INTRODUCTION

Ventstream (Profile Therapeutics) is a breath-enhanced jet nebulizer which has been shown clinically to be suitable for delivery of nebulized budesonide. In vitro studies have shown that the drug mass output, the droplet size and nebulization time will vary with the nebulizer and compressor system used. The amount of drug inhaled (inhaled mass) will also depend on the patient's breathing pattern. It is therefore important to characterize the jet nebulizer with the drug to be used in terms of inhaled mass and droplet size using a test setup that mimics the treatment situation.

AIM

The aim of the study was to characterize the Ventstream jet nebulizer - using Passport (Invacare, OH) and Pulmo-Aide (DeVilbiss, IL) compressors - in terms of inhaled and exhaled masses, mass median aerodynamic diameter (MMAD), and the amount of budesonide in the respirable fractions ≤6µm and ≤3.5µm.

METHODS

The Ventstream nebulizer was connected via a filter to a Harvard sinus pump which generated a simulated breathing pattern (V, 200ml, 25 BPM, duty cycle 0.5) through the nebulizer. Each nebulizer was charged with 1.0 mg budesonide in 2 ml (Pulmicort Respules [AstraZeneca LP] and run until dryness, using either Passport or Pulmo-Aide compressors. Five Ventstream nebulizers were used with each compressor. The inhaled and exhaled masses were determined with filters attached to the nebulizer (Fig. 1a). Droplet size and amount of budesonide in the respirable fractions were determined through a low flow cascade impactor connected in line between the nebulizer and the inhaled mass filter (Fig.1b).

RESULTS

The nebulization times to dryness were 7.3 min for Ventstream/Passport and 9.1 min for Ventstream/Pulmo-Aide. The mean inhaled and exhaled masses of budesonide, the MMAD and the amount of budesonide in the respirable fractions are shown in the table below.

<table>
<thead>
<tr>
<th>Nebulizer/compressor</th>
<th>Inhaled mass (sd)</th>
<th>Exhaled mass (sd)</th>
<th>MMAD (GSD)</th>
<th>Respirable fraction ≤ 6 µm</th>
<th>Respirable fraction ≤ 3.5 µm</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ventstream/Passport</td>
<td>139 µg (14)</td>
<td>38 µg (13)</td>
<td>2.6 µm (2.0)</td>
<td>87%</td>
<td>68%</td>
</tr>
<tr>
<td>Ventstream/Pulmo-Aide</td>
<td>136 µg (26)</td>
<td>43 µg (10)</td>
<td>2.5 µm (1.8)</td>
<td>91%</td>
<td>77%</td>
</tr>
</tbody>
</table>

DISCUSSION

In Fig. 2 (modified from ref. 3) the inhaled mass of budesonide for the two Ventstream nebulizers (bars 8 and 11) has been added to the inhaled mass of budesonide of 27 other nebulizers. The inhaled mass of budesonide achieved with the Ventstream nebulizer was comparable to that of the most efficient previously tested nebulizers. The amount of budesonide in the respirable fractions was, however, clearly larger than the other nebulizers.

CONCLUSIONS

- For budesonide inhalation suspension delivery, the inhaled mass of the Ventstream jet nebulizer is comparable to that of other efficient jet nebulizers.
- The respirable fraction of the inhaled mass of budesonide achieved with Ventstream is, however, larger.
- The positive ratio of respirable fraction: inhaled mass achieved with the Ventstream nebulizer should in clinical practice minimize oropharyngeal deposition and increase lung deposition.

REFERENCES