P148 THE DEVELOPMENT OF THE DCIS SCORE: SCALING AND NORMALIZATION IN THE MARIN GENERAL POPULATION

Poster Abstracts I

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Goals: We previously reported that in selected low-risk patients with ductal carcinoma in situ (DCIS) treated with wide local excision (WLE) without radiation (RT), the DCIS Score™ was significantly associated with 10 year risk of an ipsilateral breast event (IBE – recurrence of in situ or invasive carcinoma), (P = 0.02). (Solin; SABCS 2012). As part of the development of the DCIS Score, scaling from 0 to 100 and determination of risk group cutoff values was done using 100 patient DCIS samples from Marin General Hospital (MGH), selected to have a wide range of tumor characteristics.

Methods: For the 100 patient samples provided by Marin General Hospital, the Oncotype DX® assay was conducted, the normalized expression levels for each of the 16 cancer related genes were determined, and the DCIS Score value and Recurrence Score result were calculated. The distributions of the DCIS Score, RS, and individual gene expression levels were described overall and according to tumor characteristics. Treatment and patient outcome data were not available in this study.

Results: Samples for 96 patients satisfied laboratory criteria. Of the evaluable 96 patient samples, 47% had high nuclear grade, 52% had comedo necrosis present, 32% had tumor size >10 mm, and 9% were ER-negative by IHC. After scaling and risk group cutoff determination, the DCIS Score was in the low risk group (0–38) for 49%, the intermediate risk group (39–54) for 27%, and the high risk group (?55) for 24% of patients (see Table). The DCIS Score was widely distributed within subgroups defined by each of the clinical and pathology characteristics examined. The proliferation gene expression levels were low, on average, relative to studies in invasive breast cancer. 92% of samples had a proliferation group score <6.5, the threshold used when the score is calculated; no threshold is used in calculating the DCIS Score.

DCIS Score risk group distribution by clinical and pathology characteristics Variable

Nuclear grade

Comedo necrosis

Tumor size

Conclusion: Optimal scaling and risk cutoff determination for a wide range of all clinicopathologic covariates provides for a wide distribution for the DCIS Score value.As an employee at Genomic Health, Inc., I am compensated with salary, benefits, and stock. I also have stock options as an employee of Genomic Health, Inc.