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Comparing the Effectiveness of the Video Laryngoscope with the Direct Laryngoscope in the Emergency Department: A Meta-Analysis of the Published Literature

D. Sean DeGarmo

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COMPARING THE EFFECTIVENESS OF THE VIDEO LARYNGOSCOPE WITH THE DIRECT LARYNGOSCOPE IN THE EMERGENCY DEPARTMENT:
A META-ANALYSIS OF THE PUBLISHED LITERATURE

A DISSERTATION
SUBMITTED IN PARTIAL FULFILLMENT OF THE REQUIREMENTS
FOR THE DEGREE OF DOCTOR OF PHILOSOPHY IN NURSING

THE UNIVERSITY OF TEXAS HEALTH SCIENCE CENTER AT HOUSTON
SCHOOL OF NURSING

BY
D. SEAN DEGARMO, MSN, RN

AUGUST, 2017
To the Dean for the School of Nursing:

I am submitting a dissertation written by Sean DeGarmo, RN, ENP-BC, FNP-BC, CNSA-BC and entitled "Comparing the Effectiveness of the Video Laryngoscope with the Direct Laryngoscope in the Emergency Department: A Meta-analysis of the Published Literature." I have examined the final copy of this dissertation for form and content and recommend that it be accepted in partial fulfillment of the requirements for the degree of Doctor of Philosophy in Nursing.

Deanna E. Grimes, DrPH, RN, FAAN, Committee Chair

We have read this dissertation and recommend its acceptance:

[Signatures]

[Signature]
Dean for the School of Nursing
ACKNOWLEDGEMENTS

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A special thank you goes out to all of the doctoral faculty and my cohort who have supported me and provided me with constructive criticism to help me grow.
COMPARING THE EFFECTIVENESS OF THE VIDEO LARYNGOSCOPE WITH THE DIRECT LARYNGOSCOPE IN THE EMERGENCY DEPARTMENT: A META-ANALYSIS OF THE PUBLISHED LITERATURE

D. SEAN DEGARMO, MSN, RN

Abstract

Purpose: Rapid intubation is essential for the critically ill patient in the emergency department (ED) to ensure adequate oxygenation. Regardless of presenting illness or injury, the first pass success rate (FPS) can impact patient morbidity and mortality. The aim of this study was to evaluate the FPS of video laryngoscopy (VL) compared with direct laryngoscopy (DL) in adult patients intubated in the ED. Methods: Ovid Medline, Cochrane Library database, Embase, and Google Scholar were searched for peer-reviewed articles on studies of human subjects reporting a comparison of FPS rates between VL and DL in adult patients who were orotracheally intubated in the ED. A meta-analysis was performed using odds ratio (OR) as the summary effect measure for FPS. A pooled effect size with 95% Confidence Interval (CI) was calculated using a random effect model with the inverse weighted method. Results: 8,428 intubations (2,588 VL and 5,840 DL) from nine studies (five observational and four randomized control trials) were included in the sample. The pooled OR for first pass success across all studies was 1.89 [95% CI 1.17-3.07, p< 0.01], favoring VL when compared with DL. The results were limited by potential bias (selection and performance) and high levels of heterogeneity [I² = 88%; 95% CI: 79%-93%; Q = 64.61; p< 0.01]. Conclusions: Threats
to validity made it difficult to conclude with certainty that one device is better than the other for achieving a successful intubation on the first attempt in the ED.

*Keywords: emergency, intubation, video laryngoscopy, meta-analysis*
Approval Form D-3

The University of Texas Health Science Center at Houston
School of Nursing
Houston, Texas

6/30/2017
Date

To the Dean for the School of Nursing:

I am submitting a dissertation written by Sean DeGarmo, RN, ENP-BC, FNP-BC, CNSA-BC and entitled "Comparing the Effectiveness of the Video Laryngoscope with the Direct Laryngoscope in the Emergency Department: A Meta-analysis of the Published Literature." I have examined the final copy of this dissertation for form and content and recommend that it be accepted in partial fulfillment of the requirements for the degree of Doctor of Philosophy in Nursing.

Deanna E. Grimes, DrPH, RN, FAAN, Committee Chair

We have read this dissertation and recommend its acceptance:

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Accepted
Dean for the School of Nursing

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**Summary of Study**

On January 26, 2016, “Comparative and Cost Effectiveness Analysis of the Video Laryngoscope” was approved by Center for Protection of Human Subjects (CPHS) at the University of Texas Health Science Center – Houston (UTHSC-Houston) HSL-SN-16-0032 (Appendix A). The study was planned to use existing data from a database. On September 12, 2016, Baylor IRB gave approval. H-39327 – “Comparative and Cost Effectiveness Analysis of the Video Laryngoscope” (Appendix B - Approval from Baylor College of Medicine IRB).

After one year of attempting to access the data, the data were unattainable due to unforeseen circumstances. The dissertation committee was reconvened on December 6, 2016, and they decided that a systematic review of the literature should be performed. A meta-analysis may also be required to determine a first pass success rate from the published literature. On February 28, 2017, a protocol change request was granted from CPHS (Appendix C - Change approval from CPHS).

While performing the systematic review of the literature, it became apparent that there was a difference between studies. The principal investigator (PI) met with the dissertation chair and discussed with committee members that a meta-analysis would need to be performed to address the comparative effectiveness to calculate an effect size. They agreed that this change in methodology needed to occur so that the AIM 1 could be adequately addressed. The PI had experience and training in performing systematic reviews, but limited exposure to performing a meta-analysis.
The PI completed an online systematic review and meta-analysis course in meta-analysis authorized by Johns Hopkins University and offered through Coursera (Introduction, 2107). To further assist in understanding and experiencing meta-analysis, the author attended a professional development and training extended course on advanced meta-analysis at the April 28, 2017 annual meeting of the American Educational Research Association (AERA). The course, PDC12: Advanced Meta-Analysis was taught by Terri D. Pigott, Loyola University Chicago; Joshua R. Polanin, Development Services Group; Ryan Williams, American Institutes for Research; and Ariel M. Aloe, University of Iowa (2017).

After attending the course, a meta-analysis of the published literature was carried out. A meta-analysis is an extension of the systematic review process. It is the statistical procedure for combining data from multiple studies to calculate a ‘standardized effect size’ that summarizes the effect sizes across all of the studies that met the inclusion criteria for the review. The additional steps performed were a quality evaluation (See Table 3A and 3B), data analysis, heterogeneity examination, assessing publication bias, and interpretation and reporting of the results.

The PICOS format was used for the research question to be consistent with studies in the literature: Among adults emergently intubated in the Emergency Department, does Video Laryngoscopy (VL) have a higher first pass success rate compared with Direct laryngoscopy (DL)?

a. Population- is Adults emergently intubated

b. Intervention- is Video laryngoscopy

c. Control- is Direct laryngoscopy
d. Outcome- is the first pass success rate

e. Setting- is the Emergency Department

The research question was not able to be answered due to the significant heterogeneity that prevented appropriately combing these studies. The difference between studies was not due to happenstance. Even with the risk of bias found in the RCTs, there remained acceptable heterogeneity. However, there was no accounting for excessive variation in the observational studies. This variation was most likely a confounder that was controlled for randomized studies.

The conclusion of the meta-analysis was that there was no way to answer the research question with certainty due to the heterogeneity and high risk of bias. A cost effectiveness analysis (AIM 2) could not be performed due to the heterogeneity and bias effect, summary effect measurement and the lack of reported adverse events reported. The dissertation chair and committee members agreed that continuing to perform a cost effectiveness analysis was not possible. It was, therefore, recommended that it be part of a future study post-graduation.
Specific Aims

AIM 1: Determine the comparative effectiveness among matched patients from the Baylor/Ben Taub ED database using VL compared to those using DL regarding the first pass success rate as the measurement of “effect.”

Hypothesis: The VL will have a higher first pass success rate than the DL.

AIM 2: Estimate the incremental cost effectiveness ratio (ICER) using the first pass rate as the “effect” measurement while controlling for the amount and type of DACs comparing the VL to the DL in the ED from the perspective of the ED administration in matched patients.

Research Strategy

Significance.

**Intubation indications.** Intubation of the critically ill or emergent patient in the ED is complex and associated with variables that can impact the patient’s morbidity and mortality regardless of the presenting injury or illness (Table 2). It is estimated that there are 267,750 patients intubated annually in the United States (Weingart, Carlson, Callaway, Frank, & Wang, 2013). The most common indications for intubation in the ED for medical emergencies are cardiac arrest, drug overdose and congestive heart failure (CHF). Head trauma is the leading indication for intubation in the trauma patient (Walls, Brown III, Bair, & Pallin, 2011). Rapid intubation is essential to ensure adequate oxygenation, yet up to 26% of these patients will experience complications related to intubation difficulty, such as multiple attempts, prolonged periods without ventilation,
and esophageal intubation (Nable et al., 2012; Sakles et al., 1998; Wang & Yealy, 2006; Wayne & McDonnell, 2010; Wong & Ng, 2008).

**First attempt success.** Success on the first attempt is defined as the proper placement of an endotracheal tube on the initial attempt (Mosier, Stolz, Chiu, & Sakles, 2012; Sakles & Kalin, 2012). The success rate of the first attempt at intubation is critical because multiple attempts to increase the likelihood of adverse events (AEs): airway trauma, aspiration, dysrhythmias, hypoxemia, anoxia, brain injury or even death (Jaeger et al., 2000; Nable et al., 2012; Sakles et al., 2013; Wang & Yealy, 2006). The likelihood of AEs to occur more than triples from the first attempt (14.2%) to the second attempt (47.2%) (Sakles et al., 2013).

**Difficult intubation.** A difficult intubation has been defined as a situation in which an airway that cannot be securely intubated using standard methods with multiple attempts (Bair, Filbin, Kulkarni, & Walls, 2002) by a traditionally trained anesthesiologist (Apfelbaum et al., 2013). Difficult intubations have been reported to occur in a range of 4% to 26% of all intubations performed in the ED (Sakles et al., 1998; Wong & Ng, 2008). The difficulty of the intubation is associated with patient characteristics, the setting, skill, and experience of the clinician (Apfelbaum et al., 2013). In some cases, a difficult intubation can be anticipated before the initial attempt (Bair et al., 2002; Walls & Murphy, 2008). Unfortunately, there are a significant number of cases in which the intubator may not be able to determine if the intubation is difficult until he or she is making an attempt (Bair et al., 2002; Walls & Murphy, 2008).

**Difficult Airway Characteristics (DACs).** Several patient characteristics associated with preventing the alignment of the oropharyngeal axes make successful
intubation more difficult or impossible (Mosier, Chiu, Patanwala, & Sakles, 2013; Mosier et al., 2012). These characteristics are termed DACs (Sakles et al., 2014). The DACs most commonly reported are obesity, large tongue, short neck, small mandible, cervical immobility, blood, vomit (emesis), airway edema, and facial or neck trauma (Mosier et al., 2012; Patanwala et al., 2011; Sakles & L. Kalin, 2012). As the amount of DACs increase, the more likely a difficult intubation will be encountered, which is associated with a higher rate of hypoxia, esophageal intubation, airway trauma and cardiac arrest (Mort, 2004).

**Measurements to predict a likelihood of difficult airways.** Anesthesiologists often have the ability to perform airway assessment measurements that are useful in predicting a difficult airway. The most common assessments include the Cormack-Lehane (CL) grading scale and the Mallampati classification (Bair, Caravelli, Tyler, & Laurin, 2010; Levitan, Everett, & Ochroch, 2004). The CL grading scale was developed as a visual scale to determine the view of the larynx obtained during direct laryngoscopy (Appendix A-1). It is measured using a scale of I to IV, where I and II are associated with intubations that are classified as easy and III and IV are difficult (Cormack & Lehane, 1984). The CL grading system has inferior inter-rater reliability (kappa=0.16) in the operating room (OR) and the ED (Ochroch, Hollander, Kush, Shofer, & Levitan, 1999). While the Mallampati classification considers a large tongue that obscures the oropharynx the most significant predictor of a difficult intubation (Appendix A-2). The larger the tongue, the more likely the intubation will be difficult. A Mallampati class III or IV is anticipated to be a difficult intubation whereas a class I or II classification is predictive of a less challenging intubation (area under the sROC curve = 0.83 ± 0.03)
(Lee et al., 2006). The Mallampati classification has been demonstrated as helpful in assessing patients in the preoperative setting. However, in the ED Mallampati scoring was unobtainable in 75% of patients because it requires a cooperative patient (Bair et al., 2010).

**Adverse Events (AEs).** Complications that occur in conjunction with, or as a result of, intubation are known as adverse events (AEs) (see Table 3). These include airway trauma, aspiration, dysrhythmias, hypoxemia, anoxia, brain injury or even death (Hasegawa et al., 2012; Jaeger et al., 2000; Mort, 2004; Nable et al., 2012; Sakles et al., 2013; Wang & Yealy, 2006). An increase in the number of attempts made is associated with the likelihood of an adverse event (Hasegawa et al., 2012; Martin, Mhyre, Shanks, Tremper, & Kheterpal, 2011; Mort, 2004). During the intubation procedure, failure to intubate is the primary cause of death from an anoxic event in 85% of the cases (Niforopoulou et al., 2010). Failure to intubate occurs when the primary method used to secure an airway is not successful, and a secondary method must be utilized (Bair et al., 2002).

**Direct Laryngoscopy (DL).** Direct laryngoscopy (DL) was patented in the 1940’s. This invention was designed to give the intubator a direct view of the glottic opening by aligning the oral, pharyngeal, and laryngeal axes to visualize insertion of the endotracheal tube (ETT) (Jephcott, 1984). Visualization of the glottic opening by DL requires line of sight by alignment of anatomic axes that naturally exist at extreme angles (Mosier et al., 2013) This obscured view of the vocal cords can create a difficult or failed airway situation. In some patients, it has been noted that certain patient characteristics are
associated with preventing the alignment of the axes, making it more difficult or impossible for a successful intubation (Mosier et al., 2013; Mosier et al., 2012).

**Video Laryngoscope (VL).** An innovation called the video laryngoscope (VL) was introduced in 2001 as a means for intubating patients with known or predicted difficult airways (Chemsian, Bhananker, & Ramaiah, 2014). The VL uses a micro sized video camera at the end of the laryngoscopic blade (Sakles, Rodgers, & Keim, 2008) that eliminates the need to align the oral, pharyngeal, and laryngeal axes (Chemsian et al., 2014). VL showed promise in reducing the number of failed airway attempts (Cooper et al., 2005; Xue et al., 2007). The VL has demonstrated advantages over direct laryngoscopy DL. The advantages include: 1) better visualization of the glottic opening (Brown III, Bair, Pallin, Laurin, & Walls, 2010; Mosier et al., 2012); 2) decreased need to manipulate the cervical spine when inserting the device, thereby reducing the risk of further damage to a cervical spine injury (Malik et al., 2008); 3) less lift required to open and manipulate the jaw reducing the potential for airway trauma (Cooper et al., 2005); and 4) demonstrated increased first attempt success over traditional direct visualization of endotracheal intubation (Cooper et al., 2005; Sakles et al., 2014; Sakles et al., 2013).

When comparing the VL to the DL in the ER, the VL has a higher first attempt success rate than the DL in intubations that were predicted to be difficult (Mosier et al., 2012; Sakles, Mosier, Chiu, Cosentino, & Kalin, 2012; Sakles et al., 2014).

**Setting.** VL has been shown to be successful in the OR, especially in cases of predicted difficult intubation and as a rescue device (Aziz et al., 2011; Noppens et al., 2010). Anesthesiologists are the experts in intubation and perform the procedure routinely (Rothfield & Russo, 2012). The experience of the intubator is a variable that has
been shown to be a predictor in obtaining better laryngoscopic views and success rates (Graham, Oglesby, Beard, & McKeeown, 2004; Kim, Kim, Choi, Je, & Kim, 2013; Patanwala, Stahle, Sakles, & Erstad, 2011; Sakles & Kalin, 2012; Shah et al., 2011). An example is demonstrated by the incidence of failed intubation in the ED of 1.5 %, while the OR is 0.1% (Cook & MacDougall-Davis, 2012). In the OR, a difficult intubation occurs in 1-4% of patients who have seemingly normal airways. However, this number increases to at least 10% when an emergent situation is encountered. Patients who are difficult to intubate in the OR are at higher risk for adverse events ranging from 4.1% to 28% (Martin et al., 2011). The frequency in which the device is used may justify the added cost of the VL in the OR.

Patient intubation in the ED presents a challenging situation for providers because of the increased risk of injury to the patient (Cook & MacDougall-Davis, 2012) and litigious nature of the ED compared to the OR. The OR is unlike the ED because of situational stressors, high patient acuity, cervical restriction, noise, workforce, poor oxygen reserves, as well as the necessity to secure an airway in the patient who may or may not have a known difficult airway, make intubation in the ED more challenging. The situation is further compounded by physiologic time constraints posed by a deteriorating patient with the frequent presence of blood and secretions not seen in the OR (Brown III et al., 2010; Shah et al., 2011). Intubation in the ED is a high risk, low-frequency procedure where the ED provider does not have the ability to cancel the case as can be done in the OR (Walls & Murphy, 2008).

Experience does not necessarily predict success. Even anesthesiologists have a difficult time when intubating outside of the controlled environment of the OR. In
reviewing patterns of liability associated with anesthesiologist malpractice claims arising from the management of difficult airways from 1985-1999, 23 of the 179 cases occurred outside of the OR. All of the 23 cases were associated with brain damage (3 cases) or death (20 cases). More than half of the cases were settled for an average of $305,000 (range $49,050-$2,010,000 in 1999 U.S. dollars) (Peterson et al., 2005).

Practice guidelines for difficult airway management for anesthesiologists recommend a VL to be available for the difficult intubation (Apfelbaum et al., 2013). The Office of the Inspector General reported that 11,007 intubations performed outside of the OR in Veterans Affairs (VA) facilities with a 12% difficult intubation rate (Stalhandske, Bishop, & Bagian, 2008). There were four difficult intubations per day, and half of those were esophageal intubations (Stalhandske et al., 2008). As a result of this report and the updated guidelines, all VA facilities are required to have a VL immediately available at all times for intubations outside of the OR (VHA, 2012).

Until recently, due to the impracticalities of obtaining informed consent from the trial participant, an RCT comparing the VL to the DL was not practical in the ED setting. However, a group of researchers was successful in obtaining approval from the institutional review board (IRB) using a delayed consent process and performed the only RCT to date comparing the VL to the DL in trauma patients. This protocol allowed for consent to be obtained from the patient (or legal representative) after being intubated based on the emergently time-sensitive nature as well as the inability of the patient to provide consent due to the injury or illness related to a state of cognitive impairment. The authors concluded that there was no statistical difference in the first-pass success rates between the two devices or influence on mortality between the two groups (Yeatts et al.,
2013). It is important to note that this study only evaluated trauma patients even though twice as many intubations are performed for medical emergencies compared to traumatic injuries (Walls et al. 2011). Furthermore, 25% of the data had to be discarded because some of the attending physicians did not follow the established protocol (Yeatts et al., 2013).

To date, a cost effectiveness analysis comparing the VL to the DL in the ED has not been published. The contribution of the proposed research study will provide decision makers new information to assist in the decision-making process regarding this new technology.

The importance of proposed research to health and nursing. The results of this study may assist the potential adopter in another prospective by looking at justifying the added cost of the new technology. The results of this study will demonstrate another method of evaluating new technology using the existing data without having to perform a time and cost intensive RCT.

**Innovation**

Although advances in technology can result in considerable improvements in patient outcomes, use of new technology may create new problems. Given that some devices are safer and effective than others, it is important to assess the appropriateness and efficacy of each device in every situation where it is planned to be used (McKay et al., 2009). The cost has become a critical factor in adopting any new technology that may benefit patient outcomes. While previous research has examined the effectiveness of the video laryngoscope in the OR and ED, this study is the first to address the cost effectiveness (CEA) of implementing this new technology in the ED. A CEA may assist
in providing evidence that new spending is justified by studies of cost and effectiveness for new technologies being equal to the gain in patient benefits (Chandra, Jena, & Skinner, 2011). Furthermore, this study will explore the use of a contextual method with a clear clinical application for evaluating new technology. The clinical application is a real-world scenario clinicians face when intubating patients emergently in the context of the ED. By using existing data, this study provides an alternative evaluation of new technology without the intensive investment of time and cost associated with the more traditional RCT. The results of this study may assist ED administrators by determining if the added cost of this new technology would be offset by cost reduction associated with improved patient outcomes.

**Approach**

**Research Design.**

This study will be a secondary data analysis using retrospective observational data from a major metropolitan ED using a comparative effectiveness and cost effectiveness analysis approach (Table 1).

Comparative Effectiveness Research (CER). CER is culminating and synthesizing substantiation that compares the benefits and harms of new methods or treatments designed to improve care (Sox & Greenfield, 2009). The purpose of CER is to facilitate informed decision making on behalf of consumers, clinicians, and policy makers that will improve health care at the individual and population level. Three elements are key to CER: direct comparison of effective interventions; studying everyday patients in a “real world” clinical setting; and identification of clinical characteristics of those patients most likely to benefit (Sox & Greenfield, 2009). This study will address the three key elements
by (a) directly comparing the two devices based on the first pass success rate; (b) studying everyday patients in “real world” clinical setting by using an existing database that includes all those patients with a limited exclusion criteria (Adults and intubations done by ED providers); (c) Identify clinical characteristics (DACs) for patients most likely to benefit.

Cost effectiveness analysis (CEA). The CEA identifies measures and compares the cost of the health output (effects) achieved by one device with at least one alternative. Effectiveness is measured regarding physical units of inputs, clinical indicators, and health outcomes. In this study, effectiveness is measured by the first pass attempt success rate. The results are calculated and presented in a ratio of incremental costs to incremental effect. The aim of a CEA is to address the relative (incremental) cost per unit (ICER) of effect (outcome) between two or more technologies that have a common effect (Drummond et al., 2005). An effective health care intervention is supported by evidence that it addresses the question of whether the technology works in the clinical practice setting instead of in theory or principle (Luce et al., 2010). The indication of effectiveness will be obtained from an existing database for this study.

Study Population.

The data used in this study comes from a population of critically ill and injured patients who have received immediate airway protection in the ED over a period of 32 months in a major metropolitan public hospital. Data from a population intubated in the ED was chosen because when intubating in the ED, AEs tend to occur more frequently compared to the OR (Cook & MacDougall-Davis, 2012). Because this population has a higher baseline risk, it will be more cost-effective to treat with an intervention that
establishes a proportional risk reduction than a subgroup with a lower risk when other factors being equal (Drummond et al., 2005). Eligible study participants include patients who were orotracheally intubated in the ED using the VL or the DL and are 18 years old and older. Nasotracheal and surgical methods of intubation, such as cricothyrotomy, needle, and tracheostomy will not be included.

The Baylor/Ben Taub ED, an academic, level I trauma center, there are approximately 110,000 patients treated annually with an average of 2-3 patients intubated daily. In 2012, the VL to DL ratio was approximately 1:3. An increase in the usage of VL has been observed over the last two years, bringing the VL to DL ratio closer to 1:1. There are an estimated 2,000-3,000 intubations that occurred during 2012-2014.

Statistical power and sample size needed. Based on previous studies that report a higher VL first pass success rate when compared to DL (75%-68%) (Mosier et al. 2012; Sackles et al. 2012), an estimate of a 7% difference between VL and DL groups will be considered clinically significant. A sample size of 385 patients per group will be necessary to achieve a statistical power of 0.80 and a significance level of 0.05. All of the subjects meeting the inclusion and exclusion criteria would be included to ensure adequate statistical power.

Data Sources

Data will be abstracted from the Baylor/Ben Taub electronic medical record, Epic Care, by Dr. Michael Gonzales and Sean DeGarmo in Excel format to an encrypted portable hard drive. Encrypted data will be de-identified and securely housed in a locked room and in a locked drawer. Access will only be granted to Sean DeGarmo and Dr. Michael Gonzales.
Data Extraction

Prior to the examination and analysis of data, IRB approval will be obtained from UT CPHS and Baylor College of Medicine’s IRB.

The databank will be searched for all patients who have been intubated using the video laryngoscope, direct laryngoscope, and the presence of DACs prior to intubation from January 2012 to August 2015. Data will be abstracted based upon a priori inclusion and exclusion criteria. DACs for subjects who meet inclusion and exclusion criteria will be included. Other variables will be collected from the databank including: patient characteristics; intubator characteristics; adverse events; and effect variables (see Table 2 for detailed explanation).

Cost data for each device will be provided by Baylor/Ben Taub (hospital/ED administration). Dr. Gonzales has requested that cost data be provided for this study from hospital administration. The cost variables are displayed in Table 2. Invoices for those costs will be provided to Dr. Gonzales from the institution.

The most meaningful measure of cost associated with multiple attempts is the increased cost associated with a greater probability of an AE to occur. Avoiding adverse events is to be calculated as cost savings. The cost associated with AEs is not expected to be provided by the institution. Therefore, the Closed Claims Study Database will provide the cost associated with AEs. The AEs are listed in Table 3 and are also reported in studies commonly associated with emergency intubation (Brown, et al, 2015; Sakles, et al, 2013). If cost data for AEs is not granted or is not found in the database, then cost data obtained from a literature review will be used. If any cost data is missing, then a literature
review will be conducted to provide a cost range. For those cost data that are not located in the literature search, an estimate will be made and noted.

Certain costs will be excluded from this study. Reimbursement for the intubation procedure will be excluded because reimbursement is at the same rate regardless of the device used. Opportunity cost will be excluded because of the difficult nature to calculate from the retrospective data.

Due to the nature of the data collection, the analysis does not precisely account for the total amount of time taken to intubate the patient. Time required by the provider to perform intubation should be the same because the time to intubate with either device may deviate only by a few seconds.

**Data Analysis**

Data will be assessed for completeness. Subjects with data missing values will be identified and excluded from analysis with STATA. Patterns of missing values will be assessed to identify potential bias that may be introduced when deleting subjects. If bias is found, that variable will not be included in matching.

**Overall Analysis Plan**

AIM 1: Determine the comparative effectiveness between matched patients from the Baylor/Ben Taub ED database using VL compared to those using DL in terms of the first pass success rate as the measurement of “effect.”

Comparative effectiveness will be calculated using a first pass success rate as measurement of clinical effectiveness. Clinical effectiveness will be determined by looking at the mean difference in first pass rates between the two technologies (VL or DL) while controlling for DACs and other confounding factors. Since this data will be
extracted from a clinical database rather than from a rigorously designed research study, patients were not randomized into VL or DL groups. In order to reduce selection bias, a propensity score analysis will be used.

A propensity score analysis is a statistical method developed for estimating treatment effect using a single score that represents the probability of receiving a treatment conditional on a set of patient characteristics (covariates) in observational or quasi-experimental studies (Garrido, et al., 2014; Guo & Fraser, 2015). Propensity scoring will be used to match subjects who are intubated using DL with a subject who has a similar profile in the VL group. A single composite score is generated by propensity scoring and reflects the conditional probability of being intubated with the VL based upon external characteristics (covariates) that are used for matching. Propensity scores for this study represent the likelihood that VL would be used for the intubation and range from 0-1 where 1 equals a subject will be intubated with VL and 0 equals a subject will not be intubated using the VL.

To generate propensity scores in this study, all potential covariates will be entered into a logistic regression model without regard to the outcome of being intubated with VL (Garrido, et al., 2014).

The propensity scores will be checked for balance between the VL and DL groups and will be evaluated for common support. Common support is the extent that the distribution of propensity scores of VL and DL groups overlap. Balance will be evaluated by examining the distribution across VL and DL groups and testing whether the mean propensity score is equal between both groups. Since the propensity score is based upon covariates, each observed covariate will then be assessed for balance within quintiles (or
smaller blocks) (Garrido, et al., 2014). Once balance has been achieved, a single VL subject will be matched to a single DL subject with the most similar estimated propensity score using 1:1 nearest neighbor method. Stata programs (teffects, psmatch, and tebalance) will be used to check for balance of the characteristics between the matched samples, a p-value of >0.05 will be used as the threshold for assessing balance. These programs produce box plots that show the degree of balance. For example, in the proposed database there may be 3000 subjects in the pool; 1000 who have been treated with VL and 2000 with DL. After matching the subjects, the database is left with 1000 subjects in each group. VL (n=500) and DL (n=500). After checking for equivalence, an estimation of the treatment effect will be established by comparing the first pass success rate between the cohorts. Based on the data from these groups, costs will be identified for VL and DL and placed in the ICER formula.

Specifically, a propensity score estimate will be determined using STATA software (College Station, TX) for each subject based on the independent variable (DL or VL) from the pretreatment patient characteristics (Table 2). The pretreatment characteristics include: age, gender, trauma status, number and type of DACs, GCS, medications used and if an attempt was made prior to arrival by EMS (Table 2). The matched patients will be divided into five equal sized groups (strata) according to their estimated propensity score. Matching will be performed without replacement in order to prevent adding additional bias or variance (Rosenbaum, 2010). A power analysis with a priori criteria (alpha = 0.05, beta = 0.8) will be used to determine if the sample size meets the minimum requirement for those levels. If the sample size is less than the required
sample size to achieve these minimums, caliper matching without replacement will be used.

AIM 2: Estimate the incremental cost effectiveness ratio (ICER) using the first pass rate as the “effect” measurement while controlling for the number and type of DACs comparing the VL to the DL in the ED from the perspective of the ED administration in matched patients.

The data analysis for AIM 2 will use the treatment effect calculated from AIM 1 in the calculation for the ICER\textsubscript{mean} using the sum of the cost variables between the two devices. The ICER is formulated as:

\[ \text{ICER}_{\text{mean}} = \frac{(\text{Cost VL}_{\text{mean}} - \text{Cost DL}_{\text{mean}})}{(\text{Effect of VL}_{\text{mean}} - \text{Effect DL}_{\text{mean}})} \]

and will be calculated by TreeAge software.

A decision tree cohort model will be used to provide a visual representation of the scenarios and potential outcomes a subject will encounter when being intubated by either the video laryngoscope or the direct laryngoscope (Appendix C). Each scenario is depicted by a pathway from the possible outcomes the subject could encounter. For example, one pathway would be if the subject was successfully intubated on the first attempt using the VL and no adverse event occurred. Following the structure of the model, TreeAge software will be used to determine the cost and effects of the two competing technologies (VL or DL). Cost for each pathway will be input into the model of each particular scenario as applicable from Table 2. The cost payoffs specified for each outcome will be calculated by combining the appropriate costs for each particular scenario. The probabilities of each intubation attempt will be calculated based on the
percentage of successful or failed attempts obtained from the databank. The probabilities of adverse events will be estimated using published data.

A probabilistic sensitivity analysis will be performed using TreeAge software to simulate the analysis using assumed distributions sampled from the databank for the cost and effect parameters. A probabilistic sensitivity analysis is used to quantify parameter uncertainty by using a distribution instead of a single value (Briggs, Sculpher & Claxton, 2006). A Monte Carlo simulation will be used to resample parameter values using 10,000 iterations. The results will be presented using a cost effectiveness scatter plane, where each iteration is plotted graphically showing the incremental cost and incremental effectiveness of the intervention evaluated to determine overall confidence in the conclusions.

**Study Limitations**

There are several limitations to this study. The data used for this study lacked randomization where there would ideally be an equal likelihood that the patient could have been intubated using the VL.

Propensity score matching will be used in order to reduce selection bias. However, the propensity scoring method is limited in terms of the ability to eliminate selection bias because it does not correct for unobservable and unmeasured confounding variables that affect whether one subject was intubated with the VL or the DL.

Eliminating subjects with missing data could introduce measurement bias. Alternatives to this approach include assessing the data that is missing and add it as a covariate or performing multiple imputation to handle the missing data (Guo & Fraser, 2015).
Self-reporting bias will be inherently introduced because the data is collected from patients’ charts where the provider who performed the intubation is self-reporting. Ideally, a researcher would record the data in order to prevent this potential source of measurement bias.

Generalizability will be limited to the facility where the study is performed. Cost and effect are limited to the sample obtained from the database at the study site. Costs omitted from this study include reimbursement and hospitalization. Reimbursement will be excluded because the facility will be reimbursed at the same rate regardless of the device used. Hospitalization cost will also be excluded because there are too many confounders that may be introduced that are not relevant to the treatment effect.

Data regarding the cost of AEs will be included. However, there are some anticipated difficulties that can be attributed to this data reporting. These difficulties include the inability to define the time when an AE occurred either ideopathically or as a result of the intubation. Another difficulty anticipated is that AEs are often not noted in the ED record because they may not be identified immediately. The final anticipated difficulty is in determining a cost associated with each AE. The only AE reported cost data has been performed for anesthesia, not emergency medicine. Further investigation of the cost associated with adverse events is required.

Ideally, an estimate of the cost associated with a second attempt should be identified in order to account for the potential for VL to save costs by avoiding second attempts and the potential problems associated with those attempts. A limitation of dealing with retrospective data is that you can only use the data that was collected and in
the manner in which it was collected. The time taken for each intubation attempt would be a great asset to be able to associate a cost with each additional attempt. However, the most meaningful measure of cost associated with multiple attempts is the potential increased cost associated with a greater probability for an adverse event to occur. Future studies should track time for each attempt more precisely.
Literature Cited


Sakles, J., Patanwala, A., Mosier, J., & Dicken, J. (2014). Comparison of video laryngoscopy to direct laryngoscopy for intubation of patients with difficult airway characteristics in the emergency department. *Internal and Emergency Medicine, 9*(1), 93.

Sakles, J., Rodgers, R., & Keim, S. (2008). Optical and video laryngoscopes for emergency airway management. *Internal and Emergency Medicine, 3*(2), 139-143.


StataCorp. 2015. *Stata Statistical Software: Release 14*. College Station, TX: StataCorp LP.


PROPOSAL APPENDIXES
Appendix A-1

Cormack and Lehane Grading System

*Cormack-Lehane Scale*

*Note.* The Cormack and Lehane grading system for the view of the larynx obtained during direct laryngoscopy (Cormack & Lehane, 1984)
Appendix A-2

LEMON Airway Assessment Tool

L Look externally
Look at the patient externally for characteristics that are known to cause difficult laryngoscopy, intubation or ventilation.

E Evaluate the 3:3:2 rule
In order to allow alignment of the pharyngeal, laryngeal, and oral axes and therefore simple intubation, the following relationships should be observed. The distance between the patient’s incisor teeth should be at least 3 finger breadths (3), the distance between the hyoid bone and the chin should be at least 3 finger breadths (3), and the distance between the thyroid notch and the floor of the mouth should be at least 2 finger breadths (2).

1 – Inter-incisor distance in fingers
2 – Hyoid mental distance in fingers
3 – Thyroid to floor of mouth in fingers

M Mallampati
The hypopharynx should be visualized adequately. This has been done traditionally by assessing the Mallampati classification. The patient is sat upright, told to open the mouth fully and protrude the tongue as far as possible. The examiner then looks into the mouth with a light torch to assess the degree of hypopharynx visible. In the case of a supine patient, Mallampati score can be estimated by getting the patient to open the mouth fully and protrude the tongue and a laryngoscopy light can be shone into the hypopharynx from above.

Class I: soft palate, uvula, fauces, pillars visible
Class II: soft palate, uvula, fauces visible
Class III: soft palate, base of uvula visible
Class IV: hard palate only visible

O Obstruction?
Any condition that can cause obstruction of the airway will make laryngoscopy and ventilation difficult. Such conditions are epiglottis, peritonsillar abscesses, and trauma.

N Neck mobility
This is a vital requirement for successful intubation. It can be assessed easily by getting the patient to place his or her chin down onto the chest and then to extend the neck so the patient is looking towards the ceiling. Patients in hard collar neck immobilization obviously have no neck movement and are therefore harder to intubate.

*Note.* (Reed, et al., 2005)
### Appendix B

#### Steps in Conducting Propensity Score Matching

| Step 1. Choose variables to include in the propensity score | • List potential confounders  
• Evaluate the feasibility of including the confounders  
• Calculate the propensity score with logit or probit regression |
|---|---|
| Step 2. Ensure that propensity score is balanced across treatment and comparison groups | • Check range of common support  
  ○ Extent to which distributions of propensity scores in treatment and comparison groups overlap (Stata, pscore)  
• Check balance of propensity score  
  ○ Does the propensity score have similar distribution across treatment and comparison group?  
  ○ Estimate distribution by splitting sample by quintiles or other strata propensity score  
  ○ Test whether mean of propensity score is equal in treatment and comparison groups within each quintile  
  ○ If not equal, split one or more quintiles into smaller blocks and compare means |
| Step 3. Ensure that covariates are balanced across treatment and comparison groups within blocks of the propensity score | • Ideally, for each unique value of the propensity score, the distribution of X (composite of all covariates) is the same for the treatment and comparison groups  
• Due to practicality, the balance of each observed covariate is examined within blocks of the propensity score (Stata, t-test)  
  ○ Improve the balance of the propensity score by focusing on the balance of covariates that are more theoretically relevant (Stata, error message if not balanced)  
    ▪ Consider interactions/correlations between covariates  
    ▪ If not balanced, drop 1-2 covariates that are less important and repeat Step 2  
    ▪ Re-categorize variables  
    ▪ Include higher order terms  
    ▪ If balanced, continue to Step 4 |

*Note. Starks & Garrido (2014)*
(continued from previous page)

| Step 4. Choose a matching or weighting strategy | • Quality and quantity on continuum  
• No universal best strategy  
  o Nearest neighbor  
  o Radius matching  
  o Kernal weighting  
  o Stratified matching  
• Inverse probability of treatment weighting  
• Without measuring outcome, evaluate covariate balance in several strategies  
• Choose the method that has the best balance and still meets the analytic goal |
|---|---|
| Step 5. Ensure that covariates are balanced across treatment and comparison groups in sample matched or weighted by propensity score | • Perform multiple checks  
  o Standardized differences  
    ▪ Percentage of bias calculated in matched  
  o Graphs  
    ▪ Summary of covariate imbalance that is reported as a summary of mean and median bias pre-and post-matching (Stata, output from `ps`test)  
    ▪ Quantile-quantile plots  
    ▪ Plots of covariates in treated and comparison groups  
• Ratios of variance  
• Histogram  
  o Visualized inspection of standardized difference |
| Steps 1-5 can be repeated several times as necessary |
| Step 6. Proceed with analysis based on sample matched or weighted by propensity score | • Delete observations from individuals not within the range of common support  
• Choose the treatment effect of interest  
• Calculate correct standard error for propensity score matched or weighted sample  
• Guard against misspecification of the propensity score |
Table 1

*Seven Steps Involved in Conducting a Cost Effectiveness Analysis (CEA)*

<table>
<thead>
<tr>
<th>Steps of CE Analysis</th>
<th>Activity</th>
<th>Application in Study</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. State the problem</td>
<td>Describe the situation and rationale</td>
<td>Need to compare VL with DL in ED without conducting an RCT</td>
</tr>
<tr>
<td>2. Create a conceptual model</td>
<td>Describe the technology and effects on healthcare</td>
<td>Pathway patient will encounter when being intubated using VL or DL using descriptions of the intubation from database</td>
</tr>
<tr>
<td>3. Define the perspective</td>
<td>Define how health outcomes and costs are valued</td>
<td></td>
</tr>
<tr>
<td>4. Identify costs and gather data to value costs</td>
<td>Identify, measure, and value cost</td>
<td>Perspective is ED Administration</td>
</tr>
<tr>
<td>5. Identify and gather data to validate outcomes</td>
<td>Determine an outcome measurement common to each technology</td>
<td>Cost of equipment, training, maintenance, and adverse events</td>
</tr>
<tr>
<td>6. Estimate cost effectiveness</td>
<td>Calculate to incremental cost effectiveness ratio (ICER)</td>
<td>Outcome is measured as successful first attempt or failure as reported in the database</td>
</tr>
<tr>
<td>7. Perform sensitivity analysis</td>
<td>Determine plausible range that may contain the ICER and how the parameter estimates vary and affect the CEA</td>
<td>ICER = (Cost VL - Cost DL) / (Effect of VL - Effect DL)</td>
</tr>
</tbody>
</table>

*Note. Petitti (2000)*
Table 2
**Categories, Variables, Definitions, and Measurement**

<table>
<thead>
<tr>
<th>Category</th>
<th>Variable</th>
<th>Description/Definition</th>
<th>Measurement</th>
<th>Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>Independent</td>
<td>Device Used</td>
<td>Video laryngoscope (VL) or Direct laryngoscope (DL) used for first intubation attempt</td>
<td>VL or DL</td>
<td>Provider report from chart review</td>
</tr>
<tr>
<td>Variable</td>
<td>First intubation attempt</td>
<td>Introduction of the device blade (VL or DL) into the patient’s mouth regardless of whether an endotracheal tube was inserted or not.</td>
<td>Number of attempts</td>
<td>Provider report from chart review</td>
</tr>
<tr>
<td>Dependent</td>
<td>First attempt success</td>
<td>Correct placement of an endotracheal tube into the trachea on the first attempt.</td>
<td>Yes or No</td>
<td>Provider report from chart review</td>
</tr>
<tr>
<td>Variables</td>
<td>First attempt failure</td>
<td>Intubation requiring more than one attempt, changing intubator during a single attempt or changing devices during an attempt will be considered a failure</td>
<td>Yes or No</td>
<td>Provider report from chart review</td>
</tr>
<tr>
<td></td>
<td>Cost of Device (VL)</td>
<td>The initial cost of purchasing the VL</td>
<td>US $</td>
<td>Financial report from facility in US $</td>
</tr>
<tr>
<td></td>
<td>Cost of Device (DL)</td>
<td>The initial cost of purchasing the DL</td>
<td>US $</td>
<td>Financial report from facility in US $</td>
</tr>
<tr>
<td></td>
<td>Cost of training (VL)</td>
<td>The cost of training the ED providers on the VL initially (first year)</td>
<td>US $</td>
<td>Financial report from facility in US $</td>
</tr>
<tr>
<td></td>
<td>Cost of training (DL)</td>
<td>The cost of training the ED providers on the DL initially (first year)</td>
<td>US $</td>
<td>Financial report from facility in US $</td>
</tr>
<tr>
<td></td>
<td>Cost of maintenance/repair (VL)</td>
<td>The cost of maintaining and repairing VL</td>
<td>US $</td>
<td>Financial report from facility in US $</td>
</tr>
<tr>
<td></td>
<td>Cost of maintenance/repair (DL)</td>
<td>The cost of maintaining and repairing VL</td>
<td>US $</td>
<td>Financial report from facility in US $</td>
</tr>
</tbody>
</table>
### Table 2 (continued)

**Categories, Variables, Definitions, and Measurement**

<table>
<thead>
<tr>
<th>Category</th>
<th>Variable</th>
<th>Description/Definition</th>
<th>Measurement</th>
<th>Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>DACs</td>
<td>Obesity/Weight</td>
<td></td>
<td>Kilograms</td>
<td>Provider report from chart review</td>
</tr>
<tr>
<td></td>
<td>Large tongue</td>
<td></td>
<td>Yes or No</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Mallampati</td>
<td></td>
<td>(Class I, II, III, IV) (Appendix A-2)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Short neck</td>
<td></td>
<td>Yes or No</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Small mandible</td>
<td></td>
<td>Yes or No</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Cervical immobility</td>
<td></td>
<td>Yes or No</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Cervical collar in place</td>
<td></td>
<td>Yes or No</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Presence of blood or emesis in airway</td>
<td></td>
<td>Yes or No</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Facial trauma</td>
<td></td>
<td>Yes or No</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Cormack and Lehane</td>
<td></td>
<td>Grades I, II, III, IV (Appendix A-1)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>LEMON</td>
<td></td>
<td>Performed visually by intubator (Appendix A)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Chart abstraction</td>
</tr>
<tr>
<td>Age</td>
<td>Age in years</td>
<td></td>
<td>Chart abstraction</td>
<td>Chart abstraction</td>
</tr>
<tr>
<td>Confounding Variables</td>
<td>Gender</td>
<td>Male or Female</td>
<td>Chart abstraction</td>
<td>Chart abstraction</td>
</tr>
<tr>
<td></td>
<td>Patient Type</td>
<td>Trauma or medical patient</td>
<td>Chart abstraction</td>
<td>Chart abstraction</td>
</tr>
<tr>
<td></td>
<td>GCS</td>
<td>Summation of scores for eye, verbal, and motor response</td>
<td>Chart abstraction</td>
<td>Chart abstraction</td>
</tr>
<tr>
<td></td>
<td>Intubation attempt before arrival to</td>
<td>Intubation attempted before attempt made in ED</td>
<td>Yes or No</td>
<td>Chart abstraction</td>
</tr>
<tr>
<td></td>
<td>ED by EMS</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Indication for Intubation</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>1. Trauma</td>
<td></td>
<td>Chart abstraction</td>
<td>Chart abstraction</td>
</tr>
<tr>
<td></td>
<td>2. Arrest</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>3. Failed to oxygenate</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>4. Failed to ventilate</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Category</td>
<td>Variable</td>
<td>Description/Definition</td>
<td>Measurement</td>
<td>Source</td>
</tr>
<tr>
<td>----------</td>
<td>----------</td>
<td>------------------------</td>
<td>-------------</td>
<td>-------------------------</td>
</tr>
</tbody>
</table>
|          | 1. Medications used to perform intubation | 1. Paralytic and sedation  
2. Sedation only  
3. None | Paralytics: Succinylcholine, Vecuronium, Rocuronium  
Sedation: Etomidate, Versed, Ketamine | Chart abstraction |
| Intubator related factor | 2. Provider experience | 1. Year in residency training (Program year [PGY])  
2. Attending (MD or DO)  
3. Nurse Practitioner (NP) or Physician Assistant (PA)  
4. Medical Student  
Resident from service other than ED | 1. PGY 1-4  
2. Attending Physician  
3. NP or PA  
4. Medical Student  
5. Off-service Resident | Chart abstraction |

*Note:* DACs, PGY, NP, PA, GCS, EMS, VL, DL
Table 3

**Most Common Reported Adverse Events Associated with Emergency Intubation**

<table>
<thead>
<tr>
<th>Variable</th>
<th>Description/Definition</th>
<th>Measurement</th>
<th>Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oxygen Desaturation</td>
<td>SPO2 &lt; 80% during intubation attempt(s)</td>
<td>Yes or No</td>
<td>Chart abstraction</td>
</tr>
<tr>
<td>Aspiration</td>
<td>Presence of vomit at the glottic inlet visualized during intubation in a previously clear airway</td>
<td>Yes or No</td>
<td>Chart abstraction</td>
</tr>
<tr>
<td>Failed Intubation</td>
<td>More than two attempts without successful placement of the ET tube in the trachea</td>
<td>&gt; 2 attempts</td>
<td>Chart abstraction</td>
</tr>
<tr>
<td>Cardiac Arrest</td>
<td>Asystole, bradycardia, or dysrhythmia w/non-measurable BP &amp; CPR during or after intubation (5 min)</td>
<td>Yes or No</td>
<td>Chart Abstraction</td>
</tr>
<tr>
<td>Pneumothorax</td>
<td>Identified on a post intubation chest radiograph in the absence of chest trauma to the affected side</td>
<td>Yes or No</td>
<td>Chart Abstraction</td>
</tr>
<tr>
<td>Dental trauma</td>
<td>Injury to teeth (Fracture or avulsion)</td>
<td>Yes or No</td>
<td>Chart Abstraction</td>
</tr>
<tr>
<td>Bleeding</td>
<td>Blood in mouth or airway</td>
<td>Yes or No</td>
<td>Chart Abstraction</td>
</tr>
<tr>
<td>Hypotension</td>
<td>Decrease in systolic blood pressure to &lt;90 mmHg, unexplained by underlying pathophysiology</td>
<td>Yes or No</td>
<td>Chart Abstraction</td>
</tr>
<tr>
<td>Esophageal Intubation</td>
<td>ET tube placed in esophagus</td>
<td>Yes or No</td>
<td>Chart Abstraction</td>
</tr>
</tbody>
</table>

*Note.* (Brown et al., 2015; Sakles et al., 2013).
Appendix C

Decision Tree Cohort Model

*Note.* Decision tree cohort model illustrating the potential pathways the subject could encounter when being intubated by the video laryngoscope or direct laryngoscope.
Cover Letter to Editor for Manuscript Submission

July 17, 2017

K. Sue Hoyt, PhD, RN, FNP-BC, ENP-C, CEN, FAEN, FAANP, FAAN
Emergency Nurse Practitioner
St. Mary Medical Center
1050 Linden Ave
Long Beach, CA 90813

Dear Dr. Hoyt,

I am writing you regarding the submission of our manuscript to *Advanced Journal of Emergency Nursing*. The manuscript is entitled, “Comparing the Effectiveness of the Video Laryngoscope with the Direct Laryngoscope in the Emergency Department: A Meta-Analysis of the Published Literature.” This manuscript examines the first pass success rate of video laryngoscopy compared with direct laryngoscopy in adult patients intubated in the emergency department.

Given that there is major debate regarding whether VL should replace the DL as the standard intubation practice, we believe that the findings presented in our paper will appeal to the Advanced Practice Providers who subscribe to AJEN. Our findings will allow your readers to determine the current state of evidence available when comparing these devices in the emergency department.

This manuscript has not been previously published nor has it been submitted to other journals.

Thank you kindly for your consideration.

Sincerely,

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Comparing the Effectiveness of the Video Laryngoscope with the Direct Laryngoscope in the Emergency Department: A Meta-Analysis of the Published Literature
Manuscript Abstract

Purpose: Rapid intubation is essential for the critically ill patient in the emergency department to ensure adequate oxygenation. Regardless of presenting illness or injury, the first pass success rate (FPSR) can impact patient morbidity and mortality. The study aim was to evaluate the FPSR of direct laryngoscopy (DL) compared with video laryngoscopy (VL) in adult patients intubated in the emergency department.

Methods: Ovid Medline, Cochrane Library database, Embase, and Google Scholar were searched for peer-reviewed articles on studies of human subjects reporting a comparison of FPSR between VL and DL in adult patients who were orotracheally intubated in the emergency department. A meta-analysis was carried out using odds ratio (OR) as the summary effect measure for FPSR. A pooled effect size with the 95% Confidence Interval (CI) was calculated using a random effect model with inverse weighted method.

Results: 8,428 intubations (5,840 DL and 2,588 VL) from nine studies (five observational and four randomized controlled trials) were included in the sample. The pooled OR for FPSR across all studies was 1.89 [95% CI = 1.17, 3.07; p < 0.01], favoring VL when compared with DL. The results were limited by potential bias (selection and performance) and high levels of heterogeneity [I² = 88%; 95% CI: 79%, 93%; Q = 64.61; p < 0.01].

Conclusions: Threats to validity made it difficult to conclude with certainty that one device is better than the other for achieving a successful intubation on the first attempt in the emergency department.

Keywords: emergency, intubation, video laryngoscopy, meta-analysis
Background

Establishing and maintaining a patent airway in a critical care situation is paramount to patient survival. Proactive airway assessment and protection are especially important in a critical care area such as an emergency department (ED). Emergency intubation is associated with a high rate of complications, including intubation failure, multiple attempts, prolonged periods without ventilation and esophageal intubation. Errors occur more frequently with providers who infrequently perform intubation (Nable, Lawner, & Stephens, 2012; Wang & Yealy, 2006; Wayne & McDonnell, 2010). Failure to secure an airway has been associated with an increase in morbidity and mortality in operative and emergency settings (Malik, Maharaj, Harte, & Laffey, 2008; Niforopoulou, Pantazopoulos, Demesthi, Koudouna, & Xanthos, 2010). Difficulty in laryngeal visualization is one of the leading causes of intubation failure (Malik et al., 2008; Niforopoulou et al., 2010). The first intubation attempt is critical as multiple attempts increase the likelihood of adverse events (AEs): airway trauma, aspiration, dysrhythmias, hypoxemia, anoxia, brain injury or death (Jaeger, Ruschulte, Osthaus, Scheinichen, & Heine, 2000; Nable et al., 2012; Sakles, Chiu, Mosier, Walker, & Stolz, 2013; Wang & Yealy, 2006).

While there have been advances identifying patients who may be difficult to intubate, difficult intubations have been reported to occur in 4% to 26% of all intubations performed in the ED (Sakles, Laurin, Rantapaa, & Panacek, 1998; Wong & Ng, 2008). Difficult airway characteristics have been associated with increased intubation difficulty and can be used to identify patients who are at risk for intubation failure (Sakles, Patanwala, Mosier, & Dicken, 2014). The current standard for intubation technology is
direct laryngoscopy (DL), a technology that has been in use since the 1940’s (Jephcott, 1984). A more recent technology, video laryngoscopy (VL), available since 2001, was designed for patients with known or predicted difficult airway characteristics (Cooper, Pacey, Bishop, & McCluskey, 2005; Xue et al., 2007).

There has been much debate regarding whether VL should replace the DL as the standard intubation practice (Rothfield & Russo, 2012). In the operating room, there is limited substantiation for this change; however, intubating in the ED presents a challenging situation because of the high risk, low-frequency nature of the procedure and the variability of intubation experience among providers when compared with operating room providers who perform this procedure routinely (Cook & MacDougall-Davis, 2012). Unlike the operating room, there are situational stressors present in the ED that may make intubation more challenging, including high patient acuity, cervical restriction, noise, inadequate staffing, poor patient oxygen reserves, as well as the necessity to secure an airway in the patient who may or may not have a known difficult airway. The situation is further compounded by physiologic time constraints posed by a deteriorating patient; much greater risk for vomiting and aspiration because patients have not fasted; and, the frequent presence of blood and secretions not seen in the operating room (Brown, Bair, Pallin, Laurin, & Walls, 2010; Griesdale, Liu, McKinney, & Choi, 2012; Shah et al., 2011).

Systematic reviews and meta-analyses comparing VDL devices have reported an increase in first pass success with the use of VL (De Jong et al., 2014; Griesdale et al., 2012); however, these studies were limited to adults intubated in the operating room or intensive care unit (ICU) and did not examine subjects who were emergently intubated in
the ED. In 2012, Griesdale et al. published a meta-analysis comparing the Glidescope (VL) to the DL using studies with a randomized controlled trial (RCT) and quasi-randomized experimental designs. The authors reported no significant difference in the first-pass success rate (FPSR) when comparing VL with DL. De Jong et al. (2014) published a meta-analysis comparing FPSR achieved using VL, compared with using the DL, in the ICU. The authors reported an odds ratio (OR) favoring the VL in FPSR compared with the DL (OR = 2.07, 95% CI 1.35, 3.16; p < 0.001). The meta-analysis described in this current manuscript focused on adults who require emergent intubation in the ED setting because the ED represents a unique clinical area, with specific challenges related to high patient risk and low-frequency intubation.

**Methods**

**Study Design**

The purpose of this study was to determine the FPSR of VL compared with DL in adult patients intubated in the ED. This study was conducted by performing a systematic review and meta-analysis of the published literature.

**Search Strategy**

The main search was constructed in Ovid Medline on December 15, 2016. Using terms harvested from relevant published literature (see Box 1), the terms were then mapped to subject headings, title, abstract, and keyword searches. This search strategy was then translated into the Cochrane Library, Embase, and Google Scholar databases. The Google Scholar search was limited to the first 100 articles retrieved and sorted by relevancy. Following the recommendations of the librarian, a pre-set limit of the first 100 articles was established because of the algorithm the Google Scholar search engine uses.
is constantly changing and can result in thousands of entries not related to the subject matter. The first 100 articles are typically the best matches and most relevant citations. The CINAHL database was not included in the search because the potential limitations when searching for published literature. No date limits were given as the subject matter is date limiting. A reference list search was performed on February 28, 2017, to locate additional studies; this search resulted in four additional studies to be evaluated for inclusion.

**Selection Criteria**

The researcher and a librarian independently screened abstracts and qualifying articles recorded with Rayyan systematic review software (Ouzzani, Hammady, Fedorowicz, & Elmagarmid, 2016). The Rayyan systematic review tool was used to upload database searches to filter, label, identify duplicate articles. The blinding function in Rayyan was enabled to reduce selection bias. Articles were included if they reported a comparison of FPSR between VL and DL in adult patients (18 years old or older) who were intubated orotracheally in the ED and were described as RCTs or observational studies. Manikin studies, simulations, case reports, reviews, and articles that reported intubations outside of the ED setting (e.g., operating room, ICU, pre-hospital), pilot studies, and studies that contained pediatric patients were excluded.

To avoid duplication, six studies (Cho, Cho, Chung, & Investigators, 2015; Choi et al., 2010; Kim et al., 2012; Mosier, Stolz, Chiu, & Sakles, 2012; Sakles, Mosier, Patanwala, & Dicken, 2014; Sakles, Mosier, Chiu, & Keim, 2012) were excluded that reported using the same registry/database collected during the same date range. Lee et al. (2016) reported data collection during two separate time periods, reported as seasons.
Results from season I were excluded because Choi et al. (2015) reported results from the same data base during the same period. Data reported from season II were included in this review because the period was independent of other studies reporting results from the same registry/database (Lee, Kang, & Choi, 2016).

Two studies (Sakles, Mosier, Chiu, Cosentino, & Kalin, 2012; Sakles, Mosier, Patanwala, Arcaris & Dicken, 2016) were excluded because the C-MAC without the video component was considered DL. Intubators used the C-MAC on the first attempt with the video camera turned off (considered DL) and then turned the video camera on if they were having difficulty intubating (considered VL) during that same attempt. These studies were excluded because the definition of an effort using VL versus DL was unclear when changing from the VL to DL method. The threshold may be lowered for changing from VL to DL due to the ease of switching from one method to the other.

**Quality Assessment**

Cochrane Collaboration tools for randomized controlled trials (RCT) and cohort studies were used to assess selection, performance, detection, attrition, reporting, and other sources of bias (see Tables 3A & 3B). Selection bias was assessed by evaluating the adequacy of random sequence generation and allocation concealment. Performance and detection biases were evaluated by the adequacy of blinding. Attrition bias was evaluated by assessing the number and percentage of participants for whom outcomes were not reported. Reporting bias was evaluated by the adequacy of reported findings. Other sources of bias included such conditions as a population markedly deviant from the majority of the other studies included in the review. The risk of bias tool for observational studies additionally addressed potential confounding variables that may
impact the observed effect, including eligibility criteria, temporal differences in
intervention administration, and intubation outcome(s) reported by the intubator (see
Table 3A).

Data Extraction

Data were independently abstracted by the researcher and an assistant into Excel
spreadsheets. Data abstracted included publication author(s), publication date, purpose of
study, study design, study location, number of EDs included in the study, sample size,
date range of data collection, exclusion criteria, relevant outcomes, outcome definitions
and measurement method(s), VL device type, experience and type of intubator,
proportion of trauma/medical patients included in the population studied, number of
subjects with difficult airway characteristics and method used to assess the
characteristics, adverse events reported, VL and DL training provided to intubators.

Analysis

Included Studies

The initial literature search resulted in 366 citations, and the manual reference list
check found four additional citations (Figure 1). After removing 71 duplicates and 240
articles that did not meet eligibility criteria based on a review of the title and abstract, 58
articles were retrieved; 41 of these were excluded based on eligibility criteria. Nine
articles were included in the meta-analysis: four RCTs and five observational studies
(Figure 1).

Study Characteristics

Population. The mean age (50.52 years) and age range (19.5 and >100 years old)
of subjects were consistent across studies, although subjects included in the Goksu, Kilic,
Yildiz, Unal, & Kartal, (2016) study were younger (VL 35 +/- 15.5 years and DL 39 +/- 19 years). The gender of subjects also was consistent across studies; approximately 51% of subjects were male. All study reports included data from participants who were exposed to trauma. Two studies (Park et al., 2015; Sulser et al., 2016) excluded trauma patients who were immobilized in cervical collars. Park et al. (2015) reported data obtained exclusively from participants intubated during cardiac arrest, regardless of exposure to trauma. While Choi et al. (2015), Sulser et al. (2016), and Yeatts et al. (2009) excluded data from participants intubated during cardiac arrest.

**Intervention.** A total of 8,428 intubations (2,588 VL and 5,840 DL) were included in the analysis of the nine studies. Observational studies accounted for nearly 87% of the total intubation attempts. There were two types of VL devices found in the studies that were utilized which included the GlideScope (GVL) and the C-MAC. The GVL was used in all the observational studies, while the CMAC was utilized in all but one (Yeatts et al., 2013) of the RCTs.

Most studies defined an intubation attempt as the introduction of the laryngoscope into the patient’s mouth, and the attempt was considered completed when the endotracheal tube and laryngoscope were removed. Goksu et al. (2016), Platts-Mills et al. (2009), and Sakles et al., (2017) used a more precise definition, explicitly stating that the introduction of the laryngoscope into the patient's mouth was considered an attempt, regardless of any effort made to insert an endotracheal tube. Park et al., (2015) did not explicitly state their definition of an intubation attempt; however, they defined the time to complete an intubation as "the time from the advancement of the blade into the patient's mouth to the delivery of the first successful ventilation using the bag.” Because the first
part of the Park et al. definition mirrors the explicit definition in an effort by other studies, there is confidence in the assumption that the Park et al. definition of an effort is congruent with other studies included in this analysis.

There were variations in classification of data that reported on training, experience, and identification of a potential or difficult airway. Provider training and expertise were extremely diverse; some providers had no experience at all using the VL while others had extensive experience, including those anesthesiologists with a minimum of seven years of experience. One study (Platts-Mills et al., 2009) noted that for some intubators utilized VL on a real patient for the first time as part of the study protocol. In most of the studies, the number of intubations each provider had experienced was difficult to determine, and there was much variation in experience. Rather than reporting the experience by each provider with a minimum number of intubations they have performed with each device, the experience was reported by the year of medical education status. Even then, there was no consistency in how the studies stratified intubator experience level. It appeared that most intubators had some training in using the VL across studies. However, there was not a standard minimum. Training ranged from two 30-minute orientation sessions provided by the manufacturer (Platts-Mills et al., 2009) to highly skilled staff anesthesiologists with at least seven years of experience (Sulser et al., 2016).

There was no consistency in the measurement or instrument used to identify a difficult airway. The majority of the studies, (except Driver et al., 2016; Park et al., 2015) utilized one or more components of the LEMON pneumonic, according to the assessment method for difficult glottis exposure with laryngoscopy (look externally, evaluate mouth
opening, thyromental distance, hyothyroidal distance, morbid obesity, airway obstruction, and neck mobility]. Driver et al. (2016) did not use a formalized measure but relied on the provider’s judgment to determine if the intubation was difficult or not. There was no report of either a measurement or instrument by Park et al. (2015).

**Setting.** All the studies were conducted in Academic Emergency Departments. Of the nine studies, four were carried out in the United States, three in Korea, one in Turkey and one in Switzerland. The studies performed in Korea reported data from two or more EDs (Choi et al., 2015 reported data from four EDs); the other EDs abstracted data from single sites.

**Adverse events.** There were only three types of adverse events reported: esophageal intubations, aspiration pneumonia, and hypoxemia. Two studies reported esophageal intubations (Goksu et al. 2016; Park et al. 2015). There were no cases of esophageal intubations using the VL (0/75; 0/49). Both studies did report esophageal intubation using the DL (7/75; 6/34). Two studies reported higher incidents of hypoxemia using VL than DL. Driver et al. 2016 reported 26/103 intubations using VL and 26/95 intubations using DL. Yeatts et al., 2013 had 27/54 using VL and 15/63 using DL. Only one study (Driver et al., 2016) reported aspiration pneumonia, and there were fewer cases of reported using VL than DL (VL 7/96; DL 11/90). Sulser et al., reported no adverse events by using either device. Adverse events were not listed in two of the studies (Choi et al., 2015; Lee et al., 2016). There were two studies that reported cricothyrotyomies in both the VL and DL groups. Platts-Mills et al., (2009) reported one of the patients who was assigned to the DL group had a cricothyrotomy performed. In Sakles et al., (2017), there were four patients (4/950) who had cricothyrotyomies performed that the initial
effort was VL, and only one subject had a cricothyrotomy who had an initial attempt was using DL it could not be determined if this was an adverse event from the first effort or if there were multiple attempts made.

**Analysis of the Outcomes**

**First-Pass Success Rate**

These nine studies reported discrete FPSR based on independent samples of patients in the ED who were emergently orotracheally intubated. The FPS of DL ranged from 55.88% to 100%. The FPS for VL was 62.67% to 98.6%. The mean DL FPS was 77.40% and 86.2% for the VL (see Table 2). None of the RCTs reported a significant difference in the FPS between the VL and DL. Two of the observational studies reported a significant difference: VL 419/442 (94.8%); DL 365/479 (76.2%), p <0.001 (Lee et al., 2016); VL 45/49 (91.8%); DL 19/34 (55.9%), p <0.001 (Park et al., 2015).

The pooled Odds Ratio (OR) for first pass success across all studies was 1.89 [95% CI 1.17-3.07, p< 0.01] (see Figure 2), indicating a higher first pass attempt rate for VL than DL (see Table 2). There was significant heterogeneity observed in the meta-analysis, I² = 88% [79%; 93%] with Q = 64.61 and p-value < 0.01.

In the subgroup analysis by study type (Figure 3), the observational studies exhibited a statistically significant effect of VL against DL with Odds Ratio 2.49 [95% CI 1.32-4.71, p< 0.01]. In the subgroup analysis by VL Device Type (see Figure 4), the GlideScope (GVL) OR was 2.08 [95% CI 1.17-3.73, p<0.01], indicating better odds of achieving a successful intubation on the first pass with the GVL compared to the DL. There were no statistically significant results from the subgroup analysis by study.
location (Figure 5), either study conducted in the USA or those not carried out in the USA.

**Computation of Effect Sizes**

A meta-analysis was performed using the Odds Ratio (OR) as the summary measure for FPSR. A pooled effect size with the 95% Confidence Interval (CI) was calculated using the Random Effect Model with the inverse variance weighted method (R Core Team, 2017). A sensitivity analysis was also carried out. A sensitivity analysis is employed to determine how dissimilar values of an independent variable effect a specific dependent variable under a particular set of assumptions. A meta-analysis was performed with a sensitivity analysis to evaluate the robustness of the meta-analysis (Sutton et al., 2000). The leave-one-out method was conducted by removing one study at a time and measuring the pooled estimate (Figure 8). Analyses were conducted with the "meta" package in the R environment (R Core Team, 2017; Schwarzer, 2007).

**Analysis of the Quality of the Studies**

**Threats to Validity**

Heterogeneity is a known threat to the validity of meta-analyses. Heterogeneity among studies was assessed using the chi-square ($X^2$) and quantified with the $I^2$ index to determine whether observed differences were real or by chance (Higgins, Thompson, Deeks, & Altman, 2003). A low p-value (or a large $X^2$ relative to its degree of freedom) provides evidence of heterogeneity of intervention effects (variation in effect estimates beyond chance). The $I^2$ index is interpreted as: 0% to 40%, low heterogeneity; 30% to 60%, moderate heterogeneity; 50% to 90%, substantial heterogeneity and 75% to 100%, considerable heterogeneity (Higgins & Greene, 2011). For the present study, a $I^2$ index >
60% indicated substantial heterogeneity and was assessed using subgroup analysis. Subgroup analyses for study design, location, VL device type, training, cardiac arrest, and trauma were assessed for potential sources of heterogeneity.

Another threat to the validity of the summary effects is publication bias (studies with statistically significant or clinically favorable results are more likely to be published than studies with non-significant or unfavorable results). Other biases subsumed under publication bias are time lag bias (studies with unfavorable findings take longer to be published), language bias (non-English language articles are more likely to be rewritten in English if they report significant results), and selective outcome reporting (where non-significant study outcomes are entirely excluded from publication). Such biases lead to meta-analyses which synthesize an incomplete set of the evidence and produce summary results potentially biased towards favorable treatment effects (Sutton, Abrams, Jones, Sheldon & Song, 2000).

The existence of publication bias was evaluated by funnel plot symmetry. A funnel plot is a scatterplot of treatment effect against a measure of study precision (Light & Pillemer, 1984). The points of the scatterplot will form in the shape of a funnel centrally around the total overall estimated effect that is symmetrical in shape in the absence of reporting bias (Light & Pillemer, 1984).

Egger’s test was used to confirm the presence and magnitude of publication bias (Egger, Smith, Schneider, & Minder, 1997). The impact of missing data was evaluated by the trim-and-fill method (Duval & Tweedie, 2000) that also provides an estimated intervention effect ‘adjusted’ for publication bias (based on the filled studies). Grubbs’ (1969) test was used for outlier detection in determining the distribution of the effect size.
(odds ratio) values. An outlier was determined if the confidence intervals did not overlap. The impact of missing data was assessed by trim-and-fill method (Borenstein et al., 2009).

**Risk of Bias in Included Studies**

Primary sources of bias included method of device selection, data collection methods, and protocol deviations. Most of the reports from observational studies stated that device selection was made by the intubator rather than following protocol. Data collection by intubator self-report was found across both types of study design, increasing the risk of detection bias. Protocol deviation was present in three of the RCT study reports (Driver et al., 2016; Goksu et al., 2016; Yeatts et al., 2013). Yeatts et al. (2013) removed 210 patients from randomization because three attending anesthesiologists did not follow and excluded the data from analysis. In Driver et al., (2016), five subjects assigned to the DL were intubated with VL and 16 patients assigned to VL were intubated using the DL, authors excluded data from those subjects during analysis; however, data from those 16 subjects were included in their report. Goksu et al. (2016) reported three subjects assigned to DL were exposed to VL and six patients assigned to VL were exposed to DL. Authors did not provide a clear report of how the data from these subjects were handled during the analysis. Table 3A lists detailed information about the risk of bias in studies included in this meta-analysis.

**Risk of Publication Bias**

Although several studies are out of the funnel shape, the funnel plot is symmetrical for this meta-analysis, indicating no significant evidence of publication bias (see Figure 6). Further indication demonstrating there was no significant publication bias
was confirmed by the Egger’s test (p = 0.9611) and Begg’s (1994) test (p = 0.6767). Using trim-and-fill method (Figure 7), estimated values of the possible missing data were input. Only one replacement was required on the right side of the funnel plot in the trim-and-fill method. After the replacement, the pooled OR was 1.95 [95% CI 1.21-3.16, p = 0.0061], which did not alter the pooled estimate of the main data OR of 1.89 [95% CI 1.16-3.07, p= 0.0098]. Again, these results indicate there is no significant effect of the missing data for this meta-analysis.

**Outliers**

The test showed that there are two outliers in the studies, Lee et al., 2016 OR: 5.69 [95% CI 3.56-9.10] and Park et al., 2015 OR: 8.88 [95% CI 2.61-30.28]. Both studies are observational studies and have very high Odds Ratios (OR), which may affect the pooled Odds Ratio.

**Subgroup Analysis**

In the subgroup analysis, the results showed that the sources of heterogeneity could be attributable to the Observational Studies and GVL device Type. To see how much heterogeneity is caused by these two studies (Lee et al., 2016 and Park et al., 2015), the studies were removed, and the meta-analysis was performed. With the presence of these studies the heterogeneity was $I^2 = 87.6\% \ [95\% \text{ CI} \ 78.6\% -92.8\%]$, and with the absence of these studies the heterogeneity was $I^2 = 82.1\% \ [95\% \text{ CI} \ 64.3\% -91.1\%]$.

**Robustness of the Meta-Analysis**

From the results of heterogeneity from the subgroup analysis, outliers, sensitivity analysis, and cumulative analysis it is observed that two studies Lee et al., (2016) OR: 5.69 [95% CI 3.56-9.10] and Park et al., (2015) OR: 8.88 [95% CI 2.61-30.28] are
primarily causing an apparent deviation from the results. Both of studies are observational and use the GVL device. These studies produce a slight deviation in the forest plot of sensitivity analysis and cumulative meta-analysis (see Figure 8).

**Discussion**

This review included nine studies comparing the impact of VL with DL on FPSR in adults who required emergent intubation in the Emergency Department. The pooled OR for FPSR across studies was 1.89 [95% CI 1.17, 3.07; p< 0.01] favoring VL when compared with DL; this OR is considered a small summary effect (Chen, Cohen & Chen, 2009) and there was significant heterogeneity associated with it.

The meta-analysis is the statistical procedure for combining data from multiple studies. When the effect size is consistent with one study to the next, meta-analysis can be used to determine this common effect. However, when the effect varies from one study to the next, a meta-analysis may be utilized to identify the reasons for the variation. In this meta-analysis, there was significant variation among the studies.

Subgroup analyses were performed for study design, patient characteristics and intubator-related factors to identify the sources of heterogeneity (Borenstein et al., 2009). There has been debate as to whether observational studies and RCTs should be combined when performing a meta-analysis because of variability in study design and risk of bias. Although there is support for the inclusion of both observational studies and RCTs, it is recommended that they be analyzed separately (Borenstein et al., 2009). A meta-analysis concluded there was no significant difference in effect estimate between observational studies and RCTs, regardless of observational study design and heterogeneity (Anglemyer, Horvath, & Bero, 2014). Therefore, the two study design types were
combined as a likely source of heterogeneity. Subgroup analyses of observational studies and RCTs showed that the RCTs were homogeneous, indicating that the findings among the RCTs were similar and consistent and the observational studies were a source of variance, as shown in Figure 2. All but one of the observational studies reported that the provider had the ability to choose which device to use on which patient. This practice risks introducing selection and performance bias. Even the RCTs, which used “intention to treat” analysis, subject assignment to the intervention was not consistently randomized.

A critical feature of RCTs is that randomization and blinding limit bias by controlling for known and unknown confounders (Borenstein, 2009). Performing RCTs in the ED is a challenge because one cannot blind the intubator, and the intubator knows that patient characteristics (maxillo-facial trauma, cervical spine immobilization (Sulser et al., 2016; Driver et al., 2016), blood or vomitus in the airway, airway edema, small mandible, short neck, large tongue, restricted mouth opening and obesity (Sakles et al., 2017) may make the intubation difficult. Such characteristics may not have been anticipated until immediately before or during the initial intubation attempt, forcing a reassessment of the airway and device choice.

Clinical heterogeneity, variability in participants, interventions, and outcomes (Higgins & Green, 2011), likely influence the true intervention effect from study to study. The two studies (Park et al., 2015; Sulser et al., 2016) with the most extreme ORs (0.33 and 8.88) differed completely in intubator experience and subjects they included or excluded. Park et al. (2015) reported data obtained exclusively from participants intubated during a cardiac arrest while Sulser et al. (2016) excluded data from participants intubated during a cardiac arrest. Subgroup analyses on trauma, full arrest,
intubator experience, and training could not be performed because of the inability to parse them out to observe if they were confounders. Other sources of variance are likely due to the inability to detect a confounder that was controlled in randomized studies, which is the major bias in observational studies compared with RCTs (Valentine & Thompson, 2013). The GlideScope (GVL) device was a source of heterogeneity ($I^2 = 92\%$) (see Figure 4).

Statistical heterogeneity is evidenced by greater variation in effect size between studies than one would expect due to random error (Higgins & Green, 2011). However, subgroup analysis excluding the two studies with outlier effect sizes (Lee et al., 2016; Park et al., 2015) did not improve the heterogeneity estimates materially; therefore, these studies were not a significant source of heterogeneity (see Figure 6).

In an effort to identify other sources of heterogeneity, a subgroup analysis was performed with studies where data were collected before 2011 compared with studies in which data were collected in 2011 and later. The Sakles et al. (2017) article was excluded because they reported data that included both pre-and-post 2011. The rationale for this was exposure to, and experience with, a VL device limited to before 2011 as demonstrated by the number of VL attempts outnumbering DL attempts by more than 4 to 1 (VL=906; DL=403) in studies reporting data before 2011. VL and DL attempts were almost equal from 2011 to 2015 (VL=732; DL=767;). This also was a source of heterogeneity $I^2=79\%$ ($p<0.0001$).

This may be the first meta-analysis to compare the devices for emergent oro-tracheal adult intubation in the ED. There have been systematic reviews and meta-analyses comparing these devices in other settings (De Jong et al., 2014; Griesdale et al.,
2012; Lewis, Butler, Parker, Cook, & Smith, 2016). Those meta-analyses had similar challenges with heterogeneity. In 2012, Griesdale et al. published a meta-analysis comparing the GlideScope to the DL from RCTs and quasi-randomized trials not limited to the ED. When analyzing the FPSR, they reported significant heterogeneity ($I^2 = 88.9\%$) and found intubator experience level and potential airway difficulty were sources of heterogeneity. Unfortunately, the data could not be extracted to perform a subgroup analysis for either of these moderators. In 2014, DeJong et al. published a meta-analysis comparing the VL to the DL in the ICU and found similar findings favoring VL (OR=2.07; 95% CI 1.35, 3.16; p<0.001) similar to the present study favoring the VL in FPSR compared with the DL. They also combined RCTs with observational studies and found significant heterogeneity ($I^2 = 68\%$), which they attributed to a trauma study. Lewis et al. (2016) published a meta-analysis in the Cochrane Library comparing the VL to the DL for adult patients. Their study differed from the present one in that they only reviewed RCTs and included participants scheduled for surgery and patients requiring tracheal intubation in the ICU as well as the ED. Lewis and colleagues attributed an OR of 1.27 (95% CI 0.77, 2.09) favoring the VL and significant heterogeneity ($I^2 = 79\%$), attributed to performance bias (blinding of participants and personnel).

**Conclusion**

Based on results of this meta-analysis, it cannot be concluded with certainty that one device is better than the other for achieving successful intubation on the first attempt in the ED. For example, significant heterogeneity prevented appropriately combining studies. However, even with the risk of bias found in the RCT’s, there was still acceptable heterogeneity. Moreover, the difference between the studies was not due to
happenstance. Uncertainty also resulted from (a) variability in the observational studies (confounder was controlled in randomized studies); (b) selection and performance bias in the ED setting; and (c) clinicians’ utilization of whichever device they are most comfortable with to achieve a successful intubation, as demonstrated by protocol violations that occurred in the RCTs. There also needs to be standardized reporting for these outcomes. Therefore, these issues need to be addressed in future study protocols.

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<td><strong>Electronic Database Search Strategy</strong></td>
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**Ovid Medline Database**
1. intubation/ or intubation, intratracheal/
2. intubation*.ti,ab,kw.
3. 1 or 2
4. laryngoscopy/ or laryngoscopes/
5. (glidescope or e-mac or v-mac or mcgrath or king vision or pentax or copilot or vividtrac or miller or macintosh or laryngoscopy*).ti,ab,kw.
6. 4 or 5
7. treatment outcome/ or (first pass or success* or overall success or attempt* or fail* or event).ti,ab,kw.
8. emergency service, hospital/ or trauma centers/
9. (ER or emergency room* or emergency department* or trauma center*).ti,ab,k
10. 8 or 9
11. adult/ or adult*.ti,ab,kw.
12. 3 and 6 and 7 and 10 and 11

**Embase Database**
1. 'adult'/exp OR adult*
2. AND
3. 'emergency health service'/exp OR 'emergency ward'/exp/mj OR ('er'/exp OR er OR 'emergency'/exp OR emergency AND room* OR 'emergency'/exp OR emergency AND department* OR 'trauma'/exp OR trauma AND center* OR 'emergency'/exp OR emergency AND ('health'/exp OR health))
4. AND
5. 'treatment outcome'/exp OR (outcome* OR first AND pass OR success* OR overall AND ('success'/exp OR success)) OR attempt* OR fail* OR event
6. AND
7. 'intubation'/exp OR intubat*
8. AND
9. 'laryngoscope'/exp OR 'direct laryngoscopy'/exp OR 'videolaryngoscope'/exp OR ('dl' OR 'vl' OR 'glidescope'/exp OR glidescope OR 'c mac'/exp OR 'c mac' OR 'v mac' OR 'mcgrath'/exp OR mcgrath OR king AND ('vision'/exp OR vision)) OR pentax OR copilot OR vividtrac OR miller OR macintosh OR laryngoscop*
10. 12.21.16
11. Embase Session Results
12. 'emergency ward'/exp/mj OR (er:ab,ti OR emergency:ab,ti AND room*:ab,ti OR emergency:ab,ti AND department*:ab,ti OR trauma:ab,ti AND center*:ab,ti) OR 'emergency health service'/exp
13. AND
14. 'treatment outcome'/exp/mj OR (outcome*:ab,ti OR first:ab,ti AND pass:ab,ti OR success*:ab,ti OR overall:ab,ti AND success:ab,ti) OR attempt*:ab,ti OR fail*:ab,ti OR event:ab,ti
15. AND
16. 'intubation'/exp/mj OR intubat*:ab,ti
17. AND
18. 'laryngoscopy'/exp/mj OR ('dl':ab,ti OR 'vl':ab,ti OR glidescope:ab,ti OR 'c mac':ab,ti OR 'v mac':ab,ti OR mcgrath:ab,ti OR king:ab,ti AND vision:ab,ti) OR pentax:ab,ti OR copilot:ab,ti OR vividtrac:ab,ti OR miller:ab,ti OR macintosh:ab,ti OR laryngoscop*:ab,ti OR 'laryngoscope'/exp OR 'direct laryngoscopy'/exp OR 'videolaryngoscope'/exp
19. AND
20. 'adult'/exp/mj OR adult*:ab,ti

Cochrane Library Database
1. (intubat*)
2. AND
3. ("dl" or "vl" or glidescope or c-mac or v-mac or mcgrath or king vision or pentax or copilot or vividtrac or miller or macintosh or laryngoscop*)
4. AND
5. (outcome* or first pass or success* or overall success or attempt* or fail* or event)
6. AND
7. (ER or emergency room* or emergency department* or trauma center*)
8. AND
9. (adult*)
<table>
<thead>
<tr>
<th>Step</th>
<th>Search Term</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>intubation</td>
</tr>
<tr>
<td>2</td>
<td>AND</td>
</tr>
<tr>
<td>3</td>
<td>laryngoscop*</td>
</tr>
<tr>
<td>4</td>
<td>AND</td>
</tr>
<tr>
<td>5</td>
<td>(outcome* or first pass or success* or overall success or attempt* or fail* or event)</td>
</tr>
<tr>
<td>6</td>
<td>AND</td>
</tr>
<tr>
<td>7</td>
<td>adult*</td>
</tr>
<tr>
<td>8</td>
<td>(&quot;dl&quot; or &quot;vl&quot; or glidescope or c-mac or v-mac or mcgrath or king vision or pentax or copilot or vividtrac or miller or macintosh or laryngoscop*)</td>
</tr>
<tr>
<td>9</td>
<td>AND</td>
</tr>
<tr>
<td>10</td>
<td>(outcome* or first pass or success* or overall success or attempt* or fail* or event)</td>
</tr>
<tr>
<td>11</td>
<td>AND</td>
</tr>
<tr>
<td>12</td>
<td>(ER or emergency room* or emergency department* or trauma center*)</td>
</tr>
<tr>
<td>13</td>
<td>AND</td>
</tr>
<tr>
<td>14</td>
<td>(adult*)</td>
</tr>
</tbody>
</table>
Table 1

*Characteristics of Studies that Examine the Impact of Emergency Intubation Using Direct Laryngoscope (DL) Compared to the Video Laryngoscope (VL)*

<table>
<thead>
<tr>
<th>Author(s), Date</th>
<th>Study Design</th>
<th>Location/ No. of EDs</th>
<th>Sample</th>
<th>No. of Intubations</th>
<th>DL Attempts</th>
<th>VL Attempts</th>
<th>Percent Of Trauma Patients/ Medical Included</th>
<th>Participants Excluded</th>
<th>Dates Data Collected</th>
<th>VL Device</th>
<th>Provider</th>
</tr>
</thead>
<tbody>
<tr>
<td>Choi, Kim et al. 2015</td>
<td>Prospective</td>
<td>Korea/44</td>
<td>Adult patients requiring emergent intubation</td>
<td>4041</td>
<td>3501</td>
<td>540</td>
<td>226/540 41.8% Trauma cases</td>
<td>Cardiac arrest</td>
<td>Jan 2007- Dec 2010</td>
<td>GVL</td>
<td>EM Residents [Junior (&lt;=PGY3, Senior(PGY 4&amp;5)] and Attendings</td>
</tr>
<tr>
<td>Lee et al., 2016</td>
<td>Prospective</td>
<td>Korea/22</td>
<td>Adult patients requiring emergent intubation</td>
<td>921</td>
<td>479</td>
<td>442</td>
<td>188/921 20.4% trauma Combined</td>
<td>Surgical methods and extraglottic devices were used on first intubation attempt, or the first operator was not EM physician</td>
<td>Season II*, Jan 2013-Dec 2015</td>
<td>GVL</td>
<td>EM Residents (PGY 1, 2, ≥3) and Attendings</td>
</tr>
</tbody>
</table>
Table 1 (continued)

Characteristics of Studies that Examine the Impact of Emergency Intubation Using Direct Laryngoscope (DL) Compared to the Video Laryngoscope (VL)

<table>
<thead>
<tr>
<th>Author(s), Study Design, Date</th>
<th>Location/No. of EDs</th>
<th>Sample</th>
<th>No. of Intubations</th>
<th>DL Attempts</th>
<th>VL Attempts</th>
<th>Percent of Trauma Patients/Medical Included</th>
<th>Participants Excluded</th>
<th>Dates Data Collected</th>
<th>VL Device</th>
<th>Provider</th>
</tr>
</thead>
<tbody>
<tr>
<td>Park et al., 2015 Interrupted time series observational cohort</td>
<td>Korea/22</td>
<td>Adults out-of-hospital cardiac arrest patients requiring emergent intubation during CPR in ED</td>
<td>83</td>
<td>34</td>
<td>49</td>
<td>UTD</td>
<td>(1) “Do not attempt CPR” request (2) Patients intubated before arrival (3) Traumatic arrest patients wearing cervical collars, and (4) First attempt by other residents or staff.</td>
<td>May 2011 - Apr 2013</td>
<td>GVL</td>
<td>PGY1 &amp; PGY2 EM Residents</td>
</tr>
<tr>
<td>Platts-Mills et al., 2009 Prospective observational</td>
<td>United States/1</td>
<td>Adult patients requiring intubation</td>
<td>280</td>
<td>217</td>
<td>63</td>
<td>(17/63 27% Trauma VL; 80/217 37% Trauma DL; 97/280 34.6% Combined)</td>
<td>Patients intubated before arrival</td>
<td>Aug 2006 - Feb 2008</td>
<td>GVL</td>
<td>EM Residents (PGY2, PGY3, PGY4)</td>
</tr>
</tbody>
</table>
Table 1 (continued)

*Characteristics of Studies that Examine the Impact of Emergency Intubation Using Direct Laryngoscope (DL) Compared to the Video Laryngoscope (VL)*

<table>
<thead>
<tr>
<th>Author(s), Date</th>
<th>Study Design</th>
<th>Location/ No. of EDs</th>
<th>Sample</th>
<th>No. of Intubations</th>
<th>DL Attempts</th>
<th>VL Attempts</th>
<th>Percent of Trauma Patients/ Medical Included</th>
<th>Participants Excluded</th>
<th>Dates Data Collected</th>
<th>VL Device</th>
<th>Provider</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sakles et al., 2017</td>
<td>Prospective observational United States/1</td>
<td>Adult patients requiring emergent intubation</td>
<td>1985</td>
<td>1035</td>
<td>950 (489/950 51.5% trauma VL/ 332/1035 32.1% trauma DL) 821/1985 41.4% combined)</td>
<td>Intubated by Non-EM Residents, Non GVL and Non-DL; Non-RSI, Pediatrics Pregnant or a prisoner or if the treating physician planned an approach other than DL on the first intubation attempt.</td>
<td>July 1, 2007-June 2016</td>
<td>GVL</td>
<td>EM Residents [PGY 1, 2, ≥3(PGY 3,4,5)]</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Driver et al. 2016</td>
<td>RCT United States/1</td>
<td>Patients requiring emergent intubation</td>
<td>198</td>
<td>106</td>
<td>92 UTD</td>
<td></td>
<td>Nov 2011-Feb 2013</td>
<td>CMAC</td>
<td>PGY 2 Residents, Senior EM residents (≥PGY3) and Attending EM Physicians</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Author(s), Date</td>
<td>Study Design</td>
<td>Location/ No. of EDs</td>
<td>Sample</td>
<td>No. of Intubations</td>
<td>DL Attempts</td>
<td>VL Attempts</td>
<td>Percent of Trauma Patients/ Medical Included</td>
<td>Participants Excluded</td>
<td>Dates Data Collected</td>
<td>VL Device</td>
<td>Provider</td>
</tr>
<tr>
<td>----------------------</td>
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<td>---------------------------------------------</td>
<td>-----------------------</td>
<td>---------------------</td>
<td>-----------</td>
<td>---------------------------------</td>
</tr>
<tr>
<td>Goksu et al., 2016</td>
<td>RCT</td>
<td>Turkey/1</td>
<td>Blunt trauma patients requiring emergent intubation</td>
<td>150</td>
<td>75</td>
<td>75</td>
<td>100% Trauma/ 0% Medical</td>
<td>Patients with penetrating trauma, pediatrics or intubated before ED arrival</td>
<td>May 2013-Oct 2013</td>
<td>CMAC</td>
<td>Residents and Attending EM physicians</td>
</tr>
<tr>
<td>Sulser et al., 2016</td>
<td>RCT</td>
<td>Switzerland/11</td>
<td>Patients requiring RSI</td>
<td>147</td>
<td>73</td>
<td>74</td>
<td>(88/147 59.9% Trauma; 59/147 40.1% Medical)</td>
<td>Patients with maxillo-facial trauma, immobilized cervical spine, known difficult airway or ongoing cardio-pulmonary resuscitation</td>
<td>Nov 2014-Dec 2015</td>
<td>CMAC</td>
<td>Experienced Anesthesia Attendings</td>
</tr>
</tbody>
</table>
Table 1 (continued)

Characteristics of Studies that Examine the Impact of Emergency Intubation Using Direct Laryngoscope (DL) Compared to the Video Laryngoscope (VL)

<table>
<thead>
<tr>
<th>Author(s), Date</th>
<th>Study Design</th>
<th>Location/ No. of EDs</th>
<th>Sample</th>
<th>No. of Intubations</th>
<th>DL Attempts</th>
<th>VL Attempts</th>
<th>Percent of Trauma Patients/ Medical Included</th>
<th>Participants Excluded</th>
<th>Dates Data Collected</th>
<th>VL Device</th>
<th>Provider</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yeatts et al., 2013</td>
<td>RCT</td>
<td>United States/1</td>
<td>Trauma patients requiring emergent intubation</td>
<td>623</td>
<td>320</td>
<td>303</td>
<td>100% Trauma/ 0% Medical</td>
<td>Minors, pts. w/suspected laryngeal trauma or extensive maxillo-facial injury requiring immediate surgical airway, known, or strongly suspected spinal cord injury for whom awake flexible fiber-optic intubation was indicated. Patients in cardiac arrest on arrival and those who died in the TRU</td>
<td>July 15, 2008- May 15, 2010</td>
<td>GVL</td>
<td>Anesthesia residents &amp; Attendings, Critical Care residents, Emergency Medicine residents, Surgery residents, CRNAs, SRNAs (Not reported separately by FPS)</td>
</tr>
</tbody>
</table>

Note. EM = emergency medicine specialty; PGY= post graduate year of medical education training; RSI= rapid sequence intubation; GVL = GlideScope; CMAC=McGrath C-MAC; UTD= Unable to determine based on how data were reported. TRU = trauma resuscitation unit; GVL = GlideScope; CRNA = certified Registered Nurse anesthetist; SRNA = student Registered Nurse anesthetist; FPS = first pass success.
Table 2

*First-Pass Intubation Success Rate (FPSR) and First Pass Attempts (FPA) for the Video Laryngoscope (VL) and Direct Laryngoscope (DL)*

<table>
<thead>
<tr>
<th>Author(s), Date</th>
<th>VL FPS</th>
<th>VL FPA</th>
<th>VL FPSR</th>
<th>DL FPS</th>
<th>DL FPA</th>
<th>DL FPSR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Choi, Kim et al., 2015</td>
<td>463</td>
<td>540</td>
<td>85.74%</td>
<td>2880</td>
<td>3501</td>
<td>82.26%</td>
</tr>
<tr>
<td>Lee et al., 2016</td>
<td>419</td>
<td>442</td>
<td>94.80%</td>
<td>365</td>
<td>479</td>
<td>76.20%</td>
</tr>
<tr>
<td>Park et al., 2015</td>
<td>45</td>
<td>49</td>
<td>91.84%</td>
<td>19</td>
<td>34</td>
<td>55.88%</td>
</tr>
<tr>
<td>Platts-Mills et al., 2009</td>
<td>51</td>
<td>63</td>
<td>80.95%</td>
<td>182</td>
<td>217</td>
<td>83.87%</td>
</tr>
<tr>
<td>Sakles et al., 2017</td>
<td>835</td>
<td>950</td>
<td>87.89%</td>
<td>755</td>
<td>1035</td>
<td>72.95%</td>
</tr>
<tr>
<td>Driver et al., 2016</td>
<td>86</td>
<td>92</td>
<td>93.48%</td>
<td>91</td>
<td>106</td>
<td>85.85%</td>
</tr>
<tr>
<td>Goksu et al., 2016</td>
<td>47</td>
<td>75</td>
<td>62.67%</td>
<td>44</td>
<td>75</td>
<td>58.67%</td>
</tr>
<tr>
<td>Sulser et al., 2016</td>
<td>73</td>
<td>74</td>
<td>98.65%</td>
<td>73</td>
<td>73</td>
<td>100.00%</td>
</tr>
<tr>
<td>Yeatts et al., 2013</td>
<td>242</td>
<td>303</td>
<td>79.87%</td>
<td>259</td>
<td>320</td>
<td>80.94%</td>
</tr>
<tr>
<td>FPSR Mean</td>
<td></td>
<td></td>
<td>86.2%</td>
<td></td>
<td></td>
<td>77.40%</td>
</tr>
<tr>
<td>FPSR Range</td>
<td></td>
<td></td>
<td>62.7%</td>
<td></td>
<td></td>
<td>55.88%</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>98.6%</td>
<td></td>
<td></td>
<td>100.00%</td>
</tr>
<tr>
<td>FPSR Median</td>
<td></td>
<td></td>
<td>87.89%</td>
<td></td>
<td></td>
<td>80.94%</td>
</tr>
<tr>
<td>Author(s), Date</td>
<td>Allocation concealment (selection bias)</td>
<td>Blinding of participants and personnel (performance bias)</td>
<td>Blinding of outcome assessment (detection bias)</td>
<td>Incomplete outcome data (attrition bias)</td>
<td>Selective reporting (reporting bias)</td>
<td>Other bias</td>
</tr>
<tr>
<td>----------------</td>
<td>----------------------------------------</td>
<td>----------------------------------------------------------</td>
<td>-----------------------------------------------</td>
<td>----------------------------------------</td>
<td>-----------------------------------</td>
<td>------------</td>
</tr>
<tr>
<td>Choi et al., 2015</td>
<td>High</td>
<td>High</td>
<td>High</td>
<td>Low</td>
<td>High</td>
<td>High</td>
</tr>
<tr>
<td>Lee et al., 2016</td>
<td>High</td>
<td>High</td>
<td>High</td>
<td>Unclear</td>
<td>High</td>
<td>High</td>
</tr>
<tr>
<td>Park et al., 2015</td>
<td>High</td>
<td>High</td>
<td>High</td>
<td>Low</td>
<td>Unclear</td>
<td>High</td>
</tr>
<tr>
<td>Platts-Mills et al., 2009</td>
<td>High</td>
<td>High</td>
<td>High</td>
<td>Unclear</td>
<td>High</td>
<td>High</td>
</tr>
<tr>
<td>Sakles et al., 2017</td>
<td>High</td>
<td>High</td>
<td>High</td>
<td>High</td>
<td>High</td>
<td>High</td>
</tr>
</tbody>
</table>
Table 3B

Risk of Bias for RCT Studies that Examined the Impact of Emergency Intubation Using the Direct Laryngoscope (DL) Compared to the Video Laryngoscope (VL)

<table>
<thead>
<tr>
<th>Author(s), Date</th>
<th>Random sequence generation (selection bias)</th>
<th>Allocation concealment (selection bias)</th>
<th>Blinding of participants and personnel (performance bias)</th>
<th>Blinding of outcome assessment (detection bias)</th>
<th>Incomplete outcome data (attrition bias)</th>
<th>Selective reporting (reporting bias)</th>
<th>Other bias</th>
</tr>
</thead>
<tbody>
<tr>
<td>Driver et al., 2016</td>
<td>High</td>
<td>Low</td>
<td>High</td>
<td>High</td>
<td>Low</td>
<td>Unclear</td>
<td>High</td>
</tr>
<tr>
<td>Goksu et al., 2016</td>
<td>Unclear</td>
<td>Low</td>
<td>High</td>
<td>High</td>
<td>Unclear</td>
<td>Unclear</td>
<td>High</td>
</tr>
<tr>
<td>Sulser et al., 2016</td>
<td>High</td>
<td>Low</td>
<td>High</td>
<td>High</td>
<td>Unclear</td>
<td>Unclear</td>
<td>High</td>
</tr>
<tr>
<td>Yeatts et al., 2013</td>
<td>Unclear</td>
<td>Low</td>
<td>High</td>
<td>High</td>
<td>High</td>
<td>Low</td>
<td>High</td>
</tr>
</tbody>
</table>

Note. High= high risk of bias; Unclear= cannot determine risk based on evidence reported; Low= low risk of bias. RCT, randomized controlled trial.
Figure 1. Flowchart of studies selected for the meta-analysis. Preferred reporting items for systematic reviews and meta-analyses (PRISMA)
Figure 2. The pooled Odds Ratio (OR) is 1.89 [1.17, 3.07] with p-value <0.01 indicating a significantly better effect for the VL than the DL. Significant heterogeneity ($I^2=88\%$) was found among the studies.
Figure 3. The observational studies showed statistically significant effect of VL against DL with Odds Ratio (OR) 2.49 [1.32; 4.71] with p-value < 0.01. There is high heterogeneity in the observational studies ($I^2=91\%$) and low heterogeneity in the RCTs ($I^2=14\%$).
In the subgroup analysis by VL device type the GlideScope (GVL) showed statistically significant results of VL against DL with Odds Ratio 2.08 [95% CI 1.17-3.73, p < 0.01]. There was homogeneity among the studies using the C-MAC device ($I^2=4\%$). GVL was a source of heterogeneity ($I^2=92\%$).

![Figure 4](image.png)
Figure 5. In the subgroup analysis by study location (studies conducted in the USA or those carried out outside of the USA), no statistically significant results were found.
Figure 6. The funnel plot is symmetrical for this meta-analysis. Although several studies are out of the funnel shape, the Egger’s test found there is no publication bias (p-value = 0.9611). The Begg’s (1994) test also found there is no publication bias (p-value = 0.6767).
Figure 7. The trim-and-fill method was utilized by inputting the estimated values of the possible missing data to assess of missing data bias. Only one replacement was needed on the right side of the funnel plot. After the replacement, the pooled OR was 1.95 [95% CI 1.21-3.16, p = 0.0061], which did not alter the pooled estimate of the main data OR of 1.89 [95% CI 1.16-3.07, p= 0.0098]. Again, these results indicate there is no significant effect of the missing data for this meta-analysis.
Figure 8. Removes one study each time and measures the pooled estimate. Pooled estimates are calculated omitting one study at a time to check the influence of the study.

<table>
<thead>
<tr>
<th>Study</th>
<th>Odds Ratio</th>
<th>OR</th>
<th>95%–CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Omitting Choi et al., 2015</td>
<td></td>
<td>2.02</td>
<td>[1.13; 3.62]</td>
</tr>
<tr>
<td>Omitting Driver et al, 2016</td>
<td></td>
<td>1.85</td>
<td>[1.10; 3.11]</td>
</tr>
<tr>
<td>Omitting Gosku et al, 2016</td>
<td></td>
<td>2.02</td>
<td>[1.19; 3.43]</td>
</tr>
<tr>
<td>Omitting Lee et al., 2016</td>
<td></td>
<td>1.58</td>
<td>[1.00; 2.48]</td>
</tr>
<tr>
<td>Omitting Park et al., 2015</td>
<td></td>
<td>1.66</td>
<td>[1.02; 2.71]</td>
</tr>
<tr>
<td>Omitting Platts–Mills et al, 2009</td>
<td></td>
<td>2.11</td>
<td>[1.26; 3.52]</td>
</tr>
<tr>
<td>Omitting Sakles et al, 2017</td>
<td></td>
<td>1.79</td>
<td>[1.00; 3.18]</td>
</tr>
<tr>
<td>Omitting Sulser et al., 2016</td>
<td></td>
<td>1.96</td>
<td>[1.20; 3.20]</td>
</tr>
<tr>
<td>Omitting Yeatts et al, 2013</td>
<td></td>
<td>2.12</td>
<td>[1.27; 3.55]</td>
</tr>
<tr>
<td><strong>Random effects model</strong></td>
<td></td>
<td><strong>1.89</strong></td>
<td><strong>[1.17; 3.07]</strong></td>
</tr>
</tbody>
</table>
Box 2

Quality Assessment and Risk of Bias Tools

### Cochrane Risk of Bias Tool for Randomized Controlled Trials

#### RANDOM SEQUENCE GENERATION

**Selection bias (biased allocation to interventions) due to inadequate generation of a randomised sequence.**

<table>
<thead>
<tr>
<th>Criteria for a judgment of ‘Low risk’ of bias.</th>
<th>The investigators describe a random component in the sequence generation process such as:</th>
</tr>
</thead>
<tbody>
<tr>
<td>□ Referring to a random number table;</td>
<td>□ Using a computer random number generator;</td>
</tr>
<tr>
<td>□ Coin tossing;</td>
<td>□ Shuffling cards or envelopes;</td>
</tr>
<tr>
<td>□ Throwing dice;</td>
<td>□ Drawing of lots;</td>
</tr>
<tr>
<td>□ Minimization*</td>
<td></td>
</tr>
</tbody>
</table>

*Minimization may be implemented without a random element, and this is considered to be equivalent to being random.

<table>
<thead>
<tr>
<th>Criteria for the judgment of ‘High risk’ of bias.</th>
<th>The investigators describe a non-random component in the sequence generation process. Usually, the description would involve some systematic, non-random approach, for example:</th>
</tr>
</thead>
<tbody>
<tr>
<td>□ Sequence generated by odd or even date of birth;</td>
<td>□ Sequence generated by some rule based on date (or day) of admission;</td>
</tr>
<tr>
<td>□ Sequence generated by some rule based on hospital or clinic record number.</td>
<td></td>
</tr>
<tr>
<td>Other non-random approaches happen much less frequently than the systematic approaches mentioned above and tend to be obvious. They usually involve judgement or some method of non-random categorization of participants, for example:</td>
<td></td>
</tr>
<tr>
<td>□ Allocation by judgement of the clinician;</td>
<td>□ Allocation by preference of the participant;</td>
</tr>
<tr>
<td>□ Allocation based on the results of a laboratory test or a series of tests;</td>
<td>□ Allocation by availability of the intervention.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Criteria for the judgment of ‘Unclear risk’ of bias.</th>
<th>Insufficient information about the sequence generation process to permit judgement of ‘Low risk’ or ‘High risk’.</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Criteria for the judgment of ‘Unclear risk’ of bias.</th>
<th>(unless clear justification for their reporting is provided, such as an unexpected adverse effect);</th>
</tr>
</thead>
<tbody>
<tr>
<td>□ One or more outcomes of interest in the review are reported incompletely so that they cannot be entered in a meta-analysis;</td>
<td></td>
</tr>
<tr>
<td>□ The study report fails to include results for a key outcome that would be expected to have been reported for such a study.</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Criteria for the judgment of ‘Unclear risk’ of bias.</th>
<th>Insufficient information to permit judgement of ‘Low risk’ or ‘High risk’. It is likely that the majority of studies will fall into this category.</th>
</tr>
</thead>
</table>
**ALLOCATION CONCEALMENT**  
Selection bias (biased allocation to interventions) due to inadequate concealment of allocations prior to assignment.

<table>
<thead>
<tr>
<th>Criteria for a judgment of ‘Low risk’ of bias.</th>
<th>Participants and investigators enrolling participants could not foresee assignment because one of the following, or an equivalent method, was used to conceal allocation:</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Central allocation (including telephone, web-based and pharmacy-controlled randomization);</td>
<td></td>
</tr>
<tr>
<td>- Sequentially numbered drug containers of identical appearance;</td>
<td></td>
</tr>
<tr>
<td>- Sequentially numbered, opaque, sealed envelopes.</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Criteria for the judgment of ‘High risk’ of bias.</th>
<th>Participants or investigators enrolling participants could possibly foresee assignments and thus introduce selection bias, such as allocation based on:</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Using an open random allocation schedule (e.g. a list of random numbers);</td>
<td></td>
</tr>
<tr>
<td>- Assignment envelopes were used without appropriate safeguards (e.g. if envelopes were unsealed or non-opaque or not sequentially numbered);</td>
<td></td>
</tr>
<tr>
<td>- Alternation or rotation;</td>
<td></td>
</tr>
<tr>
<td>- Date of birth;</td>
<td></td>
</tr>
<tr>
<td>- Case record number;</td>
<td></td>
</tr>
<tr>
<td>- Any other explicitly unsealed procedure.</td>
<td></td>
</tr>
</tbody>
</table>

| Criteria for the judgment of ‘Unclear risk’ of bias. | Insufficient information to permit judgement of ‘Low risk’ or ‘High risk’. This is usually the case if the method of concealment is not described or not described in sufficient detail to allow a definite judgement – for example if the use of assignment envelopes is described, but it remains unclear whether envelopes were sequentially numbered, opaque and sealed. |

**SELECTIVE REPORTING**  
Reporting bias due to selective outcome reporting.

<table>
<thead>
<tr>
<th>Criteria for a judgment of ‘Low risk’ of bias.</th>
<th>Any of the following:</th>
</tr>
</thead>
<tbody>
<tr>
<td>- The study protocol is available and all of the study’s pre-specified (primary and secondary) outcomes that are of interest in the review have been reported in the pre-specified way;</td>
<td></td>
</tr>
<tr>
<td>- The study protocol is not available but it is clear that the published reports include all expected outcomes, including those that were pre-specified (convincing text of this nature may be uncommon).</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Criteria for the judgment of ‘High risk’ of bias.</th>
<th>Any one of the following:</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Not all of the study’s pre-specified primary outcomes have been reported;</td>
<td></td>
</tr>
<tr>
<td>- One or more primary outcomes is reported using measurements, analysis methods or subsets of the data (e.g. subscales) that were not pre-specified;</td>
<td></td>
</tr>
<tr>
<td>- One or more reported primary outcomes were not pre-specified</td>
<td></td>
</tr>
</tbody>
</table>
Box 3

Risk of Bias

**Tool to Assess Risk of Bias in Randomized Controlled Trials**

1. **Was the allocation sequence adequately generated?**
   
<table>
<thead>
<tr>
<th>Definitely yes</th>
<th>Probably yes</th>
<th>Probably no</th>
<th>Definitely no</th>
</tr>
</thead>
<tbody>
<tr>
<td>(low risk of bias)</td>
<td></td>
<td></td>
<td>(high risk of bias)</td>
</tr>
</tbody>
</table>

Examples of low risk of bias: Referring to a random number table; Using a computer random number generator; Coin tossing; Shuffling cards or envelopes; Throwing dice; Drawing of lots; Minimization with or without a random element.

Examples of high risk of bias: Sequence generated by odd or even date of birth; Sequence generated by some rule based on date (or day) of admission; Sequence generated by some rule based on hospital or clinic record number; Allocation by judgment of the clinician; Allocation by preference of the participant; Allocation based on the results of a laboratory test or a series of tests; Allocation by availability of the intervention.

2. **Was allocation adequately concealed?**

<table>
<thead>
<tr>
<th>Definitely yes</th>
<th>Probably yes</th>
<th>Probably no</th>
<th>Definitely no</th>
</tr>
</thead>
<tbody>
<tr>
<td>(low risk of bias)</td>
<td></td>
<td></td>
<td>(high risk of bias)</td>
</tr>
</tbody>
</table>
Examples of possible low risk of bias: Sequentially numbered drug containers of identical appearance; Sequentially numbered, opaque, sealed envelopes.

Examples of high risk of bias allocation generation techniques: Using an open random allocation schedule (e.g. a list of random numbers); Assignment envelopes were utilized without appropriate safeguards (e.g. if envelopes were unsealed or non-opaque or not sequentially numbered); Alternation or rotation; Date of birth; Case record number; Any other explicitly unconcealed procedure.

1. **Blinding: Was knowledge of the allocated interventions adequately prevented?**

<table>
<thead>
<tr>
<th>Definitely yes</th>
<th>Probably yes</th>
<th>Probably no</th>
<th>Definitely no</th>
</tr>
</thead>
<tbody>
<tr>
<td>(low risk of bias)</td>
<td></td>
<td></td>
<td>(high risk of bias)</td>
</tr>
</tbody>
</table>

Examples of low risk of bias: No blinding, but the review authors judge that the outcome and the outcome measurement are not likely to be influenced by lack of blinding; Blinding of participants and key study personnel ensured, and unlikely that the blinding could have been broken; Either participants or some key study personnel were not blinded, but outcome assessment was blinded and the non-blinding of others unlikely to introduce bias.

Examples of high risk of bias: No blinding or incomplete blinding, and the outcome or outcome measurement is likely to be influenced by lack of blinding; Blinding of key study participants and personnel attempted, but likely that the blinding could have been broken;
Either participants or some key study personnel were not blinded, and the non-blinding of others likely to introduce bias.

3.a) Were patients blinded?
- Definitely yes
- Probably yes
- Probably no
- Definitely no

3.b) Were healthcare providers blinded?
- Definitely yes
- Probably yes
- Probably no
- Definitely no

3.c) Were data collectors blinded?
- Definitely yes
- Probably yes
- Probably no
- Definitely no

3.d) Were outcome assessors blinded?
- Definitely yes
- Probably yes
- Probably no
- Definitely no

3.e) Were data analysts blinded?
- Definitely yes
- Probably yes
- Probably no
- Definitely no

2. **Was loss to follow-up (missing outcome data) infrequent?**
- Definitely yes
- Probably yes
- Probably no
- Definitely no

(low risk of bias) (high risk of bias)

Examples of low risk of bias: No missing outcome data; Reasons for missing outcome data unlikely to be related to true outcome (for survival data, censoring unlikely to be introducing
Examples of high risk of bias: Not all of the study's pre-specified primary outcomes have been reported; One or more primary outcomes are reported using measurements, analysis methods or subsets of the data (e.g. subscales) that were not pre-specified; One or more reported primary outcomes were not pre-specified (unless clear justification for their reporting is provided, such as an unexpected adverse effect); One or more outcomes of interest in the review are incompletely reported so that they cannot be entered in a meta-analysis; The study report fails to include results of a key outcome that would be expected to have been reported for such a study.

1. **Was the study apparently free of other problems that could put it at a risk of bias?**

<table>
<thead>
<tr>
<th>Definitely yes</th>
<th>Probably yes</th>
<th>Probably no</th>
<th>Definitely no</th>
</tr>
</thead>
<tbody>
<tr>
<td>(low risk of bias)</td>
<td></td>
<td></td>
<td>(high risk of bias)</td>
</tr>
</tbody>
</table>

Examples of low risk of bias: The study appears to be free of other sources of bias.

Examples of high risk of bias: Had a potential source of bias related to the specific study design used; Stopped early due to some data-dependent process (including a formal-stopping rule); Had extreme baseline imbalance; Has been claimed to have been fraudulent; Had some other problem.
### OTHER BIAS
Bias due to problems not covered elsewhere in the table.

<table>
<thead>
<tr>
<th>Criteria for a judgment of ‘Low risk’ of bias.</th>
<th>The study appears to be free of other sources of bias.</th>
</tr>
</thead>
</table>
| Criteria for the judgment of ‘High risk’ of bias. | There is at least one important risk of bias. For example, the study:  
- Had a potential source of bias related to the specific study design used; or  
- Has been claimed to have been fraudulent; or  
- Had some other problem. |
| Criteria for the judgment of ‘Unclear risk’ of bias. | There may be a risk of bias, but there is either:  
- Insufficient information to assess whether an important risk of bias exists; or  
- Insufficient rationale or evidence that an identified problem will introduce bias. |

### BLINING OF PARTICIPANTS AND PERSONNEL
Performance bias due to knowledge of the allocated interventions by participants and personnel during the study.

| Criteria for a judgment of ‘Low risk’ of bias. | Any one of the following:  
- No blinding or incomplete blinding, but the review authors judge that the outcome is not likely to be influenced by lack of blinding;  
- Blinding of participants and key study personnel ensured, and unlikely that the blinding could have been broken. |
|---|---|
| Criteria for the judgment of ‘High risk’ of bias. | Any one of the following:  
- No blinding or incomplete blinding, and the outcome is likely to be influenced by lack of blinding;  
- Blinding of key study participants and personnel attempted, but likely that the blinding could have been broken, and the outcome is likely to be influenced by lack of blinding. |
| Criteria for the judgment of ‘Unclear risk’ of bias. | Any one of the following:  
- Insufficient information to permit judgment of ‘Low risk’ or ‘High risk’;  
- The study did not address this outcome. |

- For continuous outcome data, plausible effect size (difference in means or standardized difference in means) among missing outcomes enough to induce clinically relevant bias in observed effect size;  
- ‘As-treated’ analysis done with substantial departure of the intervention received from that assigned at randomization;  
- Potentially inappropriate application of simple imputation. |
<table>
<thead>
<tr>
<th><strong>Criteria for a judgment of ‘Low risk’ of bias.</strong></th>
<th><strong>Any one of the following:</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>□ No blinding of outcome assessment, but the review authors judge that the outcome measurement is not likely to be influenced by lack of blinding;</td>
<td>□ No blinding of outcome assessment, but the review authors judge that the outcome measurement is not likely to be influenced by lack of blinding;</td>
</tr>
<tr>
<td>□ Blinding of outcome assessment ensured, and unlikely that the blinding could have been broken.</td>
<td>□ Blinding of outcome assessment ensured, and unlikely that the blinding could have been broken.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Criteria for the judgment of ‘High risk’ of bias.</strong></th>
<th><strong>Any one of the following:</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>□ No blinding of outcome assessment, and the outcome measurement is likely to be influenced by lack of blinding;</td>
<td>□ No blinding of outcome assessment, and the outcome measurement is likely to be influenced by lack of blinding;</td>
</tr>
<tr>
<td>□ Blinding of outcome assessment, but likely that the blinding could have been broken, and the outcome measurement is likely to be influenced by lack of blinding.</td>
<td>□ Blinding of outcome assessment, but likely that the blinding could have been broken, and the outcome measurement is likely to be influenced by lack of blinding.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Criteria for the judgment of ‘Unclear risk’ of bias.</strong></th>
<th><strong>Any one of the following:</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>□ Insufficient information to permit judgment of ‘Low risk’ or ‘High risk’;</td>
<td>□ Insufficient information to permit judgment of ‘Low risk’ or ‘High risk’;</td>
</tr>
<tr>
<td>□ The study did not address this outcome.</td>
<td>□ The study did not address this outcome.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>INCOMPLETE OUTCOME DATA</strong></th>
<th><strong>Attrition bias due to amount, nature or handling of incomplete outcome data.</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Criteria for a judgment of ‘Low risk’ of bias.</strong></td>
<td><strong>Any one of the following:</strong></td>
</tr>
<tr>
<td>□ No missing outcome data;</td>
<td>□ No missing outcome data;</td>
</tr>
<tr>
<td>□ Reasons for missing outcome data unlikely to be related to true outcome (for survival data, censoring unlikely to be introducing bias);</td>
<td>□ Reasons for missing outcome data unlikely to be related to true outcome (for survival data, censoring unlikely to be introducing bias);</td>
</tr>
<tr>
<td>□ Missing outcome data balanced in numbers across intervention groups, with similar reasons for missing data across groups;</td>
<td>□ Missing outcome data balanced in numbers across intervention groups, with similar reasons for missing data across groups;</td>
</tr>
<tr>
<td>□ For dichotomous outcome data, the proportion of missing outcomes compared with observed event risk not enough to have a clinically relevant impact on the intervention effect estimate;</td>
<td>□ For dichotomous outcome data, the proportion of missing outcomes compared with observed event risk not enough to have a clinically relevant impact on the intervention effect estimate;</td>
</tr>
<tr>
<td>□ For continuous outcome data, plausible effect size (difference in means or standardized difference in means) among missing outcomes not enough to have a clinically relevant impact on observed effect size;</td>
<td>□ For continuous outcome data, plausible effect size (difference in means or standardized difference in means) among missing outcomes not enough to have a clinically relevant impact on observed effect size;</td>
</tr>
<tr>
<td>□ Missing data have been imputed using appropriate methods.</td>
<td>□ Missing data have been imputed using appropriate methods.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Criteria for the judgment of ‘High risk’ of bias.</strong></th>
<th><strong>Any one of the following:</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>□ Reason for missing outcome data likely to be related to true outcome, with either imbalance in numbers or reasons for missing data across intervention groups;</td>
<td>□ Reason for missing outcome data likely to be related to true outcome, with either imbalance in numbers or reasons for missing data across intervention groups;</td>
</tr>
<tr>
<td>□ For dichotomous outcome data, the proportion of missing outcomes compared with observed event risk enough to induce clinically relevant bias in intervention effect estimate;</td>
<td>□ For dichotomous outcome data, the proportion of missing outcomes compared with observed event risk enough to induce clinically relevant bias in intervention effect estimate;</td>
</tr>
</tbody>
</table>
**Box 4**

Quality Assessment and Risk of Bias Tool for Cohort Studies

<table>
<thead>
<tr>
<th>Tool to Assess Risk of Bias in Cohort Studies</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Was selection of exposed and non-exposed cohorts drawn from the same population?</td>
</tr>
<tr>
<td>Definitely yes (low risk of bias)</td>
</tr>
<tr>
<td>Examples of low risk of bias: Exposed and unexposed drawn for same administrative data base of patients presenting at same points of care over the same time frame</td>
</tr>
<tr>
<td>Examples of high risk of bias: exposed and unexposed presenting to different points of care or over a different time frame</td>
</tr>
<tr>
<td>2. Can we be confident in the assessment of exposure?</td>
</tr>
<tr>
<td>Definitely yes (low risk of bias)</td>
</tr>
<tr>
<td>Examples of low risk of bias: Secure record [e.g. surgical records, pharmacy records]; Repeated interview or other ascertainment asking about current use/exposure</td>
</tr>
<tr>
<td>Examples of higher risk of bias: Structured interview at a single point in time; Written self report; Individuals who are asked to retrospectively confirm their exposure status may be subject to recall bias – less likely to recall an exposure if they have not developed an adverse outcome, and more likely to recall an exposure (whether an exposure occurred or not) if they have developed an adverse outcome.</td>
</tr>
<tr>
<td>Examples of high risk of bias: uncertain how exposure information obtained</td>
</tr>
<tr>
<td>3. Can we be confident that the outcome of interest was not present at start of study</td>
</tr>
<tr>
<td>Definitely yes (low risk of bias)</td>
</tr>
</tbody>
</table>
4. Did the study match exposed and unexposed for all variables that are associated with the outcome of interest or did the statistical analysis adjust for these prognostic variables?

- **Definitely yes** (low risk of bias)
- **Mostly yes**
- **Mostly no**
- **Definitely no** (high risk of bias)

Examples of low risk of bias: comprehensive matching or adjustment for all plausible prognostic variables.

Examples of higher risk of bias: matching or adjustment for most plausible prognostic variables.

Examples of high risk of bias: matching or adjustment for a minority of plausible prognostic variables, or no matching or adjustment at all. Statements of no differences between groups or that differences were not statistically significant are not sufficient for establishing comparability.

5. **Can we be confident in the assessment of the presence or absence of prognostic factors?**

- **Definitely yes** (low risk of bias)
- **Probably yes**
- **Probably no**
- **Definitely no** (high risk of bias)

Examples of low risk of bias: Interview of all participants; self-completed survey from all participants; review of charts with reproducibility demonstrated; from data base with documentation of accuracy of abstraction of prognostic data.

Examples of higher risk of bias: Chart review without demonstration of reproducibility; data base with uncertain quality of abstraction of prognostic information.

Examples of high risk of bias: Prognostic information from data base with no available documentation of quality of abstraction of prognostic variables.
6. Can we be confident in the assessment of outcome?

<table>
<thead>
<tr>
<th>Definitely yes</th>
<th>Probably yes</th>
<th>Probably no</th>
<th>Definitely no</th>
</tr>
</thead>
<tbody>
<tr>
<td>(low risk of bias)</td>
<td></td>
<td></td>
<td>(high risk of bias)</td>
</tr>
</tbody>
</table>

Examples of low risk of bias: Independent blind assessment; Record linkage; For some outcomes (e.g. fractured hip), reference to the medical record is sufficient to satisfy the requirement for confirmation of the fracture.

Examples of higher risk of bias: Independent assessment unblinded; self-report; For some outcomes (e.g. vertebral fracture where reference to x-rays would be required) reference to the medical record would not be adequate outcomes.

Examples of high risk of bias: uncertain (no description)

7. Was the follow up of cohorts adequate?

<table>
<thead>
<tr>
<th>Definitely yes</th>
<th>Probably yes</th>
<th>Probably no</th>
<th>Definitely no</th>
</tr>
</thead>
<tbody>
<tr>
<td>(low risk of bias)</td>
<td></td>
<td></td>
<td>(high risk of bias)</td>
</tr>
</tbody>
</table>

Examples of low risk of bias: No missing outcome data; Reasons for missing outcome data unlikely to be related to true outcome (for survival data, censoring is unlikely to introduce bias); Missing outcome data balanced in numbers across intervention groups, with similar reasons for missing data across groups; For dichotomous outcome data, the proportion of missing outcomes compared with observed event risk is not enough to have a important impact on the intervention effect estimate; For continuous outcome data, plausible effect size (difference in means or standardized difference in means) among missing outcomes is not large enough to have an important impact on the observed effect size; Missing data have been imputed using appropriate methods.

Examples of high risk of bias: Reason for missing outcome data likely to be related to true outcome, with either imbalance in numbers or reasons for missing data across intervention groups; For dichotomous outcome data, the proportion of missing outcomes compared with observed event risk is enough to induce important bias in intervention effect estimate; For continuous outcome data, plausible effect size (difference in means or standardized difference in means) among missing outcomes is large enough to induce clinically relevant bias in the observed effect size.
8. Were co-interventions similar between groups?

<table>
<thead>
<tr>
<th>Definitely yes (low risk of bias)</th>
<th>Probably yes</th>
<th>Probably no</th>
<th>Definitely no (high risk of bias)</th>
</tr>
</thead>
</table>

Examples of low risk of bias: Most or all relevant co-interventions that might influence the outcome of interest are documented to be similar in the exposed and unexposed.

Examples of high risk of bias: Few or no relevant co-interventions that might influence the outcome of interest are documented to be similar in the exposed and unexposed.
Literature Cited


Sakles, J. C., Patanwala, A. E., Mosier, J. M., & Dicken, J. (2014). Comparison of video laryngoscopy to direct laryngoscopy for intubation of patients with difficult airway characteristics in the emergency department. *Internal and Emergency Medicine, 9*(1), 93.


APPENDIXES
Appendix A

Approval University of Texas Health IRB

Daniel Degarmo, MSN
UT-H - SN - Department of Family Health

January 26, 2016

HSC-SN-16-0032 - COMPARATIVE AND COST EFFICIENCE ANALYSIS OF THE VIDEO LARYNGOSCOPE

The above named project is determined to qualify for exempt status according to 45 CFR 46.101(b)

CATEGORY #4: Research, involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified directly or through identifiers linked to the subjects.

CHANGES: Should you choose to make any changes to the protocol that would involve the inclusion of human subjects or identified data from humans, please submit the change via IRIS to the Committee for the Protection of Human Subjects for review.

STUDY CLOSURES: Upon completion of your project, submission of a study closure report is required. The study closure report should be submitted once all data has been collected and analyzed.

Should you have any questions, please contact the Office of Research Support Committees at 713-500-7943.
Appendix B

Approval Baylor College of Medicine IRB

September 12, 2016

MICHAEL GONZALEZ
BAYLOR COLLEGE OF MEDICINE
MEDICINE: EMERGENCY MEDICINE

H-39327 - COMPARATIVE AND COST EFFETIVENESS ANALYSIS OF THE VIDEO LARYNGOSCOPE

APPROVAL VALID FROM 9/12/2016 TO 9/11/2017

Dear Dr. GONZALEZ

The Institutional Review Board for Human Subject Research for Baylor College of Medicine and Affiliated Hospitals (BCM IRB) is pleased to inform you that the research protocol named above was reviewed and approved by Expedited procedures on 9/12/2016 by Board 3.

The study may not continue after the approval period without additional IRB review and approval for continuation. You will receive an email renewal reminder notice prior to study expiration; however, it is your responsibility to assure that this study is not conducted beyond the expiration date.

Please be aware that only IRB-approved informed consent forms may be used when written informed consent is required.

Any changes in study or informed consent procedure must receive review and approval prior to implementation unless the change is necessary for the safety of subjects. In addition, you must inform the IRB of adverse events encountered during the study or of any new and significant information that may impact a research participants' safety or willingness to continue in your study.

The BCM IRB is organized, operates, and is registered with the United States Office for Human Research Protections according to the regulations codified in the United States Code of Federal Regulations at 45 CFR 46 and 21 CFR 56. The BCM IRB operates under the BCM Federal Wide Assurance No. 00000286, as well as those of hospitals and institutions affiliated with the College.

Sincerely yours,

[Signature]

SHITAL MAHENDRA PATEL, M.D., B.A.
Institutional Review Board for Baylor College of Medicine and Affiliated Hospitals

https://brain.bcm.edu/esp1/reports/Human/Approval.asp?protocol=328593&title_code=0

1/1
Appendix C

Notice of Approval to Implement Requested Changes

NOTICE OF APPROVAL TO IMPLEMENT REQUESTED CHANGES

February 28, 2017

HSC-SN-16-0032 - COMPARATIVE AND COST EFFETIVENESS ANALYSIS OF THE VIDEO LARYNGOSCOPE
PI: Dr. Daniel Degarmo

Reference Number: 149452

PROVISIONS: Unless otherwise noted, this approval relates to the research to be conducted under the above referenced title and/or to any associated materials considered at this meeting, e.g. study documents, informed consent, etc.

APPROVED: By Expedited Review and Approval

CHANGE APPROVED: Changing source of data to published literature

REVIEW DATE: February 28, 2017

APPROVAL DATE: February 28, 2017

CHAIRPERSON: L. Maximilian Buja, MD

Upon receipt of this letter, and subject to any provisions noted above, you may now implement the changes approved.

CHANGES: The principal investigator (PI) must receive approval from the CPHS before initiating any changes, including those required by the sponsor, which would affect human subjects, e.g. changes in methods or procedures, numbers or kinds of human subjects, or revisions to the informed consent document or procedures. The addition of co-investigators must also receive approval from the CPHS. ALL PROTOCOL REVISIONS MUST BE SUBMITTED TO THE SPONSOR OF THE RESEARCH.

UNANTICIPATED RISK OR HARM, OR ADVERSE DRUG REACTIONS: The PI will immediately inform the CPHS of any unanticipated problems involving risks to subjects or others, of any serious harm to subjects, and of any adverse drug reactions.

RECORDS: The PI will maintain adequate records, including signed consent documents if required, in a manner that ensures subject confidentiality.
Appendix D

Study Operations Procedures

Study Protocol

The PICOS format was used for the research question to be consistent with studies in the literature: Among adults emergently intubated in the Emergency Department, does Video Laryngoscopy (VL) have a higher first pass success rate compared with Direct Laryngoscopy (DL)?

i. Population- is Adults emergently intubated
ii. Intervention- is Video laryngoscopy
iii. Control- is Direct laryngoscopy
iv. Outcome- is the first pass success rate
v. Setting- is the Emergency Department

The inclusion and exclusion criteria are defined as:

Inclusion criteria (must include all of the following):
1. Compare FPS between VL and DL
2. Patients orotracheally intubated
3. ED patients
4. Adult patients (≥ 18 years old)

Exclusion criteria (any one of the following)
1. Manikin studies
2. Simulations
3. Case reports
4. Reviews
5. Pilot studies
6. Pediatrics
7. Intubation performed Outside ED (e.g., OR, ICU, or pre-hospital)
8. other types of intubations (e.g., nasotracheal)
Search Strategy

1. Using terms from relevant documents and previous systematic reviews (see Appendix Electronic Database Search Strategy for search terms)
2. The main search was conducted in Ovid Medline database using terms mapped to subject heading in addition to the title, abstract and keyword searches.
3. The search strategy was then translated into the Cochrane Library database, Embase, and Google Scholar.
4. The Google Scholar search was limited to the first one hundred articles retrieved sorted by relevancy (see Appendix Electronic Database Search Strategy)

De-Duplication

1. Import database search results into citation reference manager (e.g. Endnote, Refworks, Mendeley)
2. If using Endnote, open Endnote software, select “Import.”
3. A pop-up screen will appear with the files you have saved in the database search results.
4. Select the file that the search was saved in, and click on the “Import” icon on the bottom right side of the pop-up screen
5. Repeat will all database search results.
6. Once all database search results have been imported, select the References tab on the tool bar.
7. Scroll down to “Find Duplicates” and hit enter.
8. Duplicate records will be displayed.
9. Record number of duplicates found.
10. Click on delete duplicates.

Rayyan Online Systematic Review Tool

1. Go to https://rayyan.qcri.org
2. Click on the “SIGN UP” icon
3. Fill in Sign up form, which includes email, title, first name, last name, organization, position, country, and the reason for joining (all fields must be filled in).
4. Click on “Sign up” icon at the bottom of the form.
5. Establish an account for all collaborators; each individual must sign up for an individual account.
6. The owner of the review (called creator of the review) invites collaborators.
7. The creator of the review invites other reviewer(s) by sending email from Rayyan to join in the review.
8. Each reviewer will fill in sign up form (as done in step 5a-d)
9. Click on the hyperlink “Check your browser compatibility” at the bottom of the Rayyan sign on screen.
10. Create a new review by selecting "New review...” from the Rayyan home screen.
11. Blinding is turned on by the creator of the review by selecting the setting (Blind OFF/ON) to “ON.”
12. Before importing records into Rayyan, perform de-duplication process by using citation manager (e.g. Endnote, Refworks, Mendeley)
13. After de-duplication is performed, search results from search strategy will be imported to Rayyan from individual databases.
14. Import search results from search strategy into Rayyan from individual databases.
15. Import can be done with the following text formats: EndNote Export (.enw), RIS, CSV and PubMed XML.
16. If using Endnote, click on the file tab, scroll down, and select “Export.”
17. An Export File Name pop-up window will appear
18. Select the file as type “Text Only.”
19. Output Style should be “Select Another Style…”
20. A Choose A Style pop-up window will appear
21. Select Export
22. Under Name of Style, highlight the Endnote Export Category then hit the “Choose” icon
23. Another Export File Name pop-up window will appear, select “Save.”
24. If possible duplicates are detected in Rayyan, a square icon will appear next to each record as a possible duplicate.
25. If possible duplicate, select the record, "possible duplicate" tag will appear as well as the option to accept the duplicate and delete it, or reject it and keep it as a separate record.
26. Select option to delete record if it is a duplicate
27. If the record is not a duplicate, select reject and the record will be kept.
28. If the record is deleted in error, select the 'undo' option to undelete the record.

Screening

1. Use the inclusion criteria to label record as “include” if they met all of the inclusion criteria:
   a. Compare intubation first pass attempt success between VL and DL
   b. Patients orotracheally intubated
   c. ED patients
   d. Adult patients (≧18)
2. If any of terms in the exclusion criteria are found in the study, then exclude with a reason
3. The exclusion criteria included are:
a. Manikin studies
b. Simulations
c. Case reports
d. Reviews
e. Pilot studies
f. Pediatrics
g. Intubation performed Outside ED (e.g., OR, ICU, or pre-hospital)
h. Other types of intubations (e.g., nasotracheal)

4. Reason and Label can be input by typing the reason or label into the “Reason” or “Label) box to the right of the “Include” or “Exclude” icons

5. If the reviewer cannot decide whether an article should be included or excluded, click “Undecided.”

6. When reviewers agreed that all articles had been reviewed, then Blinding is turned off by the creator of review by selecting the setting (Blind OFF/ON) to “Off.”

7. Articles not agreed on are listed as “conflict.”

8. Discussed articles where there was disagreement and decided if the study should be included or excluded from the review.

9. If the conflict cannot be resolved, have an objective party be the deciding vote.

Data Extraction

1. Using the studies included in the review of the data, input into Excel spreadsheet (Provide sample data log)

2. Data to be abstracted includes:
   - Title of Study
   - Purpose of Study
   - Study Design
   - Sample Size
   - Location study was performed
   - Setting
   - Dates Collected
   - Participants included
   - Participants excluded
   - Intervention
   - Bias
   - Study Size
   - Quantitative variables
   - Statistical Methods
   - Outcomes
   - Outcome: Definition and How Measured
   - DL First Pass Success, * mandatory for inclusion
- VL First Pass Success, * mandatory for inclusion
- Success in ≤ 3 Attempts
- DL Overall Success,
- VL Overall Success,
- VL utilized
- N
- Difficult Airway Characteristics listed
- Instrument used to identify difficult airway
- Adverse Events Reported
- Training received by intubators on VL and DL
- Key Results listed in study
- Limitations listed in study
- Generalizability
- Funding
- Comment
- Other

3. Evaluate studies to see if dates of data collected overlaps, if any studies overlap that use the same database, keep only the most recent study.

**Quality Assessment**

Assess the quality of study design and risk of bias:

1. Use the Cochrane Collaboration tools for randomized controlled trials (RCTs) and cohort studies (see Box 3 and 4)
2. Answer the questions for selection bias by assessing by evaluating adequacy of random sequence generation and allocation concealment (see examples of low risk and examples of high risk).
3. RCTs and observational studies are assessed for Selection, performance, detection, attrition, reporting and other sources (the top six domains)
4. Observational studies are also assessed for potential confounding variables that may impact the observed effect which include: eligibility criteria, intervention administration and outcomes reported by the intubator.
5. If study follows is low risk then label “low risk”. If study is high risk then label “high risk”. If it cannot be determined if study is high risk or low risk then label, unknown.
6. After all studies have been evaluated, compare findings with another evaluator to ensure no potential bias has been introduced.
7. Discusses articles where there was disagreement and decide if the domain should be “low, high or unknown”.
8. If the conflict cannot be resolved, have an objective party be the deciding vote.
Data Analysis were initially conducted by PI in RevMan 5.

Constructing a comparison table:

1. Add a comparison
2. Right-click the Data and Analyses heading in the outline and choose Add Comparison. The New Comparison Wizard opens.
3. Enter a Name for the comparison (VL versus DL)
4. Type in the name, or base the name on that of an existing comparison.
   To do so:
   • Click the down arrow at the end of the Name box to open a pull-down list of all comparisons.
   • Choose the comparison you wish to base the name on.
   • Edit the name.
5. Click Finish.
6. Other ways of adding a comparison:
   • Click the Data and Analyses heading in the outline, and then click the Add button on the toolbar.
   • Click the Add Comparison button in the Data and analyses section in the Text of Review.

Outcomes:

1. Add an outcome
2. Right-click the relevant comparison in the outline and choose Add Outcome.
3. The New Outcome Wizard opens.
4. Choose the data type for the outcome, and click Next.
5. Enter a Name for the outcome (first pass success)
6. Edit the Group Labels, and click Next.
7. Specify the analysis method, and click Next.
8. Specify the analysis details, and click Next.
9. Specify the graphs details, and click Next.
10. Choose the next action, and click Finish.
11. Once you have created an outcome, you can change the details of the analysis by modifying the properties of the outcome. See Outcome properties.

Subgroups:

1. Add a subgroup
2. Right-click the relevant outcome in the outline and choose Add Subgroup.
3. The New Subgroup Wizard opens.
4. Enter a Name for the Subgroup.
5. type in the name, or use the name of an existing subgroup.
6. To do so:
   a. Click the down arrow at the end of the Name box to open a pull-down list of all subgroups.
7. Choose the subgroup name you wish to use. You can edit the name, if necessary.
8. Click Finish.

Comparison properties:

1. Use the comparison properties window to modify:
2. The name of the comparison.
3. The group labels used in all outcomes for that comparison.
4. To change the group labels for all outcomes for a comparison - Open the outcome properties
5. Click the outcome and the click the Properties button in the outline toolbar.
6. Select Set Group Labels for all Outcomes.
7. Enter the labels you wish to use.
8. Note: Even if you only wish to modify one of the labels, you must fill in both in Group Label 1 (VL) and Group Label 2 (DL). If you leave one blank, this would be applied to all outcomes.
9. Click OK.
10. The new labels are applied to all outcomes for that comparison.
11. Use the outcome Name to describe the outcome (FPS)
12. Choose the following Data type:
13. Dichotomous: number of events and participants in the two groups.
14. The Group Labels (VL and DL) are used as headings in the data tables, and are published on those analyses graphs that are included as figures. The default labels are 'Experimental' and 'Control'. You can edit the labels for an individual outcome on the outcome properties, but you can also change the labels used in all outcomes for a comparison, see Comparison properties.

Entering data:

1. To enter data for a study, you must first have added the study to an analysis. Data can be either typed in
2. or pasted in, e.g. from a spreadsheet.
3. As you enter data, these are dynamically updated in the Analysis graph.
4. To open a data table-
5. Click the outcome you wish to enter data for.
6. Click the Edit Outcome button on the outline toolbar.
7. The outcome data table and analysis will open in a new tab.
Calculating data:

The calculator tool can assist you with data imputation and obtaining suitable data for meta-analysis.

1. To calculate data- Open an Outcome tab and click a study.
2. Click the calculator icon
3. The calculator window opens. Any study data already entered is used in the corresponding fields.
4. For Dichotomous and Inverse variance outcomes, select the statistical methods to show.
5. Enter the data you have.
6. If the number you enter is valid, the background in the cell is green, but if there is an error in the data, the background is red.

Funnel plots:

To view a funnel plot for an outcome

1. Open the data table for the outcome FPS
2. Click the Funnel Plot button.

The funnel plot opens in a new window.

Sensitivity analysis:

1. To perform sensitivity analysis, one can temporarily omit some of the studies used in an outcome or subgroup from the analysis. Such exclusions will be stored in the review file while you are working on it, but you cannot submit a review for publication if studies have been omitted from analysis.

Note:

Analyses included as figures are automatically updated, so if studies are temporarily omitted this will be reflected in the figures.

To omit a study:

1. Click the check box in front of the study name.

The check mark is removed, and the study no longer contributes to the analysis.
To convert data into R, please see

https://cran.r-project.org/web/packages/meta/meta.pdf

Under Details (page 3):

1. Import data from 'RevMan 5' (read.rm5; see also metacr)
2. Follow steps on p. 128
EDUCATION:

Doctor of Philosophy in Nursing 2017
*University of Texas Health Science Center at Houston*

Post Master of Science in Nursing 2006
Emergency Nurse Practitioner
*University of Texas Health Science Center at Houston*

Master of Science in Nursing 2006
Emergency Clinical Nurse Specialist
*University of Texas Health Science Center at Houston*

Emergency Medical Technician- Paramedic 2004
*San Antonio College*

Bachelor of Science in Nursing 1999
*University of Incarnate Word*

Emergency Medical Technician- Intermediate 1995
*San Antonio College*

Emergency Medical Technician- Basic 1992
*Pima Community College*

WORK EXPERIENCE:

University of Texas Health Science Center at Houston 2017 - Present
*Nursing Instructor*

Memorial Hermann- Texas Medical Center 2014 - 2017
*Director of Advanced Practice Providers*

EmCare 2008 - 2014
*Emergency Nurse Practitioner*
Curriculum Vitae
D. SEAN DEGARMO
Page 2

Frontier Healthcare (now Liberty Dayton) 2007 - 2010
Emergency Nurse Practitioner

University of Texas Health Science Center at Houston 2006 - 2013
Nursing Instructor/ Guest Lecturer

Air Evac Lifeteam 2006 - 2007
Flight Nurse

Memorial Hermann- Southwest Hospital 2005 - 2006
Education Resource Specialist & Clinical Nurse Specialist

Petroleum Helicopters Incorporated Air Medical 2004 - 2005
Flight Nurse

Intelistaff Travel Nursing 2003 - 2004
Emergency Department and Trauma RN

American Travel Mobile Nursing 2001 - 2003
Trauma, ED, and ICU RN

St. Joseph’s Medical Center 2000 - 2001
Emergency Department and Trauma RN

Good Samaritan Medical Center 1999 - 2000
Trauma, ED, and ICU RN

PROFESSIONAL MEMBERSHIPS:

Air Surface Transport Nurses Association 2004 – Present

Advanced Practice Provider Executives 2015 – Present

American Academy of Emergency Nurse Practitioners 2015 – Present

American Association of Nurse Practitioners 2015 – Present

American Educational Research Association 2017 – Present
American Nurses Association  2000 – Present

Emergency Nurses Association  2001 – Present

National Association of Clinical Nurse Specialists  2006 – Present

Sigma Theta Tau Nursing Honor Society  1999 – Present

Texas Nurses Association  2006 – Present

PUBLICATIONS:


PEER REVIEWED ABSTRACTS:


MASTER’S THESIS:

AWARDS AND RECOGNITION

Advanced Practice Provider Executives (APPex) 2016 - 2017
Leadership Summit Planning Committee

American Nurses Credentialing Center (ANCC) 2013
Content Expert
Emergency Nurse Practitioner Board Certification

AWARDS AND RECOGNITION

American Nurses Credentialing Center (ANCC) 2013
External Validation Committee
Emergency Nurse Practitioner Board Certification

American Nurses Credentialing Center (ANCC) 2013
Standard Setting Panel
Emergency Nurse Practitioner Board Certification

Advanced Practice Registered Nursing 2006 – Present
Clinical Nurse Specialist- Emergency Care
Texas State Board of Nurse Examiners

Advanced Practice Registered Nursing 2007 – Present
Emergency Nurse Practitioner
Texas State Board of Nurse Examiners

Family Nurse Practitioner Board Certification 2007 – Present
American Nurses Credentialing Center

Clinical Nurse Specialist- Adult Health Board Certification 2006 – Present
American Nurses Credentialing Center

Emergency Nurse Practitioner Board Certification 2013 – Present
American Nurses Credentialing Center

Licensed Paramedic 2006 – Present
Texas Department of State Health Services
Advanced Disaster Life Support Instructor 2005 – 2009  
Basic Cardiac Life Support Instructor 2004 – 2008  
Core Disaster Life Support Instructor 2005 – 2009  
Basic Disaster Life Support Instructor 2005 – 2009  
Recognition and Responding to Bioterrorism and Other Public Health Emergencies Instructor 2005 – 2009  
Advanced Burn Life Support 2003 – 2012  
Advanced Cardiac Life Support 1999 – Present  
Advanced Trauma Care for Nurses 2001 – 2008  
Hyperbaric Medicine & Problem Wound Management 2013  
Neonatal Resuscitation Provider 2001 – 2012  
Night Vision Goggle Ground and Flight Training Certification 2004  
Emergency Services Diver Instructor 1996  
NAUI  
Scuba Instructor-PADI 1996