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Effect of Endometrial Ablation by Thermal Balloon vs. Hysteroscopy Ablation on Amenorrhea Rates in Patients with Abnormal Uterine Bleeding: A Randomized Clinical Trial

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Abstract

Background: Abnormal uterine bleeding (AUB) that is any irregularity in menstrual cycles causes women to refer to clinics. This study aimed to compare the efficacy, safety, and complications of endometrial ablation by the thermal balloon (Cavaterm) method with the hysteroscopy loop resection method in the treatment of AUB.

Materials and Methods: The present study is an open-label, randomized clinical trial that was performed in the two hospitals, Shahid Akbarabadi and Hazrat Rasoul Akram, of Tehran, Iran, from December 2019 to October 2020. Patients were randomly allocated to the two groups of interventions by a simple randomization method. The proportion of amenorrhea (as primary outcome) and consequent hysterectomy and patient satisfaction (as secondary outcomes) was assessed using the Chi-square test and independent t test.

Results: There was no significant difference between the two groups in the baseline characteristics. The percentage of intervention failure was statistically higher in the hysteroscopy group (24%) in comparison with the Cavaterm group [8.2%, P=0.03, relative risk (RR)=1.63, 95% confidence interval (CI): 1.13-2.36]. Mean ± standard deviation of satisfaction based on the Likert score in the Cavaterm group and hysteroscopy group were 4.3 ± 1.21 and 3.7 ± 1.56, respectively, that showed a significant difference (P=0.04). Assessing the procedural complications, the rate of spotting, bloody discharge, and malodor discharge was significantly higher in the Cavaterm group. In contrast, postoperative dysmenorrhea is more common in the hysteroscopy group.

Conclusion: Cavaterm ablation is accompanied by a higher success rate of amenorrhea and patients' satisfaction than hysteroscopy ablation (registration number: IRCT20220210053986N1).

Keywords: Ablation Technique, Dysfunctional Uterine Bleeding, Endometrial, Hysteroscopy

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Introduction

Abnormal uterine bleeding (AUB), one of the most common problems of reproductive age women, accounts for about 30% of outpatient gynecological visits. AUB is defined as a heavy menstrual bleeding or an extra-menstrual bleeding (1, 2). Mahoney and colleagues attributed 2.3% of hysterectomies and 25% of gynecological surgeries to bleeding. Endometrial ablation can be used as a treatment for AUB in patients who have not responded to medication, where the endometrial cavity is normal and without sub-mucosal leiomyoma, endometrial hyperplasia, or malignancy. Different methods are used to ablate the endometrium, which generally differs in the type of device, energy source, and endometrial ablation mechanism. These techniques include warm air balloon ablation, intrauterine warm saline insertion, cryo-ablation with a cryo-probe, microwave endometrial ablation, and the use of radiofrequency electromagnetic energy (2, 3). Endometrial ablation with Cavaterm is considered as a safe surgical procedure with minimal bleeding complications and systemic adverse events. This surgical approach benefits from less technical proficiency and facilitates

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post-operative follow-up. Furthermore, the Cavaterm procedure does not only take less time than most other alternative treatments, but also can be quickly learned by surgeons in training. There are several reports about success rates and side effects of this approach, that makes comparison difficult, particularly due to heterogeneity in implementation methods and/or study populations with different AUB background. A dual comparison between ablation methods will be more informative for clinicians to select the best choice of therapeutic strategies. This experimental study compares the efficacy, safety, and complications of endometrial ablation by the Cavaterm method with the hysteroscopy loop resection method to treat abnormal uterine bleeding.

Materials and Methods

Samples

The present study is an open-label, randomized clinical trial performed in the two hospitals, Shahid Akbarabadi and Hazrat Rasoul Akram hospitals, Tehran, Iran, from December 2019 to October 2020.

Ethical considerations

The study was approved by the Iran University of Medical Science Ethical Committee (IR.IUMS.FMD.REC.1398.437) and was registered retrospectively as IRCT20220210053986N1 in the Iranian registry of clinical trials on 2022/03/06.

The inclusion criteria were included:

1. Non-nulliparous affected of 35 to 55 year age range with a complaint of AUB
2. No sign of malignancy in the pathology specimen that was prepared by pipple or curettage
3. Inadequate response drug therapy following of, an up to 18 months of oral contraceptive pills or various progesterone drugs)
4. Not trying to conceive (completion of fertility)
5. Unwillingness for a hysterectomy due to various reasons [including patient dissatisfaction with the removal of the uterus, high risk of surgery due to underlying disease and high body mass index (BMI)].
6. The exclusion criteria comprised grade 0 and 1 submucosal myoma in the uterine ultrasound, uterine cavity distortion, and uterine size higher than 12 weeks.

Patients were randomly divided into two groups by simple randomization using Excel software and using the RAND function. Excel software creates a column of 100 numbers, equal groups for Cavaterm group (n=50) and hysteroscopy group (n=50). The RAND function generated parallel columns contain of one hundred random numbers. After arranging the randomized column, a random sequence was prepared, and patients were divided into two groups, respectively. Four-digit unique codes were assigned to each participant to conceal the allocation. The allocation codes were put in opaque pockets and revealed to the surgery team one by one through the enrollment process.

Interventions

Endometrial destruction by the hysteroscopy method First, in eligible patients referred to a gynecological clinic due to abnormal uterine bleeding, endometrial biopsy was performed by pipple. If there was no atypia or malignancy sign, they were contained the criteria for endometrial destruction by the method. In the hysteroscopy treatment group, in the operating room, after emptying the bladder, uterus, adnexa were examined bimanually. After ventilating the normal saline dilation media system and white balance, the lower vaginal valve was inserted and the anterior lip of the cervix was grasped with a tenaculum (Sialkot, Pakistan). Endometrium was coagulated according to the standard of destruction with a resectoscope (Storz Hamou Endomat Mod. 26331020) with a power of 50-150 watts, depending on the size of the electrode, so that first the fundus, both cornea, the anterior wall, lateral wall and finally the posterior wall were destroyed. In this method, it was tried to avoid the cervical mucosa destruction. The endometrium was coagulated to a depth of 5 mm underlying the myometrial layer.

Endometrial destruction by Cavaterm method

Cavaterm method is based on rotating hot water with a temperature of about 80°C at a constant pressure between 240-230 mm Hg in a silicone balloon for 10 minutes. The cavaterm system (CAVATERMTM C-FACT04070101) (Veldana, Switzerland) consists of a disposable catheter with an adjustable silicone balloon and a central unit. The 10-minute treatment is a combination of heat, circulation and water pressure to coagulate the endometrium and the underlying myometrial layer to a depth of 5 to 9 mm. One surgeon with experience more than twelve years experience did all Cavaterm, and another surgeon with more than ten years of experience performed Hystroscopy ablations.

Outcome

The primary outcome was defined as changing the status of menstrual patterns in patients based on the International Federation of Gynecology and Obstetrics (FIGO) classification. Other consequences and complications such as fever, infection and vaginal discharge, abdominal pain, and number of surgical complications were asked during the first hospitalization and the day after the procedure. Patients' satisfaction, menstrual pattern, and need for hysterectomy in each study group were also asked one year in the subsequent visits and registered in the researcher-made checklist for each patient directly. Overall satisfaction with the treatment was assessed and recorded using the 5-point Likert scale (4).

Patients follow up

All patients were visited two weeks after the interventions to evaluate immediate adverse events, complications and

also the time to recovery. Subsequent visits were done in the third and 12th month after the surgery to assess the menstrual situation, patient satisfaction, and delayed complications.

Statistical analysis

In this study, to compare quantitative data between the two groups, first the normal distribution of data was assessed by the Kolmogorov-Smirnov test and then independent t test and the Mann-Whitney test were used, for parametric data and non-parametric data, respectively. The Chi-square test was used to compare categorical variables. A significance level of 0.05 was considered.

A sample size of 50 patients in each group was calculated based on the Brun's results, one-tailed and with type one error of 0.05 and power of 0.8.

Results

Baseline comparison

During 11 months, screening of 145 patients for eligibility criteria led to 100 enrolled patients. Then, equal numbers of patients were randomly divided in each surgery group, Cavaterm and hysteroscopy (Fig.1). The demographic data of participants presented in Table 1. The U Mann Whitney test result showed no significant difference between the two groups in terms of age (P=0.072) and BMI (P=0.424). No significant difference was observed in parameters, including gravid, parities, abortion and a history of caesarian section, between our group.

Outcomes

Postoperative menstrual pattern change

Table 2 shows the status of menstrual patterns of the participants, before and after their intervention. A comparison of menstrual status with the Chi-square method did not show a significant difference between the two groups before the intervention (P=0.36). Our results showed that patients treated with the Cavaterm method did not show a menometrorrhagia pattern. Only 4 cases of menorrhagia have been observed in the Cavaterm group. In contrast, in the hysteroscopy group, twelve menorrhagia cases experienced abnormal menstrual bleeding after the procedure.

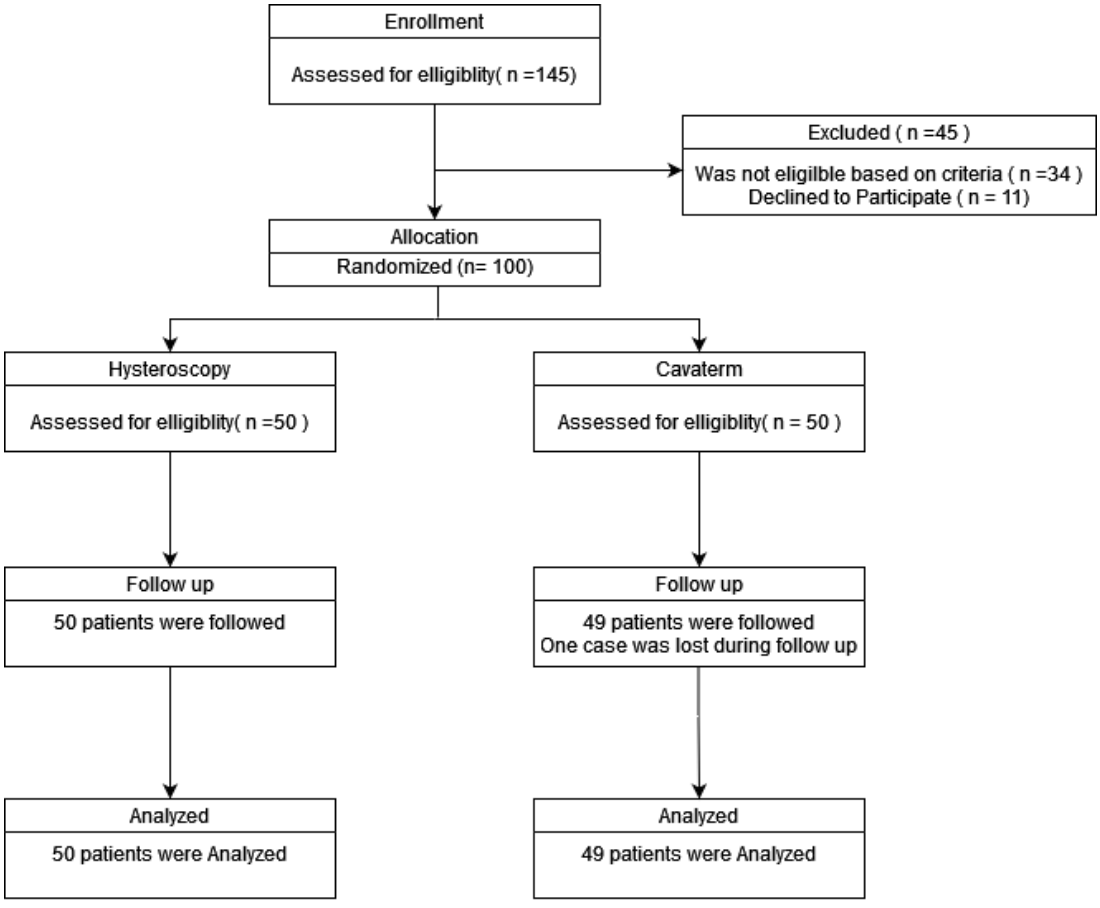

Fig.1: Study population and patients follow up.

Table 1: Demographic data of participants

Demographic data of participants		Hysteroscopy (n=50)	Cavaterm (n=49)	Total	P value
Age-median (range) (Y)		48 (35-53)	48 (35-59)	48 (35-53)	0.072 Man Whitney test
BMI-median (range) (kg/m^2)		29.38 (24.1-39.38)	31.11 (21.26-39.45)	30.44 (21.26-39.45)	0.424 Man Whitney test
Gravid -frequency (%)	1	4 (8)	2 (4.1)	6 (6.06)	0.736 - Chi square
	2	17 (34)	14 (28.57)	23 (23.23)	
	3	14 (28)	17 (34.69)	32 (32.32)	
	≥4	15 (30)	16 (32.65)	38 (38.38)	
Parity -frequency (%)	1	4 (8)	2 (4.1)	6 (6.06)	0.747 - Chi square
	2	16 (32)	13 (12.2)	29 (29.29)	
	3	14 (28)	17 (30.6)	31 (31.31)	
	≥4	15 (30)	15 (46.9)	30 (30.3)	
Abortion-frequency (%)		1 (2)	2 (2.02)	3 (3.03)	0.492 - Chi square
Previous cesarean section -frequency (%)		17 (34)	17 (34)	16 (32.65)	0.779 - Chi square
Comorbidities-frequency (%)	Diabetes	4 (8)	11 (22.44)	15 (15.15)	0.06 - Chi square
	Hypertension	0	4 (8.2)	4 (4.04)	0.056 - Chi square
	Hypothyroidy	3 (6)	2 (4.1)	5 (5.05)	0.663 - Chi square

BMI; Body mass index.

Table 2: Distribution of menstrual pattern before and after interventions

Menstrual pattern	After/Before	Amenorrhea	Light regular frequent	Oligomenorrhea	Normal regular frequent	Heavy regular frequent	Total
Cavaterm group	Heavy regular frequent	12	0	6	5	2	25
	Light irregular infrequent	2	1	0	0	0	3
	Heavy irregular infrequent	12	1	1	5	1	20
	Heavy irregular frequent	0	0	0	0	1	1
	Total (%)	26 (53)	2 (4.1)	7 (14.3)	10 (20.02)	4 (8.16)	49
Hysteroscopy group	Heavy regular frequent	1	0	1	16	6	24
	Metrorrhagia	0	1	0	1	0	2
	Heavy irregular infrequent	2	2	4	8	5	25
	Heavy irregular frequent	2	0	0	0	1	3
	Total (%)	5 (10)	3 (6)	5 (10)	25 (50)	12 (24)	50

Intervention failure rate

Failure cases were considered in which the patient's menstrual pattern was still abnormal. Considering this criterion and by the cases specified in Table 2, 16 cases were failed in our groups: Cavaterm group (n=4, 8.2%) and hysteroscopy group (n=12, 24%). This difference was statistically significant, that indicates a higher success of the Cavaterm approach in comparison with the hysteroscopy procedure [P=0.03, relative risk (RR)=1.63, 95% confidence interval (CI): 1.13-2.36].

Recovery time after the intervention

The time to return to daily activities was compared in our groups with an independent sample t test. The Cavaterm group with a mean ± SD of 2.61 ± 1.3 days was significantly different from the hysteroscopy group with a mean ± SD of 2.1 ± 1.12 days, P=0.06. Also, the comparison of time to return to work activity in the two groups was compared with the independent t test. The Cavaterm group with a mean ±SD of 2.67 ± 1.29 days reported a longer time to return to work than the hysteroscopy group with a mean ±

SD of 1.78 ± 1.26 days, which was statistically significant P=0.01.

Need for hysterectomy after the intervention

Out of 12 cases of treatment failure in the hysteroscopy group, six patients (50%) required hysterectomy after the initial intervention, which one of them was a member of the Cavaterm group (25%). This difference was not statistically significant (P=0.395). In the Cavaterm group, none of the successfully treated patients were needed a hysterectomy approach, but in the hysteroscopy group, one person was needed this surgery. Without considering mentioned treatment success, no significant difference in the need for hysterectomy after endometrial ablation was observed in our participants (Table 3).

Patients' satisfaction with the operation

The level of satisfaction, classified into the 5 Likert scores, including excellent, good, average, bad and very bad, that the Cavaterm group showed 67.3, 12.2, 12.2, 0 and 8.2%, respectively, while the hysteroscopy group displayed 54, 4, 18, 8 and 16% rate, respectively. Comparison of satisfaction scores in the two groups based on the Likert scores (excellent=5, 1=very bad) represented that satisfaction with the intervention with Cavaterm (mean ± SD=4.3 ± 1.21) compared to hysteroscopy (mean ± SD=3.7 ± 1.56) was higher which was statistically significant with P=0.04.

Post-treatment complications

The intervention complications showed that the rate of spots, bloody discharge and malodor discharge was significantly higher in the Cavaterm group. In contrast, postoperative dysmenorrhea is more common in the hysteroscopy group (Table 3).

Table 3: Comparison of complications between two groups of the study

Type of complication	Cavaterm group	Hysteroscopy group	P value†
Spotting	21 (42.8)	6 (12)	0.001
Bloody discharge	27 (55.1)	5 (10)	0.001
Malodor discharge	5 (10.2)	0	0.027
Supra-pubic pain	23 (46.6)	1 (2)	0.001
Need for hysterectomy	3 (6.1)	7 (14)	0.167
Need for medical treatment	9 (18.4)	15 (30)	0.132

Data are presented as number (%). †; Chi square test was performed.

Discussion

Using Cavaterm or hysteroscopy, this study compared the success rate and complications of two treatments for endometrial ablation in the AUB patients. Our results showed that the success of the Cavaterm method in the treatment of AUB and the menstrual pattern change one year after surgery (91.2%) was significantly higher than the hysteroscopy method (76%). On the other hand, despite adverse events including spotting, malodor vaginal discharge and supra pubic pain, participants' satisfaction with uterine bleeding was higher than endometrial ablation one year after Cavaterm intervention in comparison with hysteroscopy. In addition, the chance of hysterectomy in the first-year post-intervention in the Cavaterm group was 25%, which was lower than the hysteroscopy ablation group, although this difference was not statistically significant compared to this percentage in hystroscopy group (50%). No serious adverse events (including perforation, sepsis, prolonged hospitalization, or death) were observed in both intervention groups. The reported success rates for these two methods in previous interventional and observational studies are largely consistent with our results. Most of these studies have considered the ultimate success of ablation in achieving amenorrhea status for patients (4-9). However, in some cases, achieving normal menstrual patterns or hypomenorrhea has also been considered as a success in these interventions (5).

Smith et al. conducted a comparative clinical trial between Cavaterm and bipolar ablation in a 5-year follow-up, they observed a 60% success rate for Cavaterm ablation while in their bipolar group reached 62%, the highest reported results of the success of the Cavaterm method. They considered achieving amenorrhea as a success rate (6). This ratio is equivalent to 56% in quarterly and one-year follow-up in the Bouzari et al. (7) study, which is a retrospective cross-sectional study performed in the Cavaterm patients in the Babol, Iran. A 5-year follow-up, Kleijn et al. (8) reported amenorrhea (32%) in their Cavaterm group. Karimi-Zarchi et al. (9), evaluate the long-term outcome of endometrial ablation (EA) therapy with a Cavaterm Thermal Balloon in patients with AUB and showed prevalence of amenorrhea was 41.2%. Penezic et al. (10) to determine long-term patient satisfaction after thermal balloon EA 7 to 10 years postoperatively in a population previously surveyed at the Penn State Milton S. Hershey Medical Center at 1 to 5 years postoperatively and observed 58% amenorrhea over 7 to 10 years. In the study of Hokenstad et al. (11), the ratio of amenorrhea following EA in patients without a history of ovulation dysfunction was 13.8%, which is consistent with the results of the present study.

However, other comparative studies have conflicting results, for example Brun et al. (12) reported a 36% success rate for Cavaterm, while hysteroscopy group showed a 29% success rate. The results obtained in other studies are contradictory (13). The study of Ajao et al. (14) reported 29.7% amenorrhea and 27.2% amenorrhea in a cohort study. Amenorrhea rates were also similar in both. The high risk (HR) cohort had a higher proportion

of women with cardiac disease (27.1 vs. 6.7%, P<0.001) and more women with nongynecologic cancer (12.3 vs. 2.9%, Fisher exact test, P<0.001). Nonetheless, EA had comparable efficacy in both the HR and low risk (LR) cohorts with a 5-year failure rate of 11.7 and 14.8% (P=0.659). It seems that the differences in the success rate of amenorrhea in these studies are due to patient selection methods and differences in surgical techniques. The higher amenorrhea rate in the Cavaterm group might be due to its homogenous circumambient ablative ability in comparison with focal intervention in the hysteroscopy ablation.

In general, regarding the amenorrhea rate following hysteroscopic ablation, which is lesser than 50%, leads to the conclusion that EA by both methods is not a good choice for women who prefer postoperative amenorrhea (15).

EA success was considered as an AUB cessation (conversion to amenorrhea or eumenorrhea) in the present study, this value in two methods of ablation by Cavaterm or hysteroscopy was 91.8 and 76%, respectively, which is also a statistically significant difference and demonstrates the better performance of the Cavaterm method. Bouzari et al. (7) also defined the success of Cavaterm as improving the bleeding status and reported its rate in the quarter and six months as 92.5 and 93.5%, respectively. Their result is consistent with the present study. The success percentage of Cavaterm in the study of Karimi-Zarchi et al. (9) was about 94% after 6 month follow up that was higher than present study. In a same direction a 7-year success proportion for the Penezic et al. (10) study was 91.5%. Brun et al. (12) reported a 87% success rate of the hysteroscopy degrading treatment, which is somewhat higher than the present study. Similar results have been suggested by Ajao et al. (14), and Hokenstad et al. (11), 85 and 87% respectively.

The treatment failure rate leading to hysterectomy following treatment with Cavaterm has different reports. The Bouzari et al. (7) one-year follow-up study did not report any hysterectomy, but this number was about 2% in Karimi-Zarchi et al. study (9), 12.9% in Kleijn et al. (8) study and 21.6% in the Penezic et al. (10) study. We reported a 25% failure in the Cavaterm group which is consistent with what was mentioned. It seems that the difference in the number of reports is affected by the duration of follow-up of patients, which in these four studies was one year, about two years, 5 years and 7 years, respectively. The reports of the articles mentioned that the patients' satisfaction after treatment is incomparable in many cases due to the satisfaction assessment method. In a Cochran review article, the postoperative satisfaction with different methods is almost equal and comparable, but another meta-analysis found patients' satisfaction with thermal methods higher than other methods (16), that was consistent with our results.

The main limitation of our study was the impossibility of long-term follow-up due to lack of access to them and the impossibility of standardizing the long-term evaluation of postoperative outcomes. It is suggested to consider long-term follow-up in future studies.

Conclusion

Cavaterm ablation is accompanied by a higher success rate of amenorrhea and patient satisfaction compared with hysteroscopy ablation. Major adverse events will not be expected frequently.

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Authors' Contribution

M.M.; Participated in study design, patient selection and surgical intervention. A.M.; Contributed in data analysis and manuscript preparation. S.R.; Performed patients' selection, surgical intervention and manuscript preparation. Z.M., M.Y., S.Gh.; Performed patient selection and patients follow up. M.A.; Participated in the pre-surgical intervention and patients post surgical follow up. S.A.; Contributed in study design, patients' selection, surgical intervention and manuscript preparation. All authors read and approved the final manuscript.

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