INVASIVE BREAST CASE STUDY

NODE
Positive (1-3)

PATIENT	62 Year-Old Female Patient
TUMOR SIZE (cm)	2.4
MENOPAUSAL STATUS	Post-Menopausal
TUMOR TYPE	Lobular
ER STATUS (IHC)	ER positive
PR STATUS (IHC)	PR positive
HER2/NEU STATUS	Negative
HISTOLOGIC GRADE	3
LYMPH NODE STATUS	Positive (1-3)
GENERAL HEALTH	Fair
OTHER INFORMATION	African American, 1/1 positive nodes

Kelly Dempsey, MD
Sugar Land, TX

RESULTS

Recurrence Score®

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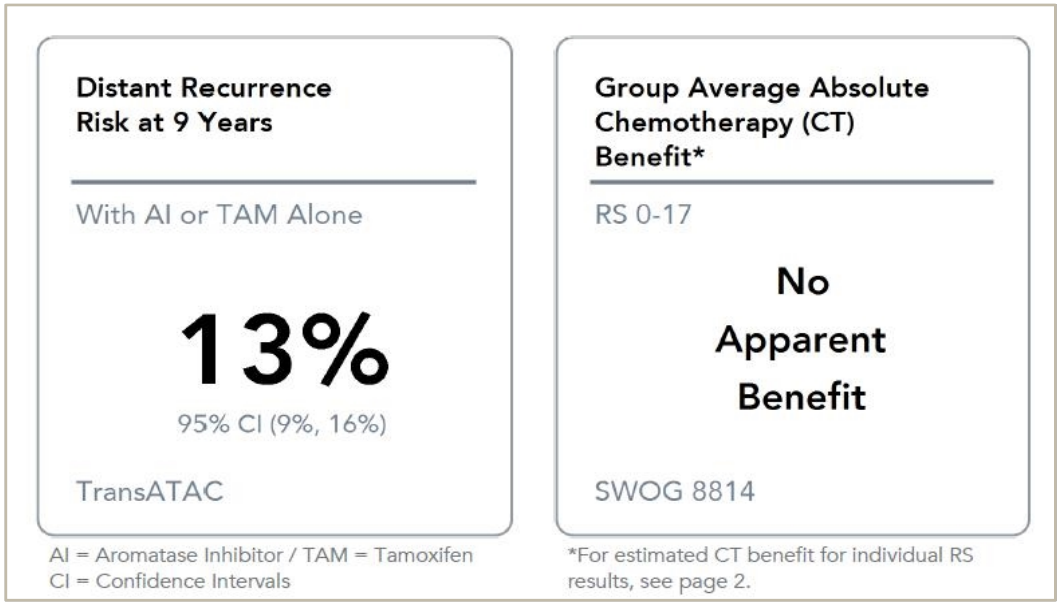
INVASIVE BREAST CASE STUDY

CLINICAL EXPERIENCE

The Distant Recurrence Risk at 9 Years (Prognosis), in patients treated with tamoxifen or arimidex alone, is provided by the TransATAC[1] trial. Risk is for individual RS results. The 95% confidence intervals for distant recurrence at 9 years are ±3 to ±6% for RS 0-22, and range from ±6 to ±12% as RS increases from RS 23-50. The TransATAC trial enrolled 1,231 patients and 243 patients had 1-3 positive nodes, including micrometastases.
The Absolute Benefit of Chemotherapy is provided by the SWOG 8814[2] trial. Results for reduction in distant recurrence or death at 5 years are for the RS groups 0-17, 18-30, and 31-100. The SWOG 8814 trial enrolled 367 patients with N+ (including micrometastases), ER+ breast cancer who were randomized to tamoxifen alone or tamoxifen plus CAF (anthracycline-containing) chemotherapy. The benefit of chemotherapy increased with an increase in the RS result. The upper bound of the 95% confidence interval for RS 18-30 was 7% absolute chemotherapy benefit.



oncotypeDX®
Breast Recurrence Score

INVASIVE BREAST CASE STUDY

RESULTS

Recurrence Score®

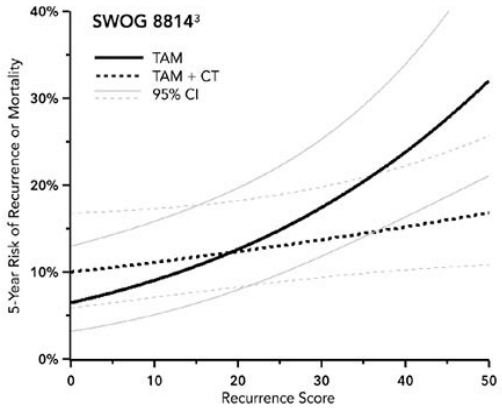
11

CLINICAL EXPERIENCE

Real World Evidence of SEER Registry Outcomes in Patients Treated Without Chemotherapy Based on RS Results. SEER had 6,814 patients with HR+, HER2-, node positive (1-3 positive nodes or micrometastases) breast cancer, diagnosed between January 2004 and December 2014, who were reported to have no or unknown chemotherapy use. Two additional prospective studies also demonstrated favorable outcomes with endocrine therapy alone for patients with 1-3 positive nodes and RS 0-11 (PlanB[3]) or RS 0-17 (Clalit[4]).

	RS 0-10	RS 11-15	RS 16-20	RS 21-25	RS 26-100
# of Patients	1808	2196	1754	692	364
BCSS at 9 Years	98.2%	99.0%	96.7%	93.1%	84.2%

ESTIMATED CHEMOTHERAPY BENEFIT FOR INDIVIDUAL RECURRENCE SCORE RESULTS



TREATMENT GIVEN: HR Therapy

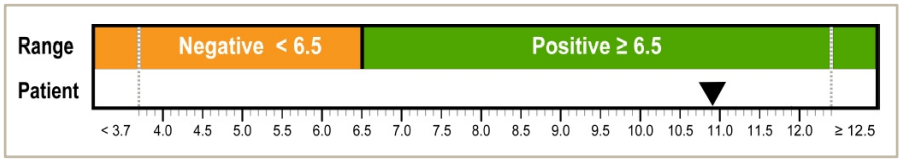
oncotypeDX® Breast Recurrence Score

INVASIVE BREAST CASE STUDY

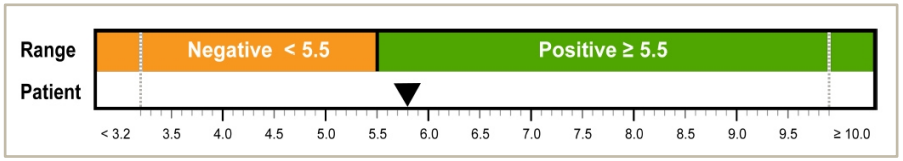
QUANTITATIVE HORMONE RECEPTOR ANALYSIS

Quantitative Single-Gene Scores for quality control. The Oncotype DX test uses quantitative RT-PCR to determine the RNA expression of ER, PR, and HER2, using the published validated cut-offs[4]. The standard deviations of single-gene results are less than 0.5 units. The RT-PCR single-gene results may differ from ER, PR, or HER2 results reported using other methods or reported by other laboratories.

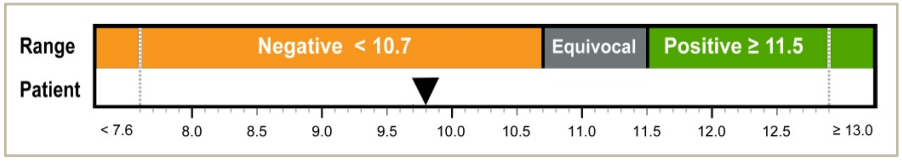
ER Score
10.9



PR Score
5.8



HER2 Score
9.8



References
1. Albain et al.Lancet Oncol. 2010.
2. ER Score based on quantitative ESR1 expression (estrogen receptor); PR Score based on quantitative PGR expression (progesterone receptor).
3. Kim et al. J Clin Oncol. 2011.
4. Badve et al. J Clin Oncol. 2008. May 20;25(15):2473-81
5. Paik et al. ASCO 2005.

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