Review of IUCD Complications: Lessons from CAT

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INTRODUCTION

• The intrauterine device (IUD) is a reliable long term reversible, cost-effective, easy to use and low maintenance method of contraception.

• Contains either copper (Cu T380A) or Levonorgestrel (LNG 20 or LNG 14)

• Has very few contraindications and generally advantages outweigh risks

• Side effects from the IUD are minimal and complications are rare.
Introduction

• Can be inserted at any point during a woman’s menstrual cycle (if pregnancy excluded) or immediately postpartum and, once inserted, provides immediate efficacy
• May be used for emergency contraception.
• Data on the use of the copper IUD in the developing world is limited
• It is so cost effective: why is the use of IUCD so limited?
Barriers To IUCD

• Three key barriers to IUCD uptake have been identified at MTN sites:
  1. Bias: provider, community, and participant
  2. Lack of IUD insertion training especially among nurses
  3. Lack of IUCDs on site
The ASPIRE Experience

• We trained Nurses & Physicians IUCD insertion
• IUCD were made available on site
• Of 2629 women enrolled in ASPIRE, 595 (23%) had an IUD inserted during study participation.
  – Of these, 403 were inserted at MTN sites

• Questions:
  1. Was IUD insertion equally well tolerated when done by nurses vs physicians?
  2. Were expulsion rates similar for nurses and physicians?
  3. How do our rates of complications compare with published data?
The ASPIRE Experience - methods

- Data abstracted from study charts:
  - type of provider performing the IUD insertion
  - related complications
  - side effects
- Descriptive statistics were used to summarize key factors
- The proportion of women experiencing select complication/side effects were compared across provider types using the Chi-squared test.
## Characteristics of 556 Women Getting IUCDs in ASPIRE

<table>
<thead>
<tr>
<th>Characteristics at enrollment</th>
<th>N(%) or Median (IQR)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, years</td>
<td>27 (22, 31)</td>
</tr>
<tr>
<td>Currently married</td>
<td>235 (42%)</td>
</tr>
<tr>
<td>Number of prior pregnancies</td>
<td>2 (1,3)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Method of contraception at enrollment</th>
<th>N(%) or Median (IQR)</th>
</tr>
</thead>
<tbody>
<tr>
<td>IUD*</td>
<td>269 (48%)</td>
</tr>
<tr>
<td>Oral contraceptive pills</td>
<td>56 (10%)</td>
</tr>
<tr>
<td>Injectable method</td>
<td>205 (37%)</td>
</tr>
<tr>
<td>Implants</td>
<td>30 (5%)</td>
</tr>
</tbody>
</table>

*IUDs were inserted between screening and enrollment and considered inserted as part of study participation in ASPIRE*
## Complications of IUD Insertion

### Complications/side effects with the first IUD insertion

<table>
<thead>
<tr>
<th>Complication</th>
<th>Study nurse n=215</th>
<th>Study doctor n=238</th>
<th>All Others* n=103</th>
<th>Total N=556</th>
</tr>
</thead>
<tbody>
<tr>
<td>IUD expulsion</td>
<td>36 (17%)</td>
<td>23 (10%)</td>
<td>16 (16%)</td>
<td>75 (13%)</td>
</tr>
<tr>
<td>PID with IUD in place</td>
<td>7 (3%)</td>
<td>3 (1%)</td>
<td>4 (4%)</td>
<td>14 (3%)</td>
</tr>
<tr>
<td>Bleeding irregularities</td>
<td>96 (45%)</td>
<td>97 (41%)</td>
<td>53 (51%)</td>
<td>246 (44%)</td>
</tr>
<tr>
<td>Pelvic pain</td>
<td>69 (32%)</td>
<td>30 (13%)</td>
<td>28 (27%)</td>
<td>127 (23%)</td>
</tr>
<tr>
<td>Confirmed Pregnancy</td>
<td>3 (1%)</td>
<td>7 (3%)</td>
<td>0 (0%)</td>
<td>10 (2%)</td>
</tr>
<tr>
<td>Difficult removal</td>
<td>1 (0.5%)</td>
<td>0 (0%)</td>
<td>1 (1%)</td>
<td>2 (0.4%)</td>
</tr>
<tr>
<td>Missing strings</td>
<td>6 (3%)</td>
<td>8 (3%)</td>
<td>4 (4%)</td>
<td>18 (3%)</td>
</tr>
<tr>
<td>Other**</td>
<td>7 (3%)</td>
<td>9 (4%)</td>
<td>4 (4%)</td>
<td>20 (4%)</td>
</tr>
</tbody>
</table>

*All others includes those insertions by staff at health facility, staff at private health facility or unknown.

**Uterine pain, backache, anaemia, partner feeling the IUD at intercourse, urinary tract infection, nausea and vomiting. P-values generated using Chi-squared test comparing differences across the three groups for the selected complications/side-effect.
Key Findings

• The majority of women had IUDs inserted by study staff (trained nurses or physicians)

• Overall, the most common side effects were irregular bleeding (44%) and post-insertion pelvic pain (23%).

• No reports of uterine perforation were observed.

• IUD expulsions occurred more often than observed in US studies.
A 3-year multicentre randomized controlled trial of etonogestrel- and levonorgestrel-releasing contraceptive implants, with non-randomized matched copper-IUDs

- Large WHO study published in 2015 reported results from Brazil, Chile, Dominican Republic, Hungary, Thailand, Turkey and Zimbabwe. Study Population: 2982 women
  - ENG-implant  n=1003  (PP n=995)
  - LNG-implant  n=1005  (PP n=997)
  - IUD groups   n=974    (PP n=971)
- Follow-ups: 2 weeks, 3 and 6 months, and semi-annually thereafter for 3 years or until pregnancy, removal or expulsion of the implant/IUD occurred.
- Outcomes: pregnancy rates, bleeding, discontinuation rates and IUD expulsions

WHO Study Method Continuation

Rates

- ENG: 2.5 years 69.8 (95% CI 66.8-72.6)
  3.0 years 12.1 (95% CI 5.2-22.0)
- LNG: 2.5 years 71.8 per 100 W-Y (68.8-74.5)
  3 years 52.0 per 100 W-Y (95% CI 41.8-61.2)

- Top reason for discontinuation?
  Bleeding disturbances!
  More common in the ENG vs LNG group
  16.7 vs 12.5, P =0.019
WHO Study IUD Results

• IUD 3-year expulsion rate; 17.8 per 100 W-Y (95% CI 14.5-21.9)

• Discontinuation rate for bleeding disturbances was 8.5 (95% CI 6.7-10.9) lower than for implants.

• Bleeding complications
  – irregularities more frequent among implant users (P < 0.0001)
  – Heavy bleeding and lower abdominal pain more frequent among IUD vs implant users (P < 0.0001).
Conclusions

• Complications similar between physician and nurses:
  – PID,
  – bleeding irregularities
  – missing strings

• Complications different:
  – pelvic pain
  – expulsions

• Additional investigation is required to understand the contributors to IUD expulsion and pelvic pain in this setting in order to reduce its frequency in the future.
THANK YOU VERY MUCH!
We are grateful to:
• Study participants
• The research communities
• CABs
• Jen Balkus
• The Protocol Management team and MTN Leadership