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ABSTRACT

Many surgical procedures require general anesthesia in which endotracheal intubation and mechanical ventilation is utilized in order to maintain adequate patient oxygenation. Endotracheal intubation, helps assure delivery of the adequate ventilation and prevention of aspiration of stomach contents into the lungs. In this study endotracheal cuff pressures were measured and correlated to currently utilized cuff inflation techniques. Data was analyzed using descriptive statistics. In 46% of the cases the cuffs were inflated using the pilot balloon palpation technique, 28% were inflated using the set volume technique, and 26% using the minimum occlusive pressure technique. Regardless of the technique used, none of the cuff pressures collected were found to be in the acceptable range of 18 to 25 mmHg. Thirteen percent of cuff pressures were below the minimum value required to prevent aspiration, and 87% of the sample were inflated above the maximum acceptable pressure, risking tracheal ischemia. These results suggest that the currently used techniques expose patients to excessive endotracheal cuff pressures.

Key Words: Endotracheal tubes, Cuff Pressure, Inflation Techniques, Minimal Occlusive Pressure, Set Volume, Pilot Balloon Palpation, Nitrous Oxide.

THE EFFECT OF ENDOTRACHEAL INFLATION TECHNIQUE ON
ENDOTRACHEAL CUFF PRESSURE

by

Capt Mark Lee Evans, BSN

THESIS

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PREFACE

This research was conducted to provide information on the effect of endotracheal cuff inflation techniques, and resulting endotracheal cuff pressures. This study was designed to provide anesthesia providers information to assist with endotracheal cuff related complications.

DEDICATION

I would like to dedicate the creation of this thesis to my wife Rebecca, and my daughters Chelsea and Allison. Without their love, encouragement, and support the attainment of a dream and the creation of this thesis would not have been possible.

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CHAPTER I: INTRODUCTION

This study addresses endotracheal tube cuff induced ischemic complications, and describes currently utilized cuff inflation techniques, and their associated tube cuff pressures.

Many surgical procedures require general anesthesia, in which endotracheal intubation and mechanical ventilation are utilized in order to maintain adequate oxygenation for the patient. Endotracheal intubation helps to prevent aspiration of stomach contents into the lungs, and deliver adequate tidal volumes to the lungs. The technique currently utilized by most anesthesia providers involves inflating an endotracheal tube cuff until it comes in contact with the tracheal wall. This creates a seal between the trachea and the endotracheal tube (see Figure 1).

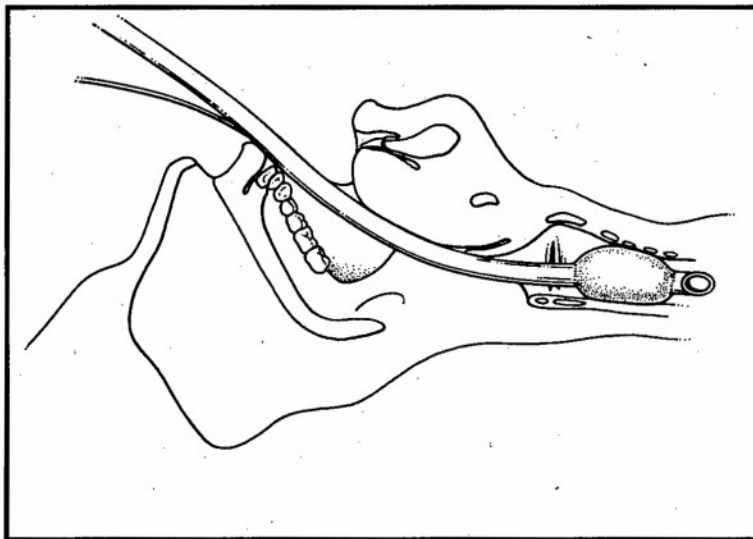


Figure 1.

Endotracheal Tube in Trachea

The cuff effectively seals the airway allowing delivery of predetermined tidal volumes, and helps prevent aspiration of oropharyngeal secretions or stomach contents into the lungs. However, the cuff also exerts pressure on the tracheal wall. If excessive, this pressure can markedly decrease tracheal capillary perfusion, and predispose patients to tracheal necrosis (Seegobin & Hasselt, 1984). In this chapter the types of endotracheal tubes are presented, followed by effects of nitrous oxide and current techniques to minimize the risk of over inflation.

Background

The ideal cuffed endotracheal tube should provide an airway seal that would allow positive pressure ventilation, protect the airway from aspiration of gastric contents, and avoid traumatizing the trachea (O'Donnell, 1995). Although not all risks of trachea damage or aspiration can be eliminated, they can be reduced.

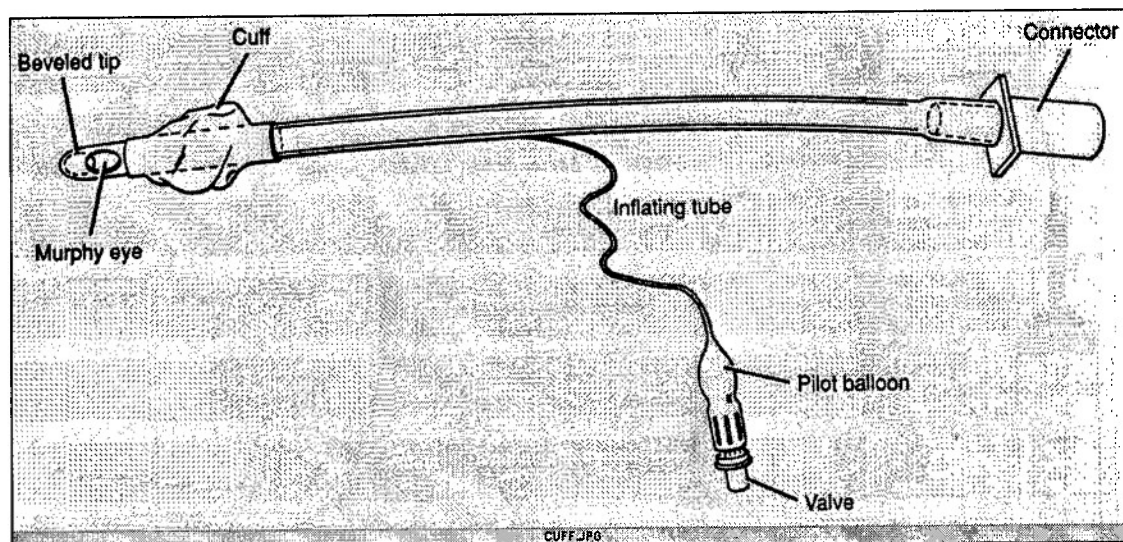


Figure 2.

Endotracheal Tube

Tracheal ischemic complications, which range from mild sore throat to tracheoesophageal fistulas, are associated with excessive pressures exerted by an endotracheal tube cuff pressure on the tracheal mucosa (Guyton, Barlow, & Bresselievre, 1997). A 1984 study conducted by Seegorbin and Hasselt demonstrated that cuff pressures greater than 25 mm Hg cause tracheal ischemia due to occlusion of mucosal capillary blood flow. If tracheal wall pressure remains above 50 mm Hg for 15 minutes, destruction of columnar epithelium occurs.

Types of Endotracheal tubes.

Early endotracheal tubes were made of a stiff rubber, requiring high pressure to inflate, and utilized low cuff volumes. These low-volume, high-pressure cuffs tended to

inflate in a non-circular fashion because the thickness of the cuff wall is usually non-uniform. This caused endotracheal tubes to be displaced away from the center of the trachea. The tip of the tube would often come in contact with the trachea, producing serious damage during tidal breathing. A second problem with these early endotracheal tubes was the fact that the cross section of the trachea is not always circular. If the trachea is not circular, low-volume, high-pressure cuffs must reshape the cross-section of the trachea to a circular shape before a seal can be created. As a result, low-volume, high-pressure endotracheal tube cuffs commonly created cuff to trachea pressures of greater than 100 mm Hg, even when inflated to the minimum occlusive pressure. This caused tracheal ischemia, and necrosis in an estimated 5% to 20% of patients (Guyton et al, 1997).

In an effort to reduce cuff induced tracheal ischemia, an improved cuff design was introduced in the late 1960s. High-volume, low-pressure cuffs were designed to have a large resting diameter and a thin wall. With the diameter of the cuff being larger than the trachea, inflation of the high volume ultra-thin cuff conformed passively to tracheal contours, resulting in large areas of contact and required lower pressures to provide a seal (see Figure 2) . In addition, when compared to high-pressure cuffs, inflation beyond that required to create an adequate seal caused smaller increases in tracheal wall pressure. The high-

volume, low-pressure cuff markedly reduced the incidence of tracheal sequelae related to endotracheal cuff pressure (O'Donnell, 1995).

Effect of Nitrous Oxide.

Nitrous oxide has the ability to diffuse into the cuff of an endotracheal tube 34 times faster than nitrogen can diffuse out, causing an increase of the cuff volume and intracuff pressure (Patel, Oh, & Epstein, 1983). This process is enhanced with increased exposure time to nitrous oxide, decreased cuff thickness, and increased inspired partial pressure of nitrous oxide. Increasing the thickness of the cuff material would reduce the amount of nitrous oxide diffusion. However, a thick non-compliant cuff will not conform well to the contour of the trachea, leading to uneven pressure and formation of channels, increasing the risk of aspiration. In 1995 O'Donnell demonstrated that nitrous oxide use can raise a properly inflated endotracheal cuff to a pressure sufficient to cause tracheal ischemia (greater than 25 mm Hg) in as little as eight minutes (median time).

Many techniques and design changes have been developed to minimize the effect of nitrous oxide on endotracheal cuff pressure. The endotracheal cuff itself can be inflated using nitrous oxide, reducing over-inflation while using nitrous oxide during the case. However, when nitrous oxide is discontinued the cuff can deflate effectively increasing the

risk of aspiration. Another suggested technique is inflating the cuff with a mixture of nitrous oxide and air. The problem with this is that the cuff may deflate or increase in pressure depending on the concentration of nitrous oxide used throughout the case (Revenas & Lindholm, 1976).

Endotracheal tubes have been introduced that had large external reservoirs (pilot balloon) allowing some of the nitrous oxide to diffuse into the environment, thus preventing an increase in the endotracheal tube cuff pressure. The problem with the nitrous oxide diffusing out of the external reservoir was that it increased the nitrous oxide levels in the anesthetists' breathing area, possibly above acceptable OSHA standards (Fill, Dosch, & Bruni, 1994). Mechanical devices have been developed to maintain constant cuff pressure, in addition to controlling the effect of nitrous oxide on endotracheal cuff pressure. These devices have not become popular because of cost and the fact that they can cause brief increases in endotracheal cuff pressures during coughing and positive pressure ventilation (Morris & Latta, 1985). In the clinical setting few of these devices or techniques are used by anesthesia providers.

Current techniques to minimize the risk of over
inflation.

Introduction of the high-volume, low-pressure endotracheal cuffs has reduced the incidence and severity of endotracheal tube cuff induced complications (Crawley &

Cross, 1975). However, over inflation of any cuff can markedly increase intracuff pressure. Inflation of the endotracheal cuff with 2 to 3 additional milliliters of air beyond that required for adequate seal can result in an intracuff pressure differences of greater than 30 mm Hg. A number of techniques have been developed to minimize the risk of over inflation of the endotracheal tube cuff. The most commonly utilized techniques include: Inflation with a predetermined volume of air, pilot balloon palpation by anesthesia provider, utilization of a minimal leak technique, minimal occlusive volume technique, and direct intracuff pressure measurement.

Providers who use a predetermined volume technique for inflating the endotracheal tube cuff, inject the cuff with a predetermined volume of air, such as 10 cubic centimeters (cc's). The difficulty with this is the anesthesia provider can not determine the exact amount of pressure a predetermined volume of air will exert on the trachea, it could be too low risking aspiration, or too high inducing tracheal damage.

The palpation technique entails injecting air into the cuff until the pilot balloon becomes firm to fingertip palpation. A study in 1990 demonstrated low accuracy for finger palpation estimation of cuff pressure, with no effect of provider experience on accuracy (Fernandez, Blanch, Mancebo, Bonsoms, & Artigas, 1990).

With the minimal leak technique, anesthesia providers

inject air into the cuff until a seal is achieved, then a small volume of air is removed until a small leak is noted at peak inspiration. The disadvantages of this technique include the fact that the cuff tends to move in the trachea and can cause tracheal damage. Also, by the cuff moving in the trachea there is an increase risk of aspiration (O'Donnell, 1995).

The minimal occlusive volume technique, a variation of the minimal leak technique, is when the cuff is inflated until a seal is obtained at peak inspiration, then a small volume of air is removed until a leak is heard at that point the cuff is inflated with the least amount of air to eliminate the leak. Although this technique reduces movement of the endotracheal tube and provides a lower risk of aspiration, one study demonstrated that using this technique is associated with up to a 38% incidence of aspiration (Benard et al, 1979).

One of the most accurate techniques of sealing the endotracheal tube cuff is by using direct intracuff pressure measurement as an indicator of adequate seal. Using this technique a manometer is connected to the pilot balloon after inflation and cuff pressures are adjusted to appropriate levels. The major disadvantage in using this technique is the lack of readily available manometers for anesthesia providers (O'Donnell, 1995).

Rationale and Significance of the Problem

Many devices and techniques are available to certified registered nurse anesthetists (CRNAs) to prevent or minimize tracheal ischemic complications induced by endotracheal tube cuff pressures. CRNAs have a professional obligation to provide the safest anesthesia possible. In a recent study involving 44 patients, 43% of the endotracheal cuffs were under-inflated (increasing patient risk for aspiration), 35% were over-inflated (increasing potential risk of ischemic complications), and only 19% were inflated to ideal cuff pressure (O'Donnell, 1995). This disparity in safe cuff pressures increases the risk for patient morbidity, and demonstrates the need for a comparison of anesthesia provider endotracheal cuff inflation techniques.

Purpose of the Study/Problem

Problem

Professional literature abounds with scientific studies indicating that over inflation of the endotracheal cuff is the leading cause of cuff induced complications. Because there are many techniques for inflating a endotracheal cuff, used by anesthesia providers, there is a need for baseline knowledge as to what techniques are used and what are the resulting endotracheal cuff pressures from each technique.

Purpose

The purpose of this study is to compare the currently

accepted techniques for inflating and monitoring endotracheal cuffs, and to describe cuff pressures associated with each technique.

Research Questions

The following research questions have been identified:

1. What endotracheal cuff inflation techniques do anesthesia providers utilize in their practice?
2. What is the associated endotracheal tube cuff pressure with each inflation technique utilized?

Conceptual/Theoretical Framework

The conceptual framework utilized in this study is Virginia Henderson's theory of nursing and the 14 components of nursing care. Virginia Henderson presented her definition of nursing before concepts and theories of nursing became prevalent. Her intent was to identify the specific functions the nurse performs rather than to describe the theoretical basis of nursing practice. Henderson's concept of nursing and the 14 components of basic nursing are logical, simple, and self-explanatory, making them an easy guide for nursing practice (George, 1990).

According to Henderson:

The unique function of the nurse is to assist the individual, sick or well, in the performance of those activities contributing to health or its recovery (or

peaceful death) that he would perform unaided if he had the necessary strength, will, or knowledge. And to do this in such a way as to help him gain independence as rapidly as possible" (George, 1990, pg. 64).

Henderson considered other philosophies in developing her concept of nursing including biophysiology, culture, interaction-communication, and fundamental human needs (George, 1990).

Henderson identified 14 basic needs of the patient. The nurse, as seen by Henderson, assesses the patient's ability to perform these tasks independently. She places emphasis on the different relationships that develop between nurses and patients. Nurse-patient relationships can range from dependent to independent depending on patients' needs and the conditions or pathological states that alter them. The 14 basic needs of patients include:

1. Breathe normally.
2. Eat and drink adequately.
3. Eliminate body wastes.
4. Move and maintain desirable position.
5. Sleep and rest.
6. Select suitable clothes- dress and undress.
7. Maintain body temperature within normal range by adjusting clothing and modifying the environment.
8. Keep the body clean and well groomed and protect the integument.
9. Avoid dangers in the environment and avoid injuring

others.

10. Communicate with others in expressing emotions, needs, fears, or opinions.
11. Worship according to one's faith.
12. Work in such a way that there is a sense of accomplishment.
13. Play or participate in various forms of recreation.
14. Learn, discover, or satisfy the curiosity that leads to normal development and health and use the available health facilities.

While patients are anesthetized they are unable to attend to their own basic needs, making it the nurse anesthetist's role to act as an external regulator of the patients environment. In the act of placing an endotracheal tube and utilizing mechanical ventilation, the nurse anesthetist is ensuring the patient that he or she has a patent airway as well as adequate oxygenation during the surgical procedure. The nurse anesthetist must also ensure that endotracheal cuff pressure is sufficient to maintain an adequate tracheal seal while minimizing complications of cuff induced ischemia and aspiration. According to Henderson, patients who are unable to control their environment must be assisted in avoiding dangers in the environment. Since patients lose this ability during anesthesia, it becomes the nurse anesthetist's responsibility to ensure patient safety by being an external regulator of the patient's environment. The nurse

anesthetist can decrease the likelihood that the endotracheal tube cuff will induce tracheal ischemia by ensuring that cuffs are inflated utilizing the best inflation technique (George, 1990).

Definitions-Conceptual and Operational

The definition for Henderson's concept of a nurse as an external regulator of environment requires the nurse to act as an agent for the incapacitated patient. The nurse modifies the environment to provide for the patient's safety.

The operational definition for the nurse as an external regulator of the patient's environment is regulating the patient's environment by utilizing inflation techniques to prevent endotracheal cuff pressures from exceeding 25 mm Hg. The anesthesia provider techniques include:

1. Inflation with a predetermined volume of air.
2. Pilot balloon palpation by anesthesia provider.
3. Minimal leak technique.
4. Minimal occlusive volume technique.
5. Direct intracuff pressure measurement with a manometer.

The operational definition of an anesthesia provider: Certified Registered Nurse Anesthetists (CRNA), Student Registered Nurse Anesthetists (SRNA), and Anesthesiologists.

The operational definition for associated pressure of endotracheal tube cuffs: A Posey Cufflator manometer is

attached to the pilot balloon of the endotracheal tube cuff, and a pressure reading is obtained in millimeters of mercury.

Assumptions

1. Nitrous oxide diffusion into the endotracheal tube cuff will equilibrate after 30 minutes.
2. The patients position will not change in a way that will effect endotracheal tube cuff pressure.
3. Anesthesia providers will record the inflation technique they utilized.

Limitations

Hawthorn effect: Because the data was collected at one institution over a period of time it is possible the anesthesia providers may have changed their practice because they were participating in a study (Burns, & Grove, 1997).

There may be disparity between the actual endotracheal inflation techniques utilized, and the technique anesthesia providers report they utilized.

CHAPTER II: REVIEW OF LITERATURE

Introduction

An extensive amount of literature has been published regarding endotracheal cuff induced complications. Early literature addresses the advantages of using low-pressure, high-volume cuffs over the use of high-pressure, low-volume cuffs. Literature after the general acceptance of low-pressure cuffs identified complications associated with the low-pressure cuffs. The following review will discuss the history of the endotracheal tube, and attempt to describe important studies related to endotracheal tube cuff induced ischemia, aspiration, and the factors that can affect these complications i.e. nitrous oxide, and cuff inflation techniques.

History

In the late 1840s, anesthesia providers began placing tubes orally into the larynx during anesthetic emergencies to protect the patient's airway from aspiration of gastric contents. These early rigid tubes were placed in the larynx, and gauze was packed around them to prevent aspiration of blood and debris.

In 1869, Friedrich Trendelenburg developed a device to deliver anesthetics to the lungs through the trachea by means of a soft tube maintained in place with the inflation of a balloon surrounding the tube. The balloon was found to

be superior to gauze at preventing aspiration.

In 1880, William Macewen developed and promoted a technique of intubating the trachea orally, eliminating the need for a tracheotomy in many head and neck procedures. In 1893, Victor Eisenmenger constructed an apparatus which consisted of a wide bore semi-rigid endotracheal tube with an inflatable cuff modeled after that of Trendelenburg's (Duncum, 1947).

The combined work of Joseph O'Dyer and George Fell, led to the development of an artificial respiration apparatus. Surgeons quickly recognized the benefit of these devices; it gave them the ability to perform thoracic surgery. Prior to development of these devices few thoracic procedures were performed because pneumothorax led to poor outcomes. The advantages of endotracheal anesthesia and the fact positive pressure so closely approximates physiological respiration supported its use which endures to the present day (Keyes, 1978).

Ischemia

Som, Khilnani, Keller, and Som (1972) described the pathology of endotracheal tube cuff induced ischemia. The cuff injury results from progressive ischemic pressure necrosis of the mucosa over the stiff cartilaginous rings. The blood supply of the trachea is derived primarily from the inferior thyroid artery, which sends branches transversely in the fibromuscular intercartilaginous

membrane. Vertical channels connect the horizontal vessels. These vertical vessels, interposed between the rigid cartilage externally and the mucosal surface internally, are especially vulnerable to early occlusion by the inflated cuff. With sustained pressure, the transverse arteries in the intercartilaginous membrane may be compressed. For these reasons, ischemia initially involves the antero-lateral two-thirds of the tracheal mucosa covering unyielding cartilage. The posterior membranous tracheal wall is corrugated and distensible. This common wall with the esophagus has an abundant vascular network both from tracheal and esophageal vessels. These vessels contained between pliable mucosal surfaces are less readily occluded by distention of the cuff. These anatomic features explain the less frequent or late involvement of the posterior tracheal wall in stenotic cuff lesions. With continuation of excessive pressure, necrosis of all layers of the wall, including the cartilage, can ensue (Som et al, 1972).

Tracheal ischemic complications at the cuff site were a major risk when low-volume, high-pressure cuffs were used. Since the trachea is not circular the low-volume, high-pressure cuffs must reshape the cross-section of the trachea roughly to a circle before a seal is created. As a result, very high pressures are created.

Tracheal tissue is at risk for injury when the cuff to tracheal wall tension exceeds mucosal capillary perfusion, which is usually 30 mm Hg (Ganong, 1973). If tracheal wall

pressure remains above 50 mm Hg for 15 minutes, destruction of columnar epithelium occurs. Inflammation and histologic changes occur within 24-48 hours. If tracheal wall pressure continues to be elevated deep ulcerations with exposure of cartilage occur within one week. The most prevalent hazard associated with high-pressure cuffs is the tendency to exert dangerously high pressure on the tracheal wall secondary to over-inflation (Demers & Saklad, 1977). Such complications result because pressures exerted by the cuff exceeds tracheal capillary perfusion pressure, resulting in minimal or absent blood flow at the point of the cuff. Although perfusion pressure of tracheal tissue in a normotensive person has been estimated at about 30 mm Hg (Ganong, 1973), many critically ill patients are not hemodynamically stable and thus probably do not have normal perfusion pressures. Therefore, the number of patients who experienced complications was large.

Because of the many complications, efforts were undertaken to design a low-pressure cuff, which would seal the trachea at low intra-cuff pressures. Low-pressure cuffs have a large resting diameter and are thin walled, resulting in a larger area of contact with the trachea. The major advantage of this cuff is that its ultrathin wall drapes the irregularities of the trachea and exerts a fairly even pressure on the tracheal wall. In addition, intracuff - pressure closely approximates that on the wall of the trachea until the cuff wall is stretched. Also, in

comparison with high-pressure cuffs, inflation beyond seal causes a smaller increase in tracheal wall pressure (Nordin, 1977).

Crawley and Cross (1975) designed a study to determine if pressures exerted by low-pressure cuffs changed in a dynamic manner or remained static during mechanical ventilation. Before the ventilator initiated the inspiratory phase, airway pressure was at atmospheric pressure. As the ventilator started to inflate the lungs, airway pressure increased. As the ventilator pressure continued to increase, airway pressure ultimately exceeded intracuff pressure. It then exerted a positive pressure on the front face of the cuff. If the cuff was a floppy high-volume cuff, it was unable to resist this pressure and moved back. This had the effect of reducing cuff volume, and, as it was a closed system, increased the pressure in the cuff. Equilibrium was re-established when the intra-cuff pressure was equal to airway pressure. Similarly, during the expiratory phase cuff pressure decreased until the resting cuff pressure was reached (Crawley & Cross, 1975).

Intracuff pressure therefore followed airway pressure during that part of the inspiratory cycle when airway pressure was greater than the resting intracuff pressure. As a consequence, blood supply to the tracheal mucosa was interfered with as little as possible. The pressure applied to tracheal mucosa at the cuff interface was no more than that applied to the trachea below the cuff. The work of

Crawley and Cross (1975) suggested that high volume, low-pressure cuffs can effectively seal the trachea during the time period when airway pressures change in response to change in ventilator pressure.

Dorbin and Canfield (1977) compared the pressure exerted by inflated endotracheal tube cuffs against the tracheal mucosa and determined the effect that the mucosal pressure had upon tracheal wall blood flow of anesthetized dogs. This study found that low-volume, high-pressure cuffs required 320 to 360 mm Hg of pressure to seal within the trachea, while compliant low-pressure, high-volume cuffs required 20-40 mm Hg of pressure to achieve seal. The high-pressure, low-volume cuffs generated mucosal pressures of 147 to 205 mm Hg at seal while the low-pressure, high-volume cuffs generated only 17 to 30 mm Hg mucosal pressures at seal. This showed that not only do low-pressure, high-volume cuffs require less pressure to seal, but not all of the pressure in the cuff is exerted against the tracheal wall.

Dorbin and Canfield (1977) also measured tracheal blood flow when the endotracheal tube cuffs were inflated to seal in the trachea, and found that the low-volume, high-pressure cuffs reduced mucosal blood flow from 20% to 40%. Low-pressure, high volume cuffs reduced mucosal blood flow only by 2% when inflated to seal in the trachea.

The in vivo experiment showed that increased mucosal pressure decreases tracheal wall blood flow. This results from a reduction in caliber of the tracheal blood vessels.

The authors do warn that even though the study results favored the low-pressure, high-volume cuffs, each step increase in cuff pressure was associated with a synchronous increase in mucosal pressure. Since the compliant low-pressure, high volume cuffs offer little resistance to inflation, over-inflation of these cuffs could lead to a significant reduction in mucosal blood flow (Dorbin & Canfeild, 1977).

A similar study performed by Tonnesen, Vereen, and Arens (1981) concluded that the cuff pressure always exceeded wall pressure, and that if the cuff pressure is measured routinely and maintained at a level below 20-30 mm Hg, wall pressure will be below the theoretical capillary pressure (30 mm Hg) in the tracheal mucosa.

A 1984 study performed by Seegobin and Hasselt confirmed the effect of lateral wall pressure on human mucosal blood flow; earlier studies were performed using animals or model tracheas. This study used fiberoptic bronchoscopes to determine mucosal blood flow while varying the cuff inflation pressure. The study involved 40 normotensive (mean arteriole pressure of 85 mm Hg) patients undergoing surgical procedures. Seegobin and Hassle (1884) found that above 22 mm Hg mucosal capillary blood flow was compromised, and above 37 mm Hg mucosal capillary blow flow was occluded, and above 75 mm Hg flow along mucosal arterioles was intermittent. The study concluded that while large volume cuffs may achieve clinical seal at low

intracuff pressure, inflation beyond the point of seal, with small increments of air, readily generates excessive intracuff pressure, and thus lateral wall pressure (Seegobin & Hasslet, 1984).

A study of acute complications of endotracheal intubation by Rashkin (1986) showed the most serious complications (tracheomalacia, posterior pharyngeal abscess) were associated with persistently elevated cuff pressures, defined as pressures greater than 25 mm Hg. In this study, nine of 29 patients had cuff pressure recorded as more than 25 mm Hg at least once, and five patients had elevated cuff pressures on three or more occasions. In the later group, two patients (40%) had tracheolaryngeal complications. Rashkin's data documented that low-pressure cuffs still have potential for damaging the tracheal mucosa, since over inflation of any cuff can markedly increase intracuff pressure.

Aspiration

Cottrell, Bernard, Sivakumaran, Patel, and Turndorf (1977) attempted to determine the minimum intracuff pressure needed to prevent aspiration around high-volume, low-pressure cuffs. After standardized induction of anesthesia of 12 patients, two types of cuffs were inflated with air. Low-volume, high-pressure cuffs were inflated to minimal occluding volume and high-volume, low-pressure cuffs to an intracuff pressure of 15 or 18 torr, or to minimal occlusive

volume. Ten ml's of blue dye was placed in the posterior oropharynx under direct vision to achieve a column of dye 5-10 cm above the larynx. At the end of surgery, bronchoscopy was done to check if there was any dye distal to the cuff. Dye aspiration did not occur in the 12 intubated patients with low-volume, high-pressure cuffed tubes filled to minimal occlusive volume. Lateral wall pressures for these patients were above 35 mm Hg. Also, no aspiration occurred in 20 spontaneously breathing and 21 mechanical ventilated patients intubated with high-volume, low-pressure cuffed tubes when intracuff pressure was controlled at 18 torr. In contrast, seven of 12 patients aspirated dye when intracuff pressure in high-volume, low-pressure cuffs was maintained at 15 torr. Six of 11 patients intubated with high-volume, low-pressure cuffed tubes filled to minimal occlusive aspirated. No information was given in regard to whether minimal occlusive volume was greater or equal to 18 torr. The authors concluded that aspiration protection might be achieved utilizing high-volume, low-pressure cuffed tracheal tubes and advocated careful regulation of intracuff pressure to at least 18 torr.

A study of 133 adult patients by Bernard et al, (1979) reported similar findings. The authors noted that cuff diameter, wall thickness and intracuff pressure determine the number and size of folds lying against the tracheal mucosa and consequently the potential sites through which liquids may travel down the trachea. They suggested using

endotracheal tubes with large-diameter, thin-walled cuffs, whenever possible. Controlling intracuff pressure in large diameter thin-walled cuffs between 19 and 26 mm Hg should prevent significant aspiration and still allow adequate capillary mucosal blood flow. This can be done with a pressure-regulating valve or by periodically measuring intracuff pressure and adjusting intracuff volume.

Nitrous Oxide Diffusion

Nitrous oxide is 34 times more soluble in blood than nitrogen. Meaning that nitrous oxide can diffuse into an air filled space 34 time faster than nitrogen can diffuse out, resulting in the volume of the air filled space increasing.

Stanley (1973) demonstrated that nitrous oxide would diffuse into an endotracheal tube cuff, and increase volume proportional to the time exposed, and the concentration of nitrous oxide.

Revanas and Linholm (1976) demonstrated that in patients administered 70% nitrous oxide the volume of the endotracheal tube can increase 3.3 times the original volume.

Patel et al, (1983) tested endotracheal tubes exposed to 70% nitrous oxide and 30% oxygen and varying temperatures to determine which had the greatest effect in the change in volume of the cuff. The study found that 76-88% of the volume change resulted from inward diffusion of nitrous oxide, and 2-10% was due to oxygen. Temperature played a

minimal role in the change in volume of the cuff.

A study performed by O'Donnell in 1995 demonstrated that 50-70% nitrous oxide could raise the intracuff pressure from 19 mm Hg to greater than 25 mm Hg in a median time of eight minutes. This demonstrates the need for vigilance in assessing the endotracheal cuff pressure frequently to prevent nitrous oxide induced volume changes.

Inflation Techniques

In 1990 Fernandez and colleagues identified palpation of the pilot balloon on the endotracheal tube to be one of the most common methods to estimate cuff pressure. This study tested 20 intensive care personnel's ability to estimate cuff pressure based on pilot balloon palpation. 69% were able to detect if the cuff was over-inflated, 58% were able to identify that the cuff was inflated to acceptable pressures, and 73% were able to detect if the cuff was under-inflated. The study concluded that manual estimation is an unacceptable method to monitor cuff pressure, mostly because of the physical properties of the tubes and the variability of the observers. Reliable systems of measurement should be used to avoid deleterious effects due to abnormal cuff pressures.

O'Donnell (1995) determined that when minimal occlusive volume technique was used, 80% of the patients were at risk for aspiration (cuff pressure below 18 mm Hg), 7% were at risk for tracheal ischemia (cuff pressure greater than 25 mm

Hg), and 13% were in the ideal range. When the palpation technique was utilized 22% of the patients were at risk for aspiration, 45% were at risk for tracheal ischemia, and 33% were in the ideal range. When the predetermined volume technique was utilized 25% of the patients were at risk for aspiration, 60% were at risk for tracheal ischemia, and 15 % were in the ideal range. This study demonstrated that current cuff inflation techniques are not adequate to prevent cuff-induced complications.

Summary

The main advantage of using low-pressure, high-volume cuffs are that they offer protection from cuff induced complications. However, there are still problems associated with their use. Over-inflation of the cuff can cause ischemic complications, and under-inflation places patients at risk for aspiration. This study attempted to identify an inflation technique that consistently provides a cuff pressure between 18 mm Hg and 25 mm Hg, in order to minimize cuff induced complications.

CHAPTER III: METHODOLOGY

Introduction

This study was a comparative descriptive study (Burns, & Grove, 1997). Data was collected to compare the type of inflation techniques anesthesia providers use, and the associated cuff pressures with each.

Setting

The study took place at a 350 bed community hospital in a northeastern city. The anesthesia department supports 8,000 cases a year. Of the total number of cases, 40% are general anesthesia, 40% are monitored anesthesia care (MAC), and 20% are regional anesthesia. The anesthesia department has five anesthesiologists and eleven Certified Registered Nurse Anesthetists (CRNA's). There are also a variable number of Student Registered Nurse Anesthetists (SRNA's) training at the facility. No anesthesiology resident physicians are trained at this facility.

Sample

The subjects were chosen from a convenience sample of patients scheduled for general surgery procedures during a two month collection period. The subjects were informed of the study the morning of the scheduled surgery, risks and benefits were explained, and informed consent were obtained

from those who volunteered. The sample size of 50 subjects was determined to have a power of .80 using a two tailed test with and an alpha level of .05 (Burns & Grove, 1997). The sample consisted of adult general surgery patients, scheduled for surgical procedures of at least thirty minutes in duration. This study did not include patients requiring surgical procedures where the head and neck are positioned out of a neutral alignment. Subjects were not included if the anesthesia provider described the intubation as difficult on the anesthesia record, or if more than one attempt at intubation was required.

Measurement

Endotracheal cuff pressures were measured 30 minutes after intubation. This 30 minute delay allowed for the cuff volumes to equilibrate, for those procedures utilizing nitrous oxide. The pressure in the endotracheal tube cuffs were measured using a calibrated Posey manometer, accurate within the range of (-40 to +80) centimeters of water.

Additional demographic data collected include:

1. Type of provider
 - a. Anesthesiologist
 - b. Certified Registered Nurse Anesthetist
 - c. Student Registered Nurse Anesthetist
2. Type of surgical procedure
3. Type of endotracheal tube
4. Identifying if nitrous oxide was used

5. The resulting endotracheal cuff pressure

Protection of Human Rights

Approval by the Institutional Review Board (IRB) was obtained. A patient consent form was obtained from each patient prior to inclusion in the study.

Participation in this study was voluntary, and each of the subjects had the opportunity to withdraw from the study at any time. Patients were not identified thereby maintaining confidentiality. This study measured existing endotracheal cuff pressures, no modification to the pressure was performed.

Plan for Data Analysis

Data obtained from this study was analyzed using descriptive statistics. Analysis of variables was used to compare inflation techniques. The Statistical Package for the Social Sciences (SPSS), version 8.0 for Windows 95, was utilized for processing and analysis of the data.

CHAPTER IV: PRESENTATION, ANALYSIS AND INTERPRETATION OF
DATA

This study was conducted, to determine what techniques anesthesia providers are utilizing to inflate the endotracheal cuffs, and which technique is best at preventing endotracheal cuff related complications.

Sample

Samples were collected from 39 adult patients undergoing general anesthesia, for surgical procedures lasting one hour or longer. Endotracheal cuff pressures were measured using a calibrated Posey manometer. All measurements were obtained by the investigator. Anesthesia providers were not informed about patient enrollment into the study, however many of them observed patients signing consent documents. However, this did not appear to influence the data collected (see Table 1).

Results

Three endotracheal cuff inflation techniques were found to be used by anesthesia providers. Forty-six percent of the cuffs were inflated using the pilot balloon palpation technique, 28% were inflated using the set volume technique, and 26% using the minimum occlusive pressure technique.

None of the cuff pressures collected were found to be in the acceptable range of eighteen to twenty-five mmHg. This is surprising given the fact that many of the

anesthesia providers were aware of the nature of the study, and that their patients were being enrolled.

Thirteen percent of the cuff pressures were below the minimum value required to prevent aspiration; and 87% were inflated above twenty-five mmHg, placing patients at risk for tracheal ischemia; 62% of the cuffs were inflated above thirty-seven mmHg, which could occlude mucosal capillaries; and 23% were inflated above seventy-five mmHg which can occlude mucosal arterioles (Seegobin & Hasslet, 1984).

Among the minimum occlusive pressure sample, 20% were at risk for aspiration (with cuff pressures less than eighteen mmHg); 80% were at risk for ischemia (with cuff pressures greater than twenty-five mmHg). In the "set volume group" 9% were at risk for aspiration, and 91% were at risk for ischemia. In the pilot balloon palpation group 11% were at risk for aspiration, and 89% were at risk for ischemia.

Sixty-nine percent of the cuffs were inflated by CRNAs, and 31% by Anesthesiologists. Among the minimum occlusive group 50% of the providers were CRNAs, and 50% anesthesiologists. For the preset volume group, 9% of the providers were anesthesiologists and 91% were CRNAs. In the pilot balloon palpation group, 33% were anesthesiologists and 67% were CRNAs.

In 74% of the cases, nitrous oxide was used, for this reason all of the samples were collected at least thirty minutes after the procedure had begun in order to allow the endotracheal cuff pressure to equilibrate. The mean cuff

pressure in cases in which nitrous oxide was used had a mean of 10.2 mmHg higher cuff pressures in cases which nitrous oxide was not used.

The minimal occlusive technique had a mean cuff pressure of 47.5 mmHg and a standard deviation of 28.6. The set volume technique had a mean cuff pressure of 61.8 mmHg with a standard deviation of 23.9. The pilot balloon palpation technique had a mean cuff pressure of 67.1 mmHg and a standard deviation of 22.3.

Table 1.

Endotracheal Cuff Pressure Data by Inflation Technique

Technique	n	Mean	Standard Deviation
Min Occlusive Pressure	10	47.5	28.7
Set Volume	11	59.8	23.6
Pilot Balloon Palpation	18	54.9	26.1

Each endotracheal inflation technique was compared to the others in a two-tailed t-test to determine if there was statistical significance between the mean cuff pressures. There was no statistical significance found when each of the techniques were compared against the others (see Table 2).

Table 2.

Endotracheal Inflation Technique Comparison

Technique Comparison	Significance
Pair 1 Minimum Occlusive Pressure & Set Volume	.605
Pair 2 Set Volume & Pilot Balloon Palpation	.918
Pair 3 Minimum Occlusive Pressure & Pilot Balloon Palpation	.185

In cases in which nitrous oxide was used the mean cuff pressures were 57.1 mmHg, while in the cases where nitrous was not used the mean cuff pressure was 46.9 mmHg (see Table 3). There was no statistical significance found between the two groups using a t-test (significance of .701).

Table 3.**Cases Using and Not Using Nitrous Oxide**

Group	n	Mean	Std Deviation
Nitrous Oxide	29	57.1	26.3
No Nitrous	10	46.9	23.7

CHAPTER V: SUMMARY, CONCLUSIONS AND RECOMMENDATIONS.

Many surgical procedures require general anesthesia, in which endotracheal intubation is used in order to maintain adequate ventilation for patients. Endotracheal intubation helps in the prevention of aspiration of stomach contents into the lungs, and delivery of the adequate tidal volumes. Currently this involves inflating an endotracheal tube cuff with air until it comes in contact with the tracheal wall, which creates a seal between the trachea and the endotracheal tube. However, the cuff also exerts pressure on the tracheal wall. If excessive, this pressure can markedly decrease tracheal capillary perfusion, and predispose patients to tracheal necrosis (Seegobin & Hasselt, 1984).

The ideal cuffed endotracheal tube should provide an airway seal that would allow positive pressure ventilation, protect the airway from aspiration of gastric contents, and avoid traumatizing the trachea (O'Donnell, 1995). Although not all risk of trachea damage or aspiration can be eliminated, they can be reduced.

A number of techniques have been developed to minimize the risk of over inflation of the endotracheal tube cuff. The most commonly used techniques are: Inflation with a predetermined volume of air, pilot balloon palpation by anesthesia provider, utilization of a minimal leak technique, minimal occlusive volume technique, and direct intracuff pressure measurement.

While patients are anesthetized they are unable to

attend to their basic needs, making it necessary that nurse anesthetists act as external regulators of their environment. The nurse anesthetists must ensure that endotracheal cuff pressures are sufficient to maintain an adequate tracheal seal while minimizing complications of cuff induced ischemia and aspiration. According to Henderson, patients who are unable to control their environment must be assisted in avoiding dangers in the environment. Since patients lose this ability during anesthesia, it becomes the responsibility of the nurse anesthetist to ensure patient safety by being an external regulator of the patient's environment. Nurse anesthetists can decrease the likelihood that endotracheal tube cuff will induce tracheal ischemia by ensuring that cuffs are inflated using the best inflation technique (George, 1990).

Subjects in this study were chosen from a convenience sample scheduled for general surgery during a two month data collection period. Subjects were informed of the study the morning of the scheduled surgery, risks and benefits were explained, and informed consent obtained. The sample consisted of adult general surgery patients, scheduled for surgical procedures of at least thirty minutes in duration. Patients requiring surgical procedures where the head and neck are positioned out of a neutral alignment were not included. Subjects were not included if the anesthesia provider described the intubation as difficult on the anesthesia record, or if more than one attempt at intubation

was required (trauma or edema may affect cuff pressures).

Endotracheal cuff pressures were measured 30 minutes after intubation. This 30 minute delay allowed for the cuff volumes to equilibrate, when nitrous oxide was used. The pressure in the endotracheal tube cuffs were measured using a calibrated Posey manometer, accurate within the range of (-40 to +80) centimeters of water. Additional demographic data collected include:

1. Type of provider
 - a. Anesthesiologist
 - b. Certified Registered Nurse Anesthetist
 - c. Student Registered Nurse Anesthetist
2. Type of surgical procedure
3. Type of endotracheal tube
4. Identifying if nitrous oxide was used
5. The resulting endotracheal cuff pressure

Conclusions

The first research question was; what endotracheal cuff inflation techniques do anesthesia providers utilize in their practice? Three endotracheal cuff inflation techniques were found to be used by the anesthesia providers in this study. In 46% of the cases the cuffs were inflated using the pilot balloon palpation technique, 28% were inflated using the set volume technique, and 26% using the minimum occlusive pressure technique.

The second research question was, what is the

associated endotracheal tube cuff pressures with each inflation technique utilized? The results demonstrated that regardless of the technique used, or type of anesthesia provider, none of the endotracheal cuff pressures measured were in an acceptable range to prevent complications. Thirteen percent of cuff pressures were below the minimum value required to prevent aspiration, and 87% of the sample were inflated above the maximum acceptable pressure, risking tracheal ischemia. These results would suggest that the currently used techniques are ineffective at maintaining adequate cuff pressures.

Recommendations

In this study anesthesia providers described the type of inflation technique they used. It was not determined if the technique was used properly. It is possible that they did not properly use the named technique (i.e. for minimal occlusive pressure the cuff is deflated until a leak is heard, and then is re-inflated with just enough air to prevent the leak). It may be important to evaluate providers knowledge of the proper use of each technique.

The anesthesia providers were occasionally aware that their patient was a participant in this study, but this did not appear to impact the results. Future studies may want to evaluate the degree of importance anesthesia providers place on preventing endotracheal cuff related complications. It may be that because no immediate sequela are observed by

anesthesia providers, that little concern is given to endotracheal cuff complications.

Recommendation for Practice

Technology is continually making available new and improved tools to anesthesia providers that can enhance patient safety. The introduction of the high-volume, low-pressure endotracheal cuff did lower the risk of tracheal ischemia to patients, but continued vigilance on the part of the anesthesia provider is required to prevent injuries. All inflation techniques were associated with improper cuff pressures. None of the providers used a manometer. Routine use of manometers to monitor endotracheal cuff pressures may be the safest way to prevent cuff related injuries.

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APPENDIX A: INFORMED CONSENT

Informed Consent

Research Study

" THE EFFECT OF ENDOTRACHEAL INFLATION TECHNIQUE ON
ENDOTRACHEAL CUFF PRESSURE"

My name is Capt Mark L Evans. I am a Nurse Anesthesia graduate student conducting research for my master's thesis. I am conducting a research study along with Lt Col McAuliffe CRNA Ph.D from the Nurse Anesthesia Department of the Uniformed Services University of the Health Sciences. You are being asked to take part in a research study. Before you decide to be a part of this research study, you need to understand the risks and benefits so that you can make an informed decision. This is known as informed consent. This consent form provides information about the research study, which has been explained to you. Once you understand the study and the tests it requires, you will be asked to sign this form if you desire to participate in the study. Your decision to participate is voluntary. This means you are free to choose if you will take part in the study.

Purpose and Procedures

The Department of Nursing Anesthesia of the Uniformed Services University of the Health Sciences is carrying out this research study to measure the pressure of the balloon in your breathing tube during surgery.

The study procedure will consist of measuring the balloon of the breathing tube 30 minutes after surgery has begun. The balloon helps hold the breathing tube in place during

the procedure.

You will not be aware of the breathing tube or the measurements of the balloon. You will not be expected to do anything and the quality of your anesthesia will not be effected by this study.

Benefits

The benefits of this study will be to add to the current body of anesthesia knowledge and practice.

Time Commitment

The time commitment for this study will last the duration of the surgical procedure for which you are scheduled. You will not be aware of the study while you are under anesthesia.

Risks

You will not feel the measurement of the balloon. The potential risks of this study are the risks of general anesthesia. The breathing tube balloon will only be measured, no change in the pressure of the balloon will be made.

Cost of participation

There is no cost to you to participate in this study.

Research Related Injury

This study should not entail any physical or mental risks beyond those described above. We do not expect complications to occur, but if, for any reason, you feel that continuing this study would constitute a hardship for you, we will end

your participation in the study.

If at any time you believe you have suffered an injury or illness as a result of participating in this research project you should contact the Office of Research Administration at the Uniformed services University of the Health Sciences, Bethesda, MD 20814 at (301) 295-3303. This office can review the matter with you, can provide you information about your rights as a subject, and may be able to identify resources available to you. Information about judicial avenues of compensation is available from the University's General Counsel (301) 295-3028.

Confidentiality of Records

All information that you provide as part of this study will be confidential and will be protected to the fullest extent of the law. Information that you provide and other records related to this study will be kept private, accessible to those persons directly involved in conducting this study and members of the Uniformed Services University of the Health Science's Institutional Review Board, who provide oversight for human use protection. However, please be advised that under UCMJ, a military member's confidentiality cannot be strictly guaranteed. Any reports generated from this study will not divulge your name or identity.

Withdraw

I understand that I may withdraw at any time during the course of this research study, revoke my consent, and

withdraw from this study without prejudice. I have been given an opportunity to ask questions concerning this research study, and any such questions have been answered to my complete satisfaction. If you have any concerns or questions, call Capt Mark Evans at (301) 482-1225 or Maura S. McAuliffe Ph.D., CRNA at (301) 295-6565, chair of my thesis committee. If you have any questions about your rights as a research subject, you should call the Director of Research Programs in the Office of Research at the Uniformed Services University of the Health Sciences at (301) 295-3303. This person is your representative and has no connection to the researchers conducting this study.

I do hereby volunteer to participate in the research study entitled : THE EFFECT OF ENDOTRACHEAL INFLATION TECHNIQUE ON ENDOTRACHEAL CUFF PRESSURE. The implications of my voluntary participation: the nature, duration and purpose; the methods and means by which it is to be conducted; and the inconveniences and hazards to be expected have been thoroughly explained to me by

By signing this consent form you are agreeing that the study has been explained to you and that you understand this study. You are signing that you agree to take part in this study. You will be given a copy of this consent form. I have been given the opportunity to ask questions concerning this study, and any such questions have been answered to my full and complete satisfaction.

Signature

Date

Signature (witness)

Date

I certify that the research study has been explained to the above individual, by me and that the individual understands the nature and purpose, the possible risks and benefits associated with taking part in this research study. Any questions that have been raised have been answered.

Investigator

Date

APPENDIX B: DATA COLLECTION SHEET

Data Collection Sheet

1. Type of provider
 - a. Anesthesiologist
 - b. Certified Registered Nurse Anesthetist
 - c. Student Registered Nurse Anesthetist

2. Type of surgical procedure _____

3. Type of endotracheal tube _____

4. Was nitrous oxide was used Yes No

5. Was the neck in neutral alignment Yes No

6. Measurement of the endotracheal cuff pressure _____