



Complete Summary

GUIDELINE TITLE

Pelvic organ prolapse.

BIBLIOGRAPHIC SOURCE(S)

American College of Obstetricians and Gynecologists (ACOG). Pelvic organ prolapse. Washington (DC): American College of Obstetricians and Gynecologists (ACOG); 2007 Sep. 13 p. (ACOG practice bulletin; no. 85). [82 references]

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: American College of Obstetricians and Gynecologists (ACOG). Pelvic organ prolapse. Washington (DC): American College of Obstetricians and Gynecologists (ACOG); 2007 Feb. 13 p. (ACOG practice bulletin; no. 79).

** REGULATORY ALERT **

FDA WARNING/REGULATORY ALERT

Note from the National Guideline Clearinghouse: This guideline references a drug(s) for which important revised regulatory and/or warning information has been released.

- [October 22, 2008, Surgical mesh devices](#): The U.S. Food and Drug Administration (FDA) informed healthcare professionals of serious complications associated with transvaginal placement of surgical mesh in repair of pelvic organ prolapse (POP) and stress urinary incontinence (SUI). The FDA provided recommended actions for both physicians and patients to reduce the risks.

COMPLETE SUMMARY CONTENT

** REGULATORY ALERT **

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INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT

SCOPE

DISEASE/CONDITION(S)

Pelvic organ prolapse, including prolapse of the:

- Uterine cervix
- Vaginal apex
- Anterior vagina
- Posterior vagina
- Peritoneum of the cul-de-sac

GUIDELINE CATEGORY

Evaluation
Risk Assessment
Treatment

CLINICAL SPECIALTY

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 current treatment options for pelvic organ prolapse

TARGET POPULATION

Women with pelvic organ prolapse

INTERVENTIONS AND PRACTICES CONSIDERED

Evaluation

1. Pelvic symptom assessment
2. Stress testing with and without prolapse reduction
3. Classification of pelvic organ prolapse
 - Baden-Walker system

- Stages of pelvic organ prolapse
 - Pelvic organ prolapse quantification system
4. Risk assessment

Treatment

1. Nonsurgical treatment
 - Observation
 - Pessaries
 - Symptom-directed therapy: weight loss, exercise
 - Pelvic floor muscle rehabilitation: Kegel exercises
2. Surgical Treatment
 - Hysterectomy
 - Abdominal sacral colopexy
 - Uterosacral and sacrospinous ligament fixation by vaginal approach
 - Sacral hysteropexy by abdominal approach
 - Transvaginal posterior colporrhaphy
 - Colpocleisis
 - Intraoperative cystoscopy
 - Burch procedure
 - Round ligament suspension (considered but not recommended)

MAJOR OUTCOMES CONSIDERED

- Surgical procedure complication rates
- Anesthetic complication rate
- Perioperative complication rate
- Procedure failure rates
- Reoperation rate
- Postoperative stress incontinence rate
- Prolapse recurrence rate
- Operative time
- Mortality

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 August 2006. 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 and conclusions are based on good and consistent scientific evidence (Level A):

- The only symptom specific to prolapse is the awareness of a vaginal bulge or protrusion. For all other pelvic symptoms, resolution with prolapse treatment cannot be assumed.
- Pessaries can be fitted in most women with prolapse, regardless of prolapse stage or site of predominant prolapse.

- Cadaveric fascia should not be used as graft material for abdominal sacral colpopexy because of a substantially higher risk of recurrent prolapse than with synthetic mesh.
- Stress-continent women with positive stress test results (prolapse reduced) are at higher risk for developing postoperative stress incontinence after prolapse repair alone compared with women with negative stress test results (prolapse reduced).
- For stress-continent women planning abdominal sacral colpopexy, regardless of the results of preoperative stress testing, the addition of the Burch procedure substantially reduces the likelihood of postoperative stress incontinence without increasing urgency symptoms or obstructed voiding.
- For women with positive prolapse reduction stress test results who are planning vaginal prolapse repair, tension-free vaginal tape (TVT) midurethral sling (rather than suburethral fascial plication) appears to offer better prevention from postoperative stress incontinence.

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

- Clinicians should discuss the option of pessary use with all women who have prolapse that warrants treatment based on symptoms. In particular, pessary use should be considered before surgical intervention in women with symptomatic prolapse.
- Alternative operations for uterine preservation in women with prolapse include uterosacral or sacrospinous ligament fixation by the vaginal approach, or sacral hysteropexy by the abdominal approach.
- Hysteropexy should not be performed by using the ventral abdominal wall for support because of the high risk for recurrent prolapse, particularly enterocele.
- Round ligament suspension is not effective in treating uterine or vaginal prolapse.
- Compared with vaginal sacrospinous ligament fixation, abdominal sacral colpopexy has less apical failure and less postoperative dyspareunia and stress incontinence, but is also associated with more complications.
- Transvaginal posterior colporrhaphy is recommended over transanal repair for posterior vaginal prolapse.

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

- Clinicians should discuss with women the potential risks and benefits in performing a prophylactic anti-incontinence procedure at the time of prolapse repair.
- Women with prolapse who are asymptomatic or mildly symptomatic can be observed at regular intervals, unless new bothersome symptoms develop.
- For women who are at high risk for complications with reconstructive procedures and who no longer desire vaginal intercourse, colpocleisis can be offered.
- Cystoscopy should be performed intraoperatively to assess for bladder or ureteral damage after all prolapse or incontinence procedures during which the bladder or ureters may be at risk of injury.

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 Recommendation

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 evaluation and treatment of pelvic organ prolapse

POTENTIAL HARMS

Surgical Approaches

- Longer procedure time and longer patient recovery time for some surgical procedures
- Intra-abdominal adhesions
- Small-bowel obstruction
- Ureteral injury
- Hemorrhage, hematoma
- Buttock pain
- Recurrent prolapse
- Wound infection
- Incisional hernia
- Mesh erosion
- Postoperative dyspareunia
- Perioperative complications in older women: blood loss, pulmonary edema, heart failure
- Need for reoperation
- Postoperative stress incontinence

Poor Surgical Candidates

- In general, perioperative risk is increased in patients with concomitant medical problems. However, if surgery becomes necessary, limited data support its relative safety; morbidity occurs frequently but mortality is rare.
- Complications were more frequent in women aged 80 years and older and in women who had reconstructive rather than obliterative surgery.

Women Considering Pregnancy

Ideally, childbearing should be complete before considering surgery for prolapse to avoid the theoretical but plausible risk of recurrent prolapse after subsequent pregnancy and delivery. For women who become pregnant after prolapse repair, decisions regarding mode of delivery should be made on a case-by-case basis; evidence to guide such decisions is lacking.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

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

Audit Criteria/Indicators

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

Getting Better

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

2007 Feb (revised 2007 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

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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

Proposed performance measures are included in the original guideline document.

PATIENT RESOURCES

None available

NGC STATUS

This NGC summary was completed by ECRI Institute on October 5, 2007. The information was verified by the guideline developer on December 3, 2007. This summary was updated by ECRI Institute on July 29, 2008. The updated information was verified by the guideline developer on August 20, 2008. This summary was updated by ECRI Institute on October 27, 2008 following the U.S. Food and Drug Administration (FDA) advisory on surgical mesh devices.

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