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Immune-related toxicities and pathological response to neoadjuvant pembrolizumab in triple-negative breast cancer: Real-world data from a Canarian center

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Background

Triple-negative breast cancer (TNBC) is an aggressive subtype with limited treatment options. The addition of pembrolizumab to neoadjuvant chemotherapy improves pathological complete response (pCR) and event-free survival. Nevertheless, this can lead to immune-related adverse events (irAEs).

Methods

We retrospectively analyzed patients with stage II–III TNBC treated with anthracycline- and taxane-based neoadjuvant chemotherapy plus pembrolizumab, followed by adjuvant pembrolizumab. Clinical data, tumor-infiltrating lymphocytes (TILs), irAEs, pathological response (ypT, ypN), and Residual Cancer Burden (RCB) were collected.

Results

Among 45 patients (median age 47), pCR (ypT0/ypN0) was achieved in 46.7%, and RCB 0 in 55.6% of patients. RCB 0 was observed in 73.9% of patients with moderate or abundant TILs, versus 20% in scarce TILs cohort (p=0.078). Overall, 42.2% of patients experienced irAEs. Of these, 24.4% were grade 1–2, typically self-limited and manageable with supportive measures. Grade 3 irAEs occurred in 17.8% of patients, required hospitalization, being nephritis the most frequent. 9 (20%) discontinued neoadjuvant pembrolizumab prematurely due to irAEs, with most of these occurring during the anthracycline phase. Additionally, 4 patients (9%) discontinued adjuvant pembrolizumab due to irAEs, primarily endocrine. Patients who developed irAEs had lower pCR rates compared to those without (30.8% vs 53.1%, p=0.302). The toxicity profile in this real-world setting highlights a higher than expected frequency of irAEs, leading to treatment interruption in 28.9% of patients.

Conclusions

In this real-world cohort, nearly half of patients experienced irAEs, with grade 3 events in 18%. Although most events were low-grade and manageable, immune toxicity was the main cause of pembrolizumab discontinuation. While not statistically significant, high TILs showed an association with improved pathological response. Nevertheless, irAEs did not correlate with higher pCR in our study. These findings emphasize the need for close monitoring and early management of toxicity, and support the integration of immune biomarkers in the treatment algorithm in early TNBC.

Legal entity responsible for the study

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Disclosure

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