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Research Article

Effect of Thermal Balloon Endometrial Ablation in Management of Menorrhagia in High Risk Surgical Candidates

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Abstract: To study the effect of thermal balloon endometrial ablation in management of menorrhagia in high risk surgical candidates. The method is thirty patients with menorrhagia who were high risk candidates for surgery underwent uterine balloon therapy. Results were statistically analyzed regarding procedure, safety, side effects and prognostic factors at follow-up periods of one month, three months, and six months. After undergoing uterine balloon therapy 39.28% had amenorrhea, 10.7% had hypo menorrhea, 32.14% had eumenorrohea, and 14.28% had persistence of menorrhagia at 6 months follow up. Prolonged duration of menstruation, endometrial thickness of at least 8mm and uterine depth >8 cm were associated with an increased risk of treatment failure. Thermal balloon endometrial ablation is safe and effective in treating menorrhagia when other therapies are contraindicated or difficult to perform.
Keywords: menorrhagia, uterine balloon therapy, endometrial ablation.

INTRODUCTION

Menorrhagia is Greek word, men means menses and rrhagia means burst forth. It is essentially a symptom and not in itself a disease. It is a significant contributor to the deterioration of quality of life among women and also towards health care costs [1].

Surgical treatment is usually indicated when medical management is unsuccessful, poorly tolerated or rejected. Although hysterectomy provides a cure for menorrhagia. It is often accompanied by numerous intra operative, postoperative complications, physical and psychological implications.

Endometrial ablation is safe and effective in treating menorrhagia when other therapies are contraindicated or difficult to perform [2]. Neuwirth RS *et al*.; [3] introduced a thermal uterine balloon therapy system. It offers women the dual advantages of relatively conservative surgery and freedom from prolonged medical therapy.

METHODS

This prospective randomized clinical trial study was conducted in the Department of Obstetrics and Gynecology, SMS Medical College, Jaipur during the year 2011-2012.

Thirty patients were treated with uterine balloon therapy for menorrhagia. Patients having an anatomically normal uterine cavity not greater than 12 cm along with a negative cervical pap's smear and endometrial biopsy for premalignant and malignant lesions and a normal pelvic sonography. Those who are at high risk to surgery, obese, having diabetes, thyroid disorders, hemolytic anaemia, hypertension, bleeding diathesis or underwent uterine and other abdominal surgeries, previous cardiac surgeries, patients on anticoagulant therapy and other medical disorders were included in the study.

Exclusion criteria included atypical endometrial hyperplasia, pathology distorting uterine cavity, suspected genital tract infection or malignancy, desire for preservation of fertility, previous classical caesarean section or transmural myomectomy and history of latex allergy. Before thermal balloon ablation, all patients were subjected to exhaustive clinical history, physical examination, investigations, Pap's test, pelvic sonography and endometrial histologic examination. Preprocedure data were recorded regarding the duration of menstrual flow, phase of endometrium, preprocedure sonographic thickness of endometrium, length of cavity.

The Uterine Balloon System was used for the procedure, according to the manufacturer's instructions. The device is preset to heat 5% dextrose water in the balloon to 87°C, which sustains the intrauterine pressure within 160 to 180 mmHg, for 8 minutes. The

procedure was done in the operation theatre under general, local or regional anesthesia. The patients undergoing the procedure were reviewed at one, three, six months postoperatively or if any problem was felt and analysis of the variables was done regarding the outcome of the procedure. Reduction in the blood flow from menorrhagia to eumenorrhea or less was the cut off for success of the procedure.

RESULTS

Follow up data at 1 month, 3 month and 6 months of menstrual flow were included in the statistical analysis for this report:

Women with menorrhagia, at high risk because of hematological disorders [4] , heart ailments [7], endocrinological disorder [6], respiratory disorder [2] , multiple surgeries [4] , mutisystemic diseases [7] majority of them were obese, subjected to balloon therapy procedure (Table 1).

Table-1: Distribution of Cases According to History of Medical and Surgical Illness

Medical and Surgical Illness	No. of Cases	%
Hematological disorder	4	13.33
Endocrinological disorder	6	20.00
Cardio vascular disorder	7	23.33
Respiratory disorder	2	6.67
Multiple surgeries	4	13.33
Multi systemic diseases	7	23.34
Total	**30**	**100.00**

Balloon therapy was done successfully under local anesthesia (paracervical block) in 16 cases. General anesthesia was administered to 13 cases. 20 Cases tolerated procedure well, 9 cases suffered from abdominal pain, 1 case suffered- from severe pain, respiratory discomfort and hypotension during procedure (Table 2).

Table-2: Balloon Therapy Procedure: type of anaesthesia, intraoperative complications, post procedural complaints

	No. of Cases	%
Type of Anaesthesia		
Local anaesthesia	16	53.33
General anaesthesia	13	43.33
Local changed to General anaesthesia	1	3.33
Complains During Procedure		
Pain abdomen	9	30.00
Respiratory discomfort and Hypotension	1	3.33
Post Procedural Complaints		
Discharge PV	4	13.33
Pain abdomen	8	26.67
Bleeding PV	1	3.33
Discharge PV and pain abdomen	3	10.00

Endometrial thickness measured by transvaginal sonography prior to procedure. At 1 month, 8 cases with ET 6-8mm had successful outcome. While 10 cases with ET 9-11 had successful outcome and 4 cases were unsuccessful at the end of 1 month (Table 3).

Table-3: Outcome of the Procedure in Relation to Thickness of Endometrium

Thickness of Endometrium (mm)	No. of Cases	Outcome of the procedure					
		At 1 month		At 3months		At 6 months	
		Successful	Unsuccessful	Successful	Unsuccessful	Successful	Unsuccessful
<5	2	1	1	2	0	2	0
6-8	'11	8	3	10	1	10	1
9-11	14	10	4	10	4	11	3
12	1	1	0	1	0	1	0
Total	**28**	**20**	**8**	**23**	**5**	**24**	**4**

Uterine cavity length measured by uterine sound during balloon therapy procedure. With cavity length of 6.35 cm successful outcome was seen in 2 cases. With cavity length of 7.62 only 1 unsuccessful outcome seen while 6 cases were successful. With cavity length 8.89, eight cases had successful outcome. Later on at 3 and 6 months 10 cases had successful outcome and none had unsuccessful outcome. There were 4 cases with successful outcome with cavity length 10.16. With cavity length of 11.43 two cases had unsuccessful outcome and only one succeeded (Table 4).

Table-4: Outcome of the Procedure in Relation to Uterine Cavity Length

Length of cavity (in cm) approx.	No. of Cases	Outcome of the procedure					
		At 1 month		At 3months		At 6 months	
		Successful	Unsuccessful	Successful	Unsuccessful	Successful	Unsuccessful
6.35	2	2	0	2	0	2	0
7.62	7	6	1	6	1	6	1
8.89	10	8	2	10	0	10	0
10.16	6	4	2	4	2	4	2
11.43	3	1	2	1	2	1	2
Total	**28**	**21**	**7**	**23**	**5**	**23**	**5**

Menstrual pattern obtained after first, third and six months during follow up. 2 cases out of 30 lost to follow-up. 28 cases were followed-up out of which 39.28% case had amenorrhea at the end of 3 and 6 months. 10.7% had hypomenorrohea at the end of 6 months, 32.14 % cases had eumenorrrohea and menorrhagia persisted in only 14.28% cases at 3rd and 6 months (Table 5).

Table-5: Relation of Thermal Balloon Ablation with Post Procedural Menstrual Pattern

Menstrual Pattern	Outcome of the procedure		
	At 1 month	At 3 months	At 6 months
Amenorrhea	10 (35.71%)	11(39.28%)	11 (39.28%)
Hypomenorrhea	1 (3.57%)	3 (10.7%)	3 (10,7%)
Eumenorrohea	9 (32.14%)	9 (32.14%)	9 (32.14%)
Menorrhagia	8 (28.57%)	4 (14.28%)	4 (14.28%)
Total	**28 (100.00)**	**28 (100.00)**	**28 (100.00)**

DISCUSSION

This study evaluated the effectiveness of uterine balloon therapy for menorrhagia in high risk surgical candidates and its correlation with prognostic factors.

30 candidates with coexistent medical morbidities or high risk factors for surgery safely underwent UBT. No major intra operative complication occurred and postoperative morbidity was minimal. Similarly in a study by Aletebi FA *et al*; [4] high risk women with menorrhagia underwent UBT with minimal intraoperative and postoperative morbidity.

UBT undertaken under LA in 17 cases with or without sedation. 16 cases underwent procedure under LA successful!'/. In 13 cases procedure done successfully under effect of GA. Similar results were obtained in study done by H Fernandez *et a*l .; [5] all eighteen cases underwent UBT successfully under LA during the procedure.

Inverse relationship was observed between successful outcome and preoperative endometrial thickness. In our study success rate was more with endometrial thickness <8mm and balloon therapy was less effective with endometrial thickness >8 mm. This is in accordance to study done by Swarnima *et al.*; [6] in which, best results were obtained with endometrial thickness of <8 mm, whereas ES-Nashar *et al.*; [7] concluded that thermal balloon ablation is less effective in cases with an endometrial thickness of >4 mm.

Increasing uterine cavity length was associated with worst outcome. Our study showed best results with uterine cavity length of <8 cm and worst outcome with uterine cavity length of >10 cm. This is in accordance with study of Swarnima *et al.;* [6], best results were seen with uterine cavity length of <8 cm, EL Nashar *et al.;* [7] reported more success with cavity length of <9 cm, Nazar N Amso *et al.;* [8] reported improved outcomes with shorter uterine cavity but Vilos et al [9] found no significant effects of cavity length on the outcome.

Heaviness and duration of menstrual flow decreased significantly after the procedure. At first month of follow-up, 35.71% had amenorrhea, 3.57% had hypo menorrhea, 32.14% had eumenorrohea, 28.57% still had menorrhagia.

After 3rd month of follow up 39.28% had amenorrhea, 10.7% had hypomenorrhea, 32.14% had eumenorrohea, and 14.28% had persistence of menorrhagia. After 6 month of follow up 39.28% had amenorrhea, 10.7% had hypomenorrhea, 32.14% had eumenorrohea, and 14.28% had persistence of menorrhagia.

In a similar study, Bongers *et al.;* [10] reported 18% of the cases with complete amenorrhea at three months follow-up, 2.1% at six months follow-up and 22% at one year follow-up. These rates were 42%, 39%, 43% and 57% respectively for menstruation of less than four days.

In study by H. Fernandez *et al*.; [5] all 18 cases had a decrease or normalization of their excessive menstrual bleeding and six (33%) cases had amenorrhea 1 year after the procedure. In a study by Shaamash *et al.;* [11] at 2-year follow-up the overall improvement of menstrual pattern was 85%; with reported 29% amenorrhea, 23.5% hypomenorrhea and 32.5% euomenorrhea. Menorrhagia persisted in 15% of cases.

CONCLUSION

UBT is a minimally invasive procedure. It appears to be the treatment of choice for menorrhagia during perimenopause in cases who are reluctant to undergo hysterectomy. With good case selection balloon therapy can be done under local anaesthesia. It is a boon for women with coexistent medical morbidity because general anaesthesia is not mandatory for this procedure. The facts that bleeding was significantly reduced in amount and duration by thermal balloon endometrial ablation, no intraoperative complication occurred, and postoperative morbidity was minimal. UBT can be considered as a safe and effective therapy.

REFERENCE

1. Coulter A, Kelland J, Long A; The management of menorrhagia. Effective Health Care Bulletin, 1995; 9: 1-14.
2. Lalonde A; Evaluation of surgical options in menorrhagia. Br J Obstet Gynecol, 1994; 101(11): 8-14.
3. Neuwirth RS, Duran AA, Singer A, MacDonald R, Bolduc L; The endometrial ablator: A new instrument. Obstet Gynecol, 1994; 83: 792-6.
4. Fatima A Altebi, George Vilos MT; Journal of American Association of Gynecologic Laparoscopies, 1999; 6(4): 435-439.
5. Fernandez H, Capella S, Audibert F; Uterine thermal bailoon therapy under local anaesthesia for the treatment of menorrhagia: a pilot study. Hum Reprod, 1997; 12(11): 2511-4.
6. Agarwal Swarnima, Bhargava Adarsh, Chuttani Nimmi, Nagar Pushpa; Uterine balloon therapy in treatment of menorrhagia. Journal of Obstetrics and Gynaecology of India, 2011; 67-71.
7. El-Nashar SA, Hopkins MR, Creedon DJ, Cliby WA, Famuyide AO; Efficacy of bipolar radiofrequency endometrial ablation vs thermal balloon ablation for management of menorrhagia: A population-based cohort. Minim Invasive Gynecol, 2009; 16(6): 692-9.
8. Nazar N. Amso, Herve A Fernandez, George Vilos, Claude Fortin, Peter McFaul, Monika Schaffer et al.;Uterine endometrial thermal balloon therapy for the treatment of menorrhagia: long-term multicentre follow-up study. Human Reproduction, 2003; 18(5): 1082-1087.
9. Vilos GA, Fortin Ca, Sanders B, Pendley L, Stabinsky SA; Clinical trial of the uterine thermal balloon for treatment of menorrhagia. J Am Assoc Gynecol Laparoscopy, 1997; 4(5): 559-65.
10. Bongers MY, Bourdrez P, Heintz AP, Brolmann HA, Mol BW; Bipolar radio frequency endometrial ablation compared with balloon endometrial ablation in dysfunctional uterine bleeding: impact on patients' health- related quality of life. Fertile Sterile, 2005; 83(3): 724-34.
11. Shaamash AH, Sayed EH; Prediction of successful menorrhagia treatment after thermal balloon endometrial ablation. J Obstet Gynaecol Res, 2004; 30(3): 210-6.