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Since being introduced more than 30 years ago, endovaginal ultrasonography (US) and quantitative testing of serum levels of the beta subunit of human chorionic gonadotropin have become the standard means of establishing the presence of normal intrauterine pregnancy (IUP), failed IUP, and ectopic pregnancy. Appropriate use of these powerful tools requires clear, standardized interpretations based on conservative criteria to protect both the pregnancy and the mother. Since diagnoses are assigned earlier and available medical treatments for ectopic pregnancy and failed IUP are expanding, emphasis must carefully shift toward watchful waiting when the mother is clinically stable and a definitive location for the pregnancy cannot be established with US. To this end and to prevent inadvertent harm to early normal pregnancies, the Society of Radiologists in Ultrasound convened a consensus panel of radiologists, obstetricians, and emergency medicine physicians in 2012 with the goal of reviewing current literature and clinical practices and formulating modern criteria and terminology for the various first-trimester outcomes.

Introduction

Pelvic ultrasonography (US) and testing of the beta subunit of human chorionic gonadotropin (β-hCG) serum levels are key to diagnosis of early pregnancy and guide management of its associated complications. US imaging in early pregnancy should be primarily endovaginal, with transabdominal imaging used for adnexal masses high in the pelvis and documentation of the amount of free fluid. These tests allow distinction among the diagnostic possibilities of early pregnancy—intrauterine pregnancy (IUP) versus ectopic pregnancy, viable versus nonviable IUP, IUP of uncertain viability, and pregnancy of unknown location—and have contributed to the marked decline in mortality from ectopic pregnancy since the 1980s (1). However, misuse of these tests and misinterpretation of the findings can lead to unintentional harm to potentially viable pregnancies, such as administration of methotrexate for suspected ectopic pregnancy when, in fact, an early IUP is present but not recognized, resulting in embryonic demise or clinically significant birth defects (2). In several case reports, the teratogenic effects of methotrexate in fetuses have been documented (3–5), but inappropriate use of methotrexate due to misdiagnosis is likely underreported in the

Abbreviations: β-hCG = beta subunit of human chorionic gonadotropin, CRL = crown-rump length, IUP = intrauterine pregnancy, MSD = mean sac diameter

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SA-CME LEARNING OBJECTIVES

After completing this journal-based SA-CME activity, participants will be able to:

■ Describe issues related to safe interpretation of US findings in first-trimester pregnancy, including definitely normal findings, definitely abnormal findings, and indeterminate findings that require follow-up.

■ List criteria that are diagnostic for pregnancy failure and suspicious for pregnancy failure.

■ Identify the correct management strategy for a pregnancy of unknown location with normal or near-normal adnexa.

See www.rsna.org/education/search/RG.
TEACHING POINTS

- On the basis of the much higher prevalence of IUP compared with ectopic pregnancy and the fact that a minority of ectopic pregnancies have small intrauterine fluid collections, a nonspecific fluid collection with a smooth, rounded, or oval contour represents an IUP until proven otherwise.
- Because of interobserver variability in endovaginal US measurements of CRL, a 7-mm CRL is necessary to yield a specificity and positive predictive value of 100%, thereby decreasing the likelihood of a false-positive diagnosis associated with a 5-mm CRL cutoff.
- The same reasoning applies to using (a) an MSD cutoff of 25 mm without an embryo as a criterion for pregnancy failure, rather than the previously recommended MSD of 16 mm, and (b) an MSD range of 16–24 mm without an embryo as an indicator of suspicion of pregnancy failure.
- Pregnancy of unknown location is the term given to the transient state of early pregnancy during which no definite IUP is visualized at US and the adnexa are normal—in other words, a “normal” pelvic US finding. At this stage, the three main possibilities include early IUP, occult ectopic pregnancy, and completed spontaneous abortion. Unfortunately, a single β-hCG serum level does not allow reliable differentiation among these possibilities.
- In a patient who is hemodynamically stable and has a pregnancy of unknown location, it is less harmful to wait, monitor the β-hCG levels, and repeat the US examination than to presumptively treat an ectopic pregnancy.

The role of follow-up pelvic US and monitoring of β-hCG levels is reviewed.

Normal Development of Early IUP between 4 and 8 Weeks of Gestational Age

Gestational age is calculated from the first day of a woman’s last menstrual period; however, it is important to appreciate that conception does not take place until after ovulation, approximately 2 weeks after the last menstrual period. This accounts for the 2-week discrepancy between the clinical and histologic gestational age. A gestational sac can first be visualized at endovaginal US at 4.5–5.0 weeks of gestational age as a 2–3-mm rounded intrauterine fluid collection (7). The mean sac diameter (MSD) growth rate is 1.13 mm per day but is often variable (8). Before visualization of a yolk sac or embryo to confirm the fluid collection as a true gestational sac, two signs may be used. The intradecidual sign (Fig 1), defined as an eccentrically located gestational sac within the echogenic decidua, with a relatively undisturbed collapsed uterine cavity visualized as a thin echogenic line, is highly suggestive of an IUP (9–11). The double sac sign (Fig 2), consisting of two concentric echogenic rings surrounding the fluid collection and separated by a thin crescent of endometrial fluid, is a sign of definitive IUP. The outer echogenic ring represents the decidua parietalis, and the inner ring represents the decidua capsularis and chorion (12). The intradecidual sign is visible before the double sac sign because in the intradecidual sign, the gestational sac is not large enough to deform the contour of the uterine cavity, while in the
double sac sign, the gestational sac has grown large enough to protrude into the endometrial cavity. The US appearance of early gestational sacs is variable, and while these two signs are highly suggestive of an early IUP, they will be absent in at least 35% of gestational sacs (13). Thus, absence of these signs does not exclude an IUP. A nonspecific, empty, rounded intrauterine fluid collection seen in a pregnant patient has more than a 99.5% probability of representing a gestational sac (14). Therefore, on the basis of the much higher prevalence of IUP compared with ectopic pregnancy and the fact that a minority of ectopic pregnancies have small intrauterine fluid collections, a nonspecific fluid collection with a smooth, rounded, or oval contour represents an IUP until proven otherwise.

The yolk sac is the earliest intragestational sac structure to be visualized at US that can absolutely confirm an IUP. It is the primary maternal-fetal transport system before the establishment of a fully developed placental circulation (15) and can be visualized at approximately 5.5 weeks of gestational age (1) as a round 3–5-mm structure, usually eccentrically located within the gestational sac (Fig 3a). In gestational sacs at 5.0–5.5 weeks, the yolk sac may sometimes appear as two parallel lines, representing the leading edge and the posterior wall—within a small gestational sac. The MSD is 4 mm, projecting to a gestational age of 5 weeks 0 days.

The embryo is first visible at approximately 6 weeks of gestational age as a 1–2-mm structure (7,16) at the periphery of the yolk sac. The length of the embryo is measured from the head (crown) to the buttocks (rump), hence the term crown-rump length (CRL) (Fig 4), which is the most accurate measurement of gestational age through the first 12 weeks of pregnancy. The embryo should be visualized when the MSD is at least 25 mm (6).

The embryo resides within the amniotic cavity, and the yolk sac resides within the chorionic cavity. The amniotic membrane is thinner than the yolk sac, and although it is seen more easily after
7 weeks (Fig 5), it can be seen as early as 6.5 weeks of gestational age (17). Between 6.5 and 10 weeks of gestation, a linear relationship exists between the diameter of the amniotic cavity and the CRL, with the mean diameter of the amnion 10% larger than that of the CRL (18). In normal gestation, the chorionic cavity, amniotic cavity, and CRL grow proportionally until the onset of fetal urine production at about 10 weeks. The fetal urine disproportionately enlarges the amniotic cavity, which then grows faster than the chorionic cavity, with eventual fusion of the amnion and chorion at 14–16 weeks (19).

Cardiac pulsation in the two paired endocardial heart tubes begins at approximately the 6th week of gestation; thus, it is possible to observe cardiac activity in embryos as small as 1–2 mm. However, absence of cardiac activity in embryos smaller than 4 mm may also be normal (Figs 6, 7) (20). To allow for measurement inaccuracies, differing types of equipment, and other variations in US imaging, the Society of Radiologists in Ultrasound established a measurement of 7 mm and larger as the CRL at which cardiac activity should be present (6). Thus, a definitive diagnosis of failed pregnancy may be assigned only if the embryo is at least 7 mm and lacks cardiac activity. The embryonic heart rate accelerates over the first 6–8 weeks of gestation, with the lower limit of normality near 100 beats per minute at 6.2 weeks of gestation and 120 beats per minute at 6.3–7.0 weeks of gestation (21). Embryonic tachycardia, defined as a heart rate of 135 beats per minute and higher before 6.3 weeks of gestation or 155 beats per minute and higher at 6.3–7.0 weeks of gestation, has been shown to have a good prognosis, with a high probability of a normal outcome (22).

Embryonic morphology is rather featureless until 7–8 weeks, when the spine can be visualized. At approximately 8 weeks of gestation, the head curvature can be separated from the body, and the four limb buds become apparent (23). The rhombencephalon, which is the developing hindbrain, is a prominent landmark at 8–10 weeks of gestation (24), appearing as an anechoic round structure within the head (Fig 5). Intrinsic motion of the embryo may be seen as early as 8.0–8.5 weeks. A timeline of normal early pregnancy development is listed in Table 1.

**Abnormal Early IUP**

The timing of visualization of early pregnancy landmarks—gestational sac at approximately 5 weeks of gestation, yolk sac at 5.5 weeks, and embryo at 6 weeks, with variation of ±0.5 weeks (7)—is accurate and consistent. Thus, any deviation from this expected time course may be either indicative of or definitive for a failed pregnancy. Discriminatory values for absence of cardiac activity at a certain CRL, absence of an embryo at a certain MSD, and time-based non-visualization of a live embryo were established in the 1980s, when endovaginal US was first deployed. The criteria were based on small cohorts and originated in single-institution academic centers at a time when interobserver variability and standard deviation in measurements were not widely used. More recently, reports of large population-based studies performed by heterogeneous groups of imagers have shown greater variability (25,26). In addition, modern treatment of ectopic pregnancy has shifted to use of nonsurgical therapy. Use of methotrexate instead of surgery does not allow corroboration of the US-based diagnosis and will also potentially harm an IUP. With the goal of absolute certainty
Figure 6. Endovaginal M-mode US image in a pregnant patient demonstrates normal cardiac activity of 122 beats per minute (bpm). The CRL is 3 mm, projecting to a gestational age of 6 weeks 3 days.

Figure 7. Endovaginal US images in a pregnant patient with vaginal bleeding and a serum β-hCG level of 5420 mIU/mL (5420 IU/L) show development of cardiac activity. (a) Initial image shows a normal yolk sac and a CRL of 2 mm (arrow), projecting to a gestational age of 5 weeks 6 days. No cardiac activity was detected. (b) Follow-up image obtained 12 days later shows appropriate interval growth of the embryo (arrow). The CRL is 11 mm, projecting to a gestational age of 7 weeks 3 days. (c) M-mode image shows normal cardiac activity of 150 beats per minute (bpm).

For many years, an empty gestational sac (without a yolk sac) of 8 mm and larger was considered diagnostic of pregnancy failure, but this criterion is now considered too narrow and has been abandoned (6,25–27).

Previously, a CRL of 5 mm without cardiac activity fulfilled the criterion for pregnancy failure; however, in one series, this resulted in a false-positive rate of 8.3% (25). There have also been reports of embryos with a CRL of 6 mm and no cardiac activity resulting in viable pregnancies (28). Because of interobserver variability in endovaginal US measurements of pregnancy failure before initiation of irrevocable medical or surgical management, the Society of Radiologists in Ultrasound 2012 consensus panel revisited the traditional discriminatory values to establish more conservative criteria for definitive pregnancy failure (Table 2) and suspicion of pregnancy failure (Table 3) (6).
CRL (29), a 7-mm CRL (Fig 8) is necessary to yield a specificity and positive predictive value of 100%, thereby decreasing the likelihood of a false-positive diagnosis associated with a 5-mm CRL cutoff (6). The same reasoning applies to using (a) an MSD cutoff of 25 mm without an embryo as a criterion for pregnancy failure (Fig 9), rather than the previously recommended MSD of 16 mm (30); and (b) an MSD range of 16–24 mm without an embryo as an indicator of suspicion of pregnancy failure (Fig 10). Using an MSD of 16 mm as a cutoff to diagnose pregnancy failure resulted in a false-positive rate of 4.4% in one series (25). Gestational sacs with

<table>
<thead>
<tr>
<th>Time Period</th>
<th>Developmental Milestone (Threshold)</th>
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<tbody>
<tr>
<td>Week 0</td>
<td>Patient has last menstrual period</td>
</tr>
<tr>
<td>Week 2</td>
<td>Conception occurs</td>
</tr>
<tr>
<td>Week 4.5–5.0</td>
<td>Gestational sac appears</td>
</tr>
<tr>
<td>Week 5.0–5.5</td>
<td>Yolk sac appears</td>
</tr>
<tr>
<td>Week 6.0</td>
<td>Embryo appears; cardiac pulsation begins, with a lower limit of 100 beats/min</td>
</tr>
<tr>
<td>Week 6.5–7.0</td>
<td>Amniotic membrane appears; cardiac pulsation lower limit is 120 beats/min</td>
</tr>
<tr>
<td>Week 7–8</td>
<td>Spine develops</td>
</tr>
<tr>
<td>Week 8</td>
<td>Head curvature separates from the body; four limb buds appear</td>
</tr>
<tr>
<td>Week 8.0–8.5</td>
<td>Intrinsic motion of the embryo occurs</td>
</tr>
<tr>
<td>Weeks 8–10</td>
<td>Rhombencephalon develops</td>
</tr>
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</table>

<table>
<thead>
<tr>
<th>Finding</th>
<th>Imaging Appearance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Absent cardiac activity by the time the CRL is a certain size</td>
<td>CRL ≥7 mm with no heartbeat</td>
</tr>
<tr>
<td>Absent embryo by the time the gestational sac is a certain size</td>
<td>MSD ≥25 mm with no embryo</td>
</tr>
<tr>
<td>Absent embryo by a certain point in time; requires two US examinations</td>
<td>Absence of embryo with a heartbeat 2 or more weeks after US showed gestational sac without yolk sac</td>
</tr>
<tr>
<td></td>
<td>Absence of embryo with a heartbeat 11 or more days after US showed gestational sac with yolk sac</td>
</tr>
</tbody>
</table>

Note.—Adapted and reprinted, with permission, from reference 6.

<table>
<thead>
<tr>
<th>Finding</th>
<th>Imaging Appearance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Absent cardiac activity by the time the CRL is a certain size</td>
<td>CRL &lt;7 mm with no heartbeat</td>
</tr>
<tr>
<td>Absent embryo by the time the gestational sac is a certain size</td>
<td>MSD of 16–24 mm with no embryo</td>
</tr>
<tr>
<td>Absent embryo by a certain point in time</td>
<td>Absence of embryo with a heartbeat 7–13 days after US showed gestational sac without yolk sac</td>
</tr>
<tr>
<td></td>
<td>Absence of embryo with a heartbeat 7–10 days after US showed gestational sac with yolk sac</td>
</tr>
<tr>
<td></td>
<td>Absence of embryo 6 or more weeks after last menstrual period</td>
</tr>
<tr>
<td>Morphology of gestational sac, amnion, and yolk sac</td>
<td>Empty amnion (amnion seen adjacent to yolk sac, with no visible embryo), enlarged yolk sac (&gt;7 mm), small gestational sac in relation to size of embryo (&lt;5-mm difference between MSD and CRL)</td>
</tr>
</tbody>
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Note.—Adapted and reprinted, with permission, from reference 6.
Figure 8. Endovaginal US image shows a nonviable IUP. An amorphous embryo (arrowhead) is seen with a CRL of 20 mm, projecting to a gestational age of 8 weeks 4 days, but there was no cardiac activity. These findings are consistent with a nonviable IUP because the CRL measures at least 7 mm. Note the irregular gestational sac contour (arrow), a sign of poor prognosis.

Figure 9. Endovaginal US image demonstrates a nonviable IUP. There is an empty gestational sac with an MSD of 29 mm. Fine linear echogenic debris is noted in the sac, but there is no yolk sac or embryo. The estimated gestational age is 8 weeks 1 day. The findings are in keeping with a nonviable IUP because the MSD measures at least 25 mm.

Figure 10. Endovaginal US images show findings suspicious for but not diagnostic of pregnancy failure at initial US and findings of nonviable IUP at follow-up US. (a) Initial findings are suspicious for pregnancy failure but not diagnostic. There is an irregular gestational sac (arrowheads) with an MSD of 17 mm, an enlarged empty amnion (arrows), and no embryo or yolk sac. (b) Follow-up image obtained 10 days later shows a nonviable IUP. There is a lack of appropriate interval growth of the gestational sac and no embryo. Note the hydropic changes in the chorionic villi (arrow). The MSD is 19 mm, projecting to a gestational age of 6 weeks 6 days.

Mean diameters between 17 and 21 mm and no visible embryo have resulted in viable pregnancies (25,26). Because of interobserver variability in endovaginal US measurements, an MSD cutoff of 25 mm increases the specificity to 100% (29). Not all failed or potentially nonviable intrauterine pregnancies demonstrate a 7-mm CRL without cardiac activity or a 25-mm MSD with no embryo, necessitating additional criteria based on nonvisualization of a live embryo by a certain time interval (Fig 11).

Morphologic assessment of the individual components of a pregnancy—including the gestational sac, the yolk sac, the amnion, the embryo, cardiac activity, and the decidua—is helpful in evaluating the prognosis of the pregnancy (Table 4). Additional findings that are suspicious for pregnancy failure in the consensus panel criteria include an empty amniotic sac, an enlarged yolk sac, and small gestational sac size relative to embryo size. Given the similar length of the amniotic cavity to the CRL during 6.5–10 weeks of gestation in a normal pregnancy, the presence of an “empty amnion” with no identifiable embryo adjacent to a yolk sac is an indication of poor prognosis (Figs 10a, 12) (31) and should prompt US follow-up. An enlarged yolk sac larger than 7 mm (Fig 13) (15) and small gestational sac size relative to embryo size (defined as less than a 5-mm difference between the MSD and
Table 4: US Indicators of Poor Prognosis in Early Pregnancy

<table>
<thead>
<tr>
<th>Feature</th>
<th>Imaging Appearance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gestational sac</td>
<td>Irregular contour, low-lying position</td>
</tr>
<tr>
<td>Yolk sac</td>
<td>Calcified, larger than 7 mm</td>
</tr>
<tr>
<td>Amnion</td>
<td>Empty, enlarged, or expanded</td>
</tr>
<tr>
<td>Embryo</td>
<td>Amorphous shape</td>
</tr>
<tr>
<td>Cardiac activity</td>
<td>Bradycardia of 85 beats/min or less</td>
</tr>
<tr>
<td>Chorionic villi</td>
<td>Hydropic change</td>
</tr>
<tr>
<td>Subchorionic hemorrhage</td>
<td>Large, particularly if it encircles at least two-thirds of the gestational sac circumference</td>
</tr>
</tbody>
</table>

The CRL (Fig 14) have also been associated with poor pregnancy outcome (32). An irregular gestational sac (lack of a smooth contour and/or presence of a distorted sac shape) is highly suggestive of an abnormal IUP. In one series, this finding had a 100% specificity and a 100% positive predictive value for an abnormal IUP, but it had a low sensitivity of 10% (Fig 10a) (33). The presence of a calcified yolk sac (Fig 15) suggests that the embryonic demise is likely of a relatively long-lasting duration of 2 weeks or longer (34). An enlarged or expanded amnion (amnion too large for the size of the embryo) (17,18) (Figs 15, 16), embryonic bradycardia of 85 beats per minute or less (35), degenerative hydropic changes (Fig 10b) within the chorionic villi, and amorphous shape of the embryo at 7–8 weeks of pregnancy can also be observed.
Figures 13, 14. (13) Endovaginal US image shows an enlarged yolk sac, a sign of poor prognosis. An enlarged 7-mm yolk sac (arrow) is seen within an irregular gestational sac with an MSD of 10 mm, projecting to a gestational age of 5 weeks 5 days, and contains no embryo. Findings are suspicious for pregnancy failure but are not diagnostic. (14) Endovaginal US images demonstrate small gestational sac size relative to CRL, a sign of poor prognosis. (14a) Initial image shows a gestational sac with an MSD of 14 mm, projecting to a gestational age of 6 weeks 1 day. The sac contains an embryo with a CRL of 11 mm, projecting to a gestational age of 7 weeks 3 days. The difference between the MSD and CRL is less than 5 mm, a sign of poor prognosis. (14b) M-mode image shows regular cardiac activity of 160 beats per minute. Despite the presence of cardiac activity, the findings are suspicious for pregnancy failure but are not diagnostic. (14c) Follow-up M-mode image obtained 2 days later for vaginal bleeding shows an amorphous embryo (with a CRL of 16 mm) without cardiac activity, in keeping with a nonviable IUP.

gestation (Fig 8) are also signs of poor prognosis and should prompt US follow-up.

Subchorionic hemorrhage is reported in 18%–22% of first-trimester pregnancies with vaginal bleeding (36,37). The clinical significance depends on the size of the hematoma (Fig 17). The risk of pregnancy loss is doubled in large hematomas, particularly when there is encirclement of more than two-thirds of the chorionic circumference (38). The chorionic bump, thought to represent a small hematoma at the choriodecidual surface that bulges into the gestational sac (Fig 18), is a controversial sign and has been associated with a guarded prognosis (39), but a more recent study demonstrated a more equivocal prognosis (40).

Pregnancy of Unknown Location

Pregnancy of unknown location is the term given to the transient state of early pregnancy during which no definite IUP is visualized at US and the adnexa are normal—in other words, a “normal” pelvic US finding. At this stage, the three main possibilities include early IUP, occult ectopic pregnancy, and completed spontaneous abortion. Unfortunately, a single β-hCG serum level does not allow reliable differentiation among these possibilities (6,41). In the setting of a positive pregnancy test with low β-hCG levels, it may be too early to visualize the site of blastocyst implantation. Despite several studies in which a discriminatory β-hCG level (the value above which
Figure 17. Endovaginal US image shows a large subchorionic hemorrhage. A large hypoechoic collection (arrows) separates the chorion from the echogenic decidua and encircles almost one-half of the circumference of the gestational sac.

Figure 16. Endovaginal US image shows an expanded amnion, which is a sign of poor prognosis. The expanded amnion (arrows) surrounds a 5-mm embryo that lacked cardiac activity on M-mode images. Note the adjacent yolk sac (arrowhead). The MSD is 14 mm, projecting to a gestational age of 6 weeks 1 day.

Figure 15. Endovaginal US image shows a calcified yolk sac (arrow), which is a sign of poor prognosis. There is also an enlarged amnion (arrowheads). The CRL (not shown) was 20 mm, projecting to an estimated gestational age of 8 weeks 5 days, and no cardiac activity was seen, findings consistent with a nonviable IUP.

When an intrauterine gestational sac is consistently seen at US in normal pregnancies (of 1000–2000 mIU/mL (1000–2000 IU/L)) was reported, the reliability of the discriminatory level in ruling out a viable pregnancy is less than that reported initially. For example, studies have reported cases of embryos with cardiac activity at follow-up US after initial US showed no gestational sac with a β-hCG level above 2000–3000 mIU/mL (2000–3000 IU/L) (42,43). In addition, a multiple-gestation pregnancy results in higher β-hCG levels at any gestational age compared with those in a singleton pregnancy (7,44). While the probability of an ectopic pregnancy is substantially increased with an empty uterus and higher β-hCG levels, particularly if the level is higher than 3000 mIU/mL (3000 IU/L), there is still a 0.5% likelihood of a viable IUP (6). Thus, in a patient who is hemodynamically stable and has a pregnancy of unknown location, it is less harmful to wait, follow the β-hCG levels, and repeat the US examination than to presumptively treat an ectopic pregnancy. By explaining the limits of our technology, health care providers can help patients appreciate the uncertainty of diagnosis and the need for appropriate follow-up. As so eloquently stated by Doubilet and Benson (14), “First, do no harm.”

Application of Terminology

Accurate interpretation of first-trimester US findings requires application of appropriate and consistent terminology, as set forth by Doubilet et al (6). Figure 19 lists the possible impressions when radiologists dictate the findings of an early-pregnancy US examination. Viable IUP and nonviable IUP findings are straightforward. However, IUP of unknown viability is a broad category and is potentially confusing. To be precise, IUP of unknown viability can apply to normal situations before development of an embryo that has cardiac activity, including an empty sac, a sac with a yolk sac but no embryo, and a sac with a yolk sac and an embryo smaller than 4 mm but no cardiac activity (20). A second category of unknown viability applies when there are findings suspicious for pregnancy failure (signs of poor prognosis). We have found that using the term IUP of unknown viability is more appropriate in this instance because it conveys a sense of caution. Alternatively, for the small gestational sacs, we use the term early intrauterine gestational sac at __ gestational age instead of IUP of unknown viability and recommend follow-up US to confirm normal development of the pregnancy.
Figure 19. Diagram outlines various early-pregnancy US impressions.

Pregnancy of unknown location has several subsets, and we have encountered these scenarios during application of the terminology to our patient population. With essentially normal pelvic US findings, the differential diagnosis of “very early IUP,” “nonvisualized ectopic pregnancy,” or “completed spontaneous abortion” is provided (Fig 20). When there is vaginal bleeding and a thickened heterogeneous endometrium due to blood products (Fig 21), we have used “pregnancy of unknown location, favoring a spontaneous abortion in progress.” A finding of focal low-resistance arterial trophoblastic flow can be helpful to confirm the intrauterine implantation site in these situations (45). However, spectral Doppler US should not be used in the first trimester if there is a possibility of a normal viable IUP. A third scenario is an indeterminate intrauterine collection. While an intrauterine gestational sac and early IUP may be most likely, the differential diagnosis also includes a decidual cyst (Fig 22) and localized intrauterine fluid (Fig 23) (46). Thus, in these situations, it is recommended that follow-up β-hCG levels be obtained and that follow-up endovaginal US be performed after 7–10 days.

It is important to note that not all cases fit nicely into the scenarios described previously. For example, in a patient who likely has an intrauterine gestational sac and blood in the pelvis (Fig 24), is the blood due to a leaking hemorrhagic ovarian cyst or a heterotopic pregnancy? If the patient is clinically unstable, she may require surgery to determine the origin of the bleeding. Regardless of the variable imaging features, the principle to remember is that if there is a potential IUP, methotrexate should not be administered to the patient. If the patient is stable, follow-up endovaginal US should be performed, and β-hCG levels should be obtained.

Conclusion

The combination of pelvic US findings and quantitative β-hCG levels provides us with powerful tools in diagnosis of early pregnancy, including normal IUP, nonviable IUP, and ectopic pregnancy. While patients may desire
definitive results, our goal must be to protect both mother and baby by providing accurate and clear interpretations that lead to intervention only in cases of definitively failed IUP or visualized ectopic pregnancy. It can be much more harmful to intervene in patients with a “pregnancy of unknown location” (because a small percentage of these may be nonvisualized ectopic pregnancies) or in cases of “unknown viability” than to perform follow-up at appropriate intervals by obtaining β-hCG levels and conducting repeat US. The effect of the increased number of necessary follow-up examinations as a result of these conservative guidelines has been studied, and it is not costly. It has been shown that only 12% of pregnancies...
previously categorized as nonviable are placed in the more conservative “suspicious for pregnancy failure” category, necessitating a follow-up examination before treatment (47). Therefore, with safety and cost-effectiveness in mind, discriminatory US landmarks should be set for 100% specificity at the expense of sensitivity. The Society of Radiologists in Ultrasound 2012 consensus panel of radiologists, obstetricians, and emergency medicine physicians established new terminology and a new set of discriminatory criteria to address these issues. In addition, they recognized a variety of US findings and associated time intervals for which a diagnosis of “suspicion for pregnancy failure” should be used and discussed with the patient. Radiologists should be familiar with the progression of normal and abnormal first-trimester US
findings and develop an understanding of the accepted terminology to use in their interpretations, so that referring physicians will clearly understand our intent and treat their patients safely.

References