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COMPARISON OF TIMES FOR TWO EASYTUBE PLACEMENT TECHNIQUES

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ABSTRACT

Airway management is vital to anesthetic management. Multiple devices exist to facilitate airway management, including endotracheal tubes, masks and supraglottic airway devices. Supraglottic airway devices, including EasyTube, Combitube, and laryngeal mask airways, are becoming increasingly utilized. However, in hospitals, only laryngeal mask airways are commonly used. However, supraglottic devices are being increasingly recommended for difficult airways. A "difficult airway" indicates severe difficulty of either ventilation or oxygenation of patients through traditional methods (endotracheal tube or mask ventilation), and present a unique opportunity for new airway management devices. Novel placement techniques of supraglottic devices may improve difficult airway management. In this study, skilled providers from the Penn State Hershey Anesthesiology Department placed the EasyTube device with two techniques: the manufacturer-recommended blind technique, and a novel laryngoscopic technique. The goal was to determine if a significant difference existed in placement times. Using a simulation mannequin, each technique was performed twice after an explanation and short practice session. All study participants were uncompensated volunteers who gave verbal consent after the research explanation. Each was randomly assigned the first placement method, and followed with the second method. 32 volunteers participated in the study. The participants' level of training and previous experience were compared with their results and familiarity with the device. The hypothesis was that placement times between the two techniques would differ by no more than ten seconds with a standard deviation of ten seconds. The results were analyzed using appropriate statistical methodology. The conclusion is that no statistically significant difference exists in placement times.

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Thank you.

Chapter 1: Introduction

1.1 Background

One of the most critical aspects of the field of anesthesiology is airway management. In all surgical cases in which a patient must be stabilized, whether undergoing routine surgery or in emergent and critical care cases, constant and patent access to the airway is of vital importance. In more serious cases, a patient may present in what is referred to a "difficult airway", or an airway that cannot be intubated after two attempts by an experienced provider. Difficult airways are not confined to intubation, but may also occur when the provider is unable to ventilate and oxygenate a patient by a mask.

Due to the urgency of a situation in which a difficult airway is presented, whether involving patients undergoing surgery or with impending respiratory failure, particular algorithms have been created in order to guide a provider through a process to secure an airway. This difficult airway algorithm is constantly being revised as new methods and devices are introduced. The ultimate goal is to improve patient care by ensuring that a secure airway is quickly established while minimizing trauma to the patient.

To ensure that providers are able to secure difficult airways, many devices have been created to assist in securing the airway. One class of devices is designed to be placed above the glottis rather than through it; these are referred to as supraglottic airway devices (SADs). This study examines a novel method of placement for a particular SAD, the EasyTube. The EasyTube is currently used primarily by emergency medical technicians and other providers in a pre-hospital setting, and placed blindly: the EasyTube is inserted above the glottis without use of an instrument to allow visual confirmation of the anatomy, which may cause additional trauma to the patient due to the inability of the provider to see where the device is being inserted.

As a result, it would be beneficial to the patient if a laryngoscope is used in order to place the device without applying unnecessary pressure to the surrounding tissue. However, since the device is intended to be used during emergent situations when the life of the patient may depend upon the time to secure an airway, the insertions times must be studied to determine whether or not the laryngoscopic method would substantially increase the risk to the patient as compared with the blind placement technique. Based on knowledge of gas exchange and blood flow to the brain, a difference of no more than ten seconds would be acceptable.

This study is designed to compare the two methods of insertion for the EasyTube: laryngoscopic placement versus blind insertion. The hypothesis is that insertion times of the EasyTube in conjunction with a laryngoscope will be no more than ten seconds longer than blind insertion, with a standard deviation of ten seconds. Therefore, the decreased trauma and more dependable access to the airway would outweigh the additional time necessary to achieve the airway.

1.2 Hypothesis and Research Question

The main purpose of this study is to determine if there is a statistical difference in the time to achieve an effective airway between the two insertion techniques (blind and laryngoscopic). The manufacturer recommends the blind technique, and this is the current method accepted by the FDA. The laryngoscopic method is novel, and not currently accepted in practice. The hypothesis is that a statistical difference cannot be shown, suggesting that an effective airway can be achieved quickly and efficiently using either method, thus providing an additional, potentially less traumatic and safer option for a practitioner in the operating theater.

Chapter 2: Literature Review

2.1 Overview of Difficult Airway Management

Approximately every ten years, the American Society of Anesthesiologists (ASA) completes an authoritative review of the difficult airway algorithm, in order to consider new devices and methods which may improve patient care. This algorithm is used by current anesthesiologists worldwide.[1] Using the guideline, practitioners can rely on a standard of best practices, based on the current research available. The algorithm helps the skilled provider (i.e. a provider such as an anesthesiologist or certified registered nurse anesthetist (CRNA) specifically trained in various methods to obtain airways in routine usage, as opposed to emergency personnel) to determine the best method to facilitate management of the difficult airway.

A recent article of *Anesthesiology* details specific historical and examination components that increase the risk of difficult airway management. One major addition to the 2013 article as opposed to the prior algorithm is the inclusion of supraglottic airway ventilation in the definition of the difficult airway[*], as well as suggesting the relative success of video-assisted laryngoscopy, in which a small camera attached to the end of the laryngoscope allows the provider to better view the anatomy when placing the device. The authors strongly recommended that practitioners always document the presence and nature of the airway in the anesthesia record, as well as discuss any complications with the patient post-operatively.

Like its counterpart in the United States, the Royal College of Anaesthetists in the United Kingdom periodically reviews the practices of airway management in an effort to continuously

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[*] The esophageal-tracheal Combitube had been discussed in the 2003 algorithm; however, the 2013 article elaborated on the use of SADs in the definition of the difficult airway.

improve airway technique and guidance to physicians.[3] The findings of the Fourth National Audit Project of the Royal College of Anaesthetists and the Difficult Airway Society (DAS) focus on three main areas of interest: airway management during anesthesia, airway management in the emergency department and airway management in the intensive care unit (ICU).

The Audit by the Royal College focused on the incidence of major complications in airway management during anesthesia outside the controlled operating theater—specifically in ICUs and emergency departments. As a result, the patients presenting in these situations are emergent. The study noted significant complications that arose in attempts to gain airways. Of note, two cases of unrecognized esophageal intubation both led to mortality; both of these cases involved physicians with limited anesthesiology experience.

The Audit detailed several outcomes and recommendations from the study. First, much like the ASA, the Royal College strongly emphasized the need for a strategy for failure in managing airways, much like the ASA's difficult airway algorithm. In addition, "an important recurrent finding was interpretation of capnography[†] when oesophageal intubation occurred. . . Clinicians, mostly anaesthetists, failed to recognize that a flat capnograph trace indicated absence of ventilation and a misplaced tracheal tube."[3] This finding is especially notable as esophageal intubation using an endotracheal tube or other such device must be corrected immediately and the device reintroduced. Other devices, such as SADs, greatly reduce the risk of unidentified incorrect placement and the possible catastrophic consequences, and so are considerably safer in this aspect as they are able to facilitate ventilation when placed in the esophagus.

[†] Capnography is the measurement of carbon dioxide in respiratory gases during inspiration and expiration.

2.2 Management of Difficult Airways

There are several different techniques for managing a difficult airway, as outlined in the guidelines published by the ASA.[1] In determining the most appropriate technique for a particular situation, many factors are considered, especially those related to the physical presentment of the patient. One such confounding factor occurs when a patient presents as obese. Budde et al. discuss methods by which a provider may predict, before admittance into the surgical theater, a difficult airway in obese patients using an older technique called indirect mirror laryngoscopy (ILM).[2] Budde et al. concluded that no method, even when analyzed independently, was able to predict a difficult airway at a statistically significant level, although ILM was a stronger predictor than most.[2] Their study highlights the power that ILM may possess as a useful tool for airway management in obese patients.[2] ILM is also relatively inexpensive and easy to complete and generally well-tolerated by patients. Therefore, it may prove helpful in the determination of patients with difficult airways.

Another aspect of difficult airway management occurs in certain situations in which mask ventilation proves to be impossible (known in the field as "impossible mask ventilation," or "IMV"), understanding the incidence, predictors and outcomes associated IMV is crucial. Kheterpal et al. (year?) examined the issues dealing with IMV, including frequency, associated factors and outcomes.[5] The focus of their study was to determine how frequently IMV, which can potentially be catastrophic, can occur, as well as to understand what factors can best predict future poor outcomes. They concluded that IMV often occurred during instances of exceptionally difficult intubations, even if IMV was relatively rare in occurrence (only 77 of over 50,000 cases resulted in IMV). This scarcity may occur because the highest-risk patients (those likely to undergo IMV) were more likely to undergo more precautionary techniques, such as the

utilization of an awake fiberoptic intubation rather than induction, thereby bypassing the need or opportunity for mask ventilation. An awake fiberoptic intubation also allows the patient to continue spontaneous ventilation and oxygenation, which helps avoid the risks of hypoxia/brain death associated with an asleep non-breathing patient that the provider is unable to oxygenate and ventilate.

A difficult airway can be especially alarming when it occurs during pregnancy, as both the mother and the fetus can experience poor outcomes. Vaida (year) published a review focusing on the increased risk and possible crisis that may occur when a difficult airway occurs in the parturient.[10] The difficult airway is eight times more common during pregnancy, and morbidity is thirteen times higher when compared with non-pregnant women. Vaida noted that anesthetic complications were the sixth leading cause of death in the pregnancy-related mortality in the United States. She concluded that most of these deaths are due specifically to airway management problems.

Considering these complications, Vaida succinctly reviews the causes for difficult intubation in pregnant patients, the risks of hypoxia and aspiration and the use of cricoid pressure. These reasons for difficult airway in pregnancy include increased mucosal engorgement and friability associated with labor and elevated progesterone levels, increased risks of aspiration associated with lower esophageal sphincter tone and elevated intra-abdominal pressure, significant airway changes that may occur with pushing and the generalized anasarca of labor and delivery, and weight gain and breast enlargement associated with pregnancy.

Of special concern to anesthesiologists in difficult airway management is the algorithm specifically dealing with situations known as “can’t intubate, can’t ventilate” (CICV). Heard et al. (year) examined how to manage a difficult airway and developed the best CICV algorithm for

educational training.[4] When a provider has exhausted all other possibilities and is into the CICV scenario, which falls at the end of the difficult airway algorithm designated by the ASA, as well as the procedures later established by the DAS.

CICV scenarios are, by their nature, the most critical situations, in which the patient may rapidly deteriorate into an unrecoverable state without immediate surgical intervention. Heard et al. describe four separate techniques: cannula cricothyroid puncture, scalpel bougie, Melker emergency cricothyroidotomy kit and the scalpel finger technique.[4] Each is an invasive technique, only used when all other attempts have failed.

Heard et al. emphasized that the technique employed by the provider should be that best suited to the provider's skills. For example, the ASA and the DAS both propound two recommendations at the end of their algorithms: cannula and scalpel cricothyroidotomy. As Heard et al. noted that a surgeon by necessity was more skilled in the use of the scalpel than the anesthesiologist, whereas a skilled anesthesiologist would generally utilize a cannula far better than a surgeon. For these reasons, the algorithm will vary depending on who is primary in the particular scenario. Heard et al. then detailed the four techniques, outlining an algorithm for each, noting the specific advantages and drawbacks of each method.

2.3 An Introduction to Supraglottic Airway Devices

A myriad of patients in a myriad of circumstances present a myriad of complications. The severity and life threatening consequences associated with difficult airway management necessitates the creativity and originality of multiple devices. Often, the so-called "gold

standards"[‡] of intubation are adequate and preferred for most cases. Each device has specific attributes that make it attractive in particular situations. In addition, the familiarity that a particular provider has with certain devices will weigh in the decision as to which device or technique is employed with a given patient.

Although most placements and intubations during routine procedures are performed without complication, there are situations in which the parameters shift. In emergent cases, the overriding goal is to maintain the airway in order to ensure that the patient receives adequate oxygenation and ventilation (depending on the circumstance). While the standard LMA has been used during routine procedures, other supraglottic airway devices (such as the esophageal-tracheal Combitube (ETC) and the EasyTube) are relatively recent additions and are primarily used for pre-hospital scenarios.

LeFrancois et al. released a study that served as an early evaluation of the use of the ETC by skilled emergency medical technicians (EMTs).[6] The objective of the study was to determine the success of the ETC by EMTs with automatic external defibrillator (AED) training but no prior training in advanced airway management. The ETC was a novel device at the time of this study; at the time of publication, ETC use in the pre-hospital situation had not been fully assessed. The conclusion by LeFrancois et al. was that ETC use by EMTs decreased patient morbidity and mortality in emergency pre-hospital cases.

As mentioned previously, SADs are placed above the glottis, in contrast to endotracheal tubes (ETTs) which are placed through the glottis. Although SADs have historically been used

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[‡] The term "gold standard" is used liberally in the literature and in practice, but does not always refer to the same devices. Generally, however, the endotracheal tube (ET) and laryngeal mask airway (LMA) are among the most commonly used devices mentioned both in journals and by practitioners.

for emergent cases, recent research has been conducted into the efficacy and safety of using SADs within hospital settings, as opposed to strictly pre-hospital settings. In addition, research comparing SADs to other airway devices has also become more prevalent.

One such study evaluating several newer airway devices (circa 2009) with their relationship to patient safety was conducted by Martin and Buggy.[8] This study specifically compared eight broad categories for airway devices, including tracheal tube guides, SADs (specifically the laryngeal mask airway (LMA)), and indirect videolaryngoscopes. Certain factors were considered in evaluating the devices, such as the success of each to provide an appropriate airway, to create the necessary seal, ease of use, and the amount of trauma and aspiration associated with use. Martin and Buggy also detailed improvements in the various devices that helped improve patient safety, which served to highlight the advancements that actually contributed to increased safety and lower morbidity and mortality.

The main conclusion found by Martin and Buggy was that videolaryngoscopy, when available, provides an excellent method by which intubation can be completed in a safer manner than previously performed. The authors emphasized, however, that skilled providers should be familiar with all techniques, and that videolaryngoscopy was not always a valid option due to technical limitations.

Analysis of various devices allows skilled providers to facilitate intubation in a variety of different situations, as every intubation is different. During emergent circumstances, it is vital for providers to be familiar with actual results of particular devices in the field. In 2005, Bein et al. reviewed several classes of supraglottic airway devices.[12] Their study focused on the laryngeal mask airway (LMA)—as well as the ProSeal variant (PLMA)—the standard laryngeal tube (LT) and the LT with integrated suctioning tube (LTS), and the ETC, which were in widespread use at

the publication of the article (2005). The review of the then recent literature discussed how the LMA showed significant deficiencies with regard to protection against aspiration, which the PLMA had yet to adequately address with reliable results.

Timmermann[9] expanded Bein et al.'s study with a comprehensive review of the uses and misuses of supraglottic airways, which at the time of publication (2011) had not been discussed in such detail in the literature. Timmermann's specific research question focused on which supraglottic airway device (SAD) should be used in particular settings. The motivation of his study is to demonstrate how SADs can be useful and helpful tools if used correctly and safely. Timmermann's study provides an excellent summary of the current SADs available and their appropriate uses.[§] Further, it serves as a useful companion to that of Bein et al. as it primarily examines limitations, weaknesses and how to use each correctly, whereas Bein et al. examine the appropriate uses and helpfulness of the various SADs.[12]

Timmermann's article defines the general considerations of each type of SAD, succinctly summarizes mannequin vs. patient based studies, the ventilation capabilities, and use of each in pre-hospital settings as well as the level of evidence behind each one. Drawing on a review of 116 different articles, the study provides an excellent introduction to SADs, as well as a comparison between them, succinctly detailing the strengths and weaknesses of each.

In contrast with Timmermann and Bein et al., Vaida[20] commonly used SADs by anesthesiologists, as opposed to pre-hospital providers. Vaida's study demonstrates the uses, strengths, weaknesses and insertion techniques in providing a solid overview on the devices

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[§] Timmermann divides SADs into first and second generation. The article also defines those to assist or enable tracheal intubation such as the LMA-Fastrach, Air-Q, Laryngeal Airway Device, and the Intubating LMAs (ILMAs). A further category of the esophageal blockers are outlined which were initially for emergency pre-hospital use such as the ETC, EasyTube, LT-D, the Laryngeal Tube suction mask and the classic LMA (cLMA).

currently in use.[**] Her study is educational in nature and neutral in tone, and does not revolve around a specific research question. Her study focuses on teaching how the devices may be used and presenting lesser well-known supraglottic devices. Rather than taking a stance for or against particular devices, the motivation of the author is to describe each device and educate the audience.

2.4 Individual Supraglottic Airway Devices

Several studies examined one particular device in order to ascertain particular strengths and weaknesses of the device. One such article was written by Pearson and Young, who released a case study involving use of the LMA-Supreme device in an emergent scenario.[7] Due to various factors, including limitations of facilities and skilled providers, the LMA-Supreme allowed the patient to be ventilated while also providing means by which the stomach could be drained of excess bile.

The authors submitted the case study as an example of how supraglottic airway devices can be successfully employed for emergency use when other methods fail or may take too long to prevent loss of brain function. An advantage of the second generation SADs is that they can provide methods by which airways may be maintained when integral esophageal drainage tubes are vital whence first generation SADs do not. The relevance of the finding is clear since no time was available in which to place an endotracheal tube without allowing significant harm to the patient.

[**] Vaida specifically discusses the standard LMA, the ProSeal LMA, the Portex Soft Seal LMA, the LMA Fastrach, the ETC, the EasyTube, Laryngeal Tube Suction, the Laryngeal Tube, the Cobra, and the ELISHA.

Cavus et al. examined three more recent introductions into the supraglottic airway device category. They compared the standard endotracheal tube (ETT), Laryngeal tube S II (LTS II), the ProSeal laryngeal mask (PLMA) and the EasyTube, specifically the insertion success rates for each by trained professionals.[13] The authors concluded that professionals had a much lower success rate with the EasyTube during first intubations, although the EasyTube, once properly inserted, was observed to have the lowest airway leak pressure thus decreasing risk of mucosal injury and gastric insufflation. As a result, once the technique was learned, the end result was a more effective airway placement.

The success rate of the LMA-Fastrach in elective and emergent cases over a four-year span was examined by Ferson et al.[14] The authors focused on the success of the LMA-Fastrach in situations where rapid laryngoscopic intubation has failed, as well as with patients with immobilized cervical spines. The overall success rates for blind and fiberoptically-guided intubations using the LMA-Fastrach were 96.5% and 100%, respectively. Familiarity with the device by providers was not measured, so it is unclear whether the success rates were due to ease of use of the device itself or because of the preference of the provider.

Hooshangi et al. studied the available literature on the Cobra Perilaryngeal Airway (CobraPLA) and the Streamlined Liner of Pharyngeal Airway (SLIPA) devices.[16] They indicated that the CobraPLA was superior to the classic laryngeal mask airway (cLMA) with respect to airway sealing pressure, placement in patients with limited mouth opening and limited head extension, and was comparable to the cLMA in terms of insertion times and sore throat incidence and severity. The CobraPLA is an attractive alternative to the cLMA.

The SLIPA is a possible alternative to the PLMA. Hooshangi et al. concluded that while the SLIPA is specifically designed to contain regurgitated fluid, protection against pulmonary

aspiration has not been established. The significance of this article is that it identifies a gap in the literature on a main perceived strength of the SLIPA in comparison to the well-studied PLMA. Based on the literature, these devices each appear to be satisfactory upgrades to the more standard alternatives.

A more modern device now in use is the VivaSight Single Lumen, which combines an endotracheal tube with a video camera and a light source in the tip. The device allows the provider to have continuous visual observation of the airway. Gaitini et al. released a study consisting of patients with normal airways, scheduled for elective surgery, and combined insertion with the Fastrach laryngeal mask airway (FT-LMA).[15] The FT-LMA was placed successfully in 95% of the cases.

Combining a camera with the intubation device is becoming a more common method for intubation. Although more study is necessary in order to determine the overall impact on patient safety and success in intubation, early reports show that the technique has been well-received and provides decreased trauma and increased patient safety. Still, Gaitini et al. only focused on the initial intubation during elective surgeries, as opposed to emergent situations, which must still be studied.

Of note among the various SADs is the esophageal-tracheal Combitube (ETC). Agro et al. conducted a review of over 50 studies on the ETC. They concluded that the device had a success rate of over 95% with a very low prevalence of complications.[11] However, their study also found tension between articles recommending the use of the ETC solely in the pre-hospital setting, as opposed to studies that found it to hold significant value within the surgical theater. Argo et al. noted that the literature found limitations of the device when suctioning of tracheal

secretions is necessary, and that problems with the ETC tended to occur with longer periods of ventilation.

2.5 Teaching devices

When any invasive medical device is introduced, especially devices used in such critical tasks as airway management, the providers must first be taught the correct placement techniques and indications. As teaching tools, mannequins are frequently utilized in training medical personnel in the use of medical devices. The objective of a project by Jackson and Cook[17] was to evaluate the performance of four currently available mannequins with eight supraglottic airway devices, and to see if the type of mannequin had an impact on a particular airway device. Of the mannequins studied, the Trucorp mannequin performed best, followed by the Laerdal mannequin, although no mannequin performed best for all individual supraglottic airway devices. This conclusion is important as it demonstrates that the effect of the type of mannequin can have on a study and provide a confounding factor which many researchers may not consider in study design.

One study in which training devices played a crucial role was conducted by Robak et al.[18] The objective of their study was to determine the feasibility and speed of insertion in multiple different types of supraglottic airway devices to determine which devices were safe and feasible under simulated airway conditions. Endotracheal intubation is considered the absolute standard for protecting the airway. Alternative devices for airway protection have been developed that can be used by untrained personnel, by those with less experience, and for when endotracheal intubation is not possible. Therefore, it was necessary to determine whether the devices could be properly inserted under simulated critical conditions. The data demonstrated that, when

personnel have not been trained in the use of particular devices, the ETC and the EasyTube were able to be inserted when others were not.††

One of the major complications associated with intubation, especially with difficult airways, is potential trauma caused by device insertion, which was the focus of a study by Ulrich-Pur et al.[19] The objective of the article was to compare the pressures exerted by the cuffs and balloons of different types of airway devices. Soft tissue injury is a significant issue in airway management; possible complications may range from minor laceration to perforation of the trachea or esophagus which, depending on severity, can require immediate surgical repair to the point of a thoracotomy or sternotomy.

After analysis, the ETC was demonstrated to have significantly elevated mucosal pressure in comparison to the EasyTube or the endotracheal tube during standard inflation; this difference in pressure can cause severe trauma to the patient without sufficient care, a reason that many providers are hesitant to use supraglottic devices. However, the study demonstrates a major difference between two supraglottic devices designed for use in pre-hospital settings, as the EasyTube displayed similar pressure readings to endotracheal intubation, in contrast to the significant pressure difference present with the ETC. The study provides a clear differentiation between the three devices: the endotracheal tube (ETT) is the standard within the operating theater, while the ETC has been used for pre-hospital settings. The EasyTube combines the rapid

†† Only the ETC and the Easytube could be successfully inserted in simulations of trismus, limited mobility of the cervical spine, or a combination of pathologic conditions such as trismus plus limited mobility of the spine and trismus plus tongue edema. The insertion time was significantly longer with LMA Unique, Fastrach, and I-Gel devices in both the first and second runs. The ETC and the EasyTube were most easily inserted under simulated conditions such as trismus, limited mobility of the cervical spine, and combined pathologic conditions.

intubation design commonly associated with the ETC with the safer pressure considerations of the ETT, and so can be viewed as combining the better attributes of the two devices.

2.6 The EasyTube Supraglottic Airway Device

Although intubation via ETT has remained the standard within the operating theater, it is a complex task that requires significant training and practice and may be in impossible in certain pre-hospital settings. Furthermore, several unsuccessful intubation attempts may cause a crisis and precipitate a severe decline in the patient's condition to the point of brain injury or death due to the subsequent hypoxia. Given this information, Chenaitia et al. created a research project to determine if the EasyTube was a suitable device for airway management in the pre-hospital setting.[22] They found that providers had a high success rate in ventilating with the EasyTube and a low failure rate after a which, when combined with the opportunity for blind insertion as opposed to requiring visual guidance. As a result of the study, the EasyTube was introduced in new difficult airway guidelines for the pre-hospital setting.

As more studies demonstrate the safety and efficacy of SADs, the use of supraglottic airway devices has become increasingly prevalent and useful in the area of anesthesia and airway management. However, one notable complication that has been reported is aspiration of gastric contents. Aspiration can have disastrous consequences and is one reason why some providers shy away from the use of supraglottic devices.

Seeking to determine which devices can best withstand esophageal pressure and, therefore, best prevent aspiration, Bercker et al. completed a study looking at the seal created by seven different supraglottic airway devices in cadavers.[21] The researchers used an elevated esophageal pressure model to determine if different supraglottic devices could withstand

different levels of esophageal pressures, as well as ascertain whether or not SADs could be used in elevated esophageal pressure situations. Under these conditions, the ETC, EasyTube and Fastrach were best able to tolerate an increased esophageal pressure without allowing aspiration of contents. Their study provided a rebuttal to those with concerns about using supraglottic devices in patients with possibly elevated esophageal pressures (such as pregnancy, GERD[‡‡], morbid obesity or laparoscopic abdominal surgery).

Since many similarities exist between the ETC and EasyTube, Gaitini et al. sought to compare and contrast the use of the two devices with respect to various predetermined metrics[§§] in order to determine an alternative to supraglottic airway management.[23] The study found that the EasyTube was easier to place and faster to achieve an effective airway. In addition, the EasyTube allowed passage of gastric tubes of a larger diameter than the ETC could contain. A larger oropharyngeal leak pressure was present for the EasyTube, and the peak airway pressure for the EasyTube was lower than that of the ETC. These results indicate that the EasyTube is more effective in decreasing the risk of aspiration. The benefits are crucial, especially with consideration to easier airway placement and shorter time to effective airway, which can be vital in maintaining patient safety.

Lorenz et al. conducted a similar study comparing the EasyTube with the standard endotracheal tube (ETT) in terms of effectiveness, ease of placement and ventilator parameters. The goal of their study was to determine if the EasyTube is an appropriate and viable alternative during routine use as compared to the ETT, which is generally considered to be the gold standard

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‡‡ Gastroesophageal reflux disease.

§§ The metrics included ease of use, difficulty of insertion, time to achieve an effective airway, insertion success rate, maneuvers to achieve an effective airway, oropharyngeal leak pressure, ventilator parameters, frequency of adverse effects were compared, intra-cuff pressure, and success rate of gastric tube insertion.

of intubation.[24] Lorenz et al. found that the EasyTube was easier and faster to insert, and there was no significant difference between leak pressure or pulsoximetry reading. Lorenz et al. also found that the EasyTube displayed reduced time and better facilitation of device airway placement in contrast to ETT placement via direct laryngoscopy.

Thierback et al. created a retrospective study to appraise all placements/uses of the EasyTube over an eighteen-month period.[25] The authors evaluated the device for safety and use. Their study was one of the first studies to directly address the safety and efficacy of use of the EasyTube. In Thierback's investigation, the EasyTube was used to either help patients with unanticipated difficult airways during their anesthesia induction or in the pre-hospital airway management course. In all patients, the EasyTube was successfully placed and effective oxygenation and ventilation was achieved within 25-40 seconds. The data and methodology were to evaluate all airway management over an eighteen month period and review when the EasyTube was used, determining the time to effective airway, ease of use, number of repositioning maneuvers, lack of blood or other indications of patient injury.

2.7 Conclusion

In reviewing the literature regarding difficult airway management, supraglottic airway devices, and specifically the EasyTube, there appears to be a need to determine whether a novel placement for the EasyTube would be effective within the surgical theater as well as the pre-hospital setting. As the EasyTube is currently accepted for use in the pre-hospital setting, an evaluation of potential benefits within the hospital setting is necessary. This study looks toward that goal by evaluating whether there is a significant difference in time of placement by providers using two different methods of placement.

Chapter 3: Methodology

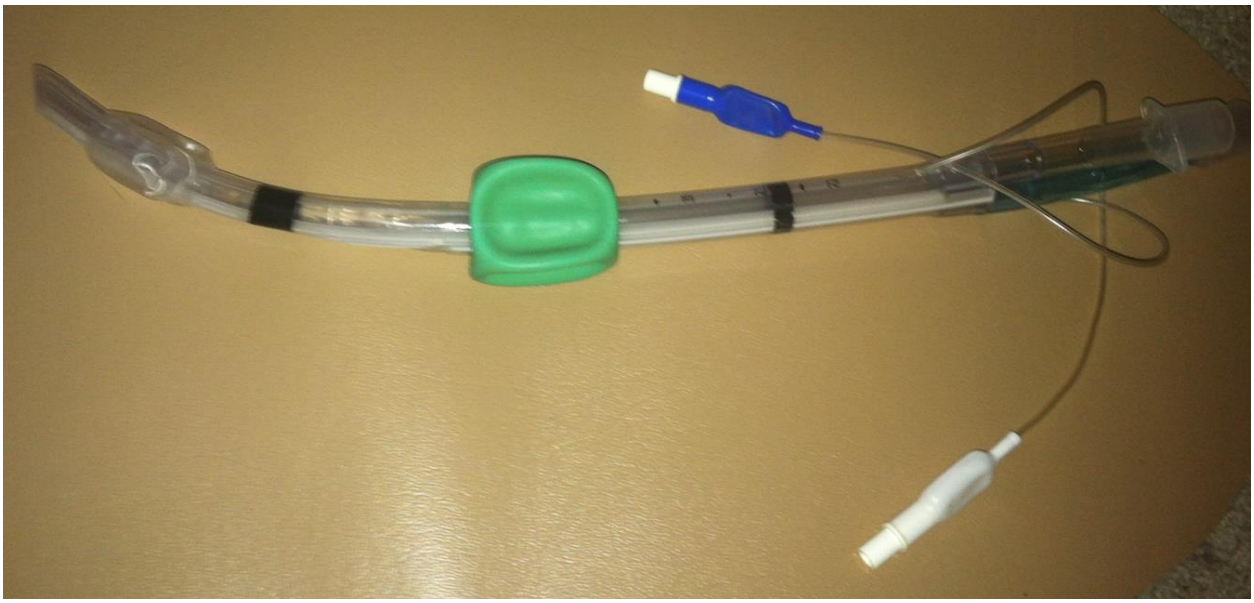

Figure 1. EasyTube Supraglottic Airway Device.

3.1 Methods of Placement

3.1.1 Blind Placement Technique[***]

There is currently one method accepted placement technique for the EasyTube. Using universal standard precautions, the practitioner inserts the left hand into the mouth and places the distal edge of the thumb under the dental ridge of the mandible. Using a quick motion with the least amount of force necessary, the mouth is opened and the mandible lifted towards the ceiling.

[***] A video demonstration of this technique is available at http://youtu.be/Y7Z2-080tQU

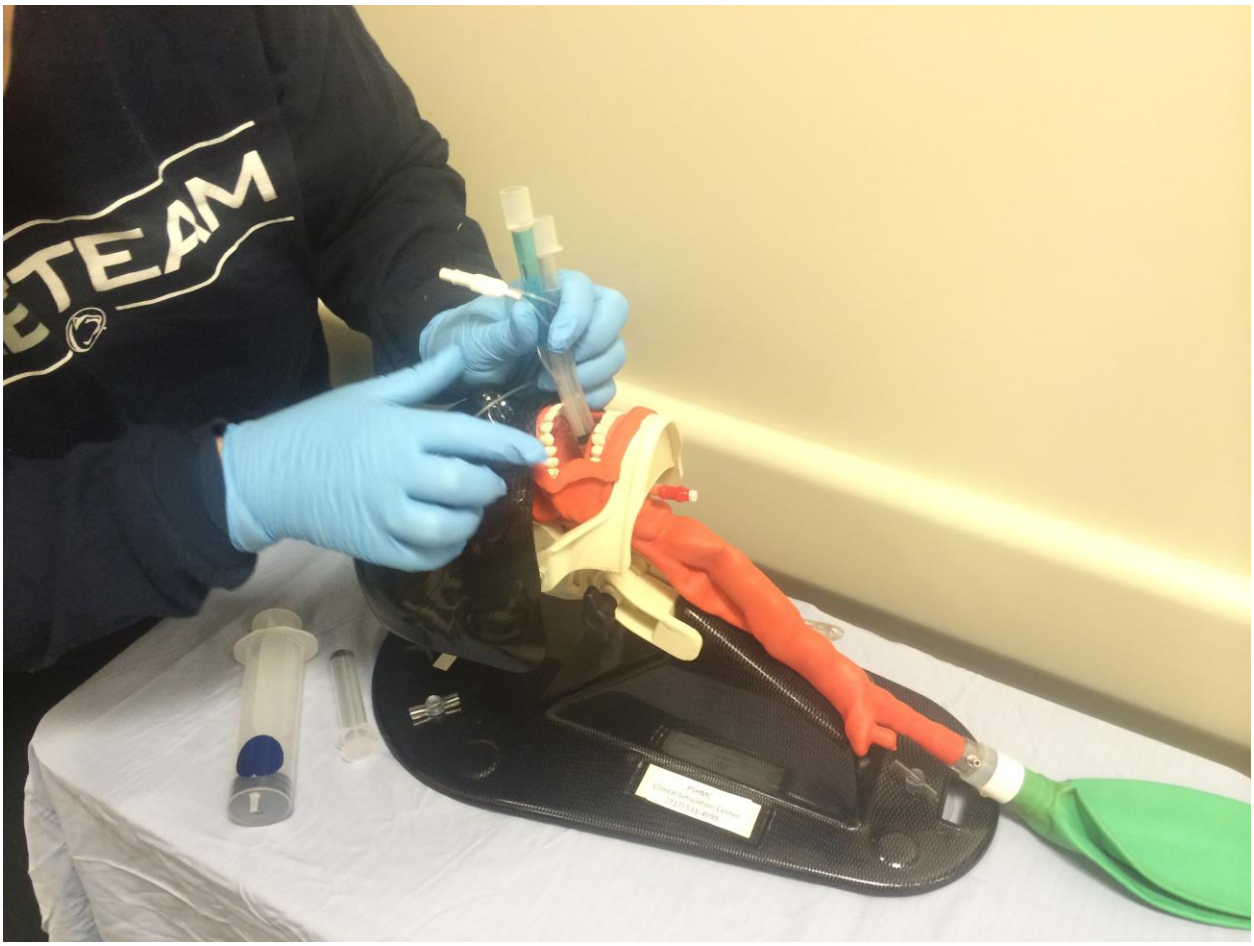

Figure 2. Blind insertion of the EasyTube device

Figure 3. Prior to insertion, the mandible is lifted

Using the right hand, the EasyTube device is then placed into the oropharynx and pressed downward.

The device is inserted until the black guide line on the device is at the level of the teeth or the gums.

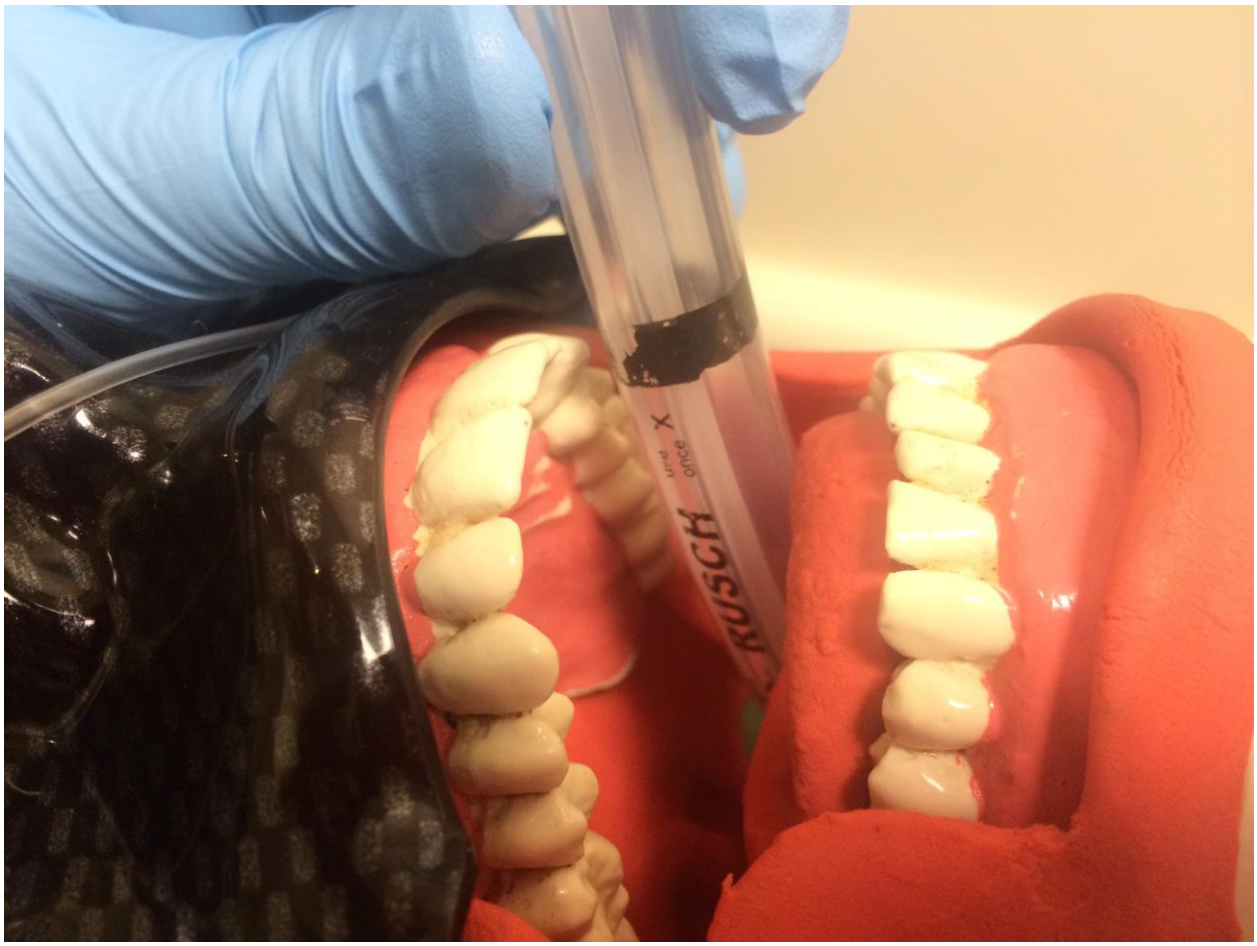

Figure 4. The black line on the device should be even with the patient's teeth.

After insertion, the distal end of the EasyTube is more likely to be located in the esophagus, given its larger orifice and its anatomic position posterior to the trachea. 80 cc of air are placed into the larger oropharyngeal balloon.

Figure 5. An 80 cc syringe is used to inflate the oropharyngeal balloon.

Afterwards, 10 cc of air is inserted into the endotracheal balloon.

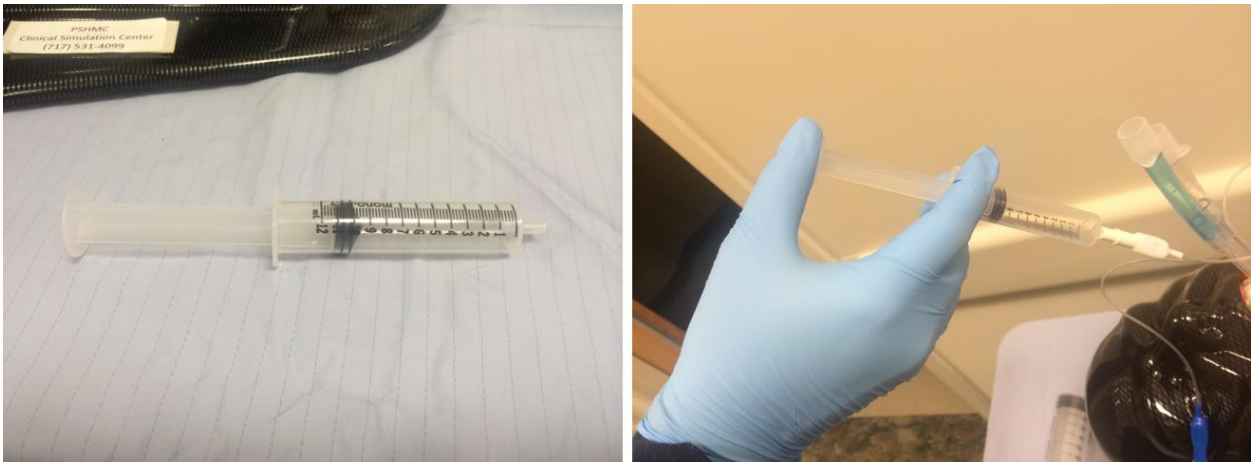

Figure 6. A smaller 10 cc syringe is used to inflate the endotracheal balloon.

The oropharyngeal lumen is connected to the ventilating device (either closed circuit or Ambu bag) and the patient is ventilated.

Figure 7. An Ambu bag is connected to the device to determine device placement.

If lung inflation occurs bilaterally, ventilation is continued through the oropharyngeal lumen.

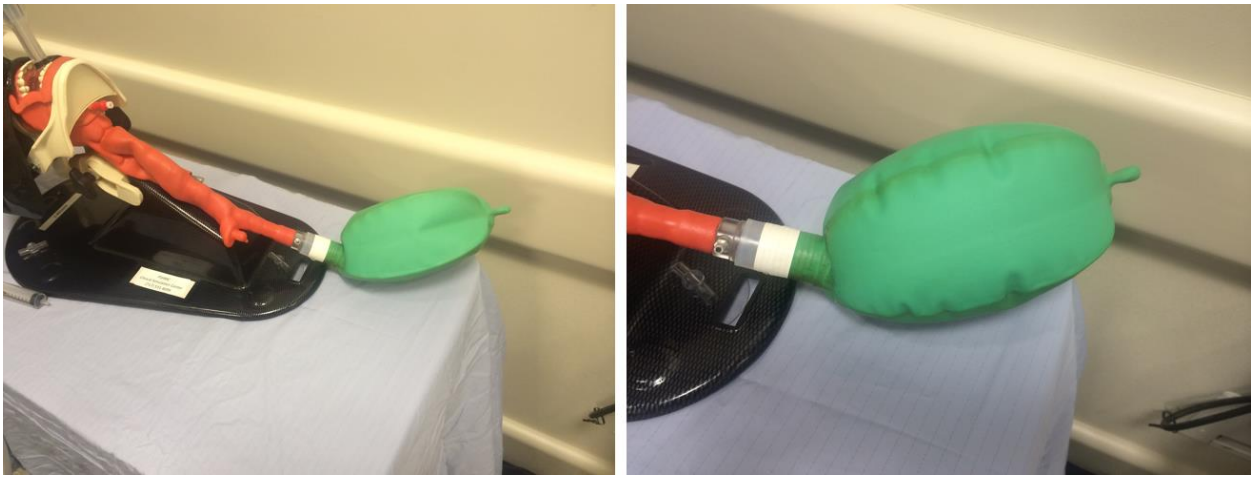

Figure 8. On the mannequin, a balloon represents the lungs to simulate correct placement.

If bilateral breath sounds do not occur, the opposite lumen is connected to the ventilating device; the absence of sounds is an indication that the device is endotracheal instead of endo-esophageal. Since the device is pushed into the oropharynx without direct visualization of its pathway, this is considered to be a "blind" insertion technique.

3.1.2 Laryngoscopic Placement Technique[†††]

The protocol in the present study is designed to evaluate a new method placement using laryngoscopy, rather than the blind method. In this novel method of placement, the practitioner uses the right hand to open the patient's mouth in a scissor fashion.

[†††] A video demonstration of this technique is available at http://youtu.be/DFS8kXKRISU

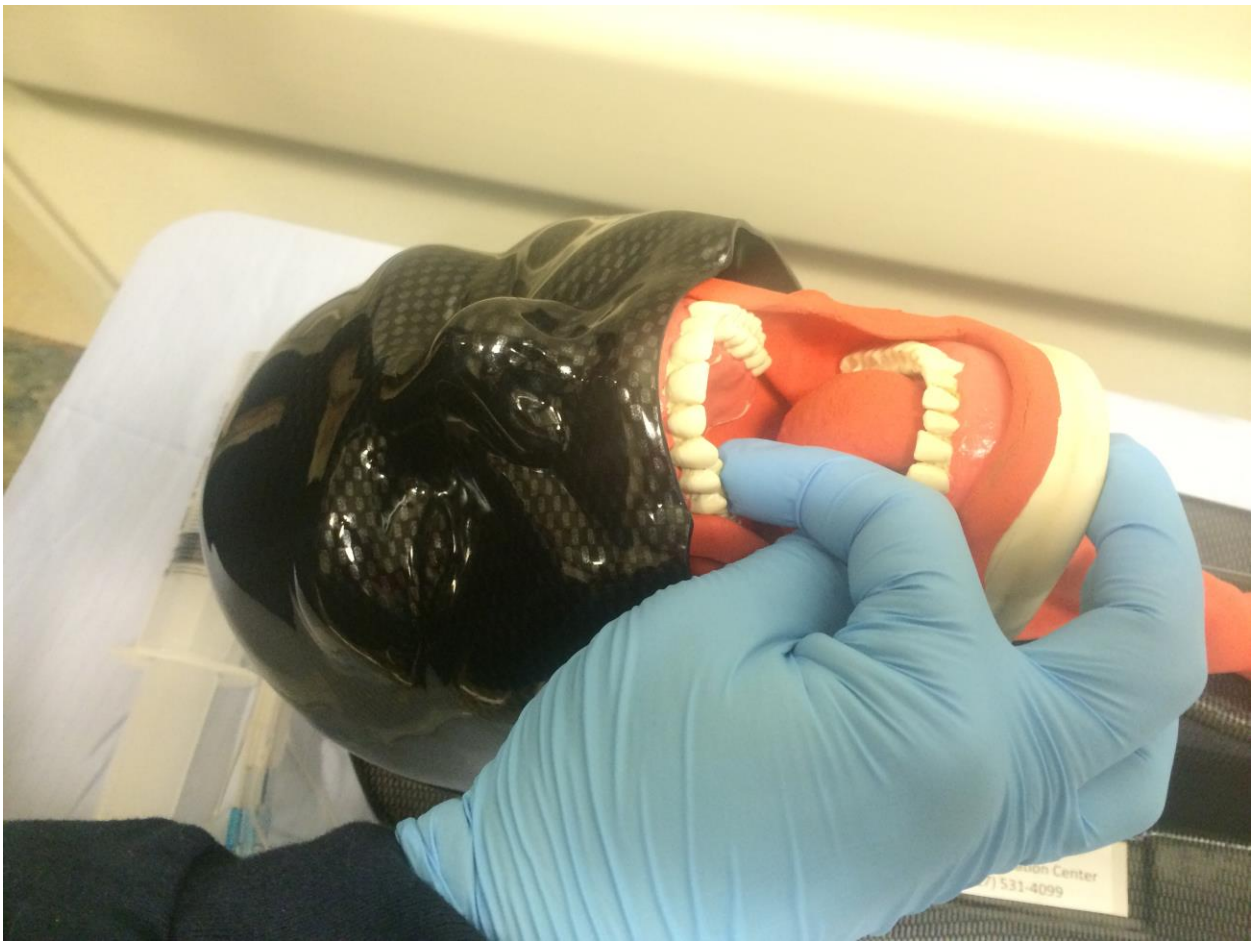

Figure 9. The right hand to opens the mouth to allow for laryngoscopic positioning.

The laryngoscope is inserted in a right to left sweeping motion by the left hand.

Figure 10. The laryngoscope (left) is inserted using the left hand.

The left hand exerts the minimum force necessary in order to visualize the larynx and vocal cords and place the EasyTube into the esophagus.

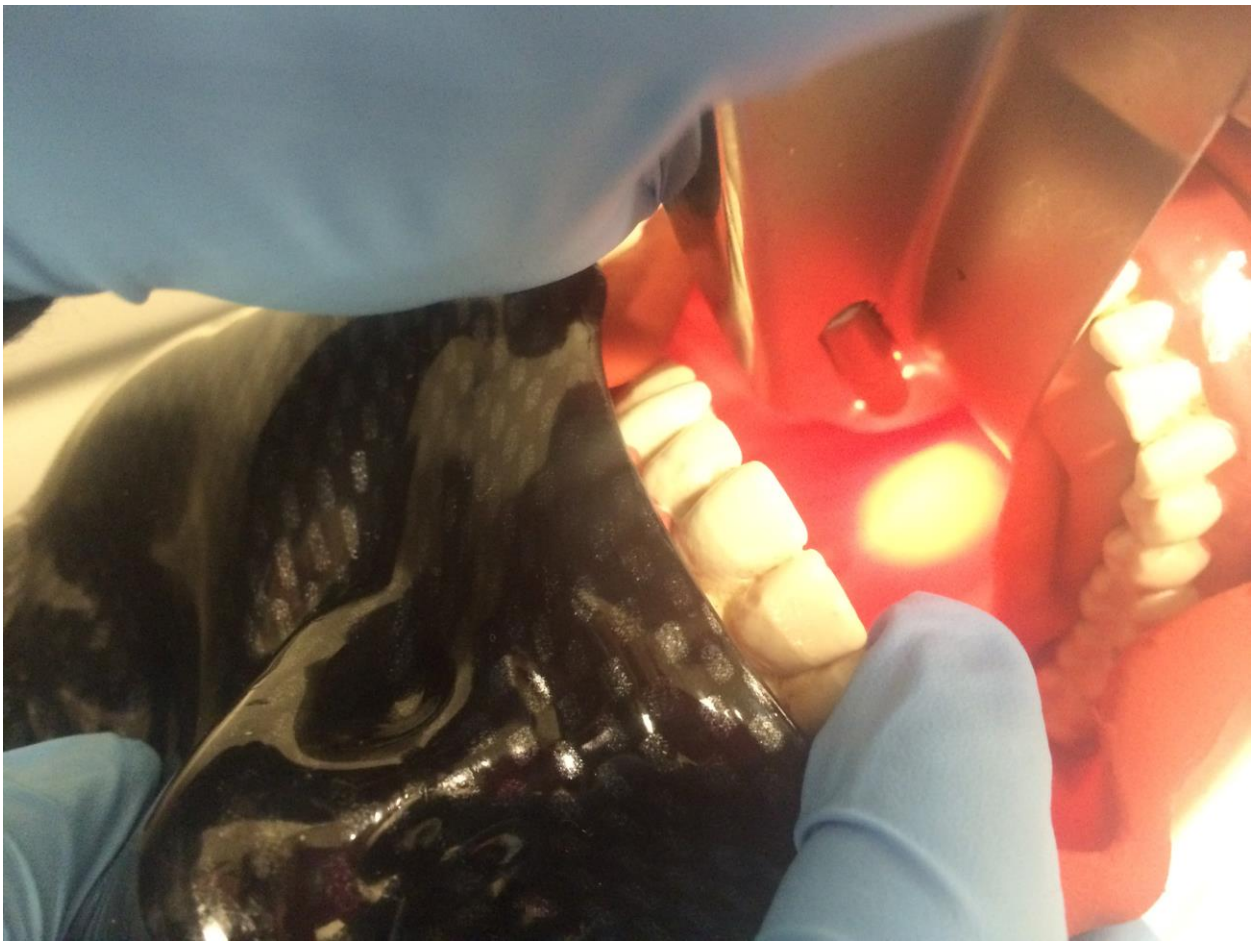

Figure 11. The laryngoscope allows direct visualization placement of the device.

The device is placed up to the black teeth/gum mark, as in the blind technique.

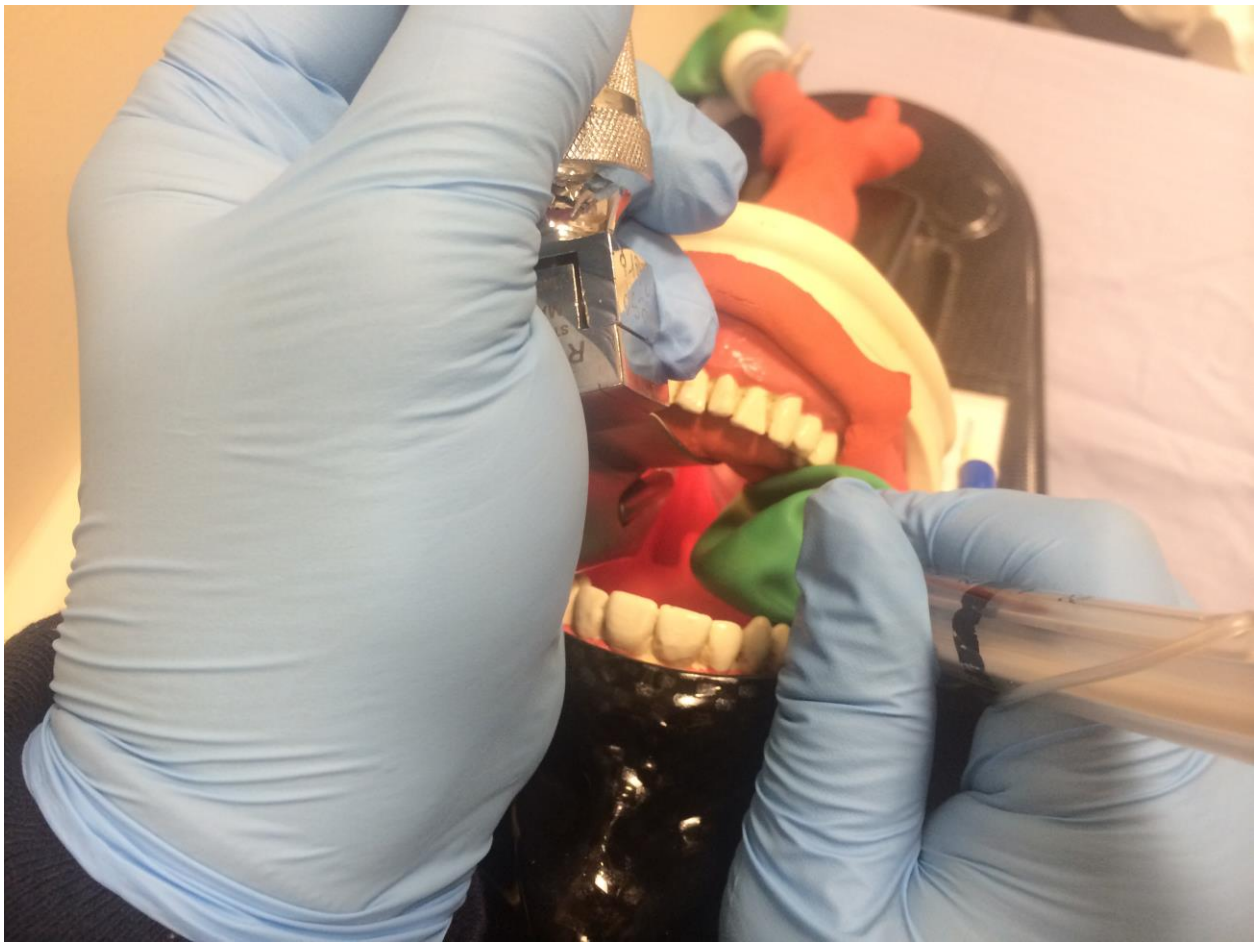

Figure 12. Visualization of the larynx allows for more effective device placement.

The 80cc and 10cc cuffs are inflated. A ventilating device is connected to the oropharyngeal lumen and bilateral inflation is confirmed; otherwise, the ventilating device is attached to the tracheal lumen.

3.1.3 Comparison of the Two Methods

The benefits of the blind method are multifold. No prior knowledge of laryngoscopy is necessary. The method is easily taught and mastered by the practitioner, who can perform the placement in the field, rather than a controlled environment. Visualization is not required; as a

difficult airway may present with a field occluded by blood, other fluids or anatomy, especially after the patient has experienced trauma.

Conversely, blind insertion carries certain risks. The possibility of trauma is increased due to the inability of the provider to know where the device is being placed. Such trauma can include perforation of the trachea or esophagus, the creation of a false passage. Damage to great vessels (such as the carotid, internal or external jugular), nearby nerves (including the phrenic, vagus or recurrent laryngeal nerve) or the vocal cords can also occur. The practitioner is likely uncertain of the location of the distal aspect of the device. Furthermore, a blind technique is difficult to place around a large tongue or slack oropharyngeal tissues.

The laryngoscopic method creates improved visualization of the anatomy and placement location and improved likelihood of knowledge of location of the distal aspect of the device. Due to increased visualization, associated placement trauma is likely to be decreased. The laryngoscope allows the practitioner to move the tongue and oropharyngeal tissues out of the way during placement.

The main risks associated with laryngoscopic placement is an increase in the time of insertion, and the level of training necessary to place the device using laryngoscopy. As a result, only practitioners skilled in laryngoscopic use should perform this technique.

3.2 Data Collection and Methodology

This study and the associated protocol received institutional review board approval at the Milton S. Hershey Medical Center.‡‡‡ After approval was obtained, volunteers were solicited

‡‡‡ Please see Appendix B for IRB materials - #43548EM

from among the anesthesiology residents, attending physicians and certified registered nurse anesthetists within the Hershey Medical Center Anesthesiology Department. All participation was voluntary and no compensation was received by the participants.

All participants were given a summary explanation of research, and informed verbal consent was obtained. A short scripted introduction to the study and the EasyTube were read to the participants.[§§§] Participants were given the opportunity to ask questions and receive further information before participation. Each subject was asked to complete a short survey detailing their prior experience with supraglottic airway devices, prior experience with the EasyTube, and the participant's overall anesthesiology experience and training level.[****]

Figure 13. The TruCorp AirSim mannequin.

[§§§] Please see Appendix C for explanation of study.
[****] Please see Appendix D for this survey tool.

Trials were performed using the TruCorp AirSim mannequin. This mannequin was used due to the ease of use, the ability to verify inflation and placement of the device. The mannequin was secured to a table in order to prevent movement that might interfere with placement times. The mannequin was placed at a set height for all participants, who were not allowed to adjust the position.

Each participant completed two placements using the blind technique and two placements using the laryngoscopic technique. Each subject was allowed up to two minutes in order to familiarize themselves with the device. Volunteers were randomized in order to determine which technique to complete first. Insertions were timed using an iPhone 5 stopwatch from the moment when a subject picked up any device until lung ventilation was visually confirmed. Timing was performed by the same individual during each trial in order to control for reaction times in using the stopwatch. These times were recorded by the primary investigator and listed on the study tool.[††††]

[††††] See Appendix D.

Chapter 4: Results and Discussion

4.1 Summary of Data

The data collected from this study is summarized in Appendix E. 32 volunteers participated in the study. One participant was excluded from statistical analysis due to the inability to correctly place the device in two separate attempts.

4.2 Statistical Analysis

The study was conducted in a 2 x 2 crossover design with two trials for each type of placement per participant. The biostatistics department of Penn State Hershey Medical Center was consulted for this project. Upon their recommendation, a repeated measurements analysis of variance (RM ANOVA) was applied with a 95% confidence interval and an interval of no difference set to be ten seconds (±10.0 seconds). The mean time of blind placement was 24.2 seconds; the mean time of laryngoscopic placement was 29.4 seconds, for a difference of 5.2 seconds between the two averages. The 95% confidence interval was -7.5 to -3.0 seconds. The computed confidence interval was contained within the desired ±10.0 second interval. It was therefore possible to conclude that the procedures are statistically equivalent.

Chapter 5: Conclusions

5.1 Major Findings

Since the placement times between the blind and laryngoscopic placement techniques was determined to not be statistically significant, the major implication is that the laryngoscopic method is an appropriate method for placement when feasible. Since the benefits to using a laryngoscope in placing the EasyTube include decreased likelihood of trauma and incorrect placement, the implication is that practitioners can more safely intubate patients presenting with a difficult airway within the operating theater.

5.2 Strengths and Weaknesses of Study

This study had a randomized crossover design, which allowed data to be collected comparing a subject's times to their own results. Therefore each participant acted as his or her own control. Volunteers were not told in advance which technique would be used first, eliminating an element of preparation. The alternation between blind-first and laryngoscopic-first placements aided in removing possible bias toward the second technique used as the participant became more familiar with the mannequin and procedure.

The number of participants was limited to the available pool of practitioners in the Hershey Medical Center Anesthesiology Department. As participation was not mandatory, there was an unavoidable element of self-selection bias introduced into the study. Based on previous studies, power analysis dictated a minimum sample size of 30 participants. By including only 32 volunteers (minus one excluded subject), the sample was just over the necessary size. In addition, all of the practitioners were from the same facility, and likely had similar training, for which a larger sample could control.

5.3 Future Studies

The results of this study imply that there is no statistical difference between the times of blind and laryngoscopic placement techniques for the EasyTube. As such, the increased time determined to secure an effective airway using a laryngoscope does not merit the exclusion of the EasyTube from being used within the operating theater.

Further studies might include enlarging the sample size, utilizing difficult mannequins to determine if the results are replicated with anatomical differences, or to introduce difficult airway scenarios in a simulation laboratory, such as the introduction of heme or emesis in the airway.

The next logical step would be to introduce the EasyTube into the operating theater in order to determine if placement times in true difficult airway scenarios differ in a statistically significant manner.

Appendix A: Institutional Review Board Approval

PENNSTATE HERSHEY Milton S. Hershey Medical Center

PENNSTATE HERSHEY College of Medicine

Date: October 03, 2013

To: Julia C. Caldwell, MD, Anesthesiology (HERSHEY)

From: Patricia L. Gordon, MD
Institutional Review Board Executive Chair
Executive Director, Human Research Protection Program

Subject: IRB Protocol No. 43548EM - Comparison of placement methods of supraglottic airway devices by skilled providers

Confirmation of Exempt Status

Thank you for your application to the Institutional Review Board (IRB) for the above research. The activity was screened for exempt status according to the policies of this institution and the provisions of applicable federal regulations and, as submitted, was found not to require formal IRB review because the research met the criteria for exempt research according to the following category in the Code of Regulations:

45 CFR 46.101(b)(1) - Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instruction strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula or classroom management methods. *(This category may NOT include prisoners or be FDA-regulated.)*

- This determination was based on the research as described in the application materials
- No investigators for this research participated in the review determination

Retain this letter as evidence of IRB review and determination of exempt status for this research. Annual review of this research is not required provided the investigation is conducted as proposed. Therefore, no progress reports or IRB annual review letters will be issued.

The IRB requires notification and review in the following circumstances:

- Report any unanticipated problems involving risk to subjects or others that occur as a result of participation in this research.
- Report any proposed changes in the research activity that may affect the exempt status, outlined above. Prior IRB review is needed before such changes are initiated except where necessary to eliminate apparent immediate hazards to the subject.

IRB Protocol Number - Please include the IRB protocol number on any future documentation submitted for this research. The Board appreciates your efforts to conduct research in compliance with the institutional policies and federal regulations that have been established for the protection of human subjects.

PG\jak

Appendix B: Institutional Review Board Submission

Human Subjects Protection Office
Penn State College of Medicine | Penn State Milton S. Hershey Medical Center
600 Centerview Drive, PO Box 855, Mail Code A115
Hershey, PA 17033-0855 | 717-531-5687 | hspo@psu.edu

Submitted by: Christie Mulvey
Date Submitted: September 12, 2013 2:15:15 PM
Date: September 13, 2013
IRB#: 43548
PI: Julia C Caldwell

Study Title

1>Study Title
Comparison of placement methods of supraglottic airway devices by skilled providers

2>Type of eSubmission
New

Home Department for Study

3>Department where research is being conducted or if a student study, the department overseeing this research study.
Anesthesiology (HERSHEY)

Review Level

4>What level of review do you expect this research to need? NOTE: The final determination of the review level will be determined by the IRB Administrative Office.
Choose from one of the following:
Expedited

Basic Information: Association with Other Studies

5>Is this research study associated with other IRB-approved studies, e.g., this study is an extension study of an ongoing study or this study will use data or tissue from another ongoing study?
No

6>Is this an investigator-initiated clinical trial (i.e., the protocol was written by a PSU/HMC investigator and it prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes)?
No

7>Is this a clinical trial* that is required by law to be registered in the ClinicalTrials.gov registry?
No

***All clinical trials of devices, drugs and biologics (except for preliminary, early Phase 1 or feasibility trials), which are subject to FDA regulations must be registered in ClinicalTrials.gov.**

In addition, clinical trials require registration in a public registry in order to be considered for publication according to a policy of the International Committee of Medical Journal Editors (ICMJE). Details of the ICMJE requirement are described at the ICMJE website

at http://www.icmje.org

For additional information about clinical trial registration, see http://prsinfo.clinicaltrials.gov.

8>Where will this research study take place? Choose all that apply.

[X] Hershey Medical Center

9>Does this research study involve any of the following Penn State Research Centers?

[X] Simulation Center at Penn State Hershey

10>Does this research study involve the use of Hershey Medical Center hospital and/or clinic facilities, equipment or staff?

Yes

NOTE: If Yes, the study must be registered with the Office of Research Affairs using the Proposal Internal Approval Form and the Hershey Blue Form. These forms are available at http://www.research.psu.edu/osp/prepare-proposals/internal-approval-forms/documents/PIAF..

Personnel

11>Personnel List

PSU User ID	Name	Department Affiliation	Role in this study	Added
jcc180	Caldwell, Julia C	Anesthesia (HERSHEY)	Principal Investigator	119204 09/12/2013
dpd109	Dekorte II, David Paul	Anesthesia (HERSHEY)	Co-Investigator	119204 09/12/2013
clm46	MULVEY, CHRISTIE L	ANESTHESIOLOGY	Project Coordinator	119204 09/12/2013
sjv10	Vaida, Sonia J	Anesthesia (HERSHEY)	Co-Investigator	119204 09/12/2013

Caldwell, Julia C , MD (Principal Investigator)	
PSU User ID: jcc180	**Phone:** (717) 531-5167
Email: jcaldwell@hmc.psu.edu	**Alt:**
Email Notifications: Yes	**Pager:**
PSU Person Type: Faculty	**Fax:**
Dept: Anesthesia (HERSHEY)	
Address 1: 500 University Drive	
Address 2:	
Mail Stop:	
City, State, Zip: Hershey, PA 17033-0850	
Qualifications: Prior research and publication experience	

Dekorte II, David Paul , JD, MBA, M.Ed, MSI (Co-Investigator)	
PSU User ID: dpd109	**Phone:** 734-255-2117
Email: dpd109@psu.edu	**Alt:**
Email Notifications: No	**Pager:**
PSU Person Type: Undergraduate Student	**Fax:**
Dept: Anesthesia (HERSHEY)	
Address 1: 110 Hartford Drive	
Address 2:	
Mail Stop:	
City, State, Zip: Middletown, PA 17057	
Qualifications: Principal investigator, researcher, prior research, publication and statistical experience	

MULVEY, CHRISTIE L (Project Coordinator)	
PSU User ID: clm46	**Phone:** +1 717 531 7988
Email: clm46@psu.edu	**Alt:**
Email Notifications: Yes	**Pager:**
PSU Person Type: Staff	**Fax:**
Dept: ANESTHESIOLOGY	
Address 1: H187 ANESTHESIOLOGY	
Address 2: HERSHEY MEDICAL CENTER	
Mail Stop:	
City, State, Zip: HERSHEY, PA 17033	
Qualifications: Research Coordinator	

Vaida, Sonia J , MD (Co-Investigator)	
PSU User ID: sjv10	**Phone:** (717) 531-8433
Email: svaida@hmc.psu.edu	**Alt:**
Email Notifications: No	**Pager:**
PSU Person Type: Faculty	**Fax:**
Dept: Anesthesia (HERSHEY)	
Address 1: 500 University Drive	
Address 2:	
Mail Stop: H187	
City, State, Zip: Hershey, PA 17033-0850	
Qualifications: Vice Chair of research for Department of Anesthesiology, prior research and publication experience, expertise in educational simulation and airway management	

12>Is the Clinical Trials Office being used for HMC Regulatory Service for Initial Review?
No

Funding Source

13>Is this research study funded? Funding could include the sponsor providing drugs or devices for the study.
No

NOTE: If the study is funded or funding is pending, submit a copy of the grant proposal or statement of work for review.

14>Does this research study involve prospectively providing treatment or therapy to participants?
No

Conflict of Interest

15>Do any of the investigator(s), key personnel, and/or their spouses or dependent children have a financial or business interest(s) as defined by PSU Policy RA20, "Individual Conflict of Interest," associated with this research? NOTE: There is no de minimus in human participant research studies (i.e., all amount must be reported).
No

Multi-Center Study

16>Is this a multi-center study (i.e., study will be conducted at other institutions each with its own principal investigator)?
No

Participant Numbers

17>Maximum number of participants/samples/records to be enrolled by PSU investigators. NOTE: Enter one number – not a range. This number should include the estimated number that will give consent but not qualify after screening or who will otherwise withdraw and not qualify for inclusion in the final data analysis. This number should be based on a statistical analysis, unless this is a pilot study, and must match the number of participants listed in the consent form.
40

18>Was a statistical/power analysis conducted to determine the adequate sample size?
Yes

19>Name of person responsible for the statistical/power analysis and his/her affiliation (if any):
David DeKorte, research assistant, JD MBA

Age Range of Participants

20>Age range of participants
25-65

Participant Information: Participant Categories

21>Choose all categories of participants who will be involved in this research study.
[X] Other

22>Identify the 'other' categories of participants that will be used in this research study.
Anesthesiologists, Certified Registered Nurse Anesthetists, and Anesthesia residents

23>Does this research exclude any particular gender, ethnic or racial group, and/or a person based on sexual identity?
No

Recruitment

24>Describe the specific steps to be used to identify and/or contact prospective participants, records and/or tissue. If applicable, also describe how you have access to lists or records of potential participants.
Prospective participants will be attending anesthesiologists, resident anesthesiologists and certified registered nurse practitioners in the Department of Anesthesiology at Penn State Hershey Medical Center. Emails will be sent and announcements will be made at faculty and other departmental meeting. Prospective participants are limited to Penn State Hershey faculty and staff. No incentives will be offered for participation.

25>Will recruitment materials be used to identify potential participants?
Yes

26>Choose the types of recruitment materials that will be used.

[X] Other

27>You indicate potential participants will be recruited using methods other than those described previously. Describe the other methods that will be used to recruit participants.

Email solicitation

28>Before potential participants sign a consent document, are there any screening/eligibility questions that you need to directly ask the individual to determine whether he/she qualifies for enrollment in the study?

[X] Not Applicable, not obtaining informed consent

NOTE: Please provide, as appropriate, a procedure and script for the screening/eligibility questions. Also, provide a copy of the screening/eligibility question data collection sheet with the supporting documents sent with this application.

29>Will researchers who are not involved in the care of potential participants review and/or use protected health information before a consent/authorization form is signed in the course of screening/recruiting for this research study (e.g., reviewing medical records in order to determine eligibility)?

No

30>Does this research study use health information within the study?

No

(1) is created or received by a health care provider, health plan, public health authority, employer, life insurer, school or university, or health care clearinghouse; and

(2) relates to the past, present or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present or future payment for the provision of health care to an individual.

31>Are any identifiers (according to HIPAA regulations) attached or linked to the health information, e.g., name, initials, address, phone/fax numbers, email address, dates, medical record number, social security number, linking code list?

No

32>Based on your answers to the preceding questions, you ARE NOT using Protected Health Information in your research study.

Informed Consent/Parental Permission and Authorization Information

NOTE: Per federal regulations, (45 CFR 46.117), the informed consent process must be followed by documentation using a written consent form approved by the IRB and signed by the

participant or the participants' legally authorized representative. A copy must be given to the person signing the form. (Refer to the IRB web site for the general instructions, the required elements for the informed consent process and the format for the written consent form.)

In some instances, however, the IRB has authority to waive the requirement to obtain informed consent from participants or the requirement to have participants sign a consent document.

33>Informed consent requirement: Choose all that apply:

[X] Verbal consent – participant gives consent verbally (e.g., in-person interview, telephone interview)

34>Indicate who will be responsible for obtaining consent from participants.

A member of the research team.

35>Describe when and where participants will be approached to obtain informed consent (include the timing of obtaining consent in the response).

Verbal consent will be sought. Once the potential participant expresses interest in the study, a member of the research team will explain the study using a summary explanation of research.

36>Describe the steps taken to minimize the possibility of coercion or undue influence.

We will explain to the participants that this study is voluntary and that we are not collecting any identifiable information. It will also be explained that their decision to participate in the study will have no effect on their employment or their standing in the Resident program

Email solicitations will be sent using a blind distribution list and the list containing participants will be stored in the locked office of the research coordinator.

37>Will consent be solicited from non-English or limited English speaking participants?

[X] No

38>Provide a justification for excluding non-English or limited English speaking participants. Choose all that apply.

[X] Enrollment window is too short to obtain translator

[X] Other

39>Describe the 'other' reason(s) for excluding non-English or limited English speaking participants.

All eligible anesthesia providers at PSHMC speak english

40>Which of the following two conditions applies to the research? Choose only one.

[X] The research presents no more than minimal risk of harm to participants and involves no procedures for which written consent is normally required outside of the research context.

41>Explain how your research fits the category selected.

No identifying information or personal heath information will be stored Participants are at minimal risk to selves by participating in this study.

42>Indicate what materials, e.g., a letter accompanying a questionnaire, verbal script or summary explanation of the research, will be used to inform potential participants about the research

We will use a Summary Explanation of Research with verbal consent.

Cost to Participants: Compensation

43>Will the participant bear any costs which are not part of standard of care?

No

44>Will individuals be offered compensation for their participation?

No

Data Collection Measures/Instruments

45>Choose any of the following data collection measures/instruments that will be used in this study. Submit a copy of all instruments, measures, interview questions, and/or focus group topics/questions for review.

[X] Questionnaires, surveys, diaries or journals

46>List the titles of the surveys, diaries or questionnaires that will be used.

Data collection sheet

Drugs/Medical Devices/Other Substances

47>Does this research study involve the use of any of the following? Choose all that apply.

[X] None of the above will be used in this research study

Biological Specimens

48>Will biological specimens (including blood, urine and other human-derived samples) be used in this study?

No

Recordings - Audio, Video, Digital, Photographs

49>Will any type of recordings (audio, video or digital) or photographs be made during this study?

No

Computer/Internet

50>Will any data collection for this study be conducted on the Internet or via email (e.g. on-line surveys, observations of chat rooms or blogs, on-line interviews surveys via email)?

No

51>Will a commercial service provider (i.e., SurveyMonkey, Psych Data, Zoomerang) be used to collect data or for data storage?
No

Risks: Summary

52>Summarize the major discomforts and risks of interventions that are part of the experimental portion of the study. This description should include physical, psychological, legal, social and/or financial risks. (Note: For studies presenting no more than minimal risk, loss of confidentiality may be the main risk associated with the research.)
There is a potential risk of breach of confidentiality.

53>Describe how the discomforts and risks will be minimized and/or how participants will be protected against potential discomforts/risks throughout the study (e.g., label research data/specimens with code numbers, screening to assure appropriate selection of participants, identify standard of care procedures, sound research design, safety monitoring and reporting).
There is a potential risk of breach of confidentiality. All research data will be identified with a code number that is not linked to the participant. The risk will be minimized by use of the HIPAA-compliant REDCap data management system for collection and proper secure maintenance of the data. The standard PSHMC procedures to maintain patient confidentiality will be followed. No patient identifiable information will be collected.Participants will be informed that their employment or resident status will be in no way affected by their decision to participate or not. Also, their simulated intubation will not affect their employment or resident status.

54>Is it possible that you will discover a participant's previously unknown condition (e.g., disease, suicidal thoughts, wrong paternity, etc.) as a result of the study procedures?
No

55>Is it possible that, as a result of the study procedures, you will discover a participant is engaging in illegal activities (e.g., drug use, domestic violence, child abuse/neglect, underage drinking, etc.)?
No

56>Does this research involve greater than minimal risk to the participants?
No

Benefits to Participants

57>What are the potential benefits to the individual participants of the proposed research study? (If none, state "None.") NOTE: Compensation cannot be considered a benefit.
Possible education of new skills as well as improvement of current skills. Increased knowledge

of airway placement techniques

58>What are the potential benefits to others from the proposed research study?

Improved knowledge regarding placement techniques for an underutilized supraglottic airway device which, potentially, could be life-saving both in the field and in the hospital.

Deception

59>Does this study involve giving false or misleading information to participants or withholding information from them such that their "informed" consent is in question?

No

Confidentiality

60>Describe the provisions made to maintain confidentiality of the data, including medical records and specimens. Choose all that apply.

[X] Password protected computer files
[X] Locked offices

61>Describe the provisions made to protect the privacy interests of the participants and minimize intrusion.

No identifying information about any participants will be recorded, with the sole exception being a list of participants, in order to ensure that no participant participates more than once. Once the data collection is complete, that list will be destroyed. All research data will be labeled with a code number not traceable to the individual participant.

Email solicitations will only be sent twice at designated intervals and they will be sent using a blinded distribution list.

62>Will the study data and/or specimens contain identifiable information?

No

63>Who will have access to the study data and/or specimens?

Researchers listed on the IRB.

64>Will identifiers be disclosed to a sponsor or collaborators at another institution?

No

65>Will a record or list containing a code (i.e., code number, pseudonym) and participants identity be used in this study?

No

66>What will happen to the data when the research has been completed? Choose one.

[X] Stored indefinitely with identifiers removed

67>Is information being collected for this research that could have adverse consequences for participants or damage their financial standing, employability, insurability or reputation?
No

68>Will a "Certificate of Confidentiality" be obtained from the federal government?
No

Security and Integrity of Human Research Data - Security Levels

The following questions are about your data security and integrity plan for this research as required by the Penn State College of Medicine IRB SOP Addendum: Security and Integrity of Human Research Data.

69>What is/are the category(ies) of the human research data collected in this research study as defined in the IRB Standard Operating Procedure Addendum: Security and Integrity of Human Research Data? (Select all that apply)

[X] **Level 1**
- Examples:
• De-identified research information
• Coded research information that does not include any of the 18 HIPAA identifiers.
(Note: The list linking code numbers to identifiers is Level 3 human research data.)
• Publicly available data

[ ] **Level 2**
- Examples:
• Identifiable, non-health, non-sensitive research information

[ ] **Level 3**
- Examples:
• Identifiable health research information
• Identifiable, sensitive, non-health research information
• Lists that link code numbers to identifiers for coded datasets
• Data that include identifiable non-sensitive research information linked to social security numbers

Please use this space to provide additional comments or clarifications as necessary:

70>Describe how the Level 1 human research data will be stored and secured.
De-identified information will be stored electronically in the REDCap system. Paper records will be stored in a locked cabinet in the locked office of the PI or coordinator.

71>Is there a list of the people who have access to the data (electronic and/or paper)?
[X] Yes
[ ] No

If No, explain why not(contact the IT Helpdesk at 717-531-6281 for an IT managed desktop or PHS Helpdesk at 717-531-7682, email helpdesk@hes.hmc.psu for a PHS-managed desktop to ensure technical compliance):

Please use this space to provide additional comments or clarifications as necessary:
Only those listed on the IRB will have access to the data.

72>Describe the mechanism in place to ensure only permitted users have access to the stored research data (electronic and paper).
Data will be kept in the locked office of the researchers listed on the IRB at Penn State Hershey. The electronic data will be entered into the secure REDCap system which restricts access to members of the research team.

73>Does the research involve collection or transfer of electronic data outside of PSU/HMC?
[X] No
[ ] Yes

If Yes, answer the following questions:

Describe how the data will be securely collected and/or transferred.

Are the data being transferred under a sponsor contract or a data use agreement negotiated by the Office of Research Affairs or the Office of Technology Development?
[ ] Yes
[ ] No *

*** If "No" was selected above, contact the Office for Research Affairs at 717-531-8495 (if the research is externally funded) or the Office of Technology Development at 717-531-8496 (if the research is not externally funded) to ensure compliance.**

74>What is the process for ensuring correctness of data entry?
[ ] Double data entry to reduce risk of transcription errors
[ ] Electronic edit checks to ensure data being entered are not obviously incorrect
[X] Random internal quality and assurance checking of research data
[ ] **Other:**

Please use this space to provide additional comments or clarifications as necessary:

Additional PSU Committee Approvals

75>Choose all that apply.
[ ] Human Use of Radioisotope Committee (HUIC)

Review by this committee is required if the study involves radiation procedures specifically for the research. The HUIC review letter is required before IRB approval will be issued.
[ ] Institutional Biosafety Committee (IBC)
IBC Registration Number:

Review by this committee is required if the research involves the use of human biological specimens, biological toxins, carcinogens, infectious agents, recombinant viruses or DNA, or gene therapy. The IBC registration number is required before IRB approval will be issued.

[X] Departmental Scientific Review Committee

All investigator-written human research studies (IITs) requiring review by the convened IRB must provide documentation of scientific review with the IRB submission. For IITs receiving external peer review (e.g., NIH grants), a copy of the grant will be documentation of scientific review. For other IITs, a copy of the memo or review checklist from the departmental scientific review committees or Clinical Research Center Advisory Committee will serve as scientific review documentation. See the IRB website for more information about this requirement.

Review by the Penn State Hershey Cancer Institute Scientific Review Committee is required for all studies that involve cancer patients, records and/or tissues or cancer prevention. A copy of the committee's report must be submitted with the application materials.

[ ] Anatomic Pathology

Protocols involving the collection of tissues or use of pathologic specimens must receive approval from Anatomic Pathology. Include a copy of the Human Tissue for Research Form with the application materials.

[ ] Conflict of Interest Review Committee (CIRC)

Review by this committee is required if a significant financial or business interest or PSU intellectual property interest is indicated. The CIRC report is required before IRB approval will be issued.

Radiation

76>Will any participants be asked to undergo a diagnostic or therapeutic radiation procedure (including radiographic, nuclear medicine, DEXA) while enrolled in this study?

No

Abstract

77>Background and Rationale: Provide background information and explain why the study hypothesis needs to be addressed. For studies using drugs, summarize the drug's class and mechanism.

Multiple types of devices exist to facilitate oxygenation and ventilation during proper airway management. These devices include endotracheal intubation devices, which are constructed with either single or double lumen tubes, and require passage through the vocal cords. In addition, there are several supraglottic devices, including esophageal tracheal combitube, EasyTube, and laryngeal mask airway, which do not require passage through the vocal cords. These types of airways have become increasingly used in the recent past (1). The supraglottic airway is a device used in the area above the vocal cords to maintain airway and improve ability to ventilate and oxygenate the patient (2) especially in the case of the unexpected difficult airway including when the patient is unable to be ventilated or intubated.

The utility of these supraglottic airway devices has made them increasingly popular and good alternatives to endotracheal intubation. An EasyTube is similar to esophageal tracheal combitube (ETC), but with several significant differences. The distal end is only a single lumen in contrast to the double lumen of the ETC. The pharyngeal lumen ends just below the oropharyngeal cuff; this is less likely to cause trauma while allowing for an easier placement both in adults and for smaller patients. The open end of this lumen also allows the passage of a fiberoptic scope.(3) Additionally, the cuff balloon is latex free (3). The EasyTube allows for ventilation and oxygenation after placement in the supraglottic area, either in the esophageal (where it most often is placed with blind technique) or in the tracheal area (which can occur with blind placement)(4). An EasyTube is similar to a Combitube/ETC but has been modified to improve the perceived short comings of the ETC (5). The EasyTube has been reported to even be used in elective surgery without serious complication (3). The Combitube has also been reported to be used in elective surgery with positive pressure ventilation (6) as well as in the intensive care unit (7).

Supraglottic devices have many advantages in comparison to either mask/oropharyngeal airway or endotracheal intubation. They provide a more definitive airway with improved ventilation/oxygenation in contrast to mask ventilation; they are easier to place than endotracheal intubation and can be completed by pre-hospital or other health care providers (8). They can be used in moving vehicles as well as less than optimal conditions in the pre-hospital and field arenas. Often health care providers can successfully place supraglottic devices without significant training or advanced degrees. These supraglottic devices are also recommended by the ASA Task Force on Management of the Difficult Airway for the unrecognized difficult airway problems, in especial cases those where the patient is unable to be ventilated or intubated (5). One such supraglottic device is the EasyTube, which was discussed as a possible emergency airway by Thierbach et al. (9).

There has never been any comparison however of the use of EasyTube in different methods of placement in the hands of skilled providers. Most often these devices are used by EMS/ER in the pre-hospital setting only. In this study, our aim is to compare the methods of blind insertion versus laryngoscopic insertion by skilled providers. In the study by Lorenz et al. (3), patients were randomized to either receive intubation with an endotracheal tube or an EasyTube; ease of insertion as well as insertion time was shown to be shorter with the EasyTube, with no difference in pressures recorded and no laryngo-pharyngeal discomfort.
In the case of our study, skilled providers are anesthesia attending physicians, certified registered nurse anesthetists and anesthesiology residents. Our theory is that there will be no statistically significant difference in placement time between these methods. The skilled providers may actually exhibit a propensity towards shorter times with the laryngoscopy, indicating an advantage given the providers' knowledge in contrast to unfamiliarity associated with placement of this new technique. While there has been some research into the use of Combitube for elective surgery, there remains little in terms of evaluating the use of differing methods of placement of the EasyTube in the hands of skilled providers, where this tool may be able to a valuable step in the difficult airway algorithm, especially in the cannot intubate/cannot ventilate category. In evaluating this method of placement, we intend to determine the validity of a novel manner of placement of this supraglottic device in hopes of further improving airway management and algorithms regarding it.

78>Key Objectives: List the study's objectives, aims or goals.

1. Determine the time to effective airway management,in a TruCorp AirSim™ airway simulation mannequin, utilizing the supraglottic device, Easytube, using two placement techniques (blind and laryngoscopic) by experienced providers.

2. Determine if there is a preferential placement technique.
3. Provide the participant education and the ability to learn a potentially new skill, if the skill is not new, then the participant may improve their skills with an underused technique and device.
4. Improve knowledge of use and placement techniques of EasyTube.

79>Study Population: Healthy volunteers or participants with a specific illness? Students? Include the age range of the participants. Include controls, if any.

Anesthesiologists, Certified Registered Nurse Anesthesiologists (CRNA's), and Anesthesia residents

80>Major Inclusion & Exclusion Criteria: List the characteristics required to be in the study and those which would make an individual ineligible. For studies with a research protocol, describe only the major criteria).

Major Inclusion Criteria:
1. Participant has volunteered to participate in the study.
2. Participant is an experienced provider of anesthesiology as previously defined.
3. Participant voices interest to complete the study protocol.

Major Exclusion Criteria:
1. Participant voices a disinterest or lack of interest in participating.
2. Participant does not attend session.
3. Participant is not an experienced provider.
4. Participant is unable to complete the study protocol.

81>Method of Identification of Participants, Samples and/or Medical Records: Indicate how potential participants, samples or medical records will be identified for this research. Describe any recruitment materials.

All eligible Anesthesia providers will be approached using both verbal and written announcements of the study (email, and departmental meetings).

82>Consent Process and Documentation: Who will conduct the consent discussion? Briefly describe the process [e.g., when and where consent will be obtained].

Verbal consent will be sought. Once the potential participant expresses interest in the study, a member of the research team will explain the study using a summary explanation of research.

83>Study Design: Describe the study design [e.g., case series, retrospective case-control study, etc.] Include the method of group assignment including randomization process and study comparison groups, if applicable. For case-control studies, provide the criteria used to identify participants for the control group. For simple research, this section may describe observational methods, medical chart review, etc.

This is a prospective observational study design with one study group. Volunteer experienced provider participants will present at their own recognizance to the Simulation Center at the appointed times. Only experienced providers will be sought to avoid the confounding factors of lack of experience or confidence in airway management possibly seen in inexperienced providers.The study will be performed on a TruCorp AirSim™ airway simulation mannequin.

Using the mannequin, each participant will participate in two trials of each of the two methods of placement (blind and laryngoscopic) for a total of four airway placements. The starting type of placement will alternate for each participant, in the order in which the participant arrives to begin the trial.

84>Summary of Procedures: Describe the procedures involving the participants, how they will be done and when as well as any post-treatment follow-up. For chart review studies, list the data elements to be recorded for research.

One of the investigators will give all of the participants the same short educational lecture and introduction to the EasyTube by one of the investigators as well as the two placement techniques. The participants will then be able to practice these techniques in mannequins with additional help as requested. After the participants complete the practice interval, they will be timed using a stopwatch from the time the first airway tool is picked up to the time of effective airway as described by ventilating of bilateral lungs in the TruCorp AirSim airway simulation mannequin. Each participant will complete two dual trials as described as the placement of the Easytube using both blind and laryngoscopic techniques. Researchers will be completing the data collection form during the simulation

85>Outcome Measures: Describe the endpoints used to answer the aims of the study. For studies with a research protocol, state "See protocol section X."

The outcomes measured will be time to effective airway (TTEA) from the time the first airway tool is picked up to time of ventilation of both lungs using Simulation Center TruCorp AirSim airway simulation mannequins. The TTEA will be compared between the blind and laryngoscopic methods of placements by experienced providers.

86>Statistical Plan and Sample Size Justification: Give details of the power analysis used to justify the sample size for the study. Provide a data analysis plan including statistical methods to be used for each aim of the study. For studies with a research protocol, state "See protocol section X."

This is not a study that has yet been conducted; as such, certain assumptions were made in order to use power analysis to determine the sample size. The size was determined based on a 99% significance level and a statistical power of 90%. An assumption was made that the differences in procedure time will be 10 seconds with a standard deviation of 10 seconds. Using these assumptions, a minimum of 30 participants will be necessary. This study looks to have a maximum of 40 participants, which allows leeway in the case of dropouts.

Standard descriptive statistics will be constructed for each method of placement. The times to effective airway will be determined and compared and it will be determined if there is a statistically signficant difference between blind and layrngosopic placement of the EasyTube supraglottic device.

87>Major Risks & Discomforts: Describe the risks and discomforts that are reasonably foreseeable.

There is a potential risk of breach of confidentiality. The risk will be minimized by use of the HIPAA-compliant REDCap data management system for collection and proper secure maintenance of the data. The standard PSHMC procedures to maintain confidentiality will be

followed. No identifiable information will leave the physical bounds of the medical center or be released for publication. Participants will be informed that their employment or resident status will be in no way affected by their decision to participate or not. Also, their simulated intubation will not affect their employment or resident status.

88>Potential Benefits: Describe the anticipated benefits for the participants and/or others.

1. Improved knowledge and skills associated with the placement of the supraglottic device, Easytube, by experienced providers.
2. Determination of possible novel method of placement of the Easytube. Manufacturer recommended method of placement is blind insertion. Our assertion is that laryngoscopic techniques performed by skilled providers will not increase time to effective airway using the EasyTube and will allow improved and more informed placement.
3. Decrease chances of inappropriate placements of the Easytube.
4. Improve skill repetoire and airway management skills of the research participants.

89>Privacy & Confidentiality: Indicate measures to protect participant privacy and maintain confidentiality of the research data. Indicate whether information or a code will be linkable to participants in anyway. Who will have access to the identifiers, codes or the key? How will information be protected? Will participant identifiers or codes leave the institution?

No protected health information will be collected, with the exception of noting which participants have taken part, which will be used strictly in order to ensure that no participant takes part more than once.. This list will be destroyed immediately upon completion of the data collection. All research data will be labeled with a code number that is not linked to the individual participants identity. No identifying remarks regarding the identity or job title of the participants will be marked,

All email solicitations will be sent using a blind distribution list.

90>Qualifications & Research Experience of Principal Investigator: Briefly summary the PI's qualifications and relevant research experience.

Julia Caldwell is an Assistant Professor of Anesthesiology and pain medicine with both research and publication experience.

Sonia Vaida is a Professor of Anesthesiology and Vice Chair for Research at the Department of Anesthesiology at PSHMC. She has significant research and publication experience, especially in the auspices of airway management.

David DeKorte has completed a Masters in Education with significant teaching experience both at the high school and college level. He has also completed a Masters of Science in Information with specific interest and focus on information transmission. He has significant statistical, research and publication experience.

91>Study Site Location(s): List all sites to be involved.

Penn State Hershey Simulation Center.

92>References: List a few of the most relevant references. For studies with a research protocol, state "See protocol section X."

(1) Vaida S, Airway Management - Supraglottic Airway Devices. Cursul National de Ghiduri si Protocoale în ATI, 2004, 57-60.
(2) Lorenz V et al. Comparison of the Easytube and the endotracheal tube during general anesthesia in fasted adults. Journal of Clinical Anesthesia, 2009,21,341-347.
(3) Gaitini Luis et al. Propsective randomized comparison of the Easytube and the esophageal-tracheal Combitube airway devices during general anesthesia with mechanical ventilation. Journal of Clinical Anesthesia (2011) 23, 475-481.
(4) American Society of Anesthesiologists Task Force on Management of the Difficult Airway. Practice Guidelines for management of the difficult airway: an updated report by the American Society of Anesthesiologists Task Force on Management of the Difficult Airway. Anesthesiology 2003; 98: 1269-77.
(5) Argo F et al. Current Status of the Combitube: a review of the literature. Journal of Clinical Anesthesia 2002; 14:307-14.
(6) LeFrancois DP et al. Use of the esophageal tracheal combitube by basic emergency medical technicians. Resuscitation 2002; 52: 77-83.
(7) Thierbach AR et al. A new device for emergency airway management: the Easytube. Resuscitation 2004; 60:347.
(8) Gaitini LA et al. The Combitube in elective surgery: a report of 200 cases. Anesthesiology 2001; 94:79-82.
(9) Frass M et al. Mechanical Ventilation with the esophageal trancheal combitube in the intensive care unit. Arch Emergency Medicine 1987; 4: 219-25.

Data Security - Assurance Statement

Upload a scanned copy of the signed certification signature page with this application - Applications for Human Research (Expedited and Full Review) - Assurance Statement. Keep the originals for the research study file in case they are requested during an inspection.

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CONSENT FORMS

Document 1001 Received 09/12/2013 10:16:56 - Summary Explanation of Research 43548 SER

DATA COLLECTION INSTRUMENTS

Document 1001 Received 09/12/2013 10:16:17 - 43548 Data Collection Sheet

RECRUITMENT

Document 1001 Received 09/12/2013 14:13:46 - Recruitment Materials 43548 Recruitment email

SUBMISSION FORMS

Document 1001 Received 09/12/2013 14:04:59 - Signature Pages 43548 Signature page
Document 1002 Received 09/12/2013 14:05:32 - Other 43548 Dept Approval

Appendix C: Survey Explanation of Research

SUMMARY EXPLANATION OF RESEARCH

Penn State College of Medicine
The Milton S. Hershey Medical Center

Title of Project: Comparison of placement methods of supraglottic airway devices by skilled providers

Principal Investigator: Julia Caldwell, MD

Other Investigators: Sonia Vaida, MD, David DeKorte, JD MBA, Chris Mulvey

You are being invited to volunteer to participate in this research study because you are a skilled Anesthesia Provider. Research studies include only people who voluntarily choose to take part. This summary explains information about this research. You are urged to ask questions about anything that is unclear to you.

In this study we will be testing two models of placement (blind and laryngoscopic placement), for a supraglottic airway device, the EasyTube. We are asking participants in this study to place the Easytube in a TruCorp AirSim™ airway simulation mannequin using both methods. You will be asked to perform both methods twice, for a total of four placements, in order to evaluate and compare methods. We will be measuring the time required to place an EasyTube using both the blind method as well as direct laryngoscopy to achieve an effective airway. No identifying information will be kept nor recorded. Participation would involve approximately 15 minutes of your time in the Simulation Center.

The potential risk to you is loss of confidentiality; however, we will not be collecting any identifiable information. The data collection form will be labeled with a random, consecutive study code number which will not be linked to the actual participants. We will maintain a list of all participants to ensure that we do not duplicate anyone. This list will be stored in the locked office of the research team and destroyed once the data collection period is complete. You will not benefit directly from taking part in this research study. The findings of this study may lead to improved education of new skills as well as increased knowledge regarding placement techniques of an underutilized supraglottic airway device which potentially could be life-saving both in the field and in the hospital .

You have the right to ask any questions you may have about this research. If you have questions, complaints or concerns or believe you may have been harmed from participating in this research, you should contact Julia Caldwell, MD at 717-531-5167 or 717-531-0003 ext 287723. If you have questions regarding your rights as a research participant or concerns regarding your privacy, you may contact the research protection advocate in the HMC Human Subjects Protection Office at 717-531-5687. You may call this number to discuss any problems, concerns or questions; get information or offer input.

Taking part in the research study is voluntary, you do not have to participate. Your decision to participate or to decline the research will not result in any penalty or loss of benefits to which you are entitled. Whether or not you choose to participate will have no effect on your employment or resident status. This is also true of the data collected. Tell the researcher your decision regarding whether or not you wish to participate in this research.

Appendix D: Participant Survey

Data Collection Sheet

Subject number: _____

Age: _____

Sex: Male / Female

Title: Attending / Resident / CRNA

Years of Anesthesia Experience: _____

PGY: 1 / 2 / 3 / 4 / 5

Previous experience with an Easytube supraglottic airway: Yes / No

Approximate number of times: _____

Previous experience with any supraglottic airway device other than the LMA: Yes / No

Approximate number of times: _____

Blind Placement Technique

Attempt #	Success	Time (sec)
1		
2		

Laryngoscopic Placement Technique

Attempt #	Success	Time (sec)
1		
2		

Appendix E: Data Table

A	B	C	D	E	F	G	H	I	J	K	L	M	N	O	P	Q	R	S	T
1	B	R	2	2	No	0	No	0	30.11	29.14	45.86	36.87	29.625	41.365	11.74	29.14	36.87	23.48	7.73
2	L	A	8	0	Yes	5	No	0	No	No (90.51)	44.74	27.77	N/A	N/A					
3	B	R	0.4	1	No	0	No	0	32.94	23.82	34.66	20.19	28.38	27.43	0.96	23.82	20.19	1.91	3.63
4	B	R	0.4	2	No	0	No	0	25.17	28.62	25.59	25.14	26.90	25.37	1.53	25.17	25.14	3.06	0.03
5	B	A	15	0	Yes	100	Yes	100	20.54	16.16	24.36	21.92	18.35	23.14	4.79	16.16	21.92	9.58	5.76
6	L	C	5	0	No	0	Yes	10	17.17	19.59	22.27	23.49	18.38	22.88	4.50	17.17	22.27	9.00	5.10
7	B	R	2	3	No	0	No	0	44.12	31.02	43.21	35.17	37.57	39.19	1.62	31.02	35.17	3.24	4.15
8	L	C	3	0	No	0	Yes	5	18.31	23.61	43.32	31.29	20.96	37.31	16.35	18.31	31.29	32.69	12.98
9	L	R	1.5	2	No	0	No	0	40.03	18.32	26.71	28.07	29.18	27.39	1.79	18.32	26.71	3.57	8.39
10	B	C	3	0	No	0	No	0	19.07	19.49	29.61	24.11	19.28	26.86	7.58	19.07	24.11	15.16	5.04
11	L	A	5	0	No	0	No	0	18.92	18.66	30.54	27.06	18.79	28.80	10.01	18.66	27.06	20.02	8.40
12	L	A	9	0	Yes	0	Yes	0	21.72	20.69	26.77	24.51	21.21	25.64	4.44	20.69	24.51	8.87	3.82
13	B	R	0.4	2	No	0	No	0	27.73	23.34	30.21	27.99	25.54	29.10	3.57	23.34	27.99	7.13	4.65
14	L	A	28	0	No	0	Yes	12	16.12	13.27	25.67	22.13	14.70	23.90	9.21	13.27	22.13	18.41	8.86
15	L	C	8	0	No	0	Yes	1000	25.07	19.52	62.12	29.13	22.30	45.63	23.33	19.52	29.13	46.66	9.61
16	L	R	5	2	No	0	Yes	2	21.78	18.46	23.46	23.68	20.12	23.57	3.45	18.46	23.46	6.90	5.00
17	B	R	2.5	3	No	0	Yes	4	35.25	23.66	21.66	18.75	29.46	20.21	9.25	23.66	18.75	18.50	4.91
18	L	R	1.5	2	No	0	No	0	30.55	17.03	28.43	23.10	23.79	25.77	1.98	17.03	23.10	3.95	6.07
19	L	R	2.5	3	No	0	No	0	18.85	20.38	30.85	22.33	19.62	26.59	6.98	18.85	22.33	13.95	3.48
20	B	R	3	4	No	0	No	0	31.46	22.48	26.01	22.20	26.97	24.11	2.87	22.48	22.20	5.73	0.28
21	B	R	3.5	4	No	0	Yes	2	27.53	21.46	27.61	32.88	24.50	30.25	5.75	21.46	27.61	11.50	6.15
22	L	C	7	0	No	0	No	0	23.20	20.45	31.50	35.40	21.83	33.45	11.63	20.45	31.50	23.25	11.05
23	L	R	1	1	No	0	No	0	22.06	15.76	41.51	26.06	18.91	33.79	14.88	15.76	26.06	29.75	10.30
24	L	R	0.5	1	No	0	No	0	37.61	32.60	36.80	37.40	35.11	37.10	1.99	32.60	36.80	3.99	4.20
25	L	A	6	0	No	0	No	0	42.17	29.47	35.16	28.78	35.82	31.97	3.85	29.47	28.78	7.70	0.69
26	B	R	4	4	No	0	No	0	16.13	16.86	20.26	18.01	16.50	19.14	2.64	16.13	18.01	5.28	1.88
27	L	A	8	0	No	0	No	0	20.06	20.90	31.81	22.43	20.48	27.12	6.64	20.06	22.43	13.28	2.37
28	L	R	2.5	4	No	0	No	0	18.23	19.35	34.96	26.60	18.79	30.78	11.99	18.23	26.60	23.98	8.37
29	L	R	2	2	No	0	Yes	5	21.45	23.33	37.60	26.96	22.39	32.28	9.89	21.45	26.96	19.78	5.51
30	B	R	0.4	1	No	0	No	0	32.80	27.63	31.41	31.87	30.22	31.64	1.43	27.63	31.41	2.85	3.78
31	B	A	30	0	Yes	10	Yes	10	22.60	30.74	29.38	34.93	26.67	32.16	5.49	22.60	29.38	10.97	6.78
32	L	R	0.4	1	No	0	No	0	20.60	18.25	34.15	24.95	19.43	29.55	10.13	18.25	24.95	20.25	6.70
							Averages:		25.79	22.07	32.44	26.91	23.93	29.47					

Note: Participant #2 did not complete the study. Data was discarded from analysis.

Legend by column

A: Participant Number
B: First Insertion - Blind or Laryngoscopic
C: Attending Physician (A) / Resident Physician (R) / Certified Registered Nurse Anesthetist (C)
D: Years of Anesthesia Experience
E: Program Year (for resident physicians)
F: Prior EasyTube Experience
G: Approximate Number of EasyTube Insertions
H: Prior Experience with Other Supraglottic Airway Devices (Except LMA)
I: Approximate Number of SAD Insertions
J: Time for First Blind Insertion
K: Time for Second Blind Insertion
L: Time for First Laryngoscopic Insertion
M: Time for Second Laryngoscopic Insertion
N: Blind Insertion Average
O: Laryngoscopic Average
P: Absolute Difference Between Insertion Averages
Q: Minimum Blind Insertion Time
R: Minimum Laryngoscopic Insertion Time
S: Absolute Difference Between Total Insertion Times (Blind vs. Laryngoscopic)
T: Absolute Difference Between Minimum Insertion Times

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DAVID P. DEKORTE II, J.D., M.B.A., M.ED., M.S.I.

Academic Vita

Education

08/2012 – Present **The Pennsylvania State University** **Harrisburg, PA**
The Schreyer Honors College

- Master of Health Administration
  - Thesis: The Next Generation of Medicine: Freshman Undergraduate Premedical Student Perceptions of the Future of the Health Care Field
  - Thesis Supervisor: Karen Buhr PhD
- Bachelor of Science in Science
  - Life Sciences
- Bachelor of Science in Public Policy
- Honors in Science
  - Thesis: Comparison of times for two EasyTube placement techniques
  - Thesis Supervisor: Katherine Baker PhD
  - Honors Adviser: Thomas Eberlein PhD
- Minor in Biology
- Minor in Mathematics

08/2004 – 05/2008 **The University of Michigan Law School** **Ann Arbor, MI**

- Juris Doctor

08/2005 – 05/2008 **The University of Michigan** **Ann Arbor, MI**

- Master of Science in Information
  - Information Economics, Management & Policy

06/2001 – 05/2004 **Xavier University** **Cincinnati, OH**

- Master of Business Administration
- Master of Education
  - Secondary Education
  - Thesis Title: A Correlational Study of the Ohio High School Twelfth-Grade Proficiency Test
  - Thesis Supervisor: Holly Kaminski M.Ed.

08/1993 – 05/2000 **The Pennsylvania State University** **University Park, PA**
The Schreyer Honors College

- Bachelor of Science in Education
  - Secondary Mathematics
- Bachelor of Arts in American Studies
- Honors in Science, Technology & Society
  - Thesis Title: The Use of Technology in Education From Student Perspectives
  - Thesis Supervisor: Franz Foltz PhD

- Honors in American Studies
  - Thesis Title: Vietnam in Memory
  - Thesis Supervisor: James Rambeau PhD
- Minor in Natural Science
- Minor in Science, Technology & Society

Professional Experience

05/2013 – Present **Penn State Hershey Medical Center** **Hershey, PA**
- Medical Researcher – Department of Anesthesiology
- Technical Assistant – Clinical Simulation Center

03/2011 – 06/2012 **Gillette College** **Gillette, WY**
- Adjunct Professor
  - Wyoming & Federal Government
  - Technical Mathematics

08/2009 – 06/2011 **University of Houston** **Houston, TX**
- Legal Research Fellow

08/2008 – 08/2009 **University of Houston Law Center** **Houston, TX**
- Research / Reference Librarian

09/2005 – 05/2008 **The University of Michigan** **Ann Arbor, MI**
- Law School - Research Assistant
- School of Information - Undergraduate Research Supervisor

08/2006 – 05/2008 **The University of Michigan Law School** **Ann Arbor, MI**
- Michigan Telecommunications & Technology Law Review
  - Associate Editor

08/2003 – 06/2004 **Covington Independent Schools** **Covington, KY**
- Holmes Alternative School
- Mathematics Department Chair, Junior High

08/2000 – 06/2003 **Northwest Local School District** **Cincinnati, OH**
- Mathematics Teacher
- Chess – Varsity Interscholastic Coach

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Publications

Peer-Reviewed Articles

Caldwell JC, **DeKorte DP**, Doll RE, Vaida SJ: A Comparison of Blind and Laryngoscopic Insertion of the EasyTube. Manuscript submitted.

Gavin Clarkson and **David DeKorte**, *Unguarded Indians: The Complete Failure of the Post-Oliphant Guardian and the Dual-Edged Nature of* Parens Patriae, 2010 U. ILL. L. REV. 1119.

Book Chapter

CLARKSON, G. and **DeKORTE, D.** (2006), The Problem of Patent Thickets in Convergent Technologies. Annals of the New York Academy of Sciences, 1093: 180–200.

Conference Presentations

Julia Caldwell, **David DeKorte**, Hengameh Hosseini. "Barriers to Quality Improvement and Their Solutions." Global Landscapes Conference 2015, Wilkes-Barre, PA, April 17, 2015.

David DeKorte, Thomas Eberlein, Julia Caldwell. "Comparison of Times for Two EasyTube Placement Techniques." Penn State Undergraduate Exhibition, University Park, PA, April 8, 2015.

David DeKorte. "The Next Generation of Medicine: Freshman Undergraduate Premedical Student Perceptions of the Future of the Health Care Field." Penn State Graduate Exhibition, University Park, PA, March 22, 2015.

Brandon Rein, Andrey Bilko, Michael Akerley, Elbert Mets, **David DeKorte**, Sonia J. Vaida, Julia Caldwell. "Analysis of Ambient Operating Room Noise During Induction and Emergence." Graduate Medical Resident Research Day, Hershey, PA, May 23, 2014.

Brandon Rein, Andrey Bilko, Michael Akerley, Elbert Mets, **David DeKorte**, Sonia J. Vaida, Julia Caldwell. "Analysis of Ambient Operating Room Noise During Induction and Emergence." Pennsylvania Anesthesiology Resident Research Conference, Pittsburgh, PA, May 10, 2014.

Andrey Bilko, Michael Akerley, Elbert Mets, **David DeKorte**, Sonia J. Vaida, Julia Caldwell. "Analysis of Ambient Operating Room Noise During Induction and Emergence." New York State Society of Anesthesiologists, Post Graduate Assembly, New York, NY, December 14, 2013.

Gavin Clarkson & **David DeKorte**. "Nanothickets and Nanopools: A Small Suggestion for Promoting Innovation." Session: "Knowledge Management." Academy of Management Annual Meeting, Atlanta, GA, August 15, 2006.

DAVID P. DEKORTE II, J.D., M.B.A., M.ED., M.S.I.

Professional and Organization Memberships

American Society of Anesthesiologists
American College of Medical Quality
Penn State Alumni Association – Life Member

Activities

The Pennsylvania State University **Harrisburg, PA**

09/2013 – Present — Penn State Harrisburg Health Sciences Club
- Founder
- President: 04/2014 – 03/2015
- Vice-President: 09/2013 – 04/2014

12/2012 – 02/2015 — Student Government Association
- Senate Leader: 08/2013 – 02/2015
- Senator: 12/2012 – 02/2015

08/2012 – Present — Penn State Harrisburg Blue & White Society
- Secretary: 03/2014 – 10/2014
- Vice-President: 08/2013 – 03/2014

08/2012 – 09/2013 — Penn State Harrisburg Lion Ambassadors

The University of Michigan Law School **Ann Arbor, MI**

09/2004 – 05/2008 — American Civil Liberties Union – Michigan Law Chapter
- Treasurer: 09/2005 – 05/2007

The Pennsylvania State University **University Park, PA**

1995 – 1997 — American Civil Liberties Union – Penn State Chapter
- Co-Founding Member
- Co-Chair, 1996 – 1997

Awards and Honors

Dean's List, Pennsylvania State University – 9 semesters
Eagle Scout – Boy Scouts of America