Comparison of treatment of incomplete abortion with misoprostol by midwives and physicians at district level in Uganda – a randomized controlled equivalence trial

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Background

Post abortion care (PAC)

- Emergency treatment of complications of unsafe and spontaneous abortion
- Misoprostol - safe and effective for treatment of incomplete abortion ≤12 gestational age

Task shifting/sharing

- Shortages of physicians - limited access to safe PAC
- Induced abortion provided by midwives using MVA * and medical abortion** has shown to be equally effective as provided by physician

* Warriner, 2006 ** Warriner et al, 2011, Kopp-Kallner et al, 2014,
Background Uganda

- Low income country in East Africa – restrictive abortion law
  - TFR 6.3
  - Contraceptive prevalence rate: 23%
  - Unintended pregnancies: 56%
  - MMR 438/1000 live births
  - Abortion complications are common

- Physicians are main providers of PAC using surgery and midwives informal providers *

- Health care workers in Africa – shortages and unequal distribution

- Limited access to post abortion care (PAC)
Objective

**Misoprostol** is established for the treatment of incomplete abortion but has not been systematically evaluated when provided by midwives at district level in a low resource setting.

**To investigate** the effectiveness and safety of midwives diagnosing and treating incomplete abortion with misoprostol, compared with physicians.
Design and method

A randomised controlled equivalence trial was carried out at district level at six facilities in Uganda.
Participants and procedure

**Inclusion criteria:** Women with first trimester incomplete abortion ≤12 weeks of gestation

**Randomisation:** Eligible women randomly allocated to be diagnosed and treated for incomplete abortion with misoprostol by a physician or a midwife (intervention).

**Follow up 14-28 days**
Primary outcome and measurements

**Complete abortion** not requiring surgical intervention 14 days + 2 weeks (within 14 to 28 days), following initial treatment.

**Analysis** of the primary outcome was performed on the per-protocol population, using a generalized linear mixed effects model.
Findings

In total 955 women were randomized (472 to midwife and 483 to physician) and included in the per protocol analysis.

Primary outcome

- Women with complete abortion among midwives were 95.8% (n=452) and physicians 96.7% (n=467).
- The model based risk difference for midwife versus physician group was -0.79% (95% CI -2.90 to 1.35)
- The overall proportion of women with incomplete abortion was 3.8%, similarly distributed between the two groups.
Clinical implications

- Diagnosis and treatment of incomplete abortion with misoprostol by midwives is equally safe and effective as when provided by physicians, in a low resource setting.

- Scaling up midwives’ involvement in treatment of incomplete abortion with misoprostol at district level would increase access to safe post abortion care.
Comparison of treatment of incomplete abortion with misoprostol by physicians and midwives at district level in Uganda: a randomised controlled equivalence trial

Amanda Cleeve1,2*, Josephine Asigwa1,2, Kuwaiti Basirah1,2, Ikasoba Rukinta1,2, Wambwiro David1,2, Mbekei Morgan1,2, Njoroge Kevin1,2, Katwe Shadrack1,2, Ambrose Chacha1,2, and Mwinekula Annette1,2

Summary
Misoprostol is established as the treatment of incomplete abortion but has not been systematically assessed when provided by midwives or district nurses in a low-resource setting. We investigated the effectiveness and safety of midwives diagnosing and treating incomplete abortion with misoprostol, compared with physicians.

Methods
We did a multicentre randomised controlled equivalence trial at district level in Uganda. Eligible women were women with signs of incomplete abortion. We randomly allocated women with first-trimester incomplete abortion to clinical management and treatment with misoprostol either by a physician or a midwife. The randomization (1:1) was done in blocks of 12 and was stratified by study site. Primary outcome was complete abortion not needing surgical intervention and was assessed after 48 hours. The study was not blinded. Analysis of the primary outcome was done on the per-protocol population with a generalised linearised-effects model. The predefined equivalence range was 0% to 8%. The trial was registered at ClinicalTrials.gov, number NCT01846124.

Results
From April 13, 2013, to July 31, 2014, 1000 women were assessed for eligibility. 999 women were randomly assigned to each group (500 to midwifery group and 500 to physician group). 100 women (5%) in the midwife group and 100 women (5%) in the physician group had complete abortion and 467 (77%) in the physician group. The model-fitted risk difference for complete abortion was 0.04% (95% CI: −0.2% to 0.2%) within the predefined equivalence range (0% to 8%). The prevalence of women with incomplete abortion was 3.1% (95% CI: 2.6% to 3.8%) in the midwife group and 2.1% (95% CI: 1.6% to 2.9%) in the physician group. The serious adverse events were amended.

Interpretation
Diagnosis and treatment of incomplete abortion with misoprostol by physicians and midwives in a low-resource setting. Scaling up misoprostol use in Uganda at district level would improve access to safe abortion.

Funding
The Swedish Research Council, Karolinska Institute, and Stockholm University.

Introduction
Un satisfactory abortion contributes substantially to the global burden of maternal mortality and morbidity. Misoprostol is a non-steroidal prostaglandin with a simplified, cost-effective, and long-lasting action on the uterus.

RESEARCH ARTICLE
Women’s Acceptability of Misoprostol Treatment for Incomplete Abortion by Midwives and Physicians - Secondary Outcome Analysis from a Randomised Controlled Equivalence Trial at District Level in Uganda

Amanda Cleeve1,2, Josephine Asigwa1,2, Kuwaiti Basirah1,2, Ikasoba Rukinta1,2, Wambwiro David1,2, Mbekei Morgan1,2, Njoroge Kevin1,2, Katwe Shadrack1,2, Ambrose Chacha1,2, and Mwinekula Annette1,2

Abstract
Objective
This study aimed to assess women’s acceptability of diagnostic and treatment of incomplete abortion with misoprostol, either by physicians or midwives.

Methods
This was an analysis of secondary outcomes from a multicentre randomised controlled equivalence trial at district level in Uganda. Women with first-trimester incomplete abortion were randomly allocated to clinical management and treatment with misoprostol by a physician or a midwife. The randomisation (1:1) was done in blocks of 12 and stratified by study site. Acceptability was measured as expected and satisfied with the service received.

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Thanks for listening!