Negative-Pressure Isolation Mask for Endoscopic Examination During the Coronavirus Disease 2019 Pandemic: A Randomized Controlled Trial

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INTRODUCTION: **During the coronavirus disease 2019 (COVID-19) pandemic, endoscopists have high risks of exposure to exhaled air from patients during gastroscopy. To minimize this risk, we transformed the oxygen mask into a fully closed negative-pressure gastroscope isolation mask. This study aimed to evaluate the effectiveness, safety, and feasibility of use of this mask during gastroscopy.**

METHODS: **From February 28, 2020, to March 10, 2020, 320 patients undergoing gastroscopy were randomly assigned into the mask group (n = 160) or conventional group (n = 160). Patients in the mask group wore the isolation mask during gastroscopy, whereas patients in the conventional group did not wear the mask. The adenosine triphosphate fluorescence and carbon dioxide (CO_2) concentration in patients' exhaled air were measured to reflect the degree of environmental pollution by exhaled air. Patients' vital signs, operation time, and adverse events during endoscopy were also evaluated.**

RESULTS: **Four patients were excluded because of noncooperation or incomplete data. A total of 316 patients were included in the final analysis. The difference between the highest CO_2 concentration around patients' mouth and CO_2 concentration in the environment was significantly decreased in the mask group compared with the conventional group. There was no significant difference in the adenosine triphosphate fluorescence, vital signs, and operation time between the 2 groups. No severe adverse events related to the isolation mask, endoscopy failure, or new coronavirus infection during follow-up were recorded.**

DISCUSSION: **This new isolation mask showed excellent feasibility of use and safety compared with routine gastroscopy during the COVID-19 pandemic.**

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INTRODUCTION

Coronavirus disease 2019 (COVID-19) has become a severe pandemic situation worldwide (1–3). Studies have shown that respiratory droplets and contact are the main transmission routes (4); thus, infection control during endoscopic examination is a major concern. According to the guidelines of the American Society for Gastrointestinal Endoscopy and the Asian-Pacific Society for Digestive Endoscopy for endoscopy during the COVID-19 outbreak, endoscopy centers should reasonably plan for endoscopies to reduce the risk of infection and should minimize unnecessary endoscopies (5). Several gastroscopies are undertaken for urgent indications such as acute gastrointestinal bleeding, biliary sepsis, gastrointestinal obstruction requiring stenting or dilatation, management of gastrointestinal perforation and leakage, foreign body retrieval, and establishment of access for enteral nutrition. As the pandemic eased in China, we gradually restored some nonemergency endoscopy procedures to perform routine medical activities. In general, patients need to take off their breathing masks to undergo gastroscopy. Thus, the pathogen spreads easily through droplets or aerosols because endoscopy centers often do not have a negative-pressure laminar flow examination room. Endoscopists have a high risk of

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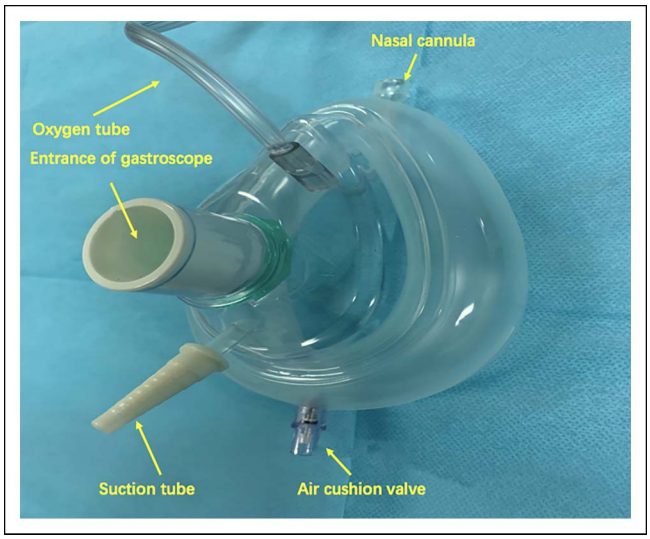

Figure 1. Outer surface of the mask.

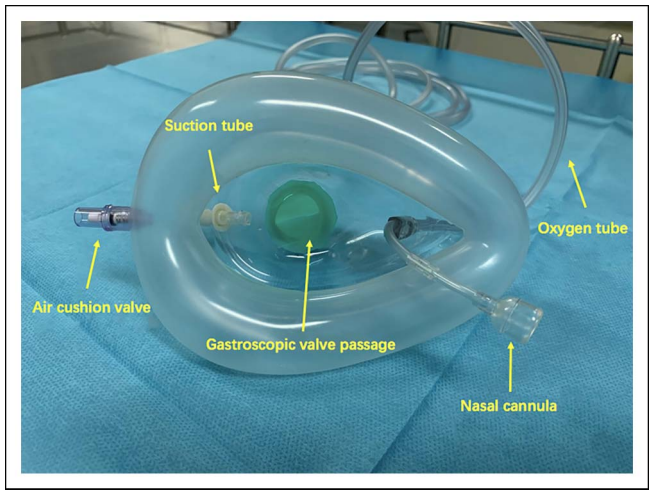

Figure 2. Inner surface of the mask.

exposure to expired air from patients during gastroscopy. Based on the idea that negative-pressure isolation must be used to prevent external infection in the isolation ward of patients with airborne infectious diseases (6,7), we transformed the original oxygen mask into a fully closed gastroscope isolation mask, which can simultaneously meet the requirements of oxygen inhalation and negative-pressure suction.

Our trial aimed to evaluate the effectiveness, safety, and feasibility of use of this gastroscope isolation mask for gastroscopy. We hypothesized that this mask was effective for respiratory isolation and could show usability and safety during the COVID-19 pandemic.

METHODS

Study design

This single-center, prospective, randomized controlled study was conducted at the Endoscopy Center of West China Hospital, Sichuan University, China. The study protocol was approved by the Biomedical Research Ethics Committee, West China Hospital of Sichuan University (Number: HX-IRB-AF-03-V3.0) and was registered in the Chinese Clinical Trial Registry (Number: ChiCTR2000030317).

Design of the negative-pressure isolation mask

The mask is a fully enclosed negative-pressure isolation mask for patients undergoing upper gastrointestinal endoscopy and was modified from a breathing mask with air mattress, thus providing both oxygen inhalation and negative-pressure suction (Figures 1 and 2). It closely fits the patient's face to avoid leakage after inflation. There is a unidirectional flap at the entrance of the endoscope, which can prevent patients' expired gases from leaking. It has 2 openings on each side of the mask bulge: one opening is preserved for the oxygen tube and the other is used for the negative-pressure suction tube. The apertures between the openings and tubes are tightly sealed. The oxygen inhalation flow rate was conventionally adjusted to 6–8 L/min. The suction tube was connected to the central negative-pressure system, and the extracted liquid (gas) was continuously disposed to the hospital waste liquid (gas) treatment center for harmless treatment (Figure 3). This mask is still in the patent application stage.

Patients

The prevalence rate of novel coronavirus pneumonia was unknown; therefore, the sample size was not calculated. Patients who underwent gastroscopy at our endoscopy center from February 28, 2020, to March 10, 2020, were consecutively enrolled in this study. The inclusion criteria included (i) age of 18–80 years, (ii) outpatients undergoing gastroscopy, and (iii) American Society of Anesthesiologists (ASA) physical status classification 1 and 2 patients at low risk of pulmonary aspiration (8). Exclusion criteria included (i) pregnant women, (ii) patients undergoing colonoscopy at the same time, and (iii) suspected or confirmed patients with COVID-19. Written informed consent was obtained from all patients or their legal representatives.

Randomization

The participants were randomized in a 1:1 ratio into the mask group or conventional group by using computer-generated

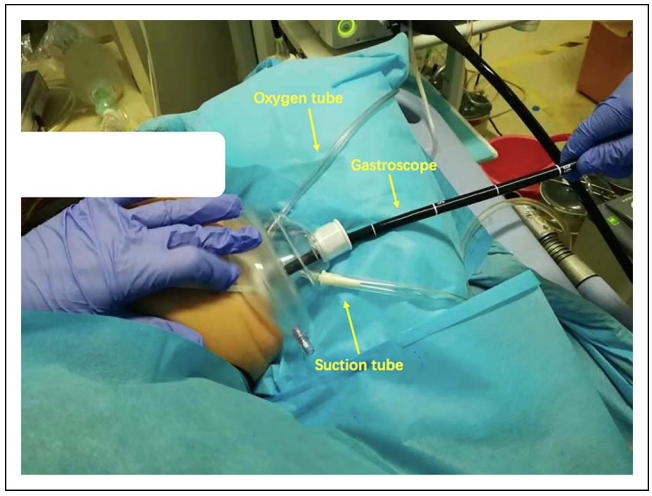

Figure 3. Usage of the mask during gastroscopy.

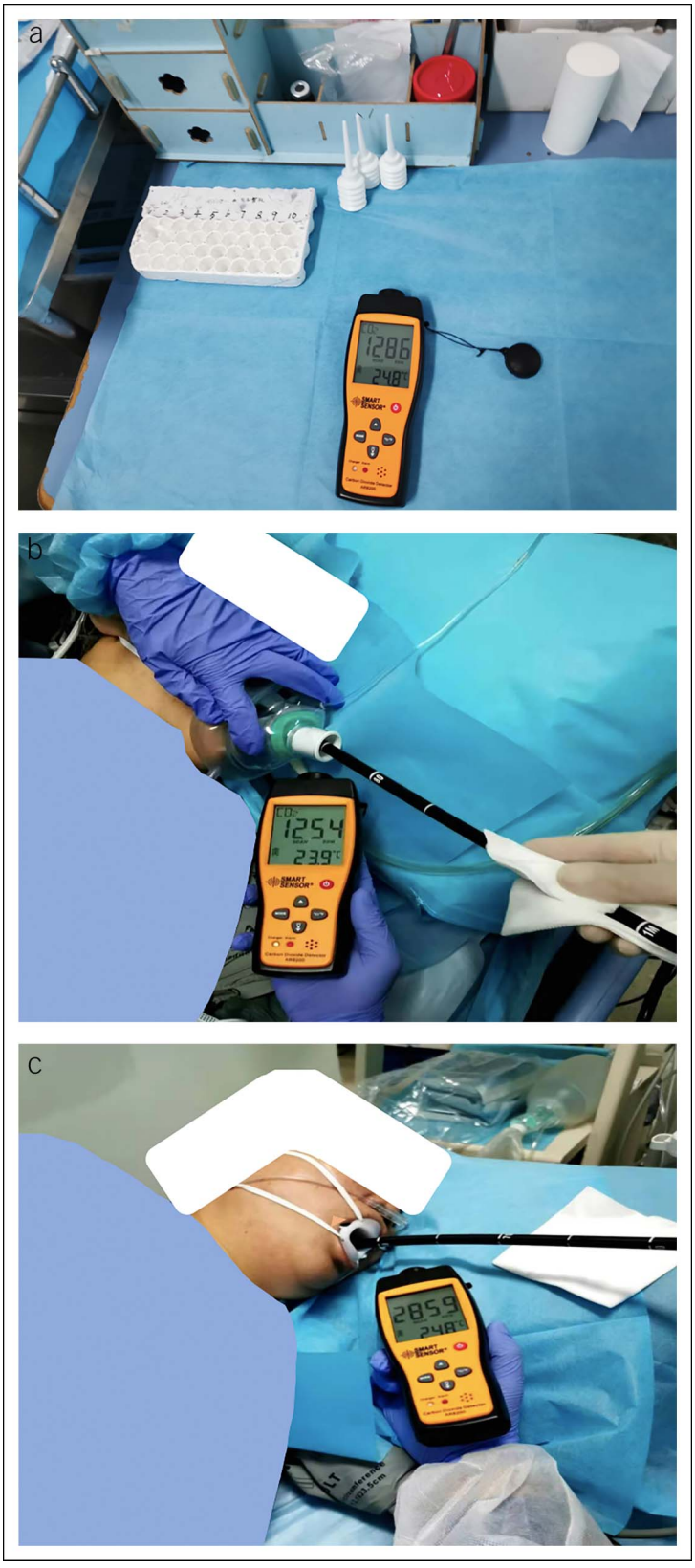

Figure 4 (**a**) Measurement of baseline concentration of carbon dioxide in the environment. (**b**) Measurement of maximum concentration of carbon dioxide in air exhaled by a patient in the mask group. (**c**) Measurement of maximum concentration of carbon dioxide in air exhaled by a patient in the conventional group.

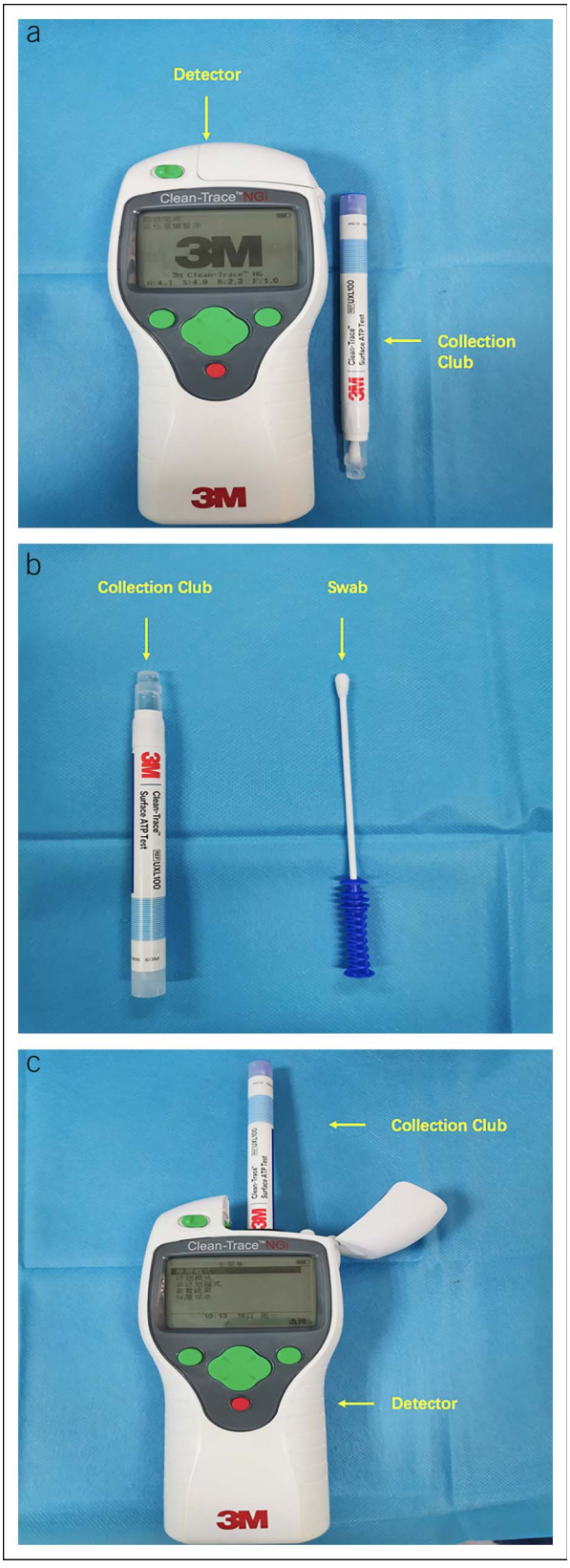

Figure 5. (**a**–**c**). Adenosine triphosphate fluorescence detector and swab.

Figure 6. Measurement of adenosine triphosphate fluorescence in air exhaled by a patient in the mask group.

randomization numbers. Two nurses who were not directly involved in medical care were assigned to allocate the eligible patients into either of the 2 groups, with the sequence numbers concealed in an opaque envelope. Investigators involved in data analysis and patients signing the informed consent document before endoscopy were blinded to the group assignments, until all data collection and data queries had been completed and the database was locked. The operator and data collector could not be blinded to the patients' assignments.

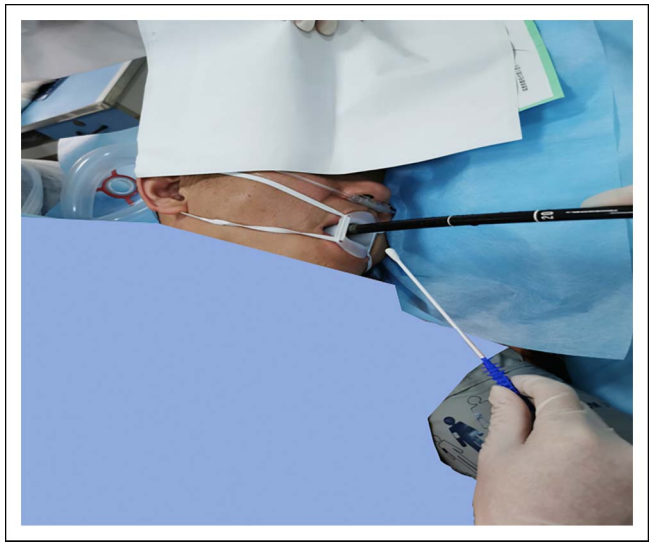

Figure 7. Measurement of adenosine triphosphate in air exhaled by a patient in the conventional group.

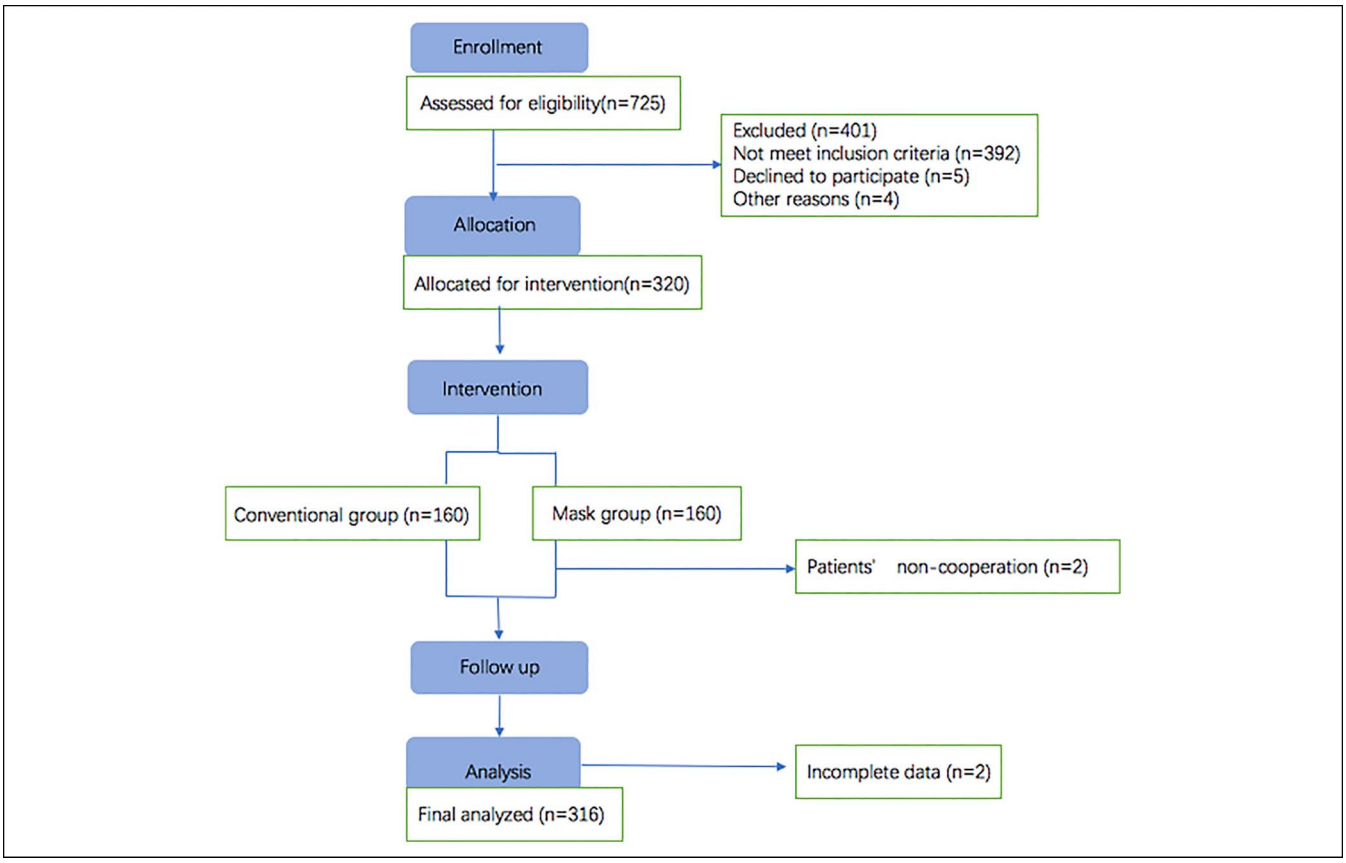

Figure 8. Flow chart of recruitment and participants.

Intervention and follow-up

All involved doctors and nurses received training in using the negative-pressure isolation mask in advance. Patients in the mask group wore the negative-pressure isolation mask for endoscopic examinations after removing their surgical masks, whereas patients in the conventional group directly had endoscopic examinations after removing their surgical masks. Upper endoscopy for the 2 groups was performed after routine anesthesia and examination (9). Anesthesia was induced with midazolam 1 mg, sufentanil 0.1 μg/kg, and propofol 1–2 mg/kg. Gastroscopy was started when the sedation degree reached level 3 or 4. According to the Ramsay classification method, the degree of sedation was assessed as follows: 0—awake, 1—drowsy but with good reaction, 2—falling asleep but easy to wake up, 3—falling asleep but with difficulty in arousing and present eyelash reflex, and 4—falling asleep with absent eyelash reflex (10). Additional 20–30 mg propofol, if necessary, was administered during examination according to the patient's reaction and examination time. After endoscopy, patients in both groups were followed up for 1 month, and any abnormality or coronavirus infection was recorded in detail.

Outcome measurements

The primary outcomes were the difference between carbon dioxide (CO_2) concentration in the examination room at baseline and the peak value during examination (Figure 4) and adenosine triphosphate (ATP) fluorescence value (Figures 5–7). The measurement point of the baseline concentration of CO_2 was the examination desk before patient entry, whereas the measurement point of the peak concentration of CO_2 was 5–10 cm from the mouth and nose of the patient. The swab for ATP was collected at 2 minutes after insertion of the endoscope, 5–10 cm from the mouth of patient, and ATP fluorescence was detected with a matching detector. The concentration differences of CO_2 and ATP fluorescence were used to assess the isolation effects of the mask. These 2 methods were used successively in our experiment. Considering that endoscopy and treatment already take considerable amount of time, to avoid further delay, only one of the primary outcomes, and not both, was measured in each patient.

Table 1. Baseline of all included patients

	Mask group (n = 157)	Conventional group (n = 159)	*P*
Sex ratio (M/F)	80/77	85/74	0.656
Age(yr)	48.34 ± 14.59	49.73 ± 14.08	0.403
HR(times/min)	81.79 ± 13.28	79.38 ± 12.25	0.093
RR(times/min)	20 (19–20)	20 (19–20)	0.301
SpO_2(%)	97 (96–99)	98 (96–99)	0.174

The sex ratio between groups were compared by χ^2 tests. The age and heart rate were compared by *t* tests. The respiratory rate and pulse oxygen saturation were compared by Mann–Whitney *U* tests.
HR, heart rate; M/F, male/female; RR, respiratory rate; SpO2, pulse oxygen saturation.

Table 2. Baseline of 100 patients with ATP fluorescence value of exhaled gas detected

	Mask group (n = 49)	Conventional group (n = 51)	P
Sex ratio (M/F)	20/29	26/25	0.308
Age(yr)	46.71 ± 16.44	43.88 ± 16.39	0.427
HR(times/min)	74.80 ± 5.73	74.12 ± 5.67	0.578
RR(times/min)	18 (17–19)	18 (18–20)	0.088
SpO_2(%)	97 (96–98)	98 (97–99)	0.095

The sex ratio between groups were compared by χ^2 tests. The age and heart rate were compared by *t* tests. The respiratory rate and oxygen saturation were compared by Mann–Whitney *U* tests.
HR, Heart rate; M/F, Male/Female; RR, Respiratory rate; SpO2, Pulse oxygen saturation.

Secondary outcomes were adverse events, COVID-19, and examination time. Adverse event was defined as any abnormality, such as aspiration or instability of vital signs, that occurred during examination. Examination time was defined as the time from insertion to pulling back of the endoscope. COVID-19 was defined if the patient was diagnosed with it during the 1-month follow-up.

Statistical analysis

The statistical analysis was performed with IBM SPSS for Mac (version 26.0 statistical software package; IBM Corp, Armonk, NY). The measurement data were described with mean (standard deviation) or median (interquartile range) according to normality and compared with *t*-tests or Mann–Whitney *U* tests. The rate or composition ratio of the counting data was described with χ^2 tests or Fisher exact tests as appropriate. *P* value less than 0.05 was defined as statistically significant.

RESULTS

Baseline characteristics

From February 28, 2020, to March 10, 2020, a total of 725 patients underwent gastroscopy at West China Hospital. Among them, 324 were eligible for inclusion in the study, and 4 of these were excluded because they met the exclusion criteria. A total of 320 patients who gave informed consent were randomized in a 1:1 ratio into the mask group and conventional group by using computer-generated randomization numbers. Two gastroscope insertion failures (more than 3 failed attempts each) occurred among the 160 patients assigned into the mask group, resulting in 158 patients receiving the allocated intervention (gastroscopy performed through the endoscopy channel). Two patients were excluded because of incomplete data. Finally, 316 patients were included in the final analysis. The study flow chart is shown in Figure 8. The baseline data of all included patients were similar (Tables 1–3).

Table 3. Baseline of 216 patients with CO2 concentration detected

	Mask group (n = 108)	Conventional group (n = 108)	P
Sex ratio (M/F)	60/48	59/49	0.891
Age(yr)	49.08 ± 13.69	52.22 ± 11.92	0.080
HR(times/min)	84.96 ± 14.49	81.79 ± 13.68	0.108
RR(times/min)	20 (20–20)	20 (19–20)	0.869
SpO_2(%)	98 (96–99)	98 (96–99)	0.579

The sex ratio between groups were compared by χ^2 tests. The age and heart rate were compared by *t* tests. The respiratory rate and oxygen saturation were compared by Mann-Whitney *U* tests.
HR, Heart rate; M/F, male/female; RR, respiratory rate; SpO2, pulse oxygen saturation.

Table 4. Comparison of basic value, maximum value, and difference of carbon dioxide concentration between 2 groups

	Mask group (n = 108)	Conventional group (n = 108)	P
Basic value (ppm)	868.5 (762.5–950.0)	873.0 (789.0–964.0)	0.175
Maximum value (ppm)	885.5 (781.25–970.25)	2152.0 (1873.25–2773.5)	<0.001
Difference of CO_2 (ppm)	9 (5–16)	1242 (972.5–1934.25)	<0.001

Difference of CO2 = maximum value − basic value.
CO2, carbon dioxide.

Primary outcomes

During the study, we measured the ATP fluorescence of exhaled air for 100 of 316 patients (31.65%) and CO_2 concentration for 216 of 316 patients (68.35%). The median difference between the highest CO_2 concentration around the patients' mouth and CO_2 concentration in the environment was significantly lower in the mask group than in the conventional group (9 ppm vs 1,242 ppm, respectively, $P < 0.001$) (Table 4). There was no significant difference in the average ATP fluorescence values between the mask group and conventional group: 8 relative light units (RLUs) vs 9 RLUs, respectively, $P = 0.141$ (Table 5).

Table 5. Comparison of ATP fluorescence value of exhaled gas and vital signs between 2 groups

	Mask group (n = 49)	Conventional group (n = 51)	P
ATP fluorescence value(RLUs)	8 (6.5–11)	9 (7–13)	0.141
HR(times/min)	74.94 ± 5.73	74.94 ± 6.25	1.000
RR(times/min)	18 (17–19)	18 (17–19)	0.790
SpO_2(%)	98 (96–98)	98 (97–99)	0.207
Operation time(s)	482.02 ± 14.74	484.24 ± 13.15	0.375

The heart rate and operation time were compared by *t* tests. The respiratory rate, oxygen saturation, and ATP fluorescence value were compared by Mann–Whitney *U* tests.
ATP, adenosine triphosphate; HR, heart rate; RR, respiratory rate; SpO2, pulse oxygen saturation.

Table 6. Vital signs and operation time between the 2 CO2 groups

	Mask group (n = 108)	Conventional group (n = 108)	*P*
HR	84.92 ± 14.32	81.79 ± 13.68	0.113
RR	20 (20–20)	20 (19–20)	0.964
SpO_2 (%)	97 (96–99)	97.5 (96–99)	0.201
Operation time (s)	483.29 ± 34.53	491.64 ± 34.76	0.074

The heart rate and operation time were compared by *t* tests. The respiratory rate and oxygen saturation were compared by Mann–Whitney *U* test.
HR, heart rate; RR, respiratory rate; SpO2, pulse oxygen saturation.

Secondary outcomes

Table 6 shows patients' vital signs (heart rate, respiratory rate, and peripheral oxygen saturation) and the operation time during gastroscopy. There was no significant difference in vital signs and operation time between the 2 groups.

Adverse event

No severe adverse event related to the isolation mask was observed. No endoscopy failure occurred, and no new COVID-19 case was recorded during follow-up.

DISCUSSION

This study evaluated the effectiveness, safety, and feasibility of use of a novel gastroscope isolation mask for gastroscopy. One important finding was that the self-made mask facilitated a high success rate of upper gastrointestinal endoscopy, with first-attempt success rate of 99% (95% confidence interval [CI]: 98%–100%). Furthermore, the mask was effective, and the endoscopists reported easy gastroscope insertion (defined as no more than 3 attempts to pass the gastroscope into the esophagus through the endoscopy channel of the mask) in 95% of cases (95% CI: 93–97%). Together, these findings suggest that the mask has high feasibility of and safety for use during gastroscopy.

The primary outcome, which was used to evaluate the effectiveness of the trial, was the difference in CO_2 concentration between the highest value in exhaled air and the baseline value in ambient air. Previous investigations of respiratory diseases showed that lower indoor CO_2 concentration indicated better ventilation (11). Theoretically, the exhaled air of patients with respiratory diseases contains high levels of CO_2 and related pathogenic microorganisms (12). The negative-pressure isolation mask used during gastroscopy in this study can avoid direct spray of droplets and achieve mechanical ventilation through continuous negative-pressure suction, thus reducing environmental pollution with patients' exhaled air. Therefore, the difference in CO_2 concentration can reflect the isolation effect of the negative-pressure isolation mask. Our study showed that the difference between the highest CO_2 concentration about 5–10 cm from the faces of patients and CO_2 concentration in the environment was significantly reduced in the mask group compared with the conventional group (9 (5–16) ppm vs 1,242 (972.5–1934.25) ppm, $P < 0.001$) (Table 4). These data provide further evidence that the mask is effective for clinical use during gastroscopy. There was no significant difference in the operation time and vital signs between the 2 groups, as shown in Table 6, which also verifies the safety and feasibility of use of this mask.

Another important primary outcome is the ATP fluorescence in patients' exhaled air. Because of its presence in living organisms, ATP was first used as an indicator of cleanliness in the food industry. Subsequently, ATP measurements have been extensively used to assess hospital cleanliness and to monitor the cleanliness of cleaned surfaces (13). Currently, the ATP fluorescence detection method is extensively used to evaluate cleanliness because readings expressed in relative light units (RLUs) can be obtained on site. Its principle is that ATP reacts with a fluorescent enzyme to release light ions and produce fluorescence. The intensity of fluorescence is directly proportional to the amount of ATP contained in the tested substance. Previous studies have shown that the concentration of bacteria and inorganic and organic substances in the exhaled air of patients can affect the RLU value of the ATP fluorescence detection method (14). In view of this, we set the ATP fluorescence value as an outcome measurement, which was defined as the fluorescence value displayed on the detector. However, our study showed that there was no significant difference in the ATP fluorescence value between the 2 groups: 8 (6.5–11) RLUs vs 9 (7–13) RLUs, $P = 0.141$. Insufficient sample size may be the main reason for this observation. Nonstandard mask wearing, poor patient compliance, and measurement errors may also lead to negative results for this outcome.

Strengths of this study are as follows.

1. This study is a prospective randomized controlled trial with high reliability.
2. This study has high originality and clinical relevance, and the research results are easy to be transformed into clinical practice.

There are also some limitations to this clinical trial. First, our center did not perform endoscopy for patients with confirmed or suspected COVID-19. We therefore could not evaluate the protective effect of the mask through the clinical incidence rate; this is the largest but inevitable limitation in this study. It is necessary for a confirmed or suspected COVID-19 patient to undergo endoscopic diagnosis and treatment in a laminar flow ward. However, endoscopy centers usually do not have such conditions. Our endoscopy center mainly performed endoscopy for ordinary patients who were screened for and tested negative to COVID-19 during the pandemic. Owing to the peculiarity of clinical trials during the pandemic period and ethical considerations, we did not include patients with severe illness, such as those with ASA physical status of 3 or above or patients with new coronavirus infection. Our research has proven the safety, feasibility of use, and exact isolation effect of the negative-pressure mask in patients with mild disease. We may carry out further research in the future to apply our mask to patients with severe disease. Second, there might be some data bias in the study because it is open and conducted in a single center. Third, although the results showed that the CO_2 concentration around the patient's mouth significantly decreased with the negative-pressure mask, no difference in ATP fluorescence value was found between the 2 groups. This indicates the necessity of a larger sample size and further evaluation. Finally, this mask is still in the patent application stage and has not been widely promoted. The price of the conventional surgical mask is 1–2 yuan per mask, whereas the cost of our self-

made mask is 31 yuan per mask (8 yuan for unidirectional flap, 15 yuan for breathing mask, and 8 yuan for nasal tube). The self-made mask will be more affordable when mass-produced.

In conclusion, sequential use of this mask by gastroscopy patients was associated with high endoscopy success rate, which shows the safety and feasibility of use of the mask. The reduction in air pollutants, indicated by decreased CO_2 concentration around the patients' mouths, showed that the mask has the effect of respiratory isolation to some extent.

CONFLICTS OF INTEREST

Guarantor of the article: Bing Hu, MD.

Specific author contributions: Y.G., L.-S.Y., and B.H.: Conception and design. J.X. and J.D.: Collection and interpretation of the data. Y.G.: Drafting of the article. L.-S.Y., Q.-Y.Z., and B.H.: Critical revision of the article for important intellectual content. Y.G., J.X., L.-S.Y., J.D., Q.-Y.Z., and B.H.: Final approval of the article.

Financial support: None to report.

Potential competing interests: None to report.

Study Highlights

WHAT IS KNOWN

- ✓ Coronavirus is spread through aerosols and droplets.
- ✓ Endoscopists are at risk of contracting the virus from patient's expired air during endoscopic procedures.

WHAT IS NEW HERE

- ✓ A negative-pressure isolated mask can reduce environmental contamination from patients' expired air during endoscopy.

TRANSLATIONAL IMPACT

- ✓ The innovative isolation mask is useful for reducing transmission of respiratory pathogens during endoscopy.

REFERENCES

1. Guan WJ, Ni ZY, Hu Y, et al. China medical treatment expert group for covid-19. Clinical characteristics of coronavirus disease 2019 in China. N Engl J Med 2020;382(18):1708–20.
2. Li Q, Guan XH, Wu P, et al. Early transmission dynamics in wuhan, China, of novel coronavirus-infected pneumonia. N Engl J Med 2020; 382(13):1199–207.
3. Wang FS, Zhang C. What to do next to control the 2019-nCoV epidemic?. The Lancet 2020;395(10222):391–3.
4. Zhou F, Yu T, Du RH, et al. Clinical course and risk factors for mortality of adult inpatients with COVID-19 in wuhan, China: A retrospective cohort study. The Lancet 2020;395(10229):1054–62.
5. Chiu PWY, Ng SC, Inoue H, et al. Practice of endoscopy during COVID-19 pandemic: Position statements of the asian pacific society for digestive endoscopy (APSDE-COVID statements). Gut 2020;69(6):991–6.
6. Repici A, Maselli R, Colombo M, et al. Coronavirus (COVID-19) outbreak: What the department of endoscopy should know). Gastrointest Endosc 2020;92:192–7.
7. Zhang YF, Zhang XD, Liu L, et al. Suggestions for infection prevention and control in digestive endoscopy during current 2019-nCoV pneumonia outbreak in Wuhan, Hubei province, China. Endoscopy 2020; 52:1–3.
8. Qadeer MA, Rocio Lopez A, Dumot JA, et al. Risk factors for hypoxemia during ambulatory gastrointestinal endoscopy in ASA I–ii patients[J]. Dig Dis Sci 2009;54(5):1035–40.
9. Terblanche NCS, Middleton C, Choi-Lundberg DL, et al. Efficacy of a new dual channel laryngeal mask airway, the LMA ® Gastro™ airway, for upper gastrointestinal endoscopy: A prospective observational study. Br J Anaesth. 2018;120(2):353–60.
10. Thompson R, Seck V, Riordan S, Wong S. Comparison of the effects of midazolam/fentanyl, midazolam/propofol, and midazolam/fentanyl/ propofol on cognitive function after gastrointestinal endoscopy[J]. Surg Laparosc Endosc Percutan Tech 2019;29:441–6.
11. Diehl JL, Boisramé-Helms J, Chardon-Couteau A, et al. The role of extracorporeal removal of CO 2 (ECCO 2 R) in the management of respiratory diseases [J]. Rev Mal Respir. 2017;34(6): 598–606.
12. Siobal MS. Monitoring exhaled carbon dioxide [J]. Respir Care2016; 61(10):1397–416.
13. Nante N, Ceriale E, Messina G, et al. Effectiveness of ATP bioluminescence to assess hospital cleaning: A review. Prev Med Hyg 2017;58(2):E177–E183.
14. Sanna T, Dallolio L, Raggi A, et al. ATP bioluminescence assay for evaluating cleaning practices in operating theatres: Applicability and limitations. BMC Infect Dis 2018;18(1):583.