Comparison of preoxygenation efficiency measured by the oxygen reserve index between high-flow nasal oxygenation and facemask ventilation: A randomized controlled trial

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Abstract

Background

The novel high-flow nasal oxygenation is gaining popularity for preoxygenation. The oxygen reserve index (ORI), which is a non-invasive and innovative modality that reflects the arterial oxygen content, are recently introduced in general anesthesia. In our study, we compared the preoxygenation efficiency of high-flow nasal oxygenation and facemask ventilation using the ORI in adult patients undergoing general anesthetic induction for non-emergent surgery.

Methods

This single-center, two-group, randomized controlled trial included 197 patients aged ≥20 years who underwent orotracheal intubation for general anesthesia for elective surgery. The patients were randomly allocated to receive preoxygenation via facemask ventilation or high-flow nasal oxygenation. The ORI was monitored continuously during anesthetic induction period until the endotracheal intubation was completed, and compared between the two groups. The primary outcome was the highest ORI value achieved by oxygenation. The secondary outcome was the time required to reach the highest ORI observed during the induction of anesthesia.

Results

The ORI increased during preoxygenation in all patients and tended to decrease from the injection of the neuromuscular blockers to the completion of intubation. At 1 minute of preoxygenation, the ORI was significantly higher in the high-flow nasal oxygenation group (0.34 ± 0.33) than in the facemask ventilation group (0.21 ± 0.28; P = 0.003). The highest ORI was not significantly different between the two groups (0.68 ± 0.25 in the high-flow nasal oxygenation group vs. 0.70 ± 0.28 in the facemask ventilation group; P = 0.505). The time required to reach the highest ORI value was not significantly different between the two groups (3.1 ± 2.2 minutes in the high-flow nasal oxygenation group and 3.6 ± 2.2 minutes in the facemask ventilation group; P = 0.113).

Conclusions

High-flow nasal oxygenation results in an ORI-measured oxygenation state similar to that provided by facemask ventilation during the general anesthesia induction. We conclude that high-flow nasal oxygenation is a feasible and alternative preoxygenation technique for facemask ventilation.

Trial Registration

This study was registered at clinicaltrials.gov (registration number: NCT04291339, registration date: 02/03/2020)

Background

Endotracheal intubation requires an anesthetic induction process that results in loss of consciousness and neuromuscular block. This process includes hypoventilation and apnoea, resulting in a risk of hypoxia, which further exacerbates in case of difficult endotracheal intubation[1]. Therefore, careful preoxygenation before anesthesia induction is recommended when a patient is breathing spontaneously[2].

The conventional preoxygenation method includes the use of a facemask, which allows patients to spontaneously breathe oxygen[2]. The Optiflow device (Fisher & Paykel Healthcare, Auckland, New Zealand) supplies heated and humidified oxygen through a nasal cannula. This high-flow nasal oxygenation (HFNO) method is gaining popularity owing to its ease of use and potential for hands-free anesthesia induction[3].

In previous studies, HFNO in patients undergoing anesthesia induction for emergency surgery resulted in similar arterial oxygen partial pressure (PaO_2), oxygen saturation (SpO_2), and desaturation incidence compared to standard facemask oxygenation immediately after endotracheal intubation, suggesting that HFNO is an effective preoxygenation method[4–6]. However, these studies were either conducted with rapid sequence induction, without facemask ventilation being performed during the facemask oxygenation, or with endotracheal intubation being conducted 1-2 minutes after the administration of hypnotics and neuromuscular blocking drugs. Therefore, these data do not reflect the general anesthetic induction process of patients undergoing non-emergent surgery.

A previous study on non-rapid sequence induction demonstrated that the post-endotracheal intubation PaO_2 was significantly lower with HFNO than with facemask oxygenation[7]. Another study reported no significant difference in the incidence of SpO_2 < 92% during anesthesia induction[8]. Therefore, the efficacy of HFNO for non-rapid sequence induction is controversial. Moreover, prior studies did not implement manoeuvres such as jaw thrust, which are recommended for maintaining upper airway patency with HFNO.

The oxygen reserve index (ORI^{TM}, Masimo Corp., Irvine, CA) continuously monitors the amount of oxygen non-invasively, similar to what is done for SpO_2. The ORI reflects a PaO_2 range of 80–200 mmHg as a value between 0 and 1[9]. The ORI enables the control of preoxygenation and provides an early warning of hyperoxia or desaturation[10]. Therefore, the ORI was used in this study to investigate the preoxygenation efficiency of HFNO and facemask ventilation (FMV) during anesthesia induction.

We aimed to determine the preoxygenation efficiency of HFNO in non-rapid sequence induction. In this randomized controlled study, we hypothesized that HFNO would have higher preoxygenation efficiency than FMV in adult patients undergoing general anesthetic induction for non-emergent surgery. The ORI was monitored to evaluate oxygenation status during the anesthesia induction period, and the highest ORI values obtained using HFNO and FMV were compared as the primary outcome.

Methods

Patients

This prospective, single-centre, randomized controlled trial was performed at Severance Hospital, Yonsei University Health System, Seoul, South Korea.This study was approved by the institutional review board of Severance Hospital, Seoul, South Korea (#4-2019-1336). Written informed consent was obtained from all individuals participating in the trial. The trial was registered prior to patient enrolment at clinicaltrials.gov (Registration number: NCT04291339, Principal investigator: Hyun Joo Kim, Date of registration: March 2, 2020). The study was performed in accordance with the Declaration of Helsinki and Good Clinical Practice guidelines.

Inclusion and exclusion criteria

Patients aged ≥20 years who were scheduled to undergo orotracheal intubation for general anesthesia from November 2020 to January 2021 were enrolled in this study. Patients with cranial fractures or craniofacial malformations that prevented oxygen delivery through the nostrils, those who could not cooperate due to impaired consciousness, and those who could not fast prior to surgery or were at risk of aspiration of gastric contents due to gastroesophageal disease were excluded from the study. Patients who required awake intubation were also excluded.

Randomisation

A computer-generated randomisation table (available at https://www.randomizer.org/form.htm) was used to randomly assign patients to the HFNO group or the FMV group at a 1:1 ratio. Due to differences in the appearance of the preoxygenation devices, the patients and anesthesiologists could not be blinded to group allocation once the induction process was initiated. Prior to surgery, group allocations were concealed in sequentially numbered, sealed, opaque envelopes. Randomisation was performed after enrolment but before the start of the study protocol by Hyun Joo Kim.

Anesthetic management and measurements

In the operating room, patients were placed in a supine position with a pillow behind their head. An electrocardiogram was obtained, and blood pressure, oxygen saturation, and brain function (SedLine®, Masimo Corp., Irvine, CA, USA) were monitored non-invasively. Each patient's pulse oximetry was measured using the RD Rainbow SET®-2 Neo sensor (Massimo Corp.) attached to the patient's finger and covered with a light-shielding black bag. The ORI was monitored using the Rainbow SET Radial-7 Pulse CO-Oximeter (software version 2.1.3.5, Masimo Corp.).

Prior to initiating anesthesia induction, an airway assessment was performed, including assessments for obstructive sleep apnoea, snoring while sleeping, interincisor distance, hyomental distance, and head and neck movement. The modified Mallampati and upper lip bite test scores were also determined.

In the HFNO group, the Optiflow (Fisher & Paykel Healthcare, Auckland, New Zealand) nasal cannula was placed on the patient's nares. Preoxygenation was performed for 3 minutes at 40 L/min at an FiO_2 of 1.0.

During the preoxygenation period, the patient was asked to rate whether they were comfortable with the oxygen administration method using a four-level scale (comfortable, acceptable, uncomfortable, intolerable). If the patient complained of nasal discomfort, the oxygen flow rate was reduced in increments of 5 L/minto a minimum of 30 L/min.

After preoxygenation, anesthesia induction was accomplished intravenously using propofol (1–2 mg/kg). Neuromuscular blockade was induced using intravenous rocuronium (0.6 mg/kg) after the patient lost consciousness in both groups. Oxygen was administered via nasal cannula at 70 L/min for 3 minutes, and the patient's jaw was lifted using the operator's hands to maintain upper airway patency. At 3 minutes after rocuronium administration, endotracheal intubation was attempted using a videolaryngoscope and an endotracheal tube. The high-flow nasal cannula was used to continuously supply oxygen at 70 L/min during intubation attempts until the endotracheal tube was placed.

In the FMV group, the facemask was placed in contact with the patient's nose and mouth, and oxygen was supplied at 10 L/min at an FiO_2 of 1.0 for 3 minutes. During preoxygenation, the patient's comfort level was assessed using the same scale as that used in the HFNO group. If discomfort was reported, the oxygen flow rate was lowered in increments of 1 L/min to a minimum flow rate of 6 L/min. When the patient lost consciousness, FMV was continued for 3 minutes using the volume-controlled mode of the mechanical ventilator with an oxygen flow rate of 2 L/min, tidal volume of 8 mL/kg, respiratory rate of 15 breaths per minute, peak end-expiratory pressure of 0 cmH_2O, and FiO_2 of 1.0. A two-handed jaw thrust manoeuvre was performed to maintain upper airway patency. Endotracheal intubation was performed using a videolaryngoscope at 3 minutes after the administration of rocuronium. The facemask was removed from the patient's face, and oxygenation was discontinued during intubation attempts.

The ORI was continuously monitored until the endotracheal intubation was completed. ORI and SpO_2 values were collected at 10 time points: at baseline (before preoxygenation), at 1, 2, and 3 minutes of preoxygenation, during the propofol and rocuronium injections, at 1 and 2 minutes after the rocuronium injection, and at the initiation and completion of intubation.

Patient characteristics such as age, sex, height, weight, and the American Society of Anesthesiologists physical class were recorded. The number of intubation attempts, intubation time, and Cormack–Lehane grade were recorded. The primary outcome was the highest ORI value achieved by oxygenation. The secondary outcome was the time required to reach the highest ORI observed during the induction of anesthesia.

Sample size calculation

Data from previous studies were used to calculate the sample size[11]. The highest mean ORI value during anesthesia induction was estimated as 0.5 ± 0.11 (mean ± standard deviation), and a significant difference of 0.05 was assumed between the two groups. The estimated sample size was 76 patients per group with a power of 80% and type-1 error of 0.05. As this was a novel study to monitor the ORI throughout the anesthesia induction period, and because the ORI is a new parameter and the risks of data

collection failure, inter-individual variability, and patient dropout are high, the sample size was increased to 100 patients per group.

Statistical analysis

Continuous variables are reported as mean ± standard deviation, and categorical variables are reported as numbers (percentages). Continuous variables were analysed using Student's t-test or Mann–Whitney U test, as appropriate. Categorical variables were analysed using the chi-square test or Fisher's exact test. ORI and SpO_2 during the induction process were analysed using Student's t-test. All analyses were performed using R package version 4.1.0 statistical software (http://www.R-project.org, The R Foundation for Statistical Computing, Vienna, Austria). Statistical significance was defined as a two-sided P-value < 0.05.

Results

Among 218 patients scheduled for elective surgery under general anesthesia who required orotracheal intubation, 8 patients did not meet the inclusion criteria and 10 patients declined to participate in this study (Fig. 1). Three patients were excluded from the study due to technical problems regarding the recording of vital signs, including the oxygen reserve index. A total of 197 patients were included in the final analysis. Patients in the HFNO group had a greater mean height than those in the FMV group (P = 0.027), and there were significantly more males in the HFNO group (P = 0.017, Table 1).

Table 1. Characteristics of the patients in the two groups

		FMV (n=98)	HFNO (n=99)	P-value
Age (years)		51.5±15.6	48.7±17.4	0.248
Sex: male		49 (50%)	67 (68%)	0.017
Height (cm)		164.7±9.5	167.5±8.3	0.027
Weight (kg)		66.5±12.3	67.5±11.2	0.583
BMI (kg/m^2)		24.4±3.3	23.9±3.2	0.332
American Society of Anesthesiologists physical class	1	34 (35%)	49 (50%)	0.078
	2	48 (49%)	34 (34%)	
	3	16 (16%)	16 (16%)	
Obstructive sleep apnoea		3 (3%)	0 (0%)	0.241
Snoring		58 (59%)	55 (56%)	0.711
Modified Mallampati score	1	59 (60%)	60 (61%)	0.998
	2	31 (32%)	31 (31%)	
	3	8 (8%)	8 (8%)	
	4	0 (0%)	0 (0%)	
Interincisor distance (cm)		4.3±0.6	4.1±0.6	0.159
Hyomental distance (cm)		4.7±0.8	4.8±0.8	0.654
Head and neck movement	Normal	97 (99%)	98 (99%)	1.000
	Limited	1 (1%)	1 (1%)	
Upper lip bite test[a] score	I	96 (98%)	98 (99%)	0.993
	II	2 (2%)	1 (1%)	
	III	0 (0%)	0 (0%)	

Data are presented as mean ± standard deviation, or the number of patients (percentage).[a]Upper lip bite test was rated as class I if the lower incisors could bite the upper lip above the vermilion line, class II if the lower incisors could bite the upper lip below the vermilion line, and class III if the lower incisors could not bite the upper lip. FMV, facemask ventilation, HFNO, high-flow nasal oxygenation.

Patients in the HFNO group reported more discomfort than those in the FMV group (P < 0.001, Table 2). The oxygen flow rate was adjusted to 6 L/min in one patient in the FMV group and to 30–35 L/minin 23 patients in the HFNO group. All patients underwent successful preoxygenation with the adjusted gas flow rates.

Table 2. Level of comfort and intubation characteristics in the two groups

		FMV (n=98)	HFNO (n=99)	P-value
Level of comfort	Comfortable	95 (97%)	63 (64%)	<0.001
	Acceptable	1 (1%)	13 (13%)	
	Uncomfortable	1 (1%)	18 (18%)	
	Intolerable	1 (1%)	5 (5%)	
Number of intubation attempts	1	96 (98%)	99 (100%)	0.360
	≥ 2	2 (2%)	0 (0%)	
Cormack–Lehane grade	1	95 (97%)	97 (98%)	0.840
	2	2 (2%)	1 (1%)	
	3	1 (1%)	1 (1%)	
Intubation time (min)		1.2±0.9	1.2±0.8	0.702

Data are presented as mean ± standard deviation or the number of patients (percentage). FMV, facemask ventilation, HFNO, high-flow nasal oxygenation.

The ORI increased during preoxygenation in all patients (Fig. 2 and Table 3). The ORI at 1 minute of preoxygenation was significantly higher in the HFNO (0.34 ± 0.33) than in the FMV group (0.21 ± 0.28, P = 0.003) (Fig. 3). The ORI was not significantly different between the two groups at other points during the induction of anesthesia. At the completion of intubation, the ORI was 0 in 2.0% of patients in the HFNO group and in 6.1% of patients in the FMV group (P = 0.136). The highest ORI was not significantly different between the HFNO (0.68 ± 0.25) and FMV (0.70 ± 0.28, P = 0.505) groups, nor was the time required to reach the highest ORI (3.1 ± 2.2 minutes and 3.6 ± 2.2 minutes, respectively, P = 0.113).

Table 3. Changes in the oxygen reserve index during anesthetic induction in the two groups

Time points	FMV (n=98)	HFNO (n=99)	P-value
Baseline, before preoxygenation	0.00±0.00	0.00 ± 0.00	0.839
At 1 minute of preoxygenation	0.21±0.28	0.34 ± 0.33	0.003
At 2 minutes of preoxygenation	0.56±0.30	0.57 ± 0.29	0.840
At 3 minutes of preoxygenation	0.60±0.30	0.57 ± 0.29	0.553
Injection of propofol	0.60 ± 0.31	0.57 ± 0.28	0.438
Injection of rocuronium	0.63 ± 0.30	0.57 ± 0.27	0.179
At 1 minute after rocuronium injection	0.45 ± 0.24	0.47 ± 0.23	0.536
At 2 minutes after rocuronium injection	0.42 ± 0.23	0.42 ± 0.21	0.964
Start of intubation attempt	0.40 ± 0.21	0.38 ± 0.19	0.478
Completion of intubation	0.38 ± 0.21	0.38 ± 0.20	0.834

Data are presented as mean ± standard deviation. FMV, facemask ventilation, HFNO, high-flow nasal oxygenation.

The baseline mean SpO_2 was 97.9 ± 1.4% and 97.8 ± 1.5% in the HFNO and FMV groups, respectively (P = 0.517, Fig. 2), two patients had a baseline SpO_2 < 96%. After 3 minutes of preoxygenation, the mean SpO_2 was similar as 99.9 ± 0.4% and 99.9 ± 0.3% in the HFNO and FMV groups, respectively (P = 0.422). All patients had an SpO_2 > 98% after preoxygenation.

All patients underwent successful tracheal intubation. Two patients required more than one intubation attempt, including one patient with a loose tooth and another patient with a Cormack-Lehane grade of 3 who required additional acute-angled videolaryngoscope (AceScope, Acemedical Co., Korea followed by Glidescope®, Saturn Biomedical System Inc., Burnaby, BC, Canada).

Discussion

The present study revealed that the highest ORI during general anesthetic induction for elective surgery was not significantly different between patients receiving HFNO and FMV. Moreover, the time required to reach the highest ORI was not significantly different between the two groups.

The ORI reflects a wider range of PaO_2 values than the SpO_2[9]. Szmuk et al.[12]reported that the ORI decreased as the SpO_2 remained at 100% in 25 paediatric patients who experienced apnoea. When rapid sequence induction was performed for surgery in 16 adult patients, facemask preoxygenation increased the median ORI from 0 to 0.50[11]. Similarly, in our study, continuous changes in oxygenation status during entire anesthesia induction period could be successfully observed using ORI. During the 3 minutes

of preoxygenation, the ORI increased from 0 at baseline to various values such as 0.02–1.0, and this reflected an improvement of oxygen reserve.

In present study, there was no significant difference in the maximum ORI obtained by preoxygenation between the HFNO and FMV groups or in the time required to reach the maximum ORI. We suggest that HFNO can be an alternative and reliable preoxygenation technique for FMV in general anesthesia induction of elective surgery. Pillai et al. reported that HFNO at 60 L/min did not result in significantly different end-tidal O_2 than that achieved with facemask preoxygenation after 3 minutes, which is consistent with the present study results[13]. However, Hanouz et al. reported that HFNO at 60 L/min resulted in significantly lower end-tidal O_2 than facemask preoxygenation in 50 volunteers[14]. The conflicting results may be due to the fact that the previous study included healthy volunteers and measured the end-tidal O_2 only once immediately after preoxygenation. The current study was aimed at patients who underwent endotracheal intubation after induction of general anesthesia, and ORI was used to continuously monitor the oxygenation state throughout the induction of anesthesia. As a result, we found that the ORI at 1 minute was significantly higher in the HFNO group than in the FMV group, suggesting that HFNO might induce hyperoxia more rapidly. However, this initial difference was offset over time during 3 minutes of preoxygenation. More research using the ORI is necessary to determine whether the oxygenation reserve status can change when details of HFNO are applied differently.

We found that 23% of patients who underwent HFNO reported discomfort at a flow rate of 40 L/min. This is consistent with the findings of a previous study wherein 40% of patients reported discomfort when 60 L/min of HFNO was administered[13]. In another study, 21% of patients experienced discomfort at 50 L/min HFNO[7]. The flow rate used in this study was lower than that used in previous studies, nevertheless, discomfort was still reported. However, per another previous study, patients found HFNO more comfortable than facemask oxygenation[8], possibly because an oxygen flow rate as low as 30 L/min was used. In this study, no patients reported discomfort when the flow rate was reduced to 30 L/min, and an appropriate preoxygenation effect was obtained at this flow rate. Therefore, it is crucial to verify that the equipment is comfortable for the patient and to adjust the flow rate appropriately during HFNO.

While ORI increased during preoxygenation, ORI decreased after neuromuscular blocker injection until endotracheal intubation was completed. In the FMV group, although positive pressure ventilation was applied using a facemask, oxygenation status was found to decrease when ORI was observed. We estimate that the FMV has a limit to overcome the ventilation/perfusion mismatch caused by atelectasis after anesthesia induction and the decreased functional residual capacity due to muscle paralysis[15]. Whereas, HFNO achieved and maintained oxygenation status similar to that of the FMV by continuously injecting oxygen through the nasal cannula without positive pressure ventilation. These findings are consistent with the results of the previous study that HFNO did not cause significant differences in patient lung volume relative to positive-pressure ventilation, as measured via electrical impedance tomography[16].

During endotracheal intubation in the FMV group, the facemask had to be removed so as not to interfere with the placement of the videolaryngoscope. On the other hand, in the HFNO group, oxygen was continuously provided through the nasal cannula. Oxygen moves from the pharynx to the alveoli and from the alveoli to the bloodstream according to the difference in blood solubility of oxygen and carbon dioxide, and this apneic oxygenation occurs without diaphragm movement or lung expansion[17]. Because of the benefit of apneic oxygenation, previous studies have shown that HFNO reduces the risk of hypoxemia when performing rapid sequence induction in pregnant women, patients undergoing emergency surgery, and those in the intensive care unit[6, 18, 19]. Therefore, we expected a higher ORI in the HFNO group during intubation attempts, but there was no significant difference between the two groups. This is thought to be because in our study, endotracheal intubation was effectively and quickly performed with an average duration of 1.2 minutes, resulting in a short apnea period.

This study had some limitations. First, the ORI may differ at different flow rates of HFNO. A flow rate of 40 L/min was used when the patient was awake in this study, and it was increased to 70 L/min when the patient lost consciousness. The gold standard for the method of HFNO need to be determined [3]. Second, critically ill patients or rapid sequence induction situations were not included in this study. Third, the two-handed jaw thrust technique was used regardless of the group to maintain upper airway patency [20]. The details of the FMV technique can cause different results. Further studies are needed on the effect of different FMV techniques on ORI values.

Conclusions

HFNO during the general anesthesia induction process required for endotracheal intubation improves and maintains the ORI similarly to the FMV. Therefore, HFNO can be used as an alternative to FMV to secure oxygenation reserve during general anesthesia induction in elective surgery.

Abbreviations

FMV: facemask ventilation, HFNO: High-flow nasal oxygenation, ORI: Oxygen reserve index, PaO_2: arterial oxygen partial pressure, SpO_2: oxygen saturation.

Declarations

Ethics approval and consent to participate

This study was approved by the institutional review board of Severance Hospital, Seoul, South Korea (#4-2019-1336). Written informed consent was obtained from all individuals participating in the trial. The trial was registered prior to patient enrolment at clinicaltrials.gov (Registration number: NCT04291339, Principal investigator: Hyun Joo Kim, Date of registration: March 2, 2020). The study was performed in accordance with the Declaration of Helsinki and Good Clinical Practice guidelines.

Consent for publication

Not applicable.

Availability of data and materials

The datasets analysed during the current study are available from the corresponding author on reasonable request.

Competing interests

The authors declare that they have no competing interests.

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Authors' contributions

SP, SYK, MSK, WKP, and HJK conducted the research. SP and HJK designed the research. SP, SYK, MSK, WKP, and HJB collected data. SP, SYK, MSK, and HJK analysed and interpreted data. SP wrote initial manuscript. SP and HJK edited and revised the manuscript. All authors have approved the final version of manuscript.

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Figures

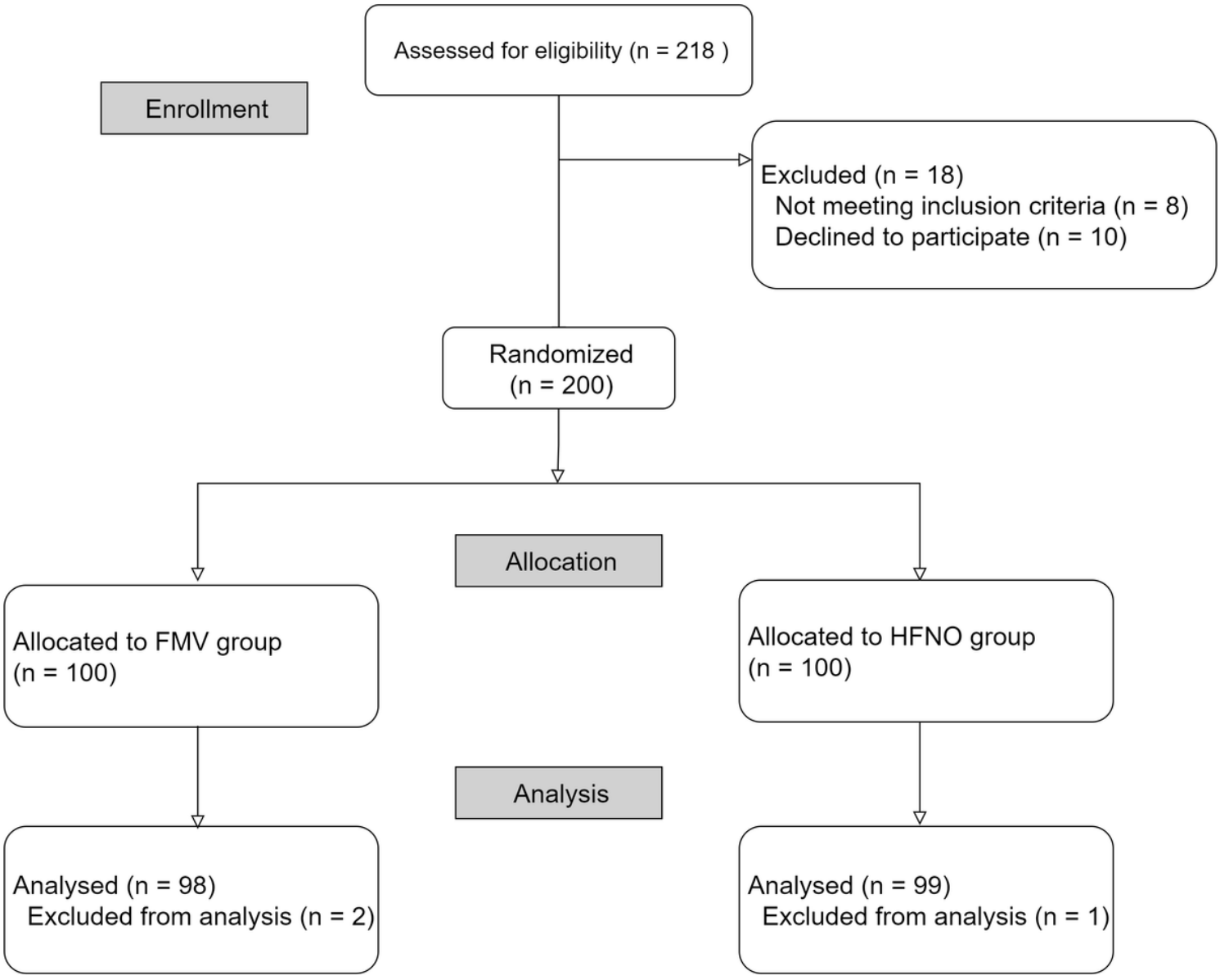

Figure 1

Patient enrolment flowchart. Abbreviations: FMV, facemask ventilation, HFNO, high-flow nasal oxygenation.

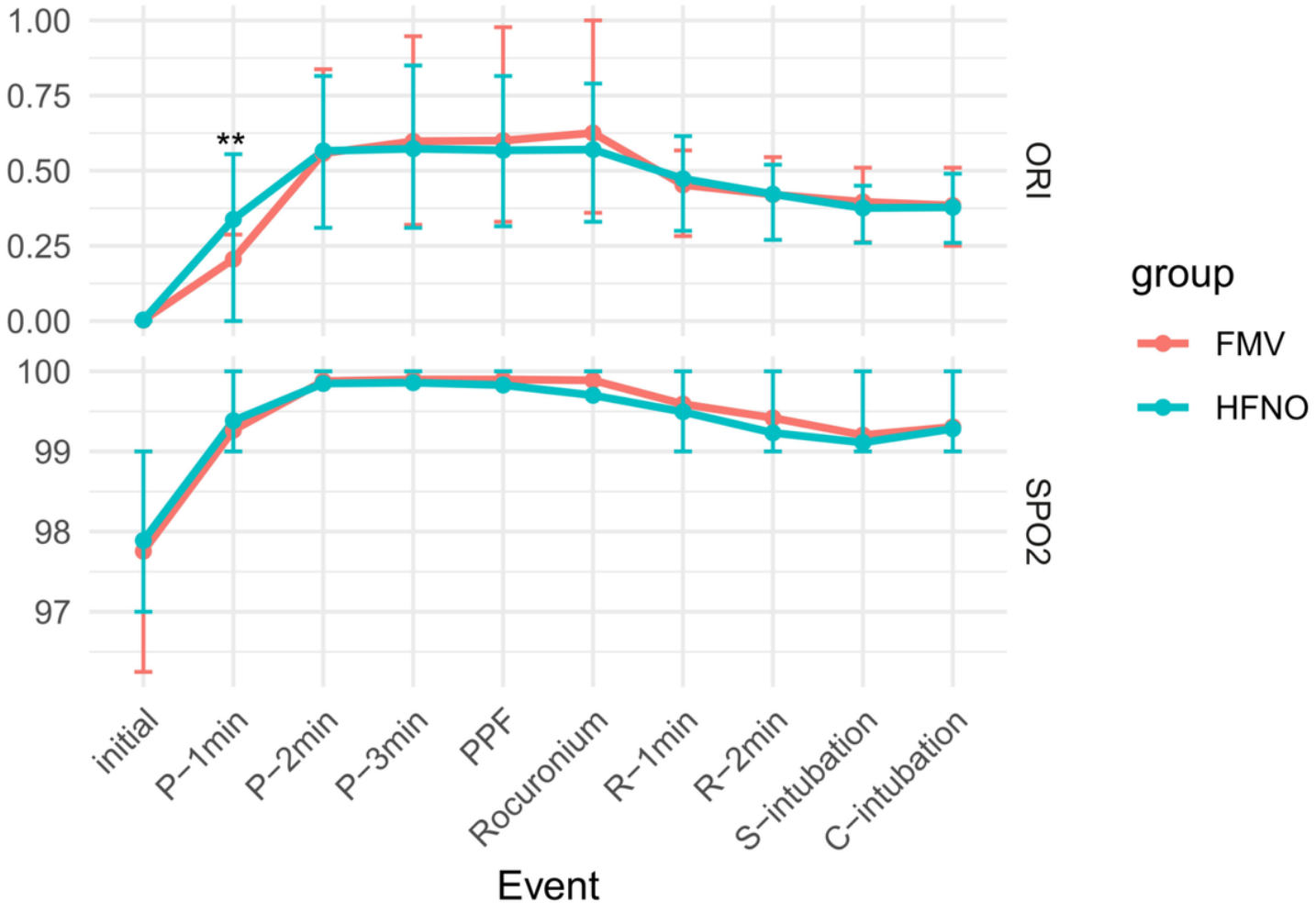

Figure 2

Changes in ORI and SpO_2 during the anesthetic induction period

Changes in the ORI and SpO_2 that occurred during the anesthetic induction period in the HFNO and FMV groups are shown. ORI and SpO_2 during the induction process were analysed using Student's t-test. **Indicates $P < 0.01$ when the two groups are compared. The dots represent the mean values, and the top and bottom lines represent the standard deviations. Abbreviations: ORI, oxygen reserve index, SpO_2, oxygen saturation, HFNO, high-flow nasal oxygenation, FMV, facemask ventilation, P-1 min, 1 minute of preoxygenation, P-2 min, 2 minutes of preoxygenation, P-3 min, 3 minutes of preoxygenation, PPF, propofol injection, R-1 min, 1 minute after rocuronium injection, R-2 min, 2 minutes after rocuronium injection, S-intubation, start of first intubation attempt, C-intubation, completion of intubation.

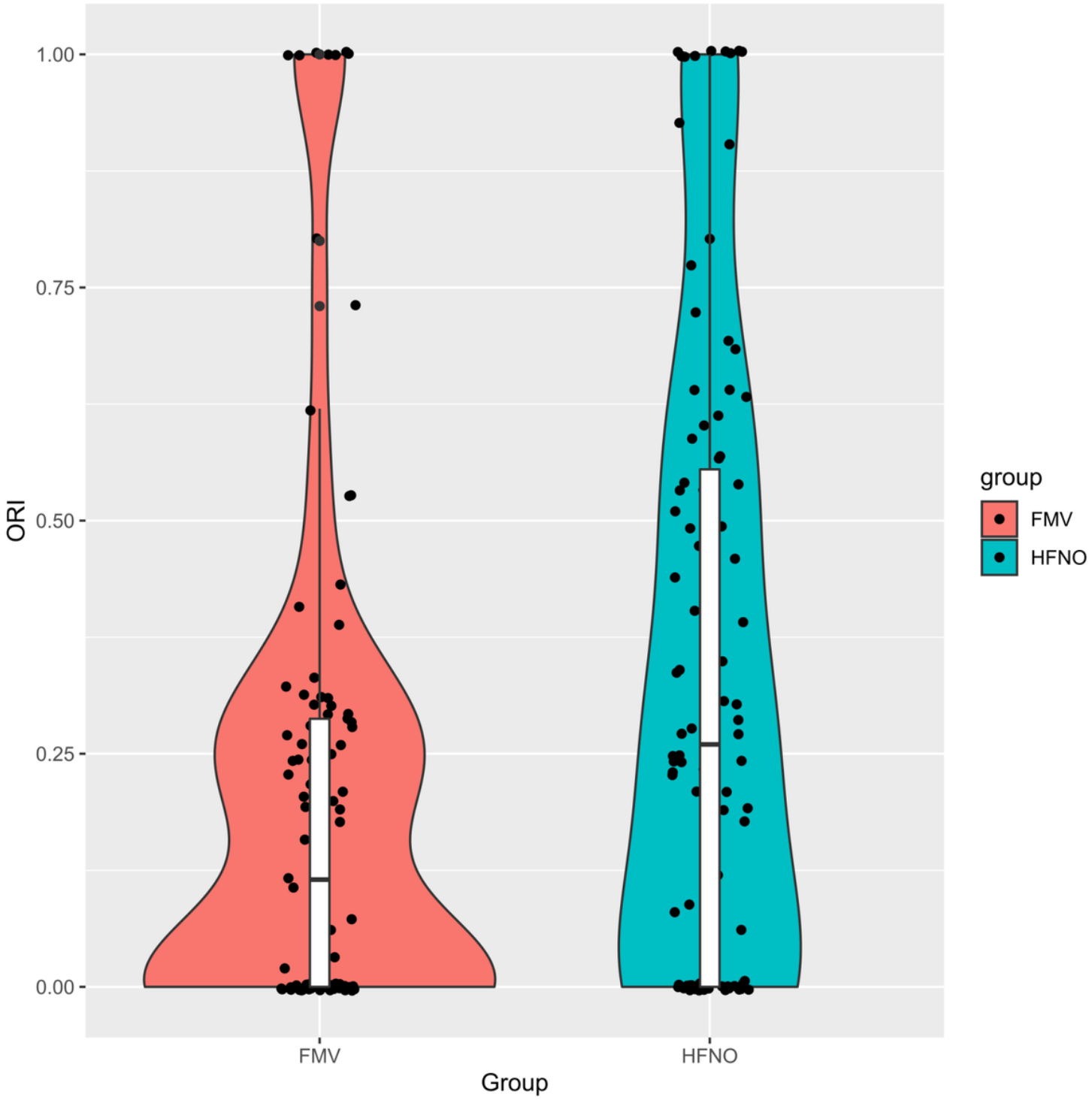

Figure 3

The ORI at 1 minute of preoxygenation

Violin plots show the distribution of the ORI at 1 minute of preoxygenation for patients in the HFNO and FMV groups. A boxplot comparing the ORI at 1 minute of preoxygenation between the two groups, which was assessed using Student's t-test ($P < 0.01$), is also shown. The horizontal bar represents the median, and the edges of the box represent the interquartile range, with the whiskers representing the lower

quartile. Abbreviations: ORI, oxygen reserve index, HFNO, high-flow nasal oxygenation, FMV, facemask ventilation.