Methods Patients with chronic respiratory disease undertook a HCT by the ROBD and Ventimask methods. The FiO_2 was 15.1% to simulate 8,000 ft which is equivalent to the maximum cabin altitude patients are likely to encounter during commercial air travel.
Results 60 patients, (45 males) with stable chronic obstructive or restrictive respiratory disease participated in the study; age mean (SD) 57 (15) years, FEV_1 66 (27)%, FVC 66 (27)%, FEV_1/FVC ratio 60 (18). There was no significant difference between PaO_2 pre-ROBD HCT 9.74 (1.19) and pre-Ventimask HCT 9.72 (1.05) paired t-test $p>0.05$. PaO_2 measured post-ROBD HCT (7.36 (0.93)) was significantly lower compared to PaO_2 post-Ventimask HCT (7.96 (0.97)) ($p<0.01$). There was no significant difference in the mean decrease in SpO_2 in-flight mean (SD) 6 (3) compared to the mean decrease in SpO_2 post-ROBD HCT 5 (3) (p 0.334). In contrast, there was a significant difference in the mean decrease in SpO_2 post-Ventimask HCT 3 (2) compared to the mean decrease in SpO_2 in-flight and post-ROBD HCT ($p<0.01$)
Conclusion The ROBD HCT results in a lower PaO_2 compared to a Ventimask HCT at a FiO_2 of 15.1%. The ROBD assessment more accurately reflected actual changes in SpO_2 in-flight and may be a better method of assessment for in-flight oxygen.

Clinical interventions in COPD

P137 EFFICACY AND SAFETY OF ONCE-DAILY ACLIDINIUM BROMIDE 200 μG IN COMBINATION WITH FORMOTEROL IN PATIENTS WITH COPD

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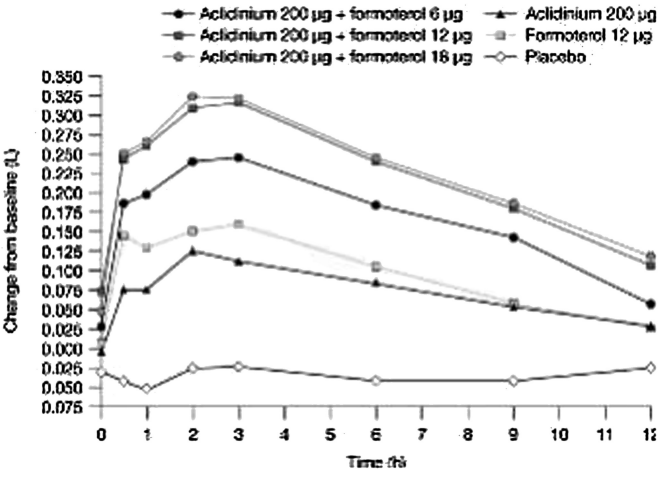
Introduction Combinations of different classes of medication used in the management of chronic obstructive pulmonary disease (COPD) may provide additional improvements compared with monotherapy. This study assessed the efficacy and safety of aclidinium bromide 200 μg, a novel long-acting muscarinic antagonist, combined with formoterol, a long-acting β-agonist. All combination and monotherapy treatments were delivered as single inhalations.
Methods 566 patients with moderate to severe COPD were randomised in a double-blind manner to receive aclidinium plus formoterol 6 μg (n=121), 12 μg (n=120) or 18 μg (n=125), or monotherapy with aclidinium (n=76), formoterol 12 μg (n=65) or placebo (n=59). Treatment was administered once-daily for 4 weeks via the Genuair® inhaler, a multidose dry powder inhaler. The primary efficacy endpoint was change from baseline in normalised forced expiratory volume in 1 second (FEV_1) area under the curve over 12 h (AUC_{0-12h}) at 4 weeks. Safety was assessed throughout the study.
Results There was a mean (±SE) increase from baseline in normalised FEV_1 AUC_{0-12h} at 4 weeks with aclidinium plus formoterol 6, 12 or 18 μg (0.170±0.022, 0.219±0.22 and 0.230±0.022 l, respectively), and aclidinium (0.075±0.027 l) and formoterol (0.099±0.031 l) monotherapy. No improvement was observed in the placebo group. All combinations were significantly superior to placebo ($p<0.0001$) and to both monotherapies ($p<0.001$), except for the comparison between aclidinium and formoterol 6 μg and formoterol 12 μg monotherapy. Mean change from baseline in 12-h FEV_1 at 4 weeks is shown in the figure. Aclidinium plus formoterol 6, 12 or 18 μg was well-tolerated with a safety profile similar to that observed with monotherapy or placebo.
Conclusions Aclidinium combined with formoterol provided greater improvements in pulmonary parameters than either drug alone or placebo. The bronchodilation provided by aclidinium and formoterol 18 μg was comparable to aclidinium and formoterol 12 μg, suggesting the optimal dose of formoterol was 12 μg. No safety concerns arose during the study. These findings support the combination of aclidinium and formoterol for the treatment of COPD.



Abstract P137 Figure 1

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P138 EFFICACY OF INHALED PAN-SELECTIN ANTAGONIST BIMOSIAMOSE ON OZONE-INDUCED AIRWAY INFLAMMATION IN HEALTHY SUBJECTS

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Selectins, a family of adhesion molecules, play a key role in the activation and extravasation of leukocytes in inflammatory diseases, like COPD. We investigated the effect of repeated inhalations of the pan-selectin antagonist Bimosiamose on ozone-induced airway inflammation in healthy volunteers. In a double-blind, placebo-controlled, randomised, cross-over study the effect of a 4-days treatment with 10 mg of Bimosiamose bid inhaled by a breath actuated nebuliser (AKITA2 APIXNEB®) on cellular and non-cellular composition of induced sputum after inhalation of ozone (250 ppb) for three hours was evaluated. 18 subjects were randomised and completed the study. All treatments were safe and well tolerated. Bimosiamose, compared to placebo treatment, reduced numbers of sputum neutrophils by 40% (p=0.068) and lymphocytes by 65% (p=0.004). Sputum concentration of interleukin-8 and MMP-9 was diminished by 35% (p=0,004) and 46% (p=0,022), respectively. Inhalation of Bimosiamose showed a broad and favourable significant effect on ozone-induced airway inflammation in healthy subjects. Further studies have to proof and translate this anti-inflammatory effect of Bimosiamose into a clinical benefit in patients with COPD.