Complete Summary

GUIDELINE TITLE

Breast cancer screening.

BIBLIOGRAPHIC SOURCE(S)

American College of Obstetricians and Gynecologists (ACOG). Breast cancer screening. Washington (DC): American College of Obstetricians and Gynecologists (ACOG); 2003 Apr. 12 p. (ACOG practice bulletin; no. 42). [94 references]

GUIDELINE STATUS

This is the current release of the guideline.

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SCOPE

DISEASE/CONDITION(S)

Breast cancer

GUIDELINE CATEGORY

Counseling
Diagnosis
Evaluation
Prevention
Screening

CLINICAL SPECIALTY

Obstetrics and Gynecology
Oncology
Preventive Medicine

INTENDED USERS

Physicians

GUIDELINE OBJECTIVE(S)

- To clarify the rationale for current breast cancer screening guidelines and evaluate the evidence regarding screening techniques
- To focus on mammography and other detection techniques as screening tools to identify nonpalpable lesions
- To aid practitioners in making decisions about appropriate obstetric and gynecologic care

TARGET POPULATION

Adult women

INTERVENTIONS AND PRACTICES CONSIDERED

1. Mammography screening
2. Clinical breast examination and breast self-examination
3. Ultrasonography
4. Biopsy (needle location or stereotactic)
5. Referral to a professional experienced in the diagnosis of breast cancer
6. Genetic counseling and testing

Note: The following screening techniques were considered but not recommended: magnetic resonance imaging, color Doppler ultrasonography, computer-aided detection, positron emission tomography, scintimammography, step-oblique mammography, and thermography.

MAJOR OUTCOMES CONSIDERED

- Breast cancer survival and mortality rates
- Risks and benefits of mammography screening
- Sensitivity and specificity of clinical breast examination
- Risk factors for breast cancer

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 July 2002. 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

The guideline developer reviewed published cost analyses.

Two detailed analyses of mammography for women aged 40-49 years concluded that mammography screening was relatively cost-ineffective because of the decreased efficacy of mammography (related to a higher percentage of women with dense breast tissue) and the low incidence of breast cancer in this age group.

Medical comorbidity and life expectancy should be considered in a breast cancer screening program for women aged 75 years or older because the benefit-to-risk ratio of screening mammography continues to shift adversely with advancing age. A consensus of recommendations does not exist. However, a meta-analysis concluded that screening mammography in women aged 70-79 years is moderately cost-effective and yields a small increase in life expectancy.

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 limited and inconsistent scientific evidence (Level B):

- Women aged 40 to 49 years should have screening mammography every 1 to 2 years.
- Women aged 50 years and older should have annual screening mammography.

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

- Despite a lack of definitive data for or against breast self-examination, breast self-examination has the potential to detect palpable breast cancer and can be recommended.
- All women should have clinical breast examinations annually as part of the physical examination.

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 breast cancer screening using mammography and other screening techniques

POTENTIAL HARMS

Adverse Effects of Screening Techniques

Mammography

Initial concerns about the risk of radiation (e.g., induction of breast cancer by radiation) have largely been allayed by improvements in mammography technique, technology, and clinical experience. False-positive mammograms (i.e., those with perceived abnormalities requiring further evaluation to verify that the lesion is not cancer) are a continuing concern. False-positive screening mammograms require diagnostic mammography with supplementary views, ultrasonography, and even biopsy in 20 to 30% of cases in an attempt to reach an accurate diagnosis. Psychosocial consequences of screening mammography have been identified and reviewed. These psychologic, behavioral, and quality-of-life issues seem to be intrinsic to the fear of breast cancer.

Breast Self-examination

An analysis by the Canadian Task Force on Preventive Health Care revealed fair evidence that breast self-examination had no benefit and good evidence that it was harmful. This group concluded that among women aged 40 to 69 years, routine teaching of breast self-examination should be excluded from breast cancer screening. Increased physician visits and higher rates of benign breast biopsies

were documented to be adverse effects of breast self-examination. In addition, studies were cited that revealed patients experienced increased worry, anxiety, and depression associated with breast self-examination. Despite a lack of definitive data for or against breast self-examination, breast self-examination has the potential to detect palpable breast cancer and can be recommended.

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.
- Of the eight published randomized, controlled trials of screening for breast cancer with mammography, questions have been raised regarding trial design, randomization, exclusions, reallocations, contamination (the number of women in the control group who underwent mammography on their own), compliance (the number of women in the study group who, for whatever reason, did not undergo screening mammography), mammography screening of the control group before they entered the study, verification of a disease-specific cause of death, autopsy rates, and variations in cancer therapy. The variability of the design, technology, methodology, interpretation, and endpoints of most of the trials does not permit meaningful comparisons. All the screening mammography trials were designed and carried out before the current stringent and exacting format for a population-based randomized trial was established. No consensus exists regarding the optimum details of the design and formatting of a population-based, randomized clinical trial to assess breast cancer screening.

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

Staying Healthy

IOM DOMAIN

Effectiveness
Patient-centeredness
Timeliness

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 Apr

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: 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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