

Evaluation of the Success Rate of Endometrial Ablation by Cavaterm™ plus Technique

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Background: Dysfunctional uterine bleeding (DUB) is the most common gynecologic disorder in women of reproductive age. Medical treatments are often ineffective. Endometrial ablation is an alternative to hysterectomy for these women.

Objectives: To evaluate the response to treatment rate of the Cavaterm™ plus technique for management of menorrhagia secondary to dysfunctional uterine bleeding (DUB).

Patients and Methods: In this clinical trial study 40 women aged 35-50 years with menorrhagia secondary to DUB, who had been referred to the gynecology clinic of Arash Hospital, Tehran, Iran, were recruited. They underwent endometrial ablation via Cavaterm™ plus system and were followed for one year.

Results: The observed mean number of days of bleeding per month decreased significantly from 14.95 ± 6.7 days before treatment to 3.42 ± 3.04 days after treatment ($P < 0.001$). Intervals between hemorrhagia increased significantly from 16.25 ± 5.50 to 21.30 ± 11.10 days ($P = 0.01$). The rate of dysmenorrhea decreased significantly from 32.5% to 10% ($P < 0.05$). The improvement rate of dysmenorrhea was 69.5%. The overall improvement of menorrhagia was reported 92.5% ($P < 0.001$). After one year the rates of hypomenorrhea, amenorrhea and eumenorrhea were 47.5%, 27.5% and 17.5%, respectively.

Conclusions: The Cavaterm™ plus system is a safe and effective technique and it can be an excellent alternative to hysterectomy for the treatment of menorrhagia due to DUB. The failure to treatment rate was reported 7.5%. Patient satisfaction rate was 85%.

Keywords: Menorrhagia; Endometrial Ablation; DUB

1. Background

Menorrhagia, secondary to dysfunctional uterine bleeding (DUB), is the most common gynecologic disorder with a prevalence of approximately 10-15% in women of reproductive age and accounts for 3 million referrals to gynecological practice. Excessive menstrual bleeding is responsible for more than 1/3 of the annual hysterectomies (1-4). In approximately 50% of cases no pathological cause is found and the term "dysfunctional uterine bleeding" is used (5). Heavy menstrual bleeding is defined as a loss of more than 80 mL blood per cycle or longer than 7 days (1). Since abnormal uterine bleeding has an enormous impact on women's quality of life and is associated with disruptions in social life, patients with menorrhagia seek a proper treatment (2). Most medical treatments of menorrhagia are ineffective, not tolerated or not acceptable as a long-term treatment by patients (6). Hysterectomy had been the only definitive sur-

gical option in women with menorrhagia for a long time that was usually recommended when excessive menstrual bleeding remained unresolved by medical therapies (7).

Endometrial ablation was introduced in the 1980's as an alternative to hysterectomy for women with abnormal uterine bleeding who do not wish to retain their fertility (8, 9). Endometrial ablation techniques are classified as either first or second generation. First generation techniques are done by resectoscope via hysteroscopy and require experienced and expert surgeons. Second generation techniques, named non hysteroscopic techniques, are significantly easy to use, and safe and do not require extensive endoscopic skills and general anesthesia (6). Thermal balloon endometrial ablation (TBEA) was the first method which was approved by FDA in 1990 (10) and Cavaterm was described in 1993 (11).

Implication for health policy/practice/research/medical education:

Menorrhagia, secondary to dysfunctional uterine bleeding (DUB), is the most common gynecologic disorder in women of reproductive age and is responsible for more than 1/3 of the annual hysterectomies, an invasive surgery with many complications. Endometrial ablation is an alternative to hysterectomy for these women, which is done via some techniques classified as first or second generation. First generation techniques are done by resectoscope via hysteroscopy and require experienced and expert surgeons. But second generation techniques, named non hysteroscopic techniques, are significantly easy to use, and safe and do not require extensive endoscopic skills and general anesthesia. The Cavaterm™ plus system, used in this study, is a new version technique with many benefits. This is the first study in Iran to evaluate the clinical performance and acceptability of Cavaterm™ plus (Pnn Medical SA.) for management of menorrhagia secondary to DUB.

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The various endometrial ablation techniques have been introduced as an alternative to hysterectomy for women who wish to preserve their reproductive function or those who are not fully satisfied by medical therapy (12, 13). First-generation techniques (including resection with laser, monopolar or bipolar electrosurgery) require extensive endoscopic skills whereas second-generation techniques (including thermal balloon, microwave, radiofrequency, cryoablation and hydrothermal ablation) are non hysteroscopic methods and easier to use (14). The Cavaterm™ system has been successfully used since 1993 and has reported amenorrhea cure rate from 68% to 98%. (15-17). The Cavaterm™ plus system (new version of Cavaterm) was used in this study. In several studies it has been reported that treatment of DUB with Cavaterm™ plus has more efficacy compared to the older version (18, 19). The significant difference between Cavaterm plus and older version is that the diameter of catheter shaft is smaller (6 mm) compared to the 9 mm diameter in older version that leads to less cervical dilation in many cases and that the balloon length in cavaterm plus is more adjustable that permits a greater range of uteri to be treated. And that the older version was filled with 1.5% glycine to a pressure of 180-220 mmHg and the fluid was then heated to 75–80°C but Cavaterm plus is set for a lower temperature (65–75°C) and higher balloon pressure (230–240 mmHg), in addition, a solution of 5% dextrose is used to fill the silicon balloon. And finally that the treatment duration was 15 minutes in older version which was reduced to 10 minutes in Cavaterm plus (6, 18, 19).

2. Objectives

This is the first study in Iran to evaluate the clinical performance and acceptability of Cavaterm™plus (Pnn Medical SA) for management of menorrhagia secondary to DUB.

3. Patients and Methods

This clinical trial study was performed on 40 women 35-50 years old with menorrhagia secondary to DUB, who had referred to the gynecology clinic of Arash Hospital, Tehran, Iran, between March 2011 and March 2012. The inclusion criteria were as following: menorrhagia secondary to DUB, uterine size ≤ 12 cm, no further fertility desired, normal endometrial biopsy, failed or declined medical treatment, no desire for hysterectomy. The exclusion criteria were as following: uterine cavity measuring >12 cm in length, desire for pregnancy, any kind of abnormal pathology in the uterine cavity, suspected genital or urinary tract infection, hereditary malformations of the uterine cavity, history of classical cesarean delivery, endometrial hyperplasia and malignancy.

The study was approved by the Ethics Committee of Tehran University of Medical sciences. In the beginning, the conditions of the study were completely explained to the patients and then written informed consent was taken

from them. If they had complete consent form for participating in the study, they were recruited to the study.

Prior to surgery, baseline information including age, body mass index, parity, pattern of bleeding, endometrial thickness, endometrial disease, uterine length, uterine position, serum haemoglobin concentration and treatment history was obtained. As a comment of the manufacturer, all patients underwent curettage in the operating room immediately before the surgery. We made notes of all adverse events, complications, details of surgery and medications used at the time of the procedure. Ablation procedure was performed under general or local anesthesia via paracervical block with intravenous sedation. Endometrial ablation was performed using the Cavaterm plus system according to the protocol provided by the manufacturer. The catheter was introduced into the uterine cavity and the balloon catheter was filled with 5% dextrose, inflated until intrauterine pressure was stabilized between 230-240 mmHg. It was heated to 78°C for 10 minutes. To reduce pain after surgery, all women received 100 mg rectal suppository of diclofenac. The rates of menstrual bleeding and dysmenorrhoea were assessed before and after the procedure using a 10 cm visual analogue scale (VAS).

12 months after the operation, patient satisfaction and pattern of menstrual cycle were evaluated. Statistical analysis was carried out using SPSS software, version 17 (SPSS, Chicago, IL, USA). The data were analyzed by means of chi-square test, Student's t-test and Fisher's exact test. Level of significance was set at $P < 0.05$.

4. Results

Table 1 shows demographic and clinical characteristics of patients with menorrhagia before surgery. The mean number of bleeding days per month was 9.8 ± 3.44 days and 90% of women had been treated previously.

Table 1. Baseline Patient Characteristics

| Characteristic | Value |
|--|-----------------|
| Age, y | 43.2 \pm 5.46 |
| Body mass index, kg/m ² | 29.2 \pm 7.01 |
| Parity, median | 2 (2-5) |
| Previous cesarean delivery, No. (%) | 16 (40.0) |
| Tubal ligation, No. (%) | 11 (27.5) |
| Preoperative dysmenorrhoea, No. (%) | 13 (32.5) |
| Uterine length, mean (SD), cm | 9.2 \pm 1.2 |
| Hemoglobin, mean (SD), g/dL | 12 \pm 1.7 |
| Endometrial thickness, mean \pm SD, mm | 11.5 \pm 5.66 |
| Previous curettage, No. (%) | 26 (65.0) |
| Duration of menorrhagia, mo | 9.8 \pm 3.44 |
| History of medical treatment for menorrhagia | 36 (90.0) |
| Used pads per cycle | 82 (10-200) |

At Table 2 summarizes the treatment effects of Cavaterm plus on the menstrual status after 1 year. The observed mean number of bleeding days per month decreased significantly, from 14.95 ± 6.7 days before the treatment to 3.42 ± 3.04 days after the treatment ($P < 0.001$). Intervals between haemorrhagia increased significantly from 16.25 ± 5.50 to 21.30 ± 11.10 days ($P = 0.01$). The rate of dysmenorrhoea decreased significantly from 32.5% to 10% ($P < 0.05$). The overall improvement of menorrhagia was 92.5% ($P < 0.001$). After one year the rates of hypomenorrhoea, amenorrhoea and eumenorrhoea were 47.5%, 27.5% and 17.5%, respectively, and the rate of hypermenorrhoea (failure of treatment) was 7.5%. Patient satisfaction rate was 85%.

Patient's characteristics of both, amenorrhoea and treatment failure groups are described in Table 3. Endometrial thickness and balloon volume were significantly higher in patients with treatment failure ($P < 0.001$) and mean age of patients and intrauterine pressure was significantly lower in patients with failure of treatment ($P < 0.001$).

Within four hours after surgery, the severe pain rate was 52.5%. Mean surgical time was 30 ± 8.5 minutes and the rates of general and paracervical anesthesia were 75% and 25%, respectively (Table 4). No long term severe complication was observed in patients.

5. Discussion

In this study we evaluated the response rate to the Cavaterm™plus technique for management of menorrhagia secondary to DUB.

In the study by Sophia Julian, the efficacy of Cavaterm™plus system was investigated and the rates of amenorrhoea and hypomenorrhoea were reported 19.4% and 34%, respectively; the authors reported that there were no major complications in their study and the rates of hysterectomy, satisfaction and treatment failure were 10%, 78.6% and 10%, respectively (18). In this study the rates of amenorrhoea, hypomenorrhoea and total improvement of menorrhagia were reported 27.5%, 47.5% and 92.5%, respectively; and there were no hysterectomies within the follow-up period. In our study, the failure rate was 7.5%.

In one study in 2004, in which 220 patients underwent Cavaterm plus system and were followed for one year, amenorrhoea and hypomenorrhoea rates were reported 48% and 27%, respectively, and dysmenorrhoea was reported to decrease in 72% of patients (19). In our study, the improvement rate of dysmenorrhoea was 69.5%.

In one study performed in 2010, intrauterine high pressure, increased age, volume of intrauterine balloon lower than 10 cc and shorter uterine depth were reported as successful treatment factors (20). In this study, age less than 40 years, high endometrial thickness, coagulation factors disorders, high volume of balloon and intrauterine low pressure were associated with an increased risk of treatment failure. In the study

Table 2. Effects of Treatment with Cavaterm After 1 Year (n = 40)

| Variable | Before Treatment | After Treatment | P Value |
|--|------------------|-----------------|---------|
| Days of bleeding per month | 14.95 ± 6.7 | 3.42 ± 3.04 | 0.001 |
| Used pads per cycle | 82 (10-200) | 11.6 (2-20) | 0.01 |
| Intervals of bleeding, day | 16.25 ± 5.50 | 21.30 ± 11.10 | 0.01 |
| Dysmenorrhoea, No. (%) | 13 (32.5) | 4 (10.0) | < 0.05 |
| Clot discharge | 33 (82.0) | 0 (0.0) | 0.001 |
| Menstrual outcomes | - | - | - |
| Amenorrhoea, No. (%) | 0 (0.0) | 11 (27.5) | 0.001 |
| Hypomenorrhoea, No. (%) | 0 (0.0) | 19 (47.5) | 0.001 |
| Eumenorrhoea, No. (%) | 0 (0.0) | 7 (17.5) | 0.012 |
| Menorrhagia, No. (%) | 40 (100) | 3 (7.5) | 0.001 |
| Rate of satisfaction with treatment | | | |
| High satisfied | - | 28 (70.0) | - |
| Moderate satisfied | - | 6 (15.0) | - |
| Relatively satisfied | - | 6 (15.0) | - |

Table 3. Comparison Patients Characteristics in Both, Amenorrhoea and Treatment Failure Group^a

| Patients Characteristics | Amenorrhoea | Treatment Failure |
|------------------------------------|-------------|-------------------|
| Mean Age, y | 46.6 2.79 | 38.3 5.50 |
| Endometrial thickness, mm | 9.12 3.79 | 16.53 6.50 |
| Volume of balloon, cc | 9.40 3.71 | 24 5.29 |
| Intrauterine pressure, mmHg | 225.4 4.44 | 201 17 |

^a Data are presented as Mean SD.

Table 4. Surgical Procedure Variables

| Items | Value |
|--|---------------|
| General anesthesia, No. (%) | 30 (75.0) |
| Paracervical anesthesia, No. (%) | 10 (25.0) |
| Duration of procedure, mean ± SD, min | 30 ± 8.5 |
| TBA balloon fluid volume, mean ± SD, mL | 15.85 ± 14.29 |
| TBA balloon pressure, mean ± SD, mmHg | 225 ± 12.35 |
| TBA balloon temperature, mean ± SD, °C | 75.2 ± 2.71 |
| Pain with ablation (VAS) | - |
| Mild | 4 (10.0) |
| Moderate | 15 (37.50) |
| Severe | 21 (52.5) |

efficacy of bipolar radiofrequency and endometrial ablation (RFA) was compared with thermal balloon ablation (TBA) and the failure rate was 9.3% for RFA and 11.9% for TBA; age, parity, pretreatment dysmenorrhea, and tubal ligation were defined as treatment failure factors (2). Endometrial ablation has been reported as a safe and effective procedure with an overall complication rate of 1.25%-4.58% (5, 21). There was no major complication in our study and 85.0% of women who underwent Cavaterm treatment were satisfied. In previous published data a satisfactory rate of 90-96% has been reported (22, 23).

The results of this study indicated that the Cavaterm™ plus system is safe and effective and can be an excellent alternative to hysterectomy for the treatment of menorrhagia secondary to DUB.

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Authors' Contribution

Study concept and design: Dr. Zahra Asgari, Interpretation of data: Dr. Farideh Hoseinzadeh, Drafting of the manuscript: Dr. Farideh Hoseinzadeh and Dr. Aazam Hoseinzadeh, Doing the surgery and follow up: Dr. Zahra Asgari and Dr. Leili Hafizi. Critical revision of the manuscript for important intellectual content: Dr. Leili Hafizi.

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