Leak-Testing of an Endoscopic Aerosol Box for Preventing SARS-CoV-2 Infection during Upper Gastrointestinal Endoscopy

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ABSTRACT

Objective: The SARS-CoV-2 virus has infected many healthcare professionals. Endoscopy is an aerosol-generating procedure and the endoscopy team is at risk of exposure and infection. We describe the leak-testing of an aerosol box that uses a glove-covering for the endoscope.

Materials and Methods: An endoscopic aerosol box with a glove-covering over the endoscope was made for gastroscopy, EUS and ERCP procedures and was tested for leakage of aerosol/airborne particles. Fine particulate matter (PM) from burnt incense sticks was used as a model for viral aerosol. The leakage from the box was measured by comparing readings from 2 PM light-scattering sensors, one placed inside the box and the other just outside the glove opening in a sealed container. Negative pressure conditions were also used to see if this had any effect on the leakage.

Results: The concentration levels of the particulate matter differed with different negative pressure conditions and movement of the endoscope through the glove. Very little leakage was seen with the endoscope stationary even with no negative pressure, at 2.4%, 0.17% and 0.07% for PM1, PM2.5 and PM10, respectively. The maximum leakage was 14% for PM1, 8.7% for PM2.5 and 2.6% for PM10 in the moving-endoscope condition and no negative pressure. This reduced to 6.2%, 1.3% and 0.37% respectively when suction was applied at full strength (negative pressure of -0.05 bar).

Conclusion: The glove covering significantly reduced the passage of particles. The particulate leak was seen most with the smallest particles and reached 14% for PM1 without negative pressure. This reduced to 6.2% with maximum negative pressure using the wall suction.

Keywords: SARS-CoV-2, Endoscopy; aerosol; barrier; aerosol generating procedure (Siriraj Med J 2021; 73: 702-709)

INTRODUCTION

The current SARS-CoV-2 pandemic has caused worldwide social and economic disruption and death. The SARS-CoV-2 virus causes gastrointestinal symptoms[1] and has been found in the gastrointestinal tract[2-4] and oral mucosa.[5] There is a risk that the virus may aerosolize during upper GI endoscopy[6], putting the endoscopy staff at risk of infection. International guidelines have recommended, amongst other things, postponing routine procedure, screening patients and wearing appropriate

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personal protective equipment (PPE) during the endoscopic procedure.[7,8] However, guidelines have not recommended the use of any additional barrier methods other than PPE in preventing aerosolized droplet spreading to the endoscopist.

A similar concern for the infection risk from aerosolized droplets has arisen during intubation and extubation of endotracheal tubes for COVID-19 positive patients and a report has suggested that an "aerosol box" can limit the aerosol exposure of the anesthetist during endotracheal tube manipulation.[9] A similar aerosol box has recently been proposed for use in upper GI endoscopy to prevent aerosol exposure of the endoscopist.[10] More recently another report has described an adaptation of the aerosol box by using a glove covering for the endoscope as it enters the box.[11]

Our upper GI endoscopy aerosol box is an adaptation of the aerosol box described above, made specifically for upper GI endoscopy. Although the core concept of our aerosol box is similar in the use of a glove-covering for the endoscope, we had designed it prior to seeing the report above and have some differences to the design. In this report we describe our design of the endoscopic aerosol box and the results of leak testing from the box using fine particulate matter (PM1, PM2.5, PM10) as a model for viral aerosol particles.

METHODS AND MATERIALS

The aerosol endoscopic box used in this study was designed, tested and produced using transparent acrylic plastic material (Fig 1) prior to seeing the reports from Japan.[10,11] The essential component of the adapted aerosol box in this study is the opening through which the scope is passed. The opening uses a rubber glove to cover the endoscope to prevent viral aerosol and droplets from reaching the endoscopist. The adapted aerosol box has a round opening with raised rounded edges with a diameter of 9 cm specifically made so that the rubber glove may be stretched over and attached to it (Fig 1). This opening is on a separate acrylic plate that can be slid into a slot on the main aerosol box (Figs 1 & 2). Three plates, each with the opening at a different position on the plate, are available for use with each endoscopic aerosol box, so that the position of the opening can be adjusted to be opposite the mouth of each patient.

To use the rubber glove as a covering for the endoscope, a small cut is made in one of the finger-ends of the glove, through which the endoscope could be passed (Figs 3 & 4). The size of the glove can be varied depending the diameter of the scope. During the procedure, the scope has room to maneuver as the opening of the box where the glove is attached to is 9 cm in diameter. As the scope is removed at the end of the procedure, the glove finger can be pinched to prevent leakage and another glove can be placed over the opening to seal off any possible aerosol leak once the endoscope is completely removed. The glove(s) can then be removed and disposed appropriately at the end of the procedure. The other sides of the box have openings which can be opened and closed, to be used for reaching into the box as necessary, while the pedal side of the box (where the patient's body extends) can be covered with a waterproof material that is attached to the box and sealed around the patient (see example in Fig 2 below).

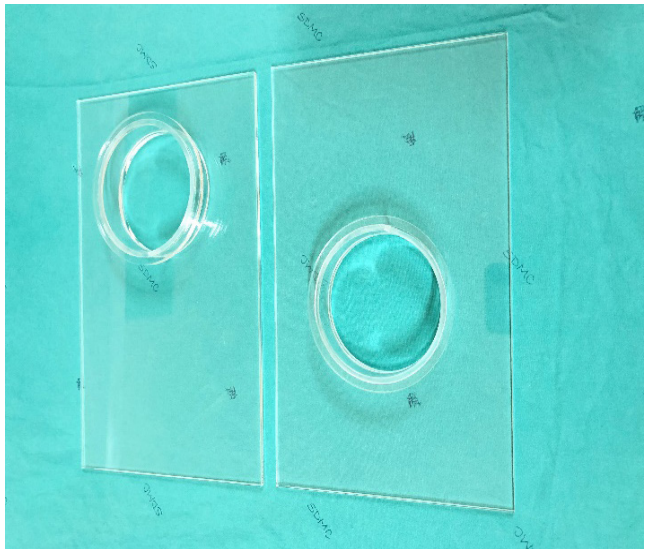

Fig 1. Acrylic plates with the opening for the glove cover at different positions.

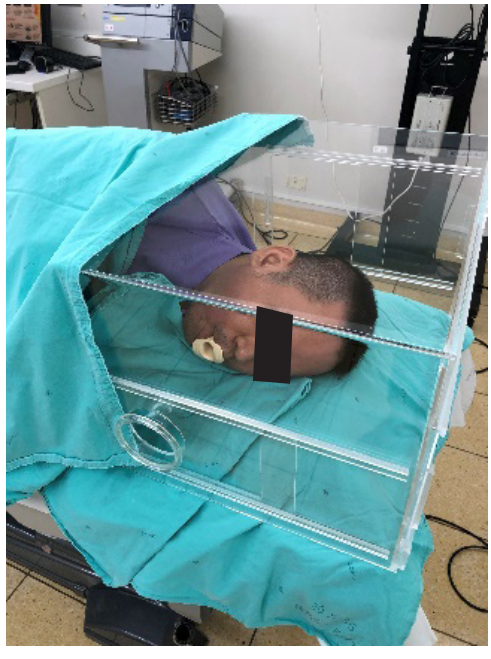

Fig 2. The transparent endoscopic aerosol box, showing the opening for the scope (An endoscopy unit staff is modeling as the patient).

Fig 3. The endoscope passing through the cut end of the finger of the glove.

Fig 4. The insertion of the endoscope through the glove when attached to the opening of the endoscopic aerosol box. (An endoscopy unit staff is modeling as a patient).

The adapted aerosol box also has other smaller openings to allow various tubes to pass through (but can be closed if not used). It has a separate smaller hole through which a rubber tube can be inserted and negative pressure applied using an additional wall suction. In our experiment, two modes were used, regular and high suction modes, producing pressures of -190 mmHg and -280 mmHg respectively. This tube, which could be attached to a ventilator HEPA filter, is used to suck out the air inside the box and remove both the carbon dioxide and viral aerosol from the box. There is also another opening through which the ventilator's corrugated tube can pass in cases where the patient is intubated.

The design of the box is shown in the supplemental materials.

The endoscopic aerosol box was tested for leakage of fine particulate matters (PM1, PM2.5, PM10) produced from burning a commercially available incense stick inside the endoscopy aerosol box. This was used as a model for viral particles. In order to monitor the leakage characteristics of the box, the testing method similar to that done by Ng et al.[12] was adapted. The leaked fine particulate matter was measured with an optical sensor (PMS7003 G7 sensor Module Air Particle dust laser sensor) capable of scattering and absorbance measurements of light to target in situ sensing of fine particulate matter. The sensing system had the capability to measure the averaged concentration of particulate matter sized 1.0 mm, 2.5 mm and 10 mm. One sensor was placed in the endoscopic aerosol box with the burning incensing stick and another was placed in a sealed container attached to the endoscope-glove-opening of the box to measure the percentage leakage of the particulate matter through the opening. The sealed container prevented entry of fine particulate matter from the ambient environment which would distort the readings of the leaked PM from the box. The concentration of the particulate matter was measured simultaneously and at the steady state, defined as no progressive increase or decrease in concentration over 2 mins of observation.

The light scattering sensor was also able to measure the ambient pressure and this was used to measure the level of negative pressure achieved in the box at different levels of wall suction (no suction, regular suction, high suction). An Arduino UNO was used as an interface between a computer and the sensing system. The data acquisition was performed through a serial communication application that was developed within the Arduino platform. Due to the sealed container holding the PM sensor, an actual endoscope could not be passed through the glove and a large pen with a similar diameter to a gastroscope was used in its stead. The attached glove was cut at the fingertip and the pen was passed through the cut opening connecting the inside of the aerosol box to the sealed container holding the sensor. The PM leakage was measured when the pen in a stationary position, and also when the pen was moved vigorously (to mimic movement of the endoscope), and at different levels of suction/negative pressure within the box. The ambient leakage of the particulate matter was also measured near the other openings on the side of the box closest to the patient's vertex, through which the corrugated tubes leading to the ventilator would pass. The PM sensors would measure the three PM levels every second and record these in the computer.

The set up for the PM leakage test is shown in Fig 5.

The study was approved by the local ethics committee of the hospital (COA. MURA2020/799) on the 14th May 2020

Fig 5. The set up for testing PM leakage from the opening with glove attached. The burning incense stick can be seen in the endoscopic aerosol box and the two PM sensors are placed inside the aerosol box and the sealed compartment attached to the endoscope-glove opening respectively.

Statistical analysis

Statistical analysis was performed using SPSS Statistics by IBM version 25. Continuous variables with normal distribution were expressed as mean (standard deviation) and analyzed with student T-test. Paired t-tests and Pearson correlation were performed to compare the leakage rates using different suction pressures within the endoscopic aerosol box.

RESULTS

The overall averaged concentrations of PM 1.0, 2.5 and 10 inside the chamber (n=14, $p<0.05$) were found to be 140 μg/m^3, 2,134 μg/m^3 and 6,089 μg/m^3 respectively.

Tests were conducted at different pressure conditions to identify the role of pressure/suction on the concentration of particulate matter in the chamber and the effects in controlling the leakage. The results are shown in Table 1. As can be seen from the table, negative pressures produced by wall suction reduced the PM concentration in the chamber, particularly PM1 and PM10.

To determine the rate of leakage from the chamber, paired t-test was conducted on the set of raw data measured from the chamber and the target location corresponding to the different testing scenario. The results are tabulated below in Table 2. Thus the leakage was calculated as a percentage of the averaged concentration in the endoscopic aerosol box.

Very little leakage occurred when the pen was stationary, with PM1 leak of 2.4%, PM2.5 0.17% and PM10 leak of 0.07%. There was no detectable leakage when the pen was stationary and the suction was on. The highest leakage of 14% was recorded the pen was moved vigorously in the glove without any suction pressure. But the averaged concentration of leaked PM1 decreased subsequently to 8.9% and 6.2% when negative suction pressure was increased from zero to -0.01 and -0.05 bar respectively. A similar trend was observed in the ambient leakage test. Another trend was evident regarding the size of the particles; the leakage was higher for smaller particle size.

The effect of pressure on leakage can also be comprehended from a Pearson-correlation test which correlated between the pressure and PM concentration levels as shown in Table 3 below.

TABLE 1. Concentration of particulate matter for each pressure condition at stable state.

Pressure (bar)	Concentration of Particulate Matter inside Chamber at Stable condition(μg/m^3)		
	PM1.0	PM2.5	PM10
0	210.53 (SD=12.46 CV=0.059)	2531.7 (SD=85.5 CV=0.03)	10792.8 (SD=408.5 CV=0.03)
-0.01	148.5 (SD=12.44 CV=0.08)	2312.01 (SD=213.1 CV=0.09)	6662.2 (SD=562.6 CV=0.08)
-0.05	96.3 (SD=8.67 CV=0.09)	2298.4 (SD=155.99 CV=0.067)	3831.817 (SD=491.9 CV=0.12)

Abbreviations: SD= standard deviation, CV= Coefficient of Variation.

TABLE 2. The percentage of particulate matter leak from the averaged PM level in the endoscopic aerosol box for each pressure level

		Leakage %		
	Chamber Gauge Pressure(bar)	PM1	PM2.5	PM10
Without Moving pen	0	2.4	0.17	0.07
	-0.01	0	0	0
	-0.05	0	0	0
Moving pen	0	14	8.7	2.6
	-0.01	8.9	1.5	0.75
	-0.05	6.2	1.3	0.37
Ambient Leakage	0	9.6	7.6	3.7
	-0.01	3.2	0.6	0.4
	-0.05	2.4	0.4	0.2

TABLE 3. The effect of pressure on PM leakage

	Pressure	Pm1.0	PM2.5	PM10	
Pressure	Pearson Correlation	1	.434	.481	.501
	Sig. (2-tailed)		.243	.190	.170
	N	9	9	9	9

When the incense stick was removed from the box, the rate of reduction of the fine particulate matter inside the box, with the wall suction at -0.05 bar, is shown in Fig 7. As can be seen from the graph, it took approximately 2 mins, using the high suction mode, for the PM10 concentration to decrease by 50%.

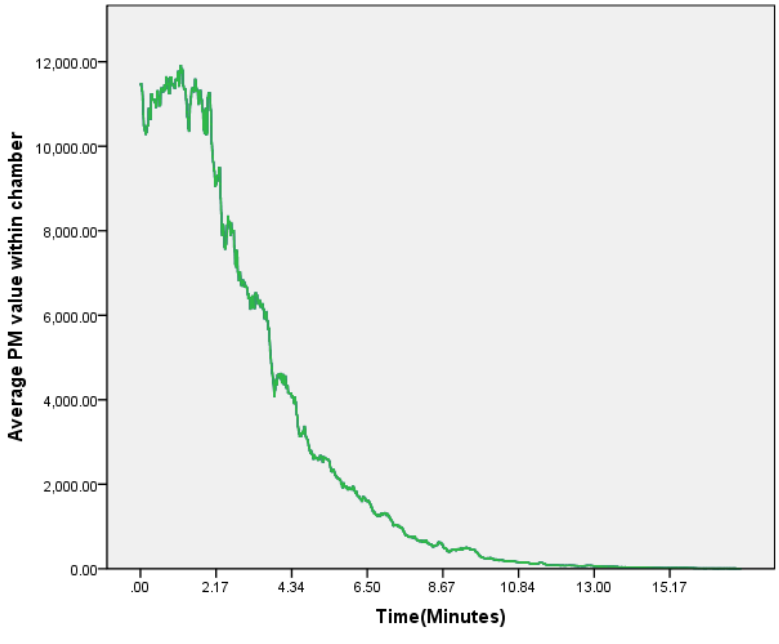

Fig 7. The rate of reduction of PM10 within the box with aspiration of the air inside using full strength wall suction.

DISCUSSION

The SARS-CoV-2 virus has infected many healthcare workers[13,14] and is transmitted by aerosols and droplets.[15] It has also been found in the buccal mucosa and the gastrointestinal tract.[2,4,5] Gastroscopy and EUS/ERCP are thought to be at-risk procedures because of aerosol generation from the patient.[6] For protection various endoscopic societies have recommended endoscopists wear PPE for protection.[7,8] Here we report the evaluation of an endoscopic aerosol box using a glove-cover opening, which was designed to decrease aerosol exposure to the endoscopist.

Previously an aerosol box for endoscopy has been reported, similar in design to that suggested for intubation by anaesthetists, with just a hole for the endoscope to pass through. However, there is a concern that the virus may be airborne and much smaller particles are produced by the patient[16] and therefore the risk of exposure may not be solely from the spray of large particles. Another recent report in fact raised the concern that these 'open' aerosol boxes may actually increase the exposure for medical personnel to the virus.[17] An endoscopic aerosol box barrier with a glove-covering for the endoscope may thus be a solution to reduce the exposure of viruses to the endoscopist, both from direct spray of large particles and leakage of smaller particles from the box.

Although there has been an earlier publication describing an aerosol endoscopy box using a glove-covering for the endoscope[11], our aerosol box was designed independently and our study was performed before seeing the publication. Our aerosol box design also varied in some ways from the prior published design. Our aerosol box used a different method to attach the glove, had sliding doors/ openings which could be used to pass tubes or for assistants to insert their hands to help the patient if necessary, and our aerosol box was also smaller in design so that it would be easier to close off the open side where the patient's body protruded, to prevent small particulate matter/aerosol leak, rather than just preventing direct spray from the patient's mouth.

We tested the passage of fine particulate matter of different sizes leaking through the glove-covering of our aerosol box. Although previous articles have demonstrated visually that such a design may decrease the amount of sprayed droplets from patients[10,11], we quantified the amount of leakage of small particles of different sizes. The different sizes of the particulate matter used in our experiment was used to demonstrate the different levels of leakage of SARS-CoV-2 virus particles depending on their size, as there is a concern that viral particles are produced from infected patients in a variety of sizes.[16] This leakage is likely to be more pronounced in 'open' aerosol boxes.

Our results demonstrated that there was very little leakage of PM of all sizes when the glove covering was used and pen/endoscope model was stationary (2.4%, 0.7% and 0.17% for PM1, PM2, PM10 in the no suction group respectively, and no leakage when suction was switched on), but this increased when the pen was moved vigorously. The results also demonstrated that smaller particles leaked more than larger particles. The percent leakage was 14%, 8.7% and 2.6% for PM1, PM2.5 and PM10 respectively, when measured in the worst condition, namely vigorous movement of the pen with no suction applied. The leakage was reduced when the suction was turned on and negative pressure was applied through a rubber tube inserted into the box. The leakage dropped to 6.2%, 1.3% and 0.37% for PM1, PM2.5 and PM10, respectively. We suspect that this situation would be closest to clinical practice, and this would therefore mean than the glove-covering, along with wall suction, would help reduce the exposure of approximately 93.8%, 98.7% and 99.6% of exhaled aerosol with approximate sizes of PM1, PM2, PM10, respectively, for the endoscopist during the procedure. We also demonstrated that the wall suction, commonly used for aspirating saliva during an endoscopic procedure, when used to suck out the air in the endoscopic aerosol box, was able to reduce the PM level by 50% over an interval of approximately 2 minutes. The use of the pen as a model for the endoscopy was necessary to keep the particulate matter inside the container for analysis. However, during the testing of our model, we wiggled the pen very vigorously, much more than an endoscope would normally be moved in a procedure done by an expert. Consequently, we think that our results cover the range of leakage that would be seen in a normal gastroscopy. In a separate on-going study, the use of the box (in non-COVID-19 patients) was not difficult for expert endoscopists, and the movement of scope was not thought to be limited nor need to be specifically adapted for the glove covering. The normal endoscopic movements in and out of the glove in a straight path would minimize the aerosol leakage from the covering.

The glove covering set-up for our aerosol box could be used repeatedly with cheap and commonly available materials. It also allowed flexibility of movement of the scope during the procedure whilst also preventing viral aerosol directly reaching the endoscopist. A report has suggested that uncovered openings of the aerosol/intubation boxes actually increase the risk of airborne exposure from the patient.[17] Although we did not directly compare with

other aerosol box models, our glove-covering model for the endoscopy should decrease exposure from both the direct spray of large particle aerosols, and the leakage of smaller airborne particles from the patient in comparison to uncovered intubation boxes. Although in our model we used the rubber gloves available in our endoscopic unit as it was cheap and easily available, other gloves, such as latex-allergy gloves could be used. Theoretically other elastic materials could also be used as the endoscope cover, but we thought that general availability and cost of the material would be important in the situation of the pandemic, so we did not try to test other materials in our model.

We also note that another group has suggested using an anesthetic mask to prevent aerosol droplet spread during the endoscopic procedure.[18] We think that our endoscopic aerosol box allows more flexibility for the endoscopist in two ways. Firstly, larger endoscopes, such as those used for endoscopic ultrasound or ERCP with stent removal, may be more easily manipulated using our endoscopic aerosol box, as the opening size can be varied as needed. Secondly, the box can easily be used for the intubated patient, in comparison to the anesthetic mask which would impede the endotracheal tube. This may be particularly pertinent for the patient with COVID-19 who may have problems with oxygenation or in cases with variceal bleeding who require intubation.

In comparison to a box with a single uncovered hole for the scope, as suggested by Sagami et al[10], we think that our design is also more flexible. The positioning of the opening hole and scope can be adjusted to different patient size and anatomy, as well as the opening can be adapted for endoscopes of differing sizes. As mentioned previously, Kagami et al. reported the use of the glove-covering for an endoscopic aerosol box.[11] Their design appears to be slightly different to ours, and as their design has only been reported briefly, so we are unable to see if there is any practical difference compared with our design.

We have used the endoscopic aerosol box in our unit on patients for EGD, ERCP and EUS without any complications. However, because Thailand had managed to control the initial spread in the country well, and testing was limited to symptomatic or high-risk patients, we did not have any confirmed COVID-19 infected patients to use the aerosol endoscopic box on. Nevertheless, we feel that the box is a useful equipment to improve the safety of the endoscopy team, and we wanted to report and share the design of the endoscopic aerosol box for other endoscopists to use in view of the ongoing infection from SARS-CoV-2 virus in many countries. The design can be seen in the supplementary data, and can be copied and used without asking for further permission. Some adaptation and change in size of the box may be required for the larger Caucasian and African population. In the future the glove-covered aerosol box may be useful for endoscopy of patients with risk of other infections such as patients with active tuberculosis.

The main limitation of this study was that the use of fine particulate matter from burning an incense stick, as a model for viral aerosol, may not have been identical to real-life conditions as the concentration from the incense stick did not fluctuate with respiration or coughing. Further testing with models that are closer to human respiration/coughing would be useful to confirm the benefit of the box and the level of particle leakage from the box. Also, we could not measure the leakage of particles at the time of removal of the box for cleaning. We do not know if endoscopy assistants would be at increased risk during the removal of the box and during cleaning or not. However, the endoscopic aerosol box is easily cleaned by wiping with 75-90% alcohol solution and washing with liquid soap.

CONCLUSION

An endoscopic aerosol box using a glove-cover for the endoscope decreased the leakage of fine particles of various sizes substantially. The addition of negative pressure to remove the air inside the box using standard wall suction decreases this leak even further. The combination of the endoscopic aerosol box with a glove cover and in-box suction would decrease the risk of infection from COVID-19 infected patients for the endoscopist and other team members. The box may be replicated and used in areas with high COVID-19 prevalence to reduce the transmission to healthcare staff during endoscopy.

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Supplemental material: Design specifications of the endoscopic aerosol box.

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