

ACR, SBI Statement on Skaane et al – Tomosynthesis Breast Cancer Screening Study

The publication describes a pre-planned interim analysis of two arms of a four-arm study from Oslo, Norway. While the study results are promising, they do not provide adequate information to define the role of tomosynthesis in clinical practice. The reported data is from a prospective, single institution study analyzing results from 12,631 examinations interpreted by using mammography alone and mammography plus tomosynthesis. The study group was derived from 29,652 women aged 50-69 years of age invited to undergo routine, biennial two-view (CC and MLO) screening mammography. Of the invitees, 17,960 attended the screening program and 12,631 women agreed to participate in the study. Computer aided detection was not included in this part of the study and was not used for interpretation.

By performing additional imaging for all women in the form of a tomosynthesis exam, there was improvement in the cancer detection rate and a reduction in the recall rate. Benefit accrued to those who had a cancer detected by the addition of tomosynthesis and those who were not recalled because of the addition of tomosynthesis. The cancer detection rate for mammography alone was 6.1/1000 screenings (77 of 12,631 cases) and 8.0/1000 screenings (101 of 12,621 cases) with mammography plus tomosynthesis (31percent increase). The false positive rate was 13 percent less with mammography plus tomosynthesis compared to mammography alone (670 vs. 771).

Twenty-five (25) additional invasive cancers (81 vs. 56 cancers) were detected with mammography plus tomosynthesis vs with mammography alone. Although many of the cancers were primarily small and of lower grades at detection, 10 of the 25 detected only with mammography plus tomosynthesis (40 percent) were grade 2 or higher, providing a 26 percent (48 vs 38 cases) increase in the detection of higher grade cancers. There was no improvement in the detection of ductal carcinoma in situ.

Most cases were assessed as having BIRADS parenchymal density category 2 or 3. The additional cancers detected with mammography plus tomosynthesis were distributed across all breast densities, including fatty breasts.

In this study, with average breast thickness of 54 mm, the radiation dose for the combined study was 2.24 times that of mammography alone. The detector size is not as large as available with full field digital mammography. Women with larger breasts may not be able to have tomosynthesis of the entire breast volume without additional views, further raising the radiation dose. During an average of 9 months of follow-up to date, the investigators are aware of three interval cancers, all three cases interpreted with the same score for both mammography and mammography plus tomosynthesis.

These overall results raise questions as to how to implement tomosynthesis in clinical practice. Although the cancer detection rate was higher when tomosynthesis was added to mammography alone, it is not known if an equal incremental benefit will be realized in

a second screening round. This small study does not supply statistical information regarding subgroups of women that might benefit, or might not benefit from adding tomosynthesis. How the technology will affect screening accuracy among women of different ages, risk profiles and parenchymal density is uncertain. In addition, how this technology would affect reader performance among U.S. radiologists with varying practice patterns and expertise is also uncertain. Other questions include whether computer aided detection will provide any further benefit, and if reconstructed images can be used, in lieu of standard full field digital images, to reduce radiation dose.

In summary, an overall significantly higher cancer detection rate was found using mammography plus tomosynthesis, along with a significantly higher detection rate for invasive cancers. There was a reduction in the false positive rate with mammography plus tomosynthesis, although not as high as reported in previous studies. There are practical issues relative to radiation dose, cost, efficiency, and benefit that need to be addressed. Additional information from completion of the entire study will add value to the assessment of this new technology.