Vaginal Misoprostol Administered 1, 2, or 3 Days After Mifepristone for Early Medical Abortion
A Randomized Trial

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Mifepristone, a synthetic antiprogestrone, has been shown to be an effective abortifacient when combined with a prostaglandin administered 2 days later, by competitively blocking the progesterone necessary to maintain a pregnancy. Effectiveness ranges from 92% to 97%.1-4

Oral misoprostol is a synthetic prostaglandin widely marketed worldwide for prevention of nonsteroidal anti-inflammatory drug–induced gastric ulcer. Used 2 days after mifepristone, it increases the success rate of a medical abortion. For more advanced gestations (>49 days), misoprostol administered vaginally compared with orally has fewer adverse effects, a shorter wait to start of bleeding, and increased effectiveness.5 Vaginal administration of misoprostol results in a sustained blood level of the drug rather than the quick peak level and rapid metabolism noted after oral administration,6 a profile that might explain the greater effectiveness in patients with more advanced gestational age.

Conventional timing mandates misoprostol administration 48 hours after mifepristone for medical abortion is 2 days, but more flexible intervals, which may make the regimen more convenient, have not been studied.

Context The conventional timing of misoprostol administration after mifepristone for medical abortion is 2 days, but more flexible intervals, which may make the regimen more convenient, have not been studied.

Objective To determine whether vaginal misoprostol administered 1, 2, or 3 days after mifepristone influences safety or effectiveness for abortion at up to 56 days’ gestation.

Design Prospective, randomized, open-label trial conducted from March 1998 to June 1999.

Setting Sixteen US primary care and referral abortion facilities.

Patients A total of 2295 healthy patients aged 18 years or older who were 56 or fewer days pregnant. Forty (1.7%) were lost to follow-up.

Interventions Patients received 200 mg of oral mifepristone and were randomly assigned to self-administer 800 µg of vaginal misoprostol at home 1 (n = 745), 2 (n = 778), or 3 (n = 772) days later. Women returned to the clinic up to 8 days after mifepristone for ultrasonographic evaluation. A second dose of misoprostol was administered if the abortion was not complete. Patients with continuing pregnancy, excessive bleeding, or retained pregnancy tissue 5 weeks later received an aspiration curettage.

Main Outcome Measures Effectiveness of the procedure (ie, a complete medical abortion without surgical intervention), adverse effects, acceptability of the procedure based on patient questionnaires, reasons for surgical intervention, and adverse outcomes, compared among the study groups.

Results Of the 2255 women completing follow-up, complete medical abortion rates were 98% (95% confidence interval [CI], 97%-99%) among those using misoprostol after 1 day, 98% (95% CI, 97%-99%) for those using misoprostol after 2 days, and 96% (95% CI, 95%-97%) among those using misoprostol after 3 days. Fifty-five subjects aborted before taking misoprostol, 9 had early surgery, and 103 did not take misoprostol on their assigned day. No blood transfusions were required. Cramping and nausea were the most common adverse effects reported, with similar percentages of patients in all 3 groups reporting such effects. Thirteen unexpected or serious adverse events occurred: 6 in those using misoprostol after 1 day; 4 in those using it after 2 days; and 3 in those using it after 3 days. Nearly all women (>90%) found the procedure to be acceptable.

Conclusions Our results suggest that vaginal misoprostol, 800 µg, can be used from 1 to 3 days after mifepristone, 200 mg, for early medical abortion, and need not be administered strictly 48 hours after mifepristone.

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ter mifepristone, but no studies have investigated alternative schedules. More flexible intervals would make the regimen substantially more convenient for patients and clinicians, for example, by permitting clinicians who want to observe patients taking each of the drugs to schedule mifepristone administration visits on Thursdays and Fridays, even if their clinics were closed on weekends.

We sought to determine whether 800 µg of vaginal misoprostol could be administered 1, 2, or 3 days after 200 mg of mifepristone without reducing the safety and efficacy of the standard 2-day protocol for women seeking early abortion. The US Food and Drug Administration’s labeling of mifepristone may require misoprostol to be used in a clinical setting 2 days after mifepristone, with clinical monitoring for up to 4 hours, as occurs in France. In the United States, many clinicians likely would not want to administer mifepristone on a Thursday or Friday because they generally do not have office hours 2 days later during the weekend, when mifepristone would be taken. It is evident from US trials of methotrexate and misoprostol and mifepristone and misoprostol that women can safely self-administer misoprostol outside the clinic. We hypothesized that the 2-day protocol was unnecessarily restrictive and that misoprostol could be administered at home from 1 to 3 days after mifepristone administration, without compromising effectiveness.

METHODS

This study was a prospective, open-label, randomized multicenter trial. Randomization was stratified by site. Sixteen sites participated, including hospital abortion services, abortion clinics, private family practice offices, and gynecology offices. All sites had institutional review board approval and all participants provided written informed consent. Study drug was supplied by the Abortion Rights Mobilization.

Participants were at least 18 years old, no more than 56 days pregnant, healthy, and desired an abortion of a confirmed intrauterine pregnancy. The inclusion and exclusion criteria and method of routine gestational dating by ultrasonography followed previously reported protocols. All women had transvaginal ultrasonographic dating and monitoring of their abortion, and β-human chorionic gonadotropin testing was not required. On study day 1, women drew their concealed, computer-generated randomized assignments of misoprostol 1, 2, or 3 days after mifepristone. Women then received mifepristone, 200 mg, in the office and were instructed to use the vaginal misoprostol between 7 AM and midnight on their assigned day. Women in the group assigned to use misoprostol 1 day after mifepristone were instructed to wait at least 24 hours before using misoprostol but could administer it until midnight of the assigned day. Women had the option of inserting the misoprostol at home or returning to the office for administration by clinic staff. Those using misoprostol at home were given 800 µg (four 200-µg tablets) of misoprostol and instructed on how to insert the dry misoprostol tablets high into the vagina with a finger. Women were provided with acetaminophen with codeine as analgesia. All women using misoprostol at home were required to have an emergency plan to seek medical care in case bleeding became excessive. Women returned for their follow-up visit at their discretion anytime between 1 day after misoprostol use to 7 days after mifepristone administration (ie, study day 8).

At the first follow-up visit, if ultrasonography demonstrated that the gestational sac was no longer present, the abortion was considered complete. Patients with a persistent gestational sac received a second dose of misoprostol, 800 µg vaginally, and returned between 1 day later and study day 15 after mifepristone use, at the subject’s discretion. At the second follow-up visit, if the gestational sac was still present but there had been no interval growth, patients were permitted to keep waiting for a successful medical abortion and to return on or before study day 36. If there had been interval growth, indicating an ongoing pregnancy, an aspiration curettage was performed. An aspiration curettage was also performed if a gestational sac was still present at study day 36 or if excessive bleeding or other severe symptoms occurred at any time. At each visit, we interviewed patients about symptoms and use of medications. Patients who requested oral contraceptive pills started taking them on the first Sunday after vaginal bleeding started after a documented complete abortion. Women reported by telephone or postcard the date when vaginal bleeding stopped.

After the abortion was confirmed by ultrasonography, regardless of whether it was a successful medical abortion or an aspiration curettage following a failed medical abortion, participants completed an acceptability questionnaire. Patients used Likert scales (strongly disagree, disagree, neutral, agree, or strongly agree) to rate the acceptability of the overall procedure, cramping pain, bleeding, adverse effects from the medications, waiting time to complete abortion, willingness to recommend using misoprostol at home, willingness to recommend the procedure to another woman, and willingness to choose medical abortion again if they ever wanted another abortion. We combined the ratings of “agree” and “strongly agree” for our analysis.

Women were considered lost to follow-up if there was no documentation of their outcomes after multiple attempts by study personnel to contact them by telephone and certified letter. We accepted documentation of a negative home pregnancy test result as evidence of a complete medical abortion for women who did not return for follow-up.

Outcome measures included effectiveness rates (by Pearson χ² test), reasons for surgical intervention, adverse effects, acceptability of the procedure (by Pearson χ² test, logistic regression), and adverse outcomes. Detecting a 5% difference from 95% to 90% efficacy among the 3 groups with a power of 95% and a 2-tailed α of .05 required 700 women in each randomized group. Data were analyzed using SAS Version 6.12 (SAS Institute Inc, Cary, NC).

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Sixteen sites enrolled 2295 patients between March 1998 and June 1999. Seven sites in the larger cities (Rochester, NY; San Francisco, Calif; New York, NY; Cleveland, Ohio; Cherry Hill, NJ; Seattle, Wash; and Atlanta, Ga) enrolled 85% of the participants.

Table 1 shows that the initial demographic and clinical characteristics of the 3 misoprostol groups were similar. About three quarters of the patients were white, with approximately half reporting at least 1 prior live birth and half reporting at least 1 prior abortion. The mean age was 28 years and the mean length of current pregnancy was 46 days.

Table 2 shows the number of patients who completed their correct random assignment. Only 12 patients chose to use misoprostol in the office setting rather than at home. Forty patients (1.7%) were lost to follow-up despite attempts to contact them by telephone calls and certified letters. Another 56 (2.4%) completed their abortion without using misoprostol, 8 had a surgical completion before taking misoprostol, and 103 patients (4.5%) did not comply with their random assignment and used misoprostol either earlier or later than assigned. The patients who were most compliant with their random assignment were those randomized to 2 days (97%) compared with 96% randomized to 1 day and 92% to 3 days ($\chi^2 = 24.3; P < .001$). The remaining 2088 patients were the focus of subsequent analyses.

Effectiveness rates appear in Table 3. A complete medical abortion was evidenced by a negative home pregnancy test result among 60 women (2.6%). When all women were included (n = 2255), complete medical abortion rates were 98% (95% confidence interval [CI], 97%-99%) at 1 day, 98% (95% CI, 97%-99%) at 2 days, and 96% (95% CI, 95%-97%) at 3 days ($\chi^2 = 5.19; P = .07$). When only those participants who completed their randomly assigned timing were included (n = 2088), the results were identical: 98%, 98%, and 96%, respectively ($\chi^2 = 4.80; P = .09$).
The results were also similar for the 103 patients who used misoprostol on the wrong day. Among the 51 patients from the compliant group who had aspiration curettage, 27 patients had delayed excessive bleeding occurring at a mean (SD) of 28 (18) days in the 3 groups and requiring surgical intervention; 1 patient had excessive bleeding at 9 hours after misoprostol; 16 patients had a continuing pregnancy; 4 patients had persistent nonviable pregnancies with the longest followed up to day 29; 2 patients elected to have surgical curettage for nonmedical reasons; and 1 patient received surgical curettage because of excessive pain.

Seventy-five patients (4%) had a persistent gestational sac at their first follow-up visit and 53 used a repeat dose of misoprostol. At their next follow-up, only 16 women had a gestational sac present. No women required follow-up through study day 36.

Table 4 shows that 86% of patients started to bleed within 4 hours of using misoprostol. An additional 12% started bleeding between 4 and 24 hours after inserting misoprostol, and the remaining 2% began bleeding more than 24 hours later or never bled at all. There were no differences among groups.

Among patients who used misoprostol on their assigned day and had complete data on bleeding cessation (n=1859), the mean (SD) number of bleeding days was 17 (11).

Table 5 shows adverse effects that were reportedly made worse from either mifepristone or misoprostol compared with the baseline of symptoms from early pregnancy. Cramping (nearly universal) and nausea (nearly two thirds of patients) were the most commonly reported adverse effects, and headaches (nearly one quarter) and diarrhea (approximately one fifth) were the least common of the precoded adverse effects. Adverse effects were similar among the 3 treatment groups.

Thirteen unexpected or serious adverse events occurred, 6 in the day 1 group, 4 in the day 2 group, and 3 in the day 3 group. The 2 patients who were hospitalized presented with pelvic infections after aspiration curettage and were treated with intravenous antibiotics. Two patients, both of whom had complete medical abortions, were treated for clinically diagnosed endometritis with oral antibiotics and did not require further intervention. Two patients reported transient rashes, 1 after taking mifepristone only and 1 after taking both mifepristone and misoprostol. One patient had a vasovagal reaction to cramping pain from misoprostol and was treated with intravenous fluids. Four patients presented to the emergency department and received intravenous fluids; 2 for delayed excessive bleeding and 2 for vomiting and dehydration. One patient experienced a panic attack and another reported extreme irritability similar to premenstrual syndrome.

The results of the acceptability questionnaire are shown in Table 6. More than 90% of patients in each group agreed or strongly agreed that the overall procedure was acceptable. Approximately three quarters found the associated pain acceptable. The only major difference between groups was in the percentage who found the waiting time
to complete abortion acceptable. Patients clearly preferred the shortest waiting time possible. Specifically, patients assigned to take misoprostol 3 days after mifepristone were the least likely to report that the waiting involved in their regimen was acceptable; 86% in the day 1 group agreed or strongly agreed that the waiting time was acceptable compared with just 79% in the day 2 group and 76% in the day 3 group ($\chi^2 = 31.76; P = .001$). Three percent (64/2070) found using misoprostol at home to be unacceptable.

The results of the 2 logistic regression analyses are shown in Table 7. Women who had experienced 1 or more prior live births were more likely to find pain acceptable (odds ratio [OR], 2.6; 95% CI, 2.1-3.31), whereas women with more advanced pregnancies were less likely to find pain acceptable (OR, 0.97; 95% CI, 0.95-0.98). Variables found to influence overall acceptability were acceptability of waiting (OR, 4.9; 95% CI, 3.28-7.28), pain (OR, 10.0; 95% CI, 6.3-15.93), and bleeding (OR, 4.9; 95% CI, 3.24-7.46). Younger women found the procedure somewhat more acceptable (OR, 0.96; 95% CI, 0.93-0.99).

### Table 7. Odds of Agreement That Pain and Overall Procedure Were Acceptable

<table>
<thead>
<tr>
<th>Odds Ratio (95% Confidence Interval)</th>
<th>Pain Acceptability (n = 2057)</th>
<th>Overall Acceptability (n = 2056)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Misoprostol assignment at 1, 2, or 3 days</td>
<td>1.2 (1.07-1.41)</td>
<td>1.0 (0.78-1.30)</td>
</tr>
<tr>
<td>Waiting acceptable (vs not acceptable)</td>
<td>2.4 (1.87-3.14)</td>
<td>4.9 (3.28-7.28)</td>
</tr>
<tr>
<td>Pain acceptable (vs not acceptable)</td>
<td>10.0 (6.30-15.93)</td>
<td>4.9 (3.24-7.46)</td>
</tr>
<tr>
<td>Bleeding acceptable (vs not acceptable)</td>
<td>4.9 (3.63-6.74)</td>
<td>4.9 (3.24-7.46)</td>
</tr>
<tr>
<td>Minority race/ethnicity (vs white)</td>
<td>1.2 (0.96-1.63)</td>
<td>1.6 (0.96-2.61)</td>
</tr>
<tr>
<td>Patient age</td>
<td>1.0 (0.98-1.02)</td>
<td>0.96 (0.93-0.99)</td>
</tr>
<tr>
<td>Having a prior abortion (vs no prior abortions)</td>
<td>1.0 (0.84-1.30)</td>
<td>0.77 (0.51-1.14)</td>
</tr>
<tr>
<td>Having a prior live birth (vs no prior live births)</td>
<td>2.7 (2.10-3.41)</td>
<td>1.3 (0.81-1.96)</td>
</tr>
<tr>
<td>Gestation</td>
<td>0.97 (0.95-0.99)</td>
<td>1.0 (0.98-1.04)</td>
</tr>
</tbody>
</table>

To women. This study shows that 800 µg of vaginal misoprostol can be administered anytime from 1 to 3 days after 200 mg of oral mifepristone without any loss in the regimen’s effectiveness. These findings mean that clinics that offer mifepristone administration only on Monday through Wednesday can now offer it Monday through Friday, even if they wish to observe patients taking both drugs and remain closed on weekends.

The logistic regression analyses have the advantage over bivariate analyses of simultaneously controlling for the effects of several variables on pain and overall acceptability. Patients who had had a prior live birth found the pain associated with the procedure more acceptable, which is likely related to prior dilatation of the cervix due to childbirth. While the day of misoprostol administration did not affect the overall acceptability of the procedure, patients assigned to take misoprostol 3 days after mifepristone were more likely to take the misoprostol earlier than assigned. They were also significantly less likely to characterize the waiting interval to complete abortion as acceptable.

This study also provides additional information about the safety and acceptability of the regimen. Fewer than 1% of our study patients opted to use misoprostol in the office, 91% found home administration of misoprostol acceptable, and only 3% found it unacceptable. No interventions were required within 4 hours or during the time that the standard protocol requires patients to be observed.

These results are consistent with the safety noted with home administration of misoprostol in our other published trials involving 2440 patients and the US experience with methotrexate for abortion.9 Endometritis is very rare after medical abortion, and prophylactic antibiotics are not warranted. Although 40 patients (1.7%) were lost to follow-up, this percentage should be compared with the 85% of patients who do not return for requested follow-up care after surgical abortion.

The standard reasons to monitor patients in the office after misoprostol have been to identify any medical complications and to provide emotional support to the patient throughout the process. Complications are rare during these initial 4 hours and do not appear to warrant requiring women to spend time under medical supervision. Most patients prefer the privacy of their homes. Home use of misoprostol also has the advantage of reducing the costs of treatment by decreasing the number of office visits and eliminating the most lengthy visit.

The safety of medical abortion with mifepristone has been consistent in studies worldwide. This trial used geographically diverse clinical sites in the United States and found no differences in safety. Patients who want or need additional medical supervision should have the option of using misoprostol in the clinical setting. Patients will need advice about and access to pain medications. Clinicians should expect telephone calls from women using misoprostol at home. That adverse effects were common yet acceptable to our patients likely reflects the success of detailed counseling and provision of information.

Vaginal misoprostol, 800 µg, can be used between 1 and 3 days after mifepristone, 200 mg, for abortion at up to 56 days’ gestation, increasing the flexibility of the regimen. In our study, patients preferred the shortest regimen.

### ADDENDUM

**Added at Press Time**

On September 28, 2000, the US Food and Drug Administration approved mifeprin-
tione (trade name, Mifeprax) for the termination of intrauterine pregnancy at 49 days’ gestation or less from the beginning of the last menstrual period. Labeling includes use of mifepristone, three 200-mg tablets (600 mg total) orally as a single dose, followed by misoprostol, two 200-µg tablets (400 µg total) orally at an office visit 2 days later. Labeling does not include clinical monitoring after taking misoprostol, but does include ensurance of access to medical facilities should adverse reactions occur.

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Disclosure: Dr Ellerton works for the Population Council, which holds the US patent for mifepristone and has worked toward market approval for the drug in the United States.

Funding/Support: This study was funded in part by the David and Lucile Packard Foundation and the Abortion Rights Mobilization, a nonprofit advocacy group.

Previous Presentations: Preliminary results of this study were presented at the Annual National Abortion Federation Meeting, April 25, 1999, Atlanta, Ga. Results were also presented at a meeting of the Association of Reproductive Health Professionals, September 16, 2000, Chicago, Ill.

Acknowledgment: Collaborating investigators include James H. Armstrong, Sr, MD, Kalispell, Mont; Paul Blumenthal, MD, Johns Hopkins University, Baltimore, Md; LeRoy Carhart, MD, Bellevue, Neb; George Dainoff, MD, Cherry Hill, NJ; Joan Fleischman, MD, Albert Einstein College of Medicine, New York, NY; Bernard Gore, MD, San Francisco, Calif; Stephen Kaali, MD, Dobbs Ferry, NY; Ulrich Georg Klopfer, DO, South Bend, Ind; Tyrone Malloy, MD, Atlanta, Ga; Elizabeth Newhall, MD, Oregon Health Sciences University, Portland; Suzanne Poppema, MD, University of Washington, Seattle; Laszlo Sogor, MD, PhD, Cleveland, Ohio; and Elisabeth K. Wegner, MD, University of Vermont, Burlington.

REFERENCES


Work is an essential factor for health. It balances and gives significance to our lives, ennobling them and permitting man to create those material and cultural values without which human existence would be meaningless.

—Henry E. Sigerist (1891-1957)
the cap, whether in quarterly or annually capped plans, we identified the first month of the year in which the capped limit was exceeded. Unlike Rector, we were not able to identify and exclude members who disenrolled nonvoluntarily. Like Rector, we used an extended Cox model with the internally defined time-dependent variable of reaching the cap to analyze the relationship between reaching the cap and disenrollment from the health plan. Models were estimated for each plan and each year controlling for participant age, sex, and chronic disease score.

Results. The percentages of members reaching their annual prescription cap for plans A, B, and C, respectively, were 22.6%, 0.7%, and 1.6% in 1997 and 12%, 4.1%, and 3.9% in 1998. Disenrollment rates among those enrolled in the first 3 months of each year for plans A, B, and C, respectively, were 19.3%, 28.9%, and 6.8% in 1997 and 10.4%, 22.9%, and 14.0% in 1998. Among those disenrolling in 1997, 21%, 7%, and 7%, respectively, re-enrolled in 1998.

The risk of disenrollment across all plans and both years was significantly associated with older age, greater disease burden (ie, higher chronic disease score), and reaching the cap. In 1997, the relative risks (RRs) of disenrollment in any given month for those reaching the cap for the 3 plans were 2.62 (95% confidence interval [CI], 2.15-3.19), 2.21 (95% CI, 1.70-2.88), and 2.24 (95% CI, 1.43-3.50); in 1998, the RRs of disenrollment were 3.04 (95% CI, 2.40-3.86), 1.79 (95% CI, 1.12-2.86), and 2.30 (95% CI, 1.86-2.86) in plans A, B, and C, respectively.

Comment. Exhaustion of prescription coverage, whether administered on a quarterly or annual basis, was associated with a 2- to 3-fold increase in the RR of disenrollment. These findings expand on those of Rector and suggest that this relationship holds under various scenarios including variation in underlying use, cap amounts, and cap administration.

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CORRECTIONS

Incorrect Unit of Measure and Numbers: In the Original Contribution entitled “Cognitive-Behavioral Therapy, Imipramine, or Their Combination for Panic Disorder” published in the May 17, 2000, issue of THE JOURNAL (2000;283:2529-2536), the units of measure for imipramine and desipramine should be ng/mL instead of ng/dL on page 2532 and ng/mL instead of mg/mL on page 2535. On page 2530 under “Study Design” patients randomized to CBT+placebo should number 5 per block of 24, not 25. In the “Treatment Conditions” section on page 2531, near the end of the third paragraph, “…the dosage [of imipramine] could be increased up to 300 mg/d by week 5” should read “week 7.”

Author Omitted: In the Caring for the Critically Ill Patient article entitled “Ketoconazole for Early Treatment of Acute Lung Injury and Acute Respiratory Distress Syndrome” published in the April 19, 2000, issue of THE JOURNAL (2000;283:1995-2002), an author was inadvertently omitted from the ARDS Network listing on page 2002. Brian Christman, MD, should have been listed with the Vanderbilt University group and identified as an author.

Acknowledgment Omission: In the Original Contribution entitled “Menopausal Estrogen and Estrogen-Progestin Replacement Therapy and Breast Cancer Risk” published in the January 26, 2000, issue of THE JOURNAL (2000;283:485-491), acknowledgments were omitted. The authors wish to thank the Breast Cancer Detection Demonstration Project study participants as well as Susan Englehart, Cathy Ann Grundmayer, and the staff at Westat Inc, Rockville, Md, for conduct of the Breast Cancer Detection Demonstration Project Follow-up Study.

Incorrect Data in Table: In the Original Contribution entitled “Estrogen Replacement Therapy for Treatment of Mild to Moderate Alzheimer Disease: A Randomized Controlled Trial” published in the February 23, 2000, issue of THE JOURNAL (2000;283:485-491), incorrect data appeared in Table 3 on page 1013. In the placebo group column, the mean (SD) changes in scores at 12 months for the Emotional Face Recognition Test and the Grooved Pegboard Test should have been −5.7 (22.4) and −5.2 (42.4), respectively.

Photo Misidentification: In the Medical News & Perspectives article entitled “Psychiatrists Help Survivors in the Balkans” published in the March 8, 2000, issue of THE JOURNAL (2000;283:1277-1278), the photo on page 1278 identified as Ismet Ceric, MD, should have been identified as Vlado Jukić, MD.

Acknowledgment Omission: In the Original Contribution entitled “Vaginal Misoprostol Administered 1, 2, or 3 Days After Mifepristone for Early Medical Abortion: A Randomized Trial” published in the October 18, 2000, issue of THE JOURNAL (2000;284:1948-1953), an acknowledgment was omitted. The authors wish to acknowledge the contributions of Larry Lader, president of the Abortion Rights Mobilization, for making the study possible.