Role of the Truview EVO2 laryngoscope in the airway management of elective surgical patients: A comparison with the Macintosh laryngoscope

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ABSTRACT

Background: The Truview EVO2(C) laryngoscope (TL) is a recently introduced optical device designed to provide an unmagnified anterior image of the glottic opening and allow indirect laryngoscopy. Aim: This study is designed to determine whether the TL is a better alternative to the Macintosh laryngoscope (ML) for routine endotracheal intubations in patients with usual airway characteristics. Methods: We compared the Truview EVO2(C) and MLs in 140 elective surgical patients requiring general anaesthesia and intubation in a prospective crossover fashion. The two blades were compared in terms of Cormack and Lehane grades, time required for intubation, anaesthetists' assessment of ease of intubation, intubation difficulty score, attempts at intubation, success rate, soft tissue damage and arterial oxygen saturation during laryngoscopy. The Student t test and Chi-square test were used to determine the statistical significance of parametric data and categorical data, respectively. Results: The Truview EVO2(C) blade provided a better laryngoscopic view than the Macintosh blade as suggested by improved Cormack and Lehane grades (in 48 patients), but required a longer time for intubation than the Macintosh blade (34.1 vs. 22.4 s), i.e., an improved view at the cost of longer mean intubation time. In spite of lower intubation difficulty scores, Truview EVO2(C) was considered as difficult to use on subjective assessment by the anaesthesiologist when compared with Macintosh. There was no difference observed between the two groups in attempts at intubation, success rate, soft tissue damage and arterial oxygen saturation during laryngoscopy. Conclusion: We opine that although Truview provides a better laryngoscopic view than Macintosh in difficult cases, it does not have an extra benefit over Macintosh otherwise, further indicating the need for more experience with the use of a Truview laryngoscope.

Key words: Airway, difficult intubation, equipment, Macintosh laryngoscope, tracheal intubation

Truview EVO2(C) laryngoscope

INTRODUCTION

The Macintosh laryngoscope (ML) remains the most popularly used laryngoscope for endotracheal intubation in routine surgical patients. Despite its popularity, failures during intubation are not uncommon, especially in patients with unanticipated difficulty (1.5-8.5% of all general anaesthetics).[1] Better laryngoscopes are being devised in an effort to reduce the incidence of unforeseen complications in such patients.[2] But, their clinical efficacy and practical application in operating rooms still awaits approval.

The Truview EVO2(C) laryngoscope (TL) (Truphatek International®, Israel), a novel device, applies the optical principle of light refraction to provide a good view of an anteriorly placed larynx. An inexpensive telescope helps provide unmagnified anterior refraction of 42 degrees in the line of sight [Figures 1 and 2] with minimal manipulation of the head, neck, instrument or soft tissues.[2]
Li et al.[3] studied 200 patients with normal airway characteristics and no estimated intubation difficulty in a crossover manner and found a better laryngoscopic view with TL as compared with ML. Many other studies claim better intubating conditions with TL in patients at low risk for difficult intubation, but at the cost of longer intubation time.[4,5] On the other hand, some studies report its successful use as a rescue device in difficult airway situations where intubation attempts with ML fail.[4] In one such study, Singh et al.[6] reported that the Truview EVO2(C) improves Cormack and Lehane grading by one or more grades without much difference in time required for negotiation of the endotracheal tube when compared with ML in patients with anticipated difficult airway.

These clinical studies outline a discrepancy between the seeming advantages of this device in the management of difficult or normal airway and its routine use inside the operating room – whether the device could be accepted only as a rescue device or as a tool for routine airway management. For answering this question, further clinical evaluation comparing this novel device with the conventional one is needed. Therefore, the present study was planned to determine whether TL can be used routinely for endotracheal intubation in place of ML in patients with normal distribution of airway characteristics. For this purpose, we considered the Cormack and Lehane grading and time taken for intubation as the primary outcome measures. Subjective ease of intubation and intubation difficulty score[7] were recorded as secondary outcome measures.

**METHODS**

After acquiring informed consent, this study was conducted on 140 consecutive adult patients who required general anaesthesia and endotracheal intubation for elective surgery. The study was approved by an institutional review board. We recruited patients between the age group of 20 and 70 years, from both sexes and with ASA physical status grade I-III. ASA grade III patients included four patients with diabetes, four patients with systemic hypertension and two patients with liver disease. Patients requiring cervical spine surgery, head and neck surgery, rapid sequence induction or having raised intracranial tension were excluded.

The study design was crossover, prospective, randomized and controlled. Blinding of the anaesthesiologists regarding the laryngoscope used was impractical. Computerized, open, crossover randomization was performed to determine the sequence of the two laryngoscopies. Patients were distributed in two groups of 70 patients each (n=70) according to the laryngoscope used for intubation. Patients in the TRU group were intubated with TL and patients in the MAC group were intubated with ML.

All patients were subjected to a thorough pre-anaesthetic checkup and airway evaluation, including mouth opening, thyromental distance and revised Mallampati scoring[8] 1 day before the surgery. Two anaesthesiologists with 2 years experience in anaesthesiology and each having a minimum of 100 successful intubations with ML and 25 successful intubations with TL performed all the intubations.
A common anaesthesia protocol was followed in all patients, which included oral alprazolam in the morning, standard monitoring with pulse oximetry, non-invasive blood pressure, end tidal CO₂ and three-lead electrocardiogram. Adequate sniffing position was maintained by an 8-cm intubating pillow. After pre-oxygenation with 100% oxygen, midazolam 0.02 mg/kg i.v. and fentanyl 1.2 μg/kg i.v. were given, followed by propofol 1.5-2 mg/kg, which was sufficient to abolish verbal response. After confirming adequacy of facemask ventilation, vecuronium 0.1 mg/kg was administered to facilitate endotracheal intubation. After 180 s, laryngoscopy was performed with one laryngoscope and then by the other. A peripheral nerve stimulator was not used due to its unavailability. Size 3 or 4 of standard ML and adult blade of TL were chosen. The laryngoscopic view was scored according to the Cormack and Lehane grading during both laryngoscopies without any external manipulation. Tracheal intubation was accomplished by the second laryngoscope and confirmed by end tidal CO₂. In between the two laryngoscopies, patients received bag and mask ventilation. A maximum of three attempts at intubation were allowed for either laryngoscope, after which it was considered as a failed intubation. For intubation with the Truview EVO2, the standard technique was used. Continuous oxygen insufflation was used for demisting of the optical lens. External laryngeal manipulation as required by the anaesthesiologist during intubation was allowed. Time taken for intubation in seconds (from removal of mask to earliest detection of end tidal CO₂), incidence of arterial desaturation (<90%) and injury to the oral structures were recorded. After intubation, the anaesthetist was enquired about ease of intubation on a subjective basis as easy, difficult or very difficult. Intubation difficulty was also scored on a seven-point scoring system (intubation difficulty score) as devised by Adnet et al., 1997 [Table 1].

**Statistical analysis**

We hypothesized that the Truview EVO2(C) would improve the laryngoscopic view of the glottis on Cormack and Lehane grading as compared with Macintosh in more than 20% of the patients. To confirm this hypothesis, we calculated a sample size of 140 patients, with α=0.01 and power=90%.

We used SPSS and statpages.org for all analyses. Mean and standard deviation were used to describe parametric data and patient numbers and percentages to describe categorical data. Statistical significance of parametric data was determined by the Student t test and categorical data by the Chi-square test.

**RESULTS**

Demographic and airway assessment data of the recruited patients are shown in Table 2. The two groups were comparable in terms of age, sex, weight and height. There was an even distribution of airway assessment parameters among the two groups, i.e., majority of the patients in each group had airway characteristics depicting easy intubation. The MAC group had 14 and the TRU group had 16 patients with anticipated difficult airway (patients with restricted mouth opening or low thyromental distance in the TRU group also possessed higher Mallampati grades) [Table 2]. On performing laryngoscopy with ML (total 140 patients), we observed that 75 patients had Cormack and Lehane grade I, while 56, six and two patients had grade II, III and IV, respectively [Table 3]. Using TL, 123 patients had Cormack and Lehane grade I, 15 had grade II and one patient had grade III, while no patient recorded grade IV. The Cormack and Lehane grading depicted that, of these patients (123 minus 75), 47 patients showed improvement by 1 grade (i.e., from grade II to I, grade III to II and grade IV to III) and one
The fibreoptic technology used in TL circumvents many barriers and enables the operator to see glottic structures not visualized during DL, culminating in an improved Cormack and Lehane grade. A number of clinical[3‑5,10] and manikin[8,11,12] studies support improved glottic view with Truview EVO2(C).

Although TL improves the glottic view, the oropharyngeal and laryngeal axes are not aligned. Therefore, under inexperienced hands, the intubation takes a longer time.[12] This has been a consistent finding in many other studies.[3‑5,11,12] We opine that the difference of around 12 s in TTI (34 minus 22 s) may be of no significance in elective patients and tends to improve with experience, but may raise concerns in emergency procedures where rapid sequence intubation is required.[4]

Ease of intubation was assessed subjectively as well as by intubation difficulty score. Our results showed lower intubation difficulty score but more difficulty in using TL on subjective assessment,[13] and vice versa for ML. The paradoxical results of the two variables comparing ease of intubation could be partly due to a peculiar technique for intubation with TL and partly due to need for more experience with it. The use of TL requires intubation to be performed in an indirect manner, seeing the tube through the lens. The tube has to be advanced blindly until its tip enters the optic visual field and thereafter introduced through the vocal cords. This maneuver requires a good eye–hand coordination and expertise.[4,14] While using ML, the anaesthesiologist looks straight at the glottis and the tip of the endotracheal tube and, therefore, can negotiate the tube under direct vision. Lower intubation difficulty score in patients intubated with TL could be attributed to improvement in glottic view and non-reward of laryngeal pressure or increased lifting force with TL as reported previously.[15]

Despite these differences, none of the patients in any group had arterial desaturation during laryngoscopy.

During the study, TL improved the Cormack and Lehane grade in 48 patients (i.e., more than 20% patients in accordance with our hypothesis), but required a longer time for intubation than the ML (34.1 vs. 22.4 s). As per subjective assessment, intubation was found to be easier with ML than with TL (54 vs. 22 patients). The results show that TL had lower mean intubation difficulty score than ML (0.32 vs. 0.68), while there was no significant difference in attempts at intubation, success rate, soft tissue damage or arterial oxygen saturation.

Table 3: Study data (primary and secondary outcome measures)

|                          | MAC group | TRU group | P value |
|--------------------------|-----------|-----------|---------|
| Cormack and Lehane grade | III/IV/IV | II/II/III | 0.000   |
| Time in seconds (mean±SD)| 22.4±12.68| 34.1±1.19 | 0.000   |
| Subjective assessment of | 54/10/6   | 22/28/20  | 0.000   |
| intubation-easy/difficult/very difficult score | 0.68±1.032 | 0.32±0.716 | 0.021 |

MAC – Macintosh laryngoscope; TRU – Truview EVO2 laryngoscope; SD – Standard deviation;

patient improved by 2 grades (i.e., from grade IV to grade II). In no patient was TL noted to worsen the Cormack and Lehane grade. Table 3 also shows that the mean time for laryngoscopy in the MAC group and the TRU group was 22.42±12.68 s and 34.15±1.19 s, respectively ($P=0.000$). The subjective evaluation of difficulty of intubation by the anaesthesiologist as well as intubation difficulty score in each group are shown in Table 3. This table depicts that 54 patients were graded by the anaesthesiologist as easy in the MAC group as compared with only 22 patients in the TRU group ($P=0.000$). But, the MAC group had an intubation difficulty score of 0.68 while the TRU group had score of 0.32 ($P=0.02$). There was no significant difference in success rate or number of attempts required for intubation in both groups and, throughout the laryngoscopy and intubation, majority of the patients maintained peripheral oxygen saturation $>95\%$. No failed intubation or significant oral injury was noted in any group.

**DISCUSSION**

Direct laryngoscopy (DL) using ML is a time-tested routine maneuver in anaesthesia practice. But, failure of DL to expose the glottic inlet is often associated with multiple attempts at intubation using the same device,[9] especially in unanticipated cases, frequently leading to serious complications. Clearly, there is a need to search alternative devices. However, use of novel devices in cases of failed DL requires expertise in patients with no such difficulty.

Through this study, we aimed to determine the applicability of TL in operating rooms as routine equipment in place of ML. We selected the Cormack and Lehane grading of the laryngeal view of glottic opening and time to intubate (TTI) as primary outcome measures. The secondary outcome measures included subjective assessment of difficulty and intubation difficulty score.
or intubation. Adequate pre-oxygenation before each laryngoscopy and continuous oxygen insufflation through oxyport in TL prevented desaturation in spite of prolonged intubation time.

There were some factors lending robustness to this study. Advanced fibreoptic and digital technology have led to the advent of loads of novel devices, but with little if any clinical following. Therefore, in an attempt to establish or refute the routine use of Truview EVO2(C), it was compared with the gold standard, i.e., ML. Also, three important airway parameters were combined to make the airway assessment sufficiently predictable as the Mallampati test has poor predictability when used alone.[16] Further, the crossover design of the study reduced the chances of group allocation bias and improved the validity of the results.

This study had some limitations. First, blinding of the anaesthesiologist to the device used was unfeasible and could not be done. Also, the haemodynamic parameters could not be assessed due to dual laryngoscopies performed in each patient. Second, due to the low incidence of difficult intubation in the general population,[16] the number of patients recruited in the study was not sufficient to find enough number of difficult cases. Thus, majority of the patients belonged to Cormack and Lehane grade I or II in the MAC group, and no further improvement could be expected with TL. Further, in this study, overall, 19.3% patients had predicted difficult intubation on airway assessment while only 3.2% laryngoscopies were actually difficult, depicting poor predictability of the bedside tests even if combined. Also, the participating anaesthesiologists were very experienced with standard ML, while they had limited experience with TL. This may be a potential source of bias in the recorded difference in intubation time and anaesthesiologists’ evaluation of intubation difficulty.

A systemic analysis[17] reviewing intubating conditions provided by various video/optic devices involving both patients with predicted difficult or normal airway showed that improved laryngeal view did not always match with a higher intubation success rate. They also found that most studies involved heterogeneous populations and that the operators had insufficient training with alternative devices. The authors concluded that although promising, the precise role of these devices in airway management remains to be established.

The study supports the previous view that use of Truview may reduce failed laryngoscopy by improving the glottic view, which may not translate into a reduction in failed intubation, possibly due to inexperience. Thus, it brings out the importance of carefully designed multicentre trials involving appropriately trained anaesthesiologists and relevant patient populations. We believe that this advanced laryngoscope under skilled hands can reduce the damage associated with repeated blind attempts in unanticipated difficult intubations.

CONCLUSION

TL does not seem to provide any additional advantage over ML in intubation of patients with normal airway, but the efficacy of TL in difficult cases cannot be underestimated.[18] Before recommending TL for routine use in place of ML, equal familiarity with the device needs to be ensured by including it in the training of anaesthesiologists followed by large multicentre trials providing more definite results.

Further research involving comparison of TL with other devices (e.g., Glidescope, C-Mac) is required for its implementation as clinical guidelines that may improve health care by reducing morbidity and mortality in patients with unanticipated difficult airway.

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