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Christine H.

Aurora Imaging Technology, Inc. 39 High Street North Andover, MA 01845

Phone: 978.975.7530 Toll free: 877.975.7530 Fax: 978.975.9930

AUR©RA ADVANCING BREAST IMAGING

Aurora® 1.5T Dedicated Breast MRI Adds Valuable Benefits to Practice Dedicated to High-Risk Women



Christine H. Murphy, M.D. is a radiologist and a founding member of the Breast Care Specialists LLC of Atlanta.

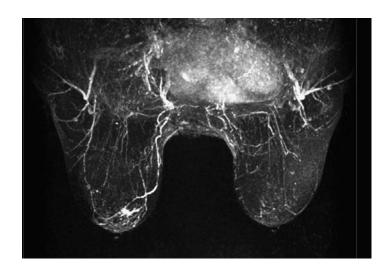
Magnetic resonance imaging (MRI) is proving to be a powerful weapon in the fight against breast cancer, which still strikes close to 200,000 women in the United States each year.

Widespread mammography screening programs are helping to detect more cancers in women in their earliest stages when they are most treatable. Indeed, the 10-year survival rate for breast carcinomas detected when they are Stage I (confined to the breast) is 90 percent.

However, while mammography remains cost-effective for screening large populations, its benefits are somewhat

limited in patients who have radiographically dense breasts, a prior history of breast cancer, breast augmentation and/or postoperative scarring. Even with computer-aided detection (CAD) programs, mammography misses up to 15 percent of cancers that are present in women in their 50s, and up to 25 percent of cancers in women in their 40s¹. Many women who are at risk for breast cancer are relatively young, and younger women tend to have denser breasts, which lowers the sensitivity of mammography.

Our practice, Breast Cancer Specialists LLC of Atlanta, sees only women at high risk for breast cancer, or those who have had recent abnormal imaging or symptoms of breast disease. We recommend alternating screenings at six-month intervals between mammography and MRI to our high-risk population. This biannual schedule coincides with the American Cancer Society's guidelines, updated in 2007, which recommend high-risk women have annual breast cancer screening with MRI in addition to their yearly mammogram.



Breast MRI: High-risk patient



The Aurora 1.5T Dedicated Breast MRI System, the only fully integrated MRI system designed specifically for breast imaging



A tremendous help in identifying DCIS

Major problems in the detection of breast cancer in dense breasts include finding invasive lobular carcinoma and locating early cancer, such as ductal carcinoma in situ (DCIS), when it is not calcifying on the mammogram. MRI can help tremendously in these cases.

Early on, almost all the false-negatives reported on breast MRI screening trials involved DCIS, a precursor to invasive breast cancer. About 20 percent of new cancers will begin with DCIS, which is highly curable in its early stages.

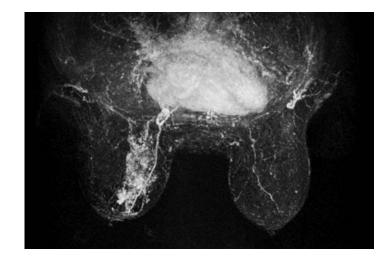
Because DCIS does not exhibit washout enhancement curves, most MRI CAD programs will not detect it. DCIS can resemble proliferative changes on MRI that are not cause for alarm. However, with the Aurora Breast MRI system, designed exclusively for breast imaging, the spatial resolution is of such high quality that it is possible to see linear branching, a fairly characteristic morphology of DCIS.

Likewise, lobular carcinoma often is occult on mammography, but is routinely displayed accurately on MRI. Lobular carcinoma accounts for approximately 15 percent of all breast cancers.

Uses of breast MRI in our practice

Since our office has had the 1.5T Dedicated Breast MRI System developed by Aurora Imaging Technology, Inc. of North Andover, MA, we now schedule approximately 10 patients a day for MRI. In October, our busiest month of 2006, we performed 190 MRIs. Fifty of these were for staging of new cancer diagnoses or for follow-up of patients on neoadjuvant chemotherapy. The remaining 140 MRIs were screening for women who are at high risk for one of several reasons, including family history of breast cancer, personal history of breast cancer, BRCA1 or BRCA2 gene mutation, or prior biopsy showing atypia. Research shows that for every 100 women who exhibit atypia, nearly 20 will develop breast cancer some time in the next 15 years.²

Of the 140 MRI screenings, we generated 23 (16 percent) that needed further study with biopsy. This means we had 23 patients in which MRI found an abnormality not seen on any other imaging modality. Of those 23, seven were new cancers. These were proven at biopsy performed either under MRI guidance or second-look ultrasound guidance. Biopsy with our dedicated breast MRI system is much easier than with other MRI units.



Breast MRI: DCIS

Because our system has such high spatial resolution, we know the needle is heading for the correct spot, which obviously is critical in obtaining accurate results.

That's why we believe in routine MRI screening for women who are at high risk for breast cancer. Our experience shows that if you have a high-risk population, you are finding cancer on MRI that you are not finding with any other modality. A growing number of studies in the literature corroborate our anecdotal evidence.³⁻⁸

A major advantage to the Aurora system is its dedicated elliptical MR imaging capability that allows us to scan both breasts at the same time, with a broad image range including the entire chest wall and axillae. Many other MRI machines that were designed to image the whole body require two days for breast scanning because they can only center one breast at a time, and the contrast agent that is used can only be safely injected once in a 24-hour period.

Some insurance companies will not pay for breast MRI for high-risk women. To address this concern, we request guidelines from insurers as to what they deem high risk and try to adhere to them when pre-certifying a patient. Some women will opt to have a screening MRI even if their insurance will not reimburse for it because it gives them peace of mind.

Managing disease better

If we find disease, our dedicated breast MRI system allows us to better manage it. Tumor size and multiple tumors can be characterized with MRI for more effective treatment-planning and surgical management. We try to perform MRI on every newly diagnosed breast cancer prior to definitive therapy because knowing the extent of disease will help determine the best treatment option. Since we began using the Aurora System, we cannot imagine sending a new cancer patient to surgery without the benefit of MRI mapping the extent of disease.

Some argue that MRI can lead to more callbacks and biopsies than mammography. Studies indicate that MRI among high-risk groups results in 15 to 25 percent of patients requiring some form of procedure, whether ultrasound or biopsy, because of suspicious findings. Of those who undergo biopsy, about 40 percent are found to have malignancies.⁹⁻¹⁰ That is a significant positive-predictive value (PPV), certainly enough to justify MRI screening of high-risk groups. Besides, multiple studies have shown that MRI has the highest sensitivity of all available modalities for invasive cancers.¹¹

Others have expressed a fear that MRI converts patients scheduled for breast-conserving lumpectomy to mastectomy. In some cases, MRI shows unexpected extent of disease or bilateral disease that appropriately converts the patient to mastectomy or even bilateral mastectomy. However, we're finding that the reverse is true, as well. One is able to mark the anterior and posterior points of the lesion using MRI-directed biopsy or localization. Using those markings, the surgeon can better ensure removal of the entire tumor on the first surgery.

MRI also can define the effectiveness of radiation therapy and chemotherapy to provide improved information on nonsurgical treatments of breast cancer. We have found that MRI is much more sensitive to the true residual size of the treated tumor than either mammography or ultrasound.

Recently, one of our patients had a multifocal recurrence that involved the reconstruction (transverse rectus abdominal muscle flap) and the patient's skin. After the oncologist treated her with chemotherapy, she was placed on aromatase inhibitors. Three MRIs taken over the course of her one year of treatment showed a conclusive reduction in the malignancy to the point where she had virtually no enhancing areas left on the third scan. The MRI confirmed that her oncologist was using the right course of treatment to increase her survival rate.

Truly dedicated breast MRI impacts lives, improves diagnosis

Clearly, the addition of Aurora's truly dedicated breast MRI system to our busy practice is having a tremendous impact on the lives of our patients. Not only is it helping us find unsuspected cancers in our high-risk population, it also is improving our assessment of extent of disease for staging and treatment planning. We have been and will continue to be very liberal with our use of MRI and will continue to be because of the tremendous benefits it provides the patients entrusted in our care.



Breast MRI: Pre-neoadjuvant chemotherapy



Breast MRI: Post-neoadjuvant chemotherapy