Journal of Minimally Invasive Gynecology (2006) 13, 424–430

THE JOURNAL OF
MINIMALLY INVASIVE
GYNECOLOGY

Cavaterm thermal balloon endometrial ablation versus hysteroscopic endometrial resection to treat menorrhagia: The French, multicenter, randomized study

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KEYWORDS:
Menorrhagia;
Transcervical endometrial resection;
Thermal balloon ablation

Abstract

STUDY OBJECTIVE: To compare the efficacy and safety of Cavaterm thermal balloon endometrial ablation with hysteroscopic endometrial resection.

DESIGN: Multicenter randomized trial (Canadian Task Force classification I).

SETTING: Departments of obstetrics and gynecology in French university hospitals.

PATIENTS: Fifty-one women with menorrhagia unresponsive to medical treatment.

INTERVENTIONS: Women were randomized to thermal destruction of the endometrium or to hysteroscopic endometrial resection. Women completed preoperative, 6-, and 12-month postoperative pictorial charts to determine Higham blood loss scores and a satisfaction questionnaire. Operative time, discharge time, complication rate, and resumption of normal activities were evaluated for each group.

MEASUREMENTS AND MAIN RESULTS: Amenorrhea rates were 36% (95% CI 19%–56%) and 29% (95% CI 8%–51%) in the Cavaterm and the endometrial resection groups at 12 months, respectively (ns). Both treatments significantly reduced uterine bleeding. The median decrease in Higham score at 12 months was significantly higher in women treated by Cavaterm (377, range 108-1300) than in women treated by resection (255, range −82 to 555) ($p = .006$). A subsequent hysterectomy for recurrent bleeding was performed in 2 women, both previously treated by resection. The rate of women reporting good or excellent satisfaction was 89% (95% CI 72%–98%) in the Cavaterm group and 79% (95% CI 54%–94%) in the resection group at 12 months. Discharge time was significantly lower in women treated by Cavaterm, although postoperative pain at 1 hour was higher. There were no major complications in either group.

CONCLUSIONS: Cavaterm thermal balloon ablation was as effective as hysteroscopic endometrial resection to treat menorrhagia, both resulting in a significant reduction in menstrual blood loss and high patient satisfaction.

Menorrhagia, a common problem in women of reproductive age, is responsible for more than one third of the hysterectomies performed annually in Europe and North America.[1] Endometrial ablation has proven to be a cost-effective and well-accepted surgical alternative to hysterectomy in women with excessive menstrual bleeding.[2] Women treated with the hysteroscopic methods (neody-

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Submitted March 9, 2006. Accepted for publication May 12, 2006.

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doi:10.1016/j.jmig.2006.05.006

mium:yttrium-aluminum-garnet[Nd:YAG] laser photovaporization, rollerball electrocoagulation, and transcervical endometrial resection) became amenorrheic and hypomenorrheic in 90% of cases at 1 year, a figure that remained above 70% after 5 years of follow-up.[3–7] Most of these methods require preoperative medical regimens to thin the endometrium and extensive hysteroscopic training and may result in complications (hemorrhage, uterine perforation, intravascular fluid overload from distension media). Global ablation methods have been developed to be performed on an outpatient basis with the patient under local anesthesia, to reduce complication rates and to standardize success rates, independent of the surgeon's skill.[8] Thermal balloon ablation is the oldest of these new generation techniques and has become the most popular in Europe.[9] Preliminary studies showed a satisfaction rate of about 90% at 1 year.[9–12] Long-term studies confirm that thermal balloon ablation gives similar results to hysteroscopic methods, the probability of women avoiding any subsequent surgery being 75% at 4 to 6 years with Thermachoice (Gynecare, Somerville, NJ) and 85% at 4 years with Cavaterm (Wallsten Medical, Morges, Switzerland).[13,14] However, most of the results were obtained from observational or nonrandomized trials. Three randomized trials comparing thermal balloon ablation to the hysteroscopic methods have been published recently.[15–17] Two types of balloon were considered, and various methods of hysteroscopic endometrial ablation were used. In 2000, a multicenter randomized study was conducted in France to compare Cavaterm thermal balloon ablation with transcervical endometrial resection, focusing on objective results by assessing pictorial charts before and 1 year after treatment.[17]

Materials and methods

Women with menorrhagia unresponsive to medical treatment requesting conservative surgical management of their condition were recruited in a clinical study comparing the effectiveness and safety of the thermal intrauterine balloon device Cavaterm with those of transcervical endometrial resection in the treatment of menorrhagia. Six French investigative centers participated. All investigators had been trained in the use of the Cavaterm balloon and were experienced in endometrial resections, having performed between 30 and 100 operative hysteroscopies a year for 6 to 20 years. The study design was approved by the ethics committee at Victor Segalen University in Bordeaux. Written informed consent was obtained from each woman.

Women who no longer wished to become pregnant were eligible to participate if they had a Higham blood loss score[18] > 100, an internal uterine cavity length of between 4 and 12 cm, normal endometrial biopsy, normal cervical cytologic study result, had completed her family, and was using a reliable method of contraception, excluding progestins. Exclusion criteria included endometrial malignancy, active pelvic infection, submucous fibroids, polyps, uterine malformation, a history of endometrial ablation procedure, and hormone treatment (gonadotropin-releasing hormone agonists, danazol) during the 6 months preceding inclusion.

The primary outcome measures were the amenorrhea rate and the amount of uterine bleeding. Uterine bleeding was documented by a validated pictorial chart.[18] Women were required to keep daily records of menstrual bleeding by completing a chart recording the amount of staining on pads or tampons. Diary data were converted into diary scores. A score > 100 corresponds to blood loss > 80 mL with 86% sensitivity and 81% specificity. The secondary measures were patient satisfaction and the safety of the procedures (posttreatment morbidity and identification of adverse effects).

Women were assigned to Cavaterm therapy or endometrial resection by means of a computer-generated randomization telephone number sequence in a 1:1 allocation ratio. The required sample size was based on estimated response rates for women undergoing either treatment. In our experience, transcervical endometrial resection results in amenorrhea in 26% of cases.[3] A pilot study with the Cavaterm system reported an amenorrhea rate of 68% for a mean follow-up of 14 months.[11] To detect a similar difference (68% vs 26% at 12 months), a sample size of 26 women in each trial arm was required for 80% power and a 5% level of significance.

Complete medical, gynecologic, and drug histories were taken. All women underwent a clinical examination with cervical smear, endometrial sampling, and pelvic ultrasonography. No pretreatment was given to thin the endometrium. Procedures were not scheduled to coincide with a specific time in the cycle. The protocol did not specify the anesthesia technique to be used.

Standard techniques were used for both Cavaterm therapy and endometrial resection. The original Cavaterm device and its use have been described previously.[11] Briefly, after having dilated the cervix to the size of a Hegar probe No. 9, a silicon balloon with a self-regulating heating element was introduced into the uterine cavity and filled with glycine solution. The balloon was inflated until intrauterine pressure stabilized between 180 and 220 mm Hg. A pump induced circulation of the fluid inside the catheter to distribute the heat from the heating elements located in the device handle to the balloon surface. The temperature of the balloon surface set by the manufacturer was 80°C, which yielded an operative temperature of 75°C. The treatment lasted 15 minutes.

Transcervical endometrial resection was carried out with a resectoscope (26F gauge) fitted with a cutting loop, a continuous irrigation and suction sheath, and a 3-mm forward-oblique 12-degree telescope.[3] Briefly, the uterine cavity was distended with 1.5% glycine solution (at a standardized irrigation pressure of 75 mm Hg), and irrigation

Table 1 Women's baseline characteristics

Characteristic	Cavaterm (n = 31)	Resection (n = 20)
Age (y)	45 (35–55)	46 (33–54)
Parity	3 (0–4)	2 (0–5)
Body mass index (kg/m^2)	26 (16–37)	26 (16–41)
Uterine cavity length (cm)	10 (9–12)	9 (8–12)
Myomas	6 (19)	5 (25)
Duration of symptoms (m)	14 (3–170)	15 (3–50)
Dysmenorrhea	3 (10)	3 (15)
Length of period (d)	7 (3–30)	8 (3–30)
Types of bleeding		
Menorrhagia	11 (35)	8 (40)
Metrorrhagia	3 (10)	2 (10)
Menometrorrhagia	17 (55)	10 (50)
Menstrual blood loss chart*	400 (110–1300)	266 (108–555)

Values are given as numbers (%) or medians (range).
*p = .002.

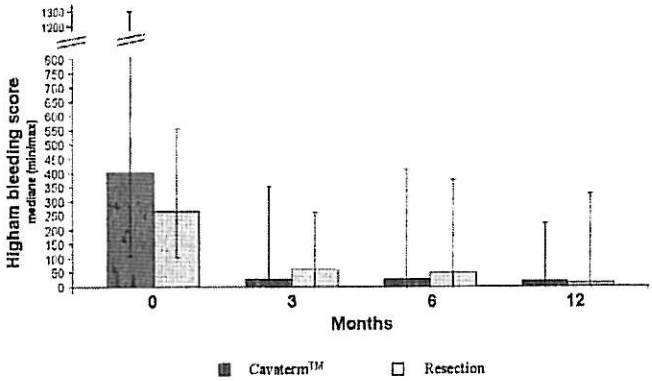

Figure 1 Higham bleeding score at baseline, 3, 6, and 12 months. Median (range) values at baseline were 400 (110–1300) and 266 (104–555) in Cavaterm and resection groups, respectively. Corresponding values at 12 months were 18 (0–222) and 12 (0–324), respectively.

pressure was carefully monitored throughout the procedure. After careful inspection of the cavity, the entire endometrium and 1 to 2 mm of the underlying myometrium were resected with a pure cutting waveform unipolar current. Endometrial ablation of the fundus and the cornual areas was completed by rollerball, if insufficiently treated by resection alone.

One hour after the operation, the women were asked to record their level of pain by means of a visual analog scale from zero (no pain) to 100 (unbearable pain). At discharge, they were asked to record their pain for a week, as well as the duration of vaginal bleeding, and the number of days to the resumption of normal daily activities at home, and normal occupational activity (if relevant). The follow-up visits were performed at 6 and 12 months after the operation. Women were told to expect a reduction in bleeding (including eumenorrhea, hypomenorrhea, and amenorrhea) without any new pain. They were asked to bring along the bleeding card they had filled in over the month preceding the visit. Amenorrheic women were investigated by serum follicle-stimulating hormone (FSH) measurements to ensure they had not begun menopause. They were asked to record any postsurgical disorders, such as dysmenorrhea or abnormal vaginal discharge. To evaluate the satisfaction rate, women were asked to choose 1 of 4 different assessments (excellent, good, moderate, bad) at each consultation.

Statistical analysis was performed with a commercial software program (Sigmastat and Systat 9, SPSS Inc., Chicago, IL). Qualitative variables of the study were compared by use of the χ^2 test. Quantitative variables were compared by use of Student's t test or the Mann-Whitney rank sum test depending on the normality of the distribution of the data (Kolmogorov-Smirnov test). Other non-parametric tests were also used such as the

Table 2 Menstrual outcomes at 6, and 12 months*

	Cavaterm		
Outcome	Baseline (n = 31)	6 months (n = 30)†	12 months (n = 28)†
Amenorrhea	0 (0) (95% CI 0–11)	6 (20) (95% CI 8–39)	10 (36) (95% CI 19–56)
Normal menses	0 (0) (95% CI 0–11)	20 (67) (95% CI 47–83)	16 (57) (95% CI 37–76)
Menorrhagia	31 (100) (95% CI 89–100)	4 (13) (95% CI 4–31)	2 (7) (95% CI 0–17)

Normal menses (including hypomenorrhea) are defined by scores on a menstrual blood loss chart comprised between 1 and 99.
Menorrhagia is defined by a menstrual blood loss chart score over 100.
*Values are given as numbers (%) and (95% confidence intervals).
†Two women were withdrawn from the study (onset of menopause during postoperative phase, pulmonary embolism after 6 months) and one woman was lost to follow-up after 6 months.
‡Two women underwent a hysterectomy at 1 month and 12 months respectively and one woman was lost to follow-up after 6 months.

Kruskal Wallis 1-way analysis of variance on ranks test followed by Pairwise multiple comparison procedures (Dunn's method). The differences were significant when $p < .05$.

Results

From February 2000 through December 2001, 62 women were recruited, signed written informed consent, and were allocated to Cavaterm treatment (n = 33) or resection (n = 29) according to the randomization procedure.

Nine women (one Cavaterm and eight resections) were secondarily excluded from the study before treatment (pregnancy desired, hysterectomy eventually performed, onset of menopause, polyps, Higham score < 100). Of the 53 remaining women, 31 were treated by Cavaterm, 20 by resection and 2 women (1 Cavaterm and 1 resection) decided to withdraw before treatment. As a result, randomization was unbalanced. Despite the number of women not being reached in the resection group, the decision was taken not to lengthen the trial inclusion period as statistical analysis of data was possible (80% power, 5% level of significance).

The distribution of the women between centers was as follows: 13 women were recruited in Bordeaux (7 Cavaterm and 6 resections), 13 in Grenoble (9 Cavaterm and 4 resections), 11 in Nancy (6 Cavaterm and 5 resections), 9 in Clermont-Ferrand (6 Cavaterm and 3 resections), 3 in Avignon (3 Cavaterm), and 2 in Reims (2 resections).

Women reported menorrhagia, metrorrhagia, or both. There were no differences in terms of age, parity, body mass index, uterine length, myomas, symptom patterns, and duration of symptoms between the two groups (Table 1). However, women treated by Cavaterm had a significantly higher menstrual blood loss chart than women treated by resection.

Most of the women underwent general anesthetic: 20 (65%) in the Cavaterm group and 12 (60%) in the resection group. Analgesics (acetaminophen or non steroidal anti-inflammatory drugs, morphinic drugs) were given throughout the procedure in 14 (45%) women treated by Cavaterm and in 8 (40%) women treated by resection. There was no difference in morphinic drug prescription, 18% and 14%, respectively. The median (range) operative times were 48 minutes (24-150) and 45 minutes (23-105), respectively. Concomitant surgeries (tubal sterilization, laser vaporization, etc.) were performed in 12 (23%) and 10 (20%) women, respectively. Five technical complications were reported in the Cavaterm group: 1 balloon rupture during inflation and 4 instances of low energy levels because the battery had not been not fully charged before treatment. All treatments were successfully performed after replacement of the balloon or the battery. There were no clinical operative complications in either group.

Women treated by Cavaterm experienced more pain than women treated by resection 1 hour after the procedure. The median (range) visual analogical values were 45 (0-100) and 10 (0-90), respectively ($p = .012$). However, the median (range) duration of their hospital stay was shorter: 21 hours (0-36) and 30 hours (6-72), respectively ($p = .012$).

The immediate postoperative period was uneventful in all women, except for 2 treated by resection who declared unexpected bleeding for 24 hours that did not require further treatment. None of them had any postoperative pain requiring analgesics the week after discharge.

Three minor events were reported during the first postoperative month: cystitis treated with a 2-day course of antibiotics (Cavaterm), transient urinary incontinence (Cavaterm), and vaginal mycosis (in a woman treated by endometrial resection). The median (range) number of days to resumption of normal activities was not different in women treated by Cavaterm and in women treated by resection: 4 (1-20) and 2 (1-30), respectively, for daily life at home and 5 (0-35) and 3 (1-30), respectively, for normal professional activity.

Table 2—Continued

Resection		
Baseline (n = 20)	6 months (n = 19)‡	12 months (n = 17)‡
0 (0) (95% CI 0-17)	4 (21) (95% CI 6-46)	5 (29) (95% CI 8-51)
0 (0) (95% CI 0-17)	9 (47) (95% CI 25-70)	10 (59) (95% CI 35-82)
20 (100) (95% CI 83-100)	6 (32) (95% CI 11-53)	2 (12) (95% CI 2-36)

Table 3 Satisfaction rate at 6 and 12 months*

	Cavaterm		Resection	
Satisfaction	6 months (n = 30)	12 months (n = 28)†	6 months (n = 20)	12 months (n = 19)‡
Excellent	20 (67) (95% CI 47–83)	21 (75) (95% CI 55–89)	12 (60) (95% CI 36–81)	11 (58) (95% CI 34–80)
Good	8 (26) (95% CI 12–46)	4 (14) (95% CI 4–33)	4 (20) (95% CI 6–44)	4 (21) (95% CI 6–46)
Moderate	2 (7) (95% CI 1–22)	2 (7) (95% CI 1–24)	3 (15) (95% CI 3–38)	2 (10.5) (95% CI 1–33)
Bad	0 (0) (95% CI 0–10)	1 (4) (95% CI 0–18)	1 (5) (95% CI 0–25)	2 (10.5) (95% CI 1–33)

*Values are given as numbers (%) and (95% confidence intervals).

†Two women were withdrawn from the study (onset of menopause during postoperative phase, pulmonary embolism after 6 months), and one woman was lost to follow-up after 6 months.

‡One woman was lost to follow-up after 6 months.

Among the 51 women treated, 2 treated by resection were dissatisfied with the treatment and required a hysterectomy, 2 treated by Cavaterm were withdrawn from the study because of the onset of menopause or a pulmonary embolism after 6 months, and 2 patients were lost to follow-up, resulting in 45 menstrual assessments at 1 year. The menstrual outcomes at 6 and 12 months are shown in Figure 1 and Table 2. There was a significant decrease in the amount of uterine bleeding after surgery in both treatment groups. The median decrease in menstrual blood loss at 12 months was significantly higher in women treated by Cavaterm (377, range 108 to 1300) than in women treated by resection (255, range −82 to 555), because of the difference in baseline records ($p = .006$). The amenorrhea rate at 12 months was slightly higher in women treated by Cavaterm (36%) than in those treated by resection (29%) ($p = 0.736$). None of these women became menopausal during follow-up. Among the six women who initially reported dysmenorrhea, none, except for one treated by resection, reported this symptom after surgery. Four women (three Cavaterm and one resection) declared new light to moderate dysmenorrhea, which readily responded to analgesics (acetaminophen, mefenamic acid). Four women (two Cavaterm and two resections) had vaginal discharge at 3 months, whereas only one of them (resection) still declared spotting after 12 months of follow-up.

The satisfaction rates at 6 and 12 months are shown in Table 3. Each questionnaire gave high percentages of women who considered their satisfaction to be either good or excellent, more than 70%. More specifically, the rate of women reporting good or excellent satisfaction was 93% after Cavaterm and 80% after resection at 6 months ($p = 0.201$), 89% after Cavaterm and 79% after resection at 12 months ($p = 0.417$). Of the three dissatisfied women, two previously treated by resection underwent a subsequent hysterectomy after 1 and 12 months of follow-up. The first reported persistent bleeding, which could not be explained by pathologic examination of the uterus, except for the presence of blocks of thin functional-like endometrium. The second reported progressive pelvic pain, and bleeding reoccurred after 6 months, indicating a hysterectomy. Deep adenomyosis and fibroids were found in the specimen. The other woman treated by Cavaterm was dissatisfied because of dysmenorrhea but did not wish to have a hysterectomy because of the good results on menstrual bleeding (pictorial chart = 53).

Discussion

Thermal balloon ablation was as effective as hysteroscopic endometrial resection for the treatment of menorrhagia in our trial. No clinical intraoperative complications occurred in either group. Minor technical complications that did not, however, prevent treatment were noted in the Cavaterm group. Global ablation methods, such as balloons, are known to be associated with a greater risk of equipment failure than classical endometrial resection.[8] However, the improvement of the Cavaterm device (connection to a main power supply, reduction of the diameter of the catheter, adjustable structure of the balloon) has decreased the technical complications rate. The improved device (Cavaterm Plus) has been shown to be very reliable since 2001. Therefore the results from this trial can be extrapolated to this newer device, as shown by recent data published.[19]

Postoperative pain at 1 hour was significantly higher in women treated by Cavaterm (moderate pain) compared with resection (mild pain), despite the same analgesic and morphinic drug prescription in our study. Thermal balloon ablation is known to be more painful than resection.[16,20,21] Values similar to ours have been reported in women treated under local anesthesia (38, range 30–100).[20] In women treated under local analgesia and intravenous sedation who did not undergo postoperative analgesia, the median visual analogue score was 5, range 0 to 51, for intraoperative pain, and 56, range 14 to 100,

for pain assessed 2 hours after the procedure.[21] Therefore women should benefit from systematic and effective analgesic therapy during the first 2 postoperative hours. The discomfort related to the thermal action of the balloon did not influence the duration of hospitalization in our experience, and the absence of subsequent bleeding made it possible to discharge these women earlier than those treated by resection.[16]

No major postoperative event related to thermal balloon ablation was declared in our series or in the literature.[11,12,16,20,21] Cystitis, endometritis, bleeding, or retention occur rarely. However, women need to be informed that vaginal discharge typically described as spotting or an intermittent pink-watery loss is possible during the first postoperative month.

Both treatments significantly reduced uterine bleeding (median postoperative menstrual blood loss chart < 20), resulting in a high rate of patient satisfaction. The greater reduction in blood loss in women treated by Cavaterm was due to the higher baseline menstrual blood loss chart in comparison with women treated by resection despite randomization, 400 (110 to 1300) and 266 (108 to 555), respectively. Women with excessive menstrual blood loss may also benefit from endometrial ablation, especially by balloon therapy, because this technique is applied to the entire uterine cavity reducing the risk of untreated corporeal areas responsible for bleeding recurrence. In another study, excessive baseline menstrual blood loss has been shown to negatively influence the results of thermal balloon ablation at 6 months, but the significance of this prognostic factor disappeared after 1 year of follow-up.[12,13]

High rates of amenorrhea ($> 50\%$) after Cavaterm treatment were reported in pilot studies.[11,22] However, these have not been confirmed in the comparative trials.[15,17] The rate of amenorrhea was 29% after Cavaterm balloon therapy and 39% after laser endometrial ablation, at 1 year.[17] Similar results, although lower, have been reported in a study where Thermachoice balloon therapy was compared to rollerball ablation.[15] Indeed, the rate of amenorrhea was 13% to 15% and 22% to 26% after 2 to 3 years of follow-up, respectively. Women in the former study had been pretreated with GnRH agonists, which have been shown to induce higher rates of amenorrhea.[23] There was a trend toward a lower rate of amenorrhea after balloon therapy compared with laser or roller ball, whereas an inverse trend was observed in our study, 36% (Cavaterm) and 29% (resection). The large reduction in menstrual blood loss after endometrial ablation results in a high satisfaction rate, 93% to 89% after Cavaterm and 80% to 79% after resection at 6 and 12 months of follow-up, respectively. Thermal balloon ablation studies show a 93% to 94% satisfaction rate that remains steady over 1 year.[15–17] There was no difference when compared with rollerball or Nd:YAG laser.[15,17] However, the satisfaction rate tended to be lower in women treated by resection in our study and in the literature. It has been shown that the percentage dropped from 89% at 1 year to 70% at 2 years, whereas there was no change in the Cavaterm group.[16] The efficacy of transcervical resection of the endometrium is known to be related to surgical skill and to decrease year by year.[3] Inversely, most studies have claimed a steady satisfaction rate for thermal balloon ablation, even after 5 years of follow-up.[13,15]

To conclude, this study confirms that thermal balloon ablation, which was invented 10 years ago, is a good alternative to endometrial resection. Clinical and health-relative quality of life outcomes, as well as patient satisfaction and rate of subsequent uterine surgery are similar in follow-up intervals that ranged from 1 to 5 years.[24] Thus hysteroscopic methods have largely been replaced in clinical practice by global ablation devices for this indication irrespective of any small difference in their effectiveness relative to the operator skill. Resection offers the advantage of being able to treat irregular uterine cavities and yields material for pathologic assessment, but these advantages are outweighed by systematic hysteroscopy and endometrial biopsy before thermal ablation.

Acknowledgement

The authors thank Mr. Emmanuel Ryembault and Dr. Werner Meier† (Wallsten, Morges, Switzerland) for their technical assistance and their statistical advice, Dr. Henrik Harboe and Mr. Casper Barsøe (Engineers and Doctors, Kvistgaard, Denmark), and Mrs. Lesley Graham (Bordeaux University, France) for reviewing this manuscript.

†Deceased during the clinical trial.

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