

Effect of Oncotype DX Recurrence Score (RS) on chemotherapy (CT) decision-making by providing information beyond intrinsic subtypes in both luminal A and B breast cancer (BC) patients (pts): A retrospective study in the Spanish population.

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Background: St Gallen guidelines recommend the use of Ki67 by IHC as a surrogate marker for luminal A and B BC subtypes, such that pts with luminal B ($\geq 14\%$) subtypes should be considered for adjuvant CT. Oncotype DX RS is a predictor of CT benefit. The aim of this study is to assess the distribution of the RS in luminal A and B BC subtypes as defined by Ki67 and to assess treatment changes based on RS.

Methods: Data were collected from 210 pts with invasive breast cancer for which Oncotype DX results and pathology data were available. Estrogen (ER) and progesterone (PR) receptor was assessed by immunostaining (cut-off 10% nuclear staining). Ki67 was assessed by IHC [high ($\geq 14\%$) and low ($< 14\%$)]. Grading was performed using the Nottingham grading system. Results: Median age: 50 years (35-78); premenopausal status: 122 pts (58.1%). Median tumor size: 1.7 cm (2-10); Overall, 65.7% of cases had grade II tumors, and 13.3% grade III. All pts had HER2 negative tumors, 90 were luminal A and 120 luminal B. Of those with positive lymph nodes (36.7%), 51.9% had macrometastasis. Median ER value was 95 (range: 35-100) and PR 85 (0-100). Median Ki67 index was 15 (2-63) and RS 16 (1-55). Luminal A and B subtypes showed statistical differences with respect to tumor size, grade III and levels of ER and PR ($p = 0.027$, $p < 0.001$, $p < 0.001$, and $p = 0.009$, respectively) in favor of luminal B. In the luminal A group, 56 (62.2%) pts presented low RS, 30 (33.3%) intermediate, and 4 (4.4%) high RS. Similar distribution in the luminal B group: 67 patients (55.8%), 41 (34.2%) and 12 (10%), respectively. Overall, 103 pts (49%) changed their treatment. In the luminal A group, RS results changed initial treatment recommendation in 43.3% vs 53.3% in the luminal B group, both groups in favor of hormone therapy. Conclusions: A substantial number (55.8%) pts with luminal B BC subtype had a low RS, therefore preserving them from adjuvant CT treatment. According to this data, luminal subtyping by Ki67 is not always a reliable surrogate marker for receiving chemotherapy, confirming the important role of Oncotype DX in treatment decision-making.