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ORIGINAL ARTICLE

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Three-year experience in outpatient microwave endometrial ablation

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Abstract The objective was to assess the feasibility, acceptability, efficacy and safety of outpatient microwave endometrial ablation (MEA) under local anaesthesia in the treatment of therapy-resistant menorrhagia. This was carried out as a prospective observational study with a follow-up postal questionnaire at the Royal United Hospital Bath, NHS Trust, Bath, UK. For the study, 117 selected women fulfilled the selection criteria with a mean age of 42.4 years (range 29–53 years), referred because of uncontrolled menorrhagia. They were recruited between April 2000 and March 2003. Preoperative evaluation included history taking, physical examination and ultrasound scanning. Follow-up was by specially designed home postal questionnaire, which was mailed to all women 3 to 6 months after surgery. The acceptability of MEA under local anaesthesia, efficacy in changing the menstrual pattern and operative and postoperative complications were measured. For a total of 117 women, 116 procedures were successfully performed under local anaesthesia. One procedure was abandoned. There were no intraoperative or postoperative complications. The procedure was well tolerated. The menstrual satisfaction rate was 89.5%. The percentage of women reporting amenorrhoea was 41.2%. All other measures of pain were improved. Five women requested a repeat MEA, and 12 women underwent hysterectomy following MEA. In conclusion, MEA is a feasible, safe, easy and effective outpatient method of endometrial ablation in women suffering from therapy-resistant menorrhagia. Outpatient MEA is accepted and tolerated by patients. It has a place in current modern practice in treating menorrhagia.

Keywords Output · Microwave · Endometrial · Ablation

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Introduction

Hysteroscopic surgery became a well-recognised alternative to hysterectomy for women with therapy-resistant menorrhagia. Initially, coagulation or vaporisation of the endometrium was used in the first generation hysteroscopic techniques (thermal, electrical or laser). In 1981, the neodymium yttrium-aluminium-garnet (Nd-YAG) laser was adopted by Goldrath and colleagues [1]. Electrosurgical techniques to perform transcervical resection of the endometrium (TCRE) followed in 1983 [2]. In 1989, Vancaille [3] introduced Rollerball coagulation. These techniques, however, carry some potentially serious risks such as excessive fluid overload (cerebral, pulmonary and peripheral oedema), uterine perforation and haemorrhage. In addition, they require a relatively long learning curve. This has led, over the last 12 years, to the development of simpler, safer and effective, second generation ablation techniques: microwave endometrial ablation (MEA) and thermal balloon therapies [4].

Microwave endometrial ablation (Microsulis PLC, Waterlooville, UK) was introduced by Sharp (1994) as an alternative to TCRE [5]. One of the initial design parameters for MEA was a requirement that the treatment should take less than 10 min to be a useful improvement. The first report [5] in a fairly selected group of patients receiving drug pre-treatment showed a mean treatment time of 132 s (far quicker than originally envisaged or hoped for). Subsequent reports have shown a mean treatment times of 141 s [6], 176 s [7] and 207 s [8]. This brevity of treatment has made the introduction of a local anaesthetic approach an obvious development for MEA.

Once a local anaesthetic technique was established as a reliable technique, it was then a natural progression to transfer the service to the out-patient environment. It seems that the main limitation to the widespread use of outpatient procedures is pain [9]. Therefore, over the past 20 years, there has been a trend towards assessing and performing some procedures in outpatients [10]. Outpatient procedures are associated with fewer anaesthetic risks, reduced hospital admissions, easy access and quick

recovery, with no increase in postoperative analgesia [9]. This has obvious advantages for the women and also the health provider.

During hysteroscopy, the most painful steps may occur during application of the tenaculum, dilatation of the cervix and distension of uterine cavity [11, 12]. Also, the pain recorded is directly related to hysteroscopic diameter [13].

For reasons that are not clear, the main approach to cervical anaesthesia has been the use of the paracervical block. Cicinelli et al. [14] found in their randomised placebo control study that paracervical anaesthesia significantly reduced the pain perception at hysteroscopy and endometrial sampling. However, some other studies [15, 16] showed no significant difference, which it seems is highly dependent on the technique. The technique used for analgesia in this study is an intracervical block technique. It is a modification of that originally described by Ferry and Rankin [17].

Subjects and methods

Patients

Patients were seen in the Menstrual Ablation Clinic (MAC) for assessment [medical history, abdominal and pelvic examination and transvaginal scan (USS)]. The menstrual history (converted to a score) [5] as well as the medical, surgical, obstetric and family history along with contraception and fertility status were recorded. Any women with a history of caesarean section had the uterine scar measured with transvaginal ultrasound (TVS). A scar thickness of less than 8 mm represents a contraindication to MEA. Fibroids are not a contraindication to microwave provided the uterine cavity is not unduly distorted by their presence. The outcome of the initial consultation and management plan were recorded.

Methods

One hundred and seventeen patients were recruited from the Menstrual Ablation Clinic (MAC) between April 2000 and March 2003. All of these patients had therapy-resistant menorrhagia. The procedures were done as a part of our current prospective study approved by our ethical committee.

Initially selection for outpatient treatment was relatively unrefined. However, as difficulties were encountered, it became clear that patient selection was fairly critical. The exclusion criteria developed for use in our outpatient clinic now are given in Table 1. These may appear stringent in some respects, but since the patients are semi-recumbent in a modest Lloyd-Davis position with leg supports in the post-genicular position, access is restricted. For those women found to be suitable for the local anaesthetic, outpatient option, then a brief familiarisation visit to the outpatient treatment unit was given at the end of the MAC consultation.

Table 1 Exclusion criteria. *Access issue, **tolerance issue, ***analgesia issue, ****difficulty dilating cervix

Anxious disposition**	Previous unpleasant experience in delivery or TOP**
Overweight (BMI >30)*	Previous unwelcome sexual contact**
Virgo intacta*	History of mental illness**
Nulliparous*	Vaginal infection
No vaginal birth*	Intolerance of NSAIDs***
Previous vaginal surgery*	Restricted hip/knee mobility*
Co-existent medical problem	Long-standing GnRH agonist therapy****

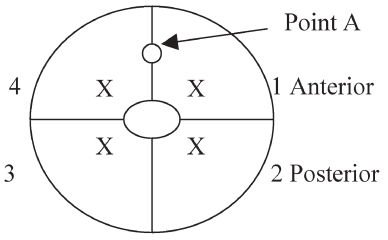

Fig. 1 The cervix showing cervical anaesthetic application sites

Technique

On admission to the outpatient treatment unit, patients would receive 100 mg of Voltarol PR at least 1 h before MEA. This has been found to be an important part of the analgesia strategy for these patients, and is the reason why intolerance of non-steroidal anti-inflammatory drugs represents a contraindication to outpatient therapy. After taking informed consent and giving written information, IV access is established in case it should be required at a later point. The patient is placed in the semi-recumbent Lloyd-Davis position. A transvaginal ultrasound scan is then performed to confirm previous findings. The vulva and vagina are cleansed with warm antiseptic solution and a warmed Sim's speculum passed to expose the cervix. Having visualised the anterior lip of the cervix, a small amount of local anaesthetic is placed in the anterior lip, and this is given a few moments to act whist the operator prepares the rest of the instruments. The local anaesthetic used is citanest and octapressin (prilocaine 3% with felypressin) in 4×2.2-ml glass cartridges (Astra). The cervix is then grasped with a tenaculum at point A and a four-quadrant block completed using one cartridge per quadrant. The needle is inserted into the centre of each quadrant point X (Fig. 1) parallel to the cervical canal and the cartridge contents injected at full depth.

The aim is to establish a ring block at the internal os of the cervix. The two posterior quadrants are probably the more important, as the intention here is to block the insertion at the uterosacral ligaments. Prilocaine produces a rapid onset, but brief anaesthesia. To provide postoperative analgesia the block is then repeated using 20 ml of 0.25% bupivacaine or chirocaine using the standard 20-ml syringe and 21-g needle. Care must be taken at this point, because the cervix can be quite vascular and a degree of intravasation of local anaesthetic is possible. Patients should be asked to report any tingling in their lips or face, buzzing in their ears, blurring of vision or feeling of light headedness. If any of these symptoms are reported the remainder of the long-acting anaesthetic should be given post-treatment.

Having established the block, the uterine cavity is then sounded in the usual fashion. The sounding is checked against a sterile steel ruler. Occasionally, the uterine fundus defies attempts at local anaesthetic blockade. If this is the case the patient will sense the sound touching the uterine fundus. Even with residual fundal sensitivity it is still usually possible to dilate the cervix without any discomfort. After dilating the cervix to hegar 9 the cavity length is sounded a second time using the number 9 hegar dilator. This should correspond to the initial sounding.

The patients in this study were also part of an evaluation of suction curettage of the uterine cavity as an alternative to drug pretreatment. They therefore had the loose endometrium stripped out using a 7-mm Cory suction termination curette, and the endometrium was sent for histology.

The microwave applicator, having been connected to its cables, is then introduced through the cervix into the cavity until the tip rests against the fundus. The series of graduations on the shaft

enable the depth of insertion to be confirmed and this should correspond with the two previous soundings. This triple check is an important safety check. At this point the patient should be warned that there may be some initial discomfort (in case of residual fundal sensitivity) and they are offered the use of inhalational analgesia (nitrous oxide/oxygen) if required. If despite this they have intolerable discomfort, then they should be given intravenous midazolam (Hypnoval-Roche) 4 mg IV in conjunction with alfentanil (Rapifen-Janssen) 0.4 mg by the operator before resuming treatment.

If IV agents are required, then supplemental oxygen at 4 l per min via a face mask in conjunction with pulse oximetry is required.

After energising the microwave applicator the temperature will be seen to rapidly rise. After 6 s (approximately 60°C on screen) the applicator tip is moved gently from side to side to evenly heat the uterine fundus and cornual areas. A recent software modification to the system now provides a screen prompt to commence "fundal sweeping". For many women a sensation of cramp or dysmenorrhoea-type discomfort is appreciated, but is usually tolerable and rapidly passes once the applicator is moved away from the fundal area.

A more complete description of the microwave technique is given elsewhere [6]. The whole of the uterine cavity is treated with a steady side-to-side motion of the applicator and a slow but steady withdrawal. Once a yellow mark appears at the external os, a slow steady withdrawal is all that is required until the mark is totally visible, at which time the power is switched off, as the active tip has reached the internal os of the cervix. The applicator is then withdrawn. Repeat suction aspiration of the cavity with the 7-mm Cory curette was undertaken to remove the coagulated debris. If the patient had not received sedation she was simply able to walk through to the recovery area. Those who had received sedation were moved onto a trolley for transfer. Care of the patient after the procedure includes further analgesia if required, routine observations and recording of any other comments. Tea and biscuits were offered, and if problem free, all were discharged within 2 h of MEA with oral antibiotics and analgesia for 5 days. Patients who did not feel well were admitted.

Follow-up was by postal questionnaires to record improvement in menstruation and dysmenorrhoea. There was also a section for additional free comments. The questionnaires were completed 3 to 6 months post-treatment.

Results

One hundred and seventeen women were included in this study. Two women have been lost to follow-up. One patient was found to have been assessed incorrectly and had a large fibroid polyp inside the uterine cavity; the procedure had to be abandoned. Table 2 shows patient parameters and treatment times.

The mean age of the patients is 42.4 years (range 29 to 53 years). This mean age has been extremely consistent throughout all points in the past when data have been analysed [6, 7, 8]. The mean treatment time is slightly longer than that previously reported. We believe this is due to the increased vascularity of the uterus and endometrium in these patients who had not had any drug pre-treatment. It equates to approximately 1 min longer. One of the benefits of avoiding drug pre-treatment is the ease with which the cervix can be dilated (sometimes a difficulty with GnRH agonist pre-treatment). No procedure had to be abandoned because of excessive pain, although some patients did require analgesia in addition to the local anaesthetic, and the results given in Table 3.

Table 2 Patient parameters and treatment times

	Mean	Range
Age (years)	42.4	29–53
Parity	2	0–5
Cavity length (mm)	87	60–120
Treatment time(s)	254	103–573

Table 3 Patients requiring analgesia in addition to the local anaesthetic

	(*n*)	(%)
Patients treated	116	
LA alone	94	(81%)
Entonox required only	7	(6.1%)
I.V. sedation/analgesia required	14	(12.1%)
I.V. sedation/analgesia requested by patient	1	(0.8%)
Admitted overnight	3	
Delayed admission (24–72 h)	3	

Ninety-four (81%) of patients had their treatment under local anaesthesia alone. Twenty-one (18%) women required additional analgesia. Fourteen (12.1) patients had intravenous sedation with midazolam and alfentanil as well. (As a note of caution, both these drugs are capable of causing respiratory depression, and it is recommended that initial experience be gained in the company of an anaesthetist.)

Side effects recorded during the procedure included two patients who felt faint and two other patients whose blood pressure was noted to have fallen. These occurred during a very hot spell in the weather and may have been due to a degree of dehydration. One patient felt nauseated. One patient had a hysteroscopy for reassurance regarding cavity integrity. It is now a recommendation that hysteroscopy be routine for all patients having suction aspiration/mechanical preparation of the endometrium (Microsulis protocol: "MEA instructions for use").

Drugs

1. Diclofenac (voltarol) 100 mg suppository (Geigy) Ibuprofen tabs
2. Prilocaine 3% with Felypressin (Citanest with Octapressin) 2.2-ml glass cartridges (Astra)
3. Bupivacaine 0.25% (Marcain) (Astra) or Chirocain 0.25% (Levobupivacaine) (Abbott)
4. Midazolam (Hypnoval) 10 mg amps (Roche)
5. Alfentanil (Rapifen) 1 mg amps (Janssen)
6. Anexate (Flumazenil) 500 μg (Roche) (reversant for Midazolam)
7. Naloxone (Narcan) 400 μg (DuPont) (reversant for Alfentanil)
8. Atropine 600 μg (to correct bradycardia)

Admissions

There were six admissions to the gynaecology ward. Three were admitted from the outpatient treatment facility and three were delayed readmission, 24 to 72 h post-discharge. All admissions were for abdominal pain. The pain was due to abdominal cramps and the patients settled with additional analgesia. One patient was readmitted at 72 h and also gave a history of bleeding per-rectum in addition to the abdominal pain. There appeared to be a degree of peritonism on examination and the patient therefore underwent laparotomy with hysterectomy as there was concern that this patient may have suffered thermal injury to her bowel. At operation, however, the uterus was found to be intact with no evidence of thermal penetration to the serosa and inspection of the bowel revealed no abnormality or injury to explain the history of rectal bleeding. Hysterectomy was undertaken as agreed.

Outcome

Of 114 patients with follow-up complete, 101 patients were satisfied (88.6%). Twelve patients were dissatisfied (11.4%). Of those, five opted for repeat microwave endometrial ablation, which confirmed that for these patients it was a very acceptable procedure. Of this small group only one subsequently had a satisfactory outcome and the other four opted for hysterectomy. There were therefore a total of 12 patients subsequently requiring hysterectomy in this group (10.5%), with an overall satisfaction/avoidance of hysterectomy of 89.5%. Forty-seven patients reported amenorrhoea at follow-up (41.2%) (Figs. 2, 3). A general improvement in dysmenorrhoea was also reported and pain outcomes as in Fig. 1.

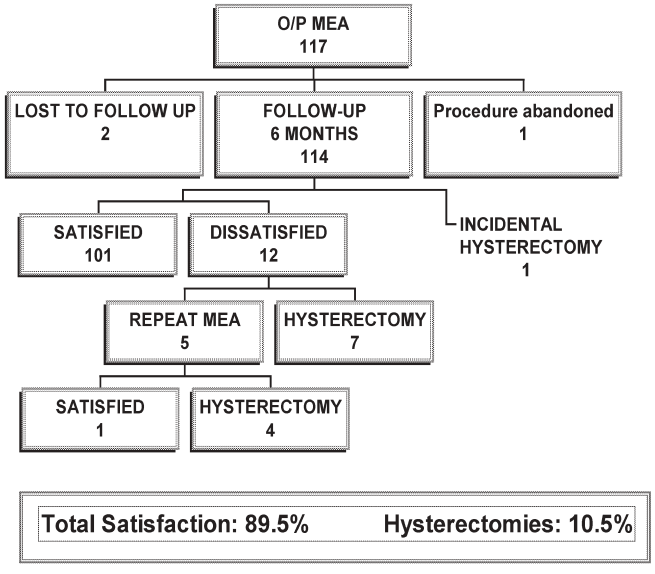

Fig. 2 MEA outpatient outcome

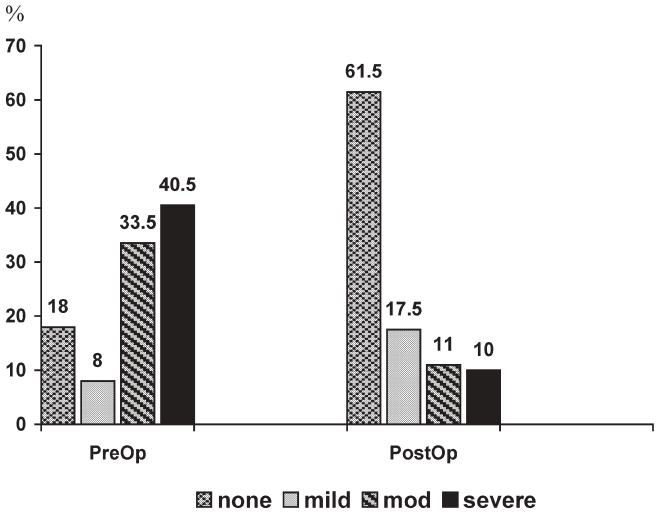

Fig. 3 Dysmenorrhoea outcomes

Table 4 Hysterectomy indications

Four after repeat MEA	Continuous p.v. bleeding
One in 3 days following MEA	Pain and bleeding
Three between 6–18 M following MEA	Dysmenorrhoea
Three between 12–24 following MEA	Continuous irregular bleeding
One incidental	Torsion of ovarian cyst
One following abandoned MEA	Large fibroid uterus with large intracavity fibroid polyp

Hysterectomy

Despite the concerns about one patient with delayed admission, there were no major complications or perforations in the treatment group. Indications for hysterectomy are given in Table 4.

Discussion

We believe this is the first study to assess and evaluate outpatient microwave endometrial ablation in the management of menorrhagia. Following the initial report mentioning the use of local anaesthesia for MEA [6], a randomised control trial has been undertaken comparing MEA and local and general anaesthesia [18]. In the randomised study there was a significant conversion rate to general anaesthesia in the local anaesthetic group. This was probably because the procedure was undertaken in an operating theatre with an anaesthetist handy. Also, the amount of local anaesthesia used was less than the amount described here. In our group all patients were successfully treated in the outpatient setting. No anaesthetist was in attendance, and the intravenous sedation was given by the operator (with re-gloving if necessary).

The staffing required for an outpatient session consists of the operator, a senior nurse to attend to the pa-

tient, a nurse or healthcare assistant to assist the surgeon and a recovery nurse for preoperative and postoperative care.

The development of this novel service was greatly facilitated by the enthusiasm, care and thought provided by the nursing staff in the outpatient clinic. With learning through experience and debriefing after initial outpatient sessions, protocols and patient management were improved to the point where it is now a comfortable regular session. During the treatment process, the patient's attention is distracted with conversation, and background music is provided in addition to produce a soothing atmosphere. The nursing team is now fully knowledgeable about MEA and its indications, contraindications, patient selection criteria as well as the risks, benefits and safety guidelines.

Provided patients are selected carefully before treatment in this environment, and this particularly includes a robust personality, the outpatient ablation provides a very satisfactory experience for all concerned. Good analgesia can be reliably obtained, and this permits full treatment to be given to each patient. Outcomes are identical to those treated in a theatre setting.

Whilst the clinic has not been formally assessed in terms of costs and savings, the avoidance of theatre use, ward beds and the need for an anaesthetist represents a genuine saving.

The patients in this study were part of a wider evaluation using suction aspiration at the endometrium as an alternative to drug pre-treatment. It is, however, a current recommendation that mechanical endometrial preparation should be replaced with hormonal methods, of which the administration of a GnRH agonist 5 weeks prior to microwave endometrial ablation is the treatment of choice. Another alternative will be "scheduling", where the patients are admitted immediately after their menstrual period. In our unit this would be logistically difficult to arrange, although in some centres it will be a practical solution.

Conclusions

Outpatient MEA can be performed in selected woman under local anaesthesia. The patients tolerate the treatment well. Because there is no use of hysteroscopic fluids and no risk of bleeding, it is very clean and easily accomplished in the outpatient setting. The risk of excessive fluid abortion and haemorrhage, described with hysteroscopic methods, are avoided by MEA. The patients may anticipate outcomes identical to those achieved in a theatre setting with general anaesthesia. For many hospitals with an outpatient hysteroscopy facility, outpatient microwave ablation may well prove an attractive development.

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