

Results of the Turkish prospective multi-center study utilizing the 21-gene *Oncotype DX* assay: Decision impact analysis.

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Background: The 21-gene *Oncotype DX* assay is accepted as an important predictive factor in the adjuvant treatment of node negative, estrogen receptor (ER) positive and HER2 (-) breast cancer. The test is not widely available for Turkish physicians as it is currently not reimbursed. We performed a prospective analysis to find the impact of the Recurrence Score result (RS) on treatment decisions.

Methods: Ten centers across Turkey participated in this prospective trial. Consecutive breast cancer patients with pT1-3, pN0-N1mic, ER(+), and HER2 (-) tumors were identified and adjuvant treatment decisions were made at breast tumor boards. The pre assay treatment decision was recorded on a questionnaire form. Cases were discussed at tumor boards again when the RS was available and investigators filled the post-assay questionnaire forms with the final decision.

Results: 165 patients were enrolled. Mean age was 49.8 (SD±10.3) years. 108(65.5%) patients had pT1 tumors. Mean RS was 18.8±14.0. RS was low in 56.8%, intermediate in 35.2% and high in 8.5%. There was an overall treatment decision change in 33% of patients with a reduction of chemotherapy (CT) from 56% to 35% overall and a 48% reduction in patients originally recommended CT. Among the patients with low and intermediate results, the decision changed from CT to hormonal therapy (HT) alone in 36 (85.7%) and 7 (36.8%) patients, respectively.

Conclusions: The 21-gene assay has a significant impact on treatment decisions at specialty tumor boards in Turkish hospitals. Our initial findings warrant further consideration for the use of this genomic assay in patients with early stage breast cancer in Turkey. Health economic analysis will be reported separately in the near future.

Chemotherapy decision in patients before and after RS by risk groups.

			Post-RS Decision				p value*	
			HT		CT+HT			
Pre-RS Decision			N	n	%	n	%	
All patients	HT		73	63	86.3	10	13.7	<0.001
	CT+HT		92	44	47.8	48	52.2	
	Total		165	107	64.8	58	35.2	
Low RS	HT		51	51	100.0	0	0.0	
	CT+HT		42	36	85.7	6	14.3	
	Total		93	87	93.5	6	6.5	
Intermediate RS	HT		19	12	63.2	7	36.8	
	CT+HT		39	8	20.5	31	79.5	
	Total		58	20	34.5	38	65.5	
High RS	HT		3	0	0.0	3	100.0	
	CT+HT		11	0	0.0	11	100.0	
	Total		14	0	0.0	14	100.0	

*McNemar test