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THE GENERAL MAMMOGRAPHY SCREENING PROGRAM IN STOCKHOLM

Organisation and first-round results

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This presentation describes the organization and first-round results of the Stockholm mass mammography screening program, and discusses ways of checking the quality of an ongoing screening program. The Stockholm mammography screening program started in 1989 at five independent screening units, and comprises more than 150 000 women aged 50 to 69 years. The first round was completed in June 1991. Compliance during the studied period was 70.6%, and the recall rate was 3.0% of the attending women. Breast cancer was diagnosed in 676 women, of whom 90 (13.3%) had a cancer in situ. The cancer prevalence rate was thus 6.3 cancers per 1 000 screened women. Surgery was performed on 925 women, of whom 249 had benign lesions, giving a benign/malignant ratio of 0.37 to 1. Fifty-two per cent of the cancer patients were operated with breast conserving surgery. The median size of the invasive cancers was 12 mm; almost 80% were node-negative. Experience from the first two years of this mass mammography screening program shows that it meets the major quality requirements. One of the main future goals is to maintain the high quality of the program. Another important goal is a further increase in compliance.

Several randomized mammography screening studies (1–4) have demonstrated an ability to decrease breast cancer mortality among women aged 50–69 years. In the recently published overview of Swedish randomized trials, a reduction of breast cancer mortality by 29% was observed among women aged 50–69 years at randomization (5). Results from the 'two-county' study (2) formed the basis for Swedish guidelines on mammography screening published by the National Swedish Board of Health and Welfare in 1986 (6). In December of the same year, the Stockholm County Council decided to introduce general mammography screening for women aged 40–74 years. In 1988, the recommendations were supplemented with advice to give priority to screening of women aged 50–69 at 24-month intervals. When planning the mammography screening program efforts were made to establish all the links in the long chain of examination and treatment of selected women before starting up. Experience from the 'two-county' study (2) was used to calculate the need for clinical mammography, cytology, surgery and postoperative treatment.

Stockholm County is divided into 5 districts, each with an independent screening unit. One of the units (The South Hospital) started a randomized mammography screening trial in 1981 (7) and this was completed in 1985, after which date the control group was also screened. As the Stockholm general mammography screening program started in August, 1989, the screening unit at the South Hospital thus performed its fifth round of 'incidence' screening and the other four units their first round of 'prevalence' screening. The first combined round was completed in June, 1991.

This presentation describes the organization of this large-scale screening program, presents the combined re-

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sults from the first round and discusses ways of checking the quality of an ongoing screening program.

Material and Methods

The Stockholm mammography screening program was decided to start screening women aged 50–69 years, with a screening interval of 24 months. Of the five screening units in the region, only one (the South) had previous experience of screening, and the others of clinical mammography only. Training programs for radiologists and radiographers were run half a year before starting of the screening program.

The Stockholm population register provided the basis for inviting women to the screening activities. This register is ordered as per the personal identification number, i.e. a unique 10-digit code used for all inhabitants in Sweden. The population register yielded 152 790 women between 50 and 69 years of age in Stockholm County. With a 24-month invitation interval, around 75 000 women a year were invited to screening at one of the five units.

The calling system was fully computerized. Once a year, all women in the present age group (including those who would turn 50 during the year) were retrieved from the population register, which contains all individuals in Stockholm County and is updated regularly for deaths and changes of address. The retrieved group of women formed the Mammography Register, which was also updated regularly.

Each screening centre designed a schedule for the number of women invited during a defined period, assuming 70–80% compliance. During the first year, women born on days 1–15 of a month were invited to screening, whereas those born on days 16–31 were screened during the second year. The screening was performed during 40 weeks of each year and it took about 3–4 weeks to complete one day of birth.

Each woman received a personal invitation, mailed to her home address, stating the date and time of an appointment. The letter included a short questionnaire about previous breast disease and present breast abnormalities as lumps, secretion or skin changes. The women were offered a possibility to rebook the appointment. The computerized booking system made this rebooking simple.

For the sake of simplicity, all invited women were pre-coded 'examined without abnormalities'. Non-attenders were then re-coded, including the reason for not attending for those who informed the unit. Attenders judged as normal at the screening examination, being the majority of women, were thus already registered as normal. Those women received a personal letter, not more than one week after the examination, telling them that no signs of malignancy had been detected on their mammograms but that they should contact their physician should they notice any symptoms before the next screening round.

Mammography. In the four units that performed 'prevalence screening', a baseline two-view examination was made. In the South unit, performing 'incidence screening', a single oblique view was taken, except in women with very dense breasts, who underwent a two-view examination. All units had a double reading system with two experienced radiologists independently evaluating the mammograms.

Follow-up. Attenders in whom a lesion was found on the mammograms or who had an anamnestic indication of a lump were referred for complete mammography. For these women a follow-up form was used. All women who still had a pathological finding after the complete mammography were referred to the department of oncology or surgery, the majority of them within a week. Women with breast cancer were treated in accordance to guidelines used by the Stockholm Breast Cancer Study Group, a region-wide program covering all five centres.

The data were sent on tape, one week at a time, to the Oncologic Centre for Stockholm, at the regional cancer register. The follow-up form included the results of the screening examination, type of FNA biopsy, cytology, surgery and pathology, and were, when completed, sent to the Centre. To evaluate the quality of the screening program, the database at the Oncologic Centre continuously produced lists on the outcome, i.e. number of women examined and selected, results of examinations, and type of treatment. The results were presented for each screening unit as well as for the whole region, the latter for comparisons of quality between the units. No women were lost to follow-up since all women with mammographic or clinical pathological findings had to be presented with a follow-up form. Lists on women, on whom no follow-up forms had been received by the Oncologic Centre, were regularly sent to the screening units. The screening database will be matched annually with the Regional Cancer Register and the National Cause-of-Death Register for detection of interval cancers and of deceased subjects. Since it takes about two years to complete one year at the cancer register, no such matching has been made as yet.

Results

A breakdown of the total study population is given in Table 1. During the period of the first round, July 1, 1989, to June 30, 1991, nearly 153 000 women were invited to screening, 70.6% attended and 3.0% were recalled for complete mammography.

Invasive breast cancer was diagnosed in 586 women, and non-invasive carcinoma (CIS) in 90 women. Bilateral invasive cancer was found in 9 women. The number of cancers in the total group was 6.3 per 1 000 screened women of which 5.4 were invasive and 0.83 CIS. As expected, the cancer detection rate was lower in the South unit, 4.1 (invasive and CIS), where 'incidence' screening was per-

Table 1

Study population

	Prevalence screening units (n = 4)		Incidence screening units (n = 1)		All units	
	No.	%	No.	%	No.	%
No. invited	103 754		49 036		152 790	
No. examined	71 085	(69)	36 842	(75)	107 927	(71)
No. recalled due to mammographic findings	2 377	(3.3)	482	(1.3)	2 859	(2.6)
No. recalled due to clinical findings	257	(0.36)	86	(0.23)	343	(0.32)
No. referred to the clinician for further investigations	1 406	(2.0)	299	(0.81)	1 705	(1.6)
Prevalence of cancer/1 000 screened women	7.4		4.1			6.3
Breast conserving surgery (%)	50		58		52	
Median size invasive cancer (mm)	12		12		12	
Lymph node invasion (%) in invasive cancer	20		23		21	
CIS (%)	13		16		13	
Benign-to-malignant biopsy rate	0.41 to 1		0.23 to 1		0.37 to 1	

formed (Table 1). The cancer detection rate (invasive and CIS) in the other four regions was 7.4 per 1 000 in the first screening round. A comparison between the unit performing 'incidence' screening and the four units performing 'prevalence' screening concerning attendance rate, recall rate, cancer detection rate, percentage breast preserving surgery, median tumor size, lymph node invasion, detection rate of CIS, and benign/malignant surgery ratio, is shown in Table 1. Fine-needle aspiration biopsy (FNA) of both non-palpable and palpable lesions, the former with stereotaxic equipment, gave a cancer diagnosis in 65% of the cancer cases (Table 2). The results of FNA, clinical decision and pathology related to type of FNA are shown in Table 2.

Surgery was performed in 925 women. Of these, 249 had benign lesions and 676 had invasive cancer or CIS, giving

Table 2

Results of fine-needle aspiration biopsy (FNA) (n = 1 654), clinical decision and pathology results. No. of women = 1 574

	Fine-needle aspiration biopsies			
	Total (n = 1 654)	Palpable (n = 632)	Stereotaxic (n = 1 007)	Ultrasound (n = 15)
No. of women = 1 574				
Not evaluable	177	19	157	1
Benign or normal	865	295	561	9
Atypical cells	173	62	109	2
Cancer	439	256	180	3
Clinical decision				
No follow-up	452	166	283	3
Clinical follow-up	250	67	176	7
Diagnostic biopsy	459	122	335	2
Definite cancer surgery	490	275	212	3
Refuses op	3	2	1	0
Pathology results (946 operations on 925 women)				
Benign (249 women, 11 bilateral)	260	57	202	1
CIS (90 women, 1 bilateral)	91	11	80	0
Invasive cancer (586 women 9 bilateral)	595	326	265	4

Table 3

Axillary lymph node status related to size of cancer

	Total number	Number of lymph node metastases			Tumours (%) with axillary metastases (%)
		0	1–3	>4	
Invasive cancer	586	466	80	40	20.5
⩽10 mm	244	219	21	4	10.2
11–20 mm	257	202	38	17	21.4
⩾20 mm	80	43	18	19	46.3
unknown size*	5	2	3	0	
CIS	90				
Invasive cancer and CIS	676				

* Multiple cancers, size impossible to measure

a total benign-to-malignant ratio of 0.37 to 1. Six women refused surgery despite pathological findings on their mammograms. No cases were considered inoperable. Of the cancer patients, including CIS, 52% were operated with breast conserving surgery. This figure was higher in the South unit (Table 1). The median size of the invasive cancers was 12 mm, ranging from 1 mm to 70 mm. The proportion of node-negative invasive cancers was almost 80%. The percentage of axillary node-positive patients was 10.2% and 21.4% for invasive carcinomas <10 mm and 11–20 mm respectively (Table 3). Patients with tumors >20 mm had axillary node involvement in 46.3%. A total of 343 women, having normal mammograms were referred to further examination because of anamnestic information of a breast lesion, and among these women 11 cancers (1.6%) were found. Still 98.4% of the cancers were detected from suspicious lesions found on the mammograms.

Discussion

The present paper describes the organization of mass mammography screening in Stockholm and the results after the first round. One of the principal prerequisites for this population-based screening, covering more than 150 000 women, was the existence of the Stockholm population register, and the unique personal identification numbers that are used in all Swedish population statistics. With this register, no women were lost to follow-up. Five screening units undertook the screening program and the coordination between them was not a serious problem. Four of the five units started during 1989, the fifth in March, 1990.

The attendance rate in these two years was slightly more than 70%. It differed between the units, being higher at the South Unit. One likely reason for this difference is that many women living in the reception area of the other four units had already been examined on their own initiative. It seems reasonable to assume that some of these women chose to continue with this arrangement and ignored the invitation to the present screening program. In a study of the reasons for non-attendance in the Stockholm screening program, Lidbrink et al. (in manuscript) found that 32% of non-attenders were breast examined with mammography outside the program. Still, an attendance rate of 70% is by international standards high, though lower than rates reported in the Swedish randomized trials (2–4).

The main aim of this screening program was to detect early 'curable' breast cancers, thus decreasing the mortality. A second effect was to achieve a higher proportion of small tumours, thereby increasing the feasibility of breast-conserving surgery. Although this was mainly a prevalence screening, more than half of the cancer patients (52%) were operated on with breast-conserving surgery. This was a higher percentage than in the Stockholm trial (7), where breast-conservative surgery was performed in 28% in the study group, and in the Malmö trial (3), where 23.8% of all cancers (invasive and CIS) were operated with breast-conserving surgery and 3.5% (almost only CIS) with subcutaneous mastectomy, a method seldom used in Stockholm at that time.

Tabár et al. (8) have suggested that, with a screening interval of 33 months, as in the 'two-county study', at least 50% of the tumours should be less than 15 mm (median value). This was the result in their study of women over 50 years of age. In the present program, still mainly in its 'prevalence phase', the median size of the invasive cancers was 12 mm, ranging from 1 to 70 mm. The median tumour size, 12 mm, was the same in the units performing prevalence screening and in that with incidence screening (Table 1). One possible explanation for this fact is that many women in Stockholm, although not being offered screening mammography earlier, had underwent mammography before they entered the present program.

Another important aim of the present screening program was to detect the cancers before invasion of regional lymph nodes. According to Tabár et al. (8), the detection rate of axillary metastases should not exceed 30%, as was the case in the two-county study. In the present program, positive lymph nodes were found in 20.4% of the patients with invasive cancers, and among those with tumours 20 mm or larger 46.3% had lymph node metastases as

shown in Table 3. The number of positive lymph nodes ranged from 1–14, with a median of 3 affected nodes.

Of the 676 cancers, detected in the present program, 90 were CIS (13.3%), which is somewhat lower than the figure of 16% in the Malmö trial (3). In the Stockholm trial (4, 7) at the South Hospital the rate of CIS in the first round was 11.7%, and after two rounds 14.7%. Differences in the frequency of in situ tumours might be due to differences in the criteria used by different pathologists in the interpretation of the slides. It is claimed by those working with mammography screening that the rate of CIS should not exceed 15% in a screening program. Overdiagnosis of CIS will cause non-neglectable side-effects, such as unnecessary surgery and investigations, causing anxiety among the patients. The aim of a mammography screening program is rather to find invasive carcinomas in an early stage which was satisfactorily fulfilled in the present program. Whether finding a large number of CISs improves the overall effect of reducing breast cancer mortality remains still to be proven.

The initiation of a mass screening program, like the present one, involving more than 150 000 women, poses many management problems. First, every screening unit had to have at least two skilled radiologists and a sufficient number of experienced radiographers. In the present program, four of the five units started simultaneously. Lack of staff forced the fifth centre to start half a year later. The Oncologic Centre frequently provided reports on the latest statistics, as an important feedback. Regular meetings, with all responsible radiologists, surgeons, pathologists and oncologists from the five units, were held at the Oncologic Centre at least four times a year whereby all kinds of problems concerning the program were discussed.

When a pathological finding had been confirmed at the complete mammography the delay before further investigation was made was short for all women. Immediately after the complete mammography examination, the woman was informed by the radiologist and then referred to either a surgeon or an oncologist in less than a week, in one of the units even on the same day. Further examination and treatment were made according to the routine procedure, used for all patients. The capacity for surgical treatment, radiotherapy and chemotherapy was acceptable; from the day when a decision to perform surgery was made, more than 50% of the patients were operated on within three weeks. A majority of the women, especially those with non-palpable tumours, were operated by surgeons in close cooperation with the radiologist. A presurgery localization of the tumour was made by the radiologist and pre-operative radiography of specimens was done to confirm that the appropriate area was being extirpated. After surgery the patients were informed, treated and followed up by their respective surgeon or oncologist. Those women who had a CIS diagnosed were told that they had no cancer but a pre-phase of cancer with no increased risk of death but with a slightly increased risk of developing an invasive cancer in the future and that further controls, including an annual mammography, were recommended.

To minimize unnecessary anxiety among healthy women, induced by a public screening program, it is important to maintain a high specificity of the screening test. In the present program, 3.0% of them were recalled for complete mammography (1.5% from the incidence screening at the South Hospital and 3.7% from the prevalence screening at the other 4 units), which is less than in other major screening trials or programs.

The number of surgical biopsies resulting in a benign tumour has been kept low. In the present program the benign/malignant ratio was 0.37 to 1, i.e., about one-quarter of the selected women had benign and three-quarters malignant lesions, which is equal to the benign-to-malignant ratio discovered in the later rounds of the 'two-county study' (8). However, a lower ratio was obtained at one of the four prevalence screening units (9). According to the report 'European guidelines for quality assurance in mammography 1993' (10), an acceptable level of benign-to-malignant biopsy rate is 3 to 1, but a desirable rate for prevalence screening was set at 1.5 to 1. For incidence screening, a desirable level should be 0.5 to 1. The use of fine-needle aspiration biopsy in both palpable and non-palpable lesions is one explanation for the low benign-to-malignant ratio, found in the present program (9, 11). Without the skilful integration of cytology results in the total assessment of a radiological finding, it would not have been possible to keep the benign-to-malignant biopsy ratio at such a level.

The benefit of screening is elusive and might be lost if a high quality of a screening program is not maintained. Experiences from the first two years of this large-scale mammography screening program have shown that reasonable quality requirements were met. According to Day et al. (12), compliance in a screening program should not be below 60% and no less than 60% of the detected cancers should be in state I. These goals were met with good margins in the present program. The recall rate and the rate of benign/malignant surgery have been kept low, both factors of high importance for avoiding unnecessary worry to healthy women. Goals for the future include a further increase of attendance, maintenance of high quality, and a continuous feedback of results to all working in the program.

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