

SAFETY AND SEVERE NEUTROPENIA IN PATIENTS TREATED WITH PALBOCICLIB AND RIBOCICLIB IN REAL WORLD CLINICAL PRACTICE

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Background and importance: Palbociclib and Ribociclib are oral inhibitors of cyclin-dependent kinases for the treatment in first and second line of breast cancer (BC) hormone receptor (HR)-positive and HER2-negative locally advanced or metastatic. The most common adverse events (AE) described in clinical trials(CT) were haematological, especially neutropenia.

Aim and Objectives: To compare the safety and incidence of severe neutropaenia in patients treated with palbociclib and ribociclib in clinical practice.

Material and methods:

A descriptive and retrospective study was performed in patients treated with palbociclib and ribociclib in a third level hospital from January 2018 to September 2020. We registered demographic data (sex and age), median number of cycles received (mNCR), discontinuations, number of patients with dose reductions (NDR) and absolute neutrophil count (ANC). Demographic and clinical data were obtained from digital clinical history and toxicity grade (G) of neutropaenia was classified by CTCAE.v5.0.

Results:

- N= 62
- median age =60
- metastatic BC HR-positive/HER2-negative

PALBOCICLIB

- N=35
- mNCR =10 (1-28)
- N severe neutropenia= 19 (54,2%): 3 (8,6%) G4 y 16(45,7%) G3.
- median discontinuations: 2
- NDR= 16 (45,7%)

RIBOCICLIB

- N=27
- mNCR =7 (2-28)
- N severe neutropenia= 10(37%): 1(3,7%) G4 y 9 (33,3%)G3.
- median discontinuations: 3
- NDR= 8 (29,6%)

The causes of suspension of treatment were:

Toxicity (medullary aplasia, severe exanthema, asthenia and anaemia) in 4 (11,4%) patients treated with palbociclib and 5(18,5) with ribociclib, interactions (1 patient treated with palbociclib) and disease's progression in the rest of patients.

Conclusion and Relevance:

In clinical practice, the incidence of severe neutropaenia in patients treated with palbociclib and ribociclib was higher than in CT with less incidence of neutropaenia G4 and G3 in patients treated with ribociclib. However, severe neutropaenia was successfully manageable with dose reductions and discontinuations in both treatments, so any patient had to stop treatment due to neutropenia. On the other hand, the proportion of patients treated with palbociclib and ribociclib that required dose reductions were equal.