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CLINICAL ARTICLE

Misoprostol as first-line treatment for incomplete abortion at a secondary-level health facility in Nigeria

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ABSTRACT

Objective: To determine the feasibility of introducing misoprostol as first-line treatment for incomplete abortion at a secondary-level health facility. *Methods:* An open-label prospective study was conducted in a secondary-level health facility in Nigeria. Eligible women diagnosed with incomplete abortion received 400-μg sublingual misoprostol as first-line treatment. Nurse–midwives took the lead in diagnosis, counseling, treatment, and assessment of final outcome. The primary outcome was the proportion of women who completed the abortion process. *Results:* Complete evacuation was achieved in 83 of 90 (92.2%) eligible women. The most common adverse effects were abdominal pain/cramps (58 [64.4%]), heavy bleeding (21 [23.3%]), spotting (15 [16.7%]), and fever/chills (11 [12.2%]). More than 90% of women reported that the procedure was satisfactory, that pain and adverse effects were tolerable, and that bleeding was acceptable. Eighty-four (93.3%) and 86 (95.6%) women, respectively, would use the method in the future and recommend it to friends. *Conclusion:* Misoprostol is an effective, safe, and acceptable method for treating incomplete abortion. It can be successfully used as first-line treatment by nurse–midwives. Success rates over 90% are consistent with findings from previous studies in which drug administration was controlled solely by physicians. Clinical trials.gov: NCT01539408.

1. Introduction

Restrictive abortion laws in Nigeria, as in most low-resource countries, continue to drive the high rates of unsafe abortion. Approximately 21.6 million unsafe abortions occur annually and almost all of these take place in low-income countries [1]. Abortion-related complications continue to make substantial contributions to maternal morbidity and mortality in Sub-Saharan Africa [2–4].

The postabortion care model emerged in the 1990s as a means to address complications related to unsafe abortion, especially in legally restrictive settings [5]. One of the major advances in postabortion care was the use of manual vacuum aspiration for uterine evacuation when uterine size is consistent with fewer than 12 weeks of gestation [6,7]. Major requisites for manual vacuum aspiration include availability of equipment and a skilled provider; these requirements are major constraints to access in low-resource countries.

Misoprostol—a prostaglandin E_1 analog—is cheap and heat stable, making it attractive for use in the tropical conditions of Sub-Saharan Africa. In recent years, several studies from Africa [8–14] and low-resource settings in Latin America [15] and Asia [16] have shown misoprostol to be as effective as manual vacuum aspiration for the treatment of incomplete abortion. Reported rates of completed abortion in these studies ranged from 84.4% to 100% [8–16].

Misoprostol was more frequently associated with higher rates of adverse effects—namely, longer bleeding after treatment, nausea, vomiting, and fever [12]. However, at 1-week follow-up, the majority of women who used misoprostol reported these effects to be easily tolerable [8,12].

Misoprostol treatment is also reported to be associated with high levels of satisfaction and acceptability; many women who used misoprostol would prefer to use it in the future and would recommend it to friends [8–15]. Consequently, misoprostol for treatment of incomplete abortion is considered to be an effective, safe, and acceptable alternative to manual vacuum aspiration. Furthermore, 400-μg sublingual misoprostol and 600-μg oral misoprostol have been reported to have similar safety and effectiveness profiles [11].

The American Congress of Obstetricians and Gynecologists (ACOG) recommends that "misoprostol must be readily available especially for women who do not otherwise have access to post-abortion care" [17]. WHO has also included misoprostol as an essential drug for the treatment of incomplete abortion in the first trimester [18]. In light of available evidence and recommendations, urgent steps are required to scale-up and expand to primary and secondary levels of care the use of misoprostol for treatment of incomplete abortion in order to increase access among women in Africa.

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The aim of the present study—designed as implementation research—was to assess the feasibility of introducing misoprostol as first-line treatment for women with incomplete abortion at a secondary-level health facility in southwestern Nigeria.

2. Materials and methods

An open-label prospective study was conducted at the Adeoyo Maternity Hospital—a secondary level health facility in Ibadan, Nigeria—between August 1, 2009, and October 27, 2010.

Incomplete abortion was defined as past or present history of vaginal bleeding and evidence of an incomplete abortion with substantial debris in the uterus if ultrasound was used or, if no ultrasound was used, past or present history of vaginal bleeding during pregnancy and an open cervical os. Women presenting to the hospital who lived or worked within 1 hour of the facility and who had a confirmed incomplete abortion were invited to participate in the study once it had been determined that they would be advised to undergo a surgical evacuation based on the standard practice at the hospital.

Women were eligible to participate in the study if they had no contraindications to misoprostol: uterine size was not consistent with more than 12 weeks of gestation; there were no signs of severe infection (defined as at least 1 of the following: foul-smelling discharge; fever above 38 °C; and uterine tenderness); they were hemodynamically stable (pulse <110 per minute and systolic blood pressure ≥100 mm Hg); they were in general good health; and they were willing to provide contact information for the purposes of follow-up. Women were excluded if they had an intrauterine device in place, were suspected of having an ectopic pregnancy, or were younger than 18 years of age and had no accompanying adult to provide informed consent. Written informed consent was obtained from all participants. Ethics approval for the study was obtained from the Oyo State Ethical Review Committee.

The research nurse gave 400-μg sublingual misoprostol (Cytotec; Pfizer, New York, NY, USA) to all participants. The women were counseled about adverse effects and postabortion contraception, and were discharged from the hospital after a minimum 2-hour period of observation. Prior to discharge, participants were given a prescription of paracetamol tablets for pain relief, if required.

Participants were requested to return to the clinic 1 week later to confirm their clinical status. In the event of continued heavy bleeding, enlarged uterus, or suspicion of ectopic pregnancy, women were referred for ultrasound and follow-up care. In the event of continued incomplete abortion, women were given the option of immediate surgical evacuation or return for additional follow-up in 1 week to see whether expulsion would occur spontaneously. If abortion was not complete after the second follow-up visit, surgical completion was performed.

Research nurses were responsible for recruitment, diagnosis of incomplete abortion, counseling for participation in the study, administration of the drug, and follow-up. The performance of these leading roles by research nurses was specific to the present study; normally, they would be carried out by physicians. Physicians were, however, available for consultation if needed.

All women were advised to return to the hospital at any time if complications arose or if they had questions. They were also given telephone numbers of research team members to call if needed. At the follow-up visits, women underwent physical examination and were asked whether they thought the abortion was complete, what their level of satisfaction was, and whether they would use the method again. Research team members, trained to maintain confidentiality, conducted home visits to trace participants who failed to return for the follow-up visits.

The intention was to include all consenting eligible women during the study period. Data entry was performed with Excel version 11 (Microsoft, Redmond, WA, USA) and analysis was carried out using SAS version 8 (SAS Institute, Cary, NC, USA) via χ^2 test. The level of statistical significance was set at $P<0.05$.

Table 1
Demographic characteristics of participants (n = 90).

Characteristic	No. (%)
Age[a], y (n = 88)	
≤20	7 (7.9)
21–25	13 (14.7)
26–30	35 (39.7)
31–35	19 (21.6)
≥36	14 (15.9)
Parity	
0	2 (2.2)
1–2	36 (40.0)
3–4	31 (34.4)
≥5	19 (21.1)
Marital status	
Single	7 (7.8)
Married	82 (91.1)
Divorced	1 (1.1)
Education	
None	1 (1.1)
Primary	15 (16.7)
Secondary	49 (54.4)
Tertiary	25 (27.8)
Occupation	
Unemployed	3 (3.3)
Student	6 (6.7)
Housewife	4 (4.4)
Self-employed	51 (56.7)
Employed	26 (28.9)

[a] Mean age, 30.6 ± 5.7 years.

3. Results

In total, 90 eligible women consented to participate and were recruited into the study. The demographic profile of the women is shown in Table 1. The mean age of the participants was 30.6 ± 5.7 years, and 49 (54.4%) women had received secondary-level education. The median duration of stay following misoprostol administration was 2.0 hours (range, 0.5–48 hours).

Cramping/abdominal pain and increased vaginal bleeding were the symptoms most commonly reported by women shortly after administration of misoprostol (Table 2). All participants were followed-up. At the 1-week follow-up, 76 (84.4%) women reported completion of the abortion process. In total 7 (7.8%) women underwent surgical intervention. Of the 7 women who had surgical intervention, 4 with ongoing incomplete abortion requested surgical evacuation before the scheduled 1-week follow-up because of heavy bleeding; the remaining 3 women had surgical evacuation for persistent bleeding after the second follow-up visit (i.e. 2 weeks after misoprostol administration). Six (6.7%) women made unscheduled calls to investigators, and 4 (4.4%) made unscheduled visits to the hospital (Table 3). The reasons for these calls and visits were spotting and bleeding. The research nurses reinforced information previously provided to the women and reassured them that these effects were to be expected.

At follow-up, most women experienced adverse effects following the use of misoprostol (Table 4). Abdominal pain/cramps, bleeding, and fever/chills were the most common adverse effects reported.

Table 2
Symptoms reported by women after administration of misoprostol (n = 90).

Symptom	No. (%)
Cramping/abdominal pain	13 (14.4)
Vomiting	2 (2.2)
Fever/chills	2 (2.2)
Profuse bleeding	1 (1.1)
Nausea	4 (4.4)
Diarrhea	1 (1.1)
Increased bleeding (but not profuse)	10 (11.1)

Table 3
Outcomes and service delivery (n = 90).[a]

	Value
Outcome	
Complete abortion at 1-week follow-up	76 (84.4)
Complete abortion at 2-week follow-up	83 (92.2)
Surgical intervention	7 (7.8)
Participant requested surgical intervention before 1-week follow-up	4 (4.4)
Service delivery	
Made unscheduled visit to hospital	4 (4.4)
Made unscheduled call to clinic	6 (6.7)
Median duration of hospitalization following misoprostol administration, h	2.0 (0.5–48.0)

[a] Values are given as number (percentage) or median (range).

Only 4 (4.4%) women were not satisfied with the procedure, whereas 47 (52.2%) were satisfied and 39 (43.3%) were very satisfied (Table 5). In total, 67 (74.4%) women considered the bleeding to be acceptable and 16 (17.8%) rated it as very acceptable. Only 3 (3.3%) and 4 (4.4%) participants reported the bleeding to be unacceptable and very unacceptable, respectively (Table 5). Of the 7 women who underwent surgical evacuation, 2 reported the bleeding associated with misoprostol to be unacceptable. Pain associated with misoprostol use was tolerable for 74 (82.2%) women and very tolerable for 6 (6.7%) women (Table 5). Six (6.7%) women experienced no pain and 4 (4.4%) considered the pain to be intolerable.

In total, 74 (82.2%) and 8 (8.9%) participants reported that adverse effects were tolerable and easily tolerable, respectively (Table 5). Seven (7.8%) women reported the adverse effects to be severe and 1 (1.1%) woman perceived them to be very severe. Fifty-nine (65.6%) women said that they would have felt comfortable taking the medication at home ($P = 0.003$). Eighty-four (93.3%) participants would select the method if they experienced an abortion in the future ($P < 0.0001$) and 86 (95.6%) would recommend the method to their friends ($P < 0.0001$).

4. Discussion

Access to postabortion care services in low-resource countries is limited by a combination of factors. In addition to restrictive abortion laws, high costs and weak health infrastructure (which manifests as poorly equipped health facilities and lack of skilled personnel) are some of the major issues. Inequitable distribution of health personnel also deprives women in rural areas access to skilled providers. Measures are, therefore, required to increase women's access to postabortion care services in order to help reduce the substantial contribution of unsafe abortion to maternal morbidity and mortality.

The present study was implemented in the typical clinical setting of a secondary health facility. Nurses had prominent roles in the study. The findings confirm the high success rates attributed to misoprostol in randomized controlled trials conducted mainly in tertiary health facilities [8–14]. The success rate may have been higher but 4 of the women did not wish to wait until the end of the first week of follow-up. High levels of tolerance of adverse effects, satisfaction with the procedure, and willingness to use the method in the future or recommend it to friends also confirm the reported acceptability, safety, and effectiveness of misoprostol as an alternative treatment to manual vacuum aspiration for incomplete abortion [8,10,12].

Table 4
Adverse effects reported by participants at follow-up (n = 90).

Adverse effect	No. (%)
Heavy bleeding	21 (23.3)
Normal bleeding	48 (53.3)
Spotting (like menses)	15 (16.7)
Nausea	6 (6.7)
Vomiting	4 (4.4)
Pain/cramps	58 (64.4)
Fever/chills	11 (12.2)

Table 5
Participant reports of satisfaction and acceptability.

	No. (%)
Reported satisfaction with the procedure	
Unsatisfactory	4 (4.4)
Satisfactory	47 (52.2)
Very satisfactory	39 (43.3)
Acceptability of bleeding	
Very unacceptable	4 (4.4)
Unacceptable	3 (3.3)
Acceptable	67 (74.4)
Very acceptable	16 (17.8)
Perception of pain associated with misoprostol use	
No pain	6 (6.7)
Intolerable	4 (4.4)
Tolerable	74 (82.2)
Very tolerable	6 (6.7)
Perception of adverse effects	
Very severe	1 (1.1)
Severe	7 (7.8)
Tolerable	74 (82.2)
Easily tolerable	8 (8.9)

The findings also justify the calls for decentralization of postabortion care in Africa [19]. Nurses are more widely distributed than medical doctors and, thus, are closer to women in the community. With proper training, nurses can competently provide effective postabortion care services, thereby increasing access among women in Africa [19]. ACOG also supports the position that nurses can provide misoprostol as first-line treatment for incomplete abortion, even in outpatient settings, provided they receive appropriate training and support [17].

Concerted efforts are needed to promote this approach and increase its adoption, pushing for incorporation of misoprostol as treatment for incomplete abortion in clinical protocols and guidelines. Professional groups will have prominent roles in advocacy to ensure its acceptance among policy makers across Africa. Public enlightenment and community mobilization are crucial aspects in promoting widespread acceptance.

The main strength of the present study was the setting in which it was implemented. The health facility is typical of a secondary-level facility in a low-resource country. Furthermore, all women recruited to the study were followed-up and their perspectives documented. The major limitation of the study was the small number of women; however, the findings are consistent with those from previous research.

The results of the present study reinforce the understanding that misoprostol can be effectively used as first-line treatment for incomplete abortion. Nurses are capable of providing misoprostol for incomplete abortion—making it possible to recommend the adoption of misoprostol as first-line treatment by health systems in Africa, particularly in places where access to services is limited.

Conflict of interest

The authors have no conflicts of interest.

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