Breast cancer prevention in the ASL of Lecco: local guidelines for a mammographic screening program


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Summary
Breast cancer is the first cause of mortality due to cancer in women, with an incidence rate in Lombardy of 80.6 cases per 100,000 women every year. Screening through mammography in women aged 50 to 69 is widely believed to be effective in reducing mortality. In Italy few cities and regions are running organized screening programs, while the request for breast cancer prevention is increasing. For these reasons the Health Agency of Lecco (ASL Lecco) organized and developed a Breast Cancer Screening program as a Strategic issue in the years 1999-2001. The organization process started with the analysis of the breast cancer incidence and the frequency of ‘spontaneous screening’ in the Province of Lecco. Afterward two work groups were established: an Operative Project Group with the aim of producing local guidelines and of preparing the operating plan; and a Technical Committee to validate the guidelines and to provide scientific and technical aid to the operative group. According to the guidelines, women aged between 50 and 69 are invited by letter every 2 years with a prearranged appointment that can be changed by phone. An Organisation and Evaluation Unit and a Breast Cancer Diagnostic Unit are activated.

Introduction
Cancer is the second cause of death in industrialized countries. Breast cancer, the major cause of death in women aged 35-54, is the primary type of cancer affecting women and is accountable for the 18% of all cancers in this group 1-2. In Italy more than 25,000 cases per year are identified 3 and about 11,000 deaths are due to it 4. The epidemiology in Lombardy shows an incidence of 80.6 cases/100,000 women per year and a prevalence of 625 cases/100,000 women 5-6.

Actions of primary prevention, like revoking risk factors, are poorly suitable for this type of cancer. On the contrary, secondary prevention strategies are considered to be effective in allowing a better prognosis in early detected cases 7-14. Even though self-palpation and periodic clinical examination are helpful means to reveal disease at early stage, mammography is actually the only accepted screening program, supported by clinical trials, that has widely proved its effectiveness in reducing mortality due to early detection 12.

Mammography is a sensitive, reasonably specific, poorly invasive and easily replicable practice and, due to its characteristics, can be used as screening procedure in asymptomatic women 14. Nevertheless, researchers have given both positive and negative opinions for its application in Public Health strategies.

Several campaigns have shown an important reduction in mortality rate (about 30%), after periodic mammographic screening of women in the age-groups at high risk 3,15-17. The European Society for mastology, a recent meta-analysis 18 and an overview of 5 Swedish studies 19 calculated that the introduction of mammographic screening has reduced by approximately 25% the risk of dying of breast cancer (range from 29% to 13% in women aged respectively more or less than 50 years, with a 12 years long follow-up). In the same direction goes Baum’s study 20, which confirms a mortality rate reduction and reveals positive cost-effectiveness.

On the other hand, different Authors 21 are debating about the opportunity of using this procedure as Public Health strategy due to the following considerations: a little reduction observed in the overall mortality in certain cases, the negative outcome in false positive and false negative cases and the high cost of the programs. These two diverging views have been also underlined by two recent works: Gøtzsche and Olsen 22 remark that trials indicating screening effectiveness are in fact not methodologically correct, while De Koning 23 confirms previous positive results.

Actually the most important studies differ as far as concerns some characteristics – including size – of the population involved, as well as the age-grouping considered and the choice of the screening interval. General agreement has been reached in order to involve women aged 50 to 64, moreover the extension of the
program to the age-group 65-69 has afterwards revealed to be effective as well, in terms of mortality reduction and cost-effectiveness. Economic evidence shows that, due to a high incidence in the older age-groups, the inclusion of women aged 65-69 leads to a better cost-benefit of the program and to a lower cost for life-year gained. On the contrary considering women older than 69 does not have a positive influence on cost-benefit and on cost for life-year gained. On the contrary considering better cost-benefit of the program and to a lower cost groups, the inclusion of women aged 65-69 leads to a shows that, due to a high incidence in the older age-group a reduction of almost 1/3 can be found. For women in their forties a 10-15 years long follow-up is needed to detect a mortality reduction related to screening, with 5 times higher cost-effectiveness compared with the 50-69 age-group. The «NIH Consensus Statement» came to the conclusion that available data don’t allow to suggest screening programs for all women aged 40-49.

National screening programs are so far active only in Great Britain, Holland, Sweden and Finland. Together with regional screenings and pilot studies 22 programs have been set up all over the world, with several different organization strategies. In Italy only few cities and regions have their own screening programs and all the data provided are collected by the «Gruppo Italiano per lo Screening Mammografico» – G.I.S.Ma (Italian group for mammographic screening), created in Venice in 1990. By now all the programs have joined the group and send their data every year. Even if more and more women are asking for mammography – 10-30% of the women older than 40 years undergo this exam regularly – coverage of women over 50 years is shown to be only 5-6%. This means that tests for asymptomatic women are obtainable outside the organized screening programs, and have a higher cost and higher potential negative effects, such as false positive and over treatment. In the hypothesis of a national program, under the condition that North European standards are met, in the next 30 years 48.361 lives and 439,311 life-years could be saved, with positive cost-effectiveness. Reviewing literature on this topic, we can conclude that the best way to increase women’s participation is to invite them for a fixed appointment, leaving them the possibility to change it by phone. All these considerations led the Local Health Agency of Lecco (ASL Lecco) to propose the mammographic screening as one of the objectives of the Strategic Plan for the years 1999-2001. The aim was to invest resources and to begin the program as soon as possible.

Specific characteristics have been studied at local level in order to provide local guidelines, as a basis for developing an operating plan and for ensuring quality in the program.

Materials and methods

Our work began with the analysis of the specific characteristics of the local area in which the program would have taken place. We have first considered the age and sex distribution of the population, with particular attention to the female part and to the age-groups chosen as target of the program. Epidemiological aspects of breast cancer as well as incidence of «spontaneous screening» have been then evaluated for the area of Lecco. Data sources considered are:

- regional register for medical public care, in order to study the anagraphic composition of the population;
- vital statistics collected by the National Institute of Statistics (ISTAT) with reference to the population of Lecco, to calculate overall and cause-specific mortality;
- hospital admission and discharge records with reference to the population of the area. We considered hospitalised women in the whole region between 1996 and 1997 with primary diagnosis «malignant breast cancer» (ICD IX 174.0-174.9): this information allowed to define hospitalisation related to breast cancer in the province of Lecco;
- activity registers of all accredited medical structures of the provinces of Lecco and Como (neighbouring area), with the aim of verifying the number of spontaneous mammographies made by female residents of Lecco. Unfortunately we couldn’t have complete regional data to establish the exact number.

Database DB IV was used to store data and statistical analysis was performed with SPSS. After the definition of local features, work went on with the institution of:

- a Project Operative Group;
- a Technical Committee.

The Project Operative Group had the objective of identifying local guidelines for the implementation of the program and therefore reconsidering national and international literature, regulations in force, available guidelines.

The group was managed by the Director of the Oncological Department, together with 2 medical doctors of the Local Health Agency Direction and the Chief of the Radiological Department.

Afterwards the proposed guidelines have been approved and the group was given the task to develop a feasibility study, and an activity plan to ensure co-ordination, monitoring and evaluation of the program.

The Technical Committee had the mission to implement a validation process of the proposed guidelines and to collaborate with the Project Operative Group. Key figures have been identified in: Directors of the Local Health Agency and of the local hospitals, mem-
members of the radiological, oncological, surgical and physiatric wards of the territory, general practitioners and leaders of voluntary associations.

RESULTS

1. STRUCTURE OF THE LOCAL POPULATION
Sex and age distribution of the local population in 1996 shows the presence of 155,716 women, 37,504 of which in the age-group 50-69. Up to 31/12/97 medical public care assisted 36,593 women in the specific age-group. Considering a screening Interval of two years, as suggested by international literature, 18,297 women should be invited per year.

2. REGIONAL AND LOCAL CANCER MORTALITY RATES
Local cause-group specific mortality rates, standardized by sex and age, are similar to the regional ones. Among 2,700 deaths counted in the area, 840 (32%) are related to cancer. Women dying from cancer in the province are 27%, while at the regional level they are 29%. Nevertheless deaths due to breast and colon cancer are higher in the considered area than in the region (Fig. 1). These data confirm the importance of a specific prevention program.
Furthermore, the analysis of the local distribution by age highlights that deaths caused by breast cancer begin to occur in women aged 35-44, increase progressively with age and have a peak in the age-group 55-64 (Fig. 2).

3. HOSPITALISATION ANALYSIS FOR THE YEARS 1996-97
A total of 898 hospitalisations with principal diagnosis of breast cancer have been identified for the years 1996/97. In 1997, ordinary hospitalisation remains stable, while the use of Day Hospital is increased.

Looking at the frequency of admissions, we found out that in many cases these are multiple for single patients, therefore we decided to consider the first ones apart from the others. Moreover we distinguished ordinary hospitalisations from Day Hospitals.
In both cases the greatest number of patients is sent by specialists (a total amount of 66.4%). The major part enters without emergency with programmed hospitalisation.
Aim and type of hospitalisation have been then evaluated: more than 40% of the ordinary hospitalisations end up with surgery, while day hospitals receive mostly patients after diagnosis. Patients’ average stay in hospital is 11 days for ordinary hospitalisations and 2 days for day hospitals.
Hospitalisation percentage due to breast cancer begins to rise in the age-group 40-49 and increases up to the age-group 80-89.
A total amount of 223,19/100,000 women have been hospitalised because of breast cancer during the years 1996-97. Analysis of the hospitalisations’ distribution shows that the hospital of Lecco is in charge for almost the half, while an important part of patients chose specialized structures.
Attributable costs to breast cancer hospitalisation are calculated in 1,550,000 Euro considering ordinary hospitalisations and 77,500 Euro taking Day Hospitals into account.

4. EARLY DETECTION: EXPRESSED AND POTENTIAL REQUEST
In 1997 a total amount of 8,372 mammographies have been undertaken by women of the Local Health Agency*, of these 5,260 were aged 50-69: these numbers mean a «spontaneous» coverage rate of 32% in the target population, while a coverage rate of at least 70% is usually regarded as acceptable to consider a program as valid.

* Local Health Agency: it represents the district level in public health system.
Tab. I. Local guidelines.

1) **Target population composition:** all resident women of the Local Health Agency in the age-group 50-69.

2) **Invitations:** letters must be sent by mail and must give precise indications about place, date and time of the programmed mammography. A telephone number to call for any information or to change appointment must be also indicated. If a woman doesn't arrive at the fixed time and place another letter must be sent with the invitation to get in touch with the call centre in order to organize another appointment or to be excluded from the program.

3) **General practitioner's role:**
   - Should inform his patients about screening procedures and objectives
   - Should monitor patient's health during the program and collaborate with the reference oncologic department
   - Should counsel during the whole program

4) **Key issues for successful programs:**
   - General Practitioners' involvement
   - Associations' involvement
   - Town councils' involvement
   - Large diffusion of information through mass media, meetings, transmission of data and results

5) **Screening test:** biennial mammography performed in 2 projections (oblique medi-lateral and cranio-caudal).

6) **Test's implementation:** must be done in defined screening centres. Centres must be accessible to the target population and must assure necessary qualifications, following national indications on mammography's quality 14.

7) **X-rays reading and reporting:** must be done in a single centre. The centre must ensure, if needed, further investigation and involve radiologists that have taken part in previous reporting.

8) **Double X-rays reading:** must be performed by radiologists with competence in screening mammography. Possible reporting results are:
   - Negative
   - Recall because of symptoms
   - Recall because of technical concern
   - Recall because of positive mammography and suspected cancer

9) In case of double negative report: a standardized letter must be sent to all women with the result. They must be also invited to contact their general practitioner in case of symptoms before next test.

10) If at least one of the readers asks for a recall the woman must be invited by phone to do further investigation. Psychological and communication aspects must be taken into account and qualified staff must be involved for the telephone calls.

11) Further investigation must be carried out only in the centre indicated in the program. Clinical examination must be always performed. The centre must be able to execute also further exams suggested case by case by the radiologist in charge. Examinations to be assured are: enlarged mammography using a device with micro focus, ultrasonography using sounds with a frequency of at least 7.5 MHz, tissue abstraction under ultrasonographic guide, stereotaxic ultrasonography in the presence of a cytopathologist and the possibility to contact a surgeon.

12) **Classification of cytological reporting:**
   - Not significant
   - Negative: normal breast tissue
   - Negative: consistent with a benign lesion
   - Hyperplastic lesion with high cellular index
   - Suspected for cancer
   - Positive: cancer

13) **Additional investigations must lead to an hypothesis of diagnosis and to one of these suggestions:**
   - Adjournment to the normal screening protocol: next test in 2 years – Anticipation of the following mammography
   - Surgical biopsy
   - Surgery or other treatment

14) **Any final recommendation,** except the adjournment to the normal screening protocol, must be given directly to the woman. Psychological and communication aspects must be taken into account and qualified staff must be involved. If surgery is required the woman must be informed on specific reference centres. In case of agreement to surgical treatment an appointment must be immediately fixed.

15) **Not palpable lesions requiring biopsy or surgery** must be identified using a metallic thread or carbon tracer, under ultrasonographic or stereotaxic guide. Radiology Units carrying out additional investigation must be involved in this case, too.

16) **X-ray of the extracted tissue must follow not palpable lesion's biopsy. Copy of the x-ray must be conserved in the screening archives.**

17) **At least every two months interdisciplinary meetings must be organized to analyse particular cases. Reference radiologists, pathologists and surgeons must at least take part in those meetings.**

18) **Quality monitoring and data dissemination to the Screening management and evaluation Unit must be ensured by the reference centres.**

19) **Dedicated staff of the information system unit must ensure that reporting for I and II level investigation is always available for every woman. They are also supposed to verify that every woman requiring further investigation or treatment has followed the suggestions or has otherwise been solicited.**

20) **General practitioners must be kept informed on their patients' adhesion and on screening results in order to ensure adequate counselling.**

21) **Operative instructions must be defined for all mentioned points.**
5. LOCAL GUIDELINES FOR A MAMMOGRAPHIC SCREENING PROGRAM

The Project Operative Group, bearing in mind national and international literature and the analysis of local features, developed specific guidelines (Tab. I) that have been afterwards approved and validated by the Technical Committee. A feasibility study and the operating plan of the program have been then elaborated on the basis of those guidelines. Special Units have been furthermore activated to run the program: the Screening management and evaluation Unit and several Breast cancer diagnosis Units.

The Screening management and evaluation Unit relies on an expert consultant who supervises the work, that can be summarized as follows:
- identification of the population to be inserted in the program;
- linkage with General Practitioners;
- information to general population, associations, mass media;
- management of invitations, reminders, first level mammography’s planning;
- scheduling of first level mammography;
- mailing of first level negative results;
- call centre information activity;
- selection of specific indicators to evaluate the program and perform statistical analysis;
management of the information system;
- training of the staff;
- periodic diffusion of the evaluation process’ results.

The Breast cancer diagnosis Units on the other hand is in charge for:
- assessment of the department opening hours and of the activity burden, as well as periodic communication of those information to the Screening management and evaluation Unit;
- patient’s admission and registration;
- explanation and achievement of the woman’s informed consent;
- medical reporting as required by the information system;
- recording of all radiographies in the archives;
- women’s recall if further investigation is needed;
- management of all the II level examinations;
- training of the staff;
- quality assessment of all the exams.

6. OPERATIVE PLAN: FIRST PHASES

Eligible women were defined looking at the anagographic lists obtained on line from the Regional register for medical public care.

To estimate the amount of women to invite and the number of tests to provide per day, we have calculated the number of women to call per day over a period of 200 workdays. In order to invite them all within 2 years (a total of 38,406 women), under the hypothesis of an adhesion rate of 70%, 96 invitations and 67 mammographies had to be planned per day.

We have decided to start calling the oldest women and to come later to the youngest. Calls are performed first of all by district, then by municipality or municipality groups. Calendars are available for the public before the beginning of the campaign. The Information campaign includes specific events to present the program and subsequently to maintain public awareness. The call centre makes plans for the I level testing, sends invitations, recalls and negative results, and arranges eventual modifications of the prearranged appointments.

Figure 3 summarizes all the steps a woman has to go through in order to carry out her screening.

The planned program started on November the 29th, 1999.

Discussion and conclusions

Overall cancer mortality, and especially breast cancer mortality, in the area, confirmed the opportunity to perform a specific prevention program. Discharge records’ analysis with main diagnosis «breast cancer» appeared useful to define the burden of the local structures to be involved for the issue.

Coverage rate in the target population (women aged 50-69) is only 32%, underlying the necessity of an action. In fact a coverage rate of 50% is considered acceptable, while 70% should be reached. Aim of our program is therefore to catch 12,800 women per year.

Data regarding the period 29/11/99 – 31/10/2001 show a good onset of the program: 66% of the invited women have adhered and recalls for II level exams were 10%. These results can be compared to suggested standards and allow to forecast a long-term mortality rate reduction of 20-40%, thus similar to the reduction rates indicated by literature.

References