King Vision Video Laryngoscope vs. Glidescope Video Laryngoscope: A Comparative Study in Ambulatory Surgery Center Patients

Revision Date: April 4, 2013

NCT02324465

King Vision Video Laryngoscope vs. Glidescope Video Laryngoscope: A Comparative Study in Ambulatory Surgery Center Patients

Revision Date: April 4, 2013

Douglas Hester, M.D.
Principal Investigator
Assistant Professor of Anesthesiology
Vanderbilt University Medical Center
Department of Anesthesiology
[redacted]
Nashville, TN 37232-5614

Paul St. Jacques, M.D.
Associate Professor of Anesthesiology
Vanderbilt University Medical Center
Department of Anesthesiology
[redacted]
Nashville, TN 37232-5614

Michael S Higgins, M.D.
Professor of Anesthesiology
Vanderbilt University Medical Center
Department of Anesthesiology, Division of Multi-Specialty
[redacted]
Nashville, TN 37232-5614

Stuart McGrane, M.D.
Assistant Professor of Anesthesiology
Vanderbilt University Medical Center
Department of Anesthesiology
[redacted]
Nashville, TN 37232-5614

Table of Contents:

1.0 Background

Both the King Vision and Glidescope video laryngoscopes are advanced airway devices that are relatively low cost and are designed to improve the efficiency of both routine and difficult intubation. Both systems use disposable blades, which eliminates the need for blade sterilization and may minimize the risk of infectious exposure to patients and improve cost and efficiency associated with the sterilization processing of non-disposable laryngoscopes. The Glidescope has been commercially available longer than the King Vision, and has been more frequently studied.

Although similar in many respects, the King Vision and Glidescope systems have differing designs which may result in differences in speed and success in the management of routine and/or difficult airways.

2.0 Rationale and Specific Aims

We plan to conduct a randomized trial comparing the intubation success rate and time of the King Vision VL to the Glidescope VL in order to demonstrate the comparability of the devices.

Hypothesis

The King Vision VL with the disposable "guided tract blade" has comparable intubation success rates and times to intubation as the Glidescope VL.

Primary Aim

Determine if the KingVision VL offers comparable intubation success rates and times to intubation as compared to the Glidescope VL.

3.0 Inclusion Criteria

- Adult patients scheduled for elective, ambulatory surgery requiring general anesthesia and endotracheal intubation.

4.0 Exclusion Criteria

- Patients who require rapid sequence induction and intubation or fiberoptic intubation.
- Pregnancy

5.0 Enrollment

Sample size calculation was done via inference of means, and using time parameter estimates from prior studies. We will enroll 122 subjects in our pilot study as determined by our sample size calculation for a no difference study on the primary outcome of intubation time whereby a 10 second difference would be considered clinically significant (alpha 0.05, power 0.90).

6.0 Study Method

1. Patients would be identified who meet inclusion/exclusion criteria. After obtaining written informed consent, airway assessment and baseline vital signs would be documented.

2. Information regarding the experience level of the resident/anesthetist assigned to perform the intubation as well as number of prior VL experiences would be collected.

3. The patient would be randomized to one of two groups: intubation via use of the Glidescope VL then King Vision VL, or the King Vision VL then Glidescope VL.

4. Before the intubations, one of the investigators will educate the airway provider about proper use of the device.

5. In the operating room, patients would undergo application of monitors and induction of anesthesia per routine.

6. Patients would then be intubated with the devices in random order.

7. The intubation time will be recorded as the time from the introduction of the VL into the oral cavity to ETT reaching the glottic aperture. The actual intubation would occur during the second device.

8. An attempt failure will be defined as the inability to visualize the glottis and/or successfully pass the endotracheal tube within 90 seconds or before the oxygen saturation falls below 90%.

9. When an attempt is deemed to have failed the patient will receive mask ventilation and will then be intubated with standard direct laryngoscopy or other method at the discretion of the anesthesia team.

10. Additional data collected will include:

- Lowest pulse oximetry saturation value reading during intubation
- Assistance required during the intubation (larngeal manipulation, head lift, etc.)
- Notation of any injury to lips, teeth, soft tissue.

7.0 Reporting of Adverse Events or Unanticipated Problems involving Risk to Participants or Others

Information regarding AEs will be obtained by examining the patients and questioning them postoperatively in the recovery room. All new complaints and symptoms (i.e., those not existing prior to signing of informed consent) must be recorded on the AE CRF. All AEs must be characterized in terms of their start and stop dates, start and stop times, intensity, action taken, relationship to research study, subject outcome and whether or not the AE led to an SAE.

8.0 Statistical Considerations

Statistics including means, medians, and variances will be calculated on variables of interest.

All individual data (including any relevant derived variables) will be stored in a password protected electronic database.

9.0 Privacy/Confidentiality Issues

All reasonable efforts will be made to keep a patient's protected health information (PHI) private and confidential. There will be limited access to medical records and de-identification of all records. Federal privacy guidelines will be followed when using or sharing any protected health information.

10.0 Follow-up and Record Retention

The study will be completed after the participation of 122 patients. This data will be used to draw conclusions about use of the King Vision VL as compared with the Glidescope VL.

The investigator will keep a record (i.e., Master Subject Log) relating the names of the subjects, date informed consent was signed, subject status, and date when subject completed the trial.