

Managing Abnormal Uterine Bleeding: A Comparative Study of Modified Thermal Balloon Ablation and Hysterectomy

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Abstract

Objective: To compare the outcome of modified thermal balloon ablation and hysterectomy for management of heavy menstrual bleeding in terms of frequency of patient satisfaction.

Methods: All women aged between 35 to 45 years with heavy menstrual bleeding and who have completed their family were selected for the study. All 267 patients fulfilling inclusion criteria were recruited with uterine length less than 12cm, without any intrauterine pathology and normal endometrial biopsy.

Results: Group A Patients underwent hysterectomy and patient's satisfaction rate was 91.3% (126/138). Group B patients underwent modified thermal balloon ablation and patient's satisfaction rate was 82.6% (114 / 138).

Conclusion: In the management of heavy menstrual bleeding, results of hysterectomy and modified thermal balloon ablation are comparable to each other in terms of achievement of patient's satisfaction especially when we have to choose between definitive and conservative surgical options.

Keywords: Abnormal uterine bleeding, hysterectomy, modified thermal balloon ablation.

How to cite: Asghar S, Amir F, Parveen S, Naheed S, Jahan M, Iqbal I, Qasim S. Managing Abnormal Uterine Bleeding: A Comparative Study of Modified Thermal Balloon Ablation and Hysterectomy. *Esculapio - JSIMS* 2021;17(04):367-370.

DOI: <https://doi.org/10.51273/esc21.2517412>

Introduction

Abnormal uterine bleeding is a common incapacitating problem in women of reproductive age that severely affects their quality of life.¹ It is defined as excessive menstrual blood loss which interferes with woman's physical, emotional, social and material quality of life.² Five percent of women between the ages of 30 and 49 consult their general practitioner for this complaint. Dysfunctional uterine bleeding is responsible for 80% cases of menorrhagia.³ Hysterectomy has been known as a promising treatment for excessive menstrual

bleeding which do not respond to other medical treatments.⁴ The requirement of general anesthesia, longer hospital stay, increased blood loss and slow recovery makes it an expensive, hazardous and associated with significant morbidity and mortality.⁵

Minimally invasive procedures to destroy the endometrium are alternatives to hysterectomy. The first-generation techniques like endometrial laser ablation and trans cervical resection of the endometrium are all hysteroscopic procedures require surgical expertise, expensive and are associated with clinically significant complications. Alternatively, the techniques which are safe with minimal stay at hospital such as 2nd generation non hysteroscopic methods were employed to meet the issue⁶ including thermal balloon ablation, microwave ablation and radiofrequency ablation. Thermal balloon ablation is signature method of this series.⁶⁻⁷ In a society where resources are scarce these techniques are more expensive so a comparatively less expensive procedure using a modified foley's catheter to achieve endometrial ablation in treatment of heavy menstrual bleeding has been introduced.

The rationale of this study was to introduce thermal balloon ablation using Foley's catheter in an under privileged setting as a promising alternative to hysterectomy

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Submission Date:	26-08-2021
1st Revision Date:	02-09-2021
Acceptance Date:	22-10-2021

thereby reducing the burden of resources. This study compares the outcome in terms of patient satisfaction and utilize these results to recommend the suitable and safe procedure for the betterment of patients.

Materials and Methods

This study was conducted at HBS-Medical and Dental College, Lahtrar road, near Taramri Chowk, Islamabad. All the patients fulfilling the inclusion criteria were selected for study after explaining the risk-benefit ratio, addressing the ethical issues and taking informed consent. Exclusion criteria were strictly followed to limit the confounding variables. At initial visit patients were thoroughly evaluated by taking detailed history including age, demographic data, past obstetric and menstrual history and past medical/surgical history. General physical examination (pulse, blood pressure, temperature, pallor, weight, edema, goiter or any other positive finding), abdominal, pelvic and systemic examination were carried out. Investigations like blood group, full blood count, urine complete examination, random blood sugar, liver function tests, urea, creatinine, screening for hepatitis B and C, transvaginal ultrasound in orders to rule out any pelvic pathology or intrauterine lesion and endometrial sampling with endosampler plus histopathology to rule out malignancy was done. The patients were divided in two groups (group A and group B) by computer generated table of random numbers. Patients in group A underwent hysterectomy performed by consultant gynecologists under general or spinal anesthesia. After surgery patients were shifted to recovery room and later on moved to post-operative bay of gynecology and obstetrics ward. The patients were discharged on 3rd or 4th post-operative day if there were no complications like infection or pyrexia. Patients in Group B underwent treatment with modified thermal balloon ablation. This procedure was accomplished under saddle block in lithotomy position. A silicon treated Foley's balloon catheter of 18 FR with balloon capacity of 30-45 ml was used. The tip of the catheter was cut to occupy the uterine cavity. The cervix was being held with vulsellum and catheter was introduced in cavity using sponge holder until resistance felt. The balloon was inflated with 15-30 ml of hot saline at temperature of 85°C and hot saline was aspirated after 7 minutes. Three cycles of 7 minutes each were repeated. Patients were allowed to go home next day. The follow up visits to assess the main outcome measures, i.e patient satisfaction after modified thermal balloon ablation in terms of reduction in amount of bleeding, were carried out at one monthly interval for 6 months. A standardized Performa was filled regarding main outcome measures by these patients at each visit. Data was analyzed with SPSS-20. Age, parity, number of bleeding days and number

of sanitary napkins was presented as mean±SD. Patients satisfaction was presented as percentage or frequency. Patients satisfaction between 2 groups as compared by P– value of <0.05 was taken as significant.

Results

In this interventional study comparison of efficacy of modified thermal balloon ablation with hysterectomy in management of heavy menstrual bleeding was conducted. Patients satisfaction between 2 groups is compared by P– value of <0.05. A total of 276 patients were included for one-year period. All the patients were between 35 to 45 years of age and parity range between 1-to-6. Out of 276 patients, 144 (52%) were between 35-40 years of age and 132 (48%) were between 41-45 years of age. Patients were divided into 2 groups (namely, Group A and Group B) by computer generated table of random numbers. Each group had 138 patients. Group A patients underwent hysterectomy and patient satisfaction rate was 91.3% (126/138), while Group B patients underwent modified thermal balloon ablation and patient's satisfaction rate was 82.6% (114/ 138). The results are presented in (Table 1).

Table 1: Overall patient satisfaction in two groups.

Patient's satisfaction	Hysterectomy (Group A)	Thermal Balloon Ablation (Group B)	Total
YES	126 91.3%	114 82.6%	240 87.0%
TOTAL	138	138	276

p-value ≤0.05 is considered significant. The results of patient satisfaction with respect to age are presented in (Table-2). A total of 75% patients of age between 35 to 40 years were found satisfied. Under this age boundary, from Group A (who went under Hysterectomy) a total of 84 patients out of 96 (87.5%) were satisfied while 24 out of 48 patients (50%) from Group B were satisfied. In the age group 41-to-45 years we have 42 patients in Group A while 90 patients belong to Group B. Surprisingly, the satisfaction rate in this age boundary was 100% for both Group A and Group

Table 2: Patient satisfaction according to age distribution.

Age distribution	Patient's satisfaction	Group		Total
		Hysterec- tomy (Group A)	Thermal balloon ablation (Group B)	
35-40 years	Yes	84	24	108
		87.5%	50.0%	75.0%
41-45 years	Yes	42	90	132
		100.0%	100.0%	100.0%

B patients.

(Table-3) presents the patient's satisfaction with

respect to parity. With parity less than 3, 75% patients from Group A were satisfied while none of the patient from Group B were satisfied with this parity. On the other hand, with parity greater than 3, a 100% satisfaction rate was observed from both groups. If we look on overall patients from both group, 50% patients were satisfied with parity less than 3 while 100%

Table 3: Patient satisfaction according to parity distribution

Parity Distribution	Group			Total
	Patient's satisfaction	Hysterectomy (Group A)	Thermal Balloon Ablation (Group B)	
<3	Yes	36 75.0%		36 50.0%
>3	Yes	90 100.0%	114 100.0%	204 100.0%

were satisfied with parity greater than ³.

Discussion

The women of reproductive age often observe problem of heavy menstrual bleeding which interferes with woman's physical, emotional, social and material quality of life. When medical therapy fails to control heavy menstrual bleeding then the surgical interventions such as Hysterectomy can be considered for treatment. However, this require general anesthesia, prolonged hospital stay, more loss of blood and more time for recovery. The efficacy of second generation non hysteroscopic techniques specially balloon thermal ablation is well documented in various trials. The use of modified thermal balloon ablation using Foley's catheter appears to be promising alternative because of low cost and need of less expertise. Existing data is sparse to draw conclusions reliably. Owing to the higher incidence of heavy menstrual bleeding in women, the endometrial destruction with hot balloon like Foley's catheter can be used in underprivileged settings. Therefore, the study was conducted to establish its efficacy. This study was carried out to compare the efficacy of modified thermal balloon ablation and hysterectomy for the management of heavy menstrual bleeding. The study compares the effects of MTBA and Hysterectomy in achieving patient satisfaction which is a key to manage the heavy menstrual bleeding. The study had special interest in reduction of menstrual blood flow and achieving the higher rates of patients' satisfaction. These parameters have always been an index for prevailing reproductive health care in a certain community reflecting the need of better health care facilities. The patients recruited for the study had mean age of 41 years. Patients were experiencing heavy menstrual bleeding for 6 to 12 months. The main target outcome during study was of achievement of patients satisfaction in terms of reduction in number of sanitary

napkins to less than 2- 3per day and reduction in number of bleeding days to less than 5-6 days per cycle after 6 months post treatment. Please note that in abnormal uterine bleeding, it's a common practice to get an idea of amount of blood loss by number of bleeding days and number of sanitary napkins used.

In our study the patient satisfaction rate after hysterectomy was 91.3% and is comparable to results of study conducted by S Bhattacharya and colleagues in UK.⁸⁻⁹ The patient satisfaction rate after undergoing MTBA was 82 .6% which was comparable to studies of same series.¹⁰⁻¹³ A total of 17.4% percent of patients undergoing MTBA were not satisfied and ended up in radical surgical procedure in the form of hysterectomy.¹⁴⁻¹⁵ Studies in resource rich setting consider treatment failure when patients after procedure needed another conservative procedure like hysteroscopic guided destruction of endometrium or hysterectomy.¹⁶

Patients in third world countries like Pakistan convincingly consider hysterectomy as ultimate radical treatment for any menstrual irregularity after childbearing is complete. Due to non-availability and expensive equipment of ablative techniques, the next step was more radical approach to improve patient compliance.¹⁷ A thorough literature survey has been done for local studies conducted in Pakistan to compare the results of our study and one such study was found using the MTBA for control of heavy menstrual bleeding. The results of this study were also comparable to that in findings.¹⁸ In the context of Pakistani population with significant prevalence of heavy menstrual bleeding, there is a need to identify the women with the disease and along with their proper treatment. Although hysterectomy is recommended as definitive treatment worldwide, but research is going on to evaluate and establish the efficacy of minimally invasive techniques of endometrial ablation among these, thermal balloon ablation is most widely studied procedure.

Conclusion

We conclude that modified thermal balloon ablation with Foley's catheter can be a promising alternative to conservative management for heavy menstrual bleeding in poor resource settings as it is less invasive and cost effective. Reassuring results inform that procedure can be adopted with reasonable confidence in future. Other alternatives can be LNG-IUS. Long term follow up should be considered for better results.

Conflict of interest

None

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Authors Contribution

SQ, SN, SA: Conceptualization of Project

SA, MJ, SN: Data Collection

FA, SA, MJ: Literature Search

II, SP, SA, FA: Statistical Analysis

II, SP, SQ: Drafting, Revision

SA, SQ: Writing of Manuscript