

## A Prospective Study on Thermal Balloon Endometrial Ablation for the Treatment of Heavy Menstrual Bleeding

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### Abstract

**Introduction:** Abnormal uterine bleeding affects most of the peri-menopausal women and accounts for most of all gynaecologic visits by peri-menopausal women. Thermal balloon endometrial ablation (TBEA) technologies were introduced as an alternative to hysterectomy in those women having abnormal uterine bleeding who failed medical management and/or dilatation and curettage. The present study was conducted to assess the short term treatment outcomes of TBEA and patient satisfaction after the procedure and to identify the factors influencing its outcome.

**Material and Methods:** This prospective study was conducted for a period of one year. Premenopausal women with heavy menstrual bleeding were included in the study. TBEA was done using the uterine thermal balloon system under anaesthesia. After the procedure, the patients were followed up after 3 months, 6 months and one year using a prevalidated questionnaire. Both improvement in symptoms and quality of life were taken in to consideration. The data was analyzed with statistical package for the social sciences version 21.0.

**Results:** A total of 36 were included as study population the median age of the study population was 42 years. Out of the 36 cases, 26 (72.3%) patients developed amenorrhea, 7 (19.4%) patients had hypomenorrhoea and 3 (8.3%) patients continued to have heavy menstrual bleeding and underwent hysterectomy. 88.9% patients reported satisfaction after TBEA. There was no significant association of amenorrhea after TBEA with either BMI or endometrial thickness or parity or prior dilatation and curettage.

**Conclusion:** TBEA is a suitable alternative to hysterectomy as majority of the patients developed amenorrhea in the one year follow up and most of the patient had better satisfaction rates after TBEA.

**Keywords:** Amenorrhea, hysterectomy, uterine bleeding

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### Background

Heavy menstrual bleeding is a significant health problem in premenopausal women. In developing countries, abnormal uterine bleeding appears to affect about 5– 15% of

women of reproductive age and probably a higher percent of women in older age groups [1]. Hysterectomy has been the surgical treatment of choice which is

effective in producing amenorrhea but is associated with surgical complications, and has a greater impact in term of cost and prolonged recovery time. Hysteroscopic endometrial ablation was introduced in the early 1980s to treat women with abnormal uterine bleeding from benign causes, but after its introduction into clinical practice it was realized that this technique required additional training and surgical expertise to prevent serious procedure-related complications such as fluid overload from distension media, electrolyte imbalance, cardiac arrhythmia, uterine perforation, haemorrhage and visceral damage [2,3]. These complications have caused a decline in usage of hysteroscopic endometrial ablation [4].

The second-generation endometrial ablation techniques was developed, with the aim to provide simpler, quicker, and more effective treatment options for menorrhagia compared with first-generation endometrial ablation techniques and hysterectomy [5]. These depend less on the people operating them and more on the actual devices to ensure safety and efficacy. With this background, the present study was conducted to assess the short term treatment outcomes of thermal balloon endometrial ablation (TBEA) and patient satisfaction after procedure and to identify factors influencing the outcome of the procedure.

### Material and Methods

This prospective study was conducted for a period of one year in the department of obstetrics and gynecology after obtaining approval from the ethics committee of the medical faculty of the institution and after obtaining informed consent from the patient. Premenopausal women with menorrhagia were enrolled in a prospective clinical study to test clinical effectiveness of thermal balloon endometrial ablation therapy. Inclusion criteria included premenopausal women with heavy menstrual bleeding, women who have completed their family, women

in whom pap smear and endometrial biopsy showed normal cervical cytology and normal (benign) endometrial histology, no organic lesion on ultrasound or leiomyoma < 2cm on ultrasound and uterocervical length <12 cm. Those patients with atypical endometrial hyperplasia, genital tract malignancy, women who wish to preserve their fertility and women with anatomical uterine anomalies were excluded from the study. All the study population underwent routine pre-operative evaluation and underwent transvaginal ultrasound, pap smear and endometrial biopsy. Demographic details like age, body mass index (bmi), status of their parity, mode of previous delivery were captured.

TBEA was done using the uterine thermal balloon system (santherm, pune) which consists of a 16 cm long and 4.5 mm diameter catheter with a latex end, which houses a heating element. The catheter is connected to a control unit, which monitors, displays and adjusts pre-set intrauterine balloon pressure, temperature and duration of the treatment. The catheter was inserted transcervically to touch the uterine fundus. The balloon was filled with a variable volume of 5% dextrose/water until the intrauterine pressure stabilized between 160 and 180 mmhg. The fluid was heated to approximately 87°C, after which the treatment lasted for 10-12 min and the catheter was removed. The procedures were performed under anaesthesia and always by the same experienced surgeon. After the procedure, the patients were followed up after 3 months, 6 months and one year using a prevalidated questionnaire. Both improvement in symptoms and quality of life were taken in to consideration.

Data was entered in predesigned proforma and later in microsoft office excel (microsoft corporation, redmond, wa). All continuous data were expressed as mean, standard deviation and median (inter quartile range) as appropriate. Continuous data was analysed by student t-test/mann

whitney u test as appropriate. Categorical data expressed as percentages and was analyzed using chi-square/fisher's exact test. A 'p' value of less than 0.05 was considered as statistically significant. The data was analyzed with statistical package for the social sciences (SPSS) version 21.0 (SPSS, INC., CHICAGO, IL).

## Results

The study population consisted of 36 cases who presented to the department of obstetrics and gynaecology with complaints of abnormal uterine bleeding. Relevant history was elicited and clinical examination was done. The age of the patients ranged from 31 years to 54 years with a median age of 42 years (figure 1). It was found that out of the 36 cases, bmi of 27.8% of cases were within normal range, 30.5 % were overweight, 22.2% were obese and 16.6% were morbidly obese and the remaining 2.8% were underweight.

Among the study population, 80.6% were multipara followed by primipara with 16.7% and nullipara with 2.7%. In this study, 6 (16.7%) cases had a previous caesarean delivery and 30(83.3%) cases had previous vaginal delivery. The PAP smear reports were analysed and it was found that all 36 cases (100%) had normal pap smear i.e., negative for intraepithelial lesions or malignancy. All women underwent an endometrial biopsy, the results of which were described in figure 2.

Local paracervical block was given in 55.6% of cases who underwent the procedure followed by spinal anaesthesia in 25% and general anaesthesia in 19.4% of cases. Only 11(30.5%) cases underwent dilatation and curettage prior to TBEA in order to achieve pre-thinning of the endometrium and the remaining 69.9% did

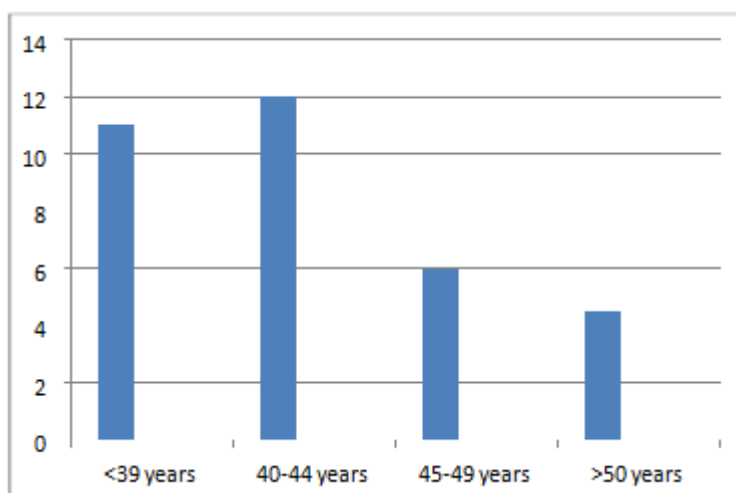
not undergo dilatation and curettage.

The patients were followed up for a period of one year. After 3 months of the procedure, out of 36 cases, 27 (75%) cases developed amenorrhea, 7 (19.5%) cases had hypo menorrhoea and 2 (5.5%) cases continued to have heavy menstrual bleeding (figure 3). The 2 patients who continued to have heavy bleeding underwent hysterectomy after 3 months of TBEA. After 6 months of the procedure, out of 34 cases (after excluding the two cases who underwent hysterectomy), 24 (66.7%) were still amenorrhoeic, 9 (25%) had hypo menorrhoea and 1(2.7%) had heavy menstrual bleeding (after 3 months of amenorrhea) (figure 4).

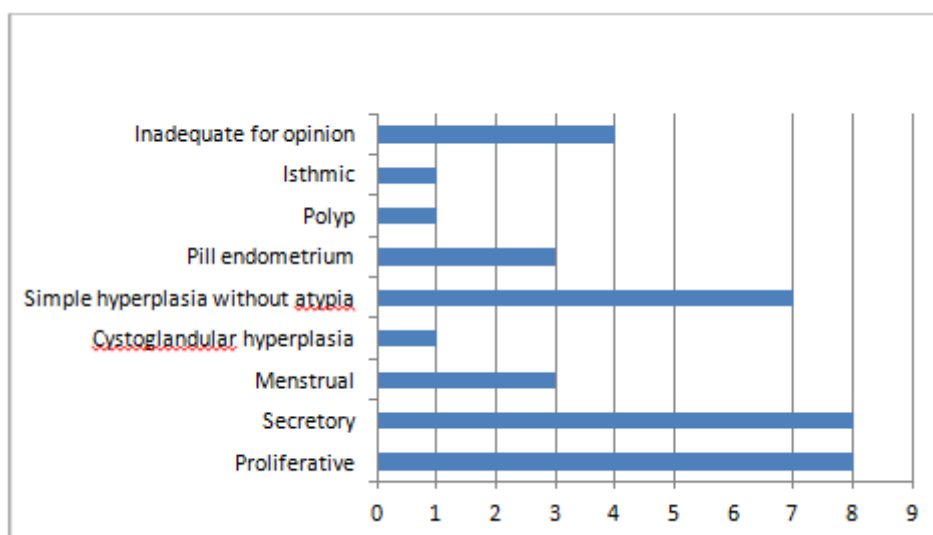
Between six months and 1 year of the procedure, out of 34 cases, 26(72.3%) were amenorrhoeic, 7 (19.4%) had hypo menorrhoea and 1(2.7%) continued to have heavy menstrual bleeding, who underwent hysterectomy after a year of TBEA (figure 5). Hence out of the 36 cases, the final results were, 26 (72.3%) patients were amenorrhoeic, 7 (19.4%) patients had hypomenorrhoea and 3 (8.3%) patients continued to have heavy menstrual bleeding and underwent hysterectomy.

In this study 32 (88.9%) patients reported satisfaction after TBEA and 4 (11.1%) patients were dissatisfied with the procedure. Of these 4 patients, 3 continued to have heavy menstrual bleeding, hence underwent hysterectomy and 1 patient had severe dysmenorrhoea after procedure.

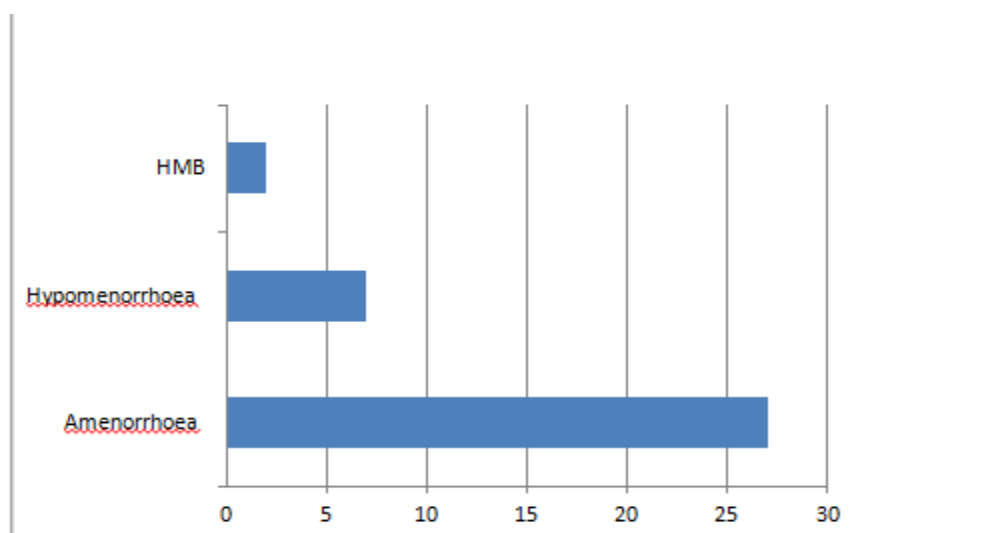
In this study, we found that there was no significant association of amenorrhea after TBEA with either BMI( $p=0.736$ ), or endometrial thickness ( $p=0.436$ ) or parity ( $p=0.952$ ) or prior dilatation and curettage ( $p=0.539$ ).



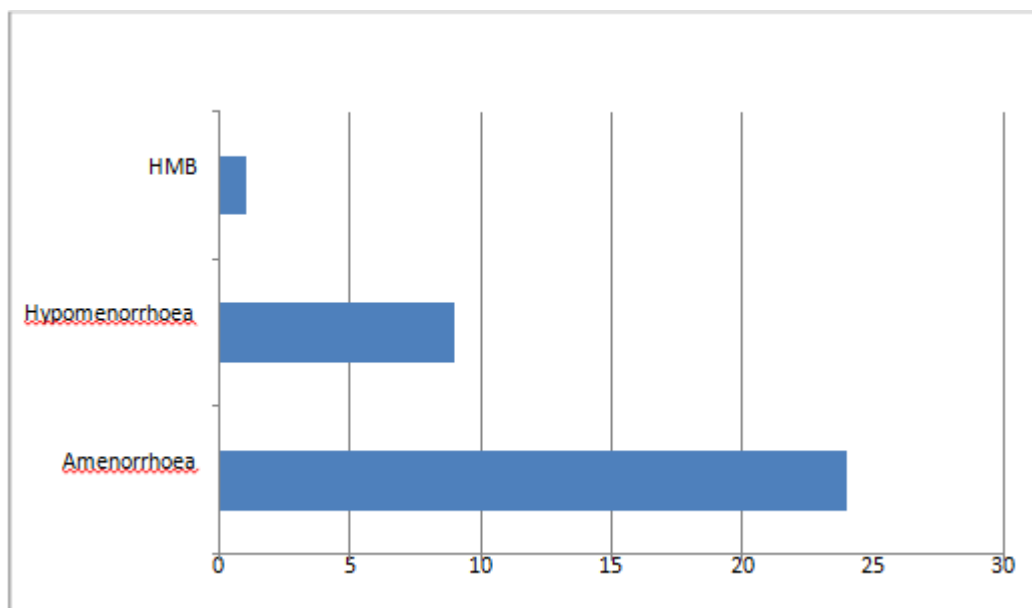
**Figure 1: Age distribution of the study population.**



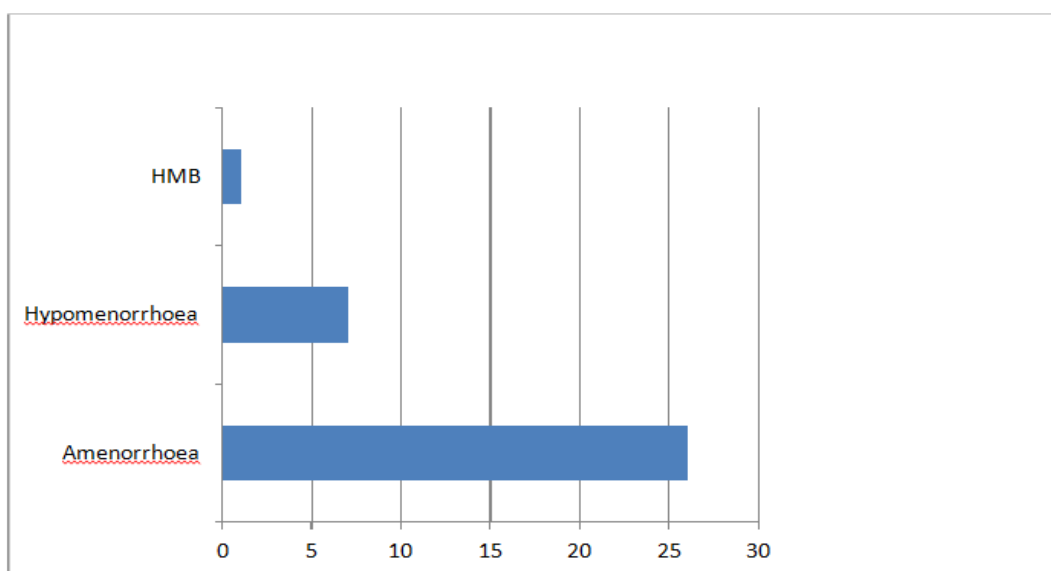
**Figure 2: Findings of endometrial biopsy of the study population**



**Figure 3: Outcome after 3 months of TBEA**



**Figure 4: Outcome after 6 months of TBEA**



**Figure 5: Outcome after 1 year of TBEA**

**Discussion**

Heavy menstrual bleeding is a common problem that affects 5-15% women in developing countries [6,7]. About 1 in 20 women in their reproductive age group consult their general practitioners for heavy menstrual bleeding and it accounts for 20% of gynaecologic outpatient consultation. Menstrual morbidities constitute an important unmet area of health services in developing countries [7].

The causes for heavy menstrual bleeding vary according to age group and so do the management of heavy menstrual bleeding. When menorrhagia fails to respond to medical therapy, hysterectomy has been the definitive treatment, but it's a major surgical procedure with significant physical and emotional complications as well as social and economic costs. Minimal invasive procedures causing ablation of endometrium reduce

complication; costs, operative duration, and hospital stay and have a short recovery period [5].

This present study was carried out in 36 cases that had undergone TBEA as a treatment for heavy menstrual bleeding. The distribution of age in the present study was 31 to 54 years with a median age of 42 years. Penezic *et al* studied women ranging from 33- 63 years with a median of 51 years [8]. Our study was concordant with the study done by hazard *et al* wherein the median age was 42 years [9].

There is an increasing prevalence of obesity worldwide and who has estimated global obesity of approximately 300 million [10]. In this study the BMI varied between 18- 40 kg/m<sup>2</sup>. However, there was no significant correlation found between BMI and chances of success of procedure. With TBEA, the possible mortality and morbidity associated with hysterectomy in obese patients can be avoided. Faikh *et al* in their study concluded that global endometrial ablation is a minimally invasive, safe and effective option for obese women with menorrhagia [11].

In this study 55.6% of patients underwent TBEA under local anaesthesia, i.e., para cervical block. This eliminates the risk associated with general anaesthesia and sub arachnoid block. Fernandez *et al* conducted a study on uterine thermal balloon therapy under local anaesthesia in 18 cases. They concluded that using endometrial ablation under local anaesthesia in clinical settings can not only reduce operative room utilization but can also decrease complications associated with general anaesthesia [12]. Pennix JP *et al* conducted endometrial ablation under local anaesthesia and concluded that it is a safe, feasible and efficacious procedure [13].

Endometrial thickness in this study ranged from 3 to 20mm. About 30.5% women with thick endometrium underwent curettage before the procedure. In this

study there was no significant correlation found between endometrial thickness and chances of success of procedure. Nashar *et al* in their study concluded that endometrial thickness less than 4 mm is a predictor of amenorrhea. They also concluded that the difference in post ablation amenorrhea between those who had uterine curettage before procedure and those who did not, was not statistically significant which was similar to our study [14]. Bongers *et al* similarly concluded that endometrial thickness of more than 4mm showed a statistically increased risk of treatment failure [15].

The study population was followed up at 3 months, 6 months and at one year post TBEA. Out of 36 cases, 26 (72.6%) became amenorrhoeic, 7 (19.4%) had hypomenorrhea and 3 (8.3%) underwent hysterectomy. Hazard and Harkins in their study in 2005 reported 40% amenorrhea, 39% moderate bleeding, 15 % minimal bleeding and 7% heavy bleeding (9). Penezic *et al* in their study showed that amenorrhea was reported by 44 of 76 (57.9%) women, 27 (35.5%) reported minimal to no bleeding, 3 patients had heavy bleeding and 21 (35.5%) patients underwent hysterectomy at 10 years of follow up (8). Amso *et al* reported that of the 162 women who had not had a hysterectomy after TBEA, 76 (46.9%) were amenorrhoeic, 48 (30%) had light bleeding, 22 (13.6%) had normal periods and 14 (8.5%) had heavy bleeding at five years of follow up [16].

Post ablative patient satisfaction rates in this study were 88.9%. Varma *et al* in their study had satisfaction rate of 78 (76%) [17]. Mayer *et al* in their comparison study between thermal balloon and rollerball ablation reported a satisfaction rates of 96% in patients who have undergone thermal ballon ablation [18]. Feitoza *et al* reported in their study that patients with amenorrhea or hypomenorrhea were more likely to be "very satisfied" with the procedure (84% and 89%, respectively) which was similar to our study [19].

Similarly Clark *et al* in 2004 reported that 67% were satisfied after TBEA [20].

### Conclusion

Based on the results of this study it can be concluded that TBEA is a suitable alternative to hysterectomy as majority of the patients developed amenorrhea in the one year follow up and most of the patient had better satisfaction rates.

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