DCISionRT®

San Antonio Breast Cancer Symposium 2023

Title: Changes in Treatment Recommendation for Patients with Ductal Carcinoma In Situ Using a 7-Gene Predictive Biosignature: Analysis of the PREDICT Australia Study

Background: The role of adjuvant radiotherapy (RT) following breast-conserving surgery (BCS) for women with ductal carcinoma in situ (DCIS) remains controversial. Although there is Level 1 evidence supporting the use of RT to reduce the risk of local recurrence, prognostic and predictive tools are needed to better stratify individual risks and benefits of RT. The 7-gene predictive DCIS biosignature provides a validated score (DS) for women receiving BCS that assesses 10-year risk of DCIS recurrence and development of invasive breast cancer with and without adjuvant RT. We established a registry to evaluate the decision impact of the 7-gene predictive biosignature on DCIS treatment recommendations in an Australian setting.

Methods: The PREDICT study is a prospective, multi-institutional registry for patients who received DCISionRT testing as part of their routine care. The registry includes females 26 and older who are diagnosed with DCIS and are candidates for BCS and eligible for RT. Treating physicians completed treatment recommendation forms before and after receiving test reports to capture surgical, radiation and hormonal treatment (HT) recommendations and patient preferences.

Results: This planned interim analysis was performed in 483 patients with complete data treated at 43 clinical sites in Australia. The median age of patients was 61 years, 19% were 50 or younger, nuclear grade was high in 51%, and tumor size was 2.5 cm or greater in 15%. Overall, RT recommendation (yes/no) was changed for 41% of women and HT recommendation was changed for 9% after testing with a net reduction in recommended RT of 14% (66% pre-assay to 52% post-assay $p< 0.001$). Of patients recommended to receive RT pre-test, 42% were recommended to not receive RT post-test and of the patients recommended to not receive RT pre-test, 40% were recommended to receive RT post-test. The post-test RT recommendation rate increased with increasing DS score (< 2, 2-4, >4), with 9% of patients recommended RT for DS< 2, 62% for DS 2-4, and 100% for DS 4-10. The use of the test resulted in different RT recommendations than with clinicopathology alone, where RT recommendations were changed for 49%, 37%, and 34% for women of age< 50 yrs, with Grade 3 DCIS, or with DCIS > 2.5 cm, respectively. Collectively, this suggests that physicians had a high confidence in the test results when making their final treatment recommendations with the test results.

Conclusion: This analysis demonstrates that the use of the 7-gene predictive biosignature resulted in significant changes in recommendations to add or omit RT in this study of 483 women. The integration of DCISionRT into the clinical decision-making processes has a substantial impact on recommendations to personalize care and prevent over- or under-treatment.

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Table 1. Impact of DCISionRT on Adjuvant Radiation Recommendations by Clinicopathologic Features

		RT recommended			Pre- to post-test change in RT recommended		Total change in RT recommended		
Clinical factor	**N**	**Pre-test (%)**	**Post-test (%)**	**Net change (%)**	**Yes to no (%)**	**No to yes (%)**	**Overall-change (%)**	**95% CI**	**p-Value**
All Cases	483	66%	52%	-14%	42%	40%	41%	37-46%	<0.0001
Age									
Under 50	69	65%	42%	-23%	56%	38%	49%	38-61%	0.0061
50 - 69	308	67%	46%	-20%	46%	30%	41%	35-46%	<0.0001
70 and over	106	66%	75%	8%	23%	69%	39%	30-48%	0.1599
Nuclear Grade									
Grade 1	52	27%	54%	27%	36%	50%	46%	33-59%	0.0043
Grade 2	186	51%	40%	-11%	56%	36%	46%	39-53%	0.0310
Grade 3	245	86%	60%	-26%	36%	38%	37%	31-43%	<0.0001
Tumor size									
≤1 cm	212	43%	38%	-5%	59%	36%	46%	39-53%	0.3232
1 - 2.5 cm	228	79%	59%	-20%	38%	46%	40%	33-47%	<0.0001
>2.5 cm	105	93%	68%	-26%	32%	60%	34%	24-45%	0.0001
Tumor Necrosis									
Present	380	80%	55%	-25%	42%	43%	42%	34-48%	<0.0001
Absent	204	45%	49%	4%	48%	46%	47%	37-56%	0.5637
RTOG-9804-like									
Good Risk	185	40%	40%	0%	57%	38%	46%	38-53%	1.0000
Not Good Risk	308	83%	59%	-24%	38%	43%	39%	33-44%	<0.0001
DS Risk Groups									
Low Risk	274	64%	19%	-45%	75%	7%	50%	44-56%	<0.0001
Elevated Risk	209	69%	95%	26%	3%	91%	30%	24-36%	<0.0001

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