

## Cost-effectiveness of gene expression profiling for ductal carcinoma in-situ (Oncotype DCIS Score)

Alvarado MD, Harrison L, Solin LJ, Ozanne EM

General Surgery, University of California San Francisco, San Francisco, California, United States, 94116 and  
Radiation Oncology, Albert Einstein Medical Center, Philadelphia, PA, United States, 19141.

**BACKGROUND:** Ductal carcinoma in-situ (DCIS) affects nearly 50,000 women each year. More than 75% of women who receive lumpectomy (BCS) for DCIS undergo whole breast radiation (XRT), which is known to prevent local recurrences. A molecular assay for DCIS has recently been validated, that identifies low-risk biology and may give insight into the need for adjuvant XRT. We sought to determine the cost-effectiveness of the Oncotype DCIS Score™ for risk stratification in newly diagnosed DCIS.

**METHODS:** We conducted a cost-effectiveness analysis of using this molecular assay (validated in the E5194 study) compared to standard clinical assessment to determine treatment recommendation for XRT. A Markov model was developed in TreeAge Pro 2011 and simulated relevant outcomes over a lifetime horizon for 55-year-old women. For those in the intervention arm who are stratified by the assay, it was assumed that 75% of women (low DCIS score) did not receive XRT and had local risk of recurrence (LRR) of 12%; 25% were intermediate or high risk by the DCIS score (LRR of 26%) and received 6 weeks of XRT with an assumed LRR of 13%. For those in the standard care arm who are stratified by clinical assessment, an assumed 25% did not receive XRT and had LRR of 15.4%; 75% received 6 weeks of XRT with an estimated LRR of 7.7%. Recurrence rates were based on ECOG 5194 and assumed 50% reduction with XRT. Utilities were derived from literature. Direct medical costs were obtained from Medicare fee schedule; indirect costs (time and transportation for XRT) were ascertained.

**RESULTS:** On average, the intervention (assay) strategy was less costly than the clinical assessment strategy by approximately \$1000/patient, with similar life expectancies (17.15 vs 17.11, respectively) and quality-adjusted lifeyears (QALYs) (16.777 vs 16.789). The incremental cost-effectiveness ratio (ICER) for changing strategy from the assay to clinical assessment was approximately \$95,000/QALY, at the upper limit of the societal accepted willingness to- pay threshold.

**CONCLUSIONS:** Based on the conservative assumptions that the benefit of XRT is independent of biology and that at least 75% of patients in E5194 would typically be offered XRT, the assay strategy is more cost-effective than standard clinical assessment. Additional research is needed to better understand health state utilities associated with less treatment as it pertains to risk of recurrence. Further validation studies of the assay are needed to accurately assess radiation benefit across all risk groups.