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DESCRIPTIVE COMPARATIVE EFFECTIVENESS AND SAFETY ANALYSIS OF PALBOCICLIB AND RIBOCICLIB IN METASTASIC BREAST CANCER HER2-NEGATIVE WITH POSITIVE HORMONAL RECEPTORS

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BACKGROUND:

Palbociclib and ribociclib are equivalents in terms of effectiveness in the treatment of metastatic breast cancer (mBC) HER2-negative with positive hormone-receptors (RH). The randomized studies PALOMA-2/3 and MONALEESA-2/3 conclude that the median PFS was 24,8 and 25,2 months severally, and the most frequent AE is neutropenia of any degree with an incidence of 75.8% and 71.5% for palbociclib and ribociclib, respectively.

PURPOSE:

To know the PFS and long term safety profile of palbociclib and ribociclib in real clinical practice.

MATERIALS AND METHODS:

Observational, descriptive and retrospective study. All patients diagnosed with mBC HER2-negative and RH-positive who started treatment with palbociclib and ribociclib between November 2017 and October 2019 were selected. The main outcomes was the PFS stimated by the Kaplan-Meier method, and percentage of patients that required dose reduction due to EA, its causes and time of onset. The clinical and analytical data was obtained from the history-clinical-electronic-program (Diraya®) and the treatment data from the prescription program (OncoFarm®).

RESULTS:

In the study period, 22 patients began treatment with palbociclib and 50 with ribociclib. 85.7% of patients treated with palbociclib did it in second-line (fulvestrant-associated) and all patients treated with ribociclib did it in first-line (aromatase inhibitors-associated). The median duration of treatment was 17,1 months in the palbociclib-group and 5,0 months in the ribociclib-group. FPS in whole sample of patients was 19,7 [IC 95%, 9,75-NR], with 33 censored patients on the analysis date. In the palbociclib-group 36% (n=8) patients reduced the dose due to neutropenia(6/8), thrombocytopenia(1/8) and unknown cause(1/8); while in the ribociclib-group, 6%(n=3) patients had to reduce the dose due to AE, 4% due to neutropenia and 2% to nausea. With a median appearance in both groups of 28 days [13-229]. At the time of analysis,

7 patients with ribociclib and 12 palbociclib had discontinued the treatment for any cause.

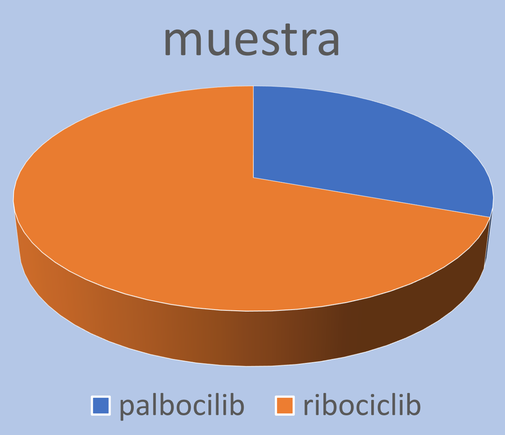
DOSE REDUCTION DUE TO AE:

PALBOCICLIB GROUP -> 8 pat:

Neutropenia

Thrombocytopenia

Uknown



DOSE REDUCTION DUE TO AE:

RIBOCICLIB GROUP -> 3 pat:

Neutropenia

Nausea

CONCLUSIONS:

In our sample of patients the FPS was 5,2 mounths lower than previous trials, and the tolerance of ribociclib was better than that of palbociclib. These data are not consistent with previous studies, and it can not be ruled out that the differences are due to differences in the profile of the patients.

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