Performance of a Valved Holding Chamber with Tracheostomy Adapter: Aerosol Delivery from Soft Mist Inhalers

M. Nagel1, R. Ali1, C. Doyle1, D.P. Coppolo2, J. Suggett3
1 Trudell Medical International, London, Canada. 2 Monaghan Medical Corporation, Plattsburgh, NY, USA.

RATIONALE
• Patients with asthma or obstructive airways disease who have a tracheostomy tube (TT) or tracheal stoma have difficulty using Metered Dose Inhalers (MDIs) because of a failure to achieve a good seal between the TT and delivery device.
• We report the outcome of a study that investigated aerosol delivery from Soft Mist Inhalers (SMI) to a breathing tracheostomy model via a Valved Holding Chamber (VHC) with tracheostomy adapter.

MATERIALS AND METHODS
• AeroTrach Plus® VHCs were evaluated for active pharmaceutical ingredients (API) from the 3 different SMI formulations.
  • n = 5 replicates/device
  • The tracheostomy adapter of the VHC was attached to the 15 mm adapter of the adult TT (6 mm I.D., 70 mm long Portex)
  • The cuff of the tube was used to seal the exit to a bacterial viral filter.
  • The filter was in turn connected to a breathing simulator (ASL 5000, IngMar Medical) which was operated to simulate tidal breathing
    • Tidal Volume = 500 mL
    • 13 breaths per minute (bpm)
    • Inspiratory: Expiratory ratio of 1:2
  • The SMI was placed in the adapter of the VHC and following actuation of the SMI, 5 breathing cycles were undertaken, following which the test apparatus was disassembled and the mass of API deposited on the filter assayed by HPLC.

RESULTS

<table>
<thead>
<tr>
<th>Soft Mist Inhaler Formulation</th>
<th>Active Ingredient (label claim, µg)</th>
<th>Dose Delivered to Distal End of Tracheostomy Tube (µg)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Spiriva® Respimat®†</td>
<td>tiotropium bromide monohydrate (2.5 µg)</td>
<td>1.9 ± 0.2</td>
</tr>
<tr>
<td>Inspiolto® Respimat®†</td>
<td>olodaterol hydrochloride (2.5 µg)</td>
<td>1.1 ± 0.2</td>
</tr>
<tr>
<td>Combivent® Respimat®†</td>
<td>tiotropium bromide monohydrate (2.5 µg)</td>
<td>1.1 ± 0.2</td>
</tr>
<tr>
<td></td>
<td>salbutamol (100 µg)</td>
<td>27.2 ± 5.3</td>
</tr>
<tr>
<td></td>
<td>ipratropium bromide (30 µg)</td>
<td>4.9 ± 1.0</td>
</tr>
</tbody>
</table>

CONCLUSIONS
• Based on these laboratory data, the VHC with tracheostomy adaptor appears to provide a reliable means of delivering SMI aerosols to patients with a tracheostomy tube or tracheal stoma.
• Further research is required to determine the clinical relevance of these in vitro findings.