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Impact of a 21-gene RT-PCR assay on treatment decisions in early-stage breast cancer: an economic analysis based on prognostic and predictive validation studies.

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Abstract

BACKGROUND: The prognostic accuracy for distant recurrence-free survival using a 21-gene reverse-transcriptase polymerase chain reaction (RT-PCR) assay underwent validation in 668 lymph node-negative, estrogen receptor-positive women with early-stage breast cancer receiving tamoxifen on National Surgical Adjuvant Breast Program (NSABP) B-14. The predictive accuracy for treatment efficacy also underwent validation in 651 patients randomized on NSABP B-20 and 645 patients on NSABP B-14.

METHODS: Patients were classified as high (recurrence score [RS] ≥ 31), intermediate (RS 18-30), or low (RS < 18) risk for distant recurrence at 10 years. Cost-effectiveness ratios were estimated for RS-guided treatment compared with either tamoxifen alone or the combined chemotherapy and tamoxifen.

RESULTS: Distant recurrence was reported in RS low-risk, intermediate-risk, and high-risk patients at 10 years in 3.7%, 17.8%, and 38.3% receiving tamoxifen alone and 5.0%, 10.1%, and 11.1% receiving the chemotherapy and tamoxifen. RS-guided therapy is associated with a gain in individual life expectancy of 2.2 years compared with tamoxifen alone, whereas it is associated with similar life expectancy to that seen with the chemotherapy and tamoxifen strategy. RS-guided therapy is estimated to provide a net cost savings of \$2256 compared with chemotherapy and tamoxifen with an incremental cost-effectiveness ratio of \$1944 per life year saved compared with tamoxifen alone.

CONCLUSIONS: Treatment decisions based on RS-guided therapy compared with tamoxifen alone are associated with greater efficacy with acceptable cost-effectiveness ratios, and associated with similar efficacy and lower cost compared with chemotherapy and tamoxifen for patients with lymph node-negative, estrogen receptor-positive early-stage breast cancer.

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