Original Research Article

SAGE Open Medicine

SAGE Open Medicine
Volume 9: 1–8

DOI: 10.1177/20503121211047060
journals.sagepub.com/home/smo
SAGE

A mask-based infection control method for screening endoscopy may prevent SARS-CoV-2 transmission and relieve staff anxiety

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Abstract

Objectives: Endoscopy confers high risk for acquiring coronavirus disease 2019. Although guidelines recommend that medical staff use personal protective equipment, no infection control equipment have been established for patients. This study aimed to clarify the usefulness of two face masks we had designed for transnasal and transoral endoscopy.

Methods: The efficacy of the masks was evaluated by simulating coughing in a mannequin with fluorescent dyes and mapping the droplet trajectory and number. The number of aerosols generated during endoscopy was clinically evaluated in the endoscopy room. Overall, 4356 screening endoscopies were performed with the patients wearing our masks at Medcity21, a health checkup facility, between June and December 2020; the effects of the masks on the patient's condition were evaluated retrospectively. An 11-item paper-based survey was performed by the endoscopy staff 6 months after the adoption of the mask-based infection control method.

Results: Use of both masks reduced the number of droplets released during the simulation. Clinically, the use of both masks did not affect the patients' conditions during endoscopy and prevented an increase in the aerosols in the endoscopy room. This mask-based infection control method was favorably received, and all staff indicated that understanding the efficacy of our mask-based infection control reduced their anxiety regarding infection. Until December 2020, none of our staff had contracted SARS-CoV-2.

Conclusion: Our mask-based infection control method is easy to adopt, inexpensive, and effective; understanding its effectiveness may help ease the fear of infection among endoscopy staff.

Keywords

COVID-19, infection control, endoscopy, personal protective equipment

Date received: 20 April 2021; accepted: 31 August 2021

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Introduction

Coronavirus disease 2019 (COVID-19), caused by SARS-CoV-2 (a novel coronavirus), emerged in December 2019 and was declared a pandemic by the World Health Organization on 11 March 2020. Osaka, where our facility is located, is one of the endemic areas for COVID-19 in Japan and was placed under a mild lockdown from 7 April 2020 to 21 May 2020, that is, during the first wave of the disease.[1,2] The second wave of COVID-19 in Japan occurred in summer 2020, and the third wave hit Japan in December 2020; the fourth wave has recently ended in July 2021. Currently, 819,013 patients are COVID-19 positive in Japan, and 14,954 patients have died. In Osaka, 104,849 people have tested positive for COVID-19, and 2693 people have died.[3]

Endoscopy is considered a high-risk medical procedure for COVID-19, because droplets and aerosols are transmitted directly from the patient to the medical staff.[4,5] Many organizations, including the Japan Gastroenterological Endoscopy Society (JGES), recommend that non-urgent endoscopy be postponed in the interest of infection prevention during a COVID-19 outbreak.[6,7] Therefore, screening upper gastrointestinal (GI) endoscopy tends to be postponed, especially during the outbreak period.[8] After the first outbreak in Japan, in accordance with a novel infection control policy, screening upper GI endoscopy has gradually become available on a regular basis due to the importance of early detection of GI cancers. However, many patients infected with SARS-CoV-2 are prevalent in society.

As a novel infection control policy during endoscopy, the JGES recommends that medical staff use personal protective equipment (PPE) including masks, double gloves, long-sleeved fluid-impermeable gowns, goggles, and disposable hair caps.[6,9–11] Several groups are currently testing candidate infection control equipment for use by patients during endoscopy; some have suggested that barrier enclosures, such as aerosol boxes, are useful for preventing the dispersal of droplets and aerosols.[12,13] Others, including endoscope equipment manufacturers, are developing a novel cover for mounting during endoscopy. We have previously suggested the use of a surgical mask with a slit for endoscope insertion during oral endoscopy and a mask with an exposed nasal area for nasal endoscopy.[14] However, all methods have their advantages and disadvantages; while it is agreed that inhibiting the release of droplets from the patient could be effective in infection control, there is no consensus on which device should be worn by the patient during endoscopy.

Therefore, the aim of this study was to evaluate the usefulness of two types of patient-wearable masks during screening endoscopy, which we had designed; one covers the mouth, but exposes the nasal cavity for transnasal endoscopy (Figure 1(a)), and the other bears a slit for endoscope insertion during transoral endoscopy (Figure 1(b)). This study also focused on the effect of our mask-based infection control method on relieving COVID-19-related anxiety among medical staff.

Materials and methods

Patient masks for endoscopic procedures

For transnasal endoscopy, the patients wore masks that we had designed; to prevent saliva from accumulating in the mask and subsequent pulmonary aspiration, these masks were closed at the top, but not at the bottom. Furthermore, they covered the mouth, but exposed the nasal cavity for endoscope insertion (Mask of Abeno [N]; Figure 1(a) and (b)).

For oral endoscopy, the patients wore surgical masks that we had also designed; as described previously, these bore a slit for endoscope insertion after the patient wore the mouthpiece (Mask of Abeno [O]; Figure 1(c) and (d)).[15]

Evaluation of the efficacy of the masks by endoscopic simulation

We evaluated the efficacy of our designed masks using a mannequin for the oral and nasal insertion of a small-caliber endoscope (GIF-XP290N, Olympus, Japan). Cough was simulated using a 0.4 MPa pressure accumulation sprayer containing 10 mL of a fluorescent dye (Glitterbug Potion; Brevis Corporation, Salt Lake City, UT), as described previously.[13,14,16] The spread of the scattered dye droplets was visualized under ultraviolet light, and the droplet spreading status in each situation was evaluated thrice. For the purpose of comparison, an aerosol box was prepared; this was attached to a disposable plastic bag with a slit for endoscope insertion inside the framework (Figure 1(e)).

A survey questionnaire was administered to the staff after they watched the simulation. This questionnaire consisted of two questions: (1) "Did understanding the results of the simulation using our mask-based infection control methods reduce your anxiety about infection?" and (2) "Do you think that the medical staff should look at the results of the simulations to determine the effectiveness of the infection control procedures?"

New infection control policy for endoscopy in our institution

All screening endoscopies were performed in accordance with Japanese guidelines at Medcity21, a health checkup facility affiliated to the Osaka City University,[6] without sedation. Only patients with a low probability of contracting COVID-19 underwent screening endoscopy with the new infection control method.[6]

Before the patients entered our institution, they were (1) questioned on whether they had any close contact with a patient with confirmed or probable COVID-19 and (2) checked for symptoms associated with COVID-19, such as a high body temperature and low O_2 saturation. After admission to the institution, patient chest radiographs were checked for pulmonary lesions. In accordance with the Japanese guidelines, endoscopy was postponed for those who were

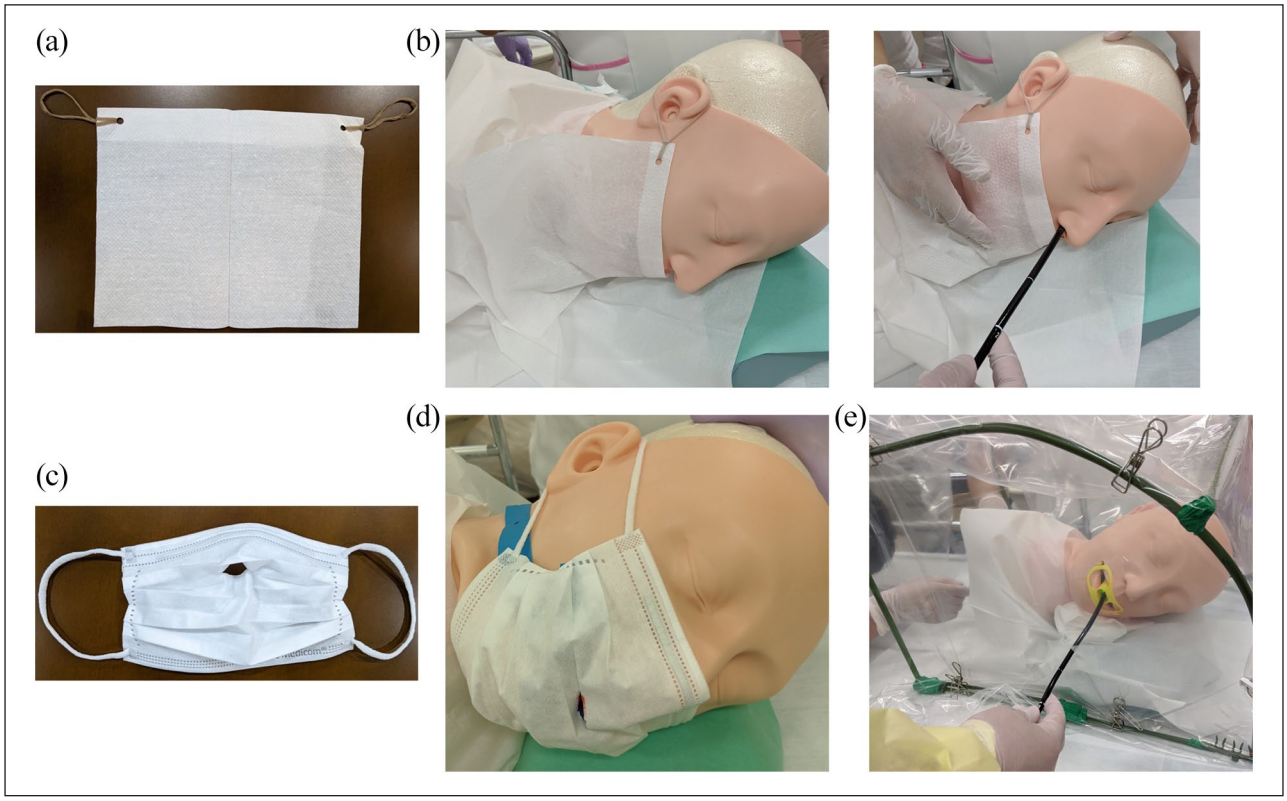

Figure 1. Details of the mask used during endoscopy. Infection control items worn by the patient were used during endoscopy. (a and b) For transnasal endoscopy, patients wore our designed masks that were closed at the top but not at the bottom, to prevent saliva from accumulating in the mask and subsequent suffocation. The mask covered the mouth, but exposed the nasal cavity for endoscope insertion (Mask of Abeno [N]). (c and d) For oral endoscopy, the patients wore a surgical mask with an endoscope insertion slit after wearing the mouthpiece (Mask of Abeno [O]). (e) The aerosol box was created by attaching a disposable plastic bag with a slit for endoscope insertion inside the framework.

symptomatic or reported possible exposure to COVID-19. The remaining patients were diagnosed with a low probability of COVID-19 and underwent endoscopy in the endoscopy room while wearing the designed masks[6,17] (Supplemental Figure 1).

In the endoscopy room, air purifiers with the HEPA filters (ACP-897CH, AIRTECH, Tokyo, Japan) were placed in front of the patient. Only one patient was brought into the endoscopy room at a time to limit contact between individuals, and the patient wore the personal mask for as long as possible. The decision to perform oral or nasal endoscopy was made in accordance with the patient's request, considering the nasal condition. Pretreatment, such as local anesthesia and pre-medication, was administered as per the standard procedure. Immediately prior to endoscopy, the patients replaced their personal masks by the previously described mask we had designed for endoscopy. After the endoscopy, the masks were replaced with personal masks.

Doctors and nurses wore surgical or N95 masks, double gloves, long-sleeved fluid-permeable gowns, face shields, disposable hair caps, scrubs, and endoscopy-specific shoes.

We have been performing endoscopy under this new COVID-19 control policy since June 2020 after the mild lockdown in our city.

Assessing the effects of our designed masks on patients during endoscopy by retrospective chart review

We conducted a retrospective medical chart review of all patients who underwent the endoscopy with our designed mask at Medcity21, between June 8 and December 11, approximately half a year. We retrospectively evaluated the effects of our designed mask on their condition, including their O_2 saturation and blood pressure, and their complaints during the endoscopic procedure; this was based on patient observation charts obtained from the medical records prepared during endoscopy.

Measurement of aerosols during endoscopy

The total number and variability of aerosols in the endoscopy room during the procedure were evaluated for eight randomly selected patients, who underwent oral and nasal endoscopy wearing our designed masks. Measurements were obtained using a portable HHPC6+ handheld particle counter (Beckman Coulter, Inc., USA). The six-channel particle sizes were programmed at 0.3, 0.5, 1, 2, 5, and 10 µm. This device can measure the particle counts per cubic feet of each

Table 1. Questionnaire for the medical staff after 6 months from the initiation of the new infection control procedures.

	Doctor		Nurse	
	Yes	No	Yes	No
General questions regarding infection control				
Do you think the current PPE is enough to protect you from infection?	17	1	7	11*
Would you prefer to use an N95 mask rather than a surgical mask during endoscopy?	1	17	1	17
Do you have fears regarding COVID-19 infection during endoscopy, even if you are wearing PPE and your patient is wearing a mask?	1	17	11	7*
Do you think it is necessary for patients to wear any kind of infection control items?	18	0	15	3
Have you ever thought about resigning to avoid COVID-19?	1	17	0	18
Questions regarding the mask we designed				
Was it a burden to have patients wear masks?	0	18	0	18
Have you had any problems with patients wearing masks?	0	18	0	18
Have you ever had a patient complain about the mask?	0	18	0	18
Do you agree that patients should wear our designed masks during endoscopy?	18	0	17	1
Questions regarding endoscopy using the mask we designed				
Did the operability of the endoscope worsen when the patient wore our designed mask?	2	16	NA	NA
Did the diagnostic performance of the endoscope decrease when the patient wore our designed mask?	0	18	NA	NA

PPE: personal protective equipment; COVID-19: coronavirus disease 2019; NA: not applicable.
*$p < 0.05$ for comparison of the responses between the doctors and nurses.

particle size with continuous monitoring every 5 s. The particle counter was set inside the endoscope station, and aerosol measurements were made as previously reported.[18,19] As a negative control, the pre-endoscopy aerosol count in the endoscopy room was measured. As a positive control, the aerosol count was measured when the patients deliberately coughed without masks in the left lateral position.

Questionnaire survey among the medical staff 6 months after the initiation of the new infection control procedures

We designed an 11-item paper-based questionnaire survey, which was conducted among all endoscopy staff of Medcity21 in December 2020, 6 months after the adoption of the new infection control procedure (sTable 1). All nurses were specialists with at least 1 year of work experience, and the doctors were specialists with at least 5 years of work experience. These paper-based questionnaires were collected, anonymized, and counted; the questionnaire data are shown in detail in Table 1.

Statistical analysis

Values are expressed as means ± SD. For categorical data, comparisons between groups were performed using the Fisher exact test, and significant differences among groups of three or more were identified using the Kruskal–Wallis test. The results were analyzed by the Dunn's multiple comparisons test using GraphPad Prism 7.03

Ethics

The research protocol complied with the principles of the Declaration of Helsinki. This study was approved by the Osaka City University ethical committee (approval number: 2020-134).

Results

The masks prevented droplet directory during endoscopic simulation

When transoral and transnasal endoscopy were performed on an unmasked mannequin, simulated coughing caused the fluorescent dye to radiate from the mannequin's mouth and spread across the entire surface of the bed and the endoscopist's gloves, gown, and feet (Figure 2(a)–(d); sFigure 2(a, b); sTable 2). However, when coughing was simulated during transnasal endoscopy while the mannequin was wearing our designed mask, the dye mostly stopped at the mask and did not scatter around (Figure 2(e); sFigure 2(c)–(e); sTable 2).

When coughing was simulated with the mannequin wearing our designed mask during transoral endoscopy, a very small amount of the dye was observed to have spread slightly from the mouth; it was found to have adhered to the bed and the endoscopist's gloves and gown (Figure 2(f); sFigure 2(f)–(i); sTable 2). When coughing was simulated with the mannequin in an aerosol box, the dye was found to adhere mainly to the inner walls of the aerosol box, and a very small amount of the dye adhered to the bed and the endoscopist's

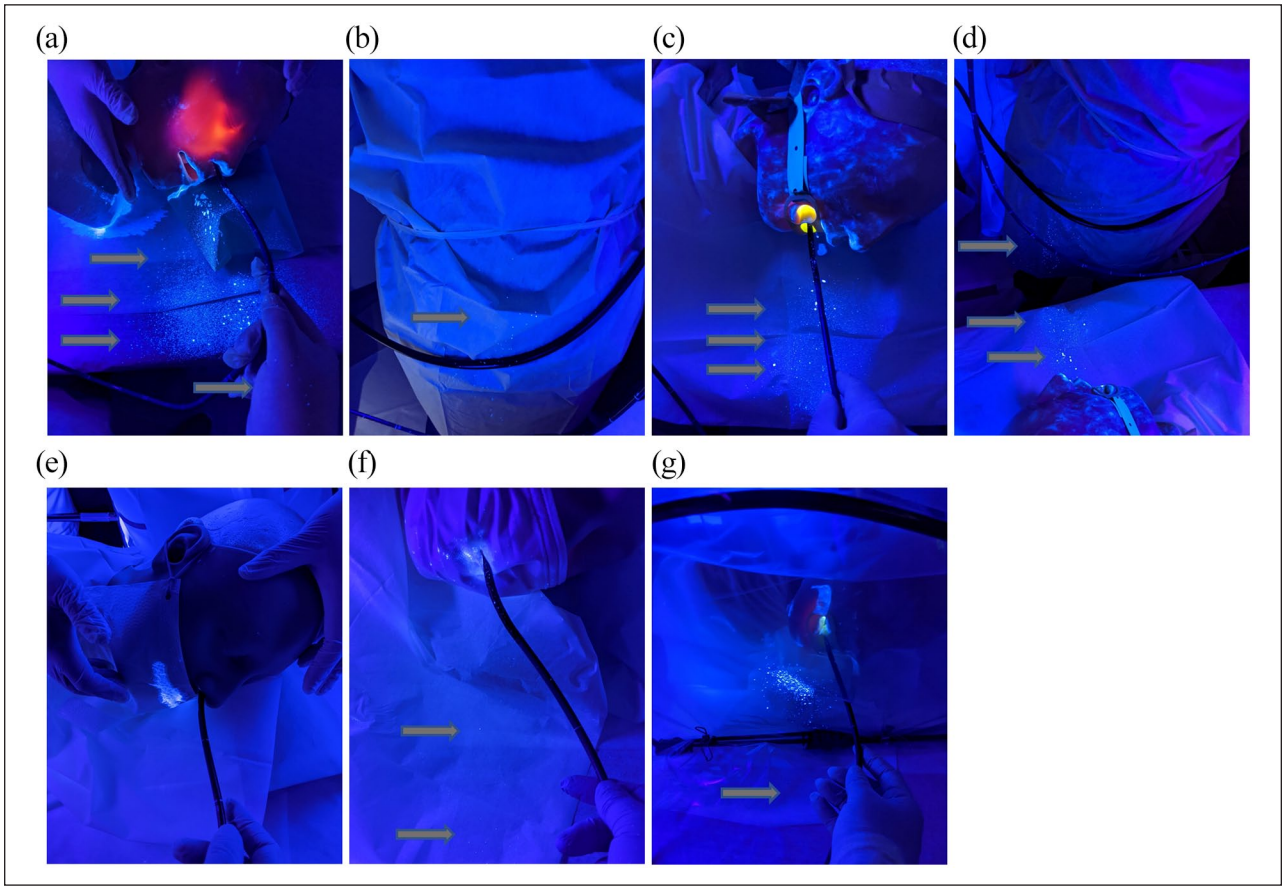

Figure 2. Evaluation of the infection control ability of our original masks during endoscopy using a simulation model with fluorescent dye. Examination of the extent of droplet dispersion caused by artificial coughing using fluorescence. The arrow indicates the splashed fluorescent dye. (a and b) Simulation of unprotected endoscope insertion through the nose. There were splashes of the fluorescent dye from the mouth to the gown in a radial pattern. (c and d) Simulation of unprotected endoscope insertion through the mouth. There were splashes of the fluorescent dye from the mouth to the gown in a radial pattern. (e) Simulation using a mask for nasal endoscope insertion. Almost no fluorescent dye splattering was observed. (f) Simulation using a mask for oral endoscope insertion. A very small amount of the fluorescent dye was splattered on the bed. (g) Simulation using a mask for an aerosol box. Most of the dye adhered to the inner walls of the aerosol box, and only very small amounts were visible on the bed.

gloves (Figure 2(g); sTable 2). Thus, this simulation showed that as opposed to their non-use, the use of both masks and the aerosol box clearly reduced the number of droplets released near the endoscopist.

The use of masks did not affect the patient's condition during endoscopy in clinical settings

Observation records were obtained for 4356 patients who underwent endoscopy between 8 June and 11 December 2020. Overall, 852 patients (360 male and 492 female, mean age: 53.8 ± 10.8 years) underwent oral endoscopy and 3504 (1912 male and 1592 female, mean age: 53.6 ± 10.6 years) underwent nasal endoscopy. Endoscopy was postponed in one case with suspected COVID-19 on interview, and in one case with suspected pneumonia on the chest radiograph. Both cases were confirmed negative for SARS-CoV-2 by polymerase chain reaction; endoscopy in these two cases was performed later. Endoscopies newly revealed 9, 2, 7, 11, and 10 cases of cancer, adenoma, submucosal tumor (diameter ⩾ 2 cm), ulcer, and eosinophilic esophagus, respectively (sTable 3). Regarding adverse events, endoscopic examination was interrupted in one case due to severe Mallory–Weiss syndrome, and follow-up endoscopic examination was performed. Except for one case, endoscopic procedures were not discontinued for any reason, and all patients were able to continue wearing the mask during the endoscopy. No patient experienced severe depletion of O_2 saturation (<90%) or any incident that required hospitalization. There was no record of a patient complaining of discomfort from wearing the mask.

The use of masks prevented the increase of aerosols during endoscopy in a clinical setting

Deliberate coughing (positive control) resulted in an increased aerosol concentration when compared to in the air in the room (Figure 3, Supplemental Figures 1–3). However,

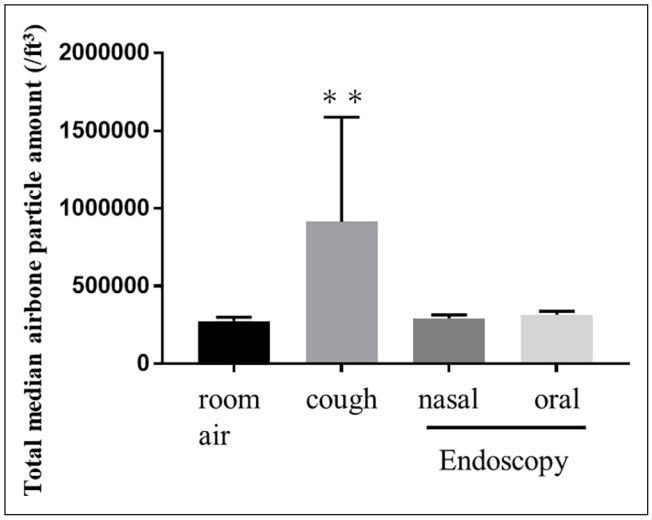

Figure 3. Aerosols during endoscopy. Total counts of the six-channel particle sizes. The device obtained measurements per cubic foot of each particle size. N = 8; **p < 0.01 when compared to the state of the endoscopy room. Coughing: coughing against the aerosol measuring device at a close linear distance of 1 m. Nasal: transnasal endoscopy with our designed mask. Oral: transoral endoscopy with our designed mask.

aerosol measurements obtained from patients wearing the masks during endoscopy revealed no increase in the aerosol concentration in any case (Figure 3, Supplemental Figure 3). This suggested that the aerosols did not circulate around the endoscopist significantly during transoral and transnasal endoscopies, when the patient was wearing our designed mask.

The use of masks reduced the anxiety of doctors and nurses regarding SARS-CoV-2 infection

In a survey on 18 doctors and 14 nurses who watched the simulation on mannequins with our designed mask, all responded that understanding the simulation results using our mask-based infection control methods reduced their anxiety regarding infection. All responders also believed that medical staff should know the effectiveness of infection control procedures by examining the results of the simulation.

After 6 months, another survey on the new infection control method was conducted, and 18 doctors and 18 nurses responded. Some staff members had concerns regarding COVID-19 under the current infection control system and wanted greater protection; the fear was higher among nurses than among doctors. The idea of having patients wear our designed masks during endoscopy to protect against infection was favorably received by almost all participants (Table 1). Regarding endoscope operability, 2 of the 18 endoscopists felt that operating through the mask was not a suitable approach; however, no one judged that this would affect their diagnostic ability (Table 1).

Until the end of December 2020, no staff member at our institution had been infected with SARS-CoV-2 or had taken a leave of absence or resigned due to fears pertaining to COVID-19.

Discussion

In this study, we demonstrated that the generation of infective droplets and aerosols from COVID-19 patients during endoscopic examinations can be suppressed by making them wear our designed masks during the examination. According to patient observation records, wearing the mask was not found to be harmful to the patients themselves during endoscopy. By demonstrating its effectiveness through simulation, this mask-based infection control method may also reduce staff stress regarding COVID-19.

We did not adopt the aerosol box-based infection control method at our institution, although such airtight containers have been reported as effective infection control devices for patients during endoscopy.[12,20] This was mainly attributed to the fact that patient stress levels during endoscopy were greater with the use of an aerosol box, compared with the use of our designed mask: In our trial using an aerosol box, some patients could not tolerate the claustrophobic feeling that arose from the presence of the box walls. Therefore, we concluded that using the aerosol box-based infection control method would be problematic during endoscopy without sedation in our institution (data not shown). Another reason was that compared to the aerosol box-based infection control method, our mask-based infection control method was more convenient for the endoscopy staff. When using aerosol boxes, the staff must clean the boxes several times in a short period of time taking extra care, because the aerosols inside the boxes may be released to the surroundings. In contrast, our designed masks are simple in construction, disposable, and easily replaceable. In addition, during our trial using the aerosol box, many endoscopists complained that operability of the endoscope with the aerosol box was slightly difficult due to the distance between the insertion hole and the patient's body. Therefore, we concluded that our mask-based infection control method was superior to the aerosol box-based method for screening endoscopy.

Based on the fact that 39 of 4356 cases required immediate treatment or further examination 6 months after the mild lockdown in our city, it is not recommended to postpone screening endoscopy owing to fears regarding COVID-19. Other institutions have also reported that postponing endoscopy may delay the detection of diseases.[6,9] Therefore, considering gastrointestinal disease progression, it is preferable to not postpone screening endoscopy, but proceed with it using an adequate infection control method after assessing the risk of COVID-19.

The simulation results in our study showed that endoscopy via both routes (nasal and oral) using our mask-based infection control method was significantly better than that

without it. Two insertion routes may be selected using a small-caliber endoscope, namely, nasal and oral. Based on our simulation, nasal insertion using our mask-based infection control method was slightly more effective in preventing droplet release. Regarding aerosols, no significant increase was observed using both mask-based infection control methods compared to that in the air in the room before the endoscopy. In view of these findings, nasal insertion of the endoscope with our designed mask should be considered first, if possible. However, neither route was inferior, because both methods of our mask-based infection control strategy are highly effective in preventing infection.

Even with recommended protection, such as full-body protection including masks and goggles, the psychological load on the endoscopy staff is high; this is because it is not a complete method of protection against SARS-CoV-2 infection. Interestingly, our results show that nurses were more apprehensive of the infection, although they used the same infection control equipment as doctors. This may be because most of the nurses used the PPE as ordered, while the doctors completely understood the concept of PPE before using it. It may be important for the staff to have a better understanding of the control method in order to reduce their anxiety, because demonstrating the effectiveness of the infection control method that they used through our simulation reduced their anxiety in this study.

This study has some limitations. First, the effectiveness of our designed masks has not been completely validated in clinical situations; however, we selected patients with a low probability of SARS-CoV-2 infection before performing endoscopy at our facility and were able to evaluate the masks' actual effectiveness in preventing infection. Based on the results of this study, we are convinced that wearing our designed mask can protect the medical staff from direct droplets, as it suppresses the release of aerosols from the patients and reduces the risk of SARS-CoV-2 transmission. Indeed, we have performed endoscopy using this mask-based infection control method for 6 months in our COVID-19-prevalent area, and none of our staff have been infected to date.

Second, the condition of the patients during endoscopy using our mask-based infection control method could not be rigorously compared to the condition of the patients during endoscopy without masks; this is because performing endoscopy without masks for patients is not possible, as it clearly increases the risk of infection. However, performing an endoscopy with the patient wearing a mask did not cause any serious problems in our study, and we did not receive any claims from patients using this method.

Finally, this study was conducted without sample size calculation/power analysis because this study is short-term retrospective study. The questionnaires used in this study are not validated/pilot-tested.

In conclusion, this mask-based infection control method, in addition to PPE, is not only easy to initiate and inexpensive, it has also proven effective as none of our staff have been infected with SARS-CoV-2 during the 4356 endoscopies performed in the COVID-19 endemic area. Understanding the effectiveness of this mask-based infection control may also help ease the fear of infection among endoscopy staff.

Acknowledgement

We would like to thank the medical and office staff of Medcity21 for their cooperation.

Author contributions

Y.N. and A.H. contributed to study concept and design. Y.N., A.H., H.M., S.F., and N.K. contributed to design of a mask. Y.N., A.H., and S.T. contributed to planning and executing simulations. Y.N., S.T., H.F., A.N., T.K., and S.F. contributed to collecting patient information. K.O., S.H., F.T., and Y.N. contributed to survey processing. Y.N. and A.H. contributed to drafting of the manuscript. K.T., T.W., N.K., and Y.F. contributed to supervision of research.

Declaration of conflicting interests

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

Funding

The author(s) disclosed receipt of the following financial support for the research, authorship, and/or publication of this article: This research was performed with funding from the Osaka City University.

Ethical approval

This study was approved by the Osaka City University ethical committee (approval number: 2020-134). The ethics committee has also approved a web-based opt-out of the study.

Informed consent

Written informed consent was not sought for the present study because this study is retrospective study. In order to give participants the opportunity to refuse to participate in the study, we are providing them with a web-based opt-out of the study content.

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Supplemental material

Supplemental material for this article is available online.

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