Foley catheter balloon endometrial ablation: Successful treatment of three cases

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Abstract

Endometrial ablation is one of the most effective methods for treatment of dysfunctional uterine bleeding (DUB). Balloon devices with circulating hot water inside or electrodes on the outer surface and radiofrequency-induced thermal destructors are the most recently introduced available tools for endometrial ablation. All of these methods are effective and simple but expensive technologies. The aim of this brief report is to evaluate the effectiveness and safety of a new, simple and money-saving procedure, namely foley catheter balloon endometrial ablation (FCBEA), for treatment of DUB. We present our experience with FCBEA performed on 3 women with severe meno-metrorrhagia unresponsive to medical therapy. There were no procedure-related complications with achievement of complete amenorrhea for a 19 months follow-up period. Although FCBA has yielded encouraging results, there exists a need for further investigation and validation on larger groups, before its universal application.

Keywords: Endometrial ablation, Foley catheter, Uterine bleeding.

Introduct?on

Menorrhagia, the loss of 80 ml or more of blood per period without an identifiable cause is a common complaint. At least 22% of gynaecologic referrals are attributed to menstrual disorders and it is responsible for one-third of the hysterectomies performed in the western countries.1 Such women are treated with progestogens, oral contraceptives or gonadotrophin-releasing hormone agonists.1

Hysterectomy has traditionally been regarded as the definitive surgical treatment for heavy menstrual bleeding but in spite of a 100% success rate, it is a major surgical procedure with significant physical complications and economic costs.2

Different methods for endometrial ablation have been introduced to preserve the uterus and decrease comorbidities, such as laser photovapourisation,3 rollerball ablation,4 transcervical resection of the endometrium. These methods are termed first generation methods and are widely regarded as the gold standard for endometrial ablation.5 They all require direct visualization by hysteroscopy.2 The cost and
availability of these surgical instruments limit their universal usage and cause patients to opt in favor of more morbid and costly procedures, like hysterectomy. Therefore, several non-hysteroscopic techniques, i.e. second generation techniques, have recently been introduced with the aim of providing simpler, quicker and safer procedures. Furthermore, they do not require general anaesthesia and can be performed in outpatient settings. These are cryoablation, hot saline solution irrigation, diode laser hyperthermy and microwave ablation. However, only, few trials have been undertaken to assess their efficacy and safety.

Amongst these techniques Thermal Balloon Endometrial Ablation (TBEA) is one of the alternatives. TBEA is a minimally invasive non-hysteroscopic technique, which combines heat and pressure within the uterine cavity to destroy endometrium and part of the myometrium. A flexible balloon attached to a catheter is placed into the uterus. The balloon is then inflated up to 160-180 mm Hg with a sterile fluid, which is heated up to 87°C and is maintained in the cavity for 8 min.

Although TBEA provides a good alternative requiring low surgical skills together with acceptable success and complication rates, its use is still limited due to the price of the devices and probe expenses.

In this pilot study, we used foley catheter balloon endometrial ablation, which was presumed to be a cheaper and highly available equipment.

**FCBEA Method**

The FCBEA method was performed on 3 patients at the Outpatient Department of our tertiary center between April 2008 and December 2009. The patients' primary complaints were menometrorrhagia refractory to medical therapy. All of the patients underwent a clinical examination with relevant investigations including full blood count, ultrasonographic (USG) examination and endometrial biopsy which were normal in all of the patients.

The procedure was performed under sedoanalgesia in the outpatient clinic via the following steps: First of all, the tip extension above the balloon of an 18-Gauge silicone Foley catheter was cut by a scalpel and then the balloon was instilled with boiling water to check if it was intact. Following the preparation of the Foley catheter balloon, patients were positioned in the dorsal lithotomy position. Graves' speculum was introduced into the vagina and betadine was applied for vaginal disinfection. The cervix was fixed by a tenaculum and dilated with 2/8 Hegar dilators. Then, the Foley catheter was introduced into the uterine cavity and its balloon was inflated with 30 ml. of 0.09% NaCl whose temperature was brought up to 100°C by boiling in a kettle beside the operator. It was placed inside the uterus for 3 minutes. Following this, the fluid was sucked out of the balloon and this procedure was repeated twice. The speculum was kept in place throughout the procedure and small sponges were placed between the lateral vaginal wall and the catheter in order to avoid lateral vaginal wall burns. Postoperatively, the patients were prescribed NSAIDs and an oral antibiotic. All patients recovered fully and were discharged on the same day. Table summarizes the patients characteristics.

**Case-1:**

A 45-year old woman, G4P4, was referred to our clinic due to severe menorrhagia refractory to medical therapy and full curettage. Consequently, the patient was scheduled for abdominal hysterectomy. However, the patient was classified as a Class IV risk according to American Society of Anesthetists (ASA) Physical Status (PS) classification system due to her cardiac insufficiency necessitating digoxin therapy. Therefore, FCBEA was performed after having the patient's informed consent. Following the procedure, menometrorrhagia remained resolved during a 38 month follow-up period. Watery discharge for 18 days was the sole problem following the procedure.

**Case-2:**

A 44-year old, G7P4A3, woman presented with heavy menstrual bleeding refractory to medical therapy which necessitated blood transfusion. She was offered FCBEA since her risk evaluation was Class III according to ASA PS system. After taking her informed consent, FCBEA was performed, which resulted in complete amenorrhea during 35

<table>
<thead>
<tr>
<th>Age</th>
<th>Parity</th>
<th>Symptoms</th>
<th>Previous treatment</th>
<th>Follow up</th>
<th>Adverse effects</th>
</tr>
</thead>
<tbody>
<tr>
<td>45</td>
<td>4</td>
<td>Severe menorrhagia, faintness and lower abdominal pain</td>
<td>Gestagen therapy and full curettage</td>
<td>38 months</td>
<td>Watery discharge persisting for 18 days</td>
</tr>
<tr>
<td>44</td>
<td>4</td>
<td>Heavy menstrual bleeding and blood transfusion requiring anemia</td>
<td>Gestagen therapy and tranexamic acid</td>
<td>35 months</td>
<td>Watery discharge persisting for 27 days</td>
</tr>
<tr>
<td>32</td>
<td>2</td>
<td>Menorrhagia</td>
<td>Hysteroscopic resection of myoma, an abdominal myomectomy, gestagen therapy</td>
<td>19 months</td>
<td>Watery discharge persisting for 14 days</td>
</tr>
</tbody>
</table>
months of follow-up period. The patient's only complaint was watery vaginal discharge which lasted for 27 days.

Case-3:

A 32-years old woman, G2P2, presented with menorrhagia. She had had hysteroscopic resection of a submucous myoma, one third of intramural component of which had been left in situ. Since menorrhagia persisted for 11 months following the operation, she underwent an abdominal myomectomy. However, she still experienced gestagen refractory menorrhagia and levonorgestrel releasing intrauterine system (Mirena®) application did not alleviate her bleeding. Consequently, FCBEA was performed after taking her informed consent. After a period of watery discharge persisting for 14 days, the patient has complete amenurhea over a 19 months of follow-up period.

Discussion

A variety of nonhysteroscopic techniques for endometrial ablation offer safety and efficacy comparable with hysteroscopic techniques, while requiring less technical skill and operative time. However, one of their disadvantages is being expensive and relative unavailability. Garside et al. concluded that second-generation techniques are likely to be more cost-effective than first-generation techniques in most cases with heavy menstrual bleeding and hysterectomy continues to be a very cost-effective procedure compared to all endometrial ablation methods.

In order to assess histopathological changes in the endometrium of patients undergoing FCBEA, a prospective, randomised study was performed in Turkey and it was found to cause necrosis in the endometrial glands and stroma. Consequently, this was suggested to be a simple method applicable on outpatient basis for the treatment of resistant menometrorrhagia. However, up to date, this method has not been used in any clinical study.

Therefore, we wanted to apply this method as an alternative to nonhysteroscopic techniques of endometrial ablation. Although foley catheter is not originally designed for this purpose, it was successfully used for FCBEA in our patients. Similarly, Foley catheter has also been used to treat postpartum haemorrhage and postmyomectomy uterine bleeding.

However, we still do not have sufficient data to support claims of safety. Variables needed to be assessed include temperature measurements of the serosal surface, area of mucosa affected by thermal damage and depth of thermal damage. Consequently, it seems to be worth conducting trials using FCBEA in selected patients who are not appropriate candidates for hysteroscopy or hysterectomy.

Foley catheter balloon ablation is a new method of TBEA which itself is reported to be a promising, safe and effective minimal invasive method for the treatment of abnormal uterine bleeding. In two of our patients, the contraindication for general anaesthesia was the primary reason for the application of this new method. Nonhysteroscopic techniques of endometrial ablation carry the advantage of being used in cases where general anaesthesia may be associated with particular risk.

The median follow-up period for our patients was 31 months. The only complaint was watery vaginal discharge presumed to be due to increased capillary permeability and transudation secondary to burn injury of the endometrium. Menometrorrhagia successfully resolved in all cases who declared to be greatly satisfied with the method although the comparison of the technique with other various methods for endometrial ablation is not available.

Conclusion

In conclusion, there is a need for more data on the outcomes of the patients treated with FCBEA. With a limited follow up, it seems to yield promising results and is especially beneficial for patients whose access to first-generation endometrial ablation techniques is limited.

References