NATIONAL INSTITUTE FOR CLINICAL EXCELLENCE

INTERVENTIONAL PROCEDURES PROGRAMME

Interventional procedure overview of balloon thermal endometrial ablation (Cavaterm)

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
Thermal endometrial ablation (Cavaterm)

SERNIP procedure number
99

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 with lasers, radiofrequency waves, electrocautery, heated saline, a heated balloon, or microwaves. Balloon thermal endometrial ablation is one of these minimally invasive procedures.

Cavaterm thermal balloon endometrial ablation involves inserting a balloon into the uterine cavity through the cervix. The surgeon inflates the balloon with a glycine solution to a pressure of 180 to 220 mmHg. The solution is heated to 75°C for 15 minutes to destroy the endometrium. It can often be carried out under local anaesthetic on a day-case basis.
The claimed advantage of Cavaterm over Gynecare Thermachoice, another thermal balloon endometrial ablation system, is that the balloon size is adjustable to fit different sized uterine cavities.

**Literature review**

**Appraisal criteria**

We only included studies on balloon thermal ablation using the Cavaterm procedure in women with menorrhagia. Studies where the technique was not specified were excluded.

**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 randomised controlled trial using Cavaterm.\(^2\) We found two further randomised controlled trials.\(^3,4\)

We found nine case series. The table provides details of the three largest of these.\(^5-7\) The annex provides references to smaller studies.
## 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><strong>Romer T²</strong>&lt;br&gt;Randomised controlled trial&lt;br&gt;Germany&lt;br&gt;Date not stated (published 1998)&lt;br&gt;n=20, age 35 to 52&lt;br&gt;• Cavaterm; n= 10&lt;br&gt;• Rollerball ablation; n= 10&lt;br&gt;Follow up: 9 to 15 months&lt;br&gt;Exclusion criteria:&lt;br&gt;• desire for future fertility&lt;br&gt;• fibroids&lt;br&gt;• intrauterine abnormality</td>
<td>No difference between Cavaterm and Rollerball in satisfaction&lt;br&gt;No difference between Cavaterm and rollerball in amenorrhoea rate</td>
<td>Complications not reported in English abstract or Cochrane review</td>
<td>Report in German: data taken from English abstract and Cochrane systematic review&lt;br&gt;• Randomisation method not described&lt;br&gt;• Comparison of baseline data not described&lt;br&gt;• Power very limited&lt;br&gt;• Follow up short&lt;br&gt;• Losses to follow up not described&lt;br&gt;• Blinding not described</td>
</tr>
</tbody>
</table>
| **Romer T³**<br>Randomised controlled trial<br>Germany<br>Date not stated (published 1997)<br>n=30<br>• Cavaterm; n= 15<br>• Rollerball; n= 15<br>Minimum follow up: 6 months<br>Exclusion criteria:<br>• intrauterine abnormality | Amenorrhoea:<br>• Cavaterm: 33%<br>• Rollerball: 33%
Reduction of menstrual flow:<br>• Cavaterm: 100%
• Rollerball: 100% | ‘No intra- or postoperative complications’ | Abstract presented at conference; full report not found in peer-reviewed journal<br>• Randomisation method not described<br>• Comparison of baseline data not described<br>• Power very limited<br>• Follow up short<br>• Losses to follow up not described<br>• Outcomes not defined<br>• Blinding not described<br>May be duplication of women from those described in Romer T² |
### Summary of key efficacy and safety findings (2)

<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>
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</thead>
<tbody>
<tr>
<td>Pellicano M*</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Randomised controlled trial</td>
<td>Operation time:</td>
<td>Cavaterm (number of women):</td>
<td>Randomisation method: computer-</td>
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<tr>
<td>Italy</td>
<td>• Cavaterm: 24 minutes</td>
<td>• fever (1)</td>
<td>generated random number sequence</td>
</tr>
<tr>
<td>1998 to 1999</td>
<td>• TCRE: 37 minutes</td>
<td>• haemorrhage (5)</td>
<td>No large differences between groups</td>
</tr>
<tr>
<td>n=82</td>
<td>p&lt;0.01</td>
<td>• blood transfusion (2)</td>
<td>in baseline characteristics</td>
</tr>
<tr>
<td>Follow up: 2 years</td>
<td>Return to normal activities</td>
<td>TCRE (number of women):</td>
<td>Blinding not described</td>
</tr>
<tr>
<td>Exclusion criteria:</td>
<td>• Cavaterm: 4 days</td>
<td>• fever (2)</td>
<td>Losses to follow up:</td>
</tr>
<tr>
<td>• age &gt;50</td>
<td>• TCRE: 6 days</td>
<td>• urinary infection or retention (1)</td>
<td>• Cavaterm: 5 women</td>
</tr>
<tr>
<td>• weight &gt;100 kg</td>
<td>p&gt;0.05</td>
<td>• haemorrhage (4)</td>
<td>• TCRE: 9 women</td>
</tr>
<tr>
<td>• abnormal endometrium or Pap</td>
<td>Bleeding recurrence at 2 years (not further defined):</td>
<td>fluid overload (5)</td>
<td>Outcomes appropriate</td>
</tr>
<tr>
<td>smear</td>
<td>• Cavaterm: 8%</td>
<td>• cervical tear (1)</td>
<td></td>
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<tr>
<td>• uterine size &gt;12 weeks pregnancy</td>
<td>• TCRE: 24% p&lt;0.01</td>
<td>• conversion to hysterectomy (2)</td>
<td></td>
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<tr>
<td>• fibroids</td>
<td>Pain recurrence at 2 years:</td>
<td></td>
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<tr>
<td>• prolapse</td>
<td>• Cavaterm: 6%</td>
<td></td>
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<tr>
<td>• endometriosis</td>
<td>• TCRE: 27% p&lt;0.01</td>
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<tr>
<td>• urinary symptoms</td>
<td>Satisfaction at 2 years ‘excellent’:</td>
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<tr>
<td></td>
<td>• Cavaterm: 46%</td>
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<tr>
<td></td>
<td>• TCRE: 6% p&lt;0.001</td>
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<tr>
<td></td>
<td>Reoperation at 2 years</td>
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<td></td>
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<tr>
<td></td>
<td>• Cavaterm:6%</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• TCRE: % p&lt;0.01</td>
<td></td>
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</tr>
</tbody>
</table>
## Summary of key efficacy and safety findings (3)

<table>
<thead>
<tr>
<th>Authors, location, date, patients</th>
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</thead>
</table>
| **Friberg B**<sup>5</sup>  
Case series  
Sweden  
1993 to 1996  
n=117, mean age 43  
Mean follow up: 25 months, range 10 to 49 months  
Inclusion criteria:  
- no desire for future fertility  
- no genital malignancy  
- general anaesthesia (n=95)  
- spinal anaesthesia (n=18)  
- local paracervical block (n=4)  | Returned home on day of treatment: 91/117  
Treatment ‘successful’ in 94%  
Amenorrhoea: 30/102  
Satisfaction ‘excellent’: 97/106  
Subsequent hysterectomy: 10 women | ‘No immediate perioperative complications’  
Complications:  
- endometritis: 3 women  
- abdominal pain and fever: 1 woman | Uncontrolled case series  
Outcomes appropriate  
Follow up variable length  
Short follow up for some women |
| **Gerber J**<sup>6</sup>  
Case series  
Switzerland  
Date not stated (published 1999)  
n=67  
Follow up available on 55 women  
Follow up: > 6 months | Satisfaction ‘good’ to ‘excellent’: 93%  
Amenorrhoea: 30%  
Hysterectomy: 3 women | ‘No complications occurred’ | Uncontrolled case series  
Paper in German; data extracted from English abstract  
Short follow up |
### Summary of key efficacy and safety findings (4)

<table>
<thead>
<tr>
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<th>Key safety findings</th>
<th>Key reliability and validity issues</th>
</tr>
</thead>
</table>
| Hawe J  
Case series  
UK  
Date not stated (published 1999)  
n=50; mean age 45, range 28 to 54  
Mean follow up: 14 months, range 6 to 24 months  
Exclusion criteria:  
• desire for future fertility  
• endometrial hyperplasia  
• uterine cavity length >12 cm  
• polyps or fibroids  
• General anaesthesia (n=36)  
• Sedation and paracervical block (n=14) | Amenorrhea: 34 women  
Spotting: 12 women  
Normal periods: 2 women  
Subsequent hysterectomy or laser ablation: 2 women | ‘No major complications occurred’  
Complications:  
• streptococcal infection: 2 women  
• unexplained right iliac fossa pain for 24 hours: 1 woman  
• endometritis: 1 woman | Uncontrolled case series  
Short follow up in some women  
Methods of measuring outcomes not described |
Validity and generalisability of the studies

We found three randomised controlled trials.²⁻⁴ Two may have included the same study participants.²,³ Reports of these two trials were only available as abstracts, so it was difficult to assess quality. Both trials were very small and follow up was short. The third trial was of reasonable quality, though also small, and blinding of outcome assessment was not described.⁴

The first two trials²⁻³ compared Cavaterm with Rollerball hysteroscopic ablation. The third trial compared Cavaterm with hysteroscopic resection.⁴

We found three case series including 50 or more women.⁵⁻⁷ Follow up was short for many of the included women.

Bazian comments

None

Specialist advisor’s opinion / advisors’ opinions

Specialist advice was sought from the Royal College of Obstetricians and Gynaecologists

Cavaterm is now established practice. It does not require hysteroscopic skills.

Issues for consideration by IPAC

None other than those described above.
References


## Annex: References to smaller case series

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

Overview prepared by:
Bazian Ltd
November 2002