The 12-gene Oncotype DX® Breast DCIS Score™ assay: A summary of clinical evidence and commercial experience

Michael Alvarado,1 Debbie McCullough,2 Anna Lau,3 Frederick L. Baehner,1,2 Melissa C. Stöppler2
1University of California, San Francisco, San Francisco, CA; 2Genomic Health, Inc., Redwood City, CA.

BACKGROUND
- Most patients with ductal carcinomas in situ (DCIS) receive radiation therapy (XRT) after breast-conserving surgery (BCS) to reduce local recurrence rates [1-3], despite no improvement in disease-specific survival [4,5].
- Although risk models based on clinicopathologic factors (eg, Van Nuys Prognostic Index [VNPI] or Memorial Sloan Kettering Cancer Center [MSKCC] nomogram) can help assess a patient’s risk of recurrence [6-11], they are based on population averages and may lose precision when applied to individual patients [12].
- The 12-gene DCIS Score assay is the first multigene assay that provides individualized estimates of 10-year local recurrence risk (invasive and non-invasive) [12,13].
- The assay has been commercially available since 2015.

OBJECTIVES
- To summarize the clinical evidence supporting use of the DCIS Score assay.
- To assess use of the DCIS Score assay in routine practice, as represented by the Genomic Health, Inc. commercial database.
- To identify areas for future research and clinical study.

METHODS
- Peer-reviewed publications were reviewed through January 2017.
- Studies that generated clinical evidence on the validation and utility of the 12-gene DCIS Score assay were included.
- DCIS assay results were performed by Genomic Health from January 2012 to October 2016 were analyzed.
- Study findings and commercial database information were summarized descriptively.

RESULTS

Figure 1. DCIS Score Distribution
- DCIS Score distribution by risk group is similar across all cohorts examined.
- The 2017 cohort was selected for XRT analysis, as this cohort had the lowest percentage (42.5%) of low DCIS Score results.
- The majority of patients tested had low DCIS Score results.

Figure 2. Kaplan-Meier Estimates of Risk, by DCIS Score Group

Table 1. List of Studies Included

Table 2. Multivariable Analyses of Factors Associated With Risk

Table 3. Decisional Conflict Scale and State-Trait Anxiety Inventory Scores, Pre- and Post-assay (Manders 2016)

Figure 3. XRT Treatment Recommendations Pre- and post-assay Overall

Figure 4. XRT Treatment Recommendations Pre- and post-assay by DCIS Score Risk Group

Figure 5. Commercial DCIS Score Distribution by Clinical and Pathologic Characteristics

Table 4. Characteristics of Patients in the Genomic Health Commercial Database (N=11,350)

Table 5. Characteristics of Patients in the Genomic Health Commercial Database (N=11,350)

REFERENCES

CONCLUSIONS
- The 12-gene DCIS Score assay is the first clinically validated multigene assay that provides individualized local recurrence risk information for patients with DCIS—information based on tumor biology and independent of clinicopathologic features.
- This information is actionable and useful to physicians and patients alike when making XRT decisions, and may reduce the overtreatment of patients with biologically low-risk disease.
- Analysis of samples sequenced in clinical practice showed that real-world, contemporary patients are overall similar to those who were enrolled in clinical studies of the DCIS Score assay.