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

*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 analyze 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.

**Results**

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

**Neoadjuvant treatment**
- Paclitaxel + Adriamicine (conventional or liposomal) + Cyclophosphamide + Trastuzumab + Pertuzumab
- Paclitaxel + Carboplatine + Trastuzumab + Pertuzumab
- Paclitaxel + Trastuzumab + Pertuzumab
- Docetaxel + Trastuzumab + Pertuzumab

**Neoadjuvant treatment toxicities**
- Any grade asthenia or constitutional syndrome
- Any grade gastrointestinal toxicities
- Any grade neurotoxicity
- Any grade liver enzymes increase
- Presented any grade thrombocytopenia
- Presented any toxicity

**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)

**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**