



ORIGINAL ARTICLE

## Endometrium Ablation using a Foley catheter with a cost-effective technique in a hospital environment.

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**ABSTRACT... Objective:** To evaluate the effectiveness of employing Foley's catheter and modified thermal balloon ablation to treat heavy menstrual bleeding (HMB). **Study Design:** Prospective Interventional Randomized Control study. **Setting:** Departments of Gynecological of Three Semi Government Hospitals of the City. **Period:** January 2021 to September 2022. **Material & Methods:** In the study, 12 patients between the ages of 42 and 50 who complained of menorrhagia and who had not responded to treatment for at least 6 months were recruited. Pre-ablation endometrial curettage was performed on each patient. A 30-50 ml latex covered Foley's Catheter was evaluated after being introduced into uterine cavity, inflated as much as the cavity would allow under moderate pressure, and changed every two minutes with fresh boiling saline for eight minutes. Following that, hysteroscopic examination and a 6-month follow-up were performed to look for endometrial scarring. **Results:** Significantly shorter hospital stays, shorter recovery times following surgery, and quicker return to normal daily and sexual activities. Regarding problems, menstrual alterations, amenorrhea rate, and failure rate during the course of follow-up, there was no discernible difference between patients. This method has a success rate of almost 88%. **Conclusion:** In situations with limited resources, improved thermal balloon ablation with a Foley's catheter can be a potential treatment for HMB. It is a more affordable option than the preliminary endometrial ablation approaches.

**Key words:** Amenorrhea, Endometrial Ablation, Foley's Catheter, Heavy Menstrual Bleeding, Menorrhagia, Thermal Balloon Ablation.

### INTRODUCTION

Menorrhagia is described informally as an abnormally large or protracted loss of blood during regular periods or technically as bleedings during menstruations of greater than 80 ml per cycle.<sup>1</sup> It is a frequent gynecological condition in women or reproductive age, with a global frequency of 19% and up to 30% of women report excessive menstrual bleeding at some point in their lives.<sup>2</sup> Its cause is unknown in the absence of an organic disease and is regarded as dysfunctional hemorrhage.

Endometrial ablation technique such as laser photovaporisation, rollerball ablation, and transcervical resection of the endometrium have been presented to retain the uterus and reduce chronic health conditions. These are known as

first generation models, and they are universally recognized as the benchmark in endometrial ablation.<sup>3</sup> All of these necessitate microscopic examination via hysterectomy. As a result, several non-hysteroscopic techniques, referred to as second generation models, have recently become available with the goal of making procedure simpler, faster, and safer.<sup>4</sup> They also do not require general anesthesia and can be conducted in an outpatient environment. Cryoablation, hot saline solution irrigation, diode laser hyperthermy, and microwave ablation are among them.<sup>5</sup> However, few studies have been carried out to evaluate their effectiveness and safety.

All ablative treatments rely on eliminating the endometrium's regenerations potential, which necessitates a 4mm depth of ablation.<sup>6</sup> The

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endometrium, on the other hand, has the potential to endure or regenerate. Reproductive age group women should therefore be educated before to surgery about the importance of appropriate post-surgical contraception and avoiding future pregnancy. Thermal balloon endometrial ablation (TBEA) seems to be safe and secure compared to all others embolization methods and as efficacious as hysteroscopic endometrial ablation for treating menorrhagia; it is a simple, convenient, and almost noninvasive procedure with fewer intraoperative or postoperative negative implications on the patient; and it can be done under iv fluids general anesthesia with paracervical block.<sup>7</sup>

Singer and Neuwirth utilized hot dextrose 5% in a silicon balloon in 1944 and achieved an 83% rate of success.<sup>8</sup> Since then, numerous devices have been used, such as thermal choice system, consist of a disposable silicon foley catheter which is connected to a control unit that reveals and control temperature, pressure and duration.<sup>9</sup>

Kishor et al. conducted preliminary research employing a latex silicone wrapped Foley's catheter balloon and heating saline as an endometrial ablator rather than pricey instruments, and results are highly positive in terms of technology's safety and efficacy.<sup>10</sup>

The articles' goal is to analyze the effectiveness and safety of endometrial thermal ablation utilizing a simple approach using a Foley's catheter balloon to cure instances with persistent menorrhagia, as well as to make comparisons both with and without pre-ablation uterine hysterectomy.

## **MATERIAL & METHODS**

Between January 2021 and September 2022, this prospective, controlled study was conducted in three distinct semi-government hospitals' Obstetrics and gynecology department and outpatient gynecological clinic after approval from institution ethical committee (DME/12). Twelve patients between the ages of 40 and 50 who complained of menorrhagia and who had not responded to medication or dilation and curettage for at least six months are included in

the study.

The selection parameters were used to choose the women:

Patients with uterine cavities larger than 10 cm, endometrial histological patterns with lesion obtained by endometrial curetting, related endometrial histology, such as polyps, adenomyosis, leiomyomas, malformations and cancer of the uterine cavity, or other pelvic pathology, such as prolapse, ovarian mass, or endometriosis, as well as known as histories of coagulopathy or bleeding disorders, were not included in study.

### **Inclusion Criteria**

Inclusion criteria included the following: (1) perimenopausal women; (2) menstrual periods caused by abnormal flow in women over 40; (3) heavy periods caused by autonomic dysfunction; (4) tiny numerous intracellular fibroids; (5) families completed and no intention for more children; and (6) ladies who do not want serious surgery or uterine ablation.

### **Exclusion Criteria**

Exclusion criteria includes (1) Endometritis, (2) big intramural or submucosal fibroids, endometrial polyps, (3) women of reproductive age or who wish to have more children, (4) and women who seek permanent treatment like a hysterectomy for menorrhagia are all signs of histology that are not benign.

All participants were given the opportunity to provide written consent after being notified of the advantages and potential dangers associated with the management technique. To rule out clinically observable organic examination. Transvaginal ultrasonography (TVUS) is used to detect endometrial thickness, evaluate uterine size, and shape, and rule out organic abnormalities. Laboratory tests (including an ECG, a full blood count, blood sugar, and a blood clotting profile to check for broad hemorrhagic diseases) were also performed.

### Foley's catheter endometrial thermal balloon ablation technique

Patients were contacted the very next week after the period. A consent was obtained. Six hours before the surgery, two tablets of misoprostol were inserted vaginally. The treatment was performed under short-interval general anesthesia with a supraglottic airway device. The Foley catheter was 20 gauge. It has its pre-bulb teat severed. Duct tape was applied to the arm of the object where the bulb is inflated to increase pressure. Water was added to a coffee mug using a little electric rod (used for heating) and heated until it was boiling. The patient had lithotomy and underwent the same asepsis preparations as a vaginal surgery.

Endometrial curettage was performed after the Sims speculum and vulsellum forceps was inserted. The cervix was dilated before the prepared Foley Catheter was placed. The misoprostol tablet placed in the vagina six hours before the treatment helped soften the cervix and facilitate the dilation.

To keep the water temperature from dropping below 100 degrees Celsius, it was continuously brought to a boil. A 20cc disposable syringe was then filled with the boiling water, and the Foley Catheter bulb was inflated. In this manner, 30 cc of hot water were added to the bulb. After being kept in the bulb for two minutes, the water was withdrawn, and the Foley bulb was promptly filled with the same volume of continually heating water. The bulb was maintained full and under pressure approximately two minutes before shrinking, same as before, subsequently the same process was carried out a third time. In total, 3 inflations were completed in n8 minutes. The surgery resulted in an average uterine bleeding volume of 50cc. Mefenmic acid was used to treat post-procedure pain, and an oral precautionary antimicrobial was given for 05 days.

### Follow-up

The patients/cases were monitored for pain/bleeding for 24 hours. For two weeks, four months, six months, and one year, they were monitored. Monitoring of the patient's heart rate, blood

pressure, vaginal bleeding, and abdominal pain was done with a focus on any clinical indications of fluid overload. Patients were instructed to come to the hospital 2 weeks later for follow up of the postoperative adverse effects. At each meeting to examine the menstrual cycle, a uniform questionnaire was employed. The following scale was used to ask patients to rate alterations in the amount of blood loss: better (amenorrhea, hypomenorrhea, and eumenorrhea), worst, or unaffected.

### Statistical Analysis

Outcomes were entered, tabulated, and given to statistical analysis using SPSS. Frequently tables, Fisher's exact test, and Chi-squared test were used to analyze the data. For data that was perfectly correlated, the results were reported as mean values, and for flawed statistics, as average values. A 0.05 average p-value was deemed relevant.

### RESULTS

A total of 12 patients had endometrial ablation as part of the study. Patients who meet the inclusion criteria were admitted, while those who did not were turned away based on the exclusion criteria. Between cases with and without pre-ablation endometrial curettage, no discernible variations in the demographic and clinical traits were found.

Parameters	Numbers (n=12), n (%)
Age (years), mean $\pm$ SD	46.75 $\pm$ 5.01
BMI (kg/m <sup>2</sup> ), mean $\pm$ SD	30.03 $\pm$ 3.08
Parity	
Nulliparous (0)	0
Multiparous (1-4)	3 (25.00)
Grand multiparous ( $\geq$ 5)	0 (75.00)
Menopausal state	
Pre menopause	12 (100.00)
Post menopause	0 (0.00)
Duration of Bleeding (years)	
< 1	2 (16.67)
1-4	8 (66.67)
$\geq$ 5	2 (16.67)
Dysmenorrhea	
Yes	3 (25.00)
No	9 (75.00)

**Table-I. Personal, obstetric, and gynecological parameters of the study sample**

Clinical Findings	Numbers
Endometrial thickness (mm)	
<8	3 (25.00)
≥8	9 (75.00)
Other 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

**Table-II. Preoperative ultrasound findings and operative findings**

Intraoperative Complications	Numbers (n=12), n (1%)
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 abdomen pain	3 (25.00)
Fever	2 (16.67)

**Table-III. Intraoperative and short-term postoperative complications**

For the follow-up after 2 weeks, every patient was able to attend. For 3-5 days, every patient had a consistent and a pain-free vaginal discharge. Some people had blood-mixed discharge for about a week. Ten out of twelve patients experienced total amenorrhea after four months for about a week. Ten out of twelve patients experienced total amenorrhea after four months, with vaginal discharge lasting no longer than 10 to 15 days. It was suggested to one of the two patients that she undergo ablation, and she agreed the other person received some prescription painkillers. All of the patients had entirely stopped menstruating after six months. After a year, everyone but the patient who underwent a second endometrial ablation procedure did not return.

Outcome	Two Weeks	Four Months	P-Value
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

**Table-IV. Outcome measure**

## DISCUSSION

In this review, a variety of endometrial ablation or resection procedures for women who experience heavy monthly bleeding have been evaluated for their effectiveness, satisfaction, and safety. In certain situations, endometrial thermal ablation is regarded as one of the simplest, safest, and most promising alternatives to the traditional care of HMB.<sup>11</sup> Comparing first-generation with second-generation methods generally. First-generation ablation procedures were more likely to cause intraoperative and postoperative complications including oedema, cervical gashes, and haematometra: second-generation methods were more likely to cause issues like nausea and vomiting, uterine cramps, and pain. No conclusive evidence demonstrates that first- and second-generation procedures have different perforation rates.

In published research, concerns that these “blind” procedures can cause bowel damage from uterine perforation that is not identified did not seem to be confirmed. However, several anecdotal cases show that such occurrences are possible, and extreme caution must be exercised to reduce the likelihood of such potentially dangerous complications.

When compared to hydrothermal ablation, bipolar ablation boosted amenorrhea and satisfaction rates as well. Bipolar ablation took less time to complete than hydrothermal ablation, and women were less likely to need additional surgery at a later follow-up. When compared to balloon,

amenorrhea rates seemed to be higher with the microwave, but trials found no differences in PBAC scores or patient satisfaction. Microwave ablation also cut down on operation time. Instead of using objective measurements of blood loss, the diagnosis of HMB is made based on subjective symptoms and how it affects quality of life.<sup>12</sup> When specifically questioned, however, a large number of women with heavy menstrual bleeding (HMB) who have been referred from primary to specialized care do not specifically state that they have HMB, indicating a propensity for a general description of menstrual characteristics to be reframed as excessive bleeding at referral and during management.<sup>13</sup> This will probably lead to women obtaining care that is inappropriate and will affect how effectively HMB is actually and perceived to be treated.

It would be unusual in regular practice to recommend endometrial resection or ablation without trying any medicinal therapies, according to current clinical approaches to HMB, which advocate offering medical therapy first. In fact, levonorgestrel-releasing intrauterine systems (Mirena, Schering) are just as successful as thermal balloon ablation<sup>14,15</sup>, rollerball endometrial ablation,<sup>16</sup> and endometrial ablation in reducing menstrual blood loss (MBL) by 94% at 3 months.<sup>17</sup> After medical treatments, surgical methods to resect or destroy the endometrium are typically used. On women whose medical care of HMB had failed, fourteen had been published.

Collection of information, duplicate and impartial study selection, quality rating of research, and a thorough search for pertinent studies have all worked together to reduce the possibility of bias in the review process.

Thermal balloon ablation indicated a success rate of (80-97%)<sup>18</sup>, and first-generation procedures reported successful menstruation outcomes in 61.5-90%.<sup>19</sup> Another study found that 76% of women were happy with the TBEA operation after a lengthy follow-up of five years, which is commendable outcome.<sup>20</sup> The results of this study show an 83.3% satisfaction rate, 179.2% improvement in monthly bleeding and

a 75% diagnosis of endometrial scarring by hysteroscopic examination.

Along with patient satisfaction and an improvement in menstrual outcomes, instances with pre-ablation curettage showed a considerably greater prevalence of hysteroscopically detected endometrial scarring than cases without curettage. We believe that curettage causes the endometrium to shrink, exposing the basal layer, the site of regeneration, to increased thermal stress. Additionally, no cancers were identified in these investigations.

The sole benefit for ablation without curettage that has been documented in this study is that it takes less time to complete the procedure than ablation with curettage, but there have been no discernible changes in intraoperative or retrospective problems.

The number of patients included in our study is one of its limitations, while this may indicate that the patients who underwent the surgery were carefully chosen, and patient compliance with study participation also plays a role. Due to the lack of recorded long-term follow-up for all patients, another drawback is the lack of evidence for potential long-term problems or operation failure. We anticipate that a similar study will be conducted on more people in the future. A longer time of follow-up is also required in order to draw a more elaborative conclusion about the procedure's potential late consequences.

Future research should evaluate different second-generation techniques to identify the true benefits of one approach over the others. It is also important to compare third generation against second-generation approaches to determine which is superior.

## CONCLUSION

In some instances, the modified thermal balloon endometrial ablation with the Foley's catheter can be used to treat HMB instead of hysterectomy because it is a straightforward, inexpensive safe, and effective operation. In a situation with limited resources, it is a more affordable substitute for





the original endometrial ablation devices. Results that are reassuring have excellent success rates, a decent safety profile, and the absence of serious complications indicate that the treatment can be used in the future with some degree of confidence.

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2	Syeda Uzma	Data collection, Introduction and part of discussion.	
3	Rabiya Akbar	Data collection, Discussion and methodology.	
4	Shazia Firdos Chohan	Data collection, Proof reading and conclusion writing, References.	
5	Talat Shaheen	Data collection, Proof reading and references.	