

183P - Prospective evaluation of the impact of the 21-gene recurrence score® assay on adjuvant treatment decisions for women with node-positive breast cancer in Ontario, Canada

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Background The 21-gene Recurrence Score® (RS) assay is reimbursed by the single payer Ontario Health Ministry for node-negative early-stage breast cancer (EBC). We carried out a prospective study to evaluate the impact of the RS® assay on treatment decisions for women with node-positive (N+), estrogen receptor-positive (ER+) EBC.

Methods Women with ER + , human epidermal growth factor receptor 2-negative, EBC and 1-3 positive axillary lymph nodes, who were candidates for adjuvant chemotherapy (CT), in addition to hormonal treatment, were eligible. Primary objective was to characterize how the results of the RS assay impacted decision making processes of medical oncologists by evaluating recommendations for adjuvant therapy prior to and after the RS assay. Secondary objectives were to characterize changes in physician level of confidence in their recommendation, whether the results of the RS assay affected patients' preferences and level of confidence in treatment recommendations, and to evaluate the actual treatment administered.

Results From October 2014 to May 2016, 68 patients were recruited (target:70 patients); RS assay results are currently available for 64 patients. Mean age was 61 (range: 41-84); 70% were post-menopausal. Tumor size was ≤2 cm in 47%, >2-5 cm in 45% and >5cm in 8%. Tumors were grade 1 in 22%, grade 2 in 58% and grade 3 in 20%. RS was low (<18) in 56% of cases, intermediate (RS 18-30) in 36% and high (≥31) in 8%. Treatment recommendations changed in 34% of all evaluable patients (21 out of 62). The most significant change was in the group with a low RS (<18): 45% of the recommendations changed from upfront CT pre-assay, to endocrine therapy only post-assay. Physicians' confidence in recommendations increased in 52% of cases and decreased in 11%. Patients' confidence in their treatment choice increased in 58% and decreased in 13%. Upfront CT was recommended to 78% of patients pre-assay, 43% ultimately received CT (net reduction in CT use: 35%).

Conclusions The RS assay resulted in a substantial decrease in the number of N+ patients who would receive CT and in an increase of the physicians' and patients' confidence in the adjuvant treatment recommendations.

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Legal entity responsible for the study Sunnybrook Odette Cancer Centre

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