


# Systems on Top of Nasal Cannula Improve Oxygen Delivery in Patients with COVID-19: a Randomized Controlled Trial



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**BACKGROUND:** Treating hypoxemia while meeting the soaring demands of oxygen can be a challenge during the COVID-19 pandemic.

**OBJECTIVE:** To determine the efficacy of the surgical facemask and the double-trunk mask on top of the low-flow oxygen nasal cannula on arterial partial pressure of oxygen (PaO<sub>2</sub>) in hypoxemic COVID-19 patients.

**DESIGN:** Randomized controlled trial.

**PARTICIPANTS:** Hospitalized adults with COVID-19 and hypoxemia treated with the low-flow nasal cannula were enrolled between November 13, 2020, and March 05, 2021.

**INTERVENTIONS:** Patients were randomized in a 1:1:1 ratio to receive either the nasal cannula alone (control) or the nasal cannula covered by the surgical facemask or the double-trunk mask. Arterial blood gases were collected at baseline and 30 min after the use of each system. The oxygen output was adapted afterwards to retrieve the baseline pulse oxygen saturation. The final oxygen output value was recorded after another 30-min period.

**MAIN MEASURES:** The primary outcome was the absolute change in PaO<sub>2</sub>. Secondary outcomes included changes in oxygen output, arterial partial pressure of carbon dioxide (PaCO<sub>2</sub>), vital parameters, and breathlessness.

**KEY RESULTS:** Arterial blood samples were successfully collected in 24/27 (8 per group) randomized patients. Compared to the nasal cannula alone, PaO<sub>2</sub> increased with the surgical facemask (mean change: 20 mmHg, 95% CI: 0.7–38.8; *P* = .04) and with the double-trunk mask (mean change: 40 mmHg; 95% CI: 21–59; *P* < .001). Oxygen output was reduced when adding the surgical facemask (median reduction: 1.5 L/min [95% CI: 0.5–4.5], *P* < .001) or the double-trunk mask (median reduction: 3.3 L/min [95% CI: 2–5], *P* < .001). The double-trunk mask was associated with a PaCO<sub>2</sub> increase of 2.4 mmHg ([95% CI: 0–4.7], *P* = .049). Neither mask influenced vital parameters or breathlessness.

**CONCLUSIONS:** The addition of the surgical facemask or the double-trunk mask above the nasal cannula improves arterial oxygenation and reduces oxygen consumption.

**KEY WORDS:** coronavirus disease 2019; hypoxemia; oxygen therapy; double-trunk mask; surgical mask.

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## INTRODUCTION

Hypoxemia is a typical feature of the coronavirus disease 2019 (COVID-19) caused by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection. An early epidemiological study indicated that 19% of infected patients develop a severe or critical pneumonia and present a pulse oxygen saturation  $\leq 93\%$  at rest.<sup>1</sup> While 5% of patients will necessitate intensive care, most hospitalized COVID-19 patients will require supplemental oxygen therapy<sup>2,3</sup> that can be managed on a regular ward.<sup>4</sup>

Low-flow nasal cannulas are the most commonly used oxygen delivery systems to treat mild to moderate hypoxemia.<sup>5,6</sup> Those open systems of supplementation are characterized by a high amount of leaking air around the oxygen source. The high respiratory rate observed in COVID-19 patients<sup>2,3,7,8</sup> will further decrease the fraction of oxygen delivered into the lungs. To meet the patient's oxygen needs, the oxygen output must be increased. However, higher flows of dry gas into the nasopharyngeal passage are uncomfortable and increase the risks of mucosa dryness, nasal resistance,<sup>9</sup> and epistaxis,<sup>10</sup> which reduce compliance to therapy. In addition, the COVID-19 pandemic has exposed countries to a sudden spurt in oxygen demand, overwhelming the deficient oxygen supply systems of unprepared regions and threatening patient survival.<sup>11</sup> Oxygen distribution and delivery are particularly compromised in low- and middle-income countries.<sup>12–14</sup> Some settings of high-income countries have

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also experienced shortages of oxygen, such as nursing homes and ambulatory care.<sup>15</sup>

Because of the above-mentioned concerns, there is an imperative need to improve the performance of patients' oxygen delivery with easy-to-perform procedures with the objective of reducing oxygen consumption. For instance, studies showed that the double-trunk mask, an aerosol mask in which two tubes have been fixed in each of the side holes, had the potential to improve the performance of the nasal cannula<sup>16–18</sup> (Figure E1 and online data supplement). More recently, Montiel et al. have observed that the placement of a surgical facemask in patients already treated with a high-flow nasal cannula improved their oxygenation without relevant side effects.<sup>19</sup> However, there is no study assessing the effect of the surgical facemask above the low-flow nasal cannula, nor data comparing the relative effectiveness of these two systems. The objective of this study was thus to compare the relative impact of the surgical facemask and the double-trunk mask in improving blood oxygenation in hospitalized COVID-19 patients already treated with the low-flow nasal cannula. We also assessed their relative impact in saving oxygen supplies.

## METHODS

### Study Design

All adult patients hospitalized between November 13, 2020, and March 05, 2021, at Cliniques universitaires Saint-Luc, Brussels, Belgium, with hypoxemic COVID-19 pneumonia requiring low-flow oxygen therapy between 3 and 7 L/min with a nasal cannula to maintain peripheral capillary oxygen saturation (SpO<sub>2</sub>) between 92 and 96% were invited to participate in this trial. According to our routine practice, patients undergo supplemental oxygen flow titration at least twice daily by physicians not involved in the study to achieve a target SpO<sub>2</sub> of 94% at the lowest output. Exclusion criteria were chronic respiratory diseases, language barriers, confusion, altered consciousness, and arterial puncture contraindications.

Patients who provided written informed consent were placed in a semi-recumbent position and instructed to remain lying over the 60-min-long experiment with continuous pulse oximeter reading. Oxygen flow was fixed (unless clinical deterioration) during the first half of the experiment. Arterial blood gas was taken at the onset of the experiment. Then, the patients were randomized to continue oxygen therapy via the nasal cannula alone (control group), or to receive oxygen via the nasal cannula covered by either the surgical facemask or the double-trunk mask. A second arterial blood gas sample was collected 30 min later.

If the pulse oximeter reading differed between the start and the end of the first 30-min period, the oxygen flow was adapted for the second half of the experiment to retrieve the baseline SpO<sub>2</sub> following a predefined protocol (detailed in the online supplement). The final oxygen output was recorded after the second 30-min period. All along the process, correct

placement of the masks was verified and patients received no instructions regarding nasal or mouth breathing.

The study was approved by the local ethics committee (B403202000009) and is registered in [ClinicalTrials.gov](https://www.clinicaltrials.gov/ct2/show/study/NCT04629989) (NCT04629989).

### Outcomes

The primary outcome was the arterial partial pressure of oxygen (PaO<sub>2</sub>) change after 30 min. Secondary outcomes were changes in arterial blood gases (oxygen saturation [SaO<sub>2</sub>], partial pressure of carbon dioxide [PaCO<sub>2</sub>], pH) and vital parameters (temperature, respiratory rate, heart rate, blood pressure) between baseline and the end of the first 30-min period, and changes in oxygen output and breathlessness between baseline and end of the experiment (i.e., after 60 min). Details are provided in the online data supplement.

### Statistical Analysis

Normality of data was verified with the Shapiro-Wilk test. Data are presented as mean ± standard deviation (SD) or median and interquartile range (IQR) as appropriate. Paired *t* test or Wilcoxon test was applied for within-group changes between the different time points. Between-group differences were compared using one-way analysis of variance or Kruskal-Wallis test. Bonferroni correction was applied for pairwise comparisons. The natural variability of repeated PaO<sub>2</sub> measurements within individuals was represented by the coefficient of repeatability and was calculated as  $1.96 \times \text{SD of PaO}_2$  differences in the control group. It reflects the 95% range of physiological and technical variability in PaO<sub>2</sub>. A PaO<sub>2</sub> change greater than the coefficient of repeatability was considered as physiologically meaningful. Correlations were calculated via Pearson *r* coefficient. All tests were two-sided and *P* values ≤ .05 were considered significant. Secondary outcomes were analyzed as exploratory analyses. Statistical analyses were performed using SPSS v27 (IBM, New York, USA).

Randomization procedure, sample size, and power calculation are described in the supplements.

## RESULTS

### Participants

Of 34 consecutive eligible patients who were proposed trial inclusion, 27 agreed to be enrolled and were randomized. Owing to procedural failure in obtaining two arterial blood samples in 3 participants, analyses were performed for the 24 patients (8 per group) who completed the entire study procedure (study flowchart in Fig. 1). The mean (SD) age of participants was 67 (10) years; 18 (75%) were males with a body mass index of 28.3 (5.4) kg/m<sup>2</sup>. Table 1 details baseline characteristics for the entire cohort as well as for each group. There was no difference in any baseline parameters between groups. The mean delivered oxygen flow at inclusion was 4.7

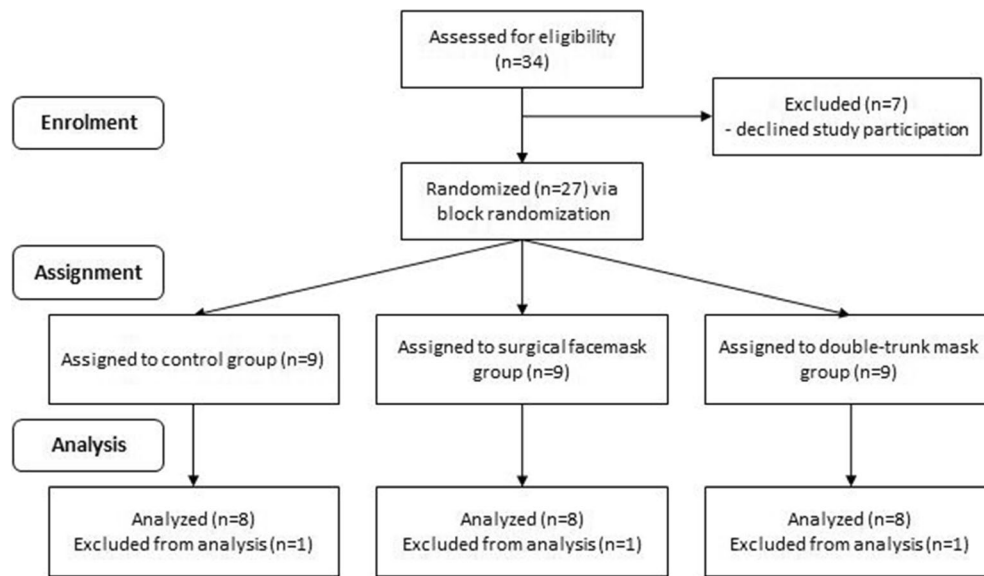


Figure 1 Study flowchart.

(1.4) L/min. The median (IQR) SpO<sub>2</sub> measured at this flow rate was 94% (92–95).

### Primary Outcome

Compared to the nasal cannula alone, PaO<sub>2</sub> increased with the surgical facemask (mean change: 20 mmHg, 95% CI: 0.7–38.8;  $P = .04$ ) and with the double-trunk mask (mean change: 40 mmHg; 95% CI: 21–59;  $P < .001$ ). The double-trunk mask outperformed the surgical facemask on arterial oxygenation (mean change: 20.5 mmHg, 95% CI: 1.5–39.5,  $P = .032$ ) (Fig. 2, Table 2).

### Secondary Outcomes

Adding the systems on top of the nasal cannula resulted in an average (SD) oxygen output reduction of 40% (21) with the surgical facemask (median reduction: 1.5 L/min [95% CI: 0.5–4.5],  $P < .001$ ) and 73% (7) with the double-trunk mask (median reduction: 3.3 L/min [95% CI: 2–5],  $P < .001$ ). The difference between both systems was not statistically significant (Fig. 2, Table 2).

Compared to the control group, the SaO<sub>2</sub> significantly improved with each mask. There was, however, no significant difference on SaO<sub>2</sub> between those two systems (Table 2). The double-trunk mask was associated with an increase in arterial partial pressure of carbon dioxide (PaCO<sub>2</sub>) of 2.4 mmHg (95% CI: 0–4.7,  $P = .049$ ) and a decrease in pH of 0.02 (95% CI: 0.00–0.03,  $P = .024$ ). The surgical facemask showed no impact on PaCO<sub>2</sub>. Neither of the two masks influenced vital parameters (except SpO<sub>2</sub> which followed the pattern of SaO<sub>2</sub> change) nor breathlessness (Table 2).

There was a significant positive relationship between the baseline oxygen output and the PaO<sub>2</sub> change with the surgical facemask ( $r = 0.83$  [95% CI: 0.29–0.97],  $P = .011$ ), but not with the double-trunk mask ( $r = 0.04$  [95% CI: –0.69 to 0.72],

$P = .93$ ). The PaO<sub>2</sub> difference elicited by the surgical facemask exceeded the coefficient of repeatability (15.2 mmHg) only when baseline oxygen flows were  $\geq 5$  L/min. There was a systematic PaO<sub>2</sub> improvement outside the coefficient of repeatability with the double-trunk mask, regardless of the baseline oxygen output (Fig. 3).

Finally, there was a significant negative relationship between the PaO<sub>2</sub> change and the relative oxygen output difference both with the surgical facemask ( $r = -0.73$  [95% CI: –0.95 to –0.06],  $P = .039$ ) and the double-trunk mask ( $r = -0.73$  [95% CI: –0.95 to –0.05],  $P = .040$ ).

### DISCUSSION

This randomized controlled trial demonstrated that both the surgical and double-trunk masks improved arterial oxygenation in hypoxemic COVID-19 patients receiving low-flow oxygen nasal cannula therapy. Unlike the surgical facemask, the double-trunk mask had a systematic effect regardless of the baseline oxygen flow. In addition, for a set SpO<sub>2</sub> target, the surgical facemask and the double-trunk mask enabled the reduction of the oxygen flow by 40% and 73%, respectively, compared to the nasal cannula alone.

Our findings collected with the double-trunk mask are supported by other trials using the same mask or variant masks with tubes inserted on each side.<sup>17,20–22</sup> More recently, we have shown that the double-trunk mask was able to preserve a target oxygenation level while reducing the oxygen output by more than 50% of the output required by conventional oxygen delivery systems.<sup>7</sup> The oxygen-boosting effect of the double-trunk mask is likely explained by its storing capacity. The addition of the double-trunk mask on the patient's face adds a static dead space of approximately 210 mL.<sup>16</sup> Therefore, this mask acts as a reservoir which collects and stores non-consumed oxygen during expiratory phases with nasal

Table 1 Baseline Characteristics

	Total (n = 24)	Control (n = 8)	SFM (n = 8)	DTM (n = 8)	P value
<b>Demographics</b>					
Age, mean (SD), years	67 (10)	64 (5)	66 (10)	71 (14)	0.407
Sex, no. males (%)	18 (75)	6 (75)	8 (100)	4 (50)	NA
BMI, mean (SD), kg/m <sup>2</sup>	28.3 (5.4)	26.6 (3.5)	26.8 (2.6)	31.6 (7.6)	0.110
<b>Symptoms and disease severity</b>					
Symptom duration, median (IQR), days	11 (10–14)	12.5 (10–16)	11.5 (8.5–13)	10.5 (8.5–13)	0.672
CRP level at admission, median (IQR), mg/L	79.4 (49.7–121.2)	61.4 (31.8–104.1)	76.4 (50.8–210)	85.9 (71.4–118)	0.468
CRP level at the study day, median (IQR), mg/L	59.6 (19.6–96.5)	26.2 (13.6–69.4)	85.8 (39.6–129.1)	60.9 (19.8–128)	0.170
Oxygen flow, mean (SD), L/min	4.7 (1.4)	4.7 (1.4)	4.9 (1.7)	4.6 (1.5)	0.917
Breathlessness, median (IQR), 0–100 mm	13 (0–38)	10 (0–35)	27 (16–47)	0 (0–23)	0.096
<b>Arterial blood gases</b>					
SaO <sub>2</sub> , mean (SD), %	94.6 (2.3)	95.9 (1.5)	94.1 (2.8)	93.7 (2.1)	0.119
PaO <sub>2</sub> , mean (SD), mmHg	71.5 (10.1)	76.5 (10.7)	70.9 (10.5)	67.1 (7.7)	0.176
PaCO <sub>2</sub> , mean (SD), mmHg	33.9 (3.3)	35.6 (2.9)	33 (3.3)	33 (3.4)	0.195
pH, mean (SD)	7.45 (0.04)	7.47 (0.04)	7.44 (0.04)	7.45 (0.04)	0.457
<b>Vital parameters</b>					
SpO <sub>2</sub> , median (IQR), %	94 (92–95)	94.5 (94–95)	93 (92–95.5)	93.5 (92–95)	0.293
Temperature, mean (SD), °C	36.0 (0.6)	36.1 (0.5)	35.9 (0.9)	35.9 (0.5)	0.651
Respiratory rate, mean (SD), breaths/min	24.8 (5.9)	24.6 (5.3)	26.5 (5.0)	23.3 (7.5)	0.569
Heart rate, mean (SD), beats/min	74.6 (11.9)	75.5 (9.8)	76.5 (14)	71.9 (12.7)	0.735
Systolic blood pressure, mean (SD), mmHg	130 (19)	130 (16)	132 (27)	129 (15)	0.952
Diastolic blood pressure, mean (SD), mmHg	73 (12)	76 (10)	71 (15)	72 (9)	0.689

Abbreviations: BMI body mass index, CRP C-reactive protein, PaCO<sub>2</sub> arterial partial pressure of carbon dioxide, PaO<sub>2</sub> arterial partial pressure of oxygen, SaO<sub>2</sub> arterial oxygen saturation, SpO<sub>2</sub> pulse oxygen saturation

cannula oxygen therapy. During subsequent inspiratory phases, the gas from this reservoir is first inspired before inhaling room air, thereby reducing air entrainment and increasing inspired oxygen concentration.

The large dead space volume associated with the double-trunk mask could be a subject of concern because of potential CO<sub>2</sub> rebreathing. Nevertheless, the PaCO<sub>2</sub> increase when adding this mask was mild and of limited clinical significance as it

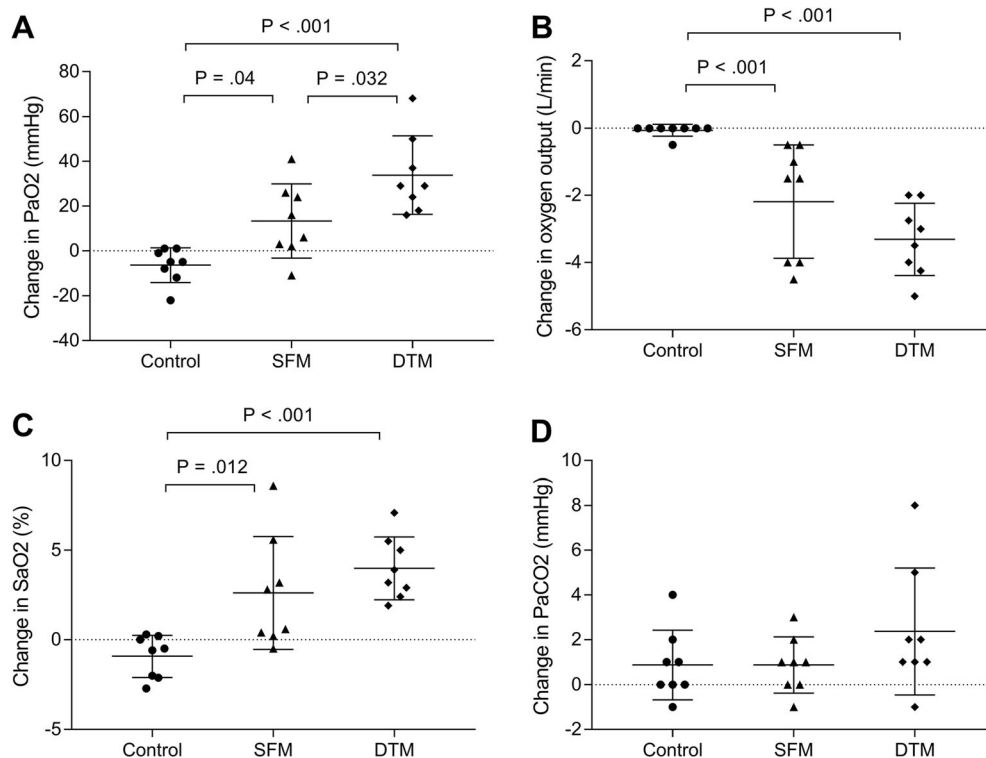


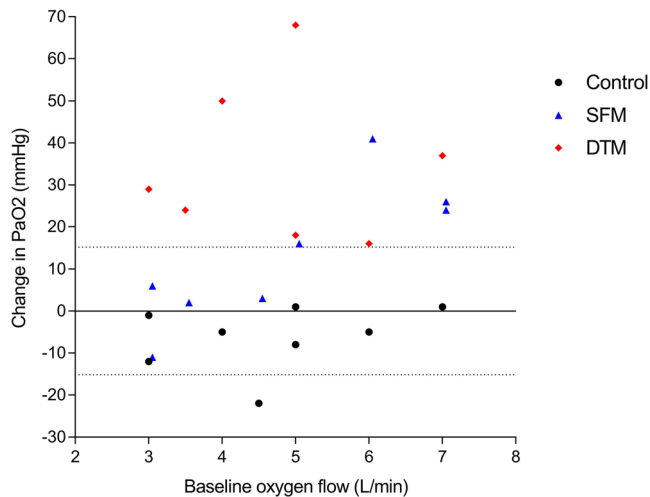
Figure 2 Changes in blood gas outcomes and oxygen output with and without the surgical and the double-trunk masks. The figure shows the difference in arterial partial pressure of oxygen (A), oxygen output (B), arterial oxygen saturation (C), and arterial partial pressure of carbon dioxide (D) before and 30 min after wearing either the nasal cannula alone (control, circles) or the nasal cannula covered by the surgical facemask (triangles) or the double-trunk mask (diamonds). Error bars indicate mean and standard deviation. Abbreviations: SFM, surgical facemask; DTM, double-trunk mask.



Table 2 Change in Outcomes at Different Time Intervals in Each Group

	Groups		Between-group difference, P-value	Mean or median pairwise difference (95% CI), adjusted P value	DTM vs SFM
	Control	DTM			
Change in clinical outcomes between values collected before and 30 min after the randomization in each group					
<b>Primary outcome</b>					
PaO <sub>2</sub> , mean change (95% CI), mmHg	-6.4 (-12.9 to 0.1)	13.4 (-0.5 to 27.3)	33.9 (19.2 to 48.5) <sup>a</sup>	19.8 (0.7 to 38.8), P = 0.04	DTM vs SFM = 20.5 (1.5 to 39.5), P = 0.032
<b>Secondary outcomes</b>					
SpO <sub>2</sub> , median change (95% CI), %	0 (-1 to 1)	3 (1.5 to 6) <sup>a</sup>	5 (4 to 6) <sup>a</sup>	3 (1 to 6), P < 0.001	5 (4 to 6), P < 0.001
SaO <sub>2</sub> , mean change (95% CI), %	-0.9 (-1.9 to 0.1)	2.6 (0.0 to 5.2) <sup>a</sup>	4.0 (2.5 to 5.5) <sup>a</sup>	3.5 (0.7 to 6.4), P = 0.012	4.9 (2.1 to 7.8), P = 0.001
PaCO <sub>2</sub> , mean change (95% CI), mmHg	0.9 (-0.4 to 2.2)	0.9 (-0.2 to 1.9)	2.4 (0.0 to 4.7) <sup>a</sup>	0.245	0.245
pH, mean change (95% CI)	0 (-0.01 to 0.01)	0 (-0.01 to 0.01)	-0.02 (-0.03 to 0.00) <sup>a</sup>	0.058	0.058
Temperature, mean change (95% CI), °C	0.1 (-0.2 to 0.4)	0 (-0.3 to 0.3)	0.2 (0 to 0.5)	0.348	0.348
Respiratory rate, mean change (95% CI), breaths/min	-1 (-3 to 1)	-0.8 (-2.5 to 1)	1.9 (-1.9 to 5.7)	0.159	0.159
Heart rate, mean change (95% CI), beats/min	-2.3 (-4.5 to 0) <sup>a</sup>	0.4 (-3.9 to 4.7)	-1.3 (-2.9 to 0.4)	0.342	0.342
Systolic blood pressure, mean change (95% CI), mmHg	0 (-4 to 4)	1 (-12 to 13)	3 (-6 to 12)	0.848	0.848
Diastolic blood pressure, mean change (95% CI), mmHg	-1 (-9 to 7)	2 (-2 to 6)	2 (-3 to 6)	0.653	0.653
Change in clinical outcomes between values collected before and 60 min after the randomization in each group					
Oxygen flow, median change (95% CI), L/min	0 (-0.2 to 0)	-2.2 (-4.5 to 0.5) <sup>a</sup>	-3.3 (-4.3 to -2.4) <sup>a</sup>	< 0.001	< 0.001
SpO <sub>2</sub> , median change (95% CI), %	0 (-0.5 to 0.5)	0 (0 to 0.5)	0 (-0.5 to 0)	0.293	0.293
Breathlessness score, median change (95% CI), mm	0 (-23 to 6)	0 (-28 to 30)	0 (0 to 20)	0.401	0.401
Temperature, mean change (95% CI), °C	-0.2 (-0.5 to 0.2)	0.2 (-0.3 to 0.6)	-0.1 (-0.5 to 0.4)	0.474	0.474
Respiratory rate, mean change (95% CI), breaths/min	-0.5 (-2.8 to 1.8)	-0.5 (-2.7 to 1.7)	1.5 (-2.3 to 5.3)	0.423	0.423
Heart rate, mean change (95% CI), beats/min	-4.8 (-0.9 to 0.1) <sup>a</sup>	-1.3 (-5.6 to 3.1)	0.4 (-2 to 2.7)	0.106	0.106
Systolic blood pressure, mean change (95% CI), mmHg	0 (-5 to 5)	-2 (-13 to 9)	4 (-2 to 10)	0.373	0.373
Diastolic blood pressure, mean change (95% CI), mmHg	1 (-8 to 9)	2 (-3 to 8)	3 (-3 to 10)	0.794	0.794

Abbreviations: SpO<sub>2</sub> pulse oxygen saturation, SaO<sub>2</sub> arterial oxygen saturation, PaO<sub>2</sub> arterial partial pressure of oxygen, PaCO<sub>2</sub> arterial partial pressure of carbon dioxide  
<sup>a</sup>Paired t test indicates a significant (P ≤ 0.05) within-group change between both time points



**Figure 3 Individual change in arterial partial pressure of oxygen in relation to the baseline oxygen output. Individual changes in the control group (nasal cannula alone) are displayed as circles, nasal cannula with surgical facemask as triangles, and nasal cannula with double-trunk mask as diamonds. The middle solid line represents the null difference and the dotted lines the upper and lower limits of the coefficient of repeatability of arterial oxygen difference calculated in the control group ( $1.96 \times \text{SD}$  of  $\text{PaO}_2$  differences), respectively. Abbreviations: SFM, surgical facemask; DTM, double-trunk mask.**

did not translate into hypercapnia or blood acidosis, confirming previous findings.<sup>7</sup> Instead, respiratory alkalosis was mitigated in patients with COVID-19 pneumonia where hypocapnic hypoxemia is a typical feature.<sup>8</sup> Moreover, the patients did not report any change in their sensation of shortness of breath when the double-trunk mask was added. Most likely, these findings are explained by the facemask leaks and the streaming effect of gas through the system. The latter phenomenon is the result of the continuous oxygen flow beneath the mask through the nasal cannula, thereby reducing the dynamic dead space volume.<sup>23–25</sup> It should be highlighted that we excluded patients with chronic pulmonary diseases in whom the safety, tolerance, and efficacy of the double-trunk mask has not been tested.

Interestingly, the surgical facemask placed over the nasal cannula also improved arterial oxygenation, albeit to a lesser magnitude than the double-trunk mask. These findings could also be explained by an increased oxygen concentration in the dead space created between the face and the mask.<sup>19</sup> However, the magnitude of individual responses was variable, with only 50% of our participants exceeding the natural variability of consecutive  $\text{PaO}_2$  measurements. Based on Figure 3, it is tempting to speculate that a minimal baseline oxygen flow must be achieved to elicit a sensible increase in oxygen concentration in the mask dead space and, thus, in the patient's blood oxygen level. Below this threshold, the oxygen filling of the mask dead space may be insufficient to trigger a sensible effect on oxygenation beyond the natural  $\text{PaO}_2$  variability. However, this hypothesis must be interpreted with caution because of our small sample size. In addition, this speculation conflicts with the study of Montiel et al. who showed that the surgical facemask on top

of the high-flow nasal cannula set at 60 L/min also generated heterogeneous inter-individual responses.<sup>19</sup>

Another explanation would be that the surgical facemask promoted nasal breathing. Although we did not provide any instruction regarding nasal or mouth breathing, the addition of a facemask in mouth breathers may have elicited facial thermal discomfort. Indeed, mouth breathing is associated with a higher heat loss than nasal breathing.<sup>26</sup> This heat loss is retained in the microenvironment created by the surgical facemask (i.e., dead space) which is acknowledged to generate discomfort.<sup>26</sup> We therefore speculate that the surgical facemask favored nasal breathing in our participants which, in turn, improved the oxygen uptake through the nasal cannula. Furthermore, compared to oral breathing, nasal breathing improves ventilation/perfusion matching.<sup>27</sup> Indeed, human paranasal sinuses produce nitric oxide that diffuses into the bronchial tree where it induces locally bronchodilation and vasodilation.<sup>27</sup> Of note, Montiel et al. often observed spontaneous opened-mouth breathing in their cohort under a high-flow nasal cannula without a facemask.<sup>19</sup> Unfortunately, we did not collate the proportion of mouth and nose breathers at baseline. This hypothesis should thus be investigated in further studies.

Many public health facilities across the globe have struggled to provide medical resources to patients, including the most basic oxygen therapy.<sup>28,29</sup> The World Health Organization recently published guidance urging health facility administrators and decision-makers to set up a surge oxygen delivery capacity.<sup>30</sup> Enabling physicians to deliver the required oxygen to patients is critical because management of hypoxemia is the cornerstone of COVID-19 patient management. This study demonstrated that both the surgical facemask and the double-trunk mask have the potential to save a limited resource that is currently in high demand. Settings where oxygen supplies remain limited may benefit most from these systems, such as in nursing homes, health care centers in deprived medical areas, or during patient transport. In our opinion, the double-trunk mask (patent-free) should be favored over the surgical facemask, regardless of the nasal cannula oxygen flow, because of the more favorable blood oxygen level response with the double-trunk mask. The components of the double-trunk mask (aerosol mask and tubes) cost between 2 and 5€ and, depending on available resources, can be replaced or reused after daily cleaning (disinfection and rinsing as for reusable nebulizers). If the double-trunk mask disposables (which are for single-patient use only) are not available, or if the cost is an issue, the surgical facemask is an interesting approach in patients needing at least 5 L/min of oxygen flow through the nasal cannula.

## LIMITATIONS

First, our study was not powered to assess oxygen savings with each system. However, the large effect size observed in this secondary outcome combined with the strong relationship observed between the  $\text{PaO}_2$  improvement and the relative

oxygen flow reduction supports our findings. Moreover, although patients were properly randomized and no statistical differences in baseline characteristics are observed between groups, we cannot rule out the possibility that some heterogeneity occurred between study groups. Second, we did not estimate the long-term tolerance or efficacy of these masks for longer periods than 60 min. However, since the double-trunk mask has been integrated in our hospital in a step-by-step oxygenation algorithm for hospitalized COVID-19 patients, this mask was found to be well tolerated by patients despite wearing it for days or even weeks. Third, our trial focused on the effect of each system on short-term oxygenation and vital parameters. We are thus unable to determine the role of the intervention in reducing the relative risk of intensive care unit admission.

## CONCLUSIONS

We showed that the addition of the surgical facemask or the double-trunk mask on top of the nasal cannula increases arterial oxygenation and reduces oxygen supplies.

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**Declarations:**

**Conflict of Interest:** The authors declare that they do not have a conflict of interest.

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