Effect of surgical mask on exercise capacity in COPD: a randomised crossover trial

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To the Editor:

Patients with COPD infected with SARS-CoV-2 are more likely to require intensive care and have a higher risk of mortality [1, 2]. Vaccine strategies are critical in reducing the risk of coronavirus disease 2019 (COVID-19); however, vaccination alone cannot ensure prevention and control due to the emergence of new variants of the coronavirus [3, 4]. The use of masks in community settings is another strategy to prevent COVID-19 [5]. Therefore, it is reasonable for patients with COPD to use face masks in public places during the COVID-19 pandemic.

A previous study found that face masks do not affect gas exchange in patients with COPD or healthy individuals; however, no comparisons were made with the unmasked state [6]. Therefore, the effect of surgical masks on exercise capacity, desaturation or dyspnoea during physical activity in patients with COPD compared to when not wearing a mask is unknown. The 6-min walk test (6MWT) is a clinical tool that is commonly used to evaluate exercise capacity in patients with COPD [7], and the effect of wearing a surgical mask on the 6MWT in patients with COPD remains unknown. To clarify these clinical questions, we performed the 6MWT with and without surgical masks in outpatients with COPD.

This single-centre, crossover, randomised trial was registered on the website of the University Hospital Medical Information Network Clinical Trials Registry (UMIN000042596). Participants were patients with COPD who visited Showa University Hospital, Tokyo, Japan, and were invited to participate in the study from December 2020 through February 2021. COPD was diagnosed by spirometry (post-bronchodilator forced expiratory volume in 1 s (FEV_1) to forced vital capacity ratio <0.7) according to the Global Initiative for Chronic Obstructive Lung Disease (GOLD) 2021. Patients with heart failure and those with contraindications for undergoing 6MWT were excluded (full inclusion/exclusion criteria at https://upload.umin.ac.jp/cgi-open-bin/ctr/ctr_view.cgi?recptno=R000048614). This study was approved by our ethics committee (approval number: 3248), and all patients provided informed consent. Participants were randomised into either group A that underwent the 6MWT wearing a surgical mask followed by a 6MWT without wearing a surgical mask, or group B that underwent 6MWT in the reverse order. Participants were randomly assigned when consent was obtained and the 6MWT was performed at a later date in most patients.

Participants were provided with commonly used surgical masks (2827J; 3M Japan Limited, Tokyo, Japan) and were checked for appropriate mask fitting. A 6MWT was conducted on the same day with and without the mask, and a 30 min wash-out period was provided between each measurement [8]. Each patient's heart rate and oxygen saturation (S_{pO_2}) were continuously measured using the same pulse oximeter (AnypalWalk ATP-W03; Fukuda Denshi Co., Ltd, Tokyo, Japan) with the patient blinded to the readings. Values were recorded every minute and there were no deficiencies due to measurement errors. Before and after 6MWT, the severity of dyspnoea was assessed using the modified Borg scale.

The primary outcome was the difference in the 6-min walk distance (6MWD) with and without a surgical mask. The required sample size was 38. Therefore, we enrolled 42 patients, and of these, five participants were excluded (two had acute low back pain, one did not meet the inclusion criteria, one had onset of angina, and one had high systolic blood pressure before the study). Repeated-measures ANOVA was used

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Although patients with COPD using a surgical mask while walking were more likely to develop dyspnoea than those without a mask, there was no decrease in 6MWD or S_{pO2}. A surgical mask can be safely recommended for COVID-19 prevention in patients with COPD. https://bit.ly/3xldw4P

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to evaluate the effects of the surgical mask, controlling for time and allocation effects. All statistical analyses were performed using JMP Pro for Macintosh, version 15 (SAS Institute, Cary, NC, USA) and R (R Core Team, 2021).

In total, 37 patients underwent the 6MWT. The mean±SD age of the patients was 72.49±5.63 years and 34 (91.89%) were males. The mean FEV_1 was 62.22±17.30% predicted, and the proportion of patients with GOLD stages 1, 2, 3 and 4 COPD were five (13.5%), 24 (64.9%), seven (18.9%) and one (2.7%), respectively. The mean COPD Assessment Test score was 14.92±5.66 points, median (range) duration between the consent and the testing day was 30 (14–53) days, mean number of moderate and severe acute exacerbations in the past year was 0.16±0.37, and 100% of the patients were using bronchodilators regularly.

Table 1 presents the impact of a surgical mask, including the primary outcome, after adjusting for the time and allocation effects. Surgical mask did not affect the 6MWD in patients with COPD (adjusted effect of surgical mask −5.86 m, 95% CI −13.38, 1.56). It had no effects on S_{pO_2}, heart rate and the Borg score at rest. Similarly, it had no effects on the lowest S_{pO_2} and highest heart rate during the 6MWT; however, wearing a mask worsened the Borg score at the end of the 6MWT (adjusted effect 0.91, 95% CI 0.45, 1.37).

The main finding of this study was that wearing a surgical mask did not affect the results of the 6MWD in patients with COPD. Similarly, it did not affect the S_{pO_2} and heart rate during the 6MWT. A previous study showed that alveolar ventilation and gas exchange were not significantly affected by face masks in healthy subjects [9]; our findings demonstrated similar results in patients with COPD.

A notable result of this study was that wearing a surgical mask significantly worsened the Borg score at the end of the 6MWT. Wearing a face mask increases dyspnoea during exercise due to re-inhalation of CO_2 and the cause of dyspnoea associated with wearing surgical masks is the perception of increased ventilation [10]. Another cause of worsening dyspnoea might be an increase in temperature at the facial surface [11]. Previous studies have shown that placing a fan near the face of patients with COPD reduces dyspnoea by decreasing the temperature and humidity of the air [12].

TABLE 1 Effects of surgical mask compared to when not wearing surgical mask

	Mean±SD	Least squares mean (95% CI)	Adjusted effect of surgical mask[#] (least squares mean, 95% CI)
6MWD (m)			
With surgical mask	430.95±99.10	431.06 (399.50, 462.62)	−5.86 (−13.28, 1.56)
Without surgical mask	436.89±87.01	436.92 (405.37, 468.48)	
S_{pO_2} at rest before 6MWT (%)			
With surgical mask	95.30±1.68	95.30 (94.72, 95.88)	−0.17 (−0.51, 0.16)
Without surgical mask	95.46±1.77	95.47 (94.89, 96.05)	
Heart rate at rest before 6MWT (beats per min)			
With surgical mask	79.97±10.29	79.91 (76.57, 83.25)	0.26 (−1.39, 1.91)
Without surgical mask	79.7±9.96	79.65 (76.30, 82.99)	
Borg score at rest before 6MWT			
With surgical mask	0.53±0.71	0.52 (0.30, 0.75)	0.14 (−0.07, 0.36)
Without surgical mask	0.38±0.61	0.38 (0.16, 0.60)	
Lowest S_{pO_2} during 6MWT (%)			
With surgical mask	88.81±5.62	88.81 (86.97, 90.64)	−0.49 (−1.02, 0.04)
Without surgical mask	89.30±5.23	89.30 (87.46, 91.14)	
Highest heart rate during 6MWT (beats per min)			
With surgical mask	116.41±16.81	116.39 (111.62, 121.17)	0.21 (−3.61, 4.04)
Without surgical mask	116.14±10.87	116.18 (111.40, 120.95)	
Borg score at the end of 6MWT			
With surgical mask	3.22±1.78	3.21 (2.57, 3.85)	0.91 (0.45, 1.37)
Without surgical mask	2.30±2.01	2.30 (1.66, 2.94)	

[#]: clinical data values without surgical mask − clinical data values with surgical mask, by statistically controlling the time effect and allocation effect. A repeated-measures ANOVA, which can estimate the treatment effect, was used. 6MWD: 6-min walk distance; S_{pO_2}: oxygen saturation measured by pulse oximeter; 6MWT: 6-min walk test.

There were several limitations to this study. First, patients could not be blinded to wearing a surgical mask, which might have affected the Borg scores. Second, all participants in this study were Japanese, there was no random sampling, and the majority were men with moderately severe COPD. Third, patients who provided consent and knew that they would be walking wearing a mask might have practiced it privately before the test. Fourth, this study was not performed using a cloth mask or a combination of a surgical mask and a cloth mask. However, the strength of the study is that the measurements were carried out in both unmasked and masked conditions, which is difficult during the current COVID-19 pandemic. Future studies including a larger number of patients in GOLD 3 and 4 stages, using various types of masks, and including other diseases such as interstitial pneumonia and heart failure, are desirable.

In conclusion, wearing a surgical mask has negligible effects on exercise capacity and results of 6MWT in patients with COPD wearing surgical masks in clinical practice and research should not introduce significant measurement bias. Furthermore, although walking with a surgical mask resulted in worse dyspnoea, there was no reduction in S_{pO_2}. Therefore, wearing a surgical mask can be safely recommended for patients with COPD since it could reduce the risk of contracting COVID-19 and other respiratory-transmitted infectious diseases.

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This randomised controlled trial was registered on the website of the University Hospital Medical Information Network Clinical Trials Registry (UMIN000042596). All raw data collected for the study will be made available to others after request.

Author contributions: All authors had full access to all data in the study and had final responsibility for the decision to submit for publication. K. Hirai and H. Sagara contributed to the study concept and design. K. Hirai, H. Sato, Y. Sato and Y. Uchida collected and interpreted the data. K. Hirai wrote the draft manuscript. E. Inoue and K. Hirai performed the statistical analyses. A. Tanaka, E. Inoue and H. Sagara revised the manuscript for important intellectual content. K. Hirai obtained the funding.

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