

中文題目：21 基因表達檢驗使用於台灣女性早期乳癌病患的真實世界數據分析

英文題目：Real-world utilization of the 21-gene assay in Taiwanese patients with early female breast cancer

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**Background:** Adjuvant therapy is crucial to reduce recurrence risk in patients with early female breast cancer. Several genomic tests are developed to optimize the use of adjuvant chemotherapy in patients with estrogen receptor-positive (ER+), human epidermal growth factor 2-negative (HER2-) breast cancer. Clinical trials have demonstrated that the 21-gene Oncotype DX® assay can predict benefit of adjuvant chemotherapy in patients with ER+HER2- breast cancer; however, clinical impact of this assay on Taiwanese patients remains unclear. In this study, we aimed to evaluate real-world utilization of the Oncotype DX assay in Taiwanese patients with early breast cancer.

**Methods:** We compiled recurrence score (RS), clinicopathological characteristics and treatment outcome of female patients with early HR+/HER2- breast cancer that received the Oncotype DX assay at National Cheng Kung University Hospital between August 2016 and August 2021. Survival outcomes were estimated and analyzed using the Kaplan-Meier method and the Log-rank test, respectively. The correlations between clinicopathological characteristics and RS were analyzed using the Chi-square test or the Fisher's Exact test. In all analyses, a *P* value < 0.05 was recognized as being statistically significant.

**Results:** For adjuvant therapy of 106 recruited patients, 34 and 72 were recommended based on conventional and TAILORx-based cut points, respectively. In the conventional scoring group, 21 (61.8%) patients were classified into the RS 0–17 (low-risk), 10 (29.4%) into the RS 18–30 (intermediate-risk) and 3 (8.8%) into the RS 31–100 (high-risk) category. Chemotherapy was recommended for 20% (2/10) and 100% (3/3) of patients in the intermediate and high-risk category, respectively. In the TAILORx scoring group, 13 (18.1%) patients were divided into the RS 0–10, 52 (72.2%) into the RS 11–25 and 7 (9.7%) into the RS 26–100 category. 1.9% (1/52) of patients in the RS 11–25 category and 85.7% (6/7) in the RS 26–100 category received chemotherapy as their adjuvant therapy. During a median follow-up of 659 days, one patient who had RS 22 and no adjuvant chemotherapy judged by conventional cut points experienced tumor recurrence with local lymph node metastases. However, in the conventional scoring group, no statistical significance of recurrence-free survival (RFS) was found among patients in the low-, intermediate- and high-risk category. Moreover, there was no statistical significance in RFS between patients who received adjuvant chemotherapy and those who did not. In the correlation studies of all 106 patients, high risk of recurrence determined by TAILORx-based cut points (RS ≥ 26) was associated with the

percentage of progesterone receptor-positive cell less than 30% ( $P = 0.0015$ ), the percentage of Ki-67 positive cell greater than 14% ( $P = 0.004$ ) and tumor histology grade III ( $P = 0.001$ ).

**Conclusion:** Among Taiwanese patients with early HR+/HER2– breast cancer, a small proportion of those were classified as high-risk category determined by the Oncotype DX assay. Based on RS-guided treatment decisions, the survival outcomes were similar between patients who received adjuvant chemotherapy and those who did not. In clinical practice, tumor tissues classified into high-risk category were correlated with low percentage of progesterone receptor-positive cell, high percentage of Ki-67 positive cell and advanced tumor histology grade.