

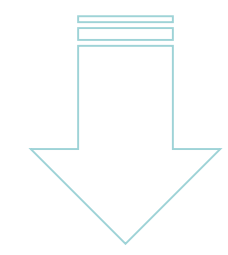
# OFF-LABEL USE OF NEBULISED AZTREONAM LYSINE IN PATIENTS WITH CHRONIC GRAM-NEGATIVE BACTERIAL LUNG COLONISATION

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## 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

### Analyzed variables

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

### Respiratory function tests

**FVC**

**FEV1**

**FEF25-75**

Mean and standard deviation → each patient along AZLI treatment

## 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 %

**Bronchiectasis (BC)**  
[n= 7; 28.6 % male]

**Lung transplant (LT)**  
[n= 8; 50.0 % male]



→ "on/off" cycles in combination with other nebT

→ Monotherapy

→ **BC**: n= 1; 14.3 %

→ **LT**: n= 3; 37.5 %

**Annual emergency admissions** → 0.07 before AZLI  
→ 0.42 during AZLI

**Annual rate of hospital admissions** → 0.44 before AZLI  
→ 0.55 during AZLI

10.1 ± 9.7 months

20.6 ± 14.2 months

AZLI treatment duration

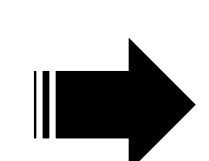
### Respiratory function test during AZLI (mean values of population):

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

Comparing BC with LT statistically **significant improvement was observed in FVC (p= 0.011) and FEF25-75 (p= 0.005)**, however it was **not clinically relevant**.

### Remission data

(negative results in sputum burdens):



**BC**: n= 2 (28.6 %)

**LT**: n= 1 (12.5 %)

### Reported treatment-emergent adverse effects (AE):



**BC**: n= 3; 42,9 %

**LT**: no AE

Dyspnoea, bronchospasm and artralgies

**No deaths in either group**

## 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**.

