# IMPACT OF THE 21-GENE RECURRENT SCORE ASSAY ON TREATMENT DECISION IN EARLY BREAST CANCER (EBC) PATIENTS WITH FAVORABLE PROGNOSTIC FACTORS

Markopoulos C.  
Athens University Medical School, Athens - Greece

## Background

- The 21-gene OncotypeDX® assay is a clinically validated test that predicts the likelihood of chemotherapy benefit and the risk of distant recurrence for patients with early-stage estrogen receptor-positive (ER+), breast cancer.  
- It has been demonstrated that the result of the assay, the Recurrence Score® (RS) value, provides additional information independent of traditional prognostic markers.  
- The use of Oncotype DX for adjuvant decision-making is described in several guidelines, including St Gallen, NCCN®, ASCO®, and ESMO.  
- The 2009 St Gallen guidelines state that “validated multigene tests, if readily available, could assist in deciding whether to add chemotherapy to cases where its use was uncertain after consideration of conventional markers.”

- The NCCN guidelines describe the application of the Oncotype DX assay for patients with node-negative or micrometastatic disease.  
- Clinical utility studies have shown that use of the assay predominantly results in a reduction of adjuvant chemotherapy recommendations.  

## Objective

To describe the results from our institution’s three-year experience using the Oncotype DX assay to identify patients who need chemotherapy despite the presence of primarily favorable characteristics.

## Patients and Methods

- All patients considered for evaluation with Oncotype DX assay were pre- or post-menopausal with ER+, HER2-, early-stage breast cancer.  
- One patient was identified as HER2+ and was not included in the analysis.  
- Unfavorable factors were defined as tumor size >2 cm, tumor grade II or III, Ki67 >10%, or the presence of lymph node micrometastases.  
- The Oncotype DX assay was performed on formalin-fixed paraffin embedded tissue at the Genomic Health, Inc. laboratory in Redwood City, California.  
- The risks and benefit of adjuvant chemotherapy (CT) were discussed with each patient after knowledge of the RS results. All patients were treated with endocrine therapy.

## Results

- There was a range of Oncotype DX Recurrence Scores for all patients, regardless of the presence of unfavorable characteristics.  
- This distribution is comparable to previously described cohorts ascertained in a clinical setting.

- Among the 15 patients with No Unfavorable Characteristics:  
  - 10 patients had a Low RS (RS<18); CT was not recommended.  
  - 5 patients had an Intermediate RS (RS 18-30); CT was recommended in two.

- Among the 10 patients with One Unfavorable Characteristic:  
  - 8 patients had a Low RS (RS<18); CT was not recommended.  
  - 2 patients had an Intermediate RS (RS 18-30); both received CT.

- Among the 17 patients with 2 or 3 Unfavorable Characteristics:  
  - 9 patients had a Low RS (RS<18); CT was not recommended but 2 patients chose to receive CT.  
  - 3 patients had an Intermediate RS (RS 18-30); CT was recommended in two.  
  - 5 patients had a High RS (RS≥31); all of them received CT.

## Summary and Conclusions

- This small study of a non-randomized series of early breast cancer patients shows the experience of a single institution and further reinforces that the clinicopathologic criteria for categorizing patients does not predict the RS from the 21-gene Oncotype DX assay.

- The majority of the patients with one or more unfavorable prognostic factors would be classified as “intermediate risk” by St Gallen criteria.  
  - For patients with an intermediate risk by St Gallen criteria, there is no clear cut recommendation regarding the choice of adjuvant chemotherapy; recommendation is either hormonal therapy alone or chemotherapy followed by hormonal therapy.  
  - In this study, approximately 41% of patients with one or more unfavorable prognostic factor was recommended or received chemotherapy.

- The RS classified 80% of patients with One Unfavorable Characteristic to low risk and thus spared them exposure to chemotherapy.

- The RS classified 52.9% with Two or Three Unfavorable Characteristics as Low Risk, 17.7% as Intermediate Risk and 29.4% as High Risk.

- Among all patients, only in 26.2% of them CT was recommended following the result of the OncotypeDX RS (two more patients with low RS chose to receive adjuvant CT).

- The results from this study indicate that Oncotype DX may be a useful decision tool in clinical practice.

## References

6. Markopoulos C.  
8. Markopoulos C.  

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