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Palbociclib in real-world practice before and during COVID-19 pandemic - a single institute experience.

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Abstract:

Palbociclib is one of three available CDK4/6 inhibitors. This prospective observational study looked at the utilization of Palbociclib in metastatic breast cancer (MBC) during the COVID-19 pandemic period, particularly outlining the disease course and its impact on patients and health services. The rapid spread of the SARS-CoV-2 pandemic and the increased risk of clinically severe diseases in cancer patients were worrying. During this period, it was observed that oral. Palbociclib was tolerated well during the pandemic with minimal toxicity and good response. In the context of the COVID-19 pandemic, Palbociclib is an option for patients with HR+ and HER2-negative advanced breast cancer.

Introduction:

Palbociclib is a medication used in the treatment of certain types of breast cancer. It belongs to a class of drugs called cyclin-dependent kinase 4/6 (CDK4/6) inhibitors, which work by blocking the activity of proteins involved in the regulation of cell division. Palbociclib is often used in combination with other medications and therapies for the treatment of hormone receptor-positive, HER2-negative advanced breast cancer. Palbociclib is one of three available CDK4/6 inhibitors. During the COVID-19 pandemic, the use of many anti-cancer medications has continued, with adjustments made to ensure patient safety and continuity of care. Oncologists and healthcare providers have taken precautions to minimize the risk of exposure to the virus for patients undergoing cancer treatment, including offering telemedicine appointments, implementing enhanced cleaning protocols in clinics and hospitals, dose modifications, and prioritizing treatments based on individual patient needs and risk factors. Patients receiving palbociclib have also been advised to follow their healthcare provider's guidance closely and to adhere to recommended safety measures to reduce the risk of COVID-19 transmission. During the pandemic, the situation was evolving, and many rapid guidelines were issued to manage cancer patients, aiming for their safety and well-being.

Aims and objectives:

To understand the utility of Palbociclib in metastatic breast cancer (MBC) during the COVID-19 pandemic period, particularly outlining their disease course and its impact.

Methods:

A prospective observational study was conducted with endpoints of disease progression or death due to any cause during treatment. Electronic databases of the hospital were utilized to describe and analyze the clinical utility of palbociclib in routine clinical practice for the treatment of advanced breast cancer during the COVID-19 pandemic period. The period covered ranged from March 2020 to June 2020 and from February 2019 to July 2019 before the COVID-19 period in the Cancer Centre at University Hospitals of North Midlands United Kingdom. All patients with advanced breast cancer taking palbociclib were included. Results were compared among both periods and analyzed using univariate and multivariate methods, including survival analysis.

Results:

Twenty patients were on palbociclib prior to the COVID-19 pandemic in the first-line setting in combination with aromatase inhibitors, and a total of 32 patients received palbociclib during the COVID-19 period of four months. During the pandemic period, 75% (24/32) were started in combination with aromatase inhibitor (AI) as first-line treatment, and 25% (8/32) were started with Fulvestrant in second-line settings. Median age was 71 years (SD=10). In this study, 50% were above 70 years of age, and there was no patient less than 50 years of age. One patient was pre-menopausal and underwent ovarian ablation, with the remaining patients being postmenopausal.

There was one male patient in this population. There were two cohorts of patients, one from before the COVID10 period and the other one during

COVID-19. Age and specific sites of metastatic disease were comparable in both cohorts. However, significantly more patients were treated with visceral disease during the COVID-19 period. **(Fig: 1)**.

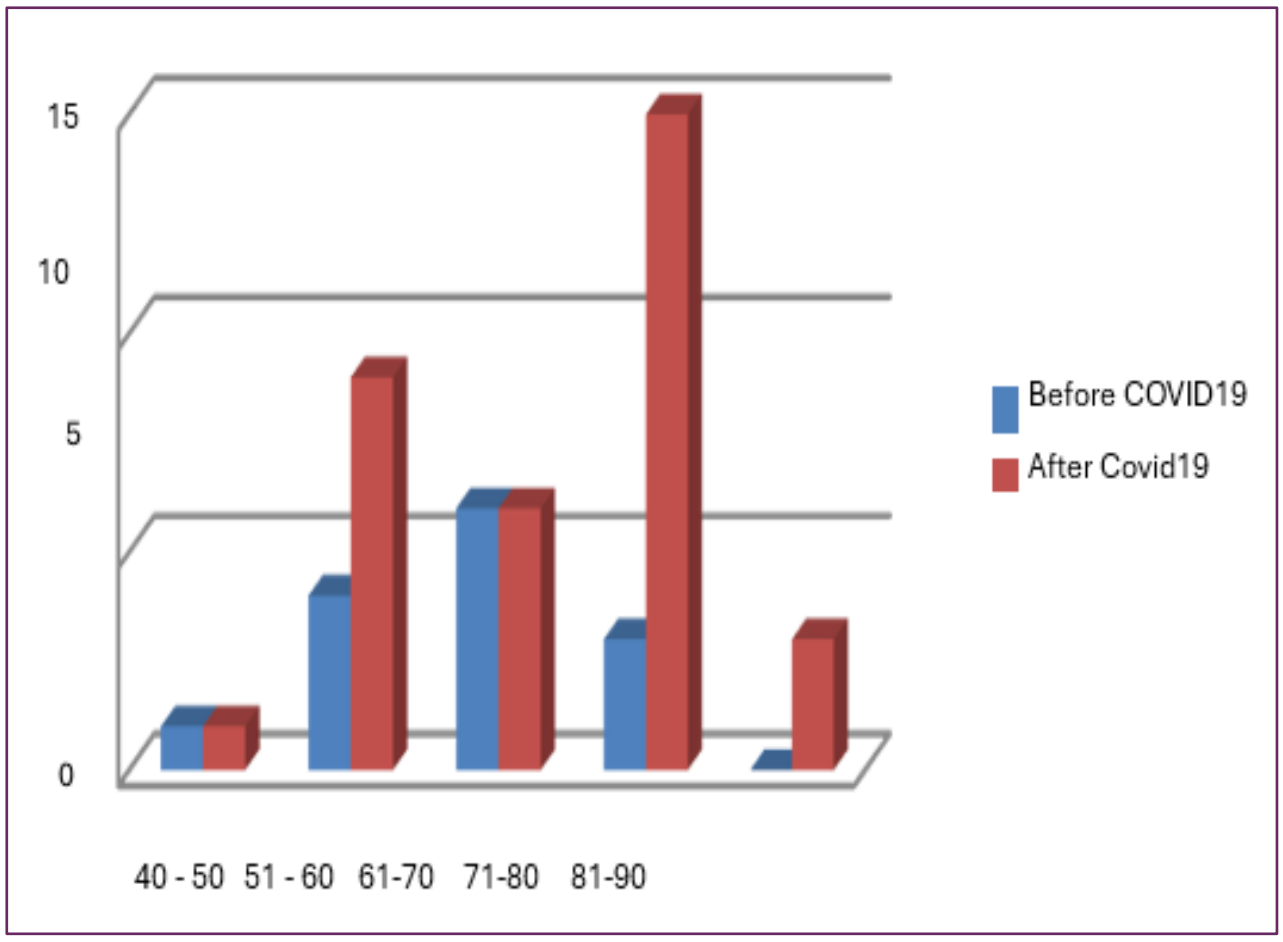

Fig: 1. Age comparison of patients taking palbociclib before and during the COVID-19 pandemic.

The Average number of cycles given was 10 (range 1-31 cycles). This was similar in both groups. **(Fig: 2)**.

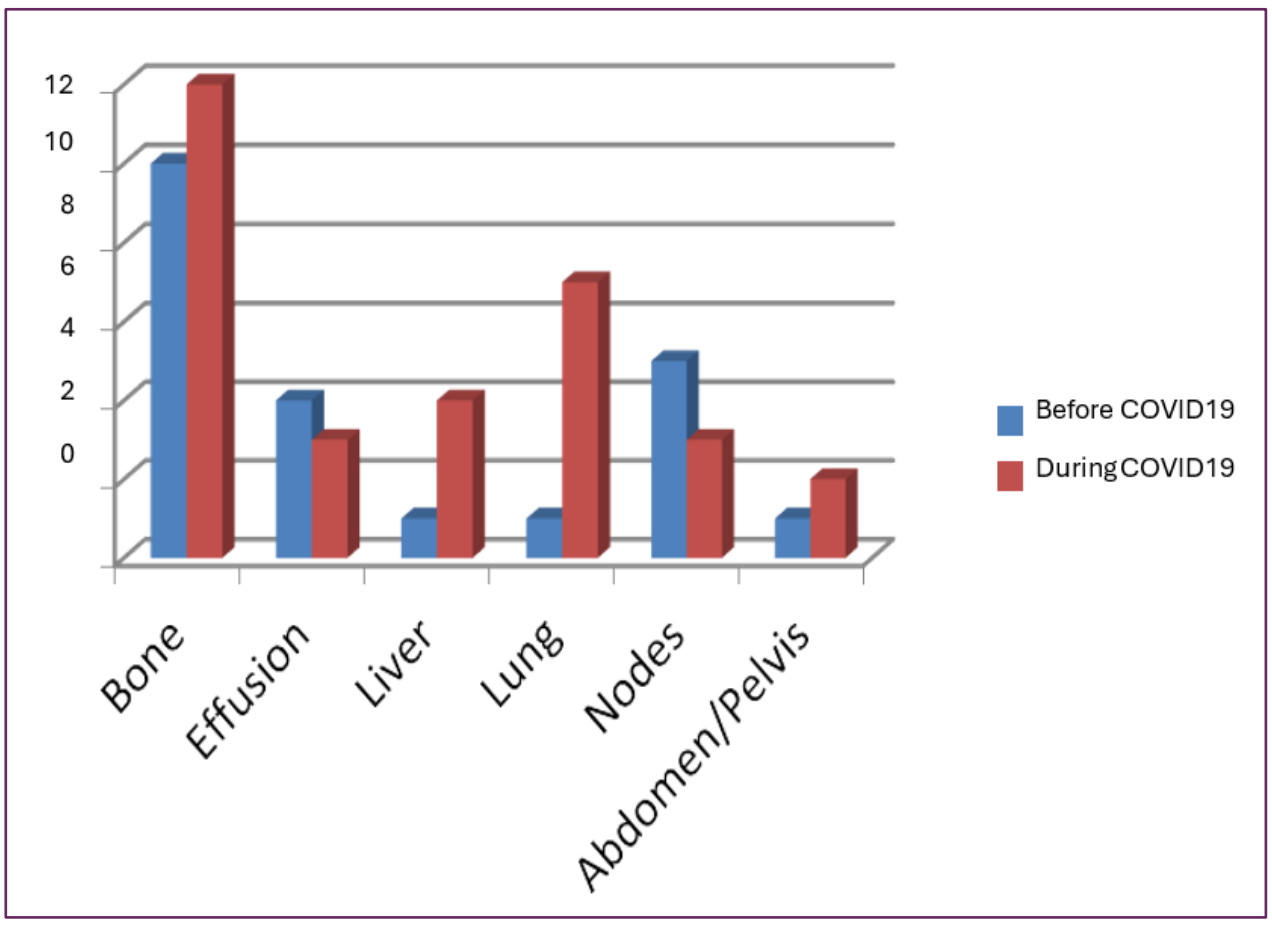

Fig: 2. Specific sites of metastatic disease taking palbociclib before and during the COVID-19 pandemic.

Radiological partial response (PR) or stable disease (SD) was found in 50% of patients during the COVID10 period. However, 10 patients had less than 3 cycles, making it difficult for radiological assessment. Three patients had disease progression, and one of them died due to disease progression. One patient had intermediate radiological evidence of COVID-19 infection in the lungs, as seen in the CT scan. Viral PCR nasopharyngeal swab was negative in this patient. No other patient developed COVID-19 symptoms (cough, fever, or loss of smell). Fig: 1. Age comparison of patients taking palbociclib before and during the COVID-19 pandemic.

Bone or nodal disease was present in 34%, and visceral disease was present in 68% of them. Almost 80% had mild to moderate co-morbidities. Performance status on the ECOG (Eastern Cooperative Oncology Group) scale was between 0 and 2. All of them were started on the recommended starting dose of 125 mg daily. The first dose reduction (100 mg) was seen in 20% of patients due to grade 3 neutropenia and fatigue. Two patients had a second dose reduction (75 mg) due to persistent grade 3 neutropenia. Both of them developed delayed neutropenia after five cycles. One patient was older than 85 years. There was no drug interruption for more than two weeks. In 40% of patients with cancer, antigen 15-3 (CA 15-3) measurement was

normal at the start of treatment, making it difficult to use it as a prognostic indicator in the majority of them. In this study, both groups have shown similar results in terms of response and toxicity **(Fig: 3)**.

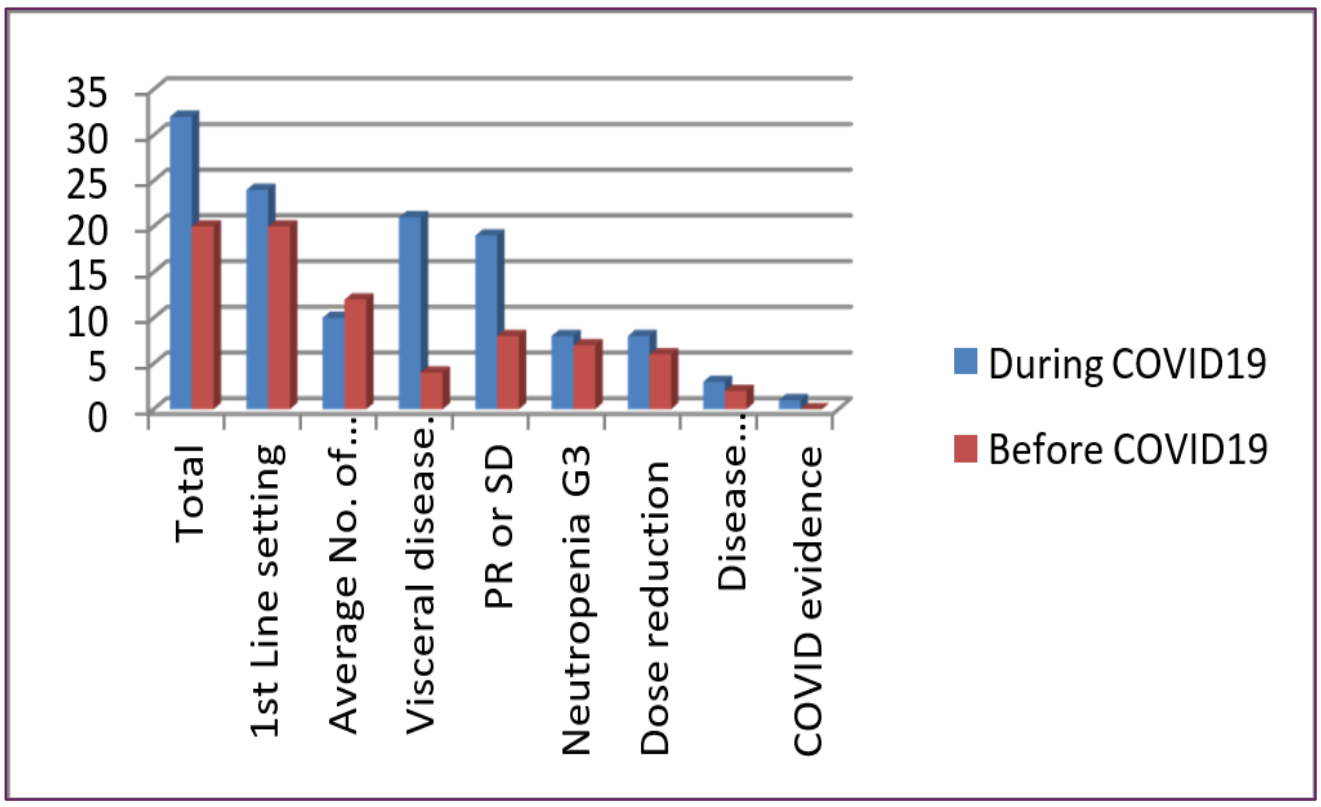

Fig: 3. Patients treated before and during COVID-19. PR: Partial Response, SD: Stable disease

Median Progression Free Survival (PSF) during COVID-19 was 6 months (SD=8.9). **(Fig: 4)**.

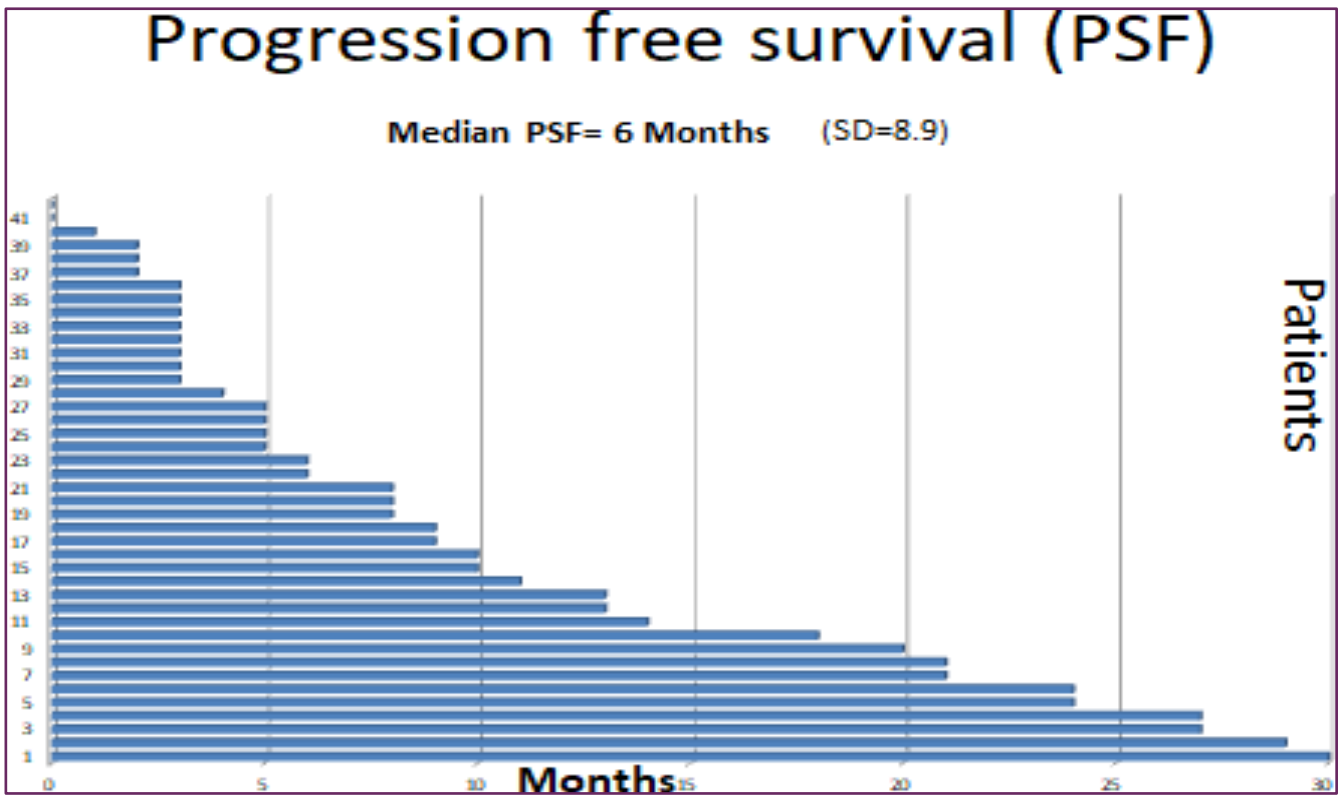

Fig: 4. Waterfall plot showing Progression Free Survival (PFS) with Median PFS=6 months during COVID-19

Majority of patients were still on treatment. Kaplan-Meier survival analysis showed a 65% survival probability at 9.5 months. **(Fig: 5)**.

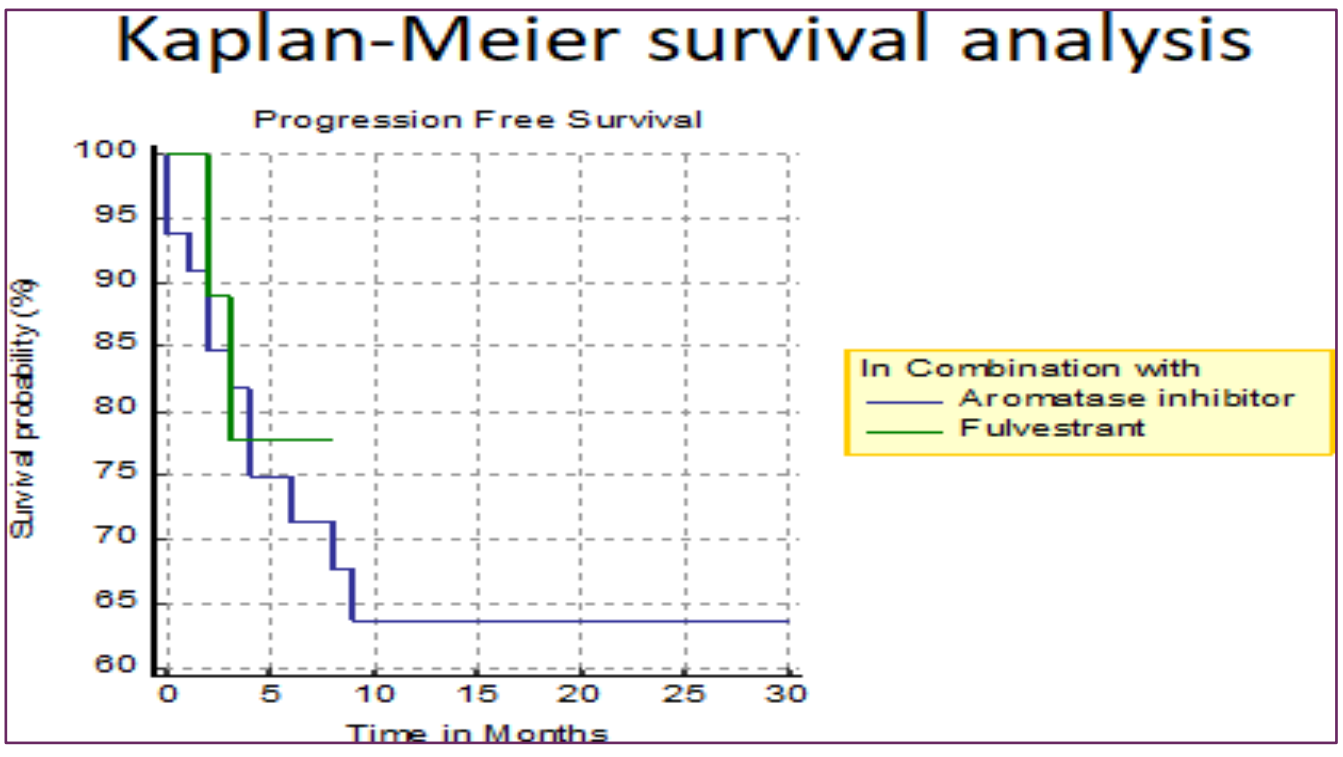

Fig: 5. Kaplan-Meier survival analysis showed a 65% survival probability at 9.5 months.

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Discussion:

Since April 2020, severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) associated diseases (COVID-19) has already established itself globally, causing an overload of hospital systems worldwide **[1]**. Healthcare resources were overwhelmed by a large influx of patients **[2]**, which consequently led to the disruption of routine medical care, including the treatment of cancer patients **[3]**. Travel restrictions and fear of contracting COVID-19 in immune-compromised cancer patients have created difficulty, particularly for MBC patients, in reaching the hospitals timely **[4]**. In this situation, oral treatment was deemed more appropriate considering reduced Visits/contacts into the hospital, being the hot zone, the logistics, and reduced toxicity **[4]**. This led to the development of rapid guidelines to manage metastatic breast cancer patients **[5]**. For a vast majority of oestrogen receptor (ER) positive and HER2 receptor negative MBC patients, endocrine-based therapy was recommended as a preferred choice following usual international guidelines **[5]**. During the COVID-19 period, the most difficult decision was to add CDK 4/6 inhibitors on top of endocrine treatment due to their immunosuppressive effects **[5].**

Recent major studies like PALOMA-2, PALOMA-3, MONALEESA-2, MONALEESA-7 and MONARCH-2 and MONARCH-3 have shown the genuine advantages of CDK 4/6 inhibitors, including palbociclib, ribociclib, abemaciclib, in first and second line settings in ER+/HER2- negative MBC patients **[6]**. The most common side effects of palbociclib are neutropenia, leukopenia, fatigue, and nausea **[7]**. In recent large trials, respiratory infections were also recognized during CDK 4/6 inhibitors treatment **[8]**. During COVID-19 pandemic conditions, the decision to choose the CDK 4/6 inhibitors was crucial as well as challenging **[5]**. This study shares a single institution's experience with palbociclib during a pandemic.

Conclusion:

The majority of patients have tolerated oral CDK4/6 very well in the form of palbociclib during the COVID-19 pandemic period without a major impact on patients or healthcare services. The main side effects of palbociclib remained mild immunosuppression, requiring dose modification. This study supports the use of palbociclib during the COVID-19 pandemic in ER+/HER-2 negative metastatic breast cancer patients in first-line or second-line settings without major complications. Cancer patients remain at potential risk for severe COVID-19 infection, requiring vigilant surveillance. Palbociclib appeared to be a reasonable choice in this setting in case of an epidemic surge in the future.

Summary:

The rapid spread of the SARS-CoV-2 pandemic and the increased risk of severe clinical disease in cancer patients were worrying. During this period, it was observed that oral Palbociclib was tolerated well during the pandemic with minimal toxicity and good response. In the context of the COVID-19 pandemic, Palbociclib remained an option for patients with HR+ and HER2-negative advanced breast cancer.

Impact statement:

Palbociclib was tolerated extremely well during the COVID-19 pandemic.

Acknowledgment:

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