

Breast cancer-specific survival (BC SS) in patients (pts) with node-negative (N0) and node-positive (N+) breast cancer (BC) guided by the 21-gene assay: A SEER-genomic real-world evidence study

Poster Abstracts

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Goals: The 21-gene Breast Recurrence Score[®] (RS) in the randomized NSABP B-20, SWOG S8814, and TAILORx studies predicted chemotherapy (CT) benefit for pts with N0 and N+ disease. Based on a new update of the SEER cancer registries with additional years of follow-up and additional pts, we now estimate 9-year BCSS and CT benefit, in the context of the TAILORx cutpoints.

Methods: RS results were provided electronically to SEER registries per their linkage methods (Petkov *npj Breast Cancer* 2016). Eligible pts were diagnosed Jan 2004 - Dec 2014 with N0 and N+(N1mic, 1-3 positive nodes[N1]), HR+, HER2-negative BC, and had no prior malignancy or multiple tumors, with follow-up information through Dec 2015. Unadjusted BCSS estimates without reported CT use were computed by nodal status, and CT benefit was estimated using propensity score weighting to account for the lack of randomization.

Results: There were 80,605 pts with RS results; 70,087 with N0 disease, 4,336 with N1mic, and 6,182 with N1. Median follow-up was 49 months, with 20,151 pts followed >76 months. 1,020 pts had experienced breast cancer death. Reported CT use increased with increasing RS result. There was a significant positive association between higher RS results and decreased BCSS ($p < 0.001$) without and with adjustment for nodal status, age, tumor size, and grade. 9-y BCSS was >97% without CT for pts with RS 0-18 and N0 and N+ disease (Table). RS result was predictive of CT benefit in patients with N0 disease, with RS 26-100 vs. RS 0-25 predictive ($p=0.009$), and no apparent CT benefit with RS 0-25.

		N0; No CT Use (N=55726)	N1mic; No CT Use (N=3004)	N1; No CT Use (N=3810)
RS 0-10	n	13982	803	1005
	9-y BCSS ± SE	98.6 ± 0.3	98.6 ± 0.9	97.8 ± 0.9
RS 11-17	n	23665	1378	1664
	9-y BCSS ± SE	98.1 ± 0.2	99.4 ± 0.3	97.1 ± 1.1
RS 18-25	n	14281	682	918
	9-y BCSS ± SE	96.8 ± 0.3	95.0 ± 1.6	95.8 ± 1.0
RS 26-30	n	2326	85	137
	9-y BCSS ± SE	92.7 ± 1.0	NC	85.2 ± 6.1
RS 31-100	n	1472	56	86
	9-y BCSS ± SE	89.0 ± 1.2	73.2 ± 10.5	83.9 ± 6.0

[Table: 9-year BCSS by RS group and nodal status in pts with no reported CT use.]

Conclusions: TAILORx has defined the RS-guided treatment paradigm for patients with N0 disease, with the cutoff for CT benefit around RS 26; SEER 9-year real world evidence for prognosis and prediction supports that paradigm. SEER 9-year real world evidence for prognosis supports the option of hormone therapy alone for patients with 1-3 positive nodes and RS < 18, while we await RxPONDER for randomized results in RS 18-25.