DCISionRT®

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Title: Clinical utility of a biologic signature to assess DCIS recurrence risk in patients meeting 'good-risk' criteria (RTOG 9804, ECOG 5194): Interim analysis of the DCISionRT PREDICT study

Background: When considering health-related, quality-of-life and monetary costs associated with post-surgical treatments for women diagnosed with Ductal Carcinoma In Situ (DCIS), there remains a need for prognostic and predictive tools to help design individual treatment planning. DCISionRT (PreludeDx, Laguna Hills, CA) is a validated biologic signature to assess the 10-year event risk for DCIS patients managed with breast conserving surgery (BCS). The 10-year risks are provided separately for patients treated with and without adjuvant radiation therapy (RT) after BCS. The study was designed to measure the change in adjuvant RT recommendation. This is a planned interim analysis of the study, which will eventually comprise up to 2,500 patients and 100 sites.

Methods: The registry includes females over the age of 25 who are candidates for breast conserving surgery and eligible for RT. Survey forms are completed pre- and post-DCISionRT test to capture treatment recommendations and patient preferences. This interim analysis was performed to assess changes in RT recommendation for patients treated with BCS in different clinicopathologic subgroups. Specifically, 'good risk' profiles were based on the RTOG 9804 and ECOG 5194 study designs. RTOG 9804 like criteria was screening detected tumors with nuclear grade of 1 or 2, size of ≤ 2.5 cm, and clear (≥ 2 mm) surgical margins. ECOG 5194 like criteria was tumors with nuclear grade of 1 or 2, size of ≤ 2.5 cm, and clear surgical margins, or nuclear grade of 3, size of ≤ 1 cm, and clear surgical margins. Statistics were provided as percentages and counts, and McNemar's test was used to assess change in RT with a p-value of <0.05 considered statistically significant.

Results: There were 513 patients from 32 sites with testing completed after treatment with BCS. Of these patients, 16% were ≤ 50 years of age, 60% were ≥ 60 years of age, and 26% were ≥ 70 years of age. The DCIS tumor nuclear grade was high in 32% of patients, and the size of the tumor was ≤ 1 cm for 68% of patients. There were 49% of patients who met RTOG 9804 like criteria, 51% who met the ECOG 5194 (grade 1 or 2) criteria, and 45% of patients who met the ECOG 5194 (grade 3) criteria. RT was recommended to 52% and 53% patients for RTOG 9804/ECOG 5194 (grade 1 or 2) criteria pre-testing, and 42% post-testing. For ECOG 5194 (grade 3) like criteria, 64% of patients were recommended RT pre-test, and 40% were recommended RT post-test. In all criteria groups, for patients whom were initially recommended RT pre-test, 51% to 54% were not recommended RT post-test, while patients initially not recommended RT pre-test, 25% to 37% were recommended RT post-test. Overall, the post-test RT recommendation was significantly changed from between 42% and 46% for patients with 'good-risk' clinicopathologic criteria.

Conclusions: The PREDICT study interim analysis demonstrates a significant absolute overall change post DCISionRT testing for RT recommendation in patients with 'good-risk' clinicopathology. RT recommendations were changed post-test for 42% to 46% of patients meeting RTOG 9804/ECOG 5194 like criteria. Integration of DCISionRT testing had a significant impact on the RT recommendations aimed at reducing overtreatment and minimizing undertreatment.

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TABLE 1 – Pre-Post DCISionRT Impact by 'good-risk' criteria.

	n	% RT Pretest Yes	% RT Posttest Yes	% RT Pre-Yes, Post-No	% RT Pre-No, Post-Yes	% Total Decision Change	95% CI	pvalue
RTOG 9804 criteria								
Grade 1 or 2, Size ≤ 2.5 cm, screen detected, wide margins	252	52	42	54	37	46%	40 - 52%	1.2E-02
ECOG E5194 criteria								
Grade 1 and 2, Size ≤ 2.5 cm, wide margins	262	53	42	53	36	45%	39 - 51%	0.010
Grade 3, Size ≤ 1 cm, wide margins	231	64	40	51	25	42%	36 - 48%	2.4E-08

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