Intrauterine instillation of Mepivacaine for pain relief at IUD insertion: A double-blind randomized controlled trial
WHO I AM

Registered nurse midwife - RNM
RFSU Clinic in Stockholm Sweden
STI and Contraceptive counseling

PhD Student
Dept. of Women’s and Children’s Health
Div. of Obst. and gyn.

Conflicts of interest
NONE
WHY ANOTHER TRIAL?

IUDs - the "Golden" contraception

- Highly effective with a PI below 1
- High satisfaction among users
- High continued use between 80-90%
- Very few contraindications

HOWEVER IUDs are underutilized

- Worldwide use of IUDs is estimated to be 14%*
- IUDs are still not considered as a first option by some service providers
- Fear of pain during insertion - a often stated barrier**

*United Nations, 2015
**Bharadwaj P et al. 2011 & 2012
WHAT WE DID

Intrauterine Instillation (IUI)

A Double-blind randomized controlled trial
Two study sites in Stockholm

Inclusion criteria:
At least 18-year-old, opting for an IUD, nulliparous.

Exclusion criteria:
Previous conization, known cervical stenosis, signs of ongoing genital infection, known uterine abnormality, bleeding disorder or contraindications to any local anesthetic

Women randomized using SNOSE, Allocation ratio 1:1
• This catheter is thin
• It has no balloon tip
  -> less pain during instillation

**Intervention:** 10 ml of Mepivacaine, 10 mg/ml (1%), administered through IUI 5 minutes prior to IUD insertion
  • Mepivacaine is widely used in clinics
  • Mepivacaine is less toxic than Lidocaine*
  • Hyphotesized to numd the uterine and cervical lining

**Placebo:** 10 ml of NaCl, 0.9 mg/ml, same administration.

*Kazaba et al, 2003*
Data collection

Primary outcome: Difference in VAS at IUD insertion

Pain experience during procedure
(mark with a vertical line on this line)

No pain

Worst pain imaginable

Secondary outcomes:
- Pain in VAS at IUI
- Tenaculum placement
- Uterine sounding
- Before leaving the clinic.
- Method acceptability - could recommend or not recommend?
- Entire insertion procedure experienced as easier than expected, as expected or worse than expected

Follow up:
Telephone interviews after 10 days, 3 months and 6 months measuring
- Continued use of IUD
- Reasons for discontinuation
- Acceptability of IUD as willingness to use again and recommending IUD use to a friend
RESULTS

Study population:

- 105 women assessed for eligibility
- 86 accepted and were randomized
- 2 failed insertions, 2 failed instillations, 1 excluded from analysis (not nulliparous)
- 81 in the analysis
### Characteristics

**Table 1. Characteristics of Study Participants by randomized study arm.**

<table>
<thead>
<tr>
<th></th>
<th>Intervention</th>
<th>Placebo</th>
<th>$P^*$</th>
</tr>
</thead>
<tbody>
<tr>
<td>n=41</td>
<td>n=40</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age (years)</td>
<td>22.6±4.2</td>
<td>22.8±4.0</td>
<td>.73</td>
</tr>
<tr>
<td>Normal menstrual cramping (VAS)</td>
<td>4.3±2.4</td>
<td>4.1±2.6</td>
<td>.41</td>
</tr>
<tr>
<td>Previous Medical abortion</td>
<td>6 (14.6)</td>
<td>5 (12.5)</td>
<td>1</td>
</tr>
<tr>
<td>Previous Surgical abortion</td>
<td>1 (2.4)</td>
<td>3 (7.5)</td>
<td>0.36</td>
</tr>
<tr>
<td>Previous IUD insertion</td>
<td>7 (17.1)</td>
<td>6 (15)</td>
<td>1</td>
</tr>
<tr>
<td>Type of inserted IUD</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>LNG-IUS 52</td>
<td>20 (48.8)</td>
<td>18 (45)</td>
<td>.82</td>
</tr>
<tr>
<td>Copper-IUD 380</td>
<td>7 (17.1)</td>
<td>11 (27.5)</td>
<td>.29</td>
</tr>
<tr>
<td>LNG-IUS 13,5</td>
<td>13 (31.7)</td>
<td>11 (27.5)</td>
<td>.62</td>
</tr>
<tr>
<td>LNG-IUS 19,5</td>
<td>1 (2.4)</td>
<td>0 (0)</td>
<td>1</td>
</tr>
</tbody>
</table>

Randomization successful – no significant differences between groups.
Primary and secondary outcome

Table A2. Primary and secondary outcomes, VAS at all procedures and overall experience by randomized study arm

<table>
<thead>
<tr>
<th></th>
<th>Intervention</th>
<th>Placebo</th>
<th>P*</th>
</tr>
</thead>
<tbody>
<tr>
<td>n=41</td>
<td>n=40</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>VAS</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baseline</td>
<td>0,12±0.21</td>
<td>0,19±0.51</td>
<td>.402</td>
</tr>
<tr>
<td>Instillation of study drug or placebo</td>
<td>1,79±1.39</td>
<td>2,32±2.02</td>
<td>.178</td>
</tr>
<tr>
<td>Tenaculum</td>
<td>2,41±2.17</td>
<td>2,69±2.29</td>
<td>.583</td>
</tr>
<tr>
<td>Sounding</td>
<td>3,7±2.46</td>
<td>4,63±2.23</td>
<td>.079</td>
</tr>
<tr>
<td>IUD insertion</td>
<td>4,63±2.21</td>
<td>5,67±2.62</td>
<td>.058</td>
</tr>
<tr>
<td>Before leaving the clinic</td>
<td>1,97±2.08</td>
<td>2,32±2.42</td>
<td>.479</td>
</tr>
<tr>
<td><strong>Experience of IUD insertion procedure</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Easier than expected</td>
<td>26 (63.4)</td>
<td>15 (37.5)</td>
<td></td>
</tr>
<tr>
<td>As expected</td>
<td>12 (29.3)</td>
<td>11 (27.5)</td>
<td></td>
</tr>
<tr>
<td>Worse than expected</td>
<td>3 (7.3)</td>
<td>14 (35)</td>
<td>.003**</td>
</tr>
</tbody>
</table>

- Pain reduction at insertion didn't reach statistical significance
- Only 3 in the intervention group compared to 14 in the placebo group experienced the insertion procedure as worse than expected
Mean VAS at all procedures

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Intervention</th>
<th>Placebo</th>
</tr>
</thead>
<tbody>
<tr>
<td>baseline</td>
<td>0.12</td>
<td>0.19</td>
</tr>
<tr>
<td>instillation</td>
<td>2.32</td>
<td>1.79</td>
</tr>
<tr>
<td>tenaculum</td>
<td>2.41</td>
<td>2.69</td>
</tr>
<tr>
<td>sounding</td>
<td>3.7</td>
<td>4.63</td>
</tr>
<tr>
<td>insertion</td>
<td>4.63</td>
<td>5.67</td>
</tr>
<tr>
<td>before leaving</td>
<td>1.97</td>
<td>2.32</td>
</tr>
</tbody>
</table>
Conclusion

• Pain reduction in VAS for the intervention didn’t reach statistical significance compared to placebo ($p=0.058$). Future studies with larger sample size needed

• Significantly fewer women in the intervention group stated that the procedure was worse than expected ($p=0.003$)
Implications

- Mepivacaine and the catheter is easy to access - easy to use
- Experiencing the IUD insertion as easier or as expected is **clinically important** since it might affect future use and immediate recommendation of IUDs.
Thank you!

Your queries – my pleasure

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