

Clinical Scenario #2

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Adjuvant! Online Results

Calculated for Relapse

Patient Information

Age:

Comorbidity:

ER Status:

Tumor Grade:

Tumor Size:

Positive Nodes:

Calculate For:


10 Year Risk:

Adjuvant Therapy Effectiveness

Horm:


Chemo:

No additional therapy:




71.2 alive and without cancer in 10 years.
24.5 relapse.
4.3 die of other causes.


With hormonal therapy: Benefit = 8.8 without relapse.



With chemotherapy: Benefit = 8.6 without relapse.



With combined therapy: Benefit = 14.4 without relapse.



21-Gene Recurrence Score Results

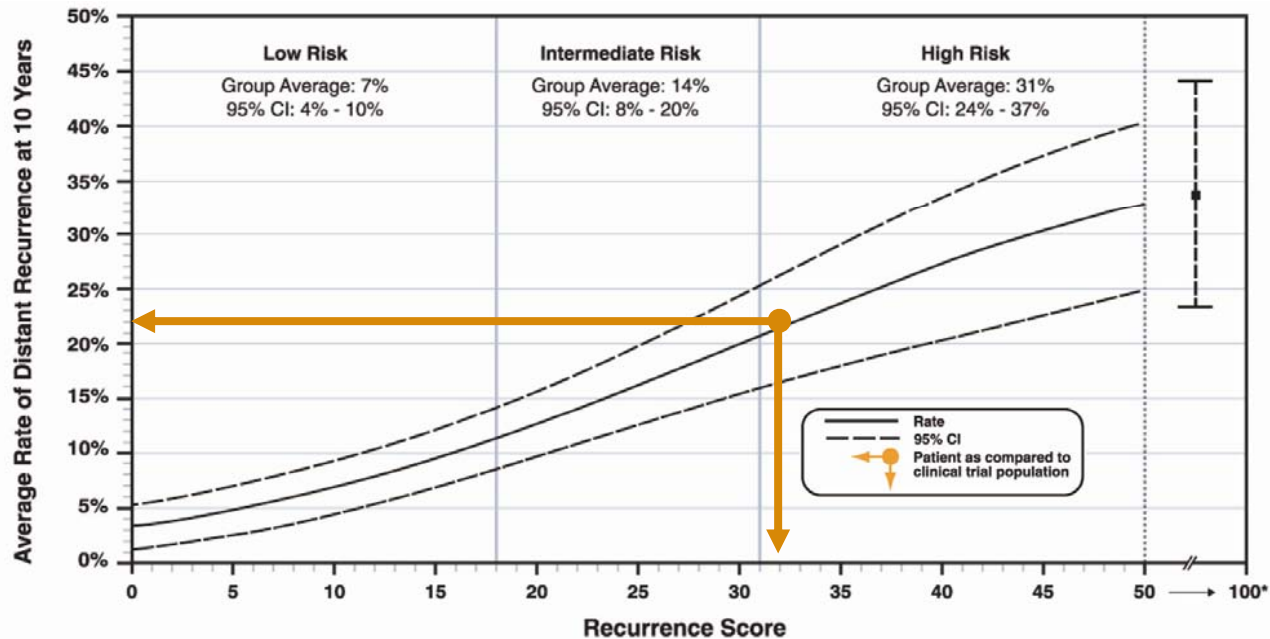
RESULTS

Recurrence Score =

32

CLINICAL EXPERIENCE

Patients with a Recurrence Score of **32** in the clinical validation study had an Average Rate of Distant Recurrence at 10 years of **22%** (95% CI: 17% to 26%).



*For Recurrence Scores >50, group average rate of distant recurrence and 95% CI shown

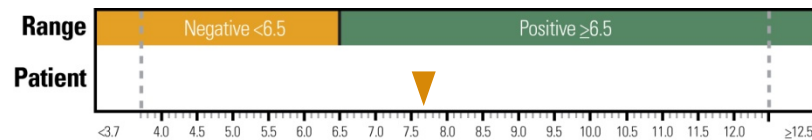
21-Gene Recurrence Score Results

QUANTITATIVE HORMONE RECEPTOR ANALYSIS

The *Oncotype DX* assay uses RT-PCR to determine the RNA expression of the hormone receptor genes below. These results may differ from ER, PR, or HER2 results reported using other methods or reported by other laboratories.¹

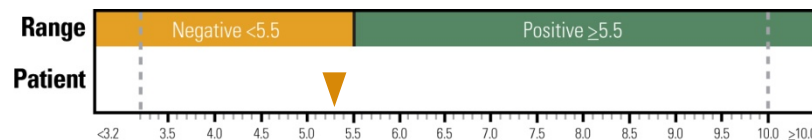
The ER, PR, and HER2 Scores are also included in the calculation of the Recurrence Score.

ER Score = 7.7



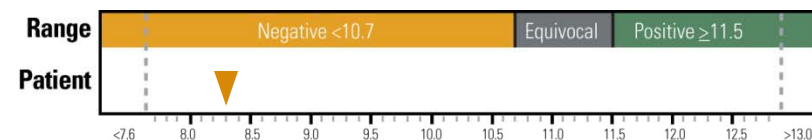
Clinical Experience: For ER positive breast cancer, the magnitude of tamoxifen benefit increases as the ER Score increases from 6.5 to ≥ 12.5 .² Please note: The Average Rate of Distant Recurrence reported on Slide 3 based on the Recurrence Score assumes 5 years of tamoxifen treatment and takes into account the magnitude of tamoxifen benefit indicated by the ER Score.

PR Score = 5.3



The ER Score positive/negative cut-off of 6.5 units and PR Score positive/negative cut-off of 5.5 units were validated from multiple studies. The standard deviation for both the ER Score and the PR Score is less than 0.5 units.³

HER2 Score = 8.3



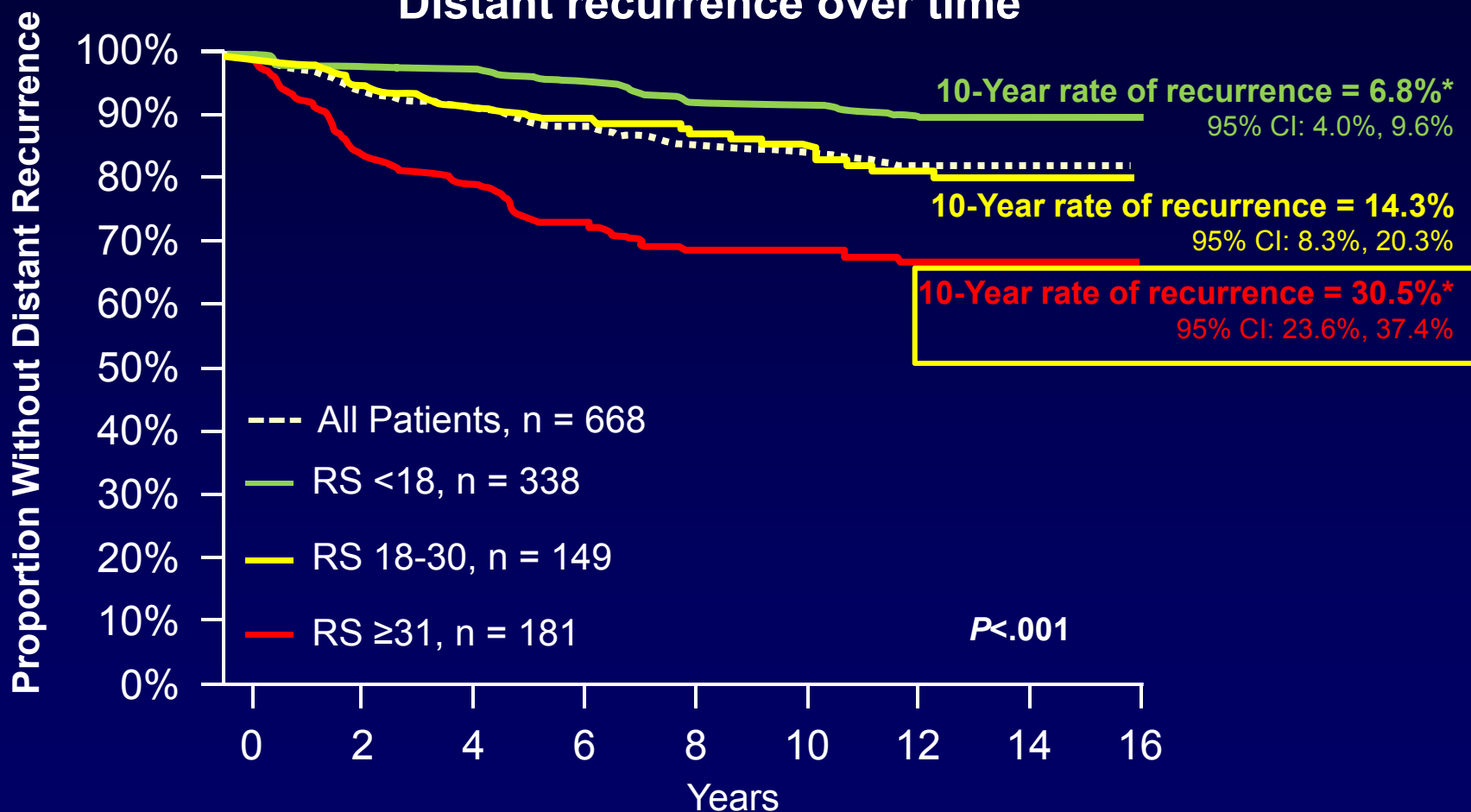
The HER2 positive cut-off of ≥ 11.5 units, equivocal range from 10.7 to 11.4 units, and negative cut-off of <10.7 units were validated from concordance studies of 755 samples using the HerceptTest™ assay (immunohistochemistry) and another study of 568 samples using the PathVysion® assay (FISH). The standard deviation for the HER2 score is less than 0.5 units.⁴

References

1. ER Score based on quantitative ESR1 expression (estrogen receptor); PR Score based on quantitative PGR expression (progesterone receptor); HER2 Score based on quantitative ERBB2 expression.
2. *ASCO Annual Meeting 2005* Abstract #510 by S. Paik et al.
3. *ASCO Breast Cancer Symposium 2007* Abstracts #87 by S.S. Badve et al., and #88 by F.L. Baehner et al.
4. *ASCO Breast Cancer Symposium 2008* Abstracts #13 by F.L. Baehner et al., and #41 by F.L. Baehner et al.

21-Gene Recurrence Score Clinical Validation: NSABP B-14, Distant Recurrence

Distant recurrence over time

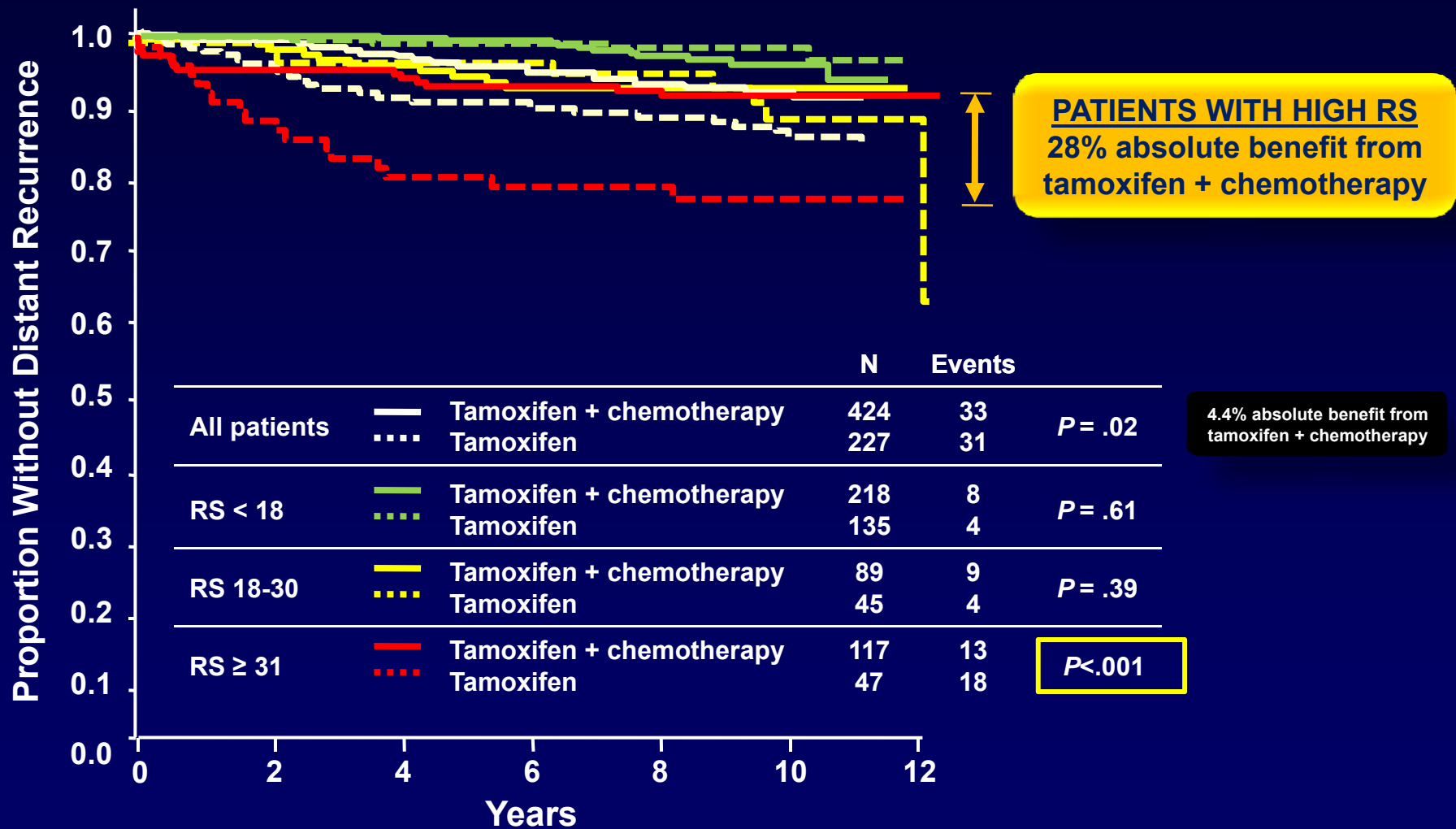


*10-Year distant recurrence comparison between low- risk and high-risk groups: $P < .001$

Paik S, et al. *N Engl J Med.* 2004;351(27):2817-2826.

RS, Recurrence Score® result

High Recurrence Score Result Correlates with Greater Benefit from Chemotherapy (NSABP B-20)



How Was This Patient Treated?

**Docetaxel / cyclophosphamide (TC) x 4 cycles
and tamoxifen x 5 years**