

Outcome Predictors for Thermal Balloon Endometrial Ablation in Treatment of Abnormal Uterine Bleeding

Sudha Saluja¹, Pushpa Nagar², Shweta Goyal³, Rajani Nawal^{1*}, Nidhi Gupta⁴

¹Assistant professor, Department of Obstetrics and Gynecology, S.M.S Medical College, Jaipur Rajasthan India

²Senior Professor, Department of Obstetrics and Gynecology, S.M.S Medical College, Jaipur Rajasthan India

^{3,4}Medical Officer, Department of Obstetrics and Gynecology, S.M.S Medical College, Jaipur Rajasthan India

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*Corresponding author
Rajani Nawal

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Abstract: Abnormal uterine bleeding is defined as a change in frequency of menstruation, duration of flow and amount of blood loss. It is a significant contributor to the deterioration of quality of life in women. Thermal balloon endometrial ablation also known as uterine balloon therapy is a non hysteroscopic ablative device used for endometrial destruction without visual control [1]. This system is introduced by Neuwirth RS *et al.* It has been considered safe and effective in treating abnormal uterine bleeding when other therapies are contraindicated or difficult to perform [2]. To determine the success rate and predictors of successful outcome of uterine balloon endometrial ablation in treatment of abnormal uterine bleeding in medically morbid women. A prospective study was conducted at department of Obstetrics and Gynecology of a tertiary care hospital during the year of 2011-2012. Twenty eight women with abnormal uterine bleeding and without any detectable pathology treated with uterine balloon therapy were included in study and outcome was assessed at one, three and six months after procedure. After uterine balloon endometrial ablation, 82.1% women had successful outcome at 6 months follow up. Favourable outcome was seen more in patients with endometrial thickness < 8 mm and in patients with uterine cavity length < 10 cm. uterine balloon therapy is an effective, safe, minimally invasive, permanent, non-hormonal procedure for abnormal uterine bleeding in high risk patients. Endometrial thickness and uterine cavity length could be used as predictors of outcome. **Keywords:** Abnormal uterine bleeding, uterine balloon therapy, endometrial thickness, uterine cavity length.

INTRODUCTION

Abnormal uterine bleeding is defined as a change in frequency of menstruation, duration of flow and amount of blood loss. It is a significant contributor to the deterioration of quality of life in women. Surgical treatment is usually indicated when medical management is unsuccessful, poorly tolerated or rejected. Hysterectomy is a radical treatment but it should be the last resort. Newer techniques have been developed to accomplish endometrial destruction along with the uterine conservation. Thermal balloon endometrial ablation also known as uterine balloon therapy is a non-hysteroscopy ablative device used for endometrial destruction without visual control. Thermal balloon endometrial ablation has been considered safe and effective in treating abnormal uterine bleeding when other therapies are contraindicated or difficult to perform.

Very few studies have been conducted in India, especially western India, regarding these newer modalities like balloon ablation for treatment of

abnormal uterine bleeding. This study was conducted with the objective to assess the effect of uterine balloon endometrial ablation in treatment of abnormal uterine bleeding in terms of menstrual outcome, patient satisfaction and need for other subsequent treatment and to determine the factors associated with favourable outcome of balloon endometrial ablation.

MATERIALS AND METHODS

A prospective study was conducted at Department of Obstetrics and Gynaecology, of a tertiary care hospital of Western India during the period of November 2011 to September 2012.

Sample size: A total of 28 eligible women were included in the study. Sample size was calculated at alpha error 0.05 and study power 80%, with expected improvement in menstrual blood loss in 80% of cases and assuming 10% loss to follow up.

Eligibility criteria were decided prior to study subject recruitment and written informed consent was obtained from all subjects prior to inclusion in study.

Inclusion criteria

- Women with abnormal uterine bleeding
- Negative cervical pap smear and endometrial biopsy for malignant lesion
- Women who have completed their family.
- Women with obesity, hypertension, diabetes mellitus, previous abdominal and cardiac surgery or thyroid disorders
- Patient having an anatomically normal uterine cavity < 12cm.

Exclusion criteria

- Pathology distorting uterine cavity or any congenital malformation in uterus
- Suspected genital tract infection, malignancy or endometrial hyperplasia
- Uterine cavity depth >12 cm
- History of latex allergy
- Women who wanted to retain their fertility

Before thermal balloon ablation, all women were subjected to detailed clinical history, physical examination, investigations related to abnormal uterine bleeding including CBC, LFT, RFT, BT, CT, S.TSH, blood sugar, pap's test, pelvic ultrasonography and endometrial histological examination.

Assessment of uterine pathology done by-

- USG (for uterine architecture and endometrial thickness)
- Endometrial sampling
- Hysteroscopy
- Sono-hysteroscopy
- Cytological examination

Uterine balloon therapy (UBT) system is a software controlled device designed to ablate endometrial tissue by thermal energy, heating of sterile injectable fluid (5% dextrose in water) within a latex balloon. UBT system consists of a controller with power cord, single use sterile catheter and umbilical cable. The software contained in the medical device completely controls time and temperature for thermal ablation.

Procedure: A silicon balloon catheter is inserted through the cervix into the uterus and inflated with a small amount of sterile fluid. Catheter used is 16 cm long and 3 mm wide and at its end is a latex balloon.

During use, the catheter is inserted into the uterine cavity and the latex balloon at the distal tip is filled with two to thirty ml sterile, injectable fluid (5% dextrose in water). Fluid pressure is manually adjusted

to 160-180 mm Hg for 30-45 seconds. The heating element within the balloon can be manually activated if the pressure is above 150 mm Hg. The system achieves endometrial ablation by maintaining the fluid temperature at 87° C for 8 minutes. At the completion of heat cycle, the fluid inside the balloon is withdrawn and the balloon catheter is removed from the uterine cavity. Uterus takes 7-10 days to heal, while the woman can get back to her normal life the very next day.

Some minor side effects are common after endometrial ablation e.g. menstrual cramps like pain for 1-2 days, thin, watery discharge mixed with blood, which can last a few weeks. The discharge may be heavy for 2-3 days after the procedure. Ethical clearance was obtained from the Institute's Ethical committee prior to initiation of study.

STATISTICAL ANALYSIS

Quantitative data was presented as mean and standard deviation. Qualitative data was presented as number and percentage and was analysed using Chi square test / Fischer exact test as applicable. Analysis was done using intention to treat analysis. A p value < 0.05 was taken as statistically significant.

RESULTS

The mean age of high risk women with abnormal uterine bleeding in present study was 40.17 years (ranging from 32-48 years), which is the known to be the commonest period in life for development of abnormal uterine bleeding. In present study, 17 (60.7%) cases were from urban area and only 11 (39.3%) cases were from rural area. Most (85.7%) cases were Hindus and only 4 (14.3%) cases were Muslims (Table-1).

Successful outcome defined as attainment of amenorrhoea, Hypo/Amenorrhoea which was achieved in 75%, 82.1% of subjects at one and three months respectively. After 6 months of follow up there was no change as compared to outcome pattern at 3 month (Table 2).

Inverse relationship was observed between successful outcome and preoperative endometrial thickness. At three and six month follow up success rate was more in subjects with endometrial thickness < 8 mm and balloon therapy was less effective in patients with endometrial thickness > 8 mm (Table-3).

Increasing uterine cavity length was associated with worse outcome. Highest success rate was seen in patients with uterine cavity length < 10 cm and worst outcome with uterine cavity length >10 cm (Table-4). Uterine cavity length was found to be significantly associated with outcome at 3 and 6 months follow up (P<0.05).

Table-1: Socio-demographic profile of study subjects

| Variable | Sub group | No. of cases | % |
|------------------|-----------|--------------|------|
| Age Group (Year) | 30-34 | 5 | 17.9 |
| | 35-39 | 5 | 17.9 |
| | 40-44 | 12 | 42.9 |
| | 45-50 | 6 | 21.4 |
| Religion | Hindu | 24 | 85.7 |
| | Muslim | 4 | 14.3 |
| Residence | Urban | 17 | 60.7 |
| | Rural | 11 | 39.3 |

Table-2: Outcome of at thermal balloon ablation at different follow up time

| Outcome | Follow up time | | |
|--|----------------|-------------|-------------|
| | At 1 month | At 3 months | At 6 months |
| Successful (Amenorrhea/ Hypo/ Eumenorrhea) | 21 (75%) | 23 (82.1%) | 23 (82.1%) |
| Unsuccessful (persistent Heavy menstrual flow) | 7 (25%) | 5 (17.9%) | 5 (17.9%) |
| Total | 28 (100) | 28 (100) | 28 (100) |

Table-3: Outcomes of Balloon endometrial ablation in relation to endometrial thickness

| Follow up Time | Outcome | Endometrial thickness | | P value |
|----------------|--------------|-----------------------|--------------|---------|
| | | ≤8 mm (N=13) | >8 mm (N=15) | |
| At 1 month | Successful | 10 (76.9%) | 11 (73.3%) | 0.827 |
| | Unsuccessful | 3 (23.1%) | 4 (26.7%) | |
| At 3 month | Successful | 12 (92.3%) | 11 (73.3%) | 0.416 |
| | Unsuccessful | 1 (7.7%) | 4 (26.7%) | |
| At 6 month | Successful | 12 (92.3%) | 11 (73.3%) | 0.416 |
| | Unsuccessful | 1 (7.7%) | 4 (26.7%) | |

Table-4: Outcome of Balloon ablation in Relation of Uterine Cavity Length

| Follow up Time | Outcome | Uterine cavity length | | P value |
|----------------|--------------|-----------------------|--------------|---------|
| | | ≤10 cm (N=19) | >10 cm (N=9) | |
| At 1 month | Successful | 16 (84.2%) | 5 (55.6%) | 0.243 |
| | Unsuccessful | 3 (15.8%) | 4 (44.4%) | |
| At 3 month | Successful | 18 (94.7%) | 5 (55.6%) | 0.046* |
| | Unsuccessful | 1 (5.3%) | 4 (44.4%) | |
| At 6 month | Successful | 18 (94.7%) | 5 (55.6%) | 0.046* |
| | Unsuccessful | 1 (5.3%) | 4 (44.4%) | |

*statistically significant at $p < 0.05$

DISCUSSION

This study evaluated the effect of uterine balloon therapy on abnormal uterine bleeding in high risk surgical candidates and factors affecting favourable outcome. Mean age of patients with abnormal uterine bleeding in this study was 40.17 years which was similar to mean age of 43 years (33-53 years) reported in study by Clark *et al.* [3]. Rishma Dhillon Pai *et al.* also found mean age of 41 ± 2.5 years in patients presenting with abnormal uterine bleeding [4].

In this study, most patients (81.2%) had favourable menstrual flow outcome as was similarly reported by Swarnima *et al.* [5]. In study by Swarnima *et al.* After 3 months of UBT, 32% cases achieved Eumenorrhoea which is similar to present study results but 17.33% had Amenorrhoea and 21.33% had Hypomenorrhoea which is slightly less from present

study result. This difference might be because of difference in uterine cavity length or endometrial thickness.

Favourable outcome was seen more in patients with endometrial thickness ≤ 8 mm. This was in accordance with results of study by Swarnima *et al.* in which best results were obtained in patients with endometrial thickness < 8 mm. Another study by El-Nashar *et al.* reported UBT to be less effective in cases with Endometrial Thickness < 4 mm [6].

In present study, highest success rate was seen in patients with uterine length < 10 cm as was similarly reported by Swarnima *et al.* EL Nashar *et al.* also reported higher success rate in subjects with uterine cavity length < 9 cm.

These findings support the effectiveness of Balloon endometrial ablation in treatment of abnormal uterine bleeding in High risk patients with higher success among patients with endometrial thickness ≤ 8 mm and canal length < 10 cm.

Limitations of study – Relatively smaller sample size and lack of comparison with other treatment modality are few limitations of this study. Further studies with larger sample size and comparison groups could help better establish efficacy of the procedure and identify the independent prognostic factors.

CONCLUSION

Uterine Balloon Therapy is a minimally invasive method for premenopausal women with abnormal uterine bleeding. With good patient selection, it gives excellent results in women with coexistent medical morbidity. This method offers dual advantages of relatively conservative intervention and freedom from prolonged medical therapy. Endometrial thickness and uterine cavity length at presentation could be used as predictors of outcome of balloon therapy.

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