Force-Dependent Static Dead Space of Face Masks Used With Holding Chambers

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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-dependent 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 not suitable for use in children, especially if discomfort from the stiff mask makes its use less acceptable to the child. *Key words: aerosol, dead space, drug delivery, metered-dose inhaler, pMDI, valved holding chamber, masks, child.* [Respir Care 2006;51(2):140–144.

Introduction

Valved holding chambers (VHCs) have improved inhalation therapy with pressurized metered-dose inhaler to young children and have been shown to be at least as effective as medication delivered via jet nebulizer.[1] The addition of a face mask to the VHC makes it possible for even the youngest child to use a pressurized metered-dose inhaler. Aerosol travels through the VHC, and as particles decelerate they pass through the one-way valve and to the face mask, where they are inhaled with tidal breathing.

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Drug delivery is influenced by the mask seal on the child's face, the mask dead space, the VHC dead space, and the opening pressure of the inspiration and exhalation valves. Drug delivery decreases when static dead space is increased, and drug delivery increases with smaller VHC volume when lower tidal volume (V_T) is used.[2] However, with increasing breath frequency, drug output from large-volume VHCs approximates the drug output from small-volume VHCs.[2,3] Mathematical models of aerosol drug delivery suggest that VHC dead space and aerosol settling decrease drug delivery when lower V_T is used[4]; however, the effect of mask dead space was not examined.

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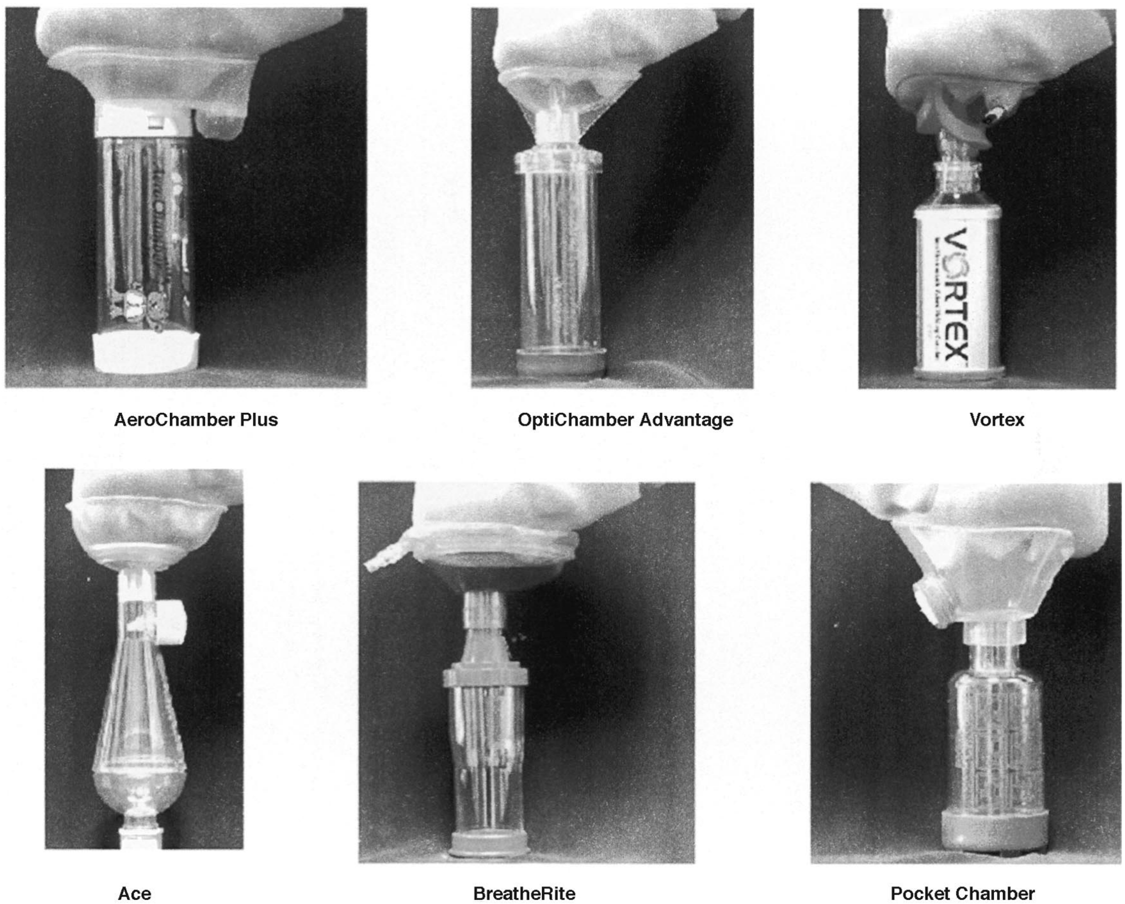

Fig. 1. Face masks used in this study. Face masks were placed on the mannequin face at medium (3.5 pounds) force in the orientation used for testing.

The seal between the mask and the face is critical for drug delivery.[5–8] Studies have suggested that face-mask seal is at least as important as dead-space volume (DSV) to drug delivery. The effect of mask dead space has not been evaluated as a factor of applied force or mask stiffness and fit.

The objective of our study was to measure the force-dependent static DSV of face masks currently used with VHCs for aerosol drug delivery and to examine the effect of increasing force on face-mask seal and DSV.

Methods

Face Masks

Seven commercially available face masks were purchased and evaluated (six of which are shown in Fig. 1). These were the masks used with the Aerochamber (Monaghan Medical Corporation, Plattsburgh, New York), Optichamber (Respironics HealthScan Asthma and Allergy Products, Cedar Grove, New Jersey), Easivent (Dey Laboratories, Napa, California), BreatheRite (Ventlab, Mocksville, North Carolina), Ace (DHD Healthcare, Wampsville, New York), Pocket Chamber (Ferraris Respiratory, Louisville, Colorado), and Vortex (Pari Respiratory Equipment, Midlothian, Virginia). In all cases, the mask was purchased along with the VHC, as a set.

DSV Measurement

The volume of water needed to fill the mask to capacity was the measured mask volume. The mask was then positioned with the distal end on a force gauge (Chatillon DFM-10, Ametek Test and Calibration Instruments, Largo, Florida) and a 2-year-old-child mannequin head (Laerdal Medical, Wapinger Falls, New York) was positioned on the mask. This mannequin has a firm but flexible facial covering and is used for cardiopulmonary resuscitation training, including mask placement. Force was slowly and continuously applied to the mannequin head, forcing water out of the mask, until the desired force was reached. Three forces were used, low (1.5 pounds), medium (3.5 pounds), and high (7.0 pounds). The absolute DSV was the water remaining in the mask after application of force. DSV percent (DSV%) was calculated as the DSV divided by the original mask volume. This was a measure of mask flexibility.

DSV is influenced by the absence of a seal. In designing this study we realized that our assessment of DSV by measuring the amount of water remaining in the mask after applied pressure would be accurate only if the mask was fully sealed on the face. When the mask fails to seal, air is entrained with each breath, which increases the effective DSV, and thus our measurement would substantially underestimate DSV. Thus, we evaluated the ability of the mask to seal at different forces by first coating the mannequin face with fine charcoal powder and then applying the mask. When the mask was removed, we visually assessed the distribution of powder on both the mask margins and the mannequin face. The charcoal marking was easily read and there was concordance in interpretation among the investigators. Testing was repeated if there was a discrepancy between the mask and face distribution. We scored the results of this testing at each applied force as positive (indicating a complete seal) or negative (indicating inability to form a complete seal). We could not accurately evaluate the amount of leak or the effectiveness of a partial seal using this technique.

Statistical Analysis

All measurements were performed 3 times on a single mask from each manufacturer. We confirmed that force and volume data were normally distributed, so that between-brand mask comparisons could be evaluated by analysis of variance. Changes at each applied force were evaluated with regression analysis. Significance was set at $p < 0.05$, by convention. Least-squares linear regression analysis was used to determine the slope of the line modeling DSV% of each mask against the applied force of 0, 1.5. 3.5, and 7 pounds.

Results

Static Force-Dependent Face-Mask Dead Space

Table 1 shows the variability in DSV with applied force. The Pocket Chamber mask was too stiff to seal at any force applied during these experiments, and thus the DSV-versus-force slope was 0. It was the only mask that did not decrease its DSV with increasing force. Of the remaining masks, the Ace, BreathRite, and Easivent had the largest mask volume and the largest DSV at 1.5 pounds of force. However, the Ace and the Easivent masks were the most flexible (with the greatest negative DSV/force slope) and had an acceptably lower DSV at 7 pounds of force.

DSV decreased with increasing force for most masks, and the decrease was greater with masks made of more flexible material (ie, with either a lower DSV% or a greater negative DSV/force slope (see Table 1). DSV at 3.5 pounds of force (medium) ranged from 29 mL to 100 mL, with the Aerochamber, Optichamber, and Vortex having DSV < 50 mL at medium force. The other masks all had volumes > 60 mL (Fig. 2). The Pocket Chamber and Vortex were quite stiff and had very little decrease in DSV when force was increased (see Fig. 2). It was also difficult to form a seal with these masks. The Ace decreased DSV only when 7 pounds of force was used, and it sealed only at this force.

DSV% at 1.5 pounds of force ranged from 46% (Aerochamber, $p < 0.01$ compared with other masks) to 100% (Pocket Chamber) (Fig. 3). The Vortex mask had the lowest DSV, the lowest mask volume, the second-highest DSV%, and the second highest stiffness (see Table 1), and the Vortex did not make a complete seal except at 7 pounds of force.

In this report we used the DSV% to estimate mask flexibility, but the slope of the DSV-versus-force regression line (measured at 0, 1.5, 3.5, and 7 pounds of force) is an alternative way to measure flexibility. The DSV/force regression lines were indeed quite linear, with slope (m) and regression (r^2) values as follows: Ace (−10.65, 0.89), Aerochamber (−9.32, 0.69), BreatheRite (−6.72, 0.61), Easivent (−12.80, 0.77), Optichamber (−5.59, 0.79), Pocket Chamber (0, 1.0), and Vortex (−1.96, 0.71). Furthermore, the regression of slope versus DSV% at each force was linear, which shows that these are independent measures of mask flexibility. Using data from all 7 masks, the correlations were:

DSV at 1.5 pounds: $p = 0.05$, $r^2 = 0.55$
DSV at 3.5 pounds: $p = 0.03$, $r^2 = 0.65$
DSV at 7 pounds: $p = 0.01$, $r^2 = 0.73$

This is consistent with the greatest change in DSV at the largest applied force being best correlated with flexibility.

Face-Mask Seal

Only the Aerochamber and Optichamber sealed at 1.5 pounds of force. Vortex, Ace, Easivent, and BreatheRite achieved a good seal with increasing force. The Pocket Chamber was the only mask that would not seal at any force tested in this study.

Discussion

Drug delivery to infants and children depends on several variables. The interface between the mask and the child's face is critical. Several authors have demonstrated the importance of the face-mask seal.[5–8] A study using an upper-airway model showed that the amount of drug de-

Table 1. Mask Volume and Mask Dead Space at 3 Different Forces, and Slope of the Line Regressing Dead Space and Force

Mask	Mask Volume (mL)	Dead Space (mL)			Slope of Dead Space vs Force*
		at 1.5 pounds	at 3.5 pounds	at 7 pounds	
Aerochamber	100	46.0	33.7	24.0	−9.32
Optichamber	75	47.7	40.0	30.7	−5.59
Easivent	150	95.7	61.7	52.7	−12.80
Ace	125	82.3	75.3	42.0	−10.65
BreatheRite	140	94.2	89.0	83.0	−6.72
Vortex	43	32.3	29.0	27.3	−1.96
Pocket Chamber	100	100.0	100.0	100.0	0

* The slope of the regression line is inversely related to mask flexibility.

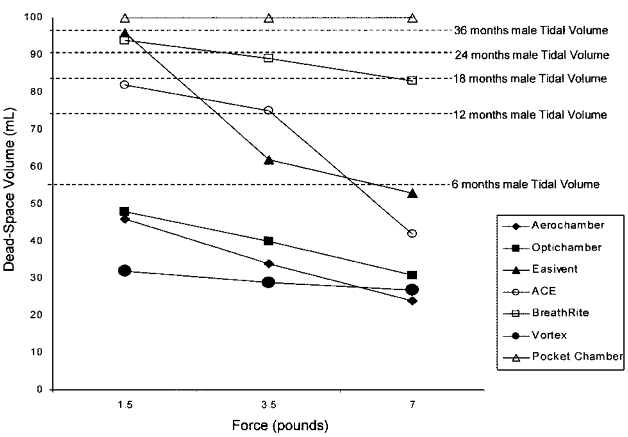

Fig. 2. Dead-space volume (DSV) at the 3 applied forces. The dotted lines indicate the mean tidal volume for male children age 6, 12, 18, 24, and 36 months of age. Only Aerochamber, Optichamber, and Vortex had a DSV less than the tidal volume (7 mL/kg) of a 6-month-old male infant.

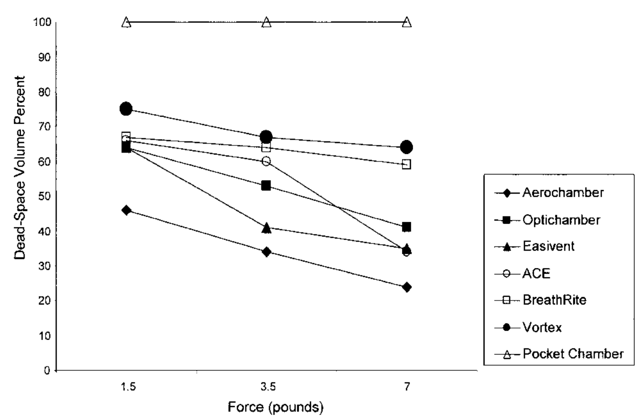

Fig. 3. Dead-space volume percent (DSV%) at the 3 applied forces. DSV% is a measure of relative mask flexibility. The Aerochamber had significantly lower DSV% than the other masks tested ($p < 0.05$) at 1.5 pounds of force. The Pocket Chamber mask was too stiff to seal at any force tested.

livered depends on the size of face-mask leak.[7] Similar results were found in a "real life" scenario, where it was suggested that improving face-mask seal improves drug delivery, even with higher DSV.[6]

In our study all the tested masks showed a good seal with the mannequin head, except for the Pocket Chamber mask. DSV differed significantly among the masks. Some masks tested had DSV $\geq$ 70 mL, which is the V_T of a 1-year-old, 10-kg infant (see Fig. 3). Masks that decreased DSV to a greater extent with increasing force indicated that these masks are more flexible. For stiffer masks a seal forms only with greater force. Unfortunately, any improvement in aerosol delivery using a seal that must be ensured by increasing force can be offset if it leads to patient distress, as crying will compromise particle deposition[9] and potentially lead to the child breaking the mask seal or the parent prematurely terminating the therapy.

Several authors have reported the detrimental effect of using larger-volume VHCs to deliver aerosols to infants breathing at low V_T.[2,3] Taking more breaths might compensate for the larger mask and VHC volume, but this would require a longer administration time, making it more difficult to maintain a comfortable mask with infants and young children. As well, with this additional time, the aerosol remaining in the VHC will settle in the VHC body and be unavailable for inhalation. Everard et al showed that adding dead space to the face/mask interface reduced the drug delivered to a filter at the mouth by up to 65% in vitro.[2] However, no difference was apparent in lung deposition of a radionuclide aerosol between a chamber tested with face mask and mouthpiece, even though the latter had a lower DSV.[10] Amirav et al reported an increase in drug delivery due to better face mask "seal," despite an increase of DSV.[6] In their study the reported DSV was measured via water displacement, without a face in position, and so was not a force-dependent volume, as reported here. Using a lung model and masks used for noninvasive mechanical ventilation, there was a 30% increase in dynamic DSV when a face mask was used in the setup.[11] However, the force used for holding the face mask against the mannequin face was not measured.

In this study we did not measure drug delivery. This would have required a bench study with a breath simulator, appropriate filters, and comparing only one VHC with each mask. This was not possible for our study because of lack of fit between the body of a VHC and masks made for other VHCs. We physically isolated each mask from the VHC with a seal, thus effectively testing the mask independent of the VHC used. We acknowledge that the VHC volume is an additional dilutional volume for the child to inhale,[4] but we neither measured this nor added reported values to the mask DSV measured. In this way, we effectively measured the properties of the mask in isolation from the VHC.

Another potential limitation is that this study was performed at the bench, with a mannequin face, rather than in vivo. We specifically chose a mannequin face that is used for teaching cardiopulmonary resuscitation, because this face is used to teach the application of a bag-valve-mask apparatus. By using a mannequin we examined dead space under the best-case scenario. It is impractical to secure the cooperation of awake and healthy infants for the repeated application of many different face masks at 3 different forces while requiring that the infant subject remain immobile as force and DSV is measured. Any extrapolation of data so obtained to medication administration in an asthmatic child would be highly dubious. Therefore, the minimum and maximum forces used were those generated by two of the authors (ABB and BKR) while placing face masks on the mannequin face as they would while demonstrating VHC use to a parent. These authors are experienced pediatric pulmonologists who routinely demonstrate face mask application to parents in clinic. Thus we believe that these forces most closely and reliably approximate what could be expected while using these masks in small children.

Conclusions

We found that mask DSV changes in response to force and that this DSV change differs significantly among commercially available face masks attached to VHCs. These force-dependent changes are related to the flexibility of the mask. These data suggest that some of these masks may be unsuitable for use with infants or small children, either because of their relatively large DSV or because of their inability to form an effective seal at the pressures tested.

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