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Original Article

Aerosol and Droplet Dispersion Control during Bronchoscopy Using a Newly Developed Oxygen Mask

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Abstract

Background: This study aimed to evaluate the efficacy and safety of a newly modified oxygen mask to contain droplets and aerosols during bronchoscopy. The coronavirus disease-2019 (COVID-19) pandemic has generated attention to the importance of infection control, especially in aerosol-generating procedures, such as bronchoscopy. A modified mask was designed to allow bronchoscope insertion, oxygen administration, and aspiration of oral secretions while preventing droplet and aerosol dispersion.

Materials and Methods: The mask was created by modifying a commercially available non-rebreathing oxygen mask. All the exhalation holes were sealed, and two new holes were drilled for the oxygen tube, bronchoscope, and suction tube. The holes were covered with rubber and provided with X-shaped slits to prevent aerosol and droplet dispersal. This study used a particle visualization system to visually assess the spread of particles during simulated coughing with and without a modified mask. The particles were quantified using a counting system. Mask safety was evaluated by monitoring a healthy volunteer's carbon dioxide levels, oxygen saturation, and heart rate. Additionally, these parameters were monitored in seven patients undergoing bronchoscopy.

Results: The modified masks significantly reduced droplet and aerosol dispersion. The modified mask successfully prevented aerosol leakage during bronchoscopy in a human model. The mask reduced droplet and aerosol dispersion by approximately 97% in a human participant. Safety assessments in the seven patients suggested that the mask was safe for use during bronchoscopy as it did not significantly affect the carbon dioxide levels or oxygen saturation.

Conclusions: This study demonstrated that the modified masks effectively minimized the spread of potentially infectious particles during bronchoscopy and were safe for patients. This is especially important considering the potential for asymptomatic individuals to transmit infectious diseases, such as COVID-19. This study advocates the universal use of such masks during bronchoscopy to protect healthcare workers and patients from airborne transmission.

Keywords

COVID-19, oxygen mask, droplets, aerosols, bronchoscopy

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Introduction

Flexible bronchoscopy is commonly employed by respirologists and thoracic surgeons for diagnostic and therapeutic purposes. Pulmonary nodules are frequently detected owing to the widespread use of computed tomography, and the diagnosis and management of pulmonary nodules are increasingly needed in pulmonary medicine and thoracic surgery. With innovations, such as virtual bronchoscopy and endobronchial ultrasonography using a guide sheath (EBUS-GS), transbronchial lung biopsy (TBLB) for small pulmonary nodules has been extensively adopted[1,2].

The coronavirus disease-2019 (COVID-19) pandemic has generated attention to aerosol and droplet infection control and reaffirmed the importance of infection control for healthcare workers in bronchoscopy. Although COVID-19 has been contained, healthcare workers should take precautions against the emergence of unknown infectious diseases. Considering the recent COVID-19 era, infection through bronchoscopy is a problem that should be prevented. How-

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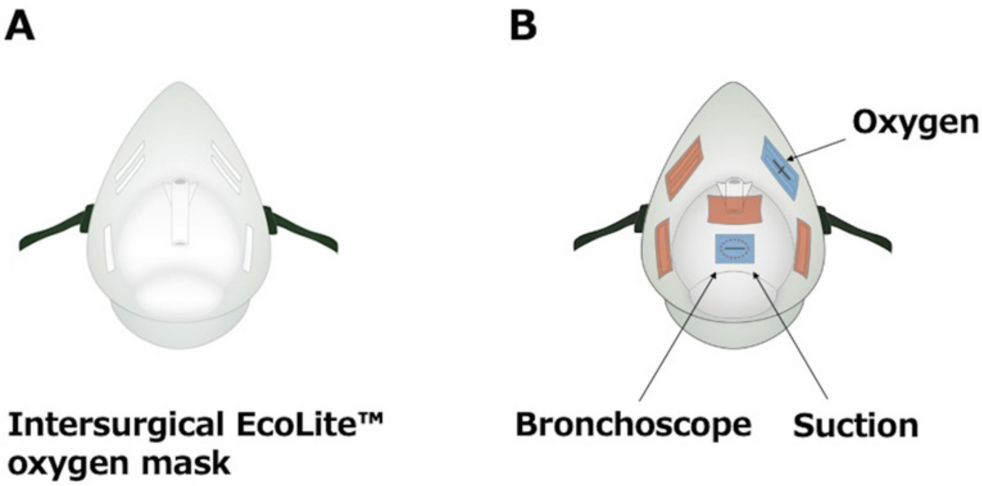

Figure 1. Images of the original mask (A) and the newly modified non-rebreathing oxygen mask (B). The newly modified oxygen mask has two new holes: one for the oxygen tube and another for the bronchoscope and suction tube, with each hole sealed by rubber featuring X-shaped slits (indicated in blue) to contain aerosols and droplets. The original mask's exhalation holes and the oxygen tube connection hole are securely closed with hermetic seals (indicated in orange) to contain droplets and aerosols.

ever, asymptomatic individuals can carry severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) and infect others. Some studies have reported that asymptomatic infections account for 40%-45% of asymptomatic transmissions[3-5]. A study by Gonzalez et al., which visualized cough dispersal during tracheal intubation using a special fluorescent dye, reported significant amounts of dispersed droplets[6]. Therefore, concerns have been raised regarding the safety of healthcare workers during bronchoscopy. Under COVID-19 infestation, doctors and nurses wear full personal protective equipment (PPE) and perform simulations in advance, requiring time, effort, and resources[7]. Precautions were taken to prevent the spread of droplets and aerosols from the patients. Various reports exist regarding patients using masks or modified face masks while undergoing bronchoscopy to prevent the spread of droplets[8-10].

Thus, this study aimed to evaluate the usefulness of a modified oxygen mask for preventing droplet and aerosol dispersion and the safety of its use during bronchoscopy, allowing safe bronchoscope insertion, oxygen administration, and oral secretion aspiration. Furthermore, we investigated the effectiveness of the developed masks in preventing the spread of aerosols and droplets using fluid engineering studies with a particle visualization device and simulated studies with a particle counting device.

Materials and Methods

Newly modified non-rebreathing oxygen mask

We developed a new non-rebreathing oxygen mask by modifying a commercially available Intersurgical EcoLite Oxygen Mask (Intersurgical Ltd., Berkshire, UK). All the exhalation holes in the original mask were closed by covering them with a hermetic seal to contain droplets and aerosols. The hole connecting the oxygen tube to the original mask was closed using a hermetic seal. Next, two new holes were made in the modified mask: one for placing the oxygen tube, and a second for the bronchoscope and the suction tube, which removes saliva from the oral cavity. The two holes were covered with rubber, and X-shaped slits were placed in the rubber to contain aerosols and droplets (**Figure 1A and B**).

Particle visualization system

We used a scanning laser sheet light source, Parallel Eye H (Shin Nippon Air Conditioning Co., Ltd., Tokyo, Japan), to visualize approximately 0.08-10 μm particles[11]. The particles included aerosols (<0.5 μm) and droplets (1-1000 μm). In Parallel Eye H, a 532-nm YAG laser beam was reflected by an oscillating mirror and scanned at a high speed with an appropriate waveform to produce a laser sheet made of optical film. Parallel Eye H was characterized by its ability to produce uniform and intense scattered light and precisely control the sheet's divergence angle, irradiation angle, and oscillation frequency. The system used a unique light source for visualization to ensure a highly sensitive evaluation of suspended particles (**Figure 2A**).

We conducted the following experiments under two conditions by running Parallel Eye H: one using a human body model, and the other using a human participant coughing. In the human model experiment, an oil mist generator (Shin Nippon Air Conditioning Co., Ltd., Tokyo, Japan) was utilized to generate oil mists of the same size as the aerosols from the mouth of the model. In the human experiment, the aerosols and droplets were observed when the participant coughed in the supine position. The bed was raised to a height of 70 cm above the floor, and the model and participant were placed on top of the bed. The experiments were performed in a clean room equivalent to ISO 14644-1 Class 5. The room was dark, with an area of 2.3 m × 5.9 m × 2.0

m and a high-efficiency particulate air filter on the ceiling.

Regarding the conditions of the experiment using a human model, the human model was sprayed with oil mists through the mouth without a mask, designated as the control. To evaluate the effect of the mask on reducing aerosol dispersion, a nonwoven surgical mask and a modified mask were placed on the mouth of the human model, and aerosol dispersion was monitored using Parallel Eye H.

Next, the human experiment was designed to visualize the dispersal of droplets or aerosols when a participant coughed. When the same participant coughed with the same intensity, the following three conditions were applied: (1) no mask, (2) wearing a nonwoven surgical mask, and (3) use of the modified mask. The effectiveness of the mask in suppressing droplet dispersal was assessed in this experiment. Since aerosol dispersion occurs later than droplet dispersion, the aerosol was visualized only a few seconds later.

Counting system for aerosols or droplets

Particles, including aerosols or droplets, could be visualized and counted using "Type-S" (Shin Nippon Air Conditioning Co., Ltd., Tokyo, Japan)[12]. The Type-S counting system integrates a light source and an image sensor to visualize and count particles in real-time. The system could detect particles as small as 0.5 μm and sample particles 30 times per second. The particle visualization area was 200 × 40 mm^2, and the particles passing through the visualization area were counted (**Figure 2B**).

Similar to the above study that used the particle visualization system, aerosols and droplets were generated by the participant coughing and counted by Type-S. A mobile visualization and counting device, Type-S, was installed 30 and 60 cm above the mouth of the participant to count the number of airborne droplets, with and without the modified mask. Coughing was repeated three times to produce a similar pattern of particle generation. The bronchoscopist's face was assumed 60 cm from the mouth, and the caregiver's hand was assumed 30 cm from the mouth (**Figure 2C**).

Safety evaluation of the newly modified non-rebreathing oxygen mask

Since the modified mask is tightly sealed, its safety must be evaluated by considering its effects on the body, such as carbon dioxide (CO_2) sequestration. We evaluated the safety of the mask by monitoring the CO_2 concentration using an end-tidal carbon dioxide ($EtCO_2$) monitor.

The safety evaluation experiment described above was first conducted on a healthy participant. The participant wore a modified mask with and without an oxygen supply, and the $EtCO_2$ concentration was measured. Percutaneous oxygen saturation (SpO_2) and heart rate (HR) were monitored. The same safety evaluation of the mask was performed in patients undergoing bronchoscopy (OLYMPUS BF-P290 or OLYMPUS BF-UC260FW, Olympus Medical Systems, Japan) under oxygen supply. All patients were sedated using midazolam and pethidine during bronchoscopy. Between July 1, 2020, and April 31, 2021, the $EtCO_2$, SpO_2, and HR were monitored in seven patients who underwent bronchoscopy with the modified mask (IRB no. T2022-0096.). All the patients provided written informed consent.

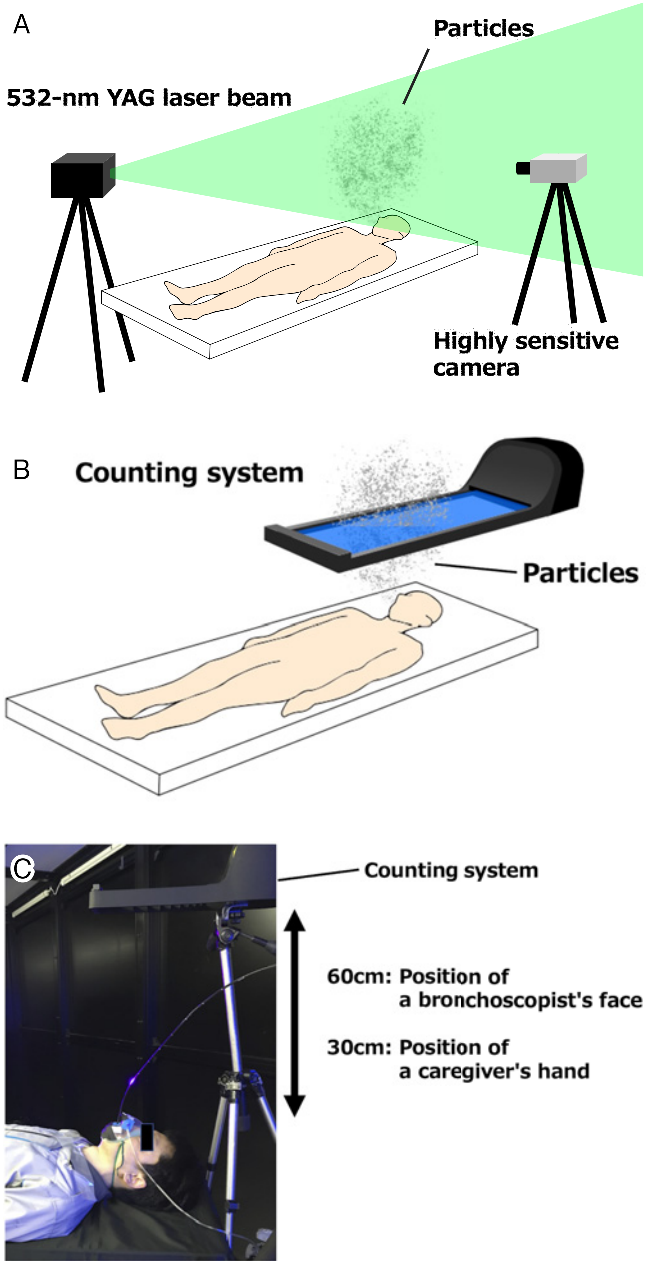

Figure 2. Images of the particle visualization system, "Parallel Eye H," was a unique light source for visualization to ensure a highly sensitive evaluation of suspended particles (A). Images of the particle counting system, "Type-S," integrated a light source and an image sensor to visualize and count particles passing through the visualization area in real-time (B). Configuration image showing the measurement of cough-generated aerosols and droplets at 30 cm (caregiver's hand) and 60 cm (bronchoscopist's face) using the Type-S device, with comparisons of mask efficacy (C).

Results

Assessment of the modified mask for preventing the spread of aerosols and droplets

1. Visualizing test for aerosol spread in the human model

Aerosol dispersion in the human model was visualized using Parallel Eye H and an oil mist generator. The model was sprayed without a mask as a control. Then, the effect of a surgical mask and a modified mask on aerosol spread was assessed using Parallel Eye H.

This study investigated whether aerosol dispersion could be reduced using nonwoven and modified masks. In the control, the aerosol spread was high in the vertical direction. In the human model wearing a nonwoven surgical mask, aerosols leaked from the head and tail sides of the mask and spread vertically. However, the aerosol did not leak from the mask when the human model with the modified mask was placed under a bronchoscope (**Figure 3A, B and C**). These results suggest that patient-derived aerosols did not leak outside the modified mask during the bronchoscopy examination.

2. Visualizing test for spread of droplets or aerosol from the human participant

After visualizing aerosol dispersion with Parallel Eye H and an oil mist generator, we extended our assessment to the human participant to further investigate droplet and aerosol suppression. We investigated whether nonwoven and modified masks could contain droplet and aerosol dispersion. When the participant coughed without a mask, droplets immediately dispersed while aerosols took a five-second delay. After coughing with a nonwoven surgical mask, droplets hardly dispersed and only a small amount of aerosol was observed in five seconds. When the participant coughed while the bronchoscope was inserted into the modified mask, a few droplets or aerosols escaped (**Figure 4A, B and C**).

3. Counting test for droplets and aerosols from the human participant

Next, we used Type-S to quantify droplets and aerosols from coughs, measuring at 30 and 60 cm from the participant's mouth with and without a modified mask, to simulate physician exposure during bronchoscopy. We verified the effectiveness of the modified masks in suppressing the number of droplets and aerosols generated when the participant coughed during bronchoscopy. When the participant coughed without masks, the number of droplets and aerosols was 2556 and 2552 at 30 and 60 cm, respectively. In contrast, the numbers measured using the modified mask were 68 and 39 at 30 and 60 cm, respectively. The measurement was conducted in a single trial. The results demonstrated that approximately 97% of the droplet and aerosol counts were suppressed by the modified masks at both heights (**Figure 5**).

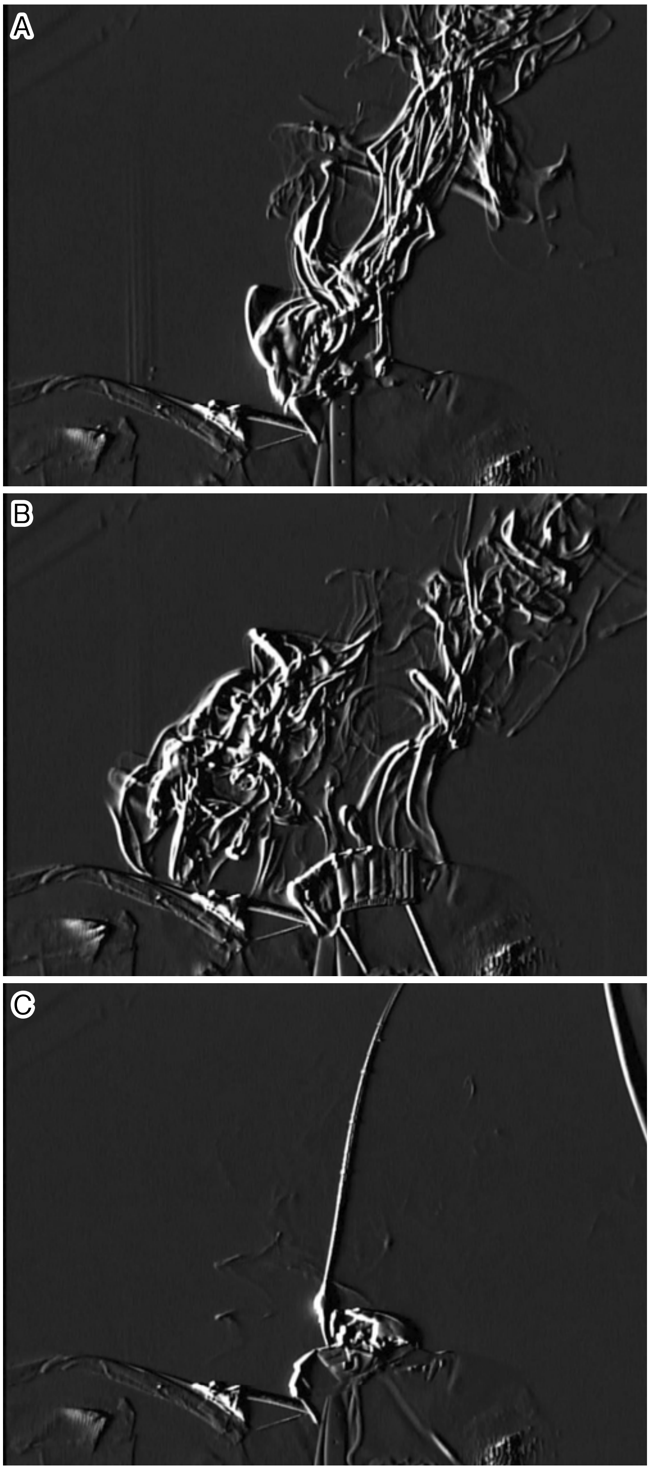

Figure 3. Visualizing test for aerosol spread in the human model. In the human model without the mask, the aerosol was observed to spread high in the vertical direction (A). Aerosols leaked from the head and tail sides of the mask, with vertical spread in the model wearing the nonwoven surgical mask (B). Aerosols did not leak out of the mask when the human model with the modified mask was placed using a bronchoscope (C).

Evaluating the safety of wearing the modified mask

The safety of the modified mask was evaluated by monitoring the $EtCO_2$, SpO_2, and HR in a healthy volunteer. We first monitored the participant's $EtCO_2$, SpO_2, and HR without an oxygen supply every 5 min for 15 min when the participant was placed in a modified mask with a bronchoscope inserted. At 10-15 minutes, the $EtCO_2$ of the participant was 41 mmHg, with a 33% increase; their HR was 84 bpm,

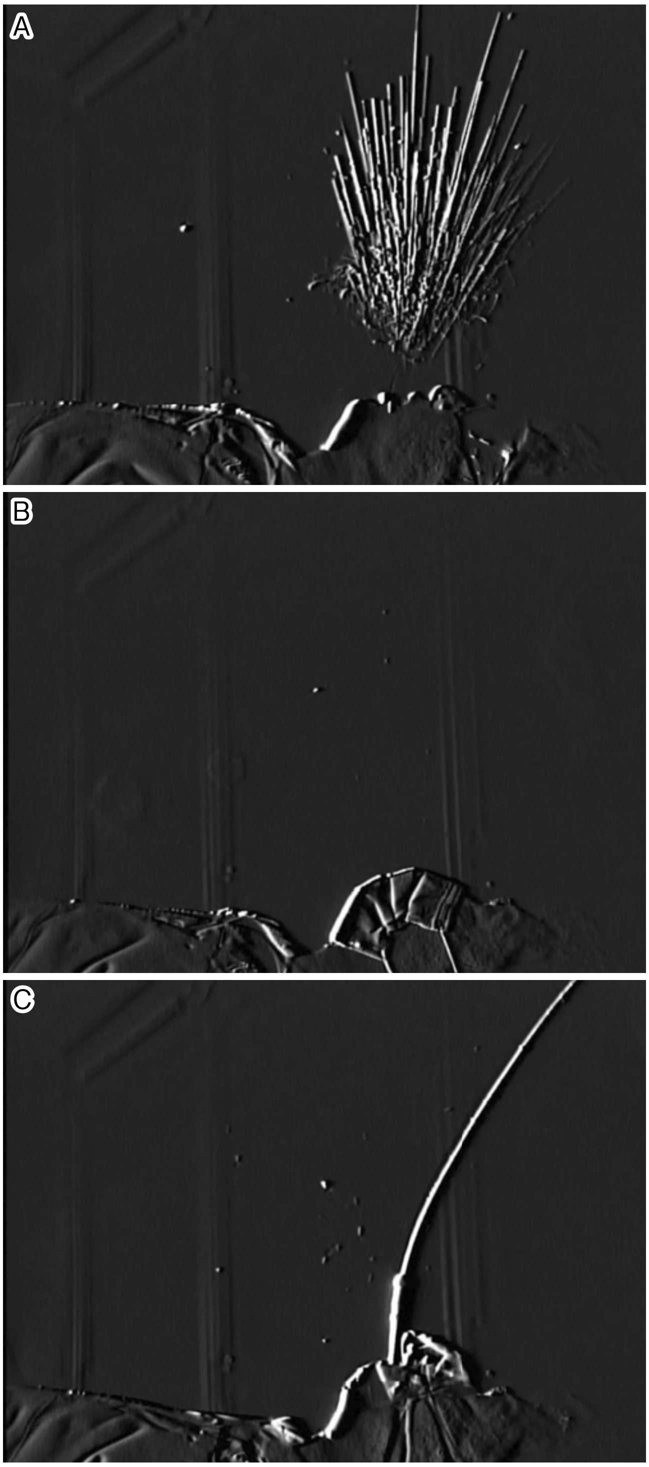

Figure 4. Visualizing test for droplet or aerosol spread from the human participant. Droplets spread when the participant coughed without a mask (A). Droplets rarely spread after the participant coughed with a nonwoven surgical mask (B). A minimal quantity of droplets or aerosols escaped from the mask when the participant coughed while the bronchoscope was inserted into the modified mask (C).

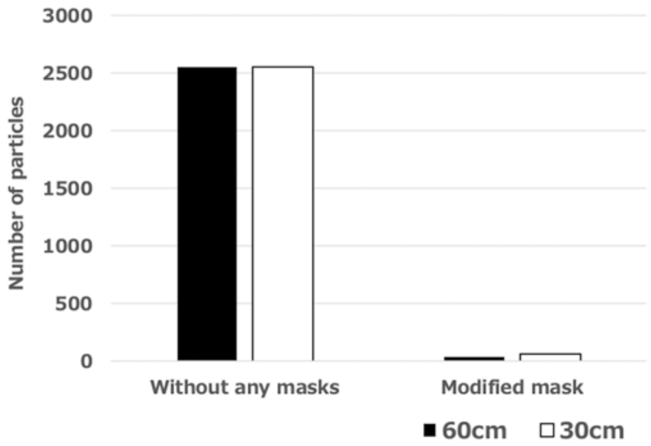

Figure 5. Comparison of the number of droplets and aerosols emitted from the participant. The number of droplets and aerosols were measured as 2556 and 2552 at 30 cm and 60 cm, respectively, when the participant coughed without any mask. The number measured with the modified mask was 68 and 39 at 30 cm and 60 cm, respectively.

which increased by 7%; and their SpO_2 was 97%, which decreased by 2% (**Figure 6A**). The participant did not exhibit any symptoms during the experiment. Next, we conducted the same experiment, in which the participant was supplied with oxygen at a flow rate of 2 liters per minute. At 15 min, the $EtCO_2$ of the participant was 35 mmHg, with a 20% increase; their HR was 74 bpm, which increased by 7%; and SpO_2 was 100%, which was unchanged (**Figure 6B**). The participant did not experience dyspnea during the experiment. These results indicate that the modified mask is safe for use with an oxygen supply.

$EtCO_2$ and SpO_2 were monitored in seven patients wearing modified masks with oxygenation at a flow rate of 3 liters per minute when they underwent bronchoscopy. Among the seven patients, five were males and two were females, with a median age of 76 years (range: 34-85 years). Six had a smoking history, and five presented with pulmonary emphysema. All cases underwent TBLB, EBUS-TBNA, or both. In **Figure 6C**, the mean and standard deviations of the $EtCO_2$ and SpO_2 are shown at 5-minute intervals for up to 30 min during bronchoscopy. The SpO_2 level did not decrease over time, remaining above 95% at all times. Meanwhile, the mean $EtCO_2$ was 33.6 during insertion, gradually decreasing to <30.0 without any symptoms. These results suggest that using oxygen masks is safe during bronchoscopy, with no evidence of elevated $EtCO_2$ or decreased SpO_2.

Discussion

We evaluated the exposure level of healthcare workers and the safety of wearing a modified oxygen mask during bronchoscopy to control the spread of droplets and aerosols from patients. In this study, we visually and quantitatively evaluated the suppression of droplet and aerosol spread using modified masks. In addition, we assessed the SpO_2 and $EtCO_2$ levels for safety using a modified mask. This study suggested that modified masks would be safe when using oxygen during bronchoscopy because they would reduce the diffusion of droplets and aerosols and maintain the $EtCO_2$ and SpO_2 values.

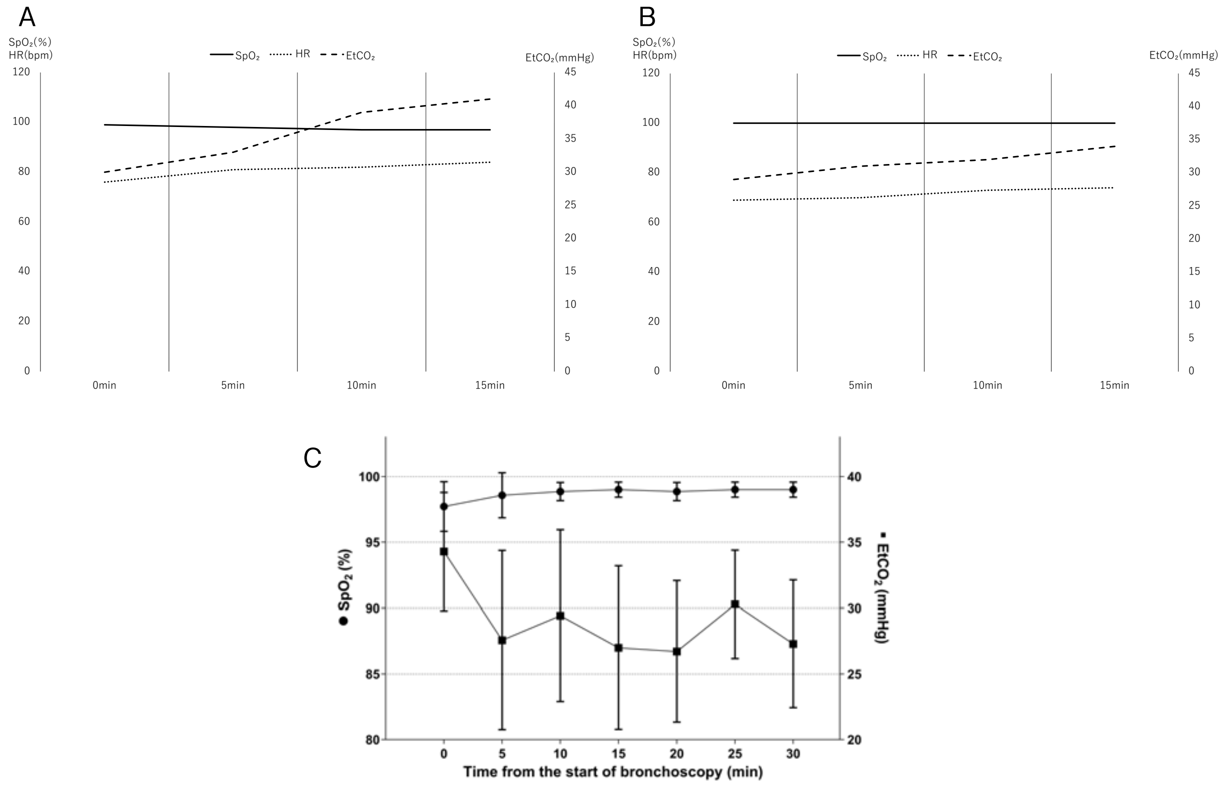

Figure 6. Graphs depicting the heart rate (HR), percutaneous oxygen saturation (SpO_2), and end-tidal carbon dioxide ($EtCO_2$) were monitored during bronchoscopy. The HR, SpO_2, and $EtCO_2$ values are presented while the participant underwent bronchoscopy wearing the modified mask without oxygen supply (A). The HR, SpO_2, and $EtCO_2$ values were shown, while the participant underwent bronchoscopy wearing the modified mask with 2 liters per minute of oxygen supplied (B). The mean and the standard deviation of $EtCO_2$ and SpO_2 are shown in seven patients wearing the modified masks with oxygenation at a flow rate of 3 liters per minute during bronchoscopy (C).

To prevent healthcare workers from being exposed to droplets and aerosols, wearing PPE during bronchoscopy was recommended before the COVID-19 pandemic; nevertheless, many guidelines and consensus statements have been published since the COVID-19 pandemic[8,13-16]. The Centers for Disease Control and Prevention statement in 2007 recommended healthcare workers to wear a face shield, a mask with an attached shield, or a mask and goggles along with gloves and gowns, during aerosol-generating procedures, such as bronchoscopy. Recent reports have demonstrated that PPE should be worn at the beginning of bronchoscopy. PPE includes gowns, masks, eye shields, gloves, and disposable caps. Performing hand hygiene is essential before donning and after doffing PPE. Furthermore, several reports exist regarding patients wearing masks to prevent droplet and aerosol dispersion, in addition to healthcare workers wearing PPE to protect themselves[9,10,17]. The study by Yasui and Ito demonstrated significant effectiveness in preventing dispersion using a surgical mask with holes, supported by video evidence captured with a high-speed camera[9,17]. However, concerns arise regarding the obscured view of the mask's lower portion, including potential interference with the suction of mucus and saliva from the oral cavity and durability issues during prolonged bronchoscopies.

Virus- or bacteria-containing particles, such as aerosols and droplets, can transmit infections. Generally, aerosols are <0.5 μm, and droplets are 1-1000 μm in size. The Food and Drug Administration has cleared surgical masks for use by testing particulate and bacterial filtration efficiencies, including other tests. This study confirmed that aerosols leaked from around the surgical mask, and a plume of exhaled breath was emitted from the patient, although this was expected for patients without masks. Such potentially infectious plumes could be directed toward healthcare workers at the facial level. The area of the plume can be expanded by breathing flows or when the exhalation flow also increases with coughing or sneezing. Since viruses, such as SARS-CoV-2, are also embedded in aerosols of <0.5 μm in diameter[18], aerosols can stick to the PPE of a healthcare worker. Moreover, when bronchoscopy is performed on a patient suspected of having pulmonary tuberculosis, *Mycobacterium tuberculosis* is present via infectious droplet nuclei in particles less than 5 μm in size, while the droplets remain suspended in the air[19]. Therefore, bronchoscopists should wear fit-tested N95 particulate respirators to minimize the risk of undetermined infections.

Using the newly modified oxygen mask to suppress aerosols and droplets during bronchoscopy effectively prevented infection. When a patient wears a surgical mask for examination, particles leak during exhalation owing to the distance between the mask and the patient's mouth, while it blocks the patient's mouth during inhalation. The newly developed mask has a stable shape that does not deform during patient inhalation and exhalation and allows sufficient oxygen supply and CO_2 emission while minimizing the risk of infection due to particle dispersal.

This study had several limitations. First, this was a single-center study and not a randomized control trial, making it difficult to exclude clinical differences in the baseline characteristics. Second, the study had a small sample size, enrolling only seven patients, limiting the generalizability of the findings. Finally, although this study demonstrated the efficacy of newly developed masks against aerosols generated by spray generators and test models, their effectiveness against bioaerosols containing viruses and other pathogenic microorganisms was not investigated. Future studies should address these limitations by including large and diverse patient populations.

This study successfully demonstrated that the newly modified oxygen mask effectively reduced aerosol and droplet dispersion during bronchoscopy, thereby reducing the potential infection risk. Safety assessments indicated that the mask was safe without significantly affecting the $EtCO_2$ or SpO_2 levels. Considering the potential for asymptomatic individuals to transmit infections, such as SARS-CoV-2, this study advocates the universal use of such masks during bronchoscopy to protect healthcare workers and patients from airborne transmission. Lastly, large randomized trials are warranted to confirm these findings.

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Conflicts of Interest: There are no conflicts of interest.

Statement of Ethics: The study protocol was reviewed and approved by the Institutional Review Board of Tokyo Medical University (approval number: T2022-0096).

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