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Dose-dense versus 3-weekly ac during neoadjuvant chemoimmunotherapy for early-stage triple-negative breast cancer: GBECAM 0123 – the neo-real study

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Objective: This analysis aims to evaluate the effectiveness and safety of dose-dense AC (ddAC) compared with every 3 weeks (q3w) AC during neoadjuvant pembrolizumab plus chemotherapy (P+CT) for triple-negative breast cancer (TNBC). **Methodology:** The Neo-Real study is a collaborative real-world data effort evaluating patients treated with neoadjuvant P+CT since July 2020 in 10 cancer centers. Effectiveness endpoints were pathologic complete response (pCR) and residual cancer burden (RCB) 0–1. Factors associated with pCR and RCB 0–1 were also explored. Safety endpoints included drug discontinuation, grade ≥3 adverse events (AEs), and antibiotics use. **Results:** Among 333 patients included to date, 311 finished the neoadjuvant therapy phase (safety cohort) and 279 underwent surgery with available pathology reports (effectiveness cohort). ddAC was used in 58.2% and q3w AC in 41.8% of the cases. Most patients (69.1%) had stage II TNBC. A pCR was observed in 65.4% with ddAC and 58.7% with q3w AC (p=0.260), while RCB 0–1 occurred in 82.4% and 73.5%, respectively (p=0.115). Patients with stage III disease had a numerically higher pCR with ddAC (59% vs. 40%, p=0.155), while pCR rates were similar regardless of AC schedule in stage II disease (66.6% vs. 64.5%; p=0.760). Ki67 ≥50%, tumor grade 3, and TILs ≥30% were identified as predictors of higher pCR rates, while clinical stage III and receiving <6 cycles of neoadjuvant pembrolizumab were associated with a decreased pCR. While no significant disparities in drug discontinuation or antibiotics use were noted, ddAC showed a trend toward higher rates of grade ≥3 AE (40.5% vs. 30.7%, p=0.092), particularly febrile neutropenia (16% vs. 9.2%). **Conclusion:** The Neo-Real study found no statistically significant differences in effectiveness or safety between ddAC and q3w AC during neoadjuvant P+CT. However, the numerically higher pCR rates with ddAC in patients with stage III disease deserve further investigation.

Keywords: triple-negative breast neoplasms; immunotherapy; anthracyclines; neoadjuvant therapy.