Complete Summary

GUIDELINE TITLE

Cervical insufficiency.

BIBLIOGRAPHIC SOURCE(S)

American College of Obstetricians and Gynecologists (ACOG). Cervical insufficiency. Washington (DC): American College of Obstetricians and Gynecologists (ACOG); 2003 Nov. 9 p. (ACOG practice bulletin; no. 48). [56 references]

GUIDELINE STATUS

This is the current release of the guideline.

COMPLETE SUMMARY CONTENT

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SCOPE

DISEASE/CONDITION(S)

Cervical insufficiency

GUIDELINE CATEGORY

Management
Screening

CLINICAL SPECIALTY

Obstetrics and Gynecology
Surgery

INTENDED USERS

Physicians

GUIDELINE OBJECTIVE(S)

- To aid practitioners in making decisions about appropriate obstetric and gynecologic care
- To provide a review of current evidence on cervical insufficiency, including screening of asymptomatic at-risk women, and offer management guidelines

TARGET POPULATION

Pregnant women with cervical insufficiency

INTERVENTIONS AND PRACTICES CONSIDERED

Diagnosis/Evaluation/Screening

1. Patient history, including history of diethylstilbestrol exposure
2. Ultrasonography (routine ultrasound screening not recommended)
3. Patient selection for cerclage based on history of cervical insufficiency

Management/Treatment

1. Frequent examination
2. Counseling
3. Cerclage (Shirodkar and McDonald procedures, transabdominal cervicoisthmic cerclage)
4. Perioperative antibiotics and tocolytics, with caution

MAJOR OUTCOMES CONSIDERED

- Sensitivity and specificity of ultrasound screening of the cervix
- Duration of gestation
- Neonatal morbidity and mortality
- Rate of bacterial infection
- Incidence of complications with cerclage placement

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' own internal resources and documents were used to conduct a literature search to locate relevant articles published between January 1985 and July 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

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 recommendation (A-C) are defined at the end of the "Major Recommendations" field

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

- Serial assessments in low-risk women to screen for cervical insufficiency are of low yield and should not be done routinely.
- Serial ultrasound examinations should be considered in a patient with historical risk factors for cervical insufficiency and should be initiated between 16 and 20 weeks of gestation or later.
- An elective cerclage can be considered in a patient with a history of 3 or more unexplained midtrimester pregnancy losses or preterm deliveries.
- Women exposed to diethylstilbestrol (DES) in utero may be evaluated for cervical insufficiency using the same clinical criteria as nonexposed individuals.

The following recommendations are based primarily on consensus and expert opinion (Level C):

- The evaluation of a patient with cervical shortening or funneling should include a comprehensive ultrasonographic assessment of the fetus to rule out anomalies, as well as physical and laboratory assessments to rule out labor and chorioamnionitis.
- Given the advances in neonatal care and the potential maternal and fetal morbidity associated with cerclage, surgical correction of cervical insufficiency should be limited to pregnancies before fetal viability has been achieved.

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

Appropriate screening and management of cervical insufficiency

POTENTIAL HARMS

The use of unnecessary antibiotics may lead to the development of resistant strains of bacteria and other morbidity for the woman and her fetus.

Cerclage

- Rupture of membranes, chorioamnionitis, and suture displacement are the most common complications associated with cerclage placement, and their incidence varies widely in relation to the timing and indications for the cerclage.
- Urgent and emergency cerclages are associated with a higher incidence of morbidity as a result of cervical shortening and exposure of the fetal membranes to the vaginal ecosystem.
- Transabdominal cerclage can be complicated by rupture of membranes and chorioamnionitis. It carries the added risk of intraoperative hemorrhage from the uterine veins when the cerclage band is tunneled between the bifurcation of the uterine artery, as well as the known risks associated with laparotomy.
- Life-threatening complications of uterine rupture and maternal septicemia are extremely rare but have been reported with all types of cerclage.

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
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

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ADAPTATION

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

DATE RELEASED

2003 Nov

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: None available

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 NGC summary was completed by ECRI Institute on October 12, 2007. The information was verified by the guideline developer on December 3, 2007.

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