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Prospective multi-center study of the impact of the 21-gene Recurrence Score (RS) assay on medical oncologist (MO) and patient (pt) adjuvant breast cancer (BC) treatment selection

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Background: The 21-gene RS assay has been validated to quantify the risk of distant recurrence in tamoxifen treated pts in N-ER+BC and predict magnitude of chemotherapy benefit. Since there is little data regarding the impact of RS on MO and pt decision making, this multi-center study was designed to prospectively examine whether RS affects MO and pt adjuvant treatment selection.

Methods: MOs stated their treatment recommendation and confidence in it while pts indicated treatment choice pre and post RS assay. RS were returned to MO and pt for routine clinical care. Frequency distributions and co-frequency tables are used to display categorical distributions of nominal variables; means and standard deviations are used to summarize continuous variables.

Results: 15 MOs at 1 community and 3 academic practices consecutively enrolled 93 pts (89 evaluable) with N-ER+BC. The treatment plan changed in 31.5% of MOs and 27% of pts. The frequency of treatment changes are in the table below. The largest change induced by RS results was conversion from pre-test CHT to post-test HT (22.5% of MO, 10.1% of pts). MOs stated RS results increased confidence in 68 (76%). 90% of pts felt the assay influenced their treatment choice; 95% were glad they took the test.

Conclusion: The results of this study indicate that the RS assay does impact MO adjuvant treatment recommendations, pt treatment choice, and confidence in the treatment plan.

Pre-Post Treatment Option	MOs (%)	Patients (%)
Treatment plan did not change	61 (68.5)	65 (73)
Hormone Therapy (HT) to Chemo/Hormonal Therapy (CHT)	3 (3.4)	7 (7.9)
CHT to HT	20 (22.5)	9 (10.1)
CHT or HT to Equipoise	5 (5.6)	0
HT to Observation	0	2 (2.2)
Observation to HT	0	1 (1.1)
Undecided to CHT or HT	0	4 (4.5)
Undecided to Equipoise 0	0	1 (1.1)
Total	89 (100)	89 (100)

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