# ANALYSIS OF APPLICATION OF CRICOID CARTILAGE PRESSURE

BY

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## Abstract

*Background.* Cricoid cartilage pressure was formally described in 1961 by Dr. B. A. Sellick. Research has demonstrated a lack of formalized training in cricoid pressure application, leaving the patient at risk for pulmonary aspiration.

*Methods.* This study was non-experimental and correlational with a descriptive aspect. Operating room registered nurses were sampled at urban medical centers.

*Results.* There was no statistically significant correlation between the registered nurses' cognitive or application results and their gender, hand dominance, frequency of application, or having previous training. There was a correlation between years of clinical experience and the actual applied pressure, $p = .022$. The descriptive aspect revealed significant deficiencies in knowledge and application skills.

*Conclusions.* Despite 60% of the study participants acknowledging having prior training, the results demonstrated that they were no more likely to identify, correctly state, or apply the proper cricoid pressure. Factors suggested by other authors as having influence on the ability to apply pressure were also unfounded by this study.

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# Chapter 1

## Introduction

### Background

The application of cricoid cartilage pressure to decrease the incidence of regurgitation and pulmonary aspiration during the induction of general anesthesia is widely accepted in practice. The use of cricoid pressure is considered the gold standard for rapid sequence induction in the “full stomach” patient.

Cricoid pressure was first described in the 1770’s by Dr. Monro and later by Hunter. However, Dr. Sellick receives the most credit for introducing application into modern practice based upon his observational study in 1961. The technique of applying cricoid cartilage pressure is synonymous with the term “Sellick’s maneuver”.

Sellick’s maneuver is described as firm backwards pressure exerted on the cricoid cartilage, the only complete cartilaginous tracheal ring, against the cervical vertebrae to obliterate the esophageal lumen (Sellick, 1961). This technique is performed by an assistant, most commonly an operating room registered nurse. The pressure should be maintained until the airway is secured with an endotracheal tube and the cuff is inflated.

Research indicates that 30 – 40 Newtons or 3 – 4 Kilograms of force should effectively occlude the esophageal lumen. Pressure applied prior to loss of consciousness may result in retching or vomiting. Insufficient pressure may result in regurgitation and subsequent aspiration. Excessive pressure has been associated with

airway obstruction, airway distortion, impaired glottic view during direct laryngoscopy, and esophageal rupture (Cadamy & Bong, 2003; Clark & Trethewy, 2005; Georgescu, Miller, & Lecklitner, 1992; Hartsilver & Vanner, 2000; Landsman, 2004; Ralph & Wareham, 1991; Snider, Clarke, & Finucane, 2005; Vanner & Pryle, 1992).

Cricoid pressure is commonly applied to patients considered high risk for aspiration. These patients include those with full stomach, acute abdominal pathology, obesity, trauma, and pregnancy. Aspiration of gastric contents into the lungs is associated with increased morbidity and mortality. However, recent literature challenges evidence that cricoid pressure is effective in preventing aspiration and cites the lack of consensus in teaching proper application technique as the reason for its ineffectiveness.

## Problem Statement

The application of Sellick's maneuver has been challenged suggesting lack of cognitive knowledge in proper application and lack of evidence in efficacy. Improper and inconsistent application may increase the patient's risk for regurgitation and subsequent aspiration of gastric contents. The clinical implications associated with improperly applied cricoid pressure warrants evaluation of the cognitive knowledge and application technique of registered nurses.

## Purpose of Study

The purpose of this study is to evaluate registered nurses' cognitive knowledge, ability to correctly identify the cricoid cartilage, and ability to correctly

apply cricoid pressure. This is evaluated through the six purposes of this study. The first is to assess the cognitive knowledge of registered nurses as to the proper amount of force required for effective cricoid pressure in the unconscious adult patient. The second purpose is to determine the ability of registered nurses to correctly identify the anatomical location of the cricoid cartilage on an airway model. The third purpose is to assess the amount of cricoid pressure applied by registered nurses to an airway model mounted on an infant scale. The fourth purpose is to evaluate the influence gender, hand dominance, years of clinical experience in application of cricoid cartilage pressure, frequency of application of cricoid cartilage pressure, and the presence or absence of previous training or testing have on cognitive knowledge of the recommended cricoid cartilage pressure on an unconscious adult. The fifth purpose is to evaluate the influence gender, hand dominance, years of clinical experience in application of cricoid cartilage pressure, frequency of application of cricoid cartilage pressure, and the presence or absence of previous training or testing have on actual cricoid force applied to an airway model mounted on an infant scale. The final purpose is to evaluate the influence gender, hand dominance, years of clinical experience in application of cricoid cartilage pressure, frequency of application of cricoid cartilage pressure, and the presence or absence of previous training or testing have on the ability to correctly identify the anatomical location of the cricoid cartilage on an airway model.

## Research Questions

The research questions for this thesis are:

1. What percentage of registered nurses know the recommended cricoid pressure for prevention of aspiration in the unconscious adult patient?
2. What percentage of registered nurses are able to correctly identify the cricoid cartilage on the scale mounted airway model?
3. Is there a correlation between the cognitive knowledge of amount of cricoid pressure the registered nurses stated for the unconscious adult patient and the amount actually applied to the scale mounted airway model?
4. Is there a correlation between the correct location of application of cricoid pressure and the actual pressure applied to the scale mounted airway model?
5. Is there a correlation between gender, hand dominance, years of clinical experience in application of cricoid cartilage pressure, frequency of application of cricoid cartilage pressure, or previous training or testing in application of cricoid cartilage pressure and the stated cricoid cartilage pressure?
6. Is there a correlation between gender, hand dominance, years of clinical experience in application of cricoid cartilage pressure, frequency of application of cricoid cartilage pressure, or previous training or testing in application of cricoid cartilage pressure and the actual pressure applied to an airway model?

7. Is there a correlation between gender, hand dominance, years of clinical experience in application of cricoid cartilage pressure, frequency of application of cricoid cartilage pressure, or previous training or testing in application of cricoid cartilage pressure and the ability to correctly identify the cricoid cartilage on an airway model?

Operational Terminology

The operational terminology used for this thesis is:

*Cricoid pressure*: Defined as the backward force applied to the cricoid cartilage against the cervical vertebrae in order to temporarily occlude the esophageal lumen. The appropriate applied force of cricoid pressure for the unconscious adult patient in this study was considered to be 40 Newtons or 4 Kilograms (9.81 Newtons = 1 Kilogram).

*Sellick's maneuver*: Defined as being synonymous with cricoid cartilage pressure. The maneuver is named after Dr. B. A. Sellick.

*Rapid sequence induction*: Defined as the administration of intravenous induction agents followed immediately by a fast acting neuromuscular blocking agent while cricoid cartilage pressure is being applied. The tracheal is secured with an endotracheal tube with the cuff inflated in the least amount of time possible.

# Chapter 2

## Literature Review

### Historical Background

Cricoid cartilage pressure was first described in the 1770's by Dr. Monro for the use in resuscitation of drowning victims to prevent gastric distention with air. Later, Hunter reported using cricoid pressure for the prevention of inflating the stomach with air when using bellows during ventilation of the lungs. In the 1960's, Dr. B. A. Sellick researched and described applying cricoid cartilage pressure in an attempt to prevent aspiration of gastric contents. This technique became known as the Sellick maneuver and remains a standard in modern anesthesia practice (Salem, Sellick, & Elam, 1974).

### Current Views

The use of cricoid pressure for the prevention of pulmonary aspiration, in high risk surgical patients, is considered standard practice amongst the majority of anesthesia providers. The incidence of aspiration associated with general anesthesia, was reported as frequently as 1 in 38 (133 cases in 5,000) in a retrospective analysis by the Australian Anaesthetic Incident Monitoring Study (AIMS). Those cases of aspiration that were considered clinically significant occurred much less frequently (1 in 35,000). The incidence of fatal pulmonary aspiration has declined over the past decades to a reported incidence of 1 in 70,000 to 1 in 100,000 anesthetic cases depending on source (Crenshaw & Winslow, 2002; Sakai, Quinlan, Handley, Kim, & Hilmi, 2006; Smith & Ng, 2003). This reduction in incidence of mortality has been

attributed to strict nil per os (NPO) guidelines, preoperative acid reduction and prokinetic medications, better identification of high risk patient populations, and the use of cricoid pressure with induction of general anesthesia in high risk patients (Ljungqvist & Soreide, 2003).

Recent evidence, however, has demonstrated that prolonged preoperative fasting is unnecessary and may cause more complications than it prevents. These complications include: patient dissatisfaction, headache, hypoglycemia, dehydration, hypovolemia, anxiety, increased gastric volume, and nausea (Crenshaw & Winslow, 2002; Ljungqvist & Soreide, 2003; Nagelhout, 2003). In 1999, the American Society of Anesthesiologists (ASA) examined NPO status and fasting guidelines. Due to the statistically rare occurrence of clinically significant pulmonary aspiration associated with general anesthesia, the ASA concluded that a two hour NPO status of clear liquids for pediatric patients and a two to four hour NPO status for adults is appropriate (American Society of Anesthesiologists [ASA], 1999).

The effectiveness of cricoid pressure has been questioned due to the continued occurrence of pulmonary aspiration, despite its application. There are no controlled clinical trials to assess actual effectiveness of cricoid pressure. Denying at risk patients, the application of cricoid pressure with the induction of general anesthesia, cannot ethically be performed (Priebe, 2005).

The strongest arguments questioning effectiveness of cricoid pressure center upon the lack of consensus in actual application technique, as well as a lack of knowledge by those who are applying the cricoid pressure. Several studies have formally and

informally discussed the fact that often less than 30% of anesthesia assistants, operating room registered nurses, anesthetists, or anesthesiologists could correctly state the recommended level of cricoid pressure to be applied. Furthermore, these individuals often could not correctly identify the cricoid cartilage either (Gardiner & Grindrod, 2005; Koziol, Cuddeford, & Moos, 2000; Meek, Gittins, & Duggan, 1999; Moos, 2007; Schmidt & Akeson, 2001; Stanton, 2006).

Published methods that clearly define and describe hand placement, timing of application, pressure to conscious and unconscious patients, and competency evaluation of the person applying cricoid pressure, are lacking. Associated complications including: airway obstruction, esophageal rupture, awareness, regurgitation, pulmonary aspiration, and a diminished glottic view during direct laryngoscopy have all been described despite presumed proper application technique (Cadamy & Bong, 2003; Clark & Trethewy, 2005; Georgescu, Miller, & Lecklitner, 1992; Hartsilver & Vanner, 2000; Landsman, 2004; Ralph & Wareham, 1991; Snider, Clarke, & Finucane, 2005; Vanner & Pryle, 1992).

Despite lacking evidence to the contrary on efficacy, the argument still remains that abandoning cricoid pressure in patients with known or suspected aspiration risk factors would not only be unethical but may also border upon the realm of malpractice. Until there is conclusive evidence to suggest otherwise, cricoid cartilage pressure must be utilized for patients suspected to be at risk for aspiration (Priebe, 2005; Stanton, 2006).

Pathophysiology of Gastric Regurgitation

Gastric regurgitation or gastro-esophageal reflux is influenced by several factors. Intra-gastric pressure results in backpressure on the lower esophageal sphincter (LES) and is a result in part by gastric content volume and a decrease in the LES tone. The difference between LES pressure and gastric pressure is referred to as esophageal barrier pressure. Normal LES pressure range is 15-25 cm $H_20$ higher than the intragastric pressure of seven cm $H_20$ or less (Brimacombe & Berry, 1997; Ruben, Knudsen, & Carugati, 1961; Tournadre, Chassard, Berrada, & Bouletreau, 1997).

Several preoperative factors impact the degree of LES tone, gastric volume or distention, and therefore barrier pressure. Medications can affect all of these factors. Common medications that decrease LES pressure include: anticholinergics, beta-blockers, calcium channel blockers, diazepam, opioids, intravenous induction agents, and volatile inhalation agents. Administration of succinylcholine increases intragastric pressure transiently during muscle fasciculations. Prokinetic medications such as metoclopramide as well as antisecretory medications may be helpful in decreasing gastric volume (Clark & Trethewy, 2005; Liu & Saltzman, 2006; Pisegna & Martindale, 2005).

Bag mask ventilation may lower barrier pressure due to inadvertent gastric insufflation with air, leading to regurgitation, difficult ventilation, and decreased cardiac output. Gentle hand ventilation with peak airway pressures, less than 30 cm $H_2O$, with the application of cricoid pressure may prevent gastric insufflation (Brimacombe & Berry, 1997). According to Tournadre et al. (1997) the actual cricoid

cartilage pressure itself has been shown to cause a decrease in LES pressure without a significant change in intra-abdominal pressure.

The upper esophageal sphincter (UES) is formed primarily by the cricopharyngeus muscle. The muscle tone of the UES is drastically decreased with the administration of neuromuscular blocking agents, opioids, and diazepam. Application of cricoid pressure attempts to overcome and compensate for the decrease in UES tone during induction of general anesthesia, thus preventing regurgitation. The median UES pressure is reported to be 38 cm $H_2O$ in conscious patients, decreasing to six cm $H_20$ after induction of general anesthesia and administration of muscle relaxants. Several studies suggest that a cricoid pressure of 40 Newtons sufficiently protects most patients from regurgitation (Tournadre et al. 1997; Vanner, O'Dwyer, Pryle, & Reynolds, 1992; Wraight, Chamney, & Howells, 1983).

The postural position of patients has been evaluated for the influence that these changes have on barrier pressure and subsequent gastric reflux. Gravitational influence on patients in trendelenburg or lithotomy positions is considered to increase the incidence of reflux and therefore increase aspiration risk due to increased intragastric pressure. The use of reverse trendelenburg position has been suggested as a means of preventing passive regurgitation via gravitational force. However, a study of 21 non-fasting, non-obese, conscious patients that did not have gastric reflux disease, suggested position had no significant impact on passive reflux (Jeske,

Borovicka, von Goedecke, Meyenberger, Heidegger, & Benzer, 2005; Smith & Ng, 2003).

An endotracheal tube (ETT) successfully placed in the trachea with cuff inflated has traditionally been thought to be the point at which cricoid cartilage pressure can safely be released. A recent study determined that high-volume, low-pressure (HVLP) endotracheal tube cuffs do not reliably prevent the passage of fluid distal to the inflated balloon (44% leakage static test). This was attributed to the stiffness and lack of conformity of the inflated cuff against the tracheal wall resulting in creases that allowed passage of fluids distal to the cuff. A low-volume, low-pressure (LVLP) cuff prevented leaks in all trachea tested with both static and dynamic testing methods (Young, Pakeerathan, Blunt, & Subramanya, 2006).

Pathophysiology of Pulmonary Aspiration

In 1946, Mendelson described the pulmonary aspiration of gastric contents in the obstetric population during the induction of general anesthesia, resulting in increased mortality. Aspiration pneumonitis or Mendelson's syndrome is the pathophysiologic state as a result of aspiration of acidic gastric contents into the pulmonary system resulting in obstruction, inflammation, progressive respiratory failure, and possible death. The greatest risk appears to be related to pH, volume, and particulate size. A pH < 2.5 along with a gastric volume of 0.4 ml/kg or greater, increases the risk of Mendelson's syndrome. The aspiration of particulate matter sizable enough to cause large airway obstruction also contributes to morbidity and

mortality (Ljungqvist & Soreide, 2003; Smith & Ng, 2003; Schreiner, 1998; Whittington, Robinson, & Thompson, 1979).

High Risk Surgical Patients

Preoperative anesthetic management of patients at risk for pulmonary aspiration focuses upon prevention via gastric emptying, decreasing gastric secretions, and increasing pH of the gastric secretions. Gastric emptying can be accomplished through use of prokinetic medications such as metoclopramide. Decreasing gastric secretions and acidity is accomplished with antacids, histamine-2 antagonists, and proton pump inhibitors (Liu & Saltzman, 2006; Pisegna & Martindale, 2005; Smith & Ng, 2003). However, the routine use of these medications, except in patients identified as high risk for regurgitation, is unfounded and not recommended by the ASA. One study suggested that the oral intake of clear liquids up to two hours prior to anesthesia did not increase gastric volume or acidity of gastric secretions (Ljungqvist & Soreide, 2003).

Patients identified as high risk for aspiration should have cricoid pressure applied during the induction of general anesthesia. Risk factors include: obesity, diabetes, pregnancy, trauma, the elderly, non-fasting state, gastrointestinal obstruction or dysfunction, uncontrolled gastro-esophageal reflux, uncoordinated swallow and respiration pattern, decreased level of consciousness unrelated to head trauma, esophageal pathology, and/or presence of hiatal hernia (Brimacombe & Berry, 1997; Ljungqvist & Soreide, 2003; Pisegna & Martindale, 2005; Sakai et al. 2006).

Certain surgical procedures increase the risk of reflux and pulmonary aspiration in the perioperative setting. Surgery of the esophagus, especially thoracic, had an incidence of 1 in 1,166 for pulmonary aspiration in one retrospective analysis. Intra-abdominal surgery or monitored anesthesia care (MAC) cases with over sedation resulting in the loss of pharyngeal reflexes were attributed to higher incidences of perioperative pulmonary aspiration (Sakai et al. 2006).

Contraindications to Cricoid Pressure

Just as there are conditions considered mandatory for the application of cricoid pressure, there are certain circumstances that are relative or absolute contraindications to its use. These contraindications include: unstable cervical spine fracture, active vomiting prior to induction of general anesthesia, cricotracheal injury, foreign body in upper airway, and/or a history of difficult airway management. Other situations that may necessitate the reduction in pressure or actual release of cricoid pressure include inability to intubate, inability to advance the endotracheal tube, inability to ventilate, or active vomiting during the induction of general anesthesia (Brimacombe & Berry, 1997; Hartsilver & Vanner, 2000; Landsman, 2004; Lewis & Magee, 2003; Palmer & Ball, 2000; Stanton, 2006).

Cricoid Cartilage Anatomy

The cricoid cartilage is the only complete tracheal ring. The anterior and lateral aspect is attached to the cricothyroid muscle and membrane. The posterior side of the ring is attached to the inferior constrictor muscle. The posterior aspect is broader than the anterior and is also the attachment point of the longitudinal fibers of

the esophagus. On each side of these fibers are the posterior and lateral cricoarytenoid muscles. The cricoid cartilage corresponds to the C6 spinal level in adults (Brimacombe & Berry, 1997; Gray, 1996; Moore & Dalley, 2006). Surface landmark identification is performed by moving slightly inferior to the thyroid cartilage and the cricoid notch, or just inferior to the thyroid prominence or "Adam's apple" (Koziol et al. 2000; Patten, 2006).

Determining Cricoid Force (Kg and N)

Various terms and descriptions for the amount of force that is required for sufficient cricoid pressure has created difficulty for most individuals to understand and apply a numerical value. Descriptions include pressure such that would cause discomfort if applied to the bridge of your nose or enough pressure to make swallowing difficult or uncomfortable. Most researchers and practitioners alike have come to agree upon the Kilogram (Kg) and/or the Newton (N) as the standard descriptive unit, despite one being a measurement of weight and the other of force. Many authors accept the values of one Kg being equivalent to 9.81 N, with some simplifying more to say one Kg equals 10 N. Furthermore, a consensus has been made that application of cricoid cartilage pressure to the conscious patient should be 1 – 2 Kg or 10 – 20 N. Once the patient becomes unconscious, that pressure should increase to 3 – 4 Kg or 30 – 40 N. One author states that 44 N should reasonably protect all patients from aspiration (Brimacombe & Berry, 1997; Escott, Owen, Strahan, & Plummer, 2003; Herman, Carter, & Van Decar, 1996; Koziol et al. 2000;

Landsman, 2004; Patten, 2006; Priebe, 2005; Vanner & Asai, 1999; Wraight et al. 1983).

Cricoid Pressure Application Techniques

Sellick described the patient position for the application of cricoid cartilage pressure as supine with the head slightly down and with the head and neck fully extended as if positioned for tonsillectomy. The preferred or position considered optimal for direct laryngoscopy (DL) and intubation is the Magill or ”sniffing” position. The position described by Sellick makes application of cricoid pressure easier due to the neck being extended and fully exposed. Direct laryngoscopy is potentially more difficult in this position. The reverse seems to be true with the Magill position. In this position, there is better alignment of the airway axes for visualization under direct laryngoscopy but exposure to the cricoid cartilage is not as great (Barash, Cullen, & Stoelting, 2006; Salem et al. 1974; Sellick, 1961).

Timing application pressure, with level of consciousness, has also resulted in controversy. Several studies suggest patients can tolerate up to 20 N while conscious. Pressure greater than 20 N, prior to loss of consciousness, may result in: pain, anxiety, coughing, bucking, retching, vomiting, recall, and/or feelings of dyspnea (Campbell, Turley, Wilkes, & Hall, 2003; Stanton, 2006; Vanner & Asai, 1999; Vanner et al. 1992). There are published case reports of recall during cricoid pressure when utilized during a rapid sequence induction (RSI) resulting in post-traumatic stress disorder (Cadamy & Bong, 2003).

The ability of an individual to maintain an adequate cricoid pressure may become significant in the case of a difficult airway. Researchers examined the ability of six male operating room assistants to apply cricoid pressure for a prolonged period of time. They found that a force of 30 – 40 N could only be maintained for two to four minutes without significant fatigue, discomfort, and/or allowing the sustained force to drop below recommended acceptable levels for esophageal occlusion (Meek, Vincent, & Duggan, 1998). Another study of 40 individuals, who routinely apply cricoid pressure, demonstrated that only 7.5% were able to maintain force in the desirable range for a one minute time frame (Clayton & Vanner, 2002). It was also determined in a separate study that in a sample of 40 patients, 20 N would improve glottic view and 30 N was likely to hinder the glottic view during direct laryngoscopy. The researchers further determined that if the glottic view was poor to increase pressure initially and then gradually decrease pressure until visualization improved (Haslam, Parker, & Duggan, 2005).

One Hand Technique

Predominate positioning for the clinician applying cricoid pressure is to stand on the patient's right side, facing their head. Using the right hand, cricoid pressure is applied to the patients' trachea. The left hand is then free to pass the endotracheal tube off to the person intubating the patient. This is important since DL is performed with the left hand and passage and manipulation of the ETT is done with the anesthesia providers' right hand. Also, most individuals have greater strength and dexterity with their right hand making that the natural choice for application of the

most effective and sustainable cricoid pressure. One study demonstrated an average mean force of 5 – 12 N less when cricoid pressure was performed using the left hand rather than with the right hand by right hand dominant persons (Cook, Godfrey, Rockett, & Vanner, 2000). Another study of 48 subjects, who reported regularly applying cricoid pressure, demonstrated no significant difference in the ability to apply and maintain force with either hand (Schmidt & Akeson, 2001).

Actual hand/finger placement for cricoid pressure is described and taught primarily in one of two ways. The first approach is using three fingers with the thumb placed on the right, the index finger directly over the cricoid ring, and the middle finger on the left side of the patient's trachea. This method is often preferred since it is less likely to cause lateral displacement which could hinder the glottic view during direct laryngoscopy. The other common method is either using the thumb and index finger or thumb, index, and middle fingers together as if picking up some small item, then applying pressure as one unit directly on the cricoid ring. Other techniques have been described including application using the extended thenar web (Fezer, 1987; Howells, Chamney, Wraight, & Simons, 1983; Sellick, 1961).

Bimanual Technique

Many authors describe a bimanual or two handed technique. This method is similar to the one hand technique with cricoid pressure being applied with the assistant's right hand. The difference being that the left hand is placed underneath the patient's neck for support. Reported advantages include the prevention of over flexion of the cervical spine, greater control against lateral displacement of the trachea, and

less disruption of the glottic view with direct laryngoscopy (Brimacombe & Berry, 1997; Turgeon, Nicole, Trepanier, Marcoux, & Lessard, 2005). Others suggest that neck support offers no benefit in glottic view and may actually become problematic since the assistant would have both hands occupied and unable to further assist the clinician intubating (Cook, Nolan, & Gabbott, 1997; Haslam et al. 2005; Vanner, Clarke, Moore, & Raftery, 1997).

A compelling study evaluated the position of the esophagus relative to the cricoid cartilage before and during the application of cricoid pressure. In greater than 50% of the subjects, magnetic resonance imaging (MRI) revealed that the esophagus was displaced laterally. Displacement of the esophagus to the left occurred more frequently than displacement to the right prior to the application of cricoid pressure. When a bimanual cricoid pressure technique was applied, a 1.5 fold increase in amount of lateral displacement was noted. There was also a 1.5 fold increase in the number of unopposed esophageal lumens. This study was limited due to the patients being conscious and by having their head and neck in neutral positions for greater tolerance of the cricoid pressure (Smith, Dobranowski, Yip, Dauphin, & Choi, 2003).

Cricoid Yoke

A cricoid yoke is an application device with a padded “V” shaped end designed for the comfort of the conscious patient. Increased tolerance is achieved by covering a greater surface area than that of traditional manual cricoid pressure. Many different variations of the yoke have been developed. Some models have a light that comes on when the desired pressure has been reached while others have an actual

digital display of the pressure being applied. Two benefits in the use of the cricoid yoke is in the reported ease of learning to use the device and in greater consistency in achieving the desired amount of pressure due to the constant/instant feedback display (Brimacombe & Berry, 1997; Campbell et al. 2004; Landsman, 2004; Lawes, Duncan, Bland, Gemmel, & Downing, 1986). Palmer and Ball (2000) reported force dependant deformation of the cricoid cartilage resulting in complete airway obstruction at 44 N in half of the sample population using the cricoid yoke, with the greatest percent occurring in females (78.5% vs. 26.6%).

Cricoid Pressure: Airway Obstruction and Difficult Laryngoscopy

A potential complication of cricoid cartilage pressure is partial to complete airway obstruction. Suspected causes may be related to difficult anatomy including lingual thyroid, benign tumors, and malignant lesions that act like a ball-valve to occlude the trachea during inspiration. Airway obstruction may occur do to the improper use of cricoid pressure including the use of excessive pressure. A rapid sequence induction (RSI) of general anesthesia is often taught and preformed without ever attempting to ventilate the patient until either an endotracheal tube is successfully placed or until after failed intubation attempt(s) and patient desaturation occurs. A failed first attempt intubation during RSI is a scenario where airway obstruction may be discovered. Bag-mask ventilation may be found to be unsuccessful due to difficult patient anatomy or due to the pathology previously mentioned. This can result in a can not ventilate and/or can not intubate situation. In this case, the recommendation is to gradually release cricoid pressure until the ability

to ventilate is achieved. The establishment of a patent airway always takes precedence, so despite a presumed aspiration risk; the complete release of cricoid pressure may become necessary. It is recommended that cricoid pressure be used when performing rapid sequence induction of general anesthesia (Brimacombe & Berry, 1997; Georgescu, Miller, & Lecklitner, 1992; Hartsilver & Vanner, 2000; Haslam et al. 2005; Palmer & Ball, 2000; Vanner et al. 1997). Modified RSI has become more acceptable which allows for a test ventilation breath to establish the presence of a patent airway prior to administration of a neuromuscular blocking drug.

The teaching of the backwards, upwards, right pressure (BURP) maneuver applied to both the thyroid and cricoid cartilage for better visualization during direct laryngoscopy is often used instead of or inadvertently to, Sellick's maneuver. There are conflicting reports of the success of DL and subsequent endotracheal intubation using the BURP or modified BURP maneuvers. One study reported that using the modified BURP, which is a combination of BURP and Sellick's maneuvers, resulted in a diminished glottic view in 30% of cases and a worse view in 12.5% of cases when only cricoid pressure was applied (Snider et al. 2005). Another study, using the modified BURP, had a higher incidence of complete airway obstruction when compared to traditional cricoid pressure technique (Hartsilver & Vanner, 2000). Turgeon et al. (2005) reported no difference in the ability to successfully intubate with or without the application of cricoid pressure. The authors attribute their positive results to well trained and practiced anesthesia assistants. The manipulation of the

thyroid cartilage by the free hand of the clinician intubating is commonly practiced to aide in visualization with or without cricoid cartilage pressure application.

Cricoid Pressure and Esophageal Rupture

The risk of esophageal rupture has been associated with active vomiting during the application of cricoid cartilage pressure with the induction of general anesthesia. Spontaneous rupture of the esophagus may occur if the cricopharyngeus muscle (upper esophageal sphincter) fails to relax.

One case report described an esophageal rupture in an 81 year old female admitted for gastrectomy subsequent to ulceration. On induction of general anesthesia with cricoid pressure applied, the patient vomited prior to loss of consciousness. Cricoid pressure was released as recommended. The patient reportedly had a complicated postoperative course in part due to the rupture of her esophagus, resulting in death 10 days later. The premature application of excessive cricoid pressure may have contributed to the patient vomiting, which is impossible to confirm. The proper timing of cricoid pressure as well as the actual pressure applied is crucial in the prevention of retching and possible vomiting (Ralph & Wareham, 1991; Vanner & Pryle, 1992).

Cricoid Pressure and the Nasogastric Tube

The effectiveness of cricoid cartilage pressure with the presence of a nasogastric (NG) tube remains controversial. Dr. Sellick originally speculated that a NG tube should be used to suction the stomach thoroughly and then be removed prior to induction of general anesthesia. His concern was that the tube would “trip” the

esophageal sphincters, therefore increasing the risk for regurgitation. Also, he believed that it would interfere with complete occlusion of the esophageal lumen when cricoid pressure was applied (Sellick, 1961). One study demonstrated no decrease in efficacy of cricoid pressure with a NG present as evidence by lack of regurgitation. The authors even speculated a decrease in intragastric pressure through venting is beneficial (Vanner & Pryle, 1992).

Cricoid Pressure and Gastric Insufflation

An additional indication for cricoid pressure is in prevention of gastric insufflation with air during bag/mask ventilation with induction of general anesthesia or during cardiopulmonary resuscitation (CPR). The use of cricoid cartilage pressure in the prevention of gastric distention was described by Dr. Monro in the 1770's during the resuscitation of drowning victims. Hunter described a similar experience later that same decade. They both determined that the provision of artificial respirations, either by another person or with bellows, may result in distention of the stomach by air. It was also noted that individuals whose stomachs were distended with air had a greater likelihood of vomiting. Furthermore, they realized that the application of backwards pressure on the throat, preferably on the cricoid cartilage, would minimize or even prevent gastric distention (Salem et al. 1974).

Gastric insufflation with air increases the incidence of nausea and subsequent regurgitation, reduces ventilation, and results in decreased cardiac output (Brimacombe & Berry, 1997; Sellick, 1961). Studies have determined that the minimum airway pressure required to overcome the barrier pressure or LES tone,

insufflating the stomach during bag/mask ventilation, to be 19 cm $H_20$ (Jeske et al. 2005). The pressure required to insufflate the stomach during the application of cricoid pressure is much greater, therefore decreasing the likelihood of distention. This is provided that the cricoid pressure is applied with the proper technique and pressure.

One study on pediatric patients determined that cricoid pressure was 100% effective in preventing gastric insufflation when pressure up to 40 cm $H_20$ was used. The pressure was measured using the pop-off valve on an anesthesia machine in both paralyzed and nonparalyzed patients (Moynihan, Brock-Utne, Archer, Feld, & Kreitzman, 1993). The distribution of gas between the lungs and stomach is also influenced by changes in airway resistance and lung compliance. Lung compliance has been shown to be decreased in anesthetized patients. The result is a propensity for gastric insufflation with air. In order to prevent gastric insufflation, the peak inspiratory pressure (PIP) must be less than the LES pressure. A lower PIP may be achieved through both a longer inspiratory time and sufficient expiratory time (Melker, 1986).

Cricoid Pressure and Laryngeal Mask Airways (LMAs)

The contraindications for the use of a LMA are identical to the indications for the application of cricoid pressure. However, LMAs are included in the difficult airway algorithm where passage of an ETT has failed (Heidegger & Hans Jorg, 2004). The continuation of cricoid pressure is often still indicated. The effect of cricoid pressure on the ability to place a LMA has been investigated. Cricoid pressure

is thought to make insertion more difficult due to the need to place the tip in the hypopharynx behind the cricoid cartilage. Because of this, changes in anatomical angles during the application of cricoid pressure may prevent the proper seating of the LMA. It is suggested that if failure to successfully place a LMA occurs, during application of cricoid pressure, to transiently release pressure and reattempt insertion (Brimacombe & Berry, 1997; Nagelhout, 2003; Palmer & Ball, 2000; Smith & Ng, 2003).

Knowledge Base and Teaching of Cricoid Pressure

Learning and retaining knowledge of the correct location, timing, and applied pressure are paramount for optimal patient protection and successful insertion of an ETT during cricoid pressure. Overwhelming evidence has determined that there are significant deficits in all of these areas. The method of learning to apply cricoid pressure was most often reported as verbal instructions and/or hands on with actual patients. A recent study suggests instituting a didactic component in training which focuses on anatomy, physiology, indications, and complications of cricoid pressure. Additional education would include hands on practice sessions and testing with a life sized airway model followed by a post-test reinforcement discussion. A regularly scheduled competency assessment is also suggested (Moos, 2007).

Formalized training methods, using one or more commercially available or homemade models, along with repeated skills lab sessions in order to maximize consistency and proficiency, is suggested as having the best results. The frequency of training varies from weekly to at least once every six months based upon individual

recommendations of the researchers. Various levels of success was demonstrated with each method and frequency of training and is the basis of the authors' recommendations of frequency for refresher sessions (Ashurst, Rout, Rocke, & Gouws, 1996; Clark & Trethewy, 2005; Clayton & Vanner, 2002; Escott et al. 2003; Flucker, Hart, Weisz, Griffiths, & Ruth, 2000; Gardiner & Grindrod, 2005; Herman et al. 1996; Howells et al. 1993; Kopka & Crawford, 2004; Kopka & Robinson, 2005; Koziol et al. 2000; Landsman, 2004; Matthews, 2001; Meek et al. 1999; Owen, Follows, Reynolds, Burgess, & Plummer, 2002; Schmidt & Akeson, 2001; Walton & Pearce, 2000).

The 50cc Syringe Model

One readily available and inexpensive training method is through the use of a 50 cc syringe. The syringe is mounted vertically, after filling with air to the 50 cc mark and securing the cap. Compressing the plunger by 17 cc or to the 33 cc mark approximates 30 N of pressure. Some have described using a roll of tape or barrel of a smaller syringe mounted horizontally on the plunger of the 50 cc syringe in an attempt to represent the trachea and cricoid cartilage for added realism. Criticism exists with this model including that there is too great of distance of displacement to achieve the desired level of pressure compared to the distance one would expect with an actual patient. In addition, the subjects being tested were not able to attempt to correctly identify anatomic structures. However, greater accuracy in applied pressure and retained consistency has been demonstrated. Statistically significant improvements from pretest rates, varying from 47% to 100%, were obtained in post

testing study parameter pressures (Clayton & Vanner, 2002; Flucker et al. 2000; Kopka & Crawford, 2004; Kopka & Robinson, 2005; Matthews, 2001).

Life Size Airway Models

Another described method is using a life sized model of the airway placed upon a scale. One benefit of this training model is in the assessment of a trainee's ability to correctly identify the cricoid cartilage, which is described as an area of concern. The most common technique includes placing a life sized airway model on a calibrated and zeroed infant scale. The test subjects apply what they believe to be the correct amount of cricoid pressure which is displayed on the scale in Kilograms. This can easily be performed in an operating room with table height adjusted to represent actual clinical conditions. There is a great degree of accuracy depending on the infant scale, with the ability to measure a range of 0 to 20 kg and with up to a 0.005 kg resolution. This equipment is usually readily available in most clinical settings. Variations of the model include commercially available mannequins with pressure sensors and digital displays. Results vary with this method as well. Participants in one study were never able to reach the desired study goal of 40 N despite practicing with the applied force displayed to them as well as receiving verbal instructions. Others only had a 25% success rate despite prior education and training; while another had 61% that were able to reach an acceptable pressure range and 18% reach the correct pressure range (Ashurst et al. 1996; Clark & Trethewy, 2005; Herman et al. 1996; Koziol et al. 2000).

# Chapter 3

# Methodology

## Research Design

The design of this study is non-experimental and correlational. A descriptive aspect was also incorporated.

## Setting

The setting of this study included two locations. Both were urban medical centers in the Midwest. Operating room registered nurses within each medical center were sampled.

## Institutional Approvals

Exempt status was obtained from the University of Kansas Medical Center Human Subjects Committee. Institutional approval was obtained from the Administrative Research Approval Committee at BryanLGH Medical Centers.

## Subjects

The study population consisted of a sample of male and female registered nurses from two urban Medical Centers. All subject participation was voluntary.

## Inclusion Criteria

Subjects included registered nurses who might be required to apply cricoid cartilage pressure in their practice and who were currently employed with BryanLGH Medical Centers. All participants voluntarily participated in this study. Completion of the data collection form (Appendix B) by the test subjects constituted consent to participate in this study.

Variables

The dependent criterion for this study were the participants' perception of the recommended cricoid cartilage pressure for unconscious adult patients, the pressure actually applied to a model, and the ability to identify the correct anatomical location of the cricoid cartilage on a model either yes or no. The independent predictors are the participants gender, hand dominance, prior cricoid cartilage pressure training or testing experience in the previous 12 months either yes at BryanLGH Medical Center, yes at another facility, or no, frequency of application of cricoid cartilage pressure in the past two months, and years of experience in application of cricoid cartilage pressure.

Limitations

1. Sampling of selected medical center departments limits generalizability.
2. The degree of accuracy of pressure measured by the scale.
3. Possible data collection bias by the investigator.
4. Larger sample size would increase generalized application of findings.
5. Representation of an adult airway by use of a plastic model.

Assumptions

1. Data was collected and recorded accurately by the investigator.
2. The scale used was accurate and pressure measured correlates with that applied in the clinical setting.
3. Research participants applied pressure in the same or similar manner in which they apply pressure in the clinical setting.

4. The sample used is representative.
5. Research participants honestly answered questions asked.
6. Previous competency testing or training was performed correctly.
7. The airway model accurately represents an adult airway.

Procedure

A form describing the research study purpose, data collected, investigator information, and assurance of anonymity was presented to each potential research participant (Appendix A). The data collection form (Appendix B) was completed by each research participant prior to applying cricoid pressure to the model. After completion, the form was given to the investigator. Each participant received an educational handout (Appendix C) with their applied value written on the back immediately after participating in the study. The handout described proper cricoid cartilage pressure application for conscious and unconscious patients, cricoid anatomy, indications, and contraindications for use of cricoid cartilage pressure. References were provided for clarification or follow-up.

Cricoid pressure was measured using a life size airway model mounted on an infant scale that had been zeroed prior to each research participant's single attempt. Each participant was asked to apply cricoid cartilage pressure to the model in the same or similar manner in which they would apply to an actual unconscious adult patient in the clinical setting. The investigator noted whether or not the correct anatomical site was used by the research participant applying pressure to the model on that person's data collection form as either yes or no. Research participants were

asked to inform the investigator when they were applying what they believed to be the correct pressure. The investigator then recorded the pressure applied on the data collection form in order to correlate participants' cognitive knowledge with their applied value. The digital display of the scale was visible only to the investigator. The data collection form was placed in a folder used to protect the anonymity of each research participant.

Instrumentation

A life sized upper airway model that has clearly defined airway anatomy including oropharynx, thyroid cartilage, cricoid cartilage, trachea, and esophagus was used for the actual application of cricoid cartilage pressure. This model was also used to determine whether or not the correct anatomical location or the cricoid cartilage was identified by the participants.

A Tanita Model 1580 infant scale with a digital display of 0 – 20 Kg that has a 0.01 Kg resolution was used. A green surgical towel was used to cover the surface of the scale and to obscure the digital display from each participant. The scale was zeroed with the model and towel prior to each individual application.

Data Collection Instruments

The data collection form (Appendix B) consisted of a single page with directions for completing the form, four multiple choice questions, and two open ended fill-in-the-blank questions. The investigator recorded correct identification of airway anatomy, either yes or no, and the actual cricoid pressure in Kg generated by the participant on the bottom of the data collection form.

Statistical Analysis

The percentage of operating room registered nurses who knew the recommended cricoid pressure will be calculated and compared with the percent who did not. The percent of registered nurses who correctly identified the anatomical position of the cricoid cartilage will be calculated and compared with the percent who did not. Statistical analysis will determine if there is a significant difference between the cricoid pressure actually applied and the recommended pressure. Statistical analysis will also be performed to determine if there is a significant difference between the cricoid pressure actually applied by participants who demonstrated the correct anatomical position and those that did not. Correlations between gender, hand dominance, years of clinical experience in application of cricoid cartilage pressure, frequency in application of cricoid pressure, or previous testing or training in application of cricoid cartilage pressure with the cognitive knowledge, actual applied pressure, and the correctness of identifying anatomical location will be analyzed. Data will be analyzed using Statistical Package for the Social Sciences (SPSS) computer software. Statistical significance will be based upon a $p < 0.05$.

# Chapter 4

# Findings

## Purpose of Study

The purpose of this study was to evaluate registered nurses' knowledge of and ability to, correctly identify the cricoid cartilage and to apply cricoid cartilage pressure. This was evaluated through six specific purposes. The first was to assess the cognitive knowledge of registered nurses as to the proper amount of force required for effective cricoid pressure in the unconscious adult patient. The second purpose was to determine the ability of registered nurses to correctly identify the anatomical location of the cricoid cartilage on an airway model. The third purpose was to assess the amount of cricoid pressure applied by registered nurses to an airway model mounted on an infant scale. The fourth purpose was to evaluate the influence of gender, hand dominance, years of clinical experience in application of cricoid cartilage pressure, frequency of application of cricoid cartilage pressure, and the presence or absence of previous training or testing on cognitive knowledge of the recommended cricoid cartilage pressure on an unconscious adult. The fifth purpose was to evaluate the influence of gender, hand dominance, years of clinical experience in application of cricoid cartilage pressure, frequency of application of cricoid cartilage pressure, and the presence or absence of previous training or testing on actual cricoid force applied to an airway model mounted on an infant scale. The final purpose was to evaluate the influence of gender, hand dominance, years of clinical experience in application of cricoid cartilage pressure, frequency of application of

cricoid cartilage pressure, and the presence or absence of previous training or testing on ability to correctly identify the anatomical location of the cricoid cartilage on an airway model.

Research Question 1

What percentage of registered nurses were able to state the recommended cricoid pressure for prevention of aspiration in the unconscious adult patient?

*Findings.* A total of 45 registered nurses participated in the data collection. The recommended cricoid cartilage pressure for the unconscious adult patient in this study was 4 Kg. Three or 6.7% of the participants corrected stated this value. There were 22 or 48.9% that underestimated and 20 or 44.4% that overestimated the recommended value. A minimum of 1 Kg and a maximum of 13.2 Kg were stated with a mean of 4.43 Kg and a standard deviation of 2.97 Kg.

Cognitive Knowledge of Recommended Cricoid Pressure

| | Percentage | Range (Kg) |
|---|---|---|
| Under Estimation | 22 (48.9%) | 1 – 3.5 |
| Correct Estimation | 3 (6.7%) | 4 |
| Over Estimation | 20 (44.4%) | 4.5 – 13.2 |

*Discussion.* Data revealed that 42 of the 45 participants or 92.7% incorrectly stated the recommended cricoid pressure for the unconscious adult patient. The lack

of cognitive knowledge on the correct recommended pressure has been echoed in many previous studies. A study by Walton and Pearce (2000) found one of nine anesthesia trainees were able to state the correct recommended force. Another study had better, but still concerning results, with 33% of the 135 practitioners and trainees able to correctly state the required force (Meek et al. 1999).

Research Question 2

What percentage of registered nurses were able to correctly identify the cricoid cartilage on the scale mounted airway model?

*Findings.* A total of 45 registered nurses participated in the data collection. A total of 25 or 55.6% of participants correctly identified the cricoid cartilage on the scale mounted airway model as determined by observation of the investigator.

*Discussion.* The adult airway model used clearly represents the structures of interest for this study. The anatomical structures represented by the airway model included the trachea, thyroid cartilage, thyroid prominence, crico-thyroid membrane, and cricoid cartilage ring.

The first step in being able to correctly apply cricoid cartilage pressure is the identification of the correct anatomical location of the structure. Although the majority (55.6%) of participants in this study were able to correctly identify the anatomy, there was still a large percentage that did not. A study by Patten (2006) demonstrated that 39.2% of participants were able to choose the correct anatomical location from a list of four possible descriptive answers.

Many difficulties can arise for both the patient as well as the anesthetist if cricoid pressure is applied in the incorrect location. The patient is at risk for aspiration due to an incompletely occluded esophagus or possible injury to the thyroid or surrounding tissue. The anesthetist may have difficulty with visualization of the glottic opening, distortion of the airway, difficulty advancing the endotracheal tube, or difficulty with bag mask ventilation due to the improper application of pressure to the airway (Brimacombe & Berry, 1997).

Research Question 3

Is there a correlation between the cognitive knowledge of amount of cricoid pressure the registered nurses stated for the unconscious adult patient and the amount actually applied to the scale mounted airway model?

*Findings.* A total of 45 registered nurses participated in the data collection. The Wilcoxon signed ranks test demonstrated 19 negative ranks in which the actual applied pressure was less than the pressure the participant believed to be correct, 25 positive ranks in which the actual pressure was greater than the pressure believed to be correct ($Z = -.216$), and 1 where the actual applied pressure equaled the pressure that the participant believed to be correct. The pressures believed to be correct ranged from 1 Kg to 13.2 Kg with a mean of 4.43 and standard deviation of 2.97. The actual applied pressure ranged from 0.4 Kg to 9.2 Kg with a mean of 4.13 and a standard deviation of 2.05. No significance between cognitive knowledge and actual applied pressure was demonstrated by Pearson Correlation of -.138 with a 2-tailed significance of .366.

If an acceptable range of 3.5 Kg to 4.5 Kg were to be accepted then data collection demonstrated that seven participants correctly stated a value within that range while 15 participants were able to actually apply pressure within that range. Furthermore, there were three of 45 participants that both stated and applied cricoid cartilage pressure within the stated acceptable range.

*Discussion.* Data collection demonstrated that there was no significant correlation between the registered nurses' cognitive knowledge of cricoid cartilage pressure and what that nurse actually applied to the airway model. This dissociation between cognition and application ability is of particular concern. Most participants did not know the correct pressure and also were unable to apply the correct cricoid pressure. A few knew the correct pressure but did not apply the correct pressure and yet many nurses did not know the correct pressure but were still able to apply the correct pressure. If an acceptable range of 3.5 to 4.5 Kg was accepted then results demonstrated that seven participants correctly stated the pressure, 15 participants applied acceptable pressure, and only three were able to both state and apply an acceptable pressure. All three of these participants acknowledged having previous training or testing. Again 27 of the 45 participants acknowledged previous training or testing so only 11.1% of those with previous training or testing were able to both state and apply cricoid cartilage pressure within an acceptable range. There was no participants that denied previous training or testing that were able to both state and apply cricoid pressure within the an acceptable range. Other studies have shown similar findings.

In one such study perioperative nurses correctly stated the recommended pressure 5% of the time while 13% were able to correctly apply the recommended pressure. Further more, 78% underestimated the correct pressure and 69.5% applied force below the level recommended in that study (Koziol et al. 2000). These results raise the question of whether it is worse to apply too little pressure with the possibility of leaving the esophagus unoccluded and the patient at risk for regurgitation and aspiration or too great of pressure resulting in airway management difficulties or patient injury. Since true clinical studies to determine the ramifications of either too great, too little, or no cricoid pressure at all cannot be ethically performed, this will remain a significant albeit debatable topic.

Research Question 4

Is there a correlation between the correct location of application of cricoid pressure and the actual pressure applied to the scale mounted airway model?

*Findings.* A total of 45 registered nurses participated in data collection. There were 25 of 45 (55.6%) participants that were able to correctly identify the cricoid cartilage on the airway model. Those that correctly identified the anatomy had a mean actual pressure of 4.05 Kg with a standard deviation of 1.80 compared with the 20 participants who did not correctly identify anatomy who had a mean actual pressure of 4.24 Kg and a standard deviation of 2.36. There was no statistically significant difference between the groups with $t = -.295$, $p = .770$.

*Discussion.* The participants that applied pressure in the incorrect location had a greater mean pressure as well as a greater standard deviation than those that applied

pressure to the cricoid ring. Applying the correct force to the correct location is of significance to patient safety even though the results of this study's actual application pressure were not statistically significant. The important point is that even if the correct force is applied but to the incorrect anatomical position, it is potentially more dangerous to the patient than if attempts at cricoid cartilage pressure were not done at all. The patient still remains at risk for regurgitation and aspiration, upper airway injury, airway management difficulties by the anesthetist, and a false sense of security by both the person applying the pressure and the anesthetist attempting to secure the airway that the effort to protect the airway from gastric contents is effective. These results further emphasize the importance of cognitive skill as well as correct application technique; which literature suggests only comes from proper training and frequent reinforcement of skills.

Research Question 5

Is there a correlation between gender, hand dominance, years of clinical experience in application of cricoid cartilage pressure, frequency of application of cricoid cartilage pressure, or previous training or testing in application of cricoid cartilage pressure and the stated cricoid cartilage pressure?

*Findings.* A total of 45 registered nurses participated in data collection. There were 5 males and 40 females that participated. The mean stated pressure by the males was 4.7 Kg with a standard deviation of 0.97. The mean stated pressure by the females was 4.4 Kg with a standard deviation of 3.13. No significance between groups was demonstrated $t = .21$, $p = .83$.

There were 5 left hand and 40 right hand dominant participants. The left hand dominant participants had a mean stated pressure of 2.7 Kg with a standard deviation of 1.57 while the right hand dominant participants had a mean of 4.65 Kg with a standard deviation of 3.04. No significance between groups was demonstrated $t = -1.4$, $p = .168$. Stated years of clinical experience during which the nurse may have been required to apply cricoid pressure ranged from a low of one year to a maximum of 40 years. There were 15 nurses with 5 years or less of clinical experience and 30 that had greater than 5 years of experience. Those with two or less years of experience comprised 20% of the sample and had one participant that stated a pressure within 0.5 Kg of the correct pressure of 4 Kg. Those with 3 to 5 years of experience comprised 13.3% and had no participants that were within one half kilogram of the correct pressure. The participants with 6 to 10 years of experience comprised 26.6% of all participants and had three that were within one half kilogram of the correct pressure. The final grouping of participants with greater than 11 years of clinical experience (40%) had three participants that stated a pressure within one half kilogram of the correct pressure. A stated pressure that was greater than one half kilogram above the correct pressure was most likely in the group with the least years of experience (77.7% of nurses with 0 to 2 years experience, 7 of 9). The opposite was true with those with between 6 and 10 years of experience. Those participants were more likely to state a pressure that was lower than one half kilogram below the correct value (58.3%, 7 of 12). That group did also have the highest percentage of

participants that feel within the range of 3.5 to 4.5 Kg (3 of 12, 25%). However there was no statistical significance to these differences.

Cognitive Value vs. Years of Clinical Experience in Application of Cricoid Pressure

| | Clinical Years | | | | |
|---|---|---|---|---|---|
| Estimation (Kg) | 0 – 2 | 3 – 5 | 6 – 10 | 11+ | Total |
| < 3.5 | 1 | 2 | 7 | 9 | 19 (42.2%) |
| 3.5 – 4.5 | 1 | 0 | 3 | 3 | 7 (15.5%) |
| > 4.5 | 7 | 4 | 3 | 6 | 19 (42.2%) |
| Total | 9 (20%) | 6 (13.3%) | 12 (26.6%) | 18 (40%) | 45 (100%) |

There were 24 participants that reported that they had applied cricoid cartilage pressure 5 times or less and 21 that applied pressure greater than 5 times in the clinical setting in the previous two months. The group that applied pressure 5 times or less had a mean pressure of 4.03 Kg with a standard deviation of 2.85. The greater than 5 times group, had a mean pressure of 4.9 Kg with a standard deviation of 3.1. No statistically significant difference was found t-test was -.977, $p = .334$. Comparing participants that had not applied cricoid pressure in the previous 2 months (N=11) with those that had (N=34), demonstrated similar results. Those that did not apply cricoid pressure clinically in the previous 2 months had a stated mean of 4.39 Kg with

standard deviation of 3.72. Those that acknowledged applying pressure clinically had a stated mean of 4.45 Kg and standard deviation of 2.74. These values were not statistically significantly different t = -.054, p = .957.

The majority of participants acknowledged having received prior testing or training in the 12 months prior to data collection (27 of 45, 60%). The stated pressure for those that received training or testing had a mean of 4.11 Kg with a standard deviation of 2.93 versus those that didn't receive training or testing having a mean of 4.92 Kg with a standard deviation of 3.04. No significance was noted p = .833. Of the trained participants (N=27), two were able to correctly state the pressure and seven were within one half kilogram of the correct pressure. The range of stated values for trained individuals ranged from 1 to 13.2 Kg. The untrained participants (N=18) one person correctly stated the pressure and eight were within one half kilogram. This group had a stated range of 1 to 12 Kg.

Cognitive and Applied Values vs. Acknowledgement of Previous Training

| Attended | | Actual Applied Value (Kg) | | Cognitive Value (Kg) | |
|---|---|---|---|---|---|
| Training | N | Mean | SD | Mean | SD |
| Yes | 27 | 4.10 | 2.10 | 4.11 | 2.93 |
| No | 18 | 4.19 | 2.02 | 4.92 | 3.04 |
| | | p = .884 | | p = .833 | |

*Discussion.* The results demonstrate no significant difference between males and females as well as right hand dominant versus left hand dominant in the ability to correctly state the recommended cricoid cartilage pressure.

Years of clinical experience seemed to make no difference in the ability of the participants to correctly state the recommended pressure. Those with the least experience, tended to over estimate; while those with more experience tended to under estimate the correct pressure. The number of participants that had applied cricoid cartilage pressure in the clinical setting was slightly greater than those that had not in the previous two months. However, there was no real difference in either groups ability or lack there of, to correctly state the recommended pressure. The same held true for those that had received some form of either testing or training in the previous year. The majority (60%) acknowledged having done so but were no better at stating the correct pressure than those that had not been taught or trained. The trained group had a larger range than the group that did not receive training and they also had a smaller percentage of participants that were within one half kilogram of the correct value (25.9% v. 44.4%).

Research Question 6

Is there a correlation between gender, hand dominance, years of clinical experience in application of cricoid cartilage pressure, frequency of application of cricoid cartilage pressure, or previous training or testing in application of cricoid cartilage pressure and the actual pressure applied to an airway model?

*Findings.* There were 45 registered nurses that participated in the study with 5 being males and 40 females. The mean applied pressure for the males was 3.88 Kg with a standard deviation of 1.38. The females mean applied pressure was 4.17 Kg with a standard deviation of 2.13. These values were not found to be statistically different $t = -.290$, $p = .773$.

There were 40 right hand dominant and 5 left dominant study participants. The right hand dominant mean applied pressure was 3.99 Kg with a standard deviation of 1.98. The left hand dominant persons had a mean applied pressure of 5.3 Kg with a 2.47 standard deviation ($t = 1.364$, $p = .180$).

Years of clinical experience ranged from 1 to 40 years. Those with two years or less years of experience had the greatest percent that applied too little pressure (66.7%). Those with between 3 and 5 or 6 and 10 years of experience had the greatest number of participants that applied pressure within one kilogram of the correct pressure, 83.3% and 58.3% respectively. The participants with the most clinical experience, greater than 10 years, tended to be within one kilogram of the correct value or greater than that range, 38.9% and 44.4% respectively. These findings were statistically different chi-square = 14.777, $df = 6$, $p = .022$.

There were 11 participants that denied applying cricoid cartilage pressure clinically in the previous two months, 24 that applied between 1 and 10 times, and 10 that applied greater than 11 times. Those that did not apply had a mean of 4.63 Kg and a standard deviation of 1.83. The group that applied between 1 and 10 times had a mean applied pressure of 3.57 Kg and a standard deviation of 1.72. The third group,

that applied greater than 10 times, had a mean applied pressure of 4.95 Kg with a 2.71 standard deviation. A one-way ANOVA demonstrated no statistically significant differences among these groups, $F = 2.1$, $p = .13$. Comparing those that acknowledged applying cricoid cartilage pressure clinically in the previous two months ($N = 34$) with those that had not applied ($N = 11$) resulted in a mean actual applied pressure of 3.97 Kg ($SD = 2.11$) and 4.63 Kg ($SD = 1.83$) for the later. There was no statistical significance $t = .918$, $p = .364$.

There were 27 of 45 participants that had attended training or testing of cricoid cartilage pressure competency in the previous year. Only one person that had previous training or testing applied the correct pressure for this study. There were 7 of the 27 previously trained or tested participants that applied pressure within one half kilogram of the recommended study level. The range of actual applied pressure by those that had received previous training or testing was 0.4 to 8.7 Kg. The 18 remaining participants that denied receiving previous training or testing in the prior 12 months had a range of actual applied pressure of 0.9 to 9.2 Kg. Eight participants were within one half kilogram of the correct pressure in the untrained or tested group. The mean applied pressure for those that had training was 4.1 Kg ($SD = 2.1$) and 4.19 Kg ($SD = 2.02$) for those that had not. There was no statistical significance $t = -.147$, $p = .884$.

Cognitive and Applied Values vs. Acknowledgement of Previous Training

| | Actual Applied Value (Kg) | Cognitive Value (Kg) |
|---|---|---|
| Attended | | |

| Training | N | Mean | SD | Mean | SD |
|---|---|---|---|---|---|
| Yes | 27 | 4.10 | 2.10 | 4.11 | 2.93 |
| No | 18 | 4.19 | 2.02 | 4.92 | 3.04 |
| | | p = .884 | | p = .833 | |

*Discussion.* There were no statistically significant differences appreciated between males and females or right or left hand dominant persons and their actual applied pressure. Hand dominance would seem to be an important factor since cricoid pressure is classically applied with the right hand. However, previous studies have found that hand dominance does not seem to be a major contributing factor as to the amount of pressure applied nor does gender (Cook et al. 2000; Schmidt & Akeson, 2001).

The amount of practice and training a person has at a particular task typically is reflected in that person's ability to perform that task proficiently. That was certainly not the findings of this or other similar studies. Participants in this study with the least years of clinical experience in application of cricoid cartilage pressure tended to over estimate the stated pressure then apply too little pressure. Those with the greatest number of years of experience tended to do the exact opposite. The factors suggested by other authors for the poor performance that is frequently discovered through simulated application reflects on the lack of formalized or standardized training, infrequency of the training, and lack of strong clinical

guidelines (Brimacombe & Berry, 1997; Gardiner & Grindrod, 2005; Moos, 2007). None of those factors appeared to make a meaningful difference in this study.

Research Question 7

Is there a correlation between gender, hand dominance, years of clinical experience in application of cricoid cartilage pressure, frequency of application of cricoid cartilage pressure, or previous training or testing in application of cricoid cartilage pressure and the ability to correctly identify the cricoid cartilage on an airway model?

*Findings.* There were 45 registered nurses that participated in this study. Of those participants, 25 were able to correctly identify the cricoid cartilage on the model. There were 5 male participants of which 4 correctly identified the anatomy and one that did not. There were 40 female participants of which 21 (52.5%) correctly identified the anatomy and 19 (47.5%) that did not. These values were not found to be statistically significant in difference chi-square = 1.361, df = 1, p = .24.

There were five left hand dominant participants, three (60%) were able to correctly identify the cricoid cartilage. Right hand dominant persons were slightly more divided with 22 (55%) of the 40 able to correctly identify the anatomy, chi-square = .045, p = .83.

Participants with the least number of years (2 years or less) of experience had the greatest percent that were able to correctly identify the cricoid cartilage on the airway model (77.8%). Half of those with 3 to 5 years, 66.7% with 6 to 10 years, and

38.9% of participants with greater than 10 years of experience were able to correctly identify the cricoid cartilage on the model chi-square value = 4.5, df of 3, p = .212.

Participants who indicated that they had not applied cricoid cartilage pressure clinically in the previous two months were less likely to correctly identify the cricoid cartilage on the model than those that applied between 1 and 10 times (45.5% correct versus 54.2% correct). The group that applied between 1 and 10 times were less likely to correctly identify the anatomy than those that applied greater than 10 times over the previous two months (54.2% correct verses 70% correct). No statistically significant difference was found, chi-square = 1.318, df = 2, p = .517.

Participants that had acknowledged previously attending training or testing, were more likely to correctly identify the cricoid cartilage than those that had not. There were 25 of 45 that had been trained or tested with 59.3% of those correctly identifying the anatomy. Half of the 18 untrained individuals correctly identified the cricoid cartilage. Chi-square = .375, df = 1, p = .54.

*Discussion.* This study demonstrated that it did not matter if the person was male or female, left hand dominant or right, the likelihood that the correct anatomical location of the cricoid cartilage would be identified was uncertain at best. This also held true with years of clinical experience in applying cricoid cartilage and knowledge of anatomical location of the cricoid. This is particularly alarming when considering the number of times these nurses have applied cricoid cartilage or some sort of airway pressure, over the course of their careers. Considering the alternative is that it may truly not matter whether the application is done by what is considered

correct or not and that the arguments by some authors that Sellick's maneuver is unnecessary to be true. However, that determination is not expressed or implied as part of this research study.

It did seem that the more often the nurse applied cricoid pressure clinically, the more likely they were to correctly identify the anatomy however these observations were not statistically significant. Theoretically, it would make sense though. Most authors agree that experience and practice does further enhance the cognitive aspect of cricoid cartilage pressure application and increases the nurses' ability to properly perform. Repeated training sessions with simulators has shown improvement and consistency in trainees' ability to correctly identify and apply cricoid cartilage pressure (Kopka & Crawford, 2004; Stanton, 2006).

The airway model used consisted of the lower jaw including oropharynx, the esophagus, trachea, thyroid cartilage, crico-thyroid membrane, and cricoid cartilage ring. Observationally, the participants that did apply pressure to the cricoid ring tended to apply pressure to the thyroid prominence. This may have been due to the larger size of the thyroid making it seem like the logical location or it may just have been pure lack of cognitive knowledge of anatomy. Either way, potentially dangerous complications could result clinically due to this deficiency. This observation further emphasizes the role of the anesthetist as an advanced practice nurse in being the patient advocate by ensuring that the person assisting in airway management is properly educated and aware of the expectations of the procedure. A brief discussion

of the steps in application of proper cricoid pressure, including where to apply, when to apply, and how hard to apply, should be done each time for patient protection.

Additional Findings

A strong consensus emerged after talking with the registered nurses after they had participated in this study. They commonly questioned how much pressure to apply and stated that the anesthesia provider would often simply tell them to ‘push here’ or to ‘push harder/softer’. Many expressed concern that they had never received what they would consider adequate training. Another concern was that they would be asked to apply cricoid pressure so infrequently that they did not feel comfortable doing so. The medical center where this study took place has developed and instituted an annual competency in the application of cricoid cartilage pressure in the previous year using the same equipment that was used in this study. Many authors agree that training needs to be no less frequent than every three months with more frequent training being preferred. Time constraints and shear numbers of employees makes this a daunting but very important task that in every setting where cricoid cartilage pressure is applied should consider instituting. A collaborative effort between anesthesia and nursing would result in the most appropriate and encompassing competency based upon current literature and research. The use of models and scales such as that used in this study would help to solidify the proper technique and application pressure.

The actual identification of the cricoid cartilage emerged has a topic of concern. Although the majority of participants correctly identified the structure, many

more did not. Again this may reflect the lack of comfort and confidence by those that are called upon to apply cricoid pressure.

# Chapter 5

# Summary

## Summary

Cricoid cartilage pressure or Sellick's maneuver is the technique of applying firm force to the cricoid ring on patients at risk for gastric regurgitation with the intention of temporarily occluding the esophagus. This maneuver is considered a standard of care in airway management for at risk patients and during the rapid sequence induction of general anesthesia. Effective cricoid pressure results in maintenance of the airway patency and prevention of regurgitation of gastric contents, by pinching the esophagus closed between the cricoid cartilage and the cervical vertebrae.

There are many consequences when improper application of cricoid pressure is performed including difficulty with ventilation, tracheal cartilage injury, distortion of glottic view during direct laryngoscopy, and regurgitation. Knowledge of the correct anatomical location and recommended force are important for proper technique. Research has shown that this knowledge is lacking in those that are responsible for this vitally important procedure.

The actual application of cricoid cartilage pressure is traditionally performed by an anesthesia assistant or the operating room registered nurse. This study evaluated operating room registered nurses' knowledge of the recommended pressure for the unconscious adult patient as well as their ability to correctly identify the anatomical location of the cricoid ring. They were also evaluated on their ability to

apply the proper amount of cricoid pressure to an airway model mounted on a digital infant scale. The correct pressure for this study was four kilograms which is widely supported in research literature. Certain demographic and clinical background information, that research has suggested may impact a persons knowledge base and application ability, was also collected and evaluated for correlative relationships. Information collected included the participants gender, hand dominance, years of clinical experience in the application of cricoid cartilage pressure, number of times that they had applied cricoid cartilage pressure in the previous two months, and whether they had received any formal training or competency testing in application of cricoid cartilage pressure in the previous 12 months.

Power analysis determined that at a significance level of $p<0.05$, a sample size of 46 was needed. The sample size of this study was 45 which was limited by the studies aim to scrutinize operating room registered nurses at only two urban medical centers and the willingness of staff to participate in the study. The medical centers sampled had developed and instituted a cricoid cartilage competency in the previous year. A part of the analysis of this study was to compare those participants that had received this training and testing session with those that had not. Results of this study were so widely distributed that a large sample size would not be expected to have changed results in a significant manner.

Various statistical testing was used to evaluate significance and correlational relationships. Individual demographic and clinical type data was evaluated in frequency tables. Descriptive statistics were used to determine range, mean, and

standard deviation. Wilcoxon signed-rank test was used to compare over and under estimation of cognitive knowledge and actual applied values against the correct value of this study. A t-test for equality of means was used to determine 2-tailed significance. Cross tabulations of certain data of interest, such as hand dominance and correct application pressure, was used to determine correlations and significance. Pearson's chi-square tested for difference among several different groups in order to determine if significance existed. All significance levels were determined at $p<0.05$ for this study.

Conclusions

The results of this study demonstrated significant deficiencies in both the cognitive knowledge and hands on application skills of operating room registered nurses related to cricoid cartilage pressure. Data suggested that there was no statistically significant difference among the groups based upon gender, hand dominance, frequency of clinical application, or previous training or testing competencies in cricoid cartilage pressure and that nurses' ability to state or apply the correct amount of pressure. Furthermore, none of these factors were predictors in the ability to correctly identify the proper anatomy either. There was a statistical significance between years of clinical experience and actual pressure applied. Despite generally lacking statistical significance, the descriptive portion of this study proved to be very important.

Lacking all three components for proper application of cricoid cartilage pressure is an alarming finding. A person who does not know the anatomy, have the

cognitive knowledge, and/or is unable to apply the proper amount of pressure should not be responsible for such an important task. The consequences for the patient could be severe. The fact that 60% of participants acknowledged having received prior training or testing in the previous year and were no more likely to state or apply correct pressure further emphasizes the seriousness of the findings of this study. The positive side is that literature reports that frequent training sessions, using a model and scale setup similar to that used in this study, results in greater proficiency in correct application skills. The equipment used for this study is inexpensive and readily available at most medical centers or community hospitals. There are also numerous commercial models available.

Recommendations

1. Establish a competency for all staff involved in airway management including registered nurses, respiratory therapists, student registered nurse anesthetists, certified registered nurse anesthetists, and anesthesiologists. The competency needs to be based upon the consensus of research and evaluated on at least an annual basis.

2. Incorporate didactic and hands on training into all nurse anesthesia education programs. It is very important to have a strong knowledge base especially in the area of expertise.

3. Evaluate efficacy of competency training sessions through post testing. This would help determine how well staff learned and retained the information and would help guide frequency of future refresher sessions.

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Appendix A

BryanLGH Registered Nurse,

As a registered nurse you are being invited to participate in a research study examining registered nurses' knowledge of the ability to apply cricoid cartilage pressure. This study is being conducted through the University of Kansas Medical Center in collaboration with BryanLGH with James Cuddeford, CRNA, MA as the primary investigator. This study is also part of the graduate thesis requirements for Ross Beavers, SRNA, BSN.

All information collected as part of the study is completely anonymous and confidential. No individually identifiable information will be collected. Only aggregate (combined) data will be published. There are no foreseeable risks involved in this study. Your total participation time is expected to be less than five minutes. Your participation in this study is completely voluntary. Deciding not to participate in this study will have no affect on your employment at BryanLGH and will have no affect on your current or future relationship with the University of Kansas Medical Center.

**Procedure:** Please read and complete the questionnaire attached. When finished, proceed to the hands-on model station and give the form to the investigator.

**Model**: Please apply cricoid cartilage pressure to the model in the same or similar manner that you would apply to an actual unconscious adult patient in the clinical setting. Please inform the investigator when you think that you are applying the correct pressure. You will only do this one time and one time only. Your applied pressure will be recorded on the questionnaire form as part of the data collection as well as on an educational handout for your information only.

Thank you for considering participation in this study. If you have any questions please contact Ross Beavers at 402-770-7649 or rbeavers@kumc.edu.

Appendix B

Data Collection Form

**Instructions:** Please carefully read each question, then mark or fill-in your answer as indicated.

1. What is your gender? **(please circle)** Male or Female

2. Which is your dominate hand? **(please circle)** Left or Right

3. How many years have you worked in a clinical setting that may require you to apply cricoid cartilage pressure? **(please write in your answer)**

_____ years

4. Please estimate the number of times that you have actually applied cricoid cartilage pressure in the clinical setting in the last <u>two months</u>. **(please circle)**

a. did not apply cricoid pressure
b. 1 - 5 times
c. 6 - 10 times
d. 11 - 15 times
e. 16 - 20 times
f. greater than 20 times

5. Have you participated in any cricoid cartilage pressure competency training or testing within the previous <u>12 months</u>? **(please circle all that apply)**

a. yes – at BryanLGH Medical Center(s)
b. yes – at other medical center(s)
c. no – have never participated

6. What is the recommended cricoid cartilage pressure for the unconscious adult patient? (**please write in your answer**)

_____ Kilogram (Kg)

# Appendix C

## Educational Hand-Out

Cricoid cartilage pressure is synonymous with Sellick's maneuver.

**Anatomy and location**:

The cricoid cartilage is the only complete ring of cartilage in the trachea. It is located at the C6 spinal level. The esophagus is located behind the trachea and therefore the cricoid cartilage. The cricoid cartilage can be located by moving slightly inferiorly to the thyroid cartilage and the cricoid notch or just inferior to the thyroid prominence or "Adam's apple".

**Purpose of cricoid cartilage pressure**:

Applying backward pressure on the cricoid cartilage is intended to compress the esophagus and prevent the regurgitation of gastric contents from entering the oropharynx during the induction of general anesthesia. It is also used for the prevention of gastric insufflation with air during bag/mask ventilation.

**Application technique**:

Once the anatomy has been properly identified, using the right hand place the thumb on the right side of the patient's trachea, the first finger directly on the cricoid, and the second finger on the left side of the trachea. A pressure of approximately 2 Kg or 20 Newtons for the conscious patient, increasing to 4 Kg or 40 Newtons in the unconscious patient is applied directly backwards towards the patient's vertebral column. Amount and timing of pressure demands attention to patient condition and will be directed by the clinician intubating or mask ventilating the patient. Cricoid pressure should only be reduced or terminated if instructed by the clinician intubating or masking the patient.

**Significance of proper application**:

The prevention of regurgitation and possible pulmonary aspiration of gastric contents relies significantly upon proper application of cricoid pressure. Improper identification of anatomy can render the technique ineffective. The amount of applied force is crucial. Too little force leaves the esophagus open and at risk for regurgitation while too much may make ventilation and/or intubation difficult. Timing is crucial to prevent the conscious patient from pain, anxiety, coughing, bucking, retching, vomiting, recall, or dyspnea.

**Indications and Contraindications**:

Cricoid pressure is applied most often for the rapid sequence induction (RSI) of general anesthesia in patients identified as high risk for aspiration. Patient risk factors include: obesity, diabetes, pregnancy, trauma, non-fasting state, gastrointestinal obstruction or dysfunction, the elderly, uncontrolled gastro-esophageal reflux, uncoordinated swallow and respiration pattern, decreased level of consciousness unrelated to head trauma, esophageal pathology, and/or presence of hiatal hernia.

Cricoid pressure is contraindicated in patients with unstable cervical fracture, active vomiting, cricotracheal injury, foreign body in upper airway, and/or history of a difficult airway.

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Appendix

# The University of Kansas Medical Center

Human Research Protection Program

December 12,2007

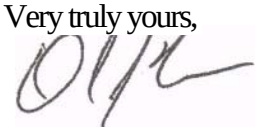
| | |
|---|---|
| **Project Number:** | 11144 |
| **Project Title: Sponsor:** | Analysis of Cricoid Pressure as Applied by Registered Nurses |
| **Protocol Number:** | None |
| **Primary Investigator:** | N/A |
| **Department: Meeting** | James D. Cuddeford |
| **Date: HSC Approval** | Nurse Anesthesia Education |
| **Date: Type of** | 12/4/2007 |
| **Approval:** | 12/11/2007 |
| | Exemption Class b (2) |

Dear Investigator:

This is to certify that your research proposal involving human subject participants has been reviewed and **approved** by the KUMC Human Subjects Committee (HSC). This "exempt" approval is based upon the assurance that you will notify the HSC prior to implementing any revisions to the project. The HSC must determine whether or not the revisions impact the risks to human subjects, thus affecting the project's "exempt" status. Projects that do not meet the "exempt" criteria must comply with all federal regulations regarding research.

If you have any questions regarding the human subject protection process, please do not hesitate to contact our office.

Very truly yours,



Daniel J. Voss, M.S., J.D.
IRB Administrator

Mail-Stop 1032, 3901 Rainbow Blvd., Kansas City, **KS** 66160 Phone: (913588-1240 Fax: (913) 588-5771
humansubjects@kumc.edu

Appendix E


October 25, 2007

Ross Beavers 1810S.W.
25th Street Lincoln, NE
68522

Dear Ross:

On behalf of the Administrative Approval for Research/Clinical Studies Committee (AARC) of BryanLGH Medical Center, I am pleased to inform you that the research study proposal, "Analysis of Cricoid Pressure as Applied by Registered Nurses," (Study #272) has been given final approval. You may start data collection as soon as you receive IRB authorization.

The AARC provides a process for the review and approval of all research/clinical studies conducted at BryanLGH Medical Center, subject to IRB approval when appropriate. Objectives of this committee include: (a) reviewing all proposed clinical study/research proposals for congruence with the Mission of BryanLGH Medical Center; (b) assuring that the study is appropriate from clinical relevance, methodological and a human value's perspective; (c) minimizing duplication with other studies being conducted; (d) determining resource requirements and fiscal feasibility; and (e) assuring timeliness of education when appropriate. This committee is not an Institutional Review Board (IRB).

Please keep in mind, as principal investigator, you are responsible for informing this committee in writing of any changes, adverse occurrences or unanticipated problems, and submitting a final report which will be kept on file. You may also be asked to present the study outcomes/findings to the AARC.

We wish you much success with your study.

Sincerely,

June Smith

'June Smith Chairperson, Administrative Approval for Research/Clinical Studies Committee