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Bipolar versus balloon endometrial ablation in the office: a randomized controlled trial

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ABSTRACT

Objective: To compare the effectiveness of bipolar radiofrequency (Novasure®) ablation and balloon endometrial ablation (Thermablate®).
Study design: We performed a multi-center double blind, randomized controlled trial in three hospitals in The Netherlands. Women with heavy menstrual bleeding were randomly allocated to bipolar or balloon endometrial ablation, performed in the office, using a paracervical block. The primary outcome was amenorrhea. Secondary outcome measures were pain, satisfaction, quality of life and reintervention.
Results: 104 women were randomized into the bipolar (52) and balloon (52) groups. After 12 months amenorrhea rates were 56% (29/52) in the bipolar group and 23% (12/52) in the balloon group (relative risk (RR) 0.6, 95% confidence interval (CI) 0.4–0.8). The mean visual analog pain score of the total procedure was 7.1 in the bipolar group and 7.4 in the balloon group ($P < .577$). 87% (45/52) of the patients in the bipolar group were satisfied with the result of the treatment versus 69% (36/52) in the balloon group (RR 0.44, 95% CI 0.2–0.97). The reintervention rates were 5/52 (10%) in the bipolar group and 6/52 (12%) in the balloon group (RR 1.02, 95% CI 0.9–1.2). Quality of life (Shaw score) improved over time ($P < .001$) and was significantly higher in the bipolar group at 12 months follow-up ($P = .025$).
Conclusion: In the treatment of heavy menstrual bleeding, bipolar radiofrequency endometrial ablation is superior to balloon endometrial ablation as an office procedure in amenorrhea rate, patient satisfaction and quality of life.

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Introduction

Excessive menstrual bleeding is a significant health problem (incidence 9–22%) [1–3]. About 16% of the hysterectomies are performed for heavy menstrual bleeding (HMB) [4]. Hysterectomy is a major surgical procedure with a high complication rate [5]. Endometrial ablation is a less invasive alternative. First-generation endometrial ablation techniques were laser ablation, transcervical resection of the endometrium and rollerball ablation. Disadvantages of these techniques were the chance of fluid overload or water intoxication [6–9]. Second-generation techniques overcame these disadvantages. They are technically simpler, quicker to perform and require less skills of the surgeon, while satisfaction rates and reduction in HMB are similar [10].

NovaSure® second generation endometrial ablation (Hologic, Bedford, MA) uses bipolar radiofrequency to vaporize endometrial tissue. The Novasure® measures the impedance of the tissue. Impedance of the endometrium is less than impedance of the myometrium. The NovaSure® stops by itself when the endometrial tissue is vaporized and the impedance rises or after the maximum duration of two minutes. Bipolar ablation is reported to be superior to balloon ablation (ThermaChoice® 1) and hydrothermablation, making it the most requested ablation technique for HMB [11–13].

We reported that NovaSure® with local anesthesia as an office procedure is a safe and feasible, procedure [14]. A majority of women (70%) prefer outpatient treatment, spending less time in

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the hospital, attending for one visit and feeling well directly after treatment [15].

The Thermablate® balloon ablation (Sigma Medical, The Netherlands) is relatively new on the market. It seems favorable for outpatient treatment with local anesthesia with its small diameter and relatively short treatment time of two and a half minutes with a high treatment temperature (173 °C) [16,17]. There are no randomized trials comparing Thermablate® with other ablation techniques. We performed a randomized controlled trial comparing the NovaSure® and Thermablate® with local anesthesia in the office.

Materials and methods

We performed a multi-center randomized controlled trial (RCT) in the Máxima Medical Centre Veldhoven, Twee Steden Hospital Tilburg and Zuidoost Clinic Amsterdam, The Netherlands. The study was registered in the international trial registration (ISRCTN17974690). Women with HMB were eligible for the trial with a minimum score of 150 points, counted during one period on the pictorial chart (Highman et al. [18]).

All women were submitted to sonography. Women with intracavitary pathology were excluded, except for women with intracavitary polyps <1 cm. Saline infusion sonography or diagnostic hysteroscopy was required to confirm a normal uterine cavity (cavity length 6–12 cm). A histologically benign endometrium was confirmed within 6 months of screening by endometrium in the office (Pipelle®, CooperSurgical, Trumbull, USA). All women had a normal Pap smear and a follicular stimulating hormone (FSH)-level of less than 40 IU/L. Exclusion criteria were presence of coagulopathies, use of anti-coagulants, desire to preserve fertility, prior uterine surgery other than low segment Cesarean section and (suspected) uterine malignancy. All women preferred to be treated in the outpatient setting. The procedure was planned at day 3–8 of the menstrual cycle. No medical endometrial pretreatment was given.

Women were randomly allocated to bipolar or balloon ablation. A sealed opaque envelope was taken just before treatment in every center (1:1 ratio). Patients and doctors were masked for the randomization allocation during the study. The doctors performing the ablation did know which device was used. However the physician seeing the patient at the follow-up visit did not know which device was used.

The bipolar ablation system (NovaSure®) consists of a generator and a disposable device. After introducing the device in the uterine cavity, a cavity assessment check has to be completed. The system uses a small amount of CO_2 to verify cavity integrity to be sure that there is no perforation. The bipolar ablation is suitable for an uterus with a minimum of 2.5 cm cornu-to-cornu distance, and an uterine soundinglength of 6–11 cm [19].

The balloon endometrial ablation (Thermablate®) consists of a hand-held automated Treatment Control Unit (TCU) and a single-use catheter balloon cartridge. The TCU heats 28 mL of fluid to a temperature of 173 °C in 8 min. This heating process takes place before or during patient preparation. After heating the 6 mm wide catheter is brought into the uterine cavity (an uterine soundinglength to 12 cm is suitable). The silicone balloon within the cavity is automatically filled with heated fluid to a pressure of 220 mmHg. During treatment three depressurization and repressurization cycles are performed to maintain balloon surface contact with the uterine cavity with uniform temperature of the fluid within the balloon. The treatment time is 2 min and 38 s [17]. The Thermablate® does not verify cavity integrity before treatment. We performed a hysteroscopy before and after the procedure.

All procedures were performed at the outpatient clinic. The device was covered with a sheet until women were covered with sterile blankets. They could not see the device used. As a painkiller women used an oral nonsteroidal anti-inflammatory drug (Naproxen 500 mg) one hour before treatment. A paracervical block with articaïn with adrenalin (12–20 mL) was injected just under the epithelium of the cervix at 2, 5, 7 and 10 o'clock. There was a 3 min waiting time for the anesthetic effect before dilatation of the cervix. After the procedure, patients could take paracetamol 1000 mg four times a day and one more Naproxen 500 mg. If necessary they could take tramal 100 mg. They reported the medication that was used. Visual analog scale (VAS) was used to measure pain when dilating the cervix, during endometrial ablation, and 1, 4, 12 and 24 h after the procedure. The VAS is a straight line based on a scale of 0–10, where 0 stands for no pain and 10 for maximum pain.

Follow-up visits were at the outpatient clinic or by telephone at 6 weeks, 6 and 12 months after treatment. The duration of menstruation, presence of clots and dysmenorrhea were registered. Patients completed a pictorial chart and expressed their satisfaction about the treatment result. Levels of satisfaction were completely satisfied, satisfied, doubtful or not satisfied.

Menstrual bleeding was quantified using the Pictoral Blood loss Assessment Chart (PBAC). A score of zero defined "amenorrhea". Women with amenorrhea after a hysterectomy were not included in the amenorrhea group. All patients were asked to complete the menorrhagia multi-attribute scale (Shaw questionnaire) at baseline and each follow-up visit to assess the effects of HMB on quality of life. The scores of the domains rated a score of zero points (worst) to 100 points (best) [20,21]. Furthermore, we registered whether a reintervention was performed (oral contraceptives, re-ablation and hysterectomies).

The primary outcome was amenorrhea at 12 months post-treatment. Secondary outcomes were pain, reduction in bleeding, patient satisfaction, quality of life and reinterventions.

Based on information of the Thermablate® and other balloon devices, an amenorrhea rate of 30% was anticipated in the balloon group and 50% in the bipolar group [11,12,22–25]. Using an 1-tailed test of proportions with $P = 0.05$, the proposed sample size of 94 patients has 80% power to detect a treatment difference of 20% or greater. Assuming that approximately 90% of enrolled patients would complete the study protocol, a total of 104 patients (bipolar:balloon 1:1) had to be enrolled.

Analysis was performed according to the 'intention-to-treat' principle. Repeated measures analysis of variance was used to evaluate changes in effect over time (time effect), differences in effect between both treatment groups (treatment effect), and we evaluated if changes over time are different for both groups (time-by-treatment effect). Patients with missing measurements were included in the repeated measure analysis if data were available for at least two different time points [26].

P-values less than 0.05 were considered to indicate statistical significance. When a statistically significant difference in menstrual pattern, patient satisfaction or multi utility scale score between both treatment groups or an interaction between changes in menstrual pattern and patient satisfaction over time and treatment group was found, the differences between treatment groups at specific points in time were examined. In case of dichotomous endpoints this was done by calculating relative risks and 95% confidence intervals. The pictorial chart score and VAS score were compared using the Wilcoxon test [27,28]. We calculated treatment satisfaction after treatment with a *T*-test. All data were analyzed using IBM SPSS statistics 20 for Windows.

Results

Between June 2009 and December 2011 104 women were included in the study; 52 in the bipolar group and 52 in the balloon

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