



Complete Summary

GUIDELINE TITLE

Management of preterm labor.

BIBLIOGRAPHIC SOURCE(S)

American College of Obstetricians and Gynecologists (ACOG). Management of preterm labor. Washington (DC): American College of Obstetricians and Gynecologists (ACOG); 2003 May. 9 p. (ACOG practice bulletin; no. 43). [74 references]

GUIDELINE STATUS

This is the current release of the guideline.

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SCOPE

DISEASE/CONDITION(S)

Preterm labor

GUIDELINE CATEGORY

Evaluation
Management
Prevention

CLINICAL SPECIALTY

Obstetrics and Gynecology

INTENDED USERS

Physicians

GUIDELINE OBJECTIVE(S)

- To aid practitioners in making decisions about appropriate obstetric and gynecologic care
- To present the various methods proposed to manage preterm labor and the evidence for their roles in clinical practice

TARGET POPULATION

Women in preterm labor

INTERVENTIONS AND PRACTICES CONSIDERED

1. Sonography and fetal fibronectin testing to determine women at risk of preterm birth
2. Amniocentesis to determine fetal lung maturity and intra-amniotic infection
3. Tocolytic therapy including beta-mimetics (terbutaline, ritodrine); magnesium sulfate; calcium channel blockers; non-steroidal anti-inflammatory drugs (NSAIDs) (indomethacin, ketorolac, sulindac)
4. Antibiotics (for group B streptococcal prophylaxis only)
5. Antenatal corticosteroid use (betamethasone, dexamethasone)

Note: Bed rest, hydration, and pelvic rest were considered but not routinely recommended. Repeated and maintenance tocolytic therapies were also considered, but not recommended as a general practice.

MAJOR OUTCOMES CONSIDERED

- Predictive value of tests for risk of preterm birth
- Neonatal outcome
- Effectiveness of tocolytics and antibiotics in prolonging pregnancy or improving neonatal outcome

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

The MEDLINE database, the Cochrane Library, and the American College of Obstetricians and Gynecologists' (ACOG's) own internal resources and documents were used to conduct a literature search to locate relevant articles published between January 1985 and January 2003. The search was restricted to articles

published in the English language. Priority was given to articles reporting results of original research, although review articles and commentaries also were consulted. Abstracts of research presented at symposia and scientific conferences were not considered adequate for inclusion in this document.

Guidelines published by organizations or institutions such as the National Institutes of Health and the American College of Obstetricians and Gynecologists were reviewed, and additional studies were located by reviewing bibliographies of identified articles.

NUMBER OF SOURCE DOCUMENTS

Not stated

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

Studies were reviewed and evaluated for quality according to the method outlined by the U.S. Preventive Services Task Force.

I Evidence obtained from at least one properly designed randomized controlled trial

II-1 Evidence obtained from well-designed controlled trials without randomization

II-2 Evidence obtained from well-designed cohort or case-control analytic studies, preferably from more than one center or research group

II-3 Evidence obtained from multiple time series with or without the intervention. Dramatic results in uncontrolled experiments also could be regarded as this type of evidence.

III Opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees

METHODS USED TO ANALYZE THE EVIDENCE

Review of Published Meta-Analyses
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

Analysis of available evidence was given priority in formulating recommendations. When reliable research was not available, expert opinions from obstetrician-gynecologists were used. See also the "Rating Scheme for the Strength of Recommendations" field regarding Grade C recommendations.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Based on the highest level of evidence found in the data, recommendations are provided and graded according to the following categories:

Level A - Recommendations are based on good and consistent scientific evidence.

Level B - Recommendations are based on limited or inconsistent scientific evidence.

Level C - Recommendations are based primarily on consensus and expert opinion.

COST ANALYSIS

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

METHOD OF GUIDELINE VALIDATION

Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Practice Bulletins are validated by two internal clinical review panels composed of practicing obstetrician-gynecologists generalists and sub-specialists. The final guidelines are also reviewed and approved by the American College of Obstetricians and Gynecologists (ACOG) Executive Board.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

The grades of evidence (I-III) and levels of recommendations (A-C) are defined at the end of the "Major Recommendations."

The following recommendations are based on good and consistent scientific evidence (Level A):

- There are no clear "first-line" tocolytic drugs to manage preterm labor. Clinical circumstances and physician preferences should dictate treatment.
- Antibiotics do not appear to prolong gestation and should be reserved for group B streptococcal prophylaxis in patients in whom delivery is imminent.
- Neither maintenance treatment with tocolytic drugs nor repeated acute tocolysis improve perinatal outcome; neither should be undertaken as a general practice.
- Tocolytic drugs may prolong pregnancy for 2 to 7 days, which may allow for administration of steroids to improve fetal lung maturity and the consideration of maternal transport to a tertiary care facility.

The following recommendations are based on limited or inconsistent scientific evidence (Level B):

- Cervical ultrasound examination and fetal fibronectin testing have good negative predictive value; thus, either approach or both combined may be helpful in determining which patients do not need tocolysis.
- Amniocentesis may be used in women in preterm labor to assess fetal lung maturity and intra-amniotic infection.
- Bed rest, hydration, and pelvic rest do not appear to improve the rate of preterm birth and should not be routinely recommended.

Definitions:

Grades of Evidence

I Evidence obtained from at least one properly designed randomized controlled trial

II-1 Evidence obtained from well-designed controlled trials without randomization

II-2 Evidence obtained from well-designed cohort or case-control analytic studies, preferably from more than one center or research group

II-3 Evidence obtained from multiple time series with or without the intervention. Dramatic results in uncontrolled experiments also could be regarded as this type of evidence.

III Opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees

Levels of Recommendations

Level A - Recommendations are based on good and consistent scientific evidence.

Level B - Recommendations are based on limited or inconsistent scientific evidence.

Level C - Recommendations are based primarily on consensus and expert opinion.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

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

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Overall Benefits

Appropriate management of preterm labor

Benefits of Specific Medication

- *Antenatal corticosteroids* significantly reduced the incidence and severity of neonatal respiratory distress syndrome. The incidence of intraventricular hemorrhage and necrotizing enterocolitis also are reduced by the use of antenatal corticosteroids.
- *Tocolytic drugs* may prolong gestation for 2 to 7 days, which can provide time for administration of steroids and maternal transport to a facility with a neonatal intensive care unit.

POTENTIAL HARMS

Side Effects of Tocolytic Medication

Terbutaline

- Maternal side effects: Cardiac or cardiopulmonary arrhythmias, pulmonary edema, myocardial ischemia, hypotension, tachycardia
- Fetal and neonatal side effects: Fetal tachycardia, hyperinsulinemia, hyperglycemia, myocardial and septal hypertrophy, myocardial ischemia

Ritodrine

- Maternal side effects: Metabolic hyperglycemia, hyperinsulinemia, hypokalemia, antidiuresis, altered thyroid function, physiologic tremor, palpitations, nervousness, nausea or vomiting, fever, hallucinations
- Fetal and neonatal side effects: Neonatal tachycardia, hypoglycemia, hypocalcemia, hyperbilirubinemia, hypotension, intraventricular hemorrhage

Magnesium Sulfate

- Maternal side effects: Flushing, lethargy, headache, muscle weakness, diplopia, dry mouth, pulmonary edema, cardiac arrest
- Fetal and neonatal side effects: Lethargy, hypotonia, respiratory depression, demineralization with prolonged use

Calcium Channel Blockers

- Maternal side effects: Flushing, headache, dizziness, nausea, transient hypotension. Caution should be used in patients with renal disease and hypotension when administering calcium channel blockers. In addition, concomitant use of calcium channel blockers and magnesium sulfate is potentially harmful and has resulted in cardiovascular collapse.
- Fetal and neonatal side effects: None noted as yet

Indomethacin

- Maternal side effects: Nausea, heartburn
- Fetal and neonatal side effects: Constriction of ductus arteriosus, pulmonary hypertension, reversible decrease in renal function with oligohydramnios, intraventricular hemorrhage, hyperbilirubinemia, necrotizing enterocolitis

Note: Combining tocolytic drugs potentially increases maternal morbidity and should be used with caution.

CONTRAINDICATIONS

CONTRAINDICATIONS

- *Tocolysis*. General contraindications for tocolysis include severe preeclampsia, placental abruption, intrauterine infection, lethal congenital or chromosomal abnormalities, advanced cervical dilatation, and evidence of fetal compromise or placental insufficiency.
- *Beta-mimetic*. Contraindications include cardiac arrhythmias (for terbutaline) and poorly controlled thyroid disease and diabetes mellitus (for ritodrine).
- *Magnesium sulfate*. Contraindications include myasthenia gravis.
- *Calcium channel blockers*. Contraindications include cardiac disease; should not be used concomitantly with magnesium sulfate.
- *Prostaglandin synthetase inhibitors*. Contraindications include significant renal or hepatic impairment (for indomethacin), active peptic ulcer disease (for ketorolac), coagulation disorders or thrombocytopenia, nonsteroidal anti-inflammatory drug (NSAID)-sensitive asthma, other sensitivity to NSAIDs (for sulindac).

QUALIFYING STATEMENTS

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These guidelines should not be construed as dictating an exclusive course of treatment or procedure. Variations in practice may be warranted based on the needs of the individual patient, resources, and limitations unique to the institution or type of practice.

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
Staying Healthy

IOM DOMAIN

Effectiveness

IDENTIFYING INFORMATION AND AVAILABILITY

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ADAPTATION

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

DATE RELEASED

2003 May

GUIDELINE DEVELOPER(S)

American College of Obstetricians and Gynecologists - Medical Specialty Society

SOURCE(S) OF FUNDING

American College of Obstetricians and Gynecologists (ACOG)

GUIDELINE COMMITTEE

American College of Obstetricians and Gynecologists (ACOG) Committee on Practice Bulletins-Obstetrics

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Not stated

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Not available at this time.

Print copies: Available for purchase from the American College of Obstetricians and Gynecologists (ACOG) Distribution Center, PO Box 4500, Kearneysville, WV 25430-4500; telephone, 800-762-2264, ext. 192; e-mail: sales@acog.org. The ACOG Bookstore is available online at the [ACOG Web site](#).

AVAILABILITY OF COMPANION DOCUMENTS

None available

PATIENT RESOURCES

None available

NGC STATUS

This summary was completed by ECRI on February 4, 2004. The information was verified by the guideline developer on July 26, 2004.

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