expression of PD-L1, performance status (ECOG-PS), treatment duration, toxicity (CTCAE V.5.0) and outcome were collected from the local electronic medical records. OS, defined as the time from the start of therapy to death or last follow-up, was compared in subgroups of patients using the log rank test (with R software); p<0.05 was considered statistically significant.

Results This investigation provided preliminary results for 98 patients (of whom 64% were male). Median age was 73 years (range 44–89). ECOG-PS was 0 or 1 in 91% of cases and 29.6% of patients had a PD-L1 >90%. Median duration of treatment was seven cycles. At a median follow-up of 14.6 months, the percentage of patients still alive was 51% and median OS was 13.3 months (95% CI 10.5 to 31.4). The analysis revealed that OS was not influenced by sex or PD-L1, but significantly associated with ECOG-PS (p<0.001). Immunorelated adverse events occurred in 75.5% of patients (29.6% cutaneous, 24.5% gastrointestinal and 19.4% endocrinological). Patients with toxicity showed a significantly higher median OS (29.6 months, 95% CI 12.2 to NA) compared with those without significant toxicity (6.5 months, 95% CI 1.3 to 13.1, p=0.002).

Conclusion and relevance These real life findings in the setting of advanced NSCLC patients with PD-L1 TPS  $\geq$ 50% demonstrated the effectiveness of pembrolizumab. A median OS of 13.3 months was similar to that estimated in the real world Pembreizh study (15.3 months). The detection rate of AE of 75.5% was comparable with 73.4% in the KEYNOTE-024 study. However, pembrolizumab as mono-immunotherapy represents the standard of care as firstline treatment but results from trials evaluating combinations with chemotherapy (KEYNOTE189) could further change the therapeutic approaches.

## REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

# 5PSQ-171 TOCILIZUMAB IN PATIENTS WITH COVID-19: RESULTS IN CLINICAL PRACTICE

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Background and importance Tocilizumab is an immunosuppressive agent, an inhibitor of interleukin 6. In March 2020, it was included in the treatment plan of SARS-CoV-2 infection with the aim of slowing down the inflammatory phase. Therefore, tocilizumab constitutes a possible alternative therapy within the various experimental strategies available.

Aim and objectives To evaluate the effectiveness and safety of tocilizumab in patients with COVID-19.

Material and methods An observational retrospective study was conducted in every patient with COVID-19 treated with tocilizumab between March and August 2020. Demographic and clinical variables were collected from the electronic medical records: sex, age, diagnosis of pneumonia, dates of admission, discharge and administration of tocilizumab, and dose and treatment criteria. Analytical parameters related to disease severity (APRDS) were recorded: C reactive protein, ferritin, D-dimer and lactate dehydrogenase. Determination of interleukin 6 was not available at our hospital. To evaluate

effectiveness, the clinical and analytical response after the administration of tocilizumab was recorded. Adverse effects were recorded to assess safety.

Results 50 patients were included (64% men), median age 68.53 years (range 25-89). All patients presented with pneumonia. Median length of hospital stay was 14 days (range 1-37). Treatment criteria were: rapid worsening of the disease in 50% of patients, 30% presented with criteria of severe systemic inflammatory response, 16% severe respiratory failure, 2% extrapulmonary organ failure and 2% of patients needed intensive care. 70% of patients had an increase in all of the APRDS, 24% in three parameters and 6% in two parameters. Meeting weight related dose criteria, 34 patients received tocilizumab 600 mg and 16 patients received 400 mg on the first administration. 13 patients received a second dose and one received a third for worsening APRDS. 53.10% obtained a good clinical-analytical response. In 38.8% there was no improvement, and the remaining 4 patients (8.1%) were transferred to another hospital before the response was assessed. No treatment related adverse effects were recorded.

Conclusion and relevance The results obtained in our population indicated that tocilizumab was well tolerated. With regards to the data on effectiveness, they showed unsatisfactory results. The available data on the use of tocilizumab in patients with COVID-19 are limited so it is important to carry out studies that allow global data to be collected.

## REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

# 5PSQ-172 EXPERIENCE WITH TOCILIZUMAB IN SEVERE ACUTE RESPIRATORY SYNDROME CORONAVIRUS 2 (SARS-COV-2) INFECTION

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Background and importance Tocilizumab is an immunosuppressive agent which has demonstrated high efficacy in clinical trials for the treatment of coronavirus because its mechanism of action seems to inhibit the inflammatory cascade.

Aim and objectives To evaluate the efficacy and safety of tocilizumab during the global pandemic.

Material and methods A descriptive, observational, prospective study was conducted in patients receiving treatment with tocilizumab for SARS-CoV-2 during the pandemic in March 2020. Clinical data were collected: sex, age, medical history, diagnosis, hospitalisation days, patients admitted to the intensive care unit (ICU), patients who required mechanical ventilation, dose of tocilizumab, time from onset of symptoms to administration, concomitant drugs for SARS-CoV-2, final situation and adverse reactions. The data were obtained from the electronic medical records. All patients met the criteria established by the Spanish Agency of Medicines and Medical Devices (AEMPS): adequate biochemical parameters and absence of ongoing infections.

Results 130 patients were included in the study, 8 patients met the criteria of AEMPS, 75% were men and mean age

was 70 (57-83) years. Background: 50% had arterial hypertension, 37.5% heart disease, 25% diabetes, 25% chronic obstructive pulmonary disease and 12.5% active neoplasia. The diagnosis was severe pneumonia in all cases. The average duration of hospitalisation was 29 (4-73) days. 50% of patients were admitted to the ICU and required mechanical ventilation. In 75%, the dose was 600 mg and the rest required 400 mg, all single doses. The average time from symptom onset to drug administration was 15 (10-30) days. Concomitant drug therapy for SARS-CoV-2: 100% hydroxychloroquine with azithromycin, 87.5% lopinavir/ritonavir, 37.5% methylprednisolone boluses, 25% oral methylprednisolone and 12.5% interferon-ß-1b. 87.5% of patients were discharged. No adverse reactions were reported.

Conclusion and relevance Treatment with tocilizumab could be considered a safe and effective option in patients with severe SARS-CoV-2 pneumonia. Further studies are necessary to confirm these preliminary results. Adjustment of the treatments to the criteria established by the regulatory agencies and the recording of health outcomes could contribute to more efficient therapies.

## REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

# 5PSQ-173 PERSISTENCE OF ABATACEPT TREATMENT IN RHEUMATOID ARTHRITIS PATIENTS

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Background and importance Abatacept (ABA) is indicated as firstline treatment in patients diagnosed with moderate–severe active rheumatoid arthritis (RA). Persistence of ABA in patients diagnosed with RA and the prognostic factors that are associated with treatment discontinuation may help optimise its use. Aim and objectives To assess the persistence of abatacept and identify factors that contributes to its discontinuation in patients diagnosed with RA.

Material and methods A retrospective, observational, cohort study was conducted in RA patients treated with ABA between 2009 and 2019 (n=190). Sociodemographic, clinical and pharmacological characteristics of patients were collected. Clinical disease activity indicated by disease activity score (DAS) 28-ESR as well as adverse drugs effects (AEs) were evaluated. Kaplan–Meier survival analysis was used to obtain the time to discontinuation, and the log rank test was used to examine the difference in therapy continuation rate. Cox proportional hazards model was used to identify factors associated with durability.

Results 190 RA patients were evaluated; 75.26% (143/190) were women, disease duration was 14 (8–20) years and age at the start of ABA was 58.5 (49.25–68) years. Overall, 96.16% (177/190) had concomitant therapies with ABA (methotrexate, leflunomide, hydroxychloroquine). A total of 22.11% (42/190) were bionaive, 26.32% (50/190) began treatment after failure

of one tumour necrosis factor inhibitor (TNFi) and 51.57% (98/190) began treatment with ABA after failure of two or more TNFis. The causes of ABA withdrawal were therapeutic failure in 28.95% (55/190) and adverse effects in 13.15% (25/190). Infections were the most frequent AEs (56.3%). Median persistence of ABA was 65 (95% CI 45 to 116) months. Kaplan–Meier analysis showed a trend of high persistence of ABA in naïve patients (89 months) compared with patients with one, or two or more previous biological therapies (TBs) (89 vs 65 and 29 months, respectively) (log rank p=0.06). According to Cox's model, duration of disease, duration of previous TB and number of previous TBs were associated with a higher risk of treatment interruption (log rank p=0.002).

Conclusion and relevance Median duration of ABA persistence was 65 months. Factors associated with the duration of the disease as well as previous biological therapies influenced the persistence of ABA.

## REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

5PSQ-174 EFFECTIVENESS AND SAFETY OF ABATACEPT
THERAPY IN PATIENTS WITH RHEUMATOID ARTHRITIS
AFTER PREVIOUS FAILURE WITH TNFI TREATMENT

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Background and importance Abatacept (ABA) is a soluble fusion protein consisting of the extracellular domain of human CTLA-4 linked to a modified Fc portion of human IgG1, used in rheumatoid arthritis (RA) in patients with an inadequate or unsustained response to tumour necrosis factor inhibitors (TNFi).

Aim and objectives The aim of this study was to investigate the effectiveness and safety of ABA at 12 months in patients diagnosed with RA.

Material and methods A retrospective cohort study was conducted in patients diagnosed with RA treated with ABA between 2009 and 2019. Sociodemographic, clinical and pharmacological characteristics of the patients were collected. The influence of clinical parameters on ABA effectiveness was evaluated by applied linear or logistic regression models. Effectiveness was measured according to the European League Against Rheumatism (EULAR) response (satisfactory or unsatisfactory), after 12 months of therapy in RA patients. Safety was assessed by adverse events.

Results 171 RA patients were evaluated, 74.27% women (127/171) and age at the start of ABA was  $58.40\pm13.60$  years. Administration of ABA was intravenous (iv) in 61.4% (105/171) of patients. Concomitant glucocorticoids were administrated in 84.21% (144/171) of cases and disease modifying antirheumatic drugs (methotrexate or leflunomide) in 50.87% (87/171) of patients. Rheumatoid factor was positive in 78.36% (134/171) of patients and cyclic citrullinated peptide antibodies in 72.51% (124/171). 75.44% of patients had