

COMPARATIVE ANALYSIS OF CHANGES IN TREATMENT RECOMMENDATION FOR BLACK AND WHITE PATIENTS WITH DUCTAL CARCINOMA IN SITU USING A 7-GENE PREDICTIVE BIOSIGNATURE: ANALYSIS OF THE PREDICT STUDY

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Background

- Previous studies have demonstrated that compared with White women, Black women are more likely to have second tumors (invasive and noninvasive) in either breast and die of invasive breast cancer (IBC) after DCIS. (1)
- Although multiple studies have presented results on the treatment of invasive breast cancer, there are very few studies examining the impact of race/ethnicity on the treatment of DCIS.
- Thus, there is a need to further determine whether clinicopathologic factors are associated with the recommendation of therapy in patients from different races/ethnicities in DCIS.
- In this study, we evaluated the decision impact for RT recommendations incorporating the 7-gene predictive biosignature by race (White vs. Black) in women with DCIS enrolled in the PREDICT study.

Methods

- The PREDICT study was a prospective, multi-institutional registry for patients who received DCISionRT testing as part of their routine care.
- The registry included females, age 26 and older who were diagnosed with DCIS and were candidates for BCS and eligible for adjuvant RT or systemic therapy.
- Treating physicians completed treatment recommendation forms before and after receiving test reports to capture surgical, radiation, and endocrine therapy treatment (HT) recommendations and patient preferences.
- The primary endpoint was to identify the proportion of patients where testing led to a change in RT recommendation.
- Additional analyses included changes in recommendations in patient subgroups based on race/ethnicity.
- Changes in RT recommendation were analyzed by the McNemar test.

Results

- Analysis was performed in 2,305 patients treated at 63 clinical sites.
- Overall, 80% of the patients were White and 12% patients were Black.
- No significant differences were observed in the distribution of Black and White with respect to clinicopathological factors where the median age was 63 in White patients and 62 in Black patients with 34% and 28% of patients having nuclear grade 3 respectively.
- Overall RT recommendations were changed in 39%and 37% of White (p< 0.001) and Black patients (p=0.003), respectively.
- Pre-test, the rates of RT recommendation were not different between the Black and White patients (p=.8).
- Post-testing, there was a significant difference in the net change of RT recommendation in Black (p=.01) and White (p< 0.001) patients.
- Black patients had a 10% higher rate of RT recommendation when compared with White patients(p=0.004).

- DCISionRT changed RT recommendations in 38% of women overall (n=2305).
- DCISionRT score distributions were not significantly different between Black and White patients.
- Black patients had a 10% higher rate of RT recommendation than the White patients.

Figure 1. RT Recommendation Pre- and Post DCISionRT Test Results

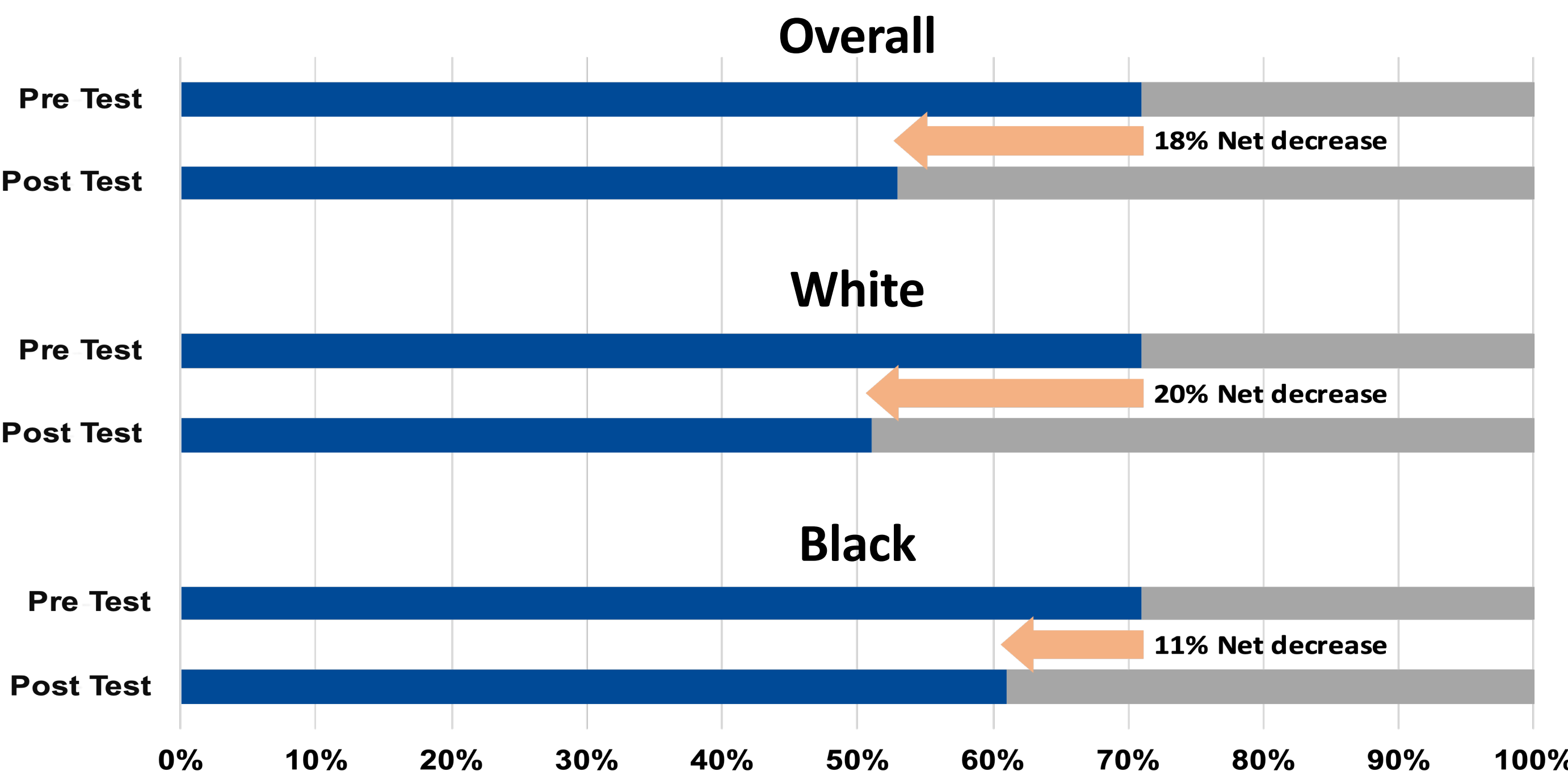


Figure 2. RT Recommendation Post DCISionRT Test Results

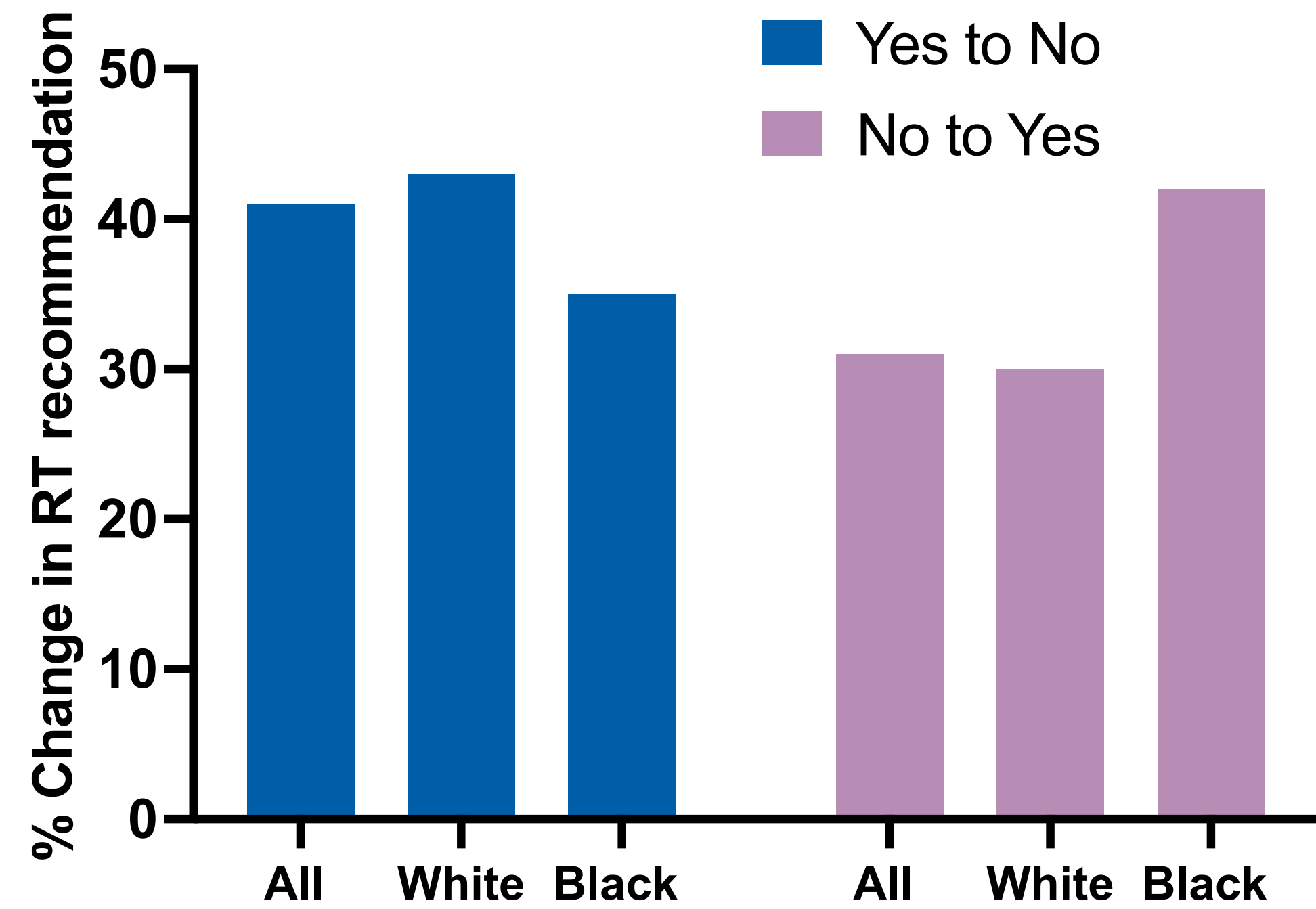


TABLE 1. RT Recommendation Pre- and Post DCISionRT Test Results

Clinico-pathologic Factor	N	RT Recommended			Pre- to Post-Test Change in RT Recommended		Total Change in RT Recommended		
		Pre-Test	Post-Test	Net Change	Yes to No	No to Yes	Overall Change	95% CI	p-Value
All Cases	2259	71%	53%	-18%	40%	34%	38%	36-40%	<0.0001
White	1858	71%	51%	-20%	41%	33%	39%	37-41%	<0.0001
Black	265	72%	61%	-11%	33%	46%	37%	31-43%	0.0032
DS ≤ 2	1117	72%	30%	-42%	62%	10%	47%	44-50%	<0.0001
White	914	72%	29%	-43%	64%	9%	49%	45-52%	<0.0001
Black	131	77%	40%	-37%	52%	13%	44%	35-52%	<0.0001
DS > 2 to ≤ 4	787	65%	67%	2%	24%	51%	33%	30-37%	0.2661
White	661	65%	66%	1%	25%	50%	34%	30-38%	0.6885
Black	89	66%	75%	9%	17%	60%	31%	23-42%	0.1306
DS > 4	355	79%	90%	11%	5%	73%	20%	16-24%	<0.0001
White	283	80%	89%	9%	7%	73%	20%	16-25%	0.0005
Black	45	69%	96%	27%	0%	86%	27%	16-41%	0.0005

Results, continued

- Furthermore, 33% of the Black women and 41% of White women who were recommended to receive RT pre-testing were not recommended to receive RT post-testing (p=0.10).
- In addition, 46% of Black women who were initially not recommended to receive RT pre-testing were recommended to receive RT post-testing in contrast to 33% of White women (p=.04).
- In contrast, there were no significant differences observed in proportion in the DS groups 0-2, 2-4 and >4 by Black vs White (p=.7).

Table 2. Clinicopathologic Features

Clinpath Factor	All Cases		White		Black		Fisher's p-Value
	N	%	N	%	N	%	
All Cases	2305		1858	81%	265	11%	
Age							
50 or Under	422	18%	318	17%	45	17%	0.93
Over 50	1883	82%	1540	83%	220	83%	
Nuclear Grade							
Grade 1 or 2	1551	67%	1223	66%	192	72%	0.03
Grade 3	754	33%	635	34%	73	28%	
Tumor Size							
≤ 1 cm	1515	66%	1230	66%	165	62%	0.23
> 1 cm	790	34%	628	34%	100	38%	
Margin Status							
Close (≤ 2 mm)	191	8%	153	8%	20	8%	0.80
Negative (> 2)	2069	90%	1669	90%	239	90%	
Tumor Necrosis							
Present	1231	70%	997	71%	145	70%	0.68
Absent	519	30%	402	29%	63	30%	
RTOG 9804-Like							
Good Risk	1203	53%	957	52%	145	55%	0.29
Not Good Risk	1084	47%	886	48%	117	45%	
Decision Score (DS)							
DS ≤ 2	1141	50%	914	49%	131	49%	0.69
DS > 2 to ≤ 4	803	35%	661	36%	89	34%	
DS > 4	361	16%	283	15%	45	17%	

Conclusions

- This analysis demonstrates significant changes in recommendations to add or omit RT based on the 7-gene predictive biosignature in 2,305 patients.
- Black patients had significantly higher rates of RT recommendation compared to White women with similar biosignature scores.



Reference:
(1) Narod SA, Iqbal J, Giannakeas V, Sopik V, Sun P. Breast Cancer Mortality After a Diagnosis of Ductal Carcinoma In Situ. JAMA Oncol. 2015 Oct;1(7):888-96. doi: 10.1001/jamaoncol.2015.2510. PMID: 26291673.