

Trends in first-generation endometrial ablation procedures performed in a district general hospital, 1995–2005

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Abstract Heavy menstrual bleeding is a common presenting complaint and can significantly affect the quality of life of affected women. The 2007 National Institute for Clinical Excellence guideline on heavy menstrual bleeding states that in women with heavy menstrual bleeding alone, endometrial ablation should be considered preferable to hysterectomy. The choice of the type of endometrial ablation procedure would depend on several factors including the availability of first-, second- or even third-generation endometrial ablation equipment, clinician experience and preference as well as patient choice and if procedure is intended to be performed as an office procedure without the use of general anaesthetic where second- or third-generation endometrial ablation equipment would be used. The number of first-generation endometrial ablation procedures being performed is expected to decrease over time. This is as a result of clinicians' preference, due to reported higher operative complication rates in some studies, even though a meta-analysis of individual patient data has found it to be as effective as the second-generation techniques for heavy menstrual bleeding. We performed a retrospective clinical audit to investigate the trend from January 1995 to December 2005 in the use of first-generation endometrial ablation techniques performed at a district general hospital in the UK. We found that the general trend is of a rapidly decreasing number of first-generation endometrial ablation procedures being performed. We also found that the operative complication rates are low and similar to rates in the published

literature. The long-term hysterectomy rate after first-generation endometrial ablation procedure in our audit population is also low and similar to the rates in the published literature. We conclude from our audit data that first-generation endometrial ablation techniques such as transcervical resection of the endometrium for heavy menstrual bleeding are effective and in experienced hands have fairly low operative complication rates and long-term hysterectomy rates. These are similar to rates in the published literature for second-generation endometrial ablation techniques. We recommend that until further larger scale randomised controlled trials comparing first generation and the newer second-generation endometrial ablation techniques are performed which would provide clinicians with better evidence, first-generation endometrial ablation equipment should not yet be condemned to gather dust in hospital storage facilities and become 'museum pieces'. Rather, a concerted effort must be made to increase training opportunities in the use of first-generation endometrial ablation techniques especially in institutions that have already made the financial investment and are in possession of perfectly functioning equipment. This would ensure that the valuable clinical skill in the use of available first-generation endometrial ablation technique is not lost over time.

Keywords Trends · First-generation endometrial ablation · Second-generation endometrial ablation · Heavy menstrual bleeding

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Background

Heavy menstrual bleeding (HMB) is a significantly common health problem in women of reproductive age. The 2007 National Institute for Clinical Excellence (NICE) guideline on heavy menstrual bleeding states that in women with HMB alone, with a uterus no bigger than a 10-week pregnancy,

endometrial ablation should be considered preferable to hysterectomy [1]. First-generation endometrial ablation methods considered the ‘gold standard’ include trans-cervical resection of endometrium (TCRE), roller ball and laser ablation [2]. The NICE guideline also states that women considering endometrial ablation for heavy menstrual bleeding should have access to second-generation ablation techniques such as microwave endometrial ablation (MEA), thermal balloon endometrial ablation and impedance-controlled bipolar radiofrequency ablation [1]. The choice of the type of endometrial ablation technique used would depend on many factors including availability of equipment, clinician experience and preference as well as patient choice. Avoidance of use of general anaesthetic and even local anaesthetic for office procedures using second- and third-generation endometrial ablation techniques is gaining popularity with clinicians and patients alike.

A survey in 2008 of 1,460 UK gynaecologists showed that second-generation endometrial ablation devices were preferred and used by most compared to first-generation devices [3]. The clinician’s preferred choice of second-generation endometrial ablation techniques over first-generation techniques is likely influenced by published literature that indicate fewer operative complications, a shallow learning curve, quicker and technically easier as well as less need for general anaesthesia when second-generation endometrial ablation techniques are used compared to first-generation ablation techniques.

At the Royal Cornwall Hospital, Truro (RCHT), only one consultant at the time of this clinical audit performed first-generation endometrial ablation procedures. The expectation therefore is that the number of first-generation endometrial ablation procedures performed for heavy menstrual bleeding will decrease over time due to the availability and widespread use of second-generation and third-generation endometrial ablation techniques. The clinical skill in the use of first-generation endometrial ablation technique is at risk of becoming lost over time.

A randomised controlled trial (RCT) that compared second-generation endometrial ablation–MEA with a first-generation endometrial ablation–TCRE with a minimum 10-year follow-up showed that both techniques achieve significant and comparable improvements in menstrual symptoms, health-related quality of life and high rates of satisfaction. Bleeding and pain score reductions were significantly reduced and similar amenorrhea rates of up to 88 % were achieved in both groups. The only difference found in this randomised controlled trial was a significantly higher hysterectomy rate after 10 years of 28 % in the TCRE arm compared to 17 % in the MEA arm [4].

An individual patient data meta-analysis of existing randomised controlled trials and population-based retrospective cohort study based on record linkage found that more women were satisfied after hysterectomy than after

endometrial ablation [5]. They concluded that, although the most cost-effective strategy, hysterectomy may not be considered an initial option owing to its invasive nature and higher risk of complications.

A further individual patient data meta-analysis supplemented with cost and outcome data from published sources taking a National Health Service (NHS) perspective showed that hysterectomy is the preferred strategy for the first intervention for heavy menstrual bleeding. They demonstrated that although hysterectomy is more expensive, it produces more quality adjusted life years relative to other remaining strategies like first- and second-generation endometrial ablation techniques and the Mirena intrauterine system and is therefore likely to be considered cost effective. The authors did argue that the incremental cost-effectiveness ratio for hysterectomy compared with second-generation ablation per additional quality adjusted life year was £970.00. Using a mathematical cost-effectiveness model based on costs associated with treatment for heavy menstrual bleeding in the UK at 2008 prices, this article did demonstrate marginally higher quality adjusted life years with second-generation- compared to first-generation endometrial ablation techniques [6].

The Cochrane Systematic review shows an overall favourable comparison in terms of the success rates and complication profiles of the second-generation techniques compared to first-generation techniques. Despite this however, the review also concludes that the rapid development and introduction of a number of new second-generation methods of endometrial ablation techniques make it difficult to systematically compare them to the ‘gold standard’ [7]. A meta-analysis of individual patient data found that second-generation endometrial ablation techniques were at least as effective as first-generation techniques [8]. A recent network meta-analysis of 19 randomised controlled trials involving 3,287 women who had different types of second-generation endometrial ablation techniques performed for heavy menstrual bleeding did show relatively low but variable rates of heavy bleeding across the studies such as 0–32 % for thermal balloon ablation and 8–18 % for bipolar radiofrequency ablation. This network meta-analysis did also look at trends in types of second-generation endometrial ablation procedures performed in England, 2004–2011, and indicates a sharper rise in number of bipolar radio frequency ablative technique compared to other second-generation techniques [9].

The current state of the global economy and financial state of the national health service in UK and the need for efficiency savings in health care make it essential to review the cost-effectiveness of every medical procedure.

Second-generation endometrial ablation techniques have marginally lower costs associated with treatment compared to first-generation techniques [10, 11]. However, the cost-effectiveness calculations in these studies are based on relatively lower purchase price and operational costs compared to

the current significantly higher purchase price and operational costs for available second- and third-generation endometrial ablation equipment. The recent exponential increases in purchase price and operational costs for these newer second-generation endometrial ablation techniques are multi-factorial and may include the effects of the global economic downturn and the falling value of the Pound Sterling. It may therefore be reasonably prudent for NHS Trusts not to abandon in a knee jerk attitude their available and fully functioning first-generation endometrial ablation equipment. There is clearly the need for large-scale, well-designed RCT's that would compare cost-effectiveness across the many new and emerging second- and third-generation endometrial ablation techniques with first-generation techniques.

The apparent decreasing number of first-generation endometrial ablation techniques being performed across the nation may lead to decreasing training opportunities and loss of this clinical skill in the near future.

This clinical audit was therefore undertaken to clearly determine the trend in first-generation endometrial ablation techniques performed at a district general hospital in England.

Aims of this study include the following:

1. Primarily to audit the trend at RCHT of first-generation endometrial ablation procedures for heavy menstrual bleeding from January 1995 to December 2005.
2. Secondly to audit the intra-operative and post-operative complication rates as well as the long-term hysterectomy rate.
3. To ensure compliance with local guidelines and NICE guidelines in the management of women with heavy menstrual bleeding who opt for endometrial ablation procedure

Methods

This is a retrospective clinical audit. The clinical audit was registered with the Clinical Effectiveness, Quality and Safety Department at the RCHT and allocated a clinical audit number 1459.

A formal request was sent to the Information Services Department at RCHT using the Information Gateway Process for the clinical record numbers of all patients who had undergone TCRE as coded between January 1995 and December 2005. The following search words were used: endometrial resection, hysteroscopic resection of endometrium, TCRF, and TCRE. At the Royal Cornwall Hospital, the only first-generation endometrial ablation technique available since 1995 is TCRE. This is performed solely by one senior consultant gynaecologist between 1995 and 2005. Second-generation endometrial ablation techniques such as microwave endometrial ablation (recently withdrawn) and bipolar

radiofrequency ablation (NOVASURE) are performed by most of the rest of the consultant body at RCHT on a regular basis.

A proforma was produced for data gathering of all patients who satisfied the inclusion criteria of trans-cervical resection of endometrium performed for heavy menstrual bleeding. A total of 710 patient notes were retrieved based on the search words by the Information Services department. All the 710 patient notes were reviewed by the two authors (TD and VB) with respect to the proforma. Following data collection, Microsoft Excel software was used for computing and analysis of data.

Findings

We reviewed 710 notes for eligibility based on the list of all clinical record numbers generated by RCHT Information Services Department. One hundred eighty-five satisfied the inclusion criteria and 525 were excluded. The mean age of patients was 45 years of age. Twenty-three (12 %) of these patients were lost to follow-up; however, the majority (162 patients, 88 %) were followed up for a minimum of 3 months after their procedure. One patient in the reviewed group fell pregnant a few years following the procedure. The indications for the procedure were (1) HMB only (87 patients, 47 %), (2) HMB and pain (51 patients, 27 %), (3) peri-menopausal bleeding (20 patients, 11 %) or other reasons including inter-menstrual bleeding, post-coital bleeding, irregular bleeding or combinations of these after full investigations (27 patients, 15 %).

The following graph (Fig. 1) demonstrates the number of first-generation endometrial ablation procedures performed at RCHT over the 10-year period (1995–2005).

The mean recorded pre-procedure bleeding in these patients was 8 days which reduced to 2 days post-procedure. Treatment options tried before ablation included the Mirena intrauterine system, non-steroidal anti-inflammatory drugs, the combined oral contraceptive pill, progestogens, gonadotropin releasing hormone analogues, fibroid embolisation,

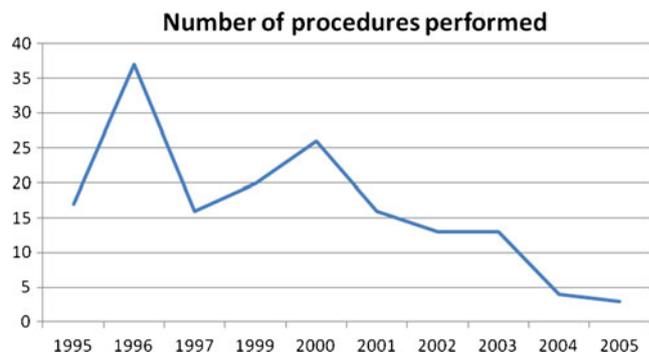


Fig. 1 Number of TCRE performed at RCHT between 1995 and 2005

myomectomy and other treatments such as herbal remedies and other self medications. Intra-operative and short-term complications were uncommon but included uterine perforation (three cases—1.6 %), excessive bleeding (seven cases—3.7 %), excessive (>800 ml deficit) fluid absorption (six cases—3.2 %), hysterectomy (two cases—1 %), uterine infection requiring antibiotics (four cases—2 %), failed attempt of procedure (one case—0.5 %) and ventricular ectopic beats during surgery (one case—0.5 %). Nine (4.9 %) patients required overnight admission for minor complaints such as nausea and vomiting or pain.

Eighty-one percent (44 %) of patients reported being satisfied with their procedure, 63 (34 %) were unsatisfied and satisfaction was not recorded for 18 (10 %) patients. Ten patients (5 %) required additional medical treatment in the long term after ablation and 60 (32 %) required an additional surgical treatment in the long term.

These additional surgical procedures were carried out in a time range of 2 weeks to 9 years following the initial ablation. The mean time between procedures was 3 years. They are summarised in Table 1:

Conclusions

The general trend is that of a rapidly decreasing number of first-generation endometrial ablation procedures being performed at RCHT. Despite this, the minor and major operative complication rates for first-generation endometrial ablation technique at RCHT are low and similar to rates in the published literature. The long-term hysterectomy rate of 21 % after TCRE in our audit population is similar or lower than the published figures in the region of 28 %.

First-generation endometrial ablation procedures in well-trained hands are comparatively safe and have low patient dissatisfying rates in the long term compared to second-generation endometrial ablation methods. There is a great need for well-designed multi-centred large randomised controlled studies that would compare the many new and emerging second- and third-generation endometrial ablation techniques to the ‘gold standard’. Until there is stronger evidence in favour of second- and third-generation endometrial ablation

techniques over the first-generation ablation techniques, we recommend that Hospital Trusts take a moment’s pause and not rush to condemn their existing perfectly functioning first-generation endometrial ablation equipment as a ‘museum piece’ to gather dust in a storage facility. Increasing the number of first-generation endometrial ablation techniques performed would also increase training opportunities and enhance the acquisition of this clinical skill by both trainees and consultants.

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Declaration of interest We the authors, Vincent Boama (VB) and Tania Dexter (TD), report of no conflict of interest.

Informed consent Informed consent from patients was not required for this clinical audit. The audit was registered with and approved by the clinical effectiveness and audit department of the hospital.

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Table 1 Additional surgical procedures performed after initial TCRE

Procedure	Number of patients
Hysterectomy (excluding the 2 performed intra-operatively)	38 (21 %)
First-generation ablation	19 (10 %)
Second-generation ablation	3 (2 %)
Uterine artery embolisation	1 (<1 %)