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ORIGINAL ARTICLE – BREAST ONCOLOGY

# Results of Magnetic Resonance Imaging (MRI) Screening in Patients at High Risk for Breast Cancer

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## ABSTRACT

**Background.** Screening MRI as an adjunct to mammography is recommended by the ACS for patients with a lifetime risk for breast cancer > 20%. While the benefits are clear, MRI screening is associated with an increase in false-positive results. The purpose of this study was to analyze our institutional database of high-risk patients and assess the uptake of screening MRI examinations and the results of those screenings.

**Methods.** Our institutional review board-approved High-Risk Breast Cancer Database was queried for patients enrolled from January 2017 to January 2023 who were at high risk for breast cancer in a comparative analysis between those who were screened versus not screened with MRIs. Variables of interest included risk factor, background, MRI screening uptake, and frequency and results of image-guided breast biopsies.

**Results.** A total of 254 of 1106 high-risk patients (23%) had MRI screening. Forty-six of 852 (5.3%) patients in the non-MRI-screened cohort and nine of 254 (3.5%) patients in the MRI-screened cohort were diagnosed with a malignant lesion after image-guided biopsy ($p = 0.6$). There was no significant difference between MRI and non-MRI guided biopsies in detecting breast cancer. All malignant lesions were T1 or in situ disease. The 254 patients in the MRI-screened group underwent 185 biopsies. Fifty-seven percent of MRI-guided biopsies yielded benign results.

**Conclusions.** Although the addition of MRI screening in our high-risk cohort did not produce a significant number of additional cancer diagnoses, patients monitored in our high-risk cohort who developed breast cancer were diagnosed at very early stages of disease, underscoring the benefit of participation in the program.



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The incidence of breast cancer continues to rise globally. In 2018, there were approximately 2.1 million new cases of breast cancer worldwide, and breast cancer is thought to be the leading cause of cancer-related deaths in many developed countries.[1] In the United States alone, there are approximately 250,00 new cases of breast cancer per year.[2] Established risk factors for breast cancer include pathogenic mutations in breast cancer susceptibility genes, family history of breast or ovarian cancer, atypical hyperplasia, lobular carcinoma in situ (LCIS), reproductive factors, including early age of menarche, delayed menopause, nulliparity or first live birth older than age 30 years, obesity, and usage of alcohol and tobacco.[1]

Various mathematical risk-factor assessment models are used to estimate a patient's risk of developing breast cancer.[3] The Gail and Tyrer-Cuzick (TC) models are commonly used risk assessment calculators. The risk estimates generated by these models can provide guidance regarding appropriate breast cancer screening and risk-reduction strategies for individual patients.[2] Although the Gail model can underestimate risk in individuals with extensive non-first-degree relative history of cancers and with other genetic risk factors, both models perform similarly in estimating risk in patients without significant family history of cancer.[3,4]

In the 1980s, screening mammography significantly impacted the age-adjusted breast cancer-specific mortality

in the United States by reducing cancer-related deaths from 20 to 40%.[2] Mammography can detect 2–8 cancers per 1000 screens, although sensitivity is decreased among women with denser breasts as attenuated images and overlapping tissue can obscure tumors. Digital breast tomosynthesis (DBT) attempts to reduce overlapping breast tissue from obscuring masses and can detect malignancies occult on mammography. DBT increases the cancer to detection rate to approximately 8.1 per 1000 examinations. Mammography can be supplemented by ultrasound (US), which can increase cancer detection rate even further and also is useful in patients with dense breasts by detecting an additional 2–4 cancers per 1000 women. In the ACRIN 6666 study, screening US had a 76% sensitivity and 84% specificity when used in combination with mammography.[5] However, US utilization can be limited by the increased false-positive rate and operator dependency.[2]

Among breast imaging modalities available, breast MRI offers the highest cancer detection rate.[6] MRIs allow for discriminating between benign versus malignant disease, detection of additional lesions or extent of disease of already detected cancers, and evaluating response to systemic therapy.[7] The American College of Radiology recommends incorporating MRI into the screening of higher-risk patients characterized by a lifetime risk of developing breast cancer > 20%.[8] The sensitivity of MRI has been shown to be higher in patients with known history of genetic mutations as opposed to high-risk patients without known genetic mutations, although both populations appear to benefit.[8]

The benefit of MRI in high-risk patients is established. However, there are recognized downside risks, including false-positives requiring increased biopsies, increased costs, possible accumulation of gadolinium contrast, and time commitments.[6,7] The issue of insurance coverage also may affect patients' uptake of MRI screening. The purpose of this study was to utilize our institutional database of patients at high risk for developing breast cancer and to assess the uptake of screening MRI examinations as well as analyze the results of those screenings.

## METHODS

Our institutional review board-approved High Risk Breast Cancer Consortium Database was queried for patients enrolled from January 2017 to January 2023 who were at high risk for developing breast cancer. Enrollment criteria for our high-risk registry included patients with genetic mutations associated with an elevated risk of breast cancer, family history of breast cancer, atypical hyperplasias, and lobular carcinoma in situ (LCIS). Patients were followed by specialty breast practitioners, and all patients were regularly examined by breast surgeons. Clinical follow-up was a minimum of annual, with many patients twice yearly. A comparative analysis between MRI screened versus non-MRI screened patients was performed. Although not required, most patients had imaging within the hospital system. The system's breast imaging specialists review abnormal outside facility imaging.

The study population was stratified by utilization of MRI screening. MRIs were offered using established NCCN guidelines for patients with greater than 20% lifetime risk for developing breast cancer. For patients who underwent screening MRI, we evaluated the results of those screenings, including pathology and subsequent interventions. Biopsy pathology consisting of atypical ductal hyperplasia (ADH), atypical lobular hyperplasia (ALH), intraductal papilloma, and radial scars were categorized as demonstrating high-risk lesions. Malignant lesions were categorized as invasive cancers of any type and ductal carcinoma in situ (DCIS).

Variables of interest included risk factor background, the uptake of MRI screening, and frequency and results of image-guided breast biopsies along with subsequent interventions. All lesions that underwent MRI guided biopsies were only visualized by screening MRI. Statistical analysis was performed with the R Project for Statistical Computing.[9–11]

## RESULTS

The study population consisted of 1,106 women in the NYU Langone High-Risk Breast Cancer Database. The mean age was 51.2 (standard deviation [SD] 12.9) years. In total, 108 participants (18.8%) were BRCA1-positive, 122 (21.2%) were BRCA2-positive, 506 (46.1%) had a family history of breast cancer, 252 (29.8%) had ADH, 152 (17.3%), and 169 (18.7%) had LCIS. Approximately one quarter of the patients (254/1106, 23.0%) underwent MRI screening (Table 1). Forty-nine of 108 (45.4%) BRCA1 patients and 69 of 122 (56.6%) BRCA2 patients had screening MRIs.

Patients in the MRI-screened cohort were on average younger (48 vs. 52 years, $p < 0.001$), were more likely to have undergone genetic testing ($p < 0.001$), more likely to be BRCA1- or BRCA2-positive ($p = 0.006$ and $p < 0.001$ respectively), and more likely to have a family history of breast cancer ($p < 0.001$). Patients in the non-MRI screened cohort were more likely to have ADH or ALH ($p = 0.003$ and $p = 0.026$ respectively; Table 2).

During our study period, 46 of 852 (5.3%) patients in the non-MRI-screened cohort and nine of 254 (3.5%) patients in the MRI-screened cohort were diagnosed breast cancer. There was no significant difference in breast cancer diagnosis between these groups ($p = 0.6$).

Among the 254 MRI-screened patients, 94 (37%) patients had MRI guided biopsies of lesions only detected on MRI, and 91 (35.8%) patients had non-MRI guided biopsies (Table 3). The majority of MRI-guided biopsies produced

**TABLE 1** Clinical characteristics of high-risk breast cancer registry patients

| Overall | |
|---|---|
| *n* | 1106 |
| Age (mean (SD)) | 51.15 (12.92) |
| Genetic testing performed (%) | 617 (57.3) |
| BRCA1 positive (%) | 108 (18.8) |
| BRCA2 positive (%) | 122 (21.2) |
| ATM positive (%) | 4 (1.4) |
| BARD1 positive (%) | 1 (0.4) |
| BRIP1 positive (%) | 4 (1.4) |
| CHEK2 positive (%) | 11 (3.9) |
| PALB2 positive (%) | 2 (0.7) |
| PTEN positive (%) | 3 (1.1) |
| TP53 positive (%) | 1 (0.4) |
| Family history breast cancer (%) | 506 (46.1) |
| Family history ovarian cancer (%) | 116 (10.9) |
| History of ADH (%) | 252 (29.8) |
| History of ALH (%) | 152 (17.3) |
| History of LCIS (%) | 169 (18.7) |
| Patients with screening MRI (%) | 254 (23.0) |

benign results (57%). While not statistically significant, 31 patients were diagnosed with high-risk lesions that were only detected on MRI, which required risk-reducing interventions. Six of nine malignancies detected in this group were diagnosed by non-MRI-guided biopsy techniques. In the MRI-screened cohort, all malignant lesions were either T1 or in situ disease. In the non-MRI screened cohort, 35 of 46 patients (76%) with malignant disease were either T1 or in situ disease; the remaining 11 patients had unavailable staging information.

Thirty-six (14%) of the 254 patients undergoing MRI screening had bilateral mastectomies in our study period, which included either bilateral prophylactic mastectomies or contralateral prophylactic mastectomy after resection for ipsilateral disease. Five of these patients had been diagnosed with breast cancer, and four of those five carried BRCA1 or 2 mutations. An additional 23 BRCA positive patients underwent prophylactic mastectomies while under surveillance (Table 4). Eighty-eight (10.3%) of the 852 patients not undergoing screening MRI had bilateral mastectomies. Nine of these patients had a cancer diagnosis, and two of these patients had BRCA1 or 2 mutations. Of the remaining 79 patients, an additional 55 patients underwent prophylactic mastectomies.

## DISCUSSION

There are multiple benefits from incorporating MRI into breast cancer screening. Although mammography is the only breast cancer screening imaging modality proven to decrease the mortality from breast cancer, the sensitivity of the exam is reduced in patients with increasing breast density, ranging from 75 to 85% in nondense breasts to 50% in dense breasts.[12] As a result, contrast-enhanced imaging with MRI may be used in these patients with improved sensitivity as much as 79–98%.[12]

Although MRIs have a higher sensitivity, patients undergoing regular screening with breast MRIs are likely to have additional diagnostic imaging studies, which subsequently lead to more biopsies without increasing the yield of DCIS

**TABLE 2** Comparative clinical characteristics in patients who had MRI screening versus no MRI screening

| *n* | No MRI 852 | MRI 254 | *p* value for difference |
|---|---|---|---|
| Age (mean (SD)) | 52.08 (12.44) | 48.02 (13.99) | < 0.001 |
| Genetic testing performed (%) | 414 (50.1) | 203 (80.9) | < 0.001 |
| BRCA1 positive (%) | 59 (15.2) | 49 (26.2) | 0.006 |
| BRCA2 positive (%) | 53 (13.8) | 69 (35.9) | <0.001 |
| ATM positive (%) | 1 (0.6) | 3 (3.0) | 0.234 |
| BARD1 positive (%) | 1 (0.6) | 0 (0.0) | 0.346 |
| BRIP1 positive (%) | 4 (2.2) | 0 (0.0) | 0.309 |
| CHEK2 positive (%) | 8 (4.4) | 3 (3.1) | 0.788 |
| PALB2 positive (%) | 1 (0.6) | 1 (1.0) | 0.398 |
| PTEN posnive (%) | 2 (1.1) | 1 (1.0) | 0.388 |
| TP53 positive (%) | 1 (0.5) | 0 (0.0) | 1 |
| Family history breast cancer | 338 (39.8) | 168 (67.5) | < 0.001 |
| Family history ovarian cancer (%) | 94 (11.5) | 22 (8.9) | 0.305 |
| History of ADH (%) | 209 (32.4) | 43 (21.3) | 0.003 |
| History of ALH yes (%) | 128 (18.9) | 24 (11.9) | 0.026 |
| History of LCIS (%) | 134 (19.1) | 35 (17.2) | 0.59 |

**TABLE 3** Diagnoses in MRI-guided versus non-MRI-guided biopsies

| | Non-MRI-guided | MRI guided | *p*-value for difference |
|---|---|---|---|
| *n* | 91 | 94 | |
| Image guided biopsy result | | | |
| Benign (%) | 23 (25.3) | 54 (57.4) | < 0.001 |
| High risk (%) | 31 (34.1) | 31 (33.0) | 0.971 |
| LCIS (%) | 31 (34.1) | 6 (6.4) | < 0.001 |
| Malignant (%) | 6 (6.6) | 3 (3.2) | 0.151 |

or invasive cancer.[13] MRI exams have a higher callback rate than mammography and US with rates of 24%, 10%, and 9% respectively.[14] Even with a higher callback rate, the majority of MRI-guided biopsies tend to be benign.[15]

In keeping with the higher sensitivity of the exam, the specificity of MRI is reduced, with false-positive rates up to 10%.[16] False-positives results from screening have been found to cause psychological distress in patients. Although daily functioning was not impaired, patients screened with MRI have been known to have higher-than-baseline levels of anxiety.[17] However, the reassurance from the high sensitivity of MRIs outweighs the distress of abnormal screens.[16] In a survey study by Geuzinge et al., high-risk patients preferred to undergo screening with MRI as opposed to mammograms, likely due to this increased sensitivity.[18]

In addition to the psychological concerns for patients who undergo MRI screening, the accumulation of gadolinium in the setting of gadolinium-based contrast agents is being studied. Most recent data show that allergic reactions and severe acute reactions are rare as well as nephrogenic systemic fibrosis. Further long-term studies are required to see whether long-term accumulation in the brain can create adverse effects in patients regularly screened with MRIs.[19]

The current study demonstrates a higher rate of detecting high-risk lesions in patients undergoing MRI screening. Although benign, lesions, such as atypical hyperplasia and LCIS, contribute to the lifetime risk of developing breast cancer and may encourage patients to consider risk-reducing interventions such as chemoprevention.[20] In addition, surgical excision of ADH is recommended after biopsy, because upgrade rates ranging from 0 to 84% have been demonstrated in literature.[21]

Whether their screening included MRI or not, high-risk patients in our study who developed breast cancer were uniformly diagnosed with early-stage disease. Our study clearly demonstrated the benefit of mammography and US in screening high-risk patients, supporting the continued use of conventional imaging in this population. Although the benefits of screening MRIs have been demonstrated in the literature, participation in high-risk registries such as ours may provide patients with the consistent focus on screening and prevention methods that support their compliance with the recommended regimens leading to detection of breast cancer at the earliest stages. Aside from adjunctive imaging modalities, patients in our high-risk registry benefit from meeting with a genetics counselor, discussing risk-reducing strategies with medical oncology, and undergoing regular follow-up with surgical oncology. While screening programs may not change the risk of our patients' being diagnosed with breast cancer, a focus on early detection should reduce their risks of dying from the disease.

There are several limitations to our study. Although offered to the high-risk patients, not all patients agreed to screening MRIs or had contraindications. Some patients may not have received prior authorization from insurance companies resulting in cost being an obstacle. Breast density also was not taken into consideration for this study. This is a single-institution study of patients receiving care at a tertiary referral center in an urban area. At enrollment in our high-risk program, patients fill out a fairly extensive questionnaire regarding their personal and family history. We do not confirm documentation of family history by reviewing pathology reports for affected family members. We also did not require central review of all imaging from outside facilities, with the exception of studies that triggered biopsies and surgical intervention.

## CONCLUSIONS

In our cohort of high-risk patients, those who underwent MRI screening did not have a higher rate of breast cancer detection compared with the group that did not incorporate MRI into their screening. While the majority of MRI-guided biopsy results were benign, a large number of high-risk lesions were detected on screening MRI that were not visualized by other imaging modalities, although this was not statistically significant. The presence of these lesions could potentially affect the patient's estimated risk for breast cancer and consideration of risk-reducing interventions. Whether MRI-detected or not, all patients in our high-risk cohort who were diagnosed with breast cancer in the study period had very early-stage disease, demonstrating the benefit of participation in these programs. The addition of screening MRIs did not make a significant difference in breast cancer detection if patients were enrolled in a high-risk monitoring program involving a multidisciplinary approach.

**TABLE 4** Characteristics of patients with subsequent bilateral mastectomies based on biopsy result in non-MRI guided versus MRI-guided cohorts

| | Benign biopsy result | | | High risk biopsy result | | | LCIS result | | | Malignant result | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Non-MRI-Guided Biopsy | MRI-Guided Biopsy | *p*-Value For Difference | Non-MRI-Guided Biopsy | MRI-Guided Biopsy | *p*-Value For Difference | Non-MRI-Guided Biopsy | MRI-Guided Biopsy | *p*-Value For Difference | Non-MRI-Guided Biopsy | MRI-Guided Biopsy | *p*-value for difference |
| Number of patients with bilateral mastectomies following biopsy | 7 | 17 | 0.614 | 1 | 3 | 0.629 | 2 | 1 | 1 | 2 | 3 | 0.165 |
| BRCA1 positive (%) | 3 (42.9) | 7 (41.2) | 0.976 | 0 (0.0) | 1 (33.3) | 0.235 | 0 (0.0) | 0 (0.0) | NA | 1 (50.0) | 1 (33.3) | 0.453 |
| BRCA2 positive (%) | 2 (28.6) | 9 (52.9) | 0.313 | 0 (0.0) | 0 (0.0) | NA | 0 (0.0) | 0 (0.0) | NA | 1 (50.0) | 2 (66.7) | 1 |
| Family history breast cancer (%) | 7(100.0) | 14 (82.4) | 1 | 1 (100.0) | 1 (33.3) | 1 | 0 (0.0) | 0 (0.0) | NA | 1 (50.0) | 3 (100.0] | 0.777 |
| Family history ovarian cancer (%) | 4 (57.1) | 3 (17.7) | 1 | 0 (0.0) | 1 (33.3) | 0.987 | 1 (50.0) | 0 (0.0) | 1 | 0 (0.0) | 1 (33.3) | 1 |
| ADH (%) | 1 (14.3) | 2 (11.8) | 0.905 | 0 (0.0) | 2 (66.7) | 0.905 | 1 (50.0) | 0 (0.0) | 1 | 1 (50.0) | 1 (33.3) | 0.905 |
| ALH (%) | 1 (14.3) | 0 (0.0) | 1 | 1 (100.0) | 0 (0.0) | 1 | 1(50.0) | 1 (100.0) | 1 | 0 (0.0) | 0 (0.0) | NA |
| LCIS (%) | 0 (0.0) | 0 (0.0) | NA | 1 (100.0) | 0 (0.0) | 0.97 | 1 (50.0) | 0 (0.0) | 1 | 1 (50.0) | 0 (0.0) | 1 |
| Mean number of screening MRIs | 3.29 | 1.76 | 0.58 | 2 | 1 | 0.02 | 1.5 | 2 | 0.332 | 4.5 | 6.33 | 0.233 |
| Mean number of image guided biopsies | 1.29 | 1.18 | 0.15 | 1.33 | 1 | 0.193 | 1 | 3 | 0.11 | 1.5 | 2.33 | 0.526 |

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