Effectiveness and outcomes of thermablet endometrial ablation system in women with heavy menstrual bleeding

Ghadeer Al-Shaikh, Ghada Almalki, Mujahed Bukhari, Amel Fayed & Hazem Al-Mandeel

To cite this article: Ghadeer Al-Shaikh, Ghada Almalki, Mujahed Bukhari, Amel Fayed & Hazem Al-Mandeel (2017): Effectiveness and outcomes of thermablet endometrial ablation system in women with heavy menstrual bleeding, Journal of Obstetrics and Gynaecology, DOI: 10.1080/01443615.2017.1292228

To link to this article: http://dx.doi.org/10.1080/01443615.2017.1292228
Effectiveness and outcomes of thermablative endometrial ablation system in women with heavy menstrual bleeding

Ghadeer Al-Shaikh, Ghada Almaliki, Mujahed Bukhari, Amel Fayad and Hazem Al-Mandeel

Abstract

Heavy menstrual bleeding (HMB) is a common problem in women of reproductive age group with major impact on their quality of life (QoL). The aim was to study the short-term effectiveness of Thermablative Endometrial Ablation System (EAS) and its impact on QoL in women with HMB. This was a prospective cohort study conducted on consecutive 72 women suffering from HMB. The success rate was estimated and patients’ QoL was compared before and after the procedure using the Aberdeen menorrhagia severity scale. The mean follow-up period was 18 months (6–24 months). The mean age and body mass index were 48 (±5.2) years 33.2 (±7.4) kg/m² respectively. Among treated participants, 58 (80.6%) reported the absence of bleeding. A significant decrease was observed in the rate of missed social activity and increase in the leisure time activities. The overall patient satisfaction was 95.7%. Thermablative EAS is an effective minimally invasive treatment with marked improvement in QoL in women with HMB.

Impact Statement

• Heavy menstrual bleeding (HMB) is a common problem that affects 11–13% of reproductive age women with major impact on their quality of life (QoL). A variety of methods for endometrial ablation has been used for the destruction of the endometrial lining to treat HMB.
• The short-term results of this study shows amenorrhea rate of (80.6%) after the procedure and a significant decrease in the rate of missed social activity and increase in the leisure time activities with marked improvement in QoL. The overall patient satisfaction was 95.7%.
• Thermablative Endometrial Ablation System is an effective minimally invasive treatment for HMB with advantages of shorter operating time, shorter hospital stay and high-level patient satisfaction. However, further clinical research with large-scale studies and possible comparison with other treatment options are recommended.

Introduction

Abnormal uterine bleeding (AUB) is a common and significant health problem in women of reproductive age group. The prevalence of AUB is estimated at 11–13% in the general population and increases with age reaching from 24% to 30% in women aged 36 and above (Marret et al. 2010; Pramsothy et al. 2014).

The causes of AUB during reproductive years have been reclassified by the International Federation of Gynecology and Obstetrics (FIGO) in 2010. The system of classification is based on the acronym PALM-COEIN that describes the structural causes, i.e. polyp, adenomyoma, leiomyoma, malignancy, as well as the non-structural causes including coagulopathy, ovulatory disorders and endometrial causes, iatrogenic, and not yet classified (Munro et al. 2011; Madhira et al. 2014).

Heavy menstrual bleeding (HMB), which is a form of AUB, can occur alone and in combination with other symptoms. The National Institute of Clinical Excellence (NICE) – UK reported that HMB is having a major impact on a woman’s quality of life (QoL), and any intervention should aim to improve this point, rather than focusing on the amount of menstrual blood loss (NICE. Clinical Guidelines 44, 2007). Similarly, a working group from National Institute of Child Health and Human Development – USA has suggested that studies on reproductive health should measure patient-centred QoL changes (Accquadro et al. 2003).

Currently, a variety of pharmacological and surgical treatments are available to reduce menstrual blood loss or to eliminate menstruation altogether. Management options for HMB generally start with the least invasive method (medical treatment) and may progress to reach endometrial ablation procedure or even hysterectomy, which is a major operation that has risks but the only method that guarantees amenorrhea (Roberts et al. 2011). Patient’s preferences for different treatments depend on a woman’s wish for amenorrhea as an outcome and/or avoidance of surgical treatment.

Hysterectomy has long been considered the ‘gold standard’ in the management of medically refractory HMB despite
being a major operation that has risks. However, since the 1980s, the endometrial ablation procedures have become alternative treatments, being minimally invasive, cost-effective and having a shorter recovery period (Sadoun et al. 2006). In 2004, NICE published the guidelines for the use of thermal endometrial ablation and concluded that evidence on safety and efficiency of balloon ablation supports the use of the procedure (Läderger et al. 2015). Endometrial ablation is a technique that involves destruction of the endometrial lining to suppress or decrease menstruation using a variety of methods, such as cryotherapy, heated saline, radio-frequency and thermal balloon device (Brun et al. 2006; Tam et al. 2006; Lavazzo et al. 2008). Thermal balloon endometrial ablation (TBEA) technique is gaining popularity because of its surgical simplicity and efficacy but usually reserved for normal uterine cavities. The reported success rate ranges from 79% to 91%, with long-term patient satisfaction and overall 11%, probability of proceeding to subsequent hysterectomy over 8 years (Grainger et al. 2000; Loffer and Grainger 2002; Mettler 2002; Clark and Gupta 2004; Brun et al. 2006; Lavazzo et al. 2008; Pai 2009). Thermablade Endometrial Ablation System (EAS) is relatively new in the market and to the author’s knowledge there are few papers in the literature on its efficacy and subsequent effects on QoL. The aim of this study was to evaluate the short-term success rate of the procedure and the impact on QoL after endometrial ablation using Thermablade EAS device for the treatment of HMB.

Materials and methods
This was a prospective cohort study conducted on women, who were referred from primary health care clinics to a university hospital with the history of HMB for at least 6 months duration or more, from April 2013 to April 2015. Approval of research protocol was obtained by the University Institutional Review Board. All women were assessed in the General Gynaecology Outpatient Clinics at King Khalid University Hospital (KKUH) in Riyadh, Saudi Arabia. The inclusion criteria were: AUB-COEIN, failed medical treatment, no desire for hysterectomy and no desire for fertility. The exclusion criteria included the presence of malignancy, leiomyoma, uterine cavity anomalies, abnormal Pap smear and the desire to preserve fertility. Women who met the inclusion criteria and opted for surgical treatment were invited to participate in the study and an informed consent was obtained prior to enrolment.

The primary outcome measure was the success rate of the procedure. A successful procedure was defined by: (i) the onset of amenorrhoea within 6 months after balloon ablation, or (ii) menstrual loss described as spotting or light, or (ii) menstrual loss described as moderate bleeding, provided that it was heavy before, and no further treatment was required. Failure of treatment was defined as: (i) the need for further medical or surgical treatment following balloon ablation till time of reporting or (ii) menstrual loss described as heavy. The secondary outcomes were the assessment of the improvement in the QoL of participants after the procedure, satisfaction rate and whether the patient would recommend the procedure to others. The satisfaction rate was determined on a scale of 1–10, six and above was considered satisfactory.

Data collection
Age, weight and height of participants were noted and their body mass index (BMI) was calculated. A detailed medical history, parity, desire for further pregnancy and previous hormonal and surgical treatment were taken. For the assessment of menstrual flow and the impact of HMB on participants QoL, a specific patient-administered questionnaire ‘Aberdeen Menorrhagia Severity Scale’ (AMSS) was used (Ruta et al. 1995). The questionnaire was previously translated and validated in Arabic language and published in the literature (Abu-Rafea et al. 2012). It includes seven questions about gynaecological history, length of menstrual bleeding, heaviness and regularity of the period, presence of dysmenorrhoea, social and occupational effect of the period on the patient (missed work, missed social events, inability to perform activities of daily life, energy level and pain level) and the effect of the period on the sexual life of patients. Participants were asked to select one of the several responses to each of the questions of scale. Possible responses to each question were then assigned ordinal score between 0 and 100, which was used to assess the QoL pre and post ablation. The questionnaire was administered by a research assistant before and after the procedure and he/she was available for any clarification or help in filling the questionnaire. Although objective measurement of menstrual blood loss has been used in many studies for the evaluation of woman reporting HMB, measured blood loss does not provide a comprehensive picture and correlates poorly with presenting symptoms and health-seeking behaviour (O’Flynn and Britten 2000; Warner et al. 2004).

Preoperative objective assessments of all subjects included a blood sample to measure haemoglobin level; transvaginal ultrasound to rule out structural uterine pathology, uterine congenital anomaly and to confirm normal size of uterine cavity; and office endometrial biopsy to rule out precancerous or malignant endometrial changes. All participants underwent endometrial balloon ablation and were followed up for a minimum period of 6 months. Endometrial ablation was achieved by a device named Thermablade EAS (Idoman Teoranta, Ireland) under general anaesthesia in the operating room. Thinning of the endometrium was performed by sharp curettage before ablation. This device is intended to ablate the endometrial lining of the uterus using a treatment liquid that is heated in the device to reach a temperature of 178°C. The total treatment cycle takes less than three minutes, which is the time taken to obtain a treatment depth of 4–5 mm. The authors performed diagnostic hysteroscopy before and after the ablation in the operating theatre. All patients were discharged from hospital on the same or next day. Preoperative prophylactic antibiotics were not routinely given to all patients.

Data analysis
Normality testing of continuous variables was done using the Kolmogrov–Smirnov test. Descriptive statistics for normally
distributed variables was presented in mean ± standard deviation. Those skewed variables were displayed as median and inter-quartile range (IQR). Categorical variables were displayed as frequencies and percentages. Pre- and post-intervention comparisons were examined according to the type of variable. Quantitative variables were compared using the Wilcoxon matched pair test (for skewed data) or paired t-test (for normally distributed data) and dichotomous categorical variables were analysed by the McNemar test after fitting the data into 2 × 2 tables. p-value of < 0.05 was considered statistically significant. All analyses were done using SPSS software (version 20. IBM, Armonk, NY).

Results

Seventy-two consecutive women who underwent Thermablate EAS balloon ablation, during the study period, met the inclusion criteria. The median age of all participants was 48 years with IQR 45.3–52 years. Their median BMI was 32.1 and the IQR was 28.3–36.6 kg/m² with only 9.4% of participants having normal weight (< 25 kg/m²). Preoperative data showed that 70 women (97.2%) had HMB with mean duration flow of 10.6 ± 2.4 days. Thirty-eight (52.8%) women reported pre-procedure regular cycles and the same percentage reported dysmenorrhea. Participating women had an average haemoglobin level of 10 ± 2.2 g/dl. Other baseline characteristics of patients obtained prior to surgery are described in Table 1.

Women were followed up on average of 18 months (range 6–24 months). The outcome measures of study after the procedure revealed amenorrhoea rate of 80.6%, overall success rate of 94.4% and all subjects would recommend the procedure to others. Details of the outcome results are described in Table 2. Only four women reported continuation of their heavy bleeding (5.6%), where two of them were on anti-coagulation therapy due to previous history of thromboembolism and both opted for a hysterectomy; the other two cases of failed treatment were controlled with further medical treatment. Regarding the frequency of dysmenorrhea, it dropped significantly post-ablation, as 88% women reported no dysmenorrhea whereas 5.6% had less cramps after the procedure (Table 2). There were no cases of uterine perforation or any significant complications.

The overall average score of Aberdeen Menorrhagia Severity score dropped from 25.8 ± 8.4 preoperatively to 4.5 ± 8.4 post-operatively (p < 0.01). Regarding the impact on QoL in women before and after the treatment, all indicators showed significant improvement as observed in women’s energy levels, ability to perform activity of daily living, dysmenorrhea, leisure time activity, sex life and amount of bleeding since surgery (p < 0.01). Reduction in disturbances in work and daily activities was reported by 55.6% women after the procedure, while 66% women reported reduction in confinement to bed owing to menses. About 66.7% women had very limited leisure time activity before surgery, which declined to 2.8% after surgery.

Discussion

This study was carried out to evaluate the short-term efficacy of Thermablate EAS on patients with HMB and to assess its effect on their QoL. The rate of amenorrhoea after endometrial ablation using Thermablate EAS device in this study was 80.6%, which is higher in comparison with other studies that reported amenorrhoea rates following endometrial ablation technique of 46–58% (Alaily et al. 2003; Bouzari et al. 2014; Penezic et al. 2014). A possible explanation for the higher rate is that the median age of participants was 48 years. In addition, as follow-up time increases, some patients may become naturally menopausal. Another possible explanation is the use of sharp curette for thinning of the endometrium at the time of ablation, which was described in a pilot study before (Karamanidis et al. 2009).

Table 1. Baseline characteristics of the studied sample: (n = 72).

<table>
<thead>
<tr>
<th>Age at the time of procedure</th>
<th>48.0 (45.3–52)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Parity</td>
<td>5 (6–7)</td>
</tr>
<tr>
<td>BMI (kg/m²)</td>
<td>32.1 (28.3–36.6)</td>
</tr>
<tr>
<td>Normal weight</td>
<td>6 (9.4%)</td>
</tr>
<tr>
<td>Overweight</td>
<td>18 (28.1%)</td>
</tr>
<tr>
<td>Obese (&gt;30 kg/m²)</td>
<td>40 (62.3%)</td>
</tr>
<tr>
<td>Hormonal treatment n (percentage)</td>
<td>11 (15.3%)</td>
</tr>
<tr>
<td>Oral contraceptive pills</td>
<td>2 (37.5%)</td>
</tr>
<tr>
<td>Progesterone</td>
<td>6 (8.3%)</td>
</tr>
<tr>
<td>None</td>
<td>14 (19.4%)</td>
</tr>
</tbody>
</table>

Table 2. The outcome measures after the procedure.

<table>
<thead>
<tr>
<th>Outcome measure</th>
<th>No (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall Satisfaction</td>
<td>67 (95.7)</td>
</tr>
<tr>
<td>≤5</td>
<td>3 (4.3)</td>
</tr>
<tr>
<td>&gt;5</td>
<td>67 (95.7)</td>
</tr>
<tr>
<td>Recommend the procedure</td>
<td>72 (100.0)</td>
</tr>
<tr>
<td>Bleeding Pattern</td>
<td></td>
</tr>
<tr>
<td>No bleeding</td>
<td>58 (80.6)</td>
</tr>
<tr>
<td>Light</td>
<td>10 (13.9)</td>
</tr>
<tr>
<td>Moderate</td>
<td>0 (0.0)</td>
</tr>
<tr>
<td>Heavy</td>
<td>4 (5.6)</td>
</tr>
<tr>
<td>Dysmenorrhea</td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>62 (86.1)</td>
</tr>
<tr>
<td>Mild</td>
<td>4 (5.6)</td>
</tr>
<tr>
<td>Moderate</td>
<td>4 (5.6)</td>
</tr>
<tr>
<td>Severe</td>
<td>2 (2.8)</td>
</tr>
</tbody>
</table>
The study found that dysmenorrhea rate was greatly reduced in a proportion of women from 52.8% to 8.4% following the procedure which was statistically significant, and there were no new cases of dysmenorrhea after endometrial balloon ablation. This was reported by another study where a significant (72%) reduction in both dysmenorrhea and premenstrual symptoms after the procedure (Alaily et al. 2003) was noted. It is difficult to ascertain the relative importance of dysmenorrhea to overall patient satisfaction, but it is possible that pain was caused by the heavy bleeding in some cases. Careful counselling is advisable in women complaining of significant dysmenorrhea and remains an area for future research.

The study found an overall satisfaction rate by subjects of 95.7%, and 100% recommended the procedure, which is a consequence of marked improvement in QoL after ablation. The participants reported a highly significant change in pleasure and discomfort scores as well as an increased level of energy, very few missed social events, fewer days unable to perform activities of daily living, fewer days of missed work and less pain after surgery ($p < .01$). A consistently high satisfaction rate for TBEA with different devices has been reported by many studies, even after longer follow up periods such as 8–11 years (Hazard and Harkins 2009; Shavell et al. 2012; Penezic et al. 2014).

Despite the known risks of all different types of TBEA, there were no intraoperative complications such as uterine perforation, cervical laceration, vaginal burn or injury of other adjacent organs. This is mainly due to the rarity of such complications, especially when we assess it in a small sample size.

The strengths of study comprise prospective study design, decrease of selection bias and use of QoL questionnaire in the assessment of objective outcomes. The limitations of the present study include lack of power calculation, small sample size, data collected from one centre only and short period of follow-up.

The results of this study support the use of Thermablate EAS as an effective option of endometrial balloon ablation for women with HMB, with advantages of shorter operating time, shorter hospital stay and high level of patient satisfaction. However, due to small sample size, further clinical research with large-scale studies and possible comparison to other treatment options are recommended.

Conclusions

The subjective success rate of Thermablate EAS device, as a treatment for HMB in perimenopausal women, is high (up to 94%) with amenorrhea rate reaching 80% within two years following treatment. Treated women reported improvement in their QoL as noted by a significant drop in all indicators of Aberdeen Menorrhagia Severity score.

Acknowledgements

The authors would like to acknowledge the support they received from the Deanship of Scientific Research at King Saud University for funding this project through Research Group Project # RGB-241. The authors wish to acknowledge also the technical and administrative help extended by Ms. Bella Rowena Magnaye.

Disclosure statement

No potential conflict of interest was reported by the authors.

Funding

The authors would like to acknowledge the support they received from the Deanship of Scientific Research at King Saud University for funding this project through Research Group Project # RGB-241.

References


