

## **A retrospective study in the Spanish population with Oncotype dx recurrence score (RS) in breast cancer patients with positive and negative-lymph nodes.**

Author(s): Laura G Estevez, Isabel Calvo, Maria Fernandez Abad, Juan Jose Cruz, Sofia Perea, Ana Suarez, Fernando Lopez Rios, Manuel Hidalgo; Centro Integral Oncologico Clara Campal, Madrid, Spain; Centro Integral Oncológico Clara Campal, Madrid, Spain; Universidad Autonoma de Madrid, Madrid, Spain; Centro INtegral Oncologico Clara Campal, Madrid, Spain

**Background:** The international guidelines include the use of Oncotype DX as a predictor of chemotherapy (CT) benefit in hormonal sensitive breast cancer patients (pts) with node negative and node positive (1-3 positive nodes) disease. The aim of this study was to assess the distribution of the RS in breast cancer pts regardless lymph nodes status, and the association with treatment recommendations. **Methods:** Retrospective data from 131 pts with invasive breast cancer for which the OncotypeDX Assay had been ordered, and pathology data were available. Estrogen (ER) and progesterone (PR) receptor was assessed by IHC (cut-off 10% nuclear staining). Ki67 by IHC [high ( $\geq 14\%$ ) and low ( $< 14\%$ )]. Positive-lymph nodes pts was classified as isolated tumoral cells (ITC), micrometastasis (MIC) and macrometastasis (MAC). **Results:** Median age: 51 (range: 35-78); premenopausal status: 74 pts (56%). Median tumor size: 1.5 cm (0.3- 6); Median Ki 67 index: 15 (3-63); Median ER: 93 (35-100) and PR: 85(0-100). 42 pts (32%) had positive-lymph nodes: 6 ITC (14%), 14 MIC (33%) and 22 MAC (52%). RS was low in 82 (63%) cases, intermediate 39 (30%), and high 10 (7%). RS according to nodal status was: positive nodes, 31 pts (74%) low RS, 10 pts (24%) intermediate and 1 pts (2%) high; negative nodes: 50 pts (57%) low RS, 26 (29%) intermediate and 12 pts (14%) high RS. ER and Ki67 was similar between both lymph-nodes groups whereas a higher PR expression (median 90) was seen in positive-lymph nodes vs 76 in negative nodes. First recommendation in positive-lymph nodes: hormonotherapy (HT) 33%, CT 55% and 12% no defined (ND); after RS, HT 83% and CT 17% ( $p=0.021$ ). Negative nodes first recommendation: HT 68%, CT 23% and ND 14%; after RS, HT 68% and CT 32%. **Conclusions:** Although based on a small case series, the results show that a substantial number (73%) pts with positive-lymph nodes have low RS, indicating minimal if any benefit from adjuvant CT. The proportion of patients with low scores is higher than in the validation studies and selection bias can't be excluded. The wide range of RS in both negative and positive-lymph nodes breast cancer confirm the important role of Oncotype DX in treatment decision- making.