Original Article

Effectiveness of Face mask only oxygenation and apnoeic oxygenation in addition to face mask in sustaining PaO_2 during rapid sequence induction - A randomized control trial

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Abstract

Background and Aims: Apnoeic oxygenation, although useful during elective intubations, has not shown consistent beneficial results during emergency intubations in critically ill patients. We aimed to study the effectiveness of adding apnoeic oxygenation to our routine practice of using facemask alone, in emergency laparotomy patients needing rapid sequence induction (RSI), for sustaining partial pressure of oxygen (PaO_2).

Material and Methods: Seventy-two patients undergoing RSI for emergency laparotomy were randomly allocated to either receive pre-oxygenation with 5 L/min of oxygen (O_2) with a facemask (Group-FM) or apnoeic oxygenation with 10 L/min of O_2 through a nasal catheter in addition to pre-oxygenation (Group-NC). Apnoea (90 s) was allowed from the removal of the facemask before the resumption of ventilation. Arterial blood gas analysis was done at the baseline, following pre-oxygenation and after 90 s of apnoea to study the PaO_2 and partial pressure of carbon dioxide ($PaCO_2$). The circuit O_2 concentrations (fraction of inspired [FiO_2] and end-tidal [EtO_2]) were also noted to ensure a steady state of O_2 uptake was reached.

Results: The circuit O_2 concentrations were 90 ± 4% in group FM and 93 ± 5% in Group-NC. The FiO_2-EtO_2 difference was 4% in both groups. During the 90 s apnoea following pre-oxygenation, there was a fall in the PaO_2 by 38% in Group-FM and 12% in Group-NC ($P = 0.000$). Increase in $PaCO_2$ was similar in both groups (Group-FM: 44 [range: 32–55] mmHg; Group-NC: 42 [range: 33–54] mmHg, $P = 0.809$).

Conclusion: Apnoeic insufflation of O_2 using a nasopharyngeal catheter along with facemask oxygenation is more effective in sustaining PaO_2 for 90 s during RSI than facemask-only oxygenation in patients undergoing emergency laparotomy.

Keywords: Anesthesia, apnea, general, insufflation, oxygen, rapid sequence induction and intubation

Introduction

Pre-oxygenation prolongs the safe apnoea time by optimizing the oxygen (O_2) stores.[1] Nevertheless, during rapid sequence induction (RSI), there is a high risk of desaturation as mask ventilation is contraindicated following induction. The problem of desaturation is higher in patients posted for emergency laparotomy, as the elevated splinted diaphragm decreases the functional residual capacity (FRC), limiting the effectiveness of pre-oxygenation, which is further compounded with an increased O_2 demand caused by the ongoing sepsis.[2]

The time course of oxyhemoglobin desaturation during apnoea is five times more rapid in critically ill patients when compared to healthy adults (23 s vs. 502 s).[3] Apnoeic oxygenation (AO)

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has been proved useful for prolonging the safe apnoea time in the American Society of Anesthesiologists (ASA) physical status 1 and 2 patients undergoing elective surgeries, morbidly obese patients, and pregnant patients, whereas consistent beneficial effects have not been reported during emergency intubations in critically ill patients.[4-6] AO during RSI in patients undergoing emergency laparotomy has not yet been investigated and the results from the above studies cannot be extrapolated to this group of patients. We hypothesized that AO, as it continues to replenish the O_2 stores by passive diffusion, is likely to be beneficial in enduring the apnoea during RSI when compared to face mask alone. We aimed to study the effectiveness of AO using a nasal catheter during RSI in emergency laparotomy. Our primary objective was to assess the decrement in the partial pressure of oxygen (PaO_2) following 90 s of apnoea. The secondary objective was to assess the attained circuit O_2 concentration and determine whether a steady-state of O_2 uptake was reached.

Material and Methods

This prospective, randomized study (PG Dissertation/02/2019/61) was approved by the institutional human ethics committee and registered with the Clinical Trial Registry of India (CTRI/2019/05/025797). The study was done from June 2019 to September 2020 and followed the principles laid down in the declaration of Helsinki.

Patients coming to the institute for emergency laparotomy formed the study population. Using continuous sampling methods, of the 80 patients enrolled, 72 patients 18 to 60 years of age, ASA 1 to 3, who gave written informed consent were included [Figure 1]. Patients with an anatomically difficult airway, baseline oxygen saturation (SpO_2) <95% on room air, hemoglobin <8 g/dL, hemodynamically unstable (systolic blood pressure <90 mmHg on vasopressor support), and coronary artery disease were excluded. Written informed consent was taken from each patient recruited in the study.

To ensure uniform distribution of patients into either group at any time, block randomization was performed using the "Permuted block" feature of the "Statistics and Sample Size" app, version 1.0 developed by Truc TT, with a pre-defined block size of eight. The randomisation sequence was generated by a resident not involved in the study and handed over to the investigators in sealed opaque sequentially numbered envelopes containing the allocated group: Group-FM, pre-oxygenation with facemask only or Group-NC, AO with 10 L/min through a nasal catheter in addition to pre-oxygenation with facemask. The envelopes were selected in a sequential order to decide the group to be allocated. The patients and the investigator analyzing the arterial blood gas reports were blinded to the allocated group.

In the pre-anesthetic holding room, the intravenous line was checked for patency. The baseline hemodynamic parameters

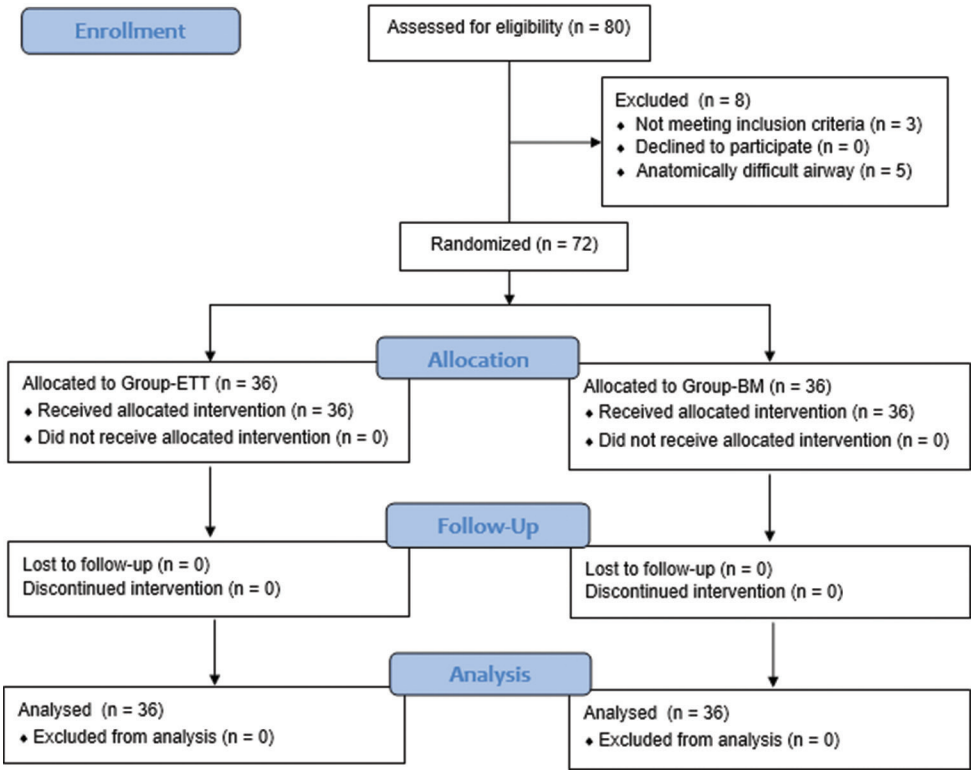

Figure 1: CONSORT flow diagram

and SpO_2 were noted. The radial artery was cannulated in either the right or the left upper limb and an arterial sample was sent for baseline blood gas analysis (ABL™ 5 Radiometer, Copenhagen, arterial blood gas analyzer) in a container filled with ice slush. An anesthesia resident, who was not involved in the study, took the samples and analyzed them within 5 min of collection.

In the operating theater, monitoring (ProCare Monitor B40, GE Healthcare, United States) included electrocardiography, SpO_2, non-invasive blood pressure, and airway gas monitoring (E-miniC module with the carbon dioxide setup adjusted to enable O_2 and nitrous-oxide compensation). Patients were positioned in a sniffing position and prepared for RSI. After thorough nasogastric suctioning, the nasogastric tube (NGT) was removed.

A semi-closed circle system with a limb-O circuit (total volume: 2.75 L) was used in the study. The circuit was primed by activating the emergency flush for 30 s with the patient end closed, and end-tidal O_2 (EtO_2) and the fraction of inspired O_2 (FiO_2) were confirmed to be ≥98% before using it on the patient. The group allocation envelope was then opened to determine the randomization group. In Group FM, patients were pre-oxygenated with a tight-fitting facemask, and an O_2 flow of 5 L/min, for 3 min. In Group-NC, a 14 Fr (4.667 mm outer diameter) nasal catheter was inserted with the tip positioned at the nasopharynx. This catheter was connected to a separate O_2 cylinder with a flowmeter and an additional flow of 10 L/min was initiated during the 3-min pre-oxygenation. The circuit adjustable pressure limiting valve was kept fully open to avoid the buildup of any positive end-expiratory pressure or continuous positive airway pressure during pre-oxygenation in either group.

The FiO_2 and EtO_2 concentrations were noted after the first inspiration. At the end of 3 minutes of pre-oxygenation, FiO_2, EtO_2, and SpO_2 were noted and a second arterial sample was collected. The choice and dose of opioids and induction agents were based on the anesthesiologist's preference. During the application of cricoid pressure, care was taken to ensure that the airway patency was not compromised. Following induction, Inj. suxamethonium hydrochloride 1.5 mg/kg was administered. Airway patency up to the glottis was ensured during induction until intubation using head tilt, chin lift, jaw thrust, and if necessary an oropharyngeal airway. The facemask was removed after 45 s or following the cessation of succinylcholine fasciculation and intubation was attempted.

The removal of the facemask for intubation was taken as the beginning of apnoea. In Group-NC, O_2 insufflation continued during intubation. To ensure correct placement of the tracheal tube (TT), without initiating ventilation and altering the gas concentrations, all intubations were done by consultants and an esophageal detector device was used. If intubation was done within 90 s, in Group-FM, the TT was left open to the ambient atmosphere until the 90 s apnoea time was over. In Group-NC, the TT was connected to the circuit, with the expiratory limb open to the atmosphere to continue AO through the circuit. This was done to study conditions of 90 s apnoea. SpO_2 and the third arterial blood sample were taken 90 s after the removal of the facemask before the commencement of ventilation or earlier if saturation dropped to less than 90% and the duration was noted. The circuit was then connected and ventilation started. Further anesthetic and ventilatory management were according to the anesthesiologist's preference.

The primary outcome was PaO_2 levels following apnoea. The sample size calculator app by Mr. Truc TT (version 1.0) was used for calculating the sample size. The sample size was calculated based on a previous study by Sahay *et al*.,[7] who reported a 30% fall in PaO_2 during apnoea. With a power of 80%, an alpha error of 0.05 to detect a 5% fall in PaO_2 in the AO group, the sample size was estimated as 36 patients for each group. Statistical analysis was carried out using the SPSS version 16.0 (IBM SPSS, US) software. Unpaired Student's *t*-test was used for comparing the age, body mass index, baseline vital parameters, ABG values, the time taken for intubation, inspired and expired O_2 in both the groups. Chi-square test for sex, ASA, and MPC grading. Mood's median test was used for the comparison of medians.

Results

Seventy-two patients completed the study [Figure 1]. Five patients with an anatomically difficult airway, two patients with baseline hemoglobin <7 g/dL, and one patient with a saturation of 88% on room air were excluded. The two study groups were comparable for age, weight, sex, and ASA physical status [Table 1]. The baseline respiratory rate, SpO_2, the potential of hydrogen (pH), partial pressure of carbon dioxide ($PaCO_2$), PaO_2, and bicarbonate (HCO_3) were similar in both groups. We did not encounter unanticipated difficult intubation in any patient. The fasciculations due to suxamethonium subsided within 45 s and all intubations in either group were performed well within 90 s in the first attempt itself.

The circuit O_2 concentration was 90 ± 4% in Group-FM and 93 ± 5% in Group-NC. The FiO_2–EtO_2 difference was 4% in both groups [Table 2]. The PaO_2 attained following pre-oxygenation was similar (P = 0.57) in both

groups [Figure 2a]. During the 90 s apnoea following pre-oxygenation, there was a fall in the PaO_2 by 38% in Group-FM and 12% in Group-NC ($P = 0.000$) [Figure 2b]. The increase in $PaCO_2$ levels following 90 s of apnoea was similar ($P = 0.809$) in both groups [Figure 3].

Discussion

Currently, there are no data on the usefulness of AO during RSI in patients undergoing emergency laparotomy. Our study shows that in this group of people with reduced pulmonary reserves, the fall in PaO_2 levels following apnoea is higher without O_2 supplementation. The technique of nasopharyngeal insufflation of O_2 for AO does not need any specialized equipment such as that required for high-flow nasal oxygen and hence can be easily put into practice. Sustaining PaO_2 with such a simple technique is encouraging particularly in the present post-coronavirus (COVID) situation when we may increasingly encounter COVID-recovered patients with compromised pulmonary reserves.

PaO_2, as opposed to SpO_2, indicates the O_2 reserves available and was preferred in our study. Our methodology ensured that the arterial blood collection procedure and pre-oxygenation technique were standardized and the adequacy of pre-oxygenation was confirmed to accurately reflect what we wanted to determine.[8,9]

The NGT was removed after thorough suctioning in both the groups before pre-oxygenation but the presence of the nasopharyngeal catheter in Group-NC interfered with the mask seal. To compensate for the mask leak, O_2 insufflation in this group was initiated during pre-oxygenation itself. It is difficult to attain a FiO_2 of 1.0 during pre-oxygenation unless non-rebreathing circuits are used. We could achieve a $FiO_2 \geq 0.95$ in 15 out of 32 patients in Group-NC but could attain only 0.90 in Group-FM. In a group of healthy adult volunteers, Nimmagadda *et al.*[10] were also able to achieve FiO_2 of only 0.95 with a fresh gas flow (FGF) of 5 L/min using a circle system. Further, the inability to achieve a FiO_2 of 0.95 in all patients in Group-NC can be attributed to the face mask leak caused by the presence of the nasal catheter.[11] Despite higher FiO_2 in Group-NC, the PaO_2 attained at the end of 3-min pre-oxygenation was similar in both the groups.

Denitrogenation during pre-oxygenation is exponential and an EtO_2 of approximately 90% indicates adequate

Table 1: Demographic data and baseline parameters

	Group-FM (n=36)	Group-NC (n=36)	P
Age (y)	40±14	42±13	0.53
BMI	24±5	22±4	0.07
Sex (Male:female)	20: 16	22: 14	0.68
ASA (1:2:3)	14: 17: 5	16: 15: 5	0.82
MPC (1:2)	20: 16	18: 18	0.40
Baseline respiratory rate (Breaths/min)	22±8	25±7	0.09
Baseline ABG			
pH	7.43±0.41	7.40±0.43	0.76
PaO_2	90 (69 to 117)	87 (50 to 112)	0.185
$PaCO_2$	32 (25 to 41)	29 (20 to 39)	0.15
HCO_3	19.4±2.8	19.5±3.5	0.89
Time from induction to removal of FM (s)	63±6	63±8	1.0
Time from induction to intubation (s)	74±7	74±10	1.0

Values are mean±SD, median [range] or number of patients. MPC, Mallampati class; ASA, American Society of Anesthesiologists

Table 2: FiO_2 and EtO_2 values following pre-oxygenation in the two groups

Parameter	Group FM (n=36)	Group NC (n=36)
FiO_2%	90±4	93±5
EtO_2%	86±5	89±5
$FiO_2 - EtO_2$	4	4

Values are Mean±SD

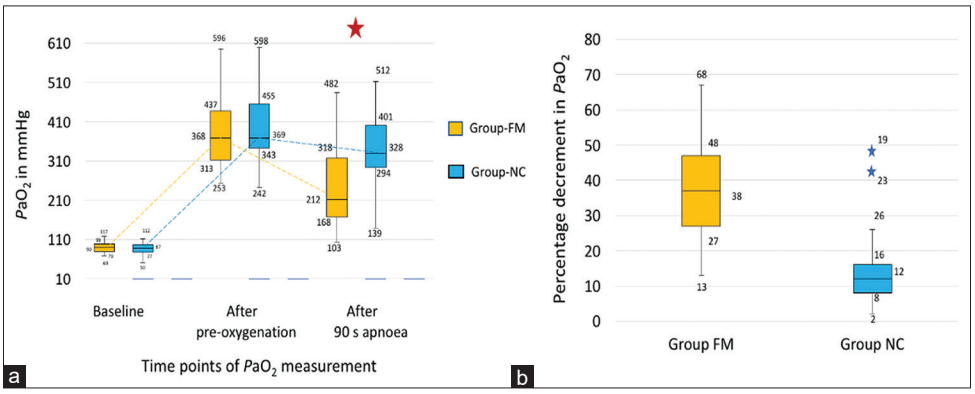

Figure 2: Box and whiskers plots. Box shows the median and 25–75 dispersion and the whiskers the range. (a) PaO_2 at different time points in the two groups. ★ Indicates significant difference between the two study groups. ($P = 0.00$). (b) Percentage decrease in post-apnoea PaO_2 from post oxygenation values in two groups. ★ Denotes extreme values with case number

pre-oxygenation. Although this is often reported to be achieved in 3 min using FGF of 5 L/min with a circle system, we could not achieve that consistently.[12] Machlin *et al.*[13] were able to achieve an EtO_2 of 89% only with a fresh gas flow of 8 L/min. Investigators who have used EtO_2 of 90% as an end-point of adequate pre-oxygenation also mention that this took >5 min in some patients.[4,14] An inadequate face mask seal and low tidal volumes may be confounding factors while interpreting EtO_2.[15] In our study, satisfactory expansion and contraction of the reservoir bag and a capnograph accompanying each exhalation were monitored to ensure that the end-tidal gas values represented alveolar gas concentrations. Further, the EtO_2–FiO_2 difference following pre-oxygenation was only 4%, indicating that a steady-state was achieved in both groups.

Regarding the technique for AO, nasopharyngeal insufflation has shown better efficacy than nasal insufflation.[4,5,7,14,16,17] Hence, we preferred to use nasopharyngeal insufflation in our study. With regard to the patient factors, AO has not been consistently beneficial in critically ill patients.[6,18,19] This is probably because critical care unit and emergency department intubations involve a heterogeneous group of people with varying indications for intubation, in an anarchic situation where the need for imminent intubation often precludes pre-oxygenation. In those with low baseline saturations and in whom pre-oxygenation can be employed, it might only help to push the SpO_2 higher up on the steep portion of the oxygen dissociation curve (ODC), ultimately resulting in an accelerated fall during airway manipulation. White *et al.*[20] in their meta-analysis have also concluded that the technique has not helped patients in respiratory failure. In our study cohort, the baseline PaO_2 with the corresponding SpO_2 values, when plotted on the ODC, lay on the plateau portion and not on the critical steep portion of the curve. This provided an opportunity for enhancing the PaO_2 reserves (PaO_2 of 368 and 369, respectively, in Group-F and Group-NC) with pre-oxygenation rather than merely increasing the SpO_2, showing that AO is advantageous in patients with decreased pulmonary reserves rather than in those with no reserves [Figure 4].

Varying flows of O_2 from 5 L/min to 10 L/min have been used by different investigators for AO; however, the optimal flow of O_2 to be used has not yet been investigated. All India Difficult Airway 2016 guidelines for the management of unanticipated difficult intubation in adults recommend the use of 10 to 15 L/min of O_2 insufflation into the pharynx routinely during all intubations.[21]

As the ventilation is paused, the CO_2 entering the alveoli immediately drops from 200 mL/min to 20 mL/min with a consequent increase in $PaCO_2$.[22] In our study, we observed a similar increase in $PaCO_2$ in both groups. In most of our patients, the baseline pH was in the normal range (7.4 ± 0.4 in Group-FM and 7.4 ± 0.4 in Group-NC) despite HCO_3 values of 19.4 ± 2.8 in Group-FM and 19.5 ± 3.5 in Group-NC, indicating a certain extent of respiratory compensation (baseline $PaCO_2$: Group-FM: 32 [range: 25–41] mmHg; Group-NC: 29 [range: 20–39] mmHg), which was taken away once apnoea was induced, thereby resulting in a rapid increase in $PaCO_2$. Although most of the prior studies also point out that AO does not affect ventilation or CO_2 removal, Jain *et al.* and Lee contrarily report a significant decrease in the rise of CO_2 with AO.[22-24] Recently, Booth *et al.*[25] have demonstrated that with the high-flow nasal O_2 technique for AO, the average increase in $PaCO_2$ was 1.8 mmHg/min.

Our study had a few limitations. The study could not be blinded as it involved the insertion of a nasopharyngeal catheter and the O_2 insufflation in the test group produced a buzz that could not be mimicked in the control group. As our study was done on ASA 1 to 3 patients requiring RSI

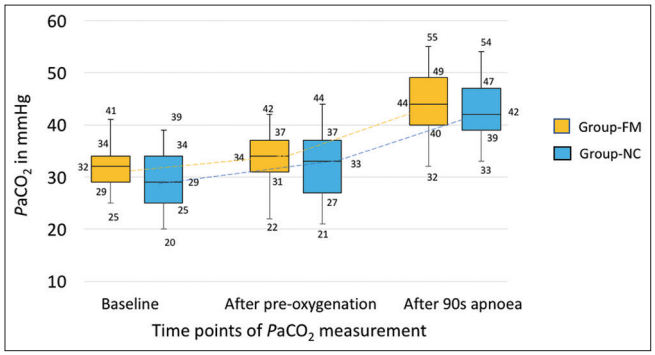

Figure 3: Box and whiskers plot showing the $PaCO_2$ at various time points in the two groups. Box shows the median and 25–75 dispersion and the whiskers the range. There was no significant difference between the two groups

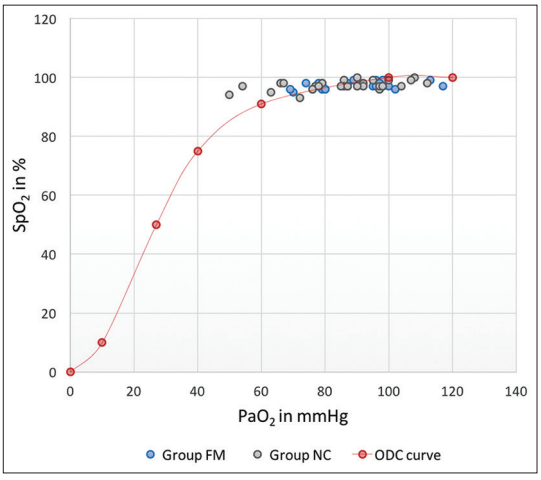

Figure 4: Baseline SpO_2 and PaO_2 values of individual patients in either group plotted on the ODC curve

for emergency laparotomy, we preferred to resume ventilation following 90 s of apnoea, and hence PaO_2 levels were measured to determine the effectiveness of the technique. We did not assess the efficiency of the technique by noting the duration taken for the saturation to drop to 92%.

Conclusion

Apnoeic insufflation of O_2 using a nasopharyngeal catheter along with facemask oxygenation is more effective in sustaining PaO_2 for 90 s during RSI than facemask-only oxygenation in patients undergoing emergency laparotomy despite a steady-state of O_2 uptake attained with either technique at the end of pre-oxygenation.

Key messages

- Apnoeic oxygenation is advantageous in sustaining PaO_2 during RSI in patients undergoing emergency laparotomy.
- Nasopharyngeal O_2 insufflation, a very simple technique for apnoeic oxygenation, is beneficial, particularly when anesthetizing patients with borderline pulmonary reserves.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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