

P4-07-30: The prognostic and predictive value of Oncotype DX® in ER+/HER2-/pT2N0, cM0 Breast Cancer Patients

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Abstract

Based on AJCC Anatomic Stage Groups, breast cancer patients with ER+/HER2-/pT2N0, cM0 tumors are categorized as stage IIA. If the Oncotype Dx® test is performed in such cases and the Recurrence Score (RS) is less than 11, the case should be assigned as Pathological Prognostic Stage Group IA¹.

We conducted a retrospective analysis of data from a Greek cohort of 524 ER+/HER2-/pT2N0, cM0 breast cancer pts who underwent Oncotype DX® testing between 2008 and 2020. Pts were categorized based on their Oncotype DX® RS according to AJCC Prognostic stage guidelines into RS<11 and RS ≥11. RS 0-10 was reported in 105 (20%) of these cases. All these pts are assigned Pathological Prognostic Stage Group IA.

Subgroup analysis for pts ≤50 years old was performed in reference to their Oncotype DX® RS and clinical risk status. Among pts ≤50 years (n=200), the same percentage (19,5%) had a RS<11. Also, 49,5% out of them had a RS 0-15 and should be treated with only endocrine therapy based on NCCN Guidelines.

Further stratification of pts ≤50 years old according to their clinical risk status, identified 163 (81,5%) of them as high clinical risk (T2/G2, G3). RS 0-10 was reported in 25 (15%) and RS<16 in 74 (45,4%) of these cases.

Introduction

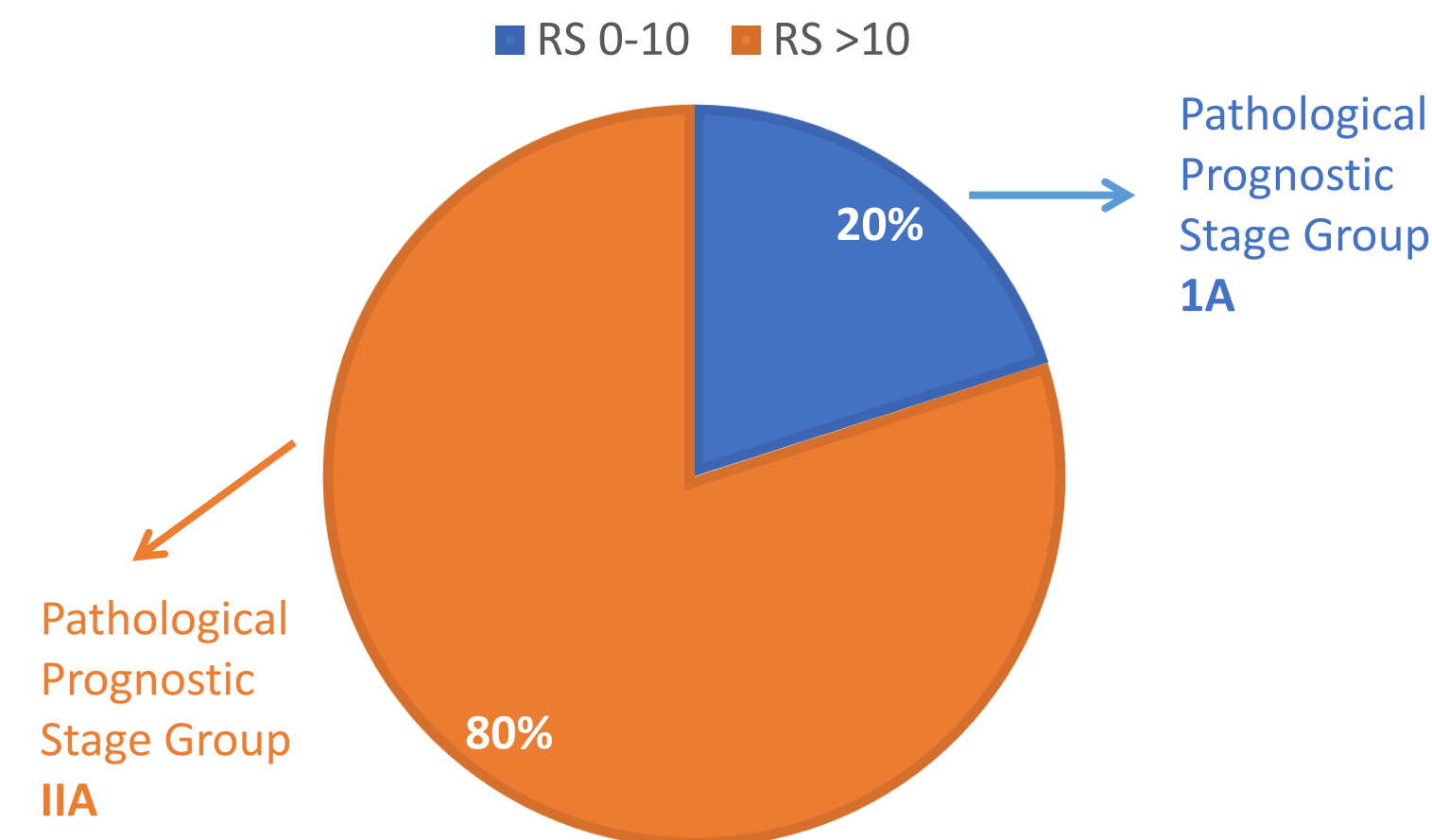
The Oncotype DX® assay is a 21-gene assay used to predict the likelihood of breast cancer recurrence and benefit from chemotherapy in early-stage, estrogen receptor-positive (ER+), HER2-negative (HER2-) breast cancer pts. Oncotype DX® RS has been incorporated in the AJCC Prognostic stage guidelines.

This study aims to evaluate the utility of Oncotype DX® in providing a better prognosis and predicting the benefit of chemotherapy in ER+/HER2-/pT2N0, cM0 breast cancer patients.

Table 1. AJCC prognostic stage guidelines

TNM	Grade	HER2	ER	PR	RS	Prognostic Stage Group
T1N0M0 T2N0M0	Any	Negative	Positive	Any	0-10	IA

Chart 1. Recurrence score in 524 ER+/HER2-/pT2N0, cM0 patients.



Methods and Materials

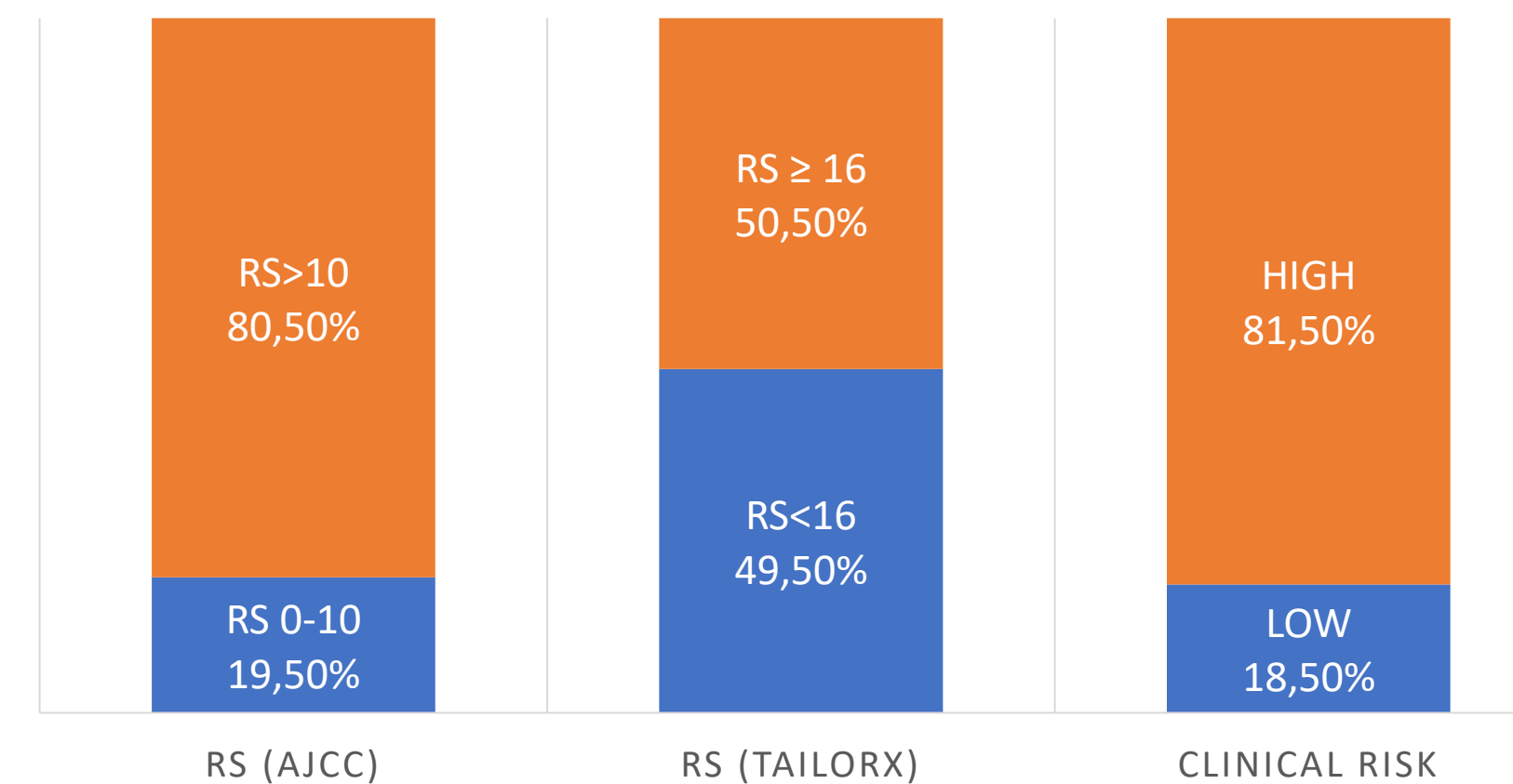
We conducted a retrospective analysis of data from a Greek cohort of 524 ER+/HER2-/pT2N0, cM0 breast cancer pts who underwent Oncotype DX® testing between 2008-2020. Pts were categorized based on their RS according to AJCC Prognostic stage guidelines into RS<11 and RS ≥11. Subgroup analysis for pts ≤50 years old was performed in reference to their RS and clinical risk status.

Results

RS 0-10 was reported in 105 (20%) of the cases (mean RS was 17,3). In the above cohort, 200 patients (38,2%) were ≤50 years old. RS 0-10 was reported in 39 (19,5%) and RS<16 in 99 (49,5%) of them.

Further stratification of pts ≤50 years old according to their clinical risk status, identified 163 (81,5%) as high clinical risk (T2/G2, G3). RS 0-10 was reported in 25 (15%) and RS<16 in 74 (45,4%) of them.

Table 2. Characteristics of the ≤50 years old patients (n=200)



Discussion

Among breast cancer pts with pT2N0, cM0 ER+/HER2- tumors, 20% had a RS<11. All these pts based on the AJCC 8th Edition Cancer Staging Manual are assigned Pathological Prognostic Stage Group IA when initially considered as stage group IIA. These pts based on TAILORx^{2,3} data have 0,7% distant recurrence risk at 5 years, 3% distant recurrence risk at 9 years and no chemotherapy benefit.

Among younger pts (≤50 years) with pT2N0, cM0 ER+/HER2- tumors, the same percentage (19,5%) had a RS<11 (Pathological Prognostic Stage Group IA). Also, 49,5% out of them had a RS 0-15 and should be treated with only endocrine therapy based on TAILORx results and NCCN Guidelines.

Additionally, taking into consideration the clinical risk status of the younger patients (≤50 years), 45,4% of those with high clinical risk had a RS<16 and could safely forego chemotherapy.

Conclusions

These findings highlight the critical role of Oncotype DX in enhancing risk stratification, predicting recurrence, and guiding treatment decisions for patients with ER+/HER2-/pT2N0, cM0 breast cancer irrespective of their age.

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