Uterine Balloon Therapy : An Alternative Therapy for Menorrhagia

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Abstract

Background : Menorrhagia is a common problem in women of reproductive age. Its aetiology in the absence of organic pathology, hormonal or haematological disorders remains largely unknown. Traditional medical therapy may not be beneficial in the long run. Hysterectomy for this condition is an invasive over treatment. First generation endometrium ablation techniques aimed at destroying the endometrium, were associated with life threatening complications. The second generation endometrial ablation techniques like uterine thermal balloon therapy have reduced these problems.

Methods : Fifty patients were selected for the procedure between 2002 and 2005. The patients qualified for the procedure if they had completed their family, had normal pelvic ultrasound findings, benign endometrial histology, normal PAP smear and clinically a normal size or bulky uterus.

Results : 50% patients were in the age group of 35-45 years. 28(56%) procedures were done under local anaesthesia and 22(44%) under general anaesthesia. The patients were followed up for a period of 3 to 29 months (median 16 months). Seven(14%) had amenorrhoea and 40(80%) had normal periods or hypomenorrhoea. Three(6%) patients continued to have menorrhagia and were considered failures. 94% patients were satisfied with the procedure and there were no complications in this series.

Conclusions : Uterine balloon therapy is a simple, safe and effective method for the treatment of menorrhagia in selected patients.

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Key Words : Uterine balloon therapy; Menorrhagia

Introduction

Menorrhagia defined as menstrual blood loss in excess of 80 millilitre per cycle is a common problem in women of reproductive age. Its aetiology in the absence of organic pathology, hormonal imbalance, haematological disorders or uterine structural abnormalities remains largely unknown [1].

Historically few options have existed for managing this condition. The traditional medical therapy with hormones, non steroidal anti inflammatory drugs (NSAIDs) or anti prostaglandins is not beneficial in the long run and the side effects unacceptable. The dilatation and curettage is useful as a diagnostic measure and has its place as a temporary measure in cases of intractable bleeding. Hysterectomy in an otherwise healthy woman is not indicated since only the endometrium is responsible for the patients condition. In view of the above it was conceptualized that if the endometrium could be destroyed, the patient could be cured of her complaints. The hysteroscopic approach was resorted to as the first measure and first generation endometrial ablative techniques such as transcervical resection of

endometrium (TCRE) and rollerball endometrial ablation were devised in the nineties. These methods were effective but required an elaborate operative endoscopy set up and few gynaecologists were sufficiently trained in these technically difficult procedures. These techniques were associated with dangerous intra operative complications such as fluid overload from distention media, electrolyte imbalance, cardiac arrhythmia, uterine perforation, haemorrhage and visceral damage.

To do away with these problems second generation endometrial ablative techniques such as uterine thermal balloon therapy were introduced originally by Neuwirth in 1994 [2].

Materials and Method

Fifty patients attending the gynaecological out patient department (OPD) between 2002 and 2005 of a service hospital were selected for the procedure. The patients primarily complained of increased menstrual blood loss. All the patients underwent a clinical examination and were investigated with haemogram and ultrasound examination. The patients subsequently underwent an endometrial biopsy or

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hysteroscopy with endometrial biopsy and Papanicolaou (PAP) smear. Patients who had completed their family, had normal (benign) endometrial histology with no organic lesion on ultrasound, a clinically normal to bulky uterus (utero-cervical <10cm) and who had been on medical therapy for menorrhagia without relief were offered either hysterectomy or uterine balloon therapy (UBT). Patients suffering from medical diseases such as haematological conditions (like aplastic anaemia), cardiac conditions or renal diseases were primarily offered UBT over hysterectomy as they were high risk for major surgery.

Patients who were willing for uterine balloon therapy were enrolled in this study. The patients suffering from severe medical disorders or those with previous two caesarean section were taken up for the procedure under general anaesthesia (GA). All other patients were given a choice of having the procedure under local anaesthesia (LA) or GA. Most patients opted for LA. No drugs were given to any patient for endometrial preparation (thinning of endometrium) and patients were listed for the procedure irrespective of the time of the menstrual cycle.

The procedure was carried out using the Uterine Balloon Therapy System (UBTS) which consists of an electric controller, a sterile balloon catheter with heating element and an umbilical cable (Fig. 1). The solution used for the procedure was 5% glucose. The uterine balloon (Fig. 2) was connected to the UBTS and the balloon distended with about 30ml of 5% glucose to check for any leakage. Then the fluid was sucked out of the balloon creating a negative pressure of about -150 mmHg that was indicated on the machine. This negative pressure was important for the procedure as it ensures that all air is sucked out of the balloon before the procedure. Patients taken up for the procedure under LA were given injection diclofenac sodium 75mg IM and metoclopramide 10mg IM half an hour before the procedure. A paracervical block with 10ml of 1% plain lignocaine solution was given after cleaning and draping the patient.

After an internal check up, the uterine cavity was sounded to determine the utero-cervical length and the cervix was dilated to 5/8 with Hawkin Ambler dilators and a thorough curettage of the endometrial cavity was done so that a raw area was created in the uterus and excessive endometrium removed. The endometrium obtained was sent for histopathological examination (although an earlier report of

endometrial histology was available).

Now the uterine balloon with a negative pressure of -150mmHg was inserted in the uterine cavity and 5% glucose solution was slowly instilled in the uterine cavity over a period of three minutes till an intra uterine pressure of 160 – 180 mmHg was achieved. Then the heating element in the catheter was activated and the temperature of the solution in the balloon raised to 87°C. An eight minute treatment cycle at this temperature ablates the endometrial tissue. Postoperatively the patients were given oral or parenteral NSAID for pain relief and oral antibiotics. Cases done under LA were sent home the same evening or detained overnight and those done under GA were discharged the next day.

Response to therapy was judged by the number of days of bleeding and number of pads used per day.

Results

Table 1 gives the age distribution of patients who underwent UBT. One patient (a case of mental retardation) was less than 20 years whereas most of the patients 25 (50%) were in the age group of 35 – 45 years. Of the 50 procedures, 28 (56 %) were done under local anaesthesia and 22 (44 %) under GA. The indications for the patients who underwent the procedure under GA are given in Table 2.

The patients in this study have been followed up for a period ranging from 3 – 29 months (mean 16 months). Seven (14%) had amenorrhoea whereas 40 (80%) had either normal periods or hypomenorrhoea. Three (6%) of patients continued to have menorrhagia and were failures (Table 3). Forty seven (94%) patients were satisfied with the procedure.

The amount of 5% glucose instilled in the uterine balloon ranged from 8 - 15 ml (average 12ml).

In this series there were no significant complications in patients who underwent the procedure under GA but one patient under LA had a vasovagal reaction and had to be resuscitated. 48 out of 50 patients had postoperative spasmodic pain which lasted for one day and required administration of NSAID. 22 (78.5%) of 28, who underwent

Table 1

Age group of patients

Age group of patients (years)	Number of patients	Percentage (%)
< 20	1	2
25-35	13	26
35-45	25	50
45-50	11	22
Total	50	100

Fig. 1 : Uterine balloon therapy system

Fig. 2 : The uterine balloon

Table 2**Indications for procedure under GA**

Indication for GA	Number of patients
Rheumatic heart disease(RHD)/RHD(Optd)	4
Chronic Renal Failure	4
Haematological Disorders	2
Previous two caesarean sections	4
Previous two caesarean sections with VVF repair	1
Mental retardation	1
Patient demand	6
Total	22

the procedure under LA had post operative vomiting and required post operative antiemetics with parenteral hydration. The vomiting in most cases lasted for 5 - 6 hours. 38 (76%) patients had post operative serous watery discharge per vaginum which lasted for 2 - 3 weeks.

Discussion

Uterine Balloon Therapy has been available in Europe since 1997 and in United States since 1998. A large multi centre observational study [3] and others comparing UBT with established first generation ablation treatments such as rollerball [4] and TCRE [5,6] reported success in reducing menstrual blood loss and outcomes comparable with first generation ablation techniques. This intervention fulfilled a largely unmet women's health need of permanent treatment of menorrhagia with avoidance of hysterectomy. The technique of UBT is technically uncomplicated and serious side effects are rare.

In our study 50% of the patients were in the age group of 35 - 45 years being the commonest period in life to develop abnormal uterine bleeding. UBT can be undertaken under LA with or without sedation [7]. In this series 28 (56%) cases were done under LA and 22 (44%) under GA. Cases were taken under GA only if the patient so desired or if the patient suffered from debilitating medical disease due to which she had poor pain tolerance to the procedure under local anaesthesia or had previous two caesarean sections. In cases with previous two caesarean sections, GA is preferable as there is some possibility of the scar giving way during the procedure which will manifest as a sudden loss of intrauterine pressure and the patient can be better managed under GA if this unexpected complication occurs. This compares favourably with other series [4] where 47% cases were done under LA.

In this series where the follow up period ranged from 3 - 29 months with a median of 16 months, 47 (94%) patients had eumenorrhoea (normal periods) or less. Of these 27(54%) patients had hypomenorrhoea and seven (14%) had amenorrhoea. Persistent menorrhagia

Table 3**Menstrual pattern at follow up ranging from 3-29 months**

Menstrual pattern	Number of patients	Percentage (%)
Amenorrhoea	7	14
Eumenorrhoea	13	26
Hypomenorrhoea	27	54
Menorrhagia	3	6
Total	50	100

was present in three (6%) patients and of these two patients underwent hysterectomy at two and six months, while one patient with persistent menorrhagia is being worked up for hysterectomy. The histopathology of the uterus in patients who underwent hysterectomy showed no specific pathology.

Long term follow up at 4 - 6 years [8] showed that the overall probability of avoiding surgery was 75%. 47% patients were amenorrhoeic, 30% hypomenorrhoeic, 13.6% eumenorrhoeic and 8.5% had heavy periods. The failure rate of 8.5% in this study compares well with a failure rate of 6% in our series. In another series which compared UBT to rollerball ablation 7 of 10 women were cured of menorrhagia without additional intervention five years after UBT or rollerball ablation thus making the clinical outcomes of rollerball ablation and UBT similar[9]. 94% of our patients were satisfied with the procedure and this compares well with the satisfaction level of 93 - 96% in other series [9, 10].

The procedure of UBT is started with an intra uterine pressure of 160 -180 mmHg but as the procedure progresses there is a fall in the intra uterine pressure. In this series we have avoided the pressure from going below 120 mmHg. If the pressure went below 120 mmHg, then the therapy cycle was restarted. This is in view of the fact that at lower intra uterine pressure the efficacy of the procedure is reduced [11]. After UBT the patients should be advised to use either natural or barrier contraception if not already sterilised, as this procedure does not guarantee contraception.

To conclude, UBT is a safe, simple and effective method for treatment of menorrhagia in selected patients and it avoids the need for hysterectomy. Larger trials are required before it is introduced in the armed forces for routine use.

Conflicts of Interest

None identified

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