Analysis of Oncotype DX recurrence score and its clinical implications in invasive lobular carcinomas of the breast

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Background: The Oncotype DX breast cancer assay is increasingly being used to guide treatment decisions for patients with early stage, hormone-positive, Her-2 negative breast cancer, regardless of the histologic subtype. The utility of the Oncotype DX in decision making for treatment of invasive lobular carcinoma (ILC) has not been investigated.

Methods: We performed a retrospective analysis of early stage breast cancer patients treated at Penn State Cancer Institute from 2001 to 2011 and identified 102 patients with ILC. We evaluated the clinicopathological features and compared the Recurrence Score (RS) distribution in this population to that reported by Genomic Heath for the ductal histology (Kruskal-Wallis test). Median follow-up was 4.5 years

Results: We found that the RS distribution for ILC differed significantly from that reported by Genomic Health (P < 0.0001). The vast majority of patients (97.8%) have low/intermediate RS and only 2.2% high RS whereas the RS distribution reported by Genomic Health is 54.2% for low RS, 20.6% for intermediate and 25.2% high RS. We also found a statistically significant difference in the RS distribution between pure ILC and pleomorphic ILC (P = 0.027). When using RS of 25 as cutoff for chemotherapy recommendation, 93.3% of ILC patients have RS ≤ 25 and would not be candidates for adjuvant chemotherapy. Most tumors were T1-T2 (93.5%) and 6.5% were T3. Most tumors (64.4%) were node negative, 21% had 1-3 lymph nodes positive and 14.4% had N2/N3 disease. All the pure ILC tumors were hormone positive and only one pleomorphic ILC tumor was HR negative. 5.8% tumors were Her 2 +. The 5 yr. Disease free survival (DFS) for the entire cohort was 84.9% and 5 yr. overall survival (OS) was 91.4%. OS varies significantly by histologic subtype with 5 yr. OS being 100% for pleomorphic ILC, 92% for pure ILC and 73% for mixed subtypes.

Conclusions: The Oncotype DX RS distribution in invasive lobular carcinoma is unique, differing significantly from that in invasive ductal carcinoma. Majority of patients (97.8%) have low/intermediate RS and 93.3% have RS ≤ 25 and would not be candidates for adjuvant chemotherapy. The clinical usefulness and cost-effectiveness of the Oncotype DX in guiding treatment for ILC should be further investigated.

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