Complete Summary

GUIDELINE TITLE

Clinical policy: critical issues in the initial evaluation and management of patients presenting to the emergency department in early pregnancy.

BIBLIOGRAPHIC SOURCE(S)

Clinical policy: critical issues in the initial evaluation and management of patients presenting to the emergency department in early pregnancy. Ann Emerg Med 2003 Jan;41(1):123-33. [66 references] PubMed

GUIDELINE STATUS

This is the current release of the guideline.

This release of the guideline represents a revision of a 1997 American College of Emergency Physicians clinical policy (American College of Emergency Physicians. Clinical policy for the initial approach to patients presenting with a chief complaint of vaginal bleeding. Ann Emerg Med March 1997;29:435-458).

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Ectopic pregnancy

GUIDELINE CATEGORY

Diagnosis
Evaluation

Management
Treatment

CLINICAL SPECIALTY

Emergency Medicine
Family Practice
Internal Medicine
Obstetrics and Gynecology

INTENDED USERS

Physicians

GUIDELINE OBJECTIVE(S)

To address the following critical diagnostic and management issues:

- Interpretation of beta-human chorionic gonadotropin (beta-hCG) assays and usefulness of transvaginal ultrasound
- Use of Rh prophylaxis in the first trimester of pregnancy
- Outpatient management of ectopic pregnancy with a cytotoxic agent

TARGET POPULATION

Women presenting to the emergency department in early pregnancy

INTERVENTIONS AND PRACTICES CONSIDERED

Diagnosis/Evaluation

1. Assessment of serum human chorionic gonadotropin (hCG) levels
2. Transvaginal ultrasound

Treatment/Prevention

1. Methotrexate
2. Anti-D immunoglobulin

MAJOR OUTCOMES CONSIDERED

Not stated

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Hand-searches of Published Literature (Secondary Sources)
Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Independent literature searches were conducted for each of the questions. Searches were limited in all areas to English-language, human studies, and included articles from bibliographies of selected papers and personal knowledge base.

For the introduction, a MEDLINE search for articles published between 1980 and 2000 was performed using the key words: ectopic pregnancy, epidemiology, and risk factors; pregnancy rates, assisted reproduction, in vitro fertilization; embryo transfer, with a yield of 31 pertinent articles for review, of which 16 were used in the final document.

For the area on the use of serum hCG levels, a MEDLINE search for articles published between 1985 and 2000 was performed using the key words: pregnancy, ectopic; serum hCG; diagnostic ultrasonography, transvaginal, with a yield of 18 pertinent articles for review, of which 11 were used in the final document.

For the section on methotrexate use in ectopic pregnancy, a MEDLINE search for articles published between 1980 and 2000 was performed using the key words: methotrexate, ectopic pregnancy, side effects, drug interactions, with a yield of 68 pertinent articles for review, of which 15 were used in the final document.

For the section on use of Rh prophylaxis in first trimester pregnancy, a MEDLINE search for articles published between 1960 and 2000 was performed using the key words: Rh immunization, anti-D immunoglobulin, Rh sensitization, Rh-negative pregnancy complications, with a yield of 35 pertinent articles for review, of which 24 were used in the final document.

Abstracts and articles were reviewed by subcommittee members, and pertinent articles were selected. These were evaluated, and articles addressing the questions considered in this document were chosen. Subcommittee members also supplied references from bibliographies of initially selected articles or from their own knowledge base.

NUMBER OF SOURCE DOCUMENTS

Introduction: 16

Use of serum human chorionic gonadotropin (hCG): 11

Methotrexate: 15

Use of Rh prophylaxis: 24

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Strength of Evidence

Strength of evidence Class I: Interventional studies including clinical trials, observational studies including prospective cohort studies, aggregate studies including meta-analyses of randomized clinical trials only.

Strength of evidence Class II: Observational studies including retrospective cohort studies, case-controlled studies, aggregate studies including other meta-analyses.

Strength of evidence Class III: Descriptive cross-sectional studies; observational reports including case series and case reports; consensus studies including published panel consensus by acknowledged groups of experts.

Strength of evidence Class I and II articles were rated on elements the committee believed were most important in creating a quality work. Class I and II articles with significant flaws or design bias were downgraded from 1 to 3 levels on the basis of a set formula. Strength of Evidence Class III articles were downgraded 1 level if they demonstrated significant flaws or bias. Articles downgraded below Class III strength of evidence were given an "X" rating and were not used in formulating this policy.

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Not stated

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Strength of Recommendations

Level A recommendations. Generally accepted principles for patient management that reflect a high degree of clinical certainty (i.e., based on "strength of evidence Class I" or overwhelming evidence from "strength of evidence Class II" studies that directly address all the issues.)

Level B recommendations. Recommendations for patient management that may identify a particular strategy or range of management strategies that reflect moderate clinical certainty (ie, based on "strength of evidence Class II" studies that directly address the issue, decision analysis that directly addresses the issue, or strong consensus of "strength of evidence Class III" studies).

Level C recommendations. Other strategies for patient management based on preliminary, inconclusive, or conflicting evidence, or, in the absence of any published literature, based on panel consensus.

There are certain circumstances in which the recommendations stemming from a body of evidence should not be rated as highly as the individual studies on which they are based. Factors such as heterogeneity of results, uncertainty about effect magnitude and consequences, strength of prior beliefs, and publication bias, among others, might lead to such a downgrading of recommendations.

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

External Peer Review
Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Expert review comments were received from emergency physicians, members of the American College of Emergency Physicians (ACEP) Section of Emergency Ultrasound, and physicians from specialty societies, including members of the American Academy of Family Physicians and members of the American College of Obstetricians and Gynecologists´ (ACOG) Committee on Gynecologic Practice. Their responses were used to further refine and enhance this policy.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Definitions for the strength of evidence (Class I-III) and strength of recommendations (Level A-C) are repeated at the end of the Major Recommendations field.

Interpretation of Serum Human Chorionic Gonadotropin (hCG) Levels

1. **Is transvaginal ultrasound useful in detecting intrauterine pregnancy when the serum hCG level is less than 1,000 mIU/mL?**

   Level A recommendations. None specified.

   Level B recommendations. None specified.

   Level C recommendations. Consider transvaginal ultrasound because it may detect intrauterine pregnancy when the serum hCG level is below 1,000 mIU/mL.

2. **Is transvaginal ultrasound useful in detecting ectopic pregnancy when the serum hCG level is less than 1,000 mIU/mL?**

   Level A recommendations. None specified.

   Level B recommendations. None specified.

   Level C recommendations. Consider transvaginal ultrasound because it may detect ectopic pregnancy when the serum hCG level is below 1,000 mIU/mL.

3. **What is the role of serial quantitative hCG determinations in either diagnosing or excluding ectopic pregnancy?**

   Level A recommendations. None specified.

   Level B recommendations. Obtain a repeat serum hCG determination at least 2 days after the initial presentation because it is useful in characterizing the risk of ectopic pregnancy and the probability of a viable intrauterine pregnancy.

   Level C recommendations. None specified.

4. **Above what serum hCG level is the absence of intrauterine pregnancy by transvaginal ultrasound presumptive evidence of ectopic pregnancy?**

   Level A recommendations. None specified.

   Level B recommendations. Arrange follow-up for patients with a nondiagnostic transvaginal ultrasound and a serum hCG level above 2,000 mIU/mL because they have an increased likelihood of ectopic pregnancy.

   Level C recommendations. None specified.

Methotrexate in Ectopic Pregnancy

5. **What is the frequency of treatment failure in methotrexate therapy for ectopic pregnancy and its implication for emergency department (ED) management?**

   Level A recommendations. None specified.

   Level B recommendations. None specified.

   Level C recommendations. Because the symptoms associated with gastrointestinal side effects of methotrexate therapy may mimic an acute ectopic rupture, rule out ectopic rupture resulting from treatment failure before attributing gastrointestinal symptoms to methotrexate toxicity. Treatment failure with single dose methotrexate for ectopic pregnancy can occur in up to 36% of patients.

Rh Seroconversion and Indications for anti-D Immunoglobulin

6. **Is the administration of anti-D immunoglobulin indicated among Rh-negative women during the first trimester of pregnancy with threatened abortion, complete abortion, ectopic pregnancy, or minor abdominal trauma?**

   Threatened or Complete Abortion or Ectopic Pregnancy

   Level A recommendations. None specified.

   Level B recommendations. Administer 50 micrograms of anti-D immunoglobulin to Rh-negative women in all cases of documented first trimester loss of established pregnancy.

   Level C recommendations. None specified.

   Minor Abdominal Trauma

   Level A recommendations. None specified.

   Level B recommendations. None specified.

   Level C recommendations. Consider administration of anti-D immunoglobulin in cases of minor trauma in Rh-negative patients.

Definitions:

Strength of Evidence

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Strength of evidence Class II: Observational studies including retrospective cohort studies, case-controlled studies, aggregate studies including other meta-analyses.

Strength of evidence Class III: Descriptive cross-sectional studies; observational reports including case series and case reports; consensus studies including published panel consensus by acknowledged groups of experts.

Strength of Recommendations

Level A recommendations. Generally accepted principles for patient management that reflect a high degree of clinical certainty (i.e., based on "strength of evidence Class I" or overwhelming evidence from "strength of evidence Class II" studies that directly address all the issues.)

Level B recommendations. Recommendations for patient management that may identify a particular strategy or range of management strategies that reflect moderate clinical certainty (i.e., based on "strength of evidence Class II" studies that directly address the issue, decision analysis that directly addresses the issue, or strong consensus of "strength of evidence Class III" studies).

Level C recommendations. Other strategies for patient management based on preliminary, inconclusive, or conflicting evidence, or, in the absence of any published literature, based on panel consensus.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified for each recommendation (see "Major Recommendations").

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Appropriate evaluation, diagnosis, and management of selected critical issues in patients with ectopic pregnancy

POTENTIAL HARMS

- Treatment failure
- Side effects and drug interactions of methotrexate

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

Recommendations in this policy are not intended to represent the only diagnostic and management options that the emergency physician can consider. The American College of Emergency Physicians (ACEP) clearly recognizes the importance of the individual clinician´s judgment. Rather, they define for the clinician those strategies for which medical literature exists to provide strong support for answers to the critical questions addressed in this policy.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better

IOM DOMAIN

Effectiveness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Clinical policy: critical issues in the initial evaluation and management of patients presenting to the emergency department in early pregnancy. Ann Emerg Med 2003 Jan;41(1):123-33. [66 references] PubMed

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2003 Jan

GUIDELINE DEVELOPER(S)

American College of Emergency Physicians - Medical Specialty Society

SOURCE(S) OF FUNDING

American College of Emergency Physicians

GUIDELINE COMMITTEE

American College of Emergency Physicians (ACEP) Clinical Policies Subcommittee on Early Pregnancy

ACEP Clinical Policies Committee

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Members of the Clinical Policies Subcommittee on Early Pregnancy: Barbara A. Murphy, MD (Chair); Alfred R. Hansen, MD, PhD; John M. Howell, MD; Bonnie Simmons, DO

Members of the Clinical Policies Committee: Stephen V. Cantrill, MD (Chair 1996-2000); William C. Dalsey, MD (Chair 2000-2002, Co-Chair 2002-2003); Andy S. Jagoda, MD (Co-Chair 2002-2003); Stephen A. Colucciello, MD; Wyatt W. Decker, MD; Francis M. Fesmire, MD; Steven A. Godwin, MD; John M. Howell, MD; J. Stephen Huff, MD; Alan H. Itzkowitz, MD (Emergency Medicine Residents´ Association [EMRA] Representative 2000-2001); Stephen Karas, Jr, MD; Edwin K. Kuffner, MD; Thomas W. Lukens, MD, PhD; Benjamin E. Marett, RN, MSN, CEN, CNA, COHN-S (Emergency Nurses Association [ENA] Representative 2002); Thomas P. Martin, MD; Jessie Moore, RN, MSN, CEN (ENA Representative 2001); David L. Morgan, MD; Barbara A. Murphy, MD; Devorah Nazarian, MD; Scott M. Silvers, MD (EMRA Representative 1999-2000, Member 2000-2002); Bonnie Simmons, DO; Edward P. Sloan, MD, MPH; Suzanne Wall, RNC, MS, CEN (ENA Representative 1999-2000); Robert L. Wears, MD, MS; Stephen J. Wolf, MD (EMRA Representative 2001-2002); George W. Molzen, MD (Board Liaison 1997-2000); Robert E. Suter, DO, MHA (Board Liaison 2000-2001); Susan M. Nedza, MD, MBA (Board Liaison 2001-2003); Rhonda Whitson, RHIA, Staff Liaison, Clinical Policies Committee and Subcommittees

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

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GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) from the American College of Emergency Physicians Web site.

Print copies: Available from the American College of Emergency Physicians, P.O. Box 619911, Dallas, TX 75261-9911, or call toll free: (800) 798-1822.

AVAILABILITY OF COMPANION DOCUMENTS

None available

PATIENT RESOURCES

None available

NGC STATUS

This NGC summary was completed by ECRI on June 5, 2003. The information was verified by the guideline developer on July 18, 2003.

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DISCLAIMER

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Readers with questions regarding guideline content are directed to contact the guideline developer.

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