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Intraluminal gas escape from biopsy valves and endoscopic devices during endoscopy: caution advised during the COVID-19 era

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ABSTRACT

Background and study aims The risk of aerosolization of body fluids during endoscopic procedures should be evaluated during the COVID-19 era, as this may contribute to serious disease transmission. Here, we aimed to investigate if use of endoscopic tools during flexible endoscopy may permit gas leakage from the scope or tools.

Material and methods Using a fresh 35-cm porcine rectal segment, a colonoscope tip, and manometer were placed intraluminally at opposite ends of the segment. The colonoscope handle, including the biopsy valve, was submerged in a water bath. Sequentially, various endoscopic devices (forceps, clips, snares, endoscopic submucosal dissection (ESD) knives) were inserted into the biopsy valve, simultaneously submerging the device handle in a water bath. The bowel was slowly inflated up to 74.7 mmHg (40 inH_2O) and presence of gas leakage, leak pressure, and gas leakage volume were measured.

Results Gas leakage was observed from the biopsy valve upon insertion and removal of all endoscopic device tips with jaws, even at 0 mmHg (60/60 trials). The insertion angle of the tool affected extent of gas leakage. In addition, gas leakage was observed from the device handles (8 of 10 devices) with continuous gas leakage at low pressures, especially two snares at 0 mmHg, and an injectable ESD knife at 0.7 ± 0.8 mmHg).

Conclusions Gas leakage from the biopsy valve and device handles commonly occur during endoscopic procedures. We recommend protective measures be considered during use of any tools during endoscopy.

Introduction

Since the onset of the Coronavirus Disease 2019 (COVID-19) pandemic, the risks of aerosol-generating procedures (AGPs) as the COVID-19 transmission route is of universal concern among health care personnel [1]. Under experimental circumstances, SARS-CoV-2 has exhibited aerosol transmission and remains viable and infectious up to 3 hours [2]. Currently, a growing body of published evidence points towards endoscopic procedures being considered as aerosol-generating [3, 4]. In addition to esophagogastroduodenoscopy (EGD), endoscopic retrograde cholangiopancreatography (ERCP) [5] and colonoscopic procedures have a risk of infection, considering the recent detection of the SARS-CoV-2 in specimens and feces [6–8]. Contaminated droplets and aerosols originate mainly from the patients' upper or lower gastrointestinal tract and previous reports have mainly focused on preventing the spread of these aerosols [9, 10].

However, contaminated aerosolization emanating directly from the flexible endoscope device (e. g. air/water, suction and biopsy valves) or endoscopic tools have not been explored [11, 12]. The aim of this study was to investigate if use of endoscopic tools during flexible endoscopy may permit gas leakage from the scope or tools. Specifically, we investigated areas within the endoscope handle and endoscope tool (as these areas are close to the operators' and assistants' faces during a procedure).

Material and methods

Ex-vivo setting

In an ex-vivo model using a 35-cm fresh porcine rectum segment, an endoscope (PCF-H180AL, Olympus) was inserted from the distal end of the rectum, and the manometer (Noshok) was placed inside of the proximal end to measure the intraluminal pressure near the endoscope tip (**Supplementary Fig. 1**). Both sides of the intestine were tightened using tie bands and rubber bands to create a closed system.

Leakage from the biopsy valve

A semi-disposable (#MB-358, Olympus) or disposable (Orca-Pod, Boston Scientific) biopsy valve were sequentially attached to the endoscope. The endoscope handle was placed in a water bath and completely submerged to test for the presence of gas leakage. Ten trials, confirmed by the presence or absence of bubble formation, were performed under three different conditions:

1. No endoscopic device was placed inside the biopsy channel.
2. Each of 10 endoscopic devices was inserted into and removed from the biopsy valve.
3. Each endoscopic device was inserted into the biopsy channel and its insertion angle was changed manually.

The intestine was then inflated up to 74.7 mmHg (40 inH_2O) or until gas leakage from the biopsy valve was detected, using the inflation button on the endoscope to pump air into the intestine. The average time to reach 74.7 mmHg was 10 seconds. The shaft of devices was clamped to prevent the gas leakage from the device handles. We chose 74.7 mmHg as the highest pressure limit as higher pressures will tear mucosa and muscle wall of the fresh pig colon in our experience.

Leakage from endoscopic tools

Endoscopic tools during the study included: two biopsy forceps (Single-Use Radial Jaw [Boston Scientific] and Single-Use Radial Jaw Hot [Boston Scientific]); two endoscopic clips (DuraClip [ConMed] and Resolution Clip [Boston Scientific]); three endoscopic snares (Singular Polypectomy Snare [ConMed], Captivator Single-Use Snare [Boston Scientific] and SnareMaster [Olympus]); three endoscopic submucosal dissection (ESD) knives (DualKnife [Olympus], DualKnife J [Olympus] and Flush Knife [Fujifilm]) were investigated in this study. Endoscopic snares, endoscopic knives, and Resolution Clip, which has the jaw inside the over-sheath when inserting into the biopsy channel, were termed devices without an exposed jaw. Other devices (biopsy forceps and DuraClip^{M}) were termed devices with an exposed jaw.

Each endoscopic device was inserted into the biopsy channel whilst the entire endoscope handle was submerged in the water bath. The intestine was slowly inflated up to 74.7 mmHg (40 inH_2O) 10 times or until gas leakage was detected. We used semi-disposable biopsy valves for this experiment and confirmed no gas leakage from the biopsy valve.

Outcomes measurements

Videos were recorded during all the experiments. The primary outcome measurement was the visible presence of gas bubbles emanating from the biopsy valve or the device handle. Secondary outcome measurements included the leak pressure and the amount of gas leakage. Instantaneous or continuous gas leakage was quantified as below.

Instantaneous gas leakage from the biopsy valve upon the insertion of each endoscopic device was evaluated by using the change in intraluminal pressure from the initial pressure (18.7 mmHg [10 inH_2O]). A pressure of 18.7 mmHg is commonly achieved during endoscopic insufflation to distend the bowel wall. Continuous gas leakage from the biopsy valve by changing the insertion angle (from 0 to 30 degrees) of devices or from the device handles was evaluated. The required time for the intraluminal pressure to drop from 18.7 to 0 mmHg was measured, which was termed the required time$_{18.7\ to\ 0\,mmHg}$. The testing was terminated if it took longer than 90 seconds.

Statistical analysis

Differences in continuous variables between groups were evaluated by the Mann-Whitney U test. The association between two non-continuous parameters was evaluated by the Fisher exact test. All analyses were performed using SPSS for Windows v.10 (SPSS, Chicago, IL). $P < 0.05$ was considered as significant.

Results

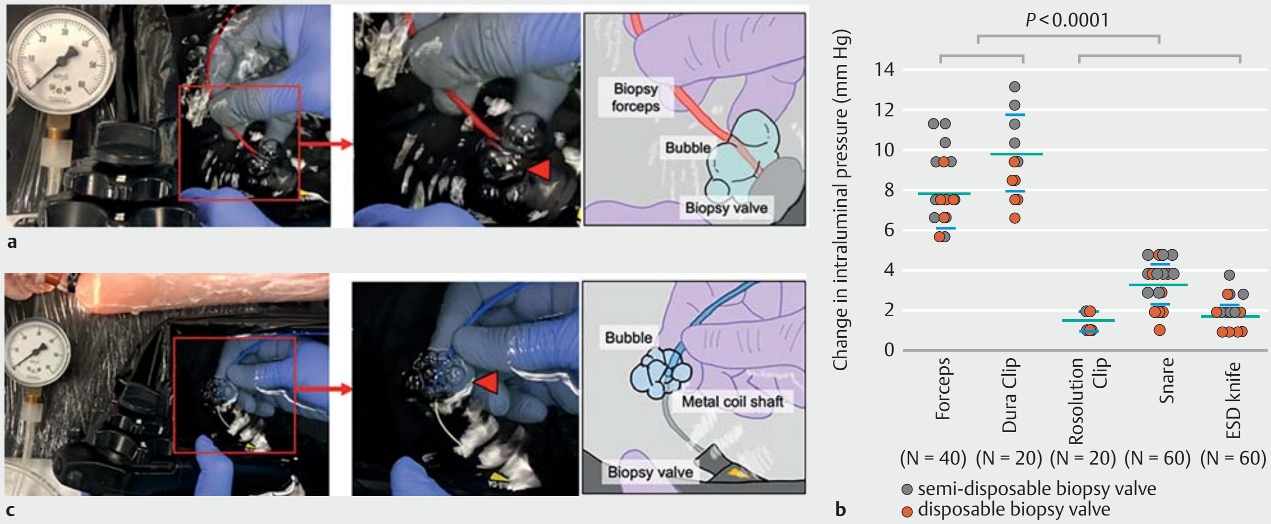
Gas leakage from the biopsy valve

Without tool Insertion

No gas leakage as confirmed with lack of bubbles was observed from semi-disposable or disposable biopsy valves up to 74.7 mmHg (40 inH_2O) without endoscopic device insertion.

Upon inserting and removing endoscopic tools

Gas leakage, as confirmed with presence of bubbles, was always present upon insertion and removal of the biopsy forceps and DuraClip (exposed jaw tools) at 0 mmHg (60/60 trials, 100 %,



▶ **Fig. 1** Gas leakage from the biopsy valve upon insertion and removal of endoscopic tools. a Gas leakage from the biopsy valve upon insertion of biopsy forceps (red arrowhead: bubble formation). b Change in intraluminal pressure upon insertion and removal of endoscopic devices was evaluated. Each dot indicates each trial (black dot; semi-disposable biopsy valve, red dot; disposable biopsy valve). Bars indicate the mean ± SD. c Gas leakage from metal coil shaft, which is covered with an outer sheath (red arrowhead: bubble formation).

▶ **Fig. 1a**), but infrequently with other devices (e. g. Resolution Clip, endoscopic snares, and ESD knives) (17/140 trials, 12.1 %, ▶ **Table 1**). However, these devices had a higher frequency of gas leakage at even 1.9 mmHg (1 inH_2O) (95/140 trials, 67.9 %).

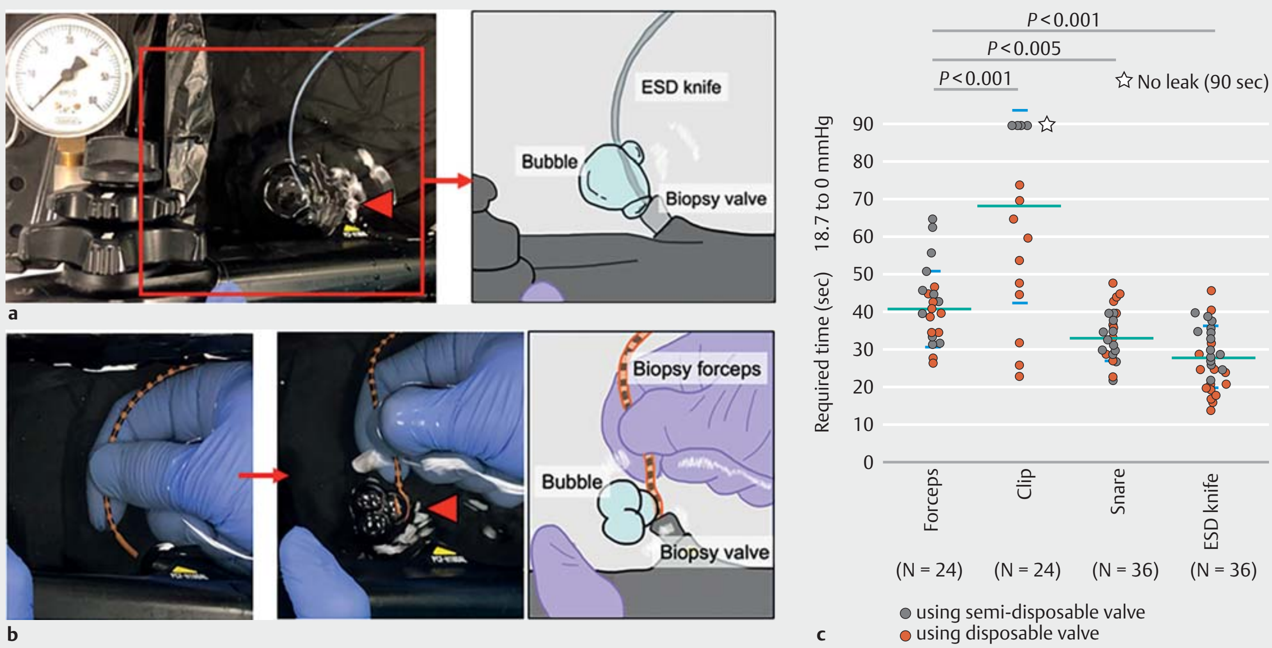
To measure the extent of instantaneous gas leakage, the drop in intraluminal pressure upon insertion and removal of each device at 18.7 mmHg (10 inH_2O) was measured. The drop in pressure was significantly greater in using devices with an exposed jaw than other devices (8.4 ± 2.0 vs 2.3 ± 1.1 mmHg, $P < 0.001$, ▶ **Fig. 1b**). When analyzed via semi-disposable and disposable biopsy valve groups, 5 out of 10 devices had significantly higher gas leakage from the semi-disposable biopsy valve than from the disposable one (**Supplementary Table 1**).

Regarding DuraClip, which has an area of metal coil shaft which is uncovered with a polyethylene outer sheath near its tip, there was gas leakage from this area (▶ **Fig. 1c**).

▶ **Table 1** Gas leakage from the biopsy valve up insertion and removal of endoscopic devices.

Endoscopic device		Gas leakage at 0 mmHg		Gas leakage at 1.9 mmHg (1 inH_2O)	
		Semi-	Disposable	Semi-	Disposable
Biopsy forceps	Single-Use Radial Jaw	10/10 (100 %)	10/10 (100 %)	10/10 (100 %)	10/10 (100 %)
	Single-Use Radial Jaw Hot	10/10 (100 %)	10/10 (100 %)	10/10 (100 %)	10/10 (100 %)
Endoscopic clip	DuraClip	10/10 (100 %)	10/10 (100 %)	10/10 (100 %)	10/10 (100 %)
	Resolution Clip[1]	1/10 (10 %)	1/10 (10 %)	7/10 (70 %)	2/10 (20 %)
Endoscopic snare	Singular Polypectomy Snare	0/10	0/10	10/10 (100 %)	8/10 (80 %)
	Captivator Single-Use Snare	0/10	0/10	9/10 (90 %)	2/10 (20 %)
	SnareMaster	5/10 (50 %)	5/10(50 %)	10/10 (100 %)	10/10 (100 %)
ESD knife	DualKnife	0/10	2/10 (20 %)	10/10 (100 %)	0/10
	DualKnife J[2]	2/10 (20 %)	0/10	9/10 (90 %)	0/10
	Flush Knife[2]	0/10	1/10 (10 %)	9/10 (90 %)	9/10 (90 %)

Semi-, semi-disposable biopsy valve; Disposable, disposable biopsy valve; ESD, endoscopic submucosal dissection.
[1] This device has a jaw inside its over-sheath.
[2] Injectable ESD knife.



▶ **Fig. 2** Gas leakage from the biopsy valve while inserting endoscopic tools all the way. a Gas leakage from the disposable biopsy valve without changing the insertion angle of ESD knife (red arrow: bubble formation). b Before (left) and after (right) changing the insertion angle of biopsy forceps (red arrow: bubble formation). c The required time$_{10\ to\ 0\,mmHg}$ while changing the insertion angle of endoscopic devices was evaluated. Each dot indicates each trial (black dot; semi-disposable biopsy valve, red dot; disposable biopsy valve). Bars indicate the mean ± SD. †; No gas leakage was noted, and the testing was terminated in 90 seconds (N = 12). **P* < 0.005, ***P* < 0.001.

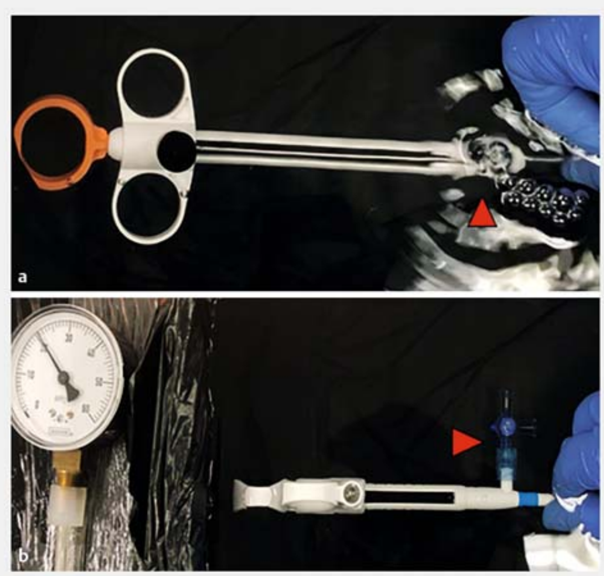
Gas leakage from the biopsy valve upon insertion angle alteration

After tip insertion, as each endoscopic device was passed until it protruded from the tip of the endoscope, there was no gas leakage from the semi-disposable biopsy valve. However, a continuous gas leakage was confirmed from the disposable biopsy valve in inserting ESD knives (DualKnife and DualKnife J), whilst no gas leakage in inserting other devices (▶ **Fig. 2a**).

Gas leakage occurred from the biopsy valve whilst the insertion angle of each endoscopic device was changed manually from zero degrees to approximately 30 degrees of angulation (▶ **Fig. 2b** and **Supplementary Table 2**). The required time$_{18.7\ to\ 0\,mmHg}$ was significantly shorter in using endoscopic snares and ESD knives than biopsy forceps and endoscopic clips (snares vs ESD knives vs forceps vs clips = 33.5 ± 6.0 vs 28.3 ± 8.3 vs 41.2 ± 10.0 vs 68.3 ± 25.3 sec, ▶ **Fig. 2c**). Divided into semi-disposable and disposable biopsy valve groups, 5 out of 10 endoscopic devices had significantly shorter required time$_{18.7\ to\ 0\,mmHg}$ in using the disposable biopsy valve than in using the semi-disposable one (**Supplementary Table 2**).

Gas leakage from endoscopic device handles

Each endoscopic device handle was submerged whilst inserted into the endoscope biopsy channel. Eight of 10 devices had a continuous gas leakage from their handles at low intraluminal pressures, particularly endoscopic snares (0 mmHg) and Flush Knife (0.7 ± 0.8 mmHg) (▶ **Fig. 3a** and ▶ **Table 2**). As for these three devices, two endoscopic snares had similar



▶ **Fig. 3** Gas leakage from endoscopic device handles.a Gas leakage from the handle of an endoscopic snare (red arrowhead). b Injectable ESD knife with a three-way stopcock connected to the water jet cap (red arrowhead).

▶ **Table 2** Gas leakage from endoscopic device handles.

Endoscopic device		Gas leakage at 74.7 mmHg (40 inH$_2$O)	Leak pressure (mmHg)	Required time$_{18.7\text{ to }0\text{ mmHg}}$ (sec)
Biopsy Forceps	Single-Use Radial Jaw	10/10 (100 %)	16.8 ± 2.5	90[1]
	Single-Use Radial Jaw Hot	0/10 (0 %)	No leak	No leak
Endoscopic Clip	DuraClip	10/10 (100 %)	11.6 ± 1.1	90[1]
	Resolution Clip[2]	0/10 (0 %)	No leak	No leak
Endoscopic Snare	Singular polypectomy snare	10/10 (100 %)	0	31 ± 4.4
	Captivator single-use snare	10/10 (100 %)	0	28.3 ± 2.6
	SnareMaster	10/10 (100 %)	7.9 ± 1.7	90[1]
ESD Knife	DualKnife	10/10 (100 %)	13.9 ± 2.7	90[1]
	DualKnife J[3]	10/10 (100 %)	7.9 ± 1.7[4]	90[1]
	Flush Knife[3]	10/10 (100 %)	0.7 ± 0.8[4]	79.8 ± 3.9

ESD, endoscopic submucosal dissection.
[1] The testing was terminated when it took longer than 90 seconds.
[2] This device has a jaw inside its over-sheath.
[3] Injectable ESD knife.
[4] Three-way stopcock was connected to the injection fluid cap of Injectable ESD knife.

time$_{18.7\text{ to }0\text{ mmHg}}$ of handle gas leakage as compared to gas leakage from the biopsy valve while changing the insertion angle (**Supplementary Table 2** and ▶ **Table 2**).

For two injectable ESD knives, there was gas leakage from the water jet cap. However, connecting a 3-way stopcock onto the cap prevented gas leakage when exchanging syringes for submucosal injection (▶ **Fig. 3b**).

Discussion

In the present study, to our knowledge we have presented for the first time the presence of significant gas leakage from the biopsy valve upon insertion and removal of endoscopic tools. In addition, we have shown that the alteration of the endoscopic tool insertion angle through the biopsy channel affects the degree of gas leakage. Moreover, continuous gas leakage was noted from the endoscope tool handles as well as a clear disparity in leakage between disposable and semi-disposable biopsy valves.

Bronchoscopy is known as a common AGP and likely presents a high potential risk of COVID-19 transmission to health care workers [1, 13, 14]. Besides the high exposure to bronchoscopists, the bioaerosol concentrations in bronchoscopy units also increases during procedures [15]. The same risk should be considered during upper endoscopy, which causes the patient to cough and mechanically create and disperse aerosols [3, 4]. A prospective study demonstrated unrecognized exposure of contaminated splash to the endoscopist's face, and also individuals standing up to 6 feet away from the patients during the endoscopy [16]. Our results indicated one of the causes might be the gas leakage from the biopsy valve or endoscopic device handles, an alarming finding considering the short distance from the endoscopy teams' faces.

Given there was no gas leakage from the biopsy valve without endoscopic device insertion, screening endoscopy alone (without biopsy or intervention) could be relatively safe in terms of the exposure to gas leakage from the biopsy valve. During the COVID-19 outbreak, most elective and non-urgent endoscopy has been postponed or canceled, whilst emergency (e. g. acute gastrointestinal bleeding, obstructions, and acute cholangitis) or time-sensitive endoscopy (e. g. cancer) has continued. These latter procedures require the frequent use of various endoscopic tools [3, 17–20]. These urgent procedures will continue to be required, for potentially COVID-19 positive patients or untested patients due to the lack of time prior to the procedure, thus our data seems extremely important during this time period.

The amount of gas leakage from the biopsy valve varied depending on the devices in this study. Upon inserting and removing endoscopic tools, the shape of the device tip (with or without an exposed jaw) was the main factor. Moreover, the devices with smaller diameter had more gas leakage. On the other hand, while we changed the insertion angle of endoscopic tools, the softer device shafts caused more gas leakage in addition to the smaller diameter.

Interestingly, semi-disposable biopsy valves had less gas leakage whilst we changed the insertion angle of endoscopic tools, but more gas leakage upon inserting and removing tools. Generally, semi-disposable biopsy valves are more durable to keep their shape compared with disposable biopsy valves. On the other hand, the insertabilty of semi-disposable valves is a little worse, which might lead to taking more time to insert and remove endoscopic tools in semi-disposable valves. We believe that these are the reasons for the difference in the amount of gas leakage happened between these valves.

Our study highlights special concerns during ESD procedures: maximal leakage was noted whilst changing the insertion angle of ESD knives and upon insertion and removal of forceps. ESD procedures require the long-time use of ESD knives and frequent insertion and removal to exchange other therapeutic devices, such as hemostasis forceps. In addition, ESD procedures can produce more electrocautery smoke, with viable cellular material that subsequently has a risk of infection [21].

Continuous gas leakage was noted more frequently from the disposable biopsy valve compared to the semi-disposable valve, and this should be considered when choosing which equipment to use.

Gas leakage from endoscopic device handles was a surprise observation during our study. This was observed from most tools as a steady leak and with the proximity of these tool handles to the endoscopists' and assistants' faces was a cause for concern.

Based on the results of this study, we recommend the following:

1. Insert and remove endoscopic devices from the biopsy valve quickly under a low intraluminal pressure,
2. Keep the devices vertical (at a straight angle) to the biopsy valve,
3. Consider use of semi-disposable biopsy valve, and
4. Place some kind of protective shield between the valve and the endoscopist and assistant who may be holding the device handle.

Based on our study as well, we suggest that the biopsy valve and endoscopic device handles be kept as far away as possible from the faces of endoscopy personnel.

The use of personal protective equipment (PPE) in performing AGPs is recommended by all societies in this COVID-19 pandemic era [3, 22, 23]. It is unknown how much amount of aerosol exposure is related to the risk of infection of endoscopy personnel with PPE. Based on these recommendations, most of the endoscopy personnel use PPE which includes a respirator (e. g. N95, FFP2, or equivalent), gown, gloves, eye protection, and apron, focusing on aerosols from the patients. However, our study suggests that endoscopy personnel also need to pay attention to the risk of possible COVID-19 transmission near the biopsy valve and the device handles.

This study has several limitations. We did not investigate whether aerosols are generated from the biopsy valve, just gas leakage, not to mention whether certain bacteria and viruses, including COVID-19, remain viable from the biopsy valve and endoscopic device handles. Further investigation is needed to clarify the risk of such exposure, for example, the exact volume of gas leakage. Gas leakage from the biopsy valve and device handles in an ex-vivo model doesn't necessarily occur in clinical cases. The intraluminal pressure of a porcine intestine model may not be identical to that in humans. A previous study showed that the average of maximum intraluminal pressure was more than 100 mmHg [24].Therefore, pressures we achieved, up to 74.7 mmHg (40 inH2O), is transiently possible during endoscopy. The optimal intraluminal pressure during endoscopy is yet to be clear, though it might exist between 8 and 16 mmHg [25, 26]. Nevertheless, the pressure up to 18.7 mmHg (10 inH2O) could happen under manual insufflation. Our study didn't cover all kinds of endoscopic devices, like ERCP. ERCP requires a wide variety, and multiple diameter devices to be moved in-and-out of the endoscope. For example, ERCP for acute cholangitis, which might be one of the most common indications for ERCP during the COVID-19 pandemic, requires use of a sphincteroctome, guidewire, and biliary stent at least. In the case of the choledocholithiasis, retrieval balloon/baskets are often used as well [27]. The use of these various devices in emergency ERCP may carry a higher risk of exposure to gas leakage from the biopsy valve and the control handle.

In the future, device modifications should be developed to lower this risk of gas leakage, which could lead to aerosolization. Perhaps a new device with double membranes or antireflux valves like a laparoscopic trocar despite the current biopsy valve might solve some of these problems [28].

Conclusion

In summary, gas leakage from the biopsy valve and device handles commonly occur during endoscopic procedures where tools must be inserted in and out of the biopsy valve. Due to the proximity of these tools to the endoscopists' and assistants' faces and length of the therapeutic procedures, the potential risks of this gas leakage, which could contribute to aerosolization, should not be neglected. In the short term, effective technical and protection strategies should employed to minimize risk. In the long term, endoscopic and endoscopic tool design changes should be considered to minimize the risk of pathogenic contamination.

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Competing interests

The authors declare that they have no conflict of interest.

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