Complete Summary

GUIDELINE TITLE

Diagnosis of breast disease.

BIBLIOGRAPHIC SOURCE(S)

Institute for Clinical Systems Improvement (ICSI). Diagnosis of breast disease. Bloomington (MN): Institute for Clinical Systems Improvement (ICSI); 2003 Nov. 48 p. [91 references]

COMPLETE SUMMARY CONTENT

SCOPE
METHODOLOGY - including Rating Scheme and Cost Analysis
RECOMMENDATIONS
EVIDENCE SUPPORTING THE RECOMMENDATIONS
BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS
QUALIFYING STATEMENTS
IMPLEMENTATION OF THE GUIDELINE
INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES
IDENTIFYING INFORMATION AND AVAILABILITY

SCOPE

DISEASE/CONDITION(S)

Breast disease, including breast cancer

GUIDELINE CATEGORY

Diagnosis
Evaluation

CLINICAL SPECIALTY

Family Practice
Internal Medicine
Oncology
Radiology
Surgery

INTENDED USERS

Advanced Practice Nurses
Allied Health Personnel
Health Care Providers
Health Plans
Hospitals
Managed Care Organizations
Nurses
Physician Assistants
Physicians

GUIDELINE OBJECTIVE(S)

- To reduce the length of time between first knowledge of a breast abnormality to diagnostic resolution. The ultimate goal is to decrease the time from identification of a breast abnormality to notification of the patient of biopsy results.
- To ensure that needle biopsies demonstrating ductal hyperplasia with atypia are followed by performance of an open biopsy

TARGET POPULATION

Everyone who has a breast abnormality

INTERVENTIONS AND PRACTICES CONSIDERED

1. Primary care evaluation of the breast, including history and physical exam, screening mammogram, ultrasound if indicated, aspiration of a dominant palpable mass if needed, and referral to surgery
2. Evaluation of breast for nipple discharge
3. Evaluation and management of breast pain, including history and physical exam; quantitative pain assessment; non-pharmacologic interventions, such as mechanical support and lifestyle changes; and/or pharmacologic interventions, such as evening primrose oil, analgesics, danazol, bromocriptine, and tamoxifen
4. Radiologic evaluation (mammogram, magnetic resonance imaging [MRI], ultrasound)
5. Image-directed core needle biopsy
6. Surgical evaluation

MAJOR OUTCOMES CONSIDERED

- Positive predictive value of x-ray mammography and other diagnostic techniques
- Risk for malignancy in patients with biopsy-proven ductal hyperplasia with atypia

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Not stated

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Not stated

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

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

Not stated

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

Clinical Validation-Pilot Testing
Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Institute Partners: System-Wide Review

The guideline annotation, discussion, and measurement specification documents undergo thorough review. Written comments are solicited from clinical, measurement, and management experts from within the member groups during an eight-week review period.

Each of the Institute's participating member groups determines its own process for distributing the guideline and obtaining feedback. Clinicians are asked to suggest modifications based on their understanding of the clinical literature coupled with their clinical expertise. Representatives from all departments involved in implementation and measurement review the guideline to determine its operational impact. Measurement specifications for selected measures are developed by the Institute for Clinical Systems Improvement (ICSI) in collaboration with participating member groups following implementation of the guideline. The specifications suggest approaches to operationalizing the measure.

Guideline Work Group

Following the completion of the review period, the guideline work group meets 1 to 2 times to review the input received. The original guideline is revised as necessary, and a written response is prepared to address each of the responses received from member groups. Two members of the Committee on Evidence-Based Practice carefully review the input, the work group responses, and the revised draft of the guideline. They report to the entire committee their assessment of four questions: (1) Is there consensus among all ICSI member groups and hospitals on the content of the guideline document? (2) Has the drafting work group answered all criticisms reasonably from the member groups? (3) Within the knowledge of the appointed reviewer, is the evidence cited in the document current and not out-of-date? (4) Is the document sufficiently similar to the prior edition that a more thorough review (critical review) is not needed by the member group? The committee then either approves the guideline for release as submitted or negotiates changes with the work group representative present at the meeting.

Pilot Test

Member groups may introduce the guideline at pilot sites, providing training to the clinical staff and incorporating it into the organization's scheduling, computer, and other practice systems. Evaluation and assessment occur throughout the pilot test phase, which usually lasts for three to six months. At the end of the pilot test phase, ICSI staff and the leader of the work group conduct an interview with the member groups participating in the pilot test phase to review their experience and gather comments, suggestions, and implementation tools.

The guideline work group meets to review the pilot sites' experiences and makes the necessary revisions to the guideline, and the Committee on Evidence-Based Practice reviews the revised guideline and approves it for release.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

The recommendations for the diagnosis of breast disease are presented in the form of seven algorithms: Diagnosis of Breast Disease Main Algorithm; Primary Care Evaluation of the Breast with 19 components; Evaluation of Breast for Spontaneous Nipple Discharge with 15 components; Breast Pain with 11 components; Radiologic Evaluation of the Breast (if indicated) with 24 components; Image-Directed Core Needle Biopsy (if indicated and available) with 13 components; and Surgical Evaluation of the Breast (if indicated) with 26 components, all accompanied by detailed annotations. Clinician highlights and selected annotations (numbered to correspond with the algorithm) follow.

Class of evidence (A-D, M, R, X) definitions are provided at the end of the "Major Recommendations" field.

Clinical Highlights

1. A bloody tap or a persistent mass following aspiration of a palpable dominant mass should be referred to a surgeon or radiologist regardless of a negative mammogram. (Algorithm I, Annotation #10)
2. It is imperative that communications between the radiologic and surgical consultants and the primary care provider are thorough and consistent. (Algorithm I, Annotation #12)
3. Patients with bloody or unilateral watery discharge should have a mammogram, with or without an ultrasound, and be referred to a surgeon. (Algorithm II, Annotations #2, 3, 4, 5--see the original guideline document for annotations #4 and 5)
4. The risk of cancer with a negative evaluation for breast pain is less than 1%. (Algorithm III, Annotation #10)
5. Any image-directed biopsy showing ductal hyperplasia with atypia requires a surgical consultation. (Algorithm V, Annotation #4)

Primary Care Evaluation of the Breast Algorithm Annotations

1. History and Physical Exam

   Guidelines for primary care evaluation are initiated with a history aimed at uncovering and characterizing any breast-related symptoms. Likewise, a risk assessment should also be undertaken for identified risk factors: personal history of any breast cancer, personal history of ductal hyperplasia with atypia on previous breast biopsies, or family history of breast cancer in first degree relatives. A physical examination should include inspection of the breast for any evidence of ulceration or contour changes. This includes examining the nipple for Paget's disease. Palpation should be performed both in the upright and supine position to determine the presence of a palpable mass.

   Evidence supporting this recommendation is of class: C

4. Is Screening Mammogram Due?

Following completion of a physical examination in which no palpable mass is identified, a routine screening mammogram should be obtained if one has not been done within the recommended interval.

Refer to the National Guideline Clearinghouse (NGC) summary of the Institute for Clinical Systems Improvement (ICSI) guideline Preventive Services for Adults for mammography screening intervals.

8. Complete All Radiologic Recommendations

Should any abnormality be uncovered, it will be the responsibility of the radiologist to complete any additional imaging studies required for the complete radiographic characterization of the lesion. The radiologist should make certain that all recommendations including additional views, follow-up films, ultrasounds, etc., have been completed prior to referral to surgery. However, it is important that the provider ordering the mammogram review the results of these studies to fully understand the impression of the radiologist, and to insure that all recommendations by the radiologist have been completed within the department of radiology. Should the recommendation be made by radiology that a surgical consultation is warranted, it will be the responsibility of the primary care provider to establish this referral.

9. Dominant Mass? (Consider Ultrasound Imaging)

A dominant mass is a palpable finding which is discrete and clearly different than the surrounding parenchyma. Should a palpable mass be identified, it should be characterized as to whether it represents a dominant (i.e., discrete) mass that requires immediate evaluation. Should physical examination demonstrate a palpable mass that is not clearly discrete and dominant, its size, location, and character should be documented in anticipation of follow-up examination.

10. Aspirate Mass or Refer to the Appropriate Consultant for Aspiration

Aspiration of a dominant palpable mass should be performed by the primary care provider or by the appropriate consultant for completion of cyst aspiration. A successful aspirate would yield a non-bloody fluid with complete resolution of the dominant mass. The breast skin is prepped with alcohol. Then, with the lesion immobilized by the non-operating hand, an 18 to 25 gauge needle mounted on a 10 cc syringe is directed to the central portion of the mass for a single attempt at aspiration. If the lesion is a simple cyst, the mass should completely resolve.

Cyst fluid should be examined cytologically if it is bloody or unusually tenacious. Typical watery fluid may be discarded.

If the aspiration attempt is unsuccessful, refer to the appropriate consultant, either radiology or surgery, for follow-up.

11. Residual Mass or Blood Aspirate?

Should the mass remain following the attempt at aspiration or should a bloody aspirate be obtained during the process, the presence of a malignancy cannot be ruled out. Patients with a residual mass or a bloody aspirate should be referred to radiology or surgery for further consultation, work-up, and possible biopsy.

Evidence supporting this recommendation is of class: R

12. Mammogram if None Done in Six Months and Age >35

Prior to the referral, a mammogram should be obtained for any patient over age 35 who has not had a mammogram within the preceding six months. In patients under 35, any other breast imaging studies should be left to the discretion of the surgeon or radiologist.

13. Refer to Surgery or Radiology

For recommendations regarding appropriate further work-up and possible biopsy, refer to the following algorithms below and in the original guideline document:

- Radiologic Evaluation of the Breast
- Image-Directed Core Needle Biopsy
- Surgical Evaluation of the Breast

The importance of communication between the radiologic and surgical consultants and the primary care provider cannot be overstated. Patients undergoing biopsy should have results reported to both the radiologist or surgeon performing the biopsy and to the primary care provider. More importantly, patients who do not require biopsy following radiologic or surgical consultation should be returned to the routine screening process. This process is under the supervision of the primary care provider. Therefore, it is absolutely necessary for the primary care provider to know when the patient re-enters the routine screening population. In the event that new symptoms arise or occur during the screening interval, the patient should be evaluated by the primary care provider using the primary care evaluation process of this guideline.

Refer to NGC's summary of the ICSI guideline Preventive Services for Adults for mammography screening intervals.

14. Is Screening Mammogram Due?

In patients with findings of non-bloody fluid return or no residual mass following aspiration, or if the dominance of a palpable mass is questionable, a screening mammogram should be done if one has not been done within the recommended interval.

Refer to NGC's summary of the ICSI guideline Preventive Services for Adults for mammography screening intervals.

17. Follow-up Clinical Breast Exam in 4 to 6 Weeks at Discretion of Clinician

    If no mammogram is required, or if a required mammogram demonstrates no abnormality, a repeat examination should be performed in 4 to 6 weeks at the discretion of the clinician. The optimum time for this exam is after one menstrual cycle.

18. Residual Mass?

    Persisting non-dominant palpable masses not resolving in one month and all recurring cystic masses should be referred to radiology for further evaluation. If subsequent ultrasound is unable to confirm the presence of a benign cystic lesion, or if the lesion is worrisome to the patient, surgical consultation is indicated.

    If no mass is apparent at the time of this examination, the patient should be informed of the appropriate date of her next routine screening evaluation.

    Refer to NGC's summary of the ICSI guideline Preventive Services for Adults for mammography screening intervals.

Evaluation of Breast for Spontaneous Nipple Discharge Algorithm Annotations

1. History and Physical Exam

   History

   Patients presenting with complaint of spontaneous nipple discharge should be evaluated with a breast-related history and physical.

   Guidelines for primary care evaluation are initiated with a history aimed at uncovering and characterizing any breast-related symptoms, including whether discharge has been spontaneous, persistent, unilateral vs. bilateral, single or multiple ducts, its relation to menses, pregnancy, exercise, trauma, medications, and/or thyroid disorders. Likewise a risk assessment should also be undertaken for identified risk factors: personal history of any breast cancer, personal history of atypia on previous breast biopsies, or family history of breast cancer in first-degree relatives.

   Physical

   A physical examination should include inspection of the breast for any evidence of ulceration or contour changes. This includes presence of breast nodule(s), nipple disease, evidence of infection, and evidence of discharge from single or multiple ducts. The site around nipple should be examined for discharge upon pressure. Hemoccult test for blood may also be administered. Palpation should be performed both in the upright and supine position to determine the presence of a palpable mass.

Evidence supporting this recommendation is of classes: D, R

2. Is Mammogram/Ultrasound Normal?

A mammogram should be obtained on patients over age 35, and ultrasound may be helpful to locate an intraductal nodule or dilated duct.

Evidence supporting this recommendation is of classes: B, R

3. Complete All Radiologic Recommendations

A patient with an abnormal mammogram should be further evaluated within the department of radiology to best characterize the lesion, and then be referred to surgery if appropriate. Make certain that all recommendations for additional views, ultrasound examinations, and follow-up studies have been obtained prior to referral to surgery. A ductogram may be completed as part of the radiologic work-up.

11. Endocrine Evaluation

Prolactin and thyroid stimulating hormone (TSH) levels are obtained to determine an endocrinologic basis for the nipple discharge. A prolactinoma typically causes a milky or clear discharge bilaterally. (See the original guideline document for a discussion of discharge appearance.)

Evidence supporting this recommendation is of class: R

13. Bloody Discharge

Bloody or, less commonly, watery discharge raises the possibility of cancer, although the most common causes of hemoccult-positive discharges are benign. The most common causes of bloody nipple discharge are intraductal papilloma (45%), duct ectasia (36%), carcinoma (8 to 15%), and infection and other causes (5 to 10%).

Evidence supporting this recommendation is of class: R

14. Refer to Surgeon (+/- Ductography)

Most pathologic nipple discharges should be treated with duct excision. The use of ductography is controversial, and depends on the decision of the surgeon and radiologist.

Evidence supporting this recommendation is of class: D, R

15. Inform of Next Screening Date/Recommended Treatment

If the mammogram and the endocrinologic screening studies are normal, the patient should schedule a follow-up visit at the discretion of the responsible clinician.

If the evaluation at the time of that follow-up visit fails to reveal any palpable or visible abnormalities, the patient should be returned to the routine screening process with interval studies described in the NGC summary of the ICSI guideline Preventive Services for Adults.

Breast Pain Algorithm Annotations

2. History and Physical Exam

The symptom of breast pain prompts many patients to make an appointment for a medical examination out of concern for the possible presence of breast cancer. A patient history is directed toward identifying and characterizing breast-related symptoms. The information gathered should include location and severity of pain, relationship to physical activities or the menstrual cycle, and interference with routine activities. Hormonal influences, such as pregnancy, use of contraceptives, and hormone therapy, should also be reviewed. Obtaining a history may also provide information identifying non-breast sources of pain. The patient should also be asked about any new medications, or those which can be associated with breast pain should be noted. Risk assessment for breast cancer should include the appropriate reproductive, medical, and family history.

Breast pain is commonly categorized into three classifications:

- Cyclic mastalgia occurs in premenopausal women and is clearly related to the menstrual cycle. The pain is typically bilateral and diffuse, often located in the upper outer quadrants of the breasts with frequent radiation to the axilla and the ipsilateral arm. Occasionally, breast pain may be unilateral or more intense in one breast.
- Non-cyclic mastalgia may involve continuous or intermittent pain that does not concur with the menstrual cycle. The pain is more often unilateral and localized with the pain in the lower inner portions of the breast. Non-cyclic breast pain generally occurs in older women, with symptoms often occurring in postmenopausal women.
- Non-mammary pain may present with the symptom of breast pain. Following the history and physical exam, differentiating breast pain and pain radiating from the chest wall or another site is usually straightforward. Occasionally the origin of pain is not evident, or there are multiple origins of pain, making evaluation more challenging.

A clinical examination of the breast should be performed with careful inspection and palpation of each breast, nipple-areolar complex, and regional lymph nodes. Localized, generalized, or bilateral breast tenderness should be noted. In addition to palpating the breasts while the patient is supine, examining the breasts while the patient is sitting or lying on her side may allow breast and chest wall tenderness to be distinguished.

Laboratory studies are generally not useful. A pregnancy test, however, should be considered in women of reproductive age if the history or examination suggests pregnancy. Other hormone levels (e.g., estrogen, progesterone, and prolactin) are typically normal in patients with breast pain.

Breast pain may occur as a result of pregnancy, mastitis, trauma, thrombophlebitis, macrocysts, benign tumors, or cancer; however, only a minority of breast pain is explained by these conditions. Most breast pain is of unknown cause. A variety of conditions can result in pain perceived in the breast. A variety of conditions can be revealed as a result of a directed history and physical. As appropriate, an exam directed at the cervical and thoracic spine, chest wall, shoulders and upper extremities, sternum, heart, lungs, and abdomen may be helpful in assessing other potential causes of the pain, such as:

- mastalgia
- rib fracture
- fibromyalgia
- costochondritis (Tietze syndrome)
- cervical radiculopathy
- cholelithiasis/cholecystitis
- sickle cell anemia
- coronary artery disease
- pleurisy
- gastroesophageal reflux
- peptic ulcer disease
- pericarditis
- shoulder pain
- pulmonary embolus
- psychological pain

Evidence supporting this recommendation is of classes: D, R

3. Breast Mass or Nipple Discharge Found?

Abnormalities detected during a clinical breast examination – such as masses or nodules, nipple discharge or inflammatory changes – require thorough evaluation and prompt treatment.

5. Mammogram and/or Ultrasound at the Discretion of the Clinician

Imaging studies are frequently utilized in the evaluation of the breast. A mammogram should be considered for women 35 years or older or women with a family history of early breast cancer. Ultrasound may be useful for focal breast pain in both younger and older women. Subclinical breast cancer has been reported to occur in 1 to 7% of women who have pain as the only symptom. It is unclear whether the pain is related to the cancer or whether this symptom initiates a breast evaluation in which an asymptomatic cancer is identified. Breast pain secondary to malignancy is typically unilateral and persistent. In these cases, imaging with directed ultrasound may be a more valuable assessment tool.

Evidence supporting this recommendation is of class: B

8. Quantitative Pain Assessment

Breast pain may be difficult to assess as the symptoms may appear and subside without provocation, with certain activities, or with the menstrual cycle. An attempt must be made to measure the amount and severity of the patient's breast pain over time, which is difficult as there is no standard unit of pain. Prospective assessment of breast pain may be a valuable tool when considering an intervention. Possible tools to document an individual's pain include pain rating instruments, a daily breast pain chart or a diary to document the occurrence and severity of pain, use of medications, and interferences with lifestyle. These tools are particularly important in making an initial diagnosis of cyclic mastalgia and response to therapy.

Evidence supporting this recommendation is of classes: D, R

10. Initiate Non-Pharmacologic and/or Pharmacologic Intervention(s)

The first line of treatment for breast pain is to reassure the patient that she does not have breast cancer. The risk of malignancy following a negative examination has been estimated to be only 0.5%, so reassurance following a negative evaluation is appropriate. Approximately 15% of women choose a treatment intervention to reduce the symptom of pain. During encounters for breast pain, the patient's description of the pain, quantitative assessment of the pain, and decisions regarding reassurance, follow-up, or therapeutic intervention should be documented.

Few women will require treatment with more than reassurance and well-tolerated medications such as evening primrose oil. For those with severe, refractory breast pain, the significant side effects of some of these medications must be balanced against the potential benefit in ameliorating breast discomfort and pain.

Non-pharmacologic interventions for breast pain are appropriate for women with breast pain. Although there has been little scientific investigation into the effectiveness of these non-pharmacologic approaches, they are frequently found to improve breast pain symptoms in clinical practice and are of low risk and expense to the patient.

Potential non-pharmacologic therapies include:

<u>Mechanical Support</u>

A professionally fitted support bra, irrespective of age, cup size, or underlying breast disease, has been shown to relieve breast pain even in patients who have not responded to hormonal treatments. Support bras are recommended for exercise. A soft supportive bra during sleep may also improve symptoms.

<u>Lifestyle Changes</u>

Lifestyle changes such as smoking cessation, stress reduction and improving coping skills may be possible low-risk interventions. Hot packs, cold packs, and massage may also relieve symptoms.

The effectiveness of dietary measures is unclear. Studies have demonstrated improvement in breast pain symptoms following dietary reduction of saturated fat. Caffeine reduction or elimination has been found to be helpful by some patients, particularly those who consume large quantities of caffeine. Clinical studies have not shown this to be a consistent outcome.

Pharmacologic Interventions

The decision whether to treat breast pain along with the selection of a particular agent to utilize requires balancing the need for symptom relief against the likelihood of medication side effects. If considering a pharmacologic therapy, consult with a specialist should be considered.

Pharmacologic interventions may include the adjustment of medications that may be contributing to breast pain, such as oral contraceptives, hormone therapy, spironolactone, and others. Eliminating or decreasing the dose of estrogen in an oral contraceptive or hormone regimen is often effective.

Possible pharmacologic therapies include:

Evening Primrose Oil

Evening primrose oil is often used as an initial treatment for breast pain because of its low incidence of side effects and positive response rates for cyclic and non-cyclic pain. It is rich in gamma-linolenic acid and is believed to alter the saturated/polyunsaturated fat balance and decrease sensitivity to hormonal influences. The average dose is 2 x 500 mg soft-gel capsules 3 times a day for a minimum of 3 to 4 months.

Analgesics

Analgesics, such as ibuprofen, 400 mg every 4 to 6 hours, may reduce breast pain.

Danazol

Danazol is the only medication that is labeled by the United States Food and Drug Administration for treatment of breast pain. Danazol is an antigonadotropin with some androgenic activity.

Danazol relieves breast pain in 75 to 92% of women. A typical initial dose of 200 mg per day is recommended with gradual tapering to an alternate day or luteal phase dosing; doses from 100 to 400 mg per day have also been described. Reported side effects are common and include hair loss, acne, decrease in voice pitch, weight gain, irregular menses, and depression. There may also be a possible increase in venous thromboembolic events. Barrier contraception must be utilized. Danazol administered in the luteal phase only has been found to relieve premenstrual breast pain in women with premenstrual syndrome with minimal side effect. It was not effective for other premenstrual syndrome symptoms.

Bromocriptine

One of the few hormonal abnormalities detected in breast pain has been an increase in thyrotropin-induced prolactin secretion. Bromocriptine has been shown to decrease serum prolactin levels in normal and hyperprolactinemic women and may decrease dynamic secretion of prolactin in cyclic mastalgia patients. In several European studies, bromocriptine has shown significant decreases in breast pain (approximately 54%), as well as heaviness and tenderness in the breasts. Prolactin levels decline during therapy while estrogen, progesterone, testosterone, and gonadotropin releasing hormones do not significantly change. Side effects are common and dose related, including nausea, vomiting, headache, dizziness, and fatigue. An incremental dosing regimen is used beginning with 1.25 mg at bedtime, gradually increasing until a dose of 2.5 mg twice daily is reached. The beneficial effects lasted 3 to 6 months after bromocriptine was discontinued.

Tamoxifen

Tamoxifen is a selective estrogen receptor modulator (SERM) utilized for the prevention and treatment of breast cancer. Response rates have demonstrated tamoxifen to be effective in reducing pain in 75 to 90% women with cyclic and 56% of women with non-cyclic mastalgia in controlled trials. Tamoxifen has significant side effects, with the principle concerns being from thromboembolic disease and endometrial cancer. Additional side effects include hot flashes, nausea, menstrual irregularity, and vaginal dryness or discharge. The 10-mg daily dose of tamoxifen appeared to be as effective as the 20-mg daily dose, with fewer side effects. Tamoxifen, like other hormonal interventions, should be reserved for women with severe mastalgia. Contraception must be utilized.

Other medications that have been found to be effective for the treatment of breast pain include goserelin, gestrinone, buserelin, leuprolide, quinagolide, cabergoline, thyroxine, and topical nonsteroidal anti-inflammatory agents. Medroxyprogesterone has shown variable results in the treatment of breast pain. In general, antibiotics, diuretics, and most vitamins have not been effective in the treatment of breast pain.

Evidence supporting this recommendation is of classes: A, D, R

Radiologic Evaluation of the Breast Algorithm Annotations

1. Screening or Diagnostic Mammogram

Patients referred to the department of radiology most commonly enter for screening mammography. However, patients will occasionally be referred for diagnostic mammography based on the presence of symptoms or findings on examination. In the event of an abnormal finding on mammography, it is recommended that a complete evaluation be undertaken within the department of radiology under the direction of a radiologist in order that a full characterization of the lesion will be provided back to the primary care physician ordering the original study. It will be the responsibility of the radiologist to complete the radiologic assessment of the patient within the

department of radiology so that the best possible characterization of the abnormality may be provided to the primary care physician in an expeditious fashion. Any recommendations for referral to the department of surgery for possible biopsy should be made directly to the primary care physician. However, the ultimate responsibility to make the referral will rest with the primary care provider.

Refer to the NGC summary of the ICSI guideline Preventive Services for Adults for mammography screening interval.

Evidence supporting this recommendation is of classes: C, D, M, R

2. Presence of: Solid Mass? Abnormal Microcalcifications? Architectural Distortion? Other Abnormalities?

   For patients referred with an abnormal mammogram, the surgeon or radiologist should determine whether the above suspicious changes are present. If not, the patient should report to ordering provider for follow up and clinical exam.

4. High Risk?

   Patients considered high risk may have one or more of the following:

   1. Previous breast biopsy demonstrating ductal hyperplasia with atypia
   2. Family history of breast cancer in patient's mother, sister, or daughter
   3. Past personal history of breast cancer
   4. A breast cancer gene
   5. Previous radiation to the chest (i.e., Hodgkin's Disease)

5. Consider Magnetic Resonance Imaging (MRI)

   Magnetic resonance (MR) imaging has excellent sensitivity and specificity with new breast coils and new 3-D sequencing. The use of dynamic and architectural information extracted from gadolinium-enhanced MR images has been shown to be useful in characterizing breast masses as benign or malignant. Presently, MR breast imaging is being used for:

   1. Staging existing cancer
   2. Detecting occult breast cancer (e.g., positive axillary lymph node with negative mammogram)
   3. Distinguishing postoperative scar vs. tumor recurrence
   4. Screening in high-risk patients with a breast cancer gene mutation
   5. Monitoring response to neo-adjuvant chemotherapy
   6. Evaluating integrity of breast implants including rupture

   Evidence supporting this recommendation is of classes: C

6. Additional Mammographic Studies and/or Ultrasound if Needed

Upon obtaining an abnormal finding on a mammogram, the radiologist will determine whether further mammographic images or ultrasound are required for completion of the evaluation process. This may include a repeat image of the breast at 6 months to document stability of low risk, probably benign lesions. Alternatively, spot compression and/or magnification may be necessary to obtain further characterization of indeterminate lesions of the breast. These additional studies should be done with the radiologist present, to reduce the risk of patient recall for further studies necessary to evaluate the same lesion.

7. Change Present but Appears to be Benign?

   If further mammographic studies or sonography demonstrate findings which are felt to be benign, repeat mammography should be performed in 6 to 12 months to rule out progressive changes warranting further diagnostic work-up.

10. Sort Abnormalities

    Upon completion of these views, each and every abnormality uncovered for each independent lesion of the breast studied should be sorted according to the nature of the abnormality. The radiologist should classify the lesion as representing either suspicious microcalcifications, architectural distortion, or a soft tissue mass.

11. Mass

    In the event that a soft tissue mass is identified in the mammogram, further studies are required to determine its relative risk for malignancy.

15. Image-Directed Core Biopsy and/or Surgical Consultation for Open Biopsy

    For lesions that have demonstrated findings suspicious for cancer (microcalcification, architectural distortion, masses), biopsy will be recommended. Biopsy should also be considered for any suspicious lesions identified as having associated microcalcifications, architectural distortion, or interval growth in comparison to the previous mammogram.

    Refer to the algorithms Image Directed Core Needle Biopsy and Surgical Evaluation of the Breast.

16. Ultrasound (if not Already Performed)

    Should the mass not be immediately suspicious for cancer, an ultrasound should be performed to determine whether or not the lesion is solid, if not already performed. (See Annotation #6 titled "Additional Mammographic Studies and/or Ultrasound if Needed," above.)

18. Fits Benign Criteria?

A solid mass should be further characterized for its risk of malignancy according to 3 criteria. Lesions may be observed and followed with studies repeated in 6 months if they fit all 3 of the following criteria:

- size less than 15 mm
- three or fewer lobulations
- more than 50% of the lesion margin appears well-circumscribed in any view

Any lesion not fitting all 3 of the above criteria for benignity should be considered indeterminate and the patient should be referred for surgical evaluation regarding open biopsy or large-core image-guided core biopsy.

Evidence supporting this recommendation is of classes: C, D

21. Indications for Aspiration?

If the ultrasound of the soft tissue mass demonstrates that this is a cystic lesion, the cyst should be further categorized according to the following criteria:

- internal echoes
- palpability within the region of the ultrasound-proven cyst
- complex septated appearance

All cysts do not have to be aspirated if they meet benign criteria with an ultrasound exam.

If one or more of the preceding criteria is present, ultrasound-directed aspiration of the cyst is indicated. Likewise, aspiration should be offered if the patient so requests.

Evidence supporting this recommendation is of classes: C, R

22. Aspirate and Single View Mammogram

Following cyst aspiration, a single view mammogram should be performed to demonstrate complete resolution of the mammographic lesion. If sufficiently complex, a pneumocystogram with post mammogram view may be completed by radiology.

23. Residual Mass?

Should any residual mass be present or if the pneumocystogram is abnormal, a biopsy should be recommended, and this could be excisional by a surgeon or large-core needle biopsy by the radiologist.

24. Return to Screening Mammography/Report to Ordering Provider

If the lesion represents a simple cyst not fitting any of the criteria mentioned in Annotation #21 titled "Indications for Aspiration?," the patient should be

referred back to the screening process and completion of this evaluation should be reported to the ordering provider. Refer to the ICSI guideline Preventive Services for Adults for mammography screening intervals.

Image-Directed Core Needle Biopsy Algorithm Annotations

1. Patient Referred For Stereotactic or Ultrasound-Guided Large Core Biopsy

   Patients referred for biopsy based on the presence of a mammographic and/or sonographic finding that is suspicious for or highly suggestive of malignancy will undergo either conventional open excisional biopsy (see the algorithm Surgical Evaluation) or large core needle biopsy.

   Large core imaging-guided breast biopsy is now the technique of choice in many institutions in the United States for biopsy of nonpalpable breast masses and abnormal calcifications. Either stereotactic or ultrasound-guided breast biopsy may be used for reliable diagnosis of breast cancer. Stereotactic guidance is preferable for biopsy of calcifications. Most solid breast masses are amenable to large core needle biopsy with either stereotactic or ultrasound guidance. The location of the lesion, its visibility at ultrasound, equipment availability, and the radiologist's expertise will determine the approach selected. Wire localization by grid technique or with stereotactic or ultrasound guidance may be used for nonpalpable or palpable breast lesions.

   In some institutions, biopsy is performed for tissue diagnosis in cases of obvious cancer, as it saves the patient an additional surgical procedure, as well as expediting the diagnostic process.

   See Image-Directed Core Needle Biopsy Algorithm Discussion #5, "Open Biopsy" in the original guideline document for current changes in breast disease diagnosis.

3. Definitive Therapy

   If cancer is diagnosed, definitive therapy may be performed on the basis of stereotactic core biopsy alone.

4. Ductal Hyperplasia with Atypia?

   If frank cancer is not identified, the pathologic specimen should be evaluated for the presence of atypia. Patients with biopsy-proven atypical hyperplasia have an associated 4 to 5 times relative risk for malignancy over their lifetimes. Furthermore, atypia on core biopsy suggests that the mammographic lesion may be malignant and is of sufficient risk to require excision to rule out core sampling error.

5. Open Biopsy

Ductal hyperplasia with atypia, as well as any questionable pathologic findings, are indications for repeat biopsy by excision to rule out the presence of occult malignancy in the region of the mammographic abnormality.

Evidence supporting this recommendation is of class: C

6. Are Calcifications Present on Specimen Radiograph?

To assure that an adequate core biopsy sample has been obtained for patients with suspicious microcalcifications, evidence of microcalcifications must be present on the specimen micrographs following stereotactic biopsy (if calcifications were present on mammogram).

Evidence supporting this recommendation is of classes: C, R

7. Re-Biopsy by Core or Open Biopsy

If calcium cannot be demonstrated mammographically in the specimen, repeat biopsy, open or stereotactic, is necessary to assure that the abnormal mammographic lesion has been sampled. Biopsy must be repeated until the calcifications can be confirmed in the specimen.

8. Is Mass Fibroadenoma?

If the mass is a fibroadenoma, then only yearly screening mammogram is necessary for follow-up. Refer to the NGC summary of the ICSI guideline Preventive Services for Adults for mammography screening intervals.

Evidence supporting this recommendation is of classes: C, R

10. Mammogram in 6-12 Months, Then Annually for 3 Years

For all patients who have benign results from stereotactic biopsy, a repeat mammogram of the involved breast in six months, then annually for three years, is necessary to document stability of the lesion. The exception is patients with findings of benign fibroadenoma, who may be followed at routine screening intervals. The radiologist should correlate the pathology results with the mammographic abnormalities for all patients. If they do not correlate, re-biopsy with image-directed core needle or open biopsy is necessary.

Evidence supporting this recommendation is of classes: C, R

12. Open Biopsy or Repeat Image Directed Core Needle Biopsy

Any lesion which has grown or has become more dense on mammography, despite a previous benign core biopsy, must be re-biopsied or excised to rule out cancer.

Surgical Evaluation of the Breast Algorithm Annotations

1. Patient Referral to Surgeon

   Patients referred to the department of surgery for the evaluation of breast disease will have undergone previous mammography that has demonstrated an abnormality warranting biopsy or may be referred on the basis of a physical finding uncovered in the primary care provider's office. It is the role of the surgeon to evaluate each and every abnormality uncovered in each patient. It is important for the surgeons to recognize that mammographically depicted lesions and palpable abnormalities may co-exist as separate entities within the breast. It is therefore important that each lesion be evaluated for its own merit, using this algorithm.

   The importance of communication between the surgical consultant and the primary care provider cannot be overstated. Patients undergoing biopsy should have results reported both to the surgeon and the primary care provider. More importantly, patients who do not require biopsy following surgical consultation should be returned to the routine screening process. This process is under the supervision of the primary care provider. Therefore, it is absolutely necessary for the primary care provider to know when the patient re-enters the routine screening population. In the event that new symptoms arise or occur during the screening interval, the patient should be evaluated by the primary care physician using the primary care evaluation process stated in the algorithm Primary Care Evaluation of the Breast.

2. Palpable Mass

   Patients with palpable masses referred to surgery should first be evaluated to determine the presence of a dominant and discrete mass. Palpable masses should not be biopsied with image-directed techniques.

3. Consider Imaging Prior to Aspiration

   Consider an ultrasound and determine if the mass is solid or cystic.

4. Aspirate Mass?

   If a palpable and discrete mass is present, an attempt should be made by the surgeon to aspirate the mass to rule out the presence of a simple cyst. An 18 to 25 gauge needle mounted on a syringe is inserted into an alcohol-prepped dominant breast mass for attempted aspiration.

   Evidence supporting this recommendation is of class: R

5. Residual Mass or Bloody Aspirate?

   A simple cyst is one that resolves with aspiration of non-bloody fluid. If fluid is clear and non-spontaneous (i.e., as in compression mammogram) a work-up is not always necessary as this is benign. Surgical excision should be performed for those cysts with bright red bloody aspirates and those which do not completely resolve with aspiration. A cyst that recurs may be re-aspirated, but the number of times this procedure can be repeated without

surgical excision will depend upon the surgeon and patient's level of confidence that the lesion is benign. See also the algorithm Evaluation of the Breast for Spontaneous Nipple Discharge

Evidence supporting this recommendation is of classes: C, D

6. Obtain Appropriate Imaging Studies

A mammogram should be obtained for any patient over age 35 who has not had a mammogram within the preceding six months. In patients under 35, breast imaging studies should be left to the discretion of the surgeon or radiologist.

10. Breast Pain

Patients with breast pain referred to the surgical department should be evaluated for any focal findings identified on physical examination or on mammography. Any abnormalities uncovered warrant biopsy before consideration of symptomatic treatment of the process.

Please see the algorithm Breast Pain.

12. Nipple Discharge

Patients who present with nipple discharge or morphologic abnormality should be evaluated to determine the presence of bloody or unilateral discharge or palpable abnormality. Paget's disease of the nipple must be excluded. Open biopsy is recommended if any of these symptoms are present.

15. Suspicious Solid Mass? Abnormal Microcalcifications? Progressive Changes? Architectural Distortion?

For patients referred with an abnormal mammogram, the surgeon should determine whether the above suspicious changes are present. If not, the patient should undergo a repeat mammogram in six months, at a minimum, to document stability of the lesion.

17. Image-Directed Biopsy?

Patients referred for biopsy based on the presence of a mammographic finding highly suspicious for cancer will undergo either conventional open excisional biopsy or image-directed needle core biopsy (see the algorithm Image-Directed Core Needle Biopsy). Indications for biopsy are: establishing a definitive diagnosis, finding multicentric lesions or associated intraductal pathology which may influence the choice to perform either mastectomy or breast conserving surgery for definitive treatment of the malignancy.

Image-directed core biopsy is the method of choice if sentinel lymph node study will be completed.

See the following algorithms in this guideline for other indications for open excisional breast biopsy:

- Radiologic Evaluation of the Breast
- Image-Directed Core Needle Biopsy
- Evaluation of the Breast for Spontaneous Nipple Discharge

18. Ductal Hyperplasia with Atypia

If frank cancer is not identified, the pathologic specimen should be evaluated for the presence of ductal hyperplasia with atypia. Patients with biopsy-proven ductal hyperplasia with atypia have an associated 4 to 5 times relative risk for malignancy over their lifetimes. Furthermore, atypia on core biopsy suggests that the mammographic lesion may be malignant and is of sufficient risk to require excision to rule out core sampling error.

19. Open Biopsy

Ductal hyperplasia with atypia, as well as any questionable pathologic findings, are indications for repeat biopsy by excision to rule out the presence of occult malignancy in the region of the mammographic abnormality.

21. Definitive Therapy

If cancer is diagnosed, definitive therapy may be performed on the basis of stereotactic core biopsy alone.

23. Return in 6 Months for Breast Examination

If no focal findings are uncovered, a repeat examination within six months is warranted to rule out the presence of occult neoplastic process.

24. Progression?

If the lesion is progressing in size and density or is otherwise worrisome, open biopsy is recommended.

Definitions:

Classes of Research Reports:

A. Primary Reports of New Data Collection:

Class A

- Randomized, controlled trial

Class B

- Cohort study

Class C

- Non-randomized trial with concurrent or historical controls
- Case-control study
- Study of sensitivity and specificity of a diagnostic test
- Population-based descriptive study

Class D

- Cross-sectional study
- Case series
- Case report

B. Reports that Synthesize or Reflect upon Collections of Primary Reports:

Class M

- Meta-analysis
- Systematic review
- Decision analysis
- Cost-effectiveness analysis

Class R

- Consensus statement
- Consensus report
- Narrative review

Class X

- Medical opinion

CLINICAL ALGORITHM(S)

Seven detailed and annotated clinical algorithms are provided for diagnosis of breast disease:

- Diagnosis of Breast Disease Main Algorithm
- Primary Care Evaluation of the Breast
- Evaluation of the Breast for Spontaneous Nipple Discharge
- Breast Pain
- Radiologic Evaluation of the Breast
- Image-Directed Core Needle Biopsy
- Surgical Evaluation of the Breast

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The guideline contains an annotated bibliography and discussion of the evidence supporting each recommendation. The type of supporting evidence is classified for selected recommendations (see "Major Recommendations").

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

- Appropriate and timely identification and diagnosis of breast abnormalities
- Earlier detection of breast disease
- Reduced morbidity and mortality associated with breast cancer

Subgroup(s) Most Likely to Benefit

Patients with a high risk profile for breast cancer/disease are most likely to benefit from radiologic evaluation:

- Previous breast biopsy demonstrating ductal hyperplasia with atypia
- Family history of breast cancer in the patient's mother, sister, or daughter
- Past personal history of breast cancer
- A breast cancer gene
- Previous radiation to the chest (i.e., Hodgkin's Disease)

POTENTIAL HARMS

Side Effects of Medications

- Danazol may cause hair loss, acne, decrease in voice pitch, weight gain, irregular menses, and depression. There may also be a possible increase in venous thromboembolic events.
- Side effects of bromocriptine are dose related and include nausea, vomiting, headache, dizziness, and fatigue.
- Tamoxifen has significant side effects with the principle concerns being from thromboembolic disease and endometrial cancer. Additional side effects include hot flashes, nausea, menstrual irregularity, and vaginal dryness or discharge.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

- These clinical guidelines are designed to assist clinicians by providing an analytical framework for the evaluation and treatment of patients, and are not intended either to replace a clinician's judgment or to establish a protocol for all patients with a particular condition. A guideline will rarely establish the only approach to a problem.
- This clinical guideline should not be construed as medical advice or medical opinion related to any specific facts or circumstances. Patients are urged to consult a health care professional regarding their own situation and any specific medical questions they may have.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

Once a guideline is approved for general implementation, a medical group can choose to concentrate on the implementation of that guideline. When four or more groups choose the same guideline to implement and they wish to collaborate with others, they may form an action group.

In the action group, each medical group sets specific goals they plan to achieve in improving patient care based on the particular guideline(s). Each medical group shares its experiences and supporting measurement results within the action group. This sharing facilitates a collaborative learning environment. Action group learnings are also documented and shared with interested medical groups within the collaborative.

Currently, action groups may focus on one guideline or a set of guidelines such as hypertension, lipid treatment, and tobacco cessation.

Detailed measurement strategies are presented in the original guideline document to help close the gap between clinical practice and the guideline recommendations. Summaries of the measures are provided in the National Quality Measures Clearinghouse (NQMC).

RELATED NQMC MEASURES

- Diagnosis of breast disease: percent of patients with less than 14 days between breast abnormality noted by RN or MD and completion of a biopsy.
- Diagnosis of breast disease: percentage of class 4 or class 5 abnormal mammograms that are followed by a biopsy within 14 days.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better

IOM DOMAIN

Effectiveness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Institute for Clinical Systems Improvement (ICSI). Diagnosis of breast disease. Bloomington (MN): Institute for Clinical Systems Improvement (ICSI); 2003 Nov. 48 p. [91 references]

ADAPTATION

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

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1994 Jan (revised 2003 Nov)

GUIDELINE DEVELOPER(S)

Institute for Clinical Systems Improvement - Private Nonprofit Organization

GUIDELINE DEVELOPER COMMENT

Organizations participating in the Institute for Clinical Systems Improvement (ICSI): Affiliated Community Medical Centers, Allina Medical Clinic, Altru Health System, Aspen Medical Group, Avera Health, CentraCare, Columbia Park Medical Group, Community-University Health Care Center, Dakota Clinic, ENT Specialty Care, Fairview Health Services, Family HealthServices Minnesota, Family Practice Medical Center, Gateway Family Health Clinic, Gillette Children's Specialty Healthcare, Grand Itasca Clinic and Hospital, HealthEast Care System, HealthPartners Central Minnesota Clinics, HealthPartners Medical Group and Clinics, Hutchinson Area Health Care, Hutchinson Medical Center, Lakeview Clinic, Mayo Clinic, Mercy Hospital and Health Care Center, MeritCare, Mille Lacs Health System, Minnesota Gastroenterology, Montevideo Clinic, North Clinic, North Memorial Care System, North Suburban Family Physicians, Northwest Family Physicians, Olmsted Medical Center, Park Nicollet Health Services, Pilot City Health Center, Quello Clinic, Ridgeview Medical Center, River Falls Medical Clinic, Saint Mary's/Duluth Clinic Health System, St. Paul Heart Clinic, Sioux Valley Hospitals and Health System, Southside Community Health Services, Stillwater Medical Group, SuperiorHealth Medical Group, University of Minnesota Physicians, Winona Clinic, Ltd., Winona Health

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GUIDELINE COMMITTEE

Committee on Evidence-Based Practice

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

In the interest of full disclosure, ICSI has adopted a policy of revealing relationships work group members have with companies that sell products or services that are relevant to this guideline topic. The reader should not assume that these financial interests will have an adverse impact on the content of the guideline. Readers of the guideline may assume that only work group members listed below have potential conflict of interest to disclose.

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This is the current release of the guideline.

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GUIDELINE AVAILABILITY

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Print copies: Available from ICSI, 8009 34th Avenue South, Suite 1200, Bloomington, MN 55425; telephone, (952) 814-7060; fax, (952) 858-9675; Web site: www.icsi.org; e-mail: icsi.info@icsi.org.

AVAILABILITY OF COMPANION DOCUMENTS

The following is available:

- Diagnosis of breast disease. In: ICSI pocket guidelines. April 2003 edition. Bloomington (MN): Institute for Clinical Systems Improvement, 2003 Mar. p. 312-320.

Print copies: Available from ICSI, 8009 34th Avenue South, Suite 1200, Bloomington, MN 55425; telephone, (952) 814-7060; fax, (952) 858-9675; Web site: www.icsi.org; e-mail: icsi.info@icsi.org.

PATIENT RESOURCES

None available

NGC STATUS

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