The efficacy, safety, and acceptability of medical abortion provided by nurse midwives or physicians—
a randomized controlled equivalence trial

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Background

- Task sharing is defined as sharing less advanced medical tasks with staff who have a lower level education but still the right level of education
- In medical abortion, surgical abortion and provision of caesarian sections this has been shown to be safe in a low resource setting

- In Sweden nurse midwives
  - have 4.5 years of university education (nurse 3 yrs- midwife 1.5 yrs)
  - provide contraceptive advice and prescriptions to healthy women
  - insert IUDs
  - Supervise all uncomplicated pregnancies
  - manage all uncomplicated vaginal deliveries
  - oversee all uncomplicated medical abortion
Preparation for the study

- 2 nurse midwives experienced in abortion care were trained in vaginal ultrasound
  - Theroretical education
  - Practical education, 50 supervised ultrasounds, 50 ultrasound passed after confirmation by physician.

- Women were eligible if they had a pregnancy of less than 9 weeks and 0 days estimated according to LMP.
- There was no pre-examination or screening.
  - 597 women were randomized to the nurse midwife group
  - 583 women were randomized to standard care.
Treatment

- 200 mg mifepristone
- 800mcg misoprostol vaginally after 24-48 hours
  → at home or in the clinic
- 400mcg misoprostol po if no bleeding after 3 hours

- Follow-up with low sensitivity u-hcg (cut off 500 IU/ml) by nurse midwife after 3-4 weeks

- Questionnaire at follow-up
## Reasons for exclusion after allocation

<table>
<thead>
<tr>
<th>Reason</th>
<th>Allocated to Nurse midwife</th>
<th>Allocated to Physician</th>
<th>Total number of women</th>
</tr>
</thead>
<tbody>
<tr>
<td>Language difficulties</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Withdrew consent</td>
<td>0</td>
<td>2</td>
<td>4</td>
</tr>
<tr>
<td>Ectopic pregnancy</td>
<td>3</td>
<td>3</td>
<td>6</td>
</tr>
<tr>
<td>Postponed TOP</td>
<td>4</td>
<td>3</td>
<td>7</td>
</tr>
<tr>
<td>Miscarriage</td>
<td>8</td>
<td>4</td>
<td>12</td>
</tr>
<tr>
<td>Continued with pregnancy</td>
<td>10</td>
<td>5</td>
<td>15</td>
</tr>
<tr>
<td>Too advanced gestational age</td>
<td>16</td>
<td>12</td>
<td>28</td>
</tr>
<tr>
<td>Chose surgical TOP</td>
<td>18</td>
<td>12</td>
<td>30</td>
</tr>
<tr>
<td>Total</td>
<td>62</td>
<td>43</td>
<td>105</td>
</tr>
</tbody>
</table>

None of the differences reached significance
## Reason for second opinion

<table>
<thead>
<tr>
<th>Reason for consultation</th>
<th>Allocated to nurse midwife N (%)</th>
<th>Allocated to physician N (%)</th>
<th>Total N (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>No consult</td>
<td>396 (74)</td>
<td>510 (95.7)</td>
<td>906 (84.8)</td>
</tr>
<tr>
<td>Multiple pregnancy</td>
<td>7 (1.3)</td>
<td>1 (0.2)</td>
<td>8 (0.7)</td>
</tr>
<tr>
<td>High s-hCG</td>
<td>0 (0)</td>
<td>1 (0.2)</td>
<td>1 (0.9)</td>
</tr>
<tr>
<td>Information</td>
<td>3 (0.6)</td>
<td>1 (0.2)</td>
<td>4 (0.4)</td>
</tr>
<tr>
<td>Medical reasons</td>
<td>13 (2.4)</td>
<td>4 (0.8)</td>
<td>17 (1.6)</td>
</tr>
<tr>
<td>Ultrasound</td>
<td>59 (11)</td>
<td>8 (1.5)</td>
<td>67 (6.3)</td>
</tr>
<tr>
<td>Unknown</td>
<td>3 (0.6)</td>
<td>4 (0.8)</td>
<td>7 (0.7)</td>
</tr>
<tr>
<td>Prescription/second opinion for bacterial vaginosis</td>
<td>54 (10)</td>
<td>4 (0.8)</td>
<td>58 (5.4)</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>535</strong></td>
<td><strong>533</strong></td>
<td><strong>1068</strong></td>
</tr>
</tbody>
</table>
Follow up after 3-4 weeks

- 54 women in nurse midwife group were lost to follow up
- 76 patients in the physician group were lost to follow up
- Significant difference between groups

500 IU/ml cut off
Overview of outcome measures

<table>
<thead>
<tr>
<th>Outcome measure</th>
<th>Allocated to nurse midwife (%)</th>
<th>Allocated to physician (%)</th>
<th>Total (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Efficacy</td>
<td>476/481 (99)</td>
<td>445/457 (97.4)</td>
<td>923/940 (98.2)</td>
</tr>
<tr>
<td>Safety</td>
<td>453/473 (95.8)</td>
<td>414/443 (93.5)</td>
<td>867/916 (94.7)</td>
</tr>
<tr>
<td>Acceptability</td>
<td>200/535 (37.4)</td>
<td>12/533 (2.3)</td>
<td>212/1068 (19.9)</td>
</tr>
</tbody>
</table>

- Efficacy defined as no need for surgical intervention,
- Safety defined as no complication (no intervention for presumed complication)
- Acceptability defined as women preferring their allocated provider.
Primary outcome measure - efficacy

- Risk difference for surgical intervention was 1,6% with CI 0.2-3.0%
  → Nurse midwife group 5 patients
  → Physician group 12 pat
  → Total 17 patients = 1,8%

- Equivalence was used as nurse midwife provision may have additional advantages for women
  → Having to meet only one provider
  → Shorter waiting times
  → Increasing access
Contraceptive advice

- Nurse midwives prescribed long acting reversible contraceptives to 290/532 women
- Physicians prescribed LARC to 241/528 women

- The difference is statistically significant p=0.004).
Conclusion

- Nurse midwife provision of medical abortion in a high resource setting where vaginal ultrasound is part of the protocol is
- Effective
- Safe
- Highly acceptable

- Experienced and motivated nurse midwives prescribe LARCs to a larger extent than physicians in standard care
  → may have impact on repeat abortion rates

- Nurse midwife provision of medical abortion may increase access to medical abortion services