
THE ROLE OF BREAST SELF-EXAMINATION IN EARLY BREAST
CANCER DETECTION (RESULTS OF THE 5-YEARS USSR/WHO
RANDOMIZED STUDY IN LENINGRAD)

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A randomized population-based study has been carried out since 1985 in Leningrad in order to evaluate the efficacy of breast self-examination (BSE) in early breast cancer detection. The population under study covers 120,310 women aged 40-64 years with no history of breast cancer. About half of these women were exposed to BSE training (60,221) and 60,098 women constituted the control group. BSE teaching was carried out on a person-to-person basis and each patient received the BSE calendar. BSE education sessions resulted in a higher frequency of visits to specialists with complaints about "pathology" of the breast, a higher rate of referral to a specialized institution for an examination, and a higher number of excision biopsies due to a benign lesion (RR = 1.5; 95% C.I. = 1.1 - 1.9) as compared with the control group. As a result of examination, 190 breast cancer patients in the BSE group and 192 patients in the control group were detected. Comparisons of patients from both groups with regard to the size of primary tumor and the incidence of metastatic lesion in the regional lymph nodes showed no differences. The study is ongoing and all cases of breast cancer in the BSE group will be registered up to 1994 and followed-up to 1999; information will then be available on the impact of BSE upon breast cancer mortality.

INTRODUCTION

A number of studies on the efficacy of breast self-examination in early breast cancer detection have been carried out in recent years (2-6). The results are contradictory and the majority of specialists are pessimistic about the possibilities of this method. However, there exists so far no scientific basis for such an approach, since there is a lack of key information on the impact of self-examination on breast cancer mortality rates.

Presently, mammographic screening is thought to be promising for detection of breast cancer at an early

stage. The results of studies undertaken in Holland and Sweden show its high efficacy. Given this, programmes of total screening were initiated in several countries in Western Europe, in the USA and Canada. However, this is a relatively expensive method requiring special facilities, highly qualified personnel, sufficient compliance rates, and may possibly not be a completely safe method. Besides, it is obvious that the problem of early detection can not be entirely solved by means of mammography. There exist no convincing evidence on breast cancer mortality reduction due to a mammographic screening in women aged less than 55 years. Furthermore, heterogeneity of breast cancer predetermines the peculiarities of its natural history with different growth

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rates and the time of tumor doubling (from less than 30 days up to 200 days and more). Judging by the results of experimental mammographic screenings in the USA, Sweden and the Netherlands, a rather high incidence of "interval" cancers (up to 25%) overlooked even with annual mammography is explained by the presence of tumours with a short doubling time.

To improve the efficacy, the annual mammography should be complemented with a cheap, frequently repeated, safe and easily practised method. Monthly breast self-examination (BSE) may prove to be such a method.

Under the WHO auspices, a prospective randomized trial was initiated in 1985 in the USSR (Leningrad and Moscow) to evaluate the impact of BSE upon breast cancer mortality rates. This report presents data on the results of the 5-year study in Leningrad.

MATERIAL AND METHODS

From the experience of some studies on the early detection of breast cancer e.g., the HIP study (6), it is clear that the results of screening trials can be biased by the overall health differences between those who voluntarily accept screening programmes and those who do not. To avoid this strong bias, groups from the healthy female population need to be randomly allocated to either BSE education or control groups.

In Leningrad, the study was implemented through 18 district polyclinics and 10 other clinics (located in large businesses with well-developed health care services). BSE had not been taught in these facilities previously. The random assignment of these clinics to either "BSE" or "control" was conducted at WHO, Geneva, using a table of random digits; nine district and five business polyclinics were allocated to the "BSE" group and the same number of district and business polyclinics were allocated to the "control" group.

The study population, consisting of women aged 40-64 years in the areas covered by the above-mentioned clinics, had no history of breast cancer at the time of their recruitment. As a prerequisite for avoiding selection bias, all women in the BSE group, regardless of whether they started and continued to practise BSE or not, were (and will continue to be) compared with the population in the control group. The medical records in the polyclinics assigned to the control group are therefore being compared to the records of a similar number of women attending the polyclinics assigned to the BSE group.

The BSE educational programme was initiated in the designated polyclinics after the medical personnel had completed their training in the subject. The programme, which is based on person-to-person communication, was run by trained nurses or doctors and delivered to groups of 5-20 women at a time. The teaching session always included a demonstration of the BSE technique on one of the women. At the end of the teaching sessions each woman filled in a special

questionnaire (concerned with demographic data and risk factors) and received a leaflet and BSE follow-up calendar, the latter indicating the doctor's address and consulting hours. Posters and local broadcasting were employed in the various worksite clinics to remind women of the necessity of BSE practice. Calendars were renewed and the entries reviewed on an annual basis. Due to the fact that neither health authorities of Leningrad nor mass media were involved in carrying out the BSE public education programmes, the possibility of obtained relevant information on control proved to be rather limited. In order to determine the compliance rate, a selective interview of women was undertaken at a certain time interval after the BSE training sessions. The quality of the performance of the breast self-examination technique was also evaluated in these women.

Women who detected symptoms of breast disease were referred for examination to establish the diagnosis and for treatment, if necessary; this referral was carried out according to a standard scheme which made use of the existing health care structure and specialized service. Women who detected symptoms had free access to the project medical officer indicated on their BSE calendar. On the basis of the physical examination, obvious and suspicious cases were referred to the Petrov Research Institute of Oncology where the necessary diagnostic (mammography, ultrasound, thermography, aspiration biopsy, excision biopsy) and therapeutic procedures were performed. All patients were treated at the Institute by taking into account the extent of local-regional spread of the tumour, the patient's age and menstrual status, and the level of estrogen and progesterone receptors in the tumour cells. Patients underwent a thorough follow-up examination at three months, twelve months and yearly thereafter, or more frequently if needed. The examination included mammography, chest X-ray, echography of the breast and liver, gynecological examination, and scintigraphy of the skeleton and liver. The same procedures for referral and treatment were available for women in the control group whenever a breast abnormality was noted either accidentally or during a medical check-up.

The study is statistically designed so that a 20% decrease in breast cancer mortality in the women performing BSE could be detected, if such a decrease should occur.

RESULTS

During the period of 1985-1990 the programme in Leningrad included 120,310 women aged 40-64 years, of them 60,221 were in the BSE training group and 60,089 women were in the control group. As seen in figure 1, after BSE training 3553 women (5.9%) went to doctors with complaints about "pathology" of the breast. In the control group this rate was 2.8% (1682 women). Most of the cases in both groups were false-positives (81.4% in the BSE group and 72.2% in the

control group), with the frequency of self-referral statistically higher in the BSE group ($p < 0.05$). Following examination by a doctor, 18.6% of women in the BSE group (662 persons) and 27.8% of women in the control group (467 persons) were referred to the Petrov Research Institute of Oncology for examination, which accounted for 1.1% of all BSE-taught women and 0.78% of all control women. At the Institute all patients underwent an examination which included a physical examination by a mammologists, mammography, echography, aspiration biopsy and, if needed, an excision biopsy. Excision biopsy was performed in the target group with a statistically significant higher frequency (RR = 1.5, 95% C.I. = 1.1 - 1.9).

Over the 5-year period there were 190 breast cancer patients detected in the BSE group and 192 patients in the control group.

Table 1 presents data on the expected and observed number of patients by year. It can be

observed that by the 5th year these rates differ insignificantly and it can be concluded that the majority of cases with breast cancer in the study population have been detected.

Comparison of patients in the BSE and control groups with regard to the size of the primary (Table 2) and the incidence of metastatic involvement of the regional lymph nodes (Table 3) revealed no statistically significant differences.

Comparison of women from both groups by age demonstrates a similar age distribution (Table 4).

Table 5 shows BSE self-reported compliance rate at different time intervals following BSE training. During the 5-year period this rate gradually decreased.

The quality of performance of BSE techniques is of great importance for the beneficial effect of this method. Table 6 shows the results of an evaluation of BSE performance by BSE-taught women using the Canadian National Breast Screening Study (CNBSS) criteria.

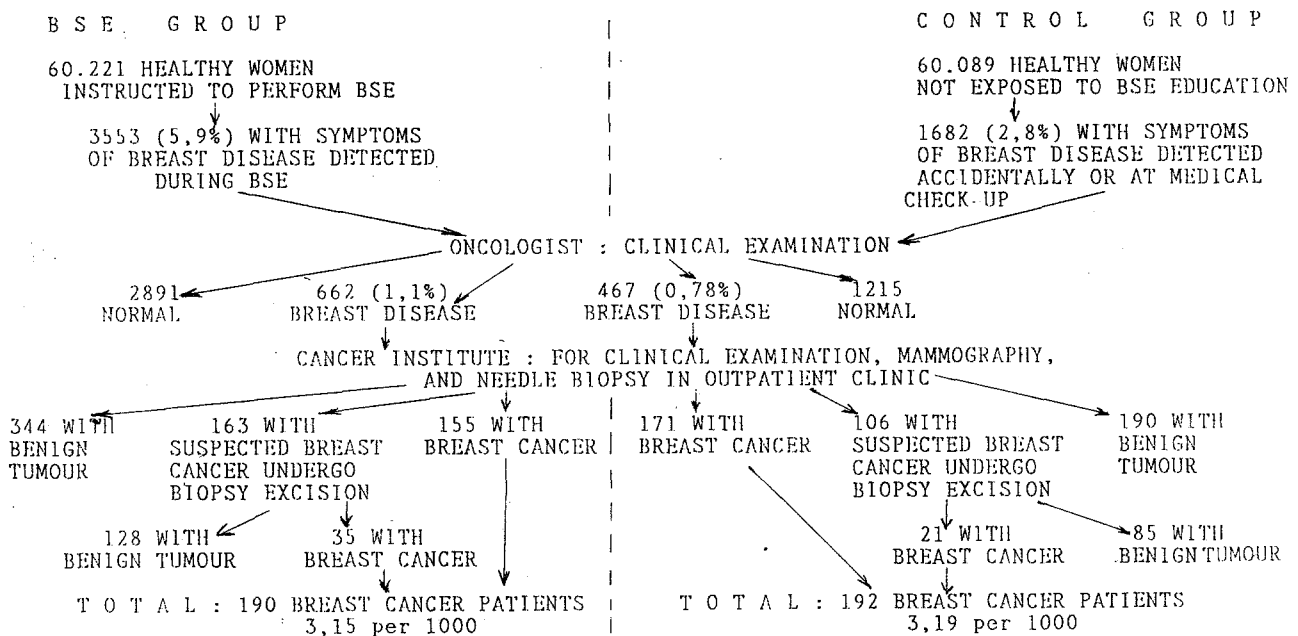


Figure 1. - Main results of the USSR/WHO programme in Leningrad 1985-1990.

TABLE 1. - Annual data on recruitment of the population for the programme on breast cancer patient detection.

Years of study	Population entered	Number of cases		Cumulative no. of cases		Number of deaths	Cumul. Number of deaths
		Expected.	Obs.	Expected.	Obs.		
1985-1986	62,252	31.1	52	31.1	52	8	8
1986-1987	27,720	76.2	58	107.3	110	6	14
1987-1988	19,082	99.4	89	206.7	119	2	16
1988-1989	11,256	114.7	90	321.4	289	10	26
1989-1990		120.3	93	441.7	382	5	31
Total	120,310						

TABLE 2. - Distribution of breast cancer patients in the BSE and control groups according to the size of primary tumour (pT).

pT	BSE group	Control group
pT 1-2	115 (60.5%)	106 (55.2%)
pT 3-4	75 (39.5%)	86 (44.8%)
Total number of patients	190	192

TABLE 3. - Distribution of breast cancer patients in the BSE and control groups according to presence of metastases in the regional lymph nodes (pN).

pN	BSE group	Control group ^x
pN ₀	91 (47.9%)	94 (49.2%)
pN ₊	99 (52.1%)	97 (50.8%)
Including:		
a) pN ₁	49 (49.5%)	47 (48.5%)
b) pN ₂	50 (50.5%)	50 (51.5%)

^x - 1 patient had fibrous histiocytoma of the breast.

TABLE 4. - Comparison of breast cancer patients of the BSE and control groups with regard to main demographic characteristics.

Characteristics	BSE group (190 patients)	Control group (192 patients)
Age:		
40-49 years	31.1%	31.2%
50-59 years	46.8%	43.8%
60-64 years	22.1%	25.0%
Education		
Incomplete and complete secondary education	42.1%	47.4%
Secondary special education	25.9%	23.4%
Higher education	28.4%	29.2%
Marital status:		
Married	68.4%	56.7%
Single	31.6%	43.2%

TABLE 5. - Self-reported BSE compliance rate (5 times or more per year) at different periods after BSE training.

Year after BSE training	1	2	3	4
Frequency of BSE performance	82%	81.2%	74.1%	55.8%

TABLE 6. - Evaluation by medical personnel of the performance of the technique.

Criteria	
1. Inspection of the breast	82.5%
2. 3-4 fingers are used in palpation	85.3%
3. Thumb is not used	96.2%
4. Palpation is done with the finger pads	65.1%
5. Palpation is performed with concentric and radial movements	62.2%
6. Breast is fully examined	72.0%
7. Axillary area is examined	86.0%

DISCUSSION

Carrying out a population-based study requires a well-developed information system which can be provided by cancer registries. Unfortunately, such a system does not exist in Leningrad, which resulted in a number of serious organizational problems. In order to avoid patient loss, all primary breast cancer cases registered over the last 5 years at the "BSE" polyclinics (an overall number of about 1200 persons, aged 40-64 years) were collated with the computer lists of women of the BSE and control groups. The identifying parameters were: the number of the polyclinic, name of patient, the year of birth. This measure allowed the identification of 36 additional women.

The adequacy of the control group is a key problem in any controlled trial. Taking into consideration the group-based character of randomization and a possible impact of the biases, we compared women of the BSE and control groups by age - a parameter of crucial importance in determining disease occurrence. It is apparent from Table 4, that the age distribution in the BSE and the control groups is nearly identical.

Information on the number of patients in the BSE and control groups and their stage distribution is very important for prognosing the final results of the study. As Table 1 demonstrates, the number of breast cancer cases detected in both groups proved to be the same. It is known, however, that the use of methods for early

diagnosis leads to the detection of a greater share of breast cancer cases. The absence of this phenomenon may be due to the fact that the method under consideration is not a method of early detection, or, if it is, then it has a very short lead time.

Comparison of both groups of patients with respect to the most important prognostic parameters, such as size of the primary tumour and incidence of metastatic lesion in the regional lymph nodes, does not allow us to expect differences in the mortality rates. Nevertheless, there are only preliminary results and it would be untimely to use these results as the basis for making any far reaching conclusions (registration of new breast cancer cases will be continued up to 1994, with follow-up until 1999).

In addition to the peculiarities of the screening method itself, its efficacy is determined by the compliance rate. Even in the presence of a highly sensitive and specific method, low benefit can be expected if women do not practise this method. Referring to BSE, this problem appears still more complicated since the information comes from self-reported data. Different from a mammographic screening, where precise information is available about the number of women attending the first, second and further rounds, such data on BSE can be considered to a certain extent as subjective and conventional. Furthermore, since the interview is carried out by the same medical personnel previously engaged in BSE teaching, some of the women may tend to give a positive reply about the BSE performance even if they do not practise it at all or only rarely. From this viewpoint, the information on BSE compliance should be approached with a certain amount of caution. The information on the quality of BSE performance technique is a different matter. Because of this, the problem becomes still more complicated; many of the women need to continually improve their performance of the BSE techniques during their contacts with medical personnel, and should be reminded of the BSE practise with the help of TV, booklets, and journals. However, this is not

enough either. The results of our interview indicate that about 20% of women refuse to perform breast self-examination because they "don't like doing it themselves", and they are not going to perform it even after repeated training and motivation. Thus, the utility of BSE in practical health care aimed at an earlier detection of breast cancer may be undervalued or disguised because of the low compliance rate and poor performance of the BSE techniques.

In conclusion, 5-year results of the BSE study demonstrate no difference in tumour size and lymph node metastases (TNM) between the BSE and control groups and implementation of the BSE programme is accompanied by a statistically significant increase in the rate of attendance at polyclinics and eventually leads to an increase in the number of unnecessary excision biopsies due to benign lesions.

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