Original Investigation

Diagnostic Accuracy of Digital Breast Tomosynthesis in the Evaluation of Palpable Breast Abnormalities

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Rationale and Objectives: The role of digital breast tomosynthesis (DBT) in evaluating palpable abnormalities has not been evaluated and its accuracy compared to 2D mammography is unknown. The purpose of this study was to evaluate combined 2D mammography, DBT, and ultrasound (US) at palpable sites.

Materials and Methods: Two breast imagers reviewed blinded consecutive cases with combined 2D mammograms and DBT examinations performed for palpable complaints. By consensus, 2D and DBT findings were recorded and compared to US. Patient characteristics, demographics, subsequent workup, and outcome were recorded.

Results: A total of 229 sites in 188 patients were included, with 50 biopsies performed identifying 18 cancers. All 18 cancers were identified on 2D and US, whereas 17 cancers were identified on DBT. Cancer detection sensitivities for 2D, DBT, and US were 100.0%, 94.4%, and 100.0%. The negative predictive value, when combined with US, was 100% for both. The sensitivity and the specificity for both benign and malignant findings with 2D and DBT were 70.5% versus 75.4% ($P = 0.07$) and 95.3% versus 99.1% ($P = 0.125$). Palpable findings not identified by 2D and DBT were smaller than those identified (11.5 ± 8.3 mm vs 23.9 ± 12.8 mm, $P < 0.001$). Patients with dense breasts were more likely to have mammographically occult findings than patients with nondense breasts (27.4% vs 8.3%).

Conclusions: DBT did not improve cancer detection over 2D or US. Both mammographic modalities failed to identify sonographically confirmed findings primarily in dense breasts. The diagnostic use of DBT at palpable sites provided limited benefit over combined 2D and US. When utilizing DBT, US should be performed to adequately characterize palpable sites.

Key Words: Tomosynthesis; breast cancer; palpable; mammography; breast imaging.

INTRODUCTION

Palpable abnormalities of the breast are one of the most common indications for which patients present for diagnostic breast imaging. Although most palpable abnormalities are benign, new palpable findings are a common presenting sign of breast cancer (1). Physical examination of the breast may be difficult as breasts have varying volumes of parenchymal tissues and fat. Previous research has shown that cystic causes of palpable abnormalities cannot be readily distinguished from solid masses by physical examination, and significant disagreement often occurs in the characterization of palpable breast masses even among experienced examiners (2,3).

Many breast masses do not exhibit definitive physical findings, and diagnostic breast imaging is often required to differentiate between benign and malignant causes of palpable abnormalities. The American College of Radiology (ACR) publishes appropriateness criteria guiding the recommended imaging examinations performed in the diagnosis of palpable breast masses (4). Typically, diagnostic imaging evaluations include some combination of mammography and targeted ultrasound (US) depending on patient age. Diagnostic mammography is recommended as the initial imaging step for women aged 40 or greater with palpable breast masses. Women aged 30–39 may either utilize diagnostic mammography or targeted US initially, depending on physician or practice preference. Imaging findings, which are not definitively benign on initial imaging evaluation, typically require additional evaluation with the alternate modality. Women under 30 years of age typically undergo US initially with mammography

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reserved to clarify indeterminate features or for further evaluation of suspicious findings.

Several previous studies of palpable breast abnormalities have shown the sensitivity of mammography alone to be between 86% and 91% (5–7). The combination of mammography and US in evaluating palpable abnormalities has been well studied. The combined diagnostic evaluation has been shown to have a high negative predictive value (NPV) and reduces false-negative interpretations (5–9). These previous studies have all involved the use of routine 2D mammography. The role of digital breast tomosynthesis (DBT) has yet to be fully defined in regard to palpable abnormalities. Although several studies of DBT in the diagnostic setting have included patients with palpable complaints and the ACR appropriateness criteria provide favorable ratings for its diagnostic use, there is little direct data on DBT's performance in this clinical setting or its value when combined with US (10–12). The purpose of the present study was to evaluate the diagnostic accuracy of DBT in the evaluation of palpable breast abnormalities while comparing it to the performance of routine mammographic views and US.

MATERIALS AND METHODS

Study Population

A keyword-based search of our institution's information warehouse was performed to identify female patients over 18 years of age who underwent routine 2D mammography, DBT, and US for the clinical complaint of a palpable breast abnormality between July 2012 and March 2015. Medical records of patients included in the study were reviewed to determine if a biopsy or an aspiration was performed, or in the absence of diagnostic sampling, whether imaging or clinical follow-up occurred. Patients who did not undergo a definitive diagnostic intervention or lacked follow-up were excluded from the study. True-positive and false-negative cases were determined on the basis of cancer diagnosis at the site of palpable concern within 1 year from imaging either at diagnostic sampling or upon follow-up. Cases with negative imaging findings were considered as true negatives if there was no evidence of cancer at the palpable site on clinical or imaging follow-up or after a benign result from diagnostic sampling.

Image Interpretation and Acquisition

Two dedicated fellowship-trained breast imaging radiologists (ALK and JRH) with 3 and 4 years' experience, respectively, interpreting DBT images participated in the imaging review. The interpreting radiologists were blinded to the clinical imaging interpretations and follow-up results in each case and by consensus characterized the patient's breast density, as well as the presence or the absence of a mammographic abnormality at the site of palpable concern on both 2D and DBT images and associated BI-RADS characteristics (13). Separately, US findings in the area of palpable concern were also recorded and correlated with the mammography results. The imaging reviewed included routine mammographic views, as well as additional spot compression or magnification views obtained in the diagnostic evaluation, if available, in addition to the DBT images. The areas of palpable concern were typically identified with a skin marker placed at the site. In the absence of a skin marker being present, the area of mammographic interest was indicated to the interpreting radiologists by one of the noninterpreting coauthors utilizing information from the medical record. Prior imaging studies were not utilized in the interpretation of the clinical cases. All mammographic imaging was performed by dedicated mammography technologists using the Hologic Selenia Dimensions system (Hologic, Inc., Marlborough, MA) and by dedicated breast US technologists with the GE LOGIQ P9 and E9 systems (GE Healthcare, Chicago, IL).

Data Analysis

Summary statistics, means and standard deviations for continuous variables, and counts and percentages for categorical variables were generated for variables of interest. Confidence intervals for the sensitivity and the specificity were based on the exact method using the binomial distribution. The comparison of palpable sizes between groups was conducted using the Mann-Whitney test because of the non-normal distribution of the palpable size. The agreement of the BI-RADS descriptors between different methods was evaluated using the Cohen kappa coefficient, where arbitrary guidelines characterize kappas over 0.75 as very good, 0.60–0.75 as good, and 0.45–0.60 as moderate.

RESULTS

A total of 188 patients with 229 separate sites of palpable concern were included in the final study population. The demographic information of included patients is summarized in Table 1. The mean patient age was 44.7 ± 11.3 years (range 23–88). With regard to breast density, 66% of the patients had dense breast tissue (BI-RADS C and D), whereas 34% were nondense (BI-RADS A and B). Diagnostic sampling, either through core biopsy or diagnostic aspiration, was performed at 21.8% (50/229) of the sites of palpable concern. In patients who did not undergo diagnostic sampling, the mean follow-up was 25.7 months (range 2–57 months). The mean mammographic size of palpable abnormalities, as measured in the greatest single dimension, was 2.5 cm (range 0.6–12.8 cm). The mean sonographic size of the findings detected at palpable sites was 2.0 cm (range 0.2–7.8 cm).

Cancer was detected in 7.9% of all palpable areas (18/229) with a 36.0% (18/50) positive predictive value of diagnostic sampling. All 18 carcinomas were correctly identified with the use of routine 2D mammography and US. Although all 17 breast carcinomas were correctly identified with the use of DBT, there was one false negative with the use of DBT, a lung carcinoma metastasis. The lung carcinoma metastasis