PREVALENCE OF NIVOLUMAB ADVERSE EVENTS IN ROUTINE CLINICAL PRACTICE

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BACKGROUND AND IMPORTANCE

- Nivolumab is an anti PD-1 antibody, authorized in 2015.
- It is indicated in:
  - Adjuvant or metastatic melanoma (MC)
  - Metastatic non-small cell lung cancer (NSCLC)
  - Renal cell carcinoma (RCC)
  - Squamous cell carcinoma of the head and neck (HNC)
- No data reported about adverse events (AE) on long-term treatments.

AIM AND OBJECTIVES

To assess the nivolumab tolerability and to identify and calculate the prevalence of AE related to nivolumab. Compare its frequency with the one described on the data sheet.

MATERIALS AND METHODS

- Descriptive retrospective observational study
- Patients treated with nivolumab since it was commercialized (March 2016 – September 2019)

<table>
<thead>
<tr>
<th>Variables collected</th>
<th>Sex</th>
<th>Age</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diagnosis</td>
<td>No. nivolumab doses</td>
<td></td>
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<tr>
<td>Adverse Events</td>
<td>Deaths</td>
<td></td>
</tr>
<tr>
<td>Start/End date of nivolumab</td>
<td>Stop reason</td>
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- AE classified according the prevalence described on the summary of product characteristics:
  - Very common (>10%)
  - Common (1-10%)
  - Not common (0,1-1%)
  - Rare (0,01-0,1%)
  - Very rare (<0,01%)

RESULTS

- 48 patients
- 77% male
- Median of 63 years old
- 77% interrupted nivolumab

Prevalence main diagnosis

- MC 10%
- NSCLC 40%
- RCC 29%

Reason to interrupt

- Progression 78%
- AE 17%
- Finish point; 6%

Deaths:
- 84,2% NSCLC
- 60% HNC
- 50% RCC
- 20% MC

CONCLUSION

- Relevant AE occurred during the period studied.
- Higher prevalence of AE in clinical practice than expected leading to treatment interruption.
- A strict monitoring of analytical parameters is needed to detect AE as early as it could.

Prevalence of hypothyroidism, colitis, hepatitis, nephritis and arthritis is higher than the one reported in clinical trials.