Interventional procedure overview of
microwave endometrial ablation

Introduction
This overview has been prepared to assist members of IPAC advise on the safety and efficacy of an interventional procedure previously reviewed by SERNIP. It is based on a rapid survey of published literature, review of the procedure by one or more specialist advisor(s) and review of the content of the SERNIP file. It should not be regarded as a definitive assessment of the procedure.

Procedure name
Microwave endometrial ablation

SERNIP procedure number
65

Specialty society
Royal College of Obstetricians and Gynaecologists

Indication(s)
Heavy menstrual periods, also known as menorrhagia.

Menorrhagia is a very common problem. We found no routine data on the numbers of gynaecological procedures carried out each year in the UK by indication. In 2000/2001, about 45,000 hysterectomies and 17,000 therapeutic endoscopic uterine procedures were carried out in England (Hospital Episode Statistics; ungrossed for missing data; Department of Health). About half of these are likely to be for heavy menstrual bleeding.¹

Summary of procedure
Hysterectomy has been the traditional treatment for women with menorrhagia that has not responded to medical treatment. Minimally invasive procedures to destroy the lining of the uterus (endometrium) may reduce complications and recovery time compared with hysterectomy. They involve destroying the endometrium using lasers, radiofrequency waves, electrocautery, heated saline, a heated balloon, or microwaves. Microwave endometrial ablation is one of these minimally invasive procedures.

Microwave endometrial ablation (MEA) involves inserting a microwave probe into the uterine cavity which heats the endometrium. The probe is moved from side to side with the temperature maintained at 75 to 80°C to destroy the endometrium.


**Literature review**

**Appraisal criteria**
We included studies on microwave endometrial ablation in women with menorrhagia.

**List of studies found**
We found one Cochrane systematic review of endometrial destruction techniques.\(^1\) The systematic review concluded that women undergoing thermal ablation techniques had a similar reduction in bleeding and were as satisfied as women having hysteroscopic resection of the endometrium. Advantages of thermal ablation techniques were that general anaesthetic was not required, and the procedures were quicker and easier to perform. The systematic review did not come to any conclusions about the relative benefits and harms of the different thermal endometrial destruction techniques.

The systematic review included one relevant randomised controlled trial.\(^2\) We found a subsequent report of this randomised controlled trial describing outcomes after a further year.\(^3\)

We found one retrospective comparison of case series.\(^4\)

We identified six case series. The two largest of these are described in the table.\(^5-6\)
### Summary of key efficacy and safety findings (1)

<table>
<thead>
<tr>
<th>Authors, location, date, patients</th>
<th>Key efficacy findings</th>
<th>Key safety findings</th>
<th>Key reliability and validity issues</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cooper KG²</td>
<td>Mean operating times:</td>
<td>Complications</td>
<td>Randomisation method computer-</td>
</tr>
<tr>
<td>Randomised controlled trial</td>
<td>• MEA : 11 minutes</td>
<td>MEA:</td>
<td>generated random number sequence</td>
</tr>
<tr>
<td>Aberdeen, UK</td>
<td>• TCRE: 15 minutes</td>
<td>• equipment failure:11 women</td>
<td>Baseline characteristics similar in</td>
</tr>
<tr>
<td>1996 to 1998</td>
<td>p=0.001</td>
<td>• blunt perforation:1 woman</td>
<td>MEA and TCRE groups</td>
</tr>
<tr>
<td>n=263</td>
<td></td>
<td>• minor secondary haemorrhage:4 women</td>
<td>Losses to follow up:</td>
</tr>
<tr>
<td>• MEA; n= 129; mean age 41</td>
<td>Amenorrhoea:</td>
<td>• bladder or bowel complications: none</td>
<td>MEA: 13 women</td>
</tr>
<tr>
<td>• Transcervical resection of the</td>
<td>• MEA : 40%</td>
<td>TCRE:</td>
<td>Power adequate</td>
</tr>
<tr>
<td>endometrium (TCRE); n= 134,</td>
<td>• TCRE: 40%</td>
<td>• equipment failure:3 women</td>
<td>Outcome assessors not stated to be</td>
</tr>
<tr>
<td>mean age 41</td>
<td>95% confidence interval (CI) for</td>
<td>• perforation: 1 woman</td>
<td>blind to treatment allocation</td>
</tr>
<tr>
<td>Follow up 12 months</td>
<td>difference -14% to 20%</td>
<td>• haemorrhage: 5 women</td>
<td>Outcome measures appropriate</td>
</tr>
<tr>
<td>Inclusion criteria:</td>
<td>&gt;3 days of heavy bleeding:</td>
<td>• bladder or bowel complications: none</td>
<td>Funded by manufacturer of Microwave</td>
</tr>
<tr>
<td>• completed families</td>
<td>• MEA : 7%</td>
<td></td>
<td>equipment</td>
</tr>
<tr>
<td>• uterine size equivalent to 10</td>
<td>• TCRE: 6%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>weeks pregnancy or less</td>
<td>95%Cl for difference -10% to 31%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• no abnormal histopathology</td>
<td>‘Totally’ or ‘generally’ satisfied:</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• MEA : 77%</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• TCRE: 75%</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>95%CI for difference -12% to 17%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>No difference in components of SF-36 score between MEA and TCRE</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Microwave endometrial ablation
### Summary of key efficacy and safety findings (2)

<table>
<thead>
<tr>
<th>Authors, location, date, patients</th>
<th>Key efficacy findings</th>
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<th>Key reliability and validity issues</th>
</tr>
</thead>
</table>
| **Bain C**
RCT
Aberdeen, UK
1996 to 1998 |

n=263
- MEA; n= 129; mean age 41
- Transcervical resection of the endometrium (TCRE); n= 134, mean age 41

Follow up 24 months

Inclusion criteria:
- completed families
- uterine size equivalent to 10 weeks pregnancy or less
- no abnormal histopathology

**Amenorrhoea:**
- MEA : 47%
- TCRE: 41%
95%CI for difference -9% to 15%

>3 days of heavy bleeding:
- MEA : 2%
- TCRE: 7%
95%CI for difference -9% to 1%

‘Totally’ or ‘generally’ satisfied:
- MEA : 79%
- TCRE: 67%
95%CI for difference 7% to 22%

Hysterectomy:
- MEA : 5%
- TCRE: 4%

None described

As for Cooper KG; study following up same women for an additional year

Losses to follow up:
- MEA: 9 women
- TCRE: 5 women

| **Henshaw R**
Retrospective comparison of case series
Adelaide, Australia
1998 to 2001 |

n=62
- MEA; n=39; mean age 41
- levonorgestrel-releasing intrauterine device (IUD); n=23; mean age 37

Mean follow up:
- MEA: 8 months
- IUD: 21 months

**Mean bleeding score:**
- MEA: 5
- IUD: 8
p=0.32

**Mean dysmenorrhea score:**
- MEA: 2
- IUD: 6
p=0.06

**Satisfaction:**
- MEA: 80%
- IUD: 75%
p>0.05

**Complications:**
- MEA:
  - equipment failure : 1 woman
- levonorgestrel-releasing intrauterine device (IUD):
  - unexplained pelvic pain: 2 women

**IUD:**
- unexplained pelvic pain: 1 woman

How it was decided who should receive MEA and who should receive IUD not described

Baseline characteristics:
- Mean age:
  - MEA : 41
  - IUD: 37
- Mean parity:
  - MEA: 3
  - IUD: 2

Authors shareholders in Microsulis which manufactures MEA equipment
## Summary of key efficacy and safety findings (3)

<table>
<thead>
<tr>
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</thead>
</table>
| Parkin DE<sup>5</sup>  
Case series  
13 centres, UK and Canada  
1994 to 1999  
n=1433 MEA procedures  
Complications reported as they occurred to manufacturer, and then to Medical Devices Agency | No efficacy data, study examining complications | Complications:  
- small bowel burn: 1 woman  
- blunt perforations: 4 women  
- cervical burn: 1 woman  
- postoperative pain: 2 women  
- endometritis: 14 women  
- burns to vagina: none  
- emergency hysterectomy: none  
Total complication rate: 15/1000 | Large case series of all women undergoing MEA (equipment supplied on condition all complications reported; microchip in probe confirms this)  
Dataset included first procedures carried out during learning curve  
Author received part funding for research fellow form equipment manufacturers |
| Milligan MP<sup>6</sup>  
Case series  
Canterbury, UK  
1997 to 1999  
n=151, age range 26 to 54  
Follow up: 3 months  
General anaesthesia (n=98); local anaesthesia (n=63) | Changes in menstrual symptoms not reported  
Return to normal activities at 1 week: 70%  
Return to normal activities at 3 weeks: 95% | Postoperative pain:  
- moderate pain: 25%  
- intravenous opiate analgesia: 4%  
Abdominal pain during follow up:  
- none: 25%  
- lasted <1 week: 44%  
- pain > 4 weeks: 8%  
- iv opiate analgesia: 4%  
Vaginal bleeding/discharge:  
- bleeding: 64%  
- discharge: 87%  
- discharge requiring antibiotics: 3%  
Other symptoms:  
- vaginal dryness: 21%  
- change in bowel habit: 16%  
- urinary frequency and urgency: 23% | Uncontrolled case series  
Outcomes measured by questionnaire; no details presented  
Short follow up |
Validity and generalisability of the studies
We found one randomised controlled trial comparing MEA and hysteroscopic transcervical resection.\textsuperscript{2,3} It was of reasonable quality, though blinding of outcome assessment was not described. It found that outcomes at one and two years were similar for MEA and transcervical resection. Operating time was shorter for MEA than resection.

We found one retrospective comparison of case series comparing MEA and levonorgestrel-releasing intrauterine device.\textsuperscript{4} Differences in outcome are likely to be confounded by differences in characteristics or other treatments of women receiving MEA and levonorgestrel-releasing intrauterine device.

We found one large case series that is likely to include all women who have received MEA.\textsuperscript{5} It provide comprehensive information on frequency of complications, but not efficacy, compared with other procedures.

Bazian comments
None.

Specialist advisor’s opinion / advisors’ opinions
Specialist advice was sought from the Royal College of Obstetricians and Gynaecologists.

MEA is now established practice. It does not require training in hysteroscopy.

One specialist advisor describes a case series collated by his/her unit which includes efficacy data on 800 women. Amenorrhoea was achieved in 35%.

Issues for consideration by IPAC
None other than those described above.
References


Annex: Excluded studies

<table>
<thead>
<tr>
<th>Reference</th>
<th>Number of study participants</th>
</tr>
</thead>
</table>

Overview prepared by:
Bazian Ltd
November 2002