

Early pregnancy loss needn't require a trip to the hospital

Don't just think "hospital D&C" when a patient miscarries. Consider these 3 outpatient alternatives.

PRACTICE RECOMMENDATIONS

› Family physicians can provide in-office treatment for patients with early pregnancy loss, as long as they are hemodynamically stable. **A**

› Manual vacuum aspiration in the office is as effective as surgical emptying of the uterus (dilatation and curettage) in the operating room. **A**

› No single in-office option for managing early pregnancy loss—wait and watch, misoprostol, or vacuum aspiration—is clearly more beneficial than another. Patients should be free to choose the method they prefer. **A**

Strength of recommendation (SOR)

- A** Good-quality patient-oriented evidence
- B** Inconsistent or limited-quality patient-oriented evidence
- C** Consensus, usual practice, opinion, disease-oriented evidence, case series

CASE 1 ▶ Janet C is 22 years old, excited about her first pregnancy and eager to do all the right things to have a healthy baby. But now, in her third month, she has started to bleed and has pelvic pain. She calls in a panic. You tell her to come in immediately. In the office, an ultrasound shows a residual gestational sac.

CASE 2 ▶ Lizbeth G, 40, is a successful professional, recently married, with a down-to-earth, decisive personality. She and her husband are eager to start a family. But now, in her second month, she calls to say she's been having severe cramps and heavy bleeding. She knows she is having a miscarriage. When you see her in the examining room, she's saddened but calm, eager to know what went wrong and what she needs to do now.

CASE 3 ▶ Lola M, 36, mother of 2, is in your office for a routine prenatal visit. She's in her third month, expecting this pregnancy to be as uneventful as her previous ones. But your ultrasound exam reveals that her fetus has no heartbeat.

What would you tell each of these patients? What options would you offer them?

Chances are good that you've cared for any number of patients like Janet, Lizbeth, and Lola. Approximately 15% of clinically recognized pregnancies end in early pregnancy loss (EPL), defined as a miscarriage that occurs earlier than the 12th week of pregnancy. When clinically unrecognized miscarriages are included, the EPL rate may be as high as 30%.¹ Most pregnancy losses (80%) occur during the first trimester.²

In the past, EPL was routinely considered an indication for uterine dilatation and curettage (D&C) performed in the operating room.³ This approach was effective, but had serious drawbacks: Costs were high and women had to undergo a surgical procedure that many would prefer to avoid.⁴

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> A Cochrane review revealed that expectant management carried a higher risk of incomplete miscarriage, while vacuum aspiration was associated with a higher risk of infection.

More recently, professional organizations such as the American Academy of Family Physicians and the United Kingdom's Royal College of Obstetricians and Gynecologists have encouraged a wider range of treatment options that can be provided in an outpatient setting.^{5,6} These choices, which are available to women with confirmed intrauterine—not ectopic—pregnancy, include “watch and wait” (expectant management), medical management with misoprostol, and outpatient manual vacuum aspiration (MVA) of the uterus.

But before you can even discuss these options, it's important to find out how your patient has been feeling about her pregnancy: Was it planned or unplanned? Is she happy or unhappy about being pregnant? Does she have a supportive partner, or is her relationship in turmoil? Having a clear sense of where she is emotionally will better enable you to counsel her on her options.

Know, too, that managing EPL patients in their family “medical home” has many advantages. Patients can remain with a caregiver they know and trust. Because they can choose the treatment option they prefer, they are more likely to be satisfied with their care.⁷ Their quality of life after treatment is better, and the emotional support they can receive in these familiar surroundings has been shown to decrease the psychological sequelae of a miscarriage.⁸⁻¹⁰

How best to define, and describe, what's happened

Providing your patient with an accurate description of her situation is essential to adequately counseling her on treatment options. Types of EPL include:

■ **Missed abortion**, which occurs when a nonviable pregnancy is detected on ultrasound. The patient is usually without bleeding. A missed abortion is further distinguished sonographically as either an “anembryonic pregnancy”—a mean sac diameter of >10 mm and no yolk sac or a mean sac diameter of 20 mm and no embryo on transvaginal ultrasound—or as an “embryonic demise”—a crown rump length of ≥6 mm without cardiac activity on transvaginal ultrasound.⁵

■ **Incomplete abortion** occurs when a residual gestational sac is detected on ultra-

sound, and vaginal bleeding and pelvic pain are present.

■ **Inevitable abortion** occurs when the internal os is open, but the pregnancy has not yet passed.

■ **Complete abortion** occurs when no gestational sac is detected on ultrasound, the cervical os is generally closed, and significant cramping and bleeding have resolved.

Women experiencing a complete abortion require no treatment; they have already successfully passed the pregnancy. Women with a missed, incomplete, or inevitable abortion can be offered the choice of expectant management, medication, or uterine aspiration.

Does your patient want to wait it out?

The success rate for expectant management depends on the time-frame studied and the type of EPL.¹¹ (Success in EPL is defined as complete uterine evacuation.) Patients who choose this approach are usually seen every 1 to 2 weeks so that you can evaluate symptoms and do a physical examination. In some cases, assessment also includes serial serum human chorionic gonadotropin (hCG) testing or ultrasonography.

Expectant management is usually more efficacious for women with an incomplete abortion than for women with anembryonic gestation or embryonic demise.¹²⁻¹⁶ TABLE W1, available at jfponline.com, provides a comparison of the efficacy of expectant management and misoprostol. In 1 observational study of 1096 women who chose expectant management, 91% of those with incomplete abortion were successful and 84% completed within 14 days of diagnosis. By comparison, only 59% of those with a missed abortion completed within 14 days.¹⁷

According to a study performed by Wieringa-de Waard and colleagues, increased bleeding appears to be the greatest predictor of completion. They showed that the median blood flow and pain were heaviest on the third day of vaginal bleeding, which then decreased steeply after 8 days to slight bleeding and spotting. Of the patients they followed, 50% completed during the first 8 days of bleeding.¹⁸

■ **A Cochrane review of 5 studies com-**

paring expectant management with vacuum aspiration found expectant management carried a higher risk of incomplete miscarriage, need for vacuum aspiration, and bleeding. In contrast, vacuum aspiration was associated with a significantly higher risk of infection.¹⁹

A low-cost option that can speed things up

EPL can be treated with prostaglandins to hasten the time to completion.²⁰ Misoprostol is a synthetic prostaglandin E₁ analog that causes contractions of the uterus and gastrointestinal tract. This medication is approved by the US Food and Drug Administration (FDA) only for the treatment of gastric ulcers, but it is commonly used off-label for labor induction, postpartum hemorrhage, and cervical ripening prior to gynecological procedures—as well as for the management of miscarriage.²¹ Misoprostol's low cost and stability at room temperature make it easy to use.²²

Route of administration. Although misoprostol is manufactured and approved for oral use only, administration by vaginal, buccal, or sublingual routes can increase the desired effect on the uterus, with the added benefit of decreased gastrointestinal side effects.²³

The dosage and dosing intervals for misoprostol for treatment of EPL have not been well established. A comprehensive review article recommends a single dose of 800 mcg vaginal misoprostol or, alternatively, 600 mcg sublingual misoprostol for anembryonic pregnancy or embryonic/fetal demise.²⁴ A single dose of 600 mcg oral or 400 mcg sublingual misoprostol is recommended for incomplete abortion.²⁵ The vaginal route may not be feasible when bleeding is heavy.

Safety and efficacy. Multiple studies have found that misoprostol is a safe and acceptable alternative to vacuum aspiration or expectant management.^{11,26-29}

A study comparing 652 women randomized to misoprostol vaginally or vacuum aspiration found that 84% of the misoprostol group had complete expulsion within 8 days of treatment initiation.³⁰

Infection rates. The Miscarriage Treatment (MIST) trial randomized 1200 women with a diagnosis of embryonic demise or in-

complete abortion at <13 weeks to medical (n=398), expectant (n=399), or vacuum aspiration management (n=403).³¹ Overall, the researchers found a low incidence of gynecologic infection (2.3%), and no evidence of difference in the infection rate attributable to the type of management selected.

Antibiotic use to reduce infection rates after misoprostol for EPL has not been studied. Nonetheless, a recent retrospective study examined infection rates after medical abortion with mifepristone and misoprostol.³² The study demonstrated a reduction in severe infection rates from 0.25 per 1000 abortions to 0.06 per 1000 (absolute reduction, 0.19 per 1000; 95% confidence interval [CI], 0.02-0.34; *P*=.03) with the routine use of doxycycline 100 mg PO twice daily for 7 days. The risk reduction is in comparison to the prior practice of either testing for sexually transmitted infection (STI) or using prophylactic doxycycline. The authors also reported a decrease in infection rate with a change from vaginal to buccal administration of misoprostol. The benefit of this change is unknown, because the practice of routine screening for STI or routine antibiotic provision was introduced at the same time.³²

Follow-up. After misoprostol administration, follow-up includes confirmation of passage of the embryo or gestational sac by a combination of history, clinical examination, and serial hCG measurement or ultrasound. A completed abortion can be demonstrated by quantitative serum hCG showing a 50% drop between first and repeat test 48 to 72 hours after the passage of tissue.³³ Follow-up 1 to 2 weeks after treatment is common practice, but can be scheduled sooner if the patient has not had bleeding and cramping. In that situation, you can give her the option of proceeding to uterine aspiration or trying a second dose of misoprostol (see doses given earlier), as long as she remains hemodynamically stable.²⁴

Women who experience successful treatment with misoprostol like the method. In a multicenter, randomized clinical trial, 154 women with EPL confirmed by ultrasonography who had not passed the pregnancy after a week were randomly assigned to treatment with misoprostol (n=79) or curettage (n=75). In cases where misoprostol had caused complete evacuation, 76% of the women would

 The manual vacuum aspirator is safe and provides the same degree of suction as an electric pump.

Management of early pregnancy loss with misoprostol: A protocol^{24,25}

Candidates

Women with ultrasound diagnosis of a nonviable pregnancy up to 10 weeks' gestation. Nonviable pregnancy is diagnosed by ultrasound and subnormal, rising quantitative human chorionic gonadotropin (hCG) levels. Misoprostol treatment is not suitable in ectopic pregnancy, which must be excluded before treatment is begun.

Laboratory workup

Rh screen, hemoglobin, and quantitative serum hCG.

Procedure

Insert 800 mcg misoprostol in the vagina. (This can also be done by the patient at home.) If passage of tissue does not occur, the physician can give the patient a second dose of 800 mcg misoprostol. Anembryonic pregnancy or fetal demise can also be treated with 600 mcg given sublingually. Incomplete abortion is treated with a single dose of 600 mcg orally or 400 mcg sublingually.

Pain management

Provide a prescription for ibuprofen 800 mg and Tylenol #3 to the patient. Instruct her to take a tablet of ibuprofen at the time of misoprostol insertion and then every 6 hours as needed for pain. If pain is severe, she may take 1 to 2 tablets of Tylenol #3 every 3 to 4 hours as needed.

Instructions to patient

Tell the patient to call the office for "heavy bleeding," defined as soaking 2 pads an hour for more than 2 hours. Tell the patient that there is no need to bring the expelled material for your inspection. Make sure she has your phone and pager numbers. If she needs to go to an emergency department or a hospital, tell her to request that you be called.

Follow-up

Schedule a follow-up visit 1 to 2 weeks after misoprostol insertion. A completed abortion can be demonstrated by quantitative serum hCG showing a 50% drop between first and repeat test 48 to 72 hours after the passage of tissue. Alternatively, a transvaginal ultrasound should show absence of a sac.

Of note: If one of these criteria is met, no further follow-up of serum hCG is warranted. Patients may elect manual vacuum aspiration at any time if the gestational sac and/or embryo have not passed.

opt for the same treatment, whereas only 38% of women who needed vacuum aspiration after unsuccessful misoprostol would do so ($P < .01$).³⁴

A sample protocol for medical management of EPL is provided in the box above.

Manual vacuum aspiration means less blood loss

A Cochrane review that compared vacuum aspiration with surgical D&C found that vacuum aspiration was associated with significantly less blood loss, pain, and time needed for the procedure.³⁵ Traditionally, vacuum aspiration for EPL has occurred in the OR, using electrical suction and general anesthesia. Recently, a manual vacuum aspirator that allows women to have the procedure done in the outpatient setting has become available. It is used with an analgesia given PO and a paracervical block.^{4,36}

The manual vacuum aspirator (MVA) is a handheld syringe that works well in the ambulatory setting because it is small, quiet, portable, and inexpensive. The MVA is safe, provides the same degree of suction as an electric pump, and is as effective as electrical vacuum aspiration for the management of both spontaneous and induced abortion.³⁷

■ As safe, as effective. A study by Goldberg and colleagues compared complication rates with MVA and electric suction in EPL of up to 10 weeks' gestation.³⁸ The researchers found no significant difference in perforation or need for re-aspiration. A comparison of the 2 methods in gestations of less than 6 weeks found a similar, small risk of failed abortion (<3%).³⁹ A study of 1677 women treated with MVA as outpatients in a primary care practice had a complication rate of only 1.25%.⁴⁰

■ Faster, cheaper. Blumenthal and Remsburg demonstrated that MVA in an outpatient setting decreases anesthesia requirements, hospital stay times, patient waiting times, and procedure times when compared with aspiration done in the OR. They showed a substantial saving, with the cost of uterine evacuation in the OR estimated at \$1404 vs \$827 per case when the aspiration was done as an outpatient procedure in the labor and delivery suite.⁴¹ The MVA syringe costs about \$30 and is reusable after appropriate cleaning through sterilization or high-level disinfectant. The disposable plastic suction cannulas cost less than \$3 each.

■ Pain management. A combination of an oral nonsteroidal anti-inflammatory (NSAID) medication and a paracervical block is a practical approach to managing the pain of this procedure. No published reports demonstrate that 1 type of local anesthetic is better than

another, and many different techniques and combinations of medicines used for the paracervical block have been described.⁴²

To minimize the effects of accidental blood vessel injection, the lowest anesthetic dose should be used, usually 10 to 20 mL of a 0.5% to 1% lidocaine or 0.25% bupivacaine solution. A common technique is to inject 8 to 10 cc of 1% lidocaine with epinephrine or vasopressin at 4 and 8 o'clock at the cervicovaginal reflection after careful aspiration to ensure the needle is not in a blood vessel.

Oral narcotics. Clinicians can also choose to manage pain with oral narcotics, benzodiazepines, or intravenous conscious sedation. Moderate cramping during and immediately after the procedure is common and can often be alleviated with verbal support.

For patients whose anxiety level is high, conscious sedation or general anesthesia may be the most appropriate choice. Your patient's preference and your evaluation of her medical risk and emotional state together determine the most appropriate course.⁴³ The technique for MVA is described in **TABLE W2**, available at jfponline.com.

Which approach is best for your patient?

Because all 3 approaches to managing EPL are effective and safe, family physicians can empower patients to make the choice themselves. Counseling about treatment options should include consideration of the patient's support at home, availability of transportation in case of emergency, her desire to avoid surgery, and her need for a definitive resolution.

Counseling should also include information on the likely efficacy of each option, given the type of EPL the patient has experienced. For example, women who have had a missed abortion (embryonic demise or anembryonic gestation) are less likely to complete with expectant management than women with an in-

complete abortion. Efficacy rates for different types of EPL are shown in **TABLE W1**, available at jfponline.com.

There's time for your patient to change her mind

A woman may opt for 1 approach to start with, but choose a different option later. She may choose expectant management for a week, and then if the pregnancy has not passed on its own, decide that she wants to try misoprostol. If that fails, too, she may want a uterine aspiration procedure.

How did our 3 patients fare?

CASE 1 ▶ At first, Janet was content to wait and see whether her miscarriage would pass without further intervention. But when a week went by and nothing happened, she wanted to get it over with. She asked to try MVA, under conscious sedation. The procedure was successful. Now, a year later, she's very happy to be pregnant again and confidently awaits a happy outcome.

CASE 2 ▶ By the time Lizbeth called, you suspected her abortion was complete. Your examination confirmed that diagnosis. She required no treatment, and a year later was ready to try again.

CASE 3 ▶ Lola was shocked when she learned her fetus had died in utero. But once she and her husband had taken in the sad news, they wanted to know what options were available. They talked it over and chose treatment with misoprostol. The miscarriage was completed 8 days later. They are content with their current family size and have decided not to try for another pregnancy. **JFP**

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▶ The cost of uterine evacuation in the OR is estimated at \$1404 vs \$827 when the aspiration is done as an outpatient procedure.

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➤ Because all 3 approaches to early pregnancy loss are safe and effective, you can empower patients to make the choice themselves.



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