Impact of an improvised system on preserving oxygen supplies in patients with COVID-19.

Supplementary files

Methods

This pre-post intervention study was conducted in the Cliniques universitaires Saint-Luc, Brussels, Belgium.

Material

The Double-Trunk Mask (DTM) is made up of a regular aerosol mask (Sidestream, Philips Respironics, New Jersey, USA) with two corrugated tubes (ISO 22) or "trunks", 15 cm in length, inserted in the exhalation ports (e-Fig 1). This system is applied on the face of the patient, above the nasal cannula used for the delivery of oxygen therapy. By means of the tubing and the collector of the nebulizer, the DTM sequesters the amount of oxygen that is wasted during expiratory phases and restitutes it on subsequent inspiratory phases. Therefore, for a similar oxygen output, the DTM acts as a booster of the fraction of inspired oxygen.

Study design

Oxygen flow requirements determined the baseline oxygen delivery system. Nasal cannulas were applied for flows up to 6 L/min, simple facemasks (oronasal masks) for oxygen flows between 7 and 10 L/min, and non-rebreathing masks (NRM) for flows between 11 and 15L/min. In circumstances where SpO_2 jumped from less than 92% with the oronasal mask at 10L/min to more than 96% with the NRM, one of the two one-way valves at the exhalation ports was removed in order to achieve the desired baseline target SpO_2 value.

Outcomes

Arterial blood gases, vital parameters (SpO_2, respiratory rate, heart rate, arterial blood pressure, temperature) and oxygen output were measured at baseline (T_0) and at the end of the 30-min period under the DTM (T_{30}). Blood gas sampling was performed by medical staff not involved in this study and analysed using the ABL90 FLEX blood gas analyser (Radiometer, Denmark). Vital parameters and oxygen output were measured again 30 minutes after the DTM was withdrawn (T_{60}).

At T_{30} and T_{60}, the patients were asked to note the comfort-discomfort level and preference using a 5-point Likert scale ranging from “strongly disagree” to “strongly agree”. Questions were as follows: 1. “Is the oxygen delivering system comfortable?”, 2. “is the oxygen delivering system more comfortable than the previous one?”, 3. “is the oxygen delivering system inconvenient leading to a risk of its removal?”.

Results of computed tomography (CT) performed at hospital admission as part of routine evaluation of patients suspected of COVID-19 were reviewed in patient medical records. The severity of pulmonary involvement was classified using the recent consensus statement on reporting of chest CT findings related to COVID-19[1].

Statistical analysis

The primary outcome was the change in oxygen flow generated by using the DTM. Assuming an α risk of .05 and a power of 90% in a two-sided test, a sample size of 11 subjects was needed to detect a mean difference of 2 L/min[2] with a standard deviation of paired difference 1.8 L/min (PASS 14, NCSS, LLC, Utah, USA). This conservative standard deviation was chosen because of the expected high variability of the fraction of delivered oxygen between patients with rapid breathing patterns and on low-flow oxygen therapy and between oxygen delivery systems[3,4]. Because SpO_2 may inaccurately reflect SaO_2 and therefore interfere with our

design, patients were retrospectively excluded from the analysis if the mismatch between both SpO_2 and SaO_2 measurements exceeded the expected error of 4%[5,6].

Normality of data was verified with Shapiro-Wilk tests. Data are presented as mean ± standard deviation or median and interquartile range (IQR) as appropriate. Paired t-test and Wilcoxon test was applied for pairwise comparisons, as appropriate. Ordinal paired data were compared using the Wilcoxon test. Post-hoc analysis for correlations were calculated by Spearman's rho coefficient. All tests were two-sided and p-values ≤.05 were considered significant. Statistical analyses were performed using SPSS version 25 (IBM, Armonk, New York).

Results

The patients rated the standard oxygen delivery system as more comfortable than the DTM and preferred the former over the latter (median difference, 1 [95% CI 0 to 3]; p=0.016). However, there was no significant difference in the inconvenience generated by each system (p=0.13) (e-Table 3). Post-hoc analysis indicated that there was a negative association between oxygen flow at onset and a greater preference for the standard oxygen delivery system (rho = -0.75 [95% CI, -0.93 to -0.25], p=0.008) and a trend towards a negative correlation between baseline oxygen flow and greater comfort rating with the standard oxygen delivery system (rho = -0.57 [95% CI, -0.88 to 0.07], p=0.07), indicating that the DTM was more easily tolerated by patients receiving high oxygen flows (e-Fig 2).

References

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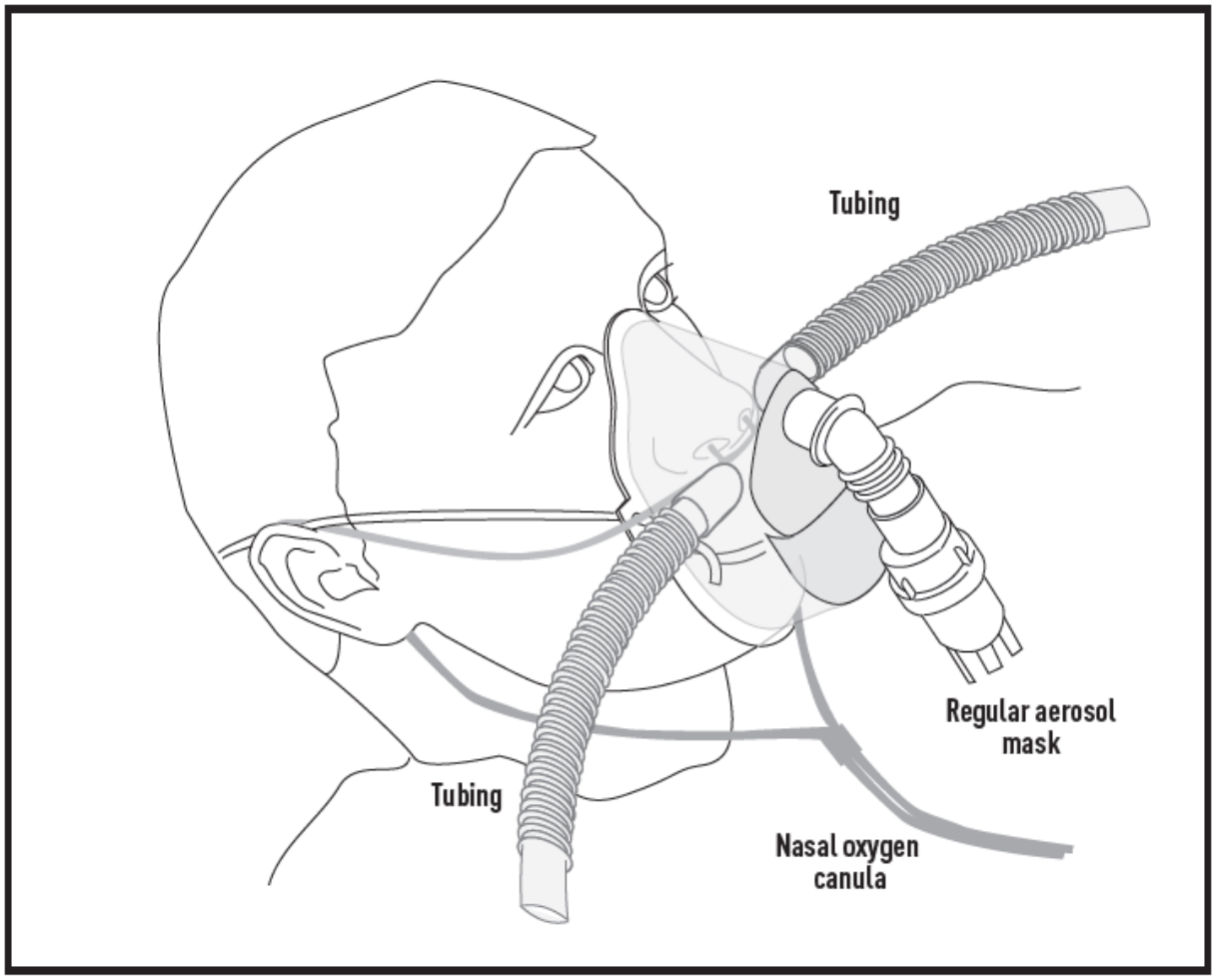
e-Figures

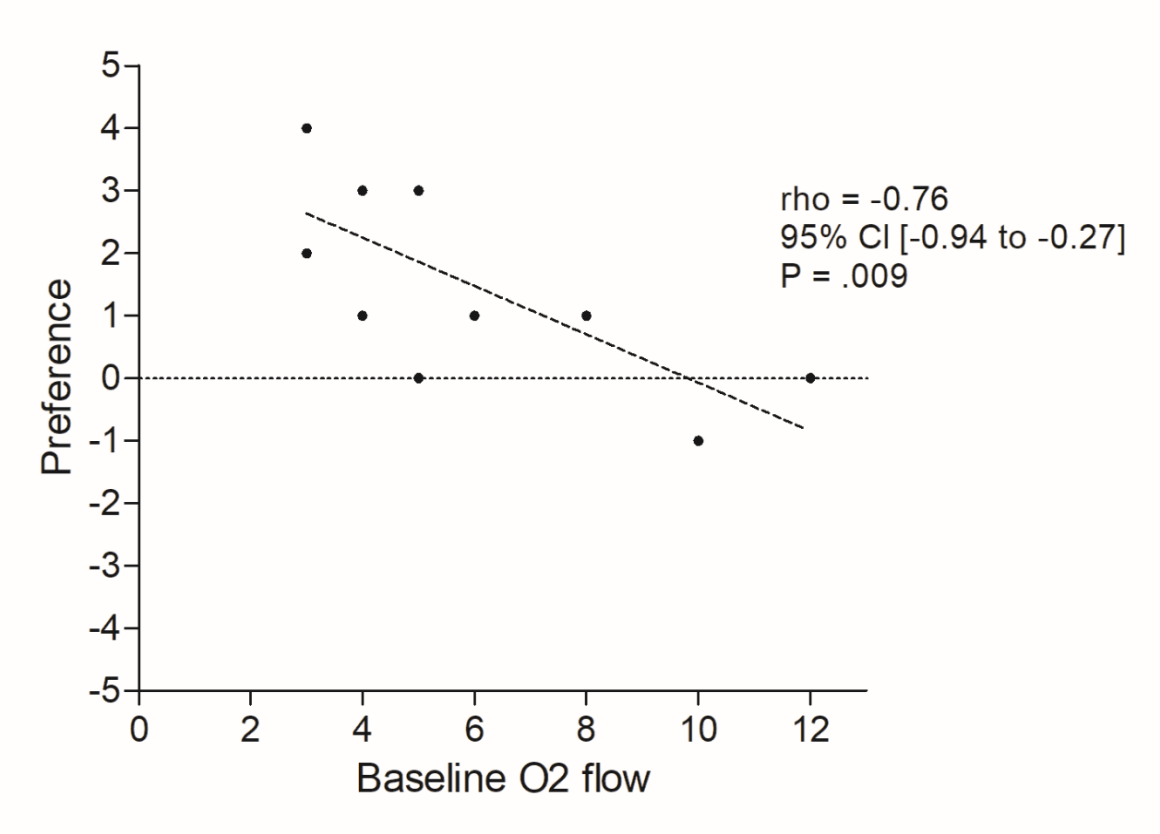
e-Figure 1. Illustration of the Double-Trunk Mask.

The double-trunk mask consists of a regular aerosol mask with two corrugated tubes inserted in the lateral hole of the mask. The double-trunk mask is placed above the nasal cannula where the oxygen is delivered.



e-Figure 2. Correlation between baseline oxygen flow and the difference of preference between each oxygen delivery system.

Positive values indicate that participants preferred the standard oxygen delivery method over the double-trunk mask. Negative values indicate preference for the double-trunk mask over the standard oxygen delivery method.



e-Tables

e-Table 1: Baseline characteristics

Variables	n=11
Age, mean (SD), years	61 (14)
Sex, No. (%)	
Male	8 (73)
Female	3 (27)
BMI, mean (SD), kg/m²	28.5 (4.0)
Oxygen flow, median (IQR), L/min	5 (4-8)
Oxygen delivery system, No. (%)	
Nasal cannula	8 (73)
Oronasal mask	2 (18)
Non-rebreathing mask[a]	1 (9)
CT, severity of lesions, No. (%)	
Mild (< 10%)	0 (0)
Moderate (10-25%)	5 (45)
Extensive (25-50%)	2 (18)
Severe (50-75%)	4 (36)
Critical (> 75%)	0 (0)
Interval between the study and CT, median (IQR), days	6 (2-18)
Interval between the study and onset of symptoms, median (IQR), days	10 (6-25)
CRP level at hospital admission, mean (SD), mg/L	112.49 (64.66)
CRP level the study day, mean (SD), mg/L	107.33 (72.27)
Setting, No (%)	
Intensive care unit	1 (9)
Medical wards	10 (91)

List of abbreviations: BMI, body mass index; CRP, C-reactive protein; CT, computed tomography.
[a] One of the two one-way valves on the front of the mask was withdrawn.

e-Table 2: Clinical outcomes at any time point of the study.

				Mean or Median change between time points, 95% CI, p-value	
Outcomes	T_0 (Standard system)	T_{30} (Double-trunk mask)	T_{60} (Standard system)	Change between Pre-Post intervention (T_{30}-T_0)	Change between Baseline and End of study (T_{60}-T_0)
Oxygen output, median (IQR), L/min	5 (4-8)	1.5 (1.5-4)	4 (3-8)	-3 (-4 to -1.5), p=0.003	0 (0 to 0), p=0.32
SpO_2, median (IQR), %	94 (94-95)	95 (94-95)	94 (94-95)	0 (0 to 2), p=0.19	0 (-1 to 1), p=0.71
SaO_2, median (IQR), %	95.5 (94.2-97.1)	95.7 (94.2-97.3)	/	0.2 (-0.6 to 1.5), p=0.24	n/a
PaO_2, median (IQR), mmHg	76 (65-82)	75 (69-86)	/	2 (-2 to 15), p=0.23	n/a
$PaCO_2$, median (IQR), mmHg	36 (34-39)	37 (35-41)	/	1 (0 to 2), p=0.006	n/a
pH, median (IQR)	7.48 (7.45-7.49)	7.45 (7.44-7.48)	/	-0.02 (-0.02 to 0), p=0.009	n/a
Temperature, mean (SD), °C	36.6 (0.55)	36.6 (0.58)	36.5 (0.55)	0.0 (-0.1 to 0.2), p=0.60	-0.1 (-0.3 to 0.1), p=0.31
Heart rate, mean (SD), beats/min	88.6 (17.9)	88.6 (17.3)	87.3 (17.2)	0.0 (-2.0 to 2.0), p>0.99	-1.3 (-3.5 to 0.9), p=0.23
Systolic blood pressure, median (IQR), mmHg	130 (120-143)	120 (110-143)	121 (110-135)	1 (-10 to 10), p=0.53	0 (-20 to 8), p=0.17
Diastolic blood pressure, median (IQR), mmHg	78 (70-83)	72 (70-83)	73 (70-80)	0 (-5 to 10), p=0.40	0 (-10 to 0), p=0.11
Respiratory rate, mean (SD), breaths/min	26 (4)	30 (7)	27 (5)	3 (0 to 7), p=0.054	1 (-1 to 3), p=0.45

List of abbreviations: SpO_2, pulse oxygen saturation; SaO_2, arterial oxygen saturation; PaO_2, arterial oxygen tension; $PaCO_2$, arterial carbon dioxide tension. T_0, baseline; T_{30}, 30 minutes after baseline, the double-trunk mask being worn 30 minutes; T_{60}, 60 minutes after baseline, the standard oxygen delivery system being worn 30 minutes between T_{30} and T_{60}.

e-Table 3. Comfort questions

Comfort questions, using scale 1-5*	Double-trunk mask	Standard system	p-value
Q1. Is the oxygen delivery system comfortable?	3 (2-4)	5 (4-5)	0.016
Q2. Is the oxygen delivery system more comfortable than the previous one?	3 (2-4)	5 (4-5)	0.016
Q3. Is the oxygen delivering system inconvenient leading to a risk of its removal?	4 (1-4)	1 (1-3)	0.13

Results are displayed as median (IQR)

* Comfort questions were assessed using 1-5 Likert scale. 1: strongly disagree, 2: disagree, 3: neutral, 4: agree, 5: strongly agree.