Molecular Characterization of Breast Cancer Core Biopsy Specimens by RT-PCR Gene Expression Analysis

Presentation discussed in this issue:


Slides from a presentation at SABCS 2009

Molecular Characterization of Breast Cancer Core Biopsy Specimens by Gene Expression Analysis Using Standardized Quantitative RT-PCR

Anderson JM et al.
SABCS 2009;Abstract 6021.
Introduction

- Core biopsies are the initial diagnostic procedure of choice for breast masses identified by imaging or physical examination.
- The Oncotype DX assay process, which involves RT-PCR to evaluate the expression of 21 prespecified genes, was optimized to require small amounts of tumor tissue (Clin Chem 2007;53:1084).
- **Current study objectives:**
  - To determine if core biopsy specimens are comparable to surgical resection specimens in their sufficiency as well as in the results obtained.

Anderson JM et al. SABCS 2009;Abstract 6021.

Study Methods

- Submissions to Genomic Health Clinical Laboratory for Oncotype DX assay were obtained from July 2005 through May 2009.
  - Specimens (n=103,863) were stratified by core biopsy vs surgical resection specimen.
- Specimens were analyzed by pathology review and reverse transcriptase polymerase chain reaction.
- Causes of failure were derived from standard laboratory operating procedures and failure types.
  - Insufficient invasive tumor: <5% invasive carcinoma or <2.0 mm carcinoma
  - PCR process failure: PCR unable to be completed
  - Insufficient RNA: insufficient RNA extracted from the formalin-fixed paraffin-embedded tumor tissue specimen
  - Other: unavailable slide, scant tissue in block, incomplete requisition

Anderson JM et al. SABCS 2009;Abstract 6021.
Results

Overall Success Rate > 97% in both

Anderson JM et al. SABCS 2009;Abstract 6021.

Results (continued)

<table>
<thead>
<tr>
<th></th>
<th>RS &lt; 18</th>
<th>RS 18-30</th>
<th>RS &gt; 30</th>
</tr>
</thead>
<tbody>
<tr>
<td>Core Biopsy Specimen</td>
<td>58.8%</td>
<td>28.6%</td>
<td>12.6%</td>
</tr>
<tr>
<td>Surgical Resection Specimen</td>
<td>52.3%</td>
<td>35.6%</td>
<td>12.1%</td>
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</tbody>
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<table>
<thead>
<tr>
<th></th>
<th>Mean RS</th>
<th>Average RNA Yield (µg)</th>
<th>Manual Micro-dissection Rate to Remove Non-tumor Tissue</th>
</tr>
</thead>
<tbody>
<tr>
<td>Core Biopsy Specimen</td>
<td>18.9</td>
<td>2.5</td>
<td>3.9%</td>
</tr>
<tr>
<td>Surgical Resection Specimen</td>
<td>19.7</td>
<td>4.2</td>
<td>33%</td>
</tr>
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The distribution of quantitative ER, PR and Her2 were similar in core biopsy and surgical resection specimens

Anderson JM et al. SABCS 2009;Abstract 6021.
Conclusions

- Core biopsy specimens less frequently require manual microdissection to remove non-tumor tissue.

- Initial failure rate is higher with core biopsy compared to surgical specimens (8.4% vs. 4.3%).

- Quantitative single genes and RS means and distributions were similar between the two specimen types.

- The overall success rate (initial + resubmission, > 97%) was similar between the two specimen types.

- Needle core biopsy specimens may be used for the Oncotype DX assay.

Anderson JM et al. SABCS 2009;Abstract 6021.