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# Treatment patterns and safety of adjuvant therapy after chemoimmunotherapy for early-stage triple-negative breast cancer in a real-world scenario: the Neo-Real/GBECAM-0123 study

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**Introduction:** The KEYNOTE-522 trial established neoadjuvant pembrolizumab plus chemotherapy (P+CT) followed by adjuvant pembrolizumab as the standard of care for stage II–III triple-negative breast cancer. However, integrating this regimen with other adjuvant therapies, such as capecitabine or olaparib, remains uncertain in clinical practice. **Objective:** This study aimed to evaluate real-world treatment patterns and safety outcomes of adjuvant therapies following neoadjuvant P+CT. **Methods:** This multicentric Neo-Real/GBECAM-0123 study included triple-negative breast cancer patients treated with neoadjuvant P+CT since July 2010 across ten cancer centers. The analysis focused on treatment patterns and safety, particularly grade  $\geq 3$  adverse events (AEs). **Results:** Out of the 410 patients enrolled, 359 underwent surgery and 185 completed adjuvant therapy. The median age was 43 years; 69.5% had stage II and 25.8% had stage III disease. A pathologic complete response was achieved in 62.5% (n=218); among them, 85.9% continued adjuvant pembrolizumab. In breast cancer wild-type unknown patients with residual disease (n=114), 54.4% received pembrolizumab plus capecitabine (P+C), 26.3% pembrolizumab alone, and 10.5% capecitabine alone. Among breast cancer-mutated patients with residual disease (n=12), 75% received pembrolizumab plus olaparib (P+O), 16.7% P+C, and 8.3% olaparib alone. Grade  $\geq 3$  AEs rates were higher with P+C (16.3%) and P+O (14.3%) compared to pembrolizumab alone (6.3%; p=0.057). Anemia grade  $\geq 3$  occurred in 14.3% of P+O patients *vs.* 0% pembrolizumab alone, while diarrhea (6.1%) and hand-foot syndrome (8.2%) were more frequent with P+C. No increase in immune-related grade  $\geq 3$  AEs was observed with combinations. **Conclusion:** In a real-world scenario, most patients with triple-negative breast cancer continued adjuvant pembrolizumab after a pathologic complete response, while adjuvant capecitabine and adjuvant olaparib were frequently used in combination with pembrolizumab for those with residual disease. Combined adjuvant strategies showed higher rates of grade  $\geq 3$  AEs and drug discontinuations. The efficacy of the combined adjuvant strategies remains to be determined.

**Keywords:** breast neoplasms; adjuvant chemotherapy; immunotherapy; poly (ADP-ribose) polymerase inhibitors; capecitabine.