Systemic Treatment Decision Making for Patients with Stage I and II, Hormone Receptor Positive, HER2/neu Negative Breast Cancer

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**Background:** Oncotype DX is a clinically validated risk stratification tool that can predict the risk of recurrence and the benefit of adjuvant chemotherapy in women with hormone receptor positive (HR+), HER2/neu negative early stage breast cancer (EBC). This tool has been available to oncologists in Ontario since April 2010 at significant cost, yet no guidelines exist regarding their use.

**Objective:** The objective of this study was to determine the factors that were associated with use of the Oncotype DX assay at the Ottawa Hospital Cancer Centre.

**Study Design:** A retrospective case-control study involving patients who underwent Oncotype DX testing and matched control patients who did not undergo testing

**Setting:** Outpatient oncology clinic

**Patient Population:** One hundred patients (pts) diagnosed with HR+, HER2/neu negative EBC (stage I-II), who underwent Oncotype DX testing between April 1, 2010, and June 30, 2011 were included in the study. A second control group of 100 patients with similar disease characteristics but who did not receive Oncotype DX testing were randomly selected.

**Interventions:** Data collection included age, menopausal status, comorbidities, tumor stage, tumor grade, and Adjuvant! Online recurrence risk scores. The distribution of patients in each category was compared using the chi-square test to detect statistically significant differences between distributions.

**Outcomes:** The difference in distribution of patients between the two groups within each data category.

**Results:** Median age in the Oncotype DX group was 58 years and 63 years in the control group. 20 patients in the Oncotype DX group were aged 35-49, 57 patients were aged 50-64, and 23 patients were aged 65 or older, while the control group had 16, 43, and 41 patients, respectively (p=0.02). The Oncotype DX group had 72 pre- and perimenopausal pts and 28 postmenopausal patients, while the control group had 81 and 19 patients, respectively (p=0.13). 20, 56, and 24 pts in the Oncotype DX group had grade 1, 2, and 3 histology, respectively, vs. 44, 44, and 12, respectively in the control group (p<0.01). The Oncotype DX group had 7 patients with tumors between 1-10 mm, 55 between 10.1-20 mm, 34 between 20.1-50 mm, and 4 greater than 50 mm, vs. 29, 42, 23, and 1, respectively in the control group (p<0.01). When 10-year Adjuvant Online recurrence scores were calculated using tamoxifen, 17, 67, and 16 patients in the Oncotype DX group had risk scores of <15, 15-25, and >25, respectively, vs. 62, 33, and 5 in the control group (p<0.01). When the scores were calculated using tamoxifen plus aromatase inhibitor, 49, 42, and 9 patients in the Oncotype DX group, and 75, 24, and 1 patients in the control group fell into these categories, respectively (p<0.01).

**Conclusions:** Physicians were more likely to request Oncotype DX testing for patients that were younger, had larger and higher grade tumors, and higher Adjuvant! Online recurrence risk scores. Age, tumor size and grade, and Adjuvant! Online scores are risk factors for disease recurrence; this represents a higher risk group for which additional testing is more likely to reveal meaningful benefits from adjuvant chemotherapy. From this data, we plan to conduct a national study to delineate the importance of these factors to Canadian oncologists in influencing their decision-making involving Oncotype DX usage.