

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

Presentation discussed in this issue:

Anderson JM et al. **Molecular characterization of breast cancer core biopsy specimens by gene expression analysis using standardized quantitative RT-PCR.** San Antonio Breast Cancer Symposium 2009;**Abstract 6021.**

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.

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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.

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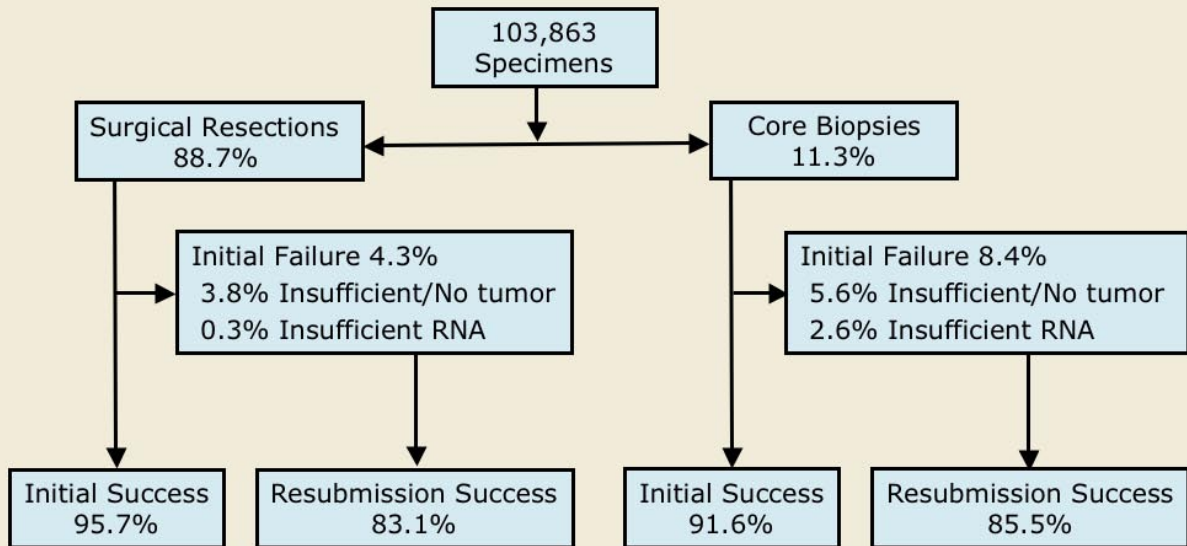
Study Methods

- 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

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Results



Overall Success Rate > 97% in both

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Results (continued)

	RS < 18	RS 18-30	RS > 30
Core Biopsy Specimen	58.8%	28.6%	12.6%
Surgical Resection Specimen	52.3%	35.6%	12.1%

	Mean RS	Average RNA Yield (µg)	Manual Micro-dissection Rate to Remove Non-tumor Tissue
Core Biopsy Specimen	18.9	2.5	3.9%
Surgical Resection Specimen	19.7	4.2	33%

The distribution of quantitative ER, PR and Her2 were similar in core biopsy and surgical resection specimens

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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.

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