Screening Mammography in Finland — 1.5 Million Examinations with 97 percent Specificity

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A nationwide mammography screening program including women aged 50–59 years at the time of the first invitation and involving more than 100 radiologists was started in Finland in January, 1987. From 1987 through 1997, a total of 1690496 invitations to biennial two-view mammography screening was sent out. The compliance for screening was 88.5% with 1 495744 screening examinations performed during this 11-year period. There were 49020 recalls (3.28% of those attending) for further work-up studies and 9689 women (0.65% of those attending) were referred for surgery. The total number of screening-detected breast cancers was 5595, giving a detection rate of 3.7 cancers per 1000 screening studies. More than half (57.7%) of all surgical biopsies revealed breast cancer and 67.8% of the invasive cancers were at Stage I. The positive predictive value of referral to surgical biopsy increased from 33.2% in 1987 to 65.5% in 1997, and the ratio of malignant to benign biopsies more than tripled from the first to the fifth year of screening. The observed/expected ratio of invasive cancer detection was 2.44. Only 0.27% (1 out of every 372) of all screening mammograms were followed by a benign biopsy, and 2.90% (1 out of every 34) of all screening mammograms were followed by the women being recalled for further studies and not found to have breast cancer. This gave a specificity of recall after screening mammography greater than 97.0% and a specificity of referral to surgical biopsy greater than 99.7%. Measures of specificity improved considerably during the first three years of the screening program. The high specificity of screening mammography can be attributed to the nature of the screening process as well as to the opportunity for individual radiologists to attain a greater level of experience and competence. The decision to recall appears to have been crucial in determining the specificity.

The success of mammography screening in reducing breast cancer mortality by 30% (1–4) led to a demand for nationwide mammography screening in Finland (population 5.0 million). Although Finland had a relatively low age-specific breast cancer incidence and mortality in 1985, breast cancer was already the most common cancer and leading cause of death from cancer in women (5). The decision to begin screening was made in November 1986, with the project set to start at the beginning of 1987, less than two months later (6). On this short notice, the nationwide program to screen all women aged 50–59 years (total 275000 women) at 2-year intervals was put into action.

MATERIALS AND METHODS

The nationwide screening program was initially financed by the national government but was administered at the community level. All women aged 50–59 years were sent their first invitation to free-of-charge screening by the end of 1991. Biennial screening began in January 1987 with three birth-year cohorts screened that year; the addition of new birth-year cohorts is shown in Table 1 (6). Women who turned 60 years continued to receive invitations to screening through 1991, but thereafter the decision to finance screening of the birth-year cohorts older than 59 was made at the community level based on local financial and political pressures, with considerable variation among the 452 communities. Some communities invited women older than 60 years on a self-paying basis and some continued to invite on a free-of-charge basis. Only those women invited on a free-of-charge basis are included in this study.

Two-view (craniocaudal and mediolateral oblique) screen-film mammograms were performed as the primary and only screening examination. All screening mammograms were reviewed by two radiologists. Those women selected for further studies were recalled for one or more of the following examinations: repeat mammography with additional views, microfocus magnification mammography without and/or with coned-down spot views, breast palpation, breast ultrasound, galactography, pneumocystography, fine-needle aspiration biopsy, and core needle biopsy.

If it was not possible to exclude breast cancer with these additional examinations, the women were referred for surgery. The number of women with breast cancer detected through screening and operated on, and the number of women undergoing surgery without breast cancer being detected (benign biopsy) were recorded, as was the number of women who did not undergo breast surgery despite the recommendation from the screening center. The size and stage of the breast cancers were recorded.

The data presented here have been collected annually since 1987 by the radiologists in charge of each of the mammography screening centers, and have been reported to one of the authors (MP) under the auspices of the Mammography Working Group of the Radiological Society of Finland. Some reports have been made earlier of the collected data (7–11). The Finnish mammography screening program provides the opportunity to evaluate the performance of mammography screening on a large scale with a heterogeneous structure of screening centers, since most screening work is performed by centers in which the radiologists had initially limited experience in diagnostic mammography and few had any experience in mammography screening.

Because training was not included in the Finnish mammography screening program, the Radiological Society of Finland invited Professor László Tabár to give a series of teaching courses in mammography and mammography screening. Simultaneous courses for technologists were also arranged. In a country with approximately 350 practicing radiologists in 1986, 240 attended the introductory courses and 140 attended the screening courses. Half of these courses were held in 1987 after nationwide screening had already begun. The courses were attended by most (but not all) of the radiologists who participated in the screening programs.

Fifty screening centers were set up to cover the country, most of them under the auspices of either the national cancer society or the former tuberculosis screening organization. Up to 17000 women were screened yearly in a single center, the median number being about 2600 examinations annually per center. It was necessary to negotiate the contracts for screening with the local government officials on a yearly basis in each of the 452 communities. In the majority of cases these contracts were renewed by the organization having performed the previous years screening, but continuity of screening was not guaranteed to any particular organization.

The 50 screening centers were not all in operation for the entire 11-year period, and 7 of these centers carried out fewer than 1000 screening examinations each. Approximately 100 radiologists worked at the remaining 43 screening centers, mostly working evenings and weekends on a fee-for-service basis. Only four full-time screening positions have so far been established by the cancer society, and by 1997 there were another 17 radiologists screening in public hospitals as part of their regular duties. The remaining screening centers are located in small private clinics. This is in striking contrast to the situation in Sweden, The Netherlands and the UK, where screening is performed in large, hospital-based centers by radiologists as a full-time occupation, and where breast surgery is generally performed in the same hospitals.

The data reported here have been collected by the individual radiologists responsible for each screening center, with no differentiation between prevalent cancers detected in the first screening examination and incident cancers detected in subsequent screening examinations. Women whose breast cancers were detected outside of the screening program have not yet been identified, nor are data on interval cancers and cancers in non-participants yet available for analysis.

RESULTS

The number of women invited, those participating in screening, recalled for further diagnostic studies, referred for operative biopsy, and the number of biopsies per-

Table 1

Mammography screening in Finland 1987–1997. Distribution of birth year cohorts invited to biennial screening

Screening year	Calendar year	Consecutive numbering of screening rounds for each birth year cohort																			
		1928	1929	1930	1931	1932	1933	1934	1935	1936	1937	1938	1939	1940	1941	1942	1943	1944	1945	1946	1947
1st	1987	1				1				1											
2nd	1988			1				1				1									
3rd	1989	2			1	2				2	1										
4th	1990			2			1	2	1			2	1								
5th	1991	3	1		2	3				3	2			1	1						
6th	1992			3			2	3	2			3	2			1					
7th	1993	4	2		3	4				4	3			2	2		1				
8th	1994			4			3	4	3			4	3			2		1			
9th	1995	5	3		4	5				5	4			3	3		2		1		
10th	1996			5			4	5	4			5	4			3		2		1	
11th	1997	6	4		5	6				6	5			4	4		3		2		1
Mean age, first screen		59	62	58	58	55	57	54	55	51	52	50	51	51	50	50	50	50	50	50	50

Table 2

Mammography screening in Finland: annual results of 11 years, 1987–1997

Screening year	Invited	Participated	Percentage of invited	Recalled	Percentage of participated	Referred for surgery	Percentage of participated	Breast cancer	Percentage of participated	Benign histology	Percentage of participated	Referred for surgery No operation	Percentage of participated
1987	64 471	57 375	89.0	2 724	4.75	653	1.14	217	0.38	432	0.75	4	0.007
1988	87 035	77 532	89.1	3 496	4.51	644	0.83	282	0.36	358	0.46	4	0.005
1989	129 651	11 5061	88.7	3 778	3.28	742	0.64	397	0.35	341	0.30	4	0.003
1990	150 185	133 090	88.6	4 236	3.18	813	0.61	433	0.33	377	0.28	3	0.002
1991	186 680	164 319	88.0	5 050	3.08	1 035	0.63	623	0.38	397	0.24	15	0.009
1992	160 496	143 580	89.5	3 871	2.70	743	0.52	472	0.33	264	0.18	7	0.005
1993	173 457	152 935	88.2	4 249	2.78	908	0.59	555	0.36	347	0.23	6	0.004
1994	163 873	144 482	88.2	4 463	3.09	904	0.63	537	0.37	358	0.25	9	0.006
1995	186 820	165 512	88.6	6 030	3.64	1 078	0.65	680	0.41	387	0.23	11	0.007
1996	181 896	161 452	88.8	5 444	3.37	1 043	0.65	661	0.41	381	0.24	5	0.003
1997	205 932	180 506	87.7	5 679	3.15	1 126	0.62	738	0.41	377	0.21	11	0.006
1987–97	1 690 496	1 495 744	88.5	49 020	3.28	9 689	0.65	5 595	0.37	4 019	0.27	79	0.005

formed (breast cancer detected, benign findings) and biopsies recommended but not performed are presented on an annual basis in Table 2, along with total values for the 11-year period 1987–1997. The participation rate has remained at around 89%. The recall rate decreased from an initial 4.7% to 3.3% during the first three years, with little change in subsequent years. The biopsy referral rate underwent a similar decline from 1.14% to 0.64% during the first three years, with little variation thereafter. This decrease in the biopsy referral rate reflects the remarkable decrease in the rate of benign biopsy over the first three years, whereas the rate of cancer biopsy changed little throughout the 11-year period (Fig. 1).

The positive predictive value (PPV) of surgical biopsy (ratio of cancers detected per operation) increased during the first five years from 33% to 60% (Fig. 2). During the 11-year period of screening more than half (57%) of all surgical biopsies revealed breast cancer, and during the last seven years of screening more than 62% of all screening-initiated operations were for breast cancer. The ratio of malignant to benign biopsies more than tripled from the first to the fifth year of screening, and had nearly quadrupled by the eleventh year (Fig. 3, Table 3).

The stage distribution of breast cancers detected clinically (before the era of screening) has been carefully documented in Helsinki during the years 1951–1980, with three-quarters (75.2%) of the invasive cancers Stages II–IV (Fig. 4A) (14). The stage distribution of the breast cancers detected through screening (in 5595 women) is given on an annual basis in Table 4. Of the invasive cancers detected at screening, two-thirds (67.8%) were Stage I tumors (Fig. 4B).

The risk of being recalled for further work-up without cancer being detected was only 2.9% (1 out of every 34 women screened) and the risk of undergoing a benign biopsy was less than 0.3% (1 out of every 372 women screened) (Table 2). Fewer than 20% (19.77%) of those women recalled for further work-up were actually sent to surgical biopsy (Table 3). Probabilities for some of the more important events (risks) associated with screening are summarized in Table 5.

Specificity requires knowledge of false-negatives, which is not yet available to us since data on interval cancers have not yet been identified. However, false-negative results will have an extremely small effect on the specificity. For example, the specificity of recall for further studies will change by only 0.011%, depending on whether we assume that there would be no false-negatives (97.086%) or that the number of false-negatives would equal the number of cancers detected (97.075%). Correspondingly, the specificity of referral for operation is greater than 99.7%, even if we were to assume that as many cancers were missed as were detected. Since the majority of all the breast cancers detected in Finnish women aged 50–59 years was detected

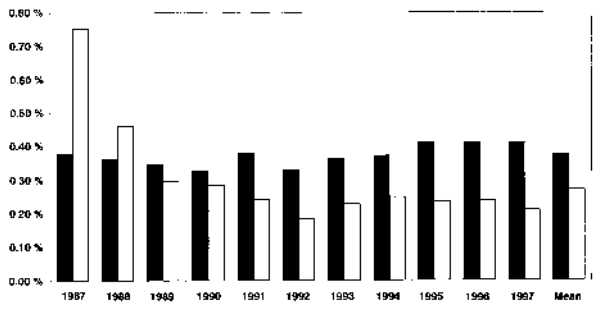

Fig. 1. Percentage of women screened who underwent screening-initiated surgical biopsy revealing malignant (black) and benign (white) pathology.

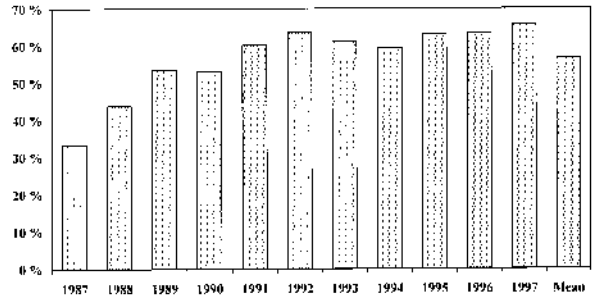

Fig. 2. Positive predictive value (PPV) of referral to surgical biopsy after work-up of mammography screening findings.

through screening (12), the number of false-negative cases must be smaller than the true-positive cases. Thus the specificity of recall after screening mammography is greater than 97.0% and the specificity of referral to surgical biopsy is greater than 99.7% (Fig. 5, Table 6).

The average incidence of breast cancer among women aged 50–59 was calculated for the years 1980–1985 for each of the 21 central hospital districts, using data obtained from the Finnish Cancer Registry (13). The year 1986 was not included in this calculation of baseline (prescreening) breast cancer incidence, as a number of communities began large-scale breast cancer screening in that year. The average nationwide incidence of breast cancer was 1.367 per 1000 women aged 50–59 during the years 1980–1985. The rate of invasive breast cancer detection through screening for each screening center was divided by the baseline breast cancer incidence value for the corresponding healthcare district in which the women resided in order to obtain an observed/expected ratio of invasive cancer detection, which averaged 2.44 over the 11-year period (Table 3). This can be interpreted as an approximately 2.4-year lead time advantage resulting from the screening program, compared to the prescreening situation.

DISCUSSION

Population screening is practiced in several European countries, including Sweden, Finland, the UK, Iceland, The Netherlands, Denmark and Norway, but has still reached only a small minority of European women at risk for breast cancer. It has been most effectively practiced in Sweden, where excellent sensitivity and high specificity results have been reported.(15, 16) Mammography screening, as practiced in many Western countries, includes patients referred for breast symptoms (clinical mammography) and asymptomatic women who have been referred by their physicians for mammography (case finding) or who have sought mammography through their own health awareness. This is in contrast to population screening, where entire populations of women of a defined age are offered mammography at regular intervals. By its very nature, population screening leads to a lower sensitivity and higher specificity since most women in a population are asymptomatic.

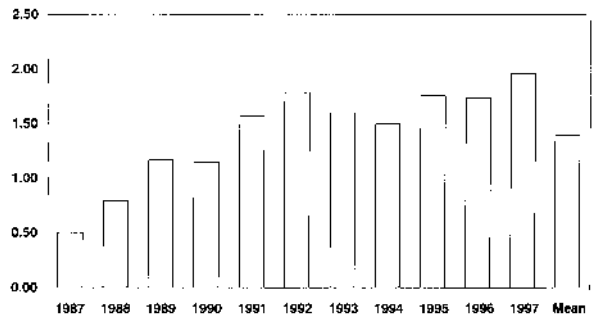

Fig. 3. Ratio of malignant to benign biopsies initiated through mammography screening.

Another factor leading to higher specificity is training and experience. Table 6 clearly documents the increase in specificity occurring in our program over the first three years, an increase which can be attributed to accumulated experience in screening, allowing individual radiologists to attain a greater level of experience and competence. The greater availability of previous mammograms at later studies is also a contributing factor to the improved specificity. Equally relevant measures of specificity are the ratio of malignant to benign operations (Fig. 3, Table 3) and the positive predictive values of recall and referral to biopsy (Fig. 2, Table 3).

The ratio of biopsies vs. recalls (PPV of surgical biopsy/recalled, Table 3) remained nearly unchanged, indicating that the decision to recall a suspicious mammogram was the most crucial factor affecting specificity.

From the perspective of the woman undergoing screening, recall for further studies causes anxiety, discomfort and, occasionally, needle biopsy, which is relatively minor in comparison to the harm caused by surgical biopsy. We maintain that the frequency of benign surgical biopsy (0.27%) is a more realistic measure of the harm caused by mammography screening than is the frequency of recall for further examinations (3.28%). The false-positives of the full diagnostic work-up are an undesirable but necessary evil; they represent the price paid for maximizing the number of small cancers detected. Women undergoing benign surgical biopsies thus represent the most realistic measure of the false-positives of the screening process, since the actual harm (physical and emotional) of being recalled for additional mammograms, breast ultrasound, needle biopsy, etc., is much less than the harm of a surgical biopsy.

With fewer than 0.3% of all screening studies leading to a benign surgical biopsy, the harm caused by mammography screening can be regarded as truly minimal. Clinical mammography and case finding, as described above, have

Table 3

Measures of the effectiveness of mammography screening

Screening year	PPV	PPV	PPV	Ratio of malignant to benign biopsy	Observed/ expected	BC detection ratio
	Surgical biopsy/ recalled(%)	BC recalled (%)	BC/referral for surgery (%)		All cancers	Invasive cancers
1987	23.97	7.97	33.2	0.50	2.77	2.49
1988	18.42	8.07	43.8	0.79	2.66	2.44
1989	19.64	10.51	53.5	1.16	2.52	2.24
1990	19.19	10.22	53.3	1.05	2.38	2.15
1991	20.50	12.34	60.2	1.57	2.77	2.46
1992	19.19	12.19	63.5	1.79	2.40	2.12
1993	21.37	13.06	61.1	1.60	2.65	2.41
1994	20.26	12.03	59.4	1.50	2.72	2.37
1995	17.88	11.28	63.1	1.76	3.00	2.70
1996	19.16	12.14	63.4	1.73	2.99	2.65
1997	19.83	13.00	65.5	1.96	2.99	2.62
1987–1997	19.77	11.41	57.7	1.39	2.74	2.44

a higher rate of false-positives, as was documented in a recent controversial report with a false-positive rate of 6.5% per mammography examination.(17) Their suggestion that 'radiologists in the United States are interpreting too many mammograms as abnormal' misses the point. The differences are not a question of geography. Specificity improves with experience and can be optimized in a large-scale mammography screening program, but such programs are still a rarity in the United States. This is illustrated in that there were approximately 93 radiologists reporting 9762 'screening' mammograms in the 10-year study by Elmore et al. (17), but in our 11-year study approximately 100 radiologists reported 1495744 mammograms. This emphasizes the important and often overlooked distinction between high-volume population screening and mammography of clinically referred patients.

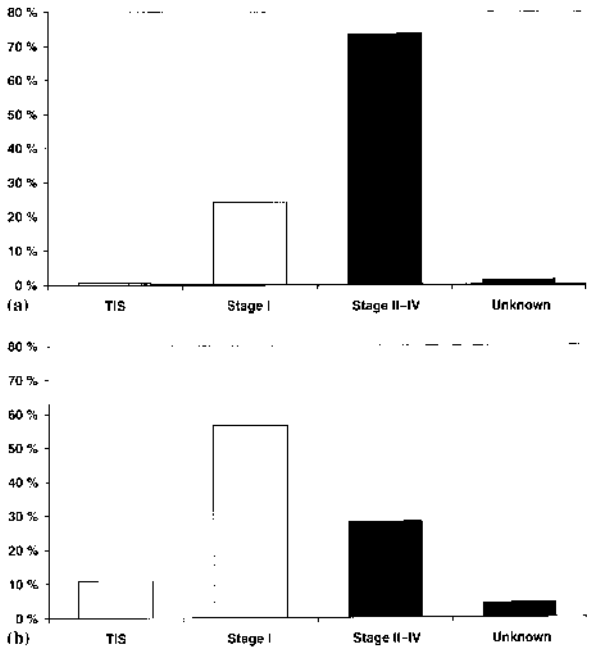

Fig. 4. A: Clinically detected breast cancer, stage at operation, Helsinki, 1951–1980 (data from Saario et al. (15)). B: Screening-detected breast cancer, stage at operation, Finland, 1987–1997.

An important factor for the high specificity and sensitivity is also the double reading of all the mammograms. Double reading with consensus decisions can decrease the number of recalled women by 45% and increase the number of detected breast cancers by 9% (18).

A significant reduction of 24% (95% CI = 0.53–1.09) in breast cancer mortality has already been demonstrated using the results of the Cancer Society covering only the first three years of screening in Finland followed up through the end of 1992 (19). The control group consisted of women in age cohorts not yet invited to screening. Since all age cohorts had been invited by the end of 1991, this demonstration of mortality reduction cannot be repeated, as there is no longer a control group of unscreened women in the age groups from 50 and over. Our study, on the other hand, is a quantitative analysis of the screening-detected breast cancers and of the efficiency with which the radiologists succeeded in detecting them.

The false-negatives are a serious issue as the potential benefits of the entire screening process remain unrealized if a detectable breast cancer is not actually detected and removed surgically. The low recall and biopsy rates could be responsible for a small number of missed cancers, but increasing the percentage of women sent to surgery is an inefficient mechanism for increasing the number of true-positives (20). A more efficient approach to increasing the sensitivity of screening is the continuing education of the personnel involved in screening, in particular the radiologists interpreting the screening mammograms. Competence in mammography screening is

Table 4

Stage distribution of the breast cancers detected at screening

Screening year	Stage 0 TIS	Percent	Stage Ia ≤10 mm	Percent	Stage Ib–c 11–20 mm	Percent	Stage II–IV	Percent	Stage unknown	Percent	Total number
1987	22	10.1	56	25.8	57	26.3	72	33.2	10	4.6	217
1988	23	8.2	81	28.7	62	22.0	94	33.3	22	7.8	282
1989	45	11.3	107	27.0	99	24.9	124	31.2	22	535	397
1990	42	9.7	136	31.4	129	29.8	106	24.5	20	4.6	433
1991	70	11.2	162	26.0	215	34.5	161	25.8	15	2.4	623
1992	55	11.7	138	29.2	158	33.5	100	21.2	21	4.5	472
1993	52	9.4	173	31.7	164	29.5	152	27.4	11	2.0	555
1994	68	12.7	153	27.5	129	24.0	167	31.1	20	3.7	537
1995	69	10.1	233	34.3	149	21.9	189	27.8	40	5.9	680
1996	75	11.3	193	29.2	160	24.2	201	30.4	32	4.8	661
1997	92	12.4	225	30.6	184	25.0	210	28.4	27	3.5	738
1987–97	613	11.0	1 660	29.7	1 506	26.9	1 576	28.2	240	4.3	5 595

beyond the scope of any radiology residency program and currently taught in a few fellowship programs, nor is mammography screening currently a popular subject for continuing medical education courses. Since there is a wide range in the competence of radiologists performing mammography screening (21), continued training and self-evaluation are likely to lead to improved results in terms of both specificity and sensitivity (22). Our data confirm the improvement in specificity that has taken place during the first 3–5 years of the program, a type of 'learning curve'. In the absence of data on false-negative results, we are unable to confirm any improvement in sensitivity with experience, although such an improvement is likely to have occurred.

The Finnish screening program lacks several quality assurance programs integral to the European Guidelines (23): a formal teaching program with established teaching centers to achieve and maintain a high standard quality of screening, a mechanism for the review and audit of interval cases, and obligatory quality control standards. Annual competitive bidding hinders the continuity of screening by the established centers, and the emphasis on low bids rather than upon the quality of the screening centers further hinders achievement of optimal screening results.

Many of the lessons we learned from screening cannot be proven with the data collected here. The centers that have been set up with a long-term commitment have performed well. Collection of the results of surgery presented here has been extremely laborious, as most patients underwent surgery in hospitals not associated with the screening centers, and recent patient privacy legislation has further complicated this process. The training given to radiologists has been considered very useful but an extended period of training (several months) would undoubtedly have been better. The self-evaluation performed annually has been well-received, but there has been no mechanism for improvement of the performance in the few screening centers whose performance has been well below the national average. Peer pressure and the circulation of annual results for each screening center to all the screening centers has been moderately effective in persuading some of the less competent radiologists to discontinue screening.

Table 5

Risk (probability) of the following events after every mammography screening examination

1 per 31	(0.03277)	Recall for additional work-up
1 per 34	(0.02903)	Recall for additional work-up, no breast cancer detected
1 per 38	(0.02644)	Recall for additional work-up, no recommendation for surgery
1 per 267	(0.00374)	Breast cancer operation
1 per 365	(0.00274)	Recommendation for surgery, but breast cancer not detected
1 per 372	(0.00269)	Operation, no cancer detected
1 per 731	(0.00137	Annual risk of breast cancer prior to screening, women aged 50–59
1 per 19342	(0.00005)	Biopsy recommended, but no operation performed

Note: each number in parentheses is the probability of the corresponding event.

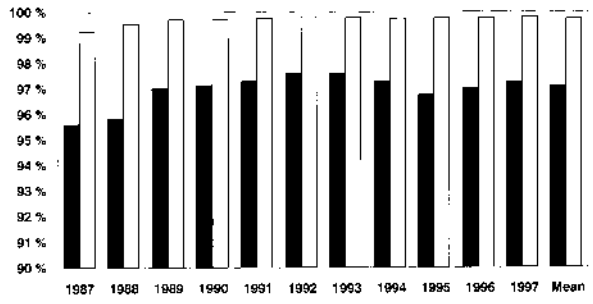

Fig. 5. Specificity of recall (grey) and specificity of surgical biopsy (white) after mammography screening.

Table 6

Specificity of screening assuming that the number of false-negatives (FN) is either equal to 0 or equal to the number of false-positives (FP)

Year	Specificity of recall	Specificity of recall	Specificity of referral to biopsy	Specificity of referral to biopsy
	FN = 0	FN = TP	FN = 0	FN = TP
1987	0.95614	0.95597	0.99237	0.99234
1988	0.95839	0.95824	0.99531	0.99530
1989	0.97051	0.97041	0.99699	0.99698
1990	0.97133	0.97124	0.99714	0.99713
1991	0.97294	0.97284	0.99748	0.99747
1992	0.97625	0.97617	0.99811	0.99810
1993	0.97576	0.97567	0.99768	0.99767
1994	0.97273	0.97262	0.99745	0.99744
1995	0.96754	0.96741	0.99759	0.99758
1996	0.97025	0.97013	0.99762	0.99761
1997	0.97251	0.97240	0.99784	0.99783
1987–97	0.97086	0.97075	0.99725	0.99724

The Radiological Society of Finland began a new series of mammography screening teaching courses for radiologists in 1996. A screening examination is also included in these courses, with certificates awarded to those with successful performance, but the examination has not yet been officially accredited by the government health authorities. Despite suboptimal working conditions, the program has been enthusiastically carried out by many dedicated radiologists.

SUMMARY

Mammography screening in Finland has produced an early reduction in breast cancer mortality (16) along with the high specificity associated with population screening programs. There is at present no consensus on whether the specificity of screening should be measured on the number of women recalled for additional mammographic images and other diagnostic procedures, or whether it should be restricted to those women sent to surgery, and there are valid arguments for both measures. In the absence of extended training in screening mammography, the first two years of the screening program served as a training period for the improvement of specificity to nearly the current levels. The decision to recall appears to have been crucial in determining the specificity. The commitment to screening by the responsible government officials reflects an understanding that breast cancers diagnosed and removed when still small and impalpable will have a significantly better prognosis than breast cancers that are allowed to grow to a size large enough to be palpated.

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