Gas leakages from gastrointestinal endoscopy system—its visualization and semi-quantification utilizing schlieren optical system in the swine models

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Abstract

Background and aims With the global epidemic of SARS-CoV-2, there has been a growing concern regarding the risk of aerosol exposure to healthcare workers and patients during medical/surgical interventions. The Schlieren device is capable of visualizing fine gas-flows by using refractive index differences in the medium. We aimed to reveal the existence of gas leakage from gastro-intestinal endoscopy system by utilizing Schlieren device and to clarify the factors which relates to the amount of gas leakage.

Methods The experiments were performed on the excised swine stomach while maintaining a constant pressure environment in the stomach. The System Schlieren (SS100,KatoKoken) was used to visualize possible gas leakages from forceps plugs of endoscopy. We attempted to semi-quantify the leakage by referring to the image of the gas from the forceps plug and by measuring the initial velocity and diffusion area of the leakage.

Results Regardless of the type of forceps plugs, a certain amount of leakage was detected during both insertion and removal of forceps. The initial velocity and the diffusion area of the leakage increased with the increase in intragastric pressure. Semi-quantitative comparison showed that there was a difference in the amount of gas leakage among various forceps plugs. Furthermore, the amount of gas leakage was significantly greater in the forceps plugs that were used repeatedly.

Conclusion It was possible to visualize gas leakages from the gastrointestinal endoscope system using the Schlieren optical device. Avoiding too high intragastric pressure and not using deteriorated plugs may reduce the risk of aerosol exposure.

Keywords Gastrointestinal endoscopy · Gas leak · Biopsy plug · Schlieren
patients and the risk of exposure to the virus via aerosols has been reduced, it is important to evaluate gas leaks from medical devices and develop countermeasures in an attempt to prevent a possible future pandemic of an unknown infectious disease.

Schlieren optical systems are used mainly in engineering fields to visualize minute changes in gas-flow that are invisible to the naked eye, by using differences in the density and refractive index of the medium [6]. This visualization method has the potential to semi-quantitatively analyze the gas leakage from various parts of the endoscopic system, but no systematic studies have been conducted.

Even if there is gas leakage from the endoscopy system, it is not certain whether the gas contains the virus RNA that is the source of infection; as far as SARS-CoV-2 is concerned, it has been reported that the gastric juice contains viral RNA [7]. As long as it has not been proven that there is no risk of infection, countermeasures are necessary, and gas leaks are not desirable in any case, even in the case of unknown infectious diseases other than SARS-CoV-2.

In this study, we aimed to obtain answers to the following questions; Question 1: Can gas leakage from forceps plugs be visualized using the Schlieren device? Question 2: Is gas leakage from the plug associated with internal pressure in the stomach? Question 3: Is gas leakage from the plug related to the type and condition of the plug itself?

Materials and methods

Study settings

Procedures were performed on bench-top simulators containing an explanted swine stomach.

The steady pressure automatically controlled endoscopy (SPACE) system

Steady pressure automatically controlled endoscopy (SPACE) system was constructed according to our previous reports but with several modifications [8–11]. In order to ensure the reproducibility of the experiments, the intragastric pressure had to be kept constant at an arbitrary pressure, and each experiment was performed under the control of the SPACE system. Briefly, a detachable leak-proof device with an anti-reflux valve and a Luer lock connection (Leak Cutter; Top, Tokyo, Japan) was connected to a standard endoscopic overtube (#16,630; Top). A standard flexible GI endoscope (GIF-Q260J; Olympus Medical Systems; Tokyo, Japan) was advanced into the stomach through the overtube. For CO₂ insufflation, a dedicated CO₂ insufflator (GW-200; Fuji-film) was connected to the side channel of the Leak Cutter. The intragastric pressure was controlled at 0–15 mmHg via GW-200. The entire observation system is shown in Fig. 1. The performance of the SPACE system has already been verified in a previous report [8].

Fig. 1 The experimental setting for visualizing gas leakages by System Schlieren using the SPACE system. A SPACE system: CO₂ insufflation system (GW-200, Fujifilm, Tokyo, Japan) was connected to Leak Cutter (Top, Tokyo, Japan) inserted into the esophagus of a swine to create a SPACE environment. B The body of Schlieren optical system (System Schlieren, SS100, Kato Koken, Tokyo, Japan). C The part of the forceps plug to be observed was placed in the area between the achromat lens and the reflector of the Schlieren device
Schlieren optical system

We used a large, sensitive Schlieren optical system (System Schlieren, SS100, Kato Koken, Tokyo, Japan: Fig. 2A) based on a 10 cm diameter parabolic telescope mirror to image the gas-flows from the biopsy plugs of endoscopy. The schlieren system is located in a 10 × 10 × 3.6 m laboratory. Room air-conditioning is turned off while imaging to provide a quiescent ambient atmosphere. The average air temperature during testing is set at 22 °C, the same as in a typical clinical setting in our hospital. High-definition 1024 × 1024-pixel, 200 frame/second video records of gas leakages were captured by a digital SLR camera (Nikon D90, Tokyo, Japan) with 1/40000 shutter speed. Details on the Schlieren system are given in Supplemental Figs. 1 and 2.

The procedure of inserting and removing forceps

In order to minimize variability due to the procedure, the method of insertion and removal of the endoscopic instrument was standardized as follows. The forceps were inserted perpendicularly to the biopsy plug and advanced vertically by 1 cm per second; after 3 cm insertion (i.e., after 3 s), the forceps were held in place for 1 s and then withdrawn vertically by 1 cm per second till complete removal. We marked 3 cm from the tip of the forceps and inserted it for 3 s while having a timekeeper measure the time to get there, making the speed as uniform as possible. The same procedure was repeated five times for all plugs. The method of insertion and removal of the forceps is summarized in Fig. 3.

Image analysis

The methods to analyze the images of gas leakages are shown in Fig. 4. In this study, the following two parameters were used to semi-quantify the gas leakages.

Initial velocity

The images 50 ms (10 frames) after the initial gas leakage emerged was utilized to decide the initial velocity (Fig. 4A). The distance between the advanced edge of the leakage gas-flow and the entrance of the plug was measured by Image J (National Institute of Health, Maryland, US), which is an open source, public domain image processing software. The initial velocity of gas leakage was calculated by dividing the distance by the time required (50 ms). The mean and standard deviation of the five measurements were calculated.
Fig. 3 Visualization of gas leakage from biopsy plug. A Device insertion and removal procedure. (1) Insert the device upright to the entrance hole. (2) Advance the device 1 cm/s keeping upright to the plug. (3) Advance 3mc and pause 1 s. (4) Extract the device 1 cm/s keeping upright to the plug. (5) Remove the device. B. C Sequential photographs of the insertion and removal of instruments taken using a schlieren optical system every 50 ms; B Insertion, C Removal.

Fig. 4 Analyzing methods to quantify gas leakages. A: Initial velocity: The images 50 ms (10 frames) after the initial gas leakage emerged was utilized. The distance between the advanced edge of the gas and the entrance of the plug (X) was measured by Image J and the velocity of gas was calculated. The initial velocity was calculated using the following formula; Initial velocity (cm/s) = X (cm)/0.05 (s). B. C Maximum leakage area. B Insertion: Analyze the image when the initial gas reached the edge of the vision (Y). C Removal: Analyze the image when the whole body of the device is removed from the plug (Z). The area of the gas diffused was traced manually and measure the area by Image J.
Maximum leakage area

The images when the leakage gas-flow reached the edge of the circular vision was utilized to decide the maximum leakage area of insertion (Fig. 4B). On the other hand, the images when the whole body of the device is removed from the plug was utilized to decide the maximum leakage area of removal (Fig. 4C). The area of the leakage gas-flow diffused was traced manually and measure by Image J. The mean and standard deviation of the five measurements were calculated.

Experiment 1

We investigated whether gas leakages can be visualized using a Schlieren device when biopsy forceps are inserted into a reusable plug. Intragastric pressure was maintained at 8 mmHg, close to the normal intragastric pressure during upper GI endoscopy as daily practice reported by Ushimaru et al. [12].

Experiment 2

The changes in gas leakages were studied when the intragastric pressure was varied at 4–15 mmHg using GW-200. Experiments were repeated five times for each intragastric pressure, and the data are presented as mean ± SD.

Experiment 3

The differences in gas leakages among three types of plugs were investigated: (1) reusable, (2) disposable, and (3) universal types. Repeatedly used (deteriorated) reusable plugs were also investigated in the same way. The details of each plug are as follows: reusable type is MB-358 (Olympus, Tokyo, Japan); disposable type is MAJ-1555 (Olympus); universal type is 711124 (US Endoscopy, Ohio, US). Repeatedly used (deteriorated) is a reusable plug after the biopsy forceps has been inserted and removed more than ten times. Through the experiment, standard biopsy forceps were used. Experiments were performed five times for each plug, and the data are presented as mean ± SD.

Statistical analysis

Data were analyzed with JMP14 software (SAS Institute Inc., Cary, NC, USA). Continuous data are reported as the mean ± standard deviation. ANOVA (analysis of variance) was used for group comparisons of continuous data at a single time point. P values < 0.05 were considered significant.

Results

Experiment 1

Gas leakages were observed on the very moment of insertion and removal in every procedure, but no leakages were observed during forceps advancement, at rest, and during extracting (Fig. 3B and C).

Experiment 2

The initial velocity and maximal leak area (mean ± SD) of gas leakage during forceps insertion at 8 mmHg were 67.5 ± 15.3 cm/s and 16.5 ± 3.9 cm², respectively (Table 1, and Fig. 5). Both initial velocity and maximal leakage area tended to increase with higher intragastric pressure conditions. There was a significant difference between the mean values of initial velocity under each intragastric pressure condition (P = 0.001). As for the gas leakage at the time of forceps removal, both initial velocity and maximal leakage area tended to increase with higher intragastric pressure conditions. There was a significant difference in the mean values (P < 0.0001).

Experiment 3

During both insertion and removal of forceps, both initial velocity and maximal leakage area tended to be large for disposable type and deteriorated reusable type forceps plugs (Table 2 and Fig. 6). On the contrary, both the initial velocity and the maximal leakage area of Universal type forceps plugs were smaller than those of other forceps plugs.

Discussion

Although the SARS-CoV-2 pandemic has prompted a major reevaluation of the risk of infection in healthcare settings, [13] the risk of viral transmission during GI endoscopy has been mainly focused on the secretions from the patient's

### Table 1

|                  | 4 mmHg   | 8 mmHg   | 12 mmHg  | 15 mmHg  | P-value |
|------------------|----------|----------|----------|----------|---------|
| **Insertion**    |          |          |          |          |         |
| Initial velocity (cm/s) | 66.9 ± 3.8 | 67.5 ± 15.3 | 99.2 ± 14.7 | 96.6 ± 13.8 | 0.001   |
| Maximal leak area cm² | 14.3 ± 3.7 | 16.5 ± 3.9 | 19.3 ± 3.3 | 20.3 ± 3.7 | 0.079   |
| **Removal**      |          |          |          |          |         |
| Maximal leak area (cm²) | 2.9 ± 0.5 | 4.6 ± 1.0 | 8.9 ± 1.6 | 13.3 ± 1.4 | <0.001  |

Data represent mean ± SD (n = 5). ANOVA (analysis of variance) was used for group comparisons.
It is not clear whether aerosols or body fluids from the oral cavity pose a greater threat of infection, as these were not evaluated in this study. In any case, wearing PPE is central to infection prevention, but past reports indicate that even with perfect PPE it is difficult to reduce the risk of infection to zero [3]. While perfect PPE is of course very important, we believe it is also important to try to limit aerosol leakage from the plug as well as limit the risk of exposure from coughing and other secretions from the patient’s oral cavity (e.g., wearing a patient mask) in order to further minimize the risk.

In the Experiment 1, we firstly succeeded in visualizing gas leakages from the forceps plug of a GI endoscope using Schlieren optical system. Because of the assumption that the GI endoscopy system itself is essentially a “closed” circuit, aerosol exposure control in GI endoscopy has focused only on aerosols from the patient’s mouth. This study showed that there is a risk of aerosol exposure not only from the patient’s oral cavity, but also from forceps plugs. In the previous study, Urakawa et al. proved that there is a gas leakage from the forceps plug by submerging the endoscope in a water tank and recognizing it as an air bubble [15]. In this study, we examined the leakage in more detail. Visualizing gas leakage as a “jet” and semi-quantifying it in an environment similar to actual clinical practice and identifying factors associated with the amount of gas leakage is an achievement not seen in previous reports. The detailed mechanism of gas leakage was not examined in this study. We plan to analyze the mechanism of gas leakage through non-destructive analysis of plugs in the future, and to develop products that can minimize gas leakage.

The results of Experiment 2 showed a correlation between the intragastric pressure and the initial velocity of gas leakages. Physically, the higher the internal pressure, the higher the external force that pushes the gasflow out of the leakage, and thus the higher the flow velocity, which is a reasonable result. This result suggests that one effective way to reduce gas leakages from the forceps opening is to use lower gastric pressure, i.e., avoid unnecessary gas insufflation. On the other hand, the results of Experiment 1 showed that gas leakage from the plug occurred only when the forceps was inserted or withdrawn, and no leakage was observed when
the forceps tip was in the stomach and the operation was being performed. Based on the above, we do not necessarily recommend low pressure at all times, but believe that it is acceptable to avoid “unnecessary” insufflation only during forceps insertion and removal, and to insufflate adequately during forceps manipulation.

In Experiment 3, there was a difference in the gas leakage velocity and diffusion area depending on the type of plugs. The initial velocity and leakage area of gas leakages from the reusable and disposable plugs were larger than those of the universal type. The difference in the internal structure of the forceps plug might be largely responsible for the difference in airtightness. In particular, plugs that had been used repeatedly had approximately 1.5 times the amount of leakage compared to plugs before use. In the case of the “exhausted” plug that had been used repeatedly and deteriorated, the distortion of the plug was assumed to be much larger than that of other plugs, and as a result, the gas leakages become more significant. In addition, the valve of the deteriorated reusable plug remained distorted even when the forceps was not inserted, and as a result, persistent gas leakages were observed even when the forceps was not inserted (Supplemental Fig. 3). In terms of infection prevention, excessive reuse of reusable plugs should be avoided.

Does the gas leakage from the GI endoscopy system that we visualized contain any infectious viruses? Miyake et al. reported that asymptomatic patients, even those with no detectable virus in their saliva, had SARS-CoV-2 in their GI tract [7]. On the other hand, Flemming et al. reported that SARS-CoV-2 is detectable in the respiratory system but not in the GI samples [16]. In other words, there is still no consensus on whether gas leakages from GI endoscopy systems carry a latent risk of SARS-CoV-2 infection. However, since there is no proof that the virus does not exist, it is important to assume that it does exist and to take all possible measures to prevent infection. We do not want to emphasize the danger of a gas leak from the plug itself, but rather the danger of performing a procedure without being aware of the presence of a gas leak. It is not clear how much gas leakage from the plug actually poses a risk of infection, but theoretically there is a certain risk for aerosol infection because gas leakage is from the gastrointestinal lumen adjacent to the airway at its most oral side. Furthermore, future unknown pathogen which can be more transmittable from the gastrointestinal fluid and/or mucosa will be in the gas leakage. We believe that one of the most significant aspects of this study is that it visualized gas leaks that carry a risk of infection and raised the need for countermeasures.

Routine testing for SARS-CoV-2 is being performed worldwide for daily screening tests, and the potential infection risk for healthcare workers with respect to SARS-CoV-2 has decreased. However, even with such a recent infection control situation, there are several reasons why gas leaks from plugs should be addressed as a source of infection. First of all, the sensitivity of the screening test itself is not 100% [17]. We should not assume that subjects who pass the screening test are not a source of infection. In addition, there are often situations in clinical practice where there is not enough time to perform the screening test. Life-threatening situations, such as hemostatic emergencies, can be handled quickly without a screening test. In such situations, healthcare workers tend to focus on saving the patient’s life, and the gas leakage may become a secondary concern. In addition, there is no screening test for emerging infectious diseases other than SARS-CoV-2, so it is important to prevent...
gas leakage from plugs as a “sustainable” infection control measure.

There are several limitations in this study. First of all, all of the experiments in this study were performed under benchtop settings using ex vivo models, and there might be many differences from our daily clinical practice. Clinically, the forceps would contain a tissue sample and be contaminated with patient fluids which may alter the dynamics of gas leakage, the fluid content of the leaked gas. In fact, we have confirmed that gas leakage does occur in actual living organisms (i.e., living swine), but we omitted it from this study because stable and reproducible data cannot be obtained due to the influence of body fluids (data not shown). When we develop a new forceps plug with less gas leakage, we test its feasibility in living bodies or in the clinical setting.

Secondly, Schlieren converts three-dimensional information into two-dimensional information, i.e., depth information is dismissed. Therefore, the accuracy of leakage quantification using Schlieren is potentially limited. Even though the purpose of this study was not to quantify but to visualize, the method of quantifying gas leakages using Schlieren needs to be further investigated. The third limitation is that we have not been able to prove the existence of viruses in leaking gas. Additional virological approaches such as PCR testing of particulates in leaking gas would be desirable. However, under the current social conditions, it is difficult to establish an experimental system to prove the presence of viruses in gas leakages. It is necessary to assume that there is a certain risk of viral exposure and to be prepared to take countermeasures. Thirdly, all forceps insertions and removals in this study were performed manually, and thus contain compound human error. It may be possible to reduce the influence of human error by further increasing the number of trials. However, the measurement error was small for each of the five trials in this study, and the influence of human error is assumed to be relatively small.

In conclusion, gas leakage was found during insertion and removal of forceps into the plug of GI endoscopy. The type of plug and the internal pressure of the stomach were taken into account? Dig Endosc 32:723–731

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Data availability The data that support the findings of this study are available on request from the corresponding author, Kiyokazu Nakajima.

Declarations

Disclosures All the authors (Drs. Tomo Ishida, Yoshinori Hayashi, Takuro Saito, Kazuysoshi Yamamoto, Kotarou Yamashita, Koji Tanaka, Tomoki Makino, Tsuyoshi Takahashi, Yukinori Kurokawa, Hitoshi Eguchi, Yuichiro Doki, and Kiyokazu Nakajima) have no conflicts of interest or financial ties to disclose.

Ethical approval This research is not medical research on human subjects and does not require IRB approval or written consent.

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