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# 222PD PROSPECTIVE TRANSGEICAM STUDY OF ONCOTYPE DX IN CLINICAL DECISION MAKING IN ESTROGEN RECEPTOR-POSITIVE NODE-NEGATIVE BREAST CANCER WOMEN

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**Purpose:** The Oncotype DX 21-gene Recurrence Score (RS) assay quantifies the risk of distant recurrence in hormone treated patients with lymph node-negative, estrogen receptor-positive breast cancer and predicts magnitude of chemotherapy benefit. U.S. studies have shown an impact in clinical decision making. Whether RS might affect clinical recommendations in European countries is, as yet, not reported. For this reason, we performed a multicenter study in seven GEICAM (Spanish Group of Breast Cancer Research) sites to prospectively examine whether RS affects medical oncologist adjuvant treatment selection.

**Patients and methods:** Patients with lymph node-negative, estrogen receptor-positive, HER2 negative, early-stage breast cancer, without contraindication to hormonal treatment and chemotherapy, were enrolled. Before and after obtaining the Oncotype DX assay, medical oncologists stated their adjuvant treatment recommendation and confidence in it.

**Results:** To date, 92 patients have been recruited and pre- and post-RS recommendations are available from 71 cases; 40 (56.3%) with low RS (<18), 25 (35.2%) with intermediate RS (18-30) and 6 (8.5%) with high RS (> 31). Treatment recommendation changed for 20 patients (28%); in 11 (15.5%) patients the shift was from chemotherapy plus hormonal therapy (CHT) to hormone therapy alone (HT) and in 9 (12.7%) from HT to CHT. All patients with low RS received HT and all with high RS received CHT. In the group with intermediate RS, 11 received HT and 14 CHT. The probability of changing the initial recommendation based on the RS was 10% (2/20) in low grade, 29.4% (12/34) in intermediate grade, and 43% (6/14) in high grade tumors, suggesting a possible relation between tumor grade and the likelihood of recommendation shift. Tumor grade was not available in 3 tumors. In 47 (66%) cases, the medical oncologist's confidence in their recommendation increased by assessing RS.

**Conclusion:** The results support the concept of clinical utility for RS assay on medical oncologist adjuvant treatment recommendations in a GEICAM setting.

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