Comparison of BI-RADS categories and recommendations from mammography alone and mammography with subsequent breast ultrasound in women with BI-RADS 1 and 2 screening mammogram

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Tiraratchailert B. Comparison of BI-RADS categories and recommendations from mammography alone and mammography with subsequent breast ultrasound in women with BI-RADS 1 and 2 screening mammogram. Chula Med J 2009 Jul – Aug; 53(4): 293 - 307

Objective

: To evaluate false negative rate of mammography according to BI-RADS categories and recommendations before breast ultrasound (US) in women with BI-RADS 1 and 2 screening mammography and to study the effects of breast composition, age and availability of prior mammography on changing of recommendation after breast US.

Setting

: Bangkok Metropolitan Administration General Hospital

Research design

: A retrospective cohort study.

Patients

: Women who received screening mammography with mammographic BI-RADS 1 and 2, and subsequent breast US were performed in the same day from July 2005 to February 2007.

Methods

: Mammograms of 1003 women were reviewed. Mammographic findings were recorded and mammographic BI-RADS category (BI-RADS_M) and recommendation (RECOM_M) were assigned. Breast US reports and images were reviewed. US findings, final BI-RADS

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category (BI-RADS_F) and final recommendation (RECOM_F) were recorded. False negative rate of BI-RADS_M and RECOM_M were analyzed using BI-RADS_F and RECOM_F as the gold standards. The effects of age, breast composition and availability of previous mammogram on incorrect recommendation were evaluated.

Results

False negative rate of BI-RADS_M categories was 7.68% (95% CI = 6.14 - 9.56) and of $RECOM_M$ was 2.59% (95%CI = 1.73 - 3.83). The effects of breast composition and availability of prior mammogram for comparison on recommendation change after breast US were statistically significant. Women with dense breasts were 10.64 times (95%CI = 1.43 - 79.13) more likely to have recommendation change than women with non-dense breasts. Women without prior mammogram were 11.44 times (95%CI = 2.68 - 48.78) more likely to have recommendation change than women with prior films. Age had no significant effect on recommendation change after breast US.

Conclusion

A small proportion (2.59%) of women with mammographic BI-RADS 1 and 2 in screening mammography had recommendation change following breast US, particularly women with non-dense breasts and women with prior mammography available for comparison. This suggests lack of necessity to perform breast US in women with negative or benign findings on screening mammography of non-dense breast group and also in the group with available interval mammographic images.

Keywords

BI-RADS Categories, Recommendations, Breast Ultrasound, BI-RADS 1, BI-RADS 2, Screening Mammogram.

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วัตถุประสงค์

: เพื่อศึกษาผลลบลวงของ BI-RADS categories และคำแนะนำการตรวจ รักษาจากผลแมมโมแกรมอย่างเดียว ในการตรวจคัดกรองมะเร็งเต้านม ที่มีผลแมมโมแกรมเป็น BI-RADS categories 1 และ 2 และศึกษาผล กระทบของอาย ความหนาแน่นของเนื้อเต้านม และการเปรียบเทียบกับ ฟิล์มแมมโมแกรมเก่าต่อการเปลี่ยนแปลงคำแนะนำหลังการตรวจ อัลตราชาวด์เต้านม

สถานที่ที่ทำการวิจัย

: โรงพยาบาลกลาง กรุงเทพมหานคร

รูปแบบการวิจัย

: การศึกษาแบบย้อนหลัง

ผู้ป่วยที่ได้ทำการวิจัย : ผู้หญิงซึ่งมารับการตรวจคัดกรองมะเร็งเต้านมโดยแมมโมแกรม ที่มีผล แมมโมแกรมอย่างเดียวเป็น BI-RADS 1 และ 2 และได้รับการตรวจ อัลตราชาวด์เต้านมเพิ่มเติมในวันเดียวกัน ระหว่างเดือนกรกฎาคม 2548 ถึง กมภาพันธ์ 2550

วิธีการ

ะ ศึกษาย้อนหลังจากฟิล์มแมมโมแกรมของผู้หญิง 1003 ราย บันทึก ความผิดปกติจากฟิล์มแมมโมแกรม และ BI-RADS categories (BI-RADS.) และคำแนะนำ (RECOM) จากผลแมมโมแกรมอย่างเดียว ศึกษาภาพและ ผลอัลตราชาวด์เต้านม และบันทึกความผิดปกติที่พบ BI-RADS categories (BI-RADS) และคำแนะนำ (RECOM) ในใบรายงานผล วิเคราะห์อัตรา การเกิดผลลบลวงของ BI-RADS และ RECOM จากการทำแมมโมแกรม อย่างเดียว โดยใช้ BI-RADS ู และ RECOM ู หลังการทำอัลตราชาวด์ ร่วมด้วยเป็นเกณฑ์สำหรับเปรียบเทียบตามลำดับ และวิเคราะห์ผลกระทบ ของอายุ ความหนาแน่นของเนื้อเต้านม และการมีภาพแมมโมแกรมเก่า เปรียบเทียบต่อการเปลี่ยนแปลงคำแนะนำหลังการตรวจคัลตราชาวด์

ผลการวิจัย

ผลลบลวงของ BI-RADS เป็น 7.68% (95%CI = 6.14-9.56) และของ RECOM เป็นเพียง 2.59% (95%CI = 1.73-3.83) ความหนาแน่นของเนื้อ เต้านม และการมีฟิล์มแมมโมแกรมเก่าสำหรับเปรียบเทียบมีผลต่อการ เปลี่ยนแปลงคำแนะนำหลังการตรวจอัลตราชาวด์เต้านม อย่างมีนัยสำคัญ ทางสถิติ ผู้ที่มีความหนาแน่นของเนื้อเต้านมมากมีความเสี่ยงที่จะมี การเปลี่ยนแปลงคำแนะนำสูงกว่าผู้ที่มีความหนาแน่นของเนื้อเต้านมน้อย 10.64 เท่า (95%CI = 1.43 - 79.13) ผู้ที่ไม่มีฟิล์มแมมโมแกรมเก่าสำหรับ เปรียบเทียบมีความเสี่ยงที่จะมีการเปลี่ยนแปลงคำแนะนำสูงกว่าผู้ที่มีฟิล์ม แมมโมแกรมเก่า 11.44 เท่า (95%CI = 2.68 - 48.78) อายุไม่มีผลต่อการ เปลี่ยนแปลงคำแนะนำหลังการตรวจอัลตราชาวด์ อย่างมีนัยสำคัญทาง สถิติ

วิจารณ์และสรุป

ผู้ที่ผลแมมโมแกรมอย่างเดียวเป็น BI-RADS 1 และ 2 ในการตรวจคัดกรอง มะเร็งเด้านมเพียงส่วนน้อย (2.59%) ที่มีการเปลี่ยนแปลงคำแนะนำ การตรวจรักษาหลังจากการตรวจอัลตราชาวด์เพิ่มเติม โดยเฉพาะอย่างยิ่ง ในผู้ที่มีความหนาแน่นของเนื้อเต้านมน้อย และผู้ที่มีฟิล์มแมมโมแกรมเก่า สำหรับเปรียบเทียบ ดังนั้นจึงไม่จำเป็นต้องตรวจอัลตราชาวด์เต้านม เพิ่มเติมในผู้ที่ผลแมมโมแกรมเพื่อตรวจคัดกรองมะเร็งเต้านมเป็น BI-RAD 1 หรือ 2 ในกรณีที่มีความหนาแน่นของเนื้อเต้านมน้อย และในกรณีที่มี ฟิล์มเก่าเปรียบเทียบ

คำสำคัญ

BI-RADS categories, คำแนะนำการตรวจรักษา, อัลตราชาวด์เต้านม, BI-RADS 1, BI-RADS 2, การตรวจคัดกรองมะเร็งเต้านม.

การศึกษาเปรียบเทียบ BI-RADS categories และคำแนะนำการตรวจรักษา จากแมมโมแกรมอย่างเดียว Vol. 53 No. 4 และแมมโมแกรมร่วมกับอัลตราชาวด์เต้านม ในการตรวจศัดกรองมะเร็งเต้านมที่มีผล July - August 2009 แมมโมแกรมอย่างเดียวเป็น BI-RADS categories 1 และ 2

Mammography is the most accurate method for breast cancer screening and can reduce mortality rate from breast cancer. (1,2) According to American College of Radiology's breast imaging reporting and data system (ACR BI-RADS), an overall impression of mammography report comprises of BI-RADS assessment category and recommendation that is appropriate for each category. (3) Both BI-RADS category 1 and category 2, which indicate that there is no mammographic evidence of malignancy, have same recommendation - routine screening mammogram, while other BI-RADS categories have different recommendations.

Interpretation of screening mammography can be performed in two ways: (a) immediate interpretation, which images are evaluated and results are communicated with the patient at the time of the initial visit and additional examination can be performed in the same visit, and (b) batch interpretation, which images are evaluated after the patient has left the hospital and the suspicious cases or the cases need further examinations are recalled for additional imaging on a different day. Batch interpretation shows higher efficacy and higher specificity than immediate interpretation, without significant difference in cancer detection rate and it is one measure to improve the economic efficiency of screening mammography. (4-,6) Nowadays 93% of hospitals in the United States use batch interpretation. (7) Almost all hospitals in Thailand including the BMA General Hospital still use immediate interpretation in screening mammography service, and additional breast ultrasonography (US) is performed in most cases including women who have negative or benign findings on mammographic

films. This type of practice results in limitation of number of women appointed per day because the radiologists have to spend more time per case performing breast US. Abnormalities detected by additional breast US may affect final BI-RADS category and recommendation. However, the negative and benign US findings do not alter the recommendation. If additional breast US causes no significant change in final recommendation in women with negative or benign findings on screening mammographic films, performing breast US may not be necessary in this group of women; batch interpretation should be used instead of immediate interpretation for screening mammography service to serve growing demand for breast cancer screening.

This study had as its objectives to evaluate false negative rate of BI-RADS categories and recommendations of screening mammography before breast US compared with those after breast US, in women with negative and benign findings on screening mammography, and to study the influence of breast composition, age and availability of prior mammography on changing of recommendation after breast US.

Materials and Method

This study has been approved by the Ethics Committee for Researches Involving Human Subjects of the Bangkok Metropolitan Administration.

Study location:

The BMA General Hospital is a 400-bed hospital with 5 full-time radiologists. All radiologists have experience in mammography for 6 - 17 years.

Mammographic screening practice in the BMA General hospital includes:

Routine practice of screening mammography is performed by acquiring two standard views (mediolateral oblique and craniocaudal views) of each breast. Mammograms are obtained using mammographic unit (Senix SF 600T; General Electric Medical Systems, Milwaukee, WI), cassettes (Min-R 2000; Kodak, Rochester, NY), films (Min-R 2000; Kodak, Rochester, NY) and processing (Kodak miniloader 2000P; Kodak, Rochester, NY).

After immediate evaluation of mammograms by an attending radiologist, additional mammographic views may be requested whether an abnormality is suspicious. Then, whole breast US is performed by the same radiologist, using a high-resolution US unit (Acuson 128XP/10C; Acuson, Mountain View CA.) with a high-frequency (7.5 - MHz) linear-array transducer. Hard-copy US image of any positive finding is printed on thermal print paper and the radiologist makes decision on final BI-RADS categories and final recommendation.

Study design:

A retrospective cohort study was conducted from June to December 2008. List of all patients (2,102 patients) who received mammography at the hospital from July 2005 to February 2007 was complied. Clinical data, written in request forms by referring physicians and recorded in patient information forms by mammographic technologists, were retrospectively reviewed to identify patients who had no breast symptom and received mammography on screening purpose. One thousand, two hundred and ninety six asymptomatic patients

(1,296) were identified and included into this study. For each patient, the original mammograms were reviewed by the principle researcher (B.T.). If previous mammograms were available, comparison of current with previous films would be done. The findings were recorded and the researcher assigned mammographic BI-RADS category (BI-RADS_M) according to the ACR BI-RADS manual, as well as mammogram recommendation (RECOM_M). Then, the breast US report and hard-copy image (available only for women with positive finding) were reviewed. The US findings, the original final BI-RADS category (BI-RADS_F) and the final recommendation (RECOM_F) which was assigned by attending radiologists were recorded.

Women's age, total number of mammography and intervals between each consecutive mammography were recorded. Breast composition was estimated. Breast compositions were grouped according to ACR BI-RADS guideline (3) and later into two large groups: (a) dense breasts, which included homogeneously and heterogeneously dense breasts, and (b) non-dense breasts, which included scattered dense and almost entirely fatty breasts.

Exclusion criteria:

Persons with the following conditions were excluded: mammogram not available (n = 123), radiologist requested additional mammographic views (n = 37), BI-RADS_M categories 3, 4 or 5 (n = 80), previous unilateral mastectomy (n = 17), previous breast implant (n = 1) and no subsequent breast US due to almost entirely fatty breasts (n = 35).

Vol. 53 No. 4 July - August 2009

Statistical analysis:

BI-RADS and RECOM were used as gold standards.

The false negative rates of BI-RADS, was defined as:

> Number of patients whose BI-RADS, changed from BI-RADS, x100

> > Number of all patients

The false negative rates of RECOM, was defined as:

> Number of patients whose RECOM_F changed from RECOM_M x100

> > Number of all patients

The effects of age, breast composition and availability of previous mammogram on incorrect recommendation were evaluated. The statistics used for bivariate analysis were relative risk (RR) and 95% confidence interval (95%CI), t-test for different between two means and chi-square test for different between two proportions. The statistics used for multiple logistic regression were odd ratio (OR) and its 95%CI. Data were analyzed by Epiinfo 6 and Stata 6 software.

Result

Of 1,003 patients recruited in the study, the

age range was between 28 - 82 years with the mean of 52.9 years. More than half had heterogeneously dense breast. Four hundreds and seventy patients (470, 46.86%) had previous mammograms from 1 to 8 times (median 2 times). Time between the first and current mammogram was from 5 to 106 months (median 27 months). Five hundred and eighteen patients (518, 51.65%) had negative mammograms (BI-RADS_M category1), while 485 (48.35%) had benign findings (BI-RADS_M category 2). Detailed characteristics of the findings are in table 1. There were two positive findings in 5 patients.

Breast US findings showed 855 negative findings, 116 benign and 32 probably benign findings. BI-RADS, was category 1 in 855 patients (85.25%), category 2 in 122 patients (12.16%) and category 3 in 26 patients (2.59%) (Fig. 1 - 4). There were no BI-RADS categories 4 and 5 in this review. Comparison of BI-RADS, and BI-RADS, categories is shown in table 2. They were unchanged in 926 patients (92.32%) and changed in 77 patients (7.68%). Of the 77 patients with BI-RADS categories changed, recommendations remained unchanged (RECOM. similar to RECOM_F) in 51 patients who had BI-RADS_M category 1 and BI-RADS_E category 2.

Table 1. Characteristics of the 490 positive benign mammographic findings in 485 patients.

Findings	Number	%	
Round mass	5	1.02	
Benign-appearing calcifications	459	93.67	
Architectural distortion, stable	1	0.20	
Intramammary lymph node	6	1.22	
Global asymmetry	5	1.02	
Focal asymmetry, stable	13	2.65	
Skin thickening, postsurgical	1	0.20	

Note: There were five patients who had two positive findings.

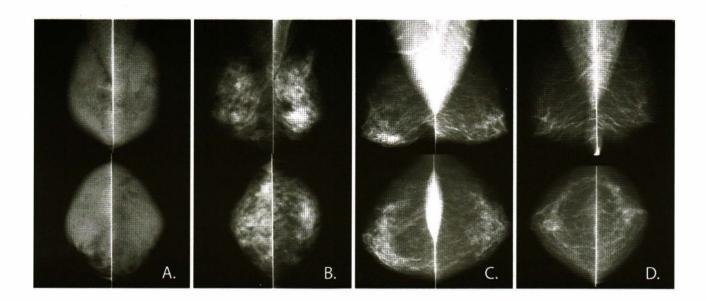


Figure 1. Examples of women with various breast compositions with mammographic BI-RADS 1 or 2: (A.) homogeneously dense breast, (B.) heterogeneously dense breasts, (C.) scattered dense breasts and (D.) almost entirely fatty breast. Breast US of all cases showed no abnormality.

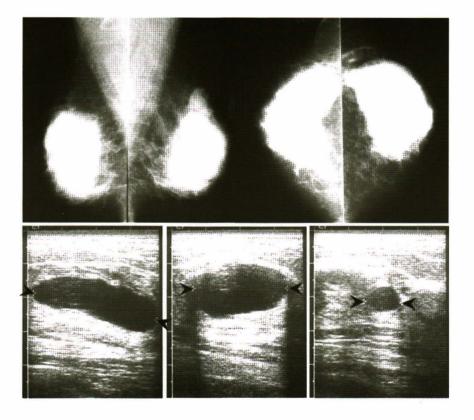


Figure 2. A 51-year-old woman with homogeneously dense breasts and bilateral scattered eggshell calcifications, benign mammographic findings. US showed three cysts (◀) in both breasts, 1.1-3.7cm in sizes, also benign findings. Recommendation was unchanged - routine screening mammography.

Vol. 53 No. 4 July - August 2009

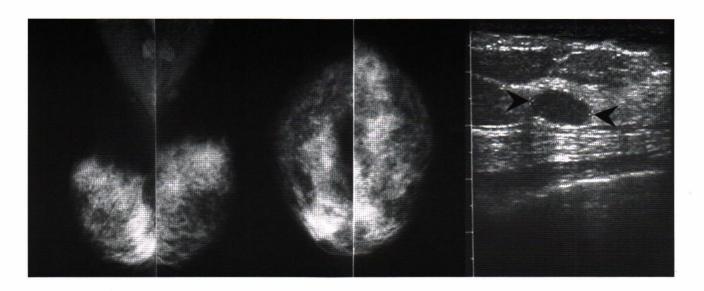


Figure 3. A 44-year-old woman with homogeneously dense breasts and negative mammogram. US showed a 1.2cm oval hypoechoic mass (◀) in LUIQ. After breast US, recommendation was changed from routine screening mammography to initial short-interval follow-up.

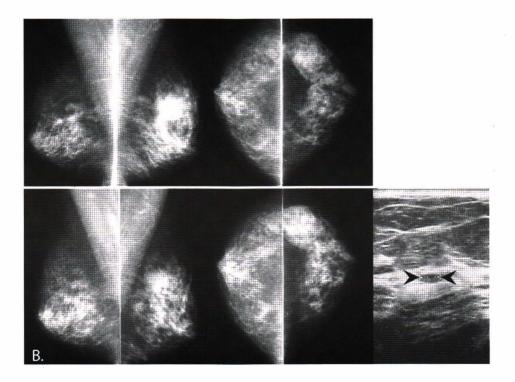


Figure 4. A 50-year-old woman with heterogeneously dense breasts and bilateral coarse and eggshell calcifications. Current films (B) unchanged from prior films from 26 months ago (A). US showed a new 0.4cm oval hypoechoic mass (◀) in LUIQ. After breast US, recommendation was changed from routine screening mammography to initial short-interval follow-up. This is one of two cases with prior mammography available for comparison whose recommendation changed after breast US.

Table 2. Comparison of mammographic BI-RADS categories with final BI-RADS categories after subsequent breast US.

BI-RADS _M	BI-RADS _F					
	BI-RADS _F	Total				
	1	2	3	4	5	
BI-RADS _M category 1	456	51	11	0	0	518
BI-RADS _M category 2	0	470	15	0	0	485
Total	456	521	26	0	0	1003

 $\mathsf{BI\text{-}RADS}_{_\mathsf{M}}$ is mammographic BI-RADS categories, before breast US.

 $\mathsf{BI}\text{-}\mathsf{RADS}_{\scriptscriptstyle\mathsf{F}}$ is final $\mathsf{BI}\text{-}\mathsf{RADS}$ categories, after breast US.

False negative rate of BI-RADS_M categories was 7.68% (95%CI = 6.14 - 9.56) and of RECOM_M was 2.59% (95%CI = 1.73-3.83). Table 3 displays percentage of patients with same and changed

recommendation after breast US according to age groups, breast composition and availability of prior mammograms.

Table 3. Comparison of 1,003 patients with same and changed recommendation, according to age group, breast composition and availability of prior films.

	Same		Changed		Total	
	recomm	nendation	recom	mendation		
Age group	No.	%	No.	%	No.	%
< 40 years	53	5.42	4	15.38	57	5.68
40-49 years	269	27.53	8	30.77	277	27.62
50-59 years	457	46.78	9	34.62	466	46.46
60-69 years	178	18.22	5	19.23	183	18.25
> 70 years	20	2.05	0	0	20	1.99
Total	977	100	26	100	1003	100
Breast composition						
Homogeneously dense	191	19.55	9	34.62	200	19.94
Heterogeneously dense	506	51.79	16	61.54	522	52.04
Scattered dense	216	22.11	1	3.85	217	21.64
Almost entirely fat	64	6.55	0	0.00	64	6.38
Total	977	100	26	100	1003	100
Prior mammograms						
No	509	52.10	24	92.31	533	53.14
Yes	468	47.90	2	7.69	470	46.86
Total	977	100	26	100	1003	100

In bivariate analysis, mean age, breast compositions and availability of previous mammogram had significant effects on recommendation change after breast US (Table 4). Younger patients were more likely to fall into changed recommendation group (p-value 0.042). The patients with dense breasts were 9.73 time (p-value 0.0054) more likely and the patients with prior mammograms were 0.09 time (p-value 0.00005) less likely to fall into changed recommendation group.

After using multiple logistic regressions to control confounding effects between these 3 factors,

only breast composition and having prior mammogram had significant effects on recommendation change (Table 5). Women with dense breasts were 10.64 times (95%CI = 1.43 -79.13) more likely to receive recommendation change following breast US than women with non-dense breasts. Women with prior films for comparison were 0.087 time (95%CI = 0.02 - 0.37) less likely to receive recommendation change following breast US than women without prior films. In the other words, women without prior films were 11.44 times (95%CI = 2.68 - 48.78) more likely to have recommendation change.

Table 4. P-value, relative risk and its 95%Cl of factors associated with changing of recommendation after breast US, by bivariate analysis.

	Changed	Same		RR	
Risk factor	recommendation (N = 26)	recommendation (N = 977)	p- value	[95% CI]	
Mean age (years)	49.7	53.0	0.042	NA	
Breast composition					
Homogeneously dense					
and heterogeneously					
dense breast	25	697	0.0054	9.73[1.32 - 71.41]	
Scattered dense and					
fatty breast	1	280			
Previous mammogram for					
comparison					
Yes	2	468	0.00005	0.09[0.02 - 0.04]	
No	24	509			

Table 5. Adjusted odd ratio and its 95% confidence interval of factors associated with changing of recommendation, by multiple logistic regression.

Risk factors	Adjust Odds	95% confidence	
	Ratio	interval	
Homogeneously dense and	10.64	1.43-79.13	
heterogeneously dense breast			
Previous mammogram available for comparison	0.087	0.02-0.37	

Discussion

In this study, most asymptomatic women with negative or benign findings on the screening mammographic films had no recommendation change following breast US. Upstage of BI-RADS categories is found in 7.68%, and recommendation change is found in only 2.59% after breast US. Since BI-RADS categories 1 and 2 have same recommendation, when breast US reveals benign findings such as breast cysts and intramammary lymph node, final BI-RADS category 2 will be assigned without recommendation change. Recommendation change is made when US reveals more suspicious findings and final BI-RADS categories are assigned into categories 3, 4 or 5. Previous reviews reported that about 90% of screening mammography are negative or benign⁽⁸⁾ and screening breast US may leads to false-positive results which possibly requiring unnecessary biopsy. (9,10) Because only small proportion of women with negative or benign screening mammography had recommendation change after breast US in this study, along with the facts that most screening mammography are negative or benign, batch interpretation should be considered to be used instead of immediate interpretation in screening mammography and additional breast US should be performed only when screening mammography reveals suspicious abnormality or malignant findings.

This study demonstrated, as expected, that breast composition had significant effects on recommendation change and patients with dense breasts (i.e. homogeneously and heterogeneously dense breast compositions) about ten times more likely to have recommendation change following breast US than women with non-dense breasts (i.e.

scattered dense and almost entirely fatty breasts). Similarly, literatures about usage of breast US in various subject groups reported that clinically and mammographically occult breast cancers tend to occur in dense breasts and breast US is useful in demonstrating these cancers which were obscured by fibroglandular tissue on mammography. (2,11,12) While all women with fatty breasts in this study had negative breast US, similarly, another study also reported very few of mammographically missed breast cancer detected by US in fatty breasts. (12)

Women who did not have previous screening mammography for comparison were about eleven times more likely to receive recommendation change after breast US in this study. Demonstration of stability or regression of a suspicious area on current mammography compared previous films help increased confidence in assigning mammographic categories as BI-RADS 1 and 2. Several articles have established the value of comparing current screening mammography by reduction of false negative rate when subtle parenchymal changes identified. (13,14) Reduction of recall rate, about 50%, without reduction of cancer detection rate when present films are interpreted in comparison with previous films are reported. (8,15-18) In this study, 2 of 26 women with recommendation change had previous mammography with interval duration of mammography ranged from 26 to 36 months. Current films of both women revealed no detectable change as compared to previous films. Since there were only two cases of this condition, evaluation of time interval effect on recommendation change cannot be performed.

After controlling effects of breast composition and availability of prior mammography for comparison, age did not show significant influence on recommendation change. This is similar to those of earlier literatures that reported no significant effect of age on sensitivity of screening mammography. (19, 20)

Vol. 53 No. 4

There are some limitations in this study. First, this is retrospective study; mammographic BI-RADS categories did not assigned by the attending radiologists but retrospectively assigned by the researcher based on mammographic films and reports. Second, breast US is operator-dependent imaging that requires real-time recognition of abnormalities and these US were performed by radiologists with knowledge of mammographic result. Therefore, the radiologists may have been influenced by the level of suspicion from mammographic result. Third, there is no suspicious abnormality or highly suggestive of malignant findings from breast US in this review, which is lower than average cancer detection rate (0.3%). (21) This may resulted from operator-dependency of US as previously discussed. To overcome limitations in this study, further prospective control studies in larger population group to study benefit of breast US in asymptomatic women with negative or benign screening mammography may be very useful.

Conclusion

The findings in the study suggest lack of necessity for performing additional US in women with negative or benign findings on screening mammography, particularly in women with scattered dense breasts or almost entirely fatty breasts and in women with prior mammography available for comparison. Because of increasing demand for breast cancer screening and inadequate manpower, one practical application of these data is to use batch interpretation in screening mammographic service instead of immediate interpretation and skip performing breast US in asymptomatic women with mammographic BI-RADS categories 1 and 2 who are in non-dense breast group or who have previous films for comparison. These should increase efficiency and cost-effectiveness of screening mammography service. However, in women in dense breast group and in women whose interval mammographic films are not available, in spite of negative or benign mammographic findings, additional breast US is still necessary.

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การศึกษาเปรียบเทียบ BI-RADS categories และคำแนะนำการตรวจรักษา จากแมมโมแกรมอย่างเดียว Vol. 53 No. 4 และแมมโมแกรมร่วมกับอัลตราชาวด์เต้านม ในการตรวจคัดกรองมะเร็งเต้านมที่มีผล July - August 2009 แมมโมแกรมอย่างเดียวเป็น BI-RADS categories 1 และ 2

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