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A comparative study between high-flow nasal oxygen therapy and venturi mask oxygen therapy for postoperative laparoscopic bariatric surgery patients with atelectasis: a randomized clinical trial

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Abstract

Background: Obesity has been identified as an independent risk factor for postoperative respiratory complications in several studies. In the pediatric and newborn populations, high-flow nasal oxygen ($HFNO_2$) therapy was initially demonstrated to be an effective treatment for acute respiratory failure. It becomes increasingly popular as a therapy for adult patients, with a growing range of clinical applications.

Results: One hundred ten patients were admitted to the ICU for postoperative care after laparoscopic sleeve gastrectomy. They were examined and randomized equally into two groups: group A ($HFNO_2$ therapy group) who received high-flow nasal oxygen therapy, group B (VMO_2 therapy group) who received venturi mask oxygen therapy. The partial pressure of oxygen in arterial blood (PaO_2), partial pressure of oxygen/fraction of inspired oxygen (PaO_2/FiO_2), respiratory rate, and length of ICU stay were recorded. The partial pressure of oxygen in the arterial blood (PaO_2) was 131.764 (95% CI 124.562–138.965) in the $HFNO_2$ group versus 106.767 (95% CI 99.565–113.968) in the VMO_2 group, partial pressure of oxygen/fraction of inspired oxygen (PaO_2/FiO_2) was 321.81 (95% CI 307.486–336.153) in the $HFNO_2$ group versus 276.767 (95% CI 262.433–291.100) in the VMO_2 group, and respiratory rate was 20.778 (95% CI 20.172–21.385) in the $HFNO_2$ group versus 24.047 (95% CI 23.441–24.654) in the VMO_2 group, while the length of ICU stay was the $HFNO_2$ group ($1.09 \pm .29$ days) and ($1.00 \pm .000$ day) in the VMO_2 group.

Conclusions: In conclusion, our study has shown that high-flow nasal oxygen therapy in postoperative laparoscopic sleeve gastrectomy patients with atelectasis-maintained oxygenation represented as PaO_2 and PaO_2/FiO_2 higher than the venturi mask and significantly decreased the respiratory rate but did not decrease the length of ICU stay when compared to venturi mask oxygen therapy.

Trial registration: Clinical trial registered with http://www.pactr.org (PACTR202108492295773).

Keywords: High-flow nasal oxygen therapy, Venturi mask, Bariatric surgery, Atelectasis

Background

Obesity is expressed as body mass index (BMI) which is the weight in kilograms divided by the height in square meters (kg/m^2) of more than 30. Obesity is associated with multiple comorbidities; one should pay attention to

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respiratory complications. It affects lung volumes causing restrictive pattern and decreases the functional residual capacity (FRC) to the point that is less than the closing volume resulting in atelectasis and hypoxemia. Obesity also increase the minute ventilation and hence work of breathing, decreases lung compliance, and increases airway resistance. It can result in obstructive sleep apnea (OSA) (Hines and Marschall 2018).

Obesity combined with postoperative respiratory muscle dysfunction may lead to respiratory failure. As a result, obesity is associated with a higher risk of postoperative hypoxemia (Stéphan et al. 2017).

Baltieri et al. (2016) reported a 37% prevalence of atelectasis in obese patients after bariatric surgery in a retrospective observational study. Respiratory complications, on the other hand, are not uncommon in the general surgical population and have been demonstrated to lengthen hospital stays and increase death (Fulton et al. 2018).

High-flow nasal oxygen ($HFNO_2$) therapy provides warmed humidified oxygen and low-level, flow-dependent positive airways pressure, and may be more tolerable than the continuous positive airway pressure (CPAP) or non-invasive ventilation; also, $HFNO_2$ improves washout of nasopharyngeal dead space, resulting in improved oxygenation. In giving prophylactic support to preterm newborns after extubation, $HFNO_2$ has been demonstrated to be both safe and non-inferior to standard CPAP (Zochios et al. 2018).

Aim of the study

The aim of this study is to compare the clinical outcome of treating postoperative laparoscopic sleeve gastrectomy surgery patients having atelectasis by using high-flow nasal oxygen therapy versus Venturi mask oxygen therapy.

Methods

After the approval of our institutional ethics committee, number FMASU M D 239/2019 and FMASU M D 239a/2019/2020, this prospective randomized, controlled, unblinded, single-center clinical trial was conducted over 110 patients (55 patients in each group) for 18 months from December 2019 to June 2021. Written informed consent was obtained from the patients or the first kin relative. The study protocol was explained to the patients before taking their informed consent.

Inclusion criteria

All patients had BMI above 40 kg/m^2 from both genders, aged 18–60 years old, with preoperative Physical Status ASA III, underwent laparoscopic sleeve gastrectomy who had postoperative atelectasis confirmed clinically, by chest X-ray (CXR) and lung ultrasound in the ICU. All patients were fully conscious upon ICU admission.

Exclusion criteria

Patients were excluded due to refusal of the intervention or participation in the study, age below 18 years old and above 60 years old, pregnancy or lactation, psychiatric illness, or known comorbidities such as chronic pulmonary diseases and cardiac diseases.

All patients were admitted to the ICU for postoperative care and were randomized using a randomization table created by a computer software program, allocated by the holder of the sequence who was situated off-site and assigned in a 1:1 ratio to one of the following two groups:

- Group A: $HFNO_2$ therapy group: patients who were randomized to high-flow nasal oxygen therapy.
- Group B: VMO_2 therapy group: patients who were randomized to venturi mask oxygen therapy.

In the operating theater, all patients were premedicated with intravenous (IV) 8 mg ondansetron and 8 mg dexamethasone. Standard monitors were applied, an ECG, pulse oximeter, non-invasive arterial blood pressure monitor, and the arterial line was inserted. Preoxygenation was carried out for 3 min by means of a face mask with 100% oxygen. Anesthesia was classically induced by IV fentanyl 1–2 μg/kg, propofol 2 mg/kg, and atracurium 0.5 mg/kg. After endotracheal intubation, capnography was applied. The lungs were ventilated with a tidal volume of 6–8 ml/kg, FiO_2 0.6, and the respiratory rate was adjusted to maintain $ETCO_2$ between 35 and 40 mmHg. Maintenance was done with 1.5 MAC isoflurane and top-up doses of atracurium every 20 min. At the end of the surgery, the muscle relaxant was reversed and all patients were extubated and sent to the intensive care unit (ICU). All patients received 5 mg IV nalbuphine for analgesia when the pain was present (postoperative pain was assessed using a visual analog scale (VAS)) donated by VAS 4–10.

Upon ICU admission, medical history and examination of all patients were done; standard monitors were attached including continuous electrocardiogram, non-invasive blood pressure, and pulse oximeter; the arterial line was inserted in the operating room and was used for sampling (Vygon Leadercath Arterial PE - UK); arterial blood gas was obtained, CXR (13) (Parke et al. 2014); and lung ultrasound (15, Table 1) (Lee 2016, Mongodi et al. 2017) was done for assessment of atelectasis. Patients were monitored at least every 1h (for monitoring but not all readings were analyzed).

In the $HFNO_2$ group, the $HFNO_2$ cannula (AIRcon gen Respiratory Humidifier WILAmed, WILAmed high-flow

Table 1 Lung ultrasound score calculation

Score 0—normal aeration	A lines—max 2 B lines
Score 1—moderate loss of aeration	≥ 3 well-spaced B lines
Score 2—severe loss of aeration	Coalescent B lines
Score 3—complete loss of aeration	Tissue-like pattern

AIR/O_2 blender with flowmeter and Oxi. Plus nasal high flow kit) was applied at a flow of 30 L/min at FiO_2 of 0.6 at a temperature of 36 °C. Flow and FiO_2 were adjusted according to the attached $HFNO_2$ therapy Algorithm, Fig. 1, Table 2. Weaning was also be adjusted according to it. For the VMO_2 group, the venturi mask with FiO_2 0.6 was applied. The FiO_2 was adjusted according to the attached venturi mask oxygen therapy algorithm, Fig. 2.

Data collection, measurements, and outcome

Upon ICU admission age, weight, BMI, sex, and duration of surgery were recorded. During ICU stay, the respiratory rate was recorded on admission, 1, 2, 3, 4, 8, 12, 16, 20, and 24 h, and ABGs and PaO_2/FiO_2 were recorded on admission, 2, 4, 8, 12, and 24 h. Chest X-ray (CXR) was done on admission assessed by Modified RAS score (13) (Parke et al. 2014). Lung ultrasound (Mindray M5 Diagnostic Ultrasound System (China)) was done on admission (using both 3C5s and L14-6s probes) as well assessed by lung U/S score for regional atelectasis (15, Table 1) (Mongodi et al. 2017). The primary outcome of this study was to compare PaO_2/FiO_2 during 24 h of oxygen therapy in both groups, and the secondary outcome was to compare the respiratory rate during 24 h and the length of ICU stay.

Statistical method

Data were collected, coded, tabulated, and then analyzed using the SPSS software package (SPSS for Windows®, Version 16.0. Chicago, SPSS Inc.). Numerical variables were presented as mean (standard deviation), and categorical variables were presented as frequency (%). Between-group comparisons were done using unpaired *t* test and Fisher's exact test, for numerical variables and categorical variables, respectively. Repeated-measured variables were analyzed using repeated-measures ANOVA. Sphericity assumption of repeated-measures ANOVA was tested using Mauchly's test of sphericity. A greenhouse-Geisser correction was applied whenever a lack of sphericity was evident. Error bars represent a 95% confidence interval. Any difference with a *p*-value < 0.05 was considered statistically significant.

Sample size

The sample size was calculated using the STATA program, setting the type-1 error (α) at 0.05 and the power (1-β) at 0.8. The result from a previous study (Testa et al. 2014) showed that the mean PaO_2/FiO_2 was 140±90 among conventional oxygen therapy compared to 190±100 among the $HFNO_2$ group. Calculation according to these values produced a minimal sample size of 52 cases per group approximated to 55 per group (total 110).

Results

Between December 2019 and June 2021, 122 patients underwent laparoscopic sleeve gastrectomy surgery with successful extubation and 12 were excluded as shown in the CONSORT flow chart (Fig. 3 and Table 3).

PaO_2 was found to be significantly higher 131.764 (95% CI 124.562–138.965) in the $HFNO_2$ group versus 106.767 (95% CI 99.565–113.968) in the VMO_2 group (*p*-value < 0.001). PaO_2/FiO_2 was found to be significantly higher 321.81 (95% CI 307.486–336.153) in the $HFNO_2$ group versus 276.767 (95% CI 262.433–291.100) in the VMO_2 group (*p*-value < 0.001). The PaO_2/FiO_2 was maintained in both groups till the 8 h reading. That was followed by a comparable gradual increase in PaO_2/FiO_2 in both groups (p-value > 0.05), but higher in the $HFNO_2$ group than in the VMO_2 group (*p*-value < 0.05) as shown in Fig. 4 and Table 4.

The respiratory rate was found to be significantly lower 20.778 (95% CI 20.172–21.385) in the $HFNO_2$ group versus 24.047 (95% CI 23.441–24.654) in the VMO_2 group, noted from the first hour (*p*-value < 0.001). That was followed by a continuous drop till 12 h after initiation. Then, the respiratory rate was maintained till the end of the study in both groups as shown in Fig. 5 and Table 5.

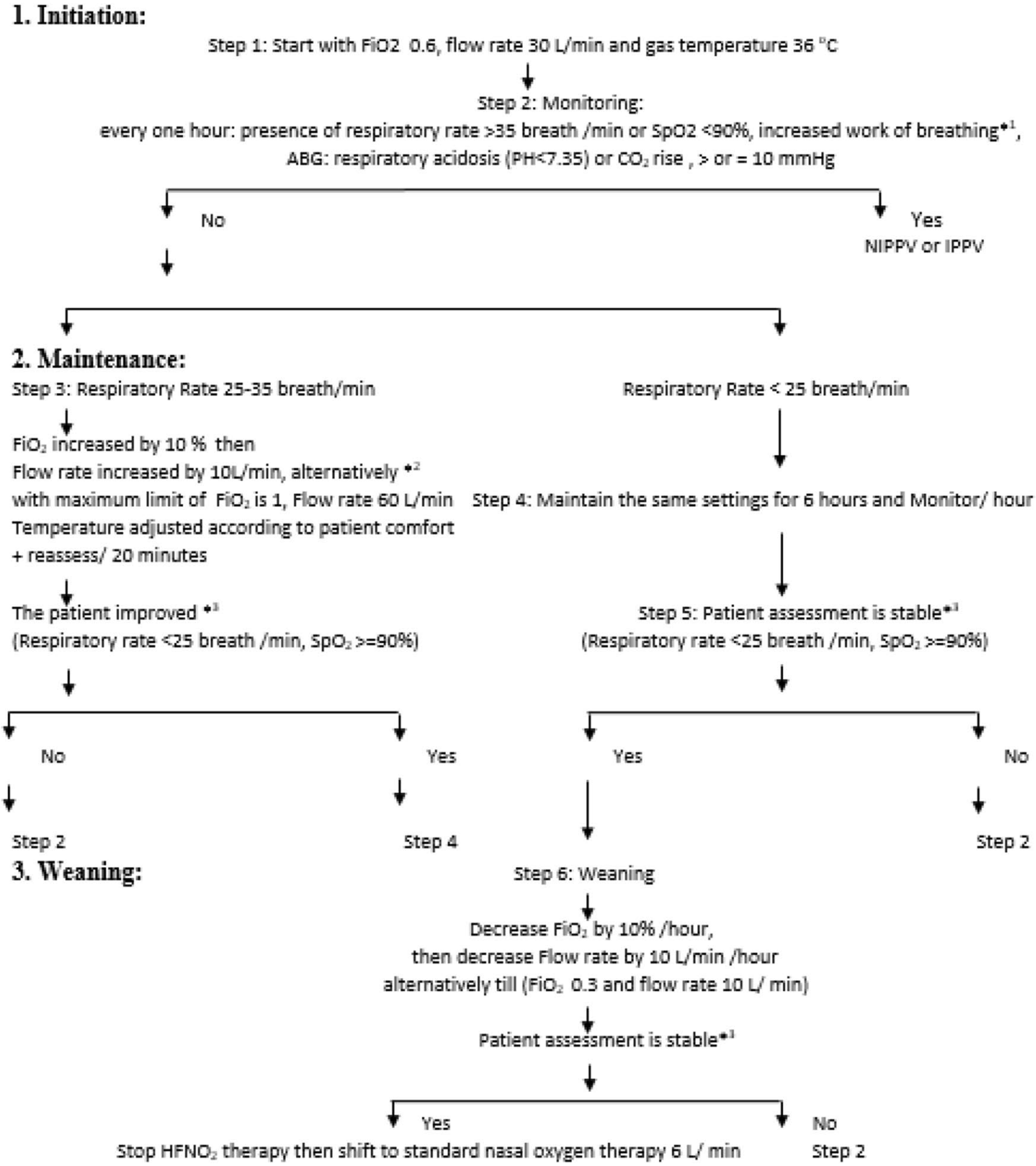
The length of the ICU stay was 1.09 ± .29 days in the $HFNO_2$ group when compared to 1.00 ± .000 day in the VMO_2 group (*p*-value 0.002), but this difference is about 2 h and 10 min as shown in Table 5.

Discussion

In our study, postoperative laparoscopic sleeve gastrectomy surgery patients with confirmed atelectasis by chest auscultation, mRAS score, and lung ultrasound examination (lung US score) were randomly assigned

(See figure on next page.)

Fig. 1 High-flow nasal oxygen therapy algorithm. *1: Thoraco-abdominal asynchrony and/or persistent auxiliary muscle use. *2: The table shows escalation and de-escalation of oxygen in the $HFNO_2$ group (Table 2). *3: Respiratory rate <25 breath/min or SpO_2 ≥90%, no increased work of breathing. ABG, no respiratory acidosis (PH>7.35), no CO_2 rise for > or = 10 mmHg; $HFNO_2$, high-flow oxygen therapy; VMO_2, venturi mask oxygen therapy; NIPPV, non-invasive positive pressure ventilation; IPPV, invasive positive pressure ventilation; SpO_2, oxygen saturation



*1: Thoraco-abdominal asynchrony and/or persistent auxiliary muscle use.

*2:

FiO_2	0.6	0.7	0.7	0.8	0.8	0.9	0.9	1
Flow Rate (L/min)	30	30	40	40	50	50	60	60

*3 respiratory rate <25 breath /min or SpO2 >=90%, no increased work of breathing, ABG: no respiratory acidosis (PH>7.35), no CO_2 rise for > or = 10 mmHg.

$HFNO_2$: High Flow Oxygen Therapy

VMO_2: Venturi Mask Oxygen Therapy

NIPPV: Non invasive positive pressure ventilation

IPPV: Invasive positive pressure ventilation

SpO_2: Oxygen saturation

Fig. 1 (See legend on previous page.)

Table 2 The table shows escalation and de-escalation of oxygen in the $HFNO_2$ group

FiO_2	0.6	0.7	0.7	0.8	0.8	0.9	0.9	1
Flow rate (L/min)	30	30	40	40	50	50	60	60

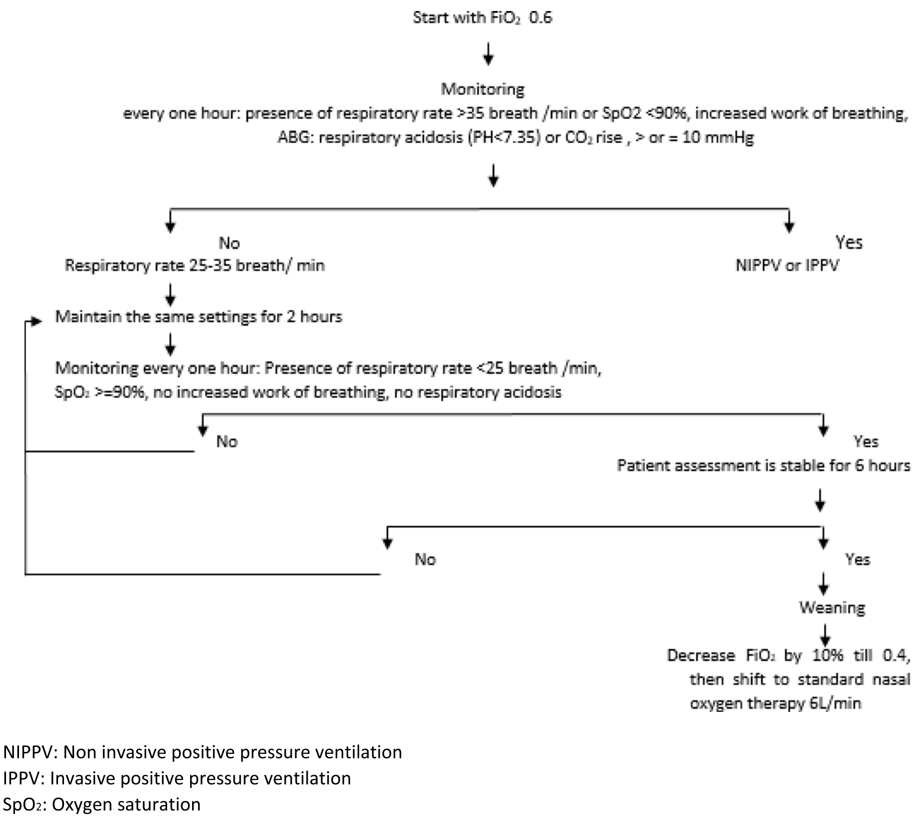


Fig. 2 Venturi mask oxygen therapy algorithm. NIPPV, non-invasive positive pressure ventilation; IPPV, invasive positive pressure ventilation; SpO_2, oxygen saturation

to either the $HFNO_2$ group or VMO_2 group. The study showed that $HFNO_2$ resulted in a significantly higher oxygenation represented by PaO_2, PaO_2/FiO_2, and effectively decrease the respiratory rate.

Comparing both groups across the first 24 h postoperatively, they showed a statistically significant increase in PaO_2/FiO_2 along the 2-h, 4-h, and 24-h values with p-value < 0.05 as shown in Table 4 and Fig. 4. They also showed a statistically significant decrease in respiratory rate along the first 12 h with a p-value < 0.05 as shown in Table 5 and Fig. 5.

Maurizio et al. study showed that oxygenation for the same set FiO_2 was improved by $HFNO_2$ therapy when compared to the venturi mask in patients with acute respiratory failure in the post-extubation period, and PaO_2/FiO_2 was 287.2 ± 74.3 versus 247.4 ± 80.6 mmHg (p-value 0.03). In addition to that, the $HFNO_2$ therapy decreased the respiratory rate with a mean difference of 4 ± 1 breaths/minute (Maurizio et al. 2014).

Yu et al. underwent a multicenter randomized interventional trial showed that the application of $HFNO_2$ therapy to patients who underwent thoracoscopic lobectomy after the extubation could decrease the risk of hypoxemia (29.62% with conventional oxygen therapy, 12.51% with $HFNO_2$) and reintubation as well as improve oxygenation represented by PaO_2, PaO_2/FiO_2, and SaO_2/FiO_2 when compared to conventional oxygen (p-value < 0.05) (Yu et al. 2017).

Testa et al. found that the $HFNO_2$ therapy was not able to affect the partial pressure of carbon dioxide in the arterial blood ($PaCO_2$) in the pediatric population following open-heart surgeries. $PaCO_2$ was used as a primary

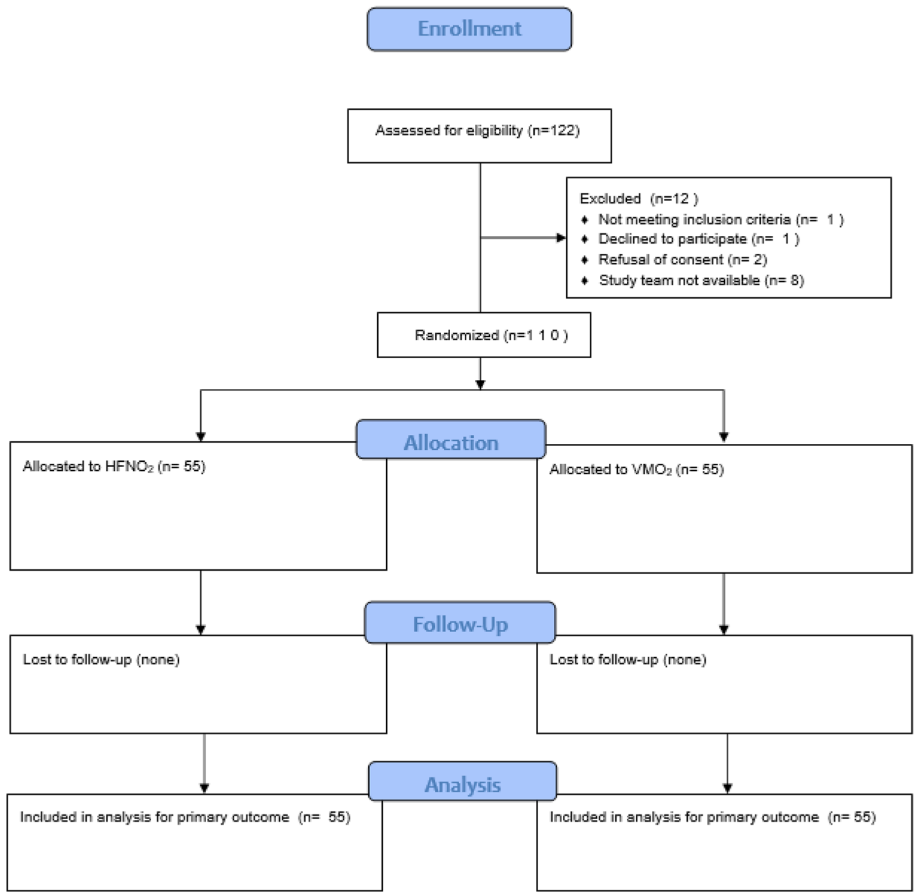


Fig. 3 Flow chart for patient enrollment

Table 3 Baseline characteristics of the patients participating in the study presented as mean ± SD or frequency (%) as appropriate

Patients data	$HFNO_2$ group (mean ± SD) (no 55)	VMO_2 group (mean ± SD) (no 55)	*p*-value
Age (years)	42.33 ± 10.23	33.96 ± 7.32	< 0.001*
Sex (%)			
Female	72.7%	61.8%	*0.310*
Weight (kg)	145.38 ± 26.01	142.13 ± 14.08	0.417
BMI (kg/m^2)	53.11 ± 6.99	51.82 ± 5.33	0.278
Duration of surgery (min)	175.64 ± 48.81	175.91 ± 61.75	0.980
LUS score	7.76 ± 4.172	6.84 ± 2.658	0.168
mRAS score	7.76 ± 2.099	7.65 ± 1.766	0.769
PaO_2 at the end of surgery	75.31 ± 12.963	72.35 ± 6.269	0.130
PaO_2/FiO_2 at the end of surgery	358.964 ± 62.669	346.551 ± 29.830	0.188

*p-value < 0.05 means statistically significant and donating statistically significant means

endpoint as the patients had both cyanotic and cyanotic heart diseases; however, $HFNO_2$ was found to improve PaO_2 levels in both categories, and PaO_2 was significantly higher in $HFNO_2$ (p-value 0.01). PaO_2/FiO_2 was found to be also statistically significant (p-value < 0.001) (Testa et al. 2014).

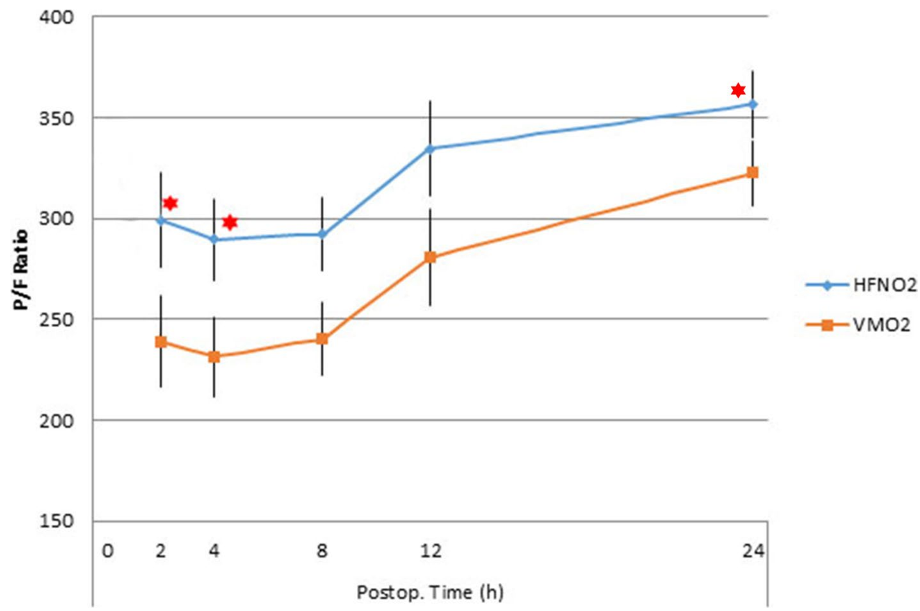


Fig. 4 PaO_2/FiO_2 throughout the study time is significantly higher in the $HFNO_2$ group. The red marks mean that the *p*-value was found to be significant

Table 4 PaO_2/FiO_2 is significantly higher in the $HFNO_2$ group

PaO_2/FiO_2 *(Mean ± SD)*	$HFNO_2$ group	VMO_2 group	*p*-value
At 2 h	298.66 ± 88.51	239.04 ± 52.73	< 0.001
At 4 h	289.64 ± 76.58	231.55 ± 48.88	< 0.001
At 8 h	292.16 ± 69.17	240.17 ± 43.63	0.063
At 12 h	334.55 ± 89.56	280.68 ± 40.23	0.331
At 24 h	356.58 ± 61.63	322.59 ± 21.39	0.047

According to Corley's study, using the $HFNO_2$ therapy resulted in a decrease in respiratory rate by 3.4 breaths/min (95% CI 1.7–5.2) and improved oxygenation. Thus, $HFNO_2$ therapy may be a useful treatment option for patients experiencing respiratory dysfunction post-cardiac surgery, especially those who cannot tolerate non-invasive ventilation and those with BMI $\geq$ 30 kg/m^2 (Corley et al. 2011).

In contradiction to the previous studies, in patients with a BMI $\geq$ 30 kg/m^2, direct extubation onto $HFNO_2$ therapy following cardiac surgery did not improve atelectasis, oxygenation (PaO_2/FiO_2 in the 24 h post-extubation with a mean of 227.9 for $HFNO_2$ and 253.3 for the control group with *p*-value 0.08), and respiratory rate (mean was 16.7 in control the group and 17.24 in $HFNO_2$ with a difference of 0.54 and *p*-value 0.17) when compared to standard oxygen therapy, or reduce the need for escalation of respiratory support, a result found by Corley et al. They suggested further research clarifying the role of $HFNO_2$ therapy (Corley et al. 2015).

As regards the length of the ICU stay in our study, there was the significantly longer length of ICU stay (1.09 ± .29 days) in the $HFNO_2$ group when compared to (1.00 ± .000 day) in the VMO_2 group, yet it is clinically insignificant as the increased duration in $HFNO_2$ group can be attributed to the longer weaning of high-flow nasal oxygen therapy applied in our study protocol.

According to Xiang et al., when compared to conventional oxygen therapy, $HFNO_2$ therapy reduced the rate of intubation or non-invasive ventilation for respiratory failure in postoperative patients at high risk of pulmonary complications, but did not reduce the length of stay in the hospital or ICU, the rate of oxygen requirement after discontinuation, or hypoxemia. Although $HFNO_2$ does not reduce mortality, there was little harm associated with its usage, suggesting that it could be a better alternative to conventional oxygen therapy in postoperative patients at high risk of pulmonary complications. Future studies should concentrate on determining which subgroups of postoperative patients are most likely to benefit from $HFNO_2$ therapy (Xiang et al. 2021).

Study limitations

Our study has some limitations, it has a relatively short duration and was limited to 24 h. $PaCO_2$ was not analyzed and the 2-h difference in the ICU stay may not be attributable to the interventions being practiced, but due to logistic issues or the longer weaning hours of the $HFNO_2$ as mentioned in its algorism, the pain assessment was not analyzed

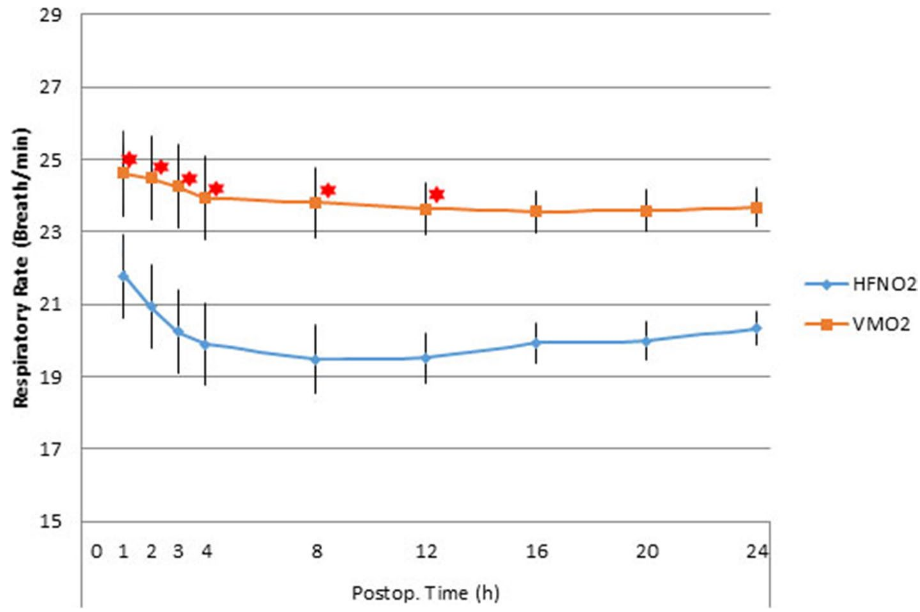


Fig. 5 The respiratory rate is significantly lower in the $HFNO_2$ group. The ICU stay is statistically signi. The red marks mean that the *p*-value was found to be significant

Table 5 The respiratory rate is significantly lower in the $HFNO_2$ group. The ICU stay is statistically significantly

Respiratory rate (*mean* ± *SD*)	$HFNO_2$ group	VMO_2 group	*p*-value
At 1 h	21.78 ± 4.40	24.62 ± 1.50	< 0.001
At 2 h	20.93 ± 4.37	24.49 ± 1.50	< 0.001
At 3 h	20.24 ± 4.34	24.25 ± 1.14	< 0.001
At 4 h	19.89 ± 4.32	23.93 ± 1.27	< 0.001
At 8 h	19.47 ± 3.57	23.80 ± 1.09	< 0.001
At 12 h	19.51 ± 2.61	23.64 ± 0.93	0.001
At 16 h	19.93 ± 2.08	23.56 ± 1.15	0.190
At 20 h	19.98 ± 1.99	23.58 ± 1.49	0.293
At 24 h	20.33 ± 1.78	23.67 ± 1.76	0.816
ICU stay (days)	1.09 ± .29	1.00 ± .000	0.002

and patient satisfaction was not studied, data about complications was not collected, follow-up with CXR and lung U/S were not recorded and analyzed, and hospital stay was not studied; these data can be considered in future studies.

Conclusions

In conclusion, our study has shown that high-flow nasal oxygen therapy in postoperative laparoscopic sleeve gastrectomy patients with atelectasis-maintained oxygenation represented as PaO_2 and PaO_2/FiO_2 higher than the venturi mask and significantly decreased the respiratory rate but did not decrease the length of the ICU stay when compared to venturi mask oxygen therapy.

Appendix 1

Modified RAS score

The modified radiological atelectasis score (m-RAS):

Including the lingua, each lobe is scored 0–3 as shown below. The scores of the six lobes are then summed to give a (0–18) score.

0=Normal
1=Plate or minor infiltrate
2=Moderate atelectasis
3=Total atelectasis (Parke et al. 2014)

Appendix 2

Lung ultrasound score

To assess the lateral chest wall, patients were examined in a semi-recumbent position with arms abducted. The anterior and posterior axillary lines divide each hemi-thorax into anterior, lateral, and posterior areas. The regions were further divided into upper and lower sections, resulting in a total of 6 regions in each hemi-thorax, allowing for the evaluation of the dependent lungs (Lee 2016)

The probe was applied for both longitudinal and transverse views, and the score was calculated as shown in Table 2 with a total of 36.

Abbreviations
$HFNO_2$: High-flow nasal oxygen; VMO_2: Venturi mask oxygen; PaO_2: Partial pressure of oxygen in arterial blood; PaO_2/FiO_2: Partial pressure of oxygen/fraction of inspired oxygen; ICU: Intensive care unit; BMI: Body mass index; FRC: Functional residual capacity; CPAP: Continuous positive airway pressure; ASA: American Society of Anesthesiologists; CXR: Chest X-ray; mRAS: Modified radiological atelectasis; Lung U/S: Lung ultrasound; $PaCO_2$: Partial pressure of carbon dioxide in arterial blood; OSA: Obstructive sleep apnea.

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Not applicable.

Authors' contributions
MA designed the study, revised literature, followed the patients and critically reviewed the manuscript. GA designed the study, analyse the data, wrote and critically revised the manuscript. MH and AF revised literature followed the patients. AA collected the data, performed the analysis and wrote the manuscript. All authors approved the final version of the manuscript.

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Availability of data and materials
The datasets generated and/or analyzed during the current study are not publicly available due [Publishing the clinical data about any study conducted in our hospitals and approved by the institutional ethical committee is against the policy of the Faculty of medicine, Ain Shams university unless there is a reasonable request] but are available from the corresponding author on reasonable request.

Declarations

Ethics approval and consent to participate
This study was approved by ethical committee of Ain Shams University with approval number (FMASU M D 239 / 2019 and FMASU M D 239a /2019 / 2020). Written informed consent was obtained from the patients or the first kin relative. This clinical trial is retrospectively registered by PACTR, PACTR202108492295773 Registered 26 August 2021 - http://www.pactr.org/PACTR202108492295773.

Consent for publication
Not applicable.

Competing interests
The authors declare that they have no competing interests.

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