

Experience With Uterine Balloon Therapy For Dysfunctional Uterine Bleeding

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Abstract

Uterine balloon therapy is a minimally invasive technique for dysfunctional uterine bleeding done on day care basis. It can be offered as a treatment of option to women who have completed their family and have a diagnosis of dysfunctional uterine bleeding. The study was undertaken to analyse the success rate, complications of UBT and incidence of patients requiring alternative methods of treatment for DUB. Twenty four patients were treated with UBT (Thermachoice) for DUB. Efficacy of the procedure was analyzed at follow up periods of one, 3, 6 and 12 months. After undergoing UBT, at twelve months follow up, amenorrhea was achieved in 29.17% of patients, 33.33% were having oligomenorrhea, 33.33% were eumenorrheic and no response was seen in 4.17% of patients. Our overall treatment success and patient satisfaction rate was 95.83%. Uterine balloon therapy is a safe, minimally invasive day care procedure requiring no extra expertise for the treatment of DUB in patients who want to save uterus with instant results. Post procedure there is improved patient well being and high treatment satisfaction.

Key Words

Dysfunctional uterine bleeding (DUB), Uterine balloon therapy (UBT)

Introduction

Dysfunctional uterine bleeding (DUB) describes all forms of conditions where there is abnormal bleeding for which any organic cause cannot be found. It is classified as ovulatory (polymenorrhoea, polymenorrhagia and menorrhagia) or anovulatory (acyclical heavy bleeding). This bleeding is a common cause of iron-deficiency anaemia contributing to worsening of health (1) with deteriorated quality of life and exaggerated cost of medical expenditure due to increased number of ill health days in a year.

When medical treatments fail to provide satisfactory relief from DUB, surgical interventions, including hysterectomy or annihilation of the endometrium, can be considered. (2) To begin with first generation endometrial ablation techniques like rollerball ablation, transcervical resection, and laser ablation were performed under direct hysteroscopic vision to treat abnormal uterine bleeding. These procedures led to significant decrease in the

number of hysterectomies performed. (3) Over the past decade, second generation non-hysteroscopic techniques have become the method of choice for treating DUB. Complete destruction of endometrium in the uterine cavity is achieved using high temperature fluids within a balloon (Thermachoice and Cavaterm) (4,5,6) or application of microwave (Microsulis) (7,8) or bipolar radiofrequency electrical energy (Novasure). (9)

Uterine balloon therapy (Thermachoice) (*Fig 1*) a second generation endometrial ablation technique is a safe, effective, acceptable, simple to perform, readily available technique with instant results for the management of DUB. This procedure does not require any specialized skill, has less postoperative morbidity with shorter recovery period and can be performed in day care surgery settings under regional or general anaesthesia.

Material and Methods

In this retrospective study, 24 adult female patients

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who had undergone UBT for DUB from July 2004 to June 2006 and were followed till June 2007 in the Department of Obstetrics and Gynecology at Mohan Dai Oswal Cancer Treatment and Research Foundation, Ludhiana, Punjab, India, were analyzed. UBT was performed in these patients if:

1. Patients had intractable menorrhagia / polymenorrhagia without any organic cause
2. Further fertility was not a concern
3. Patients were pre menopausal
4. They had a normal uterine cavity with uterine length from 4 to 12cm
5. Patients had no uterine or cervical pathology
6. Informed consent for UBT was taken

Before thermal balloon ablation, all patients were subjected to meticulous clinical history, physical examination and routine investigations (CBC, BT - CT, RFT, ECG and Chest X Ray). Ultrasound pelvis, PAP smear and D&C was done in all the patients to rule out any uterine pathology.

The Uterine Balloon Therapy System (THERMA CHOICE SYSTEM, *Fig 1*) was used for the procedure according to the manufacturer's instructions. Pre treatment endometrial preparation was done by sharp curettage in all the patients. A balloon tipped, 16cm long, 5mm diameter catheter with a heating element contained in a latex balloon on the treatment end was used. The device was preset to heat 5% dextrose water in the balloon to 87°C, which sustained the intrauterine pressure within 160 to 180 mmHg, for 8 minutes. The procedure was done in the operation theatre under general or spinal anaesthesia. After the therapy was over, the temperature of the balloon was allowed to come down to 50 degrees, 5% dextrose was taken out followed by gentle balloon extraction. At the end of the procedure, all patients were given injection diclofenac sodium (75mg) intramuscularly for pain relief. Vitals of the patient were monitored throughout the procedure and they were shifted to recovery room in a stable condition. All patients who underwent the procedure were reviewed at one, three, six and 12 months on follow up or if any problem was felt by them at any time of observation period.

Results

In our study, age of the patients ranged from 21 to 50 years (< 30 years 3 patients, 30- 40 years 13 patients, 41-50 years 8 patients). Twenty one patients had 1 to 3 and three patients had more than 3 children. Menorrhagia was the presenting complaint in 75% (18) patients, while

6 presented with polymenorrhagia. Endometrial thickness on USG was 6-10mm in 11, less than 6mm in 9, 10-15mm in 2 and 16-20mm in 2 patients. In 21 patients the uterine length varied between 7-10cms whereas in rest of the three patients it was 4-7cms. On histopathological examination after D&C, 15 were proliferative, 8 secretory and 1 was cystic hyperplasia. The procedure lasted from 20-30 minutes and was done under general anaesthesia in 23 and spinal anaesthesia in one patient. No complications were seen during or after the procedure. All patients who underwent UBT under general anaesthesia were discharged on the same evening in supervision of a responsible attendant and instructions were given to report back immediately in case any problem was observed. All patients were advised to use some contraception method in future. One patient who underwent procedure under spinal anaesthesia was discharged next day in a satisfactory condition. The response to the UBT was observed as shown in *Table I*.

Discussion

Our study evaluated the effectiveness of uterine balloon therapy for DUB. Majority of the patients were around 40 years of age with endometrial thickness near 10 mm and uterine length 7-10 cm. Amount and duration of menstrual bleeding decreased significantly after endometrial ablation by Uterine Balloon Therapy. At three months follow up amenorrhea was seen in 20.83% of patients, 37.5% were having oligomenorrhea, 33.33% were eumenorrhic and no response was seen in 8.34% of patients. At six months follow up amenorrhea was achieved in 25% of patients, 37.5% were having oligomenorrhea, 33.33% were eumenorrhic and no response was seen in 4.17% of patients. At twelve months follow up amenorrhea was achieved in 29.17% of patients, 33.33% were having oligomenorrhea, 33.33% were eumenorrhic and no response was seen in 4.17% of patients. Our overall treatment success and patient satisfaction rate was 95.83%.

A randomized control trial by Meyer, *et al* (4), showed that thermal endometrial ablation (Gynecare Thermachoice) was successful in reducing menstrual flow in 80% of the cases with amenorrhea in 15% cases at 12 months of follow up. Patient's satisfaction rate was 86% and no intraoperative complication was seen. Mean age of patients in their study was 40 years. Out of total 128 cases, hysterectomy was done in 2 cases within one year.

In 2009, Karamanidis, *et al* (10) treated 72 premenopausal menorrhagic women with two-minute hot

Table 1. Response (menstrual pattern) and satisfaction of the patient to UBT

Menstrual Pattern	At 3 months	At 6 months	At 12 months
	Number of patients (%age)		
Amenorrhea	5(20.83)	6(25.00)	7(29.17)
Oligomenorrhoea	9(37.50)	9(37.50)	8(33.33)
Eumenorrhoea	8(33.33)	8(33.33)	8(33.33)
No response	2(8.34)	1 (4.17%)	1 (4.17%)
Patient satisfaction	22(90.67)	23(95.83)	23(95.83)

Fig1. Uterine Balloon Therapy (THERMACHOICE SYSTEM) used



liquid balloon endometrial ablation system (Thermablate) and showed a trend towards reduced monthly blood flow. Combined amenorrhea and hypomenorrhea rates at 3, 6, 12 and 24 months were 39%, 73%, 77% and 70%, respectively. The corresponding satisfaction rates were 86%, 93.5%, 93.5% and 82.4%, respectively. These results closely bear a resemblance to our observations.

In a 10 years experience for effectiveness of a global method of endometrium ablation - Thermachoice (Gynecare; Johnson & Johnson) balloon therapy in treatment of excessive uterine bleeding, Hrazdirova *et al* (11) showed that out of 92 women, 38% were amenorrheic at 12 months follow up and five years later there were 63% of them. Thirteen women (14%) ended with hysterectomy - two patients without any connection with the operation. In 3 cases there was a therapeutic cycle failure, because the acquired intrauterine pressure was not reached.

In our study, hysterectomy was done in one patient in whom no response was seen following UBT. No intra or post operative complications were seen during our study. All our patients except one with failure of the response to the therapy were highly satisfied with the treatment given to them.

Conclusion

Uterine balloon therapy is a safe, minimally invasive, day care procedure for the treatment of DUB in patients who want to save uterus and have completed their family. Other benefits are convenience of the procedure and no extra expertise is required to perform the procedure.

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