Original Article

Uterine Balloon Therapy for the treatment of Menorrhagia

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Abstract

Objective(s): To evaluate the effectiveness of uterine balloon therapy for the treatment of menorrhagia and to determine its prognostic factors. **Method(s):** Seventy five patients were treated with uterine balloon therapy with thermachoice II for intractable menorrhagia without detectable pathology and the results were statistically analyzed regarding procedure efficacy, safety, side effects and prognostic factors at follow-up periods of one month, three months, six months and 12 months. **Results(s):** After undergoing uterine balloon therapy, 41.30% patients attained eumenorrhea, 30.43% hypomenorrhea and 15.21% amenorrhea at the end of 12 months follow-up. Retroverted uterus, prolonged duration of menstruation, endometrial thickness of at least 9mm and uterine depth >10 cm were associated with an increased risk of treatment failure. **Conclusion(s):** Uterine balloon therapy is an efficient and reliable modality to treat women with intractable menorrhagia especially those who have completed their families but do not want to part with their uterus which of course is without any organic pathology.

Keywords : menorrhagia, uterine balloon therapy, endometrial ablation

Introduction

Menorrhagia is a significant contributor to the deterioration of quality of life among women and also towards health care costs.

Surgical treatment is usually indicated when medical management is unsuccessful, poorly tolerated or rejected. Hysterectomy is unquestionably the radical solution for menorrhagia but because of the cost, risks of peri and post operative complications, emotional impli-

cations and no histological abnormality found in majority of the cases, the question of validity of such extirpative surgery for this problem is raised.

Newer techniques have been developed to accomplish endometrial destruction along with uterine conservation as a treatment option for women with intractable uterine bleeding who wish to retain their uteri. Thermal balloon endometrial ablation or uterine balloon therapy is a non-hysteroscopic endometrial ablative device used for endometrial destruction without visual control in premenopausal women. It is a quick and safe procedure and does not require specialized skill. It has less post-operative morbidity and shorter recovery period and can be performed as day surgery with or without general anesthesia.

Methods

The study was conducted at the Department of Obstet-

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Seventy five patients were treated with uterine balloon therapy for intractable menorrhagia without detectable pathology. Patients having an anatomically normal uterine cavity of at least four centimeters but not greater than 12cm along with a negative cervical pap's smear and endometrial biopsy for premalignant and malignant lesions and a normal pelvic sonography were included in the study.

Exclusion criteria included atypical endometrial hyperplasia, pathology distorting uterine cavity, suspected genital tract infection or malignancy, uterine cavity depth >12cm, previous endometrial ablation, desire for preservation of fertility, previous classical cesarean 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, position of uterus and pretreatment endometrial thinning regimens (included follicular phase timing, uterine curettage, and hormonal manipulation).

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 and 12 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.

Table - 1

Outcome of the procedure in relation to pretreatment endometrial preparation

Pretreatment	Outcome of the procedure					
	At 3 months		At 6 months		At 12 months	
	Successful	Unsuccessful	Successful	Unsuccessful	Successful	Unsuccessful
Used						
None	5	1	4	1	2	-
Follicular Phase Thinning	9	2	6	1	4	1
Curettage	46	2	41	1	32	1
Danazol	9	-	7	-	6	-
GnRH	1	-	1	-	-	-
Total	70	5	59	3	44	2

Table – 2

Outcome of the procedure in relation to thickness of endometrium

Thickness of Endometrium (mm)	Outcome of the procedure					
	At 3 months		At 6 months		At 12 months	
	Successful	Unsuccessful	Successful	Unsuccessful	Successful	Unsuccessful
< 5	16	0	14		0	11
5-8	43	1	37	0	28	0
9-12	10	1	7	1	4	1
> 12	1	3	1	2	1	1
Total	70	5	59	3	44	2

Table – 3

Outcome of the procedure in relation to length of cavity

Length of cavity (cm)	Outcome of the procedure					
	At 3 months		At 6 months		At 12 months	
	Successful	Unsuccessful	Successful	Unsuccessful	Successful	Unsuccessful
6.35	1	-	1	-	-	-
7.62	16	1	12	-	8	-
8.89	43	2	38	1	30	-
10.16	8	1	6	1	5	1
11.43	2	2	2	1	1	1
Total	70	6	59	3	44	2

Results

Follow up data at 3 and/or 6 and/or 12 months of menstrual flow were mandatory for inclusion in the statistical analysis for this report. Twelve months data were available for 46 of the 75 women (61.33%).

Pretreatment endometrial preparation with Danazol (200mg twice daily for at least a week) and GnRh analogue (single depot injection of 3.75mg four weeks prior to the procedure) were associated with successful outcome as compared to prior curettage or follicular phase thinning (Table 1).

Successful outcome showed an inverse relationship

with the preoperative sonographic thickness of endometrium. Best results were obtained with the endometrial thickness of <8 mm (Table 2).

Uterine cavity depth adversely affected the treatment outcome. Best results were seen with uterine depth <8 cm and worst outcome with uterine depth >10cm (Table 3).

Majority of the patients (62.67%) had anteverted uterus while retroverted uterus was found in 28% of the cases. Retroverted uterus was associated with more failures than anteverted and axial uterus (Table 4).

Significant decrease was found between pre and post

Table – 4**Outcome of the procedure regarding menorrhagia in relation to uterine position**

Uterine position	Outcome of the procedure					
	At 3 months		At 6 months		At 12 months	
	Successful	Unsuccessful	Successful	Unsuccessful	Successful	Unsuccessful
Anteverted	45	2	39	1	29	-
Mid Position	6	1	4	-	3	-
Retroverted	19	2	16	2	12	2
Total	70	5	59	3	44	2

Table – 5**Relation of thermal ablation with postprocedure menstrual pattern**

Menstrual pattern	At 3 months	At 6 months	At 12 months
	No. of patients (%)		
Amenorrhea	13(17.33%)	12(19.35%)	7(15.21%)
Hypomenorrhea	16(21.33%)	17(27.4%)	14(30.43%)
Eumenorrhea	24(32%)	22(35.5%)	19(41.30%)
Metrorrhagia	17(22.67%)	8(12.9%)	4(8.69%)
Menorrhagia	5(6.67%)	3(4.83%)	2(4.34%)
Total	75	62	46

procedure heaviness and duration of menstrual flow, indicating the success of the procedure (Table 5).

Discussion

This study evaluated the effectiveness of uterine balloon therapy for menorrhagia and its correlation with prognostic factors.

Varied pretreatment endometrial thinning regimens were used viz. follicular phase timing, uterine curettage, and hormonal manipulation. Pretreatment with danazol and GnRh analogue were associated with 100% successful outcome (Table 1). These findings are supported by Amso et al¹ who reported statistically higher rates of post procedure amenorrhea in women receiving GnRh analogue before balloon treatment. Contrary to our study they experienced more failures in cases that had

dilatation and curettage prior to the procedure. Vilos et al² found no significant effect of preoperative endometrial preparation on the clinical outcome, which is in contrast to the present study (Table 1). Sowter³ reported that when compared with no treatment, GnRH analogues were associated with a higher rate of postoperative amenorrhea at 12 months. GnRH analogues produce more consistent endometrial atrophy than danazol.

Inverse relationship was observed between successful outcome and preoperative endometrial thickness. Best results were obtained with endometrial thickness of <8 mm in our study (Table 2), whereas Bongers⁴ and El-Nashar et al⁵ concluded that thermal balloon ablation is less effective in patients with an endometrial thickness of >4mm.

Increasing uterine depth was associated with failures. Our study showed best results with uterine depth <8 cm and worst outcome with uterine depth >10 cm (Table 3). Shaamash⁶ also demonstrated the shorter uterine depth as a predictive factor for successful outcome but Vilos et al² found no significant effects of cavity depth on the outcome.

Retroverted uterus was associated with more failures than anteverted and axial uterus (Table 4). Same was reported by Bongers⁴.

Heaviness and duration of menstrual flow decreased significantly after the procedure. At three months follow-up, 32% of the patients achieved eumenorrhea, while hypomenorrhea was observed in 21.33% cases; 17.33% of the cases achieved amenorrhea, 22.67% of the patients complained of spotting off and on 6.6% of the patients continued to bleed as previously (Table 5).

After six months, 35.5% of the cases attained eumenorrhea, while hypomenorrhea occurred in 27.4% of the cases. After six months 19.35% of the cases were amenorrheic and 4.8% of the cases still had menorrhagia.

At 12 months follow-up, 41.3% of the patients reported normal periods while 30.43% were having hypomenorrhea. Even after 12 months post-procedure, 15.21% of the patients were amenorrheic. Two patients who still reported menorrhagia underwent hysterectomy for their problem.

In a similar study, Bongers⁴ reported 18% of the patients with complete amenorrhea at three months follow-up, 21% 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. These results closely resemble our observations. Buckshee⁷ reported 92.3% hypomenorrhea and 15.4% amenorrhea. In contrast, amenorrhea was reported by 14% and eumenorrhea by 54% of the women in the study by Ahonkallio⁸

Conclusion

Thermal balloon ablation is an outpatient treatment, re-

quiring no extra expertise for unexplained menorrhagia for women who do not want future pregnancy and who have no other indications for hysterectomy. The convenience of this ambulatory therapy will benefit the patients by expediting effective treatment for this entity. It is a boon for women with coexistent medical morbidity because general anaesthesia is not mandatory for this procedure. In addition, potential economic benefits of this therapy are not questionable.

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