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4CPS-106 - ATC code: 4. Historical research

SAFETY OF ADJUVANT TRASTUZUMAB EMTANSINA FOR RESIDUAL INVASIVE HER2-POSITIVE EARLY BREAST CANCER

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Background and importance

Trastuzumab emtansine (T-DM1) is a treatment approved by the EMA in 2020, as a single agent, for the adjuvant treatment of adult patients with HER2-positive early breast cancer (EBC) who have residual invasive disease, in the breast and/or lymph nodes, after neoadjuvant taxane-based and HER2-targeted therapy.

Aim and objectives

Describe our experience with T-DM1 adjuvant for EBC treatment in real world conditions (RWC).
We analize T-DM1 safety profile and compare it with pivotal trial (PT) results(1).

Methods

Retrospective study
Tertiary hospital
Patients with EBC treated with adjuvant T-DM1 between 2019-2021.

Collected variables

Demographic data
Basal ECOG
Neoadjuvant therapy schedule
T-DM1 cycles received
Adverse events
Pegfilgastrim use
Intentional delay doses
Treatment interruptions
Dose reductions

Results

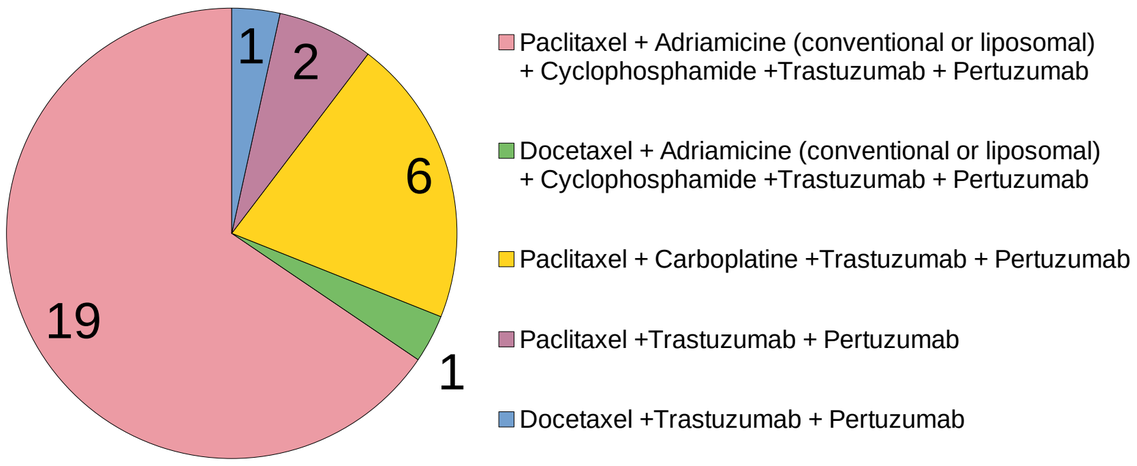
Basal data

- 29 Patients
- Average age 52
- 100% Women
- 2/29 basal ECOG≥1

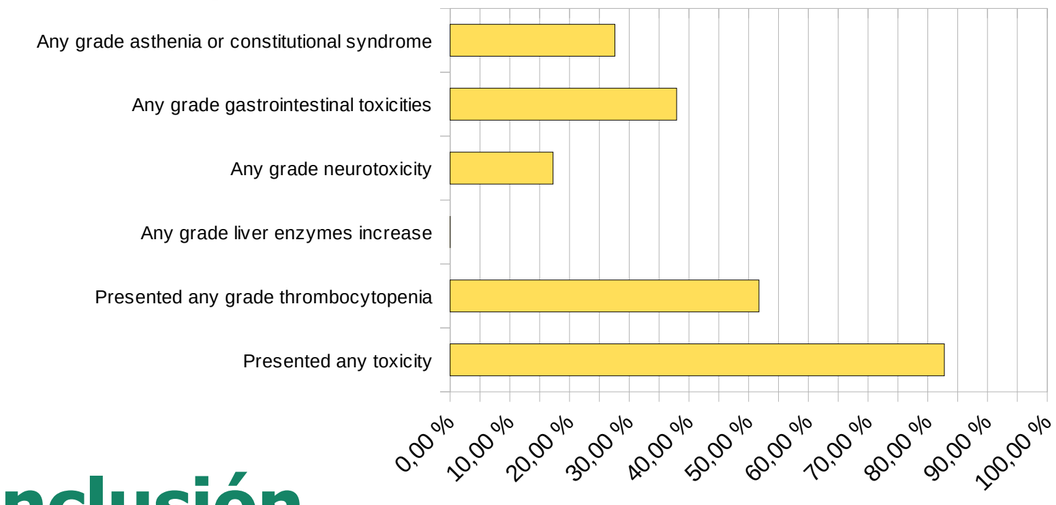
TDM-1 therapy

- 10/29 still receiving treatment during the study
- 8/19 less than 14 cycles
- 2/29 received pegfilgastrim
- 7/29 experienced dose delayed due to toxicities
- T-DM1 starting dose:
  28/29 subjects: 1.6 mg/kg/21 days
  1/29 subjects: 1 mg/kg(thrombocytopenia)

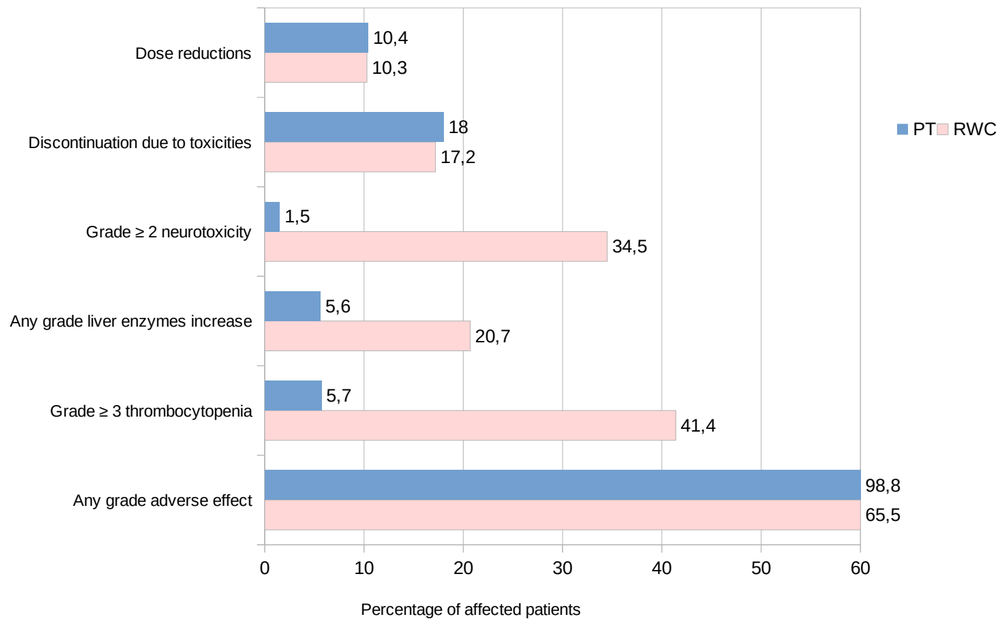
Neoadjuvant treatment



Neoadjuvant treatment toxicities



Safety profile of T-DM1 in RWC compared with PT



Conclusión

Safety profile of T-DM1 in RWC is consistent with PT results. Overall adverse effects in real world conditions were lower than in pivotal trial. Grade ≥2 adverse effects were higher in RWC. However, the proportion of discontinuations and dose reductions were similar. Our results may be interpreted with caution, due to sample size.

References

(1) vonMinckwitz G, Huang CS, Mano MS, Loibl S et al. Trastuzumab-Emtansine for Residual Invasive HER2-Positive Breast Cancer. *N Engl J Med*. 2019 14;380(7):617-628.