INVASIVE BREAST CASE STUDY

NODE
Negative

PATIENT	41 Year-Old Female Patient
TUMOR SIZE (cm)	2.8
MENOPAUSAL STATUS	Pre-Menopausal
TUMOR TYPE	Ductal
ER STATUS (IHC)	ER positive
PR STATUS (IHC)	PR positive
HER2/NEU STATUS	Negative
HISTOLOGIC GRADE	2
LYMPH NODE STATUS	Negative
GENERAL HEALTH	Excellent
OTHER INFORMATION	ER90% PR30% Her2-, Ki67-15%. Multifocal cancer

SuEllen Arentz
Houston, TX

oncotype DX®
Breast Recurrence Score

RESULTS

Recurrence Score®

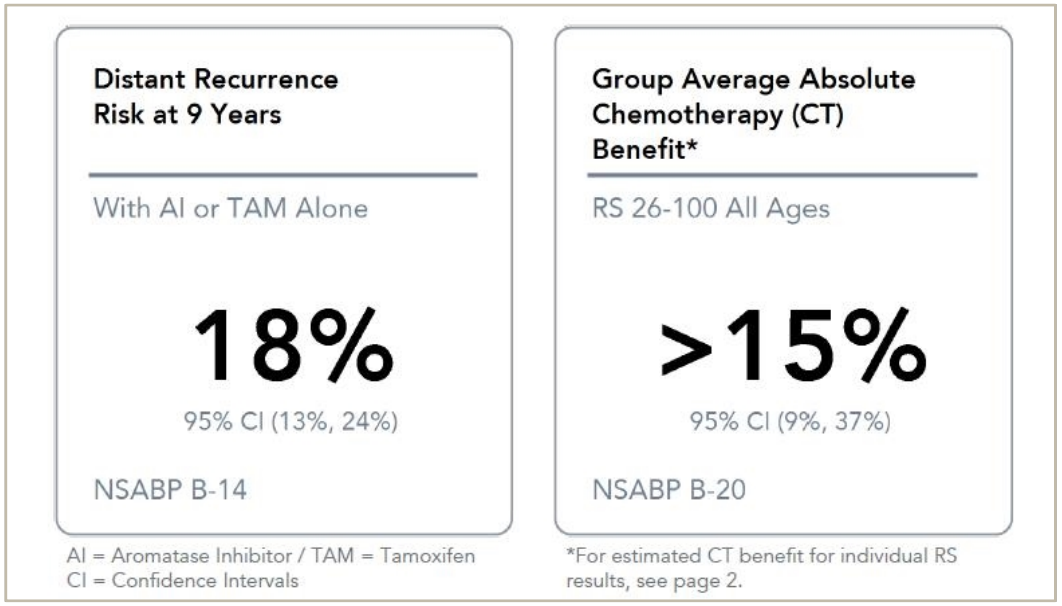
29

INVASIVE BREAST CASE STUDY

CLINICAL EXPERIENCE

The Distant Recurrence Risk at 9 Years (Prognosis), in patients with N–, ER+ breast cancer treated with endocrine therapy alone, is provided by the TAILORx[1] trial for RS 0-25 and by the NSABP B-14[2] trial for RS 26-100. Risk is for individual RS results. The 95% confidence intervals for distant recurrence at 9 years are ±2% or less for RS 0-22, and range from ±3% to ±11% as RS increases from 23-50. The TAILORx trial enrolled 10,273 patients and 5,018 patients with RS 0-25 were treated with endocrine therapy (tamoxifen or an aromatase inhibitor) alone. The NSABP B-14 trial enrolled 668 patients who were treated with tamoxifen alone.

The Absolute Benefit of Chemotherapy for all ages is provided by the TAILORx trial for RS 11-25 and by the NSABP B-20[3] trial for RS 0-10 and RS 26-100. Results for the reduction in distant recurrence at 9 years are for the TAILORx-defined RS groups 0-10, 11-25, and 26-100. TAILORx trial enrolled 10,273 patients and 6,711 were randomized to endocrine therapy (tamoxifen or an aromatase inhibitor) alone or endocrine therapy plus chemotherapy (including anthracyclines and/or taxanes). The NSABP B-20 clinical trial enrolled 651 patients who were randomized to treatment with tamoxifen alone or tamoxifen plus CMF/MF chemotherapy. The magnitude of the absolute benefit of chemotherapy was ~6% at RS 26, and increased as the RS results increased from 26-100, with an average absolute benefit of ~24% and a conservative group estimate of >15% based on the width of the confidence intervals.



RESULTS

Recurrence Score®

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INVASIVE BREAST CASE STUDY

CLINICAL EXPERIENCE

Exploratory Subgroup Analysis for TAILORx and NSABP B-20 indicate that RS and age are the strongest predictors of chemotherapy benefit. The absolute reduction of distant recurrence from chemotherapy for patients >50 years and ≤50 years is shown here for RS groups: 11-15, 16-20, and 21-25 from TAILORx, and 0-10 and 26-100 from NSABP B-20.

Age	RS 0-10	RS 11-15	RS 16-20	RS 21-25	RS 26-100
>50 years	No CT Benefit (<1%)				>15% CT Benefit
≤50 years	No CT Benefit (<1%)		~1.6% CT Benefit	~6.5% CT Benefit	>15% CT Benefit

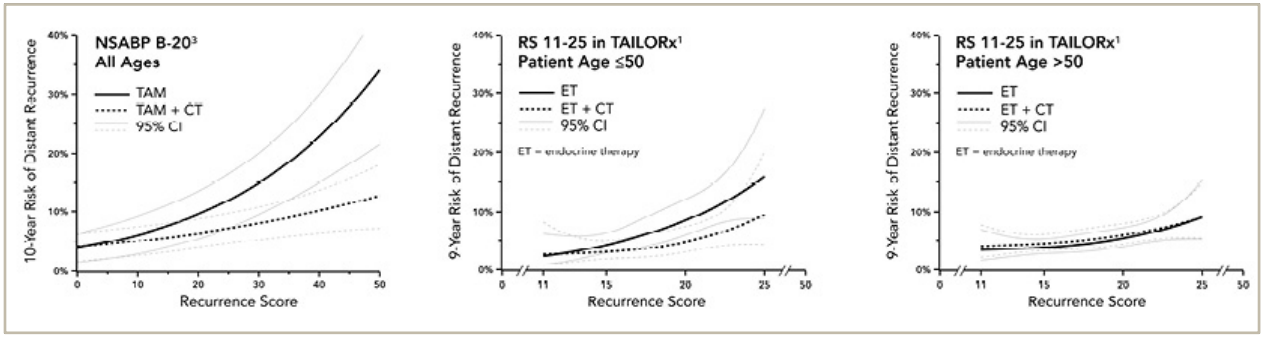
oncotypeDX® Breast Recurrence Score

INVASIVE BREAST CASE STUDY

29

ESTIMATED CHEMOTHERAPY BENEFIT FOR INDIVIDUAL RECURRENCE SCORE RESULTS

Recurrence Score ranges shown reflect randomized patients in NSABP B-20 and TAILORx.



TREATMENT GIVEN: Neoadjuvant chemotherapy

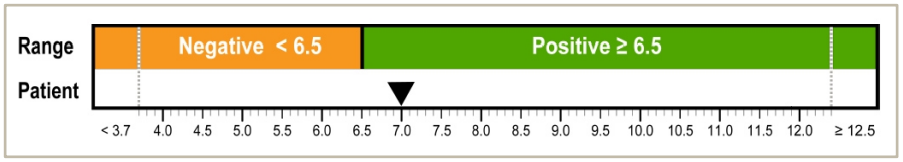
oncotypeDX® Breast Recurrence Score

INVASIVE BREAST CASE STUDY

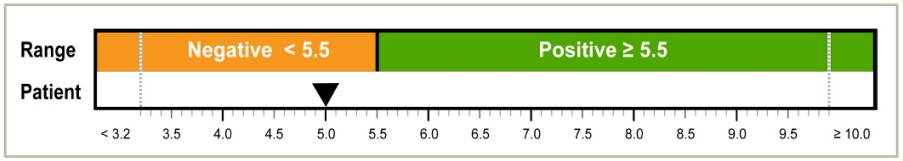
QUANTITATIVE HORMONE RECEPTOR ANALYSIS

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.

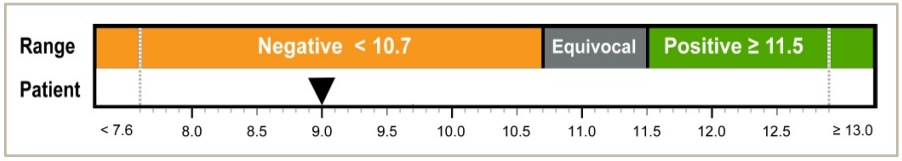
ER Score
7



PR Score
5



HER2 Score
9



References
1. Paik et al. N Engl J Med. 2004.
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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