

Decision impact of the 21-Gene Oncotype DX Recurrence Score Assay® in the Czech Republic on recommendations for adjuvant chemotherapy in estrogen receptor positive early stage breast cancer (ESBC) patients

Poster Abstracts

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Goals: Adjuvant chemotherapy (CT) is not beneficial to every patient with ESBCs expressing hormone receptors (HR). The 21-gene Oncotype DX Breast Recurrence Score® (RS) assay is designed to aid and personalize chemotherapy treatment decisions for HR+, HER2- ESBC patients. Multiple studies demonstrated its prognostic validity, predictive value for CT benefit and its clinical utility. In this Oncotype DX® patient registry, we assessed the impact of the RS on the frequency of CT use in ESBC patients in Czech medical centers from June 2014 to May 2018.

Methods: Eligible ER+, HER2-, N0 patients had grade 2 tumors and one secondary risk factor (high Ki67, micrometastatic disease or low/negative PR expression) or grade 3 tumors. The Oncotype DX® assay was performed post-surgery. Primary treatment recommendations were re-evaluated following availability of the RS result. The primary objective was to determine the percent change in treatment recommendations post versus pre RS result availability.

Results: The registry recruited 433 consecutive patients at 14 centers, with RS data available for 432 (RS 0-17: 232 (53.7%), RS 18-30: 171 (39.6%), and RS 31-100: 29 (6.7%)). Prior to RS testing, 71.9% had recommendations of CT+HT. This proportion declined to 15.5% after availability of the RS result. 58.9% of all patients had their recommendation changed from CT+HT to HT alone, while 2.6% were changed from HT to CT+HT. The majority of the physicians agreed (55.7%) or strongly agreed (38.3%) that the RS result impacted their treatment recommendation.

	Before RS testing		
After RS testing	HT	CT-HT	Total
HT	25.5% (n = 110)	58.9% (n= 254)	84.5% (n = 364)
CT-HT	2.6% (n = 11)	13.0% (n = 56)	15.5% (n = 67)
Total	28.1% (n = 121)	71.9% (n = 310)	100% (n = 431*)

*treatment recommendation after RS testing was not available for 1 patient

According to the RS-based risk classification used in the recently published TAILORx study, 83.2% of 309 patients >50 years of age would have had no benefit, and 16.8% of this groups substantial benefit from CT. From 123 patients ≤50 years of age, 37.1% would have had no benefit, and 14.5% substantial benefit from CT, while 29.8% and 17.7% would have had ca. 1.6% and 6.5% benefit from CT, respectively.

Conclusions: In this population patients with grade 2 ESBC and an additional risk factor or grade 3 ESBC, RS testing resulted in a 56.4% absolute and 78.4% relative net reduction of chemotherapy recommendations, with 94% of physicians indicating that the test result impacted their treatment recommendation. These findings indicate a significant potential for overtreatment with chemotherapy based on clinical pathological parameters alone that can be prevented with the results of the Oncotype DX assay.