Speech Abstract

Topic:

Immunotherapy in Early TNBC: Evolving Evidence, Maximizing Benefit Through Thoughtful Patient Selection

Abstract

Triple-negative breast cancer (TNBC) is the most aggressive subtype of breast cancer, defined by the absence of ER, PR, and HER2 expression. Therapeutic options remain limited, with chemotherapy as the mainstay of treatment. Among patients with high-risk early-stage TNBC, the risk of early relapse and breast cancer–specific mortality is notably high. The integration of immune checkpoint inhibitors into neoadjuvant chemotherapy—most notably pembrolizumab in the KEYNOTE-522 trial—has become the new standard of care, demonstrating improved event-free survival (EFS). Yet, despite this advancement, a substantial proportion of patients still relapse early, even among those achieving pathologic complete response (pCR), underscoring the limitations of current strategies. Biomarkers such as PD-L1 expression and tumor-infiltrating lymphocytes (TILs) have been explored for predictive value, but no validated molecular signature exists to reliably identify patients at risk of early failure. Therefore, further efforts are warranted to explore and validate prognostic and predictive biomarkers, evaluate real-world outcomes in Taiwanese cohorts, and assess the efficacy and clinical benefit of the KEYNOTE-522 regimen (immunotherapy plus anthracycline- and taxane-based chemotherapy), with the ultimate goal of identifying which patients are most likely to benefit from the combined approach.

To complement the evolving global evidence, we conducted a single-center retrospective analysis of early-stage TNBC patients in Taiwan who received pembrolizumab-based neoadjuvant therapy. Treatment regimens were largely aligned with the KEYNOTE-522 protocol. Preliminary results from our cohort suggest clinically meaningful pCR rates, especially among patients with favorable tumor characteristics—including lower T stage, high Ki-67, elevated TILs, and low ER positivity. Additionally, immune-related adverse events were observed, most commonly thyroid dysfunction, and were generally manageable. Patterns of recurrence, including a subset of central nervous system failures even among pCR responders, mirrored trends seen in exploratory analyses of KEYNOTE-522. These real-world findings from an Asian population reinforce the importance of thoughtful patient selection and the urgent need for predictive biomarkers to optimize benefit. Full data, including subgroup analyses and recurrence patterns, will be presented during the conference.