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Dose reduction and its influence on diagnostic accuracy and radiation risk in digital mammography: an observer performance study using an anthropomorphic breast phantom

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Abstract

This study aimed to investigate the effect of dose reduction on diagnostic accuracy and radiation risk in digital mammography. Simulated masses and microcalcifications were positioned in an anthropomorphic breast phantom. Thirty digital images, 14 with lesions, 16 without, were acquired of the phantom using a Mammomat Novation (Siemens, Erlangen, Germany) at each of three dose levels. These corresponded to 100%, 50% and 30% of the normally used average glandular dose (AGD; 1.3 mGy for a standard breast). Eight observers interpreted the 90 unprocessed images in a free-response study and the data was analyzed with the jackknife free-response receiver operating characteristic (JAFROC) method. Observer performance was assessed using the JAFROC figure of merit (FOM). The benefit of radiation risk reduction was estimated based on several risk models. There was no statistically significant difference in performance, as described by the FOM, between the 100% and the 50% dose levels. However, the FOMs for both the 100% and the 50% dose were significantly different from the corresponding quantity for the 30% dose level (F-statistic = 4.95, p-value = 0.01).

A dose reduction of 50% would result in 3-9 fewer breast cancer fatalities per 100,000 women undergoing annual screening from the age of 40 to 49 years. The results of the study indicate a possibility of reducing the dose to the breast to half of the dose level currently used. This has to be confirmed in clinical studies and possible differences depending on lesion type should be further examined.

Keywords

Digital mammography; Average glandular dose; Dose reduction; Diagnostic accuracy; Anthropomorphic phantom; JAFROC

INTRODUCTION

In Sweden, breast cancer accounts for 29% of all female cancers [1]. Each year, approximately 6,500 women are diagnosed with breast cancer and about 1,500 die from this disease [1,2]. Screening mammography has been shown to reduce the mortality through earlier detection [3,4]. Each year, approximately 750,000 mammographic examinations are performed in Sweden, of which 75% are screening examinations and 25% are clinical investigations [5]. As the female breast is one of the most radiosensitive organs [6,7], it is important to evaluate the

risk/benefit ratio for mammography, especially if it is to be used for screening purposes. Furthermore, optimisation is required [8], and with regard to patient exposure this refers to the determination of the lowest average glandular dose (AGD) that yields a sufficient level of clinical image quality.

The term Diagnostic Reference levels (DRLs) was introduced by the International Commission on Radiological Protection [7] and recommended for use [9] as a practical guide in the management of patient doses in radiology. There are currently DRLs under consideration in Great Britain [10]. Sweden has established comparatively low DRLs required by legislation since 2002 [11]. This legislation prevents the use of a higher AGD than 1.5 mGy for a standard breast [12] without specific motivation. For some full-field digital mammography (FFDM) units this reference level has been exceeded [13,14]. Earlier studies using contrast-detail phantom images [15] and clinical images from a screening program [16] with a Senographe 2000D (GE Healthcare, Milwaukee, WI) have indicated that doses down to 50% of the Swedish reference AGD level are adequate in maintaining clinically acceptable image quality.

The aim of the current study was to (1) investigate how the diagnostic accuracy in digital mammography may be affected by the AGD at levels below the Swedish reference dose levels by studying the detection of simulated lesions in an anthropomorphic breast phantom and (2) estimate the reduction of radiation induced lethal breast cancers resulting from the possible dose reduction.

MATERIALS AND METHODS

The anthropomorphic breast phantom

The breast phantom used in this study was a commercially available anthropomorphic breast phantom (RMI 165, Radiation Measurement Inc, Middleton, WI). As shown in Figure 1, an X-ray image of the phantom appears similar to that of a human breast, and it consists of material that makes it comparable to a standard breast regarding exposures [17]. The phantom has a 1 mm thick transverse slot at the midplane, into which a film containing structures resembling masses and microcalcifications can be inserted. These structures can be placed at arbitrary locations on the film.

Simulation of masses

In order to simulate the radiographic appearance of tumour masses, discs made of polytetrafluoroethylene (PTFE, Teflon®) were placed on the film. In total, eight such discs, with diameters 11.0 ± 0.5 mm were used. The centre thickness (0.75 ± 0.04) mm decreased gradually towards the edges, where the thickness was approximately 0.12 mm. The edges of the discs were irregular shaped in order to appear like realistic malignant masses (Figure 1).

Simulation of microcalcifications

The microcalcifications were simulated using deposits of aluminum oxide (AlO_2), each with an approximate diameter of 200 μm and produced by the manufacturer of the phantom. As shown in Figure 2, 10-12 non-overlapping microcalcifications were distributed on an area of up to 25 mm^2 to produce clinically realistic clusters [18]. The individual microcalcifications making up the clusters were distributed randomly, so each cluster had a unique appearance.

Image acquisition

Ninety images of the phantom were acquired - 30 at each of the three dose levels. The 100% dose level was determined through automatic exposure of the phantom, and images were subsequently acquired at 50% and 30% of that dose level. The settings of the mammography unit (Mammomat Novation; Siemens, Erlangen, Germany) were 126, 63 and 36 mAs,

corresponding to the three dose levels, in each case using the W/Rh anode/filter combination and tube potential of 28 kVp. The beam qualities follow the recommendations of Siemens, which are based on a Monte Carlo study [19]. Each of the 30 images contained zero to three lesions. The distributions of masses and microcalcifications in the images are shown in Table 1. When producing the 14 images containing lesions, the masses and microcalcifications were placed at different positions in the phantom to have the various background regions represented and to minimize observer memory effects. The same spatial distribution of the lesions was used for all three dose levels. This was done to minimize loss of statistical power due to variability in detection difficulty at different locations for the three dose levels. The study was performed with unprocessed digital images.

Observer study

Eight observers (three radiologists experienced in mammography and five medical physicists) participated in a free response study [20,21], i.e. they viewed the images one at a time and searched them for lesions (masses and microcalcifications). The free response paradigm requires regions that are sufficiently suspicious for the presence of lesions to be marked and rated by the observers. Each observer interpreted the images on a DICOM calibrated 5 mega-pixel monitor (Siemens model number SMM 21190 P, Erlangen, Germany). Although optimal window/level settings were pre-selected for each dose level by an experienced radiologist, the observers were allowed to alter these settings. A graphical user interface [22] was used to display the images in random order and to record the observers' responses. No limit was imposed on the number of possible marks placed by an observer on any image. Each mark was accompanied by a rating according to a four-point rating scale (Table 2).

The observers were told that there were between zero and three lesions per image, but were blinded to the exact number, type, or positions of the lesions. To minimize any learning curve effects, the observers had a training session where they evaluated 20 images to become familiar with the appearance of the normal structures in the phantom as well as the inserted lesions. These training results were not used in the following evaluation.

Statistical analysis of observer performance data

Prior to analysis, the observer-chosen marks were compared to the known positions of the lesions in the phantom. Each mark was classified as a true positive if it fell within the boundary of the lesion. Otherwise, it was classified as a false positive. The ability of the observer to localize the lesion is explicitly accommodated in the FROC scoring step. The scored FROC data was analyzed by the jackknife free-response receiver operating characteristic (JAFROC) method [20,23,24]. The analysis yields an F-statistic and a p-value for rejection of the null hypothesis that the modalities (the three dose levels) have identical performance, and 95% confidence intervals for differences in performance.

Assessment of benefit and reduced radiation risk of late effects

An estimate was made of the expected number of deaths prevented as a result of mammography screening (benefit) in relation to what a dose reduction by half would mean in reduced risk of late effects (additional benefit), i.e. the number of reduced deaths due to dose reduction by 50%, assuming that such a dose reduction would not affect the diagnostic accuracy. The number of deaths prevented as a result of mammography screening has earlier been assessed from the Malmö Mammographic Screening Trial (MMST) [25]. For the calculations of risk reduction of late effects, the following assumptions were made: two views are acquired per breast with an AGD of 1.3 mGy per view; screening involves an 80% participation rate; the loss of life expectancy occurs in the latter half of the remaining life; and there is a linear dose-response relationship and an age-related risk [6-7,26-30]. The risk reduction of late effects was calculated for 100 000 women undergoing annual screening from 40 to 49 years of age, i.e. on

10 occasions. Four different risk models were used: the Gilbert (NUREG/CR-4214) [23,24, Pawel D. Radiation Protection Division, US Environmental Protection Agency, Washington DC 20460-0001, Personal communications, 2006], the National Radiological Protection Board (NRPB) [National Health Service Breast Screening Programme (NHSBSP)] [28,29], and the Holmberg [31] models were used to calculate the number of fewer breast cancer fatalities; and the Iinuma (ICRP) model [7, 30, 32, Iinuma T. Department of Medical Physics, the National Institute of Radiological Sciences, Chiba-city, Japan. Personal communications, 2005] was used to calculate the number of fewer years lost in life expectancy. The risk values obtained using the Holmberg model [31] were calculated using a non age-specific excess relative risk (ERR) value that was applied to data of expected breast cancer deaths [2] within intervals, consisting of a minimum and a maximum latency time in which all cases of expected breast cancer deaths resulting from the radiation exposure at mammography were assumed to be distributed. Four such intervals were assumed – from age at 10 years after the screening examination until: (A) age 74 years, (B) age 79 years, (C) age 89 years; and (D) rest of the women's lives. The Swedish National Board of Health and Welfare [2] and Statistics Sweden [32] provided the statistical data used to estimate the risk to die of breast cancer.

Results

Observer performance

Table 3 illustrates the individual observer JAFROC figure of merit (FOM) for the respective dose levels. As can be seen, the radiologists generally had higher FOM values than the medical physicists.

JAFROC analysis yielded $F = 4.95$ and $p\text{-value} = 0.01$, showing that at least one of the differences in FOMs between the three possible modality pairings was statistically significant. Table 4 shows the 95% confidence intervals (CIs) for the difference in FOM values between all pairs of dose levels. A range that includes zero indicates that the difference in FOM values is not statistically significant. The JAFROC method indicated no statistically significant difference in FOM values between the 100% and the 50% levels, but the other two pairings (100% – 30% and 50% – 30%) were different.

Benefit and risk reduction of late effects

The results of the benefit and risk assessment are shown in Table 5. As shown in the last column in the first row, the number of prevented deaths among the group of women undergoing mammography screening was 200 per 100 000 compared to the group not undergoing screening, according to the MMST. As shown in the remaining rows, the additional number of fewer breast cancer fatalities associated with a dose reduction of 50% depended on the risk model used. According to the Gilbert model, three fewer breast cancer fatalities would occur per 100 000 women, according to the NRPB model five fewer breast cancer fatalities per 100 000 women, whereas four, five, eight or nine fewer breast cancer fatalities per 100 000 women were calculated using the Holmberg model and alternatives A, B, C and D respectively (each representing increasing intervals of latency times for induced cancer). Based on the Iinuma model, a dose reduction of 50% resulted in an estimated 32 fewer years lost in life expectancy per 100 000 women.

Discussion

The primary purpose of this study was to determine if further dose reduction is possible for a direct digital mammography system already operating below the Swedish reference AGD level (1.5 mGy). The issue of dose cannot be regarded as separate from image quality, and any dose optimization strategy must take into account the image quality. The JAFROC method has

recently been introduced in clinical situations [20,23,33] and was chosen to measure image quality objectively. There was no statistically significant difference between the 100% and the 50% dose level, and the results therefore indicate a possibility to reduce the AGD to half of the dose level currently used.

The estimates of reduced risk were dependent on the risk model used. For example, the numbers of fewer breast cancer fatalities calculated with the Holmberg model [31] increased when one considered a longer follow up time. This interval depended on the latency time, and the intention was to include only the cases of expected breast cancer deaths for which the mammography radiation could be an initiator for the cancer. The risk models used were relative risk models, which depend on the baseline rates from the population where the risk values were derived. It has been shown that the transferring of absolute risk values for breast cancer between populations is more stable than of relative risk values [31]. These estimates, however, were considered appropriate for a Swedish population, since similar [26-29] or identical [2,31] baseline rates have been used.

Using the Biological Effects of Ionizing Radiation (BEIR) V model [6] for breast cancer, with the same assumptions, yielded a value of 2.4 fewer breast cancer fatalities per 100 000 women (i.e. the added benefit of dose reduction). However, the BEIR V model incorporated incorrect breast cancer incidence data from the Japanese atomic bomb survivor study [28,29], and may therefore have resulted in an underestimate. The number of fewer deaths due solely to a reduction in induced cancers calculated with the risk models ranged from three to nine. A dose reduction per projection may alternatively lead to benefit in the form of increased diagnostic information from additional projections for the same total dose as is currently used.

The radiologists were asked to comment on the realism of the phantom images and the simulated lesions and to give their impressions on whether they felt dose reduction was possible based on these images. Their general opinion was that differences between the images acquired at 100% and 50% of the AGD were minimal. However, for the images acquired at the 30% level, the radiologists noticed a significant degradation in image quality, with fewer details clearly visualized among the background structures and the lesions. Regarding the radiological appearance of the phantom, the radiologists agreed that the background structures in the phantom were not as detailed as in clinical images, but that otherwise the phantom was a reasonable representation.

Prior to presentation, digital mammography images are usually processed for grey level equalization as well as edge and contrast enhancement [34]. Although the anthropomorphic phantom used in this study produces similar density patterns to actual mammograms, these algorithms have generally not been optimised for such phantoms. Therefore, in order not to introduce any disturbing effect on the study by the processing algorithm, optimally windowed unprocessed images were used in the study.

Bernhardt et al [19] studied signal difference to noise ratios normalized to AGD and showed that, for this digital system, the W/Rh anode/filter combination is superior to other available combinations (Mo/Mo or Mo/Rh). Accordingly, it is unlikely that the lesion detectability in the current study would improve with the use of Mo/Mo or Mo/Rh anode/filter combinations. However, the impact of these combinations was not investigated.

While the number of cases was too small to further subdivide the data according to lesion type, certain qualitative statements can be made. For each dose level, relatively more clusters of microcalcifications were detected than masses. Although the number of true positives (i.e. lesions rated 1 and above) for both lesion types decreased with decreasing dose, the detection of clusters microcalcifications was more dose dependent. The effect on the detection of clusters of microcalcifications became evident at the 50% level, while the effect of dose reduction on

masses became evident only at the 30% level. However, differences depending on lesion type remains to be further examined and each lesion type also needs to be related to their typical clinical occurrence and significance.

One of the limitations of the study is the relatively small number of cases (33) that were used. This may have undersampled the case-dependent variability of the microcalcifications, which made up about one third of the lesions used in the study. This is because microcalcification detection is expected to be more dependent on quantum and system noise, which changes between different image acquisitions. On the other hand, as mass detection mainly is determined by the anatomy-like background, which is unchanging, a few images are expected to suffice as far as averaging over case sampling variability is concerned. In either case, using more cases would have reduced the variability resulting from the case-reader variance component [35] interaction term. The use of multiple lesions per image is another limitation. This was done for the convenience of the readers, but it may have resulted in an overestimate of the significance of observed differences in performance, i.e. the true p-value may be larger than the quoted. In addition, multiple lesions are clinically less common. Therefore, using more cases with fewer lesions per case would have improved the statistical accuracy of the study, at the expense of increased reading time. The use of only one phantom sacrifices the realism of the study since one phantom image cannot represent the clinical situation where the observers view images from different patients. Observer variability is generally the largest source of variability, so the use of 8 observers may have worked in our favour. For all of these reasons a clinical study involving adequate numbers of patient images should be performed to further investigate the preliminary conclusions of this study.

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Figure 1.
The image on the left shows a radiograph of the breast phantom with structures added to simulate lesions. The arrows indicate added masses. The corresponding image to the right has no added pathological structures.

Figure 2.
A close-up of an X-ray image illustrates one of the simulated clusters of microcalcifications in the phantom.

Table 1

The distribution of the number of lesions for the 30 images at each of the three dose levels.

# Images	# Tumour masses	# Clusters of microcalcifications
16	0	0
4	3	0
3	2	0
3	0	2
3	1	1
1	2	1

Table 2

The four-level confidence scale used in the JAFROC study.

Confidence level	Significance
1	Probably not a lesion
2	Possibly a lesion
3	Likely to be a lesion
4	Very likely to be a lesion

Table 3

The individual and mean JAFROC figures of merit (FOM), respectively. Observers 1-3 were radiologists experienced in mammography.

Observer	The JAFROC FOM's for each relative dose level		
	100%	50%	30%
1	0.710	0.727	0.662
2	0.742	0.690	0.637
3	0.758	0.742	0.706
4	0.639	0.626	0.585
5	0.660	0.640	0.564
6	0.726	0.727	0.658
7	0.630	0.646	0.584
8	0.658	0.633	0.625
Mean	0.690	0.679	0.628

Table 4

The 95% confidence intervals for the difference in figure of merit (FOM) values between pairs of dose-levels for the JAFROC. A range that includes 0 means that the difference was non-significant (ns), otherwise significant (sig).

Method	FOM-comparison for the relative dose levels		
	100%-50%	100%-30%	50%-30%
JAFROC	[-0.031, 0.054] - ns	[0.020, 0.105] - sig	[0.009, 0.094] - sig

Table 5

The number of death prevented as a result of screening mammography, according to the Malmö Mammographic Screening Trial (25) and the number of fewer breast cancer fatalities or fewer years lost in life expectancy because of an AGD reduction by 50%, according to different relative risk assessment models described in the text. All figures refer to annual screening involving 100,000 women of age 40-49 (80% participation rate).

Benefit/Risk reduction of late effects, women of age 40-49	Model (source)	n
Number of prevented deaths	MMST [25]	200
Number of fewer breast cancer fatalities due to a dose reduction by 50%	Gilbert (NUREG/CR-4214) [26,27]	3.3
	NRPB (NHSBSP) [28,29]	5.2
	Holmberg [2,31]	
	From the age at screening plus 10 years until:	
	age 74, A	4.1
	age 79, B	5.4
	age 89, C	8.0
	the rest of the women's lives, D	9.1
Fewer years lost in life expectancy due to a dose reduction by 50%	Iinuma (ICRP) [7,30,32]	32