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
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 progesteron 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