2. Investigation of lesions detected by mammography

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

Abstract

Objective: To provide information and recommendations to facilitate decision-making when a mammographic abnormality is detected by screening.

Evidence: References identified by use of MEDLINE, AIDSLINE, CANCERLIT and reference lists of review articles to December 1996. Where experimental evidence is lacking, recommendations are based on expert opinion. The evidence is graded accordingly in "levels" (page S2).

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

Recommendations:
- When an abnormality is detected on screening mammography, clinical evaluation and thorough radiologic work-up are needed to determine its significance.
- Clinical evaluation should include a history and a thorough examination of the breast, axilla and supraclavicular areas.
- In the radiologic work-up, diagnostic mammograms should be obtained with additional views, spot compression and magnification views as appropriate.
- Current mammograms should be compared with previous mammograms whenever possible.
- The mammographic report should include a precise description of the abnormal features visualized and an estimate of the level of suspicion of cancer they imply.
- Whenever there is any doubt in the interpretation of mammograms, the interpretation of 2 experienced readers should be obtained. (The following radiologic classification into 4 categories is suggested: 1 — benign, not due to cancer; 2 — low risk, probability of cancer under 2%; 3 — intermediate risk, probability of cancer 2% to 10%; 4 — high risk, probability of cancer over 10%.)
- Ultrasonography can be used to clarify the nature of noncalcified nodular lesions.
- Management decisions require close communication between the woman and her physicians. Throughout, a clinician in charge should be identified who will coordinate and transmit all decisions. Management will depend on the estimated level of risk
- *Category 1* abnormalities require no further investigation.
- *Category 2* abnormalities may be followed up by periodic mammographic and clinical examinations.
- Follow-up examination of category 2 abnormalities should be carried out at approximately 6 and 12 months. If the abnormality is stable, examination should be repeated annually for 2 to 3 years thereafter.
- The rationale of follow-up should be explained, and women should be made aware that it is not possible to provide complete assurance that an abnormality is benign.
- *Category 3* abnormalities usually require image-guided fine-needle or core biopsy.
- Every image-guided needle biopsy should be accompanied by a full report.
- *Category 4* abnormalities should usually be excised. This may be preceded by image-guided needle biopsy.
- When surgical biopsy is carried out, the margins of the resected specimen must be free of tumour.
- The intact pathology specimen should be examined radiographically to confirm that all mammographic abnormalities have been removed.
- The patient should be kept fully informed as to the reason for each test and the meaning of its results. The process, from initial detection of the mammographic abnormality to the final management decision, should be completed as rapidly as possible.

Validation: The guidelines were reviewed and revised by a writing committee, expert primary reviewers, secondary reviewers selected from all regions of Canada and by the Steering Committee. The final guidelines reflect a consensus of all these contributors.

Sponsor: The Steering Committee on Clinical Practice Guidelines for the Care and Treatment of Breast Cancer was convened by Health Canada.

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As the use of mammographic screening increases, more radiographic abnormalities are being detected in apparently normal, healthy women. Although most of these abnormalities turn out not to be due to cancer, all of them cause anxiety. Therefore, each time an abnormality is detected on a screening mammogram it is important that a diagnosis be made as soon as possible with the minimum of anxiety, pain and inconvenience to the patient.

Once a screening mammogram is reported to show an abnormality, a physical examination of the breast is required, along with a thorough radiologic work-up. (When a breast lump is detected the investigative steps are different, as described in guideline 1: "The palpable breast lump: information and recommendations to assist decision-making when a breast lump is detected.") The objective of the radiologic work-up of a nonpalpable mammographic abnormality is to produce an accurate description of the abnormality and an estimate of the level of suspicion of cancer, based on high-quality diagnostic mammograms. With this information, the decision can then be taken whether to ignore the abnormality, to follow it up with periodic clinical and mammographic examinations or to carry out a biopsy of the abnormality.

Method

Draft guidelines were initially prepared by an academic surgical oncologist experienced in the management of patients with breast cancer and by a family physician. A systematic search was carried out for all relevant articles using the Medlars database which includes MEDLINE from 1966, HEALTH from 1975, AIDSLINE from 1980 and CANCERLIT from 1983, up to December 1996. Additional titles were obtained from the reference lists of review articles and books. The evidence was evaluated and categorized into 5 levels (see page S2). As much as possible, statements and recommendations were based on objective evidence (levels I, II and III) and, where this was lacking, on the experience and judgement of expert authorities (evidence levels IV and V).

The draft guidelines were then reviewed and revised successively by a writing committee consisting of 5 members of the Steering Committee, by expert primary reviewers (surgical oncologists and diagnostic radiologists) and by all members of the Steering Committee. The document was then submitted to secondary reviewers consisting of nurses, surgical and medical oncologists, breast cancer survivors, diagnostic radiologists and family physicians from all across Canada. After revision, the final guideline document was approved by the Steering Committee. This document reflects a consensus of all of these contributors.

Recommendations (including evidence and rationale)

The abnormal mammogram

- **When an abnormality is detected on screening mammog-**

raphy, clinical evaluation and thorough radiologic work-up are needed to determine its significance.

The report of an "abnormality" on a mammogram does not necessarily indicate the presence of cancer. Cancers may leave clues on the radiographic image of the breast, such as small flecks of calcium or some distortion of the normal breast architecture. Even though these features may suggest the presence of cancer, they are not diagnostic of cancer. In fact, most of such findings are not due to cancer. In the British Columbia screening program, approximately 6% of mammograms were reported to be "abnormal." However, of these, less than 6% were caused by cancer.[1]

- **Clinical evaluation should include a history and a thorough examination of the breast, axilla and supraclavicular areas.**

Clinical evidence of cancer and of nonmalignant conditions should be sought to explain the mammographic abnormalities. The issues to be considered in the history and the steps to follow when a breast lump is found are described in guideline 1: "The palpable breast lump: information and recommendations to assist decision-making when a breast lump is detected." The value of the clinical work-up depends on adequate experience and expertise.

- **In the radiologic work-up, diagnostic mammograms should be obtained with additional views, spot compression and magnification views as appropriate.**

Screening mammograms are those obtained when mammography is carried out in the absence of abnormal signs or symptoms with the goal of detecting cancer early. Once a screening mammogram indicates an abnormality, high-quality diagnostic mammograms are used, since these may show better definition of the extent and location of abnormalities than routine screening mammograms and may clarify the characteristics of poorly defined or indeterminate lesions.[2,3] Magnification and spot compression views, in which local pressure is used to displace some of the surrounding breast tissue, frequently provide clearer definition of small densities and clarify the structure and extent of larger lesions.[4] Microcalcifications in particular warrant further evaluation with magnification mammographic examination, which permits better evaluation of the size, density, shape, number and extent of microcalcifications. Magnification mammographic examination should be performed in craniocaudal and straight lateral projections to verify, localize and characterize the calcifications.

Each mammogram should be scrutinized to verify that it is of high quality, that 2 projections have been obtained (mediolateral oblique and craniocaudal), that identification markers are present and that all breast tissue is present on the films. Both the sensitivity and specificity of the mammogram are highly dependent on its quality. The Canadian Association of Radiologists has defined the minimal standards of equipment and levels of personnel training for high-quality mammo-

graphic examinations.[5] Mammographic facilities that are certified by this body maintain these standards.

- **Current mammograms should be compared with previous mammograms whenever possible.**

A change in the mammographic images over time can have diagnostic significance and can substantially influence the probability of malignant disease.[6] Thus, it is important to ensure satisfactory storage of mammograms, with easy retrieval (level V evidence).

The report of the mammographic work-up

- **The mammographic report should include a precise description of the abnormal features visualized and an estimate of the level of suspicion of cancer they imply.**

The report should include a precise description of the abnormalities, including specific comment on the presence of masses, with a precise description of their size, density, shape and margins. Other features that should be noted include microcalcifications, architectural distortion, abnormal vasculature and asymmetry (level IV evidence).[7]

The probability of cancer ("index of suspicion") indicated in the report will directly influence subsequent management decisions. Some abnormalities, such as microcalcifications occurring in a spiculated mass, are associated with a relatively high probability of cancer. However, at the other extreme, well-circumscribed masses with smooth margins usually represent benign lesions. Thus, based on the different mammographic appearances, an approximate estimate of the cancer risk can be made.[4]

Some radiologists may use this information to make management recommendations. However, others prefer to categorize the abnormalities according to the estimated risk of cancer that the abnormalities imply. The following risk stratification system is adapted from Morrow and colleagues,[8] and is similar to the classification suggested by the American College of Radiology:[9]

- Category 1. Benign. Not due to cancer.
- Category 2. Low risk. Probability of cancer less than 2%.
- Category 3. Intermediate risk. Probability of cancer 2% to 10%.
- Category 4. High risk. Probability of cancer over 10%.

The attribution of a numeric percentage risk has no precise quantitative meaning; it is intended only to give more meaning to the expressions "low," "intermediate" and "high" risk, comparable to the descriptions "probably benign," "suspicious" and "highly suspicious."[9,10]

Since performing a biopsy of every mammographic abnormality would result in numerous unnecessary interventions, management strategy should aim for the highest biopsy positivity rates consistent with safety (level V evidence). At present, however, there is considerable variability in the management decisions that are made after mammographic abnormalities have been detected. In a review of 17 reports, the proportion of positive biopsies varied between 9% and 65%, with most authors reporting positivity rates between 15% and 30% for in situ and invasive cancers.[4]

It has been shown that, based on risk classification schemes similar to those already noted, management strategies can be developed which are safe and efficient and which minimize recourse to biopsy (level III evidence).[8] Of 267 women referred for surgical breast biopsy to Morrow and her colleagues, 44% were considered to have benign lesions (category 1 or 2) on the basis of the mammogram and were not investigated further. In none of these patients did cancer develop in the subsequent 2 years. Sixteen percent were judged to be at intermediate risk (category 3) and were followed up with regular mammography. Of these, changes were noted in 5%. Surgical biopsy was carried out on this group and 1 cancer was found. Forty percent were considered to be at high risk (category 4), and all of these women underwent a biopsy, with cancer positivity rates of 36% for surgical biopsy and 15% for stereotactically guided needle biopsy. Thus, fewer than half of the referred women underwent a biopsy, with an overall surgical biopsy positivity rate of 36%. Of the tumours identified, 90% were either stage I or ductal carcinoma in situ (DCIS).[8] Comparable results have been reported by other researchers using the same approach.[11]

- **Whenever there is any doubt in the interpretation of mammograms, the interpretation of 2 experienced readers should be obtained.**

Radiologists' interpretations of the mammographic image can sometimes differ substantially, and it has been shown that predictive accuracy can be increased by a second reading (level III evidence).[12–15] In all but completely straightforward cases, or whenever a referring physician who is experienced in mammographic interpretation disagrees with the radiologist's interpretation, the opinion should be obtained of a second radiologist who is also experienced in mammographic interpretation (level V evidence).

- **Ultrasonography can be used to clarify the nature of noncalcified nodular lesions.**

There is level III evidence, based on descriptive case series, of the value of ultrasonography in differentiating simple cysts from complex cysts or solid masses.[16] Whenever doubt exists, aspiration under ultrasonographic guidance can both diagnose and treat the abnormality, thus avoiding the need for further mammography.[17]

Communication of management decisions

- **Management decisions require close communication between the woman and her physicians. Throughout, a clinician in charge should be identified who will coordinate and transmit all decisions.**

A woman experiences much anxiety between the time she is informed of an abnormality and the time that its significance is established. The importance of the manner in which information is imparted has not been quantitated but has been vividly described.[18] It is therefore important that the work-up be completed rapidly and that the patient be helped to understand all management decisions and encouraged to participate in the decision-making process.[8] This requires close cooperation between the members of the management team and explicit identification, at all times, of the team member who is responsible clinical management decisions (level IV evidence).

The type of investigation/management will depend on the estimated level of risk.

Once optimal mammographic information has been obtained, the decision must be made whether to reassure the patient, arrange for follow-up, perform a biopsy or excise the growth. The advice given will largely depend on the estimated level of risk. The following management decisions are suggested on the basis of the risk classification categories outlined earlier.

- *Category 1* abnormalities require no further investigation.

Even though a woman may receive assurance that a mammographic abnormality is not a malignant mass, she may still experience significant anxiety. In a follow-up study, women with a false-positive mammogram had a greater prevalence of anxiety (29%) than those with a negative mammogram (13%) for as long as 18 months afterward (level III evidence).[19] Thus, careful counselling is important, even of women with category 1 abnormalities (level V evidence).

- *Category 2* abnormalities may be followed up by periodic mammographic and clinical examinations.

The extent to which mammographic surveillance can be considered a reliable means of follow-up depends on several factors: the accuracy with which the level of risk was determined, the probability that mammographic surveillance will identify (by a change over time) those lesions that are malignant and the probability that cancers diagnosed by these means will be diagnosed early in their course when they still carry a favourable prognosis.[6]

There are several concerns regarding reliance on periodic follow-up. These include the lack of absolute assurance that the lesion in question is benign, the possibility that small, occult breast cancers may be missed at a time when a successful clinical outcome from treatment would be most likely and fear of potential litigation.[9] However, it has been shown that mammographic surveillance of lesions that are likely benign can be carried out safely (level III evidence).[4,20–22] In a follow-up study of 543 abnormalities in 382 women, biopsies were eventually carried out on 3 abnormalities and, of these, 1 proved to be caused by ductal carcinoma in situ (DCIS) and

the other 2 were benign.[23] Follow-up is now a widely accepted strategy for women with low-risk abnormalities.

- **Follow-up examination of category 2 abnormalities should be carried out at approximately 6 and 12 months. If the abnormality is stable, examination should be repeated annually for 2 to 3 years thereafter.**

No studies have yet defined the optimal surveillance interval by comparing the efficacy of different follow-up protocols.[6] Therefore, the timing of mammographic follow-up must be based on estimates of tumour doubling time. Most cancers will show a change within 1 year, although very rarely some may appear to remain stable for more than 2 years.[24] Mammographic examination is usually carried out at 6 and 12 months and again after 1 and 2 years if the previous mammograms show no change (level IV evidence).[24]

- **The rationale of follow-up should be explained, and women should be made aware that it is not possible to provide complete assurance that an abnormality is benign.**

The ultimate decision regarding whether to follow up or to perform a biopsy on a lesion that has a low probability of being malignant must be made only after full discussion with the patient.[25] Some patients may feel strongly that any risk is too high, and these women will prefer to undergo a biopsy. If the follow-up option is chosen, the patient should be made fully aware that the lesion is being kept under observation because it may not be benign.

- *Category 3* abnormalities usually require image-guided fine-needle or core biopsy.

Image-guided needle biopsy should generally be used to investigate category 3 lesions unless there are widespread calcifications or the lesion cannot be identified in the stereotactic views when surgical biopsy will be necessary. In the case of a suspected papillary lesion, the patient should also be referred for open surgical biopsy because of the difficulty in pathologically interpreting the core specimen (level V evidence).

There is no objective evidence to indicate the level of suspicion at which a biopsy should be performed on a mammographically detected, nonpalpable lesion. It has been suggested that the estimated risk of malignancy should be at least 2% (level IV evidence).[26]

Biopsy techniques are evolving and there is variation from centre to centre as to the technique that may be chosen. Cells can be obtained by fine-needle aspiration (FNA) for cytologic analysis (FNAC) under ultrasonographic guidance. FNAC has the advantage of being minimally traumatic and can give reliable information, when the samples are interpreted by an experienced cytologist. However, ultrasonography does not allow for visualization of very small carcinomas or those that appear on mammograms as microcalcifications only.[27] Furthermore,

this technique cannot distinguish between invasive cancer and DCIS, and inadequate samples are not uncommon. In a series of 254 surgically verified, nonpalpable, noncystic mammographic lesions sampled by ultrasound-directed FNAC, 11% of samples were inadequate. However, analysis of the remaining samples showed a sensitivity of 91% and specificity of 97%, and 2% gave false-negative results.[28] The technique must be learned, and its accuracy depends on the experience and skill of the operator and the cytologist. In a Canadian study, the first 226 stereotactic FNAs were successful in only 70% of attempts.[29] In general, the sensitivity of FNAC ranges between 68% and 93% and the specificity from 88% to 100%, with insufficient sampling rates ranging from 0% to 38%.[26]

In contrast to FNAC, core biopsy does not require special cytologic expertise and can sometimes give a more definitive result. The reported reliability varies in different studies. In reports comparing stereotactic core biopsy to surgical biopsy, the sensitivity of core biopsy for malignant lesions varies from 85% to 98%.[26,30] However, in a multi-institutional study in which the results of 1363 image-directed core biopsies were compared with the results of subsequent surgical biopsies, there was 98% agreement and only 1.1% false-negative core biopsies (level III evidence).[31] Stereotactic core biopsy is also a technique that must be learned, and before placing reliance on this technique, each centre should verify its sensitivity and specificity by comparing results with those of surgical biopsy.[26]

Both FNAC and core biopsy provide reliable information that can result in the avoidance of many surgical biopsies and allow for better planning of surgery. Also, both rarely cause syncope or minor bleeding (occurring in approximately 1% of 203 fine-needle or wire-placement procedures).[32] In the multi-institutional study cited above, of 3765 image-directed core biopsies 6 resulted in complications (3 hematomas and 3 infections, which required drainage or antibiotics or both).[31] No case of seeding of the needle track was reported.

- **Every image-guided needle biopsy should be accompanied by a full report.**

An image-guided breast biopsy is as much a surgical procedure as is an open biopsy done by a surgeon. Thus, it should be accompanied by an accurate and informative report which should include comment on such factors as the use of local anesthesia, the size of needle used, how closely it was situated to the lesion, the quantity of material obtained, how the patient tolerated the procedure and whether the pathological features correlate with the mammographic findings (level V evidence).

- *Category 4* **abnormalities should usually be excised. This may be preceded by image-guided needle biopsy.**

When the probability of cancer is very high, fine-needle and core biopsies can be omitted and surgical biopsy carried out directly.[26] However, in some centres where image-guided needle biopsy has been proven to have very high sensitivity and specificity, it may be the next step in the diagnostic procedure. The choice of biopsy technique must be guided by the local level of confidence established for each technique and by the need to arrive at a final diagnosis and treatment with the minimum of interventions.

- **When surgical biopsy is carried out, the margins of the resected specimen must be free of tumour.**

Before the surgical biopsy of a nonpalpable abnormality is performed, the lesion must be localized. This is usually done by placing fine wires under radiographic or ultrasonographic control. The number of wires placed varies in different centres and with the extent and complexity of the lesion.[33] Consultation with the radiologist and review of the mammogram are essential to determine the placement of the wires, the site of the incision and the volume of tissue to be removed.[34] The biopsy should be performed as if it were a therapeutic segmental mastectomy, and incisions should be planned according to National Surgical Adjuvant Breast Project guidelines (level IV evidence).[17,35]

- **The intact pathology specimen should be examined radiographically to confirm that all mammographic abnormalities have been removed.**

The lesion should be removed in one piece and the edges of the specimen marked with sutures to indicate proper orientation (level IV evidence).[35] Guide wires should remain in place, and the specimen should be examined radiographically immediately after excision to confirm the presence of all of the mammographic abnormalities. The radiologist should supply a written report to confirm that the mammographic abnormality has been completely removed (level V evidence).

- **The patient should be kept fully informed as to the reason for each test and the meaning of its results. The process, from initial detection of the mammographic abnormality to the final management decision, should be completed as rapidly as possible.**

A woman's anxiety regarding a mammographic abnormality can be reduced substantially if she is kept informed and if the diagnosis is expedited. Maintenance of good communication between the patient and her physicians has been shown to diminish immediate anxiety and increase psychologic well-being many months later (level III evidence).[36,37] Thus, full and sympathetic explanations at every step, with ample time for questions, are important components of health care for these women.

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