Endometrial Ablation for Heavy Menstrual Bleeding

Jonathan Lord
Consultant gynaecologist
Declaration of Interests

Affiliation:
• NICE – HMB guideline committee member

Expenses & honaria:
• Hologic (manufacturer of Novosure and Myosure) –
  • Two clinical advisory board meetings, Sept 2017 & 2018

See NICE website (TOP guideline) for current full list
In next 20 minutes...

• Outline of endometrial ablation

• How NICE assessed the evidence

• Outcomes and Comparisons

• Future Trends
Endometrial Ablation

**First Generation**
- TCRE (transcervical resection of endometrium)
- Rollerball
- Vaporisation

**Second Generation**
- Radiofrequency (Novasure®)
- Thermal Balloon (Thermachoice®)
- Cryoablation
- Hydrothermal
**First Generation**
- Uses glycine or saline
- Longer operating time
- Results dependent on skill
- Longer training time
- More surgical control
- Can be used in larger cavities or with fibroids

**Second Generation**
- Computer controlled
- Short operating time
- Less operator dependent
- Short training time
- Less adaptable for larger cavities or with fibroids
Counselling & Patient Selection

- Effective in ~80%
- About half have amenorrhoea; half lighter, acceptable periods
- Must have effective contraception – pregnancy not safe
- Less effective in:
  - Young
  - Fibroids
  - Irregular cavities
  - Pain

Assessing the Evidence

Network Meta-analysis

“A” ➔ “B”

“B” ➔ “C”

“C” ➔ “?” ➔ “C”

“Next Generation Meta-analysis”

• Powerful & complex
• Garbage in, garbage out
• Useful to validate meta-analysis
PICO

Population
• RCTs of women with HMB
  • No Fibroids vs fibroids (>3cm)

Intervention
• Pharmacological
• Mirena
• First generation ablation
• Second generation ablation
• Hysterectomy

Comparison
...vs each other or no treatment
Outcomes

• Quality of Life
• Patient satisfaction
• Adverse Events
• Reduction in blood loss
Literature Identified

No fibroids:
• 5 Cochrane reviews
• 58 RCTs (54 incl. ablation)

Suspected or Confirmed Fibroids
• 1 Cochrane review
• 16 RCTs from 11 trials
Outcomes

Health Related Quality of Life

• Short term – no difference
• Long term – ablation inferior to medical treatment, Mirena, hysterectomy

But...

• Few studies – poor network
• Statistical but not clinical significance (e.g. Mean Difference 0.1 (0.01-0.2) for hysterectomy vs ablation)
• Medical treatment dominated by trial with primary care population
• Likely medical-only treatment means less severe symptoms
• Inappropriate to have hierarchy of major surgery before minor
Health Related Quality of Life

Blood Loss
Blood Loss

Novosure 91% probability of being best for reducing blood loss (Mirena last)

With fibroids, ablation better than Mirena (no 2nd generation studies)
Patient Satisfaction

22 trials of 2719 women

Serious incoherence & heterogeneity

Split into sub-analyses

Probability of being best treatment:

- Novosure – 49%
- Hysterectomy – 17%
- Mirena – 2%
- Balloon – 0%
- 1st Generation – 0%
Economics & Adverse Effects

• In line with expectations

• Does not contradict other findings

• No significant differences between all choices
Recommendations

[Consider Mirena or other medical treatments in primary care]

If treatment is unsuccessful, the woman declines pharmacological treatment, or symptoms are severe, consider referral to specialist care for:

- Investigation
- Management:
  - Other pharmaceutical options
  - Second generation endometrial ablation
  - Hysterectomy

Surgical options first-line where:

- Do not wish to have pharmaceutical treatment
- Do not want to conserve fertility
Type of Ablation

Novosure superior, but not recommended as 2\textsuperscript{nd} generation of choice:

- Post hoc analysis owing to incoherence
- Fast developing area – new evidence likely in lifetime of guidance

Select 2\textsuperscript{nd} generation technique that is expected to offer outcomes at least equivalent to Novosure
Outcome Data for Clinic Novosure

- Mean pain score from procedure – 4.6 out of 10
- Mean pain from normal menstruation – 5.8

If you were in the same position again, would you choose the same way of having this procedure?

Overall, how would you rate the care you received in the clinic?
# Process – Patient Perspective

<table>
<thead>
<tr>
<th>Day Case &amp; Admission</th>
<th>Ambulatory</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Admitted at beginning of session regardless of procedure time</td>
<td>• Booked appointment slot</td>
</tr>
<tr>
<td>• Staff busy with others – one of many on ward</td>
<td>• All staff focussed on patient</td>
</tr>
<tr>
<td>• Need collection and care overnight</td>
<td>• Walk-in, walk-out</td>
</tr>
<tr>
<td>• Starved</td>
<td>• Eat &amp; drink freely</td>
</tr>
<tr>
<td>• Disconnect from procedure – only record may be discharge note</td>
<td>• Can witness procedure and understand findings</td>
</tr>
<tr>
<td></td>
<td>• Equipment permits less trauma and more finesse</td>
</tr>
<tr>
<td></td>
<td>• Probably safer, better, less bleeding</td>
</tr>
</tbody>
</table>
Future Trends

- Ablation well tolerated as outpatient procedure
- Advances in nerve block mean pain scores less than menstruation
- Quick recovery – oral analgesia
- ? vs laparoscopic sub-total
- ? Next generation in community
Summary

Second generation ablation valid as first or second line treatment

Particularly suits:
- Mid to late 40’s / perimenopause
- Contraception not needed
- Dislikes hormone treatment
- Desires outpatient procedure with quick recovery

Works best with normal cavity

Ambulatory use likely to increase its uptake