

Thermal Balloon Endometrial Ablation in the Treatment of Heavy Menstrual Bleeding

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ABSTRACT

Aim: Heavy menstrual bleeding is one of the common health problems in women. The first-line therapy of heavy menstrual bleeding is the medical therapy, but this is not successful. Currently, global ablation procedures were introduced for treating of heavy menstrual bleeding. The aim of this study was to the analysis of the patient with menorrhagia performed operations of Cavaterm in our university affiliated hospital, and explores its effectiveness and acceptability. **Methods:** A retrospective study was conducted on 30 patients with menorrhagia who were unresponsive to hormone therapy or not candidates for hysterectomy underwent endometrial ablation using Cavaterm. Preoperative and postoperative PBAC Scoring System was used to assess menorrhagia. Outcome measures were amenorrhea rates, reduction of menstrual flow rates, heavy bleeding, menstrual and patients' satisfaction rates at 3, 6 and 12 months postoperative. **Results:** After a follow-up at 3, 6, and 12 months postoperative, 36.7%, 43.3%, and 36.7% of women had a reduction in vaginal bleeding, respectively. Amenorrhea rates were 56.7%, 50.0%, and 56.7% in the Cavaterm at 3, 6, and 12 months. The rate of women's reported good or excellent satisfaction was 93.3% in 12 months. During the follow-up period, no woman received a subsequent hysterectomy. **Conclusion:** The findings of this research indicated that outcome with the Cavaterm was as good for women with menorrhagia. Therefore, it is necessary to emphasize on lower operative and post-operative procedural risk and a deleterious effect on patients who were unresponsive to hormone therapy.

Key words: Abnormal uterine bleeding, Cavaterm, menorrhagia, thermal balloon endometrial ablation

1. INTRODUCTION

Heavy menstrual bleeding is a significant health problem in premenopausal women and that would be equivalent to menorrhagia (1, 2). The treatment of menorrhagia can either be medical therapy, hysterectomy or destruction of the endometrial. Medical therapy is the first-line therapy, but this is not successful while hysterectomy is effective in treatment of bleeding but it is associated with many complications (3, 4). In addition, it is often more expensive than medical therapy (5). In the 1980's, endometrial ablation procedures were introduced in treatment of dysfunctional uterine.

The endometrial ablation is a technique of removing (ablating) the lining of the endometrium to suppress or decrease menstruation for treating menorrhagia in women who failed standard therapy. Various methods such as cryotherapy, heated saline, microwaves, and thermal balloon exist to destroy the endometrium as a treatment for menorrhagia. The thermal balloon endometrial ablation includes four kinds of devices: ThermaChoice[®], Menotreat[™], Cavaterm[™], and Thermablate[™]. These procedures

are a less invasive alternative compare to hysterectomy (2, 6-12) and approved by the US Food and Drug Administration (FDA) for women with menorrhagia whom child-bearing is complete, but they are not generally available for use in Iran. Cavaterm has a low-allergen silicon material, and the balloon length can be adjusted to cavity length of different size of uterine, which it can protect surrounding tissues from thermal damage. Recently, Cavaterm was activated to treatment of dysfunctional uterine bleeding (DUB) for women with menorrhagia that has not responded to medical treatment in Iran (13, 14). We found no routine data on the Cavaterm procedure carried out in Iran. The researcher has come across the reality that Cavaterm may still be required to conduct this study to assess the effectiveness and acceptability of Cavaterm method. The aim of this study was to the analysis of the patient with menorrhagia performed operations of Cavaterm in our university affiliated hospital, and assesses the effectiveness and acceptability of the Cavaterm system.

2. PATIENTS AND METHODS

This study was approved by the ethics committee of the Medical Sciences University of Babol. A compilation sheet was developed for the study after taking the written permission and satisfaction of the patients. A retrospective study was done for all women with menorrhagia who have undergone endometrial destruction with thermal balloon in our university affiliated hospital. All patients had completed her family and agreed to undergo endometrial ablation with Cavaterm. The patients with heavy menstrual bleeding or prolonged uterine, vaginal bleeding unresponsive to medical treatment, or not candidates for hysterectomy used of tampons during the course period and recorded their use of tampons. A sonography was used to rule out endometrial pathology and uterine congenital anomaly. An endometrial biopsy in order to assess endometrial cancer was done.

Exclusion criteria included uterine tumors (fibroids or polyps), uterine cavity less than 4 cm, active urinary tract infection and pelvic infection, history of surgery (myomectomy), endometrial ablation and classical caesarean section.

In all eligible patients, were given rectal diclofenac, pre- and postoperative. Cavaterm endometrial thermal ablation technique with disposable balloon (FDA approval obtained in 1997) was performed under local anesthetic. The vaginal pain/ fever at postoperatively assessed visual analogue scale 1 to 10. Women were discharged the same day.

Preoperative and postoperative PBAC Scoring System was used to record size of clots/ flooding row under the relevant day. If the score was 100 or greater was indicated that the women had a heavy menstrual period or menorrhagia (15).

All patients completed health status questionnaires included questions on the amenorrhea, reduction of menstrual flow, heavy bleeding postoperative in the 3rd, 6th, and 12th months after the end of treatment. In addition, intra-operative and postoperative complications include fluid overload, hematometra, uterine rupture, and laceration of cervix was measured. The return to normal activities and return to occupation activities was questioned through phone. It included questions on the amenorrhea, reduction of menstrual flow, heavy bleeding postoperative, In addition, intra-operative and postoperative complications include fluid overload, hematometra, uterine rupture, and laceration of cervix was measured.

3. RESULTS

The mean age of the patients was 43.3 ± 5.8 years at the time of treatment. The patient characteristics were shown in Table 1. The mean of pelvic pain/cramping with visual analogue scale scores of pain was reported 5.8 ± 2.2 in 24 hours of the procedure. Around 20% of the patients reported pelvic pain/cramping until 1 week of the procedure.

After a follow-up in 3, 6, and 12 months postoperative, 36.7%, 43.3%, and 36.7% of women had reduction in vaginal bleeding, respectively. Amenorrhea rates were 56.7%, 50.0%, and 56.7% in the Cavaterm at 3, 6, and 12 months,

Variables	Mean \pm SD	Range
Age	43.3 \pm 5.8	30, 57
BMI	31.3 \pm 6.8	19.1, 52.7
Pregnancy	3.2 \pm 1.4	0, 6
Parity	2.6 \pm 1.1	0, 5
Abortion	0.5 \pm 0.8	0, 5
Score of bleeding	361.3 \pm 227.5	140,900

Table 1. Characteristics of the women with heavy menstrual bleeding undergoing endometrial ablation procedure (Cavatherm) (n=30)

	Mean	SD
Operation time (minutes)	12.0	1.8
pelvic pain/cramping at 24 hour	5.8	2.2
pelvic pain/cramping at 1 week	1.3	2.1
Return to normal activities (day)	1.8	0.9
Return to occupation activities (day)	12.7	5.8
	N	%
Amenorrhea rate at 3 months'	17	56.7
Reduction of menstrual flow rate at 3 months'	11	36.7
Heavy bleeding rate at 3 months'	3	10.0
Amenorrhea rate at 6 months'	15	50.0
Reduction of menstrual flow rate at 6 months'	13	43.3
Heavy bleeding rate at 6 months'	2	6.7
Amenorrhea rate at 12 months'	17	56.7
Reduction of menstrual flow rate at 12 months'	11	36.7
Heavy bleeding rate at 12 months'	2	6.2
Patient' satisfaction rate at 3 months' 'good' to 'excellent'	29	96.7
Patient' satisfaction rate at 6 months' 'good' to 'excellent'	26	86.7
Patient' satisfaction rate at 12 months' 'good' to 'excellent'	28	93.3
Subsequent hysterectomy at 12 months	0	0.0

Table 2. Outcome of endometrial ablation procedure (Cavaterm) among women with heavy menstrual bleeding (n=30)

respectively, and the remaining two women (6.7%) were considered treatment failures.

Rates of heavy bleeding in 12 month were relatively low around 6.2%. A subsequent hysterectomy for recurrent bleeding was not performed in the treated individuals by Cavaterm. The rate of women's reported good or excellent satisfaction was 93.3% in the Cavaterm in 12 months (Table 2). There were no major complications.

4. DISCUSSION

Some researchers have shown the Cavaterm endometrial ablation system to destroy the endometrium reduces initial cost, operating time, and postoperative complications compared with hysterectomy (3). According to the followed researches with the Cavaterm system some studies reported amenorrhea rates between 22%, and 68%, respectively (16, 17). The Cavaterm ablation is not usually used in Babol, Iran. It only used to selectively destroy uterine for a short time in the hospital. There were no reportable complications with the Cavaterm endometrial ablation system of health care providers in Iran. Any new technique is introduced, it is essential to evaluate carefully in routine practice. Reduction of menstrual flow

rates, amenorrhea rates, and patient satisfaction rates can be important to assess Cavaterm. We found that amenorrhea rates at 6 and 12 months of 50.0%, and 56.7% for Cavaterm. The rate amenorrhea at 12 months was more than rates reported by Friberg et al. (31%) (18), but Hawe et al. reported less than our study (68%) (11). In addition, in our study, patient satisfaction rates of Cavaterm were similar to those reported by a retrospective assessing Cavaterm on 156 women with dysfunctional uterine bleeding (around 90%) (2).

Researchers have shown that rates of heavy bleeding are variable of 0-32% for Cavaterm (12). However in this study 6.7% patients reported heavy bleeding rate at 12 months, but no subsequent hysterectomy rate at 12 months reported, this figure was lower than that reported by Hawe et al. (9%) (16). There were no major complications reported for Cavaterm, the outcomes of this procedure among women with menorrhagia where improvement procedure outcomes, satisfaction with postoperative complications and the outcome. However hysterectomy is obviously 100% effective in treatment of heavy menstrual bleeding but it causes severe complications (3). In this study, we were not able to compare the efficacy of hysterectomy with Cavaterm. Moreover many safety and efficacy of the new technique of endometrial destruction with thermal balloon must be evaluated. Therefore, if the women's preference is for a shorter hospital stay and lower inter-post-operative procedural risk, endometrial ablation is recommended.

5. CONCLUSION

We suggest that the outcomes with the Cavaterm endometrial ablation system are as good for women with menorrhagia. However, because of the limited total number of samples and cross-sectional design to determine effectiveness of the Cavaterm system we make no claims from this study that either procedure provides superior outcomes, but it seems that the Cavaterm is a fast action procedure and a short hospital stay with a deleterious effect on menorrhagia in women who failed standard therapy. Certain types of adverse events and rates of intervention with this procedure to endometrial ablation were low. Rates of dissatisfaction with treatment or ongoing heavy bleeding were generally low in this study. Larger clinical trial randomized studies may be required to determine the effectiveness of the Cavaterm thermal balloon ablation system for treatment menorrhagia and long term studies is needed to determine the costs of ablative surgery approach and the cost of hysterectomy due to the requirement for subsequent surgery. A number of newer procedures have recently been developed and available in many countries, most of which are less time consuming.

CONFLICT OF INTEREST: NONE DECLARED.

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