

Spring 4-23-2010

Effects of Heat and Moisture Exchangers Designed to Allow Aerosol Delivery on Airflow Resistance and Aerosol Deposition

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EFFECTS OF HEAT AND MOISTURE EXCHANGERS DESIGNED TO ALLOW AEROSOL
DELIVERY ON AIRFLOW RESISTANCE AND AEROSOL DEPOSITION

By

William Sonny Bowers

A Thesis

Presented in Partial Fulfillment of Requirements for the

Degree of

Master of Science

in

Health Sciences

in

the Department of Cardiopulmonary Care Sciences

in

the College of Health and Human Sciences

Georgia State University

Atlanta, Georgia

2010

ACCEPTANCE

This thesis, EFFECTS OF HEAT AND MOISTURE EXCHANGERS DESIGNED TO ALLOW AEROSOL DELIVERY ON AIRFLOW RESISTANCE AND AEROSOL DEPOSITION, by William Sonny Bowers was prepared under the direction of the Master's Thesis Advisory Committee. It is accepted by the committee members in partial fulfillment of the requirements for the degree Master of Science in the College of Health and Human Sciences, Georgia State University.

The Master's Thesis Advisory Committee, as representatives of the faculty, certify that this thesis has met all standards of excellence and scholarship as determined by the faculty.

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ACKNOWLEDGEMENTS

I would like to thank the Respiratory Therapy department at Georgia State University for the use of their facilities and supplies that were used in order to complete this thesis. Special thanks go to Dr. Arzu Ari for all the guidance, knowledge, and time she gave to me and this thesis. Her patience and wisdom made the entire process a smooth and enjoyable experience. She was an outstanding thesis advisor. Also, I would like to thank Mr. Bob Harwood for the many lengthy discussions after class that brought me to this topic, as well as for his help in setting up the experiments and his commitment to this thesis. Mr. Chip Zimmerman also has my gratitude for his role serving on my committee, his suggestions that helped strengthen my thesis, and for teaching me what an HME does when I first started in the program. Finally, I'd like to thank all my family and friends who supported me through this process and understood when I had to spend the entire weekend in the library working on completing this thesis.

ABSTRACT

EFFECTS OF HEAT AND MOISTURE EXCHANGERS DESIGNED TO ALLOW AEROSOL DELIVERY ON AIRFLOW RESISTANCE AND AEROSOL DEPOSITION

By

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Introduction: Several problems arise when HMEs are used while giving aerosolized medication including increased airway resistance (R_{aw}) or the need to open the ventilator circuit. Recently, heat and moisture exchangers designed to allow aerosol delivery (HME-AD) have been developed to solve this problem, but no tests have been performed to confirm their effectiveness. The purpose of this study is to evaluate the effect of HME-ADs on aerosol deposition and R_{aw} .

Methods: An in-vitro lung model consisting of an 8.0 mm ID endotracheal tube (ETT) connected to a standard ventilator circuit and ventilator was connected to a rubber test lung via cascade humidifier set to deliver 37°C and 100% relative humidity. The ventilator settings were as follows: V_t 450 ml, RR 20/min, PIF 50 L/min, PEEP 5 cm H_2O , and I:E ratio 1:2. HME-ADs used in this study include Circuvent HME/HCH bypass (Smiths-Medical, Keene, NH), Gibeck Humid-Flo HME (Hudson RCI, Arlington Heights, IL), and Airlife BHME (Carefusion, San Diego, CA). As a control, albuterol sulfate (2.5 mg/3mL) was delivered with a vibrating mesh nebulizer (Aeroneb Solo, Aerogen Inc) placed at the wye without any HME-AD in the circuit. Then, the aerosol and HME configurations of each HME-AD were tested by measuring pre-post R_{aw} and aerosol deposition at the end of each run. Each condition was repeated in triplicate ($n=3$). Aerosol deposition between the aerosol and HME configurations of each HME-AD was compared with a series of student t-tests. Then, differences both in aerosol deposition and in airway resistance among the HME-ADs were analyzed using one-way analysis of variance (ANOVA). Significance was determined as $p<0.05$.

Results: R_{aw} increased after each albuterol treatment with every HME-AD. In the aerosol configuration, the Circuvent and Humid-Flo delivered significantly less aerosol compared to the control ($p=.004$ and $p=.002$, respectively), while there was no significant difference on aerosol delivery between the Airlife and the control ($p=.084$). The Airlife gave the highest aerosol deposition which was not significantly different than control ($p=.084$). When aerosol delivery between the HME and aerosol configurations in each HME-AD was compared, aerosol deposition with the Humid-Flo was not significantly different ($p=.078$) but both the Airlife and the Circuvent showed a statistically significant reduction in aerosol deposition with the HME configuration ($p=.002$ and $p=.005$).

Conclusions: Aerosol delivery and R_{aw} with each HME-AD differ in simulated mechanically ventilated patients. Further studies are needed to determine the effectiveness of these devices over time and with different aerosol generating devices.

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ABBREVIATIONS

HME	Heat and moisture exchanger
PEEP	Positive end expiratory pressure
HME-AD	Heat and moisture exchanger designed to allow aerosol delivery
COPD	Chronic obstructive pulmonary disease
PEEP _i	Intrinsic Positive end expiratory pressure
FRC	Functional residual capacity
CPAP	Continuous positive airway pressure
ICU	Intensive care unit
M1	Icor Mediflux 1
M2	Icor Mediflux 2
WOB	Work of breathing
HMEF	Heat and moisture exchanger with filter
ETT	Endotracheal tube
BAN	Breath actuated nebulizer
VMN	Vibrating mesh nebulizer
ANOVA	Analysis of variance

CHAPTER I

INTRODUCTION

During mechanical ventilation, airway humidification is essential for pulmonary function. In normal breathing without intubation, air is warmed to 37° C and humidified to 100% relative humidity, (Shelly, Lloyd, & Park, 1988). While the upper airway is responsible for this function in normal spontaneously breathing individuals, it is bypassed during mechanical ventilation. Therefore, heat and humidity must be provided for the patient. Traditionally, this has been accomplished via a heated humidifier. Recently, heat and moisture exchangers (HME), also called artificial noses, are being used more frequently for this purpose. In a mechanically ventilated patient, an HME is placed in the ventilator circuit between the endotracheal tube and wye piece, and collects heat and moisture from a patient's expired breath, which is used to warm and humidify the subsequent inspired breath.

HMEs offer several benefits over heated humidifiers. HMEs are inexpensive, do not require electrical power, and since there is no need to refill water as in heated humidifiers, HMEs are simpler and more cost efficient to maintain (Ploysongsang, Branson, Rashkin, & Hurst, 1988). In fact, studies have shown that leaving HMEs in the ventilator circuit for extended lengths up to 5-7 days is safe and does not increase the risk of ventilator associated pneumonia (Davis, et al., 2000; Thomachot, et al., 2002). Also, some HMEs offer microbial filtering capabilities, which were shown to decrease colonization of the ventilator circuit to 12%, as opposed to 68% in heated humidifiers (Boots, Howe, George, Harris, & Faoagali, 1997). Clearly, HMEs are an interesting alternative to heated humidifiers.

Despite the benefits of HMEs, there are drawbacks to their use. Inclusion of HME in a ventilator circuit has been shown to increase airflow resistance (Chiaranda, et al., 1993; Hart, 2009; Ploysongsang, et al., 1988). However, the clinical significance of this resistance is negligible. Particularly, the administration of aerosolized medication creates a dilemma. Introduction of aerosolized medication into the HME has been shown to appreciably increase resistance (Hart, et al., 2009). One solution is to remove the HME when giving aerosol treatments. However, in order to remove the HME, the ventilator circuit must be disconnected, which entails its own problems. Disconnection causes a loss of positive end expiratory pressure (PEEP), which leads to derecruitment of lung units. A further risk associated with disconnection is the opening of the circuit to possible infection. Consequently, careful consideration must be taken for which method of humidification should be used for mechanically ventilated patients needing aerosolized therapy.

To resolve this quandary associated with aerosols and HME use, specialty HMEs designed for aerosol delivery (HME-AD) have recently become available. These HME-ADs operate by turning a lever or dial to position the device so aerosol can bypass the HME portion of the device (aerosol configuration). A second turn of the lever or dial redirects the air through the HME (HME configuration). With these devices, aerosol can be delivered without disconnecting the ventilator circuit.

Because these devices are fairly new, there is little literature to support their use. As HME-ADs must provide a separate route for aerosol to bypass the HME, it is possible that they would cause greater impaction of the aerosol causing it to fall out of suspension before it enters the respiratory tract. In a preliminary report from Brady and Hess (2004), one HME-AD was

shown to decrease aerosol deposition by as much as 40% . Another concern is if the aerosolized medication enters the HME division, it may contribute to resistance. Nevertheless, early evidence suggests this is not the case (Badescu, Volsko, & Chatburn, 2007; Branson & Johannigman, 2004). Therefore, the purpose of this study is to evaluate the effectiveness of HME-ADs designed to allow aerosol delivery on aerosol deposition and airway resistance.

These novel HMEs offer a useful solution to allow the delivery of aerosol with the use of HME but it is important to understand the function of these devices before their use. With the increasing cost of healthcare, answering these questions will allow the healthcare provider to make the best decision about which humidification device to choose.

Therefore the questions asked during this study include:

1. How is deposition of aerosolized albuterol affected when passed through HME-ADs in the aerosol and HME configurations?
2. How is resistance affected when giving aerosolized albuterol through HME-ADs when in the aerosol and HME configurations?

CHAPTER II

REVIEW OF LITERATURE

A review of literature was conducted to develop a better understanding of the influence of HMEs on airflow resistance and delivery of aerosols during mechanical ventilation. The studies reviewed in this chapter were derived from searches of bibliographic databases including PubMed, CINAHL, Web of Science, Science Direct, Ebscohost. Further, a search was completed via *Respiratory Care* journal. The search terms used include the following: heat and moisture exchanger, nebulizer, vibrating mesh nebulizer, and mechanical ventilation. Both in vivo and in vitro studies were included in this chapter. Articles not written in English were excluded, and only articles pertaining to adults were used. Once these articles were obtained, the reference lists were reviewed to ensure no relevant articles were excluded. A total of 24 articles were chosen for review. This review of literature will explore resistance through an HME, aerosol delivery during mechanical ventilation, vibrating mesh nebulizers during mechanical ventilation, and HMEs designed to allow aerosol delivery.

Resistance through a Heat and Moisture Exchanger

In a benchmark study on added airflow resistance associated with HMEs, Ploysongsang, et al. (1988) tested six common HMEs (Portex Hygroscopic Humid-Vent-1, Siemens Servo Humidifier 150, Siemens Elema Ventilator Systems, Siemens Servo Humidifier 151, National Catheter Corporation Humidifier, Engström Edith Humidifier, and the Pall Humidifier) in a ventilator circuit with a water bath heated to 37°C connected to a bench top lung model. Their research showed that all six HMEs tested increased air flow resistance. Further, the resistance increased with increased flow rates and longer duration of use. Extended use of the HME allows the increased moisture content in the HME to clog small pores. The authors conclude that HMEs

should be used cautiously in critically ill and weak patients because the extra resistance could lead to fatigue or ventilatory failure.

Another *in vitro* study conducted by Hart (2009) investigated the effects of added humidity with an HME in a ventilator circuit. The ventilator circuit was kept at 37°C with 100% relative humidity. Thirty minutes after the HME was placed in the circuit, the resistance increased from 8.99 cm H₂O/l/sec to 9.23 cm H₂O/l/sec and the weight of the HME increased from 27.92 g to 28.62 g. Neither of these findings was statistically significant. This research illustrates that an HME added to a ventilator circuit for a short time does not have a profound effect on resistance.

The implications of increased resistance were unknown for chronic obstructive pulmonary disease (COPD) patients, but increased expiratory resistance from an HME has the potential to affect intrinsic PEEP (PEEP_i). To discover the consequences of this resistance *in vivo*, Conti, et al. (1990) tested the effects of three different HMEs on 10 COPD patients undergoing mechanical ventilation. The research showed no significant increases in PEEP_i or functional residual capacity (FRC) in any of the patients tested after one or 12 hours. The authors conclude that the amount of resistance to airflow through an HME over 12 hours is not significant during mechanical ventilation of COPD patients.

To further elucidate the effects of increased resistance by adding HME into ventilator circuits *in vivo*, Chiaranda, et al. (1993) tested the effectiveness of HMEs on 96 patients who were intubated and receiving mechanical ventilation. Hygroscopic HMEs were used to provide warmth and humidity to the airway during a 24 hour test period. The results showed the mean resistance was increased by 0.5 hPa/l*s and based on subjective scoring there was no significant change in bronchial secretion characteristics. The authors conclude that use of HMEs is

effective in heating and humidifying inspired air, and although the HMEs do increase airflow resistance, the increase is only slight. Nevertheless, caution should be used in patients with thick secretions.

Another *in vivo* study examined the effects of HMEs on the ventilatory pattern and respiratory mechanics in patients. Natalini, Bardini, Latronico, and Candiani (1994) conducted a study on nine patients in the intensive care unit (ICU) who were spontaneously breathing with continuous positive airway pressure (CPAP). The patients had humidification added by active humidification, or one of two HMEs: the Icor Mediflux 1(M1) or Icor Mediflux 2 (M2). Each apparatus was administered for one hour. At the end of the study, they found that the tidal volume was increased in the M1, which has the most mechanical deadspace, but remained the same with the active humidifier. The M1 also increased work of breathing, but was clinically well tolerated. The study also showed no differences in PEEP_i or airway resistance between any of the groups. The study illustrated that HMEs did not change resistance in spontaneously breathing patients, but smaller HMEs are preferable due to the increased work of breathing associated with increased deadspace.

Manthous and Schmidt (1994) conducted a similar study to determine how HMEs affect resistance in the ventilator circuit over time *in vivo*. Their study involved 23 patients who were mechanically ventilated in assist control mode with the Siemens 153 condenser humidifier. Resistance was measured when the HME was first placed in the circuit (new) and at a point less than 24 hours later (old). The findings showed that the old HME caused a 64% increase in the circuit compared to no humidifier. The authors also found an increase in mean resistive pressure from 4.8 to 6.3 cm H₂O between new and old HMEs. In five patients, the same HME was measured initially and 24 hours after being placed in the circuit. These HMEs showed a mean

increase in resistance from 3.4 to 7.0 cm H₂O—a two-fold increase. The authors conclude that HMEs may add clinically significant resistance with time, which could lead to unnecessary therapies or slow ventilator weaning.

Increase in resistance in the ventilator circuit, as noted in studies above, may lead to increased work of breathing (WOB). Pelosi, et al (1996) examined the effects of adding an HME to a ventilator circuit on a patient's WOB. The study was conducted on 14 patients admitted to the ICU for acute respiratory failure and ventilated with pressure support ventilation. Each patient was provided humidity by both heated humidifier and HME, each for 90 minutes. The authors found that the HME increased minute ventilation as a result of increased tidal volume from the added deadspace associated with using an HME. Further, patients using the HME showed increased WOB and PEEPi. In fact 5 of 14 patients appeared visibly fatigued during HME breathing trial. The authors attribute the increase in WOB and PEEPi to the increased resistance from HME, and note WOB can be attenuated by increasing pressure support.

The mechanical effects that lead to the increased work of breathing found by Pelosi et al. (1996) include resistance and dead space. To expand the knowledge on these mechanical effects of HMEs, Iotti, et al. (1997) compared the effects of a heated humidifier, HME without filtering function, and HME with filter (HMEF) on 10 patients receiving pressure support mechanical ventilation. The authors found that minute ventilation, dead space, airflow resistance, and work of breathing were all increased with the HME devices. In the patients using HME devices, an increase in pressure support was required to maintain alveolar ventilation. HMEF increased these values further than HME without filter, and also caused an increase in PEEPi. The authors concluded that the use of HMEs should be monitored carefully when used clinically.

The resistive effects of an HME could be further exacerbated by the accumulation of excess condensation or patient secretions within HMEs which may lead to increased work of breathing and occlusion of the circuit. To test the effect of accumulation of secretions and condensation within HMEs, Morgan-Hughes, Mills, and Northwood (2001) added 0.9% saline to the patient end of three different HMEFs. Resistance of the HMEF across a BiPAP circuit was measured with each 5 ml saline until the maximum volume that the HMEF could hold was attained. The results showed that addition of saline resulted in a “tampon” effect which significantly increases bi-directional airflow resistance in all three HMEFs. This increase was most significant in the composite designs that typically provide highest humidity. This research shows that HMEs should be monitored closely by the patient’s caretakers for the presence of secretions or buildup of condensation.

Expanding the research of Morgan-Hughes, et al. (2001), Turnbull, Fisher, Mills, and Morgan-Hughes (2005) tested fourteen different HMEFs in the manner previously described by Morgan-Hughes. These HMEFs fell into three categories: HMEs made of polyurethane foam or corrugated cellulose fiber, both with polypropylene fiber filters, or ceramic pleated membrane HMEF. An important variable that was included is the concealment volume—the amount of liquid the HME may hold before excess moisture is visible on the HMEF. This signifies the volume the HME may contain before becoming visible and the health practitioner would replace it. The pleated membrane HMEF did not absorb saline and thus had a low concealment volume and low resistance. However, these HMEF provides poor moisture output. Polyurethane foam, showed a moderate concealment volume with moderate increase in resistance, and corrugated cellulose fiber HMEF had a high concealment volume with the highest resistance. The authors

conclude the optimal design should provide the most humidification with the least concealment volume and resistance.

In addition to adding resistance via airflow through the HME, HMEs may also add resistance from the narrowing of the lumen of an endotracheal tube (ETT) as a result of increased secretions. Adherence of secretions forming a biofilm is a known phenomenon, but it is unknown if use of an HME for greater than 48 hours would increase this biofilm more than a heated humidifier. In a study by Villafane, et al. (1996), 23 patients who were mechanically ventilated were randomly assigned to receive humidification by hygroscopic HME, hydrophobic HME, or heated humidifier. Their results showed that after 48 hours the group with hydrophobic HME had a significantly greater reduction in inner ETT diameter, while there were no significant differences between the hygroscopic HME and heated humidifier. The authors state that since hygroscopic HMEs are more effective at providing humidification, the less humidified secretions are the cause of ETT narrowing. Based on their results, they conclude that hydrophobic HMEs should be avoided for extended use, and that hygroscopic HMEs are good alternatives to heated humidifiers.

Davis, et al. (2000) also examined the use of HMEs on patients for up to five days. The patients in the study were receiving mechanical ventilation and designated to one of three groups: one group used a hygroscopic HME designed for short term use changed every 24 hours (HHME-24), the second used hygroscopic HME designed for short term use changed every 120 hours (HHME-120), and the third used a hydrophobic HME designed for long term use changed every 120 hours (HME-120). The authors found that there was no difference in bacterial colonization or nosocomial pneumonia between the groups. During use of the HME there was

no clinical significance in change in airway resistance from day 1 to 5. The authors conclude that long-term as well as short-term use HMEs can safely be used for up to 5 days, which will result in savings for hospitals.

Building off the Villafane, et al. study (1996), Jaber, et al. (2004) investigated how HME use impacted ETT patency and resistance when used for longer than a week . Patients in this study received humidification with either a hydrophobic-hygroscopic HME or heated humidifier for a mean duration of 10 days. At the midpoint of the study (mean-5 days) there were no significant differences in ETT volume or resistance, which agrees with the findings of Villafane, et al. (1996) and Davis et al. (2000). However, at the end point of the study resistance was significantly increased and ETT volume was significantly decreased in the HME group. Further, the mean daily resistance increased in the HME group. The authors concluded that for short periods of mechanical ventilation HMEs are safe, but when providing humidification for longer than a week the risk of ETT occlusion and added resistance increases, and a heated humidifier should be considered.

Aerosol Deposition during Mechanical Ventilation

MacIntyre, et al. (1985) conducted a benchmark study to determine the effectiveness of aerosol delivery during mechanical ventilation. Seven clinically stable patients were intubated and mechanically ventilated for acute respiratory failure and three nonintubated volunteers were given radiolabeled aerosol via jet nebulizer. Imaging revealed that in the mechanically ventilated patients, 2.9% of the aerosol reached the lung parenchyma, and tracheal deposition was increased versus nonintubated patients. In a second part of the study, 15 intubated patients and 20 nonintubated patients were given metaproteronol via jet nebulizer to compare physiologic

response to the medication. Intubated patients had no significant changes in heart rate or respiratory mechanics, compared to nonintubated patients who had significant responses to the medication. The authors concluded that aerosol delivery to the lungs is reduced during mechanical ventilation.

Following the studies demonstrating low delivery of aerosols to the lungs, O'Doherty, Thomas, Page, Treacher, and Nunan (1992) developed an in vitro model to test the effects ventilator settings, nebulizer type and volume of fill had on deposition. The system used a Servo 900c mechanical ventilator with heated water bath. At the end of the ETT a filter was placed to collect and measure the aerosol entering the lung. Lower respiratory rate and increased flow through the nebulizer improved deposition, most likely due to smaller particle size. Increased fill volume also improved deposition and ultrasonic nebulizers were shown to provide better deposition than jet nebulizers. In their in vitro system, the authors were able to achieve a 5-11% deposition versus 2.9% seen in vitro. Therefore, they conclude that delivery to patients may be improved by appropriately selecting the methods and parameters during aerosol delivery.

The early studies suggested impaction on the ETT was responsible for low aerosol deposition in the lungs. To test this theory, Thomas, et al. (1993) administered radiolabeled saline via jet nebulizer to nine mechanically ventilated patients mechanical ventilation following open heart surgery. The results showed that only 3.2% of the initial nebulizer dose reached the respiratory tract, with 1% being deposited on the ETT or trachea. Most of the dose was retained in the nebulizer unit or connections. The 2.2% lung deposition was consistent with previous research, but they showed only a small amount was deposited on the ETT. The authors note the nebulizer produced the most aerosol at the end of inspiration. This aerosol is likely to be carried out of the circuit through the expiratory limb, bypassing the patient.

O’Riordan, Palmer and Smaldone (1994) designed an in vivo system to investigate aerosol deposition in mechanically ventilated patients. Seven patients were mechanically ventilated through tracheostomy tubes and administered 2 ml radiolabeled saline via jet nebulizer. During the nebulizer administration, the humidifier was turned off. The results showed that 30.6% of the drug was inhaled, 1.8-3.0% was deposited in the tracheostomy tube, 12.6% was exhaled, and 15.3% was deposited in the lungs. Therefore, pulmonary deposition of the aerosol was relatively high—53% of inhaled particles were deposited in the lung. The authors conclude that aerosol delivery with mechanical ventilator can be practical with the proper choice of nebulizer and ventilator, and with the humidification system switched off during aerosol delivery.

It is important to understand how newer ventilator design—with features such as bias flow—affects the delivery of aerosols. Miller, Palmer, Shah, and Smaldone (2003) designed a two-part study to determine the best delivery method for aerosolized medication. First, a ventilator was used to ventilate a test lung via an ETT. Albuterol was administered via jet nebulizer placed 12 inches from the wye piece and was sampled at the distal end of the ETT. The aerosol was given by continuous or breath actuated nebulizer (BAN) with the humidifier on or off. The test showed that treatment using continuous nebulizers with humidified circuits gave a 5.7% deposition, while BAN without humidification gave 37.4% deposition. Second, when comparing the sputum given one hour after aerosolized antibiotics were given to intubated and mechanically ventilated patients, BAN with no humidification gave a 20 fold increase in deposition over continuous nebulizers with humidification. This research supported O’Riordan, et al. (1994), showing that deposition improves with humidification off. Further, it showed that

in newer ventilators, using breath actuated nebulizers without humidification gives a remarkable increase in aerosol deposition.

Vibrating Mesh Nebulizers during Mechanical Ventilation

Vibrating mesh nebulizers (VMN) are a novel technology for delivering aerosols. VMNs use vibrating mesh or plates with apertures to create an aerosol. The aerosols generated by VMNs have a high fine particle fraction which have been shown to be more effective at delivering drugs to the respiratory tract (Dhand, 2004). Several studies have recently investigated the use of VMNs with mechanical ventilation. Ari, Aerabi, and Fink (2010) examined the effects of various aerosol generation devices at different positions in the ventilator circuit on aerosol deposition. In vitro, a ventilator was used to deliver albuterol sulfate to a model lung via by jet nebulizer, VMN, ultrasonic nebulizer or pMDI. Deposition was measured by spectrophotometry of a filter placed distal to the ETT. The results showed that the highest deposition was obtained with VMN placed six inches from the wye piece. Further, deposition was increased almost two fold through a nonhumidified circuit compared to a humidified circuit. In fact, with VMN through a nonhumidified circuit, 30.2% of aerosol was delivered to the lungs. The authors conclude that the delivery device is important for optimizing aerosol delivery during mechanical ventilation.

In a follow-up study, Ari, et al., (2010) examined the effects of nebulizer type and position with bias flow on aerosol deposition during mechanical ventilation. This study used a similar in vitro model to their previous work, with albuterol sulfate delivered via jet nebulizer or VMN and bias flows of 2 and 5 liters per minute. Results showed that VMN increased aerosol deposition 2-4 fold over jet nebulizer. Bias flow was shown to influence aerosol deposition. Contrary to the previous study by Ari, et al (2010) where no bias flow was used, deposition was

greatest when the VMN was placed proximal to the ventilator. This study shows that VMNs deliver higher doses of aerosolized medication than jet nebulizers and that placement of the VMN is important when using bias flow.

The reports of higher aerosol delivery lead Hart, et al. (2009) to investigate how VMN affected HMEs used in the ventilator circuit. In an in vitro study, a ventilator was used to ventilate a test lung with an HME placed at the end of the wye. VMN, jet nebulizer, or pressurized metered dose inhaler were used to deliver albuterol sulfate and placed between the HME and ETT. After six treatments were given, the increase in HME weight and resistance was measured. The results showed that after the treatments the weight of the HME increased by 25.75% with the VMN compared to 16.7% with the jet nebulizer. The VMN also showed a significant increase in resistance compared to the other aerosol generators. This study demonstrates how the increased aerosol particle generation of the VMN may lead to complications when using an HME.

HMEs Designed to Allow Aerosol Delivery (HME-AD)

Published information regarding the performance of HME-ADs is difficult to locate, however several abstracts were found pertaining to these devices. Branson and Johannigman (2004) studied the effects of a prototype HME-AD from Thayer Medical. The device had a lever that in the aerosol configuration allowed aerosol to be delivered through its center, and the HME configuration diverted the air through the HME portion of the device. Two groups were tested as described by ISO 9360 lung model for 24 hours; one group was given 0.5ml/5ml albuterol/saline every 2 hours for the duration and the second group received no albuterol. The authors found that when turned to the off position the moisture output was similar to currently available HMEs.

Resistance increased throughout the 24 hours, but there was no statistical significance between the HME-AD with or without albuterol.

The Circuvent made by DHD is another HME-AD device. When turned to the aerosol configuration this device allows a separate route for aerosol, bypassing the HME. Brady and Hess (2004) performed an in vitro test to determine how the HME-AD affects aerosol deposition. Their design used a mechanical ventilator to deliver tidal volume to a test lung in a circuit at 35°C with 100% relative humidity or a dry circuit. Albuterol was administered via pressurized metered dose inhaler while the HME-AD was in the aerosol configuration. The results showed that both the wet circuit and HME-AD significantly reduced aerosol delivery. Compared to a dry circuit without an HME, the HME-AD decreased aerosol deposition 40%. The authors concluded that if the HME-AD is used, medication should be doubled to deliver aerosol.

One criticism of the HME-ADs is that the operator may forget to turn the device to the HME configuration after an aerosol treatment, or may incompletely turn the device to the aerosol configuration for aerosol delivery. The Humid-Flo by Gibeck is an HME-AD that allows aerosol to pass through its center in the aerosol configuration, similar to the prototype device by Thayer. Badescu, Volsko, and Chatburn (2007) tested the effects of aerosol treatments through the HME-AD when the device was not completely placed in the aerosol configuration. The authors tested for the presence of PEEP_i and resistance after a double lung simulator being ventilated in assist control mode was given six aerosol treatments of normal saline. At the end of the study the authors did not detect PEEP_i nor change in resistance. The authors concluded that even when the device is not completely in the aerosol configuration, the HME-AD is safe and functional.

With a complete understanding of resistance through an HME, aerosol delivery in mechanical ventilation, and a survey of the early reports on HME-ADs, the effectiveness of

HME-ADs can be ascertained. The literature shows that addition of an HME to the mechanical ventilator circuit does cause an increase in airflow resistance, which is intensified by the addition of aerosolized medication. Further, aerosol deposition is compromised during mechanical ventilation. However, techniques such as using VMN, optimal aerosol generator position, and pausing humidifier during aerosol treatment can be used to improve this deposition. In order for HME-ADs to be practical, their addition must not significantly diminish the amount aerosol delivered to the lungs, and must not increase resistance through the HME.

CHAPTER III

METHODS

Instruments

Lung Model: As shown in Figure 1, the in-vitro lung model of this study consisted of a rubber test lung and cascade humidifier (Covidian-Puritan Bennett, Boulder, CO) set to deliver 37° C and 100% relative humidity which was verified via digital hygrometer/thermometer (Control Company, Friendswood, TX). The humidifier was attached to an 8.0 mm ID ETT via an anesthesia filter (Respirgard II filter model 303, Vital Signs, Inc., Totowa, NJ) connected to a ventilator (Phillips/Respironics, Murrysville, PA) through a standard ventilator circuit (Allegiance Healthcare Corporation, McGraw Park, IL).

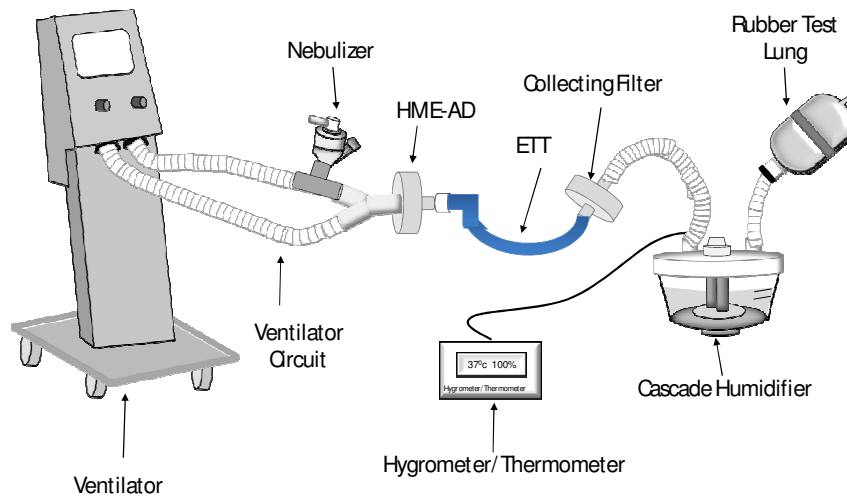


Figure 1. Diagram of lung model and ventilator setup

Ventilator Settings: Prior to each experiment the ventilator circuit and test lung were checked to ensure connection integrity and proper functionality. All calibration tests were passed successfully. The ventilator settings used during all experiments were as follows: tidal volume of 450 ml, respiratory rate of 20/min, peak inspiratory flow of 50 L/min, PEEP of 5 cm H₂O, I:E ratio of 1:2, and decelerating flow.

Study Variables: The independent variables of this study were the three HME-AD placed in the HME or aerosol configuration. Outcome variables include change in airway resistance and aerosol deposition distal to the ETT.

HME-AD: The three HME-ADs tested in this study include the Circuvent HME/HCH bypass (Smiths-Medical Keene, NH), Gibeck Humid-Flo™ HME (Hudson RCI, Arlington Heights, IL), and Airlife bypass HME (Carefusion, San Diego, California). Each HME-AD has two functional configurations: (1) aerosol (bypassing the HME) and (2) HME.

The Circuvent (Figure 2) requires placement of a standard HME. For this experiment, the Gibeck Humidvent Filter Light S (Hudson RCI, Arlington Heights, IL) was used. A ring on the body of the device controls the path the gas takes. Two symbols are located on the ring: an arrow and a ⊙ symbol. To allow aerosol delivery, the ring is twisted until clicked into place with the arrow pointing towards the tubing and the ⊙ lining up with the HME. This is the aerosol configuration, which directs air through tubing that bypasses the HME. To change to the HME configuration, the ring is twisted until clicking into place with arrow pointing towards the HME and ⊙ symbol lining up with the tubing. In this configuration, gas is directed through the HME.

The Humid-Flo (Figure 2) has a rotatable blue collar that changes the conformation of the HME-AD. To activate the aerosol configuration, the collar is rotated until “AEROSOL” is displayed in a white box with block letters which allows aerosol through the center passageway of the device while bypassing the HME element. The HME configuration is achieved by rotating the collar until a green box with “HME” is seen. This diverts the incoming gas through the HME. The collar should be completely rotated to ensure proper delivery of aerosolized medication or heated and humidified gas.

The Airlife bypass HME (Figure 2) has a lever that controls a gate managing the direction gas flows through the device. Pushing the lever down until it clicks in place and points toward the graphic of aerosol particles opens the gate and allows aerosolized medication to flow straight through the device. This is the aerosol configuration. When the lever is up and pointed toward the water droplet graphic the gate is closed and gas flows into the HME segment of the device, which is the HME configuration.



Figure 2. The HME-ADs. A: Circuvent HME/HCH bypass with Gibeck Humidvent Filter Light S inline. B: Humid-Flo HME. C: Airlife bypass HME.

Data Collection

Control: Albuterol (2.5 mg/3 mL) was delivered via VMN (Aerogen Solo, Aerogen Inc., Ireland) placed between the inspiratory limb and wye piece without HME-AD in the circuit (n=3). Aerosol deposition was measured at the end of each run.

HME-AD: Before testing each HME-AD the point which the HME became saturated was established by placing the HME-AD in the circuit in the HME configuration and measuring resistance every five minutes until the resistance stabilized and no further changes occurred. The Circuvent and Humid-Flo each had no further increase in resistance after 10 minutes in the humidified ventilator circuit. The Airlife required 20 minutes to plateau. Consequently, each HME-AD was placed in the circuit in the HME configuration and allowed to plateau according to these times prior to each test run.

For each experimental run, one HME-AD was placed in the circuit between the wye piece and ETT. A 90° elbow was placed between the HME-AD and ETT. HME-AD and collecting filter were positioned superior to the ETT using the natural bend of the ETT to maintain its inferior position. Aerosol was delivered in a total of three runs (n=3) with HME-AD in the HME and aerosol configurations. A new HME-AD was used in each run. Airway resistance and aerosol deposition were measured at the end of each run. This was repeated for each HME-AD.

Airway Resistance: Airway resistance was measured via the ventilator using the resident software to determine inspiratory resistance. The values recorded were taken from the resistance display on the ventilator monitor. Resistance was recorded prior to aerosol treatment and again at the conclusion of the treatment.

Aerosol Deposition: Albuterol (2.5 mg/3 mL) was placed in the VMN, which was placed between the inspiratory limb and the wye piece. Treatments were allowed to proceed until aerosol was no longer produced. After each treatment the anesthesia filter was removed from the circuit and soaked with 0.1 N HCl to elute the drug and analyzed via spectrophotometry. The spectrophotometer (Beckman Instruments, Fullerton, California) was calibrated prior to trials using holmium oxide filter (Beckman Instruments, Fullerton, California) to determine wavelength accuracy, and set to zero, using the solvent alone before each analysis. The percent of drug deposited was evaluated based upon the original dose.

Data Analysis

Data was analyzed using PASW (version 18.0). First, aerosol deposition between the aerosol and HME configurations of each HME-AD was compared with a series of student t-tests. Then, differences on aerosol deposition and airway resistance among the HME-ADs were analyzed using one way analysis of variance (ANOVA). Significance was determined as $p < 0.05$.

CHAPTER IV

RESULTS

Airway Resistance

The initial resistance through the HME-ADs in the HME configuration prior to saturation were as follows: Circuvent—8.62 cm H₂O/L/sec, Humid-Flo—8.6 cm H₂O/L/sec, and Airlife—7.71 cm H₂O/L/sec. The mean and standard deviation values attained before and after the experimental runs are shown in Table 1. Airway resistance significantly increased after the albuterol was administered in each case.

Table 1

Mean airway resistance (cm H₂O/L/sec) and standard deviation before and after albuterol treatment using Circuvent, Humid-Flo, and Airlife.

	Circuvent				Humid-Flo				Airlife			
	Aerosol		HME		Aerosol		HME		Aerosol		HME	
	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post
Mean	7.96	9.16	9.49	10.46	7.71	9.42	8.53	9.06	7.3	8.92	8.03	9.06
SD	0.15	0.27	0.07	0.12	0.06	0.14	0.07	0.02	0.29	0.39	0.14	0.19

Airway Resistance in the Aerosol Configuration: The results for airway resistance in the aerosol configuration are shown in Figure 3. Prior to aerosol administration, resistance was significantly different between Circuvent and Airlife (p=.009). There were no significant differences between Circuvent and Humid-Flo (p=.389), or Airlife and Humid-Flo (p=.096). After the albuterol treatment there were no statistically significant differences in resistance between any groups (p>0.05).

Mean Airway Resistance (cm H₂O/ L/ sec) in the Aerosol Configuration Prior to and After Albuterol Treatment

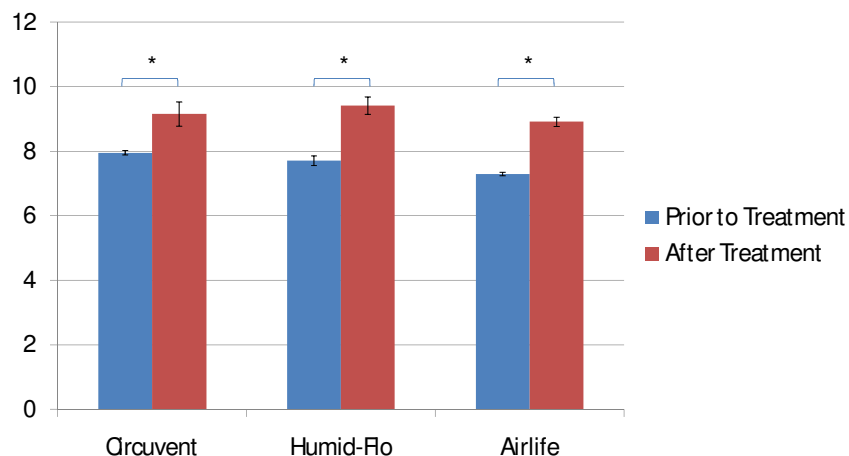


Figure 3. Airway resistance (cm H₂O/L/sec) in the aerosol configuration prior to and after aerosol administration. * indicates statistical significance ($p < 0.05$).

Airway Resistance in the HME Configuration: The results for airway resistance in the HME configuration are shown in Figure 4. Prior to albuterol treatment, the differences between each HME-AD were statistically significant. The Circuvent had the highest resistance with 9.49 ± 0.06 cm H₂O/L/sec, and the Airlife had the least resistance with 8.02 ± 0.13 cm H₂O/L/sec. Following the treatment, the Circuvent continued to give the highest airway resistance with 10.46 ± 0.11 cm H₂O/L/min. Resistance in the Airlife increased to 9.06 ± 0.19 cm H₂O/L/sec and the Humid-Flo increased to 9.06 ± 0.02 cm H₂O/L/sec following the treatment. These values were not statistically significant ($p = .999$).

Mean Airway Resistance (cm H₂O/ L/ sec) in the HME Configuration Prior to and After Albuterol Treatment

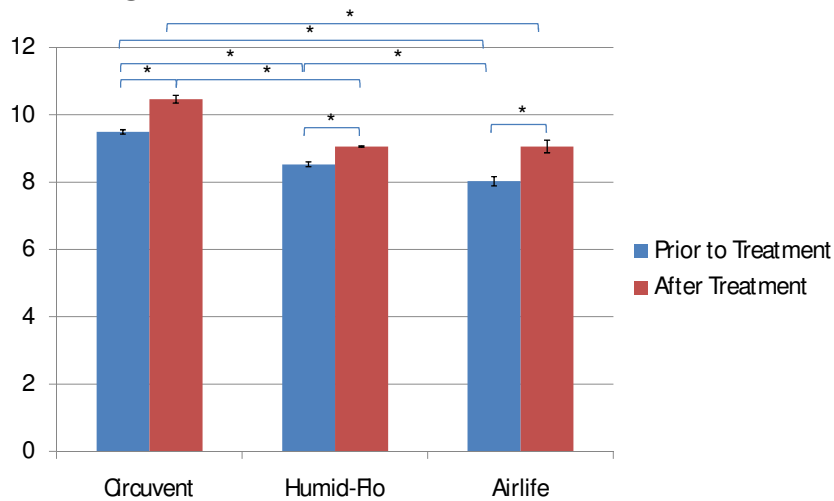


Figure 4. Mean airway resistance (cm H₂O/L/sec) in the HME configuration prior to and after albuterol treatment. * indicates statistical significance (p<0.05)

Aerosol Deposition

The percentages of mean and standard deviations attained for aerosol deposition after the experimental runs are presented in Table 2. Aerosol deposition was significantly different between the aerosol configuration and HME configuration in the Circuvent (p=.005) and Airlife (p=.002). In the Humid-Flo, there was no significant difference in aerosol deposition between the aerosol and HME configurations (p=.078).

Table 2

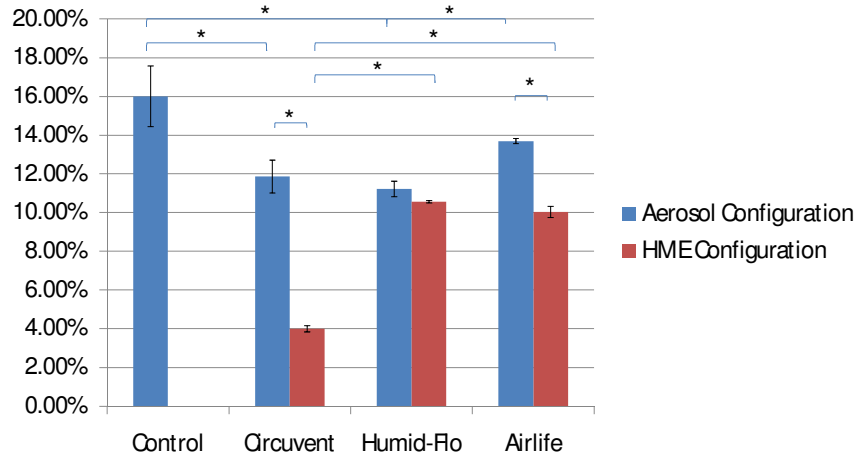
*Mean and standard deviations (SD) of inhaled drug mass percent in both aerosol and HME configurations using the Circuvent, Humid-Flo, and Airlife. *indicates statistical significance (p<0.05).*

	Control	Circuvent*		Humid-Flo		Airlife*	
		Aerosol	HME	Aerosol	HME	Aerosol	HME
Mean	16.00%	11.86%	4.00%	11.22%	10.56%	13.69%	10.03%
SD	1.57%	0.85%	0.16%	0.40%	0.06%	0.13%	0.29%

Aerosol Deposition in the Aerosol Configuration: Aerosol deposition in the aerosol configuration is shown in Figure 5. Control had the highest mean albuterol deposition at $16 \pm 1.57\%$ followed by the Airlife with $13.69 \pm 0.13\%$. The difference between control and Airlife was not significant ($p=.084$). Both Circuvent ($p=.004$) and Humid-Flo ($p=.002$) delivered significantly less aerosol compared to control. The differences among the HME-ADs were not significantly different ($p>0.05$).

Aerosol Deposition in the HME Configuration: Aerosol deposition in the HME configuration is shown in Figure 5. The Circuvent gave the least deposition with $4.00 \pm 0.16\%$. Airlife and Humid-Flo gave $10.03 \pm 0.29\%$ and $10.56 \pm 0.06\%$ respectively. The differences in aerosol deposition between HME-ADs in the HME configuration were all statistically significant.

Comparison of aerosol deposition between aerosol and HME configurations, using the Circuvent, Humid-Flo, and Airlife



*Figure 5. Comparison of aerosol deposition between aerosol and HME configurations, using the Circuvent, Humid-Flo, and Airlife. * indicates statistical significance ($p < 0.05$).*

CHAPTER V

DISCUSSION

Novel devices for allowing aerosol delivery while using an HME to heat and humidify the patient's airway are advantageous and may improve cost effectiveness. However, the clinician should be aware of the implications of these devices when used. Of particular importance is how these devices affect the aerosol deposition of the medication that is being delivered since it is paramount that the patient receives effective doses. The airway resistance is also important to consider ensuring PEEP_i and work of breathing are not increased. The purpose of this study was to determine the effects that three commercially available HME-ADs have on aerosol deposition and airway resistance. After running the tests and analysis of the data, it is noted the design of HME-ADs impact both airway resistance and aerosol deposition. The following discussion will analyze the observations made during the study, evaluate how this study compares with the available literature, and define the limitations of the study.

Observations

The most surprising finding of this study was aerosol deposition in the HME configuration. The amount of deposition in the HME configuration is a function of the ability of the HME to filter out aerosol particles. This was the case in the Circuvent where the HME configuration significantly reduced aerosol deposition to $4.0 \pm 0.16\%$. The use of a conventional HME had the effect of removing most of the aerosol particles. However, there was no significant difference between the aerosol and HME configurations for the Humid-Flo. Examining the Humid-Flo revealed relatively large holes visible in the HME portion of the

device. These holes are substantial enough to allow small aerosol particles, which would be most likely to enter the airway, to pass through the HME and allow similar aerosol deposition in both configurations. In the Airlife, deposition was significantly decreased but only by 3.66%, allowing $10.03 \pm 0.29\%$ deposition. This higher than expected deposition could be due to the size of the holes in the HME. Another explanation is that the area adjacent to the “gate” is not sealed, and allows aerosol particles to enter the ETT without passing through the HME portion of the device. Whatever the cause, the fact that aerosol particles are able to bypass the HME leads to the possibility that gas from the ventilator may also bypass the HME and give inadequate heat and humidity to the patient’s airway. The efficiency of the HME portion of these devices is beyond the scope of this study, but is a good topic for future research.

In the HME configuration prior to aerosol administration, each HME-AD had a significantly different airway resistance. This disparity is due to variations in the design of the HME within the devices. The Circuvent had the highest resistance. Since the Circuvent requires placement of a standalone HME, this resistance is more a function of the HME used (Gibeck Humidvent Filter Light S, Hudson RCI, Arlington Heights, IL) than a reflection of the Circuvent. After the aerosol treatment, the Circuvent again had a higher resistance, and the resistance through the Airlife and Humid-Flo were no longer statistically significant. One possible explanation is that the albuterol being delivered collected in the HME and caused increased resistance.

The highest deposition was seen in the control group. In the Airlife with the aerosol configuration, there was no significant difference in aerosol deposition compared to control, while the Humid-Flo and Circuvent had significantly less deposition. This change in deposition

is likely due to the design of these HME-ADs. In the Humid-Flo, the lumen is reduced by tabs in the center of the device used to direct gas, which increases aerosol impacting against the apparatus and reduces the amount of medication delivered to the airway. In the Circuvent, gas is redirected through a semicircular piece of corrugated tubing. This change in direction also leads to impaction. In the Airlife, the mechanism of switching to the aerosol configuration involves moving a “gate” out of the path of the gas. Therefore, little impaction is expected. The direct path allows for greater amounts of aerosol particles to enter the ETT and gives similar deposition compared to control.

Implications

Based on the evidence, the Airlife gives the highest aerosol deposition, which was not significantly different from the control. Further, airway resistance associated with the Airlife was the lowest before treatment in both configurations. However, after one treatment in the HME configuration, its resistance was similar to the Humid-Flo. This increase may become substantial after more treatments are delivered in this configuration. The resistance of the Circuvent is largely influenced by the HME used. Choosing an HME with lower resistance would be advisable for all patients, especially those with a potential for air trapping and difficulty weaning from mechanical ventilation. These experiments show that resistance is not increased by delivering aerosol to the patient in the HME configuration compared to the aerosol configuration. Therefore, a caregiver forgetting to turn the device to the aerosol configuration will not increase airway resistance.

The fact that the albuterol delivered to the airway was not affected by configuration in the Humid-Flo and only affected minimally in the Airlife is noteworthy. It appears that these

devices are always in a semi-bypass configuration. Thus, if a healthcare provider forgot to switch the device configuration prior to delivering an albuterol treatment, the patient would still receive the drug. The similar airway resistance and lack of variation of aerosol deposition between the aerosol and HME configurations raises the question of the effectiveness of the HME portion of the devices. If the HME portion is effective, then the aerosol configuration may not be necessary with the Humid-Flo or Airlife.

Cost is important for hospitals considering using these devices in their facility. The suggested retail prices per unit are as follows: Circuvent—\$6.00, Humid-Flo—\$10.14, and Airlife—\$6.04. These prices indicate the Circuvent is the cheapest. However, the Circuvent also requires an external HME. In this experiment, the Gibeck Humidvent Filter Light S was utilized. The list price of this HME is \$7.04, which brings the total cost of using the Circuvent to \$13.04. However, less expensive HMEs are available. Some HMEs cost as little as \$2.05. With this price, the total cost of the Circuvent is less than the Humid-Flo. Nevertheless, the Airlife is still the least expensive HME-AD and most cost-efficient assuming it provides adequate heat and humidity.

Comparisons with Literature

Since there was only a limited number of articles on HME-ADs available in the literature, only two studies will be used for comparison. First, Brady and Hess tested the Circuvent using the aerosol configuration in 2004. Their study found that when using a pressurized metered dose inhaler, aerosol was reduced 40% from control. In this study, the Circuvent reduced aerosol deposition by 26% compared to control, and overall the HME-ADs reduced aerosol deposition by 15-30% compared to control. The higher numbers found in this experiment were due to the

use of VMN, which has a greater efficiency. Badescu, et al. (2007) found that during aerosol delivery with the Humid-Flo incompletely turned to the aerosol configuration the resistance did not increase significantly. Similarly, in this study after one treatment with albuterol, the resistance did not increase further than control in the Humid-Flo or any of the HME-ADs.

Limitations

This study had four limitations. First, this was an in-vitro study. While our study used a homogenous test lung, human subjects would have heterogeneous lungs with varying lung mechanics. Second, only one albuterol treatment was given per HME-AD. Clinically, these devices are used for 24 hours or longer and patients would generally receive albuterol treatments every four hours. Thus, the HME-AD would have more aerosol passing through it than tested, which could lead to increases in resistance beyond what was found in this study. Third, no assessment was made to determine the effectiveness of the HME portion of the HME-ADs for providing adequate temperature and humidification, this would be critical to determine how the partial bypass of the HME impacts primary function. Finally, only one type of aerosol generator was used in this study. The VMN was chosen based on its low residual volume and high percent of dose nebulized and previous reports associating that output volume with changes of resistance with the HME. However, jet nebulizers and pressurized metered dose inhalers are more prevalent clinically. Therefore, data on aerosol deposition and airway resistance with these devices would be relevant.

These limitations elicit questions for response at a later time. Does an in-vivo model affect airway resistance and aerosol differently than the in-vitro model used? Do airway resistance and aerosol deposition change as subsequent albuterol treatments are given? How

effective are HME-ADs at providing heat and humidity during mechanical ventilation? How are airway resistance and aerosol deposition affected when different types of aerosol generators are used?

Conclusions

Aerosol delivery and airway resistance with each HME-AD differ in simulated mechanically ventilated patients. The design and composition is responsible for the variation in resistance and aerosol deposition. The best choice is an HME-AD that allows for the greatest aerosol deposition with the least increase in airway resistance, while providing the best humidification of the airway. Further studies are needed to determine the effectiveness of these devices over time and with different aerosol generating devices.

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