

3rd

International Congress
of Breast Disease Centers

2013

**THE BREAST CENTER :
A MODEL TO IMPROVE PATIENT CARE**

**REQUIREMENTS FOR INTERNATIONAL
ACCREDITATION OF BREAST
CENTERS/UNITS**

The Radiology Aspects

Miri Sklair-Levy , Israel

RADIOLOGY – GUIDELINES FOR QUALITY ASSURANCE IN BREAST CANCER SCREENING AND DIAGNOSIS



- Radiologists take prime responsibility for the **mammogram**
 - **Image quality**
 - **Diagnostic interpretation**

RADIOLOGY – GUIDELINES FOR QUALITY ASSURANCE IN BREAST CANCER SCREENING AND DIAGNOSIS



- Requirements of the radiologist
 - ▣ Medical qualification
 - ▣ Specific training in screening and diagnostic mammography
 - ▣ Participation in continuing medical education program and external quality assessment

Requirements of the radiologist – Cont'

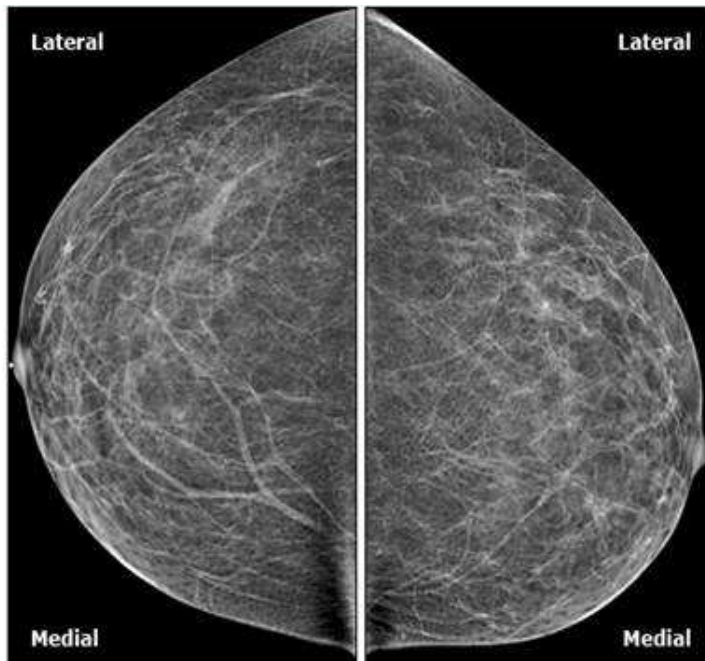
- **Breasts Radiologist** read at least **1000** mam/year
 - Screening programs - **5000** mam/year

- **Radiologists** should refuse to accept unsatisfactory mammograms and demand that they be repeated.
 - All repeated mammograms should be recorded

- **Radiologist** - lead the assessment process when women are recalled for examination based on an abnormal findings at screening .
 - Triple assessment -clinical examination , further imaging and tissue sampling

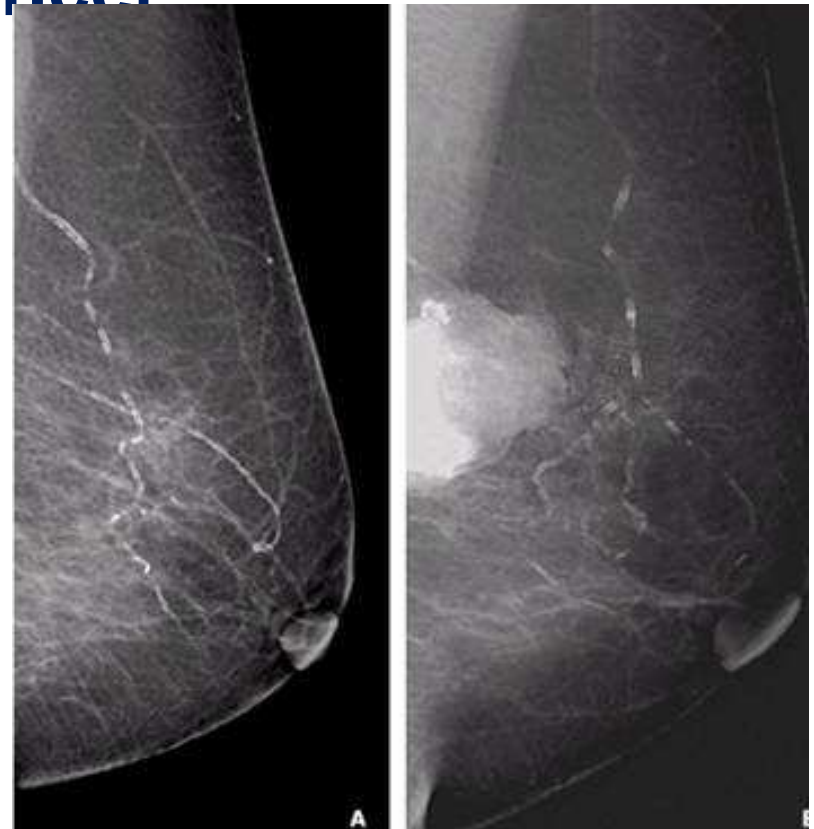
THE MAMMOGRAPHIC EXAMINATION

- 2 views (craniocaudal and mediolateral oblique) of each breast.
- **Breast positioning is critical**



THE MAMMOGRAPHIC EXAMINATION

- Improper positioning may lead to exclusion of parts of the breast from the field of view
- **non-visualization of a cancer**



Requirements of the radiologist – Cont'

- Radiologists must review cases of **interval cancers**

- Radiologists - as part of a **multidisciplinary team**.
 - ▣ The multidisciplinary teams composed of specialists for all disciplines of the diagnosis and treatment
 - Surgeon, Oncologist , Pathologist
 - Frequent **meetings** for the discussion of clinical cases.

EQUIPMENT - MAMMOGRAPHY

- Technical aspects
 - ▣ **Analog mammography** – should be tested for
 - Standard quality control testing, including , the developer equipment adjunct to mammography.
 - Measurements performed by the local team , medical physicists as indicated by the company.
 - Those measurements should be recorded according to a known protocol

EQUIPMENT - MAMMOGRAPHY



- Technical aspects
- **Analog mammography**

- **Parts of the system that should be monitored**
 - ▣ The mammography machine
 - ▣ Bucky (film cassette holder) and image receptor
 - ▣ The developer unit
 - ▣ Printers
 - ▣ Reading room

Digital mammography



- Quality control adjusted for digital system
- The systems are new
 - ▣ Should be continuously updated about the instructions.

EQUIPMENT



- Ultrasound
- MRI
- Image guided biopsies – ultrasound guidance , stereotactic guidance , MRI guidance

EQUIPMENT



- **The equipment should be recorded :**
- Analogue mammography Device ... Model...
Year:
- Digital Mammography DeviceModel:....
Year:....
- System of processing:.....
- Ultrasound Device :.....Model... Year:.....
- MRI: Model..... Year.....
- Biosv equipment:..... Model..... Year:.....

Radiographers

- Radiographers must have the experience and the **special training to perform mammography.**
- Radiographers responsible for producing a **high quality mammograms** necessary to detect breast irregularities , and for processing and assessing the mammograms.
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- Radiographers implement and conduct quality control procedures for equipment monitoring

Radiographers

- Radiographers in **screening** programs must work a minimum of **2 days per week** to maintain their mammography skills
- Radiographers **not working in a screening program** , should perform at least **20 mam. in a week**
- **More than 97%** of the women screened should have an acceptable examination
- **Less than 3% of the women should have a repeat examination**

Radiographers



- **Training :**
 - 3d - 1week of academic mammography training
 - 2-6 weeks of clinical training.

- Should participate in multidisciplinary team meetings

Diagnostic breast imaging center

- Perform at least **2000** mammograms in a year
 - Ability to perform mammography
 - Mammography diagnostic and additional projections
- US
- MRI
 - Clinical breast examination
 - Image guided biopsies – FNA, core needle biopsies-using the different imaging modalities
 - Pathological service

Diagnostic breast imaging center

- Radiologist reading 1000 mam./year , screening program 5000 mam./year.
- Be a part of a regular multidisciplinary team
- Participate in a continuous medical education
- Monitoring the data and the results of the mammography and the biopsies
- **90% of symptomatic women should be examined within 2weeks**
- **The time to receive mammography answer should be < 5 working days**

Diagnostic breast imaging center

- **Work in Multidisciplinary Teams**

- Discussion of all cases of breast cancer
 - ▣ To plan the treatment - before surgery ,after surgery

- Discussion of problematic cases - in multidisciplinary committee -radiologists, pathologists , surgeons

Radiology Interventionist



- **Needle biopsies:**
- Ultrasound guided
- Mammography guided
- MR guided
- Placement of clip markers

Radiology Report



- BIRADS Lexicon
- **Statistics of Diagnostic radiology**
 - Number of : MX
 - Number US
 - Number of Biopsies
 - Diagnostic MRI - indications

Mammography



- Screening mammography is the primary imaging modality for early detection of breast cancer
- The only method of breast imaging that consistently has been found to decrease breast cancer-related mortality
 - Ann Intern Med. 2002
 - Cancer. 2001

THE MAMMOGRAPHIC EXAMINATION

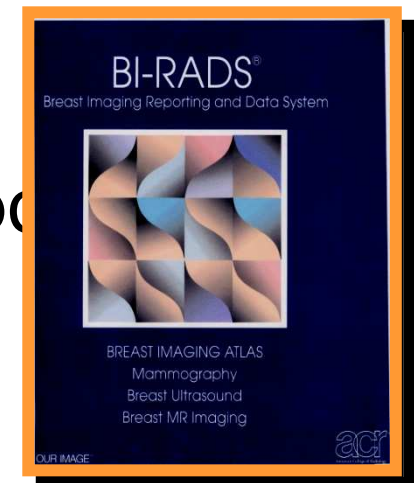
- **Radiation dose** — The purpose of screening mammography is to decrease mortality by identifying early stage breast cancer.
- There is no evidence that routine screening mammography in women, initiated at age 40, is associated with increased risk from radiation
 - Benefits versus risks from mammography: a critical reassessment. Cancer. 1996
- Digital mammography is associated with a lower radiation dose than film screen mammography for the same image quality
 - Eur J Radiol. 2007

MAMMOGRAPHY QUALITY CONTROL

- Variation in mammographic quality and standard of practice in **United States** led to the development of the mammographic accreditation program by the American College of Radiology in 1987
- The **Mammography Quality Standards Act (MQSA)** was passed in 1992 by Congress
- The MQSA establishes guidelines for quality control for individual imaging centers and mandates that all US facilities should be accredited by the American College of Radiology.

MAMMOGRAPHY QUALITY CONTROL

- BI-RADS - The Breast Imaging Reporting and Data System - developed by the American College of Radiology
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- To **standardize** the mammography reports
 - ▣ Findings , conclusions
 - Mammography, extended for US , MRI
- The FDA mandates that all mammography reports should have the final BI-RADS assessment category



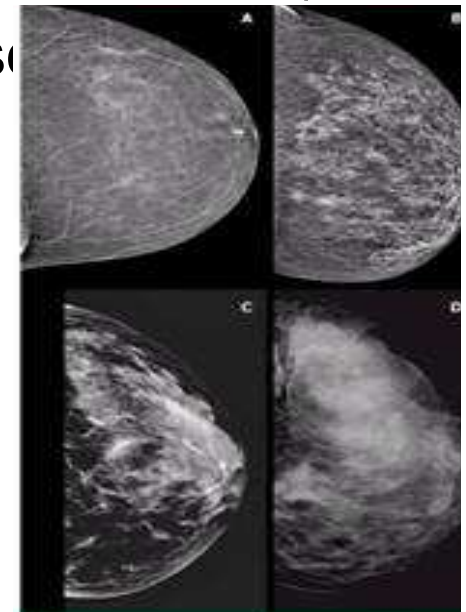
The mammography report

- The use of BI-RADS
 - ▣ Standardized reporting
 - ▣ Helps guide decision making
 - ▣ Collecting data and in auditing individual practices.

- **Indication** — The main indication for the study and type of examination (screening versus diagnostic) is stated.
 - ▣ Any previous examinations used for comparison are mentioned in the beginning of the report.

Breast density - BIRADS

- All reports have a statement regarding the breast density.
- 4 main categories :
 - Predominantly fatty (0 to 25 % dense)
 - Scattered fibroglandular densities (25 to 50 % dense)
 - Heterogeneously dense (51 to 75 % dense)
 - Dense (greater than 75%)



The mammography report

- **Description of abnormalities**
- **Summary** — The report concludes with a pertinent summary stating the most important findings and the final BIRADS assessment category
- BI-RADS category only refers to the **imaging findings**
 - Does not take clinical findings or presentation into account.
 - **Therefore**, if the patient has negative imaging evaluation but has a clinically-suspicious lump, a biopsy may still be indicated even though the BI-RADS category is 1 or 2

The FDA mandates that all mammography reports include a final BI-RADS assessment category.

BI-RADS mammographic assessment categories

Assessment category	Recommendation	Probability of malignancy
0: Incomplete	Need for further evaluation	Not applicable
1: Normal	Normal interval follow-up	0 percent
2: Benign	Normal interval follow-up	0 percent
3: Probably benign	A short interval follow-up is recommended	≤2 percent
4: Suspicious abnormality	A biopsy should be considered	>2 to 95 percent
		(a) Low-risk
		(b) Intermediate-risk
5: Highly suggestive of malignancy	Biopsy or surgery should be performed	(c) Moderate to high-risk
		≥95 percent
6: Biopsy-proven carcinoma	Appropriate action should be taken	

BI-RADS: Breast Imaging Reporting and Data System.
Breast Imaging Reporting and Data System (BI-RADS) Atlas. 4th Edition. American College of Radiology, Reston, VA, 2003

In Summary

- RADIOLOGY – GUIDELINES FOR QUALITY ASSURANCE IN BREAST CANCER SCREENING AND DIAGNOSIS
- Radiologist - responsible –image quality ,equipment, diagnostic, screening center
 - ▣ Training radiologists , radiographers
- BIRADS report
- Work in multidisciplinary teams -diagnosis and treatment ,frequent meetings
- Database available for audit.



THANK YOU

STANDARDS OF QUALITY

- Recognition by the Health Centers that their Units of the Breast are independent units and with self capacity. For the start of the formalities of accreditation is required to have an age of 3 years.
- Work in multidisciplinary teams composed of specialists for all disciplines of the diagnosis and treatment and with frequent meetings for the discussion of individualized clinical cases
- Training accredited all specialists members of the Unit of Breast
- Protocols of Diagnosis, Treatment and Monitoring of Breast Cancer updated
- Top have a Database own in the recorded all the Indicators Quality. These data are available to carry out an audit.

Supplemental screening in women with dense breasts

- The recognition of the increased risk of breast cancer in women with dense breasts, and the availability of screening ultrasound as an adjunct to mammography, has led to new guidelines and legal requirements for reporting breast density in the United States.
- Preliminary data demonstrate that US screening of women with dense breasts detects on average 0.8 to 10.0 additional cancers per 1000 women screened but has substantial false positives with the biopsy positivity rate being under 10 percent
 - Radiology. 2012
 - Improved breast cancer detection in asymptomatic women using 3D-automated breast ultrasound in mammographically dense breasts. Giuliano Clin Imaging. 2012

ULTRASOUND

- As adjunct to mammography for screening
- The use of ultrasound as an adjunct to mammography in primary screening for breast cancer has been evaluated in many studies
- The addition of ultrasonography to mammography increases sensitivity for small cancers but decreases specificity
- A large prospective, multicenter trial conducted through the American College of Radiology Imaging Network (ACRIN Protocol 6666) evaluated the diagnostic yield of screening ultrasound in addition to mammography in high-risk women with at least heterogeneously dense breasts on mammography
 - JAMA. 2008
 - adding screening ultrasound to mammography will identify an additional 4.3 cancers per 1000 women screened
- For women with dense breasts as their only risk factor for breast cancer, the American College of Radiology states that “the addition of ultrasound to screening mammography may be useful for incremental cancer detection
- The US Food and Drug Administration approved an automated ultrasound device in September 2012 to be used as an adjunct to mammography for asymptomatic women with dense breasts and a negative mammogram

Tomosynthesis

- Breast tomosynthesis (also known as “3-D mammography”) has been approved by the US Food and Drug Administration for routine clinical use
- Tomosynthesis is a modification of digital mammography and uses a moving x-ray source and digital detector.
- A three dimensional volume of data is acquired and reconstructed using computer algorithms to generate thin sections of images
 - ▣ thin slice reconstruction improves the delineation of a lesion in the slice by eliminating overlap from surrounding structures
 - ▣ At present, tomosynthesis is approved only to be performed in conjunction with a conventional mammogram
 - ▣ Hence, when performed in the screening setting, the patient is exposed to approximately twice the usual radiation dose, which sometimes is greater if the patient had dense or thick breasts

THE MAMMOGRAPHIC EXAMINATION

- The effective radiation dose is often expressed in sievert or millisievert (mSv) units.
- Sievert units account for relative sensitivities of different tissues and organs exposed to radiation
- The effective dose received from a routine screening mammogram is 0.7 mSv, equivalent to the dose received from natural background radiation over three months.

THE MAMMOGRAPHIC EXAMINATION

- The radiation dose absorbed by the breast depends upon the breast tissue thickness, with the dose absorbed increasing with the thickness of the breast
- Most mammography equipment delivers a mean glandular dose of 0.1 to 0.2 rads (1 to 2 mGy) per exposure.
- The American College of Radiology recommends that the mean glandular dose exposure for a breast that is 4.2 cm thick should not exceed 0.3 rads (3 mGy) per image.

THE MAMMOGRAPHIC EXAMINATION



- film mammography remains an acceptable screening modality for all women.
- Digital mammography, when available, may offer a small screening advantage in women younger than 50 years old.

The mammography report

- Clinical decision making
- A positive mammography report — All reports with BIRADS 0, 4 or 5 need further intervention.
 - ▣ The clinician is contacted to convey the need for biopsy, and both the clinician and patient are contacted to convey the need for further imaging
 - ▣ A BI-RADS 4c or 5 should alert the pathologist that a malignant diagnosis is strongly suspected and that further evaluation of the specimen (and possible rebiopsy) is needed if the biopsy is initially interpreted as benign
 - ▣ A negative mammography report — should not deter further intervention if there is clinical suspicion for malignancy
 - false-negative rate of screening mammography -10 to 30%
 - false-negative rate highest in women with markedly dense breast tissue

MAMMOGRAPHY QUALITY CONTROL

- The **Breast Imaging Reporting and Data System (BI-RADS)** - developed by the American College of Radiology to standardize the mammography report.
- BI-RADS was initially developed for mammography, extended to breast ultrasound and MRI
- The BI-RADS manual consists of standardized language to describe the radiological findings and conclusions.