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21-gene RT-PCR assay in lymph node negative (LN-), estrogen receptor positive (ER+) breast cancer: An economic analysis including prognostic and predictive information.

Background: The prognostic accuracy of a 21-gene RT-PCR assay has undergone validation in 668 evaluable LN-, ER+ early stage breast cancer patients receiving tamoxifen on NSABP B-14 (Paik, NEJM 2004) and its economic evaluation (Hornberger, Am J Man Care 2005). Assay predictive accuracy for response to chemotherapy or tamoxifen has also undergone recent validation in 651 patients on NSABP B-20 and 645 patients on NSABP B-14 (Paik, SABCS 2004).

Methods: Based on the model recurrence score (RS), women with LN-, ER+ breast cancer with and without adjuvant chemotherapy (C) or tamoxifen (T) were classified as high (RS >31), intermediate (RS 18-30) or low (RS <18) risk of distant recurrence at 10 years. Incremental costs (\$), life-years (LYs), quality-adjusted LYs (QALYs) and cost-effectiveness (C/E; cost per LY gained) were estimated for: RS-guided treatment (RSGT) with T for low and intermediate risk patients and C+T for high-risk patients, compared to either T alone or C+T for all patients.

Results: Under base case assumptions, no significant difference in life expectancy at 10 years is estimated between the RSGT and C+T strategies whereas RSGT is associated with a gain in individual life expectancy of 2.7 LYs compared to T alone. RSGT is estimated to yield a net cost savings of \$4,502 compared to C+T with an incremental C/E of \$1,059 per LY saved compared to T alone. At a utility of 90% associated with adjuvant chemotherapy, RSGT is associated with a gain in individual QALYs of 1.82 compared to T alone at a cost utility of \$1,573/QALY and a gain in 3.21 QALYs compared to C+T. RSGT is associated with lower expected cost than C+T for total chemotherapy costs above \$3,998. The gain in LYs with RSGT compared to T alone increases with healthy age-specific life expectancy (years) while the cost per LY gained decreases.

Conclusions: Treatment based on the RSGT compared to T alone is associated with acceptable C/E ratios and substantially lower toxicity and cost compared to C+T.

Age-Specific Life Expectancy (LY)	10	20	30	40	50
LY gained over T alone	1.32	2.70	4.08	5.46	6.84
C/E (\$/LY gained)	2,167	1,059	700	523	418