

Thermal balloon endometrial ablation in dysfunctional uterine bleeding

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ABSTRACT

Objective: To study the clinical efficacy, safety and acceptability of endometrial ablation by uterine balloon therapy in dysfunctional uterine bleeding. **Methodology:** This prospective study was carried out from February 2001 to February 2012. Endometrial ablation was done on 35 patients having dysfunctional uterine bleeding (DUB) not responding to medical treatment. Patients were evaluated by proper clinical examination and investigations to rule out other causes of menorrhagia. Results were analysed to find out efficacy, safety and acceptability of uterine balloon therapy (UBT). **Results:** Within one year 7 (21.2%) patients became amenorrhic. Oligomenorrhoea and eumenorrhoea occurred in 19(57.5%) and 4(12.1%) patients respectively. Hysterectomy had to be done in 5 patients including 1 for endometritis, 2 for cellular atypia (detected in concurrent Dilatation and Curettage) and 2 for persistent menorrhagia. Regarding patients of high surgical risk hysterectomy could be avoided in 15 out of 16 cases having medical disorder and 6 out of 9 post CS cases. Except one case of endometritis no other complication observed. Excluding 2 cases of cellular atypia, 30 out of 33 patients were satisfied showing a success rate of 90.91%. **Conclusion:** UBT is a safe, easy to use, effective and minimally invasive procedure. Creating awareness acceptability can be increased to avoid hysterectomy and related morbidity.

Keywords: Uterine balloon therapy, dysfunctional uterine bleeding

Hysterectomy was the only option till few years back for cases of menorrhagia not responding to medical therapy. Emergence of various techniques of endometrial ablation has made it possible to avoid hysterectomy today in majority of such cases [1]. First generation techniques roller ball (RB) ablation [2] or transcervical resection of endometrium (TCRE) are highly effective but special training is required as these

are done hysteroscopically and even may lead to serious complication at times. This led to subsequent introduction of safer, non-hysteroscopic second generation procedures for endometrial ablation [3]. Uterine balloon therapy (UBT) is one of the earliest second generation technique originally introduced by Neuwirth in 1994 [4]. It is safe, easier, day care procedure with short recovery period and efficacy is

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comparable to first generation technique as observed in several studies. There was widespread use and rapidly rising acceptability of UBT since its introduction into clinical practice in 1995. Menorrhagia is a common gynecological problem and was the most common indication of hysterectomy which can be avoided today by much easier procedure like endometrial thermal ablation. Hence this study was carried out with the aim to find out efficacy, safety and acceptability of endometrial ablation by UBT in DUB.

Materials and Methods

In this prospective study from February 2001 to February 2012 thirty five (35) cases of DUB not responding to medical treatment were managed by thermal ablation using Thermachoice UBT unit at International Hospital, Guwahati. Patients desirous of future childbearing, with uterine cavity length > 10cm were not taken up for this mode of therapy. During counseling patients were asked about their awareness regarding UBT and were explained about the procedure and possibility of amenorrhoea, transient abdominal cramp and vaginal discharge for 10-14 days following UBT. Patients were evaluated by proper clinical examination and following investigations to rule out other causes of menorrhagia and malignancy or pre-malignant lesion; R/E blood, Sr. creatinine, platelet count, TSH, pelvic USG, D&C and Pap smear. In 5 cases concurrent D&C was done as they were in the midcycle and hysterectomy had to be done in 2 of them for cellular atypia and were excluded from follow up. In 30 cases UBT was done in follicular phase. Thermal ablation was done under general anesthesia and anteverted or retroverted position of uterus was noted. Length of uterine cavity was measured and cervical dilatation was done just to insert the balloon catheter. The balloon was checked before insertion for leakage by distending with 30 ml. of 5% dextrose. Fluid is then gradually withdrawn till a negative pressure of -150mm Hg is achieved. With this negative pressure balloon is inserted in the uterine cavity and 5% dextrose is gradually instilled till intrauterine pressure is 160-180mm Hg. Maximum 30ml of fluid required to

achieve this starting pressure. Then the heating element was activated and treatment cycle commenced when the fluid temperature reached 87°C and continued for 8 minutes. Balloon is slowly deflated then withdrawn once temperature becomes normal. Patients were given prophylactic antibiotic and antispasmodic for 2 days and were allowed to go home after 2 -4 hours. Cases were followed up to know the outcome.

Results and Observations

Total number of cases was 35 in 11 years. Patients were in the age group of 29 – 51 years with 13 cases less than 40 years and 22 cases more than 40 years. Thirty out of 35 (85.5%) cases were not aware about UBT.

Hb% level ranged from 6gm% to 9gm% and 4 required blood transfusion. Uterus was found to be retroverted in 8 cases and anteverted in 27 cases. Length of uterine cavity varied from 6 -10 cm. 5 -30 ml of fluid required to raise intrauterine pressure up to 160 – 180 mm Hg.

Regarding associated problem 1 post renal transplant, 1 nephritis, 3 CRF including one on CAPD, 5 diabetes mellitus, 4 hypothyroid and 6 patients had 1-3 mm uterine fibroid (sub serous or intramural), 1 ischaemic heart disease with cardiomyopathy, 1 epilepsy, 5 had hypertension, 1 treated case of colloid nodular goiter. Regarding endometrial biopsy 18 cases had secretory endometrium, proliferative 9, adenomatous hyperplasia 1, glandular hyperplasia 5 and atrophic endometrium in 2 cases. One case each from secretory and proliferative group was detected to have cellular atypia on concurrent D&C and hysterectomy done subsequently. There were 9 post caesarean cases: once CS – 5, twice CS- 3, thrice CS -1. One of these post CS cases had simple serous cyst which was removed by laparoscopy at the time of UBT. In this patient we could visualize uterine surface which looked absolutely normal during thermal ablation.

All cases had watery discharge for 10 -14 days and cramping lower abdominal pain for 1-2 days. Seven (21.2%) patients became amenorrhic, oligomenorrhoea

Author	No.	Success	Complication	Follow-up
Meyer et al (1998)	128	80%	Nil	12 months
Buckshee et al (1998)	13	92.3%	Nil	2-13 months
Nazar et al (1998)	3000	88-91%	Nil	12 months
A Gervaise et al (1999)	147	83%	3%	3 years
Amso et al (2003)	188	90.6%	3%	4-6 years
Kapur et al (2005)	50	94%	Nil	3-29 months
Anderson et al (2007)	56	97%	Nil	6 years
Ahonkallio et al (2008)	172	76%	Nil	6 years
Swarnima A (2011) et al	75	86.7%	Nil	12 months
Sood et al (2014)	24	95.9%	Nil	12 months
Present study	33	90.9%	3%	2-14 years

occurred in 19 (57.5%) and eumenorrhoea in 4(12.1%) patients at one year. Amenorrhoea, oligomenorrhoea or eumenorrhoea was not found to be related to type of endometrium, menstrual phase at the time of UBT or concurrent curettage but was related to age, position of uterus, and presence of fibroid. Out of 6 cases of fibroid 1 excluded for atypia, 3 (60%) had good

response. Twenty two cases >40 years had significant reduction of menstrual blood loss (MBL), including 7 amenorrhoea, 15 oligomenorrhoea. Response was better in anteverted than retroverted uterus. Regarding complication one had endometritis.

Hysterectomy done in 5 patients: 1 endometritis, 2 cellular atypia, 2 cases of small fibroid for persistent menorrhagia. Excluding 2 cases of cellular atypia, hysterectomy could be avoided in 30 out of 33 patients showing a success rate of 90.91%. Avoidance of hysterectomy included patients of increased surgical risk, 21 out of 22(95.4%) cases of medical

disorder and 6 out of 8 (75%) post CS cases. One post CS case was excluded for cellular atypia. Cases were followed up till 2015 and follow up period ranged from 1-14 years. 3 cases completed 14 years, 1 case 13 years, 1 case 11years, 1 case 7 years, 1 case 4 years and 26 cases up to 2 years.

High risk condition	No. of cases	Hysterectomy
Renal transplant	1	--
CRF on CAPD	3	- -
Ischaemic heart disease	1	--
Epilepsy	1	--
Diabetes	5	--
Hypertension	5	1
Post CS	8	2
Total	24	3
Hysterectomy avoided in 21 out of 24 cases: 87.5%		

Discussion

Among 33 cases 21.2% became amenorrhoeic and in 69.6% cases there was marked reduction of MBL at 12 months showing success rate of 90.9%. Meyer et al [5] found 15% amenorrhoea, 80% significant reduction of blood loss in 128 women at 1 year. Buckshee et al [6] observed 15.4% amenorrhoea after 2-19 months among 13 women and Nazar et al [7] reported 88% - 91% success range in a multicentric study including 300 patients. In a 6 years retrospective study in 172 women Ahonkallio [8] reported satisfaction rate 76%, amenorrhoea 14% and hypomenorrhoea 54%.

Response was not found to be affected by UBT done in follicular phase or in midcycle with concurrent D&C. Similar was the observation by Kapur et al [9] who performed UBT irrespective of menstrual phase with concurrent D&C. Swarnima et al [10] observed similar outcome with pretreatment Danazol, GnRh, preprocedure curettage or follicular phase ablation but

Nazar et al [7] reported pretreatment with GnRh increases amenorrhea which they used in 5 cases only.

All cases above 40 years had marked reduction of MBL. Similarly Nazar et al [7] reported improved result with increasing age and long term efficacy over 40 years observed by Ahonkallio et al [8]. Twenty seven cases of anteverted uterus with cavity 6-10cm in our study had significant reduction of MBL including amenorrhoea. Similarly more treatment failure in retroverted uterus observed by Swarnima et al [10]. Minor complication (endometritis) was observed in 3% which was same as reported by Nazar et al [7] and Gervaise et al [11]. Uterine surface visualised during laparoscopic ovarian cystectomy done with UBT appeared normal. Anderson S, et al [12] reported highest temperature measured at uterine serosa during procedure for 8-16 min was 39.1⁰ C which is unlikely to cause visceral injury even if adherent to uterus and maximum depth of coagulation was 11.5mm.

There were 24 patients of high surgical risk including 16 cases of various medical disorders and 8 post CS cases (table 2). Only 3 required hysterectomy and avoidance of hysterectomy was possible in 21 cases (87.5%). Similarly Kapur et al [9] reported favourable outcome in severe medical disorder and post CS cases.

Conclusion

UBT is a safe, easy to use, effective and minimally invasive procedure. Only limiting factor is the cost of the balloon. Though motivation becomes difficult at times majority of our patients were found to be satisfied with this mode of treatment with 90.9% success rate. Proper counseling and patient selection gives satisfactory result. Creating awareness can increase the acceptance of UBT thereby avoiding hysterectomy and related morbidity.

Conflict of interest: None. **Disclaimer:** Nil.

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