

**Impact of the 21-gene Recurrence Score assay on the adjuvant treatment of breast cancer patients with 1-3 positive lymph nodes in an academic centre in Ontario.**

Author(s): Sofia Torres, Maureen E. Trudeau, Sonal Gandhi, Ellen Warner, Sunil Verma, Kathleen I. Pritchard, Teresa M. Petrella, Mark Hew-Shue, Calvin Chao, Andrea Eisen

Background: The 21-gene Recurrence Score (RS) assay has been shown to be both prognostic and predictive of chemotherapy (CT) benefit in patients with node negative and node positive (N+), estrogen-receptor positive (ER+) early-stage breast cancer (EBC). Currently, the assay is only reimbursed by the provincial single payer Ontario Health Ministry for node-negative EBC. Methods: The primary objective of this prospective study is to characterize how the results of the RS assay impact the decision making processes of medical oncologists in an academic centre in Ontario by evaluating recommendations for adjuvant therapy for 70 patients with ER+, HER2-negative EBC and 1-3 positive lymph nodes. Secondary objectives are to characterize changes in the physician's level of confidence in their recommendation, to determine whether the results of the RS affect patients' treatment preferences and their level of confidence and to evaluate the actual treatment administered. Recruitment will be completed by the time of the ASCO meeting. Here we report the results for the first 50 patients, enrolled from October 2014 to December 2015. Results: Mean patients' age was 61 (range: 41-84). Tumor size was  $\leq 2$  cm in 46% of patients,  $> 2-5$  cm in 44% and  $> 5$ cm in 10%. Tumors were grade 1 in 24% of patients, grade 2 in 50% and grade 3 in 26%. RS was low ( $< 18$ ) in 52% of cases, intermediate (RS 18-30) in 38% and high ( $\geq 31$ ) in 10%. Treatment recommendations changed in 35% of all evaluable patients (17 out of 48). The most significant change was in the group with a low RS ( $< 18$ ), with 48% of the recommendations changing from upfront CT pre-assay, to endocrine therapy only post-assay. Physicians' confidence in the recommendations increased in 46% of cases and decreased in 12.5%. Patients' confidence in their treatment choice increased in 65% of cases and decreased in 13%. Upfront CT was recommended to 75% of patients pre-assay, 43% ultimately received CT. Conclusions: The RS assay resulted in a substantial decrease in the number of node positive patients who would receive CT and in an increase of the physicians' and patients' confidence in the adjuvant treatment recommendations.