Background and importance Daratumumab is an anti-CD38 monoclonal antibody now extensively used for multiple myeloma. Due to the high risk of infusion related reactions (IRRs), it is administered over a period of 1.5 hours. The French Myeloma Intergroup, as part of COVID-19, has authorised infusions of daratumumab over 1.5 hours in clinical trials (CT) based on studies showing a safety profile comparable with long infusions.

Aim and objectives The aim of this study was to evaluate IRRs associated with rapid injection of daratumumab in a real life population.

Material and methods From June to July 2020, after medical approval, patients who were given two or more doses of daratumumab with standard infusion rates were authorised to receive ‘rapid dara’ (infusion 1.5 hours). A group was organised by the pharmacy for the nursing team to present the new infusion rate and to remind them of the risks of IRRs. Patient characteristics (age, sex, comorbidities), previous daratumumab infusions (including if patients experienced IRRs) and type of protocols were collected. IRRs were directly recorded in validation administration software.

Results 23 patients received ‘rapid dara’ during the study period and no IRRs were reported. Mean age was 69.5 years; 5/23 patients were between 45 and 65 years old, 13/23 between 65 and 75 years old and 5/23 were >75 years old. 15/23 were women and 8/23 were men. 15/23 patients had at least one comorbidity; 13/23 had at least one cardiovascular comorbidity, 3/23 had one pneumological comorbidity and 6/23 had renal impairment. In terms of treatment, 21/23 patients were receiving multidrug therapy (compared with 2/23 on daratumumab monotherapy). 6/23 had previously received between 3 and 10 INJ, 14/23 between 11 and 20 INJ and 3/23 had received >20 INJ.

Conclusion and relevance Our findings suggest that in real life patients, ‘rapid dara’ is safe in terms of IRRs. These results are in agreement with those presented in previous CT. In the context of the COVID-19 crisis, decreased infusion time allows a reduction in contact time, decreased hospitalisations, and optimises nurse timing. Rapid daratumumab appears to be a safe and economic alternative while waiting for subcutaneous daratumumab.

REFERENCES AND/OR ACKNOWLEDGEMENTS
Conflict of interest No conflict of interest

SAFETY AND SEVERE NEUTROPENIA IN PATIENTS TREATED WITH PALBOCICLIB AND RIBOCICLIB IN REAL WORLD CLINICAL PRACTICE

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Background and importance Palbociclib and ribociclib are oral inhibitors of cyclin dependent kinases for firstline and secondline treatment of hormone receptor (HR) positive, HER2 negative locally advanced or metastatic breast cancer (BC). The most common adverse events (AE) described in clinical trials (CT) were haematological, especially neutropenia.

Aim and objectives To compare the safety and incidence of severe neutropenia in patients treated with palbociclib and ribociclib in clinical practice.

Material and methods A descriptive and retrospective study was performed in patients treated with palbociclib and ribociclib in a third level hospital from January 2018 to September 2020. We registered demographic data (sex and age), number of cycles received, discontinuations, dose reductions and absolute neutrophil count (ANC). Demographic and clinical data were obtained from digital clinical history and toxicity grade (G) of neutropenia was classified by CTCAE V.5.0.

Results 62 patients (35 treated with palbociclib and 27 with ribociclib) with a median age of 60 years diagnosed with metastatic HR positive/HER2 negative BC were included. The median number of cycles received was 10 (1–28) and 7 (2–28) in patients treated with palbociclib and ribociclib, respectively. 19 (54.2%) patients treated with palbociclib developed severe neutropenia (3 (8.6%) grade 4 and 16 (45.7%) grade 3) and 10 (37%) patients treated with ribociclib developed severe neutropenia (1 (3.7%) grade 4 and 9 (33.3%) grade 3) after the first 15 days of treatment, leading to a median number of discontinuations of 2 and 3, respectively. 16 (45.7%) patients treated with palbociclib and 8 (29.6%) patients treated with ribociclib required dose reductions. The causes of suspension of treatment were: toxicity (medullary aplasia, severe exanthema, asthenia and anaemia) in 4 (11.4%) patients treated with palbociclib and in 5 (18.5%) with ribociclib, interactions (1 patient treated with palbociclib) and disease progression in the rest of the patients.

Conclusion and relevance In clinical practice, the incidence of severe neutropenia in patients treated with palbociclib and ribociclib was higher than in CT, with a lower incidence of neutropenia grade 4 and grade 3 in patients treated with ribociclib. However, severe neutropenia was successfully managed with dose reduction and discontinuation for both treatments, so any patient had to stop treatment due to neutropenia. In contrast, the proportions of patients treated with palbociclib and ribociclib that required dose reductions were the same.

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PEMBROLIZUMAB IN NON-SMALL CELL LUNG CANCER: ANALYSIS IN REAL LIFE OF TOXICITY AND EFFECTIVENESS

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Background and importance Many studies support pembrolizumab (a humanised monoclonal antibody directed towards programmed cell death protein-1 (PD-1)) as the firstline treatment of advanced non-small cell lung cancer (NSCLC) without EGFR/ALK alterations.

Aim and objectives The aim of this observational was to report clinical outcome in terms of overall survival (OS) analysis, as well as in stratified OS, in subgroups of patients.

Material and methods Between 1 July 2017 and 28 February 2020, 98 patients with NSCLC were eligible to be treated with pembrolizumab (200 mg q3w fixed dose). The last follow-up date was 24 August 2020. Clinical data, such as