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ORIGINAL ARTICLE

Comparison of pre-oxygenation using spontaneous breathing through face mask and high-flow nasal oxygen

A randomised controlled crossover study in healthy volunteers

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BACKGROUND High-flow nasal oxygen (HFNO) therapy has been proposed for pre-oxygenation before intubation, but the end-tidal fraction of oxygen (ETO_2) obtained remains unknown.

OBJECTIVE(S) To compare the ETO_2 following a 3 min pre-oxygenation with HFNO and face mask.

SETTING Operating room in a primary university hospital.

DESIGN A randomised crossover study.

PARTICIPANTS Fifty healthy volunteers.

INTERVENTIONS Participants were randomly pre-oxygenated through spontaneous breathing 100% oxygen in a face mask and with HFNO (mouth closed, heated and humidified gas flow at 60 l min^{-1}). In the face mask group, the ETO_2 was measured continuously. In the HFNO group, the nasal cannula was quickly exchanged with a face mask while the subject held their breath at end inspiration and the ETO_2 was measured after a deep expiration. The protocol ended when ETO_2 reached 90% or otherwise at 6 min.

MAIN OUTCOME MEASURES The primary endpoint was the ETO_2 after 3 min of pre-oxygenation. Secondary endpoints were the proportion of participants with an ETO_2 at least 90% and the time until the ETO_2 at least 90%.

RESULTS The ETO_2 after 3 min of pre-oxygenation was 89 (2) % and 77 (12) % in the face mask and HFNO groups [difference 12% (95% confidence interval, 95% CI: 8 to 15]; $P < 0.001$), respectively. After 3 min of pre-oxygenation, 54 and 4% ($P < 0.001$) of volunteers had an ETO_2 at least 90% in the face-mask and HFNO groups, respectively. After 6 min of pre-oxygenation, 96 and 46% ($P < 0.001$) of volunteers had an ETO_2 at least 90% in the face-mask and HFNO groups, respectively. In the face mask group, the hazard ratio to achieve an ETO_2 of 90% was 5.3 (95% CI: 3.2 to 8.9; $P < 0.001$).

CONCLUSION Our study demonstrates that pre-oxygenation with HFNO is not a reliable method of pre-oxygenation before the induction of anaesthesia.

TRIAL REGISTRATION clinical trial NCT03399695.

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Introduction

The Difficult Airway Society guidelines recommended that all patients should be pre-oxygenated with 100% inhaled oxygen before induction of general anaesthesia.[1] The goal of pre-oxygenation is to increase the oxygen store within the functional residual capacity of the lung thus delaying the onset of hypoxaemia in case of unanticipated difficult airway management.[2]

The most widely used method is spontaneous breathing of 100% oxygen for 3 min or until the expired fraction of oxygen (ETO_2) reaches 90%.[1,3] However, the efficacy of pre-oxygenation depends on many factors such as the fit between the mask and patient's face, the fresh gas flow, the duration of pre-oxygenation and patient's characteristics such as age and obesity.[3–5] Thus, the prevalence of inadequate pre-oxygenation (defined as $ETO_2 < 90\%$) has been reported as high as 56% during induction of anaesthesia.[4] This emphasises the importance of monitoring ETO_2 to ensure a near complete denitrogenation at the functional residual capacity level.[6,7]

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Over the past decade, high-flow nasal oxygen (HFNO) therapy has been increasingly used to treat acute hypoxaemic respiratory failure. In this setting, it has been shown to improve oxygenation, dyspnoea and comfort as compared to conventional oxygen therapy.[8,9] In contrast, pre-oxygenation and apnoeic oxygenation using HFNO was not more effective than pre-oxygenation with face mask in preventing desaturation during orotracheal intubation in hypoxaemic patients.[10] Because HFNO is easy to use and allows for high-flow apnoeic oxygenation, it has been studied also for pre-oxygenation before intubation.[11–14]

In morbidly obese patients, pre-oxygenation with HFNO resulted in a higher arterial oxygen partial pressure (paO_2) than face mask pre-oxygenation but only if the duration of pre-oxygenation was at least 5 min.[12] During rapid sequence induction, pre-oxygenation with HFNO resulted in a comparable paO_2 levels with a 3 min pre-oxygenation through a face-mask.[13,14] However, the blood oxygen content estimated by paO_2 is not representative of the oxygen reserve stored in the functional residual capacity volume. The amount of oxygen reserve should be estimated by the ETO_2 that more closely reflects the alveolar fraction of oxygen. Thus, the goal of the present study was to measure the ETO_2 following pre-oxygenation with face mask and HFNO in healthy volunteers. We hypothesised that pre-oxygenation through HFNO could be less effective than face mask because it may allow for inward air dilution of gas flow during inspiration.[4,5,11]

Materials and methods

This study was approved by the local Ethics Committee (Comité pour la Protection des Personnes Sud Est VI, Clermont-Ferrand, France, Committee reference: ID RCB 2017-A02343–50) and registered in ClinicalTrial registry NCT03399695).

Experimental design

This was a prospective randomised (computer-generated random list and sealed envelopes) crossover controlled study including volunteers in two groups according to the pre-oxygenation method (face mask group and HFNO group). The allocation ratio was 1 : 1 and a resting time of 60 min was mandatory between each pre-oxygenation procedure.

The two groups were as follows:

(1) the face mask group: pre-oxygenation was performed by spontaneous breathing through a tightly held face mask connected to the anaesthesia machine,
(2) the HFNO group: pre-oxygenation was performed by spontaneous breathing through specific high-flow oxygen nasal cannula (Nasal Cannula OPT844 and OPT 846; Fisher and Paykel Healthcare SAS, Courtaboeuf, France) connected to the oxygen delivery system (AIRVO-2; Fisher and Paykel Healthcare SAS). A medium of large size nasal cannula was used according to the volunteer's nostrils size.

Inclusion criteria were adult healthy volunteers, aged 18 years old and over, who completed written inform consent and medical contraindication forms. Each participant received verbal and written information about the study protocol before giving their written informed consent for participation, data acquisition and analysis.

Exclusion criteria were participant's refusal, any medical illness, active tobacco and BMI more than 30 $kg\,m^{-2}$.

Experimental protocol

All experiments were carried out under the supervision of two senior anaesthesiologists in an operating room of a primary university hospital. Fifteen minutes before the study, volunteers were allowed to rest in the supine position in a quiet, dimly light and temperature-controlled room (21°C to 22°C). The resting period between two pre-oxygenation procedures was 60 min.

Face mask group

Volunteers were pre-oxygenated through a tightly held face-mask connected to the anaesthesia machine (Aisys CS^2; GE Healthcare, Aulnay sous Bois, France) delivering a fresh O_2 gas flow of 12 $l\,min^{-1}$. Before the beginning of pre-oxygenation, the circle breathing system of the anaesthesia machine was flushed with the O_2 bypass for 30 s. The dead space of the anaesthesia machine was 9.5 ml and its resistance to flow was 0.5 cmH_2O at 30 $l\,min^{-1}$. The size of the face-mask was chosen to fit the volunteer's face. During all the pre-oxygenation period, the face-mask was firmly applied to the volunteer's face to avoid air leaks.

Inspired and expired fraction of O_2 was measured continuously (range 0 to 100 vol%; accuracy ± 1 vol%; Carescape Monitor; GE Healthcare) and displayed on the anaesthesia monitor.

The pre-oxygenation ended as soon as ETO_2 reached 90% otherwise at the end of a 6 min period.

High-flow nasal oxygen group

Volunteers were pre-oxygenated through a specific nasal cannula and high-flow O_2 delivery system (AIRVO-2; Fisher and Paykel Healthcare SAS). The inspired fraction of O_2 was set at 100%, the gas flow was set at 60 $l\,min^{-1}$. Gas flow was heated (37°C) and humidified (absolute humidity >30 $mg\,l^{-1}$).

Before pre-oxygenation, volunteers were instructed to breathe through the nose and to keep the mouth closed throughout the procedure. In order to measure the ETO_2, 3 to 5 s before the end of the pre-oxygenation period (3, 4, 5 and 6 min), volunteers were asked to take a slow maximal inspiration and to stop breathing. The nasal

cannula was quickly removed, a face mask tightly applied to volunteer's face and then volunteers were asked to breathe out. This changeover took less than 2 s because one person removed the nasal cannula, while another one was ready to apply the face mask. The face mask was connected to the anaesthesia machine (Aisys CS^2; GE Healthcare) and its integrated gas monitor (Carescape Monitor; GE Healthcare). Before the protocol began, volunteers were trained three times to ensure the good understanding and performance of the procedure.

If the ETO_2 was less than 90% after a 3 min pre-oxygenation through nasal high flow O_2, volunteers were allowed to rest for 60 min before a further period of pre-oxygenation through HFNO for a duration equal to the previous attempt plus 1 min. The protocol ended as soon as ETO_2 reached 90% otherwise at the end of 6 min.

Primary endpoint

The primary endpoint was the ETO_2 measured at the end of 3 min pre-oxygenation, the most widely reported duration for pre-oxygenation.[3,5,12–15]

Secondary endpoints

Secondary endpoints were the proportion of volunteers with an ETO_2 at least 90% at 3 min, the time (s) required to reach a ETO_2 of 90% with a maximal recording time set at 6 min, the proportion of volunteers with a ETO_2 at least 90% at 6 min.

The self-reported tolerance of the pre-oxygenation procedure was evaluated through a four-item Likert scale (not tolerable, poorly, fairly and fully tolerable). Self-reported comfort during pre-oxygenation was evaluated with a verbal rating scale from 1 (uncomfortable) to 10 (totally comfortable).

Statistical analysis

The sample size was calculated based on the hypothesis that following 3 min of pre-oxygenation, the nasal high flow O_2 would be less effective because the volunteers did not breath in a closed space (i.e. a tightly applied face-mask) ensuring a true 100% inspired O_2 fraction. Previous data in volunteers showed that the ETO_2 following 3 min of pre-oxygenation through a face-mask was 90% with a standard deviation of 1%.[4] We hypothesised that ETO_2 in the nasal high flow O_2 group should be 88% with a standard deviation of 4%. According to a 5% two-sided alpha risk and a 10% beta-risk, 46 volunteers must be included in each group in a crossover study. We planned to include 50 volunteers allowing a 10% margin for missing data.

Normality of quantitative data was tested using the Kolmogorov and Smirnov test. Data are reported as mean (SD) or median [interquartile range] as required. Quantitative data were compared between groups with Student's *t*-test or Mann–Whitney test, as appropriate. Ordinal data from the verbal rating scale were compared between groups using the Wilcoxon matched-pairs Signed ranks test. Qualitative data were compared with the Fischer's exact test. The Bonferroni correction was applied to correct for multiple comparisons.

The comparison of the ETO_2 measured at the end of each period of pre-oxygenation (3, 4, 5 and 6 min) was carried out using an analysis of variance for repeated measures. Multiple post hoc pairwise comparisons were performed with the Tukey's posthoc test.

A Kaplan–Meier plot and a log-rank test were used to analyse the rate of volunteers in whom ETO_2 at least 90% within the time limits of the experiments between groups. Hazards ratio and its 95% confidence interval (95% CI) were reported for groups.

All statistical tests were two-sided.

Statistical analysis was performed using MedCalc Software v 12.2.1.0 (MedCalc Software, Mariakerke, Belgium) and R 3.4.1: A Language and Environment for Statistical Computing (http://www.R-project.org) with 'survival' package.

Results

From 2 January 2018 to 31 March 2018, 50 volunteers were included in the study (Fig. 1). There was 22 women and 28 men, aged 30 (7) years, the weight, height and BMI were 70 (14) kg, 173 (10) cm and 23 (3) $kg\,m^{-2}$, respectively. Fifteen volunteers had a beard.

Primary endpoint

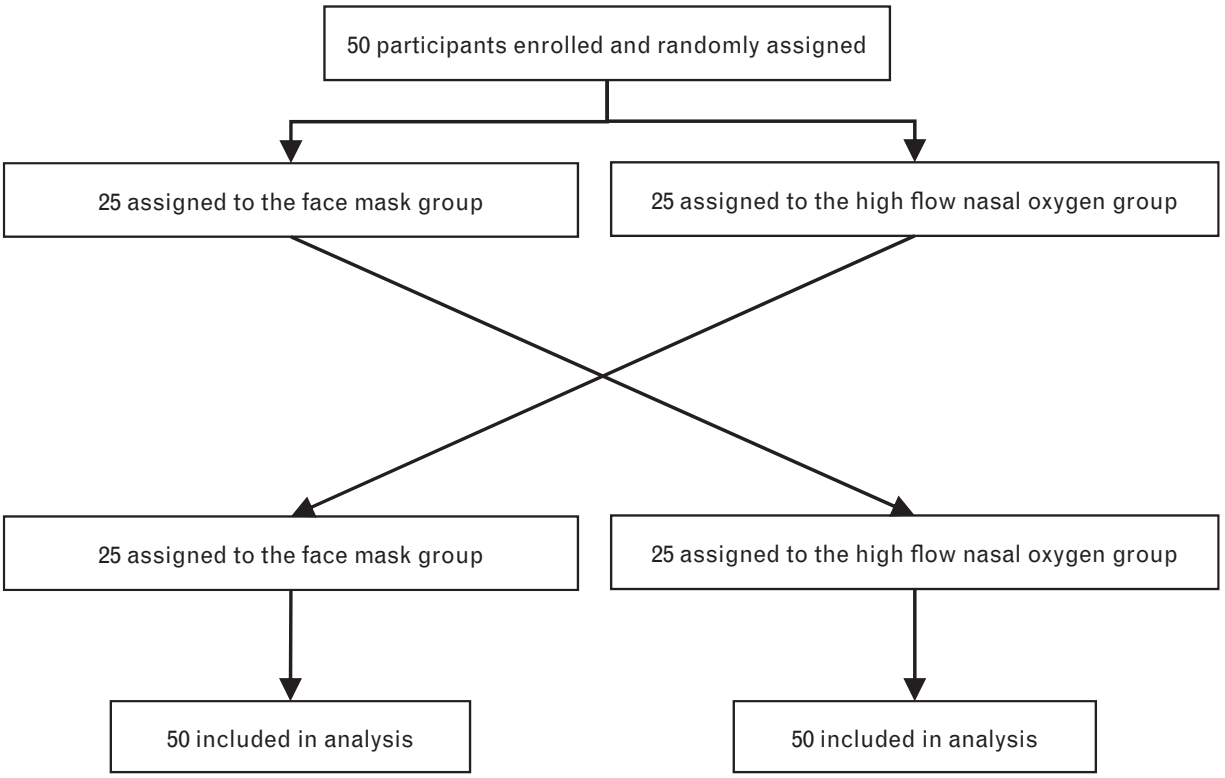
The ETO_2 after 3 min of pre-oxygenation was 89 (2)% in the face mask group and 77 (12)% in the HFNO group [difference 12% (95% CI 8 to 15); $P < 0.001$].

Secondary endpoints

Figure 2 depicted the time course of ETO_2 in the face mask group and in the nasal high flow O_2 group. Table 1 reported the ETO_2 measured at the end of pre-oxygenation periods according to groups. The proportion of volunteers with a ETO_2 at least 90% at 3 min was 54% in the face mask group, and 4% in the HFNO group ($P < 0.001$). After 6 min of pre-oxygenation, the proportion of volunteers with an ETO_2 at least 90% was 96% in the face-mask group, and 46% in the HFNO group ($P < 0.001$). Table 2 reported within each group the number of volunteers with and without an $ETO_2 \geq 90\%$ at the end of 3, 4, 5 and 6 min of pre-oxygenation.

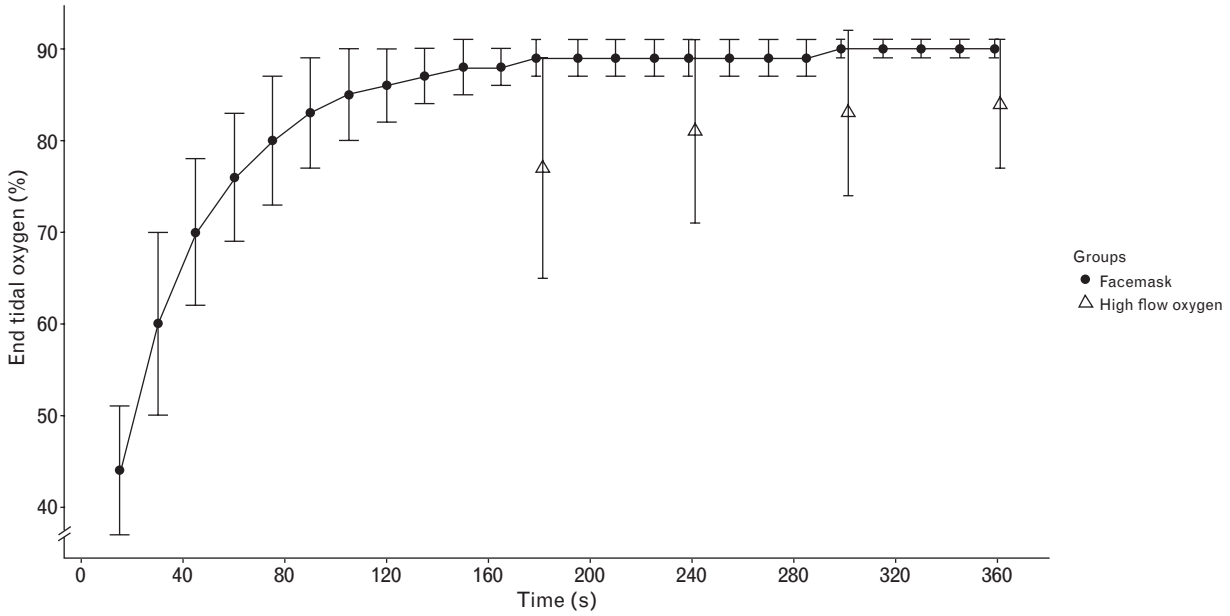
The Kaplan–Meier plot for the probability that ETO_2 reached 90% is depicted in Fig. 3. The median (interquartile range) time in seconds to obtain an $ETO_2 = 90\%$ was 172 [120 to 250], and 360 [240 to 360] in the face mask and HFNO groups, respectively. In the face mask group, the hazard ratio to achieve an ETO_2 of 90% was 5.3 (95% CI 3.2 to 8.9; $P < 0.001$).

Fig. 1



Flow chart of the study.

Fig. 2



Time course of expired oxygen fraction between groups. In the face mask group, the ETO_2 was measured continuously and recorded every 15 s. In the high-flow nasal oxygen group, the ETO_2 was measured at the end of each period of pre-oxygenation after a quick exchange between nasal cannula and face mask during which the volunteers held their breath at end inspiration before exhaling through the face mask.

Table 1 End-tidal fraction of oxygen within groups

	Face mask group ($n = 50$)	High-flow nasal oxygen group ($n = 50$)	P
ETO_2 at 3 min	89 (2)	77 (12)	<0.001
ETO_2 at 4 min	89 (2)	81 (10)	<0.001
ETO_2 at 5 min	90 (1)	83 (9)*	<0.001
ETO_2 at 6 min	90 (1)	84 (7)*	<0.001

Data presented as mean (SD). ETO_2 in the face mask group was continuously monitored and data recorded every 15 s. ETO_2 in the high-flow nasal oxygen group was measured at the end of 3, 4, 5 and 6 min of pre-oxygenation. * $P < 0.01$ vs. ETO_2 at 3 min according to the Tukey's post hoc test.

Table 2 Number of volunteers with and without an end-tidal fraction of oxygen at least 90% according to the time of measurement

	Face mask group ($n = 50$)		High-flow nasal oxygen group ($n = 50$)		
Time	$ETO_2 \geq 90\%$	$ETO_2 < 90\%$	$ETO_2 \geq 90\%$	$ETO_2 < 90\%$	P
3 min	27	23	2	48	<0.001
4 min	37	13	16	34	<0.001
5 min	44	6	17	33	<0.001
6 min	48	2	18	32	<0.001

Data presented as number of volunteers with/without an $ETO_2 \geq 90\%$ at each time period. ETO_2 in the face mask group was continuously monitored and data recorded every 15 s. ETO_2 in the high-flow nasal oxygen group was measured at the end of 3, 4, 5 and 6 min of pre-oxygenation. Volunteers in whom ETO_2 was $\geq$ 90% completed the study. P values were corrected for multiple comparisons using the Bonferroni correction.

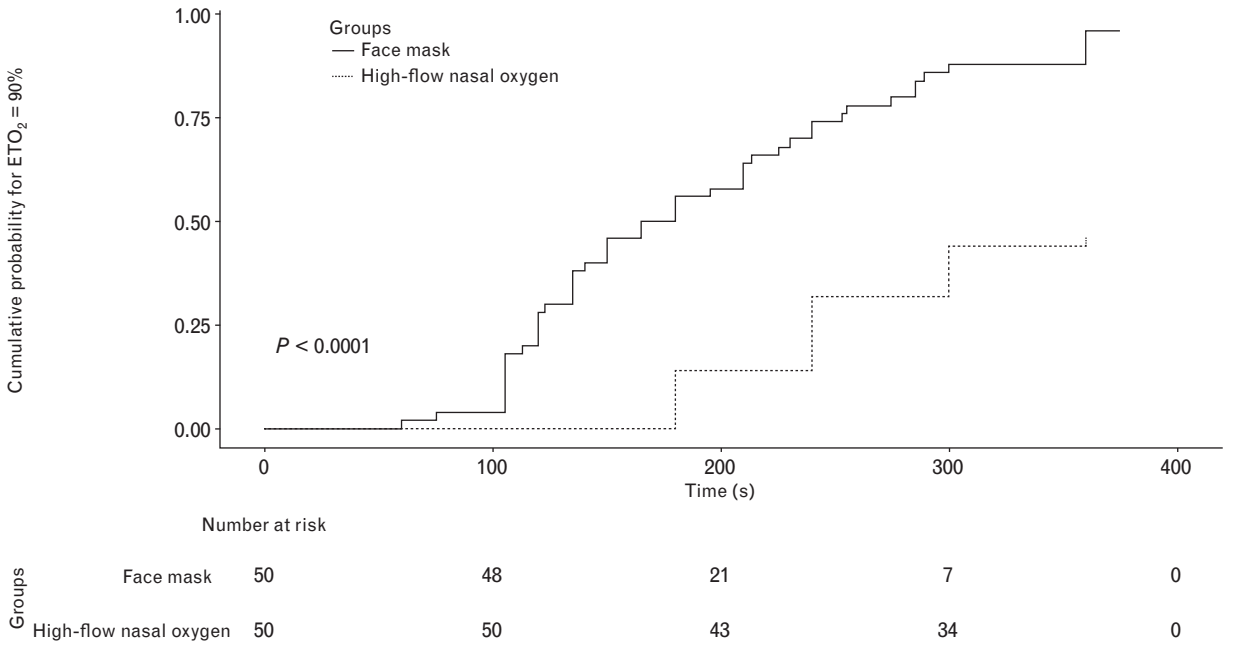
The self-reported tolerance of the pre-oxygenation procedure was not different between face mask (not tolerable: 0%, poorly: 6%, fairly: 58%, fully tolerable: 36%) and HFNO groups (not tolerable: 0%, poorly: 6%, fairly: 52%, fully tolerable: 42%; $P = 0.296$). The self-reported comfort score during pre-oxygenation was not different between face mask (7 [6 to 8]) and HFNO groups (8 [6 to 9]; $P = 0.296$).

Discussion

The main finding of our study in healthy volunteers is that pre-oxygenation with HFNO resulted in a lower efficacy (as evaluated by ETO_2) than pre-oxygenation with spontaneous breathing through a face mask. After a 6 min pre-oxygenation period, an ETO_2 of at least 90% was observed in only half of the volunteers with HFNO, but in 96% of the volunteers with a face-mask. Finally, the probability that an individual would experience an ETO_2 of at least 90% at a particular given point in time after the pre-oxygenation began was five-fold lower in the HFNO group.

High-flow nasal O_2 allows for delivering up to 60 l min^{-1} of heated and humidified gas with 21 to 100% inspired oxygen fraction. Several respiratory effects of HFNO have been shown, including a decreased resistance of the upper airway, a decreased work of breathing, positive airway pressure and a reduced oxygen dilution with room air.[11] Clinical trials looking at HFNO therapy have mainly focused on its use in ICUs.[8,9,16,17] Recently, HFNO has been proposed for pre-oxygenation of patients before the induction of general anaesthesia

Fig. 3



Kaplan–Meier plot for the probability that the expired oxygen fraction reached 90% in face mask and high-flow nasal oxygen groups.

and for apnoeic oxygenation during prolonged airway invasive procedures.[12–14,18]

In hypoxaemic acute respiratory failure, HFNO therapy was superior to standard O_2 therapy in terms of paO_2, patient comfort, respiratory rate and dyspnoea.[8,9] A large multicentre randomised study showed that HFNO therapy decreased ICU and 90 days mortality as compared to standard oxygen therapy and noninvasive ventilation.[16] Recently, HFNO therapy has been shown not to be inferior to noninvasive ventilation in preventing postextubation respiratory failure and re-intubation in patients at a high risk of extubation failure.[17,19]

During airway invasive procedures, HFNO allowed for apnoeic oxygenation that maintained patients oxygenated for up to 30 min.[18] Thus, HFNO associated with apnoeic oxygenation might be used for pre-oxygenation before tracheal intubation and during laryngoscopy. In critically ill patients, in whom hypoxaemia is the most common complication of tracheal intubation, pre-oxygenation through HFNO associated with apnoeic oxygenation was not more effective in preventing desaturation as compared to pre-oxygenation through face mask.[10] In contrast, pre-oxygenation with noninvasive ventilation and HFNO, allowed apnoeic oxygenation during the intubation procedure resulting in an increased minimal SpO_2 value recorded during the intubation procedure as compared to noninvasive ventilation alone.[20]

In patients requiring a rapid sequence induction of anaesthesia for emergency surgery, pre-oxygenation with HFNO and apnoeic oxygenation has been shown not to be superior to pre-oxygenation with face-mask in terms of the lowest SpO_2 recorded during the procedure and paO_2 after tracheal intubation.[13,14] Nevertheless, there was a lower proportion of patients experiencing arterial desaturation below 93% suggesting that HFNO might be useful in case of unanticipated difficult airway resulting in a prolonged apnoea time.[21] In morbidly obese patients, Heinrich *et al.*[12] measured the paO_2 after 7 min of pre-oxygenation with HFNO, continuous positive airway pressure and face-mask. The paO_2 was not different between HFNO and continuous positive airway pressure, but higher than after pre-oxygenation with a face-mask.[12]

However, these studies measured the efficacy of pre-oxygenation through paO_2, which cannot be representative of the oxygen reserve stored in the functional residual capacity because of confounding factors, including absorption atelectasis resulting in intrapulmonary shunting, alveolar-arterial gradient and cardiac output.[2,3,7] The expired fraction of oxygen and nitrogen, as indirect measurement of alveolar gases partial pressure, is the most useful indicator of efficacy of pre-oxygenation, but it cannot be monitored in patients breathing HFNO. To our knowledge, only one study has measured ETO_2 after a 3-min period of HFNO in 10 healthy volunteers.[22] The authors showed that the ETO_2 during HFNO highly depends on whether volunteers breathe with their mouth open or closed. With the mouth open, the ETO_2 after 3-min HFNO was 50% but was associated with a large inter-individual variability. However, the small sample size and the 3-min study period limit the interpretation of the study. In the present study, we showed that the ETO_2 measured during pre-oxygenation through HFNO with a gas flow set at 60 l min^{-1} did not reach 90% and was highly variable between volunteers despite them being directed to breathe with their mouth closed.

The most likely explanation of the difference in oxygenation from our results is the occurrence of inward air leak through the mouth and unexpected high inspiratory flow rate during use of the nasal cannulae. The importance of the mouth open or closed during HFNO therapy has already been shown in terms of the positive airway pressure generated.[23,24] When the mouth is open, the mean upper airway positive pressure range was between $+1\,cmH_2O$ and $+2\,cmH_2O$, less dependent of the gas flow, and highly variable between patients.[23,24] Importantly, no positive airway pressure could be observed during the inspiratory phase, which might allow oxygen dilution by room air during the inspiratory phase.[4,23,24] Although the gas flow during HFNO was 60 l min^{-1}, it has been shown that the median peak nasal inspiratory flow was 110 l min^{-1} in patients.[25] Because this is almost twice the HFNO gas flow, an inward room air flow might contributed to dilution of oxygen flow during the inspiratory phase. Consequently, as reported during pre-oxygenation with calibrated inward air leak, the ETO_2 cannot reach 90%.[4] Thus, our results show that after 3-min and 6-min of pre-oxygenation with HFNO, the proportion of volunteers with ETO_2 at least 90% was only 4 and 46%, respectively. In addition, there was a large inter-individual variability in the ETO_2 values measured in the HFNO group.

Finally, the present data showed that HFNO was not superior to face mask in terms of self-reported tolerance and comfort.

The following limitations of the present study must be pointed out. First, we could not study the time of apnoea until desaturation in healthy volunteers. Although there is a close relationship between ETO_2 and the time of apnoea before desaturation, this endpoint should be studied in further studies.[2,3,26,27] Second, we only studied the ETO_2, which is the recommended parameter to assess the efficacy of pre-oxygenation in clinical practice. We did not measure expired fraction of nitrogen nor paO_2, but ETO_2 is the most representative indicator of the fraction of alveolar oxygen. Third, during HFNO, it is not possible to obtain a continuous measure of the ETO_2. Consequently, we performed intermittent measurements using a quick exchange of the nasal cannula with a face mask connected to the anaesthesia machine with a gas

monitor. Although we cannot be sure that this method accurately estimates ETO_2, a value of at least 90% was measured in 4 and 46% of volunteers at 3 and 6 min respectively. Fourthly, we did not measure the inspiratory flow rate of volunteers during the pre-oxygenation period nor during the maximal inspiration asked before exchange of the cannula for face mask. During HFNO therapy (FiO_2: 60%, gas flow: 50 l min^{-1}), it has been shown that inspired fraction of O_2 and ETO_2 measured through a hypopharyngeal catheter was lower than expected if the peak inspiratory flow rate was increased by exercise.[28] Thus, it can be hypothesised that some volunteers had an inspiratory flow rate greater than the HFNO gas flow resulting in a lower ETO_2; this can also be the case in patients. Finally, we used specific cannula designed for HFNO therapy. However, specific nasal prongs designed to limit inward air leak exist and must be evaluated.

Conclusion

We have shown that pre-oxygenation through HFNO is not a reliable method of pre-oxygenation before the induction of anaesthesia. Within the limits of being able to accurately measure ETO_2 in the current study, we demonstrated that even taking efforts to keep the mouth closed in the nasal cannulae group, there was a lower ETO_2 and a large inter-individual variability in ETO_2 compared with pre-oxygenation through a face mask. Nevertheless, because HFNO allows for apnoeic oxygenation, it should be considered to prolong the well tolerated duration of apnoea in patients with difficult airway management.

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Conflicts of interests: none.

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