## **European Respiratory Society Annual Congress 2013**

**Abstract Number: 1956** 

**Publication Number: P3384** 

Abstract Group: 5.1. Airway Pharmacology and Treatment

Keyword 1: Airway management Keyword 2: COPD - management Keyword 3: No keyword

Title: Comparative in vitro performance of the new drug aclidinium in a novel multidose dry powder inhaler

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**Body:** Background: With new inhalation products, lack of knowledge of how much drug is deposited at the site of action in the lungs plus variation in performance of inhalation devices can lead to inaccurate conclusions about drug efficacy. Aim: To compare the consistency of delivered dose (DD) and fine particle dose (FPD) from four inhalation devices. Methods: This in vitro study compared inhalers used for delivery of: aclidinium 400 μg (Genuair®); tiotropium 18 and 2.5 μg (HandiHaler®, Respimat®); and indacaterol 150 µg (Breezhaler®) at three different inhalation flow rates. Measurements included airflow resistance, consistency of DD, FPD and dose emission times. Results: Airflow resistance was highest with HandiHaler, medium with Genuair and lowest with Respimat and Breezhaler. Flow rates corresponding to a 4 kPa pressure drop across the dry powder inhalers were: 38.8 L/min, HandiHaler; 64.5 L/min, Genuair; and 105.3 L/min Breezhaler. Generally, mean DDs were independent of flow rate and consistent over labelled contents. FP mass fractions of 1–3 µm and 3–6 µm differed among devices. Genuair delivered the finest particles within the FPD <6 µm at medium flow rate (mass median aerodynamic diameter: 2.4 µm) followed by Breezhaler (2.9 μm); HandiHaler and Respimat delivered the coarsest particles (3.5 and 3.3 μm, respectively). However, Respimat delivered the highest very fine particle mass fraction <1.0 µm; it is the only device delivering particles <0.3 µm. Conclusions: Based on known in vitro in vivo correlations<sup>1</sup> it can be assumed that different inhalation systems will have significantly different lung depositions. <sup>1</sup>Usmani et al. AJRCCM 2005;172:1497-1504.