Objectivity and accuracy of mammogram interpretation using the BI-RADS final assessment categories in 40- to 49-year-old women

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To determine if use of the five final assessment categories of the American College of Radiology’s Breast Imaging Reporting and Data System (BI-RADS) improved objectivity or accuracy of mammographic evaluation in 40- to 49-year-old women, fifty mammograms of 40- to 49-year-old women that were obtained at a tertiary referral teaching hospital were classified according to those five final assessment categories. The mammograms were blinded to six American Osteopathic Board of Radiology–certified radiologists who were asked to classify each mammogram within the five final BI-RADS categories based on the mediolateral oblique and craniocaudal views presented. No history was allowed. Use of the BI-RADS five final assessment categories provided moderate interobserver objectivity, moderately high agreement among the radiologists’ interpretation (reliability), and moderate accuracy of interpretation (validity) when compared to criterion. Moderate interobserver reliability and accuracy has been previously identified; however, no scientific review of the BI-RADS five final assessment categories in 40- to 49-year-old females was discovered in the current literature. No overall improvement of objectivity or accuracy was demonstrated using the five final assessment categories of the BI-RADS lexicon in 40- to 49-year-old women.

(Key words: mammography, Breast Imaging Reporting and Data System, breast cancer)

Breast cancer remains the most frequently diagnosed female malignancy in the United States. It is the single leading cause of death for women aged 40 to 49 years in the United States, with more than 40% of the lost years of life from breast cancer diagnosed before the age of 50. The number of deaths caused by breast cancer can be reduced by early detection and intervention. The interpretation and management recommendation of mammographic studies can influence the stage and progression of detected breast cancer and thus affect mortality.

To standardize mammographic reporting, reduce confusion in breast imaging interpretation, and facilitate outcome monitoring, the American College of Radiology developed the Breast Imaging Reporting and Data System (BI-RADS). The BI-RADS lexicon includes evaluation of appropriateness and accuracy of examination interpretation to provide peer review and data for quality assurance in an effort to improve overall patient breast healthcare. The mammographic details guide the classification and recommendation by the interpreting radiologist. The BI-RADS is believed to achieve reduction in description ambiguity of mammography. The five final assessment categories of the BI-RADS lexicon are outlined in Table 1. An “assessment incomplete” category is included in the BI-RADS lexicon, but is not a focus of this study.

The purpose of this study was to describe the objectivity and accuracy of radiologists’ interpretation of mammograms in 40- to 49-year-old women using the five final assessment categories described within the BI-RADS lexicon in a tertiary referral teaching hospital.

Methods
Fifty screening and diagnostic mammograms obtained at a tertiary referral teaching hospital from 1993 to 1997 were selected and classified according to the five BI-RADS final assessment categories. The hospital’s mammography department is accredited by the Food and Drug Administration according to the Mammography Quality Standards Act requirements. The mammograms included in this study were either stable for at least 2 years or had histopathologic diagnosis. A biopsy was not required to verify lack of cancer.

The patients were 40- to 49-year-old females. Women with previously benign biopsies were included in this study. Patients with a history of breast cancer, large breasts requiring multiple or special film, previous cosmetic surgery, or mastectomy or augmentation, as well as films of inadequate technical quality were excluded. Standard mediolateral oblique and craniocaudal views of original films were available for each breast. Mammography was performed with a Bennett MF-150 unit (1992) using Kodak MIN-R screen and Kodak MIN-RE single emulsion film. All were processed with a dedicated mammographic processor using a 3-minute development process. The mammograms were randomly coded by number for confidentiality, blinded to the radiologist.

To determine if use of the five final assessment categories of the American College of Radiology’s Breast Imaging Reporting and Data System (BI-RADS) improved objectivity or accuracy of mammographic evaluation in 40- to 49-year-old women, fifty mammograms of 40- to 49-year-old women that were obtained at a tertiary referral teaching hospital were classified according to those five final assessment categories. The mammograms were blinded to six American Osteopathic Board of Radiology–certified radiologists who were asked to classify each mammogram within the five final BI-RADS categories based on the mediolateral oblique and craniocaudal views presented. No history was allowed. Use of the BI-RADS five final assessment categories provided moderate interobserver objectivity, moderately high agreement among the radiologists’ interpretation (reliability), and moderate accuracy of interpretation (validity) when compared to criterion. Moderate interobserver reliability and accuracy has been previously identified; however, no scientific review of the BI-RADS five final assessment categories in 40- to 49-year-old females was discovered in the current literature. No overall improvement of objectivity or accuracy was demonstrated using the five final assessment categories of the BI-RADS lexicon in 40- to 49-year-old women.
Criterion is defined as placement of the mammographic examination retrospectively into a BI-RADS final assessment category, 1 to 5, based on the known stability or tissue diagnosis. The five categories were also condensed and recoded into three categories representing similar patient management recommendations: benign (BI-RADS 1 and 2), probably benign (BI-RADS 3), and suspicious (BI-RADS 4 and 5). The distribution in the management categories is shown in Table 3.

Reliability is the comparison of two radiologists’ interpretations. The five final assessment BI-RADS categories and the three condensed management recommendations were assessed for reliability using Pearson correlation coefficients \( r \) for comparison of all possible paired combinations of radiologists. A concordance coefficient \( W \) was calculated to determine the general agreement among the radiologists and was the measure of interobserver objectivity for the five category and three management recommendations. Thus, interobserver objectivity is defined as the overall agreement of the group of six radiologists.

Validity is the correlation of the individual radiologists’ categorical placement of a mammogram versus the final diagnostic criterion, determined with Pearson correlation coefficient. For each radiologist, the Pearson correlation coefficient was also used to determine validity for the three patient management categories. Group validity was determined by calculating a concordance coefficient for the group of radiologists versus the final diag-

### Table 1
ACR Breast Imaging Reporting and Data System (BI-RADS): Final Assessment Categories

<table>
<thead>
<tr>
<th>Category</th>
<th>Assessment</th>
<th>Description and recommendation</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Negative (N)</td>
<td>Nothing on which to comment, annual mammogram</td>
</tr>
<tr>
<td>2</td>
<td>Benign (B)</td>
<td>Definitely benign finding described, annual mammogram</td>
</tr>
<tr>
<td>3</td>
<td>Probably benign (P)</td>
<td>High probability of being benign. Short-term follow-up recommended to establish stability.</td>
</tr>
<tr>
<td>4</td>
<td>Suspicious abnormality (S)</td>
<td>Not characteristic, but has a reasonable probability of being malignant. Biopsy urged.</td>
</tr>
<tr>
<td>5</td>
<td>Highly suggestive of malignancy</td>
<td>High probability of cancer. Appropriate action should be taken.</td>
</tr>
</tbody>
</table>

*BI-RADS = Breast Imaging Reporting and Data System.

### Table 2
Subject Distribution of Diagnostic Criterion Using Five Final Assessment BI-RADS Categories

<table>
<thead>
<tr>
<th>BI-RADS category</th>
<th>n</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>14</td>
<td>28</td>
</tr>
<tr>
<td>2</td>
<td>20</td>
<td>40</td>
</tr>
<tr>
<td>3</td>
<td>10</td>
<td>20</td>
</tr>
<tr>
<td>4</td>
<td>2</td>
<td>4</td>
</tr>
<tr>
<td>5</td>
<td>4</td>
<td>8</td>
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</tbody>
</table>

### Table 3
Subject Distribution of Diagnostic Criterion Using Three Recommended Management Categories

<table>
<thead>
<tr>
<th>Category</th>
<th>Recommendation</th>
<th>n</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Benign</td>
<td>Annual mammography</td>
<td>34</td>
<td>68</td>
</tr>
<tr>
<td>Probably benign</td>
<td>6-month follow-up to establish stability</td>
<td>10</td>
<td>20</td>
</tr>
<tr>
<td>Suspected malignancy</td>
<td>Recommend tissue sampling</td>
<td>6</td>
<td>12</td>
</tr>
</tbody>
</table>
nostic criterion of the five BI-RADS categories and again for the three patient management categories. Descriptors of correlation and concordance statistics include no correlation, $<0.20$; low, $0.20$ to $0.39$; moderate, $0.40$ to $0.59$; moderately high, $0.60$ to $0.79$; and high, $>0.79$.

One-way analysis of variance (ANOVA) with repeated measures on the subjects with the Dunnett test post hoc compared each radiologist with the criterion to assess significant differences in interpretation for the five BI-RAD categories and three management recommendations. The repeated-measures ANOVA was used to reduce variability attributed to subject differences. Sensitivity and specificity were not included due to the error created by the limited number of subjects in this study.

Results

The mean score of the five-category BI-RADS criterion was $2.24 \pm 1.15$ (mean ± SD). The radiologists’ mean score ranged from $1.74 \pm 1.10$ to $2.42 \pm 1.05$ (Table 4). Radiologists 1 and 6 mean scores were significantly lower than the criterion ($P<.01$). This was due primarily to disagreement within categories 1 and 2. When condensed into three categories based on similar patient manage-

<table>
<thead>
<tr>
<th>Radiologist</th>
<th>Criterion</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>0.74</td>
<td>1.00</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>0.69</td>
<td>0.69</td>
<td>1.00</td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>3</td>
<td>0.61</td>
<td>0.61</td>
<td>0.68</td>
<td>1.00</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>0.70</td>
<td>0.75</td>
<td>0.70</td>
<td>0.41</td>
<td>1.00</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>0.53</td>
<td>0.49</td>
<td>0.59</td>
<td>0.48</td>
<td>0.53</td>
<td>1.00</td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>0.80</td>
<td>0.73</td>
<td>0.66</td>
<td>0.55</td>
<td>0.71</td>
<td>0.47</td>
<td>1.00</td>
</tr>
</tbody>
</table>

*BI-RADS = Breast Imaging Reporting and Data System.
†Significantly different from criterion ($P<.01$).

Figure 1. Correlation matrix for radiologists’ comparisons using the five BI-RADS categories.

Figure 2. Correlation matrix for radiologists’ comparisons using the three patient management recommendation categories.
Mean reliability for paired radiologist agreement for the five BI-RADS categories was $r=0.60$ (range, $r=0.41$ to 0.75; $P<.01$). The concordance coefficient demonstrated moderate interobserver objectivity among the radiologists ($W=0.52$) and moderate validity ($W=0.58$) compared with the five-category criterion (Figure 1). Individual radiologist validity ranged from $r=0.53$ to $r=0.80$ (moderate to high).

When condensed into three categories based on patient management recommendations, mean reliability remained $r=0.60$ (range, $r=0.41$ to 0.83), interobserver objectivity among radiologists remained moderate ($W=0.58$), and validity was $W=0.60$. There was no significant improvement in interobserver objectivity or validity when comparing the five BI-RADS categories to the three patient management categories ($P>.05$; Figure 2). An example of a mammogram with complete agreement between radiologists is demonstrated in Figure 3. The breasts are heterogeneous but without focal densities or calcifications. All radiologists interpreted this exam as BI-RADS Category 1.

Figure 4 and Figure 5 illustrate mammograms for which all of the radiologists were suspicious, placing them into categories 4 and 5. Although there was
disagreement on the specific category, all agreed on recommended management. Each demonstrates invasive ductal adenocarcinoma.

Considerable variability occurred with the mammograms in Figure 6 and Figure 7. Figure 6, a biopsy-proven benign radial scar, received category ratings of 2, 3, and 4. Figure 7 demonstrates focal parenchymal density that has remained stable for 3 years; however, without prior mammograms or patient history, this example received category ratings of 2, 3, and 4.

Comments
The management recommendation from the radiologist to the referring physician is the most significant component of the mammogram report. For that reason we included performance based not only on the five final BI-RADS assessment categories, but on the three management recommendation categories. Two radiologists demonstrated significant under-scoring within categories 1 and 2. Radiologists interpret findings differently based on variable thresholds of concern; however, the agreement and accuracy remained moderate to moderately high, comparable to previously published literature. It is important for the literature to continue to demonstrate only moderate to moderately high accuracy, but no study design will ever simulate radiologists’ interpretation conditions. Accuracy is improved when mammography is combined with physical examination. Improved interpretation skills have been demonstrated with high-quality comparison exams and complete diagnostic workup of mammographic abnormalities, but these were not components of this study design.

This study was not designed to simulate clinical conditions of mammographic interpretation. The fifty mammograms were selected to provide an adequate spectrum of variable findings. Many of the women had not had annual mammography performed in the past and, in preparing for this study, were variable in the timing of their mammograms. It was necessary to provide at least 2 years’ stability, several patients having 4 years between examinations. The goal was to determine interobserver objectivity and accuracy based solely on the presenting mammographic characteristics.

One scientific review of the ACR BI-RADS final assessment categories was discovered in the literature; however, no review specifically addressed 40- to 49-year-old women; however, due to the limited number of subjects of this study, further investigation is recommended.

References
5. Fletcher SW, Black W, Harris R, Rimer BK, Shapiro S. Report of International Workshop on...


The D.O.

The November issue of The D.O. will outline the AOA Campaign for Osteopathic Unity’s new advertising initiative, as well as offer early critiques of the AOA’s new ads from members of the profession.

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- “Thoracic lymphatic pumping and the efficacy of influenza vaccination in healthy young and elderly populations”
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