Breast ultrasound outcomes for mass lesions on breast imaging reporting and data system, category 0, mammograms

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Purpose

Ultrasonography (US) plays an important role in detecting breast lesions that are either palpable or only detected by imaging [1-3]. US is the current choice for the evaluation of dense breasts in young patients, the differentiation of cystic and solid lesions, and for guidance procedures [4-9]. Nonetheless, US has traditionally been the preferred adjunctive method when further evaluation is required after mammography [10]. However, the impact of sonography after a Bi-RADS 0 mammogram has not been thoroughly investigated in the literature [11]. Although some authors have addressed the value of US in Bi-RADS categories from 3 to 5 [12-13], to date, there are no studies assessing US performance and its resolution under the scenario mentioned above. The purposes of this study were:

1. to investigate the performance of US as a secondary diagnostic tool and to assess the outcome of mammograms initially classified as Bi-RADS category 0.

2. to assess if diagnostic performance of US varies according to breast parenchymal density on mammography
Methods and Materials

This retrospective study included all consecutive screening mammography data collected between January 2005 and July 2006. For patients with mammograms classified as Bi-RADS 0, we retrieved the method subsequently used, the results obtained, and the approach adopted after the additional imaging. Medical records were reviewed to determine the final outcome.

Imaging techniques

All mammograms exams consisted of the routine craniocaudal and oblique mediolateral views of both breasts and additional incidences (magnification, compression, etc) if indicated. All ultrasound exams were performed with real-time, dynamic equipment, with a high-resolution, phased-array transducer with frequency ranging from 7.0 to 12.0 MHz, using Color and Power Doppler.

Imaging Interpretation

Mammograms were evaluated and reported using the Bi-RADS lexicon and a final Bi-RADS category was reported. Breast parenchymal density was evaluated, using Bi-RADS systematization: American College of Radiology density 1 (ACR D1), almost entirely fat; ACR D2, scattered fibroglandular densities; ACR D3, heterogeneously dense; and ACR D4, dense.

US was considered diagnostic if the Bi-RADS category changed to 2, 4 or 5, based on the definition suggested by Kubiak et al [14]. If cases returned for follow-up by mammography, then US was considered indeterminate, and the mammogram category changed to Bi-RADS 3.

The US criteria for probably benign solid lesions were as follows:

a) shape: oval or round;

b) margins: circumscribed;

c) echo pattern: isoechoic, hyperechoic or hypoechoic;

d) orientation: parallel (wider than taller); and

e) posterior acoustic features: enhancement or no posterior acoustic features.
Results

The study is summarized in table 1. The mean age of the patients was 53.3 (35 to 81 years old). After applying inclusion and exclusion criteria, we retrieved 241 patients who had US and for whom an adjuvant method was indicated.

The distribution of all lesions according to the Bi-RADS Lexicon was the following:

- 62/241 (25.7%) - round or oval, circumscribed lesions;
- 81/241 (33.6%) - round or oval lesions, but with obscured margins;
- 21/241 (8.8%) - mass-like asymmetries;
- 38/241 (15.7%) - focal asymmetries;
- 10/241 (3.9%) - multiple round, circumscribed lesions;
- 29/241 cases represented mixed findings (11.3%).

Among the 391 Bi-RADS category 0 mammograms, 302 (77.2%) required additional views before final classification.

After US, the exams of 95 out of 241 (39.40%) patients were considered indeterminate, Bi-RADS category 3. And, in 146 cases (60.6%), US was considered diagnostic. In the diagnostic group, for 70.2 % of cases (111/146), US changed the Bi-RADS category to benign, category 2, and for the remaining 35 cases (29.8%), US moved the level to suspicious category 4. For the 111 patients who had Bi-RADS reassigned to category 2, the US findings were cysts in 72 patients (64.9 %), ductal ectasia in 13 cases (11.7%), ultrasonographic benign-appearing mass in 21 cases (18.9%) and other benign features, such as linear scars, in 5 (4.5%) cases.

For the 35 patients with Bi-RADS 4 determined by US, 25 (71.4%) patients had benign findings, while cancer was found in 10 patients (28.6%); 5 with Invasive Ductal Carcinoma (Figures 4 to 6), 2 with Ductal Carcinoma in situ, 1 with Invasive Lobular Carcinoma (Figures 7 to 9), 1 with a malignant Phyllodes tumor and 1 with undifferentiated carcinoma, metastatic from the uterine cervix.

Over the follow-up period (at least two years), no lesions defined as benign by US turned out to be malignant. The diagnostic performance of US, according to breast parenchymal density shows no significant difference between fatty (grades D1 and D2) and dense
breasts (grades D3 and D4) using the Chi-Square (Table 2). The overall diagnostic performance of US is shown in Table 3.
Fig. 0: Flowchart of entire study.

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<table>
<thead>
<tr>
<th>Breast Parenchymal Density</th>
<th>Grade D1+D2 Fatty Breasts</th>
<th>Grade D3+D4 Dense Breasts</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diagnostic Ultrasonography</td>
<td>113/147 (76.1%)</td>
<td>94/113 (83.1%)</td>
</tr>
<tr>
<td>Breast Cancers found</td>
<td>6/147 (4.0%)</td>
<td>4/113 (3.5%)</td>
</tr>
</tbody>
</table>

Fig. 0: US diagnostic performance according to breast parenchymal density
<table>
<thead>
<tr>
<th>TEST RESULT</th>
<th>Disease +</th>
<th>Disease -</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>US +</td>
<td>10 (TP)</td>
<td>25 (FP)</td>
<td>35</td>
</tr>
<tr>
<td>US -</td>
<td>0 (FN)</td>
<td>206 (TN)</td>
<td>206</td>
</tr>
<tr>
<td>Total</td>
<td>10</td>
<td>231</td>
<td>241</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Formula</th>
<th>Value (%)</th>
<th>95% Confid. Interval</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sensitivity</td>
<td>TP/TP+FN</td>
<td>100.0</td>
<td>65.5 – 100.0</td>
</tr>
<tr>
<td>Specificity</td>
<td>TN/TN+FP</td>
<td>89.1</td>
<td>84.2 – 92.7</td>
</tr>
<tr>
<td>Accuracy</td>
<td>TP+TN/Total</td>
<td>89.6</td>
<td>83.3 – 94.1</td>
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<tr>
<td>Positive Predic. Value</td>
<td>TP/TP+FP</td>
<td>28.6</td>
<td>15.2 – 46.5</td>
</tr>
<tr>
<td>Negative Predic. Value</td>
<td>TN/TN+FN</td>
<td>100.0</td>
<td>97.7 – 100.0</td>
</tr>
<tr>
<td>Error Rate</td>
<td>FP+FN/Total</td>
<td>10.4</td>
<td>6.7-13.1</td>
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<tr>
<td>Prevalence</td>
<td>TP+FN/Total</td>
<td>4.1</td>
<td>2.1-7.7</td>
</tr>
</tbody>
</table>

**Fig. 0:** US diagnostic performance for breast cancer detection

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Fig. 0: Figure 4. Oblique view of both breasts. A focal asymmetry is seen in the left upper quadrant (arrow).

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**Fig. 0:** Figure 5. Magnified view showing an irregular mass lesion and indistinct margins (arrow).

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**Fig. 0:** Figure 6. US shows an irregular, hypoechoic mass with indistinct margins (arrow). Core biopsy revealed a Ductal Invasive Carcinoma.

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**Fig. 0:** Figure 7. Oblique views of both breasts. A subtle asymmetry is hardly seen on right breast.

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**Fig. 0:** Figure 8. Magnified view. A subtle round asymmetry is seen in the right breast (arrows).

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Fig. 0: Figure 9. US demonstrates an irregular mass. Invasive Lobular Carcinoma at histology.

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Conclusion

Our study indicates that:

1- US provides a very efficient alternative to a screening mammogram for obtaining more information about specific breast lesions, which is the rationale for the Bi-RADS 0 category. It has the potential ability to change the management of a case in which a biopsy might be recommended but for which the risk of carcinoma is estimated to be relatively low.

2- A significant fraction of our patients (95/241 - 39.4%) was classified as Bi-RADS 3. We didn’t move patients whose exams were re-classified to Bi-RADS 3 into the diagnostic group, as we focused on immediate resolution and discharged these cases as being promptly solved by US.

3 - The sensitivity of ultrasonography was equivalent for all grades of density. And, in our series, the distribution of Bi-RADS 0 cases according to breast parenchymal density did not show any predominance.
References

