Thermal Balloon Ablation Versus Endometrial Resection for the Treatment of Abnormal Uterine Bleeding


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Abstract
This study compares the clinical efficacy and safety of a thermal uterine balloon system with hysteroscopic endometrial resection in the treatment of dysfunctional uterine bleeding. In all, 47 women were treated by two experienced gynaecological surgeons: One performed 73 thermal balloon ablations and the other 74 endometrial resections between November 1998 and December 1999. The inclusion criteria were similar in both groups. The operative time was reduced significantly with the uterine balloon technique. There were no intraoperative complications in either group and postoperative morbidities were minimal and not statistically different. Multivariate analysis noted two prognostic factors associated with failures: Retroverted uterus with thermal balloon ablation and age under 43 years with endometrial resection. The overall success rate did not differ significantly between the two groups 83.0 ± 5% for balloon ablation and 76.3 ± 6% for endometrial resection. Uterine balloon ablation appears to be as efficacious as endometrial resection. The former is much easier to perform, making the technique readily reproducible, especially by those with limited expertise in hysteroscopic surgery and thus more widely applicable and safer.

Key Words: Abnormal uterine bleeding – Thermal balloon ablation – Endometrial resection.

Introduction
MENORRHAGIA is a common disorder for many reproductive age women, with significant impact on their medical, social, economic and psychological well-being [1]. The worldwide prevalence is reported to be as high as 19% [2]. This disorder often exists in the absence of organic lesions of the endometrium in the perimenopause. Later, in the post-menopausal period, the problem of excessive uterine bleeding affects women receiving hormonal replacement treatment.

Traditionally, the first-line treatment is medical in menstruating women and discontinuation of hormonal replacement in the menopausal. Except for gonadotrophin-releasing hormone agonists (GnRHa), the various medications generally employed (progestogens, combined oral contraceptives, prostaglandin synthetase inhibitors, antifibrinolytics or danazol) do not achieve amenorrhea, but can reduce menstrual bleeding by 25-80% [3]. Moreover, medical therapy may be fraught with side-effects and symptoms of menorrhagia invariably return once therapy is stopped. Second-line therapies include the surgical approaches of dilatation and curettage, hysteroscopy and/or hysterectomy. In a randomized study, it was shown Cooper, 1997 [4] that medical treatment was less effective than hysteroscopic endometrial resection. The Royal College of Obstetricians and Gynaecologists (RCOG) reported that 42% of hysterectomies in the UK are performed for dysfunctional uterine bleeding [5]. Dilatation and curettage is a temporary treatment with limited efficacy [3,6] and the patient would be better served by operative hysteroscopy. In fact, data indicate that hysteroscopic endometrial resection or ablation with Nd Yag laser and electrocoagulation appear to be the procedures of choice for the control of menorrhagia. Worldwide, a 70-90% success rate has been demonstrated using hysteroscopic endometrial resection or ablation [7,8]. Hysteroscopy surgery is effective and is associated with less morbidity and mortality, shorter hospitalization and convalescence when compared with hysterectomy. However, it requires additional specialized training and surgical expertise and involves a significant learning curve [9]. Moreover, serious complications may occur, including fluid overload, uterine perforation, infection, haemorrhage, thermal injuries and even death. In a series of 525 patients treated with hysteroscopic endometrial resection, an operative complication rate of 6% was reported for patients undergoing their first procedure and of 15% for repeat procedures [8]. In the Mistlestoe study Overton et al., [10] comprising 10 686 women treated with endometrial
ablation performed by 690 different surgeons and by different methods, the complication rate was 4.4%. The Roller-Ball and Nd Yag laser techniques had a lower complication rate than endometrial resection.

In the interests of overcoming many of these disadvantages and risks, a thermal uterine balloon therapy system was introduced [11]. This has since been evaluated in several clinical studies of endometrial destruction [12,13,14]. These results indicate that the balloon ablation procedure requires skills similar to those necessary for inserting an intrauterine device.

The purpose of this study was to compare two conservative surgical approaches in the management of abnormal uterine bleeding: Thermal uterine balloon ablation versus endometrial resection, which is the technique commonly used in France. We compared the safety and the efficacy of the two techniques and attempted to identify the factors influencing outcome. All balloon ablations were done by a skilled gynaecological surgeon (H.F.) and the endometrial resections by a pioneer in hysteroscopic surgery (J.H.).

Material and Methods

Patient selection:

Between November 1998 and December 1999, 22 women were enrolled in a prospective study of a thermal uterine balloon system (TheraChoice Gynecare, Inc, Menlo Park, CA, USA). This study was carried out in Gynecological department in Ormiskirk general district hospital. The control group was selected from examination of the records of patients undergoing resection (n=25) and treated during the same period by endometrial ablation for abnormal uterine bleeding. Institutional review board approval was obtained for this study. All patients gave informed consent.

Inclusion in the study required that women be 40 years of age or older (excepting for two patients in each group who had a serious medical contraindication for pregnancy in addition to menorrhagia). The indication for treatment in both groups was excessive menstrual blood loss that was quantified by the number of pads used per cycle. The premenopausal women in these series had either failed medical therapy with progestins or were unwilling or unable to carry on with medical treatment. The post-menopausal patients were not willing to discontinue hormonal replacement therapy.

Women with submucous fibroids, polyps, premalignant lesions, a uterine cavity measuring >12cm in length, or those of reproductive age wishing to retain fertility were excluded. Each patient had a routine history taken and underwent a routine physical examination, as well as a PAP smear, pelvic sonogram and a hysteroscopic evaluation. All of the patients had documented benign endometrial histology without atypia. None of the patients, in either group, received pretreatment for endometrial thinning and procedures were not scheduled to coincide with a specific time of the cycle. The operating time was measured from the initiation of anaesthesia to the end of the procedure. All patients were monitored for peroperative and postoperative morbidity.

Choice of anaesthesia:

One hour prior to the initiation of the procedure irrespective of the type of anaesthesia, the patients received non-steroidal anti-inflammatory drugs orally (except for two patients, who had a contraindication) and 1g of paracetamol intravenously. This drug regimen was used to alleviate anxiety, pain and/or cramping during the procedure. The duration of action of these medications was 6h. The same medication was repeated as necessary during the immediate postoperative period, in the event of persistent uterine cramps.

All endometrial resections were done under general anaesthesia. For the patients in the balloon group, the type of anaesthesia was not dictated in the protocol and was left up to the patient, anesthetist and surgeon to determine. Local anaesthesia was used when it was medically necessary or when the patient desired this form of anaesthesia, provided she demonstrated her ability to relax by good toleration of the pelvic examination and the diagnostic hysteroscopy which was performed without anaesthesia.

Local anaesthesia was achieved by the establishment of a paracervical block with 1% lignocaine HCl and epinephrine 1:200 000 (20ml) diluted 1:20 with normal saline. A total of 40ml was used per patient: 5ml of the solution was injected into each of four points of the cervix corresponding to 01.00, 05.00, 07.00 and 11.00h on a clock face. The cervix was then grasped with a tenaculum and 5 ml of the solution was injected into each of the following sites in the isthmus, corresponding to 02.00 and 10.00 on a clock face and into each of the uterosacral ligaments (1 cm depth). A time of 3-5min was allowed to elapse for the anaesthetic to take effect before starting the procedure.
Equipment and operative technique:

The ThermaChoice™ uterine balloon therapy system consisted of a 16cm long, 4.5mm diameter catheter with a latex balloon at its distal end which housed a heating element. The controller unit monitored, displayed and controlled the preset intra-balloon pressure, temperature and duration of treatment. For safety, the device automatically deactivated when the pressure fell below 45mmHg or rose above 200mmHg.

The patients were placed in the dorsolithotomy position in the procedure room. The bladder was not catheterized and when necessary the cervix was dilated to 5.5mm. The balloon was inserted transcervically to touch the fundus and then was inflated with 5% dextrose in water (typically 10-15ml) until the intrauterine pressure stabilized between 150-170mmHg. The heater was then activated and it maintained the intra-balloon temperature at 87±5°C. An effective therapy cycle was 8min in duration, based on previous in-vitro and in-vivo studies and this typically resulted in a 0.4-0.6cm depth of tissue coagulation [11].

Endometrial resection was performed using standard hysteroscopic equipment and a previously described technique [15]. Low viscosity (1.5% glycine) medium was used for uterine distention. The fluid balance was monitored continuously.

Neither group of patients received routine antibiotic prophylaxis and in both groups, the patients were discharged on the day of the procedure.

Follow-up:

The patients in the balloon group were contacted by phone 3, 6 and 12 months postoperatively and annually thereafter. Their postoperative follow-up varied between 3 and 44 months. Those in the resection group were called once: Their follow-up varied from 3 to 36 months. During the telephone interview, we attempted to ascertain the characteristics of the menstrual flow, the number of pads used per cycle and the degree of dysmenorrhoea, when present before the procedure.

Statistical analysis:

The primary end-point was defined as elimination of menses (amenorrhoea) or a significant reduction of flow compared with normal (eumenorrhoea) or less than normal (hypomenorrhoea). The secondary end-point was the disappearance of dysmenorrhoea, when present before the procedure.

The analysis was done after the first patient completed 44 months of follow-up. The significance of the differences between groups in categorical variables was tested with the 2 test. Student’s t-test was used to determine the significance of the differences between groups in continuous variables. Life-table analysis was based on a technique in which time to failure was the dependent variable, which made it possible to use all of the available information about the participants for as long as they had been followed-up. The Kaplan-Meier survival curves were used to describe the ‘survival’ distributions of the two treatments (balloon and resection) and the differences were tested with Mantel-Cox (log-rank) statistics. The Cox proportional hazards model was applied in order to analyse the simultaneous relationships between event failure and the possible covariates and to study the influence of prognostic factors on the appearance of failure. Failed clinical outcome was defined as persistent menorrhagia. All statistical analyses were performed using Release 7.0 (BMDP Statistical Software, Inc., Cork, Ireland).

Results

No patients were lost to follow-up. The demographic data and gynaecological histories of the 47 patients treated either by the balloon technique or by endometrial resection demonstrated no differences in average age, pads per cycle used, uterine cavity depth and position. However there was a difference for parity and menopausal status (Table 1).

Table 1: Characteristics of patients in both treatment groups.

<table>
<thead>
<tr>
<th></th>
<th>Balloon (n=22)</th>
<th>Resection (n=25)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years) a</td>
<td>46.3±1.3</td>
<td>47.4±1.4</td>
<td>NS</td>
</tr>
<tr>
<td></td>
<td>(34-66)</td>
<td>(34-65)</td>
<td></td>
</tr>
<tr>
<td>Menopausal status b</td>
<td>5 (6.8)</td>
<td>20 (27)</td>
<td>0.001</td>
</tr>
<tr>
<td></td>
<td>(0-9)</td>
<td>(0-4)</td>
<td></td>
</tr>
<tr>
<td>Pads/cycle (mean ± SD)</td>
<td>86±40.4</td>
<td>81±41.7</td>
<td>NS</td>
</tr>
<tr>
<td></td>
<td>(80.8/19.2)</td>
<td>(85.1/14.9)</td>
<td></td>
</tr>
<tr>
<td>Uterine cavity depth (cm) a</td>
<td>8.9±0.3</td>
<td>9.1±0.2</td>
<td>NS</td>
</tr>
<tr>
<td></td>
<td>(6-12)</td>
<td>(7-12)</td>
<td></td>
</tr>
</tbody>
</table>

NS = Not significant.
a Mean ± SD with range shown in parentheses.
b Percentages shown in parentheses.

The mean operating time was 20.3min for the balloon group versus 44.8min for endometrial resection (p<0.05). In the balloon group, the procedure was completed within 30min in all of the cases, whereas in the resection group, the procedure was completed within 30min in only 52.6% of the cases (p<0.05).
The postoperative bleeding pattern of the two groups is outlined in Table (2). The rate of eumenorrhoea was significantly higher in the balloon therapy group. The failure rates related to bleeding were 17.6% (n=13) for endometrial resection and 15.1% (n=11) for balloon treatment. After endometrial resection, seven patients were treated with progestins before deciding on further surgical treatments, one patient underwent a second endometrial resection and five patients underwent hysterectomy for persistent bleeding. In the balloon treatment group, postoperatively four patients had progestin treatment and seven underwent hysterectomy for persistent bleeding.

Table (2): Postoperative bleeding patterns for the whole study population.

<table>
<thead>
<tr>
<th></th>
<th>Balloon ablation n (%)</th>
<th>Endometrial resection n (%)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amenorrhoea</td>
<td>6 (24.7)</td>
<td>9 (37.8)</td>
<td>NS</td>
</tr>
<tr>
<td>Hypomenorrhoea</td>
<td>4 (21.9)</td>
<td>8 (31.1)</td>
<td>NS</td>
</tr>
<tr>
<td>Eumenorrhoea</td>
<td>9 (38.4)</td>
<td>3 (13.5)</td>
<td>0.0006</td>
</tr>
<tr>
<td>Menorrhagia</td>
<td>2 (11.0)</td>
<td>3 (12.2)</td>
<td>NS</td>
</tr>
<tr>
<td>Metrorrhagia</td>
<td>1 (4.1)</td>
<td>2 (5.4)</td>
<td>NS</td>
</tr>
<tr>
<td>Total</td>
<td>22 (100)</td>
<td>25 (100)</td>
<td>NS</td>
</tr>
</tbody>
</table>

NS = Not significant.

The postoperative changes in the bleeding patterns over time for balloon ablation and endometrial resection are depicted respectively. The median ± SD follow-up was 18.3 (±2.7) months (range 3-44) for the balloon group and 19.2 (±2.3) months (range 3-36) for endometrial resection. Table (3) shows the outcomes with both techniques 24 months after the procedure. The results were similar, including the failure rates (menorrhagia or metrorrhagia), with the exception of eumenorrhoea which appeared to be higher with the balloon (34 versus 17% for resection) but the difference was not significant (p=0.06).

Table (3): Findings at 24 months follow-up.

<table>
<thead>
<tr>
<th></th>
<th>Balloon ablation n (%)</th>
<th>Endometrial resection n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amenorrhoea</td>
<td>6 (36.4)</td>
<td>8 (38.3)</td>
</tr>
<tr>
<td>Hypomenorrhoea</td>
<td>5 (15.9)</td>
<td>6 (27.7)</td>
</tr>
<tr>
<td>Eumenorrhoea</td>
<td>6 (34.1)</td>
<td>5 (17)</td>
</tr>
<tr>
<td>Menorrhagia</td>
<td>2 (9.1)</td>
<td>2 (14.9)</td>
</tr>
<tr>
<td>Metrorrhagia</td>
<td>1 (4.5)</td>
<td>1 (2.1)</td>
</tr>
<tr>
<td>Total</td>
<td>20* (100)</td>
<td>22** (100)</td>
</tr>
</tbody>
</table>

There were no significant differences between the groups.

* Excluding patients receiving surgery: Five hysterectomies.  **Excluding patients receiving surgery: Three hysterectomies and one endometrial resection.

All the women undergoing endometrial resection received general anaesthesia compared with 62% of those who had balloon therapy. 3 of the 8 patients who received local anaesthesia had severe medical conditions: Hypofibrinogenaemia, valvulopathy with coumarin treatment, prior renal or heart-lung transplantation. For these women, local anaesthesia offered a lower risk without disrupting their ongoing medical treatment.

In both groups, there were no intra-operative complications. Postoperatively, there were two cases of probable endometritis that responded to oral antibiotics in the endometrial resection group. One pregnancy occurred 18 months after the balloon procedure. This pregnancy was spontaneously aborted at 10 weeks of amenorrhoea. This patient underwent vaginal hysterectomy 3 months after the miscarriage, for uterine myomata.

Predictors of failure:

Menopausal status and parity were forced into the Cox model in order to ensure that their possible confounding effects were controlled for. Other factors that could explain the variations in failure, i.e. age, uterine cavity depth, uterine position and dysmenorrhoea, were introduced together into the Cox model as potential predictors and the stepwise procedure was followed.

The overall success rates did not differ significantly between thermal balloon ablation and endometrial resection. At 24 months follow-up, these rates were 83.0±5% for the balloon and 81.1±5% for resection. At 36 months postoperatively, these rates were 83.0±5 and 76.3±6% respectively.

Discussion

The results obtained with the uterine balloon in this study are comparable to those previously reported Singer et al. [12]; Friberg et al. [16]; Vilos et al. [13]; Amso et al. [14] and Römer. [17], as are those of hysteroscopic endometrial resection DeCherney & Polan, [18]; Garry et al. [7]; Goldrath, [19]; Valle, [20] and O'Connor & Magos, [8]. All of these studies demonstrate the efficacy of both methods in the treatment of dysfunctional uterine bleeding in the premenopause. There are no data in the literature about the use of these techniques in the post-menopausal period for patients experiencing abnormal uterine bleeding while on hormonal replacement. The population in our study is different from others in that all of the patients (except two in each group as described above) were 40 years of age or older. The results demonstrate that
there is no significant difference in the efficacy of both techniques before or after menopause.

Thermal balloon therapy was developed to simplify endometrial ablation. The level of difficulty of performing the balloon procedure is similar to that required for inserting an intrauterine device. This technique does not require the direct use of endometrial visualization, distending solutions and high-energy sources (electrosurgical generators or lasers) and it rarely requires cervical dilatation. The risk of a balloon rupture causing thermal burns from hot solution inside the uterine or peritoneal cavity seems remote [11]. In fact, the introduction of a hot solution directly into the uterine cavity has recently been proposed as an endometrial ablation method [21]. In a continuing multicentre thermal balloon trial of 300 patients Amso et al., [14] and in 2500 procedures world-wide, such complication has not been reported. Minor complications (cystitis, low-grade endometritis, haematometra) were observed in ~3% of cases. The rate of major complications (endometritis, septicaemia, pneumonia, peritonitis, hysterectomy, laparotomy and bowel repair, pulmonary embolism and death) associated with hysteroscopic endometrial resection is reported to be ~4% Hulka et al. [22] and Overton et al. [10].

The clinical difficulty of mastering the endometrial resection technique may have led the gynaecologists to avoid this conservative surgical option and to perform hysterectomy instead, for abnormal uterine bleeding. This study clearly demonstrates that the balloon technique, which is relatively simple and mastered easily, is as effective as endometrial resection performed in this instance by a skilled surgeon with experience of >1000 such procedures. A randomized multicentre clinical trial comparing uterine balloon therapy with electrosurgical rollerball ablation has been reported Meyer et al. [23]. The outcome was similar for both procedures.

Proper patient selection (n=28) permitted us to perform successfully the ThermaChoice uterine balloon procedure under local anaesthesia in the outpatient clinic, obviating the use of the operating room. In addition to the convenience it offers to both patients and health professionals, such an approach is associated with a significant reduction in costs. Especially in the presence of severe medical disease, this technique appears to minimize the procedural risks.

The multivariate analysis highlighted only two factors that increase the recurrence rate of menorrhagia. As previously noted [7,8], patients <40 years of age have an increased chance of failure after endometrial resection. The chance of failure after thermal balloon ablation is increased 6.2-fold in those with a retroverted uterus. A hypothesis for this increase is that a retroverted uterus modifies the pressure of the balloon in the uterine walls. It is possible that due to the retroverted position of the uterus, the precise site of the heater element within the cavity is not central and hence, one wall of the uterine cavity is further away from the heater element than it should be. The heat distribution within the uterine cavity is therefore not symmetrical, leading to differences in ablation, which would be a possible explanation for the increased failures; however, the validity of this hypothesis is yet to be investigated by ultrasonography or other studies.

In conclusion, endometrial ablation with thermal balloon is as efficacious as hysteroscopic endometrial resection. The ease of use of the thermal uterine balloon therapy system may allow more gynaecologists, especially those who remain untrained or unskilled at operative hysteroscopic surgery, to perform this conservative treatment. The potential of performing the procedure under local anaesthesia, the shorter time and the lower rate of intra-operative complications (reported in the literature but not in our study) may increase the use of this form of treatment. However, when the uterus is retroverted, the use of one of the other techniques may be preferable.

The simplicity and efficacy of the balloon technique may result in a broader and earlier use of this treatment, thus reducing the number of patients treated medically or at least reducing the length of such treatment for abnormal uterine bleeding. In addition, the efficacy of this technique and its more frequent use for abnormal uterine bleeding may reduce the rate of hysterectomies practised for this indication resulting in decreased morbidity and reduction in direct and indirect treatment costs.

References