patient who presents to the emergency department with abdominal pain and/or vaginal bleeding and a β-human chorionic gonadotropin (β-hCG) level below a discriminatory threshold? (2) In patients who have an indeterminate transvaginal ultrasound result, what is the diagnostic utility of β-hCG for predicting possible ectopic pregnancy?

INTRODUCTION

Emergency physicians frequently evaluate and manage patients with abdominal pain and/or vaginal bleeding in the first trimester of pregnancy (also referred to here as "early pregnancy"). Their primary concern in this group of patients is to identify ectopic pregnancy. The prevalence of ectopic pregnancy in symptomatic emergency department (ED) patients is as high as 13% in some series, which is much higher than the incidence in the general population.[2,3]

Ultrasound is part of the usual workup for patients with symptomatic early pregnancy. A meta-analysis[4] and systematic review[5] both found that bedside ultrasound performed by emergency physicians can be used as a screening tool for ectopic pregnancy; however, a review of the evidence supporting this practice is beyond the scope of this policy. The term *bedside ultrasound* is used here to refer to pelvic ultrasounds that are performed in the ED by the emergency clinician, rather than in the radiology department. In this clinical policy, the term *pelvic ultrasound* implies the use of a transvaginal approach unless transabdominal images have identified an intrauterine pregnancy. According to the 2014 American College of Emergency Physicians (ACEP) policy statement "Emergency Ultrasound Imaging Criteria Compendium," the primary indication for bedside ultrasound of the pelvis is to evaluate for the presence of intrauterine pregnancy, thus minimizing the likelihood of an ectopic pregnancy when modifying factors such as infertility treatment (putting patients at risk of heterotopic pregnancy) are not present.[6] The multidisciplinary association the American Institute of Ultrasound in Medicine (AIUM) further specifies that the definitive diagnosis of an intrauterine pregnancy be based on visualizing an intrauterine gestational sac containing a yolk sac or embryo-fetus with cardiac activity.[7] A bedside ultrasonographer may or may not visualize the adnexa. A comprehensive ultrasound, in contrast, is usually performed in a radiology department and is expected to include views of the uterus, adnexa, and cul-de-sac. Studies using either or both categories of ultrasound were reviewed and this distinction is highlighted in the text and Evidentiary Table.

Ultrasound has facilitated the evaluation of complications of early pregnancy; however, diagnostic algorithms still vary considerably among providers and institutions. Algorithms guiding the evaluation of abdominal pain or vaginal bleeding in early pregnancy generally incorporate the results of quantitative serum β-human chorionic gonadotropin (β-hCG) measurements and pelvic ultrasonography. Many algorithms apply the principle of the discriminatory threshold that historically has been defined as the level at which the sensitivity of ultrasound is thought to approach 100% for the detection of intrauterine pregnancy for the presumptive diagnosis of ectopic pregnancy if an intrauterine pregnancy is not visualized when the β-hCG is above that defined cutoff. This threshold depends on the ultrasound criteria used to define an intrauterine pregnancy and is institution, operator, and patient dependent, but is commonly reported as ranging from 1,000 to 2,000 mIU/mL for transvaginal sonography performed in the radiology department.[8,9] Although the traditionally defined discriminatory threshold has been widely accepted, its applicability to ED practice is not as well established, and the concept itself has been called into question.[10,11] For these reasons, this policy refers to the term "discriminatory threshold" where necessary but does not endorse the concept or refer to any specific β-hCG cutoff level.

The first critical question deals with the diagnostic and management variability that occurs when the clinician obtains a β-hCG result, and it is below a commonly defined discriminatory threshold. Some clinicians may not perform an ultrasound for these patients because of incorrect assumptions (eg, ectopic pregnancy is unlikely because the β-hCG level is low, because of a misunderstanding that the risk of rupture is low in this subgroup). However, it is well documented that ectopic pregnancies can present at almost any β-hCG level, high or low,[8] and rupture has been documented at very low β-hCG levels.[8,12] In addition, ultrasound determination of pregnancy location for symptomatic patients has been designated as a Centers for Medicare & Medicaid Services (CMS) Core Quality Measure, with few exclusions such as lack of ultrasound availability. A β-hCG level is not part of the inclusion or exclusion criteria for this CMS core measure.[13]

The emergency physician is faced with another diagnostic and management question when an ultrasound result is described as indeterminate, "nondiagnostic," or a "pregnancy of unknown location." The second critical question examines this subgroup of patients with indeterminate ultrasound results and addresses whether the initial β-hCG level can help risk-stratify these patients.