Cosmetic Outcome from Post Lumpectomy Whole Breast Irradiation (WBI) Versus Partial Breast Irradiation (PBI) on the NRG Oncology/NSABP B39-RTOG 0413 Phase III Clinical Trial

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Disclosures for Dr. White

• I have no conflicts of interest to disclose.

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NSABP B-39/RTOG 0413 Study Design

Selected Eligibility Criteria

- Lumpectomy
- Stage 0, I, II
- Tumor size ≤3.0 cm
- Negative margins (No ink on tumor)
- N0, N1 ≤3 positive nodes
- Age >18

Randomly Assigned

Stratification

- Disease Stage (DCIS; Invasive N0; Invasive N1)
- Menopausal Status (pre- and post-)
- Hormone Receptor Status (ER and/or PR+; ER− and PR−)
- Intention to Receive Chemotherapy

Whole Breast Irradiation (WBI)

50 Gy (2.0 Gy/fraction) or 50.4 Gy (1.8 Gy/fraction) to whole breast, followed by optional boost to ≥ 60 Gy

5-6 weeks

Partial Breast Irradiation (PBI)

10 fractions/ BID / 5-8 days
34 Gy in 3.4 Gy fractions Interstitial Brachytherapy or Mammosite Balloon Catheter
Or 38.5 Gy in 3.85 Gy fractions 3DCRT

5-8 days

2019 AMERICAN SOCIETY FOR RADIATION ONCOLOGY (ASTRO) ANNUAL MEETING
QOL SubStudy: Cosmetic Outcome Assessments

- 975 enrolled from March 2005 to May 2009
- 900 (420 CT and 480 no-CT) had baseline forms and at least one PT/Site MD/DP Review at 12 or 36 months

**Global Cosmetic Score (GCS):** Patient (PT) and MD (Site)
- 4 Point Scale NRG-RTOG
  - 1-Excellent, 2-Good, 3-Fair, 4-Poor

**Digital Photos (DP):**
- Both breasts and close-up of treated breast
- Submitted separate database

**Time points:**
- PT – baseline; last day of treatment; 4 weeks, 6, 12, 24, and 36 months after treatment
- MD – baseline; 12 and 36 months after treatment
- DP – baseline; 12 and 36 months after treatment
NRG/NSABP B39-RTOG 0413: Comparing Cosmetic Outcome between Treatment Arms - PBI and WBI

\[ \Delta^* = \text{[36-Month Scores - Baseline Scores]} \]

<table>
<thead>
<tr>
<th>Treatment</th>
<th>( \Delta^* \text{ in GCS by Patient} )</th>
<th>( \Delta^* \text{ in GCS by Site MD} )</th>
<th>( \Delta^* \text{ in GCS by DP Central MD Review} )</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Chemo</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diff (µPBI- µWBI):</td>
<td>n=307</td>
<td>n=261</td>
<td>n=191</td>
</tr>
<tr>
<td>95% Cl:</td>
<td>0.06 (0.02 to 0.53)</td>
<td>0.27 (-0.35 to 0.35)</td>
<td>0.18 (-0.37 to 0.37)</td>
</tr>
<tr>
<td>Bound:</td>
<td>-0.14 to 0.25</td>
<td>-0.42 to 0.42</td>
<td>NOT Equivalent (PBI worse)</td>
</tr>
<tr>
<td>Effect Size:</td>
<td>Equivalent</td>
<td>NOT Equivalent (PBI worse)</td>
<td>0.26</td>
</tr>
<tr>
<td><strong>Non-Chemo</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diff (µPBI- µWBI):</td>
<td>n=368</td>
<td>n=343</td>
<td>n=213</td>
</tr>
<tr>
<td>95% Cl:</td>
<td>0.04 (-0.01 to 0.33)</td>
<td>0.16 (-0.33 to 0.328)</td>
<td>-0.20 (-0.31 to 0.31)</td>
</tr>
<tr>
<td>Bound:</td>
<td>-0.15 to 0.22</td>
<td>-0.33 to 0.328</td>
<td>NOT Equivalent (PBI worse)</td>
</tr>
<tr>
<td>Effect Size:</td>
<td>Equivalent</td>
<td>NOT Equivalent (PBI worse)</td>
<td>0.19</td>
</tr>
<tr>
<td><strong>Combined</strong>*</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diff (µPBI- µWBI):</td>
<td>n=675</td>
<td>n=604</td>
<td>n=404</td>
</tr>
<tr>
<td>95% Cl:</td>
<td>0.04 (0.05 to 0.35)</td>
<td>0.20 (-0.37 to 0.37)</td>
<td>-0.024 (-0.19 to 0.14)</td>
</tr>
<tr>
<td>Bound:</td>
<td>-0.09 to 0.17</td>
<td>-0.37 to 0.37</td>
<td>Equivalent</td>
</tr>
<tr>
<td>Effect Size:</td>
<td>Equivalent</td>
<td>Equivalent</td>
<td>-0.028</td>
</tr>
</tbody>
</table>
36-Month Global Cosmetic Score (GCS) by Treatment Arm

All Patients
Adjusted Mean Change ($\Delta^+$) in GCS by Patient at Each Time Point

$\Delta^+ = [\text{Time Point Scores} - \text{Baseline Scores}]$

- $p=0.70$
- $p=0.91$
Adjusted Mean Change ($\Delta^+$) in GCS by Site MD at Each Time Point

$\Delta^+ = \text{[Time Point Scores - Baseline Scores]}$

- p=1.00
- p=0.001

Least Square Means of the Change in GCS

WBI

PBI

0.43

0.17

12 mos after Tx

36 mos after Tx

Time Point
Adjusted Mean Change (Δ†) in GCS by MD Central Digital Photo Review at Each Time Point

Δ† = [Time Point Scores - Baseline Scores]
Patients’ Satisfaction with Treatment and Cosmetic Outcome

At 36 Months

Change ($\Delta^+$) in Patients’ Satisfaction

<table>
<thead>
<tr>
<th></th>
<th>Chemo</th>
<th>Non-Chemo</th>
<th>Combined</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diff ($\mu$PBI - $\mu$WBI):</td>
<td>n=327</td>
<td>n=386</td>
<td>n=713</td>
</tr>
<tr>
<td>95%CI:</td>
<td>0.013</td>
<td>0.045</td>
<td>0.03</td>
</tr>
<tr>
<td>Bound:</td>
<td>($-0.18$ to $0.21$)</td>
<td>($-0.13$ to $0.22$)</td>
<td>($-0.10$ to $0.16$)</td>
</tr>
<tr>
<td>Effect Size:</td>
<td>Equivalent</td>
<td>Equivalent</td>
<td>Equivalent</td>
</tr>
<tr>
<td></td>
<td>0.014</td>
<td>0.053</td>
<td>0.035</td>
</tr>
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$\Delta^+ = [36$-Month Scores - Baseline Scores$]$
Conclusions

• Patient rated cosmetic outcome based on the GCS was equivalent for PBI and WBI.
• Accruing site MDs rated cosmetic outcome worse at 36 months for PBI. The change in cosmetic outcome over time was equivalent for PBI and WBI.
• Digital photo cosmetic outcome rated by MDs blinded to treatment arm and time point was equivalent for PBI and WBI.
• Patient Satisfaction was equivalent for PBI and WBI.