Safety and acceptability of UBT: Findings from a prospective cohort study

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This data is unpublished. Please refrain from citing.
Evaluating condom-catheter UBT for PPH

- **Countries**: Egypt, Senegal, and Uganda
- **Sites**: 18 secondary/district level hospitals (6/country)
- **Study population**: Vaginal deliveries diagnosed with PPH due to uterine atony
- **Aim**: Assess risk of postpartum infection, pain levels during course of PPH care, and satisfaction with care
- **Study Design**: Prospective cohort study comparing outcomes among UBT and no-UBT groups
  - Sample size estimates: 75 women in UBT cohort and 1437 in the no-UBT cohort
- **Key outcomes**: Reported pain (scale 0-10), receipt of antibiotics in 4 weeks postpartum (proxy for infection)
- **Ethical approval** from 4 ethical review committees and established Data Safety Monitoring Board
Outcomes on effectiveness:

Safety and satisfaction with care:
- Pre-discharge interviews on pain levels and satisfaction
- Postpartum follow-up interviews at 4 weeks to ask about infection
## Background characteristics

<table>
<thead>
<tr>
<th>PPH interventions</th>
<th>PPH, no-UBT group N=2279</th>
<th>PPH, UBT group N=58</th>
<th>P value ^</th>
</tr>
</thead>
<tbody>
<tr>
<td>Manual exploration / removal of clots</td>
<td>1923 (84.4%)</td>
<td>54 (93.1%)</td>
<td>0.229</td>
</tr>
<tr>
<td>Suturing</td>
<td>898 (39.4%)</td>
<td>20 (34.5%)</td>
<td>0.506</td>
</tr>
<tr>
<td>Bimanual compression</td>
<td>1020 (44.8%)</td>
<td>33 (56.9%)</td>
<td>0.161</td>
</tr>
<tr>
<td>Invasive surgery</td>
<td>26 (1.1%)</td>
<td>4 (6.9%)</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

**Pain management**

<table>
<thead>
<tr>
<th>Received any pain management</th>
<th>N=2278</th>
<th>N=58</th>
<th>0.366</th>
</tr>
</thead>
<tbody>
<tr>
<td>Received any pain management</td>
<td>679 (29.8%)</td>
<td>24 (41.4%)</td>
<td></td>
</tr>
</tbody>
</table>

**Antibiotic use before or at discharge**

<table>
<thead>
<tr>
<th>Discharged on oral antibiotics</th>
<th>N=2263</th>
<th>N=58</th>
<th>0.921</th>
</tr>
</thead>
<tbody>
<tr>
<td>Discharged on oral antibiotics</td>
<td>1882 (83.1%)</td>
<td>48 (82.8%)</td>
<td></td>
</tr>
</tbody>
</table>

^ P value accounts for clustering by study facility.
Women’s self-reported outcomes on pain and infection

### Pain levels after delivery*

<table>
<thead>
<tr>
<th></th>
<th>PPH, no-UBT</th>
<th>PPH, UBT</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>0-3</td>
<td>21%</td>
<td>11%</td>
<td></td>
</tr>
<tr>
<td>4-7</td>
<td>59%</td>
<td>52%</td>
<td>0.01</td>
</tr>
<tr>
<td>8-10</td>
<td>20%</td>
<td>37%</td>
<td></td>
</tr>
</tbody>
</table>

*n=1881 in no-UBT group and n=46 in UBT group. Excludes women who answered “don’t know” (21% in both groups).

### Infection at 4 weeks postpartum^

<table>
<thead>
<tr>
<th></th>
<th>PPH, no-UBT</th>
<th>PPH, UBT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Received antibiotics</td>
<td>5%</td>
<td>6%</td>
</tr>
<tr>
<td>Diagnosed with infection</td>
<td>2%</td>
<td>0%</td>
</tr>
</tbody>
</table>

^*n=2141 in no-UBT group and n=53 in UBT group. Excludes women who did not know or remember (1% in no-UBT group and 7% in UBT group).
Women’s perspectives on PPH care

Liked most about care (N=2023)

- Good quality service: 44%
- Fast/rapid care: 26%
- Friendly/kind staff: 24%
- Harworking staff: 12%
- Saved her life: 12%

Liked least about care (N=1510)

- Medicine unavailable: 33%
- Supplies unavailable: 16%
- Hospital unclean: 5%
- Pain/painful procedure: 3%
- Staff were rude/abusive: 5%
Main findings

• Risk of postpartum infection among this population (with high use of prophylactic antibiotics) did not appear to be a concern

• Pain management among the UBT cohort may not have been adequate area for future research and important for improving the quality of care

• Women’s satisfaction with their care and stock-outs of medications and other supplies deserve greater attention when introducing new technologies like UBT
Thanks to all!

- **Collaborating Institutions:**
  - Massachusetts General Hospital, USA
  - Ministry of Health, Uganda
  - Makerere University College of Health Science, Uganda
  - Ministry of Health, Senegal
  - Ministry of Health, Egypt
  - Alexandria University, Egypt
  - El Galaa Teaching Hospital, Egypt

- DSMB members
- All site and study coordinators
- Hospital staff at 18 sites
- Women who participated in our study