The GlideScope®-specific rigid stylet and standard malleable stylet are equally effective for GlideScope® use

[Le mandrin rigide spécifique au GlideScope® et le mandrin flexible standard sont tous deux aussi efficaces pour l'utilisation avec le GlideScope®]

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Purpose: The GlideScope® videolaryngoscope usually provides excellent glottic visualization, but directing an endotracheal tube (ETT) through the vocal cords can be challenging. The goal of the study was to compare the dedicated GlideScope®-specific rigid stylet to the standard malleable stylet, assessed by time to intubation (TTI).

Methods: Eighty patients requiring orotracheal intubation for elective surgery were randomly allocated to either the GlideScope® rigid stylet (GRS) or a standard malleable stylet to facilitate intubation using the GlideScope®. Time to intubation was recorded by blinded assessors; operators were blinded until after laryngoscopy. The operator assessed the ease of intubation using a visual analogue scale (VAS). The number of intubation attempts, number of failures, glottic grades, and use of external laryngeal manipulation were documented.

Results: The median TTI was 42.7 sec (inter-quartile range (IQR) 38.9–56.7) for the GRS group compared to 39.9 sec (IQR 34.1–48.2) for the control group ($P = 0.07$). The median VAS score for ease of intubation was 20 (IQR 12.0–33.0) for the GRS group compared to 18 (IQR 9.5–29.5) for the control group ($P = 0.21$). There was no significant difference in TTI or VAS between stylets. The overall incidence of a Cormack-Lehane grade I or II glottic view was 98%.

Conclusions: In a group of experienced operators using the GlideScope®, the dedicated GRS and the standard malleable ETT stylet are equally effective in facilitating endotracheal intubation.

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***Objectif** : Le vidéolaryngoscope GlideScope® fournit en général une excellente visualisation glottique, mais diriger une sonde endotrachéale (SET) entre les cordes vocales peut être un défi. L'objectif de cette étude était de comparer le mandrin rigide spécifique au GlideScope® au mandrin flexible standard, évalués par le temps requis pour l'intubation (TTI).*

***Méthode** : Quatre-vingts patients nécessitant une intubation orotrachéale pour une chirurgie élective ont été randomisés à être intubés à l'aide soit du mandrin rigide GlideScope® (GRS), soit du mandrin flexible standard pour faciliter l'intubation avec le GlideScope®. Le temps requis pour l'intubation a été mesuré par des évaluateurs en aveugle ; les opérateurs étaient également en aveugle jusqu'à ce que la laryngoscopie soit terminée. L'opérateur a évalué la facilité d'intubation à l'aide d'une échelle visuelle analogique (EVA). Le nombre de tentatives d'intubation, le nombre d'échecs, le grade d'intubation et le recours à une manipulation laryngée externe ont été notés.*

***Résultats** : Le TTI médian était de 42,7 sec (intervalle interquartile (IQR) 38,9-56,7) pour le groupe GRS comparé à 39,9 sec (IQR 34,1-48,2) pour le groupe témoin (P = 0,07). Le score EVA médian pour la facilité d'intubation était de 20 (IQR 12,0-33,0) pour le groupe GRS comparé à 18 pour le groupe témoin (P = 0,21). Il n'y a pas eu de différence significative dans le TTI ou l'EVA entre les mandrins. L'incidence globale de la visualisation glottique selon l'échelle de Cormack-Lehane de grade I ou II était de 98 %.*

***Conclusion** : Dans un groupe d'opérateurs expérimentés se servant du GlideScope®, le mandrin GRS spécial et le mandrin flexible standard ont la même efficacité pour faciliter l'intubation endotrachéale.*

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THE GlideScope® videolaryngoscope (GVL; Verathon Medical Inc., Bothell, WA, USA) uses a high-resolution video camera embedded into a plastic laryngoscope blade. It consistently provides a good glottic view,[1] but advancing the endotracheal tube (ETT) through the vocal cords can be difficult[2,3] and trauma is possible.[4–7] Due to the curvature of the GVL blade, a stylet must be used to position the ETT tip at the glottic opening.[2] Various authors have recommended different curvatures of the ETT/stylet to optimally place it into the trachea, including matching the blade's 60° angle,[1,A] configuring the ETT with a 90° bend,[2] or using a "J-shaped" ETT.[8] "Reverse loading" of the ETT on the stylet has also been proposed.[9] A randomized controlled trial involving malleable stylets showed that a stylet with a 90° bend resulted in faster intubation and perceived easier use than matching the GVL blade's 60° angle,[10] with no benefit from reverse loading.

The GlideScope® manufacturer has made available a stylet optimized for use with the GVL. This GlideScope®-specific rigid stylet (GRS) is substantially more rigid than the standard malleable stylet. Its curvature approaches 90° with approximately 6 cm radius of curvature. The stylet is re-usable and can be autoclaved or cleaned similarly to the GVL (Figure 1).[A]

It is not uncommon for anesthesia devices to come to market prior to in-depth clinical evaluation. To evaluate the potential incremental benefit of the GRS in clinical practice, a randomized controlled trial was undertaken using experienced GVL operators on a heterogeneous group of patients to compare the GRS to the traditional malleable stylet, in regards to time to intubation (TTI) and ease of use.

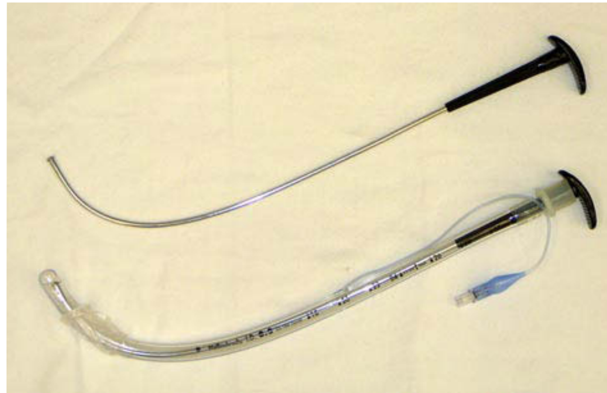

FIGURE 1 GlideScope®-specific rigid stylet, shown alone and with an endotracheal tube *in situ*.

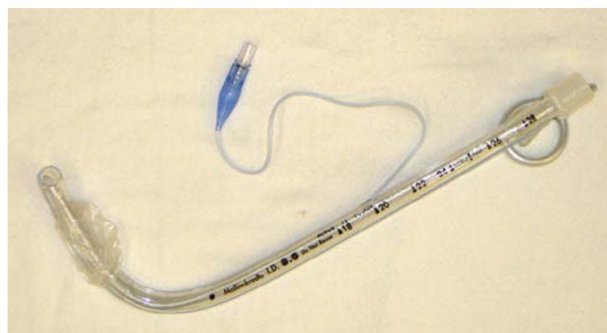

FIGURE 2 Malleable Rusch 14 French stylet inserted into an endotracheal tube. The 90° bend was formed 8 cm from the tip.

Methods

This study took place at the three teaching hospitals in London, Ontario, Canada, from January to April 2007, and involved patients having surgery in most every surgical discipline. The trial was registered at ClinicalTrials.gov (NCT00434720) after obtaining local Research Ethics Board approval. Adult patients scheduled for elective surgery requiring orotracheal intubation were invited to participate. Exclusion criteria included: known difficult airway, required rapid sequence induction, or a contraindication to GVL use.[4,5] Staff anesthesiologists and experienced anesthesiology residents were eligible to be operators if they had successfully performed at least 15 GVL intubations, and were encouraged to practice using the GRS prior to participation in the trial. Written informed consent was obtained from all patients and operators.

The null hypothesis was that there would be no difference in TTI between the stylets. The GRS was used as according to the instructions supplied by the manufacturer (Figure 1).[A]

The control group used the standard local practice[10] – the ETT was loaded with forward camber onto a 14 French Rusch Flexi-Slip malleable stylet (Teleflex Medical, Bannockburn, IL, USA). A 90° angle was formed 8 cm from the distal end of the ETT; there was no other angulation of the ETT (Figure 2).

Patient demographics and airway assessments[11] were recorded preoperatively. The operator chose the ETT size prior to patient randomization. Each patient

A Verathon Medical Inc. BWU. GlideScope Video Intubation System - Operator and Service Manual, 2003.

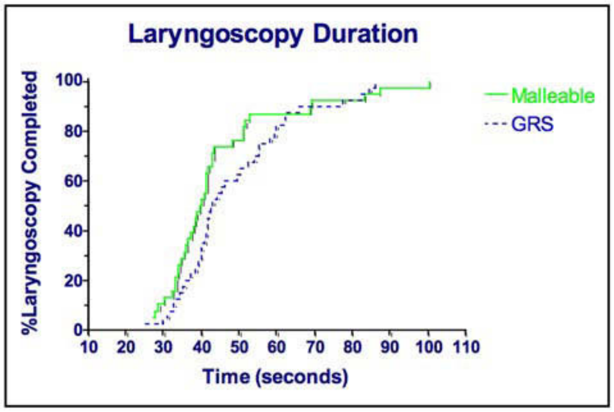

FIGURE 3 Kaplan-Meier plots comparing the time to intubation with the GlideScope®-specific stylet and malleable Rusch 14 French stylet. $P = 0.07$.

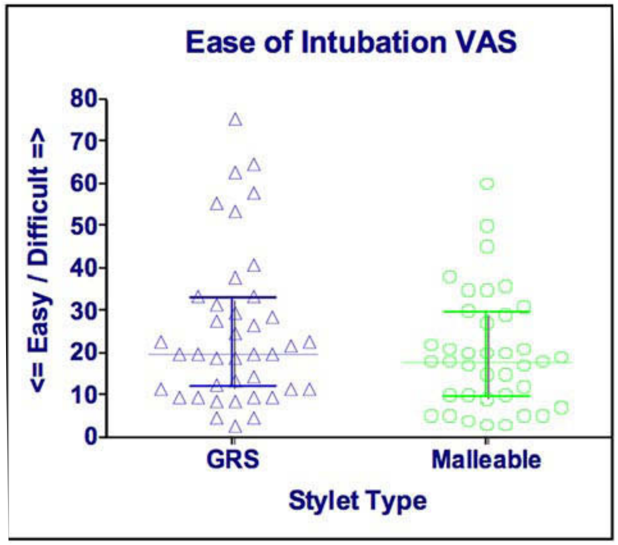

FIGURE 4 Ease of intubation by GlideScope® operators as measured on a 100-mm visual analogue scale (VAS). $P = 0.21$. The VAS scored by the operators was marked "Easy" at 0 mm and "Difficult" at 100 mm. Bars indicate median and inter-quartile range. GRS = GlideScope rigid stylet.

was allocated by a computer-generated random code enclosed within an opaque envelope, opened as the patient entered the operating room. Each envelope also contained a paper template to verify correct curvature of the GRS and to allow precise replication of control ETT stylet curvature. An ETT with each of the stylets was prepared according to the templates by one of the study investigators, who concealed the assigned ETT with a towel. This investigator then had no further involvement with that patient's clinical care or outcome assessment. The remaining ETT was concealed in another towel to be used if the operator was unsuccessful with the assigned stylet. Each ETT was concealed so that the GVL operator would remain blinded until after GVL laryngoscopy had been completed, to avoid any potential bias during induction, GVL laryngoscopy or glottic view scoring.[10]

Induction and maintenance of anesthesia were not standardized, but pre-oxygenation was mandated to an end-tidal oxygen concentration of ≥ 80% and all patients were paralyzed. The dosing of rocuronium or succinylcholine was at the discretion of the operator. After induction, the patient's lungs were ventilated with a volatile anesthetic agent in 100% oxygen until the operator deemed it appropriate to begin intubation. With rocuronium, a minimum delay of 90 sec was utilized for onset of paralysis.

The operator performed laryngoscopy with the GVL and graded the Cormack & Lehane (CL) grade of view.[12] The ETT was then revealed, unblinding the operator, and the patient was intubated with the ETT and assigned stylet. Operators were permitted to use external laryngeal manipulation in order to improve the glottic view or to facilitate intubation. If the operator removed the GVL blade or ETT from the mouth, this was counted as an additional attempt at intubation. If the assigned stylet proved unsuitable, the operator was permitted to use the other stylet and ETT on the second or third attempt.

The primary outcome was the TTI as measured by a blinded observer. The TTI was defined from when the GVL blade first passed the teeth to when end-tidal CO_2 of at least 30 mmHg was present on the anesthesia monitor. After timer initiation, the blinded observer turned so that only the anesthesia monitor was visible; at no point did the observer see the ETT or stylet. If the intubation attempt took longer than 150 sec or three attempts, it would be deemed a failure and the airway would then be managed using any technique deemed appropriate by the attending anesthesiologist. Ventilation between attempts was permitted if necessary. Pre-specified secondary outcomes for each group included: ease of intubation [as scored by the operator immediately after laryngoscopy on a 100-mm visual analogue scale (VAS)], the number of attempts made, CL grade,[12] whether external laryngeal manipulation was used, and whether the ETT was advanced off the stylet by an assistant. The data collection sheet also included a blank "comments" box where operators could add comments. The TTI was not divulged to the operator until after the data collection sheet had been completed.

Statistical analysis

For sample size calculation, a between-group difference of ten seconds in TTI was considered clinically significant. The standard deviation (SD) of TTI was estimated from a simulation study that demonstrated a SD of ten seconds[13] and a human study that showed a SD of 12 sec.[14] An estimate of 15 sec for TTI SD was employed with standard type I and type II error rates ($\alpha = 0.05$, $\beta = 0.20$). The calculated sample size was 36 per group; a total sample size of 80 patients was selected.

The TTI and the ease of intubation VAS were compared using the Mann-Whitney U test. Kaplan-Meier plots were constructed to graphically represent the temporal component of intubation. Chi-square or Fisher's exact test were used as appropriate for categorical data. Results were considered statistically significant when $P < 0.05$.

Results

Eighty patients were recruited; no patients were lost to follow-up. Baseline demographics and ETT size were similar between study groups (Table I). One patient in the GRS group could not be intubated using the GRS but was intubated on the second attempt using the malleable stylet. Two patients were withdrawn from analysis after randomization, both in the (control) malleable stylet group. In one case, the operator did not adhere to the protocol. In the other case, the GVL could not be inserted into the patient's mouth; Macintosh laryngoscopy yielded a CL[12] grade IV view and the patient was intubated uneventfully using a lighted stylet.

The median TTI was 42.7 sec [inter-quartile range, (IQR) 38.9 –56.7] for the GRS group compared to 39.9 sec (IQR 34.1– 48.2) for the control group ($P = 0.07$), (Figure 3). The median VAS for ease of intubation was 20.0 mm (IQR 12.0– 33.0) for the GRS group compared to 18.0 mm (IQR 9.5–29.5) for the control group ($P = 0.21$), (Figure 4). There was no significant difference in TTI or VAS between the two stylets.

Table II shows the distribution of number of attempts, glottic grade,[12] use of laryngeal manipulation, and cases where the ETT was advanced off the stylet by an assistant. The groups were similar with respect to the pre-specified parameters. Additionally, the number of written comments expressing dissat-

TABLE I Demographic data

Characteristic	*GlideScope® rigid stylet (n = 40)*	*Malleable Rusch 14 French (n = 38)*
Age	44.4 ± 12.9	51.9 ± 16.3
Male/female	18 / 22	17 / 21
ASA I / II / III / IV	7 / 14 / 15 / 4	12 / 14 / 7 / 7
BMI ($kg \cdot m^{-2}$)	30.0 ± 6.5	29.0 ± 5.9
Mallampati score[11] I / II / III / IV	16 / 21 / 3 / 0	15 / 18 / 4 / 1
Presence of upper teeth yes / no	38 / 2	32 / 6
ETT ID 7.0 / 7.5 / 8.0 / 8.5	8 /13 / 15 / 4	2 / 19 / 10 / 7

Values are mean ± SD or categorical. BMI = body mass index; ETT ID = endotracheal tube inner diameter.

TABLE II Clinical outcomes

Outcome	*GlideScope® rigid stylet (n = 40)*	*Malleable Rusch 14 French (n = 38)*	*P value*
Time to intubate (sec)	42.7 (38.9 - 56.7)	39.9 (34.1 - 48.2)	0.07 ^{m}
Ease of intubation (100 mm VAS)	20 (12.0 - 33.0)	18 (9.5 - 29.5)	0.21 ^{m}
Glottic view grade I / II / III / IV	36 / 4 / 0 / 0	32 / 5 / 1 / 0	0.52 ^{c}
Attempts 1 / 2 / 3	38 / 2 / 0	36 / 2 / 0	1.00 ^{f}
Laryngeal manipulation Yes / No	2 / 38	1 / 37	1.00 ^{f}
ETT advanced from stylet by assistant yes / no	18 / 22	14 / 24	0.50 ^{f}
Comments expressing dissatisfaction	17 (43%)	5 (13%)	0.005 ^{f}

Values are median and interquartile range or categorical. *P* values obtained from: ^{m} = Mann-Whitney U test, ^{c} = Chi-square, or ^{f} = Fisher's exact test. Glottic grade as described by Cormack and Lehane.[12]

isfaction was tabulated and is also shown in Table II. Overall, there were more comments expressing dissatisfaction towards the GRS, 43% *vs* 13% ($P = 0.005$).

Discussion

One issue with GVL usage has been the occasional difficulty in advancing the ETT despite excellent glottic visualization.[1–3,8] This study confirms the excellent glottic view that one regularly obtains with the GVL (Table II); 98% of patients had a grade I or II glottic view,[12] in agreement with previous work.[1,10,15] In this group of experienced GVL operators, there was no significant difference between the GRS and a standard malleable stylet for TTI or perceived ease of intubation. Although there was a trend towards shorter TTI with the malleable stylet, a larger trial would be required to reach statistical significance if the calculated point estimates are accurate, and the clinical relevance of a three-second shorter duration of intubation is debatable. There was a trend toward preference for the standard malleable stylet in terms of ease of use, but the statistical non-significance suggests that the choice can be a matter of preference for anesthesiologists.

Tracheal intubation was unsuccessful for one patient in the GRS group, but his airway was secured using the malleable stylet. This suggests that, if the GRS is used for GVL intubation, malleable stylets should also be available. There was no evidence of oral trauma in any patient during this study, but rare cases have been reported with both GRS[7] and malleable stylet[4–6] use. Considering that the GRS is markedly more rigid than the malleable stylet, there could well be increased potential for trauma using the GRS. Irrespective of the device chosen to facilitate GVL use, ETTs must be inserted with care and minimal force. The tip of the GRS or the malleable stylet should be covered by the ETT.

The endpoint of TTI was observation of end-tidal CO_2 on the anesthesia monitor, similar to other trials investigating intubation techniques.[10,15,16] This was done to be clinically meaningful and to provide an objective blinded endpoint. If the TTI had ended at ETT cuff inflation or GVL blade removal, the observer could have become unblinded watching stylet removal, which could have biased observations.

In this study, anesthesiologists expressed comments of dissatisfaction with the GRS more frequently than when using the malleable stylet. This suggests that the GRS was not quickly accepted by our colleagues and did not engender satisfaction. However, a limitation to this trial is that most operators had greater prior experience with the malleable stylet. All operators were encouraged to practice with the GRS on mannequins and patients prior to study participation, but the malleable stylet with a 90° bend had the benefit of greater experience since it had become the local standard of care.[10]

It is noteworthy that the GlideScope® is now available in a second-generation colour model with a slightly smaller blade profile, ~14 mm *vs* 18 mm, but similar shape and radius of curvature (GlideScope® Lo Pro Adult, Verathon Medical Inc., Bothell, WA, USA). During this trial, the first-generation GVL was used, and although it is unlikely that using the newer blade would result in clinically relevant differences in the results, the conclusions of this trial might not be applicable to the more recent design. Operators were aware that their actions were being timed. This could lead to superior or inferior clinical performance via the Hawthorne effect.[17] However, any improvement or deterioration would likely have been distributed equally between the groups – minimizing the impact of this effect.

In summary, the rigid GRS did not result in shorter TTI or improved operator satisfaction in this group of experienced anesthesiologists, but more anesthesiologists expressed comments of dissatisfaction in the GRS group. The choice of stylet for intubation using the GlideScope® is therefore a matter of anesthesiologists' preference.

Acknowledgements

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