

It's never been as clear

to identify node-positive patients who can safely be spared chemotherapy¹⁻⁷

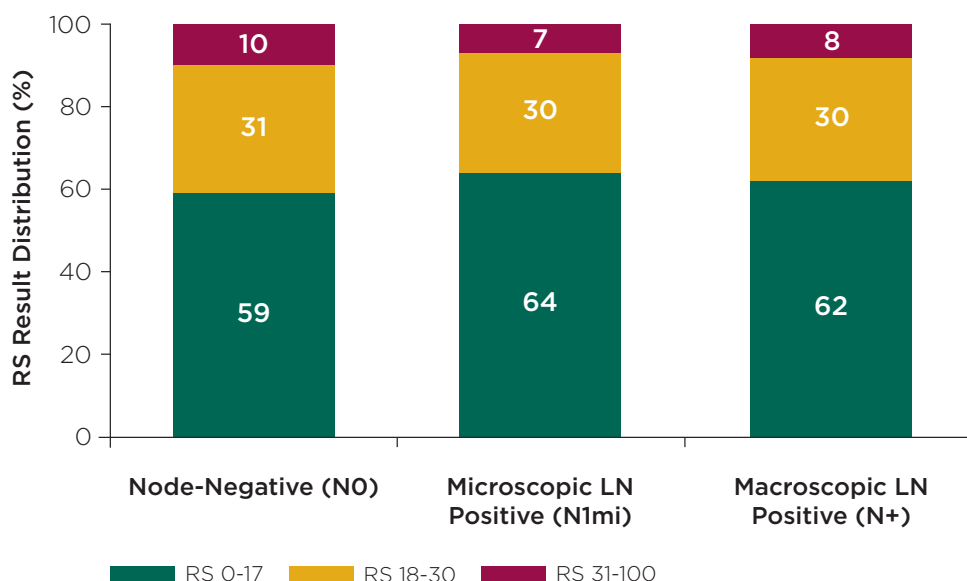
The
Oncotype DX® test:
Node-positive
results you can
count on

Node-positive patients may be overtreated

Node-positive patients are believed to have higher risk of distant recurrence and worse prognoses if not treated with chemotherapy.¹ However, evidence suggests a biological spectrum exists across patients with node-positive disease similar to patients with node-negative disease.²

Recurrence Score® result analysis by nodal status (N = 610,350)

The majority of patients with nodal metastases have Recurrence Score (RS) results 0-17²



Large-sample, comparative study of breast cancer specimens



13 years
(Feb 2004-Aug 2017)



N0, N1mi, N+

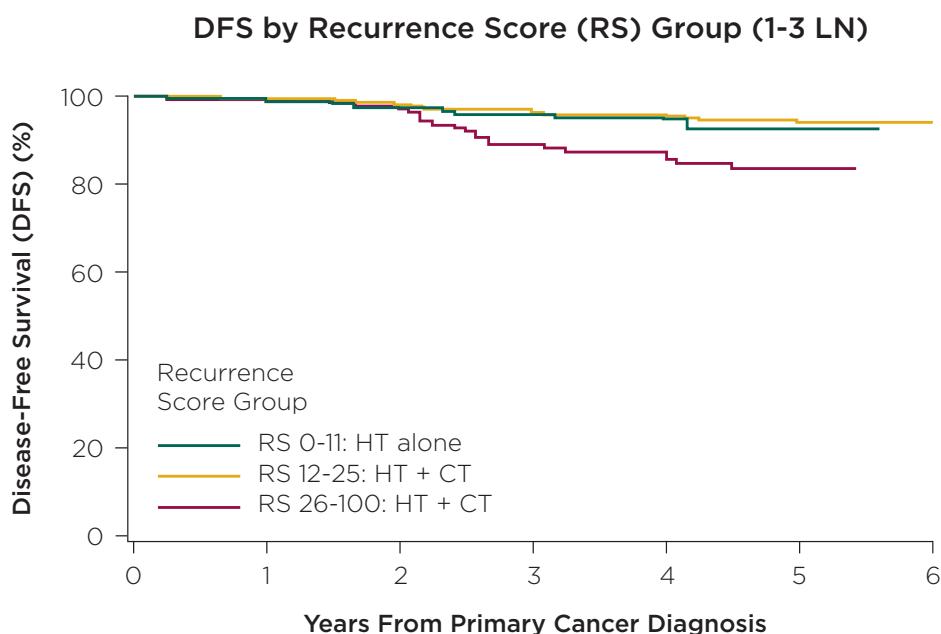


N0 = 486,013
N1mi = 24,325
N+ = 56,100

Nodal status does not predict tumor biology²—only the Oncotype DX Breast Recurrence Score® test can identify which node-positive patients will and will not benefit from chemotherapy³

WSG Plan B

>94% DFS at 5 years in patients with 1 to 3 positive nodes and Recurrence Score® results 0-11 treated with hormonal therapy alone⁴



WSG Plan B



Prospective, randomized, phase 3 trial



5-year outcomes



1-3 LN



1-3 LN* = 782

WSG Plan B trial demonstrated Level 1A evidence¹

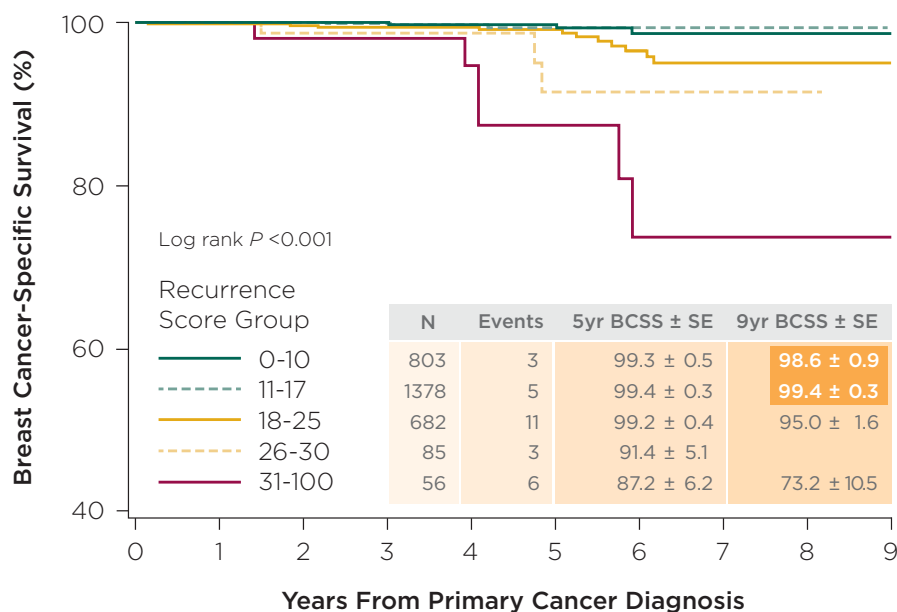
*29% of (N0 to N1, RS 0-11 with ET alone) patients were ≤50 years old. Data on file.

CT = chemotherapy; DFS = disease-free survival; HT = hormonal therapy; LN = lymph node(s); WSG = West German study group.

SEER Registry

>97% BCSS at 9 years without chemotherapy in patients with micrometastases or 1 to 3 positive nodes and Recurrence Score® results 0-17⁵

BCSS by Recurrence Score Group (N1mi)



SEER registry



Real-life, prospective, observational US registry



9-year outcomes in patients treated with HT alone

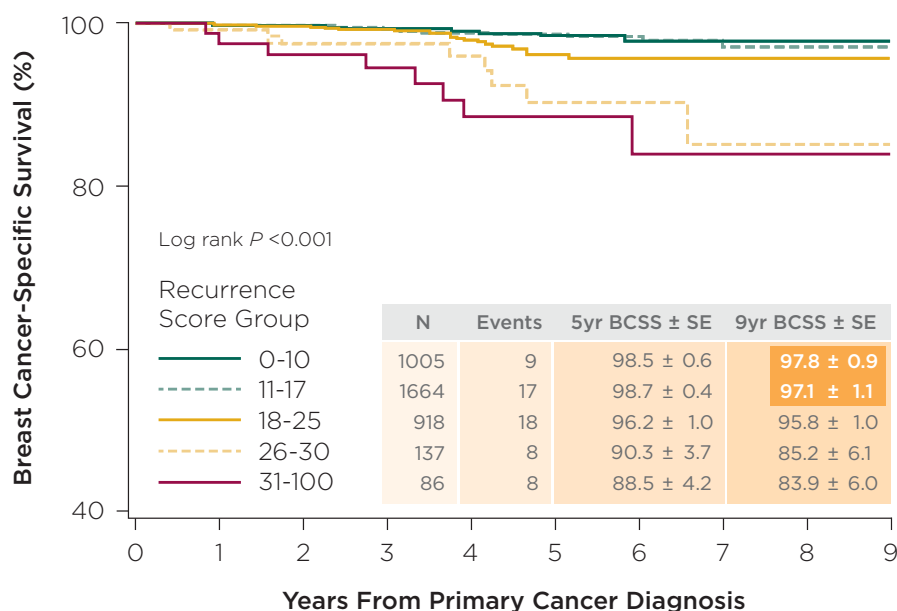


N1mi, 1-3 LN



N1mi* = 4336
1-3 LN+ = 6182

BCSS by Recurrence Score Group (1-3 LN)



*44.1% of N1mi patients were ≤ 50 years old. Data on file.

[†]54.3% of 1-3 LN patients were ≤ 50 years old. Data on file.

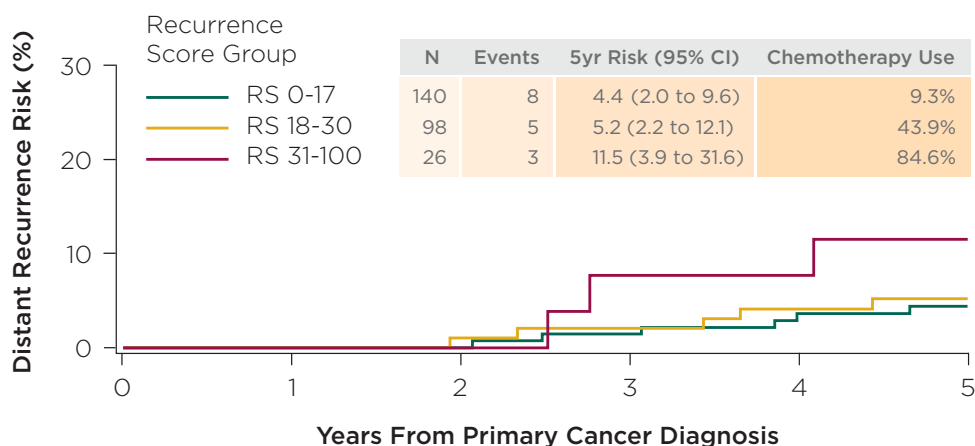
BCSS = breast cancer-specific survival; HT = hormonal therapy; LN = lymph node(s); SEER = surveillance, epidemiology, and end results program.

Patients with Recurrence Score® (RS) results 0-17 and micrometastases or 1 to 3 positive nodes have excellent 5-year outcomes⁶

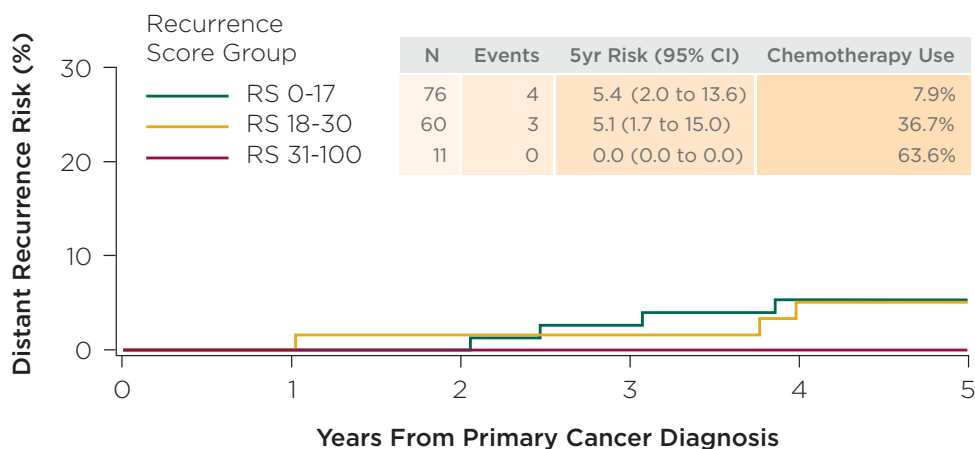
DR by Recurrence Score Group (N1mi)

n = 298	RS 0-17 (n = 163)	RS 18-30 (n = 100)	RS 31-100 (n = 35)
5-yr DR (95% CI)	1.2% (0.3%, 4.8%)	8.1% (4.1%, 15.6%)	26.4% (14.6%, 44.7%)

DR by Recurrence Score Group (1 LN)



DR by Recurrence Score Group (2-3 LN)



Clalit registry



Real-life, prospective, observational Israeli health service registry



>5-year outcomes



N1mi, 1 LN, 2-3 LN



N1mi* = 298
1 LN* = 264
2-3 LN* = 147

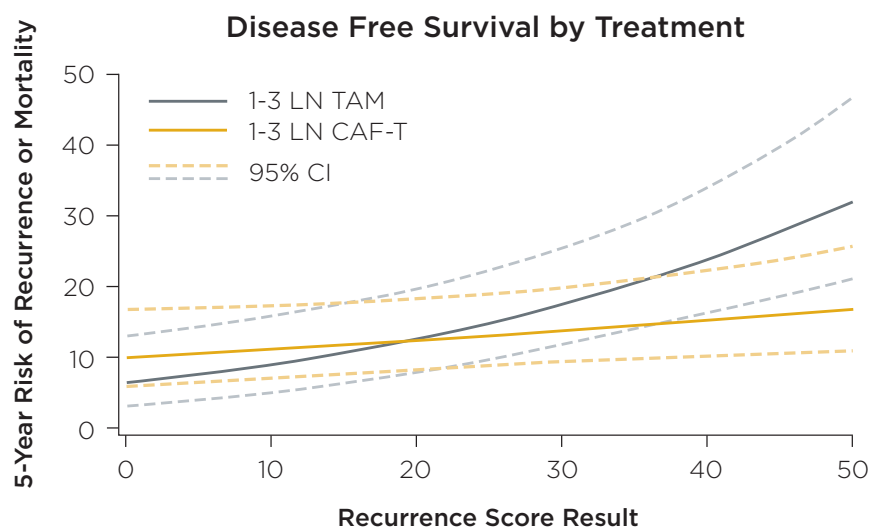
*13% of (N1mi/N1, RS 0-17 with ET alone) patients were ≤50 years old

DR = distant recurrence; ET; endocrine therapy; HT = hormonal therapy; LN = lymph node(s).

Identifies which node-positive patients will and will not benefit from chemotherapy³

SWOG 8814

Recurrence Score® (RS) results 0-17 indicate no benefit from chemotherapy; RS results 31-100 indicate chemotherapy benefit^{3*}



SWOG 8814



Phase 3, open-label, parallel-group, randomized controlled clinical trial



5-year outcomes



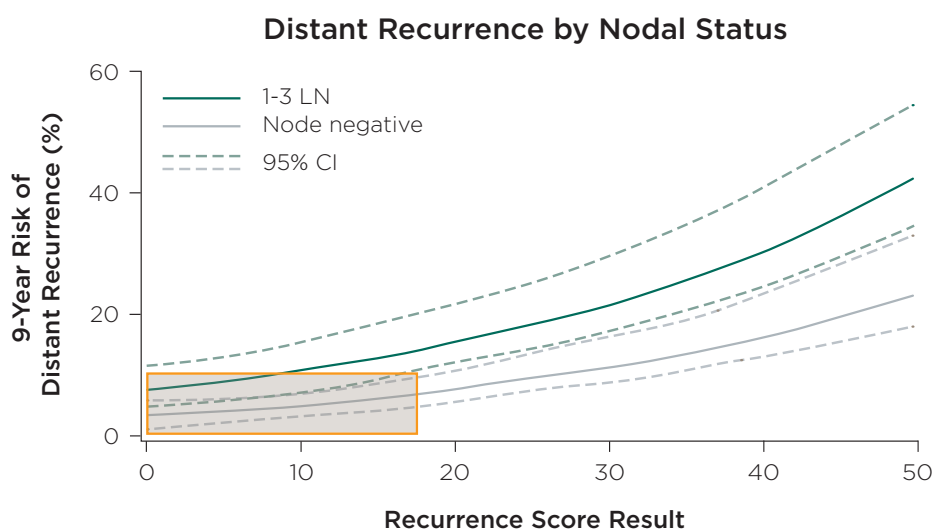
1-3 LN



1-3 LN = 227

TransATAC

Patients with Recurrence Score results 0-17 and 1 to 3 positive nodes have a similar prognosis to patients with node-negative disease⁷



TransATAC



Large, contemporary population study



9-year outcomes



NO, 1-3 LN



NO = 872
1-3 LN = 243

*Chemotherapy benefit in addition to endocrine therapy.

CAF-T = cyclophosphamide, doxorubicin, and fluorouracil before tamoxifen; CI = confidence interval; DR = distant recurrence; LN = lymph node(s); SWOG = Southwest Oncology Group; TAM = tamoxifen; TransATAC = translational study of anastrozole or tamoxifen alone or combined.

The only multigene assay proven to predict chemotherapy benefit, regardless of nodal status

The 21-gene test has been incorporated into major clinical practice guidelines worldwide⁸⁻¹⁴

NCCN Guidelines®

- **Preferred** for patients with HR+, node-negative disease, backed by Level 1 evidence⁸
- **Strongly considered** for patients with HR+, node-negative, HER2- disease and tumors >0.5 cm⁸
- Patients with HR+, 1-3 positive lymph nodes, and Recurrence Score results 18-100 should be **considered for adjuvant chemotherapy** in addition to endocrine therapy⁹

Only the Oncotype DX Breast Recurrence Score test is:

STANDARD OF CARE

with **prospective** outcomes in over 96,000 patients^{4-6,15-17}—including over 12,000 node-positive patients^{4-6*}

PROVEN

to be predictive of chemotherapy benefit in both **node-positive** and node-negative patients^{3,18}

VALIDATED

in multiple studies with **consistent results** (Level 1 evidence for risk of distant recurrence and prediction of chemotherapy benefit)^{3,18}

Oncotype DX® tests for breast, colon, and prostate cancers have helped over 1 million patients make more informed treatment choices.¹⁹

Order the Oncotype DX® test for your eligible node-positive and node-negative patients

HER2 = human epidermal growth factor receptor 2; HR = hormone receptor.

*Includes patients with micrometastases (N1mi).

References: 1. Mamounas et al. *npj Breast Cancer*. 2018. 2. Bello et al. *Ann Surg Oncol*. 2018. 3. Albain et al. *Lancet Oncol*. 2010. 4. Nitz et al. *Breast Cancer Res Treat*. 2017. 5. Hortobagyi et al. *SABCS* 2018. 6. Stemmer et al. *npj Breast Cancer*. 2017;3:32. 7. Dowsett et al. *J Clin Oncol*. 2010. 8. Telli et al. *J Natl Compr Cancer Ntwk*. 2019. 9. NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®): *Breast Cancer*. V1.2019. 10. Senkus et al. *Ann Oncol*. 2015. 11. Harris et al. *J Clin Oncol*. 2016. 12. Coates et al. *N Engl J Med*. 2015. 13. NICE diagnostic guidelines. Published December 2018. 14. Andre et al. *J Clin Oncol*. 2019. 15. Stemmer et al. *npj Breast Cancer*. 2017;3:33. 16. Sparano et al. *N Engl J Med*. 2018. 17. Sparano et al. *N Engl J Med*. 2015. 18. Paik et al. *J Clin Oncol*. 2006. 19. Data on file, Genomic Health, Inc.

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