EVALUATION OF COMMON BREAST PROBLEMS: A PRIMER FOR PRIMARY CARE PROVIDERS

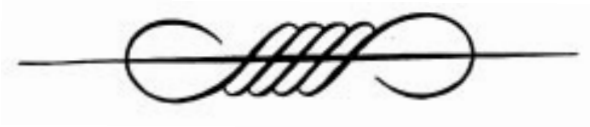
Prepared By The Society of Surgical Oncology

and

The Commission on Cancer of The American College of Surgeons

for

The Centers for Disease Control and Prevention



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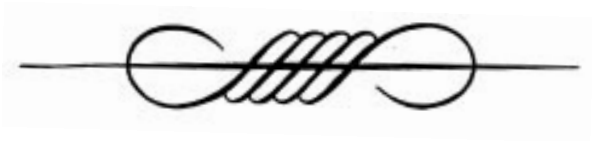

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This document is a modification of an algorithm developed by Barbara L. Smith, MD, PhD, et al that can be found in: Diercks DB, Cady B. Lawsuits for failure to diagnose breast cancer: Tumor biology in causation and risk management strategies. Surgical Oncology Clinics of North America 1994;3:125-139. August 1995

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INTRODUCTION

The Centers for Disease Control and Prevention (CDC) believe that guidelines for the evaluation and management of common breast problems can be useful to primary care providers in state breast cancer screening programs. To draft the guidelines, CDC convened a group of general surgeons with extensive experience in the evaluation and management of breast abnormalities. The surgeons represented the Society of Surgical Oncology and the Commission on Cancer of the American College of Surgeons. The governing bodies of both organizations approved the guidelines that were developed.

The draft guidelines were then circulated to other experienced professionals in breast evaluation, representing the fields of diagnostic radiology, obstetrics and gynecology, and surgery, as well as individuals active in state breast cancer screening programs.

The guidelines here are organized so that they will be useful to physicians, physician assistants, and nurse practitioners in evaluating women with common breast problems.

MEDICAL HISTORY

Risk Assessment

Evaluation should begin with a thorough risk assessment but should recognize that approximately 75% of women with newly diagnosed breast cancer have no identifiable risk factors. The most obvious risk factor is age—breast cancer incidence increases as age increases. A family history should identify any first-degree relatives (mother, sisters or daughters) with breast cancer and the age at which cancer developed. Patients who have a first-degree relative diagnosed with premenopausal breast cancer have a considerably greater risk (3 to 4-fold) of developing breast cancer than the general population. If a premenopausal first-degree relative had bilateral cancer, or if more than one first-degree relative had breast cancer, the risk for the woman may be 8 to 10 times the risk for the general population. It is critical that the examiner obtain a specific history from the patient about previous biopsies, the pathology discovered, and the presence of a previous breast cancer. For a woman with a personal history of breast cancer, the risk of developing a new primary breast cancer is approximately 0.5% to 1% per year of her remaining life. The examiner should also obtain information regarding child birth, such as parity and age at first live birth. A woman who has no children, or whose first full-term pregnancy occurred after age 35 may have a substantially increased risk of breast cancer. Other risk factors include early age at menarche and late cessation of menses.

Symptom Assessment

Patients by definition should be asymptomatic in the screening setting. Many patients do present with symptoms, however. Thus, the examiner should inquire about common symptoms, such as breast mass, breast pain, skin or nipple changes, and nipple discharge. The patient should be asked about the duration of the symptom and whether it is associated with the menstrual cycle. The following features of nipple discharge are suspicious for benign or malignant breast neoplasm and necessitate prompt referral of the patient to a surgical consultant: 1) spontaneous; 2) unilateral; 3) occurring in an older patient; 4) confined to one duct; or 5) clear, serous, bloody, or serosanguinous.

BREAST PHYSICAL EXAMINATION

Examination of the breast is inherently subject to interobserver variation and interpretation. However, certain elements in the examination should be noted: 1) It should be conducted unhurriedly in a setting that allows for minimal distraction and adequate patient privacy. Examination gowns should be adjusted to minimize unnecessary or unintended exposure of the patient. 2) The patient should be examined in both the upright and supine positions. 3) The approximate size (measured with a ruler), location, mobility, and consistency of any mass should be recorded. Any associated skin changes such as dimpling, retraction, erythema or nipple scaling should be noted. 4) Each nipple should be gently squeezed to examine discharge. 5) The lymph nodes in the axillae should be examined. The assessment should state whether the nodes are clinically negative (normal size, soft, and mobile). If the nodes are suspicious, the assessment should indicate their consistency, and whether the nodes are single or multiple, and whether movable or fixed. 6) The breast examination should be completely documented, even if the examination is normal.

A *clinically suspicious mass* is one that is discrete or firm, which may or may not be fixed to adjacent tissue. It is usually unilateral and nontender, but may be sensitive. However, breast cancers are known to present clinically in a highly variable manner.

METHODS FOR SCREENING AND DIAGNOSIS OF BREAST CANCER

Screening Guidelines

Screening Mammography

Conclusive scientific data are not available to define precisely the appropriate age groups for screening mammography. Several national organizations recommend mammography every 1 to 2 years for women aged 40 to 49 years, but others do not support this

position. Scientific data support the recommendation of annual screening mammography in women aged 50 to 74 years. Controversy exists concerning the frequency of examination for women 75 years and older. There is little to be gained by the routine use of screening mammography for women younger than age 40.

Physical Examination

Examination of the breast should be part of all routine physical examinations for women older than age 30 and should be encouraged at younger ages. Physical examination by primary care providers such as internists, family practitioners, gynecologists, and nurse practitioners should include the breast.

Breast Self-Examination

The role of breast self-examination in the early detection of breast cancer is not clear. Pressure from physicians and nurses for the woman to perform self-examination may not result in its practice and frequently causes patient anxiety. Breast self-examination should be taught, demonstrated, and encouraged but not unduly emphasized. On the other hand, if a patient values the role of breast self-examination in breast cancer screening, the practice should be reinforced and encouraged. If a woman finds a mass during breast self-examination, she should be seen promptly for the appropriate clinical and imaging evaluation.

Diagnostic Evaluation

Diagnostic Mammography

The workup of a patient with a solid, dominant mass should include a diagnostic bilateral mammogram, and may also include either aspiration or ultrasonography. Keep in mind that in this situation, the primary purpose of the mammogram is to screen the normal surrounding breast and the opposite breast for nonpalpable cancers, and not to make a diagnosis of the palpable mass.

The usefulness of mammography in younger women is greatly limited by the increased density of the breast. Mammography for a palpable mass should not be performed on women under the age of 30 because of the rarity of cancer and the ineffectiveness of the examination among women in this age group. Exceptions may occur, such as a young woman with a clinically suspicious breast mass whose mother had premenopausal breast cancer, or after cancer has been diagnosed, to inspect the remaining breast tissue. **It should be emphasized that a normal mammogram at any age does not eliminate the need for further evaluation of a palpable mass.**

Ultrasonography

The chief value of an ultrasound is to differentiate solid from cystic masses. Ultrasonography may be useful when a palpable mass is partially or poorly seen on a mammogram, especially in young women. Ultrasonography can diagnose a simple cyst if four criteria are fulfilled: 1) round or oval shape, 2) sharply defined margins, 3) lack of echoes, and 4) posterior acoustic enhancement. A mural nodule in a cyst may be visualized by ultrasonography and should arouse suspicion of the rare diagnosis of intracystic carcinoma or carcinoma adjacent to a cyst.

Because of the inconsistent depiction of microcalcifications, ultrasound is contraindicated for routine breast cancer screening.

Other Imaging Modalities

There is no role for thermography in breast cancer screening or diagnostic evaluation. The role of magnetic resonance imaging (MRI), computerized tomography, positron emission tomography, or other imaging modalities for screening or diagnosis of breast lesions has not yet been determined. None of these techniques has currently accepted indications for their use except MRI in the detection of silicone implant ruptures that cannot be recognized or excluded using other imaging techniques.

Fine Needle Aspiration

Fine needle aspiration (FNA) for cytologic analysis represents a useful extension of the clinical evaluation of a palpable mass. FNA can accomplish cyst aspiration, in which the intent is both diagnostic and therapeutic, by eliminating a fluid-filled cyst, or can be diagnostic for solid masses, by aspirating tissue for cytologic evaluation.

Every palpable mass should be considered for needle aspiration to diagnose and treat cysts and to submit aspirated cellular material for cytologic examination. Physicians and patients need to understand the limitations of FNA; the false-positive rate is negligible but the false-negative rate may be as high as 15% to 20%. Any residual mass must be excised if not eliminated by aspiration of a cyst.

Stereotactic Biopsy

There are two types of stereotactic biopsy: a) stereotactic cutting needle biopsy to obtain a core of tissue for histology, and b) the less frequently used stereotactic needle aspiration for cytology. Currently, the role of stereotactic biopsy is not totally defined. Its indiscriminate use in all breast lesions detected by mammography is unjustified. Its use in obvious cancers to confirm the diagnosis before surgical excision is probably unjustified.

The principle use of stereotactic biopsy is to obtain tissue from a lesion that is probably benign but has changed during repeated mammograms, and the patient wishes to avoid

more extensive surgery. Lesions with smooth outlines that have increased in size, where the risk of cancer is less than 10% but not zero, may be appropriate for stereotactic biopsy. Stereotactic core cutting biopsy often removes only a piece of the lesion; the same area of concern may be present in subsequent mammograms.

One of the newest uses of stereotactic core cutting biopsy is for suspicious clustered calcifications. These lesions have only a 20% risk of being a cancer, and one-half of these cancers are in situ. The biopsy, which involves obtaining multiple tissue cores, should be followed immediately with a specimen mammogram to prove removal of some of the clustered calcifications. Use of this biopsy method may decrease the number of excisional biopsies done for lesions which have a low risk of being cancer. However, this procedure is known to miss cancers; its use is open to some question until further data can be obtained.

Stereotactic biopsy is a method to get tissue for pathologic examination while avoiding an open surgical biopsy. Whether it will ultimately be found to be cost-effective depends on how frequently it is used and the savings that are actually achieved.

Open Surgical Biopsy

Whether performed on palpable lesions or on nonpalpable lesions after mammographic localization, the ultimate test of a mass in the breast is an open surgical excisional biopsy. At present, excisional biopsies of lesions suspicious for cancer should be performed to satisfy the requirement of a "lumpectomy," that is, they should be removed with at least a 1 centimeter margin of normal tissue. Palpable lesions that are almost certainly benign but require removal need only minimal margins. In fact, fibroadenomas can be simply shelled out of the surrounding compressed breast tissue.

Because the exact location within the breast of nonpalpable lesions found by mammography is uncertain, excision of these lesions, which requires needle localization, is necessarily more extensive than what is needed for palpable lesions. All needle localization biopsies should have a mammogram of the specimen to be sure that the lesions seen on the screening and localization mammograms were actually removed. The biopsy should be performed in such a way that the entire lesion (or all the calcium) visualized on the localization mammogram is removed by the surgical excision.

All biopsies or lumpectomies for palpable or nonpalpable breast lesions should be performed in such a way as to keep a single, intact tissue specimen. Biopsy should **not** be done piecemeal. In addition, the borders or margins of the breast tissue specimen should be coated with ink so that the histologic margins around any cancer found can be accurately defined.

EVALUATION AND MANAGEMENT OF COMMON BREAST PROBLEMS

Thorough communication with patients about all management options and their associated risks, all test results, as well as written documentation of these discussions, is of the utmost importance to the provision of quality care.

Palpable Mass

Cyst

Cysts are commonly found in the pre- and perimenopausal age groups. It may not be possible to distinguish a solid from a cystic mass by physical examination alone, in which case ultrasound and/or cyst aspiration can be diagnostic. A palpable mass suspected to be a cyst can be confirmed most rapidly and easily by aspiration; however, if the primary care provider does not routinely perform aspirations, the patient should be referred to a surgeon. If a cyst is aspirated, the patient should be reexamined for cyst recurrence in approximately six weeks. If a cyst rapidly recurs after aspiration, the patient should be referred for a surgical consultation.

If the mass does not disappear completely with aspiration, or if the aspirated fluid is grossly bloody, the fluid should be sent for cytologic analysis and the patient should be referred for radiologic and surgical consultation. Cyst fluid should be otherwise discarded.

The most efficient and cost-effective method of diagnosing a cyst should be used. If a woman has a physical examination of the breast that reveals a probable cyst, simple aspiration can be performed at that time, for it is both diagnostic and therapeutic. If the cyst is painful, aspiration should relieve that symptom. On the other hand, if the woman is in the radiology department and is found to have a mass on mammography suggestive of a cyst, confirmatory ultrasound can be done. If the cyst is obviously benign and nonpalpable, the patient should be informed but no intervention recommended, unless an ultrasound-guided aspiration is done for pain relief.

Solid Mass

A patient with a discrete solid mass should be referred to a surgeon even when the mammogram is negative. Surgical biopsy is the procedure of choice for any solid, dominant, persistent mass. There should be few exceptions.

Young women in their teens or twenties with a palpable mass most likely have a fibroadenoma. FNA or ultrasonography may be performed to complete the diagnostic evaluation but these women should have excision of the mass. **Regardless of the age of a woman, a clinically suspicious lesion should be evaluated completely. All palpable, discrete, solitary, noncystic masses should be excised.**

An area of thickening that is not a discrete mass and judged to be: 1) clinically negative by the surgeon; 2) negative cytologically (no malignant cells seen in the aspiration specimen); and 3) negative mammographically may be closely observed by the surgeon every 2-3 months until resolution or excision (negative triad). However, the surgeon and patient should recognize the possibility of an occasional delayed breast cancer diagnosis.

Vague Nodularity

There may be a discrepancy between what the patient perceives as a breast mass and what the examiner finds on careful physical examination of the breast. Where the patient feels a "lump," the examiner may find only slightly lobulated breast tissue. The patient may note the "lump" during the premenstrual phase. It may be a diffuse, poorly defined thickening that may or may not be matched in the opposite breast, or an area of irregularity or prominence such as normal, but nodular breast tissue. The areolar margin and the area beneath the inframammary fold may contain a number of small palpable nodules of normal breast tissue that are not suspicious and do not require biopsy. If the patient is concerned or anxious, it is good medical practice to advise her to return bimonthly or quarterly for reexamination until she and the examiner are convinced of the benign nature of the change. In menstruating women, return visits should occur at midcycle. If the mass persists after 3 months and can be distinguished from the remaining breast tissue, the patient should be referred to a surgeon.

If the patient or examiner is uncertain about the nature of a vague mass, an FNA, mammogram, and/or an ultrasound should be considered. Imaging should be performed before aspiration as FNA may produce bleeding that can cause difficulty in interpreting the mammogram or ultrasound.

Nonpalpable Mammographic Abnormality

Refer the patient to a surgeon if her mammography results are reported as American College of Radiology (ACR) categories[1] four *(suspicious abnormality)* or five *(highly suggestive of malignancy)*. If further mammographic evaluation with spot compression or magnification is suggested, or if ultrasound is advised *(assessment is incomplete)*, these imaging studies should be completed prior to surgical referral, since many equivocal mammographic abnormalities may be resolved with additional radiologic workup.

If the mammogram result is ACR category three *(probably benign—short interval follow-up suggested)*, the lesion is almost certainly benign, and there is only a maximum 2% possibility of cancer. Follow-up for these patients may include sequential imaging stud-

1. The American College of Radiology recognizes five levels of concern based on mammography: 1) negative; 2) benign finding; 3) probably benign finding—short interval follow-up suggested; 4) suspicious abnormality-biopsy should be considered; 5) highly suggestive of malignancy.

ies; the radiologist should determine the interval and type of follow-up. The low but measurable risk for a delayed diagnosis of breast cancer should be clearly communicated to the patient. If she is unwilling to accept this risk or is a high-risk patient, she should be referred to a surgeon. However, the patient should have a careful breast examination before the decision is made to follow with sequential mammograms, because clinical signs associated with the mammographic abnormality may mandate a biopsy.

Nonpalpable cysts detected by mammography and confirmed to be simple cysts by ultrasonography need not be aspirated except for relief of pain. A nonpalpable cyst not fulfilling complete criteria for a simple cyst may be aspirated with image guidance. If the mass has suspicious characteristics by ultrasound, an imaging-directed biopsy, either percutaneous or surgical, should be performed.

A decision as to what form of biopsy is appropriate for any given nonpalpable lesion found on mammography or ultrasound may be made by a surgeon in consultation with the radiologist and in accordance with the patient's wishes. The biopsy options that should be discussed with the patient include: 1) stereotactic or ultrasound-guided FNA; 2) stereotactic, large core needle biopsy; or 3) open surgical biopsy after needle localization.

Breast Pain

Breast pain is a common and often nonspecific symptom. The most common cause of a painful mass is a cyst. However, symptoms of pain or discomfort do not preclude a diagnosis of malignancy. A common cause for delay in the diagnosis of breast cancer is a failure to recognize the potential significance of a painful mass. Pain associated with a mass does not eliminate the possibility of cancer.

If results of the physical examination and mammography are negative, the most likely explanation of breast pain are “fibrocystic” changes or menstrual cycle influences. An explanation of the effects of hormonal cycling will reassure most patients. A trial of nonnarcotic analgesics such as ibuprofen, acetaminophen, or aspirin and the use of a brassiere that provides good support are suggested. 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. There is no role for therapy with male hormones. Refer the patient to a surgeon if there is persistent localized pain that is not responsive to conservative measures.

Nipple Discharge

The patient with a suspicious nipple discharge (characterized in the section on Symptom Assessment), should be referred to a surgeon, even in the absence of a palpable mass. Patients with any nipple discharge and a palpable mass should be referred to a surgeon.

Diagnostic mammography for a suspicious nipple discharge should be performed even though the yield is low. If a nonsuspicious nipple discharge is present, diagnostic mammography is of no benefit, but screening mammography should be recommended as appropriate for the patient's age.

Cytologic analysis of nipple discharge is rarely useful and is not cost-effective. Galactography (injection of contrast medium into spontaneously discharging ducts to delineate intraluminal abnormalities) is not widely available and is of questionable value. Medical workup of galactorrhea may be appropriate for profuse, persistent milky discharge, but pituitary adenomas are rare.

A spontaneous, bloody nipple discharge occurring in the third trimester of pregnancy may be regarded as a physiologic event that does not require evaluation unless it persists for several months after delivery. Milky, green, gray, or black discharge expressed from several ducts is not suspicious for cancer, and referral of the patient is not necessary, especially if the discharge is bilateral.

Skin or Nipple Changes

Patients complaining of any skin breakdown on the nipple-areola complex should be referred to a surgeon. Paget's disease of the nipple (the presence of in situ or invasive breast cancer with involvement of the nipple) may be the source of this symptom. Although eczema may involve the areola, it is rare.

The Persistently Worried Patient With a Negative Workup

Such a patient should be referred to a surgeon for a second opinion.

Breast Examinations That Are Difficult

The patient should be referred to a surgeon for evaluation when the breast examination is difficult because she: 1) has had a reduction mammoplasty or augmentation implantation; 2) has extremely large or dense multinodular breasts; 3) has had multiple biopsies with multiple scars; 4) is pregnant or lactating.

Physical diagnosis of breast cancer in pregnant or lactating women may be extremely difficult. Any pregnant or lactating woman with a clinically suspicious lesion should be referred to a surgeon without delay. Approximately 1 in 2,000 pregnant or lactating women has breast cancer, and 1% to 2% of breast cancers are diagnosed in pregnant women. Ultrasound imaging of a palpable mass or thickening can confirm a fluid-filled or complex mass (e.g. cyst or galactocele), a solid mass requiring biopsy, or a drainable abscess.

High-Risk Patients

Patients with a history of breast cancer should have oncologic follow-up with regularly scheduled clinical and imaging examinations. Patients at high risk of developing breast cancer as indicated by a family history of breast cancer among premenopausal first-degree relatives, diagnosis of atypia on breast biopsy, or multiple previous biopsies, may require different screening regimens. In such instances, a referral to a physician who is expert in the diagnosis of breast cancer is appropriate.

The authors are grateful to the following reviewers:

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UCLA School of Medicine
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APPENDIX 1
Management of Common Breast Problems

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Thorough communication with patients about all management options, their risks, and all test results, as well as written documentation of these discussions, is of the utmost importance to the provision of quality care.

Palpable Mass

Cyst

Ultrasound or cyst aspiration useful to differentiate between solid and cystic mass.

With aspiration, if mass does not disappear or fluid is bloody, send for cytology and refer to surgeon. Fluid can otherwise be discarded. Re-examine breast in six weeks for recurrence. If cyst recurs refer to surgeon. Otherwise, follow routinely.

Solid

Refer patient to surgeon for solid, dominant, persistent mass as biopsy is almost always indicated.

A normal mammogram does not eliminate need for further evaluation of a clinically suspicious mass. However, if mass is clinically benign on breast exam, and this is confirmed by cytologic exam and mammography, patient may be followed by a surgeon every three months until biopsy or resolution of problem.

Women <30 most likely have cyst or fibroadenoma. Ultrasound or needle aspiration may be used to confirm. Refer to surgeon for solid, dominant, persistent mass as biopsy is almost always indicated.

Vague Nodularity

If significant doubt exists about nature of mass, consider mammogram or ultrasound first and then fine needle aspiration (FNA) for cytologic exam. If mass appears benign — slightly lobulated breast tissue, or poorly defined thickening not matched in opposite breast — recheck bi-monthly or quarterly. If mass persists after 3 months and can be distinguished from remainder of breast tissue, refer to surgeon.

Abnormality of mammography — nonpalpable

For American College of Radiology (ACR) categories **four** (*suspicious abnormality-biopsy should be considered*) and **five** (*highly suggestive of malignancy*), refer to surgeon.

For ACR category **three** (*probably benign-short interval followup suggested*), patient may be followed with sequential imaging at an interval suggested by the radiologist. Clearly communicate to woman need for clinical and imaging followup.

If further mammographic/ultrasound evaluation advised (*assessment is incomplete*), obtain recommended imaging studies to better characterize the abnormality.

Nonpalpable simple cysts confirmed by ultrasound do not need aspiration except for pain relief. Cysts having suspicious characteristics need to be biopsied.

Breast Pain

Perform clinical breast examination (CBE) and mammography, if age-appropriate.

If exam and mammography negative, fibrocystic change is most likely. Reassure patient, offer a trial of a non-narcotic analgesic, and recommend use of a well-supporting brassiere.

If conservative measures do not relieve pain symptoms, referral to surgeon is indicated.

Skin/Nipple Change and Nipple Discharge

Women with skin breakdown on the nipple or areola should be referred to a surgeon.

Patient with palpable mass and any nipple discharge should be referred to a surgeon.

If discharge suspicious for neoplasm (*spontaneous; unilateral; confined to single duct; occurring in older patient; clear, bloody, serous, or serosanguinous*) send patient for mammography and surgical consult.

Nipple discharge, particularly if bilateral or multiductal, or milky, green, gray, or black, is not suspicious for cancer and needs no referral. If milky discharge is profuse, medical work-up for galactorrhea may be indicated.

The Worried Patient with a Negative Workup

Refer patient to a surgeon for a second opinion.

Difficult Breast Examinations

May refer woman to surgeon if she has had reduction or augmentation mammoplasty; if breasts very large or multinodular; if multiple biopsies severely scar breasts.

All women who are pregnant or lactating and have a breast mass or area of patient concern should be referred to a surgeon.

High Risk Patients

Consult breast cancer specialist for a woman with prior history of breast cancer, strong first-degree family history, or previous history of atypia or multiple biopsies.

Such a woman may need a special followup regimen.

APPENDIX 2
Breast Cancer Screening

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Screening Mammography

Scientific data support a recommendation for annual screening for women aged 50-74. Conclusive scientific data are not available to precisely define guidelines for other age groups. Several national organizations recommend screening mammography every 1-2 years for women 40-49; other organizations recommend that screening mammography begin at age 50 years.

Physical Examination

Breast examination should be performed annually as a part of a woman's routine physical examination if over 30, and should be encouraged for younger women as well.

Breast Self-Examination

Role of breast self-examination (BSE) in early detection of breast cancer is not clear. BSE should be taught, demonstrated, and encouraged, without placing undue emphasis on it.