

AeroChamber® Valved Holding Chamber (VHC)

Mask Clinical Summary

The following summaries have been extracted from various journals and resources to produce a comprehensive analysis of clinical data.

- **The AeroChamber® mask performed best and was considered the “gold standard.”** ⁽²⁾
- **A facemask should have an effective seal, be flexible and soft with a large inward curved rim and have minimal dead space.** ⁽³⁾
- **The facemask has been recognized as a vital part for efficient aerosol delivery.** ⁽⁴⁾
- **The facemask is the preferred patient interface for use by infants and small children, as well as geriatric patients, due to poor coordination skills.** ⁽⁵⁾

- ① **Salyer, J.W., DiBlasi, R.M., Crotwell, D.N., Cowan, C.A., Carter, E.R.** The Conversion to Metered-Dose Inhaler with Valved Holding Chamber to Administer Inhaled Albuterol: A Pediatric Hospital Experience. *Resp Care* 2008, March;53(3): 338-345.

INTRODUCTION: Inhaled bronchodilators are one of the most frequently prescribed medications for children hospitalized with respiratory disorders. Historically, the most common method of administration has been via the small-volume nebulizer (SVN). The methods and effectiveness by which these medications are administered to pediatric patients has been evaluated extensively over the last decade. There is a large body of literature that indicated that the metered-dose inhaler with valved holding chamber (MDI_VHC) is at least as effective as SVN for the delivery of bronchodilators to infants, children and adults. In the past it was thought that young children were unable to use MDIs because they could not coordinate inhalation and that these devices would not be effective in delivery of bronchodilators. However, with the use of VHCs with face masks, infants and small children can now be successfully treated via MDI.

- ② **Amirav, I., Newhouse, M.T.** Review of Optimal Characteristics of Face-Masks for Valved Holding Chambers (VHCs). *Pediatr Pulmonol.* 2008 Mar;43(3):268-74.

Inhaled drugs are frequently given to infants and young children with a pressurized metered-dose inhaler (pMDI) attached to a valved holding chamber (VHC) with face mask. In young children and infants who cannot breathe through a mouthpiece, the face mask serves as the interface between the patient and the VHC. Although the mask interface is one of the most important factors determining the dose of medication delivered from the VHC to the nose and mouth in these patients, its optimal characteristics are not well known. Recent studies clearly identify several face mask factors that determine the success or failure of drug delivery with these devices. This review summarizes the most important features of an optimal mask design such as: face seal/leak, volume of dead space, contour, flexibility, transparency, weight and cost. By optimizing these characteristics it should be possible to improve mask design. This will maximize the magnitude and reduce the variability of the dose presented to the respiratory tract while making the mask more comfortable and patient/caregiver friendly. “The **AeroChamber®** mask performed best and was...considered the ‘gold standard’.”



- ③ **Erzinger, S., Schueepp, K., Brooks-Wildhaber, J., Devadason, S., Wildhaber, J.** Facemasks and Aerosol Delivery In Vivo. *J. Aerosol Med.* 2007; Suppl 1:S78-83.

It has been shown in vitro that even a small air leak in the facemask can drastically reduce the efficiency of drug delivery. In addition, it has been shown that drug deposition on the face does significantly add to overall drug loss and has the potential of local side effects. The aim of this study is therefore to verify these findings in vivo. Eight asymptomatic recurrently wheezy children, aged 18-36 months, inhales a radiolabeled salbutamol formulation either from a pressurized metered-dose inhaler through a spacer with attached facemask or from a nebulizer with attached facemask. Drug deposition of radiolabeled salbutamol was assessed with a gamma camera and expressed as a percentage of the total dose. Lung deposition expressed as a percentage of the total dose (metered dose and nebulizer fill, respectively) was 0.2% and 0.3% in children who inhaled with a non-tightly fitted facemask. Lung deposition was 0.6% and 1.4% in screaming children with a tightly fitted facemask and between 4.8% and 8.2% in patients breathing normally. Overall mask deposition was between 0.8% and 5.2%. Overall face deposition was between 2.6% and 8.4%. The results from this pilot study support the results found in in vitro studies, where a facemask leak greatly reduces drug deposition to the patient. "A facemask should have an effective seal, be flexible and soft with a large inward curved rim and have minimal dead space."

- ④ **Janssens, H.M., Tiddens, H.A.W.M.** Facemasks and Aerosol Delivery by Metered Dose Inhaler – Valved Holding Chamber in Young Children: A Tight Seal Makes the Difference. *J. Aerosol Med.* 2007; 20 Suppl 1:S59-63.

A facemask on a valved holding chamber (VHC) facilitates the inhalation of aerosols from metered dose inhalers (MDI) for young children. Only recently the facemask has been recognized as a vital part for efficient aerosol delivery. Several in vitro and in vivo studies show that a tight seal of the facemask is crucial for optimal aerosol deposition to the lungs. Even a small leak can reduce the dose delivered to the lungs considerably. However, a tight seal is difficult to obtain when a child is not cooperative. Depending on the design of the facemask, it is easier to obtain a good seal. Factors such as dead space, shape, and material should be considered when designing a facemask. However, when a child is upset and not cooperative during the administration, aerosol deposition will be minimal, even with the best-designed facemask.

- ⑤ **Morton, R.W., Mitchell, J.P.** Design of Facemasks for Delivery of Aerosol-Based Medication via Pressurized Metered Dose Inhaler with Valved Holding Chamber: Key Issues that Affect Performance. *J. Aerosol Med.* 2007; 20 Suppl 1:S29-42.

Valved holding chambers (VHCs) are widely prescribed for use with pressurized metered dose inhalers (pMDIs) for the treatment of respiratory disease by aerosol therapy. The facemask is the preferred patient interface for use by infants and small children, as well as by geriatric patients, due primarily to poor coordination skills. However, care is required in the design of the facemask-VHC system to optimize the delivery of medication. In particular, it is essential to achieve an effective mask-to-face seal and to minimize the volume of dead space. It is also important to ensure that the fit of the facemask is comfortable to the patient when applied with sufficient force to create a seal. We review each of these design principles and their application in the evolution of a range of VHCs from the same family of devices during the past fifteen years. We also examine the various methods available for evaluating VHC-facemasks as a system, recommending where future work might be directed.

- ⑥ **Shah, S.A., Berlinski, A.B., Rubin, B.K.** Force-Dependant Static Dead Space of Face Masks Used with Holding Chambers. *Respir Care*. 2006 Feb;51(2):140-4.

BACKGROUND: Pressurized metered-dose inhalers with valved holding chambers and masks are commonly used for aerosol delivery in children. Drug delivery can decrease when the dead-space volume (DSV) of the valved holding chamber is increased, but there are no published data evaluating force-dependant DSV among different masks. METHODS: Seven masks were studied. Masks were sealed at the valved holding chamber end and filled with water to measure mask volume. To measure mask DSV we used a mannequin of 2-year-old-size face and we applied the mask with forces of 1.5, 3.5, and 7 pounds. Mask seal was determined by direct observation. Intra-brand analysis was done via analysis of variance. RESULTS: At 3.5 pounds of force, the DSV ranged from 29 mL to 100 mL, with 3 masks having DSV of <50 mL. The remaining masks all had DSV >60 mL. At 3.5 pounds of force, DSV percent of mask volume ranged from 33.7% (AeroChamber p<0.01 compared with other masks) to 100% (Pocket Chamber). DSV decreased with increasing force with most of the masks, and the slope of this line was inversely proportional to mask flexibility. Mask fit was 100% at 1.5 pounds of force only with the **AeroChamber**[®] and Optichamber. Mask fit was poorest with the Vortex, Pocket Chamber, and BreatheRite masks. CONCLUSION: Rigid masks with large DSV might not be suitable for the use in children, especially if discomfort from the stiff mask makes its use less acceptable to the child.

- ⑦ **Louca, E., Leung, K., Coates, A.L., Mitchell, J.P.** Comparison of Three Valved Holding Chamber for the Delivery of Fluticasone Propionate – HFA to an Infant Face Model. *J Aerosol Med*. 2006 Summer;19(2):160-7.

The purpose of this study was to compare three valved holding chambers (VHC) with facemasks attached. One VHC (**AeroChamber MAX**[®] with medium mask) was made with materials that dissipate surface electrostatic charge, and the others (Optichamber[®] Advantage and ProChamber[™] with pediatric facemask) were made from non-conducting materials. The OptiChamer Advantage and ProChamber VHCs were each washed with an ionic detergent and drip dried before testing to minimize surface electrostatic charge. The **AeroChamber MAX**[®] VHCs were tested “out of the package” and also after wash, rinse, and drying. An infant face model incorporating an electrostatic filter in the oral cavity was connected to a breath simulator using a standard waveform for a small child. The fit of each VHC with facemask was demonstrated by agreement of inspiratory flow measurements between pneumotachograph connected to the system with those set on the simulator. An HFA-fluticasone propionate metered dose inhaler (MDI; 125 µg/dose) was inserted into the VHC, two actuations were delivered, and the filters were subsequently assayed using high-pressure liquid chromatography (HPLC). Testing and sample assay order was randomized, and HPLC assays were undertaken blinded. Drug delivery efficiency expressed as percentage of the total dose of fluticasone propionate (250 µg) for the **AeroChamber MAX**[®] VHC “out of the package” was 22.0%(0.7)% (mean [99% CI]) and 21.2(1.5)% when pre-washed/rinsed. Results for the pre-washed ProChamber and OptiChamber Advantage VHCs were 10.2(0.55)% and 8.8(1.9)%, respectively. The more efficient delivery of medication via VHCs made from electrostatic charge dissipative materials should be considered when choosing doses for small children.

- ⑧ **Esposito-Festen, J.E., Ates, B., van Vliet, F.J., Verbraak, A.F., de Jongste, J.C., Tiddens, H.A.** Effect of Facemask Leak on Aerosol Delivery from a pMDI-Spacer System. *J Aerosol Med*. 2004 Spring;17(1):1-6.

The objective of this investigation was to study the relation between size and position of a mask leak on spacer output and lung dose. An upper-airway model (SAINT model, Erasmus MC) was connected to a breathing simulator. Facemasks with leaks ranging between 1 and 1.5 cm² were examined. Leaks were located close to the nose or close to the chin. During simulated breathing, 200 µg budesonide (Pulmicort[®], AstraZeneca) was delivered to the model via NebuChamber[®] (AstraZeneca) with facemask. Spacer output and lung dose were measured by placing a filter between spacer and facemask or between model and breathing simulator, respectively. Budesonide trapped on the filter was quantified by means of HPLC, and expressed as percentage of the nominal dose. Mean spacer output doses for the nose position were 50, 38, 28, 12, 10, 6, and 0%, and for the chin position were 50, 40, 31, 11, 9, 4, and 0% for leaks of 0, 0.05, 0.1, 0.16, 0.2, 0.3, and larger than 1.4 cm², respectively. Mean lung doses for the nose position were 10, 8, 6, 3, 3, 1, 0, 0, 0, and 0%, and for the chin position were 10, 9, 8, 6, 6, 5, 1, 1, 0, and 0% for leaks of 0, 0.05, 0.1, 0.16, 0.2, 0.3, 0.4, 0.5, 1, and 1.5 cm². Efficiency of a pMDI-spacer facemask strongly depends on the size of a facemask leak. Spacer output did not depend on the position of the leak. Lung dose was higher for leaks near the chin than for leaks near the nose.

- ⑨ **Coates, A.L., Louca, E., Leung, K., Nagel, M.W., Mitchell, J.P.** In Vitro Comparison of Valved Holding Chambers (VHCS) with Facemasks Using an Infant Face Model. CHEST 2004; 126(4):910S.

PURPOSE: The delivery of aerosolized medication from pressurized metered-dose inhalers (pMDIs) by VHC with facemask electrostatic charge. Our study attempted to examine medication delivery via VHC with facemask attached, using a model infant face (ADAM) based on a Laerdal head mannequin, modified to simulate natural facial texture. “The facemask was applied with a pressure of 1.6 kg to the face, based on practice at a university pediatric asthma clinic. An acceptable facial seal was confirmed...”



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