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

K Petrakova1, L Petruzelka2, M Holanek3, T Svoboda3, V Benesova4, M Palacova1, I Kolarova5, Z Bielcikova, M Chrapava6

1Masaryk Memorial Cancer Institute, Brno, Czech Republic
2Prague General University Hospital, Prague, Czech Republic
3University Hospital, Plzen, Czech Republic
4Jihlava Hospital, Jihlava, Czech Republic
5Pardubice Hospital, Pardubice, Czech Republic
6Institute of Biostatistics and Analyses, Brno, Czech Republic

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.

| Table 1. Treatment recommendations before and after availability of the RS result |
|---------------------------------|-----------------|-----------------|-----------------|
| After RS testing                | Before RS testing | 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 group 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.