DOI: https://doi.org/10.53350/pjmhs2115102537

ORIGINAL ARTICLE

Patients Satisfaction Undergoing Endometrial Thermal Balloon Ablation for the Treatment of Intractable Menorrhagia

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ABSTRACT

Background: Heavy amounts of menstrual blood loss regularly in three or more consecutive cycles are characterized as menorrhagia which has been shown to be present among in many peri-menopausal and premenopausal women.
Aim: To determine the frequency of patients' satisfaction with TBA for the treatment of intractable menorrhagia.
Methods: This descriptive study was undertaken in Department of Obstetrics and Gynecology, Lady Wallington Hospital Lahore from January to July 2017. A sample size of 200 patients was calculated and informed consent was taken to fill predesigned Performa. Prophylactic dose of 1g Ceftriaxon antibiotic was administered and Foly's catheters were placed simultaneously in uterine cavity of patients after curettage and dilations. The uterine balloon catheter was then entered into the uterus and balloon was filled with sterile fluid.
Results: A high number of 157(78.5%) women were found to be satisfied with thermal balloon ablation while different age groups presented an insignificant difference on level of satisfaction. Level of education and BMI had insignificant difference ($p > 0.05$) while a significant difference ($p < 0.05$) was observed among patients suffering from long duration of >6 months as compared to short duration of 3-6 months.
Conclusion: Thermal balloon ablation is the method of choice for treatment of women suffering from menorrhagia and high number of patients revealed their trust on this method.
Keywords: Menorrhagia, Dysmenorrhea, Blooding, Satisfaction, Endometrium.

INTRODUCTION

Considerable numbers of reproductive age women suffer from menorrhagia, posing a momentous impact on medical, psychological, economic and social health with a high global prevalence varied in different geographical strata. Frequency of menorrhagia is almost the same with more or less differences ranging from 12-25%[1]. World Health Organization (WHO) on the other hand presented a range of ailment as 8-27% among women of reproductive age[2]. Heavy amount or prolonged duration of menstrual bleeding with >80ml loss of blood regularly in three or more consecutive cycles is characterized as menorrhagia. Literature shows further wide range as 27-54% of menorrhagia in various parts of world with a high prevalence of 37.9% in Pakistan[3]. Effects of menorrhagia are shown to be present among 50% peri-menopausal and 10-30% of premenopausal women with unknown etiology lacking organic lesions therefore considered as dysfunctional bleeding[4].

Management of menorrhagia varies with reference to the known etiology of disease or unidentified pathology. Treatment options include levonorgestrel-releasing intrauterine system treatments (LNG-IUS), endometrial ablation, and hysterectomy. Similarly, three main types of treatment classes exist, comprising pharmacological (may be hormonal or non-hormonal), uterine artery embolization for fibroids and surgical (may be myomectomy or hysterectomy)[5].

Hysterectomy remained only decisive surgical intervention for so long amongst women suffering from treatment resistant menorrhagia[6]. Hysterectomy is a major surgical process comprising key complications and bears long recovery time[6]. Hysterectomy has been adopted as a routine surgical treatment for medically non respondent patients, being alone surgical choice in Pakistan which has been reported to cause hormonal changes and psychologically affects the life of patients[7].

Endometrial ablation techniques have shown to improve the cases around the globe, by which surgeons can efficiently target the benign origin of abnormal uterine bleeding[4]. Though, endometrial ablation has established it as an effective alternative to hysterectomy which is an outpatient procedure and destroys or removes endometrial layers. The opposite walls of the myometrium fold onto each other while impaired tissue diminishes to develop a scar[8].

The LNG-IUS is also a minimally-invasive potential procedure being used to treat menorrhagia. Although this technique has a number of advantages including simplicity, economic, does not require analgesics, effective and reversible in desire of fertility[9] but could not replace hysterectomy. Thermal balloon endometrial ablation (TBA) the second generation technique appears to be safer than all other ablation techniques and is as effective as primary endometrial ablation[10]. Clinical efficacy of TBA has been considered as an effective, valid and minimally invasive intervention over hysterectomy further appeared as an efficient method in reducing scores on pictorial blood loss assessment chart[11].

Consensus on TBA is yet debatable and requires further investigations especially regarding the levels of patient satisfaction. Variable results from different regions have been reported regarding patients' satisfaction[10] while local data lacks the information. Therefore, present study was undertaken to

Received on 19-04-2021
Accepted on 27-09-2021

determine the frequency of patients' satisfaction with TBA for the treatment of intractable menorrhagia.

MATERIALS AND METHODS

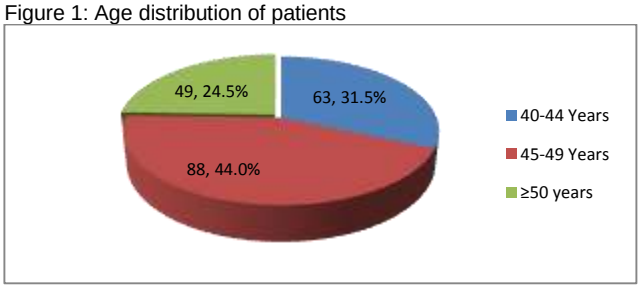
This descriptive study was undertaken in Department of Obstetrics and Gynecology, Lady Wallington Hospital Lahore from January to July 2017 after permission from Hospital Ethical Committee. A sample size of 200 patients was statistically calculated and non-probability sampling technique was used to collect the data from patients. Female patients aged 40-52 years, presenting a complaint of intractable menorrhagia from at least three months, not willing to continue pharmacological treatment and undergoing TBA were included in this study. Patients wishing to maintain fertility, consisting a uterine length of >12 cm, history of cesarean section, suspected pelvic infections or showing abnormal presentations on ultrasound were excluded from this study.

Data Collection: After taking the informed consent a predesigned Performa was used to collect the information including demography, history and relevant investigations. Prophylactic dose of 1g Ceftriaxon antibiotic was administered through intravascular injection 30 minutes afore starting the procedure. Beginning from dilations, curettages were performed and endometrial biopsy was obtained which was sent to histopathology laboratory. Foly's catheters were placed simultaneously in uterine cavity of patients after curettage and dilations. The uterine balloon catheter was then entered into the uterus through the cervix and balloon was filled with sterile fluid to maintain a pressure of 160-180 mm mercury. Already in placed heating element inside the balloon was plugged in raise the temperature and maintain it at 87±0.5ºC for 8 minutes, which was then deflated and removed. All the patients were then administered a single dose of Diclofenac Sodium (75mg) through intramuscular injection after procedure and were discharged to home. Patients were then followed in outpatients for twelve weeks to observe the treatment outcomes in terms of satisfaction. Bias was controlled by facilitating the management of all study subjects by a single consultant. The collected data was entered and analyzed by using SPSS version 20.0.

RESULTS

A total of 200 women suffering from menorrhagia aged 40-52 years were successfully followed in this study and included for data analysis. Mean age of women was recorded as 46.07±3.66 years. Age was further distributed in three age groups and highest numbers of patients 88(44%) were found in median age range of 45-49 years in this study as presented in figure 1.

Figure 1: Age distribution of patients



Body mass index (BMI) of the patients was also considered and fond to be high among as 151(75.5%) patients had BMI ≥30Kg/m^2 in this analysis. Further demographic and physical characteristics including level of education, parity were also noted. Most of the 116(58%) women had educational level of middle schooling while only 57(28.5%) passed their matriculation while 27(13.5%) were illiterate. Mean duration of intractable menorrhagia was found to be 6.31±1.99 months with a range of 3-10 months. Similarly most of the 61(30.5%) patients had 3 parity while least 2(1.0%) had 6 parity as shown in table 1.

Table 1: Characteristics of Study Subjects

Characteristics		n	%
Educational status	Illiterate	27	13.5
	Middle	116	58.0
	High	57	28.5
Duration of Intractable menorrhagia in Months	3 Months	18	9.0
	4 Months	26	13.0
	5 Months	32	16.0
	6 Months	32	16.0
	7 Months	25	12.5
	8 Months	32	16.0
	9 Months	28	14.0
	10 Months	7	3.5
Parity	1	28	14.0
	2	48	24.0
	3	61	30.5
	4	18	9.0
	5	43	21.5
	6	2	1.0

Table 2: Level of satisfaction regarding BMI, Duration of Menorrhagia and level of Education

Variable	Indication	Satisfaction	n(%)	p-value
BMI	≥30Kg/m2	Yes	118(75.2)	0.98
		No	33(76.7)	
	<30Kg/m2	Yes	39(24.8)	
		No	10(23.3)	
Duration of Intractable Menorrhagia	3-6 Months	Yes	79(50.3)	0.05
		No	29(67.4)	
	>6 months	Yes	78(49.7)	
		No	14(32.6)	
Level of Education	Illiterate	Yes	21(13.4)	0.452
		No	6(14.0)	
	Middle	Yes	88(56.1)	
		No	28(65.1)	
	High	Yes	48(30.6)	
		No	9(20.9)	

A high number of 157(78.5%) women were found to be satisfied TBA while rest of 21.5% unsatisfied women desired further treatment. Different age groups presented an insignificant difference (p=0.252) on level of satisfaction. Stratification of data was done with reference to the level of education, BMI and duration of intractable menorrhagia and no significant difference (p >0.05) was observed among level of education and BMI while a significant difference (p<0.05) was observed among patients suffering from long duration of >6 months as compared to short duration of 3-6 months in this study as presented in Table 2.

DISCUSSION

Primary techniques to target endometrial lining was initially developed in 1936, which used radiofrequency electrosurgical probe to enter endometrial cavity by passing through cervical canal deprived of endoscope which was then modified by use of endoscope[12]. Both of these techniques were not well recognized until hysteroscopy was introduced in 1980. The magnitude of hysteroscopy was based on three different approaches including laser ablation, roller ball ablation, and trans-cervical endometrial resection and used to remove basal

endometrial glands and uterine endometrial lining present on the superficial myometrium[12].

These techniques were extensively studied and became gold standard to be called first generation with good outcomes as compared to pharmacological interventions. Then the era of second generation of hysterectomy included wide range of approaches like the microwave, phototherapy, the hard liquid balloons, chemical destruction and phototherapy to abolish endometrial lining[13]. Development of these interventions considerably shortened the hospital stay of patients and increased the levels of satisfaction[12].

Findings of present study endorsed TBA a safe, easy, and promising technique as proposed an auspicious alternative to conventional techniques being used to manage menorrhagia in times of least surgical access. [14] Presently around 78.5% patients were found to be satisfied with TBA and showed considerable improvement in menorrhagia whereas 21.5% still need hysterectomy. These findings are in agreement with a recent study undertaken in Netherland which presented a success rate of TBA as 81.2% however poked a significant risk of recurrence among women having a menstrual cycle of >7days[15].

A study undertaken to observe long term satisfaction with TBA presented a data of 97 patients completed the survey with a follow up period of 93-129 months. Results are higher as 87% patients showed satisfaction with procedure and outcomes however around 9% of the succeeding women required hysterectomy after 1-5 years of follow up period while almost double (21.6%) required it after 7-10 years. Rest of 76 women who did not undergo hysterectomy presented with either amenorrhea or minimal bleeding[16]. Another study presented comparable results which aimed to observe the menstrual outcomes after TBA among premenopausal women in Iran revealed 88% response of treatment with mean duration of bleeding as 13.6 days per cycle significantly decreased ($p<0.001$) remained 4 days per cycle and mean baseline pictorial amount of blood loss as 535.4 ml also significantly decrease ($p<0.001$) to 38.6 ml after treatment.[17] Hence it is difficult to believe now on the older concepts endometrial thinning using endometrial curettages or pharmacological agents which have been already reported to not have any impact on TBA outcomes[18].

Generally patient characteristics are play a vital role and act as confounding factors in final outcomes of any treatment. At present segregation of age groups, BMI and level of education were studied and presented insignificant differences with p-values 0.252, 0.98, and 0.452 respectively. On the other hand duration of menorrhagia presented a significant difference (p-value <0.05) and patients suffering from long duration had lower level of dissatisfaction in this study. A study proposed previous caesarean section as risk factor which was not studied presently. Similarly younger age, dysmenorrhea and parity ≥5 were reported as predictors of unsuccessful ablation[15] hence not in concomitant to present study. A long term follow up study proposed a much higher 89% level of satisfaction with TBA of which 44% reported minute bleeding, 37% reported amenorrhea while only 9% were taken up for hysterectomy[19] showed much better outcomes.

CONCLUSION

Conclusively, TBA is the method of choice for treatment of women suffering from menorrhagia and high number of patients revealed their trust on this method. Thus the TBA is effective and safe substitute over hysterectomy which must be second choice in few treatment failure cases. Long term follow up on the other hand is also important to observe recurrence.

Conflict of interest: Nil

Authors' Contribution: SE: Conceptualization Write up, **MR:** Literature review, Write up, **AR:** Data Collection, Data Management, **NN:** Literature Search, Data Analysis, **AM:** Case Evaluation, Data Collection, **MA:** Revision, Technical assistance

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