Mammography Audit of Screening and Diagnostic Examinations

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ABSTRACT

Objective: Mammography has been recognized as the gold standard for screening breast cancer. To achieve the effectiveness of mammography performance, mammography audit is recommended as a method for evaluating the accuracy of mammography interpretation. This study aimed to evaluate the key parameters of screening and diagnostic mammography audit in our dedicated breast imaging center.

Methods: Retrospective analyses of 54,204 out of 64,049 mammography with or without breast ultrasound at Thanyarak Breast Center, Siriraj Hospital, Mahidol University during 1 Jan 2001 to 31 Dec 2005 were performed. These comprised of 26,735 screening (SCR) and 27,469 diagnosis (DX). Demographic data, image assessment category, biopsy results and mammography audit were analyzed base on BI-RADS (4th edition) recommendation.

Results: The mean age of SCR group was 50.1 years compared to 46.2 years for DX. Family history of breast cancer found in SCR and DX were 9.9 and 10.9%. The positive predictive value (PPV2 or biopsy recommended) were 19.5% and 33.7% in SCR and DX respectively. The cancer detection rate (CDR) in SCR and DX were 3.8 per 1,000 and 40.0 per 1,000. The sensitivity/ specificity in SCR and DX were 73.6%/98.4% and 96.3%/ 75.1 % respectively.

Conclusion: Significant difference key parameters among SCR and DX mammography were well established. Our study represents key parameters of mammography audit of SCR and DX of Thai women comparing to other reports. However, variation in these key parameters of mammography audit depends on definition when comparing to other institute outcomes.

Keywords: Screening mammography, diagnostic mammography, mammography audit, cancer detection rate (CDR), key parameters

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INTRODUCTION

Breast cancer has become the most common female cancers, account for 37.5% of all Thai female cancer.[1] Mammography has been recognized as the gold standard for early detection of breast cancer.[2,3] The effectiveness of mammographic screening in reducing breast cancer mortalities in women is well documented.[4-12] The goal of SCR mammography is to detect earlier or small breast cancer rather than just more cancer. The purpose of DX mammography intends to provide specific analytic evaluation of patients with breast symptoms and differentiate breast cancer from benign breast diseases.[8,5]

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To achieve the effectiveness of mammography performance, medical audit of mammography is a recognized method for evaluating the accuracy of mammography interpretation. In the USA, federal regulation on the Mammography Quality Standards Act (MQSA) requires all mammography facilities to perform medical audit.[6,7,8]

The comprehensive audits were described by the American College of Radiology in Breast Imaging Reporting and Data System (ACR BI-RADS).[9] Successful medical audits for mammography practices depends on well design database system, comprehensive and accurate data input, tailor made software for audit and capacity to analyze and produce routine report. It is time and efforts consume, and also need team supports. By using statistic key parameters i.e., cancer detection rate (CDR) per 1,000 exams, positive predictive value (PPV), sensitivity and specificity, the audits are valuable tools to measure the success of a mammography practice in detecting clinically occult, early stage breast cancer, as well as the suggestion of the presence of any deficiencies in technical performance and image interpretation.[10,11,12]

In mammography practice, there are combine service of screening (SCR-those asymptomatic or no breast symptom) and diagnosis (DX-those with breast symptom). Nowadays, there are abundant of breast cancer survivors who come for mammogram for breast cancer follow-up every day in addition to SCR and diagnosis cases. Many studies grouped those with previous history of breast cancer whose underwent breast conservative treatment were grouped in diagnosis group[13] and breast cancer underwent mastectomy were grouped in SCR group.[14,15] However, this study had excluded those with previous known breast cancer cases for other special research.

There were few reports of key parameters or indicators of mammography performance among Asian countries,[16-19] mostly were SCR mammography outcomes. In general, the audit is designed for SCR though some practices audit their overall practice, including DX examinations. The ACR strongly recommends that SCR and DX examinations be audited separately.[16] This study presents the key parameters of the medical audit of mammography (MG) practice with or without breast ultrasound (US) in SCR and DX group separately of Thai women which has never been reported before.

MATERIALS AND METHODS

Institutional review board approval of this retrospective study was obtained. The data collection and medical audit method used for analysis key parameters of mammography performance were based on the 4th edition of the American College of Radiology BI-RADS manual.

Patients

A total of 64,049 mammography examinations with or without breast US during 1 January 2001 to 31 December 2005 were retrieved from database of Thanyarak breast information at Thanyarak Breast Centre, Siriraj Hospital Mahidol University. Only 54,204 mammography with or without US examinations were included in this study.

The SCR group means those with asymptomatic or no breast symptom, including those with previous breast imaging assessment proved of benign. The DX group means problem-solving cases with symptoms of palpable mass, nipple discharge, pain, follow-up previous study of probably benign lesion including those with breast implant.

There were 26,735 SCR and 27,469 DX examinations included in this study. We excluded (1) cases with undetermined cancer status or no follow up history at least 12 months after the examination date (2) for screening, cases with US only.

Breast cancer status was verified by either positive histopathology from pathology department, confirmation breast cancer in Siriraj Cancer Registry, or follow-up with information for our breast information system (BIS). Their demographic data, date of previous

examination, breast cancer among family members and their previous history of breast cancer were collected.

Mammography, interpretation and biopsy

Mammography was performed with conventional mammography machine (GE mammography T800 and Lorad M-IV mammography machine) and GE Full Field Digital Mammography Senographe in standard craniocaudal (CC), mediolateral oblique (MLO) technique. A majority of mammography of Asian women had heterogeneous to extremely dense breast composition (ACR BI-RADS lexicon).[17] Therefore it is a common practice to have breast US in addition to mammography examinations. Therefore, our medical audit included breast US where appropriated. Additional special mammography views and breast ultrasonography were provided where necessary in the same visit. In our study the mammography examinations in SCR referred to mammography alone and/or mammography with US, while in DX group referred to mammogram alone, mammogram with US or US alone.

All examinations were assessed by 26 radiologists with one to ten years of breast imager experiences, based on the BI-RADS 2003 (4th edition).[17] The category assessment were combined study in case of mammography plus breast US study. BI-RADS assessment category is as follow, BI-RADS 1=Negative, BI-RADS 2= Benign Finding, BI-RADS 3 = probably benign findings and short interval follow up suggested, BI-RADS 4 = suspicious abnormality and biopsy should be considered, BI-RADS 5 =highly suggestive of malignancy and appropriate action should be taken.

Positive interpretation in our study refers to BI-RADS category 4 and 5 while negative interpretations are BI-RADS category 1, 2, or 3 in both SCR and DX, to make both the same understanding. This is different from ACR BI-RADS recommendation for screening mammography audit which do not including BI-RADS 3 in both positive and negative interpretation and including BI-RADS 0 as positive interpretation. However, ACR BI-RADS allow facilities and institute to adjust the definition. BI-RADS category 0 (incomplete study) in our institute is zero, as additional imaging are done to complete data in same day visit. BI-RADS 6 was excluded as recommended by BI-RADS.

Data of all breast imaging and reports including histopathology of breast intervention were stored in Thanyarak BIS.

Breast cancer status was verified by either positive histopathology from breast surgery or at least core needle biopsy, or confirmed breast cancer with Siriraj Cancer Registry, or follow-up with record in our Breast Information System or Medical Record of Siriraj Hospital within 12 months after the date that mammography was performed. Non breast cancer status means no breast cancer after at least 12 months follow up.

Statistical Analysis

Data cleaning, tabulations and statistical computations were accomplished using the SPSS version 11.5. The student's *t* test was performed on normal distribution and the Chi-square test was performed for comparison of the proportional data.

- True positive (TP) cases are defined as those with positive interpretations and subsequent diagnoses of malignancy within 12 months.
- False positive (FP) cases are those with positive interpretations but no accompanying diagnoses of cancer within 12 months.
- False negative (FN) cases are those read as normal but subsequently found to be malignant within 12 months.
- True negative (TN) cases are those read as normal that remain no evidence of subsequent cancer in follow up mammogram 12 months.
- Non-cancer status was considered when examination had no a histological diagnosis of cancer within one year or before the next SCR examination.

Key parameters of mammography performance in this study included:

Sensitivity is the percentage of cancers that had a positive interpretation or TP/ (TP + FN). *Specificity* is the percentage of non-cancers that had a negative interpretation or TN/(TN + FP). *Positive predictive value (PPV)* is the percentage of examinations with a positive interpretation that result in a tissue diagnosis of cancer. Three sets of PPV estimate with the application of ACR BI-RADS[7] methods are:

- PPV_1 is the percentage of all positive examinations (BI-RADS 0, 4 and 5) that result in a tissue diagnosis of cancer within one year.
- PPV_2 (biopsy recommended) is the percentage of all examinations recommended for biopsy or surgical consultation (BI-RADS 4 and 5) that result in a tissue diagnosis of cancer within one year.
- PPV_3 (biopsy performed) is the percentage of all known biopsies done as a result of a positive examinations that result in a tissue diagnosis of cancer within one year.

In this study we calculated only PPV2 which is true reflection of image interpretation.

Cancer detection rate (CDR) refers to the number of cases of breast cancer correctly detected by mammogram per 1,000 examinations.

RESULTS

Among included 26,735 SCR and 27,469 DX mammography examinations in year 2006-2007, the mean age of SCR group was 50.1 years compared to 46.2 years for DX group. The mean age of breast cancer detected by SCR and DX were 53.8 and 52.8 years. The abnormal interpretation rate in SCR and DX were 1.9% and 11.4% while biopsy rate performed were 1.8%, and 11.7% in SCR and DX. The number of patients performed biopsy is slightly higher than the abnormal interpretation rate, due to cases referred for biopsy from outside the centre.

The overall CDR of SCR was 3.8 per 1,000 while CDR of DX was 40.0 per 1,000. The CDR of both SCR and DX are increase with older age group (Table 1). Twenty seven

TABLE 1. Demography data of Mammography performance 2001-2005.

	Screening		Diagnosis	
	n	Cancer detected (CDR per 1,000)	n	Cancer diagnosed (CDR per 1,000)
All examinations	36,190		27,859	
No. of included examinations	26,735		27,469	
% of excluded examination	26.1		1.4	
Age				
<40	2,377	5 (2.1)	6,602	133 (20.1)
40-49	11,688	29 (2.5)	12,375	338 (27.3)
50-59	9,649	48 (5.0)	6,501	364 (56.0)
60-69	2,551	12 (4.7)	1,567	161 (102.7)
>70	470	8 (17.0)	424	104 (245.3)
Mean age	50.1	53.8	46.2	52.8
Min age	26.4	35.3	15.0	21.0
Max age	88.5	79.0	94.0	92.0
Family history of breast cancer (%)				
No	90.1	84.3	89.1	91.8
Yes, 1st degree FH	9.9	15.7	10.9	8.2
Previous mammography (%)				
No	31.6	51.0	62.4	90.8
Yes	68.4	49.0	37.6	9.2

TABLE 2. Key parameters of screening and diagnostic mammography audit year 2001-2005.

	Screening Standard[17]	This Study	Diagnosis Recommend[32]	This Study
N		36,190		27,859
% of exclusion uncertain breast cancer status		26.1		1.4
No. of included mammographic examinations		26,735		27,469
Abnormal interpretative rate (%)		1.8	8-25	11.4
No. of breast cancer detected		102		1,100
Cancer Detection Rate per 1,000 (CDR)	2-10	3.8	>20	40.0
Percentage of DCIS	10-20	27.9		9.1
Percentage of minimal cancer*	>30	46		-
PPV2 (Biopsy recommended)	25-40	19.5	15-40	33.7
Sensitivity	>85	73.6	>80	96.3
Specificity	>90	98.4	80-95	75.1

* DCIS + invasive carcinoma ≤10 mm

percent (27%) of intraductal carcinoma (DCIS) and 46% of minimal cancer (DCIS and invasive ductal carcinoma (IDC) were found for SCR which were in normal standard range (Table 2) The PPV2 (biopsy recommended) were 19.5% and 33.7% in 2 groups respectively. The sensitivity/ specificity in SCR and DX were 73.6%/98.4% and 96.3%/ 75.1 % respectively.

DISCUSSION

It has been reported in several studies of different outcome of medical audits in SCR and DX [24,25,26,27,17,18,19] by using key parameters. Our study is one of limited Southeast Asia reports about key parameters of SCR and DX mammography audit.

For SCR reports of Asia, Ng EH[25] from Singapore reported CDR was 4.6 while Muttarak et al[26] reported CDR was 3.0 from North Thailand. Our institute reported CDR of SCR was 3.8 which are closed to those previous studies.[25,26]

Chan LK[24] reported from Hong Kong in 1998 that the overall CDR of the opportunistic screening of Chinese women Hong Kong was 4.9. Lui CY[27] reported from same hospital in Hong Kong in 2007 that the CDR of Hong Kong women 40-49 years and ≥ 50 years were 5.9 and 3.7 respectively. Our CDR of Thai women 40-49 years and ≥ 50 years were 2.5 and 5.4 per 1,000 respectively which was different from Lui CY[27] findings. The percentage of DCIS of Lui CY and our study are 28% and 27.8% which are nearly the same.

For screening, the false negative or interval cancer in our SCR mammographic practice (with or without breast US) is classified into 2 categories: the true interval cancer and the missed or false-negative cancer. The true interval cancer refers to new cancer, no visible positive finding in retrospective review of the previous mammogram. These cancers are not related to radiologist ability or expertise. The missed or false-negative cancer refers to cancer visible but is not diagnosed by the radiologist. Strict attention to quality of mammography is mandatory to ensure that poor technical or clinical standard are not contributing to non visualization of lesions and incorrectly judged true interval cancers. In 35,701 SCR examinations during 2001-2005, seventeen interval cases arose in 12 months after a negative screen. We found 8 true interval cancers (47%), and 9 missed interval cancers (53%). Most studies reported that true interval cancer were the largest proportion (about half) ranging from 18-63% of all interval cancer.[27]

TABLE 3. Comparison of key parameters of mammography audit with previous studies.

	Studied year	Study group	Sample size	Abnormal cases	Abnormal %	Cancer Detected, cases	CDR per 1,000	Sensitivity	Specificity	PPV2
Chan et al[24]	1993-1995	Scr	13,033	-	-	42	3.2	-	-	-
Muttarak et al[26]	1994-1997	Scr	1,000	-	-	3	3	-	-	-
Lui CY et al[27]	1998-2002	Scr	46,637	-	-	232	5.0	-	-	-
Poplack et al[30]	1996-1997	Scr	47,651	1,381	1.8	-	3.3	72.4	97.3	-
		Dx	6,152	584	6.6	-	21.5	78.1	89.3	-
Dee & Sickles[20]	1997-2000	Scr	36,850	1,925	5.2	197	5.3	-	-	-
		Dx	10,007	1,141	14.4	551	55.1	-	-	-
Rosenberg et al[22]	1996-2002	Scr	2,580,151	253,169	4.8	12,068	4.7	-	-	24.6
Sickles et al[19]	1996-2001	Dx	332,926	12,431	12.3	3,120	30.8	-	-	24.6
Ansusinha et al*	2001-2005	Scr	26,735	482	1.8	102	3.8	73.6	98.4	19.5
		Dx	27,469	3,132	11.4	1,100	40.0	96.3	75.1	33.7

*This study

The interval cancer rate equals the number of interval cancers divided by the sum of screen-detected plus false negative cases.[20] Our interval cancer rate in SCR group is 14.2% at 12 month follow-up which is in acceptable range. (The Europain and United Kingdom guideline[32]: recommend interval cancer rate ≤ 30% of 12 months follow-up and ≤ 50% of 24 months follow-up). Twelve cases (71%) of interval cancers were age over 50 year-old which is contradict to the previous report that found interval cancer rates are higher in younger women than older women.[27,32]

The sensitivity and specificity among SCR group are 73.6% and 98.3%. The sensitivity is slightly lower than standard recommendation (recommend at 85%). However, among our the false negative cases, 5 cases (29.4%) had detected lesion with BI-RADS 3 assessment and detected breast cancer at next six month follow- up which did not changed the staging of cancer.

The sensitivity among DX group was 96% while the specificity is lower, 75.1%. The lower specificity than the other study is due to we applied BIRADS 4[th] edition which indicated that the palpable lesions without typical benign appearance had to be categorized as BIRADS assessment 4 which include those of fibroadenoma like, while other studies applied previous BI-RADS versions.

From Table 3, comparison mammography audit with prior studies, our abnormal interpretation rate of SCR was 1.8% which was much lower than other studies[7,19,22,24,26,27,30] because this study excluded BI-RADS 0. While our abnormal interpretation rate among DX was 11.4%, which was close to Dee and Sickles[7] findings.

For Dx, rare report from Asia was found. Our study reported CDR of DX was 40.0 which value is between reports of Dee&Sickle (CDR 55.1)[20] and Sickle (CDR 30.8).[31]

There are some limitations in our studies compare to the previous studies. First, our study was based on MG with or without breast US while most of the previous studies in Western

countries were based on mammography examination alone. Our report assessments were combination of mammogram and breast US study in cases with mammogram with breast US. Second, all of our studies (SCR and DX) were interpreted immediately after imaging including tailored mammographic extra views and appropriated breast US in the same visit of the patient. Therefore, in this study, the abnormal interpretation did not include BI-RADS 0 as recommended medical audit in ACR BI-RADS. Third, this study excluded 26.1% screening examinations (due to no follow up history or uncertain breast cancer status) which was quite a large number. This may cause increase cancer detection rate than usual.

CONCLUSION

In conclusion, this study presented different key parameter outcomes of SCR and DX mammography audit of Thai women and comparing to previous reports. Variation in these key parameters of mammography audit depend on definition, time period of study, place or geography and breast cancer incidence. So, when comparing mammography parameter outcomes between institutes, please remind of these factors. It is essential for breast imaging center to divide service into screening and diagnosis with regular auditing to monitor and improve the performance of breast centre.

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