194P Real-life utilization of genomic testing for invasive breast cancer patients in Italy and France reduces chemotherapy recommendations

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Background: Oncotype DX® (ODX) is a multigene assay allowing physicians to tailor treatment in HR+, HER2- early-stage breast cancer patients. Clinical validation and utility of ODX have been demonstrated across multiple studies in over 63,000 breast cancer patients worldwide. It provides level 1A evidence and has been incorporated in major international clinical guidelines. A market access program was initiated in 2015 in France and 2016 in Italy to assess real-life test utilization and its impact in current clinical practice.

Methods: The program allows for prospective data collection reflecting real life use of ODX by physicians in various clinical practice settings throughout France and Italy. Patient data were collected through an online dedicated platform including classical pathological and clinical parameters (e.g. histology, tumor grade and size, ER, PR, HER2 and Ki67), patient age, ODX Recurrence Score (RS) Results and recommended treatment both before and after the test results have been reported.

Results: A total of 53 and 19 qualified breast cancer centers, in France and Italy respectively, participated in the program and collected 2632 case reports. Study results demonstrated that ODX is used among a wide variety of patient profiles: 24% N1, 7% Nmic & 69% N0, 11% G1, 64% G2 and 25% of G3, 32% pre-, 8% peri- & 59% are post-menopausal, 34% are 35-50, 52% 51-70 and 13% are older than 70, 13% have Ki67%<10%, 35% KI67 10-20%, 30% KI67 21-30% & 18% Ki67>30%, 12% tumor <1cm, 59% 1-2cm and 27% tumor 2.1-5cm. RS distribution is the following: <18 (56%), 18-30 (35%) and >30 (9%). In addition, pre-ODX 60% and 48% patients had a treatment recommendation for chemo-hormonotherapy (CT-HT) in France and Italy respectively. Post-testing, the number of patients recommended CT-HT decreased to 29% and 31% for France and Italy respectively, highlighting that the test reduced unnecessary use of CT and homogenized treatment decisions.

Conclusions: In France and Italy, the use of the ODX test results in an overall reduction in CT recommendations, while also identifying patients more likely to benefit from CT.

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