

Abstract #2285

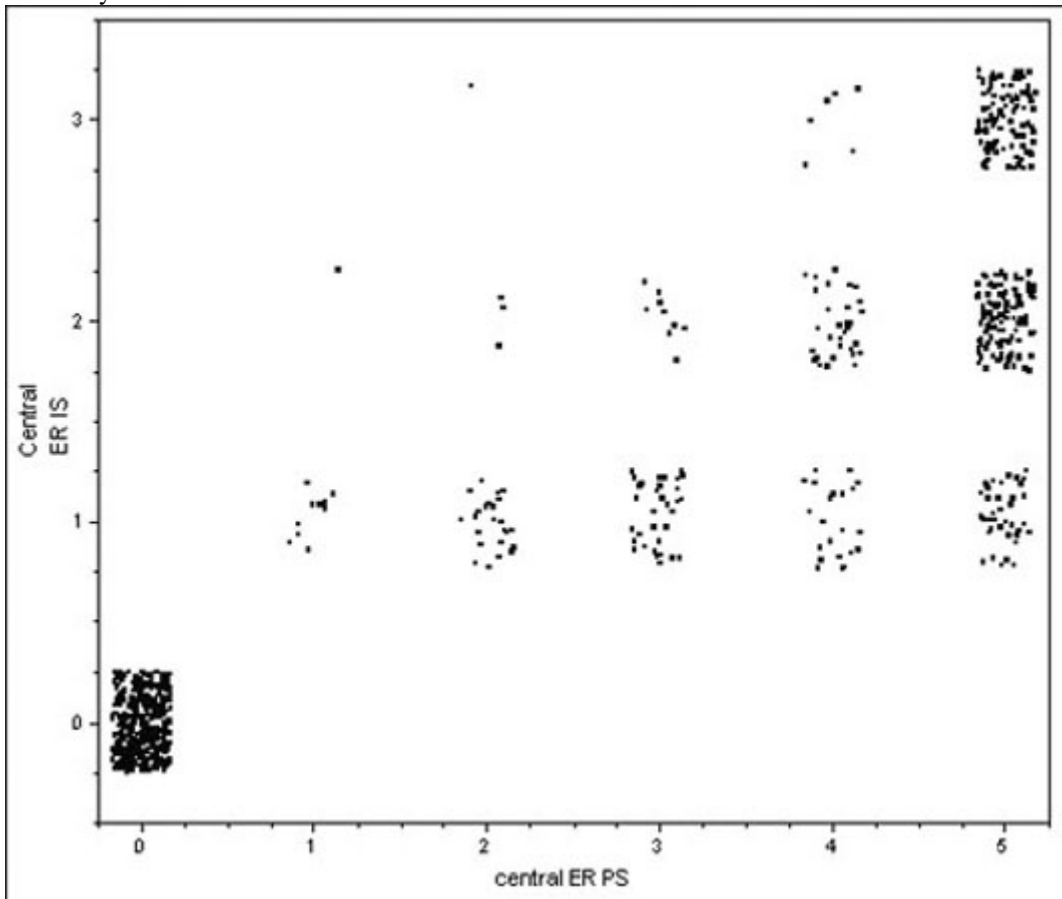
Title: ER and PR Assessment by Central IHC: Examination and Comparison of Percent Positive Cells and Nuclear Staining Intensity in ECOG Breast Cancer Study 2197

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Background: Accurate laboratory assessment of hormone receptors (HR) in breast carcinoma is therapeutically important. Using central laboratory IHC results for ER and PR, we explored the Allred Score and its constitutive components, the nuclear intensity score (IS) and proportion score (PS), and examined these measurements to patient outcome data.

Design: Tumors from 776 pts (179 of whom relapsed) enrolled on E2197 were examined; pts had 0-3 positive nodes and all received doxorubicin and cyclophosphamide or docetaxel plus hormonal therapy (if local laboratory HR+). Central IHC for ER (1D5) and PR (636) used two 1.0 mm tissue microarrays. The staining intensity (0-3 scale) and proportion of positive cells (0-5 scale) were reported and the Allred score (AS) that combines the two was calculated.

Results: The Spearman rank correlation between ER IS and PS was high (0.98). The same high correlation was observed for PR IS and PS. For ER, the distribution of proportion score tended to be bimodal (45% of patients have a PS of 0 and 36% of patients have a PS of 5); whereas, the distribution of IS is more uniformly distributed.



These distributions are reflected in the Allred score which also tended towards a bimodal distribution (58% of ER positive patients have an Allred score of 7 or 8). ER IS and ER PS are both significantly associated with recurrence ($p=0.0006$ and $p<0.0001$ respectively). While the 5-year recurrence rates decreased monotonically from 15% in PS category 2 to 7% in PS category 5, the 5-year recurrence rates for IS decreased from IS categories 0 to 2 (from 16% to 7%) but then increased again for category 3 (10%). The pattern of 5-year recurrence rates by IS category was similar to that for the Allred Score.

Conclusions: By central IHC assessment of ER and PR status using the Allred Score, there is a high degree of correlation between the intensity score and proportion score, and both are significantly associated with 5-year recurrence rates.

Category: Breast

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Poster Session V # 15, Wednesday Morning