

Societal economics of the 21-gene Recurrence Score[®] in estrogen-receptor-positive early-stage breast cancer in Japan

Yamauchi H, MD¹, Nakagawa C, MPP¹, Yamashige S, PhD², Takei H, PhD³, Yagata H, MD, PhD¹, Yoshida A, MD¹, Hayashi N, MD, PhD¹, Hornberger J, MD, MS^{4,5}, Yu T, BS, BA⁴, Chien R, BA^{4,6}, Chao C, MD⁷, Yoshizawa C, PhD⁷, Nakamura S, MD, PhD^{1,8}.

Background: Breast cancer incidence and breast-cancer mortality have been increasing in Japan.

Primary data on the clinical validity and decision impact of the 21-gene Recurrence Score for guiding the use of adjuvant chemotherapy has been studied among a Japanese population.

Objective: The cost-effectiveness of the clinically validated 21-gene Recurrence Score for estrogen-receptor-positive, lymph-node-negative, early-stage breast cancer (ESBC) was assessed from a Japanese societal perspective.

Methods: The proportion of patients with low, intermediate, and high risk of recurrence by the 21-gene Recurrence Score and the influence of the Recurrence Score on use of adjuvant chemotherapy were obtained in a study of 104 patients. A Markov model was used to track time until distant recurrence and time from distant recurrence to death. Effect of adjuvant chemotherapy based on 21-gene Recurrence Score was based on published clinical validation studies. Direct and indirect medical costs were obtained from the referral center. Utilities associated with progression and adverse events associated with chemotherapy were extracted from the literature. Sensitivity analyses were performed to assess the key drivers of cost-effectiveness and the robustness of the findings to variations in the input estimates.

Results: Forty-eight percent of patients were identified by the 21-gene Recurrence Score as low-risk, 36% as intermediate-risk, and 16% as high-risk. Chemotherapy use overall decreased by 19%, resulting in an average increase of 0.235 QALYs. Testing with the 21-gene Recurrence Score cost ¥350,000 per patient with ¥153,490 lower acute costs because fewer women were treated with adjuvant chemotherapy. Eighteen percent more women who were identified as high risk were recommended adjuvant chemotherapy, which results in longer progression-free survival. On average across all risk groups, cost of monitoring until recurrence per patient increased by ¥3,572 and costs associated with recurrence declined by ¥43,687. Use of the 21-gene Recurrence Score resulted in a net cost of ¥665,455 (\$8,386) per QALY gained.

Conclusion: The change in decisions resulting from use of the 21-gene Recurrence Score in women with estrogen-receptor-positive, lymph-node-negative, ESBC is projected to be societally cost-effective in Japan.