

# EFFECTIVENESS AND SAFETY OF NEOADJUVANT PEMBROLIZUMAB COMBINED WITH CHEMOTHERAPY IN TRIPLE-NEGATIVE BREAST CANCER

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4CPS-156

## BACKGROUND AND IMPORTANCE

Triple-negative breast cancer (TNBC) is an aggressive subtype with limited therapeutic options.

Neoadjuvant pembrolizumab combined with chemotherapy has shown improved pathological response and survival in pivotal clinical trials.

Real-world evidence is required to validate efficacy and safety in routine clinical practice.

## OBJECTIVES

Assess the **effectiveness** of neoadjuvant pembrolizumab plus chemotherapy in early-stage TNBC.

Evaluate **safety** in a real-world population.

Compare outcomes with those reported in the pivotal clinical trial (PCT).

## MATERIAL AND METHODS

**Design:** Retrospective observational study.

**Population:** Stage II–III TNBC patients treated between Jun-2022 and Aug-2025.

**Data collected:** sex, age, performance status, disease stage.

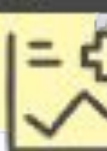


**Treatment regimen:** pembrolizumab 200 mg every 3 weeks (8 cycles), paclitaxel 80 mg/m<sup>2</sup> weekly + carboplatin AUC 5 every 3 weeks (4 cycles) followed by doxorubicin 60 mg/m<sup>2</sup> + cyclophosphamide 600 mg/m<sup>2</sup> every 3 weeks (4 cycles).

**Outcomes:**

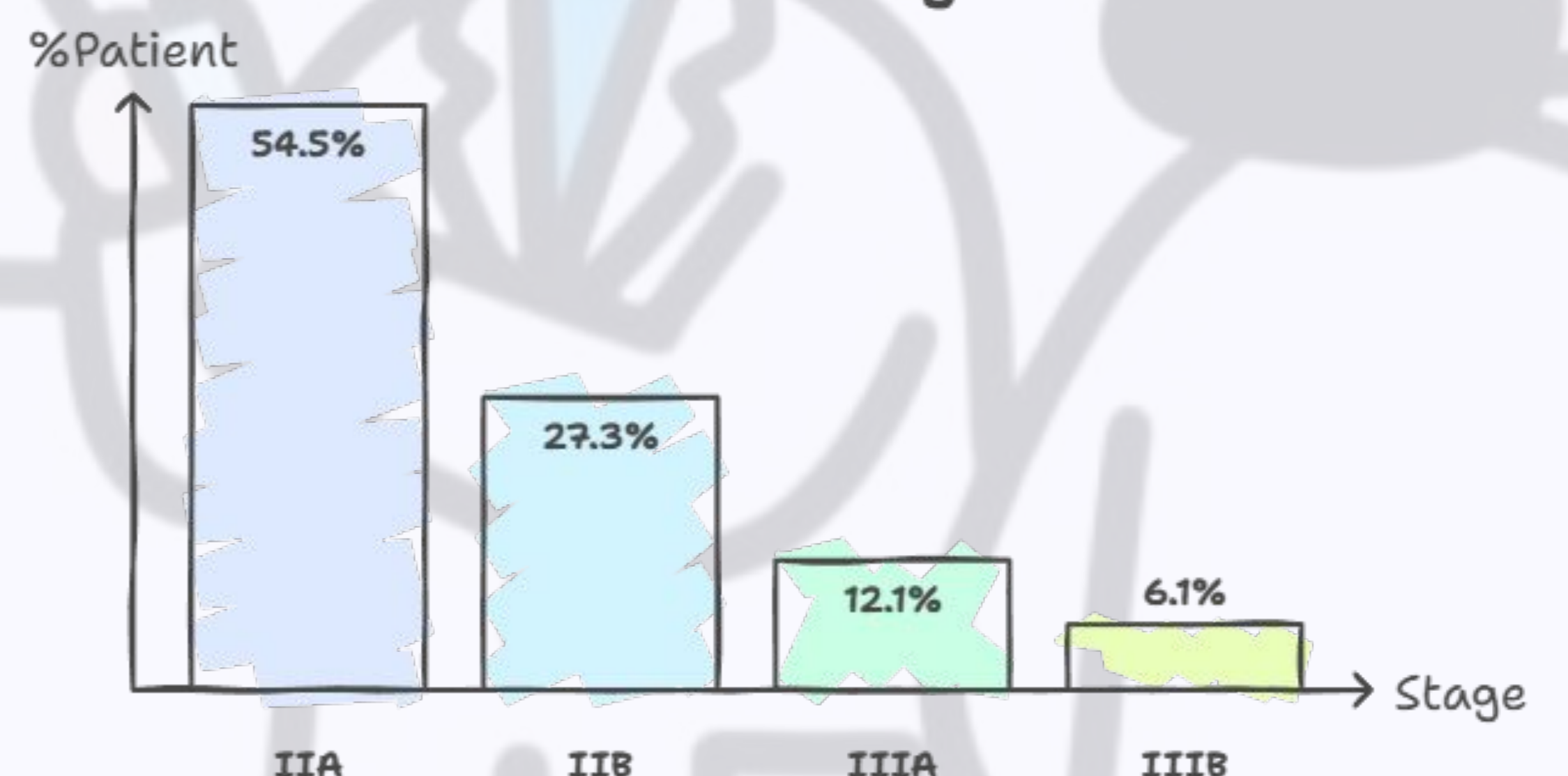
- **Effectiveness:** pathological response using Residual Cancer Burden (RCB) classification.
- **Safety:** treatment-related adverse events (TRAEs).

## RESULTS

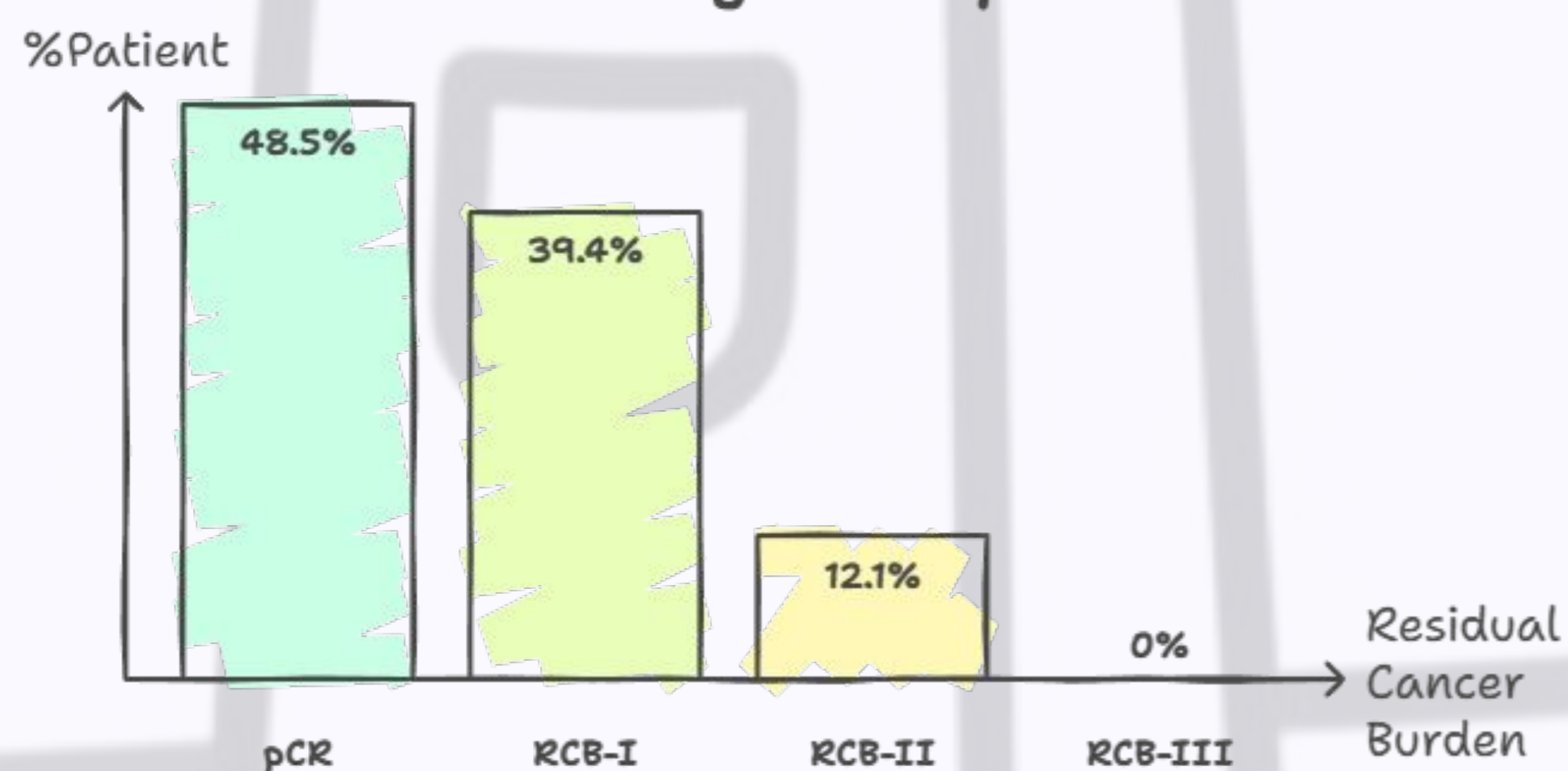
### Patient Characteristics

Characteristic	Value
 Number of Patients	33
 Median Age	55 years (30–78 years)
 Performance Status	0 (100% patients)






### Cancer stage



### Pathological response



### TRAEs

Adverse Event	Percentage
 Fatigue	87.8%
 Nausea	60.6%
 Neutropenia	45.4%
 Infection	36.3%
 Diarrhea	27.2%

## PCT:

- pCR rate: 64.8%.
- Similar safety profile, with comparable frequencies of gastrointestinal and hematological toxicities.

## CONCLUSIONS

Neoadjuvant pembrolizumab plus chemotherapy showed **meaningful effectiveness** in real-world early-stage TNBC.

Although pCR rate was lower than in the PCT, a high proportion of patients achieved minimal residual disease.

Safety outcomes were **consistent with pivotal trial data**.

These findings support the **clinical applicability and robustness** of this regimen in routine practice.

