Introduction

Dysfunctional uterine bleeding (DUB) is one of the most common causes of menorrhagia. There are varied approaches used to treat this common condition, starting from medical treatment to hysterectomy. The medical management often fails to give relief. The minor surgical procedure like dilatation & curettage (D&C), though may be helpful to arrive at a definite diagnosis, falls short in effectively treating the condition even for a short duration. The advent of thermo-ablation in recent years has shown effective treating the condition even for a short duration. However this UBT is also an expensive technique to treat excessive menstrual flow. Hysterectomies can be avoided with this simple technique and it is also useful in patients in whom anesthesia is contraindicated.

Key words: uterine thermal ablation, Foley’s catheter, menorrhagia

Summary. Objectives. To introduce a simple and cost-effective ablative technique to treat excessive menstrual flow. Design. Prospective study from Oct 2005 to May 2007. Total 50 patients were studied. Methods. The endometrium was treated with boiling normal saline for 9 minutes with the use of Foley’s catheter. Side effects, complications and outcome of the operative procedure were studied. Results. The success rate according to reduction in blood flow was 92% at 3 months, 93.75% at 6 months, 89.58% at 9 months and 91.3% at 12 months post-operatively. Over all satisfaction rate of the procedure was 88%. 70% patients had mild cramps or lower abdominal pain and 80% patients had pink or watery vaginal discharge in the immediate post-operative period. No patient had complaint of pain or discharge at the end of 12 months. 10% patients required hysterectomy due to persistence of symptoms. Conclusion. Thermal ablation with Foley’s catheter is a simple, effective, less invasive and inexpensive technique to treat excessive menstrual flow. Hysterectomies can be avoided with this simple technique and it is also useful in patients in whom anesthesia is contraindicated.
Material and methods

This prospective study was carried out in the Department of Obstetrics and Gynecology at B. J. Medical College, Ahmedabad, India from Oct-2005 to May, 2007. In 50 patients with excessive menstruation: menorrhagia (21), polymenorrhagia (26) or polymenorrhoea (3) were treated with a very simple technique of thermal ablation. Pregnancy and pelvic infection were ruled out in all patients. Hypothyroidism or bleeding disorders were also ruled out when suspected clinically. Trans vaginal sonography (TVS) was performed in all patients prior to the procedure and during each subsequent visit. Four patients with small fibroid or endometrial polyp were included in the study.

Inclusion criteria

- Menorrhagia, polymenorrhoea, polymenorrhagia or excessive anovulatory bleeding (sufficient to cause anemia or bleeding is repeatedly profuse or occurring at less than 21 day interval);
- Has completed childbearing;
- Uterine size < 12 weeks gestation;
- Utero cervical length < 10 cm & antero-posterior diameter < 7 cm.
- Diagnostic evaluation of the uterine cavity by ultrasound failed to show evidence of verifiable pathology (except small leiomyoma or small polyp);
- Endometrial thickness (ET) <18 mm.

Exclusion criteria

- Pregnancy or desire to become pregnant in future;
- Known or suspected endometrial or cervical carcinoma;
- Premalignant changes in endometrium;
- Prior classical cesarean delivery or transmural myomectomy;
- Uterine anomaly e.g. septate, bicornuate or unicornuate uterus;
- Intrauterine device in place;
- Active urinary tract infection at the time of treatment.

Procedure

The procedure was done under local anesthesia. We performed dilatation and curettage just before the procedure in the same sitting to reduce the endometrial thickness for better effectiveness of the procedure and as well as to obtain endometrial biopsy.

Preparation: Foley’s catheter (No.16) was prepared for use. The balloon of catheter was inflated with 7 mL of normal saline and then the tip of main channel was cut above the level of inflated balloon. This was done to remove the tip which would otherwise reduce the effectiveness by coming in the way of the heat transmission in the area where it comes in the contact with the endometrium. Then the balloon was deflated.

Procedure: After completion of D&C, Foley’s catheter was inserted through cervix up to just beyond internal os with the help of uterine packing forceps. Then the balloon was inflated with boiling normal saline through a syringe. The temperature of fluid which is going to be filled in the syringe was recorded on thermometer in initial few cases. It was around 98°C. The inflation was continued till some resistance was felt. Around 5 to 7 mL fluid could be injected on an average. The hot saline was left in situ for 3 minutes. Then the balloon was deflated. The procedure was repeated for another 2 times so that endometrium was actually treated with hot saline for a total of 9 minutes. Then the catheter was removed.

The patients were kept admitted for observation for one day. They were advised 4 follow-up visits at every 3 months up to 1 year. We have 3 months follow up (F1) of 50 patients, 6 months follow up (F2) of 48 patients, 9 months follow up (F3) of 48 patients and 12 months follow up (F4) of 46 patients. Patients who underwent hysterectomy due to persistence of symptoms were dropped out from further follow up. This is a primary study. The research is still continued for studying long term results.

In each follow up visit, patients were enquired about subsequent bleeding pattern, lower abdominal pain and watery or pinkish vaginal discharge during the past 3 months. Local examination and TVS were carried out in each follow-up visits. Patients with post-operative amenorrhoea, oligomenorrhoea or eumenorrhoea were considered having good bleeding pattern and the treatment was considered successful in them while patients with post operative bleeding pattern of menorrhagia, polymenorrhoea or polymenorrhagia were considered having bad bleeding pattern and the treatment was considered unsuccessful in them. Patients’ satisfaction rate was also studied in terms of »very good«, »good«, »ok« or »bad«.

The other factors of consideration in our study were: age of the patient, duration of abnormal bleeding, number of bleeding days per cycle and number of pads used per day. Histo-pathological report of D&C was also correlated with the outcome. Statistical analysis was per-
formed using Microsoft Excel. Graphs were prepared using the same software package.

**Results**

We studied 50 patients with excessive menstrual bleeding. Majority of the patients (82%) were in the 31–45 year age group. There was only one patient (2.0%) aged 25 years in 20–25 year age group (Fig. 1).

![Percentage of age groups of patients](image)

The pre-operative endometrial thickness (ET) varied from 4 mm to 18 mm. One patient had a 4 cm anterior wall fibroid, one had a 14 mm posterior wall fibroid, one had a 9 mm and another had a 15 mm submucous fibroid while another one had a small endometrial polyp on TVS. The utero-cervical length (UCL) varied from 6–10 cm.

In this study, in 11 patients (22%) there was significant past history of medical disorder or surgical treatment; 5 patients had hypertension, 1 had diabetes melitus, 1 had hypothyroidism, 1 was suffering from intervertebral disc prolapse, 2 patients were having history of previous 2 lower segment cesarian sections and 1 patient was having history of previous 3 lower segment Cesarian sections.

In this study, preoperative duration of menstrual flow was on an average 9.7 days per cycle (Table 1.) and average pad usage was 4.5 per day (Table 2.) while in last post-operative follow up average duration of menstrual flow was 1.6 days per cycle (Table 3.) and pad usage was 0.7 per day (Table 4.) showing highly significant results (p<0.0001).

Following procedure 10% patients required hysterectomy due to continuation of symptoms. Progestin therapy was started in one patient in whom procedure was failed. 80% patients had pink or watery discharge in the immediate post-operative period. None of the patients had the same complaint in the subsequent visits.

One patient had uterine perforation during D&C procedure and she had to undergo laparotomy for intestinal injury.

**Discussion**

Thermal endometrial ablation is a safe and effective treatment for menorrhagia. It achieves significant decreases in pictorial blood loss assessment chart (PBAC). 50 patients of excessive menstrual bleeding were treated with this simple and cheap technique of thermal ablation. The proprietary systems available in the market...
use very costly disposables, while the price of a Foley’s catheter is very less in comparison to them. The technique used in present study is somewhat cumbersome but the extra effort is well compensated against the high price.

Patients with post operative amenorrhoea, oligomenorrhoea or eumenorrhoea were considered having good bleeding pattern and the treatment was considered successful in them while patients with post operative bleeding pattern of menorrhagia, polymenorrhoea or polymenorrhagia were considered having bad bleeding pattern and the treatment was considered unsuccessful in them (Table 5. Figure 2).

All the patients who had oligomenorrhoea or eumenorrhoea had scanty flow.

The success of the procedure was evaluated in terms of reduced blood flow (amenorrhoea, oligomenorrhoea or eumenorrhoea) and patient’s satisfaction level. The success rate according to reduction in blood flow was 92.0% at 3 months, 93.75% at 6 months, 89.58% at 9 months and 91.30% at 12 months (Figure 3). Above graph (Figure 3) shows that the success rate of the procedure was 92.0% at 3 months (F1), 93.75% at 6 months (F2), 89.58% at 9 months (F3) and 91.3% at 12 months (F4).

In Feitoza et al’s study (thermachoice II uterine balloon was used), follow up was done for 2 years and in last follow up 60–70% of patients were either amenorrhoeic or hypomenorrhoeic after Thermal Balloon Ablation and <11% of patients reported menorrhagia. Kapur et al used Uterine Balloon Therapy System (UBTS) and follow up ranged from 3–29 months with a median of 16 months; 94% patients had either normal or less or no menstruation. In the same study, 76% patients had post operative serous discharge per vagina which lasted for 2–3 weeks.

Overall satisfaction rate was 88% defined as above. Above table shows that only 12% patients had bad experience while the overall satisfaction rate was 88%.

There was significant correlation of cystic hyperplasia with failure of treatment (Table 7). Above table shows correlation of hysto-pathological report of D&C and rate of hysterectomy. It was highest with cystic hyperplasia type of endometrium.

### Table – Tablica 5. Post operative bleeding pattern / Postoperativni tip krvarenja

<table>
<thead>
<tr>
<th>Bleeding Pattern</th>
<th>F1 (After 3 months)</th>
<th>F2 (After 6 months)</th>
<th>F3 (After 9 months)</th>
<th>F4 (After 12 months)</th>
</tr>
</thead>
<tbody>
<tr>
<td>No.</td>
<td>%</td>
<td>No.</td>
<td>%</td>
<td>No.</td>
</tr>
<tr>
<td>Amenorrhoea</td>
<td>16</td>
<td>32.00</td>
<td>7</td>
<td>14.58</td>
</tr>
<tr>
<td>Oligomenorrhoea</td>
<td>11</td>
<td>22.00</td>
<td>7</td>
<td>14.58</td>
</tr>
<tr>
<td>Eumenorrhoea</td>
<td>19</td>
<td>38.00</td>
<td>31</td>
<td>64.58</td>
</tr>
<tr>
<td>Menorrhagia</td>
<td>1</td>
<td>2.00</td>
<td>3</td>
<td>6.25</td>
</tr>
<tr>
<td>Polymenorrhoea</td>
<td>1</td>
<td>2.00</td>
<td>0</td>
<td>0.00</td>
</tr>
<tr>
<td>Polymenorrhagia</td>
<td>2</td>
<td>4.00</td>
<td>0</td>
<td>0.00</td>
</tr>
<tr>
<td>Total</td>
<td>50</td>
<td>–</td>
<td>48</td>
<td>–</td>
</tr>
</tbody>
</table>

(F1. Follow up after 3 months; F2. Follow up after 6 months; F3. Follow up after 9 months; F4. Follow up after 12 months)

Figure 2. Post op bleeding pattern
Slika 2. Postoperativni tip krvarenja

(Amenorrhoea/Oligomenorrhoea/Eumenorrhoea = Good pattern = successful procedure)
(Menorrhagia/Polymenorrhagia/Polymenorrhoea = Bad pattern = unsuccessful procedure)
Figure 4 shows that 70% patients had mild cramps or lower abdominal pain in their immediate post-op period. None had any pain at the end of 12 months. There were no significant complications. There was only one case of uterine perforation during D&C procedure. There wasn’t any problem of balloon rupture during the procedure.

Hysterectomy had been performed in 5 (10%) patients. One patient had the complaint of polymenorrhagia for 6 months. Her preoperative ET (endometrial thickness) was 9 mm. Her endometrial biopsy report was suggestive of cystic hyperplasia. She continued polymenorrhagia at the end of 3 months so hysterectomy was performed. The second patient had menorrhagia for 3 months with preoperative ET 16 mm. Histopathological report was suggestive of cystic hyperplasia. Her menstrual pattern was polymenorrhagia at the end of 3 months. The third patient had menorrhagia for 12 months with preoperative ET 9 mm. Histopathological report was suggestive of cystic hyperplasia. Her menstrual pattern was persistent menorrhagia at the end of 9 months so hysterectomy was planned. The fourth patient had polymenorrhagia for 10 months with preoperative ET 6 mm. Histopathological report was suggestive of cystic hyperplasia. Her menstrual pattern was oligomenorrhoea, menorrhagia & metrorrhagia at the end of 3, 6 & 9 months respectively so hysterectomy was performed. The fifth patient had preoperative polymenorrhagia for 4 years, her preoperative ET was 9 mm and histopathological report was suggestive of proliferative phase. The menstrual pattern was amenorrhoea, eumenorrhoea, and polymenorrhagia at the end of 3, 6, 9, and 12 months respectively. Hysterectomy was performed at the end of fourth visit.

In Hazard et al study 9% patients went on to have a hysterectomy after the TBA procedure, 4% had D&C and 2% underwent repeat TBA. In Feitoza et al7 study during follow up out of 141 patients, 21 patient undergone hysterectomy i.e. 15%, one patient undergone myomectomy and 6 patients were given hormonal treatment.

The hysterectomy rate of our unit due to DUB has been decreased significantly in the years of 2006 & 2007. So many hysterectomies due to DUB could be prevented with this simple, cheap and noninvasive technique.

Conclusions

D&C followed by thermal ablation with Foley’s catheter is a simple, effective, less invasive and inexpensive technique to treat menorrhagia.

Immediate post-operative side effects of the procedure like lower abdominal pain and discharge per vaginam are tolerable and not much bothersome.

Hysterectomies can be avoided with this simple technique and it is also useful in whom anesthesia is contraindicated.

Acknowledgements

We are thankful to all the 50 patients who allowed us to perform the new technique and who also supported us in our study by regular follow-up. We are also thankful to residents of our unit: Dr. Nimisha Pandya, Dr. Shital Kapadia, Dr. Arti Sardana, Dr. Priya Gupta, Dr. Shushma Gupta, Dr. Chetna Vaghela, Dr. Jigar Desai and Dr. Pragna Panchal for their contribution towards successful completion of this study. We are also thankful to Dr. Lalit Kapadia, Associate Professor, Obst. & Gyn, for his invaluable co-operation. We are also thankful to Ankita Shah for her invaluable co-operation for statistical assistance.

Disclosure of Interests

There are no interests of any sort involved with the study.

Contribution to Authorship

Dr. Tejal Patel has performed the surgical technique. She has analysed and interpreted the data. She has fi-
nally approved the version. This paper has not been published anywhere else till now.

Dr. Bakul Leuva has given substantial contribution to conception and design of this study. He has revised the article critically for important intellectual content.

Details of Ethics Approval

The technique has been used routinely in the unit since a long time however the study was done to properly evaluate the efficacy of the technique and the ethical committee approval was obtained.

Funding

The study was self funded. There are no other monitory interests involved.

References


Paper received: 17. 08. 2011.; accepted: 15. 05. 2012.

Author’s address: Teaching Institute, Obstetric and Gynecology Department, B.J. Medical College, Ahmedabad, India 380016; E-mail: tejallpatel@yahoo.co.in

SLJEDEĆI SASTANCI – NEXT MEETINGS

<table>
<thead>
<tr>
<th>Mjesto i datum</th>
<th>Naziv sastanka</th>
<th>Informacije na adresu</th>
</tr>
</thead>
<tbody>
<tr>
<td>15.–17. XI. 2012. Zagreb, Hotel »Dubrovnik«</td>
<td>2. hrvatski kongres ginekološke onkologije</td>
<td>SPEKTAR PUTOVANJA, Zagreb, Tkalciceva 15/II, Tel. +385 1 48 62 600, fax. +385 1 48 62 622, E-mail: sanja.vukov-colicspektar-holidays.hr; <a href="http://www.hgod2012.org">www.hgod2012.org</a></td>
</tr>
</tbody>
</table>

* * *

VIJESTI

NEWS