Journal of Clinical and Translational Research
10.18053/Jctres/06.202006.001

TECHNICAL REPORT

A box-shaped, shielding device for reducing the risk of COVID-19 droplet infection during gastrointestinal endoscopic procedures

Hideaki Kawabata*, Yuji Okazaki, Kazuhisa Watanabe, Takato Inoue, Katsutoshi Yamaguchi, Yuki Ueda, Misuzu Hitomi, Masatoshi Miyata, Shigehiro Motoi

Department of Gastroenterology, Kyoto Okamoto Memorial Hospital

*Corresponding author
Hideaki Kawabata,
Kyoto Okamoto Memorial Hospital, 100 Nishinokuchi, Sayama, Kumiyama-cho, Kuze-gun, Kyoto 613-0034, Japan
TEL: +81774 48 5500
FAX: +81774 44 7159
E-mail: hkawabata@okamoto-hp.or.jp

Article information:
Received: June 16, 2020
Revised: July 28, 2020
Accepted: July 29, 2020

Journal of Clinical and Translational Research
10.18053/Jctres/06.202006.001

Abstract

Background and Aims. Endoscopists and endoscopic assistants are easily exposed to germs, including COVID-19, during aerosol-generating procedures such as gastrointestinal endoscopy. This retrospective study investigated the utility of a box-shaped, shielding device for reducing the risk of COVID-19 droplet infection during endoscopic procedures.

Methods. We created a cuboid box (500 × 650 × 450 mm), with four sides were covered with a transparent, vinyl-chloride sheet having two windows for endoscopic passage and assistance. The shielding box was then placed over a patient's head and shoulders and covered with another transparent vinyl sheet. We assessed its utility and safety using the medical data concerning the procedure time and vital signs and a questionnaire for the endoscopic staff and patients.

Results. We performed endoscopic retrograde cholangiopancreatography-related procedures using this device for two patients suspected of having COVID-19-associated pneumonia. Both patients were smoothly and successfully treated without any complications. No difficulties were noted with either endoscopic operation or in assisting the procedure, and the transparency was good enough to observe the patients' faces and movements.

Conclusions. This box-shaped, shielding device can be used to reduce the risk of COVID-19 droplet infection during endoscopic procedures in the clinical setting.

Relevance for patients. The COVID-19 outbreak has reminded healthcare personnel working in endoscopy units of the importance of infection prevention during endoscopy. The box-shaped, shielding device device can help endoscopic staff avoid hospital-setting COVID-19 infection.

Keywords: shielding box, COVID-19, gastrointestinal endoscopy, ERCP, infection prevention

1. Introduction

The coronavirus disease 2019 (COVID-19) outbreak has reminded healthcare personnel working in endoscopy units of the importance of infection prevention during endoscopy [1-3]. Human-to-human transmission occurs primarily through direct contact or air droplets [4]. The greatest risk of transmission is within approximately one meter from the infected person [5]. Endoscopists and endoscopic assistants are easily exposed to such germ, not only by directly touching endoscopes that are contaminated with patients' respiratory secretions but also by close proximity exposure to unexpected contaminated droplets produced by patients' coughing, belching or vomiting.

Several countermeasures have been recommended in order to prevent contamination, including narrowing endoscopic indications, wearing personal protective equipment (PPE) and operating in negative-pressure rooms [1-3,6]. However, emergent endoscopic procedures for patients with acute GI bleeding, foreign bodies in upper GI tract, obstructive jaundice or acute ascending cholangitis should always be performed [2], and such urgent situations may distract medical staff from taking care to avoid personal contamination. Furthermore, PPE shortages and the lack of widespread access to negative-pressure endoscopy rooms [3,7] can also increase the risk of viral transmission. We should also remember that molecular tests that detect viral RNA can produce false negative results [8].

The 'aerosol box' is a novel device that shields doctors from droplet infection of coronavirus while intubating patients [9], and such devices have already been used in clinical practice [10,11]; however, we have found no similar devices suitable for use during endoscopy.

Therefore, we developed a box-shaped, shielding device to reduce the risk of COVID-19 droplet infection during endoscopic procedures and herein report its utility in the clinical setting.

2. Patients and methods

We retrospectively reviewed the clinical data of all consecutive patients who were suspected of having COVID-19-associated pneumonia and underwent endoscopic procedures with a shielding device in our institution between April 2020 and May 2020.

The shielding device is shown in Figure 1. It consists of a plastic, cuboid framework (500 × 650 × 450 mm), with 4 sides covered with a transparent, vinyl-chloride sheet. This shielding box has 2 windows: one (150 × 180 mm) on the front side for passing an endoscope

through and another (200 × 400 mm) at the head side for assistance maneuvers, such as suction.

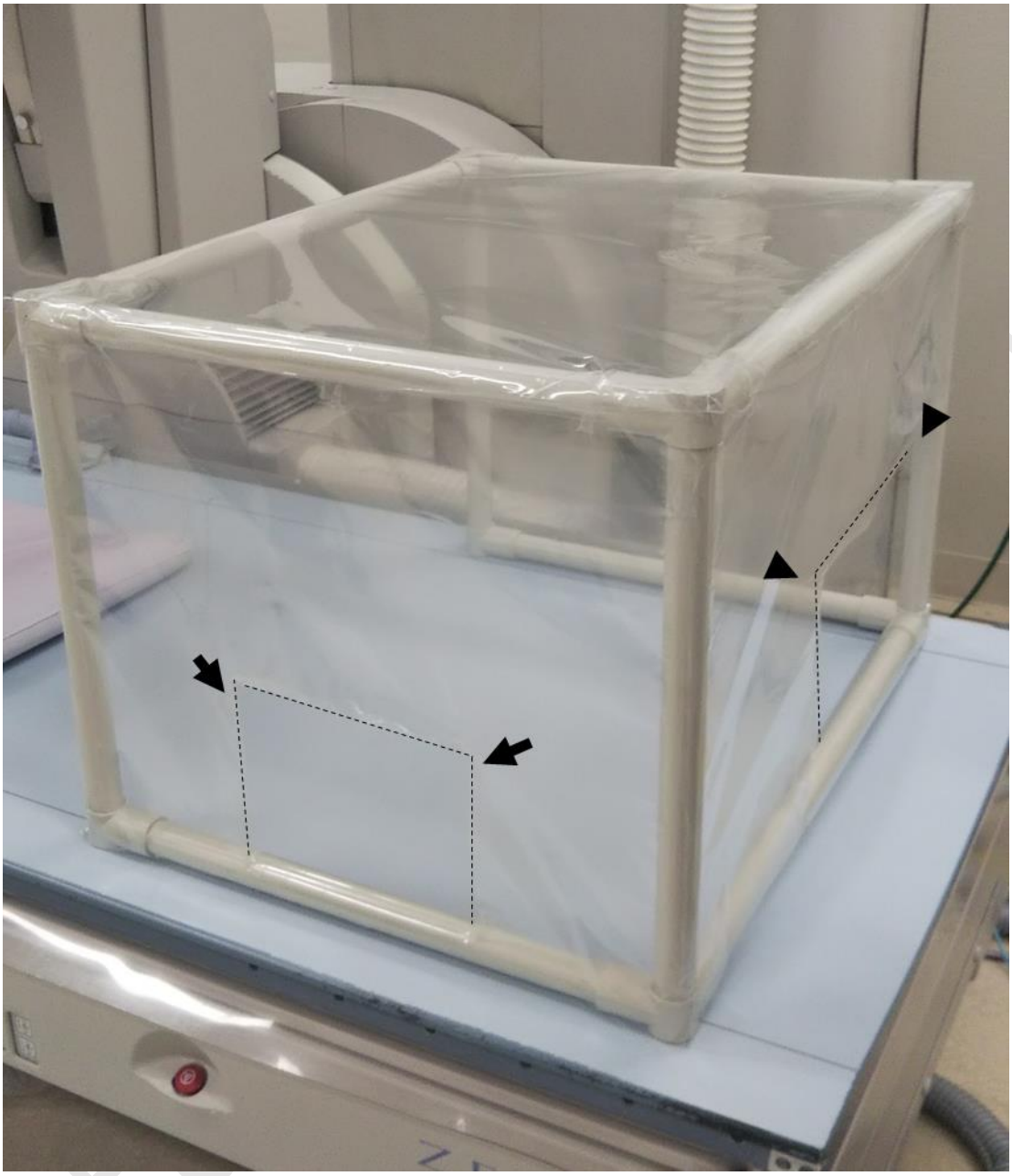

Figure 1. Four of six sides of a plastic, cuboid framework (500 × 650 × 450 mm) were covered with a transparent, vinyl-chloride sheet, which had two windows: one (150 × 180 mm) on the front side for passing an endoscope through (arrows) and another (200 × 400 mm) at the head side for assistance maneuvers (arrowheads).

Before starting endoscopic procedures, patients were asked to place themselves into the prone position or left lateral position, and 2 L/min of oxygen was administered via nasal

cannula. The heart rate, SpO_2, respiratory rate, electrocardiogram findings and non-invasive blood pressure were monitored during the procedure. Sedative drugs (midazolam and pentazocine) and antispasmodic drug (glucagon) were then administered intravenously. After confirming the sedative condition, the shielding box was placed over the patient's head and shoulders. In addition, the box was covered with another transparent vinyl sheet that shielded the windows and was stuck to the box using adhesive tape (Figure 2). After the procedure, the vinyl sheet was discarded, while the shielding box was disinfected with alcohol and reused.

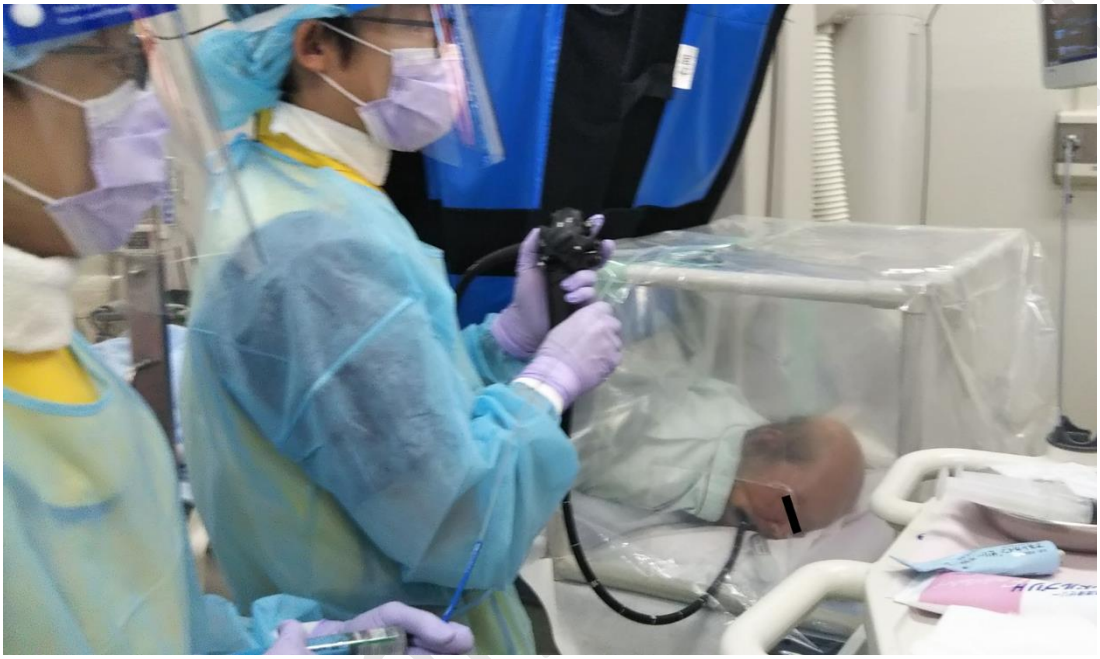

Figure 2. The shielding box was placed over the patient's head and shoulders. In addition, the box was covered with another transparent vinyl sheet, which shielded the windows, and stuck to the box using adhesive tape.

We extracted the medical data concerning the time required for endoscope insertion and the endoscopic procedure as well as vital signs before, during and after the procedure. We then asked the operators and assistant nurses to answer a questionnaire to assess the operability, visibility (transparency), and sense of security against droplet exposure using a numerical rating scale (1, poor; 5, excellent). In addition, we interviewed the patients about their impression during the procedure.

All of the patients gave their written informed consent. This study followed the ethical guidelines for studies involving human subjects based on the Helsinki Declaration. The study

protocol was approved by the institutional review board of Kyoto Okamoto Memorial Hospital.

3. Results

We performed endoscopic retrograde cholangiopancreatography (ERCP)-related procedures using this shielding device for two male patients in their 80s. The total amount of sedative drugs, procedure duration and vital signs before, during and after the procedure of each patient are shown in Table 1. One patient (Case 1) suffered from acute cholangitis due to choledocholithiasis and was suspected of having COVID-19-associated pneumonia based on computed tomography (CT) findings. ERCP had to be started before the polymerase chain reaction (PCR) results for a COVID-19 test were obtained due to severe inflammation with septic shock that required the administration of norepinephrine. He underwent endoscopic sphincterotomy (EST) followed by biliary stenting. The total procedure time was 12 minutes, and it took 2 minutes to achieve endoscope insertion. Instability of the vital signs, except for the SpO_2 level, was observed due to his septic shock; however, he was smoothly and successfully treated without any complications.

Table 1. Total amount of sedative drugs, the procedure duration and vital signs before, during and after the procedure in each patient.

Case	Sedative drugs (total, mg)		Total procedure time (min)	Endoscope insertion time (min)	Blood pressure (mmHg)			Heart rate (/min)			SpO_2 (%)			Respiratory rate (min)		
	Midazolam	Pentazocine			Before	During	After	Before	During	After	Before	During	After	Before	During	After
1	2.5	7.5	12	2	97/62	76-96/52-60	118/70	96	93-98	90	97	97-98	98	18	19-22	25
2	3	7.5	10	3	102/65	99-101/64	93/62	91	79-81	82	97	96-97	96	15	15-17	15

Another patient (Case 2) who had a history of EST for choledocholithiasis suffered from an attack due to recurrent choledocholithiasis. He was suspected of having COVID-19-associated pneumonia based on CT findings, although PCR for COVID-19 was ultimately negative. He underwent endoscopic stone removal. The total procedure time was 10 minutes, and it took 3 minutes to achieve endoscope insertion. All vital signs were stable during the procedure, and he was also smoothly and successfully treated without any complications.

The assessment of the shielding device by an operator and an assistant nurse in each case is shown in Table 2. The rating scores obtained from the operator and assistant nurse were the same, with the operability and visibility (transparency) being rated 4/5 and the sense of security being rated 5/5; the scores were the same in both cases. Neither patient recalled the

endoscopic procedure.

Table 2. The assessment of the shielding device by an operator and an assistant nurse in each case using a numerical rating scale (1, poor; 5, excellent).

Case	Operator			Assistant nurse		
	Operability	Visibility	Sense of security	Operability	Visibility	Sense of security
1	4	4	5	4	4	5
2	4	4	5	4	4	5

4. Discussion

In the present study, we mainly assessed three concerns associated with using a shielding device during endoscopic procedures: operability, visibility (transparency) and risk of hypoxia due to shielding a patient. We also demonstrated its utility and safety in the clinical setting.

First, no difficulties were noted using this shielding device for GI endoscopy with either the endoscopic operation itself or in assisting the procedure, including with regard to the secretory suction and head fixation. Begley [12] reported aerosol boxes for intubation may increase intubation times and therefore expose patients to the risk of hypoxia. However, it did not take long for the procedure to be performed, including endoscopic insertion, and the assessment of operability by the operators was satisfactorily high.

Second, the transparency of this device was good enough to observe the patients' faces and movement despite having to see through two vinyl sheets while using this device, findings that differed from those with an aerosol box made of acrylic or transparent polycarbonate sheet. Fogging inside the device was also not observed during the procedure although the procedure time was not very long.

Third, no deterioration of SpO_2 was observed during the procedure. The risk of hypoxia due to shielding a patient was able to be avoided as not only was nasal O_2 administrated, but the foot end of the box was open enough for ventilation.

Furthermore, it can provide endoscopic staff the psychological sense of security against droplet exposure. However, endoscopy under sedation is recommended to relieve compressive or occlusive feelings induced by the shielding device.

Larger, prospective, multicenter studies including GI endoscopic procedures, such as hemostasis, are needed to clarify the utility and safety of this device. Furthermore, experimental studies showing the reduction of aerosol or contamination when using these shielding boxes are also expected, although this may be clinically obvious.

In conclusion, this box-shaped, shielding device can used to reduce the risk of COVID-19 droplet infection during endoscopic procedures in the clinical setting. We hope that this device will help endoscopic staff to avoid hospital-setting COVID-19 infection.

Conflict of Interest: The authors declare that they have no conflict of interest.

Acknowledgement: none

Financial Disclosure or Funding: none

References

1. Irisawa A, Furuta T, Matsumoto T, Kawai T, Inaba T, Kanno A, Katanuma A, Kawahara Y, Matsuda K, Mizukami K, Otsuka T, Yasuda I, Tanaka S, Fujimoto K, Fukuda S, Iishi H, Igarashi Y, Inui K, Ueki T, Ogata H, Kato M, Shiotani A, Higuchi K, Fujita N, Murakami K, Yamamoto H, Ito T, Okazaki K, Kitagawa Y, Mine T, Tajiri H, Inoue H. Gastrointestinal endoscopy in the era of the acute pandemic of COVID-19: Recommendations by Japan Gastroenterological Endoscopy Society (Issued on April 9th, 2020.). Dig Endosc 2020
2. Gralnek IM, Hassan C, Beilenhoff U, Antonelli G, Ebigbo A, Pellisè M, Arvanitakis M, Bhandari P, Bisschops R, Van Hooft JE, Kaminski MF, Triantafyllou K, Webster G, Pohl H, Dunkley I, Fehrke B, Gazic M, Gjergek T, Maasen S, Waagenes W, de Pater M, Ponchon T, Siersema PD, Messmann H, Dinis-Ribeiro M. ESGE and ESGENA Position Statement on gastrointestinal endoscopy and the COVID-19 pandemic. Endoscopy 2020
3. Repici A, Maselli R, Colombo M, Gabbiadini R, Spadaccini M, Anderloni A, Carrara S, Fugazza A, Di Leo M, Galtieri PA, Pellegatta G, Ferrara EC, Azzolini E, Lagioia M. Coronavirus (COVID-19) outbreak: what the department of endoscopy should know. Gastrointest Endosc. 2020
4. Wang C, Horby PW, Hayden FG, Gao GF. A novel coronavirus outbreak of global health concern. Lancet 2020;395:470-473.
5. Siegel JD, Rhinehart E, Jackson M, Chiarello L, Health Care Infection Control Practices Advisory Committee. 2007 Guideline for isolation precautions: preventing transmission of infectious agents in health care settings. Am J Infect Control 2007;35(10 Suppl 2):S65-164.
6. Hormati A, Niya MHK, Ghadir M, Lankarani KB, Ajdarkosh H, Tameshkel FS, Zamani F. COVID-19 in the endoscopy ward: A potential risk for gastroenterologists. Infect Control Hosp Epidemiol 2020
7. Repici A, Pace F, Gabbiadini R, Antonelli G, Ebigbo A, Pellisè M, Arvanitakis M, Bhandari P, Bisschops R, Van Hooft JE, Kaminski MF, Triantafyllou K, Webster G, Pohl H, Dunkley I, Fehrke B, Gazic M, Gjergek T, Maasen S, Waagenes W, de Pater M, Ponchon T, Siersema PD, Messmann H, Dinis-Ribeiro M. Endoscopy units and the COVID-19 Outbreak: A Multi-Center Experience from Italy. Gastroenterology 2020
8. Rashid ZZ, Othman SN, Samat MNA, Ali UK, Wong KK. Diagnostic Performance of COVID-19 Serology Assays. Malays J Pathol 2020;42:13-21.
9. Everington K. Taiwanese doctor invents device to protect US doctors against coronavirus. 23 March 2020. https://www.taiwannews.com.tw/en/news/3902435 (accessed 20/05/2020).
10. Colasimone D. Australian doctors design and make life-saving equipment needed for

coronavirus pandemic. 6 April 2020. https://www.abc.net.au/news/2020-04-06/doctors-designing-medicalequipment-to-face-coronavirus-covid-19/12120588 (accessed 20/05/2020).

11. Reeser B. The Intubation Box is an inexpensive and reusable personal protective device that functions as a barrier between Covid-19 patients and healthcare providers. 2020. https://intubationbox.com (accessed 20/05/2020).
12. Begley JL, Lavery KE, Nickson CP, Brewster DJ. The Aerosol Box for Intubation in COVID-19 Patients: An In-Situ Simulation Crossover Study. Anaesthesia 2020