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975 – The high unmet need among patients with early relapse after the KEYNOTE-522 regimen: evidence from the Neo-Real/GBECAM-0123 study

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Introduction: Triple-negative breast cancer (TNBC) is an aggressive subtype marked by a high risk of early recurrence, typically within two years of treatment. With the incorporation of pembrolizumab into neoadjuvant chemotherapy as in the KEYNOTE-522 regimen, real-world data on recurrence patterns remain limited.

Objective: To describe rates and patterns of early recurrence in patients treated with pembrolizumab-based neoadjuvant chemotherapy.

Methods: Neo-Real/GBECAM-0123 is a real-world cohort including TNBC patients treated with pembrolizumab plus neoadjuvant chemotherapy across Brazil and Argentina since 2020. Early recurrence was defined as progression during therapy or recurrence within six months after treatment completion; subsequent events were classified as late recurrence. Event-free survival and overall survival were calculated from diagnosis.

Results: Among 726 patients (median age 44 years), most had stage II disease (70.5%), grade 3 tumors (68.9%), and high proliferation (Ki-67 expression $\geq 50\%$ in 71.1%); 14.5% carried BRCA1/2 pathogenic variants. After a median follow-up of 22 months, 74 patients (10.2%) developed recurrence, and eight (1.1%) died without recurrence. Two-year event-free survival was 86.9%. Of the recurrences, 67.6% were early, including a small proportion with progression during neoadjuvant therapy that precluded surgery. Early recurrence occurred in 2.1% of patients who achieved pathologic complete response *versus* 15.2% in those with residual disease ($p < 0.001$). Among patients with early recurrences after surgery, 80.4% had residual disease. Recurrence patterns differed by response: central nervous system involvement was common among patients with pathologic complete response, while locoregional, nodal, and visceral recurrences predominated in those with residual disease. Post-recurrence survival was poor among patients with early relapse. Two-year overall survival was 95.6%, but only 62.3% among patients with early recurrence *versus* 91.0% among those with late recurrence.

Conclusion: Most recurrences following pembrolizumab plus neoadjuvant chemotherapy occur early and are strongly associated with residual disease and poor survival. These findings highlight a critical unmet need for effective post-neoadjuvant strategies in high-risk TNBC patients.

Ethics: Research Ethics Committee Approval (CAAE 67950623.0.1001.0068).

Keywords: triple-negative breast cancers; recurrence; treatment outcome; pembrolizumab.