Breast Cancer Screening with Mammography

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Abstract: Breast cancer has been increasing in Japanese women. It ranks first in prevalence among female cancers, and it has been decided to include mammography in breast cancer screening examinations. The Ministry of Health and Welfare's notice "Policy for Health Education Stressing Cancer Prevention and the Conduct of Screening Examinations" emphasizes the importance of preparing an implementation system and of quality assurance of the equipment, images, and interpretation, and it directs that implementation be started in places where the system has been prepared. Mammography machines that fulfill the standards of the Japan Radiological Society and mammography that fulfills the image quality and imaging technology evaluation standards are required. Interpretation is performed twice, and the imaging technician and interpreting physician are required to have completed the training sessions conducted by the Mammography Screening Examination Quality Assurance Central Committee Education and Training Committee or similar training sessions. The goal of breast cancer screening examinations is to reduce breast cancer deaths, and the targets of the screening examinations that include mammography are women 50 years of age and over, in whom it has been demonstrated to be effective in the West. Since the peak incidence of breast cancer in Japanese women is in the 5th decade, the optimal approach to breast cancer screening examinations for women under 50 years of age is now being assessed.

Key words: Mammography; Breast cancer screening; Quality assurance; Cancer screening with mammography

Introduction

Breast cancer continues to increase in Japan, and the breast cancer incidence has finally become the highest in the country. Because the cure rate is high if detected early, and methods of early detection are available, screening examinations can be expected to be useful against breast cancer. Nevertheless, based on the results of studies that have shown that conventional inspection and palpation methods are inadequate and the results of examinations (including mammography) that are comparable to the West, screening that includes mammography has come to be performed since 1998 in Japan as well.

In this paper, the author reports on why mammography has been adopted and what is...
required for screening examinations that use mammography to yield good results.

**Background behind the Introduction of Mammography**

Breast cancer screening have been taken up by the 2nd Health Care Project for the Elderly since 1987, and screening examinations have been performed by inspection and palpation. Breast cancer screening by inspection and palpation were stated in the report of the Hisamichi Group (Study Group for E valuation of the Efficacy of Cancer Screening)\(^1\) funded by the Ministry of Health and Welfare in March 1998. “Despite the favorable 5-year survival rate for breast cancer detected on screening examinations compared to breast cancer detected in the outpatient clinic, no significant differences were found in the 10-year survival rates, and no mortality-reducing effect was shown.” “A 45% mortality risk reduction effect was observed in persons who had not detected a lump themselves at the time of the screening examination.” These statements showed the necessity of introducing examinations that allow breast cancer to be detected before patients feel a lump themselves.

Eight randomized controlled trials and 5 case-control studies on mammography have already been published in the West, and efficacy has been observed in its life-saving effect in the 50-year-old and over age range. Since the sensitivity, specificity, and early cancer ratios obtained in the Miyagi trial in Japan\(^2\)\(^3\) were comparable to those reported in the West, where efficacy had already been demonstrated, screening examinations that include mammography were evaluated as having a high probability of being effective in Japan as well, and the conclusion was reached that “the introduction of mammography is indispensable to reliable reduction of breast cancer deaths by screening examinations” in Japan.

By contrast, although ultrasound examinations have received high evaluations clinically, the screening examination data were inadequate when used for primary screening. Therefore, they could not be used as material for assessment. In addition, there were many variations in the ultrasound examinations, including the equipment used, scanning methods, the persons performing the examinations, and the recording methods, and unfortunately, no recommended screening examination method or evaluation have yet been decided.

**Policy of the Ministry of Health and Welfare’s Policy in Conducting Screening Examinations That Include Mammography**

Mammography was included in screening examinations for the first time in 2000. According to the “Policy for Health Education Stressing Cancer Prevention and the Conduct of Screening Examinations” dated March 31, 2000, “The target population of the introduction of mammography will be women 50 years of age and over, and an interview, inspection, palpation, and x-ray breast examination, consisting basically of medial and lateral oblique films of both breasts, will be conducted, and the films will be read twice in a suitable reading environment”. What differs from the past is that the Ministry of Health and Welfare has directed that the mammography examinations “be started at sites where preparations have been made”.

Especially in breast cancer screening examinations, since “when conducting breast cancer screening examinations, it is important to prepare a system for implementing screening examinations that includes quality assurance, etc.” and “carrying out appropriate methods and quality assurance is essential, especially in regard to breast x-ray examinations”, the quality assurance aspect has been emphasized in detail for the equipment, operators, readers, and quality assurance, in regard to implementation of the screening examinations and quality assurance by clear statements such as, the “Municipalities shall consider the relevant persons at public
health centers, local medical societies, contract provider institutions, etc., the implementation systems and implementation potential in the individual regions” and “the Breast Cancer Section of the Adult Disease Screening Examination and Guidance Council make arrangements with the relevant persons so that the screening examinations are performed smoothly, by appropriate methods, and under quality assurance”.

The Ministry of Health and Welfare has mentioned quality assurance, because it has been demonstrated that adequate results cannot be expected when the quality of mammography is poor, even in mammography screening examinations of women 50 years of age and over, and it is important that Japan, which is a country that is behind in terms of instituting mammography examinations, not follow the same path.

**Quality Assurance of Mammography Screening Examinations**

Maintaining the precision of mammography screening examinations requires maintenance of the precision of the mammograms, the precision of the reading, and the precision of the system as a whole. This will be outlined below.

1. **Quality assurance of mammograms**

Mammograms are unique radiograms. Because the entire object being imaged is composed of soft tissue, special modifications are made so that even small differences in x-ray absorption between the soft tissue components create large differences in density on the x-ray films. Low-voltage x-rays having special properties are used. Ordinary x-ray tubes having molybdenum targets are basically used. Since image quality is altered considerably by even minor changes in voltage, machines having good voltage stability are essential, and molybdenum or rhodium filters must be used to reduce excessive “blurliness” or exposure.

Moreover, because of its shape, production of radiographs that enable observation of the interior of the breast requires machines and techniques that expand and compress the breast (mammary gland) so as to make it as thin and uniform as possible.

In addition, the screen film systems must possess the special high sensitivity and high contrast needed for mammograms. Therefore, development requires processing at a slower speed than usual radiography, and it is preferable that the intensifying screens and film systems be used exclusively for mammograms.

Quality assurance of mammography equipment requires that 3 simulated mass points, 3 simulated calcification points, and 4 simulated fiber points be cleared on RMI-156-type breast phantom films and that image quality and technical evaluation be cleared in clinical cases. Detailed standards for the equipment and mammograms are described in the “Mammography guidelines” edited by the Japan Radiological Society/Japanese Society of Radiological Technology and the “Quality assurance manual for breast cancer screening examinations by mammography” based on “Research related to promotion of breast cancer screening examinations by mammography and improving their precision”, supported in part by the 1999 Health Care Project for the Elderly Fund.

To ensure quality assurance and the use of proper techniques, it is stipulated that it is preferable for mammography screening films to be taken by medical radiology technicians who have completed the training sessions held by the Education and Training Committee of the Central Committee on Quality Control for Mammographic Screening (composed of seven societies and groups related to the breast cancer care: the Japan Association of Breast Cancer Screening, Japanese Breast Cancer Society, Japan Radiology Society, Japanese Society of Radiological Technology, Japan Society of Obstetrics and Gynecology, Japanese Association of Medical Physics, and Japanese Association of Radiological Physics) or equivalent training sessions.
2. Quality assurance of mammogram interpretation

Mammograms are quite different from ordinary radiograms. First, the optical density of the film is greater than that of ordinary film (darker). Therefore, the amount of light provided by ordinary view boxes is insufficient, and interpretation of the films is impossible. Special mammography view boxes must be used, and preparation of the environment for interpretation is also important.

It is essential to interpret mammograms by using standard national terminology and evaluation criteria. They are described in detail in the “Mammography guidelines” mentioned above and will be outlined below.

The special terminology (Lexicon) used to describe mammogram findings are explained by dividing them into terms for masses, calcification, and other findings. It is recommended that the evaluations be made by first clearly recording the degree of likelihood of being...
When a mass has been found, its shape (round or oval, polygonal, lobulated, irregular), borders and margins (circumscribed, microlobulated/micro-serrated, associated with spicules, borders indistinct, obscured), and its density (low density, including fat density, equal density, high density). The borders and margins are especially important. Their use is also clearly prescribed in the form of a category decision tree (Fig. 1).

After first recognizing calcification that is typically benign and excluding it, calcification that needs to be differentiated according to whether it is benign or malignant is categorized according to its shape and distribution.

Typically benign calcification includes calcification of the skin, calcification of blood vessels, calcification associated with duct ectasia, solitary round calcifications, centrally radiolucent calcifications, milk of calcium calcification, calcification at suture sites, dystrophic calcification, etc. Calcification that requires differentiation between benign and malignant is divided, on the basis of shape, into fine round calcification, amorphous (or indistinct) calcification, pleomorphic or heterogeneous calcification, and fine linear or fine branching calcification, and on the basis of distribution, into diffuse/scattered, regional, segmental, linear, and clustered, and as shown in Fig. 2, it is categorized according to combinations of them.

The other findings have been organized into mammary gland parenchymal findings (tubular density/solitary dilated duct, asymmetric breast tissue, focal asymmetrical density, architectural distortion, trabecular thickening), cutaneous findings (skin lesions, skin thickening, skin retraction, nipple retraction), and lymph node findings (axillary adenopathy, intramammary lymph nodes).

One of these findings, architectural distortion, differs from the conventional concept of “mass plus calcification”, which has been interpreted as mammographic evidence of breast cancer, and it is now possible to recognize abnormal findings by taking mammary gland architecture into consideration. In concrete terms, this means findings in which there is no clear mass shadow, and spicules radiating from a single point and a mass shadow are not present or cannot be seen, but there are such findings as the margin of the mammary gland parenchyma being locally indented, or the mammary gland parenchyma being warped (Fig. 3), and these findings should arouse suspicion of cancer in patients with no history of surgery or severe inflammation. A correct interpretation of these findings must be based on proper imaging techniques and scrupulous methods of interpretation.

3. Quality assurance of the system

The conduct of screening examinations is currently the responsibility of local governments. It is stipulated in regard to the quality assurance of screening examinations that “the breast cancer sections of the adult disease screening examination and guidance councils
established in the prefectures shall make arrangements with the relevant members of the regional medical society, the contract provider institutions, the detailed testing institutions, etc., so that the screening examinations are carried out smoothly by appropriate methods and under quality assurance”; however, in concrete terms, it is necessary to maintain the accuracy of mammogram image quality and interpretation, to prepare records, and to provide guidance in understanding the results of definitive diagnosis and the circumstances of treatment, etc.

The institutional image evaluation committees of the Central Committee on Quality Control for Mammographic Screening mentioned above are expected to play a role in these quality assurance operations.7)

**Radiation Exposure as a Result of Mammography**

Although the radiation dose to the breast during mammography differs slightly according to the physique of the subject and according to the machine used, measurements have shown it to be approximately 1–3 milliGray (mGy; absorbed radiation dose). When this is converted to actual radiation dose, it amounts to 0.05–0.15 milliSieverts (mSv), and comparison with the definite-effect threshold value shows that they are one order of magnitude smaller and constitute no problem whatsoever. From the standpoint of probable effect as well, an increase in cancer incidence has only been demonstrated at several hundred mSv or more. They are truly an order of magnitude different and constitute no problem at all.6) In other words, as long as mammography screening examinations are carried out properly, there is no need to consider the negative effects of the radiation exposure.

**Breast Cancer Screening Examinations of the Future**

Breast cancer incidence is still continuing to increase, and it is impossible to lower breast cancer mortality by conventional examinations. Screening examinations in the future will be expected to decrease breast cancer deaths even if the rate of occurrence of breast cancer increases. Accordingly, it will be necessary, first, to implement high-precision screening examinations capable of detecting breast cancer before the occurrence of symptoms, such as a self-detected “lump”, and, second, to increase the percentage of the population that undergoes breast cancer screening examinations.

While screening examinations that include mammography are currently being provided to women 50 years of age and over, the peak incidence of breast cancer in Japan is in the 5th decade, and breast cancer mortality peaks in the 6th decade. Thus, it is very important to rapidly design and implement breast cancer screening examinations that can decrease breast cancer mortality in women under 50. One of the groups supported by the Ministry of Health and Welfare Cancer Research Fund, the group conducting “Research on the optimal method of breast cancer screening examination for women under 50 years of age” is engaged in the collection of material from both mammography and ultrasound examinations, and results are expected very soon.

**Conclusions**

The background underlying the introduction of mammography and the importance of quality assurance are described on the occasion of the start of screening examinations including mammography in Japan.

It is very important that high-precision screening examinations be implemented in screening examinations that include mammography only after attending training sessions on the production and interpretation of mammograms, and a reduction in breast cancer deaths is expected as a result. In the future mammography may be applied to women under 50 years of age, and the concept of quality assurance will become increasingly important.
REFERENCES


6) Study group for the “Promotion of breast cancer screening examinations by mammography and improvement of their precision”: Manual for quality assurance of breast cancer diagnosis by mammography, supported in part by the 1999 Geriatric Health Project Promotion Fund. 2000. (in Japanese)