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REPORTS OF ORIGINAL INVESTIGATIONS

Comparison of the Truview PCD™ and the GlideScope® video laryngoscopes with direct laryngoscopy in pediatric patients: a randomized trial

Comparaison des vidéolaryngoscopes Truview PCD™ et GlideScope® à la laryngoscopie directe chez les enfants : une étude randomisée

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Abstract

Introduction *The GlideScope® video laryngoscope has a 60° angled blade and the blade of the Truview PCD™ video laryngoscope has an optical lens that provides a 46° refraction of the viewing angle. Despite successful results using the GlideScope in adults, few studies have been published regarding its use in pediatric patients. We therefore tested our joint primary hypothesis that the GlideScope and the Truview PCD video laryngoscopes provide superior visualization to direct laryngoscopy and are non-inferior regarding time to intubation.*

Methods *One hundred thirty-four patients (neonate to ten years of age, American Society of Anesthesiologists physical status I-III) scheduled for general surgical procedures were randomized to tracheal intubation using the Truview PCD or GlideScope video laryngoscope or direct laryngoscopy (Macintosh blade). The laryngoscopic view was scored using the Cormack-Lehane scale. Time to intubation (defined as the time from the moment the device entered the patient's mouth until end-tidal CO_2 was detected) and the number of attempts were recorded.*

Results *The Cormack-Lehane views attained using the GlideScope ($P > 0.99$) and Truview PCD ($P = 0.18$) were not superior to the views attained with direct laryngoscopy. Furthermore, the view attained using the GlideScope was significantly worse than that attained using direct laryngoscopy ($P < 0.001$). Fewer patients showed Cormack-Lehane grade I views with the GlideScope than with the Truview PCD (14% vs 82%, respectively; 95% confidence interval [CI] −91% to −46%). The observed median [Q1, Q3] times to intubation were: 39 [31, 59] sec, 44 [28, 62] sec, and 23 [21, 28] sec with the GlideScope, Truview PCD, and direct laryngoscopy, respectively, with median differences of 14 sec (95% CI 7 to 26, GlideScope – direct laryngoscopy) and 17 sec (95% CI 6 to 28, Truview PCD – direct laryngoscopy).*

Conclusion *The Cormack-Lehane views attained using the GlideScope and the Truview PCD video laryngoscopes were not superior to views attained using direct laryngoscopy. Visualization with the GlideScope was significantly worse than with direct laryngoscopy. Use of the GlideScope and Truview PCD systems should be restricted to patients with specific indications.*

Author contributions *Ricardo Riveros, Wai Sung, Daniel I. Sessler, Ivan Parra Sanchez, Edward J. Mascha,* and *Julie Niezgoda* have contributed substantially to the conception and design of the study, the acquisition, analysis, and interpretation of data, and drafting and critically revising the article for important intellectual content.

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Résumé

Introduction *Le vidéolaryngoscope GlideScope® possède une lame recourbée à 60°, et la lame du vidéolaryngoscope Truview PCD™ dispose d'une lentille optique qui fournit une vue réfractée à 46° de l'angle de vision. Malgré les bons résultats obtenus avec le GlideScope chez l'adulte, peu d'études publiées portent sur son utilisation chez l'enfant. C'est pourquoi nous avons testé notre hypothèse primaire en deux volets, soit que les vidéolaryngoscopes GlideScope et Truview PCD offraient une meilleure visualisation que la laryngoscopie directe et qu'ils n'étaient pas inférieurs quant au temps nécessaire à l'intubation.*

Méthode *Cent trente-quatre patients (nouveau-nés à 10 ans, statut physique ASA [American Society of Anesthesiologists] I-III) devant subir une intervention en chirurgie générale ont été randomisés à recevoir une intubation trachéale avec un vidéolaryngoscope Truview PCD ou GlideScope ou avec une laryngoscopie directe (lame de Macintosh). La visualisation de la glotte a été notée à l'aide d'une échelle de Cormack-Lehane. Le temps nécessaire à l'intubation (défini comme le temps entre le moment où le dispositif est entré dans la bouche du patient jusqu'à détection de CO_2 télé-expiratoire) et le nombre de tentatives ont été notés.*

Résultats *Les scores de Cormack-Lehane obtenus à l'aide du GlideScope ($P > 0,99$) et du Truview PCD ($P = 0,18$) n'étaient pas supérieurs à ceux obtenus par laryngoscopie directe. En outre, le score obtenu avec le GlideScope était significativement moins bon que celui obtenu par laryngoscopie directe ($P < 0,001$). Il y a eu moins de scores de Cormack-Lehane de grade I avec le GlideScope qu'avec le Truview PCD (14 % vs. 82 %, respectivement; intervalle de confiance [IC] 95 % −91 % to −46 %). Les médianes [Q1, Q3] du temps nécessaire à l'intubation étaient : 39 [31, 59] sec, 44 [28, 62] sec, et 23 [21, 28] sec avec le GlideScope, le Truview PCD, et la laryngoscopie directe, respectivement, et les médianes des différences étaient de 14 sec (IC 95 % 7 à 26, GlideScope – laryngoscopie directe) et 17 sec (IC 95 % 6 à 28, Truview PCD – laryngoscopie directe).*

Conclusion *Les scores de Cormack-Lehane obtenus à l'aide des vidéolaryngoscopes GlideScope et Truview PCD n'étaient pas supérieurs à ceux obtenus par laryngoscopie directe. Avec le GlideScope, la visualisation était significativement moins bonne qu'avec la laryngoscopie directe. L'utilisation des systèmes GlideScope et Truview PCD devrait se restreindre aux patients présentant des indications spécifiques.*

Airways are usually relatively easy to manage in infants who do not suffer congenital malformations. Fibreoptic tracheal intubation has been the traditional approach in infants with a suspected difficult airway; however, advances in airway management have led to the development of video laryngoscope devices, such as the GlideScope® (Verathon, Inc., Bothell, WA, USA) and, most recently, the Truview PCD™ (Truphatek International Ltd., Netanya, Israel). The GlideScope has a 60° angled blade with a camera on the inferior aspect just at the inflection point. In contrast, the Truview PCD has a prism and lens system that provides a 46° angle of refraction. The Truview PCD also has a port through which oxygen can be injected, typically at a rate of 4-6 $L \cdot min^{-1}$.[1]

In adults, these devices reduce airway trauma and improve glottic visualization,[2,3] but use of video laryngoscopes has not been extensively investigated in pediatric patients and is limited to a few small trials using these devices in a normal pediatric airway. In a randomized trial comparing the use of the GlideScope with direct laryngoscopy in 203 pediatric patients, the Glidescope showed better or equal laryngoscopic views but with longer time for intubation than direct laryngoscopy.[4] Another pediatric study compared the Truview PCD video laryngoscope with direct laryngoscopy using a Miller blade in a younger population of neonates and infants. The Truview system was also shown to improve visualization of the larynx but with prolonged intubation time compared with direct laryngoscopy with a Miller blade.[5]

Pediatric anesthesiologists are increasingly becoming familiar with the use of video laryngoscopes for intubating both normal and difficult pediatric airways. Nevertheless, they still have more experience with direct laryngoscopy on a daily basis and usually turn to fibreoptic intubation or supraglottic airway devices, such as a laryngeal mask airway device, when faced with a challenging pediatric airway. Video laryngoscopes have nonetheless gained popularity for securing both normal and difficult pediatric airways.

Given the expanded use of both the Glidescope and the Truview PCD in our clinical practice and the paucity of evidence of the effectiveness of these devices in the management of the pediatric airway, we designed a trial to compare the effectiveness of these two video laryngoscope systems with the effectiveness of standard direct laryngoscopy in pediatric patients. Specifically, we tested the joint primary hypothesis that the GlideScope or Truview PCD would provide superior visualization and would be non-inferior on time to intubation when compared with direct laryngoscopy. Additionally, we aimed to assess the safety of the three devices regarding hemodynamics and episodes of desaturation in pediatric patients with a normal airway.

Methods

With approval of the Cleveland Clinic Institutional Review Board (IRB #09-902 – approved 11/19/2009) and written

consent from parents or guardians, we studied patients aged neonate to ten years with American Society of Anesthesiologists (ASA) physical status I-III who underwent elective general surgical procedures at the Cleveland Clinic Children's Hospital. We excluded patients with increased intracranial pressure, history of severe gastrointestinal reflux, sore throat, upper respiratory airway infection, known or suspected difficult airway, or coagulopathy.

After admission to the preoperative surgical area, a study coordinator randomly assigned the patients to tracheal intubation using the Truview PCD, GlideScope, or Macintosh blade. The study statistician first generated randomization codes using the PLAN procedure in SAS® statistical software by using permuted blocks of varying size (nine to 24 patients, i.e., three to eight per randomized group). The codes were then uploaded to a secure Web site designed and maintained by the study statistician and database developer in the Anesthesia Institute at the Cleveland Clinic. Allocation was thus concealed until the time of randomization, shortly before tracheal intubation.

Patients older than twelve months were premedicated with midazolam 0.5 $mg \cdot kg^{-1}$. Patients were induced with sevoflurane and a mixture of 30%/70% oxygen/nitrous oxide through a face mask. After an intravenous catheter was inserted, the patients were given propofol 1 $mg \cdot kg^{-1}$, fentanyl 1 $\mu g \cdot kg^{-1}$, and rocuronium 0.6 $mg \cdot kg^{-1}$. Before laryngoscopy, the patients' lungs were ventilated with 2-6% vol sevoflurane in 100% oxygen using face mask.

The tracheal intubations were performed by three staff anesthesiologists who had individually performed tracheal intubations for at least 20 pre-study patients each with the Truview PCD and the GlideScope. A Macintosh size-1 blade was used for infants and small children, and a size-2 blade was used for older children. Small GlideScope and Truview PCD blades were used for neonates and infants, whereas medium-sized blades were used for children. The internal diameter (mm) of the endotracheal tube was calculated using the formula: age (yr)/4 + 4. All intubations were performed using an endotracheal tube stylet, and oxygen was insufflated through the Truview PCD system at a rate of 4-6 $L \cdot min^{-1}$.

Intraoperative monitoring included electrocardiography, noninvasive blood pressure, capnography, and inspired and expired sevoflurane concentration. Values were recorded before laryngoscopy and at one-minute intervals thereafter for ten minutes.

The laryngoscopic view was scored using the Cormack-Lehane grade. Laryngeal manipulation to improve the laryngeal view was permitted. The time to intubate was defined as the time from when the device entered the patient's mouth until end-tidal carbon dioxide was detected, including the time between attempts. The number of attempts was recorded as well. Subsequent management was entirely at the discretion of the attending anesthesiologist.

Statistical analysis

The GlideScope and Truview PCD groups were each compared with the direct laryngoscope group for balance on demographics and baseline characteristics using standard summary statistics and the standardized difference, defined as the difference in means or proportions divided by the pooled standard deviation.

Our primary analysis was a joint hypothesis test comparing the GlideScope and Truview PCD with direct laryngoscopy in relation to time to intubation as well as Cormack-Lehane grade of laryngoscopic view. We used a joint hypothesis framework since both visualization and time to intubation are important for evaluating whether one method of intubation is more effective than another. Either the GlideScope or the Truview PCD would be deemed more effective than direct laryngoscopy if (and only if) both superiority on view and non-inferiority on time to intubation were established for that device. We employed a significance criterion of 0.025 (i.e., 0.05/2) for the comparison of each intubation method with direct laryngoscopy to preserve an overall type I error rate of 0.05. No further correction to the significance criterion was needed to assess the two primary outcome variables since both superiority on view and non-inferiority on time to intubation were required to conclude that the intervention was superior to direct laryngoscopy.[6,7]

The GlideScope and Truview PCD video laryngoscopes were individually assessed for superiority *vs* direct laryngoscopy on Cormack-Lehane grade using one-tailed exact Wilcoxon rank-sum tests. Each device was individually assessed for non-inferiority on time to intubation *vs* direct laryngoscopy at the 0.025 significance level using an *a priori* specified non-inferiority delta of seven seconds (about 40% of the expected standard deviation of 18 sec[4] and not thought to be clinically important). The expected mean in a pediatric population is about 14[4] sec, and non-inferiority was claimed if the upper limit of the two-sided 95% confidence interval (CI) (equivalent to a one-sided 97.5% CI) for the difference in medians (GlideScope or Truview PCD minus direct laryngoscopy) was less than seven seconds. The CI for the difference in medians was estimated using the Gardner and Altman method.[8] We also tested the same non-inferiority hypotheses using one-tailed exact Wilcoxon rank-sum tests after first subtracting seven seconds from each patient's GlideScope or Truview PCD tracheal intubation time.

The three randomization groups were descriptively compared on mean hemodynamic response (i.e., heart rate, mean arterial blood pressure) over time (from intubation for ten minutes, at one minute intervals). Additional binary secondary outcomes were summarized as well, including incidence of desaturation (defined as occurrence at

induction or any time from intubation to ten minutes after), proportion of success on the first attempt, and incidence of bleeding, trauma, teeth injury, and lip injury. The association between number of attempts (one attempt *vs* more than one attempt) and Cormack-Lehane grade was assessed with an exact logistic regression that included randomization group as a factor.

Kim *et al.*[4] observed a mean (standard deviation) of 24 (14) sec and 36 (18) sec intubation time for direct laryngoscopy and GlideScope, respectively. Assuming a standard deviation of 18 sec per group, a sample size of 158 patients per group ($n = 474$) was needed to provide 90% power at the 0.025 significance level (0.05 overall – including two comparisons with direct laryngoscopy) to detect non-inferiority on time to intubation between either the GlideScope or the Truview PCD *vs* direct laryngoscopy using a non-inferiority delta of seven seconds and a one-sided test. Our same sample size estimate also provided 90% power at an overall 0.05 significance level for detecting differences as large as 0.75 *vs* 0.90 in the proportion of Cormack-Lehane grade 1 view between the GlideScope *vs* direct laryngoscopy or between the Truview PCD *vs* direct laryngoscopy. These calculations include adjustment for interim analyses— the above sample size for time to intubation was 140 per group for a single-analysis design (i.e., no interim analyses) and 158 per group after adjusting for interim analyses.

Interim analyses were planned after each 25% of the planned enrolment. Group sequential boundaries with gamma spending functions (gamma = −4 for efficacy and futility) were used. [9] The *P* value boundaries for efficacy (futility in parentheses) for the planned three interim analyses and the final analysis were $P < 0.0008$ ($P > 0.858$), $P < 0.0024$ ($P > 0.494$), $P < 0.0074$ ($P > 0.158$), and $P < 0.0220$ ($P > 0.0220$), respectively.

SAS® software version 9.2.2 (SAS Institute, Cary, NC, USA), R software version 2.12.0 (The R Foundation for Statistical Computing, Vienna, Austria), and East® 5 software (Cytel, Inc., Cambridge, MA, USA) were used for analyses.

Results

The Executive Committee stopped the study for futility at the first interim analysis after 134 patients were enrolled from January 2010 to March 2011.

Randomized groups had similar body mass index and ASA physical status. Patients randomized to GlideScope tracheal intubation were slightly older on average and more likely to be male than those randomized to direct laryngoscopy. Patients assigned to Truview PCD were about one year older on average than those assigned to direct laryngoscopy (Table 1).

At the final analysis with 134 patients (29% of the maximum planned sample size), the *P* value boundaries for efficacy and futility were ≤ 0.0015 and > 0.366, respectively (Fig. 1). All CIs were adjusted for interim monitoring using z-statistics corresponding with the above efficacy *P* value criterion, i.e., $z = 2.97$ and $z = 2.75$ for 95% and 90% CIs, respectively.

Neither GlideScope ($P > 0.99$) nor Truview PCD ($P = 0.17$) were superior to direct laryngoscopy on Cormack-Lehane grade (Table 2), and the *P* value for GlideScope *vs* direct laryngoscopy crossed the futility boundary. In fact, the median grade with the GlideScope was significantly worse than with direct laryngoscopy (estimated difference in median grade, 1; 95% CI 1 to 2).

Neither the GlideScope nor the Truview PCD were found to be non-inferior to direct laryngoscopy on time to intubation, since the upper limits of both CIs for the differences in mean intubation time were above the non-inferiority criterion of seven seconds (Table 2, Fig. 2); both crossed the futility boundary (both $P > 0.99$). Median time to intubation was an estimated 14 sec longer (95% CI 7 to 26) with the GlideScope than with direct laryngoscopy and an estimated 17 sec longer (95% CI 6 to 28) with the Truview PCD than with direct laryngoscopy.

Table 1 Demographics and baseline characteristics ($n = 134$)

Factor	GlideScope ($n = 44$)	Truview PCD ($n = 45$)	Direct laryngoscopy ($n = 45$)	D1 *	D2 *
Age, yr	4.6 (2.7)	5.2 (2.8)	4.0 (2.8)	0.22	0.43
Male, %	75	69	64	0.23	0.09
Body mass index, $kg \cdot m^{-2}$	16 [15, 18]	16 [16, 18]	17 [15, 19]	−0.09	−0.10
ASA physical status, %				0.13	0.13
I	45	42	42		
II	52	56	53		
III	2	2	4		

ASA = American Society of Anesthesiologists

Summary statistics are presented as percent of patients, median [1st, 3rd quartiles], or mean (standard deviation)

*Standardized difference, defined as the difference in means or proportions divided by the pooled standard deviation; > 0.2 in absolute value suggests more imbalance than would be expected by chance.[23]

D1 = GlideScope – direct laryngoscopy; D2 = Truview PCD – direct laryngoscopy

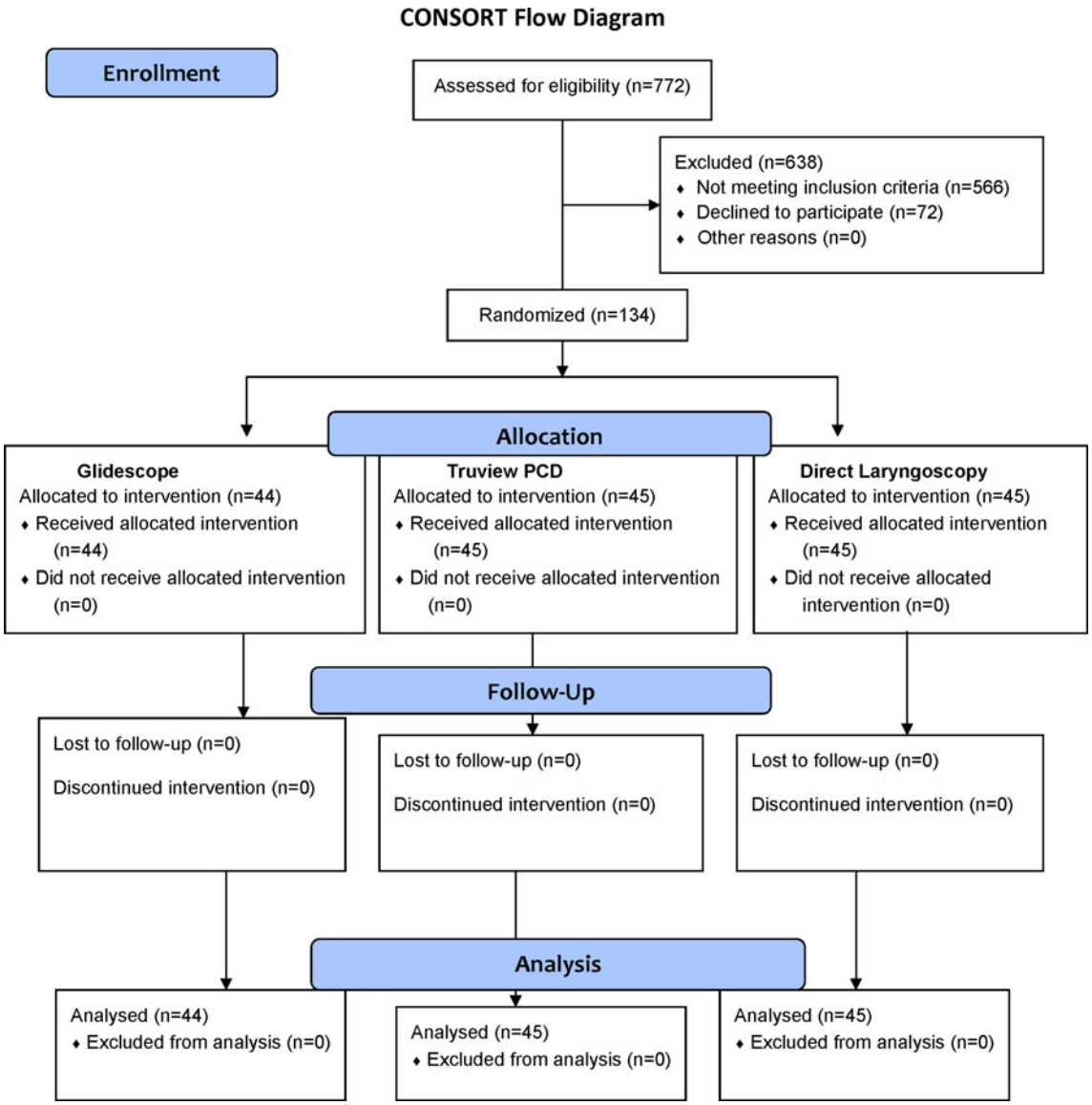

Fig. 1 Consort flow diagram

No clinically important differences between the three randomization groups were observed in either intubation success rate on the first attempt or in the occurrence of any of the listed complications (Table 3). The intubation success rates on the first attempt were 95% for the GlideScope group, 87% for the Truview PCD group, and 98% for the direct laryngoscopy group. Trauma and tooth injury were not observed in any patient; however, bleeding and lip injury were both observed in two patients in the Truview PCD group; no bleeding or lip injury was observed in the other two groups. During the period from intubation time to ten minutes after intubation, no important differences in mean arterial blood pressure or heart rate were observed between the three randomization groups. Nevertheless, we caution against making inferences on these secondary outcomes, particularly on the binary variables for which the study was underpowered.

Intubation success on the first attempt was 92% (71/77), 96% (25/26), 93% (27/29), and 100% (2/2) for patients with Cormack-Lehane grades 1 to 4, respectively. The number of attempts (one attempt *vs* more than one attempt) was not significantly associated with Cormack-Lehane grade ($P = 0.85$ after adjusting for randomization group). The relationship between number of attempts and Cormack-Lehane grade did not differ between the three randomization groups (interaction $P > 0.99$).

Discussion

In this study, the GlideScope was less effective than the standard direct laryngoscopy as evidenced by a lower-quality view and inferiority regarding time to intubation in

Table 2 Primary results – comparing GlideScope and Truview PCD with direct laryngoscopy on view and time to intubation

Primary outcome	GlideScope – ($n = 44$)	Truview PCD ($n = 45$)	Direct Laryngoscopy ($n = 45$)	Delta	GlideScope—DL Difference (95% CI)	*P* value	Truview PCD—DL Difference (95% CI)	*P* value
Cormack-Lehane grade (1/2/3/4), *n*	6/13/23/2	37/7/1/0	34/6/5/0	< 0 *	1 (1 to 2)	> 0.99 *	0 (0 to 0)	0.17 *
Intubation time, sec	39 [31-59] (16-302)	44 [28-62] (21-345)	23 [21-28] (16-70)	< 7 †	14 (7 to 26)	> 0.99 †	17 (6 to 28)	> 0.99 †

DL = direct laryngoscopy

Summary statistics are presented as number of patients, median [1st-3rd quartiles] (minimum-maximum); CI = confidence interval; DL = direct laryngoscopy

* Superiority of each of GlideScope and Truview PCD *vs* DL on Cormack-Lehane grade was assessed using a one-tailed exact Wilcoxon sum-rank test against a difference of 0 (< 0 indicates superiority) with interim-adjusted significance criterion of $P < 0.0015$. Neither group was superior to DL; GlideScope was inferior

† Non-inferiority of each of GlideScope and Truview PCD *vs* DL on time to intubation using the *a priori* non-inferiority delta of seven seconds was assessed using a one-tailed Wilcoxon rank-sum test with interim-adjusted significance criterion of $P < 0.0015$; since the upper limit of the confidence interval is well above seven seconds for each comparison, non-inferiority was not claimed for either device *vs* DL ($P > 0.99$)

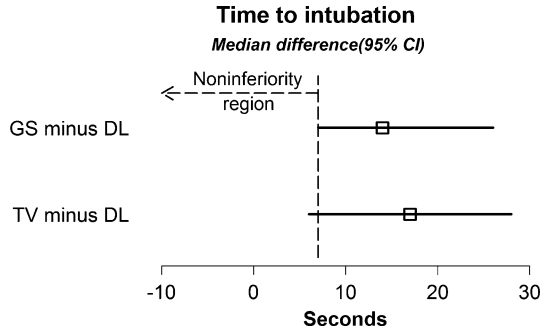

Fig. 2 Results of comparisons of time to intubation among the three intubation devices: GlideScope (GS), $n = 44$; Truview PCD (TV), $n = 45$; and direct laryngoscopy, $n = 45$. Time to intubation was worse by more than seven seconds using the GlideScope compared with using direct laryngoscopy; non-inferiority on time to intubation was not found using the Truview PCD compared with using direct laryngoscopy; intubation time using the GlideScope vs using Truview PCD was not equivalent

pediatric patients with a normal airway. Although laryngeal views did not differ between the Truview PCD and direct laryngoscopy, intubation with the Truview took significantly longer. None of the three groups showed changes in vital signs despite longer times to intubation with the GlideScope and the Truview PCD.

Our findings differ from previous reports using indirect video laryngoscopes in children. Our study included younger children than were included in a trial involving 203 children that reported equal or better laryngeal views with the GlideScope, with or without BURP (backward, upward, and right lateral displacement), than with direct laryngoscopy.[4] Pediatric airway anatomy differs from adult anatomy, and the differences are most important in younger children and neonates. At birth, the laryngeal inlet is at the C3-4 level. A combination of factors, including the cephalic position of the larynx, a large omega-shaped

Table 3 Comparison of the GlideScope, Truview PCD, and direct laryngoscopy on secondary outcomes

Secondary Outcome	GlideScope ($n = 44$)	Truview PCD ($n = 45$)	Direct laryngoscopy ($n = 45$)
Mean arterial blood pressure, † mmHg	63 (9)	66 (12)	62 (12)
Heart rate, † beats · min^{-1}	127 (15)	128 (18)	126 (21)
Desaturation †, §, *n*	0	1	1
Success on the first attempt, *n*	42	39	44
Bleeding, *n*	0	2	0
Trauma, *n*	0	0	0
Teeth Injury, *n*	0	0	0
Lip Injury, *n*	0	2	0

Summary statistics are presented as number and mean (standard deviation)

† Hemodynamics (i.e., heart rate, mean arterial blood pressure, and saturation) were measured at one minute intervals at induction time and from intubation for 10 minutes

§ Desaturation was defined as SpO_2 less than 90% at induction time or any time from intubation to ten minutes after. Both patients experienced desaturation only at their induction time

epiglottis, prominent arytenoids, deep-seated anteriorly angled vocal cords, and a posteriorly placed tongue makes it difficult for the pediatric anesthesiologist to visualize the laryngeal opening, even in the normal airway. The 60° angle of view with the GlideScope possibly worsens the view of the larynx compared with the direct approach. On the other hand, in a recent prospective randomized study involving 60 neonates and infants with normal airways, the GlideScope Cobalt was found to yield faster times and better glottic views when compared with direct laryngoscopy using a Miller blade. The time to tracheal intubation was similar in the two groups; however, because the GlideScope patients had slower endotracheal tube passage times than the direct laryngoscopy patients,[10] we used a second generation of the GlideScope with limited size options for patients in the age range we enrolled in our study. This may have been a potential factor affecting the view in our younger pediatric patients. Our use of the Truview PCD in this novel study provides the means to see the image on a screen and facilitates making a fair comparison between the two video laryngoscope systems. We found no difference in view between the Truview PCD and direct laryngoscopy in children up to ten years of age with normal airways. This finding differs from the improved laryngeal view reported in the Truview PCD study in neonates and infants.[5] We intubated patients' tracheas using a Macintosh blade, whereas a Miller blade was used in the Truview PCD study, which possibly explains the different outcomes. Nevertheless, we point out that Miller blades are used far more often in infants and children than Macintosh blades.

Prolonged apnea time provokes hemodynamic changes that could cause hypoxia, especially in children with reduced oxygen stores or increased oxygen consumption. In our study, only one patient each in the Truview PCD and direct laryngoscopy groups experienced desaturation just before tracheal intubation. The observed differences were not clinically important, although we caution that our study was not powered for binary outcomes, and larger studies would be needed to assess them rigorously.

An advantage of our study is the group-sequential design with preplanned interim analyses during which we assessed the efficacy and futility of the GlideScope and the Truview PCD *vs* direct laryngoscopy. Our design had the statistical property of preserving the type I error (false positives) and type II error (false negatives) at their predefined levels across the entire study. This was the case even if the study were to cross a boundary and terminate early, as did ours. We used flexible spending functions to control the type I and type II errors; this allowed us to perform the first interim analysis at 134 patients rather than at the planned 118 patients without statistical penalty or issue. The study was stopped early for futility at the first pre-planned interim analysis after crossing *a priori* boundaries. Nevertheless, because of the *a priori* statistical protections built into the design, it was appropriate to cease enrolment when we did, and this should not be considered a typical "stopped early" trial.

That being said, stopping studies early decreases the precision of the treatment effect estimates (indicated by wider CIs) than would be the case if the study were to continue to the maximum planned sample size. Even so, our conclusions are clear and robust since the observed differences were well into the counter-hypothesized direction, thus leading to the conclusion of futility for claiming that either the GlideScope or the Truview PCD was more effective than direct laryngoscopy. The study was stopped at a pre-defined interim analysis for compelling and pre-defined statistical reasons. It seems unlikely that enrolling additional patients would result in clinically meaningful differences in our conclusions. Another limitation of our study was the impossibility of blinding the intubating anesthesiologist to the designated laryngoscopy system. It is thus possible that bias or preference for a particular system influenced outcomes.

Finally, our study was completed in a normal pediatric airway, and no measurements, such as Mallampati classification, thyromental distance, presence of deciduous or permanent teeth, or size of mouth opening, were recorded. Nevertheless, in a randomized trial, there is no reason to expect substantial inhomogeneity across baseline characteristics. Greater familiarity with direct laryngoscopy by the involved anesthesiologists may have biased the results. Each of the three anesthesiologists participating in the study had good experience using the Truview PCD and the GlideScope; of course, they had far greater experience with Macintosh blades. In spite of this, given the airway anatomy in small children, the 46° angle offered by the Truview PCD blade can potentially improve visualization in neonates without a significant difference in visualization in older children. Additionally, the Truview PCD requires substantial eye-hand coordination because it uses an indirect laryngoscopy principle. This means that the endotracheal tube enters the patient's mouth laterally before the tip is seen on the Truview optical system, and only then is the tube advanced through the vocal cords. This maneuver requires practice and could explain the longer time for intubation between groups.

Randomized trials in adults have shown a higher rate of successful intubation of the difficult airway using video laryngoscopes compared with direct laryngoscopy.[11-16] It has been possible for anesthesiologists to use video laryngoscopes in the pediatric patient for little more than a decade. Several pediatric studies have shown improved views of the normal airway in patients with indirect laryngoscopy.[4,5,10] Theoretically, a better view of the glottic

opening should increase successful tracheal intubation. In addition, when viewing the laryngeal image on the video screen, laryngeal manipulations to improve the glottic view can be observed by both the practitioner and the assistant simultaneously to aid intubation. Video laryngoscopy demands fine hand-eye coordination and most likely explains the prolonged time to intubation in pediatric studies; however, this is also true for fibreoptic intubation, which is the present gold standard for the patient with a difficult airway. Learning the nuances of video devices can be acquired over time.[16] Case series and single reports have been published on the use of video laryngoscopes for successful intubation of the difficult pediatric airway.[17-22] The patients in our study had normal airways. It is usually recommended that the practitioner master the use of any new airway device or technique by acquiring the skills in a normal airway before attempting to use them in a difficult or critical airway. With future studies or practitioner experience from multicentre data bases, it remains possible — perhaps even likely — that video systems will provide better laryngoscopic views and thus afford the potential for tracheal intubation in the occasional pediatric patients with seriously abnormal airway anatomy.

In conclusion, neither the GlideScope nor the Truview PCD appears more effective than direct laryngoscopy using a Macintosh blade in the pediatric population with a normal airway. Specifically, results from this unblinded randomized trial suggest that neither device meets our criterion of being both superior to direct laryngoscopy on view and non-inferior to direct laryngoscopy on time to intubation — in fact, neither device met either condition. More studies are needed to assess the use of each system for special indications, such as pediatric patients with known or suspected difficult airways.

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