Complete Summary

GUIDELINE TITLE

Benefits and risks of sterilization.

BIBLIOGRAPHIC SOURCE(S)

American College of Obstetricians and Gynecologists (ACOG). Benefits and risks of sterilization. Washington (DC): American College of Obstetricians and Gynecologists (ACOG); 2003 Sep. 12 p. (ACOG practice bulletin; no. 46). [104 references]

GUIDELINE STATUS

This is the current release of the guideline.

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Unintended pregnancy

GUIDELINE CATEGORY

Assessment of Therapeutic Effectiveness
Counseling
Evaluation
Prevention

CLINICAL SPECIALTY

Family Practice
Internal Medicine
Obstetrics and Gynecology
Surgery
Urology

INTENDED USERS

Physicians

GUIDELINE OBJECTIVE(S)

- To aid practitioners in making decisions about appropriate obstetric and gynecologic care
- To review the evidence for the safety and effectiveness of sterilization in comparison with other forms of contraception
- To review the evidence of the likelihood that a woman will regret having had a sterilization procedure

TARGET POPULATION

Women and men of reproductive capability

INTERVENTIONS AND PRACTICES CONSIDERED

1. Timing of tubal sterilization procedure (postpartum, post-abortion, or other)
2. Patient and partner presterilization counseling
3. Surgical/occlusive methods of tubal sterilization
    - Laparoscopy
    - Minilaparotomy
    - Transcervical approaches (e.g., Essure device)
    - Transvaginal approaches (e.g., fimbriectomy or Pomeroy methods)
    - Electrocoagulation
    - Mechanical occlusion (e.g., Falope ring, Hulka-Clemens clip, Filshie clip)
    - Ligation
    - Chemical sclerosing agents (not currently approved in the United States)
4. Vasectomy

MAJOR OUTCOMES CONSIDERED

- Minor and major complications of sterilizations procedures, including mortality
- Failure rate
- Ovarian cancer incidence
- Rate of subsequent hysterectomy
- Rate of subsequent regret

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 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

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" field

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

- Tubal sterilization may be recommended as a safe and effective method for women who desire permanent contraception. Women should be counseled that tubal ligation is not intended to be reversible; therefore, those who do not want permanent contraception should be counseled to consider other methods of contraception.
- Patients should be advised that neither tubal sterilization nor vasectomy provides any protection against sexually transmitted diseases, including human immunodeficiency virus (HIV) infection.
- Patients should be advised that the morbidity and mortality of tubal ligation, although low, is higher than that of vasectomy, and the efficacy rates of the 2 procedures are similar.
- Patients should be counseled that tubal sterilization is more effective than short-term, user-dependent reversible methods.
- Patients should be counseled that failure rates of tubal sterilization are comparable with those of intrauterine devices (IUDs).

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

- If a patient has a positive pregnancy test result after a tubal ligation, ectopic pregnancy should be ruled out.
- Indications for hysterectomy in women with previous tubal sterilization should be the same as for women who have not had tubal sterilization.

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

Safe and effective use of sterilization procedures for women and men

POTENTIAL HARMS

Women

- Dilation and curettage concurrent with all interval sterilizations as a routine practice is not recommended on the basis of effectiveness, cost, and morbidity.
- Death from tubal sterilization is a rare event, and overall complication rates are low. (See the original guideline document for a detailed discussion of complication rates and risk factors.)
- The disadvantages of laparoscopy include the risk of bowel, bladder, or major vessel injury after insertion of the needle or trocar. The use of general anesthesia also increases risk.
- One major disadvantage to the transvaginal approach is the need for adequate vaginal surgical training to minimize potential complications, such as cellulitis, pelvic abscess, hemorrhage, proctotomy, or cystotomy.
- Unipolar electrocoagulation is associated with thermal bowel injury.
- Mechanical devices are most likely to be effective when used to occlude a normal fallopian tube; tubal adhesions or thickened or dilated fallopian tubes increase the risk of misapplication and subsequent failure. Spontaneous clip migration or expulsion is rare.
- For all methods of sterilization except postpartum partial salpingectomy, women younger than 30 years were more likely to experience ectopic pregnancy than women older than 30 years

- Post-sterilization regret

Men

- Minor complications of vasectomy include infection at the site of incision, bleeding and hematoma formation, granuloma formation, and epididymitis. Vasectomy-related major morbidity and mortality are extremely rare in the United States.
- "Postvasectomy pain syndrome," or chronic testicular pain, has been described in the literature and is poorly understood.

CONTRAINDICATIONS

CONTRAINDICATIONS

Contraindications to the transvaginal approach include suspicion of major pelvic adhesions, enlarged uterus, and inability to place the patient in the lithotomy position.

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.

IMPLEMENTATION TOOLS

Foreign Language Translations
Patient Resources

For information about availability, see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Staying Healthy

IOM DOMAIN

Effectiveness
Patient-centeredness
Safety

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

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ADAPTATION

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

DATE RELEASED

2003 Sep

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-Gynecology

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

The following is available:

- Sterilization for women and men. Atlanta (GA): American College of Obstetricians and Gynecologists (ACOG); 2005. Available from the American College of Obstetricians and Gynecologists (ACOG) Web site.
- Sterilization by laparoscopy. Atlanta (GA): American College of Obstetricians and Gynecologists (ACOG); 2003. Available from the American College of Obstetricians and Gynecologists (ACOG) Web site. Copies are also available in Spanish.
- Postpartum sterilization. Atlanta (GA): American College of Obstetricians and Gynecologists (ACOG); 2003. Available from the American College of Obstetricians and Gynecologists (ACOG) Web site. Copies are also available in Spanish.

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.

NGC STATUS

This NGC summary was completed by ECRI Institute on August 3, 2007. The information was verified by the guideline developer on September 10, 2007.

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