2013

The effects of oral vs nasal intubation on endotracheal tube complications in cardiac patients

BOSTON UNIVERSITY

SCHOOL OF MEDICINE

Thesis

THE EFFECTS OF ORAL VS NASAL INTUBATION ON ENDOTRACHEAL TUBE COMPLICATIONS IN CARDIAC PATIENTS

by

DANIEL S. CHOI

B.A, Dartmouth College, 2011

Submitted in partial fulfillment of the

requirements for the degree of

Master of Arts

2013

Approved by

First Reader ____________________________________

Phillip J. Stone, Ph.D.
Professor of Biochemistry

Second Reader ____________________________________

Annette Y. Schure, M.D.
Associate in Cardiac Anesthesia
Boston Children's Hospital

ACKNOWLEDGEMENTS

I would like to thank Dr. Phillip Stone for agreeing to be my first reader and for always supporting me during the past two years as my MAMS program advisor. I would also like to thank Dr. Annette Schure for allowing me to work with her on this research project and for being my second reader. I would not have been able to complete this thesis without Dr. Schure's guidance and mentorship. Additionally, I would also like to thank Izabela Gasior, Justine Bode, Rachel Dabek and Vanessa Young for providing me with the opportunity to work at Boston Children's Hospital under the Anesthesia Clinical Research Unit. They have been amazing mentors and supervisors in every step of this project. Finally, I would like to thank Kevin Bullock and David Zurakowski for all their help with the data collection and statistical analysis, respectively. I would not have been able to gather the correct information and discover or interpret important results without their insight.

THE EFFECTS OF ORAL VS NASAL INTUBATION ON ENDOTRACHEAL TUBE COMPLICATIONS IN CARDIAC PATIENTS

DANIEL S. CHOI

Boston University School of Medicine, 2013

Major Professor: Phillip J. Stone, Ph.D. Professor of Biochemistry

ABSTRACT

Objective: To test the hypothesis that nasal endotracheal tubes are more secure and associated with fewer complications than oral endotracheal tubes. This involves establishing the incidence of specific endotracheal tube complications between cardiac patients who are intubated via the oral and nasal route. In addition, a secondary objective is to identify specific risk groups that could benefit from a change in practice or implementation of guidelines.

Design: A retrospective chart review of 100 patients who were admitted to the Pediatric Cardiac Intensive Care Unit with an endotracheal tube in place was performed. Patients involved in this preliminary study were selected from a larger patient population admitted to Boston Children's Hospital during the fiscal year of 2011 (October 1, 2010 through September 30, 2011). Variables that were collected include: gender, type of mechanical ventilation, reasons for admission, RACHS-1 scores, outcome of respiratory support, age and weight of patients, duration of ventilation, reason for ventilation, cuffed vs. un-cuffed ETT, size of

ETT, initial tube depth, route of intubation, location of intubation, duration of ventilation, CICU and hospital length of stay, and inotropic scores. The specific complications that were analyzed were: inadequate ETT positioning or securing with the need for re-adjustment, accidental or unplanned extubations, device related pressure ulcers and skin breakdown, and feeding problems related to dysphagia. The Z-test was used to determine if the difference in rate of complications between cardiac patients who were orally intubated and cardiac patients who were nasally intubated was statistically significant. The Fisher's Exact test was also used to confirm the z-test since the sample size was relatively small. Finally, a multi-variable regression with select variables was performed to observe possible confounding factors. The Fisher's Exact test and Mann-Whitney U-test were used to determine which covariates would be included in the multivariable regression.

Results: There were 67 patients in the oral ETT group and 33 patients in the nasal ETT group. 17 out of 67 or 25% of the oral ETT patients experienced complications, whereas 6 out of 33 or 18% of the nasal ETT patients experienced complications. The difference between the two proportions was 7%, and the Z-test revealed the p value to be 0.2107 and 0.4214 for the two-tail test. Both p values were > 0.05; therefore, the null hypothesis could not be rejected. The Fisher's Exact test revealed that the 2X2 contingency table, made from the two treatment groups and outcomes, had a p value of 0.4621. This also confirmed that the null hypothesis could not be rejected. Overall, the incidence rate of any complication was 23 out of 100 or 23%. Mann-Whitney U tests and Fisher's Exact tests were performed on critical variables including gender, age, weight, RACHS-1 score, total CMV hours, maximum inotropic score, and cuffed vs uncuffed ETT. Results showed that only four of those variables – age, weight, CMV hours, and inotropic score – had p values < 0.05. These four variables, along with the route of intubation, were used as the covariates for the multivariate logistic regression with respect to ETT complications as the outcome. The regression revealed that only higher inotropic scores and age could be associated with a higher risk for complications. Inotropic score had a p value of 0.009 and age had a p value of 0.025; both were < 0.05. Weight, CMV hours, and ETT route had p values of 0.92, 0.93, 0.77, respectively.

Conclusions: Our hypothesis that cardiac patients with nasal ETT's have statistically lower complication rates than cardiac patients with oral ETT's could not be proven to be correct. The observed proportion difference between the two groups may be due to chance. However, our results revealed several other variables that may be associated with increased risks of ETT complications. A continuation of this preliminary study is being performed to include a much larger group of patients in order to gain more conclusive data on both the oral and nasal ETT groups and other important covariates.

TABLE OF CONTENTS

Title	i
Reader's Approval Page	ii
Acknowledgements	iii
Abstract	iv
Table of Contents	vii
List of Tables	viii
List of Figures	ix
List of Abbreviations	x
Introduction	1
Objectives	24
Specific Aims	25
Methods	26
Results	29
Discussion	36
List of Journal Abbreviations	42
References	43
Vita	48

LIST OF TABLES

Table	Title	Page
1	Individual procedures by risk category	21
2	VIS equation	23
3	Fisher’s Exact test contingency table	30
4	Comparison of oral vs nasal ETT groups	31
5	Comparison of patient with and without complications	33
6	Regression model for ETT complications	34
7	Additional regression model for ETT complications	35

LIST OF FIGURES

Figure	Title	Page
1	Artificial Ventilation in the ICU	3
2	Endotracheal Intubation	5
3	Endotracheal Tube	9
4	Scar tissue on the upper lip	15
5	Nasotracheal Intubation	18

ABBREVIATIONS

AB	Age-Based
ACRU	Anesthesia Clinical Research Unit
BRT	Broselow Pediatric Resuscitation Tape
CATH LAB	Catheterization Laboratory
BCH	Boston Children’s Hospital
CICU	Cardiac intensive Care Unit
CMV	Continuous Mandatory Ventilation
CO2	Carbon dioxide
EP	Electro-Physiology lab
ETT	Endotracheal Tube
OR	Operating Room
PEEP	Positive End-Expiratory Pressure
PO	Per Os
RACHS -1	Risk Adjustment for Congenital Heart Surgery 1
TEE	Transesophageal Echocardiogram
VIS	Vasoactive-Inotropic Score

INTRODUCTION

Patients in the Pediatric Cardiac Intensive Care Unit

The patients selected for this retrospective study were mainly diagnosed with and treated for various types of heart diseases. Patients with congenital and acquired heart diseases require complex surgeries or procedures and appropriate intensive care towards recovery (Jenkins, Gauvreau, Newburger, Spray, Moller, & Iezzoni, 2002; Varma, 2011). At Boston Children's Hospital, this specific patient population receives specialized support in the pediatric cardiac intensive care unit. While most of the patients are children, there are also occasionally adults and older patients admitted to the pediatric CICU at BCH for continual and long-term treatment of congenital heart diseases (Boston Children's Hospital, 2011).

The main role of this CICU is to maintain respiratory and cardiovascular physiology, neurological activity, and function of other organ systems in cardiac patients in order to improve their outcomes (Boston Children's Hospital, 2011). With respect to this support, one important device used in the CICU (and OR) is artificial ventilation (Boston Children's Hospital, 2011). Artificial ventilation, or mechanical ventilation, delivers high levels of oxygen – in adjustable amounts and frequencies - to patients who are otherwise unable to breathe on their own due to illness or general anesthesia (American Thoracic Society, 2005; National Heart Lung and Blood Institute, 2011). These devices can also help patients exhale CO2 and prevent their alveoli from collapsing by providing positive pressure ventilation via PEEP in their lungs (American Thoracic Society, 2005). In conjunction with other instruments such as the blood pressure cuff and pulse oximeter, artificial ventilation also helps physicians monitor patients' vital signs regarding cardiovascular and respiratory physiology.

Although there are various types of artificial ventilation for different conditions, they all need to be connected to the patient's airway, mainly through an endotracheal tube (Boston Children's Hospital, 2011; Schiffman, & Stoppler, 2007). Thus, the endotracheal tube serves as an essential tool that maintains a patent airway, and allows patients to breathe artificially in the OR and during postoperative recovery (Schiffman, & Stoppler, 2007). Additionally, the ETT allows physicians to administer medications and anesthesia, view the upper respiratory tract, and suction fluids and mucus when necessary (American Thoracic Society, 2005; MedlinePlus, 2013). The setup of the ventilator and ETT is shown in figure 1.

With regards to this study, patients with congenital heart defects or diseases have several different indications for endotracheal intubation (Chang, Hanley, Wernovsky, & Wessel, 1998). Some patients may arrive to BCH already intubated in order to prevent respiratory complications during transport between facilities; others may require airway protection and positive pressure ventilation after cardiorespiratory arrest, pulmonary edema (to decrease the workload on the lungs), or left ventricular dysfunction (Chang et al., 1998). Still, many patients who require surgeries or procedures undergo general anesthesia, which may disrupt regular breathing; they are intubated in the OR or CATH LAB and then slowly weaned off the artificial ventilator as they recover in the CICU (American Thoracic Society, 2005; National Heart Lung and Blood Institute, 2011; Schiffman, & Stoppler, 2007).

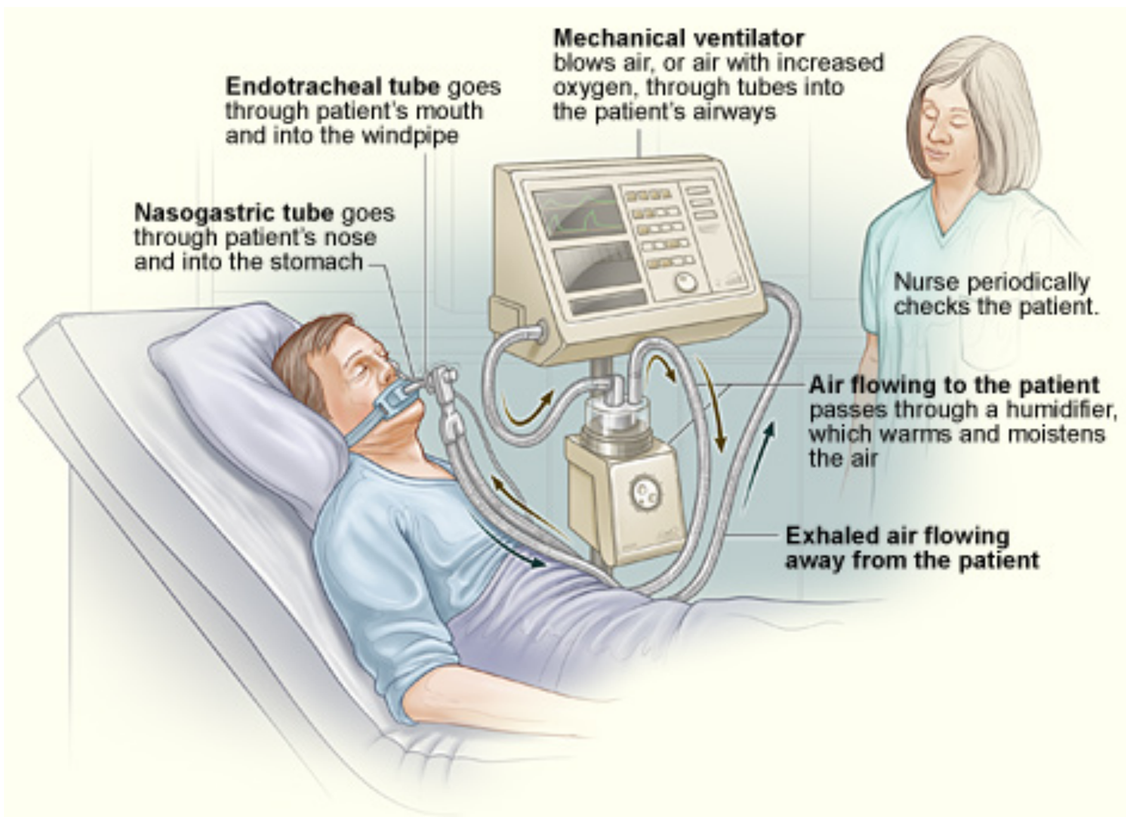

Figure 1: Patient on a Ventilator. This picture depicts how the artificial ventilator is connected to the secured endotracheal tube and shows the airflow that occurs. Although this is an adult patient, the general setup applies to pediatric patients as well. (Figure downloaded from "National Heart Lung and Blood Institute, 2011").

The Process of Endotracheal Intubation

In order to guide the endotracheal tube to the correct position, physicians usually follow a general procedure that involves the use of a laryngoscope. The laryngoscope serves to open up the passageway to the vocal cords and provide a better view for ETT insertion (Kabrhel, Thomsen, Setnik, & Walls, 2007; Schiffman, & Stoppler, 2007). Upon administration of general anesthesia, the physician can open the patient's mouth and use the laryngoscope to push back the tongue and advance the blade (position depending on the type of blade) towards the epiglottis (Kabhrel et al., 2007). Once the epiglottis is lifted, the vocal cords should be exposed, allowing the physician to insert the ETT through and into the patient's trachea (Kabhrel et al., 2007). While this is the basic outline of the procedure, there are various details including: angle of blade, entry point of ETT, adjustments to head/neck position, landmarks and signs, etc., which influence proper intubation (Kabhrel et al., 2007). Proper intubation is shown in figure 2. The critical steps of this process, that may influence complications both during and after intubation, include selection of the ETT type and size, positioning or depth of the ETT, and the route of intubation itself (nasal vs oral).

Once the ETT is inserted, there are multiple methods of confirmation to ensure proper ventilation to the lungs. Using an end-tidal carbon dioxide detector on the ETT allows the physician to observe if CO2 is being exhaled from the patient, which indicates that normal gas exchange is occurring in the lungs (Kabhrel et al., 2007). A second method of confirmation is to listen to the patient's stomach and lungs using a stethoscope; breath sounds should be bilateral and equal and not present in the stomach (Kabhrel et al., 2007). Finally, a chest x-ray can be used to view the lungs and also confirm that the ETT is positioned above the carina – by observing the radio-opaque line (figure 3) along the tube - and not in one of the main bronchi (Kabhrel et al., 2007).

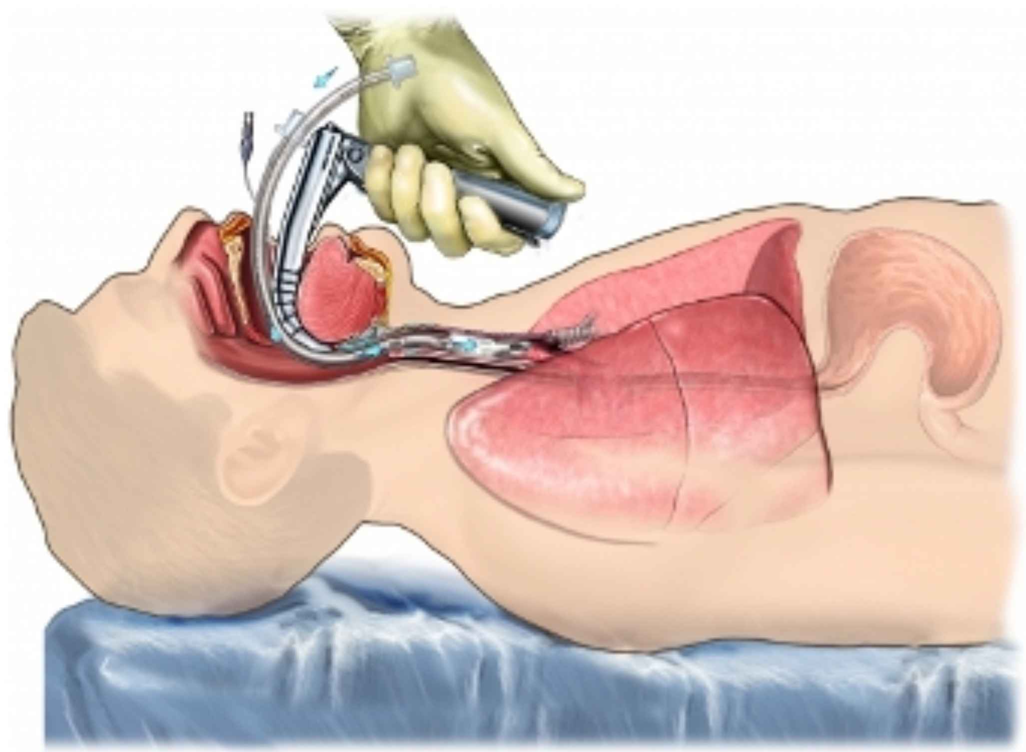

Figure 2: Endotracheal Intubation. This figure illustrates how a laryngoscope is used to place an oral ETT into the upper airway of the patient. Note that the trachea is located anterior to the esophagus. (Figure downloaded from "Martin, 2011")

Choosing the proper ETT size and type

Finding the right endotracheal tube for each pediatric patient is a critical step in ensuring proper ventilation. However, this is a difficult task due to the small size and sensitivity of the pediatric airway (Davis et al., 1998). If the tube were too large, it could cause swelling and damage to the vocal cords and eventually tracheal stenosis (Davis et al., 1998). Furthermore, unlike the adult airway, the pediatric airway significantly decreases in cross sectional area proportionally to edema and swelling (Davis et al., 1998). This would constrict the airway and limit the amount of air ventilation. If the tube were too small, then it would create a leak around the tube and cause improper ventilation (Davis et al., 1998). Endotracheal tubes are assigned numbers such as 3.0, 4.5, and 7.0, which indicate the internal diameter of the tube in millimeters (Kabrhel et al., 2007). In order to determine the proper size for the ETT, physicians commonly use the age-based (AB) formula, which is: (the age of the patient + 16) divided by four (Davis et al., 1998). However, there are many other methods of choosing the right ETT size that take different variables into account when the age is not available. Some examples include: the Broselow pediatric resuscitation tape method using body length, the fifth finger diameter method, and the fifth fingernail width method (Davis et al., 1998; King, Baker, Braitman, Seidl-Friedman, & Schreiner, 1993). Thus, the variability in ETT size selection can influence both immediate complications during intubation and delayed complications during post-intubation.

Along with the ETT size, another factor to consider is whether the ETT is cuffed or uncuffed. The uncuffed form is the original design that pediatric anesthesiologists first used and still continue to use on a wide basis (Weber, Salvi, Orliaguet, & Wolf, 2009). In fact, until the 2000's, uncuffed ETT's were always used for intubation and anesthesia administration in patients under the age of 8 (Weber et al., 2009). The cuff was introduced in order to make positive pressure ventilation much more effective with the ETT (Spiegel, 2010). Generally, the optimal placement of the cuff would be right under the vocal cords (Spiegel, 2010). Figure 3 shows how the cuff is located distal to the double black lines on the ETT to ensure that the cuff is positioned correctly. The cuff itself is also connected to a separate thin tube running along the ETT with a valve and pilot balloon; this allows physicians to adjust the cuff pressure by inserting or drawing back air with a syringe (Spiegel, 2010). Figure 4 shows the cuff and pilot balloon in place.

While the selection of ETT type depends on each individual case, there are several important components that should be considered. First, a cuffed ETT requires a smaller diameter within the tube itself because of the extra space needed for the cuff (Weber et al., 2009). Second, anesthesiologists need to spend more time and energy maintaining the correct cuff pressure (Weber et al., 2009). If the cuff pressure were too high, it could cause damage to the patient's airway and even stridor (Weber et al., 2009). High pressure could also puncture or break the cuff itself and cause major problems in the trachea (Weber et al., 2009). If the cuff pressure were too low, then the cuff would fail to secure the airway. In addition, external factors such as temperature and muscle relaxation keep the cuff pressure from staying constant (Weber et al., 2009). Third, there are numerous manufacturers and designs for cuffs, which make it difficult to have standard protocols and methods for intubation (Spiegel, 2010; Weber et al., 2009).

Despite these disadvantages, cuffed ETT’s also bring a whole new set of benefits to the pediatric patient. The cuff itself provides a better, tighter seal between the ETT and the airway (Weber et al., 2009). This allows more efficient ventilation, especially for PEEP in patients with low lung compliance (Weber et al., 2009). Having a tighter seal also allows anesthesia to be precisely administered and leak into the atmosphere less (Weber et al., 2009). Another strong benefit of cuffed ETT’s is the increased prevention of gastric aspiration due to the tight seal around the airway (Weber et al., 2009). The cuff also helps center the ETT in the trachea in order to prevent the distal tip from damaging the airway tissues (Spiegel, 2010). Finally, cuffed ETT’s may also reduce the incidence of unplanned extubations or multiple intubations, which are part of the complications observed in this study (Weber et al., 2009). While uncuffed ETT’s require reintubation when adjusting for correct tube diameter, cuffed ETT’s can be adjusted by increasing or decreasing cuff pressure to provide a closer fit (Weber et al., 2009). Overall, it seems that cuffed tubes may be especially useful for pediatric cardiac patients with compromised cardio-respiratory functions and patients undergoing both anesthesia and major surgery as well (Lonnqvist, 2009). However, it has not been proven that cuffed tubes are less associated with ETT complications compared to uncuffed tubes. Examples of commonly used ETT's, both cuffed and uncuffed, are shown in figure 3.

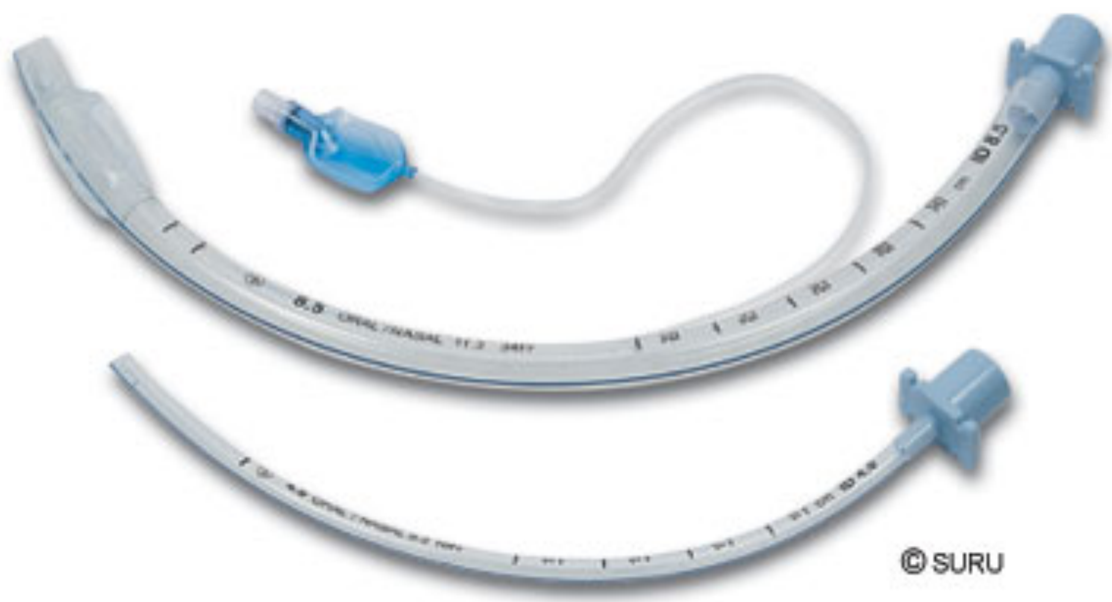

Figure 3: Endotracheal Tube. Above are two ETT's; the top one is cuffed while the bottom one is uncuffed. Both have connecting points on the far right to artificial ventilation. The thin line running down the tube's length is the radio-opaque line. The number (size) of the ETT would be written on the left of the position markers indicated by numbers and bold lines along the width of the tube. The top ETT shows the double black line near the cuffed end as used in determining ETT depth. These ETT's can be used both in the oral or nasal route as labeled above. (Figure downloaded from "Intensive Care Coordination and Monitoring Unit, 2011")

Depth of the Endotracheal Tube

Even with the correct size and type of ETT, the position or depth of the endotracheal tube in the patient's airway is an essential factor in the intubation process. Since children have much shorter airways than adults, finding the right depth of the ETT in pediatric patients is an especially crucial and difficult task for physicians (Mariano E.R., Ramamoorthy, C., Chu, L.F., Chen, M., & Hammer, G.B., 2005). If the ETT is positioned too high in the trachea, it can increase the chance of an unplanned extubation and loss of a secured airway (Mariano et al., 2005). If the ETT is positioned too low, it may hit the carina or go into one of the main bronchi and ventilate only one side of the lungs; this can cause pneumothorax, atelectasis (lung collapse), and/or traumatic lung tissue injury (Mariano et al., 2005; Schiffman, & Stoppler, 2007). A common method of determining the correct placement is using the formula: [(Patient's age in years / 2) +12] and using the resulting number as the centimeter mark on the ETT (Kabrhel et al., 2007). However, just as there are various methods of size selection, there are different methods used by physicians to determine the appropriate depth of the ETT. One method involves intentionally intubating a patient endobronchially and then pulling back the ETT until bilateral lung sounds can be heard; the ETT is pulled back an additional 2 cm and then taped down (Mariano et al., 2005). Another method involves advancing the ETT until the double black lines near the distal end are aligned with the vocal cords (Mariano et al., 2005). However, this method would only work if the ETT used has the double black line design as shown in figure 3. A third alternative method uses another formula: three times the millimeter diameter of the ETT (Mariano et al., 2005). All of these methods are approximations at best; the best way to confirm the correct depth is “direct visual verification” using radiography, fluoroscopy, or fiberoptic bronchoscopy (Mariano et al., 2005).

Complications that may occur during ETT placement

While endotracheal intubation is a very common procedure, it still requires intensive training and practice because of the associated life-threatening complications that may occur (Schiffman, & Stoppler, 2007). Improper placement of the ETT into the esophagus can cause inadequate ventilation, which can lead to hypoxemia and neurological and cardiovascular damage (Kabrhel et al., 2007). Undesired ventilation through the esophagus can also cause aspiration of stomach contents, leading to pneumonia and acute respiratory distress syndrome (Kabrhel et al., 2007; Schiffman, & Stoppler, 2007). Improper placement of the ETT into one of the main bronchi can also occur, which can damage lung tissue and prevent bilateral ventilation as previously mentioned (Mariano et al., 2005; Schiffman, & Stoppler, 2007). In addition, stimulation of the pharynx with the ETT can cause “bradycardia, laryngospasm, bronchospasm, and apnea” in some patients (Kabrhel et al., 2007). The use of the laryngoscope and ETT can also damage the patient’s teeth, lips, vocal cords, and throat if inserted improperly or too forcefully (Kabrhel et al., 2007).

Complications that may occur during post-intubation

One of the major complications that are associated with indwelling ETT's is the need for ETT manipulation and adjustment post-intubation. This type of complication involves the need to advance or pull back an ETT, and also re-tape or re-secure the ETT. This repositioning of the ETT requires additional sedation, respiratory staff assistance, and radiological confirmation (Rigini, Boaz, Ezri, Evron, Trigub, Jackobashvilli, & Izakson, 2011; Yoo, Kim, Han, & Oh, 2007). The ETT size, type, and depth all play an important role in the development of this complication. Even though endotracheal intubation as a procedure has been well established, the selection of cuffed vs. uncuffed ETT is still controversial and often highly dependent on provider bias (Newth, Rachman, Path, & Hammer, 2003). In addition, there are different methods available for choosing the proper size and depth of endotracheal tubes, based on patient demographics (Davis, Barbee, & Ririe, 1998; Hofer, Ganter, Tucci, Klaghofer, & Zollinger, 2002). Thus, the variability in ETT selection and insertion, based on physician preference and patient condition, may influence the onset of these acute complications. Essentially, ETT manipulation is generally an indication that the ETT selection was incorrect, the intubation method was flawed, or the ETT became displaced due to the patient's head and neck movements (Kabrhel et al., 2007; Yoo et al., 2007). If the ETT is not repositioned and secured properly, the patient can experience an accidental or unplanned extubation, which is another major complication (Silva, & Carvalho, 2010).

Unplanned extubation is an undesired and life-threatening event where an airway device such as the ETT becomes accidentally displaced and ceases to ventilate the patient adequately (Silva, & Carvalho, 2010). Unplanned extubations can be caused by inadequate initial positioning of the tube, improper securing of the ETT, or movements of the patient's head and neck (Silva, & Carvalho, 2010; Yoo et al., 2007). Unplanned extubations can also occur when necessary readjustments of the ETT are not performed (Silva, & Carvalho, 2010). This type of complication is particularly more prevalent in pediatric patients since children are more susceptible to the discomforts of ETT's, and they have a much shorter trachea than adults (Silva, & Carvalho, 2010). As mentioned previously, the type, size, and placement of the ETT can greatly influence the risk of unplanned extubation. Furthermore, the wide variety of methods used by physicians to secure and/or tape down the ETT may be an important factor in the incidence of unplanned extubations (Silva, & Carvalho, 2010). The main consequences associated with this specific complication include: the need for reintubation or multiple intubations, extended duration of artificial ventilation, and longer ICU and hospital stay (Groot, Dekkers, Herold, Jonge, & Arbous, 2011). All of these factors may then increase the risk for the other two major complications, dysphagia and skin breakdown, and reintroduce the risk of ETT adjustment.

In addition to the risk for potential hypoxia and acute airway injury, ETT's can also be associated with pressure ulcers at the site of insertion after intubation has occurred (Souza, & de Carvalho, 2009; Taylor, Subaiya, & Corsino, 2011; Weber, Salvi, Orliaguet, & Wolf, 2009). For patients who are orally intubated, the oral ETT can cause skin breakdown on the lips, mouth, gums, and even tongue (Zaratkiewicz, Teegardin, & Whitney, 2012). The damage is caused by the abrasive contact between soft tissues and the hard plastic surface of the ETT (Fletcher, 2012). Furthermore, the duration of contact between mucosal tissue and an external surface (the plastic ETT lining) may dictate the severity of the skin damage and stage (1-4) of the pressure ulcer (McCord, McElvain, Sachdeva, Schwartz, & Jefferson, 2004). While nasal ETT's are not associated with oral pressure ulcers, they may cause nasal tissue breakdown in a similar manner (Zaratkiewicz et al., 2012). These complications may be difficult to prevent because of the need to secure the ETT tightly, which also limits the view of the breakdown site (Zaratkiewicz et al., 2012). Proper positioning of the ETT, along with special pads and dressings, may help alleviate skin damage (Fletcher, 2012). Overall, pressure ulcers can cause pain and discomfort in patients, especially for children (Fletcher, 2012). If the skin damage is severe, it can leave permanent scars, which may require plastic surgery (Fujioka, Oka, Kitamura, & Yakabe, 2008). Figure 4 shows an example of a pediatric patient with a scar on the upper lip due to an oral ETT.

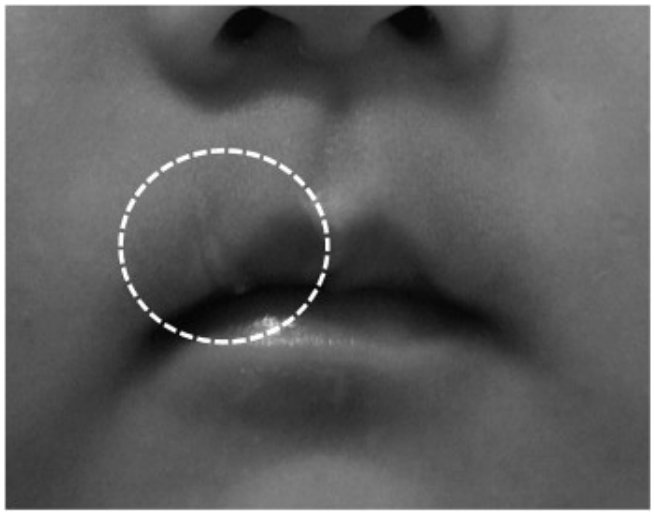

Figure 4. Scar tissue on the upper lip. This image shows an example of a year old scar (indicated within the dotted white circle) left by a pressure ulcer from an oral ETT. (Figure downloaded from “Fujioka et al., 2008”).

Specific to the pediatric cardiac patient is the oftentimes complicated postoperative or post-procedure course precluding early extubation, which makes the patient more susceptible to the complications of prolonged intubation and ventilation (Meissner, Scharf, & Schroth, 2008; Barker, Martino, Reichardt, Hickey, & Ralph-Edwards, 2009). While some patients may be weaned off the artificial ventilator within a few hours after surgery, other patients with severe illnesses may require several days, weeks, or longer to breathe on their own (American Thoracic Society, 2005). Dysphagia, which refers to problems with swallowing or oral feeding, is an example of a dangerous complication that may occur due to long-term endotracheal intubation and ventilation (Barker et al., 2009; Skoretz, Flowers, & Martino, 2010). Dysphagia, according to Barker et al., is a fairly common complication especially for cardiac patients who are intubated for longer than 48 hours postoperatively (Barker et al., 2009). Artificial airways, such as the ETT, have a risk of damaging the upper airway and laryngeal tissues and also causing infections to occur (Skoretz et al., 2010). This trauma can then lead to airway stenosis or swelling, and also negatively affect important breathing and swallowing reflexes (Skoretz et al., 2010). Just as the case for ETT manipulation, dysphagia also may be caused by incorrect ETT selection or placement. When patients experience dysphagia, they are unable to eat or drink properly and are at a high risk for malnutrition, dehydration, aspiration, poor weight gain, and slow recovery (Barker et al., 2009; Skoretz et al., 2010). In addition to dysphagia, prolonged intubation in the CICU may also cause pressure ulcers (as mentioned previously) to develop in superficial areas and internal respiratory tissues that are in contact with the endotracheal tube (Curley, Quigley, & Lin, 2003; McCord, McElvain, Sachdeva, Schwartz, & Jefferson, 2004).

Oral and Nasal Routes of Intubation

Although the route of intubation is the critical variable being analyzed for this ETT study, there is a relatively limited amount of research comparing oral vs. nasal routes for pediatric patients. Therefore, this preliminary study may have an important role in better understanding the indications and consequences of selecting one route of intubation over the other. While oral intubation is generally the easier and more common route, there are situations where nasal intubation is indicated and more preferred (Holzapfel, 2003; Shindell, Windle, & Meyers, 2012). The nasal ETT is usually used for patients undergoing any sort of dental, oral, or maxillofacial procedures, as well as patients with difficult oropharyngeal access (Shindell et al., 2012). The nasal ETT is also preferred by some anesthesiologists because it is easier to secure and more comfortable for the patient; it is not associated with tissue breakdown at the lips and tongue as with the oral ETT (Berry, 2007; Holzapfel, 2003) However, the nasal ETT may increase the risk of sinusitis and bacteremia by introducing nasal pathogens into the sinuses and upper airway, respectively (Holzapfel, 2003; Shindell et al., 2012). Additionally, nasal intubation can cause epistaxis or bleeding in the nasal passageways (Shindell et al., 2012). These are important complications unique to the nasal ETT that should be considered on a case-by-case basis when deciding the route of intubation.

In terms of method and technique, the nasal ETT route involves a slightly different process that may be more difficult to learn and practice. First, the ETT should be properly lubricated to prevent abrasions; then it is passed through the left or right nare and into the nasopharynx (Berry, 2007; Shindell et al., 2012). Oftentimes the ETT needs to be adjusted and angled when met with resistance in the nasal airway (Shindell et al., 2012). Once the tube reaches the oropharynx, it can then be guided to the vocal cords using a laryngoscope and if necessary, a pair of magill forceps (Berry, 2007). A properly placed nasal ETT is depicted in figure 4.

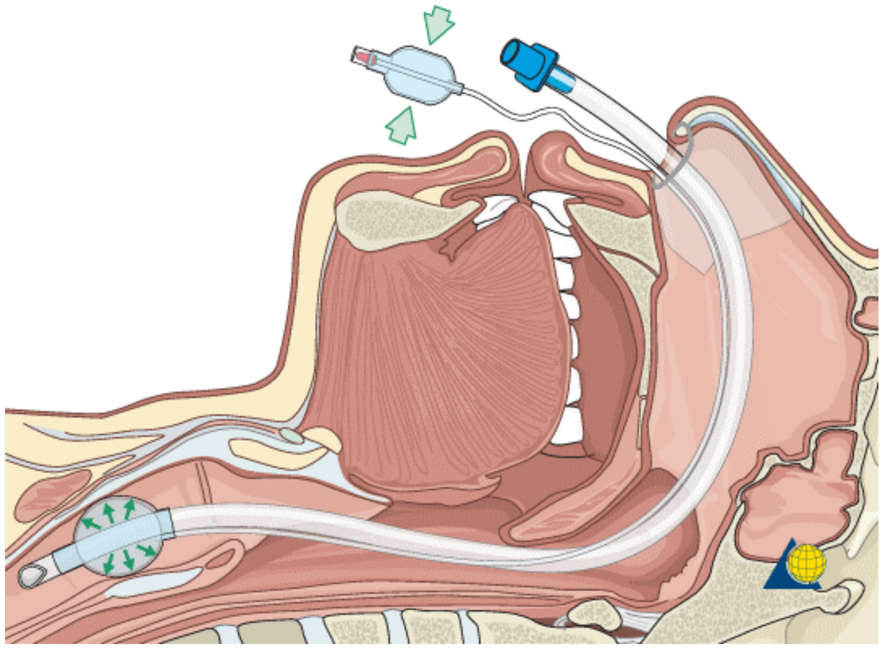

Figure 5: Nasotracheal Intubation. This picture shows the correct placement of a cuffed nasal ETT along with the cuff location and pilot balloon as well. (Figure downloaded from “Nasotracheal Intubation, n.d.”)

One particularly relevant study, by Spence & Barr, 1999, observed newborns in the neonatal intensive care unit and compared complication rates for nasally vs orally intubated patients. While complications may have been influenced by other factors such as tube size and depth, there was no significant difference between oral vs. nasal intubation in terms of effects on complications (Spence, & Barr, 1999). The incidence rates of incorrect ETT positioning, accidental extubation, re-intubation, local trauma, and airway infection were the main complications studied (Spence, & Barr, 1999). Despite this conclusion, Spence & Barr claimed that more research in the form of randomized controlled trials is necessary to determine whether oral or nasal ETT’s are more risky. Further research is also necessary for pediatric patients across all age groups as well. Another study, by Depoix et al., focused specifically on adult patients undergoing cardiac surgery. The factors that Depoix et al. measured were: time needed to intubate, presence of bleeding or trauma and mechanical issues such as cuff rupture, incidence of bacteremia and sinusitis, comfort levels of the patient, and the incidence of dysphagia, dysphonia, and dyspnoea (Depoix, Malbezin, Videcoq, Hazebroucq, Barbier-Bohm, Gauzit, & Desmonts, 1987). Besides the fact that the nasal route took fairly longer than the oral route, there were no statistically significant differences in the two methods regarding the listed factors (Depoix et al., 1987).

When considering both studies by Depoix et al. and Spence & Barr, there is no conclusive data that favors one route of intubation over the other with regards to accidental extubation rates and infection rates (Holzapfel, 2003). However, neither study specifically examined the pediatric cardiac patient population. Therefore, further research - such as this preliminary study - may potentially reveal distinct advantages in selecting one route of intubation over another in the pediatric CICU setting.

RACHS-1 Categories

Regarding the patient population involved in this study, one factor that may help identify risk groups for endotracheal tube complications is the type of cardiac procedure that the patient undergoes. Most of the patients that are admitted to the CICU have one or multiple congenital heart diseases that are being treated. Furthermore, most of the patients involved in this study have gone through special surgical procedures designed to correct heart defects and problems. Although congenital heart defects are rare, they are one of the "leading causes of death" in children (Jenkins et al., 2002). Congenital heart defects are the "most common type of birth defect" and the most deadly type of defect for children under the age of one (A.D.A.M. Medical Encyclopedia, 2011). Some examples include: tetralogy of fallot, ebstein's anomaly, atrial septal defect, patent ductus arteriosus, and coarctation of the aorta (A.D.A.M. Medical Encyclopedia, 2011). These defects may weaken the ability of the heart to properly pump oxygenated blood to the rest of the body and deoxygenated blood to the lungs. Therefore, congenital heart defects in pediatric patients are very serious conditions that affect cardiovascular, respiratory, and other organ functions. In particular, the severity of the illness and the associated procedure can dictate the pediatric patient's outcome and vulnerability to undesired complications (Jenkins et al., 2002). One way to assess the difficulty and complexity of certain cardiac procedures is the RACHS-1 score (Jenkins et al., 2002). Created by Jenkins et al. with the help of a panel of 11 medical experts across the nation, the RACHS-1 score system was specifically designed to assign mortality risk levels to surgeries addressing congenital heart disease (Jenkins et al., 2002). Some of the variables that were used to create the system include: in-hospital mortality, age, major noncardiac structural anomaly, and surgical procedure codes (Jenkins et al., 2002). Table 1 shows the 6 different risk categories and procedures that are included under each group. Instead of being used to predict the risk of death in individual cases, Jenkins et al. created this list to separate the broader pediatric cardiac patient population into distinct groups for clinical comparisons (Jenkins et al., 2002). Therefore, the RACHS-1 score system can be used to observe if patients in the higher risk categories are also associated with increased risk of ETT complications.

Table 1: Individual procedures by risk category. The table below shows how each pediatric cardiac procedure is categorized based on risk levels, 1 being the lowest and 6 being the highest. (Table taken from "Jenkins et al., 2002")

TABLE 2. Individual procedures by risk category

Risk category 1	
	Atrial septal defect surgery (including atrial septal defect secundum, sinus venosus atrial septal defect, patent foramen ovale closure)
	Aortopexy
	Patent ductus arteriosus surgery at age >30 d
	Coarctation repair at age >30 d
	Partially anomalous pulmonary venous connection surgery
Risk category 2	
	Aortic valvotomy or valvuloplasty at age >30 d
	Subaortic stenosis resection
	Pulmonary valvotomy or valvuloplasty
	Pulmonary valve replacement
	Right ventricular infundibulectomy
	Pulmonary outflow tract augmentation
	Repair of coronary artery fistula
	Atrial septal defect and ventricular septal defect repair
	Atrial septal defect primum repair
	Ventricular septal defect repair
	Ventricular septal defect closure and pulmonary valvotomy or infundibular resection
	Ventricular septal defect closure and pulmonary artery band removal
	Repair of unspecified septal defect
	Total repair of tetralogy of Fallot
	Repair of total anomalous pulmonary veins at age >30 d
	Glenn shunt
	Vascular ring surgery
	Repair of aorta-pulmonary window
	Coarctation repair at age ≤30 d
	Repair of pulmonary artery stenosis
	Transection of pulmonary artery
	Common atrium closure
	Left ventricular to right atrial shunt repair
Risk category 3	
	Aortic valve replacement
	Ross procedure
	Left ventricular outflow tract patch
	Ventriculomyotomy
	Aortoplasty
	Mitral valvotomy or valvuloplasty
	Mitral valve replacement
	Valvectomy of tricuspid valve
	Tricuspid valvotomy or valvuloplasty
	Tricuspid valve replacement
	Tricuspid valve repositioning for Ebstein anomaly at age >30 d
	Repair of anomalous coronary artery without intrapulmonary tunnel
	Repair of anomalous coronary artery with intrapulmonary tunnel (Takeuchi)
	Closure of semilunar valve, aortic or pulmonary
	Right ventricular to pulmonary artery conduit
	Left ventricular to pulmonary artery conduit
	Repair of double-outlet right ventricle with or without repair of right ventricular obstruction
	Fontan procedure
	Repair of transitional or complete atrioventricular canal with or without valve replacement
	Pulmonary artery banding
	Repair of tetralogy of Fallot with pulmonary atresia
	Repair of cor triatriatum
	Systemic to pulmonary artery shunt
	Atrial switch operation
	Arterial switch operation
	Reimplantation of anomalous pulmonary artery
	Annuloplasty
	Repair of coarctation and ventricular septal defect closure
	Excision of intracardiac tumor
Risk category 4	
	Aortic valvotomy or valvuloplasty at age ≤30 d
	Konno procedure
	Repair of complex anomaly (single ventricle) by ventricular septal defect enlargement
	Repair of total anomalous pulmonary veins at age ≤30 d
	Atrial septectomy
	Repair of transposition, ventricular septal defect, and subpulmonary stenosis (Rastelli)
	Atrial switch operation with ventricular septal defect closure
	Atrial switch operation with repair of subpulmonary stenosis
	Arterial switch operation with pulmonary artery band removal
	Arterial switch operation with ventricular septal defect closure
	Arterial switch operation with repair of subpulmonary stenosis
	Repair of truncus arteriosus
	Repair of hypoplastic or interrupted arch without ventricular septal defect closure
	Repair of hypoplastic or interrupted aortic arch with ventricular septal defect closure
	Transverse arch graft
	Unifocalization for tetralogy of Fallot and pulmonary atresia
	Double switch
Risk category 5	
	Tricuspid valve repositioning for neonatal Ebstein anomaly at age ≤30 d
	Repair of truncus arteriosus and interrupted arch
Risk category 6	
	Stage 1 repair of hypoplastic left heart syndrome (Norwood operation)
	Stage 1 repair of nonhypoplastic left heart syndrome conditions
	Damus-Kaye-Stansel procedure

Vasoactive Inotropic Scores

Another important variable that can help determine risk groups is the inotropic support given to the pediatric patient. Inotropic drugs or agents affect the contractile strength of a patient's heart (Texas Heart Institute Heart Information Center, 2013). Positive inotropic drugs increase the strength of the cardiac muscles, while negative inotropics drugs decrease the strength; patients with congenital heart disease usually require positive inotropic support in the OR and the CICU (Texas Heart Institute Heart Information Center, 2013). This support can be quantified into the "vasoactive-inotropic score", which is then used as an approximate measure of how well a pediatric cardiac patient is doing postoperatively or post-procedure (Gaies, Gurney, Yen, Napoli, Gajarski, Ohye, Charpie, & Hirsch, 2010). The VIS takes into account the specific use of inotropic drugs - dopamine, dobutamine, epinephrine, milrinone, vasopressin, and norepinephrine – within a given timeframe (Gaies et al., 2010). Considering these drugs, a patient with a higher inotropic score may have a more severe illness and a greater risk of morbidity and mortality, than a patient with a low inotropic score (Gaies et al., 2010). While there are several different methods of calculating the VIS, table 2 shows the equation that Gaies et al. specifically created to compare inotropic support levels between individual patients. The main conclusion that Gaies et al. discovered was that the maximum VIS - within the first 48 hours postoperatively or post-procedure - can be used as a predictor for clinical outcomes in pediatric patients (Gaies et al., 2010). Therefore, a patient with a higher VIS within the initial 48 hours may also have an increased risk for ETT complications compared to patients with a lower VIS. In particular, a patient with high inotropic support generally indicates low cardiac output (Gaies et al., 2010; Texas Heart Institute Heart Information Center, 2013). Low cardiac output is correlated with poor skin perfusion, which may then be associated with increased vulnerability to pressure ulcers (National Heart Lung and Blood Institute, 2012). With respect to this relationship, patients with higher VIS may have a greater risk to develop skin complications in particular from ETT's.

Table 2: VIS equation. This table depicts the inotropic score calculation. (Table taken from "Gaies et al., 2010")

Box 1

$$\begin{aligned} \text{Wernovsky IS} &= \text{dopamine dose } (\mu g/kg/min) \\ &+ \text{dobutamine dose } (\mu g/kg/min) \\ &+ 100 \times \text{epinephrine dose } (\mu g/kg/min) \end{aligned}$$

$$\begin{aligned} \text{VIS} &= \text{IS} + 10 \times \text{milrinone dose } (\mu g/kg/min) \\ &+ 10{,}000 \times \text{vasopressin dose } (U/kg/min) \\ &+ 100 \times \text{norepinephrine dose } (\mu g/kg/min) \end{aligned}$$

OBJECTIVES

The objective of this preliminary retrospective study is to establish incidence rates of specific postoperative endotracheal tube complications between cardiac patients who are intubated via the oral and nasal route, and to identify specific risk groups that could benefit from a change in practice or implementation of guidelines. Our hypothesis is that the nasal route of intubation may be associated with a lower incidence rate and risk of ETT complications than the oral route. In addition, the purpose of this study is to better understand the problems in current intubation methods and to identify potential changes in practice that may help reduce the incidence of ETT complications.

While certain factors cannot be changed, others could be addressed with changes in practice or monitoring guidelines. The results of this study will therefore be used to identify specific groups of pediatric cardiac patients who are at high risk to develop complications and establish practice guidelines for the insertion and monitoring of endotracheal tubes. These could include recommendations regarding the insertion site or route of intubation, type of fixation, prophylactic repositioning, monitoring intervals, sedation regiments, etc. This preliminary study will collect data from 100 patients who were admitted to the Cardiac Intensive Care Unit at Boston Children's Hospital from Oct 1st, 2010-Sept 30th, 2011. This is only a sample group of the larger population of patients who were admitted to the CICU during the same time frame.

SPECIFIC AIMS

Primary Aims:

1. To determine the incidence of certain complications associated with indwelling endotracheal tubes in pediatric cardiac patients: pressure ulcers at insertion site, accidental extubations, need for tube repositioning, and dysphagia/feeding problems
2. To discover differences in these complication rates between orally and nasally placed endotracheal tubes
3. To identify subgroups of pediatric cardiac patients who are at increased risk for developing these complications

Secondary Aims:

4. To establish changes in current practice and guidelines aiming to reduce the incidence of these complications
5. To develop new research questions based on the collected data by participating investigators

METHODS

Study Design:

The original scope of the study included all patients who were admitted to the CICU and received respiratory support with mechanical ventilation via an endotracheal tube during the fiscal years of 2010-2012 at BCH. This would've been from October 1st, 2009 through September 30th, 2012. However, the total number of patients was approximately 3600, and so a smaller (preliminary) retrospective case-control study was conducted using a sample group of 100 patients admitted to the CICU from October 1st, 2010 to September 30th, 2011. We collected a large list of variables including: reason for admission, date of admission (starting date of respiratory support), RACHS-1 scores, vasoactive inotropic scores (maximum score within first 48hrs), type of mechanical ventilation, outcomes of treatment, age and weight of patients, gender of patients, reasons for use of mechanical ventilation, duration of ventilation, cuffed vs uncuffed ETT, oral vs nasal ETT, size of ETT, location where ETT was placed, start of first PO feeding, and hospital and CICU length of stay. We then noted the incidence of four specific types of ETT complications: dysphagia, unplanned extubation and/or multiple intubations, skin complications, and need for ETT adjustments. We looked for the incidence rate of any of these complications for orally intubated patients and then nasally intubated patients. We ran a Z-test and the Fisher's Exact test to determine the difference of complication rates between the oral and nasal ETT groups and analyzed this difference in proportions for statistical significance. We then ran a multivariable regression, using selected covariates, to assess confounding factors that may have influenced the rate of complications. This retrospective case-control study was approved by the Institutional Review Board at Boston Children's Hospital.

Data Collection:

While there were about 3600 patients who were admitted to the CICU at Boston Children's Hospital between Oct 1, 2009 and September 30, 2012, the sample group analyzed for this specific study included only 100 of these patients who were admitted between Oct 1, 2010 and September 30, 2011. The Respiratory Therapy team at Boston Children's Hospital collected the initial ventilation data for each patient. Then, the Anesthesia Clinical Research Unit gathered the supplementary data through Powerchart on the hospital Cerner System. The Anesthesia Clinical Research unit will continue with the rest of the data collection beyond the sample group of this study. These additional data will be used for a follow-up or continuation study. The information on each patient was recorded onto a shared excel spreadsheet.

Statistical Analysis:

Initially the Z test was used to compare the complication rates for the orally vs nasally intubated patient. Then the Fischer's Exact test was performed to confirm the results from the Z test since the sample sizes for each group were relatively small. A P value < 0.05 would be interpreted as a rejection of the null hypothesis and confirmation that the oral vs nasal groups have a statistically significant difference in complication rates. A multivariable regression was also performed to see if there were other factors involved in influencing or affecting complication rates overall. In order to determine which factors would be used in the regression (5 covariates), Mann-Whitney U and Fisher's Exact tests were performed. Mann-Whitney U-tests were used for continuous variables when determining the p values between two groups; Fisher's Exact tests were used for all other variables respectively.

RESULTS

This study was a retrospective case-control study and essentially a quality improvement chart review involving 100 patients who were admitted to the BCH CICU for postoperative or post-procedure care. Out of the 100 patients, 67 were orally intubated and 33 were nasally intubated. Looking at the general incidence of the four major ETT complications, 17 out of the 67 orally intubated patients experienced complications. Respectively, 6 out of the 33 nasally intubated patients had at least one of the four complications. 23 out of 100 patients experienced at least one of the four complications; the overall complication rate was 23%. A Z-test was used to calculate the difference between the complication rates of oral vs nasal ETT groups. The difference between the two independent proportions was calculated to be 0.0719 or approximately 7%. With respect to the 95% confidence interval, the difference between the two proportions was between -0.1129 and 0.222 or -11% and 22%. This range alone reflects the uncertainty of the actual difference in complication rates. The z value equaled 0.804 and the two-tailed analysis gave p values of 0.2107 and 0.4214. Both p values were significantly greater than 0.05 and therefore, the null hypothesis (no difference in oral vs nasal groups) was not rejected. This was further affirmed by observing the 95% confidence interval for each individual proportion. For the oral ETT group, the rate of complication ranged from 0.1649 or 16% to 0.3693 or 37%. For the nasal ETT, the rate of complication ranged from 0.0861 or 9% to

0.3439 to 34%. There is a significant overlap in the two ranges that suggests that a significant difference cannot be determined.

The Fisher's Exact test involved setting the two groups into a 2 by 2 contingency table as shown in table 3. Once the table was prepared, the two-tailed p value was calculated and assessed in the same manner as the z-test.

Table 3. Fisher's Exact test contingency table. This table splits up the two groups - nasal and oral ETT – and the two outcomes – complications and no complications.

	Complications	**No Complications**	**Total**
Oral ETT	17	50	67
Nasal ETT	6	27	33
Total	23	77	100

The p value was determined as 0.4621. Since 0.4621 > 0.05, the null hypothesis that the differences in complication rates are insignificant cannot be rejected. Thus, the Fisher's Exact test further confirms that there is no statistically significant difference in complication rates between the oral and nasal ETT patients.

In order to run the multivariable regression, Mann-Whitney U-tests and Fisher's Exact tests were performed to determine which variables would be used as covariates for the incidence of any of the four ETT complications. The following variables were tested in order to select five covariates for the regression analysis: age, weight, gender, total CMV hours, maximum inotropic score (within the first 48 hrs), RACHS-1 score, cuffed or uncuffed ETT, and route of intubation (oral vs nasal). The p values of each variable (with respect to the two study groups) as well as the descriptive statistics on the sample group data are shown in table 4.

Table 4. Comparison of oral vs nasal ETT groups. This table lists the variables that may be potential confounders, while also looking at differences between orally and nasally intubated patients. Data for age, weight, RACHS-1 score, CMV duration, inotropic scores are shown as the median followed by the interquartile range.
*Statistically significant group difference in this variable.

Comparison of Oral and Nasal Endotracheal Tube Groups			
Variable	**Oral ETT (n = 67)**	**Nasal ETT (n = 33)**	**P value**
Gender			0.29
Male	33 (49%)	12 (36%)	
Female	34 (51%)	21 (64%)	
Age, years	3 (0.5 – 11.0)	0.4 (0.1 – 1.9)	<0.001*
Weight, kg	13.1 (5.4 – 36.3)	5.5 (3.6 – 10.4)	<0.001*
RACHS-1 score	2 (1 – 3)	2 (1 – 3)	0.42
Total CMV, hours	17 (7 – 43)	42 (19 – 117)	<0.001*
Max. VIS	5 (0 – 10)	5 (0 – 10)	0.82
Cuff	60 (90%)	27 (82%)	0.35
Skin complications	7 (10%)	2 (6%)	0.71
Dysphagia	4 (6%)	2 (6%)	1.00
Unplanned extubation	5 (8%)	2 (6%)	1.00
ETT manipulation	11 (16%)	3 (9%)	0.38
Any complication	17 (25%)	6 (18%)	0.46

Mann-Whitney U-tests were used to calculate p values for age, weight, CMV hours, maximum inotropic scores, and RACHS-1 scores since they were all continuous without normal distribution. Fisher's Exact tests were used respectively for cuff, gender, and ETT complications since these variables were non-continuous. The p values represent the relationship between the values for oral and nasal ETT groups with respect to the listed variable in the same row. The three factors – age, weight, CMV hours - that have P values < 0.05 were selected for the multivariate regression as confounding factors, since they reflected the largest difference between the oral and nasal ETT groups. The last five rows in table 4 show the difference in complication rates between oral vs nasal groups for each individual complication as well as any of the four complications. None of the p values are less than 0.05; therefore, there is no statistically significant difference observed in the two rates for each or all of the complications. Nevertheless, ETT manipulation shows the greatest difference in rates between the two study groups. Table 5 looks at the same variables as table 4 but with respect to two different groups: patients with complications and patients without any complications. Just as in table 4, the Mann-Whitney and Fisher's Exact test were used for the variables in table 5. Table 5 shows whether certain factors may be correlated to the incidence of ETT complications. Lower p values indicate a potential predictor effect. The only p value that is actually < 0.05 is listed for the maximum inotropic score. Therefore, this variable was included as the fourth covariate for the multivariable regression.

Table 5. Comparison of patients with and without complications. This table shows possible predictor variables of ETT complications. Data for age, weight, RACHS-1 score, CMV duration, inotropic scores are shown as median, followed by interquartile range.
*Statistically significant group difference in this variable.

Comparison of Patients With and Without Complications			
Variable	**Any Complication (n = 23)**	**No Complication (n = 77)**	**P value**
Gender			0.24
Male	13 (57%)	32 (42%)	
Female	10 (43%)	45 (58%)	
Age, years	3 (0.2 – 11.0)	1.2 (0.3 – 5.0)	0.42
Weight, kg	12.8 (3.6 – 47.8)	9.2 (4.5 – 19.4)	0.34
RACHS-1 score	3 (1 – 3)	2 (1 – 3)	0.31
Total CMV, hours	39 (8 – 120)	19 (8 – 56)	0.18
Max. VIS	8 (0 – 20)	5 (0 – 10)	0.04*
Cuff	19 (83%)	68 (88%)	0.49
Skin complications	7 (10%)	2 (6%)	0.71
Dysphagia	4 (6%)	2 (6%)	1.00
Unplanned extubation	5 (8%)	2 (6%)	1.00
ETT manipulation	11 (16%)	3 (9%)	0.38
Any complication	17 (25%)	6 (18%)	0.46

The multivariate logistic regression technique was used to analyze the covariates selected for possible associations with a higher risk of ETT complications. The fifth covariate was chosen as the route of intubation (oral vs nasal) by default. The results of the regression revealed that only two of the five variables are statistically associated with the incidence of ETT complications. The first predictor variable is age - with a p value of 0.025 - where older patients are at a higher risk for complications. The second predictor variable is maximum inotropic score – with a p value of 0.009 – where higher scores are linked with a higher risk for complications. The other covariates - weight, CMV time, and route of intubation - showed p values of 0.92, 0.93, and 0.77, respectively. Tables 6 and 7 represent the multivariate logistic regression results and the p values for each covariate.

Table 6. Regression model for ETT complications. This table shows the results of the multivariate regression where the significance of the change (on the right column) can be interpreted as the p value with regards to whether a covariate strongly affects the outcome (complications).

	Variable	Model Log Likelihood	Change in -2 Log Likelihood	df	Sig. of the change
Step 1	Oral vs Nasal ETT	-46.473	0.088	1	0.767
	Age (yr)	-46.672	0.487	1	0.485
	Weight (kg)	-46.437	0.018	1	0.895
	Total CMV (hrs)	-46.433	0.009	1	0.923
	Max VIS (48hr)	-49.853	6.849	1	0.009
Step 2	Oral vs Nasal ETT	-46.477	0.088	1	0.767
	Age (yr)	-46.681	0.495	1	0.482
	Weight (kg)	-46.441	0.015	1	0.901
	Max VIS (48hr)	-49.897	6.928	1	0.008
Step 3	Oral vs Nasal ETT	-46.482	0.082	1	0.774
	Age (yr)	-48.906	4.930	1	0.026
	Max VIS (48hr)	-49.901	6.920	1	0.009
Step 4	Age (yr)	-48.979	4.994	1	0.025
	Max VIS (48hr)	-49.901	6.838	1	0.009

Table 7. Additional regression model for ETT complications. This table examines the covariates that were determined to be unassociated with the risk of complications based on the results from table 6.

	Variable	Score	df	Sig. of the change
Step 2a	Total CMV hrs	0.010	1	0.921
	Overall statistics	0.010	1	0.921
Step 3b	Weight (kg)	0.016	1	0.901
	Total CMV hrs	0.008	1	0.931
	Overall statistics	0.025	2	0.987
Step 4c	Oral vs Nasal ETT	0.083	1	0.773
	Weight (kg)	0.010	1	0.920
	Total CMV hrs	0.008	1	0.931
	Overall statistics	0.108	3	0.991

For table 6, the regression can be broken down into four steps. Step 1 includes all five covariates to see which factors may be associated with the observed outcome. Step 2 removes the term or covariate that has the least association, CMV hours, and calculates the p values again for the other four covariates. Step 3 and 4 repeat this process until the two remaining covariates, age and inotropic score, reveal significantly low p values. Table 7 takes the variables that were removed from table 6 and calculates separate p values. Step 4 from both tables gives the p values that are used as the final regression results.

DISCUSSION

The original hypothesis that cardiac patients with nasal ETT's have statistically lower complication rates compared to cardiac patients with oral ETT's could not be proven to be true. The Fisher's Exact test determined that the p value for the 2 X 2 contingency table (as previously noted) was 0.4621. This means that the 7% difference observed in complication rates can be interpreted as pure chance and not based on the characteristics of the two treatment groups. While the null hypothesis cannot be rejected, based on the preliminary p value, the multivariate logistic regression revealed other variables that are associated with the risk of ETT complications. Patients with older age and patients who undergo higher inotropic support (up to 48 hours postoperatively) are at a greater risk to develop at least one of the four major complications. As mentioned in the introduction, patients with higher inotropic support may be associated with poor skin perfusion and greater risk to develop pressure ulcers. As for age, older patients tend to be orally intubated, while children may be nasally intubated due to the increased comfort and decreased difficulty in securing the ETT. If the original hypothesis can be proven to be true, then the correlation between older age and increased complication rates can be validated via the route of intubation. Nevertheless, further research is necessary to determine how age and VIS are associated with risks of ETT complications.

With regards to the first aim of this study, the overall incidence rate of ETT complications was discovered to be 23 out of 100 patients or 23%. While the oral vs nasal group results may be inconclusive, the general incidence rate indicates that over 1 in 5 patients in the CICU experience at least one of the four major ETT complications. This is an alarmingly high proportion that needs to be addressed by changing guidelines and current practices of endotracheal intubation. When looking at individual complication rates, it seems that the most common complication is ETT manipulation. It also seems that the oral and nasal ETT groups show the greatest difference in rates within this particular complication. Therefore, the results of this study show that initial placement and proper securing of the ETT may be important in terms of lowering overall complication rates. Furthermore, there may be a greater risk for ETT displacement using the oral ETT compared to the nasal ETT (although the data is inconclusive due to the lack in power). The second most common complication is skin complication or breakdown. While the difference in proportions is only 4%, further research may potentially reveal a correlation in increased pressure ulcers and oral ETT use (as opposed to the nasal ETT). The third and fourth most common complications are unplanned extubation, and dysphagia, respectively; none of these reflect significant proportional differences in rates for the two treatment groups.

Due to the relatively small sample size of patients, the results related to the second aim are preliminary at best. In order to find a clinically significant difference in complication rates between the orally intubated and nasally intubated patients, this study requires at least 80% power. This means that the study should have at least 80% chance of correctly rejecting the null hypothesis and only 20% chance of not rejecting the null hypothesis when it is actually false (Sullivan, 2012). In other words, it is more likely that the null hypothesis is not rejected when it should be rejected, if the study achieves a smaller power (Sullivan, 2012). Since this study did not achieve the minimum desired power of 80%, there is a small chance that the null hypothesis may actually be false – leading to the conclusion that the original hypothesis may actually be true. Therefore, while the preliminary results disprove the hypothesis, there needs to be further data collection and statistical analysis to confirm that the null hypothesis cannot be rejected. If this retrospective study were to be able to achieve 80% power, it would require at least 200 patients per treatment group (400+ total). This projected sample size and power would allow clinically relevant differences of rates in complications to be detected (as small as 10%). Smaller differences would require larger sample sizes, but for the purpose of this study, any difference smaller than 10% would not be clinically conclusive. Since the difference detected in this study was only 7% and since 80% power was not achieved, further research is necessary.

The third aim was addressed through the multivariable regression, as stated before. The multivariate logistic regression identified two important factors, age and inotropic score, that may act as predictors for ETT complication. Therefore, it may be important to involve these factors in separate or additional studies to detect statistically significant differences across new treatment groups. In particular, further research on VIS and the incidence of pressure ulcers may reveal an important connection. While the regression ultimately excluded gender, weight, RACHS-1 score, CMV hours, oral vs nasal ETT, and cuffed vs uncuffed ETT, these variables should still be included in future studies that involve larger sample sizes since they may have clinical relevance in complications. In particular, the last three variables listed above should be included because they were selected for the regression through Mann-Whitney U tests and Fisher's Exact tests. As mentioned in the introduction, cuffed and uncuffed ETT's may have implications on all four types of complications since the cuffs may help secure the ETT but raise the risk of airway damage. Longer CMV hours may also increase the risk of skin breakdown and dysphagia, and oral vs nasal routes of intubation may differ in terms of securing the ETT and incidence of pressure ulcers.

Prior to running the regression, the variables initially used as additional covariates – age, weight, gender, RACHS-1 score, total CMV hours, maximum inotropic score, cuff/uncuffed ETT - were chosen based on the likelihood of affecting complication rates. Other factors, such as location of intubation, length of hospital stay, ETT position, and ETT size were excluded because of the difficulty of analysis, lack of variation, or weak association with risks of complication. Reason for admission was also excluded because the RACHS-1 score and inotropic score were more useful in terms of describing the severity of the patient's heart disease and postoperative conditions of the patient. The type of ventilator was also excluded because all the patients in this study received the same method of artificial ventilation. Although there are many different alternatives - such as assist-control ventilation, intermittent mandatory ventilation, pressure support breathing, and noninvasive ventilation – the most commonly used method of ventilation in this study was CMV or controlled (continuous) mandatory ventilation (Amitai, Sinert, Conrad, Talavera, Blackburn, Halamka, & Mosenifar, 2011). CMV delivers a certain volume of air consistently at set time intervals; this is most effective for patients who are unconscious and apneic due to general anesthesia (Amitai et al., 2011).

Regarding the fourth aim, it may be difficult to implement any changes in practice or intubation methods based on this preliminary study. When future studies with higher power are performed, we can implement better guidelines for choosing an oral or nasal ETT in order to reduce the risk of complications. If the oral ETT is proven to have a significantly greater complication rate than the nasal ETT, then we can shift towards using the nasal ETT especially for pediatric cardiac patients who are at high risk for complications. We can assess risk levels based on variables that are identified to be strongly associated to complications, such as age and VIS. Designing follow-up prospective studies on the same type of patients may allow us to determine whether implemented changes in practice can actually lower the incidence of ETT complications.

While the fifth aim also requires additional research, one of the questions that we can ask is: can we find a strong association between certain variables and individual complications, instead of overall complications? Another question that we can ask is: does the use of a transesophageal echocardiogram influence the development of complications, especially dysphagia?

Conclusions:

Our original hypothesis that the nasal route of intubation has a significantly lower risk and incidence rate of ETT complications compared to the oral route could not be proven to be correct. A follow-up study with a much larger sample size of patients may help prove our original hypothesis as long as it achieves at least 80% power. Conversely, it may actually disprove our hypothesis if the difference between complication rates for oral vs nasal ETT groups is proven to be statistically insignificant. The uncertainty of the results in this preliminary study, due to the small sample size, indicates the necessity for future studies to be performed. Additional research can also help reveal how patient age and maximum inotropic score may act as predictors for ETT complications.

A continuation of this retrospective study will be conducted using additional patients who were admitted to the CICU between October 1st, 2010 and September 30th, 2012. The results and conclusions taken from additional research can then be used to design prospective studies that involve changes in endotracheal intubation protocol and postoperative respiratory care for pediatric cardiac patients.

LIST of JOURNAL ABBREVIATIONS

A.D.A.M.	Animated Dissection of Anatomy for Medicine
AO	Arbeitsgemeinschaft für Osteosynthesefragen

REFERENCES

A.D.A.M. Medical Encyclopedia. (2011). Congenital Heart Disease. *PubMed Health.* Retrieved February 5, 2013, from http://www.ncbi.nlm.nih.gov/pubmedhealth/PMH0002103/

American Thoracic Society. (2005). Mechanical Ventilation. *American Journal of Critical Care Medicine, 172.*

Amitai, A., Sinert, R.H., Conrad S.A., Talavera, F., Blackburn, P., Halamka, J.D., & Mosenifar, Z. (2011). Ventilator Management. *Medscape from WebMD.* Retrieved February 28, 2013, from http://emedicine.medscape.com/article/810126-overview#aw2aab6b4.

Barker, J., Martino, R., Reichardt, B., Hickey, E.J., & Ralph-Edwards, A. (2009). Incidence and Impact of Dysphagia in Patients Receiving Prolonged Endotracheal Intubation After Cardiac Surgery. *Canadian Journal of Surgery, 52*(2), 119-124.

Berry, J.M. (2007). Conventional (Laryngoscopic) Orotracheal and Nasotracheal Intubation (Single Lumen Tube). In J. Benumof & C.A. Hagberg (Eds.), *Benumof's Airway Management: Principles and Practice* (pp. 379-392). Philadelphia, PA: Mosby.

Boston Children's Hospital. (2011). Cardiac ICU. Retrieved January 29, 2013, from http://www.childrenshospital.org/clinicalservices/Site880/main pageS880P1.html.

Chang, A., Hanley, F., Wernovsky, G., & Wessel, D.L. (1998). *Pediatric Cardiac Intensive Care*. Baltimore, MD: Lippincott Williams & Wilkins.

Curley, M. A. Q., Quigley, S.M., & Lin, M. (2003). Pressure Ulcers in Pediatric Intensive Care: Incidence and Associated Factors. *Pediatric Critical Care Medicine 4*(3), 284-290. doi:10.1097/01.PCC.0000075559.55920.36

Davis, D., Barbee, L., & Ririe, D. (1998) Pediatric endotracheal tube selection: A comparison of age-based and height-based criteria. *Journal of the American Association of Nurse Anesthetists 66(*3), 299-303.

Depoix, J.P., Malbezin, S., Videcoq, M., Hazebroucq, J., Barbier-Bohm, G., Gauzit, R., & Desmonts, J.M. (1987) Oral Intubation V. Nasal Intubation in Adult Cardiac Surgery. *British Journal of Anaesthesia 59*, 167-169.

Fletcher, J. (2012). Device related pressure ulcers made easy. *Wounds United*

Kingdom 8(2), 1-4.

Fujioka, M., Oka, K., Kitamura, R., & Yakabe, A. (2008). Upper lip pressure ulcers in very low birth weight infants due to fixation of the endotracheal tube. *Journal of Neonatal Nursing, 14*(6), 207-210. doi:10.1016/j.jnn.2008.07.010

Gaies, M. G., Gurney, J. G., Yen, A. H., Napoli, M. L., Gajarski, R. J., Ohye, R. G., Charpie, J. R., et al. (2010). Vasoactive–inotropic score as a predictor of morbidity and mortality in infants after cardiopulmonary bypass*. *Pediatric Critical Care Medicine*, *11*(2), 234-238. doi:10.1097/PCC.0b013e3181b806fc

Groot, R.I. de, Dekkers, O.M., Herold, I.H.F., Jonge, E. de, & Arbous, M.S. (2011). Risk factors and outcomes after unplanned extubation on the ICU: a case-control study. *Critical care 15*. doi:10.1186/cc9964

Hofer, C. K., Ganter, M., Tucci, M., Klaghofer, R., & Zollinger, A. (2002). How reliable is length□based determination of body weight and tracheal tube size in the paediatric age group? The Broselow tape reconsidered. *British Journal of Anaesthesia*, *88*(2), 283-285. doi:10.1093/bja/88.2.283

Holzapfel, L. (2003). Nasal vs Oral Intubation. *Minerva Anestesiologica, 69(5)*, 348-352.

Intensive Care Coordination and Monitoring Unit. (2011). Endotracheal Tube (ETT or Breathing tube). *New South Wales Government Agency for Clinical Innovation.* Retrieved February 1, 2013, from http://intensivecare.hsnet.nsw.gov.au/endotracheal-tube-ett-or-breathing-tube

Jenkins, K. J., Gauvreau, K., Newburger, J. W., Spray, T. L., Moller, J. H., & Iezzoni, L. I. (2002). Consensus-based method for risk adjustment for surgery for congenital heart disease. *The Journal of Thoracic and Cardiovascular Surgery*, *123*(1), 110-118.

Kabrhel, C., Thomsen, T.W., Setnik, G.S., & Walls, R.M. (2007). Orotracheal Intubation. *The New England Journal Of Medicine, 356*(15), 17-20. doi: 10.1056/NEJMvcm063574

King, B.R., Baker, D.M., Braitman, L.E., Seidl-Friedman, J., & Schreiner, M.S. (1993). Endotracheal tube selection in children: A comparison of four methods. *Annals of Emergency Medicine, 22*(3), 530-534. doi:10.1016/S0196-0644(05)81937-7

Lonnqvist, P.A. (2009). Cuffed or uncuffed tracheal tubes during anaesthesia in infants and small children: time to put the eternal discussion to rest? *British Journal of Anaesthesia, 103*(6), 783-785. doi: 10.1093/bja/aep330

Mariano, E.R., Ramamoorthy, C., Chu, L.F., Chen, M., & Hammer, G.B. (2005). A comparison of three methods for estimating appropriate tracheal tube depth in children. *Pediatric Anesthesia, 15*(10), 846-851. doi: 10.1111/j.1460-9592.2005.01577.x

Martin, J.J. (2011). Intubation and Mechanical Ventilation. *AuroraHealthCare*.org. Retrieved January 31, 2013, from http://www.aurorahealthcare.org/yourhealth/healthgate/getcontent.asp?URLhealthgate=%22112024.html%22.

McCord, S., McElvain, V., Sachdeva, R., Schwartz, P., & Jefferson, L. S. (2004). Risk factors associated with pressure ulcers in the pediatric intensive care unit. *Journal of Wound, Ostomy, and Continence Nursing*, *31*(4), 179-183.

MedlinePlus. (2013, January 24). Endotracheal Intubation. Retrieved January 31, 2013. from http://www.nlm.nih.gov/medlineplus/ency/article/003449.htm.

Meissner, U., Scharf, J., Dötsch, J., & Schroth, M. (2008). Very Early Extubation after Open-Heart Surgery in Children Does Not Influence Cardiac Function. *Pediatric Cardiology*, *29*(2), 317-320. doi:10.1007/s00246-007-9023-0

Nasotracheal Intubation. (n.d.). *AO Foundation*. Retrieved February 9, 2013, from https://www.aofoundation.org/Structure/Pages/default.aspx

National Heart Lung and Blood Institute. (2012, January 9). Heart Failure. *National Institutes of Health*. Retrieved March 6, 2013, from http://www.nhlbi.nih.gov/health/health-topics/topics/hf/

National Heart Lung and Blood Institute. (2011, February 1). Ventilator/Ventilator Support. *National Institutes of Health.* Retrieved January 31, 2013, from http://www.nhlbi.nih.gov/health/health-topics/topics/vent/printall-index.html.

Newth, C. J. L., Rachman, B., Patel, N., & Hammer, J. (2004). The use of cuffed versus uncuffed endotracheal tubes in pediatric intensive care. *The Journal of Pediatrics*, *144*(3), 333-337. doi:10.1016/j.jpeds.2003.12.018

Rigini, N., Boaz, M., Ezri, T., Evron, S., Trigub, D., Jackobashvilli, S., & Izakson, A. (2011). Prompt correction of endotracheal tube positioning after intubation prevents further inappropriate positions. *Journal of Clinical Anesthesia*, *23*(5), 367-371. doi:10.1016/j.jclinane.2010.11.002

Schiffman, G., & Stoppler, M.C. (2007, April 30). Endotracheal Intubation. *MedicineNet*. Retrieved January 29, 2013, from http://www.medicinenet.com/endotracheal_intubation/article.htm.

Shindell, M., Windle, M.L., & Meyers, A.D. (2012). Nasotracheal Intubation. *Medscape from WebMD*. Retrieved February 9, 2013, from http://emedicine.medscape.com/article/1663655-overview.

Silva, P.S.L. da, Carvalho, W.B. de. (2010). Unplanned extubation in pediatric critically ill patients: a systematic review and best practice recommendations. *Pediatric Critical Care Medicine, 11*(2), 287-294. doi:10.1097/PCC.0b013e3181b80951

Skoretz, S. A., Flowers, H. L., & Martino, R. (2010). The Incidence of Dysphagia Following Endotracheal Intubation: A Systematic Review. *Chest Journal*, *137*(3), 665-673. doi:10.1378/chest.09-1823

Souza, N. de, & Carvalho, W. B. de. (2009). Complications of tracheal intubation in pediatrics. *Revista da Associação Médica Brasileira*, *55*(6), 646-650. doi:10.1590/S0104-42302009000600007

Spence, K., & Barr, P. (1999). Nasal versus oral intubation for mechanical ventilation of newborn infants. In The Cochrane Collaboration & K. Spence (Eds.), *Cochrane Database of Systematic Reviews*. Chichester, UK: John Wiley & Sons, Ltd. Retrieved from http://www.tripdatabase.com/doc/1327713-Nasal-versus-oral-intubation-for-mechanical-ventilation-of-newborn-infants#content.

Spiegel, J.E. (2010). Endotracheal Tube Cuffs: Design and Function. *Anesthesiology News Guide to Airway Management*, 51-58.

Sullivan, L.M. (2012). *Essentials of Biostatistics in Public Health.* Sudbury, MA: Jones & Bartlett Learning.

Taylor, C., Subaiya, L., & Corsino, D. (2011). Pediatric Cuffed Endotracheal Tubes: An Evolution of Care. *The Ochsner Journal*, *11*(1), 52-56.

Texas Heart Institute Heart Information Center. (2013). Inotropic Agents. *Texas Heart Institute*. Retrieved February 20, 2013, from http://www.texasheartinstitute.org/HIC/Topics/Meds/inotropic.cfm

Varma, A. (2011). Pediatric cardiac intensive care units: The way forward. *Annals of Pediatric Cardiology, 4*(2), 127-128. doi: 10.4103/0974-2069.84649

Weber, T., Salvi, N., Orliaguet, G., & Wolf, A. (2009). Cuffed vs non-cuffed endotracheal tubes for pediatric anesthesia. *Pediatric Anesthesia*, *19*, 46–54. doi:10.1111/j.1460-9592.2009.02998.x

Yoo, S.-Y., Kim, J.-H., Han, S.-H., & Oh, A.-Y. (2007). A Comparative Study of Endotracheal Tube Positioning Methods in Children: Safety from Neck Movement. *Anesthesia & Analgesia*, *105*(3), 620-625. doi:10.1213/01.ane.0000278149.66027.0b

Zaratkiewicz, S., Teegardin, C., & Whitney, J.D. (2012). Restrospective Review of the Reduction of Oral Pressure Ulcers in Mechanically Ventilated Patients: A Change in Practice. *Critical Care Nursing Quarterly, 35*(3), 247-254. doi:10.1097/CN.0b013e3182542de3

VITA

[redacted]

[redacted] [redacted]

[redacted] [redacted]

[redacted] [redacted]

[redacted]

[redacted]

[redacted] [redacted]

- [redacted]
- [redacted]

[redacted] [redacted]

- [redacted]

[redacted]

[redacted] [redacted]

- [redacted]

[redacted] [redacted]

[redacted] [redacted]

[redacted] [redacted]

[redacted]

[redacted]

[redacted] [redacted]

[redacted] [redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted] [redacted]

[redacted] [redacted]

[redacted]

[redacted]

[redacted]

[redacted] [redacted]

- [redacted]

[redacted] [redacted]

- [redacted]

[redacted] [redacted]

- [redacted]

[redacted] [redacted]

- [redacted]

[redacted]

[redacted] [redacted]

[redacted] [redacted]

[redacted] [redacted]

[redacted] [redacted]

[redacted] [redacted]

[redacted] [redacted]

[redacted]

[redacted]

[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]