Original Article

EFFICACY OF MODIFIED THERMAL BALLOON ABLATION IN HEAVY MENSTRUAL BLEEDING

Mubashra Naz¹, Faiza Irshad², Humaira Zafar¹, Umber Fatima² ¹Asstt. Professor, Gynae and Obstetrics, University Medical & Dental College, Faisalabad. ²Senior Registrar, Gynae and Obstetrics, University Medical & Dental College, Faisalabad.

ABSTRACT

Objective:

To determine the efficacy of modified thermal balloon ablation using Foley'scatheter in the treatment of heavy menstrual bleeding.

Design:

Quasi experimental study.

Setting:

Department of obstetrics and gynaecology, University Medical and Dental College, Madina Teaching Hospital, Faisalabad.

Methodology:

Fifty three patients with heavy menstrual bleeding between 35 to 45 years of age underwent modified thermal balloon ablation using Foleys catheter. Patients were selected after complete clinical evaluation and investigations. Procedure was under taken in operation theater under saddle block .Three cycles of modified thermal balloon ablation using Foley'scatheter with hot saline were performed to ablate endometrium. Time given to each cycle was 7 minutes.

Main outcome measures:

Main outcome measures were reduction in menstrual flow, amenorrhea, minor short term side effects and need of hysterectomy after failure of procedure.

Results:

Sixty nine percent of patients experienced reasonable reduction in menstrual blood flow. Twelve percent had amenorrhea at the end of 6 months of follow up. Eighteen percent observed no change in bleeding pattern and underwent hysterectomy after failure of procedure. Six percent patients complained of minor side effects like abdominal pain and endometritis.

Conclusions:

Modified thermal balloon ablation with Foley's catheter can be promising conservative management of heavy menstrual bleeding in resource poor settings. Reassuring results dictates that procedure can be adopted with reasonable confidence in future.

Keywords: Thermal balloon ablation, heavy menstrual bleeding, hysterectomy

INTRODUCTION

Heavy menstrual bleeding is a common incapacitating problem of women of reproductive age which severely affects their

Corresponding Author: Dr. Mubashra Naz, Assistant Professor, Department of Gynae and Obstetrics, University Medical & Dental College, Faisalabad. Email: quality of life.¹ It accounts for more than two third of outpatient visits in gynecological OPD. Heavy menstrual bleeding has been constituting huge referral burdens to tertiary centers for early resort to hysterectomy due to inadequate, non compliant and failed medical treatments.² This scenario not only increases the burdon of health care professionals but also burns human and economic resources of country. On the other hand it is creating a population of young

hystrectomised women with attendant short term risks of surgery and long term sequel of pre-mature ovarian failure for a simple and benign condition of HMB.³

Hysterectomy has traditionally been the ultimate treatment option for Heavy menstrual bleeding that failed to respond to medical treatment.⁴ Owing to the morbidity associated with hysterectomy, minimally invasive methods of endometrial destruction came into play during the last couple of decades. These included roller ball, trans cervical resection of endometrium and laser ablation performed under direct hysteroscopic view. These first generation technique could not gain popularity in under resource setting because of their high cost.⁵

To over come the problem, a second generation non hysteroscopic technique which is safer to perform and involved less hospital stay was devised to meet the issue.⁶ Thermal balloon ablation (high temperature fluid with in a balloon) is signature method of the series.⁷ Other less common techniques are free fluid thermal ablation, cryoablation and endometrial laser intrauterine thermotherapy.

The Cochrane data base concluded that endometrial ablation should be offered to all the women for HMB as first line surgical treatment.⁸

Thermal balloon ablation using Foley's catheter in under privileged setting can be a promising alternative to original thermal balloon ablation reducing the cost even further. The simplicity, ease and quickness of the procedure can reasonably reduce amount of bleeding in patients with HMB destroying endometrium effectively.⁹ The existing data focuses on thermal balloon ablation, but the use of Foley's catheter has not been fully evaluated. The study will strengthen the existing evidence and proved to be a safer option.

The objective of the study was to evaluate the efficacy of endometrial balloon ablation using Foley's catheter in the treatment of HMB.

MATERIAL AND METHODS

The study was conducted in department of obstetrics and gynaecology, University Medical and Dental College Madina Teaching Hospital from June 2011 to November 2012. All

patients visiting the gynaecological outpatient department were thoroughly evaluated by taking targeted history and examination. Trans vaginal USG was performed in order to rule out sub mucous fibroids or polypoidal lesions of endometrium. Endometrial sampling was done by endosampler. After excluding malignancy on histopathology, patients were selected for study.

Fifty three patients with HMB (excessive menstrual loss interfering with physical, emotional, social and material quality of life) between 35 to 45 years of age, no further reproductive wishes and not willing for hysterectomy after failed medical treatment study were included in after strictly addressing ethical issues (explaining patients the relative innovation of procedure, side effects and possibility of failure of technique). The study gained approval by institutional research ethical committee.

Confounding variables were controlled by adhering to exclusion criteria that comprised malignancy (ruled out with endometrial sampling) intra cavity lesions like sub mucous fibroid and endometrial polyps and uterine cavity size more than 8cm assessed by TVS.

The procedure was accomplished in operation theatre with patient in lithotomy position and under saddle block after performing examination under anesthesia. A silicon treated Foley's balloon catheter of 18 FR with a balloon capacity of 30-45 millimeter was used in the procedure. The tip of catheter was cut to easily occupy the uterine cavity before starting the procedure. The cervix was held with vulsellum and catheter was introduced in cavity using sponge holding forceps till resistance was reached. The balloon was inflated with 15 to 30ml of hot saline at temperature of 85°C. Hot saline was aspirated after 7 minutes as the temperature of saline dropped. Three cycles of similar duration were repeated. The procedure was completed in about 40 to 45 minutes. Patients were allowed to go home the next day.

The women were reviewed at first follow up at one week for the assessment of short term complications including abdominal pain and endometritis. These complications responded to simple analgesics and antibiotic course. The follow up visits to assess the main outcome measures that is reduction in the bleeding, rates of amenorrhea, and need of hysterectomy were carried out at one monthly

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interval for 6 months. A standardized proforma was filled regarding the main outcome measures by these patients at each visit. Assessment scales were used to assess the reduction of menstrual bleeding at scale of three. 1 score meant no change in pattern of bleeding, 2 score denoted more than 50% improvement (decreased number of bleeding days and sanitary napkins) and three meant amenorrhea. Patients who did not experience any change in bleeding pattern that is score 1 were counseled for definitive treatment. Number of patients who requested hysterectomy after endometrial ablation was denoted to be procedure failure. Successful procedure was denoted by number of women requiring no further surgical procedure due to reduced menstrual loss scored as 2 and 3. Results of the main outcome measures were analyzed using SPSS Version 15. Results were analyzed using descriptive statistics frequency tables percentages.

Table 1. Main outcome measures in 51 patients

S.No.	Main outcome measures	No. of cases	Frequency	Percentage	p-value
1	Reduction in menstrual Bleeding (score 2)	35	35	69%	0.008
2	No change in HMB (score 1)	9	9	18%	0.000
3	Minor side effects	3	3	5.8%	0.000
4	Failed procedure/hysterectomy	9	9	18%	0.000
5	Amenorrhea (score 3)	6	6	12%	0.000

Chi-square value:

Reduction in bleeding = 7.078Failed procedure = 21.353 No change in HMB = 21.353; Amenorrhoea =29.824

Table	2.	Base	line	parameters	of	study	DISCUSSIO
		popula	ation	n=53			

Sr. No.	Characteristics	Parameters
1	Age in years	41 years (± 2 yrs.)
2	BMI kg/m 2	24 (± 1.5)
3	Pre-operative hemoglobin (g%)	10.5 (± 1 g/dl)
4	Types of anesthesia: Regional General	96 % 4%
5	Duration of symptoms in months	9 months (± 3 months)

RESULTS

During the study period, 53 patients underwent modified thermal balloon ablation. Age of the patients ranged between 35 to 45 years of age. Mean age was 41 years. Duration of symptoms was 6 months to one year. The procedure was performed in regional saddle block. Two patients had procedure under general anesthesia due to refusal to regional block. All the patients except for 2 were available for the follow up. Seventy percent (n=35) patients experienced significant reduction in the menstrual bleeding in terms of reduced bleeding days and sanitary napkins.

Twelve percent (n=6) patients experienced amenorrhea at the completion of 6 months follow up. Eighteen percent (n=9) had no change in the bleeding patterns and all of these underwent hysterectomy.

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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 promising alternative because of low cost and need of less expertise. Existing data is spars 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. There for the study was conducted to establish its efficacy.

The patients recruited for the study had mean age of 41 years. Patients were experiencing having heavy menstrual bleeding for 6 to 12 months. The main outcome measures that were observed during study was reduction in the flow of bleeding following modified thermal balloon ablation, amenorrhea, failure of procedure and minor side effects.

Minor side effects associated with the procedure were recorded in just 5.8% of patients (n=3) which is similar to the study conducted in Karolinska Institute at Huddinge University Hospital Sweden. These included endometritis and abdominal pain.¹⁰ These problems responded well to conservative treatments and no long term effect was observed at the end of follow up.

Significant loss of menstrual flow in terms of decreased use of sanitary napkins and number of bleeding days were observed in 70% (n=35) patients which closely takes after the results of the pilot study of modified balloon ablation in university of Mansoura Egypt and the study of thermal balloon ablation for treatment of menorrhagia in an outpatient settings.⁹⁻¹⁰

The study demonstrated comparable results of rates of amenorrhea 12% after 6 months with other studies of same series.^{9,10,11}

Eighteen percent patients had no change in amount of bleeding and ended up in radical procedure in the form surgical of hysterectomy.^{11,12,13} Studies in resource rich setting consider treatment failure when patients after procedure needed another conservative procedure like hysteroscopic quided destruction of endometrium or hysterectomy. As the procedure was carried out in resource poor country, the next step was a more radical approach to improve patient compliance.¹⁴ Patients in third world countries like Pakistan convincingly consider hysterectomy as ultimate radical treatment for any menstrual irregularity after child bearing is complete. The non-availability and expensive equipment of ablative techniques has contributed to this belief.¹⁵ This relatively high failure rate can be the result of this concept.

In conclusion modified thermal balloon ablation with Foley's catheter can be promising alternative conservative management of heavy menstrual bleeding in resource poor settings. Reassuring results dictates that procedure can be adopted with reasonable confidence in future.

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