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Does apneic oxygenation with nasopharyngeal cannula during intubation improve the oxygenation in patients with acute hypoxemic respiratory failure compared to the standard bag valve mask preoxygenation? An open-labeled randomized control trial

Irfan Zubair Shahul Hameed, Darpanarayan Hazra, Priya Ganesan*, Abhilash Kundavaram Paul Prabhakar

Department of Emergency Medicine, Christian Medical College, Vellore, Tamil Nadu, India
**Corresponding author*

Abstract:

OBJECTIVES: In the context of acute hypoxemic respiratory failure (AHRF), ensuring effective preoxygenation and apneic oxygenation emerges as the pivotal approach ensuring for averting hypoxemic adverse events during endotracheal intubation. To investigate this, we conducted an open-label randomized controlled trial, aiming to assess the comparative effectiveness of nasopharyngeal high-flow oxygenation in conjunction with Bag-Valve-Mask (BVM) versus standard BVM preoxygenation in patients experiencing AHRF within the emergency department (ED).

METHODS: This prospective single-center, open-labeled, randomized controlled trial enrolled patients aged 18 years and above requiring rapid sequence intubation due to AHRF in the ED. Participants were randomly assigned in a 1:1 ratio to either the intervention arm (involving nasopharyngeal high-flow oxygenation and BVM preoxygenation) or the control arm (involving BVM preoxygenation alone).

RESULTS: A total of 76 participants were enrolled in the study, evenly distributed with 38 individuals in each arm. Median (interquartile range [IQR]) SpO_2 at 0 min postintubation was 95.5 (80%–99%) versus 89 (76%–98%); z-score: 1.081, $P = 0.279$ in the intervention and control arm, respectively. The most common postintubation complications included hypoxia (intervention arm: 56.7% vs. control arm: 66.7%) and circulatory/hypoxic arrest (intervention arm: 39.5% vs. control arm: 44.7%). There were no adverse complications in 36.7% ($n = 11$) of patients in the intervention arm. Despite the best possible medical management, almost half (52.6%) of patients in the intervention arm and 47.4% of patients in the control arm succumbed to their illnesses in the ED.

CONCLUSION: The primary outcome revealed no statistically significant difference between the two arms. However, patients in the intervention arm exhibited fewer intubation-related adverse effects.

Keywords:

Apneic oxygenation, Bag-Valve-Mask preoxygenation, hypoxic arrest, nasopharyngeal cannula, nasopharyngeal high-flow preoxygenation, passive preoxygenation, randomized control trial

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ORCID:
ISHZ: 0009-0007-2491-6354
DH: 0000-0002-5941-0587
PG: 0000-0001-6542-3766
AKPP: 0000-0002-2382-4411

Address for correspondence:
Dr. Priya Ganesan, Department of Emergency Medicine, Christian Medical College, Vellore, Tamil Nadu, India.
E-mail: priyajyotsnav@gmail.com

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Box-ED section

What is already known about the study topic?

- In patients experiencing acute respiratory failure, successful preoxygenation is the sole strategy to prevent hypoxemic adverse events during intubation.

How is this study structured?

- This was a prospective single-centered, open-label randomized control trial conducted in patients presenting to the adult emergency department with acute hypoxemic respiratory failure.

What does this study tell us?

- This study demonstrates that the utilization of nasopharyngeal high-flow oxygenation, in conjunction with Bag-Valve-Mask apneic oxygenation during intubation, is highly effective in preventing the rapid decline of oxygen saturation levels within the initial minutes and is correlated with a reduction in adverse reactions.

What is the conflict on the issue? Is it important for readers?

- There is no conflict on this topic. While studies in the ICU have shown positive outcomes with HFNC preoxygenation, there is a gap in the literature regarding its application in the ED for acutely ill patients. This study was conducted in the ED to investigate potential differences between the two groups, as previously mentioned.

Introduction

Endotracheal intubation plays an integral role in treating critically ill patients who present to the emergency department (ED) with acute hypoxemic respiratory failure (AHRF). The acuity of their presentation, reflecting the urgency of their condition, may necessitate rapid placement of an endotracheal tube (ETT).[1,2]

Rapid sequence intubation (RSI), a technique intended to reduce the time between the loss of airway reflexes and the placement of an ETT in the trachea, is employed.[2-4] Preoxygenation before intubation is crucial to increase body oxygen stores, thereby postponing the onset of arterial hemoglobin desaturation during apnea.[2-4] Severe hypoxemia during RSI increases the risk of arrhythmias, hypoxic brain injury, and cardiac or respiratory arrest.[4-6] As a result, good clinical practice dictates that all patients are preoxygenated with a high fraction of inspired oxygen (O_2) through a tightly fitted face mask. Preoxygenation removes nitrogen from the lungs and fills them with O_2, extending the duration of safe apnea (i.e. the time until desaturation levels of 88%–90% is reached).[4] Obesity, underlying pulmonary disease, and critical illness can also affect safe apnea time.[5-7] Due to underlying critical illnesses such as decreased cardiac output, increased shunting, and reduced pulmonary reserves, critically ill patients experience a shorter safe apneic time, and within seconds, their oxygen saturation (SpO_2) can plummet to a critical hypoxic level of < 70%.[4,5-8] In addition, the risk of adverse outcomes increases with the number of attempts of intubation, thereby worsening hypoxia.[9] Adequate preoxygenation and apneic oxygenation would mitigate some of these negative consequences by preventing hypoxia and allowing for more time to complete successful intubation.[9,10] Apneic oxygenation increases preoxygenation to extend the duration of safe apnea by delivering O_2 at a high fraction of inspired O_2 during intubation attempts.

In the intensive critical care (ICU) settings, studies have shown the efficacy of high-flow nasal cannula preoxygenation, offering promising results.[11,12] This technique involves using a high-flow nasal cannula (15 l) for oxygenation, which does not impede laryngoscopy and thus can provide oxygen to patients during the apneic phase of ET intubation. Sustaining adequate oxygenation during this critical intubation phase is pivotal for patient well-being.

To investigate the hypothesis of achieving similar results, we conducted a prospective, nonblinded, randomized controlled trial in ED patients requiring ET intubation due to AHRF. Our objective was to assess whether apneic oxygenation with a nasopharyngeal cannula, in addition to standard care (i.e. bag valve mask [BVM] preoxygenation), is superior to conventional BVM preoxygenation alone in preventing hypoxic adverse events postintubation.

Methods

Study design and setting

This was a prospective, single-centered, open-label randomized control trial, enrolling patients who required RSI due to AHRF. The study was conducted in the ED of a large tertiary care center in India, serving approximately 75,000 patients annually. The ED has a total of 49 beds, with 9 designated for priority I patients. In situations with an increased number of critically ill patients, priority 2 beds are converted to priority 1 to accommodate additional sick patients.

Selection of participants

Patients aged 18 years and above, presenting to the ED with AHRF (defined as hypoxemia with PaO_2 < 60 mmHg or a 20% drop in saturation from baseline with an indication for intubation), were eligible for inclusion in this study. The study was conducted over 5 months, from April 2021 to August 2021, amid

the COVID-19 pandemic. Patients were enrolled without prior knowledge of their COVID-19 infectivity status, and their care was guided by evidence-based protocols while adhering to standard universal precautions.

Exclusion criteria encompassed the following

Relatives of patients unwilling or unable to provide consent for study participation, pregnant individuals, contraindications to nasopharyngeal cannula insertion (nasopharyngeal obstruction or blockage, nasal bone fractures, and base of skull fractures), and challenging airways characterized by limited neck mobility, restricted mouth opening, or a Mallampati score > 2.

Sample size estimation

Previous literature indicates that, on average, the lowest SpO_2 levels during intubation in patients with hypoxemia were 97.33% ±3.70% when using HFNC and 92% ±10.37% when using nonrebreathing bag reservoir face masks.[13] To detect a 5% mean difference in the lowest SpO_2 level between these two groups, with a 5% α error and 80% statistical power, the study necessitated a sample size of 38 patients in each group with AHRF.

Study methodology

Comprehensive training in the insertion of nasopharyngeal cannulas, oxygenation procedures, and standard preoxygenation protocols was provided to all ED registrars, physicians, technicians, and nurses before the study commenced. The insertion of a nasopharyngeal cannula is a routine procedure and does not necessitate specialized expertise; rather, it is routinely administered as a part of standard care before preoxygenation.

The study protocol, consent forms, and data collection sheets were distributed to their respective workstations. Upon arrival at the ED, patients were randomly assigned to either the intervention group, receiving oxygenation through a nasopharyngeal cannula (15 l) in conjunction with BVM preoxygenation, or the control group, receiving standard BVM preoxygenation alone. The allocation into the intervention and control groups was carried out randomly through sequentially numbered opaque-sealed envelopes.

Both groups underwent a 3 min preoxygenation period before the initiation of apneic oxygenation, as per their respective assignments. Hemodynamic parameters were assessed immediately after intubation (0 min) and subsequently at 5 min intervals for a total of 30 min postintubation. Arterial blood gas samples were collected either from the radial or femoral arteries at baseline, 0 min, 5 min, and 30 min following intubation.

There were only a limited number of trauma patients, all of whom were resuscitated according to the recent Advanced Trauma Life Support guidelines. Similarly, among Chronic Obstructive Pulmonary Disease and asthma patients, there was a small sample size. It is important to note that there were no patients with pulmonary edema in either group, and all cases were managed according to the current evidence-based guidelines, ensuring the absence of bias in this regard. Sedatives and paralyzing agents were administered based on the patient's hemodynamic conditions and blood gas values, following the point-of-care concept and were consistent across both groups, minimizing the likelihood of errors. Adverse events, including arrhythmias, hemodynamic instability, cardiorespiratory arrest, and other intubation-related complications, were meticulously documented following the intubation procedure. Outcome measures were assessed from the moment the patient entered the ED until their admission.

Study Outcomes

Primary outcome

To compare the difference in the lowest SpO_2 levels at 0 min post-intubation between the intervention and control arms.

Secondary outcomes

Adverse events occur during and after intubation, changes in blood pressure, variations in heart rate, instances of aspiration, oropharyngeal injury, and cases of circulatory or hypoxic arrests. Additionally, mortality rates that were observed within the ED.

Bias

The research team systematically collected clinical data rather than relying on attending physicians, ensuring both consistency and objectivity in the process. To minimize potential interviewer bias, a standard set of questions based on those prepared in advance in the clinical research form were asked. Because our study's outcome measures are objective physiological measurements, the risk of bias is extremely low. To mitigate selection bias, we consecutively enrolled patients exhibiting symptoms of AHRF during the study period. They were then randomly assigned to either the intervention or control groups.

Randomization

We used the Block Permutation Statistical Analysis System 9.4, developed by North Carolina State University, to randomize treatment allocation in block sizes of 2, 4, and 6. Randomization was accomplished through computer-generated block randomization. Sequentially numbered opaque-sealed envelopes were provided to patients for allocation into the intervention and control groups. However, due to the nature of the intervention, blinding of the treating clinician, ED staff, and patients postallocation was not feasible.

Data (or statistical) analysis

We conducted the data entry and analysis using the Statistical Package for the Social Sciences (SPSS) for Windows software released 2015, version 23.0, Armonk, New York, United States of America, released in 2021. Demographic and clinical characteristics were summarized, with continuous data exhibiting a normal distribution analyzed using *t*-tests, and nonnormally distributed data assessed through the Mann–Whitney U-test. Categorical variables, such as gender, comorbidities, reasons for intubation, LEMON criteria, complications postintubation, and ED outcomes, were presented in terms of frequencies and percentages, and the Chi-square test was applied to assess categorical variables. Spearman's correlation analysis was employed to evaluate the strength and direction of the association between two sets of ranked variables, whereas the analysis of variance analysis was utilized to assess the variance of means among multiple groups. Results were considered statistically significant when $P < 0.05$.

Ethical considerations

This study was approved by the Institutional Review Board (IRB Min no: 13670 dated December 16, 2020) and Clinical Trial Registry-India: (CTRI)/2021/04/032993 before the commencement. Patients were recruited after written informed consent was provided by the next of kin or an emergent procedure (investigator signature) if the next of kin were not available. Patient confidentiality was maintained using unique identifiers and password-protected data entry software with restricted users.

Results

Our study included 76 patients requiring RSI in the ED. These patients were randomly assigned to two groups: the intervention group (n = 38) and the control group (n = 38) using sealed envelopes. The study flow is depicted in Figure 1 following the Consolidated Standards of Reporting Trials.

The mean age in the intervention and control arms was 48 (standard deviation [SD]: 2.8) years and 44 (SD: 2.5) years, respectively, with a male predominance noted in the intervention (n = 26; 47.3%) and control (n = 29; 52.7%) groups. Common comorbidities included diabetes mellitus (31.6% vs. 15.8%) and hypertension (15.8% vs. 15.8%). Baseline hemodynamic variables included tachypnea (respiratory rate > 22/min) (26.3% vs. 31.6%), tachycardia (heart rate ≥ 100 b/min) (71.1% vs. 76.3%), shock (systolic blood pressure [BP] ≤90 mmHg) (47.4% vs. 34.2%), and hypoxia (SpO_2 ≤ 94 mmHg) (44.7% vs. 57.9%), as detailed in Table 1. Airway descriptions and difficulties at baseline are presented in Table 2.

Figure 2 illustrates the Box and Whisker Plot diagram, presenting the study's primary outcome, which is the difference in the lowest SpO_2 levels postintubation (0 min) between the intervention and control arms. SpO_2 was higher in the intervention arm at 0 and 5 min with a median (IQR) of 95.5 (80%–99%) and 98 (93%–100%), respectively. At 30 min, the control arm had higher SpO_2 levels with a median (IQR) of 98 (94%–100%). However, this difference was not statistically significant at any of the three time points. The most prevalent postintubation complications included hypoxia (intervention arm – 56.7% vs. control arm – 66.7%) and circulatory/hypoxic arrest (intervention arm–39.5% vs. control arm – 44.7%). Postintubation vitals, such as tachycardia and hypoxia, were higher at 0 min in the control arm (77% and 12%) than in the intervention arm (73% and 53%). However, shock (systolic BP ≤ 90 mmHg) was more prevalent (47.4%) in the intervention arm. About 57% of the participants in the intervention arm and 67% in the control arm experienced hypoxia postintubation. The partial pressure of oxygen (pO_2) levels was higher in the control arm at 0 and 5 min, with a median (IQR) of 66 (46–87) mmHg and 98 (91–100) mmHg, respectively. As expected, at 30 min, pO_2 was higher in the intervention arm with a median (IQR) of 114 (81–200) mmHg [Table 3]. Nevertheless, these differences were not statistically significant at any of the three time points.

Despite optimal medical management, almost half (52.6%) of patients in the intervention arm and 47.4% of patients in the control arm succumbed to their illnesses in the ED.

Discussion

In this trial, patients were randomly assigned to one of two groups. The intervention group received 15 l of oxygen through a nasopharyngeal cannula in addition to standard preoxygenation with BVM, whereas the control group received only standard preoxygenation. Effective preoxygenation was achieved using a BVM with a 15 l O_2 flow rate for 3 min or 8 vital capacity breaths, based on recent physiological literature.[14] During apnea, there is a transfer of approximately 250 ml/min of O_2 from the bloodstream to the alveoli, along with the movement of about 8–20 ml/min of CO_2 into the alveoli, leading to alterations in alveolar pressure and a net gas flow from the pharynx to the alveoli.[4] To optimize apneic oxygenation efficacy, we implemented several measures, including ensuring correct patient positioning, avoiding cricoid pressure, and extending the duration of apneic oxygenation. As part of our study protocol, all patients received 3 min of preoxygenation before intubation.

Premedication was administered to all patients following the established protocol, and we carefully monitored

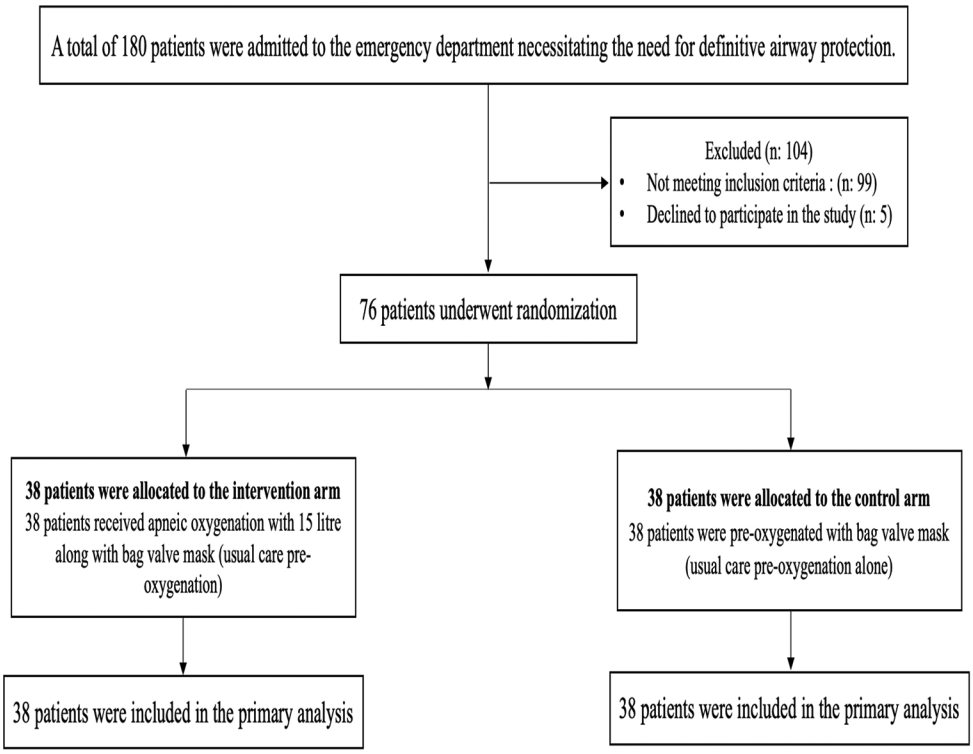

Figure 1: Consolidated standards of reporting trials diagram

Table 1: Baseline characteristics and vital signs at presentation

Factors	Intervention arm (*n*=38), *n* (%)	Control arm (*n*=38), *n* (%)	*P*
Mean age±SD (years)	48±2.8	44±2.5	0.266
Sex ratio			
Male	26 (47.3)	29 (52.7)	0.442
Female	12 (57.1)	9 (42.9)	
Comorbidities			
Diabetes mellitus	12 (31.6)	6 (15.8)	0.105
Hypertension	6 (15.8)	6 (15.8)	1
Cerebrovascular disease	3 (7.9)	0	0.077
Ischemic heart disease	2 (5.3)	0	0.152
Chronic liver disease	0	2 (5.3)	0.152
Others*	3 (7.9)	4 (10.5)	0.692
Reason for intubation			
Low sensorium (CVA/trauma)	5 (13.2)	4 (10.5)	0.363
Gasping	11 (28.9)	7 (18.4)	
Impending circulator or hypoxic arrest	4 (10.5)	2 (5.3)	
Impending respiratory failure	22 (57.9)	25 (65.8)	
Vital signs at presentation			
Tachycardia (heart rate ≥ 100 b/min)	27 (71.1)	29 (76.3)	0.602
Tachypnea (respiratory rate>22/min)	22 (57.9)	20 (52.6)	0.613
Shock (systolic BP ≤ 90 mmHg)	18 (47.4)	13 (34.2)	0.243
Hypoxia - SpO_2 ≤ 94 mmHg	17 (44.7)	22 (57.9)	0.251
Low sensorium	20 (52.6)	16 (42.1)	0.358
Arterial blood gas oxygenation before intubation, median (IQR)			
PaO_2/FiO_2 (mmHg)	191 (96–271)	138 (76–228)	0.282
PaO_2 (mmHg)	57 (50–67)	66 (46–87)	0.098
SaO_2 (%)	87 (81–92)	92 (78–96)	0.074

*Reactive airway disease (asthma/chronic obstructive pulmonary disease) and chronic kidney disease. CVA/trauma: Patients eligible for this study included those with acute cerebrovascular accidents or trauma, exhibiting a low level of consciousness (GCS<9) or displaying symptoms of AHRF related to underlying brain conditions, such as tongue fall, noisy breathing, or grunting (air hunger). In addition, trauma patients without contraindications to nasopharyngeal cannulas, such as nasopharyngeal obstruction, nasal bone fractures, base of skull fractures, or difficulty in airway management due to reduced neck movement, were also included. SD: Standard deviation, CVA: Cerebrovascular accident, BP: Blood pressure, IQR: Interquartile range, GCS: Glasgow coma scale, AHRF: Acute hypoxemic respiratory failure

Table 2: Airway descriptions and difficulties at presentation

Variables Airway description	Intervention arm (*n*=38), *n* (%)	Control arm (*n*=38), *n* (%)
Normal – externally	37 (97.4)	37 (97.4)
Abnormal facies	1 (2.6)	1 (2.6)
Facial injuries	1 (2.6)	2 (5.3)
Burns	0	0
Thick beard	0	2 (5.3)
3-3-2 (mouth opening 3 fingers width)	37 (97.4)	37 (97.4)
3-3-2 (mentum hyoid distance 3 fingers)	38 (100)	38 (100)
3-3-2 (notch of thyroid cartilage 2 fingers)	38 (100)	38 (100)
Obesity	4 (10.5)	4 (10.5)
Obstruction	0	0
Neck mobility both flexion and extension present	35 (92.1)	35 (92.1)
Cormack–Lehane grading 1–2	24 (63.2)	18 (47.4)

Table 3: Primary and secondary outcomes of our study

Variables	Intervention arm (*n*=38)	Control arm (*n*=38)	*Z*-score	*P*
Primary outcome (postintubation)				
Median SpO_2 at 0 min (IQR) %	95.5 (80–99)	89 (76–98)	1.081	0.279
Secondary outcome (postintubation) (IQR) %				
Median SpO_2 at 5 min	98 (93–100)	98 (91–100)	0.954	0.340
Median SpO_2 at 30 min	97.5 (93–100)	98 (94–100)	0.287	0.774
Median pO_2 at 0 min	57 (50–67)	66 (46–87)	−1.625	0.098
Median pO_2 at 5 min	98 (91–100)	75 (62–98)	0.883	0.212
Median pO_2 at 30 min	114 (81–200)	99.5 (77–190)	0.996	0.333
Intubation-related adverse events				
Pulse rate at 5 min	119 (82–138)	111 (94–129)	0.785	0.432
Pulse rate at 30 min	119 (91–135)	106 (89–122)	0.889	0.374
Respiratory rate at 5 min	18 (18–21)	18 (18–20)	0.833	0.405
Respiratory rate at 30 min	18 (18–20)	18 (18–20)	0.650	0.516
Systolic BP at 5 min	110 (80–150)	100 (60–140)	0.849	0.396
Systolic BP at 30 min	110 (90–140)	110 (90–130)	0.946	0.344
Circulatory/hypoxic arrest	15 (39.5)	17 (44.7)	0.723	0.395
Mortality rate in ED after intubation	20 (52.6)	18 (47.4)	1.105	0.575

IQR: Interquartile range, ED: Emergency department, BP: Blood pressure

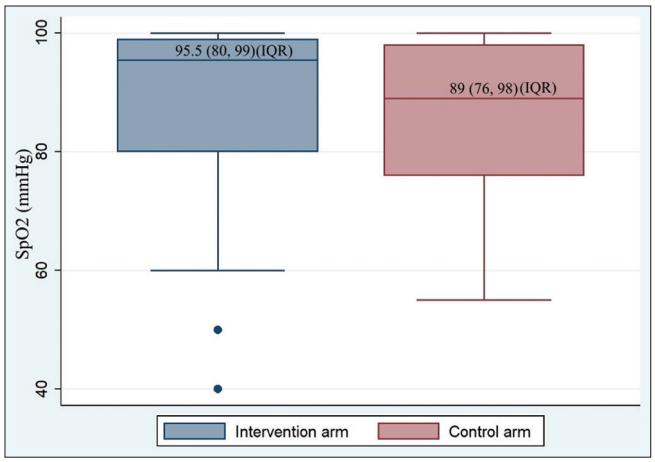

Figure 2: Box Whisker plot diagram, presenting the study's primary outcome. SpO_2 was higher in the intervention arm at 0 and 5 min with a median (interquartile range) of 95.5 (80%–99%) and 98 (93%–100%)

BVM ventilation to prevent overuse. Despite thorough randomization, the baseline characteristics of our study population exhibited minimal variations. Preintubation vital signs, such as hypoxia, tachypnea, and tachycardia, were comparable between both groups, except for a higher incidence of shock in the intervention group. However, most patients in both groups had a Cormack–Lehane Grade of 1 or 2, and the primary indication for requiring a definitive airway was impending respiratory failure.

Laryngoscopy and tracheal intubation can have adverse effects, making RSI heavily reliant on preoxygenation and apneic oxygenation.[15,16] This approach can result in complications postintubation, including hypoxia, hypoxic brain injury, cardiac arrhythmias, circulatory failure, and even hypoxic or cardiac arrests.[17-19] Studies conducted in operating theaters have indicated that the use of apneic oxygenation can prolong the time until postintubation desaturation, leading to improved outcomes. However, studies carried out in ICU and ED settings have produced conflicting results.[20-23] This disparity may be attributed to various factors, including the acuity and seriousness of patients presenting at the ED with severe oxygen deprivation on the horizon,

uncertainties regarding their pulmonary or systemic conditions, and fasting status.

In light of the impact of COVID-19 on the pulmonary system, our study specifically targeted patients with AHRF undergoing RSI. This patient group typically exhibits compromised lung function, and crucial information such as the duration of disease severity and baseline SpO_2 is unknown.[24,25] Notably, patients were enrolled without prior knowledge of their COVID-19 infectivity status, and their care strictly adhered to evidence-based guidelines while following standard universal precautions. Consequently, no noticeable differences were observed in the management of COVID-19 patients. It is essential to note that our study's primary objective did not encompass a detailed exploration of variations in apneic oxygen levels or duration among these patients, and thus these aspects were not examined.

Our primary objective was to evaluate the effectiveness of apneic oxygenation in both study groups. However, we observed no statistically significant difference in apneic oxygenation efficacy between the usual care and intervention groups. The introduction of nasopharyngeal cannula apneic oxygenation did not appear to mitigate the incidence of hypoxia during intubation, nor did it yield a statistically significant difference in the prevention of post-intubation adverse events. These findings align with those of Vourch *et al*.'s study, which reported similar results.[26] In addition, in a study conducted by Semeler *et al*., which involved 150 patients undergoing tracheal intubation in the medical ICU, and who were randomly assigned to receive either 100% oxygen through HFNC or no additional oxygen during laryngoscopy, the results indicated no significant statistical difference in the occurrence of hypoxia between the two groups.[27] However, in our study, hypoxia emerged as the most common postintubation complication, followed by cardiac/hypoxic arrest, particularly when compared to the intervention arm.

Limitations

Several considerations must be acknowledged regarding this study. First, the relatively small sample size constrained certain analyses and likely influenced study outcomes. The sample size calculation relied on data from a single preliminary study, introducing potential bias. Notable male predominance in the control group, anatomical variations such as the presence of thick beards, and variability in Cormack–Lehane grades between groups may have impacted intubation results. Consequently, the study's capacity to draw robust conclusions about secondary outcomes was limited. Conducted during the COVID-19 pandemic, the study could have benefited from assessing patients' infectivity status and a more direct comparison between the intervention and control arms. Moreover, maintaining consistent seniority among intubators was challenging amid the pandemic's "all hands on deck" situation. These limitations should be considered when interpreting the study's findings.

Conclusion

Our study involving 76 ED patients undergoing RSI found that the intervention group did not demonstrate a statistically significant decrease in the occurrence of hypoxia during intubation or the prevention of postintubation adverse events when contrasted with the control group. Despite the absence of statistical significance, the intervention yielded elevated arterial SpO_2 levels and hinted at a potential reduction in complications, indicating possible clinical advantages.

Author contributions statement

IZ: Conceptualization. Data curation, Investigations, Methodology, Resources, Writing – original draft, Writing – review and editing

DH: Data curation, Formal analysis, Investigations, Methodology, Resources, Writing – original draft, Writing – review and editing

PG: Conceptualization, Investigations, Methodology, Project administration, supervision, Writing – review and editing

KA: Conceptualization, Formal analysis, Investigations, Methodology, Project administration, supervision, Writing – review and editing.

Conflicts of interest

None Declared.

Ethical approval

This study was approved by the Institutional Review Board before the commencement of the study (IRB Min no: 13670 dated 16/12/2020) Christian Medical College and Hospital, Vellore, India, and Clinical Trial Registry-India, CTRI/ 2021/04/032993,). Patient confidentiality was maintained using unique identifiers and password-protected data entry software with restricted users.

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