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FOLLOW UP OF ABNORMAL CLINICAL AND IMAGING FINDINGS OF THE BREAST: FIVE SELF-STUDY MODULES FOR PRIMARY CARE CLINICIANS

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Breast Cancer Module III: Workup of a Palpable Mass

Module III Objectives

Upon completion of this activity, participants will be able to:

1. Assess for abnormal and suspicious clinical findings during a clinical breast examination
2. Review the algorithms for common suspicious clinical findings and determine the most appropriate plan of action for follow-up
3. Document the most pertinent characteristics of suspicious clinical findings

Workup of a Palpable Mass

Assessing and documenting clinical findings that are suspicious for cancer are essential for timely and appropriate follow-up. The primary care clinician must also correlate the clinical findings with imaging findings to determine the appropriate plan of action to prevent a delayed diagnosis of breast cancer. In this module, the Core Group discusses how to assess abnormal and suspicious clinical findings during a clinical breast examination (CBE) and describes the most pertinent characteristics of suspicious clinical findings as well as the most appropriate plan of action for follow-up.

How do I distinguish normal breast nodularity from a suspicious mass?

First Question

Is the breast nodularity symmetrical in distribution and uniform in texture bilaterally?

The key is to assess the characteristics of the nodularity, which is part of understanding whether an abnormality exists. If the nodularity is not symmetrical, or there is an area of irregularity, then further evaluation is necessary.

Second Question

Is there a discrete thickening within the "normal" background of breast texture and nodularity for this patient's breast tissue?

Evaluation of a patient with a breast mass varies according to age, clinical history, and clinical findings. Detection of a breast mass usually creates significant anxiety for a woman and her family and requires sensitive provider/patient communication.

Important questions for determining whether a suspicious breast mass should be categorized as "abnormal" include the following:

- Is it a symmetrical finding in both breasts?
- Has the mass or asymmetrical thickening (i.e., elongated ridge or cord of tissue) persisted over more than 1 menstrual cycle?
- What is its size?
- What is the consistency or texture?
- What is the shape?
- Is it mobile or fixed?
- Is it tender or nontender?
- Has there been any recent (i.e., within the past 3 months) breast imaging evaluation?

Normal glandular tissue is generally mirrored in the contralateral breast. Asymmetrical vague nodularity or thickening should be further evaluated. Clinical signs that are suggestive of benignity, but not diagnostic, include a mass that is soft or rubbery and mobile.

There is controversy about whether immediate workup is warranted in every case of a mass or whether the clinician can wait and reevaluate the woman in 30 days at a more optimal time of the menstrual cycle. The latter may be an option in cases where the clinician (or the radiologist) believes that the lesion is likely to be benign based on an individual's history and that the woman is likely to return for follow-up. To ensure that patients are not "lost to follow-up," a callback system must be in place.

Most Common Causes of a Discrete Palpable Mass

Cysts

- Commonly and frequently occur in the fourth decade (perimenopause);
- May fluctuate with the menstrual cycle;
- Usually round or oval, well circumscribed, smooth, firm, and mobile; Often have focal tenderness immediately over the site;
- Can be hard if fluid is under tension;
- Must be evaluated by ultrasound or fine needle aspiration to distinguish solid from cystic; and
- Less common in postmenopausal women not on HT.

Fibroadenomas

- Commonly present in young women in the first half of the reproductive period—median age at diagnosis is 30 years (most common mass found in young women and teens);
- Prior to advances in imaging, fibroadenomas were found in half of all palpable masses biopsied; many of which are now relegated to follow-up with imaging diagnosis (BI-RADS 2);
- Exogenous estrogen or progestin, lactation, and pregnancy can stimulate growth;
- Commonly located in upper outer quadrants, are well circumscribed, firm, rubbery, exceedingly mobile, and nontender;
- Usually have characteristic ultrasonographic appearance.

Fibrocystic Changes

- Commonly occurs in women in their 20s, 30s, and 40s;
- CBE discloses prominent rubbery, thickened symmetrical plaques of glandular breast tissue that lack discreteness, blend into the surrounding breast tissue, and are often found in the upper outer quadrant;
- Pain (mastalgia) is a frequent complaint and can be cyclical and bilateral, is poorly localized, and extends to the shoulder, axilla, or arm;
- Symptoms may remain stable or worsen until menopause.

Carcinoma

- A mass representing cancer is typically singular, unilateral, distinct, and persistent, and may be attached to the adjacent tissue, although it may present as an asymmetric thickened area;
- While it is typically nontender, occasionally it will present as an area of thickening or focal persistent pain; and
- Because breast cancer may present in such a variable manner, there are no physical exam features that reliably distinguish benign from malignant masses.

All palpable masses and thickenings require further evaluation!

Approximately how many patients do you see each week?

- Less than 50
- 50-100
- 101-150
- Greater than 150

Approximately what percentage of your patients has suspicious breast signs and symptoms?

- Less than 5%
- 5%-15 %
- 15%-25%
- More than 25%

Workup of a Clinically Suspected Cyst

Is it possible to reassure a woman that a smooth mobile lump is probably a simple cyst?

Breast cysts typically occur in perimenopausal women age 40 and older. In the postmenopausal woman, cysts are rare unless the woman is on hormone therapy. Although multiple cysts commonly occur, a woman with breast cysts needs to be advised to be particularly cautious and to seek medical advice when a new mass arises. Neither the clinician nor the woman can automatically assume that a new mass is "just another cyst."

An experienced clinician may be able to distinguish by palpation between a cyst and a solid mass with about 60% to 80% accuracy. That is not good enough and still must be confirmed by further evaluation with ultrasound or fine needle aspiration.

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Clinicians use a combination of clinical judgment and self-confidence in aspiration skills to determine the best method (aspiration or ultrasound) to diagnose a probable cyst.

Ultrasonography depicts the fluid within cysts and can diagnose cysts as small as 2 to 3 mm in diameter in small breasts.

Aspiration of a cyst can be done to confirm the diagnosis and/or relieve pain. Aspiration of a cyst can be guided by palpation and/or ultrasound. Most primary care providers do not routinely perform cyst aspiration and depend on ultrasound for diagnosis and aspiration as indicated.

- If a lump in a patient's breast is aspirated and there is no bloody fluid or residual mass after the fluid is removed, then it can be concluded that the abnormality was a simple cyst.
- If the mass does not disappear completely when aspirated, or if the fluid is grossly bloody, the fluid should be sent for cytologic analysis and the patient referred for ultrasound and surgical consult if indicated.
- A patient with an aspirated cyst should be reexamined for recurrence within 4 to 6 weeks after the initial aspiration. If a cyst recurs in the same site within this time period, the patient should be referred for surgical consultation (complex cyst).

Workup of a Solid Palpable Mass

For women older than 40 years of age, diagnostic imaging evaluation (mammography and ultrasound as indicated) is usually the first-line evaluation for a palpable mass. For women younger than 40 years of age, ultrasound is generally more useful as the sensitivity of mammography is low in this age group (due to higher breast density).

In postmenopausal women, the risk that a mass is carcinoma increases; therefore, the clinician needs to be particularly suspicious of a discrete mass or asymmetric thickening.

Mammography is used not only to investigate the palpable lesion, but also to screen the remaining breast tissue for other, and perhaps more significant lesions. Mammography, although a valuable tool for screening and identifying breast abnormalities, is not perfect. A negative mammogram should never delay further evaluation for a physical finding, such as a breast lump, skin change, or spontaneous nipple discharge. Mammography is less effective in younger women, in part due to the density of their breast tissue.

Given the limitations of mammography, palpable lesions not seen with diagnostic imaging evaluation (mammography and ultrasound) require further diagnostic workup which may include: repeat CBE and/or referral to a breast specialist for further evaluation.

Masses Found by the Patient

What if my patient has a lump that I cannot palpate?

It is important to ask the patient to assume the positioning she used to palpate the finding. Some nodularity and/or masses reported by patients are not always confirmed by clinicians. These patients, including individuals with vague nodularity, should be asked to return for a repeat CBE within the following month. For premenopausal women, try to reschedule the repeat exam for the first 5 to 10 days of the menstrual cycle.

When the patient returns, if the nodularity and/or mass have resolved from the patient and clinician perspective, the patient can return to a schedule of routine follow-up. If a more suspicious asymmetrical mass persists from the patient perspective, the patient should be referred to a breast specialist for a second opinion CBE and follow-up accordingly. Ultimately, the patient may need to be referred to a breast specialist.

See Figure 1^[1-4] for guidelines on the workup of a new palpable mass.

Algorithm 2: New Palpable Mass

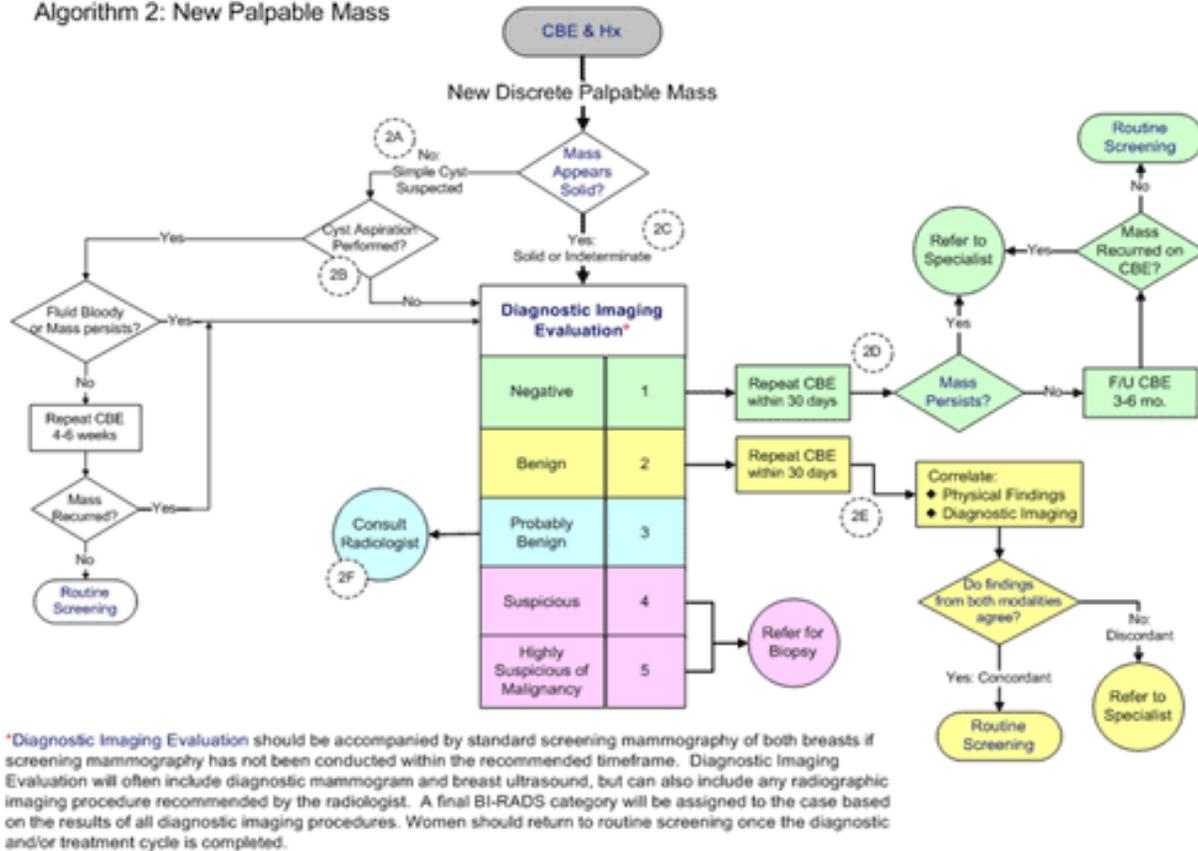


Figure 1. Algorithm: New Palpable Mass.

NOTE 2A: Upon detecting a palpable breast mass, the primary care physician may suspect a simple cyst. This diagnosis must be confirmed with ultrasound or fine needle aspiration/biopsy. A breast mass that is completely resolved by needle aspiration producing nonbloody fluid can be considered insignificant if there are no signs of recurrence 4-6 weeks post aspiration.^[2] Ultrasonography depicts the fluid within cysts and can diagnose cysts as small as 2-3 mm in diameter in small breasts, but not as easily in large, fatty breast tissue. Although multiple cysts commonly occur, the woman with breast cysts needs to be advised to be particularly cautious and to seek medical advice when a new mass arises. Neither the clinician nor the woman can automatically assume that a new mass is "just another cyst." Nonpalpable cysts detected by mammography and confirmed by ultrasound do not need to be aspirated except to relieve pain. A cyst that recurs more than 2 times within 4-6 weeks, displays bloody fluid, or leaves a residual palpable mass post-aspiration demands a diagnostic imaging evaluation. In this situation, the radiologist should be informed that an aspiration was undertaken prior to the imaging evaluation. Cysts with debris or thick material inside require further follow-up.

NOTE 2B: A clinically suspicious mass may have 1 or more features consistent with cancer: feeling firm, hard, irregular, solitary, and different from the surrounding breast tissue. Sometimes such masses are fixed and associated with skin retraction. However, any asymmetric finding should be cause for concern. ^[3, 4]

NOTE 2C: Clinician confidence level in performing cyst aspiration may vary. Proceed with diagnostic imaging evaluation (e.g., ultrasound) if routine aspiration is not offered in your practice for discrete palpable findings suspected to be cystic.

NOTE 2D: Patients with a BI-RADS category 1 or 2 should have a repeat CBE within 30 days. This allows the practitioner to correlate the physical findings with the diagnostic imaging evaluation and assure that the finding is concordant. Following the repeat examination, patients are divided into those who had an original BI-RADS category 1 from their imaging and those that had a BI-RADS category 2 in the imaging. In the BI-RADS category 2 patients, the practitioner is looking for a correlation, i.e., that the imaging finding identifies the anticipated physical finding as benign. If there is no correlation between the imaged mass and the palpable mass, then the patient should be referred to a breast specialist for the decisions regarding interval follow-up of referral for tissue biopsy. For those patients with BI-RADS category 1 imaging, a follow-up CBE will allow the PCP to determine whether the mass persists. If the mass does not persist and the patient has a BI-RADS category 1, there should be a repeat clinical examination in 3-6 months. This will confirm that the mass is no longer present and the patient can then return to routine screening intervals. Patients with negative imaging, in whom a new mass persists at the short follow-up examination period of 30 days, should be referred to a breast specialist for decisions regarding follow-up interval or need for a biopsy.

NOTE 2E: Mammography should be performed using a radiopaque marker on the skin over a palpable lesion to help determine whether the palpable mass corresponds to the mammographically identified lesion. A noncorresponding mammographic finding may represent a separate lesion, which may need further evaluation in addition to a workup for the original palpable mass. Careful correlation of the physical exam and diagnostic imaging evaluation is critical to assure appropriate and timely follow-up. If the diagnostic and imaging findings show a cyst, it can be aspirated during a follow-up CBE.

NOTE 2F: The American College of Radiology does not recommend the assignment of a BI-RADS category 3 result as the final diagnostic imaging evaluation for a patient with a palpable mass. This may occur if the radiologist is unaware of the CBE findings. If the results of your CBE screening indicate a palpable mass and you receive a BI-RADS category 3 final diagnostic imaging evaluation, contact the radiologist for further consultation.

Workup of Nipple Discharge

Do I still need to routinely squeeze the nipple for discharge?

Expressed nipple discharge in an asymptomatic woman is not a concern for breast cancer. However, reported spontaneous nipple discharge, particularly unilateral, must be further evaluated so it is appropriate to attempt to elicit the discharge for further assessment and follow-up as indicated.

Nipple discharge is often due to a benign process and has been reported in 10% to 15% of women with benign breast disease and 2.5% to 3% of women with breast cancer. [5] There are 2 general classifications of nipple discharge. Elicited nonspontaneous nipple discharge is physiologic and found in nearly half of women during their reproductive years of life. It generally only requires reassurance after appropriate assessment of endocrine or medication causes. Spontaneous nipple discharge, on the other hand, must be evaluated for pathology.

Nipple discharge originates in 1 or more duct(s). The clinical history of the nipple discharge will usually define its origin. A pathologic nipple discharge will likely be reported by the woman as having begun spontaneously (not in response to stimulation) and staining her bra, bed sheet, or sleeping garment. Therefore, the clinician may need to "milk" each quadrant to attempt to see which ducts are involved and use palpation to determine if there is a mass associated with the discharge. Important questions to consider in the workup of nipple discharge are:

- Is the discharge unilateral or bilateral?
- What medications is the woman taking?
- Is she pregnant? Has she previously breastfed?
- Is the discharge spontaneous or expressible?
- Do single or multiple ducts appear to be involved?
- Is the discharge associated with a mass?
- What is the consistency and color of the discharge?

A discharge from a single duct is of concern whether the discharge is clear/watery, serous, or bloody. Multiple duct discharges are rarely caused by cancer.

Every nonlactating woman with a unilateral, spontaneous nipple discharge (whether clear, serous, or bloody) should be referred for diagnostic breast imaging and surgical evaluation. Diagnostic mammograms in these instances may be negative but should never delay further surgical evaluation.

A duct excision (either a microductectomy guided by ductoscopy or ductography or a major duct excision) is both diagnostic and, for discharge that turns out to be benign, therapeutic. [5]

The most common cause of pathologic nipple discharge is intraductal papilloma, followed by duct ectasia.^[5] If a palpable mass is present in association with the discharge; the likelihood of cancer is greatly increased.^[5]

Bloody nipple discharge is the most common type of unilateral spontaneous nipple discharge and is mostly related to benign papilloma of the duct. The likelihood of cancer being associated with bloody nipple discharge is reported to range from 15%-25%. There is some difference according to the age of the patient. Older women are more likely to have cancer and younger women are more likely to have a benign intraductal papilloma. Although bloody nipple discharge is the most common, clear watery discharge is more likely to represent carcinoma. About 50% of patients with watery discharge do have cancer. Lactating women often have a cloudy watery discharge, so it is not to be confused with clear watery discharge indicative of cancer.

Bilateral nipple discharges usually have physiological causes, such as hyperprolactinemia. Endocrine causes of galactorrhea (milky discharge) include pregnancy, hypothyroidism, and micropituitary adenoma. It may also be secondary to nipple stimulation or chest wall trauma. Women who have breastfed for more than 4-6 months can have expressed bilateral discharge for years. Medications such as antihypertensives, oral contraceptives, phenothiazines, antidepressants, and tranquilizers may also cause nipple discharge. Breast disease that is bilateral is usually due to mammary duct ectasia, a benign condition that occurs in postmenopausal women and is characterized by dilation of the ducts, nipple secretions, and periductal inflammation.

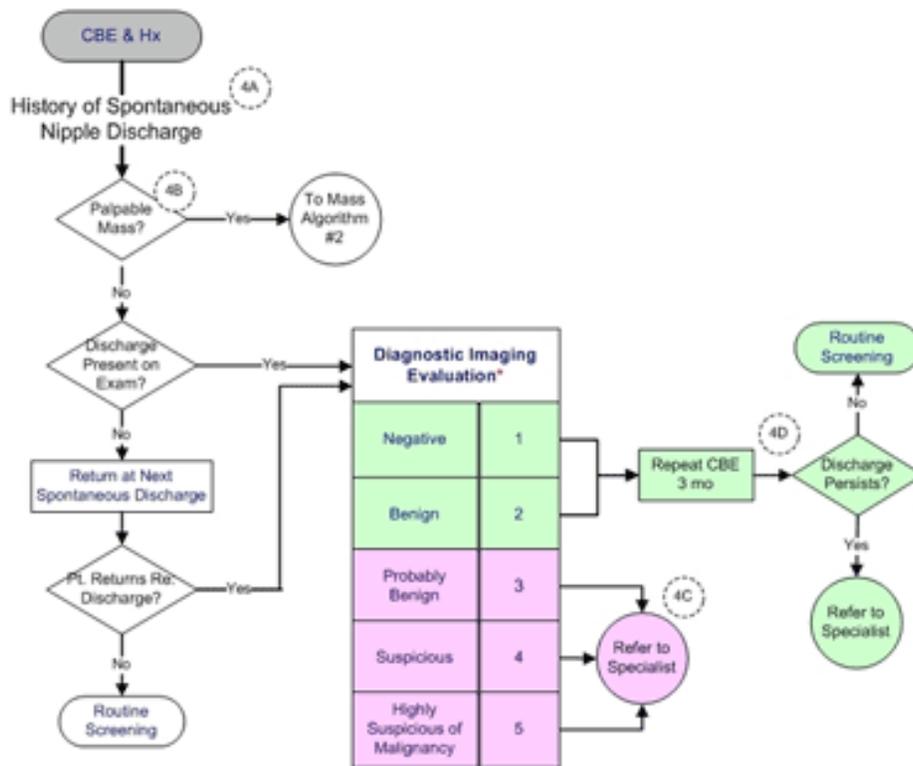
Cytology

Cytology generally is not useful because the absence of malignant cells does not exclude cancer and a positive result cannot distinguish intraductal from invasive cancer.

Galactography

The role of galactography remains controversial. A negative galactogram does not reliably rule out breast cancer and a duct excision will still be necessary. It does, however, provide a "roadmap" to guide surgical excision of a tumor.

See Figure 2^[1, 6, 7] for guidelines on the workup of a nipple discharge.



*Diagnostic Imaging Evaluation should be accompanied by standard screening mammography of both breasts if screening mammography has not been conducted within the recommended timeframe. Diagnostic Imaging Evaluation will often include diagnostic mammogram and breast ultrasound, but can also include any radiographic imaging procedure recommended by the radiologist. A final BI-RADS category will be assigned to the case based on the results of all diagnostic imaging procedures. Women should return to routine screening once the diagnostic and/or treatment cycle is completed.

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Figure 2. Algorithm: Nipple Discharge.

NOTE 4A: A nonspontaneous discharge usually is insignificant. Thus it is more clinically relevant to elicit a history of a spontaneous discharge. The patient should be asked whether she has noticed staining of her clothing. A true nipple discharge originates in one or more duct(s).^[6] Pseudo-nipple discharges can be caused by inverted nipples, eczema, infection, etc.

NOTE 4B: It is important to determine if the nipple discharge is associated with a palpable mass. "Any mass noted within 2 cm of the nipple is considered correlative."^[7] Immediate referral for diagnostic imaging followed by surgical consultation is appropriate.

NOTE 4C: The diagnostic imaging abnormality should correspond with the quadrant from which the discharge originates (i.e., a radiographic abnormality that does not correlate to the discharge quadrant may represent a separate lesion). Even a mammographic abnormality that corresponds to a palpable lesion might be a separate lesion that is not associated with the discharge, and needs separate work-up and referral to a breast specialist.

NOTE 4D: Clinical reevaluation of a woman with a BI-RADS category 1 or 2 is recommended at 6 months and is intended to assure that the nipple discharge has resolved.

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Workup of Skin Changes/Nipple Retraction

Is it still important to assess for breast skin changes through visual inspection?

The visual inspection is an important component of the physical examination. While the efficacy in reducing mortality has not been studied, most clinicians observe for skin changes and encourage their patients to do the same on a regular basis. If a skin change is present, it is important to assess how long the change has been present and whether the skin change is associated with a mass. The degree of suspicion is much higher when the skin change is unilateral.

Erythema of the Breast

There are a number of benign conditions that can make the medical management of breast skin changes challenging. Erythema may be due to subareolar abscess secondary to lactational mastitis or a breast abscess. Erythema that does not respond to medical management (e.g., topical steroids or antibiotics) after 7 to 10 days should be evaluated for inflammatory breast cancer.

Inflammatory Breast Cancer

Inflammatory breast cancer is a rare and aggressive form of breast cancer that is often initially confused with infections of the breast. The typical initial symptoms of both benign breast infection and inflammatory breast cancer are redness of the skin, local heat, breast enlargement, and thickening of the skin, which may have an orange peel appearance. Patients with inflammatory breast cancer often experience breast pain and swelling of the lymph nodes under the arm and often can feel a localized mass.

Most are initially treated with a course of antibiotics. A 10-day follow-up is critical to confirm symptom resolution or the need for evaluation for inflammatory breast cancer. Diagnostic imaging evaluation (as tolerated) the next step of the workup, but a negative result should not deter immediate referral to a breast specialist.

Peau d'orange

Peau d'orange is a symptom of later-stage inflammatory cancer. The orange peel appearance of skin overlying the breast tissue due to dermal and/or lymphatic involvement by breast cancer.

Eczema vs Paget's Disease

How can I distinguish eczema from Paget's disease?

A red-crusted nipple-areolar complex could be due to a number of dermatologic condition; such as eczema, psoriasis, nevi, keratoses, seborrheic dermatitis, contact dermatitis, neurodermatitis

and atopic dermatitis. Eczema is usually bilateral and the nipple may be spared. Traditionally, use of a topical steroid for 7-10 days has been recommended.

A recheck in 10-days is mandatory to assess the responsiveness of the rash. If symptoms are not completely resolved, referral to a breast specialist is mandatory. More recently, for highly suspicious symptoms of unilateral Paget's, some surgeons advocate not using topical steroids until Paget's disease (infiltration of the dermis by cancer cells) has been ruled out (by surgical evaluation), as some anecdotal Paget's cases have documented a temporary reduction of itching and erythema in response to topical cortisone. Misdiagnosis of Paget's disease can lead to delayed diagnosis. See Figures 3A-D.

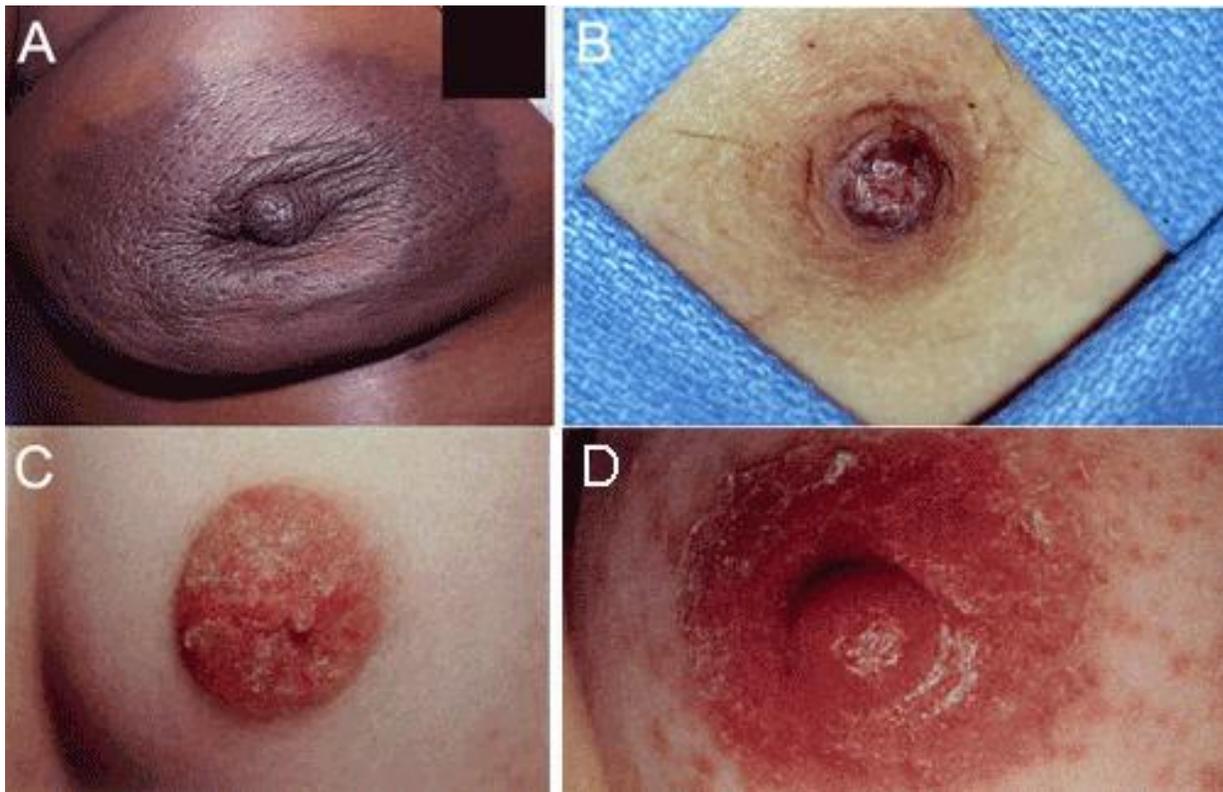


Figure 3. Eczema and Paget's disease.

Eczema primarily involves the areola, and the nipple is often spared. Paget's disease usually involves both the nipple and the areola.

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Nipple and/or Skin Retraction

Nipple/skin retraction can be related to possible periductal mastitis and deeper tissue infections or may be an indication of subareolar cancer. Timing of onset of nipple/skin retraction is of paramount importance; congenital nipple inversion is insignificant, whereas recent nipple retraction has more serious implications. Unilateral nipple/skin retraction, even slight, is also more suspicious than bilateral nipple/skin inversions.

A thorough examination is important in the assessment of the patient who presents with skin changes (e.g., inflammation, scaling) or skin/nipple retraction. Important questions to consider include:

- How long has the change been present?
- Is there an associated palpable mass or mammographic abnormality?
- Is it a unilateral finding?
- Is there a traumatic past injury that resulted in scarring?

Bilateral mammography is the first line of investigation when there are breast skin or nipple changes, even if no mass is palpable on CBE. This is done to rule out nonpalpable lesions. Mammography is often negative in these cases, but a negative mammogram must not preclude surgical referral.

Indications for immediate referral to a surgeon for further evaluation include:

- Nipple retraction or distortion of recent or sudden onset (may or may not be associated with a mass);
- Skin dimpling or changes in the skin texture (i.e., peau d'orange);
- Red and crusted nipple-areolar complex, not responsive to topical steroid treatment; and
- Inflammation or erythema, not responsive to antibiotic treatment.

See Figure 4^[1] for guidelines on the workup of breast skin changes/nipple retraction

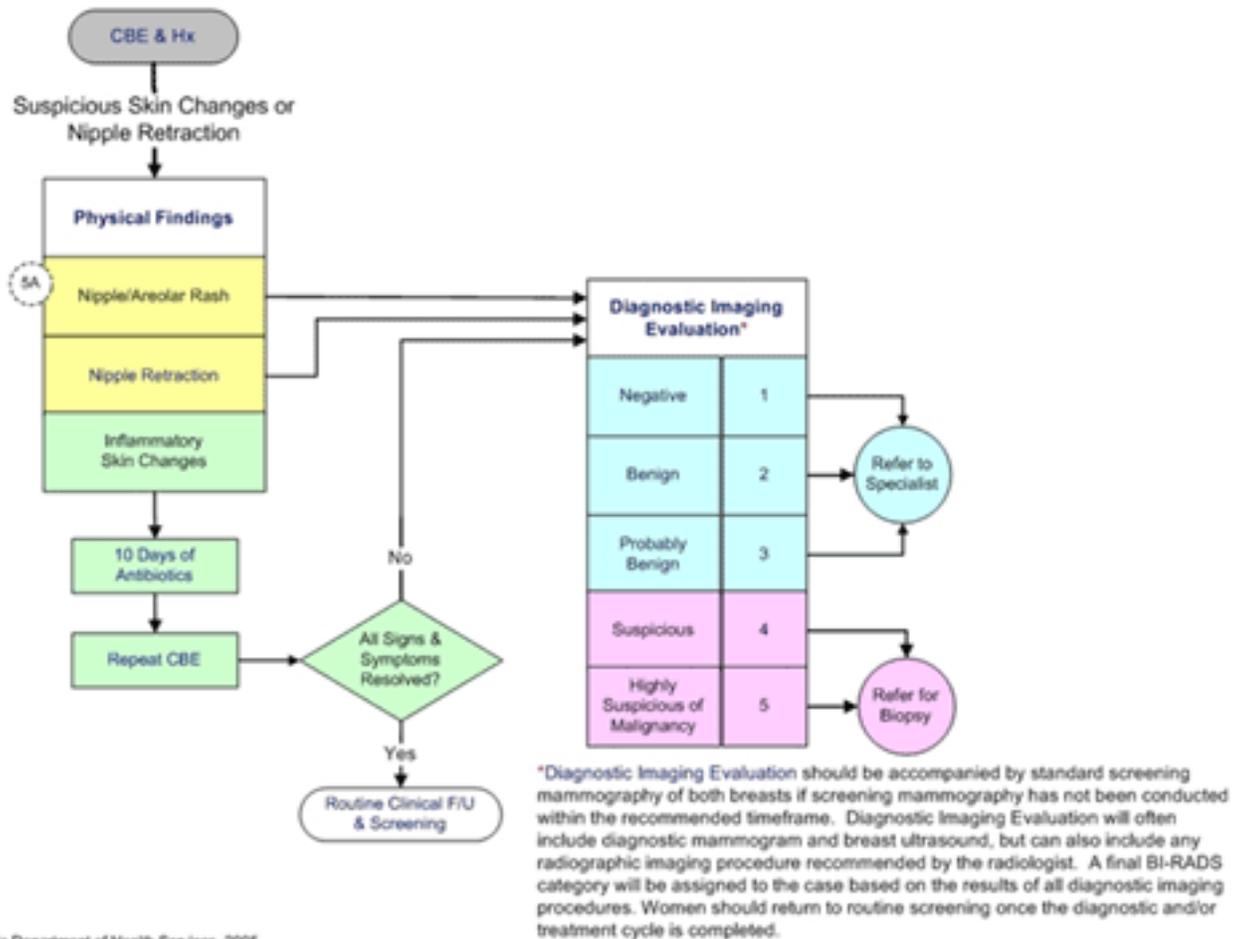


Figure 4. Algorithm: Suspicious Skin Changes or Nipple Retraction
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Workup of Breast Pain -- Nonlactating Women

How should I manage patients with breast pain?

Mastalgia (breast pain) is the most common breast-related complaint at primary care clinics and breast referral centers. Two thirds of patients complain of breast pain, which is usually cyclical in nature. [8] There are 2 types of breast pain:

- Cyclical pain is most common and relates to the fluctuation of hormones during the menstrual cycle. It is typically bilateral and diffuse in nature, but is most common in the upper outer quadrant.
- Noncyclical pain is most commonly caused by a benign breast cyst and can be more focal or constant in nature.

However, 15% of patients diagnosed with breast cancer presented with breast pain. A thorough medical history and physical exam are essential to determine the cause of breast pain. A medication and supplement history is also important, since certain medications, such as antidepressants, may cause breast tenderness.

In severe mastalgia, the pain can be frequent and diffuse, constant and localized, or persistent and lasting for years. It may or may not be cyclic. A thorough assessment will include collection of information on:

- Duration and frequency of the pain;
- Pattern of the pain, including location, diffuse vs. focal, and constant vs. cyclical (i.e., when in the menstrual cycle does the pain occur);
- History of recent HT or oral contraceptive use (can initially cause breast pain as woman adapts to changes in hormones);
- A recent history of physical activity, including any new upper body exercises (to r/o costochondritis);
- A history of any physical trauma; and
- What measures patient has used to ameliorate the pain.
- While a painful mass is most often a cyst or a focus of glandular tissue, a common misconception is that the presence of breast pain rules out malignancy. However, a painful mass is most often a cyst or a focus of glandular tissue.

Noncyclical mastalgia is most common in women 40 to 50 years of age. It is often unilateral and is described as a sharp, burning pain that appears to be localized in the breast. It is occasionally secondary to the presence of a fibroadenoma or cyst.^[3] Noncyclical pain warrants further evaluation with a thorough CBE with special attention to the area of concern and a diagnostic imaging evaluation. To reduce discomfort and get a better exam, schedule the premenopausal patient's mammogram during the follicular phase of her menstrual cycle, preferably between Day 5 and Day 10 after the onset of menses.

In most women, CBE and mammography reveal no evidence of pathology. The patient should be reassured that breast pain has a high remission rate.

Cyclical pain can be managed more conservatively. No mammogram is necessary for cyclical pain unless the woman needs one due to her screening schedule. If CBE and mammography are negative, the most common cause is the physiologic action of estrogen and progesterone on breast tissue. In postmenopausal women on hormone therapy, it is likely the effect of estrogen. In these cases, adjustment of hormones may be necessary.

Conservative measures for management include the use of a brassiere that provides good support. If it is too tight (recent weight gain) or was poorly fit or is due to an ill placed underwire, refer the woman to a professional fitter.

Nonsteroidal anti-inflammatory drugs can be recommended to reduce breast pain and could be suggested for women with tender breast tissue just prior to imaging and CBE which both use pressure for improved interpretation. Recent studies have indicated a reduction in breast cancer risk associated with the use of NSAIDs.

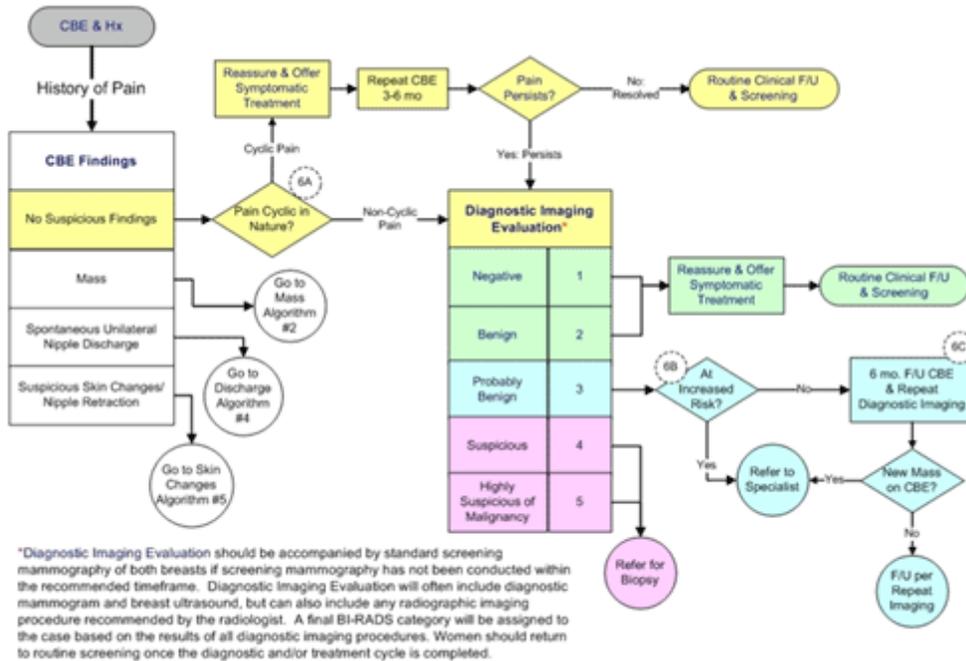
For centuries, chasteberry has been used to treat many hormone-related gynecologic conditions. The current literature supports the use of chasteberry for cyclical breast discomfort and premenstrual syndrome.^[9]

Many clinicians have promoted oil of primrose, 3 mg a day, for relief of breast pain for some patients. This dietary herbal supplement can be obtained in health food stores, but is not FDA approved. The elimination of caffeine, chocolate, or salt from the diet has no scientifically proven benefit, although some women may experience relief of pain with caffeine and sodium restriction.

If localized pain is not eliminated with conservative measures, refer the patient to a surgeon. A lactating woman with noncyclical breast pain may need a referral to an obstetrician/gynecologist for further evaluation.

Danazol is the only FDA-approved drug for the treatment of breast pain. The significant side effects limit its use to those with severe, activity-limiting pain.

See Figure 5: Algorithm: Workup of Breast Pain in Nonlactating Woman^[1] for guidelines on the workup of a breast pain in a nonlactating woman.



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Figure 5. Algorithm: Workup of Breast Pain in Nonlactating Woman. ^[1]

NOTE 6A: Distinguish between cyclic and noncyclic. Cyclic is typically bilateral and described as diffuse, dull, full, achy, and heavy. Noncyclic tends to be unilateral and described as localized, sharp, throbbing, stabbing, and burning.

NOTE 6B: As with other algorithms, a BI-RADS category 3 result requires a differential assessment of risk. See Algorithm 1, Risk Assessment, to determine whether the patient is at increased risk for breast cancer. If so, refer to a breast specialist.

NOTE 6C: For BI-RADS category 3, the vast majority of findings will be managed with an initial short-term follow-up examination in 6 months, followed by additional examinations until stability is demonstrated (2 years or longer). There may be occasions where biopsy is done (i.e., patient request or clinical concerns). Evidence from all of the published studies indicates the need for biopsy of the lesion with an increase in size or morphologic change. ^[10]

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Case One

A 39-year-old premenopausal woman comes to your office for her annual woman's health exam. The health history captures information on family history of breast cancer and you note that her mother died of premenopausal invasive breast cancer in her 50s.

When questioning the patient about previous breast cancer screenings, she remarks that she self-palpated a lump while washing under her arm in the shower in the upper-outer quadrant of her

left breast 2 years ago and an ultrasound was done. She remembers being told that it was a cyst and not to worry about it.

Her previous CBE a year ago was documented as normal and she has no current complaints. Lymph node palpation and visual inspection are unremarkable. While in the side-lying position you find a firm, non-tender discrete mass, approximately 1.5 cm in diameter, round, at the 11:00 position in the left breast, 4 cm from the nipple. You explain to the patient that the lump needs further evaluation so you are ordering a diagnostic imaging evaluation at the hospital's breast imaging center.

During the documentation of the exam you note a previous entry from last year's exam that states the patient has fibrocystic breast disease (FCBD) but there is no cytology/pathology to verify that. The US report does note fibrocystic change.

The referral for the diagnostic imaging evaluation appointment is made by the office medical assistant and no CBE documentation is sent with the referral. The patient's file is placed in a pending status for follow-up.

What further documentation/follow-up should be considered to be important for this case?

- Documentation of the health history and palpation findings/diagram for the Radiologist
- Peer coaching to the MD colleague about using fibrocystic "condition" vs disease in CBE documentation.
- Written request to have the patient's chart placed into a 10-day tickler file to assess follow-up and results from the imaging facility.
- Documentation of the position used to discover, discriminate and document the palpable finding.
- All of the above

Sixty-four days later, the results of a diagnostic imaging evaluation are delivered to the office. Evidently, the patient rescheduled the appointment with the imaging facility twice due to work conflicts. The report is placed in the medical record by the office clerk and then placed on your desk for review. 6-days later you review the report. The diagnostic imaging included an ultrasound and issued a final BI-RADS 2 category with verification of a 7-mm superficial cyst in the 9:00 position of the left breast. Imaging facility (radiologist) suggested a repeat CBE after the next menstrual cycle and reduction of caffeine intake to the patient.

When a BI-RADS 2 report is issued:

- The lesion described is determined to be radiologically benign
- The American College of Radiology (ACR)[10] recommends routine rescreening for BI-RADS category 2

- Correlation of the lesion palpated and the lesion described by the radiologist is critical to assess for concordance
- The ideal time to palpate and image breast tissue is between days 5-10 of the menstrual cycle (Day 1 being the first day of menstrual flow)
- All of the above

In actuality, you do not cross-compare your documentation of the lesion with the lesion described in the imaging report, and you ask the patient to return after her next menstrual cycle for a repeat CBE. Patient returns 14 days after the first day of her menstrual cycle and you note the lump is smaller and record it as 5 mm, mobile and firm.

Your next-highest priority step would most likely be:

- Note that your clinical findings at 11:00 do not match the 10:00 finding by the radiologist, thus a discordant result with your CBE
- Order a repeat CBE in 6 months
- Order a six month short-term follow-up diagnostic mammogram of the left breast
- Order a digital mammogram (this imaging facility only uses film with CAD)
- Order a fine needle aspiration or tissue biopsy under ultrasound
- A and E

In actuality, you order a repeat CBE in 6 months. Nine months later, after 2 attempts to reach the patient by phone and mail, the patient is scheduled for the CBE and you note 2 discrete lumps in essentially the same location as the last exam. You refer for a surgical consult and biopsy. The surgeon notes two masses adjacent to one another and requests a diagnostic imaging evaluation which again issues a BI-RADS category 2 for the unchanged cyst. The surgeon then conducts an excisional core biopsy of the second lesion and the pathology report documents comedo carcinoma with inadequate margins. A lumpectomy is performed along with sentinel node biopsy and the patient's cancer is classified as stage III, is given a stage III prognosis and is scheduled for radiation and chemotherapy.

Diagnostic concordance is confirmed when:

- CBE, imaging, and pathology are all concordant
- CBE and pathology are concordant in a woman with radiographically dense breast tissue (e.g., mammogram negative)
- BI-RADS 3, 4, or 5 clinically occult lesions are concordant with pathology results
- The lesion described as BI-RADS category 2 and malignant pathology is confirmed
- All but D

Measuring Educational Impact

In your experience, which of the following is the most important barrier to the early diagnosis of breast cancer in a patient with suspicious breast signs and symptoms?

- Patient's fear of being diagnosed with breast cancer and failure to follow up with recommendations.
- Patient's lack of access to healthcare facilities
- Low-quality CBE performance among healthcare providers.
- Inappropriate plan of action for follow-up.

Case Two

A 35-year-old woman has noticed a lump in her right breast during breast self-examination. On physical examination a firm, 1 to 2 cm, nontender, mobile mass is identified in the upper outer quadrant of the right breast. There is no nipple discharge, no pain, no axillary adenopathy, and the overlying skin of the breast appears normal. Her right breast is slightly larger than the left; which she says has been that way since puberty. Her urine pregnancy test is negative. You are almost certain that it is merely a cyst.

What is your next step?

- Perform an ultrasound
- Perform a follow-up CBE in 6 months
- Perform a follow-up CBE in 3 months
- Offer support and reassurance

You aspirate the cyst and a serous nonbloody fluid fills the syringe. The mass is no longer palpable.

When can the suspicious mass be considered insignificant?

- Now
- If there are no signs of recurrence 4-6 weeks post aspiration
- If there are no signs of recurrence 8 weeks post aspiration
- If there are no signs of recurrence 12 weeks post aspiration

Case Three

A 45-year-old woman has noted staining in her bra from a nonbloody nipple discharge from the right breast over the past 5 weeks. Physical examination is negative for a palpable mass or tenderness in her breast and for axillary nodes. The skin of this breast shows no lesions. A small amount of clear fluid can be expressed from the right nipple with milking the upper outer

quadrant area. Her urine pregnancy test is negative and she takes no medication.

What is the likelihood that this patient's signs and symptoms indicate carcinoma?

- 2%
- 15%
- 35%
- 50%

What is your next step?

- Perform a follow-up CBE in 3 months
- Obtain a cytology sample
- Refer for galactography
- Refer for mammography

If the diagnostic evaluation result(s) came back negative, what would you do next?

- Offer support and reassurance
- Perform a follow-up CBE in 30 days
- Perform a follow-up CBE in 3 months
- Refer for surgical evaluation

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Suggested Reading

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