

# A Comparison of Local Recurrence Risk Estimates After Breast-Conserving Surgery for DCIS: DCIS Nomogram Vs Refined Oncotype DX Breast DCIS Score™



Kimberly J. Van Zee, MS, MD<sup>1</sup>, Emily C. Zabor, DrPH<sup>2</sup>, Rosemarie Di Donato, MD<sup>3</sup>, Bryan Harmon, MD<sup>3</sup>, Jana Fox, MD<sup>4</sup>, Monica Morrow, MD<sup>1</sup>, Hiram S. Cody III, MD<sup>1</sup>, Susan A. Fineberg, MD<sup>3</sup>

<sup>1</sup>Breast Service, Department of Surgery, Memorial Sloan Kettering Cancer Center, New York, NY; <sup>2</sup>Biostatistics Service, Department of Epidemiology and Biostatistics, Memorial Sloan Kettering Cancer Center, New York, NY

<sup>3</sup>Department of Pathology, Montefiore Medical Center, Bronx, NY; <sup>4</sup>Department of Radiation Oncology, Montefiore Medical Center, Bronx, NY



## Abstract

**Background:** A DCIS Nomogram, integrating 10 clinicopathologic/treatment factors, and a Refined DCIS Score (RDS), incorporating a genomic assay and 3 clinicopathologic factors (Oncotype DX DCIS Score™), are available to estimate DCIS 10-year local recurrence risk (LRR). We compared these estimates.  
**Methods:** Patients age ≥ 50 years with DCIS size ≤ 2.5 cm and a genomic assay available were identified. RDS within 1-2% of the range of Nomogram LRR estimates obtained by assuming use and non-use of endocrine therapy (Nomogram +/- ET) were defined as concordant. Assuming a 10-year risk threshold for recommending radiation of 10%, Nomogram +/- ET and RDS estimates were compared; threshold concordance was determined.  
**Results:** In 54/59 (92%), the RDS and Nomogram +/- ET LRR estimates were concordant. In the remaining 5/59 (8%), the RDS LRR estimates were lower than the Nomogram + ET with an absolute difference of 3-8% and thus were discordant. For these 5, the RDS estimates of 10-year LRR were < 10% (range 5-8%) and the Nomogram + ET estimates were ≥ 10% (range 11-14%). These 5 patients with both discordant and threshold-discordant LRR estimates all had close margins (≤ 2 mm).  
**Conclusions:** Among 92% women age ≥ 50 years with DCIS ≤ 2.5 cm, free-of-charge online Nomogram 10-year LRR estimates were concordant with those obtained with the commercially available RDS (> \$4600). Among the 8% with discordant risk estimates, the RDS appears to underestimate the LRR and may lead to inappropriate omission of RT. Unless other data show it to have a clinically significant advantage, the use of RDS (Oncotype DX DCIS Score™) for women age ≥ 50 years with DCIS ≤ 2.5 cm is not warranted.

## Study Objective

- To compare 10-year local recurrence (LR) risk estimates for women age ≥ 50 years with DCIS ≤ 2.5 cm treated with breast-conserving surgery (BCS) without radiation, obtained using the Nomogram and the Refined DCIS Score (RDS).

## Background

- 2 clinically available tools designed to estimate LR risk in patients with DCIS treated with BCS:
  - Memorial Sloan Kettering DCIS Nomogram (Nomogram)
    - Incorporates 10 clinicopathologic/treatment factors, including endocrine therapy (ET)
    - Available at [www.nomograms.org](http://www.nomograms.org)
    - Free-of-charge
  - Oncotype DX Breast DCIS Score™, currently reported as a Refined DCIS Score (RDS)
    - Incorporates genomic assay and age, size, year of surgery
    - ~50% of development population treated ≥ 2000 received tamoxifen
    - Available commercially at cost = \$4,620

## Methods

- Inclusion criteria: All patients age ≥ 50 years, with DCIS ≤ 2.5 cm, with negative (tumor not on ink) margins for whom a DCIS Score was obtained.
- Estimates were defined as:
  - Concordant** if RDS LR risk estimates within 1-2% of the Nomogram +/- ET estimate range
  - Threshold concordant** if the RDS and Nomogram estimates were concordant, or if the discordant estimates were on the same side of the 10% LR risk threshold (i.e., either both did or both did not estimate risk ≥ 10%)

## Results

**TABLE 1. Demographic and clinicopathologic characteristics**

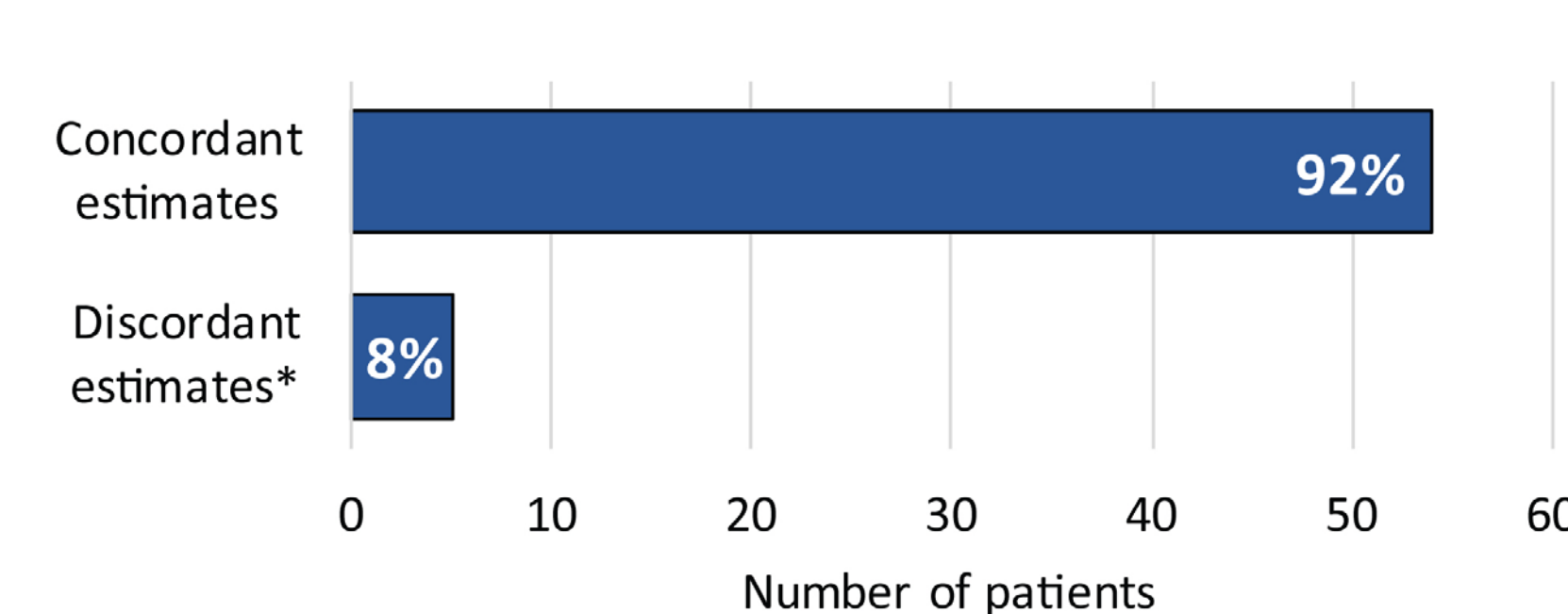
Characteristic		Median (range)
Age at surgery, years		67 (50-81)
Ductal carcinoma in situ size, cm		0.6 (0.2-2.5)
		n (%)
Presentation	Radiologic	55 (93%)
	Clinical	4 (6.8%)
Family history of breast cancer	Yes	12 (20%)
	No	47 (80%)
Nuclear grade	1	10 (17%)
	2	34 (58%)
	3	15 (25%)
Necrosis present	Yes	35 (59%)
	No	24 (41%)
Size category	≤ 1 cm	42 (71%)
	> 1 cm and ≤ 2.5 cm	17 (29%)
Number of excisions	1	55 (93%)
	2	4 (6.8%)
Margin width	> 0 mm, ≤ 2 mm	12 (20%)
	> 2 mm	47 (80%)
Estrogen receptor	Positive	58 (98%)
	Negative	1 (1.7%)

**TABLE 2. Number and proportion of patients in each risk category**

Method of risk estimation	10-year local recurrence risk estimate		
	< 10% n (%)	≥ 10% n (%)	≥ 15% n (%)
Nomogram, with endocrine therapy	47 (80%)	12 (20%)	0 (0%)
Nomogram, without endocrine therapy	3 (5%)	56 (95%)	24 (41%)
Refined DCIS Score	35 (59%)	24 (41%)	4 (7%)

**Figure 1.**

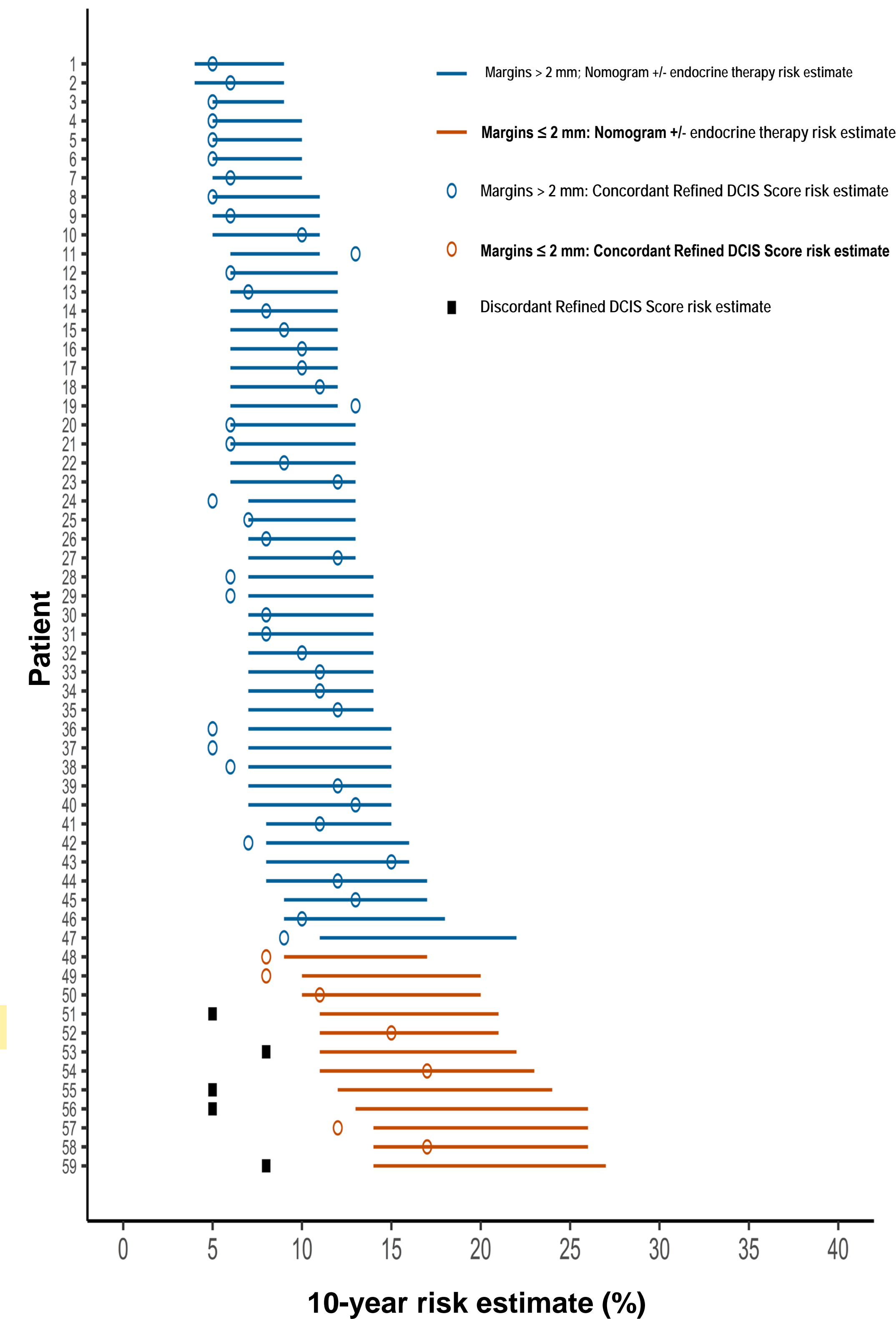
Patients with concordant or discordant risk estimates



\*All 5 discordant estimates were in patients with close (≤ 2 mm) margins; DCIS, ductal carcinoma in situ

## Results

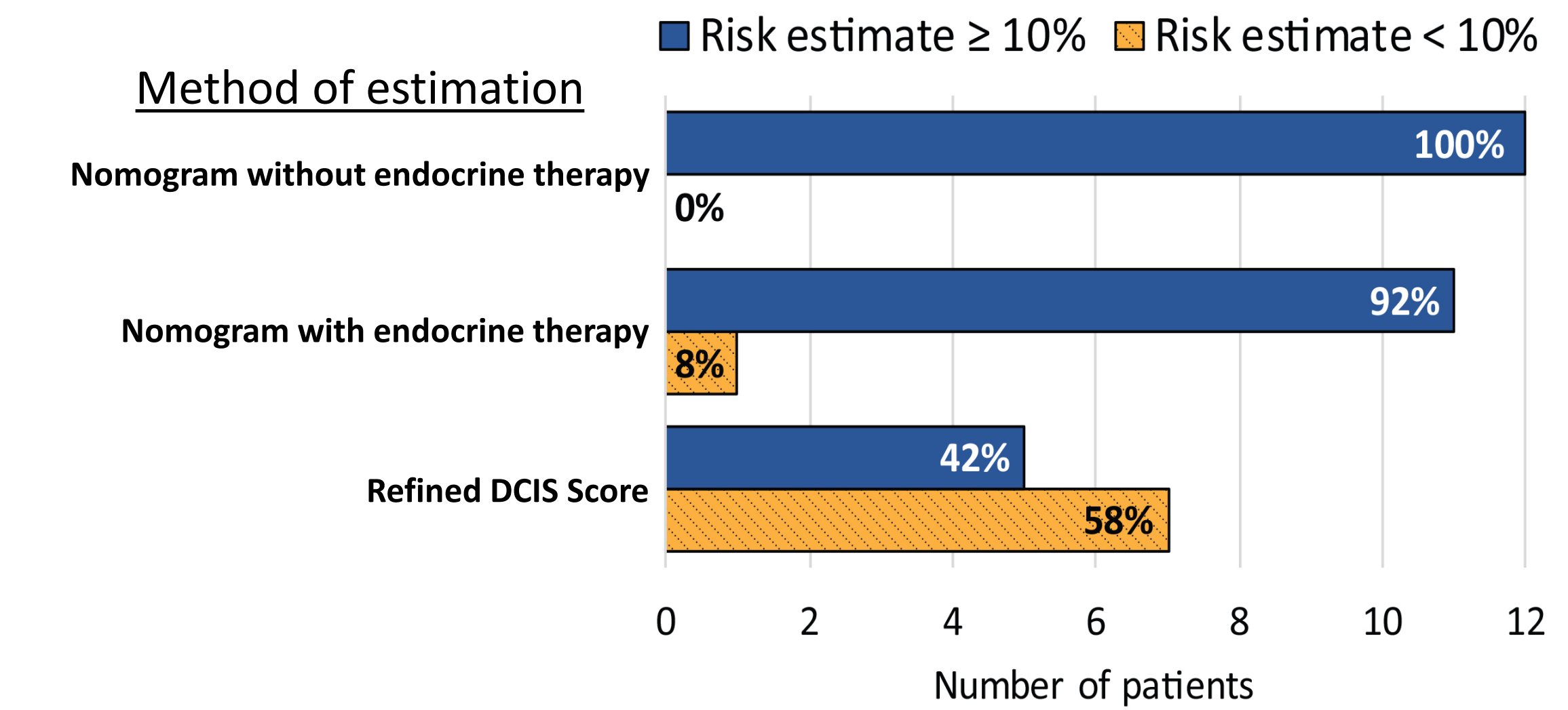
**Figure 2. Ten-year local recurrence risk estimates using Nomogram with/without endocrine therapy and Refined Oncotype DX Breast DCIS Score™ (RDS)**



## Results

**Figure 3.**

Number and proportion of patients with close margins who meet ≥ 10% risk radiation threshold



## Conclusions

- For most women (92%) age ≥ 50 years with DCIS ≤ 2.5 cm, the MSKCC DCIS Nomogram provided 10-year LR risk estimates concordant with the RDS.
  - DCIS Nomogram is available free-of-charge at [www.nomograms.org](http://www.nomograms.org)
  - Refined DCIS Score is available commercially for \$4,620
- All with discordant estimates had close margins; in all discordant cases, RDS < Nomogram estimate.
  - Close margin is incorporated into Nomogram
  - Close margin does not alter RDS estimate
  - RDS likely underestimates risk in presence of close margin
- Use of endocrine therapy is not incorporated into RDS estimate, suggesting RDS underestimates risk without ET, and overestimates risk with ET.
- Unless further data demonstrate a clinically significant advantage of the costly genomic assay, use of the RDS for women age ≥ 50 years with DCIS ≤ 2.5 cm is not warranted.