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Learning curve of fiberoptic-guided tracheal intubation through supraglottic airway device for pediatric airway management: a manikin study

Sang-Hwan Ji, M.D, Ph.D. [1]; Sung-Ae Cho, M.D., M.S.[2]; Young-Eun Jang, M.D., Ph.D. [1]; Eun-Hee Kim, M.D., Ph.D. [1]; Jin-Tae Kim, M.D., Ph.D. [1];

Hee-Soo Kim, M.D., Ph.D. [1]; and Ji-Hyun Lee, M.D., Ph.D. [1]

[1]Department of Anesthesiology and Pain Medicine, Seoul National University Hospital, Seoul National University College of Medicine, Seoul, Republic of Korea

[2]Department of Anesthesiology and Pain Medicine, Konyang University Hospital, Daejeon, Republic of Korea

Running title: Training FOB-guided intubation with SAD

Corresponding author: Professor Ji-Hyun Lee, M.D., Ph.D.

Department of Anesthesiology and Pain Medicine, Seoul National University College of Medicine and Hospital, 101 Daehak-ro, Jongno-gu, Seoul, 03080, Korea

Phone: +82-2-2072-3661, E-mail: muslab6@snu.ac.kr

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Learning curve of fiberoptic-guided tracheal intubation through supraglottic airway device for pediatric airway management: a manikin study

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Abstract

Background: Although fiberoptic-guided endotracheal intubation using a supraglottic airway device is a good alternative for the management of difficult airways, its learning curve for residents has not been evaluated in pediatric patients. We aimed to train residents using a pediatric manikin and obtain learning curves for the procedure to evaluate the efficiency of the training.

Methods: We conducted a single-armed prospective study with anesthesiology residents. Plain endotracheal tube intubation guided by a fiberoptic bronchoscope through Ambu® AuraGain™ was demonstrated in a pediatric manikin to the participants before training. The procedure was divided into four steps: supraglottic airway device insertion, vocal cord identification, carina identification, and endotracheal tube insertion into the trachea. The results and elapsed procedure times of each trial were recorded. The learning curves for the participants were constructed and analyzed using the cumulative sum method.

Results: All of the 30 participants acquired proficiency at the end of the practice between eight and 25 trials. The overall success rate for the procedure was 92.8%, and above 80% for all participants. Mean (±SD) procedure time was 71.3 (±50.7) s. The 4th step accounted for 86.2% of total failures and 48.0% of the total procedure time. The procedure time rapidly decreased in the 2nd trial, and a modest decline was observed thereafter.

Conclusions: Anesthesiology residents obtained proficiency within 25 times of practice for fiberoptic-guided intubation in a pediatric manikin through an AuraGain supraglottic airway device with acceptable success rate and procedure time. The procedure time markedly decreased following the first experience.

Keywords: airway management; laryngeal masks; intubation, intratracheal; bronchoscopy; child; learning curve.

Introduction

Airway management in children is often difficult owing to their unique anatomical and physiological features. The safe apnea time of children to maintain appropriate oxygen saturation is shorter than that of adults, and desaturation with bradycardia frequently occurs especially in children with difficult airways. Therefore, various techniques have been introduced to extend the time available for airway management and successful intubation in children with expected or unexpected difficult airway [1]. Freehand fiberoptic intubation, fiberoptic-guided intubation through a supraglottic airway device (SAD), or intubation using a videolaryngoscope are recommended techniques for difficult pediatric airway management [2]. However, although equipment available for difficult airway management is increasing, their utilization without sufficient training and skills in emergent airway management conditions is challenging.

The SAD is a useful device for securing the airway compared to endotracheal intubation [3], and can be used as an intubation conduit [4]. Fiberoptic-guided intubation via an SAD has the advantage of availability for ventilation and continuous oxygenation during the procedure [1,5]. In addition, this technique demonstrated a higher success rate and lower incidence of hypoxia compared to indirect intubation using a videolaryngoscope in infants with difficult airways [6]. Therefore, this technique can maximize the safety of children and the success rate of intubation in children with both expected and unexpected difficult airways, who are prone to hypoxia and subsequent bradycardia during apnea [1,5]. Therefore, resident training of fiberoptic-guided intubation via an SAD is necessary for safe airway management during pediatric anesthesia. Since trainees usually rotate several subspecialties of anesthesia during residency and spend only limited time in the pediatric anesthesia department, it is difficult to provide sufficient training for this technique.

The cumulative sum test, which allows monitoring the individual medical performance during the learning process by determining when a predefined acceptable level of performance is

reached, has been used in various studies on learning of certain procedures [7-10]. Limited information exists on the amount of training required for several advanced airway techniques, including fiberoptic-guided intubation through an SAD in pediatric patients.

We hypothesized that anesthesiology residents would be able to gain proficiency for fiberoptic-guided intubation via an SAD to a pediatric manikin after repeated trials, and planned a prospective study. Our primary aim was obtaining learning curves of individual residents for the procedure, and our secondary aim was analyzing the success rates and procedure times as trials accumulate.

Materials and Methods

Study design and population

This study was designed as a single-armed, prospective study. The study protocol was approved by the Institutional Review Board of the institution (approval date: 20/07/2020). This study was registered prior to participant enrolment at http://clinicaltrials.gov (publication date: 21/07/2020). Candidates were recruited from August 2020 to July 2021. We followed the recommendations from the Standards for quality improvement reporting excellence in education publication guidelines for educational improvement (SQUIRE-EDU) [11].

Medical doctors under residency training in anesthesiology and pain medicine from a single tertiary hospital in Seoul, Korea were asked to participate and enrolled in the study after obtaining an informed consent. Inclusion criteria were 30 or more pediatric SAD insertion experiences and 30 or more FOB manipulations. Exclusion criteria were prior experience with fiberoptic-guided tracheal intubation through an SAD to patients or manikin and refusal to participate in the study.

Training materials

A manikin designed for pediatric intubation training (Pediatric Intub Trainer Torso 255-00001, Laerdal Medical Korea LLC, Seoul, Korea) was prepared. When visualized using a direct laryngoscope with curved blade #2, the Cormack-Lehane grade was II. An SAD of AuraGain™ #2 (Ambu®, Ballerup, Denmark), a cuffless endotracheal tube (ETT) with an inner diameter of 5.0 mm (Shiley™ oral/nasal endotracheal tube, Medtronic Korea Co., Ltd., Seoul, Korea), and a fiberoptic bronchoscope (FOB) with a diameter of 3.8 mm (LF-GP, Olympus Korea, Seoul, Korea) were used. AuraGain was chosen owing to its frequent use and high success rate as an intubation conduit [12,13]. The glottis of the manikin seen from a direct laryngoscope or an FOB are shown in Figure 1. Upon visualization from the point approximately 1 cm proximal to the distal orifice of the SAD, the vocal

cords of the manikin could be observed with appropriate positioning of the SAD, which has a score 4 as previously recommended by Brimacombe [14]. However, anterior flexion of the bronchoscope was necessary.

Training protocol

Each 'trial' consisted of four steps, which are described in detail in Table 1. Before beginning the experiment, two investigators explained the entire procedure with a demonstration, followed by a discussion with question and answer session. Subsequently, the participant started a series of trials for the procedure. During the experiment, no real-time feedback was provided for self-reflection. A minimum of 8 trials were performed by each participant; further details are provided in the 'cumulative sum analysis' section.

At the end of the training, the participants reported self-assessment for understanding and confidence in proficiency before and after the training using a 10-point numeric scale. Moreover, the overall satisfaction with the training was surveyed using a 10-point numeric scale.

Procedure evaluation

For each step, every repositioning, withdrawal, or advancement maneuver of any device owing to difficulty in advancement or poor vision were counted as 'attempt'. For each trial, the number of 'attempts' for each step, procedure times for each step, and overall procedure time were recorded. If the number of 'attempts' for any step exceeded 5, failure for the trial was declared, and the next trial was commenced from the beginning [15]. If the participant succeeded in every step of the trial, the trial was declared successful. For failed trials, the procedure time was recorded until the end of the 5^{th} attempt of the failed step.

Cumulative sum analysis

We set our primary outcome as learning curve of each participant and employed the cumulative sum analysis to build them [9]. In adults, the success rate of fiberoptic-guided intubation via an SAD is reported to be above 90% [12,16,17]. In children, the success rate for vocal cord identification via a bronchoscope through an SAD is approximately 80% [18,19]. Considering that our participants did not possess any prior experience, we set the acceptable failure rate as 20% and unacceptable failure rate as 40%, which is twice the acceptable rate. Both the alpha and beta error rate were set as 0.1, in the conventional method [20]. With these assumptions, the parameters for the cumulative sum analysis were calculated as shown in Table 2. Three values of h_0, h_1, and s were used for plotting the learning curve for each participant. The cumulative sum score started from zero at the beginning, which decreased by s for each success and increased by $1-s$ for each failure in the trials. When the sum reached h_0, which is the lower boundary limit, the acquisition of proficiency was declared. However, when the sum reached h_1, which is the upper boundary limit, a failure in acquiring proficiency was declared. We did not limit the number of trials or total training time, and the training was completed when the cumulative sum score of the participant reached either h_0 or h_1. Additional trials up to the 15th trial were allowed if the participant wanted to continue with the practice even after acquiring proficiency. As eight consecutive successes without failure were the minimum required number of trials, each participant performed at least eight trials.

Sample size calculation

We referred to previous similar studies on training of residents, which enrolled approximately 15 participants [10,15]. Considering our institution's eligibility, we planned to enroll 30 participants.

Statistical analysis

Changes in the procedure times for each step according to number of trials were analyzed using a linear mixed-effects model with the number of trials as a fixed effect and participant as a random effect to account for the correlation between the multiple measurements within a participant. The procedure times were log-transformed owing to the skewed distributions with large values to improve normality. The relationship between the trial numbers and log-transformed procedure times were analyzed assuming a linear or piecewise linear effect, which assumed a combination of intervals with linear slopes. The points of the slope change were determined as the points at which the linear mixed-effects model had the lowest Akaike and Bayesian information criteria. The model with a single point of slope change was selected for each of the four steps and the total time. As the times were log-transformed, the ratio of the cumulative geometric means was obtained for each increment in the trial number. Procedure times for failed trials were also included in the regression, since the procedure time reflects the apnea time of patients in actual clinical settings regardless of success or failure. Self-assessment of proficiency before and after the training was compared using the Wilcoxon signed-rank test. For comparison of the means, student *t*-test or paired *t*-test was used for the parametric data and Mann-Whitney U test for the nonparametric data. Normality tests for variables were performed using the Kolmogorov-Smirnov test for data of less than 30 participants and Shapiro-Wilk test for data with more than 30 participant. Statistical analyses were performed using SPSS® version 22 (IBM®, Chicago, IL, USA) and SAS version 9.4 (SAS Institute, Cary, NC, USA).

Results

A total of 30 trainees were enrolled; no one dropped out from the study. The mean (±SD) duration of anesthesiology training of the participants before the practice was 28.0 (±11.3) months. Twelve (40%) of them were males, 18 (60%) were females. Overall, the participants performed 404 trials of the procedure, recording 375 (92.8%) successful trials. At the end of the practice, all the participants succeeded in acquiring proficiency. The median [interquartile range] number of trials required to acquire proficiency was 8 [8–12]. One participant crossed h_1 in the cumulative sum analysis but eventually succeeded in crossing h_0. Figure 2 shows the cumulative sum lines of the participants for the procedure. Figure 3 shows the cumulative success rate of participants as the number of trials increased.

Among the 29 failed trials, 25 (86.2%) were due to failure in step 4, while only 4 (13.8%) were in step 3 and none in step 1 or 2. After the end of practice, all the participants recorded a failure rate of 20% or lower, which was regarded as satisfactory. A summary of the individual results is presented in Table 3.

The mean (±SD) procedure time for each trial was 71.3 (±50.7) s overall; successful trials showed a significantly shorter time compared to failed trials (median values 52.0 s vs. 185.8 s; $P < 0.001$). Significant differences in the procedure time between successful and failed trials were also seen in step 3 (median values 13.4 s vs. 122.2 s; $P = 0.001$) and step 4 (median values 17.0 s vs. 130.8 s; $P < 0.001$). The mean procedure time for step 4 (34.2 s) accounted for 48.0% of the mean total elapsed time (71.3 s).

As the trials were repeated, the procedure time gradually decreased for every step. Trends in elapsed times for each step and total were fit into the piecewise linear effect model, which indicates there were two phases of rapid decrease and slow decrease in the procedure times. A total of 1,851 measurements from 371 trials were included in the regression models. Data from the 16th or later

trials were excluded from the piecewise linear mixed-effects model since the data were from only four trainees who failed three or more times until the 15th trial. The slope of the decrease between the 1st and 2nd trial was 32.2% [95% CI, 21.2–41.7%; $P < 0.001$], while it was 4.6% [95% CI, 3.5–5.6 %; $P < 0.001$] between the 2nd and 15th trial. For the individual steps, the decrease in the procedure times slowed down following the 5th trial for steps 1 and 3, after the 2nd trial for steps 2 and 4. The detailed data for each step are shown in Table 4. Figure 4 shows a scatter plot of the total procedure times against the trial numbers.

For steps 1 to 3, the success rates of the first attempt were 99.5%, 97.3%, and 91.6%, respectively. However, only 63.8% trials were successful in step 4 in the first attempt. The distribution of the number of attempts for each step are listed in Table 5.

The median [interquartile range] of the self-assessment scores before and after the practice on a 10-point numeric scale were 2 [2–5] and 8 [7.5–9], respectively, with a statistically significant increase following practice ($P < 0.001$). The median [interquartile range] satisfaction score of participants on a 10-point numeric scale was 10 [9.5 – 10].

Discussion

This is the first study to evaluate the learning curve of fiberoptic-guided intubation using an SAD in a pediatric manikin. The cumulative sum test is a simple method for the evaluation of learning a procedure and easily provides the number of trials required to obtain proficiency for a specific procedure after serial monitoring of the procedures, with given acceptable and unacceptable failure rates [7,9]. By this method, we observed that all the participating residents became proficient in fiberoptic-guided intubation via an AuraGain SAD using a pediatric manikin in 25 trials.

The use of SADs has been emphasized in both expected and unexpected difficult mask ventilation and intubation, and allows continuous oxygenation and ventilation while serving as a conduit during fiberoptic-guided intubation [21]. Fiberoptic-guided intubation via an SAD is particularly beneficial, especially in children with specific anomalies, such as Pierre Robin Sequence or Treacher–Collins syndrome, since the SAD can overcome anatomic airway obstruction and optimize the laryngeal view using an FOB [6]. The success rate of this technique has been known to be similar to videolaryngoscopy in children with difficult airways [6]. However, the first attempt had a success rate of approximately 50–60% [6], indicating the need for sufficient practice prior to clinical application. None of the candidates who were eligible for screening had experienced fiberoptic-guided intubation via an SAD during their residency. The strength of our study is that we present the achievement of proficiency in a reasonable number of trials for this procedure, without waiting until a challenging case actually occurs.

During the experiment, the time taken for the procedure demonstrated a decreasing trend as the trials were repeated. The decline in the procedure time became slower following the 5th trial for Steps 1 and 3, after the 2nd trial for Steps 2 and 4, and overall. These findings indicate that there was a significant improvement in the procedure time following the number of experiences for each step. In the first trial of step 2, some participants spent a long time visualizing the vocal cords since the

bronchoscope needed to be anteriorly flexed. After learning this in the first experience, the participants easily identified the vocal cords from the second trial onward; thus, a marked decrease in the procedure time for step 2 in the 2nd trial was recorded. The slow decline in the procedure time for step 3 following the 5th trial implies that advancement of the bronchoscope into the trachea required approximately 5 times of experience to gain dexterity.

In addition, the participants struggled for a long time in step 4 and showed the highest failure rate. The ETT did not easily pass the glottis over the bronchoscope owing to collision with the arytenoid cartilages or the posterior wall of the glottis [22]. Turning the bevel to face the ground is reported to facilitate advancing the ETT over the bronchoscope by minimizing impingement and reducing the gap between the ETT and the bronchoscope [22]. However, the participants achieved a significant improvement in time at the second trial. As the participants were instructed to rotate the ETT to adjust the direction of the bevel during practice when the resistance was felt, we speculated that most of them achieved self-reflection following the first trial. There are some known strategies to facilitate advancing the ETT over the bronchoscope, such as using a smaller-sized ETT or a Parker Flex-Tip™ tube [23] to reduce the gap between the bronchoscope and the ETT, or using a reinforced tube that can change its direction easily [24]. However, we did not change the size or type of the ETT for the purpose of training and maintaining consistency of the data.

Consequently, the overall success rate of fiberoptic-guided intubation via AuraGain was 92.8% in our study, which was similar to previous results in adults [12,16,17] and pediatric patients [13]. In pediatric data, the success rate of intubation via AuraGain was reported to be 100%, but the proficiency of the practitioner was not specified [13]. As shown in figure 3, cumulative success rate of participants rapidly raised from the 2nd trial, and exceeded 90% in the 5th trial. Considering the cumulative rate included failures in earlier trials in which the participants were not accustomed to the procedure, our success rate is satisfactory. In addition, the mean procedure time of 71.3 s in our study

was shorter than 96 s from previous pediatric data. As children have low oxygen reservoirs, reducing the procedure time is as important as increasing the success rate in clinical situations. Although we cannot directly compare the results from manikin with those from real patients, our results are satisfactory, and we believe our residents would reduce the time of intubation via SADs in real clinical situations.

Our study has certain limitations. First, as the practice was on a single manikin rather than patients, we cannot ensure the same level of proficiency of the procedure for patients in clinical settings. Further studies on practice with actual patients are required. Second, in many situations, this procedure is actually completed by removing the SAD, while keeping the endotracheal tube in situ. In the instruction step before the practice, removing the SAD was also demonstrated with explanation. Since the decision to remove the SAD or not varies based on clinical situations, we did not plan to evaluate procedure time or success rate for that step in our study. However, as removal of SAD is actually done in many circumstances, including that step would have been reflected the procedure time in reality. Third, we did not record or strictly control the direction of the bevel for each attempt in step 4, except for the instruction before the start of the practice. Fourth, it would have been more instructive to have performed this study in a smaller manikin with a smaller FOB, as younger children may have more chance of difficult airway and suffer more complications related ventilation. And finally, the study using other types of SAD such as air-Q laryngeal airway is necessary, as it may affect the success rate and the number of trials to achieve competency in residents.

In conclusion, anesthesiology residents obtained proficiency within 25 times of practice for fiberoptic-guided intubation to pediatric manikins through an AuraGain SAD with an acceptable success rate and procedure time. The procedure time markedly decreased following the first experience, indicating that this airway management skill is a relatively simple technique without a high entry barrier. Further studies should focus on the effect of dummy training in improving the

success rate in actual clinical situations and the learning curve of fiberoptic-guided intubation via an SAD in children with difficult airways.

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Table 1. Stepwise discrimination of the fiberoptic-guided endotracheal intubation through Ambu® AuraGain™ supraglottic airway device to a pediatric manikin.

Step 1. The supraglottic airway device was inserted into the manikin, and chest rise was confirmed following ventilation with a self-inflating bag.
Step 2. The ETT-assembled bronchoscope was passed through the supraglottic airway device and the vocal cord of the manikin was identified. The position of the supraglottic airway device should be adjusted if necessary.
Step 3. The bronchoscope was advanced through the vocal cord and the carina of the manikin was visualized.
Step 4. The ETT was slid over the bronchoscope and advanced through the trachea. Intubation success was confirmed upon bronchoscope withdrawal and ETT visualization.

ETT; endotracheal tube

Table 2. Calculation of variables in the cumulative sum method

Variables	Description	Formula	Value in this study
	Assumed variables		
α	The risk of a type 1 error		0.1
β	The risk of a type 2 error		0.1
p_0	The acceptable failure rate		0.2
p_1	The unacceptable failure rate		0.4
	Parameters for calculation		
a		$a = ln\ [(1-\beta)/\alpha]$	2.197
b		$b = ln\ [(1-\alpha)/\beta]$	2.197
P		$P = ln\ (p_1/p_0)$	0.693
Q		$Q = ln\ [(1 - p_0)/(1 - p_1)]$	0.288
	Calculated constants for cusum score		
s	The amount of subtraction of the cumulative sum score after each success	$s = Q / (P + Q)$	0.293
1-s	The amount of increase of the cumulative sum score after each failure	1-s	0.707
h_0	The lower boundary limit of the cumulative sum score	$h_0 = -b / (P + Q)$	−2.240
h_1	The upper boundary limit of the cumulative sum score	$h_1 = a / (P + Q)$	2.240

Table 3. Summary of individual results of practice

Number of trials	15 [8 – 15] (8 – 25)
Number of successful trials	14 [8 – 15] (8 – 20)
Number of failed trials	0 [0 – 1] (0 – 5)
Success rate (%)	100 [91.7 – 100] (80 – 100)
Required number of trials for acquirement of proficiency (*n* = 30)	
8	17 (56.7%)
12	8 (26.7%)
15	1 (3.3%)
18	1 (3.3%)
25	3 (10%)
Reason of failure (*n* = 29)	
Failed passing the ETT through the glottis	23 (79.3%)
Failed passing the bronchoscope through the glottis	4 (13.8%)
Dislocation of supraglottic airway device during step 4	1 (3.4%)
Dislocation of bronchoscope during step 4	1 (3.4%)
Procedure time (s)	
Step 1 (*n* = 404)	8.2 [6.7 – 10.0]
Step 2 (*n* = 404)	12.8 [10.5 – 16.3]
Step 3 (*n* = 404)	10.5 [7.3 – 15.4]
Step 4 (*n* = 400)	17.6 [12.0 – 34.5]
Overall (*n* = 404)	54.0 [41.6 – 80.4]

Data are shown in number (%) or median [interquartile range] (range). ETT; Endotracheal tube

Table 4. Changes in procedure times for each step and total practice

	Interval	Geometric mean ratio*	Decrement rate for each trial (%)	*P*-value
Step 1	Between 1st – 5th trial	0.94 (0.92 – 0.96)	6.4 (4.4 – 8.3)	< 0.001
	Between 5th – 15th trial	0.98 (0.98 – 0.99)	1.6 (0.7 – 2.5)	< 0.001
Step 2	Between 1st – 2nd trial	0.62 (0.55 – 0.70)	38.1 (30.4 – 44.9)	< 0.001
	Between 2nd – 15th trial	0.97 (0.96 – 0.98)	2.8 (2.0 – 3.6)	< 0.001
Step 3	Between 1st – 5th trial	0.83 (0.79 – 0.87)	17.1 (12.9 – 21.0)	< 0.001
	Between 5th – 15th trial	0.98 (0.96 – 1.00)	2.0 (0.0 – 4.1)	0.053
Step 4	Between 1st – 2nd trial	0.69 (0.53 – 0.89)	31.4 (11.1 – 47.0)	0.005
	Between 2nd – 15th trial	0.94 (0.92 – 0.96)	6.1 (4.3 – 7.8)	< 0.001
Total time	Between 1st – 2nd trial	0.68 (0.58 – 0.79)	32.2 (21.2 – 41.7)	< 0.001
	Between 2nd – 15th trial	0.95 (0.94 – 0.96)	4.6 (3.5 – 5.6)	< 0.001

*Geometric mean ratio is calculated as (geometric mean of the $(i+1)^{th}$ trial) / (geometric mean of the i^{th} trial), while geometric mean of (y_1, y_2, y_3, ⋯, y_n) is calculated as $\sqrt[n]{y_1 \cdot y_2 \cdot y_3 \cdots y_n}$. Data are shown in estimate (95% CI).

Table 5. Number of attempts for each step.

	Number of attempts for each step					
	1	2	3	4	5	Failed
Step 1 (*n* = 404)	402 (99.5%)	2 (0.5%)	0	0	0	0
Step 2 (*n* = 404)	393 (97.3%)	9 (2.2%)	2 (0.5%)	0	0	0
Step 3 (*n* = 404)	370 (91.6%)	18 (4.5%)	9 (2.2%)	2 (0.5%)	1 (0.2%)	4 (1.0%)
Step 4 (*n* = 400)	263 (65.8%)	50 (12.5%)	34 (8.5%)	18 (4.5%)	10 (2.5%)	25 (6.3%)

Data are shown in number (%). No failures were recorded in step 1 and 2.

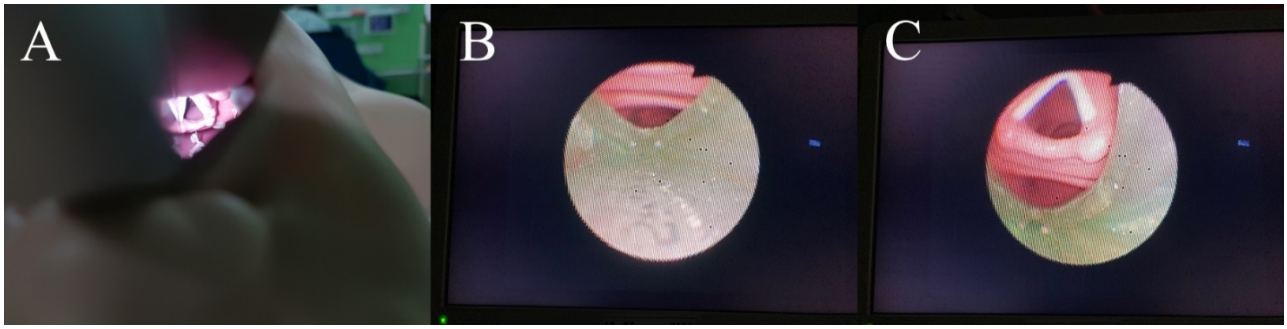

Figure 1. Visualization of the glottis of the manikin used in the training. Visualized by direct laryngoscopy (A), fiberoptic bronchoscope in neutral position (B), fiberoptic bronchoscope anteriorly flexed (C).

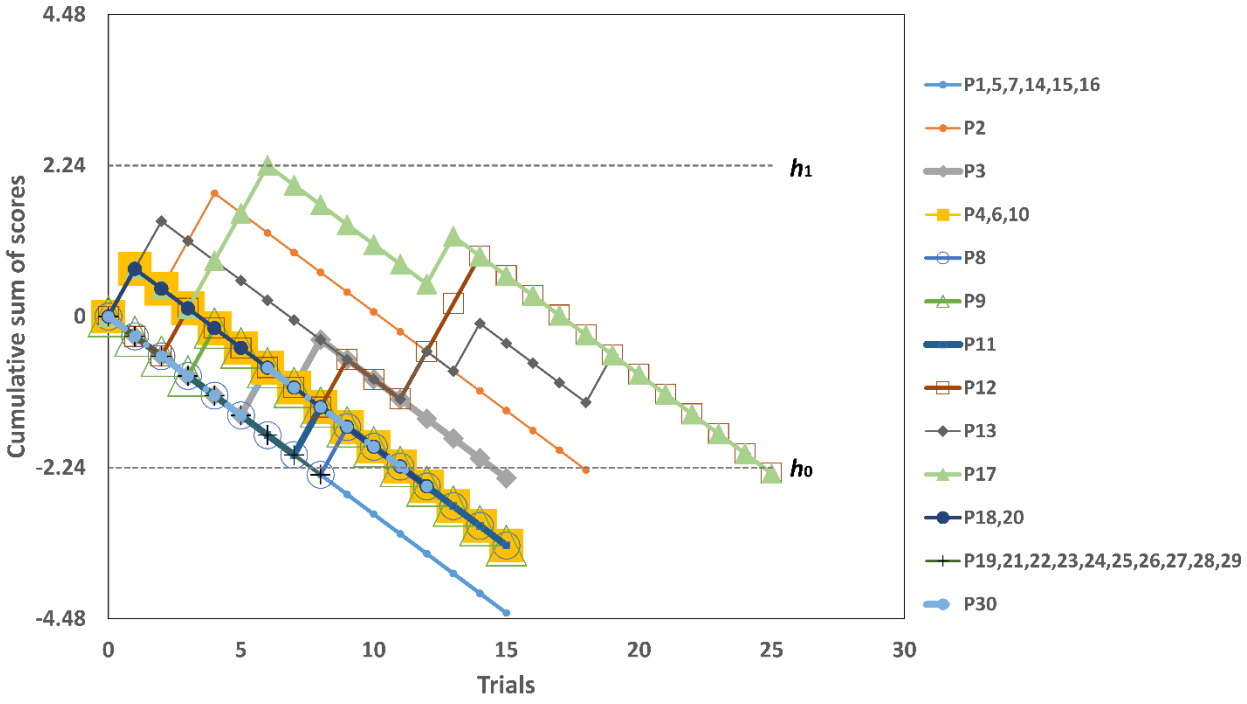

Figure 2. Cumulative sum lines of the participants for the practice. Lines h_1 and h_0 represent the upper and lower boundary limits, respectively. When the line of an individual crosses h_0, we can declare that the individual gained proficiency. At the end of the practice, all the participants succeeded in acquiring proficiency within 25 times of trial.

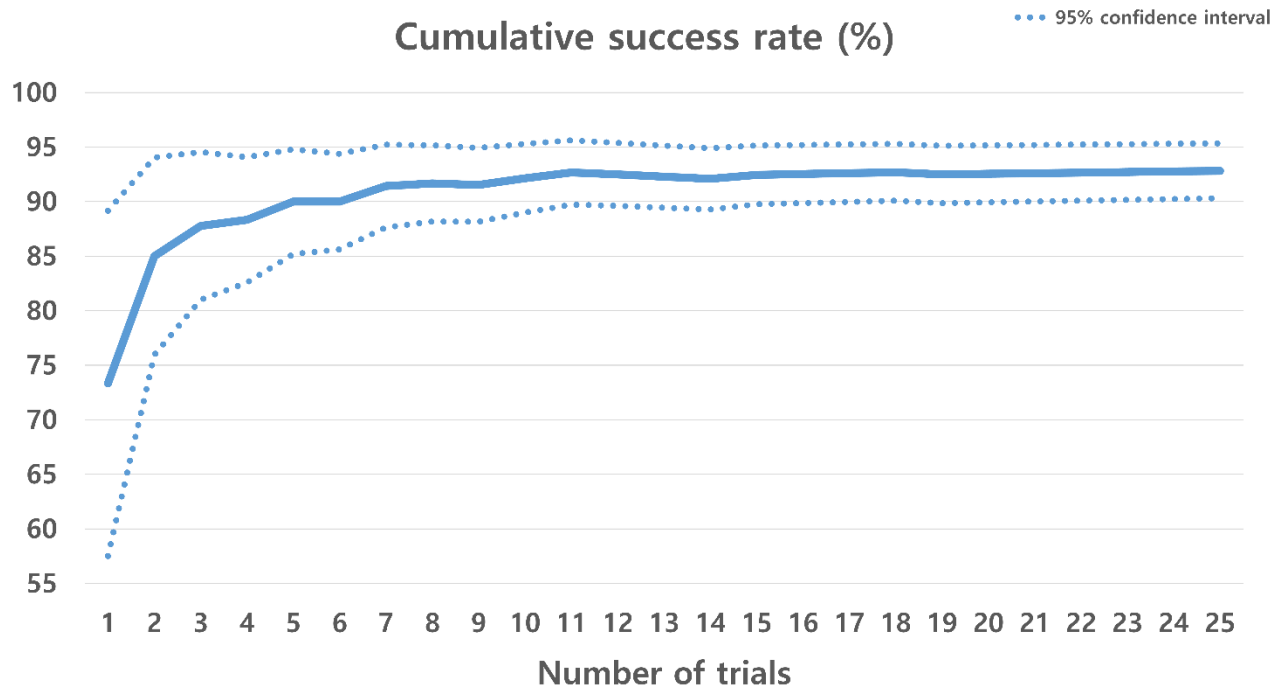

Figure 3. Cumulative success rate of the participants according to the number of trials.

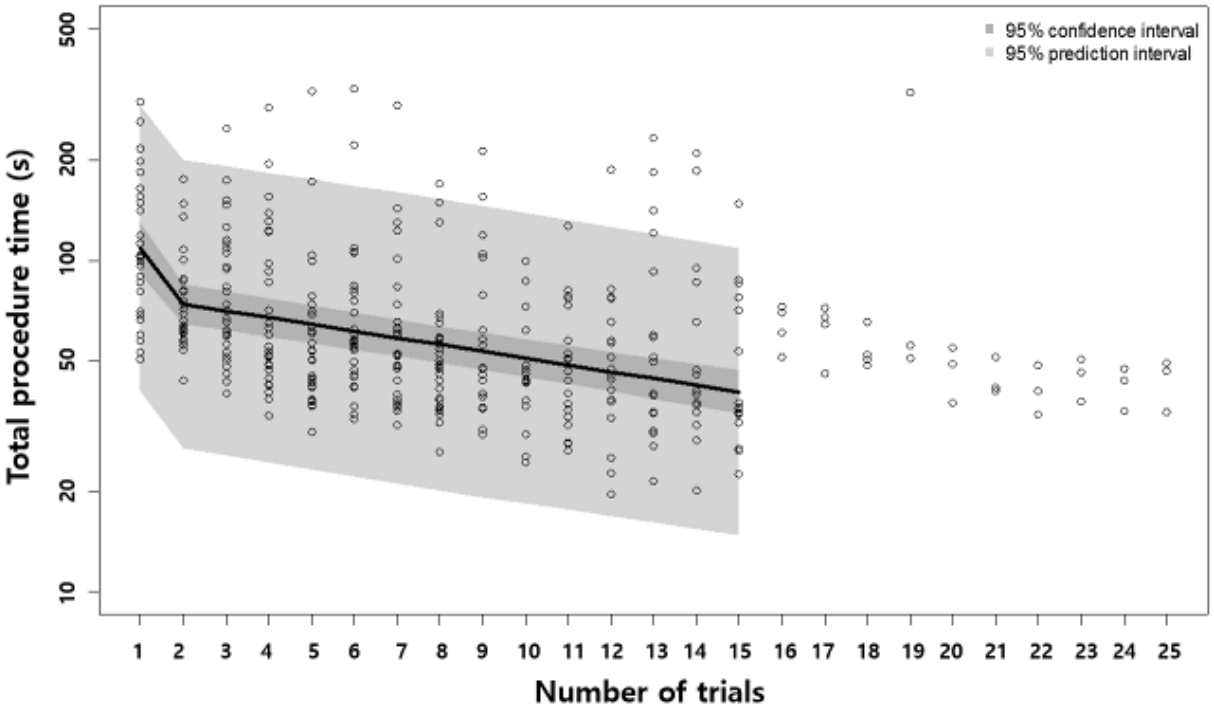

Figure 4. Scatter plots with regression lines of the total procedure time. The points of slope change are at trial 2. Lines for the 95% CI in the 95% prediction interval were not drawn from the 15th trial since the piecewise linear mixed-effects modelling was performed only until the 15th trial.