Radiology

Effect of Transition to Digital Mammography on Clinical Outcomes[1]

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Purpose: To determine the effect of transition to digital screening mammography on clinical outcome measures, including recall rate, cancer detection rate, and positive predictive value (PPV).

Materials and Methods: Institutional review board approval and the need for informed consent were waived for this HIPAA-complaint study. Practice audit data were obtained for three breast imaging radiologists from 2004 to 2009. These data were sorted by time period into the following groups: baseline (2004–2005), digital year 1 (2007), digital year 2 (2008), and digital year 3 (2009). The χ^2 and Fisher exact tests were used to assess differences in proportions among and between years. Clinical outcomes based on lesion type from 2004 to 2008 were also compared. Computer-aided detection was used.

Results: The three radiologists interpreted 32 600 screen-film mammograms and 33 879 digital mammograms. Recall rates increased from 6.0% at baseline to 7.1% in digital year 1 ($P < .0001$) and continued to increase in subsequent years to 8.5%. The cancer detection rate increased from 3.3 at baseline to 5.3 in digital year 1 ($P = .0061$), and it remained higher than that at baseline in subsequent years. PPV after screening mammogaphy (PPV_1) increased from 5.6% at baseline to 7.5% in digital year 1 and returned to baseline levels in digital year 3. In contrast, PPV after biopsy (PPV_3) decreased from 44.5% at baseline to 30.3% in digital year 3 ($P = .0021$). From 2004 to 2008, 3444 patients with 3493 lesions were recalled. The percentage of recalls for calcifications increased from 13.8% at baseline to a peak of 23.9% in digital year 1 and 17.9% in digital year 2. Both PPV_1 and PPV_3 decreased for calcifications after the digital transition.

Conclusion: Recall rate and cancer detection rate increase for at least 2 years after the transition to digital screening mammography. PPV_3 is significantly reduced after digital transition, primarily in patients with microcalcifications.

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creening mammography outcomes have improved with advances in technology. The majority of studies have shown that implementation of digital imaging at screening mammography increases the cancer detection rate compared with that achieved with screen-film mammography (1–8). However, approximately 65% of U.S. mammography clinics continue to use screen-film mammography (9). The reasons for the slow conversion to digital imaging are multifactorial and are partially due to the high initial start-up expenses, the learning curve, and the somewhat mixed outcomes with digital mammography (10). For instance, there are a few studies in which researchers found no change in cancer detection rate between

screen-film mammography and digital mammography (11,12), and there are numerous studies that have shown increased recall rates with digital screening (1,3–5,8). Some may argue that the increase in recall rates leads to greater patient anxiety and medical costs.

Given the advantages of digital mammography, including electronic archiving, teleradiology, digital magnification, higher contrast, reduced radiation, and improved diagnostic accuracy in a subset of the population (2), our institution transitioned to complete digital mammography in November 2006. Our purpose is to determine the effect that the transition to digital screening mammography has on clinical outcome measures, including recall rates, cancer detection rates, and positive predictive value (PPV).

Materials and Methods

Overview

This retrospective study was Health Insurance Portability and Accountability Act compliant. Institutional review board approval and patient informed consent were waived because this study was a chart review of deidentified records and aggregate data.

We performed a retrospective audit of key clinical outcomes before and after the transition to digital mammography at our institution. The main clinical outcomes were recall rate, cancer detection rate, and PPV. Recall rate was defined as the number of abnormal interpretations divided by the total number of examinations and expressed as a percentage. Cancer detection rate was defined as the number of cancers detected per 1000 women screened. PPV was defined as the number of true-

positive findings divided by the number of true-positive and false-positive findings. PPV_1 was the probability of cancer after a positive mammographic interpretation and was expressed as a percentage. PPV_3 was the probability of cancer among patients undergoing biopsy after a Breast Imaging Reporting and Data System (BI-RADS) assessment of 4 or 5 (suspicious or highly suspicious for malignancy) and was expressed as a percentage. PPV_1 and PPV_3 were calculated for each time period (baseline and digital years 1, 2, and 3) and for each recall reason (calcifications or noncalcifications, such as distortions, mass, focal asymmetry, and globally asymmetric tissue).

In November 2006, we converted from an analog mammography screening program to a full-field digital mammography screening program. All patients in the audit underwent imaging exclusively with a digital system (Selenia Dimensions and Selenia Base Units; Hologic, Bedford, Mass). Computer-aided detection also was used.

We conducted a mammography audit of four time periods: baseline and digital years 1, 2, and 3. The first period, baseline, comprised 2004 and 2005. During this time, all screening mammograms were obtained exclusively with screen-film mammography, and full-field digital mammography was used for diagnostic purposes only. Digital year 1

Advances in Knowledge

- A persistently elevated cancer detection rate is identifiable for at least 2 years after conversion to digital mammography screening; the cancer detection rate for digital year 2 was 5.9, which was significantly higher than the baseline value of 3.3 (P = .0016).

- Overall positive predictive value after screening mammography (PPV_1) increases after conversion to digital mammography and gradually returns to baseline levels (PPV_1 = 5.6% at baseline, 7.5% in digital year 1, 7.4% in digital year 2, and 5.3% in digital year 3); however, positive predictive value after biopsy (PPV_3) decreases (30.3% in digital year 3) and does not return to baseline levels (44.5%) for up to 3 years after switching (P = .0021).

- Both PPV_1 (15.2%, 10.5%, and 11.6% at baseline and digital years 1 and 2, respectively) and PPV_3 (41.1%, 21.8%, and 24.1% at baseline and digital years 1 and 2, respectively) for calcifications decrease after switching to digital technology; the decreases in PPV_3 were larger (P = .0038 for baseline to digital year 1 and P = .0368 for baseline to digital year 2).

Implication for Patient Care

- Radiologists can better understand the potential pros and cons of converting to digital mammography in respect to patient outcomes, including cancer detection rate, recall rate, and positive predictive value.

(2007) was the first full calendar year after complete conversion to digital mammography in November 2006. Digital year 2 (2008) was the 2nd year after conversion. Digital year 3 (2009) was the 3rd year after conversion.

For the entire audit, only radiologists (D.M.F., B.S.M, K.N.W.) who read screening mammograms during all four time periods were included. Each of the three radiologists is a Mammography Quality Standards Act–certified dedicated breast imager with at least 10 years of experience in breast imaging. The radiologists had completed training in digital mammography in compliance with the Mammography Quality Standards Act. In addition, the radiologists had participated as readers in the American College of Radiology Imaging Network Digital Mammography Imaging Screening Trial in 2002 and 2003.

Data Collection

All patients included in this study were women.

Aggregate data analysis.—Annual audit data routinely provided at our institution were reviewed to obtain the aggregate data from 2004 to 2009.

Lesion data analysis.—Individual lesion data were available for 2004–2008. The reports of all BI-RADS 0 cases from 2004 to 2008 were reviewed by two radiologists (D.M.F., C.G.G.; 15 years and 18 months of experience in breast imaging, respectively) to obtain relevant clinical data and to exclude inappropriate cases. BI-RADS category 0 was assigned when additional imaging evaluation or comparison with prior mammograms was required to determine a final BI-RADS result. Exclusion criteria were as follows: examination repeated for technical reasons; BI-RADS 0 classification resolved by comparison with prior outside images; cases recalled based only on an abnormality at screening ultrasonography; cases without a documented resolution of BI-RADS 0; and diagnostic cases misclassified as screening cases. Between 2004 and 2008, there were a total of 4455 lesions that were classified as BI-RADS category 0 on the basis of a screening mammogram. Of these, we excluded 962 cases. A total of 491 cases

were resolved the basis of comparison with outside images; 260 were technical repeat examinations; 165 had no documented resolution; and 46 were excluded for other reasons listed previously.

Data Analysis

Aggregate data analysis.—We selected key performance outcomes recommended for breast imaging annual practice quality audits (13,14). These included patient recall rate, cancer detection rate, PPV_1, and PPV_3.

The data were analyzed at the aggregate level rather than at the individual reader level. Each screening event, regardless of the number of lesions detected, was treated as one case.

Lesion data analysis.—Since digital mammography has been reported to enable better identification of microcalcifications and to possibly increase the detection rate of invasive cancers (15,16), we compared the clinical outcome of lesions with calcifications with the clinical outcome of lesions without calcifications.

The analyses to determine whether clinical outcomes differed based on lesion type (those with calcifications vs those without calcifications) were performed at the lesion level. Unlike the aggregate analyses, each lesion was treated as a separate case since some patients had more than one lesion; this enabled us to determine clinical outcomes based on lesion type. This was performed for all lesions from 2004 (baseline) to 2008 (digital year 2). The breakdown of digital year 3 lesion data was not available at the time of manuscript preparation.

Statistical Analysis

The Kolmogorov-Smirnov-Lilliefor test was used to test the normality of the age distribution, which was nonnormal ($P < .05$); therefore, median age and age range have been reported. The Fisher exact test (for 2×2 tables) and the χ^2 test (for multiway tables) were used to test for differences in proportions between *(a)* baseline and digital year 1, *(b)* baseline and digital year 2, and *(c)* digital year 1 and digital year 2. The power calculation in support of our study was based on the null hypothesis that the

recall rate would remain identical with our switch to digital mammography. Between 2004 and 2005, there were 970 recalls for 15 232 screening cases. The sample size calculation in our study indicated that with a one-sided test (we were interested in an increase only) and α set at .05 we would have a power of 72% to detect a relative 10% increase (from the observed 6.0%-7.1% increase in the baseline recall rate). In our study, the Bonferroni-adjusted *P* value (for multiple comparisons based on an α of .05) was .0013. Statistical analyses were performed with JMP statistical software (release 6.0.2; SAS Institute, Cary, NC) and StatXact 7 statistical software for Exact Nonparametric Inference (Cytel, Cambridge, Mass).

Results

Overview

During the baseline period, 54 664 screen-film mammograms were read at our institution. The three study radiologists interpreted 32 600 of these screen-film mammograms. During digital year 1, 26 550 screening mammograms were interpreted at our institution. The study radiologists read 11 358 digital screening mammograms in total. During digital year 2, 27 409 screening mammograms were read. Of these, the study radiologists read 7924. During digital year 3, 27 516 screening mammograms were read. Of these, the study radiologists read 14 597.

Regarding patient demographics, the screening population had an age range of 27–92 years and a median age of 52 years. Almost two-thirds of women were white (63.9%), with African American women making up the next largest group (30.7%), and other ethnic groups (Asian, American Indian, Hispanic, and others) accounting for only 5.4% of the total.

Aggregate Results

The recall rate increased from 6.0% at baseline to 7.1% in digital year 1 ($P < .0001$, Table 1). The recall rate significantly increased to 8.0% in digital year 2 and 8.5% in digital year 3

when compared with that at baseline ($P < .0001$).

Cancer detection rates increased from 3.34% at baseline to 5.28% in digital year 1 ($P = .0061$). The cancer detection rate in digital year 2 was 5.93% ($P = .0016$ compared with baseline). In digital year 3, the cancer detection rate decreased slightly to 4.52%. However, this rate was not significantly different from that at baseline ($P = .0592$) or that in digital year 1 ($P = .4180$).

To get an overview of disease stage, we assessed the cases reported to the tumor registry at our institution. A small number of cases could not be reported for stage (in total, 25 cases were not reportable from 2004 to 2008). This was the case in 24 patients who had abnormal mammograms but who sought treatment elsewhere and in one patient who had lymphoma of the breast. Nevertheless, an overview of the breakdown into stage 0 (ductal carcinoma in situ), stage 1, and stage 2 or higher can be gained from the registry. At baseline, 25.0% of registered cancers were classified as stage 0, 43.6% were classified as stage 1, and 18.6% were classified as stage 2 or higher, with 13.6% axillary node positivity. In digital year 1, 29.3% of registered cancers were classified as stage 0, 42.7% were classified as stage 1, and 21.3% were classified as stage 2 or higher, with 13.3% positive axillary nodes. In digital year 2, 30.8% of registered cancers were classified as stage 0, 48.7% were classified as stage 1, and 15.4% were classified as stage 2 or

higher, with 10.3% axillary node positivity. There was a slight increase in stage 0 or stage 1 disease after the digital transition.

The aggregate PPV_1 increased from baseline (5.6%) to digital year 1 (7.5%) and digital year 2 (7.4%) and decreased in digital year 3 (5.3%). The aggregate PPV_1 in digital year 3 was lower than that at baseline. None of these changes was significant (Table 1).

The aggregate PPV_3 value at baseline was 44.5%. This value was lower after digital conversion: It was 31.3% in digital year 1 ($P = .0056$), 38.2% in digital year 2 ($P = .2651$), and 30.3% in digital year 3 ($P = .0021$).

The number of cases recalled for technical reasons decreased in the 1st year after digital conversion. There was a slight increase in the number of technical repeat cases in digital year 3; however, the number of these cases was still much lower than the number of cases at baseline (Table 2).

Lesion Data Results

A total of 3444 patients with 3493 lesions were included in the study. Of the 3493 lesions, 209 were cancers.

Of the 3493 lesions (Table 3), 1859 lesions were recalled at baseline, 959 were recalled in digital year 1, and 675 were recalled in digital year 2.

For the three time periods combined, the majority of lesions were recalled for reasons other than calcifications: A total of 607 (17.4%) were recalled for calcifications, and 2886

(82.6%) were recalled for other abnormalities (Table 4).

The percentage of recalls for calcification at baseline (13.8%) increased to a peak in digital year 1 (23.9%) and did not return to baseline levels in digital year 2 (17.9%). Both PPV_1 and PPV_3 for calcifications decreased after the digital transition (Table 3). There was no significant change in PPV_1 from baseline to digital year 1 ($P = .1378$) or from baseline to digital year 2 ($P = .4277$). However, the decreases in PPV_3 were larger (baseline to digital year 1, $P = .0038$; baseline to digital year 2, $P = .0368$) (Table 3).

Within the larger group of noncalcifications ($n = 2886$), 969 cases were recalled for masses (33.6%); the remainder were recalled for focal asymmetry, asymmetric breast tissue, and architectural distortion (Table 4).

When reviewed by time period, the percentage recall for noncalcifications as a group minimally changed over the three time periods: It was 86.2% at baseline; 76.1% at digital year 1, and 82.1% at digital year 2. There was an association between year and lesion type ($P < .0001$). This was mostly attributable to the relatively high percentage (23.9%) of calcifications in digital year 1. For noncalcifications, there was no significant change in PPV_1 or PPV_3 from baseline to digital year 1 ($P = .3665$ and $P = .1992$, respectively) or from baseline to digital year 2 ($P = .7316$ and $P = .5297$, respectively) (Table 3).

Table 1

Aggregate Numbers for All Radiologists and Periods

Period	No. of Screening Examinations	No. of Recall Examinations	Recall Rate (%)*	No. of Biopsies	No. of Malignancies	PPV_1 (%)[†]	PPV_3 (%)[‡]	Cancer Detection Rate (per 1000 women)[§]
Baseline	32 600	1949	6.0 (5.7, 6.3)	245	109	5.6 (4.6, 6.7)	44.5 (36.5, 53.7)	3.34 (2.75, 4.03)
Digital Year 1	11 358	803	7.1 (6.6, 7.6)	192	60	7.5 (5.7, 9.6)	31.3 (23.9, 40.2)	5.28 (4.03, 6.80)
Digital Year 2	7924	636	8.0 (7.4, 8.7)	123	47	7.4 (5.4, 9.8)	38.2 (28.1, 50.8)	5.93 (4.36, 7.89)
Digital Year 3	14 597	1246	8.5 (8.1, 9.0)	218	66	5.3 (4.1, 6.7)	30.3 (23.4, 38.5)	4.52 (3.50, 5.75)

Note.—Data in parentheses are 95% confidence intervals.

* $P < .0001$ for baseline versus digital year 1, baseline versus digital year 2, baseline versus digital year 3, and digital year 1 versus digital year 3.

[†] $P = .0667$ for baseline versus digital year 1, $P = .1033$ for baseline versus digital year 2, $P = .7503$ for baseline versus digital year 3, and $P = .0482$ for digital year 1 versus digital year 3.

[‡] $P = .0056$ for baseline versus digital year 1, $P = .2651$ for baseline versus digital year 2, $P = .0021$ for baseline versus digital year 3, and $P = .8311$ for digital year 1 versus digital year 3.

[§] $P = .0061$ for baseline versus digital year 1, $P = .0016$ for baseline versus digital year 2, $P = .0592$ for baseline versus digital year 3, and $P = .4180$ for digital year 1 versus digital year 3.

Discussion

In our study, the recall rate increased after the implementation of digital mammography. This result is consistent with the outcome of the majority of prior studies in which researchers compared screen-film mammography with digital mammography (3–5); however, Lewin et al (11) reported a decreased recall rate with digital imaging, and Dittmar et al (12) reported that there was no change in the overall callback rate, biopsy rate, or true-positive rate in the detection of malignancy. Other researchers have reported varying degrees of experience (20–60 months) with different digital mammography manufacturers. Although our center participated in the Digital Mammographic Imaging Screening Trial study, a different digital system was installed when we converted to an entirely digital practice. Because visualization of calcifications and other lesions was improved with the newer digital system, our learning curve was possibly greater than that of the previously mentioned authors. This is one possible explanation for why our recall rate changed after digital conversion.

Digital imaging enables better contrast within breast tissue; therefore, more subtle lesions are depicted. The higher recall rate in the 2nd year of digital screening differed from findings in some prior studies, in which the 1st year of digital screening resulted in the greatest number of recalls. Overall, studies have shown that there is increased cancer detection with digital imaging (1–8,17). However, two studies (11,12) showed no change in cancer detection rates. In addition, the cancer detection rates remained higher than those at baseline for 3 years of digital mammography at our institution, although this difference was significant for only the first 2 years after digital transition. In a prior study (3), the cancer detection rate in the 2nd year of digital mammography was no different from the predigital cancer detection rate. This was attributed to breast cancers that were identified within the 1st year of digital mammography that would not have been seen with screen-film mammography in the previous year. Our

Table 2

Technical Repeat Mammography by Time Period

Period	No. of Technical Repeat Examinations	No. of Screening Examinations	Percentage of Technical Repeat Examinations
Baseline	211	32 600	0.6 (0.6, 0.7)
Digital year 1	39	11 358	0.3 (0.2, 0.5)
Digital year 2	18	7924	0.2 (0.1, 0.3)
Digital year 3	60	14 597	0.4 (0.3, 0.5)

Note.—Data in parentheses are 95% confidence intervals. P values for changes between time periods are as follows: $P = .0001$ for baseline versus digital year 1, $P < .0001$ for baseline versus digital year 2, $P = .0015$ for baseline versus digital year 3, and $P = .4174$ for digital year 1 versus digital year 3.

Table 3

Recall, PPV_1, and PPV_3 for Calcifications and Noncalcifications

Period	No. of Lesions	Calcified Lesions No. of Lesions Recalled	PPV_1 (%)	PPV_3 (%)	Noncalcified Lesions No. of Lesions Recalled	PPV_1 (%)	PPV_3 (%)
Baseline	1859	257 (13.8) [12.2, 15.6]	15.2 [10.8, 20.7]	41.1 [29.2, 56.1]	1602 (86.2) [82.0, 90.5]	4.9 [3.9, 6.1]	52.3 [41.4, 65.2]
Digital year 1	959	229 (23.9) [20.9, 27.2]	10.5 [6.7, 15.6]	21.8 [14.0, 32.5]	730 (76.1) [70.7, 81.9]	5.9 [4.3, 7.9]	43.4 [31.4, 58.5]
Digital year 2	675	121 (17.9) [14.9, 21.4]	11.6 [6.3, 19.4]	24.1 [13.2, 40.5]	554 (82.1) [75.4, 89.2]	4.3 [2.8, 6.4]	44.4 [28.5, 66.1]

Note.—Data in parentheses are recall rates. Data in brackets are 95% confidence intervals.

Table 4

Lesion Types and Percentages

Period	No. of Lesions	No. of Microcalcifications	No. of Noncalcified Lesions	No. of Masses	No. of Distortions	No. of Focal or Global Asymmetries*
Baseline	1859	257 (13.8) [12.2, 15.6]	1602 (86.2) [82.0, 90.5]	622 (33.5) [30.9, 36.2]	178 (9.6) [8.2, 11.1]	802 (43.1) [40.2, 46.2]
Digital year 1	959	229 (23.9) [20.9, 27.2]	730 (76.1) [70.7, 81.9]	203 (21.2) [18.4, 24.3]	204 (21.3) [18.5, 24.4]	323 (33.7) [30.1, 37.6]
Digital year 2	675	121 (17.9) [14.9, 21.4]	554 (82.1) [75.4, 89.2]	145 (21.5) [18.1, 25.3]	126 (18.7) [15.6, 22.2]	283 (41.9) [37.2, 47.1]
Total	3493	607 (17.4) [16.0, 18.8]	2886 (82.6) [79.6, 85.7]	969 (27.7) [26.0, 29.5]	508 (14.5) [13.3, 15.9]	1408 (40.3) [38.2, 42.5]

Note.—Data in parentheses are percentages. Data in brackets are 95% confidence intervals.

* This category includes focal asymmetries, global asymmetries and asymmetric breast tissue.

study shows that there may be a consistent increase in cancer detection rate with digital mammography over at least 2 years.

Given that digital imaging is more sensitive than screen-film mammography in the identification of microcalcifications, it is not surprising that there is a greater number of recalls for microcalcifications (16). The increased recalls with digital mammography in our study were mainly due to microcalcifications. In our study, PPV_3 and PPV for calcifications decreased because more patients with benign calcifications underwent biopsy. A possible explanation would be that we were better able to visualize calcifications with digital mammography; however, it was often difficult to determine when a cluster was new or increasing because we were used to screen-film mammography, with which calcifications were possibly more difficult to see. Many of the clusters may have been present and stable for years, but they were harder to detect prior to the digital conversion.

One potential advantage of digital mammography is a reduction in the number of technical repeat cases. One of the positive aspects of digital images is that the technologist can see the images in real time and repeat them as needed, whereas this is not always the case with screen-film mammograms. There was an 81.5% reduction in the number of technical repeats after digital conversion. Although technical repeats increased slightly in digital year 3, this is still a considerable reduction from baseline (71.6%). This decrease is advantageous to the screening program itself in that it decreases the technologists' time for performing technical repeats, thus reducing costs; it is also advantageous to the screening population, who are spared additional radiation exposure and anxiety and the inconvenience of a return visit for technical reasons.

There were a number of limitations to our study. First, we assumed that the overall screening population remained stable for the years being studied. Without prior data for comparison, the recall rate in a group with a relatively greater number of new screening studies may

be higher. In our study, this could be an additional factor leading to a perceived increased recall rate due to new technology, when in fact the increased number of new screens played a role. We did not specifically look at the percentage of new screening mammograms to confirm this assumption. However, this is a program that has been in place for many years and is well known to the potential screening population. Second, PPVs are highly dependent on the proportion of subjects who have the disease (prior probability of disease) and may be different in different clinical settings. Third, we did not collect breast glandular density data in this study. Fourth, this was a single-institution study rather than a multicenter study, and the findings reflect the experience of only three high-volume radiologists. Conversely, this could also be a strength, in that we analyzed the experience of three radiologists who worked at the institution before, during, and after the transition. This suggests that the differences in recall rate, cancer detection rate, PPV_1, and PPV_3 seen in this study were primarily due to the conversion to digital mammography rather than to other factors.

In conclusion, our experience has been that moving from analog technology to digital screening technology increased recall and cancer detection rates in the first few years after the transition. PPV_1 and PPV_3 were particularly reduced with respect to calcifications, a finding that is supported by the findings of other recent studies (3,5). Further studies and follow-up over longer periods are needed to determine whether this trend will persist or whether recall rates will return to baseline levels.

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