

Nebulization of Steroid Suspension: An *In Vitro* Evaluation of the Aeroneb® Go Nebulizer and the Pari LC Plus®

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INTRODUCTION

Pulmicort Respules® (AstraZeneca) contain a budesonide suspension approved for use with jet nebulizers based on registration trials with the LC Plus jet nebulizer (PARI).

Ultrasonic nebulizers are not recommended for administration.

The Aeroneb Go Nebulizer (Aerogen, Inc.) is an electronic micropump nebulizer that incorporates a piezo vibrational element to pump aerosol through an aperture plate.

We wanted to determine ability of this technology to nebulize a suspension.

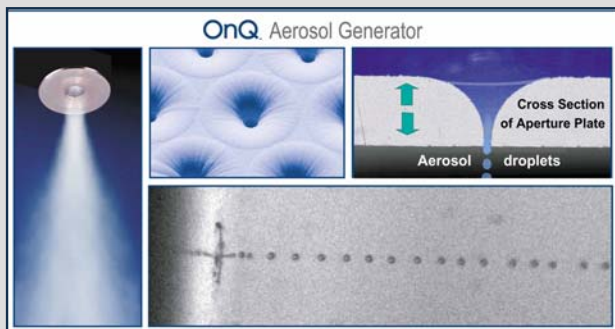


FIGURE 1: THE AERGEN ONQ™ AEROSOL GENERATOR (LEFT) WITH A MICROSCOPIC VIEW OF TAPERED APERTURES (UPPER MIDDLE), AND CROSS SECTION OF APERTURES (UPPER RIGHT). HIGH SPEED MICROSCOPIC PHOTOGRAPH OF AEROSOL GENERATED FROM A SINGLE APERTURE (LOWER RIGHT).



FIGURE 2: THE AERONEB® GO NEBULIZER

METHODS

Budesonide suspension (Pulmicort Respules®; 0.5 mg/2 mL) was aerosolized with three LC Plus and three Aeroneb Go Nebulizers.

To determine inhaled mass, aerosol was collected on a filter placed between the nebulizer mouthpiece and breathing simulator with an adult breathing pattern (Hans Rudolph; V_T 500 mL, T_I/T_{tot} .35, rate 15 breaths/min).

The Mass Median Aerodynamic Diameter (MMAD) of the aerosol was determined with cascade impaction (Anderson Mk II) at 28.3 L/min. The amount of drug deposited was determined by HPLC.

Treatment time was measured to the end of aerosol generation (Aeroneb Go) or one minute past sputter (LC Plus).

All experiments were performed in triplicate.

RESULTS

Results are shown in Table 1. Inhaled mass was greater with the Aeroneb Go than the LC Plus. Mean Mass Aerodynamic Diameter (MMAD) and Geometric Standard Deviation were less with the Aeroneb Go than the Pari LC Plus. Treatment times were similar for both devices.

Devices	Inhaled Mass (µg)	Inhaled Mass (%)	MMAD (µm)	GSD	Time (min)
Aeroneb Go	115±13	22±3	3.1+0.1	1.6±0.1	6±0
Pari LC Plus	91±14	18±3	3.8±0.4	2.3±1.1	6±1

TABLE 1: COMPARISON OF INHALED MASS (DRUG DELIVERED AND % OF DOSE), PARTICLE SIZE CHARACTERIZATION (MMAD AND GSD), AND TIME OF ADMINISTRATION FOR BUDESONIDE SUSPENSION.

SUMMARY

Both nebulizers had similar treatment times and inhaled mass of budesonide. The inhaled mass (%) for the LC Plus matches that previously reported by Smaldone et al (J Aerosol Med, 1998; 11:113-125.).

CONCLUSION

We conclude that the Aeroneb Go was as efficient as the jet nebulizer in delivering aerosolized budesonide solution.

CLINICAL IMPLICATIONS

New aerosol technologies, such as the electronic micropump, may deliver suspensions as well as the most efficient compressor nebulizer systems.