Digital Breast Tomosynthesis: Clinical Evidence and Adoption

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Full-field digital mammography (FFDM or DM, 2D-mammography) is the standard technique as of today for breast imaging. Conventional DM has, however, two inherent limitations as demonstrated in breast cancer screening: low sensitivity in women with dense breasts because of a "masking effect" caused by overlying parenchyma and low specificity due to summation of normal parenchyma causing "pseudotumors". Digital breast tomosynthesis (DBT) makes it possible to minimize these limitations and improve diagnostic performance. DBT consists of an image dataset reconstructed from low-dose exposures acquired during an X-ray source movement above the compressed breast ("pseudo-3D mammography").

The principles of DBT were published in 1997. During the following years several studies confirmed the potential of DBT to improve specificity and sensitivity through increased cancer conspicuity and visibility. DBT was approved in the USA by the FDA in 2011.

The first breast cancer screening trial comparing DBT versus DM was started in 2010, and very soon several studies were carried out. Most of retrospective studies in the USA showed a significant DBT reduction of recall rate (RR), but mixed results regarding cancer detected rate (CDR). On the other hand, all prospective European trials (except one) demonstrated a significant increase of CDR with DBT, but mixed results regarding RR. Furthermore, several diagnostic studies have shown the potential of DBT to replace conventional cone-mag views for work-up of non-calcified lesions, thus reducing biopsy rate and improving the positive predictive value for soft-tissue lesions.

Challenges regarding implementation of DBT in organized breast cancer screening include: one- vs. two-view DBT, the need for 2D images (with the additional radiation dose problem partly solved by synthetic mammograms), the (very) dense breasts with reduced visibility of masses and surrounding spiculation, DBT-only detected lesion especially if an indeterminate lesion is only visible on one DBT view, increased workload and longer reading time, so-called "overdiagnosis", subsequent interval cancer rate, and cost-effectiveness. Other imaging techniques and modalities may solve the challenge with reduced DBT sensitivity in women with dense breasts, and future AI-based CAD technology may solve the workload challenge in high-volume screening. DBT detects often small invasive cancers presenting with desmoplastic reaction (spiculations) which have a good prognosis. As of today, the challenge of "overdiagnosis" and missing proofs of subsequent interval cancer reduction are still important issues regarding DBT implementation in organized screening. Each organized screening program (country) would need cost-effectiveness studies to justify implementation of DBT as primary screening technique.

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