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LETTER TO THE EDITOR

Improvement of arterial oxygenation using the double trunk mask above low flow nasal cannula: a pilot study

Frédéric Duprez[1,2,3] · Simon Cocu[3] · Alexandre Legrand[5] · Serge Brimioulle[4] · Shahram Mashayekhi[1] · Gokhan Bodur[6] · Arnaud Bruyneel[3] · Jean Roeseler[2] · Grégory Cuvelier[3] · Grégory Reychler[2]

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To the Editor,

The Double Trunk Mask (DTM) is an original mask (Fig. 1) which boosts the Fraction inspired in Oxygen (FiO_2) during oxygen therapy with high flow nasal oxygen (HFNO) [1]. In a previous study, the association of the DTM over HFNO showed an increase of the PaO_2 without $PaCO_2$ increase despite an added dead space of 210 mL due to the mask and the trunks. It can be explained principally by the washing of the trunks by the high flow (until 60 L/min). However, few studies have examined the effect of DTM on PaO_2 and $PaCO_2$ during oxygen therapy at low flow. Indeed, the use of low flow oxygen should lead to a risk of CO_2 rebreathing [2]. In fact, during expiration, the additional oxygen does not escape but is collected in the two trunks. During inspiration, the patient receives this oxygen-enriched gas mixture from the trunks instead of the air in the room. The DTM thus acts like a "reservoir" and results in increased FiO_2. However, thanks to its dead space volume, the DTM could also contribute to increasing $PaCO_2$ by increasing rebreathing phenomenon [2]. We, therefore, prospectively investigated the effects of the DTM and its dead space on arterial blood gases in hypoxemic patients already receiving low flow oxygen through NC.

The study was conducted in the ICU of the Epicura Hospital (Hornu, Belgium) between June and November 2018. Patients were eligible if they were at least 18-years-old, had respiratory symptoms (labored breathing with using of accessory muscles of respiration and/or dyspnea and/or tachypnea and/or hyperpnea), received oxygen via NC but remain hypoxemic ($PaO_2 < 75$ mmHg) [3–5], and were not considered for intubation or tracheotomy. Exclusion criteria were COPD, hypercapnia ($PaCO_2 > 45$ mmHg), heart failure, shock or hypotension (vasopressor therapy), obesity hypoventilation syndrome, and altered consciousness (Glasgow Coma Scale score < 13). Oxygenation was ensured through standard NC (model 1616-21, Convatec™, Auckland, New Zeeland) or through standard NC with an additional DTM. The DTM is made of an aerosol mask (model 01.000.01.120 (CE0123), Dahlhausen, Köln, Germany) and two corrugated tubes of 22 mm diameter and 15 cm length ("Trunks"—ref 13.801.01.016, Dahlhausen, Köln, Germany) inserted into the lateral holes of the aerosol mask (Fig. 1). Age, height, weight, heart rate, respiratory rate, arterial blood pressure, arterial blood gases, sepsis-related organ failure assessment (SOFA) were collected upon admission. Patients were placed in a semi-recumbent position and were received oxygen at a rate initially adjusted to obtain a pulse oximetry (SpO_2) value equal to or above 90%, and this then maintained unchanged during the investigation. Each patient went through three phases of 30 min:
Phase 1: NC alone (NC).
Phase 2: NC + DTM over the NC (NC + DTM).
Phase 3: NC alone (NC).

This study is registered at ClinicalTrials.gov with the reference number NCT03457363.

✉ Frédéric Duprez
frederic.duprez@condorcet.be

1 Department of Intensive Care, Epicura Hospital, Hornu, Belgium

2 Institut de Recherche Expérimentale Et Clinique (IREC), Pole de Pneumologie, ORL & Dermatologie, Service de Pneumologie, Université Catholique de Louvain, Brussels, Belgium

3 Laboratory of Exercise and Movement, Provincial School of Hainaut HEPH-Condorcet, Tournai, Belgium

4 Department of Intensive Care, Erasme Hospital, Université Libre de Bruxelles, Brussels, Belgium

5 Department of Physiology, Physiopathology and Respiratory Readaptation, Health Institute, University of Mons, 20 Place du Parc, 7000 Mons, Belgium

6 Department of Intensive Care, Groupe Hospitalier de La Région de Mulhouse Et du Sud-Alsace, Mulhouse, France

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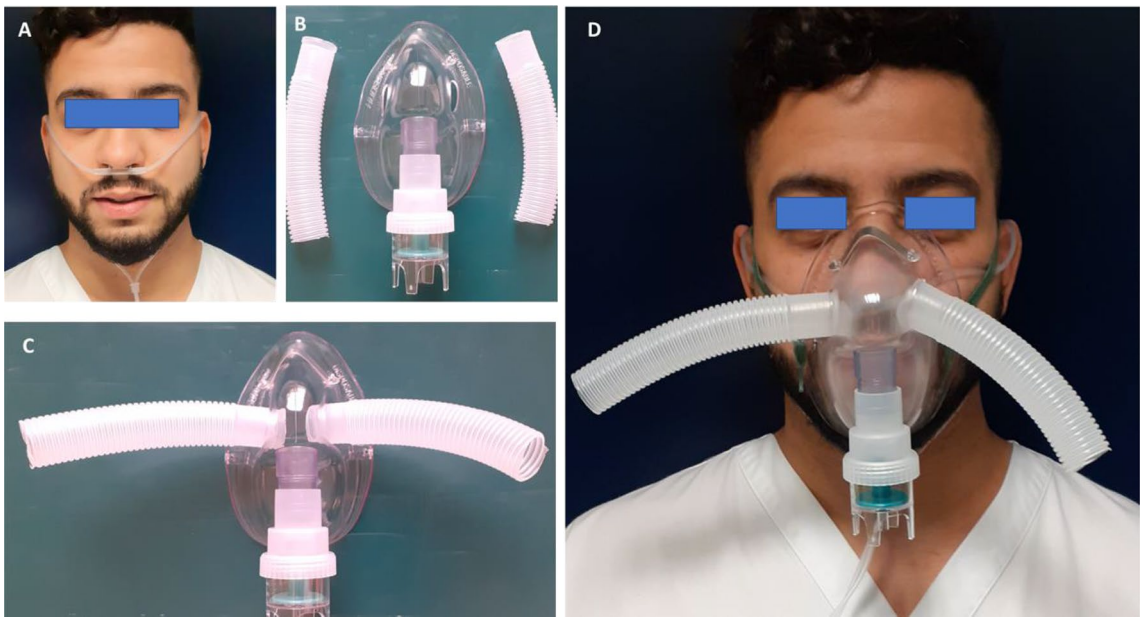

Fig. 1 **a** Subject with low flow nasal cannula (Convatec™—New Zealand—Auckland—ref. 1616–21). **b** Aerosol mask (Dahlhausen, Köln, Germany—ref: 01.000.01.120 (CE0123) with two corrugated tubing (Trunks) (ISO 22, ± 15 cm length). **c** Double Trunk Mask (DTM): Aerosol mask + two corrugated tubing ISO 22, ± 15 cm length inserted in the two lateral holes of the mask. **d** Subject equipped with DTM and nasal cannula. The DTM is just placed over the nasal prongs. Oxygen delivery is made through the nasal cannula and not into aerosol mask

The patients did not receive any instructions regarding opening or closing their mouths during the study. During the change of phase 1 (NC) to phase 2 (NC + DTM) and then phase 3 (NC again), the oxygen flow was not significantly different. At the end of each phase, blood gases were collected again. Data were analyzed with SigmaPlot programs (Version 12.0, Systat Software Inc., London, UK). Data distribution was evaluated with the Kolmogorov–Smirnov test. Overall differences were tested by 1-way ANOVA for repeated measures for parametric data, and by a Friedman test for non-parametric data. In the presence of significant differences, comparisons between specific phases were evaluated with the Tukey test. A sample size of fifteen patients was calculated to detect a clinically significant difference in PaO_2 increase at least 25% with an α of 5% at 80% power. Ten men and five women were included. The

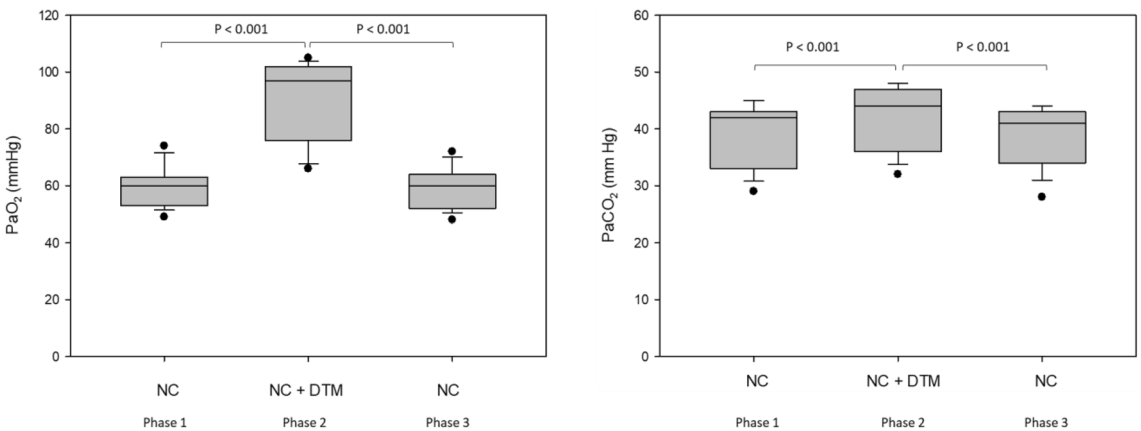

Fig. 2 PaO_2 and $PaCO_2$ changes (Friedman test followed by a Tukey test) during the 3 experimental phases. The boxes show the median (P50) and the interquartile range (P25 and P75), the whiskers show the P5 and P95 percentiles, the dots represent outliers. PaO_2 and $PaCO_2$ increase significantly ($p < 0.001$) with phase 2 (NC + DTM) and returned to baseline after DTM removal. Between phases 1 and 3, no statistical difference was found for PaO_2 ($p = 0.229$) or $PaCO_2$ ($p = 0.679$). During phase 2, we observed a clinically significant increase in PaO_2 and a slight (+ 3 mmHg) and not clinically significant increase in $PaCO_2$

age was 69 ± 14 years, and the body mass index 27 ± 8 kg/m^2. The SOFA score was 6 ± 2 and the oxygen flow rate 5 ± 3 L/min. Along the three study phases, PaO_2 increased from 60 ± 7 mmHg (phase 1: NC) to 90 ± 14 mmHg (phase 2: NC + DTM) and then decreased to 59 ± 7 mmHg (phase 3: NC) ($p < 0.001$). During these phases, $PaCO_2$ increased from 39 ± 5 mmHg to 42 ± 6 mmHg and then decreased to 38 ± 5 mmHg ($p < 0.001$). Arterial pH decreased from 7.42 ± 0.03 to 7.39 ± 0.03 and then increased to 7.42 ± 0.03 ($p < 0.001$). No statistical difference was found between phase 1 and phase 3 for PaO_2 ($p = 0.229$) and $PaCO_2$ ($p = 0.679$) (Fig. 2). No statistical difference was found in the respiratory rate, heart rate, or mean arterial pressure.

Before experimentation, we expected a possible increase in $PaCO_2$ due to the added dead space, to the Haldane effect and/or to a reduction of hypoxic pulmonary vasoconstriction. Several factors may contribute to the limited increase in $PaCO_2$. First, leaks between the DTM and the face allow some expiratory flow to escape, thus reducing the amount of rebreathing. Second, the continuous oxygen flow could play a role in the dead space washing during the expiration period [2]. Third, Tidal Volume (Vt) may have increased to readjust the dead volume/tidal volume ratio [6–8].

Alternatives to DTM would be a non-rebreathing with reservoir bag (NRRB) or high flow nasal oxygen (HFNO). Comparisons between HFNO and NRRB suggest that HFNO improves oxygenation and dyspnea better than NRRB [9–13]. Fewer studies have compared DTM and NRRB. In two bench studies, DTM was more effective than NRRB in term of FiO_2 [14, 15]. No confirmation has been obtained in clinical studies. One study has evaluated the impact of DTM in subjects receiving oxygen by HFNO: PaO_2 increased significantly with the DTM, while $PaCO_2$ did not show any statistically significant difference [16].

The positive effects reported here should be confirmed in a larger study of patients with hypoxemic respiratory failure. The effects of DTM could also be evaluated during longer periods of application, in more severe COPD patients, in the obesity hypoventilation syndrome, during pre-oxygenation before intubation, in "do-not-intubate" patients, and possibly in mass casualty events (sudden increase in oxygen demand but limited resources).

It should be noted that severe hypoxemia is deleterious and is an indication for mechanical ventilation. The DTM is not recommended in patients with critical hypoxemia needing mechanical ventilation.

Summary In patients with hypoxemic respiratory failure, the association of the Double Trunk Mask with low flow nasal cannula increases the PaO_2 significantly. The $PaCO_2$ increases statistically, but the size effect is small and not clinically significant.

Data availability Additional unpublished data can be obtained by sending an e-mail to the corresponding author. To gain access, data requestors will need to sign a data access agreement.

Compliance with ethical standards

Conflict of interest The authors declare no conflicts of interest.

Ethical approval Thestudy protocol has been approved by the Erasmes Hospital (Brussels) Ethics Committee.

Informed consent Written consent was obtained from all the participants before inclusion.

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