

Modified Thermal Balloon Ablation in Heavy Menstrual Bleeding

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Submitted for Publication: 07-01-2021
Accepted for Publication 16-04-2022

How to Cite: Khan S, Javed N, Ara S, Khan A, Ahmad B, Haider M. Modified Thermal Balloon Ablation in Heavy Menstrual Bleeding. APMC 2023;17(2):262-265. DOI: 10.29054/APMC/2023.xxxx

ABSTRACT

Background: Heavy menstrual bleeding is common problem of reproductive age women. In 1994, new method thermal balloon ablation was introduced to treat women suffering from this devastating condition. **Objective:** To share our experience about Minimal invasive surgical procedure like modified thermal balloon ablation using Foley's catheter to destroy uterine endometrium in the management of heavy menstrual bleeding. **Study Design:** Descriptive cross-sectional study. **Settings:** Department of Gynecology & Obstetrics, Allied Hospital affiliated with Faisalabad Medical University, Faisalabad Pakistan. **Duration:** Two years from 1st Jan 2019 to 31st Dec 2020. **Methods:** Study on 77 women who were treated with modified thermal balloon ablation. Patient satisfaction was assessed by reduction in menstrual flow, duration of amenorrhea, need for hysterectomy after procedure failure and complications observed if any. **Results:** Overall satisfaction was observed in 67 (87.92%) patients, amenorrhea was observed in 18 (23%) patients, hypomenorrhea was found in 44 (57%) patients, out of all these 5 (6.50%) patients underwent repeat endometrial ablation. While 05 (6.50%) patients ended up in hysterectomy and 5 (6.50%) were lost during follow up. **Conclusion:** Our work revealed that Modified thermal balloon ablation has good long-term efficacy and considered as an alternative in the treatment of heavy menstrual bleeding, especially for women who have risk factors for surgery and are over 40 years of age.

Keywords: Modified thermal balloon ablation (MTBA), Heavy menstrual bleeding (HMB), Foley's catheter, Uterine endometrium.

INTRODUCTION

Heavy menstrual bleeding (HMB) is defined as blood loss of more than 80 ml per cycle¹. The etiology of HMB may be hormonal or structural (mnemonic PALM COIEN) including polyps, adenomyosis, fibroids, endometrial/ cervical malignancy, coagulopathy, ovulatory disorder, iatrogenic, endometrial, intra uterine device, thyroid disease and pelvic inflammatory disease.²

Heavy menstrual bleeding affects one in five premenopausal women and significantly impair quality of life³. Medical therapy include use of prostaglandin inhibitors, anti-fibrinolytic agents, oral contraceptive pills, oral high dose progestogens and Levonorgestrel intra uterine system, which constitute first line treatment.⁴ Many women do not like continuous use of

hormones, and other medical treatments and opt for definitive treatment like hysterectomy.⁵

Minimal invasive surgery is gaining popularity day by day.⁶ These include roller ball, trans cervical resection of endometrium and laser ablation performed via hysteroscope. First generation techniques in view of their costs, prolonged operating times and safety aspects are now replaced by the second-generation non hysteroscopic techniques such as Novasure, Thermablate, Themachoice, Cavaterm and Microsulis. These all are blind techniques. Their advantages are shorter hospital stay, safe to perform and require less expertise^{3,7} but in countries like Pakistan where resources are not sufficient and cost does matter. We conducted our study with modified thermal balloon to ablate/destroy endometrium for the management of HMB.

METHODS

This was a descriptive study conducted at Department of Gynecology & Obstetrics, Allied Hospital affiliated with Faisalabad Medical University, Faisalabad Pakistan. The mean follow-up period was 2 years from 1st Jan 2019 to 31st Dec 2020. 77 patients were included by using WHO calculator by taking 20.8%⁸ outcome measure hypomenorrhea after MTBA, confidence level 95%, absolute precision 9.1%. Descriptive cross-sectional study was used to select patients.

In our study we include patients with indoor admission of HMB i.e., bleeding in terms of increased number of sanitary napkins used (5-7 per day) or having increased number of bleeding days (8-9 to 10-11 days per cycle). We also included patients having previous history of pelvic surgery, patients with co-morbidities and those who are not fit for surgery and don't wish for surgery.

We excluded all those patients having structural pathology such as sub mucosal or moderate to large intramural fibroids (4cm to > 20 weeks) and patients with suspicion of malignancy. We also excluded patients with endometrial pathology and those who wish for further conception.

Patient's satisfaction was judged by achievement of amenorrhea (no menstruation or just spotting), Hypomenorrhea assessed by decreased number of pads (i.e., < 3 pads/day) and reduction in number of days/cycle (<5-6 days) followed till 24 months.

77 patients after fulfilling inclusion & exclusion criteria and complete evaluation by history, examination, investigations, transvaginal ultrasonography & endometrial sampling with endo sampler to rule out any structural or endometrial pathology. Patient underwent MTBA under saddle block. Before introducing catheter, we performed curettage of endometrial cavity to decrease endometrial thickness to increase efficacy of procedure. We used silicon balloon catheter of 18FR with balloon capacity of 30-45ml. The tip of catheter was cut before introducing into uterine cavity. The balloon was inflated with 25-30ml of hot water having temperature of 85-90degree Celsius. Hot water was replaced after every 3 minutes, total three cycles of 3 minutes each were repeated. After completion of procedure balloon catheter was taken out & patient was discharged next day. We asked patients to have follow up visit after 3,6,12,18 & 24 months.

RESULTS

During 24 months study period 77 women underwent modified thermal balloon ablation. Mean age was 39.97 years.72.7% of patients had already tried medical treatment before this procedure as shown in table-1.

Table 1: Demographic features of patients in study (n=77)

Variables	Min.	Max.	Mean	Std. deviation
Age	35	45	39.7	3.004
BMI	24	35	27.2	2.700
Parity	3	8	5.01	1.419
Hb	8.5	11.0	9.56	.5130

There was a significant improvement in menstrual pattern from 8.01 ± 1.262 before treatment to 3.44 ± 0.87 after treatment as shown in table-2.

Table 2: Menstrual pattern before and after treatment

Variable	Before treatment	After treatment	P-value
Days/cycle	8.01 + 1.262	3.44 + 0.87	0.0001
Pads/day	8.31 + 1.17	3.49 + 0.995	0.0001

According to high-risk group 20 patients were diabetic (25.97%) followed by 17 patients with Hepatitis C with disturbed LFT'S 22.07% followed by 15patientswithhistory of risk of previous 2 or 3 C. section19.50% (table 3).

Table 3: High risk group of patients in study.

Co-morbidity	Frequency	Percentage
Diabetic Pts.	20	25.97%
Hypertensive Pts.	10	12.98%
Cardiac Pts.	05	06.50%
Morbidly obese	10	12.99%
Previous H/O of surgeries	15	19.50%
Hepatitis C+ Pts	17	22.07%
Total	77	100 %

We observed hypomenorrhea in 44 patients (57.15%) and amenorrhea in 18 (23.37%) patients. Out of 77 patients, 05 patients (6.5%) underwent repeat MTBA after 6 months. Satisfaction rate was 88% after 1 year. Only 05 (06.5%) patients had hysterectomy after 12 months (table 4).

Table 4: Outcome measures of patients after treatment with MTBA

Outcome	Frequency	Percentage
Hypomenorrhea	44	57.13%
Amenorrhea	18	23.37%
Repeat MTBA	05	06.5%
Total abdominal hysterectomy	05	06.5%
Patients lost during follow up	05	06.5%
Total	77	100%

DISCUSSION

Endometrial ablation is a safe and effective minimally invasive surgical procedure that has become a well-established alternative to major surgical treatment such as hysterectomy to treat abnormal uterine bleeding in selected cases.^{6,7} Patients treated with thermal balloon ablation experienced hypomenorrhea and amenorrhea in 80% of women and rate of satisfaction in our study was 88% which correlate with another study in which patients satisfaction rate was 88-98% at the end of 6 months.⁹ Contrary to our study by RA Busfield *et al*, showed improved quality of life by thermal balloon ablation but less effective than Levonorgestrel Intrauterine system.¹⁰ There are various studies which confirmed our results and proved the effectiveness of modified thermal balloon ablation in HMB.^{11,12,13,14}

We followed patients at 3, 6, 12, 18 and 24 months contrary to the study conducted in Egypt.^{15,16} They followed patients for 6 to 36 months. In our set up although majority of the patients do not understand the significance of follow up but we were successful because of effective counselling the proof was, that we lost only 5 patients during follow-up.

When patients after conservative procedure in study needed another conservative procedure, it is considered as treatment failure but we successfully repeated MTBA in 5 patients who otherwise would end up in abdominal hysterectomy as presented in a local study.¹⁷ In developing countries modified thermal balloon ablation is cost effective alternative to hysterectomy. We found higher rates of hysterectomy (22-24%) in a study by Kalampokas E *et al*¹⁸ which contradict our study where as the rate of hysterectomy is about 13% in a study by Smith PP *et al*.¹⁹

Considering complications of MTBA even in the hands of not much experienced are almost very few during

intraoperative or post-operative period. Further it reduces hospital stay that also is cost effective for teaching hospital in low socioeconomic country like ours.

CONCLUSION

In conclusion, modified thermal endometrial ablation is safe and cost-effective alternative to abdominal hysterectomy in high-risk cases in the treatment of abnormal uterine bleeding in low resource settings.

LIMITATIONS

Our study was conducted at single institution, it would be far better if we could possibly include data from other teaching hospitals of Punjab, Pakistan.

SUGGESTIONS / RECOMMENDATIONS

MTBA is treatment of choice for those women not willing or fit for surgery.

CONFLICT OF INTEREST / DISCLOSURE

All authors have no conflict of interest.

ACKNOWLEDGEMENTS

We would like to thanks Prof. Dr. Sarwat Ara for her dedication for this study.

REFERENCES

1. Magon N, Chauhan M, Goel P, Malik S, Kapur K, Kriplani A, et al. Levonorgestrel intrauterine system: current role in management of heavy menstrual bleeding. *J Midlife Health*. 2013;4:8-15.
2. Munro MG, Critchley HO, Broder MS, Fraser IS; FIGO Working Group on Menstrual Disorders. FIGO classification system (PALM-COEIN) for causes of abnormal uterine bleeding in nongravid women of reproductive age. *Int J Gynaecol Obstet*. 2011; 113:313
3. Lucky Saraswat, Kevin Cooper. Surgical management of heavy menstrual bleeding: part 1; TOC January 2017 Volume 19, Issue 1 Pages 37-45
4. Desai RM. Efficacy of levonorgestrel releasing intrauterine system for the treatment of menorrhagia due to benign uterine lesions in perimenopausal women. *J Midlife Health*. 2012; 3: 20-3.
5. MY Bongers. Hysteroscopy and heavy menstrual bleeding (to cover TCRC and second-generation endometrial ablation) *Obstetrics & Gynaecology*. 2015; 29(7): 930-39
6. Philippe L, Nicholas L, Ally M, Claude F, Paul M, George V. Endometrial Ablation in the Management of Abnormal Uterine Bleeding. *JOGC April 2015;37(4):362-376*.
7. Daniels JP, Middleton LJ, Champaneria R, Khan KS, Cooper K, Mol BW, et al. Second generation endometrial ablation techniques for heavy menstrual bleeding: network meta-analysis. *BMJ*. 2012; 344: e2564
8. Azza A. Abd El Hameed. Endometrial thermal balloon ablation by a simple technique using Foleys catheter with or without pre ablation endometrial curettage to treat cases with intractable menorrhagia *MEFSJ*. June 2012; 17(2):116-121.
9. Varma R, Soneja H, Samuel N, Sangha E, Clark TJ, Gupta JK. Outpatient Thermachoice endometrial balloon ablation: long-term, prognostic and quality-of-life measures. *Gynecologic and obstetric investigation*. 2010 Jun 16;70(3):145-8.
10. RA Busfield, CMFarquhar, MCSowter, ALethaby, MSprecher, YYu, et.al randomised trial comparing the levonorgestrel

- intrauterine system and thermal balloon ablation for heavy menstrual bleeding. 2006;113(3):257-63.
11. Ahonkallio S, Martikainen H and Santala M. Endometrial thermal balloon ablation has a beneficial long-term effect on menorrhagia. *Acta Obstet Gynecol Scand.* 2008; 87(1): 107-10
 12. Prachijain, Shalini Rajaram, Bindiya Gupta Randomized controlled trial of thermal balloon ablation versus vaginal hysterectomy for leiomyoma-induced heavy menstrual bleeding *International Journal of Gynecology & Obstetrics* Volume 135, Issue 2, Nov 2016: 140-144
 13. Zinatossadat Bouzari, Shahla Yazdani, Samira Azimi, Mouloud Agajani Delavar Thermal Balloon Endometrial Ablation in the Treatment of Heavy Menstrual Bleeding. *Med Arch* 2014; 68(6): 411-413.
 14. Gimpelson RJ. Ten-year literature review of global endometrial ablation with the NovaSure® device. *International journal of women's health.* 2014 Mar 11:269-80.
 15. Adel SH, El-Said AH, Abd ELMM, Mohamed EL Shafee, Lotfy S. *Arch Gynecol Obstet* 2011) 284:671-675.
 16. Azza A, Abd El Hameed. Endometrial thermal balloon ablation by a simple technique using Foley's catheter with or without pre ablation endometrial curettage to treat cases with intractable menorrhagia. *J Middle East Fertility Society.* 2012; 17 (2): 116-21
 17. Mubashra N, Faiza I, Humaira Z, UMBER F. Efficacy of modified thermal balloon ablation in heavy menstrual bleeding. *JUMDC* Vol. 3, Issue 2, Jul-Dec 2012.
 18. Kalampokas E, McRobbie S, Payne F, Parkin DE. Long-term incidence of hysterectomy following endometrial resection or endometrial ablation for heavy menstrual bleeding. *International Journal of Gynecology & Obstetrics.* 2017 Oct;139(1):61-4.
 19. Smith PP, Malick S, Clark TJ. Bipolar radiofrequency compared with thermal balloon ablation in the office: a randomized controlled trial. *Obstetrics & Gynecology.* 2014 Aug 1;124(2 PART 1):219-25.