147PD - First prospectively-designed outcome study in estrogen receptor (ER)+ breast cancer (BC) patients (pts) with N1mi or 1-3 positive nodes in whom treatment decisions in clinical practice incorporated the 21-gene recurrence score (RS) result

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Background

Recent outcome data including those from the prospective TAILORx trial strongly confirmed the RS role in node negative (N0) ER+ BC. The prospective WSG PlanB study showed excellent outcomes in high-risk N0 and node-positive (N+) pts with RS ≤ 11 and no adjuvant chemotherapy (CT). Physicians are increasingly using the RS for treatment decisions in N+ BC. We evaluated treatment and clinical outcomes in N+ pts undergoing RS testing through Clalit Health Services (CHS).

Methods

Medical records of all CHS pts with N+ ER+ HER2- BC who were tested between 1/2008 and 12/2011 were reviewed to verify treatment given and recurrence/death status. Interim results are presented herein. Final cohort results (>700 pts) will be presented at the meeting.

Results

The current analysis includes 627 pts. Median age, 61 (34-87) yrs; 270 (43%) were N1mi, whereas 231 (37%) and 126 (20%) had 1 and 2-3, positive nodes, respectively. Grade 1 (15%), 2 (53%), 3 (16%), N/A (16%); histology, IDC (82%), lobular (12%), other (6%). With a median follow-up of 5.7 yrs, proportion of patients with distant recurrence (DR)/BC death by Paik et al and TAILORx RS categorization and by nodal status are presented in the Table. As pts were not randomized to treatment, analysis of DR/BC death by CT use is only exploratory: within the RS 18-30 group, CT-untreated pts (60%) had DR rate and BC death rate of 9.6% and 3.7%, respectively, whereas in CT-treated pts (40%) these rates were 2.2% and 1.1%; within the RS 11-25 group, CT-untreated pts (82%) had DR rate and BC death rate of 4.1% and 1.2%, respectively, whereas in CT-treated pts (18%) these rates were 2.7% and 0%.

CT-treated pts (18%) these rates were 2.7% and 0%.

	CT use, %	DR rate, %	BC death rate, %
Paik et al RS categorization			
RS < 18			
N1mi (n = 146)	5	0.7	0.7
1 positive node (n = 128)	10	4.7	0.0
2-3 positive nodes (n = 65)	8	6.2	3.1
Total (n = 339)	7	3.2	0.9
RS: 18-30			
N1mi (n = 93)	37	10.8	3.2
1 positive node (n = 81)	47	3.7	2.5
2-3 positive nodes (n = 53)	38	3.8	1.9
Total (n = 227)	40	6.6	2.6

	CT use, %	DR rate, %	BC death rate, %
RS ≥ 31			
N1mi (n = 31)	97	19.4	16.1
1 positive node (n = 22)	86	18.2	13.6
2-3 positive nodes (n = 8)	75	0.0	0.0
Total (n = 61)	90	16.4	13.1
TAILORx RS categorization			
RS < 11			
N1mi (n = 45)	4	2.2	2.2
1 positive node (n = 37)	14	5.4	0.0
2-3 positive nodes (n = 20)	0	10.0	5.0
Total (n = 102)	7	4.9	2.0
RS: 11-25			
N1mi (n = 169)	14	4.1	1.2
1 positive node (n = 152)	20	3.3	0.0
2-3 positive nodes (n = 90)	22	4.4	2.2
Total (n = 411)	18	3.9	1.0
RS > 25			
N1mi (n = 56)	82	16.1	10.7
1 positive node (n = 42)	83	14.3	11.9
2-3 positive nodes (n = 16)	69	0.0	0.0
Total (n = 114)	81	13.2	9.6

Conclusions

CT use was aligned with the RS results. Pts with N1mi or 1-3 positive nodes and RS ≤ 25 had very good outcomes, even when selected for endocrine therapy alone. Updated data will be presented at the meeting.

Clinical trial identification

Trial protocol number: 0075-14-COM

Legal entity responsible for the study

Dr. Stemmer is the sponsor-investigator responsible for all aspects of the study including design and conduct of the study, collection, analysis and interpretation of the data, and preparation of the manuscript.

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Disclosure

S.M. Stemmer: Received grant funding from Teva and travel expenses from Genomic Health. L. Soussan-Gutman: Teva employee. Holds stock options for Teva Pharmaceuticals Ltd. A. Bareket-Samish: Consultant for Teva Pharmaceutical Industries and Genomic Health, Inc. O. Rosengarten: Received payments for lectures and grants for traveling from Teva Pharmaceuticals. C. Svedman, S. Shak: Genomic Health employee. Holds stock options for Genomic Health. N. Ben-Baruch: Serves on Genomic Health's speakers bureau. All other authors have declared no conflicts of interest.