

New Study Further Supports Hologic's Breast Tomosynthesis in Cancer Screening



Hologic has announced that a new study published online by European Radiology supports the use of breast tomosynthesis in combination with 2-dimensional (2D) imaging in breast cancer screening programmes using independent double reading with arbitration.

The study, "Prospective Trial Comparing Full-field Digital Mammography (FFDM) versus Combined FFDM and Tomosynthesis in a Population-based Screening Programme Using Independent Double Reading with Arbitration," was led by Per Skaane, M.D., Ph.D. of Oslo University Hospital Ullevaal. The analysis included a total of 12,621 screening examinations of women participating in the Oslo Tomosynthesis Screening Trial. In double reading, two radiologists independently read the same case and if the radiologists disagree on the diagnosis, there is an arbitration or consensus meeting where the final diagnosis of the case is decided. Double reading has been shown to increase cancer detection and is the standard method used for interpretation of mammograms for most countries outside the U.S. with organised population-based screening programmess. This study compares double reading of 2D mammography with double reading of 2D mammography plus tomosynthesis.

The researchers used Hologic's breast tomosynthesis cancer screening technology and found:

- · Tomosynthesis-based screening was successfully implemented in a large prospective screening trial.
- Double reading of tomosynthesis-based examinations significantly reduced false-positive interpretations. False-positive interpretations were decreased by 18% using 2D plus tomosynthesis.
- Double reading of tomosynthesis-based examinations significantly increased the detection of breast cancers by approximately 30%. The
 detection of invasive cancers was increased by approximately 40%.

"It is very encouraging, though not surprising, to see confirmation of the strong benefits our tomosynthesis technology can bring to users across different clinical environments," said Peter Soltani, Hologic's Senior Vice President and General Manager of Breast Health. "The Oslo data clearly indicates that double reading of 2D plus tomosynthesis imaging results in a large increase in the detection of invasive cancers and a reduction in false positives when compared with 2D double readings alone. This study reinforces a previous study measuring the benefits of tomosynthesis for a single reader and demonstrates that tomosynthesis provides major improvements in breast cancer screening for both single and double-reading screening methods. We believe that Hologic's breast tomosynthesis technology can make significant inroads in overcoming the limitations of conventional mammography, namely missed cancers and unnecessary recalls, and we expect the results of this study to further support the adoption of our tomosynthesis technology."

The European Radiology paper is the first peer-reviewed publication comparing the performance of double reading of 2D exams with double reading of 2D plus tomosynthesis imaging in a large prospective clinical trial.

Hologic's breast tomosynthesis technology has been approved for use for breast cancer screening and diagnosis in countries recognizing the CE mark since 2008. It was approved for use in the U.S. in February, 2011. Hologic systems are now in use in 48 states in the U.S. and over 50 countries.

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