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Original Article

Breast cancer screening with digital breast tomosynthesis - 4 year experience and comparison with national data

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Abstract

Background: To determine if mammography combined with digital breast tomosynthesis (DBT), leads to superior performance in screening for breast cancer compared to digital mammography (DM) alone.
Methods: We retrospectively collected data from A) the results of population-based mammography-screening provided by the National Cancer Registry in Taiwan, and B) the results from all screening mammography performed with DBT from 2012 through 2015 at Kaohsiung Veterans General Hospital (VGHKS) since the institution of DBT at the end of 2011. This was compared data from 3 years with DM performed prior to DBT implementation. We calculated the results of medical audit of VGHKS and compared this with national data. Fisher's exact test is applied.
Results: VGHKS data demonstrated a higher cancer detection rate (CDR) and positive predictive value 1 (PPV 1) than the national average. Most prominently in the year 2014, our CDR was 120% better than that of the national average. CDR ranged from 6.3 to 8.1‰ prior to the introduction of DBT, and following DBT implementation this improved to 8.5–11.4‰, reflecting a mean increase of 32.2%. Early cancer detection was 50% higher and node negative rate was 25% higher than the national average of latest year. A 17.8% reduction in recall rate (RR) was achieved due to a decrease in unnecessary recall.
Conclusion: There was a 32.2% increase in CDR and a 17.8% decrease in RR when DBT was used as an adjunct to DM, as compared to DM alone. CDRs were approximately twofold better than national average data. DBT was more effective at detecting cancer in ductal carcinoma in situ and stage 1.

Keywords: Asia; Mammography-screening; Taiwan; Tomosynthesis (DBT)

1. Introduction

Early diagnosis translates into better outcomes. Mammography is a proven screening tool for reducing the risk of death from breast cancer.[1,2] Compared with annual clinical breast examination, universal biennial mammography in Taiwan was associated with a 41% mortality reduction.[3] The major limitation to the sensitivity of screening mammography is the density of breast tissue, with cancer being obscured by overlapping structures. Breast cancer screening with full-field digital mammography (DM) fails to detect 15–30% of cancers.[4] The myriad potential harms frequently associated with screening mammography highlight the need for improved imaging technologies. One such

Conflicts of interest: The authors declare that they have no conflicts of interest related to the subject matter or materials discussed in this article.

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Table 1
The result of medical audit in VGHKS compared with that of national screening. (ACR* recommendations are listed for reference): In 2011 and years prior, the outcomes of VGHKS were screened with digital mammography. DBT was implemented after 2012. As a medical center, VGHKS shows a better cancer detection rate (CDR) than national average. The range was 6.3‰−8.1‰ before digital breast tomosynthesis (DBT) being applied and 8.5−11.4‰ after DBT being implemented, that means about 32.2% increase in CDR. The recall rates were significantly diminished after DBT implementation, with the range between 11.4 and 12.2% reduced to the range between 9.0 and 10.1%, and the mean about 17.8% reduction. DCIS: ductal carcinoma in situ; IDC: intraducal carcinoma.

Taiwan/VGHKS	2009	2010	2011	2012	2013	2014	2015	ACR* recommendations
PPV1	4.10/**5.3**	4.88/**6.6**	5.00/**6.6**	5.21/**9.4**	5.36/**10.0**	5.81/**11.4**	5.72/**9.6**	5−10%
PPV2	26.50/**30.8**	25.82/**31.5**	26.12/**30.7**	26.22/**36.1**	30.82/**34.6**	28.21/**34.6**	31.54/**27.8**	25−40%
PPV3	43.32/**35.3**	38.54/**40.5**	39.12/**39.8**	37.49/**43.0**	36.97/**40.6**	38.03/**38.8**	36.99/**31.5**	25−40%
Cancer detection rate	3.94/**6.3**	4.71/**8.1**	5.04/**7.5**	5.02/**8.5**	4.75/**10.1**	4.92/**11.4**	4.77/**8.7**	2−10‰
Early cancer rate (DCIS & <1 cm IDC)	36.42/**27.3**	41.69/**48.9**	39.74/**52.4**	39.65/**35.3**	39.05/**50.0**	39.13/**31.3**	40.72/**61.2**	>30%
Node negative rate	64.23/**62.5**	62.00/**64.3**	63.06/**53.3**	63.83/**59.5**	67.28/**64.9**	61.39/**64.3**	65.80/**82.1**	>75%
Recall rate	9.61/**11.9**	9.66/**12.2**	10.08/**11.4**	9.62/**9.1**	8.85/**10.1**	8.46/**10.0**	8.34/**9.0**	<10%
Screened no.	247,022 **(1905)**	528,401 **(5838)**	558,804 **(5767)**	670,530 **(6101)**	694,197 **(5365)**	735,720 **(5773)**	769,532 **(6568)**	

technology is digital breast tomosynthesis (DBT), also known as 3D mammography, which the U.S. Food and Drug Administration first approved in 2011 as a modality to be used in combination with DM. DBT reduces the challenges of interpretation due to overlapping structures in breast tissue,[5] and the implementation of DBT in breast imaging is rapidly increasing world-wide.[6] It has been approved for use as a screening tool in several countries. The prospective,[7−9] retrospective screening[10,11] and systematic review[12] studies comparing DM and DBT have all demonstrated that DBT has

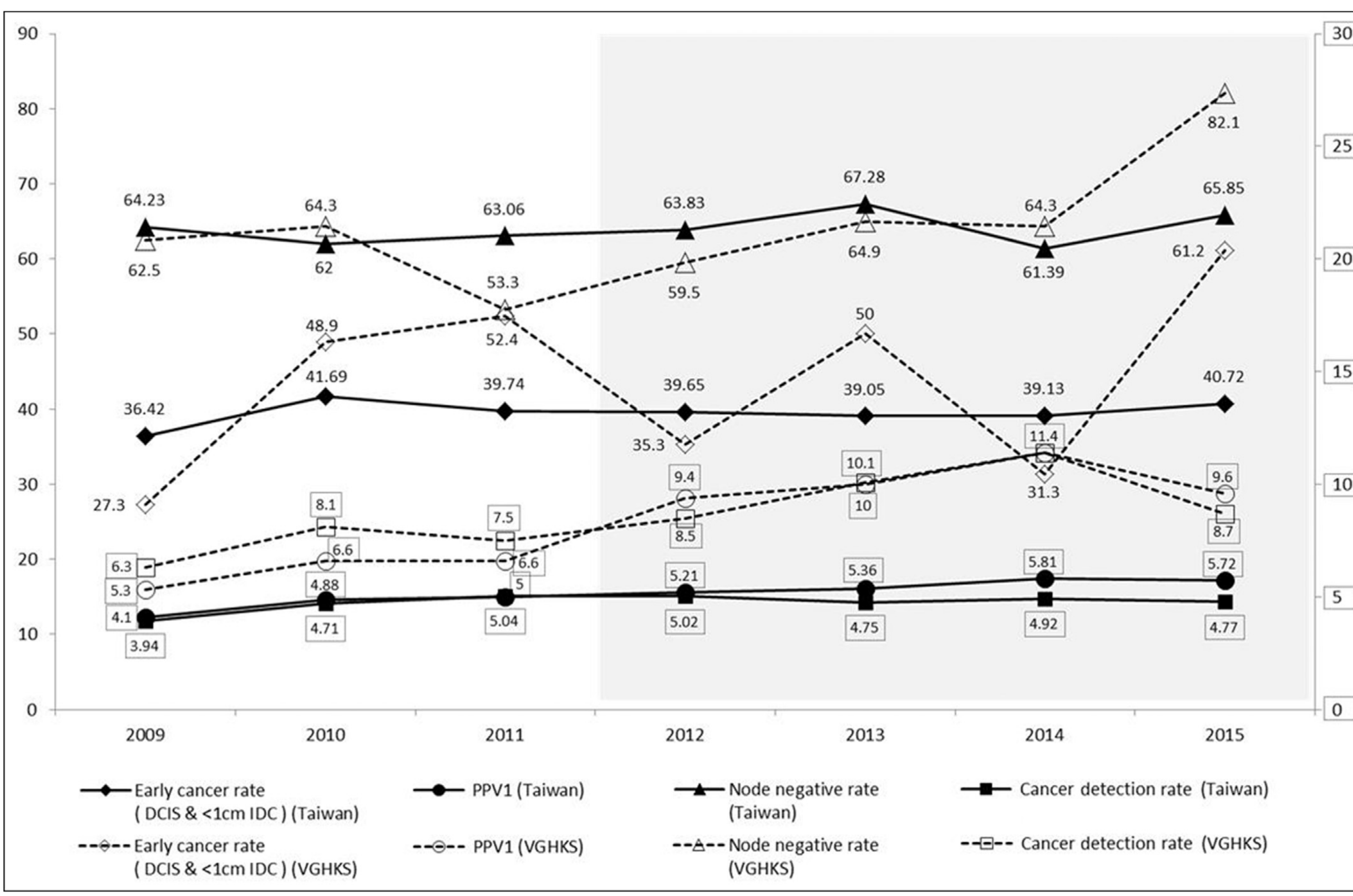


Fig. 1. The distribution of medical audit related to screened cancers before and after digital breast tomosynthesis (DBT) applied: cancer detection rate (CDR) and positive predictive value 1 were significantly higher than the national average, even higher than the upper bound of ACR recommendation. In spite of significant CDR increase, the early cancer detection rates fluctuated, due to more invasive cancer detected of size 1 cm−2 cm. The node negative rate remained relatively stable throughout the screening years. The reduction of CDR in latest year is due to limited incidence of cancer. The first-time screened women were about 1.2 times higher in year 2013 when compared with 2014 and 2015, this is a limitation of screening in a fixed geographical location. DCIS: ductal carcinoma in situ; IDC: intraducal carcinoma; VGHKS: Kaohsiung Veterans General Hospital.

great potential for improving breast cancer screening.[6] In Taiwan, 7% of screening units have DBT capability, however most institutions use DBT as a supplementary imaging tool for further evaluation of uncertain cases (category 0) or dense breasts. The obstacles to routine use include longer interpretation times, radiation dose, IT storage and connectivity, and cost effectiveness.[13,14] DBT has been implemented for screening in our hospital since 2011. In this analysis, we collected the latest four years screening outcomes of medical audit such as recall rate and cancer detection, comparing DBT and the national average outcomes in the screening population. We aimed to demonstrate the impact of the uptake of DBT screening in Taiwan, and to add to the literature regarding breast cancer surveillance in Asia.[15]

2. Methods

2.1. Strategy of screening mammography[16,17]

Since 2004, a nationwide biennial screening mammography program has been offered for asymptomatic women, free-of-charge. At its inception, the program was available to women aged 50–69 years and, since December 2009 extended to ages 45–69 years. The Health Promotion Administration of the Ministry of Health and Welfare in Taiwan has sponsored a quality improvement program to ensure the quality of screening mammography.[18]

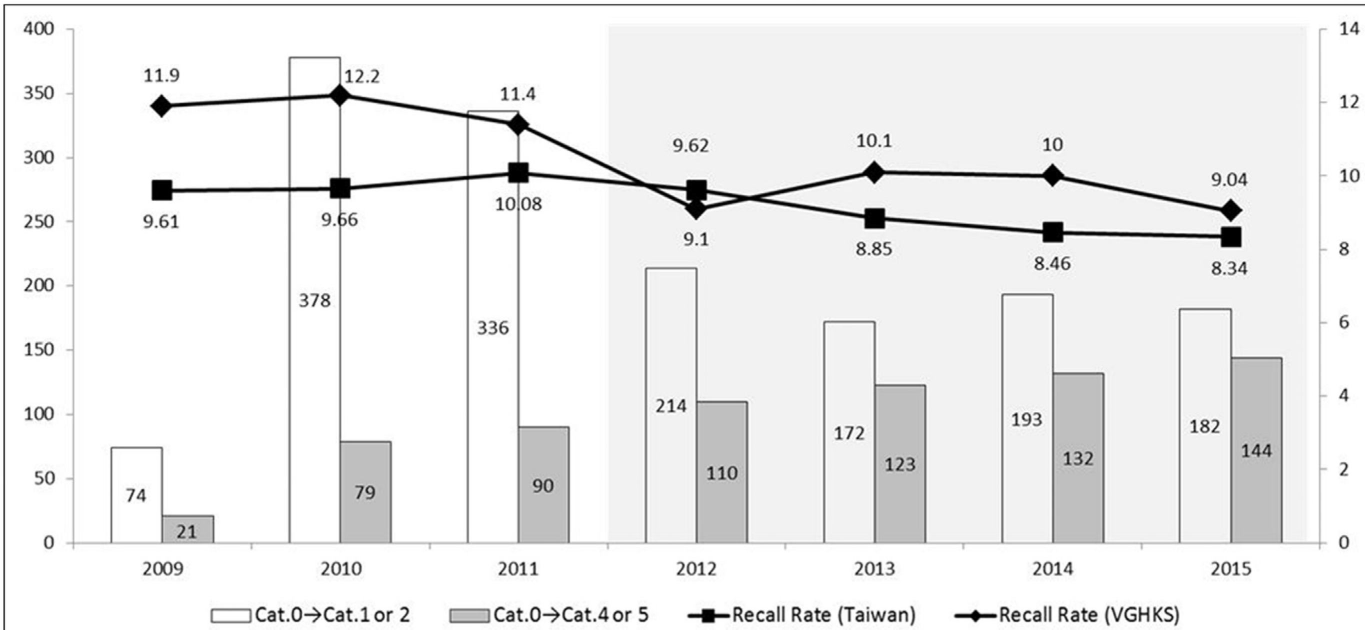
2.2. Definitions[19]

Recall rate (RR): The percentage of patients recalled from screening examinations was assessed as those given a BI-RADS assessment category 0 (additional imaging needed), 4, or 5.

Positive predictive value 1 (PPV): The percentage of all positive screening examinations (BI-RADS Categories 0, 4 and 5) that result in a tissue diagnosis of cancer within 1 year.

Cancer detection rate (CDR) from screening: The number of cancers correctly detected per 1000 patients examined on mammography (=No. of true positive/No. of screening).

Early cancer detection rate (ECR): The percentage of cases involving DCIS (ductal carcinoma in situ) and less than 1 cm invasive ductal cancer (IDC), within the cases of proven



Year	Recall Rate (Taiwan)	Recall Rate (VGHKS)	Cat.0 → Cat.1 or 2	Cat.0 → Cat.4 or 5
2009	9.61	11.9	74	21
2010	9.66	12.2	378	79
2011	10.08	11.4	336	90
2012	9.62	9.1	214	110
2013	8.85	10.1	172	123
2014	8.46	10	193	132
2015	8.34	9.04	182	144

Fig. 2. The recall rates before and after DBT implemention: The recall rates were correspondingly increased to cancer detection. The numbers of category 0 at initial assessment that turned out to be category 1 or 2 at final assessment had diminished after DBT implementation, that means less unnecessary recall. For screening purposes, category 0 is encouraged instead of category 4 or 5 in the initial assessment. The number of initial category 0 that turned out to be category 4 (or 5) at final assessment had increased after DBT implementation, meaning that those recalls were compulsory. VGHKS= Kaohsiung Veterans General Hospital; Cat.= category.

cancer. 4th edition ACR recommended levels[20] are the reference for our Screening Outcome Measurement.

2.3. Data collection

This retrospective analysis was approved by the Institutional Review Board at Kaohsiung Veterans General Hospital (VGHKS), Kaohsiung, Taiwan (VGHKS 16-CT11-10), and was performed according to the Declaration of Helsinki principles. We collected data from A) the results provided by a nationwide population-based mammography-screening program funded by Taiwan's Health Promotion Administration (received on May 2016). This data was from the database of National Cancer Registry. Data was also collected from B) the results from all screening mammography performed with DBT (combo mode, Dimensions, Hologic, Danbury, USA) from 2012 through 2015 in our hospital since the institution of DBT at the end of 2011 (Selenia, Hologic, Danbury, USA) (We considered the 3 month duration from the end of 2011–2012 as an adaptation period). This was compared against data from 3 years with DM performed before DBT implementation for comparison. We calculated the results of medical audit of VGHKS and compared this with national data to form Table 1. Radiology and pathology reports were reviewed in cases where intervention was undertaken.

2.4. Statistical analysis

The CDR and recall rate are the primary outcomes for describing the change before and after DBT applied. Other indexes of mammography such as PPV1, PPV2, PPV3, early cancer detection rate and note negative rate were used as supplementary outcomes. Fisher's exact test is applied for testing the equality of proportion and $p < 0.05$ is considered to indicate a statistically significant difference.

3. Results

3.1. The result of medical audit related to cancer detected in VGHKS before and after DBT installed at VGHKS, and comparison with national data (Table 1)

3.1.1. CDR

As a medical center, VGHKS shows higher CDRs and PPV1 than the national average. The PPV1 is even higher than the upper bound of ACR recommendations[20] (Fig. 1). Most

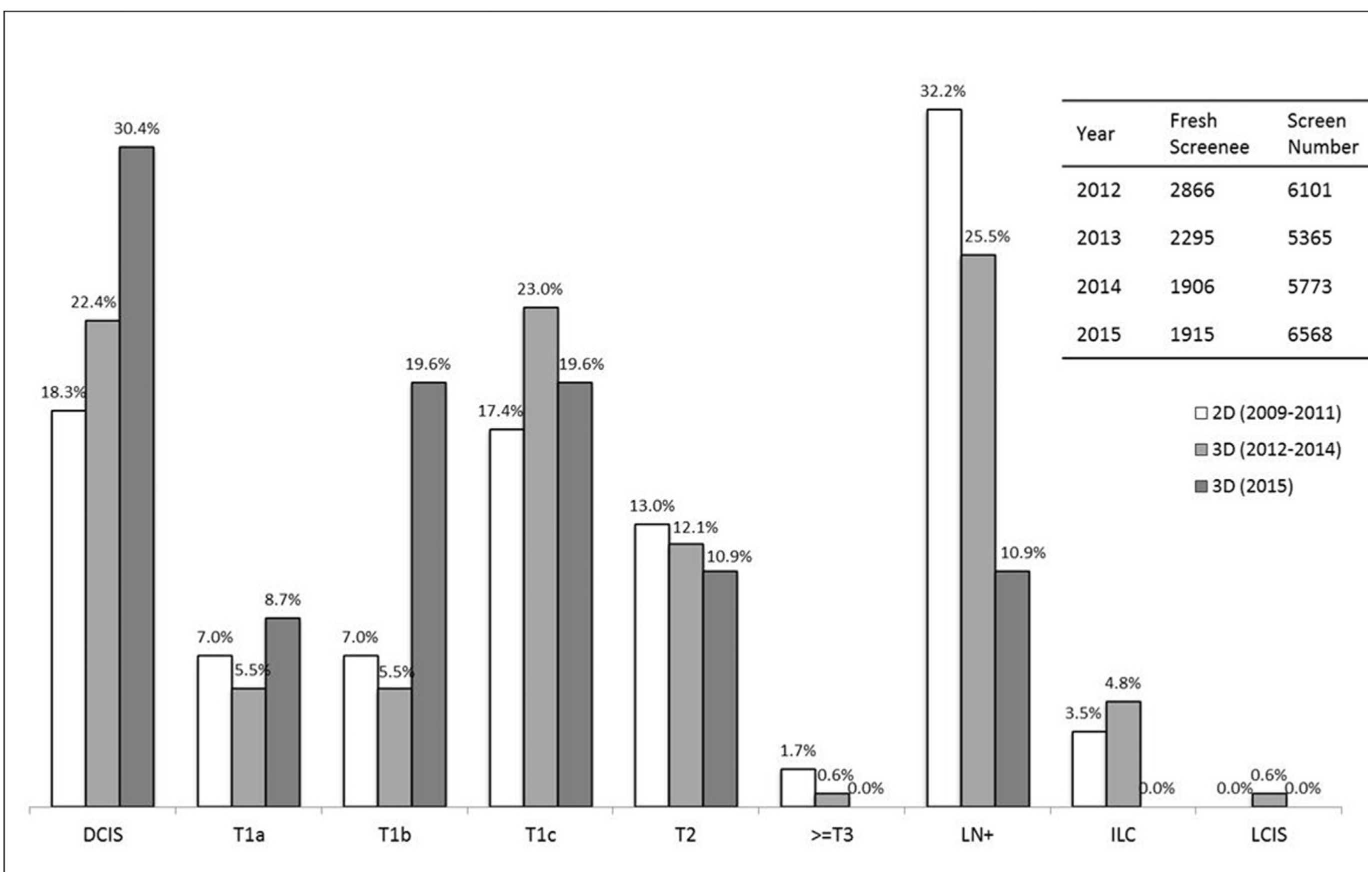


Fig. 3. The distribution of staging of screened cancers before and after digital breast tomosynthesis (DBT) implementation. We collected the data into 3 periods. Those cases in the first three years prior to DBT implementation were categorized as Period 1. Cases in the 3 years after DBT implementation were categorized as Period 2. Cases in the 4th year of DBT implementation named Period 3. The negative node cases were obviously diminished and the cancer detection rates were obviously increased after DBT implementation. Cases staged as T1c were significantly increased in Period 2. These cases are likely to have been missed with 2D mammography before reaching an advanced stage. The purpose of screening is to detect ductal carcinoma in situ and early breast cancer, and the screened early cancers became predominant in Period 3, reflecting more effective screening. Overall, DBT-detected cancers were T1 stage or less.

prominently in the year 2014, our CDR was 2.2 times that of the national average, corresponding to a 120% increase in CDR. From year 2009–2015, we divided the data into 3 chronological groups. Data from the three years prior to the commencement of DBT was named Period 1; the initial 3 years after the implementation of DBT was named Period 2; the 4th year of DBT implementation was named Period 3. The ratios of VGHKS/national average were 1.60; 1.72; 1.49 in Period 1; 1.69, 2.13, 2.22 in Period 2 and 1.82 in Period 3 respectively ($p = 0.10$ for year 2009, and $p < 0.01$ for other years, by Fisher's exact test for testing the equality of CDR between VGHKS and National, respectively). In Period 1, the outcomes of VGHKS were screened by DM alone, and following this DBT was implemented after 2012. CDR ranged from 6.3 to 8.1‰ before DBT, and after the implementation of DBT this improved to 8.5–11.4‰. This reflects an increase of up to 40% in CDR when the peak CDR of the DBT period (11.4‰ in year 2014) is compared against the peak CDR of the DM period (8.1‰ in year 2010). The mean increase in CDR is 32.2% ($p = 0.04$ by Fisher's exact test for testing the equality of CDR of VGHKS before and after 2012).

3.1.2. ECR and IDC with node negative rate

In spite of significant increase in CDR, the ECR fluctuated (Fig. 1), relating to more cases of IDC detected after DBT was introduced in Period 2 (Fig. 3). In this period, the node negative rate remained relatively stable throughout the screening years. This result implies that the detected IDC in screening were not late stage, and there were higher numbers of cases detected in stage T1c and decreased numbers in T2 or above. In Period 3 (year 2015), although the CDR was slightly lower, it was still almost 2 times better than national data. Meanwhile, ECR and detection rate of node negative cancers were increased (Fig. 1). ECR was 50% higher and node negative rate was 25% higher than national average. We additionally reviewed the cases that had received screening at our hospital for the first time, the numbers of these first-screened cases were 2866; 2295; 1906 and 1915 in year 2012; 2013; 2014 and 2015 respectively. The number of first-screened women was nearly 1.5 times higher in year 2012 when compared with 2014 and 2015. With less first-screen case pooling in the more recent years, that means nearly 30% (1915/6568) of cases in 2015 had previous mammography for comparison, a situation reflecting incidence rather than prevalence. This is an expected limitation of screening in a fixed geographical location.

3.2. Recall rate in VGHKS before and after DBT implementation in VGHKS and comparison with national data (Table 1)

The recall rates were increased with CDRs correspondingly (Fig. 1). The recall rates were almost all higher than the

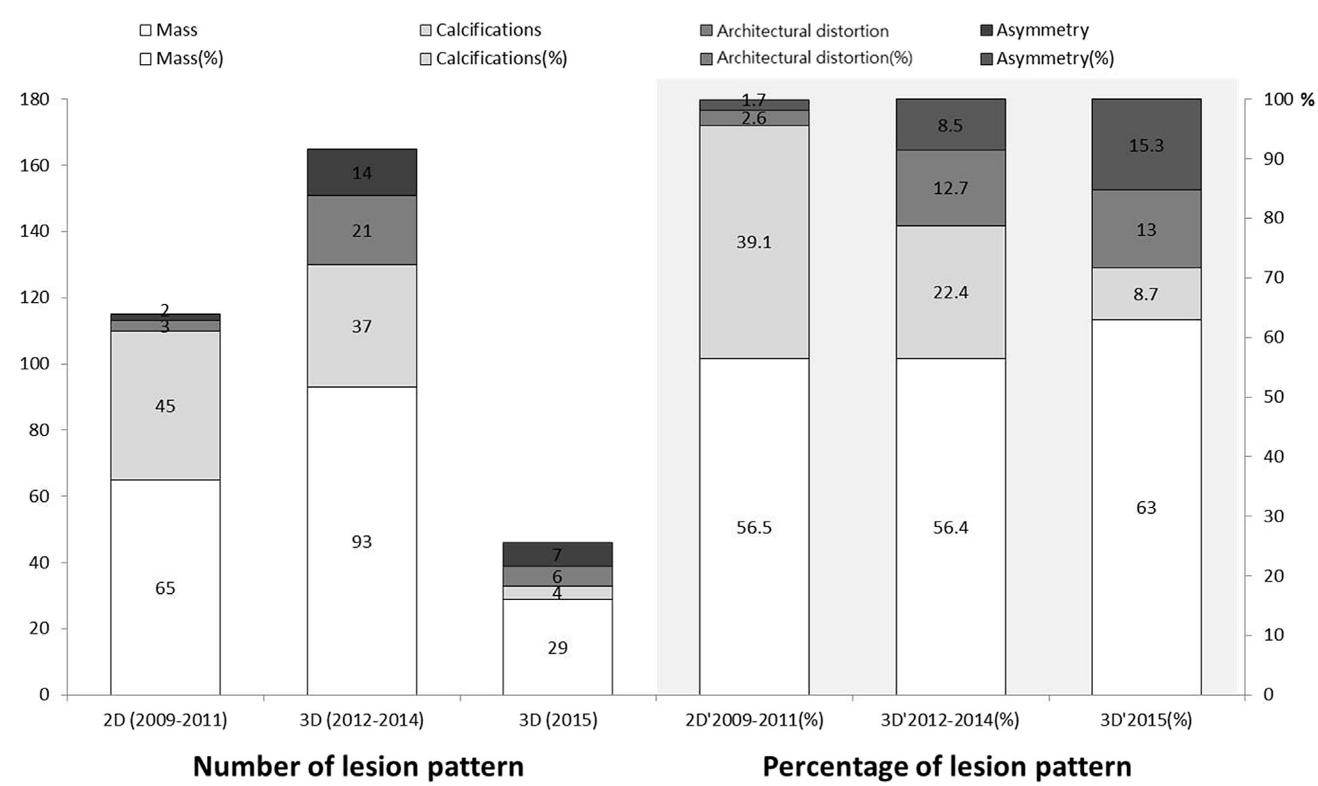


Fig. 4. The distribution (with number and percentage) showed that significantly more patterns of architectural distortion, asymmetry and mass were detected than microcalcification after digital breast tomosynthesis implementation. The proportion of the 3 periods (1: 2: 3) is 1: 5: 9 in architectural distortion; 1: 4.9: 5 in asymmetry; 1: 1: 1.2 in mass; and 1: 0.6: 0.2 in microcalcifications (Fig. 4). Less microcalcification pattern was detected, likely due to higher rates of more compelling evidence reported in tandem with microcalcifications, such as architectural distortion, rather than microcalcifications alone.

national average. The ratios were 1.24; 1.26; 1.13 in Period 1, 0.95; 1.14; 1.18 in Period 2 and 1.08 in Period 3 respectively. However, the recall rates were significantly diminished after the implementation of DBT, and there was a decrease in recall rate range 11.4%–12.2% down to 9.0%–10.1%, with mean reduction of 17.8% ($p < 0.01$ by Fisher's exact test for testing the equality of recall rate of VGHKS before and after 2012). The numbers of initial category 0 that at final assessment was deemed to be category 1 or 2 diminished after DBT implementation (from more than 300 down to less than 200 cases), which means less unnecessary recall. The number of initial category 0 that at final assessment turned out to be category 4 (or 5) increased after DBT implementation (from less than 90 increased to more than 110 cases), that indicated those recalls were compulsory (Fig. 2).

3.3. Comparison of pattern of detected cancers before and after DBT implementation (Fig. 4)

The distribution (with number and percentage) showed that significantly more patterns of architectural distortion, asymmetry and mass were detected after DBT implementation. The proportion of the 3 periods (1: 2: 3) were 1: 5: 9 in architectural distortion; 1: 4.9: 5 in asymmetry; 1: 1: 1.2 in mass; and 1: 0.6: 0.2 in microcalcifications (Fig. 4). Less microcalcification pattern was detected, likely due to higher rates of

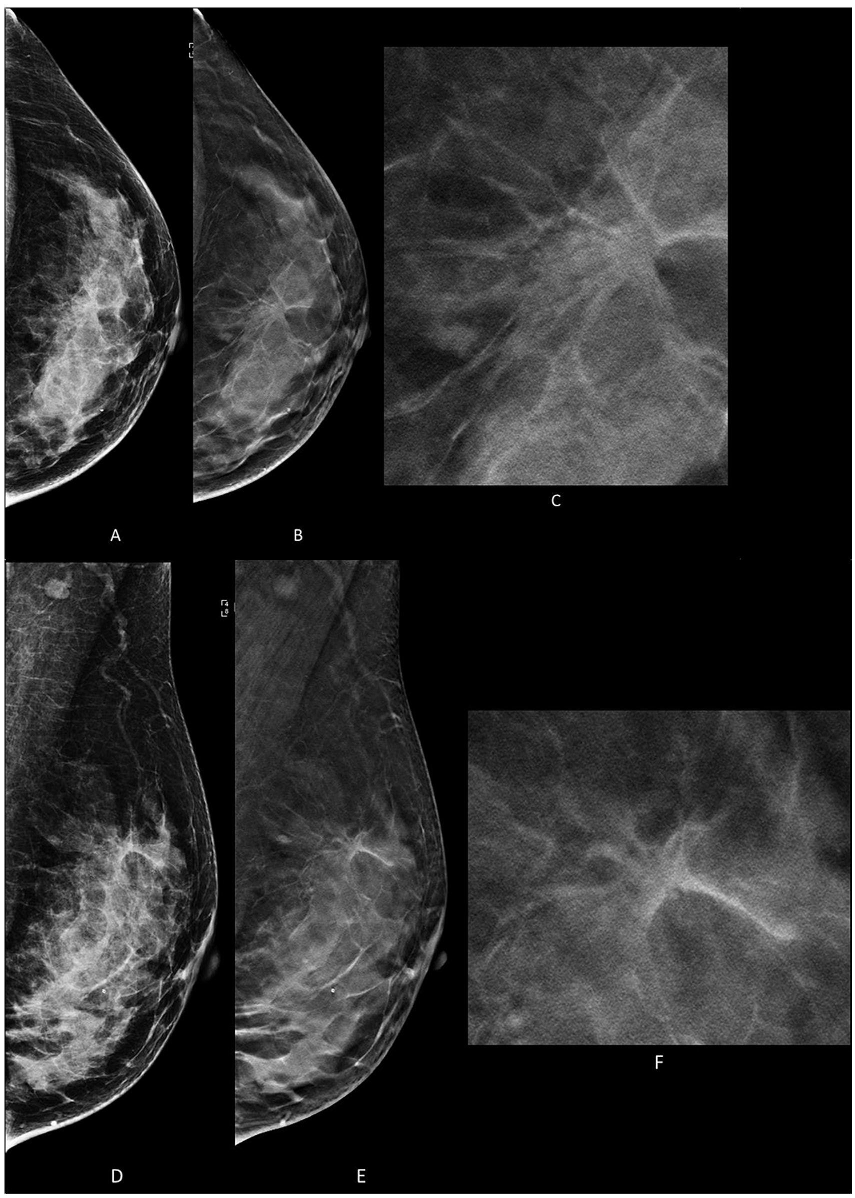


Fig. 5. AD: architectural distortion T1bN0M0. A 49-year-old screened woman with type c breast composition. Digital breast tomosynthesis showed thin radiating lines with primarily solid tissue at the point of origin in the left breast 12 o'clock direction. The lesion was indistinct in the 2D mammograms. Result of core biopsy was intraductal carcinoma. The greatest diameter of invasive component was 0.8 cm after partial mastectomy. Reactive hyperplasia of lymph nodes was noted in the sentinel region. (A: craniocaudal view of 2D; B: craniocaudal view of a slice of DBT in focus; C: close up craniocaudal view of the lesion; D: mediolateral oblique view of 2D; E: mediolateral oblique view of a slice of DBT in focus; F: close up mediolateral oblique view of the lesion.)

more compelling evidence reported in tandem with microcalcifications, such as architectural distortion, rather than microcalcifications alone.

4. Discussion

In this study, we obtained a **32.2%** increase in CDR and a **17.8%** decrease in RR when DBT was used as an adjunct to DM, as compared to DM alone. CDRs were also approximately twofold significantly better than national average data. The increased cases of screened cancers were T1c stage in the early three years after DBT implementation. In the fourth year, the result returned to a predominance of early cancer cases. For the reduction of false recall, the evidence showed more category 1 or 2 instead of category 0 interpretation after DBT implementation. Despite microcalcification detection being a strength of mammography, the patterns of DBT screened cancers provided more information regarding architectural distortion, asymmetry and mass with or without calcification.

Tomosynthesis reflects a new era in mammography screening.[21] The higher cancer conspicuity and visibility on DBT increases the cancer detection rate significantly. According to a review by Skaane[6] and systematic review,[12] the studies with statistical power have shown an increase in the cancer detection rate' and reduced recalls. Two retrospective studies with more than 20,000 American screenees showed increases of 28.6%[10] and 34.1%.[11] Furthermore, two prospective European trials showed increases of 31.2%[8] and

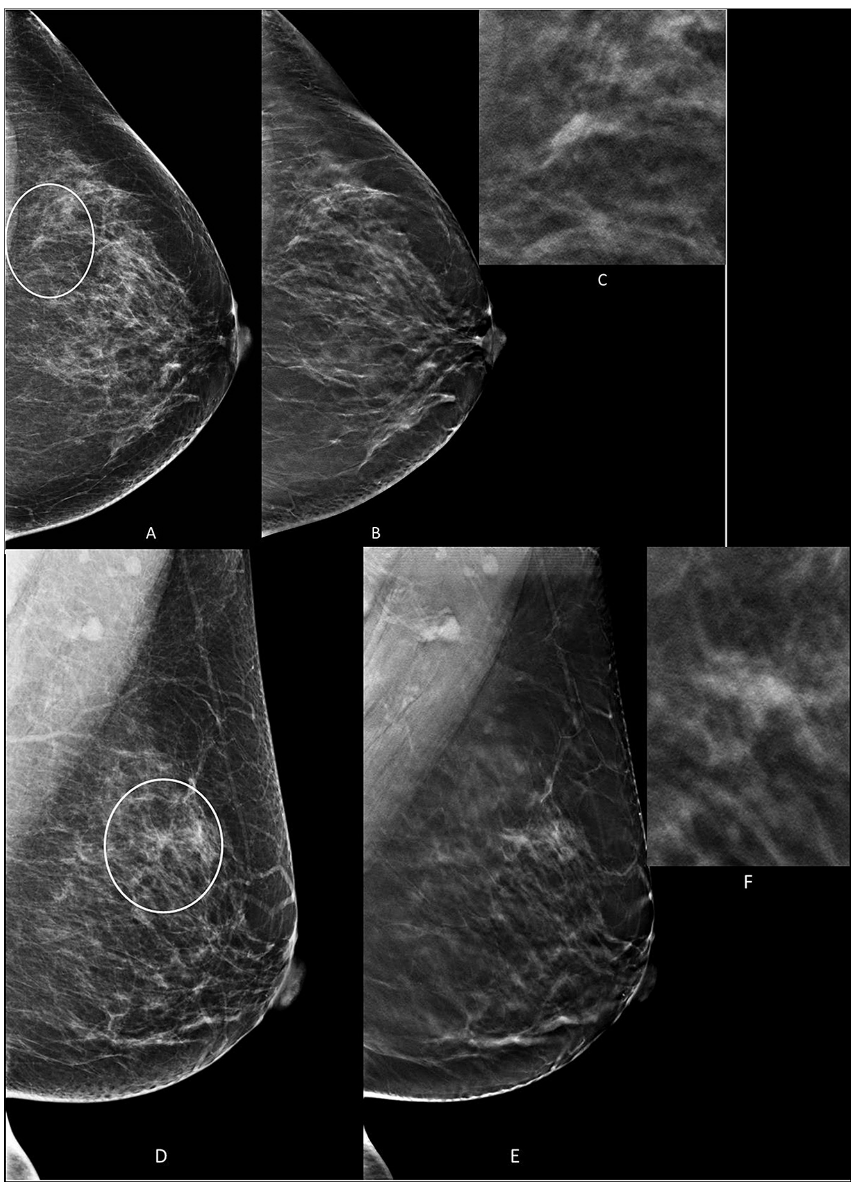


Fig. 6. Asymmetry, ductal carcinoma in situ. A 48-year-old screened woman with type b breast composition. Digital breast tomosynthesis (DBT) showed a focal asymmetry in the left breast, upper outer quadrant, presenting as a 0.5 cm ill-defined mass. The lesion was indistinct in the 2D mammograms. Following vacora biopsy and partial mastectomy, a pathological diagnosis was reached of high-grade intraductal carcinoma. (A: craniocaudal view of 2D; B: craniocaudal view of a slice of DBT in focus; C: close up craniocaudal view of the lesion; D: mediolateral oblique view of 2D; E: mediolateral oblique view of a slice of DBT in focus; F: close up view).

52.8%.[7] Our result confirmed the conclusion that DBT can increase CDR, and the performance of an increase of 32.2% is in keeping with previous studies. Examining this in detail, the increase in CDR is more pronounced in the first three years with DBT, and declined in subsequent fourth year. This result does not diminish the benefit of screening with DBT, as the advantages should be viewed in terms of early-stage cancer detection (Fig. 1), which is the purpose of screening.

Tumor size and nodal status has a major influence on overall mortality independent of age and tumor biology.[22] DCIS and less 1 cm invasive cancer were defined as early cancer in medical audit of ACR 4th edition.[20] The fluctuation

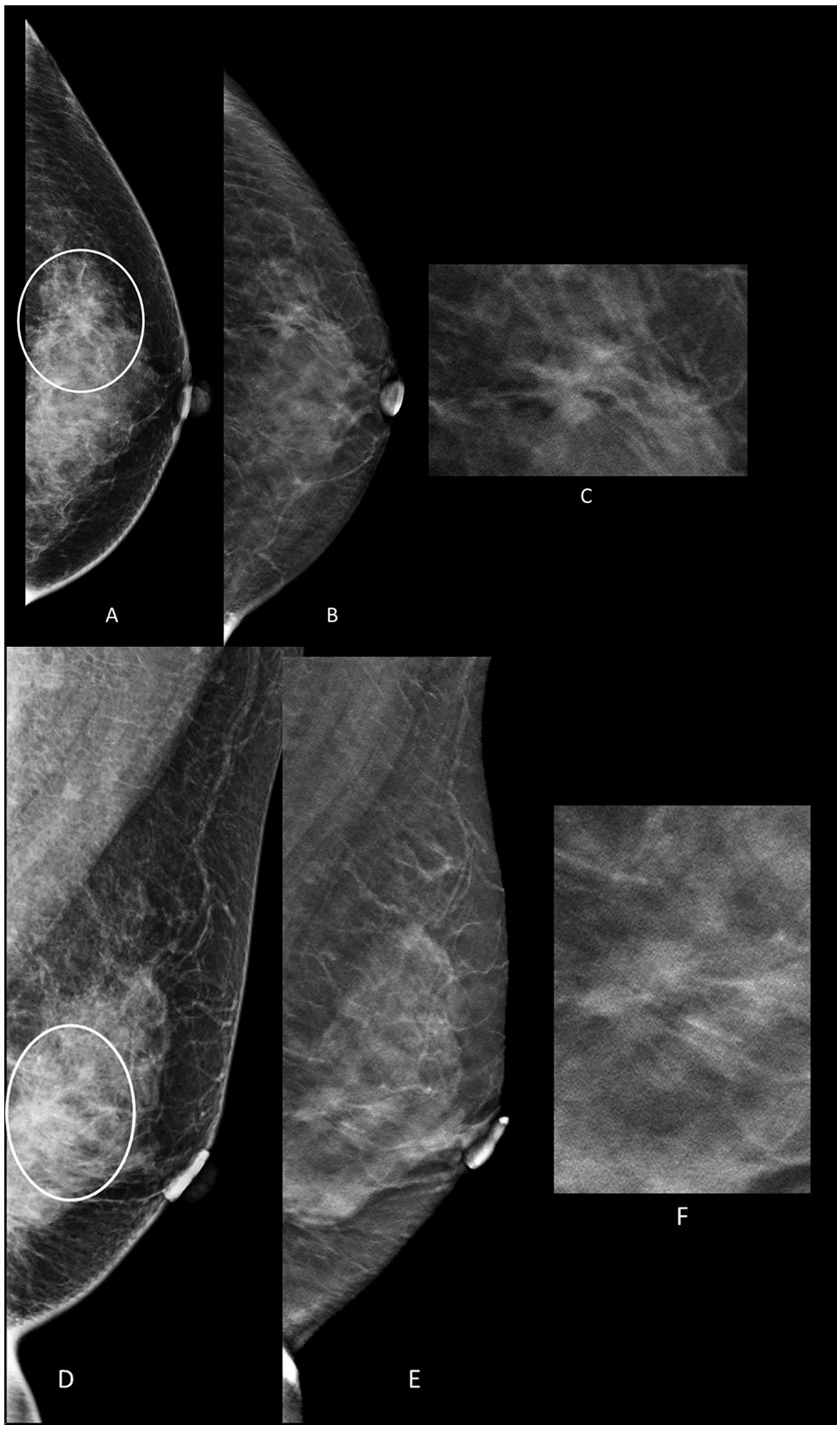


Fig. 7. Mass T1cN0M0. A 45-year-old screened woman with type d breast composition. Digital breast tomosynthesis (DBT) showed a 1.5 cm irregular mass with spiculated margin in the left breast, lower outer quadrant. The lesion was equal density in the 2D mammograms. Result of core biopsy was intraductal carcinoma. The greatest diameter of invasive component was 1.2 cm after partial mastectomy. Reactive hyperplasia of lymph nodes was noted in the sentinel region. (A: craniocaudal view of 2D; B: craniocaudal view of a slice of DBT in focus; C: close up craniocaudal view of the lesion; D: mediolateral oblique view of 2D; E: mediolateral oblique view of a slice of DBT in focus; F: close up mediolateral oblique view of the lesion.)

in ECR in our results (Fig. 1) were influenced by more invasive cancer sized 1 cm–2 cm (previously named T1c) detected after DBT implementation (Fig. 3). Five-year relative survival rate is 100% in all tumors 1 cm or smaller, and 98% for tumors between 1 cm and 2 cm.[22] Consequently, T1c tumours are calculated separately in the medical audit of ACR in 5th edition.[19] All tumor sized from 2 mm to 2 cm are considered to be stage 1 in clinical management. In other words, the proportions of our DBT-detected cancers were in the T1 stage. Invasive cancer should be more readily detectable as lesion conspicuity is increased with use of DBT. In a novel finding to previous literature,[7–10] there was also significant increase in DCIS detection (Fig. 3). In view of the fact that early diagnosis is the goal of screening, this result is supportive of a DBT screening program.

The high contrast of calcification is a well-known strength of mammography screening. However, due to the small size of T1-stage IDC and their presentation sometimes as non-calcified masses, they can be mammographically subtle or occult, particularly in dense breast tissue.[23,24] The additional breast cancers detected via DBT have been reported to have a high proportion of invasive carcinomas regardless of breast density types, and higher for distortion and asymmetry.[8] Higher grade cancers present with distortion, asymmetry and mass, as shown in our results (Figs. 5–7). Radiologists should concentrate on distortion, asymmetry or mass detection on the DBT views[25] and calcifications on the 2D (or synthetic 2D) mammograms. Calcifications are the most common indication of DCIS, but in DBT, different presentation of DCIS occurred (Fig. 8), indicating improved technology over mammography. Mass or mass-like lesions may have invasive potential compared with microcalcifications alone.

From the review of Carbonaroa et al.,[26] DBT was confirmed to reduce recall rate by previous studies (reported reduction 6–82%, median 31%). Studies performed in the real screening setting, showed a reduction in RR higher than 15%[7,10,27,28] and a 17.8% reduction RR in our result is in keeping with this finding. Recall rates stratified within the covariates of interest showed an association with sensitivity.[29] Although the RRs were slightly higher than national average, higher rates of

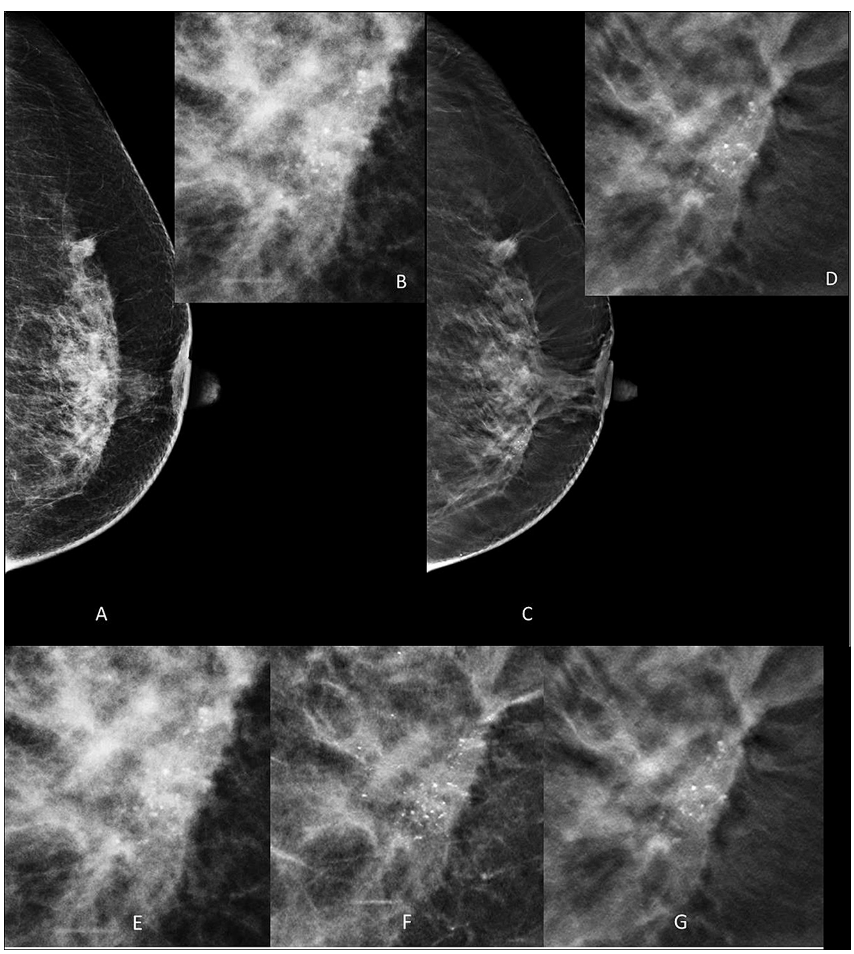


Fig. 8. Calcification. Ductal carcinoma in situ. A 45-year-old woman with type c breast composition. She had a past history of breast cancer and received right mastectomy 15 years ago. Both Digital breast tomosynthesis (DBT) and 2D mammography showed a grouped amorphous and fine pleomorphic microcalcifications in the left breast, lower inner quadrant. DBT also identified the calcifications as occurring within an ill-defined soft tissue mass. Pathological diagnosis with core biopsy and total mastectomy was DCIS. The greatest diameter of tumor was 1.7 cm. Reactive hyperplasia of lymph nodes was noted in the sentinel region. (A: craniocaudal view of 2D; B: close up craniocaudal view of the lesion. C: craniocaudal view of a slice of DBT in focus; D: close up craniocaudal view of DBT; E: close up mediolateral oblique view of the lesion in 2D; F: close up mediolateral oblique view in synthesized 2D. G: close up mediolateral oblique view of a slice of DBT in focus.)

cancer detection are tolerant of higher recall and PPV, and the RR was still significant diminished after DBT implementation in our results. The pseudo-lesions due to superimposed breast tissue can be downgraded at DBT interpretation in different breast density types, reducing the need for a call-back. This is evidenced by more category 1 or category 2 instead of category 0 in our results (Fig. 2). In our experience, most reduction comes from the identification of normal breast tissue instead of recall for asymmetry. Lourenco et al. additionally reported significant reductions for masses, distortions and calcifications.[30]

There were some limitations to this study. First, the national data is an average of whole country, including our hospital. However, the key question we posed in this study was regarding the use of DBT as a valuable screening tool. Hence, the inclusion of DBT data in the national average likely leads to an increase overall, in other words, without the contribution of DBT in some screening units, the national average may be lower than current performance. Secondly, although sensitivity is an important indicator for monitoring the outcome of screening, yet false negative rate is a delay indicator, we did not have national data available for comparison. Thirdly, our cohort, while reflective of the enrolled population of our center, may not reflect the scenarios at other screening units. Lastly, symptomatic patients may seek out specifically qualified medical centers, however, in routine screening, a larger number of screenees may prefer to undertake screening locally. This is an expected limitation of screening at a fixed geographical location. Wider application of DBT screening will solve this limitation.

In conclusion, DBT is a useful screening tool for increasing cancer detection and reducing unnecessary recall. DBT detected more cancer in DCIS and stage 1; this reflects node negative cancer which underscores the need for screening. Different radiographic presentations of DCIS were detected in our study, including calcifications, mass, architectural distortion or asymmetry, indicating technological advances of mammography.

Acknowledgments

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