

Multicenter observational study to examine the efficacy of protection during endoscopy examination for Covid-19 infection

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1. Key data

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2. Study rationale and aims

SARS-COV-2 caused the COVID-19 pandemic in Wuhan, China, in December 2019. The numbers of COVID-19-infected patients are increasing worldwide, as is virus-related mortality. SARS-COV-2 is highly infectious and causes nosocomial infections in healthcare professionals. Therefore, appropriate protection for SARS-COV-2 is urgently required.

Even in the time of COVID-19, endoscopic procedures are required to diagnose and treat gastrointestinal bleeding, intestinal obstructions, malignancy, and obstructive jaundice and cholangitis. However, the optimal personal protective equipment (PPE) for healthcare professionals remains unclear.

Recently, the Italian group reported on present PPE status during endoscopy. Many Italian hospitals require the use of face shields and double gloves [Gastroenterology 2020; <https://doi.org/10.1053/j.gastro.2020.04.003>]. However, it is unclear whether these PPE could effectively protect medical staffs from COVID-19 infection. We will evaluate associations between the types of PPE used and COVID-19 infection rates.

3. Participants

Doctors, nurses, and laboratory technicians involved in endoscopic examinations, and endoscopy reprocessing technicians working in the endoscopy suite.

4. Study methods

Design: A prospective observational study. We will perform a Web-based weekly survey over 3 months.

Primary outcome: Endoscopy-related COVID-19 incidence defined as a positive PCR test in the absence of close contact with an infected subject other than patients.

Variables: Occupation (doctor, nurse, laboratory technician, cleaning staff), age, sex,

email address, geographical area (North America, South America, Africa, Asia, Europe, Oceania), years of experience, PPE worn (a cap, goggles, globe [single or double pairs of gloves], an mask [surgical mask, N95, face shield mask], and gowns [isolation-type, vinyl gown], endoscopic procedures for COVID-19 positive and negative patients [esophagogastroduodenoscopy (EGD), colonoscopy, endoscopic retrograde cholangiopancreatography (ERCP), Endoscopic ultrasound (EUS), endoscopic hemostasis], PPE replacement frequency.

Period: April 15 2020 to March 31 2021.

5. Statistics

Planned sample size: 1,000

Analytical datasets: All data received.

General approach:

1) Descriptive statistics will be summarized by each role, geographical area, and PPE worn. We will present numbers, means, standard deviations, minima, and maxima for continuous variables, and numbers and percentages for categorical variables.

2) In inferential testing, the p-value indicating statistical significance (the Type I error risk) will be <0.025 (two-tailed).

Analyses of the primary endpoint (PPE efficacy)

1) Incidence of endoscopy-associated COVID-19 will be measured.

2) The scale is binary/categorical.

3) Incidences will be compared by PPE type, geographical area, and the variables mentioned above using the log-rank test.

4) Missing data will be removed during primary analyses; the primary endpoint analyses will be a complete case analysis.

Subgroup analyses:

The primary endpoints in North America, South America, Africa, Asia, Europe, and Oceania will be evaluated.

Sensitivity analyses:

We will compare the observed incidences per 100,000 of the population in each participating region using the chi-square test.

Interim analyses:

We will perform interim analyses 4 weeks after study commencement or when the number of participants attains 100. To improve safety during endoscopic procedures, we will share the summarized results with all participants.

6. Source documents and access to source data

The “source data” include all available information and the original responses to the Web-based questionnaire. Statisticians will access these data. Principal investigators can access anonymized data. All data will be retained for a minimum of 5 years after the end of the study.

7. Questionnaire

1. How old are you?

2. What is your sex?

Female/male/ I don't want to answer.

3. Where do you work in endoscopy?

Asia/Africa/ Europe/North America/ Oceania/South America.

4. What is your occupation?

Doctor/endoscopist/nurse/laboratory technician/cleaner.

5. Years of experience? (Doctors, nurses, and laboratory technicians: years licensed; cleaners: years since starting such work).

Less than 5 years/5 to less than 10 years/more than 10 years.

6. Have you been diagnosed with COVID-19 at present?

No/Yes, diagnosed by PCR without close contact with any infected person other than patients/Yes, diagnosed by PCR with close contact with a non-patient.

7. Did you perform endoscopic examination(s) this week on COVID-19 patients diagnosed via PCR? (Multiple selections allowed).

No/Yes, I performed upper endoscopic examinations to establish hemostasis/Yes, I performed lower endoscopic examinations to establish hemostasis/Yes, I performed biliary-pancreatic endoscopic examinations including ERCP and EUS.

8. Did you perform endoscopic examinations this week on non-COVID-19 patients? (Multiple selections allowed).

No/Yes, I performed upper endoscopic examinations/Yes, I performed lower endoscopic examinations/Yes, I performed biliary-pancreatic endoscopic examinations including ERCP and EUS/Yes, I performed upper endoscopic hemostasis/Yes, I performed lower endoscopic hemostasis.

9. Personal protection: Which type of mask did you use? (Multiple selections allowed).

Surgical mask/N95 mask/Face shield.

10. How often did you change the mask/shield?

After every endoscopy/Every day (once a day)/After more than 1 day but less than 1 week.

11. Personal protection: Did you use a cap?

Yes/No.

12. How often did you replace the cap?

After every endoscopy/Every day (once a day)/After more than 1 day but less than 1 week.

13. Personal protection: Did you use goggles?

Yes/No

14. Personal protection: Which gown did you use? (Multiple selections allowed)

Long-sleeved isolation gown/Long-sleeved vinyl-type gown/Short-sleeved vinyl type gown/Short-sleeved vinyl-type gown + arm cover/No gown.

15. How often did you replace the gown?

After every endoscopy/Every day (once a day)/After more than 1 day but less than 1 week.

16. Personal protection: What was your glove use?

Single pairs/Double pairs/No gloves.