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2013 (Resolution 13)*

ACR PRACTICE PARAMETER FOR THE IMAGING MANAGEMENT OF DCIS AND INVASIVE BREAST CARCINOMA

PREAMBLE

This document is an educational tool designed to assist practitioners in providing appropriate radiologic care for patients. Practice Parameters and Technical Standards are not inflexible rules or requirements of practice and are not intended, nor should they be used, to establish a legal standard of care¹. For these reasons and those set forth below, the American College of Radiology and our collaborating medical specialty societies caution against the use of these documents in litigation in which the clinical decisions of a practitioner are called into question.

The ultimate judgment regarding the propriety of any specific procedure or course of action must be made by the practitioner in light of all the circumstances presented. Thus, an approach that differs from the guidance in this document, standing alone, does not necessarily imply that the approach was below the standard of care. To the contrary, a conscientious practitioner may responsibly adopt a course of action different from that set forth in this document when, in the reasonable judgment of the practitioner, such course of action is indicated by the condition of the patient, limitations of available resources, or advances in knowledge or technology subsequent to publication of this document. However, a practitioner who employs an approach substantially different from the guidance in this document is advised to document in the patient record information sufficient to explain the approach taken.

The practice of medicine involves not only the science, but also the art of dealing with the prevention, diagnosis, alleviation, and treatment of disease. The variety and complexity of human conditions make it impossible to always reach the most appropriate diagnosis or to predict with certainty a particular response to treatment. Therefore, it should be recognized that adherence to the guidance in this document will not assure an accurate diagnosis or a successful outcome. All that should be expected is that the practitioner will follow a reasonable course of action based on current knowledge, available resources, and the needs of the patient to deliver effective and safe medical care. The sole purpose of this document is to assist practitioners in achieving this objective.

¹ Iowa Medical Society and Iowa Society of Anesthesiologists v. Iowa Board of Nursing, N.W.2d (Iowa 2013) Iowa Supreme Court refuses to find that the ACR Technical Standard for Management of the Use of Radiation in Fluoroscopic Procedures (Revised 2008) sets a national standard for who may perform fluoroscopic procedures in light of the standard’s stated purpose that ACR standards are educational tools and not intended to establish a legal standard of care. See also, Stanley v. McCarver, 63 P.3d 1076 (Ariz. App. 2003) where in a concurring opinion the Court stated that “published standards or guidelines of specialty medical organizations are useful in determining the duty owed or the standard of care applicable in a given situation” even though ACR standards themselves do not establish the standard of care.
I. INTRODUCTION

The establishment of technical standards of care for medical treatment of breast carcinoma is a process built on consensus of the best scientific evidence and information. For many years, the American College of Radiology (ACR) has made a collaborative effort with the American Colleges of Surgeons, the College of American Pathologists, and the Society of Surgical Oncology to produce practice parameters and technical standards for the care of ductal carcinoma in situ (DCIS) and invasive ductal carcinoma. In the past, the practice parameters for invasive breast carcinoma and carcinoma in situ have been separate with a considerable focus on the surgical management and pathologic evaluation of tissue.

As breast care advancements continue, a multidisciplinary approach for the care of cancer patients is still extremely valuable. Therefore, the ACR hopes to create an encompassing set of practice parameters to assist the radiologist with the full evaluation of breast carcinoma before and after surgery to maximize the radiologist’s contribution to the health care team.

Treatment selections for individual patients with carcinoma in situ and invasive breast carcinoma require clinical, imaging, and pathological evaluations. Full imaging evaluation of the breast and axilla are necessary to determine the best treatment modalities. As surgical and radiation treatments have evolved, breast-conserving surgery (BCS) and radiotherapy have become viable alternatives to mastectomy.

Consequently, this practice parameter covers the necessary steps for the imaging management of DCIS and invasive breast carcinoma and highlights the imaging findings that impact surgery (including the evaluation of the axilla, the optimal placement of a localizing wire, and biopsy planning), neoadjuvant chemotherapy, and radiation. Included are radiology and pathology correlation, preoperative imaging considerations (including preoperative magnetic resonance imaging (MRI) and the potential need for additional biopsies prior to surgery), and postoperative imaging recommendations. Finally, imaging findings impacting and impacted by radiation therapy (including the reconstructed breast) and follow-up care recommendations are discussed.

II. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

Interpreting physicians, medical physicists, and radiological technologists who work in breast imaging must meet the requirements that are appropriate to the scope of their practice as outlined in the following documents or practice parameters:

1. Mammography Quality Standards Act Final Regulations [1].
2. ACR Practice Parameter for the Performance of Stereotactic-Guided Breast Interventional Procedures
3. ACR Practice Parameter for the Performance of Ultrasound-Guided Percutaneous Breast Interventional Procedures
4. ACR Practice Parameter for the Performance of a Breast Ultrasound Examination
5. ACR Practice Parameter for the Performance of Contrast-Enhanced Magnetic Resonance Imaging (MRI) of the Breast
6. ACR Practice Parameter for the Performance of Magnetic Resonance Imaging-Guided Breast Interventional Procedure
7. ACR Practice Parameter for the Performance of Screening and Diagnostic Mammography
III. IMAGING EVALUATION: DIAGNOSIS AND STAGING

Imaging plays a central role in accurately establishing tumor diagnosis and evaluating the extent of disease.

A. Diagnosis

The diagnosis of breast cancer by surgical excision without prior breast imaging or percutaneous biopsy should not often occur today [2]. Preoperative diagnosis allows for more detailed surgical planning and may result in better surgical outcomes such as better surgical margin status. The sensitivity of mammography, clinical examination, and ultrasound for detecting malignancy is high [3].

The overall disparity between results of image guided percutaneous core biopsy and surgical excision is small but present. Using ultrasound guided 14-gauge core needle biopsies, an agreement rate of 95% between core needle biopsy and surgical excision or clinical follow-up is reported [2]. However, due to only partial sampling of some lesions, underestimation is a problem with percutaneous image guided biopsy. This may result in an upgrade to invasive breast cancer from a core biopsy result of DCIS or to malignancy from a core biopsy result of high risk but benign lesions. The upgrade rate of a core needle biopsy diagnosis of DCIS to invasive carcinoma is in the 20% to 25% range, higher with 14-gauge versus 11-gauge core needle devices [4].

A more significant issue for management arises when benign biopsies from an image guided core biopsy are reported as lobular neoplasia, benign papilloma, atypical ductal hyperplasia (ADH), flat epithelial atypia, or radial scar. Many articles describe the management of high risk benign lesions obtained at image guided core needle biopsy [5-10]. Since these lesions all have a greater than 2% possibility for malignancy they may not be appropriate for short-interval follow-up, and surgical excision of these high risk lesions is recommended [11].

B. Extent of Disease and Staging

For both DCIS and invasive carcinoma, imaging can allow an estimate of the extent of disease.

When breast cancer is suggested on a screening mammogram due to the presence of calcifications, their mammographic extent should be determined by a full diagnostic evaluation. This can include additional imaging with spot compression views and with magnification. When calcifications are extensive, an image guided core biopsy directed at their extreme limits will help to decide if breast conserving therapy or mastectomy is warranted.

Ultrasound may be helpful to identify an underlying mass associated with suspicious calcifications, possibly identifying an area of invasive disease. This may permit an ultrasound guided biopsy which may be better tolerated by the patient than stereotactic biopsy of calcifications. Bilateral whole breast ultrasound has been used to determine disease extent. Although extensive data for this modality are lacking, studies report 14% of unsuspected additional foci in the same breast and 4% to 14% of unsuspected contralateral malignancies are found with sonography [12,13].

Breast MRI is also useful for preoperative evaluation of patients with newly diagnosed breast cancer. MRI can detect additional foci of occult malignancy in the ipsilateral breast in approximately 15% of patients, with reported ranges of 12% to 27% [3,14-21]. The efficacy of MRI for ipsilateral disease extent is best for invasive lobular carcinoma and dense breasts [3,22]. Although there is some controversy concerning the upgrade from conservative therapy to mastectomy after an MRI for disease extent, data suggest that these upgrades are warranted as long as the suspicious MRI findings are confirmed by pathology [23-26].

In women with suspected carcinoma or suspected additional sites of cancer on MRI, biopsy confirmation is required if management would be changed by the presence of this suspected disease. Biopsy can be facilitated if the MRI detected lesion can be located sonographically. This directed sonogram works better for a mass than it does for non-mass enhancements or a focus [27].
Detection of unsuspected contralateral breast cancer at the time of initial diagnosis of the index malignancy is important to appropriately guide initial therapy. If contralateral disease is diagnosed after initial therapy for the index malignancy, additional therapy must be done.

Axillary lymph nodes are the most frequent site of breast cancer metastasis. Mammography can give some information regarding the axillary lymph node involvement if they are enlarged or of high density. However, ultrasound provides the most useful evaluation of features that suggest axillary metastasis.

The use of sonography for detecting nonpalpable axillary adenopathy is most sensitive when morphologic criteria (shape [round more suspicious than oval], hilar obliteration, cortical thickening) are used, rather than size criterion (greater than 5 mm). Using morphologic criteria, approximately 50% of nodes with disease are detected with a specificity of over 95%. However, definitive diagnosis requires tissue sampling, which increases specificity to 100% [28]. Comparison with lymph nodes in the contralateral axilla can also be helpful to establish if cortical thickening is unilateral or bilateral and may thus represent reactive hyperplasia. On MR imaging, unenhanced axial T1-weighted imaging without fat saturation is also a reliable technique, demonstrating a sensitivity, specificity, and accuracy of 88%, 82% and 85%, respectively [29].

C. Determination of Extent of Disease after Neoadjuvant Therapy

Evaluation of the extent of disease remaining in the breast after neoadjuvant therapy is limited. The accuracy of clinical breast examination in determining complete response has been reported at 33% to 63% for women who had false-negative examinations and were judged to have complete response but with pathologic residual disease [30-32].

Mammography has been reported to be superior to physical examination in evaluation of response to chemotherapy [33]. However, when women were treated with radiation, the accuracy of mammographic assessment of response fell to 50%.

Comparisons of response assessment using physical examination, mammography and sonography suggest only about 50% accuracy for all modalities in determining response to chemotherapy. The tendency of all modalities has been to underestimate the extent of disease in the treated breast in about half of patients [34-36]. The positive predictive value for an examination showing residual disease after chemotherapy or hormonal treatment is high, reported at 75%, while the determination of complete response (negative predictive value) is under 50% [37]. Fibrosis and tissue density may compromise mammographic assessment of tumor response. Tumor calcifications may persist despite successful treatment of carcinoma.

The best agreement of assessment of extent of disease after treatment is obtained using MRI. Studies have reported correlation coefficients with pathologic evaluation of 0.6 to 0.9 for MRI [38]. In a meta-analysis of 1,213 treated women, MRI had a sensitivity of 0.63 and a specificity of 0.91 [39]. Magnet strength of at least 1.5 Tesla should be used. Inaccuracies in MRI assessment may be due to treatment generated necrosis or fibrosis and the use of antiangiogenic therapies that can impair the delivery of contrast to tumor foci. When tumor shrinkage is patchy with necrotic sites between areas of tumor or when small foci of tumor scattered over a large area remain in the breast, underestimation is most frequent. Accuracy of the evaluation of response to treatment using MRI may also be influenced by the receptor status of the carcinoma, with greatest accuracy in estrogen receptor-negative/HER 2-positive tumors in those that are triple negative, and in those that are more aggressive [40,41]. Accuracy may be compromised in HER 2-negative and receptor-positive carcinomas.

Determination of whether tumor is responding to treatment before the completion of therapy is more difficult with decreased accuracy of all modalities when evaluation is done in mid-treatment compared to post-treatment assessment. Early evaluation of response of tumor to therapy has been reported with spectroscopy, diffusion weighted imaging and FDG PET, but the use of these technologies in this setting remains investigational. Flattening of the enhancement curve and decreasing lesion washout may be early indicators of tumor response to treatment on MRI.
While effective chemotherapy may result in complete disappearance of the tumor on imaging, it should not be assumed that this corresponds to a complete pathologic response as residual disease may persist despite negative imaging findings. Placement of a tissue marker at the site of the tumor prior to neoadjuvant therapy is advisable to allow accurate localization of the tumor bed for the surgeon and pathologist [42].

IV. IMAGING GUIDANCE FOR SURGICAL PROCEDURES

Preoperative image-guided localization of nonpalpable breast abnormalities is necessary to ensure that the surgeon has the best chance to remove the malignant region. The goal is complete excision with negative margins. The localization may target the breast lesion, biopsy marking clip, and/or postbiopsy hematoma, but it is necessary to know the extent of malignancy, and its location with respect to previously placed marking clip(s). More than one guidance device may be used to bracket the extent of disease [43].

Prior to localization, the radiologist should review all pertinent imaging examinations to determine the extent of disease. Review should determine if marking clips deployed at the time of biopsy were placed in the appropriate position or if they have migrated. In patients who have undergone neoadjuvant therapy, the original extent of disease and the visible residual are both important to consider.

Postlocalization mammograms should be obtained to depict the localization and to guide the operative procedure. Communication with the surgeon may avoid misunderstanding and may take the form of a telephone call, written comments, or annotation of the images.

Specimen radiography is essential to document removal of the lesion and provide some guidance to the surgeon as to the adequacy of excision [44,45]. This should occur while the patient is still in the operating room, so the surgeon can remove more tissue if warranted. Ideally, the radiologist reviewing the specimen image should be the person who performed the localization procedure. However, due to scheduling constraints it may be necessary to have another radiologist review the specimen images. If so, the reviewing radiologist should be familiar with the important preoperative images delineating the extent of disease and the localization images.

1. Wire localization

Preoperative wire localization using mammographic, sonographic, or MRI guidance is performed the day of surgery. The wire may be placed at the breast lesion, adjacent to the biopsy marking clip (if it lies at the site of the lesion), or at the postbiopsy hematoma if the lesion itself cannot be visualized and if a marker clip is not present. More than one wire may be used to bracket the full extent of disease in patients with large masses, masses with satellite nodules or accompanying microcalcifications extending from the mass or segmental or linearly distributed microcalcifications alone. If ultrasound guidance is used to place the wire, marking the location of the lesion on the overlying skin with the patient in the supine operative position and measuring the depth of the lesion can be of help to the surgeon during excision. If ultrasound or MRI guided localization is performed, postlocalization but preoperative mammograms may be useful, depending on the imaging preferences for guidance in individual practices. Mammography may compromise the accuracy of the localization by displacing the wires, and the images may be misleading due to foreshortening of the wires on standard mammography views.

2. Radioactive seed localization

Preoperative radioactive seed localization using mammographic or sonographic guidance can be performed up to several days prior to surgery. Seed localization of breast lesions provides the radiologist and surgeon flexibility in approach during the localization and excision procedures [46-48].
The radioactive seed may be placed at the breast lesion, adjacent to the biopsy marking clip (if it lies at the site of the lesion), or at the postbiopsy hematoma if the lesion itself cannot be visualized and if a marker clip is not present. More than one seed may be used to bracket the full extent of disease in patients with large masses, masses having satellite nodules or accompanying microcalcifications extending from the lesion or segmental or linearly distributed microcalcifications alone. Seed bracketing in the anterior-posterior plane should only be performed after consultation with the breast surgeon, as the superimposed seeds may appear as one radioactive source in the intraoperative supine patient. If ultrasound guidance is used to place the seed, marking the location of the lesion on the overlying skin with the patient in the supine operative position and measuring the depth of the lesion can be of help to the surgeon during excision. As with wire localizations, postlocalization preoperative orthogonal mammography may be useful in guiding the surgeon to the localized lesion.

3. Specimen imaging

The specimen should be imaged at the time of surgery to determine if the targeted lesion has been removed. Results of specimen imaging should be discussed with the surgeon in a timely fashion in case additional resection is needed.

If the lesion is a single mass, particularly if it was mammographically occult, ultrasound of the specimen can be used to document mass removal [49]. If the lesion contains microcalcifications, either extending from a mass or alone, specimen radiography is better to evaluate the adequacy of excision. Compression of the specimen can improve visibility of the lesion but may artificially decrease margin width [50]. Two-view mammography of the surgical specimen can be helpful to assess tumor location in relation to the specimen margins [51].

When tumor can be seen extending to the specimen margins on the specimen radiograph, there is a high positive predictive value for residual tumor in the breast. Conversely, the negative predictive value of clear margins on specimen radiography is low. Therefore, even though tumor may not appear to extend to the margins of the resected specimen on the specimen radiograph, residual tumor may still be present in the breast. This may be particularly true for noncalcified DCIS and infiltrating lobular carcinoma [52,53].

Lesions that are only seen with MRI may not benefit from specimen radiography.

V. POSTOPERATIVE IMAGING CONSIDERATIONS

In the patient undergoing breast conservation therapy, the purpose of postoperative imaging is 2-fold: first to evaluate the adequacy of resection, and second to detect tumor recurrence. Positive or close margins increase the likelihood of tumor recurrence which is associated with decreased survival [54]. In most cases, re-excision will be performed when there is imaging or pathologic evidence of residual disease after surgery.

Postoperative mammography should document complete excision of malignancy. In patients with cancer presenting as calcifications mammographically, early postoperative imaging is particularly important to detect residual microcalcifications before radiation therapy. Standard craniocaudal and MLO views should be obtained. The breast should be compressed only as much as tolerated. Magnification views of the lumpectomy site can be useful to detect calcifications when none are apparent on the standard views or to more completely characterize calcifications visible on the standard views. Postoperative mammography is less accurate for detecting residual tumor in the setting of noncalcified masses and noncalcified DCIS both of which can be obscured by postoperative changes.

Residual malignant calcifications should be completely resected prior to radiation therapy. However, residual calcifications on postoperative mammography should not be assumed to represent carcinoma. In one study the positive predictive value of residual calcifications was 69% overall and increased to 90% when the original tumor was DCIS, or when there were 5 or more residual calcifications present [55]. When no residual calcifications were
present, there was residual tumor in 30%. If re-excision is performed, then additional postoperative mammography should be performed to ensure that the residual calcifications have been removed.

MRI has been shown to be useful to evaluate for residual disease in patients with positive margins [56-59] and may be considered in patients with positive or close margins at lumpectomy prior to re-excision. Negative imaging, including MRI, cannot exclude the presence of residual disease, particularly if it is microscopic. If clinically indicated, re-excision should be performed despite negative imaging. MRI can direct the surgeon to areas of the lumpectomy cavity more likely to contain residual disease or may indicate additional tumor separate from the surgical site. MRI would be expected to be most useful in patients who have not undergone preoperative MRI. Specificity of postoperative MRI may be lowered by enhancing granulation tissue or fat necrosis at the surgical site which may mimic cancer. MRI may be performed as soon after surgery as the patient can tolerate it, in order to minimize delay in definitive therapy.

VI. FOLLOW-UP CARE RECOMMENDATIONS

The initial, post-treatment mammogram of the irradiated breast is performed at 6 to 12 months. If a unilateral mammogram is obtained at six months, it is designed to establish the new, mammographic pattern of the treated breast at a time when treatment failure with tumor recurrence is highly unlikely [60]. A bilateral mammogram is done at 12 months after the pretreatment bilateral study, and thereafter annual bilateral mammography can be done, although some have recommended more frequent examinations in the first 3 to 5 years.

In order to interpret the mammograms accurately and assess the direction of change, the current mammogram must be compared in sequence to preceding studies. The diagnostic radiologist can tailor mammographic studies of the treated breast to the surgical site by using special mammographic views in addition to routine mediolateral oblique and craniocaudal views. Magnification and spot compression views can be used to increase detailed visualization of the site of tumor excision. Ultrasonography can help characterize postoperative masses, such as seromas.

The usual changes seen in the conserved, irradiated breast include postoperative fluid collections, edema, skin thickening, and coarsened stroma. These will be most marked in the first six months. Architectural distortion and surgical scarring may develop as the acute changes subside. Calcifications develop in one-third to one-half of treated patients and are due to fat necrosis. For most patients, the radiographic changes related to surgery and radiation will slowly diminish after the first six to twelve months and will demonstrate stability within two years [61-63].

Diagnosing Recurrence

Patients with breast conservation, including surgical excision and postoperative radiation treatment, experience recurrences at a rate of approximately 1% to 2% per year [64-67]. There is an increased likelihood of recurrence in younger patients, those with positive surgical margins, those who do not undergo radiation therapy, and those with an extensive intraductal component (EIC) [65,68]. Importantly, DCIS tumors can recur as either in situ or invasive cancers [69,70]. Local recurrences after conservation therapy typically occur in the quadrant of the index tumor, usually within three to five years after completion of therapy [71]. Thereafter, the remaining ipsilateral breast is at increasing risk for the development of new cancers. The contralateral breast must also be monitored to screen for the development of new carcinoma.

The goal of follow-up imaging of the treated breast is early recognition of tumor recurrence. Multiple studies have shown that most (85% to 97%) recurrent cancers are mammographically visible [69,71,72]. However, postoperative and irradiation changes overlap with signs of malignancy on imaging, and, at times, these may be impossible to distinguish.

Recurrent tumor should be suspected if changes occur in a previously stable surgical scar. Magnification mammography is useful to evaluate and characterize calcifications. In cases in which the index tumor presented
with microcalcifications, the recurrence is more likely to also present with microcalcifications [69,71,72]. However, calcifications related to fat necrosis typically develop two to five years after surgery. Early on, these calcifications can be morphologically indistinguishable from recurrent tumor calcifications [61]. Image-guided needle biopsy of new and suspicious calcifications or scars demonstrating enlargement or increased density is necessary to distinguish recurrent tumor from treatment changes.

MRI can be useful in the follow-up of these women. Enhancement at the lumpectomy scar usually diminishes over time except in those with fat necrosis; enhancement at the lumpectomy site in those with a suspicion of recurrence has a high likelihood of recurrent carcinoma. Nonenhancing lesions are likely benign [73]. MRI may also be valuable in annual screening of women who have a personal history of breast cancer [74].

In the case of mastectomy, most local recurrences (90%) occur within the first five years. These are most likely to occur in the skin and subcutaneous tissues surrounding the scar. Intramuscular recurrence is uncommon. Screening mammography is not indicated for the ipsilateral chest wall after mastectomy [75]. However, evaluation of suspicious palpable findings at the mastectomy site may include diagnostic mammography, sonography, or MRI.

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