Long-term follow-up of early stage breast cancer patients with results of MammaPrint®, Oncotype DX® and Mammostrat® risk classification assays

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BASIS OF OBJECTIVES

The use of genetics tests for the prediction of breast cancer recurrence and for the choice of chemotherapy is becoming more common. MammaPrint® (Agendia), Inc.) is a 70-gene microarray assay designed to assess the 10-year risk of recurrence in early stage invasive breast cancer and was selected for use in this study. MammaPrint was clinically validated to predict the 10-year risk of distant recurrence in 851 patients treated with Tamoxifen. MammaPrint® (Agendia, Inc.), is an on assay that uses 5 antibodies and has been validated in a similar patient population as a risk classification tool. Several recent reports show the these assays classify patients differently with signiﬁcant differences in the James Shivers, et al., ASCO Breast 2011; Morton Plant Hospital, Clearwater, FL, USA; University of South Florida, Tampa, FL, USA; University of South Florida, Tampa, FL, USA. In a total of patients (Shivers, et al., ASCO 2011) who have results for all three of these risk-stratifying assays, some are in the same category, while others are in different categories.

METHODS

Patients with ER+ early stage breast cancer with an MP result obtained as part of their routine clinical care were included in the University of South Florida (USF) study and Morton Plant Hospital (MPH) Study. Slides of the original blocks were reviewed at the USF and set at 0.5 microns. Genomic data was reviewed for light pathologies.

RESULTS

184 patients with an MP result had tissue available to assess for this and MS analyses. These patients had a median age of 53 years, median tumor size 1.0 cm, 92% low grade, 9% intermediate grade and 8% high grade. In an initial analysis of this study, 174 patients with MP results were included. All patients had a confirmed mammographic diagnosis of breast cancer with an MP result obtained as part of their routine clinical care. All other authors have nothing to disclose. Charles Cox, MD and Peter Blumencranz are on the speakers’ bureau for Agendia, Inc. and Dr. Cox is on the Medical Advisory Program Number: P6-09-45

CONCLUSIONS

This study has important clinical implications since these assays are used to help make treatment decisions. These data demonstrate assays classify a large proportion of patients differently. Some patients, despite being classified as high risk with one or more of these assays, are alive and disease free at 10 years. Why some patients classified as low risk are, in fact, high risk while others classified as high risk are, in fact, low risk, are unexplained. The need for better biomarkers to classify patients as either low or high risk of recurrence is important. The significant differences in outcome of patients based on risk group, after 10 years of follow-up, underscores the need for these assays to be validated in a larger, external patient population and further studies on parameters influencing outcomes are needed. How can subjects in the same risk group on the different assays be guided for chemotherapeutic agents? What is the best approach to treat patients, in the setting of these differences? The need for independent validation of these results with a larger number of patients is relevant.

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