Soz Präventivmed 1993; *38*: 288–293

0303-8408/93/050288-06 $1.50 + 0.20/0

Mammographic screening for breast cancer: Background of a pilot program in the Canton of Vaud [1]

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In most developed countries, breast cancer is the leading cause of death among middle-aged women and the first cause of years of potential life lost (13% of the total in Switzerland in 1989[1]). The incidence of breast cancer is relatively high in Switzerland[2], and there is an upward trend as in many other countries[3]. Furthermore, demographic pressure will increase the number of new cases of breast cancer: in the Canton of Vaud, the number of women over 40 years of age will increase up to 20% in the next 20 years[4].

Since the mid-eighties, a radiologist and a gynecologist at the University School of Medicine in Lausanne have been convinced that screening for breast cancer should be offered to women in the Canton of Vaud. From the beginning, the idea was to offer the screening as an organized sequence of care from recruitment of women to diagnosis and treatment of breast cancer. The Institute of Social and Preventive Medicine of the University of Lausanne was approached to design a population survey aimed at investigating the willingness of women to participate in such a program. At the same time, the promoters set up a working group to organize its implementation. This program will be launched as a four-year pilot study[5]; its general features are presented in Table 1. Although it was initially thought that mammography would be offered using a mobile van, mammography will be performed in the two hospitals in the areas (districts) where the intervention is made (Aigle and Morges).

Figure 1 shows how the screening activities will be shared with private practitioners. The screening program itself deals with women's recruitment in the target population and mammographic screening. For Women positive on screening be referred to their private practitioners for diagnosis and treatment.

This pilot program will be carefully evaluated. Although a four-year period is too short to assess the impact of screening on mortality, the program will provide substantial information on intermediate outcomes such as the acceptability of the program by target women and practitioners, the

Tab. 1. General features of the pilot program in Canton Vaud.

Duration:	4 years (1993–1996)
Pilot zones:	Aigle + Morges
Target population:	women from 50–69 years of age
Targeted attendance:	60%
Recruitment:	information for the general population and practitioners + personal invitation of targeted population
Screening frequency:	2 years
Screening modality:	double view mammography
Radiologic reading:	double reading + third if any dissent
Organization:	private Foundation
Budget:	about 800 000.– Sfr/year
Financing:	Cancer League of the Canton of Vaud The Public Health Service of the Canton of Vaud (...)

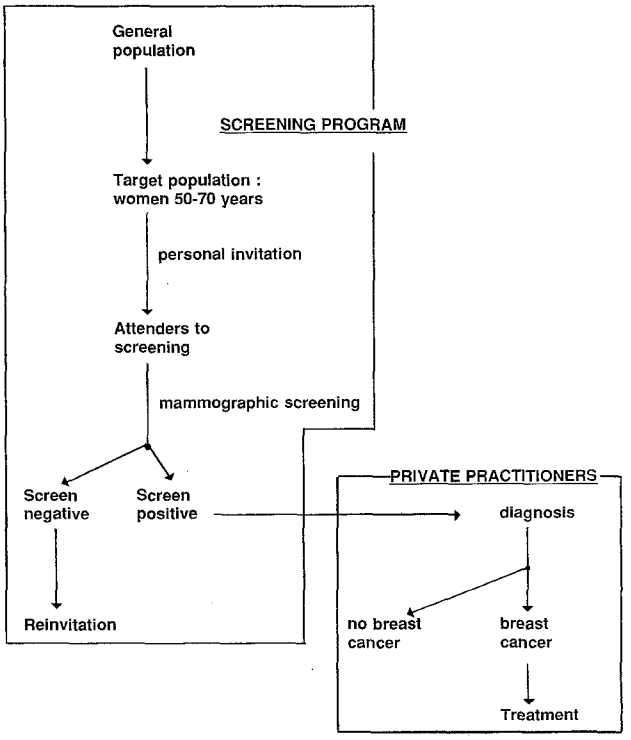

Fig. 1. Organization of the screening: Pilot-program in the Canton of Vaud.

[1] Paper presented at a symposium on "The Public Health Perspective of Social and Preventive Medicine", in celebration of the 20th anniversary of the Department of Social and Preventive Medicine, University of Berne, 25 June 1992 in Berne.

predictive values of the screening mammography, and the impact on cancer staging at screening.
Several problems need to be considered when implementing such an intervention. Three of them will be discussed below, i.e. why to screen, why mammography, and why an organized program.

Screening of breast cancer versus no screening

Primary prevention of breast cancer offers only limited possibilities: several risk factors have been identified, but they are at low prevalence, or they are associated with low elevation of relative risks, or they are not amenable to modification due to other social constraints[6]. Therefore, the impact of primary prevention on the incidence and mortality rates of breast cancer is likely to be modest.
On the other hand, treatment of breast cancer is effective in reducing the rates both of recurrence and of mortality, according to recent reviews of the literature[7,8]. Table 2 presents some results from a review on the effects of adjuvant therapy in clinical trials[9] and shows that treatment is effective both in early and in late cancers. The same table confirms that cancer staging (expressed here in terms of the presence or absence of nodes) might be more important for the vital prognosis than the treatment itself. According to Table 2, the absolute and relative effects of treatment with the three therapeutic tools considered are less important than nodal status.
Thus, considering that there are few possibilities for primary prevention, and that the treatment is effective, and probably more effective at early stages, early detection of asymptomatic cancer is an adequate approach to reduce mortality and morbidity from this major burden for public health.

Mammographic screening versus other screening tools

Several diagnostic tools have been developed for breast cancer, but only radiography, clinical examination and breast self-examination have been considered for early detection in the general population. Efficacy, safety and costs are the key elements to be considered when deciding which tool should be used for screening.
Efficacy of mammographic screening is now established: Table 3 shows the results from randomized clinical trials (RCTs) and case-control studies[10]. Although age range, type of a examination and interval between screening rounds do vary between studies, relative risks of death from breast cancer are always lower than 1.0 among women screened, the risk being somewhat lower for women over 50. Case-control studies give more favourable results than RCTs: in the former, participating women tend to be at higher risk[11] with a more favorable net effect of screening, while in RCTs, all invited women are compared. Table 3 further suggests that the magnitude of the protective effect is independent of the tool used: combining clinical examination with mammography does not seem to be more effective than using mammography alone[12]. Finally, Table 3 suggests that the efficacy of screening mammography is real, but limited; mammography provides a 40% reduction of breast cancer mortality for women aged 50 years or more five to seven years after initiating screening.
Closer analysis of these results shows that the efficacy strongly depends on the quality of screening (in terms of sensitivity and specificity) and on the participation rates.
Breast self-examination (BSE) has been considered as a screening technique for 60 years, although evidence for its efficacy is still scarce. Analysis of the recent literature[13] shows that among 112 reports published between 1989 and 1991, most provide no

Tab. 2. Adjuvant treatment for breast cancer: Annual rates of recurrence and death 5–9 years after diagnosis.

	Annual rates of recurrence (5–9 years)		Annual rates of death (5–9 years)	
	controls	intervention effect	controls	intervention effect
Tamoxifen				
node negative	4.0%	+0.03%	4.1%	−0.5%
node positive	7.7%	−0.94%	8.8%	−1.7%
Ovariectomy (< 50 years)				
node negative	2.1%	−1.5%	2.2%	−0.8%
node positive	7.0%	−2.4%	7.5%	−1.9%
Polychemotherapy				
node negative	4.0%	+0.1%	4.8%	−0.3%
node positive	8.4%	−1.4%	9.9%	−2.4%

Modified from "Early Breast Cancer Trialists' Collaborative Group", ref. 9.

Tab. 3. Some characteristics and results from studies on breast cancer screening[1].

	Age years	Methods[2]	Rhythm years	Relative risk	
				Study	> 50 years
Randomized trials					
HIP	40–64	m+p	1	0.79*	0.80
"Two Counties"	40–74	m	2–3	0.70*	0.66*
Malmö	45–69	m	1–2	0.83	0.73
Edinburgh	45–64	m+p	2	0.84	0.80
Non experimental studies					
UK Study	45–65	m+p	2	0.78	–
BCDDP	35–74	m+p	1	0.80*	0.75*
Nijmegen	35+	m+p	2	0.48	0.40*
Utrecht	50–64	m+p	1–2	0.30*	0.30*
Florence	40–70	m	2–3	0.53*	0.49*

[1] From Wald et al., Ref. 10.
[2] m = mammography, p = clinical exam.
* If RR lower than 1 with $p < 0.05$.

comparison group or are methodologically flawed. The Finnish study[14] provides encouraging results, suggesting that BSE is associated with smaller tumor size at diagnosis, but there is no direct evidence that BSE is effective in reducing mortality from breast cancer. Ongoing randomized trials in Leningrad and in Canada should provide more precise information in the coming years; the Canadian trial, to be published by the end of 1992, is aimed at knowing whether clinical examination (with BSE) provides most of the benefit from the combination with mammography, or can substitute for mammography[15].

Adverse effects of screening mammography have to be considered seriously. Not only may screening hurt individual healthy people, but the wide diffusion of the procedure may provoke vast disasters, even if the occurrence of adverse effects is rare at the individual level. The most frequently quoted adverse effects include anxiety, overtreatment of borderline cases, X-ray induced cancers and absenteeism[12]. Anxiety is, by far, the most frequently mentioned adverse effect of screening: up to 54% of false-positive women (women screened positive who do not have diagnosed cancer) express some form of anxiety after being classified positive at screening[16]. However, most studies suggest that the level of anxiety strongly depends on the way the message is delivered to women classified as suspect[17]. Furthermore, anxiety among women screened positive and subsequently found not to have cancer is not sustained, and seems to be lower than anxiety experienced by symptomatic women with benign disease[18]. Finally, the general level of fear of breast cancer is high in the general population of women (up to 30%), and reassurance of women found negative at screening decreases this prevalence (from 30% to 20%): this latter effect must be accounted as a benefit of the screening[16]. Overtreatment of borderline cases is a common issue in all screening programs[19]. The best response to the problem of overtreatment, as well as to that of anxiety, is to get the lowest possible rate of false positive cases through a high quality of mammographic screening, i.e. to get the highest possible performance of the positive predictive value of the screening program. Furthermore, cases screened positive should be provided with diagnosis performed by a highly skilled physician, using biopsy only when necessary. In the UK trial[20], for instance, about 6% of women who did not have a cancer were referred for further investigation, but only 1% had a biopsy.

The radiation risk of mammography is extremely low with the latest radiological tools applied to postmenopausal women. According to the estimates from the Forrest Report[12], two million women over 50 years of age receiving a dose at the upper end of the range of exposure at screening may suffer one extra cancer each year after a latency of ten years.

Mammographic screening is a costly procedure[21]. Cost-benefit analyses are not yet available, but reasonable estimates of cost-utility can be made, allowing comparison with other procedures in health care. Table 4 suggests that screening mammography is not more expensive than many other health services commonly provided in developed countries.

Organized versus non-organized screening

Population screening is often performed by private practitioners, and good results are observed in several fields[22]. However, breast cancer screening presents several specific problems. The first is to get optimal participation from the women, both quantitatively and qualitatively. Effectiveness of screening strongly depends on the attendance rate of the

Tab. 4. Cost utility results for selected preventive interventions [1].

	adjusted cost [2] per QALY [3] gained
Screening for rhesus incompatibility	1220
Coronary artery bypass grafting for left main coronary artery disease	4200
Neonatal intensive care (100–1499 g)	4500
Breast cancer screening	4500–6300
Neonatal thyroïd screening	6300
Treatment of mild hypertension (males 40 years old)	19100
School tuberculin testing	43700
Hospital haemodialysis	54000

[1] Adapted from Ref. 12.
[2] US dollars 1983.
[3] Quality adjusted life years.

target population (the same reduction of the proportion of advanced cancer can be achieved either by increasing the participation rate from 60 to 80% or by reducing the screening interval from three to two years [12]), and the highest participation rates have been observed within organized programs rather than with screening by private practitioners. Another issue is the appropriateness of participation: older women, i.e., those at higher risk, tend to participate less than younger ones, as has been both shown both for clinical examination of the breast [23] and for mammographic screening [24]. Here again, good attendance rates, even for aged women [25], can be achieved by personal recruitment through organized programs.

Another reason is that the monitoring of both process and outcome indicators (attendance of women, prevalence and stage distribution at screening, rate of interval cancers, rates of advanced cancers, breast cancer mortality rates) is much easier in an organized program than in a non-organized program [26].

Finally, it should be remembered that the evidence of an impact of breast cancer screening on mortality comes from RCTs which are strongly organized screening programs, from the active recruitment of women to the treatment of disease. There is no evidence that an informal program gives similar results in term of effectiveness. This observation is not specific to the screening of breast cancer [27].

Conclusions

More attention has been paid to the evaluation of the effectiveness of breast cancer screening than to that of any other cancer, and possibly more than for any other condition for which screening is currently recommended [28]. There is now convincing evidence that breast cancer is a progressive disease, that the time of diagnosis is important in determining the outcome, and that treatment of early stages of cancer can be effective. Because it makes possible the detection of a large proportion of node-negative tumors less than 15 mm [29], mammographic screening, with or without clinical examination, has consistently demonstrated its efficacy in reducing mortality from breast cancer, without increasing overall mortality. In this perspective, several countries and professional organizations have adopted recommendations on breast cancer screening [30].

From a public health perspective, the challenge is now to provide organizational frameworks aimed at maximizing the impact of screening through high participation and optimal quality of care. With or without screening programs, large resources are likely to be consumed by mammography in the coming years, both for epidemiological reasons (absolute increase of the number of cases for demographic reasons) and because of pressure from professionals and women [31,32].

The pilot program now starting in the Canton of Vaud tries to implement such an organized program. Its evaluation will allow the exploration of the acceptability of mammographic screening by the population and by practitioners, as well as the assessment of its impact on intermediate outcomes before considering its generalization.

Summary

For several years now, substantial efforts have been devoted to the development and the implementation of a screening program for breast cancer in the Canton of Vaud. A four-year pilot phase is now starting, involving two regional hospitals with their catchment areas; women over 50 and under 70 years old will be invited to participate in the program. A double view mammography will be made, with a double reading made by the hospital radiologists; a third reading will be made in case of discrepancy between the two first radiologists. Patients classified as positive for screening (e.g., with a suspect radiological image) will be referred to their practitioner for further diagnosis and treatment. The medical and public health background of this program is discussed, more specifically the reasons for developing a screening program, the choice of mammography rather than other tools, and the need to implement screening as an organized program.

Résumé

Dépistage mammographique du cancer du sein: Contexte et méthode d'un programme pilote dans le Canton de Vaud

Depuis plusieurs années, un groupe réunissant les compétences de plusieurs disciplines médicales examine les possibilités d'implanter le dépistage

du cancer du sein dans le Canton de Vaud. Un projet-pilote d'une durée de 4 ans va démarrer dans deux zones sanitaires du canton, adressé aux femmes âgées entre 50 et 70 ans: il s'agira d'une mammographie à double incidence et double lecture (avec une troisième lecture en cas de discordance entre les radiologues hospitaliers). Les femmes classées positives après l'examen de dépistage seront transférées à leur médecin traitant pour le diagnostic et, le cas échéant, le traitement. Le contexte médical et sanitaire de ce programme est discuté, en particulier les raisons spécifiques qui ont poussé les promoteurs à développer un programme organisé de dépistage par mammographie.

Zusammenfassung

Systematische Früherfassung des Brustkrebses mit Hilfe der Mammographie: Ausgangslage und Methoden eines Pilotprojektes im Kanton Waadt

Vertreter verschiedener medizinischer Fachgebiete bemühen sich seit einigen Jahren darum, für den Kanton Waadt ein Früherfassungsprogramm für den Brustkrebs auf die Beine zu stellen. In zwei Regionen des Kantons wird nun ein Pilotprojekt gestartet, das sich an die 50 bis 70jährigen Frauen richtet und vier Jahre dauern soll. Angeboten wird eine Mammographie in zwei Ebenen, die von zwei Röntgenologen unabhängig voneinander beurteilt werden wird (kommen die beiden Experten zu unterschiedlichen Beurteilungen, wird eine dritte Meinung eingeholt). Bei einem positiven Befund wird die betroffene Frau dem Hausarzt überwiesen, der die diagnostischen Abklärungen und nötigenfalls die Behandlung einleiten wird. Die medizinischen Grundlagen und der epidemiologische Hintergrund werden dargestellt; speziell erwähnt werden die Gründe für die Entwicklung eines Früherfassungsprogrammes und für die Wahl der Mammographie als Screeningmethode.

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Acknowledgments

All the work underlying this program is done under the auspices of the "Foundation pour le dépistage pour le cancer du sein, Lausanne".

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