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

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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 Thermablate 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%. Thermablate 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 amenorrhoea 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%.
- Thermablate 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.

KEYWORDS

Abnormal uterine bleeding; heavy menstrual bleeding; endometrial balloon ablation; quality of life; thermablate endometrial ablation system

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; Madhra 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 focussing 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 (Acquadro 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 amenorrhoea (Roberts et al. 2011). Patient's preferences for different treatments depend on a woman's wish for amenorrhoea 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

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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 (Sadoon 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 (Laberge 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). Thermablate 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 Thermablate 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 (iii) 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 Thermablate 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 Kolmogorov–Smirnov test. Descriptive statistics for normally

distributed variables was presented in mean \pm 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 $< .05$ 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 dysmenorrhoea. 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 dysmenorrhoea, it dropped significantly post-ablation, as 86% women reported no dysmenorrhoea 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 ($p < .01$). 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, dysmenorrhoea, leisure time activity, sex life and amount of bleeding since surgery ($p < .01$). 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).

Age at the time of procedure	48.0 (45.3–52)
Parity	5 (4–7)
BMI (kg/m ²)	33.2 (28.3–36.6)
Normal (20–24.9 kg/m ²)	6 (9.4%)
Overweight (25–29.9 kg/m ²)	18 (28.1%)
Obese (> 30 kg/m ²)	40 (62.5%)
Hormonal treatment	<i>n</i> (percentage)
Oral contraceptive pills	11 (15.3%)
Primolut	2 (37.5%)
Duphaston	5 (6.9%)
Mirena	6 (8.3%)
Primolut and Mirena	9 (12.5%)
None	14 (19.4%)
Menstruation	
Duration days	10.6 \pm 3.3
Amount	<i>n</i> (percentage)
Moderate	2 (2.8%)
Heavy	70 (97.2%)
Regularity	
Regular	38 (52.8%)
Irregular	34 (47.2%)
Dysmenorrhea	
Yes	38 (52.8%)
No	34 (47.2%)
Other symptoms	
Fatigue	18 (25.0%)
Intermenstrual bleeding	10 (13.9%)
Endometrial biopsy results	
Proliferative	29 (46.7%)
Secretory	27 (43.5%)
Endometritis	6 (9.7%)
Haemoglobin g/dl (Mean \pm SD)	10.9 (2.2%)
Anaemia treatment <i>n</i> (%)	38 (54.3%)
History of D&C	13 (18.1%)
History of polypectomy	4 (5.6%)

Table 2. The outcome measures after the procedure.

Outcome measure	No (%)
Overall Satisfaction	67 (95.7)
≤ 5	3 (4.3)
> 5	67 (95.7)
Recommend the procedure	72 (100.0)
Bleeding Pattern	
No bleeding	58 (80.6)
Light	10 (13.9)
Moderate	0 (0.0)
Heavy	4 (5.6)
Dysmenorrhea	
No	62 (86.1)
Mild	4 (5.6)
Moderate	4 (5.6)
Severe	2 (2.8)

The study found that dysmenorrhoea 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 dysmenorrhoea after endometrial balloon ablation. This was reported by another study where a significant (72%) reduction in both dysmenorrhoea and premenstrual symptoms after the procedure (Alaily et al. 2003) was noted. It is difficult to ascertain the relative importance of dysmenorrhoea 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 dysmenorrhoea 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 amenorrhoea 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.

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Disclosure statement

No potential conflict of interest was reported by the authors.

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References

- Abu-Rafea BF, Vilos GA, Al Jasser RS, Al Anazy RM, Javaid K, Al-Mandeel HM. 2012. Linguistic and clinical validation of the Arabic-translated Aberdeen Menorrhagia Severity Scale as an indicator of quality of life for women with abnormal uterine bleeding. *Saudi Medical Journal* 33:869–874.
- Acquadro C, Berzon R, Dubois D, Leidy NK, Marquis P, Revicki D, et al. 2003. Incorporating the patient's perspective into drug development and communication: an adhoc report of task force report of the patient-reported outcome (PRO) Harmonization Group meeting at the Food and Drug administration, February, 2001. *Value in Health* 6:522–531.
- Alaily AB, Auld BJ, Diab Y. 2003. Endometrial ablation with the Cavaterm thermal balloon. *Journal of Obstetrics and Gynaecology* 23:51–54.
- Bouzari Z, Yazdani S, Azimi S, Delavar MA. 2014. Thermal balloon endometrial ablation in the treatment of heavy menstrual bleeding. *Medical Archives* 68:411–413.
- Brun JL, Raynal J, Burlet G, Galand B, Quereux C, Bernard P. 2006. Cavaterm thermal balloon endometrial ablation versus hysteroscopic endometrial resection to treat menorrhagia: the French, multicenter, randomized study. *Journal of Minimally Invasive Gynecology* 13:424–430.
- Clark TJ, Gupta JK. 2004. Outpatient thermal balloon ablation of the endometrium. *Fertility and Sterility* 82:1395–1401.
- Grainger DA, Tjaden BL, Rowland C, Meyer WR. 2000. Thermal balloon and rollerball ablation to treat menorrhagia: two-year results of a multi-center, prospective, randomized, clinical trial. *Journal of the American Association of Gynecologic Laparoscopists* 7:175–179.
- Hazard D, Harkins G. 2009. Patient satisfaction with thermal balloon ablation for treatment of menorrhagia. *American Journal of Obstetrics and Gynecology* 200:e21–e23.
- Iavazzo C, Salakos N, Bakalianou K, Vitoratos N, Vorgias G, Liapis A. 2008. Thermal balloon endometrial ablation: a systematic review. *Archives of Gynecology and Obstetrics* 277:99–108.
- Karamanidis D, Nicolaou P, Byros A, Koutsougeras G. 2009. Two-year results of a new two-minute hot liquid balloon endometrial ablation system (Thermablate): a pilot study. *Clinical and Experimental Obstetrics & Gynecology* 36:256–258.
- Laberge P, Leyland N, Murji A, Fortin C, Martyn P, Vilos G, Clinical Practice-Gynaecology Committee, et al. 2015. Endometrial ablation in the management of abnormal uterine bleeding. *Journal of Obstetrics and Gynaecology Canada* 37:362–379.
- Loffer FD, Grainger D. 2002. Five-year follow up of patients participating in a randomized trial of uterine balloon therapy versus roller blade ablation for treatment of menorrhagia. *Journal of the American Association of Gynecologic Laparoscopists* 9:429–435.
- Madhra M, Fraser IS, Munro MG, Critchley HOD. 2014. Abnormal uterine bleeding: advantages of formal classification to patients, clinicians and researchers. *Acta Obstetrica et Gynecologica Scandinavica* 93:619–625.
- Marret H, Fauconnier A, Chabbert-Buffet N, Cravello L, Golfier F, Gondry J, et al. 2010. Clinical practice guidelines on menorrhagia: management of abnormal uterine bleeding before menopause. *European Journal of Obstetrics, Gynecology, and Reproductive Biology* 152:133–137.

- Mettler L. 2002. Long-term results in the treatment of menorrhagia and hypermenorrhea with a thermal balloon endometrial ablation technique. *Journal of the Society of Laparoendoscopic Surgeons* 6:305–309.
- Munro MG, Critchley HOD, Broder MS, Fraser IS. 2011. FIGO classification system (PALM-COEIN) for causes of abnormal uterine bleeding in non-gravid women of reproductive age. *International Journal of Gynaecology and Obstetrics* 113:3–13.
- NICE. Clinical Guidelines 44. 2007. Heavy menstrual bleeding. London: National Institute for Health and Clinical Excellence (NICE).
- O'Flynn N, Britten N. 2000. Menorrhagia in general practice- disease of illness. *Social Science & Medicine* 50:651–661.
- Pai RD. 2009. Thermal balloon endometrial ablation in dysfunctional uterine bleeding. *Journal of Gynecological Endoscopy and Surgery* 1:31–33.
- Penezic L, Riley K, Harkins G. 2014. Long term patient satisfaction with thermal balloon ablation for abnormal uterine bleeding. *Journal of the Society of Laparoendoscopic Surgeons* 18:e2014.00325.
- Pramsothy P, Harlow SD, Greendale GA, Gold EB, Crawford SL, Elliott MR, et al. 2014. Bleeding patterns during the menopausal transition in the multi-ethnic study of Women's Health Across the Nation (SWAN): a prospective cohort study. *BJOG*. 121:1564–1573.
- Roberts TE, Tsourapas A, Middleton LJ, Champaneria R, Daniels JP, Cooper KG, et al. 2011. Hysterectomy, endometrial ablation, and levonorgestrel releasing intrauterine system (Mirena) for treatment of heavy menstrual bleeding: cost effectiveness analysis. *British Medical Journal* 342:d2202.
- Ruta DA, Garratt AM, Chadha YC, Flett GM, Hall MH, Russell IT. 1995. Assessment of patients with menorrhagia: how valid is a structured clinical history as a measure of health status? *Quality of Life Research* 4:33–40.
- Sadoon SS, Salman GA, Kirwan P. 2006. Thermal balloon endometrial ablation (Cavaterm) in the management of menorrhagia. *Journal of Obstetrics and Gynaecology* 26:804–805.
- Shavell VI, Diamond MP, Senter JP, Kruger ML, Johns DA. 2012. Hysterectomy subsequent to endometrial ablation. *Journal of Minimally Invasive Gynecology* 19:459–464.
- Tam WH, Yuen PM, Shan Ng DP, Leung PL, Lok IH, Rogers MS. 2006. Health status function after treatment with thermal balloon endometrial ablation and levonorgestrel intrauterine system for idiopathic menorrhagia: a randomized study. *Gynecologic and Obstetric Investigation* 62:84–88.
- Warner PE, Critchley HO, Lumsden MA, Campbell-Brown M, Douglas A, Murray GD. 2004. Menorrhagia I: measured blood loss, clinical features, and outcome in women with heavy periods: a survey with follow-up data. *American Journal of Obstetrics and Gynecology* 190:1216–1223.