Breast Cancer Update for Primary Care

Ann Stroh, D.O.

April 6th, 2018
Objectives

• Understand new staging guidelines, prognostic features and selection of therapy
• Long term follow up on patient with history of breast cancer
• Understand how breast density affects screening – options
• Side effects of long term therapy
Breast Cancer

- Most frequently diagnosed cancer – over 1 million cases per year
- Leading cause of death of women from cancer world-wide
- In the US – most common female cancer and second most common cause of cancer death in women – particularly in women aged 40-49
Breast cancer is diagnosed every 29 seconds around the world, and in the U.S. it’s every 2 minutes.

It is estimated that 86.4% of people will survive 5 or more years after being diagnosed with breast cancer.

There is estimated to be more than 2.8 million breast cancer survivors in the U.S.

Breast cancer is the leading cause of cancer death in women, after lung cancer. The chance of a woman dying from early stage breast cancer is estimated to be 1 in 36 (about 3%).

**INCIDENCE OF BREAST CANCER PER 100,000 CASES BY RACE**

<table>
<thead>
<tr>
<th>Race</th>
<th>Incidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>White (Caucasian)</td>
<td>127.9</td>
</tr>
<tr>
<td>African American</td>
<td>124.4</td>
</tr>
<tr>
<td>Asian/Pacific Islander</td>
<td>96.3</td>
</tr>
<tr>
<td>Hispanic</td>
<td>92.1</td>
</tr>
<tr>
<td>American Indian/Alaska Native</td>
<td>82.0</td>
</tr>
</tbody>
</table>
Staging of Breast Cancer
DCIS and LCIS

• DCIS – ductal carcinoma in situ
  – Heterogeneous group of pre-cancerous lesions confined to breast ducts
  – Potential precursor lesion to invasive breast cancer

• LCIS – lobular carcinoma in situ - Not considered cancer in 2018 AJCC staging
  – High risk lesion of the breast
  – Question prevention
Lobular Carcinoma In Situ
Stage 0 Ductal Carcinoma In Situ
• Staged using the American Joint Committee of Cancer and International Union for Cancer control (AJCC-UICC)
• Patients are assigned a clinical stage (cTMN) and pathologic stage (pTMN)
• T – tumor size
• N - nodal status
• M - distant metastatic disease
Stage I
Tumor size <2.0 cm
Negative
Nodes – node negative
**Stage II**

Stage IIA
- tumor >2.0 cm and <5.0 cm
- nodal status negative

Stage IIB
- tumor >2.0 and <5.0 cm
- tumor >5.0 cm, node negative
- positive node – N1
**Stage III**

Stage IIIA
- lesion up to 5 cm with fixed nodes
- Lesion >5 cm with N1 disease

Stage IIIB
- any size with extension into chest wall
- any number of nodes

Stage IIIC
- Any T
- Nodes – Infraclavicular nodes, internal mammary nodes
Inflammatory Breast Cancer – Stage IIIC

Characterized by diffuse erythema and edema (peau d’orange) involving a third or more of the breast

Lymphedema
Stage IV

Disease spread to other parts of the body

- Bones
- Brain
- Liver
- Lung
PATHOLOGY
Pathology

• Various histologic types
  – Infiltrating ductal carcinoma – 70-80% of invasive breast cancer
  – Infiltrating lobular carcinoma – 8% of invasive breast cancers
  – Mixed ductal/lobular – 7% of invasive breast cancers
  – Others: metaplastic, mucinous, tubular, medullary and papillary - <5% of breast cancers
Breast Cancer

• Heterogeneous, phenotypically diverse disease composed of several biologic subtypes
• These have distinct behavior and response to therapy
• 3 major characteristics looked at:
  • 1 - Estrogen receptor status – ER
  • 2- Progesterone receptor status – PR
  • 3- Her 2 neu status
Pathology – molecular subtypes

• Luminal subtypes – most common – ER positive breast cancers
  – Luminal A – more indolent
  – Luminal B – more aggressive

• Her 2 enriched – 10-15% - overexpression of Her 2

• Basal subtypes – triple negative breast cancers
• **Subtype**  These tumors tend to be*      Prevalence (approximate)

  • Luminal AER+ and/or PR+, HER2-, low Ki67 40%
  • Luminal BER+ and/or PR+, HER2+ (or HER2- with high Ki67) 20%
  • Triple negative/basal-like ER-, PR-, HER2- 15-20%
  • HER2 type ER-, PR-, HER2+ 10-15%

• *These are the most common profiles for each subtype. However, not all tumors within each subtype will have all these features.

• ER+ = estrogen receptor-positive
• ER- = estrogen receptor-negative
• PR+ = progesterone receptor-positive
• PR- = progesterone receptor-negative
• HER2+ = HER2/neu receptor-positive
• HER2- = HER2/neu receptor-negative
8th Edition AJCC Staging

- Updated 2018
- Determined by a multidisciplinary team of breast cancer experts – recognizing the need to incorporate biologic factors into staging system
- Introduction of biomarkers to identify groups with different molecular characteristics and different prognosis
8th Edition AJCC Staging

• MD Anderson performed study – 3728 patients who were treated between 1997-2006 – update 2007-2014
  – Bioscore
  – Points 0-7 – considers grade, ER status, Her 2 neu status
  – Points for grade 3, ER negative, Her 2 neu negative
<table>
<thead>
<tr>
<th>BIOSCORE: POINTS ASSIGNED</th>
<th>DSS (95% CI), %</th>
</tr>
</thead>
<tbody>
<tr>
<td>0, n = 36</td>
<td>100</td>
</tr>
<tr>
<td>1, n = 1204</td>
<td>99.4 (98.8-99.8)</td>
</tr>
<tr>
<td>2, n = 919</td>
<td>99.2 (98.0-99.7)</td>
</tr>
<tr>
<td>3, n = 667</td>
<td>97.2 (95.2-98.4)</td>
</tr>
<tr>
<td>4, n = 339</td>
<td>94.2 (90.1-96.7)</td>
</tr>
<tr>
<td>5, n = 129</td>
<td>92.0 (84.5-96.0)</td>
</tr>
<tr>
<td>6, n = 23</td>
<td>77.3 (53.6-89.9)</td>
</tr>
<tr>
<td>7, n = 10</td>
<td>33.3 (6.3-64.6)</td>
</tr>
</tbody>
</table>

Abbreviations: 95% CI, 95% confidence interval; DSS, disease-specific survival. Source: Personal communication, Mittendorf EA (unpublished data).
### TABLE 8. Examples of Revisions to Breast Cancer Staging Using Biomarkers and Oncotype DX

<table>
<thead>
<tr>
<th></th>
<th>T</th>
<th>N</th>
<th>M</th>
<th>G</th>
<th>HER2</th>
<th>ER</th>
<th>PR</th>
<th>SEVENTH EDITION ANATOMIC STAGE/PROGNOSTIC GROUP</th>
<th>EIGHTH EDITION PROGNOSTIC STAGE GROUP</th>
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</thead>
<tbody>
<tr>
<td>Biomarkers</td>
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<td></td>
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<td>1</td>
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<td>1</td>
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<td>IA</td>
<td>IIA</td>
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<tr>
<td>1</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>3</td>
<td>-</td>
<td>+</td>
<td>-</td>
<td>IA</td>
<td>IIA</td>
</tr>
<tr>
<td>3</td>
<td>1-2</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>IIIA</td>
<td>IB</td>
</tr>
<tr>
<td>Oncotype DX recurrence score-&lt; 11 for ER-positive tumors</td>
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<tr>
<td>2</td>
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<td>0</td>
<td>0</td>
<td>Any</td>
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<td>+</td>
<td>Any</td>
<td>IIA</td>
<td>IB</td>
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<tr>
<td>1-2</td>
<td>1</td>
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<td>0</td>
<td>Any</td>
<td>-</td>
<td>+</td>
<td>Any</td>
<td>IIA/IIB</td>
<td>IB</td>
</tr>
<tr>
<td>0-2</td>
<td>2</td>
<td>0</td>
<td>1-2</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>IIIA</td>
<td>IB</td>
</tr>
</tbody>
</table>

Abbreviations: -, negative; O+, positive; ER, estrogen receptor; G, grade; HER2, human epidermal growth factor receptor 2; M, metastasis classification; N, lymph node classification; PR, progesterone receptor; T, tumor classification.
## TABLE 7. Five-Year Disease-Specific Survival Outcomes by Bioscore for The University of Texas MD Anderson Cancer Center Cohort (N = 3327)

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TABLE 9. Comparison of Outcome Studies Using Multigene Panels to Define Patients With Low-Risk Biology

<table>
<thead>
<tr>
<th>Study</th>
<th>Type of Study</th>
<th>Prospective decision-making based on multigene testing</th>
<th>Definition of low-risk biology</th>
<th>No. of low-risk patients</th>
<th>T classification T1c/T2</th>
<th>Systemic therapy</th>
<th>Median follow-up, y</th>
<th>5-Year outcomes for low-risk patients</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>TAILORX STUDY (SPARANO 2015)</td>
<td>Prospective clinical trial, not randomized</td>
<td>Yes</td>
<td>Recurrence score ≤ 10</td>
<td>1626</td>
<td>61%/31%b</td>
<td>97-100% hormones, &lt; 1% chemo</td>
<td>5.75</td>
<td>Invasive disease-free survival</td>
<td>93.8%</td>
</tr>
<tr>
<td>STEMMER 201517,18</td>
<td>Population-based, HMO (Israel)</td>
<td>Yes</td>
<td>Recurrence score &lt; 18</td>
<td>813</td>
<td>Unk</td>
<td>Unk hormones, 1% chemo</td>
<td>5.9</td>
<td>Invasive disease-free survival</td>
<td>99.5%</td>
</tr>
<tr>
<td>RASTER STUDY (Drukker 2013)</td>
<td>Community-based (Netherlands)</td>
<td>Yes</td>
<td>Low MammaPrint and low Adjuvant! Online</td>
<td>95</td>
<td>Unk/0%</td>
<td>4% hormones, 3% chemo, and hormones</td>
<td>5.1</td>
<td>Invasive disease-free survival</td>
<td>94.3%</td>
</tr>
<tr>
<td>SHAK 201519</td>
<td>SEER database (Netherlands)</td>
<td>No</td>
<td>Recurrence score &lt; 18</td>
<td>21,023</td>
<td>53%/Unk</td>
<td>7% hormones, 3% chemo, and hormones</td>
<td>3.25</td>
<td>Invasive disease-free survival</td>
<td>99.3%</td>
</tr>
</tbody>
</table>

Abbreviations: Chemo, chemotherapy; HMO, health maintenance organization; RASTER, Microarray Prognostics In Breast Cancer; SEER, Surveillance, Epidemiology, and End Results; TAILORx, Trial Assigning Individualized Options for Treatment; Unk, unknown. bThe analysis was restricted to studies that reported 5-year outcomes. bT1c and T2 tumors measured 1.0 to 1.9 cm and ≥ 2.0 cm, respectively. cClassification is for all patients, not just those with low recurrence scores. dValues indicate breast cancer-specific survival for patients with chemo vs no/unknown chemo, respectively.
TREATMENT OPTIONS – NEOADJUVANT VS ADJUVANT
Neoadjuvant

• Purpose:
  – Downstage tumor – allowing for less extensive surgery
  – Improve cosmetic outcomes
  – Reduce postoperative complications (lymphedema)
  – Permits an early evaluation of effectiveness of systemic therapy
    • Surrogate endpoint – presence of absence of residual disease – strong prognostic factor for risk of recurrence
Fig 2. Prognostic impact of pathologic complete response (pCR) on disease-free survival (DFS) in 4,193 patients according to breast cancer intrinsic subtype. (A) Patients with luminal A-like tumors, (B) luminal B/human epidermal growth factor receptor 2 (HER2)−negative−like tumors, (C) luminal B/HER2-positive−like tumors, (D) HER2-positive (nonluminal)−like tumors, and (E) triple-negative tumors; (F) comparison of DFS in 717 patients achieving pCR according to breast cancer intrinsic subtype.
Adjuvant Systemic Therapy

• Stage and Molecular features determine treatment modalities

• For example:
  – Node positive - chemotherapy standard of care
  – +/- endocrine therapy
  – +/- Herceptin
  – Node negative
Hormone receptor positive breast cancer

• Threshold for adjuvant chemotherapy in addition to adjuvant endocrine treatment – most controversial issues
• First area of focus should be on tumor biology
• What benefit endocrine therapy is likely to bring
PREDICTIVE TESTS TO ASSESS RISK
Adjuvant Online

- Tool to assess risks of an individual patient
- Discussion with physician
- Predicts the likelihood of developing recurrent disease and/or dying within a 10 year period
- Draws from SEER data base
- www.adjuvantonline.com

Ravdin, et. al. JCO 19(4) 980-991, 2001
Adjuvant! Online
Decision making tools for health care professionals

Adjuvant! for Breast Cancer (Version 8.0)

Patient Information

Age: 40
Comorbidity: Minor Problems
ER Status: Negative
Tumor Grade: Grade 3
Tumor Size: 3.1 - 5.0 cm
Positive Nodes: 1 - 3
Calculate For: Mortality
10 Year Risk: 52 Prognostic

Adjuvant Therapy Effectiveness

Horm: Tamoxifen (Overview 2000)
Chemo: 2nd Generation Regimens

Hormonal Therapy: 0
Chemotherapy: 44
Combined Therapy: 44

No additional therapy:
- 47.1 alive in 10 years.
- 51.8 die of cancer.
- 1.1 die of other causes.

With hormonal therapy: Benefit = 0.0 alive.

With chemotherapy: Benefit = 18.4 alive.

With combined therapy: Benefit = 18.4 alive.
Oncotype DX

- Recurrence Score Result
- The Oncotype DX assay analyzes the expression of 21 genes by RT-PCR to provide a Recurrence Score unique to each patient\(^1,2\)
- The Recurrence Score predicts chemotherapy benefit and indicates the 10-year risk of distant recurrence
- The quantitative nature of RT-PCR* allows for a continuous score as opposed to a binary result (low vs high only)
- This method is designed to provide you and your patients with an individual risk score and to help inform your treatment plan
- The Oncotype DX assay provides an individualized Recurrence Score result\(^1-3\)
- *RT-PCR=reverse transcriptase polymerase chain reaction.
Other testing

- MammaPrint
- Endopredict
- Other testing designed to determine prognosis, risk of recurrence and treatment options
Oncotype DX testing
ENDOCRINE THERAPY
Definition of menopause

• Very important as therapy depends on it
• For women who were premenopausal at time of treatment with chemotherapy – amenorrhea not indicative
• In menopause if the following:
  – >age 60
  – Women <age 60 – bl oopherectomy
  – Have not had a menstrual period for 12 months in absense of tamoxifen, chemo or ovarian suppression
Endocrine therapy

• Consistently improves survival outcomes for women with non-metastatic, hormone receptor positive breast cancer

• Agents used:
  – Tamoxifen
  – Aromatase inhibitors
  – Ovarian suppression or ablation
Tamoxifen

• Selective estrogen receptor modulator (SERM)
• Inhibits growth of breast cancer cells by competitive antagonism of the estrogen receptor
• Indicated in premenopausal and postmenopausal women
• Dosing: 20 mg daily
Efficacy Data

• Data to use Tamoxifen comes from 2011 Early breast Cancer Trialist Collaborative Group (EBCTCG) meta-analysis
• Compared Tamoxifen treatment for 5 years to no endocrine treatment
• Included pre-post menopausal women
• Median follow up 13 years
Tamoxifen

• With a median of 13 years tamoxifen resulted in:
  – A 13% absolute reduction in breast cancer recurrence at 15 years compared to placebo (33% versus 46% percent, relative risk 0.61)
  – A 9% absolute reduction in the risk of breast cancer mortality at 15 years (24 vs 33%, RR 0.70)

Side effects

• Increased risk of strokes compared to placebo – not statistically significant
• Increased risk of uterine cancer – 4% vs 1% in placebo: Limited to women over 55 years
• Hot flashes, vaginal discharge, sexual dysfunction and menstrual irregularities
Must be January. Strangers are standin' next to me hopin' for a hot flash.
Side effects

• Hot Flashes – most common and bothersome side effects of Tamoxifen
• Believed to be due to a central nervous system antiestrogenic effect causing thermoregulatory dysfunction
• Up to 80% of women complain, 30% say severe
Side Effects

• Thromboembolic disease
  – Especially within the first 2 years
  – Increased 2-3 fold in older women
  – Data is conflicting for increased risk of arterial events – 3 extra strokes per 1000 women during 1st 15 years
  – Offset by 3 less cardiac events per 1000 women in 1st 15 years
Side effects

• Endometrial Cancer
  – NSABP P1 updated trial 53 cases per 17 in placebo group
  – Of the 70 endometrial cancers – 67 stage I
  – Presents with Vaginal bleeding
  – ATLAS data – cumulative risk from year 5-14 was 3.1 vs 1.6 percent
  – Can subject women to Transvaginal US and endometrial biopsy
Aromatase Inhibitors

• Suppress estrogen levels by inhibiting or inactivating aromatase, the enzyme responsible for peripheral conversion of androgens to estrogens
• AI is preferred treatment of post-menopausal women
• Inactive in women with intact ovarian function
Aromatase Inhibitors

- Anastazole (Arimidex) – 1 mg daily
- Letrozole (Femara) 2.5 mg daily
- Exemestane (Aromasin) 25 mg daily
2010 EBCTCG meta-analysis

• In trials were women were randomly assigned to 5 years of tamoxifen vs AI
  – Statistically significant reduction in recurrence at 5 years compared to Tamoxifen – 12% vs 15%, RR 0.77
  – Statistically nonsignificant reduction in breast cancer mortality at 5 years – 7% vs 8%, RR 0.89

Side Effects of Aromatase Inhibitors

- Higher risk of osteoporosis
- Risk of Cardiovascular events
- Hypercholesterolemia
- Musculoskeletal symptoms
- Vaginal dryness
- Affects sexual function
Ovarian Ablation

- Indicated in women as an option for therapy in premenopausal women
- Suppression is with medications – GnRH inhibitors
- Ablation – permanent – surgical oophorectomy or radiation therapy
- Reduces risk of recurrence and mortality by 25 and 29%
- No additional benefits
Treatments selection

- Premenopausal women:
  - Tamoxifen for 5 years
  - Aromatase inhibitors are not active for women with intact ovarian function
  - This includes women who become amenorrheic from adjuvant chemotherapy
Treatment Selection

- Postmenopausal women
  - Aromatase Inhibitor Therapy for 5 years
  - Tamoxifen for 5-10 years
  - Tamoxifen followed by an Aromatase Inhibitor for up to 10 years – switching strategy
  - Aromatase Inhibitor followed by Tamoxifen for up to 10 years – alternative switching strategy
NCCN guidelines for Breast Cancer F/u

- History and physical 1-4 x’s year for 5 years then annually
- Periodic genetic assessment
- Lymphedema evaluation and management
- Mammograms every 12 months
- No labs or imaging unless clinically indicated
- On tamoxifen, yearly gynecologic assessment
- On AI, bone health as directed
- Maintain lifestyle modifications – BMI 20-25, decreased EtoH, exercise
Breast Imaging after Breast Cancer

**Mammography**
- **Purpose** – detect ipsilateral disease – approx 4% in BCT
- **Surveillance for** contralateral breast cancer
- **Performed at least 6-12 months after radiation**
- **Then Annually**

**US/MRI**
- **MRI** – not routinely recommended – based off of a 2012 review – 10 case series (494) – sensitivity and specificity was no better than mammography
  - When used?
- **US** – routine surveillance not recommended
  - Trial – 2809 pt had screening mammograms vs US- increased dx yield 8-12%, false positive 4.4- 10.4% - lowered Positive predictive value
Breast Imaging in Reconstructed Breast

- Physical exam is key
- Routine mammogram with prosthetic implants is not generally advocated
- Technically feasible in autogenous myocutaneous flap reconstruction – no consensus on this
- Cancer can occur right below the skin or just over the pectoralis muscle
- MRI used only to confirm physical findings
Role of Laboratory Testing and Imaging

• NOT Indicated for asymptomatic survivors
• Based off of 2005 meta-analysis of 2 trials – compared routine follow-up vs intensive testing – No difference in OS between the 2 groups
• Early diagnosis of metastatic disease based on imaging alone – prior to symptoms – may result in earlier intervention – does NOT CHANGE SURVIVAL

Rojas, MP. et.al, Cochrane Database Syst Review 2005
BREAST DENSITY AND SCREENING FOR BREAST CANCER
Breast Density

• Increased breast density impairs the detection of abnormalities on mammography
• Passage of legislation in multiple states in the US become focus
• Led to new/renewed discussion of optimal ways to follow women with dense breasts
Factors Affecting Breast Density

• Greater in younger women
• Varies with menopausal status, genetic factors, parity, use of estrogen, body habitus
• Vary during different phases of the menstrual cycle – increased in luteal phase compared to follicular phase (better in 1st 2nd week after menses)
• Many older women still have dense breasts – 44% in 60’s and 36% in 70’s
Breast Density and Breast Cancer Risk

• Breast density obscures cancer – decreases sensitivity to detect small lesions
• Increases density is an independent risk factor for breast cancer as most cancer develop in glandular parenchyma – not associated with increased mortality
• Compared to general population – relative risk is 1.2 and 2.1 with extremely dense breasts
• Absolute risk - more meaningful i.e. – a 45 y/o with average breast density, no family history and no prior breast biopsy has a 0.7% 5 year risk compared to a women with extremely dense breasts – 1.3% 5 year risk
How dense are you?

**LEVEL 1**<br>&lt;25% Density<br>Fatty Breast Tissue

**LEVEL 2**<br>&lt;50% Density<br>Scattered Density

**LEVEL 3**<br>&gt;50% Density<br>Heterogeneously Dense

**LEVEL 4**<br>&gt;75% Density<br>Extremely Dense
Breast Density and Primary Screening

• Mammography is the primary screening tool for breast cancer
• Mammography may miss up to 20% of breast cancer
Digital Mammography

- Largely replaced film mammography
- Sensitivity similar for dense vs fibroglandular breast – 78-82%
Digital Breast Tomosynthesis

• NCCN updated its guidelines for women with average risk starting at age 40
• For breast density – preferred over digital – although only 22% of US facilities have this technology and not universally covered
• Has equal or greater sensitivity while decreasing recall rate
• In 2600 patients – 3D detected an additional 5.4-6.2 cases per 1000 with dense breasts

Digital Breast Tomosynthesis

• Emerging studies suggest that DBT may have the greatest effect at reducing false positives in women with dense breasts

• In one study among 3200 self-referred patients – dense breasts – negative 2D films - an addition 4 cases per 1000 screens were detected – US detected more 7.1 per 1000 screens

Tagliafico, etal. JCO 2016
Supplemental Screening

• Evidence and expert consensus remains unclear as to risk-benefit balance of supplemental screening
• ABUS (whole breast) – breast is systematically scanned in orthogonal planes – recorded
• Most studies in comparison have been with hand held UA
• Increased risk of false positives
• Majority of cancers found by US are node negative
• Does not decrease mortality
Supplemental Screening

• ACR – large prospective study – Handheld US to mammogram in high-risk asymptomatic women with dense breasts and one additional risk factor for breast cancer
• Identified an additional 4.3 cancers per 1000 women
• Increased false-positive results
• Cost effectiveness – aged 50-74 – US with mammogram - 100,000 QALY gained
MRI screening

- Increased sensitivity for patient’s at high risk - >20-25% risk
- ACS finds data insufficient to recommend for or against MRI solely for breast density
- Large International trial investigating use – DENSE trial – still accruing
- Limited by cost, lack of availability and reaction to contrast
Molecular Breast Imaging

• Gamma Cameras and Tc99m- Sestamibi
• New techniques – less radiation
• Early clinical trial with a low-dose technique demonstrate that the addition of supplemental mbi detects an incremental 8.8 per 1000 cancers with only a small decrease in specificity
“The goal is to live a full, productive life even with all that ambiguity. No matter what happens, whether the cancer never flares up again or whether you die, the important thing is that the days that you have had you will have lived.”

– Gilda Radner