Comparison of a single-use GlideScope® Cobalt videolaryngoscope with a conventional GlideScope® for orotracheal intubation

Comparaison d'un vidéolaryngoscope GlideScope® Cobalt à usage unique à un GlideScope® traditionnel lors d'une intubation orotrachéale

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Abstract

Background This study was conceived to compare the single-use GlideScope® Cobalt videolaryngoscope with the conventional GlideScope® videolaryngoscope for orotracheal intubation, as judged by time to intubation (TTI) and ease of intubation.

Methods One hundred patients with normal-appearing airways requiring orotracheal intubation for elective surgery were randomly allocated to have their tracheas intubated by a heterogeneous group of operators with the Cobalt GlideScope® or the conventional GlideScope®. TTI was assessed by a blinded observer. Operators were blinded until the start of laryngoscopy. A visual analogue scale (VAS) assessed the ease of intubation. The number of intubation attempts, number of failures, glottic grades, and fogging of the video screen were recorded.

Results There was no difference between the median TTI of the GlideScope® Cobalt and the conventional GlideScope® (40.1 sec, interquartile range [IQR] 34.1, 51.3 vs

39 sec, IQR 32.6, 48.1, respectively; $P = 0.75$). The ease of intubation was similar between the two devices (median Cobalt VAS: 16 mm, IQR 10.8, 27.3, vs median conventional VAS: 12.5 mm, IQR 10, 20.5, respectively; $P = 0.12$). There were no significant differences between the two devices with respect to glottic exposure, intubation attempts, failures, or video screen fogging.

Conclusions The GlideScope® Cobalt has similar performance characteristics compared with the conventional GlideScope® videolaryngoscope when used for orotracheal intubation. The two devices can likely be used interchangeably. (ClinicalTrials.gov number, NCT00459797.)

Résumé

Contexte Cette étude a été conçue de façon à comparer un vidéolaryngoscope GlideScope® Cobalt à usage unique au vidéolaryngoscope GlideScope® traditionnel lors d'une intubation orotrachéale. Les critères d'évaluation étaient le temps jusqu'à l'intubation (TTI) et la facilité d'intubation.

Méthode Cent patients présentant des voies aériennes apparemment normales et nécessitant une intubation orotrachéale pour une chirurgie non urgente ont été randomisés à être intubés par un groupe hétérogène d'opérateurs soit avec le Cobalt GlideScope® ou le GlideScope® traditionnel. Les opérateurs étaient maintenus en aveugle jusqu'au début de la laryngoscopie, et le temps jusqu'à l'intubation a été évalué par un observateur en aveugle. Une échelle visuelle analogique (EVA) a été

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utilisée pour évaluer la facilité d'intubation. Le nombre de tentatives d'intubation, le nombre d'échecs, le grade d'intubation et la formation de buée sur l'écran vidéo ont été enregistrés.

Résultats Il n'y a pas eu de différence entre les TTI moyens du GlideScope® Cobalt et du GlideScope® traditionnel (40,1 sec, écart interquartile [IQR] 34,1, 51,3 vs 39 sec, IQR 32,6, 48,1, respectivement; $P = 0,75$). La facilité d'intubation était semblable avec les deux dispositifs (EVA moyenne Cobalt : 16 mm, IQR 10,8, 27,3, vs EVA moyenne vidéolaryngoscope traditionnel : 12,5 mm, IQR 10, 20,5, respectivement; $P = 0,12$). Il n'y a pas eu de différence significative entre les deux dispositifs en termes d'exposition de la glotte, de tentatives d'intubation, d'échecs ou de buée sur l'écran vidéo.

Conclusion Le GlideScope® Cobalt a des caractéristiques de performance semblables à celles du vidéolaryngoscope GlideScope® traditionnel lorsqu'il est utilisé pour une intubation orotrachéale. Les deux dispositifs peuvent probablement être utilisés de façon interchangeable. (Numéro de ClinicalTrials.gov, NCT00459797.)

Single-use devices are being used increasingly in anesthesia practice. Potential advantages of single-use devices include immediate availability (no cleaning time is required), a reduction in transmissible infections, lowered cost (sterile processing is eliminated), increased reliability (deterioration over time is eliminated), and simplicity. The shift to single-use airway devices has occurred, especially in recent years, because of the concern of infectious disease transmission from contaminated airway equipment.¹ Also, explicit support for single-use airway devices is found in some guidelines.²

The GlideScope® videolaryngoscope (GVL—Verathon® Medical Inc., Bothell, Washington, USA) has an established role in routine orotracheal and nasotracheal intubation.^{3–6} The single-use version of the GVL (Cobalt GVL) consists of two distinct parts: a reusable colour video camera and light source (video baton) and a disposable transparent sheath that enshrouds the video baton. Therefore, the reusable portion is not in direct contact with the patient (Fig. 1).⁷ The Cobalt GVL blade has a slightly different profile than the conventional GVL blade. The Cobalt GVL has been available since 2007, but there have been no prospective trials systematically examining the performance of the Cobalt GVL.

Although most single-use devices are designed to provide a quality product with technical performance at least as good as its conventional counterpart, this goal is not always accomplished.^{8,9} Single-use devices that purport to replace a well-established reusable device should be tested to determine whether they have similar performance metrics. Therefore, this prospective randomized trial was

Fig. 1 Top panel Flexible GlideScope® Cobalt video baton and transparent disposable sheath (small and large sheaths shown). Bottom panel Fully assembled GlideScope® Cobalt videolaryngoscope

undertaken to ascertain whether the Cobalt GVL exhibits similar performance characteristics to the conventional GVL when used for orotracheal intubation in patients with normal-appearing airways. The hypothesis of the trial was that there would be no difference between the devices in terms of time to intubation or overall ease of intubation.

Methods

This trial was registered at www.clinicaltrials.gov (NCT00459797). After obtaining local research ethics board approval, patients were screened for enrolment in the trial. Patients were eligible for inclusion if they were at least 18 yr old and scheduled for elective surgery requiring orotracheal intubation. Patients were excluded if they had a known difficult airway, if they required rapid sequence induction, or if the attending anesthesiologist considered use of the GVL to be contraindicated. The study was conducted at one teaching

hospital in London, Ontario, Canada. The conventional GVL in use at this hospital was the colour GVL (GlideScope® size five, Verathon® Medical Inc., Bothell, Washington, USA). The size four disposable blade for the Cobalt GVL was used in this trial, as it most closely approximated the size five conventional GVL. To participate in the trial, anesthesiologists and anesthesiology trainees were required to have previously performed at least ten GVL intubations to ensure their familiarity with the device. The operators were often the physicians responsible for the intraoperative care of the patient, but this was not mandated. Written informed consent was obtained from all patients and operators. The null hypothesis was that there would be no difference in time to intubation (TTI) between the groups.

Patients were randomly assigned to intubation with either the conventional GVL or the Cobalt GVL using computer-generated codes enclosed within opaque envelopes that were opened just before the induction of anesthesia. The attending anesthesiologist chose the endotracheal tube (ETT) size and prepared the ETT before the randomization envelope was opened. All ETTs had a lubricated malleable stylet inserted and were configured with a distal 90° angle 8 cm from the ETT tip.⁴

Patient demographics and Mallampati score¹⁰ were recorded preoperatively by the attending anesthesiologist. The device to which the patient had been randomized was turned on at least 1 min before intubation and obscured with a towel to ensure blinding of the operator. Appropriate monitoring for each patient was applied, and pre-oxygenation was performed to an end-tidal oxygen concentration of $\geq 80\%$. Induction and maintenance of anesthesia were not standardized. All patients had a non-depolarizing muscle relaxant administered, but the drug and dose were at the discretion of the attending anesthesiologist. After induction, the patients' lungs were ventilated with 100% oxygen until the operator deemed it appropriate to start the process of intubation. The laryngoscope to which each patient had been randomized was then given to the operator by a study assistant, unblinding the operator. Laryngoscopy was performed, the trachea was intubated, and the lungs were ventilated *via* the ETT. If the operator removed the laryngoscope or ETT from the patient's mouth, it was counted as an additional attempt at intubation. Operators were permitted to use external laryngeal manipulation or change the position of the patient's head to improve the glottic view or to facilitate intubation. Ventilation by mask was permitted between attempts if necessary.

The primary outcome was the TTI as measured by a blinded observer. The TTI began at the end of the period of bag-mask ventilation (at the moment when the mask was removed from the patient's face) and ended when end-tidal CO₂ exceeded 30 mmHg on the monitor. The blinded observer watched the patient until timing began and then

turned so that only the anesthesia monitor was visible. At no point did the observer see which laryngoscope was used. If the intubation attempt took ≥ 150 sec, it was deemed a failure, and the patient was intubated using a different modality and/or by a different operator. Failed intubations were included in the analysis (recorded as a TTI of 150 sec). Pre-specified secondary outcomes included ease of intubation (as recorded by the operator on a 100 mm visual analogue scale (VAS) immediately after intubation), the number of failures, the number of attempts, and the degree of fogging present on the video screen (rated as none, slight, or severe by the operator just after intubation). The operator recorded the ease of visualization of the glottic structures based on the classification described by Cormack and Lehane.¹¹ The TTI was not divulged to the operator until after the data collection sheet had been completed.

Sample size calculation was based on parametric analysis even though non-parametric analysis was planned for the outcomes in the study.^A A between-group difference of 10 sec in TTI was considered clinically significant. Based on the paucity of GlideScope® literature available at the time that this study was devised, the standard deviation (SD) of TTI was estimated from a simulation study investigating GVL-assisted orotracheal intubation that demonstrated a SD of 12.7 sec.¹² A conservative SD estimate of 14 sec for TTI was employed with standard Type I and Type II error rates ($\alpha = 0.05$, $\beta = 0.20$). The calculated sample size was 31 per group, but a total sample size of 100 patients was selected because the SD was estimated.

Statistical analysis

Time to intubation and ease of intubation were assessed using the Mann–Whitney test. Categorical data were analyzed using Fisher's exact test or the Chi-square test. Data are shown as median and interquartile range (IQR) unless otherwise noted. No corrections for multiple comparisons were made.¹³ Data were analyzed using GraphPad Prism software, version 5.0b for Mac OS X. Results were considered statistically significant when $P < 0.05$.

Results

Patients were screened for enrolment from June 2007 to September 2008. A total of 105 patients were screened; three patients met the trial's inclusion criteria but declined participation, and two patients did not meet the trial's inclusion criteria (both required rapid sequence induction).

^A Lehmann EL, D'Abrera HJ. Nonparametrics: statistical methods based on ranks. San Francisco: Holden-Day; 1975.

Table 1 Demographic data

Characteristic	Conventional GlideScope® (<i>n</i> = 50)	Cobalt GlideScope® (<i>n</i> = 50)
Age, yr	55.4 ± 17.1	55.6 ± 18.7
Male, <i>n</i> (%)	29 (58%)	34 (68%)
ASA I/II/III/IV (%)	14/26/24/36	10/18/30/42
BMI (kg · m ⁻²)	28.8 ± 4.9	28.0 ± 5.0
Mallampati score I/II/III/IV (%)	40/42/16/2	48/40/10/2
Presence of upper teeth, <i>n</i> (%)	41 (82%)	41 (82%)
Number of unique operators, <i>n</i>	22	21
Staff/trainee (%)	55/45	43/57

Values are mean ± SD unless otherwise indicated

ASA American Society of Anesthesiologists, BMI body mass index

One hundred patients met the inclusion criteria, gave informed consent, and were enrolled and randomized. Baseline demographics were similar between groups (Table 1). A heterogeneous group of operators was recruited, evenly divided between staff anesthesiologists and trainees. One patient in the Cobalt GVL group was not intubated within 150 sec due to a mechanical problem with the Cobalt GVL that allowed the video camera to rotate 180° and show the image upside-down, thus making intubation virtually impossible. This issue was subsequently

communicated to the manufacturer and has since been rectified (personal communication with Verathon®, 2008).

The median TTI was not significantly different between the two groups (Table 2). A Kaplan–Meier plot was constructed to demonstrate the success of intubation as a function of time (Fig. 2).

The ease of intubation was similar between groups (Table 2). The graph depicting the ease of intubation data shows that the vast majority of intubations with both the Cobalt and the conventional GVL were rated as being easy (Fig. 3).

Glottic exposure was good in both groups, and there was no difference between groups in terms of attempts at intubation, failed intubations, or fogging of the video screen (Table 2).

Discussion

In a group of heterogeneous operators and patients, the single-use Cobalt GVL exhibited similar performance characteristics as the conventional GVL. Specifically, the experienced operators had similar times to intubation and found both instruments equally easy to use for orotracheal intubation. The Kaplan–Meier plot (Fig. 2) showing the percentage of intubations as time progressed demonstrates overlap at every time point.

Table 2 Intubation data

Variable	Conventional GlideScope® (<i>n</i> = 50)	Cobalt GlideScope® (<i>n</i> = 50)	Statistical test	<i>P</i> value
Time to intubation (sec) median (IQR)	39 (32.6–48.1)	40.1 (34.1–51.3)	Mann–Whitney	0.75
Ease of intubation VAS (mm) median (IQR) (0 = easy, 100 = difficult)	12.5 (10–20.5)	16 (10.8–27.3)	Mann–Whitney	0.12
Fogging of screen, <i>n</i> (%)				
None	50	48	Fisher's exact test	0.49
Slight	0	2		
Severe	0	0		
Glottic grade ^a , <i>n</i> (%)				
1	34 (68%)	39 (78%)	Fisher's exact test	0.37
2	16 (32%)	11 (22%)		
First-attempt success rate, <i>n</i> (%)	50 (100%)	47 (94%)	Fisher's exact test	0.24
Failures to intubate within 150 sec, <i>n</i> (%)	0	1 (2%)	Fisher's exact test	1.0
ETT size				
7	7	5	Chi square	0.59
7.5	14	10		
8	23	24		
8.5	6	10		
9	0	1		

VAS visual analogue scale, ETT endotracheal tube

^a Glottic grade as described by Cormack and Lehane¹¹

Fig. 2 Kaplan–Meier plot demonstrating the success of orotracheal intubation as a function of time. Groups were compared using the Mann–Whitney test

Fig. 3 Ease of intubation by operators as measured on a 100 mm visual analogue scale. The markings filled out by the operators on the data collection form are designated “easy” at 0 mm and “difficult” at 100 mm. Bars and text indicate median VAS and the interquartile range. Groups were compared using the Mann–Whitney test. VAS visual analogue scale

Fogging of the camera lens or cover has the potential to degrade the picture quality for any videolaryngoscope. Conceivably, the Cobalt GVL could be more prone to fogging due to the transparent sheath and the small insulating air gap separating the camera/heater element and the exterior surface of the sheath. However, fogging was not an issue in this study.

It is important that single-use adaptations of reusable devices be tested systematically against the conventional device before widespread clinical adoption. Even if the single-use device has a similar look and feel to the conventional instrument, this does not necessarily mean it will perform comparably. In addition, it is useful for research purposes to have sound evidence that a single-use device has similar performance characteristics as its reusable counterpart, since data for both single-use and reusable devices may be combined and meta-analyzed. Finally, when multi-centre airway device trials are performed, it is important to appreciate that devices from various institutions perform similarly.

A limitation of this trial was the fact that the operators were aware they were participating in a clinical trial and that the intubation was being timed. This fact alone could have led to better clinical performance (the Hawthorne effect).¹⁴ However, it was expected that any improvement would have been equally distributed between the groups, thus minimizing the impact of this effect. The potential for an individual’s pre-existing bias either for or against the Cobalt GVL or the conventional GVL could conceivably have had an impact on the results of this trial. Since it is impossible to blind an anesthesiologist as to the instrument being used for intubation, all personnel in this study were blinded until the last possible moment in order to minimize any systematic bias, and the assessor of the results of the trial was fully blinded. Since this trial was conducted in patients with normal-appearing airways, the results may not be applicable to patients with abnormal airways. Finally, it is possible that the superiority of one of the devices over the other, in terms of the outcomes of this trial, could have been observed in a larger trial (a Type II error). In a trial of 100 patients, the clinical importance of an undetected difference is doubtful and would be debatable even if the difference was statistically significant.

In conclusion, the Cobalt GVL demonstrates similar performance, as measured by time to intubation and ease of intubation, when compared with conventional GVL videolaryngoscopy in patients with an unanticipated difficult airway. The two devices can likely be used interchangeably.

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Conflicts of interest Dr. Jones has received an honorarium for writing a chapter in a booklet about videolaryngoscopy using the GlideScope®.

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