Extending the Performance of an Existing Breath-Actuated Nebulizer for Domiciliary Use:
Initial Data

Jolyon P. Mitchell, Mark Nagel, Valentina Avvakoumova, Heather Schneider, and Rubina Ali

Trudell Medical International, London, Ontario, Canada

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INTRODUCTION

There is increasing interest in fully breath-actuated nebulizers (BANs) (1) because of the following reasons:
1. The delivery of medication can be optimized by the near elimination of exhaled aerosol that would otherwise be wasted;
2. The risk of contamination of the local environment by exhaled aerosol with consequent caregiver exposure is greatly reduced or eliminated altogether;
3. There is the potential for dosimetric delivery.

The AeroEclipse® BAN (Trudell Medical International (TMI), London, Canada) was initially developed for use in the hospital environment, optimized for medication delivery using air or oxygen supplied at 50 psig pressure (2, 3). This article describes initial laboratory data with a version (AeroEclipse-XL®) optimized for operation by either table-top (Ombra™ table-top compressor, TMI, 230V AC version) or portable compressor (Ombra™ portable compressor, TMI, 230V AC or battery operation), in the home setting.

MATERIALS AND METHODS

Measurements were undertaken with each compressor operating the BAN in breath-actuated mode, using a 2.5-mL fill of 1.0 mg/mL albuterol (Ventolin®, GlaxoSmithKline, Canada) and 2.0-mL fill of 0.5 mg/mL budesonide (Pulmicort®, AstraZeneca, Canada) as representative solution and suspension formulations, respectively. The nebulizer-on-test (n = 5/group) was connected to
a breathing simulator (ASL5000, IngMar Medical, Pittsburgh, PA) set to mimic adult tidal breathing (tidal volume = 600 mL; duty cycle = 33%; rate = 10 cycles/min). The emitted aerosol was captured on a filter located at the mouthpiece that was replaced at one minute intervals until the onset of sputtering occurred. Recovery and subsequent assay of the active pharmaceutical ingredient was undertaken by internally validated HPLC-UV spectrophotometry procedures. In a parallel series of measurements, fine droplet fraction (FDF_{<4.7\mu m}) was determined by laser diffractionmetry (Spraytec, Malvern Instruments, UK), with the nebulizers operated by each compressor in turn, filled with normal saline solution. Fine droplet mass (FDM_{<4.7\mu m}) at each minute interval was determined subsequently as the product of TM and FDF_{<4.7\mu m}. Benchmark measurements were made by the same procedures with the Sprint® (PARI, GmbH, Germany) air entrainment nebulizer, operated with PARI BOY®SX® and PARI Boy® Mobile-S® compressors, representing approximate equivalents to the two Ombra compressors available with the BAN.

RESULTS

Table 1. Values of FDF_{<4.7\mu m} (mean ± SD).

<table>
<thead>
<tr>
<th>Compressor / Nebulizer</th>
<th>Ombra™ with AeroEclipse-XL® BAN</th>
<th>PARI Boy® with Sprint® Nebulizer</th>
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<tbody>
<tr>
<td>Table-Top/SX</td>
<td>70.8 ± 1.0%</td>
<td>57.9 ± 3.1%</td>
</tr>
<tr>
<td>Portable/Mobile-S</td>
<td>68.1 ± 0.9%</td>
<td>52.0 ± 0.7%</td>
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Figures 1 and 2 summarize the minute-by-minute measures of FDM_{<4.7\mu m} for albuterol solution and budesonide suspension, respectively.

Figure 1. Minute-by-minute fine droplet output of nebulizer-compressor systems with 1mg/ml albuterol solution.
Figure 2. Minute-by-minute fine droplet output of nebulizer-compressor systems with 0.5mg/ml budesonide suspension.

All profiles were close to being linear for most of the duration of nebulization, preserving the option for dosimetric delivery in the case of the BAN, based on the fact that medication is not lost during exhalation with this device (4). The fine droplet output profiles for albuterol from the BAN/Ombra table-top and portable compressor systems were comparable with the respective profiles for the Sprint/SX and Mobile-S compressors that are intended for mains electricity-powered and battery applications in domiciliary use. However, the BAN/table-top combination outperformed the Sprint/SX for the delivery of budesonide, and the output from the BAN/portable was marginally greater than that from the Sprint/mobile-S system. The reason for these differences is unclear, but may be associated with more efficient incorporation of the budesonide particles from suspension into the droplets that are nebulized in the BAN.

CONCLUSIONS

The AeroEclipse-XL® BAN with either table-top or portable behaved as a dosimetric nebulizer throughout most of the medication delivery period with these representative solution and suspension formulations. Such behavior is consistent with previous work with the AeroEclipse-II® BAN that is designed to operate at 50 psig in the hospital environment.
REFERENCES


