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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 *
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- 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



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Summary

Background Misoprostol is established for the treatment of incomplete abortion but has not been systematically assessed when provided by midwives at district level 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 at six facilities in Uganda. Eligibility criteria were women with signs of incomplete abortion. We randomly allocated women with first-trimester incomplete abortion to clinical assessment and treatment with misoprostol either by a physician or a midwife. The randomisation (1:1) was done in blocks of 12 and was stratified for study site. Primary outcome was complete abortion not needing surgical intervention within 14–28 days after initial treatment. The study was not masked. Analysis of the primary outcome was done on the per-protocol population with a generalised linear-mixed effects model. The predefined equivalence range was –4% to 4%. The trial was registered at ClinicalTrials.gov, number NCT01844024.

Findings From April 30, 2013, to July 21, 2014, 1108 women were assessed for eligibility, 1010 women were randomly assigned to each group (506 to midwife group and 504 to physician group). 955 women (472 in the midwife group and 483 in the physician group) were included in the per-protocol analysis. 452 (95.8%) of women in the midwife group had complete abortion and 467 (96.7%) in the physician group. The model-based risk difference for midwife versus physician group was –0.8% (95% CI –2.9 to 1.4), falling within the predefined equivalence range (–4% to 4%). The overall proportion of women with incomplete abortion was 3.8% (36/955), similarly distributed between the two groups (4.2% [20/472] in the midwife group, 3.3% [16/483] in the physician group). No serious adverse events were recorded.

Interpretation 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 midwife management of incomplete abortion with misoprostol at district level would increase access to safe po

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Introduction

Unsafe abortion contributes substantially to the global burden of maternal mortality and morbidity.¹ Most unsafe abortions occur in low-income countries where induced

low-resource settings, misoprostol is a simplified, cost-effective, surgical interventions.² The growth of what

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RESEARCH ARTICLE

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

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Abstract

Objective

This study aimed to assess women's acceptability of diagnosis and treatment of incomplete abortion with misoprostol by midwives, compared with physicians.

Methods

This was an analysis of secondary outcomes from a multi-centre randomized controlled equivalence trial at district level in Uganda. Women with first trimester incomplete abortion were randomly allocated to clinical assessment and treatment with misoprostol by a physician or a midwife. The randomisation (1:1) was done in blocks of 12 and stratified for health care facility. Acceptability was measured in expectations and satisfaction at a follow up visit

Health worker roles in providing safe abortion care and post-abortion contraception

first trimester with misoprostol*

Health worker	Recommendation	Justification
Specialist doctors, non-specialist doctors	Recommended	Within their typical scope of practice. No assessment of the evidence was therefore conducted.
Associate and advanced associate clinicians	Recommended	There is moderate-certainty evidence for the safety and effectiveness of medical management of incomplete abortion by midwives and moderate-certainty evidence for the effectiveness of medical abortion provision by health worker types with similar or less comprehensive basic training. Additionally, there is direct evidence that these health workers can assess gestational age as part of MVA provision. The option is feasible and the potential to expand access to underserved populations is high.
Midwives	Recommended	There is evidence from a low-resource setting for the safety and effectiveness (moderate certainty) of this option and for women's overall satisfaction with the provider (moderate certainty) when midwives manage incomplete abortion. The option appears feasible and has the potential to reduce inequities in access to safe abortion.
Nurses	Recommended	There is evidence for the safety, effectiveness and satisfaction of providing medical abortion (moderate certainty; see Table 5), and the skills required for managing incomplete abortion with misoprostol are similar. The option appears feasible and has the potential to reduce inequities in access to safe abortion.
Auxiliary nurses and auxiliary nurse midwives	Recommended	There is evidence for the safety and effectiveness of the provision of medical abortion in the first trimester (moderate certainty; see Table 5), and the skills required for managing incomplete abortion with misoprostol are similar.

Thanks for listening !

