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Comparative evaluation of low-cost Macintosh video laryngoscope with conventional Macintosh laryngoscope: A randomized controlled trial

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ABSTRACT

Background: The prohibitive costs of commercially available video laryngoscopes often limit the adoption of this technique for routine airway management in economically weak countries. It has not yet been determined whether cost-effective adjustments improve intubation success rates to the required level of competence. **Aims and Objectives:** To compare a custom-made low-cost Macintosh video laryngoscope with a standard Macintosh laryngoscope (ML). The primary objectives were to compare laryngoscopy time, intubation time, and procedure time. The secondary objectives were to compare Cormack–Lehane grading (CL), rate of successful tracheal intubation, number of attempts for successful intubation, need for backward, upward, and rightwars pressure (BURP), and perceived ease of intubation based on intubation difficulty scale (IDS). **Materials and Methods:** Forty adults posted for elective surgery under general anesthesia were randomized to Group (intubated with a standard ML) and Group (intubated with a custom-made, Macintosh video laryngoscope [CMVL]). **Results:** The laryngoscopy time was 7.5 ± 2.04 s in Group CMVL and 5.85 ± 1.26 s in Group ML (P = 0.0039). The intubation time was 7.95 ± 1.73 s in Group CMVL and 7.75 ± 2.35 s in Group ML (P = 0.7615). The procedure time was 15.45 ± 2.96 s in group CMVL and 13.6 ± 2.99 s in group ML (P = 0.0571). The Group CMVL had significantly lower laryngoscopy time than Group ML. In terms of IDS, CL grading, number of successful intubation, and BURP required both groups were comparable. **Conclusion:** Both the laryngoscopes provide more or less similar results concerning all the intubation parameters studied in normal airway scenarios. Thus, emphasizing that the mere presence of a camera alone does not improve the intubation characteristics in normal airway patients.

Key words: Custom-made; Endotracheal intubation; Normal airway; Standard laryngoscope; Video laryngoscope

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INTRODUCTION

Video laryngoscope is the standard medical care for airway management.[1] It eases intubation, reduces failure rate, especially in cases of difficult airways, and may reduce complications associated with laryngoscopy.[2] Despite avantages, the prohibitive costs of the commercially available video laryngoscopes often limit the adoption of this technique for routine airway management in economically weaker countries. A custom-made video laryngoscope was first reported in 2014 by Karippacheril.[3] Various cost-effective modifications have been described since then.[4] The modifications were intended to shorten the learning curve, aid in teaching,[5] and provide better

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patient care, especially in covid scenario. However, it is yet to be ascertained whether these modifications translate into improving the success of tracheal intubation, better glottic views, and reducing complications associated with airway management thus ensuring the patient's safety.[4]

We conducted this trial to compare a standard Macintosh laryngoscope (ML) with a custom-made low-cost video laryngoscope (CMVL). It was hypothesized that the intubation parameters with CMVL shall be better than the traditional video laryngoscope.

Aims and objectives

The primary endpoints were to compare laryngoscopy time, intubation time, and procedure time. The secondary endpoints were to compare Cormack–Lehane grading (CL), rate of successful tracheal intubation, number of attempts for successful intubation, need for backward, upward, and rightward pressure (BURP), and perceived ease of intubation based on Intubation difficulty scale (IDS).

MATERIALS AND METHODS

This trial was designed as a prospective, observational, randomized study. The trial was registered in India's clinical trial registry (CTRI number: CTRI/2023/03/050412) with the permission of the Ethical Committee of our institute (BREC/22/077). The principles of the Declaration of Helsinki have been followed.

Inclusion criteria

Forty adults of either sex, 18–65 years, belonging to I and II American Society of Anesthesiologists (ASA) - physical status planned for elective surgical intervention under general anesthesia were included in this study.

Exclusion criteria

Patients with a full stomach, obstetric, bariatric, and pediatric patients, with any oropharyngeal pathology, ASA III and IV, and predicted difficult airway (Modified Mallampati class 3 or 4, <4 cm inter incisor gap, <6 cm thyromental distance) were excluded from the study.

Participants were randomized using a sealed opaque envelope technique. The study subjects were allocated to Group (intubated with a standard ML) and Group CMVL (intubated with a CMVL) with 20 patients in each group. All the patients had routine investigations. As and when necessary, any additional pertinent investigations were conducted. Willingness to join the trial was ensured by taking informed written consent from all the patients. Adequate fasting was ensured. After shifting the patient to the surgical table, standard ASA monitoring was started. A suitable intravenous cannula was inserted. Anesthesia was inducted intravenously. Intubation was done by an experienced anesthesiologist having experience of more than 5 years of direct laryngoscopy. The same anesthesiologist was trained with a custom-made video laryngoscope before commencing the study. Fifteen intubations were performed on manikin (Laederal airway management trainer) followed by fifteen intubations on patients posted for routine surgery using a custom-made video laryngoscope. A non-stylet endotracheal tube was used for all intubations done with either a conventional Macintosh or a custom-made video laryngoscope. The need for any airway adjunct such as bougie or stylet was noted. Data related to the procedure was noted by an independent observer. Laryngoscopy time, intubation time, and procedure time were observed as primary endpoints. Time from the introduction of the laryngoscope's blade to good glottic view was taken as laryngoscopy time. From the moment the endotracheal tube was placed in the patient's mouth until the end-tidal carbon dioxide trace was collected, the intubation time was recorded. Procedure time was taken as the sum of laryngoscopy and intubation time. As secondary outcomes, difficulty during intubation, total successful intubations done, reattempt required, and CL score[6] were noted. If the anesthesiologist was unable to secure the endotracheal tube or if the SpO_2 dropped below 90, the effort was deemed unsuccessful. A maximum of two attempts were allowed. After two unsuccessful attempts, an alternative intubation plan was followed as per the hospital airway protocol. The anesthesiologist doing intubation rated the difficulty felt during intubation (IDS)[7] as easy if a score of zero, little difficulty if the score lies between one and five, and major difficulty if the score is more than five. The requirement of BURP to obtain a good glottic view, mucosal or dental injury, and blood staining of a laryngoscope or endotracheal tube were documented. Hemodynamic parameters and oxygen saturation were recorded 1 min before the intubation and after 1, 3, and 5 min of intubation.

The study sample size was calculated with reference to a previous study based on intubation time among groups, where the mean intubation time was 13.5 s for conventional laryngoscopy and 16.4 s for improvised video laryngoscopy group.[8] For sample size calculation we have defined mean difference of 2.9±2.3. The sample size was calculated with 95% confidence interval, 95% power and an alpha level of 0.05. The total sample size came out to be 34 individuals (17 in each group). Hence, rounding off 20 patients were randomized to each group.

Comparison of two mean formula

n=size per group;

SD=Standard Deviation=2.3

δ=mean difference=16.4–13.5=2.9

Zα/2=Z0.05/2=Z0.025=1.96 — From Z table at type I error of Zβ=1.64 — at 95%

power

=2 (1.96+1.64)2 (2.3)2/(2.9)2

=16.30

Hence, the sample size can be taken as 17 in each group.

Microsoft Excel was used for data entry and cleaning, after which data were imported and data analysis was carried out using SPSS version 21.0 software. The mean and standard deviation have been used to summarize the quantitative (numerical) variables. Categorical Variables have been summarized through Frequency or percentages. Tests of significance were applied as per the type of data. Unpaired t-tests were applied for the quantitative variables and Chi-square tests were applied for testing the significance of categorical variables. A P=0.05 or less was regarded as statistically significant.

RESULTS

With regard to demographics and mallampati grading, the CMVL and ML groups were identical (Table 1). The time required for laryngoscopy was 7.5±2.04 s in Group CMVL and 5.85±1.26 s in Group ML (P=0.0039). The intubation time was 7.95±1.73 s in Group CMVL and it was 7.75±2.35 s in the Macintosh group (P=0.7615). The total procedure took 15.45±2.96 s in group CMVL and 13.6±2.99 s in the Macintosh group (P=0.0571). Shorter laryngoscopy times were seen in the ML Group compared to Group CMVL. In Group CMVL, the proportion of 0, 5, and >5 IDS had been 75%, 25%, and 0%, while in Group ML, it was 80%, 20%, and 0% (P=0.179) (Table 2). Both groups experienced a complete success rate of intubation (Table 2). A total of 55%, 30%, and 15% of CMVL participants had CL grades 1, 2a, and 2b, compared to 40%, 55%, and 5% of ML participants (P=0.915) (Table 2). In the CMVL Group, 25% of patients received BURP, versus 45% in Macintosh Group ML (P=0.522). 1 min before and one, three, and 5 min after tracheal intubation, hemodynamic parameters were similar in both groups.

Table 1: Demographics

Parameters	CMVL	ML	P-value
Age	30.25±10.69	32.30±10.65	0.53
Gender			
M	15 (75%)	14 (70%)	0.573
F	5 (25%)	6 (30%)	
BMI	24.23±1.02	23.5±1.46	0.07

Table 2: Comparison of intubation characteristics

Parameters	CMVL	ML	P-value
Laryngoscopy time (s)	7.5±2.04	5.85±1.26	0.0039
Intubation time (s)	7.95±1.73	7.75±2.35	0.7615
Procedure time (s)	15.45±2.96	13.6±2.99	0.0571
Incidence of successful intubation	20 (100%)	20 (100%)	
Attempts for successful intubation			
First	20	19	
Second	0	1	
Cormack and Lehane grade			
1	11 (55%)	8 (40%)	0.915
2a	6 (30%)	11 (55%)	
2b	3 (15%)	1 (5%)	
Intubation difficulty score			
Easy (0)	15 (75%)	16 (80%)	0.179
Lightly difficult (1-5)	5 (25%)	4 (20%)	
Major difficulty (>5)	0	0	
Requirement of BURP			
Yes	5 (25%)	9 (45%)	0.522
No	15 (75%)	11 (55%)	
Trauma	0	0	
Laryngoscope blood stained	0	0	
Tracheal tube blood stained	0	0	

BURP: Backward, upwards, and rightwards pressure

DISCUSSION

Different redesigns of video laryngoscopes are available as teaching and learning tools in low-resource nations.[9] Few studies have compared the custom-made video laryngoscope with a standard laryngoscope, however, well-designed randomized trials with adequate samples size are required to analyze the advantage, if any, of custom-made video laryngoscopes.[3,4]

A standard Macintosh adult laryngoscope was transformed into an improvised video-aided laryngoscope. A portable android endoscope, the tip of which has six light emitting diodes surrounding a 0.3-megapixel camera giving a resolution of 640 × 480 at a focal distance of 3–7 cm. The viewing angle is 60–70°, at par with commonly used video laryngoscopes. The camera head works with an Android system phone (version above 4.0), making it handy, and with a PC system (windows 2000/7/8/9/10/vista), making it useful for teaching purposes with a free downloadable camera application. On the Flange, a hole was drilled about 10 cm from the laryngoscope's tip, using a red hot ice breaker to provide stability, as the endoscope is cylindrical and it easily rotates leading to malalignment.

The endoscope is then passed through this hole from the outer part of the flange to its inner part and is then glued using silicon glue with the camera tip leveled with the bulb of the laryngoscope after checking visual orientation (Figures 1 and 2). Washing with water and mild detergent was followed by cleaning with a cotton ball dipped in 70% alcohol to disinfect.[10]

This research showed equivocal results with respect to total procedure time, number of successful tracheal intubation, IDS score, and laryngeal inlet view between CMVL and ML groups. However, longer laryngoscopy time was seen in the CMVL group.

Custom-made video laryngoscope showed longer laryngoscopy time than ML although total procedure time was similar in both groups. The plausible explanations for prolonged laryngoscopy time would include the better hand-eye coordination required with a video laryngoscope, the deficient in-built anti-fogging mechanism, and blood, secretions that may reduce the image quality. Our findings are consistent with a study done on normal airway patients comparing the Miller blade with the video-assisted Miller's blade. The investigators discovered that identical time was needed for tracheal intubation in both groups.[11] Contrary, LuqmanMuhamed and Devadas[12] observed shorter intubation time in USB video laryngoscope as compared to ML. Prolonged times for intubation were also observed with video endoscope laryngoscopes depending on the design and airway adjuncts used.[13,14]

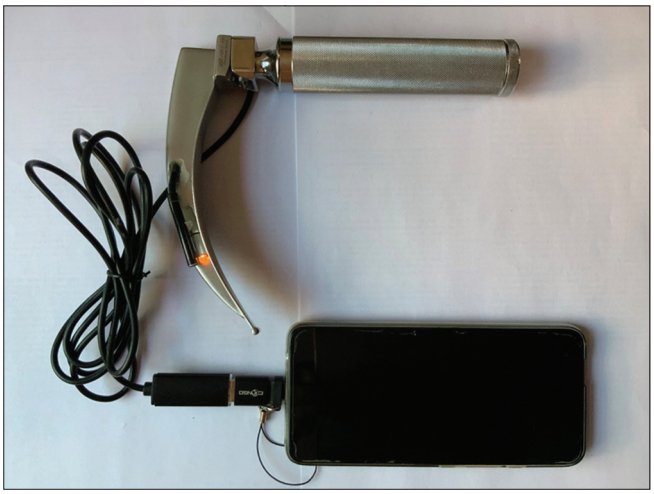

Figure 1: The set-up of custom- made video laryngoscope

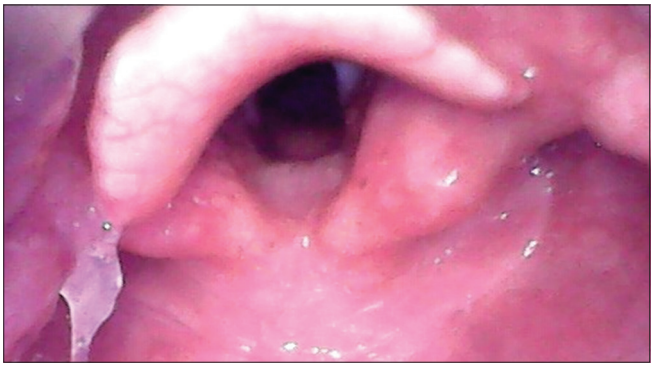

Figure 2: The view obtained with custom-made video laryngoscope

The performance of a video laryngoscope is determined by the angulation of the laryngoscope's blade, the presence of the channel, and camera specification. We assessed the function of the endoscope camera only while holding other variables constant. Faster intubations with modified blade video laryngoscopes have been seen.[15,16] Thus implying that the mere presence of a camera is not of much benefit, other factors like angulation and channel are also important to the laryngoscopist.[17]

In comparison to direct laryngoscopy, video laryngoscopy reduces the user's physical and psychological stress, and reduces the response time.[18] Thus translates to less emotional strain.[18] The intubating circumstances were assessed using IDS. Due to the fact that all intubations were carried out by skilled anesthesiologists, both sets were identical in terms of IDS.

Better glottic visuals are obtained with video laryngoscopes without having to align the laryngeal, oral, and pharyngeal axes. Improved glottis visibility prevents the negative outcomes of blind intubation.[19] Our study observed that CMVL and ML groups were comparable with respect to the glottis visibility. Conversely, most of the research projects using commercially available video laryngoscopes documented improved glottic view.[2] This can be attributed to the deficient inbuilt anti-fogging mechanism and similar blade curves in both groups.[10] In addition, the axis of visualizing the glottis may have been impacted because the camera attachment was made above the bulb of the laryngoscope.[10]

The number of successful intubations was similar in both groups. All intubations were done in the first attempt without the need for any airway adjunct in the CMVL group; however, one patient required a second attempt and the use of stylet for intubation in the Macintosh group. LuqmanMuhamed and Devadas also observed a 100% success rate in both study groups with the rate of success on the first try being more in the video group.[12] Studies have demonstrated a better successful intubation rate with video laryngoscopes as compared to direct laryngoscopy.[20,21]

The requirement of BURP was less (5/20) in the video-assisted group than in the Macintosh group (9/20), although the difference was statistically insignificant. This indicates the significant role of blade angulation in addition

to the presence of a camera.[22] Many studies have shown that the requirement of BURP during intubation is less when using video laryngoscopes.[23,24]

The use of video laryngoscope typically involves less forceful manipulation generally and, hence, lesser sympathetic stimulation than ML.[25] However, our observations suggest that there is no added advantage concerning the hemodynamic changes following the use of CMVL. In both groups, a spike in heart rate and blood pressure occurred immediately upon intubation, which approached the initial values 3 min later. The blade's angulation might determine the force required during laryngoscopy, which in turn affects the hemodynamic changes observed following intubation.[14]

No airway trauma or mucosal burns were reported in the groups. To prevent mucosal burns the device was kept off before intubation attempt.

Limitations of the study

There are certain shortcomings in our study. First, it was impossible to blind the laryngoscopist. Our study was done on adults posted for elective surgery. Hence, the results cannot be applied to emergency settings, pediatric or obstetric airways where dynamics can be different. We included ASA I and II normal airway patients only. Whether the custom-made laryngoscopes behave differently in ASA III, IV, and the difficult airway is yet to be studied. Further studies with larger sample sizes involving various patient cohorts need to be done. The anesthesiologist was made familiar with the working of a custom-made video laryngoscope but still with more experience results might change although not significantly.

CONCLUSION

The results point out that both the laryngoscopes provide more or less similar results concerning all the intubation parameters studied in normal airway scenarios. It also points out that the mere presence of a camera alone does not improve the intubation characteristics in normal airway patients.

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Authors Contribution:
SP- Conception, design of laryngoscope, material data collection, statistical analysis, manuscript preparation and submission of article, writing, critical review; **AK**- Conception, supervision, material data collection, manuscript editing, and revision; **MM**- Conception, supervision, material data collection, submission of article, submission of article; **RP**- Design of laryngoscope, statistical analysis, preparation of figures and tables; **BPP-** Design of laryngoscope, writing, literature review; **A-** Analysis, manuscript revision.

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