Focal breast lesions categorization according to the BI-RADS -US lexicon: role of a computer-aided decision-making support

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Purpose: to assess a computer-guided decision-making software (S-Detect) in the sonographic characterization of focal breast lesions (FBLs).

Methods: according to BI-RADS US lexicon, 300 FBLs (size: 2.6–47.2 mm; mean: 13.2 mm) in 255 patients (age: 13-98 years; mean 51 years) were prospectively assessed in consensus by two experienced radiologists without and with S-Detect. To evaluate intra and inter-observer agreement, two residents also assessed independently the same 300 FBLs at baseline and after 3 months. All the FBLs classified as BI-RADS 4 or 5 underwent core-biopsy whereas all the lesions classified as BI-RADS 3 were followed-up.

Results: 120/300 (40%) FBLs were malignant, 2/300 (0.7%) high-risk and 178/300 (59.3%) benign. Experts reviewers showed higher Sensitivity, Specificity, PPV and NPV with S-Detect (97.5%, 86.5%, 83.2%, 98.1%) than without (91.8%, 81.5%, 77.2%, 93.6%) ($p>0.05$), as confirmed by ROC curve analysis (0.95 with and 0.92 without [$p=0.0735$]). A significant higher area under the ROC curve was found for Resident #1 (0.85 without and 0.88 with S-Detect [$p=0.0067$]) and Resident #2 (0.83 without and 0.87 with S-Detect [$p=0.0302$]).

Intra-observer agreement (k score) improved with S-Detect from 0.69 to 0.78 for Resident #1 ($p>0.05$) and from 0.69 to 0.81 for Resident #2 ($p>0.05$). Inter-observer agreement improved with S-Detect from 0.67 to 0.7 (baseline; $p>0.05$) and from 0.63 to 0.77 (after 3 months; $p>0.05$).

According to S-Detect-guided re-classification, 27/64 (42.2%; 95%CI=[30.0; 52.3]) FBLs underwent a positive change in clinical management (CM), 25/64 (39.1%; 95%CI=[25.1; 51.0]) FBLs underwent no change and 12/68 (18.7%; 95%CI=[27.1; 51.1]) FBLs underwent a negative change in CM.
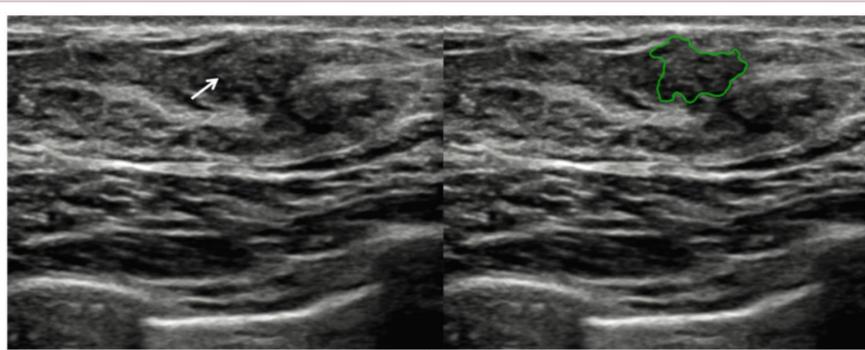
Invasive ductal carcinoma. Left: US shows a 7 mm lesion with margins initially assessed as circumscribed (arrow). Right: with S-Detect (green line contour) margins were classified as microlobulated and the lesion was correctly upgraded from BI-RADS 3 to 4.

Pericanalicular fibroadenoma. Left: US shows a 9 mm lesion with margins firstly assessed as partially indistinct (arrow). Right: with S-Detect margins were classified as circumscribed and the lesion was correctly down-graded from BI-RADS 4 to 3.
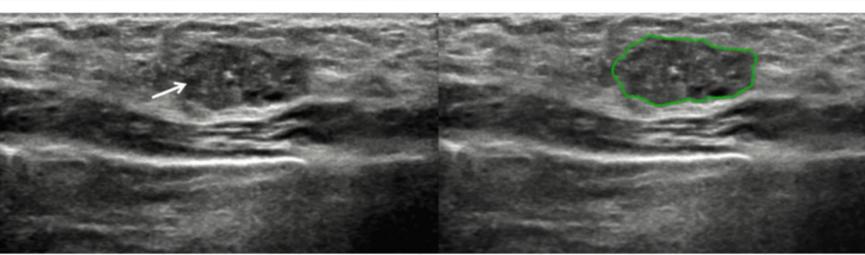
Mucinous carcinoma. Left: US shows a 15 mm mass with margins initially assessed as microlobulated (arrow). Right: with S-Detect margins were classified as circumscribed and the lesion was incorrectly down-graded from BI-RADS 4 to 3**.**

Conclusion: S-Detect is an effective tool for the classification of FBLs according to BI-RADS US lexicon, improving cancer detection rate, especially for less experienced physicians

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