mammograms.

Purpose:

Materials and

Methods:

Results:

Conclusio

Interpretation Time of Computeraided Detection at Screening Mammography¹

To prospectively determine the interpretation time associ-

ated with computer-aided detection (CAD) and to analyze

how CAD affected radiologists' decisions and their level

of confidence in their interpretations of digital screening

An Institutional Review Board exemption was obtained,

and patient consent was waived in this HIPAA compliant study. The participating radiologists gave informed consent. Five radiologists were prospectively studied as they interpreted 267 clinical digital screening mammograms. Interpretation times, recall decisions, and confidence levels were recorded without CAD and then with CAD. Software was used for linear regression fitting of interpretation times. *P* values less than .05 were considered to

Mean interpretation time without CAD was 118 seconds \pm 4.2 (standard error of the mean). Mean time for reviewing CAD images was 23 seconds \pm 1.5. CAD identified additional findings in five cases, increased confidence in 38 cases, and decreased confidence in 21 cases. Interpretation time without CAD increased with the number of mammographic views (P < .0001). Mean times for interpretation without

indicate statistically significant differences.

Radiology

Philip M. Tchou, PhD Tamara Miner Haygood, PhD, MD E. Neely Atkinson, PhD Tanya W. Stephens, MD Paul L. Davis, MD Elsa M. Arribas, MD William R. Geiser, MS Gary J. Whitman, MD

¹ From the Departments of Imaging Physics (P.M.T., W.R.G.), Diagnostic Radiology (T.M.H., T.W.S., P.L.D., E.M.A., G.J.W.), and Biostatistics and Applied Mathematics (E.N.A.), University of Texas M. D. Anderson Cancer Center, 1515 Holcombe Blvd, Houston, TX 77030. From the 2009 RSNA Annual Meeting. Received November 18, 2009; revision requested December 18; revision received March 10, 2010; accepted April 6; final version accepted April 21. Address correspondence to P.M.T. (e-mail: pmtchou@gmail.com).

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| n: | CAD and review of the CAD images both increased with the number of CAD marks ($P < .0001$). The interpreting radiologist was a significant variable for all interpretation times ($P < .0001$). Interpretation time with CAD increased by 3.2 seconds (95% confidence interval: 1.8, 4.6) for each calcification cluster marked and by 7.3 seconds (95% confi- dence interval: 4.7, 9.9) for each mass marked. The additional time required to review CAD images rep- |
|----|--|
| | resented a 19% increase in the mean interpretation time without CAD. CAD requires a considerable time invest- ment for digital screening mammography but may provide less measureable benefits in terms of confidence of the radiologists. |
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Radiology

Creening mammography is the most important and effective tool in the early detection of breast cancer, leading to improved outcomes, which include a reduction in mortality from breast cancer (1,2). However, even with the most recent advancements and the most skilled radiologists, some breast cancers go undetected on screening mammograms. An estimated 16%–31% of detectable cancers are missed when screening mammograms are read by a single radiologist (3). With a second reader, three to 11 additional cancers are found per 10000 women screened (3). To improve breast cancer detection, researchers have focused on methods to make breast cancer more apparent to the radiologist. Computer-aided detection (CAD) is one such method, with computational image analysis to identify patterns that may be associated with masses, microcalcifications, and regions of architectural distortion that, in turn, may indicate cancer.

Advances in Knowledge

- The mean time required to review computer-aided detection (CAD) images in a digital screening mammographic case was 23 seconds, which represents a 19% increase in the mean interpretation time without CAD.
- The use of CAD at digital screening mammography increased the recall rate by 11%.
- The use of CAD at digital screening mammography led to changes in the radiologists' conclusions in 2% of cases.
- The use of CAD at digital screening mammography led to changes in the radiologists' confidence levels in 22% of cases, with increasing confidence in 14% of cases and decreasing confidence in 8% of cases.
- Interpretation times with CAD increased by an estimated 3.2 seconds for each calcification cluster marked and by an estimated 7.3 seconds for each mass marked.

The first CAD system for screening mammography was approved by the United States Food and Drug Administration in 1998 (2). Since then, many studies have examined the use of CAD at screening mammography, measuring its effectiveness in terms of rates of cancer detection, false-negative findings, unnecessary biopsies, and recalls. The results have been mixed, with some studies showing improved performance associated with the use of CAD (4-11), at least one showing decreased performance (12), and several showing no statistically significant effects (3,13–16). The consensus thus far is that CAD provides some improvement in cancer detection, albeit with increased time and cost. How much additional time and cost has not been as well studied.

For our research, we focused on the effect of CAD on the radiologist. The purpose of our study was to prospectively determine the interpretation time associated with CAD and to analyze how CAD affected radiologists' decisions and their level of confidence in their interpretations of digital screening mammograms.

Materials and Methods

Participants

An Institutional Review Board exemption was obtained, and patient consent was waived. The study was Health Insurance Portability and Accountability Act compliant. The participating radiologists gave informed consent. Five radiologists were timed by the primary investigator (P.M.T., an imaging physics resident) while they were interpreting actual clinical digital screening mammograms. All readers were attending diagnostic radiologists, board-certified

Implication for Patient Care

The time added to radiologists' interpretations of screening mammograms by the use of CAD is an important consideration in the assessment of the efficiency of digital mammography interpretation. by the American Board of Radiology, and qualified to practice mammography in accordance with the Mammography Quality Standards Act. For the five readers, the digital screening mammography caseload during the fiscal year 2008-2009 (September 1, 2008 to August 31, 2009) varied from 388 to 1329 digital screening cases (average, 904 digital cases) and 96 to 461 screenfilm cases (average, 298). Experience in mammographic interpretation beyond residency at the beginning of this study ranged from 9 to 33 years (average, 17 years). All of the readers had more than 2 years of experience performing soft-copy review of screening mammograms with CAD systems from multiple vendors.

Equipment

Our study began on February 24, 2009, and the last session was held on June 11, 2009. Screening mammographic examinations were performed with Selenia systems (Hologic, Bedford, Mass). CAD images were generated by using software (R2 ImageChecker, version 8.3.17; Hologic), with the Mass Algorithm Threshold option set to 1 (Algorithm v8-balanced sensitivity) and the Microcalcifications Algorithms Threshold option set to 2 (Algorithm v8-increased sensitivity). These were the manufacturer default settings. The Selenia units and ImageChecker were installed for screening mammography in 2007.

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Abbreviations:

BI-RADS = Breast Imaging Reporting and Data System CAD = computer-aided detection

Author contributions:

Guarantors of integrity of entire study, P.M.T., T.W.S., E.M.A., G.J.W.; study concepts/study design or data acquisition or data analysis/interpretation, all authors; manuscript drafting or manuscript revision for important intellectual content, all authors; manuscript final version approval, all authors; literature research, P.M.T., T.M.H., T.W.S., W.R.G., G.J.W.; clinical studies, P.M.T., T.M.H., T.W.S., P.L.D., E.M.A., W.R.G., G.J.W.; statistical analysis, E.N.A., T.W.S.; and manuscript editing, P.M.T., T.M.H., T.W.S., E.M.A., W.R.G., G.J.W.

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Radiology

Mammograms were viewed on iSite workstations (Philips Healthcare, Andover, Mass) that initially used version 3.3 but were upgraded to version 3.5 on March 30, 2009. After the upgrade, no study readings were performed for 2 weeks so that the radiologists could become familiar with the new system and to allow time for any initial issues to be corrected. Reports were entered by the radiologist on a computer-based mammography information management system (MagView, version 6.0; MagView, Burtonsville, Md). The workstations included two primary gray-scale diagnostic monitors (5MP Dome C5-I and E5-I; NDSsi, San Jose, Calif) for viewing of digital mammograms and secondary color monitors for image navigation, selection of comparison studies, and supporting documentation, including pathology reports, reports of prior imaging studies, and clinic notes (Fig 1). All of the workstations included display calibration software (CXtra; Dome, Waltham, Mass) that conformed to the Digital Imaging and Communications in Medicine part 3.14 standard. Readers adjusted the room lighting to their own preferences.

Case Selection

Screening mammographic cases were selected by the primary investigator in advance of each reading session and were performed for patient care as part of the clinical workload. It was important that the studies be chosen such that the CAD images did not immediately appear on the diagnostic monitors and the readers could easily navigate through the other images without accidentally bringing up the CAD images. Aside from this, the intent was to provide cases that were typical of screening mammography, without implants or substantial postsurgical scars. By selecting these cases in advance, we were able to take timing measurements of acceptable cases sequentially instead of having the primary investigator and the readers spend time on cases that might be excluded.

Several inclusion and exclusion criteria were applied. Only bilateral screening mammographic cases were selected. Each case had to have four, eight, or 12 views and at least one comparison study. For the 4:1 hanging protocols used by the radiologists, these criteria prevented the CAD images from initially appearing and allowed for easy navigation of the images. While the CAD images on the navigation screen could be covered, lack of comparison images or improper navigation could result in the CAD images appearing accidentally on the diagnostic screens (Fig 2).

The first comparison study was required to be a digital mammography study rather than a digitized screen-film



Figure 1: Radiologist's workstation from a mammography reading room shows how both the mammographic views and the CAD images come up automatically on the navigation (color) and diagnostic (gray-scale) monitors.

mammography study. Digitized screenfilm mammography studies are, in our experience, more time-consuming to interpret and to use as a comparison to digital mammograms, and we wished to avoid that confounding variable. For similar reasons, cases with recent ultrasonographic (US) studies, magnetic resonance imaging studies, spot compression views, or magnification views were excluded. This typically meant excluding patients with any such studies or views performed within the preceding 3 years. No cases with implants, surgical clips, or postsurgical changes that produced substantial distortion of the breast tissue were included. Prior to each reading session, one of the five radiologists other than the assigned reader reviewed the selected cases and verified that the cases met these criteria. Each of the readers involved in the study performed this task one or more times.

Early into our study, two changes were made to our selection criteria. On March 12, 2009, we decided to no longer include cases with 12 mammographic views because they were typically for extremely large breasts, and the CAD images often covered only a portion of the breast tissue. One previously read case was excluded from analysis on the basis of this change. On March 18, 2009, we decided to allow six views to increase the pool of available cases for our study. The radiologists were able to read these cases without difficulty and without accidentally bringing the CAD images onto the diagnostic monitors.

Data Collection

Each case was read only once. For each study, the number of mammographic views, the number of CAD marks, and the types of CAD marks were recorded. When opening a case for reading, small versions of both the patient images and CAD images are displayed on the navigation screen (Fig 1). Images selected on the navigation screen show up on the primary displays for review. During the reading sessions, the radiologists were asked to avert their eyes while the primary investigator opened each case and covered the CAD images on the navigation screen with a small piece

Figure 2



Figure 2: Demonstration of a six-view mammographic study without comparison images, which caused CAD images to initially appear on the right-hand diagnostic display.

of paper. The outline of the CAD image was still visible, but the CAD markings were obscured.

A time-stamp macro (Excel; Microsoft, Redmond, Wash) was used by the primary investigator to record the start time of the reading process. The radiologist analyzed the case without using the CAD images, which remained covered, and informed the investigator when a decision was reached as to whether the patient should be called back for further testing. The investigator recorded the current time and the decision. The radiologist was then asked to assign a number from 1 to 10 indicating the level of confidence that the correct callback decision had been made, with 10 being the most confident. The investigator then uncovered the CAD images and recorded the current time. The reader analyzed the case again with the benefit of the CAD markings and made a final decision as to whether to recall the patient. The investigator recorded the current time and final decision and again asked the reader to assign a confidence level. The reader then entered a report for the case into the computerbased mammography information management system. Once the report was completed, the investigator recorded the final time. This process was repeated for each case. For each reader, the first one or two cases were used for training to familiarize the radiologist with the process. These cases were not included in the final analysis. Case readings that deviated from the established process because of interruptions, mistakes in case or patient selection, or technical recalls for suboptimal studies were disqualified and not included in the final analysis. One case was disqualified for each of these reasons, for a total of three cases disqualified.

Further follow-up data were collected for each patient who was called back. Specifically, we determined what steps had been taken in the diagnostic evaluation, whether the results of the diagnostic evaluation were positive for cancer, whether the suspicious lesion or abnormality that was being evaluated had been marked by CAD, and whether scrutiny of the CAD images had changed the callback decision, and we recorded the final Breast Imaging Reporting and Data System (BI-RADS) assessment. In some cases, when the final diagnostic imaging test had been US, no BI-RADS assessment number was assigned by the interpreting radiologist. In these cases, one was assigned by the investigator who performed this evaluation on the basis of applying BI-RADS principles to the recommendations made at the time of original interpretation.

Data and Statistical Analysis

Interpretation times, recall decisions, and confidence levels for each reader were compiled and analyzed. For each case, the recorded time stamps were used to determine the time taken for reading the images without CAD and then reviewing the CAD images. Mean reading times for both were calculated for each reader and for all cases combined. Standard errors of the mean and 95% confidence intervals were calculated. The confidence intervals were verified with bootstrap calculations by using statistical software (R; the R Foundation, Vienna, Austria) with the boot library and basic bootstrap method.

The mean times to review the CAD images were compared with the mean interpretation times without CAD. Changes in recall decisions and confidence levels due to CAD were tallied and compared. Statistical software (JMP 7; SAS Institute, Cary, NC) was used to perform linear regression fitting on the interpretation times without CAD and the review times for CAD images, with the radiologists, the reader experience, the number of mammographic views, the number of CAD marks, and the types of CAD marks used as predictors. The linear regression analysis of types of CAD marks also included estimating the time added per mark to the reading times. The radiologists were treated as fixed effects. A P value less than .05 was considered to indicate a statistically significant difference.

Results

Five radiologists interpreted 267 screening mammographic cases. Interpretation and reporting times are listed in Table 1. Patient recall decisions and confidence levels are listed in Table 2. CAD led to a change in the radiologists' conclusions in five cases but resulted in only four additional recalls. The fifth case would have resulted in a callback with CAD or without CAD, but the radiologist interpreting the case noted additional findings on account of the CAD images.

Thirty-five patients were called back, of whom 33 had been examined at our institution by the time of this writing.

Table 1

Individual and Overall Mean Interpretation Times and Reader Experience

| Parameter | Reader Experience (y)* | Total No. of Cases | Reading Time without CAD (sec) | Time to Review CAD (sec) | Time Increase with CAD (%) † | Report Time (sec) |
|-------------|------------------------|-----------------------|-----------------------------------|-----------------------------|---|-------------------|
| Reader 1 | 33 | 55 | 98 ± 5.2 (88, 109) | 41 ± 4.5 (32, 50) | 42 | 51.4 |
| Reader 2 | 17 | 59 | 82 ± 4.1 (74, 90) | $16 \pm 2.3 (11, 21)$ | 20 | 36.2 |
| Reader 3 | 10 | 50 | 94 ± 7.7 (79, 109) | $13 \pm 1.6 (10, 16)$ | 14 | 53.9 |
| Reader 4 | 18 | 53 | 196 \pm 10.7 (175, 218) | 26 ± 2.5 (21, 31) | 13 | 47.1 |
| Reader 5 | 9 | 50 | 121 ± 9.4 (102, 140) | 17 ± 3.7 (10, 25) | 14 | 32.8 |
| All readers | 17 | 267 | 118 ± 4.2 (109, 126) | $23\pm1.5(20,26)$ | 19 | 44.2 |

Note.—Unless otherwise indicated, data are means \pm standard errors of the mean, with 95% confidence intervals in parentheses.

* Reader experience refers to the number of years of experience in screening mammography, after residency and prior to 2009.

[†] Data are determined by dividing time to review CAD by reading time without CAD.

Table 2

Recall and Confidence Changes Due to CAD

| Parameter | Total No. of Cases | No. of Recalls without CAD | No. of Added Recalls Due to CAD | Increase in Recall Rate (%)* | No. of Confidence Changes Due to CAD | No. of More Confident Changes with CAD | No. of Less Confident Changes with CAD |
|-------------|-----------------------|----------------------------|------------------------------------|---------------------------------|---|---|---|
| Reader 1 | 55 | 5 | 2 | 40 | 4 | 3 | 1 |
| Reader 2 | 59 | 5 | 1 | 20 | 28 | 11 | 17 |
| Reader 3 | 50 | 13 | 0 (1)† | 0 | 0 | 0 | 0 |
| Reader 4 | 53 | 2 | 0 | 0 | 25 | 24 | 1 |
| Reader 5 | 50 | 10 | 1 | 10 | 2 | 0 | 2 |
| All readers | 267 | 35 | 4 (5)† | 11 | 59 | 38 | 21 |

* Data are determined by dividing the number of added recalls due to CAD by the number of recalls without CAD.

[†] One patient was recalled without CAD, but the case had additional findings due to CAD.

These diagnostic evaluations led to biopsy in 11 patients. In nine cases of biopsy, the lesion was the one for which the diagnostic evaluation had been initiated. In two cases of biopsy, the lesion was a separate lesion that came to attention during the course of the diagnostic evaluation. Four patients were found to have cancer. In each of these cases, the cancers were the lesion for which diagnostic evaluation had been ordered and had been marked on the CAD images. Three of these patients would have been called back even without the CAD images. All of these had a final BI-RADS score of 4. The remaining case would not initially have been called back, but it was called back after review of the CAD images. The final BI-RADS score for this case was 0. The other three cases that were recalled because of CAD were found to have negative findings, with BI-RADS scores of 2, 2, and 4. Biopsy was performed for the case with the BI-RADS score of 4, and radial scar tissue was found.

The reading time without CAD increased with the number of mammographic views (P < .0001) and with the number of CAD marks (P < .0001), while reader experience was not significant (P = .63). The time to review the CAD images increased with the number of CAD marks (P < .0001) and with the experience of the radiologist (P < .0001). The identity of the interpreting radiologist was a significant variable for both reading time and time to review CAD marks (P < .0001).

Both reading time and time to review CAD marks increased with the number of calcification cluster marks (P < .001) and the number of mass marks (P = .007 without CAD, P < .001 with CAD). The number of marks for masses with calcifications did not significantly affect reading times (P = .31 without CAD, P = .26 with CAD).

On the basis of the linear regression analysis, each calcification cluster added an estimated 3.2 seconds (95% confidence interval: 1.8, 4.6) to the time to review the CAD images. Each mass added an estimated 7.3 seconds (95% confidence interval: 4.7, 9.9) to the time to review the CAD images. Because the confidence intervals did not overlap, the times added by calcification clusters and masses were considered significantly different.

Discussion

The time added to radiologists' interpretations of screening mammograms by the use of CAD is an important consideration in the assessment of the efficiency of digital mammography interpretation. For the five readers in this study, the use of CAD represented a 19% increase in the mean interpretation time compared with reading without CAD. **Radiology**

As expected, the interpretation time without CAD increased with the number of mammographic views, and the time to review the CAD images increased with the number of CAD marks. The interpretation time without CAD also increased with the number of CAD marks. This may simply indicate that more complex images attract more CAD marks but also require more time to analyze.

The time to review the CAD images increased with the experience of the reader. This may suggest that more experienced radiologists are more cautious when reviewing CAD images or radiologists who began practicing more recently are more comfortable with CAD.

Masses marked on the CAD images were found to increase the review time for the CAD images significantly more than calcification clusters. This suggests that radiologists are able to review calcifications more expeditiously than masses, likely because of the greater conspicuity of calcifications.

The use of CAD also increased the number of recalls by 11%. Other studies (3,5,7,9–11,13–16) have shown increases in the recall rate with CAD of up to 32%. The benefits of these added recalls relative to any increase in the number of cancers detected are still being studied. In this group of readings, four (12%) of 33 callbacks resulted in a diagnosis of cancer, and one of these four would not have been found without CAD.

The perceptions of the radiologists should also be taken into account. Reader confidence associated with the use of CAD mostly stayed the same, although confidence increased more often than decreased. The preferences of the patients should also be considered. A study by Ganott et al (17) suggested that women prefer higher recall rates, given the possibility of increased early detection of breast cancer.

There were several limitations to this study. First, the study length and the number of cases were small compared with other CAD studies (12–14,18). As a result, our study had greater statistical error. In addition, although each radiologist in our study read a similar number of cases, the number of patients called back by the readers was unevenly distributed. This weighted our recall analysis more heavily toward those readers with more findings. While differences in sensitivity among radiologists are expected, the low number of cases makes it difficult to determine with confidence if these variations are because of the readers or random chance.

Second, the evaluation of CAD is complicated by the variety of mammographic and CAD technologies available; differences in experience, typical caseloads, and interpretation techniques between individual radiologists; and differences in patient populations-all of which may influence the effectiveness of CAD (2). However, a similar study by Khoo et al (7) using film reading with digitization for CAD (ImageChecker, version 5.0; R2 Technology, Los Altos, Calif) showed that CAD increased the average reading time by 20 seconds. Although their study used a screen-film mammography system rather than a digital system, used a different CAD system, was performed in the United Kingdom rather than in the United States, and took place several years prior to our study, the resulting additional time associated with CAD usage was similar.

Finally, the reading process put in place for this study is artificial in that radiologists would not normally pause to make a conscious and publicly announced decision after reviewing the images and before moving on to check the CAD images. This segmented structure may have affected the radiologists' normal reading methods and pacing. For example, the knowledge that the initial assessment without CAD would not be final may have led some radiologists to spend less time making an initial decision. However, this method allowed us to make prospective timing measurements by using actual clinical reading sessions, both with CAD and without CAD, and for the exact same cases with the same readers. We believe that this is as close to actual practice conditions as was practical for our study. Had we instead asked the radiologists to reread cases without CAD, we believe this would have had an even greater effect on the timing because none of the decisions would have affected patient care and the readings would not have been part of their clinical workload. Thus, we were willing to accept the potential errors associated with the segmented reading sessions. Similar reading structures were used in studies by Freer and Ulissey (9), Khoo et al (7), and Ko et al (5).

Despite its limitations, we believe our study offers some insights that may aid in the evaluation of the effects of CAD. Further studies are needed to draw more widely applicable conclusions. Our future aims include determining the reasons behind changes in reader confidence associated with CAD and how to reduce the time needed to analyze CAD images while maintaining the effectiveness of CAD. Future studies may involve additional radiologists, a larger pool of cases, and more detailed tracking of patient outcomes. There is also the possibility of examining the effects of CAD at other practices with different digital screening mammography systems and different CAD software.

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