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A double-blind randomized trial comparing the Cavaterm™ and the NovaSure™ endometrial ablation systems for the treatment of dysfunctional uterine bleeding

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Objective: To compare two second-generation endometrial ablation systems in women with dysfunctional uterine bleeding (DUB) who want conservative surgical treatment.

Design: A double-blind, randomized trial.

Setting: A minimal access gynecological surgery unit in northeast England.

Patient(s): Fifty-seven women diagnosed with DUB were recruited, with 55 undergoing surgery and completing 12-month follow-up.

Intervention(s): Thirty-seven women underwent a NovaSure™ endometrial ablation, and 18 had a Cavaterm™ endometrial ablation. Clinical and quality of life data were collected 6 and 12 months after treatment.

Main Outcome Measure(s): Amenorrhea, menstrual change, quality of life, sexual activity, patient satisfaction, and procedure acceptability.

Result(s): Amenorrhea, hypomenorrhea, eumenorrhea, and menorrhagia rates for the Cavaterm™ and Novasure™ groups at 12 months were 2/18 (11%) vs. 16/37 (43%); 11/18 (61%) vs. 10/37 (27%); 5/18 (27%) vs. 6/37 (16%); and 0/18 vs. 5/37 (13%), respectively. At 12 months, 83% and 92% of women were either satisfied or very satisfied in the Cavaterm™ or Novasure™ groups, respectively. There were no major complications in either group.

Conclusion(s): Both the Cavaterm™ and the Novasure™ endometrial ablation systems are effective in reducing menstrual loss in women with DUB and achieve high rates of patient satisfaction. The Novasure™ system achieved a statistically significantly higher rate of amenorrhea in this study. (Fertil Steril® 2003;80: 203–8. ©2003 by American Society for Reproductive Medicine.)

Key Words: Menorrhagia, endometrial ablation, Cavaterm™, NovaSure™, quality of life

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Menstrual disorders are common and account for 33% of referrals to gynecological practice (1). The perceived loss of excessive blood during menstruation causes 5% of women aged 20–39 years to consult their gynecologist each year (2). This problem has a significant impact on the health of the individual woman and on health care systems since its treatment is estimated to account for 1% of total health care costs (3). In over 50% of cases, no cause is found and the diagnosis of dysfunctional uterine bleeding (DUB) is made (4). Endometrial ablation provides safe and effective treatment for women with DUB (5).

Second-generation endometrial ablation techniques have now been used for over 8 years and have demonstrated similar efficacy to first-generation endometrial ablation procedures (5–9). The aim of this study is to compare the effectiveness and acceptability of two second-generation ablation procedures, the Cavaterm™ Thermal Ablation System (Cavaterm) and the NovaSure™ Impedance Controlled Endometrial Ablation System (NovaSure), in a double-blind, randomized trial.

MATERIALS AND METHODS

Approval for this study was obtained from the institutional review board. Women referred with abnormal uterine bleeding were invited to participate in the study if they had a pictorial

blood loss assessment chart score >150, no intrauterine pathology demonstrated by inpatient or outpatient hysteroscopy, a normal endometrial biopsy, a uterine length of <12 cm, premenopausal gonadotropin levels, a normal Papanicolaou smear, and if they had completed their family. Women were advised that the procedure was not contraceptive and that a reliable form of contraception should be used because pregnancy was possible after treatment. Exclusion criteria included endometrial hyperplasia and malignancy, active pelvic inflammatory disease, palpable endometriosis, or full-thickness uterine surgery. Women with a previous history of cesarean section were not excluded.

Fifty-seven women were recruited between March 1999 and March 2000. All surgical procedures were performed between July 1999 and May 2000. Randomization was performed using computer-generated sequences in balanced blocks of five. Surgical procedures were allocated using an imbalanced randomization of 2:1, NovaSure:Cavaterm. Concealment was achieved by placing the randomization code into an opaque envelope. The study allocation was revealed after entry criteria had been met and informed consent obtained.

Patients, nursing staff, and the patient's general practitioner were blinded as to the treatment arm. A research nurse, unaware of the treatment allocation, collected outcome data at 6 and 12 months. After the final assessment at 12 months, the treatment allocation was revealed to the patient.

The primary outcome measure for the study was amenorrhea after the surgical procedure. Secondary outcomes included other effects of menstrual function, patient satisfaction and procedure acceptability, health-related quality of life, sexual health, operative details, morbidity, and reintervention in the 12-month follow-up period.

After the surgical procedure, the operative notes were kept separate from the patient's file but were available in case of emergency. A separate record accompanying the patient detailed that an endometrial ablation had been undertaken, any complications that occurred, and what medications had been given in the operating room. Patients were asked to complete an acceptability questionnaire at 4 hours after their procedure. This questionnaire included a visual analogue scale (VAS) pain score measured at rest and was not adjusted for analgesia. Women were discharged home the same day and reviewed in the research clinic at 6 and 12 months.

Women in this study were asked to complete a preoperative questionnaire and follow-up questionnaires at 6 and 12 months postoperatively. These questionnaires detailed patient demographics, VAS reporting of menorrhagia, dysmenorrhea, dyspareunia, and premenstrual syndrome. Data were also collected on the duration of menses, cycle length, past obstetric history, contraception, previous medical treatments, and body mass index.

Menstrual blood loss was also assessed preoperatively and 6 and 12 months postoperatively using a pictorial blood loss assessment chart. Women completed three validated quality of life instruments; the EuroQOL-5D (10), the Short Form-12 (SF-12) (11), and a sexual activity questionnaire (12) at baseline, 6, and 12 months. In addition, at 6 and 12 months, subjective patient satisfaction, reintervention, either medical or surgical, and the presence of new symptoms not previously present were assessed.

Surgical Techniques

No medical or surgical pretreatment was used in the NovaSure group. Women in the Cavaterm group underwent a mechanical pretreatment by curettage in the operating room immediately before their surgery. This was according to the general directions for use from respective manufacturers.

All ablation procedures were performed under general anesthesia. Patients received a paracervical block of 10 mL of 0.5% bupivicaine hydrochloride and a single bolus of 1.2 g of i.v. ampicillin and potassium clavulanate, unless they were allergic to penicillin, in which case a third-generation cephalosporin was substituted. Postoperatively, all women received 1 g of paracetamol and 100 mg diclofenac sodium suppository unless contraindicated.

The Cavaterm endometrial ablation system consists of a disposable silicone balloon and a central processing unit. The balloon is inserted into the uterine cavity and distended with glycine. It is heated to 65°C–78°C for a period of 15 minutes before being withdrawn from the uterine cavity. The full procedure is described in Hawe et al. (9). The original Cavaterm system was used for this study.

The Novasure endometrial ablation system consists of a disposable unit and a modified radio-frequency generator. The disposable unit is a bipolar mesh fitted over an expandable and adjustable frame that conforms to the endometrial cavity. A bipolar current is generated to ablate the endometrial cavity in a time of 60–120 seconds. The full procedure is described in Cooper et al. (13).

Statistics

The sample size for this study was calculated based on an amenorrhea rate of 34% for Cavaterm. At the time of the study being performed, no large-scale study had been performed using the NovaSure endometrial ablation system. Initial results from an uncontrolled study report an 80% amenorrhea rate for NovaSure. To detect a similar difference (34% vs. 80% at 12 months), with 80% power and a two-sided type 1 error rate of 5% using a 2:1 randomization for NovaSure:Cavaterm, 51 women were required in a ratio of 34:17 (Epi info 6).

SPSS for Windows, version 8.0 (Microsoft, Richmond, WA), was used for statistical analysis. Dichotomous data were analyzed using the χ^2 test, with Fisher's exact correction if indicated. Continuous parametric data were analyzed

TABLE 1

Demographics for the two groups.

Variable	Cavaterm™ (n = 18)	NovaSure™ (n = 37)
Mean age, y (SD)	40.5 (8.1)	40.5 (6.0)
Parity median (range)	2 (1–4)	2 (0–4)
Mean body mass index (SD)	22.9 (4.9)	26.9 (6.2)

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by Student's *t*-test, and nonparametric data by the Wilcoxon rank sum test for paired data and the Mann-Whitney *U*-test for independent data. Significance for all analyses was set at the 5% level.

RESULTS

Fifty-seven women (Cavaterm, 19; NovaSure, 38) were randomized between June 1999 and May 2000. One woman in each group withdrew after randomization and before surgery. A total of 55 women (Cavaterm, 18; NovaSure, 37) were available for analysis. All women had surgery performed according to randomization. Questionnaires were completed at 6 and 12 months by 100% and 83% of the Cavaterm group, respectively, and 95% and 97% of the NovaSure group, respectively. All analyses were by intention to treat.

Patient Characteristics and Operative Time

Table 1 summarizes the demographic data for women in the study. There were no statistically significant differences between the two groups. Mean surgical time (defined as device in hand to device removal from the uterus) for the Cavaterm procedure was 23 minutes (range, 19–29), with a 15-minute treatment time. Mean surgical time for the NovaSure procedure was 4 minutes (range, 2–8 minutes), with a treatment time of 90 seconds (range, 48 to 120 seconds). There was a significant difference in the surgical time for the two procedures (P=.0001)

Menstrual Status

There was a significantly greater amenorrhea rate in the NovaSure group (P=.04) and a significantly greater hypomenorrhea rate in the Cavaterm group (P=.026) at 12 months. Table 2 summarizes the menstrual status for the two groups at 6 and 12 months. Table 3 summarizes the results for other menstrual data and pain.

Patient Satisfaction and Acceptability

There was no difference in patient satisfaction for Cavaterm or NovaSure at 6 months, with patients being satisfied or very satisfied in 100% (18/18) vs. 84% (31/37) of cases, respectively. Two women (5%) in the NovaSure group were dissatisfied, and one woman (3%) very dissatisfied at 6 months. Loss of follow-up data is described above. At 12 months, women in the Cavaterm group were either satisfied or very satisfied in 83% of cases (15/18). For the NovaSure group at 12 months, women were satisfied or very satisfied in 92% (34/37) of cases and dissatisfied or very dissatisfied in 5% (2/37) of cases. There were no differences in satisfaction rates between the two groups at 12 months.

Both procedures were acceptable to patients using a semantic differential technique. Patients were also asked to complete a VAS at 4 hours postoperatively; NovaSure was found to be significantly less painful than Cavaterm (VAS median, 48 vs.78; P=.01).

Complications and Further Surgery

There were no major intraoperative complications in either group. There were generator problems in 2/18 (11%) of women in the Cavaterm group, resulting in long treatment times at lower than expected temperatures. Generator problems were encountered in 3/37 (8%) of NovaSure cases, resulting in very short treatment times. All patients were discharged on the day of surgery.

Within the Cavaterm group, one woman became pregnant at 8 months after the procedure and had an incomplete miscarriage at 8 weeks requiring curettage. She continued to have light periods after her pregnancy. One other woman had a laparoscopy for pain and was found to have endometriosis,

TABLE 2

Menstrual outcomes at 6 and 12 months after treatment.

Outcome	Cavaterm™ 6 mo (n = 18)	Cavaterm™ 12 mo (n = 17)	NovaSure™ 6 mo (n = 35)	NovaSure™ 12 mo (n = 37)	Cavaterm™ vs. NovaSure™, 12 mo
Amenorrhea, n (%)	2 (11)	2 (12)	15 (43)	16 (43)	$\chi^2 = 4.21, P=.04$
Hypomenorrhea, n (%)	10 (56)	10 (59)	10 (27)	10 (27)	$\chi^2 = 4.96, P=.026$
Eumenorrhea, n (%)	6 (33)	5 (29)	5 (15)	6 (16)	$\chi^2 = 1.01, P=.31$
Menorrhagia, n (%)	0	0	5 (15)	5 (14)	$\chi^2 = 2.6, P=.1$
Repeat surgery, n (%)	0	0	0	6 (16)	$\chi^2 = 3, P=.15$

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TABLE 3

Comparisons for pain and other menstrual outcomes within and between groups.

Variable	Cavaterm original	Cavaterm 12 mo	Cavaterm original vs. 12 mo[a]	NovaSure original	NovaSure 12 mo	NovaSure original vs. 12 mo[a]	Cavaterm vs. NovaSure 12 mo[b]
Cycle length mean (SD)[c]	25 (6.6)	27.6 (8.2)	P=.72	24 (7.3)	28.4 (7.5)	P=.06	Z = 0, P=1
No. days menstruating median (range)	7 (5–12)	4.5 (2–6.5)	P=.001	8 (4–18)	2.5 (1–6)	P=.0001	Z = −2.5, P=.01
PBAC median (range)	334 (157–933)	21 (0–157)	P=.0001	482 (172–2,020)	3 (0–1,720)	P=.0001	Z = −1.3, P=.2
VAS menstrual loss median (range)	92 (58–100)	24 (0–66)	P=.0001	84 (60–100)	2 (0–88)	P=.0001	Z = −2.2, P=.026
VAS dysmenorrhea median (range)	75 (0–100)	29 (0–77)	P=.001	62.5 (0–100)	0 (0–96)	P=.0001	Z = −2.6, P=.008
VAS PMS median (range)	49 (0–100)	32 (0–100)	P=.7	50 (0–100)	0 (0–100)	P<.0001	Z = −2.68, P=.007
VAS dyspareunia median (range)	0 (0–82)	0 (0–95)	P=.23	0 (0–85)	0 (0–58)	P=.053	Z = −1.1, P=.23

Note: PBAC = pictorial blood-loss assessment chart; VAS = visual analogue scale (0–100); PMS = premenstrual syndrome.

[a] Wilcoxon rank sum test.

[b] Mann-Whitney test.

[c] For women continuing to menstruate.

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although she had menstrual spotting only. Two women (11%) were treated with oral antibiotics for suspected but unconfirmed endometritis. There were no further surgical procedures for menstrual problems in the follow-up period.

Two women (5%) in the NovaSure group were treated with oral antibiotics for suspected endometritis. One woman had significant pain from the fourth postoperative month and was diagnosed with a hematometra. She was treated by dilatation and curettage, resulting in relief of pain, although she had ongoing regular, light menstrual loss. Two women had a hysterectomy within the follow-up period for heavy bleeding. Histology of the uteri confirmed viable endometrium in one but not the other. Three women were awaiting a repeat endometrial ablation for heavy menstruation at 12 months by endometrial laser ablation.

In total, no women in the Cavaterm group had repeat procedures for menstrual problems in the follow-up time compared with 16% (6/37) in the NovaSure group. There was no statistically significant difference in the reintervention rate between the two procedures (χ^2 = 3, P=.15). No woman received medical treatment for heavy periods in the 12-month follow-up.

Quality of Life

The results of the EuroQOL-5D and SF-12 are summarized in Table 4. At baseline and 12 months, respectively, 76% and 83% of women in the NovaSure group and 72% and 74% in the Cavaterm group reported being sexually active. The most common reason for no sexual activity was lack of partner. The results of the sexual activity questionnaire suggested an increase in pleasure and habit and a decrease in discomfort for both techniques. These improvements did not reach statistical significance, with the exception of discomfort in the Novasure group, which was significantly improved from baseline (mean difference, 0.95; 95% confidence interval, 0.27–1.6; P=.008).

DISCUSSION

Endometrial ablation is reported to be a safe procedure with an overall complication rate of 1.25%–4.58% reported in an audit of over 10,000 cases (14). In this study, there were no major complications, although it does not have sufficient power to detect these problems. It would be advantageous to know whether second-generation endometrial ablation procedures produced fewer complications than the first-generation procedures reported in the MISTLETOE study, but it is unlikely that an audit of this magnitude will be repeated with the newer treatments.

The clinical outcomes in this study are similar to the reported outcomes for first-generation procedures in randomized trials, with amenorrhea rates between 32% and 47% (15–17). Reported rates of amenorrhea with second-generation procedures are between 13% and 58%. Comparisons of first- and second-generation procedures report no difference in the clinical outcomes (8, 18). This is the first study reporting a comparison of two second-generation techniques in a randomized trial.

The Cavaterm procedure was first described in 1993 and has reported amenorrhea rates of 22%–68% and an overall success rate of 92%–98% (9, 19, 20). The amenorrhea rate of 11% for this study was lower than we have previously

TABLE 4

Quality of life outcomes for EuroQOL and SF-12, within and between groups.

Variable	Cavaterm original Mean (SD)	Cavaterm 12 mo Mean (SD)	Cavaterm original vs. 12 mo[a] Mean Diff (CI), *P*	NovaSure original Mean (SD)	NovaSure 12 mo Mean (SD)	NovaSure original vs. 12 mo[a] Mean Diff (CI), *P*	Cavaterm vs. NovaSure 12 mo[b] Mean Diff (CI), *P*
EQ-5Dindex	0.66 (0.34)	0.73 (0.29)	−0.07 (−0.2, 0.12), NS	0.71 (0.23)	0.85 (0.23)	−0.14 (−0.2, −0.06), *P*=.001	−0.11 (−0.4, 0.27), NS
EQ-5Dvas	70.2 (25.8)	84.2 (14.3)	−14 (−27, −1.14), *P*=.048	75.7 (18.1)	84.4 (12.8)	−8.4 (−14.2, −2.5), *P*=.006	−2.1 (−5.9, 10.3), NS
SF-12 PCS	46.2 (10.5)	50.5 (11.7)	−4.2 (−9.4, −0.88), NS	44.9 (8.4)	52.1 (7.1)	−7.1 (−9.6, −4.7), *P*<.0001	−1.8 (−7.3, 3.6), NS
SF-12 MCS	38.5 (9.7)	42.0 (15.9)	−3.4 (−11.3, −4.1), NS	44.5 (10)	49.5 (10)	5.1 (−9.1, −1.1), *P*=.016	8.1 (−15.7, −0.34), *P*=.04

Note: Mean Diff = mean difference; CI = 95% confidence intervals; NS = not significant; SF-12 = Short-Form 12; PCS = physical component score; MCS = mental component score.

[a] Wilcoxon rank sum test.

[b] Mann-Whitney test.

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reported (9). There was no hormonal pretreatment in this current study, with women undergoing a mechanical curettage before their treatment. The case series previously reported used a GnRH analogue for pretreatment, with higher amenorrhea rates. This is in keeping with published literature that reports higher amenorrhea rates when a GnRH analogue is used before endometrial ablation (21, 22). A previous study of Cavaterm with long-term follow-up has reported a 31% amenorrhea rate using mechanical pretreatment (19). We used the original Cavaterm system in this study. A new system, the Cavaterm Plus system, is now commercially available, and clinical results are pending. In addition, it is possible that the low amenorrhea rate found in this study reflects the small sample size.

The overall "success" of the Cavaterm group was high, with 100% of women reporting eumenorrhea or better at 12-month follow-up. The amenorrhea rate in this group was significantly lower than in the NovaSure group, although the hypomenorrhea rate was significantly greater and the combined rates show no difference between the groups ($P = .88$). The overall improvement in menstrual function is highly significant, and the difference between amenorrhea and spotting does not appear to affect either patient satisfaction, which is universally high for this procedure, or quality of life, which is improved.

We encountered catheter problems in two women in this group because of unusually high resistance when core-heating temperature in the balloon remained less than 64°C. Both women continued to have menstrual loss, which was reduced from their preoperative state and placed them into the eumenorrhea category.

The Novasure technology is relatively new and there are few published data reporting the results of its clinical use. The amenorrhea rate reported in this study is comparable to amenorrhea rates that are reported by either first- or second-generation endometrial ablation procedures in randomized trials. The NovaSure procedure produced a higher amenorrhea rate and a greater improvement in quality of life in this study, compared with the Cavaterm procedure. Satisfaction rates are very high and equal to other published data. This technology has advantages, with no pretreatment required, a very fast treatment time, and the ability to treat the uterine cavity on an individually tailored basis.

The failure rate for the NovaSure group was 14%. Generator problems were a factor, with three out of the five women who had ongoing menorrhagia having very short treatment times because of an electrical problem in the generator. There were no complications encountered, although all three of these women had further intervention, with one having hysterectomy and no treatment effect apparent at histological examination and the other two having repeat ablations where the endometrial cavity was found to be normal.

It is essential that equipment failure be reported, as malfunction of the device or generator carries with it significant cost for disposable items and may require either retreatment at a later time or immediate treatment by an alternate method. In this study, equipment problems were encountered in 11% of the Cavaterm group and 8% of the NovaSure group. These problems did not seem to have a marked clinical effect in the Cavaterm group, although they contributed to poor outcomes for women in the NovaSure group. Other randomized trials using MEA and VestaDUB have reported a similar equipment failure rate of 3% and 4%, respectively (8, 23).

The overall hysterectomy rate in this trial was low, with 5% of women in the NovaSure group undergoing hysterectomy in the follow-up period. This is in keeping with other

randomized trials of second-generation devices that report hysterectomy rates of 3%, 5%, and 7% for Thermachoice, VestaDUB, and MEA, respectively (8, 18, 23). In the Cavaterm group, there were no hysterectomies within the follow-up period. In other studies, the rate of hysterectomy after Cavaterm ablation was 7% at 24 months and 15% at 49 months (9, 19). Repeat surgery rates for ongoing menstrual problems for Cavaterm and NovaSure in this study were 0 and 16%, respectively. These are similar to reintervention rates of 8%–16% in randomized trials (8) and 4%–19% in case series (6, 7, 24, 25).

Menorrhagia has a detrimental impact on quality of life and can adversely affect the physical and mental health of the sufferer. It is also associated with disruptions in vocational, family, and social life (26, 27). It is for this reason that most women seek treatment. Women in the NovaSure group reported a significant improvement in all quality of life measurements, with women in the Cavaterm group also reporting a trend to improvement, although this was not significant in all areas, perhaps because of the smaller numbers.

The results of this study indicate that there is a significant improvement in menstrual status with both of these treatments. There is a significantly greater amenorrhea rate in the NovaSure group compared with the Cavaterm group. There is a significant improvement in quality of life for both techniques, with NovaSure providing better results compared with Cavaterm. Patient satisfaction is high with both techniques, with reintervention rates comparable to those reported in other published data. Equipment failure and problems must be considered as a factor for the second-generation endometrial ablation procedures, with an associated implication for clinical and cost-effectiveness outcomes. These excellent short-term results need to be followed up in the longer term to ensure that the results are maintained.

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