

PRESENTATION: ORAL PRESENTATION (GENERAL SESSION) – 2ND BEST SYSTEMIC TREATMENT STUDY

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974 – The relationship between tumor-infiltrating lymphocytes, pathologic complete response, and event-free survival in patients with early-stage triple-negative breast cancer treated with the KEYNOTE-522 regimen in a real-world scenario

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Introduction: Tumor-infiltrating lymphocytes (TILs) are established prognostic and predictive biomarkers in early-stage triple-negative breast cancer (eTNBC). The addition of pembrolizumab to neoadjuvant chemotherapy (NAC) improves outcomes, as demonstrated in the KEYNOTE-522 trial. The role of TILs in this setting warrants further evaluation.

Methods: Neo-Real/GBECAM-0123 is a retrospective multicenter cohort including patients with stage II–III TNBC treated with pembrolizumab plus NAC in Brazil and Argentina since 2020. Baseline stromal TILs were assessed on pre-treatment biopsies according to international guidelines and categorized as <30%, 30–49%, or ≥50%. Associations with pathologic complete response (pCR) and event-free survival (EFS) were analyzed using logistic and Cox regression models.

Results: Among 248 patients (median age of 44 years; 70.8% had stage II disease), TILs <30%, 30–49%, and ≥50% were observed in 72.6%, 12.9%, and 14.5%, respectively. In multivariable analysis, TILs ≥50% (odds ratio [OR] 6.96; 95% confidence interval [CI] 1.88–25.65; $p=0.004$) and Ki-67 expression ≥50% (OR 4.88; 95%CI 2.31–10.32; $p<0.001$) were strongly associated with pCR. Nearly all patients with both high TILs and Ki-67 achieved pCR. At a median follow-up of 24 months, pCR was associated with improved 2-year EFS (95.9% *vs.* 76.5%; $p<0.001$). In multivariable Cox analysis, pCR (hazard ratio [HR] 0.20; 95%CI 0.07–0.54; $p=0.002$) and clinical stage (HR 3.68 for stage III *vs.* stage II; $p=0.002$) were independent predictors of EFS, whereas TILs were not. Among patients with pCR, 2-year EFS exceeded 93% across TIL strata. In those with residual disease, EFS appeared numerically higher with increasing TILs, though analyses were limited by small sample sizes.

Conclusion: In this real-world cohort, high baseline TILs and Ki-67 were strongly associated with higher pCR rates with pembrolizumab plus NAC. Long-term outcomes were primarily driven by pathologic response and stage, highlighting the prognostic importance of achieving pCR.

Ethics: Research Ethics Committee Approval (CAAE 67950623.0.1001.0068).

Keywords: triple-negative breast cancers; neoadjuvant therapy; pembrolizumab; tumor infiltrating lymphocytes.