The Double-Trunk Mask Improves Oxygenation During High-Flow Nasal Cannula Therapy for Acute Hypoxemic Respiratory Failure

Frédéric Duprez, Arnaud Bruyneel, Shahram Machayekhi, Marie Droguet, Yves Bouckaert, Serge Brimioulle, Gregory Cuvelier, and Gregory Reychler

BACKGROUND: High-flow nasal cannula (HFNC) oxygen therapy is used to deliver an F_{IO_2} from 0.21 to 1.0. The double-trunk mask (DTM) is a device designed to increase the F_{IO_2} in patients with a high inspiratory flow demand. The aim of our study was to evaluate the effect of DTM in hypoxemic subjects already receiving HFNC. METHODS: We report a prospective multi-center crossover pilot study including 15 subjects treated with HFNC for acute hypoxemic respiratory failure. Measurements were performed at the end of 30-min periods with HFNC only, with HFNC + DTM, and again with HFNC only. RESULTS: Compared with HFNC alone, HFNC + DTM increased P_{aO_2} from 68 ± 14 mm Hg to 85 ± 22 mm Hg ($P < .001$) and did not affect P_{aCO_2} ($P = .18$). In the 11 responders, the P_{aO_2} increased from 63 ± 12 mm Hg to 88 ± 23 mm Hg ($P < .001$). No complications were reported during DTM use. CONCLUSION: In subjects receiving oxygen via HFNC, the addition of the DTM over the HFNC increased P_{aO_2} without changing the P_{aCO_2}. *Key words: high-flow nasal cannula; high-flow oxygen therapy; acute respiratory failure; oxygen delivery; double-trunk mask.* [Respir Care 2019;64(8):908–914. © 2019 Daedalus Enterprises]

Introduction

High-flow nasal cannula (HFNC) oxygen therapy is a technique used to deliver a high flow of heated and humidified gas to hypoxemic subjects. HFNC allows a F_{IO_2} from 0.21 to 1.0 using an air-oxygen blender and can generate gas flows of 10–60 L/min.[1,2] Compared to low-flow oxygen therapy, HFNC allows better control of F_{IO_2}.[3,4] However, the F_{IO_2} delivered via HFNC remains dependent on the amount of flow, nasal cannula size, and mouth position.[5-8] In the case of respiratory distress, the inspiratory flow can exceed 100 L/min, causing dilution of the administered oxygen by room air.[7,9-11]

The double-trunk mask (DTM) is a device designed to increase the F_{IO_2} in adult patients who receive oxygen by a nasal cannula. The mask was developed by Hnatiuk et al[12] and modified by Bodur et al.[13] The DTM is composed of a regular aerosol mask with corrugated tubing (15 cm length) inserted into two lateral holes. The dead space of the mask is 210 mL, and volume of the trunks is 120 mL. The DTM was used with subjects who were already receiving oxygen via nasal cannula (Fig. 1). The tubing collects oxygen coming from the nasal cannula during expiration. During the next inspiration, the subject inhales the oxygenated gas mixture from the tubing in-

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stead of room air. The mask has been shown to increase P_{aO_2} without increasing P_{aCO_2}.[14] Our hypothesis was that the addition of the DTM to a HFNC would prevent the dilution of inspired gas by room air due to high inspiratory flow or to mouth position, thereby increasing F_{IO_2} and thus P_{aO_2}. The primary outcome of our study was to evaluate the effect of the DTM on P_{aO_2} in hypoxemic subjects treated with HFNC. The secondary outcomes were changes in P_{aCO_2} and subject comfort.

Methods

This was a prospective multi-center crossover pilot study with assessment by an independent evaluator. The ethics review boards for the Erasmes Hospital and Epicura-Tivoli Hospital approved the study protocol. Written informed consent was obtained from all participants before inclusion (NERB034008). The study was registered with ClinicalTrials.gov (NCT03319602).

We included 15 non-intubated adult subjects with acute hypoxemic respiratory failure admitted to the ICUs at Epicura Hospital in Hornu, Belgium, and at Tivoli University Hospital in La Louvière, Belgium, from October 2017 to March 2018.

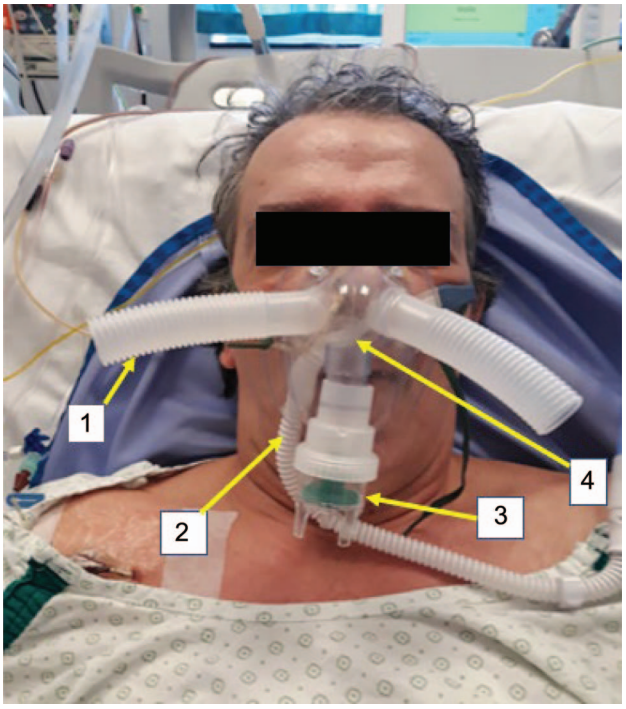

Fig. 1. Subject receiving classic high-flow nasal cannula (HFNC) therapy with a double-trunk mask (DTM). The DTM is composed of a normal aerosol mask (nebulizer and mouth piece) with 2 lateral holes (22 mm in diameter) and 15 cm of corrugated tubing inserted in the holes. The DTM was only applied to the face of subjects breathing spontaneously without obstructed airways. Subjects were already receiving O_2 via a nasal cannula. 1: trunk; 2: HFNC; 3: nebulizer; 4: aerosol mask. The nasal cannula is positioned according to the manufacturer's recommendation.

QUICK LOOK

Current knowledge

High-flow nasal cannula (HFNC) oxygen therapy might benefit patients with hypoxemia. This technique decreases oxygen dilution and anatomical dead space, increases patient comfort, and can generate positive airway pressure.

What this paper contributes to our knowledge

The double-trunk mask (DTM) boosts F_{IO_2} during low-flow oxygen via nasal cannula. In subjects receiving HFNC therapy, placing a DTM over the nasal prongs increased P_{aO_2} without significantly increasing P_{aCO_2}. These results mean the DTM can potentially improve the oxygenation status of patients during HFNC therapy.

Criteria for inclusion were hypoxemia ($P_{aO_2}/F_{IO_2} < 300$ mm Hg), new or worsening respiratory symptoms (eg, dyspnea, shortness of breath), use of accessory muscle, breathing frequency $\geq$ 30 breaths/min, and an inline arterial catheter without anticipated changes to respiratory clinical management over the next 2 h (eg, use of noninvasive or invasive mechanical ventilation). Subjects were included only when the investigators were present in the ICU. The level of severity of hypoxemia was assessed as follows: mild (P_{aO_2}/F_{IO_2} 200–300 mm Hg), moderate (P_{aO_2}/F_{IO_2} 100–200 mm Hg), and severe ($P_{aO_2}/F_{IO_2} < 100$ mm Hg).[15] Exclusion criteria included COPD, pulmonary fibrosis, hypoventilation obesity syndrome, respiratory acidosis, cardiogenic pulmonary edema, systolic arterial pressure < 60 mm Hg or treatment with epinephrine > 0.1 μg/kg/min, altered consciousness ($\leq$ 12 on the Glasgow Coma scale), and confusion. The flow chart for participant enrollment, allocation, and analysis is presented in Figure 2.

Data Collection

At enrollment, the following variables were collected: age, weight, height, arterial pressure (systolic, diastolic, mean), heart rate, breathing frequency, arterial blood gases, Sequential Organ Failure Assessment (SOFA) score on the day of the study, Medical Research Council dyspnea 5-point Likert scale, subject comfort using a numeric scale, and Glasgow Coma scale. Etiology of acute hypoxemic respiratory failure and presence of bilateral pulmonary infiltrates on a chest radiograph were reported by a physician.

Materials

The HFNC flow was generated with an AIRVO 2 (Fisher and Paykel Healthcare, Auckland, New Zealand) connected to a standard nasal prong (Optiflow nasal cannula for MR850 AIRVO, Auckland, New Zealand). The AIRVO 2 can deliver flows of 10–60 L/min. A calibrated ultrasonic oxygen analyzer measured the gas output of the system. AIRVO 2 was connected to a RTM3 oxygen Thorpe Tube (Air Liquide, Paris, France) with O_2 flow of 0–60 L/min) connected to a wall oxygen supply. The DTM consisted of an aerosol mask (Dahlhausen, Köln, Germany) and 2 corrugated tubes (Dahlaussen) of 22 mm diameter, shortened to 15 cm (Fig. 1).

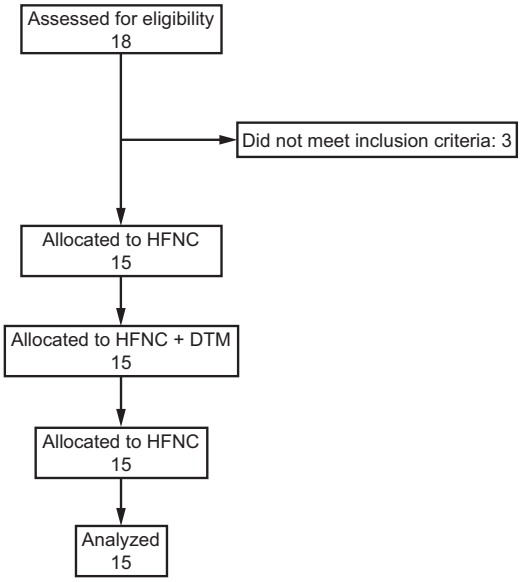

Fig. 2. Flow chart. HFNC = high-flow nasal cannula; DTM = double trunk mask.

Study Protocol

Subjects were placed in a semi-recumbent position, in a quiet environment with the Optiflow nasal cannula in place. The F_{IO_2} and flow were adjusted to obtain a peripheral $S_{pO_2} \geq 90\%$. In some cases, the flow was adjusted for subject comfort. During high inspiratory flow demand, the flow was initially adjusted to 60 L/min. No further modifications to HFNC settings were made during the investigation (Fig. 2).

Each subject went through 3 treatment phases (Figure 3). In phase 1 (HFNC), oxygen was administered using only HFNC for a period of 30 min. After that, if the subject remained stable, arterial blood gases were measured using the arterial catheter. In phase 2 (HFNC + DTM, the clinician placed the DTM over the nasal prongs without changing HFNC settings (Fig. 1). Arterial blood gases were measured after 30 min. Subjects in whom the P_{aO_2} increased by at least 10% were considered responders. In phase 3 (HFNC), the DTM was withdrawn while HFNC

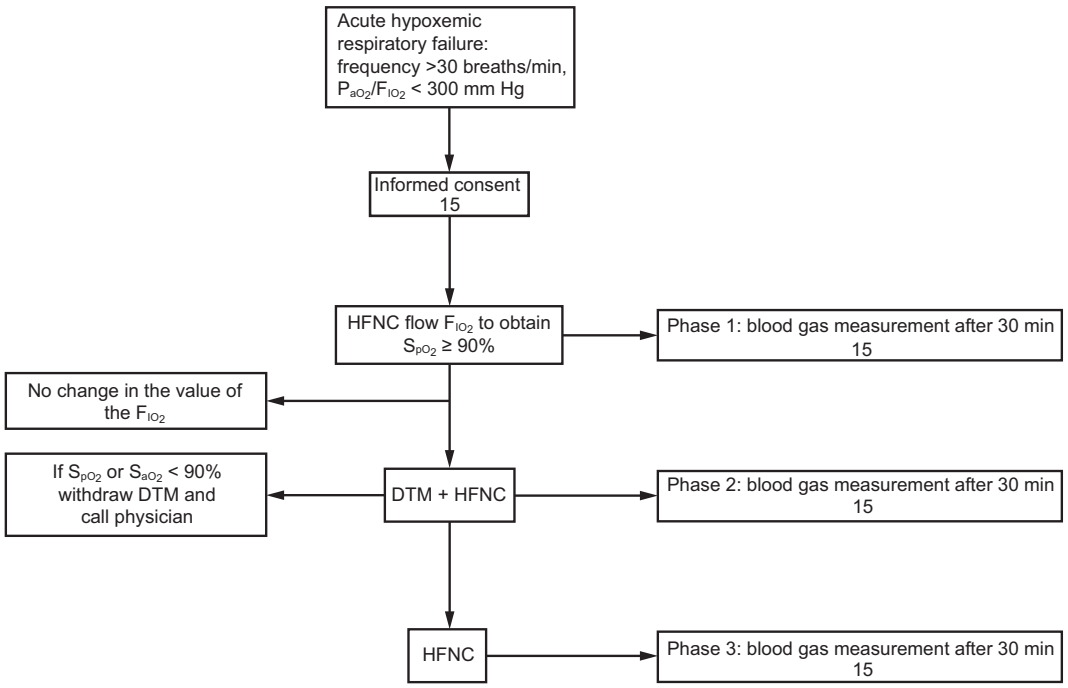

Fig. 3. Flow chart illustrating enrollment and follow-up of subjects in this crossover design. HFNC = high-flow nasal cannula, DTM = double-trunk mask.

Table 1. Subject Characteristics

Subject	Age, y	Sex	Body Mass Index, kg/m^2	Set F_{IO_2}	Flow, L/min	SOFA Score on Admission	Etiology of AHRF	Bilateral Infiltrates	Immunodeficiency	Current or Past Smoking	ROX Index
1	59	Male	34	0.80	50	4	CAP	Yes	No	No	4.8
2	63	Male	18	0.55	60	5	HAP	No	No	No	8.02
3	67	Female	21	0.80	60	4	HAP	Yes	Yes	No	5.68
4	44	Male	31	0.50	50	4	CAP	No	No	No	9.2
5	67	Male	24	1.0	60	4	CAP	Yes	Yes	Yes	4.65
6	86	Male	22	0.80	50	5	CAP	Yes	No	No	5.27
7	62	Male	28	0.70	50	3	CAP	Yes	No	No	9.33
8	23	Male	21	0.80	50	5	ES	Yes	No	No	6.86
9	54	Female	34	0.90	50	8	CAP	Yes	No	Yes	5.63
10	82	Male	23	1.0	50	4	CAP	Yes	Yes	No	4.45
11	73	Male	25	0.70	40	6	CAP	Yes	No	No	6.71
12	71	Male	31	0.70	40	5	CAP	Yes	No	Yes	9.05
13	76	Male	35	0.70	50	5	CAP	Yes	No	No	6.43
14	82	Male	23	0.90	50	5	CAP	Yes	No	No	4.31
15	76	Male	19	0.80	50	11	CAP	Yes	No	No	3.71
Total or mean ± SD	67 ± 16	13 male, 2 female	26 ± 6	0.78 ± 0.14	51 ± 6	5 ± 2	12 CAP	13 Yes, 2 No	3 Yes, 12 No	3 Yes, 12 No	6.3 ± 1.9

ROX Index is defined as the ratio of pulse oximetry/F_{IO_2} to breathing frequency.
SOFA = Sequential Organ Failure Assessment
AHRF = acute hypoxemic respiratory failure
CAP = community-acquired pneumonia
HAP = hospital-acquired pneumonia
ES = extrapulmonary sepsis

was continued with the same settings. Arterial blood gases were measured after 30 min.

Respiratory and hemodynamic status were also reassessed at the end of each study phase. The subjects did not receive any instruction regarding opening or closing their mouth during any of the study phases.

Statistical Analysis

In the absence of data allowing for the estimation of a sample size, we decided to enroll 15 subjects in this exploratory study, with the hypothesis that this number would be sufficient to detect a significant variation in P_{aO_2}. Data were analyzed with SigmaPlot version 12.0 (Systat Software, San Jose, California). Data are presented as mean ± SD for normally distributed variables, and as median and interquartile range for non-normally distributed variables. Distribution of data were evaluated with a Kolmogorov-Smirnov test. Differences between variables across the study phases were tested with 1-way analysis of variance (ANOVA) for repeated measures for parametric data, and with 1-way repeated measure ANOVA on ranks for non-parametric data. Pairwise multiple comparison procedures (Tukey test) were performed when statistically significant differences were found between groups.

Results

The subjects are described in Table 1. Fifteen subjects were included: 13 men (86%) and 2 women (13%). Mean age was 67 ± 16 y, and body mass index was 26 ± 6 kg/m^2. At enrollment, all subjects had a $P_{aO_2}/F_{IO_2} < 200$ mm Hg, with 13 (87%) having a ratio < 100 mm Hg. ROX index was defined as the ratio of pulse oximetry/fraction of inspired oxygen to breathing frequency. The flow during HFNC was 51 ± 6 L/min (range, 40–60 L/min). No adverse events were observed during the study.

Compared with HFNC alone, HFNC + DTM increased P_{aO_2} from 68 ± 14 mm Hg to 85 ± 22 mm Hg ($P < .001$) and did not affect P_{aCO_2} ($P = .18$) (Table 2, Fig. 4 and Fig. 5). In the 11 responders, P_{aO_2} increased from 63 ± 12 mm Hg to 88 ± 23 mm Hg ($P < .001$). After removal of the DTM, all variables returned to baseline values.

Discussion

The present study shows that in subjects with moderate ($n = 4$) and severe ($n = 11$) acute hypoxemic respiratory failure who were already receiving HFNC therapy, the addition of the DTM increased the P_{aO_2} from 68 ± 14 mm Hg to 85 ± 22 mm Hg ($P < .001$) and did not affect P_{aCO_2} ($P = .18$). In the 11 responders, P_{aO_2} increased from

Table 2. Median P_{aO_2} (and P_{aO_2}/F_{IO_2}) Variation Between Phases

Subject	P_{aO_2}, mm Hg			P_{aO_2}/F_{IO_2}, mm Hg			Variation Between Phase 1 and 2, %
	HFNC	HFNC + DTM	HFNC	HFNC	HFNC + DTM	HFNC	
1	62	80	48	78	100	60	29
2	95	97	91	172	176	166	2
3	80	143	100	100	179	125	79
4	69	63	66	138	125	132	−9
5	74	65	59	74	65	59	−11
6	81	80	84	101	100	105	−1
7	81	90	84	115	128	119	11
8	58	82	81	73	102	102	41
9	80	105	74	89	117	82	33
10	65	103	82	65	103	82	58
11	62	76	63	89	109	90	23
12	53	83	54	76	118	77	56
13	51	59	51	73	84	73	15
14	49	62	51	54	69	57	28
15	55	82	65	69	102	81	48

Median P_{aO_2} increased between phase HFNC and HFNC + DTM and returned to the baseline values during the washout periods. Column variation (%) corresponded to the relative P_{aO_2} variation (%) between phase HFNC and phase HFNC + DTM. Subjects 2, 4, 5, and 6 were considered nonresponsive.
HFNC = high-flow nasal cannula
DTM = double-trunk mask

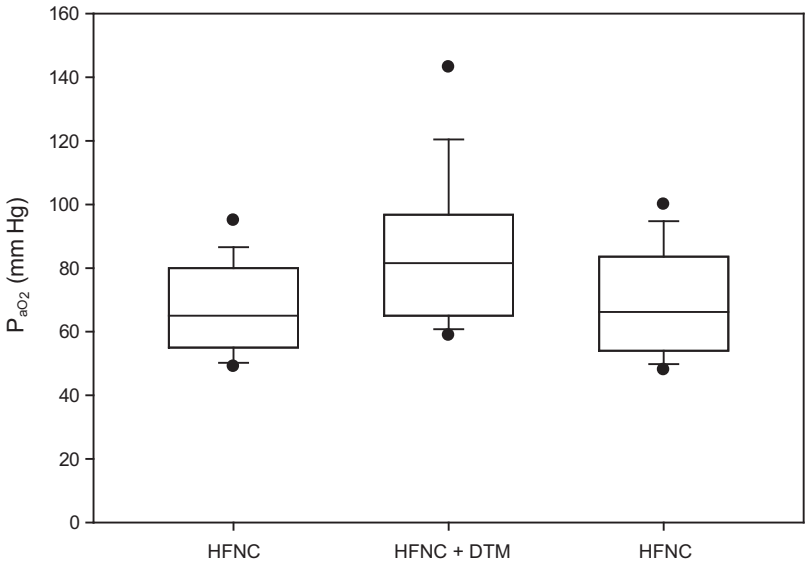

Fig. 4. P_{aO_2} comparisons by Friedman test between HFNC alone during phase 1, HFNC + DTM during phase 2, and HFNC alone during phase 3. The boxes illustrate interquartile range and 25th, 50th, and 75th percentiles; the whiskers correspond to the 5th and 95th percentiles, and dots are outliers. P_{aO_2} levels show a statistically significant increase at phase 2 compared to phase 1 (+26%). When the mask was removed, the P_{aO_2} returned to the baseline values during the washout periods and subsequently during the recovery period.

63 ± 12 mm Hg to 88 ± 23 mm Hg ($P < .001$). The P_{aO_2} increase can be explained by eliminating entrainment of room air when inspiratory flows are above the flow delivered with HFNC or when the nasals prongs are not correctly positioned in the nares. Entrainment of room air is known to dilute the gas mixture and decrease delivered F_{IO_2}.[16-26] When the DTM was added, room air was no longer entrained and the subject inspired the oxygen-enriched mixture collected in the additional tubes.[13,27] Actual F_{IO_2} increased or was closer to the set F_{IO_2}, thereby increasing oxygenation. However, we had 4 non-responders, which we believe was due to the differences in inspiratory

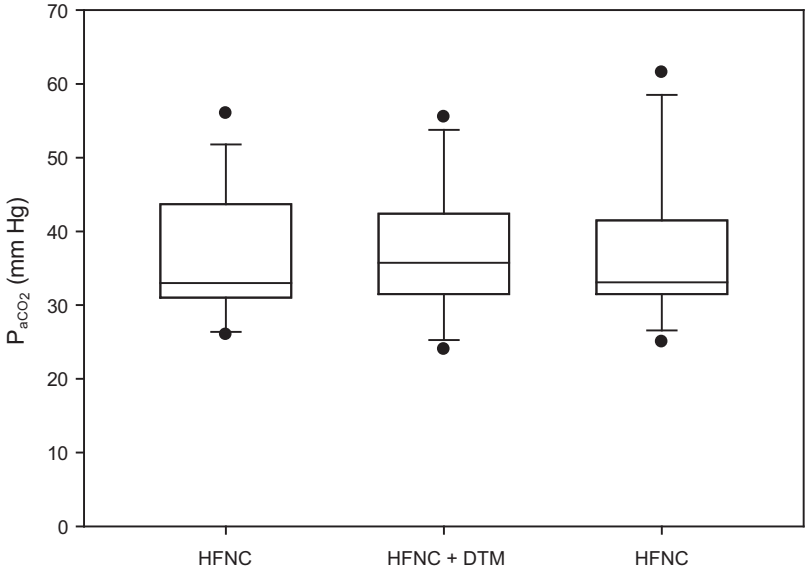

Fig. 5. P_{aCO_2} comparisons by Friedman test between phase 1, phase 2, and phase 3. P_{aCO_2} levels did not show any statistical difference between all phases ($P = .18$).

flow demand and the amount of air entrainment through leaks around the mask. Few studies have examined the inspiratory flow values during acute respiratory failure. Two studies have examined the role of inspiratory flow in healthy subjects receiving HFNC at rest and during exercise.[5,28] The authors concluded that HFNC cannot be considered a constant oxygen delivery system because the accuracy of the system depends on the patient's breathing pattern, especially if the inspiratory flow demand is above the HFNC gas flow value.

In our study, the P_{aCO_2} remained unchanged despite an increase in dead space. This observation can be explained by the tube washout caused by gas coming from the HFNC.[14] Indeed, with a 60 L/min (ie, 1,000 mL/s) flow from the HFNC, the total trunk volume of 120 mL was entirely washed out in ~0.12 s. Even with the high breathing frequency and short expiratory time of subjects with acute hypoxemic respiratory failure, this limited duration was appropriate to wash out the expired CO_2 from the tubes. According to our calculations, a frequency $>$ 60 breaths/min would be required to result in CO_2 rebreathing.

Another issue relates to our classification of subjects with acute hypoxemic respiratory failure. The main determinant of our subject's classification into subgroups with mild, moderate, or severe acute hypoxemic respiratory failure is the P_{aO_2}/F_{IO_2} ratio. Our data show that actual F_{IO_2} is overestimated in many subjects with acute hypoxemic respiratory failure, resulting in erroneously low P_{aO_2}/F_{IO_2} values. The use of the DTM may reverse this confusing effect, by minimizing the difference between set F_{IO_2} and actual F_{IO_2} and restoring an accurate P_{aO_2}/F_{IO_2} ratio.

Severe hypoxemia is deleterious to patients and should be considered an indication for positive airway pressure and mechanical ventilation.[29] Thus, caution should be used when applying the DTM to prevent delayed intubation and prolonged duration of critical hypoxemia. Suggested indications include transient hypoxemia (eg, related to cardiogenic pulmonary edema expected to respond rapidly to medical therapy), pre-oxygenation before intubation, hematological patients (in whom invasive mechanical ventilation carries specific risks), and patients with a do-not-intubate order. Although few subjects complained, the DTM has a bulky design that could potentially cause discomfort.

This study has several limitations. The number of included subjects was small, and the male/female ratio is high, which may not be representative of general ICU populations. The sequence of treatments was not randomized, but time effects can be reasonably excluded secondary to the double-crossover design. In addition, subjects were included in the study only when investigators were present in the ICU. The results thus deserve to be confirmed in a larger set of ICU subjects with hypoxemic acute respiratory failure.

Conclusion

Our data show that, in subjects with acute hypoxemic respiratory failure who are already receiving HFNC oxygenation, the addition of DTM to HFNC increased P_{aO_2} without significantly changing the P_{aCO_2}. The DTM can thus be useful in in select patients with increased inspiratory flow demands.

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