

First-Attempt Intubation Success of Video Laryngoscopy in Patients with Anticipated Difficult Direct Laryngoscopy: A Multicenter Randomized Controlled Trial Comparing the C-MAC D-Blade Versus the GlideScope in a Mixed Provider and Diverse Patient Population

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BACKGROUND: Intubation success in patients with predicted difficult airways is improved by video laryngoscopy. In particular, acute-angle video laryngoscopes are now frequently chosen for endotracheal intubation in these patients. However, there is no evidence concerning whether different acute-angle video laryngoscopes can be used interchangeably in this scenario and would allow endotracheal intubation with the same success rate. We therefore tested whether first-attempt intubation success is similar when using a newly introduced acute-angle blade, that is an element of an extended airway management system (C-MAC D-Blade) compared with a well-established acute-angle video laryngoscope (GlideScope).

METHODS: In this large multicentered prospective randomized controlled noninferiority trial, patients requiring general anesthesia for elective surgery and presenting with clinical predictors of difficult laryngoscopy were randomly assigned to intubation using either the C-MAC D-Blade or the GlideScope video laryngoscope. The hypothesis was that first-attempt intubation success using the new device (D-Blade) is no >4% less than the established device (GlideScope), which would determine noninferiority of the new instrument versus the established instrument. The secondary outcomes we observed included intubation success with multiple attempts and airway-related complications within 7 days of enrollment.

RESULTS: Eleven hundred patients were randomly assigned to either video laryngoscope. Intubation success rate on first attempt was 96.2% in the GlideScope group and 93.4% in the C-MAC D-Blade group. Although the absolute difference between the 2 groups was only 2.8%, the 90.35% upper confidence limit of the difference exceeded the predefined margin (4.98%), indicating a rejection of the noninferiority hypothesis for first-attempt intubation success. For attending anesthesiologists, and upon multiple attempts, intubation success did not differ between systems. Pharyngeal injury was noted in 1% of the patients, and the incidence did not differ between interventional groups.

CONCLUSIONS: Head-to-head comparison in this large multicenter trial revealed that the newly introduced C-MAC D-Blade does not yield the same first-attempt intubation success as the GlideScope in patients with predicted difficult laryngoscopy except in the hands of attending anesthesiologists. Additional research would be necessary to identify potential causes for this difference. Intubation success rates were very high with both systems, indicating that acute-angle video laryngoscopy is an exceptionally successful strategy for the initial approach to endotracheal intubation in patients with predicted difficult laryngoscopy. (Anesth Analg 2016;122:740–50)

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Video laryngoscopy can facilitate endotracheal intubation by providing an improved view of the larynx.^{1,2} Compared with conventional direct laryngoscopy, video-assisted direct laryngoscopy improves the first-attempt success rates of tracheal intubation and decreases intubation difficulty.^{3–5} Moreover, in the unanticipated difficult airway scenario, video laryngoscopes offer a useful rescue technique for failed direct laryngoscopy.^{6,7} Therefore, video laryngoscopy is now widely used for the management of both anticipated and unanticipated difficult endotracheal intubations in anesthetized patients.

A small number of well-powered clinical trials have demonstrated better intubation conditions with video laryngoscopy compared with direct laryngoscopy. It is unclear, however, whether these results can be generalized

to any video laryngoscope or whether improved intubation conditions are device-specific. A few studies have compared several video laryngoscopes with direct laryngoscopes and, while confirming the improved intubation conditions with video laryngoscopy, they were not adequately powered to discern meaningful differences between the video laryngoscopy systems tested.^{5,8-10}

In principle, video laryngoscopy systems can be divided into those that feature classically shaped laryngoscopy blades (e.g., **Macintosh design**) and those that feature acute-angle blades. Video laryngoscopes with classically shaped blades allow visualization either directly or via an image projected onto the video screen. The similarity in design and intubation mechanics of these blades should allow for an appropriate comparison of these devices against conventional direct laryngoscopes and thus demonstrate the value of video imaging. In contrast, video laryngoscopes such as the GlideScope™ (Verathon, Bothell, WA) and C-MAC® with D-Blade™ (Karl Storz, Tuttlingen, Germany) feature blades with **acute angles designed for use in the difficult airway, particularly if a more anterior laryngeal position is suspected.** Acute-angle video laryngoscopy fully depends on video visualization of the glottis and thus converts the passage of the breathing tube into an indirect procedure. This renders comparisons of acute-angle video laryngoscopy versus direct or video-assisted laryngoscopy difficult to interpret.

Since its introduction to perioperative practice, acute-angle video laryngoscopy has profoundly changed the management of patients with difficult airways. It remains unknown, however, whether different acute-angle video laryngoscopy systems offer the same intubation success rates and thus can be used interchangeably. This is particularly important because certain acute-angle video laryngoscope blades are elements of larger airway management systems, whereas others are the characteristic part of single-purpose devices.

Previous trials of video laryngoscopes have been powered around intubation difficulty (i.e., laryngeal view) rather than success rate and have reported first-attempt intubation success rates from 88% to 100%.^{3,5,7-9} While remarkable, such results also suggest that up to 12% of patients cannot be intubated on the first attempt with one or the other acute-angle laryngoscope. Therefore, head-to-head comparisons of intubation success with particular devices under the same controlled conditions have high clinical relevance. Reliable results can guide the individual anesthesiologist's selection of a primary device in a challenging patient, as well as guide entire practice groups when establishing new standards. The high success rates with acute-angle video laryngoscopy also influence any potential study design: feasibility concerns suggest that a head-to-head comparison of success rates with these instruments may only determine whether one device is not worse than the other (noninferiority), while trying to determine superiority of one versus the other may not be feasible.

On the basis of the earlier considerations, we conducted a large multicentered, randomized controlled trial to test the hypothesis that first-attempt success in endotracheal intubation using the C-MAC with D-Blade is noninferior to

first-attempt success using the GlideScope in anesthetized patients with predictors of difficult direct laryngoscopy.

METHODS

The study was conducted at 3 academic institutions: Oregon Health & Science University (Portland, OR), The University of Iowa (Iowa City, IA), and The University of Texas at Houston (Houston, TX) and was pre-registered at ClinicalTrials.gov (NCT01632683). The study was approved by the IRBs of all 3 sites. Patients were enrolled at all 3 centers, while a separate group of individuals at the University of Iowa, who were not involved with patient enrollment, served as the Data Management Group. Oregon Health & Science University served as the coordinating center. The study was designed as a single-blind, 2 parallel arm, randomized, controlled noninferiority trial comparing the C-MAC video laryngoscope with D-Blade to the GlideScope video laryngoscope with a **no. 4 blade** in patients with predictors of difficult direct laryngoscopy.

Patient Selection

Patients were enrolled from May 2013 to June 2014. **The history and physical examinations of all patients scheduled for surgery were screened preoperatively for predictors of difficult airway management.** Patient recruitment was conducted by one of the investigators and/or a research assistant at each site. All study patients provided written informed consent for treatment. Patients were included if they required orotracheal intubation with a single-lumen tube under general anesthesia with neuromuscular blockade and had one or more of the following objective predictors of potentially difficult direct laryngoscopy: (1) Mallampati classification score of III or IV (assessed in the sitting position, tongue protruding, and without phonation), (2) reduced mouth opening (<3 cm measured midline from upper to lower teeth or gum), or (3) enlarged neck circumference (>40 cm for males, 38 cm for females, measured at the level of the cricoid cartilage). The following criteria resulted in exclusion of patients from the study: (1) a documented easy tracheal intubation at a prior surgery per previous anesthetic records (success on first attempt with a direct laryngoscope without an exchange catheter or bougie), (2) a history of failed intubation and/or failed bag-mask ventilation per previous anesthetic records, (3) **known unstable cervical spine injury,** (4) age younger than 18 years, (5) **presentation for an emergency surgical procedure,** (6) nasal intubation route, (7) planned awake technique, (8) mouth opening ≤2 cm, and (9) currently incarcerated. In addition to the earlier inclusion criteria, the following additional examination criteria were recorded: neck mobility (normal, limited, or severely limited), jaw protrusion (normal, limited, or severely limited), and thyromental distance.

Education

To ensure uniformity across centers, all participating providers (laryngoscopists and research assistants) were given **didactic instruction on the proper use of the C-MAC D-Blade and the GlideScope, and clinicians were afforded the opportunity to use the devices before the study.** Manikin heads were available at all centers to practice with either device.

All investigators and research team members also participated in an online review and testing module of airway assessment details (e.g., Mallampati scoring), intubation performance, and the defined outcomes of the study. Before clinical participation in the study, all personnel had to pass a test to validate their learning. As a scheduled refresher, the review module and testing were readministered after the interim analysis and a passing grade was again mandated.

All laryngoscopists were required to have experience with video laryngoscopy and at least 6 months of clinical anesthesiology experience. For example, no resident was allowed to participate until at least January of his or her first clinical anesthesia year (CA1, assuming a July 1st start). Nonanesthesia providers (rotators), medical students, and other trainees were excluded from participation in the study.

Anesthetic Management

All patients were administered 100% oxygen. Investigators recorded preinduction position as supine, sniffing, or ramped (external auditory meatus at the level of the sternal notch). Induction of anesthesia was at the discretion of the attending anesthesiologist but included the use of neuromuscular blockade with succinylcholine or a nondepolarizing agent. Patients were deemed to be adequately relaxed with succinylcholine at resolution of fasciculations or after 90 seconds and adequately relaxed with nondepolarizing neuromuscular blocking agents when train-of-4 neurostimulation at the ulnar nerve receded to 1 or 2 twitches.

After confirmation of adequate relaxation, laryngoscopy was performed by attending anesthesiologists, certified registered nurse anesthetists (CRNAs), student registered nurse anesthetists (SRNAs), anesthesiologist assistants (AAs), anesthesiologist assistant students (AASs), or anesthesiology residents. CRNAs, SRNAs, AAs, AASs, and anesthesiology residents were all supervised by an attending anesthesiologist. During induction of anesthesia, both a C-MAC device and a GlideScope were available. A rigid stylet (GlideRite®, Verathon) was used with all tracheal tubes, except when a bougie was used. Because patients randomly assigned in this study presented with a variety of clinical conditions, tracheal tube size could not be standardized. Although not recorded or analyzed, we believe that the large number of patients ($n = 1100$) balanced the distribution of potentially appropriate versus potentially inappropriate tube sizes across both groups. Each of the tubes used for a given patient was prepared before randomization, thereby excluding any potential for bias related to device.

Outcome Measures

The primary outcome measure was intubation success on first attempt. This was defined as tracheal tube placement (confirmed by persistent end-tidal carbon dioxide) with a single blade insertion and without manipulation of the laryngoscope by another provider. An assistant could perform laryngeal manipulation and offer verbal instruction, but manipulation of the laryngoscope by that assistant constituted a failure of the first attempt. Removal of the laryngoscope from the mouth also constituted a failure. For patient safety, additional attempts were managed at the discretion of the attending anesthesiologist with the device of

their choosing, although the final technique used (and the number of attempts) was recorded.

In addition to the earlier measure, a number of secondary measures were recorded. These included analysis of first-attempt intubation success with the device actually used (versus the device randomized), rescue devices used, airway-related complications, and other variables of intubation difficulty as discussed later. The research team member recorded the best laryngeal view obtained, on the Cormack-Lehane scale,¹¹ as reported by both the laryngoscopist and per their own observation of the video screen. Laryngoscopy time was defined as the interval between blade insertion into the mouth and first recording of end-tidal carbon dioxide. External laryngeal manipulation was defined as any manual external manipulation of the glottis intended to facilitate tracheal tube passage. Laryngeal pressure, as a means to prevent aspiration of gastric contents, was not recorded as external laryngeal manipulation for purposes of this study. The research team also recorded the following: (1) lowest oxygen saturation (SpO₂) observed during laryngoscopy and 30 seconds after first appearance of end-tidal carbon dioxide, (2) the number of laryngoscopy attempts, (3) trauma noted by the laryngoscopist, (4) the use of a bougie, or (5) the use of alternative intubation rescue methods (e.g., fiberoptic intubation). Furthermore, the research team examined the patient's airway after successful tracheal intubation for lip or gum laceration, dental injury, or pharyngeal injury. The laryngoscopists further reported their experience with the study device by confirming or refuting that they had used that device at least 5 times previously.

Upon arrival to the recovery area, a recovery room nurse served as a blinded safety assessor. The nurse examined the airway for any signs of trauma (lip/gum lacerations, dental injury, and pharyngeal injury) and asked the patient if he/she noted a sore throat. An assessment sheet was used to document the results, and the nurse signed a statement confirming that he/she had no knowledge of the airway device(s) used. Patients who remained ventilated postoperatively were evaluated by an intensive care nurse within 48 hours of tracheal extubation according to the same protocol. The research team further screened the patients for complications by reviewing inpatient and outpatient paper and electronic medical records for evidence of delayed or persistent airway trauma (sore throat, bruising, stridor, dental injury, pharyngeal injury, treatment of airway edema with steroids or racemic epinephrine, or need for reintubation). These data were reviewed for the first postoperative week (7 days). The above complication data were then summated for each patient. Each site had a designated safety monitor, and a safety monitoring board was formed with representatives from the 3 institutions.

Data Management

Patient data were transferred onto a preprinted scannable form included in the randomization envelope. This sheet was stripped of all patient identifiers, with the exception of age, sex, date of procedure, general surgical type, and the assigned randomization number. The form was then optically scanned using specialized data-capture software (HP TeleForm; HP Autonomy, Palo Alto, CA). This software

created an initial data set for each patient. Data capture accuracy was then verified (using a second software package from the same manufacturer) by the individual who had performed the scanning. When initial verification was complete, the data were transferred (along with an image of the actual form) to a centralized SQL Server (Microsoft, Redmond, WA) at the University of Iowa. Each incoming form and associated extracted data were reviewed by a member of the Data Management Group. All scanned records were also audited a second time by a third individual. Errors or missing data items were identified by the Data Management Group and called to the attention of the study coordinators at the involved center who were tasked with making verified corrections. Weekly summary reports (all fields, all patients) were reviewed by the Data Management Group as a second level of "error identification" and protocol compliance process. However, except for the interim analysis, no information other than weekly and cumulative center-by-center and overall enrollment numbers (totals, not by group) was provided to the participating investigators. No member of the Data Management Group was ever involved in the care of any study patient. This ongoing review did not result in any protocol changes.

Statistical Analysis

Randomization

Randomization was managed by the University of Iowa Data Management Group. A randomized block design with variable block sizes, with stratification by center and with a 1:1 allocation ratio, was used. Details of the randomization (e.g., block sizes) were known only to the study statistician. Individual, sequentially numbered randomization cards were prepared in advance, placed in opaque envelopes, and delivered to each center in batches of 50. A new batch of envelopes was provided to each center when envelopes were near depletion. Both the study team and the anesthesia team were blinded to group assignment until the patient entered the operating room, at which time the randomization envelope for the consenting patient was opened. Both a GlideScope and a C-MAC D-Blade unit were present in the operating room before patient arrival. One of the investigators or a research assistant followed each patient into the operating room to verify protocol compliance and to record the relevant data.

Sample Size and Primary Outcome

Most comparative studies are superiority trials, intended to show that one treatment is better than another. There are, however, limits to such a design when the success rate in the control group is very high (e.g., $\geq 90\%$) and the differences between the success rates of the 2 treatments are expected to be small. In such situations, very large sample sizes may be needed to demonstrate a significant difference (if any), and, thus, such trials may not be reasonably feasible. We therefore chose to approach the C-MAC D-Blade versus GlideScope comparison as a noninferiority trial.

To determine the sample size, the investigators had to decide on the acceptable margin of outcome difference that would determine noninferiority between the 2 groups. On the basis of clinical considerations, it was assumed that

any difference of $<4\%$ would be an acceptable margin to conclude comparable performance, that is, noninferiority for one versus the other intervention. From the current retrospective data, the first-attempt success rate of tracheal intubation using the GlideScope in the predicted difficult airway was estimated to be 93% ,⁶ which, based on the rationale above, indicated that the C-MAC D-Blade could be considered noninferior to GlideScope, if its first-attempt intubation success rate was 89% or better. Specifically, for such a result, the upper 90.35% confidence bound of the difference in first-attempt success rates between the 2 devices ($\pi_{\text{Glide}} - \pi_{\text{C-MAC}}$) needed to be $<4.0\%$ to deem the C-MAC D-Blade noninferior to GlideScope.

On the basis of this hypothesis, sample size was estimated to be 504 patients per group, with 80% power for a 1-sided 0.05 significance level. Five hundred fifty patients per group were enrolled for this study.

Other Covariates

To compare GlideScope and C-MAC D-Blade groups for categorical variables, χ^2 or Fisher exact test was used. Similarly, to compare continuous variables between the 2 laryngoscopy groups, a 2-sample Student t test was used for normally distributed data and Wilcoxon rank sum test was used for skewed data. Normality assumption was tested with the Shapiro-Wilk test.

Interim Analysis

A planned interim analysis was conducted at the midpoint of the study to assess for efficacy and safety. Blinded results (group A versus group B) were reported to the data and safety monitoring group. Success rates were reported with 90.35% confidence intervals (CIs), which was adjusted for the interim look based on the interim monitoring method of Lan and DeMets,¹² with the O'Brien and Fleming¹³ spending function. For the final analysis, the upper 90.35% confidence bound of the difference in first-attempt success rate should be $<4\%$ to achieve noninferiority of the C-MAC D-Blade to GlideScope. To calculate the CI for differences of proportions, Wald asymptomatic CI, without continuity correction, was used.¹⁴ The outcome of the interim analysis was not shared with the research team, but confirmation of continuation without protocol changes was.

RESULTS

Figure 1 illustrates the recruitment process and describes the 2 treatment arms. A total of 1415 patients were initially screened, of which 1150 consented for treatment and 1100 were randomly assigned. Changes in the surgical plan were the most common reason for not randomly assigning patients after initial consent. Enrollment was similar among the 3 participating institutions (Oregon $n = 350$; Texas $n = 409$; Iowa $n = 341$). Three hundred sixty-six providers participated in primary airway management. There were 9 protocol deviations, all related to the study device malfunctioning or not being available.

Table 1 describes the study population in more detail. The patient demographics were similar in terms of age, sex, and body mass index. The majority of the study subjects presented for gynecologic, urologic, vascular, orthopedic,

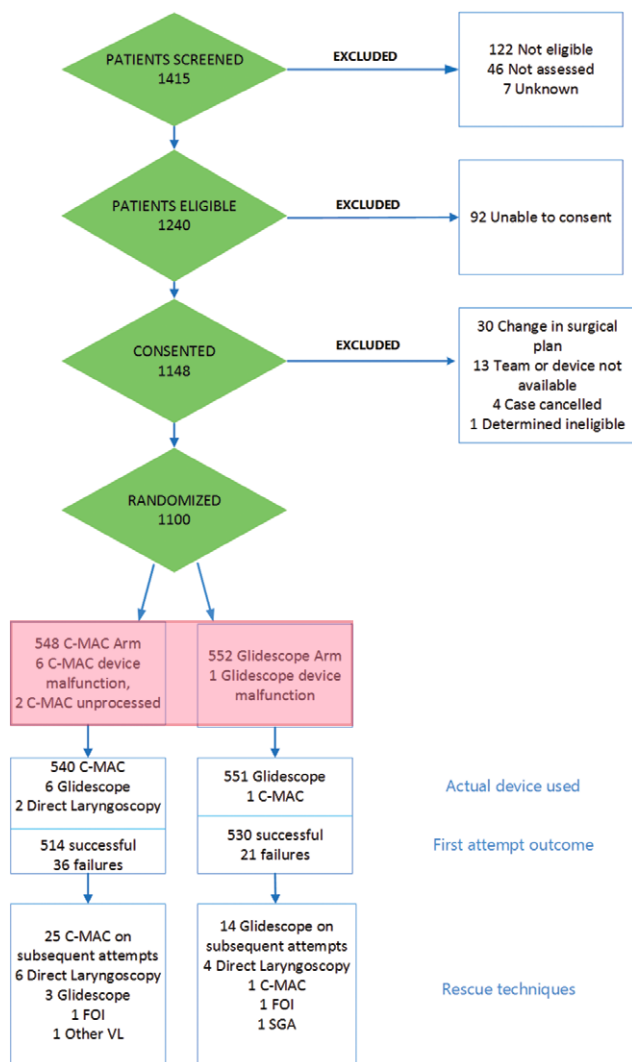


Figure 1. Flow diagram of patient recruitment, enrollment, treatment, and outcome. FOI = fiberoptic intubation; VL = video laryngoscopy; SGA = supraglottic airway.

general, or neurosurgical procedures. A small number were slated for otolaryngologic or oral surgery. Included patients were identified as being potentially difficult to intubate by presenting with a large neck circumference (90.8% of the cases), a Mallampati score of III or IV (54.7%), and/or limited mouth opening (1.2%). The 2 arms did not differ regarding the number of patients included via any of the earlier criteria.

Table 2 reports the intubation success rate for the 2 groups on first attempt for the entire cohort (primary outcome) and for several prespecified subgroups (secondary analyses). For each comparison, the upper confidence limit of the difference between the 2 treatments (C-MAC D-Blade versus GlideScope) is provided. Designed to test for noninferiority of the 2 interventions, an upper confidence limit of a difference in success of <4% was required to reject the null hypothesis (noninferiority of the C-MAC D-Blade versus GlideScope) for the respective comparison.

By intention-to-treat analysis ($n = 1100$; entire cohort), the primary intubation success rate in patients randomly assigned to the GlideScope was 96.2% (CI, 0.9484–0.9755)

and 93.4% (CI, 0.9167–0.9519) when randomly assigned to the C-MAC D-Blade. The upper confidence limit of the difference was 4.98%, which is more than the 4% upper confidence limit of the difference required to determine noninferiority. Therefore, noninferiority of the C-MAC D-Blade compared with the GlideScope regarding first-attempt intubation success was not achieved.

This result was confirmed with several protocol-compliant or subgroup analyses, such as when tested for “device actually used,” after excluding “randomization failures,” when testing for each contributing center separately, or when only considering data from providers with “>5 prior uses of the studied device.” Noninferiority was also not achieved for patients with more than one of the following predictors of difficult laryngoscopy (“multiple predictors”): enlarged neck circumference as defined in the inclusion criteria, Mallampati score III or IV, mouth opening <3 cm, limited cervical spine motion, limited jaw protrusion, and thyromental distance <6 cm. Another subgroup analysis included only those first-attempt successes that were accomplished within 90 seconds, and while the SpO_2 remained >95%. The aim of this secondary analysis was to determine whether personal preference of laryngoscopists toward the randomized device influenced the overall results. Such preferences would influence laryngoscopists to continue with a preferred device longer and tolerate more hypoxemia to be successful rather than removing the device (= failure) and to the opposite decision in cases where the nonpreferred device is randomized. However, this analysis confirmed the overall results of not noninferior, indicating that provider preference did not systematically influence the study outcome.

In contrast, eventual intubation success rate (after more than one attempt) resulted in similar success ($n = 1100$; C-MAC D-Blade success = 98.34% [0.9750–0.9927]; GlideScope success = 98.38% [0.9742–0.9925]; upper confidence limit of the difference = 1.32%).

First-attempt success for attending anesthesiologists was higher when using the C-MAC D-Blade compared with the GlideScope (noninferior), whereas for all other provider groups (residents, CRNA, AA, SRNA, AAS) first-attempt success was higher with the GlideScope (not noninferior). Eighteen patients could not be intubated after multiple tries with the assigned device (1.6% failure rate). In those cases, the providers rescued the airway successfully with direct laryngoscopy ($n = 10$), another video laryngoscope ($n = 5$), flexible bronchoscope ($n = 2$), or a supraglottic airway ($n = 1$).

Table 3 summarizes data about the intubation conditions resulting from the 2 interventions. The best glottic view (Cormack-Lehane Grade 1) was recorded more frequently in the C-MAC group than in the GlideScope group. In both interventional groups, Cormack-Lehane Grade 3 or 4 occurred rarely. The time to successful intubation was similar between treatments groups, as was the incidence of external laryngeal manipulations and the use of a bougie.

Table 4 summarizes the data relating to complications recognized within the subsequent 7 days of enrollment. Overall, the incidence of complications was low and did not differ between the 2 treatment modalities. All patients were successfully intubated or ventilated, and there were

Table 1. Patient Demographics

Characteristic	C-MAC (n = 548)	GlideScope (n = 552)	P value
Age, mean (SD)	53 (13.7)	54.4 (14.1)	0.08 ^a
BMI, mean (SD)	39.2 (9.4)	38.6 (8.9)	0.29 ^a
Sex, male (%)	256 (46.7)	285 (51.6)	0.10 ^b
Surgical procedure			
General/Gyn/Uro/Vasc (%)	300 (54.7)	309 (56)	0.48 ^b
Orthopedic (%)	90 (16.4)	98 (17.8)	
Neurosurgery (%)	86 (15.7)	72 (13.0)	
ENT/oral (%)	51 (9.3)	42 (7.6)	
Other (%)	16 (2.9)	24 (4.3)	
Neck circumference (satisfied inclusion in 90.8% of cases)			
Neck circumference (cm), mean (SD)	44.9 (5.2)	45.0 (5.3)	0.60 ^a
Mallampati scale score % (satisfied inclusion in 54.7% of cases)			
Class 1 (%)	91 (16.6)	77 (13.9)	0.42 ^b
Class 2 (%)	167 (30.5)	163 (29.5)	
Class 3 (%)	215 (39.2)	241 (43.7)	
Class 4 (%)	75 (13.7)	71 (12.9)	
Mouth opening (satisfied inclusion in 1.2% of cases)			
Mouth opening (cm), mean (SD)	4.7 (1.0)	4.7 (1.0)	0.77 ^c
Thyromental distance (cm), mean (SD)	7.8 (1.5)	7.8 (1.5)	0.95 ^c
Known history of difficult laryngoscopy (%)	17 (3.1)	15 (2.7)	0.72 ^b
Maximal jaw protrusion			
Missing (%)	1 (0.2)	0 (0)	0.53 ^b
Lower teeth protrude in front of upper (%)	418 (76.3)	436 (79)	
Lower teeth meet upper teeth (%)	85 (15.5)	73 (13.2)	
Lower teeth behind upper teeth (%)	44 (8)	43 (7.8)	
Neck mass (%)	9 (1.6)	4 (0.7)	0.18 ^b
Neck scar (%)	13 (2.4)	16 (2.9)	0.71 ^b
Neck radiation changes (%)	3 (0.5)	5 (0.9)	0.73 ^b
Prior C-spine fusion (%)	5 (0.9)	3 (0.5)	0.51 ^b

Gyn = gynecology; Uro = urology; Vasc = vascular; ENT = otolaryngology; C-spine = cervical spine; BMI = body mass index.

^aTwo-sample t test.

^bFisher exact test.

^cWilcoxon rank sum test.

Table 2. Intubation Success Rates (Noninferiority Achieved if the 90.35% Confidence Interval of the Difference in Success Was <0.04)

Outcome	C-MAC	GlideScope	Upper bounds of 90.35% confidence interval of the difference ($\pi_{\text{Glide}} - \pi_{\text{C-MAC}}$)
First-attempt success by intent-to-treat (%)	512/548 (93.4)	531/552 (96.2)	4.98%
First-attempt success by device actually used (%)	507/541 (93.7)	534/557 (95.9)	4.38%
First-attempt success excluding randomization failures (%)	506/540 (93.7)	530/551 (96.2)	4.69%
First-attempt success for providers with >5 prior uses of the studied device (%)	423/451 (93.8)	523/544 (96.1)	4.68%
First-attempt success for patients with multiple predictors	323/343 (94.2)	344/360 (95.6)	4.16%
First-attempt success within 90 seconds while SpO ₂ > 95%	449/496 (90.5)	477/506 (94.3)	6.52%
Success rate for multiple attempts (%)	532/541 (98.3)	548/557 (98.4)	1.32% (noninferior)
First-attempt success rate for attending anesthesiologists (%)	52/53 (98.1)	66/70 (94.3)	1.7% (noninferior)
First-attempt success rate for resident anesthesiologists (%)	186/198 (93.9)	184/191 (96.3)	6.01%
First-attempt success rate for CRNA or AA (%)	224/240 (93.3)	225/230 (97.8)	7.61%
First-attempt success for SRNA or AAS (%)	50/57 (87.7)	56/61 (91.8)	13.37%
First-attempt success rate Oregon (%)	165/175 (94.3)	170/175 (97.1)	6.45%
First-attempt success rate Texas (%)	185/204 (90.7)	193/205 (94.2)	7.80%
First-attempt success rate Iowa (%)	162/169 (95.9)	168/172 (97.7)	5.0%

CRNA = certified registered nurse anesthetist; AA = anesthesiologist assistant; SRNA = student registered nurse anesthetist; AAS = anesthesiologist assistant student.

no reports of anoxic brain injury or airway-related death. A peripheral oxygen saturation of <90% occurred in 4.2% vs 3.8% of the cases ($P = \text{NS}$) when using a C-MAC D-Blade versus GlideScope, respectively. Pharyngeal injury occurred in 11 cases (1%), and the incidence did not differ between groups. Dental injury occurred in only 1 patient (<0.1%). There were no major adverse events associated with airway management. One patient died of surgical hemorrhage.

DISCUSSION

This multicenter randomized trial was the largest prospective comparative study of acute-angle video laryngoscopy to date. In addition, its multicenter design and the involvement of a large number of providers with a wide range of experiences suggest that the results are broadly applicable. Clinical studies often compare airway devices to test their performance in a very small group of expert laryngoscopists

Table 3. Summary Results of Intubation Difficulty Based on Intent-to-Treat

Intubation parameter	C-MAC (n = 548)	GlideScope (n = 552)	P value
Best laryngeal view achieved (per provider)			
Grade 1	482 (88)	398 (72.1)	<0.0001 ^a
Grade 2	41 (7.5)	146 (26.5)	
Grade 3	8 (1.5)	11 (2)	
Grade 4	10 (1.8)	2 (0.4)	
Intubation time for first-attempt successful intubations in seconds (Q25, Q75)	47 (39, 60)	47 (38, 58)	0.52 ^b
Bougie used (%)	2 (0.3)	6 (1.1)	0.29 ^c
External laryngeal manipulation used (%)	115 (2.1)	122 (2.2)	0.66 ^c

^aChi-square test.^bWilcoxon rank sum test.^cFisher exact test.**Table 4. Complications Based On Intent-to-Treat**

Adverse event	C-MAC (548)	GlideScope (552)	P value (Fisher exact test)
SpO ₂ <90% (%)	23 (4.2)	21 (3.8)	0.76
Lip injury (%)	19 (3.5)	16 (2.9)	0.61
Dental injury (%)	1 (0.2)	0 (0)	0.50
Tracheal injury (%)	0 (0)	1 (0.2)	1
Pharyngeal injury (%)	4 (0.7)	7 (1.3)	0.55
Sore throat (%)	71 (13)	64 (11.6)	0.52
Remained intubated for any reason (%)	9 (1.6)	4 (0.7)	0.18
Reintubation for airway edema (%)	1 (0.2)	0 (0)	0.50
Required steroid or racemic epinephrine (%)	5 (0.9)	1 (0.2)	0.12
Any trauma (%)	80 (14.6)	70 (12.7)	0.38
Any adverse event (%)	97 (17.7)	85 (15.4)	0.33

(up to 3) to reduce variability among providers.^{8,9} In contrast, we intentionally sampled a large cross section of providers and chose a multicenter design to determine the clinical effectiveness of 2 widely used acute-angle video laryngoscopy systems for the management of the difficult airway in a real-world (academic) practice environment. This study design reflects our previous work, and the results are highly relevant to daily anesthesia practice.

Although we found a very high overall first-attempt success rate in this group of patients (94.8%), there was a small difference between the 2 studied devices (96.2% GlideScope versus 93.4% for C-MAC D-Blade) with the upper confidence limit bound exceeding the 4% margin. The extent of this difference did not allow us to conclude that the C-MAC D-Blade is noninferior to the GlideScope when comparing first-attempt intubation success rate. Interestingly, the overall intubation success rates for the 2 devices, when patients requiring more than one attempt were included, did not differ between devices.

Unfortunately, our results are somewhat ambiguous. Noninferiority trials start with a projected noninferiority margin, which represents “how close” the alternative treatment must be to the control to be deemed noninferior. We chose a margin of 4%; and indeed, absolute performance of the C-MAC D-Blade was within this margin (absolute difference versus GlideScope was 2.8%). In other words, our alternative hypothesis was that the first-attempt success rate of GlideScope is no more than 4% higher than the C-MAC. The difference could be lower or the first-attempt success rate of the C-MAC could be higher to achieve that margin. However, the accepted method for accepting or rejecting the null hypothesis is based on the CI boundaries of the difference, and the

upper 90.35% boundary was 4.98% between the 2 interventional groups. Therefore, the hypothesis that the C-MAC D-Blade is noninferior on first-attempt intubation success was not achieved. However, it is statistically invalid to conclude that the C-MAC D-Blade is inferior (much as it is invalid to conclude that, in a superiority trial, 2 groups are equivalent when there is no statistically significant difference between them). The only appropriate conclusion is that the C-MAC D-Blade is “not noninferior” to the GlideScope in this patient population.

The data from this large clinical trial suggest that after induction of anesthesia, the trachea can be intubated successfully using acute-angle video laryngoscopy. In only a very small percentage of patients (1%; *n* = 13) were methods other than video laryngoscopy needed to ultimately secure the airway (direct laryngoscopy, flexible bronchoscopy, or supraglottic airway). The success rates for tracheal intubation reported here are higher than previously reported for acute-angle video laryngoscopy in patients with concerns of a difficult airway. In particular, the first-attempt success using GlideScope was better than expected from previous reports. A meta-analysis of randomized trials from 2005 to 2010 indicated a first-attempt success rate of 87% with this device in a mixed sample of patients and providers.¹⁵ Our previous large database analysis of 71,570 cases determined a 93% success rate on first intubation attempt when using the GlideScope (*n* = 2004), also in a mixed patient population.⁶ In contrast, little is known regarding intubation success when using the C-MAC D-Blade. Although previous reports suggested 100% success based on evaluations of data from 15 and 32 patients, respectively,^{7,16} we observed a 93% first-attempt success rate in patients with predictors of difficult endotracheal intubation.

Our analysis indicates a small difference in success rate on first intubation attempt between the GlideScope and the C-MAC D-Blade. Understanding the reasons for this difference is important because, given the intended similarity between the GlideScope and the C-MAC D-Blade, it was largely unexpected. Possible explanations include specifics of the data analysis, provider experience, and device design. There were a number of technical failures with the C-MAC video system but, because difference in success rates was seen in both our primary intention-to-treat analysis and several protocol-compliant analyses (which ignore these technical failures), the difference cannot be attributed to errors in the conduct of the trial nor can it be attributed to mechanical problems in the video laryngoscope systems.

In contrast, the fact that the difference in success rate disappeared in the hands of (presumably) more experienced attending anesthesiologists suggests that the overall difference may have been related to the relative learning curve for the C-MAC D-Blade. It is also possible that a larger fraction of the providers were “farther along” the device-specific learning curves for the GlideScope than for the C-MAC D-Blade. Although the GlideScope intubation system has been available for >12 years, the C-MAC D-Blade system was introduced to the United States market only 3 years before the start of trial enrollment (2010). Thus, many participating providers may have had more experience with the GlideScope. Although analyzing our data set and controlling for the effect of at least 5 intubations with the study device (experienced versus novice) did not show an effect on the results, effects of long-term experience were not assessed because respective data would have required self-reporting years into the past, which was a priori considered unreliable. Quantitative assessment of competence in airway management is only relevant to studies that anticipate intubation success rates up to 90% and, therefore, was not an option for this study that, based on previous experience, anticipated a higher than 90% intubation success rate. Interestingly, providers chose rescue with direct laryngoscopy more frequently in the C-MAC group than in the GlideScope group. It is possible that the difference is another reflection of relative differences in experience with the C-MAC compared with the GlideScope, causing the providers in this study to intuitively revert to the more familiar direct laryngoscopy technique when initially failing with the C-MAC video laryngoscope.

Alternatively, subtle differences in device design may explain the small difference in overall first-attempt success rates. For example, the optical component on the C-MAC D-Blade is carried more distally than it is on the GlideScope. This difference in the projected video image may have presented a challenge for tube passage for some providers when using the D-Blade, particularly for those that were more experienced with the more proximal lens location of the GlideScope. Furthermore, it is possible that the use of the GlideScope stylet for both interventional groups may have influenced the results. Because the D-Blade is more acutely angulated than the GlideScope, the GlideScope-optimized stylet may not have necessarily translated into the best D-Blade performance. Unfortunately, there was no stylet available specifically designed for use with the

D-Blade at the time of the study. Initially, we considered the use of a conventional malleable stylet for both groups but were concerned that provider variability regarding shaping of the tube would introduce variability to intubation performance, and thereby randomly affect first-attempt intubation success. Alternative approaches could have been using a 90° (“hockey stick”) tube configuration for both groups because this bent has been shown to work well at least for the GlideScope¹⁷ or to optimize tube delivery by curving the tube-stylet assembly to match a shape of each individual blade for intubation. Ultimately, we decided to strictly standardize the introduction of the endotracheal tube into the glottis by selecting one single preformed rigid stylet (GlideRite) for all video intubations.

However, we do not have data to definitively explain the slight difference in first-attempt success between the 2 devices. Nevertheless, our data suggest that performance and experience with 1 video laryngoscope does not translate to equal performance with another video laryngoscope, even if the design features are as similar as they are between the GlideScope and the C-MAC D-Blade. Therefore, each video laryngoscope system requires substantial device-specific experience to achieve the highest possible proficiency. As such, long-term training needs to be emphasized when new video laryngoscope devices are introduced into practice, even if the providers are skilled with other video laryngoscopy techniques. The literature has focused on the experience required to achieve a success rate of 90%¹⁸ or to achieve “good”¹⁹ intubation conditions with direct laryngoscopy. In those studies, 57 and 47 direct laryngoscopy attempts were required to achieve that level of proficiency, respectively. It is unknown what level of experience is required to achieve intubation success rates as observed in the present study using acute-angle video laryngoscopes.

Our analysis shows that when all attempts using the same device on the same patient are included, intubation successes were similar between the GlideScope and the C-MAC D-Blade (98%). When the primary intubation attempt failed, providers typically repeated laryngoscopy with the same device (Fig. 1). Multiple-attempt success rates were 98% for either device reflecting an improvement of 4% and 2% for C-MAC and GlideScope, respectively. These results mirror a previous report of 96% intubation success on multiple attempts using the GlideScope in patients with predicted difficult airway.⁶ Overall, our data demonstrate remarkable clinical effectiveness of acute-angle video laryngoscopy in this potentially challenging patient population.

It is interesting that attending anesthesiologists had higher first-attempt success when using the C-MAC D-Blade system (98% vs 94% with GlideScope) compared with trainees or advanced practice providers, who were slightly more successful with the GlideScope. These differences may potentially be explained by an earlier exposure and higher adaptability to new technologies among more experienced providers (preferentially the attending group) and higher adherence to already mastered technology (advanced practice providers) or less overall experience (trainees).

We also measured several variables that quantify the conditions of endotracheal intubation with a particular technique (best glottic view achieved, intubation time, and the

use of adjuncts). Grade 1 Cormack-Lehane laryngeal view of the larynx was more frequently achieved with the C-MAC D-Blade compared with the GlideScope. With the video component of the C-MAC D-Blade positioned more distally (closer to the glottic opening) compared with the GlideScope (more proximally, away from the glottis), visualization of the anterior commissure is better with the C-MAC D-Blade when the tip of the blade is positioned in the vallecula, and our data confirm this in a large cohort of patients with predictors of difficult airway. However, the improvement in visualization with the C-MAC D-Blade did not translate into higher intubation success rate on first attempt, supporting assertions that a Grade 2 Cormack-Lehane view (achieved more often with the GlideScope) is most often sufficient for tracheal intubation using conventional laryngoscopy.²⁰ Nevertheless, these data support the possibility that subtle design differences between the 2 acute-angle video laryngoscopes may account for the small difference in first-attempt success rates. Other surrogate variables, such as intubation time or the use of adjunct maneuvers such as external laryngeal manipulation or use of a bougie, did not differ between the 2 interventional groups. These findings suggest that intubation was not more challenging with one device over the other.

We found complications to occur with similar frequency with both devices. The most important results of our complication analysis revealed a pharyngeal injury rate of approximately 1% with these acute-angle video laryngoscopy techniques, which depend solely on indirect visualization of the tracheal intubation. This rate is higher than previously reported, but evidence has been limited regarding the true incidence of video laryngoscopy-related pharyngeal injury. Several reports pertaining primarily to the use of the GlideScope are based on retrospective analysis, limited sample size, or inadequate follow-up.^{6,21–30} In contrast, our data come from a large prospective trial. All patients were examined for injury in the operating room and then evaluated in recovery or the critical care unit. Finally, the chart was reviewed every day for 1 week postoperatively. On the basis of the large sample size and the robust study design, we believe that our data provide solid assessment of the real-life risk for pharyngeal injury with these devices. The data also indicate that the risk may pertain to the technique (acute-angle video laryngoscopy) in general rather than being specific to one device. Accordingly, the results suggest that pharyngeal injury may be considered during the informed consent of a patient requiring tracheal intubation with this type of video laryngoscopy. Our finding of a very low incidence of dental injury when using acute-angle video laryngoscopy is reassuring and coincides with retrospective observations of the risk of dental injury during any airway management technique (1:2073 cases).³¹

This study has several limitations. First, device-specific experience of all 366 providers was not uniform. However, both video laryngoscopy techniques (GlideScope and C-MAC D-Blade) were introduced in all 3 participating centers long before the trial was initiated. Before the start of the study, each center conducted a pilot phase during which additional manikin training was available for both devices. Providers had many years of experience with the GlideScope but likely less with the C-MAC D-Blade

because of its more recent introduction into clinical practice. Our results may therefore be affected by a subtle difference in long-term experience with the devices. Although heterogeneity of the study sample may seem to be disadvantageous for interpretation, it was intended as a study design that reflected real-life environments and allowed for observations in outcomes that may not be apparent with more homogeneous samples. Specifically, studying real-life environments with a large sample size may not only be a more appropriate measure of the true clinical effectiveness of a specific intervention but also has the potential to sense subtle but important modulators that, when identified, can lead to new practice suggestions. Applied to the interpretation of our data, we can speculate that, because success with individual techniques improves over time, differences in practice introduction may have influenced the head-to-head performance of the 2 interventions.

The study also reflects clinical practice of 3 large academic medical centers. On the basis of the small performance difference and our observation from the attending anesthesiologists subgroup analysis, we suspect that in a nonteaching practice environment both techniques would perform similarly. Further research would be necessary to confirm this hypothesis.

CONCLUSIONS

Although we were unable to verify the noninferiority of the C-MAC versus GlideScope, the success rates for both devices in this population were very high, particularly when multiple attempts were included. Clinically, these findings are highly relevant because they suggest that each of the 2 tested acute-angle video laryngoscopes would be a reasonable first choice for patients similar to those studied (e.g., obese, large neck circumferences, higher Mallampati scores). The absolute differences in first-attempt success rates between the devices were small and likely not clinically relevant. However, further work would be needed to identify the reasons underlying that difference. Long-term training is likely required when new video laryngoscopes are introduced into practice, even if the providers are skilled with other video laryngoscopy techniques. The high success rate of video laryngoscopy demonstrated in this large multicenter clinical trial speaks for a more prominent role of acute-angle video laryngoscopy when current airway algorithms are being revised. Similarly, on the basis of the evidence from this large trial indicating a 1% risk of pharyngeal injury associated with acute-angle laryngoscopy, discussing this risk should be considered during the consent process when acute-angle laryngoscopy is planned. ■■

DISCLOSURES

Name: Michael F. Aziz, MD.

Contribution: This author helped design the study, conduct the study, analyze the data, and write the manuscript.

Conflicts: Michael F. Aziz received honoraria from Karl Storz Endoscopy and received research funding from Karl Storz Endoscopy.

Attestation: Michael F. Aziz has seen the original study data, reviewed the analysis of the data, approved the final manuscript, and is the author responsible for archiving the study files.

Name: Ron O. Abrons, MD.

Contribution: This author helped design the study, conduct the study, and write the manuscript.

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Attestation: Ron O. Abrons has seen the original study data, reviewed the analysis of the data, and approved the final manuscript.

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