developing severe COVID-19. One pivotal study reported a 77% reduction in disease risk compared to placebo, with protection estimated at least six months.

Aim and Objectives To evaluate how many patients have developed COVID-19 that required treatment with a specific antiviral among the ones in prophylaxis with T/C in our hospital.

Material and Methods Through the analysis of AIFA Monitoring Registers it was possible to obtain data of patients in prophylaxis with T/C and subsequently treated with COVID-19 antiviral. The data obtained refers to the period between 10th March 2022 (date of the first administration of prophylaxis in the hospital) and 10th September 2023. Cases of ineffectiveness of T/C have been reported in the National Pharmacovigilance Network.

Results During the considered period, 314 patients were treated with T/C prophylaxis. Of these, 9 (2.9%) received remdesivir, 6 (1.9%) remdesivir early treatment, 4 (1.3%) nirmatrelvir/ritonavir. 1 patient (0.3%) contracted the infection 3 times after prophylaxis (the first within 1 month and the following after 6 months) requiring 3 antiviral treatments: nirmatrelvir/ritonavir, remdesivir early treatment and remdesivir. Overall, 6.4% of patients undergoing prophylaxis were subsequently treated with at least one antiviral, 85% of them within 6 months. The average time between prophylaxis and antiviral treatment was 113 days.

Conclusion and Relevance The AIFA Monitoring Registers have been a useful tool for the clinical evaluation of the therapeutic efficacy of T/C prophylaxis and for pharmacovigilance activities. In the sample considered, 93,6% of patients who received prophylaxis didn't develop COVID-19 that required antiviral treatment in a hospital setting. Our data only refers to inpatients subjects, thus representing a limitation for the analysis; T/C prophylaxis for frail patients has however proved to be a valuable resource in addition to vaccination.

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Conflict of Interest No conflict of interest.

4CPS-097 REAL-WORLD STUDY OF APALUTAMIDE TREATMENT IN PATIENTS WITH METASTATIC HORMONE-SENSITIVE PROSTATE CANCER IN NINE HOSPITALS OF VALENCIAN COMMUNITY

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Background and Importance Systemic involvement of prostate cancer(PC) typically occurs at the bone level (65–85%). Patients with metastatic hormone-sensitive prostate cancer (mHSPC) have survival rates ranging from 1–6 years, depending on high-risk prognostic factors such as:

- Elevated levels of prostate-specific antigen(PSA>20) at diagnosis.
- High Gleason score(8–10).
- Increased volume of metastatic disease.
- Poor functional status.
- Bone symptoms or the presence of visceral metastases.

Apalutamide, abiraterone, and enzalutamide are orally administered treatments financed for use in combination with androgen deprivation therapy. They have demonstrated improvement in overall survival (OS), particularly in high-risk progression populations, and a favourable safety profile.

Aim and Objectives Study to asses the efficacy profile, safety and clinical follow-up of patients with mHSPC undergoing Apalutamide treatment.

Material and Methods A retrospective observational study was conducted on patients with mHSPC who initiated Apalutamide treatment in 9 public hospitals in Valencian Community, Spain. These patients had a minimum clinical follow-up of 6 months as of March 2023. Clinical records, PSA evolution, and toxicity reported by healthcare professionals or the patients themselves were reviewed. A comprehensive descriptive statistical analysis was conducted, both overall and by disease volume.

Results A total of 172 patients(73±8 years) were included, with high disease volume(n=80;46.5%) and low disease volume(n=92;53.5%). 41.3% had received prior local treatment. The median pre-treatment PSA level was 22.2 (3.4–97.9) ng/mL, 69.8% had metastases at diagnosis with predominantly bone metastasis (61.6%), and a median time from diagnosis to the initiation of apalutamide was 4 (2–51) months.

At 3 months, 69.7% of patients achieved >90% reduction in baseline PSA, and an 87.7% reduction >50% in PSA in real-world conditions. After 12 months of treatment, 80% of patients continued with apalutamide, with discontinuation due to toxicity in 4.2% and progression or death in 13.1% of patients.

Conclusion and Relevance We did not observe significant response differences between low and high volume groups. Apalutamide in real-world treatment of men with mHSPC demonstrates a favourable safety profile like data published in clinical trials.

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Conflict of Interest No conflict of interest.

4CPS-098 EFECTIVENESS AND SAFETY OF LONG-ACTING CABOTEGRAVIR/RILPIVIRINE IN REAL-LIFE POPULATION

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Background and Importance Simplification strategies aimed to improve antiretroviral therapy adherence, tolerability and compliance have emerged during recent decades. In this context, long-acting cabotegravir/rilpivirine injectable has been recently

commercialised as a new promising treatment alternative, and pharmacist-led long-term monitoring could be beneficial to ensure treatment effectiveness and safety.

Aim and Objectives Assess the long-term real-life effectiveness and safety of cabotegravir/rilpivirine.

Material and Methods This was an observational, longitudinal and prospective study performed between March and September 2023. Patients were included if they started treatment with either a one-month oral lead-in (OLI) with cabotegravir/rilpivirine followed by long-acting therapy or directly with the long-acting injection regimen (at month 0, 1, 3 and 5) and received at least 4 injectable doses and excluded if participated in FLAIR and ATLAS studies. Sociodemographic (age, sex at birth), anthropometric (body mass index [BMI]) and viral (HIV-RNA viral load at baseline and 5-month follow-up) data were collected. Treatment was considered effective when patients achieved or maintained virological suppression

Drug adverse effects were collected and followed-up through active pharmacist validation, and clinical and nursing-staff monitoring.

Results 30 patients were included (90% male sex at birth, mean age 43.7 years). 1 patient had a BMI>30. At baseline, all patients had undetectable viral load (HIV-RNA<50 copies/mL) and 6(20%) started with OLI.

At 5-months follow-up, 28(93.3%) patients had an undetectable viral load. 2 patients abandoned treatment after 1 month, due to an unknown archived rilpivirine mutation (one patient had a VL of 113,146 copies/mL and the other remained undetectable).

90% of patients reported at least 1 adverse effect, being the most frequent: injection-site reactions (83.3% of patients reported gluteal pain, 13.3% induration), followed-by low-grade fever (10%), fatigue (6.7%) and diarrhoea (6.7%).

Conclusion and Relevance Cabotegravir/rilpivirine effectiveness and safety were favourable in this cohort of baseline virologically suppressed patients. No treatment interruptions due to adverse effects were observed but resistance mutations need to be considered.

Although small sample size, low proportion of female patients and a short-term follow-up due to recent commercialisation, this study could be of help due to lack of studies reporting data on cabotegravir/rilpivirine effectiveness in real-life population and long-term pharmacist treatment monitoring

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

4CPS-099 CHIMERIC ANTIGEN RECEPTOR-T CELLS (CAR-T CELLS) AND ANTIBIOTICS: A NOT-SO-INNOCENT ASSOCIATION

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Background and Importance According to an American study[1], prior exposure to Piperacillin/tazobactam (P/T), Imipenem/cilastatin (I) and meropenem (M) is correlated with reduced overall survival and a 71% higher risk of death in patients treated with CAR-T cells (Chimeric Antigen Receptor T cells). This exposure is also associated with an increased risk of immune effector cell-associated neurotoxicity syndrome (ICANS).

Aim and Objectives The aim is to demonstrate if the American results apply to our real-life results.

Material and Methods For each patient who received a CAR-T cells injection between January 2019 and August 2023, the 'CAR-T cells' pharmaceutical team checked: antibiotic prescription 4 weeks prior to CAR-T cells injection, post-injection toxicities (ICANS and cytokine release syndrome (CRS)) and death within 6 months of CAR-T cells injection.

To have populations comparable to those in the study, we defined two groups: 'P/T/I/M' is patients who received P/T/I/M antibiotics, and 'Other antibiotics and naive' is patients who received antibiotics other than P/T/I/M or antibiotic naive. we selected all CAR-T cells with marketing authorisation.

Statistical comparisons were made using the Fischer test (risk = 5% bilateral).

Results Two-hundred and five patients received CAR-T cells: 172 'Other ATB and naive' patients (84%) and 33 'P/T/I/M' patients (16%) in the 4 weeks prior to injection.

In the 'P/T/I/M' population, there were 12 CRS (36.5%), 0 ICANS, 12 ICANS+CRS (36.5%) and 9 (27%) without toxicities. Seven (21%) patients died.

In the 'Other antibiotics and naive' population, there were 100 CRS (58%), 2 ICANS (1%), 43 ICANS+CRS (25%) and 27 no toxicities (16%). Twenty-four patients (14%) died.

A higher risk of CRS has been identified in the 'P/T/I/M' group (p=0.02).

No other significant difference was found between the 2 groups on: ICANS+CRS (p=0.2), ICANS (p=1), or death (p=0.29).

Conclusion and Relevance Our study shows a higher risk of CRS for patients exposed to P/T/I/M 4 weeks prior to injection.

Our study also shows no excess risk of ICANS nor toxicities and death for 'P/T/I/M' patients. Our results are therefore not similar to those of the American study.

These differences could be explained by the size of our population and the fact that the American study only selected anti-CD19 CAR-T cells.

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Conflict of Interest No conflict of interest.

4CPS-100 THE UTILITY OF EARLY PHARMACEUTICAL VALIDATION OF SELECTED HIGH-RISK DRUGS IN A HOSPITAL EMERGENCY DEPARTMENT

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Background and Importance High-risk medication and the associated errors represent a potential source of adverse effects and readmissions for patients.

Aim and Objectives To analyse the utility of early pharmaceutical validation of direct oral anticoagulants (DOACs) and long-acting insulins (LAIs) in a Hospital Emergency Department (ED).

Material and Methods This retrospective study was conducted between May 15, 2023, and September 28, 2023. Two groups of high-risk medications (HRMs) were selected: DOACs