Breast MRI BI-RADS Assessments and Abnormal Interpretation Rates by Clinical Indication in US Community Practices

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Rationale and Objectives: As breast magnetic resonance imaging (MRI) use grows, benchmark performance parameters are needed for auditing and quality assurance purposes. We describe the variation in breast MRI abnormal interpretation rates (AIRs) by clinical indication among a large sample of US community practices.

Materials and Methods: We analyzed data from 41 facilities across five Breast Cancer Surveillance Consortium imaging registries. Each registry obtained institutional review board approval for this Health Insurance Portability and Accountability Act compliant analysis. We included 11,654 breast MRI examinations conducted in 2005–2010 among women aged 18–79 years. We categorized clinical indications as 1) screening, 2) extent of disease, 3) diagnostic (eg, breast symptoms), and 4) other (eg, short-interval follow-up). We characterized assessments as positive (ie, Breast Imaging Reporting and Data System [BI-RADS] 0, 4, and 5) or negative (ie, BI-RADS 1, 2, and 6) and provide results with BI-RADS 3 categorized as positive and negative. We tested for differences in AIRs across clinical indications both unadjusted and adjusted for patient characteristics and registry and assessed for changes in AIRs by year within each clinical indication.

Results: When categorizing BI-RADS 3 as positive, AIRs were 21.0% (95% confidence interval [CI], 19.8–22.3) for screening, 31.7% (95% CI, 29.6–33.8) for extent of disease, 29.7% (95% CI, 28.3–31.1) for diagnostic, and 27.4% (95% CI, 25.0–29.8) for other indications ($P < .0001$). When categorizing BI-RADS 3 as negative, AIRs were 10.5% (95% CI, 9.5–11.4) for screening, 21.8% (95% CI, 19.9–23.6) for extent of disease, 17.7% (95% CI, 16.5–18.8) for diagnostic, and 13.3% (95% CI, 11.6–15.2) for other indications ($P < .0001$). The significant differences in AIRs by indication persisted even after adjusting for patient characteristics and registry ($P < .0001$). In addition, for most indications, there were no significant changes in AIRs over time.

Conclusions: Breast MRI AIRs differ significantly by clinical indication. Practices should stratify breast MRI examinations by indication for quality assurance and auditing purposes.

Key Words: Breast magnetic resonance imaging; audit; quality assurance.

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Breast magnetic resonance imaging (MRI) is the most sensitive modality for detecting breast cancer, often identifying malignancy otherwise occult by mammography, ultrasound, and clinical breast examination (1). As the technology improves and the interpretation and reporting by radiologists become standardized, breast MRI is used for an increasing number of purposes, including high-risk screening, evaluation of extent of malignancy, evaluation of patients with metastatic axillary adenopathy and unknown primary cancer, and surveillance after cancer treatment (2–9). Moreover, the technology has now become readily available in community settings throughout the United States with interpretation and reporting completed by both subspecialty-trained breast imagers and general radiologists (10).

To facilitate consistent reporting of and management recommendations for breast MRI findings, the American College of Radiology published the first edition of the Breast

Imaging Reporting and Data System (BI-RADS) (11) MRI lexicon in 2003, with the most recently revised edition published in 2013 (12). Similar to the previously established BI-RADS mammography lexicon, the breast MRI lexicon provides common terminology for describing MRI findings. Standardized use of the lexicon and BI-RADS assessment categories allows for improved communication among radiologists and clinicians with regards to suspicious imaging findings and clinical recommendations (13). Recent studies have shown that the MRI BI-RADS assessment categories can accurately predict the risk of malignancy (14,15).

Under the Medicare Improvement for Patients and Providers Act of 2008, all radiology practices that bill for the technical component of breast MRI under part B of the Medicare Physician Fee Schedule must be accredited as of January 1, 2012 to qualify for reimbursements (16). To be awarded accreditation, practices must meet minimum quality standards, including mandatory use of MRI BI-RADS lexicon in reporting. In addition, imaging centers must maintain a medical outcomes audit program to follow-up positive BI-RADS assessments and correlate pathology results with suspicious imaging findings (17). In general, medical audits are widely recognized as important and effective quality assurance tools for improved patient care (18,19).

Creating and maintaining a medical outcomes audit program for mammography can be difficult for community radiology practices without robust linkages to pathology and oncology databases (19). It is expected that similar challenges will affect the development of breast MRI outcome audits, and practices will need to rely on data that are readily available, such as clinical indications and image-guided biopsy results, to begin developing medical audit programs. Given the requirement for standardized use of MRI BI-RADS assessments, overall abnormal interpretation (ie, recall) rates for breast MRI (recorded as a proportion of MRI examinations with positive BI-RADS assessments) are realistic audit parameters readily determined by most community radiology practices developing breast MRI quality assurance programs.

Our study objective was to estimate abnormal interpretation rates (AIRs) overall and by clinical indications for breast MRI encountered in routine community practice. We provide a descriptive analysis of all breast MRI examinations performed across a geographically diverse set of radiology practices over a 6-year period. Based on our experience with mammography audits, we hypothesized that the proportion of positive BI-RADS assessments differs for screening versus diagnostic MRI examinations.

MATERIALS AND METHODS

Data Source

Each of the National Cancer Institute–funded Breast Cancer Surveillance Consortium (BCSC) registries sends data for breast MRI examinations to a central Statistical Coordinating Center (SCC) for pooled analyses. Each registry and the SCC follow previously reported data management and quality control procedures to ensure accurate data collection across registries (20). Each registry and the SCC obtain institutional review board approval for either passive or active patient consent or waiver of consent, linkage of patient characteristics to imaging-related outcomes, and performance of statistical analyses and results reporting. The SCC and each registry have a Federal Certificate of Confidentiality and other protections for the identity of individual women, physicians, and practices that are subjects of this research. All study procedures were compliant with the Health Insurance Portability and Accountability Act.

For this descriptive analysis, we used data from five breast imaging registries of the BCSC: the San Francisco Mammography Registry, Vermont Breast Cancer Surveillance System, New Hampshire Mammography Network, Carolina Mammography Registry, and Group Health Cooperative (Washington State). These registries comprise a geographically diverse group of breast imaging facilities in US community settings that prospectively collect patient demographic and clinical information and breast imaging interpretation data as part of routine clinical care. A total of 41 individual imaging facilities across the five registries provided breast MRI data.

Study Population

We included data from all breast MRI examinations conducted in 2005–2010 among women aged 18–79 years with reported clinical indication(s) and final BI-RADS assessment across the five BCSC registries. The registries collected standardized data on breast MRI examinations, including the clinical indication(s) for the examination and the final BI-RADS assessments for each breast, from electronic data systems, billing information, and abstraction of radiology reports. Patient risk factor information was obtained at the time of the MRI examination or from the most recent mammogram within 1 year before the breast MRI examination, including: the patient's age, race and/or ethnicity, any personal history of breast cancer (self-reported or via linkage with tumor registries), family history (first-degree relative) of breast cancer, and the reported mammographic BI-RADS breast density.

Clinical Indication Categorization

We stratified reported clinical indications for breast MRI into one of the following four categories: 1) screening (ie, asymptomatic), 2) extent of disease, 3) diagnostic, and 4) other. Our "diagnostic" indication category included MRI examinations performed for additional evaluation of a recent abnormality identified by mammography or ultrasound, evaluation of specific breast symptoms, and differentiation of cancer recurrence from postsurgical scar. Our "other" indication category included MRI examinations performed for short-interval follow-up of a probably benign MRI finding, evaluation of treatment response to neoadjuvant chemotherapy, and all other recorded indications not conforming to any other