

Modified Thermal Balloon Endometrial Ablation for Treatment of Heavy Menstrual Bleeding

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Abstract

Objectives: The objective of this study was to determine the efficacy of modified thermal balloon ablation using Foley's catheter in the treatment of heavy menstrual bleeding (HMB).

Materials and Methods: Twelve patients with HMB aged 35–55 years underwent modified thermal balloon ablation using Foley's catheter. Patients were selected after complete clinical evaluation and investigations. The procedure was undertaken in the operation theater under general anesthesia/intravenous sedation. Three cycles of modified thermal balloon ablation using Foley's catheter were performed to ablate the endometrium. The time given to each cycle was 7 min. All the cycles were performed in the same setting. The main outcome measures that were studied were reduction in the menstrual flow, the need for further treatment, and relief of dysmenorrhea if present. Outcome measure regarding reduction in menstrual flow was statistically analyzed using Fisher's exact test. Statistical significance was determined at a level of $P < 0.05$.

Results: Eighty-two percent of patients experienced a reasonable reduction in menstrual blood flow at 3-month follow-up. Eighteen percent observed no change in bleeding pattern and needed further treatment after failure of the procedure. Forty-two percent of patients complained of minor side effects such as cramp lower abdominal pain and fever. Rupture of balloon during the procedure occurred in only one case (8%).

Conclusion: Modified thermal balloon ablation with Foley's catheter can be a promising management of HMB in resource-poor settings. It is a cost-effective alternative to the original endometrial ablation techniques.

Keywords: Endometrial ablation, heavy menstrual bleeding, thermal balloon ablation

INTRODUCTION

Heavy menstrual bleeding (HMB) is the most common type of menstrual bleeding disorder.^[1] It affects 10%–30% of reproductive-aged women and up to 50% of perimenopausal women.^[2,3] HMB should be recognized as having a major impact on a woman's quality of life.^[4] Furthermore, the impact on health-care resources is considerable, with 5% of women aged between 30 and 49 consulting their general practitioner for excessive menstrual bleeding in a year and accounting for around 12% of gynecology referrals.^[1,3]

In most cases, medical therapy is effective in managing abnormal bleeding,^[5] while surgical treatment is normally

restricted to women with whom medical treatments have failed.^[4,5] Regarding surgical treatment, until recently, hysterectomy has been the standard treatment for women with menorrhagia unresponsive to medical treatment. However, since the 1980s, minimally invasive procedures to destroy the endometrium (endometrial ablation) have been developed as an efficient and cost-effective alternative to hysterectomy.^[5,6] Traditionally, endometrial ablation has been offered after failed medical therapy in women with a normal uterine cavity, negative laboratory workup results, and completed childbearing.^[7] The overall evidence now suggests that endometrial ablation is an appropriate first-line surgical approach where medical methods have failed or deemed inappropriate [A].^[3]

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Endometrial ablation was originally described with either the Nd: YAG laser or the hysteroscopic resectoscope by using either a wire loop or a rollerball technique (first-generation techniques).^[2,8,9] These techniques require advanced hysteroscopic skills, distention media with its associated risks, and usually general anesthesia.^[9,10] Second-generation, global ablation techniques allow endometrial ablation to be performed easily and quickly. These new global ablation methods also require only basic if any hysteroscopic skills.^[7,11] These include impedance-controlled endometrial ablation (NovaSure™), thermal uterine balloon therapy (ThermaChoice™), and microwave ablation (Microsulis™).^[1,2,4]

Although success rates of endometrial ablation for treatment of heavy bleeding are not as high as with hysterectomy (as a general rule, of all women undergoing endometrial ablation with a second-generation technique, 40% will become amenorrheic, 40% will have markedly reduced menstrual loss, and 20% will have no difference in their bleeding), patient satisfaction rates are surprisingly comparable.^[1,2] Moreover, resection and ablation procedures have significantly lower complication rates and more advantages when compared with hysterectomy.^[9] Most endometrial ablations can be accomplished in <30 min as opposed to the standard 1.5 h needed to perform a hysterectomy. Commonly, endometrial ablation can be performed with local anesthesia–paracervical block ± IV sedation. Typically, a patient that has undergone endometrial ablation can return to her regular activities the next day. Patients who meet the appropriate criteria for endometrial ablation should be offered this less invasive alternative for treatment of their symptoms.^[11]

All of the ablative techniques rely on destroying the endometrium's regenerative capacity, which requires a depth of destruction of at least 4 mm.^[1,6] However, the persistence or regeneration of the endometrium is possible. Therefore, premenopausal women should be counseled before surgery about the need for adequate postoperative contraception and to avoid subsequent pregnancy.^[4,7,8]

Preoperative preparations to endometrial ablation include a transvaginal scan, an endometrial biopsy in the last 6 months, and cervical smears.^[10,11]

Contraindications to second-generation techniques include abnormal Pap's smear or endometrial pathology, large or distorted endometrial cavity, previous uterine surgery or trauma resulting in a uterine wall thickness of <10 mm at any point, previous classical cesarean section or transmural myomectomy, current active pelvic inflammatory disease, and desire for future pregnancy.^[8,10,11]

Postoperatively, patients may complain of transient cramp abdominal pain and a watery brown discharge for between 3 and 4 weeks. Less commonly, the infection may occur.

Prophylactic antibiotic therapy is often used to reduce the risk of endometritis. Rarely, uterine perforation may occur (but very rare with second-generation techniques).^[2,4]

All of these methods are effective but expensive technologies. The original device (ThermaChoice) combines heat and pressure within the uterine cavity to destroy the endometrium and part of the myometrium. The device consists of a generator and a silicone balloon catheter. The silicone balloon conforms to the uterine cavity at relatively low pressures, but it is optimized to operate at an intrauterine pressure of approximately 170 mmHg. The balloon is filled with 5% dextrose in water by a syringe, which is heated up to 87°C and is maintained in the cavity for 8 min.^[9,12,13] Thermal balloon ablation using Foley's catheter can be a promising alternative to original thermal balloon ablation device in reducing the cost even further. The use of Foley's catheter for this purpose has not been fully evaluated, and the existing data are limited to draw conclusions reliably. The aim of this study was to assess the efficacy and safety of modified Foley's catheter to achieve endometrial ablation in the treatment of HMB in a low-resource setting.

MATERIALS AND METHODS

This was a prospective case series study performed in the period between October 2013 and January 2020. This long period was because of the political situation of the city (Mosul) during some part of the study's period. The study protocol was approved by the Local Research Ethics Committees of College of Medicine/Mosul University (approval number: UOM/COM/ MREC/ 20-21(13)). This study was carried out in compliance with the principles of Helsinki Declaration. The study was conducted at Al Batool Teaching Hospital and Al Khansaa Teaching Hospital which are tertiary obstetric and gynecological hospitals in Mosul/Iraq. Patients with HMB were recruited from the outpatient department clinic or referred by the gynecologist from a private clinic. All patients were thoroughly evaluated by taking targeted history and examination. Pelvic ultrasound was performed in order to rule out submucous fibroids or polypoidal lesions of the endometrium. Endometrial sampling was taken to exclude endometrial pathology (endometrial hyperplasia or carcinoma), and Pap's smear was taken or reviewed.

All eligible patients (had completed their family, had normal endometrial pathology and a regular uterine cavity, and had failed or were unwilling to continue with medical therapy) attended a consultation by the gynecologist. Patients were informed about the possible risks and benefit of the treatment using modified Foley's catheter balloon endometrial ablation, and written consent was obtained from each patient.

Twelve patients with HMB between 35 and 55 years of age were enrolled in the study.

The procedure was accomplished in operation theater with a patient in lithotomy position and under general anesthesia or intravenous sedation. Following full aseptic recommendations, the size, shape, and position of the uterus were determined by pelvic examination and uterine sound. A silicone-treated Foley's balloon catheter of 18 French with a balloon capacity of 30–45 mm was used in the procedure. The tip of catheter was cut to easily occupy the uterine cavity, and the balloon catheter was tested for any leaks before starting the procedure. The cervix was held with vulsellum and catheter was introduced in the cavity using sponge holding forceps till resistance was reached. Vaginal packing was used to protect the vagina from any possible thermal injury in case of inadvertent intraoperative rupture of the balloon. The balloon was inflated with 15–30 ml of boiled saline till resistance was felt. The balloon was left in place for 7 min and then deflated as the temperature of saline dropped. Three cycles of similar duration were repeated. At the end of the procedure, the balloon was deflated and removed. The procedure was completed in about 30 min.

Postoperatively, patients received routine antibiotic prophylaxis and analgesia if required. Patients were allowed to go home the same or the next day.

Adverse events were recorded for each patient intraoperatively, during the hospital stay, and during follow-up visits.

The women were reviewed at first follow-up at 1 week for assessment of short-term complications including abdominal pain and signs of endometritis. Then, they were reviewed at 1 and 3 months after the procedure to assess patterns of menstrual flow (heavy, normal, and light). We depended on the patient's own perception of blood loss to assess the response, as methods used to quantify menstrual blood loss are both inaccurate and impractical.^[1] Dysmenorrhea and need for further therapy were also assessed. Success rate was defined as the percentage of patients who achieved eumenorrhea (normal flow), hypomenorrhea (less than normal), or amenorrhea, while failed procedure was defined as persistent menorrhagia and need for further treatment.

Variables as patient's age, body mass index, parity, menopausal status, duration of bleeding, the presence of dysmenorrhea, uterine position, depth of the uterine cavity, endometrial thickness as well as intra- and postoperative complications were taken into consideration, and their contribution percentage was calculated. Outcome of the procedure represented by the extent of menstrual loss (heavy, normal, or light) following the procedure was analyzed using

Fisher's exact test. Statistical significance was determined at a level of $P < 0.05$.

RESULTS

During the study period, 12 patients underwent modified thermal balloon endometrial ablation. The age of the patients ranged between 35 and 55 years of age. All the patients were available for the follow-up. The study's results are represented in Tables 1-4. The outcome of the procedure is represented in Table 4. Nine patients (82%) experienced a significant reduction in menstrual bleeding at 3 months as perceived by the patient to be light or normal loss. No patients experienced amenorrhea at the completion of 3-month follow-up. Two patients (18%) had no change in the bleeding patterns. Dysmenorrhea was relieved in two patients out of three (66.66%).

DISCUSSION

Endometrial thermal ablation is considered one of the easiest, safest, and most promising alternatives to the conventional management of HMB in selected cases.^[14] Most of the thermal balloon ablation devices in use are effective, safe, and easily used, but they had the disadvantages of being expensive and unavailable in many centers in Iraq. Hence, the use of Foley's catheter balloon in this study is considered a cheap alternative to these devices, although its disadvantage is the lack of proper setting and monitoring of temperature and pressure. Being one of the few studies done in this manner will add knowledge to this topic in the field of gynecology.

The patient recruited for the study had a mean age of 46.75 years, while the mean age of similar studies done by Naz *et al.* is 41 years,^[15] and Helal *et al.* 43.6 years.^[16]

Table 1: Personal, obstetric, and gynecological parameters of the study sample patients

Parameters	Numbers (n=12), n (%)
Age (years), mean±SD	46.75±5.01
BMI (kg/m ²), mean±SD	30.03±3.08
Parity	
Nulliparous (0)	0
Multiparous (1-4)	3 (25.00)
Grand multiparous (≥5)	0 (75.00)
Menopausal status	
Premenopause	12 (100.00)
Postmenopause	0 (0.00)
Duration of bleeding (years)	
<1	2 (16.67)
1-4	8 (66.67)
≥5	2 (16.67)
Dysmenorrhea	
Yes	3 (25.00)
No	9 (75.00)

BMI: Body mass index, SD: Standard deviation

Table 2: Preoperative ultrasound findings and operative findings

US findings	Numbers (n=12), n (%)
Endometrial thickness (mm)	
<8	3 (25.00)
≥8	9 (75.00)
Others US findings	
Yes	1 (8.33)
No	11 (91.66)
Operative findings	
Uterus size (weeks)	
<6	0
6-9	7 (58.33)
10-12	5 (41.66)
Position of the uterus	
Anteverted	12 (100.00)
Retroverted	0

US: Ultrasound

Table 3: Intraoperative and short-term postoperative complications

Intraoperative complications	Numbers (n=12), n (%)
Rupture of balloon	
Yes	1 (8.33)
No	11 (91.66)
Short-term postoperative complications	
Vaginal discharge	
Serosanguinous	9 (75.00)
Purulent	0
Cramp lower abdominal pain	3 (25.00)
Fever	2 (16.67)

Table 4: Outcome measure

Outcome	First month (n=12), n (%)	Third month (n=11), n (%)	P*
Menstrual loss			
Light	1 (8.33)	5 (45.45)	
Normal	9 (75)	4 (36.36)	0.048
Heavy	2 (16.66)	2 (18.18)	0.500
Relief of dysmenorrhea (n=3)			
Yes	2 (66.66)	2 (66.66)	
No	1 (33.33)	1 (33.33)	
Need for further treatment			
Yes	1 (8.33)	2 (18.18)	
No	11 (91.66)	9 (81.82)	0.590

*Fisher's exact test was applied

The main outcome measures that were observed during this study were a reduction in the blood flow following the modified thermal balloon ablation. Those who achieved normal menstrual loss following the procedure were 75% at the 1st month and 36.36% at 3 months, and this result

was statistically significant with $P = 0.048$. The reported success rate for thermal balloon ablation is 80%–97%.^[17,18] The success rate of the procedure in our study, represented by those achieving normal or light menstrual loss at 3-month follow-up, was 81.81%. This is similar to that reported by Azza A. Abd El Hameed^[19] and Neuwirth *et al.*,^[20] while Helal *et al.* reported that 89.1% of their cases were satisfied with the procedure as indicated by reduction in days of menstrual flow per cycle.^[16] Another study reported that after long-term follow-up (5 years), 76% of women were satisfied with the procedure of thermal balloon endometrial ablation, which can be considered a good result.^[21] For our study, these exact long-term data were not available. However, although the follow-up period was stated in the methodology as 3 months, the authors were in contact with most patients for longer period, and most of the patients were satisfied with the procedure and do not require second intervention. This longer period of follow-up was not stated in the methodology and was not included in the statistical analysis of the study because it is different between different patients.

Amso *et al.* reported that 86% of women undergoing uterine endometrial thermal balloon therapy did not require hysterectomy and 75% did not have any further surgery during a follow-up period of 4–6 years.^[22]

Furthermore, Wortman highlighted in his review that late-onset endometrial ablation failures (LOEAFs) are the most common complication of endometrial ablation, and 25% of women who undergo endometrial ablation will require hysterectomy within 5 years. Reducing the incidence of LOEAFs requires improved patient selection for endometrial ablation.^[23]

Two patients (16.66%) had no change in the amount of bleeding at 1-month follow-up, and one of them underwent hysterectomy. The histopathological examination of her hysterectomy specimen reveals simple endometrial hyperplasia, while her initial endometrial sample taken by dilatation and curettage procedure was falsely interpreted as changes consistent with hormonal imbalance. Eighteen percent ($n = 2$) still had no change in the bleeding patterns at 3-month follow-up and prescribed second-line hormonal medical treatment. One of them was poorly compliant with the medical treatment to control her coexistent medical comorbidity (hypertension and thyrotoxicosis) and was advised to do that in a better way.

Rupture of the balloon during the procedure unfortunately occurred in one case; this is similar to what is recorded by Naz *et al.* in their study.^[15] The use of vaginal pack during the procedure eliminates the possible danger from hot saline on vaginal mucosa. Furthermore, the small amount of fluid (15–30 ml) used during each cycle of the procedure will eliminate such possible risk to the handling personnel (doctor

and nurse), as most of it will be soaked within the vaginal pack. This complication responds well to conservative treatment, and no long-term effect was observed during the follow-up of the patient.

One limitation of our study is the small number of the patient included, although this may indicate the careful selection of the patients for the procedure; the compliance of the patient to participate in the study also contributes. Another limitation is the absence of evidence for possible long-term complications or failure of the procedure due to lack of documented long-term follow-up for all patients. We hope that a similar study is to be done next time on a larger number of patients. Also, a follow-up is to be continued for a longer period, so a more robust outcome can be concluded, including possible late complications of the procedure.

CONCLUSION

Modified thermal balloon endometrial ablation with Foley's catheter is a safe, cheap, simple, and effective procedure and can be used as an alternative to hysterectomy to treat HMB in selected cases. It is a cost-effective alternative to the original endometrial ablation devices in a resource-poor setting. Reassuring results, represented by good success rate and good safety profile with the absence of major complications, dictates that the procedure can be adopted with reasonable confidence in future.

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Conflicts of interest

There are no conflicts of interest.

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