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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®.

Common Terminology Criteria
for Adverse Events (CTCAE)
Version 5.0
Published: November 27, 2017

Safety was assessed according to CTCAE criteria.

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

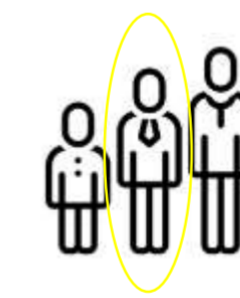
RESULTS



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 MONALEESA-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