FOCUS ON AIRWAY MANAGEMENT

COMPARISON OF SUCCESS RATES BETWEEN TWO VIDEO LARYNGOSCOPE SYSTEMS USED IN A PREHOSPITAL CLINICAL TRIAL

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ABSTRACT

Objectives. The primary aims of this study were to compare paramedic success rates and complications of two different video laryngoscopes in a prehospital clinical study. **Methods.** This study was a multi-agency, prospective, nonrandomized, cross over clinical trial involving paramedics from four different EMS agencies. Following completion of training sessions, six Storz CMAC™ video laryngoscopes and six King Vision™ (KV) video laryngoscopes were divided between agencies and placed into service for 6 months. Paramedics were instructed to use the video laryngoscope for all patients estimated to be ≥ 18 years old who required advanced airway management per standard operating procedure. After 6 months, the devices were crossed over for the final 6 months of the study period. Data collection was completed using a telephone data collection system with a member of the research team (available 24/7). First attempt success, overall success, and success by attempt, were compared between treatment groups using exact logistic regression adjusted for call type and user experience. **Results.** Over a 12-month period, 107 patients (66 CMAC, 41 KV) were treated with a study device. The CMAC had a significantly higher likelihood of first attempt success (OR = 1.85; 95% CI 0.74, 4.62; p = 0.188), overall success (OR = 7.37; 95% CI 1.73, 11.1; p = 0.002), and success by attempt (OR = 3.38; 95% CI 1.67, 6.8; p = 0.007) compared to KV. Providers reverted to direct laryngoscopy in 80% (27/34) of the video laryngoscope failure cases, with the remaining patients having their airways successfully managed with a supraglottic airway in 3 cases and bag-valve mask in 4 cases. The provider-reported complications were similar and none were statistically different between treatment groups. Complication rates were not statistically different between devices. **Conclusion.** The CMAC had a higher likelihood of successful intubation compared to the King Vision. Complication rates were not statistically different between groups. Video laryngoscope placement success rates were not higher than our historical direct laryngoscopy success rates. **Key words:** airway management; paramedics; video laryngoscope; emergency medical services

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INTRODUCTION

Video laryngoscopy (VL) has become popular as a primary device for airway management in the emergency department (ED). Use of this tool in the prehospital setting is also gaining traction. Emergency medical services (EMS) providers regularly encounter difficult airways due to emesis, blood or other fluid in the airway, facial or neck trauma, or cervical spine immobilization. VL has been proposed as an ideal approach in these situations, due to the ability to better visualize the patient's vocal cords and ideally promoting a more successful endotracheal tube placement rate.

Clinical simulation studies and a limited number of trials with live patients have been conducted with various video laryngoscopes in the prehospital setting with mixed results. Generally, EMS provider success rates in standard airways during clinical simulation trials range from 80 to 100%.[1–9] The success rate for

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difficult airway scenarios in this setting (e.g., c-collar, manikin positioning, chest compressions) varies between 50 and 100%, which is higher than the success rates reported for direct laryngoscopy in each of these studies.[1–5,7,8] A recently published simulated difficult airway study examining the use of 5 different airway devices, including video laryngoscopes, showed no difference in placement success rates between video laryngoscope systems and direct laryngoscopy.[10] Time to airway placement for EMS providers has not been shown to be consistently faster with VL.[1,2,5–7] In fact, in one emergency department study, video laryngoscopy increased the time to intubation without increasing the first-attempt success rate.[11] A preliminary report of VL using the CMAC device in helicopter EMS reported a 76% first-attempt success rate, with 98% of all patients successfully intubated within 3 attempts.[12] The recently published full report showed no difference in number of placement attempts, first-pass success rate, or the use of rescue airways between CMAC and direct laryngoscopy, but did show a superior glottic view for patients treated with CMAC.[13] Importantly, this study was conducted with a cohort of helicopter EMS providers who perform endotracheal intubation with a much higher frequency than is routinely encountered in ground EMS. This limits the generalizability of this study's conclusions regarding VL and the utility of this technology in EMS services with fewer opportunities for endotracheal intubation remains unclear.

To date, no clinical trial has compared paramedic placement success rates between two different video laryngoscope systems in a nonsimulation setting. Given the promise of VL but the limited evidence supporting its use in the prehospital setting, we evaluated the success rates of two different video laryngoscopes in a multiagency, prospective, nonrandomized, crossover clinical study. Our primary study objective was to determine if there was a difference in the first-pass or overall intubation success rates for the CMAC video laryngoscope as compared to the King Vision video laryngoscope, in adult, out-of-hospital patients requiring advanced airway management.

METHODS

Study Design

This study was an IRB-approved, multiagency, prospective, prehospital, nonrandomized, crossover trial comparing paramedic success rates and complications for two video laryngoscope systems (Storz CMAC, Macintosh #4 blade; King Vision, size 3) to each other.

Setting

The four EMS agencies involved in the study provide 9-1-1 service to approximately 460,000 residents over 359 square miles, with a combined annual run volume of approximately 34,000. The service models varied, with one urban, fire-based, full-time paid, single-tier agency; two suburban, fire-based agencies (one paid on-call and one full-time paid); and one suburban, hospital-based, third service full-time paid agency. All three fire-based services provided first response and transportation capabilities. The third service agency partners with its local fire department to provide BLS first response on high-acuity calls, but ALS care and transportation are only offered by the ambulance service. Due to device availability, devices were placed in the six highest-volume intubating EMS units in the urban and suburban services.

Participants, Consent, and Training

All eligible paramedics working at the stations where the study devices were available attended an initial training session and were asked to provide their consent. The first part of the training session consisted of a didactic presentation of the study purpose, study protocol, and information about consenting for participation. All consenting providers then completed a standardized 1-hour didactic and hands-on training session on the device they would be using during the first 6-month study period. Each provider was required to demonstrate competence by performing an intubation with their assigned video laryngoscope on a simulation mannequin placed on the floor under the direct supervision of one of the service medical directors. At 5 months into the study, consented providers were trained in the use of the crossover device that was placed on their EMS unit at the 6-month mark.

Intervention

The Storz CMAC (Tuttlingen, Germany) (Figure 1) consists of 3 parts: a reusable video laryngoscope blade, a handle containing the video components and control buttons for recording and changing the screen lighting, and the video display. There are multiple laryngoscope blades available, but only the size 4 Macintosh blade was used during the study. This device has a digital video display with enhanced image processing for real-time visualization of the airway. This

FIGURE 1. Karl Storz CMAC video laryngoscope.

FIGURE 2. King Systems King VISION.

device is unique in that it also allows the user to perform direct laryngoscopy, in the event the monitor display fails.

The King Vision (KV), manufactured by King Systems (Noblesville, Indiana, USA) (Figure 2), is a 2-piece, plastic video laryngoscope. This 2-piece, plastic device includes a reusable display and a disposable, channeled blade used to facilitate delivery of the endotracheal tube into the patient's trachea. Size 3 channeled blades were the only blades used during this study. The reusable display is battery-operated and is seated on the top of the laryngoscope blade prior to use. This device does not have recording capabilities.

Study Protocol

Six CMAC devices were placed in the urban service, and 6 KV devices were placed in the suburban agencies following a coin flip that determined device order. Paramedics were instructed to use the assigned video laryngoscope for all patients known or estimated to be ≥18 years old who required advanced airway management per uniform patient treatment guidelines established by medical direction. Exclusion criteria included 1) treating EMS provider was not trained in use of VL and 2) patient had supraglottic airway placed prior to paramedic arrival. CMAC device users were instructed to perform indirect laryngoscopy by using the video monitor and to record their placements for quality assurance use at the conclusion of the study. Following airway management with the study device, paramedics contacted the study hotline staffed 24/7/365 by the study team to complete data collection. The research team members were responsible for disposable KV blade and CMAC SIM card resupply through the duration of the trial. To ensure complete data capture for all advanced airway management cases, the research team attempted to perform quality assurance data checks weekly using a standard report within each agency's electronic medical record. If it appeared the study devices were not used on a patient who met all inclusion criteria, contact with the individual paramedics was attempted for additional information and remediation.

To facilitate continued interest in the study and adherence to the study protocol, all participating paramedics received a monthly e-mail outlining a specific educational topic related to the trial. They were entered into a $50 gift card drawing if they electronically responded to the study staff's "message of the month." The research team reviewed study data each month in a blinded fashion (device A vs. device B) for safety and efficacy endpoints. An a priori stop criteria of overall success rate of 50% or less for either device was established during the first monthly meeting.

Variable Definitions

Placement attempt was defined as tip of the video laryngoscope blade passing the patient's lips. First-attempt success rate was defined as the number of successful placements occurring on the first placement attempt. Overall success rate was calculated as the total number of successful placements divided by the total number of patients treated. The success by attempt rate was defined as successful placement of the ET tube divided by the total number of attempts.

Sample Size

Our study was constrained by a 12-month data collection period due to device availability. Target enrollment of 168 cases was determined by evaluating historical volumes of advanced airway management events over 12 months. With this enrollment volume, this study was powered at 80% to show a 22% (63 vs. 85%) difference in overall insertion success rate between systems.

Data Analysis

Patient (age, gender, BMI, race, ethnicity, primary impression, call type, and difficult airway) and provider (age, gender, years of experience, >1 VL placement during study period, agency, and phase) demographics were compared for equality between groups. First-attempt success, overall success, and success by attempt were compared between treatment groups using unadjusted chi-squared analysis. Exact logistic regression adjusted for call type (medical vs. trauma) and user experience was then performed, using the King Vision device as the reference device. Adjustments to our analysis to account for the monthly blinded safety and efficacy review were not performed, as no statistical testing was performed during those reviews. Complications were compared using unadjusted chi-square tests. The Cormack-Lehane (CL) score for each attempt was also analyzed for impact on success rates using a generalized linear mixed-effects model.

TABLE 1. Patient and provider demographics

	Total ($n = 107$)	CMAC ($n = 66$)	KV ($n = 41$)	p-value
Patient demographics				
Age (yrs)	58.4 (54.7, 62.2)	56.7 (52.0, 61.4)	61.3 (55.1, 67.5)	0.226
Gender (% male)	70.1 (60.8, 78)	71.2 (59.4, 80.7)	68.3 (53, 80.4)	0.829
Race (% Caucasian)	79.4 (70.8, 86.0)	77.3 (65.8, 85.7)	82.9 (67.7, 91.5)	0.624
Ethnicity (% Non-Hispanic)	93.5 (87.1, 96.8)	93.9 (85.4, 97.6)	92.7 (80.6, 97.5)	1
BMI (kg/m^2)	28.4 (26.9, 30.0)	28.1(26.0, 30.2)	29 (26.7, 31.4)	0.554
Primary impression (% cardiac arrest)	73.8 (64.8, 81.2)	74.2 (62.6, 83.3)	73.2 (58.1, 84.3)	1
RSI (%)	10.3 (5.8, 17.5)	15.2 (8.4, 25.7)	2.4 (0.5, 12.6)	0.035
Call type (% medical)	88.8 (81.4, 93.5)	83.3 (72.6, 90.4)	97.6 (87.4, 99.6)	0.027
Difficult airway (% yes)	76.6 (67.8, 83.7)	78.8 (67.5, 86.9)	73.2 (58.1, 84.3)	0.639
Provider demographics				
Age (yrs)	38.5 (36.8, 40.2)	38.8 (36.6, 41.1)	37.9 (35.3, 40.6)	0.713
Gender (% male)	83.5 (75.2, 89.4)	82.5 (71.4, 90)	85 (70.9, 92.9)	0.793
Experience (yrs)	11.2 (9.9, 12.5)	11 (9.3, 12.8)	11.5 (9.6, 13.5)	0.615
Experienced user (>1 attempt during study period)	63.2 (53.7, 71.8)	56.1 (44.1, 67.4)	73.2 (58.1, 84.3)	0.1
% Devices placed in first 6 months	53.3 (43.9, 62.5)	48.5 (36.8, 60.3)	61 (45.7, 74.4)	0.236

Values are means (95% CI) or percentages (95% CI). CMAC = Storz CMAC, KV = King Vision.

RESULTS

Out of 187 total paramedics eligible to participate in the study, 186 (99%) elected to participate. Between October 2011 and October 2012, a total of 162 patients met the inclusion and exclusion criteria for VL use, with 107 patients treated with a study device (66 CMAC, 41 KV) by 63 of 186 (34%) trained providers (Figure 3). No differences in provider characteristics were noted between groups. The only patient characteristics statistically different between groups were the percentage of patients with medical mechanisms of injury and the use of RSI (Table 1).

In the unadjusted chi-squared analysis, the CMAC had a higher first-attempt ($p = 0.02$), overall ($p = 0.003$) and success by total attempts ($p < 0.001$) success rate compared to the KV (Figure 4). After adjusting for call type and user experience, the CMAC still had a significantly higher likelihood of first-attempt success (OR = 1.85; 95% CI 0.74, 4.62; $p = 0.188$), overall success (OR = 7.37; 95% CI 1.73, 11.1; $p = 0.002$), and success by attempt (OR = 3.38; 95% CI 1.67, 6.8; $p = 0.007$) compared to KV. Figure 5a shows that the cumulative success rate over time for the CMAC device was relatively consistent through the duration of the study. In contrast, the success rate for the KV continued to decline throughout the study. Figure 5b shows the success rates for each device in both phase 1 and phase 2 of the study.

With the CMAC, providers reported that they only used indirect laryngoscopy techniques via the video display in 98% of placement attempts, with the remaining case using both the display and direct laryngoscopy to facilitate tracheal intubation. Providers reverted to direct laryngoscopy in 80% (27/34) of the video laryngoscope failure cases with the remaining 7 patients having their airways successfully managed with a supraglottic airway in 3 cases and bag–valve mask in 4 cases. Of the 27 patients in whom direct intubation techniques were used, 89% (24/27) had an endotracheal tube successfully placed.

A total of 49 complications were reported by providers (24 CMAC; 25 KV). The most frequent complication reported for the CMAC was vomit during (21%; 5/24) or after insertion (17%; 4/24). For the KV group, screen failure was the most often reported complication (20%; 5/25).

The Cormack-Lehane score was also predictive of first-attempt success, overall success, and success by placement rate. A provider's odds of successfully

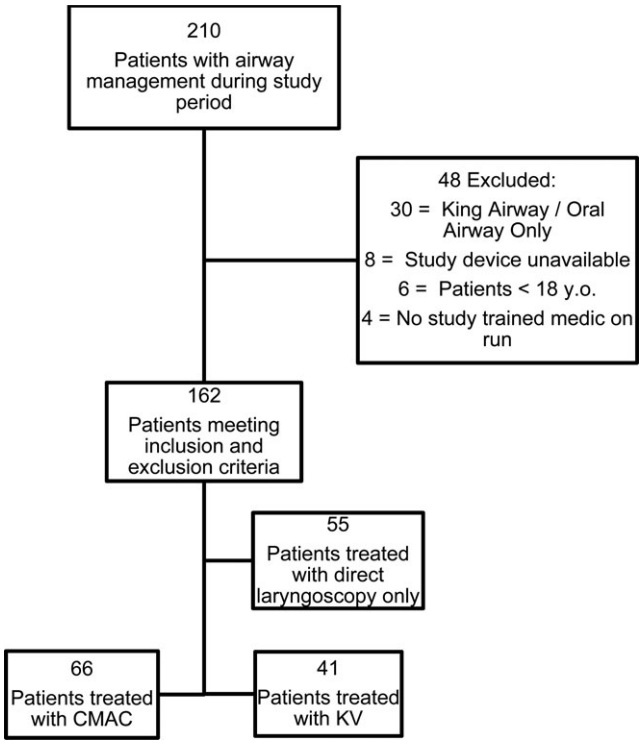
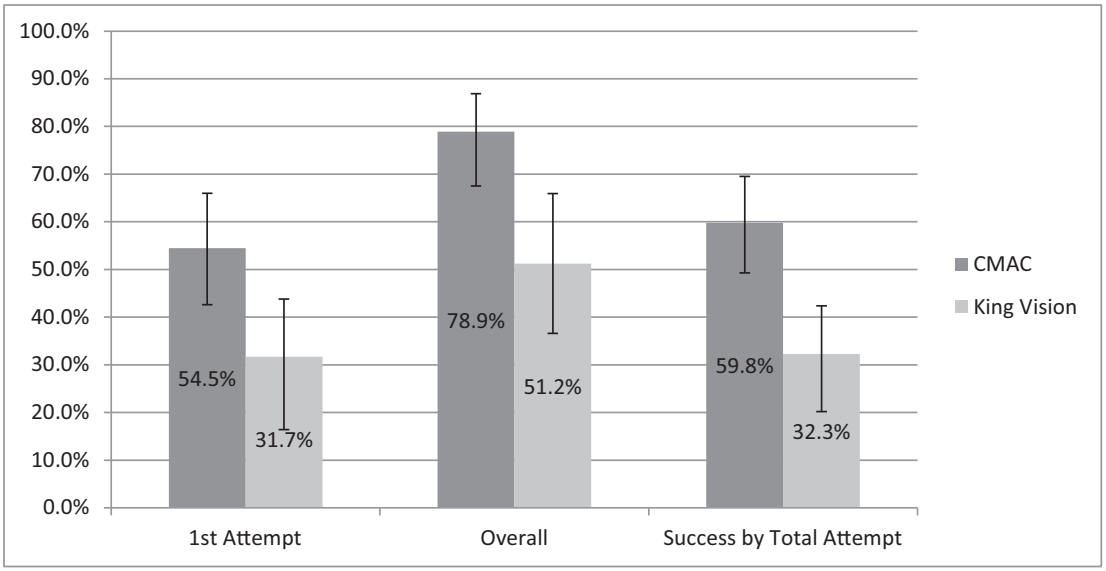


FIGURE 3. CONSORT-style enrollment diagram.



Success Rate		CMAC	King Vision	p-value
1st Attempt	Raw	36/66	13/41	0.02
	Percent (95% CI)	54.5% (42.6, 66.0%)	31.7% (19.6, 47.0%)	
Overall	Raw	52/66	21/41	0.003
	Percent (95% CI)	78.9% (67.5, 86.9%)	51.2% (36.5, 65.8%)	
Success by Total Attempts	Raw	52/87	21/65	<0.001
	Percent (95% CI)	59.8% (49.3, 69.5%)	32.3% (22.2, 44.4%)	

Figure 4. First attempt, overall, and success by attempt rates for the CMAC and KV.

placing an endotracheal tube with a video laryngoscope decreased 62%, 70%, and 64% with each 1-point increase in the 4-point scale, respectively.

Enrollment in the KV arm of the trial was halted at month 10 due to an overall success rate hovering near 50% for 3 consecutive months (Figure 5b). Due to the proximity of that rate to the predetermined a priori stopping criteria, the study team determined it was futile to continue enrollment in that treatment arm. Providers placed an additional 7 airways using the CMAC following the end of enrollment into the KV arm.

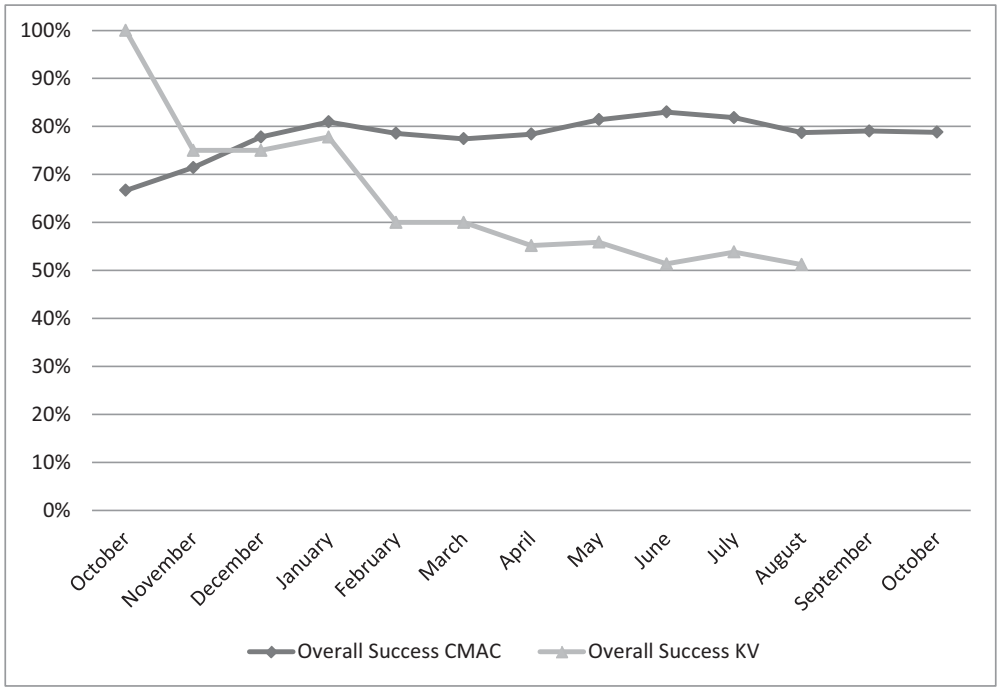
Discussion

Results of this prehospital trial of video laryngoscopes in a real-world setting showed lower overall success rates than those previously published in laboratory trials. Success rates with the CMAC device were lower than those reported for high-frequency intubators in air medical transport systems; however, the difference in intubation success rates between helicopter EMS and ground EMS have been previously reported.[14] Our provider success rate with the King Vision device was lower than anticipated. The KV overall success rate declined steadily throughout the trial until a point was reached where we felt compelled to stop enrollment.

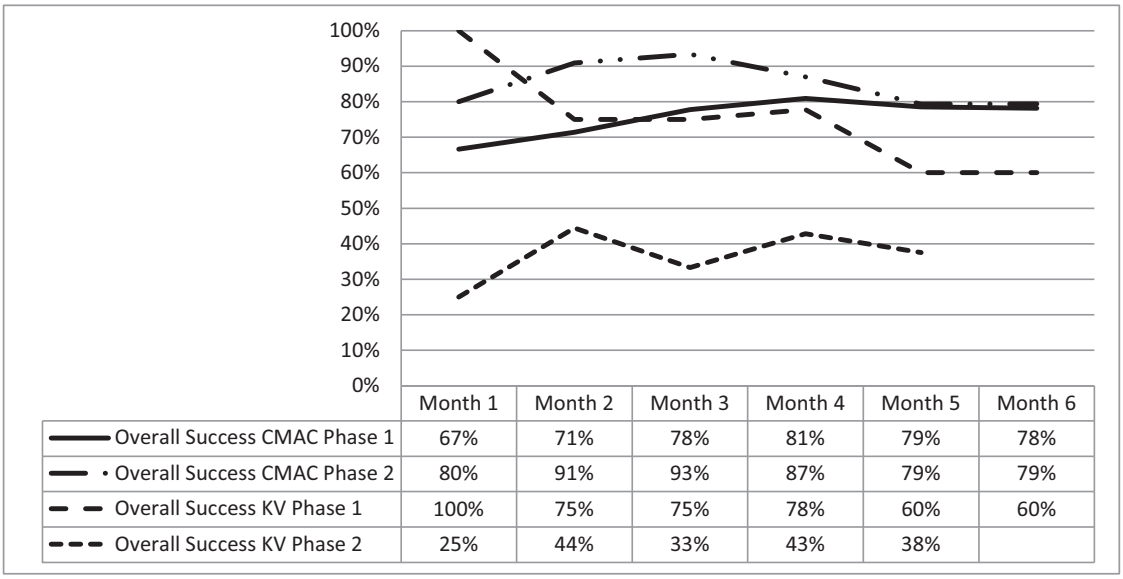
Our data showed a higher incidence of screen failure with the KV compared to the CMAC. This was due primarily to a disruption in the connection between the disposable blade and the reusable display module. While the CMAC is a reusable device constructed of metal and weighing several pounds, the KV is lightweight, made of plastic, and has a disposable blade. These design features result in very different tactile response between the devices. The grip and hand position on the KV is different from a traditional laryngoscope, with the providers needing to hold the handle with their thumb, index finger, and middle finger only. The more traditional full hand grip places the provider's hand close to or on top of the area where the blade connects to the screen, and as upward pressure is applied during placement, the provider's hand has a tendency to pull the display module apart from the disposable blade. The observation that 12% (5/41) of all KV placements resulted in the screen detaching from the blade was shared with the device manufacturer, who reported an engineering fix was in development for future KV models. Unlike the KV, the CMAC handle allowed providers to grip the handle with all fingers similar to a traditional direct laryngoscope.

In addition to the different technique for holding the device, the actual endotracheal tube placement technique for the KV is significantly different from

(a)



(b)



	Month 1	Month 2	Month 3	Month 4	Month 5	Month 6
Overall Success CMAC Phase 1	67%	71%	78%	81%	79%	78%
Overall Success CMAC Phase 2	80%	91%	93%	87%	79%	79%
Overall Success KV Phase 1	100%	75%	75%	78%	60%	60%
Overall Success KV Phase 2	25%	44%	33%	43%	38%	

FIGURE 5. (a) Cumulative success rates for CMAC and KV over the study period. (b) Cumulative overall success rates by study phase for CMAC and KV.

techniques employed during direct laryngoscopy. The channeled blade guides the endotracheal tube during placement, where it exits to the right of the camera located at the end of the blade. The view displayed on the monitor often times is optimal, but as the ET tube exits the channel, it requires rotation of the tube as the provider guides it toward the vocal cords. Providers needed to ensure they employed this new placement technique during a high-stress situation in an austere environment, which may also have contributed to the lower than anticipated success rates.

The CMAC was associated with both a statistically significant and clinically significant improvement in each measure of successful tracheal intubation compared to the KV. The higher likelihood of first-attempt success (OR 2.58) and success by attempt (OR 3.11) is particularly important, as the number of adverse events associated with tracheal intubation has been

linked to the number of intubation attempts.[15] However, video laryngoscopy did not guarantee that our providers were able to intubate the trachea in all cases. The most common successful backup method in failed video laryngoscopy cases was direct laryngoscopy with a standard laryngoscope. The fact that 27 of the 34 failed cases had direct laryngoscopy attempted and an 89% direct laryngoscopy success rate emphasizes the need for paramedics to maintain proficiency in the skill of direct laryngoscopy. There were 7 airways in which the trachea could not be successfully intubated with either video or direct laryngoscopy. Our providers were able to oxygenate and ventilate each of these patients by utilizing backup techniques, including supraglottic airways (King LTS-D) in 4 instances and oropharyngeal/nasopharyngeal airways with BVM ventilation in 3 cases. These 7 patients suggest that even with video laryngoscopes and paramedics skilled in direct laryngoscopy, medical directors must insist on proficiency in supraglottic airway placement and BLS techniques. While video laryngoscopes may add to our paramedic's airway armamentarium, this new skill does not eliminate the need for mastery of alternate methods of airway management.

Enrollment into the KV arm of the trial was halted at month 10 due to a cumulative overall success rate of near 50% for 3 consecutive months. While this rate did not actually cross the a priori determined stopping point of 50%, we felt that it was not in the best interests of our patients to continue this research arm. Contributing to this decision was the steady and consistent degradation in cumulative overall success from January until August (Figure 5a). As noted above, all patients who were not successfully intubated with a video laryngoscope did have their airways successfully managed though a variety of other techniques. There were no patients who could not be intubated and could not be ventilated.

The crossover methodology used in this study may have impacted our study results. The cumulative success rates for the CMAC device were similar from month 1 to month 6 within phase 1 and phase 2. In contrast, cumulative success rates were consistently lower in phase 2 compared to phase 1 (Figure 5b). The agency using the KV in phase 2 started the study with the CMAC device. A provider device bias could therefore have been introduced into the study by the crossover design. Specifically, having to deploy the unique technique required by the KV 6 months into the research trial may have been more challenging for providers who were assigned the KV in phase 2 as compared to those who began the trial with the KV in phase 1.

An additional important factor when considering our results is the number of patients treated with direct laryngoscopy without an attempt at video laryngoscopy. As noted in Figure 3, this number was 34% (55/162) of the sample of patients meeting eligibility criteria. Despite study staff attempts to conduct weekly quality assurance reporting and timely follow-up with individual providers, noncompliance with the study protocol remained a concern during the study. We did not prospectively track reasons for noncompliance following contact with each paramedic. Of the 55 patients not treated with VL, 23 (41%) were seen in phase 1 and 32 (58%) in phase 2. When examined by the agency, there were no significant differences in noncompliance when total airway management volume during the study period was taken into account.

The overall intubation success rates with the CMAC were not higher than the historical direct laryngoscopy success rate in our services. However, we believe video laryngoscopes do provide important secondary benefits. One benefit of the CMAC device was the ability to record intubations for later review by the service medical director. In this way the medical director was "on-scene" with the intubating paramedic even when not physically present. We were able to identify specific technique failures in unsuccessful intubations, which would allow for individualized remediation of the intubating paramedic. We were also able to observe when chest compressions were stopped during intubation. Review of the intubation video allowed us to determine the duration of apnea during the intubation attempt. Moreover, videos documenting challenging intubations that are not encountered frequently may be reviewed with providers who were not actually involved in the intubation. Finally, video evidence of an endotracheal tube passing through the vocal cords is another method of documenting appropriate placement in the trachea. These secondary benefits must be weighed against each individual agency's current direct laryngoscopy performance and philosophy, as well as the financial investment required of services when adding capital equipment to vehicles.

Limitations

There were several limitations to our study, including study noncompliance, a potential provider device bias due to the crossover design, inability to follow a randomization scheme, inability to blind devices, the relatively short data collection period, and provider self-report of data collection variables. In addition, only one size of KV and one size CMAC blade were included in the study. This was done to minimize the number of variables introduced into the study analysis.

Conclusion

The CMAC had a higher likelihood of successful intubation compared to the King Vision. Complication rates were not statistically different between groups. Video laryngoscope placement success rates were not

higher than our historical direct laryngoscopy success rates. A study comparing prehospital use of video laryngoscopes to direct laryngoscopy would provide additional valuable information regarding the utility of video laryngoscopy in EMS.

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