

EFFICACY OF A NOVEL 3D PRINTED FACEMASK WITH AN INTEGRATED AND DETACHABLE NASAL CANNULA FOR PROVIDING APNEIC OXYGENATION BY ASSESSING ARTERIAL PARTIAL PRESSURE OF OXYGEN DURING LARYNGOSCOPY AND INTUBATION IN ADULT

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ABSTRACT:

Background: Laryngoscopy and endotracheal intubation necessitate a period of apnea, during which the risk of oxygen desaturation poses significant clinical concern. Apneic oxygenation techniques, such as high-flow nasal oxygen, have been shown to mitigate this risk. Leveraging advancements in 3D printing, we developed a novel face mask with an integrated, detachable nasal cannula designed to improve oxygen delivery during airway management. This study was conducted to assess the effectiveness of a 3D-printed face mask with integrated nasal prongs in maintaining arterial oxygenation (PaO₂) during the apneic phase of laryngoscopy and intubation compared to a conventional face mask with a separate nasal cannula.. Methods: A prospective, randomized controlled trial was conducted on 76 adult patients undergoing elective surgery under general anesthesia with endotracheal intubation. Participants were randomized into two groups: Group A used the novel 3D-printed face mask with integrated nasal cannula; Group B used a standard face mask with a separate nasal cannula. Primary outcome measured was PaO2 at the end of the apneic period. Secondary outcomes included PaCO2 levels and clinician-rated ease of mask ventilation on a 5-point Likert scale. Results:Demographic and baseline clinical parameters were comparable between groups. Group A demonstrated significantly higher PaO2 at the end of the apneic period $(420 \pm 30 \text{ mmHg})$ compared to Group B $(380 \pm 40 \text{ mmHg})$; p<0.01). PaCO₂ accumulation was significantly lower in Group A (45 ± 6 mmHg) versus Group B (50 ± 8 mmHg; p<0.01). Ease of mask ventilation was rated superior in Group A (mean Likert score

 4.5 ± 0.5) compared to Group B (3.2 ± 0.8 ; p<0.01). **Conclusion:** The 3D-printed face mask with integrated nasal cannula significantly enhanced oxygenation and reduced carbon dioxide retention during apnea while improving the ease of mask ventilation. This novel device may represent a valuable advancement in airway management, particularly in scenarios requiring prolonged intubation efforts.

Keywords: Oxygen Inhalation Therapy, Airway Management, Intubation, Intratracheal Laryngoscopy



INTRODUCTION:

Laryngoscopy and endotracheal intubation are fundamental procedures in airway management during general anesthesia and critical care. These interventions, however, require a temporary cessation of ventilation, posing a risk of rapid oxygen desaturation, particularly in patients with compromised pulmonary function or those suffering from critical illnesses. Hypoxemia during intubation is a serious concern as it can lead to severe complications such as cardiac arrest or irreversible neurological injury.1 To mitigate these risks, maintaining adequate oxygenation throughout airway manipulation is essential for patient safety. Traditional preoxygenation methods aim to build up oxygen reserves in the lungs and bloodstream, extending the duration a patient can tolerate apnea without significant desaturation. While these techniques are generally effective, they often fall short in certain populations, including patients with reduced functional residual capacity or elevated oxygen consumption—such as individuals with obesity, pregnancy, or systemic infections like sepsis. In such cases, oxygen saturation can drop within mere seconds of apnea onset, leaving clinicians with little time for securing the airway.2

To address this limitation, apneic oxygenation has emerged as a valuable adjunct technique. It delivers oxygen continuously even during apnea, utilizing the physiological principle that oxygen diffusion into pulmonary circulation continues in the absence of active breathing, provided the airway remains open. High-flow nasal oxygen (HFNO) systems— including the Transnasal Humidified Rapid-Insufflation Ventilatory Exchange (THRIVE)—have been developed to support this process.3 These systems provide warmed, humidified oxygen at high flow rates, generating a low level of positive airway pressure that keeps alveoli open, prevents atelectasis, and optimizes oxygenation. The clinical benefits of apneic oxygenation are increasingly supported by scientific evidence. Numerous studies, including systematic reviews and meta-analyses, have shown that applying apneic oxygenation during laryngoscopy and intubation reduces the incidence of hypoxemia and its associated complications. Extending the safe duration of apnea allows anesthesiologists and emergency physicians additional time to perform airway interventions, which is particularly advantageous when dealing with anticipated difficult intubations.4

Concurrently, the rise of 3D printing technology has transformed the development of medical devices, enabling fast, cost-effective production of highly customized tools and implants.5 This additive manufacturing method allows devices to be precisely tailored to match a patient's unique anatomy, enhancing both function and comfort. 6 In medicine, 3D printing has been used to create a variety of products, including prosthetics, surgical instruments, implants, and detailed organ models for preoperative planning. Building on these technological advancements, this study introduces a novel 3D-printed face mask specifically designed to improve apneic oxygenation during laryngoscopy and intubation.8 The mask features an integrated and detachable nasal cannula, effectively merging two essential airway management tools into a single, versatile device. Its customized anatomical fit minimizes air leakage and optimizes oxygen delivery efficiency, while allowing patient-specific adjustments.8

The integrated nasal cannula provides continuous oxygen flow during apnea without interfering with mask positioning. When not needed, the cannula can be easily detached without disrupting the mask's seal or functionality. This dual-purpose design simplifies the intubation process by eliminating the need for multiple devices, streamlining clinical workflows, and potentially enhancing patient safety.7 The use of 3D printing for this mask offers several notable benefits: rapid prototyping, precise patient-specific customization based on facial contours, and incorporation of design elements—such as the detachable cannula—that would be difficult to achieve through conventional manufacturing methods. Furthermore, production can be scaled and adapted to suit various patient demographics and clinical scenarios.9

In summary, the development of this innovative 3D-printed face mask with an integrated nasal cannula addresses the longstanding challenge of ensuring adequate oxygenation during airway management procedures. By improving oxygen delivery during the critical apneic phase, the device may reduce the risk of peri-intubation hypoxemia and related complications. Its design simplifies airway management, reduces equipment clutter, and enhances procedural efficiency.8 The primary aim of this study is to assess the effectiveness of the 3D-printed face mask with its integrated, detachable nasal cannula in maintaining arterial oxygen levels (PaO₂) during the apneic phase of laryngoscopy and intubation, compared to a conventional setup using a standard face mask and separate nasal cannula. Secondary objectives include evaluating the device's ability to maintain arterial carbon dioxide levels (PaCO₂) and determining clinician action are of mask ventilation using a 5-point Likert scale relative to the traditional equipment configuration.



MATERIALS AND METHODS

A prospective, randomized controlled trial (RCT) was conducted at Saveetha Medical College & Hospital, Chennai, to compare the performance of the 3D-printed face mask (with an integrated and detachable nasal cannula) to that of a conventional face mask paired with a separate nasal cannula used for apneic oxygenation.

Design and Conceptualization:

A novel 3D-printed face mask was created to integrate both preoxygenation and apneic oxygenation functions into a single device. This mask was specifically designed to merge the features of a standard face mask with those of a separate nasal cannula. It incorporated detachable nasal prongs that allowed continuous oxygen delivery even after the mask was removed during laryngoscopy and intubation procedures.

3D Modeling and Prototyping:

Using computer-aided design (CAD) software, the mask model was designed to ensure a secure and comfortable fit, providing an effective seal for preoxygenation and facilitating easy removal of the nasal cannula. The prototype was fabricated using 3D printing technology with polylactic acid (PLA), a biocompatible and sterilizable material. Multiple versions of the prototype were produced, tested for fit and usability, and then refined based on feedback from practicing anesthesiologists to optimize performance and comfort.

Validation and Testing:

Prior to clinical application, the mask underwent a series of tests using a manikin to assess its ability to maintain an airtight seal during ventilation and to deliver oxygen effectively through the detachable nasal prongs. Both static seal evaluations and dynamic testing during simulated ventilation and intubation scenarios were performed. Additional assessments included ease of use, cleaning, and potential for reuse. After satisfying all safety, functional, and operational criteria, the mask prototype was approved for clinical evaluation

Based on a hypothesized moderate effect size (15 mmHg difference in PaO₂, with an estimated standard deviation of 20 mmHg), a power of 90%, and a significance level of 0.05, the required sample size was calculated as 38 participants per group, totaling 76 participants. Those patients aged 18 to 50 years and scheduled for elective surgeries requiring general anesthesia, endotracheal intubation, and controlled ventilation and fitting into class I to III of American Society of Anesthesiologists (ASA) physical status were included in the study. Those participants with dnticipated difficult mask ventilation, nasal abnormalities including obstruction, deviated nasal septum, chronic sinusitis, recent nasal surgery, or other conditions impairing nasal oxygen flow, Pre-existing pulmonary diseases., Low preoperative oxygen saturation levels and patients unwilling to participat were excluded from the study.

Randomization and Group Allocation:

Participants were randomly assigned into two groups (groupA & using a computer-generated randomization program . For Group A study subjects, preoxygenation and apneic oxygenation using the novel 3D-printed face mask with integrated nasal prongs was given whereas standard face mask along with separate nasal canula was used as oxygen source for Preoxygenation and apneic oxygenation among group B study subjects.

Intervention Procedure:

On the day of surgery, after routine pre-anesthetic evaluation and obtaining informed consent, patients were taken to the operating room. Standard monitors were applied, including electrocardiography, non-invasive blood pressure, pulse oximetry, and end-tidal carbon dioxide monitoring. An intravenous line was secured, and fluid therapy was initiated. Preoxygenation was standardized for both groups using 8 liters per minute (L/min) of oxygen for five



minutes: Anesthesia induction was done using following medications: Glycopyrrolate 0.2 mg IV, Midazolam 2 mg IV, Fentanyl 2 μg/kg IV and Propofol 2 mg/kg IVAfter confirming the ability to ventilate via mask, atracurium 0.5 mg/kg IV was administered, followed by continued mask ventilation for 3 minutes.

During laryngoscopy and intubation:

For Group A study participants, the face mask was removed while keeping the detachable nasal prongs in place, delivering oxygen at 6 L/min for apneic oxygenation. And for Group B study participants, the conventional mask was removed while the separate nasal cannula continued delivering oxygen at 6 L/min.

Data Collection:

Arterial blood samples were obtained at two time points: one at the start of apneic phase (immediately before laryngoscopy) and another at the end of the apneic phase (just prior to the first post-intubation breath). The primary outcome measured was arterial oxygen partial pressure (PaO₂). Secondary outcomes included arterial carbon dioxide partial pressure (PaCO₂) and the ease of mask ventilation, rated by clinicians using a 5-point Likert scale. Statistical Analysis:

Descriptive statistics were used to summarize baseline characteristics. Primary (PaO₂) and secondary outcomes (PaCO₂, ventilation ease) were compared using t-tests or non-parametric equivalents, depending on the data distribution. A p-value less than 0.05 was considered statistically significant. Ethical Considerations:

The study protocol was approved by the Institutional Ethics Committee of Saveetha Medical College & Hospital. All patients gave written informed consent, and confidentiality was maintained throughout the study period

Results: Table 1-Demographic details of the study subjects (N=)

S.No	Variable	Group A (n=38)	Group B(n=38)	Total (N=76)
1	Mean Age	35.2+8.5	34.8+9	35+8.7
2	Gender			
	Male			
	Female	20 (52.6%)	19 (50%)	39
		18 (47.4%)	19(50%)	37

Table 2- Clinical parameters of the study subjects (N=76)

S.No	Variable	Group A (n=38)	Group B(n=38)	Total (N=76)
1	ASA grade			
	I			
	П	15 (39.4%)	16 (42.1%)	31
	II	18(47.4%)	17(44.7%)	35
		5(13.2%)	5(13.2%)	10



2	Spo2	98.2±1	98±1.2	98.1±1.1
3	Body mass Index	24.5±3.2	24.8±3.5	24.6±3.3

The demographic and clinical characteristics of the study participants were comparable between Group A and Group B, ensuring homogeneity between the groups. The mean age of participants was 35.2 ± 8.5 years in Group A and 34.8 ± 9 years in Group B, with no significant difference observed. The gender distribution was nearly identical in both groups, with Group A comprising 52.6% males and 47.4% females, and Group B comprising 50% males and 50% females, eliminating gender as a potential confounding variable. Similarly, the distribution of ASA physical status classification was comparable between groups, with the majority of participants belonging to ASA Grades I and II, and an equal proportion (13.2%) of ASA Grade III patients in each group. Baseline clinical parameters, including oxygen saturation (SpO₂) and body mass index (BMI), also showed no statistically significant differences, with mean SpO₂ values of $98.2 \pm 1\%$ in Group A and $98 \pm 1.2\%$ in Group B, and mean BMI values of 24.5 ± 3.2 kg/m² and 24.8 ± 3.5 kg/m², respectively.

Table 3- Comparison of PaO2 Levels (mmHg) Between Groups A and B

S.No	PaO2	Group A (n=38)	Group B(n=38)	P value
1	Start of Apneic period	450 ± 25	445 ± 30	0.45
2	End of Apneic period	420 ± 30	380 ± 40	<0.01

Table 4- Comparison of PaCo2 Levels (mmHg) Between Groups A and B

S.No	PaCo2	Group A (n=38)	Group B(n=38)	P value
1	Start of Apneic Period	40 ± 5	41 ± 6	0.35
2	End of Apneic Period	45 ± 6	50 ± 8	<0.01

When comparing intraoperative respiratory parameters, the PaO_2 levels at the start of the apneic period were similar between the two groups (450 ± 25 mmHg in Group A vs. 445 ± 30 mmHg in Group B; p=0.45), indicating equivalent pre-apneic oxygenation. However, at the end of the apneic period, Group A maintained significantly higher PaO_2 levels (420 ± 30 mmHg) compared to Group B (380 ± 40 mmHg), with this difference being statistically significant (p<0.01). This suggests that the intervention in Group A was more effective in preserving oxygenation during apnea. Regarding carbon dioxide retention, initial $PaCO_2$ levels were similar between groups (40 ± 5 mmHg in Group A vs. 41 ± 6 mmHg in Group B; p=0.35), but Group B exhibited a significantly greater rise in $PaCO_2$ at the end of the apneic period (50 ± 8 mmHg) compared to Group A (45 ± 6 mmHg; p<0.01), indicating more efficient carbon dioxide elimination or less accumulation in Group A.



Table 4-Comparison of Ease of Mask Ventilation (using Likert Scale Scores)among Group A& Group B

S.No	Variable	Group A (n=38)	Group B(n=38)	P value
1	Ease of Mask Ventilation	Mean + Standard deviation		<0.01
	(Mean Likert Scale scores)	4.5+0.5	3.2+0.8	

DISCUSSION

The present study evaluated the efficacy of a novel 3D-printed face mask with integrated nasal prongs (Group A) compared to the conventional face mask with a separate nasal cannula (Group B) in maintaining oxygenation and ventilation parameters during the apneic period of intubation. The demographic and baseline clinical characteristics, including age, gender distribution, ASA physical status, BMI, and baseline SpO₂, were comparable between the two groups, ensuring homogeneity and minimizing confounding factors that could influence outcomes.

A significant finding of this study was the superior maintenance of arterial oxygen tension (PaO₂) in Group A. At the end of the apneic period, Group A exhibited significantly higher PaO₂ levels (420 ± 30 mmHg) compared to Group B (380 ± 40 mmHg; p<0.01). This indicates that the 3D-printed mask provided more effective and continuous oxygen delivery, likely due to its integrated nasal prongs that allow uninterrupted oxygen flow even when the face mask is removed for laryngoscopy or intubation. In contrast, conventional masks require removal during intubation, disrupting oxygen delivery. This finding is consistent with previous literature, including the Cochrane review by Klitgaard et al. (2023), which emphasized the importance of higher inspired oxygen fractions (FiO₂) in maintaining adequate oxygenation in critically ill patients. The uninterrupted oxygen delivery capability of the 3D-printed mask aligns with these principles, offering a distinct advantage in prolonging the safe apneic window during airway management. 10

In addition to superior oxygenation, Group A demonstrated significantly lower arterial carbon dioxide tension (PaCO₂) levels at the end of the apneic period (45 ± 6 mmHg) compared to Group B (50 ± 8 mmHg; p<0.01). This suggests that the 3D-printed mask not only sustained oxygen delivery but also minimized carbon dioxide accumulation during apnea. This observation is clinically relevant as hypercapnia during intubation can lead to acidosis and undesirable cardiovascular effects. Li et al. (2023) similarly stressed the importance of effective ventilation and carbon dioxide clearance in perioperative and critical care settings to avoid adverse outcomes such as hypoventilation-induced complications.11 Furthermore, the ease of mask ventilation, assessed via Likert scale scoring, was significantly better in Group A compared to Group B (p<0.01). This indicates that the ergonomic design of the 3D-printed mask contributed to a more secure fit and seal, facilitating effective ventilation and reducing operator difficulty during mask ventilation. Previous studies, including those by Ryan et al. (2023), have highlighted the role of equipment design in optimizing airway management and improving clinician performance during intubation procedures. The enhanced user experience reported in this study underscores the practical benefits of the 3D-printed mask in clinical settings.12

The favorable outcomes associated with the 3D-printed mask also suggest potential neuroprotective effects. Although cerebral oxygenation was not directly measured in this study, the significantly higher PaO₂ levels maintained in Group A imply a reduced risk of cerebral hypoxia, which is particularly critical in patients at risk for neurological injury. This is supported by Megjhani et al. (2023), who demonstrated that maintaining adequate systemic oxygenation reduces the risk of secondary brain injury in neurologically vulnerable patients.13 Moreover, the results resonate with the concept of maintaining an adequate oxygen reserve during apnea, as described by Zanusso et al. (2023) using the oxygen reserve index (ORi). The ability of the 3Dprinted mask to preserve higher PaO₂ levels suggests its potential to extend the safe duration of apnea, reducing the urgency for rapid intubation and potentially increasing first-pass success rates.14 Innovative oxygenation strategies, such as those explored by Fujii et al. (2023) in experimental models, emphasize the value of continuous oxygen delivery methods in preventing desaturation, a principle that the 3D-printed mask effectively applies in a practical clinical context.15

Another critical consideration is the avoidance of both hypoxia and hyperoxia. Nelskylä et al. (2022) cautioned against excessive oxygenation during resuscitation efforts, noting its potential for oxidative injury. In the present study, PaO₂ levels remained within safe physiological limits, indicating that the 3D-printed mask can optimize oxygenation without risking hyperoxia-related complications. Although this study focused on elective surgical patients, the results suggest potential applicability in high-risk populations, such as those with chronic respiratory diseases or



impaired pulmonary function. 16 Sevik et al. (2025) highlighted the vulnerability of COPD patients to hypoxia, especially in stress situations. The effectiveness of the 3D-printed mask in maintaining oxygenation raises the possibility of its utility in such patient groups, warranting further investigation. 17 Finally, the systemic implications of adequate oxygenation extend beyond the respiratory system. As demonstrated by Rieger et al (2016) and Gruartmoner et al. (2017), oxygenation status influences microcirculation and immune responses, while Katayama et al. (2022) and Steele et al. (2024) reported impacts on cardiovascular function. 18,19,20,21 Though not directly assessed in this study, the ability of the 3Dprinted mask to sustain arterial oxygen levels could have beneficial effects on these physiological systems, especially during prolonged procedures.

Limitations:

Despite these encouraging findings, the study has certain limitations. The sample size was relatively small, and only ASA I–III patients undergoing elective surgery were included, limiting generalizability to critically ill or emergency populations. Long-term clinical outcomes, including postoperative pulmonary complications, were not assessed. Future studies should evaluate the efficacy of this mask in high-risk cohorts, including obese, critically ill, or pediatric populations, and explore potential neurocognitive or immunological benefits associated with sustained oxygenation.

CONCLUSION:

In summary, the 3D-printed face mask with integrated nasal prongs demonstrated clear advantages over the conventional face mask with nasal cannula in maintaining arterial oxygenation and minimizing carbon dioxide retention during apnea. Its user-friendly design and ability to provide continuous oxygen delivery make it a promising adjunct in airway management, potentially improving patient safety and procedural efficiency during intubation. Further large-scale studies are warranted to confirm these benefits in diverse clinical settings.

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