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APPARATUS

An evaluation of the TruView EVO2 laryngoscope

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Summary

The TruView EVO2 laryngoscope was compared with the traditional Macintosh laryngoscope in 200 patients who required tracheal intubation for elective surgery. Mallampati score determined prior to laryngoscopy was significantly related to the view of the glottis during laryngoscopy for both laryngoscopes. The view of the larynx was better with the TruView EVO2 laryngoscope than with the Macintosh laryngoscope in patients with a Cormack and Lehane grade greater than 1 ($p < 0.01$). The mean time to intubate was significantly shorter with the Macintosh laryngoscope (34 s) than with the TruView laryngoscope (51 s) ($p < 0.01$).

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Many cases of difficult intubation are unanticipated and are frequently not recognised during pre-operative assessment [1]. Many different designs of laryngoscopes have been developed in an effort to reduce the incidence of this problem [2–4].

The TruView EVO2 laryngoscope (Truphatek International Ltd, Netanya, Israel) is a recently introduced device with a unique blade that provides an optical view 'around the corner'. The blade is a modified laryngoscope blade incorporating an unmagnified optic side port with anterior fraction of 35% in the line of sight allowing indirect tracheal intubation [5].

The aim of this study was to compare the TruView EVO2 laryngoscope with the direct Macintosh laryngoscope. We wished to determine whether the TruView EVO2 laryngoscope provided an improved view at laryngoscopy compared to that provided by the Macintosh laryngoscope and to also to assess the time taken for intubation with these two devices.

Methods

Approval for the study was obtained from the hospital research ethics committee and written informed consent was obtained from each patient participating. Patients were considered appropriate for recruitment if they were undergoing elective surgery for which tracheal intubation was planned. Exclusion criteria included the presence of raised intracranial pressure, cervical spine injury, risk factors for pulmonary aspiration of gastric contents and the presence of any pathology of the head and neck. Pre-operatively, patients' demographics and characteristics were reported. The Mallampati score and thyromental distance in mouth opening were also recorded.

In the operating room, standard monitoring was employed on all patients and, after pre-oxygenation, anaesthesia was induced with midazolam 0.02–0.04 $\mu g.kg^{-1}$, fentanyl 2–4 $\mu g.kg^{-1}$, and propofol 1–2 $mg.kg^{-1}$. Neuromuscular blockade was achieved using rocuronium in a dose of 0.6 $mg.kg^{-1}$ and an adequacy of neuromuscular block confirmed using a peripheral nerve stimulator. Patients were placed in the 'sniffing' position with their head on a pillow. If ventilation via face mask was considered inadequate by the anaesthesiologist, the patient was withdrawn from the study. Anaesthesia was maintained with either propofol or sevoflurane in oxygen during the study and analgesics agents administered according to preference. A standard Macintosh laryngoscope and TruView EVO2 laryngoscope were used throughout the study.

In a random cross-over fashion, the standard Macintosh laryngoscope and TruView EVO2 laryngoscopes were used in turn for direct laryngoscopy. The order was randomised by a coin toss. A blade of size 3 or 4 of the standard Macintosh laryngoscope was selected in accordance with the preference of the anaesthesiologist. The

adult blade of the TruView EVO2 laryngoscope was chosen. The view of the glottis at laryngoscopy was scored according to the Cormack and Lehane grading criteria [6]. No laryngeal manipulation was used to improve the laryngoscopic view to improve this score. The trachea was intubated after the second grading at laryngoscopy was complete. Five anaesthesiologists undertook all the laryngoscopies and intubations and all had experience of at least 20 intubations with the TruView before the study commenced.

In each patient, laryngoscopy was performed by two different anaesthesiologists. The score given by the first anaesthesiologist performing the first laryngoscopy was not available to the second anaesthesiologist performing the second laryngoscopy. The time to intubation (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. Failure to intubate after three attempts was considered to be a failure of intubation. All complications related to intubation were recorded.

Sample size calculations were based on pilot data in 50 patients. It was estimated that with a power of 90%, 168 patients would be required. To allow for drop out, 200 patients were recruited. Data were analysed using Wilcoxon test, Spearman rank, Pearson correlation and linear regression as appropriate to determine associations and correlations between airway parameters and Cormack and Lehane grades. TTI scores were compared using the Chi-squared test. A p value of less than 0.5 was considered statistically significant.

Results

Details of patient characteristics are shown in Table 1. The mean (SD) thyromental distance and mouth opening were 6.9 (1.1) cm and 5.7 (0.5) cm, respectively.

Mallampati score determined prior to laryngoscopy was significantly related to the view of the glottis of laryngoscopy for both laryngoscopes (Table 2). Ninety-one patients had the same Cormack and Lehane grade score with both laryngoscopes. Of the remaining patients, 105 showed improvement in the Cormack and Lehane grade ($p < 0.001$) when the TruView was used compared to the Macintosh laryngoscope (Table 3). In four patients, a better grade view was noted with the Macintosh laryngoscope than with the TruView laryngoscope. Two patients who had a Grade 4 view with the Macintosh laryngoscope were intubated with the TruView laryngoscope, which improved the view of the glottis to Grade 2 and Grade 3, respectively. The TruView laryngoscope overall provided a statistically significantly better view of the glottis as scored by the Cormack and Lehane Grade (Table 3).

Eleven patients (seven in the Macintosh group and four in the TruView group) were not included in the final TTI analysis because these patients required more than one attempt at intubation. The overall TTI was 34 s (95% confidence interval (CI) 32–37) in the Macintosh group and 51 (95% CI 48–53) s in the TruView group. There was an increase in the TTI with increasing Cormack and Lehane grade in the Macintosh group but not in the TruView group (Table 4). The TTI for Cormack and Lehane grade 3 was similar in both groups, but the sample size was too small for meaningful statistical analysis.

There were no cases of failure to intubate. Two patients in the Macintosh group and one patient in the

Table 1 Patients' characteristics and airway data. Values are mean (SD), median (range) or number.

Sex; M : F	107 : 93
Age; years	54 (12) (12–13)
Height; cm	164.8 (11.3) (14–15)
Weight; kg	64.0 (11.5) (16–17)
Thyromental distance; cm	6.9 (1.1) (5.6–5.8)
Mouth opening; cm	5.7 (0.5) (4.7–6.7)

Table 2 Mallampati score and the Cormack and Lehane Grade for the Macintosh and the TruView groups. Values are the numbers of patients in each group.

Mallampati score	Cormack and Lehane Grade				
	Grade 1	Grade 2	Grade 3	Grade 4	Total
Macintosh					
Class 1	68	61	5	0	134
Class 2	11	15	13	0	39
Class 3	1	1	23	2	27
Total	80	77	41	2	200
TruView					
Class 1	122	12	0	0	134
Class 2	22	17	0	0	39
Class 3	13	13	1	0	27
Total	157	42	1	0	200

Table 3 Number of patients with Cormack and Lehane Grades in Macintosh and TruView groups.

	TruView				
Macintosh	Grade 1	Grade 2	Grade 3	Grade 4	Total
Grade 1	76	4	0	0	80
Grade 2	62	15	0	0	77
Grade 3	19	22	0	0	41
Grade 4	0	1	1	0	2
Total	157	42	1	0	200

Table 4 Comparison of time to intubate between the Macintosh and the TruView groups distributed by Cormack and Lehane grading. Values are mean (95% CI).

	Macintosh (*n* = 93)	TruView (*n* = 96)
TTI(s)	34 (32–37)	51 (48–53)
TTI(s) for grade 1	30 (28–31)	48 (45–52)
TTI(s) grade 2	34 (30–37)	53 (47–59)
TTI(s) grade 3	48 (40–57)	52 (38–65)

TruView group had a small cut on the lip. There were no cases of dental or other injury in any of the patients studied.

Discussion

The TruView EVO2 laryngoscope was designed to improve the view of the larynx in patients where a traditional laryngoscope provides a poor view. It applies the optical principle of light refraction to provide a more anterior view of the larynx. The aim of this is to provide a better view in a greater proportion of patients and thus allow intubation to be performed under direct visualisation more frequently than is possible with a conventional laryngoscope.

To our knowledge, this is the first randomised clinical trial evaluating the TruView EVO2 laryngoscope in comparison with the Macintosh laryngoscope. The TruView EVO2 laryngoscope is designed to offer an optical view 'around the corner', allowing a view of the glottis via the prismatic lens without having to align oral, pharyngeal and tracheal axes. Therefore, potentially a better view of the larynx may be obtained with a TruView laryngoscope in patients who would present a grade 3 or 4 laryngoscopic view with a traditional laryngoscope. This has been demonstrated in our study. Among the 120 patients with a grade >1, 105 (87.5%) were improved with the TruView EVO2 laryngoscope ($p < 0.001$). In all the patients with a Cormack and Lehane grade 3 or 4 there was an improved view with the TruView EVO2 laryngoscope. There were four patients in whom a grade 1 direct laryngoscopic view became a grade 2 view with the TruView EVO2 laryngoscope, but this did not prevent successful intubation.

Our results are similar to those obtained using other laryngoscopes that also utilise the optical principle to provide a better view at laryngoscopy. In the evaluation of an optical laryngoscope blade by Markowitz et al. [7], the view provided by the optical side port allowed better visualisation of the passage of the tracheal tube through the vocal cords than the standard laryngoscopic view (67% vs 57%). The mirrored laryngoscope described by McMorrow and Mirakhur [8] showed a 71% improvement in laryngeal view compared with the Macintosh. Recently, in the evaluation of the Viewmax laryngoscope (an optical laryngoscope, similar to TruView EVO2 laryngoscope) by Leung et al. [9], the Viewmax laryngoscope improved the view of the larynx when compared with the Macintosh and McCoy laryngoscopes in a simulated difficult airway.

When using the direct Macintosh laryngoscope, operators had to look straight at the glottis, which was unnecessary when using the TruView EVO2 optical laryngoscope. If the angle of view changed, the lifting force of laryngoscope could be decreased, thus reducing injuries to the mouth and larynx. Lieberman and colleagues [10] reported that the Truview optical laryngoscope significantly improved the laryngeal view grades while using significantly less force.

The Cormack and Lehane grading system, although oiginally designed to compare glottic views at direct laryngoscopy [6], provided a useful comparison of the direct and indirect laryngoscopic views achieved in this study. All the patients in TruView group were intubated with the TruView EVO2 laryngoscope successfully and fewer patients required additional manoeuvres to improve the view of the glottis.

In this study, the average TTI was longer in the TruView group. The average TTI differed by 17 s and although this reflects a 50% increase in mean intubation time overall, we believe that this period of time is clinically acceptable for elective cases. However, the TruView EVO2 laryngoscope may have limitations during rapid sequence intubation.

Matsumoto et al. [11] reported the use of the TruView video laryngoscope in two patients with difficult airways. Although the TruView EVO2 laryngoscope may provide a better view of the larynx than the standard Macintosh blade, the addition of the optic port increases the overall size and weight of the blade. Consequently, it may be more difficult to insert in patients who have only limited ability to open their mouth. This study was performed in patients in whom tracheal intubation was judged as not being difficult to perform. The TruView EVO2 system is designed to provide indirect laryngoscopy with continuous oxygen insufflation, which may be helpful for some patients who have poor pulmonary function. The capability of the optic laryngoscope blade to facilitate tracheal intubation in the difficult intubation case and the benefit of oxygen insufflation were not assessed in this initial study.

When compared with the Macintosh laryngoscopes, the TruView EVO2 laryngoscope appears to improve the view of the larynx but requires a longer time for tracheal intubation. It may be useful in difficult airway situations when the Macintosh blade fails to show the glottic opening.

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