Abstract

Introduction: Airway management in paediatric patients is always a challenging task due to limited functional reserve. Recently, many airway devices have been utilized with varied success rates. The Medicam Paediatric Video Laryngoscope (MPVL) is a recent addition that may significantly impact paediatric airway outcomes. Hence, the present study was designed to assess the efficacy of MPVL and the Macintosh direct laryngoscope in terms of intubation characteristics.

Methods: Following ethical approval and informed consent, this prospective, randomized study included sixty ASA I and II patients of either sex aged between 2 and 10 years of age. Patients were randomly allocated into two groups: Medicam Paediatric Video Laryngoscope and Direct Laryngoscope (n = 30 each), to be intubated with the Medicam Paediatric video laryngoscope and Macintosh direct laryngoscope, respectively. The primary outcome was intubation time, while the secondary outcome was first attempt success rate, Cormack Lehane grade, and ease of intubation.

Results: The mean time to intubation in group MPVL was 16.0 ± 2.88 seconds, and in group DL was 12.33 ± 2.72 seconds (p-value < 0.05). Cormack-Lehane grade 1 was significantly higher in Group MPVL than Group DL (p = 0.04). The two devices were comparable in terms of first-attempt success rate and ease of intubation. No complications were observed except in one patient in the DL group.

Conclusion: MPVL provides better glottis visualization and a trend towards a higher first attempt success rate at the expense of prolonged intubation time. However, the time difference regarding intubation was not clinically significant.

Keywords: Laryngoscope; child; intubation; Glottis; Itratracheal;
Aims

The present study was designed to compare the efficacy of MPVL with paediatric Macintosh laryngoscope in children between 2 and 10 years of age. All the intubations and laryngoscopies were done by the same experienced anesthesiologist in both groups.

Methods

Following approval of the Institutional Ethic Committee (FM, 243-11.05.2019) and Clinical Trials Registry-India (CTRI/2019/12/022291), written informed consent from the patient's guardian was obtained, and procedures were conducted in accordance with the Ethical Principles for Medical Research involving Human Subjects, outlined in the Helsinki Declaration-2013. This prospective, single-blinded, randomized controlled trial included sixty children aged 2 to 10 years, ASA physical status I–II, weighing 10–30 kg, undergoing elective surgery under general anaesthesia with endotracheal intubation. Children with anticipated difficult airways such as COPUR index >10, congenital anomalies, heart disease, reactive airway disease, and metabolic disease were excluded from the study (21).

Out of 68 patients screened, sixty were selected and randomly divided into two groups of 30 patients each based on computer-generated random number tables (www.randomization.com), to be intubated using a Medicam paediatric video laryngoscope (Group MPVL) or Macintosh laryngoscope (Group DL) (Figure 1). The participant CONSORT flow diagram for the study is presented in Figure 1. Blinding the attending laryngoscopist was not possible as the two intubating devices were quite different. The learning curve was achieved by performing ten intubations on the mannequin, followed by ten intubations on patients before the start of the study.

Each patient was uniformly premedicated as per institutional protocol 15 minutes prior to the transfer of the patient to the operating room. Standard monitoring devices were attached. The anaesthetic technique comprised pre-oxygenation for 3 minutes, induction with Propofol (2 mg/kg), followed by muscle relaxation with Atracurium (0.5 mg/kg) intravenously. Intubations were carried out depending on the assigned group. Anaesthesia was maintained with a mixture of oxygen, nitrogen oxide, and sevoflurane targeting 1.3 times the minimum alveolar concentration (MAC), while atracurium was used for muscle relaxation. Immediate pre-induction values for heart rate (HR) and blood pressure (BP) were taken as the control for the two groups. Thereafter, values were recorded immediately post-intubation, 3 minutes, and 5 minutes after intubation.

Time to intubation (T2) was considered the primary objective, while time to best glottic view (T1), first attempt success rate, Cormack Lehane grade, and ease of intubation were considered secondary objectives. Time for the best glottic view was taken from the introduction of the device between the two incisors until the best glottic view on the screen, while intubation time was taken until the confirmation of end-tidal CO₂ by capnography. An attempt was defined as one in which the intubating device was withdrawn from the mouth, irrespective of the procedure’s outcome. A maximum of two attempts were allowed. An attempt was considered “failure” if proper placement of the endotracheal tube could not be accomplished in two attempts and a supraglottic airway device was used. Ease of intubation was graded as Grade I (no optimization required), Grade II (optimization required), and Grade III (failed). Optimization maneuvers comprise head repositioning, external laryngeal manipulation, and jaw thrust. Further perioperative management was as per the institutional protocol. Any complications such as bradycardia, hypoxia, bronchospasm, and blood on the device were also recorded.

Statistical Analysis:

Sample size was calculated by taking intubation times μ₁ = 7.4 sec and μ₂ = 17.3 sec (μ₁ and μ₂ are the mean intubation times of DL and MPVL, respectively) with a common standard deviation (SD) of 9.0 s from a pilot study on ten patients per group. Using type I error α = 0.05 and type II error β = 0.1, it was required to include 18 patients per group. Considering 10% drop-out and the availability of cases, it was decided to include thirty patients per group (Power and Sample Size Calculator, PS version 3.0.43). Statistical analysis was performed using IBM SPSS version 20. The results are presented in the form of numerical values, mean, standard deviation, and percentage, as appropriate. Demographic
data between the groups, like gender, were analyzed using Fisher’s exact test, and parametric data like age, weight, time taken for the best glottis view, and intubation time were analyzed using the t-test. While the first attempt success rate, Cormack and Lehane grade, ease of intubation, and complications were analyzed using the Chi-square test.

**Results**

There were no differences in demographic variables between the two groups (Table 1). The mean duration of time taken for intubation in group MPVL was 16.0±2.88 sec and group DL was 12.33±2.72 sec (p<0.05, Table 2). Time to best glottic view (T1) in Group MPVL was 5±1.70 sec and in Group DL was 8±1.90 sec (p<0.001, Table 2). In Group MPVL, 26 patients (87%) were intubated on the first attempt and four (13%) on the second attempt, compared to 21 patients (70%) and nine (30%), respectively, in Group DL (p > 0.05). Cormack-Lehane I was observed in 25 patients in MPVL and 17 patients in DL (p = 0.0486; Table 2). Ease of intubation grade I (no optimization
required) was observed in 83% of patients in MPVL compared to 70% in group DL. None of the patients developed complications like bradycardia, hypoxia, and bronchospasm. However, blood on the device was observed in one patient in the DL group.

### Discussion

We, in this study, observed significantly decreased time to glottic visualization but prolonged total intubation time with a newly introduced Medicam Paediatric Video laryngoscope compared to a standard Macintosh laryngoscope. To the best of our knowledge, no previous study has been conducted comparing intubation characteristics between the Medicam paediatric video laryngoscope and the Macintosh laryngoscope. Still, our results support most previous studies showing the advantage of a video laryngoscope over a Macintosh blade at the expense of longer intubation time, which is clinically acceptable.

Table 1: Patient Characteristics

<table>
<thead>
<tr>
<th>Variables</th>
<th>Group MPVL (n = 30)</th>
<th>Group DL (n = 30)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>5.67 ± 2.50 **</td>
<td>5.30 ± 2.24 **</td>
<td>0.548</td>
</tr>
<tr>
<td>Weight (kg)</td>
<td>19.76 ± 5.60 **</td>
<td>18.50 ± 5.15 **</td>
<td>0.368</td>
</tr>
<tr>
<td>Height (cm)</td>
<td>112.5 ± 10.65</td>
<td>114.67 ± 10.42</td>
<td>0.428</td>
</tr>
<tr>
<td>ASA Status (I/II), (n, %)</td>
<td>21/9, (70/30)</td>
<td>18/12, (60/40)</td>
<td>0.588</td>
</tr>
<tr>
<td>Sex (Male/Female), n, (%)</td>
<td>13/17, (43/57)</td>
<td>14/16, (47/53)*</td>
<td>0.795</td>
</tr>
<tr>
<td>COPUR (median [IQR])</td>
<td>7.5 [6.25 - 8]</td>
<td>8 [6 - 9.75]</td>
<td>–</td>
</tr>
<tr>
<td>Duration of surgery (minutes)</td>
<td>44.5 ± 7.46</td>
<td>47.34 ± 7.30</td>
<td>0.142</td>
</tr>
</tbody>
</table>

Table 2: Intubation Characteristics

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Group MPVL (n = 30)</th>
<th>Group DL (n = 30)</th>
<th>CI (95%)</th>
<th>p-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Time to Best glottic view (T1), n (%)</td>
<td>5 ± 1.70 **</td>
<td>8 ± 1.90 **</td>
<td>2.06 to 3.93</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Time to Intubation (T2), n (%)</td>
<td>16.0 ± 2.88 **</td>
<td>12.33 ± 2.72 **</td>
<td>2.22 to 5.1</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>First attempt success rate, n (%)</td>
<td>87 (26)***</td>
<td>70 (21)***</td>
<td>–</td>
<td>0.21</td>
</tr>
<tr>
<td>Cormack–Lehane, n (%)</td>
<td>***</td>
<td>***</td>
<td>–</td>
<td>–</td>
</tr>
<tr>
<td>Grade I (No optimization) n (%)</td>
<td>83 (25)</td>
<td>70 (21)</td>
<td>–</td>
<td>0.36</td>
</tr>
<tr>
<td>Grade II (optimization Required), n (%)</td>
<td>17 (5)</td>
<td>30 (9)</td>
<td>–</td>
<td>0.36</td>
</tr>
<tr>
<td>Grade III (Failed), n (%)</td>
<td>0</td>
<td>0</td>
<td>–</td>
<td>–</td>
</tr>
</tbody>
</table>
In this study, time to glottic visualization was found to be significantly less compared to the standard blade. This concurs with various studies showing improved glottic view using video laryngoscopes. Although multiple studies have shown encouraging results supporting the use of VLs in paediatric patients, their exact role remains unclear (6,8,9). A meta-analysis of VL and DL has observed better glottis visualization, with a word of caution to validate the findings further (6).

The significant increase in time to successful intubation using a video laryngoscope in our study is consistent with the findings of other studies in paediatric practice. [7,10-13] Most of the studies demonstrate improved views at the cost of prolonged intubation times while using a video laryngoscope in paediatric patients. A Cochrane meta-analysis included 12 studies (803 children) and showed that intubation time was prolonged when indirect laryngoscopy, or video laryngoscopy, was used rather than direct laryngoscopy (5.49 seconds, 95% confidence interval (CI) 1.37 to 9.60) (16). Another prospective study comparing the efficacy of the Airtraq (AT) to the Direct Laryngoscope (DL) in young children showed that the time to intubate was significantly increased with the Airtraq ($P = 0.002$) (9). There seems to be a lot of variation in intubation time with the VLs in different studies, possibly due to heterogeneity in the VLs design and study methodology (12,14,15).

Several reasons may account for the prolonged intubation time observed with the VL, namely operator experience, device design, and demographic characteristics. Moreover, a much narrower field of vision in VL compared to the human eye may often lead to difficulty maneuvering the endotracheal tube to its intended position. However, in contrast to our results, a recent study by Konul Hajiyeva et al. comparing the C-MAC D-Blade video laryngoscope and direct laryngoscope found significantly shorter intubation times with the C-MAC D-Blade. They have proposed that as the experience of the intubator with VLs increases, successful intubation can be achieved in a shorter period of time (16). Further, the patient population in their study is different from ours. In our opinion, the principal reason for prolonged intubation time with MPVL could have been the substantial experience of anaesthesiologists with the direct laryngoscope. Although there is gross inconsistency regarding the number of intubations for achieving the learning curve with VLs, the participating anaesthesiologists in our study had attained a sufficient learning curve with MPVL prior to the start of the study.

Secondly, good hand-eye coordination is necessary with MPVL as there is no direct line of vision and the tube is advanced into the glottic opening by viewing the image projected on the screen.

The number of attempts required for successful intubation showed a higher first-attempt success rate in cases of MPVL, although we could not reach statistical significance. The overall success of intubation was 100% in both groups, with no failed intubation. This was probably due to the exclusion of all cases with an anticipated difficult airway. However, in difficult airways, the VLs enabled a higher first-pass success rate than conventional laryngoscopy. Garcia-Marcinkiewicz et al., in a multicentre, parallel group, randomized controlled trial, concluded that the first-attempt success rate was improved with video laryngoscopy with a standard blade in comparison to direct laryngoscopy (18) . As our study sample size was small and only included non-difficult airways, the observed difference between the two devices' success rates was minor, so we could not reach statistical significance.

The Cormack and Lehane (CL) grade 1 and intubation without optimization maneuvers were possible in 83.3% of MPVL patients, compared to 56.7% of the DL group ($p = 0.0486$). The findings of our study on improved CL grade with VL are in accordance with the studies comparing different types of videolaryngoscopes such as King VisionTM, GlideScope, and McGrath VL with DL in paediatric population (19,20). A magnified view of the vocal cords and the surrounding oropharyngeal structures has been cited as the principal reason for better Cormack-Lehane grades associated with VLs. This finding may be more applicable in infants and small children, where the magnified view of small oropharyngeal structures is of utmost importance. None of the patients in the two groups had any episodes of bradycardia, desaturation, or bronchospasm during intubation attempts. There is only one incidence of blood staining on an airway device in the DL group. This could be due to the fact that we have used standard blades, so the issues associated with angulated blades were not observed.
**Conclusion**

Despite some important clinical findings, the results of this research must be interpreted considering the limitations of the study. The main drawback of the present study was the potential for observer bias since it was impossible to blind the anaesthesiologist to the device being used. Secondly, due to the small sample size, the study's results should be applied with caution to the general population. Thirdly, the study was done only on elective paediatric general surgical patients. So, the results can neither be applied to emergency room procedures nor to other groups, such as those with anticipated and unanticipated difficult airways.

So, the authors conclude that the MPVL provides a better glottis visualization and a trend towards a higher first attempt success rate at the expense of prolonged intubation time. However, the time difference regarding intubation was not clinically significant.

**References:**