

Received 13 April 2022; revised 5 September 2022; accepted 29 September 2022. Date of publication 4 October 2022; date of current version 12 October 2022.

Digital Object Identifier 10.1109/JTEHM.2022.3211660

Effect of Real-Time Carbon Dioxide Sensing Stylet Assisted Endotracheal Intubation: A Pilot Study Using the Porcine Model

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ABSTRACT Introduction: Safe and prompt endotracheal intubation is crucial to prevent morbidity and mortality in patients requiring airway management. The aim of this pilot study was to test the effect of real-time carbon dioxide (CO_2) sensing stylet assisted intubation compared with conventional intubation in porcine experiment. Methods: Thirty-four swine were assigned to either the intervention or control group in a 1:1 ratio. Real-time CO_2 sensing stylet was manually manufactured and used for assisting intubation in the intervention group. Conventional intubation using direct laryngoscopy was performed in the control group. The primary outcome was total procedure time and the secondary outcome was first attempt success rate. Cumulative hazard curves were obtained by analyzing the total procedure time to successful intubation for each swine, and the log-rank test was used to compare between the two groups. Results: Compared to the control group, a trend of shorter total procedure time was observed in the intervention group (mean \pm standard deviation, 59.8 ± 34.6 s vs. 92.2 ± 68.2 s; p-value = 0.09). The cumulative hazard plot showed a consistent trend of shorter total procedure time in the intervention group compared to the control group (p-value = 0.16). The first attempt success rate showed a higher trend (70.6% vs. 52.9%; p-value = 0.29) in the intervention group. Conclusion: The real-time CO₂ sensing stylet assisted endotracheal intubation has potential to reduce the time to successful intubation and improve first attempt success rate.

INDEX TERMS Gas detectors, medical simulation, medical treatment, real-time systems.

I. INTRODUCTION

S AFE and efficient endotracheal intubation (ETI) is crucial to prevent morbidity and mortality in patients requiring airway management [1]. While ETI is safe for most patients, some critically ill patients with ETI performed in the emergency department (ED) are vulnerable to complications [2]. Previous literature reported that the first attempt success rate, success rate within three attempts, and the rate of adverse events of ETI in the ED were 83%, 99%, and 12%, respectively [3]. In one study, two or more attempts of ETI significantly increased the risk of severe complications [4].

In another study, failure of first attempt of intubation was associated with 6.4 times odds of an occurrence of at least one complication including desaturation, aspiration, airway trauma, and cardiac arrest [5]. Procedure time is another important index for safe intubation. Although preoxygenation can extend the duration of apnea without desaturation, delayed time until success can result in hypoxia during intubation [6].

Many devices and methods were developed to improve success rate and shorten procedure time of ETI. One of the most popular and widely adopted devices is video

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laryngoscopy, which attempts to improve the view of the larynx using a camera positioned on the laryngoscope blade [7]. A recent meta-analysis showed that ETI using video laryngoscopy reduced esophageal intubation compared with direct laryngoscopy, but the overall intubation success rate was not improved [8]. Another study also did not find a significant difference in the first attempt success rate between video laryngoscopy and direct laryngoscopy performed in the ED [9]. Fibreoptic intubation, using a flexible endoscope along with a tracheal tube, has several advantages in the management of difficult airway situations but needs skilled physician and fibreoptic devices [10]. The effectiveness of video laryngoscopy and fibreoptic technology is decreased in patients with blood or vomitus in the airway since their assistance for visualizing the glottis would be limited [5]. [11]. Intubating laryngeal mask airway provided a rapid and successful method for blind tracheal intubation, but the first attempt success rate varies between studies and devices (67.9–93.3%) [12], [13].

Waveform capnography is currently the gold standard method of successful ETI confirmation, in addition to visual confirmation [14], [15], [16]. Usually, capnography waveform is checked after the intubation process is finished and the endotracheal tube is connected to the ventilator or ambubag, which delays time to confirmation of ETI. There is also a risk of stomach distension in the case of esophageal intubation because ventilation must be performed to check the capnography waveform.

To facilitate rapid and accurate ETI, real-time capnographyguided intubation was proposed [17]. A device that consisted of a suction unit connected to an intubation stylet which inhaled gas from the end of the endotracheal tube, a capnograph sensor to detect carbon dioxide (CO_2) level, and an alarm unit to provide real-time feedback was used. By providing real-time feedback, the use of this device contributes to early discrimination of tracheal or esophageal intubation and allows operators to take immediate action to correct the position of the tube. One animal study using rabbits showed that intubation time was significantly reduced by using capnography-guided intubation technique [18]. However, there are limitations in applying the study results to humans because the procedures for intubation in rabbits are considerably different from humans.

The aim of this study was to develop a user-friendly device for real-time CO_2 guided intubation and evaluate its effectiveness compared with conventional intubation in swine. We hypothesized that real-time CO_2 guided intubation using a stylet-form device would be feasible, improve the first attempt success rate, and reduce the time to intubation success.

II. METHODS

Real-Time CO₂ Sensing Stylet Assisted Intubation

We manually manufactured the device for real-time CO_2 sensing stylet assisted intubation, which consisted of a hollow tube, an air pump, a CO_2 sensor, and a controller (Fig. 1).

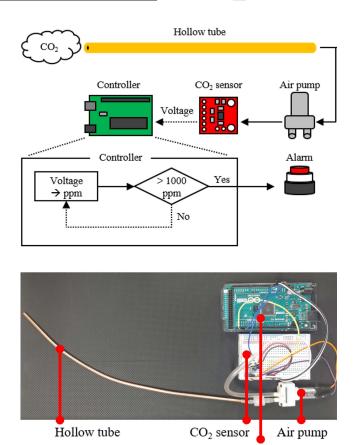


FIGURE 1. Real-time carbon dioxide sensing stylet assisted intubation device.

Controller

The hollow tube allowed passage of gas and was made of highly ductile copper. The hollow tube also functioned as a stylet (real-time CO₂ sensing stylet) to support the endotracheal tube instead of a conventional stylet. The hollow tube was connected to an air pump (JT3404PM, JG, China). The air pump created a negative pressure inside the hollow tube, thereby inhaling gas from the airways or the esophagus towards the CO2 sensor (CCS811 Air Quality Breakout, SparkFun Electronics[®], Colorado, USA). The CO₂ in the gas was detected with the CO₂ sensor and analog voltage data was acquired. The controller (Arduino Mega 2560, Arduino, Italy) converted the voltage into CO₂ concentration as parts per million (ppm) and displayed the CO₂ analysis results to the user. The sampling rate of the device is 1 Hz. It takes 1 second for the device to display the concentration from the moment it inhales CO₂.

Real-time CO_2 sensing stylet assisted intubation started similarly to the conventional intubation method, by inserting the laryngoscope blade and aiming to visualize the glottis. When the operator attempted to insert the endotracheal tube, with a full or partial view of the glottis, CO_2 concentrations were continuously measured. Operators decided for themselves whether to advance endotracheal tube considering CO_2 level and visualized glottis view.



If the elevated CO_2 concentration was sustained after insertion of the endotracheal tube, we assumed that the endotracheal tube was in the trachea. However, if the CO_2 concentration did not increase above the threshold after insertion of the endotracheal tube, we assumed that the endotracheal tube was in the esophagus. From pilot trials, the CO_2 concentrations were measured to be about 400–500 ppm when the tip of the endotracheal tube was in the oral cavity and away from the glottis. It increased much above 1000 ppm with the tip located at the glottis or in the trachea. Therefore, we predetermined a CO_2 concentration of 1000 ppm as the threshold value for the alarm.

A. ANIMAL PREPARATION

Swine are one of most often used animal species in translational research because they share many similarities with humans [19]. Swine intubation is challenging due to its thick tongue and narrow oropharyngeal space, like difficult airway situations in human [20].

A total of 34 healthy female swine of age approximately 3 months and weighing 41.5 - 58.5 kg were acquired from a local farm. They were fasted overnight and then were sedated with intramuscular injection of tiletamin/ zolazepamhypochloride (Zoletil®, Virbac, France, 2 - 4 mg/kg) and xylazine (Rompun®, BayerKorea, South Korea, 2 mg/kg) for the experiment. After the swines were adequately sedated, they were put onto a table in a dorsal recumbent position. Their peripheral oxygen saturation (SpO2) level was monitored using a photoplethysmography sensor applied on the tail or ear. Anesthesia was maintained by continuous inhalation of isoflurane (2 - 5 %).

B. INTERVENTION AND EXPERIMENT PROTOCOL

ETI was performed by Two emergency medicine physicians and one emergency medical technician. The operators had more than four years of experience in the ED but had little experience in swine intubation (2 to 10 times). The swine were assigned to either the intervention or control group in a 1:1 ratio. The allocated group (intervention or control) and the operator to perform ETI was randomly assigned by block randomization with a block size of 6 (2×3). After 3 min of mask ventilation, intubation was attempted using a conventional laryngoscope with a Miller blade (size 4) and a 7.0 mm endotracheal tube. In the intervention group, real-time CO₂ sensing stylet assisted intubation was performed (Fig. 2). When a CO₂ level above the threshold was detected, the operator was alarmed. The operator took this alarm into account to decide whether to push the endotracheal tube forward into the glottis or to keep on searching for the glottis. If the elevated CO₂ level was sustained after insertion, the operator removed the stylet from endotracheal tube and connected to the ventilator. If the CO₂ level did not increase above the threshold or the level decreased to the baseline level after a transient elevation, the operator assumed that an esophageal intubation was performed. In this case, the operator withdrew the endotracheal tube while maintaining the position of the



FIGURE 2. Intubation using real-time carbon dioxide sensing stylet.

laryngoscope and tried to insert the endotracheal tube again. In the control group, ETI was performed in the conventional method using a laryngoscope with a Miller blade (size 4), 7.0 mm endotracheal tube, and a conventional intubation stylet.

One intubation attempt was defined as a single maneuver beginning with the insertion of a laryngoscope into a swine's mouth and ending when the laryngoscope was removed. The procedure time was defined as the duration for a single intubation attempt. ETI was attempted until the swine was successfully intubated, but the experiment protocol was aborted after the third failed attempt. Therefore, data of attempts after the third failed attempt were not included in this study. Intubation failure was defined as consecutive 3 failed attempts of ETI. A successful ETI was confirmed by observing an adequate capnography waveform after connecting the endotracheal tube to the mechanical ventilator.

C. MAIN OUTCOME

Import The primary outcome of this study was total procedure time. The total procedure time was measured by the sum of the duration of procedure time for all attempts (maximum 3 times) of a given swine. The secondary outcome was first attempt success rate.

D. STATISTICAL ANALYSIS

Sample size was calculated based on a previous animal study that found that the intubation time of the conventional intubation method using laryngoscopy was 2.6 times as long as the intubation time of capnography-guided intubation in rabbits [18]. We estimated that a sample of 34 swine would provide the trial with 80% power at a two-sided significance level of 0.05, to detect a significant difference with respect to the primary outcome, using log-rank test, assuming a hazard ratio of 2.6.

Categorical variables were reported as numbers and proportions, and compared using the Fisher's exact test or chi-square test, as appropriate. Continuous variables were reported as mean and standard deviation (SD) and compared using the Student's t-test. Cumulative hazard curves were obtained by analyzing the total procedure time to successful

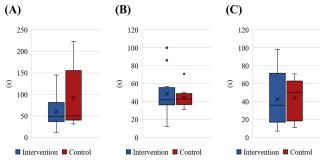


FIGURE 3. Box plots for the (A) total procedure time, (B) first attempt success time, and (C) first attempt failure time in both groups.

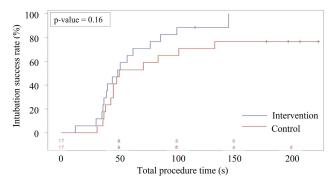


FIGURE 4. Cumulative hazard plot for total procedure time to successful intubation.

intubation for each swine, and the log-rank test was used to compare between the two groups. Swine with intubation failure were treated as censored observations. CO_2 concentration throughout the CO_2 sensing stylet assisted intubation process of successful intubations were extracted and plotted. The operator notified the researchers when he or she saw the endotracheal tube entering the presumed glottis. All statistical analyses were performed using SAS version 9.4 (SAS institute Inc., NC, USA).

E. ETHICS STATEMENT

This study was approved by the Institutional Animal Care and Use Committee of the study hospital (20-0167).

III. RESULTS

Seventeen swine were assigned to each of the intervention and control group. All animals survived the intubation procedure in good health without significant complications. Operator 1 performed intubation for 5 swine in the intervention group and 5 in the control group. The rest of the operators each performed intubation for 6 swine in the intervention group and 6 in the control group.

Total procedure time was 32.4 s shorter in the intervention group (mean \pm SD, 59.8 \pm 34.6 s vs. 92.2 \pm 68.2 s; p-value = 0.09) compared to the control group with smaller number of total attempts: mean (SD) 1.4 (0.7) in the intervention, 1.7 (0.8) in the control (Table 1 and Fig. 3). The cumulative hazard plot showed a consistent trend of shorter total proce-

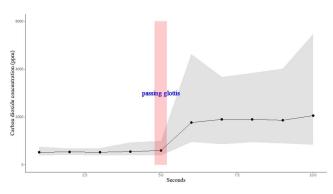


FIGURE 5. Carbon dioxide concentrations at different locations during the intubation process.

TABLE 1. Characteristics of procedure result according to study group.

	Total	Case	Control	p-	
	Total	(N=17)	(N=17)	value	
Total procedure time	76.0	59.8	92.2	0.00	
(s), mean (SD)	(55.7)	(34.6)	(68.2)	68.2) 0.09	
First attempt success	46.9	48.8	44.3	0.57	
time (s), mean (SD)	(19.1)	(23.6)	(11.7)	0.57	
First attempt failure	43.4	42.6	43.9	$\frac{43.9}{(23.1)}$ 0.94	
time (s), mean (SD)	(26.4)	(34.0)	(23.1)		
Total number of	1.6	1.4	1.7	0.20	
attempts, mean (SD)	(0.8)	(0.7)	(0.8)	0.28	
First attempt success,	21	12	9	0.29	
N (%)	(61.8)	(70.6)	(52.9)		
Success at second	7	3	4	1.00	
attempt, N (%)	(20.6)	(17.6)	(23.5)	1.00	
Success at third	1	1	0	NA	
attempt, N (%)	(2.9)	(5.9)	(0.0)		
Intubation Failure, N	5	1	4	0.34	
(%)	(14.7)	(5.9)	(23.5)		

Case, real-time CO_2 sensing stylet assisted intubation group; Control, conventional intubation group; SD, standard deviation.

dure time (p-value = 0.16) in the intervention group compared to the control group (Fig. 4). The first attempt success rate showed a higher trend (70.6 % vs. 52.9 %; p-value = (0.29), while the intubation failure rate showed a lower trend (5.9 % vs. 23.5 %; p-value = 0.34) in the intervention group. However, the study was underpowered to detect statistically significant differences between the two groups. The trend of shorter total procedure time and higher first attempt success rate was similarly identified in a subgroup analysis for each operator (Supplement 1). Learning effect was not clear when comparing the total procedure time and first attempt success rate for the first half and the second half (Supplement 2). Compared to the CO₂ levels away from the glottis (mean \pm SD, 426.2 \pm 26.5 ppm), the CO₂ levels at the glottis or inside the trachea (mean \pm SD, 2765.4 \pm 1530.6 ppm) were significantly higher (p-value < 0.01) (Fig. 5).

IV. DISCUSSION

In this pilot study, we examined the effectiveness of realtime CO_2 sensing stylet assisted intubation with 34 swines. CO_2 concentration was significantly increased when the tip of the stylet was located at the glottis or inside the trachea, compared to when it was located away from the glottis. ETI with the real-time CO_2 sensing stylet showed a trend for decreased total procedure time, intubation failure rate, and total number of attempts compared with conventional intubation. Also, first attempt success rate was likely to be improved. Although we were not able to detect statistically significant differences between the two groups, we found that real-time CO_2 sensing stylet assisted intubation may improve the intubation process.

Visualizing the glottis is difficult for health care providers who have little experience such as training residents or paramedics who rarely encounter patients with respiratory failure [21], [22]. Also, visualizing the glottis in patients with difficult airways, such as those who are obese, critically ill, or with vomitus, may be challenging with conventional intubation techniques [23], [24], [25]. Alarming the operator when the CO_2 level increased above 1000 ppm probably helped the operator to recognize that the location and direction of the endotracheal tube were proper when the tip of the stylet approached the glottis. This can be especially more helpful in the cases which the operator cannot confirm the location of glottis with the naked eye.

Real-time CO₂ stylet assisted intubation also allowed early confirmation of the location of the endotracheal tube. Confirmation of successful ETI by checking the waveform capnography can be performed after inserting the endotracheal tube, inflating the tube cuff, attaching the CO₂ cuvette, and connecting the devices to the mechanical ventilator. Due to the multiple steps that are required for the capnography waveform to be shown, detection of esophageal intubation could be delayed. Prolonged esophageal intubation can lead to hypoxemia, hypoxemia-driven bradycardia, and aspiration [26]. Also, there is a lower risk of stomach distension due to ventilation in esophageal intubations. Inappropriate intubation can be confirmed right after inserting the endotracheal tube with real-time CO₂ guided intubation. In our study, there were some cases in the intervention group in which the endotracheal tube was inserted but the CO₂ level did not rise. In these cases, the operator immediately corrected the location of the endotracheal tube even before removing the laryngoscope blade and connecting the tube to the ventilator. Due to early confirmation of the endotracheal tube location, the operator was able to withdraw the tube and try the procedure again without causing desaturation of the swine. These cases contributed to the increased trend in first attempt success rate in the intervention group because an intubation attempt was defined as a single maneuver beginning with the insertion of a laryngoscope and ending when the laryngoscope was removed.

Another strength of the device is that it may become a more effective method when it is used in adjunct with other techniques that are used for difficult airways. Blind intubation techniques such as the use of a gum-elastic bougie or angulated stylets may become easier to perform with guidance by CO_2 level [27], [28]. Also, when the view from the video laryngoscope is occluded by blood or vomitus inside the patient's oral cavity, our study's method may be an alternative TABLE 2. Procedure result according to each operator.

	Total	Case	Control
Operator 1			
Total procedure time (s), mean (SD)	78.9 (57.9)	61.0 (14.9)	96.8 (80.8)
First attempt success, N (%)	7 (70.0)	4 (80.0)	3 (60.0)
Operator 2			
Total procedure time (s), mean (SD)	95.8 (67.5)	66.8 (45.5)	124.7 (77.0)
First attempt success, N (%)	8 (66.7)	5 (83.3)	3 (50.0)
Operator 3			
Total procedure time (s), mean (SD)	53.8 (32.6)	51.7 (38.0)	56.0 (29.6)
First attempt success, N (%)	6 (50.0)	3 (50.0)	3 (50.0)

Case, real-time CO_2 sensing stylet assisted intubation group; Control, conventional intubation group; SD, standard deviation.

TABLE 3. Procedure result for the first and the second half.

	Total	Case	Control
The First Half (N=18)			
Total procedure time (s), mean (SD)	69.1 (50.3)	57.8 (35.7)	80.4 (61.7)
First attempt success, N (%)	11 (61.1)	6 (66.7)	5 (55.6)
The Second Half			
(N=16)			
Total procedure time (s), mean (SD)	83.8 (62.0)	62.0 (35.7)	105.5 (76.8)
First attempt success, N (%)	10 (62.5)	6 (75.0)	4 (50.0)

Case, real-time CO_2 sensing stylet assisted intubation group; Control, conventional intubation group; SD, standard deviation.

technique. Whether or not the real-time CO_2 sensing stylet assisted intubation is effective in these difficult airway situations should be tested in future study.

Our study has several limitations that must be considered. First, we used swine to test our intubation method in this study. Intubation in swine is not exactly same with clinical procedure. Although we assigned the operators who are not expert of preclinic experiment to simulate the difficult airway, clinical studies must be performed before the real-time CO₂ sensing stylet assisted intubation is applied at the scene. Second, the operators who performed intubation in this study were not blinded to the study groups. However, performance bias is applied to most of the studies that test new devices for intubation because blinding of the device cannot be easily done. Also, the operators were asked to perform the procedure to the best of their ability. We tried to minimize the entry of performance bias and observer bias by video recording the whole intubation procedures and analyzing the study outcomes with the videos. Third, although we observed a trend of study outcome results, we were not able to present statistically significant differences between the study groups. This is probably due to the power calculation based on the study with a very large difference with new technology. Considering the results, the effect of the device would be clarified by experiment with less skilled operators and larger sample size. Fourth, the widely adopted video-assisted intubation were



not compared in this experiment. Also, further studies under difficult airway access condition would clarify the strength of device. Fifth, in this study, the distance of the stylet from glottis was not confirmed when the CO_2 concentration increased over the threshold. Last, when the device is obstructed with a foreign object such as vomiting, the pump not able to inhale air and, CO_2 cannot be measured. It can be mistaken for esophageal intubation even ETI was performed correctly in this situation.

V. CONCLUSION

We found that ETI using a self-manufactured real-time CO_2 sensing stylet has potential to reduce the time to intubation success and improve first attempt success rate. Further simulation studies and clinical trials, aiming to transfer the results to the clinical field, are required.

APPENDIX I

See Table 2.

APPENDIX II

See Table 3.

ACKNOWLEDGMENT

There is nothing to declare.

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