Analysis of the 3D printing open source video laryngoscope for orotracheal intubation

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DOI: https://doi.org/10.53097/JMV.10070

Cite: Opolski IJ, Sousa SdR, Franck CL. Analysis of the 3D printing open-source video laryngoscope for orotracheal intubation. J Mech Vent 2023; 4(1):10-17.

Abstract

Introduction
Orotracheal intubation becomes a challenge for the anesthesiologist when the glottis is not visualized with direct laryngoscopy. Videolaryngoscopes emerged as an alternative in these situations, but the costs of these devices restrict their popularization. Doubts remain as to whether low-cost devices would be safe and effective, such as the 3D printing Open-Source video laryngoscope.

Aim
To analyze the 3D printing Open-Source video laryngoscope for orotracheal intubation for general anesthesia in its the rate of achieving, glottis visualization time, intubation time and its correlation with the order of execution.

Methods
Clinical, prospective, analytical study of a questionnaire carried out after the procedure. Statistical analysis was performed using Spearman's correlation, Kruskal-Wallis test, and chi-square test.

Results
There was a total of 64 uncomplicated orotracheal intubation procedures with an overall success rate of 93.8%. Mean time for viewing the glottis (16.4”), mean times of endotracheal intubation with Mallampati I (26.5”), II (33.7”), III (57.3”), IV (38.5”) were obtained with no statistical significance (P 0.170) and overall mean time of orotracheal intubation (36.4”) with a moderate negative correlation of –0.36 across the orotracheal intubation execution order.

Conclusion
In the analysis of endotracheal intubation with the 3D printing Open-Source video laryngoscope a high success rate was demonstrated without any complications. The time to obtain endotracheal intubation tends to reduce with subsequent experiences and learning, but it is more than twice the time required to adequately visualize the glottis and the Mallampati classification was not a relevant time predictor.

Keywords: Orotracheal intubation; Videolaryngoscopy, Airway management

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Conflict of interest/Disclosures: None
Funding: None

Introdution

Airway management is a frequent challenge and even with mastery of the technique, there may be difficulties in accessing it and performing orotracheal intubation. Approximately 30% of all deaths attributable to anesthesia are due to difficulty managing the airway. [1] Since its description as a tracheal intubation method in 1913 and blade modifications by Miller [2] and Macintosh [3] in the 1940s, direct laryngoscopy has remained the conventional technique and accepted standard for endotracheal intubation, with success rates approaching 99% in elective or emergency situations. [4-5]

Prior knowledge of the patient, general physical examination and specific assessment related to the airways allows the physician to prepare the most appropriate airway approach strategy. [6] The modified Mallampati classification comprises four categories according to the visibility of the pharyngeal structures, in which the less visible they are, the greater the technical difficulty for orotracheal intubation. [7] During laryngoscopy, the Cormack-Lehane classification is used based on the visualization of the glottis, also divided into four classes between complete visualization of the glottis and the impossibility of visualizing it that impose the difficulty or impossibility to achieve endotracheal intubation. [8]

Alternative techniques that do not require direct visualization of the vocal cords have been developed and experimented with. These indirect tracheal intubation techniques include the development and use of rigid or malleable optical stylets, rigid indirect laryngoscopes, fiberoptic technology, and videolaryngoscopes, in which video camera systems provide a focused view of the laryngeal inlet. [9]

Indirect laryngoscopy can be performed by obtaining an image of the glottic opening in two ways: by transmission through a fiber optic bundle or a system of prisms to a lens seen by the operator or a video system or with the aid of a camera known as a charge-coupled device that transmits a digital image to a monitor screen. [10]

Video laryngoscopes resemble traditional laryngoscopes but have a small video camera built into their blades to provide views of the larynx for intubation. Video-assisted laryngoscopy can provide a superior view of the larynx compared to direct line-of-sight laryngoscopy. The devices are often used as a first-line tool in early difficult laryngoscopy or in attempts to rescue difficult direct laringoscopy. [11] A problem encountered with many video laryngoscopes is the blind spot created as the endotracheal tube is advanced through the oropharynx, where it cannot be seen by the operator on the monitor screen. Advancing the tube blindly until it is visible on the screen can result in trauma to the oropharynx in some reported cases. [12]

During direct laryngoscopy a restricted view may be present due to the distance between the glottic opening and the observer as well as the viewing angle (15-30°). During videolaryngoscopy, a camera or viewing lens is placed near the tip of the laryngoscope blade with an approximate viewing angle of 50-60 degrees. [13]

In respiratory pandemics, it is recommended that the airway be approached in such a way that the exposure of the medical professional to droplets is minimized, due to the high rate of contagion. This can be done with the use of personal protective equipment, screens and videolaryngoscopy devices. [14]

By understanding that, in times of a pandemic, financial resources can become scarce and video devices have recognized applicability and a high documented success rate, this study intends to analyze the 3D printing Open-Source video laryngoscope for endotracheal intubation under general anesthesia by analyzing the rate of achieving endotracheal intubation, to identify the general average time of glottis visualization and the general average time of endotracheal intubation, to verify the differences in time for endotraqueal intubation in relation to the Mallampati classification and to correlate the time of endortacheal intubation with the number of intubations performed over time with the 3D printing Open-Source video laryngoscope.

Methods

A clinical, prospective, analytical study was carried out on patients undergoing endotracheal intubation in the operating room with the 3D Printer Open-Source Video Laryngoscope under general anesthesia at the Municipal Hospital of São José dos Pinhais - PR from 12/10/2020 to 11/24/2021. Approved by the Ethics and Research Committee of the Health Department of São José dos Pinhais under opinion number 4,443,432. Adult patients aged 18 years or older who required elective surgical procedures under general anesthesia in fasting and who signed the free and informed consent term were included in the study.

A questionnaire was elaborated using clear language in short and objective questions, to be answered after performing the endotracheal intubation with the 3D

Printing Open-Source video laryngoscope, containing the success rate, Mallampati classification, time for better visualization of the glottis, total time of endotracheal intubation. The intern in anaethesiology who would perform the endotracheal intubation were identified by letters from A to E to avoid duplication of filling, but this information remained confidential, thus guaranteeing anonymity. The data were transposed into an electronic spreadsheet in the Microsoft Excel® 2007 program (Microsoft Corporation, Redmond, USA) and subsequently analyzed with statistical resources. The database created by the characteristics of orotracheal intubations with the 3D printing Open-Source video laryngoscope was analyzed in order to verify the success rate of the first intubation attempt and the distribution of the formulated variables. The control questionnaire carried out during the procedures is present in Annex 1.

Each prototype was printed on an Ultimaker 2 Plus® printer, measuring 12.08 x 15.78 x 2.68 cm (H x W x D), with layer height of 0.2 mm, nozzle 0.4 mm and filling of 100% (Image 1). The material chosen for the manufacture was polyethylene glycol terephthalate, a non-toxic plastic compound, commonly used in engineering, which represents an excellent combination of rigidity and tenacity. Thus, once ready, the printed piece becomes washable, sterilizable and highly resistant.

The mechanical resistance of the 3D printing parts withstood tensions of 150 Newton (equivalent to 15.3 kg of load) at the tip of the blade, exceeding the loads used during intubation that revolve around 30 Newton.

Attached to each blade, a waterproof camera (Image 2) was installed, with a diameter of 7 mm, with its own cold light (six LED lamps), for easy cleaning of secretions, which allows its reuse, disinfection and sterilization. The camera used allows a viewing angle of 62º, enabling visualization of the laryngoscope tip and alignment of anatomical structures for better reference in performing endotracheal intubation.

A Samsung Galaxy J5® smartphone with the Android® operating system was used to reproduce the images captured by the camera. In addition, said camera includes a free application for the operating systems mentioned above called USB CAMERA®, which allows the link between the endoscope camera and the smartphone.

Image 1: 3D printing Open-Source video laryngoscope

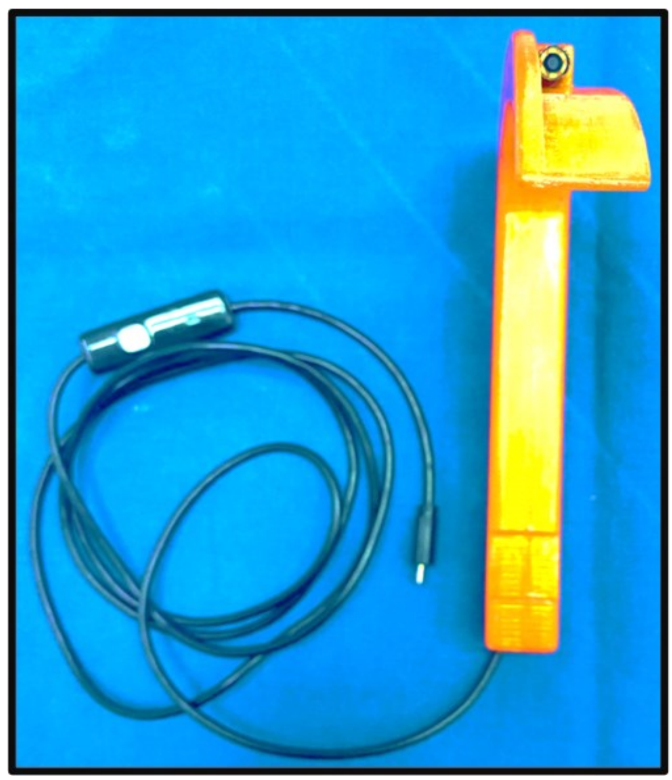

Image 2: 3D printing prototype with camera attached

The 3D Printer Open-Source video laryngoscope was handled by a single operator, when intubating, according to the following protocol: the patient was pre-oxygenated at 100% for three minutes, followed by intravenous anesthetic induction, preferably with the administration of hydrochloride of lidocaine® 1.5mg/kg, fentanyl citrate® 3mcg/kg, propofol® 2mg/kg and suxamethonium chloride® 1mg/kg. Once the time for the drugs used to work had elapsed and the patient was in a deep anesthetic plane, videolaryngoscopy was performed and the endotracheal intubation was performed with the head in the olfactory position, followed by opening the mouth and inserting the blade through the midline to the base base of the tongue, observing the anatomical structures, all the time, using the Samsung Galaxy J5® smartphone.

The epiglottis was located and the blade tip was positioned in the vallecula. A slight force was applied to the laryngoscope, upwards and towards the patient's feet, to expose the vocal cords (Image 3) and thus introduce the endotracheal tube between the vocal cords (Image 4).

Image 3: Laryngeal structures captured by the 3D printing Open-Source video laryngoscope

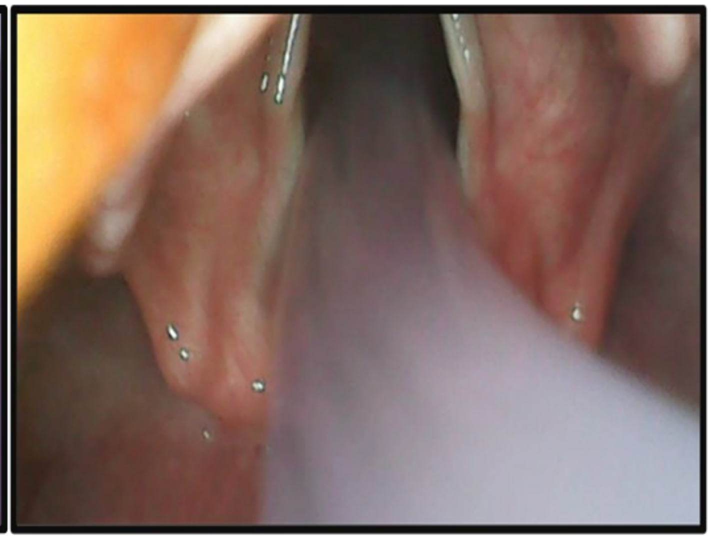

Image 4: Tracheal tube between the vocal cords captured by the 3D printing Open-Source video laryngoscope

A second medical examiner monitored the entire procedure and was responsible for timing and completing the endotracheal intubation control questionnaire with time for better visualization of the glottis, total intubation time and whether the attempt was successful or not.

The data obtained from the completed questionnaires were tabulated in a Microsoft Excel® 2007 spreadsheet (Microsoft Corporation, Redmond, USA) and subsequently analyzed with statistical resources, which were exported to the STATA® statistical software, version 11.0, to carry out the analyzes Statistics.

In the statistical analysis, for the description of the quantitative variables, the statistics of mean, median, minimum and maximum values, first and third quartiles and standard deviation were considered. For summarizing qualitative variables, frequencies and percentages were considered. To assess the association between the order of intubation and the total time for intubation, Spearman's correlation coefficient was estimated. To assess the association between the Mallampati classification and the physician who intubated with the total intubation time, the Kruskal-Wallis non-parametric test was considered. To assess the homogeneity of the distribution of the Mallampati classification among physicians, the chi-square test was considered P values less than 0.05 indicated statistical significance.

Results

The questionnaires completed after the 64 endotracheal intubation procedures with 3D printing Open-Source video laryngoscope were analyzed, which did not present any mild or severe complications.

It is observed in Table 1 that the rate of obtaining endotracheal intubation ranged from 87.5% to 100%, and that the overall rate of obtaining endotracheal intubation was 93.8%.

For the evaluation of the Mallampati classification and the total time for intubation endotracheal the null hypothesis of equal total time to intubation in all

Mallampati classifications was tested against the alternative hypothesis of at least one classification with different results from the others.
The Table 2 presents the results of the total time to intubation for each of the Mallampati classifications, as well as the *P* value of the statistical test. We can see that the mean intubation endotracheal time for a patient classified as Mallampati I is 26.5 seconds, for a Mallampati II patient this time is 33.7 seconds, for Mallampati III it is 57.3 seconds and for a patient classified as Mallampati IV is 38.5 seconds.

As shown in Table 2, the numerical amount of Mallampati classification was not homogeneous and classification IV occurred in only two cases, while classification II predominated. The time medians had a progressive increase analogous to the technical difficulty predicted by the Mallampatidos classification, however, no statistical difference was observed in the time of endotracheal intubation in relation to the Mallampatis classification (P,0.170).

The verification of the time to view the glottis with the 3D printing Open-Source video laryngoscope with the intention of differentiating it from the time to obtain endotracheal intubation.

The average time for adequate visualization of the glottis was 16.4 seconds, with a median of 12 seconds, while the average time for obtaining endotracheal intubation was a median of 36.4 seconds with a median of 30.5 seconds, that is, more than twice as long to perform orotracheal intubation after adequate visualization of the glottis.
To correlate the sequential order of procedures with the time to obtain endotracheal intubation, the null hypothesis of Spearman's correlation coefficient between the order of intubation and the total time for intubation equal to zero (no association) was tested versus the hypothesis alternative non-zero Spearman correlation coefficient (existence of association). Table 3 shows the results obtained in the study.

As shown in Table 3, there was a tendency to reduce the time to obtain endotracheal intubation as the procedures were performed. It was observed that for intern in anaethesiology A, C and D a weak negative correlation was detected without statistical relevance, however with intern in anaethesiology B and E a reduction in time with statistical relevance and a strong negative correlation with statistical relevance. The correlation of all Intern in anaethesiology together with the time to obtain endotracheal intubation, considering a weighted average of these correlations and the number of attempts as the weight, demonstrated a moderate negative correlation of -0.36, that is, denoting the idea that learning and experience has an effect on the execution time of the technique.

Table 1: The success rate for each physician and the overall success rate

Intern in anaethesiology	Achieving of entotracheal intubation				Total
	No		Yes		
	n	%	n	%	
A	1	8.3%	11	91.7%	12
B	0	0.0%	9	100.0%	9
C	1	12.5%	7	87.5%	8
D	1	3.7%	26	96.3%	27
E	1	12.5%	7	87.5%	8
General	4	6.3%	60	93,8%	64

Table 2: Relationship between Mallampati classification and time to endotracheal intubation. (*) Kruskal-Wallis non-parametric test; P<0.05

Mallampati	N	Mean (seconds)	Median (seconds)	1st quartile (seconds)	3st quartile (seconds)	Standart deviation	P-value*
I	18	26.5	25.5	20	32.3	10.1	
II	28	33.7	33	26.3	40.3	13.5	0.170
III	12	57.3	36.5	20	78.3	50.8	
IV	2	38.5	38.5	34.3	42.8	12.0	

Table 3: Correlation of sequence of procedures withthe time to achieve ndotracheal intubation

Intern in anaethesiology	Number of intubations	Spearman Correlation	P-value
A	11	-0.18	0.591
B	9	-0.78	0.014
C	7	-0.23	0.613
D	26	-0.17	0.404
E	7	-0.95	0.001

Discussion

Regarding the results obtained, it was verified that the overall success rate of endotracheal intubation in the present study was 93.8%. Comparatively, the meta-analysis identified a rate of 85% both in the use of the McGrath video laryngoscope® and the Macintosh laryngoscope. [15] Another study showed an 82.1% success rate in the first intubation of 525 patients with Macintosh laryngoscope®. [16]

Using the 3D printing Open-Source video laryngoscope, the average total time for intubation varied, depending on the intern in anaethesiology, from 11.7 to 58.2 seconds, with a total median of 30.5 seconds. This value is higher than that identified in the study that showed the endotracheal intubation time with the video laryngoscope King Vision® was 23.5 seconds and the endotracheal intubation time with the standard Macintosh laryngoscope was 7.6 seconds. [17]

Regarding the glottis visualization time, the present study also obtained a higher time, a median of 12 seconds, a value that was closed to the time found in the same work in which presented a time of 12.6 seconds with the video laryngoscope King Vision®. [17]

When correlating the number of intubations of each intern in anaethesiology with the time of endotracheal intubation, a moderate effect of -0.36 was found, which may infer that there is an effect on learning and experience. This effect can also be found in the study, in which the learning curve of three indirect video laryngoscopes was compared with direct laryngoscopy with a Macintosh blade. According this study, in a normal airway model, in all three video laryngoscopes, intubation time decreases from the first attempt to the subsequent attemptns, reflecting the acquisition of skills. [18]

In this research it was demonstrated that the time medians had a progressive increase analogous to the technical difficulty predicted by the Mallampati classification, however, no statistical difference was observed in the time of endotracheal intubation in relation to the Mallampatis classification, in agreement with another study that related improves its prediction when including dentition, thyromental distance and neck extension in the evaluation. [7]

Video laryngoscopes have been recommended for use in routine and difficult airways. [19] On the other hand, in this study, the intubations that failed with the video laryngoscopes were performed with direct laryngoscopy. In addition, the comparisons between the conventional laryngoscope and various video laryngoscopes in simulated mannequin training show evidence that intubation skills with the new devices are mastered quickly and that video laryngoscopes provide superior laryngeal views, but times to obtain endotracheal intubation can be longer as it was noticed in this research that the time to obtain endotracheal intubation was greater than twice the time for adequate visualization of the glottis, [15] a fact that may indicate that the ease of visualizing the glottis does not exempt the technical difficulty of introducing the endotracheal tube through the glottis.

Comparisons of vídeo laryngoscopes with laryngoscopes based on a variety of elements in the intubation process, such as intubation time, glottis visualization and ease of intubation are difficult to interpret because the techniques are very different. [20]

In this study, the performance of the 3D printing Open-Source video laryngoscope, was analyzed in patients with different anatomical conditions, without any mild or severe complications, and allowed some conclusions about its effectiveness and learning curve, in addition to presenting a low-cost vídeo laryngoscopes in the current scenario in front of respiratory pandemic.

The main limitation of this research is due to the small n that prevents a complete analysis of the learning curve of the Open-Source 3D printing video laryngoscope and the relationship between the time to obtain tracheal intubation and the Mallampati classification due to the numerical disproportion between each class.

Conclusion

In the analysis of endotracheal intubation with the 3D printing Open-Source video laryngoscope a high success rate was demonstrated without any complications. The time to obtain endotracheal intubation tends to reduce with subsequent experiences and learning, but it is more than twice the time required to adequately visualize the glottis and the Mallampati classification was not a relevant time predictor.

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