# EFFECTIVENESS AND SAFETY OF WEIGHT-BASED PEMBROLIZUMAB DOSING IN THE NEOADJUVANT TREATMENT OF TRIPLE-NEGATIVE BREAST CANCER: REAL-WORLD EVIDENCE VERSUS PIVOTAL TRIALS 4CPS-324

Bodas del Viejo, S[1]; Guerrero Blanca, MI[1]; Rosado Ancín, M[1]; Lara Verdejo, C[1]; Olaizola Diez, I[1]; Jerez Ros, P[1]; Bernárdez Domínguez, M[1]; Yuste Olmos, D[1]; Pinel Varona, A[1]; Miguelez Sánchez, M[1]; Ruiz Lorca, L[1];
[1]Hospital Universitario Río Hortega. Valladolid (Spain)

## BACKGROUND AND IMPORTANCE

Pembrolizumab at fixed dose (200 mg every 3 weeks) improves pathological complete response (pCR) in neoadjuvant triple-negative breast cancer (TNBC), as shown in KEYNOTE-522. In our routine practice, a weight-based regimen (2 mg/kg every 3 weeks) is used, potentially optimising resource utilisation. Evidence from real-world settings is limited.

## AIM AND OBJECTIVES

The aim of this study was to evaluate effectiveness and safety of weight-based pembrolizumab plus chemotherapy as neoadjuvant treatment for high-risk TNBC and to compare outcomes with pivotal trials.

## MATERIALS AND METHODS

Retrospective observational study conducted in a tertiary hospital. Oct 2023 – Sep 2025

All TNBC patients receiving neoadjuvant pembrolizumab plus chemotherapy were included.

Clinical data were obtained from electronic medical records and the hospital prescribing system.

**Effectiveness** was evaluated by pCR rate using the RCB index.

**Safety** was assessed by recording adverse events and grading them according to CTCAE v5.0.

## RESULTS

**43** ♀ median age of 55 years [27-81]

34 patients had completed neoadjuvant therapy* and surgery

*4 x [**pembrolizumab** + carboplatin + paclitaxel] + 4 x [**pembrolizumab** + epirubicin + cyclophosphamide]

Residual cancer burden (RCB) index

| EFFECTIVENESS | |
|---|---|
| **RCB 0** (pCR rate) | 65% |
| **RCB 1** (minimal residual disease) | 6% |
| **RCB 2** (moderate residual disease) | 20% |
| **RCB 3** (extensive residual disease) | 9% |

**SAFETY**

| | |
|---|---|
| **Grade ≥3 toxicities** (CTCAE v5.0)<br>- Neutropenia<br>- Thrombocytopenia<br>- Anemia<br>- ... | 65% |
| **Leading to cycle delays** | 59% |
| **Dose reductions** | 20% |

## CONCLUSION AND RELEVANCE

Weight-based pembrolizumab dosing showed effectiveness and safety comparable to KEYNOTE-522 fixed-dose results, supporting its use as a clinically effective and economically sustainable strategy in real-world European practice.