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RESPIRATION AND THE AIRWAY

The GlideScope® Video Laryngoscope: randomized clinical trial in 200 patients

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Background. The GlideScope® Video Laryngoscope is a new intubating device. It was designed to provide a view of the glottis without alignment of the oral, pharyngeal and tracheal axes. The aim of the study was to describe the use of the GlideScope® in comparison with direct laryngoscopy for elective surgical patients requiring tracheal intubation.

Methods. Two hundred patients were randomly assigned to intubation by direct laryngoscopy using a Macintosh size 3 blade (DL, n=100) or intubation using the GlideScope® (GS, n=100). Prior to intubation all patients were given a Cormack and Lehane (C&L) grade by a separate anaesthetist using a Macintosh size 3 blade. The patient was then intubated, using direct laryngoscopy or the GlideScope®, by a different anaesthetist during which the larynx was inspected and given a laryngoscopy score. Time to intubate was measured.

Results. In the GS group, laryngoscopy grade was improved in the majority (28/41) of patients with C&L grade >1 and in all but one of patients who were grade 3 laryngoscopy (P<0.001). The overall mean time to intubate was 30 (95% CI 28–33) s in the DL group and 46 (95% CI 43–49) s in the GS group. The time to intubate for C&L grade 3 was similar in both groups, being 47 s for the DL group and 50 s for the GS group respectively.

Conclusion. In most patients, the GlideScope® provided a laryngoscopic view equal to or better than that of direct laryngoscopy, but it took an additional 16 s (average) for tracheal intubation. It has potential advantages over standard direct laryngoscopy for difficult intubations.

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The GlideScope® Video Laryngoscope (Saturn Biomedical Systems, Burnaby, BC, Canada) is a relatively new intubating device. It is a laryngoscope with a high-resolution camera embedded within the blade and a light source mounted beside the camera for illumination (Fig. 1). The image is displayed on a small monitor (Fig. 2). The laryngoscope blade bends through 60° at the midline and is 18 mm wide. It was designed to give an improved view of the glottis, as it is able to 'look round the corner', and may be useful for all intubations. It is made from medical grade plastic, giving durability and allowing repeated sterilizations.[1]

The aim of the study was to describe the use of the GlideScope® in comparison with direct laryngoscopy for elective surgical patients requiring tracheal intubation. Our first objective was to see whether the GlideScope® would provide an improved laryngoscopic view, and the second objective was to compare it with direct laryngoscopy using the standard Macintosh (Heine, Germany) laryngoscope with respect to the time taken for intubation.

Methods

Following local institutional review board approval, patients presenting for surgery who required tracheal intubation for their procedure were approached for inclusion in the study and written informed consent was obtained. Patients were identified from the operating room schedule. Patients with raised intracranial pressure, known airway pathology or cervical spine injury and those who required rapid sequence induction were excluded.

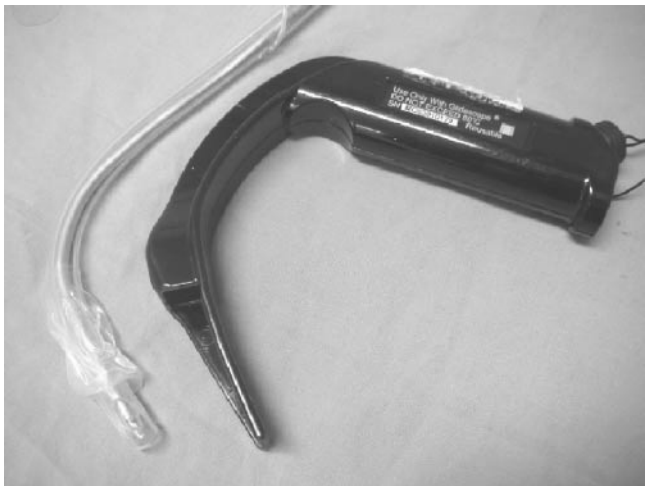

Fig 1 GlideScope® with a size 7.0 mm tracheal tube beside it.

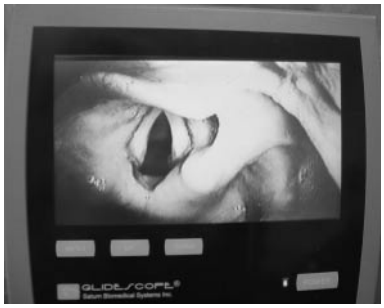

Fig 2 View of the larynx as seen on the GlideScope® monitor.

Patient characteristics and airway measurements were recorded preoperatively. The same operator recorded Mallampatti class[2] (MP) as modified by Samsoon and Young[3] with the patient sitting with mouth open and tongue protruded. Thyromental distance (TMD) was measured as the distance between the anterior chin and the thyroid notch with the head in full extension. The patients were allocated by computer-generated randomization in blocks of six to intubation with the Macintosh laryngoscope using a size 3 blade or intubation with the GlideScope®. Allocation was made prior to induction of anaesthesia.

All the patients were connected to standard monitoring devices and they received intravenous induction agents including midazolam 0.01–0.04 $\mu g\ kg^{-1}$, fentanyl 1–5 $\mu g\ kg^{-1}$ and propofol 1–2 $mg\ kg^{-1}$. Neuromuscular blockade was achieved using rocuronium 0.6 $mg\ kg^{-1}$, except for eight patients who received mivacurium 0.2 $mg\ kg^{-1}$. No antisialogogues were used. The patients were placed in the 'sniffing' position with their head on a pillow. After approximately 3 min all patients underwent an initial direct laryngoscopy which was scored according to the Cormack and Lehane[4] (C&L) grading system using the Macintosh laryngoscope with a size 3 blade. This was performed by a separate anaesthetist who was neither one of the intubators nor involved with the patient's overall care. Following initial direct laryngoscopy, positive pressure ventilation was started using a facemask and then the trachea was intubated using either the Macintosh blade (DL group) or the GlideScope® (GS group) according to the study allocation. The intubations were performed by five different anaesthetists, all of whom were experienced in anaesthesia (>10 yr experience) and the use of the GlideScope® (>20 intubations) prior to the study. The intubator was blinded to the laryngoscopy score given by the first laryngoscopist. During intubation the larynx was inspected and given a second laryngoscopy score. The difference in laryngoscopy scores between the Macintosh laryngoscope and the GlideScope® was our primary outcome measure.

Comparison of times to intubate (TTIs) between the two groups with respect to C&L grades and airway measurements were the secondary outcome measures. The TTI was measured from the time the instrument entered the patient's mouth until end-tidal carbon dioxide was detected. If more than one attempt was required, the patient received bag-and-mask oxygenation between attempts. Drugs given and haemodynamic parameters were recorded for each patient. Failure to intubate was defined as failure after three attempts. Complications including bleeding, laceration and dental damage were recorded.

As no previous studies have been published using the GlideScope®, sample-size calculations were based on the first 70 patients collected as the pilot study. For the first objective (the difference in laryngoscopy scores between the Macintosh laryngoscope and the GlideScope®), a McNemar χ^2-test for matched pairs required 18 pairs for 90% power to show a statistically significant difference. For the second objective (TTI with the GlideScope® compared with direct laryngoscopy using a Macintosh laryngoscope), we decided to look for statistical equivalence rather than statistical difference, as we had noted from previous experience (and confirmed in the pilot study) that TTI with the GlideScope® was longer than that with direct laryngoscopy. We accepted a difference of $\leqslant$30 s between the two techniques as statistically equivalent. When considering the use of a new intubating instrument, we were interested in its usefulness with difficult intubation; thus we decided to power the study for C&L grade 3 and 4 patients. Using a power of 80% and a type I error rate of 5%, we required 36 patients in each group who were C&L grade 3 or 4 to accept that the two techniques were statistically equivalent if the TTI in the GS group was $\leqslant$30 s when compared with the DL group. Analysis was by 'intention to treat'. Five patients from the pilot study were excluded from the final TTI analysis. Four of these patients required multiple attempts at intubation, and the recorded TTI included interim bag-and-mask time and did not reflect true intubation time; one of these patients was in the DL group (C&L grade 2) and three were in the GS group (one each of C&L grade 1, 2, and 3). Initially TTI was recorded continuously, but following an interim statistical review (after patient number 70) the clock was stopped between

Table 1 Patient characteristics and airway data in direct laryngoscopy (DL) and GlideScope® (GS) groups. Continuous data are expressed as mean (range), or mean (SD)

	DL group (n=100)	GS group (n=100)
Sex (M/F)	38/62	32/68
Age (yr)	54 (21–86)	52 (20–87)
Height (cm)	165 (12)	166 (12)
Weight (kg)	73 (17)	75 (21)
Physical status (ASA I/II/III/IV)	26/45/21/8	27/44/24/5
Mallampatti class (1/II/III/IV)	50/41/9/0	52/36/11/1
Thyromental distance (cm)	9.5 (1.0)	9.5 (1.2)
C&Lgrade (1/2/3/4)	63/19/18/0	59/26/15/0
>1 attempt at intubation	3	6
BURP used for C&L grade 1	0	1
BURP used for C&L grade 2	3	1
BURP used for C&L grade 3	13	0

Table 2 Comparison of laryngoscopy grades with the GlideScope® in the GS group (n=100), P<0.001 (McNemar χ^2-test). *Patients with improvement in C&L grade

Direct laryngoscopy C&L grade	GlideScope® C&L grade			
	Grade 1	Grade 2	Grade 3	Total
Grade 1	53	6	0	59
Grade 2	14*	12	0	26
Grade 3	8*	6*	1	15
Total	75	24	1	100

intubation attempts and the TTI was recorded separately for each intubation. One patient (GS group) was excluded from the TTI analysis as their result was greater than three times the standard deviation from the mean. Results are presented as mean (SD) unless noted otherwise.

Data were analysed using the McNemar χ^2-test for matched pairs to examine GS group C&L grades. Airway parameters and TTI scores were compared using χ^2, t-test and ANOVA as appropriate. Spearman rank, Pearson correlation and linear regression were used to look for associations and correlations between airway parameters, C&L grades and TTI scores. A P value <0.05 was considered statistically significant.

Results

Two hundred patients were recruited between July 2003 and March 2004. Patient characteristics and the airway parameters were similar in the two groups (Table 1). There was a significant relationship (P<0.002) between increasing MP class and decreasing TMD with the initial C&L grades, but not with BMI. There was no relationship between MP class, TMD and BMI with TTI scores.

In the GS group, the majority of patients showed improvement in the C&L grade (P<0.001) obtained with the GlideScope® compared with DL (Table 2). Fifty-nine patients were C&L grade 1. Of the remaining 41 of 100 patients with C&L grade >1, 28 (68%) had an improved laryngoscopic grade with the GlideScope®. Of the 15 patients who were C&L grade 3, 14 had an improved laryngoscopic grade with the GlideScope®. In the DL group there was no difference in laryngoscopy score between the first and second laryngoscopist. A κ test (score of 0.91) showed a high level of agreement between the first and second laryngoscopy in the DL group.

Table 3 Comparison of time to intubate between direct laryngoscopy (DL) and GlideScope® (GS) groups. Values are expressed as mean (95% CI)

	DL group (n=99)	GS group (n=96)
TTI (s)	30 (28–33)	46 (43–49)
TTI (s) for C&L grade 1	26 (24–27)	44 (41–48)
TTI (s) for C&L grade 2	31 (27–34)	50 (44–56)
TTI (s) for C&L grade 3	47 (38–55)	50 (36–63)

The overall mean TTI was 30 (95% CI 28–33) s in the DL group and 46 (95% CI 43–49) s in the GS group. There was an increase in the TTI with increasing C&L grade in the DL group but not in the GS group (Table 3). The TTI for C&L grade 3 was similar in both groups, but the sample size was too small to determine statistical equivalence. There was no difference in TTI between anaesthetists for the DL or the GS technique. There was no pattern of reducing TTI with increasing number of intubations. There were no cases of failure to intubate.

One patient failed with the Macintosh blade and was changed to GlideScope® after one attempt. Nine patients required more than one attempt at intubation (three in the DL group and six in the GS group). Of the three in the DL group, one patient was C&L grade 2 and two were C&L grade 3; one of the six in the GS group was C&L grade 3. Of the patients requiring more than one attempt at intubation, only four were excluded from the TTI analysis; one from the DL group and three from the GS group. Only one of the patients requiring multiple attempts in the GS group was C&L grade 3. One patient in each of the DL and GS groups had a small cut on the lip. There were no cases of dental or mucosal injury in either group.

Discussion

To our knowledge, this is the first randomized clinical trial evaluating the GlideScope® in comparison with the Macintosh laryngoscope. The GlideScope® is designed to offer the advantage of being able to 'look around the corner', allowing a view of the glottis via the camera without having to align oral, pharyngeal and tracheal axes. Therefore potentially a C&L grade 3 or 4 laryngoscopic view should become a grade 1 or 2 view with the GlideScope®. This has been demonstrated in our study. Of the 41 patients with a C&L grade >1, i.e. those patients in whom the view could be improved, 28 (68%) were improved with the GlideScope® (P<0.001). All but one of the C&L grade 3 patients had an improved view with the GlideScope®. However, there were six patients in whom a grade 1 direct laryngoscopic view became a grade 2 view with the GlideScope®, but this did not prevent successful intubation.

In the DL group there were 18 patients who were C&L grade 3 at initial laryngoscopy. Eleven of 18 patients converted to C&L grade 2 with 'backwards, upwards, rightwards pressure' (BURP).[5] BURP was used in 13 of these 18 patients to assist in intubation. The GlideScope® avoids potential problems associated with a 'blind' technique and external manipulation by allowing a view of the larynx and visualization of tracheal tube placement. Two of the three patients in the DL group who required more than one attempt to achieve intubation were C&L grade 3.

The average TTI was longer in the GS group because of the technique required to manipulate the stylet and endotracheal tube through the vocal cords. The TTI was used as an outcome measure as it is a variable that can be measured and is not subjective. The average TTI differed by 16 s, and although this reflects a 50% increase in mean intubation time overall we believe that this period of time is clinically acceptable. If there is no harm to the patient, the advantage of visualizing the tracheal tube passing through the cords would compensate for the slightly longer time required. Some practice/training is required to manipulate the tracheal tube through the vocal cords. The operator manual recommends a stylet configured to the shape of the GlideScope®. For the six cases in the GS group requiring more than one attempt at intubation (spread randomly throughout the study), a good view of the larynx was seen on the monitor but there was some difficulty in directing the tracheal tube into the larynx. We found that in some patients a more 'hockey-stick-like' J-curvature of the stylet at the end of the tube, with the tube passed from the lateral side of the patient's mouth, was more successful in placing the tip of the endotracheal tube in the glottis. The increased incidence of multiple attempts at intubation in the GlideScope® group compared with conventional laryngoscopy may detract from its use in routine cases. The increase in intubation time, mainly in C&L grade 1 and 2 patients, and increased chance of multiple intubations suggests that the GlideScope® may not be the first-line choice for intubation for unselected patients with no contraindication to conventional laryngoscopy.

Based on this study, using unselected patients, a further 250 patients at least would be required to achieve adequate power to demonstrate statistical equivalence between DL and GS intubation using TTI as an outcome measure. As no previous study had been published using this instrument, we felt that we had to look at all patients presenting for intubation rather than targeting potential difficult intubations. A decision to stop the study at 200 patients was made as we were able to demonstrate that there was a difference in the GlideScope® view (primary outcome measure).

For C&L grade 3 patients, a time difference for intubation of 3 s between DL and GS groups as found in our study, is clinically insignificant. This suggests that the GlideScope® has potential advantages, particularly for patients who are C&L grades 3 and 4. The use of the GlideScope in a patient with a difficult airway was demonstrated in a recent case report.[6] Further study in patients with difficult airways may further clarify the utility of the GlideScope® in this important clinical scenario.

The excluded patients are acknowledged as a potential source of bias and were among the first 70 patients (pilot study). They were not necessarily the 'difficult to intubate' patients; however, the original recorded intubation time was not a true reflection of the actual intubation time and it was felt this change in method of measuring TTI would enable a better reflection of intubation time.

A nerve stimulator was not employed routinely in this study as intubation was performed after a substantial period of elapsed time, following initial DL grading. Although this is noted as a potential source of bias, there was a high level of agreement between first and second laryngoscopy in the DL group which suggests that inadequate relaxation was not a problem in this study.

Conclusion

Our study in this small series of unselected patients showed that in the majority of patients the GlideScope® provides a laryngoscopic view equal to or better than that of direct laryngoscopy. It increases the TTI in C&L grade 1 and 2 patients but not in C&L grade 3 patients. It is potentially advantageous for use in patients with reduced neck extension or movement as alignment of the oral, pharyngeal and tracheal axes is not required. It also shows potential for use in difficult intubations, but further studies are required in this select group of patients.

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