

1. The palpable breast lump: information and recommendations to assist decision-making when a breast lump is detected

The Steering Committee on Clinical Practice Guidelines for the Care and Treatment of Breast Cancer

Abstract

Objective: To provide information and recommendations for assisting women and their physicians in making the decisions necessary to establish or exclude the presence of cancer when a lump is felt in the breast.

Evidence: Guidelines are based on a systematic review of published evidence and expert opinion. References were identified through a computerized citation search using MEDLINE (from 1966) and CANCERLIT (from 1985) to January 1996. Nonsystematic review of breast cancer literature continued to January 1997.

Benefits: Exclusion or confirmation of the presence of cancer with the minimum of intervention and delay.

Recommendations:

- Investigation of women with a breast lump or suspicious change in breast texture starts with a history, physical examination and usually mammography.
- The clinical history should establish how long the lump has been noted, whether any change has been observed and whether there is a history of biopsy or breast cancer. Risk factors for breast cancer should be noted, but their presence or absence should not influence the decision to investigate a lump further.
- The physical examination of the breast should aim to identify those features that distinguish malignant from benign lumps.
- Mammography can often clarify the nature of the lump and detect clinically occult lesions in either breast.
- Fine-needle aspiration can establish whether the lump is solid or cystic. When a tumour is solid, cells can be obtained for cytologic examination.
- Ultrasonography is an alternative method to fine-needle aspiration for distinguishing a cyst from a solid tumour.
- Whenever reasonable doubt remains as to whether a lump is benign or malignant, a biopsy should be carried out.
- When surgical biopsy is used, the aim is to remove the whole lump in one piece along with a surrounding cuff of normal tissue.
- Core biopsy, either clinically or image-guided, can usually establish or exclude malignancy, thus reducing the need for surgical biopsy.
- Thermography and light scanning are not recommended diagnostic procedures. The value of magnetic resonance imaging is still under investigation. It is not a routine diagnostic procedure at this time.
- The choice of procedure should take into account the experience of the diagnostician and availability of the technology in question.
- The work-up should be completed expeditiously and the patient kept fully informed throughout.
- Even when malignancy is not found, it may be prudent, in some cases, to arrange follow-up surveillance.

Validation: Guidelines were reviewed and revised by the Writing Committee, expert primary reviewers, secondary reviewers selected from all regions of Canada and by the Steering Committee. The final document reflects a consensus of all these contributors.

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Special Supplement

See page S83 for a list of the members of the Steering Committee

See page S7 for the names of those who also contributed to the authorship of this document

This guideline has been peer reviewed.

The detection of a lump in the breast is a common occurrence. Although most lumps are not caused by cancer, the possibility of malignancy must always be considered. Thus, from the moment a lump or a suspicious change in texture or resistance is felt in some part of the breast, a series of decisions must be taken to exclude or establish the diagnosis of cancer. These guidelines are intended to assist women and their physicians in achieving this objective using the minimum of procedures. The factors that guide the decisions to be taken are reviewed in this guideline. Each recommendation is followed by a brief review of the evidence and rationale on which it is based. The procedure for investigating suspicious features detected by mammography is considered in a separate document: "2. Investigation of lesions detected by mammography."

Method

The evidence used in developing these guidelines is based on a systematic citation search for English-language titles related to breast cancer using MEDLINE from 1966 and CANCERLIT from 1983 to January 1996, and additional references cited in published reviews plus an informal review of breast cancer literature to January 1997. Evidence was graded as indicated on page S2. As far as possible, level I-III evidence was used, but when experimental evidence was weak or lacking, the opinion of respected authorities (level IV) was employed. After the development of draft guidelines by the author, the document underwent iterative reviews and revisions by a Writing Committee consisting of 8 members of the Steering Committee for Clinical Practice Guidelines, by 3 primary expert reviewers and by all members of the Steering Committee. It was then submitted to 19 secondary reviewers consisting of surgical, medical and radiation oncologists, nurses, family physicians and breast cancer survivors selected from all regions of Canada. Throughout, each draft was reviewed by the author. The final document was approved by the Steering Committee and reflects a substantial consensus of all of those involved in its preparation.

Recommendations (including evidence and rationale)

- **Investigation of women with a breast lump or suspicious change in breast texture starts with a clinical history, physical examination and usually mammography.**

Most lumps detected in the breast are not malignant. However, once a lump or suspicious change in breast texture is discovered, it is necessary to establish whether it is malignant or not. The first step is to obtain a clinical history and carry out a physical examination. When necessary, this is followed by further diagnostic procedures (mammography, fine-needle aspiration [FNA], ultrasonography) and, if uncertainty still remains, by tissue biopsy (core or

open surgical). Throughout, the principle is to establish a reliable diagnosis using the minimum of procedures. The approach is the same for women with breast implants, with special attention paid to determining the integrity of the implant.

- **The clinical history should establish how long the lump has been noted, whether any change has been observed and whether there is a history of biopsy or breast cancer. Risk factors for breast cancer should be noted, but their presence or absence should not influence the decision to investigate a lump further.**

The presence of certain factors increases the likelihood of breast cancer developing. These factors include a history of a biopsy of either breast showing atypical hyperplasia,¹ lobular carcinoma in situ (LCIS)² or ductal carcinoma in situ (DCIS),³ a history of a resected carcinoma⁴ or radiation treatment for Hodgkin's disease in childhood,⁵ or a strong family history of breast cancer (level III evidence).⁶ The risk of breast cancer also increases with age (level III evidence). In Canada in 1992 the incidence per year of breast cancer in women was approximately 0.35/1000 for those aged 30 to 39 years, 2.2/1000 for those aged 50 to 59 years, and 4.0/1000 for those aged 70 to 79 years.⁷ Although known risk factors, including aging, all increase the risk of breast cancer, they do not substantially influence the probability that any particular lump will be malignant. **The fact remains that most women in whom breast cancer is diagnosed have no identifiable risk factors and breast cancer does not develop in most women with common risk factors.**

- **The physical examination of the breast should aim to identify those features that distinguish malignant from benign lumps.**

Breast examination should be accompanied by a thorough examination of the axilla and supraclavicular areas to check for nodal involvement. Premenopausal women are best examined 1 week after the onset of the last menstrual period when engorgement of the breast is at a minimum (level IV evidence).⁸ Descriptions of how the breast should be examined are available elsewhere.⁹ However, certain features (described below) require particular attention.

Paget's-like lesions of the nipple are frequently caused by breast cancer.¹⁰

The condition may resemble a benign dermatitis that is sometimes moist and eczematous or sometimes dry and psoriatic and usually accompanied by thickening of the nipple-areolar complex. There may be a sensation of itching and burning. These features usually reflect centrifugal spread of cancer cells from the ductal epithelium into the overlying skin of the nipple.⁹ Biopsy is indicated when the condition fails to respond rapidly to topical treatment.

Smooth, well-demarcated lumps are usually benign (level IV evidence).

These are either cysts or fibroadenomas. Lesions that are less smooth and less mobile, with poorly defined margins, increase the suspicion of carcinoma. Rubbery-type plaques that blend into the surrounding breast tissue are not true masses but are usually benign zones of fibroglandular change. In older women, the inferior ridge of the breast may become indurated in a crescent-shaped pattern as a result of the weight of the overlying breast. This feature represents simple fat compression and is benign, especially if symmetric.

Nipple discharge is not a common feature of cancer.

Persistent unilateral discharge may be due to cancer in 4% to 21% of cases.⁹ The discharge may be watery, sanguineous, serosanguineous or serous.¹¹ A nonbloody discharge is unlikely to be caused by cancer,¹² and even a sanguineous discharge is often not due to cancer.¹³ Also, a bilateral discharge is unlikely to be caused by cancer.

Breast cancer may or may not be painless.

Although breast cancers are usually painless, the cancer may be accompanied by discomfort.⁹ Thus, the presence or absence of pain and tenderness should not influence the investigation of a suspicious lump.

Three common causes of "innocent" breast lumps can often be identified by an experienced examiner through the clinical history and examination alone, without the need for further study.

These are: fibroadenomas, fibrocystic changes and gross cysts.

Fibroadenomas

Upon palpation, fibroadenomas feel very similar to cysts. They are round, circumscribed, firm and very moveable. They tend to occur in young women from the 'teens onward, whereas cysts tend to occur somewhat later in life, beginning in the third or fourth decade.

Fibrocystic changes

Pain is probably the most frequent breast complaint that brings the patient with fibrocystic changes to a physician's office. The commonest cause of pain is benign fibroglandular change, previously called fibrocystic disease. The pain is cyclic, usually beginning soon after ovulation and intensifying until menstruation begins, then disappearing rapidly. It may last from a few days to 2 or 3 weeks out of each cycle. The pain frequently radiates toward the shoulder and arm and is accompanied by a burning sensation. Fibrocystic changes are usually symmetric and occur most often in the upper, outer

quadrants. The texture is that of a rubbery, thickened plaque, but focal areas can be quite indurated. The process typically lacks discreteness. The affected tissue appears to blend into the more normal breast tissue without a clear demarcating line. In contrast, both benign and malignant tumours have a more discrete shape. Benign tumours such as cysts or fibroadenomas have very smooth surfaces. Carcinomas, although discrete, tend not to have smooth borders and may have a more irregular, ill-defined surface.

Gross cysts

These tend to be round, circumscribed and somewhat moveable. They may be painful or tender and, although they may be soft, they can be quite hard when the fluid is under tension.

The efficacy of the clinical examination in distinguishing malignant from benign breast lumps depends on the expertise and experience of the examiner.

The technique of manual examination is not self-evident; it improves with learning and practice (level III evidence).¹⁴ In a study by Rimsten and colleagues,¹⁵ cancer was found in 92.5% of patients when an experienced examiner diagnosed "definite cancer" on palpation. Van Dam and colleagues found physical examination had a positive predictive value of 73% and a negative predictive value of 87%.¹⁶

A clinically suspicious lump requires further investigation. The choice for the next step (i.e., mammography, ultrasonography or FNA) will vary according to the woman's age, the nature of the lump, the local availability and reliability of the technologies in question and the preference of the physician.

- **Mammography can often clarify the nature of the lump and detect clinically occult lesions in either breast.**

Because younger women tend to have mammographically dense breast tissue, a mammogram is unlikely to give useful information.⁹ However, once a woman reaches her mid-30s its value becomes greater, and mammography should increasingly become part of the work-up of a suspicious breast lump (level IV evidence).⁹ When a mammogram is interpreted by an experienced radiologist it can often clarify the nature of the lump in question as well as provide information about other areas of the breast. Irregular or clustered calcifications seen in the area of the mass increase the suspicion of carcinoma. Mammography can also provide information about the opposite breast. Therefore, optimal mammographic imaging should normally be carried out, including 2 views of each breast with spot compression and/or magnification views of any abnormal areas. However, the overall level of sensitivity of mammography in palpable breast cancers may be no more than 82%¹⁷ and may be even lower in premenopausal women (level III evidence).¹⁸ **Thus, although a suspicious mammogram may increase the probability of malignancy, a nor-**

mal mammogram cannot exclude a cancer that is suspected on clinical grounds.

The choice of whether to proceed first to mammography or FNA varies in different centres as well as with the patient in question. Physicians who are experienced in FNA usually proceed directly to this intervention, usually reaching a final diagnosis more rapidly. However, because of the possibility that needling may cause the mammographically smooth and sharply defined margins characteristic of benign, solid lesions to become less distinct, some physicians order mammography before carrying out needle aspiration.¹⁹

- **Fine-needle aspiration can establish whether the lump is solid or cystic. When a tumour is solid, cells can be obtained for cytologic examination.**

FNA is inexpensive, easy to perform, requires no advance preparation, is virtually painless and can be carried out in the office, usually without need of local anesthesia.²⁰ When clear or straw-coloured or grey-green fluid is obtained and the mass disappears completely, the diagnosis is a simple cyst. This is benign and the fluid should not be sent for analysis, since it is invariably normal (level III evidence).^{21,22} If the fluid is bloody, a carcinoma with a cystic component may exist,¹² and the fluid should be sent for cytologic examination.⁹ If the fluid is free of blood, the lump disappears completely and the mammogram is negative, then no further investigation is necessary.

If fluid is not obtained by FNA or the mass persists after fluid withdrawal, the same needle puncture can be used to obtain a specimen for cytologic examination. Success in obtaining satisfactory samples for cytologic examination using FNA is operator-dependent,⁹ and accuracy of interpretation depends on the availability of a pathologist experienced in cytology. The procedure should provide satisfactory specimens for cytologic examination in 90% to 95% of cases²³ and can yield an accuracy rate of 95%.²⁴ In a follow-up study of the analysis of 835 palpable breast lesions, of 135 FNAs reported "positive" there was 1 false-positive (0.7%) case. Of 92 reported "negative" there were 14 false-negative cases, resulting in a false-negative rate of 15.2% (level III evidence).²⁵ In a recent comparison of nonstereotactically guided FNA and core biopsy for palpable breast lumps, both techniques were found to be sensitive, at 97.5% for nonstereotactically guided FNA and 90% for core biopsy.²⁶

Cytologic examination of a specimen obtained by FNA can confirm the malignant nature of a highly suspect lump and also provide useful information even in cases in which the suspicion of cancer is low. For example, in a patient with typical fibroglandular changes, it can help reassure the physician and the patient that a benign process is occurring. However, the technique is most useful at the extremes of the diagnostic spectrum: when cancerous cells are not found, this confirms an obviously benign diagnosis and surgery is avoided; when cancerous cells are found, a firm diagnosis of cancer can be made, allowing better planning of surgery. When cytologic examination, mammography and physical examination all indicate cancer, the diagnosis is likely to be confirmed at open biopsy in

more than 99% of cases; when the results of all 3 indicate benign lesions, cancer will be found in less than 0.5% of cases.²⁷

- **Ultrasonography is an alternative method to fine-needle aspiration for distinguishing a cyst from a solid tumour.**

In the hands of an experienced operator, ultrasonography can be used to identify a cyst reliably (level III, IV evidence).²⁸ It is of particular value in determining whether nonpalpable mammographic abnormalities are cystic or not. (This is described in more detail in guideline 2.)

- **Whenever reasonable doubt remains as to whether a lump is benign or malignant, a biopsy should be carried out.**

In the absence of positive cytologic results, the decision regarding when to proceed to a biopsy requires judgement, using all available information including the history, clinical signs, and mammographic and ultrasonographic information. The clinician's responsibility is to establish or exclude the diagnosis of cancer but at the same time minimize the number of unnecessary biopsies. When the decision is made to perform a biopsy, either core biopsy or open surgical biopsy can be used. The choice will depend on the level of experience, expertise and preference of the examiner, which will vary in different centres.

- **When surgical biopsy is used the aim is to remove the whole lump in one piece along with a surrounding cuff of normal tissue.**

A simple biopsy that later reveals an unexpected carcinoma will often require a second operation to ensure clear margins. This makes it more difficult to perform a proper localized operation for cancer at the second intervention because the site is distorted by reaction and discoloured by hematoma (level V evidence). Thus, complete excision is more difficult, making pathological evaluation more uncertain. Surgical biopsy procedures should therefore be performed as a lumpectomy, as if the diagnosis of cancer was already established. The suspicious mass should be excised in its entirety with a cuff of normal tissue so that it can be processed by the pathologist for evaluation of margins.

- **Core biopsy, whether clinically or image-guided, can usually establish or exclude malignancy, thus reducing the need for surgical biopsy.**

Core biopsy is widely used as an alternative to surgical biopsy. For large, palpable masses, the biopsy needle can be guided by touch. The procedure provides 1 to 6 slender cores of tissue suitable for histologic diagnosis, allowing an initial differentiation of invasive disease from in situ disease and the determination of hormone receptor levels. Insufficient specimens are rare. The accuracy of clinically guided core biopsy is greater when the palpable mass is large (level III evidence). In one study of 150 core biopsies of palpable lumps, sensitivity

was 89% overall, increasing to 94% for lesions over 2.5 cm in diameter. There were no false-positive results.²⁹

For small lesions that are difficult to palpate, stereotactic or ultrasonographically directed needle core biopsy can provide precise localization (level III evidence) (see also guideline 2). In a study by Donegan of 1784 such biopsies collected from 5 different reports, there were no false-positive diagnoses. However, the false-negative diagnoses varied between 1.6% and 19%.¹⁷ Thus, in centres in which this technique has been demonstrated to have high specificity, it is an acceptable option. It is reported to be safe, reliable and cost-effective and can often spare the patient an open biopsy.^{30,31}

Regardless of whether FNA or core biopsy is used, the diagnosis of cancer should be confirmed as often as possible without recourse to open surgical biopsy. This allows for frank discussion of the diagnosis with the patient and better planning of the surgical intervention, and may often eliminate the need for second surgical procedures.

- **Thermography and light scanning are not recommended diagnostic procedures. The value of magnetic resonance imaging is still under investigation. It is not a routine diagnostic procedure at this time.**

Thermography is a technique that measures the increased heat radiating from a breast carcinoma. Introduced by Lawson in 1956, it is capable of detecting symptomatic cancers.³² However, its sensitivity to small cancers has now been shown to be close to random chance,³³ and the Beahrs Committee of the National Cancer Institute (NCI) recommended in 1977 that thermography be discontinued as a routine screening modality in the Breast Cancer Detection Demonstration Project (BCDDP) of the NCI.³⁴ In 1980, a study involving the blinded interpretation of 576 thermograms from the BCDDP by 10 experienced thermographers concluded that the "index of detectability" for the population studied was no better than would result from chance (level I evidence).³⁵ There is no role for this technique at present outside structured clinical trials involving the testing of improved technology.

Light scanning is a variation on transillumination, also called diaphanoscopy. Lack of specificity and sensitivity limit its usefulness.³³

Magnetic resonance imaging takes advantage of the contrast provided by the zone of neovascularization that surrounds growing tumours. Contrast enhancement is necessary to visualize small lesions. The technique is still cumbersome, slow and expensive, and its application is currently confined to research.

- **The choice of procedure should take into account the experience of the diagnostician and availability of the technology in question.**

Clinical examination requires skill and experience. Confidence in the results of FNA and interpretation of cytologic specimens, core biopsy results and mammograms are all dependent on skill and experience. When choosing procedures,

both the experience of the diagnostician and the availability of the technology in question must be considered.

- **The work-up should be completed expeditiously and the patient kept fully informed throughout.**

The detection of a breast lump is a source of great anxiety to a patient until its nature is determined. To diminish the psychologic stress caused by diagnostic uncertainty, the work-up of a breast lump should be completed as rapidly as possible, and long waits to obtain tests should be avoided. This requires good communication and cooperation among all involved, including family physicians, surgeons, radiologists and pathologists (level V evidence).

Maintenance of good communication between a patient and her physician will not only diminish immediate anxiety but may influence psychologic well-being many months later (level III evidence).^{36,37} Thus, full and sympathetic explanations at every step, with time for and encouragement of questions, are an important component of the health care of these women.

- **Even when malignancy is not found, it may be prudent, in some cases, to arrange follow-up surveillance.**

Benign or borderline mammographic abnormalities or indeterminate nodules for which cytologic examination does not detect malignancy may be best followed up by a repeat examination to detect possible evolution. Thus, even when a decision is made on clinical grounds that a lump is nonmalignant, it may sometimes be prudent to schedule a follow-up visit or visits (level IV evidence).

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