Palbociclib in real clinical practice: Results of a single-center observational study

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Objective

To analyze the effectiveness and safety of palbociclib in combination with endocrine therapy for patients with metastatic HR+/HER2- breast cancer (mBC) in a real-world clinical setting at the Republican Clinical Oncology Dispensary (Ufa, Russia).

Materials and Methods

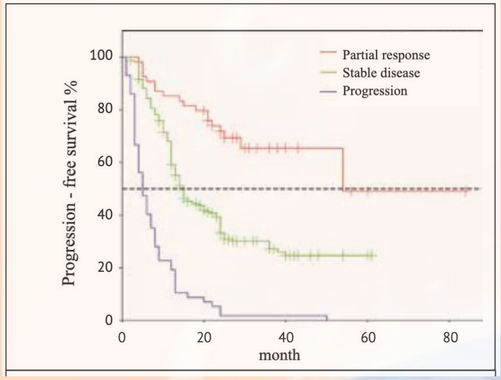
A retrospective analysis of data from 323 patients with metastatic HR+/HER2- BC who were treated with palbociclib combined with endocrine therapy (aromatase inhibitors or fulvestrant) between 2020 and 2024. Data on effectiveness (progression-free survival - PFS, objective response) and safety (adverse events) were collected from medical records and examination reports. Statistical analysis was performed using the Kaplan-Meier method and Cox regression.

Results

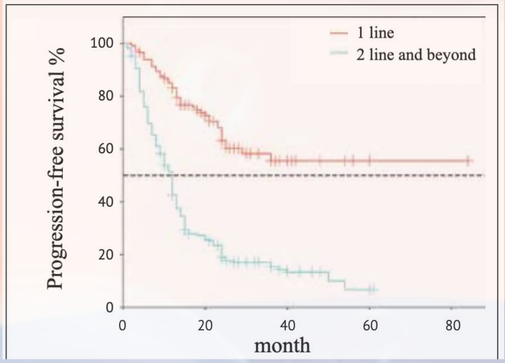
- **Effectiveness:** The median PFS for the entire group was 13 months. A partial response was recorded in 16.7% of patients, and disease stabilization in 65.6%. The best results were observed with 1st-line therapy: the median PFS was not reached, while it was 24 months in the 2nd line and only 5 months in the 5th and later lines.
- **Safety:** Grade 3 adverse events were noted in 7.1% of patients. The most common were hepatotoxicity (47.8% of all Grade 3 AEs) and neutropenia (21.7%). No cases of febrile neutropenia occurred. No patient discontinued therapy due to adverse events.
- **Prognostic Factors:** The depth of response (stabilization vs. partial response) and the duration of response (>24 months) were significant prognostic factors. The presence of visceral metastases and brain metastases did not have a statistically significant impact on PFS.

Conclusions

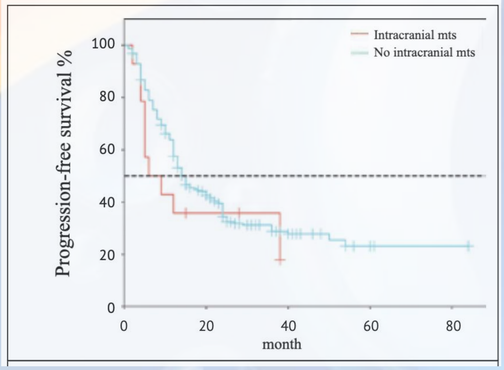
Combination endocrine therapy with palbociclib is a highly effective and safe treatment option for metastatic HR+/HER2- breast cancer in real-world clinical practice. The best outcomes are achieved when this therapy is used in the first line. Palbociclib shows activity in patients with visceral and brain metastases. These findings confirm the results of randomized clinical trials in a routine practice setting.



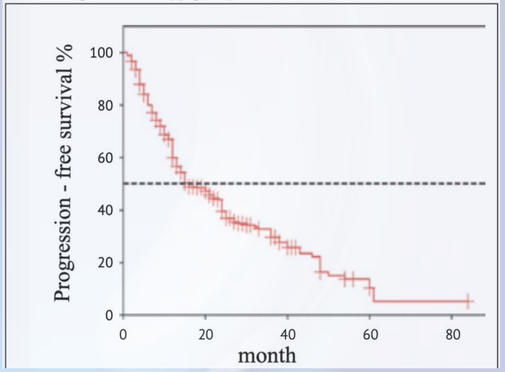
Progression-free survival according to the depth of objective response



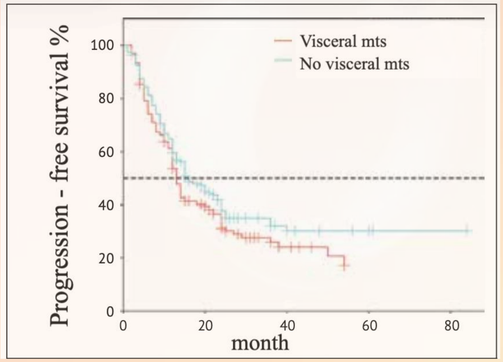
Progression-free survival according to the Palbociclib combination therapy line



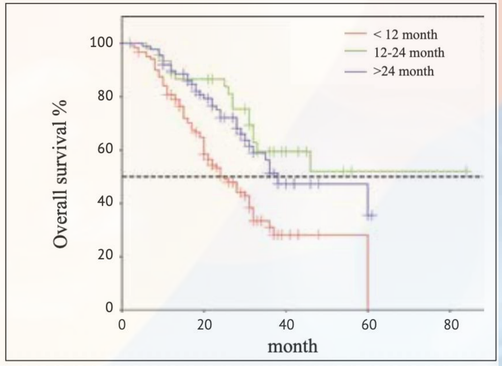
Progression-free survival according to the presence of brain metastases



Median progression-free survival in the total hormone-targeted therapy group



Progression-free survival according to the presence of visceral metastasis



Death rates according to the duration of antitumor response to palbociclib therapy

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