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A prospective multicenter study evaluating the impact of the 21-Gene Breast Recurrence Score® upon physician treatment decision and cost in lymph node-positive breast cancer patients in Quebec

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Background:
Locoregional lymph node involvement has historically been used as the most important deciding factor for the administration of chemotherapy in the adjuvant setting of breast cancer patients. The 21-gene Breast Recurrence Score® assay (the assay) is emerging as an important tool to assist with chemotherapy decisions amongst hormone receptor (HR)-positive, node-positive breast cancer (BC) patients. Previous studies have suggested that node-positive patients with low Recurrence Score (RS) results do not benefit from chemotherapy. We wanted to better understand the impact of the assay upon physician treatment decisions and treatment cost in this patient cohort.

Methods:
We conducted a multicenter prospective observational trial for ER/PR-positive HER2-negative BC patients that have undergone surgical treatment for T1-T3 disease and 1-3 positive lymph nodes. Physicians were required to complete a questionnaire indicating treatment choice prior to and post availability of Recurrence Score results. Patients were enrolled in the study from the time of consent to 6 months after the start of adjuvant therapy. The primary endpoint was change in the physician's recommendation for chemotherapy prior to and post assay results. Secondary endpoints include the change in recommendation for additional growth factor (GF) supportive therapy, change in physician's expressed level of confidence, and changes in estimated cost of recommended treatments prior to and post assay results.

Results:
70 patients were enrolled between March 2018 and September 2019 at five hospital centers, as part of the McPeak Sirois Group of Quebec. The median age of the cohort was 61 years (range, 38 to 82 years). 18.5% (n=13) of the cohort consisted of patients < 50 years, and 81.4% (n=57) were > or = to 50 years. 64.3% (n=45) of the patients had one positive lymph node and 35.7% (n=25) of the patients had 2 or 3 positive lymph nodes. 25.7% (n=18) of the patients had a RS < 11 and 68.6% (n=48) had a RS result between 11-25. For the entire cohort, we found that the proportion of patients for whom chemo-hormonal therapy was recommended was reduced by an absolute 67.1% by knowledge of the RS result (OR (odds of having chemo-hormonal therapy post-RS recommendation versus pre-RS recommendation) = 0.03 [95% CI: 0.01-0.08]; P< 50 years, and by 73.7% of patients (OR=0.02 [95% CI: 0.01-0.06]; P or = to 50 years. Changes in treatment recommendation were identified for patients with one positive node, 73.3% (OR=0.02 [95% CI: 0.01-0.07]; P<0.0001); and for patients with two or three positive nodes, 56.0% (OR=0.06 [95% CI: 0.02-0.23];P<0.0001). Recommendations for GF supportive therapy due to RS results decreased by 42.6% (OR=0.16 [95% CI: 0.07-0.34]; P <0.0001). Moreover, RS results led to an increase in confidence in physician treatment decisions for 68.6% of patients

(OR=18.3 [95% CI: 7.90-42.28]; P <0.0001). We found that the cost of chemotherapy, in addition to anti-emetics and GF supportive therapy, decreased by 69.9% per patient (pre-RS mean, $3,968 CAN; versus post-RS mean, $1,196 CAN) (P <0.0001).

Conclusions:
Overall, we found that the 21-gene Breast Recurrence Score® assay changed physician treatment decisions in about two-thirds of all patients with hormone receptor-positive, node-positive BC, regardless of the number of positive nodes (up to 3). The assay increased physician confidence and was associated with an important decrease in treatment cost. Taken together, the assay is a cost-effective approach that can decrease the use of chemotherapy amongst HR-positive, node-positive BC patients in Quebec.