175P - First prospective multicenter Italian study on the impact of the 21-gene recurrence score® (RS) in adjuvant clinical decisions for ER + /HER2- early breast cancer patients

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Background

The Breast-DX Italy study evaluates the impact of the 21-gene RS on adjuvant clinical decisions in a prospective Italian cohort of early breast cancer patients.

Methods

The study planned to enroll, in 9 centers of the Veneto Region, 250 consecutive patients with ER + , HER2-, T1 to T3 early breast cancer and 0 to 3 positive axillary nodes. Patients met protocol-defined criteria for “intermediate risk” based on clinicopathological features. Pre-RS and post-RS physicians' treatment recommendations and the type of therapy actually received by the patient were collected. Here, we present the results for the N0 patients cohort.

Results

From November 2014 to February 2016, 124 N0 patients were enrolled (66% at hub and 34% at spoke centers). The majority had PgR-positive (89%), G2 (69%) and pT1c (69%) tumors. Median age was 56 years, median Ki67 was 23% (range 5-70%). The distribution of RS was: <18 (61%), 18-30 (33%) and >30 (6%). Pre-RS physician's recommendation was hormonal treatment (HT) without chemotherapy (CT) for 61% of the patients (similar in hub/spoke centers). The post-RS recommendation differed from the pre-RS recommendation for 15 patients (12%; 10/15 changed from CT + HT to HT). The received treatment differed from the pre-RS recommendation in 19 cases (15%; 16/19 changed from CT + HT to HT: 11 with low and 5 with intermediate RS). The change was more frequent in hub centers (Table 1). Overall, 13 CT treatments were spared, being 47 the patients with pre-RS indication to CT and 34 the patients who actually received it (McNemar's p = 0.006). Physicians confirmed the RS provided additional information and influenced their decision in 63% and 32% of the cases, respectively.

Change: Pre-RS recommendation to received treatment	**Hub centers (n = 2)**	**Spoke centers (n = 7)**	**Total (n = 123; missing data: 1 patient)**
No change; n (%)	67 (64%)	37 (36%)	104
Any change; n (%)	15 (79%)	4 (21%)	19
HT to CT + HT; n	2	1	3
CT + HT to HT; n	13	3	16

Conclusions

Although a majority of patients had a pre-RS recommendation for HT alone, the use of the 21-gene RS further contributed in sparing CT administration, more so for patients enrolled at hub centers, decreasing the use of CT from 38% to 28% of patients.

Legal entity responsible for the study

Istituto Oncologico Veneto IRCCS

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Disclosure

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