[125] A Laboratory Comparison of the 21-Gene Assay and PAM50-ROR

Helen Bailey, Michael Alvarado, Frederick L Baehner, Che Prasad, Megan Rothney, Diana Chervabaz, Amy P Sing, Christer Svedman. Genomic Health, Inc., Redwood City, CA; University of California, San Francisco, CA; Marin General Hospital, Greenbrae, CA

Background: The 21-gene Recurrence Score® assay is validated in patients (pts) with ER+ early-stage invasive breast cancer (EBC) and predicts 10-year distant recurrence risk and chemotherapy (CT) benefit. The Prosigna®assay (ROR), which uses 46 of the PAM50 genes, was validated in post-menopausal pts with ER+ EBC and is a prognostic assay only. Despite differences in platforms and methods used for development and validation, it is frequently believed that the assay results are interchangeable. We performed a study comparing results from the two assays obtained from the same tumor blocks. The first 40 samples showed a substantial disagreement in how the assays stratify risk.
Design: 70 sequential BC tumors from Marin Medical Laboratories with sufficient tumor material were selected to be tested with the standard 21-gene assay. Samples were sent to an independent lab where Prosigna ROR and intrinsic subtype was performed with the operators blinded to Recurrence Score results. The first 40 cases were stratified by Recurrence Score (20 low, 10 intermediate and 10 high) Descriptive statistics were used to compare results from the 2 assays.
Results: Of the 40 initial pts evaluated, 7 were excluded: 3 for low RNA signal in the Prosigna assay and 4 were ER(-) by RT-PCR. Of the 33 remaining cases; 24 ductal, 7 lobular; 27 were N(-) and 6 were N+. The Spearman rank correlation between Recurrence Score and ROR was 0.40 (95% CI 0.06 – 0.65). Risk group assignment (low/intermediate/high) between Recurrence Score and ROR was in agreement in 56% (15/27) of N(-). Prosigna classified 19 luminal A, 12 luminal B, 2 HER2 enriched and 0 basal. In both the luminal A and B groups there was a wide range of Recurrence Score results.
Conclusions: Consistent with prior comparisons between the Onco*type* DX and other genomic assays, there are substantial differences in the way pts are risk stratified and it cannot be assumed that the assay results are interchangeable. These results suggest that there is only a modest agreement between Recurrence Score results and ROR, with almost half of N(-), ER+ pts classified differently, including ~30% of high ROR pts being classified as low risk by the Recurrence Score with expected minimal if any benefit from chemotherapy. Final data from 70 pts will be presented.
Category: Breast Pathology

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Poster Session IV # 48, Tuesday Afternoon