA were sent the MOQ. In total, 202 (86.0%) women responded, including 132 (65.3%) high-risk and 70 (35.7%) low-risk patients (Table 1). Among the non-responders, two had moved and one had died from a cause not related to the treatment (colon cancer). The median follow-up was 13 months (range 3–30); 95 (47.0%) women had follow-up at

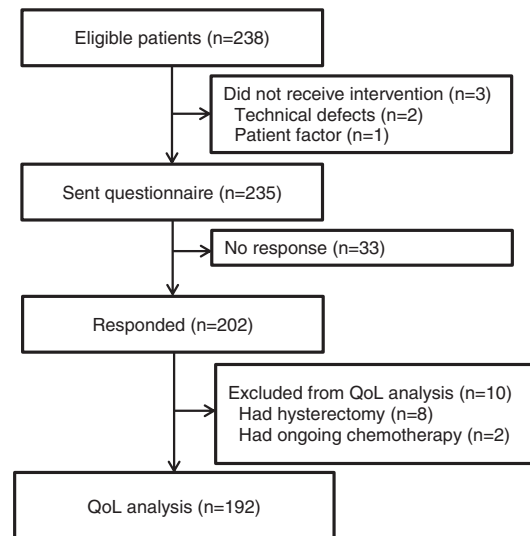


Fig. 1. Flow of patients through the study. Abbreviation: QoL, quality of life.

less than 1 year, 89 (44.1%) at 1–2 years, and 18 (8.9%) at more than 2 years after RFEA.

The low- and high-risk patients had similar baseline characteristics, except for body mass index (BMI, calculated as weight in kilograms divided by the square of height in meters), which was significantly higher in the high-risk group (Table 2). The high-risk patients had a high number of comorbidities, which was reflected by a significantly higher number of high-risk patients with severe systemic disease, as assessed by the American Society of Anesthesiologists (ASA) score ( $P = 0.002$ ) (Table 2). The two groups had similar prevalences of possible confounders such as dysmenorrhea ( $P = 0.335$ ), fibroids ( $P = 0.617$ ), and simultaneous surgery for sterilization, laparoscopic adnexectomy, adhesiolysis, or enucleation of subserous myomas ( $P = 0.423$ ) (Table 2).

All patients underwent RFEA for HMB. The mean ablation time was similar between the two groups ( $P = 0.264$ ) (Table 2). The high-risk patients stayed in hospital significantly longer than did the low-risk patients ( $P = 0.039$ ) (Table 2).

Among the 238 women who were referred for RFEA, there were 12 (5.0%) complications (Table 3). Two (0.8%) serious complications

Table 1  
Risk factors for major surgery.<sup>a</sup>

Risk factor	Low-risk patients (n = 70)	High-risk patients (n = 132)	P value
<b>Major risk factors</b>			
Anemia (hemoglobin <120 mg/L) <sup>b</sup>	0	61 (46.2)	–
Coagulopathy	0	14 (10.6)	–
Anticoagulation/antiplatelet therapy	0	15 (11.4)	–
History of thromboembolism	0	14 (10.6)	–
Obesity (BMI >30)	0	60 (45.5)	–
History of malignancy	0	11 (8.3)	–
History of transplantation	0	8 (6.1)	–
Severe cardiovascular disease	0	26 (19.7)	–
Severe chronic pulmonary disease	0	4 (3.0)	–
<b>Minor risk factors</b>			
Thyroidal disease	3 (4.3)	28 (21.2)	0.001
Hypertension	5 (7.1)	50 (37.9)	<0.001
Diabetes mellitus	2 (2.9)	3 (2.3)	0.812
Renal disease	1 (1.4)	4 (3.0)	0.476
History of cesarean delivery	12 (17.1)	35 (26.2)	0.168
Infection	1 (1.4)	5 (3.8)	0.347

Abbreviation: BMI (calculated as weight in kilograms divided by the square of height in meters).

<sup>a</sup> Values are given as number (percentage) unless indicated otherwise.

<sup>b</sup> According to WHO classification.

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