Interim Analysis of the DCISionRT PREDICT Study: Clinical Utility of a Biologic Signature Predictive of Radiation Therapy (RT) Benefit in Patients with DCIS

Pat Whitworth[1], Charles Cox[2], Rakesh Patel[3], Eric Brown[4], Linsey Gold[5], David Rock[6], Peter Beitsch[7] Jess Savala[8], Steven Shivers[9], Troy Bremer[10]

[1] Nashville Breast Center, Nashville, TN. [2,9] University of South Florida Tampa, FL. [3] Good Samaritan Cancer Center, Los Gatos, CA. [4,5] Comprehensive Breast Care, Detroit, MI. [6] 21st Century Oncology, Fort Myers, FL. [7] Dallas Surgical, Dallas, TX [7] 21st Century Oncology, Fort Myers, FL. [8,10] PreludeDx, Laguna Hills, CA.

Background

- When considered in the context of monetary, health-related, and quality-of-life costs associated with post-surgical adjuvant treatments, there remains a need for prognostic and predictive tools for women diagnosed with Ductal Carcinoma In Situ (DCIS) to help optimize individual treatment planning. DCISionRT, a biologic signature, provides a validated score for assessing 10-year risk and radiation therapy (RT) benefit using individual tumor biology in conjunction with clinical and pathologic risk factors.
- The clinical impact of DCISionRT will be evaluated in the management of patients diagnosed with pure DCIS and surgically treated compared to using traditional clinical and pathologic risk factors in physician's recommended treatment plan. The sample size of the completed PREDICT study will comprise up to 2,500 patients from up to 100 sites. This is the planned early interim analysis in this study.

Materials & Methods

- A post-market decision impact registry study is being conducted to assess the impact of DCISionRT score (DS) in changing treatment recommendations for women diagnosed with pure DCIS. The inclusion criteria consisted of females over the age of 25, who are candidates for breast conserving surgery, eligible for radiation or systemic treatment and have sufficient tissue to generate test results. All enrolled patients provided signed IRB-approved informed consent. Survey forms were completed pre- and post- DCISionRT test results. Baseline patient diagnosis, clinical and pathologic factors were collected. Summary statistics were provided as percentages and counts. All DCISionRT assays were performed at PreludeDx.
- An interim analysis was performed to assess frequency of recommended decision change pre- vs post-assay for RT and adjuvant hormone therapy (HT). Additional analyses include changes in RT recommendation by patient age, tumor nuclear grade and size subsets. Net change in treatment recommendations were assessed. All hypothesis tests were two-sided and a p-value of <0.05 was considered statistically significant.

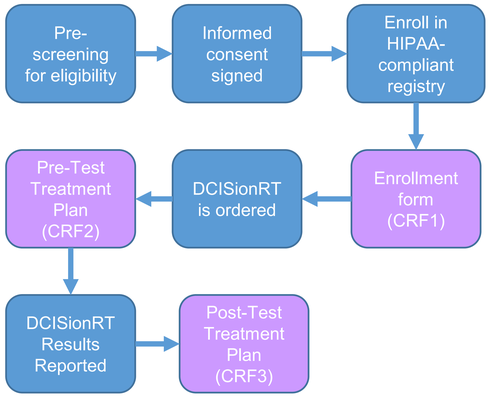
Results

- There were 195 patients with complete data available from 18 sites. The median age of the patients was 64 years. The DCIS tumor grade was high in 31% of patients, the size of the tumor was 1 cm or greater for 38% of patients, and 17% of patients were 50 years of age or younger. 59% of patients had a DCISionRT low risk result (DS≤ 3) and 41% of the patients had an elevated risk result (DS>3).
- Post-assay, the treatment recommendation for RT (yes/no) was changed for 51% of women and HT recommendation was changed for 13% of women.
- There was an overall net absolute 22% decrease in RT recommendation, 72% pre-assay to 50% post-assay (p<0.001).
- In DS low-risk patients RT recommendation decreased by 52% (p<0.001), while in DS elevated-risk patients RT recommendation increased by 20% (p=0.0046).
- The percentage changes in RT recommendations post-assay did not differ significantly for patients by age, grade or size.

Patient Distribution by Clinicopathology and DCISionRT Risk Group

	n=195	
Age in Years (median)	64	
Age Group		
≤50 years	33	17%
>50 years	162	83%
Tumor Size Group		
<10 mm	120	62%
≥10 mm	75	38%
Nuclear Grade		
Grade 1	43	22%
Grade 2	91	47%
Grade 3	61	31%
DCISionRT Risk Category		
Low Risk	116	59%
Elevated Risk	79	41%

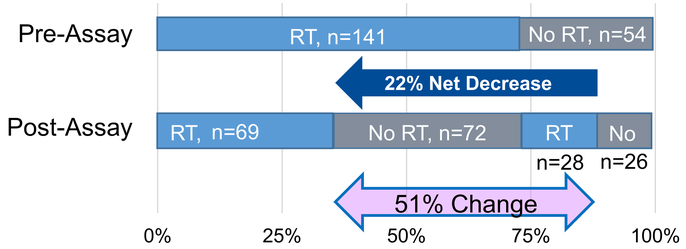
Decision Impact Study Flow Diagram



Radiation Therapy recommendation (Pre- and Post- DCISionRT test)

DCISionRT®

Total RT Impact, n=195, p<0.001



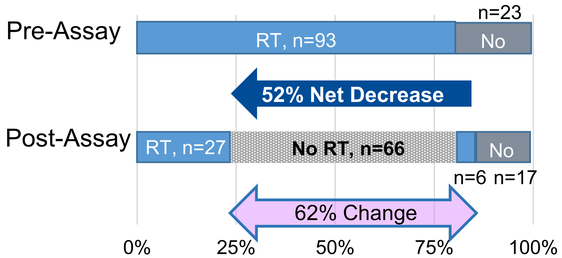
DCISionRT®

Total RT Impact by Clinicopathology

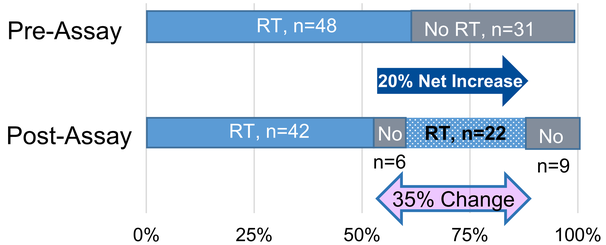
Clinical Pathology	Recommendation Change (n=195)
Age	
≤ 50	16/33 (48%)
> 50	84/162 (52%)
Tumor Size	
< 10 mm	66/120 (55%)
≥ 10 mm	34/75 (45%)
Nuclear Grade	
Grade 1 or 2	71/134 (53%)
Grade 3	29/61 (48%)

51% Total impact on Radiation Therapy recommendation

Impact in DS **Low Risk** (DS ≤ 3), n=116, p<0.001



Impact in DS **Elevated Risk** (DS > 3), n=79, p=0.0046



Discussion

- **PREDICT interim analysis demonstrates significant absolute overall change in RT recommendation based on DCISionRT.**
- **Treatment recommendations were changed post-assay for 51% of women for RT and 13% of women for HT.**
- **Integration of DCISionRT impacts the clinical-decision process as clinicians and patients consider strategies aimed at reducing overtreatment and minimizing undertreatment.**

Copyright 2019 | Prelude Corp. | 26051 Merit Circle, Suite 103 | Laguna Hills, CA | Corresponding Author: Troy Bremer | tbremer@preludedx.com | For further information about Prelude, contact Tyler Kibbee | tkibbee@preludedx.com