

ASCO 2004 Abstract Submission

Economic analysis of targeting chemotherapy (CT) using a 21 gene RT-PCR assay in lymph node negative (LN-), estrogen receptor positive (ER+) early-stage breast cancer (ESBC)

Short Title:

Economics of Expression Profiling

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Background: Guidelines for LN-, ER+ adjuvant therapy stratify women into risk categories to optimize decisions concerning adjuvant CT use. A 21 gene RT-PCR assay, Oncotype DX™ Recurrence Score (RS), has been prospectively validated as a predictor of distant recurrence-free survival (DRFS) in the NSABP B-14 study of 668 evaluable LN-, ER+ patients receiving tamoxifen (Paik et al, SABCS 2003). The economic impact of using the RS to guide CT decision-making has not been assessed.

Methods: The primary analysis was between (1) No RS Testing and CT if high risk based on NCCN criteria versus (2) RS Testing and CT based on Recurrence Score estimates of 10 yr DRFS. Using estimates of CT efficacy from NSABP B-20, and cancer care costs from CMS and literature, we calculated marginal (added) costs (\$), efficacy (life-yrs) and cost-effectiveness (C/E; cost per life-yr gained).

Results: Using NCCN criteria, 53 pts (8%) of the 668 pts would be classified as low risk with a 10-yr DRFS of 0.93 (95% CI, 0.86, 1.00). 28% of low risk patients by NCCN criteria would be reclassified to moderate or high risk by the RS. For low risk patients currently not receiving CT, recommending CT based on the Recurrence Score is predicted to increase mean 10-yr DRFS by 0.25 yrs. Using the Recurrence Score as a continuous function to identify the high-risk patients by NCCN that would be reclassified as lower risk, various RS cut-off points were evaluated. For example, model comparisons of treatment based on NCCN criteria versus RS criteria (e.g., RS<10) provide estimates of marginal costs: \$1716; effectiveness: 0.6 year; and C/E: \$3102/life-yr gained. For pts reclassified by RS as low risk, foregoing CT is also predicted to result in improved quality-adjusted survival.

Conclusions: The Recurrence Score assay is a valid prognostic tool in selecting patients for more effective and C/E treatment strategies. The C/E of the RS assay for targeting the addition of adjuvant CT in LN-, ER+ ESBC is well within accepted ranges for healthcare technologies.

Keyword (Complete): Guidelines ; Breast cancer ; Prognosis

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