

Comparative Study to Evaluate the Effect of Intubation Box on Tracheal Intubation Difficulty with King Vision ® and Truview Video Laryngoscope in Manikin in a Tertiary Care Hospital.

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Background: The procedures related to airway can be associated with increased risk of aerosolization of SARS-CoV-2 virus posing a high risk to the personnels involved. Novel methods like the intubation box have been developed to increase the safety of healthcare workers during intubation. **Methods:** In this study, 33 anaesthesiologist and critical care specialists intubated the trachea of the airway manikin (US Laerdal Medical AS) 4 times using a King Vision ® videolaryngoscope and TRUVIEW PCD TM videolaryngoscope (with and without an intubation box as described by Lai). Intubation time was primary outcome. Secondary outcomes were first-pass intubation success rate, percentage of glottic opening (POGO) score and peak force to maxillary incisors measured with a pressure sensing device. **Results:** Intubation time and the pressure exerted on the incisors (detected by a click sound) were considerably higher in both groups when an intubation box was used. (Table 1) When comparing the two laryngoscopes, intubation time with the King Vision ® video laryngoscope was lower than that of TRUVIEW laryngoscope, both with and without the intubation box. (P<0.001) In both groups, rate of first pass successful intubation was higher without the intubation box, although the difference was statistically insignificant. POGO Score was not affected by intubation box but higher score was observed with King Vision ® laryngoscope. (Table 1,2). **Conclusion:** This study indicates that use of an intubation box makes intubation difficult and increases the time. King Vision ® videolaryngoscope results in lesser intubation time and better glottic view as compared to TRUVIEW laryngoscope.

Keywords: Airway management; anaesthesiologist; intubation; laryngoscope; manikin; SARS-CoV-2 pandemic.

Introduction

The Severe Acute Respiratory Syndrome-coronavirus-2 (SARS-CoV-2) pandemic has caused a greater risk to the lives of healthcare

workers. The infection rate among healthcare workers were high during the time of pandemic in many countries.[1] During the procedures of airway management, the odds of transmission of infection to healthcare workers is 6.6 times as compared to others. [2] To overcome the risks of transmission many devices and methods were developed during the time of pandemic. One such device is the intubation box used during tracheal intubation developed by Lai, Hsien Yung; Mennonite Christian Hospital, Hua Lian, 2020. [3] However, there are concerns related to the difficulty of tracheal intubation when such intubation box is used. This study was planned to investigate the influence of intubation box on tracheal intubation when two distinct types of

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video-laryngoscopes are used in a simulated normal airway environment.

Materials and Methods:

The study was approved by the institutional ethics committee and written informed consent was obtained from all the participants. The sample size was determined by using our pilot data ($n = 7$). In our pilot study, the mean times to successful tracheal intubation were 18 and 20 sec with King Vision® video-laryngoscope and TRUVIEW video laryngoscope, respectively without the intubation box. We assumed that the use of the intubation box prolonged the time for intubation by 12 s. With type I error of 5% and type II error of 20%, 27 participants were required for the study. To compensate for dropouts 30 participants were recruited.

Anaesthesiologist and critical care specialists who had performed more than 50 oro-tracheal intubations with video laryngoscopes were included in the study. Anaesthesiologist and critical care specialists with lesser number of experience and those who denied participation were excluded from the study. Thirty anaesthesiologist and critical care specialists who fulfilled the inclusion criteria were included in the study.

The manikin used for our study was the Laerdal airway management simulator (US Laerdal Medical AS). Each participant intubated the trachea of the airway manikin 4 times as follows:

- (1) Using a King Vision® video-laryngoscope and a size #3 disposable video-laryngoscope channelled blade (KVLO3C) without an aerosol box;
- (2) Using a King Vision® video laryngoscope and a size #3 disposable video-laryngoscope channelled blade (KVLO3C) with an aerosol box;
- (3) Using a TRUVIEW PCD™ video-laryngoscope and an TRUVIEW PCD™ Optical blade size 3 without an intubation box; and

- (4) Using TRUVIEW PCD™ video-laryngoscope and TRUVIEW PCD™ Optical blade size 3 with an intubation box.

Our intubation box was made according to the standard reference as described by Lai (length × height × width equals 40 × 50 × 50 cm); diameter of the circular opening for insertion of arms, 10 cm; position of the circular opening, 25 cm from base and 5 cm from the side of the box) [4].

A PVC tracheal tube with an internal diameter of 8.0 mm was used in all intubations. A malleable stylet (Intersurgical™ satin slip intubating stylet) was used for tracheal intubation with King Vision® video-laryngoscope and Truflex™ articulating stylet for TRUVIEW PCD™ video-laryngoscope. The table on which manikin was placed was kept horizontal and a stiff headrest with a height of 7 cm was used under manikin's head to maintain standard "sniffing position". The entire bed remained horizontal. Each participant was allowed three practice intubations in all the settings on the manikin to familiarize with the process. The order of intubations was randomized for every intubator by computer-generated randomization. All the participants donned the personal protective equipment (PPE) in adherence to institutional guidelines. Expired N95 masks were used to conserve PPE. The airway assistant for all tracheal intubations was a single experienced anaesthetist who was blinded to the order of scenarios.

The primary outcome was intubation time, defined as the time from initial insertion of the laryngoscope in the mouth to the first lung inflation with positive pressure breaths using an ambu bag through the tracheal tube with an inflated cuff. Secondary outcomes were first-pass intubation success rate, percentage of glottic opening (POGO) score [5], peak force to maxillary incisors measured by force sensors attached to the manikin as default and heard as a click sound. The time to successful tracheal intubation, attempts needed to intubate and the peak force to maxillary incisors was recorded (measured by audible click)

by a single assistant who was not involved in the study design. The POGO score was evaluated by each intubator.

Data was compiled in MS Excel sheet and analyzed using SPSS 23.0 software. Results are presented as numbers, frequencies and proportions or as mean, standard deviation wherever appropriate. Testing for significant associations was done using chi square test or Fischer exact test or using student t test as required. P value was considered statistically significant if its value was below 0.05.

Result:

Thirty participants randomly performed a total of 120 intubations of which data was collected and subsequently analysed. Intubation time with the intubation box was significantly longer in both the laryngoscope groups when compared to the intubation time without the use of intubation box. (P<0.001) (Table 1) Intubation time with King Vision ® video laryngoscope was significantly shorter compared to the intubation time with TRUVIEW laryngoscope. This was observed on both occasions where intubations were done with

and without the intubation box. (P<0.001) (Table 2).

Overall, in both laryngoscope types, the first pass success rate was high when the intubations were done without the intubation box. However, the difference was statistically insignificant. (Table 1,2). The number of times a click is heard during tracheal intubation was significantly higher when using an intubation box with both the laryngoscopes, as compared to intubation without an intubation box. (Table 1).

Use of the intubation box did not affect the POGO Score of the intubations. (Table 1). POGO Score was significantly reduced with the use of TRUVIEW laryngoscope as compared to the use of King Vision ® laryngoscope, both with and without intubation box. (Table 2).

We found that the use of the intubation box significantly increases the intubation time needed and the force exerted to the upper incisors. Its use however, did not significantly affect the POGO Score and the first pass success rate. In addition, intubation time with King Vision ® video-laryngoscope was less and provided a better glottic view as compared to intubation with the use of TRUVIEW video-laryngoscope.

Table 1: Comparison of Coordinates of Tracheal Intubation Difficulty on Manikin Without and With Intubation Box.

Coordinates	TRUVIEW Laryngoscope (n=30)		P value †	King Vision ® Laryngoscope (n=30)		P value †
	Without I.B.	With I.B.		Without I.B.	With I.B.	
Time To Successful Intubation (sec)¥	21.2±1.69	31.13±2.15	<0.001	15.80±1.13	23.37±1.17	<0.001
First Pass Intubation Success Rate*¥	29 (96)	24 (80)	0.103	30 (100)	26 (86)	0.112
Click‡	0	7	0.011	0	6	0.024
POGO Score*	75-100	75-100	0.744	100	100	1.00

Values are presented as numbers or mean ± S.D. I.B: intubation box, POGO: percentage of glottic opening.

*Values are presented as numbers (%)

† statistically significant difference (P<0.05)

¥- student t test used for statistical analysis

‡- fisher exact test used for statistical analysis

Table 2: Comparison of Coordinates of Tracheal Intubation Difficulty among the Two Laryngoscopes with and Without Use of Intubation Box.

Coordinates	With intubation Box			Without intubation Box		
	TRUVIEW video-laryngoscope (n=30)	King Vision ® video-laryngoscope (n=30)	P value †	TRUVIEW video-laryngoscope (n=30)	King Vision ® video-laryngoscope (n=30)	P value †
Intubation Time(sec)¥	31.13±2.15	23.37±1.17	<0.001	21.20±1.69	15.80±1.13	<0.001
First Pass Success *¥	24 (80)	26 (86)	0.729	29 (96)	30 (100)	1.00
Click ‡	7	6	1.00	0	0	1.00
POGO Score *	75%(n=6)	100(N=30)	0.011	75%(n=5)	100(n=30)	0.021
	100%(n=24)			100%(n=25)		

Values are presented as numbers or mean ± S.D. POGO: percentage of glottic opening.

*Values are presented as numbers (%)

† statistically significant difference (P<0.05)

¥- student t test used for statistical analysis

‡- fisher exact test used for statistical analysis

Discussion:

Simulation is a well-established method for testing the safety and efficacy of medical innovations. [6] Many institutions have developed new protective barrier modalities for tracheal intubation of infected patients during COVID19 pandemic. [3] Our aim was to test the utility of an intubation box in a simulated environment with a normal airway manikin.

To our knowledge this is the first formal study using these two video laryngoscopes (TRUVIEW and King Vision ® Video Laryngoscope) and the intubation box. In our study, we found that use of an intubation box during intubation significantly prolongs the intubation time and increases the force exerted to the upper incisors, hence making the procedure of intubation more complicated. Prolongation of intubation time in a COVID 19 patients requiring mechanical ventilation can be very critical as it may lead to worsening of hypoxia with increasing morbidity and mortality. Prolongation of procedure time can result in

greater aerosolization. Increased force exerted on upper incisor during intubation with the use of aerosol box may indicate increase probability of dental trauma. We also found that the removal of assistive devices like stylet was more difficult with the use of intubation box which could be one of the factors for increased intubation time.

Our results are in agreement with another manikin-based pilot study, which concluded that the intubation times were higher when barrier devices like intubation box or plastic sheets were used. The use of barrier devices resulted in ergonomic challenges like difficult stylet removal and difficulty in movement of hands under the barrier device. [7]

In contract, a study done by Wakabayashi R et al, on aerosol box concluded that “the effect of an intubation box on tracheal intubation difficulty is clinically irrelevant when an experienced anaesthetist intubates the trachea in a normal airway condition”. [8] The difference in findings from our study could be because we used real time

simulation by wearing PPE with goggles during all intubations.

In a letter to healthcare providers the Federal Drug Administration revoked the umbrella Emergency Use Authorization for passive protective barrier enclosures issued in May.[9] This was done as some studies pointed out that barrier enclosures used during COVID 19 may not decrease exposure of health care providers to airborne particles and may add to the level of difficulty during airway management. They recommended the use of negative pressure and full PPE cover while handling the airway. The King Vision ® video-laryngoscope provides an indirect view of glottis and has a provision of single use blades which removes the concerns of contagious infections and is advantageous for the use in COVID scenarios. Its distal lens has an anti-fog coating which may be the cause for decrease intubation time when used with goggles.[10]. The TVL (Truphatek Israel) is a Macintosh-type blade with an optical lens attached.[11].

Our research has a few drawbacks. To begin with, the intubation box was not assessed in difficult airway scenario. Difficult airway conditions presents a challenge and adds additional time to intubate. When used in these settings, it may pose a greater difficulty than in patients with a normal airway. Secondly, we could not use any parameter to evaluate the amount of protection from viral exposure achieved with the use of an intubation box.

Our study analysed only laryngoscopy and endotracheal intubation as markers of airway management. However, airway management also involves other procedures like mask ventilation, oro-pharyngeal suctioning, laryngeal mask airway insertion and tracheostomy. These were not analysed in our study. Using intubation box can significantly affect the success of these procedures.

In our study only the experienced anesthesiologists were recruited for testing the use of intubation box. Healthcare providers with lesser experience

in airway management could face additional challenges with the use of intubation box.

In conclusion, the results of our study indicate that the use of an intubation box makes tracheal intubation comparatively difficult with prolong intubation time. Among the two laryngoscopes used in our study, we conclude that King Vision ® video-laryngoscope takes lesser intubation time and gives better glottic view when compared to TRUVIEW video-laryngoscope.

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