

9. Summary and Conclusions

9.1 Summary

Mammographic studies are performed for both diagnosis of breast disease and screening for cancer. Diagnostic mammography can demonstrate the presence of breast cancer in a symptomatic patient and more specifically, the size, location and extent of tumor. Mammographic screening involves examination of asymptomatic women in an attempt to detect breast cancer before it grows large enough to be palpable. The use of diagnostic mammography is well accepted due to the compelling clinical need for the information provided. The implementation of a mammographic screening program depends upon: (1) indication of a favorable benefit/risk ratio for the population being screened; (2) availability of suitably trained radiologists, medical physicists, and technologists and appropriate mammographic equipment subject to a vigorous QA program; and (3) acceptably low cost.

Breast anatomy and function must be understood (Section 2) in order to design and utilize the mammographic techniques which will effectively detect and demonstrate breast cancer. The technique which is employed for the preponderance of mammography examinations is screen-film mammography with a grid.

Good screen-film mammography requires dedicated equipment which can provide an appropriate soft x-ray beam (proper choice of operating potential, target, filter, window, HVL) (Section 3), proper compression, a target-film distance of suitable length for the given focal-spot size, and provision for vertical adjustment and mechanical rotation of the tube and image-receptor assembly for proper positioning (Section 2). The two views, which are recommended, are the CC and the MLO view (Section 2) which allow more visualization of the posterior glandular tissues, particularly in the auxiliary tail than a lateral view. The lateral view should also be employed whenever a nonpalpable lesion is discovered, in order to provide accurate three-dimensional localization. Screen-film mammography should be performed by a technologist who has had special training in compression and positioning techniques for the

standard and special views used for mammography (ACR, 1999). Only an intensifying screen designed specifically for mammography should be used in combination with a suitable single-emulsion film (Section 3). The combination should be placed in low-absorption cassettes designed for mammography.

There are many factors which affect image quality (Section 4). The three major components of image quality are contrast, sharpness and noise. Image quality can be optimized by suitable adjustment of the x-ray spectrum (operating potential, filtration, target material), breast compression, grids, imaging geometry (small focal spot, long target-film distance), choice of screens and films, and optimization of film-processing techniques. Image quality may be checked with suitable phantoms.

Section 4 provides information to allow facilities to determine whether the particular combination of x-ray machine, compression devices, technique factors and image receptors in current use, or under consideration for use, for mammography will provide optimum image quality.

A major objective of mammography dosimetry is to provide relevant information so that potential radiation risks from alternative techniques may be compared. For this purpose a single-valued "dose" per view for each technique, which corresponds reasonably well to the resulting carcinogenic potential, should be determined. This task involves consideration of tissue vulnerability to radiation effects, anatomy, technique and dosimetry. In addition, a unique dose value for each technique requires that the dose be determined for a fixed-reference breast composition with breast thickness stated.

Simple computational models of the breast have been developed for estimation of mammographic dose. Several assumptions are implicit in these models relating to radiation risk, breast anatomy, and technique (Section 5). Three specific points are relevant to radiation risk: (1) breast glandular tissue is most vulnerable as compared with adipose, skin and areolar tissues; (2) an average breast dose (namely, the mean glandular dose), rather than a maximum dose, is most useful in characterizing risk of carcinogenesis consistent with a linear dose-response relationship; and (3) the population of primary interest is women 40 y and older since younger women are likely to receive only diagnostic and baseline studies. This assumption that the population of primary interest is women 40 y and older limits application of the computational models to the older on average, more adipose breast, which helps justify certain simplifying assumptions. A major technique variable is the

degree of compression employed. Firm compression, which is assumed in dose computations, greatly distorts the breast anatomy, making more rectangular the sagittal and transverse cross-sections of the volume that includes the glandular tissue. This greatly simplifies the breast geometry and makes the computational models more appropriate than otherwise would be the case (Section 5).

The mean glandular dose (\bar{D}_g) meets the stated requirements outlined above. The computational model used in this Report for \bar{D}_g assumes that 0.5 cm thick adipose layers enclose a central "glandular tissue" containing a uniform mix of glandular and adipose tissues in roughly equal amounts. The procedure for estimating mean glandular dose for a specific population of patients is described in Table 4.3 (Approach II).

A basic requirement for maintaining optimum image quality in mammography is implementation of a suitable QA program (Section 6). Each of the items contributing to image quality must be evaluated on a regular basis. The quality administration program (medical audit) evaluates the appropriateness and accuracy of image interpretation (Section 6.3).

The benefit from screening by mammography and physical examination in the form of decreased breast cancer mortality has long been accepted for women above age 50 on the basis of a randomized trial (the HIP study, see Section 7), which indicated that the contribution of mammography to decreased breast cancer mortality was significant in older women.

The randomized clinical trials of mammographic screening have not demonstrated a benefit for women age 40 to 49, within the first 7 y of starting screening. Those trials for which 10 or more years of follow-up is available, show evidence of a 23 percent benefit in reducing mortality. Although this reduction is smaller than that observed for older women, it is statistically significant and therefore, one can reject the possibility that this may have happened by chance.

Compared with mammography practiced in the previous randomized trials, high-quality modern mammography could result in increased benefit. Even a very small benefit (*e.g.*, one percent) more than offsets any risk of radiation-induced breast cancer. The benefit versus risk will be substantial, if analysis of ongoing screening experience demonstrates a reduction in breast cancer mortality rate of 30 percent or more.

Among the various imaging methods designed to evaluate the breast for cancer, mammography is the most accurate and most widely used. It has gained clinical acceptance primarily because of

its ability to detect a cancer before the tumor mass becomes large enough to be palpable, thereby permitting “early” diagnosis. It has also been proven an invaluable tool to distinguish benign from malignant lesions and can facilitate prompt biopsy of cancers, while encouraging clinical observation (rather than biopsy) of many benign masses. Other breast imaging methods have, thus far, been considered less successful; these include thermography, transillumination, ultrasonography, and MRI and MRS all of which do not utilize ionizing radiation. Computed tomography (Section 8.4) and digital mammography (Section 3.3) which use x rays, and therefore involve the potential risk of mammary carcinogenesis are being subjected to clinical investigation to determine their role in breast cancer diagnosis. Explanations of the principles of operation, a chronology of developments, and an extensive discussion of the limitations of each of these methods is contained in Sections 3.3 and 8.4.

9.2 Conclusions

- Mammography, in conjunction with physical examination, is the method of choice for early detection of breast cancer. Other methods should not be substituted for mammography in diagnosis or screening, but may be useful adjuncts in specific diagnostic situations.
- Diagnostic mammography of symptomatic women should always be performed when indicated, utilizing recommended equipment and techniques and well-trained, knowledgeable personnel.
- Screen-film mammography requires dedicated x-ray units, firm compression, and an x-ray spectrum produced by an appropriate combination of x-ray tube target, tube window, filtration, operating potential, screen-film combination, film processors, technique, and viewing conditions. The CC and MLO views are recommended as the standard views for all types of mammography.
- Mammographic equipment should be chosen to provide acceptable image quality at a typical mean glandular dose (for a two-view examination) of 6 mGy, or less for screen-film image receptor with grid for a patient having 4.5 cm thick-compressed breasts of 50 percent adipose and 50 percent glandular tissue composition.
- Image quality and appropriate dose level should be maintained by a QA program conducted by a QA technologist and

medical physicist, involving specified periodic measurements and readjustment of all aspects of the imaging and viewing system.

- Mean glandular dose should be determined at least annually at each installation for the techniques used at representative breast thicknesses. This dose can be calculated from data supplied in this Report by measuring beam quality and in-air exposure at the entrance surface of the breast.
- A quality administration program (medical audit) should be used to compare the facility's clinical outcomes with established guidelines.
- Annual mammographic screening examinations appear to provide favorable benefit/risk ratios in terms of breast cancer mortality in women age 50 or above, if acceptable image quality and dose are maintained.
- Results of randomized clinical trials of screening mammography for women age 40 to 49, for which 10 or more years of follow-up is available, have shown evidence of a substantial benefit in reducing mortality which exceeds any risk of radiation-induced breast cancer.