ADVERSE DRUG REACTIONS DUE TO MEDICINES UNDER ADDITIONAL MONITORING

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Background and Importance

The European list of medicines under additional monitoring (MUAM), identified with a black inverted triangle, includes new active substances, biological medicines, medicines that require a post-authorisation safety study, medicines approved conditionally or authorised under exceptional circumstances and medicines authorised with specific obligations on the recording or monitoring of suspected adverse drug reactions (ADR). This list is reviewed monthly by the Pharmacovigilance Risk Assessment Committee (PRAC). A drug remains under additional monitoring for 5 years or until the PRAC decides to remove it from the list.

Aim and Objectives

To describe the ADR produced by MUAM.

Material and Methods

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Material and Methods

Descriptive retrospective study (2013 - 2018)

2nd level hospital

Pharmacy Service:

- ADR due to MUAM detection
- Electronic medical history review
- Recording and notifying to the FC

(Spontaneously or from the CAIS)

CAIS: Complex Analysis Information System. DS: Data Sheet. FC: Farmacovigilance Center.

Results

Main ADRs

<table>
<thead>
<tr>
<th>ADR</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>Febrile neutropenia</td>
<td></td>
</tr>
<tr>
<td>Bradycardia</td>
<td></td>
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<tr>
<td>Hepatocarcinoma</td>
<td></td>
</tr>
<tr>
<td>Thrombocytopenia</td>
<td></td>
</tr>
<tr>
<td>Oliguric AKI</td>
<td></td>
</tr>
<tr>
<td>Vomiting</td>
<td></td>
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</tbody>
</table>

45 ADR

26 medicines

40 patients

- Antineoplastic agents were the most involved therapeutic group in ADR.
- MUAM caused hospital admission in a high percentage of cases and were the cause of exitus in 3.
- 13,3% of ADR were considered new, so it is essential to continue reporting suspected ADR to gather new information to help define the safety profile of all medicines, especially MUAM.

Conclusion

- Antineoplastic agents were the most involved therapeutic group in ADR.
- MUAM caused hospital admission in a high percentage of cases and were the cause of exitus in 3.
- 13,3% of ADR were considered new, so it is essential to continue reporting suspected ADR to gather new information to help define the safety profile of all medicines, especially MUAM.