Adding a conduit to GlideScope blade facilitates tracheal intubation

Prospective randomized study

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ABSTRACT

الأهداف: تعريف الوقت اللازم لإدخال الأنبوب الرغامي عند إضافة بعض التعديلات على شفرة منظار جلايدوسكوب.

الطريقة: أُجريت هذه الدراسة الاستطلاعية المستقبلية في مستشفى جامعة الملك عبدالعزيز، جدة، المملكة العربية السعودية خلال الفترة من يونيو إلى أكتوبر 2011م. شملت الدراسة 60 مريضاً بالغاً في حاجة لإدخال الأنبوب الرغامي باستخدام منظار جلايدوسكوب وذلك بغية إجراء عمليات جراحية، و تم توزيعهم عشوائياً بالتساوي على أحد المجموعتين: مجموعة (م) (30) أُجريت لهم عملية إدخال الأنبوب الرغامي من خلال أنبوب تم إلصاقه بالحد الجانبي لشفرة المنظار وقطعه من الجنب ليشكل مجرى أنبوبي يتم تمرير الأنبوب التنفسي من خلاله للقصبة الهوائية، بينما يتم إدخال الأنبوب الرغامي لمرضى المجموعة (س) (30) بالاستخدام التقليدي لمنظار جلايدوسكوب.

النتائج: كانت النتائج الأساسية وأحجام الأنابيب الرغامية المستخدمة متساوية بين المجموعتين، بينما كان الوقت المستغرق لإدخال الأنبوب الرغامي أقصر في المجموعة (م) 39.6±2.1 ثانية عند مقارنته بالمجموعة (س) 66.4±8.3 ثانية (p=0.0001). وكان إدخال الأنبوب الرغامي أكثر سهولة عند المجموعة (م) بعكس المجموعة (س) (1±2 مقابل 1±6، p=0.0001). وقد تم إدخال الأنبوب الرغامي لدى مرضى المجموعة (م) من المحاولة الأولى وذلك عند المقارنة مع 90% من مرضى المجموعة (س) (p=0.009).

خاتمة: أظهرت هذه الدراسة بأن إضافة مجرى أنبوبي لشفرة منظار جلايدوسكوب الحنجري قد سهل عملية إدخال الأنبوب الرغامي وأضاف ميزة عند استخدامه.

Objectives: To determine the effect of modifying the GlideScope (GVL) blade on the intubation time.

Methods: This prospective study was conducted at the Department of Anesthesia, King Abdulaziz University Hospital, Jeddah, Saudi Arabia between June 2011 and October 2011. Sixty patients requiring endotracheal tube (ETT) intubation for elective surgery in whom airway was anticipated normal were randomly allocated to one of 2 groups. Group M (n=30): intubated via a modified GVL blade in which a tube conduit along the side of the GVL blade was created to allow the passage of ETT through the cords. Group C (n=30): intubated with the conventional GVL blade and rigid intubating stylet.

Results: Time to successful tracheal intubation (TTI) was 39.6±2.1 seconds in Group M versus 66.4±8.3 seconds in Group C (p=0.0001), tracheal intubation was deemed more easily in Group M than in Group C (VAS 2±1 versus 6±1, p=0.0001), and all patients in Group M were successfully intubated on the first attempt when compared with 90% in Group C (p=0.009).

Conclusion: The addition of a conduit to the GVL blade made the passage of the ETT easier and TTI shorter without increasing adverse events or intubation failure.

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The GlideScope® videolaryngscope (GVL) (Verathon Medical Inc., Bothell, WA, USA) incorporates a high resolution digital camera into plastic laryngoscope blade.[1] It provides a clear on screen visualization of the glottis opening, but the introduction of endotrachal tube (ETT) through the vocal cords using a stylet may be difficult,[2,3] and possibility of a trauma.[4-7] Many solutions have been suggested to overcome this difficulty. Various stylets with different angulations have been used to facilitate the passage of ETT through the vocal cord, and overcome the difficulty of placing the ETT into the glottis opening.[1,8-10] In our study, we aimed to compare intubation with conventional GVL using the rigid intubating stylet to GVL with the modified blade by adding a conduit along its side to allow the passage of ETT under direct vision through the glottis.

Methods. This prospective study was conducted at the Department of Anesthesia and Critical Care, King Abdulaziz University Hospital, Jeddah, Saudi Arabia between June 2011 and October 2011. Approval was granted from the local Research and Ethics Committee. The trial was registered at the Australian and New Zealand Clinical Trials (ANZCTR 00343308).

According to the principles of the Helsinki Declaration, a prospective, randomized, single blinded trial was conducted to compare the modified GVL blade to the conventional one. Patients were enrolled in the study if they met the following inclusion criteria: 18 years old or above, and scheduled for elective surgery requiring oral ETT intubation. They were excluded if they had a history of difficult airway or had features suggestive of difficult direct laryngoscopy according to bedside examination tools utilization (Mallampati, thyromental distance, and so forth), required rapid response induction of anesthesia or there was a contraindication to GVL use. Patients' demographic data and "preoperative" assessment including airway examination were recorded in the preoperative period by an independent anesthesiologist. Patients were assigned at random to one of 2 groups using a computer generated code enclosed in opaque envelopes.

Upon arrival to the operating rooms, an intravenous catheter was inserted, appropriate monitors were attached, and preoxygenation for 3 minutes was performed until end-tidal oxygen concentration of ≥80% was achieved. Induction of anesthesia was initiated by the administration of intravenous 2-3 μg. kg^{-1} fentanyl, 2 $mg.kg^{-1}$ propofol, and 1 $mg.kg^{-1}$ rocuronium. After the induction of anesthesia, lungs were ventilated with sevoflurane (2-5%) in 100% oxygen until the patient was ready for intubation. Both GlideScopes were assembled and prepared by a third person not involved in the study and placed in the operating room ready for use once the randomization was revealed. Randomization was revealed immediately before intubation. All tracheal intubations were performed by the same anesthesiologist with a good experience in GVL use. Experience was defined as the use of the conventional GVL to perform more than 50 GVL intubations successfully. A single operator was preferred more than multiple operators to minimize co-founding effects. The involved operator had the opportunity to intubate with the modified device in a manikin prior to the study.

Patients were randomized to one of 2 groups. In Group C (n=30): the conventional GVL size 5 was used and tracheal intubation was aided by the GVL specific rigid intubating stylet supplied by the manufacturer. The stylet's shape was modified to meet the user wishes. In Group M (n=30): the modified design of GVL size 5 blade was used. Modification was developed by attaching a size 7.0 mm internal diameter (ID) endotracheal tube to the side of GVL blade with an adhesive tapes. The ETT was curved to follow the contour of the GlideScope blade. The ETT connector was removed and its length was cut to match the length of the GVL blade. The distal end of ETT did not obstruct the visualization of the GVL camera. The attached ETT's lateral wall was split throughout its length to allow the passage of any ETT up to size 8.0 mm ID (**Figure 1**). No intubation stylet was used in the Group M.

Evaluation of the time to intubation (TTI) was the primary outcome of this study. Timing was started when GVL blade was passed between the lips and ended when end-tidal carbon dioxide reading was obtained on the anesthesia monitor. Time to intubation was measured by a blinded investigator following declaration of the start of intubation by the operator. The blinded investigator turned toward the anesthesia monitor to watch for end-tidal carbon dioxide which indicated the end of intubation time and avoid looking at the type of GlideScope used for intubation. If the operator removed the ETT or the blade from the patient's mouth, it was counted as an attempt of intubation. If the duration of intubation attempt exceeded 150 seconds, it would be deemed as failure. The operator was permitted to use external laryngeal pressure to improve the glottic exposure.

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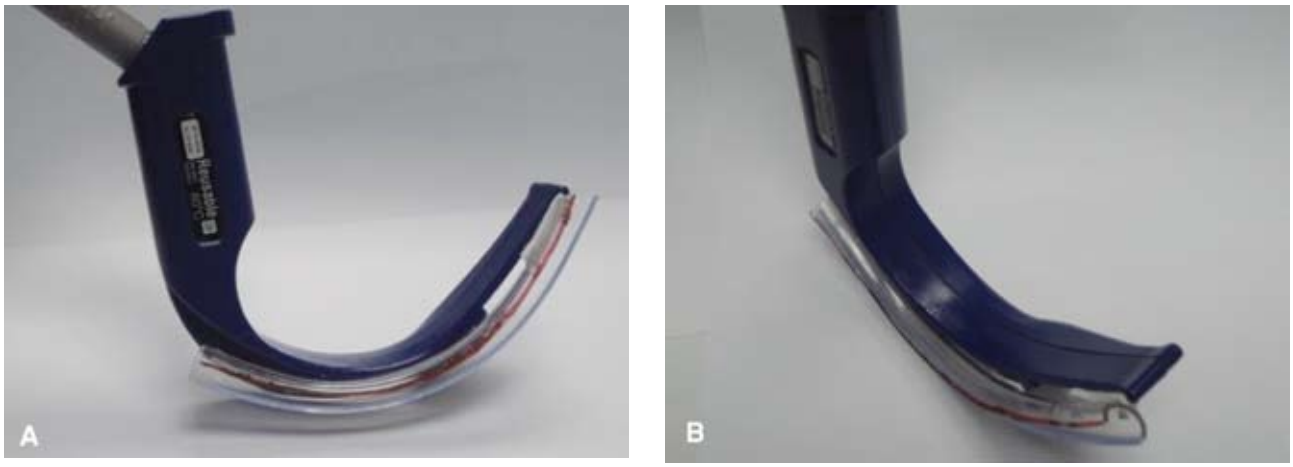

Figure 1 - Endotracheal tube was used to create a conduit along the side of the GlideScope blade, copying its curvature and with a split lateral wall throughout the entire length to facilitate tube insertion: **A**) side view, and **B**) anterior view.

The secondary outcomes of this study included: the ease of intubation which was assessed by the operator immediately at the end of intubation and measured by 10 cm visual analogue scale (VAS; 0 = easiest, 10 = most difficult), number of failures, use of external laryngeal manipulation, and the degree of glottic exposure which was recorded by the operator based on Cormack and Lehane (C&L) classification at the end of intubation. At the end of surgery all patients were examined for pharyngeal or laryngeal trauma prior to extubation and postoperatively all were interviewed to exclude upper airway injury.

Statistical analysis. Using a 2-sided alpha of 0.05, a power of 0.9, and a population variance of 20 seconds (obtained from previous study),[11] 22 patients were required per group to detect a difference of 20 seconds between the study groups in time to successful tracheal intubation. The sample size was increased to 30 patients per group to account for possible failed intubation or protocol violations. Normally distributed variables (time to successful tracheal intubation and ease of intubation) were analyzed using independent sample t-test, and skewed data (number of intubation attempts and Cormack-Lehane grade) were analyzed using Mann-Whitney U test. Proportions were examined using Fisher's Exact test. Sample size was determined using PS Power and Sample Size® software, version 3.0.43 (Copyright © 1997-2009 by Dupont WD, Plummer WD), and all other statistical procedures were performed using IBM® SPSS® Statistics package, version 19 (IBM Corporation, Somers, NY, USA). Kaplan Meier plots were constructed to graphically represent the time to intubation for both groups and the Log rank test was performed. Results are presented as mean ± SD, median [25th, 75th centile], confidence interval (CI), or absolute numbers, as appropriate, and significance was defined as $p<0.05$.

Results. Seventy patients were screened for eligibility to participate in this study; 2 patients did not meet the inclusion criteria and 8 declined to participate. Sixty patients gave written informed consent to participate in the trial, were randomized in equal numbers to 2 study groups, completed the study without protocol violations, and were analyzed in the group to which they were randomized. Baseline characteristics and the endotracheal tube sizes were comparable between the study groups (**Table 1**).

In our primary analysis time to successful tracheal intubation was shorter in patients in Group M compared with Group C (**Table 2**, $p<0.001$). Kaplan Meier plots showed that all tracheas of patients in Group M were intubated before any of the patients in the comparator Group (C) were intubated (Log rank test $p<0.001$; **Figure 2**).

In our secondary analysis, tracheal intubation was deemed easier in Group M than in Group C by the same operator who performed all tracheal intubations in the study (**Table 2**, $p<0.001$).

Furthermore, all patients in Group M were successfully intubated on the first attempt when compared with the other Group where 10% of the patients were intubated on the third attempt ($p=0.009$). However, there were no differences between groups with regard to Cormack-Lehane laryngeal grade and the use of external laryngeal pressure to aid intubation (**Table 2**). None of the study patients had failed tracheal intubation, sign of major

Table 1 - Baseline characteristics of 60 patients.

Baseline characteristics	Group C (n=30)	Group M (n=30)	95% CI for the difference (M-C)	*P*-value
Age (years)	40 ± 4	40 ± 4	(-1.6, 2.2)	0.725
Gender (M/F)	16/14	17/13		1.000
ASA class (I/II/III)[15]	17/10/3	15/13/2		0.699
Body mass index (kg/m^2)	28.8 ± 1.7	28.7 ± 1.4	(-0.7, 0.9)	0.803
Mallampati class	1 [1, 2]	1 [1, 2]		0.799
Endotracheal tube ID (mm)	7.5 ± 0.5	7.5 ± 0.5	(-0.2, 2)	1.000

Group C - conventional GlideScope group, Group M - modified GlideScope group, CI - confidence interval, ASA - America Society of Anesthesiologists, ID - internal diameter.
Data presented as mean ± SD, absolute numbers, or median [25th, 75th centile].

Table 2 - Primary and secondary outcomes of 60 patients.

Baseline characteristics	Group C (n=30)	Group M (n=30)	95% CI for the difference (M-C)	*P*-value
Time to successful intubation (sec)	66.4 ± 8.3	39.6 ± 2.1	(23.6, 29.9)	<0.001
Ease of intubation	6 ± 1	2 ± 1		<0.001
Number of attempts at intubation	1 [1, 2]	1 [1, 1]		0.009
Cormack-Lehane grade	1 [1, 1]	1 [1, 1]	NS	1.000
External laryngeal pressure (n)	3 (10%)	2 (6.7%)	NS	1.000

Group C - conventional GlideScope group, Group M - modified GlideScope group, NS - not significant, CI - confidence interval.
Data presented as mean ± SD, median [25th, 75th centile], or absolute numbers.

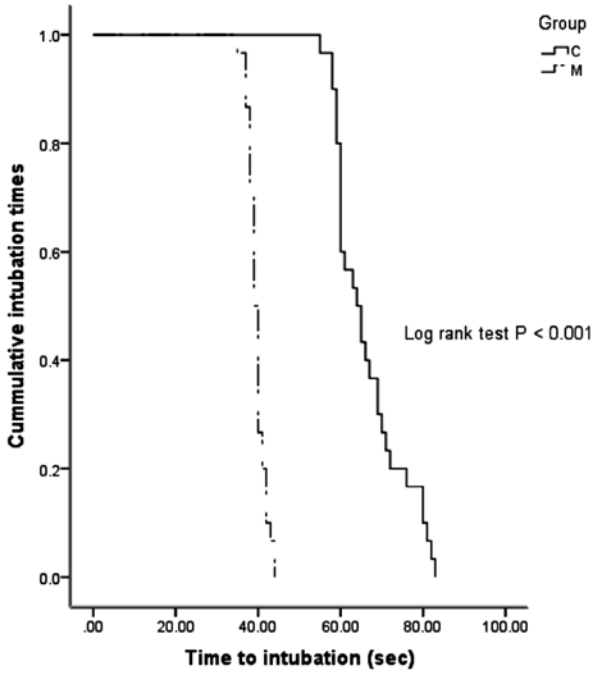

Figure 2 - Kaplan Meier plots comparing the time to intubation with the modiefied Glidescope (Group M) and the conventional Glidescope (Group C) (p<0.001).

trauma or injury in oropharynx, and there were no major adverse events during the study period.

Discussion. One of the common problems associated with GVL is the difficulty in advancing ETT through the vocal cords despite the excellent glottis visualization.[1-3,12] In this study we showed that GVL blade modification facilitated the delivery of the ETT to the glottic opening thereby reducing the intubation time, lowering the number of intubation attempts, eliminating the need of manipulation with intubating stylet, and creating a subjectively less difficult intubation. Although we cannot refute that the intubating stylet technique may still allow the operator to manipulate ETT toward the glottic opening in aberrant anatomy, the modified GVL blade provide an alternative technique to facilitate intubation. A second advantageous feature of this study is the direct comparison of intubation by stylet versus attached conduit in the same device, thereby avoiding inter-device differences that have plagued previous video laryngoscope comparison trials. Similar to previously published studies investigating mode of intubation, we measured TTI from the insertion of GVL blade in the oral cavity to the observation of end-tidal CO_2 on the

capnograph.[9,13,14] Time to intubation was significantly shorter among Group M than Group C. A short intubation time might not be needed in a starved patient with normal airway, but it is highly needed when dealing with sick patients with high metabolic requirement, poor gaseous exchanges and poorly tolerating hypoxia.[11] The greater ability of GVL in visualizing the glottis opening might be contributed to the comparable findings among both groups in glottis visualization (C&L grades) and in the need for external laryngeal manipulation. This result is similar to previous works, in which the greater ability of GVL in obtaining excellent glottic view was confirmed.[1,9,13] Although the modified GVL blade was used in patients with normal airways and those with known difficult airways were excluded from the trial, the greater ability of GVL to change poor C&L grade to a better one would encourage the use of modified GVL in a group of patients with difficult airways. The absence of failed intubations and other adverse events in this study might be related to the experience of the operator or the normal airways. Siu et al[15] reported that success with GlideScope was higher among those with previous experience and in normal airways.

Study limitation. One limitation of this study is the use of single operator with a good experience rather than multiple operators or novice ones. This decision was taken to minimize confounders in the assessment of the modified GVL blade, to avoid any failure or increased variance related to lack of experience and to avoid the problem of data clustering and non-independent trials. A second limitation is assessment of ease of intubation, which was subjective and prone to operator response and recall bias effect. Further studies are needed to detect the efficacy of utilizing this modification among patients with difficult airway of various age groups and in various hands.

In conclusion, the trachea of normal airway patients can be intubated with the modified GlideScope blade without the need for the rigid intubating stylet. The addition of a conduit to the blade made the endotracheal tube's passage easier and intubation time shorter without increasing adverse events or intubation failure.

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