OncotypeDX vs clinicopathologic factors in breast cancer: The experience from Greece and Cyprus

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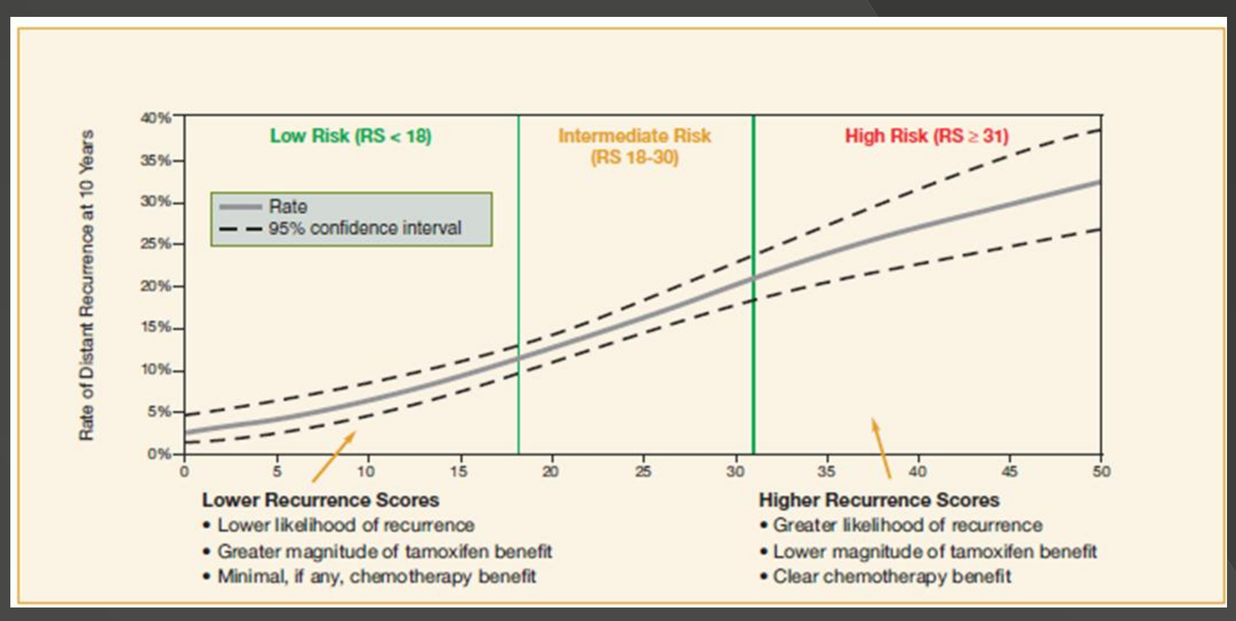
Background

The 21-gene Oncotype DX® 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.[1-5]
It has been demonstrated that the result of the assay, the Recurrence Score® (RS) value, provides additional information independent of traditional prognostic markers.[1-6]
The use of Oncotype DX for adjuvant decision-making is described in several guidelines, including St Gallen, NCCN®, ASCO®, and ESMO.[7-10]
The 2011 St Gallen guidelines state that "Oncotype DX has been shown to predict chemotherapy benefit among patients with HR+ disease
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.[11]



Paik S, Shak S, Tang G, *et al.* A multigene assay to predict recurrence of tamoxifen-treated, node-negative breast cancer. *N Engl J Med.* 2004;351(27):2817-26.

Figure 1. The RS is a Continuous Predictor of the Risk of Distant Recurrence and Likely Magnitude of Chemotherapy Benefit.

Objective

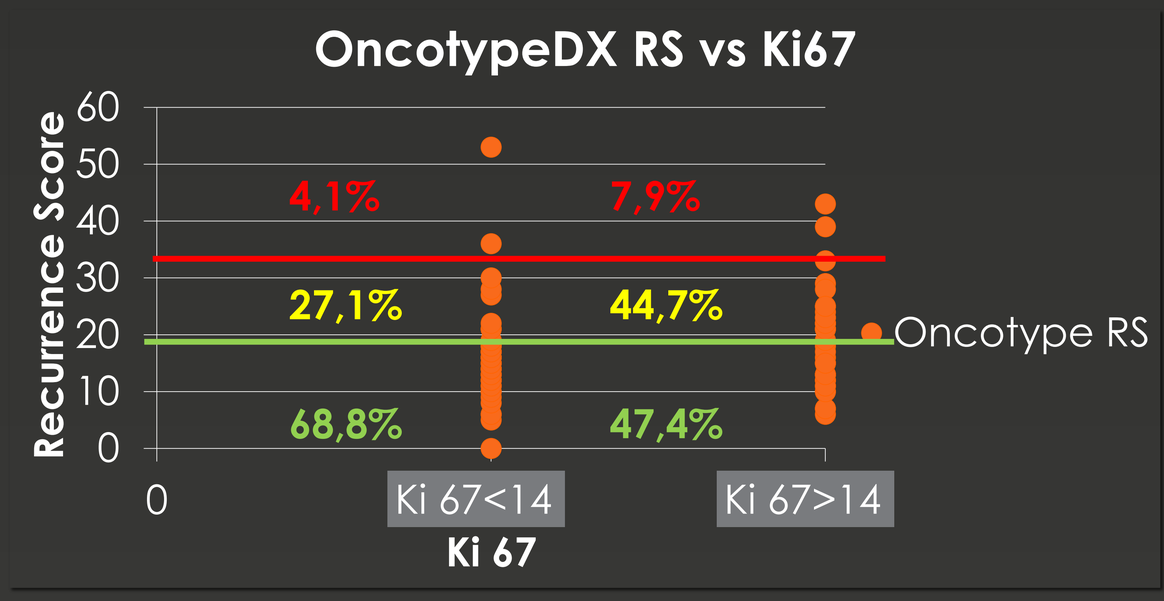
The aim of this study is to compare the OncotypeDX Recurrence Score for invasive Breast Cancer with traditional clinicopathologic factors such as age, grade and Ki67 form real life cases in Greece and Cyprus as selected by Medical Oncologists

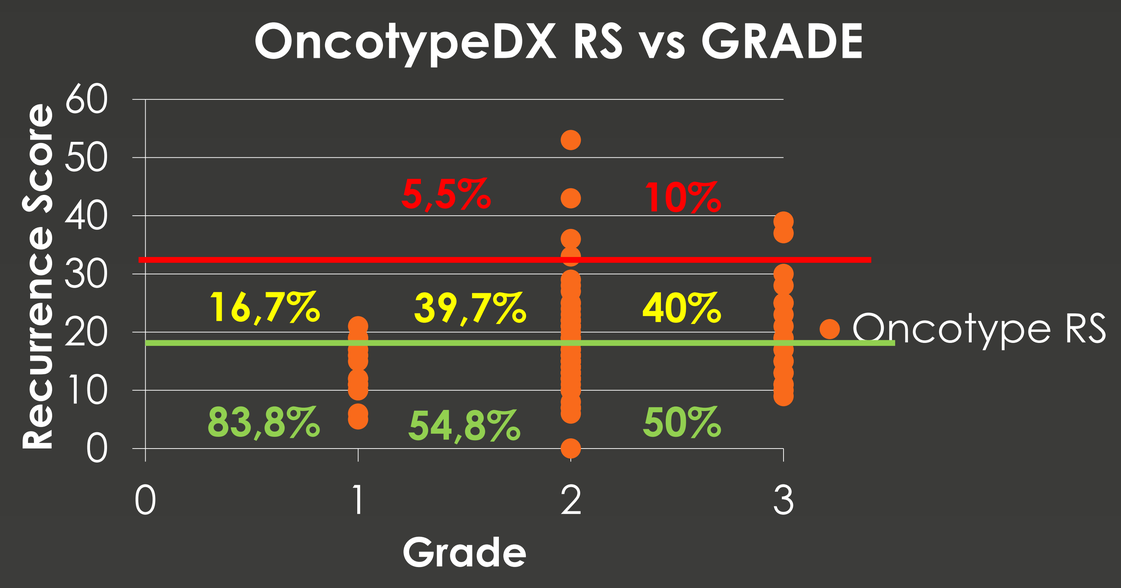
Patients and Methods

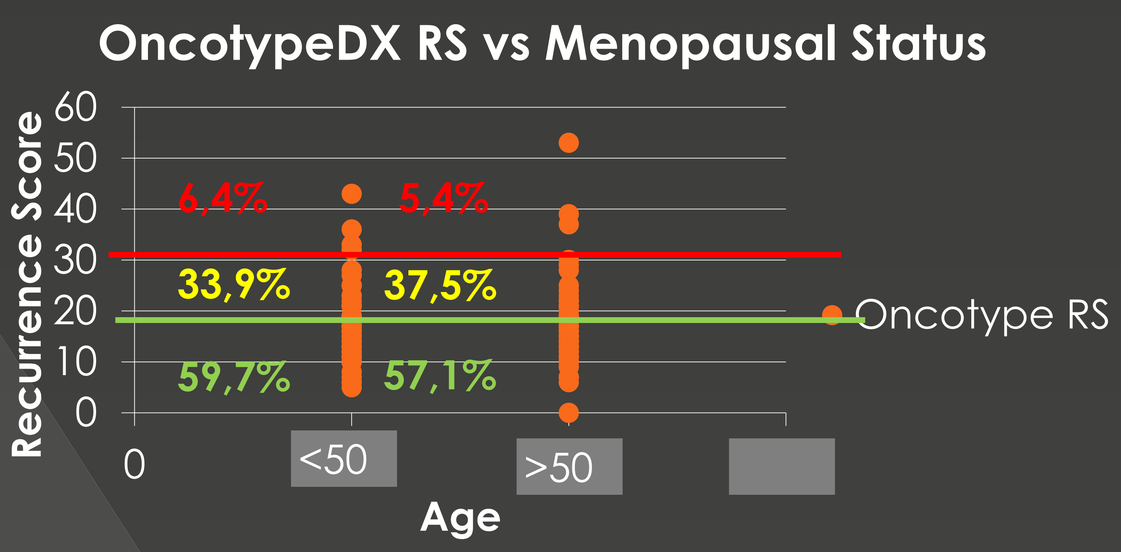
The Oncotype DX Recurrence Score was performed in 118 patients with HR+, HER2- invasive carcinoma of the breast. 62 of the patients were below the age of 50 and 56 were over the age of 50 years old. Ki67 was obtained by the histology report of each patient and was performed by the local pathology laboratory of each site. A cut-off of 14% was used to determine low vs. high for this marker based on the ASCO/CAP guideline recommendations. 48 of the patients had a low (below 14%) Ki67 and 38 had a high Ki67 (higher than 14%), Ki67 was not available for 32 patients. 18 patients had a Grade I tumor, 73 had a Grade II tumor and 20 had a Grade III tumor.

Results

In total, 69 patients had a Low RS (58.5% of the patients) 42 had an Intermediate Score (42%) and 7 had a High RS (5.9%). Among the Low Ki67 patients 68,8% had a Low RS, 27.1% had an Intermediate Ki67 and 4,1% had a High RS. Among the High Ki67 population, 47,4% had a Low RS, 44,7% had an Intermediate RS and only 7,9% had a High RS. Among the Grade I patients 83,3% had a Low RS and 16,7% had an Intermediate RS, no patient with Grade I had a High RS. Among the Grade II patients 54,8% had a Low RS, 39,7% had an Intermediate RS and 5,5% had a High RS. Among the Grade III patients 50% had a Low RS, 40% had an Intermediate RS and only 10% had a High RS. The distribution of the RS in patients younger than 50 years old was 59,7% had a Low RS, 33,9% had an Intermediate RS and 6,4% had a High RS. Similarly the patients over the age of 50 had 57,1% chance to have a Low RS, 37,5% for Intermediate RS and 5,4% chance for a High RS.







Conclusion

Our results indicate that there is no traditional marker such as Grade, age and Ki67 for ER+, HER2- patients that can predict the OncotypeDX RS. The results from this study indicate that Oncotype DX may be a useful decision tool in clinical practice.
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.

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