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THE EFFECT OF DIFFERENT INTERFACES ON AEROSOL DELIVERY IN SIMULATED SPONTANEOUSLY BREATHING ADULT WITH TRACHEOSTOMY

Prospective Laboratory Study (Bench Study)

By

Alaa Ahmed Bugis

A Thesis

Presented in Partial Fulfillment of Requirements for the

Degree of

Master of Science

in

Health Sciences

in

The Division of Respiratory Therapy

in

The College of Health and Human Sciences

Georgia State University

Atlanta, Georgia

2010

ACCEPTANCE

This thesis, THE EFFECT OF DIFFERENT INTERFACES ON AEROSOL DELIVERY IN SIMULATED SPONTANEOUSLY BREATHING ADULT WITH TRACHEOSTOMY, by Alaa Ahmed Bugis 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.

_____
Arzu Ari, Ph.D., RRT, CPFT, PT
Committee Chair

_____
Robert Harwood, MSA, RRT
Committee Member

_____
Lynda T. Goodfellow, Ed.D. RRT, FAARC
Committee Member

_____
Date

AUTHOR'S STATEMENT

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Alaa Ahmed Bugis

Local Address:

7043 Tyler Lane

Indianapolis, IN 46217

Other Address:

3004 Clearview Cir.

Houston, TX 77025

The director of this thesis is:

Arzu Ari, Ph.D., RRT, CPFT, PT

College of Health and Human Sciences

Georgia State University

Atlanta,

Georgia 30303-3083

VITA

Alaa Ahmed Bugis

Address: Local Address:

7043 Tyler Lane

Indianapolis, IN 46217

Other Address:

3004 Clearview Cir.

Houston, TX 77025

EDUCATION:

B.S. 2005 King Faisal University, Dammam, Saudi Arabia
Respiratory Care

PROFESSIONAL EXPERIENCE:

October 2007 – present: Faculty Member
King Saud Bin Abdul-Aziz University for Health Science, Riyadh, Saudi Arabia

September 2005 – August 2007: Respiratory Therapist I (ICU therapist)
King Fahad National Guard Hospital / King Abdul-Aziz Medical City

PROFESSIONAL SOCIETIES AND ORGANIZATIONS:

March 2010 – Present American Association for Respiratory Care

ABSTRACT

THE EFFECT OF DIFFERENT INTERFACES ON AEROSOL DELIVERY IN SIMULATED SPONTANEOUSLY BREATHING ADULT WITH TRACHEOSTOMY

By

Alaa Bugis, BSRC

Background: The delivery of an aerosol via a tracheostomy tube has been previously described with both a tracheostomy collar and a T-piece, but not with a Wright mask, or aerosol mask. The primary purpose of this study was to quantify lung doses using different interfaces: tracheostomy collar, Wright mask, and aerosol mask. The secondary purposes were to compare albuterol delivery between an opened vs. a closed fenestration hole and also to determine the effect of inspiratory time:expiratory time (I:E) ratio on aerosol delivery.

Methods: A teaching mannequin (Medical Plastic Labs, Gatesville, TX) with a tracheostomy opening was used. Two of the mannequin's bronchi were connected to a "Y" adaptor, which was attached to a collecting filter (Respirgard ™ II 303, Vital Signs, Englewood, CO), which was connected to a breathing simulator (Harvard Apparatus Dual Phase Control Respirator Pump, Holliston, MA) through a corrugated tube. Settings for spontaneous breathing were respiratory rate 20/min, and tidal volume 400 mL. The I:E ratios were adjusted in the first and second comparisons at 2:1 and 1:2, respectively. The nebulizer was operated by a flow meter (Timemeter, St. Louis, MO) at 8 L/min with 100% oxygen. In every condition, the flow was discontinued at the end of nebulization. The nebulizer was attached to the tracheostomy collar (AirLife™, Cardinal Health, McGaw Park, IL) in the first group, the Wright mask (Wright Solutions LLC, Marathon, FL) in the second group, and the aerosol mask (AirLife™, Cardinal Health, McGaw, IL) in the third group. Drug was eluted from the filter and analyzed by spectrophotometry (276 nm).

Data Analysis: Paired *t*-test, one-way analysis of variance (ANOVA), repeated measures ANOVA, post-hoc and pairwise comparisons were performed at the significance level of .05, using PASW version 18.0.

Results: Aerosol delivery was greater with the tracheostomy collar than the Wright mask and aerosol mask ($p < .05$). Closing the fenestration hole increased aerosol deposition significantly at 2:1 ratio ($p = .04$) compared to opening the fenestration at 1:2 ratio. I:E ratio and aerosol delivery were directly related. Increasing I:E ratio from 1:2 to 2:1 improved aerosol delivery significantly with tracheostomy collar-fenestration opened ($p = .009$), Wright mask ($p = .02$) and aerosol mask ($p = .01$).

Conclusion: This study indicates that the use of a tracheostomy collar is the best method of delivering aerosol therapy among the three interfaces. The I:E ratio of 2:1 caused greater aerosol deposition than 1:2 ratio. The aerosol deposition was better when the fenestration hole was closed compared with opened fenestration.

ACKNOWLEDGEMENTS

I would like to thank the Division of Respiratory Therapy at Georgia State University for allowing me to use their laboratory instruments while conducting a research for this thesis. Special thanks go to Dr. Arzu Ari and Mr. Robert Harwood for their patience, guidance, and suggestions during the writing of this thesis and during the research meetings. I would also like to thank Dr. James Fink for his wisdom during the setup and running of the experiment. I especially want to thank Dr. Lynda Goodfellow for reviewing this thesis and her advice in an early phase of this thesis. You have all made this a great experience for me.

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Abbreviations

ANOVA = One-Way Analysis of Variance

CLD = Chronic Lung Disease

COPD = Chronic Obstructive Pulmonary Disease

ETT = Endotracheal Tube

f = Respiratory Rate

FIO_2 = The Fraction of Inspired Oxygen

GV = Gas Ventilation

I:E = Inspiratory time to Expiratory time Ratio

ID = Internal Diameter

ICP = Intracranial pressure

ICU = Intensive Care Unit

MAP = Mean Airway Pressure

$PaCO_2$ = Partial Pressure of Carbon Dioxide in Arterial Blood

PASW = Predictive Analysis Software

PaO_2 = Partial Pressure of Oxygen in Arterial Blood

PEEP = Positive End-Expiratory Pressure

pH = Hydrogen Ion Concentration

PIP = Peak Inspiratory Pressure

PLV = Partial Liquid Ventilation

pMDI = Pressurized Metered Dose Inhalers

Vt = Tidal Volume

CHAPTER I

INTRODUCTION

In the United States, 16,000,000 people have chronic obstructive pulmonary disease (COPD). Every year, there are 120,000 deaths from COPD, making it the fourth highest cause of death (Johnson, 2007). Patients with acute or chronic respiratory failure are usually patients who have COPD or asthma. Those patients may require prolonged respiratory care and mechanical ventilation through endotracheal tubes (ETTs) or tracheostomy tubes. Tracheostomy is usually suggested if intubation is planned to last longer than several weeks. In a patient requiring more than 14 days of ventilatory support, a tracheostomy procedure is recommended within the first 2 days of intubation. It has been stated that if a tracheostomy performed in the first 2 days rather than after Day 14, it will markedly reduce the number of ventilator and intensive care unit days, and decrease both the incidence of pneumonia and overall mortality (Pierson, 2005).

There are many potential benefits of tracheostomy use such as the ability to communicate, the possibility for oral feeding, safe nursing care, and improving a patient's comfort. In addition, using tracheostomy tubes will result in lesser need for sedation and lower resistance, compared to endotracheal intubation. In turn, this will lead to a shorter hospital stay in the intensive care unit and will facilitate a more successful recovery. It has been speculated that the use of tracheostomies might decrease ventilator-associated pneumonia by preventing micro aspiration of secretions, help in the weaning process by reducing dead space and airway resistance, and improve secretion clearance (Durbin, Perkins, & Moores, 2010). The improved secretion clearance with the use of tracheostomy tubes helps in making patients more

comfortable, requiring less sedation, and reducing the likelihood of aspiration through enhanced glottic function.

The treatment of asthma patients includes the use of inhaled long-acting β-agonists and corticosteroids. The treatment of COPD patients includes the use of inhaled long-acting anticholinergic and long-acting β-agonists, which are available in dry powder aerosol form and created for oral deep inhalation. However, the delivery devices for long-acting β-agonists and long-acting anticholinergics are not designed for patients with artificial airways. A gas-powered jet nebulizer is commonly used to deliver aerosol medications. The aerosol reaches patients' airways through a mouthpiece or an aerosol mask. In a review by Hess (2000) it was stated that there was no significant difference in clinical response has been found between the mouthpiece and the aerosol mask. Moreover, delivering albuterol medication via tracheostomy tube is affected by humidification, bias gas flow, and interface. One study conducted by Piccuito and Hess (2005) concluded that the use of a T-piece resulted in more albuterol delivery as compared to a tracheostomy collar ($p = .001$). Moreover, the most effective delivery involved the nebulizer attached to the tracheostomy tube without additional gas flow ($p < .001$).

A Wright mask has been recently developed for humidification purposes for patients with tracheostomies. It consists of both a tracheostomy collar and an aerosol mask. No published articles on the Wright mask have been found in a literature search. However, in the web site on the Wright mask (www.wrighttrachsolutions.com/Abstracts) there is an abstract by Carvalho et al. (2010) that evaluated the efficacy and feasibility of the Wright mask. The abstract concluded that there are no large differences noted in blood oxygen saturation, comfort, ease of use, or ease of breathing in patients with tracheostomies used the Wright mask compared to both the tracheostomy collar and the aerosol mask.

The Importance of the Study

This study is important because the tracheostomy tube has not been very well studied. No studies have been found regarding aerosol delivery with tracheostomy collar, Wright mask, and aerosol mask all together. It is important to examine the Wright mask because it may be used with patients even though its use has not yet been studied. Also, the effect of I:E ratio and fenestration hole on aerosol delivery need to be investigated in order to provide guidance to clinicians on how to administer aerosol therapy.

Study Purposes

The delivery of aerosol therapy via a tracheostomy tube has been described with both a tracheostomy collar and a T-piece (Piccuito & Hess, 2005), but not a Wright mask or an aerosol mask. The primary purpose of this study was to quantify lung dose using different interfaces: tracheostomy collar, Wright mask, and aerosol mask. The secondary purpose was to compare albuterol delivery between an opened vs. a closed fenestration hole and also to determine the effect of inspiratory time to expiratory time **(**I:E**)** ratio on aerosol delivery.

Research Questions

Upon review of the literature, three important research questions arose:

1. What is the amount of albuterol delivered to the lungs with different interfaces using an open fenestration hole of the tracheostomy tube?
2. How much albuterol is delivered using a tracheostomy collar, while the fenestration hole is opened and closed?

3. What is the effect of I:E ratio on aerosol delivery in simulated spontaneously breathing adults with tracheostomy?

CHAPTER II

REVIEW OF LITERATURE

A literature review was performed using terms related to aerosol therapy through tracheostomy tubes. The I:E ratio was also searched. The databases used were Medline, PubMed, Science Direct, and Web of Science through both the Georgia State University and the Northeastern University libraries. From an exhaustive search, the research questions were formulated to investigate how aerosol administration changes through interfaces when I:E ratio and fenestration hole are manipulated.

Tracheostomy

Epstein (2005) indicated that the trachea was used as an easy entryway to the airways at the bedside. It provided an inlet for urgent airway cannulation in the case of acute upper airway obstruction. In addition, it provided an inlet for chronic airway access after laryngeal surgery. Tracheostomy tubes, in general, were used to allow the discontinuation of ETTs. Most of the studies indicated that the tracheostomy tube reduced both airflow resistance and work of breathing when compared to ETTs. Tracheostomy tubes differ from ETTs because they have a portable inner cannula that can be easily removed for cleaning. In addition, the tracheostomy tube has a fenestration hole that can be closed to provide proper mechanical ventilatory support. Tracheostomy tubes have important benefits in improving weaning success.

Pierson (2005) reported in a review paper that using tracheostomy tubes might facilitate weaning from ventilatory support. There were many reasons mentioned why tracheostomy tubes can improve the weaning process: (1) A tracheostomy tube can decrease airway resistance; (2) it reduces the extrathoracic dead space; (3) it enhances clearance of secretions from patients'

airways; (4) it decreases need for sedation; (5) it lowers the risk of aspiration; and (6) it also decreases the work of breathing compared to a translaryngeal ETT with the same internal diameter. The difference in dead space between a tracheostomy tube and an ETT is very low. However, the literature reviewed from laboratory experiments, short-term physiologic studies on clinically stable patients, and evidence from clinical trials indicates that airway resistance and anatomic dead space are reduced with tracheostomy tubes. The researcher reported that one clinical trial showed that there was no benefit to early tracheotomy. He also reported that in a recent clinical trial, investigators found that percutaneous dilational tracheotomy performed in the first 2 days of ventilatory support dramatically (1) reduced ventilator and intensive care unit days; (2) lowered the incidence of pneumonia; and (3) decreased mortality rate, when compared with tracheostomy performed after the Day 14. Tracheotomy tubes helped liberating patients from ventilatory support. However, clinician bias as well as physiologic effects may affect this conclusion.

Adoga and Ma'an (2010) investigated the indications and outcomes of pediatric tracheostomy in pediatric patients in a Nigerian teaching hospital. In addition, they wanted to know if there was a change in the trend of the environment compared to other centers. Historically, the most common indication for use of tracheostomy in children was acute inflammatory airway obstruction. Nowadays, the most common indication to use tracheostomy in children is prolonged intubation. The study was a retrospective chart review of 46 patients. There were 29 males and 17 females with ages ranging from 2 months to 15 years. All the 46 patients had their tracheostomy procedures done between January 2000 and December 2008 and were presented to their otorhinolaryngological facility. Most of the patients who had a tracheostomy (69.6%) were of ages ranging from 6 to 10 years old. Forty tracheostomies (87%)

were performed as emergencies while six (13%) were performed as elective procedures. The most common indication for tracheostomy was upper airway obstruction (*n* = 29, 63%) such as respiratory papilloma (*n* = 20). All the cases employed transverse skin incision. There were no intra-operative complications recorded. However, the postoperative complication rate was 15.2%. The duration of tracheostomy ranged from 5 days to 3 months. All patients were successfully decannulated. There were eight mortalities (17%). However, there was no tracheostomy-related mortality. Researchers concluded that there is no increase in the incidence of tracheostomy in patients less than 1 year of age. The percentage of tracheostomy procedures performed on patients aged less than 5 years old was 21.7%. The group that had the fewest tracheostomy procedures was within the age range of 11 to 15 years and the percentage was 8.7%. Their conclusion was that pediatric tracheostomy is safe when performed in a tertiary hospital setting.

Spontaneous Breathing and Tracheostomy

O'Callaghan et al. (1989) presented a case report of 2 ½-year-old girl with a tracheostomy who was diagnosed with asthma disease. Investigators tested a modified volumatic spacer device to deliver beclomethasone diproprionate, ipratropium bromide, and salbutamol aerosols to the child. A volumatic spacer device was prescribed into which both bronchodilator and prophylactic agents could be activated. The inhalation port of the volumatic spacer was modified by a series of tubes, connected with the tracheostomy tube, giving an airtight seal. On inhalation, the valve in the spacer device opened, allowing the aerosol to be inhaled. On expiration, the valve closed and air was dispelled though small holes near the inhalation port. The spacer device resulted in a dramatic improvement in symptoms, and marked reduction in the time spent inhaling the drugs. The advantages of this modified spacer device were several; (1) The modified spacer is easy to

use; (2) time required for taking therapy decreased from several hours to 15–20 minutes per dose daily; (3) the tracheostomy tube needed to be changed less frequently, from every day to weekly; and (4) the modified spacer had the ability to administer adequate doses of inhaled steroids and bronchodilators to improve asthma control.

Meeker and Stelmach (1992) reported that the spacer device helped ensure consistent delivery of medications to the bronchial tree. They also indicated that it minimizes the oropharyngeal deposition of pressurized metered dose inhaler (pMDI) medication. Inhaled corticosteroid is available only in pMDI form. Inhaling corticosteroids by a spacer can minimize its side effects. However, patients with artificial airways such AirIon and Jackson tracheostomy tubes, and patients with hand limitations such as patients with severe arthritis, hand weakness, and those with very small hands may be unable to successfully activate the inhaler. Meeker and Stelmach described several modifications to help this population receive their aerosol therapy effectively. They adapted spacer devices that required few simple modifications of the standard pMDI spacer to use them in a patient with a tracheostomy. They used standard Shiley, Portex, or Communitrach 15-mm adaptors, and Kamen-Wilkens on tracheostomy tube. The Aero Chamber with a mask or InspirEase Bag consisted of soft pliable silicone that easily conformed to the patient's neck. The technique of using this spacer was to apply gentle pressure by placing one hand on the mask at the stoma site while the other hand activates the pMDI. It was also adapted to fit an indwelling tracheostomy tube. The researchers mentioned that patients with hand limitations may benefit from the use of an arthritic aid (VentEase, Glaxo) which can be inserted into an Aero Chamber thereby allowing the use of a spacer device in this population. This Aero Chamber with mask simplified the delivery of pMDI medications in patients with an open stoma.

Subhedar et al. (1999) reported a study of four cases of infants with chronic lung disease (CLD). Those patients had tracheostomy procedures because of subglottic stenosis. The tracheostomy was performed due to the degree of upper airway compromise, which resulted in a failure of extubation. The other reason for performing a tracheostomy was due to further narrowing that occurred with a concurrent infection of the upper respiratory tract. The purpose of their report was to highlight the feasibility of delivering supplemental oxygen and the administration of inhaled medications in such patients. Three of the patients received supplemental oxygen. The oxygen therapy was administered via a nasal cannula attached to open tracheostomy tube and stabilized by taping the tubing to each side of the back of patient's neck. Two of the patients received nebulized bronchodilators. The nebulizer was held over the tracheostomy tube opening, and patients were breathing normally. All four patients received bronchodilator therapy, and two received inhaled steroids. Aerosol inhalers administered via aerosol spacer device were directly attached to the tracheostomy tube. This report did not mention information about the deposition of aerosol medications. However, it indicates the importance of giving advice to patients on how to administer aerosol therapy. As we studied the effect of I:E ratio on aerosol therapy, we will give advice to patients on how to inhale aerosol therapy for better outcomes. The researchers concluded that therapists and parents who provided inhaled therapy and supplemental oxygen to children with CLD who have tracheostomy should be advised and trained of administering such therapy before discharge from a hospital.

Piccuito and Hess (2005) investigated whether albuterol delivery through a tracheostomy tube is affected by the type of patient interface (T-piece vs. mask), aerosol delivery method (pMDI vs. nebulizer), humidification of the inspired gas, and bias flow. A dual-chambered lung model was used to stimulate a patient's spontaneous breathing with a lift bar placed between the

chambers. The settings they used were a respiratory rate of 20 breaths/min, tidal volume of 400 mL, and I:E ratio of 1:2. A cuffed tracheostomy tube with an inner diameter of 8 mm was placed through a semicircular model that simulated a patient's neck. In the aerosol nebulizer experiments, four combinations of humidification and gas flow were used as follows: (1) Heated humidity generated using a Concha-Therm. The oxygen outlet flow was around 30 L/min. The heat of the humidifier was set to provide a gas temperature at the proximal airway of approximately 30 °C with relative humidity greater than 95%; (2) heated aerosol generated using a heater and nebulizer. A flow meter was adjusted to power oxygen gas flow of approximately 30 L/min. The gas temperature measured at the proximal tracheostomy tube was about 30 °C and the relative humidity was greater than 95%; (3) high flow without additional humidification (around 30 L/min); and (4) a tracheostomy tube without additional flow that was attached to a nebulizer. The aerosol nebulizer device was filled with 4 mL of 2.5 mg albuterol medication, and operated at a flow rate of 8 L/min. The nebulizer was tested with a tracheostomy collar and a T-piece. An aerosol spacer device was used for the pMDI experiments and actuation of the inhaler (100 µg/ actuation) was synchronized with inhalation. Four actuations were delivered separated by more than 15 seconds. A T-piece valve was used with a one-way valve attached either distally or close to the aerosol spacer device without the use of additional flow. A filter was placed between the distal end of the tracheostomy tube and the lung model. The filter was washed to measure the amount of albuterol detected by ultraviolet spectrophotometer. The most efficient aerosol delivery method was with the use of the pMDI with a T-piece valve and attachment of a one-way valve placed in the proximal position ($p < .001$). In the nebulizer experiments, the most efficient delivery method was with no flow other than to power the nebulizer with a T-piece ($p < .001$). This study had five major findings: (1) there was a delivered amount of albuterol aerosol

through a tracheostomy tube with the use of a nebulizer and also with the use of a pMDI; (2) it was inefficient to deliver albuterol using high gas flow with the nebulizer; (3) the T-piece was more efficient in delivering albuterol than the tracheostomy mask; (4) the pMDI with valved holding chamber was more efficient than the nebulizer; and (5) the pMDI was more efficient when a T-piece was placed close to the spacer device than when placed in the distal position. They concluded that albuterol delivery through the tracheostomy tube was affected by the patient's interface, delivery method, and bias gas flow.

Lin et al. (2007) measured the albuterol delivery of a jet nebulizer in three different pediatric face masks and at three different distances from the face. There were three face masks included a standard pediatric face mask, a proprietary pediatric face mask shaped to resemble a dragon face, and a proprietary pediatric face mask shaped to resemble a fish face. Researchers used an infant mannequin face connected to a lung simulator to stimulate a spontaneously breathing patient. The inhaled aerosol mass was measured with the face masks at distances of 0 cm where the face mask placed directly to the model at 1 cm and 2 cm. For every experiment, the nebulizer cup was filled with 3 mL of albuterol sulfate and generated by a flow of 8 L/min of oxygen gas. A 5-minute nebulization time was set for each test. They measured inhaled mass by collecting the aerosol on a 2-way anesthesia filter that was attached to the back of the mannequin’s oral opening via a 15-mm silicon adapter. They also measured the remaining amount of drug left in the nebulizer cup and estimated the wasted drug lost to the atmosphere. The mean inhaled values of the nominal dose percentage at 0 cm, 1 cm, and 2 cm were as follows: In the standard face mask, 2.18 %, 1.45 %, and .92 %, respectively. In the dragon face mask, 2.65 %, 1.7 %, and 1.3 %, respectively. In the fish face mask, 3.67 %, 2.92 %, and 2.26 %, respectively. Statistically, among the three face mask experiments there was a significant

difference in delivering aerosol between the 0 cm and 2 cm distance ($p < .001$). The highest inhaled mass of albuterol significance was for the fish face mask ($p < .001$) among all three distances. When the mask was further separated from the face, the inhaled mass was significantly reduced. The study concluded that the face mask design affected the inhaled mass delivered in pediatric patients.

Johnson (2007) studied aerosolized drugs delivered through a tracheostomy tube. He recruited 23 patients in his study. The study assessed the clinical ease vs. the clinical difficulty of aerosol delivery. He designed interface to connect an Aerolizer and a HandiHaler to a trachestomy tube. The study indicated that aerosol therapies were readily delivered to all patients. Nineteen of the 23 patients (83%) were able to take the treatment on their own. A bag-assist was successfully used in the four patients who were unable to take the treatment effectively on their own. Johnson also indicated that the aerosol delivery time was less than 3 minutes. It was concluded that aerosol therapy can be easily delivered through a tracheostomy tube if the proper interface is used.

Keck et al. (2008) compared inhalation with molecular water (vaporizing humidifier) and particulate water (trachea spray) in patients with tracheostomies who were breathing spontaneously. In their study, they used a randomized two-way crossover study design and a prospective, comparative, nonblinded study. They measured the temperature and tracheal humidity before and after the use of the tracheal spray and the vaporizing humidifier for 1 week. They found that after both spray and inhalation, tracheal temperature and total water content increased significantly. The temperature gradient between tracheal air and ambient was significantly higher after spray compared to after inhalation. The water gradient after spray and inhalation increased nonsignificantly. The water gradient after spray or inhalation did not differ

significantly. The study concluded that molecular water was not superior to particulate water because humidity and temperature increased after both forms of water delivery. A tracheal spray may offer additional benefits in postoperative tracheostomy care for its ease of use, portability, and moisturizing effect.

Mechanical Ventilation and Tracheostomy

Fuller et al. (1994) performed a study to compare aerosol administrations in ventilated patients. The researchers used four different devices: (1) a 167 mL cylindrical chamber 10.5 × 4.5 cm; (2) a 700 mL cylindrical chamber 11 × 9 cm; (3) a non-chamber device that allowed pMDI attachment to the inspiratory line of the ventilator circuit; and (4) a non-chamber device that allowed pMDI attachment directly into the ETT or tracheostomy tube. For their study, they recruited 48 patients who were mechanically ventilated. Subjects were given four puffs of fenoterol labeled with technetium 99m pertechnetate via a metered-dose inhaler. At the bedside, a portable gamma camera was used to identify images of the thorax. The study showed that the deposition of radioactivity in the lungs was 5.53 ± .72, 6.33 ± 1.16, 1.67 ± .43, and 3.89 ± .52 percent for devices (1), (2), (3), and (4), respectively. The researchers did not specify whether these data were obtained with ETTs or tracheostomy tubes. There was a statistically significant difference in delivery only between devices (1) and (3) and between devices (2) and (3) (p = .004). In addition, they found a statistically significant difference between inhalation from both chamber devices and the inline non-chamber device, but not between inhalation of other devices. The study concluded that a non-chamber device significantly provided smaller amounts of aerosol from the pMDI to the lung than a chamber device in the inspiratory ventilator line similarly positioned.

O'Riordan et al. (1994) characterized factors that may affect aerosol delivery such as nebulizer device, drug volume, humidity, and ventilator settings. The researchers also characterized technical factors that may affect deposition loads such as radio-labeled compounds. They designed a study to evaluate nebulized aerosol delivery to ventilated patients in optimal situations. Seven patients were recrutied for this study. All patients were mechanically ventilated through a tracheostomy tube. The humidifier was not operated. For aerosol experiments, researchers used a saline solution labeled with 99mTechnetium bound to human serum albumin 99mTc-HSA. They administered it via a jet nebulizer that was joined into the ventilator circuit. The flow was discontinued at the end of nebulization. A mass balance/filter method was used to calculate the inhaled and deposited radioactivity. A gamma camera scanner was used to verify the distribution areas of the deposited radioactivity before and after the tracheostomy tube removal. The measured radioactivity at each site was expressed in a percentage of nebulizer charge. The results showed that the ventilated patients inhaled an average of 30.6 %. In addition, the mean deposition in the tracheostomy tube during inspiration was 2.6 %.

Palmer et al. (1998) conducted a study to determine whether aerosolized antibiotics can be delivered effectively to the lower respiratory tract in mechanically ventilated patients and to identify possible clinical reactions to these agents. Six patients were recruited with tracheostomy tubes. The patients received nine doses of nebulized therapy of gentamicin (80 mg) or amikacin (400 mg) every eight hours for 14 to 21 days. The researchers measured the doses to the lung using antibiotic concentrations and radio-labeled aerosols in airway secretions. The response was assessed by (1) changes in the volume of airway secretions, (2) effect on bacterial cultures, and (3) changes in the inflammatory cells and mediators of inflammation of the airway secretions.

The study concluded that inhaling nebulized aminoglycoside was efficient. Therefore, aerosolized antibiotics can make a significant impact on airway secretions.

Shorten et al. (2000) conducted a study to determine the effectiveness and safety of salbutamol delivered via a metered dose inhaler to intubated rabbits. The research was performed on five groups of rabbits. The first three groups had tracheal intubation through a tracheostomy and received five puffs of 99mTcO4 salbutamol. Group (1) inhaled the drug at elbow connector. Group (2) inhaled the drug through a catheter with its distal tip placed at the midpoint. Group (3) inhaled the drug at the bevel of the ETT. Rabbits in Group (4) were not exposed to any interactions. Group (5) had tracheal intubation through the mouth and received five puffs of salbutamol inhaled at the bevel of the ETT. Delivery efficiency was expressed as the ratio of radioactivity from the trachea and lungs to the total radioactivity of the delivered dose. Histopathologic injury scores were assigned to each lung specimen or trachea. Results showed that the delivery efficiency was 30 times greater with the full catheter in Groups (3) and (5) than the elbow in Group (1). The study concluded that the increased efficiency acquired by the administration of metered dose salbutamol at the distal tip of the ETT was not necessarily related with increased epithelial injury.

Smaldone (2004) reported that antibiotic drugs in the form of aerosols were very useful in intensive care. A human model was created of trachea-bronchitis in intubated patients. The model provided daily specimens of respiratory secretions, allowing serial investigations of airway inflammation and testing of different therapy modes. The local infection was determined by a unique method of measured sputum specimen. Laboratory models were invented to explain the factors that restrict aerosol delivery to intubated patients. Those models facilitated clinical experiments that determined the possible indications for targeted aerosol treatment to patients at

risk for lower respiratory disease. It was found that when inhaling antibiotic drugs via nebulizers, the drug levels in pulmonary secretions exceed by several doses when compared to the levels expected with intravenous administrations.

Dhand (2004) reported that among aerosol devices such as nebulizers, dry powder inhalers, and metered-dose inhalers, only nebulizers and metered-dose inhalers are typically used for aerosol delivery to patients on mechanical ventilators. Previously, the artificial airway and ventilator circuit were thought to be serious obstacles to deliver aerosols effectively to patients on mechanical ventilators. In the past decade, in vivo and in vitro investigations assisted good understanding of the complex array of factors that affected inhaled drug delivery in mechanically ventilated patients. Many investigators have shown that, with careful attention to aerosol delivery technique, the effectiveness in patients on mechanical ventilators is proportional to that in ambulatory patients.

Inspiratory to Expiratory (I:E) Ratio

Few references discussed the I:E ratio. For that reason the following articles are reviewed although they are not strongly related to this study.

Boros (1979) studied the relationship of I:E ratio to optimum oxygenation and ventilation. Twelve neonates who had severe lung disease were recruited. Subjects were mechanically ventilated with volume-preset infant ventilators using different I:E ratios and different airway pressure waves. The ventilator settings of fraction of inspired oxygen (FIO_2), tidal volume (Vt), respiratory rate , and positive end expiratory pressure (PEEP) remained constant. The I:E ratios were increased by reducing inspiratory flow rate or holding the inspiratory time. For each I:E ratio and pressure wave combination, the researcher measured and

compared the mean airway pressure (MAP), peak inspiratory pressure (PIP), hydrogen ion concentration (pH), partial pressure of oxygen in arterial blood (PaO_2), partial pressure of carbon dioxide in arterial blood ($PaCO_2$), and blood pressure. The study indicated that there was a direct relationship between oxygenation and mean airway pressure. The mean airway pressure can change with any change in I:E ratio, PEEP, or airway pressure wave. The study concluded that an I:E ratio and pressure wave combination helped optimize oxygenation, ventilation, and mean airway pressure.

Stewart et al. (1981) assessed the effects of changing ventilator parameters on blood gases, intracranial pressure (ICP), and MAP. Researchers recruited 20 neonates with respiratory failure which required mechanical ventilation. The study involved random changes in I:E ratio, PEEP, and PIP. The MAP, PaO_2, ICP, and end-tidal PCO_2 were observed continuously. The study showed a significant relationship between MAP and PaO_2. The mean change in PaO_2/MAP was 4.92 torr. The change of PaO_2/MAP was highest for changes in PEEP ($p < .001$), followed by PIP ($p < .001$), and I:E ratio ($p < .05$), respectively. The association between changes in PIP and PEEP vs. $PaCO_2$ and PH was significant. Decreases in PIP and increases in PEEP resulted in an increase in $PaCO_2$ and a reduction in pH. In addition, increases in PIP and decreases in PEEP resulted in a reduction in $PaCO_2$ and an increase in pH. There was no significant association between ICP and MAP. However, there was a significant relationship between changed ICP and $PaCO_2$ during changes in PIP ($p < .001$). This study concluded that increases in PEEP led to elevations in PaO_2 per change in MAP, followed by elevations in PIP and I:E ratio.

Lim et al. (1999) investigated whether extending the I:E ratio of the mechanical ventilator would decrease the heterogeneity of regional ventilation and enhance gas exchange to a greater degree than in gas ventilation (GV). Researchers inducted 18 rabbits with acute lung injury by

saline solution lavage. Three I:E ratios were used in gas ventilation and then in partial liquid ventilation (PLV). I:E ratios were changed either by modifying pause (1:2, 1:1, and 2:1; Group 1) or by modifying inspiratory flow rate (1:3, 1:1, and 2:1; Group 2). With increasing I:E ratio in all subjects, $PaCO_2$ decreased significantly (74 mmHg, 66 mmHg, and 66 mm Hg; $p = .006$), PaO_2 increased significantly (80 mmHg, 143 mmHg, and 147 mm Hg; $p = .001$). The change of PaO_2 by changing the I:E ratio was 49 % in PLV and 14 % in GV ($p = .003$). Lim et al concluded that increasing the I:E ratio by adding pause enhanced gas exchange in partial liquid ventilation. The researchers also concluded that the I:E ratio had a greater effect in the oxygenation of partial liquid ventilation than in gas ventilation. This article is related to the present study via the I:E ratios 1:2 and 2:1.

After reviewing the literature, tracheostomy tubes have important benefits in improving weaning success. Aerosol therapy can be easily inhaled through a tracheostomy tube if the proper interface is used. When inhaling antibiotic drugs via nebulizers, the drug levels in pulmonary secretions exceed by several doses when compared to the levels expected with intravenous administrations. Albuterol delivery through the tracheostomy tube was affected by the patient's interface, delivery method, and bias gas flow. In delivering albuterol, the T-piece was more efficient than the tracheostomy mask, the pMDI with valved holding chamber was more efficient than the nebulizer and the pMDI was more efficient in delivering albuterol when a T-piece was placed close to the spacer device than when placed in the distal position. Moreover, I:E ratio and pressure wave combination helped optimize oxygenation, ventilation, and mean airway pressure. The I:E ratio had a greater effect in the oxygenation of partial liquid ventilation than in gas ventilation.

CHAPTER III

METHODS

This is in vitro study. It consisted of three main interfaces, the tracheostomy collar, the Wright mask and aerosol mask. In all interfaces, two I:E ratios of 1:2 and 2:1 were used. The tracheostomy collar was tested with both opened and closed fenestration of the tracheostomy tube. This chapter explained the methodology used to answer the following questions:

1. What is the amount of albuterol delivered to the lungs with different interfaces using an open fenestration hole of the tracheostomy tube?
2. How much albuterol is delivered using a tracheostomy collar, while the fenestration hole is opened and closed?
3. What is the effect of I:E ratio on aerosol delivery in simulated spontaneously breathing adults with tracheostomy?

Experimental Setup

As shown in Figure 1 a teaching mannequin (Medical Plastic Labs, Gatesville, TX) with a tracheostomy opening was used. Two of the mannequin's bronchi were connected to a "Y" adaptor, which was attached to a collecting filter (Respirgard ™ II 303, Vital Signs, Englewood, CO), which was connected to an inhalation port of a breathing simulator (Harvard Apparatus Dual Phase Control Respirator Pump, Holliston, MA) through a corrugated tube.

The breathing parameters of this study included f 20/min, and Vt 400 mL (Piccuito & Hess, 2005). The I:E ratios were adjusted in the first and second comparisons at 2:1 and 1:2, respectively. The nebulizer was operated by a flow meter (Timemeter, St. Louis, MO) at 8 L/min

with 100% oxygen. In every condition, the flow was discontinued at the end of nebulization. The jet nebulizer was attached to the tracheostomy collar in the first group, the Wright mask in the second group, and the aerosol mask in the third group.

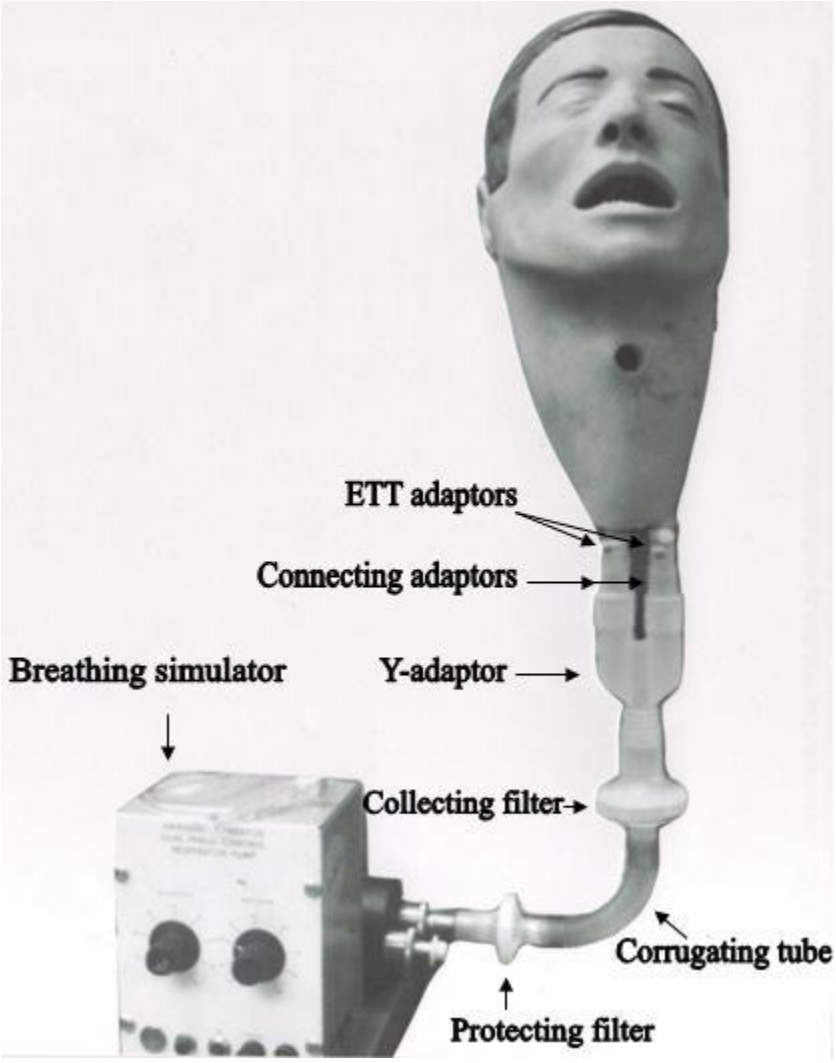

Figure 1. The experimental setup of the study.

Interfaces

As shown in Figure 2, the interfaces used in this study included a tracheostomy collar (AirLife™, Cardinal Health, McGaw Park, IL), a Wright mask (Wright Solutions LLC,

Marathon, FL), and an aerosol mask (AirLife™, Cardinal Health, McGaw Park, IL). A adult fenestrated tracheostomy tube (Shiley™, Mallinckrodt Medical Inc, Boulder, CO), size 8 mm, was placed into the mannequin's stoma. The cuff was always deflated. Each interface was tested in triplicate (*n* = 3), using I:E ratios of 1:2 and 2:1.

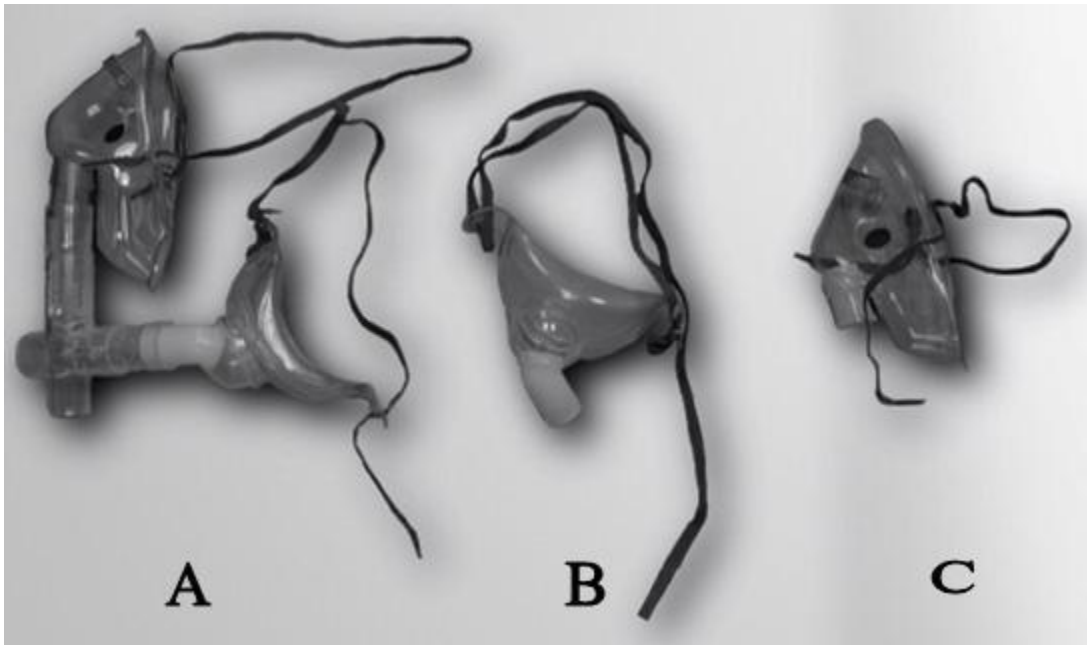

Figure 2. The different interfaces of the study: (A) Wright mask, (B) Tracheostomy collar, and (C) Aerosol mask.

Data Collection

While the Wright mask and the aerosol mask were tested with an opened fenestration hole, the tracheostomy collar was tested with the fenestration hole opened and closed. Each interface was tested in triplicate (n=3). A jet nebulizer (eValueMed, Tri-anim, Sylmar, CA) aerosolized 2.5 mg / 3 mL of albuterol sulfate (Dey Pharma Inc, Napa, CA) in each experiment. After eluting the collecting filter with 0.1% HCl, the filter was shaken for 3 minutes to ensure proper mixing. The absorption of the solution washed from the filter was measured with a

spectrophotometer (DC Series 500, Beckman Instruments, Fullerton, CA) at a wavelength of 276 nm using a 1-mL quartz cuvette. A total of 24 experiments were conducted and the same protocol was followed for each experiment. The testing system was checked for correct interface, I:E ratio, and condition of the fenestration hole before testing.

Data Analysis

The amount of aerosol deposited on the filter was quantified as a percentage of the emitted dose. The descriptive statistics including the mean and standard deviations were calculated for each condition tested in this study. Paired *t*-tests were conducted to evaluate differences in the mean inhaled presence of dose delivered by the jet nebulizer between two I:E ratios. One-Way Analysis of Variance (ANOVA) and Scheffe post-hoc multiple comparison were utilized to determine differences among the means for tracheostomy collar, Wright mask, and aerosol mask. Repeated measure ANOVA and Pairwise comparison were utilized to determine differences among the means between two fenestration holes. All data analysis was prepared using predictive analysis software (PASW, version 18.0), and statistical significance was defined as $p < .05$.

The research methods were directed by the study questions; what is the amount of albuterol delivered to the lungs with different interfaces using an open fenestration hole of the tracheostomy tube? how much albuterol is delivered using a tracheostomy collar, while the fenestration hole is opened and closed? and what is the effect of I:E ratio on aerosol delivery in simulated spontaneously breathing adults with tracheostomy? Three different interfaces, tracheostomy collar, Wright mask and aerosol mask were used. A Harvard Dual breathing simulator was used. The PASW, version 18.0 helped to control data analysis.

CHAPTER IV

RESULTS

This study compared tracheostomy collar, Wright mask, and aerosol mask with one another to quantify the amount of aerosol delivery to a patient with tracheostomy receiving those types of interfaces. Differences were considered statistically significant when $p < .05$. The questions that were answered in this section include the following:

What is the amount of albuterol delivered to the lung with different interfaces using an opened fenestration hole of the tracheostomy tube?

With an open fenestration hole the amounts of albuterol delivered to the lung with tracheostomy collar, Wright mask, and aerosol mask with 1:2 ratio were 6.98 ± .80 %, 4.08 ± .56 %, and 3.46 ± .04 %, respectively. The amounts of albuterol delivered to the lung with tracheostomy collar, Wright mask, and aerosol mask with 2:1 ratio were 11.57 ± 1.38 %, 7.15 ± .55 %, and 6.11 ± .46 %, respectively. There was a significant statistical difference between groups ($p = .001$). As shown in Figure 3 the highest deposition was with the tracheostomy collar, while the lowest deposition was with the aerosol mask.

How much albuterol is delivered using a tracheostomy collar, while the fenestration hole is opened or closed?

The results of opened fenestration were answered in the previous question. The amount of albuterol delivered while fenestration closed with 1:2 ratio was 9.37 ± 1.45 % compared to 12.44 ± 1.38 % with 2:1 ratio. There was a significant statistical difference between the fenestration closed with 2:1 ratio vs. fenestration opened with 1:2 ratio ($p = .04$). As shown in Figure 3 the deposition was higher with closed fenestration.

What is the effect of I:E ratio on aerosol delivery in simulated spontaneously breathing adults with tracheostomy?

In all groups, the total deposition was higher with 2:1 ratio 8.28 ± 2.63 % compared with 1:2 ratio 4.84 ± 1.69 %. In all opened fenestration experiments, there were significant statistical differences between 1:2 ratio vs. 2:1 ratio ($p < .05$). However, with closed fenestration in the tracheostomy collar group there was no significant statistical difference between 1:2 vs. 2:1 ratios ($p = .18$); see Figure 3. The longer the inspiratory time, the greater the amount of aerosol deposition.

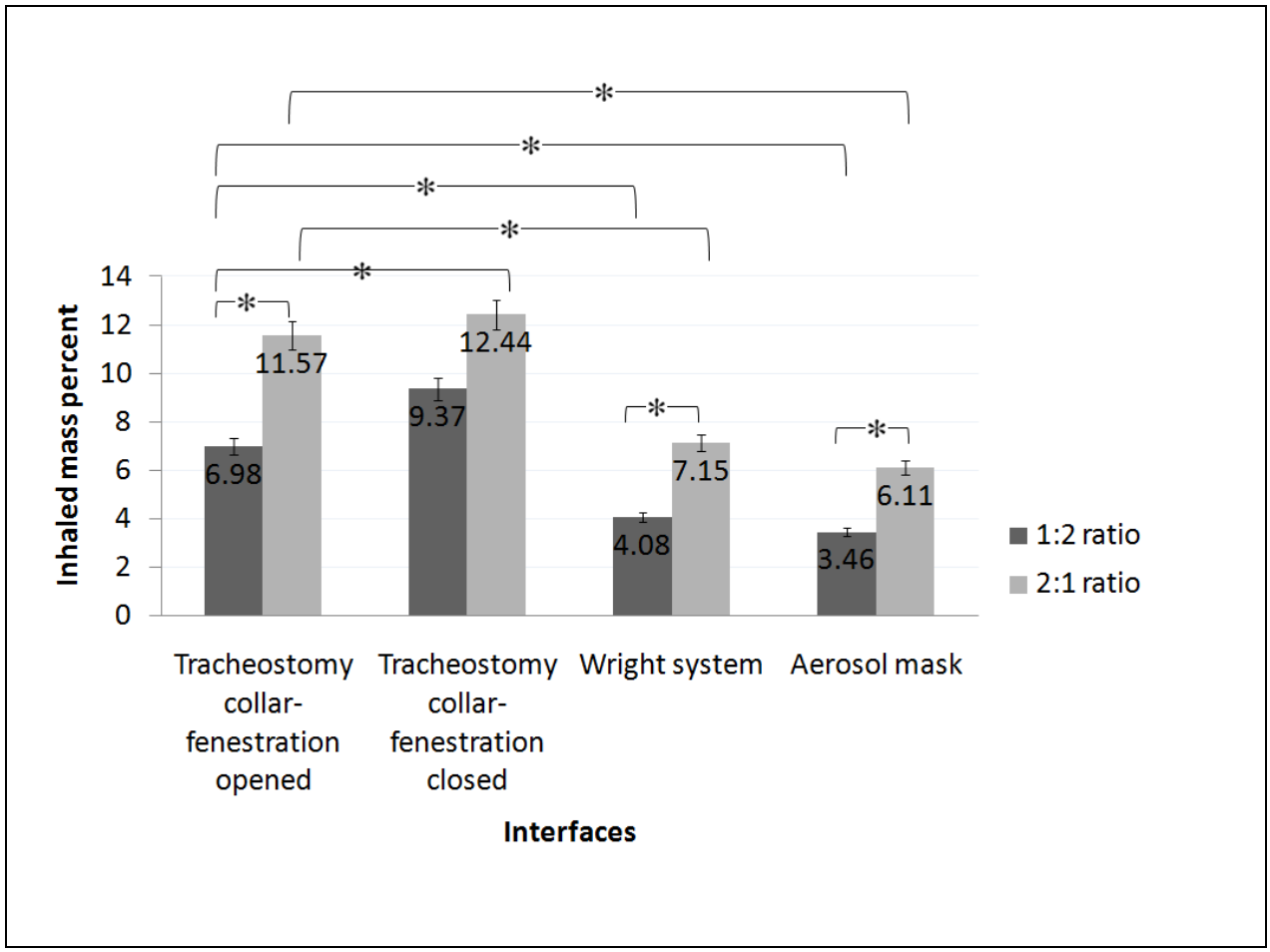

Figure 3. Inhaled mass percents among different interfaces at 1:2 and 2:1 ratios. (*) denotes $p < .05$.

In all cases, aerosol delivery was greater with the tracheostomy collar than the Wright mask and aerosol mask ($p < .05$). Closing the fenestration hole with the tracheostomy collar increased aerosol deposition significantly at 2:1 ratio compared to opening the fenestration hole with 1:2 ratio ($p = .04$). I:E ratio and aerosol delivery were directly related. Increasing I:E ratio from 1:2 to 2:1 improved aerosol delivery significantly in all opened fenestration experiments ($p < .05$).

CHAPTER V

DISCUSSION

The main purpose of this study was to investigate aerosol delivery with the Wright mask and compare it to aerosol delivery with the tracheostomy collar and aerosol mask at different I:E ratios. As answering the research questions: What is the amount of albuterol delivered to the lungs with different interfaces using an open fenestration hole of the tracheostomy tube? How much albuterol is delivered using a tracheostomy collar, while the fenestration hole is opened and closed? What is the effect of I:E ratio on aerosol delivery in simulated spontaneously breathing adults with tracheostomy? The study revealed that there is a significant amount of aerosol deposition when using jet nebulizer with tracheostomy collar when compared to the Wright mask and aerosol mask. The following discussion will look more closely at observations noted during the study and how this study was compared with the literature. It will also look at the clinical implications of the study, limitations of this study, and future studies needed.

OBSERVATIONS

Interfaces.

The results show greater delivery via tracheostomy collar than with the Wright mask and aerosol mask. The amount of albuterol delivered was significantly lower with the aerosol mask and the Wright mask. This was presumably the result of aerosol wasted into the air and in the upper airways above the stoma. When using the Wright mask and aerosol mask, aerosol travels through the nose, mouth and extrathoracic airways, which causes part of the aerosol delivered to be deposited before it reaches the collecting filter, thus reducing the effectiveness of aerosol

delivered with the Wright mask and the aerosol mask. It was not surprising that more aerosol particles were delivered with the tracheostomy collar when compared to all other interfaces in this study. It was observed that when the fenestration hole closed during the tracheostomy collar experiments, aerosol particles were forced to deposit in the lower airways. It was also observed that using a tracheostomy collar reduced the amount of drug wasted to the atmosphere. Moreover, using a tracheostomy collar caused aerosol particles to travel shorter distances to reach the collecting filter when compared to the Wright mask and the aerosol mask. In addition, it was observed that during the expiratory phase there were more aerosol particles exiting from the tracheostomy compared to the mouth and nose.

The Wright mask interface deposition results were lower than the tracheostomy collar interface deposition results. The initial expectation was that there would be greater deposition, especially when compared to the tracheostomy collar and aerosol mask interfaces. This was because the Wright mask has both a tracheostomy collar and an aerosol mask integrated in its design. Carvalho et al. (2010) evaluated the feasibility of the Wright mask and its efficacy with humidity. They concluded that there were no big differences noted in blood oxygen saturation, comfort, ease of use, or ease of breathing with the Wright mask compared to the tracheostomy collar and aerosol mask.

The result of the tracheostomy collar and fenestration closed at 1:2 ratio 9.37 ± 1.45 % is different than the result by Piccito and Hess (2005) when they compared tracheostomy collar vs. T-piece useing a non fenestrated tracheostomy tube at 1:2 ratio 12.9 ± 1.3 %. The diffrence between the results of the two studies stems from the fact that the experimental models were different. In addition, in this study, the cuff was deflated at all times allowing some aerosol particles to deposit in the upper airways. In addition, the Wright mask results indicated that there

were no big differences in aerosol depositions compared to the aerosol mask. It was also indicated that the Wright mask was less efficient compared to the tracheostomy collar. Therefore, the results of this study matches the results presented by Carvalho et al (2010). Carvalho and his colleagues indicated that the Wright mask did not have a big difference in the efficiency and feasibility when compared to the tracheostomy collar and aerosol mask.

I:E ratios.

The I:E ratio of 2:1 lead to more aerosol deposition in this study than that for 1:2. The difference in the amount of deposition between these I:E ratios can be explained by the breathing pattern and the respiratory phase in which the medication was delivered. With I:E ratio of 2:1, the inspiratory time is longer than it is with 1:2, which allows for more time to inhale the aerosolized drug, thus, causing more aerosol deposition in the lungs. In all fenestrated opened experiments, the amount of aerosolized albuterol deposition was affected significantly by the I:E ratio. These results matched the results by Lim et al. (1999) which indicate that increasing the I:E ratio by adding pause improved gas exchange in PLV. Oxygenation in PLV was affected by the I:E ratio to a greater degree than in gas ventilation.

Fenestration Hole.

In this study, aerosol deposition obtained from the tracheostomy tube while the fenestration closed was larger when compared to the open fenestration hole. The difference in the amount of deposition between fenestration opened and fenestration closed can be explained by the fact that aerosol was forced to go toward the collecting filter when the fenestration hole was closed. However, when the fenestration hole was opened some of the aerosol was leaking out of the hole and deposited up into the mouth and nose. This indicates that the pathway through

which medication was delivered affected the amount of aerosolized albuterol deposited significantly. This was confirmed by comparing the amount of aerosol deposition between fenestration closed with 2:1 ratio vs. fenestration opened with 1:2 ratio. The amount of aerosol deposited was greater with closed fenestration as compared to opened fenestration. This confirms that whether opened or closed the fenestration hole has a major impact on the aerosol deposition for the reasons mentioned earlier. This fact makes it logical that delivering aerosol therapy via tracheostomy collar will have the most aerosol deposition, which was the case in this study. During the expiration phase, it was noticed that aerosol was exiting from the stoma. Aerosol therapy administration using a tracheostomy collar with an I:E ratio of 2:1 and closed fenestration hole had the highest results, showing a greater delivery via tracheostomy collar than with the Wright mask and aerosol mask.

The anatomic dead space of a tracheostomy tube ID 7.5 mm is between 5 and 6 mL (Pierson, 2005). One study in cadavers determined the anatomic dead space of the extrathoracic airways (not including the trachea and main bronchi) to be roughly 75 mL (Nunn, Campbell, & Peckett, 1959). This is more than the dead space measured with tracheostomy tubes. Therefore, a tracheostomy tube reduces anatomic dead space. Thus, the amount of aerosol therapy delivered via tracheostomy collar is expected to be greater when compared with the Wright mask and the aerosol mask due to the reduced dead space. A review by Epstein (2005) stated that tracheostomy tubes can decrease dead space by 100 mL, when compared to a spontaneously breathing patient. In addition, when the fenestration hole is closed, aerosol mists are forced to go to the lungs; thus they will not be lost in the extrathoracic dead space including the nose and mouth. The previous discussion proves that among the three interfaces investigated in this study,

aerosol delivery with a tracheostomy collar with an I;E ratio of 2:1and closed fenestration had the highest aerosol deposition in the filter.

Clinical Implications

Based on this study, three important recommendations can be given to clinicians to achieve a better outcome when administering aerosolized Medications. First, use a tracheostomy collar whenever is possible to administering aerosolized medications. Second, close the fenestration hole during aerosol administration. Third, instruct the patient to inhale the aerosolized medication slowly and instruct them to hold their breath for seconds after inspiration.

Limitations

Because this experiment was an in vitro bench study, the results should be subjected to clinical validation. Different patients' breathing patterns may be seen in vivo. In addition, a homogenous breathing simulator was used. Human test subjects would show heterogeneous breathing patterns and different lung conditions. This investigation did not study the effect of different breathing patterns. The parameters were the same in all experiments. This study was conducted on only one type and size of tracheostomy tube.

Future Studies

The effect of changing the respiratory setting should be explored to determine how aerosol delivery would be affected in different patients' conditions, different diseases, and different ventilatory managements. Different I:E ratios should be explored further to help patients in relieving their symptoms and to provide guidance to clinicians on how to administer aerosol therapy. In addition, different types and sizes of tracheostomy tubes should be studied in

order to help other patients with different sizes or different types of tracheostomy tubes such as pediatrics tracheostomy tubes.

Conclusion

This study indicates that the use of a tracheostomy collar is the best method of delivering aerosol therapy when compared with the Wright mask and aerosol mask. The I:E ratio of 2:1 caused greater aerosol deposition when compared to I:E ratio of 1:2. The aerosol deposition was better when the fenestration hole was closed compared with opened fenestration using the tracheostomy collar.

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