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Title: Improvement in COPD symptoms with aclidinium bromide vs placebo and tiotropium: A phase IIIb study

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Body: Background: The efficacy and safety of aclidinium bromide vs tiotropium and placebo in COPD has been evaluated in a randomized, double-blind, Phase IIIb study. Aim: To report additional endpoints capturing the effect of treatment on COPD daily symptoms. Methods: 414 patients with COPD (FEV_1 1.6 L; 56% predicted) received aclidinium bromide 400 µg BID (metered dose; equivalent to aclidinium 322 µg delivered dose), tiotropium 18 µg QD or placebo for 6 weeks. Symptoms were assessed daily with the EXACT-Respiratory Symptoms (E-RS) and COPD additional symptoms questionnaires. Relief medication use was assessed. Results: Results are summarized (Table).

Change from baseline (difference vs placebo) over 6 weeks

	Aclidinium (N=171)	Tiotropium (N=158)
E-RS		
Total score[a]	- 2.0***	-1.2*
Breathlessness	- 1.1***	- 0.7**
Cough and sputum	- 0.4**	- 0.2
Chest symptoms	- 0.5**	- 0.3*
COPD additional symptoms		
Night-time symptom severity[b]	- 0.14**	- 0.07
Nocturnal awakenings (n)	- 0.12	- 0.06
Early-morning symptom severity[b]	- 0.22***	- 0.12*

Cough[c]	- 0.17**	- 0.10
Wheeze[c]	- 0.14*	- 0.06
Shortness of breath[c]	- 0.20**	- 0.11
Phlegm clearance[c]	- 0.17*	- 0.07
Activity limitation due to symptoms[b]	- 0.18**	- 0.08
Relief medication-free days (%)	9.6*	8.9*

LS mean differences: *p<0.05, **p<0.01, ***p<0.001 vs placebo (ANCOVA). Scales: [a]0-40; [b]1-5; [c]0-4 (reduction=improvement).

Conclusions: Aclidinium provides significant COPD daily symptom improvement vs placebo, including less severe early-morning and night-time symptoms, and a greater number of relief medication-free days. Improvements were consistently numerically greater with aclidinium vs tiotropium.