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ORIGINAL ARTICLE

Potential impact of tomosynthesis on the detection and diagnosis of breast lesions

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Abstract *Objective:* The aim of this study was to evaluate the clinical performance of 3D tomosynthesis in comparison with Full Field Digital Mammography (FFDM) in the detection and diagnosis of breast lesions.

Material and methods: 132 patients underwent standard digital mammography and tomosynthesis and the likelihood of malignancy was categorized according to (ACR) BI-RADS.

Results: Tomosynthesis images had significantly increased the number of cases with BI-RAD 1 or 2 (normal/benign) to 62 (42.7%) compared to 39 (26.8%) at mammogram ($p < 0.005$). Tomosynthesis helped also in more clarification of benign characters. Tomosynthesis images had significantly decreased the number of indeterminate/suspicious lesions (BI-RADS 3 and 4) from 90 (62%) cases to 39 (26.8%) ($p < 0.005$). In a total of 40 lesions (27.5%) assigned to BI-RADS 5 at tomosynthesis, the tomosynthesis showed better performance in assessment of tumor extension and higher level in detection of clusters of micro-calcifications.

The accuracy, specificity, sensitivity and positive and negative predictive values (%) of mammography alone versus when combined with the tomosynthesis were as follows: 59.3, 62.8, 55.2, 56 and 62 versus 91.7, 92.3, 91, 91, and 92.3 respectively (Table 4).

Tomosynthesis significantly improved the detection of the breast lesions on mammography images especially in the dense breast with significantly higher accurate BI-RADS scoring (P value < 0.005).

Conclusion: Breast tomosynthesis is a promising technology that offers improved diagnostic and screening accuracy, fewer recalls as well as 3D lesion localization. Lesion conspicuity is improved using DBT compared with FFDM with a more confidence in making clinical decisions.

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1. Introduction

Digital mammography has become an accepted standard of care in screening and diagnosis of breast cancer; however, it has some limitations that are mainly attributed to the superimposition of normal breast structures in the path of the X-ray beam that diminishing the positive predictive value and specificity of the examination (1–4).

Breast tomosynthesis is a modality that acquires images of a breast at multiple angles during a short scan. The individual images are then reconstructed into a series of thin, high-resolution slices so eliminating the problem of overlapping structures in the breast as well thereby enhancing margin visibility, particularly in dense breasts (5–9).

The aim of this study was to evaluate the clinical performance of 3D tomosynthesis in comparison with Full Field Digital Mammography (FFDM) in the detection and diagnosis of breast lesions.

2. Material and methods

The study protocol was approved by the Institutional Hospital Ethical Committee. All patients provided informed consent. Study was performed during the period of June 2013 to March 2015 and included 132 consenting women, showing at least one breast lesion discovered by standard digital mammography and/or ultrasound (US). They underwent standard digital mammography in two views the cranio-caudal (CC) and medio-lateral oblique (MLO) views and tomosynthesis in both views (MLO and CC) of both breasts.

Mammography examination: FFDM and 3D tomosynthesis examination was done by GE's SenoClaire 3D breast tomosynthesis system. During a tomosynthesis scan, multiple projections (10–14) of low-dose exposure the breast are acquired at different angles while the X-ray tube moves in an arc fashion across the breast. Then reconstruction into one mm-thickness slices was performed off-line (i.e., at a different time from the image acquisition) to gain about 60–90 that can be further reconstructed to a three dimensional image. Images are displayed in slice or cine loop mode on dedicated high resolution work stations. The monitors were calibrated to the DICOM Gray scale Standard Display function. The radiologists were able to pan, zoom and alter the window level of the images.

A complementary ultrasound examination was done for all patients using Aplio XG device (Toshiba, Japan) using 6–10 MHz high frequency probes.

The reviewers categorized the likelihood of malignancy according to the American College of Radiology (ACR) Breast Imaging Data and Reporting System (BI-RADS) categories (15) in each of FFDM and breast tomosynthesis by radiologists in a consensus reading.

Breast density was assigned according to the BI-RADS edition (2013) to a, b, c and d-categories (a: the breast is almost entirely fatty, b: scattered areas of fibroglandular density, c: the breast is heterogeneously dense, and d: the breast is extremely dense (10)).

Qualitative items, such as mass shape, margins, density, architectural distortion, and calcifications were also recorded.

The radiologists were blinded to the findings of other modalities, to clinical reports, patient history, histology, and clinical follow-up. If the two readers could not reach consensus, datasets were forwarded to a third reviewer.

The golden standard was histology for lesions that had undergone breast biopsy (all of which were classified as malignant lesions ($n = 67$), plus a small proportion of those considered benign ($n = 21$) and fine-needle aspiration cytology (FNAC), whenever available, and 1-year follow-up for benign classified lesions. A one year stable lesion was considered of benign nature.

2.1. Statistical analysis

The data obtained from Full Field Digital Mammography and Digital Tomosynthesis were tabulated and compared as regards detection and diagnosis. Each modality was individually assessed using the Pearson Chi Square tests. The accuracy, sensitivity, specificity and positive and negative predictive values of either modality were also calculated. P value < 0.05 is considered to be significant.

Table 1 Breast lesion visibility at FFDM alone and tomosynthesis.

Mammography	Tomosynthesis		Total
	Yes	No	
Yes	106	0	106
No	32	7	39
Total	138	7	145

Table 2 BI-RADS score at mammography and tomosynthesis.

Mammography BI-RADS	Tomosynthesis BI-RADS						
	1	2	3	4	5	6	Total
1	3	12	2	1	0	0	18
2	3	10	2	4	2	0	21
3	8	20	8	3	2	0	41
4	2	4	2	17	24	0	49
5	0	0	0	0	12	0	12
6	0	0	0	0	0	4	4
Total	16	46	14	25	40	4	149