

Galactography Using Digital Breast Tomosynthesis for the Evaluation of Pathologic Nipple Discharge: A Comparison with 2D Synthetic Digital Mammography

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Purpose: This study aimed to compare the diagnostic accuracy of galactography using digital breast tomosynthesis (DBT) to synthetically reconstructed two dimensional digital mammography (2D SM) in the diagnosis of malignancy in women with pathological nipple discharge.

Materials and Methods: Ductographic and associated mammographic findings were retrospectively analyzed and compared with the histopathological results for 35 patients. Sensitivity and specificity of galactography to predict malignant lesion for each method using DBT and 2D SM were calculated.

Results: Among the 35 lesions, 10 (28.6%) were malignant and 25 (71.4%) were benign. The most common ductographic findings were ductal wall irregularity and filling defects in DBT and 2D SM. Galactography using DBT depicted more masses than 2D-SM ($P < 0.05$). 5 of 8 masses identified on galactography using DBT were confirmed as malignancy. Mass on galactography using DBT is significantly associated with malignancy ($P = 0.027$). Galactography using DBT resulted in an improvement in sensitivity and specificity than 2D SM. Area under the curve values were 0.890 for using DBT and 0.758 for 2D-SM ($P = 0.025$).

Conclusion: Galactography using DBT has potential value in diagnostic work up of pathological nipple discharge, because DBT may facilitate more accurate evaluation of associated mammographic findings.

Index words: Breast neoplasms; Diagnosis; Galactography; Digital breast tomosynthesis

Introduction

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Nipple discharge occurs in up to 10% of women who seek medical care for breast problems (1, 2). Pathological nipple discharge is generally unilateral, emanates spontaneously from single duct orifice, and

may be clear, serous, pink, or serosanguinous. Most cases are due to a benign intraductal papilloma, but about 8–15% of patients with pathological nipple discharge are found to have an underlying malignancy (3, 4). Galactography has been the gold standard for the evaluation of patients exhibiting pathological nipple discharge (3). Recently, some intraductal lesions have been evaluated with high-resolution ultrasound, demonstrating dilated ducts and isoechoic or hypoechoic masses. However, in many cases, ultrasound fails to reveal the underlying cause of nipple discharge, as the causative lesions are frequently too small, contain no calcifications, or prove to be completely intraductal. Moreover, there are some cases of mammographically and sonographically occult intraductal cancer that manifest solely with pathological nipple discharge. Therefore, galactography remains necessary to complete the evaluation of some patients in order to not miss a diagnosis of breast cancer (3).

Significant advances have been made in the management of breast diseases, including the development of digital breast tomosynthesis (DBT), to overcome the limitations of conventional two dimension (2D) digital mammography (DM) in diagnostic breast imaging. DBT multiple projection images are reconstructed, allowing for a visual review of thin breast sections and offering the potential to unmask cancers obscured by overlapping normal tissue. DBT involves the acquisition of multiple projection exposures with a digital detector from a mammographic X-ray source that moves over a limited arc angle. These projection image data sets are reconstructed using specific algorithms (5–8). Prior studies of DBT have shown an increase in cancer detection rates, especially invasive cancers, and a decrease in recall rates. The benefits of DBT include greater accuracy with regard to observing the size, shape, and location of breast abnormalities (9).

In general, galactography has been performed using conventional 2D DM after duct cannulation.

We postulated that galactography using DBT would promote improved diagnostic accuracy owing to greater detail and spatial information and would have superior diagnostic value in the work up of pathological nipple discharge. For comparison with DBT, a 2D synthesized DM (2D SM), which simulates a conventional 2D DM, was generated from each set of tomosynthesis sections. The 2D SM images were created by summing the stack of reconstructed tomosynthesis sections, similar to the generation of a maximum intensity projection image. It has been reported that 2D SM alone, or in combination with tomosynthesis, is comparable in performance to conventional full-field digital mammography (FFDM) alone (10). Also, in a recent study, 2D SM images plus DBT showed similar cancer detection rates and false-positive scores compared to that of FFDM plus DBT, while significantly reducing the radiation dose (11). To our knowledge, no study of galactography using DBT in comparison with 2D digital mammography has been reported. The purpose of our study was to compare the diagnostic performance of galactography using DBT with that of digital 2D SM in women with pathological nipple discharge.

Materials and Methods

This retrospective study was approved by our institutional review board, and because of its retrospective design, the need for patient informed consent was waived. Signed informed consent was obtained from all patients before any biopsy or surgical procedure.

Patients

From January 2014 through March 2015, 45 patients underwent galactography for the evaluation of pathological nipple discharge. Among these patients, patients who had not undergone DBT ($n = 1$) and those who lacked pathological confirmation

(n = 9) were excluded. Finally, 35 women (mean age 46.4 y; range, 19–77 y) were included in this study according to the following inclusion criteria: 1) patients had undergone galactography using DBT and 2) lesions were correlated pathologically, via either ultrasound guided core needle biopsy, vacuum assisted excisional biopsy, or ultrasound-guided localized excision (Fig. 1). Clinical findings including discharge color and spontaneous discharge were evaluated based on a retrospective chart analysis.

Image acquisition and processing protocol

First, cannulation was performed with a 30-gauge Rabinov sialography catheter (Cook Europe, Bjaeverskov, Denmark) attached to a 1mL tuberculin syringe filled with water-soluble contrast material (Telebrix 30; Guerbet, Paris, France).

After complete insertion, contrast material was slowly injected. All galactography was obtained digitally. Following the infusion of contrast media, digital tomosynthesis images were acquired with conventional compression using a tomosynthesis system (Hologic Lorad Selenia; Danbury, USA) utilizing a tungsten tube with 15° tube motion, 0.7 mm aluminum filtration, a 10-second acquisition time, and a 1.30 mGy radiation dose. Image acquisition was performed for the mediolateral oblique and craniocaudal aspects of the breast. Low dose multiple projection images ("frames") were acquired and data from the frames were used to reconstruct 1-mm-thick sections.

A 2D SM "C-View"TM (Hologic, Inc. Bedford, MA) images were generated from each set of tomosynthesis slices, simulating conventional 2D DM. 2D SM images were created by summing and filtering the stack of reconstructed tomosynthesis

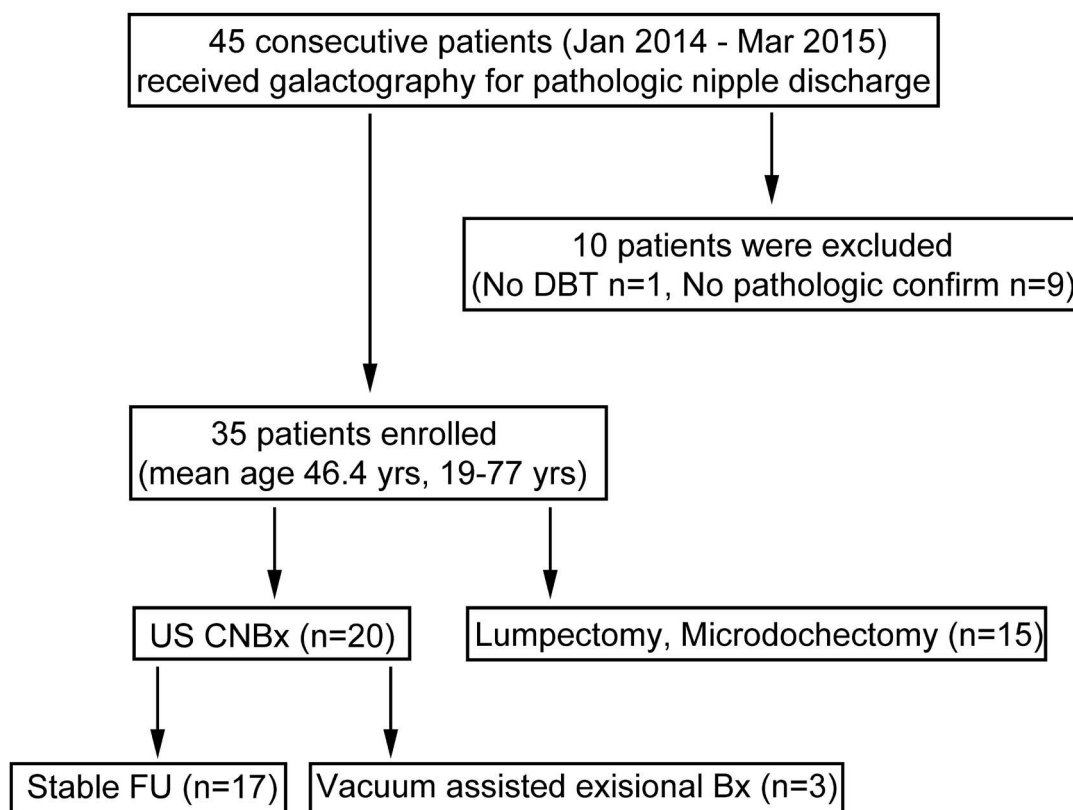


Fig. 1. Flow chart of study population. DBT, digital breast tomosynthesis; US CNBx, ultrasound guided core needle biopsy; FU, follow up

sections, similar to the method used for the generation of a maximum intensity projection image, using C-View™ software (Hologic, Inc. Bedford, MA). The 2D SM images are comparable to those of FFDM in combination with DBT (11). Targeted breast ultrasound was performed to identify intraductal lesions within 5 minutes of the galactography performed by the same radiologist who performed galactography.

All breast ultrasounds were performed with high-resolution sonography units equipped with a 7–15 MHz linear transducer (iU22 Ultrasound System, Philips Ultrasound; Bothell, WA, USA and HDI 3000, Advanced Technology Laboratories; Bothell, WA, USA). Ultrasound-guided core biopsy was done if suspicious intraductal findings were correlated with galactography abnormalities including ductal cutoff (ductal complete obstruction), duct ectasia, cystic duct ectasia, filling defect, wall irregularity, ductal displacement. If the intraductal lesion was not visualized on ultrasound, microdochectomy or lumpectomy was performed. Galactography and breast ultrasound were performed by one of five radiologists with 2–15 years of experience in breast imaging.

Image analysis

Galactography and ultrasound findings of each lesion were reviewed simultaneously and consensually by two subspecialty-trained breast radiologists (JYL, 2 years of experience, and MJ, 10 years of experience). The reviewers were blinded to the clinical information and pathological results, except for the location of the lesion. The ductographic findings were classified as negative (tapering to peripheral duct without filling defects), ductal cutoff (ductal complete obstruction), duct ectasia, cystic duct ectasia, filling defect, wall irregularity, ductal displacement, and periductal contrast extravasation. Associated mammographic findings including mammographic density

were analyzed on DBT and 2D SM. Findings were classified as negative, asymmetry, mass, microcalcification, and mass with microcalcifications according to the Breast Imaging Reporting and Data System descriptors. We independently compared mammographic and ductographic findings of DBT with 2D SM images, with an interval of 3 months between readings. We also estimated the likelihood of malignancy using a percentile scale in which 100% represented total certainty. After the comparison of both examinations, the pathological results were also evaluated.

Statistical analysis

The clinical features of pathologic nipple discharge and the difference in the numbers of pathologic galactographic findings were compared between benign and malignancy group by using the Fisher's exact test, and $P < .05$ was considered to indicate a significant difference. McNemar's test was used to calculate the sensitivity and specificity to predict malignant lesion. The accuracy of the reported probability of malignancy ratings was evaluated on the basis of the mean area under the receiver operating characteristic (ROC) curve (AUC). All data analyses were performed with SPSS ver. 21 software (SPSS, Chicago, Ill) and Med-Calculator software (Mariakerke, Belgium).

Results

Thirty-five patients underwent histopathological examination (Fig. 1). Among the 35 lesions, 10 (28.6%) were malignant and 25 (71.4%) were benign. Final pathologic diagnoses of the 10 malignant lesions revealed ductal carcinoma in situ in 8 patients and invasive ductal carcinoma in 2 patients. Benign lesions included intraductal papilloma ($n = 15$), mammary duct ectasia ($n = 4$), fibroadenoma ($n = 4$), complex sclerosing lesion ($n = 1$), and old hemorrhage ($n = 1$). Clinical

features and mammographic densities of the 35 patients are summarized in Table 1. No statistically significant differences were seen in the color of the nipple discharge between the malignant and benign groups ($P = 0.583$). All of the malignant cases were associated with spontaneous nipple discharge, but there was no statistically significant difference between these patients and those patients with benign lesions ($P = 0.152$). Also no statistically significant differences were seen in the mammographic density between the malignant and benign groups ($P = 0.056$) (Table 1).

Table 1. Clinical features of pathologic nipple discharge between patients with benign and malignant mass

	Benign (n=25)	Malignant (n=10)	P
Discharge color			0.584
Clear	1 (4%)	1 (10%)	
Yellowish	3 (12%)	0 (0%)	
Brown	5 (20%)	3 (30%)	
Bloody	16 (64%)	6 (60%)	
Spontaneous			0.152
Yes	19 (76%)	10 (100%)	
No	6 (24%)	0 (0%)	
MG density			0.056
Gr 1	1 (4%)	0 (0%)	
Gr 2	2 (8%)	2 (20%)	
Gr 3	9 (36%)	7 (80%)	
Gr 4	13 (52%)	1 (10%)	

MG, mammographic; Gr, grade

Table 2 shows the ductographic findings by 2D SM or DBT in the malignant and benign groups. The most common ductographic findings were ductal wall irregularity (11 cases, 31.4% with 2D SM vs. 13 cases, 35.1% with DBT) and filling defects (11 cases, 31.4% with 2D SM vs. 13 cases, 35.1% with DBT). In addition, there were no statistically significant differences with regard to ductographic findings between 2D SM and DBT.

Galactography results with associated mammographic findings are shown in Table 3. Galactography using DBT showed 21 (60.0%) negative results, 8 masses (22.9%), 5 asymmetry results (14.2%), and 2 microcalcifications (5.8%). One case had a mass with microcalcifications. However, galactography with 2D SM showed 25 (71.4%) negative results, 7 asymmetry results (20.0%), 2 microcalcifications (5.8%), and 1 mass (2.9%). Interestingly, galactography using DBT depicted more masses than 2D SM. In addition, five of 8 masses identified on galactography using DBT were confirmed as malignant. Mass on galactography using DBT is associated with malignancy ($P = 0.027$) (Fig. 2 and Fig. 3).

Galactography using DBT microcalcifications were viewed sequentially in several different sections, and individual calcifications within each section were often seen in areas corresponding to ductal irregularities and filling defects. However, 2D

Table 2. Analysis of ductographic findings on two-dimensional synthesized digital mammography and digital breast tomosynthesis

Ductographic findings	2D SM			DBT		
	Benign (n=25)	Malignant (n=10)	P	Benign (n=25)	Malignant (n=10)	P
Ductal complete obstruction	3 (12%)	3 (30%)	0.322	3 (12%)	3 (30%)	0.322
Duct ectasia	0	0		1 (4%)	0	1.000
Cystic duct ectasia	0	1 (10%)	0.286	1 (4%)	1 (10%)	0.496
Filling defect	9 (36%)	2 (20%)	0.447	9 (36%)	4 (40%)	0.714
Ductal Wall irregularity	7 (28%)	4 (40%)	0.689	8 (32%)	5 (50%)	0.444
Ductal displacement	1 (4%)	1 (10%)	0.496	1 (4%)	1 (10%)	0.496
Extravasation	1 (4%)	0	1.000	0	0	

2D SM, two-dimensional synthesized digital mammography; DBT, digital breast tomosynthesis, Fischer's exact test with 2-tailed P value

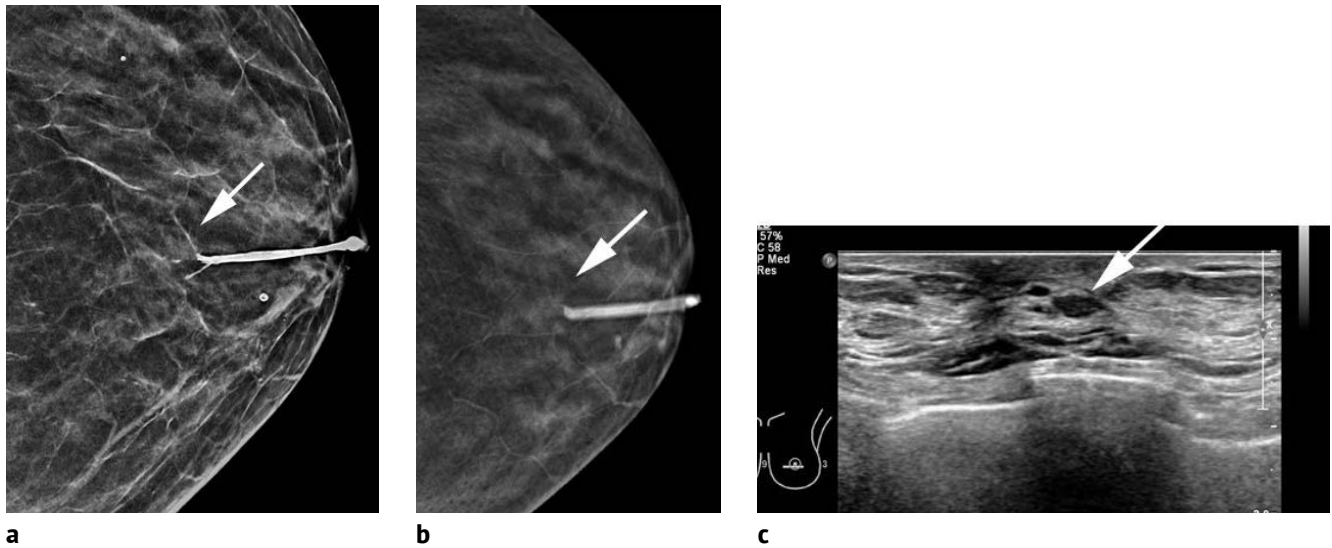


Fig. 2. A sixty-nine year-old woman with a non-spontaneous brownish left nipple discharge.

(a) Two dimensional synthesized craniocaudal digital mammography of the left breast shows ductal cut off in a subareolar segmental duct with associated mammographic asymmetry (arrow). (b) The digital breast tomosynthesis craniocaudal view of the left breast shows a ductal cut off with an associated conspicuous mass density rather than asymmetry (arrow). (c) Ultrasound imaging of the obstructing lesion reveals a small 0.5 cm hypoechoic mass (arrow) in the subareolar area. Ultrasound-guided core biopsy revealed ductal carcinoma in situ.

Table 3. Analysis of associated mammographic findings with two-dimensional synthesized digital mammography and digital breast tomosynthesis

Associated MG findings	2D SM			DBT		
	Benign (n=25)	Malignant (n=10)	P	Benign (n=25)	Malignant (n=10)	P
Negative	21 (84%)	4 (40%)		19 (76%)	2 (20%)	
Asymmetry	4 (16%)	3 (30%)	0.381	3 (12%)	2 (20%)	0.610
Mass	0	1 (10%)	0.286	3 (12%)	5 (50%) [†]	0.027
Microcalcifications	0	2 (20%)	0.076	0	2 (20%) [†]	0.076

MG, mammography; 2D SM, two-dimensional synthesized digital mammography; DBT, digital breast tomosynthesis, [†]1 malignant case in DBT shows mass and microcalcifications together

SM images showed only a nonspecific scattered distribution of calcifications (Fig. 4).

The sensitivity and specificity to predict a malignant lesion were analyzed. The use of galactography using DBT resulted in an improvement in sensitivity (90.0% vs. 80.0%) ($P=0.022$) and specificity (76.0% vs. 60.0%) ($P=0.031$) when compared to 2D SM. The probability of malignancy-based mean AUC values were 0.890 (0.785–0.995) for DBT and 0.758 (0.599–0.917) for 2D SM; this difference was statistically significant ($P = 0.025$).

Discussion

FFDM is a useful and significant imaging technology, but the images are two dimensional and the specificity is low (13, 14). DBT has three-dimensional imaging capability that allows more precise evaluation of lesions through the differentiation of overlapping breast tissue. These results in an improved accuracy compared to that of conventional DM (15). Prior studies of DBT showed a 15–40% decrease in the recall rate (12–16) and a 9.5–27% increase in the cancer detection

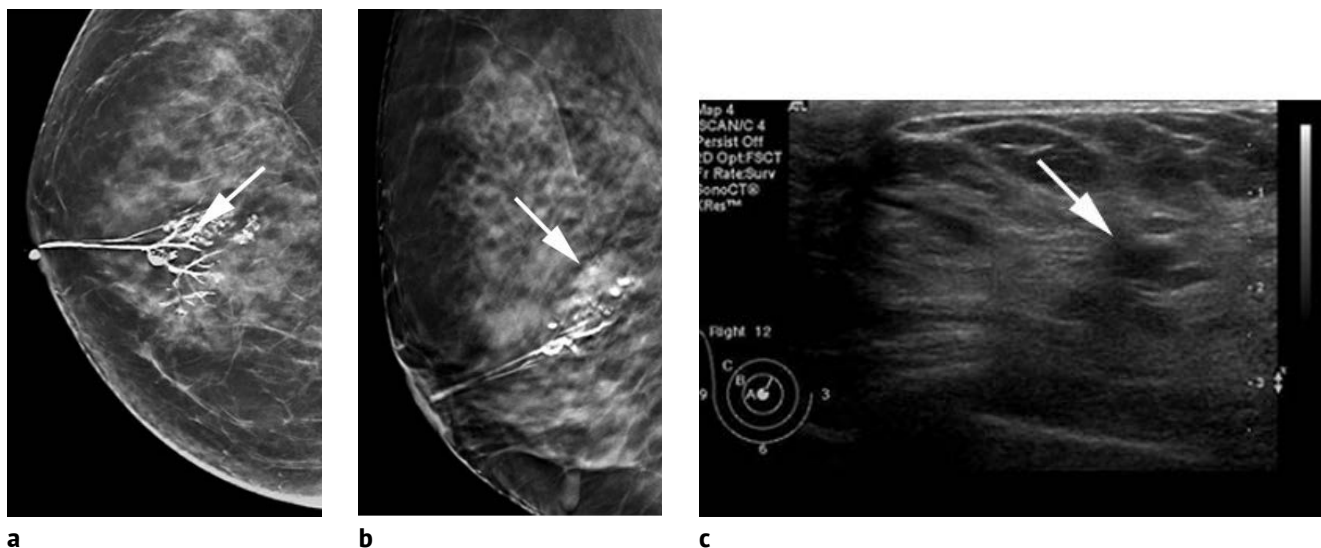


Fig. 3. A forty-four year-old woman with a spontaneous bloody right nipple discharge.

(a) Two dimensional synthesized craniocaudal digital mammography of the right breast shows a ductal wall irregularity (arrow) in subareolar segmental and subsegmental duct, with associated mammographic asymmetry. (b) The digital breast tomosynthesis mediolateral oblique view of the right breast shows a ductal wall irregularity, filling defect, and an associated irregular indistinct equal density mass (arrow). (c) Ultrasound of the obstructing lesion reveals an irregular indistinct hypoechoic mass at 1 o'clock (arrow). Core biopsy revealed invasive ductal carcinoma (0.4 cm) with a ductal carcinoma in situ component (2.5 cm).

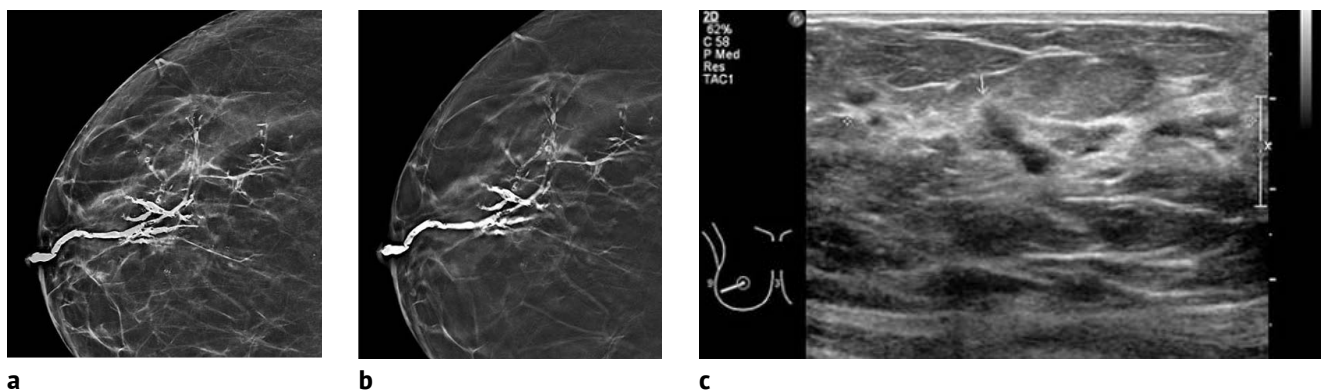


Fig. 4. A thirty-seven year-old woman with a spontaneous bloody right nipple discharge.

(a) Two dimensional synthesized craniocaudal digital mammography of the right breast shows a ductal wall irregularity and scattered punctate microcalcifications. (b) The digital breast tomosynthesis craniocaudal view of the right breast reveals a ductal wall irregularity, filling defect, and segmental punctate microcalcifications in the area of the ductal wall irregularity (c) Ultrasound reveals diffuse ductal changes manifested as multiple irregular indistinct hypoechoic masses in the lower outer quadrant. Vacuum assisted excisional biopsy revealed ductal carcinoma in situ.

rate (13, 16). In 2014, Lei et al. (17) published a meta-analysis demonstrating the superior diagnostic accuracy of DBT relative DM. Based on these reports, we examined the findings of galactography obtained with DBT. To our knowledge, this is the first study in which the diagnostic accuracy of

galactography using DBT has been compared with that of 2D SM. Conventional galactography is the established diagnostic method for the evaluation of a patient with a pathological nipple discharge and is useful in identifying the intraductal abnormality, evaluating the location and number of intraductal

lesions, and designing an optimal plan for surgical treatment (3, 4).

Pathological galactographic findings correlate significantly with the presence of a breast neoplasm, whether benign or malignant [18]. Several previous studies have evaluated the galactographic findings of malignant and benign disease. In 2009, Kim et al. [19] reported that common galactographic findings of benign diseases include ductal obstruction (48.3%) and a single filling defect (51.6%). Common findings for malignant tumors included ductal dilatation (72.7%) and stenosis (63.6%). In our study, the most common ductographic findings were ductal irregularity and filling defects in both benign and malignant symptomatic disease. In 2005, Cho et al. (3) described galactography findings in 24 cases with pathological nipple discharge. In some cases, faint microcalcifications or masses, not opacified by contrast material, were seen adjacent to the ductal abnormality. These findings were frequently subtle, and could have been easily overlooked. They emphasized the importance of maintaining a high degree of suspicion in order not to miss subtle, but suspicious, galactographic findings associated with breast cancer. Patients with diffuse intraductal cancer with microscopic invasion frequently lack palpable abnormalities and mammography may be negative or show nonspecific asymmetric densities. Therefore, we believe that galactography using DBT can improve diagnostic accuracy by unmasking cancers obscured by overlapping normal tissue. Tomosynthesis allows the examination of sequential sections through the breast and can clarify areas of overlapping ductal branches and further increase the detection of intraductal irregularities. DBT can facilitate a more meticulous examination of ductographic and any associated mammographic findings.

In our study, the sensitivity and specificity of galactography with 2D SM were 80.0% and 60.0%, respectively. The reported sensitivity and specificity of galactography are within a wide range (20).

Additionally, in our study, galactography using DBT resulted in an improvement in sensitivity (90% vs. 80%) and specificity (76% vs. 60%) when compared to 2D SM. Also, galactography using DBT depicted more masses than 2D SM, and this difference was statistically significant ($P < 0.05$). Five of 8 masses identified on galactography using DBT were confirmed as malignancy. DBT enables a better assessment of superimposed overlying breast tissue, resulting in a decrease in the number of false-positive recalls due to summation artifact from overlapping tissue (5, 21) and a better evaluation of the mass margins. This more detailed visualization of mass margins with DBT contributes to the increased sensitivity of DBT in detecting cancerous masses (22). Considering microcalcifications, previous reports showed that DBT might not be as effective in the detection of microcalcifications as it is for masses (23); however, more recent studies have shown no statistical difference between DBT and FFDM in the rate of in situ cancer detection (24). In our study, with Galactography using DBT microcalcifications were viewed sequentially in several different sections and individual calcifications within each section were often seen in areas corresponding to ductal irregularities and filling defects, while 2D SM images showed only a nonspecific scattered distribution of calcifications.

There are several limitations in our study. First, this was retrospective study with a small number of enrolled patients. Second, to avoid unnecessary radiation exposure, we selected synthetically reconstructed 2D mammographic images, i.e., 2D SM, to simulate conventional DM. Though previous reports showed 2D SM alone or in combination with tomosynthesis is comparable in performance to FFDM alone (10), 2D SM images still have some limitations. Improved synthesized images with experimentally verified acceptable diagnostic quality are needed. Finally, lesions that did not have pathological correlates from localization biopsy or excision were not included in our study, which may

have affected our results.

In conclusion, the results of our study suggest that in women with a pathological nipple discharge, the galactography using DBT shows more disease than does 2D SM. Also galactography using DBT depicted more masses than did 2D SM, and this difference was statistically significant ($P < 0.05$). Therefore, in a symptomatic patient, galactography using DBT has an increased sensitivity for the detection of malignancy, especially those manifested as a mass. Taken together, galactography using DBT has potential utility in the diagnostic work-up of patients with a pathological nipple discharge. Galactography using DBT significantly improves assessment of conspicuous mass in comparison to 2D digital mammography and helps to distinguish mass from asymmetry.

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대한유방검진학회지 2019;16:60-69

병적 유두분비물 환자에서의 디지털 유방단층촬영술을 이용한 유선조영술 평가: 인공적으로 재구성된 2차원 디지털 유방촬영술과의 비교

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목적: 본 연구는 병적 유두 분비물을 보이는 여성에서 디지털 유방단층촬영술(DBT)을 이용한 유선조영술과 인공적으로 재구성된 2차원 디지털 유방촬영술 (2D SM)을 이용한 유선조영술의 진단 정확도를 비교하였다.

대상 및 방법: 환자 35명에서 유선조영술 및 관련 유방촬영술 소견을 후향적으로 분석하여 조직병리학적 결과와 비교하였다. DBT와 2D SM을 이용한 각 검사 별 악성 병변 예측 민감도와 특이도를 계산하였다.

결과: 35개의 병변 중, 10 (28.6%)에서 악성, 25 (71.4%)에서 양성의 결과를 보였다. 가장 흔한 유선조영술 소견은 DBT와 2D SM에서 모두 유관의 불규칙성과 충만 결손이었다. DBT를 이용한 유선조영술은 2D SM과 비교하여 보다 많은 종괴를 나타내었다 ($P < 0.05$). DBT를 이용한 유선조영술 상에서 확인된 8개의 종괴 중 5개가 악성으로 확진되었다. DBT를 이용한 유선조영술에서 종괴를 보이는 경우 악성일 가능성이 2D SM보다 의미 있게 높았다. DBT를 이용한 유선조영술은 2D SM에서 얻어진 유선조영술과 비교하여 병변의 진단에 있어서 향상된 민감도와 특이도를 보였다. AUC 값은 DBT를 이용한 경우가 0.890, 2D SM를 통해 얻은 경우가 0.758이었다 ($P = 0.025$).

결론: DBT로 유선조영술을 얻으면 2D SM과 비교하여 관련 유방촬영술 소견에 대해 더 정확하게 평가할 수 있어 병적 유두 분비물을 보이는 환자에서의 진단에 있어서 잠재적 가치를 보였다.

Index words: Breast neoplasms; Diagnosis; Galactography; Digital breast tomosynthesis

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