HOLOGIC

MEDICAL EDUCATION

Digital Breast Tomosynthesis versus Digital Mammography for Detection of Early-Stage Cancers Stratified by Grade: A TOSYMA Subanalysis

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Study Goal

- To compare invasive breast cancers detected with digital breast tomosynthesis (DBT) plus synthesized mammography (SM) versus digital mammography (DM) screening regarding tumor stage, histologic grade, patient age, and breast density.

Study Population/Method

- Multicenter, multivendor randomized controlled trial in the German mammography screening program
- 99,131 women imaged (49.9% DBT + SM, 50.1% DM screening)
- Median age: 57 years (range: 50 – 70 years)
- 83 readers of varying experience
- 55.2% of women presented with non-dense breasts, 44.8% presented with dense breasts
- >51% of images acquired with Hologic Mammography Systems
  - Including 11% high-resolution / Intelligent 2D images

Key Outcome Measures

- Compared invasive cancer detection rates (iCDRs), rate differences, and odds ratios between the study arms, stratified by stage, histological grade, age group, and breast density

Nottingham Scale

- Grade 2 and Grade 3 cancers are more aggressive cancers, and may have spread to lymph nodes or beyond

Results

The interim results of TOSYMA demonstrated that DBT+SM leads to:

- Increased detection of invasive cancers with DBT plus SM, as compared to DM alone
- Stage 1 iCDR difference: +21.6/1000 women 60-70 yrs w/dense breasts
- Stage 2+ iCDR difference: +2.3/1000 women 60-70 yrs w/dense breasts

Conclusion

- DBT plus SM appears to lead to higher detection of early-stage invasive breast cancers of Grade 2 or Grade 3 than DM screening, with the highest rate among women aged 60-70 years with dense breasts
- Higher detection rates of Grade 2 and Grade 3 invasive cancers with DBT plus SM, as compared to DM alone