COMPARISON OF AEROSOL DRUG DELIVERY TO A NASO-PHARYNGEAL REPLICA VIA TWO VALVED HOLDING CHAMBERS (VHC) WITH FACEMASK VIA NEXT GENERATION CASCADE IMPACTOR

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ABSTRACT

BACKGROUND: In vitro assessments of VHC performance are primarily designed to characterize aerosol formulations during product development and to ensure consistent product quality, rather than how the device will perform when used by a patient. In vivo, delivery is influenced by numerous factors, including device design, patient interface, patient compliance and airway anatomy. The use of casts of anatomical thoraxes provides a means of reproducing the clinical situation more accurately. We report a laboratory-based comparison of aerosol drug delivery between two VHCs using a cascade impactor and a replica infant face and naso-pharyngeal airway developed from computed tomography (CT) scans.

METHODS: A Next Generation Impactor (NGI) was used to evaluate the fine particle mass < 5.4 µm of fluticasone propionate (FP) 110 µg/actuation delivered from the carinal region of the model following inhalation via either anti-static AeroChamber Plus® VHC with Flow-Vu® Infant mask or OptiChamber Diamond™ VHC/LiteTouch® small-mask. To simulate the clinical situation the VHC inlet of the NGI was replaced with a CT replica of a naso-pharyngeal airway of a 7 month old infant (ADAM-III, Trudell Medical International (TMI), reducing the operating flowrate to 15 LPM. FP was recovered from the face and airway of the model, as well as the collection plates of the NGI at the end of the model, VHC, facemask and PAPR. Delivered mass of FP (DMFP) was quantified by HPLC.

RESULTS: DMFP <5.4 µm collected from the NGI (mean±S.D.) was not significantly different between the AC-plus (22.2±2.9 µg and OD (15.4±2.8 µg) prepared t-test, p=0.052). The percentage of medication delivered to the model was greater than 97% indicating that any mass delivered past the carinal region of the model is indeed ‘respirable’, and potentially of therapeutic benefit.

CONCLUSION: There were no notable differences in fine particle mass between the AC-plus and OptiChamber Diamond™; however, additional testing looking at the absolute mass of drug delivered to a spontaneously breathing lung model is necessary.

INTRODUCTION

- Laboratory-based assessments of VHC performance are primarily designed to characterize aerosol formulations during product development
  - simplified methodology
  - ensures consistent product
- However, predicting how the device will perform when used by a patient requires methods that more closely mimic in use conditions
  - In vitro, delivery is influenced by numerous factors:
    - device design
    - patient interface
    - patient adherence to instructions for use
- The upper airway in particular, has a large effect on the particle size of medication that is inhaled and which deposits in the airways of the lungs to provide therapeutic benefit
  - The use of casts of anatomical upper airways provides a means of reproducing the clinical situation more accurately
  - In an infant, this airway is likely to be the naso-pharynx, because most are oblate nose-breathers

STUDY PURPOSE

- We report a laboratory-based comparison of aerosol drug delivery between two VHCs using a cascade impactor and a replica infant face and naso-pharyngeal airway developed from computed tomography (CT) scans.

METHODS

- Two similar-sized VHCs were evaluated (n=0/group):
  - Anti-static AeroChamber Plus® VHC with Flow-Vu® Inspiratory Flow Indicator (IFI) with infant mask
  - OptiChamber Diamond™ VHC with LiteTouch® infant mask
- Tested with Fluticasone®-110 (GSK inc.):
  - 110 µg/actuation fluticasone propionate (FP)
  - Widely used inhaled corticosteroids in asthma
- Assay for fluticasone propionate by HPLC-UV spectrophotometry

RESULTS

- Delivered mass of FP (DMFP) < 5.4 µm absolute mass of drug delivered to a spon-
  - The comparable measure available from the OptiChamber™ Diamond™ VHC was 22.2±2.9 µg
  - Unpaired t-test, p<0.002

CONCLUSIONS

- Either VHC provides a highly respirable aerosol to the carinal region of the model
- However, decreased aerosol delivery from the OptiChamber™ Diamond™ VHC may be the result of facemask losses and/or VHC design and choice of anti static materials

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