The 21-gene assay in the decision impact assessment of ER+, HER2- Breast cancer: A French real life prospective study

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BACKGROUND: Tumour gene expression analysis is useful in predicting adjuvant chemotherapy benefit in breast cancer (BC). The 21-gene assay test is used to estimate the risk of recurrence and to predict the benefit of adjuvant chemotherapy (ACT) at an early stage of hormone-receptor-positive (ER+) BC. This study aims to examine the implications of RecurrenceScore (RS) testing within the routine clinical practices in France.
METHODS: We conducted a prospective multicentert study, with voluntary participation, involving women with ER+, HER2-, BC. Performing the assay was left at the discretionof the physicians. The final treatment decision was discussed pre and post assay among tumor board (TB). The therapeutic changes after knowledge of RS were collected. RS and classical BC prognostic markers were investigated in parallel including an estimate of the budget impact of the assay.
RESULTS: 603 patients were included in this analysis (tumor size ≤ 20 mm: 70.6%; node-negative patients: 61.2%; SBR 2: 74.9%). After the first TB, ACT was recommended for 529 patients (88.0%) and hormonotherapy (HT) alone for 74 patients (12.0%). The RS was low for 59.7% of the cases, intermediate for 34.0% and high for 6.3%. Based on RS results, second TB changed treatment decision for 70.48% of patients, avoiding CT in 64 % of cases. Only 24% received ACT while 76% received HT alone. The calculated budget impact as a minimal estimate according to the French healthcare payer perspective is estimated at a savings of € 570 per patient, corresponding to a global cost-saving of € 221,730.
CONCLUSION: The results of this “real life” study confirm that the 21-gene assay had a significant impact on therapeutic decision. These findings warrant further consideration for the use of this genomic assay in patients with early stage BC in France.

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