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Clinical paper

A pilot, prospective, randomized trial of video versus direct laryngoscopy for paramedic endotracheal intubation

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ABSTRACT

Background: Prehospital intubation poses several unique challenges. Video assisted laryngoscopy has been shown to help increase intubation success in the hospital setting; however, little prospective data have examined video assisted laryngoscopy in traditional ground ambulance agencies.
Methods: We performed a randomized, cross-over, non-blinded trial in ground ambulances comparing first attempt success and overall intubation success between video assisted laryngoscopy using the King Video Laryngoscope (KVL) and direct laryngoscopy (DL). We collected patient and provider demographics along with intubation details. Success rates were compared on a per-protocol and an intention-to-treat analysis.
Results: Over 34 months, a total of 82 intubations were performed with 42 DL and 40 KVL based on the intention-to-treat analysis. First attempt success (28/42, 66.7% vs 25/40, 62.5%, p = 0.69) and overall success (34/42, 81% vs 29/40, 72.5%, p = 0.37) were similar between DL and KVL. Cormack-Lehane view and percentage of glottic opening were similar between devices. These results were consistent in the per-protocol analysis.
Conclusions: In our study utilizing two ground EMS agencies, video assisted laryngoscopy with the KVL had similar first attempt success rates to direct laryngoscopy.

Introduction

Endotracheal intubation (ETI) is one of the most critical skills performed by prehospital providers and has been advocated for decades as a method to improve the care of the critically ill patient in the prehospital setting [1]. This complicated skill can be lifesaving when performed correctly; however, can lead to complications including hypoxia, brain damage and even death if performed incorrectly [2–4]. Success with ETI in the prehospital setting can range from 45 to 99% and multiple intubation attempts can increase the risk of complications with ETI [5,6].

Recently, the development of video assisted laryngoscopy (VL) for ETI has improved first attempt and overall success rates with ETI in other acute settings [7,8]. While previous work has shown success with video laryngoscopy in the prehospital setting, the high cost of many initial devices on the market has limited their market penetration, especially among ambulance services with smaller operating budgets [9,10]. Newly developed video laryngoscopes including the King Video Laryngoscope (KVL, Ambu, Denmark) are less expensive than previous devices and observational data suggest improved ETI success in the prehospital setting however prospective data are limited [11]. Also, previous work has examined VL in agencies with high rates of intubation [9,10]. There are limited prospective data examining how VL performs in traditional, ground-based emergency medical services (EMS) agencies.

We hypothesized the use of the KVL would improve the first attempt success and overall success in prehospital intubations as compared to direct laryngoscopy.

Methods

Study design

We performed a preliminary, randomized, crossover, non-blinded trial comparing first attempt success between video laryngoscopy (KVL) and direct laryngoscopy. This study was approved by the Saint Vincent Heath Center Institutional Review Board with waiver of the requirement for informed consent [9]. In

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order to ensure relevant stakeholders were aware of the protocol, we also had the protocol reviewed by, and obtained approval from the local medical command authority physician for each agency, the Pennsylvania Department of Health, Bureau of EMS and the regional EMS council. This study was registered with ClinicalTrials.gov (NCT02208349).

Setting

We performed this study using one suburban and one rural EMS service in Pennsylvania, each chosen due to a shared medical command authority at the initiation of the study. Each EMS service uses one paramedic and one emergency medical technician (EMT) per advanced life support (ALS) unit. The suburban ambulance agency responds to roughly 6500 calls annually while the rural agency responds to roughly 2500 calls annually. Pennsylvania does not allow the use of neuromuscular blocking agents by ground EMS agencies and only a selection of staff are approved to use sedation. Neither of the EMS services included is approved to use sedation-assisted intubation in Pennsylvania.

Selection of patients

We included all patients where the provider made the decision to perform endotracheal intubation. Patients were excluded if no intubation attempts were made (e.g. bag-valve-mask only), blind or nasotracheal intubation was attempted primarily, or patients were believed to be under the age of 18.

Interventions

We equipped six ambulance bases (four suburban and two rural) with either KVL (intervention arm) or traditional direct laryngoscopy (DL) (control arm). The laryngoscope (KVL vs DL) was randomly assigned to the ambulances in each group at the beginning of the study and each base crossing over to the opposite arm at six-month intervals.

Providers were instructed to use the intended device (KVL or DL) for the first intubation attempt when the decision was made by the provider to perform intubation. Subsequent intubation attempts could be made using whichever device the provider chose; KVL (if available), DL, or other techniques such as supraglottic airways (SGA) or bag-valve-mask ventilation (BVM). In discussions with our state EMS board, local municipalities and Institutional Review Board, we did not dictate when providers elected to perform intubation. Providers were allowed to select whatever means they felt most appropriate for managing the airway (SGA, BVM, ETI, etc.); however, if intubation was performed, providers were asked to use the device specific to the current study arm. As our providers had previous experience with DL and to ensure patient safety, providers were allowed to revert back to DL from the KVL at any time they were in the intervention arm.

All paramedics from the participating agencies attended an initial training session consisting of a didactic presentation of the study purpose, study protocol, and continuing education on both direct and video laryngoscopy. Providers completed a standardized didactic and hands-on training session on the device they would be using during the study period. This didactic presentation provided an overview of each device and its appropriate use. Providers also took a written exam at after to ensure appropriate knowledge. They then had performed proctored intubations on a manikin using each device and were provided real-time feedback on their technique. Providers were allowed to practice with each device until both they and the instructor felt comfortable with their technique. The training course (including both the didactic and skills practice) was repeated at three-month intervals for the duration of the study.

Once the study was initiated, the paramedics continued to follow Pennsylvania prehospital intubation protocols, which limit the number of intubation attempts to three before switching to a supraglottic airway. For paramedics in the control arm of the study, there was no change in the care delivered. For the KVL intervention arm, paramedics were instructed to make the first attempt using the KVL. In the event of an unsuccessful first attempt at intubation, providers were to continue with the Pennsylvania state protocols for failure to intubate, and could then revert to DL at any time. Every intubation attempt and method was logged on a data collection form. While in the control arm (DL), providers could use whichever type of DL blade they felt most comfortable with (Macintosh or Miller). We did not dictate blade size or endotracheal tube size.

Outcome and other measures

Each intubation during the study period was recorded utilizing a standard data collection form. Providers were asked to complete this form after each intubation. Reports were generated monthly from the EMS charting system to ensure forms were completed on all intubations. An ETI attempt was defined as any time the tip of the laryngoscope blade passed the patient's lips. First attempt success was defined as the successful placement of an endotracheal tube on the first ETI attempt. Overall success was defined as successful placement of the endotracheal tube within three attempts as allowed by Pennsylvania protocol. Glottic view as defined by both Cormack-Lehane grade and percentage of glottic opening (POGO) score [12,13]. Pictures detailing Cormack-Lehane grade and POGO score were included on the standardized data collection form to minimize variability in reporting across providers.

Our primary outcome was first attempt success. We also examined overall intubation success and glottic view as measured by Cormack-Lehane grade and percentage of glottic opening (POGO) score.

Data collection and analysis

Prior to the initiation of the study, we assessed the average annual intubation numbers and first attempt success and determined the two EMS agencies involved in the study have historically combined for nearly 100 intubations annually with an first attempt success rate of 65%. Assuming a 15% missing data rate, we estimated needing 100 subjects to have 80% power to detect a 20% absolute increase in first attempt success (65% vs 85%.) or an approximately 50% reduction in the number of unsuccessful first attempts [10]. We also we felt this difference represented a large enough improvement to justify the financial and time commitment needed to introduce video laryngoscopy into an EMS system.

Paramedics were asked to document all intubation attempts using a pre-approved form by the State Medical Advisory Committee. This form allowed for standardized data collection of patient related factors (age, sex, etc.) at the time of the intubation. This form also allowed for the paramedics to record other intubation related factors (e.g. difficult intubation characteristics) based on previously published data examining intubation details [14–17]. Each EMS organization had a quality assurance program in place that reviewed all intubations monthly and ensured all documentation was completed as soon as possible after the intubation.

The data were analyzed with descriptive statistics. First attempt success and overall success rates were compared using the chi-squared and the glottic views were compared using the Wilcoxon-rank sum test. Given previous observations suggesting KVL may improve intubation outcomes, we sought to determine superiority of KVL over DL [11]. As such, our primary analysis was performed as an intention-to-treat (ITT) analysis to minimize bias [18]. If a provider felt the patient was more appropriate for DL