ORIGINAL ARTICLE

Comparison of Oxygen Delivery Devices in Postoperative Patients with Hypoxemia: An Open-labeled Randomized Controlled Study

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Abstract

Background: Acute hypoxemic respiratory failure is among the more commonly occurring complications in postoperative patients. Supplemental oxygen and addressing the primary etiology form the basis of its treatment.

Materials and methods: We conducted an open-labeled randomized control trial with 90 adult patients and compared three oxygen delivery vehicles (ODV), i.e., noninvasive ventilation (NIV), high-flow nasal cannula (HFNC), and venturi mask (VM) in postoperative hypoxemic patients. The primary outcome variable was a change in the P/F ratio after 2 hours of use of ODV.

Results: It was observed that the change in P/F ratio after 2 hours was similar in all three ODV groups ($p = 0.274$). The mean values of the post-ODV P/F ratio were comparable with the pre-ODV P/F ratio in all three modalities. The P/F ratio after HFNC was 358.08 ± 117.95; after NIV was 357.60 ± 220.67; and after VM was 355.47 ± 101.90 ($p = 0.997$).

Conclusion: Among HFNC, NIV, and VM, none of the devices proved superior to the other for use in postoperative hypoxemia.

Keywords: Hypoxemia, Oxygenation, Oxygen delivery device, P/F ratio.

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Highlights

- Patients with acute hypoxemic respiratory failure may require prolonged respiratory support.
- We compared three oxygen delivery vehicles (ODV): High-flow nasal cannula (HFNC), non-invasive ventilation (NIV), and venturi mask (VM) in these patients.
- None of the devices proved superior to the other for use in postoperative hypoxemia.

Introduction

Postoperative hypoxemia is one of the most frequent manifestations of respiratory failure after extubation. It is characterized by the partial pressure of oxygen in arterial blood (PaO_2) to the fraction of inspiratory oxygen concentration (FiO_2), i.e., P/F ratio ≤ 300, with clinical signs of respiratory distress caused by increased respiratory drive.[1] This results in increased mortality, length of hospital stay, more prolonged healing and recovery, and poor long-term outcomes.[2] Supplemental oxygen is often used to treat hypoxemia following ventilator support interruption and endotracheal tube removal.[3]

Fixed-performance systems such as the VM deliver a consistent FiO_2 regardless of the peak inspiratory flow of a patient. It helps in delivering a predetermined FiO_2. It delivers oxygen at lower flow rates than patients' inspiratory needs; consequently, when the inspiratory flow of the patient surpasses the gas flow rate of the mask, the surrounding room air is drawn in.[4] The size of the constrictor determines the final oxygen concentration for a given gas flow.

The HFNC is a device capable of generating a flow rate of 60 liters per minute. It uses an air/oxygen blender to deliver FiO_2 from 21 to 100%. Continuous high-flow oxygen delivery produces positive end expiration pressure (PEEP), which improves breathing by maintaining stable FiO_2 and flushing away physiologic dead space. The heating and humidification help clearance of secretions, decrease bronchospasm, and maintain mucosal integrity.[5]

Noninvasive ventilation has been used to provide mechanical ventilation without using a definitive airway. It provides positive pressure ventilation via a tight, sealed face mask. Mainly, two modes of NIV are used continuous positive airway pressure (CPAP) and bilevel positive airway pressure (BiPAP). It enhances functional residual capacity (FRC), opens up the collapsed alveoli, and increases lung compliance by improving oxygenation and reducing the work of breathing. Additionally, it lowers left ventricular afterload, boosting cardiac output and hemodynamics.[6]

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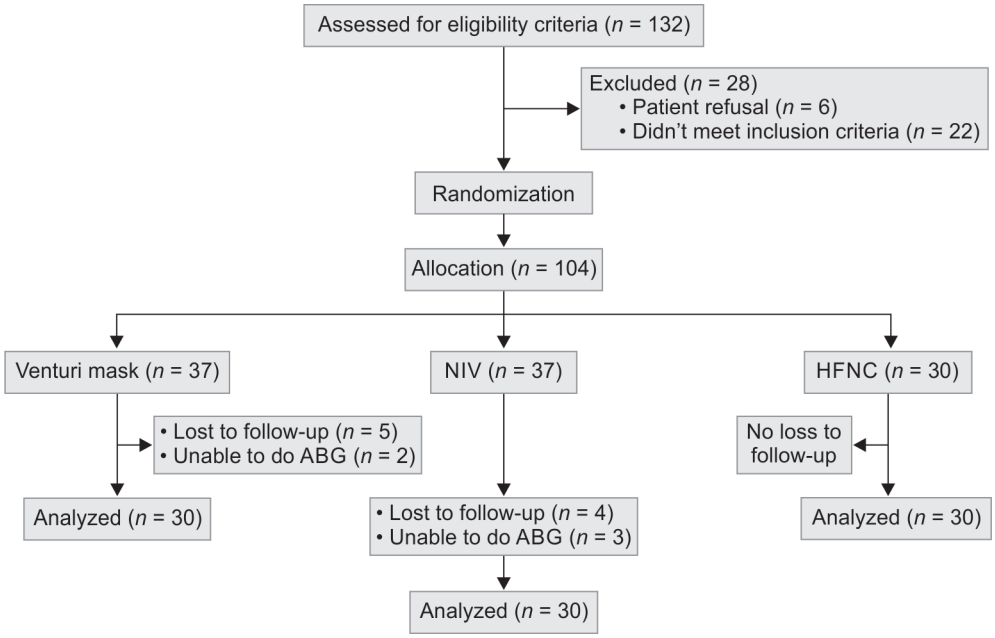

Fig. 1: CONSORT diagram

We aimed to compare different oxygen delivery devices like noninvasive NIV, HFNC, and VM for managing hypoxemia. We hypothesized no difference in P/F ratio after using these oxygen delivery devices in the postoperative period for managing hypoxemia.

Materials and Methods

The study was carried out in the Department of Anesthesiology and Critical Care at AIIMS, Jodhpur, after getting approval from the institutional ethics committee (Reference Number: AIIMS/IEC/2021/3354; dated 12/03/2021). We registered the study prospectively at the clinical trial registry of India (Ref. No. CTRI/2021/06/0044371, Date of registration: 05/07/2021). Enrolment of patients started in July 2021 and ended in September 2022. All postoperative adult patients of age between 18 and 65 years with hypoxemia who were admitted or kept for monitoring in a post-anesthesia care unit (PACU) after undergoing surgery having SpO_2 <90% on room air or SpO_2 <92% on nasal prongs/face mask were enrolled for the study. Patients with facial anomalies, those with face, nose, or airway surgery, post-thoracotomy, lung surgeries, pre-existing pulmonary complications, and those who underwent head and neck surgery were excluded from this research. Informed written consent was obtained from all the patients before inclusion in the study.

A short history of the patient's pertinent comorbidities, length of ailments, medications, and surgery was obtained. Vital indicators such as heart rate, respiratory rate, blood pressure, pulse oxygen saturation, and ABG readings were also collected, including PaO_2, $PaCO_2$, and PaO_2/FiO_2. Patients were randomized into three groups, i.e., HFNC, NIV, and VM. The randomization sequence was generated by a web-based randomization tool (www.randomizer.org) and kept in a sealed opaque envelope with a serial number. Before putting the device to use, the random assignment was seen by opening sealed packages.

High-flow oxygen (37°C and 44 mg H_2O/L) was constantly given using a nasal cannula with HFNC. The starting flow rate was 50 L/min, and the initial FiO_2 level was 50%. BiPAP was administered using a securely sealed face mask and either a ventilator mainly made for BiPAP or an ICU ventilator in pressure-support mode with 5 cm H_2O added PEEP. Starting at 8 cm H_2O, pressure support was adjusted to attain an exhaled tidal volume of 7–8 mL/kg and a respiratory rate of 25/min. The inspired oxygen fraction was 50% during the use of BiPAP. A VM with a constrictor that could provide 0.5 FiO_2 was used. ABG values were recorded before applying ODV and 2 hours after administering oxygen therapy.

The primary outcome variable was a change in the P/F ratio after 2 hours of use of ODV in PACU. Secondary outcome variables were changes in blood gas ($PaCO_2$ and PaO_2) levels, patient comfort, ease of communication, ease of oral fluids or food intake, and complaints of any other side effect (nasal crusting, headache, nausea, or vomiting).

All data were input into an Excel sheet and statistically analyzed with SPSS statistical software (version 23.0.0). All quantitative data were represented as Mean + SD. The ANOVA test was used to examine the difference between the mean values of the groups. The Chi-square test was used to assess all qualitative data. When the *p*-value was less than 0.05, it was considered significant. Schwabbauer et al.,[7] in their study, observed the global rating of NIV 4.5 + 1.7 and the VM of 3.2 + 1.7. Considering the α of 5% and power of 80% with a 95% confidence interval, we got a sample size of 27 in each group. Adding 10% contingency, the final sample size for each group was calculated as 30.

Results

In the present study, 132 patients were evaluated for eligibility; 28 patients were excluded because 22 patients did not satisfy the inclusion criteria, and six patients did not provide informed consent. The study enrolled and randomized 104 patients in total. However, seven patients in the VM group and seven in the NIV group were not included in the data analysis because ABG could not be performed, and some patients did not sustain ODV. Finally, the data of ninety patients was analyzed, and the results were computed (Fig. 1).

The PaO_2 in the HFNC group before and after ODV were 66.35 ± 10.18 mm Hg and 159.84 ± 66.83 mm Hg, respectively. At the

Table 1: Comparison of different variables between the three groups

Variables	*HFNC (n = 30)*	*NIV (n = 30)*	*Venturi mask (n = 30)*	*p-value*
Age (%)				0.214
18–30 years	13.33	3.33	20.00	
31–50 years	40.00	43.33	50.00	
>50 years	46.67	53.33	30.00	
Sex (%)				0.866
Male	63.33	66.67	60	
Female	36.67	33.33	40	
SpO_2, mean (SD)				
Before ODV	88.60 (2.92)	83.30 (11.57)	87.07 (4.31)	0.018
After ODV	98.77 (1.74)	98.77 (1.85)	98.70 (1.90)	0.986
Change in SpO_2 after 2 hours	10.17 (1.18)	15.47 (9.72)	11.63 (2.41)	0.634
PaO_2 in mm Hg, mean (SD)				
Before ODV	66.35 (10.18)	59.43 (5.10)	62.26 (6.28)	0.0024
After ODV	159.84 (66.83)	151.26 (44.76)	158.48 (50.96)	0.810
Change in PaO_2 after 2 hours	93.49 (56.65)	91.83 (39.66)	96.22 (44.98)	0.994
$PaCO_2$ in mm Hg, mean (SD)				
Before ODV	46.03 (46.29)	41.00 (5.54)	37.35 (5.77)	0.463
After ODV	36.83 (3.78)	37.19 (5.19)	35.95 (3.87)	0.526
Change in $PaCO_2$ after 2 hours	9.20 (42.51)	3.81 (0.35)	1.40 (1.9)	0.069
P/F ratio, mean (SD)				
Before ODV	281.11 (82.38)	244.54 (66.57)	258.73 (67.70)	0.150
After ODV	358.08 (117.95)	357.60 (220.67)	355.47 (101.90)	0.997
Change in P/F ratio after 2 hours	76.97 (35.57)	79.72 (113.06)	96.74 (34.22)	0.274
Comfort score (1–4)				
Median (IQR) (range)	2 (1, 2) (1–4)	4 (4, 4) (2–4)	2 (2, 3) (1–4)	$p < 0.001$

HFNC, high-flow nasal cannula; NIV, non-invasive ventilation; ODV, oxygen delivery vehicles; $PaCO_2$, partial pressure of carbon dioxide; PaO_2, partial pressure of oxygen; P/F ratio, ratio of PaO_2 to the fraction of inspiratory oxygen concentration; SpO_2, peripheral capillary oxygen saturation measured by pulse oximeter

same time, PaO_2 in the NIV group before and after ODV were 59.43 ± 5.10 mm Hg and 151.26 ± 44.76 mm Hg, respectively. The PaO_2 in the VM group before and after ODV were 62.26 ± 6.28 mm Hg and 158.48 ± 50.96 mm Hg, respectively. The change in PaO2 after 2 hours of use of ODV in the groups was analyzed using the ANOVA test which was statistically non-significant ($p = 0.994$) (Table 1).

The $PaCO_2$ in the HFNC group before and after ODV were 46.03 ± 46.29 mm Hg and 36.83 ± 3.78 mm Hg, respectively. In comparison, the $PaCO_2$ in the NIV group before and after ODV were 41.00 ± 5.54 mm Hg and 37.19 ± 5.19 mm Hg, respectively. The mean ± SD of $PaCO_2$ in the VM group before and after ODV were 37.35 ± 5.77 mm Hg and 35.95 ± 3.87 mm Hg, respectively. The change in $PaCO_2$ after 2 hours of use of ODV in the groups was analyzed using the ANOVA test which was statistically nonsignificant ($p = 0.069$) (Table 1).

The P/F ratio before HFNC was 281.11 ± 82.38, and after HFNC was 358.08 ± 117.95. Whereas the P/F ratio before NIV was 244.55 ± 66.57, and after NIV was 357.60 ± 220.67. The P/F ratio before the VM was 258.73 ± 67.70, and after the VM was 355.47 ± 101.90. The change in P/F ratio after 2 hours of use of ODV in the groups was analyzed using the ANOVA test which was statistically non-significant ($p = 0.274$) (Table 1 and Fig. 2).

On comparing the Comfort scores, in the group NIV, none had a comfort score of 1, 1 (3.33%) had a score of 2, 2 (6.67%) had a score of 3, and 27 (90%) had a score of 4. In the group, VM, 5 (16.67%) had a comfort score of 1, 17 (56.67%) had a score of 2, 6 (20%) had a score of 3, and 2 (6.67%) had a score 4. The median (IQR) (Range) of the HFNC group was 2 (1, 2) (1–4), the NIV group was 4 (4, 4) (2–4), and of the VM group was 2 (2, 3) (1–4) ($p < 0.001$) (Table 1). The data depicts that patients on NIV had maximum discomfort and difficulty in communication (Score 4).

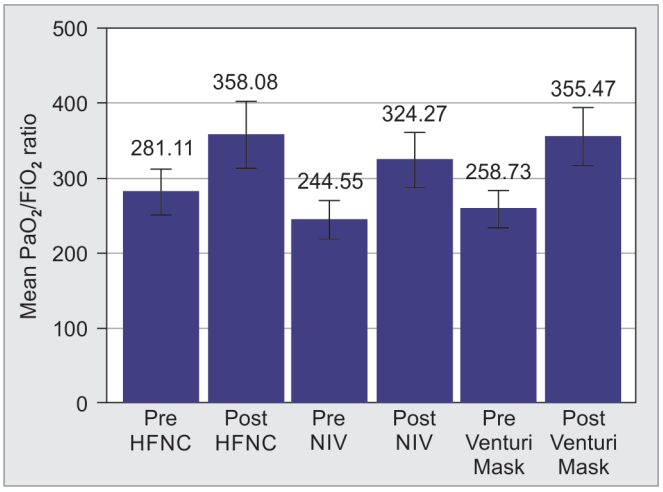

Fig. 2: Bar chart showing the mean value of P/F ratio prior to applying oxygen delivery vehicles (ODV) and after 2 hours of ODV

Discussion

Acute hypoxemic respiratory failure is one of the common complications in postoperative patients. It mainly occurs due to atelectasis, pulmonary edema, aspiration, and residual neuromuscular blockade and results in a marked increase in overall length of stay in ICU and hospital, time for rehabilitation, mortality, and financial expenditures.[8] The cornerstone of its treatment is supplemental oxygen, along with treating the primary cause.[1] Most medical practitioners tend to favor the utilization of NIV in such patients to prevent the need for reintubation. This is particularly relevant in cases when conventional oxygen therapy proves ineffective in patients who have undergone surgery or when there is a high likelihood of failure based on patient assessment.[9] However, NIV is poorly tolerated by most of the patients and requires close monitoring. In contrast, other high-flow devices like HFNC and VM are better accepted and may not need excessive monitoring. In the present study, none of the devices (HFNC, VM, and NIV) proved superior to the other for use in postoperative hypoxemia.

Various studies have been conducted to compare the efficiency of different oxygen delivery devices. A study done by Maggiore et al. concluded that HFNC was a better oxygenation device when compared to a VM in post-extubation patients.[10]

Lee et al. conducted a systematic review that evaluated the effectiveness of an HFNC to NIV and conventional oxygen treatment (COT) in individuals with hypoxemic respiratory failure.[2] They concluded that patients were more comfortable with HFNC and could tolerate it better when compared with NIV or COT in most of the studies and considered it as an intermediate level of assistance for respiration that falls in between NIV and COT (facial masks and nasal cannulas).

The study by Schwabbauer et al. evaluated the transient effects of HFNC oxygen therapy on functional and individual respiratory parameters and compared it to routine treatment via NIV and VM.[7] Under NIV, PaO_2 was highest compared to VM and HFNC ($p < 0.01$). Whereas the $PaCO_2$ after the use of the VM was 37 ± 6 mm Hg, HFNC was 37 ± 5 mm Hg, and NIV was 39 ± 7 mm Hg ($p > 0.05$). In our study, the PaO_2, 2 hours after ODV in the HFNC group was 159 ± 66.83 mm Hg, in the NIV group 151.26 ± 44.76 mm Hg, and in the VM group 158.48 ± 50.96 mm Hg ($p = 0.81$). Compared to a VM, the possible explanation for the higher PaO_2 with HFNC could be the higher delivered gas flows (up to 60 L/min) in HFNC. The intended FiO_2 of 0.5 in a VM with an oxygen flow of 10–15 L/min can only be reached with a total gas flow of less than 30 L/min. Often, acute hypoxic respiratory failure generates significantly greater inspiratory gas flows. This results in an extra room-air admixture during inspiration, particularly in loose-fitting masks like venturi systems and other masks, which lowers FiO_2.[3] In our study, $PaCO_2$, 2 hours after HFNC, was 36.83 ± 3.78 mm Hg, NIV was 37.19 ± 5.19 mm Hg, and VM was 35.95 ± 3.87 mm Hg. The improved breathing efficiency and decreased anatomic dead space caused by increased tidal volume account for the drop in $PaCO_2$ with HFNC and VM. Improvement in inspiratory air-flow dynamics adds to it.[8]

Stéphan et al.[6] conducted a study in patients with acute respiratory failure after cardiothoracic surgery to compare the efficacy of HFNC and BiPAP. On evaluating different respiratory parameters from day 1 to day 3, the P/F ratio improved in both groups, but the increment was remarkably higher with BiPAP ($p < 0.001$). There was no significant difference between the $PaCO_2$ values from day 1 to day 3 in the two groups ($p = 0.200$). Our study showed that neither of the oxygen delivery vehicles, i.e., NIV, HFNC, and VM, were superior ($p > 0.05$).

In the study by Schwabbauer et al., a numeric rating scale (NRS) with 10 points was used to grade general pain and discomfort from the oxygen application, with lower values indicating less discomfort.[7] On comparing the NRS scores, it was found that patient discomfort was minimal with VM and HFNC and highest with NIV ($p < 0.05$). In our study, we noted a comfort score where different scores were given according to the patient's comfort and ease of communication. Lower scores indicated more comfort and better communication. In the NIV group, 90% had a comfort score of 4 (very uncomfortable and unable to communicate), whereas only 6.67% in the VM group and 13.33% in the HFNC group had a score of 4. By delivering heated and humidified air, HFNC supposedly increases patient tolerance, ease, and comfort by reducing bronchospasm due to the effect of dry and cold air on the nasal mucosa. Thirty percent of the patients in the HFNC group and 16.67% of the VM group had a comfort score of 1 (very comfortable and easy communication). Active humidification remarkably improves patients' comfort by diminishing upper respiratory tract dehydration symptoms.[7]

Often, prolonged respiratory support is needed for patients with acute hypoxemic respiratory failure.[11,12] Primarily, we use HFNC or NIV in these patients to escape reintubation and enhance oxygenation.[7] In our study, since the P/F ratio after 2 hours of application of all three ODVs was comparable, we can use any of these devices to ameliorate oxygenation.

The present study was structured as a short-term experimental investigation with several limitations. The duration of the intervention was only 2 hours. However, it could have been challenging to compare different parameters for longer durations directly. The FiO_2 to be delivered was not decided according to the patient's needs. We had kept FiO_2 fixed at 0.5 irrespective of the device used and the patient's requirement. The evaluation of the patient's discomfort was based on subjective measures. Nevertheless, the numerical scale employed in this study exhibits superior reliability in assessing acute pain compared to both the visual analog scale and verbal scale. As the patients were kept nil by mouth for 2 hours in the postoperative period, the ease of taking oral fluids or oral diet using different ODV could not be assessed in these patients.

Conclusion

Among HFNC, NIV, and VM, none of the devices proved superior to the other for use in postoperative hypoxemia. There is no difference in the P/F ratio while using different oxygen delivery vehicles for managing hypoxemia.

Ethical Approval

The study was approved by the AIIMS/IEC/2021/3354; Dated 12/03/2021.

Clinical Trial Registry of India

(Ref. No. CTRI/2021/06/0044371, Date of Registration: 05/07/2021).

Author Contributions

SM, NK: Conceptualization; SM, AS, NK, SG: Methodology; DR, TM: Formal analysis and investigation; SM, AS, NK, DR and TM: Writing—initial draft preparation; All the authors: Writing—review and editing; PB: Supervision.

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