Paracervical block as pain treatment during second-trimester MTOP: an RCT

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BACKGROUND

• The most common side effect of misoprostol is pain

• Women undergoing second-trimester MTOP reported physical pain of strong intensity
  *Andersson et al PlosOne December 2014*

• Hard to find ways for pain treatment among nurses taking care of women undergoing second-trimester MTOP
  *Andersson et al Contraception January 2014*
The aim was to determine if paracervical blockade, PCB, administered before the onset of pain could decrease women’s pain experience during second-trimester MToP.
Data collection

• May 2012 - April 2015
• 102 women included in the analysis
• Indication
  fetal malformation (n= 25)
  unintended pregnancy (n= 77)
• Marital status
  single (n=27)
  boyfriend (n=20)
  married/cohabiting (n=50)
Inclusion criteria:
* > 18 years
* Understanding Swedish
* Non allergy to morphine or local anaesthesia

All women undergoing II-trim MTOP (n=589)

Excluded (n=313)
- Not meeting inclusions criteria (n=141)
- Recruited for another study (n=37)
- Researcher not available (n=118)
- Other reasons (n=17)

Did not want to participate (n=163)
- Fear of needles (n=64)
- Do not want placebo (n=28)
- Difficult situation, anxiety (n=26)
- Dislike gynaecological chair (n=6)
- No reason/other (n=39)

Informed and invited (n=276)

Study loss (n=11)
- Withdraw from the study (n=6)
- Aborted before the blockade (n=2)
- Technical difficulties (n=3)

Included to the study (n=113)

FAS (n=102)
A double-blinded RCT

- The woman got a paracervical blockade one hour after the first dose of misoprostol.

- 20 ml active substance (bupivacaine) or 20 ml placebo (sodium chloride)
Primary outcome

Pain intensity measured as any VAS $\geq 7$

Pain intensity (VAS) was measured every half hour
Secondary outcomes

• The induction-to-abortion interval

• The total morphine consumption

• Safety

• Side effects
RESULTS

• 65 – 75 % of the participants experienced severe pain, VAS $\geq 7$, at any time point during the abortion

• No differences in outcomes between the two groups
  - VAS
  - induction-to-abortion interval
  - morphine consumption

• No differences in
  - time to placenta expulsion
  - rates of surgical intervention
  - side effects
<table>
<thead>
<tr>
<th></th>
<th>Sodium chloride n=50</th>
<th>Bupivacaine n=52</th>
<th>RR (CI 95%)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Highest pain intensity</strong></td>
<td></td>
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<tr>
<td>VAS 0-6</td>
<td>17 (35%)</td>
<td>13 (25%)</td>
<td>1,1 (0,9 – 1,5)</td>
<td>0,292</td>
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<tr>
<td>VAS 7-10</td>
<td>32 (65%)</td>
<td>39 (75%)</td>
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<td><strong>Induction-to-abortion interval (min)</strong></td>
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<tr>
<td>Median (q1 – q3)</td>
<td>398 (260 – 540)</td>
<td>435 (320 – 748)</td>
<td>80 (-5 – 180)</td>
<td>0,075</td>
</tr>
<tr>
<td><strong>Morfin consumption (mg)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Median (q1 – q3)</td>
<td>6,0 (1,0 – 10,0)</td>
<td>5,0 (1,3 – 10,5)</td>
<td>0,0 (-2 – 2,5)</td>
<td>0,772</td>
</tr>
</tbody>
</table>
What may have influenced the findings?

• The study loss – 60% did not want to participate
• The study design
• The placebo effect
• Frequent presence by nurses when measuring pain
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• Increased pressure in the tissue by 20 ml fluid

• Paracervical block is not effective pain treatment for abortion pain in second-trimester MTOP (??)
Conclusion

Prophylactic PCB did not lead to a clinically significant reduction in maximal pain scores and the need for additional opiates during second-trimester MToP.

And...

...there is still a clear need for more optimal pain treatment for women undergoing second-trimester MTOP.
Thank you!
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Illustrations: Ingrid Fröhlich