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PREGNANCY OF UNKNOWN LOCATION: SERIAL BETA-HCG AND ULTRASONOGRAPHY IN THE IDENTIFICATION OF ECTOPIC PREGNANCY

GRAVIDEZ DE LOCALIZAÇÃO DESCONHECIDA: DOSAGENS SERIADAS DE BETA-HCG E ULTRASSONOGRAFIA NA IDENTIFICAÇÃO DE GRAVIDEZ ECTÓPICA

EMBARAZO DE LOCALIZACIÓN DESCONOCIDA: DETERMINACIÓN SERIADA DE BETA-HCG Y ECOGRAFÍA EN LA IDENTIFICACIÓN DEL EMBARAZO ECTÓPICO

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ABSTRACT

Pregnancy of unknown location is a temporary classification applied when a pregnancy test is positive but transvaginal ultrasonography identifies neither a definite intrauterine nor a definite ectopic pregnancy. Safe management must balance the risk of delayed ectopic diagnosis against the harm of interrupting a potentially viable intrauterine pregnancy. This focused narrative review examines PubMed-indexed guidelines, cohort studies, diagnostic evidence, and management trials on serial beta-human chorionic gonadotropin and ultrasonography. Hemodynamic instability or signs of intra-abdominal bleeding require urgent specialist intervention without waiting for serial testing. In stable patients, a repeat beta-hCG measurement after approximately 48 hours helps stratify risk, but neither a normal-looking rise nor a declining value independently establishes location. The minimum expected rise in viable pregnancies varies with the starting concentration, and the traditional requirement for doubling is too restrictive. The discriminatory concentration for visualization of an intrauterine gestational sac is probabilistic and dependent on the imaging setting; an empty uterus above a single cutoff does not by itself prove ectopic pregnancy. Repeat transvaginal ultrasonography, symptom review, and follow-up to a defined outcome remain central. Validated prediction models can organize surveillance but do not replace clinical reassessment. Methotrexate or uterine aspiration should follow an appropriate assessment of viability, pregnancy preferences, and ectopic risk rather than an isolated biochemical abnormality. The most defensible approach combines serial information with explicit safety-netting and reliable access to urgent care.

Keywords: Pregnancy of Unknown Location. Ectopic Pregnancy. Beta-hCG. Transvaginal Ultrasonography.

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RESUMO
A gravidez de localização desconhecida é uma classificação temporária utilizada quando um teste de gravidez é positivo, mas a ultrassonografia transvaginal não identifica uma gestação intrauterina nem uma gestação ectópica de forma definitiva. O manejo seguro deve equilibrar o risco de um diagnóstico tardio de gestação ectópica com o dano potencial de interromper uma gestação intrauterina viável. Esta revisão narrativa focada examina diretrizes indexadas no PubMed, estudos de coorte, evidências diagnósticas e ensaios clínicos sobre o uso de dosagens seriadas de beta-gonadotrofina coriônica humana (beta-hCG) e ultrassonografia. A instabilidade hemodinâmica ou a presença de sinais de sangramento intra-abdominal exigem intervenção especializada urgente, sem aguardar a realização de exames seriados. Em pacientes clinicamente estáveis, a repetição da dosagem de beta-hCG após aproximadamente 48 horas auxilia na estratificação de risco; contudo, tanto um aumento dentro do esperado quanto uma queda nos valores não definem, por si sós, a localização da gestação. O aumento mínimo esperado em gestações viáveis varia conforme a concentração inicial, sendo que a exigência tradicional de que o valor dobre é excessivamente restritiva. A concentração discriminatória para a visualização de um saco gestacional intrauterino é de natureza probabilística e depende do contexto do exame de imagem; um útero vazio, mesmo acima de um determinado ponto de corte, não comprova, isoladamente, a existência de uma gestação ectópica. A repetição da ultrassonografia transvaginal, a avaliação dos sintomas e o acompanhamento até um desfecho definido permanecem fundamentais. Modelos de predição validados podem auxiliar na organização do monitoramento, mas não substituem a reavaliação clínica. A administração de metotrexato ou a realização de aspiração uterina devem ocorrer após uma avaliação criteriosa da viabilidade gestacional, das preferências da paciente e do risco de gestação ectópica, e não apenas com base em uma alteração bioquímica isolada. A abordagem mais adequada combina a análise de dados seriados com estratégias explícitas de segurança e acesso garantido a atendimento de urgência.

Palavras-chave: Gravidez de Localização Desconhecida. Gravidez Ectópica. Beta-hCG. Ultrassonografia Transvaginal.

RESUMEN
El embarazo de localización desconocida es una clasificación provisional que se utiliza cuando una prueba de embarazo resulta positiva, pero la ecografía transvaginal no permite identificar con certeza un embarazo intrauterino ni un embarazo ectópico. El manejo seguro debe equilibrar el riesgo de retrasar el diagnóstico de un embarazo ectópico frente al perjuicio de interrumpir un embarazo intrauterino potencialmente viable. Esta revisión narrativa analiza guías clínicas indexadas en PubMed, estudios de cohortes, evidencia diagnóstica y ensayos sobre el manejo mediante determinaciones seriadas de la subunidad beta de la gonadotropina coriónica humana (beta-hCG) y ecografía. La inestabilidad hemodinámica o los signos de hemorragia intraabdominal requieren una intervención especializada urgente, sin esperar a realizar pruebas seriadas. En pacientes estables, la repetición de la medición de la beta-hCG tras aproximadamente 48 horas ayuda a estratificar el riesgo; no obstante, ni un aumento dentro de los parámetros esperados ni un descenso en los valores permiten, por sí solos, determinar la localización del embarazo. El incremento mínimo esperado en embarazos viables varía según la concentración inicial, y el criterio tradicional de que los valores deban duplicarse resulta excesivamente restrictivo. La concentración umbral para la visualización de un saco gestacional intrauterino es de carácter probabilístico y depende del entorno en el que se realiza la ecografía; un útero vacío, incluso por encima de un

determinado valor de corte, no confirma por sí mismo un embarazo ectópico. La repetición de la ecografía transvaginal, la evaluación de los síntomas y el seguimiento hasta alcanzar un desenlace definido siguen siendo aspectos fundamentales. Los modelos de predicción validados pueden ayudar a organizar la vigilancia, pero no sustituyen la reevaluación clínica. La administración de metotrexato o la realización de una aspiración uterina deben basarse en una valoración adecuada de la viabilidad, las preferencias de la paciente y el riesgo de embarazo ectópico, en lugar de fundamentarse únicamente en una anomalía bioquímica aislada. El enfoque más sólido combina la información obtenida mediante pruebas seriadas con estrategias explícitas de seguridad y un acceso garantizado a atención médica urgente.

Palabras clave: Embarazo de Localización Desconocida. Embarazo Ectópico. Beta-hCG. Ecografía Transvaginal.

1 INTRODUCTION

Early pregnancy pain or bleeding may occur before ultrasonography can identify a gestation. When a positive pregnancy test is accompanied by no definite intrauterine or extrauterine pregnancy on transvaginal ultrasound, the appropriate classification is pregnancy of unknown location. This describes diagnostic uncertainty at a particular visit and should not be treated as a final diagnosis or as a synonym for ectopic pregnancy.[1]

The possible outcomes include a subsequently visualized intrauterine pregnancy, a visualized ectopic pregnancy, spontaneous resolution without identification of location, or a persisting pregnancy of unknown location. Each outcome has different implications for surveillance and treatment. Standardized terminology helps prevent a resolving unlocalized pregnancy from being incorrectly counted as a confirmed ectopic pregnancy and allows evidence from different studies to be interpreted more accurately.[1]

Timely identification of ectopic pregnancy can prevent morbidity from rupture and hemorrhage, but premature treatment can harm a desired intrauterine pregnancy. Serial beta-hCG and ultrasonography are therefore complementary tools whose limitations need to be understood together. Current imaging guidance emphasizes repeat evaluation and close clinical assessment when the diagnosis remains uncertain.[2,3]

2 OBJECTIVE

This review evaluates how serial beta-hCG and transvaginal ultrasonography contribute to the identification of ectopic pregnancy in patients initially classified as having pregnancy of unknown location. It addresses interpretation of rising, falling, and plateauing concentrations, the discriminatory concept, prediction models, and persistent uncertainty. It also examines how clinical stability, patient preferences, and follow-up reliability determine safe management.

3 METHODS

Targeted PubMed searches through October 16, 2026, combined pregnancy of unknown location with beta-hCG, ultrasonography, diagnostic protocols, prediction models, and ectopic pregnancy guidelines. Additional influential records were retrieved by title or identifier, including studies of biochemical trajectories and discriminatory concentrations. PubMed metadata and available abstracts were examined, with guideline recommendations distinguished from observational estimates and randomized management evidence.

The article is a focused narrative review rather than a systematic review or a diagnostic meta-analysis. Selection was purposive, and no registered protocol, independent duplicate screening, or formal study-level risk-of-bias assessment was performed. Results are presented with their original populations and endpoints, without combining thresholds into a new clinical decision rule.

4 RESULTS AND DISCUSSION

4.1 CLINICAL STABILITY COMES BEFORE BIOCHEMICAL INTERPRETATION

The initial assessment should establish vital signs, pain severity and progression, bleeding, and evidence of peritoneal irritation or substantial intra-abdominal hemorrhage. An unstable patient with suspected ectopic pregnancy requires immediate resuscitation and gynecological or surgical management. Waiting for a second beta-hCG measurement is inappropriate when the clinical situation already suggests rupture or ongoing bleeding.[2]

For stable patients, the history should establish gestational dating, previous ultrasound findings, prior ectopic pregnancy, fertility treatment, and the possibility of a desired ongoing pregnancy. The absence of recognized risk factors does not establish an intrauterine location. Safety depends on integrating current symptoms with objective findings and ensuring that a plan for repeat assessment is feasible.[2,4]

4.2 WHAT TRANSVAGINAL ULTRASONOGRAPHY CAN ESTABLISH

A definite intrauterine pregnancy requires convincing intrauterine gestational structures rather than an isolated nonspecific fluid collection. A definite extrauterine gestation establishes ectopic pregnancy, whereas an adnexal mass or free fluid may raise suspicion without providing the same level of certainty. Reporting should distinguish definite and probable findings so that management reflects the actual strength of the imaging evidence.[1,3]

Examination should assess the uterine cavity, adnexa, and pelvic fluid rather than focus exclusively on whether a gestational sac is visible in the uterus. Image quality, operator experience, gestational age, and individual anatomy affect interpretation. A nondiagnostic examination requires follow-up when the patient remains stable; it does not justify labeling an ectopic pregnancy solely because no intrauterine sac is seen.[3,5]

Once an intrauterine pregnancy is visualized, uncertainty about viability becomes a related but separate diagnostic question. Conservative ultrasound criteria and appropriate repeat intervals help avoid diagnosing pregnancy failure before the findings are definitive.

Criteria for nonviability within the uterus must not be substituted for evidence that an unlocalized pregnancy is ectopic.[6]

4.3 SERIAL BETA-HCG AND THE LIMITS OF THE DOUBLING RULE

Beta-hCG reflects trophoblastic activity, but a single concentration provides limited information about pregnancy location. A second measurement after approximately 48 hours provides a trajectory that can help organize surveillance. The traditional expectation that every viable early pregnancy should double over this interval is inaccurate and risks classifying viable pregnancies as abnormal.[7]

In a cohort of 285 symptomatic women whose pregnancies were ultimately confirmed as viable intrauterine pregnancies, the predicted minimum two-day rise varied with the starting concentration. The first-percentile rises were 49% when the initial concentration was below 1500 mIU/mL, 40% at 1500–3000 mIU/mL, and 33% above 3000 mIU/mL. These lower limits inform cautious interpretation of viability, but they are not absolute boundaries separating intrauterine from ectopic pregnancy.[7]

A rise slower than these reference values increases concern for an abnormal pregnancy but does not identify its location. Conversely, an apparently appropriate rise cannot independently exclude ectopic pregnancy and should not terminate surveillance before a definite outcome. The value of serial testing comes from its combination with symptoms and repeat ultrasonography, rather than from treating the slope as an anatomical diagnosis.[2,8]

Whenever possible, serial measurements should use a consistent laboratory method and intervals close to those used by the chosen protocol. An hCG ratio calculated from measurements taken at substantially different times cannot be interpreted as though it were a validated 48-hour ratio. Unexpected results should lead to verification of timing and clinical reassessment before an irreversible management decision.[9,10]

4.4 THE DISCRIMINATORY CONCENTRATION IS PROBABILISTIC

The discriminatory concept describes a concentration above which an intrauterine gestational structure is expected to be seen with a specified probability. It differs from the lowest concentration at which that structure has occasionally been visualized. Confusing these concepts encourages treatment of patients whose pregnancies are simply earlier or less readily imaged than expected.[5]

Connolly and colleagues examined 651 symptomatic pregnancies, including 366 ultimately viable pregnancies. The concentration associated with a predicted 99% probability of visualizing an intrauterine gestational sac was 3510 mIU/mL, substantially higher than the lowest observed visualization threshold. The estimate was derived from a specific population and ultrasound setting, so it should not be treated as a universal concentration at which an empty uterus proves ectopic pregnancy.[5]

A later retrospective study estimated a corresponding 99% visualization concentration of 3994 mIU/mL and found that 90% of ectopic pregnancies presented below that value. This finding has two implications: many ectopic pregnancies occur below a discriminatory concentration, and some viable pregnancies remain unvisualized at concentrations near commonly used cutoffs. An isolated high beta-hCG with an empty uterus warrants careful evaluation but cannot safely replace serial assessment in a stable patient with a potentially desired pregnancy.[11]

4.5 DECLINING AND PLATEAUING CONCENTRATIONS

A declining beta-hCG suggests that the pregnancy is not progressing normally, but spontaneous decline can occur in ectopic as well as intrauterine pregnancy loss. Follow-up should continue until the location is established or resolution is documented under a validated protocol. Worsening pain, dizziness, or other concerning symptoms require reassessment regardless of whether the most recent concentration was falling.[2,12]

A retrospective cohort included 1551 symptomatic pregnancies of unknown location with declining hCG, of which 146 were ultimately ectopic. Declines of at least 85% within four days or 95% within seven days identified no ectopic pregnancies in that cohort and were separately evaluated in an ectopic validation set. These findings may support reduced follow-up intensity within an established pathway, but they should not be translated into a universal guarantee that symptoms can be ignored or surveillance stopped in every setting.[12]

A persistent plateau or insufficiently changing concentration raises concern for retained trophoblast or a nonvisualized ectopic pregnancy. The classification of persisting pregnancy of unknown location depends on serial information and should not be applied after one equivocal visit. Repeat imaging and specialist review are necessary to decide whether further observation, uterine aspiration, or medical treatment is appropriate.[1,13]

4.6 PREDICTION MODELS AND PROGESTERONE

Progesterone can contribute information about the likelihood of viability but does not reliably establish implantation site. A low value may identify a likely failing pregnancy while leaving ectopic pregnancy within the differential diagnosis. Its most defensible use is within a validated pathway that retains clinical review and follow-up rather than as an isolated indication for discharge.[9]

A systematic review of diagnostic protocols found substantial heterogeneity and differential verification bias across studies. Models combining initial hCG and its subsequent change generally performed better than a single biochemical cutoff, but performance depended on the model and validation population. This evidence supports structured risk prediction while discouraging informal combinations of thresholds from unrelated studies.[8]

External validation across eight early-pregnancy units found good discrimination for the M6-based models and the two-step strategy. Sensitivity for ectopic pregnancy was 96% for M6P and 94% for the two-step approach, with corresponding false-positive rates of 35% and 33%. These estimates describe triage performance rather than diagnostic certainty, and the approximately 10% loss to follow-up among eligible participants remains relevant when assessing applicability.[10]

A prospective clinical implementation study classified 55% of 2625 analyzed pregnancies as low risk under a two-step protocol. Fifteen of those low-risk cases ultimately had an ectopic outcome, although none resulted in rupture or significant clinical harm in the reported study. The finding demonstrates that low-risk classification requires appropriate instructions and access to reassessment rather than implying zero risk.[14]

4.7 AVOIDING PREMATURE INTERVENTION

Methotrexate should not be administered solely because beta-hCG has failed to double or because the uterus is empty above a preferred numerical cutoff. Before treatment, clinicians should assess whether a potentially viable intrauterine pregnancy has been adequately excluded and whether the patient meets the requirements for medical management. Pregnancy preferences, clinical stability, contraindications, and the ability to complete follow-up materially affect the decision.[2,4]

Uterine aspiration can provide diagnostic and therapeutic information in selected cases, particularly when an ongoing pregnancy is not desired or viability has been appropriately excluded. The interpretation of tissue findings and subsequent hCG response

should follow a defined specialist pathway. Neither aspiration nor empirical medical treatment should be presented as a routine first step for every stable patient at the initial unlocalized visit.[4,13]

The ACT or NOT trial randomized 255 stable patients with a diagnosed persisting pregnancy of unknown location. Active management achieved pregnancy resolution without changing the original strategy in 51.5%, compared with 36.0% assigned to expectant management, but 39% declined their randomized allocation and crossed over. These results inform persistent, already abnormal pregnancies and should not be generalized to newly identified uncertainty in a potentially viable pregnancy.[13]

4.8 FOLLOW-UP IS PART OF THE DIAGNOSTIC TEST

A safe plan specifies when the next blood sample and ultrasound will occur, who reviews the results, and how the patient can access urgent reassessment. Patients should understand that worsening abdominal pain, fainting, significant bleeding, or clinical deterioration can require immediate evaluation before the scheduled visit. A biochemical strategy that appears accurate in a study may be unsafe if results are not reviewed or the patient cannot return.[2,14]

The surveillance endpoint should be explicit: confirmed intrauterine pregnancy, confirmed ectopic pregnancy, or documented resolution according to the pathway. An improving symptom report or a single lower hCG value does not automatically satisfy that endpoint. Clear responsibility for follow-up prevents diagnostic uncertainty from becoming loss to care[1,12].

Table 1

Selected evidence on biochemical and ultrasound interpretation

Reference	Population / Intervention / Comparison	Outcomes	Main conclusions
Barnhart et al. (2011) [1]	International consensus on initial ultrasound findings and final pregnancy outcomes.	Defines PUL as a temporary classification.	PUL must not be equated with confirmed ectopic pregnancy.
Connolly et al. (2013) [5]	Retrospective study; 651 pregnancies, including 366 viable pregnancies.	Predicted 99% gestational-sac visualization at 3510 mIU/mL.	Discriminatory concentration is probabilistic and setting dependent.

Reference	Population / Intervention / Comparison	Outcomes	Main conclusions
Barnhart et al. (2016) [7]	Retrospective cohort; 285 symptomatic pregnancies ultimately viable within the uterus.	Minimum two-day rises: 49%, 40%, and 33% across increasing initial hCG strata.	Expected rise varies with baseline value; trajectory does not establish location.
Christodoulou et al. (2021) [10]	Multicenter external validation of PUL prediction approaches.	M6P sensitivity 96%; two-step sensitivity 94%; false-positive rates 35% and 33%.	Models support triage but require follow-up and clinical reassessment.
Park et al. (2023) [11]	Retrospective study of early pregnancy ultrasound and outcomes.	Predicted 99% sac visualization at 3994 mIU/mL; 90% of ectopics below this value.	Neither being below nor above a cutoff independently resolves location.
Barnhart et al. (2021) [13]	ACT or NOT RCT; 255 stable patients with persisting PUL.	Resolution without strategy change: active 51.5%, expectant 36.0%; substantial crossover.	Applies to persistent abnormal pregnancies, not every initial nondiagnostic scan.

hCG, human chorionic gonadotropin; PUL, pregnancy of unknown location; RCT, randomized controlled trial. Biochemical thresholds and model results are population dependent.

4.9 LIMITATIONS OF THE EVIDENCE

Many trajectory and discriminatory studies are retrospective and include selected symptomatic populations, while prediction models may depend on local ectopic prevalence and laboratory methods. Definitions of persistent pregnancy and management success also vary, making direct comparisons difficult. This focused narrative review did not exhaustively retrieve the literature or perform a new accuracy analysis, and several sources were evaluated primarily through PubMed abstracts.[8,10]

5 CONCLUSION

Serial beta-hCG and transvaginal ultrasonography are complementary components of evaluating pregnancy of unknown location. Neither a single discriminatory cutoff, an apparently normal rise, nor a declining concentration independently establishes or excludes ectopic pregnancy. Clinical stability, repeat assessment, cautious interpretation of viability, and reliable follow-up should determine the pace of investigation and the appropriateness of intervention.[2,7,11]

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