Goals: Studies performed outside Europe have shown that the 21 gene Recurrence Score (RS) Oncotype DX assay shifts adjuvant treatment in about 30% of ER+ early breast cancers. This prospective multicenter study was designed to examine the impact of RS in a population of European breast cancer patients and explore the associations between traditional clinico-pathological markers and the likelihood of change in treatment recommendations.

Methods: Enrolment was offered consecutively to all eligible women with estrogen receptor-positive, HER2-negative, node-negative breast cancer. Medical oncologists completed questionnaires recording treatment recommendation and confidence in their recommendation before and after knowing the patient's Recurrence Score.

Results: A total of 107 patients were enrolled. Treatment recommendation was changed in 31.8% of patients: in 20.6% from chemohormonal (CHT) to hormonal therapy (HT) and in 11.2% from HT to CHT. RS was significantly associated with the likelihood of change from HT to CHT (p < 0.001) and from CHT to HT (p < 0.001). Confidence of Medical oncologists in treatment recommendations increased for 60.2% of cases. Higher tumor grade and a high proliferative index (Ki-67) were significantly associated with a greater chance of changing to from HT to CHT and positive progesterone receptor status with a greater probability of changing from CHT to HT.

Conclusion: Results are consistent with those reported in U.S. and with use of multigene testing as proposed in European clinical practice guidelines. They also provide evidence on how Oncotype DX and traditional clinico-pathological factors are complementary in supporting change in treatment recommendations.