

Infant Aerosol Holding Chamber Face Masks: Not All Are Born Equal!

Face masks are used for many respiratory care applications, such as anesthesia, resuscitation, and aerosol therapy. In pediatric practice, particularly with infants and toddlers, aerosol therapy is usually administered by means of a small-volume nebulizer and face mask.

Because of their convenience, speed of administration, versatility, dose accuracy, reproducibility, near-optimal mass median aerodynamic diameter, and relatively low per-treatment cost, pressurized metered-dose inhalers have become an increasingly popular alternative for providing most therapeutic aerosols, even to very small infants and neonates.¹ In children, pressurized metered-dose inhalers are commonly used with valved holding chambers (VHCs) via a mouthpiece. In infants and children too young to use a mouthpiece, the face mask serves as the interface between the patient and the VHC. Face masks attached to VHCs have greatly advanced our ability to effectively and more economically treat even the youngest infants.²

Aerosol therapy via VHC and face mask is a relatively recent development, and many physicians, especially pediatricians who have been in practice for many years, may thus have little experience with this approach to aerosol delivery. Although the mask interface is arguably the single most important factor determining the dose of medication delivered from the VHC (or any aerosol source) to the nose/mouth of the infant or toddler, its role in the aerosol-delivery chain has not previously been very well characterized, and studies comparing various face masks are lacking. Most studies dealing with VHC performance have paid relatively little attention to the characteristics of the mask and the seal between the mask and the infant's face. For example, in previous studies of VHCs with masks,^{3,4} parents were instructed to hold the mask tightly against the infant's face, and this was monitored and reinforced during the study, thus minimizing possible leaks. However, in daily home use, and without repeated emphasis on achieving a mask-face seal, some mask designs appeared to be inherently more leaky than others.⁵⁻⁷

Only relatively recently has there been a scientific focus on mask-infant interaction. It was less than a decade ago that it was occasionally reported that the mask could be an obstacle to adequate aerosol delivery.^{5,8} Zak et al⁷ measured mask pressures in some 200 children and found them to be highly variable and much lower than those

measured when ventilation was accomplished with a simulated-breathing-programmed respirator, which suggested frequent air leaks around the mask in these children. A study published in *Pediatrics* in 2001 emphasized that an effective mask seal is crucial for adequate therapy with VHCs.⁶ In that study the amount of leakage that occurred with 3 commonly used VHC masks was compared to that with the Hans Rudolph anesthesia mask (Hans Rudolph, Kansas City, Missouri). The Babyhaler (Glaxo, Germany), Aerochamber (Trudell Medical, London, Ontario, Canada), and Nebuchamber (AstraZeneca, Lund, Sweden) masks were evaluated. Of these, the Nebuchamber performed most poorly. Ventilation measured through the Nebuchamber, when applied to the face of young children under simulated real-life conditions, was significantly less than the other 3, indicating a greater leak. The Aerochamber mask performed best and was similar to the Hans Rudolph mask, which is considered the gold standard. Furthermore, the coefficient of variation of ventilation was greatest with the Nebuchamber mask, although ventilation through the other masks was also quite variable, amounting to 25%, even with the best-performing (Aerochamber) mask.

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Face-mask seal has since received increasing attention. In an attempt to improve its performance, investigators replaced the poorly-fitting ovoid mask supplied with the Nebuchamber VHC with a better-fitting round mask that increased the delivery efficiency of therapeutic aerosols in young children by 30%.⁹ This new Nebuchamber mask was subsequently used successfully in a study of infants and young children with acute asthma presenting to an emergency department.¹⁰ A similar attempt to improve the face mask fit in clinical settings was reported by Esposito-Festen et al,¹¹ who attached a different round face mask to the Nebuchamber.

Using a single VHC and 3 different face masks, Hayden and colleagues measured the inhaled mass of budesonide in 24 young children (mean age 38 mo, range 6–81 mo). They found significant variability in drug delivery, ranging from 0 to 120 μg of the 200- μg nominal budesonide dose.¹² The authors stressed the importance of face-mask

seal, although it was not addressed specifically in that study.

In a more recent study, specifically designed to evaluate the effects of mask-seal, Smaldone et al¹³ confirmed its critical role as the most important factor in the chain from the aerosol generator to the patient. Their data demonstrated that the lack of face-mask seal negated most of the effects of detergent-coating the VHC, which was previously assumed to be the major determinant of aerosol delivery from VHCs.¹⁴

The fit of the mask will also depend on the pressure applied by the caregiver and the cooperation of the child. Young children commonly resist a face mask at first. They often squirm and cry during initial treatment attempts and push the mask away, thus making it difficult, at least until the child has become acclimatized, to maintain a good seal with any existing mask.

Another important face mask-related factor is the dead space. Any drug contained in the volume of air common to the inspiratory and expiratory pathways will be lost on expiration and does not contribute to the lung dose. The smaller the mask and/or valve system dead space, the more likely it is that a greater proportion of the dose in the VHC will be inhaled with each breath,¹⁵ thus speeding VHC emptying and improving overall aerosol delivery efficiency and lung dose. This is particularly important in neonates and infants less than 1 year old, as well as toddlers and children with low tidal volume and/or high respiratory rate due to cardiopulmonary disease or metabolic acidosis. The tidal volume ranges from 10–20 mL in neonates at 30–40 breaths/min to 25–100 mL in full-term to age 18 months.¹⁶

A distinction should be made between the physical dead space of the mask and its physiological or functional dead space. That is, when a mask is applied to the face, the variable pressure applied causes compression of the mask and a variable reduction in the mask dead space.

This issue of the Journal contains an excellent paper by Shah and colleagues,¹⁷ who specifically address the issue of mask dead space and the effect of applying various forces on the dead space of masks applied to the face of a child surrogate. The authors tested 7 commonly used face masks and measured their dead space, both under static conditions (no pressure applied) and with various applied forces. Mask dead space was measured using the face of a mannequin of a 2-year-old, to which was applied forces of 1.5, 3.5, and 7 pounds. This approximates the range of forces applied by caregivers when administering aerosols to infants and young children—a very elegant method of systematically simulating a real-world scenario, which had not been previously addressed.

Shah et al found various dead space values and various changes in dead space with the various masks. Intuitively, the greater the applied force, the greater the reduction in dead space. However, mainly because different masks are

made of different materials with different flexibility, not all masks behaved similarly under these conditions. Not surprisingly, the authors found that more rigid masks showed a smaller reduction in dead space in response to the forces applied, and one of the tested masks was so rigid that no seal could be achieved, even at the maximum force applied. This is the first time that face masks have been evaluated in this way, and the study is particularly laudable because of the considerable clinical relevance to mask design, which should improve the critical interface between the infant and the aerosol-generation device. Shah and associates have thus appropriately suggested that rigid masks that have large dead space might not be suitable for use in children, especially if discomfort from the stiff mask is likely to make VHCs less acceptable to the child or fails to provide an adequate seal, as was demonstrated by these authors.

Their conclusion is important, as this is one of the first studies to point out that not all face masks are born equal and care must be taken in mask design, particularly for the early pediatric age group. Unfortunately, face masks made for infants and young children have been merely smaller versions of those made for adults, with little consideration given to the special needs of pediatric patients.¹⁸ Previous studies of the efficiency of aerosol delivery via VHC usually ignored the issues of face-mask seal and dead space; thus the Shah et al study makes an important contribution to a better understanding of these critically important components of aerosol therapy devices used in infants and toddlers.

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