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Clinical outcomes from a randomised comparison of **Microwave Endometrial Ablation** with **Thermal Balloon** endometrial ablation for the treatment of heavy menstrual bleeding

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Presentation

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Abstract

Objective: To compare the clinical outcomes of microwave endometrial ablation (MEA™) and thermal balloon ablation (TBall) for the treatment of heavy menstrual bleeding

Design: A double blind randomised controlled trial

Setting: A UK teaching hospital

Population: 320 women requesting endometrial ablation

Methods: Operative data collection and patient completed postal questionnaires were utilised to ascertain women's satisfaction with outcome, acceptability of each procedure, changes in menstrual symptoms and health related quality of life, and additional treatments received.

Main outcome measures: Primary outcomes were satisfaction and menstrual scores one year. Secondary outcomes were operative differences, acceptability of treatment and changes in health related quality of life.

Results: - Both technologies achieved high levels of satisfaction (-1%, 95% CI (-11, 9)). Menstrual scores were also similar (4%, 95% CI (-7, 19)) Microwave had a significantly shorter operating time, reduced usage of antiemetics and opiate analgesia, increased discharge by six hours and fewer device failures.

Conclusions

Both treatments are acceptable to women, with high levels of satisfaction.

Microwave is quicker to perform with faster hospital discharge .

Key words

Menorrhagia, randomised trial, surgical treatments

Trial registered online at:

<http://www.controlled-trials.com/ISRCTN28184453>

Clinical outcomes of Microwave Endometrial Ablation v Thermal Balloon Endometrial Ablation – a randomised comparison.

Introduction

The surgical treatment of heavy menstrual loss has been revolutionised over the last fifteen years with the widespread introduction of endometrial ablation. First generation hysteroscopic endometrial ablative techniques (transcervical resection of the endometrium (TCRE), rollerball and laser) are successful but require high levels of skill.¹⁻⁵ This led to the development of second generation techniques which are technically much simpler to perform, but the majority of which are not performed under direct hysteroscopic vision.¹⁻⁵ There is a wealth of robust evidence comparing first generation endometrial ablation techniques to hysterectomy¹⁻⁵ whilst second generation techniques have been compared with first generation techniques, in order to prove their efficacy.⁶⁻¹⁵ Good quality randomised trials comparing clinical outcomes and costs between the different varieties of second generation ablative techniques are less common.¹⁶⁻¹⁸ We aimed to rectify this with a comparison of the two second generation techniques most commonly used in the UK, microwave endometrial ablation (MEATM) and thermal balloon endometrial ablation (TBall). This is in accordance with a recommendation from the National institute for Health and Clinical Excellence (NICE).¹⁹

Methods

Participants

Women complaining of heavy menstrual loss and requesting endometrial ablation were recruited by a research fellow from the gynaecology department of Aberdeen Royal Infirmary in the UK during the period January 2003 to January 2005. Patients were eligible if they were pre-menopausal, had completed their families, and had a uterine size equivalent to a twelve week pregnancy or less with no histopathological abnormalities of the endometrium and no fibroids obstructing the uterine cavity. Women with lower segment caesarean scars were included if their scar thickness was greater than 10mm on transvaginal ultrasound. All women gave informed consent to participate in the trial. The patients did not routinely undergo hysteroscopy prior to recruitment, unless transvaginal ultrasound scan suggested an abnormal uterine cavity.

Interventions

Procedures were undertaken in the post menstrual phase. This was either achieved by natural cycle or by a withdrawal bleed induced by Provera 10mg twice a day or norethisterone 5mg three times a day for seven days. Treatment was scheduled ten days after stopping the tablets.

Treatments were performed in day surgery theatres unless there were specific patient medical contraindications, for example BMI outwith the day surgery range. Treatments were either performed under general anaesthetic or local anaesthetic, with or without conscious sedation dependant on patient preference. Patients received a 100mg Diclofenac suppository 1 hour prior to treatment (patients in whom this was contraindicated received 1g

Paracetamol rectally). Intravenous access was achieved prior to commencement of the procedure. Those opting for local anaesthesia received a four quadrant intracervical block using four 2.2ml ampoules of Citanest (3% Prilocaine with Felypressin 2.2ml). They were offered intravenous sedation with Midazolam (2-4mg iv), either from the outset or at their request intra-operatively. If intra-operative analgesia was required intravenous Fentanyl was given (25-50mcgs). A member of theatre staff provided reassurance and verbal support throughout the procedure. Patient oxygen saturation and heart rate were monitored throughout the procedure.

The cervix was then dilated to 9mm for the MEA™ group and 5mm if necessary for the TBall group. A gas hysteroscopy (or saline if the view was poor, was then performed in all patients to identify the cavity and exclude false passages or perforations, immediately prior to device insertion. Women with submucous fibroids of less than 3cm were treated in the same fashion as those with normal cavities. Intrauterine polyps were removed under direct vision and treated in the same fashion, provided prior histology was within normal limits. Microwave ablation was performed in the standard fashion.²¹ The TBall procedure was adapted from the standard method⁹ by adding fluid to the balloon if necessary during the treatment cycle in order to maintain intracavity pressure at 160 -180mmHg. Total procedure time was taken from insertion of intra venous access to the patient leaving theatre. Procedure time (ablation) was taken from insertion of probe to removal of probe.

Post operatively, once comfortable, voiding and tolerating diet; patients were discharged with an information sheet and contact telephone number.

Objectives

To compare the clinical outcomes of microwave endometrial ablation (MEA™) and thermal balloon ablation (TBall) for the treatment of heavy menstrual bleeding.

Outcomes

Primary outcomes were satisfaction and menstrual scores one year. Secondary outcomes were operative differences, acceptability of treatment, and changes in health related quality of life..

Patients completed pre-operative questionnaires to obtain baseline menstrual details. These included both PBLAC²² and a menstrual bleeding and pain score used in previous endometrial ablation trials from this centre.^{7,23-25} The woman rated the blood loss on a scale from 1 least to 5 greatest for each day of her period. These values were then added for a total menstrual blood loss score. Menstrual pain was rated in an identical manner, in order to give a total pain score for the period. Baseline health-related quality of life parameters (Short form 12²⁶ and EQ-5D²⁷) and an assessment of anxiety/ depression (Hospital Anxiety and Depression Score²⁸) were also completed.

The questionnaires were repeated post treatment, at two weeks, six months and one year following the procedure.

Acceptability of the procedure and a pain questionnaire were completed on the day of surgery and two weeks post operatively. Acceptability of the procedure was assessed using a six-point scale and on a 10cm visual

analogue scale (0cm = totally acceptable, 10cm = totally unacceptable). Pain was assessed using a modified version of the McGill Questionnaire²⁹. Satisfaction with the outcome was measured at one year post procedure on a six-point scale from totally satisfied through to totally dissatisfied.

Sample Size

It was calculated a priori that 290 patients would be required to achieve 80% power to detect a 12% difference in those totally or generally satisfied with treatment. This number gives 80% power to detect a 15% difference in amenorrhoea rates ($2p < 0.05$). This is based on the only randomised trial evidence that established amenorrhoea rates for MEA™ at one year of 40 % and of TBall of around 20%.^{20,21} This number of patients would also give 90% power to detect a difference in menstrual scores (pictorial blood loss assessment chart, PBLAC) of 10, again significant at the 5% level. To account for drop outs 320 women were recruited to the trial. Previous ablation studies at this centre have shown up to a 20% loss to follow up by five years.

Randomisation

Patients were randomised in a ratio of 1:1 to the MEA™ and TBall arms of the study. Computer generated randomly permuted blocks were used with a telephone randomisation service based on a separate site to achieve concealment.

Blinding

The treatment allocation was not revealed to the participants during the course of the study. Outcome assessment was collected by means of patient completed questionnaires with the exception of the operative questionnaire data. The data was entered and analysed independently by researchers unaware of the treatment allocation.

Statistical analysis

All statistical analyses were carried out using SPSS v14 unless otherwise stated. Intention to treat analysis was utilised; that is each participant remained in their initially allocated group irrespective of the treatment received. A 95% confidence interval for the difference in proportions was calculated in Excel using Newcombe's method.³⁰ Health related quality of life measures (EQ-5D and SF-12 scores) were compared using a linear regression model to estimate the mean difference between groups, after adjusting for baseline values. Where appropriate, to account for skewness and an excess number of zeroes in an outcome, a zero inflated negative binomial regression model³¹ was used to estimate the incidence rate ratio (IRR) and 95% confidence intervals between groups, using STATA 9SE. Adjustment was made in the model for baseline values. The McGill pain score was generated using the rank weight method with a comparison between groups made using a Mann-Whitney test. The acceptability visual analogue scale was also compared using a Mann-Whitney test. Procedure times were compared using an independent t-test. A zero value was imputed for twelve months bleeding/pain scores PBLAC where the participant had

stated they no longer having periods. The CONSORT scheme³² of reporting was adhered to.

Results

Study recruitment commenced in January 2004 and treatments were completed by January 2007. Three hundred and twenty women were randomised with 157 in each arm receiving treatment (Figure1). There were six post randomisation exclusions (four withdrew consent and two were found to be unsuitable for treatment following randomisation.) These women are not included in the analysis as they withdrew prior to treatment.

Three patients withdrew following treatment one in the MEATM arm and two in the TBall arm.

AS, a specialist registrar (trainee) undertook the majority of the procedures under indirect supervision, (93%) with a consultant, K.C., undertaking the remainder.

Baseline characteristics for both groups were very similar (Table 1).

The number of participants who received their allocated treatments is reported in table 2. Three women in the MEATM arm were found to have unsuitable cavities of greater than 12cm on the day of surgery, despite pre assessment in a gynaecology clinic. These women underwent TCRE. Four women in the TBall arm were also found to have unsuitable uterine cavities of greater than

12 cm; two underwent TCRE, one had a rollerball and underwent hysterectomy. The single device failure in the MEA™ arm was due to moisture in the data cable, this patient underwent TCRE. The eleven device failures in the TBall arm were all due to failure in maintaining a stable intrauterine pressure despite an intact uterine cavity. Four of these women underwent TCRE, two had rollerball ablation and five women had MEA™. A failure in the sterile services department affected one operating list, leading to one woman in the MEA™ arm having rollerball ablation and one woman having TBall. 19% of women in the MEA™ arm and 14% of the TBall arm had either polyps or fibroids in the uterine cavity. Women were free to choose their method of anaesthetic either local or general. Similar numbers of around 60% in each group requested the procedure under general anaesthetic. In those who chose local anaesthetic there were no failures or conversion to general anaesthetic in either group.

Operative differences show a significant difference between MEA™ and TBall in total procedure time (from insertion of intravenous access to leaving theatre, (mean difference -5.9 min, 95% CI -8.5 min, -3.3 min) and in procedure time (insertion of probe to removal of probe (mean difference -6.6 min; 95% CI -7.4 min, -5.8 min) (Table 2). The median procedure related discomfort of both procedures was 3 on a scale of 1 none to 6 excruciating).

A further difference was demonstrated in the requirement for opiate analgesia and antiemetic medication between the two groups (Table 3), with the MEA™ group requiring significantly less (difference -22%, 95% CI (-32%, -11%)).

There were no serious complications in either group. By six hours, significantly more of the MEA™ group 124 (79%) were suitable for discharge home compared to 106 (68%) of the TBall group (difference 11%, 95% CI 1%, 20%).

High levels of acceptability with the procedure were found in both groups at two weeks with 118 (81%) of the MEA™ group and 122 (87%) of the TBall group describing their treatment as totally or generally acceptable (difference in proportion -6%; 95% CI -15%, 2%). There was a high level of satisfaction at twelve months with 109 (76%) of the MEA™ group and 103 (77%) of the TBall group described themselves as totally or generally satisfied with their procedure (difference in proportion -1%, 95% CI -11%, 9 %). The majority of women 91% for MEA™ and 92% for TBall would recommend the treatment to a friend at twelve months.

Menstrual outcomes between the two groups were comparable at twelve months (Table 4) both for PBLAC, pain and bleeding scores. 41% of the MEA™ group and 38% of the TBall group were amenorrhoeic. There were six hysterectomies in the MEA™ group and six in the TBall group (0.03%, 95% CI (-5%, 5%)). Quality of life scores (both physical and mental components) were not significantly different between the groups (Figure 2).

Discussion

This study demonstrates that MEA™ and TBall are both acceptable treatments which achieve high satisfaction rates for patients wishing treatment for their heavy menses. Patient quality of life shows an overall sustained improvement following both treatments.

Thermal balloon ablation achieved a high rate of amenorrhoea in this study when compared to previous reported randomised controlled trials.^{9,17,18} This may be due to the active circulation of fluid within the Thermachoice III catheters.³³ We feel that the addition of fluid into the balloon during the treatment cycle to maintain the treatment pressure above 160mmhg may also be important. This is not recommended practice by the manufacturer, at present. The amenorrhoea rates for microwave ablation are at the lower end of reports from other randomised trials from this and other centres^{7,8} This may represent the relative inexperience of the surgeon with this technique. The trainee had five years experience of the TBall technique, but had only recently been trained in the microwave procedure, having done five procedures independently prior to starting the trial.

It was felt important that the patients received treatment on the day of attending for surgery and hence an alternative method was used if there was a failure of the allocated treatment.

Both techniques are amenable to use under local anaesthesia with or without sedation. No patient required conversion to a general anaesthetic, this

concur with previous trials evaluating MEA™ under local anaesthesia and in the office setting.²¹⁻²³

Differences in time to discharge were not affected by timing of the theatre lists. The majority of patients were operated on in the afternoon research operating list with only those women with medical reasons being performed on a morning in-patient list. There was no difference in timing of procedure on the lists between the two groups. Patients were given the next space on the research list following randomisation, minimising potential bias in this respect.

The operative time differences between the two groups were predictable. TBall requires several minutes in order to achieve a stable intrauterine pressure and pre heating phase prior to the eight minute treatment cycle. The treatment cycle for MEA™ can begin immediately after insertion of the probe.

Procedure failures are an important consideration when choosing a second generation method. There was only one MEA™ device failure with eleven device failures in the TBall arm. These tended to be in women with large cavities and wide intercornual distances where it was not possible to achieve adequate intrauterine pressures in order to start the treatment cycle. The device failure in the MEA™ arm was due to moisture within the data cable. If disposable MEA™ probes (Femwave™) had been used this would not have occurred.

In this study no serious complications occurred with either technique. We feel that routine hysteroscopy prior to the start of the ablation minimises the risks of complications by excluding perforation and false passage, and confirmation of endometrial cavity by visualising cornuae.. There are documented cases of perforation and visceral damage for both techniques on the MAUDE database.

The generalisability of the results to a wider population is enhanced by the avoidance of entry criteria based on menstrual blood loss scores or a regular, normal sized uterine cavity, making this truly pragmatic. The results of the study would be genuinely reproducible if the practice of maintaining balloon were to become accepted practice. If not it is possible that lower amenorrhoea rates would occur following balloon ablation.

This is the first randomised controlled trial between these two second-generation ablation techniques. Whilst it appears that both treatments are as efficacious as each other, with the exception of a larger uterine cavity, in a climate of financial restraint MEA™ may have an economic advantage over TBall. Long-term follow up will be performed to compare satisfaction, menstrual outcomes and rates of further surgery between the two groups. The majority of repeat procedures and hysterectomies are known to take place within 24 months of MEA™, and rarely after three years.⁷

In conclusion both MEA™ and TBall achieve high levels of patient satisfaction and are acceptable to patients. Both techniques have similar effectiveness at

least up to a twelve month follow-up. MEA™ is quicker, **has less failures**, is not limited by the larger cavity and leads to quicker discharge. This provides valuable information to healthcare purchasers looking to purchase a second generation ablation device.

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Conflicts of interest

Dr Cooper has had financial support from Microsulis and Gynaecare for travel and attending meetings.

Contribution to authorship

Dr Cooper conceived the original idea for the trial and is the primary grant holder and principal investigator, edited the manuscript and is guarantor of the trial.

Dr Sambrook recruited the patients, undertook the majority of treatments, wrote the manuscript and assisted in analysing the data.

Dr Cook undertook the statistical analysis and commented upon the manuscript.

Prof Campbell, co-grant holder, methodological support and edited the manuscript

Ethics Approval

Approval from the local ethics committee was obtained to undertake a double blind randomised controlled trial (ISRCTN 28184453) comparing MEA™ (Microsulis Medical Ltd) and Thermal Balloon (Thermachoice III™, Ethicon Ltd).

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