In the era of genomics should tumor size be reconsidered as a criterion for neoadjuvant chemotherapy?

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Background: The Onco*type* DX Recurrence Score (RS) assay has been validated for prediction of 10-year risk of distant recurrence and likelihood of benefit from chemotherapy in patients with ER-positive, HER2-negative early breast cancer. Patients with high RS tumours have substantial benefit, and patients with low RS tumours have minimal if any benefit from chemotherapy. Tumour size is used as a key parameter when selecting patients for neo-adjuvant chemotherapy. The aim of this study was to assess the distribution of RS in patients selected for neo-adjuvant chemotherapy primarily due to tumour size. **Methods:** Patients with ER-positive and HER2-negative tumours, with node negative or no more than 1 positive node from three trials were included in this study. Onco*type* DX was performed at Genomic Health blinded to the clinical data. Descriptive statistics were calculated for distribution of RS for all cases. **Results:** Of 277 patients, 96 met eligibility criteria and 81 had sufficient material for analysis. Median tumour size was 40 mm (IQR 30-50 mm). Grade I, II and III were observed in 13, 49 and 17 cases, respectively. There was a wide distribution of RS with a median of 21.4 (IQR 16.05-26.75). In total, 23(28.3%) had high, 28(34.6%) intermediate and 30 (37%) low RS results. **Conclusions:** The RS may provide relevant information for neo-adjuvant treatment decisions in select patients both in clinical practice but also in studies. Inclusion of low RS disease patients in neo-adjuvant trials will likely only dilute the ability to look at treatment effects.