Upclassification of Suspicious Breast Masses Using Opto-Acoustic Imaging
San Antonio Breast Cancer Symposium, San Antonio, Texas, December 8 – 12, 2015

Philip T. Lavin, PhD1, A. Thomas Stavros, MD2, and Michael J. Ulissey3,4
Boston Biostatistics Research Foundation, Framingham, MA1, Seno Medical Instruments, Inc., San Antonio, TX2; Breast Diagnostic Center, Auburn, WA3, and Breast Diagnostic Center, Federal Way, WA4

BACKGROUND

Breast cancer diagnostic methodologies have been optimized to achieve increased sensitivity at the expense of relatively low specificity. Seno Medical’s opto-acoustic (OA) imaging fuses real-time, temporally resolved laser opto-acoustic and ultrasound imaging showing dual functional (hemin/hemoglobin de-oxygenation) and morphology findings for breast masses using a hand-held probe. We present data from the PIONEER Pilot Study (n=100). We have shown improved specificity for OA relative to the gray-scale ultrasound (CDU). We now examine the BI-RADS upgrades for 36 malignant masses achieved by OA versus IUS and the site determinations for BI-RADS 4c, and 22 BI-RADS 5 according to participating site radiologists’ clinical data or outcome. Among these masses, there were 2 BI-RADS 4b, 12 BI-RADS 4c, 11 BI-RADS 5 and 12 BI-RADS 4b, 9 BI-RADS 4c, 18 BI-RADS 5.

OBJECTIVES

The ability to upgrade BI-RADS 4b and 4c for cancer masses is an unmet need. If verified, these findings could provide additional evidence to confirm in vivo molecular and tumor stem cell diagnostic evaluations. This may help plan the efficient identification and excision of malignant masses.

METHODS

A total of 7 independent registration readers (IRRs) blindly assessed all 36 malignant masses using IUS first and OA second without any knowledge of clinical data or outcome. Among these masses, there were 2 BI-RADS 4b, 12 BI-RADS 4c, 11 BI-RADS 5. When OA was added to IUS, there was a favorable shift towards declaring BI-RADS 5. When OA was added to IUS, there was a favorable shift towards declaring BI-RADS 5. Overall, 12% of all OA reads resulted in upgrades in contrast to 4.4% for IUS alone with each compared to site CDU BI-RADS classifications. OA and IUS had comparable sensitivity.

RESULTS

Combining data from all 7 readers, OA findings enabled upgrades of site CDU-determined BI-RADS categories 43% of the time for BI-RADS 4b and 29% for BI-RADS 4c. In contrast, the overall percentages of IUS upgrades versus site CDU were 21% for BI-RADS 4b and 10% for BI-RADS 4c. Overall, 17% of all OA reads resulted in upgrades in contrast to 4.4% for IUS alone with each compared to site CDU BI-RADS classifications. OA and IUS had comparable sensitivity.

CONCLUSIONS

OA was more likely than IUS to result in a BI-RADS upgrade of a malignant mass. When OA was added to IUS, there was a favorable shift towards declaring BI-RADS 5.

This presentation is the intellectual property of the authors/presenter. Contact at SenoMedical.com for permission to reprint and/or distribute.