ABSTRACT

BACKGROUND: In order to improve patient compliance, the use of charge dissipative materials in VHC construction is becoming the standard of care. A facemask is required as the interface between patient and VHC for young children who cannot breathe through a mouthpiece. Recent studies have emphasized that a well-fitted facemask is critical for optimal drug delivery. We report a laboratory-based comparison of aerosol drug delivery between two ‘antistatic’ VHCs under simulated breathing conditions, using a anatomically correct infant face-upper airway model (ADAM-III, Trudell Medical International (TMI)).

METHODS: Delivery of fluticasone propionate (FP; 44 µg/actuation GSK) as evaluated via anti-static International (TMI)).

RESULTS: The investigation reported was undertaken at the Aerosol Laboratory of Trudell Medical International, London, Canada. † trademarks and registered trademarks of the respective companies.

INTRODUCTION

In order to improve compliance the use of charge dissipative materials in VHC construction is becoming the standard of care.

• The need for a pre-treatment before use can be avoided

• A facemask is also required as the interface between patient and VHC for young children who cannot breathe through a mouthpiece

• Recent studies have emphasized that a well-fitted facemask is critical for optimal drug delivery

• Exposito-Festen et al., in a laboratory-based study, showed that measurable decreases in exhaled drug mass occurred with leakage area only 0.05 cm²

• Almost no aerosol was collected when this area was ten times greater

• The following attributes for a well-designed facemask were summarized at an ISAM Focus Symposium**:<ref>Exposito-Festen, J. et al. J Aerosol Med 2003; 16(1): 16. †+ Puls, J.L., giraffe, SCI, J. Aerosol Med. 2007; 20: 01 S 029.

• It must seal properly to the face to avoid ingress of ambient air via leakage pathways;

• The volume of the dead-space defined by the contours of the face and inner surface of the facemask should be minimized;

• Soft facemasks with in-built flexibility do a better job of minimizing this dead-space;

• A contoured and flexible edge is more comfortable for patients than facemasks having sharp or rigid edges;

• Those intended for use by infants/children should reflect different facial contours for naso-pharyngeal region;

• It should contain a low resistance valve that opens upon exhalation and is closed during inspiration

STUDY PURPOSE

• We report a laboratory-based comparison of aerosol drug delivery between two ‘antistatic’ VHCs with soft, flexible facemasks for infant use, meeting the ISAM criteria:

• A face mask with soft tissues and anatomically correct nasopharynx, mimicking a 7-month old infant was used for the assessment

METHODS

• Two similar-sized VHCs were evaluated (n=3/group): AeroChamber Plus®/VHC with Flow-Vue® (AeroChamber Plus®, Respironics, Parsippany, NJ) and ComfortSeal w/Small Mask (VHC-facemask);

• The distal (carinal) end of the ADAM-III infant model airway was connected to an ASL 5000 breathing simulator; Tidal breathing (tidal-volume (Vt) 155 mL, duty-cycle=33%, rate= 25-breaths/min) was simulated with an Ingmar ASL 500 test lung. Each facemask was applied to the face with the same clinically-appropriate force (1.6 kg).

• FP was recovered as follows:

Location for FP Recovery
AeroChamber Plus®/VHC
15.5 ± 1.1
7.9 ± 0.8
pMDI actuator
7.5 ± 0.8
7.2 ± 1.4
VHC interior
18.5 ± 2.1
15.5 ± 1.1
Facemask
4.3 ± 0.3
4.5 ± 0.3
Surface of model face
0.3 ± 0.1
0.3 ± 0.1
Naso-pharyngeal region
1.8 ± 0.1
1.6 ± 0.1
Filter (FM,™)
17.1 ± 0.6
17.3 ± 0.6
Total Recovered
41.5 ± 4.5
41.4 ± 2.5

• The model face was mounted with the VHC in a cradle so that the facemask could be applied to the face with a known force in the correct orientation as in real-life;

• The VHC-facemask was applied to the face, observing the movement of the flow indicator on each VHC to confirm that the seal was leak-tight;

• Delivered mass of FP (MFm) was quantified by HPLC-UV spectrophotometry

• Mass of FP was recovered as follows:

• 0.3 ± 0.1 0.1 ± 0.0

• The distal (carinal) end of the ADAM-III infant model airway was connected to an ASL 5000 breathing simulator; Tidal breathing (tidal-volume (Vt) 155 mL, duty-cycle=33%, rate= 25-breaths/min) was simulated with an Ingmar ASL 500 test lung. Each facemask was applied to the face with the same clinically-appropriate force (1.6 kg).

• FP was recovered as follows:

Location for FP Recovery
AeroChamber Plus®/VHC
15.5 ± 1.1
7.9 ± 0.8
pMDI actuator
7.5 ± 0.8
7.2 ± 1.4
VHC interior
18.5 ± 2.1
15.5 ± 1.1
Facemask
4.3 ± 0.3
4.5 ± 0.3
Surface of model face
0.3 ± 0.1
0.3 ± 0.1
Naso-pharyngeal region
1.8 ± 0.1
1.6 ± 0.1
Filter (FM,™)
17.1 ± 0.6
17.3 ± 0.6
Total Recovered
41.5 ± 4.5
41.4 ± 2.5

METHODS CONT’N

• The diameter (carinal) end of the ADAM-III infant model airway was connected to an ASL 5000 breathing simulator; Inghber Medical, Pittsburgh, PA

• Tidal breathing pattern simulated:

• Tidal volume = 155 mL

• Delivered mass of FP (MFm) was quantified by HPLC-UV spectrophotometry

• Face mask in support to adjust

• Mass of FP was recovered as follows:

• VHC interior

• Surface of model face

• Naso-pharyngeal region

• Filter (FM,™)

• Face mask filter at the distal exit of the model airway equivalent to lung dose at the carina

• Delivered mass of FP (MFm) was quantified by HPLC-UV spectrophotometry

RESULTS

• Factors such as facemask dead volume and device design, including a low inhalation valve resistance are important influences in overall VHC performance

• The decreased aerosol delivery from the OD observed in this bench study is explicable in terms of leakage between facemask and face, and/or choice of antistatic materials

• Clinicians should be aware that each VHC-pMDI combination is unique

CONCLUSIONS

Poster presented at the 2013 AARC Congress November 16-19, 2013 • Anaheim, California

Robert DiBlasi RRT-NPS, Seattle Children’s Research Institute, Seattle, WA, USA
Dominic P. Coppolo, Monaghan Medical Corp., Syracuse, NY, USA
Jolyon P. Mitchell PhD, Vivian Wang BSc, Cathy Doyle and Mark W. Nagel HB.Sc, Trudell Medical Aerosol Laboratory, London, Canada