Safety, Efficacy and Acceptability of Mifepristone-Misoprostol Medical Abortion in Vietnam

By Nguyen Thi Nhu Ngoc, Beverly Winikoff, Shelley Clark, Charlotte Ellertson, Khong Ngoc Am, Do Trong Hieu and Batya Elul

Context: *In developing countries where the demand for abortion services is high, such as Vietnam, the need for safe and effective alternatives to surgical abortion is great. Medical abortion using mifepristone and misoprostol may be an appropriate option in some of these countries.*

Methods: *In a comparative study of the safety, efficacy and acceptability of medical and surgical abortion, 393 women at two urban clinics chose between a mifepristone-misoprostol medical regimen and the standard surgical procedure offered in each clinic.*

Results: *Success rates for both methods were extremely high (96% for medical abortion and 99% for surgical abortion). Medical abortion patients reported many more side effects than women obtaining surgical procedures (most commonly, cramping, prolonged bleeding and nausea), but none of these side effects represented a serious medical risk. Nearly all women, regardless of the method they chose, were satisfied with their abortion experience. Additionally, among women who had previously undergone surgical abortion, those who selected medical abortion were more likely than those who chose surgery to say that their study abortion was more satisfactory than their earlier one (32% vs. 4%).*

Conclusions: *Mifepristone-misoprostol abortion is safe, effective and acceptable for urban Vietnamese women who are given a choice of methods. If similar results are observed for rural areas, the regimen could help meet the need for abortion services nationwide.*

International Family Planning Perspectives 1999, 25(1):10–14 & 33

In the past decade, several nonsurgical options have been developed for women seeking to terminate pregnancies. To date, however, medical methods of abortion have been officially approved only in several European countries and China. Although women in developed countries benefit from these new options, women in the developing world have a greater need for safe and effective alternatives to surgical abortion: Nearly all of the estimated 70,000 deaths each year due to unsafe abortion occur in developing countries.[1]

The administration of mifepristone, a powerful antiprogestin, coupled with a prostaglandin is a highly effective medical method of terminating pregnancy.[2] Of the most widely used prostaglandins, gemeprost and misoprostol, the latter shows the greater promise for use in developing countries. Misoprostol can be administered orally and is inexpensive, stable at ambient temperatures and widely available. By contrast, gemeprost is expensive, not widely available and provided in a vaginal suppository that requires refrigeration. In 1993, a large French trial confirmed the safety and efficacy of a regimen consisting of mifepristone and oral misoprostol.[3] This regimen, with a success rate of 96%, has been used extensively in France and may be available in the United States by the end of 1999.

Only two studies, however, have focused on the potential use of mifepristone and misoprostol for medical abortion in developing countries,[4] and only one of these measured the method's acceptability to clients.[5] Given the potential of medical abortion to improve conditions for women in developing countries, these women's perceptions of the method in general and of the mifepristone-misoprostol regimen in particular is critical to its acceptability. Patients' attitudes, expectations and tolerance of side effects influence surgical intervention rates; ultimately, for the method to work successfully, women must complete the regimen and wait while the treatment takes its course.

In Vietnam, the number of pregnancy terminations has risen steadily over the past 15 years and is now estimated at more than one million per year;[6] since the early 1990s, the annual number of abortions has exceeded the annual number of births.[7] A 1994 nationwide survey found that 13% of women have had at least one abortion.[8] Moreover, in 1992, the total abortion rate was estimated as 2.5 lifetime abortions per woman, the highest in Asia and the third-highest in the world.[9]

Additionally, the surgical abortion services available in Vietnam are marked by a number of safety and quality problems.[10] For example, sterilization of instruments is inadequate in some clinics, and management of pain requires improvement. Indeed, while some women receive no pain medication, others are medicated beyond the point of conscious sedation and are consequently unable to respond to physical or verbal stimuli.

Vietnamese officials have responded to this situation by committing themselves to offering a broader range of contraceptives. They have also increased efforts to improve the quality of abortion services, including investigating the addition of alternatives to surgical abortion.

In this article, we describe a study exploring the safety, efficacy and acceptability of mifepristone-misoprostol medical abortion among women attending two clinics in Vietnam. We address three important questions: First, is medical abortion as effective as surgical abortion for women who choose the method? Second, how do the safety, risks and side effects of medical abortion compare with those of surgical abortion? Third, do women who choose mifepristone-misoprostol abortion find the method acceptable? Answers to these questions can help policymakers and providers in Vietnam, as well as in other developing countries, determine if medical abortion is a feasible and desirable alternative method of pregnancy termination.

Methods

Study design plays a paramount role in the reliability and validity of acceptability data. In randomized clinical trials, which are designed primarily to collect safety and efficacy data, women are assigned to use a particular method. In our study, which was modeled on research conducted in China, Cuba and India,[11]

Nguyen Thi Nhu Ngoc is vice director, Hung Vuong Hospital, Ho Chi Minh City, Vietnam; Khong Ngoc Am is retired director, Maternal and Child Health and Family Planning, Hanoi Obstetric and Gynecology Hospital, Hanoi, Vietnam; and Do Trong Hieu is chief, Maternal and Child Health Department, Ministry of Health, Hanoi. Beverly Winikoff is director, Reproductive Health; Shelley Clark is consultant; Charlotte Ellertson is program associate; and Batya Elul is staff program associate—all with the Population Council, New York. This study was funded by an anonymous donor. The authors thank Kurus Coyaji and Andrea Eschen for their assistance.

women were allowed to choose their abortion method. This design reflects more closely the situation under which the method will be used when offered in a clinic. Thus, a sample of women who have chosen between medical and surgical abortion constitute the correct population from which to generalize about the acceptability of both methods. A drawback, however, is that safety and efficacy data can be generalized only to women who choose between methods.

The study was conducted from January 1995 to April 1996 in the two largest urban centers in Vietnam, Hanoi and Ho Chi Minh City; one clinic in each city participated. Both facilities had legal, established surgical abortion services. Although abortion services in Vietnam generally are of rather poor quality, these clinics had among the best services.

Both sites followed a uniform study protocol. Women seeking abortions could participate if bimanual examination showed that they were no more than eight weeks pregnant (or if it had been no more than 56 days since their last menstrual period), they had no contraindications to medical or surgical abortion, they lived within one hour of the clinic and they were willing to return for follow-up visits. Women aged 35 or older were ineligible if they smoked 10 or more cigarettes per day.

If a woman met the study criteria and wished to participate, a trained provider explained both abortion methods. All women received standardized counseling about both procedures and their most common side effects. For example, women were told that medical abortion is a relatively new method, that it requires taking two sets of pills orally and that after the second set of pills, most women experience cramping for several hours and bleeding for several days.* Moreover, they were informed that in French studies, this medical abortion regimen was about 95% effective. The provider also explained the types of surgical abortion available at the clinic and that this method was nearly 100% effective. Explicit comparisons between medical and surgical abortion were avoided, however, so as not to bias women's selection. After hearing about both methods, women chose between them. Any women who could not decide would have been randomized to a method, but no participants were undecided. All women gave informed consent.

Women who chose medical abortion received 600 mg of mifepristone at their admission visit and remained under observation for 30 minutes. At a second visit, two days later, they received 400 mcg of misoprostol orally and were monitored at the clinic for at least four hours. Participants were instructed to return for a follow-up exam and an exit interview 14 days later, and were told to come to the clinic at any time before then if they were worried or if they changed their mind about the method. The women were not given any medication to control pain, since such medications are easily available over the counter in Vietnam.

Generally, if the abortion was not complete at the follow-up visit, surgical abortion was performed as a backup. Among the 10 women who had backup procedures, five underwent vacuum aspiration and three had sharp curettage; the method was unknown for the other two. Three women whose abortions were incomplete at the follow-up visit were permitted to keep waiting rather than receiving surgical abortions. They returned later for additional follow-up.

Patients who chose surgical abortion had the procedure on their first visit, in accordance with the clinics' regular practices. Nearly all of these women (98%) received vacuum aspiration without dilation. (Two women had vacuum aspiration with dilation, and one woman underwent sharp curettage.) In Ho Chi Minh City, all surgical abortion patients received local anesthesia, while in Hanoi, most did not receive any anesthesia. Fourteen days after the procedure, patients returned to the clinic for a checkup and exit interview.

Clinic physicians were already trained in providing surgical abortions and received additional training in medical abortion for the study. They provided all of the surgical procedures, administered about half of the medical abortions and supervised the nurses who administered the other half. The in-country principal investigators closely monitored the study to ensure standardized treatment. Before the main study began, each site conducted a pilot study of 10 medical patients. Data on these women are included in our analyses, since no significant changes were made to the protocol following review of their experiences.

Providers collected clinical and experiential data from each patient. Questions covered procedures, medications, side effects or problems, and the woman's reaction to the abortion experience. Additionally, women completed a daily diary of all side effects during the weeks of the study and indicated when they thought their abortion had occurred. Finally, since women who had had previous abortions may have been influenced by their earlier experiences, these women were asked to compare their study abortion and their prior abortion.

Table 1. Selected characteristics of women obtaining abortions, by method, Hanoi and Ho Chi Minh City, Vietnam, 1995–1996

Characteristic	Medical (N=260)	Surgical (N=133)
Mean age	26.4	27.9**
Mean weight (kg)	46.4	46.6
Mean height (cm)	155.8	154.5**
Mean education (yrs.)	11.6	10.6**
Mean gestational age (wks.)	5.9	6.1*
% with first pregnancy	35.4	30.1
% married/in union	73.1	84.2*
% who had used contraceptives	37.7	58.6***
% who had had previous abortion	48.5	43.6

*Difference between medical and surgical abortion patients is significant at p≤.05. **Difference between medical and surgical abortion patients is significant at p≤.01. ***Difference between medical and surgical abortion patients is significant at p≤.001. *Note:* While the number of medical patients was roughly equally distributed by site (48% from Hanoi, 52% from Ho Chi Minh City), the distribution of surgical patients was quite uneven (72% from Hanoi, 28% from Ho Chi Minh City). Thus, the background data presented for surgical clients are more heavily weighted toward Hanoi.

Data entry and analysis were performed using standard statistical software (SPSS) and procedures. All means testing used t-tests, with Levene's tests conducted to determine whether pooled or separate variance estimates were appropriate. Chi-square tests were used to analyze categorical data. All tests were two-tailed.

Results

Sample Characteristics

The sample consisted of 393 women—221 in Hanoi and 172 in Ho Chi Minh City. Overall, 260 women chose medical abortion and 133 opted for a surgical procedure (Table 1).†

Women who selected the medical method were slightly younger than those who decided on surgical abortion (26.4 vs. 27.9 years) and had had more years of schooling (11.6 vs. 10.6). Both groups sought to terminate their pregnancies quite early, but the mean gestational age was somewhat lower among women who chose the medical method (5.9 weeks) than among those who opted for surgery (6.1 weeks). Women undergoing medical abor-

*If a woman asked how long a medical abortion takes, she was informed that while the majority of women experience a complete abortion within several hours of taking the second set of pills, some wait up to two weeks to have a complete expulsion.

†This ratio is not meaningful, because many women who preferred surgical abortion (particularly in Ho Chi Minh City) saw no reason to enroll in the study rather than simply to undergo the standard procedure.

Table 2. Percentage of abortion patients citing various reasons for selecting their method, by method

Reason	Medical (N=258)	Surgical (N=131)
Effective	5.4	64.1
Simpler and faster	†	67.9
Less pain	58.9	†
Safer	40.4	47.3
Avoids surgery/anesthesia	43.4	†
Easier emotionally	30.2	†
Fewer visits	†	27.5
Convenient	7.8	26.0
Less bleeding	†	7.6
More natural	6.2	†
Private	5.8	†
Fewer side effects	†	3.8

†Cited by one woman or no women. *Note:* Women could cite up to three reasons.

tion were less likely than those having surgical procedures to be married (73% vs. 84%) and to have been using a contraceptive (38% vs. 59%). The differences in age and length of gestation, however, were no longer statistically significant once we controlled for study site (not shown).

Method Choice and Adherence to Protocol

Upon enrollment in the study, women were asked to name up to three reasons for their method selection. Among women who selected the medical method, 59% did so to avoid pain (Table 2). Substantial proportions also chose the medical method to avoid surgery or anesthesia (43%), or because they believed that it was the safer option (40%) or that it would be less traumatic (30%).

In contrast, women choosing surgical abortion did so mainly because they perceived it to be simpler and faster (68%) or more effective (64%) than medical abortion. As with the medical patients, safety concerns loomed large in the minds of surgical patients (47%). Large proportions of women also decided to undergo surgery because it entailed fewer visits (28%) or was convenient (26%). Fear of side effects was not a major concern to women in either group when they selected their method.

Only three medical abortion patients did not complete the protocol. One woman, feeling worried and fatigued, went to another clinic before taking misoprostol and obtained a surgical abortion. Another woman did not return to the clinic in time to receive misoprostol and had a surgical intervention. The third woman requested a surgical abortion at another clinic after taking misoprostol because she had experienced only spotting and not heavy bleeding. All three are included in the analysis.

Efficacy and Safety

Since medical abortion clients selected their method to avoid surgery, we considered any of these women who underwent a surgical procedure for any reason to represent a treatment failure.[12] All surgical abortion patients who had more than one surgical procedure were also deemed to represent treatment failures.

Three types of failures can occur among medical patients: user choice, provider choice (or error) and true drug failures. User choice failure occurs when a woman asks for surgical intervention prior to the end of the study or is unable or chooses not to take the complete medical treatment. Provider choice failure occurs when a provider performs or recommends medically unwarranted surgical interventions (either out of impatience or in reaction to a concern with no clear medical basis). True drug failure occurs when an adverse event requires surgical intervention during the study period or when an abortion is not complete by the end of the study.

Failure rates for both abortion methods were extremely low (Table 3). Only one surgical patient (1%) required a backup intervention. Among medical patients, there were 10 failures (for a rate of 4%): six user choice, one provider choice and three true drug failures.*

Table 3. Percentage distribution of abortion patients, by outcome, and percentage of patients citing various side effects, by method

Measure	Medical (N=257)	Surgical (N=124)
Outcome		
Successful abortion	96.1	99.2
Failure	3.9	0.8
Total	100.0	100.0
Side effects		
Nausea	39.3	0.8***
Vomiting	17.1	2.4***
Cramping/abdominal pain	96.1	37.1***
Diarrhea	5.8	0.0**
Profuse bleeding	8.9	4.8
Prolonged bleeding	80.5	25.8***

**Difference between medical and surgical abortion patients is significant at $p \leq .01$. ***Difference between medical and surgical abortion patients is significant at $p \leq .001$. *Note:* Patients who were lost to follow-up are excluded.

Diligent efforts were made to minimize loss to follow-up. All women who did not report for a scheduled appointment were sent up to three reminder letters. Only after providers made home visits in an effort to trace these patients were the women designated as lost to follow-up. In total, nine surgical patients (7%) and three medical abortion patients (1%) were lost to follow-up. All available data from these 12 women are included in our analysis.

Side effects—nausea, vomiting, cramping, pain, diarrhea and bleeding—were far more common among the medical abortion clients than among the women who chose surgery (Table 3). However, although we have included cramping and bleeding as side effects, they may be symptoms of a medical abortion; indeed, if they do not occur, the woman is unlikely to have a successful medical abortion.

Furthermore, medical abortion patients were observed on more occasions (at least three visits vs. at least two) and for a longer period of time (17 vs. 15 days) than were surgical abortion patients. More important, even for medical clients, none of the observed side effects represented a serious medical risk.

Side effects of medical abortion varied at different stages of the procedure (Table 4). Women were more likely to report nausea and vomiting after taking mifepristone than later in the abortion process, but this may reflect symptoms of pregnancy. (Indeed, upon enrollment in the study, 43% of all women reported nausea—42% who chose medical abortion and 46% who opted for surgical—and 6% reported vomiting.) Cramping and abdominal pain increased sharply during the four-hour observation period immediately after administration of misoprostol, but subsided later. Profuse bleeding, although never experienced by more than 5% of the medical abortion clients, was also most likely during these four hours.

Table 4. Percentage of medical abortion patients experiencing various side effects, by segment of the regimen

Side effect	After mifepristone, before misoprostol (N=258)	During observation after misoprostol (N=259)	After observation, until exit (N=257)
Nausea	37.6	6.9	6.2
Vomiting	15.9	0.8	2.3
Cramping/abdominal pain	38.8	93.8	37.7
Diarrhea	1.2	3.1	2.7
Prolonged bleeding	0.0	0.0	80.5
Profuse bleeding	2.7	4.2	2.3
Increased bleeding	0.0	94.6	0.0

Note: The observation period after administration of misoprostol was at least four hours.

*At the follow-up visit, three medical abortion patients had had incomplete abortions and were permitted to keep waiting for their abortions to become complete. Two of these women had complete abortions confirmed when they returned for an additional follow-up visit, a few days to one month after the first; the third woman received a surgical intervention, because her abortion still was not complete three days after her initial follow-up visit.

Among the most serious risks of abortion, regardless of the method used, is excessive blood loss during and following the procedure. On average, the women in both groups experienced minimal blood loss (Table 5). Only 2% of women who had medical abortions and 1% of their counterparts who had surgical procedures experienced a reduction in their hemoglobin levels of greater than 2 g per deciliter (which is considered clinically meaningful blood loss), and none required a transfusion (not shown).

Analysis of participants' diaries showed that medical abortion clients reported more blood loss than did surgical abortion patients. The mean number of days of bleeding (i.e., heavy, normal or light) was significantly greater for women who had medical abortions than for those who had surgical abortions.* For both groups, however, heavy bleeding accounted for only a small number of total bleeding days.

Expectations about both the amount and the duration of bleeding also differed between the medical and surgical groups. Medical abortion patients were more likely than surgical patients to have bled more and longer than they had expected to.

Acceptability

Where and when an abortion occurs after a medical procedure may significantly influence the method's acceptability. According to participants' diaries, 82% of medically induced abortions took place on the day the women received misoprostol, and 8% took place throughout the next two weeks. However, medical abortion early in gestation can escape detection; 10% of medical abortion patients did not recognize when their abortions occurred.

Table 5. Measures of bleeding experienced by abortion patients, by method

Measure	Medical	Surgical
MEANS		
Hemoglobin level (g/dl)	(N=253)	(N=123)
At entry	11.8	11.6
At exit	11.7	11.6
Change	–0.1	–0.1
Days of bleeding* **	(N=257)	(N=124)
Heavier than usual menses	1.3 (2.2)	0.4 (0.8)
Like normal menses	3.1 (2.7)	2.2 (1.2)
Lighter than usual menses	6.2 (3.5)	3.1 (1.7)
PERCENTAGE DISTRIBUTIONS		
Amount of bleeding*	(N=257)	(N=124)
More than expected	25.3	16.9
As much as expected	57.2	65.3
Less than expected	16.0	11.3
Not sure/do not know	1.6	6.5
Duration of bleeding* **	(N=257)	(N=124)
Longer than expected	49.0	24.2
As long as expected	34.2	58.1
Shorter than expected	14.8	11.3
Not sure/do not know	1.9	6.5
Total	100.0	100.0

*Difference in distribution between medical and surgical abortion patients is significant at p≤.05. ***Difference in distribution between medical and surgical abortion patients is significant at p≤.001. Notes: For days of bleeding, numbers in parentheses are standard deviations.

Most medical patients could identify where they were when the abortion occurred (even if they could not pinpoint the time of the abortion). Nearly three-quarters (72%) reported that their abortions occurred at the clinic, but many (20%) said theirs occurred at home. About 1% reported other locations, and the rest were unsure.

At the exit visit, all but one patient (who had had a surgical procedure) stated that the explanation they had received about their method adequately prepared them for the abortion experience. The remaining woman reported that the experience was worse than she had expected it to be.

The vast majority of women were satisfied with their abortion experience—97% of those who had medical procedures and 95% who had surgical abortions (Table 6). Of the 13 women who were not satisfied with the experience, five had had method failures. Nevertheless, about half of women who had failures remained satisfied with their abortions. A patient who had undergone a surgical intervention after the medical procedure failed concluded that there was nothing wrong with the medical method, but that she was simply "unlucky."

In all, 178 women had had a previous surgical abortion—60% vacuum aspiration, 37% dilation and curettage, and 3% some other surgical procedure. When asked how their experience during the study compared with their previous abortion experience, women who had medical abortions were significantly more likely than those who had surgical procedures to say that their study experience was more satisfactory (32% vs. 4%). Medical clients were less likely than surgical clients to report that the study abortion was not as satisfactory as their previous abortion (3% vs. 11%).

Women who had medical abortions were significantly more likely to say they would select the same method again than were those who selected surgical abortion (96% vs. 52%). Nearly all (95%) medical abortion clients would recommend their method, compared with only 28% of surgical abortion clients.

Additionally, 37% of surgical abortion clients would recommend medical abortion to friends, while only 2% of medical abortion clients would recommend surgical abortion. Thus, in hindsight, some of the surgical abortion clients believed that the alternative procedure was preferable to the one they had chosen, perhaps because of discussions they had with women who obtained the other procedure.

Table 6. Percentage distribution of abortion patients, by measure of satisfaction with their method, according to method

Measure	Medical	Surgical
Satisfaction	(N=257)	(N=124)
Highly satisfied	5.4	2.4
Satisfied	91.8	92.7
Not satisfied	2.7	4.8
Would choose method again* **	(N=256)	(N=123)
Yes	95.7	51.6
No	4.3	48.4
Would recommend method* **	(N=251)	(N=124)
Medical	95.2	37.1
Surgical	2.0	28.2
Either	2.8	34.7
Comparison with previous abortion* **	(N=121)	(N=57)
More satisfactory	32.2	3.5
As satisfactory	64.5	86.0
Less satisfactory	3.3	10.5
Total	100.0	100.0

***Difference in distributions between medical and surgical abortion patients is significant at p≤.001.

At their final visit, women were asked to describe the best and worst aspects of their abortion method (Table 7, page 14). Each was permitted up to three answers. For medical abortion, the features most frequently cited by patients were that the method is less painful than surgical abortion (35%), is safer (30%), does not involve surgery (20%) and is effective (14%). The emphasis on less pain is not surprising, given that surgical abortion is delivered with minimal anesthesia in Vietnam.

Prolonged heavy bleeding was most commonly reported as the worst feature of medical abortion (mentioned by 39% of women). A substantial proportion of medical clients (17%) also reported that the method involved too many visits and too lengthy a follow-up. Some 30% of women who had medical abortions, however, were unable to offer any negative features of the method.

Women who chose surgical abortion clearly appreciated the method's effectiveness (46%), as well as the ease and simplicity of the procedure (23%). Yet 23%

*Analysis of the mean number of days of bleeding, however, overestimates the total number of days of bleeding, since diary entries recording different types of bleeding on a single day were counted as separate days of bleeding. Thus, for example, if a woman recorded both normal and heavy bleeding one day, she was counted as having had a full day of each.

Table 7. Percentage of abortion patients citing various features as their method's best and worst characteristic, by method

Feature	Medical (N=257)	Surgical (N=124)
Best		
Effective	14.4	46.0
Less pain	34.6	†
Safer/less risk of complication	30.4	7.3
Faster/easier/simpler	5.1	23.4
None/not sure	8.2	22.6
Avoids surgery	19.8	†
Less mental stress/ healthier	7.4	†
Convenient/compatible with duties	6.6	4.0
Worst		
Pain	†	57.3
Prolonged heavy bleeding	38.9	22.6
None/not sure	30.0	18.5
Too many visits/lengthy follow-up	16.7	†
Fear of surgery	†	10.5
More mental stress	†	8.9
Long waiting time until abortion	7.8	†
Fatigue/dizziness	5.1	†

†Cited by one woman or no women. *Note:* Women could cite up to three reasons.

were unable to name any good characteristics of the method. Although surgical abortion clients reported far less pain during the study than did medical clients, 57% considered pain the method's worst feature. Surgical clients also included fear of surgery and mental stress among the worst features of their method.

Discussion

Our findings suggest that mifepristone-misoprostol medical abortion is a safe, effective and desirable alternative to surgical abortion in Vietnam. The method's success rate in our study (96%) is the highest documented in a developing country[13] and is comparable to the rate found in developed countries.[14] Moreover, while the medical abortion failure rate in our study exceeds that of the surgical method, many Vietnamese women apparently are willing to accept an increased risk of failure, since most said they would choose medical abortion again and would recommend it to their friends.

Three women whose pregnancies had not yet terminated as of their exit visits were advised to return for additional follow-up rather than receive surgical intervention. Two had had complete abortions by the time they returned and thus required no backup procedure, while the third eventually received sharp curettage to complete her abortion. This experience confirms that the method's failure rate is largely a function of the protocol employed and suggests that the date of the follow-up visit can be successfully delayed beyond the current standard of two weeks, which has been adopted from the surgical regimen.

Side effects were more common among medical abortion clients than among surgical clients, but they did not jeopardize the safety of the medical regimen and were tolerable for the vast majority of women who chose that method. However, women who had medical abortions reported bleeding more and longer than they had expected and more frequently than women who obtained surgical procedures. Since women's expectations may significantly affect their comfort and satisfaction with a method, medical abortion patients must receive appropriate advance information to prepare them for the method's potential side effects.

This trial was conducted in major clinics in large urban areas, where backup facilities are easily accessible and of reasonably high quality. Studies in rural areas with more basic facilities are needed before the method's safety, effectiveness and acceptability for women throughout the country can be judged. Additionally, since many medical abortion clients reported that the regimen involved too many visits and many surgical clients chose their method because it entailed fewer visits, research into a simplified protocol involving fewer clinic visits is important. Nevertheless, our results indicate that mifepristone-misoprostol medical abortion can complement available surgical services and help meet the pressing need for safe, effective and acceptable abortion services in Vietnam.

References

1. World Health Organization, *Abortion: A Tabulation of Available Data on the Frequency and Mortality of Unsafe Abortion*, second ed., Geneva: World Health Organization, 1994.

2. Bygdeman M et al., Progesterone receptor blockage: effect on uterine contractility and early pregnancy, *Contraception*, 1985, 32(1):45–51.

3. Peyron R et al., Early termination of pregnancy with mifepristone (RU 486) and the orally active prostaglandin misoprostol, *New England Journal of Medicine*, 1993, 328(21):1509–1513.

4. He C et al., Study on safety and efficacy of mifepristone plus misoprostol for termination of early pregnancy, *Reproduction and Contraception*, 1992, 3:1–10; and Winikoff B et al., Safety, efficacy, and acceptability of medical abortion in China, Cuba, and India: a comparative trial of mifepristone-misoprostol versus surgical abortion, *American Journal of Obstetrics and Gynecology*, 1997, 176(2):431–437.

5. Winikoff B et al., 1997, op. cit. (see reference 4).

6. Goodkind D, Abortion in Vietnam: measurements, puzzles, and concerns, *Studies in Family Planning*, 1994, 25(6, part 1):342–352.

7. Johansson A et al., Abortion in context: women's experience in two villages in Thai Binh Province, Vietnam, *International Family Planning Perspectives*, 1996, 22(3): 103–107.

8. Statistical Publishing House, *Vietnam Intercensal Demographic Survey, 1994: Major Findings*, Hanoi, Vietnam: Statistical Publishing House, 1995.

9. Goodkind D, 1994, op. cit. (see reference 6).

10. Vietnamese Ministry of Health, A strategic assessment of policy, programme and research issues relating to abortion in Vietnam: a draft report, Hanoi, Vietnam, 1997.

11. Winikoff B et al., The acceptability of medical abortion in China, Cuba and India, *International Family Planning Perspectives*, 1997, 23(2):73–78 & 89; and Winikoff B et al., 1997, op cit. (see reference 4).

12. Winikoff B et al., Analysis of failure in medical abortion, *Contraception*, 1996, 54(6):323–327.

13. Winikoff B et al., 1997, op. cit. (see reference 11); and Winikoff B et al., 1997, op. cit. (see reference 4).

14. Winikoff B et al., 1997, op. cit. (see reference 4); Peyron R et al., 1993, op. cit. (see reference 3); and Aubény E et al., Termination of early pregnancy (up to and after 63 days of amenorrhea) with mifepristone (RU 486) and increasing doses of misoprostol, *International Journal of Fertility*, 1995, 40(Suppl. 2):85–91.

Resumen

Contexto: *En los países en desarrollo donde es elevada la demanda de servicios de aborto, tales como Vietnam, es enorme la necesidad que existe de contar con alternativas seguras y eficaces para evitar la intervención quirúrgica. Una buena opción en algunos de estos países puede ser el aborto médico realizado mediante el uso del mifepristone y el misoprostol.*

Métodos: *En un estudio comparativo realizado sobre la seguridad, la eficacia y la aceptabilidad de los abortos médico y quirúrgico, 393 mujeres de dos clínicas urbanas eligieron entre el método médico en base a mifepristone y misoprostol y el procedimiento quirúrgico estándar.*

Resultados: *Las tasas de éxito para ambos métodos resultaron extremadamente elevadas (96% para el aborto médico y 99% para el aborto quirúrgico). Las pacientes del aborto médico indicaron un número mucho mayor de efectos secundarios que las que se sometieron a procedimientos quirúrgicos (más comúnmente dolores, sangrado prolongado y náuseas), aunque ninguno de estos efectos secundarios representó un riesgo médico serio. Casi todas las mujeres, fuere cual fuere el método escogido, se mostraron satisfechas con su experiencia. Además, entre las mujeres que previamente se habían sometido a un aborto quirúrgico, aquellas que escogieron un aborto médico eran más proclives que las que dicidieron de someterse a un aborto quirúrgico a indicar que su aborto actual era más satisfactorio que el anterior (32% contra 4%).*

Conclusiones: *El aborto médico en base a mifepristone y misoprostol es seguro, eficaz y*

(continued on page 33)

Medical Abortion in Vietnam...

(continued from page 14)

aceptable para las mujeres vietnamitas de zonas urbanas que tienen la opción de escoger un método. Si se observan resultados similares en las zonas rurales, este sistema podría satisfacer la necesidad insatisfecha de servicios de aborto que existe a nivel nacional en el país.

Résumé

Contexte: *Dans les pays en voie de développement qui présentent une demande de services d'avortement élevée (le Viet Nam, par exemple), il existe un besoin important de solutions súres et efficaces autres que les procédures chirurgicales. L'avortement médical à base de mifepristone et de misoprostol pourrait offrir une option viable dans certains de ces pays.*

Méthodes: *Dans une étude comparative de la sécurité, de l'efficacité et de l'acceptabilité de l'avortement médical et chirurgical, 393 femmes rencontrées dans deux cliniques urbaines ont choisi entre un régime médical à base de mifepristone-misoprostol et la procédure chirurgicale ordinaire offerte dans chaque clinique.*

Résultats: *Les taux de succès des deux méthodes se sont avérés extrÍmement élevés (96% pour l'avortement médical et 99% pour la méthode chirurgicale). Les patientes ayant choisi la procédure médicale ont signalé beaucoup plus d'effets secondaires que celles qui avaient demandé l'intervention chirurgicale (douleurs abdominales, saignements prolongés et nausées, surtout), mais aucun de ces effets ne présentait de risque médical grave. Indépendamment de la méthode choisie, presque toutes les femmes se sont déclarées satisfaites de leur expérience. De celles qui avaient subi un avortement chirurgical précédent, celles ayant choisi la procédure médicale se sont du reste révélées plus susceptibles, par rapport à leurs homologues qui avaient de nouveau choisi la méthode chirurgicale, de qualifier la procédure incluse dans l'étude de plus satisfaisante que la précédente (32% par rapport à 4%).*

Conclusions: *L'avortement provoqué par mifepristone-misoprostol offre une méthode súre, efficace et acceptable aux yeux des Vietnamiennes auxquelles un choix de méthode est offert. Si des résultats comparables étaient observés dans les milieux ruraux, le régime pourrait aider à répondre au besoin de services d'avortement à l'échelle nationale.*