Thermal Balloon Endometrial Ablation in the Treatment of Heavy Menstrual Bleeding

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ABSTRACT

Aim: Heavy menstrual bleeding is one of the common health problems in women. The first-line therapy of heavy menstrual bleeding is the medical therapy, but this is not successful. Currently, global ablation procedures were introduced for treating of heavy menstrual bleeding. The aim of this study was to the analysis of the patient with menorrhagia performed operations of Cavaterm in our university affiliated hospital, and explores its effectiveness and acceptability.

Methods: A retrospective study was conducted on 30 patients with menorrhagia who were unresponsive to hormone therapy or not candidates for hysterectomy underwent endometrial ablation using Cavaterm. Preoperative and postoperative PBAC Scoring System was used to assess menorrhagia. Outcome measures were amenorrhea rates, reduction of menstrual flow rates, heavy bleeding, menstrual and patients’ satisfaction rates at 3, 6 and 12 months postoperative.

Results: After a follow-up at 3, 6, and 12 months postoperative, 36.7%, 43.3%, and 36.7% of women had a reduction in vaginal bleeding, respectively. Amenorrhea rates were 56.7%, 50.0%, and 56.7% in the Cavaterm at 3, 6, and 12 months. The rate of women’s reported good or excellent satisfaction was 93.3% in 12 months. During the follow-up period, no woman received a subsequent hysterectomy.

Conclusion: The findings of this research indicated that outcome with the Cavaterm was as good for women with menorrhagia. Therefore, it is necessary to emphasize on lower operative and post-operative procedural risk and a deleterious effect on patients who were unresponsive to hormone therapy.

Key words: Abnormal uterine bleeding, Cavaterm, menorrhagia, thermal balloon endometrial ablation

1. INTRODUCTION

Heavy menstrual bleeding is a significant health problem in premenopausal women and that would be equivalent to menorrhagia (1, 2). The treatment of menorrhagia can either be medical therapy, hysterectomy or destruction of the endometrial. Medical therapy is the first-line therapy, but this is not successful while hysterectomy is effective in treatment of bleeding but it is associated with many complications (3, 4). In addition, it is often more expensive than medical therapy (5). In the 1980’s, endometrial ablation procedures were introduced in treatment of dysfunctional uterine.

The endometrial ablation is a technique of removing (ablating) the lining of the endometrium to suppress or decrease menstruation for treating menorrhagia in women who failed standard therapy. Various methods such as cryotherapy, heated saline, microwaves, and thermal balloon exist to destroy the endometrium as a treatment for menorrhagia. The thermal balloon endometrial ablation includes four kinds of devices: ThermaChoice®, Mento-treat “”, Cavaterm “”, and Thermablate “”. These procedures are a less invasive alternative compared to hysterectomy (2, 6-12) and approved by the US Food and Drug Administration (FDA) for women with menorrhagia whom childbearing is complete, but they are not generally available for use in Iran. Cavaterm has a low-allergen silicon material, and the balloon length can be adjusted to cavity length of different size of uterine, which it can protect surrounding tissues from thermal damage. Recently, Cavaterm was activated to treatment of dysfunctional uterine bleeding (DUB) for women with menorrhagia that has not responded to medical treatment in Iran (13, 14). We found no routine data on the Cavaterm procedure carried out in Iran. The researcher has come across the reality that Cavaterm may still be required to conduct this study to assess the effectiveness and acceptability of Cavaterm method. The aim of this study was to the analysis of the patient with menorrhagia performed operations of Cavaterm in our university affiliated hospital, and assesses the effectiveness and acceptability of the Cavaterm system.
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2. PATIENTS AND METHODS

This study was approved by the ethics committee of the Medical Sciences University of Babol. A compilation sheet was developed for the study after taking the written permission and satisfaction of the patients. A retrospective study was done for all women with menorrhagia who have undergone endometrial destruction with thermal balloon in our university affiliated hospital. All patients had completed her family and agreed to undergo endometrial ablation with Cavaterm. The patients with heavy menstrual bleeding or prolonged uterine, vaginal bleeding unresponsive to medical treatment, or not candidates for hysterectomy used of tampons during the course period and recorded their use of tampons. A sonography was used to rule out endometrial pathology and uterine congenital anomaly. An endometrial biopsy in order to assess endometrial cancer was done.

Exclusion criteria included uterine tumors (fibroids or polyps), uterine cavity less than 4 cm, active urinary tract infection and pelvic infection, history of surgery (myomectomy), endometrial ablation and classical caesarean section.

In all eligible patients, were given rectal diclofenac, pre-and postoperative. Cavaterm endometrial thermal ablation technique with disposable balloon (FDA approval obtained in 1997) was performed under local anesthetic. The vaginal pain/ fever at postoperatively assessed visual analogue scale 1 to 10. Women were discharged the same day.

Preoperative and postoperative PBAC Scoring System was used to record size of clots/ flooding row under the relevant day. If the score was 100 or greater was indicated that the women had a heavy menstrual period or menorrhagia (15).

All patients completed health status questionnaires included questions on the amenorrhea, reduction of menstrual flow, heavy bleeding postoperative in the 3rd, 6th, and 12th months after the end of treatment. In addition, intra-operative and postoperative complications include fluid overload, hematometra, uterine rupture, and laceration of cervix was measured. The return to normal activities and return to occupation activities was questioned through phone. It included questions on the amenorrhea, reduction of menstrual flow, heavy bleeding postoperative. In addition, intra-operative and postoperative complications include fluid overload, hematometra, uterine rupture, and laceration of cervix was measured.

3. RESULTS

The mean age of the patients was 43.3±5.8 years at the time of treatment. The patient characteristics were shown in Table 1. The mean of pelvic pain/cramping with visual analogue scale scores of pain was reported 5.8±2.2 in 24 hours of the procedure. Around 20% of the patients reported pelvic pain/cramping until 1 week of the procedure.

After a follow-up in 3, 6, and 12 months postoperative, 36.7%, 43.3%, and 36.7% of women had reduction in vaginal bleeding, respectively. Amenorrhea rates were 56.7%, 50.0%, and 56.7% in the Cavaterm at 3, 6, and 12 months, respectively, and the remaining two women (6.7%) were considered treatment failures.

Rates of heavy bleeding in 12 month were relatively low around 6.2%. A subsequent hysterectomy for recurrent bleeding was not performed in the treated individuals by Cavaterm. The rate of women’s reported good or excellent satisfaction was 93.3%in the Cavatermin 12 months (Table2). There were no major complications.

4. DISCUSSION

Some researchers have shown the Cavaterm endometrial ablation system to destroy the endometrium reduces initial cost, operating time, and postoperative complications compared with hysterectomy (3). According to the followed researches with the Cavaterm system some studies reported amenorrhea rates between 22%, and 68%, respectively (16, 17). The Cavaterm ablation is not usually used in Babol, Iran. It only used to selectively destroy uterine for a short time in the hospital. There were no reportable complications with the Cavaterm endometrial ablation system of health care providers in Iran. Any new technique is introduced, it is essential to evaluate carefully in routine practice. Reduction of menstrual flow

<table>
<thead>
<tr>
<th>Variables</th>
<th>Means</th>
<th>SD</th>
<th>Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>43.3</td>
<td>±5.8</td>
<td>30, 7</td>
</tr>
<tr>
<td>BMI</td>
<td>31.3</td>
<td>±6.8</td>
<td>19.1, 2</td>
</tr>
<tr>
<td>Pregnancy</td>
<td>3.2</td>
<td>±1.4</td>
<td>0, 6</td>
</tr>
<tr>
<td>Parity</td>
<td>2.6</td>
<td>±1.1</td>
<td>0.5</td>
</tr>
<tr>
<td>Abortion</td>
<td>0.5</td>
<td>±0.8</td>
<td>0.5</td>
</tr>
<tr>
<td>Score of bleeding</td>
<td>361.3</td>
<td>±227.5</td>
<td>140, 900</td>
</tr>
</tbody>
</table>

Table 1. Characteristics of the women with heavy menstrual bleeding undergoing endometrial ablation procedure (Cavaterm) (n=30)

<table>
<thead>
<tr>
<th>Variables</th>
<th>Mean</th>
<th>SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Operation time (minutes)</td>
<td>12.0</td>
<td>1.8</td>
</tr>
<tr>
<td>pelvic pain/cramping at 24 hour</td>
<td>5.8</td>
<td>2.2</td>
</tr>
<tr>
<td>pelvic pain/cramping at 1 week</td>
<td>1.3</td>
<td>2.1</td>
</tr>
<tr>
<td>Return to normal activities (day)</td>
<td>1.8</td>
<td>0.9</td>
</tr>
<tr>
<td>Return to occupation activities (day)</td>
<td>12.7</td>
<td>5.8</td>
</tr>
<tr>
<td>Amenorrhea rate at 3 months’</td>
<td>17</td>
<td>%</td>
</tr>
<tr>
<td>Reduction of menstrual flow rate at 3 months’</td>
<td>11</td>
<td>36.7</td>
</tr>
<tr>
<td>Heavy bleeding rate at 3 months’</td>
<td>3</td>
<td>10.0</td>
</tr>
<tr>
<td>Amenorrhea rate at 6 months’</td>
<td>15</td>
<td>50.0</td>
</tr>
<tr>
<td>Reduction of menstrual flow rate at 6 months’</td>
<td>13</td>
<td>43.3</td>
</tr>
<tr>
<td>Heavy bleeding rate at 6 months’</td>
<td>2</td>
<td>6.7</td>
</tr>
<tr>
<td>Amenorrhea rate at 12 months’</td>
<td>17</td>
<td>56.7</td>
</tr>
<tr>
<td>Reduction of menstrual flow rate at 12 months’</td>
<td>11</td>
<td>36.7</td>
</tr>
<tr>
<td>Heavy bleeding rate at 12 months’</td>
<td>2</td>
<td>6.2</td>
</tr>
<tr>
<td>Patient satisfaction rate at 3 months’</td>
<td>29</td>
<td>96.7</td>
</tr>
<tr>
<td>Patient satisfaction rate at 6 months’</td>
<td>26</td>
<td>86.7</td>
</tr>
<tr>
<td>Subsequent hysterectomy at 12 months</td>
<td>0</td>
<td>0.0</td>
</tr>
</tbody>
</table>

Table 2. Outcome of endometrial ablation procedure (Cavaterm) among women with heavy menstrual bleeding (n=30)

rates, amenorrhea rates, and patient satisfaction rates can be important to assess Cavaterm. We found that amenorrhea rates at 6 and 12 months of 50.0%, and 56.7% for Cavaterm. The rate amenorrhea at 12 months was more than rates reported by Friberg et al. (31%) (18), but Hawe et al. reported less than our study (68%) (11). In addition, in our study, patient satisfaction rates of Cavaterm were similar to those reported by a retrospective assessing Cavaterm on 156 women with dysfunctional uterus bleeding (around 90%) (2).

Researchers have shown that rates of heavy bleeding are variable of 0-32% for Cavaterm (12). However in this study 6.7% patients reported heavy bleeding rate at 12 months, but no subsequent hysterectomy rate at 12 months reported, this figure was lower than that reported by Hawe et al. (9%) (16). There were no major complications reported for Cavaterm, the outcomes of this procedure among women with menorrhagia where improvement procedure outcomes, satisfaction with postoperative complications and the outcome. However hysterectomy is obviously 100% effective in treatment of heavy menstrual bleeding but it causes severe complications (3). In this study, we were not able to compare the efficacy of hysterectomy with Cavaterm. Moreover many safety and efficacy of the new technique of endometrial destruction with thermal balloon must be evaluated. Therefore, if the women’s preference is for a shorter hospital stay and lower intra-post-operative procedural risk, endometrial ablation is recommended.

5. CONCLUSION
We suggest that the outcomes with the Cavaterm endometrial ablation system are as good for women with menorrhagia. However, because of the limited total number of samples and cross-sectional design to determine effectiveness of the Cavaterm system we make no claims from this study that either procedure provides superior outcomes, but it seems that the Cavaterm is a fast action procedure and a short hospital stay with a deleterious effect on menorrhagia in women who failed standard therapy. Certain types of adverse events and rates of intervention with this procedure to endometrial ablation were low. Rates of dissatisfaction with treatment or ongoing heavy bleeding were generally low in this study. Larger clinical trial randomized studies may be required to determine the effectiveness of the Cavaterm thermal balloon ablation system for treatment menorrhagia and long term studies is needed to determine the costs of ablative surgery approach and the cost of hysterectomy due to the requirement for subsequent surgery. A number of newer procedures have recently been developed and available in many countries, most of which are less time consuming.

CONFLICT OF INTEREST: NONE DECLARED.

REFERENCES
Data Content and Exchange in General Practice: a Review

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ABSTRACT

Background: efficient communication of data is inevitable requirement for general practice. Any issue in data content and its exchange among GP and other related entities hinders continuity of patient care.

Methods: literature search for this review was conducted on three electronic databases including Medline, Scopus and Science Direct.

Results: through reviewing papers, we extracted information on the GP data content, use cases of GP information exchange, its participants, tools and methods, incentives and barriers.

Conclusion: considering importance of data content and exchange for GP systems, it seems that more research is needed to be conducted toward providing a comprehensive framework for data content and exchange in GP systems.

Key words: primary care, data flow, data content, data model, general practice, data exchange, general practitioner, information flow, information content, information exchange, family doctor, family care.

1. INTRODUCTION

General practice is as an important component and the gatekeeper of health system. Referral for specialists and hospital are organized by GPs. Communication is vital to accomplish important tasks of general practice, and it is impossible without information and its exchange. Communication is very critical for general practice if its roles is to be realized (1). Continuity of care and its quality across health care continuum depends on the exchange of required information between primary care particularly general practice and other levels of health system (2). Efficient communication of data is inevitable requirement in general practice if the continuity of care is to be achieved (3). Information is pivotal for the quality of patient care(4) and core of care continuity resides in information continuity (5). Any issue in data content and its exchange among GP and other related centers such as other GP offices and hospitals (6) can hinder continuity of patient care (3). Consequently the quality of care and patient safety might be compromised (7, 8).

Aim of this paper is to determine content and exchange of information in General Practice by reviewing the literature.

2. METHODS

We conducted a literature search on three electronic databases including Medline, Scopus and Science Direct. The search was performed using a combination of the following terms: primary care, data flow, data content, data model, general practice, data exchange, general practitioner, information flow, information content, information exchange, family doctor, family care. Figure 1 present a process of selecting papers for the review in detail. No limitation was set for the design of studies. To be included in the review, language of paper must be English.

3. RESULTS

3.1. BASIC CHARACTERISTICS OF STUDIES

The papers included in the present review were published between 1980 and 2013. Most of the papers were published in the US (with 11 articles) (9-19). Other papers originated from England (3, 20, 21), Australia (22-24), Germany (25, 26), Finland (27), Switzerland (28) and Slovenia (29). Content of health information in GP systems have been discussed in 17 studies (3, 10, 12-19, 22-24, 26-29) and exchange of the health information has been the focus of studies in 21 cases (3, 9-23, 25-29).

Most of the studies had addressed participants of the information exchange (3, 10, 12-18, 25-29), as well as its methods and tools (3, 10, 13, 14, 16, 17, 19, 22, 25, 26, 28, 29). However there were a few papers discussing barriers to the information exchange (11, 12, 15-17, 20), its benefits (11, 12, 16, 25) and motivators (11, 12, 17).

3.2. GP’s DATA CONTENT

As shown in Table 1, data content mentioned for GPs in the studies can be categorized in three major classes including demographic data, administrative data, and clinical data. Patient’s name (22), patient’s date of birth (22), gender (22), post code (22), and telephone (22) are details...
of demographic data identified from the studies (10, 19, 22-24, 29). Referrals (14, 16, 18, 23, 24, 27-29) and discharge summary (3, 15, 17, 27) from hospital are among administrative category of data reported in the studies. In the clinical class, there are data on patient’s medical history (15, 19, 22, 24, 27, 29), problem list (14, 19, 22, 24, 27, 29), clinical status (22, 29), diagnosis (3, 26-28), test results (3, 13-19, 26, 27) and diagnostic or therapeutic procedures (14, 26-29).

3.3. GP’s DATA EXCHANGE

As it can be seen in Table 1, different studies have explored various aspects of health information exchange including its use cases, participants, tools and methods, motives and barriers. These aspects are described in detail as follows.

3.3.1. USE CASES

Use cases of GP information exchange identified from the included studies can be classified in three categories including clinical use cases, research use cases and financial and administrative ones. Clinical use cases highlighted in the studies include: viewing hospital correspondence by GP and other practice staff (3, 28); reading the correspondence by GP and doing actions based on the recommendation in it; informing the patient about their medication changes based on the secondary care recommendation; informing GP by hospital during patient’s hospitalization in case of any unexpected clinical procedures (3, 28); ordering laboratory and radiographic tests, tracking and receiving their results by GP (16, 17); e-prescribing (13, 16, 17, 21); getting access to patient child’s or parent’s medical records by GP (16); signing up for preventive health services reminders by patients (16); getting access to test results by GP (16, 17); improving referral processes (11, 16, 21, 28); and communicating clinical information among health care professionals and settings (23). Only one research use case was found for the information exchange: it was for informing patients about participating in medical research opportunities (16).

Main use cases of data from administrative and financial perspective include: Receiving the hospital correspondence by the front line staff in GP office and stamping the date after opening it (3, 28); scanning information received from hospital by administrative staff into the practice’s computer system (3, 16); amending or upgrading patient records by inputting and updating relevant information (3); documenting insurance claims and keeping track of expenses (16), deductibles and co-pays (16); filling out documents by patient before and after a visit (16); finding a physician who accepts patients’ insurance (16); scheduling the appointments (9, 16, 21); creating reports by administrative staff in GP offices (17); providing primary care services within a sustainable business model (11); invoicing for general medical services, and practice accounts; recalling patients, issuing prescriptions and repeating prescriptions for patients (21).

3.3.2. PARTICIPANTS OF THE INFORMATION EXCHANGE

Two categories of participants were identified through exploring the included studies: organizations and people. Participants in the category of organization include hospital (3, 10, 12, 13, 17, 26), laboratory (12, 17, 27), pharmacy (12, 17), public health centers (12), primary care practices (10, 17, 18), Internal medicine (15, 18), cardiology (14, 18), dermatology (18), gastroenterology (14, 18), general surgery (18), hematology/oncology (18), neurology (18), obstetrics and gynecology (18), ophthalmology, oral and maxillofacial surgery, orthopedic surgery, otolaryngology, pathology, pediatrics, psychiatry, urology, pulmonary disease (18). Participants in the category of people include administrative staff (3), GPs (3, 25, 26, 28), hospital specialists (3), radiologists (27), pharmacists (27), payer (12), physicians (13, 15, 17, 27), phlebotomist (13), Orthopedics (14), secretarial staff (27), midwife (18), Nurse practitioner (18, 27), Pediatrics (18), and patients (3, 13, 16, 27-29) and their parents (27).

3.3.3. TOOLS AND METHODS OF INFORMATION EXCHANGE

Tools and methods for exchanging information in general practice were another aspect of GP information exchange presented in the included studies (3, 10, 13, 14, 16, 17, 19, 22, 25, 26, 28-30). The most prevalent tool mentioned for exchanging information was E-mail (3, 10, 13, 14, 16, 17, 19, 22, 28). Fax (13, 17, 25, 28), direct dial connection (3, 10, 22), online forms (19, 28) were other tools and methods deployed for exchanging information in the studies. Portable memory devices (19) and Smartcard (29) were the least favourite tools used for exchanging the information. Not many of the papers provided information