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Transcatheter ventilation with a modified Rapid-O2 oxygen insufflation device

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Background: The Rapid-O2 oxygen insufflation device® (Rapid-O2) was designed primarily for rescue oxygenation in cannot intubate, cannot oxygenate (CICO) events; thus, hypercapnia is inevitable. Rapid-O2 was modified to enhance ventilation using the Venturi effect during expiration.

Methods: To determine the most effective combination of inner catheters (20 gauge [G], 18 G, 16 G, 14 G, and 2-mm inner diameter [ID] transtracheal catheter [TTC]) and insufflation catheters (16 G, 14 G, and 2-mm ID TTC) for achieving optimum ventilation, insufflating and expiratory flows were measured at an oxygen flow rate of 15 L/min. The insufflating and expiratory pressures were measured at 6–15 L/min. The flows and pressures were measured using a gas flow analyzer. The insufflating and expiratory times were measured using a trachea-lung model to obtain minute volumes. To assess the improvement by modifying the Rapid-O2, minute volumes were measured using the Rapid-O2.

Results: The most appropriate inner catheter was 18 G. The insufflating pressures ranged from 97 (2-mm ID TTC) to 377 cmH_2O (16 G) at 15 L/min. During expiration, similar negative pressures of 50 cmH_2O were measured in the insufflation catheters at 15 L/min. At lung compliance of 100 ml/cmH_2O, the minute volumes through a 2-mm ID and 14 G insufflation catheters were 7.0 and 5.37 L/min, respectively, at 15 L/min. The minute volumes were significantly greater in modified Rapid-O2.

Conclusions: Modified Rapid-O2 provided sufficient minute volumes in adults using a 14 G or 2-mm ID insufflation catheter at 15 L/min, demonstrating its potential for ventilation in CICO events.

Keywords: Airway management; Airway obstruction; Hypercapnia; Respiration, artificial; Ventilation; Ventilators, negative pressure.

Introduction

The Rapid-O2 oxygen insufflation device™ (Rapid-O2, Meditech Systems Ltd.) is a rescue oxygenation device for use in "cannot intubate, cannot oxygenate" (CICO) events or near-total airway obstruction; it consists of a T-connector with extension tubing [1,2] (Supplementary Fig. 1). Rapid-O2 can be used as a rescue and temporary maneuver to oxygenate the patient while a more secure and permanent airway is being established at the earliest opportunity.

Extrapolating data from *in vivo* animal studies to humans, Heard [3] demonstrated that 1,000 ml of oxygen was needed for an adult patient's initial rescue that is equivalent to 4 s of insufflation at an oxygen flow rate of 15 L/min. An additional 500 ml of oxygen was considered adequate once the arterial oxygen saturation (SpO_2) has decreased to 93% after the initial oxygen supply. Percutaneously, a 14 G catheter was used [2,4]. Using this

strategy, Wexler et al. [2] applied transtracheal oxygenation using Rapid-O2 as a bridge to safe transtracheal jet ventilation in a patient with a large tongue base cancer that caused near-total airway occlusion. When the SpO_2 decreased to 93%, reinsufflation was performed repeatedly for 60 min until safe conversion to transtracheal jet ventilation was achieved. At the end of the 60-min period, the peak $ETCO_2$ was 115 mmHg. Although this case demonstrated the practical utility of Rapid-O2 for rescue oxygenation, it also showed that adequate ventilation was not achieved.

To improve ventilation, the Rapid-O2 was modified to generate high-velocity gas flow and create subatmospheric pressure via the Venturi effect through a small-bore catheter during expiration. This study aimed to assess the ventilation potential of the modified Rapid-O2 in a simulated total airway occlusion. The insufflating and expiratory gas flows were measured to determine the most effective size combination of inner (negative pressure-inducing) and insufflation catheters to achieve optimum ventilation. Second, to define the oxygen flow rate that provides the maximum driving pressure and the correlation between the oxygen flow rate and insufflating or expiratory pressure for optimum ventilation, the pressures were measured during insufflation, expiration, and oxygen cut-off modes. Finally, the insufflating and expiratory times were measured using a trachea-lung model to determine the minute volumes and inspiration:expiration (I:E) ratios.

Materials and Methods

Development of modified Rapid-O2

The modified Rapid-O2 consists of a reversed T-connector (a Washington T-connector [salvaged from a Jackson Rees modification of Ayre's T-piece anesthesia circuit]) with long silicone tubing that could be occluded and released with a thumb. A 5-mm inner diameter (ID) endotracheal tube (ET) connector was connected to the opposite opening of the T-connector and a short tubing was connected to it. A Luer-lock connector for the insufflation catheter was attached to the end of the short tubing (Figs. 1A and B) (Supplementary Material 1).

Thumb occlusion at the end of the long silicone tubing results

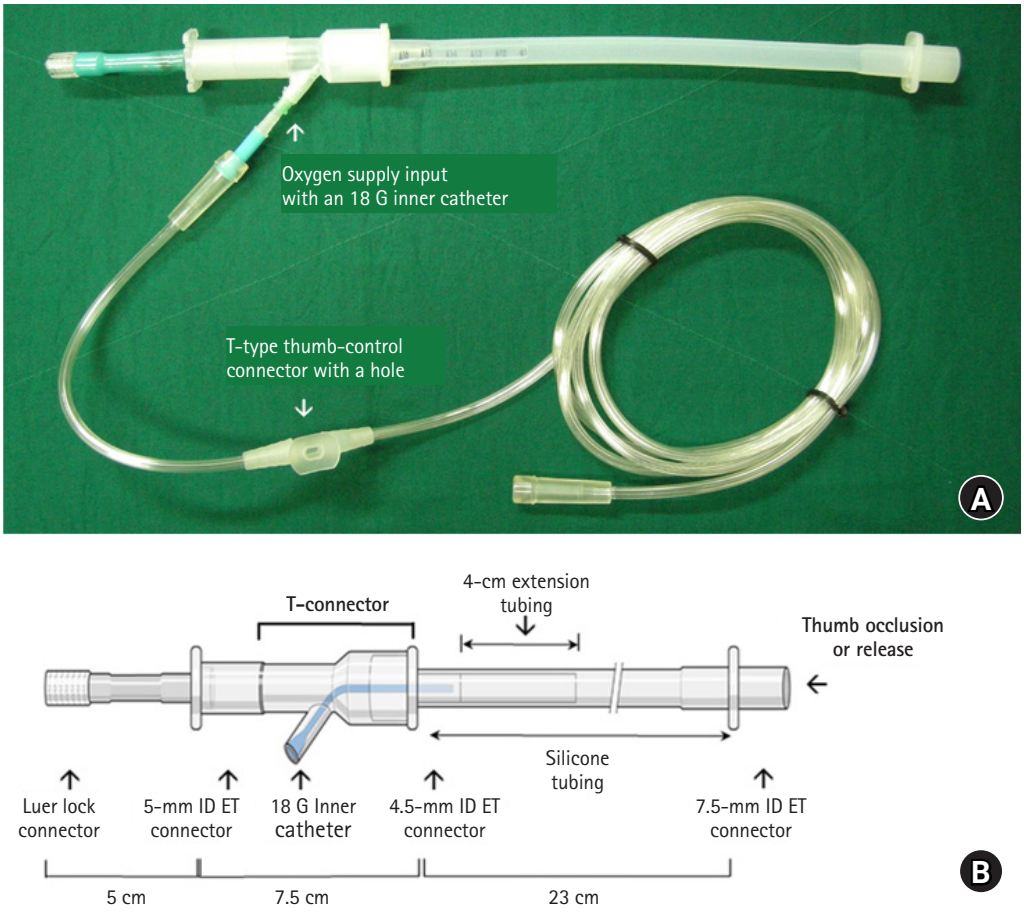

Fig. 1. (A) Modified Rapid-O2, (B) Schematic illustration of the modified Rapid-O2. ID: inner diameter, ET: endotracheal tube.

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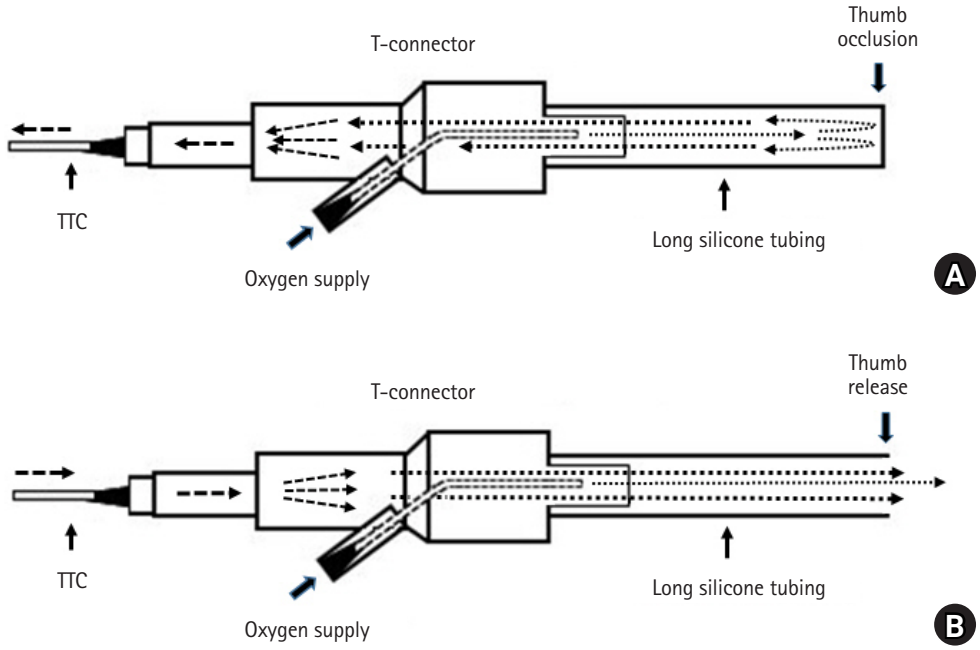

Fig. 2. (A) Schematic illustration of insufflating and (B) expiratory gas flows in the modified Rapid-O2. Expiration is induced by releasing the thumb at the end of the silicone tubing and is enhanced by negative atmospheric pressure via the Venturi effect. TTC: transtracheal catheter.

in a build-up of pressure within the device to push gas through the insufflation catheter, resulting in insufflation of oxygen (Fig. 2A), and expiration is enhanced after releasing the thumb (Fig. 2B). As a safety measure to prevent over-insufflation or lung collapse, a T-type thumb-control connector with a hole (ID: 4 mm) (Fig. 1A) was placed in the middle of the oxygen supply line. Insufflation and expiration was performed while the thumb of the opposite hand occluded the hole in the thumb- control connector. During the operation, to avoid lung collapse upon expiration or over-insufflation upon insufflation, the thumb of the opposite hand, occluding the hole of the thumb- control connector, was released to cut off the oxygen supply (oxygen cut-off mode). A wall-mounted pressure-compensated oxygen flowmeter (Ohio Medical) was used.

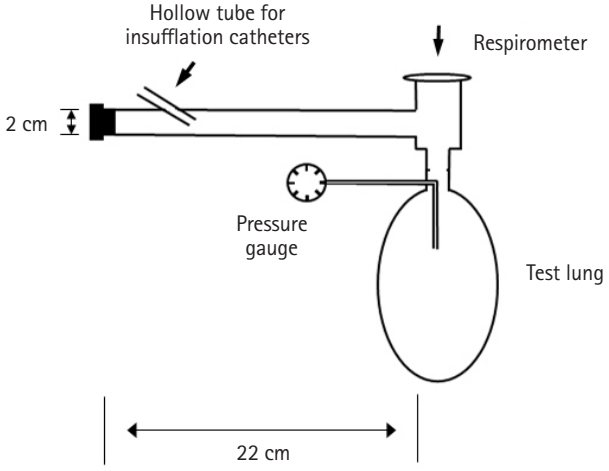

Fig. 3. The trachea-lung model.

Devices used for measurements

The insufflating and expiratory gas flows and the driving, insufflating, and expiratory pressures were measured using a calibrated pressure and gas flow analyzer (VT Plus HF Gas Flow Analyzer [VT Plus Analyzer]) (BioTek). Before each measurement, the VT Plus Analyzer was set to zero to ensure correct measurements. In addition, insufflating and expiratory times were measured using a trachea-lung model (Fig. 3). Measurements were repeated four times using the VT Plus Analyzer, and ten and six times using the modified Rapid-O2 and Rapid-O2, respectively, during the experiments using the trachea-lung model. As almost the same measurement value was obtained each time, four measurements were considered sufficient using the VT Plus Analyzer. In the trachea-lung model, slight differences were observed in each measurement because the test lung itself exhibited lung compliance. Therefore, the number of experiments increased. Unlike the Rapid-O2 experiment, the expiratory time in the modified Rapid-O2 was much shorter. Therefore, it was measured ten times to obtain

accurate results.

During most of the experiments with the VT Plus Analyzer and trachea-lung model, the thumb-control connector was not attached to the oxygen supply line to avoid any hassles. However, it was attached when the thumb-control connector function was tested.

Preliminary studies

To determine the appropriate length of the extension tubing (2–6 cm) attached to the narrow part of the 4.5-mm ID ET connector (Fig. 1B) to obtain the maximum negative pressure, we measured expiratory flow using an 18 G inner catheter in conjunction with a 14 G insufflation catheter at an oxygen flow rate of 15 L/min. Expiratory flow was measured with and without 2-, 4-, or 6-cm extension tubing. Before conducting this experiment, we tested the back-flow compensation of the pressure-compensated oxygen flowmeter using 20 G, 18 G, 16 G, 14 G, and 2-mm ID transtracheal catheters (TTC) (Cricath®) (Ventinova Medical) (Supplementary Fig. 2); others were from Becton Dickinson. When a 20 G catheter was connected to a pressure-compensated oxygen flowmeter, the oxygen flow decreased; no decrease was observed using 18 G and larger sizes (16 G, 14 G, and a 2-mm ID TTC). Hence, an 18 G catheter was used as the inner catheter in this experiment.

Second, to determine the most effective sizes of the inner and insufflation catheters for achieving optimum ventilation, the insufflating and expiratory flows were measured using these catheters at an oxygen flow rate of 15 L/min. Because the maximum expiratory flow was obtained using a 4-cm extension tubing in the above experiment, this length was used in this experiment. The inner catheters tested were 20 G, 18 G, 16 G, 14 G, and 2-mm ID TTC, and the insufflation catheters tested were 16 G, 14 G, and 2-mm ID TTC. In several random preliminary experiments before conducting this experiment, we observed that, when a 16 G insufflation catheter with an 18 G inner catheter was used, the insufflating flow through the 16 G insufflation catheter was lower (approximately 240 ml/s) than that through the 14 G and 2-mm ID insufflation catheters (approximately 250 ml/s each). Therefore, we did not examine catheters smaller than 16 G because we expected their flow to be even lower than that of the 16 G catheter.

In the first experiment, we observed a decrease in oxygen flow when a 20 G catheter was used. Nevertheless, we included this measurement to assess its impact on the insufflating flow when used as an inner catheter. The lengths of the 20 G, 18 G, 16 G, 14 G, and 2-mm ID catheters were 4.8, 4.8, 4.8, 4.5, and 7 cm, respectively, and their IDs were 0.6, 0.84, 1.19, 1.55, and 2 mm, respectively. Control experiments were performed without using an inner catheter. Insufflating and expiratory flows at the tip of the insufflation catheter were measured using the flow gauge of the VT Plus Analyzer (Supplementary Fig. 3A). Based on the results of preliminary studies, the following experiments were conducted with an 18 G inner catheter and 4-cm extension tubing in the modified Rapid-O2.

Measurements of driving, insufflating, and expiratory pressures

Driving, insufflating, and expiratory pressures through the 16 G, 14 G, and 2-mm ID insufflation catheters were measured at oxygen flow rates of 6, 9, 12, and 15 L/min. To determine the oxygen flow rate that can achieve the maximum driving pressure and the correlation between the oxygen flow rate and the insufflating or expiratory pressure, we applied oxygen flows ranging from 6 to 15 L/min. The driving pressure was measured via the side port of a y-piece placed between the oxygen tubing and flowmeter (Supplementary Fig. 3B). Driving pressures were measured during the insufflation, expiration, and oxygen cut-off modes. The driving pressure was defined as the pressure in the oxygen supply line between the flowmeter and inner catheter. Insufflating and expiratory pressures were measured at the side port of the distal t-piece, proximal to the insufflation catheter (Supplementary Fig. 3C). Insufflating and expiratory pressures were measured during the insufflation, expiration, and oxygen cut-off modes. The insufflating and expiratory pressures were defined as the pressures at the tip of the insufflation catheter during insufflation and expiration, respectively.

Measurements of insufflating and expiratory times

The insufflating and expiratory times were measured using a trachea-lung model (Fig. 3) consisting of corrugated anesthetic breathing system tubing (ID: 2 cm, length: 22 cm) connected to a test lung (Dräger SelfTestLung™) (Dräger) with a static compliance of 25 ml/cmH_2O and a resistance of 3 cmH_2O/L/s. The proximal end of the trachea was closed with a rubber stopper to simulate complete airway obstruction. A polyvinyl chloride (PVC) tubing (ID: 1 mm, OD: 2.4 mm) was inserted into the connection site between the respirometer and the test lung. The distal end was positioned in the middle of the test lung and the proximal end was connected to a pressure gauge (Smiths Medical ASD Inc.) to measure the pressure. The insufflation catheters were inserted through the wall of the short hollow tube (Fig. 3) and secured in

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place. The hub of the catheter was tightly held through the wall of the short hollow tube. In this condition, while the thumb of one hand occludes the hole in the T-type connector, the operator can use the thumb of the other hand to occlude or release the end of the long tubing for insufflation or expiration, respectively. In the preliminary study, it was found that, in the 18 G inner catheter group, both insufflating and expiratory flows in the 16 G insufflation catheter were lower than those in the 14-G and 2-mm ID TTC. In particular, the expiratory flow was much lower in the 16 G insufflation catheter compared to the others (Fig. 4). Therefore, the 16 G insufflation catheter was not examined in this study.

Insufflation of a certain volume, from the start of insufflation by thumb occlusion of the long silicone tubing to stopping insufflation by releasing the thumb, was measured using a Wright respirometer (Ferraris Development & Engineering Co. Ltd.) connected in series at the junction of the model trachea and test lung. Insufflating time was measured with a stopwatch. Based on the results of this experiment, the time required to insufflate 500 ml of oxygen was calculated.

The expiratory times were measured as follows: First, the check valve was connected to the hub of an insufflation catheter (14 G or 2-mm ID TTC) inserted in the hollow tube, and 500 ml of air

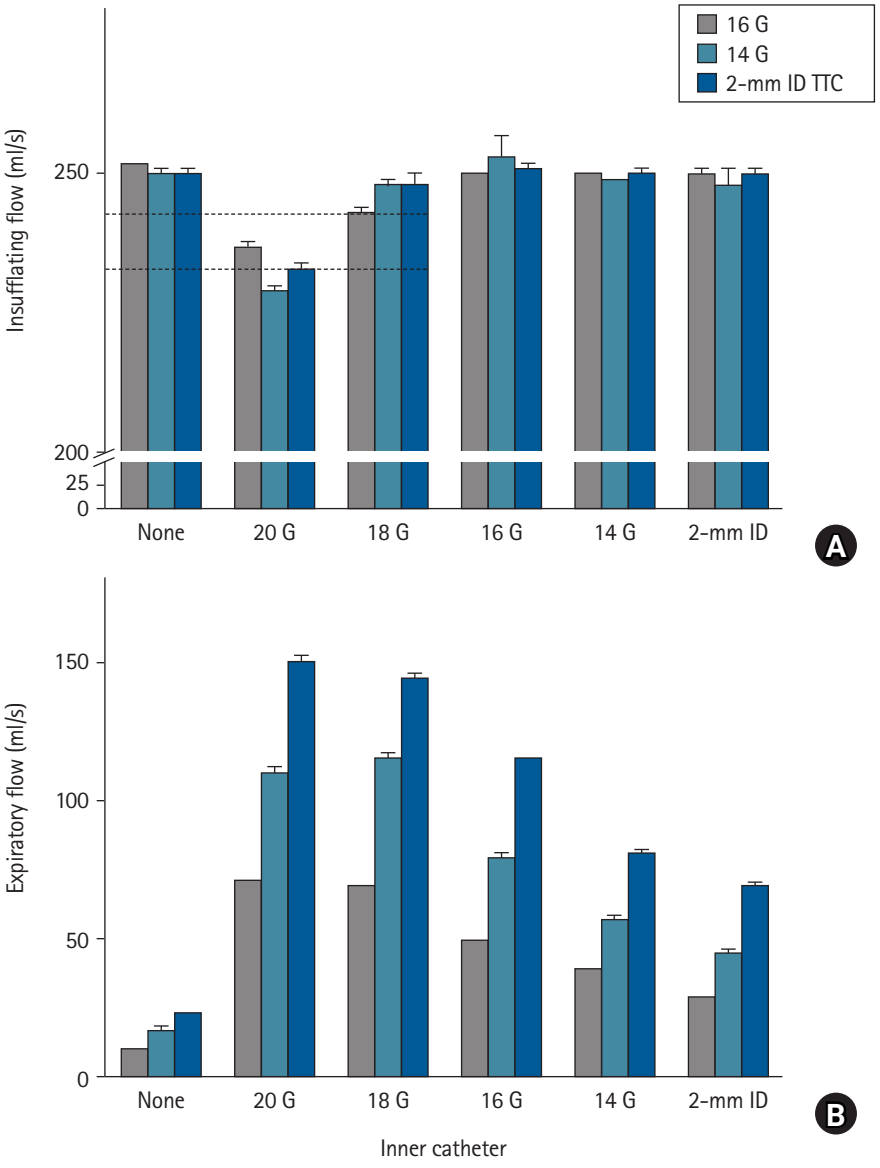

Fig. 4. (A) Insufflating and (B) expiratory flows measured using insufflation catheters of 16 G, 14 G, and 2-mm ID in conjunction with 20 G, 18 G, 16 G, 14 G, or 2-mm ID TTC inserted into the connecting port of the T-connector (inner catheter) of the modified Rapid-O2 at an oxygen flow rate of 15 L/min. None indicates the absence of inner catheters. ID: inner diameter. TTC: transtracheal catheter. N = 4 in each group.

was filled through the check valve using a syringe. Owing to the function of the check valve, the air that entered the test lung did not escape. When filled with 500 ml of air, the pressure was 18 cmH_2O. To measure the expiratory time, the end of the long silicone tubing of the modified Rapid-O2 was occluded first to insufflate the lung. When the insufflating pressure reached 18 cmH_2O, the thumb was immediately released, and the time taken for the pressure to drop from 18 to 0 cmH_2O was measured. The expiratory volume for 1 s was obtained by dividing 500 ml by the time taken for the pressure to drop from 18 to 0 cmH_2O (500 ml to escape). The insufflating and expiratory times were measured at oxygen flow rates of 12 and 15 L/min, respectively. To measure the expiratory time more accurately, the respirometer should be allowed to decrease to 0 ml by releasing the thumb after delivering a volume of 500 ml using a check valve. However, this method is cumbersome and time-consuming for each measurement (number of measurements: modified Rapid-O2 = 40, Rapid-O2 = 6). Therefore, we opted to use the current method instead.

To assess the improvement by modification of Rapid-O2, the insufflating and expiratory times, as well as the minute respiratory volumes, were measured using the Rapid-O2 and the results were compared with those obtained using the modified Rapid-O2. In the Rapid-O2 experiment, 2-mm ID insufflating catheters were only examined at 15 L/min.

To estimate the insufflating and expiratory times in the modified Rapid-O2, as well as the insufflating and passive expiratory times in the Rapid-O2 at lung compliances of 50 and 100 ml/cmH_2O, we calculated the ratios based on the insufflating, expiratory, and passive expiratory times obtained at different lung compliance levels in the study by Hamaekers et al. [5] using Ventrain® (Ventinova Medical) (Supplementary Material 2).

Based on the insufflating and expiratory times, the respiration rates, I: E ratios, and minute volumes were obtained.

Statistical analysis

Statistical processing was not performed for the measurements obtained using the VT Plus Analyzer because the number of experiments was small (n = 4); however, uniform results were obtained.

One-way analysis of variance (ANOVA) followed by a Student-Newman-Keuls post-hoc analysis for comparisons between the means was performed to compare the insufflating, expiratory times, and minute volumes at different lung compliance levels in each catheter size. Paired t-tests were used to compare the insufflating, expiratory times, and minute volumes between the 14 G and 2-mm ID TTC at each lung compliance level. Unpaired t-tests were used to compare the insufflating and expiratory times and minute volumes between 12 and 15 L/min with the same catheter size at each lung compliance level and to compare the insufflating and expiratory times and minute volumes with the same catheter size at each lung compliance level between the modified Rapid-O2 and Rapid-O2. The normality of the data distribution was assessed using the Shapiro-Wilk test. All statistical data were analyzed using SigmaPlot® 12.5 (Systat software Inc.). All results were expressed as the mean ± SD. A P value of less than 0.05 was considered statistically significant. In most cases, the data were normally distributed. However, when the data were not normally distributed, the median values were compared using ANOVA on ranks or Mann-Whitney rank sum test.

Results

Preliminary studies

The groups with 4-cm (115 ± 1 ml/s) and 6-cm (117 ± 1 ml/s) extension tubings showed similar expiratory flows that were greater than those in the other groups (no extension, 85 ± 0 ml/s; 2 cm, 106 ± 0 ml/s).

In the groups using a 16 G or larger inner catheter, the insufflating flows were similar (approximately 250 ml/s) among the three insufflation catheters. Similar results were obtained when an inner catheter was not used. In the 18 G inner catheter group, the insufflating flow through the 16 G insufflation catheter was slightly less (243 ± 1 ml/s) than the flow through the 14 G (250 ± 1 ml/s) and 2-mm ID insufflation catheters (249 ± 2 ml/s). In the 20 G inner catheter group, the insufflating flows were similar among the three insufflation catheters (16 G: 237 ± 1, 14 G: 229 ± 1, 2-mm ID TTC: 233 ± 1 ml/s), but less than those in the other inner catheter groups, indicating that the 20 G catheter significantly restricted the inflow into the device (Fig. 4A). The expiratory flows for both 20 G and 18 G inner catheter groups were similar at each insufflating catheter. In the groups using a 16 G or larger inner catheters, the expiratory flows at each inner catheter were lower than those in the 20 G and 18 G inner catheter groups. When a 2-mm ID TTC was used as an insufflation catheter, the expiratory flow was the highest in both 20 G (150 ± 2 ml/s) and 18 G (144 ± 2 ml/s) inner catheter groups. The passive expiratory flow was negligible when no inner catheter was used (Fig. 4B).

Driving, insufflating, and expiratory pressures

The driving pressures of approximately 1,670 cmH_2O were measured in the 16 G (1,691 ± 7 cmH_2O), 14 G (1,659 ± 6 cm-

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H_2O), and 2-mm ID (1,650 ± 4 cmH_2O) insufflation catheters at 15 L/min. The driving pressures were similar for all the three insufflation catheters at each oxygen flow rate. For each catheter size, the driving pressure tended to increase with higher oxygen flow rate (Fig. 5A). The driving pressures were similar, regardless of insufflation or expiration. When the hole in the thumb-control connector was opened during insufflation or expiration (oxygen cut-off mode), the driving pressure immediately decreased to 0 cmH_2O. The insufflating pressure decreased when larger insufflation catheters were used and increased with higher oxygen flow rates for each catheter size (Fig. 5B). When the hole in the thumb-control connector was opened during insufflation (oxygen cut-off mode), the insufflating pressure immediately decreased to 0 cmH_2O. During expiration, negative pressures of approximately 50 cmH_2O were measured in 16 G (56 ± 1 cmH_2O), 14 G (50 ± 1 cmH_2O), and 2-mm ID (45 ± 1 cmH_2O) insufflation catheters at 15 L/min. As with insufflating pressures, negative pressures decreased when larger-sized insufflation catheters were used and increased at higher oxygen flow rates for each catheter size (Fig. 5C). When the hole in the thumb-control connector was opened during expiration (oxygen cut-off mode), the expiratory pressure immediately decreased to 0 cmH_2O.

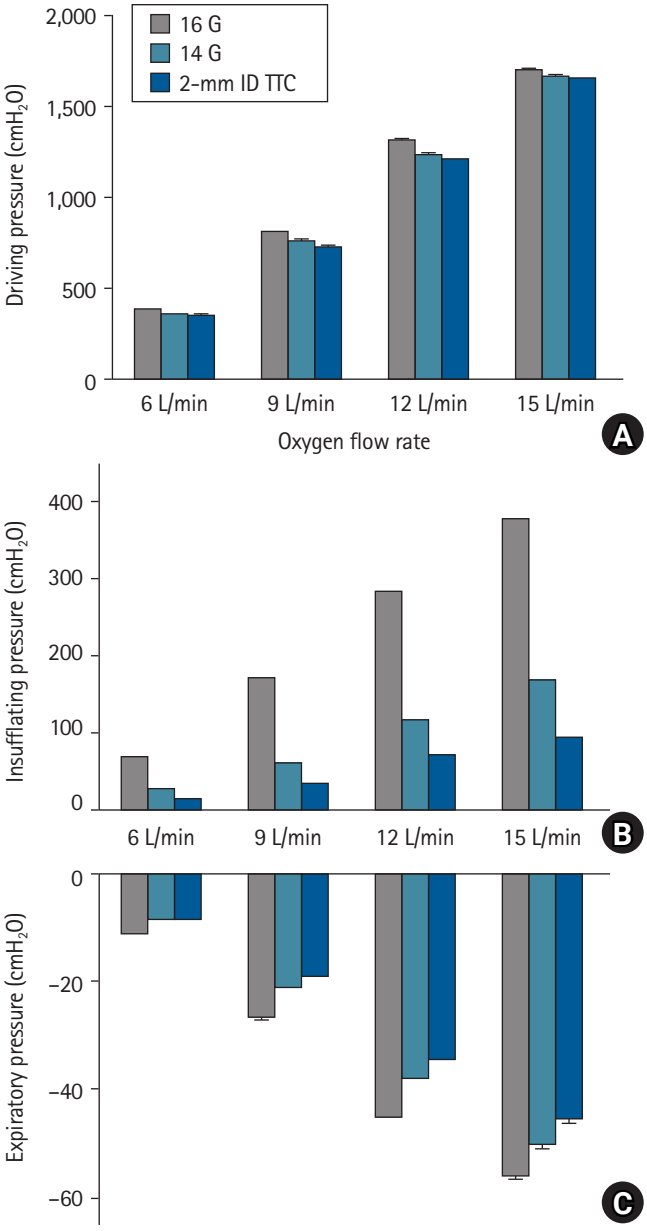

Fig. 5. (A) Driving, (B) insufflating, and (C) expiratory pressures through the 16 G, 14 G, and 2-mm ID insufflation catheters measured with an 18 G inner catheter at oxygen flow rates of 6, 9, 12, and 15 L/min. ID: inner diameter. N = 4 in each group.

Insufflating and expiratory times

Modified Rapid-O2

Whereas the insufflating times tended to decrease with higher lung compliance levels at each catheter size for both oxygen flow rates (12 L/min: 14 G, P = 0.002 or 2-mm ID TTC, P = 0.016; 15 L/min: 14 G, P = 0.014 or 2-mm ID TTC, P = 0.002), the insufflating times were similar between the 14 G and 2-mm ID TTC at each lung compliance level in each oxygen flow rate. The higher the oxygen flow rate, the lower the insufflating time for each catheter size at each lung compliance level (P < 0.001 each) (Table 1).

The expiratory times were similar at each lung compliance level for each catheter size at both oxygen flow rates. The expiratory time decreased significantly when larger-sized insufflation catheters were used at each lung compliance level at each oxygen flow rate (12 L/min: 14 G vs. 2-mm ID TTC, P < 0.001; 15 L/min: 14 G vs. 2-mm ID TTC, P < 0.001). The higher the oxygen flow rate, the shorter the expiratory time for each catheter size at each lung compliance level (P < 0.001 each) (Table 1).

The minute volumes increased at higher lung compliance levels for each catheter size at an oxygen flow rate of 15 L/min (14 G, P < 0.001; 2-mm ID TTC, P = 0.005), whereas those were similar at 12 L/min. The minute volumes increased when a larger catheter was used at each lung compliance level for both oxygen flow rates (12 L/min: 14 G vs. 2-mm ID TTC, P < 0.001; 15 L/min: 14 G vs. 2-mm ID TTC, P < 0.001). The higher the oxygen flow rate, the greater the minute volume in each catheter size at each lung compliance level (14 G: 12 L/min vs. 15 L/min, P = 0.002 each; 2-mm ID TTC: 12 L/min vs. 15 L/min, P < 0.001 each) (Table 1).

Rapid-O2

The insufflating times tended to decrease at higher lung compliance levels (P < 0.001). The expiratory times were significantly

Table 1. Insufflating and Expiratory Times, I:E Ratios, Respiration Rates, and Minute Volumes with Insufflation Catheters at Lung Compliance Levels of 25, 50, and 100 ml/cmH_2O at Oxygen Flow Rates of 12 and 15 L/min in the Trachea-Lung Model

Oxygen flow: 12 L/min			
Lung compliance (ml/cmH_2O)	25	50	100
14 G			
Insufflating time (s)	2.30 ± 0.05	2.16 ± 0.05	2.09 ± 0.05
Expiratory time (s)	4.16 ± 0.07	4.16 ± 0.07	4.16 ± 0.07
I:E ratio	1:1.79	1:1.91	1:1.97
RR (breaths/min)	9.29	9.49	9.6
MV (ml/min)	3,717 ± 59	3,798 ± 60	3,840 ± 61
2-mm ID TTC			
Insufflating time (s)	2.38 ± 0.07	2.24 ± 0.07	2.21 ± 0.07
Expiratory time (s)	2.86 ± 0.06	2.86 ± 0.06	2.86 ± 0.06
I:E ratio	1:1.20	1:1.28	1:1.29
RR (breaths/min)	11.47	11.79	11.84
MV (ml/min)	4,587 ±92	4,716 ± 94	4,738 ± 94
Oxygen flow: 15 L/min			
14 G			
Insufflating time (s)	2.06 ± 0.05	1.96 ± 0.05	1.88 ± 0.05
Expiratory time (s)	3.87 ± 0.07	3.79 ± 0.07	3.72 ± 0.06
I:E ratio	1:1.88	1:1.99	1:1.98
RR (breaths/min)	10.12	10.36	10.71
MV (ml/min)	5,058 ± 40	5,217 ± 42	5,366 ± 43
2-mm ID TTC			
Insufflating time (s)	2.05 ± 0.05	1.95 ± 0.05	1.87 ± 0.04
Expiratory time (s)	2.47 ± 0.06	2.47 ± 0.06	2.42 ± 0.06
I:E ratio	1:1.20	1:1.27	1:1.29
RR (breaths/min)	14.31	13.99	13.75
MV (ml/min)	6,644 ± 126	6,799 ± 130	7,007 ± 134

Values are presented as mean ± SD. N = 10 for each gauge. G: gauge, ID: inner diameter, TTC: transtracheal catheter, I:E: insufflating time: expiratory time, RR: respiratory rate per minute, MV: minute volume (ml/min). Insufflating time: 14 G or 2-mm ID TTC: 12 L/min vs. 15 L/min, $P < 0.001$ at each lung compliance level. Expiratory time: 12 L/min or 15 L/min: 14 G vs. 2-mm ID TTC, $P < 0.001$ at each lung compliance level. 14 G or 2-mm ID TTC: 12 L/min vs. 15 L/min, $P < 0.001$ at each lung compliance level. MV: 12 L/min or 15 L/min: 14 G vs. 2-mm ID TTC, $P < 0.001$ at each lung compliance level; 14 G and 2-mm ID TTC: 12 L/min vs. 15 L/min, $P = 0.002$ and $P < 0.001$, respectively, at each lung compliance level.

prolonged with higher lung compliance levels ($P < 0.001$). Minute volumes tended to decrease at higher lung compliance levels ($P < 0.001$) (Fig. 6, Supplementary Table 1).

Comparison between the two devices

While the insufflating times were similar between the modified Rapid-O2 and Rapid-O2 groups at each lung compliance level, the expiratory times decreased significantly at each lung compliance level in the modified Rapid-O2 group ($P < 0.001$ each). Minute volumes were also significantly greater at each lung compliance level in the modified Rapid-O2 group ($P = 0.002$ each) (Fig. 6).

Discussion

This study demonstrated the potential of the modified Rapid-O2 to provide ventilatory support. Minute volumes of 5–7 L/min could be achieved at an oxygen flow rate of 15 L/min using a 14 G or 2-mm ID insufflation catheter, which was possible because the negative atmospheric pressure (approximately −50 cmH_2O) enhanced the expiratory flow.

In CICO or near-complete airway obstruction, the insertion of a small-bore catheter through the cricothyroid membrane can provide effective reoxygenation via jet ventilation. However, the use of such a high-pressure ventilator requires an open or partially obstructed airway to allow the release of insufflated gas during expiration to prevent barotrauma. Rapid-O2, a rescue oxygen-

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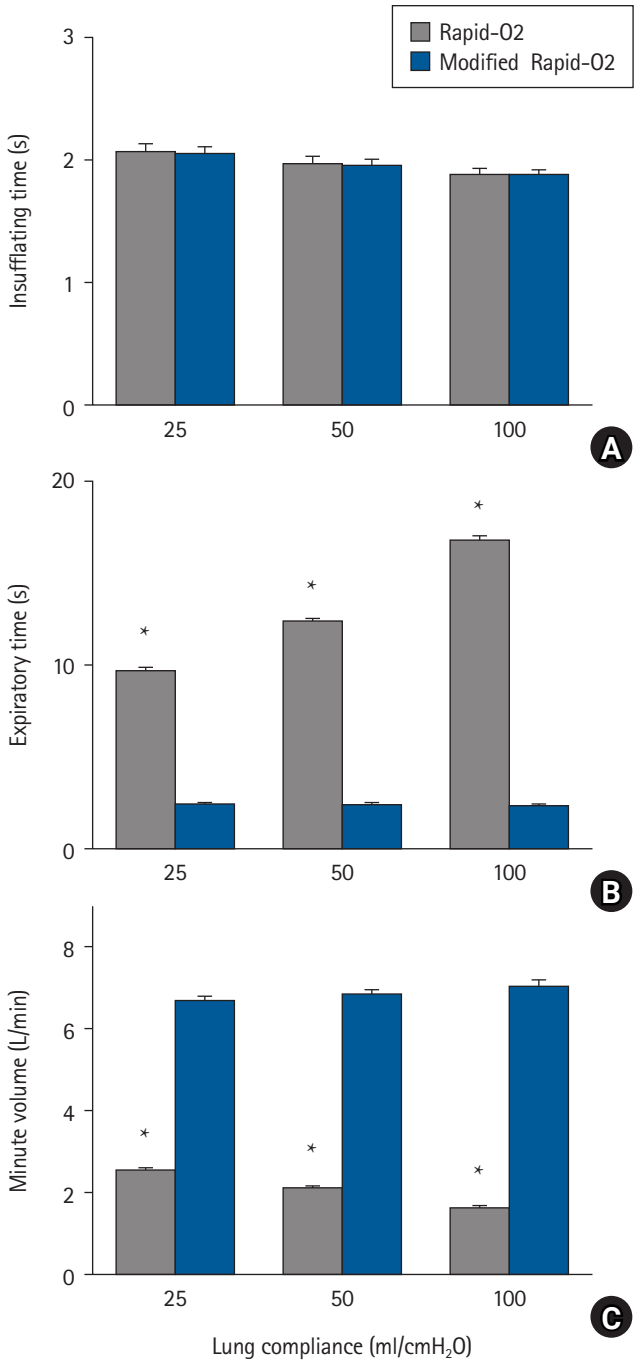

Fig. 6. Comparison of Rapid-O2 and modified Rapid-O2 for (A) insufflating and (B) expiratory times, and (C) minute volumes using a 2-mm ID TTC at lung compliance levels of 25, 50, and 100 ml/cmH2O at an oxygen flow rate of 15 L/min. ID: inner diameter, TTC: transtracheal catheter. N = 6 and 10 for Rapid-O2 and the modified Rapid-O2, respectively. Expiratory time: Rapid-O2 vs. modified Rapid-O2, $P < 0.001$ at each lung compliance level. Minute volume: Rapid-O2 vs. modified Rapid-O2, $P = 0.002$ at each lung compliance level. *Indicates significant differences between Rapid-O2 and modified Rapid-O2.

ation device, can also be used in such situations. However, passive expiratory outflow through a small-bore catheter is extremely prolonged due to the high internal resistance of the catheter; hence, ventilation might not be achievable. Various techniques have been proposed to facilitate the egress of gas through a small-bore catheter, such as the insertion of an additional catheter [6,7], application of suction to the airway catheter during the expiratory phase [8,9], or use of the Venturi effect (based on the Bernoulli principle) to create a negative pressure during expiration [10–13]. Although this concept [10–13] has already been proposed, currently, the only commercially available device that can be used for CICO or near-complete airway obstruction is Ventrain® [14,15]. The modified Rapid-O2 was also designed based on the Venturi effect to mitigate Rapid-O2-induced hypercarbia. The modified Rapid-O2 could also be considered a rescue device comparable to Ventrain® in terms of minute volume and I:E ratio, as shown in our experiments (Supplementary Table 1). It is simple to use and can be easily assembled using clinically available materials.

Rapid-O2 provides rescue oxygenation with purely passive exhalation through a small-bore catheter for the prolonged apnea time, approximately 7 min taken for SaO_2 to decrease from 98% to 93% in normal adults [16]; thus, hypercarbia is inevitable. When applied for a short period, hypercarbia may not be a problem; however, over longer durations, the resulting marked hypercarbia [2,17] may limit the duration of safe percutaneous oxygen insufflation. Therefore, we modified Rapid-O2 to provide subatmospheric pressure to actively enhance expiration to compensate for this limitation,

In our results, we found that the driving pressure (1,650 cmH_2O) measured with a 2-mm ID TTC at an oxygen flow rate of 15 L/min was lower than that of Hamaekers et al.'s measurements (2,300 cmH_2O) using Ventrain® [18]. It was also slightly lower than the measurement of 1,779 cmH_2O reported by Schmidt et al. using Ventrain® [19]. The insufflating pressures (Hamaekers et al.: 137, Schmidt et al.: 113, and our study: 100 cmH_2O), as well as expiratory pressures (Hamaekers et al.: −97, Schmidt et al.: −78 [estimated], and our study: −45 cmH_2O), showed differences similar to those in driving pressures. These differences are likely due to the variances in the IDs of the nozzle of the Ventrain® (0.7 mm) [18] and the 18 G inner catheter (0.838 mm) of the modified Rapid-O2. The minute respiratory volumes showed similar differences (Hamaekers et al.: 7.48, Schmidt et al.: 7.2, and our study: 7.0 L/min).

The measurements obtained to assess any improvement after modifying Rapid-O2 demonstrated that the modified Rapid-O2 significantly reduced the expiratory time and increased minute

volume compared to those obtained with Rapid-O2 at normal lung compliance levels (50–100 ml/cmH_2O). In the modified Rapid-O2, the expiratory time decreased 7-fold and the minute respiratory volume increased 4.5-fold in the 2-mm ID TTC at a lung compliance level of 100 ml/cmH_2O (Fig. 6). Considering that the average minute respiratory volume in adults is 5–8 L/min, the minute volume over 5 L/min at an oxygen flow rate of 15 L/min obtained in our study indicates that Rapid-O2 was sufficiently modified in terms of ventilation.

A pressure-compensated oxygen flowmeter was required for this device using an 18 G inner catheter to deliver a constant oxygen flow rate (Supplementary Material 3).

When using an 18 G inner catheter, the flow through a 16 G insufflation catheter was slightly less (approximately 240 ml/s) than those in 14 G and 2-mm ID insufflation catheters (approximately 250 ml/s) (Fig. 4A). When a 16 G or larger inner catheter was used, the expiratory flow at each inner catheter was lower than that of the 18 G inner catheter. Thus, an 18 G inner catheter appeared to be an appropriate compromise for both insufflation and expiration. When the inner and insufflation catheters were 18 G and 16 G, respectively, the expiratory flow was much lower than those in the 14 G and 2-mm ID insufflation catheters. Therefore, the 16 G insufflation catheter was not examined in the trachea-lung model.

To prevent hyperinflation or lung collapse, it is essential to adjust the duration of insufflation and expiration. Considering that the vital capacity of adults is approximately 5 L, a certain amount of hyperinflation caused by the modified Rapid-O2 may not be an issue. However, if more gas expires than is insufflated, lung collapse or even negative-pressure pulmonary edema may develop because the expiratory reserve volume (ERV) is limited in adults (approximately 1,000 ml). For example, when a 14 G insufflation catheter was used at an oxygen flow rate of 15 L/min, the insufflating time and expiratory time were 1.88 s and 3.72 s, respectively, at a lung compliance level of 100 ml/cmH_2O (Table 1); therefore, an insufflated volume of 500 ml is exhaled after 3.72 s of expiration. ERV exhalation occurs after the tidal volume, and, by calculation, ERV will be completely exhaled in approximately 7.5 s. If we assume that lung collapse occurs after complete ERV exhalation, it may occur approximately 11 s (3.7 s + 7.5 s) after augmented expiration with the modified Rapid-O2. This indicates that lung collapse may develop after a short period of actively assisted expiration if the negative pressure persists continuously during the operation of this device. For this reason, a thumb-control connector was used as a safety measure in this device. If the hole in the thumb-control connector is released when excessive gas expires, the modified Rapid-O2 becomes functionally switched off to prevent lung collapse.

When both the hole of the thumb-control connector and the end of the long silicone tubing were opened simultaneously immediately after insufflation of 500 ml with a 14 G insufflation catheter, it took 14.2 ± 0.6 s (n = 4), 35 ml/s, to passively dispense the insufflated volume of 500 ml in our trachea-lung model. By calculating the ratios based on the measured passive expiratory volumes at different lung compliance levels in a study by Hamaekers et al. [5], the resulting rates of release were 28 and 20 ml/s through the 14 G insufflation catheter at lung compliance levels of 50 and 100 ml/cmH_2O, respectively. These findings indicate that although the device was functionally switched off, the insufflated volume is passively released continuously, but slowly, through the insufflation catheter during expiration.

At a lung compliance level of 100 ml/cmH_2O, the minute volumes obtained were 3.84 (14 G) and 4.74 L/min (2-mm ID TTC) that were slightly higher than those at a lung compliance level of 50 ml/cmH_2O (3.80 [14 G] and 4.72 L/min [2-mm ID TTC]) at 12 L/min (Table 1). These results show that, at normal lung compliance levels of 50-100 ml/cmH_2O, a minute volume of at least 4.5 L/min, when a 2-mm ID TTC was used, can be achieved even when an oxygen flow rate of 12 L/min was used. Considering that the normal range of minute respiratory volume in adults is 5–8 L/min, the minute volume obtained with a 2-mm ID TTC at an oxygen flow rate of 12 L/min would be acceptable despite being slightly lower. However, 14 G and 2-mm ID insufflation catheters are considered suitable for use at a rate of 15 L/min. These minute volumes would be sufficient not only for reoxygenation but also for preventing hypercarbia in adults.

One limitation of this study is that we used a test lung with constant levels of compliance and resistance. To determine the values at normal lung compliance levels, the measured data had to be inferred by referring to the results of another study [5]. To verify the reliability of our data, we compared our results with measurements using a detailed lung simulation device (LS800™ lung simulator [5]). As shown in Supplementary Table 1, the minute volumes obtained by the test lung were slightly lower than those obtained using the detailed lung simulation device; however, this difference was acceptable.

This is a preliminary or "*in vitro* proof of concept" non-clinical study of a prototype device. Therefore, in vivo experiments are required to further compare the compatibilities of the tested device.

In conclusion, our results demonstrated the potential of the modified Rapid-O2 for providing ventilatory support. The modified Rapid-O2 can achieve adequate minute volumes in adults using a 2-mm ID TTC or 14 G catheter at an oxygen flow rate of 15 L/min. Maintaining the I:E ratio is important, however, ob-

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serving the chest wall movements to control inspiratory and expiratory times might also be essential.

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Conflicts of Interest

No potential conflict of interest relevant to this article was reported.

Data Availability

The datasets generated or analyzed during this study are available from the corresponding author upon reasonable request.

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Author Contributions

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Supplementary Materials

Supplementary Material 1. Detailed descriptions of the modified Rapid-O2.
Supplementary Material 2. Calculations of the insufflating, expiratory, and passive expiratory times at lung compliance levels of 50 and 100 ml/cmH_2O.
Supplementary Material 3. Detailed descriptions of the requirements for a pressure-compensated oxygen flowmeter for Modified Rapid-O2.
Supplementary Table 1. Comparison of Rapid-O2, modified Rapid-O2, and Ventrain® for insufflating and expiratory times, and minute volumes with 2-mm ID TTC at lung compliance levels of 25, 50, and 100 ml/cmH_2O at an oxygen flow rate of 15 L/min.
Supplementary Fig. 1. Our institution's version of the Rapid-O2 oxygen insufflation device™ (Rapid-O2).
Supplementary Fig. 2. A 2-mm ID (inner diameter) transtracheal catheter (Cricath®) (Ventinova Medical).
Supplementary Fig. 3. Schematic illustration for measurements of insufflating and expiratory gas flows (A), driving (B), and insufflating and expiratory pressures (C).

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