PALBOCICLIB SAFETY IN METASTATIC BREAST CANCER

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Background and Importance
Loss of cell cycle regulation due to pathway alterations Cyclin D-CDK4/6-Rb is common in breast cancer. Palbociclib is a CDK4/6 inhibitor, indicated in metastatic breast cancer (mBC).

Materials and Methods
- Retrospective descriptive study, from 01/07/2019 until 21/07/2020.
- Patients with mBC on treatment with Palbociclib.
- Variables recorded:
  - Sex
  - Age
  - Menopause status
  - Performance status (PS)
  - Cancer stage
  - Presence of visceral metastatic disease
  - Number of adverse events (AE)
  - Severity of AEs was graded on the basis of the “Common Terminology Criteria for Adverse Events” version 5.0.
  - Number of patients and reason for delays and dose reduction

<table>
<thead>
<tr>
<th>Nº Patients</th>
<th>Variable recorded</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>44 patients</td>
<td>Sex</td>
<td>100% women</td>
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<tr>
<td></td>
<td>Age</td>
<td>60 (47-81) years-old</td>
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<tr>
<td></td>
<td>Menopause Status</td>
<td>71% postmenopausal</td>
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<tr>
<td></td>
<td>Performance status (PS)</td>
<td>PS≤1 → 29 patients</td>
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<tr>
<td></td>
<td>Cancer stage</td>
<td>metastatic disease → 100%</td>
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<tr>
<td></td>
<td>Presence of visceral metastatic disease</td>
<td>76% patients</td>
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<tr>
<td></td>
<td>Therapeutic scheme</td>
<td>Palbociclib 125mg every 8 weeks</td>
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<tr>
<td></td>
<td>Number of cycles received</td>
<td>7 (1-17) cycles</td>
</tr>
</tbody>
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Results

- Adverse Event Reports
  - 105 AEs (31)
    - HEMATOLOGIC: 54
    - METABOLIC: 23
    - DIGESTIVE: 10
    - ASTHENIA: 7
    - INFECTIONS: 2
    - OTHERS CAUSES: 9

<table>
<thead>
<tr>
<th>AEs</th>
<th>Grade-1</th>
<th>Grade-2</th>
<th>Grade-3</th>
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<tbody>
<tr>
<td></td>
<td>%</td>
<td>59%</td>
<td>30%</td>
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- Delayed: 13 patients → Reason: Neutropenia (85%)
- Reduced doses: 6% of patients → Reason: Neutropenia and Mucositis.

Conclusion and Relevance
1. There was a high incidence of adverse reactions, the most frequent being grade 1.
2. The most common AE were hematologic, with neutropenia being the highest degree.
3. Our studies suggest a high percentage of delays and dose reduction.