Uterine thermal balloon therapy under local anaesthesia for the treatment of menorrhagia: a pilot study

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This study evaluates the use of local anaesthesia in a subset of patients undergoing uterine thermal balloon endometrial ablation for the treatment of menorrhagia. Out of 51 patients with dysfunctional uterine bleeding, 18 were included for uterine balloon therapy under local anaesthesia. Inclusion criteria were dysfunctional bleeding with absence of organic lesions in the uterine cavity, adequate relaxation and pain control during physical examination and diagnostic hysteroscopy, and patient desire to avoid a general anaesthetic. Paracervical block was performed with 20 ml of dilute 1% lignocaine HCl with epinephrine 1:200 000. Success of the procedure was defined as amenorrhoea, hypomenorrhoea, or eumenorrhoea. The median follow-up period was 13.9 ± 5 months and 11 patients (61%) had follow-up of >1 year. Treatment led to a significant decrease in menstrual flow, duration, and pad count in all patients (P < 0.0001). No intra-operative complications occurred. A pain scale (level 1–10) was used to evaluate the patients’ tolerance of the procedure (mean 3.8 ± 1.3). In light of these successful and well tolerated procedures, thermal balloon endometrial ablation, utilizing local anaesthesia, appears practical as an office-based therapy.

Key words: endometrial ablation/local anaesthesia/uterine balloon therapy

Introduction

Excessive menstrual loss, or menorrhagia, is a major problem for many women, with significant impact on their medical, social, economic and psychological well-being (Lalonde, 1994). Reports of its world-wide prevalence run as high as 19% of reproductive age women (Snowden and Christian, 1983).

Traditionally, the first-line treatment is medical therapy. Second-line therapies include the surgical approaches of dilation and curettage, hysteroscopy, and/or hysterectomy. The Royal College of Obstetricians and Gynaecologists (RCOG) reports that 42% of hysterectomies in the UK are performed for dysfunctional uterine bleeding (Value newsletter of RCOG, 1996). Among conservative surgical therapies, dilatation and curettage is a temporary treatment with limited efficacy (Grimes, 1982; Shaw, 1994) and the patient would be better served by surgical hysteroscopy. In fact, recent data indicate that hysteroscopic endometrial ablation with Nd Yag laser or electrocoagulation/resection initially appears the procedure of choice for menorrhagia control. World-wide experience has demonstrated a 70–90% success rate using hysteroscopic ablation (Garry et al., 1995; O'Connor and Magos, 1996). Hysteroscopic surgery is effective and is associated with reduced morbidity, mortality, hospitalization and convalescence when compared with hysterectomy. It does, however, require additional specialized training and surgical expertise, and involves a significant learning curve (Davis, 1989). Moreover, serious complications may occur, including fluid overload, uterine perforation, infection, haemorrhage, thermal injuries, and even death. A large series which followed 525 endometrial resections reported an operative complication rate of 6% for patients undergoing their first procedure and a complication rate of 15% for repeat procedures (O’Connor and Magos, 1996).

In the interests of overcoming many of these disadvantages and risks, Neuwirth et al. (1994) introduced a thermal uterine balloon therapy system which has been evaluated in several clinical studies of endometrial ablation (Singer et al., 1994; Vilos et al., 1996; N.N.Amso, unpublished). Those results indicate that the balloon ablation procedure requires skills similar to those necessary for inserting an intrauterine device.

Most of the estimated 1800 balloon ablations done worldwide have used general anaesthesia, with its resultant increased risk and cost. With the aim of decreasing the risks and increasing the acceptance and convenience of balloon endometrial ablation even further, we present our experience in 18 patients who elected to have thermal uterine balloon therapy under paracervical block in our outpatient setting.

Materials and methods

Patient selection

Since November 1994, 18 patients have been treated for menorrhagia using a uterine thermal balloon endometrial ablation system under local anaesthesia. During this 29 month period, 33 additional patients were treated under general anaesthesia. Institutional Review Board approvals and patient informed consents were obtained for this series.

Indications for thermal balloon therapy were excessive menstrual bleeding with the absence of organic lesions in the uterine cavity. Additionally, these patients had failed medical therapy with progestins or were unwilling or unable to carry on with conservative treatment. Patients were noted to have symptomatic menorrhagia as evidenced by pad counts and self assessment of bleeding patterns. Women with submucous fibroids, polyps, premalignant lesions, cavity length of >12 cm, or wishing to retain their fertility were excluded. Each patient underwent a routine history and physical examination, a Pap smear, a pelvic sonogram, and a hysteroscopic evaluation. All patients had documented benign endometrial histology without atypia. A daily
menstrual pad count, the number of flow days per cycle, and a dysmenorrhoea score were also ascertained prior to the outpatient procedure.

The indication for local anaesthesia was based upon the patient's desire to avoid a general anaesthetic, the ability for adequate relaxation and pain control during the physical examination and diagnostic hysteroscopy, and the lack of indication for laparoscopic tubal occlusion during the same procedure. Out of 51 patients, 18 qualified for this procedure.

Equipment
The ThermaChoice™ uterine balloon therapy system (Gynecare, Inc., Menlo Park, CA, USA) consists of a 16 cm long×4.5 mm diameter catheter with a latex balloon at its distal end which houses a heating element. The controller unit monitors, displays, and controls preset intra-balloon pressure, temperature, and duration of treatment. For safety, the device automatically deactivates when the pressure falls below 45 mm Hg or rises above 200 mm Hg.

Operative technique
Twelve patients had preoperative uterine preparation with oral progester- tons, eight of whom had suction curettage for biopsy immediately preoperatively. Six patients had the same procedure performed on cycle day 4–10. One hour prior to the procedure, 16 patients received 100 mg of ketoprofen orally (two patients had a contraindication to NSAIDs) and 18 patients received 1 g of paracetamol i.v. This drug regimen was used to alleviate anxiety, pain, and/or cramping during the procedure. The duration of action of these medications was 6 h, and they could be continued in case of persistent uterine cramps in the immediate postoperative period. The patients were placed in the dorsal lithotomy position in the procedure room. The bladder was not catheterized and the cervix was dilated to 5.5 mm if necessary. No perioperative antibiotics were used. A paracervical block was performed with 1% lignocaine HC1 with epinephrine 1:200 000 (20 ml) diluted 1:20 with normal saline. A total of 40 ml was used per patient. The solution was first injected into the cervix at 0200, and they could be continued in case of persistent uterine cramps in the immediate postoperative period. The patients were placed in the dorsal lithotomy position in the procedure room. The bladder was not catheterized and the cervix was dilated to 5.5 mm if necessary. No perioperative antibiotics were used. A paracervical block was performed with 1% lignocaine HC1 with epinephrine 1:200 000 (20 ml) diluted 1:20 with normal saline. A total of 40 ml was used per patient. The solution was first injected into the cervix at 0200, and they could be continued in case of persistent uterine cramps in the immediate postoperative period. The patients were placed in the dorsal lithotomy position in the procedure room. The bladder was not catheterized and the cervix was dilated to 5.5 mm if necessary.

Assessment
To determine the patients' pain tolerance, a pain scale assessment (from 1 to 10) was initiated by the surgeon during and following the procedure. All patients were discharged between 6 and 10 h after the procedure and were contacted at 3, 6, 12, 18 and 24 months post-procedure. At those times, menstrual pattern, degree of dysmenorrhoea, side-effects, or need for any further therapy were assessed. Treatment success was defined as elimination of menses (amenorhoea), or a significant reduction of flow to normal (eumenorrhoea) or less than normal (hypomenorrhoea). Failed clinical outcome was defined as persistent menorrhagia.

Statistical analysis included a paired t-test to compare preoperative with postoperative bleeding. The pain scale was analysed by its average score and SD. For each statistic, an acceptable type I (a) error was α =0.05.

<table>
<thead>
<tr>
<th>Uterine characteristics</th>
<th>Number of patients</th>
<th>Mean ± SD</th>
<th>Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anteverted</td>
<td>15</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Retroverted</td>
<td>2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Midposition</td>
<td>1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Depth (cm)</td>
<td>8.7 ± 1.4</td>
<td>6-12</td>
<td></td>
</tr>
<tr>
<td>Volume in the balloon (ml)</td>
<td>12.5 ± 7</td>
<td>6-30</td>
<td></td>
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</tbody>
</table>

| Table II. Menstrual flow in 18 patients receiving uterine thermal balloon therapy

<table>
<thead>
<tr>
<th>Flow</th>
<th>Pre-procedure</th>
<th>Post-procedure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pads/day*</td>
<td>10.2 ± 1.6</td>
<td>8-12</td>
</tr>
<tr>
<td>Days/cycle*</td>
<td>8.3 ± 3.4</td>
<td>6-15</td>
</tr>
<tr>
<td>Pads/cycle*</td>
<td>78 ± 40.4</td>
<td>44-165</td>
</tr>
</tbody>
</table>

Significant differences between pre- and post-procedure: *P < 0.0001.

| Table III. Post-procedure bleeding patterns in 18 patients receiving uterine thermal balloon therapy (all had menorrhagia pre-procedure)

<table>
<thead>
<tr>
<th>Bleeding description</th>
<th>No. (%) of patients at 3 months</th>
<th>No. (%) of patients at 6 months</th>
<th>No. (%) of patients at &gt;12 months</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amenorrhoea</td>
<td>4 (22)</td>
<td>4 (25)</td>
<td>6 (55)</td>
</tr>
<tr>
<td>Hypomenorrhoea</td>
<td>3 (17)</td>
<td>2 (13)</td>
<td>1 (9)</td>
</tr>
<tr>
<td>Eumenorrhoea</td>
<td>11 (61)</td>
<td>10 (62)</td>
<td>4 (36)</td>
</tr>
<tr>
<td>Menorrhagia</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Total</td>
<td>18 (100)</td>
<td>16 (89)</td>
<td>11 (61)</td>
</tr>
</tbody>
</table>

Results
The 18 patients included one nulliparous, three primiparous, and 14 multiparous. Mean parity was 2.5 ± 1.2 (range 0–6). Mean age was 47.1 ± 4.2 years (range 39–55). All patients had a biopsy in their work-up and the results showed atrophy (n = 4), benign hyperplasia (n = 7), and normal mucosa (n = 7). Uterine characteristics are listed in Table I.

The median follow-up for this series was 13.9 ± 5 months (range 4–24). Eleven patients (61%) had follow-up for 1 year (range 12–24 months). Table II compares the patients' pre-procedure and post-procedure (at last follow-up) pad counts (P < 0.0001). Table III summarizes the patients' reported change in bleeding at 3, 6 and >12 months at last follow-up.

Success of the procedure was defined as reduction in blood flow from initial menorrhagia to eumenorrhoea or less. In this local anaesthesia cohort of patients, the success rate was 100%. None required further therapy during follow-up. Of our 33 patients treated under general anaesthesia, the success rate was 90% (no significant difference) with similar follow-up duration. Pre-existing moderate to severe dysmenorrhoea was reported in 4/18 (22%) patients. All these women reported that their dysmenorrhoea was reduced at postoperative follow-up. Our study size clearly limited the power of these findings.

No complications occurred during or postoperatively in the
18 local anaesthetic procedures. Since there was no uterine incision, the blood loss was scant. The tolerance of the procedure was interpreted with a pain scale test average of 3.8 ± 1.3 (range 3–10). During the procedure, midazolam, 1 mg i.v., was required for seven of the 10 initial patients of the series. Those patients correspondingly scored at the higher end of the pain scale test. Among the last eight patients, however, none needed i.v. sedation. The typical procedure time was 15 min.

Three patients in this series had severe medical disease (hypofibrinogenemia, valvulopathy with coumarin treatment, and heart–lung transplantation). For these patients especially, local anaesthesia offered the least risk with a high level of tolerance and acceptance.

Discussion

Our preliminary results of this pilot study with a minimally invasive method of endometrial ablation are in agreement with those reported with the same technique under general anaesthesia (Singer et al., 1994; Vilos et al., 1996; Amso et al., unpublished) and are similar to the results from hysteroscopic treatment of menorrhagia (Garry et al., 1995; Goldrath, 1995; Valle, 1995; O’Connor and Magos, 1996). Based on our results and those previously reported in the literature, uterine thermal balloon therapy reduces menstrual flow to a level satisfactory to both patient and clinician and is effective under local anaesthesia.

The level of difficulty to perform this procedure is similar to that required for inserting an intrauterine device. This technique does not require distending solutions, high energy sources (electrosurgical generators or lasers), or direct endometrial visualization, and rarely requires cervical dilatation. The risk of a balloon rupture causing thermal burns from hot solution inside the uterine or peritoneal cavity seems remote (Neuwirth et al., 1994). In fact, a treatment using hot solution directly inside the cavity has recently been proposed (Barrionuevo et al. 1996). In a continuing multicentre trial of 300 patients (Amso, unpublished) and in ~1800 balloon procedures world-wide, no such complication has been reported and the minor complication rate appears to be 3% (cystitis, low grade endometritis, haematometra). In our small pilot study, it was not possible to rule out a contribution of preoperative treatment to the normalization of menses.

In our series, all 18 patients had a decrease or normalization of their excessive menstrual bleeding and six (33%) patients had amenorrhoea ≥1 years after the procedure. At the time of treatment, the mean age of our patients was 48.1 ± 1.7 years. It seems that older patients have increased chances of success and lower post-procedure pad counts independent of preoperative bleeding scores (Amso, unpublished). Thus, this minimally invasive procedure appears to be the treatment of choice for menorrhagia during the perimenopause and also in refractory postmenopausal bleeding on hormone replacement therapy.

With good patient selection for ThermaChoice uterine balloon therapy, we successfully performed endometrial ablations under local anaesthesia in our clinic setting, thus reducing operating room utilization and its associated costs and inconveniences. The reduction of the cost by this technique is mainly due to the decrease of indications for general anaesthesia. The absence of complication is the second point which appears as cost effective by comparison with other conservative surgical therapies. Moreover, the absence of medical uterine preparation before the procedure decreases the cost. Although seven women required more pain control than a purely local anaesthetic could provide, it appeared that no sedation was necessary in the last eight patients. This suggests that increased physician experience could achieve better patient comfort. This finding should be confirmed by a large number of patients. We estimate that 30–40% of patients would qualify and accept the procedure under local anaesthesia with tolerable discomfort to themselves. Especially in the presence of severe medical disease, this technique appeared to minimize the procedural risks.

We feel the results of this pilot study support balloon ablation under local anaesthesia as a minimally invasive procedure of choice for many women with dysfunctional uterine bleeding. This procedure does not require specialized training for the average gynaecologist and the results are similar among various surgeons. This simple and effective treatment could decrease the physical, emotional, and economic cost of menorrhagia. We expect it to decrease the reliance on traditional hysterectomy, sophisticated operative hysteroscopy, and often poorly tolerated medical therapies. The evidence indicates it is a safe, well tolerated, and reliable procedure which eventually may become a first line therapy for menorrhagia. Since we were commonly able to avoid general anaesthesia in this study, we conclude that uterine thermal balloon endometrial ablation, under local anaesthesia, should become an office-based procedure for the treatment of menorrhagia.

Nevertheless, we need more experience to place exactly this new method in the practice of the gynaecologist and a randomized case-control study with other conservative hysteroscopic therapies must be performed. As recently proposed by Romer and Lober (1997), for correction of a complete septate uterus, balloon technique therapies have become a new instrument for use in several surgical situations.

References


Value Newsletter of the Medical Audit Unit of the Royal College of Obstetricians and Gynaecologists. May, 1996.


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