

[P5-17-03] The 12-gene DCIS score assay: Impact on radiation treatment (XRT) recommendations and clinical utility

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Background: In the management of DCIS clinicians and patients (pts) must choose between the various options for breast conservation treatment based on an assessment of local recurrence (LR) risk. Traditional clinicopathologic (CP) factors such as age, size, grade, margin width or comedo necrosis, provide an average LR risk derived from clinical trials and population studies. The Oncotype DX® 12-gene assay for DCIS gives individual 10-yr LR risk estimates and has now been validated in two studies in a total of 893 pts. We report the 2nd study assessing the impact of the DCIS Score result on XRT recommendations. In addition, surveys assessing pt and physician confidence will provide insight into the overall clinical utility of the DCIS Score result. Baseline characteristics including the pre-assay LR risk and XRT recommendation are described here; final results on change in XRT recommendation from pre- to post-assay and distribution of the score across the CP factors will be presented.

Methods: 13 U.S. sites enrolled pts with DCIS from 3/2014-5/2015. Pts with LCIS but no DCIS, invasive BC, or planned mastectomy were excluded. Data were prospectively collected on CP factors, physician estimates of LR risk, DCIS score, and pre/post XRT recommendation. Each pt had a surgeon and radiation oncologist complete study surveys. Pt surveys were also administered pre/post assay for decision conflict and the STAIT anxiety survey. The LR risk estimates and XRT recommendations were analyzed for all physicians as well as by specialty. Descriptive statistics summarized study variables. 95% Clopper-Pearson Exact CIs were calculated for percent change in XRT recommendation. McNemar's test was used to determine if the proportion of pts had a significant change in XRT recommendation post assay. Paired t-tests were used to compare physician estimates of recurrence risk pre/post assay.

Results: Of the 121 pts enrolled, median age was 61y (34-83) and 80.2% were postmenopausal. Median size was 8mm and 40% were \leq 5mm; 22.3% were grade 1, 51.2% grade 2, and 26.4% grade 3. Comedo necrosis was noted in 55.4% and 19% had multiple foci. Median margin width was 3mm and 47.1% had margins 1-3mm. ER and PR by IHC were positive in 88.4% and 75.2% of pts. Among the 242 MD risk assessments, mean 10-yr LR risk was 14.8% (range 4-50%) for any LR; 14.2% for surgeons and 15.3% for radiation oncologists. The pre-assay XRT recommendation was 70.2%; 68.6% for surgeons and 71.9% for radiation oncologists.

Conclusions: The role of new molecular tools such as the DCIS Score assay that provide individual risk estimates for LR on treatment decisions is evolving. The DCIS pts enrolled in the study reveal inclusion of baseline features like higher nuclear grade (26%), comedo necrosis (55%) and margin width of 1-3mm (47%) that have historically been associated with XRT use. This represents a continued broadening of the assay use from the predominantly lower risk DCIS cohort in the 1st validation study (E5194). The impact on XRT decisions is critical to establishing the clinical utility of the assay. The decision impact analysis, differences in use of the assay among surgeons and radiation oncologists and the impact on overall confidence with the treatment decision will be presented.

Friday, December 11, 2015 5:00 PM

Poster Session 5: Treatment: DCIS/LCIS (5:00 PM-7:00 PM)

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