It's never been as clear

to identify node-positive patients who can safely be spared chemotherapy[1-7]
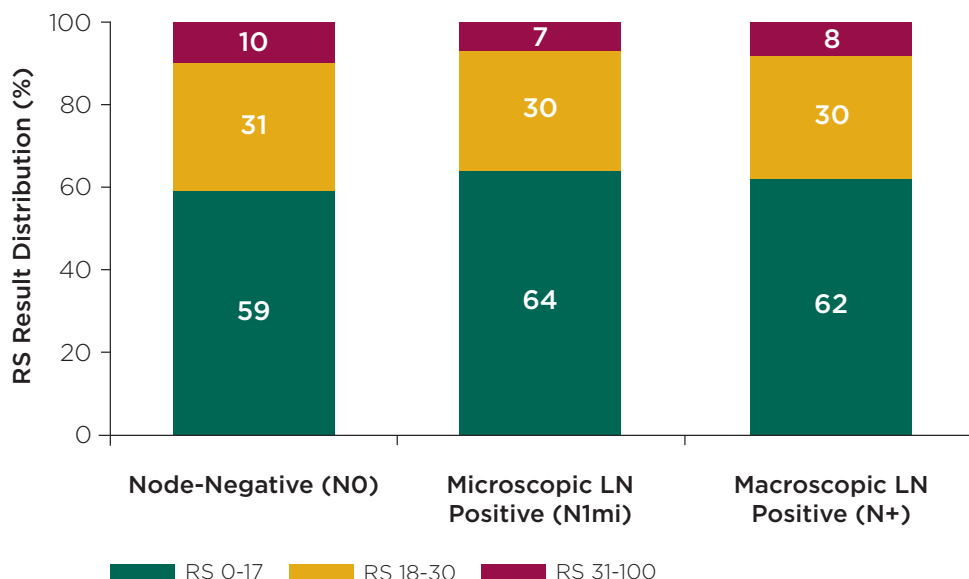
The Oncotype DX® test: **Node-positive results you can count on**

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 0-17[2]

RS Result Distribution (%)

Node-Negative (N0)	Microscopic LN Positive (N1mi)	Macroscopic LN Positive (N+)
10	7	8
31	30	30
59	64	62

- RS 0-17
- RS 18-30
- RS 31-100

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 biology[2]—only the Oncotype DX Breast Recurrence Score® test can identify which node-positive patients will and will not benefit from chemotherapy[3]

*oncotype*DX®
Breast Recurrence Score

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

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 alone[4]

DFS by Recurrence Score (RS) Group (1-3 LN)

Recurrence Score Group
— RS 0-11: HT alone
— RS 12-25: HT + CT
— RS 26-100: HT + CT
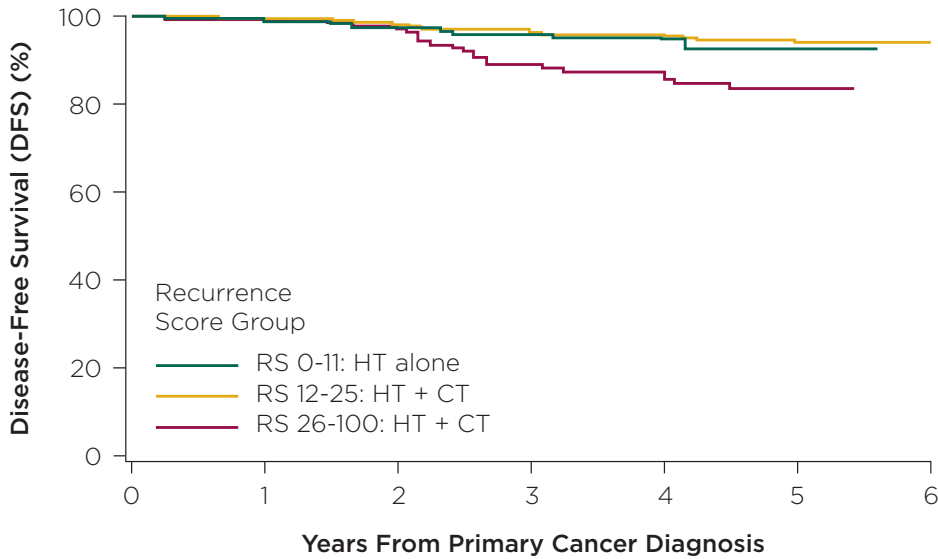
WSG Plan B

Prospective, randomized, phase 3 trial

5-year outcomes

1-3 LN

1-3 LN* = 782
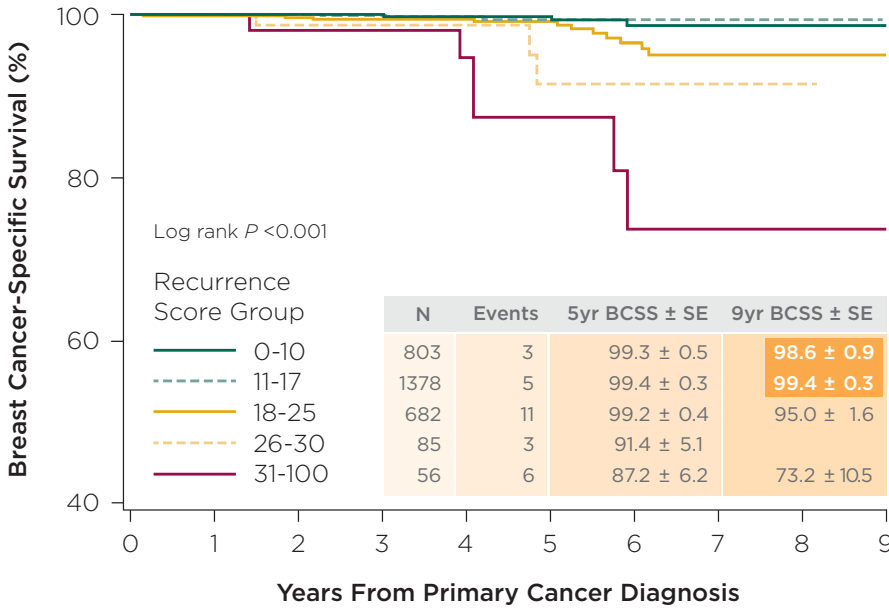
WSG Plan B trial demonstrated Level 1A evidence[1]

*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.

>97% BCSS at 9 years without chemotherapy in patients with micrometastases or 1 to 3 positive nodes and Recurrence Score® results 0-17[5]

BCSS by Recurrence Score Group (N1mi)

Breast Cancer-Specific Survival (%)

Log rank *P* <0.001

Recurrence Score Group

	N	Events	5yr BCSS ± SE	9yr BCSS ± SE
0-10	803	3	99.3 ± 0.5	**98.6 ± 0.9**
11-17	1378	5	99.4 ± 0.3	**99.4 ± 0.3**
18-25	682	11	99.2 ± 0.4	95.0 ± 1.6
26-30	85	3	91.4 ± 5.1	
31-100	56	6	87.2 ± 6.2	73.2 ± 10.5

Years From Primary Cancer Diagnosis

SEER registry

Real-life, prospective, observational US registry

9-year outcomes in patients treated with HT alone

N1mi, 1-3 LN
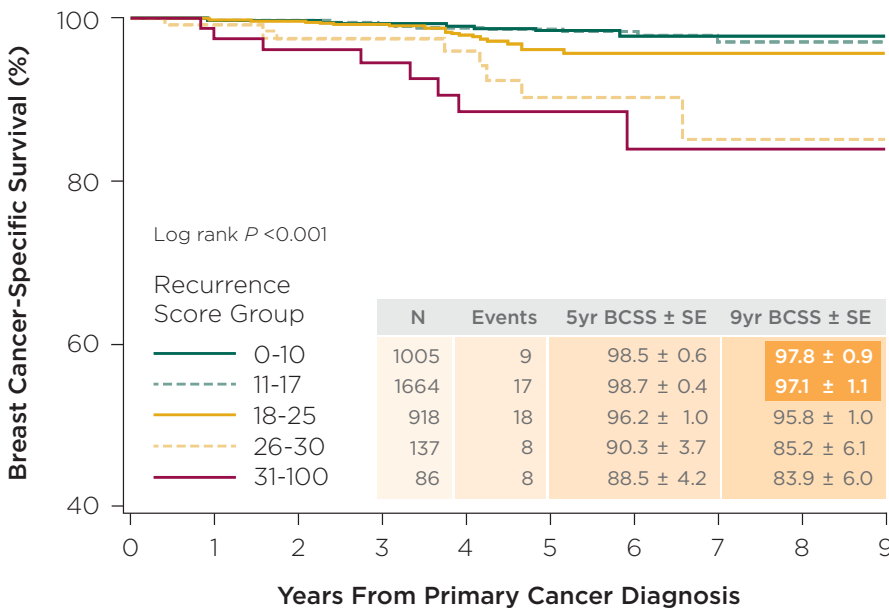
N1mi* = 4336
1-3 LN† = 6182

BCSS by Recurrence Score Group (1-3 LN)

Breast Cancer-Specific Survival (%)

Log rank *P* <0.001

Recurrence Score Group

	N	Events	5yr BCSS ± SE	9yr BCSS ± SE
0-10	1005	9	98.5 ± 0.6	**97.8 ± 0.9**
11-17	1664	17	98.7 ± 0.4	**97.1 ± 1.1**
18-25	918	18	96.2 ± 1.0	95.8 ± 1.0
26-30	137	8	90.3 ± 3.7	85.2 ± 6.1
31-100	86	8	88.5 ± 4.2	83.9 ± 6.0

Years From Primary Cancer Diagnosis

*44.1% of N1mi patients were ≤50 years old. Data on file.
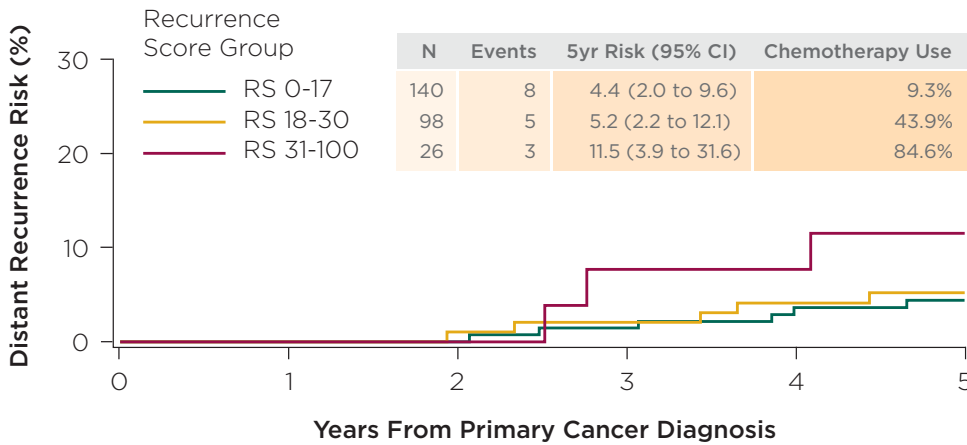†54.3% of 1-3 LN patients were ≤50 years old. Data on file.
BCSS = breast cancer-specific survival; HT = hormonal therapy; LN = lymph node(s); SEER = surveillance, epidemiology, and end results program.

Patients with Recurrence Score® (RS) results 0-17 and micrometastases or 1 to 3 positive nodes have excellent 5-year outcomes[6]
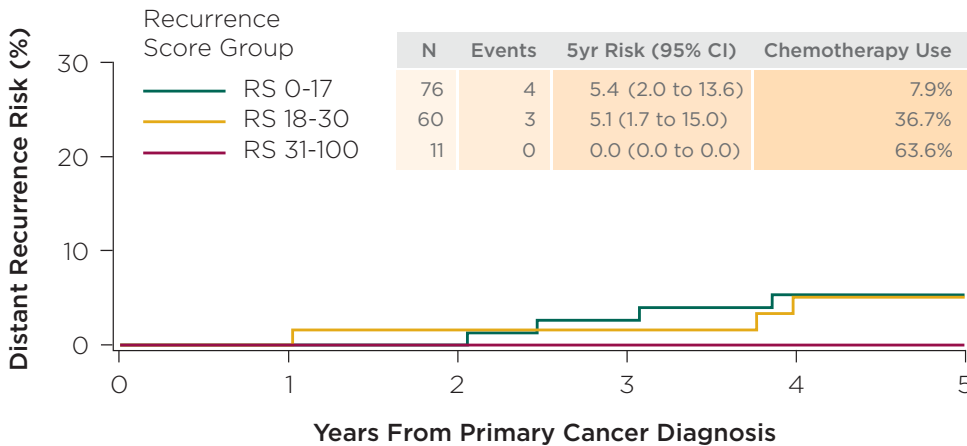
DR by Recurrence Score Group (N1mi)

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)

Recurrence Score Group	N	Events	5yr Risk (95% CI)	Chemotherapy Use
RS 0-17	140	8	4.4 (2.0 to 9.6)	9.3%
RS 18-30	98	5	5.2 (2.2 to 12.1)	43.9%
RS 31-100	26	3	11.5 (3.9 to 31.6)	84.6%

Distant Recurrence Risk (%) — Years From Primary Cancer Diagnosis

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

DR by Recurrence Score Group (2-3 LN)

Recurrence Score Group	N	Events	5yr Risk (95% CI)	Chemotherapy Use
RS 0-17	76	4	5.4 (2.0 to 13.6)	7.9%
RS 18-30	60	3	5.1 (1.7 to 15.0)	36.7%
RS 31-100	11	0	0.0 (0.0 to 0.0)	63.6%

Distant Recurrence Risk (%) — Years From Primary Cancer Diagnosis

*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 chemotherapy[3]

SWOG 8814

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

Disease Free Survival by Treatment

- 1-3 LN TAM
- 1-3 LN CAF-T
- 95% CI

Y-axis: 5-Year Disease-Free Survival (%), 0 to 50
X-axis: Recurrence Score Result, 0 to 50

SWOG 8814

- Phase 3, open-label, parallel-group, randomized controlled clinical trial
- 5-year outcomes
- 1-3 LN
- 1-3 LN = 227
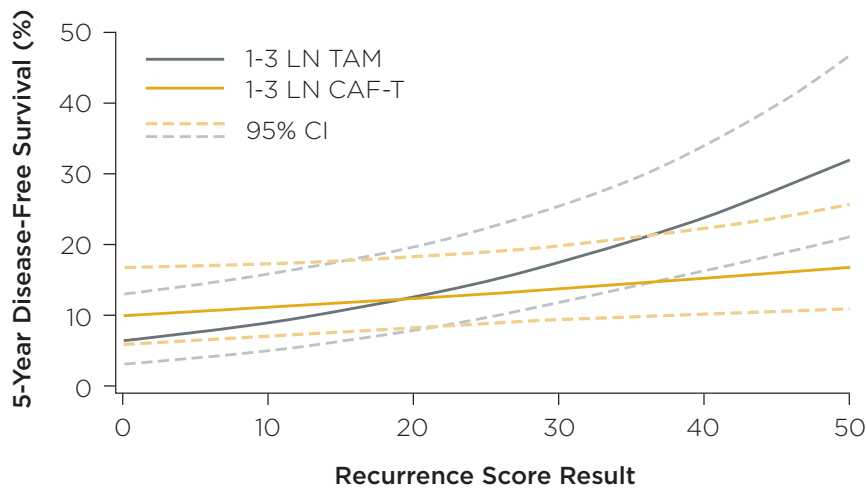
TransATAC

Patients with Recurrence Score results 0-17 and 1 to 3 positive nodes have a similar prognosis to patients with node-negative disease[7]

Distant Recurrence by Nodal Status

- 1-3 LN
- Node negative
- 95% CI

Y-axis: 9-Year Risk of Distant Recurrence (%), 0 to 60
X-axis: Recurrence Score Result, 0 to 50

TransATAC

- Large, contemporary population study
- 9-year outcomes
- N0, 1-3 LN
- N0 = 872
  1-3 LN = 243
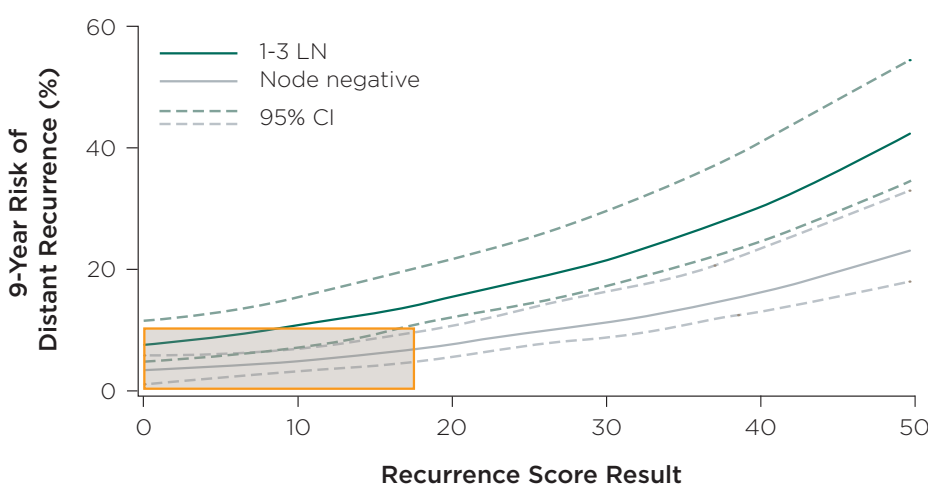
*Chemotherapy benefit in addition to endocrine therapy.

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 worldwide[8-14]

NCCN Guidelines®

- **Preferred** for patients with HR+, node-negative disease, backed by Level 1 evidence[8]
- **Strongly considered** for patients with HR+, node-negative, HER2– disease and tumors >0.5 cm[8]
- Patients with HR+, 1-3 positive lymph nodes, and Recurrence Score results 18-100 should be **considered for adjuvant chemotherapy** in addition to endocrine therapy[9]

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.

Making cancer care smarter.®

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