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Editor's Note—Controversy surrounding pregnancy termination has restricted treatment options for women, especially in the United States. The recent US approval of mifepristone (RU 486 or Mifeprex™—Danco) in September 2000 has only added fuel to the abortion debate. Its availability provides a long-awaited alternative to surgical abortion. Medical abortion may also increase both physician and patient access to services.

After extensive clinical experience in Europe and completion of the US clinical trial, mifepristone, in conjunction with a prostaglandin analogue, has been approved by the FDA for ending pregnancies up to 49 days from the first day of the last menstrual period. Mifepristone is proven to be safe and effective, with high rates of patient satisfaction.¹⁻⁶ Success rates using mifepristone with prostaglandins range from 92% to 98%.^{1,7} The FDA-approved regimen is 600 mg of mifepristone followed by 400 µg of oral misoprostol, but other combinations are comparably or more effective.

Providing medical abortion requires little additional training for physicians who are already providing gynecologic or obstetrical services. Medical abortion essentially creates a clinical picture almost identical to a spontaneous abortion. The management of patients undergoing medical abortion is very similar to that of miscarriage.

The introduction of this regimen opens a new era in US abortion services. This review will provide background information on mifepristone and misoprostol abortion, alter-

nate regimens to the approved combinations, recommendations about appropriate counseling and patient selection, and details of the potential side effects and complications of this treatment.

RU 486 for Primary Care Providers

Authors: **Mark Nichols, MD**, Associate Professor of OB/GYN, Oregon Health and Sciences University, Portland, Ore; and **Alison Edelman, MD**, Fellow, Family Planning, Department of OB/GYN, Oregon Health and Sciences University.

Historical Perspective

In the 1980s, Roussel-Uclaf, a French research group, was working on synthesizing glucocorticosteroids. They were searching for progesterone-like hormones when they created RU

38486.⁸ RU 38486 or RU 486 had a very high affinity for the progesterone receptor but was found to be antagonistic. It was demonstrated to be an effective abortifacient.

In 1988, Roussel-Uclaf was granted a marketing license for mifepristone, and it was used by French physicians for termination of pregnancies. The company received a number of personal threats. In response, the company attempted to withdraw the medication from the market. However, the French government immediately blocked this move stating that RU 486 was "the moral property of women." The drug was again made available.⁹ Although extensively studied and found to be safe and effective, the controversy over abortion in the United States delayed the approval of mifepristone until late 2000.

Access to abortion services in the United States is limited. Eighty-four percent of the counties in the country have no abortion providers. Providing abortion carries a stigma that is often viewed negatively by physicians and members of their

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communities. As a result, the bulk of abortion care provided in the United States is offered in dedicated clinics located in metropolitan areas. This has provided a target for protesters opposed to abortion. Patients often report feeling threatened when passing in front of protesters when they enter abortion clinics. It has been hoped that the availability of a medical option will motivate physicians to provide abortion care through their offices, avoiding the potentially negative experience reported by many patients receiving services in abortion clinics. It is unclear whether physicians in less-urban settings will begin to offer medical abortion.

Mechanism of Action

Progesterone is critical for initiating and maintaining pregnancy. Blockade of the progesterone receptor interrupts early gestations by creating an inhospitable endometrium.^{8,10}

Mifepristone is an anti-progestational agent that competes for the progesterone receptor. Its affinity to bind to receptors surpasses that of endogenous progesterone by 5 times.¹⁰ In addition, mifepristone stimulates the release of endogenous prostaglandins (PGs), exogenous PGs, and softens the cervix.

Mifepristone alone causes medical abortion in approximately 60% of patients at less than 9 weeks gestational age.^{40,42} In the FDA-approved regimen, mifepristone will cause medical abortion prior to the dose of misoprostol given at 48 hours in 5-6% of cases.^{2,4} Because of this low rate of success, prostaglandins have been added to stimulate uterine contractions and cause expulsion of the pregnancy.

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Statement of Financial Disclosure

In order to reveal any potential bias in this publication, we disclose that Dr. Nichols and Dr. Edelman (authors) reports no consultant, stockholder, speaker's bureau, research, or other financial relationships with companies having ties to this field of study.

Prescribing Information

The Danco group, manufacturer of the commercially available mifepristone or Mifeprex™, has released prescribing guidelines for physicians in conjunction with the FDA. The Danco group has created an agreement form, which the physician is required to sign before medication will be shipped. This medication will only be provided directly to physicians and will not be distributed through pharmacies.

Patients being considered for medical abortion must have an intrauterine pregnancy with a gestational age of 49 days or less from the first day of the last menstrual period. The gestational age of the pregnancy can be diagnosed by history, exam, and if necessary, ultrasound. Routine ultrasound evaluation is not required in the FDA labeling but is recommended. It is the standard protocol at Planned Parenthood and at other established abortion providers.

Under the FDA-approved treatment regimen, patients receive 3 200-mg tablets of mifepristone orally. Forty-eight hours later, the patients take 400 µg of oral misoprostol. Patients should be seen again in the office 14 days after initiation of Rx for confirmation of a pregnancy loss. If the pregnancy has not been interrupted then surgical intervention should take place.

Other dosages have been studied. In doses less than 600 mg, mifepristone in combination with a prostaglandin analogue has proven effective.¹¹⁻¹⁷ Extensive experience comparing regimens using 200 mg vs. 600 mg of mifepristone has shown equal effectiveness. Use of mifepristone in an off-label fashion may be of some concern to physicians. The FDA has declared that off-label use is acceptable when a body of literature supports alternative uses of a medication. The medication is packaged as 3 tablets of 200 mg of mifepristone. Many clinicians are using only 1 200-mg tablet per patient.

Vaginal vs. oral routes of misoprostol have also been researched.¹⁷⁻²⁰ The pharmacokinetics of vaginal application show that peak blood levels are lower but sustained for a longer period of time than with oral ingestion.²¹ In one randomized trial, placing misoprostol vaginally and increasing the dose to 800 µg was more effective than oral administration and had fewer side effects,³ such as nausea and diarrhea. This is probably explained by the lower peak blood levels compared to oral ingestion.³

If the physician prescribing mifepristone does not perform suction aspirations, then arrangements must be made for backup in case there is a need to perform a suction procedure. This requirement may be viewed as a burden for some; however, suction aspiration is widely available, safe, and easily learned.

The cost of medical abortion may appear to some observers to be less than surgical abortion. However, the cost to clinicians involves more than just the cost of equipment and supplies. The staff time involved with the counseling of patients considering medical abortion is greater than with surgical abortion. Specific detailed instructions must be provided to the patient about possible side effects and complications with this therapy. Parameters for the patient to call and criteria to come into the office or clinic must be reviewed in detail.

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Questions & Comments

Please call **Robin Mason**, Managing Editor, at (404) 262-5517 or e-mail: robin.mason@ahcpub.com between 8:30 a.m. and 4:30 p.m. ET, Monday-Friday.

Table 1. Medical vs. Surgical Abortion^{5,6,26-32}

	Medical	Surgical
<i>Invasiveness</i>	Lower	Higher
<i>Risk of Infection</i>	Lower	Higher
<i>Days of bleeding</i>	Longer	Shorter
<i>Pain</i>	Longer, perhaps less intense	Shorter, intense
<i>Cost</i>	Equal	Equal
<i>Counseling time</i>	Longer	Shorter
<i>Gestational age limits</i>	Up to 7 weeks	Up to 14 weeks

Abortion providers should consider establishing the same price for both surgical and medical abortion. This policy would avoid the tendency of patients to choose one abortion option over the other based only on cost rather than what is clinically better for them individually.

Mifepristone has been studied in the use of emergency contraception, suppression of endometriosis, and induction of labor.^{13,22-25} It has also been used successfully for the treatment of uterine leiomyomata, breast cancer, and meningiomas.^{23,33} Currently, mifepristone is only approved for pregnancy termination in the United States.

Patient Selection

Patients must be carefully selected for medical abortion. Physicians and their staff must accurately assess the patient’s ability to tolerate the bleeding and cramping associated with a medical abortion. Women must be prepared for the possibility of a suction procedure if the medical abortion fails. They must have a support system that will provide comfort and reassurance during the expulsion of the pregnancy. Patients choosing medical abortion should anticipate a possibly intense physical experience. If the counseling process uncovers uncertainty around tolerating strong uterine contractions at home, the clinician might encourage the patient to consider surgical abortion instead.

Ideally, counseling patients about the medical abortion should be done with the support person present. If and when problems arise, the support person will be better informed and more capable of making an appropriate decision.

The amount of time necessary to adequately counsel patients planning a medical abortion is greater than the time needed to counsel a patient planning a surgical abortion. It may require significant staff time to describe the symptoms the patient is likely to experience. Explaining in clear detail the possible complications is critical. Providing specific, detailed criteria for calling or seeking care is important. Though the responsibility for informing the patient of these facts is ultimately the physician’s, some of these details can be provided in written form, by video, or by skilled staff members.

Efficacy

Thousands of women have been studied with regard to the overall effectiveness of the mifepristone/misoprostol regimen for early abortion. Success is defined as the complete expulsion of the pregnancy without requiring a suction aspiration. The success rates have varied from 92% to 96% in the large US and French trials.^{1,4} Additional studies have been conducted. Success rates have been found to decline with increasing gestational age. In one study, the success rate for patients with pregnancies from 56 to 63 days from the last menstrual period was 77%.⁴

Patients need to be aware of the most likely time of the expulsion of the pregnancy. Because many of the clinical studies have been based in the home setting, the onset of bleeding has been recorded as the start of the expulsion process. Information gathered in the US cohort included at least 4 hours of direct patient observation after misoprostol administration. A total of 50% of women had a pregnancy loss within 4 hours of the misoprostol placement and 75% of women had a pregnancy loss within 24 hours.⁴ For some women undergoing medical abortion, the time of the expulsion is not predictable.^{1,4} Patients must be counseled about this possibility prior to the initiation of the medical abortion.

Table 2. Contraindications to Medical Abortion

- More than 7 weeks from the last menstrual period
- Known or suspected ectopic pregnancy
- IUD in place
- Chronic adrenal failure
- Concurrent long-term corticosteroid therapy
- Bleeding dyscrasias
- Concurrent anticoagulant therapy
- Unwillingness to undergo a suction procedure
- Absence of support system

One option for managing delayed expulsion is to consider a repeat dose of misoprostol. Several protocols have used regimens permitting a second dose of misoprostol at 24 or 48 hours after the first dose.³⁹ Physicians should consider whether to perform an ultrasound examination to assess the status of the pregnancy before offering a second dose of misoprostol. Some providers recommend a second dose without performing an ultrasound examination if the history from the patient is convincing that the expulsion did not occur. There have not been comparative studies to determine the optimal timing or dose of a “back-up” dose of misoprostol.

Side Effects

The most common side effects of medical abortion include bleeding, abdominal pain, nausea, vomiting, and diarrhea.^{1,4,26-32} Vaginal bleeding is, of course, a normal occurrence in all abortions. In US women, the median duration of bleeding was 13 days.⁴ The amount of bleeding increases with greater gestational age of the pregnancy. The amount of vaginal bleeding associated with medical termination is usually less than 300 mL.²⁷ Only a small number of patients studied have had a significant drop in their hemoglobin.^{30,32} Less than 0.1% of the women studied have required a blood transfusion.⁷ Patients may experience bleeding, which leads to a need for suction aspiration. In the majority of cases, the indication for suction aspiration is prolonged bleeding. The need to perform an emergent suction aspiration for severe heavy bleeding is approximately 0.1%.⁴

Patients must be informed of how much bleeding is excessive. The general recommendation is to call the physician’s office if the patient has bleeding sufficient to saturate 1 large pad every 30 minutes over 2 hours—a total of 4 saturated large pads.

In the US trial, nausea occurred in 61% and vomiting in 26% of patients less than 49 days gestational age.⁴ Diminished symptoms of nausea, vomiting, and diarrhea have been found with vaginal dosing of misoprostol. Comparing oral to vaginal misoprostol, nausea decreased from 70% to 60%, vomiting decreased from 44% to 31%, and diarrhea decreased from 36% to 18%, respectively.³

Site of Medical Abortion

The package labeling from mifepristone states that patients should be offered the opportunity to stay in the physician’s office after the ingestion of the misoprostol tablets. The US clinical trial protocol required patients to stay in the clinic for a minimum of 4 hours after taking the misoprostol.⁴ The data collected from this trial provided detailed information about the changes in vital signs, the side effects, and patient acceptability of this treatment. On the basis of these data, all of the subsequent study protocols of mifepristone abortion have had the patients either administer the misoprostol at home or immediately go home after the administration of the misoprostol. Additionally, all of the published studies of methotrexate and misoprostol abortions have been based on protocols in which patients expel the pregnancy at home.

Patient Acceptability

Women have been incredibly receptive to a noninvasive alternative for pregnancy termination. Studies that have looked at rates of acceptability demonstrate percentages above 90%, and these have been reproduced in several different countries.^{5,6} The majority of women who had failed procedures and underwent suction aspirations reported that the experience was moderately or very satisfactory. These women would choose medical abortion again and would recommend it to a friend.^{5,6}

Women who choose medical abortion cite that it is less invasive than surgical abortion. Some patients report they prefer medical abortion because it is “more natural.”^{5,6} Some patients also prefer medical abortion because it can occur in the privacy of their own home.

Protocol for Mifepristone and Misoprostol Abortion

Patients requesting first trimester abortion must first be counseled about the alternatives of carrying the pregnancy, giving the baby up for adoption, or termination of the pregnancy. Local and state statutes and regulations regarding medical abortion may differ from surgical abortion. If after counseling, the patient chooses pregnancy termination, the alternatives of medical vs. surgical termination may be explored.

Table 3. Protocol for Mifepristone and Misoprostol First Trimester Abortion

Time	Procedure	Site
Day 1	History and physical exam, informed consent process, ultrasound as indicated, mifepristone provided	Office or Clinic
Day 3	If no expulsion, misoprostol administration	Home, office, or clinic
Day 14	Evaluation to confirm completion of abortion, ultrasound as indicated	

Table 4. Advantages of Vaginal vs. Oral Misoprostol

	Oral	Vaginal
Effectiveness	Decreased	Increased
Nausea	Increased	Decreased
Vomiting	Increased	Decreased
Patient acceptance	Increased	Decreased

Patients must not have any of the contraindications for medical abortion to proceed.

The informed consent process for medical abortion should include the issues addressed in the previously discussed "Patient Selection" section. The manufacturer of mifepristone has created a patient agreement form, which the patient is required to sign. A thorough history must be obtained to exclude any of the contraindications to medical abortion and to assess the gestational age of the pregnancy. A physical examination must be performed including a speculum examination and bimanual examination of the pelvis. An ultrasound examination of the pregnancy may be considered and will assist the physician in accurately establishing the gestational age of the pregnancy.

Appropriate laboratory studies must be done, including the Rh status and hemoglobin or hematocrit tests. If a suction procedure needed to be done, the presence of bacterial vaginosis or chlamydia may increase the risk of postabortal endometritis. Therefore, screening for chlamydia and a wet mount of the vaginal secretions may be considered prior to initiating medical abortion.

If there are no contraindications of proceeding with medical abortion, the dose of mifepristone may be administered at this initial visit. Some states may have statutes that require the physician to personally administer the medication directly to the patient. Timing of this initial treatment should be considered. Since labeling information indicates that the dose of misoprostol is to be ingested 48 hours after the mifepristone, the physician may not want to start the regimen 48 hours before the office is closed, or when the physician may be less readily available. Studies have been done evaluating the effectiveness of this regimen with varied lengths of time from the mifepristone dose to the misoprostol dose. The effectiveness was essentially equal in one study that compared 24-, 48-, and 72-hour intervals.³⁹

Prior to leaving the physician's office, the patient must be provided with clear instructions about what to expect and with criteria for calling the physician or coming into the office.

Conclusion

Termination of pregnancy using mifepristone with misoprostol has been proven to be safe, effective, and well tolerated in multiple published studies. The US clinical trial⁴ used direct observation in a clinical setting to document patient signs and symptoms throughout the expulsion phase of the abortion. There were very few adverse events. The US results were con-

sistent with numerous trials in Europe and Asia.

FDA approval of mifepristone was based on the 93% effectiveness rate found in US clinical trials in gestations up to 49 days. Subsequent studies using vaginal misoprostol have found effectiveness rates of 96-98% in gestations up to 63 days.

Physicians experienced with managing spontaneous miscarriage are well prepared to offer medical abortion to their patients. As physician comfort with medical abortion increases, options for patients will hopefully expand.

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Physician CME Questions

48. The success rate of medical abortion is defined as:
 - a. the percent of patients satisfied with the treatment.
 - b. the percent of patients who complete the abortion without a suction procedure.
 - c. the percent of patients who expel the pregnancy within 24 hours after misoprostol treatment.
49. The use of ultrasound to establish the gestational age of the pregnancy in medical abortion is:
 - a. required by the FDA labeling for mifepristone.
 - b. recommended by the FDA labeling for mifepristone.
 - c. not recommended by the FDA labeling for mifepristone.
50. The upper limit of gestational age for mifepristone medical abortion, according to FDA labeling is:
 - a. 7 weeks from the last menstrual period.
 - b. 8 weeks from the last menstrual period.
 - c. 9 weeks from the last menstrual period.
51. A contraindication to mifepristone abortion is:
 - a. a patient younger than 18 years of age.
 - b. an ectopic pregnancy.
 - c. a nulliparity.
 - d. diabetes.

52. Which of the following is an advantage(s) of the vaginal route of misoprostol administration vs. the oral route?
- Less vomiting
 - Higher efficacy
 - Less diarrhea
 - All of the above
 - None of the above
53. Which one of the following laboratory studies should be obtained before medical abortion with mifepristone?
- Quantitative beta HCG
 - Liver function tests
 - Rh type
54. Where might patients obtain mifepristone?
- Local pharmacies
 - Offices of physicians who have signed a prescriber's agreement
 - All physicians' offices
55. In comparison to surgical abortion, medical abortion is associated with:
- less invasiveness.
 - shorter bleeding time.
 - higher infection rate.

PCR Takes First Place in Newsletter Reporting Awards

Primary Care Reports was recently awarded the First Place national award in instructional reporting from the Newsletter & Electronic Publishers Association in Arlington, Va. The award went to Managing Editor Robin Mason and Clayton F. Holmes, EdD, PT, ATC, author of the two-part series titled "Common Sports Injuries" that ran in the Nov. 27, 2000, and Dec. 11, 2000 editions of PCR. Dr. Holmes is a member of the Editorial Advisory Board for *Sports Medicine Reports*, a sister publication to PCR. The series noted that sports injuries account for nearly half a million visits to physicians in the United States each year. It described the clinical presentation, examination, and intervention of several of the more common pathologies derived from sports-related injuries. Copies of the award-winning series are still available. For information, contact Customer Service at (800) 688-2421 or customerservice@ahcpub.com.

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ing in the topic being covered. Once the idea for an article has been approved, deadlines and other details will be arranged. Authors will be compensated upon publication.

As always, we are eager to hear from our readers about topics they would like to see covered in future issues. Readers who have ideas or proposals for future single-topic monographs can contact Managing Editor Robin Mason at (404) 262-5517 or (800) 688-2421 or by e-mail at robin.mason@ahcpub.com.

Readers are Invited. . .

Readers are invited to submit questions or comments on material seen in or relevant to *Primary Care Reports*. Send your questions to: Robin Mason, *Primary Care Reports*, c/o American Health Consultants, P.O. Box 740059, Atlanta, GA 30374. For subscription information, you can reach the editors and customer service personnel for *Primary Care Reports* via the internet by sending e-mail to robin.mason@ahcpub.com.

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