A tailored pregnancy test offers new possibilities to women for follow-up after medical abortion

Kristina Gemzell Danielsson, MD, PhD,
WHO-center, Karolinska University Hospital,
Karolinska Institutet
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Questions

1. Do women want self-assessment of the outcome of medical abortion?
   a) Yes
   b) No
   c) NA
Questions

2. *When should the urinary test be done?*

a) 2 weeks after the MToP treatment
b) 4 weeks after the MToP treatment
c) NA
Questions

3. How should the urinary test be done?
   a) Home use
   b) Done in hospital setting
   c) Other
4. Can this approach be used by illiterate women?

a) Yes
b) No
c) NA
Women prefer fewer clinical visits in connection with their abortion

Visit to the abortion clinic
Visit for mifepristone
Visit for misoprostol, stay in clinic
Follow-up after 3-4 weeks
Impact of reducing barriers in access

Abortions 1983 - 2014

Källa: Socialstyrelsens abortstatistik

Impact of reducing barriers in access

Abortions 1983 - 2014

Källa: Socialstyrelsens abortstatistik
2012 Updated WHO guidance on safe abortion

- Emphasizes the simplifying or streamlining of abortion care,
- Notes a high value on research to demedicalize abortion care
- Affirms that home use of misoprostol is a safe option for women

The Guidance suggests the evaluation of internet provision and telemedicine, as further alternative service delivery channels of safe abortion, as a subject for future research
Medical abortion, Sweden

- Telephone booking (self referral)
- Visit 1 on Day 1 to midwife (healthy women) or gynaecologist;
  → counselling, examination, incl contraceptive counselling and provision,
  → mifepristone, misoprostol to take 24-48h later @ home/clinic, pain medication
- FU since 90ies with a midwife at 3-4 weeks, 500 IU uhCG-test.
- An increasing number of women do not come back for a scheduled FU
- **2011**: Symptom history alone unreliable to detect ongoing pregnancy (Grossman et al., )
I need an abortion

1. Mifepristone
2. Misoprostol
3. Repeated misoprostol if necessary

Do you have an unwanted pregnancy? Click here. This online medical abortion service helps women gain access to a safe abortion with pills in order to reduce the number of deaths due to unsafe abortions.

Every year 42 million women have an abortion. Every 7 minutes a woman dies unnecessarily from an illegal abortion. Show your face, share your story, donate your money and help women around the world get access to safe abortions. Discuss and share information with others. Look for support if you are considering an abortion. Participate to support abortion rights, also if you did not have an abortion. Click on one of the portraits to find out more...
Telephone FU and self-performed urine pregnancy testing after early medical abortion: a service evaluation
Cameron ST, Glasier A et al., Contraception, 2012

- Tel FU + LS hCG test introduced at Royal Infirmary, Edinburgh, as an alternative to routine US at 2 w following MA
- Evaluation of the first 8 months; 476/619 choose tel. FU (77%).
- 4 (1%) attended the clinic before tel. FU (pain/bleeding).
- 410/472 (87%) were successfully contacted.
- 60 (15%) screened ‘positive’, 3 ongoing pregnancy, 1 false ‘negative’.
- Sensitivity tel.FU: 75% [95% CI 30.1–95.4], specificity 86% (95% CI 82.2–89).
- All women surveyed (n=75) would recommend tel. FU to a friend.
Follow up: routine vs. self assessment

Objectives.

- To evaluate self-assessment using a low sensitivity u-hCG test (DUO-test, VedaLab, France)
  - at home and telephone FU
  - versus routine FU in the clinic
- in medical abortion up to 63 days' gestation

Additional questions:

- Is the test easy to use?
- Do women prefer one-stop treatment compared to hospital FU?
Home self test


Complete abortion

Incomplete abortion or failed test → 'Call the Clinic
Follow up: routine vs. self assessment

Design.

- Multinational, multicentre, randomized. non-inferiority trial

Inclusion criteria:

- Women \( \geq 18 \) years,
- Opting for medical abortion at 63 days of gestation and
- Home administration of misoprostol
- Randomized prior to treatment
Assessment of outcomes

• Group 1: Follow-up after 2-3 weeks at outpatient clinic: 466 women

• Group 2: Women responsible for own evaluation of treatment success using the commercially available hCG test (DUO-test) at two weeks at home: 458 women. Telephone follow-up within one month to evaluate success and satisfaction with method.

• All patient records reviewed after three months to control for abortion-related complications
Results

No difference in efficacy (complete abortions) and safety between groups

Per protocol population

<table>
<thead>
<tr>
<th></th>
<th>Crude risk difference (95% CI)</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Home</td>
<td>94%</td>
<td></td>
</tr>
<tr>
<td>Clinic</td>
<td>95%</td>
<td>-1.0 (-4.0-2.0)</td>
</tr>
</tbody>
</table>

No difference in efficacy (complete abortions) and safety between countries

p 0.216
Results


- No difference in demography
- Median gestational length 6 (4-9) weeks
- Rate of surgery was 4% in both groups
- 91% found the semi-quantitative urine hCG-test easy to use.
- No difference in telephone calls or extra visits (p=0.479)
Results

- 17/446 in the u-hCG arm had positive hCG screens
- 27/446 were uncertain whether the test was positive or negative
- Two ongoing pregnancies in Oslo and one in Helsinki, all in the Home group, initially undiagnosed by the patients
- Significantly more women were lost to FU in the control group (29%) vs. the intervention group (1%) (p<0.001)
- 82% in the intervention group preferred self-assessment vs. 59% in the control group in case of a future abortion (p<0.001).

But does it work in other settings?
Self-assessment of the outcome of early medical abortion versus clinic follow-up in India: a randomised, controlled, non-inferiority trial

Kirti Iyengar, Mandira Paul, Sharad D Iyengar, Marie Klingberg-Allvin, Birgitta Essén, Johan Bring, Sunita Soni, Kristina Gemzell-Danielsson

Summary
Background The need for multiple clinical visits remains a barrier to women accessing safe legal medical abortion services. Alternatives to routine clinic follow-up visits have not been assessed in rural low-resource settings. We compared the effectiveness of standard clinic follow-up versus home assessment of outcome of medical abortion in a low-resource setting.
Study setting

**Rajasthan** | %
---|---
Rural (%) | 75.1
Literacy rate (%) | 52.7
Maternal mortality ratio | 244
Total fertility rate | 2.9
Scheduled caste and tribe | 29.6
Sex ratio at birth | 875
### Study setting: Udaipur & Rajsamand districts

<table>
<thead>
<tr>
<th>Service</th>
<th>District Total %</th>
<th>Rural %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Electricity</td>
<td>61</td>
<td>54</td>
</tr>
<tr>
<td>Toilet facility</td>
<td>17</td>
<td>12</td>
</tr>
<tr>
<td>Piped drinking water</td>
<td>22</td>
<td>3</td>
</tr>
<tr>
<td>LPG for cooking</td>
<td>14</td>
<td>3</td>
</tr>
<tr>
<td>Pucca house</td>
<td>33</td>
<td>23</td>
</tr>
<tr>
<td>Has TV</td>
<td>26</td>
<td>16</td>
</tr>
<tr>
<td>Have a mobile</td>
<td>33</td>
<td>25</td>
</tr>
<tr>
<td>Motorized transport</td>
<td>20</td>
<td>13</td>
</tr>
</tbody>
</table>

19/01/17
Kirti Iyengar
Eligible women randomized into one of the groups

Clinic follow up group
Routine follow up at 10-14 days at clinic
Clinical exam. by doctor
LSUP test
Follow-up interview by RA

Home-assessment group
Woman asked to assess her outcome of abortion at 10-14 days using:
- low sensitivity pregnancy test (LSUP)
- pictorial instruction sheet
Home visit / phone call by RA
पिक्टरियल इन्स्ट्रक्शन शीट
Checklist MA Home Assessment
Check the box when the answer is YES ☑

**Complete abortion** (when 2 or more ☑):
- Did you see expulsion of products?
- If you had any pregnancy symptoms before, are they gone?
- Did the pregnancy test (1000) show negative?

**Incomplete abortion/complications** (when 1 or more ☑):
- Are you still bleeding?
  - If **yes**, more than a normal period?
- Do you have severe abdominal cramps?
- Did the pregnancy test (1000) show positive?
- Do you feel sick?
  - Have you had a fever?
  - Have you had prolonged abdominal pain?
- Do you have excessive blood loss?
- Do you feel weak/ the whole body is aching?

Contact the clinic
## Results

<table>
<thead>
<tr>
<th>Background characteristics of women (n= 731)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Rural</td>
<td>73%</td>
</tr>
<tr>
<td>Illiterate</td>
<td>55%</td>
</tr>
<tr>
<td>One or more children</td>
<td>95%</td>
</tr>
<tr>
<td>Previous induced abortion</td>
<td>32%</td>
</tr>
<tr>
<td>Paid employment</td>
<td>18%</td>
</tr>
<tr>
<td>Owned a phone</td>
<td>44%</td>
</tr>
</tbody>
</table>
Results:
Outcome of abortion in two groups

<table>
<thead>
<tr>
<th></th>
<th>Clinic follow-up group</th>
<th>Home-assessment group</th>
<th>Difference in outcome rates (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>ES analysis (n= 700)</strong></td>
<td>n=336</td>
<td>n=364</td>
<td>2.2%(-5.9 – 1.6%)</td>
</tr>
<tr>
<td>Complete abortion</td>
<td>313 (93.2%)</td>
<td>347 (95.3%)</td>
<td></td>
</tr>
<tr>
<td>Unsuccessful abortion</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ongoing</td>
<td>5 (1.5%)</td>
<td>2 (0.5%)</td>
<td></td>
</tr>
<tr>
<td>Incomplete</td>
<td>18 (5.4%)</td>
<td>15 (4.1%)</td>
<td></td>
</tr>
<tr>
<td><strong>ITT analysis (n= 731)</strong></td>
<td>n= 366</td>
<td>n=365</td>
<td>2.2% (-5.9% - 1.5%)</td>
</tr>
<tr>
<td>Complete abortion</td>
<td>340 (92.9%)</td>
<td>347 (95.1%)</td>
<td></td>
</tr>
<tr>
<td>Unsuccessful abortion</td>
<td>26 (7.1%)</td>
<td>18 (4.9%)</td>
<td></td>
</tr>
<tr>
<td>Ongoing</td>
<td>7 (1.9%)</td>
<td>3 (0.8%)</td>
<td></td>
</tr>
<tr>
<td>Incomplete</td>
<td>19 (5.5%)</td>
<td>15 (4.1%)</td>
<td></td>
</tr>
<tr>
<td>Lost to follow-up</td>
<td>11 (3.1%)</td>
<td>7 (1.9%)</td>
<td></td>
</tr>
<tr>
<td>Violation of protocol</td>
<td>6 (1.7%)</td>
<td>7 (1.9%)</td>
<td></td>
</tr>
</tbody>
</table>
Feasibility & safety

Whether women did LSUP / looked at instruction sheet (n= 289)

- Did LSUP on her own: 80.2%
- Did LSUP after reminder: 18.7%
- Looked at pictorial instruction sheet: 77.4%

Reasons for not doing pregnancy test on her own

- Planning to do it in 1-2 d / waiting for RA: 33%
- Difficult to do / no privacy: 33%
- Went out of house (marriage, parents home), lost LSUP card: 13%
- No need: 7%
- Bleeding continued/ ill: 14%

Rate of adverse events after MA (0.27%)

75% women in clinic FU group and 25% in home assessment group visited the clinic
Knowing whether the abortion is complete

- “I knew because (after I took 4 tablets), the bleeding started. When my pieces fell down, then I came to know that nothing is there”.

- “One thing is there - when anyone gets pregnant, then appetite is lost, you do not feel hungry, you feel irritable, there is nausea. After (taking the tablets), I was not feeling anything, I was eating timely, and there was no nausea …. so it means that abortion was complete. The pregnancy test was given from clinic to test after 15 days, I did the test, and it was negative”.
Women with low literacy can feasibly assess the outcome of an early medical abortion

Majority had no concerns related to home use of misoprostol, and home-assessment.

- “I was not worried at all”

- “Since I had taken tablets earlier too, I was not worried”

- “I was a bit afraid, but my husband was home. He said that if anything happens to you, we will take you to hospital in a jeep.”
Conclusion

Self-assessment as an alternative to clinic follow-up for women having early medical abortion in low resource settings

→ Effective - Self-assessment is non-inferior to clinic follow-up after early medical abortion
→ Safe - Very low rate of adverse events of medical abortion
→ Feasible-
  - most did their LSUP test on their own (80%) and interpreted it correctly
  - Only 25% had to make a visit to the clinic
The use of a low sensitivity pregnancy test to assess early medical abortion outcome in the South African public sector setting

D. Constant, K. Daskilewicz, J. Harries, L. Myer, K. Gemzell-Danielsson

1Women’s Health Research Unit, University of Cape Town, South Africa
2Division of Epidemiology and Biostatistics, University of Cape Town, South Africa
3Department of Women’s and Children’s Health, Karolinska Institutet, Sweden
Study background and aim

- Previously in CoCT CHCs (2012): A set of questions on the MTOP symptoms experienced did not identify all cases requiring additional treatment at FU, when women completed these by themselves
- To improve the accuracy of self-assessment we offered women the low sensitivity pregnancy test (LSUPT; hCG>1000mIU/ml) combined with paper symptom checklist (CL) and SMS reminders

Randomized study arms

- Demonstration: Guided practice of LSUPT
- Instruction: Pre-scripted instruction

Demonstration (n=263, 88%) vs Instruction-only (n=262)

One ongoing pregnancy not identified by LSUPT
Home self-assessment

Women are able to safely have a medical abortion with home use of misoprostol 63 days of gestation and self assessment of the outcome of the treatment using a low sensitivity urine hCG-test.

Self assessment is resource-saving. A step in demedicalising abortion and women prefer it.

Women need to be counselled of the risk of an undiagnosed ongoing pregnancy. Any introduction of self-assessment will need a careful evaluation of the test as well as of user performance.

Women with low literacy can feasibly assess the outcome of an early medical abortion.


Kirti Iyengar, et al., Lancet Global Health 2015
Conclusion

Simplifying medical abortion can help to increase access to safe abortion services through:

- Even women with low literacy can feasibly assess the outcome of an early medical abortion using the DuoTest (VedaLab, Paris France)
- New LSUP available in Europe (checkToP, Exelgyn, Paris, France)
  Investigated in SA, used in clinical routine in Sweden
- Cost:
  - DuoTest 1.05 Euro/test
  - checkToP approx 5 Euro/test
Questions

5. Is urinary test reliable?

a) Yes
b) No
c) NA
Questions

6. If tests are available, will you use them?
   a) Yes
   b) No
   c) NA
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