

Otrzymano: 2007.04.10
Zaakceptowano: 2007.05.15

Quality Standards in Mammography

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Summary

The paper presents the incidence of breast cancer in Poland and the correlation between 5-year survival and the stage at which the tumors are detected, based on epidemiological data.

Emphasizing the importance of population screening programs, the conditions that should be fulfilled by X-ray mammography – the main method of breast cancer detection – its role, limitations, approaches, and reasons for incorrect diagnoses are presented.

The clinical signs of asymptomatic breast cancer are described and the techniques of an accurate X-ray mammography performance are discussed. The BI-RADS system developed by the American College of Radiology (ACR), is suggested to be a standard for mammography interpretation in the final conclusions and recommendations for further management.

The sensitivity of the method enables detection of 80–90% clinically asymptomatic lesions, depending on a the breast structure. To obtain such results, high quality of examination is a must. Therefore, it is essential to implement a quality control program at each stage of the examination across all participating mammography labs.

Key words: mammography • breast cancer detection • BI-RADS system • quality control programs

PDF file: <http://www.polradiol.com/fulltxt.php?ICID=492493>

Breast cancer is one of the most serious health problems among the most common malignant tumors affecting women in the developed countries and the main cause of mortality in a female population between 25 and 60 years of age. Poland belongs to the countries with average morbidity. However, as over 50% of newly diagnosed cases present in advanced stages of the disease, the 5-year survival rates are low. There were almost 12 000 new cases reported in our country in 2002 and 5 thousand women died of breast cancer.

The studies conducted to date have demonstrated that significant effects on breast cancer-related mortality reduction (ca, 30%) have been obtained in most countries that introduced population screening programs, involving regular, periodically repeated mammography [1]. Clinical studies demonstrate a decrease in breast cancer-related mortality rates among women aged 50–69 years if the examinations are repeated at 12–24-month intervals. On

account of the above finding, most organizations recommend that period of time for regular mammography performance. More frequent examinations carried out once a year are more beneficial for women at premenopausal age and belonging to high risk groups. Screening for breast cancer is expensive, however appropriately designed and performed screening tests may save the lives of many women.

X-ray mammography is the basic method of breast examination but it must fulfill certain conditions – at low radiation dose images must be of very good quality that comply the established standards. Mammography is performed in 2 basic projections – oblique (medio-lateral) and cranio-caudal (CC). There are numerous additional projections, but targeted images with local compression and image enlargements are most commonly performed in practice.

The description of mammography should contain an assessment of observed morphological changes, conclusions

and recommendations for further management. American College of Radiology (ACR) developed the BIRADS (Breast Imaging Reporting and Data System), which should become a standard of mammography descriptions [2]. The final conclusions of mammography descriptions are divided according to BI-RADS into the following categories:

- category 0 – requires further investigations for category determination
 - category 1 – normal mammography
 - category 2 – benign lesion
 - category 3 – lesion probably benign
 - category 4 – suspicious lesion
 - category 5 – high probability of cancer
 - category 6 – diagnosed breast cancer
- Category 0 is usually determined in the assessment of screening results in the situations requiring further procedures for ultimate category determination. The recommendations may include comparison with previous examination results, necessity of obtaining additional mammography images, or ultrasound examination in case of a well-delineated tumor or high breast tissue density in women belonging to the risk group. In case of normal results (category 1) or typical benign lesions (category 2), routine control examinations at 1 – 2-year intervals should be recommended. In case of probably benign lesions (category 3), the date of next control examination should be scheduled or additional examinations (USG, additional projections) ordered. The description of category 4 indicates the possibility of cancer, thus a biopsy is recommended in such cases. In case of category 5 lesions, the biopsy is indispensable. The recently introduced category 6 concerns the cases of diagnosed breast cancers before radical treatment (second assessment of the diagnosed lesion, assessment of another lesion in the same or the other breast, or re-assessment of the lesion after neoadjuvant therapy).

The description, as a part of medical documentation, should include all the recommendations concerning the proposed accessory investigations, including the biopsy. A correctly performed mammography allows precise assessment of the breasts, good visualization of pathologic lesions and detection of impalpable lesions. The sensitivity of the method in detection of clinically asymptomatic lesions amounts to 90%, and 80% in breasts with „dense” structure. The value of the method in differentiation of benign and malignant lesions is low. The character of the detected lesion is verified microscopically.

The most important task of mammary gland diagnostics is the diagnosis of cancer. Large size tumors pose no diagnostic problems. The typical finding in mammography images is a round or oval mass of high density, irregular central portion, surrounded by a ring of processes – a spicular tumor. Such lesion type accounts for over 80% of palpable

malignant lesions – most frequently invasive ductal carcinomas. Microcalcifications are important symptoms, allowing diagnosing of small, impalpable breast cancer. Mammography is the only reliable method of assessment of microcalcifications, starting from 50 μ size, which are often pre-invasive cancers.

Nearly 60% of pre-clinical cancers are diagnosed only on the basis of indirect signs such as focal distortion of breast architecture, asymmetry, tissue density or increase of a microcalcification size over a period of observation [3]. Indirect signs of malignancy include also such findings as thickening and/or skin collapse, nipple retraction, signs of breast edema, dilatation of a single duct or lymphadenopathy. In most cases, additional projections, targeted or enlarged images, USG and then microscopic verification are required. The verification methods are chosen at the radiologist's discretion, and his/her choice should take into account both the types, size and location of the lesion, the breast size and structure, results of previous examinations, data obtained from anamnesis and clinical examinations, as well as the potential and limitations of particular diagnostic procedures.

Correctly performed mammography enables precise breast assessment, good visualization of pathologic lesions and detection of impalpable ones. Although the effectiveness of mammography has been proven, the examination is not ideal with respect to sensitivity and specificity. The percentage of false negative results ranges from 3% to 30%, both among patients with clinical symptoms and among asymptomatic subjects undergoing screening examinations [4]. The false negative results may be due to technical errors or inadequate quality control. Another reason for false results is a dense glandular structure of the breasts, which may obscure the presence of focal lesions. In other cases, the images visualize subtle signs of malignancy overlooked by the radiologist. A low percentage of cancers is completely invisible in radiographic images or shows the features of a benign lesion. False positive results are obtained because of similar technical limitations, or are due to increased vigilance associated with medical and legal problems resulting from a failure to diagnose a malignant tumor. Diagnostic errors may, on the one hand, cause a failure to diagnose cancer, and, on the other hand, it should be remembered that a vast majority of the screened population is healthy and will not develop breast cancer in future, either.

It should be emphasized that both diagnostic and screening mammography must be of high quality. Therefore, it is very important to implement and maintain a quality assurance program [5]. This program should concern each stage of mammography and should constitute an internal part of each examination center activity. This will ensure high and repeatable technical quality and an appropriate level of interpretation. A mammography laboratory should be assessed with respect to the equipment, its correct use, and qualification of the personnel: radiologists, technicians, medical physicists. Each member of the staff should be assigned to specific tasks in the quality assurance program, and the radiologist should be responsible for its effective implementation.

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