4CPS-048 ANALYSIS OF PAXLOVID® FOR THE TREATMENT OF COVID-19 IN ARAGÓN, SPAIN

[1]I Patier*, [1]M Perez-Moreno, [1]I Puértolas-Tena, [2]M Galindo-Allueva, [1]MC Viñuales-Armengol, [1]N Allue-Fantova, [1]MP Amador-Rodriguez. *[1]Hospital Universitario San Jorge, Pharmacy, Huesca, Spain*; *[2]Hospital Universitario Royo Villanova, Pharmacy, Zaragoza, Spain*

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Background and Importance Paxlovid® is indicated for the treatment of COVID-19 in adults who do not require supplemental oxygen and who are at increased risk for progressing to severe COVID-19. The Spanish Drug Agency published prioritisation criteria for it access. Paxlovid® has significant drug interactions, mainly due to ritonavir. Hospital pharmacists must validate the prescription, carrying out a thorough review of the patient's medical history to check its suitability, as well as the concomitant medication to avoid interactions.

Aim and Objectives Analyse the use of Paxlovid® in Huesca and Sector-1 of Zaragoza (Aragon, Spain) in early months post-authorisation.

Material and Methods All Paxlovid's prescriptions from April to September 2022 were reviewed. The following variables were collected: gender, age, vaccination schedule, prioritised high-risk criteria and renal function. All concomitant medication was reviewed for drug interactions using a protocol created by Coordination Unit for the Rational Drug Use of Aragon. The observations made to the prescribing physician by the hospital pharmacist were recorded.

Results 40 requests were received. 5 were prescription errors. 29 (82.9%) were accepted and 6 (17.1%) rejected. Median age (years, interquartile-range q1-q3) was 52.2 (45.6–65.3), 57.1% were male. Vaccination status was complete primary vaccination with booster-dose (62.8%) followed by complete vaccination (25.7%) and incomplete vaccination (11.5%). As high-risk criteria prioritised, 91.4% belonged to group composed by immunocompromised persons. 91.4% had renal function >60ml/min. Only in 3 cases (8.6%) the prescribing physician indicated the patient had potential drug interactions.

All patients had concomitant medication, median of 8 drugs (4–10). 60% had any potential interaction, with serious drug interactions in 42.9% of them. Drugs with potential serious interactions were statins (5/11); benzodiazepines (2/11) and antithrombotic agents (2/11).

44.8% prescriptions were accepted with recommendations to modify or temporary stop some of the patient's usual treatment. 80% of the rejected cases were due to serious drug interactions.

Conclusion and Relevance In the use of Paxlovid®, the role of hospital pharmacists was crucial, as drug interactions were detected in 60% of patients and were serious in 42.9% of them, leading to recommendations for adjustments in patients' drug therapy in almost half of the cases, with potentially serious drug interactions being the main reason to not dispense Paxlovid®.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-055 EFFECTIVENESS AND SAFETY OF RIBOCICLIB IN THE FIRST LINE OF LUMINAL METASTATIC BREAST CANCER

MJ Canalejo Fuentes*, AB Fernández Román, B Candel García, J Letéllez Fernández, M García Gil. *Fuenlabrada University Hospital, Pharmacy Unit, Fuenlabrada, Spain*

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Background and Importance Ribociclib is a cyclin-dependent kinase inhibitor used in the first line of luminal metastatic breast cancer (MBC).

Aim and Objectives To assess the effectiveness and safety of ribociclib in first-line treatment of hormone receptor positive and human epidermal growth factor receptor 2 (HER2) negative MBC.

Comparison with the results of the MONALEESA-2 trial.

Material and Methods Observational, retrospective study, carried out in a second level hospital between July 2017 and March 2022. All patients diagnosed with MBC treated with ribociclib in combination with hormonal therapy from diagnosis of the first metastasis to tumour progression were included.

The effectiveness variable measured was the median progression-free survival (mPFS).

The safety variables measured were adverse reactions (AR) presented and percentage of patients who required dose reduction due to adverse reactions.

Variables such as gender, age and location of metastases were also recorded.

The data was obtained from the Electronic Medical Record and the Pharmacy dispensing programme.

For analysis of mPFS, the Kaplan-Meier test was used using the statistical program SPSS® and results were compared with the results of MONALEESA-2 study.

Safety was assessed according to CTCAE criteria.

Results 34 patients were included, 100% were women with a median age of 58 years (31–73).

Locations of metastases found were bone, lung, mediastinum, liver, pleura, skin, brain, and peritoneum. 58.82% (20/34) of patients had 2 or more metastatic locations and 41.17% (14/34) had a single metastasis, this being bone location in 64.28% (9/34) of patients.

The median follow-up was 13.9 months (2.73–29.5), 41.17% (14/34) of patients progressed to treatment with ribociclib and mPFS was not reached.

In MONALEESA-2 study, median follow-up was 26.4 months and mPFS was 25.3 months.

The adverse reactions presented mainly were neutropenia in 52.94% (18/34) and asthenia in 26.47% (9/34). In MONALEESA-2 study, both were adverse reactions reported with a frequency > 20%.

55.88% (19/34) of patients required dose reduction due to adverse effects of ribociclib. In MOONALEESA-2 study, dose reduction was required in 50.6% (10/19) of patients.

Conclusion and Relevance A longer follow-up time is necessary for our patients to be able to compare the effectiveness in terms of PFS with the MONALEESA-2 study. Regarding the safety of ribociclib, the data reflected are similar to those presented in the MONALEESA-2 study.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest