

THE ACR BREAST IMAGING REPORTING AND DATA SYSTEM (BI-RADS®)

The American College of Radiology (ACR) Breast Imaging Reporting and Data System (BI-RADS®) is the product of a collaborative effort between members of various committees of the ACR with cooperation from the National Cancer Institute, the Centers for Disease Control and Prevention, the Food and Drug Administration, the American Medical Association, the American College of Surgeons and the College of American Pathologists.

This system is a quality assurance tool designed to standardize mammographic reporting, reduce confusion in breast imaging interpretations and facilitate outcome monitoring. Through a medical audit and outcome monitoring, BI-RADS® provides important peer review and quality assurance data to improve the quality of patient care.

There are two major categories of women who can benefit from breast imaging studies. All referring physicians and radiologists should be aware of the benefits and limitations of the application of imaging techniques.

SCREENING

The major role for mammography is the earlier detection of breast cancer in the asymptomatic woman. The efficacy of mammographic screening has been established by randomized controlled trials in which absolute mortality reduction has been achieved by the ability of mammography to find ductal carcinoma in-situ and infiltrating cancers of a smaller size and earlier stage than in unscreened control groups. Although mammography can detect the majority of breast cancers, there are some that elude detection yet may be palpable. Thus, although there is a paucity of stud-

ies evaluating the efficacy of the clinical breast examination (CBE), the committee feels this is an important component of screening. In addition, although mortality reduction has not been objectively shown from breast self-examination, it would seem prudent to encourage its use.

By definition, mammographic screening involves the performance of the mediolateral-oblique and craniocaudal projections. In some settings, additional images or studies will be undertaken immediately to solve a question raised on a screening image. In other settings, the patient will be recalled for further evaluation to answer a question raised on the screening study.

BREAST EVALUATION

Mammography and other breast imaging techniques such as ultrasound are useful in the evaluation of women who have signs or symptoms that may suggest breast cancer. However, there is no test or group of tests that can ever ensure that a woman does not have breast cancer. Physical examination evaluates different tissue characteristics than mammography and provides a unique set of information concerning the tissues being studied. Just as decisions must be made based on mammographic suspicion in the face of a normal clinical examination, management decisions must be made based on the clinical evaluation in the face of a negative mammogram. While it is a well-established fact that mammography does not reveal all breast cancers, some of which may be palpable, a statement indicating diminished accuracy of mammography in the extremely dense breast is often warranted.

The combination of mammography and sonography may be particularly effective in

depicting breast cancer. In the study of Kolb et al. (1), mammography alone depicted only 48% of breast cancers in dense breasts whereas mammography and sonography together depicted 97%. Similarly, in a study of 374 women with 2-year follow-up information and/or linkage with a state cancer registry, Moy et al. (2) reported only six (2.6%) women had cancer not seen on either mammography or sonography.

In addition, a finding of clinical concern without a mammographic correlation must be evaluated independently of the mammographic findings. Ultrasound is often helpful in this setting; with the combination of a negative mammogram and negative sonogram, the likelihood of malignancy has been shown to be less than 3%. A statement in the report should be included indicating the need for final management based on clinical grounds. However, universal disclaimers are not necessary since it is well established that a negative mammogram cannot exclude cancer and a clinically suspicious area should be biopsied even if the mammogram is negative.

Despite the fact that a biopsy is to be undertaken for a palpable abnormality, mammography is still important to evaluate the area in question as well as to screen the remaining ipsilateral and contralateral breast tissues for clinically occult cancer. It is important for women and physicians to understand that negative screening is not perfect and that any non-cyclic breast change should be brought to the physician's attention regardless of how soon this occurs following a negative breast evaluation.

The ACR Breast Imaging Reporting and Data System is divided into six sections.

- SECTION I: BREAST IMAGING LEXICON
- SECTION II: REPORTING SYSTEM
- SECTION III: FOLLOW-UP AND OUTCOME MONITORING
- SECTION IV: GUIDANCE CHAPTER

SECTION V: DATA COLLECTION

SECTION VI: APPENDICES

The following is a brief summary of each section.

I. BREAST IMAGING LEXICON

Terminology has evolved over many years, and the results have often led to confusion as to their meaning. The descriptive terms and definitions that follow have been recommended by the ACR Committee on Breast Cancer, and it is hoped that all those involved in breast imaging will adopt these terms, so that reports will be clear and concise. It is believed that these terms provide a fairly complete categorization of lesions, but if there are any significant substantive changes, they may be submitted to the ACR Committee on Breast Cancer for review and inclusion if accepted by the committee.

II. REPORTING SYSTEM

The reporting system is designed to provide an organized approach to image interpretation and reporting. It does not require a computer system, but the utilization of a computer in reporting is strongly encouraged. Not only does this facilitate reporting, but also data are simultaneously collected for the maintenance of a database for future review. This will permit individual radiologists or groups to monitor their own results and appraise the accuracy of their image interpretation so that they can adjust thresholds appropriately. There is no ideal computer system, but it is strongly recommended that the system used require a minimum of interaction. The radiologist's attention should be focused on the interpretation of images. The simplest input utilizes a single screen with minimal interaction needed from the radiologist. The goals are to maximize the image viewing time and minimize any distractions from the reporting.

Report Organization

Use of approved terminology is encouraged. This system categorizes the overall composition of the breast and then describes soft-tissue lesions by their basic shape, border characteristics and density. Calcifications in the system are described according to size, morphology and distribution. The findings are then interpreted and an assessment rendered that includes the degree of suspicion for malignancy, and any pertinent recommendations. Thus, the breast imaging report should be divided into:

1. INDICATION FOR THIS EXAM
2. BREAST COMPOSITION
3. FINDING(S)
4. COMPARISON TO PREVIOUS STUDIES
(If deemed necessary by the radiologist)
5. OVERALL ASSESSMENT

III. FOLLOW-UP AND OUTCOME MONITORING

This section on the mammography audit describes data to be collected and utilized to calculate important derived data, which allow each radiologist to assess his or her overall performance in mammography interpretation. In addition to the basic clinically relevant audit, more complete mammography audit data may also be collected and utilized to calculate derived data to provide other important information regarding mammographic performance. Practical examples of everyday situations are presented and then characterized using the statistical definitions included in this section.

IV. GUIDANCE CHAPTER

Over the years of continued BI-RADS® usage, the committee has received many questions and reports of problems related to the various sections that comprise BI-RADS®. It was decided to address these concerns, introduce new terminology

and assessments and explain the reasons for these changes and decisions in a single chapter. New expanded definitions and terminology will occur in the lexicon text and the explanation for their inclusion will be more fully described in the guidance chapter. At present, many of the changes do not have supportive data, however, the committee felt that inclusion was necessary to make the lexicon a more practical document. As was the case with the original BI-RADS® edition, data will accrue and as this occurs, evidence-based changes can be made. An example of this is the assessment of amorphous calcifications as an intermediate risk of malignancy. This was a consensus of the committee at the time but we now have scientific evidence that this form of calcification, other than in a scattered or diffuse distribution, can be associated with malignancy up to 20% of the time (3). The medical audit has been expanded and brought up to date in the follow-up and outcome-monitoring section utilizing various scenarios that cover frequently asked questions regarding individual radiologist assessment.

V. DATA COLLECTION CHAPTER

VI. APPENDICES

INTRODUCTION. REFERENCES

1. Kolb TM, Lichy J, Newhouse JH. Comparison of the performance of screening mammography, physical examination, and breast US and evaluation of factors that influence them: an analysis of 27,825 patient evaluations. *Radiology* 2002; 225(1):165-75.
2. Moy L, Slanetz PJ, Moore R, et al. Specificity of mammography and US in the evaluation of a palpable abnormality: retrospective review. *Radiology* 2002; 225(1):176-81.
3. Berg WA, Arnoldus CL, Teferra E, Bhargavan M. Biopsy of amorphous breast calcifications: pathologic outcome and yield at stereotactic biopsy. *Radiology* 221 (2):495-503.