

RAPID DELIVERY OF BRONCHODILATOR MEDICATION IS POSSIBLE USING A BREATH-ACTUATED SMALL VOLUME NEBULIZER AS AN ALTERNATIVE TO EXTENDED DELIVERY OF MEDICATION BY LARGE VOLUME NEBULIZER

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1. ABSTRACT

Background: Inhaled beta-2 adrenergic agonist bronchodilators are often given to patients with severe reversible airways disease by continuous nebulization in extended treatments. However data are limited as to whether or not shorter, but higher concentration delivery is as an effective treatment modality. The development of a new breath-actuated nebulizer (AeroEclipse® II, Monaghan Medical Corp., Plattsburgh, NY (AE II BAN)) provided an opportunity to compare the two treatment methods in a laboratory study before undertaking a clinical comparison. We investigated the delivery of diluted generic respirator solution albuterol by a widely used continuous jet nebulizer (MiniHeart® Hi-Flo, Westmed Corp., Tucson, AZ (CONT)) with that from the AE II BAN. **Method:** The continuous nebulizers (n=3) were operated with 8 L/min air supplied at 50 psig with a 20-ml fill (albuterol concentration of 0.5 mg/mL). A similar number of AE II BANs were operated with ca. 8.0 L/min air at 50 psi with a 1-ml fill (albuterol concentration of 5 mg/mL). Aerosol from both nebulizers was sampled onto electret filters using a breathing simulator mimicking small child use (250-ml tidal volume, inspiratory/expiratory ratio 1:2, rate 12 cycles/min) until onset of sputtering. Assay for albuterol was undertaken by UV spectrophotometry. In a parallel study, droplet size distributions were determined by laser diffractometry, so that the fine droplet fraction < 4.7 µm diameter likely to penetrate to the airways of the lungs (FDF) could be determined. **Results:** Values of FDF for the AE II BAN and CONT were 78.4% and 62.0% respectively. The AE II BAN delivered 758 ± 36 µg as fine droplets after 4-min (delivery rate of 190µg/min), compared to 180 ± 76 µg in the same period by CONT (delivery rate of 45µg/min). **Conclusions:** The faster delivery rate from the AE II BAN high albuterol concentration modality (un-paired t-test, p < 0.001) may offer an important clinical alternative to CONT/low concentration treatment modality.

4. RESULTS

- Mean values of FDF<4.7 µm were 62% for the MiniHeart® Hi-Flo LVNs, but higher at 78% for the AeroEclipse® II BAN group
- Output rates by both modalities were compared on the basis of fine droplet mass (FDM):

$$FDM = TM * (FDF_{<4.7 \mu m} / 100)$$
- The AE II BAN group delivered 758 ± 36 µg albuterol as fine droplets after 4-min
 - delivery rate of 190µg/min FDF <4.7 µm
- The LVN group delivered 180 ± 76 µg in the same period
 - delivery rate of 45µg/min FDF <4.7 µm

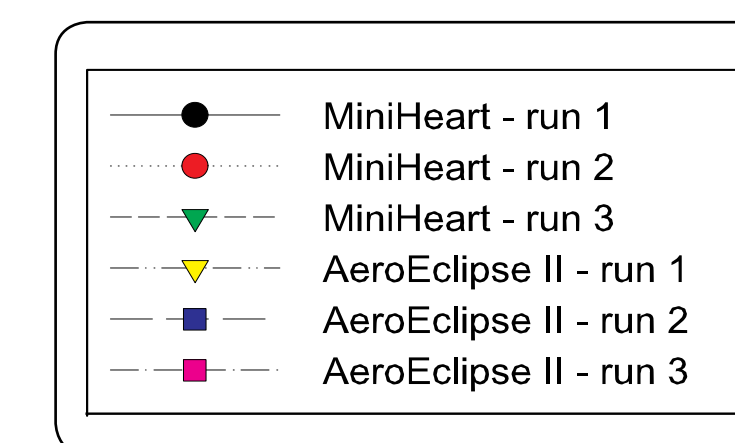
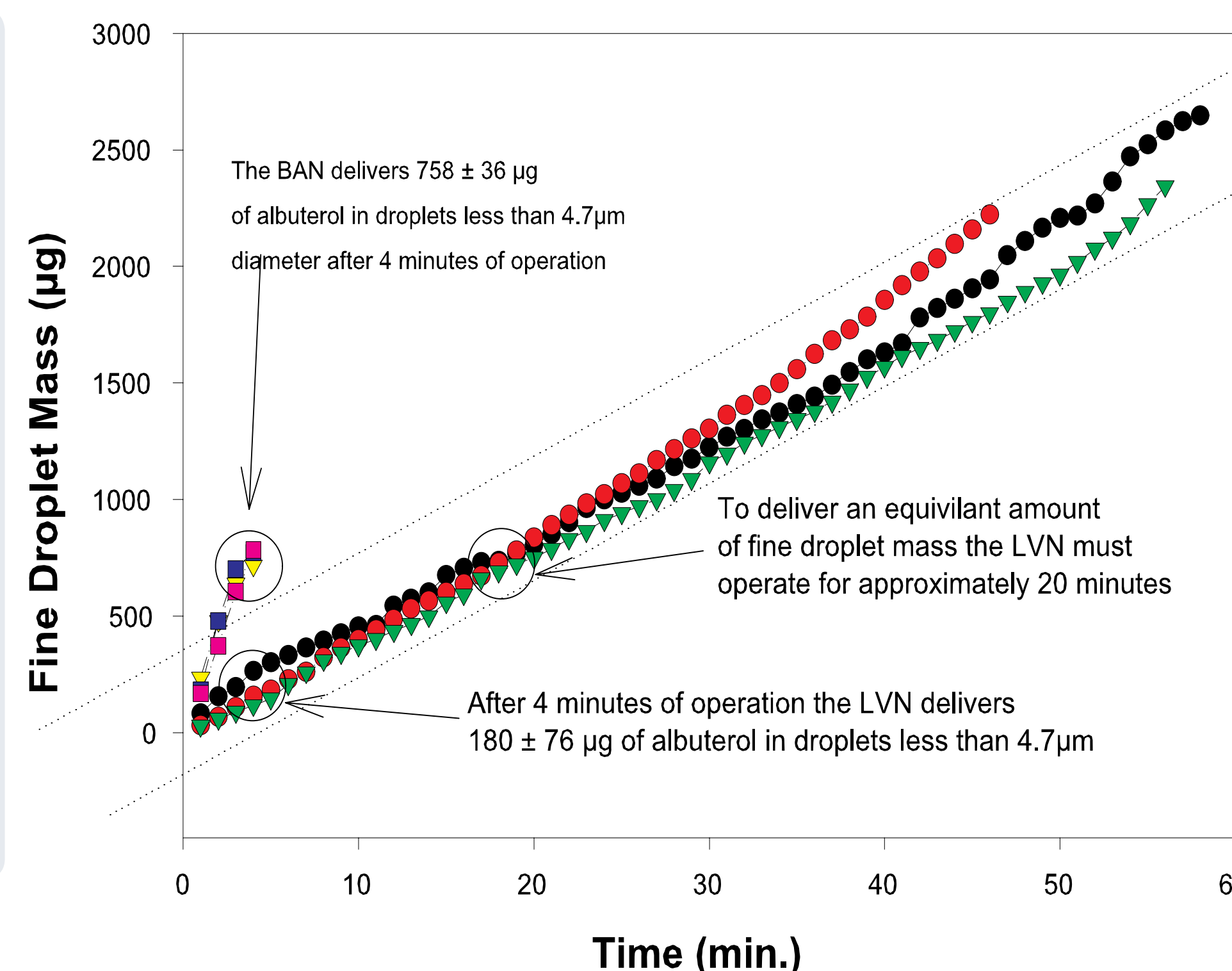
2. INTRODUCTION

- Large volume nebulizers (LVNs) are often used for the delivery of beta-2 adrenergic agonist bronchodilators in the emergency department for the treatment of severe exacerbations of reversible airways diseases McPeck M et al. Chest. 1997;111:1200-1205.
- They enable treatment to continue without having staff refill the nebulizer reservoir every few minutes. Treatment time can, however, be lengthy for the delivery of the typical LVN fill volume of 20-ml or more
- Data are limited as to whether or not shorter, but higher concentration delivery is as an effective treatment modality
- We report a study in which the delivery of a generic respirator solution albuterol by LVN was compared with that from the AE II BAN
- Both devices were operated using compressed air from wall outlet at 50 psig, simulating hospital use

3. METHODS AND MATERIALS

- LVN group of nebulizers (n = 3 devices)
 MiniHeart® Hi-Flo: Westmed Corp., Tucson, AZ
 -operated at 8 L/min from 50 psig compressed air supply; 20-ml fill
- AE II BAN group of nebulizers (n =3 devices)
 AeroEclipse-II®: Monaghan Medical Corp., Plattsburgh, NY
 - operated at 8 L/min from 50 psig compressed air supply; 1.0-ml fill
- FORMULATION – albuterol respirator solution:
 - 5 mg/ml albuterol base equivalent simulating typical hospital treatment protocols
 - Hi Tech Pharmacal, Co. Inc. Amityville NY
 - LVN group:
 -2-ml of respirator solution diluted to 20-ml total fill with normal saline (0.5 mg/ml albuterol) to provide lower drug concentration over longer treatment period
 - AE II BAN group:
 -1-ml fill with respirator solution (5.0 mg/ml albuterol) to provide high drug concentration over a short duration
- DROPLET MEASUREMENT
 - by filter connected to breathing simulator
 • tidal volume = 250ml, rate = 12 cycles/min, duty cycle = 0.33
 - fine droplet fraction (FDF) < 4.7 µm diameter assessed by laser diffractometry

Rate Output Comparison between AeroEclipse® II BAN and MiniHeart® Hi-Flo LVN: Small Child Simulation



5. CONCLUSIONS

The faster delivery rate from the AeroEclipse-II® BAN/high albuterol concentration modality (un-paired t-test, p < 0.001) may offer an important clinical alternative to LVN/low concentration treatment.

One situation of relevance would be in the emergency department where rapid delivery of a bronchodilator may be critical in the event of a severe exacerbation