Initial results from the 21-gene breast cancer assay registry: A prospective observational study in patients (pts) with ER+, early-stage invasive breast cancer (EBC).

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Background: Genomic assays such as the 21-gene breast cancer assay (Onco*type* DX), have improved the ability to individualize pt treatment based on their individual tumor's biology. Since 2004, when the 21-gene assay became commercially available, more than 300K assays have been ordered. While several studies have been conducted assessing the impact of having the Recurrence Score (Score) result on treatment decisions, most have been retrospective or evaluating the treatment recommendation. The Onco*type* DX Breast Cancer Registry is a large prospective study conducted in clinical practices evaluating the types of pts having the assay ordered and the actual treatments delivered. We report here the first set of analyses. **Methods:** Pts with ER+ EBC were eligible to enroll. Data collected at baseline (BL) included age, size, grade, ER, PR and HER2 status. Data collected at the 6-month visit included Score and treatment given. Pt demographics, Score distribution, and associations with clinicopathologic (CP) factors are described. **Results:** A total of 890 pts were enrolled at 15 U.S. sites between 11/09-3/12. 803 eligible pts were included in the analyses. The Table shows BL characteristics, Score distribution and %CT given. Distribution of Score values across the CP factors was similar to the cohort overall. 30% of pts received CT. Among low Score patients, CT was given in 17% of pts <50y, 9% of Grade 3 tumors and 11% of tumors >2cm. **Conclusions:** A large, prospective registry for pts with EBC receiving the 21-gene breast cancer assay examined the application of the Score to treatment. The Score distribution is consistent with other retrospective cohorts. The association between the Score and the CP factors was modest. The CP factors did not predict the Score. In general, CT decisions followed the Score with the exception of younger pts; 17% received CT despite a low Score. These findings from a real-world cohort underscore the importance of understanding breast cancer biology in order to make more informed and individualized treatment decisions.

	N	**%CT**		**N**	**%CT**
All pts	803	30	Size		
Age			<1cm	209	27
<50	171	43	>2cm	201	35
>70	135	15	RS		
Grade			Low	55	7.5
1	201	13	Intermed	35	47
3	134	53	High	10	86