In Vitro Performance of the Handihaler® and the Respimat® Soft Mist™ Inhaler Under Inhalation Profiles Simulating COPD

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Introduction: This study investigates the effects of simulated mild, moderate and severe chronic obstructive pulmonary disease (COPD) inhalation profiles (Global Initiative for Chronic Obstructive Lung Disease guidelines 2019) on tiotropium delivery by the Handihaler® and the Respimat® Soft Mist™ Inhaler.

Research hypothesis: It was hypothesised that the Respimat would demonstrate a higher fine particle fraction and less oropharyngeal impaction than the Handihaler, as well as a more consistent performance across simulated disease severities.

Methods: Inhalation profiles were constructed to simulate typical inhaler use by COPD patients using data from published literature. Emitted Dose (n=6) and Next Generation Impactor (NGI) analyses (n=3) were conducted to investigate Total Emitted Dose (TED) and aerodynamic particle size distribution (APSD). APSD data was interpreted in terms of fine particle fraction (FPF) and mass median aerodynamic diameter (MMAD).

Results and Discussion: The Handihaler exhibited TED values that decreased with simulated inspiratory flow rate. However, the Respimat produced similar TED values across disease states. The Respimat generated a higher FPF (60.9%-72.2%) than the Handihaler (24.4%-35.9%) under mild and moderate COPD profiles, with greater deposition on later stages of the NGI. Both devices achieved MMAD in the respirable range (1-5 μm). Analysis of the fine particle dose showed no significant difference between the inhalers for all disease states ($p>0.05$), nor between the different severities under each inhaler ($p>0.05$).

Conclusion: Both inhalers are capable of meeting the in vitro criteria for successful inhaled drug delivery but the Respimat achieves more efficient drug delivery, independent of disease severity.