Complex radiologic evaluation of breast diseases

Endre Szabó
1 thing to remember:

• Do not touch the breast before the period!
Development
• Clinical examination
  – palpable lump
  – nipple discharge
  – skin change
  – pain

• Screening
  – László Tabár
Diagnostic tools

• X-ray mammography
• ultrasound
• MRI
• CT
• nuclear medicine
• PET
• alternatives
Minimum criteria:

- high frequency generator
- Automatic Exposition Control (AEC)
- 0.4 mm nominal focal spot, Mo rotating anode
- adjustable compression plate
- 18x24 and 24x30 cm cassette holder with Bucky table
- spot compression views
- accessories for X-ray guided biopsy
- high definition screen-film system
- forced development /35 °C, 180/90 s/
- high power /5000 lux/m²/ viewing box, magnification
- QC devices /breast phantom, mammographic sensito-densitometer/
2002 Physician Insurers Association of America

- breast cancer has the highest incidence
- second highest fees claimed at court
- radiologist is the most frequently sued speciality
DIGITAL MAMMOGRAPHY

1) storage phosphor plate resolution: 50µ

IDC + EIC (1999)

FDA
Full Field Direct Digital Mammography (FFDM)

DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service
Food and Drug Administration
9200 Corporate Boulevard
Rockville, MD 20850

JAN 28 2000

P590966

Senograph 2000 D Full Field Digital Mammography System
Filed: October 29, 1999

Dear Dr. Kroeger,

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your premarket approval application (PMA) for the Senograph 2000 D Full Field Digital Mammography System. This device is indicated for generating mammographic images that can be used for screening and diagnosis of breast cancer. The Senograph 2000 D is intended to be used in the same clinical applications as traditional mammographic film-screen systems. We are pleased to inform you that the PMA is approved subject to the conditions described below and in the “Conditions of Approval” (enclosed). You may begin commercial distribution of the device upon receipt of this letter.

The sale, distribution, and use of this device are restricted to prescription use in accordance with 21 CFR Sections 801.109 within the meaning of section 516(b)(2) of the Federal Food, Drug, and Cosmetic Act (the Act) and under the authority of section 515(g)(1) of the Act. Until such time as an FDA approved accreditation process for full-field digital mammography has been developed the Senograph 2000 D Full Field Digital Mammography System must only be sold to accredited/detected facilities. FDA has also determined that, to ensure the safe and effective use of the device, the device is further restricted within the meaning of section 522(g) under the authority of section 515(g)(1) of the Act as the labeling specifies the requirements that apply to the training of practitioners who may use the device as approved in this order and (2) insofar as the labeling specifies that the device is to be used in accordance with section 515(g)(1) of the Act.

CDRH will notify the public of its decision to approve your PMA by making available a summary of the safety and effectiveness data upon which the approval is based. The information can be found on the FDA CDRH Internet Home Page located at http://www.fda.gov/cdrh/pma/appa.html. Written requests for this information can also be made to the Dockets Management Branch, (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. The written request should include the PMA number or docket number. Within 30 days from the date that this information is placed on the Internet, any interested person may seek review of this decision by requesting an opportunity for an independent advisory committee, under section 515(g) of the Federal Food, Drug, and Cosmetic Act (the Act).

FDA
Postprocessing
CAD=Computer Aided Diagnosis
Digital mammography

**Advantages:**
- Better imaging of dense breasts
- Postprocessing
- Simple storage, reproduction
- Copies
- CAD
- Telemammography, teleconsultation
- Experimental applications

**Disadvantages:**
- Price
Workup

- extra views (latero-lateral, spot-compression), invasive examinations (galactography, pneumocystography)
US mammography

Technical requirements:

- high definition device
- high frequency (10-17 MHz), linear, 40 mm transducer
- shallow focusing (0-4 cm)
- image storage
US mammography

advantages:

• dense breasts (cystic – solid)
• paramammary regions
• US guided interventions (FNAC, CB, drainage, preoperative localisation)
• simple, cheap, quick
US mammography

disadvantages:

• aspecific signs (scar– tu – chr. inflammation – granuloma)
• limited resolution (microcalcs – DCIS)
Sampling

- exfoliative (smear)
- aspiration cytology
- core biopsy
- vacuum core
- cyst drainage (pneumocystography)
- preoperative localisation
- galactography

- UH / X-ray/ MRI guidance
Biopsy

Sampling

- Cytology:
  - 23, 21, 19 Gauge

- Core biopsy (automated gun):
  - 14 G (2.1mm)

- Vacuum core biopsy (Mammotome):
  - 11 or 8 G

- ABBI:
  - 10-20 mm
Core Bx indications

- **PREOPERATIVE HISTOLOGY: THERAPY PLANNING**
  - *to avoid:* „diagnostic” surgery, frozen sections, 2nd sitting
  - choose type of operation (oncologic, psychic and legal factors)
  - preop. chemo-radiotherapy (mastitis carcinomatosa)


- after inadequate cytology:

- **RADIOLOGICALLY:**
  - solid nodule
  - architectural distortion
  - microcalc
  - mastitis carcinomatosa

  **To rule out malignancy**
  (FIBROADENOMA)
Core Bx needle

- diameter 14G (2.1 mm)
- notch: 15-22 mm

"...comparison of samples obtained with 14-, 16, and 18 gauge..."

Nath ME, Robinson TM, Tobon H. et al.
Dept. of Pathology, University of Pittsburgh
RADIOLOGY, 1995 Dec, 197:3,739-42
Vacuum core biopsy

• bigger samples
  – almost complete removal before final breast conservation surgery
Sztereotactic Vacuum Core Biopsy (Mammotome)
Breast MRI

- coil (uni-) bilateral
- compression
Breast MRI

• **Best** indications
  – ?implant rupture
  – occult primary
  – family screening of high risk patients
  – multifocality, tumor size exact measurement
  – to rule out invasive tumor and recurrence

• **Good** indications

• "problem solving"

• monitoring chemotherapy

• **Bad indications**
  – lesion can be Bx-ed (microcalc, etc)
  – lesion can be diagnosed only pathologically (radial scar)
  – VIP, aversions for X-ray mammo, axillae…
Diagnostic criteria

- kinetics
  - I: steady
  - II: plateau
  - III: washout

Tomosynthesis
Preoperative marking of non-palpable breast lesions

- skin scratch
- wire
- staining/ductography
- isotope
Isotope – ROLL, SNOLL

Radio guided Occult Lesion Localisation

Sentinel Node plus Occult Lesion Localisation