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Digital Mammography

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KEY POINTS

- Mammography has been well established through randomized controlled trials in the 1980s and 1990s to decrease breast cancer mortality. However, these trials accumulated data from patients imaged with analog imaging, one of the very earliest mammography techniques.
- In addition, rigorous quality standards had not yet been firmly established, resulting in inconsistent practice across breast imaging facilities. Not only were there differences in expertise in image acquisition, but there were also varying levels of specialization of the radiologists interpreting the mammograms.
- Significant technical improvements over the past few decades, including digital mammography and, more recently, digital breast tomosynthesis, have further improved the performance of screening mammography. These improvements will likely contribute significantly to the decline in breast cancer mortality in regions where routine screening is available.

BENEFITS OF MAMMOGRAPHY

Since mammography became a widespread screening tool in the mid-1980s, some population-wide studies have demonstrated up to a 40% decrease in disease-specific mortality [1,2]. Not only do patients who are routinely screened benefit from an improved survival, but they are also more likely to be candidates for breast conserving surgery, thus improving quality of life [3]. Despite differences in practice in European countries, it is recommended by the American College of Radiology and the National Comprehensive Cancer Network that average risk women undergo screening mammography beginning at age 40 years [4]. However, despite efforts to educate patients on the importance of screening mammography, there are suboptimal rates of patient compliance with routine screening in the United States [5]. Besides challenges in access and education, discomfort from breast compression during mammography has been found to be a factor. Some studies have found that anxiety plays an even bigger role [6]. Breast centers can improve compliance by employing well-trained technologists, who closely communicate with the patients and improve the patient experience [7]. New techniques and protocols have aimed to improve patient comfort by particularly focusing on breast compression [8]. With the implementation of Affordable Care Act, studies have shown that certain groups, such as Hispanic women and cancer survivors, have increased use of mammography, possibly due to the increase in insured women in these subpopulations [9].

DIGITAL MAMMOGRAPHY

After US Food and Drug Administration (FDA) approval in 2001, conversion from screen-film

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mammography (SFM) (analog) to the digital technique eliminated film processing, improved acquisition, display, storage, and retrieval of images. Given the popularity of digital mammography, studies were necessary to prove superiority in performance relative to film to justify the cost of adoption. In 2003, Skaane and colleagues [10] compared SFM and full-filed digital mammography (FFDM) for asymptomatic women in the Norwegian Breast Cancer Screening Program in the Oslo I study. Of the 3683 women who underwent both analog and FFDM, analog mammography resulted in a 0.76% cancer detection rate, which was remarkably similar to FFDM with a 0.62% cancer detection rate. However, the study also demonstrated a higher recall rate and thus a lower positive predictive value (PPV) for digital mammography. The Oslo II study was conducted to further evaluate the 2 types of modalities in a prospective randomized trial that enrolled 25,263 women, who were randomized to either film or digital mammography for breast cancer screening. The results demonstrated a breast cancer detection rate of 0.41% in the film mammography cohort and 0.59% in the digital mammography group; however, not statistically significant ($P = .06$). In addition, the recall rate was higher for digital mammography than with film mammography (3.8% vs 2.5% for age group 50–69 years, $P<.05$) without a significant difference in the PPV [11].

In 2005, the Digital Mammographic Imaging Screening Trial (DMIST) was conducted by the American College of Radiology Imaging Network and funded by the National Cancer Institute to further evaluate the outcome differences between SFM and digital mammography in the US environment. Among the 33 participating institutions within the United States and Canada, a total of 49,528 women were included in the study. The images from the 2 modalities were interpreted by 2 independent on-site radiologists and took place over 25.5 months. Pisano and colleagues [12] found that, among 42,760 women whose data were available for analysis, the diagnostic accuracy of digital and film mammography was similar. However, after subgroup analysis, in younger women less than 50 years of age, premenopausal and perimenopausal women, and women with heterogeneously or extremely dense breasts, digital mammography outperformed film mammography. To further evaluate the differences of diagnostic accuracy between film and digital mammography within the 3 subgroups, a retrospective study was conducted with the DMIST data in 2008, which showed persistent improvement in the diagnostic accuracy of digital mammography for younger patients (<50 years of age) with dense breasts, as well as statistically nonsignificant improvement in diagnostic accuracy of film mammography for women older than 65 years of age or women with fatty breasts. Unfortunately, there is no definitive explanation for the differences seen in these subgroups [13].

Although several large DMIST-based studies showed that the overall diagnostic accuracy did not differ between film mammography and FFDM, additional studies have shown various finding-specific benefits. In 2005, a retrospective study based at a single institution investigated images in 55 patients with microcalcifications. They found that there was a greater sensitivity (95.2% vs 91.9%) and specificity (41.4% vs 39.3%) of digital mammography compared with film mammography, as well as higher reliability for characterizing microcalcifications [14].

RADIATION DOSE WITH DIGITAL MAMMOGRAPHY

Not only was there improved efficiency and performance with digital screening mammography, the digital technique also decreased overall radiation dose to the patient. Because digital mammography has a wider dynamic range, it allows higher contrast resolution but with slightly lower spatial resolution [15]. Several studies using phantoms have found that the reduced radiation dose using digital mammography units does not significantly compromise image quality, especially given the finer contrast adjustments with appropriate window settings. In a study involving 1116 mammograms, Hermann and colleagues [16] found that digital systems needed approximately 25% less dose compared with conventional SFM.

TECHNICAL CONSIDERATIONS WITH DIGITAL MAMMOGRAPHY

Before producing the final presentation state, processing of the images acquired from the detectors is performed through a variety of algorithms. For example, some algorithms are used to correct for detector inhomogeneity or to enhance the visualization of details within fatty regions [17]. Many of these factors are manufacture dependent. At display, the images are given a Digital Imaging and Communications in Medicine header, which contains all the information necessary for storage, display, and retrieval of the images. Softcopy viewing as part of digital mammography allows digital images to be displayed at different levels and windows, which can be adjusted by the reader. Subsequently, the degree of contrast can be adjusted

leading to greater focus on areas of dense breast tissue, where cancer is often missed. In addition, it also enables advanced applications such as computer-aided detection (CAD) and diagnosis as well as remote interpretation (tele-mammography). However, Cole and colleagues [18] examined the impact of CAD systems on radiologists' diagnostic accuracy based on the DMIST data and found no statistically significant effect of CAD on diagnostic accuracy, specificity, or sensitivity.

With the rapid adoption of digital mammography, storage and archiving the images presented a technical challenge. The storage size of the images is dependent on pixel size and the number of images acquired. Although many institutions had established Picture Archive and Communication System (PACS) to facilitate image storage, factors such as long-term versus short-term storage and readily available previous studies for comparison proved to be challenging for facilities to easily display images for interpretation.

TRANSITION TO DIGITAL MAMMOGRAPHY

Although the overall diagnostic accuracy of digital mammography was found to be similar to that of SFM, digital mammography showed a significant operational benefit. The advantages not only included greater contrast resolution, lower radiation dose, but also included the ease of use, such as increased options in image manipulations at display, convenience of storage and retrieval, and enabling advanced applications. However, purchasing and managing new machines translated into large capital investments. New digital mammography units range from $250,000 to $500,000, with additional operational costs related to digital monitors, technical support, and training of technologists and radiologists [19]. However, eliminating film mammography offset some of these added expenses by removing the costs of film processing and storage of the hardcopy images.

With standardization of digital mammography, the US FDA in 2003, mandated accreditation for each digital mammography unit. However, quality control tests for digital mammography encompassed an increased number of steps, not only involving image quality at acquisition but also softcopy workstation evaluation, and thus was more complex compared with that of SFM. Facilities also faced additional challenges during the transition period; specifically, operating in a hybrid environment (having analog and digital equipment), whether or not the preexisting PACS could be used for image storage, the ability to view hardcopy for comparison with softcopy studies, and ergonomic issues regarding location and set up of reading rooms for interpreting studies.

Once patients were screened repeatedly with digital mammography in the late 2000s, the benefits of the digital technique became even clearer. In 2014, the Norwegian Breast Cancer Screening Program demonstrated that, out of 557,942 screening examinations performed for women aged 50 to 69 years, the recall rate was 2.1% for the second round or incident screen with digital mammography versus 2.6% for SFM in patients who had previous SFM ($P<.001$). In addition, the biopsy rate followed the same trend contributing to a higher PPV for biopsy for digital mammography-based screening [20]. In a smaller study, Weber and colleagues [21] found that, with digital mammography, lower-grade tumors and smaller sizes of invasive cancers were detected. By the end of 2010, nearly three-quarters of mammography units in the United States were digital machines [22]. Despite these improvements with digital units, mammography was still criticized for low sensitivity and specificity, particularly in women with dense breast tissue.

DIGITAL BREAST TOMOSYNTHESIS

Digital breast tomosynthesis (DBT), a low-dose multiangle method to obtain multiple images of the breast, was developed to improve on the main limitations of mammography. Because tissue superimposition obscures abnormalities and generates the appearance of pseudolesions, the different angled images with DBT provides more information to aid in interpretation. It was hypothesized that this technique would allow the radiologist to identify cancers more readily and dismiss findings that were not true abnormalities at the time of screening. This would translate into improved accuracy, and decreased patient recall. Following the promise of this improved technique, Skaane and colleagues performed a large prospective screening trial to evaluate the clinical value of DBT at a single European institution. The study evaluated 12,631 consented participants who were selected from a Norwegian Breast Cancer Screening Program during the period from November 2010 to December 2011. There were 4 study arms: digital mammography (DM) alone, DM plus CAD, DM plus DBT (DM/DBT), and DM plus synthetic mammography. Each study arm included the same patient population, therefore, each patient received 4 separate assessments. The interpreting radiologists scored the examinations based on a 5-point scale to indicate their level of suspicion. All cases that received a score of 2 or greater in at least 1 study arm were discussed during

a group arbitration to determine a consensus-based clinical treatment decision. Ultimately, this study design permitted comparison of cancer detection rates, false-positive rates before arbitration, PPVs for women recalled after arbitration, and the type of cancers detected for the different study arms. DM/DBT resulted in a 27% increase in overall cancer detection rate compared with DM, with a notable 40% increase in detection of invasive cancers. Furthermore, DM/DBT resulted in a 15% decrease in false-positive rates before arbitration compared with DM. These results were particularly relevant to discussions of screening harms, such as over detection of clinically insignificant low-grade malignancy, false-positive results, and excessive follow-up imaging as well as biopsies [23].

To assess the screening benefits of tomosynthesis in the United States, Friedewald and colleagues performed a multi-institutional study including academic and community-based radiology practices in the United States. Similar to Skaane's study, the screening performance of DM/DBT was compared with that of DM alone. The comparison was made by assessing 13 different sites during 2 time periods; 1 period occurred during the year preceding tomosynthesis implementation (with dates ranging from March 2010 to October 2011), and the other occurred after the initiation of tomosynthesis screening depending on date of implementation up to December 31, 2012. A total of 454,850 screening mammograms were interpreted at all 13 sites. Retrospective analysis demonstrated that the addition of tomosynthesis resulted in significant improvements across all measurements. Eleven of 13 sites observed a decreased recall rate with DM/DBT screening compared with DM. In addition, the overall cancer detection rate (CDR) per 1000 examinations increased by 1.2/1000 when screening was performed with DM plus tomosynthesis. Similar to Skaane and colleagues, the invasive CDR also increased by 1.2 per 1000 with supplemental tomosynthesis [24].

The goal of screening mammography is to detect cancer at an early stage and minimize false-positive findings that result in unnecessary testing, anxiety, and costs. The combined effect of lowering recall rates while simultaneously increasing the CDR, underscores the potential value of this technology with breast screening, and implies that the relative yield for every screening recall will increase with the use of tomosynthesis. This was specifically illustrated by the PPV for recall (likelihood of cancer diagnoses in women recalled for additional imaging), which increased from 4.3 to 6.4 (relative increase of 49%) after the addition of tomosynthesis. Similarly, the PPV for biopsy also demonstrated a relative increase by 21%. These results demonstrated that the use of tomosynthesis as a screening tool could potentially address the concerns of unnecessary tests and biopsies, while still increasing CDRs [24].

Following the demonstration of the potential benefits of tomosynthesis in screening, using the same dataset as obtained with the Friedewald study, the authors investigated whether or not there were differences in performance of DBT in different age groups. This study demonstrated that, when adjusted for age, the addition of tomosynthesis resulted in an increased CDR and decreased recall rate for dense and nondense breasts. Furthermore, on subgroup analysis, the heterogeneously dense group benefited most from the addition of tomosynthesis. Of note, there was no significant difference in cancer detection of DM compared with DM/DBT for the small population of women with extremely dense breasts. Therefore, caution should be taken to avoid overgeneralization of the benefits of tomosynthesis with regard to women with dense breasts, given that women with extremely dense breasts did not share the incremental benefits seen with the heterogeneously dense group [25].

DIGITAL BREAST TOMOSYNTHESIS AND NATIONAL GUIDELINES

The appropriate age to commence breast cancer screening has been debated owing to the relatively low incidence of breast cancer and the higher rate of false-positive screens within the 40- to 49-year age group. The United States Preventive Services Task Force guidelines advocate biennial screening for women 50 to 74 years of age and argue against routine screening for women ages 40 to 49 [26]. The American Cancer Society (ACS) guidelines recommend annual screening for women 45 to 54 years of age and a transition to biennial screening at age 55 years. In 2015, following a systematic review of evidence regarding screening mammography, the ACS issued an updated guideline for women ages 40 to 44 years stating that women in this age group should have the opportunity to begin annual screening. As a qualified recommendation, this revision acknowledged the presence of evidence regarding the benefit of screening; however, it also noted that factors such as the balance of benefits and harms as well as patient preferences within this group remain unclear [27]. Given that tomosynthesis decreases recall rates while simultaneously increasing CDRs, the technology can potentially address the concerns of screening harms within the 40- to 49-year age group. The relevance of tomosynthesis

with regard to this controversy was examined from the previously collected multicenter data collected by Friedewald and colleagues. This time, the screening performance of DM/DBT was assessed as a function of age, and data were adjusted for breast density to exclude the potential confounding factor. The addition of tomosynthesis to screening mammography resulted in decreased recall rates across all age groups. Even more striking, although, were the performance gains for the group of women in their 40s. Results for this group demonstrated the largest decrease in recall rate (relative reduction of 16%), while simultaneously resulting in a 69% relative increase in invasive cancer detection (1.6–2.7 per 1000 women screened). The invasive CDR with the use of tomosynthesis for women in their 40s was even greater than the rate for women in their 50s screened with DM alone. Therefore, the supplementation of tomosynthesis to screening seems to shift the benefits for this age group beyond the performance of screening with DM alone for women in their 50s. These results highlight the value of commencing breast cancer screening at the age of 40 years [28].

TRANSITION TO DIGITAL BREAST TOMOSYNTHESIS

The demonstration of the potential screening gains with supplemental tomosynthesis sparked excitement across the United States, and many practices quickly moved to implement the new technology. However, this shift occurred before establishing an understanding of the sustainability and clinical effectiveness of tomosynthesis. The rapid adoption prohibited long-term data collection that is required to assess sustainability and outcomes. McDonald and colleagues studied the longitudinal performance of DBT in screening mammography at a population and individual level. The study population included all women undergoing screening mammography at a large, urban academic practice from September 1, 2010, to September 30, 2014, for a total of 44,468 screening events (23,958 unique women). Women who presented during the first year of screening (year 0) underwent DM alone, and, during the following 3 years (years 1–3), underwent DM plus tomosynthesis. They found that the reduced recall rate at a population level following the implementation of DBT was sustainable in the following 2 years, and for women with more than 1 round of DBT screening, the recall rate continued to decrease with each additional DBT examination. With regard to cancer detection rate, they questioned whether the reported increase in CDR after the initial implementation of DBT was an effect of prevalence. Results from their study suggested that there is a possible prevalence-screening effect in the first round of screening with DBT, which is reflected by a decrease in the CDR from 13 per 1000 screened in the first round to 6.2 per 1000 in the second incidence round. However, the second round incidence rate of detection with DM/DBT remains higher than the published rate of 4.2 per 1000 for an incidence screening round with DM, and the CDR increased again in the third round of cancer DBT screening [29]. This demonstrates that the additional use of DBT in screening results in a sustained increase in cancer detection compared with that of DM, supporting the movement to implement DBT.

TECHNICAL CONSIDERATIONS WITH DIGITAL BREAST TOMOSYNTHESIS

The incorporation of tomosynthesis into a practice mandates attention to several technical issues. Financial implications include the cost of new equipment, additional space, and expanded technical support. Compared with a standard DM screening mammogram, a DBT examination is also a higher expense for the patient depending on insurance coverage. Alleviating some of this cost to the patient was when the Centers for Medicare and Medicaid Services began coverage for DBT effective in 2015 [30].

Most technical factors associated with DBT are related to data acquisition, storage, and image sharing. The data for a single screening examination with DBT is substantially larger than a DM study, and the significantly increased volume of data may prohibit some institutions from implementing DBT. In addition, the storage of a single DBT examination may be too large for a typical compact disc, complicating hardcopy transfer of examinations. Not only is image size challenging, the additional number of images significantly increases interpretation time for the radiologist. One study demonstrated that increased physician experience was not associated with decreased interpretation time for DBT examinations, suggesting that the number of images is the limiting factor rather than physician experience with the new technology [31]. Patient radiation dose exposure is also of note. In a literature review of clinical studies comparing DBT with DM, Svahn and colleagues [32] found that DM/DBT increases the radiation dose by a factor of approximately 2.25 in comparison with the dose of DM alone.

SYNTHETIC IMAGING

Software manufacturers have sought to address dose limitations by creating synthetic mammographic (SM)

images, which are 2D images reconstructed from the raw DBT dataset. Like DM, SM images permit global assessment of breasts for density, lesions (especially calcifications and asymmetries), and easier side by side comparison with the contralateral breast and previous images. Patients receive radiation only from the DBT component, representing a 39% to 45% decrease in radiation exposure [33]. In May, 2013, the FDA approved the use of synthetic mammography in combination with DBT. Since then, SM has been used more frequently and has replaced DM at some institutions. The images are acquired by applying a manufacturer-specific algorithm to a tomosynthesis dataset, which summates and filters the reconstructed sections of the dataset to simulate a true digital mammogram. Ultimately, the designed algorithm increases the visibility of masses, architectural distortions, and calcifications. Studies have shown that the combined implementation of SM/DBT results in accuracy, sensitivity, and specificity comparable with DM/DBT for screening mammography [34]. However, as is expected with the implementation of any new technology, SM can create artifacts. An institutional review of the experience noted specific artifacts of the technology including pseudocalcifications, decreased axillary contrast resolution, subcutaneous blurring, and decreased contrast resolution around foreign bodies [35]. The various manufacturer's equipment may perform differently, and it is important to be aware of these factors as they can influence image interpretation. Further research is needed to guide the use of SM/DBT in clinical practice.

DIGITAL BREAST TOMOSYNTHESIS-GUIDED BIOPSY

With the use of digital breast tomosynthesis, a role has arisen for DBT-guided vacuum-assisted biopsy (DBT-VAB) for sampling suspicious imaging findings that are occult on MRI and ultrasound, and are more conspicuous on DBT compared with DM. Traditionally, stereotactic VAB (S-VAB) has been the preferred method of sampling suspicious mammographic findings, such as microcalcifications and sonographically occult masses. However, DBT-VAB has demonstrated to be advantageous compared with S-VAB; in 1 study, DBT-VAB outperformed S-VAB in all evaluated aspects [36]. Although S-VAB requires the radiologist to triangulate the depth of the abnormality with the use of paired stereo images, DBT excludes this step. Rather, the depth of the target lesion is readily determined by simply selecting the DBT image that best visualizes the target lesion. The software then automatically calculates needle insertion depth, stroke margins, and distance to skin. This eliminates steps that can lead to technical errors deeming a need for additional exposures, and has shown to decrease the overall procedural time by 50% compared with S-VAB [36]. DBT-VAB also increases the accuracy of biopsy by enabling precise determination of the needle tip location with respect to the lesion, ultimately resulting in high radiographic-pathological concordance rates. A small study of 51 women who underwent DBT-VAB showed good patient tolerance and no major complications. The only complication of note was self-limiting vasovagal reaction experienced by 2 patients, which was not significantly different than the rate of vasovagal seen by the group who underwent S-DBT [36].

SUMMARY

DM and now DBT have improved on standard SFM, the only imaging test proven to decrease breast cancer mortality. As we use these techniques for breast cancer imaging, it is important to continue to refine our technology to improve performance and increase compliance with breast cancer screening.

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