DCISionRT®

San Antonio Breast Cancer Symposium 2021

Title: Interim analysis of the PREDICT Registry: Changes in treatment recommendation for a biologic signature predictive of radiation therapy (RT) benefit in patients with DCIS

Background: The role of adjuvant RT following breast conserving surgery (BCS) for women with ductal carcinoma in situ (DCIS) remains controversial. Although there is level I evidence supporting the role of RT in reducing the risk of local recurrence, prognostic and predictive tools are needed to better stratify individual risks and benefits of RT. The DCISionRT® Test (PreludeDx, Laguna Hills, CA) is a biosignature that uses individual tumor biology in conjunction with clinical and pathologic risk factors. The test 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 DCISionRT on DCIS treatment recommendations.

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 or systemic therapy. Treating physicians completed treatment recommendation forms before and after receiving test reports to capture surgical, radiation and hormonal treatment (HT) recommendations and patient preferences. The primary endpoint is to identify the proportion of patients where testing led to a change in RT recommendation. Additional analyses include changes in recommendations in patient subgroups based on clinicopathologic factors or type of treating physician.

Results: Analysis was performed in 969 patients treated at 55 sites who had definitive BCS and subsequent DCISionRT testing. The median age of patients was 62 years, 19% were 50 or younger, nuclear grade was high in 31% and tumor size was 2.5 cm or greater for 11%. Test results were DS Low risk (DS ≤ 3) for63% of women and 37% were DS Elevated risk (DS > 3). Overall, RT recommendation (yes/no) was changed for 40% of women after DCISionRT testing and HT recommendation was changed for 11%. There was a net decrease in RT recommendation from 69% pre-assay to 50% post-assay ($p<0.001$). RT recommendation decreased by 42% in DS Low risk patients, but increased 22% in DS Elevated risk patients. Among physicians, surgeons were more likely to change their RT recommendation (49%) than radiation oncologists (38%). When test results indicated DS Elevated risk, both surgeons (82%) and radiation oncologists (91%) were likely to recommended RT, but when the results were low risk, surgeons were more likely than radiation oncologists to recommend omitting RT (83% vs. 68%, respectively).

Conclusions: This interim analysis demonstrates a significant percent change in recommendations to add or omit RT based on DCISionRT results in 969 patients. Compared to traditional clinicopathologic features, the factor most strongly associated with RT recommendation was the DCISionRT result with other factors of importance being patient preference, tumor size and grade. The integration of DCISionRT into clinical decision processes has substantial impact on recommendations aimed at optimal management to prevent over- or under-treatment.

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Table 1. Impact of DCISionRT on adjuvant radiation recommended 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**
Age, years									
< 50	164	81	48	-32	43	13	37	30-45%	<0.001
≥ 50	805	66	51	-16	42	37	41	37-44%	<0.001
Grade									
1 or 2	665	61	44	-16	50	35	44	40-47%	<0.001
3	304	87	64	-23	32	33	32	27-37%	<0.001
Tumor Size									
≤ 2.5 cm	859	66	48	-18	45	35	42	38-45%	<0.001
> 2.5 cm	110	92	69	-23	27	22	26	19-35%	<0.001
RTOG 9804 criteria									
'Good risk'	500	55	41	-14	52	34	44	40-49%	<0.001
Not 'good risk'	459	84	60	-24	36	35	36	32-40%	<0.001

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Interim Analysis of the PREDICT Registry: Changes in Treatment Recommendation for a Biologic Signature Predictive of Radiation Therapy (RT) Benefit in Patients with DCIS

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Background

- The role of adjuvant RT following breast conserving surgery (BCS) for women with ductal carcinoma in situ (DCIS) remains controversial.
- Although there is level one evidence supporting the role of RT in reducing the risk of local recurrence, prognostic and predictive tools are needed to better stratify individual risks and benefits of RT.
- The DCISionRT® Test (PreludeDx, Laguna Hills, CA) is a biosignature that uses individual tumor biology in conjunction with clinical and pathologic risk factors.
- The test 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 DCISionRT on DCIS treatment recommendations.

Materials and 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 or systemic therapy.
- Treating physicians completed treatment recommendation forms before and after receiving test reports to capture surgical, radiation and hormonal treatment (HT) recommendations and patient preferences.
- The primary endpoint is to identify the proportion of patients where testing led to a change in RT recommendation.
- Additional analyses include changes in recommendations in patient subgroups based on clinicopathologic factors or type of treating physician.

Results

- Analysis was performed in 969 patients treated at 55 sites who had definitive BCS and subsequent DCISionRT testing.
- The median age of patients was 62 years, 19% were 50 or younger, nuclear grade was high in 31% and tumor size was 2.5 cm or greater for 11%.
- Test results were DS Low risk (DS ≤ 3) for 63% of women and 37% were DS Elevated risk (DS > 3).
- Overall, RT recommendation (yes/no) was changed for 40% of women after DCISionRT testing and HT recommendation was changed for 11%.
- There was a net decrease in RT recommendation from 69% pre-assay to 50% post-assay (p<0.001).
- RT recommendation decreased by 42% in DS Low risk patients, but increased 22% in DS Elevated risk patients.
- Among physicians, surgeons were more likely to change their RT recommendation (49%) than radiation oncologists (38%).
- When test results indicated DS Elevated risk, both surgeons (82%) and radiation oncologists (91%) were likely to recommended RT.
- When the results were low risk, surgeons were more likely than radiation oncologists to recommend omitting RT (83% vs. 68%, respectively).

- DCISionRT changed RT recommendations in 40% of women overall (n=969)
- **42%** of women initially recommended RT were **NOT** recommended RT after DCISionRT
- **34%** of women initially **NOT** recommended RT were recommended RT after DCISionRT

TABLE 1. Impact of DCISionRT on adjuvant radiation recommended 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
Age, years									
< 50	164	81%	48%	(32%)	43%	13%	37%	30-45%	<0.001
≥ 50	805	66%	51%	(16%)	42%	37%	41%	37-44%	<0.001
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Figure 1. RT Recommendation Pre- and Post DCISionRT Test Results

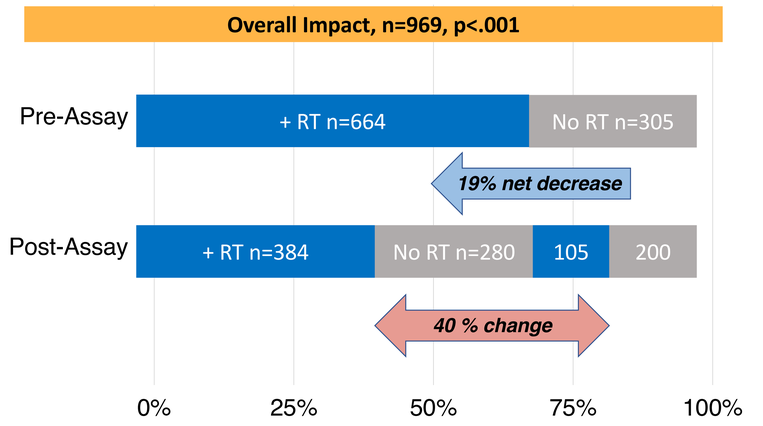
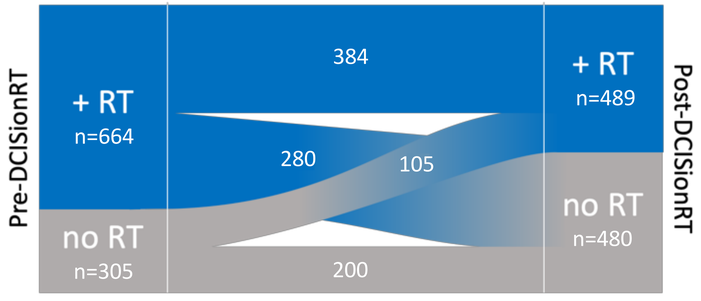


Figure 2. DCISionRT Decision Impact on RT Recommendation



Conclusions

- This interim analysis demonstrates a significant percent change in recommendations to add or omit RT based on DCISionRT results in 969 patients.
- Compared to traditional clinicopathologic features, the factor most strongly associated with RT recommendation was the DCISionRT result with other factors of importance being patient preference, tumor size and grade.
- The integration of DCISionRT into clinical decision processes has substantial impact on recommendations aimed at optimal management to prevent over- or under-treatment.