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CLINICAL ARTICLE

Oral misoprostol as first-line care for incomplete abortion in Burkina Faso

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ABSTRACT

Objective: To explore 400-μg sublingual misoprostol as primary treatment in lower-level facilities with no previous experience providing postabortion care. *Methods:* Women presenting with incomplete abortion were offered a single dose of 400-μg sublingual misoprostol. Incomplete abortion was defined as uterine size consistent with fewer than 12 weeks of gestation, open cervical os, and reports of past or present history of vaginal bleeding. Women returned to the clinic 1 week after misoprostol administration for follow-up. At that time, they were discharged if the uterine evacuation was a success or were offered a second follow-up visit or surgical completion if still incomplete. *Results:* One-hundred women received misoprostol; outcome data were unavailable for 1 woman. Complete uterine evacuation was achieved for 97 (98.0%) women. Satisfaction was high, with nearly all women indicating that they were "satisfied" (n = 57 [57.6%]) or "very satisfied" (n = 41 [41.4%]) with their experience. Adverse effects were considered "tolerable" by 72 of 97 (74.2%) women. Ninety-seven of 99 (98.0%) participants indicated that they would choose misoprostol for incomplete abortion care in the future and 95 of 97 (97.9%) stated that they would recommend it to a friend. *Conclusion:* Misoprostol is a viable option for treatment of incomplete abortion at mid-level facilities.
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1. Introduction

In limited-resource settings, the low cost, stability at ambient temperatures, and increasing availability of misoprostol have contributed to its appeal as a viable alternative to surgical treatment of incomplete abortion. Incomplete abortion, which can result from spontaneous or induced pregnancy loss, occurs when the products of conception are not completely expelled from the uterus. Left untreated, incomplete abortion may lead to a variety of complications and contributes to abortion-related morbidities. Surgical treatment is highly effective; however, the need for skilled, trained providers and special equipment is a limiting factor in many limited-resource settings [1,2]. Treatment with misoprostol eliminates some of these preconditions—such as the need for special surgical equipment—while maintaining a high safety and efficacy profile.

Numerous studies have confirmed that 600-μg oral misoprostol safely and effectively evacuates the uterus in 91%–99% of women [3–6]. One study comparing 600-μg oral and 400-μg sublingual misoprostol concluded that the 2 doses were similarly effective [7]. A more recent study comparing 400μg sublingually with manual vacuum aspiration (MVA) in 2 Egyptian hospitals provided further evidence that the sublingual dose works well: 98.3% of participants experienced complete uterine evacuation with the regimen [8]. Data from this study and others show that misoprostol is analogous to MVA as first-line treatment for incomplete abortion [8]. In 2009, WHO added misoprostol to its Model List of Essential Medicines for the treatment of spontaneous and incomplete abortion, remarking that the "evidence showed that misoprostol is as effective as surgery and in some settings may be safer as well as cheaper" [9].

The aim of the present study was to investigate the use of 400-μg sublingual misoprostol as primary treatment for uterine evacuation at lower-level facilities with no previous experience in postabortion care. Providing misoprostol treatment where no other services exist has the potential to increase availability and access to safe and effective care for incomplete abortion.

2. Materials and methods

Between September 29, 2008, and November 30, 2009, women presenting with incomplete abortion were enrolled at 2 district hospitals (in Dandé and Ziniaré) in Burkina Faso, West Africa. Providers at these facilities had not previously offered postabortion care

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services; the standard of care at both was referral to a higher-level facility. Neither facility had ultrasound services, so referral was also the norm for ultrasonography. Both hospitals were adequately staffed with physicians, nurses, and nurse–midwives. Neither had trained obstetrician–gynecologists.

All women presenting with incomplete abortion were eligible to participate. Incomplete abortion was assessed clinically to ascertain open cervical os, uterine size consistent with fewer than 12 weeks of gestation, and past or present history of vaginal bleeding during pregnancy. Ultrasound confirmation of incomplete abortion was not stipulated in the protocol but women could be referred elsewhere for ultrasound if providers were unsure of abortion status. Women were excluded if they presented with a known allergy to misoprostol or other prostaglandins, suspicion of ectopic pregnancy, signs of peritonitis and/or sepsis, hemodynamic instability, or shock.

All eligible women were given the option of participating in the study and receiving misoprostol as first-line care, or receiving standard referral to the closest tertiary-level hospital (in either Bobo Dioulasso or Ouagadougou). Women who agreed to participate consented via signature or thumbprint after information was provided verbally and in writing by study staff. The study was approved by the Burkina Faso Ministry of Health Ethical Review Board.

Enrolled women were given a single dose of 400-μg misoprostol (Cytotec; Pfizer, New York, NY, USA) to administer sublingually. Women administered the tablets at the study hospital and remained under observation for between 30 minutes and 2 hours to document any adverse effects. All participants received paracetamol to manage their pain, if needed. Each woman was scheduled for a follow-up visit 1 week later to assess the status of their incomplete abortion via clinical examination. If the uterine evacuation was complete at the 1-week follow-up, the woman was discharged from the study. If, on clinical examination, there was evidence of retained products of conception requiring additional care, women were given the option of waiting an additional week to see whether the retained products would evacuate on their own or being referred to a tertiary-level facility for standard surgical completion. Every effort was made to contact—in a confidential manner—women not returning for follow-up. In addition, at the time of discharge, all participants were asked about their satisfaction with the treatment given and whether they would use the method again if necessary.

The primary outcome was complete uterine evacuation (clinically assessed by resolution of the signs/symptoms of incomplete abortion clinically consistent with a completed abortion), without recourse to additional intervention. Secondary outcomes—including reports of adverse effects, satisfaction, and acceptability—were also recorded. All data were entered, cleaned, and analyzed using SPSS version 15 (IBM, Armonk, NY, USA).

3. Results

In total, 100 women were given misoprostol for treatment of incomplete abortion in the study. No women were lost to follow-up but outcome data were unavailable for 1 woman (all available data shown). Fig. 1 outlines the flow of participants. On average, participants were 26 ± 7 years of age, with 51 of 79 (64.6%) indicating no formal education (Table 1). Seventy-nine (79.8%) women were currently married. When asked about their current abortion, 89 of 97 (91.8%) women reported that they were experiencing a spontaneous abortion.

Complete uterine evacuation was achieved for 97 (98.0%) women (Table 2); 86 (86.9%) achieved complete evacuation at their initial 1-week follow-up visit. Two (2.0%) of the 99 women underwent surgical completion after their abortion status was determined as incomplete or uncertain. Ultrasound was performed for only 6 of 84 (7.1%) women to confirm complete uterine evacuation. Of the 2 failed evacuations, 1 woman's abortion status was determined to be uncertain at her initial 1-week follow-up visit and she agreed to return to the hospital a week later for a second visit. Between study visits, a provider at another facility performed an MVA. In the other case, the woman still had retained products of conception at her second follow-up visit and was subsequently referred to another facility, where MVA was performed.

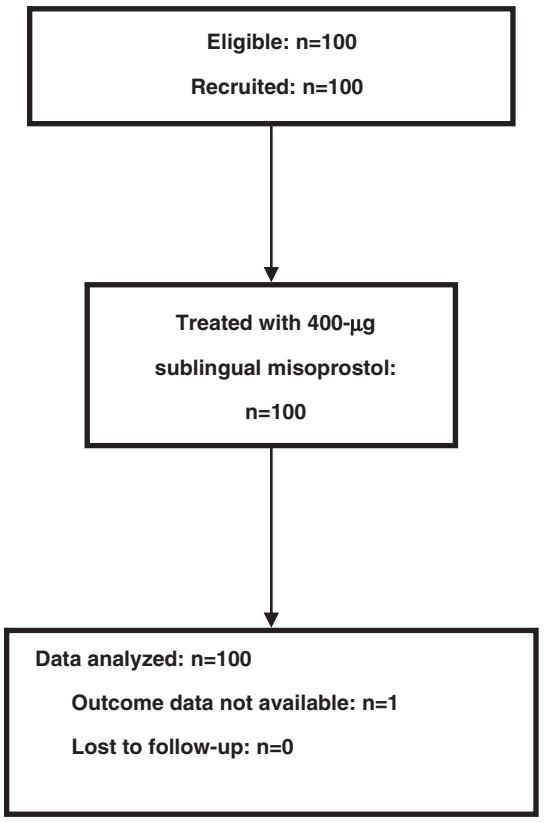

Fig. 1. Participant flow.

Fifty-seven (57.6%) and 41 (41.4%) participants rated their overall satisfaction with treatment as "satisfied" and "very satisfied," respectively. Seventy-two of 97 (74.2%) rated their overall experience with adverse effects as "tolerable" (Table 2). Thirty-eight (38.0%) women reported normal bleeding (like menses) and 31 (31.0%) reported heavy bleeding (greater than menses). When asked about perception and acceptability of the amount of bleeding, 62 (62.0%) reported that it was less than expected and 76 (76.0%) rated the amount as "acceptable." Other adverse effects reported included abdominal pain (n = 53 [53.0%]), fever/chills (n = 8 [8.0%]), nausea (n = 7 [7.0%]), and vomiting

Table 1
Participant characteristics (n = 100).[a]

Characteristic	Misoprostol
Age, y (n = 73)	26 ± 7
Parity (n = 73)	2 ± 2
Education (n = 79)	
Primary	13 (16.5)
Secondary	15 (19.0)
None	51 (64.6)
Currently married (n = 99)	79 (79.8)
Woman's report of current abortion (n = 97)	
Spontaneous	89 (91.8)
Induced	8 (8.2)
Provider's assessment of current abortion (n = 92)	
Spontaneous	78 (84.8)
Induced	14 (15.2)

[a] Values are given as mean ± SD or number (percentage).

Table 2
Efficacy rates, adverse effects, acceptability, and satisfaction (n = 100).[a]

	Misoprostol
Efficacy rates [b]	
Lost to follow-up	0/100 (0.0)
Overall success rate	97/99 (98.0)
Failure rate	2/99 (2.0)
Ultrasound used to assess outcome	6/84 (7.1)
Overall experience with adverse effects (n = 97)	
Very tolerable	13 (13.4)
Tolerable	72 (74.2)
Severe	1 (1.0)
Very severe	0 (0.0)
No adverse effects	11 (11.3)
Bleeding	
Heavy bleeding (greater than menses)	31 (31.0)
Normal bleeding (like menses)	38 (38.0)
Spotting (less than menses)	11 (11.0)
Other adverse effects	
Nausea	7 (7.0)
Vomiting	4 (4.0)
Abdominal pain	53 (53.0)
Fever/chills	8 (8.0)
Overall satisfaction (n = 99)	
Very satisfied	41 (41.4)
Satisfied	57 (57.6)
Unsatisfied	1 (1.0)
Very unsatisfied	0 (0.0)
Participant's perception of treatment difficulty	
Not at all difficult	77 (77.0)
Somewhat difficult	15 (15.0)
Difficult	0 (0.0)
Very difficult	3 (3.0)
Not sure	5 (5.0)
Participant's perception of amount of bleeding experienced	
Less than expected	62 (62.0)
More than expected	11 (11.0)
As expected	20 (20.0)
Do not know	7 (7.0)
Participant's rating of acceptability of bleeding	
Very acceptable	22 (22.0)
Acceptable	76 (76.0)
Not acceptable	0 (0.0)
Do not know	2 (2.0)
Participants' perception of pain experienced	
Very tolerable	16 (16.0)
Tolerable	75 (75.0)
No pain	5 (5.0)
Not tolerable	2 (2.0)
Do not know	2 (2.0)
Received enough medication (n = 95)	
Yes	55 (57.9)
No	40 (42.1)
Pain level compared with previous surgical evacuation [c] (n = 21)	
Less painful	16 (76.2)
As painful	0 (0.0)
More painful	2 (9.5)
Do not know	3 (14.3)
Comparison to previous surgical evacuation [c] (n = 21)	
Better	20 (95.2)
Same	0 (0.0)
Worse	0 (0.0)
Do not know	1 (4.8)

[a] Values are given as number (percentage).
[b] Outcome data unavailable for 1 woman but all available data analyzed.
[c] Among women reporting previous surgical evacuation.

(n = 4 [4.0%]). Seventy-five (75.0%) participants described the pain as "tolerable."

When asked about the perceived difficulty of misoprostol treatment, 77 (77.0%) women characterized it as "not at all difficult" and 15 (15.0%) as "somewhat difficult." Women were also asked who provided counseling and whether they believed this counseling covered all aspects of treatment. Ninety-six of 98 (98.0%) women indicated that a nurse–midwife provided counseling, and 98 (100.0%) reported that the counseling covered all aspects of treatment. Of the 21 (21.9%) women reporting a previous surgical evacuation, 16 (76.2%) reported that treatment with misoprostol was "less painful" and 20 (95.2%) characterized the study treatment as "better." Ninety-seven of 99 (98.0%) participants indicated that they would choose the misoprostol and 95 of 97 (97.9%) stated that they would recommend it to a friend.

4. Discussion

These results demonstrate that 400-μg sublingual misoprostol is a safe, effective, and acceptable option for uterine evacuation at lower-level health facilities with no previous experience providing postabortion care. Indeed, nearly all women in the study experienced successful uterine evacuation after receiving 2 tablets of misoprostol. The adverse effects of the drug were considered to be tolerable by most women and, apart from expected bleeding and abdominal pain/cramps, few effects were reported—resulting in a very high satisfaction profile for this simple medical treatment.

The integration of misoprostol into postabortion care service delivery at all levels of the healthcare system can positively contribute to larger efforts focused on shifting certain medical tasks to trained mid-level providers who, in many instances, are closer to the women needing care. Indeed, before the present study, women in Burkina Faso presenting at lower-level facilities and requiring uterine evacuation for postabortion complications were systematically referred to the closest tertiary facility for treatment—a journey that would, in many instances, require at least 1 day of travel away from home. The potential cost-effectiveness of misoprostol treatment for incomplete abortion has been previously documented [10,11]. In the case of Burkina Faso, access to misoprostol care locally enabled women to save time and money because they were able to receive care at their first point of service. Furthermore, it empowered medical staff at lower levels of care to be able to provide a simple and effective treatment for incomplete abortion.

It has been argued that ultrasound and surgical skills are needed to provide uterine evacuation services safely and effectively. The experience at the 2 facilities in Burkina Faso documents successful service delivery with neither ultrasound nor surgical skills/equipment. Indeed, providers relied on standard referral services to manage the 7.1% of women for whom they felt ultrasonography may be helpful to ascertain incomplete abortion status and complete uterine evacuation. The existing referral system was used to manage care for women requiring additional surgical back-up. Patient care was not compromised in either instance. By using the referral system for back-up instead of systematic care for all women, the majority of postabortion care services were provided at little additional cost at these lower-level facilities.

Despite the promise of these results, their applicability may be limited by the fact that recruitment occurred at only 2 facilities in 1 country. The programmatic and logistic challenges in other countries and settings may be different. Moreover, treatment was provided in the context of a study, so care, counseling, and attention to follow-up may not reflect actual day-to-day clinical realities outside of a study setting. Nonetheless, the documentation of the present successful experience can serve as an example for other countries interested in pursuing similar programs aimed at expanding the reach of postabortion care.

Although there has been considerable progress in expanding access to non-surgical methods of postabortion care over the past 10 years, there is still much room for improvement. Indeed, although a recent publication [12] on scaling-up postabortion care made curiously little mention of medical management—despite the copious availability of evidence and the inclusion of misoprostol on the WHO Model List of Essential Medicines [9] for this indication—the authors did advocate for continued momentum to expand access to postabortion care. There is ample clinical evidence of high safety, efficacy, and satisfaction rates with this method [2–8] and a favorable policy climate, given the inclusion of misoprostol on the Model List of Essential Medicines and recommendations by FIGO [13]. The time has now come to scale-up

access to the service by training providers and making the medication more widely available. The experience in Burkina Faso should serve as an impetus for the introduction of misoprostol as first-line treatment for postabortion care in health systems globally.

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Conflict of interest

The authors have no conflicts of interest.

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