Journal of the American Pharmacists Association xxx (2018) 1–5

Contents lists available at ScienceDirect

Journal of the American Pharmacists Association

journal homepage: www.japha.org

COMMENTARY

Medication abortion: Potential for improved patient access through pharmacies

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ARTICLE INFO

Article history:
Received 22 August 2017
Accepted 4 April 2018

ABSTRACT

Objectives: To discuss the potential for improving access to early abortion care through pharmacies in the United States.

Summary: Despite the growing use of medications to induce termination of early pregnancy, pharmacist involvement in abortion care is currently limited. The Food and Drug Administration's Risk Evaluation and Mitigation Strategy (REMS) for Mifeprex® (mifepristone 200 mg), the principal drug used in early medication abortion, prohibits the dispensing of the drug by prescription at pharmacies. This commentary reviews the pharmacology of medication abortion with the use of mifepristone and misoprostol, as well as aspects of service delivery and data on safety, efficacy, and acceptability. Given its safety record, mifepristone no longer fits the profile of a drug that requires an REMS. The recent implementation of pharmacy dispensing of mifepristone in community pharmacies in Australia and some provinces of Canada has improved access to medication abortion by increasing the number of medication abortion providers, particularly in rural areas.

Conclusion: Provision of mifepristone in pharmacies, which involves dispensing and patient counseling, would likely improve access to early abortion in the United States without increasing risks to women.

Pharmacists play an important role in the provision of reproductive health care, including prescribing hormonal contraception and emergency contraception in some states.[1-5] However, pharmacists have limited involvement in abortion care, despite the growing use of medications to induce termination of early pregnancy, known as medical or medication abortion (Figure 1). Federal regulations require that mifepristone, the principal drug used in medication abortion, be dispensed by a certified provider in an outpatient clinic or hospital and not by prescription in a pharmacy.[10] This dispensing restriction is not evidence-based and constrains access to medication abortion.[11] There is increasing interest in removing dispensing restrictions in the United States, which would enable pharmacists to dispense mifepristone to patients. When dispensing medications, pharmacists review the prescription to ensure safety and effectiveness and provide pertinent patient counseling on proper use and adverse effects. Pharmacy dispensing of mifepristone has already been implemented in Australia and some provinces of Canada.[12,13] As these efforts move forward, it is important for pharmacists to become more familiar with the pharmacotherapy of medication abortion.

Nearly one-half of all pregnancies in the United States are unintended (45%, or 2.8 million annually), and approximately 40% of these unintended pregnancies end in abortion.[14] Although the abortion rate has declined in recent years, the proportion of abortions that are done with medication has increased (Figure 1).[6-9] Multiple studies have demonstrated that medication abortion is an acceptable means of pregnancy termination for women who choose this method.[15,16] In a meta-analysis of approximately 4500 women who underwent medication abortion, more than 85% were satisfied with the experience.[17] Medication abortion is particularly likely to appeal to patients who desire a more natural experience or prefer to avoid surgical intervention.

Disclosure: The authors have no conflicts of interest to disclose.
Funding: This work was supported by a grant from Fidelity Charitable.
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https://doi.org/10.1016/j.japh.2018.04.011

Key Points

Background:

- Pharmacists play an important role in the provision of reproductive health care, yet they have limited involvement in abortion care.
- Medication abortion (also known as medical abortion) involves the use of mifepristone and misoprostol to terminate an unwanted pregnancy up to 10 weeks of gestation. This method is safe, effective, and preferred by many women.

Findings:

- The U.S. Food and Drug Administration's Risk Evaluation and Mitigation Strategy for Mifeprex® (mifepristone 200 mg) prohibits its dispensing by pharmacists following a prescription.
- Pharmacy dispensing of mifepristone, which has been implemented in Australia and some provinces of Canada, would likely improve access to early abortion in the United States without increasing risks to women.

Medication abortion regimen

The standard regimen for medication abortion involves two drugs, mifepristone followed by misoprostol, which are approved by the U.S. Food and Drug Administration (FDA) to terminate pregnancies up to 10 weeks of gestation.[18] Mifepristone (Mifeprex®, also known as RU-486) is a progesterone antagonist, which binds without activating the progesterone receptor, thereby leading to decidual necrosis (breakdown of the lining of the uterus), cervical softening, and increased uterine prostaglandin sensitivity. Misoprostol, a prostaglandin E1 analogue, causes cervical dilation and softening and uterine contractions to promote pregnancy expulsion.

The FDA-approved labeling for Mifeprex® was updated in March 2016 and describes an evidence-based treatment,[19-25] including 200 mg mifepristone orally, followed 24-48 hours later by 800 mcg misoprostol administered buccally. This regimen may be used up to 70 days from the last menstrual period (10 weeks' gestation).[11] The efficacy of this evidence-based regimen is 93% to 99%, meaning that 1% to 7% of patients will require a vacuum aspiration procedure to complete the abortion.[18] The U.S. Government Accountability Office recently reviewed the process that the FDA used for updating the Mifeprex® label and found that it was appropriate and based on the best available evidence.[26]

Providing medication abortion

Women seeking medication abortion first undergo standard counseling to ensure that they are certain about their decision to terminate the pregnancy, as well as their choice to have a medication abortion instead of a vacuum aspiration procedure. A clinician then screens patients for medical eligibility for medication abortion. This includes assessing gestational age with the use of ultrasound or clinical assessment of uterine size and ruling out ectopic pregnancy, because mifepristone and misoprostol do not effectively terminate or treat an ectopic pregnancy. The clinician also screens for other contraindications, including chronic adrenal failure or long-term corticosteroid therapy (because of mifepristone's anti-glucocorticoid effect), hemorrhagic disorders or concurrent anticoagulant use, presence of an intrauterine device, inherited porphyria (given the possible increased risk of precipitating an attack), and allergy to mifepristone, misoprostol, or other prostaglandins.[27,28]

Pretreatment laboratory testing commonly includes hemoglobin to assess for anemia and blood type to determine Rhesus (Rh) status.[18] Vaginal bleeding after medication administration (discussed in detail below) is unlikely to be well tolerated by women with severe anemia. In addition, women who are Rh-negative are advised to receive RhD immunoglobulin at the time of abortion to prevent the development of anti-D antibodies and to reduce the risk of alloimmunization in subsequent pregnancies.[18]

After ensuring eligibility, clinicians provide counseling on medication abortion and dispense the mifepristone directly to the patient, which may be taken in the clinic or at a later time, according to the FDA-approved labeling. Misoprostol may be dispensed directly by the clinician, or it may be prescribed and dispensed at a pharmacy; women take the misoprostol dose buccally at home 24-48 hours after mifepristone. Some providers use an off-label regimen of 800 mcg misoprostol self-administered vaginally as soon as 6 hours after mifepristone.[29] Although mifepristone is rapidly absorbed, few patients experience bleeding or pregnancy expulsion before taking misoprostol. Bleeding may occur within 1 hour of misoprostol ingestion, and 90% expel the pregnancy within 24 hours.[27,30]

Expected adverse effects of medication abortion include vaginal bleeding and uterine cramping, which almost always occur with successful pregnancy termination. Clinicians often counsel patients to expect a "crescendo-decrescendo" bleed whereby the patient's bleeding intensifies and then decreases once the pregnancy tissue is passed. The total duration of vaginal bleeding varies, but it is approximately 8 to 17 days on average.[15] The Mifeprex® medication guide that must be given to patients includes the recommendation that they should call or seek care if they feel lightheaded or are experiencing heavy bleeding, defined as soaking more than two large pads per hour for two consecutive hours.[27] Cramping pain usually peaks shortly after the patient takes misoprostol, and it can often be controlled with the use of nonsteroidal anti-inflammatory drugs or, if necessary, oral opioids. Adverse effects can include gastrointestinal complaints such as nausea (34% to 72%), vomiting (12% to 41%), and diarrhea (3% to 26%).[18] Less common adverse effects include headache, dizziness, and thermoregulatory effects such as fever or hot flashes.[21]

Patients are generally encouraged to have follow-up after medication abortion within 2 weeks to ensure that the pregnancy has been effectively terminated and is not ongoing, which occurs in 0.5%-3% of cases (a subset of the 1% to 7% who require vacuum aspiration to complete the abortion).[21] Ultrasound can be performed approximately 1 week after mifepristone administration or sooner if the patient reports pregnancy expulsion. Alternatively, serum human chorionic gonadotropin