

INVASIVE BREAST CASE STUDY

PATIENT 60 Year-Old Female Patient

TUMOR SIZE (cm) 0.5

MENOPAUSAL STATUS Post-Menopausal

TUMOR TYPE Ductal

ER STATUS (IHC) ER positive

PR STATUS (IHC) PR negative

HER2/NEU STATUS Negative

HISTOLOGIC GRADE 2

LYMPH NODE STATUS Negative

GENERAL HEALTH Diabetes, Hypothyroidism, Arthritis

OTHER INFORMATION N/A

NODE
Negative

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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 TAILORx¹ trial for RS 0-25 and by the NSABP B-14² trial for RS 26-100. Risk is for individual RS results. The 95% confidence intervals for distant recurrence at 9 years are $\pm 2\%$ or less for RS 0-22, and range from $\pm 3\%$ to $\pm 11\%$ 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-20³ 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 $\sim 6\%$ at RS 26, and increased as the RS results increased from 26-100, with an average absolute benefit of $\sim 24\%$ and a conservative group estimate of $>15\%$ based on the width of the confidence intervals.

RESULTS

Recurrence Score[®]

28

Distant Recurrence Risk at 9 Years

With AI or TAM Alone

17%

95% CI (13%, 23%)

NSABP B-14

AI = Aromatase Inhibitor / TAM = Tamoxifen
CI = Confidence Intervals

Group Average Absolute Chemotherapy (CT) Benefit*

RS 26-100 All Ages

>15%

95% CI (9%, 37%)

NSABP B-20

*For estimated CT benefit for individual RS results, see page 2.

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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%)	$\sim 1.6\%$ CT Benefit	$\sim 6.5\%$ CT Benefit	>15% CT Benefit	

RESULTS

Recurrence Score®

28

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ESTIMATED CHEMOTHERAPY BENEFIT FOR INDIVIDUAL RECURRENCE SCORE RESULTS

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

28



TREATMENT
GIVEN:

Docetaxel/Cyclophosphamide for 4 cycles
followed by adjuvant hormonal therapy
after completion of chemotherapy

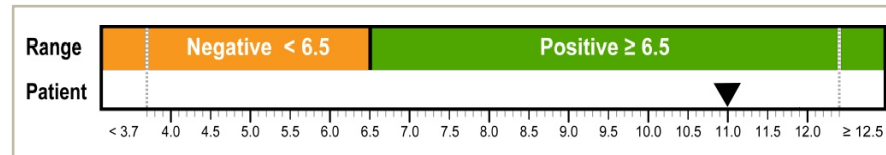
INVASIVE BREAST CASE STUDY

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-offs⁴. 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.

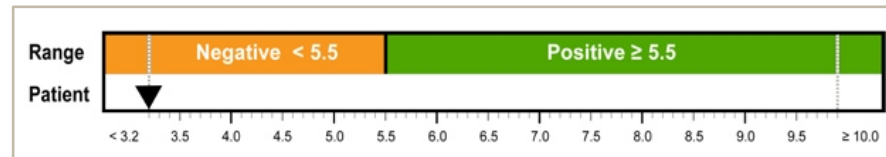
ER Score

11



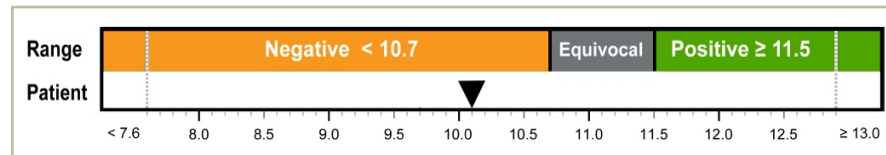
PR Score

3.2



HER2 Score

10.1



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.