

Effect of a 21-Gene RT-PCR Assay on Treatment Recommendations for Patients with Node-Positive, ER-Positive Breast Cancer

Presentation discussed in this issue:

Oratz R et al. **Effect of 21-gene recurrence score results on treatment recommendations in patients with lymph node-positive, estrogen receptor-positive breast cancer.** San Antonio Breast Cancer Symposium 2009; **Abstract 2031**.

Slides from a presentation at SABCS 2009

Effect of 21-Gene Reverse-Transcriptase Polymerase Chain Reaction Assay on Treatment Recommendations in Patients with Lymph Node-Positive and Estrogen Receptor-Positive Breast Cancer

Oratz R et al.
SABCS 2009;Abstract 2031.

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Introduction

- The *Oncotype DX*® Recurrence Score® (RS) assay reliably estimates the risk of distant recurrence in individual patients with node-negative (N-) ER-positive (ER+) early breast cancer (BC).
- The RS also allows for the identification of specific patients with N-/ER+ BC who are unlikely to benefit from chemotherapy.
- Recent studies have demonstrated similar prognostic and predictive utilities of the RS in patients with node-positive (N+)/ER+ BC (*Lancet Oncol* 2010;11:55, SABCS 2008;Abstract 53).
- **Current study objectives:**
 - Identify reasons for ordering the *Oncotype DX* assay in N+/ER+ BC
 - Determine whether the results, when obtained, have affected adjuvant treatment recommendations

Oratz R et al. SABCS 2009;Abstract 2031.

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Methods

- Web-based survey targeting medical oncologists (MO) who ordered *Oncotype DX* RS for patients with N+/ER+ BC.
 - 1,017 MO invited to participate between May and June 2009
 - Survey closed after 150 successful responses
 - N=160 total surveys included in analysis
- Descriptive analyses summarized frequency and percentage distributions of the survey responses, classifying patients by RS low (<18), RS intermediate (18-30), and RS high (≥ 31).
- Treatment recommendations categorized as hormonal therapy (HT) alone or chemotherapy (CT) + HT.
- Changes in treatment recommendation defined as:
 - Decreased intensity: CT + HT → HT alone
 - Increased intensity: HT alone → HT + CT

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Physician Demographics (n = 160)

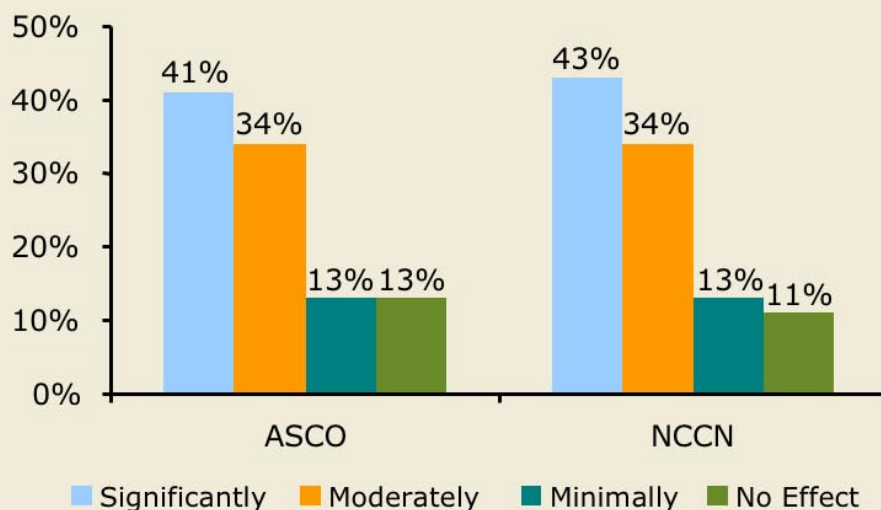
Practice Setting	%
Academic medical center	25.0
Community (multi-/single-specialty or solo practice)	71.3
Other	3.8
Geographic Region	%
East	25.6
Midwest	23.1
South	27.5
West	23.8
Years in Practice*	
Mean/median	14.5 yrs/11 yrs

* 3 missing values

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Anticipated Extent of Increased Use of Oncotype DX by Physicians for N+/ER+ Disease if it is Included in Clinical Practice Guidelines

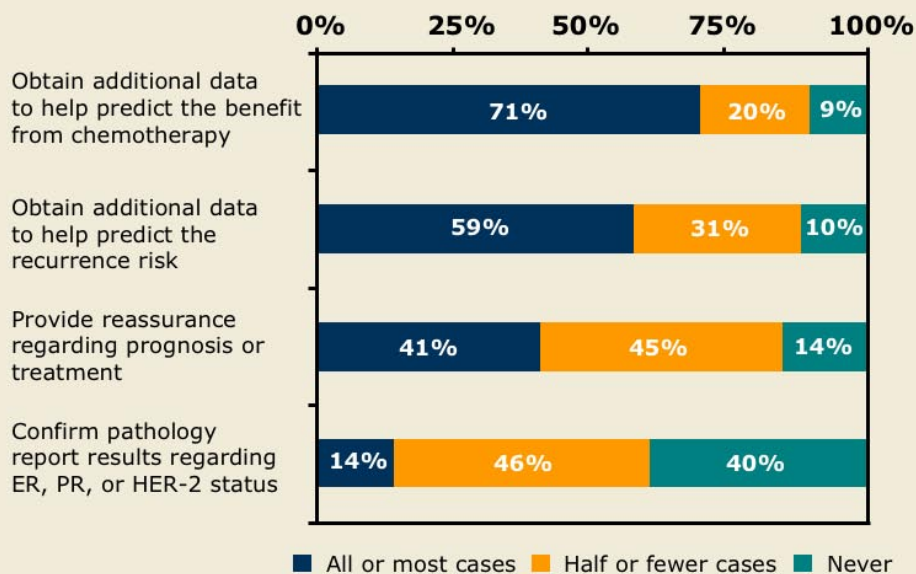


Over 70% of MOs surveyed would adopt use of the Oncotype DX assay for node-positive BC if use of the assay were to be recommended for this subtype by ASCO or NCCN guidelines.

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Reasons for Ordering Oncotype DX for N+/ER+ BC



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Select Characteristics of Patients with N+/ER+ Breast Cancer

Patient Age	All (n=160)
Mean	60.2 years
Tumor Classification	
T1 (≤ 2 cm)	61.9%
T2 (> 2 cm but ≤ 5 cm)	35.0%
T3 (> 5 cm)	2.5%
Positive Axillary Lymph Nodes*	
1	68.8%
2	17.5%
3	6.3%

* Excludes micrometastases and isolated tumor cells.

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Effect of RS on Treatment Recommendation (N = 138*)

Effect on Recommendation	Recurrence Score		
	Low (n=72)	Intermediate (n=53)	High (n=13)
Any change	43	20	7
Decreased intensity	35	11	0
Increased intensity	4	6	3
Other [†]	4	3	4
No change	29	33	6

Data shown represent number of patients.

* 22 patients did not have treatment recommendations before assay.

† 11 patients with treatment changes did not fit definitions of decreased or increased intensity.

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Conclusions

- MO who order *Oncotype DX*® for patients with N+/ER+ BC use the RS results much in the same way as they do for N-/ER+ BC.
- In more than half of the cases (n=70), information obtained from the RS resulted in alteration of the initial treatment recommendation.
 - In 66% of these cases, the treatment plan was revised to exclude chemotherapy.
 - Most of these revisions occurred in patients with a low RS.
- Limitations of current analysis:
 - Voluntary web-based survey may yield a biased sample.
 - N+/ER+ patient descriptions may be subject to recall bias.

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