


## ENDOSCOPY

# Amount of contamination on the face shield of endoscopists during upper endoscopy between patients in two positions: A randomized study

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aerosol-generating procedure, EGD, prone position.

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**Introduction**

During the Coronavirus Disease 2019 (COVID-19) pandemic, certain guidelines written by expert endoscopists from many societies worldwide, including the World Endoscopy Organization,<sup>1</sup> the European Society of Gastrointestinal Endoscopy,<sup>2</sup> the Asian Pacific Society of Digestive Endoscopy,<sup>3</sup> and the Thai Association for Gastrointestinal Endoscopy,<sup>4</sup>

advocated that esophagogastroduodenoscopy (EGD) is an aerosol-generating procedure (AGP) that may transmit the virus from infected patients to healthcare personnel. For the safety of medical personnel during the pandemic, these guidelines have recommended wearing either standard or full personal protective equipment (PPE), including a face shield, during gastrointestinal (GI) endoscopic procedures to minimize the risk of transmission to healthcare personnel.<sup>1–5</sup>

**Abstract**

**Background and Aim:** During the Coronavirus Disease 2019 pandemic, esophagogastroduodenoscopy (EGD) has been recognized as an aerosol-generating procedure. This study aimed to systematically compare the degree of face shield contamination between endoscopists who performed EGD on patients lying in the left lateral decubitus (LL) and prone positions.

**Methods:** This is a randomized trial in patients scheduled for EGD between April and June 2020. Eligible 212 patients were randomized with 1:1 allocation. Rapid adenosine triphosphate test was used to determine contamination level using relative light units of greater than 200 as a cutoff value. All eligible patients were randomized to lie in either the LL or prone position during EGD. The primary outcome was the rate of contamination on the endoscopist's face shield.

**Results:** The majority of patients were female (63%), with a mean age of  $60 \pm 13$  years. Baseline characteristics were comparable between the two groups. There was no face shield contamination after EGD in either group. The number of coughs in the LL group was higher than the prone group ( $1.38 \pm 1.8$  vs  $0.89 \pm 1.4$ ,  $P = 0.03$ ). The mean differences in relative light units on the face shield before and after EGD in the LL and prone groups were  $9.9 \pm 20.9$  and  $4.1 \pm 6$  ( $P = 0.008$ ), respectively.

**Conclusion:** As measured by the adenosine triphosphate test, performing diagnostic EGD does not lead to contamination on the face shield of the endoscopist. However, placing patients in the prone position may further mitigate the risk.

Due to the very rapid increase in the number of COVID-19 patients worldwide, the supply of PPE has not been able to meet the demand. To overcome this shortage, most medical personnel found that do-it-yourself devices and gadgets are the necessary substitutes to protect them from aerosolization.<sup>5–7</sup> However, there has been no published study evaluating the efficacy or real benefit of these tools in preventing aerosolization during EGD.

The difference in patient position, that is, left lateral decubitus (LL) *versus* prone, during EGD may be an important factor that can influence the amount of aerosolization to the face of the performing endoscopist. Hypothetically, the aerosol from the prone position could be projected less directly toward the endoscopist's face than that from the LL position.

To objectively determine the degree of contamination during EGD, a measurable test is needed. Rapid adenosine triphosphate (ATP) is a point-of-care test that can measure the remnants of microorganisms and their protein components, including viruses and proteins, with immediate available result in relative light units (RLU).<sup>8,9</sup> The result of greater than 200 RLU indicates a significant contamination<sup>10</sup> with a sensitivity of 86%, specificity of 60%, positive predictive value of 43%, and negative predictive value of 92%.<sup>11</sup> Thus, we adopted this cutoff value to determine the rate of contamination on the face shield of the endoscopist performing diagnostic EGD from the two positions. The secondary objective was to measure the difference in magnitude of contamination measured in RLU between patients lying in the LL and prone positions.

## Methods

Before randomization, the concept of differences in projection of aerosolization between the LL and prone positions was explored using the ATP test (Clean-Trace Surface ATP, 3M, Maplewood, Minnesota, USA). We measured the level of RLU after EGD on the plastic sheet placed under the patient's face at 5, 10, 15, 20, and 25 cm away from the mouth in four cases who did not cough during endoscopy, two for each position, that is, LL and prone (Table 1). These initial data indirectly supported our hypothesis that the aerosol from patient lying in the prone position would be projected less directly toward the endoscopist's face than that from the LL position.

To assess the environmental factors that may confound contamination measurement, we swabbed the face shield hanging on the

wall in an endoscopy suite at the opposite side of the patient's face before and after EGD for 10 procedures. None of the face shields had an RLU level greater than 200 or had significant doubling in RLU after EGD. The mean level of ATP on the face shield before EGD, after EGD, and the mean difference were  $12.1 \pm 9$ ,  $9.5 \pm 7$ , and  $0.9 \pm 1$  RLU, respectively. These results reaffirmed that the risk of non-patient-related contamination on the face shield during EGD was negligible.

Then we conducted a randomized trial in patients scheduled for diagnostic EGD under conscious sedation between April and June 2020. The inclusion criteria were all patients older than 18 years old with American Society of Anesthesiologists Classification (ASA class) I or II. The exclusion criteria were as follows: (i) expected therapeutic EGDs, such as EGD for active GI hemorrhage, dysphagia with potential stenting, and early upper GI tract neoplasm requiring endoscopic submucosal dissection; (ii) ascites or abdominal mass and inability to lie prone; (iii) airway-compromised conditions, that is, obesity (body mass index  $> 30 \text{ kg/m}^2$ ), mediastinal mass, and severe cardiopulmonary disease; (iv) pregnancy; (v) other factors that would make the patient unable to lie in a prone position as determined by the performing endoscopist; (vi) accidental water splash from the suction channel to the face shield; and (vii) inability to sign the consent form.

Two pre-procedural screening protocols were used in this study. At the beginning of the COVID-19 outbreak in Thailand during April and May 2020, we used both COVID-19 questionnaire and RT-PCR for COVID-19 test as the screening tools for all patients, and the results of both methods in all patients were negative. Later in June when there had been no reported new COVID-19 cases for three consecutive months, our hospital infectious advisory board recommended to abandon the routine pre-procedural RT-PCR and used only COVID-19 questionnaire for screening. All procedures were performed only in patients with no risk according to the screening questionnaire.

Before the procedure, standard face shields ( $20 \times 30 \text{ cm}$ ) were marked at 10 cm from the lateral edges and 5 cm from the upper and lower edges (Fig. 1) to standardize the testing area on the face shield for ATP measurement. Each face shield was cleaned with sterile water and underwent the ATP test to confirm that the level was lower than the cutoff level for significant contamination ( $< 200 \text{ RLU}$ ). We then applied the same swab technique for all shields by continuous painting from the top to the bottom in the examined area (the red line in Fig. 1).

**Table 1** The average levels of ATP in the different distance from patient's mouth (two cases each for the LL and prone positions)

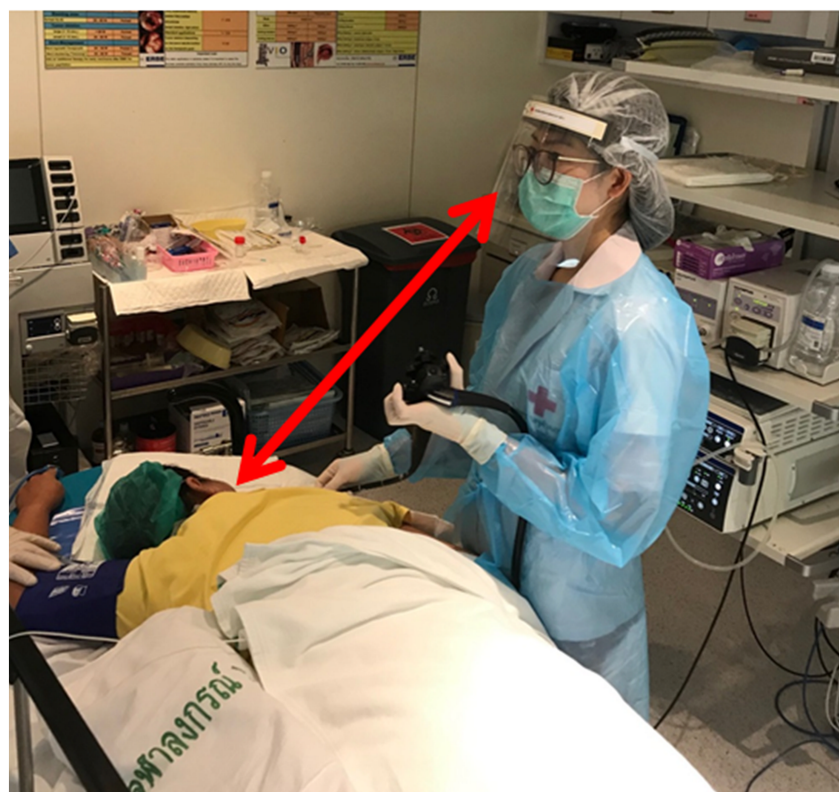
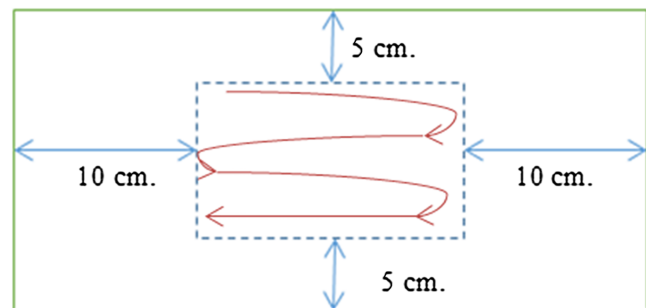
Distance from patient's mouth (cm)	ATP level in the LL position (RLU)		ATP level in the prone position (RLU)	
	Before EGD	After EGD	Before EGD	After EGD
5	5	6	37	16 587
10	9	17	8	1087
15	7	6	18	21
20	9	3	19	7
25	5	4	8	8

ATP, adenosine triphosphate; EGD, esophagogastroduodenoscopy; LL, left lateral decubitus; RLU, relative light units.

After informed consent was signed, all eligible patients were randomized to undergo EGD in either an LL or prone position (1:1 allocation). A computer-generated randomization schedule with blocks of four was applied for randomization. A research nurse who was not involved in the EGD procedure generated sealed opaque envelopes containing a letter designating the assigned position. The performing endoscopist (10 in total including trainees) opened the sealed envelope in the standard sequence. The patients in both groups underwent conscious sedation administered by a certified nurse who could administer propofol. All patients received only propofol with a 0.5–1 mg/kg bolus, followed by 0.25–0.5 mg/kg/h continuous infusion until moderate sedation level was achieved. No additional medication was administered before or

during EGD. The procedure was performed in standard endoscopy suite with normal air circulation. The endoscopist wore the prepared face shield, as shown in Figure 2, and performed the diagnostic EGD. Demographic data of the patients, procedure time, height of the performing endoscopist, direct distance between the patient's mouth and the center of face shield (the tip of the endoscopist's nose; Fig. 2) during the procedure using a tape measurement, number of coughs from the patient during the procedure, and RLU levels of ATP before and after EGD were recorded. However, the outcome assessors who performed ATP sampling were not blinded to the assigned position as this process was performed by one medical staff who was certified from the ATP manufacturer according to the Centers for Disease Control and Prevention protocol.<sup>12</sup>

**FIGURE 1** Area for adenosine triphosphate examination (inside the dot line box) and the direction of examination (line with arrow heads). [Color figure can be viewed at [wileyonlinelibrary.com](http://wileyonlinelibrary.com)]



**FIGURE 2** The distance from the patient's mouth to the endoscopist's face (2 feet) (arrow). [Color figure can be viewed at [wileyonlinelibrary.com](http://wileyonlinelibrary.com)]

This study was approved by the Institutional Review Board of Chulalongkorn University, Thailand (IRB No. 275/63). The protocol of this study was registered at ClinicalTrials.gov (NCT04329013).

**Statistical methods.** The sample size calculation aimed to detect the difference in the number of contaminated face shields (ATP > 200 RLU) by assuming that the prone position would yield a lower number of contaminated face shields. However, no such data existed in the previous literature. One recent study showed at least a 5.6% rate of unrecognized facial exposure measured by bacterial culture after a half day of procedures (EGD and colonoscopy).<sup>13</sup> Our team found that the culture positive rate for pathogenic bacteria at a duodenoscope when using ATP level > 200 RLU as a cutoff level of contamination was 44%.<sup>14</sup> Based on our previous study, the ATP test was two times more sensitive than bacterial culture when assessing bacterial contamination.<sup>14</sup> Therefore, the LL position would generate 12% contamination, and the prone position would assumingly lead to less contamination on the face shield with a 10% difference (2% contamination). A sample size of 101 per group was required (type I error of 0.05, two-sided, and a power of 80%). This study intended to enroll 106 patients in each group with a default rate

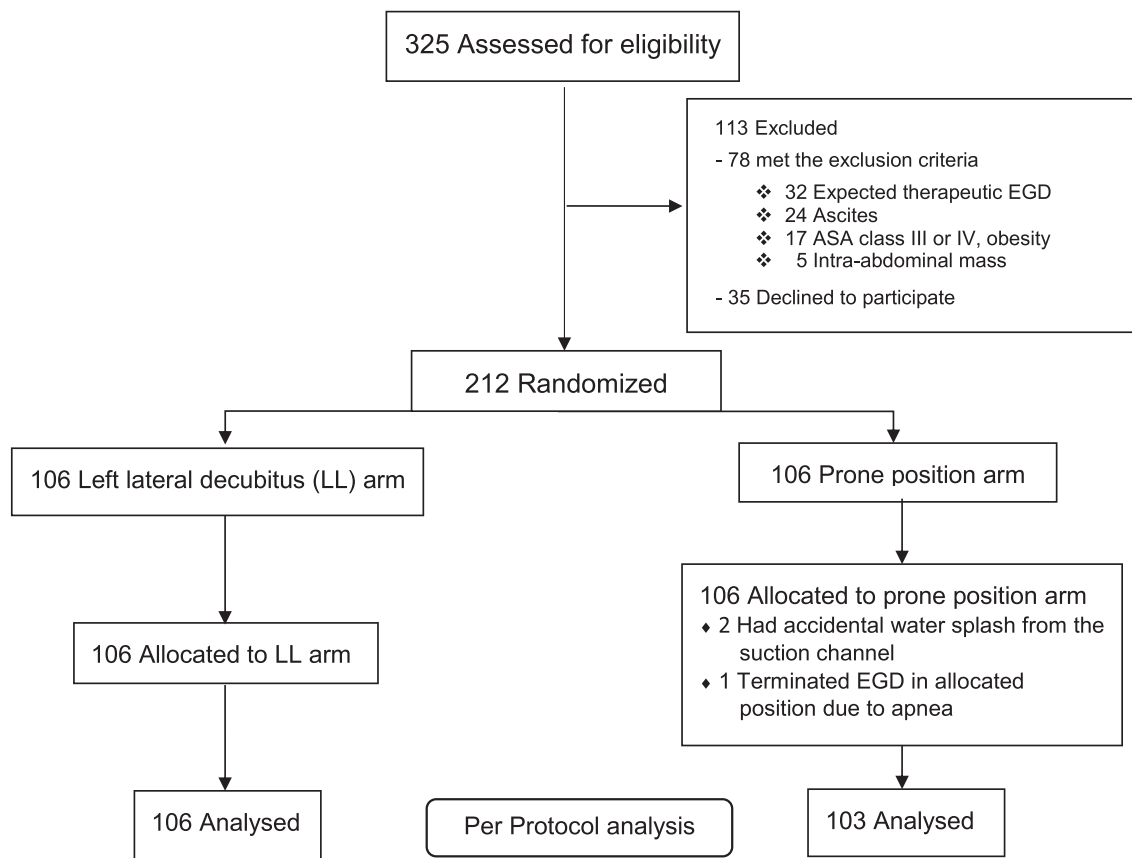
of 5%. As blocks of four were used to ensure a balance in sample size across groups over time, 53 blocks were required in this study.

Descriptive statistics were used to present continuous, ordinal, and categorical data. Unpaired *t*-tests were applied for continuous data. Chi-square and Fisher's exact tests were used for categorical data. All statistical analyses were performed using standard SPSS Statistics for Windows, version 23.0 (IBM Corp., Armonk, NY). A *P*-value of 0.05 was considered to indicate statistical significance. We used only per-protocol analysis in this study.

## Results

Two hundred twelve patients were randomized equally. Three patients were excluded from the prone position group because an accidental water splash from the suction channel causing an obviously visible contamination of the face shield occurred during the EGD (two patients), and another patient did not complete the EGD in the prone position because of an observed oxygen desaturation. Finally, 106 procedures from the patients lying in the LL position and 103 procedures from the patients lying in the prone position were analyzed (Fig. 3). The majority of patients were female (63%), with an overall mean age of  $60 \pm 13$  years. The mean procedure time was  $5.6 \pm 2.7$  min. The baseline characteristics were not significantly different between the two groups

### CONSORT Flow Diagram



**FIGURE 3** Patient enrollment. ASA, American Society of Anesthesiologists; EGD, esophagogastroduodenoscopy.



(Table 2). The mean direct distance measured by tape between the patient's mouth and the face shield was significantly longer in the prone group than in the LL group ( $63.7 \pm 6.7$  vs  $65.5 \pm 6.3$  cm;

**Table 2** Baseline characteristics of included patients

	Left lateral position (N = 106)	Prone position (N = 103)	P-value
Gender, female (%)	67 (63.2)	63 (61.2)	0.76
Age (mean $\pm$ SD)	60.4 $\pm$ 13.8	59.5 $\pm$ 12.2	0.60
Major underlying disease (%)			0.86
Healthy	64 (61.3)	62 (60.2)	
Cirrhosis	20 (18.9)	15 (14.6)	
DM	9 (8.5)	13 (12.7)	
Cardio-cerebrovascular disease	6 (5.6)	5 (4.8)	
CKD	4 (3.8)	3 (2.9)	
Others (pancreatic cancer, breast cancer)	3 (2.9)	5 (4.8)	
Indication for EGD (%)			0.95
Gastric cancer screening	30 (28.3)	32 (31.1)	
Chronic dyspepsia	27 (25.5)	24 (23.3)	
Varices surveillance	17 (16)	13 (12.6)	
Chronic GERD	9 (8.5)	7 (6.8)	
Coffee ground GI bleeding	8 (7.5)	7 (6.8)	
Iron deficiency anemia	5 (4.7)	5 (4.9)	
Dysphagia	5 (4.7)	8 (7.8)	
Other (follow-up gastric ulcer, remove gall-bladder stent)	5 (4.7)	7 (6.8)	
Height of endoscopist (mean $\pm$ SD)	167.9 $\pm$ 6.7	167.1 $\pm$ 6.6	0.30
Procedure time (mean $\pm$ SD)	5.8 $\pm$ 2.9	5.3 $\pm$ 2.5	0.25
Major EGD findings			0.68
Unremarkable	16 (15.1)	22 (21.4)	
Gastritis/duodenitis	71 (67)	58 (56.3)	
Gastric ulcer/duodenal ulcer	7 (6.6)	7 (6.8)	
Varices	8 (7.5)	8 (7.8)	
Other (gastric cancer, ampullary mass, reflux esophagitis, telangiectasia)	4 (3.7)	8 (7.8)	
Interventions			0.57
No	30 (26.3)	35 (34)	
Rapid urease test	64 (60.4)	57 (55.3)	
Biopsy	12 (11.3)	11 (10.7)	

CKD, chronic kidney disease; DM, diabetes mellitus; EGD, esophagogastroduodenoscopy; GERD, gastroesophageal reflux disease; GI, gastrointestinal; SD, standard deviation.

**Table 3** The outcomes of included patients

	Left lateral position (N = 106)	Prone position (N = 103)	P-value
Direct distance between patient's mouth and the face shield (mean $\pm$ SD)	63.7 $\pm$ 6.7	65.5 $\pm$ 6.3	0.02
Patient who coughed during EGD (%)	51 (48.1)	36 (35)	0.054
Number of bouts of cough per each patient (mean $\pm$ SD)	1.38 $\pm$ 1.8	0.89 $\pm$ 1.4	0.03
	Median 0	Median 0	
Number of patients with ATP > 200 RLU after EGD (%)	0	0	N/A
Number of patients with RLU on the face shield increased double after EGD (%)	29 (27.4)	18 (17.5)	0.08
Level of ATP on face shield before EGD (mean $\pm$ SD)	10.1 $\pm$ 5.0	10.8 $\pm$ 6.0	0.35
Incremental difference of RLU on the face shield after EGD (delta ATP; mean $\pm$ SD)	9.9 $\pm$ 20.9	4.16 $\pm$ 6.0	0.008

ATP, adenosine triphosphate; EGD, esophagogastroduodenoscopy; RLU, relative light units; SD, standard deviation.

$P = 0.02$ ). Approximately one-third to one-half of the patients in both groups (51 of 106 [48.1%] in the LL group and 36 of 103 [35%] in the prone group) coughed during the procedure. There was a significantly higher number of coughs in patients lying in the LL position, compared with the prone position ( $1.38 \pm 1.8$  vs  $0.89 \pm 1.4$ ,  $P = 0.03$ ). None of the face shields from the LL or prone groups had RLU greater than 200 after EGD. The numbers of patients who had doubled RLU levels after EGD in the LL and prone groups were 29 (27.4%) and 18 (17.5%), respectively ( $P = 0.08$ ). The mean incremental differences in RLU on the face shield before and after EGD were  $9.9 \pm 20.9$  in the LL group and  $4.1 \pm 6$  in the prone group ( $P = 0.008$ ) (Table 3).

## Discussion

The most important result of the present study is that the rate of contamination of the face shields after diagnostic EGD using > 200 RLU as the cutoff value was zero for both positions. Although the number of patients with doubled RLU values on the face shield after EGD in the LL group was higher than that in the prone group (27.4% vs 17.5%), the difference was not statistically significant and not likely to be clinically meaningful because the levels of RLU were much lower than the threshold considered as significant contamination (< 200 RLU) (Table 3). The mean incremental difference in RLU after the procedure was significantly higher for the LL position than the prone position, but again, the difference was not likely to be clinically meaningful (10 RLU vs 4 RLU). Patients in the LL position had significantly greater number of coughs compared with those lying in the prone position. This finding would lead to the statistically incremental difference of RLU on the face shield after EGD between the two positions. To interpret our results in a practical concept, we may consider diagnostic EGD as an AGP, but the risk of aerosolization that could contaminate the endoscopist's face with the patient lying in either the prone or LL position appeared to be low, as this procedure allows for more distance than other high-risk procedures such as endotracheal intubation and dental work in which the operator stays closer to the patient's mouth. In the present study, the endoscopists stood 2 feet away from the patient's mouth (Fig. 2).

Although the prone position is not the standard patient position for EGD, it is the standard position for many patients undergoing endoscopic retrograde cholangiopancreatography.<sup>15</sup> Although the novice endoscopist and trainee may perceive that this patient position may result in a more difficult scope intubation than the LL position, during the study, we found that all of our trainees were able

to perform EGD with the patient lying prone without any difficulty. Unfortunately, one patient in the prone group in this study developed oxygen desaturation during the procedure, causing a premature procedural termination. We believed the incident was due to the patient's baseline medical problem, rather than technical or operator's skill-related. Although this patient was classified as ASA class II, in retrospect, we found that she had a significant risk of developing apnea due to obesity and a short neck, and she should have been classified as ASA class III instead. There has been an anecdotal fear that the prone position may lead to poor ventilation in the patient, which in turn may compromise the patient's oxygenation. In fact, patients without lung problem had unchanged or only modestly decreased respiratory system compliance when turning from supine to prone position.<sup>16,17</sup> Moreover, the prone position is a favorable position in patients with alveolar damage, especially those with acute respiratory distress syndrome, as it can diminish the degree of ventilation-to-perfusion (VA/Q) mismatch and improve oxygenation.<sup>18</sup> In addition, during the COVID-19 pandemic, the prone position has been frequently used in COVID-19 patients who developed acute respiratory distress syndrome.<sup>19</sup>

To our knowledge, this study is the first randomized controlled trial that measured the amount of contaminated droplets splashed to the endoscopist's face shield for different patient positions during diagnostic EGD. Previously, one study from India showed that around 13% of GI procedures caused fluid splash to the endoscopist but the assessment tool was still unverified.<sup>20</sup> A recent cohort study by Johnston *et al.* on face shield contamination<sup>13</sup> analyzed face shields from endoscopists who had performed EGD and colonoscopy for half a day. They showed that 5.6% of those face shields had bacterial contamination. They confirmed the contamination by bacterial culture and concluded that the routine use of facial protection during endoscopy for all staff in the endoscopy suite was necessary.<sup>13</sup> However, they did not evaluate the risk of contamination during each individual procedure, and the reported contamination was the accumulation of many diagnostic and therapeutic (upper and lower) endoscopies during the half-day service. Perhaps the contamination might develop more as a result of the therapeutic procedure or during the intermission between the procedures. Therefore, we believe that our study was designed to elucidate more specifically the risk of endoscopist's facial contamination during the actual procedure (diagnostic EGD in particular) than the previously reported study.<sup>13</sup>

The current study also emphasized the aerosolized nature of the EGD as the samplings from 5 and 10 cm from the patient's mouth examined by the ATP test showed an extremely high RLU (> 1000 RLU). However, the risk of contamination from this aerosolization at a further distance appeared to be low because the endoscopist who stood at least 2 feet away from the patient's mouth had no contamination on their face shields (< 200 RLU) (Table 2). In other words, we might say that diagnostic EGD is definitely an AGP, but it should be listed as a low-risk procedure or distancing AGP. A recent study from Hong Kong<sup>21</sup> supported our findings that EGD is, in fact, an AGP. They measured the contamination at 10 cm from patient's mouth during EGD by using a particle measurement machine (portable GT-526S Handheld Particle Counter) and found that the level of particles generated during EGD was significantly higher than that during the baseline period. However,

they did not measure the direct contamination on endoscopist's face. Consequently, the results from our study may serve as guidance in areas with limited resources, showing that full PPE including a face shield and an N95 or an equivalent or higher-level respirator may not be necessary for an endoscopist performing diagnostic EGD in non-patient under investigation (PUI).

This study had certain limitations. First, we did not perform the standard bacterial culture from the swabbed specimen because we did not think that the number of positive face shields determined by bacterial culture of highly concerned bacteria from a short procedure like diagnostic EGD would be enough to perform statistical calculations. Second, our target organism is an RNA virus (SARS-CoV-2), not bacteria. Unfortunately, it is difficult to generate a virus model as a representative. Because ATP is a molecule found in and around living cells, as a result, it gives a direct measure of biological contamination.<sup>8</sup> Although we could not detect the virus directly, the detectable RLU as a surrogate for the level of contamination should be sufficient to proof the concept of aerosolization or splashing virus-containing particles. Thus, we decided to adopt > 200 RLU for the ATP test as the gold standard in this study. Another limitation is that we did not assess contamination by the ATP test of the other personnel in our endoscopic suite. For instance, a nurse who sedated the patient and stayed closer to the patient may be at risk. However, the projection of aerosol appeared to be opposite of where the nurse was standing; therefore, we did not consider that other personnel would be at a higher risk than the performing endoscopist. Fourth, multiple endoscopists including trainees have been involved in endoscopy; thus, such varying experience is one of the confounding factors in this study. Fifth, we found a significant difference in the distances between the patient's mouth and the endoscopist's face. However, the 2-cm difference in distance in the prone group may not cause a significant impact in real practice. Moreover, appropriate tweaking, twisting, and turning of the endoscopes could have altered the distance from the patient during endoscopy. Thus, we should not conclude that the lower splashing from the prone group was from the longer distance. Sixth, the amount of suction used and air insufflations would also have an impact on the outcome of the study. Unfortunately, it is difficult to establish the impact of these factors in droplet spreading. Last, the study was designed to evaluate only a short diagnostic EGD. Therefore, our recommendation is not applicable to other longer or therapeutic procedures because the risk of splashing could be greater for longer procedures that may cause more accumulation of GI-related excretion, including blood.

## Conclusions

Esophagogastroduodenoscopy was originally considered an AGP; however, the results from our study demonstrated no significant contamination on the face shield of the endoscopist measured by the ATP test (< 200 RLU) in either the LL or prone position. The incremental RLU difference after EGD and the number of coughs in each patient in the prone group were significantly lower than that in the LL group. Thus, in low COVID-19 endemic areas with a limited supply of face shields and respirator masks, performing diagnostic EGD in a patient lying prone may further mitigate the risk of contamination.

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