Intraccesarean insertion of the Copper T 380A vs. 6 week post-cesarean insertion: A Pilot RCT

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Background - Uganda

- **Uganda TFR=6.7**
  - 56% of pregnancies unintended
  - 7/10 don’t want to be pregnant, but not contracepting
  - Meeting 50% of unmet need
    - 519,000 fewer unintended pregnancies
    - 152,000 fewer induced abortions

- **Contraceptive Prevalence Rate (CPR), 18%**
  - IUD use <1%
  - 58% favorable attitude toward IUDs
  - Low utilization: poor access, inadequate counseling, fear of side effects

- Low rate of care-seeking behavior outside of pregnancy
  - Approximately 10% follow-up for post-partum visits
Background - Intraccesarean IUD insertion

- Intraccesarean IUD insertion: low expulsion, high continuation, low risk \(^{10, 11, 12, 13}\)

  – Observational Studies of Stainless steel ring, VCu200C, TCu8220C, Delta Loop:
    - 12-month Expulsion 3.9-13%
    - Continuation 68-92%

  – Compared to controls, no difference in:
    - Infection, vaginal bleeding, lochia, pain.
The Site

• Mulago Hospital: Kampala, Uganda
  – National referral hospital
    • Many high-risk pregnancies
    • Many referrals for c/s: repeat, obstructed labor, malpresentation
  – Strong interest in research
  – 30,000 deliveries per year
    • 25% cesarean
  – No post-partum contraception program*
  – IUD insertions done at Mulago in FP clinic by MDs and midwives
Hypothesis

• Pilot: Study will be feasible
• Proportion of women using the Copper T 380A at 6 months after delivery will be higher in the group randomized to immediate post-placental insertion.
• We also hypothesize:
  – IUD acceptability will be high
  – Expulsion rates will be similar in each group
  – The proportion of women who receive the Copper T 380A will be lower in the interval insertion group
  – Pregnancy rates will be similar between groups
  – Safety measures will be similar between groups
  – Vaginal bleeding patterns & satisfaction will be similar between groups
Basic Study Design

- Assessed for enrollment, screening and consent upon presentation to L&D for planned c/s or in antepartum clinic
- Randomized in OR
- Regular PP f/u at 6 wks, Group B gets IUD then
- Phone f/u at 3 months, in-person f/u at 6 months

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<tr>
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<th>Delivery</th>
<th>6-wks PP</th>
<th>3 mo</th>
<th>6 mo</th>
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<tr>
<td><strong>Group A</strong></td>
<td>[Icon]</td>
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<td>call</td>
<td>Final visit</td>
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<td><strong>Group B</strong></td>
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<td>IUD in situ?</td>
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</tbody>
</table>
212 Screened

116 Opted out
114 Surveys

96 Enrolled

68 Randomized

34 Immediate (all inserted)

34 Delayed

22/34 returned 6 wk f/u

18 Inserted

4 changed mind, 3 due to husband

28 withdrew
1 ruptured uterus
4 had vaginal delivery
5 changed mind
6 delivered elsewhere
9 delivered without study
3 study stopped before delivery
Opt-out Data

• 50 Opt-out Surveys reviewed
  – 17 wanted to ask husband before enrolling
  – 3 Husbands didn’t like IUD
  – 3 did not like IUD themselves
  – 4 wanted another method
  – 3 wanted to be pregnant soon
  – 2 wanted sterilization
  – 6 still considering
  – 4 for other reasons
68 randomized

34 immediate inserted

29 returned for 6 month visit

25 had IUD in place
- 24 confirmed by MD exam or u/s*
- 1 had IUD expelled and replaced at 6 weeks

4 had IUD removed
- 1 no confirmation
- 23 remained from original placement

32 returned for 6 month visit

18 delayed inserted

16 had IUD in place
- 1 had partial expulsion, but was replaced

1 had IUD removed due to husband

1 had IUD removed

* 11/24 (46%) strings seen at 6 months
83% in immediate vs 53% in delayed were confirmed to be using the IUD at 6 months

\[ p < 0.01 \]
Conclusions

• Feasible
  – Women interested in the IUD
  – Women willing to be randomized
  – Intracesarean IUD placement successful

• Higher utilization with immediate use

• Low visualization of strings by 6 months

• Husband attitudes influence uptake and continuation
Limitations

• Not generalizable to non-cesarean deliveries
• Not powered to detect differences in safety measures
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• Co-fellows: Ila Dayananda & Kari Braaten (Family Planning); Ingrid Katz & Jen Scott (GWH)
• All people doing/have done similar studies (Chen, Hohman, Bednarek)
• Reviews: Grimes, Kapp
• Sarah Averbach
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References

1. Uganda Bureau of Statistics (UBOS) and Macro International Inc. 2007 Uganda demographic health Survey 2006. Calverton, Maryland, USA.
2. Vlassoff M et al., Benefits of meeting the contraceptive needs of Ugandan women, In Brief, New York Guttmacher Institute 2009;No 4.
3. Bryant, A et al. Knowledge and attitudes towards the IUD before and after a brief educational intervention in a university-based hospital setting in Mbarara, Uganda. Abstract P710. *International Journal of Gynecology and Obstetrics* 2009;107(S2);S616.
Inclusion Criteria

- Pregnant at time of enrollment
- Scheduled for cesarean delivery > 8 hours after consent
- Desires Copper T 380A for contraception
- Willing and able to sign an informed consent
- Willing to comply with the study protocol
- Age 18 or older
- English or Luganda speaking
- Willing to be driven home from hospital and have their address recorded.
- Willing to have home visit at 6 months postpartum if they do not return for scheduled visit.
Exclusion Criteria

- Allergy to copper
- Pelvic tuberculosis, severe thrombocytopenia
- Positive *N. gonorrhoeae* or *C. trachomatis* testing
- Leiomyomata or other anomaly that prevent placement of Copper T 380A
- Cervical cancer or carcinoma in-situ
- Desire for repeat pregnancy in less than 12 months
- Chorioamionitis
- Pre-term birth prior to 34 weeks of gestation
- Diagnosis of AIDS (HIV is not an exclusion criteria)
- Fetal demise
- Hemorrhage
- Ruptured uterus
- Eclampsia