

# The American Society of Breast Surgeons Annual Meeting 2019

**Abstract:** 636072

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

**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.

**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.

**Conclusions:** There were 121 patients with complete data available from 16 sites. The median age of the patients was 62 years. The DCIS tumor grade was high in 31% of patients, the size of the tumor was 1 cm or greater for 37% of patients, and 14% of patients were 50 years of age or younger. 64% of patients had a DCISionRT low risk result ( $DS \leq 3$ ) and 36% of the patients had an elevated risk result ( $DS > 3$ ).

Post-assay, the treatment recommendation for RT (yes/no) was changed for 52% of women and HT recommendation was changed for 15% of women. There was an overall net absolute 28% decrease in RT recommendation, 76% pre-assay to 48% post-assay ( $p=0.0027$ ). In DS low-risk patients RT recommendation decreased by 52%, while in DS elevated-risk patients RT recommendation increased by 14%. The percentage changes in RT recommendations post-assay did not differ significantly for patients by age, grade or size.

**Discussion:** The PREDICT study interim analysis demonstrates a significant absolute overall change in RT recommendation based on DCISionRT for 121 patients. Treatment recommendations were changed post-assay for 52% of women for RT and 15% 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.

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TABLE 1 – Pre-Post DCISionRT Individual Recommendation Impact

Post-assay Individual Tx Recommendation	Low Risk (DS≤3) (n=77)	Elevated Risk (DS>3) (n=44)	TOTAL (n=121)
<b>RT</b>	48 (62%)	14 (32%)	62 (52%)
No to Yes	4 ( 5%)	10 (23%)	14 (12%)
Yes to No	44 (57%)	4 ( 9%)	48 (40%)
<b>HT</b>	11 (14%)	7 (16%)	18 (15%)
No to Yes	4 ( 5%)	5 (11%)	9 ( 7%)
Yes to No	7 ( 9%)	2 ( 5%)	9 ( 7%)

CLINICAL PATHOLOGY	RT Recommendation Change
AGE ≤ 50	9/17 (53%)
AGE > 50	53/104 (51%)
GRAGE 1 or 2	46/83 (55%)
GRADE 3	16/38 (42%)
SIZE < 1 cm	42/76 (55%)
SIZE ≥ 1 cm	20/45 (44%)

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