OFF-LABEL USE OF NEBULISED AZTREONAM LYSINE IN PATIENTS WITH CHRONIC GRAM-NEGATIVE BACTERIAL LUNG COLONISATION

S. Garcia García1, I. Cardona Pascual1, E. Revilla López2, M. Larrosa García1, C. Alonso Martínez1, J. Vidal Otero1, C. Alerany Pardo1, L. Cantos Gil1, P. Granollers Rabal1, M.R. Gomez Domingo1, J.B. Montoro Ronsano1.

1 Pharmacy Service, 2 Pneumology Surgery Service, 3 Artificial Intelligence Information Service, Vall d’Hebron University Hospital, Barcelona, Spain.

**Purpose**

Aztreonam lysine inhalation solution (AZLI) is approved for nebulized treatment (nebT) of pulmonary P. aeruginosa infections in patients with cystic fibrosis (CF).

To assess safety and effectiveness of AZLI for nebT in patients with NON-CF bronchiectasis or LT colonized by gram-negative chronic bacteria.

* To evaluate treatment effects (time=0 vs follow up data), variance analysis (ANOVA) was applied (SPSS®).

**Material and Methods**

**Observational retrospective study:** within 2013-2019. Patients with non-CF bronchiectasis or LT affected by chronic gram-negative bacteria infection> 18 years old

**Analized variables**

- Hospital admissions
- Infective bacteria
- Previous nebT
- Safety date of AZLI
- Effectiveness date of AZLI.

**Results**

15 patients (previously treated with alternative nebT)

Reason to stop previous treatment was:

- Tobramycin/colistin intolerance: n= 6; 40%
- Tobramycin/colistin resistance: n= 7; 46.7%
- No clinical improvement: n= 2; 13.3%

Bacteria causing chronic infection:

- Lung transplant
  - P. aeruginosa: n= 6; 75%
  - P. mirabilis: n= 2; 25%
- Bronchiectasis
  - P. aeruginosa: n= 7; 100%

**Respiratory function tests during AZLI** (mean values of population):

<table>
<thead>
<tr>
<th>Diagnostic</th>
<th>FVC (%)</th>
<th>FEV1 (%)</th>
<th>FEF25-75 (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>BC</td>
<td>56.5 ± 13.6</td>
<td>49.2 ± 8.8</td>
<td>25.3 ± 9.3</td>
</tr>
<tr>
<td>LT</td>
<td>48.1 ± 13.6</td>
<td>41.0 ± 17.0</td>
<td>25.0 ± 13.4</td>
</tr>
<tr>
<td>Mean follow-up</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>BC</td>
<td>58.0 ± 10.1</td>
<td>47.1 ± 4.0</td>
<td>21.4 ± 7.3</td>
</tr>
<tr>
<td>LT</td>
<td>48.6 ± 14.5</td>
<td>45.2 ± 13.9</td>
<td>33.5 ± 12.7</td>
</tr>
</tbody>
</table>

Remission data (negative results in sputum burdens):

- BC: n= 2 (28.6 %)
- LT: n= 1 (12.5 %)

**Conclusion**

Results suggests that off-label use AZLI in complicated chronic infected patients could control gram-negative infection and neutralize sputum burdens in some cases, while maintaining lung function and decreasing accelerated clinical deterioration.