Various studies have been undertaken at the level of the Hospital pharmacy and the cold supplier to improve the supplied isothermal enclosure.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

5PSQ-004 EPCLUSA RELATED SLEEPINESS: A CASE REPORT

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Background and Importance Epclusa is a two-drug combination administered as a single daily pill containing Velpatasvir and Sofosbuvir used to treat de Hepatitis C. The treatment duration is 12 weeks and the cure rates are from 97% to 100% in those patients without cirrhosis or with compensated cirrhosis.

Based on data obtained from phase 3 clinical studies, the percentage of patients experiencing any serious adverse event was 3.2%. The most common adverse reactions observed are headache and fatigue.

Pharmacovigilance collects information, and analyses and notifies case of suspected adverse drug reactions (ADRs) to prevent them occurring in the future

Aim and Objectives To describe a case of sleepiness in a patient treated with Epclusa and establish its possible association.

Material and Methods We describe a case of an 72-year-old woman diagnosed with hepatitis C with compensated cirrhosis and treated with Epclusa. In May 2022, before starting the treatment with Epclusa, her home medication was checked at the Pharmacy Department, which include atorvastatin, enalapril and omperazole; pointing out to separate the intake of omeprazole and Epclusa 4 hours and proving there no were any drug interactions. After 16 days receiving the treatment with Eplcusa, she was referred to the emergency department presenting sleepiness and general deterioration. As a result, she was diagnosed with common cold and treated with amoxicilin. It also coincided with constipation, which spontaneously resolved within two days. Finally Epclusa treatment was stopped.

Results 4 days after, she reported improvement in sleepiness after discontinuation of treatment, although the iatrogenic origin cannot be guaranteed since it has also coincided with catarrhal symptoms and constipation, both situations in resolution. Naranjo's algorithms establish the causality relationship as possible (score of 2). The Spanish pharmacovigilance centre was notified.

Conclusion and Relevance The European Medicines Agency's technical sheet for Epclusa does not describe sleepiness as an ADR. Patient could confuse fatigue with sleepiness in dealing with subjective symptoms. The RPC reported this case as the only Epclusa ADR notified in our country. The reporting of ADRs in hospitals is very important because innovative new drugs are usually used, severe ADRs are most likely to be seen in hospitals and it can be detected early helping others how to act.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

5PSQ-005 ANALYSIS OF ANTI-ANGIOGENESIS-RELATED ADVERSE EVENTS ASSOCIATED WITH VASCULAR ENDOTHELIAL GROWTH FACTOR RECEPTOR-TYROSINE KINASE INHIBITORS (VEGFR-TKIS) IN PATIENTS WITH METASTATIC RENAL CELL CARCINOMA

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Background and Importance Oral vascular endothelial growth factor receptor – tyrosine kinase inhibitors (VEGFR-TKIs) are standard treatments for metastatic renal cell carcinoma. The VEGF pathway plays an important role in the physiological function and homeostasis of the cardiovascular and kidney systems, resulting in anti-angiogenesis-related adverse events (AEs). Limited studies have evaluated anti-angiogenesis-related AEs involving VEGFR-TKIs using real-world data, which may provide important evidence for drug choice and monitoring in the treatment of metastatic renal cell carcinoma.

Aim and Objectives This study aimed to investigate the incidence and patterns of anti-angiogenesis-related AEs associated with the use of VEGFR-TKIs in patients with a metastatic renal cell carcinoma using real-world data.

Material and Methods This cross-sectional study included patients with a diagnosis of metastatic renal cell carcinoma who received axitinib, cabozantinib, pazopanib, sorafenib, and sunitinib at the third level hospital in South Korea between January 2007 and December 2019. Anti-angiogenesis-related AEs were rated 'possible' or higher on the WHO-Uppsala Monitoring Centre (WHO-UMC) causality assessment scale. The severity of AEs was graded using the CTCAE v.5.0. To compare the incidence of AEs associated with different VEGFR-TKIs, we divided the enrolled patients into those who had not previously received a VEGFR-TKI (VEGFR-TKI-naïve) and those who had previously received a VEGFR-TKI (VEGFR-TKI-experienced).

Results A total of 988 patients were included (75% men, median 61 years). 644 patients were VEGFR-TKI-naïve and 314 patients were VEGFR-TKI-experienced. Anti-angiogenesis-related AEs of any grade occurred in 65.1% of VEGFR-TKI-naïve patients and 54.8% of VEGFR-TKI-experienced patients. In addition, severe AEs occurred in 34.6% of VEGFR-TKI-naïve patients and 36.0% of VEGFR-TKI-experienced patients. Regardless of treatment history, the most common AE was hypertension, with a 48.6% of VEGFR-TKI-naïve and 35.0% of VEGFR-TKI-experienced. For VEGFR-TKI-experienced patients, the overall rate of anti-angiogenesis-related AEs for sorafenib (24.3%) was lower than that for other VEGFR-TKIs ($p < 0.05$). Female gender (adjusted hazard ratio [aHR] 1.23, 95% confidence interval [CI] 1.02-1.48) and high blood pressure (aHR 1.47, 95% CI 1.23-1.76) were risk factors for VEGFR-TKI-associated AEs.

Conclusion and Relevance More than half of patients with renal cell carcinoma receiving VEGFR-TKI experienced anti-angiogenesis-related AEs. Any grade of AEs occurred more frequently in VEGFR-TKI-naïve patients, while severe AEs occurred more frequently in VEGFR-TKI-experienced patients.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest