

Table 45: Clinical evidence profile: Comparison 4.3 Tobramycin versus Aztreonam lysine

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Tobramycin	Aztreonam lysine	Relative (95% CI)	Absolute		
Lung function: % change in FEV₁ % predicted (follow-up: 3 months; range of scores: 0-100; Better indicated by higher values) [TOBI nebulised versus AZLI inhaled]												
1 (Assael 2013)	randomised trials	serious ¹	no serious inconsistency	no serious indirectness	no serious imprecision	none	132	136	-	MD 2.71 lower (2.88 to 2.54 lower)	MODERATE	CRITICAL
Number of patients with 1 or more exacerbations												
NMA outcome												
Suppression of the organism: adj mean change sputum density log₁₀ PA CFU/G (follow-up 20 weeks; Better indicated by higher values) [TOBI nebulised versus AZLI inhaled]												
1 (Assael 2013)	randomised trials	serious ¹	no serious inconsistency	no serious indirectness	serious ²	none	97	97	-	MD 0.23 higher (0.3 lower to 0.76 higher)	LOW	IMPORTANT
Nutritional status: % adj mean weight change (follow-up 24 weeks; Better indicated by higher values) [TOBI nebulised versus AZLI inhaled]												
1 (Assael 2013)	randomised trials	serious ¹	no serious inconsistency	no serious indirectness	serious ²	none	132	136	-	MD 0.52 lower (1.68 lower to 0.64 higher)	LOW	IMPORTANT
Quality of life: CFQ-R respiratory, adj mean change (follow-up 20 weeks; Better indicated by higher values) [TOBI nebulised versus AZLI inhaled]												
1 (Assael 2013)	randomised trials	serious ¹	no serious inconsistency	no serious indirectness	serious ³	none	131	131	-	MD 4.1 lower (8.59 lower to 0.39 higher)	LOW	IMPORTANT
Minor adverse events: chest discomfort (follow-up 3 months) [TOBI nebulised versus AZLI inhaled]												
1 (Assael 2013)	randomised trials	serious ¹	no serious	no serious	very serious ⁴	none	13/132 (9.8%)	14/136 (10.3%)	RR 0.96 (0.47	4 fewer per 1000 (from 55	VERY LOW	IMPORTANT

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Tobramycin	Aztreonam lysine	Relative (95% CI)	Absolute		
			inconsistency	indirectness					to 1.96)	fewer to 99 more)		
Minor adverse events: cough (follow-up 3 months) [TOBI nebulised versus AZLI inhaled]												
1 (Assael 2013)	randomised trials	serious ¹	no serious inconsistency	no serious indirectness	serious ²	none	104/132 (78.8%)	96/136 (70.6%)	RR 1.12 (0.97 to 1.28)	85 more per 1000 (from 21 fewer to 198 more)	LOW	IMPORTANT
Minor adverse events: headache (follow-up 3 months) [TOBI nebulised versus AZLI inhaled]												
1 (Assael 2013)	randomised trials	serious ¹	no serious inconsistency	no serious indirectness	very serious ⁴	none	27/132 (20.5%)	29/136 (21.3%)	RR 0.96 (0.6 to 1.53)	9 fewer per 1000 (from 85 fewer to 113 more)	VERY LOW	IMPORTANT
Minor adverse events: vomiting (follow-up 3 months) [TOBI nebulised versus AZLI inhaled]												
1 (Assael 2013)	randomised trials	serious ¹	no serious inconsistency	no serious indirectness	very serious ⁴	none	14/132 (10.6%)	14/136 (10.3%)	RR 1.03 (0.51 to 2.08)	3 more per 1000 (from 50 fewer to 111 more)	VERY LOW	IMPORTANT
Major adverse events: dyspnoea (follow-up 3 months) [TOBI nebulised versus AZLI inhaled]												
1 (Assael 2013)	randomised trials	serious ¹	no serious inconsistency	no serious indirectness	serious ²	none	21/132 (15.9%)	31/136 (22.8%)	RR 0.7 (0.42 to 1.15)	68 fewer per 1000 (from 132 fewer to 34 more)	LOW	IMPORTANT
Major adverse events: haemoptysis (follow-up 3 months) [TOBI nebulised versus AZLI inhaled]												
1 (Assael 2013)	randomised trials	serious ¹	no serious inconsistency	no serious indirectness	serious ²	none	21/132 (15.9%)	31/136 (22.8%)	RR 0.7 (0.42 to 1.15)	68 fewer per 1000 (from 132 fewer to 34 more)	LOW	IMPORTANT

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Tobramycin	Aztreonam lysine	Relative (95% CI)	Absolute		
			inconsistency	indirectness					to 1.15)	fewer to 34 more)		

Abbreviations: AZLI: aztreonam lysine; CFQ-R: cystic fibrosis questionnaire revised; CFU/g: colony forming units per gram; CI: confidence interval; FEV₁: forced expiratory volume in 1 second; MD: mean difference; RR: risk ratio; TOBI: tobramycin

- 1 The quality of the evidence was downgraded by 1 because this is an open trial
- 2 The quality of the evidence was downgraded by 1 as the 95% CI crossed 1 default MID
- 3 The quality of the evidence was downgraded by 1 as the 95% CI crossed 1 clinical MID
- 4 The quality of the evidence was downgraded by 2 as the 95% CI crossed 2 default MIDs