Downgrading BI-RADS 4a and 4b benign masses using functional images of hemoglobin and blood oxygen saturation co-registered with ultrasound provide differentiation of breast tumors

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Objective

• A novel opto-acoustic (OA) system combining OA with co-registered ultrasound produced images which were independently tested by blinded readers to evaluate the ability to downgrade BI-RADS 4a and 4b cases according to conventional diagnostic ultrasound
Technology

• OA employs near-infrared laser pulses at two different wavelengths
• OA provides contrast between oxygenated hemoglobin in benign lesions and de-oxygenated hemoglobin in malignant lesions
• OA illuminates tissues through a fiberoptic bundle incorporated into a prototype hand-held opto-acoustic-ultrasound probe
• OA detects the laser pulse induced acoustic pressure waves that are then used for reconstruction of two-dimensional functional and anatomical images
• OA maps of total hemoglobin and blood oxygen saturation provide functional information that is co-registered with the morphological information from B-mode gray scale ultrasound images
Study Methodology

• A prospective observational clinical study
• A consecutive series of BI-RADS 3, 4, and 5 patients
• A total of 73 patients underwent biopsy
• A total of 74 breast masses were assessed with OA
• Histology was the gold standard
• All OA images were read by five independent readers without access to:
  – Subject history
  – Biopsy report
  – Histology report
  – Clinical records
  – Follow-up
# BI-RADS Classification

<table>
<thead>
<tr>
<th>BI-RADS</th>
<th>Probability of Malignancy</th>
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<tbody>
<tr>
<td>3</td>
<td>≤ 2%</td>
</tr>
<tr>
<td>4a</td>
<td>&gt;2% but ≤10%</td>
</tr>
<tr>
<td>4b</td>
<td>&gt;10% to ≤50%</td>
</tr>
</tbody>
</table>
BI-RADS 4 – Fibroadenoma
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Results

• All 34 cancer masses remained at original BI-RADS per site PI

• For 40 biopsied benign masses, downgrades were achieved as follows:
  – BI-RADS 3: 5/5 (100%) remained BI-RADS 3
  – BI-RADS 4a: 12/22 (54%) downgraded to BI-RADS 3
  – BI-RADS 4b: 3/13 (23%) downgraded to BI-RADS 3

• OA could potentially spare 50% of BI-RADS 4a cases and 20% of BI-RADS 4b cases
Conclusion

• The fused functional OA and gray scale anatomic information significantly improved downgrading of benign breast masses, especially within the critical BI-RADS 4a and 4b categories

• A multi-center pivotal study is underway to confirm this finding