Supplemental Breast MRI for Women with Extremely Dense Breasts: Results of the Second Screening Round of the DENSE Trial

---

Why it matters

Key takeaways

The second screening round of the DENSE trial demonstrated a large reduction in the false positive rate (FPR) seen in the first screening round of the trial. This is promising news for the feasibility of using Volpara TruDensity™ to identify candidates for supplemental MRI screening.

Study location

Netherlands, multicenter.

Study participants

40,373 participants with extremely dense breast tissue and normal mammography results, aged 50-75 years.

Study design

Prospectively collected positive MRI cases from within the DENSE trial (randomized controlled trial), 2011-2015.

Methods

- Of the women with normal mammoraphy results and extremely dense breasts (as identified by TruDensity) who participated in supplemental MRI screening during the first screening round, 3,436 women received a second round of MRI screening.
- The cancer detection rate (CDR) and FPR were measured for the second screening round.

Study results

- The CDR was 5.8 per 1000 exams, which was a decrease from the previously measured CDR of 16.5 per 1000 exams during the first stage of the trial.
- The FPR was 26.3 per 1000 exams, which was a large decrease from the previously measured CDR of 79.8 per 1000 exams during the first stage of the trial.

Conclusions

- The large reduction of the FPR is a promising performance indicators for the feasibility of supplemental MRI for women with extremely dense breasts (as identified by TruDensity).