Protocol

Performance of the King Vision Video Laryngoscope for Tracheal Intubation of Pediatric Patients

Principal Investigator
Nicole Horn, M.D.
Assistant Professor of Anesthesia
705 Riley Hospital Drive, Room 2820
Indianapolis, IN 46202
Phone: 317-944-9835
FAX: 317-944-0282
Email: nhorn@iuhealth.org

Sub Investigators

Jodie Johnson, M.D.
Assistant Professor of Clinical Anesthesia

Michael Mazurek, M.D.
Associate Professor of Clinical Anesthesia

Eugene Presto, M.D.
Assistant Professor of Clinical Anesthesia

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1.0 Background

Airway management is a critical component of anesthesia care. Failure to provide adequate ventilation and oxygenation can lead to death or permanent neurologic disability. Tracheal intubation provides a secure airway that is mandatory for many surgical procedures. Intubation of the trachea requires some type of instrument that permits visualization of the glottic inlet during insertion of the tracheal tube through the larynx and into the trachea. For many decades, the standard laryngoscope has consisted of a handle and a folding blade. The blade may be straight or curved. The purpose of the blade is to displace the tongue and sublingual tissue into the sub-mandibular space to provide the anesthesiologist with direct line-of-sight to the laryngeal inlet. Since the blade exerts pressure and displaces tissue, there is some risk of injury to the oral cavity and pharynx. Difficulty with conventional laryngoscopy can be as high as 13 percent.[1] Advances in imaging technology promoted the design of new laryngoscopes that provide an image of the larynx with indirect line-of-sight. The essence of these devices is a CCD chip or "miniature camera" that is placed at the tip of the laryngoscope. The image is transmitted to a screen for the anesthesiologist to observe. These laryngoscopes have been termed video laryngoscopes. Video laryngoscopes reduce pressure on the soft tissue of the upper airway and provide a high-resolution, wide angle view of the upper airway and larynx. Video laryngoscopes, consequently, decrease the risk of upper airway trauma and improve the ease of tracheal intubation. The first video

laryngoscope introduced into clinical practice was the Glidescope (Verathon Medical, 2003).[2] Since the introduction of video laryngoscopes most anesthesia departments and critical care departments, including ours, have had a steady increase in the use of video laryngoscopes in place of conventional laryngoscopes.[3,4,5] Many anesthesiologists now use video laryngoscopes as their standard laryngoscope. Video laryngoscopy is also included in current guidelines for difficult tracheal intubation.[6] Other video laryngoscopes in clinical use throughout the world include the CMAC (Kart Storz Imaging), Tru-View (Truphatek), McGrath (Covidien), Pentax AWS (Pentax), and the King Vision (Ambu). Some of these devices have pediatric sized blades and some do not.

Processing, portability, and cost are important aspects of video laryngoscope selection. Some devices have patient contact components that are disposable, while other devices are reusable and require processing for sterilization or high-grade disinfection. Patient cross-contamination with potentially infectious material is an increasing concern with reusable airway devices.[7] Cost is always a concern. Some video laryngoscopes require a separate stand and monitor, and reusable blades. The initial capital outlay for such reusable devices can be as high as $35,000. The initial financial outlay for the King Vision is $1500.

The King Vision video laryngoscope was introduced into clinical practice in 2011. The King Vision video laryngoscope is an FDA Device Class CCW instrument that is 510(K) exempt: regulation number 868.5540. This device

consists of a reusable, imaging wand that is inserted into a disposable blade (size 3). Published reports have documented the value of the King Vision video laryngoscope in older children and adults. [8,9] The size 3 blade is suitable for intubation of adults and children as young as 8 years. Ambu now makes size 1 and 2 blades suitable for intubation of infants and young children. The purpose of this study is to evaluate the performance of the King Vision video laryngoscope in younger patients. Advantages of the King Vision scope include a very high success rate of first pass intubation, relatively low cost ($11 per intubation) and extreme portability.

2.0 Rationale and Specific Aims

The purpose of this study is to evaluate the performance characteristics of the King Vision video laryngoscope in pediatric patients between the ages of one month and 10 years of age. If the performance is satisfactory, this device may become a standard laryngoscope for tracheal intubation in elective and emergent tracheal intubations.

3.0 Inclusion/Exclusion Criteria

Inclusion:

1. All children between the ages of 1 month to 10 years with a normal preoperative airway examination
2. Scheduled for a surgical procedure that requires tracheal intubation shall be included.

Exclusion:

1. Patients that will be excluded are those with an airway examination or previous anesthesia history that suggests difficulty with mask ventilation.

4.0 Enrollment/Randomization

100 patients will be enrolled. Data will be collected from the patients that the King Vision Video Laryngoscope is used. As this is not a comparative study, there shall be no randomization.

5.0 Study Procedures

All procedures shall be routine procedures for the administration of anesthesia appropriate for the age of the child and the type of surgical procedure. This is a data collection only study .

1. The technique of anesthesia induction will be determined for each patient by the anesthesiologist of record.
2. After the induction of anesthesia, and when the patient is at an adequate depth of anesthesia, tracheal intubation will be performed with the King Vision video laryngoscope by one of the investigators.
3. Data recorded will include gender, age, and weight of the patient.
4. Data specific to the device and tracheal intubation include; size and type of blade (standard vs. channeled), blade tip position, Cormack-Lehane score, tracheal tube size, and a subjective scoring of tracheal tube delivery.
5. See the attached data collection sheet.

6.0 Reporting of Adverse Events or Unanticipated Problems Involving Risk to Participants or Others

We do not anticipate adverse events related to this study. This is a data collections only study therefore there are minimal to no risks to the subjects. There is a minimal risk of loss of confidentiality. PHI will be accessed for recruitment purposes by the clinical care team and/or research care team. All data shared with the sponsor will be unidentifiable.

Any reports of adverse events can be made to:

Nicole Horn, M.D. @ Office number: 317-944-9835 or Pager: 317-312-2570

7.0 Statistical Considerations

As this is not a comparative study, only descriptive statistics will be applied.

8.0 Privacy/Confidentiality Issue

Data will be kept secure in a password protected database and all paper documentation will be kept in a secure office of the Anesthesia department.

10.0 Follow-up and Record Retention

There will not be a follow up period for this study. Records will be kept until all data analysis is complete and the study has been completed.

References:

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4. Silverberg MJ, Kory P: Survey of video laryngoscopy use by U.S. critical care fellowship training programs. Ann Am Thorac Soc 2014;11:1225-29.
5. Aziz MF, Kim D, Mako J, Hand K, Brambrink AM: A retrospective study of the performance of video laryngoscopy in an obstetric unit. Anesth Analg 2012;115:904-6.
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9. El-Tahhan MR, Doyle DJ, Khidr AM, AbdulShafi M, Regal MA, Othman MS: Use of the King Vision video laryngoscope to facilitate fibreoptic intubation in critical tracheal stenosis proves superior to the Glidescope. Can J Anaesth 2014;61:213-14.