Complete Summary

GUIDELINE TITLE

Nonpalpable breast masses.

BIBLIOGRAPHIC SOURCE(S)

D'Orsi CJ, Bassett LW, Berg WA, Bohm-Velez M, Evans WP III, Farria DM, Lee C, Mendelson EB, Goldstein S. Nonpalpable breast masses. [online publication]. Reston (VA): American College of Radiology (ACR); 2005. 12 p. [25 references]

GUIDELINE STATUS

This is the current release of the guideline.

It updates a previously published version: D'Orsi C, Mendelson E, Bassett L, Bohm-Velez M, Cardenosa G, Evans WP 3rd, Monsees B, Thurmond A, Goldstein S. Work-up of nonpalpable breast masses. American College of Radiology. ACR Appropriateness Criteria. Radiology 2000 Jun;215 Suppl:965-72.

The appropriateness criteria are reviewed annually and updated by the panels as needed, depending on introduction of new and highly significant scientific evidence.

COMPLETE SUMMARY CONTENT

SCOPE
METHODOLOGY - including Rating Scheme and Cost Analysis
RECOMMENDATIONS
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SCOPE

DISEASE/CONDITION(S)

Nonpalpable breast masses

GUIDELINE CATEGORY

Diagnosis
Evaluation

CLINICAL SPECIALTY

Family Practice
Internal Medicine
Nuclear Medicine
Obstetrics and Gynecology
Oncology
Radiology

INTENDED USERS

Health Plans
Hospitals
Managed Care Organizations
Physicians
Utilization Management

GUIDELINE OBJECTIVE(S)

To evaluate the appropriateness of radiologic procedures for patients with nonpalpable breast masses

TARGET POPULATION

Women with nonpalpable breast mass

INTERVENTIONS AND PRACTICES CONSIDERED

1. X-ray, diagnostic mammography with and without supplemental views
2. Ultrasound (US)
3. Short-interval follow-up
4. Magnetic resonance imaging (MRI)
5. Invasive procedures (INV)
    - Percutaneous tissue sampling
    - Percutaneous biopsy
    - Diagnostic excisional biopsy
6. Computed tomography (CT)
7. Nuclear medicine, sestamibi scan
8. Needle aspiration

MAJOR OUTCOMES CONSIDERED

Utility of radiologic examinations in differential diagnosis

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

The guideline developer performed literature searches of peer-reviewed medical journals, and the major applicable articles were identified and collected.

NUMBER OF SOURCE DOCUMENTS

The total number of source documents identified as the result of the literature search is not known.

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Not Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not stated

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

One or two topic leaders within a panel assume the responsibility of developing an evidence table for each clinical condition, based on analysis of the current literature. These tables serve as a basis for developing a narrative specific to each clinical condition.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus (Delphi)

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Since data available from existing scientific studies are usually insufficient for meta-analysis, broad-based consensus techniques are needed for reaching agreement in the formulation of the appropriateness criteria. The American College of Radiology (ACR) Appropriateness Criteria panels use a modified Delphi technique to arrive at consensus. Serial surveys are conducted by distributing questionnaires to consolidate expert opinions within each panel. These questionnaires are distributed to the participants along with the evidence table and narrative as developed by the topic leader(s). Questionnaires are completed by the participants in their own professional setting without influence of the other members. Voting is conducted using a scoring system from 1 to 9, indicating the least to the most appropriate imaging examination or therapeutic procedure. The

survey results are collected, tabulated in anonymous fashion, and redistributed after each round. A maximum of three rounds is conducted and opinions are unified to the highest degree possible. Eighty percent agreement is considered a consensus. This modified Delphi technique enables individual, unbiased expression, is economical, easy to understand, and relatively simple to conduct.

If consensus cannot be reached by this Delphi technique, the panel is convened and group consensus techniques are utilized. The strengths and weaknesses of each test or procedure are discussed and consensus reached whenever possible. If "No consensus" appears in the rating column, reasons for this decision are added to the comment sections.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

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

Criteria developed by the Expert Panels are reviewed by the American College of Radiology (ACR) Committee on Appropriateness Criteria.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

ACR Appropriateness Criteria®

Clinical Condition: Work-up of Nonpalpable Breast Mass

Variant 1: Focal asymmetries.

Radiologic Exam Procedure	Appropriateness Rating	Comments
X-ray, breast, diagnostic mammography, with supplemental views	9	
US, breast	8	

Radiologic Exam Procedure	Appropriateness Rating	Comments
Short-interval follow-up	4	Restricted to lesions that meet the criteria specified in the literature review.
MRI, breast	3	
INV, breast, percutaneous tissue sampling	2	A developing asymmetry may require sampling after appropriate evaluation.
INV, breast, excisional biopsy, diagnostic	2	
CT, breast	2	
NUC, breast, sestamibi	2	
Appropriateness Criteria Scale **1 2 3 4 5 6 7 8 9** **1 = Least appropriate 9 = Most appropriate**		

Note: Abbreviations used in the tables are listed at the end of the "Major Recommendations" field.

Variant 2: Round, oval or lobular mass with circumscribed, partially obscured margin on baseline screening mammogram.

Radiologic Exam Procedure	Appropriateness Rating	Comments
US, breast, diagnostic	9	
X-ray, breast, diagnostic mammography	9	
Percutaneous tissue sampling when ultrasound shows:		While the majority of experts prefer core biopsy, the use of FNAB could be a site-specific decision.
Complex mass (cystic/solid components)	9	
Suspicious for malignancy	9	
Solid mass, circumscribed, oval, parallel, no	3	Patient may wish biopsy or biopsy may circumvent excision.

Radiologic Exam Procedure	Appropriateness Rating	Comments
posterior features or minimal enhancement		
Clustered microcysts	2	
Short-interval follow-up	3	Restricted to lesions that meet the criteria specified in the literature review.
MRI, breast	2	
CT, breast	2	
NUC, breast, sestamibi scan	2	
Needle aspiration when ultrasound shows:		
Complicated cyst	4	
Simple cyst	2	For pain control
Clustered microcysts	2	
Complex mass (cystic/solid components)	2	
INV, breast, excisional biopsy, diagnostic	2	
Appropriateness Criteria Scale **1 2 3 4 5 6 7 8 9** **1 = Least appropriate 9 = Most appropriate**		

Note: Abbreviations used in the tables are listed at the end of the "Major Recommendations" field.

Variant 3: Spiculated and/or ill-defined masses.

Radiologic Exam Procedure	Appropriateness Rating	Comments
X-ray, breast, diagnostic	9	

Radiologic Exam Procedure	Appropriateness Rating	Comments
mammography		
INV, breast, percutaneous biopsy	9	While the majority of experts prefer core biopsy, the use of FNAB could be a site-specific decision.
US, breast, diagnostic	5	The use of US here is primarily to guide tissue sampling procedures.
INV, breast, excisional biopsy, diagnostic	4	Indicated if preceding steps are not sufficient.
CT, breast	2	
NUC, breast, sestamibi scan	2	
Short-interval follow-up	1	
MRI, breast	No consensus	Data are being collected. Appropriateness of MRI will be determined at a future date.
Appropriateness Criteria Scale **1 2 3 4 5 6 7 8 9** **1 = Least appropriate 9 = Most appropriate**		

Note: Abbreviations used in the tables are listed at the end of the "Major Recommendations" field.

Variant 4: Circumscribed (> 75%), partially obscured mass with coarse, dystrophic and/or "popcorn" calcification.

Radiologic Exam Procedure	Appropriateness Rating	Comments
X-ray, breast, diagnostic mammography	4	May be indicated if mass is not clearly benign on screening mammogram.
MRI, breast	2	
CT, breast	2	
NUC, breast, sestamibi scan	2	
US, breast	2	

Radiologic Exam Procedure	Appropriateness Rating	Comments
INV, breast, percutaneous tissue sampling	2	
INV, breast, excisional biopsy, diagnostic	2	
Short-interval follow-up	1	
Appropriateness Criteria Scale **1 2 3 4 5 6 7 8 9** **1 = Least appropriate 9 = Most appropriate**		

Note: Abbreviations used in the tables are listed at the end of the "Major Recommendations" field.

Variant 5: Circumscribed/partially obscured mass with pleomorphic/amorphous and/or heterogeneous calcifications.

Radiologic Exam Procedure	Appropriateness Rating	Comments
X-ray, breast, diagnostic mammography	9	
INV, breast, percutaneous tissue sampling	9	While the majority of experts prefer core biopsy, the use of FNAB could be a site-specific decision.
US, breast	7	To further characterize the partially obscured mass and to evaluate the possibility of using ultrasound to guide biopsy.
MRI, breast	2	
CT, breast	2	
NUC, breast, sestamibi scan	2	
INV, breast, excisional biopsy, diagnostic	2	
Short-interval follow-up	1	
Appropriateness Criteria Scale		

Radiologic Exam Procedure	Appropriateness Rating	Comments
1 2 3 4 5 6 7 8 9 **1 = Least appropriate 9 = Most appropriate**		

Note: Abbreviations used in the tables are listed at the end of the "Major Recommendations" field.

Variant 6: Irregular spiculated/indistinct mass with coarse/dystrophic and/or "popcorn" calcification.

Radiologic Exam Procedure	Appropriateness Rating	Comments
INV, breast, percutaneous tissue sampling	9	While the majority of experts prefer core biopsy, the use of FNAB could be a site-specific decision.
X-ray, breast, diagnostic mammography	8	
US, breast	8	Used to evaluate the extent of local disease and to evaluate the possibility of using ultrasound to guide biopsy.
INV, breast, excisional biopsy, diagnostic	4	In some circumstances, excisional biopsy for diagnosis may be used as the initial diagnostic biopsy.
MRI, breast	2	
CT, breast	2	
NUC, breast, sestamibi scan	2	
Short-interval follow-up	1	
Appropriateness Criteria Scale **1 2 3 4 5 6 7 8 9** **1 = Least appropriate 9 = Most appropriate**		

Note: Abbreviations used in the tables are listed at the end of the "Major Recommendations" field.

Variant 7: Irregular spiculated/indistinct mass with pleomorphic/amorphous and/or heterogeneous calcification.

Radiologic Exam Procedure	Appropriateness Rating	Comments
X-ray, breast, diagnostic mammography	9	
INV, breast, percutaneous tissue sampling	9	While the majority of experts prefer core biopsy, the use of FNAB could be a site-specific decision.
US, breast	5	The use of US here is primarily to guide tissue sampling procedures.
INV, breast, excisional biopsy, diagnostic	4	In some circumstances, excisional biopsy for diagnosis may be used as the initial diagnostic biopsy.
CT, breast	2	
NUC, breast, sestamibi scan	2	
Short-interval follow-up	1	
MRI, breast	No consensus	Evolving technology; indications currently being defined.
Appropriateness Criteria Scale **1 2 3 4 5 6 7 8 9** **1 = Least appropriate 9 = Most appropriate**		

Note: Abbreviations used in the tables are listed at the end of the "Major Recommendations" field.

With improved imaging techniques, screening mammograms enable early detection of smaller cancers. Most lesions detected mammographically are benign. The positive predictive value of mammography for breast cancer ranges from 10%-15% to 34%-40% depending on age and type of population examined.

Normal soft-tissue densities can simulate a mass, and additional mammographic and/or US evaluation may be necessary to determine the presence of a true mass. Masses are three-dimensional structures with convex outward contours. Asymmetric breast tissue is planar, often with concave outward contours. When a new mass is suspected, additional imaging is necessary using additional views and possibly ultrasound. When a mass is detected mammographically, assessment of its shape, margin, density, and size should be done as outlined in the American College of Radiology (ACR) BI-RADS® Atlas, Appendix I in the original guideline document.

Ultrasound has the ability to determine the cystic or solid nature of a breast mass. Adhering to strict criteria, this technique can separate cystic from solid masses

with an accuracy approaching 100%. Using good-quality, high-frequency equipment, cysts as small as 2-3 mm in diameter can be demonstrated. After final mammographic evaluation, round, oval, or lobular masses with circumscribed or partially obscured or ill-defined margins can be further investigated with US to identify simple cysts, complicated cysts, complex masses, and solid masses. Masses with mammographic findings that are suspicious or highly suggestive of malignancy, or masses with suspicious or typically benign calcifications, do not require US for assessment, though US can be used to guide needle biopsy if the mass is seen sonographically.

The data on the use of MRI to evaluate nonpalpable masses is being addressed. Current uses of MRI include evaluation of disease extent in the ipsilateral and contralateral breasts in women with known malignancy and screening of high-risk women with dense breasts, although benefit has not been established.

After appropriate work-up of a mass, which will usually include diagnostic mammography and US, a final assessment following BI-RADS® guidelines should be assigned. Articles have validated the approach of following probably benign lesions, as outlined in the ACR BI-RADS® Atlas--Mammography, 4th Edition guidance chapter, to decrease the number of biopsies of benign lesions and potentially substantially reduce cost. If the mass is placed in category 4 or 5, a biopsy is warranted. This biopsy may be incisional using stereotactic or US guidance to obtain a core of tissue or cellular aspirate via fine-needle technique. An incisional biopsy should only be done if the diagnostic process is shortened and/or more cost effective with comparable outcome to an excisional biopsy. For example, if a solid mass is diagnosed as fibroadenoma on core biopsy and then undergoes surgical excision for any of a variety of reasons, cost has been added and the diagnostic procedure has been lengthened with no gain. On the other hand, a core biopsy may be used to provide histology for a category 5 lesion so that excision and sentinel node biopsy can be done simultaneously. Where sentinel node biopsy will not be performed, a category 5 lesion may be directed to excision without a prior core biopsy.

There are advantages and disadvantages to core and FNAB techniques. An advantage to core biopsy is that it does not require a trained cytopathologist for review; in cases of malignancy it will frequently indicate the presence of invasion; and, for calcifications, it may demonstrate visual target removal. However, the procedure may be more traumatic than FNAB and requires more post-procedure vigilance. With incisional image-guided biopsy procedures, one must pay attention to what is present behind the target by using some automated core devices to insure that inadvertent puncture of the pleura or pectoralis muscle does not occur, or that there is adequate breast tissue behind the mass to prevent impingement of the needle onto the cassette with stereotactic guidance. Fine-needle aspiration biopsy technique requires a trained cytopathologist. The report of a multi-center randomized trial demonstrated a 10%-11% insufficiency rate for US-guided FNAB and up to 39% for stereotactically guided procedures. The overall accuracy for US-guided FNAB was 77%, while for stereotactically guided FNAB, accuracy was only 58%. There were also 9% false positive exams, which could lead to unnecessary treatment. Unlike FNAB, core biopsy allows accurate distinction between in situ and invasive carcinoma.

Abbreviations

- CT, computed tomography
- FNAB, fine needle aspiration biopsy
- INV, invasive
- MRI, magnetic resonance imaging
- NUC, nuclear medicine
- US, ultrasound

CLINICAL ALGORITHM(S)

Algorithms were not developed from criteria guidelines.

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The recommendations are based on analysis of the current literature and expert panel consensus.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Selection of appropriate radiologic imaging procedures for evaluation of patients with nonpalpable breast masses

POTENTIAL HARMS

Core biopsy may be more traumatic than fine-needle aspiration biopsy (FNAB) and requires more post-procedure vigilance.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

An American College of Radiology (ACR) Committee on Appropriateness Criteria and its expert panels have developed criteria for determining appropriate imaging examinations for diagnosis and treatment of specified medical condition(s). These criteria are intended to guide radiologists, radiation oncologists, and referring physicians in making decisions regarding radiologic imaging and treatment. Generally, the complexity and severity of a patient's clinical condition should dictate the selection of appropriate imaging procedures or treatments. Only those exams generally used for evaluation of the patient's condition are ranked. Other imaging studies necessary to evaluate other co-existent diseases or other medical consequences of this condition are not considered in this document. The availability of equipment or personnel may influence the selection of appropriate imaging procedures or treatments. Imaging techniques classified as investigational by the U.S. Food and Drug Administration (FDA) have not been considered in developing these criteria; however, study of new equipment and applications should be encouraged. The ultimate decision regarding the appropriateness of any specific radiologic examination or treatment must be made

by the referring physician and radiologist in light of all the circumstances presented in an individual examination.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

IMPLEMENTATION TOOLS

Personal Digital Assistant (PDA) Downloads

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
Staying Healthy

IOM DOMAIN

Effectiveness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

D'Orsi CJ, Bassett LW, Berg WA, Bohm-Velez M, Evans WP III, Farria DM, Lee C, Mendelson EB, Goldstein S. Nonpalpable breast masses. [online publication]. Reston (VA): American College of Radiology (ACR); 2005. 12 p. [25 references]

ADAPTATION

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

DATE RELEASED

1995 (revised 2005)

GUIDELINE DEVELOPER(S)

American College of Radiology - Medical Specialty Society

SOURCE(S) OF FUNDING

The American College of Radiology (ACR) provided the funding and the resources for these ACR Appropriateness Criteria®.

GUIDELINE COMMITTEE

Committee on Appropriateness Criteria, Expert Panel on Women's Imaging--Breast Work Group

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Panel Members: Carl J. D'Orsi, MD; Lawrence W. Bassett, MD; Wendie A. Berg, MD, PhD; Marcela Bohm-Velez, MD; W. Phil Evans III, MD; Dione Marie Farria, MD, MPH; Carol Lee, MD; Ellen B. Mendelson, MD; Steven Goldstein, MD

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline.

It updates a previously published version: D'Orsi C, Mendelson E, Bassett L, Bohm-Velez M, Cardenosa G, Evans WP 3rd, Monsees B, Thurmond A, Goldstein S. Work-up of nonpalpable breast masses. American College of Radiology. ACR Appropriateness Criteria. Radiology 2000 Jun;215 Suppl:965-72.

The appropriateness criteria are reviewed annually and updated by the panels as needed, depending on introduction of new and highly significant scientific evidence.

GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) from the American College of Radiology (ACR) Web site.

ACR Appropriateness Criteria® *Anytime*, *Anywhere*™ (PDA application). Available from the ACR Web site.

Print copies: Available from the American College of Radiology, 1891 Preston White Drive, Reston, VA 20191. Telephone: (703) 648-8900.

AVAILABILITY OF COMPANION DOCUMENTS

The following is available:

- ACR Appropriateness Criteria®. Background and development. Reston (VA): American College of Radiology; 2 p. Electronic copies: Available in Portable Document Format (PDF) from the American College of Radiology (ACR) Web site.

PATIENT RESOURCES

None available

NGC STATUS

This NGC summary was completed by ECRI on February 13, 2006.

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