NIVOLUMAB IN LUNG CANCER: FROM WEIGHT-BASED TO FLAT DOSING

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Background & Objectives

• Nivolumab:
  ✓ Monoclonal antibody targeting PD1, immunotherapy
  ✓ Approved by the EMA in 2015
  ✓ Indicated in many cancers, including non-small cell lung cancer (NSCLC)

• Industrial development strategy:
  ✓ First, a weight-based approach with 3mg/kg every 2 weeks (Q2W)
  ✓ In 2018 simplification of the dosing regimen for a flat dose of 240mg Q2W, regarding studies which assess effectiveness and safety (1–3)
  ✓ But one of these studies → non-statistically trend in more serious side effects (SSE) in low body-weight patients (LBW, <50kg)(2)
  ✓ Aim of the study: to review the new dosing regimen and to evaluate if it would represent significant financial changes for our hospital regarding the patients’ cohort.

Material & Methods

• Retrospective record of anthropometric and clinical data from all the patients treated by nivolumab for NSCLC in our center between January 2017 and June 2018
• Evaluation of the cost per milligram of nivolumab (thanks to national reimbursement data).
• Calculation of the cost for three treatment strategies:
  ✓ 3mg/kg Q2W
  ✓ 240mg flat dose Q2W (as if new dosing strategy was applied all along the treatment)
  ✓ 240mg flat dose Q2W except for patients under 50kg (mixed strategy, 3mg/kg Q2W dosing regimen, taking into account the trend in more SSE in LBW patients) (2).

Results

• Total of 49 patients included in the study

Table 1: Patients characteristics

<table>
<thead>
<tr>
<th>Patients</th>
<th>n = 49</th>
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<tbody>
<tr>
<td>Lost patients</td>
<td>8</td>
</tr>
<tr>
<td>Deaths</td>
<td>6</td>
</tr>
<tr>
<td>Sex ratio (M/F)</td>
<td>3.08</td>
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<tr>
<td>Patients &lt; 50 kg (%)</td>
<td>6 (12.2 %)</td>
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<tr>
<td>Mean age ± standard deviation (years)</td>
<td>67 ± 9</td>
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<tr>
<td>Mean height ± standard deviation (cm)</td>
<td>170 ± 9</td>
</tr>
<tr>
<td>Mean weight ± standard deviation (kg)</td>
<td>69.4 ± 19.2</td>
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<tr>
<td>Mean body area ± standard deviation (m²)</td>
<td>1.8 ± 0.26</td>
</tr>
<tr>
<td>Average number of cures (min-max)</td>
<td>13 (1 - 63)</td>
</tr>
</tbody>
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• Nivolumab average cost per milligram in our country 10.57€

Discussion & Conclusions

• Nivolumab flat dose:
  ✓ Practical benefits in terms of prescription and preparation
  ✓ Extra-cost regarding our patients’ population in NSCLC
• Prescription should be wise in LBW patients, waiting the results of clinical trials
• Flat dose strategies for monoclonal antibodies in oncology are a challenge but also a paradox in the era of personalized medicine

References