A comparative analysis of distant recurrence risk assessments by Oncotype DX recurrence score alone and integrated with clinicopathologic factors in early-stage breast cancer.

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Background: Treatment planning for patients with node negative, ER-positive, HER-2 negative breast cancer often incorporates the use of prognostic and predictive tools like Oncotype DX. Prior to the availabilty of Oncotype DX, clinicopathologic factors such as age, nodal status, tumour size and grade were used to determine risk of recurrence (ROR). RSPC represents a validated formal integration of oncotype DX recurrence score (RS) and clinicopathologic factors that further refines prognostic accuracy. RSPC does not improve the prediction of likelihood of chemotherapy benefit. The objective of this study was to compare distant recurrence risk assessment by RS and RSPC. **Methods:** We included patients with node negative, ER-positive, HER2-negative breast cancer who had Oncotype DX testing routinely or on clinical trial. We retrospectively reviewed patient charts and extracted clinicopathological and RS data. We calculated the RSPC using the RSPC educational tool. A comparative analysis was performed looking at the statification of patients into low (LR), intermediate (IR) and high (HR) ROR groups by RS and RSPC. The cut offs for low, intermediate and high risk by the RSPC were set to less than 12%, 12-20% and more than 20% risk of distant recurrence at 10yrs, corresponding to the risks of recurrence associated with the RS categories. **Results:** We identified 658 patients from 5 academic hospitals in Ireland and the US. Oncotype DX RS classified the following proportions of patients into three risk groups for distant recurrence: LR, n=334 (50.5%), IR, n=259 (39.4%), HR, n=67 (10.1%). RSPC classified the following proportion of patients into the three risk groups for recurrence: LR, n= 455 (69.1%), IR, n=110 (16.7%), HR, n=93 (14.1%). RSPC reclassified 72.6% (n=188) of the IR group (59.1% (n=153) from IR to LR and 13.5% (n=35) from IR to HR). RPSC reclassified 10.5% (n=35) of the LR group (8.1% (n=27) from LR to IR, and 2.4% (n=8) from LR to HR). RSPC reclassified 25.3% (n=17) of the HR group (17.9% (n=12) from HR to IR, and 7.4% (n=5) from HR to LR). **Conclusions:** RSPC reclassified 240 patients (36.5%) and was most helpful reassigning the IR group.