Diagnosis and management of early pregnancy loss

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Early pregnancy loss is common and often devastating. Adverse medical and psychological complications may be avoided with the provision of informed, compassionate care. Also known as miscarriage, early pregnancy loss is defined as an empty gestational sac or a gestational sac with embryo without fetal cardiac activity before 13 weeks' gestation.[1] Early pregnancy loss can be further divided into incomplete, complete, and missed, which can be diagnosed based on findings from physical examination and pelvic ultrasonography (Table 1). If the location of the pregnancy is not confirmed, an ectopic pregnancy must be ruled out.

We summarize the best available evidence on the prevalence, risk factors, presentation, diagnosis, compassionate management, and follow-up of early pregnancy loss (Box 1).

Key points

- Early pregnancy loss, also known as miscarriage, is common, distressing, and frequently poorly managed in Canada.
- Diagnosis of early pregnancy loss requires determination of serum β-human chorionic gonadotropin (β-hCG) levels and pelvic ultrasonography, preferably transvaginal, to investigate pregnancy viability and distinguish early pregnancy loss from an ectopic pregnancy.
- Treatment options include expectant, medical, and surgical management.
- Early pregnancy loss can have devastating psychological effects, which may be mitigated by empathetic communication and supportive follow-up.

Box 1: Literature review

We conducted a targeted literature search using MEDLINE and Embase from inception to July 2023. Search terms included "early pregnancy loss," "first trimester loss," "abortion, spontaneous," "abortion, threatened," or "miscarriage," combined with "diagnosis," "risk factor*," "impact," "treatment," or "management." We also searched the term "early pregnancy assessment clinic" or "early pregnancy clinic." We limited the search to articles in English. No restrictions were placed on specific article types; however, we prioritized clinical practice guidelines from obstetrics and gynecological societies and groups, systematic reviews, and meta-analyses over other article types. We used other sources such as Google Scholar to find any additional relevant sources.

How common is early pregnancy loss?

The incidence of early pregnancy loss differs globally, in part because of varying definitions. Prospective data from Europe and North America suggest early pregnancy loss affects 15%–20% of all clinically recognized pregnancies.[2] The reported incidence was even higher (31%) when pregnant people were followed with serial testing of serum β-human chorionic gonadotropin (β-hCG) in early pregnancy.[3] Many pregnancies are lost before the patient recognizes they are pregnant, and signs of early pregnancy loss may be mistaken for late or heavy menses.[3] In Canada, 2 population-based retrospective cohort studies have informed incidence estimates, with early pregnancy loss in 8.1% and 10.1%–12.5% of recognized pregnancies in Ontario and Manitoba,

Table 1: Diagnosis of types of early pregnancy loss

Type	Symptoms	Speculum findings	Ultrasonography findings
Threatened	Bleeding or cramping	Cervix closed, no tissue visualized in the vagina	May show viable pregnancy with fetal cardiac activity
Incomplete	Bleeding or cramping	Cervix open or closed, with partial passage of tissue or blood clots in the vagina	No fetal cardiac activity
Inevitable	Bleeding or cramping	Cervix open, with partial passage of tissue or blood clots in the vagina	May show viable pregnancy with fetal cardiac activity
Complete	Bleeding or cramping	Cervix closed, with all tissue passed, usually followed by ongoing spotting or bleeding	No fetal cardiac activity
Missed	Asymptomatic	Cervix closed, no tissue visualized in the vagina	No fetal cardiac activity

respectively.[4,5] Interprovincial differences make it challenging to determine the actual incidence of early pregnancy loss in Canada or to compare it with that of other countries.

What are the risk factors?

Around half of all early pregnancy losses are a result of chromosomal abnormalities in the developing embryo, such as aneuploidy.[6] Maternal age older than 35 years significantly increases the risk of early pregnancy loss; among people aged 45 years or older, this risk is nearly 65%.[2,7] Other risk factors include a history of early pregnancy loss, infection with pathogens such as *Chlamydia trachomatis*, older paternal age, extremes in body mass index, smoking, alcohol consumption, physical trauma, psychological stress, exposure to air pollution, and pesticide exposure.[2,8–10] An association between early pregnancy loss and being Black has also been reported and is thought to be related to biological (e.g., a greater prevalence of anemia, diabetes, dyslipidemia), genetic (i.e., in genes related to immunological and inflammatory pathways), and socioeconomic factors.[11–14]

What are the symptoms?

Common symptoms of early pregnancy loss include bleeding, cramping, abdominal or pelvic pain, passage of tissue, or a combination of these. Symptoms of ectopic pregnancy, which should be ruled out, include worsening abdominal pain, dizziness, bleeding, or shoulder-tip pain.[15] Septic miscarriage should be suspected in the presence of fever, elevated leukocyte count, pelvic pain, uterine tenderness, or purulent discharge. Patients may also be asymptomatic with a missed early pregnancy loss.

Cramping or pain during pregnancy is common. Nearly 85% of pregnant patients have abdominal pain during the first 7 weeks of pregnancy.[15] Vaginal bleeding occurs during the first trimester in 25% of all pregnant patients with normal pregnancy outcomes.[16] Studies have shown that the risk of early pregnancy loss is 5 times greater among patients who have both bleeding and cramping (hazard ratio 5.03, 95% confidence interval [CI] 2.07–12.20), compared with those who have cramping only.[15]

How is early pregnancy loss diagnosed?

The steps for distinguishing early pregnancy bleeding, or pain related to early pregnancy loss, from other causes are shown in Figure 1. All patients require a detailed history, and a physical exam should be conducted to remove any cervical or vaginal clots to reduce bleeding and help visualize the cervix. Initial investigations include a complete blood count and determination of blood group, Rh factor, and β-hCG levels. Serum β-hCG levels confirm pregnancy, and a baseline level can be established to compare with previous and subsequent values. If a patient is hemodynamically unstable, they should be resuscitated and urgently referred to the gynecology team.[1] Once the patient is stable, ultrasonography should be performed, preferably transvaginally.

Around 10% of people with symptoms consistent with early pregnancy loss in their first trimester will have elevated serum β-hCG without an identified location of the pregnancy by initial ultrasonography, known as a pregnancy of unknown location.[17] This may represent an intrauterine pregnancy (viable or nonviable), a resolving pregnancy of unknown location (where the location is never identified), or a persisting pregnancy of unknown location, which must be followed until an ectopic pregnancy can be ruled out. The incidence of pregnancy of unknown location is around 15% among pregnant people undergoing routine transvaginal ultrasonography early in the first trimester.[17] Patients with pregnancy of unknown location and symptoms of early pregnancy loss have an 8%–14% risk of ectopic pregnancy, and empirical medical or surgical intervention is inappropriate without further investigation.[18]

For hemodynamically stable patients, a repeat serum β-hCG should be obtained at 48 hours. The ratio of repeat β-hCG to initial β-hCG can stratify risk of ectopic pregnancy.[17] A ratio greater than 1.63 suggests an intrauterine pregnancy, and the patient should have repeat transvaginal ultrasonography 1 week later. A ratio below 0.5 indicates a failing pregnancy that will resolve naturally, without need for repeat ultrasonography. Ratios between 0.5 and 1.63 suggest ectopic pregnancy and require close follow-up with repeat ultrasonography and β-hCG in 48 hours; a gynecologist should be consulted.[17] Other risk stratification tools, such as the M6 Regression Model, are beneficial but are not yet widely used in Canada.[18] Expectant management of pregnancy of unknown location is generally safe when risk of ectopic pregnancy is low, but close follow-up with a health care provider is critical until the β-hCG level becomes undetectable.

How is early pregnancy loss managed?

Care for patients experiencing early pregnancy loss includes expectant, medical, and surgical management; care should be individualized for each patient and achieved through shared decision-making and informed consent. For patients with hemodynamic instability or suspicion of septic miscarriage, surgical management is indicated. Hemodynamically stable patients without signs of infection should be offered information to help them make choices based on their preferences. Patients who choose expectant or medical management should be aware of the possible need for surgical intervention if the initial management plan fails.

The management of confirmed ectopic pregnancy is beyond the scope of this review. If a nonviable pregnancy is identified on ultrasonography, the patient should be offered a choice of expectant, medical, or surgical management (Appendix 1, Supplementary Table 1, available at www.cmaj.ca/lookup/doi/10.1503/cmaj.231489/tab-related-content).

All patients should have the option of having at least 1 support person present with them during assessment, be educated on what to expect during and after their care, and be provided with bereavement information (Figure 2 and Table 2). If patients wish to conceive again, they can do so once emotionally ready and no earlier than after their first period following the early pregnancy loss.

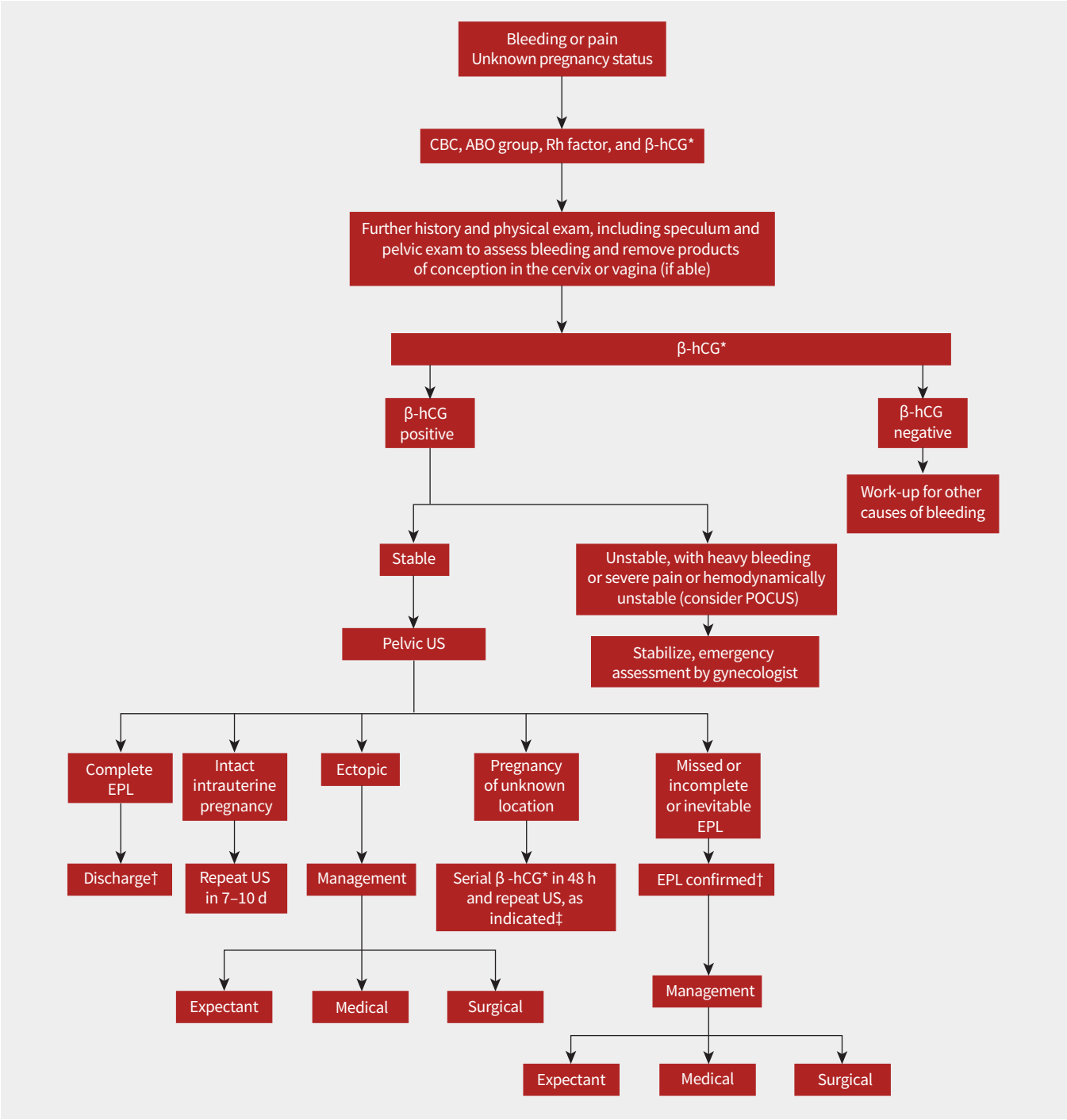

Figure 1: Diagnosis of early pregnancy loss. *Quantitative β-human chorionic gonadotropin (β-hCG) is preferred if available, but qualitative or urine β-hCG can be used if a quantitative measure is unavailable. †Patient should be offered patient-centred compassionate treatment and resources in the community. ‡The ratio of repeat β-hCG to initial β-hCG can stratify risk of ectopic pregnancy and will determine the need and timing of serial ultrasonography. See Related Content tab for accessible version. Note: CBC = complete blood count, EPL = early pregnancy loss, POCUS = point-of-care ultrasonography, US = ultrasonography.

Where available, patients with early pregnancy loss should be offered referral to an outpatient early pregnancy assessment clinic (EPAC), staffed by providers skilled in comprehensive, compassionate care.[19] These clinics can provide rapid assessment, diagnosis, and management, including facilitating dilation and curettage when indicated or chosen for early pregnancy loss.[20–22]

Expectant management

Expectant management is considered safe for patients with a known intrauterine pregnancy experiencing early pregnancy loss who are medically stable, with no active pelvic infections, without severe anemia or bleeding disorders, and without active uterine hemorrhage. Patients choosing expectant management

must be counselled to return to care if excessive bleeding, syncope, severe pain, or fever occur.

As many as half of all patients with early pregnancy loss will spontaneously pass all pregnancy tissue within 1 week of miscarriage without medical or surgical intervention, particularly if the patient is already bleeding and cramping.[23,24] In a 2002 observational study, around 80% of patients with incomplete miscarriage passed remaining pregnancy-related tissue by 14 days, and 91% passed all tissue by 46 days.[23] Patients should be informed about these possible timelines and be reassured that they can be transitioned to medical or surgical management at any time they prefer or if medically indicated. A 2017 Cochrane review comparing expectant management and medical treatment with vaginal misoprostol found no difference in the number of blood transfusions required (risk ratio [RR] 3.07, 95% CI 0.13–74.28), pelvic infections (RR 2.81, 95% CI 0.77–10.33) or pain relief (average RR 1.12, 95% CI 0.67–1.88).[25]

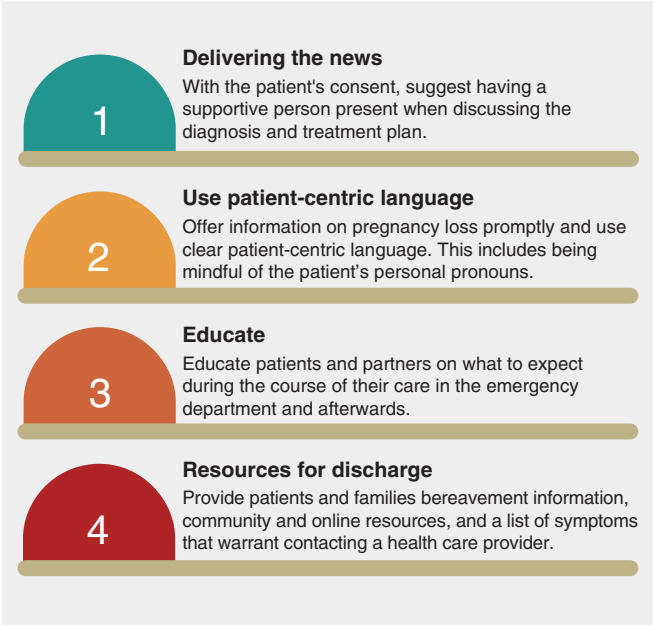

Figure 2: Communicating suspected or confirmed diagnosis of early pregnancy loss. See Related Content tab for accessible version. Adapted from the Provincial Council for Maternal and Child Health (www.pcmch.on.ca).

Pain management options include acetaminophen and nonsteroidal anti-inflammatory drugs (NSAIDs), with a limited prescription of opioid analgesics as needed. In-person or virtual follow-up visits can be scheduled every 7–14 days to confirm complete passage of tissue based on clinical history and resolution of bleeding.[17,26] Ultrasonography may be used to document the absence of the gestational sac but is not routinely indicated as clinical history can be used to ascertain resolution.[26] Expectant management is considered safe for up to 8 weeks after pregnancy loss is confirmed, as long as the patient remains clinically well, without ongoing bleeding, anemia, or evidence of infection.[27]

Medical management

Medical management achieves completed miscarriages earlier than expectant management and should be offered to all hemodynamically stable patients with a known intrauterine pregnancy experiencing early pregnancy loss.[28–30] Benefits include its noninvasive nature and the ability to self-administer at home.

Treatment consists of oral misoprostol — a prostaglandin analogue — alone or in combination with pre-treatment with oral mifepristone, a selective progesterone receptor modulator. Misoprostol induces uterine contractions, while mifepristone blocks progesterone, leading to disruption of the endometrium and termination.[31] Absolute contraindications to medical management with misoprostol and mifepristone include an intrauterine device in situ, if it cannot be removed; anti-coagulant use, other than acetylsalicylic acid; hemorrhagic disorders; inherited porphyrias; infectious symptoms; adrenal insufficiency; confirmed or suspected ectopic pregnancy; previous allergic reactions to mifepristone and misoprostol; and chronic glucocorticoid use. Relative contraindications include low hemoglobin (< 95 g/L) and lack of access to follow-up care in the community or emergency department.[32]

The combination of oral mifepristone (200 mg) with oral misoprostol (800 mg, taken 24–48 h after mifepristone) is considered first-line treatment for medical management of early pregnancy loss, with better outcomes than use of misoprostol alone.[30,31] In a randomized controlled trial, 23.5% (95% CI 16.9%–31.1%) of participants in the misoprostol-only group required further surgical intervention by vacuum aspiration 1 month after initiating medical treatment, compared with 8.8% (95% CI 4.8%–14.6%) of participants who were treated with both mifepristone and misoprostol.[29] Another randomized controlled trial, published in 2020, of 771 participants experiencing missed miscarriage found that

Table 2: Resources to share with patients experiencing early pregnancy loss

Resource	Website
PregnancyEd	www.pregnancyed.com
Royal College of Obstetricians and Gynecologists' patient information leaflet on early miscarriage	www.rcog.org.uk/for-the-public/browse-our-patient-information/early-miscarriage-patient-information-leaflet/
Provincial Council for Maternal and Child Health's list of pregnancy loss resources for families and health care providers	www.pcmch.on.ca/wp-content/uploads/2022/02/PCMCH-Early-Pregnancy-Loss-G-List-of-Pregnancy-Loss-Resources-for-Families-and-Healthcare-Providers_Updated.pdf
Women's Health Education Made Simple	www.whemscanada.org

25% in the placebo plus misoprostol group needed surgical intervention versus 17% in the mifepristone plus misoprostol group.[31]

For incomplete miscarriages, a guideline from the National Institute for Health and Care Excellence recommends monotherapy with 1 dose of misoprostol (600 µg).[33] Adverse effects include pain, diarrhea, nausea, vomiting, low-grade fever, chills, excessive bleeding, and failure necessitating surgical intervention.[34,35] Mifepristone has no additional benefit if the gestational sac has been expelled.

The American College of Obstetricians and Gynecologists' guideline recommends administering 1 dose of vaginal misoprostol (800 µg) if mifepristone is unavailable.[1] If the patient has no response, a second dose may be given within 7 days.[1] A 2005 randomized controlled trial[36] found that 71% of patients with first-trimester pregnancy loss (i.e., anembryonic gestation, embryonic or fetal death, or incomplete or inevitable spontaneous abortion) had complete expulsion by day 3 with 1 dose of misoprostol (800 µg). With a second dose of 800 µg, the rate increased to 84%.

As with expectant management, patients should be offered pain management by a combination of acetaminophen, NSAIDs, and a limited prescription of an opioid analgesic. Patients should be advised to expect heavy bleeding and cramping, which typically start a few hours after the administration of misoprostol and last for 3–5 hours.[28] Discussion should also include the possibility of seeing fetal tissue, especially for pregnancies over 9 weeks' gestation. Patients should return to the emergency department in the event of excessive bleeding (saturating 2 sanitary pads per hour for 2 consecutive hours[1]), presyncope, syncope, or severe abdominal pain. Lighter bleeding can last for an average of 9–16 days.[28] In-person or virtual follow-up can be done in 10–14 days.[26] Passage of tissue and resolution of bleeding should be confirmed using ultrasonography.[1] In situations where ultrasonography is not accessible, serum or urine β-hCG measurements may be employed as an alternative method.[1] If the patient remains symptomatic with ongoing bleeding and cramping, serial serum β-hCG measurements or ultrasonography may be necessary to ensure complete miscarriage.

Despite the addition of mifepristone to the World Health Organization's list of core essential medications,[37] it may not be accessible.[38] Barriers to stocking and dispensing mifepristone by pharmacies include cost, expiration date, relatively few prescriptions, and lack of training (despite Health Canada not requiring training for prescribing physicians and pharmacists); moreover, mifepristone for miscarriage is still considered off-label use.[38,39]

Surgical management

Surgical management requires the fewest health care interactions for the patient. It is the first-line treatment for patients with hemodynamic instability, low hemoglobin (< 95 g/dL), or a drop in hemoglobin of 20 g/dL. It is also the standard of care for patients with suspicion of molar pregnancy, an intrauterine device that cannot be removed, or signs of infection.[1,40] Uncommon risks of surgical management include cervical laceration (1.03%)[41] and pelvic infection (1.5%–5.3%).[42]

Suction dilation and curettage has better outcomes than sharp curettage.[43] A Cochrane review of surgical procedures for evacuating incomplete miscarriage reported lower complication rates for suction curettage for uterine perforation (RR 0.32, 95% CI 0.01 to 7.76), blood loss (mean difference –17.10 mL, 95% CI –24.05 mL to –10.15 mL), and pain (RR 0.74, 95% CI 0.61 to 0.90), compared with sharp curettage.[43] Endometrial scarring has been associated with sharp curettage, although it is rare.[43,44] Unlike sharp curettage, a suction evacuation can be done with a paracervical block, which offers superior pain control and fewer adverse effects than conscious sedation, and is useful in settings that lack support for the monitoring required for conscious sedation.[45] The procedure may be done in an office setting with skilled providers (i.e., EPACs) instead of in an operating room, leading to reduced wait times.[45]

Administration of RhD immunoglobulin

Early pregnancy loss is a risk factor for Rh alloimmunization in RhD antigen–negative pregnant patients if the fetus has an RhD antigen–positive blood type.[46] Exposure of maternal RhD-negative erythrocytes to those of an RhD-positive fetus can lead to maternal production of immunoglobulin G (IgG) antibodies. In subsequent pregnancies, these can cross the placenta and bind to fetal RhD-positive erythrocytes, causing hemolytic disease of the fetus or newborn, with consequences including anemia, jaundice with high risk of kernicterus, and hydrops fetalis. The administration of RhD immunoglobulin, where indicated, can prevent these outcomes. The Canadian guideline on prevention of Rh alloimmunization has been recently updated (Box 2).

What is the effect of early pregnancy loss on patients and their families?

Early pregnancy loss can have serious emotional and psychological effects, and may invoke grief, guilt, depression, anxiety, or other responses for both patients and their families.[26,27] Symptoms have been found to persist a year after pregnancy loss and during subsequent pregnancies.[48] Grief can be exacerbated by

Box 2: Prevention of Rh alloimmunization among Rh-negative patients with early pregnancy loss [47]

- Blood type and Rh status should be determined for all pregnant people.
- Patients with variants such as "weak D" or "partial D" are not at risk of alloimmunization and do not require preventative treatment.
- Patients negative for RhD:
  - < 8 weeks' GA: no prophylaxis (RhIg) required.
  - ≥ 8 and < 12 weeks' GA: consider administering RhIg (120 µg or 300 µg, IM or IV) or not.
  - 12 weeks GA: administer RhIg (300 µg, IM or IV).
  - For ongoing pregnancy, continue routine antepartum prophylaxis.

Note: GA = gestational age, IM = intramuscularly, IV = intravenously, RhIg = Rh immunoglobulin.

poor social support.[49–51] Partners who experience similar reactions may be disregarded.[52] People who identify as 2SLGBTQ+ often experience stigma and discrimination after pregnancy loss and may feel an amplified sense of shame.[53]

A phenomenologically informed qualitative study of people experiencing early pregnancy loss found areas of disconnect between the medical view of early pregnancy loss as a common and easily managed issue and patients' psychological experiences around the loss. Patients also described feeling rushed to make treatment decisions, and perceived poor provider sensitivity when the loss was experienced in early gestation.[54] Guidance on patient-centred communication of suspected or confirmed diagnosis of early pregnancy loss in the emergency department and resources for patients is outlined in Figure 2 and Table 2, respectively.

Research from Ontario and British Columbia has shown that EPACs can ameliorate patient experience and have been shown to improve clinical outcomes, reduce repeat assessments in the emergency department, and lead to improved patient satisfaction.[21,22] Strategies to increase the availability of EPACs include training more nurses and generalist physicians to confidently treat early pregnancy loss, and allowing patients at high risk to self-refer when needed.[55,56]

Conclusion

Early pregnancy loss is a common clinical presentation to primary care and the emergency department. Informed decision-making includes offering expectant, medical, or surgical management, depending on perceived benefits and contraindications. Although providers should assess and manage to prevent morbidity and death, they must also bear in mind the considerable psychological effects of early pregnancy loss and not underestimate compassion as a cornerstone of assessment, management, and follow-up.

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