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Is misoprostol a safe, effective and acceptable alternative to manual vacuum aspiration for postabortion care? Results from a randomised trial in Burkina Faso, West Africa

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Objectives Previous research has demonstrated the effectiveness of misoprostol for treatment of incomplete abortion; however, few studies have systematically compared misoprostol's effectiveness with that of standard surgical care. This study documents the effectiveness of a single 600 micrograms dose of oral misoprostol versus manual vacuum aspiration (MVA) for treatment of incomplete abortion in a developing country setting.

Design Open-label randomised controlled trial.

Setting Two university teaching hospitals in Burkina Faso, West Africa.

Population Women of reproductive age presenting with incomplete abortion.

Methods From April 2004 through October 2004, 447 consenting women with incomplete abortion were randomised to either a single dose of 600 micrograms oral misoprostol or MVA for treatment of their condition.

Main outcome measure Completed abortion following initial treatment.

Results Regardless of treatment assigned, nearly all participants had a complete uterine evacuation (misoprostol = 94.5%, MVA = 99.1%; relative risk [RR] = 0.95 [95% CI 0.92–0.99]). Acceptability and satisfaction ratings were similar and high for both misoprostol and MVA, with three out of four women indicating that the treatment's adverse effects were tolerable (misoprostol = 72.9%, MVA = 75.8%; RR = 0.96 [95% CI 0.86–1.07]). The majority of women were 'satisfied' or 'very satisfied' with the method they received (misoprostol = 96.8%, MVA = 97.7%; RR = 0.99 [95% CI 0.96–1.02]), expressed a desire to choose that method again (misoprostol = 94.5%, MVA = 86.6%; RR = 1.09 [95% CI 1.03–1.16]) and to recommend it to a friend (misoprostol = 94.5%, MVA = 85.2%; RR = 1.11 [95% CI 1.04–1.18]).

Conclusion Six hundred micrograms of oral misoprostol is as safe and acceptable as MVA for the treatment of incomplete abortion. Operations research is needed to ascertain the role of misoprostol within postabortion care programmes worldwide.

Keywords Burkina Faso, incomplete abortion, miscarriage, misoprostol.

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Introduction

Incomplete abortion continues to contribute disproportionately to maternal morbidity and mortality in much of the developing world, particularly sub-Saharan Africa, where restrictive abortion laws lead to high numbers of incomplete induced abortions, which require further care. As in many countries where access to safe, legal terminations is limited, the rate of incomplete abortions in Burkina Faso remains high.[1] To address the need for high quality of care of incomplete abortions, the country has become a leader in a large, regional postabortion care (PAC) initiative.

Providers in Burkina Faso have been familiar with international PAC standards and guidelines for about a decade and are well trained on PAC counselling and use of manual vacuum aspiration (MVA). Surgical aspirations with MVA are typically provided without pharmacological anaesthesia, with verbal anaesthesia during the procedure being the norm.

MVA is a safe and effective technology, and when used correctly, completely empties the uterus almost all of the time.[1] Unfortunately, because of the time-consuming and costly nature of training providers at all the provincial and rural levels, combined with the difficulty of maintaining an adequate stock of MVA equipment and supplies, MVA has not been able to achieve its promise as a sustainable treatment for incomplete abortion. Often, resource-poor countries such as Burkina Faso do not have ample facilities and providers to sustain MVA programmes outside of large urban centers. For this reason, dilatation and curettage, with its higher rate of complications, including infection, continues to be practiced.

To complement the country's PAC programme, the present study sought to assess the role of a single 600 micrograms dose of oral misoprostol as an alternative to MVA for evacuation of the uterus following incomplete abortion. This simple pill could provide a low cost, easy-to-use, nonsurgical treatment option for women experiencing incomplete abortion. Indeed, misoprostol has been shown to effectively treat incomplete abortion in at least 19 studies, with success rates ranging from 13 to 100%, but most showing efficacy with misoprostol regimens at around 90%.[2–17] A meta-analysis of medical, surgical and expectant management of first-trimester miscarriage by Sotiriadis *et al.*[17] concluded that surgical treatment is 1.5 times more likely to be successful than misoprostol. This review included data from women seeking treatment for both incomplete and missed abortion. The trials by Weeks *et al.* and Ngoc *et al.* testing 600 micrograms single dose of oral misoprostol were not available when this meta-analysis was conducted: together they include another 617 participants and provide supportive documentation of the efficacy of misoprostol treatment for this indication.[8,14] For instance, in the Weeks trial, a single dose of 600 micrograms of oral misoprostol performed slightly better than MVA (96.3 versus 91.5%) when used to treat 317 women with incomplete miscarriage at a large teaching hospital in Kampala, Uganda. Rates of satisfaction were similarly high for both treatments. Unfortunately, nearly one-third of participants did not return for follow up in this trial, and outcome is not available for them. The present study was therefore designed to validate the efficacy results reported in Uganda.

Methods

From April to October 2004, 460 women were recruited at a two large university teaching hospitals in Burkina Faso: Le Centre Hospitalier National Souro Sanou in Bobo Dioulasso and Le Centre Hospitalier National Yalgado Ouédraogo in Ouagadougou. Incomplete abortion and eligibility were defined as: uterine size equivalent to a gestation of less than 12 weeks LMP, open cervical os, past or present history of vaginal bleeding during pregnancy and ultrasound evidence of substantial uterine debris with evidence of fetal demise. If misoprostol care had not been available, all women would have received uterine evacuations using MVA with either local or verbal anaesthesia. Additional eligibility criteria included living or working within the hospital's geographical area of coverage, no known contraindications to misoprostol, no signs of severe infection, temperature below 38°C and general good health. Women at these hospitals are regularly asked if their current abortion is spontaneous or induced. This information was recorded according to standard procedures; however, given the clandestine nature of induced abortion in this setting, it is likely that some women may not have provided a full account of the events leading up to their incomplete abortions. Spontaneous versus induced abortion was not a specified criterion for entry into the study; however, eligibility criteria did screen out women who presented with very high fever and signs of severe infection, commonly associated with unsafe induced abortion. Providers were allowed to prescribe additional medications, such as antibiotics, if needed, for instance, to treat an infection or as a prophylaxis against later infection.

All eligible women were counselled and given detailed information about the protocol by hospital staff. Consenting women were randomised to either: (1) a single dose of 600 micrograms of oral misoprostol or (2) MVA (the local standard of care). The sample was randomised in blocks of ten using a computer-generated random sequence provided by Gynuity Health Projects and stratified by study site. The assignment was concealed from providers and participants until after informed consent was given when the next sequential opaque sealed study envelope was opened to reveal the allocation. Ethical approval for this study was provided by the Population Council's Institutional Review Board as well as by the ethical review committee at the University in Ouagadougou.

Women receiving misoprostol swallowed the pills in the presence of a study nurse. Women allocated to MVA (Ipas, Chapel Hill, NC, USA) were given surgical evacuation as soon as a trained provider became available. MVA was provided by a trained doctor in the specially designated MVA room located in the family planning ward of each hospital. All participants, regardless of treatment assignment, were given paracetamol 200 mg tablets to manage any pain, counselled about adverse effects and scheduled to return to the hospital for follow-up care 1 week later. Women were also informed that they could return to the hospital or contact the study providers at any time if they had any additional questions or concerns. After this brief follow up counselling, all women were free to go home.

At the day 7 follow-up visit, each woman's abortion status was assessed using clinical examination, including an interview, a bimanual examination and ultrasound. Women with substantial retained products in the uterus on examination on study day 7 could wait an additional week for the products to

evacuate on their own. If they agreed, a second follow-up appointment was scheduled on study day 14. Women who did not wish to wait until day 14 underwent surgical evacuation using MVA. At study day 14, women with clinical evidence of substantial retained products in the uterus underwent MVA. When the treatment was completed, women were interviewed to gauge acceptability of their assigned method.

Ultrasound examinations were performed by a trained sonographer at each hospital who was briefed on the study protocol but was not a member of the main study team. Clinical judgement about the 'need to treat' for retained products was made jointly by the sonographer with a trained study physician. In an effort to prevent errors in determination of 'retained products requiring additional intervention', in-depth training was provided at study launch and by senior physicians throughout the study period. Providers were encouraged not to overuse or over-interpret ultrasound readings.

The primary outcome measure was complete uterine evacuation without recourse to additional surgical intervention at any point for any reason. Other outcome measures included adverse effects, pain and acceptability. As the study sought to assess women's satisfaction and the acceptability of the methods, each participant was asked to name the best and worst features of her treatment to indicate whether she would select the treatment again and recommend it to a friend. Open-ended questions, such as best and worst features, were categorised and analysed quantitatively. Pain level and satisfaction with the methods were measured using seven- and five-point Likert scales, respectively.[18] For the measure of pain level, a visual analogue scale was developed by the study team in which circles ranging in size from small (no pain) to large (intense pain) were used to measure pain. Additional information about each woman's experiences with bleeding, adverse effects and pain management was collected during exit interviews.

Data entry and analysis were conducted using the Statistical Package for the Social Sciences, version 12 (SPSS Inc., Chicago, IL, USA). A chi-square test was used for comparison of outcome measures between study groups, and values ≤0.05 were considered statistically significant. To compare mean values, *t* tests were used, and a one-way analysis of variance test was used to compare mean days of reported adverse effects. Assuming a 97.5% efficacy rate for MVA, the study was designed to have a 90% power to detect whether misoprostol was no more than 7.5% less effective than MVA.

Results

Participant characteristics

A total of 460 women were enrolled and randomised to receive either MVA ($n = 233$) or 600 micrograms of oral misoprostol ($n = 227$) for treatment of their incomplete abortions. Twelve women not meeting the eligibility criteria of open cervical os and one woman with incomplete records for whom study eligibility cannot be determined were incorrectly enrolled, and as ineligible, they are excluded from analysis. Table 1 details the characteristics of study participants. There were no significant differences between women in the two groups.

Efficacy

Five women were lost to follow up (LFU), all in the misoprostol arm (Figure 1). Every attempt was made to contact these women, including providing a mobile phone to study staff. Records show the following diagnoses at last contact: three with substantial uterine debris and no sac, one with persistent uterine sac and the one for whom the clinical status was recorded as unknown.

Table 1. Participant characteristics*,**

	Misoprostol ($n = 223$)	MVA ($n = 224$)	*P value*
Age, years (mean, SD)	26.5 ± 6.4	26.3 ± 6.7	0.65
Years of education (mean, SD)	4.6 ± 5.1	4.8 ± 4.7	0.72
Currently married, % (*n*)	53.6 (119)	50.5 (112)	0.53
Parity (mean, SD)	2.17 ± 2.05	2.10 ± 2.12	0.49
Previous induced abortion reported, % (*n*)	2.8 (6)	2.3 (5)	0.99
Previous miscarriage reported, % (*n*)	17.6 (39)	17.6 (39)	0.92
Woman's report of current abortion, % (*n*)			
Spontaneous	89.7 (200)	85.3 (191)	0.17
Induced	10.3 (23)	14.7 (33)	0.17
Provider assessment that abortion was induced, % (*n*)	12.1 (27)	17.0 (38)	0.15

*There are no statistically significant differences between the two groups.
**All available data for the five women LFU are included in this table.

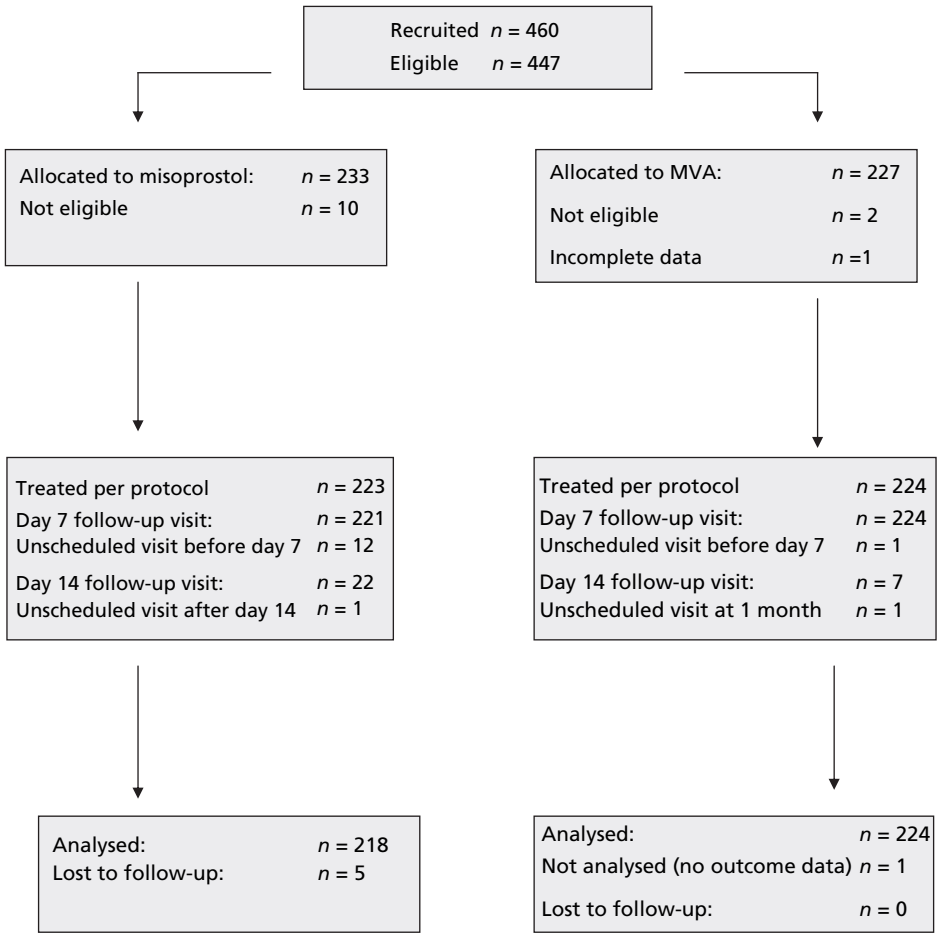

Figure 1. CONSORT flow chart.

The overall success rate for the two treatments was high: 94.5% with misoprostol and 99.1% with MVA (Table 2). While this difference is statistically significant (RR = 0.95, 95% CI 0.92–0.99), there does not appear to be a clinical difference in outcome between the two groups. Misoprostol was successful in 99.1% of women at site 1 and 89.8% at site 2. The success rate for MVA was similar at the two sites, at 100 and 98.3%, respectively. As shown in Table 2, 14 women required an additional surgical evacuation: 12 randomised to misoprostol and two with MVA. We also analysed the data including the 13 excluded women and found no practical difference in efficacy (misoprostol = 89.6%, MVA = 98.7%; RR = 0.91, 95% CI 0.87–0.95).

Two women allocated to misoprostol were hospitalised during the study period, both at site 1. One woman had signs of anaemia after treatment, and the provider requested a haemoglobin (Hb) examination. She refused the examination at the time of treatment and returned 2 days later with a measured Hb of 3.5 and was subsequently given a blood transfusion. A second woman was hospitalised for signs of infection recognised by the provider after treatment administration. She recovered shortly thereafter and returned home.

Before being examined at the follow-up visit, each woman was asked to state whether or not she felt that her abortion was complete. This information was collected, as it gauges women's comfort with the method and their ability to determine on their own whether additional care might be needed. Just over two-thirds of misoprostol users ($n = 150$) and about four-fifths of MVA users ($n = 179$) stated that they believed their abortion was complete at that time. Of these women, only four (one with misoprostol and three with MVA) were incorrect.

Experience with adverse effects

At the follow-up visit, all women were asked to give their individual assessments of the amount of pain, bleeding and adverse effects they experienced after treatment. Women randomised to MVA reported a significantly higher mean pain score, 2.73, compared with those receiving misoprostol, 2.32 ($P = 0.047$). Approximately half of the women in each

Table 2. Efficacy, % (*n*)

	Misoprostol (*n* = 223)	MVA (*n* = 224)	RR (95% CI)
LFU	2.2 (5)	0.0 (0)	*P* = 0.03
Success rate*	94.5 (206/218)	99.1 (222/224)	0.95 (0.92–0.99) *P* = 0.0056
Site 1	99.1 (109/110)	100.0 (109/109)	*P* = 0.50
Site 2	89.8 (97/108)	98.3 (113/115)	0.91 (0.85–0.98) *P* = 0.007
Type of failure (*n* = 14)			
Incomplete abortion at study end	2.8 (6)	0.8 (2)	3.08 (0.63–15.11) *P* = 0.133
Medically indicated surgical abortion before study end	1.8 (4)	0.0 (0)	*P* = 0.058
Provider or woman's choice before study end	0.9 (2)	0.0 (0)	*P* = 0.24

*Difference in efficacy between sites, *P* = 0.006.

group reported having experienced pain and cramps (misoprostol = 55.8%, MVA = 51.6%), lasting about a day and a half. Women receiving misoprostol were significantly more likely to report 'heavy' and 'normal' bleeding and that it lasted longer. MVA users were more likely to report light bleeding or 'spotting' after treatment. There were no significant differences in reports of other adverse effects or mean number of days that each adverse effect was experienced by study group, with nausea, vomiting, fever and chills being named as common adverse effects (Table 3).

Women were asked to rate their overall experiences with adverse effects following their assigned treatments. Using a five-point scale, with very bad adverse effects being the highest rating and no adverse effects being the lowest, approximately three out of four women indicated that the adverse effects were 'tolerable' (Table 3). MVA users were more likely

Table 3. Women's reports of bleeding and adverse effects

	Mean days			% Ever (*n*)		
	Misoprostol (*n* = 223)	MVA (*n* = 224)	*P* value	Misoprostol (*n* = 223)	MVA (*n* = 224)	RR (95% CI)
Bleeding						
Heavy bleeding (> period)	1.7	1.1	0.004	32.1 (72)	9.4 (21)	3.44 (2.20–5.40)
Normal bleeding (like period)	1.9	1.5	0.01	62.9 (141)	37.2 (83)	1.71 (1.40–2.08)
Light bleeding (< period)	3.1	2.9	0.09	89.3 (199)	96.4 (93)	0.93 (0.88–0.97)
Other adverse effects						
Nausea	1.3	1.5	0.51	5.4 (12)	0.9 (2)	6.03 (1.36–26.62)
Vomiting	1.0	1.0	—	2.2 (5)	1.8 (4)	1.26 (0.34–4.61)
Pain/cramps	1.4	1.3	0.08	55.8 (125)	51.6 (115)	0.61 (0.34–4.61)
Fever	1.2	1.0	0.39	4.9 (11)	1.8 (4)	2.76 (0.89–8.55)
Chills	1.0	1.0	—	0.4 (1)	0.4 (1)	1.00 (0.06–15.96)
Overall experience with adverse effects						
Very bad	—	—	—	0.9 (2)	0.9 (2)	1.03 (0.15–7.27)
Bad	—	—	—	3.7 (8)	10.5 (23)	0.36 (0.16–0.79)
Tolerable	—	—	—	72.9 (156)	75.8 (166)	0.96 (0.86–1.07)
Easily tolerable	—	—	—	19.6 (42)	11.0 (24)	1.81 (1.14–2.88)
No adverse effects	—	—	—	2.8 (6)	1.8 (4)	1.55 (0.44–5.41)

to characterise the adverse effects as 'bad' (10.5 versus 3.7%), whereas misoprostol users were significantly more likely to state that the treatment was 'easily tolerable' (19.6 versus 11.0%).

All women were given paracetamol to help manage their pain and instructed that they could take this pain medication at any time. While more than three-quarters of participants reported that the pain medication they received enabled them to manage their pain effectively (misoprostol = 77.1% [162], MVA = 85.1% [188]), some would have liked even stronger medication (misoprostol = 3.6% [8], MVA = 4.0% [9]). Providers at site 2 prescribed additional medications (mainly antibiotic coverage) to 60.9% (70) of MVA users and 34.8% (39) of misoprostol users ($P < 0.001$). In contrast, providers at site 1 gave additional medications to only five women, one assigned to misoprostol (0.9%) and four to MVA (3.7%).

Very few women sought additional contact with providers during the study period: 12 misoprostol users (5.4%) and 2 MVA users (0.9%) made one unscheduled, additional clinic visit for care related to their incomplete abortions. While additional clinic visits were more common among misoprostol users, $P = 0.006$, MVA users made more telephone calls to study providers, 3.6% (8) versus 0.8% (2).

Satisfaction and acceptability

Table 4 shows women's views on best and worst features, satisfaction and overall acceptability of their assigned treatment. The data show that women in both groups were satisfied with their treatments. Misoprostol users were significantly more likely to report that they were 'very satisfied' with the method (RR = 1.99, 95% CI 1.13–3.43).

While women in both groups described the treatment as easy, simple and efficacious (misoprostol = 37.9%, MVA = 24.6%), those randomised to misoprostol were significantly more likely to cite these features ($P < 0.001$). Both groups reported that they appreciated seeing the expulsion (misoprostol = 21.2%, MVA = 25.6%). Women randomised to MVA were more likely to highlight the good care and counselling they received (misoprostol = 16.7%, MVA = 26.5%, $P = 0.018$), and misoprostol users were more likely to mention absence of pain (misoprostol = 11.8%, MVA = 1.9%, $P < 0.001$) as a best feature.

Table 4. Women's reports of acceptability and satisfaction, % (*n*)

	Misoprostol (*n* = 218)	MVA (*n* = 224)	RR (95% CI)	*P* value
Overall satisfaction				
Very satisfied	15.2 (33)	7.7 (17)	1.99 (1.13–3.43)	
Satisfied	81.6 (177)	90.0 (198)	0.91 (0.84–0.98)	
Unsatisfied	3.2 (7)	2.3 (5)	1.42 (0.46–4.40)	
Would choose method again				
Yes	94.5 (205)	86.6 (194)	1.09 (1.03–1.16)	
No	1.8 (4)	0.4 (1)		
Not sure	3.7 (8)	12.9 (29)		
Would recommend method to friend				
Yes	94.5 (205)	85.2 (190)	1.11 (1.04–1.18)	
No	2.3 (5)	1.8 (4)		
Not sure	3.2 (7)	13.0 (29)		
Best features*				
Simple, quick and successful	37.9 (77)	24.6 (51)		<0.001
Saw expulsion	21.2 (43)	25.6 (53)		0.32
Good counselling/care	16.7 (34)	26.5 (55)		0.018
Everything	16.7 (34)	20.3 (42)		0.38
Absence of pain	11.8 (24)	1.9 (4)		<0.001
None, no best feature	6.9 (14)	12.6 (26)		0.06
Less traumatic	5.9 (12)	0.5 (1)		0.004
Other best feature	7.3 (16)	5.4 (12)		0.39
Worst features*				
None, no worst feature	78.6 (169)	72.6 (162)		0.21
Pain	14.0 (30)	26.5 (59)		< 0.001
Bleeding	4.7 (10)	0.4 (1)		0.012
Other worst feature	2.3 (5)	1.8 (4)		0.48

*Women could name up to two features.

As for worst features, pain again appeared as a significantly different aspect of the experience for women in the two treatment groups (Table 4). Over one-quarter of women with MVA reported that pain was among the worst features compared with only 14% of those receiving misoprostol ($P < 0.001$). Bleeding was more commonly cited as a worst feature by misoprostol users ($P = 0.012$). Importantly, the majority of women in both groups reported that the treatment they received had no worst feature at all.

When asked about future use and recommendations for the two methods, reports from both user groups were positive. Overall, misoprostol users were significantly more likely to choose the drug again in the future (misoprostol = 94.5%, MVA = 86.6%, RR = 1.09, 95% CI 1.03–1.16) and recommend it to a friend (misoprostol = 94.5%, MVA = 85.2%, RR = 1.11, 95% CI 1.04–1.18).

Discussion

Easy-to-use, widely available PAC technologies are vital to women's health care. Until now, PAC programmes have recommended MVA for treatment of incomplete abortion. MVA works very well and provides a highly effective means of uterine evacuation but is not always feasible in low-resource settings with limited access to skilled surgical providers and equipment. For several years, providers and policy makers have debated the potential role for misoprostol within PAC programmes, but relatively little is known about the feasibility of its use in sub-Saharan Africa. This study provides support for inclusion of misoprostol in PAC programmes by demonstrating that it is a safe, effective and acceptable nonsurgical alternative to MVA.

In this trial, 600 micrograms of oral misoprostol successfully evacuated the uterus for nearly 95% of users. The drug's safety profile is similarly strong: no unexpected adverse effects or serious adverse events was experienced by misoprostol users in this study. This high efficacy rate with 600 micrograms of oral misoprostol is similar to that shown by Ngoc *et al.*[8] in Vietnam and slightly higher than other reports using this same regimen.[7] This is likely due to several factors, including the strict inclusion criteria, which excluded women with closed cervical os and/or diagnosed missed abortions, the limited use of ultrasound readings as a determining factor of success and a longer duration of time from enrolment to assessment of abortion completion. Ultrasound use is comparatively limited in Burkina Faso, which may explain the similarity of these results to those published by Weeks *et al.*[14] in Uganda, where misoprostol and MVA has efficacy rates of 96.3 and 91.5, respectively. In the Ugandan study, no serious adverse effects or adverse effects was reported with either method and overall satisfaction was high. Both studies confirm that misoprostol can be offered in a sub-Saharan African hospital setting.

In the present study, there was a notable difference in care given at the two sites. Providers at site 2 reported a greater number of failures with misoprostol, more frequent use of additional medications during treatment and greater likelihood to intervene surgically if retained products of conception (RPOC) were suspected. These differences provide evidence of the varying levels of care that can be expected from one facility to the next. Importantly, providers from neither site reported dissatisfaction or undue concerns with the new misoprostol treatment and satisfaction, and acceptability ratings were high for women randomised to both treatments. Women allocated to misoprostol praised the method's simplicity, speed and absence of pain, while women receiving MVA lauded the good counselling and care. Their praise is evidence of more than a decade of successful PAC programmes in Burkina Faso emphasising MVA counselling and care.

The study design did inevitably have some limitations, which may affect future use of misoprostol for this indication. For one, the study could not be double-blinded, as it would be unethical to perform sham surgery on half of the participants; therefore, neither women nor their providers were blinded to treatment assignment. Concerns about the 'new' treatment could have led to a greater provider preference for surgical re-evacuation in the misoprostol group. Likewise, it could account for some differential bias in interpretation of ultrasound images of retained products in the two study groups. The study also enrolled all eligible women regardless of whether they reported their current incomplete abortions to be induced or spontaneous. Some providers may believe that the misoprostol method may work differently in these two subsets of women; however, there is no scientific evidence to support this presumption. Lastly, as in all controlled settings, the overall counselling, care and follow up given to these women may not be replicable in day-to-day clinical practice. It is likely that as misoprostol is increasingly used, there will be higher failure rates in the beginning as providers familiarise themselves with the method.

The issue of women LFU has been raised, as a very small proportion of misoprostol users will require a surgical completion. As the method is introduced in new settings, information and counselling should be provided to enable women to recognise the need for additional care and where to get it. It is worth noting that very few women were LFU in this study (about 1%), demonstrating the ability to conduct high quality randomised clinical studies in resource-poor settings, such as Burkina Faso.

Sub-Saharan African countries continue to have the highest maternal mortality and morbidity rates in the world. It is crucial that every available treatment option be used in efforts to reduce morbidity and mortality. Misoprostol offers one such option and expansion of its use in periurban and rural settings, as well as its inclusion into country-wide PAC programmes, should be aggressively pursued.

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