Comparative evaluation of Truview evo2 and Macintosh laryngoscope for ease of orotracheal intubation in children – A prospective randomized controlled trial

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Abstract

Background and Aims: Truview evo2 has been found to improve the glottic view when compared with the Miller blade in pediatric population. However, there is limited literature comparing it with Macintosh laryngoscope in children. We thus aimed to assess and compare Truview evo2 with the Macintosh laryngoscope for orotracheal intubation in children with regards to time to intubate, laryngoscopic view, ease of intubation, and associated hemodynamic changes.

Material and Methods: Fifty ASA I-II children aged 2–8 years for elective surgery requiring general anesthesia with orotracheal intubation participated in this prospective randomized-controlled study. They were randomly allocated to two groups. In group-M (N = 25), laryngoscopy and intubation were performed using Macintosh laryngoscope, and in group-T (N = 25), Truview evo2 laryngoscope was used. Modified Cormack–Lehane grade, time to intubation, intubation difficulty score (IDS), and hemodynamic changes were compared between the groups. Data were analyzed using SPSS statistical software version 17 and P value <0.05 was considered statistically significant.

Results: CL grade 1 was found in a larger number of patients of group-T (P = 0.003) and CL grades2a and 2b were found in a larger number of patients of group-M (P = 0.023 and P = 0.037, respectively). The mean time to intubation was significantly longer in group-T (19.0 ± 3.4 seconds) than in group-M (13.1 ± 2.1 seconds), P = 0.00. The overall IDS was lower in group-T than group M [i.e. median (IQR): 0 (0-0) vs 1 (0-2), respectively]. Heart rate, systolic and diastolic blood pressure, and oxygen saturation were comparable between the groups at all times.

Conclusion: Truview evo2 provides better laryngeal view and has a lesser IDS, but takes longer for intubation, when compared to the Macintosh laryngoscope in children.

Keywords: CL grade, Macintosh, time to intubation, Truview evo2

Introduction

Orotracheal intubation is the commonest method to secure the airway during general anesthesia. Direct laryngoscopy is used to facilitate orotracheal intubation and requires alignment of the oral, pharyngeal, and laryngeal axes to achieve a straight line of sight for visualization of larynx.[1]

Video laryngoscopes have been introduced into clinical practice over last decade with the purpose of improving laryngeal visualization to facilitate intubation. Video laryngoscopes have a video chip embedded in the tip of the blade, which transmits...
The Truview evo2 laryngoscope (Truphatek International Ltd, Netanya, Israel) has a unique blade that provides an optical view “around the corner.” It has a combination of an optical system with a specially profiled slim steel blade. It has a 46° refraction angle, which enlarges the view field. Three different sizes of blades are available with Truviewevo2 – adult, small (children), and infant. Its eyepiece can be connected to an endoscopic camera head with a monitor, allowing audience viewing of the procedure. In addition, the Truview blade has a port that allows connection to the auxiliary oxygen flow meter of the anesthesia machine. A recommended flow rate of 4–6 L/minute prevents misting and clears secretions from the lens and provides continuous oxygen insufflation during intubation [Figure 1].

There are several studies comparing the Truviewevo2 laryngoscope with the Macintosh laryngoscope for orotracheal intubation in adult patients. The Truview evo2 has been compared with the Miller laryngoscope for orotracheal intubation in adult patients. There are several studies comparing the Truviewevo2 laryngoscope with the Macintosh laryngoscope for orotracheal intubation in pediatric patients are very limited. Thus, we planned to compare Truview evo2 and Macintosh laryngoscope for ease of orotracheal intubation in children aged 2–8 years. We compared the two devices with respect to time to intubation as primary outcome and Modified Cormack and Lehane (CL) grade, intubation difficulty score (IDS), associated hemodynamic changes, and complications as secondary outcomes.

Material and Methods

After institutional ethics committee approval and obtaining written informed consent from parents/guardians of the child, this prospective, unblinded, randomized controlled trial was conducted in 50 children. Two to eight year-old children of either sex, ASA grades I and II, requiring general anesthesia with orotracheal intubation for elective surgery were included in the trial. Children with limited mouth opening, intraoral lesions/tumors, restricted neck movements, increased intracranial tension, and those requiring rapid sequence induction were excluded. After fasting for 6–8 hours and premedication with oral midazolam 0.5 mg/kg 30 minutes prior to induction, the patients were shifted to the operating room. Five lead electrocardiogram, noninvasive blood pressure (NIBP) and pulse oximetry monitors were attached. Patient’s head was supported on a pillow 4–6 cm in height. Anesthesia was induced with sevoflurane 8% in oxygen using Jackson-Rees modification of Ayres T-piece circuit in patients <20 kg and Bain’s circuit in patients >20 kg weight. After loss of consciousness, a peripheral intravenous access was secured and injection fentanyl 2 µg/kg was administered followed by injection rocuronium 0.6 mg/kg. Intermittent positive pressure ventilation was given for 3 minutes, using sevoflurane 4% in oxygen. Patients were randomly allocated using computer-generated randomization to one of the two groups of 25 patients each. The randomized number was sealed in opaque envelope by an independent anesthesiologist not involved in the study and opened just prior to intervention. Laryngoscopy and intubation were carried out by the same experienced anesthesiologist in both the groups, who had at least 6-year experience in anesthesia and at least 6-month experience with Truview evo2 in children. Laryngoscopy was carried out using Truview evo2 (group-T; n = 25) or Macintosh laryngoscope (group-M; n = 25) according to the group allocated. Laryngoscopic view was assessed using the Modified CL grading. Trachea was intubated with uncuffed endotracheal tube of appropriate size. The ease of intubation was assessed by IDS.

Oxygen insufflation with a flow of 4 L/minute was done during laryngoscopy and intubation in both the groups through the oxygen port in group-T and by placing a cannula in oral cavity in group-M.

Time to intubation was measured from the time of introducing laryngoscope blade in the patient’s mouth till the appearance of square wave capnogram. A maximum of 1 minute was allowed for laryngoscopy. If intubation was not achieved within 1 minute or SpO₂ fell below 92%, laryngoscope blade was to be removed and mask ventilation given for 30 seconds before the second attempt was allowed. A maximum of three
attempts were allowed and intubation time was the sum of time taken in these attempts. In case, if the patient could not be intubated in three attempts, the case was to be recorded as a failure and the airway managed according to difficult airway protocol in Group -M and conventional Macintosh blade in group-T before going to difficult airway protocol.

The placement of endotracheal tube was confirmed by auscultation of chest and presence of square wave capnography. After endotracheal intubation, ventilation was controlled using 66% nitrous oxide with 2%–2.5% sevoflurane in oxygen. The heart rate (HR), NIBP, and SpO2 were recorded at-Baseline (before induction of anesthesia), T0-just before laryngoscopy, and every minute after intubation till 5 minutes.

Anesthesia was maintained as per requirement of surgery. At extubation, any injury to lips, teeth or oral cavity, or presence of blood on endotracheal tube was to be recorded and then patient shifted to post-op unit. Post-operative complications, if any, such as sore throat or hoarseness of voice were recorded at 1 and 24 hours after extubation.

The primary outcome was the time to intubation. The secondary outcomes were modified CL grade, IDS, HR, BP and SpO2 at various time points, and complications. The complications recorded at the time of extubation included injury to lips, teeth or oral cavity, and presence of blood on endotracheal tube. Postoperative complications such as sore throat or hoarseness of voice were recorded at 1 and 24 hours.

Statistical analysis
Riveros et al. in 2012\cite{13} reported the mean time to intubation in children with Macintosh laryngoscope as 24.5 ± 5.2 seconds against 13.8 ± 8.0 seconds with Truvьюv evo2 laryngoscope reported by Inal et al. in 2010.\cite{14}

With these values as reference, the minimum required sample size at 95% power and 5% level of significance was found to be 10 patients in each group. Considering the number of such cases in our hospital, we proposed to collect a sample of 25 patients in each group.

Age, weight, height, time to intubation, and hemodynamic variables were compared between groups using unpaired t-test. Gender was compared using Chi-square test. Modified CL grade and IDS was compared using Fisher’s exact test.

Overall IDS was compared using Mann–Whitney test. Data were non-normally distributed, so outcome has been represented as median and inter quantile range. $P < 0.05$ was taken as level of statistical significance. The data were analyzed by using SPSS software, version 17.0.

Results
Fifty patients were included and randomized, 25 in each group. All 50 patients received the allocated intervention, were followed up and analysed. The demographic profile of both the groups was comparable [Table 1].

All 50 patients were intubated in the first attempt. The time to intubation was significantly longer in group-T (19.0 ± 3.4 vs 13.1 ± 2.1 seconds ; $P<0.001$) than in group-M. Laryngoscopic view was assessed by the modified CL grading system. In group-T, majority of the patients had CL grade 1, only a few had CL grade 2a, and none had CL grade 2b. CL grades 3 and 4 were not seen in any patient of either group [Table 2]. Ease of intubation was assessed in all the patients by IDS. The total IDS score was not >2 in any patient. The mean IDS in group-T was significantly less than group-M [Table 2].

The HR, and systolic blood pressure (SBP) changes were comparable between the two groups at all times [Tables 3 and 4]. Oxygen saturation did not fall below 99% in any patient during the laryngoscopy and intubation. There were no damaged teeth, soft tissue injury, or bleeding gums during laryngoscopy and intubation in any patient of either group. All the patients were followed up to 24 hours after surgery. There was no complaint of hoarseness of voice or sore throat in any of the patients 1 and 24 hours in the postoperative period.

Discussion
In our study, it took a significantly longer time to intubate with Truvьюv evo2 when compared with the Macintosh laryngoscope. In spite of fulfilling the operator’s criteria, an overall lesser experience of using Truvьюv evo2 and the indirect view of larynx, requiring hand–eye coordination for intubation, could have increased the intubation time.

Inal et al. also found a longer time to intubate using Truvьюv evo2,\cite{14} when they compared it with the Miller blade in children of the same age group. Riveros et al., although they used Truvьюv PCD, also found a significantly longer

| Table 1: Demographic variables in the two groups |
|-----------------|-----------------|---|
| **Group** | **Group** | **P** |
| **M (n=25)** | **T (n=25)** |  
| **Age (years)** | 5.4±2.1 | 4.5±2.1 | 0.081 |
| **Weight (kg)** | 16.1±4.9 | 14.7±5.0 | 0.162 |
| **Height (cm)** | 105.0±11.7 | 100.8±12.7 | 0.117 |
| **Female/Male, n (%)** | 9/16 (36/64) | 11/4 (44/56) | 0.282 |

*Group M=Laryngoscopy-intubation with Macintosh laryngoscope; Group T=Laryngoscopy-intubation with Truvьюv evo2 laryngoscope*
median time to intubate than the Macintosh laryngoscope in children.\textsuperscript{[15]}

Our study revealed a better glottic view with the Truview evo2 laryngoscope as compared with the Macintosh laryngoscope in 2- to 8-year-old children. We believe that this is due to the specialized optical system present in the Truview evo2 blade, which enables us to “look around the corners” without requiring the alignment of oral, pharyngeal, and laryngeal axes.

Our results are consistent with those of Inal \textit{et al.},\textsuperscript{[14]} who also found a better glottic view with the Truview evo2 blade than the Miller blade in pediatric population (2–8 years). They also attributed this improved view with Truview evo2 to the prismatic effect of its lens system.

There was no intubation failure in our study. An IDS of >2 was not observed in any patient. The mean IDS was significantly lower in the Truview evo2 group, suggesting easier intubation with Truview evo2 than the Macintosh laryngoscope. This difference in IDS between the two groups was attributed to mainly two parameters: CL grade (N4) and lifting force (N5). Better glottic exposure was observed and lesser lifting force was required during laryngoscopy and intubation with the Truview evo2 laryngoscope than the Macintosh laryngoscope. The unique optical system of Truview evo2 blade with a 46°refraction angle could have contributed to the lesser lifting force required during laryngoscopy.

Inal \textit{et al.}\textsuperscript{[14]} in their study in pediatric patients found no significant difference in IDS, when Truview blade was compared with the Miller blade.

The HR, and SBP changes were comparable between the two groups at all times in our study. Thus, there was no significant stress response to laryngoscopy with the Truview evo2 laryngoscope when compared with the Macintosh laryngoscope, even though it took significantly longer time to intubate. The probable reason for this could be the significantly lesser lifting force required for intubation with the Truview evo2 laryngoscope.

Our results are consistent with those of Riveros \textit{et al.},\textsuperscript{[15]} who also found hemodynamic parameters to be comparable with Truviev PCD and the Macintosh laryngoscope in pediatric patients.

In our study, $\text{SpO}_2$ did not fall below 99\% at any point of time in either group, which could be attributed to the continuous oxygen insufflation during laryngoscopy and intubation in both the groups.

Inal \textit{et al.} reported a significantly lower peripheral oxygen saturation during intubation with Truviev as compared with the Miller laryngoscope,\textsuperscript{[14]} which they attributed to the prolonged intubation time with the Truviev. Time to intubation with the Truviev laryngoscope was longer in our study as compared with Inalet \textit{et al.}, yet we did not observe any

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**Table 2: Comparison of modified CL grade and intubation difficulty score between the groups**

| Parameter        | Group M ($n=25$) | Group T ($n=25$) | $P$  |
|------------------|------------------|------------------|------|
| Modified CL Grade| $n$ Percentage    | $n$ Percentage    |      |
| I                | 13 52            | 22 88            | 0.003|
| IIa              | 9 36             | 3 12             | 0.023|
| IIb              | 3 12             | 0 0              | 0.037|
| III              | 0 0              | 0 0              |      |
| IV               | 0 0              | 0 0              |      |
| IDS              | 0 12             | 22 88            | 0.001|
| 1                | 5 20             | 2 8              | 0.111|
| 2                | 8 32             | 1 4              | 0.005|
| Overall IDS      | 1 (0-2)          | 0 (0-0)          |      |

Median (IQR)

Modified CL grade = Modified Cormack and Lehane grading.\textsuperscript{[16]}; IDS = Intubation Difficulty Score.\textsuperscript{[17]}; IQR = Inter quartile range

**Table 3: Changes in heart rate during laryngoscopy and intubation**

| HR               | Group M Mean±SD | Group T Mean±SD | $P$  |
|------------------|------------------|------------------|------|
| Baseline         | 122.8±22.2       | 120.4±20.5       | 0.346|
| 0 minute         | 123.8±21.4       | 116.6±18.4       | 0.102|
| 1 minute         | 129.1±20.9       | 124.6±18.6       | 0.210|
| 2 minutes        | 127.1±20.2       | 122.5±17.6       | 0.199|
| 3 minutes        | 120.3±29.4       | 120.9±17.1       | 0.467|
| 4 minutes        | 123.6±20.0       | 119.5±17.0       | 0.218|
| 5 minutes        | 122.3±19.8       | 118.2±16.7       | 0.213|

**Table 4: Changes in systolic blood pressure during laryngoscopy and intubation**

| SBP              | Group M Mean±SD | Group T Mean±SD | $P$  |
|------------------|------------------|------------------|------|
| Baseline         | 109.0±12.3       | 106±13.3         | 0.206|
| 0 minute         | 97.2±11.3        | 88.8±11.5        | 0.117|
| 1 minute         | 97.2±10.7        | 95.2±11.5        | 0.259|
| 2 minutes        | 91.7±20.4        | 92.8±10.7        | 0.404|
| 3 minutes        | 94.6±11.5        | 91.4±10.4        | 0.157|
| 4 minutes        | 93.9±11.3        | 90.0±10.5        | 0.109|
| 5 minutes        | 93.0±11.3        | 89.4±10.6        | 0.121|

SBP = Systolic blood pressure; DBP = Diastolic blood pressure; df = Degree of freedom; Mean Diff = Mean difference; SE = Standard error of difference; CI = Confidence interval; Cohen’s $\delta$ = Depicts estimated effect size
fall in SpO<sub>2</sub>. This was probably because we used sevoflurane in oxygen for induction, whereas they used sevoflurane with 60% N<sub>2</sub>O in oxygen.

In our study, there was no oral injury during laryngoscopy and intubation in any patient of either group. There was no complaint of hoarseness of voice or sore throat in any of the patients 1 and 24 hours after surgery.

Our findings are consistent with those of Inal et al.\textsuperscript{14} and Riveros et al.\textsuperscript{15} who did not report any significant intraoperative complications during laryngoscopy and intubation with either Truview or the conventional laryngoscope.

There were a few limitations to our study. First, the longer learning curve for using Truview evo2 laryngoscope would have added to the mean time to intubation using this device. Although the laryngoscopist had 6-month experience with Truview evo2 in children before the start of the study and 10 pilot cases were also conducted, but the overall experience with Macintosh laryngoscope was much more. Hence, it is possible that performing larger number of pilot cases or including a larger sample size would give better results. Second, the study included patients with a normal airway, so results cannot be extrapolated to patients with a difficult airway, for which further studies are required. Third, the study was not blinded as blinding the laryngoscopist was not practically possible.

**Conclusion**

We hereby conclude that for orotracheal intubation in children 2–8 years of age, the Truview evo2 laryngoscope provides a better optical view of larynx as compared with Macintosh laryngoscope and it facilitates oxygen insufflation during laryngoscopy, which increases the safety margin in children. Hence, it is a good option for intubation in children, if used by an experienced anesthesiologist.

**Financial support and sponsorship**

Nil.

**Conflicts of interest**

There are no conflicts of interest.

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