Original Article

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Complications, Bleeding and Satisfaction of Patients with Abnormal Uterine Bleeding through the Integration of Endometrial Degradation and Thermal Balloon Therapy

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ABSTRACT

BACKGROUND AND OBJECTIVE: In the patients diagnosed with abnormal uterine bleeding, if the patient does not respond to drug treatment or is not a good candidate for hysterectomy, endometrial destruction is recommended. The aim of this study was to evaluate complications, blood loss and patient satisfaction regarding this method of treatment.

METHODS: This retrospective study was performed on 56 women who admitted to Ayatollah Roohani Hospital of Babol and Imam Hossein Hospital in Tehran, Iran. Upon the diagnosis of abnormal uterine bleeding, they underwent a treatment called "endometrial destruction by thermal balloon". A questionnaire including the following items was completed after the sugery: demographic characteristics, menstrual status, postoperative complications, treatment success and a 12-month post-surgery patient satisfaction. In order to assess the patients' satisfaction, 4 questions were asked (excellent, good, fair, poor). Successful treatment was defined as 6 months of amenorrhea after treatment with cavaterm and a reduction in the menstrual blood loss in the form of spotting or volume degression.

FINDINGS: Of the 56 patients who were treated with balloon thermal endometrial destruction, 4 were excluded due to the lack of follow-up. The mean age of the patients was 91/5±38/43 years. No complications occurred in any of the new patients, and the percentage of amenorrhea was 23 after the treatment. Twelve months after the surgery, the success of treatment was reported in 46 patients (5.88%) and patient satisfaction was also rated in 45 of the patients (5.86%).

CONCLUSION: The results of the study showed that the thermal balloon treatment had no major side effects. Thus, it could be inferred that the study was a success in terms of the outcomes and high patient satisfaction. This method could be taken into consideration before a hysterectomy.

KEY WORDS: Hysterectomy, Endometrial destruction, Uterine bleeding.

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Introduction

Excessive menstrual bleeding is an important health problem which reduces the quality of life and leads to anemia which affects 15% to 10% of women in their reproductive age and 20% of women older than 35 years (1-3). Furthermore, 80% of the women diagnosed with a 50-percent menorrhagia would be referred to an emergency ward specialist and 65% of them would undergo a hysterectomy surgery (3,4). About half of these patients show no symptoms of menorrhagia. Therefore, they are diagnosed with dysfunctional uterine bleeding.

The first-line treatment for these patients would be the drug treatment. However, when the medication meets failure, hysterectomy might be considered as the next step (1,5). If possible, many women tend to avoid surgery, some of which are not actually good candidates for surgery. If the treatment of menorrhagia is inexcusable and medical treatment cannot be acceptable, successful or well tolerated, another option is the destruction of the endometrium (6) as opposed to hysterectomy. Endometrial destruction via thermal balloon therapy is a simple technique.

It consumes less surgical time, can be done with local anesthesia, has a lower surgical morbidity, shorter hospital stays and a faster recovery; hence, it will allow the patient to return to his daily life sooner (7-9). Despite the fast-growing popularity of this type of treatment around the world, it is still not widely accepted in Iran. It is mainly because so far, no study has been done on the basis of thermal balloon therapy. As a result, this study attempted to investigate the effects, the optimal amount of bleeding and the patients' satisfaction with the procedure.

Methods

This experiment was performed on 56 women who reffered to Ayat-o-Allah Rouhani Hospital in Babol, Shahid Beheshti University of Medical Sciences and Imam Hussein Hospital in Tehran, Iran. They had been diagnosed with abnormal uterine bleeding which either did not respond to medical treatments or was, in some way, resistant to medical and surgical treatments or the patient was not willing to undergo hysterectomy surgery. The treatment procedure and its advantages and disadvantages were described to the patients and a written consent was obtained from them.They were enrolled in the study if they did not wish to become fertile or provided that they had normal cervical cytology, normal histology of endometrium and no genital tract infections.

The patients with submucosal myoma larger than 2 cm or greater than 3 cm, uterine cavity length over 10 cm or smaller than 4 cm would have been considered as atypical endometrial hyperplasia. Moreover, the existence or appearance of abnormal cervical, adnexal mass without pathology and anomalies of the uterus in some other patients could prevent the balloon from opening inside the uterus. Consequently, the subjects having one of the aforementioned conditions were excluded from the survey.

They also completed a questionnaire including demographic characteristics of the cycle. The amount of menstrual bleeding was measured based on the PBA Scoring System (10). After anesthesia, the patients were placed in the lithotomy position and the cervix was opened up to 6mm using a dilator. The patients who had previously undergone a vaginal ultrasound were exempt from the abnormalities. During the ultrasound, the myometrium thickness -especially in its thinnest spot-, the length of the uterine cavity and the cervical length were measured. Furthermore, in order to reduce the thickness, endometrial curettage was performed and samples were taken for pathological examinations. Cavaterm system consists of a silicone balloon attached to a catheter with a width of 6 mm and a unit (Thermal Balloon Endometrial Ablation catheter, device model Cavaterm made in PNN Medical SA Company, Switzerland).

The length of the silicone balloon is adjusted in accordance with the size of the uterine cavity. After removing the air from the cavaterm system, the end of the catheter entered the fundus and the balloon was filled with 5% of glucose until it reached the 10 ± 230 mm Hg pressure. The pressure was maintained until the end of the treatment. Then, the fluid flow and the heating began. After reaching a temperature of 75 °C, ablution began. The treatment continued for 10 minutes at 78°C. The catheter ablution was surrounded by insulation so as to prevent thermal injury of the

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cervical canal and the vagina. After 10 minutes, the heat was automatically disconnected, the fluid returned and the catheter was pulled back. Duration of surgery, hospital stay and perioperative complications were recorded.

Postoperative complications included: thermal damage to the bowel, uterine perforation, adnexal necrosis, suprapubic pain, tachycardia, weakness, bleeding, infection and plasm discharge. One hour after the surgery, the patients were asked to report their pain using theVAS system. Scores of 5 and higher were considered as pain. At the time of discharge, the patients were asked to record their daily activities at home and return to their jobs.

All the patients were followed up for one year for treatment outcomes including rates of amenorrhea, Hypomenorrhea, yomenorrhea, menorrhagia and menstrual symptoms all of which were recorded for each patient in a period of 12 months. During the visit, the patients were asked about their menstrual bleeding severity as well as the duration and distance between their cycles (in case of menstruation).

In the absence of menstruation and non-pregnancy, the diagnosis of amenorrhea was decided upon. The patient satisfaction was also followed up for 12 months after the surgery. In order to assess the patients' satisfaction, 4 questions with the following answers (excellent, good, fair, poor) were asked. Success included the incidence of amenorrhea within 6 months after the treatment with the thermal balloon, reduction in the menstrual blood loss or reduction in spotting. Failure was in case of the need for other therapies or surgeries during the period the patients were being visited. Ultimately, data were collected and examined.

Results

Of the 56 patients treated with the thermal balloon endometrial destruction, 4 were excluded from the study. One of the patients deterred during the initial survey and underwent a hysterectomy. Three others did not show up after the surgery. The mean age of the subjects was 91.5±38.43 years (table 1). In this study, 42 patients (80%) who were treated with the thermal balloon had a history of drug consumption (including oral contraceptives, medroxyprogesterone, danazol, Decapeptyl) prior to the endometrial destruction. Also, 10 patients (19.2%) had no history of any type of medical or surgical treatments prior to the endometrial destructio. Abnormal post-surgical uterine bleeding prior to the endometrial destruction registered as follows: 1 patient (9.1%) amenorrhea, 3 patients (8.5%) metrorrhagia and 48(3.92%) Hypomenorrhea. The average and maximum amount of menstrual bleeding before the surgery was 69.234±08.403, 40cc (1 patient) to 952 cc (1 patient), respectively. In 12 cases (23.1%), the menstrual bleeding period before the endometrial destruction surgey with natural thermal balloon was 8-4 days. However, in 39 cases (75%), the duration of menstrual bleeding before the endometrial destruction was more than 8 days and in 1 patient (1.9%), the duration of menstrual bleeding was less than 8 days.

Table 1. The variables in women with abnormal uterine bleeding treated with cavaterm

Variable	Max-Min	Mean±SD
age	57-30	43.3±5.91
number of pregnancies	7-0	3.13±1.32
number of childbirths	7-0	2.67±1.13
abortion history	2-0	0.4±0.69
BMI	52.71-19.10	52.71±19.10

The most common complication after the surgery was plasma discharge in 51 patients (98%). Other complications included suprapubic pain in 34 patients (4.65%), bleeding in 3 patients (8.5%), tachycardia in 2 patients (8.3%) and weakness in 1 patient (9.1%). Nevertheless, none of the cases who had been treated with thermal balloon endometrial destruction experienced any complications like thermal injury to the intestine, uterine perforation, adnexal necrosis and infection. The mean duration of the discharge plasma was 39.16±04.20 days.

Approximately 70% of the patients experienced plasma discharge in less than 20 days after the surgery. On the other hand, 35 patients (6.68%) began their daily activities one day after the surgery and 31 patients (8.60%) started 3 days after the surgery (table 2).

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Table 2. Daily activities following the endometrial destruction surgery with thermal balloon

Activity onset	percentage
daily	
one day	35(68.6)
two days	8(15.7)
three days	7(13.7)
four days	1(2)
Careers	
one day	10(19.6)
two days	10(19.6)
three days	11(21.6)
≤four days or more	20(39.2)

Amenorrhea discharge was higher 12 months after the endometrial destruction surgery than other types of bleeding (Hypomenorrhea, yomenorrhea and hypermenorrhea) in the patients treated with cavaterm (23%). The success and failure of the treatment through endometrial destruction were 46 (5.88%) and 6 (5.11%) respectively12 months after the surgery. Twelve months after the surgery, 71% of the patients who were treated with endometrial destruction via cavaterm stated their satisfaction rate as high and 15% of them reported their satisfaction as normal while almost 2% and 12% of the patients, respectively, felt average and poor satisfaction.

Additionally, pathology reports which belonged to 43 patients (82.7%) were delivered after the proliferative endometrial biopsy whereas for 9 patients (3.17%), the reports were deliverd after the postoperative polyp or myoma. The satisfaction of the patients 12 months after the endometrial destruction surgery, based on the natural pathology results (endometrial proliferative or secretory endometrium) and artificial (fibroids or polyps), were respectively 37(86%) and 8 (9.88%).

Discussion

In the present study, none of the patients who had been treated with the endometrial destruction using cavaterm reported any complications such as perforation, bleeding and infection. Nevetheless, the most prominent complication was plasma discharge. Similar to our reseach, in a study conducted by Alaily et al, 77 women who were diagnosed with abnormal uterine bleeding were treated with cavaterm and no complications were observed after the procedure (11). El-Toukhy and colleagues also studied the effects of cavaterm therapy on 220 patients.

At the end of the experiment, there was no surgery-related complications regarding the cavaterm surgery (12). Other studies presented identical theories as well (8 and 3. Despite the aforementioned findings, in a survey conducted by Gurtcheff SE et al, certain symptoms like thermal damage to the intestines, bleeding, perforation of the uterus and adnexal necrosis were reported. It is noteworthy that these symptoms were instituted with those patients having a history of Cesarean (13).

However, in a research done on 116 women with menorrhagia premenopausal who were in treatment with cavaterm, it was revealed that 26 of these women had had a Cesarean section before. The study claimed that women with a history of C-section who had been treated with cavaterm did not have a bad outcome; so, this method can be used in future cases (14). In our study, the patients with a history of C-section experienced no symptoms at all. In the present study, the rate of amenorrhea during the following 12 months after the endometrial destruction surgery was relatively higher than other types of bleeding (Hypomenorrhea, yomenorrhea and hypermenorrhea) in the patients who were treated with cavaterm (2/44%).

However, if we consider the amenorrhea, Hypomenorrhea and yomenorrhea as the success of the treatment and hypermenorrhea as the failure within 12 months after the surgery, the success rate is equal to 5/88% which is a high score. In Hawe's study, the occurrence of amenorrhea and hyper menorrhea in the patients treated with cavaterm was 29% and 73% respectively (15).

In a similar study conducted by El-Toukhy and colleagues, the incidence of amenorrhea- hypomenorrhea was reported as much as up to 83-74% over 24 months in the patients treated with cavaterm (220 patients) (12). Vihko and colleagues also studied the thermal destruction methods which are commonly used in Finland (mono-arthritis and cavaterm) and compared the results in 31 patients. The effectiveness of the two methods proved to be similar. They concluded that

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these methods are effective for all patients (16). In another study done by Abbott and colleagues, of 55 women with dysfunctional uterine bleeding, 18 patients were treated with cavaterm. After a period of 12 months, 11% amenorrhea, 61% hypomenorrhea, 27% yomenorrhea and zero percent of menorrhagia were reported(9).

Thus, it can be inferred that other studies have confirmed the effectiveness of this method of therapy (17-19). The review of 7 clinical trials done on 1,167 women with abnormal uterine bleeding who had been treated with hysterectomy and endometrial destruction revealed that although hysterectomy is an effective treatment for women with abnormal uterine bleeding, there is a high risk of complications in doing so. Due to the differences in scale, there is a heterogeneity in the results of these studies. Therefore, data are insufficient to compare the outcome of amenorrhea, and the evidence manifesting the bleeding control or the adventage of hysterectomy over the destruction is average (20).

The postoperative satisfaction of 12 patients undergoing the cavatrm endometrial destruction was desirable. Similar to this study, other studies which have exploited different methods of endometrial destruction also reported the same rate of satisfaction. The satisfaction rate of the patients in the treatment method of Brun et Kavatrm was 83% after 12 months (3), in that of the EI-Toukhy and colleagues it was 89% (12), it was 77% in the research done by Herman MC & Associates in 2013 after a 10-year follow-up (19) and in the study of Alaily and colleagues it was 90% after 12 and 24 months (11). Other studies also reported remarkable satisfaction feedback regarding the amount of menstrual flow after the surgical treatment with endometrial destruction via cavaterm (1,15,16,18).

Likewise, the results of the current study showed no complications after the surgery in the patients treated with cavaterm.For another thing, the amount of amenorrhea and the treatment success rate after the cavaterm surgery resulted in satisfactory outcomes in the patients. The rate of satisfaction in the patients with abnormal uterine bleeding using cavaterm endometrial destruction technique appeared to be ample within 12 months after the surgery.

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