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Effectiveness of Mammographic Screening for Breast Cancer in Women Aged over 50 Years in Japan

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The optimal age for effective screening of subjects for breast cancer by mammography in Japan was studied based on the results of two mammographic screening systems (systems I and II) in Tokushima Prefecture. System I consisted of visit screening using a bus equipped with a mammographic apparatus. System II consisted of central screening performed at Tokushima Health Screening Center. The examinees numbered 2,500 and 3,707 in systems I and II, respectively. There was a significant difference between the two screening systems in the age distribution of the examinees. The detection rates of breast cancer were 0.6% and 0.24% in systems I and II, respectively, which are 2–5 times higher than that (0.12%) obtained by conventional screening using physical examination alone. The detection rate increased especially in the sixth and seventh decades of life. The sensitivity of mammography screening was 93.3% in system I and 81.1% in system II. Higher sensitivity (100%) than that (73%) of screening by physical examination was obtained in women aged over 50. The proportion of stage I was 60% in system I and 66.7% in system II, compared with 32–65% in the United States and Europe. The rates of no nodal involvement were high, being 77.8% and 83.3% in systems I and II, respectively, compared with 57–71% in other countries. Breast-conserving therapy was applied to 18 of the 24 patients with breast cancer detected by the two screening systems. In addition, in Wolfe's classification of mammograms, the proportion of DY (mammary dysplasia) pattern was remarkably low, being 3.2% in the sixth decade and 0.8% in the seventh decade, compared with 16.6% in women aged 49 years. These results indicate that mammographic screening is effective in women aged over 50 years in Japan, as has been found in other countries.

Key words: Breast cancer — Mammographic screening — Early detection — Screening sensitivity — Effectiveness

In the United States and Europe the high mortality of breast cancer was significantly reduced by mammographic screening of women aged over 50 years, and the effectiveness of this approach has been confirmed in many reports.[1–3] In contrast, the effectiveness of this screening in women aged from 40 to 49 remains controversial.[4] In Japan, breast cancer screening has been carried out by physical examination alone, using inspection and palpation.[5,6] More than half of the patients with breast cancer detected by this screening system are already aware of their lumps, the detection rate has been a little less than 0.1%, and the proportion of early-stage disease among breast cancers is nearly 50%. It is difficult to detect breast cancer consisting of non-palpable tumors by physical examination, and the low accuracy of the screening, especially the low sensitivity, has been pointed out.[5,6] It has been reported that there is no difference in overall survival between cases detected by screening and cases detected in outpatient clinics.[7] Accordingly, it is advocated that in Japan, too, screening of asymptomatic women for breast cancer should be done by means of mammography to give higher diagnostic sensitivity, and to increase the proportion of early-stage breast cancers.[8–11] However, sufficient data on the effectiveness of mammographic screening have not been available in Japan. In this study, we added more data to our previous report[10] and conducted a similar analysis using another mammographic screening system. The optimal age of the screening subjects and the effectiveness of screening by mammography in Japan are discussed based on the results of our mammographic screening in Tokushima Prefecture.

MATERIALS AND METHODS

Two screening systems were investigated in this study. One system consisted of visit screening using a bus equipped with a mammographic apparatus, performed as a model project of the Ministry of Health and Welfare of Japan. In principle, all subjects aged over 30 years living in a model community were screened by physical examination, and mammography was performed on those aged over 50 years. Craniocaudal and mediolateral oblique

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images of the breasts were obtained with a mammographic unit (Mammomat II, Siemens, Tokyo). Reading of films was double checked, and the results of the physical examination and mammography were determined independently, so that further detailed examinations were recommended separately. Hereinafter this screening is referred to as screening system I.

The second system consisted of screening performed at Tokushima Health Screening Center. The subjects of screening were asymptomatic women aged over 30 years, examined by health screening, workplace screening and community screening. All subjects underwent both physical examination and mammography in combination. Only mediolateral oblique images of the breasts were obtained with a mammographic unit (MGU-10C, Toshiba, Tokyo). Further detailed examinations were recommended on the basis of the results of the physical examination and mammography applied in combination. Hereinafter, this screening is referred to as screening system II.

In both systems, each subject was evaluated as normal or abnormal based on the previously reported criteria of physical examination.[12] We divided the mammographic findings into 5 categories for each of the two characteristics of mass shadow and calcification, i.e., category 1: no finding; category 2: benign; category 3: benign, but malignancy not ruled out; category 4: malignancy suspected; and category 5: malignancy. Subjects rated as category 3 or more were recommended to undergo further detailed examinations at Tokushima Health Screening Center and Tokushima Breast Care Clinic. Further examinations consisted of diagnostic mammography, ultrasonography together with careful physical examination of the breasts, fine needle aspiration cytology, and if necessary, surgical biopsy.

For the purpose of determining the optimal age for mammographic screening, mammographic breast patterns were studied with reference to Wolfe's classification using the mammograms obtained in system I only. Wolfe defined the breast parenchymal patterns as follows[13]: N1 — The breast is composed primarily of fat, often with a fine trabecular appearance. P1 — "Prominent" ducts occupy 25% or less of the breast volume. P2 — "Prominent" ducts occupy more than 25% of the breast volume. DY — Mammary dysphasia (fibrocystic change) containing sheetlike areas of increased density.

The data from the physical examination were compared with the results of earlier screening performed by the authors[14] as a control for this study. Our results with the two screening systems were compared with the mammographic screening data reported in the United States and Europe.

"Breast cancer detected in screening" was defined as a case diagnosed within a year of screening in which it had been judged as "positive." "False negative" was defined as an "interval breast cancer" within a year after screening. "Interval breast cancer" was defined as those detected by any method other than screening during the interval between a negative screening examination and the next scheduled screening. Sensitivity and positive predictive value were calculated from the results of the two screening systems. Sensitivity was defined as the ratio of screen-detected cancers to screen-detected plus false negative (interval) cancers. Positive predictive value was defined as the ratio of cancer cases to all cases requiring detailed examination in the examinees. The clinical stage of the detected breast cancer was based on the TNM clinical classification (UICC, 1987). The histological type was based on "The General Rules for Clinical and Pathological Recording of Breast Cancer," issued by the Japanese Breast Cancer Society.[15] Statistical analysis was performed using the χ^2 test and Fisher's exact test.

RESULTS

Age distribution of subjects (Tables I, II) The examinees in system I and system II numbered 2,500 and 3,707, of which 2,095 (83.8%) and 3,071 (82.8%) were first-time examinees, respectively, within the period from 1992 to 1996. Table I presents the age distribution of the examinees. The examinees of the two screening systems were divided into two groups using the age of 50 years as a boundary. In system I, those aged under 49 years and those over 50 years accounted for 26% and 74%, respectively. Thus, women aged 50 years and over were an overwhelmingly majority in system I. In system II, the two age groups accounted for 60% and 40%, respectively. There was a significant difference between the two screening systems in the age distribution of the examinees.

Percentages of cases with findings, requested to undergo detailed examinations, and who underwent detailed examinations The rates of those with findings (categories 2–5) were 47.0% and 27.5% in system I and in system II, respectively. The rates of those requested to undergo detailed examinations (recall rates) were 9.2% and 7.1%. Of these, the rates of those who underwent detailed examinations were 95.6% and 91.1%.

Detection rates of breast cancer (Tables I, II) Breast cancer was detected in 15 of the 2,500 women screened in system I (0.6%) and nine of the 3,707 women screened in system II (0.24%). All 15 system I cases were first-time examinees, while eight of the nine system II cases were first-time examinees. The detection rate of breast cancer as a function of age was 0.38% in system I and 0.28% in system II in the fifth decade of life. In the sixth decade, the detection rate was higher, being 0.57% in system I and 0.38% in system II, while in the seventh

Table I. Age Distribution of Number of Examinees for Breast Cancer in Each Mammography Screening System

Age distribution	Number of examinees in system I			Number of examinees in system II		
	First-time examinees	Periodic examinees	Total[a] (%)	First-time examinees	Periodic examinees	Total[b] (%)
–39	106	10	116 (4.6)	653	78	731 (19.7)
40–49	470	54	524 (21.0)	1,145	269	1,414 (38.1)
50–59	737	146	883 (35.3)	861	204	1,065 (28.7)
60–69	689	164	853 (34.1)	386	82	468 (12.6)
70–	93	31	124 (5.0)	26	3	29 (0.8)
Total	2,095	405	2,500 (100)	3,071	636	3,707 (100)

a) vs. *b*) $P<0.0001$ ($\chi^2=840.538$).

Table II. Breast Cancer Detection Rate as Function of Age Distribution in Each Mammography Screening System

	System I				System II			
	Number of examinees (%)	Number of breast cancers	Detection rate (%)	(95% CI)[c]	Number of examinees (%)	Number of breast cancers	Detection rate (%)	(95% CI)[c]
–39	116 (4.6)	0	0		731 (19.7)	0	0	
40–49	524 (21.0)	2	0.38	(0–0.79)	1,414 (38.1)	4[b]	0.28	(0.01–0.55)
50–59	883 (35.3)	5	0.57	(0.32–0.82)	1,065 (28.7)	4	0.38	(0.01–0.75)
60–69	853 (34.1)	8	0.94	(0.28–1.59)	468 (12.6)	1	0.21	(0–0.62)
70–	124 (5.0)	0	0		29 (0.8)	0	0	
Total	2,500 (100)	15[a]	0.6	(0.30–0.89)	3,707 (100)	9	0.24	(0.09–0.39)

a) All cases were detected in first-time examinees.
b) One of four cases was detected in periodic examinees.
c) CI is the confidence interval.

decade of life it was 0.94% and 0.21%, respectively. The detection rate thus increased with age in both systems, and was higher in system I.

Sensitivity of screening (Table III) With regard to the sensitivity of screening in system I, breast cancer was detected in 15 of the 2,500 examinees, and 14 cases were checked by mammography with one case of false-negative. This one case was detected by physical examination only. Accordingly, the sensitivity of mammographic screening was 93.3%. On the other hand, in system II, breast cancer was detected in nine of the 3,707 examinees, and two cases were false-negative. Thus, the sensitivity was 81.1% for screening by combined mammography. Further, when the screening sensitivity was studied as a function of age, it was 50% in system I and 66.9% in system II in those aged under 49 years, and 100% each in those aged over 50 years, indicating the usefulness of mammographic screening for those aged over 50 years. The sensitivity of screening by physical examination alone was approximately equal in those under 49 years and those over 50 years, being 72.7% and 73.7%.

Table III. Sensitivity of the Screening Modality as a Function of Age Distribution

Screening modality	Sensitivity of screening (%)		
	49 years or younger	50 years or older	Total
Physical examination[a]	72.7	73.7	73.3
Mammography[b] (screening system I)	50	100	93.3
Mammography[c] (screening system II)	66.9	100	81.8

a) Data from reference 14.
b) Mammography only.
c) Mammography with physical examination.

In addition, the positive predictive value was 6.5% in system I and 3.4% in system II.

Breast cancer detected by systems I and II (Tables IV, V) Table IV presents the data for the 15 cases of breast cancer detected by system I. These cases included two

Table IV. Cases of Breast Cancer Detected in System I

Case No.	Age (yr)	Physical examination	Mammographic findings	Stage	Tumor size (cm)	Lymph node metastasis	Histological type	Treatment
1	52	Non-palpable	Mass shadow	I	0.8	n (−)	Scirrhous	BCT
2	64	Non-palpable	Mass shadow	I	0.6	n (+)	Pap. tub.	BCT
3	64	Non-palpable	Microcalcification	I	—	—	DCIS[a)]	BCT
4	59	Non-Palpable	Microcalcification	I	—	—	DCIS[a)]	BCT
5	63	Non-palpable	Mass shadow	0 (TIS)	1.6	—	DCIS	BCT
6	56	Non-palpable	Microcalcification	0 (TIS)	—	—	DCIS	BCT
7	60	Non-palpable	Microcalcification	0 (TIS)	—	—	DCIS	BCT
8	47	Non-palpable	Mass shadow	I	1.0	n (−)	Scirrhous	BCT
9	57	Mass	Mass shadow	II	2.0	n (+)	Scirrhous	Mx
10	67	Non-palpable	Mass shadow	0 (TIS)	0.5	—	DCIS	BCT
11	67	Non-palpable	Microcalcification	I	—	n (−)	Pap. tub.	BCT
12	65	Non-palpable	Microcalcification	I	0.7	n (−)	Pap. tub.	BCT
13	63	Mass	Mass shadow	II	2.0	n (−)	Solid tub.	Mx
14	53	Non-palpable	Microcalcification	I	1.0	n (−)	Pap. tub.	Mx
15	49	Mass	Normal	I	1.0	n (−)	Pap. tub.	BCT

Scirrhous, scirrhous carcinoma; Pap. tub., papillotubular carcinoma; DCIS, ductal carcinoma *in situ*; BCT, breast-conserving therapy; Mx, mastectomy. *a*) Microinvasion (+).

Table V. Cases of Breast Cancer Detected in System II

Case No.	Age (yr)	Physical examination	Mammographic findings	Stage	Tumor size (cm)	Lymph node metastasis	Histological type	Treatment
1	55	Non-palpable	Mass shadow	I	0.4	—	Tub.	BCT
2	55	Non-palpable	Microcalcification	0 (TIS)	—	—	DCIS	BCT
3	67	Non-palpable	Microcalcification	0 (TIS)	—	—	DCIS	BCT
4	48	Lumpy	Diffuse shadow	I	0.8	n (−)	Scirrhous	BCT
5	54	Lumpy	Microcalcification	0 (TIS)	—	n (−)	DCIS	Mx
6	44	Non-palpable	Mass shadow	I	1.5	n (−)	Pap. tub.	Mx
7	42	Lumpy	Mass shadow	I	2.0	n (−)	Inv. lob.	Mx
8	44	Non-palpable	Mass shadow	I	0.5	n (+)	Pap. tub.	BCT
9	58	Lumpy	Mass shadow	I	1.0	n (−)	Pap. tub.	BCT

DCIS, ductal carcinoma *in situ*; Tub., tubular ca; Scirrhous, scirrhous ca; Pap. tub., papillotubular ca; Inv. lob., invasive lobular ca; BCT, breast-conserving therapy; Mx, mastectomy.

cases in the fifth decade of life, five cases in the sixth decade and eight cases in the seventh decade. Palpation detected an abnormal mass in only three of the 15 cases. The mammographic findings revealed a mass shadow in seven cases and microcalcification in seven cases. In one case (No. 15), the mammogram revealed no abnormal findings, and this case was detected by physical examination only. The clinical stages of the breast cancers were stage 0 (TIS) in four cases, stage I in nine cases, and stage II in two cases. Seven of the nine cases had no involvement of the lymph nodes (77.8%). Twelve of the 15 cases underwent breast-conserving therapy.

Table V presents the data for the nine cases of breast cancer detected by system II. These cases included four cases in the fifth decade, four cases in the sixth decade and one case in the seventh decade. In four cases, palpation of the breasts found lumpy abnormalities. The mammographic findings revealed a mass shadow in five cases, a diffuse shadow in one case and microcalcification in three cases. The clinical stages were stage 0 (TIS) in three cases and stage I in six cases. Five of the six cases had no involvement of the lymph nodes (83.3%). Six of the nine cases underwent breast-conserving therapy.

Breast parenchymal pattern by Wolfe's classification (Fig. 1) The parenchymal pattern was classified into four categories, namely, N1, P1, P2 and DY. DY is a so-called dense breast, showing sheetlike areas of increased density, with images of prominent ducts being hardly distinguishable. When Wolfe's classification was applied to the mammograms in system I as a function of age, the proportion of DY influencing the mass shadow was 16% in those aged under 49 years, 3.2% in the sixth

Table VI. Comparison of Results in Our Screening Programs with Those from Screening Trials in Europe and US

	PE[a]	S-MMG[b] (system I)	S-MMG[c] (system II)	HIP	Sweden	UK	Finland	Canada NBSS1	Canada NBSS2
Number of subjects	18,619	2,500	3,707	30,239	78,085	23,226	39,164	25,214	19,711
Number of controls	NA	NA	NA	30,756	56,782	21,904	19,943	25,216	19,694
Referral rate (%)	7.7	9.2	7.1	NA	5.0	6.2	2.9	NA	NA
Detected cancer prevalence (per 1000 at first screening)	1.9	7.1	2.6	2.72	6.0	6.23	4.0	3.89	7.20
Sensitivity	73.3	93.3	81.8	74	76	88	81	81	88
Positive predictive value	1.5	6.5	3.4	12	12	4–15	8–10	2	4–6
% in situ	0	26.7	33.3	12.8	8.4	10.1	10.5	18.9	16.7
% stage I	31.8	60	66.7	56	53	32	65	NA	NA
% node-negative	59.0	77.8	83.3	57	71	63	NA	65	69

PE, physical examination; S-MMG, screening mammography; NA, not applicable; HIP, Health Insurance Plan of Greater New York; Canada NBCC, Canadian National Breast Screening Study.
a) Data from reference 14.
b) Mammography and physical examination separately.
c) Mammography and physical examination in combination.

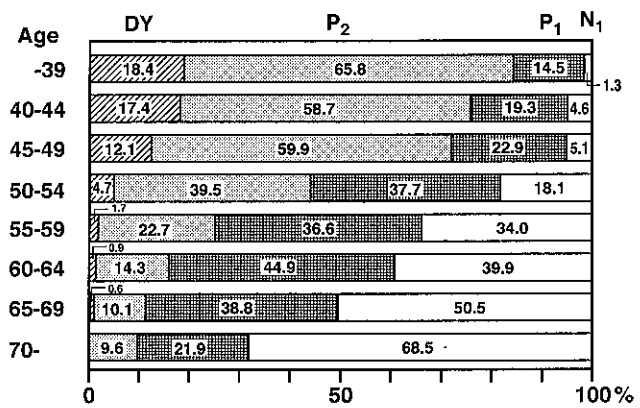

Fig. 1. Wolfe's classification of mammograms as a function of age distribution. N1, the breast is composed primarily of fat, often with a fine trabecular appearance. P1, prominent ducts occupy 25% or less of the breast volume. P2, prominent ducts occupy more than 25% of the breast volume. DY, mammary dysplasia containing sheetlike areas of increased density.

decade, and 0.8% in the seventh decade. The percentage thus decreased in the higher age groups, which revealed high proportions of P1 and N1. These results also indicate that mammographic screening is suitable for women aged over 50 years.

DISCUSSION

The purpose of breast cancer screening is to detect early-stage cancer, thereby improving the survival and reducing the mortality of subjects from breast cancer. Application of reduction surgery as breast-conserving therapy upon early detection of breast cancer can be considered as leading to an improvement of the postoperative quality of life (QOL) of the patients. In Tokushima Prefecture, mammographic screening has been carried out since 1992, and a high detection rate of breast cancer has already been reported.[10, 11]

In this paper, we deal with the optimal age of subjects and the effectiveness of screening mammography, based on our results. System I of mammographic screening employed mammography and physical examination separately in the visit screening, and system II employed them in combination in central screening. There was a difference between the two systems in the mammographic units and the age distribution of subjects. Therefore, we can not directly compare the results of the two mammographic screening systems. In both systems, both the detection rate of breast cancer and the sensitivity of screening were higher than that obtained in conventional screening by physical examination alone. The detection rate of breast cancer was high because there seemed to be many first-time examinees in the two screening systems, i.e., 83.8% and 82.8%, respectively. With regard to the detection rate as a function of age, it was 5–8 times higher than that of screening by physical examination in the sixth and seventh decades of life. Further, regarding the sensitivity of mammographic screening as a function of age, higher sensitivity than that with screening by physical examination only was obtained in those aged over 50 years. In the study of Wolfe's classification of mammograms related to the breast parenchymal pattern, the proportions of DY pattern, which seems to exert a strong influence on the mass shadow, were remarkably age-dependent, being 3.2% in the sixth decade and 0.8%

in the seventh decade, compared with 16.6% in those aged under 49 years. In Miyagi Prefecture, a trial of mass screening for breast cancer using combined physical examination and mammography has been carried out on women aged over 50 years,[8,9] and the detection rate of breast cancer was elevated to 0.31% by the concomitant use of mammography, compared with 0.08% by physical examination alone. The proportion of early-stage breast cancer increased from 39% to 73%. Moreover, the false-negative rate by physical examination combined with mammography was 2.8%, which was significantly lower than that (33.3%) by physical examination alone. Ohuchi *et al.*[9] supported the usefulness of mammography as an appropriate modality for breast cancer screening in women aged over 50 years. It can also be concluded from our present results that, based on studies of the detection rate, screening sensitivity and Wolfe's classification of mammograms by age, mammographic screening, with mammography and physical examination either separately or in combination, is suitable for women aged over 50 years in Japan, as is the case in other countries.

The recall rates (rate of request of further detailed examinations) of the two systems of mammographic screening were 9.2% and 7.1%, respectively, which are higher than those reported in the United States and Europe, i.e., 2.9–6.2% (median 4.6%).[1,2] Further, the proportions of ductal carcinoma *in situ* (DCIS) among the cancers detected in our study were 26.7% and 33.3%, respectively, which are higher than the values of 8.4–18.9% reported abroad.[1,2] The reason why the proportion of DCIS was high is considered to be our high recall rate. Accordingly, the definition of an appropriate recall rate should be studied further.

It has been demonstrated in the United States and Europe that breast cancer screening using mammography is effective in reducing the mortality of subjects aged over 50 years.[1-4] Using our present data, the proportions of early-stage cancers and absence of nodal involvement were compared with the results of mammographic screenings in the United States and Europe. The proportion of stage I was 60% in system I and 66.7% in system II, which are higher than that of 31.8% found by conventional screening using physical examination alone. Those rates are also comparable to or higher than the percentages reported abroad, 32–65%.[1,2] The proportions of DCIS were higher in both systems, being 26.7% and 33.3%, respectively, compared with the values of 8.4–18.9% reported in the United States and Europe.[1,2] Further, the proportions of no involvement of lymph nodes were high, being 77.8% in system I and 83.3% in system II, compared with 59% for screening by physical examination alone. Thus, our results with mammographic screenings were better than those (57–71%) reported abroad[1,2] (Table VI). Furthermore, breast-conserving therapy was applied to 18 of the 24 patients with breast cancer detected by both systems (application rate: 75%). Thus, it was considered that early-stage breast cancer can be detected by mammographic screening, which is useful for improving the postoperative QOL. Accordingly, the effectiveness of breast cancer screening by physical examination alone seems relatively poor, but based on the results obtained in this study, we consider that mammographic screening, with mammography and physical examination either separately or in combination, is effective for women aged over 50 years in Japan, as well as in other countries. However, with regard to those aged under 49 years, further studies are needed.

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