EFFECTIVENESS AND SAFETY OF RIBOCICLIB IN THE FIRST LINE OF LUMINAL METASTATIC BREAST CANCER

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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

1. 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.
2. Comparison with the results of the MONALEESA-2 trial.

MATERIALS AND METHODS

WHAT? Observational and retrospective study
WHERE? In a second level hospital
WHEN? July 2017 – March 2022

WHO? All patients diagnosed with MBC treated with ribociclib in combination with hormonal therapy from diagnosis of the first metastasis to tumor progression.

MAIN QUESTIONS

- Median progression-free survival (mPFS).
- Adverse reactions (AR) presented.
- Percentage of patients who required dose reduction due to adverse reactions.

OTHER QUESTIONS

- Age
- Sex
- Location of metastases

HOW?

Data was obtained from the electronic medical record and the pharmacy dispensing program.

For analysis of mPFS, the Kaplan-Meier test was used using the statistical program SPSS®.

Safety was assessed according to CTCAE criteria.

The results of main questions were compared with the results of MONALEESA-2 study.

RESULTS

34 patients were included.

100% of patients were women.

The median age was 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.
41.17% (14/34) had a single metastasis, this being bone location in 64.28% (9/34) of patients.

EFFECTIVENESS

The median follow-up was 13.9 months (2.73-29.5), the 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

SAFETY

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%.
The 55.88% (19/34) of patients required dose reduction.

In MOONALEESA-2 study, dose reduction was required in 50.6% (10/19) of patients.

CONCLUSIONS 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.