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Acceptability of home use of mifepristone for medical abortion☆

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Abstract

Background: Most medical abortion protocols require women to take mifepristone in the doctor's office. We assessed the acceptability of home use of mifepristone among women and their providers.
Study Design: In this multicenter trial, eligible women requesting termination of early pregnancy (n=301) chose whether to take mifepristone in the office or at home. Data on safety, efficacy, acceptability and disability were collected.
Results: One hundred thirty-nine women (46%) chose to take mifepristone at home, and 162 (54%) chose office administration. Ninety-five percent of home users said that they would take the mifepristone in the same place in the future. Home users were not more likely to call the doctor's office or make an unplanned visit, and providers would recommend home use again for 95% of patients who chose home use.
Conclusions: Home administration of mifepristone was safe and acceptable to women and providers in our study. Women should be offered this choice to allow more flexibility, comfort and privacy in their abortion experiences.

Keywords: Medical abortion; Mifepristone; Home use

1. Introduction

Due to the politicized nature of abortion in the United States, mifepristone is distributed and dispensed in a highly unusual manner. Mifepristone is supplied only to physicians who sign an agreement with the distributor and is not available in pharmacies. In addition, mifepristone is generally administered under the direct observation of a physician or nurse. These conditions are specified in the manufacturer's label approved by the Food and Drug Administration [1]; however, there is a long history of off-label use in the US for other aspects of mifepristone provision where supportive data exist. Despite the fact that mifepristone has few to no side effects for most women, no data have been gathered on mifepristone use outside the constraints of office provision in the US. A descriptive study of women overseas who acquired both mifepristone and misoprostol from the Women on the Web website and self-administered the tablets reported a success rate similar to rates reported for other outpatient settings (93%) [2].

Women considering medical abortion may assume incorrectly that the abortion will occur on the day of their appointment and accordingly plan their visit around the demands of childcare, work and school. However, the most severe bleeding and cramping usually occur 1 to 3 days after the appointment, after the woman takes the misoprostol. Therefore, requiring women to take mifepristone in the doctor's office can interfere with patients' ability to plan how the abortion will fit into their lives because it forces them to

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initiate the bleeding process at a time when it may be costly or inconvenient. Appointments are often not available at the most convenient times for patients. By contrast, if a woman were sent home with both medications, she could plan to experience bleeding over the weekend or at another time that is suitable for her so that she can avoid schedule disruption or loss of income. Offering women the option to take mifepristone at home may also enhance patient choice for those women who come to the doctor's office intending to have a medical abortion but ultimately choose to have a surgical abortion because of scheduling issues. Lastly, home use of mifepristone has the potential to increase patient satisfaction for those women who wish to start the medical abortion process in the privacy of their homes, with their partners or families.

Many studies of medical abortion have sought to increase acceptability by giving women greater flexibility and autonomy [3–21]. Similarly, the objective of this study was to assess the acceptability of home use of mifepristone for termination of pregnancy among women who choose it and their providers. We also aimed to compare the experiences of women using mifepristone at home to those of women taking mifepristone in the doctor's office and to estimate the proportion of women who might be interested in this new option.

2. Methods

Women presenting for termination of pregnancies up to 63 days of gestation were recruited for this prospective, nonrandomized multicenter trial. The study was conducted from May 2009 through November 2010 at four urban, demographically diverse clinical sites in New York City, Philadelphia and Atlanta. Ethical approval for the study was obtained from the Allendale Institutional Review Board, as well as the institutional review boards of the Montefiore Medical Center, the Institute for Family Health and the University of Pennsylvania. All participants gave written informed consent.

Study participation was generally offered to women after they had made the decision to have a medical abortion, although at three of the sites, the study was mentioned to some women during options counseling. Gestational age was determined according to clinical protocols (two sites by transvaginal ultrasound, one site by first day of last menstrual period (LMP) plus bimanual examination and one site by either or both methods). Participants were given a choice between taking the mifepristone at home or in the office setting. Since one of our primary objectives was to evaluate the acceptability of home use of mifepristone, participant preference was important.

At enrollment, study staff completed a questionnaire with each participant, which included questions about mifepristone administration location choice, pregnancy history and employment status. Women were also asked open-ended questions about their reasons for choosing to take the mifepristone where they did. Those who chose home use were asked to provide a date and time for when they planned to take the mifepristone. Providers counseled women to select a date within the 63-day gestational limit and within 1 week of their abortion appointment. Participants were then given 200-mg mifepristone to take orally either at home or in the doctor's office, depending on their stated choice. Each participant was given four 200-mcg pills of misoprostol to be taken 6 to 48 h after mifepristone per their site's medical abortion protocol. Women also received a home study card with instructions to record the time and date of mifepristone and misoprostol administration, number of missed days of work and/or school and hours of paid childcare needed due to the abortion. Pain, antidiarrheal and antinausea medications were recommended according to each site's standard clinical protocol.

Participants returned to the doctor's office 1 to 2 weeks after mifepristone administration for a follow-up visit. If a clinician determined that the abortion was complete (based on clinical history, examination and/or vaginal ultrasound, as per clinical protocol), an exit interview was administered to collect data on aspects of participant satisfaction. Responses on the home study card regarding time of medication administration and days of missed work, school or childcare needed due to the abortion were also reviewed with the participant during the follow-up visit. If the participant was unable to return for her follow-up visit, this information was obtained over the phone by study staff when possible. For participants requiring additional follow up or a surgical completion, the exit interview was conducted once the abortion was complete. After a participant was discharged from the study, providers answered a hypothetical question about whether or not they would recommend this participant take mifepristone at home in the future.

Studies have demonstrated that 87–97% of women find home use of misoprostol acceptable [7,22,23]. We wished to show that the satisfaction rate for home use of mifepristone is comparable to reported satisfaction rates for home use of misoprostol, which is now standard in the US. We chose 87% as the minimum value that would be regarded as consistent with the conclusion that home use of mifepristone is as acceptable as standard care. Enrolling 114 women in the home-use group would allow us to estimate an acceptability rate of 92% with a confidence interval of ±5%. Since the study was not randomized, we could not know a priori what proportion of women were going to choose the home-mifepristone regimen. Therefore, we planned to enroll participants until at least 114 women were followed up in the home-use group and at least 100 women in the office-use group so as to be able to provide adequate descriptive data for women in both groups.

When analyzing our results, we used Fisher's Exact Test to determine differences in proportions, and for continuous variables, we used the Student's *t* test to assess differences in means. In our analysis of primary and secondary outcomes,

we considered two-tailed p values of less than .05 to be statistically significant. We calculated 95% confidence intervals for rates as exact binomial confidence intervals. We analyzed data using Statistical Package for the Social Sciences (SPSS) 17.0 (SPSS, Chicago, IL, USA).

3. Results

Between May 2009 and November 2010, the study sites enrolled 301 women, 139 (46.2%) who chose home use of mifepristone and 162 (53.8%) who chose office use. The proportion of women who chose home use ranged from 41%–54% among the four study sites. Thirteen women (9.4%) in the home-use group and 25 women (15.4%) in the office-use group were lost to follow up (p=.11). Outcome data were available for a total of 260 participants, and success rates did not differ between groups (96.7% for home users vs. 95.6% for office users, p=.75). Four women in the home-use group and five women in the office-use group reported visiting the emergency room (ER) for care related to their abortion. Only one of the women who visited the ER received a surgical completion as part of her care; she was also the only one who was subsequently admitted to the hospital (the other women received fluids, pain and antinausea medication). Besides that case, no serious adverse events occurred among the study participants.

Despite the nonrandomized sample, baseline characteristics, including age, gravidity and employment status, were similar for the two groups (Table 1). Home users were more likely to have had a previous abortion, but this difference was not statistically significant. Women were asked to provide reasons for their choice of where to take the mifepristone; more than half of home users cited the flexibility in schedule, and more than one fourth felt that it would be more comfortable (Table 2). Office users also reported comfort as a common reason for their choice; 28% reported that they wanted to start the process immediately, and 26% answered that they had already planned their schedule accordingly, reflecting the extensive phone counseling that precedes many medical abortion appointments.

Table 1
Participant characteristics

	Home mifepristone users n=139	Office mifepristone users n=162	p value
Age, years (mean, range)	28.0 (16–42)	27.4 (14–48)	.51
Gravidity, mean (range)	2.5 (1–9)	2.5 (1–9)	.93
Gestational age, days (mean, range)	47.3 (28–64)	47.4 (28–66)	.85
Had previous abortion, %	51.4	40.1	.06
Had previous medical abortion, %	25.5	26.1	1.0
Doing paid work, %	68.3	69.8	.80
Student, %	31.9	35.8	.54
Part-time student, %	9.4	9.9	1.0
Full-time student, %	22.5	25.9	.50

Table 2
Top five reasons for choosing mifepristone location

Home mifepristone users, n=139	Office mifepristone users, n=161
More flexibility in schedule (62%)	More comfortable (35%)
More comfortable (28%)	Want to start abortion immediately (28%)
More private (17%)	Already planned timing (26%)
Miss less work/school (15%)	Less anxiety (16%)
More compatible with household duties (14%)	Like provider presence (14%)

Women could give more than 1 answer.

Among participants in the home user group who returned for follow up and recorded a date and time of mifepristone administration, 74% took mifepristone at the scheduled time (defined as within a window of 12 h around the time they had recorded with the provider). Three women decided to keep the pregnancy and opted not to take the mifepristone. Of the 31 women who took the mifepristone at a time different from what they scheduled, 9 took it before, and 22 took it after their scheduled time (Table 3). For those women who delayed taking the mifepristone, the median delay was 25 h. Reasons women provided for not taking the mifepristone at the scheduled time included work/school conflicts, family schedule conflicts, wanting more time to consider the abortion and greater convenience. No participant took the mifepristone after 63 days' LMP.

Over 90% of women in both groups took the misoprostol at the scheduled time (Table 3). Participants in the home-use group were slightly more likely to take the misoprostol on a Saturday or Sunday (41% vs. 35%), but this difference was not significant. All participants took the misoprostol within 72 h of taking the mifepristone, including those women who did not take mifepristone at the scheduled time.

Nearly all women who chose home use said that they would choose to take the mifepristone at home again if they needed another abortion (95.0%), whereas 81.7% of office users said that they would choose office use again (p=.001) (Table 4). Most home users (97.5%) and 75% of office users would recommend home use to a friend (p=.001).

Participants in both groups were asked to report the best and worst features of taking the mifepristone where they did (Table 4). Home users most valued being able to schedule the bleeding around their responsibilities and found home use comfortable. Almost three fourths of home users could not cite a single worst feature; however, 11% did report feeling anxious. Office users also reported comfort as a key best feature, and about a third valued the presence of a provider when they administered the mifepristone. Four in five office users

Table 3
Timing of mifepristone and misoprostol administration

	Home mifepristone n=117	Office mifepristone n=124	p value
Mifepristone administration[a]			
Took mifepristone at scheduled time, % (n)	73.5 (86)	n/a	n/a
Took mifepristone before scheduled time, % (n)	7.7 (9)	n/a	n/a
Took mifepristone after scheduled time, % (n)	18.8 (22)	n/a	n/a
Median delay, h (range)	25 h (7 h–9 d)	n/a	n/a
Misoprostol administration			
Took misoprostol at the scheduled time, % (n)[b]	94.2 (81/86)	91.1 (113/124)	.59
Took misoprostol on the weekend, % (n)	41.0 (48/117)	35.4 (45/127)	.43
Median mifepristone–misoprostol interval, h (range)[c]	24 (6–49 h)	24 (5–69 h)	n/a

n/a=not applicable.

[a] Among women who returned for follow up and completed a patient diary.

[b] Excludes women who did not take mifepristone at the scheduled time.

[c] Clinical protocols at two sites allowed for mifepristone–misoprostol intervals as short as 6 h. Home mifepristone group is n=117 and n=125 for office mifepristone group.

could also not cite a worst feature of taking the mifepristone in the doctor's office.

There were no significant differences in the mean number of days of work missed, school missed and hours of paid childcare needed due to the abortion between study groups, although the associations are in the hypothesized directions (Table 5). Most women made no additional calls (85% for home users and 90% for office users) or unscheduled visits to the doctor's office (96% for home users and 99% for office users). Providers recommended home use in the future for over 90% of participants in both groups (95.1% for home users and 90.2% for office users).

4. Discussion

Our study shows that women are able to administer mifepristone safely and properly outside of the doctor's office and that administration under direct medical supervision is unnecessary. There were no differences in rates of efficacy or complications between participants who took the mifepristone at home or in the office. All women who opted for home use of mifepristone took it within 63 days' LMP, which is the current evidence-based gestational age limit for use, and all study participants took the misoprostol within 72 h of mifepristone administration, regardless of mifepristone

Table 4
Participant satisfaction and best/worst features of taking mifepristone at the chosen location

	Home mifepristone	Office mifepristone
Would take mifepristone in same place again, % (n)[a]	95.0 (114/120)	81.7 (103/126)
Would recommend home use to a friend, % (n)[b]	97.5 (115/118)	75.0 (93/124)
Best features (%):	n=120	n=132
Scheduled around responsibilities/flexibility	55.8	19.7
Comfortable	39.2	43.2
Private	34.2	4.5
Chose bleeding time	30.0	3.8
Partner/Friend present	13.3	0.0
Provider present	0.0	32.6
Not anxious	4.2	14.4
Not confusing	2.5	9.1
Worst features (%):		
None	74.2	81.8
Anxious	10.8	2.3
Confusing	4.2	0.8
Could not schedule around responsibilities	0.8	4.5
Opportunity for 2nd thoughts/delay	3.3	0.0

[a] p=.001.

[b] pb.001.

Table 5
Lost productivity[a] and service delivery burden

	Home mifepristone	Office mifepristone	p value
	n=85	n=95	
Mean days work missed (range)	0.51 (0–5)	0.81 (0–7)	
Missed 0 days, %	71.8	60.6	.16
	n=36	n=41	
Mean school days missed (range)	0.56 (0–7)	0.59 (0–5)	
Missed 0 days, %	77.8	65.9	.32
	n=49	n=53	
Mean h of paid childcare needed (range)	0.73 (0–24)	0.98 (0–16)	
Needed no paid childcare, %	95.9	88.7	.27
	n=138	n=161	
Unscheduled visits, # (range)	7 (0–2)	2 (0–1)	
Women making no unscheduled visits, %	96.4	98.8	.26
Total doctor's office calls, # (range)	40 (0–8)	25 (0–4)	
Women making no calls, %	84.8	90.1	.22

[a] Participants who were not employed, not in school or did not have children were excluded from the respective analyses.

administration location. Women who took the mifepristone at home were very satisfied with their experiences, and offering this option did not result in increased burden on clinical services in the form of calls and extra visits.

Regardless of where participants chose to take the mifepristone, many reported that the ability to plan when the abortion would occur was important to them. The option of home use enhances women's ability to plan their abortion experiences. Although it is reassuring that 74% of the participants in the home-use group took the mifepristone when they said they would during their initial visit, those women who took the mifepristone at a different time made good use of their greater autonomy; some took it earlier, some later, and several women used the flexibility as an opportunity to reflect further on their abortion decision. None of these women took the mifepristone and misoprostol in a nontherapeutic manner or in a way that was inconsistent with current guidelines.

A strength of our study is that our results are readily applicable to current clinical practice. Because our study design permitted participants to choose the place of mifepristone administration, we are able to report acceptability based on choice of where to initiate the abortion. Had we randomized participants to office versus home use, we would not have been able to describe this important outcome. Some providers reported improved counseling as an unanticipated benefit of the study. The process of talking through when and where women would take the abortion pills led to a greater understanding of the participants' privacy issues and support networks.

Our study has several limitations. We cannot predict with accuracy the future uptake of home use of mifepristone among all women seeking abortion because our study sites mainly offered the option of home use to those women who had already expressed interest in medical abortion. In addition, some women may have been interested in the option of home use but did not want to enroll in a research study to be able to have the opportunity. However, as almost half of participants chose home use, it is a fair conclusion that a substantial number of women would be interested in this option if it were incorporated into regular clinical practice.

Another potential limitation of our study is that more than half of our cases came from sites that offered medical abortion on Fridays and Saturdays. Because of the large number of participants who could take mifepristone in the office and still have weekend bleeding, we were likely unable to describe adequately the potential of home use for reducing childcare costs and the number of missed days of work or school for women undergoing medical abortion.

Home use of mifepristone is an innovation that stands to improve women's abortion experiences. In states where laws require women to receive inperson counseling 24 h or more before their abortion, home use has the potential to make medical abortion more accessible to women by eliminating a doctor's visit. Women who chose home use overwhelmingly approved of it, and taking the mifepristone at home did not result in increased complications or burden on clinicians. Our results support the use of home use of mifepristone, and this option should be offered to all women who undergo medical abortion.

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