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Original Article

Simplifying medical abortion: home administration of misoprostol

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Abstract

Objective: To increase access to safe abortion, the feasibility, efficacy and acceptability of a medical abortion regimen entailing a reduced dose of mifepristone and the option of home administration of sublingual misoprostol was assessed at a government hospital providing legal abortion services on a regular basis.*Methods:* Consenting women (n=99) with amenorrhea of =56 days received mifepristone 200mg orally at the hospital. Two days later, women either returned to the hospital for 400µg sublingual misoprostol or took it at home. All women returned after two weeks for abortion confirmation. *Results:* The vast majority of women (88%) chose home use of misoprostol and did so mainly to decrease the number of clinic visits (65%) and to take care of their household responsibilities (16%). Adherence to the drug protocol was comparable among home and clinic users, with only a single woman in each group not taking misoprostol at the scheduled time. Efficacy was similarly high in both groups (home users 95% vs. clinic users 96%). No serious side effects were noted in either home or clinic users. *Conclusion:* The safety, efficacy and acceptability of home use of misoprostol observed in our study suggest this option should be available to women in India.

Key words: medical abortion; mifepristone; misoprostol; home use; India.

Introduction

Mifepristone- misoprostol abortion holds great promise to reduce abortion morbidity and mortality where they remain highest—in less-developed countries [1]. In April 2002, the Drug Controller of India approved 600 mg mifepristone coupled with 400µgm oral misoprostol for pregnancy termination in gestations of 49 days or less. Since then, several refinements to the dose of mifepristone (e.g. reduced dose to 200 mg) and the route of misoprostol administration (e.g. sublingual administration) have been shown to be safe, effective and acceptable [1-5].

However, while researchers have refined several biomedical aspects of the regimen, few have explored ways of making it more feasible and affordable in less-developed countries. The typical regimen requires three or more visits to the clinic, which women can ill afford because of time lost from work, transportation costs, household chores and child care. These visits are

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burdensome and inconvenient and should be eliminated if not necessary to safeguard the woman's health. Repeated clinic visits also compromise privacy, important in countries where abortion is stigmatised. In view of the limited availability of physicians, it is also imperative to review the levels of clinician's involvement in the abortion process and reduce it if not warranted medically [1].

Available evidence suggests that a relaxed protocol that allows women the option of eliminating the longest of the three previously required visits, that is on the day of misoprostol administration, is highly acceptable, has a high success rate, and does not compromise the safety profile of the regimen. In addition, such a regimen also reduces the staff costs of providing medical abortion and improves women's privacy and autonomy [1,7-9].

In India, medical abortion is primarily available in urban settings and is not yet provided by the public health care system, presumably due to cost and staffing considerations. A regimen consisting of a reduced dose of mifepristone and the option of home administration of misoprostol, however, may increase the feasibility of providing non-invasive abortion in rural areas and through the public health care system, thereby greatly increasing access to safe abortion in India. We thus assessed the feasibility and acceptability of such a simplified medical abortion regimen.

Methods

The study was undertaken at the Family Welfare Center (FWC) in the Department of Obstetrics and Gynecology at the Government Medical College in Nagpur, Maharashtra state in India. The FWC provides legal surgical abortion up to 12 weeks gestational age, as well as a variety of temporary and permanent contraceptive services.

In preparation for the study, two doctors at the FWC received a two-day medical abortion training which emphasised gestational age dating in early pregnancy using menstrual history and pelvic examination, abortion status confirmation using clinical parameters, clinical management of medical abortion and counselling techniques. Case studies on assessing abortion status and abnormal bleeding patterns were used during the training.

Women seeking pregnancy termination between February 2005 and June 2005 were screened for eligibility. Women were eligible if they had a positive urine pregnancy test, an intrauterine pregnancy of 56 days or less since last menstrual period based on clinical exam, menstrual history and if required by ultrasonography (12% of the time), were in good general health; had no contraindications to mifepristone or misoprostol, lived within an hour of the clinic, and were willing to return for at least two additional visits. Eligible women were informed about the option of medical abortion when they came to the clinic for surgical termination. All women gave written consent, either by providing their signature or their thumb print.

Women made two visits to the clinic or more. At the first visit, they received 200mg mifepristone, were observed for 15 minutes, and asked to select clinic or home administration of misoprostol. Before selecting the misoprostol administration site, women were counseled to expect bleeding and pain after misoprostol ingestion. We advised women who chose home administration to rest for several hours after taking the prostaglandin and to have someone nearby during those hours. Women selecting home administration of 400mg misoprostol were instructed to take the prostaglandin sublingually in about 48 hours. Women choosing clinic administration returned to the clinic on the third day where they took 400mg misoprostol sublingually and were observed for 4 hours. All women received four 500mg paracetamol tablets at the end of visit one to use at their own discretion. Women returned for follow-up on the 14th day for a pelvic examination and if required ultrasonography (13% of the time). Those with complete abortions were discharged from the study. We offered surgical interventions to women with ongoing pregnancies. Women with incomplete abortions selected additional follow-up or surgical termination. Those choosing additional follow-up returned to the clinic 7 days later. At each visit, providers completed standardized questionnaires translated in Marathi. Women also completed daily symptom diaries during the study period.

The study protocol was approved by the Institute Ethical Committee, Government Medical College and Hospital, Nagpur and the Population Council's Institutional Review Board. Data were entered, cleaned and analyzed using STATA Version 9.

Results

Of 236 women who sought termination of pregnancy at the study site, 145 were eligible for participation in the study and 100 were enrolled. The balance 45 women refused to participate in the study, even though eligible, as they wanted a tubal ligation procedure at the same time and did not want to make another visit to the facility. As the site had no previous medical abortion experience, the first 10 women enrolled were treated as pilot cases and were not given the option of home administration of misoprostol. One woman, who reportedly had missed menses, had a positive pregnancy test and an enlarged uterus, received both mifepristone and misoprostol but was subsequently found to have been falsely diagnosed as pregnant. As she did not experience any bleeding or cramping after taking either mifepristone or misoprostol, she was evaluated for suspected ongoing pregnancy at her follow-up visit. However, clinical examination and ultrasound indicated that she had never been pregnant. We excluded information collected from this woman in our analysis and thus our final sample consists of the remaining 99 women and compares the experiences of those who opted for home administration of misoprostol with those who selected clinic administration.

Sample characteristics

As indicated in Table 1, the 99 participants in the study averaged 26.6 years of age and had completed 11.6 mean years of schooling. The mean gravidity was 2.4 and 13.1 % of the women had a previous induced abortion. The majority of women (73.7 %) presented with gestational ages of 6 or 7 weeks and the mean gestational age was 6.6 weeks (±0.7).

Misoprostol administration

Among the 89 women who were given an option of home or clinic administration of misoprostol, a significant majority (88%) chose home administration. However, two women who initially selected home administration changed their minds and subsequently returned to the clinic for misoprostol administration. The main reasons given by women for their choice of home use of misoprostol were fewer visits (65%) and compatibility with household duties including child care (20%). The minority who selected clinic administration indicated that availability of doctors at the facility (36%) and lack of anyone at home to assist them in case of trouble (27%) were the main reasons guiding their choice. (Table 2)

Women who opted for home administration of misoprostol were encouraged to have someone nearby in the hours after they ingested the prostaglandin. Amongst the 75 women who used misoprostol at home and returned for follow-up, three-quarters (75%) reported that they had followed this advice. In most cases, they had their husbands/ partners (64%), mothers-in-law (31 %) or mothers (24%) nearby.

Compliance and efficacy

Nearly all women who opted for home use took misoprostol on the scheduled date and time (99%). Most women also returned for their follow-up visit on time (67%). Ultimately, only a single home user (1%) never returned for her follow-up visit. To insure that she had ingested misoprostol on the scheduled date and time and had not experienced any problems, she was contacted by phone at which point she indicated that she had undergone a surgical termination at another facility, fearing ill effects of mifepristone (Table 3). Similar results were observed among clinic users, with 96% returning on the scheduled date and time for misoprostol and 78% returning for confirmation of their abortion status as scheduled. The rest were late but did return for final assessment of their abortion status. Efficacy was defined according to standard methods with any woman undergoing a surgical intervention for any reason considered to have had a failed medical abortion. Success rates were high overall (95%), as well as among home users (95%) and clinic users (96%) (Table 4). Among home users, one woman (1%) had an incomplete abortion and two (3%) had ongoing pregnancies at the end of the study; all received surgical interventions at the study site. As indicated above, one additional home user (1%) did not take her misoprostol at all and received a surgical abortion at another facility at her request. Among women who had opted for clinic use of misoprostol, only a single failure was recorded, accounting for 4% of all clinic users, and was due to user failure as the woman changed her mind about the method and obtained a surgical intervention at a private clinic before the scheduled misoprostol.

Table 1: Characteristics of participants (n=99).

	All users n = 99	Home users n = 78	Clinic users n = 21
Age in completed years: n (%)			
16-24	30 (30.3)	23 (29.4%)	7 (33.3)
25-29	44 (44.4)	35 (44.8)	9 (42.8)
30 and above	25 (25.2)	20 (25.6)	5 (23.8)
Mean	26.6 (±4.2)	26.6 (±4.1)	26.5 (±4.5)
Education (years of education)			
4-6	5 (5.05)	4 (5.3)	1 (4.7)
7-9	15 (15.15)	11 (14.1)	4 (19.0)
10 and above	79 (79.80)	63 (80.7)	16 (76.1)
Mean years of education	11.6 (±3.1)	11.5 (±3.0)	11.5 (±3.0)
No. of previous abortion:			
0	86 (86.8)	69 (88.4)	17 (81.0)
1	11 (11.1)	7 (8.9)	4 (19.0)
2	1 (1.0)	1 (1.2)	
3	1 (1.0)	1 (1.2)	
Mean	0.1 (±0.4)	0.1 (±0.4)	0.1 (±0.4)
Gestational age in weeks			
5	8 (8.08)	7 (8.97)	1 (4.76)
6	40 (40.40)	33 (42.31)	7 (33.33)
7	33 (33.33)	23 (29.49)	10 (47.62)
8	18 (18.18)	15 (19.23)	3 (14.29)
Mean	6.6 (±0.7)	6.6 6.7	
Gravidity			
2	63 (63.6)	49 (62.8)	14 (66.6)
3	31 (31.3)	26 (33.3)	5 (23.8)
4	3 (3.0)	2 (2.5)	1 (4.7)
More than 4	2 (2.0)	1 (1.2)	1 (4.7)
Mean	2.4 (± 0.7)	2.4 (±0.6)	2.4 (±0.8)

Table 2: Reasons for selecting site of misoprostol administration (n=89)*.

		N (%)
Home use 78(87.6%)		
	Less visits	51 (65.3)
	Continue household responsibility	16 (20.0)
	Convenience	3 (3.8)
	Feels better at home	3 (3.8)
	No one to accompany	2 (2.5)
	Privacy	3 (3.8)
Clinic Use 11(12.3 %)	Doctors available	4 (36.3)
	No one at home	3 (27.2)
	No rest at home	2 (18.1)
	Fears bleeding/side effects	2 (18.1)

* Multiple responses possible.

Table 3:Compliance.

	All users(n =99) n (%)	Home users(n= 76) n (%)	Clinic users(n=23) n (%)
Misoprostol on time	97 (97.9)	75 (98.7)	22 (95.6)
Misoprostol not taken	2 (2.02)	1 (1.3%)	1 (4.3%)
Follow up as scheduled	69 (69.7)	51 (67.1)	18 (78.2)
Late for follow up visit	29 (29.2)	24 (31.5)	5 (21.7)
Lost to follow up	1 (1.01)	1 (1.3)	

Table 4: Efficacy.

	All users n = 99 n (%)	Home users n= 76 n (%)	Clinic users n = 23 n (%)
Success rate	94 (94.9)	72 (94.7)	22 (95.6)
Method failure			
On-going pregnancy at study end	2 (2.02)	2 (2.6)	—
Incomplete abortion at study end	1 (1.01)	1 (1.3)	—
User (provider or woman) failure	2 (2.02)	1 (1.3)	1 (4.3)

Table 5. Women's reports of bleeding and side effects.

	All users N =98	Home users n= 75	Clinic users N =23
Prevalence of side effects, n(%)			
Any bleeding	98 (100)	75 (100)	23 (100)
Heavy bleeding	83 (85.8)	64 (87.1)	19 (80.9)
Normal bleeding	79 (80.8)	62 (83.3)	17 (71.4)
Spotting	68 (69.7)	51 (69.2)	17 (71.4)
Nausea	52 (53.5)	39 (52.5)	13 (57.1)
Vomiting	44 (45.4)	34 (44.8)	10 (47.6)
Abdominal cramps	68 (68.6)	52 (69.2)	16 (66.6)
Fever/chills	26 (28.2)	23 (30.7)	3 (19.0)
Mean days of side effects ± SD			
Any bleeding	8.0 (3.1)	8.3 (3.1)	7.3 (3.0)
Heavy bleeding	3.5 (2.5)	3.5 (2.6)	3.3 (1.9)
Normal bleeding	3.5 (2.0)	3.6 (2.1)	3.4 (1.6)
Spotting	3.3 (2.2)	3.6 (2.3)	2.5 (1.6)
Nausea	2.3 (1.8)	2.4 (2.0)	1.8 (0.8)
Vomiting	1.6 (1.0)	1.7 (1.1)	1.2 (0.4)
Abdominal cramps	3.6 (3.3)	3.8 (3.2)	3.0 (3.6)
Fever/chills	2.4 (2.0)	2.4 (2.0)	2.3 (2.3)

Table 6: Satisfaction with administration of Misoprostol.

	All users n=98 (%)	home users n=75 (%)	clinic users n=23 (%)
Satisfaction with treatment			
Satisfactory	79 (80.6)	60 (80.0)	19 (82.6)
Neutral	13 (13.2)	10 (13.3)	3 (13.0)
Unsatisfactory	6 (6.1)	5 (6.6)	1 (4.3)
Best feature (n=98) *			
No surgery	43 (43.8)	30 (40)	13 (56.5)
No hospitalization	17 (17.3)	11 (14.7)	6 (26.0)
Easy, simple and convenient	13 (13.2)	11 (14.7)	2 (8.7)
Successful in completing abortion	7 (7.1)	7 (9.3)	0
Less bleeding	5 (5.1)	5 (6.7)	0
Less painful	4 (4.0)	3 (4.0)	1 (4.3)
Privacy	4 (4.0)	4 (5.3)	0
None	5 (5.1)	3 (4.0)	2 (8.7)
Worst feature (n=98) *			
Pain	48 (48.9)	35 (46.7)	13 (56.5)
Bleeding	15 (15.3)	13 (17.3)	2 (8.7)
Nausea, vomiting, diarrhea	13 (13.2)	11 (14.7)	2 (8.7)
Weakness and giddiness	7 (7.1)	7 (9.3)	0
Uncertainty	6 (6.1)	6 (8.0)	0
None	4 (4.0)	4 (5.3)	0
Others (fever, itching)	3 (3.0)	2 (2.7)	1 (4.3)
Incomplete abortion	2 (2.0)	2 (2.7)	0

* Multiple responses possible.

Abortion experiences

Study participants did not experience any serious complications as a result of their medical abortions. No blood transfusions or hospitalizations were required. As indicated in Table 5, however, all women (100%) reported at least some bleeding, with an average of 8.0 days of bleeding recorded in their daily symptom cards. Abdominal cramping was also common (68.6%) and experienced for an average of 3.6 days.

Additional care required by women such as unscheduled visits or calls made to the clinic were recorded to assess how they managed their side effects and abortion experiences. Overall, 11% of patients made unscheduled visits to the clinic, the vast majority of them home-users (home users 13% vs. clinic users 4%). Home users (28%) similarly made substantially more calls to the hotline than clinic users (10%). Most unscheduled visits and calls were to discuss concerns about their abortion status and/or bleeding.

Acceptability

At the end of the study, participants were asked if they would choose medical abortion again if they needed another abortion, and if so, where would they elect to take misoprostol. Women nearly universally (99%) indicated that they would choose non-invasive abortion again if they needed another abortion. While both, a majority of home users (88%) and clinic users (63%) said they would select the same place of misoprostol administration if they had another medical abortion, clinic users were more likely to say that they would switch the site of misoprostol (to home use) than were home users (to clinic use).

Women were also asked to rate their overall satisfaction with the abortion process. Most women reported that they were 'satisfied' whether they took misoprostol at home (80%) or in the clinic (83%) with the method. Dissatisfaction was restricted to a few home users (7%) and a single clinic user (4%).

Open-ended questions were used at the follow-up visit to identify the best and worst features of women's experiences with medical abortion (Table 6). There were no significant differences in reporting best features of the method between home users and clinic users. Almost half the women (44%) responded that avoiding surgical abortion was its best feature. 26% clinic users and 15% home users appreciated that the abortion was done in an out-patient setting and thus no hospitalization was required. As far as the method is concerned, many more home users (15%) as compared to clinic users (9%) liked the fact that it is an easy, simple and convenient method. When asked about the method's worst features, 49% of women reported discomfort with the amount of pain they had experienced. However, many more home users as compared to clinic users indicated that they found bleeding (17%), nausea, vomiting and diarrhea (15%), uncertainty (8%) as the worst features of the method. Conclusion A simplified abortion regimen of 200mg mifepristone followed by the option of home or clinic use of 400µg sublingual misoprostol is a feasible and viable option in India. The 5% failure rate is comparable to that found in protocols using a higher dose of mifepristone and requiring strict medical supervision of misoprostol. The vast majority of both home users and clinic users adhered to the protocol with all but two taking misoprostol at the recommended time.

When given the option of home or clinic administration of misoprostol, most women opted for home administration and the vast majority of home users were 'satisfied' with their abortion experience. Many appreciated the decrease in the number of required clinic visits and the flexibility of home administration of misoprostol afforded them to continue their household responsibilities. Ultimately, the vast majority of home users and many clinic users indicated that they would take misoprostol at home if they had another medical abortion, providing additional support for a regimen that allows women the option of home administration. .

As more home users made unscheduled clinic visits and called the clinic hotline, often to obtain confirmation that the bleeding they were experiencing was 'normal', however, detailed counseling regarding bleeding patterns both before and after misoprostol ingestion should be considered as an essential aspect of the regimen. Additionally, low literacy patient materials that explain clearly what to expect at different stages of the abortion process should be developed.

In conclusion, our study provides evidence about the safety, efficacy and acceptability of home use of misoprostol in an urban setting in India and suggests that women, together with their providers, should discuss the feasibility of this option when considering medical abortion.

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