

[P5-15-01] Breast cancer specific survival in 38,568 patients with node negative hormone receptor positive invasive breast cancer and oncotype DX recurrence score results in the SEER database

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Introduction: The SEER Program of the National Cancer Institute (NCI) is an authoritative source of cancer incidence and survival statistics, collecting population-based data for ~28 percent of the US. As innovations in molecular testing are validated and recommended in guidelines, new genomic research models are needed to characterize their use and impact on patient outcomes in clinical practice. To that end, Genomic Health and SEER have collaborated to electronically supplement the SEER registries with Oncotype DX results. This first report characterizes breast cancer specific survival (BCSS) in node (N)- hormone receptor (HR)+ HER2- invasive breast cancer.

Methods: The prospectively-defined population-biomarker-outcomes linkage had objectives, analysis cohort, standardized biomarker, and outcome defined prior to data linkage. Patients were eligible if N-, HR+, HER2- (by RT-PCR), had no prior malignancy, were 40-85 years of age, and were diagnosed between Jan 2004 (Oncotype DX available in Jan 2004) and Dec 2011 (SEER survival analysis complete through 2012). BCSS was defined as previously described and assessed rigorously (Howlader et al, JNCI 2010). Oncotype DX Recurrence Score results were provided to SEER as mandated by their registry operations. Analysis by treatment was interpreted in the context of the lack of randomization and well known limitations of registry reporting of chemotherapy (CT) treatment (Noone et al, Medical Care 2014).

Results: Among 169,158 eligible patients, 38,568 (23%) had a Recurrence Score (RS), increasing from 2% of 2004 diagnoses to 35% of 2011 diagnoses. Patients with RS had median age of 57 yr, were 99.4% female, 84% white, 29% grade 1 and 54% grade 2, 25% 1cm or less and 53% between 1 and 2cm. Median follow-up was 39 mo with 8,239 patients having >5 yrs follow-up. Among low risk RS <18 (N=21,023), intermediate risk RS 18-30 (N=14,494) and high risk RS ≥31 (N=3,051) patients, chemotherapy use was reported in 7%, 34%, and 69%, respectively. 5-year BCSS (with 95%CI) are provided in Table. Continuous RS was significantly associated with BCSS unadjusted ($p<0.001$), and after adjusting for age, grade, and tumor size ($p<0.001$), and when stratified by treatment ($p<0.001$).

Conclusions: 5 yr BCSS outcomes are excellent (99.6%) in the over 21,000 patients with low RS disease. As expected, high RS disease is associated with lower 5 yr survival despite addition of chemotherapy. More rigorous ascertainment of treatment is planned to draw conclusions regarding chemotherapy treatment benefit. Analyses that examine test utilization as well as annual survival updates to obtain longer term event rates will be important to gain additional insights into patient subgroup outcomes that can be characterized by large population-based genomic studies.

	RS<18		RS 18-30		RS≥31	
	N	BCSS (95%CI)	N	BCSS (95%CI)	N	BCSS (95%CI)
Analysis all pts	21023	99.6 (99.4-99.7)	14494	98.6 (98.3-98.9)	3051	95.6 (94.4-96.6)
Analysis by CT reported						
No/Unknown CT	19554	99.6 (99.5-99.7)	9570	98.6 (98.2-98.9)	936	94.0 (91.1-96.0)
Yes CT	1469	99.3 (98.4-99.7)	4924	98.6 (98.0-99.0)	2115	96.4 (95.0-97.4)

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Poster Session 5: Treatment: Adjuvant Therapy -- Other (5:00 PM-7:00 PM)

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