American College of Radiology
ACR Appropriateness Criteria®
First Trimester Vaginal Bleeding

Variant 1:   First trimester vaginal bleeding. Initial imaging.

Procedure	Appropriateness Category	Relative Radiation Level
US pelvis transabdominal	Usually Appropriate	O
US pelvis transvaginal	Usually Appropriate	O
US duplex Doppler pregnant uterus	May Be Appropriate	O
MRI pelvis without IV contrast	May Be Appropriate	O
MRI pelvis without and with IV contrast	Usually Not Appropriate	O
CT pelvis with IV contrast	Usually Not Appropriate	☢☢☢
CT pelvis without IV contrast	Usually Not Appropriate	☢☢☢
CT pelvis without and with IV contrast	Usually Not Appropriate	☢☢☢☢

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Summary of Literature Review

Introduction/Background

Approximately 25% of pregnant women will experience vaginal bleeding of varying severity during their first trimester [1,2]. Underlying etiologies include a normal intrauterine pregnancy (IUP) with or without subchorionic hematoma, nonviable IUP, gestational trophoblastic disease (GTD), and ectopic pregnancy (EP) [3]. Given the wide range of both relatively benign and potentially life-threatening conditions that may be causing a patient's presentation, accurate diagnosis and prompt effective treatment is imperative to improve outcomes for both the patient and the fetus [4].

Initial Imaging Definition

Initial imaging is defined as imaging at the beginning of the care episode for the medical condition defined by the variant. More than one procedure can be considered usually appropriate in the initial imaging evaluation when:

- There are procedures that are equivalent alternatives (ie, only one procedure will be ordered to provide the clinical information to effectively manage the patient's care)

OR

- There are complementary procedures (ie, more than one procedure is ordered as a set or simultaneously where each procedure provides unique clinical information to effectively manage the patient's care).

Discussion of Procedures by Variant

Variant 1: First trimester vaginal bleeding. Initial imaging.

Light bleeding or spotting can occur normally in early pregnancy as the fertilized egg implants into the endometrium and the cervix becomes hypervascularized. Although it can be normal, bleeding can also be a manifestation of early pregnancy-related pathology such as a nonviable IUP or EP. Early imaging can help differentiate the etiology of bleeding, allowing for prompt diagnosis and treatment of the patient, improving both maternal and fetal outcomes.

CT Pelvis With IV Contrast

CT should generally not be performed in the first trimester due to the ionizing radiation and its known teratogenic effects. Occasionally, CT is performed unknowingly during pregnancy and an IUP or EP may be identified [5,6]. Alternatively, CT may be intentionally performed when MRI and US are limited or in particularly challenging cases. Although it was previously thought that intravenous (IV) iodinated contrast administration should be avoided during pregnancy, there is no definitive evidence that iodinated contrast harms the developing embryo. The use of iodinated contrast often improves the sensitivity of CT for identifying pathology. Ultimately, the decision to perform a CT with iodinated contrast should involve a balanced discussion between the patient, referring clinicians, and radiology team [7]. Contrast-enhanced CT may occasionally be helpful in diagnosing complicated cases of retained

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products of conception (RPOC) [6,8]. Enhanced CT can also be helpful in determining the extent of extrauterine spread in malignant GTD.

CT Pelvis Without and With IV Contrast
Performing a CT both with and without IV contrast significantly increases the radiation dose to both the patient and the fetus as compared with only acquiring one phase of imaging. Additionally, the acquisition of both noncontrast and contrast-enhanced studies does not improve diagnostic accuracy in the overwhelming majority of diagnoses in the first trimester patient with vaginal bleeding. Rarely, this study may be helpful when evaluating for extrauterine spread of malignant GTD because it allows one to characterize any enhancement more definitely.

CT Pelvis Without IV Contrast
CT should generally not be performed to evaluate vaginal bleeding in the first trimester because of the ionizing radiation and its known teratogenic effects. Occasionally, CT is performed unintentionally during pregnancy, and in such cases, an IUP or EP may be identified [5,6]. RPOC can also be identified on CT, but it has little role in making the diagnosis, particularly in the absence of IV contrast [6,8]. Unenhanced CT may be helpful in diagnosing intraperitoneal bleeding.

MRI Pelvis Without and With IV Contrast
MRI can sometimes be helpful in cases of diagnostic dilemmas as described above. However, the use of gadolinium contrast is not recommended due to its potential teratogenic effects [6,9-11]. For further details regarding the use of contrast during pregnancy, please refer to the Safety Considerations in Pregnant Patients section below. In cases of suspected GTD, contrast-enhanced MRI can help stage disease by evaluating the extent of myometrial invasion and local extrauterine spread. In such cases, the use of IV contrast may be warranted.

MRI Pelvis Without IV Contrast
MRI is rarely needed in the evaluation of an IUP or tubal EP. When an IUP or tubal pregnancy is identified on MRI, it is usually because the pregnancy status is unknown or the patient is being imaged for other reasons [5,8]. MRI without gadolinium is considered safe in the first trimester [6,9-11]. MRI may be a useful problem-solving tool when pelvic ultrasound (US) evaluation is limited, particularly in patients with severe pain or large body habitus. MRI is also helpful when a nontubal EP is suspected or in patients with uterine anomalies [5,12,13]. RPOC can also be visualized on MRI and is occasionally useful as an adjunct imaging modality in complicated cases. RPOC and GTD have overlapping features on MRI, and thus, clinical context is essential [14].

US Duplex Doppler Pregnant Uterus
When a normal or potentially normal IUP is present, Doppler US modalities (whether spectral, color, or power) should not be routinely used in the first trimester due to the potential thermal bioeffects on the developing embryo [15]. If Doppler US is felt to be clinically useful, exposure times should be minimized [16]. Evaluation of embryonic cardiac activity can be performed using cine clips and M-mode US. However, if there is suspicion for EP, Doppler US of the adnexal regions may be useful, with care taken to avoid the uterus while scanning with Doppler.

US Pelvis Transabdominal
Transabdominal pelvic US is typically performed in combination with transvaginal pelvic US. However, in some instances transvaginal pelvic US may not be performed due to patient or clinical limiting factors, and transabdominal pelvic US can serve as the primary initial imaging modality. Transabdominal US is more likely to be adequate later in the first trimester.

Ectopic pregnancy: If an abnormal amount of free intraperitoneal fluid is seen in the pelvis, a transabdominal US can be used to evaluate the flanks and dependent portions of the upper quadrants to quantify any additional fluid. Although it is incredibly difficult to predict tubal rupture in EP with US, larger amounts of free fluid have been associated with a ruptured fallopian tube [13,17,18].

US Pelvis Transvaginal
Transvaginal US provides high-resolution images of both normal and abnormal early pregnancy changes and, when coupled with serum human chorionic gonadotropin (hCG) levels, can usually differentiate the most common underlying pathologies seen in the first trimester.

Intrauterine fluid collection: The earliest US finding of an IUP is a gestational sac, which appears as a round anechoic fluid collection with an echogenic rim at 5 weeks gestational age (GA) [19]. More recent research has shown that in women with a positive hCG and no extraovarian adnexal mass, the sonographic identification of an intrauterine sac-like structure is virtually certain to be a gestational sac [3,18,20].

The discriminatory serum level of hCG at which a gestational sac should always be seen on US has been historically cited as 1,000 to 2,000 mIU/mL; however, more recent research suggests that even 2,000 mIU/mL is too low to exclude a normal IUP. Ultimately, decisions should not be made on a single serum hCG level, and hemodynamically stable patients should be followed with serial hCG and US [21-23].

A subchorionic hematoma occurs when there is hemorrhage around the gestational sac with blood accumulating between the chorion and myometrium. Sonographically, it appears as a crescentic avascular collection adjacent to the chorion, typically hypoechoic or anechoic [1,2,24]. Subchorionic hematomas are a relatively common finding in the first trimester, occurring in approximately 18% to 22% of patients with live IUPs and vaginal bleeding [1]. It has been traditionally thought that subchorionic hematomas were associated with an elevated risk of early pregnancy loss, but several recent studies have shown that there may not be an independent increased risk of pregnancy loss [3,25-29]. The presence of 2 or more separate fluid collections in the endometrial cavity of a patient with elevated serum hCG levels should be followed to rule out presence of hematoma(s) or multiple gestations.

Definite intrauterine gestation: The yolk sac is the first definitive sign of an IUP and is usually visible sonographically at 5.5 weeks GA or when the gestational sac has a mean sac diameter (MSD) >8 mm. The yolk sac initially appears as 2 echogenic parallel lines at the periphery of the gestational sac but then eventually acquires its more typical appearance of a thin-walled, rounded structure with an anechoic center [3,26]. When a yolk sac is identified, the likelihood of a live first trimester outcome is significantly higher than when no yolk sac is seen [30].

An embryo (also referred to a fetal pole early on) is the next sonographic structure to develop and is usually identified at 6 weeks GA or when the gestational sac has an MSD of 16 mm [3,22]. Initially, the embryo is a relatively featureless echogenic linear or oval structure adjacent to the yolk sac. The crown rump length (CRL) is the measurement between the cranial and caudal ends of the embryo and is the most accurate estimate of GA in the first trimester [26].

The absence of a yolk sac in a gestational sac with MSD >8 mm or the absence of an embryo in a gestational sac with MSD >16 mm is concerning for a failed IUP, but it is not diagnostic, and such pregnancies should be followed closely with serial hCG and US [22].

A pregnancy loss can be appropriately diagnosed once a gestational sac has an MSD of ≥25 mm and no embryo is identified. Because not all failed pregnancies will achieve an MSD of ≥25 mm, time-based criteria can also be used for diagnosis. If an initial US shows a gestational sac and yolk sac without an embryo, a pregnancy loss can be diagnosed if there is no embryonic cardiac activity at least 11 days later. If an initial US shows a gestational sac without a yolk sac, a failed IUP can be diagnosed if there is no embryonic cardiac activity 14 or more days later [22,31,32].

Cardiac activity can be identified as early as 6 weeks GA but must be definitively identified when the CRL is 7 mm. Absence of a detectable heartbeat in an embryo with a CRL of ≥7 mm is diagnostic of pregnancy loss [26]. Absence of cardiac activity in an embryo with a CRL of <7 mm is considered suspicious for pregnancy loss, and a follow-up US should be obtained in 7 to 10 days [22,32,33].

Once an IUP has been identified, any abnormal sonographic features should be identified because several have been associated with an increased likelihood of pregnancy loss. Bradycardia; an empty amnion; an enlarged yolk sac (>7 mm); a large MSD; abnormal morphology of the gestational sac, amnion, or yolk sac; and a disproportionately small gestational sac are all suspicious findings for pregnancy loss, and these cases should be followed closely [19,26,31,33].

Pregnancy of unknown location: Pregnancy of unknown location refers to a condition in which a woman has a positive pregnancy test but no evidence of an IUP or EP on US [23]. Diagnostic possibilities include early live IUP, pregnancy loss, and EP [22]. There is considerable overlap in the hCG levels seen in these 3 entities. As discussed earlier, serum hCG levels are not dependable for ruling out a live IUP as was initially thought. When the hCG level is >2,000 mIU/mL in a woman with a pregnancy of unknown location, however, the most likely diagnosis is a pregnancy loss [22]. After such diagnosis, the presence of continued bleeding or persistent elevation of hCG may suggest RPOC.

Both grayscale and color Doppler US are considered the first-line imaging modality for diagnosing RPOC [8]. Findings suggestive of RPOC include an endometrial or intrauterine mass, or a thickened endometrial echo complex, especially when there is associated increased vascularity on Doppler [8].

The second most likely diagnosis in a woman with a pregnancy of unknown location with elevated hCG is EP. Vaginal bleeding is a common early sign of an EP and can range from spotting to menstruation like levels, because of the breakdown of decidual endometrium in the uterine cavity due to low levels of hCG. It can be diagnostically challenging to differentiate an early IUP from a nonvisualized EP. If the patient is hemodynamically stable, follow-up hCG and US should be performed to protect against harming a potentially live pregnancy [22,26,31].

Ectopic pregnancy: An EP occurs when blastocyst implantation occurs outside the endometrial cavity and is estimated to occur in up to 2% of all pregnancies [4,13,25]. Maternal mortality from EP has decreased significantly over the last several decades, but it remains the most common cause of maternal death in the first trimester [3]. When an IUP is not visualized in a patient with a positive pregnancy test, one must consider the possibility of an EP.

Approximately 95% of ectopic pregnancies occur in the fallopian tube, and thus, when there is concern for an EP, the adnexa should be carefully evaluated [13]. The most common US finding in a tubal EP is a nonspecific extraovarian adnexal mass [17]. In some cases, an extraovarian adnexal gestational sac may be identified. The tubal ring sign is highly specific for tubal EP and appears as a gestational sac with a thick, echogenic wall. The specificity of this finding approaches 100% when a yolk sac is also identified [13]. A common mimicker of tubal EP is a corpus luteum. To differentiate an adnexal mass that is intraovarian (such as a corpus luteum) from one that is extraovarian, the sonographer can apply pressure with the US probe to determine whether the structure moves with the ovary [3,13].

An interstitial EP is a type of tubal EP occurring in the most proximal portion of the fallopian tube within the myometrium, and it can be very difficult to differentiate from a high-lying IUP or angular pregnancy [13]. Three-dimensional coronal reconstructions can further help confirm the location [3,34].

Evaluation for free intraperitoneal fluid is essential in cases of suspected EP. A small volume of simple free fluid in the posterior cul-de-sac is almost always physiologic. Larger volumes of free fluid and increasing complexity of the fluid raises concern for hemoperitoneum and increases the likelihood of an EP [13,17].

The overwhelming minority of ectopic pregnancies occur in locations other than the fallopian tube. The most common include cervical, ovarian, abdominal, and cesarean scar ectopic pregnancies [3,4,35]. Ovarian ectopic pregnancies are rare and appear sonographically as a cystic structure with echogenic wall inseparable from the ovary [13]. This is a particularly challenging diagnosis to make because an ovarian mass in a patient with a positive hCG is overwhelming likely to represent a corpus luteum [3]. The coexistence of an IUP and EP (referred to as a heterotopic pregnancy) is exceedingly rare, although the risk is increased in patients using assisted reproductive technology [4]. In a woman with a spontaneously occurring pregnancy, identification of an IUP almost always excludes a coexisting EP.

Gestational trophoblastic disease: GTD refers to a spectrum of disorders involving abnormal growth of placental trophoblastic tissue. GTD ranges from benign hydatidiform moles to malignant invasive moles, choriocarcinoma, and trophoblastic tumors [3].

Hydatidiform moles, either partial or complete, are the most common presentation of GTD. Complete moles are diploid and entirely paternal in origin and appear sonographically as a complex, multicystic, and often hypervascular endometrial mass without fetal tissue [36]. Hydropic failed pregnancies can have a similar appearance and can be misdiagnosed in up to 10% of cases [3]. Partial moles are triploid with both maternal and paternal genetic material. They can be challenging to diagnose on US because they are often indistinguishable from complete mole or hydropic failed pregnancy. On US, one may see a growth restricted and abnormally formed fetus with a thickened placenta containing cystic changes. Histopathologic evaluation of uterine products is required for definitive diagnosis [3,36].

Malignant variants of GTD include invasive molar pregnancy, choriocarcinoma, placental-site trophoblastic tumor, and epithelioid trophoblastic tumor. These entities are challenging to differentiate from each other on US because they all present as echogenic, highly vascular uterine masses [3].

Summary of Highlights

This is a summary of the key recommendations from the variant tables. Refer to the complete narrative document for more information.

- **Variant 1**: When evaluating a patient with first trimester vaginal bleeding, transvaginal and transabdominal pelvic US are the initial recommended studies as both modalities provide high-resolution images of normal and abnormal early pregnancy changes. US pelvis transvaginal and US pelvis transabdominal are complementary examinations and performed together. When combined with hCG levels, the most common underlying pathologies can be identified quickly and efficiently. In addition, the lack of ionizing radiation and use of IV contrast agents limits potential harm to the patient and fetus. Duplex Doppler US of the pregnant uterus may be appropriate in cases in which an EP is suspected, but scanning should be minimized and limited to the adnexa in order to minimize potential thermal bioeffects to the fetus. MRI of the pelvis without IV contrast may also be appropriate in cases of troubleshooting when US is limited due to patient habitus or when a nontubal ectopic is suspected.

Supporting Documents

The evidence table, literature search, and appendix for this topic are available at https://acsearch.acr.org/list. The appendix includes the strength of evidence assessment and the final rating round tabulations for each recommendation.

For additional information on the Appropriateness Criteria methodology and other supporting documents, click here.

Safety Considerations in Pregnant Patients

Imaging of the pregnant patient can be challenging, particularly with respect to minimizing radiation exposure and risk. For further information and guidance, see the following ACR documents:

- ACR–SPR Practice Parameter for the Safe and Optimal Performance of Fetal Magnetic Resonance Imaging (MRI) [37]

- ACR-SPR Practice Parameter for Imaging Pregnant or Potentially Pregnant Patients with Ionizing Radiation [38]

- ACR-ACOG-AIUM-SMFM-SRU Practice Parameter for the Performance of Standard Diagnostic Obstetrical Ultrasound [39]

- ACR Manual on Contrast Media [7]

- ACR Manual on MR Safety [11]

Gender Equality and Inclusivity Clause

The ACR acknowledges the limitations in applying inclusive language when citing research studies that pre-dates the use of the current understanding of language inclusive of diversity in sex, intersex, gender, and gender-diverse people. The data variables regarding sex and gender used in the cited literature will not be changed. However, this guideline will use the terminology and definitions as proposed by the National Institutes of Health [40].

Appropriateness Category Names and Definitions

Appropriateness Category Name	Appropriateness Rating	Appropriateness Category Definition
Usually Appropriate	7, 8, or 9	The imaging procedure or treatment is indicated in the specified clinical scenarios at a favorable risk-benefit ratio for patients.
May Be Appropriate	4, 5, or 6	The imaging procedure or treatment may be indicated in the specified clinical scenarios as an alternative to imaging procedures or treatments with a more favorable risk-benefit ratio, or the risk-benefit ratio for patients is equivocal.
May Be Appropriate (Disagreement)	5	The individual ratings are too dispersed from the panel median. The different label provides transparency regarding the panel's recommendation. "May be appropriate" is the rating category and a rating of 5 is assigned.
Usually Not Appropriate	1, 2, or 3	The imaging procedure or treatment is unlikely to be indicated in the specified clinical scenarios, or the risk-benefit ratio for patients is likely to be unfavorable.

Relative Radiation Level Information

Potential adverse health effects associated with radiation exposure are an important factor to consider when selecting the appropriate imaging procedure. Because there is a wide range of radiation exposures associated with different diagnostic procedures, a relative radiation level (RRL) indication has been included for each imaging examination. The RRLs are based on effective dose, which is a radiation dose quantity that is used to estimate population total radiation risk associated with an imaging procedure. Patients in the pediatric age group are at inherently higher risk from exposure, because of both organ sensitivity and longer life expectancy (relevant to the long latency that appears to accompany radiation exposure). For these reasons, the RRL dose estimate ranges for pediatric examinations are lower as compared with those specified for adults (see Table below). Additional information regarding radiation dose assessment for imaging examinations can be found in the ACR Appropriateness Criteria® Radiation Dose Assessment Introduction document [41].

Relative Radiation Level Designations		
Relative Radiation Level*	Adult Effective Dose Estimate Range	Pediatric Effective Dose Estimate Range
O	0 mSv	0 mSv
☢	<0.1 mSv	<0.03 mSv
☢☢	0.1-1 mSv	0.03-0.3 mSv
☢☢☢	1-10 mSv	0.3-3 mSv
☢☢☢☢	10-30 mSv	3-10 mSv
☢☢☢☢☢	30-100 mSv	10-30 mSv
*RRL assignments for some of the examinations cannot be made, because the actual patient doses in these procedures vary as a function of a number of factors (eg, region of the body exposed to ionizing radiation, the imaging guidance that is used). The RRLs for these examinations are designated as "Varies."		

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