A Long Term Follow up of Results of Women undergoing an Office based Thermablate Endometrial Ablations for the Treatment of Menorrhagia

Abstract

**Background:** Heavy menstrual bleeding (HMB) or menorrhagia accounts for 20% of outpatient referrals to secondary gynaecological services. The Thermablate Endometrial Ablations system (EAS) is an example of a second generation of EAS used for treating menorrhagia of benign origin; reducing the necessity for a hysterectomy. The study aimed to explore long term results and success of this system’s use in an outpatient setting.

**Methods:** This prospective observational study examined the long term follow up of 175 women attending an outpatient setting, having a Thermablate EA between July 2008 and July 2013. Women included had menorrhagia unresponsive to medical or hormonal therapy; and demonstrated a normal uterine cavity on hysteroscopy. They all received oral analgesia preceding ablation and welfare was ensured post procedure. Final outcomes were gathered using NOTIS; determining intervention rates following Thermablate EAS and satisfaction and improvement of quality of life through minimisation of bleeding and better symptom control.

**Results:** Of the 173 women, 93 women (53.7%) had lighter menstrual periods and 45 women (26%) became amenorrhoeic. 130 women (79.7%) had no interventions following Thermablate EAS. Our complication rate was 1.2%. 11 women went on to have hysterectomy for persistent uterine bleeding.

**Key message:** Thermablate EAS is an extremely well tolerated device ideal for use in the outpatient office setting. The long term results demonstrate high satisfaction rates and better symptom control acceptable to most women. Low intervention rate demonstrated in the form of hysterectomy has important cost implications for the NHS.

Introduction

Heavy menstrual bleeding (HMB) or menorrhagia, is defined as menstrual blood loss lasting more than 7 days over consecutive cycles, or more than 80ml per cycle [1]. This a common problem amongst premenopausal women. Such excessive loss can lead to detrimental consequences affecting all aspects of a woman’s life. Their physical health can be affected as a result of iron deficiency anaemia. HMB can also have effects on daily activities such as employment or socialising; through to the implications on emotional quality of life with issues of embarrassment, depression and problems with their sex lives [2].

It is a common gynaecological condition affecting up to 30% of women during their reproductive years and accounts for 20% of outpatient referrals to secondary gynaecological services [2]. In the UK, it is likely that one in five women will undergo a hysterectomy by the age of 55 years [3]. Although a definitive treatment resulting in a menorrhoea, it is not without significant risk. It has the mortality of 0.4-1.1 per 1000 operations; as well as major complications in 1 in 30 women, including anaesthetic problems, haemorrhage, pulmonary embolism, urinary retention and peripheral nerve injuries. In addition, many psychological issues can ensue such as loss of femininity and depression [4]. Of those women being treated for menorrhagia, as many as half can be found to have a normal uterus [5].

In light of this evidence, current guidelines [1,6] recommend exploring a more conservative approach initially through less invasive procedures such as endometrial ablation. The Thermablate Endometrial Ablations system (EAS) is one such example of a second generation of EAS used for treating menorrhagia of benign origin [7].

The literature has already suggested that this method is effective in achieving a menorrhoea or lighter periods and so reducing the necessity for a hysterectomy [8]. The aim of this study was to explore the long term results and success of this system’s use in an outpatient setting.

Methods

This prospective observational study looked at the long term follow up of 175 women attending the Ambulatory Menstrual Disorders Clinic at the Nottingham Circle Treatment Centre. These women had a Thermablate EAS between July 2008 and July 2013.

Patients

The inclusion criteria were defined as women identified as having menorrhagia and a demonstration of unresponsiveness to conservative medical or hormonal therapy. All women were demonstrated to have a normal uterine cavity on a diagnostic hysteroscopy and endometrial biopsy and a cervical to uterine...
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Results

175 women underwent a Thermablate ablation. 2 patients did not attend their follow-up appointment and hence, were excluded from this study although no record was found on NOTIS of subsequent intervention. 20 women did not require any follow-up the procedure. All women had a telephone consultation the day after and were given contact details in case of any questions or problems encountered.

Of the 173 women, 93 women (53.7%) had lighter menstrual periods and 45 women (26%) became amenorrhoeic. However, 35 women complained of unacceptable bleeding (20.2%), of whom 2.3% continued to have on-going bleeding and pelvic pain. 2 women additionally had symptoms of pelvic pain despite havings at is faction in their menstrual period (Figure 1).

Our complication rate was 1.2%. Two women had a post-operative infection, where one of them developed a haematometra. One woman became pregnant after the ablation and had a successful full-term pregnancy.

138 women (79.7%) had no interventions following Thermablate EAS. 2 women (1.2%) had non-hormonal conservative treatment, i.e. analgesia and counselling. 6 women (3.5%) had hormonal medical treatment (oral nor-ethisterone, or Gonadotrophin-releasing hormone (GnRH) analogues).

Figure 1: Thermablate EAS Symptom Outcomes (no of women).

Figure 2: Interventions following Thermablate Ablations (no of women).

Figure 3: Interventions following Thermablate EA.
Discussion

The TEAS provides a valid and effective alternative therapy in those women where other choices are either contra indicated or would prove technically challenging due to an irregular uterine cavity [9,10].

It is a lightweight device that employs a usable hand-held treatment control unit with a disposable fluid-filled balloon catheter system. An automatic treatment cycle involves inflation and eflation of the 13ml balloon catheter over 2 minutes. Uniform destruction of the myometrium is facilitated by the therapeutic high temperature (173°Celsius) and pressure (220 millimeter of mercury (mmHg)) employed. Our experience has demonstrated that the procedure is simple to perform. The short operation time and narrow catheter facilitate this, allowing it to be well tolerated. In another prospective observational study performed in our centre, Thermablate EAS appeared to be well-accepted and safe procedure for treating menorrhagia [9].

Thermablate EAS has not been as extensively reported as other balloon thermal ablation. The available studies have been in small numbers ranging from 16 to 90 patients and shorter follow-up of 6 months and up to 2 years [11-14]. Amenorrhoea rates of 25% were reported, with success rates of 90%. No major complications were reported in either study [11,12]. Our study of a larger population demonstrates a menorrhoea rates of 26.0% and satisfaction around 80%. We have as lighter higher complication rate of 1.2% as compared to other studies [11-14]. This can be due to the higher number of cases in our studies.

There can be other cause of menorrhagia in women over 40 years old other than dysfunctional uterine bleeding. Therefore, in our unit, we ensure that all the women had an endometrial biopsy prior to the TEAS treatment. Further, during hysteroscopy prior to the treatment, the endometrium is assessed for abnormal appearance before proceeding. Out of all our women, none had any abnormal uterine pathology. Other study had similar outcomes with their endometrial pathology of 1.7% [14] (Figure 4).

Of the women that were treated 5% of women classified themselves from ethnic minorities with the remaining demographic of 95% classifying themselves as White British. This representation of ethnic minorities is slightly less than the national average figures in the UK [15] (Table 1).

National Institute for Health and Clinical Excellence (NICE) estimates that if all hysterectomies were to be replaced by endometrial ablation using second-generation devices, the NHS would save £32 million per year. NICE concedes that his assumption is simplistic, as some women will in variably need or prefer hysterectomy [16]. Although hysterectomy is associated with longer operating time (particularly for the laparoscopic route), a longer recovery period and higher rates of postoperative complications, it offers permanent relief from heavy menstrual bleeding. Endometrial ablation offers an alternative to hysterectomy as a surgical treatment for heavy menstrual bleeding. It is effective, and satisfaction rates are high [17] (Table 2).

Table 1: Patient demographics including ethnicity.

| Parameter                        | No. of women |
|----------------------------------|--------------|
| Age (Year); mean(range)          | 47(30-59)    |
| Ethnicity                        | 175          |
| White British                    | 164          |
| Black Caribbean                  | 2            |
| Indian                           | 2            |
| Pakistani                        | 1            |
| Mixed: White & Black Caribbean   | 2            |
| Any other Mixed background       | 1            |
| Any other Asian background       | 1            |

Table 2: Mean follow-up duration.

| Parameter                           | No. of days |
|-------------------------------------|-------------|
| No further intervention             | 214         |
| Amenorrhoeic                        | 117         |
| Lighter menstrual bleeding          | 267         |
| Non hormonal conservative treatment | 236         |
| Hormonal treatment                  | 664         |
| Surgical intervention               | 492         |
| Hysterectomy                        | 403         |

Conclusion

Thermablate EAS is an extremely well-tolerated device that is ideal for use in the outpatient office setting. The long term results demonstrate high satisfaction rates and better symptom control acceptable to most women. We have also demonstrated the low intervention rate in the form of hysterectomy, which has important cost implications for the NHS.

References

1. National Collaborating Centre for Women's and Children's Health, National Institute for Health and Clinical Excellence (2007) Heavy Menstrual Bleeding, Clinical Guideline No.44. NICE, London.
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2. RCOG (2011) National Heavy Menstrual Bleeding Audit: A national audit to assess patient outcomes and experiences of care for women with heavy menstrual bleeding in England and Wales. First annual report p. 1-68.

3. Vessey MP, Villard-Mackintosh L, McPherson K, Coulter A, Yeates D (1992) The epidemiology of hysterectomy: findings in a large cohort study. Br J Obstet Gynaecol 99(5): 402-407.

4. Coulter A, McPherson K, Vessey M (1988) Do British women undergo too many or too few hysterectomies? Soc Sci Med 27(9): 987-994.

5. Maresh MJ, Metcalfe MA, McPherson K, Overtton C, Hall V, et al. (2002) The VALUE national hysterectomy study: description of the patients and their surgery. BJOG 109(3): 302-312.

6. NICE (2004) Fluid filled thermal balloon and microwave endometrial ablation techniques for heavy menstrual bleeding. National Institute of Health and Clinical Excellence guidelines.

7. Neuwirth RS, Duran AA, Singer A (1994) The endometrial ablator: a new instrument. Obstet Gynecol 83: 792-796.

8. Daniels JP, Middleton LJ, Champeneria R, Khan KS, Cooper K, et al. (2012) Second generation endometrial ablation techniques for heavy menstrual bleeding: network meta-analysis. BMJ 344: e2564.

9. Prasad P, Powell MC (2008) Prospective Observational Study of Thermablate Endometrial Ablation System as an Outpatient Procedure. J Minim Invas Gyn 15(4): 476-479.

10. Karamanidis D, Nicolaou P, Byros A, Koutsougenas G (2009) Two-year results of a new two-minute hot liquid balloon endometrial ablation system (Thermablate): a pilot study. Clin Exp Obstet Gynecol 36(4): 256-258.

11. Mangeshikar PS, Kapur A, Yackel DB (2003) Endometrial ablation with a new thermal balloon system J Am Assoc Gynecol Laparosc 10(1): 27-32.

12. Douglass B, Yackel DB, Vilos G (2004) Thermablate EAS: a new endometrial ablation device. Gynecol Surg 2(2): 1:29-132.

13. Justin W, Ibrahim M, Bagharia S, Haloo B (2007) Current minimal access techniques in the treatment of heavy menstrual bleeding. The Obstetrician & Gynaecologist 9(4): 223-232.

14. Hou X, Feng L (2014) Long-term efficacy analysis of abnormal uterine bleeding treated with thermablate TMEASTM. Journal of Minimally Invasive Gynecology 21(6): S143.

15. (2012) Ethnicity and National Identity in England and Wales: 2011. Office for National Statistics.

16. National Institute of Health and Clinical Excellence (2004) Menstrual Bleeding-Fluid-filled Thermal Balloon and Microwave Endometrial Ablation. Technology Appraisal 78. NICE, London.

17. Lethaby A, Shepperd S, Cooke I, Farquhar C (1999) Endometrial resection and ablation versus hysterectomy for heavy menstrual bleeding. Cochrane Database Syst Rev (2): CD000329.