Effect of the 21-gene RT-PCR assay on treatment administered in early-stage, node-positive (N+) breast cancer.

2015 ASCO Annual Meeting

Abstract No:e11510

Citation: J Clin Oncol 33, 2015 (suppl; abstr e11510)

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Background: Guidelines for treatment of ER+, HER2- breast cancer (BC) recommend the 21-gene RT-PCR assay in node-negative (N-) disease, but remain silent on use of the assay in node-positive (N+) disease since chemotherapy (CT) is recommended for all N+ patients. The assay has been validated for prognosis and prediction of CT benefit in both N- and N+ patients. Influence of the assay on treatment decisions in N- disease has been frequently reported, but there are fewer reports of its effects on CT usage patterns in N+ disease. RainTree Oncology Services evaluated the effect of the assay on CT usage in early-stage, N+ BC at Tennessee Oncology, one of its member practices.

Methods: Patients who received the 21-gene assay (Cohort A) were identified by Genomic Health. Patients who had not received the assay (Cohort B) were identified from RainTree's electronic database. Inclusion criteria were BC surgery between 2009 and 2013, inclusive, for early stage, ER+, HER2- disease with 1-3 positive nodes. Patient demographics, BC metrics, and use of CT were recorded.

Results: In Cohort A (N = 119), 62% of patients who received the assay had a Low Recurrence Score (RS) result. Of those, 82% avoided CT. Patients in Cohort A were less likely to receive CT than those in Cohort B (N = 70); 35% versus 60%, respectively.

Conclusions: The 21-gene assay identifies many N+ patients to have low risk and low expected benefit from CT. CT usage rates are lower among ER+, HER2- N+ patients receiving the 21-gene assay; however patient selection factors may have contributed to clinicians' decisions to use the assay for individual patients. The utility of the assay is supported by the large proportion of tested N+ patients who had Low RS results, 82% of whom avoided CT (see data table below).

Cohort A recurrence scores and CT use				
	Recurrence Score		**CT**	
	n (%)		**Y** **n (%)**	**N** **n (%)**
Low (≤ 17)	74 (62)		13 (18)	61 (82)
Intermediate (18-30)	35 (30)		19 (54)	16 (46)
High (≥ 31)	10 (8)		10 (100)	0 (0)
Total	*119*		*42 (35)*	*77 (65)*