

Breast Density and Breast Cancer Screening with Digital Breast Tomosynthesis: A TOSYMA Trial Subanalysis



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Purpose

To compare the invasive breast cancer detection rate (iCDR) of DBT plus SM versus DM screening for different breast density categories.

Materials and Methods

An exploratory subanalysis of the TOMosynthesis plus SYNthesized MAMmography (TOSYMA) study, a randomized, controlled, multicenter, parallel-group trial recruited within the German mammography screening program from July 2018 to December 2020. Women aged 50–69 years were randomly assigned (1:1) to DBT plus SM or DM screening examination. Breast density categories A–D were visually assessed according to the Breast Imaging Reporting and Data System Atlas. Exploratory analyses were performed of the iCDR in both study arms and stratified by breast density, and odds ratios and 95% CIs were determined.

Results

A total of 49 762 women allocated to DBT plus SM and 49 796 allocated to DM (median age, 57 years [IQR, 53–62 years]) were included. In the DM arm, the iCDR was 3.6 per 1000 screening examinations in category A (almost entirely fatty) (16 of 4475 screenings), 4.3 in category B (102 of 23 534 screenings), 6.1 in category C (116 of 19 051 screenings), and 2.3 in category D (extremely dense breasts) (six of 2629 screenings). The iCDR in the DBT plus SM arm was 2.7 per 1000 screening examinations in category A (12 of 4439 screenings), 6.9 in category B (154 of 22 328 screenings), 8.3 in category C (156 of 18 772 screenings), and 8.1 in category D (32 of 3940 screenings). The odds ratio for DM versus DBT plus SM in category D was 3.8 (95% CI: 1.5, 11.1). The invasive cancers detected with DBT plus SM were most often grade 2 tumors; in category C, it was 58% (91 of 156 invasive cancers), and in category D, it was 47% (15 of 32 invasive cancers).



Conclusion

The TOMosynthesis plus SYNthesized MAMmography trial revealed higher invasive cancer detection rates with digital breast tomosynthesis plus synthesized mammography than digital mammography in dense breasts, relatively and absolutely most marked among women with extremely dense breasts.

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