EARLY STAGE BREAST CANCER AND THE EMERGING ROLE OF IORT
Objectives:

1. List treatment options for early stage breast cancer.

2. Describe the different ways of delivering radiation as part of breast conserving therapy.

3. List patient and tumor factors that are important in determining a patients’ suitability for IORT.

4. Describe the process of Intraoperative Radiation Therapy (IORT) for breast cancer.
Early Stage Breast Cancer

- NCI Definition: cancer that has not spread beyond the breast or the axillary lymph nodes. This includes ductal carcinoma in situ and stage I, stage IIA, stage IIB, and stage IIIA breast cancers.
Early Stage Breast Cancer by NCI definition is all but Stage 4, but we’ll be focusing on Stage 0-1.

Stages of Breast Cancer

0
Abnormal cells in lining of the ducts or sections of the breast. Results in increased risk of developing cancer in both breasts.

1
Cancer in the breast tissue tumor less than 1 inch across.

2
Cancer in the breast tissue tumor less than 2 inches across. Cancer may also spread to auxiliary lymph nodes.

3
Tumor is larger than 2 inches across with extensive spread to auxiliary or nearby lymph nodes. Possible dimpling, inflammation or change of skin color.

4
Spread of cancer beyond the immediate region of the breast.

100% SURVIVAL RATE
98% SURVIVAL RATE
88% SURVIVAL RATE
52% SURVIVAL RATE
16% SURVIVAL RATE
Early Stage Breast Cancer / IORT

- More select group than NCI definition
- Tumors less than 2-3 cm
- No clinically evident lymph nodal spread
- Unifocal disease
Treatment options for Local Management of Early Stage Breast Cancer

1. Mastectomy plus axillary node dissection was historically the gold standard.
Treatment Options for Local Management of Early Breast Cancer.

2. Partial Mastectomy, axillary node sampling, radiation to the intact breast.
   a. standard fractionation – 6.5 weeks
   b. hypo-fractionation “Canadian Fractionation” 3 weeks.

3. Partial Mastectomy, axillary node sampling, radiation to just the tumor cavity.
   a. APBI- 2 treatments daily x 5 days
   b. IORT- 1 treatment at time of surgery.
6 - 7 weeks of treatment

5 days twice a day

As little as 8 min. during surgery

WBRT

APBI

IORT
Breast Conserving Therapy (BCT) Vs. Mastectomy

- NSABP B-06
- EBCTCG
- NCI

- All show that “lumpectomy” with negative margins plus post operative radiation to whole breast is effective in treating early stage breast cancer. There is no difference in disease-free or overall survival. Slightly higher local recurrence with BCT that does not effect survival. Good to excellent cosmetic results seen.
IORT for breast cancer
TARGeted Intraoperative radioTherapy: TARGIT
TARGIT Trial inclusion

- 45 or older
- Unifocal disease clinically and on Mammogram, MRI was not required.
- Node negative disease clinically
- Invasive Ductal or Ductal Carcinoma-in-situ
- Less than 3 cm.
- Resection Margin negative.
Local Control in both arms similar as were survival.

Survival curves

A  Breast cancer deaths

<table>
<thead>
<tr>
<th>Years</th>
<th>TARGIT 20 events</th>
<th>EBRT 16 events</th>
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</thead>
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<tr>
<td>0</td>
<td>1000</td>
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<tr>
<td>1</td>
<td>997</td>
<td>978</td>
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<tr>
<td>2</td>
<td>706</td>
<td>693</td>
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<tr>
<td>3</td>
<td>514</td>
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<td>4</td>
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<tr>
<td>5</td>
<td>1721</td>
<td>1730</td>
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</table>

Log-rank p=0.56

B  Non-breast cancer deaths

<table>
<thead>
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<th>Years</th>
<th>TARGIT 17 events</th>
<th>EBRT 35 events</th>
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<tr>
<td>0</td>
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</table>

Log-rank p=0.0086
Who is a candidate for IORT?

IORT is a new modality, but very similar to APBI is patient selection. Presently we rely on guidelines for APBI to select appropriate patients.

IORT clinical trial is also ongoing and participation is encouraged.

Patient factors often help guide treatment choices.
Who is a candidate for IORT Guidelines?

### Selection criteria

<table>
<thead>
<tr>
<th>ABS Recommendations¹</th>
<th>ASBS Recommendations²</th>
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<tbody>
<tr>
<td><strong>Age</strong></td>
<td>≥ 45</td>
</tr>
<tr>
<td><strong>Diagnosis</strong></td>
<td>Unifocal, invasive ductal carcinoma</td>
</tr>
<tr>
<td><strong>Tumor size</strong></td>
<td>≤ 3cm</td>
</tr>
<tr>
<td><strong>Surgical margins</strong></td>
<td>Negative microscopic surgical margins of excision</td>
</tr>
<tr>
<td><strong>Nodal status</strong></td>
<td>NO</td>
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</table>


Who is a candidate for IORT Guidelines?

<table>
<thead>
<tr>
<th></th>
<th>ASTRO “suitable”</th>
<th>ASTRO “cautionary”</th>
<th>ASTRO “unsuitable”</th>
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<tbody>
<tr>
<td>Age</td>
<td>≥ 60</td>
<td>50-59</td>
<td>&lt; 50</td>
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<tr>
<td>Diagnosis</td>
<td>Invasive ductal,</td>
<td>Invasive lobular, EIC &lt; 3 cm</td>
<td>Extensive LVI, pure DCIS &gt; 3 cm,</td>
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<tr>
<td></td>
<td>mucinous, tubular,</td>
<td>limited or focal LVI, ER-,</td>
<td>neoadjuvant chemo</td>
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<tr>
<td></td>
<td>or colloid, no EIC or</td>
<td>DCIS &lt; 3 cm</td>
<td></td>
</tr>
<tr>
<td></td>
<td>LVI, ER+</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tumor Size</td>
<td>Unifocal, &lt; 2 cm</td>
<td>2.1-3 cm</td>
<td>&gt; 3 cm, T3, T4 or multifocal,</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>multicentric</td>
</tr>
<tr>
<td>Surgical Margins</td>
<td>≥ 2 mm</td>
<td>&lt; 2 mm</td>
<td>+</td>
</tr>
<tr>
<td>Nodal Status</td>
<td>N0 or IHC (+) only</td>
<td></td>
<td>N(+) or undissected</td>
</tr>
</tbody>
</table>
Who is a candidate for IORT Guidelines?

- Current Xoft Axxent eBx IORT System Trial criteria.
  - older than 40, not pregnant
  - tumor less than 3 cm,
  - Invasive Ductal or Ductal Carcinoma-in-situ
  - Unifocal disease
  - Node negative, no LVSI
  - No previous cancer or XRT
  - BRCA-1 and 2 carriers, excluded.

May 16, 2016
Intraoperative Radiation Therapy (IORT)
No Modifications to the OR
Tumor Removal and Cavity Evaluation
1. Tumor is removed
2. Balloon applicator is placed into the cavity
3. Radiation treatment is delivered in as little as 8 minutes
4. Balloon is removed and the cavity is closed
Balloon Applicator Features

- **Drainage holes** for seroma management to potentially reduce infection and improve dosimetry.
- **Radiolucent Balloon Wall** for improved visibility while imaging.
Electronic Brachytherapy Controller Components

- Display Screen/Touch Screen Control
- Handheld Barcode Scanner
- Adjustable arm (in storage position)
- Well Chamber
- Wheel Brakes
eBx Controller Components
Miniaturized X-ray Tube:
The Electronic Brachytherapy Source

The Source Operates at 50 kV and 300 microamps (15 Watts)
eBx® High Dose, Low Energy Delivers Less

IORT Video at MedStar UMH
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