A Prospective Randomized Equivalence Trial of the GlideScope Cobalt® Video Laryngoscope to Traditional Direct Laryngoscopy in Neonates and Infants

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ABSTRACT

Background: Intubation in children is increasingly performed using video laryngoscopes. Many pediatric studies examine novice laryngoscopists or describe single patient experiences. This prospective randomized nonblinded equivalence trial compares intubation time for the GlideScope Cobalt® video laryngoscope (GCV, Verathon Medical, Bothell, WA) with direct laryngoscopy with a Miller blade (DL, Heine, Dover, NH) in anatomically normal neonates and infants. The primary hypothesis was that intubation times with GCV would be noninferior to DL.

Methods: Sixty subjects presenting for elective surgery were randomly assigned to intubation using GCV or DL. Intubation time, time to best view, percentage of glottic opening score, and intubation success were documented. We defined an intubation time difference of less than 10 s as clinically insignificant.

Results: There was no difference in intubation time between the groups (GCV median = 22.6 s; DL median = 21.4 s; \( P = 0.24 \)). The 95% one-sided CI for mean difference between the groups was less than 8.3 s. GCV yielded faster time to best view (median = 8.1 s; DL 9.9 s; \( P = 0.03 \)). Endotracheal tube passage time was longer for GCV (median = 14.3 s; DL 8.5 s; \( P = 0.007 \)). The percentage of glottic opening score was improved with GCV (median 100; DL 80; \( P < 0.0001 \)).

Conclusions: Similar intubation times and success rates were achieved in anatomically normal neonates and infants with the GCV as with DL. The GCV yielded faster time to best view and better views but longer tube passage times than DL.

What We Already Know about This Topic

- Use of GlideScope improves performance of tracheal intubation in adults and children compared with direct laryngoscopy with a Macintosh blade
- We do not know its performance in neonates and infants

What This Article Tells Us That Is New

- Overall intubation performance with the GlideScope is equivalent to that of direct laryngoscopy with a Miller blade in normal neonates and infants
- Notably, time to best view is faster but endotracheal tube passage time is longer in the GlideScope intubations

The GlideScope Cobalt® video laryngoscope (GCV; Verathon Medical, Bothell, WA) is a recently introduced video laryngoscope designed for use in children. A reusable, flexible camera baton is inserted into a disposable plastic curved blade. The high-resolution image from the camera is displayed on a dedicated portable monitor, allowing all care providers to view the intubation process. The camera and display facilitate guidance of a novice laryngoscopist and provide confidence to the supervising physician that the endotracheal tube is placed correctly. Much of the available literature on video laryngoscopy in children examines manikins,1–3 focuses on older children,4–7 studies inexperienced laryngoscopists,8–10 or describes single patient experiences.9–12

Recent publications examining older children demonstrate that the GlideScope may offer improvements in intubation time compared to direct laryngoscopy.13–15

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bation over traditional direct laryngoscopy. The presence of anatomical differences between infants and older children requires validation of these findings in the infant and neonatal population. Neonates and infants have large occiputs, larger tongues relative to their pharyngeal space, omega-shaped floppy epiglottides, and, most significantly, more cranially located larynges. These differences make laryngoscopy more challenging in the smaller child. Of note the original pediatric GlideScope was found to be inappropriate in the neonatal population. We sought to investigate whether the advantages of the GlideScope Cobalt® in older children and adults remained in the infant and neonatal population. We specifically evaluated differences in intubation time and laryngoscopy view between the GlideScope Cobalt® and direct laryngoscopy with a Miller 1 blade (DL, Heine, Dover, NH). The Neonatal Resuscitation Program established by the American Academy of Pediatrics and the American Heart Association is the accepted standard for teaching neonatal resuscitation. The Neonatal Resuscitation Program recommends an intubation time of 20 s or less for newborns. Based on this recommendation we assumed that a difference in intubation time of 10 seconds (half the recommended time) could be clinically relevant during the intubation of a newborn and set our limit of indifference between the two devices to 10 s.

Video laryngoscopy improves laryngeal exposure in infants, but data regarding intubation time and success has been less clear. Some studies report prolonged intubation times with video laryngoscopes when compared with direct laryngoscopy, whereas others report similar or faster intubation times. Some of these investigations are confounded by the use of novices as the intubators.

We conducted this single-site prospective randomized evaluation to compare intubation times of the GCV with DL in an infant population with normal airway anatomy. Our primary hypothesis was that intubation times with GCV would be similar (noninferior) to those with DL in experienced hands.

Materials and Methods

After Institutional Review Board approval (Committees for the Protection of Human Subjects, Philadelphia, Pennsylvania), healthy infants (American Society of Anesthesiologists physical status 1 or 2), with normal craniofacial anatomy were recruited to obtain 60 evaluable subjects less than 12 months of age undergoing elective surgery requiring tracheal intubation. Subjects were recruited from the population of patients presenting for surgery at our tertiary care children’s hospital in Philadelphia, Pennsylvania. Written informed consent was obtained for all enrolled subjects. Subjects were excluded from participation if they were known or suspected to be difficult to intubate or if they required a rapid-sequence intubation.

Subjects were randomly assigned to intubation with the GlideScope Cobalt® with a size 2 blade or DL with a Miller 1 blade. Subjects were allocated in a 1:1 ratio. Randomization was performed by a research assistant using a computer random number generator to generate 1 s and 2 s. The number 1 was assigned to GCV and 2 to DL. The randomization was concealed from the laryngoscopist in a sealed envelope and was revealed after an investigator had obtained parental consent for study participation. All intubations were performed with a styledet endotracheal tube (Microcuff tube; Kimberly-Clark, Roswell, GA). The laryngoscopists performed all intubations while standing. A shoulder roll was not used in any subject; a soft donut-shaped foam headrest was used to support the head in all patients. The styledet endotracheal tubes for GCV intubations were shaped to mimic the curve of the size 2 Cobalt®, whereas the styledet tubes for DL were shaped with a hockey stick bend at the tip. Laryngoscopy with the GlideScope was performed with the aid of the blade placed in the vallecula. Laryngoscopy with the Miller blade was performed with the blade inserted in the right labial commissure of the mouth, displacing the tongue to the left side of the mouth. The blade tip was advanced into the vallecula and the styledet tube was passed to the right of the blade. If the view was partly obstructed by the epiglottis, the epiglottis was elevated in order to obtain the best possible view. All intubations were performed by one of two attending anesthesiologists who had each performed more than 50 GCV intubations in infants.

Anesthetic Management

Following inhaled induction with sevoflurane, vecuronium (0.1 mg/kg) was administered 3 min before laryngoscopy with the study-assigned device. An unblinded research assistant recorded the time from insertion of the randomized device past the teeth/gums until its removal after intubation as the time to intubation. The time interval between the laryngoscope passing the teeth/gums to the announcing of the best glottic exposure was recorded as the time to view (TTBV). The laryngoscopist announced the percentage of glottic opening (POGO) score once the best glottic exposure had been obtained. The POGO score is a method of assessing laryngeal exposure that assigns a percentage to the amount of the glottis visualized from the anterior commissure to the interarytenoid notch. In accordance with standard clinical practice, the laryngoscopist was allowed to perform optimal external laryngeal manipulation as needed during laryngoscopy. The endotracheal tube passage time was defined as the time to intubation minus the TTBV. All intubations were confirmed by direct visualization, auscultation, and detection of end tidal carbon dioxide. In the event of intubation failure a subsequent laryngoscopy was performed and the sum of the tracheal intubation times were added to determine the overall intubation time.

After securing the endotracheal tube the pharynx was suctioned to detect the presence of pharyngeal blood. The presence of blood during suctioning was recorded as none, trace,
or heavy. An intubation attempt was documented each time the randomized device was removed past the gum or teeth.

Sample Size Consideration
This study was powered for equivalence between the GCV and DL groups in time to tracheal intubation. A 95% CI was derived for the adjusted difference between the mean scores. Based on prior data we assumed that the expected difference in mean time to intubation between the two groups to be 6 s and the common SD for both groups to be 6s. The equivalence boundary was set at 10 s (i.e., equivalence was declared if the 95% CI was included between −10 and 10 s). A sample size of 30 in each group was required for this equivalence study at a one-tailed α level of 0.05 (equivalence test) to have 81% power to declare that the GCV and DL groups were equivalent.

Statistical Analysis
Means and standard deviations were calculated for time to intubation and difference in time to intubation between GCV and DL. Medians were reported for time to intubation, TTBV, endotracheal tube passage time, and POGO score by GCV and DL. Histograms were used to examine the distribution of continuous outcome measures. Intubation success rates were calculated and compared for GCV and DL. We defined a difference of less than 10 s to be a clinically insignificant difference in intubation time between GCV and DL. The 95% one-sided CI of the mean difference in time to intubation between GCV and DL was calculated. The CI was compared with the limit of equivalence (10 s). As TTBV, endotracheal tube passage time, and POGO score were not normally distributed (even with transformation of the data), the Wilcoxon rank sum test was used to verify any difference between GCV and DL for TTBV, endotracheal tube passage time, and POGO score. Chi-square test was used to detect the association between intubation success and the laryngoscopy type (GCV and DL). Statistical significance was declared if \( P \) was 0.05 or less. Statistical analysis was performed using SAS 9.2 (SAS Institute Inc., Cary, NC). Figures were generated using IBM SPSS Statistics 19 (SPSS Inc., Chicago, IL).

Results
Subject flow through the study is shown in fig. 1. Sixty-six families consented to participate in the study. One subject was withdrawn before any study procedures at the discretion of the attending anesthesiologist because of laryngospasm during the induction of anesthesia. Four subjects were not included because a study laryngoscopist was unavailable after consent was obtained. One additional subject was excluded because of errors made in timing during the intubation.

There was no significant difference in patient demographics (table 1). There was no difference in intubation time between the groups (GCV median 22.6 s, range: 13.3–61.0 s; DL median 21.4 s, range: 9.5–66.1 s). The one-sided 95% CI for the mean difference between GCV and DL was less than 8.3 s, which was less than the limit of equivalence of 10 s.
Table 1. Demographic Data of Study Subjects by Randomized Group

<table>
<thead>
<tr>
<th></th>
<th>GCV</th>
<th>DL</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (mean ± SD)</td>
<td>5.9 ± 3.4</td>
<td>5.1 ± 3.3</td>
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</tr>
<tr>
<td>Sex (M, F)</td>
<td>26, 4</td>
<td>19, 11</td>
<td>0.07</td>
</tr>
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<td>ASA (1, 2)</td>
<td>19:11</td>
<td>17:13</td>
<td>0.59</td>
</tr>
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</table>

ASA = American Society of Anesthesiologists physical status; DL = direct laryngoscopy with a Miller blade; GCV = GlideScope Cobalt® video laryngoscope.

One patient in the GCV group required a second laryngoscopy because the endotracheal tube stylet configuration did not exactly match the GlideScope blade curvature; intubation ensued smoothly after readjustments were made to the stylet. Two patients in the DL group required a second laryngoscopy attempt. Both were related to difficulty controlling the epiglottis during the initial laryngoscopy, and intubation was successful on the second attempt in both cases.

There was a statistically significant difference in endotracheal tube passage time and TTBV between the two devices (figs. 3, 4). TTBV was shorter with GCV than DL (median 8.1 s, range: 3.3 to 36.3 s) compared to DL (median = 9.9 s, range: 5.1–28.6 s; P = 0.03), however endotracheal tube passage time was slower with GCV (median = 14.3 s, range: 2.8–55.2 s) compared with DL (median = 8.5 s, range: 3.7–37.5 s; P = 0.007). The POGO score was significantly greater with GCV (median 100, range 60–100) compared with DL (median = 80, range: 50–100; P < 0.0001) (table 2, fig. 5). There was no difference in the success rate of intubation between the two devices (96% for GCV vs. 94% for DL). There was no pharyngeal blood observed after intubation with either device and no study related complications noted in any patient.

Discussion

Options for managing the airway in children have been limited when compared to those for adults. Recently there has been a proliferation of new devices marketed for infant use; however, many of these represent scaled-down versions of their adult counterparts. The different airway anatomy found in neonates and infants mandates rigorous examination of these designs before widespread use.
This study compared intubation time using the infant GCV with DL. We found no clinically significant difference in overall intubation time between the two devices when used by experienced laryngoscopists. However, GCV was associated with faster times to best laryngoscopic view but slower endotracheal tube passage times when compared with DL. Faster views were likely achieved with the GlideScope because of the magnified, brighter image it provides, and because it can be inserted quickly in the midline in the pharynx without displacing the tongue. The view of the glottis achieved with GCV was significantly improved over that with DL, although in all cases this view was satisfactory for tracheal intubation. There was no difference in success rates between the two devices and there were no traumatic injuries to the airway using either device.

Our results offer a likely explanation for the reports of longer intubation times by novice laryngoscopists using video laryngoscopes. Most of the increase in time in these studies is likely related to passage of the endotracheal tube. With experience endotracheal tube placement becomes quicker as laryngoscopists acquire the hand-eye coordination necessary for indirect intubation. Also with experience, the prolonged endotracheal tube passage time is offset by faster glottic visualization, and practitioners can reasonably expect similar intubation times to those obtained with DL.

Although the Neonatal Resuscitation Program recommends an intubation time of 20 s in neonates, two of our subjects were intubated in more than 60 s, one in the GCV group and the other in the DL group. One reason for this was that whenever a patient had multiple attempts we combined the times of both the attempts to obtain the overall intubation time; this occurred in one DL patient with an intubation time of greater than 60 s. A second DL patient required two attempts but was intubated in less than 60 s. One patient in the GlideScope group presented challenges with directing the tube into the trachea despite a good view and represented the second patient with an intubation time of more than 60 s. Obtaining the best view possible before intubation also likely prolonged our intubation times in both groups. There are very few studies examining intubation times using DL in neonates with normal airways, but our results with DL are similar to those of O’Donnell et al., who reviewed delivery room video recordings of intubations by neonatology residents, fellows, and consultants. They reported mean (SD) times of 51 (13), 32 (13) and 25 (17) s, respectively, and concluded that intubation attempts were often unsuccessful and successful attempts frequently took more than 30 s. Another trial reported mean intubation times of 10 s in neonates and infants, but intubation time was undefined in their paper, making it difficult to compare their results to ours. The previous recommendation of less than 20 s for intubation time in newborns has recently been updated to 30 s by the Neonatal Resuscitation Program.

We compared the GlideScope Cobalt® video laryngoscope (a curved blade) to direct laryngoscopy with a Miller blade (a straight blade) when used by practitioners who had extensive experience with both devices. We chose to compare a curved video laryngoscope to a standard laryngoscope for the following reasons. The most popular curved traditional blade (the Macintosh blade) is quite dissimilar in curvature from the GlideScope blade and therefore comparing the two would still represent a comparison of two disparate blades. Second, traditional clinical teaching suggests that the straight blade offers the best glottis exposure in neonates and infants because of the higher located glottis. Although evidence in the literature for this is lacking, the straight blade is thought to facilitate elevation of the tongue base to allow

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Table 2. Comparison of Times between the GlideScope Cobalt® and Miller Laryngoscopy

<table>
<thead>
<tr>
<th></th>
<th>DL</th>
<th>GCV</th>
<th>P Value</th>
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<tr>
<td>Time</td>
<td>Median</td>
<td>Range</td>
<td>Median</td>
</tr>
<tr>
<td>TTI</td>
<td>21.4</td>
<td>9.5–66.1</td>
<td>22.6</td>
</tr>
<tr>
<td>TTBV</td>
<td>9.9</td>
<td>5.1–28.6</td>
<td>8.1</td>
</tr>
<tr>
<td>POGO</td>
<td>80</td>
<td>5–100</td>
<td>100</td>
</tr>
<tr>
<td>TPT</td>
<td>8.5</td>
<td>3.7–37.5</td>
<td>14.3</td>
</tr>
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</table>

DL = direct laryngoscopy with a Miller blade; GCV = GlideScope Cobalt® video laryngoscope; POGO = percentage of glottic opening score; TPT = endotracheal tube passage time; TTBV = time to best view; TTI = time to tracheal intubation.

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Fig. 5. Box and whisker plots illustrating the percentage of glottic opening score (POGO) with direct laryngoscopy with a Miller blade (DL) and with the GlideScope Cobalt® video laryngoscope (GCV). The heavy horizontal line within the box represents the median score and the outer horizontal lines of the box represent the 25th and 75th quartiles. The horizontal lines of the whiskers represent the 95% CIs.
better glottic exposure than the curved blade. The Miller blade therefore represents the most commonly utilized straight blade in infant and neonatal intubations. We chose to compare what we felt was the best direct laryngoscopy tool in neonates and infants with the GlideScope.

Video laryngoscopy is emerging as an important adjunct in airway management; this evaluation demonstrates the applicability of video laryngoscopy to airway management in infants with normal airways. Noted drawbacks of some video laryngoscopes have included cost, difficulty with endotracheal tube placement despite full glottic exposure, difficulty with visualization in the presence of copious secretions or blood, and the need for good hand-eye coordination. Our results suggest that problems with tube passage and hand-eye coordination are infrequent with experience. The main cost of a video laryngoscope system is the acquisition cost of the unit, which can range from $5,000 to $25,000; the cost of each disposable GCV blade is approximately $10. Endotracheal tube placement was accomplished readily in all but one subject. Despite the high success rate observed in this study, laryngoscopists need to be cognizant of the potential difficulty and the possibility of injurious complications attendant upon tube insertion. Multiple passes of the endotracheal tube that strike the larynx without entering the glottic opening can lead to edema and airway obstruction.

With experience the GlideScope Cobalt® video laryngoscope can be readily used in routine intubations in infants. Although the number of laryngoscopies necessary to assure competence with standard direct laryngoscopy has been defined, the number of attempts needed by a novice to perform similarly with video laryngoscopes remains undefined. Limitations of our study include a lack of binding, which was not feasible, and the small number of laryngoscopists. Assessment of the POGO score and best view could be influenced by intentional and/or unintentional bias by the two operators involved. We considered photographing the best view and having the photographs read by an independent evaluator to mitigate this potential bias, but this was associated with unacceptable increases in intubation time (a Hopkins rod was necessary to obtain optimal images) and therefore was abandoned. This bias is difficult to control for without increasing the number of laryngoscopists, but because increasing the number of laryngoscopists adds the confounders of variable experience and differing learning curves, we chose to limit the study to experienced practitioners in our department. Some studies have standardized the experience of the laryngoscopists by providing prior training with a manikin. We felt that this training was not a satisfactory substitute particularly in neonates and infants for clinical experience in human subjects. Many reports have examined novice users of the GlideScope; we chose to sacrifice generalizability to all laryngoscopists in order to evaluate the expected performance with clinical experience. We did not measure the train-of-four before laryngoscopy in our study as it is not part of our usual clinical practice. We felt the elapsed time of 3 min after vecuronium administration was adequate for good intubation conditions, furthermore none of the study patients moved during laryngoscopy and intubation after this period of time. It should be noted that even though the laryngoscopists had significant experience with GCV, their experience with DL was significantly greater.

This study demonstrates the applicability of video laryngoscopes to infants with normal airways; further evaluations need to be carried out to investigate the performance of the GlideScope Cobalt® in patients with difficult airways. Published data in children suggests that video laryngoscopes are superior for intubation than traditional direct laryngoscopy in children with difficult direct laryngoscopy; however, the gold standard for difficult airway management in this population remains the flexible fiberoptic bronchoscope. We encourage future investigations in this area to compare the performance of video laryngoscopes with flexible fiberoptic intubation in children with difficult direct laryngoscopy.

Conclusions

The GlideScope Cobalt® is associated with better views of the glottis during intubation, quicker times to obtaining the best view, longer endotracheal tube passage time, similar intubation time, and similar success rate compared with like measures for direct laryngoscopy in children younger than 12 months of age with normal airways.

References

The GlideScope Cobalt® Video Laryngoscope in Children