

Risk of DCIS recurrence by Oncotype DCIS technology - some concerns

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Re: Cancerscope: New method to predict DCIS recurrence. Cancer 119: 3899. November 15, 2013.

Predicting patients with DCIS who will recur locally: we've been trying to do that for 30 years. But now we can, the Holy Grail has been recovered in the form of Oncotype DCIS, or so we've been told. A single genetic test capable of identifying risk of local recurrence after breast conservation for mammographically detected DCIS would obviate the need to factor in DCIS grade, size, margin width and age.

The Oncotype DCIS gene signature assay was validated in a registration trial (Solin et al 2013) which strictly defined permissible size 25 mm or less for low-intermediate grade and 10 mm or less for high grade and margin widths (3 mm or more).

Unfortunately most medical oncologists ordering the Oncotype DCIS assay do not appreciate the limitations of the validated results. They order the \$4,000 test for all sizes of DCIS and all margin widths. The test, if valid, is only valid if the strict protocol required of ECOG-E5194 is adhered to. A transected DCIS is likely to recur in spite of a low Oncotype DCIS score. A recent example of a 46 year old with a low risk Oncotype DCIS score had 42 mm of disease and 3 mm margins. Her DCIS grade was intermediate with focal necrosis. A Van Nuys Prognostic Index calculation results in a total score of 9 (grade= 2, size-3, margin-2 and age-2). Oncotype DX provided a 10 year risk of recurrence of 15% whereas the UISC/VNPI projects a local recurrence risk of 40-50% without irradiation,. The Oncotype DX assay is in essence a grading system based on gene expression, and is comparable to histologic grading of DCIS. Because it does not factor in a variety of important predictive factors such as age, margin width, extent of DCIS, nuclear grade and necrosis, it is not likely to be accurate for the majority of patients. No single test, especially one in which other prognostic factors are ignored can validly estimate risk of local recurrence for DCIS.

REFERENCES:

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Solin LJ, Gray R, Baehner FL et al. 2013. A multigene expression assay to predict local recurrence risk for ductal carcinoma in situ of the breast. J Natl Cancer Inst, 105: 701-71