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Original Article

Anaesthesia Section

Efficacy of Apnoeic Oxygenation by Nasal Prongs in Preventing Desaturation during Airway Management in Infants Undergoing General Anaesthesia: A Randomised Controlled Study

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ABSTRACT

Introduction: Neonates and infants are more prone to desaturation during the apnoeic period of laryngoscopy and intubation. Various options exist to reduce this risk beyond conventional preoxygenation.

Aim: To assess whether continuous apnoeic oxygenation via nasal prongs during intubation can extend the safe apnoea period compared to standard management with preoxygenation alone.

Materials and Methods: A randomised controlled, two-group parallel clinical study was conducted at the Department of Anaesthesiology, Vijayanagar Institute of Medical Sciences, Ballari, Karnataka, India, from July 2019 to November 2020. The study involved 63 infants aged one day to six months undergoing elective or emergency surgeries under general anaesthesia. Preoxygenation via a mask was followed by sevoflurane induction and vecuronium-induced muscle relaxation. Conventional laryngoscopy and intubation were performed in 32 infants in Group-C (Control group), while 31 infants in Group-O (Apnoeic Oxygenation group) also received oxygen (O_2) via nasal prongs at 4 L/min in addition to preoxygenation. The primary outcome parameter was the time taken for desaturation by 1%. The time taken to desaturate by 2%, 3%, 4%, and 5%, as well as their incidences, lowest observed saturation, safe apnoea period, and Heart Rate (HR) trends, were also noted. Data were analysed using Statistical Package for Social Sciences (SPSS) version 20.0 and OpenEpi version 3.01.

Results: Demographic and clinical parameters were comparable between the groups. The mean time for 1% desaturation was 18.33±4.3 seconds in Group-C, while all Group-O cases maintained 100% saturation during the study period. No significant difference was found in the safe apnoea period between the groups (p=0.503). The average lowest O_2 saturation observed in Group-C was 98.81±1.28%, while it was 100% in Group-O. Only one infant in Group-C showed desaturation down to 95%. Both groups exhibited similar HR trends.

Conclusion: Apnoeic oxygenation by nasal prongs in healthy infants helps prolong the time to desaturation and can be beneficial for those at risk of desaturation and hypoxia.

Keywords: Co-oxygenation, Hypoxia, Intubation, Nasal oxygen, Paediatric

INTRODUCTION

Infants with normal and difficult airways may experience hypoxaemia due to repeated laryngoscopy attempts during intubation [1]. Airway management is one of the fundamental clinical skills in anaesthesiology. When patients are paralysed in preparation for intubation, they become apnoeic and are not oxygenated or ventilated while the airway is being secured [1,2]. Preoxygenation, which is the standard practice before intubation, aims to maintain oxygen saturation (SpO_2) levels during the apnoeic period and extend the safe apnoea period. The safe apnoea period is defined as maintaining SpO_2 levels above 90% or additional 1% levels upto 95%, depending on the age and physiology of the patient [1,3-6]. It is crucial to maintain oxygen (O_2) levels during the apnoeic period because desaturation below 70% puts patients at risk of hypoxaemia and its complications [7].

Managing the airway of an infant is even more challenging, as there is no room for error in the small airway space. The anatomical and physiological differences in infants result in a shorter safe apnoea period. Neonates and infants, particularly those under six months of age, are prone to brief episodes of O_2 desaturation during laryngoscopy and intubation attempts due to lower Functional Residual Capacity (FRC), high closing volume, higher O_2 consumption rate, and an immature pulmonary apparatus [1,8]. Therefore, it is beneficial to extend the safe apnoea period in infants. Apnoeic oxygenation is a method of continuously delivering O_2 through nasal prongs during the apnoeic period, without obstructing the laryngeal view. It is based on the principle of passive diffusion of O_2 from the conducting airway into the lungs [2,9]. This technique provides a longer safety margin, allowing more time to secure the airway on the first attempt [7].

Many studies supporting apnoeic oxygenation in adults have been found in the literature, but only a few exist in the paediatric population [3,5,8-10]. Olayan et al., conducted a study on apnoeic oxygenation using nasal cannula administered at 3 L/min during apnoea in patients aged 1 to 8 years. The study assessed outcome measures such as safe apnoea time for SpO_2 to fall below 92% and 95% [11]. The intervention group maintained SpO_2 at 100% in all patients. Vukovic AA et al., investigated the benefits of nasal oxygen as apnoeic oxygenation in children in an emergency department and observed a decreased incidence of hypoxaemia. They also emphasised the simplicity of the technique [12]. Apnoeic oxygenation, by extending the safe apnoea time, may reduce the morbidity and mortality rates associated with hypoxia during intubation. Additionally, it can help trainees and novice practitioners

improve their paediatric airway management skills. The aim of the present study was to observe the effects of apnoeic oxygenation during airway management in infants upto six months of age undergoing surgeries under general anaesthesia. The study aimed to assess the prolongation of the safe apnoea time and the time to desaturation by 1%, 2%, 3%, 4%, and 5%, as well as their incidences.

MATERIALS AND METHODS

The present randomised controlled, two-group parallel clinical study was conducted at the Department of Anaesthesiology, Vijayanagar Institute of Medical Sciences, Ballari, Karnataka, India, from July 2019 to November 2020. After obtaining approval from the Institutional Ethics Committee (VIMS/STD.II/PGEC/19/2019-2020) and registering the study under the Clinical Trials Registry of India (CTRI/2019/07/020346), informed and written parental consent was obtained to initiate the study.

Infants scheduled for surgeries under general anaesthesia, without significant systemic diseases (correlated on a case-by-case basis with American Society of Anesthesiologists – (ASA) Physical Status I and II), were included as study subjects. These infants underwent thorough preanaesthetic evaluation and the necessary investigations were performed. Fasting status was advised and confirmed.

Sample size calculation: A previous 3-group study [10], revealed an incidence of desaturation of 49% in the group receiving O_2 by mask for preoxygenation. With nasal oxygenation, the anticipated incidence of desaturation was expected to be reduced by atleast 30% of this value (effect size - 14.7%). With a power of 80% and a 2-sided confidence interval (1-α) of 95% (α-error at 0.05), a total sample size of 56 was required (Fleiss), with 28 patients in each group. Anticipating a dropout rate of upto 15%, a total of 66 infants were considered, with 33 in each group (www.openepi.com).

Inclusion criteria: Term infants between one day and six months scheduled for elective and emergency surgeries, including gastrointestinal surgeries, neurosurgical procedures, urological procedures, and general surgeries, with no anticipated or diagnosed airway problems were included in the study.

Exclusion criteria: Parent/guardian refusal to participate in the study, dental, airway, and thoracic surgeries, anaemia for age, significant systemic conditions, diagnosed congenital diseases including airway disorders and syndromic disorders were excluded from the study.

Study Procedure

After assessing the infants for eligibility, the study subjects were allocated into two groups: Group-C (Control group) and Group-O (Apnoeic Oxygenation group) using computer-generated randomisation (http://www.randomisation.com). Allocation concealment was done using the Sequentially Numbered Opaque Sealed Envelope (SNOSE) technique, and the envelope was opened just before shifting the patient to the operating table.

The infants were transferred to the operating table while wearing warm clothing. Infusion of Ringer's lactate was initiated at a rate based on the infant's weight and expected fluid losses during surgery. A pulse oximeter probe was positioned and secured on the fleshy portion of the infant's right hand, ensuring no gaps between the sensor and probe. A splint was applied from the wrist to the middle phalanges to minimise motion artifacts. Additional monitors, including Electrocardiogram (ECG), Non Invasive Blood Pressure (NIBP), tympanic temperature probe, and End-Tidal Carbon Dioxide ($EtCO_2$) monitoring after intubation, were also applied.

The infants were preoxygenated with 100% O_2 at a rate of 2.5 times the calculated minute ventilation using a Mapleson F circuit. The pulse oximeter probe position and readings on the monitor were confirmed, and fentanyl 2 µg/kg was administered. Sevoflurane induction was performed, followed by neuromuscular blockade with injection vecuronium 0.1 mg/kg intravenously. Bag-mask ventilation was continued for three minutes.

At this stage, laryngoscopy was performed, followed by intubation in Group-C. In Group-O, a paediatric nasal prong (1 cm length) was prepositioned over the face mask and placed over the nares by a trained assistant after removing the mask to facilitate apnoeic oxygenation when the primary anaesthesiologist picked up the laryngoscope. Laryngoscopy was performed using Macintosh blade sizes 0 and 1, based on the standard of care in the Institution.

During laryngoscopy and intubation, infants in Group-O received O_2 at a rate of 4 L/min via nasal prongs, connected to the auxiliary O_2 supply port of the workstation. Infants in Group-C did not receive any O_2 [Table/Fig-1]. Monitoring was continued throughout the apnoeic period. The operating room temperature was maintained at 24°C, and the child was adequately protected with warm towels and padding. Mask ventilation with 100% O_2 was planned to be resumed if saturation dropped below 95% or if bradycardia occurred. If abdominal distension was observed (due to nasal insufflation or mask ventilation), a feeding tube was to be immediately inserted after intubation and the stomach deflated.

[Table/Fig-1]: Nasal prongs during preoxygenation, laryngoscopy and intubation in Group-O. (Images from left to right)

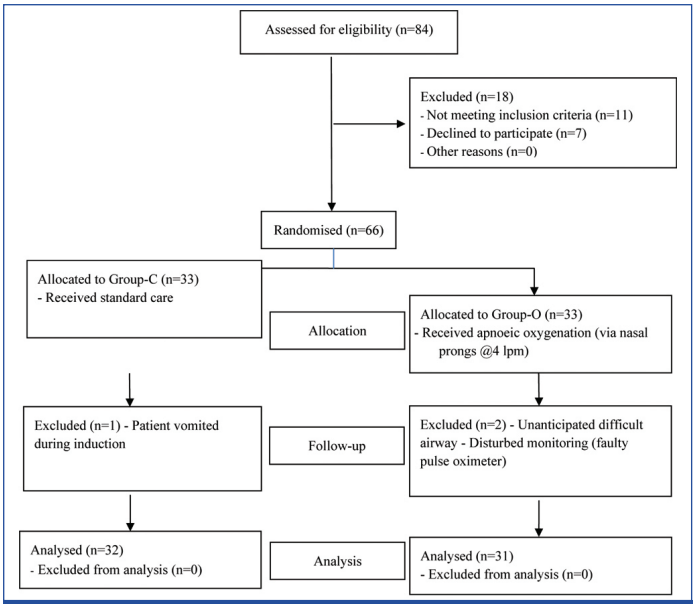
The apnoea period/intubation time was calculated as the time from the end of preoxygenation (mask ventilation) until positive pressure ventilation was reinitiated after confirming the position of the endotracheal tube through 5-point auscultation, capnography value, and tracing. The primary outcome measured was the time taken for saturation to decrease by 1%. The time to decrease in saturation by 2%, 3%, 4%, and 5%, as well as the lowest recorded saturation value during the apnoea period, the safe apnoea time (the duration of apnoea during which the oxygen saturation did not fall below 95%), trends in heart rate, Systolic Blood Pressure (SBP), Diastolic Blood Pressure (DBP), and gastric inflation (if any) were the secondary outcome parameters studied.

STATISTICAL ANALYSIS

Statistical analysis was performed using SPSS® Version 20.0 (IBM SPSS Statistics for Windows, Armonk, NY: IBM Corp; 2011) computer software. Continuous variables were presented as mean±Standard Deviation (SD), and categorical variables were presented as frequency (percentages). The difference between the two groups in terms of continuous variables was assessed using Student's t-test, and categorical variables were analysed using the Chi-square test. A p-value of 0.05 or below was considered statistically significant.

RESULTS

Out of the 84 infants initially screened for eligibility, 66 were randomised into the two groups, and ultimately, 63 infants were included in the analysis [Table/Fig-2]. There were no differences between the groups in terms of patient characteristics, baseline haemoglobin levels, and types of surgeries [Table/Fig-3]. Baseline measurements of SpO_2, HR, SBP, and DBP were comparable between the two groups [Table/Fig-4], and there were no incidences of bradycardia in either group. Both groups maintained SpO_2 at 100% at the end of preoxygenation.



[Table/Fig-2]: Study flowchart.

Characteristics	Group (n)	Mean±SD	
Age (days)	C (32)	84.31±6.17	0.158
	O (31)	61.68±16.40	
Gender (Male:Female)	C (32)	15:17	0.707
	O (31)	16:15	
Weight (kg)	C (32)	4.69±1.53	0.121
	O (31)	4.19±1.42	
Length (cm)	C (32)	58.56±5.78	0.190
	O (31)	56.13±6.49	
Haemoglobin (gm/dL)	C (32)	14.59±1.07	0.215
	O (31)	15.29±2.12	
Types of surgeries (Gastrointestinal: neurosurgical: urological: general surgery)	C (32)	14:7:7:4	0.618
	O (31)	18:7:5:1	
ASA physical status (I:IE:IIE)	C (32)	14:7:11	0.08
	O (31)	8:15:8	

[Table/Fig-3]: Demographics, basal haemoglobin and surgical parameters.

Parameters		Group-C (n=32)		Group-O (n=31)		t-test	p-value
		Mean	SD	Mean	SD		
Baseline	SpO_2 (%)	97.22	1.24	97.48	1.34	0.817	0.417
	HR (bpm)	147.22	13.8	146.58	10.39	-0.207	0.837
	Systolic BP mmHg	76.41	8.67	74.23	8.14	-1.028	0.31
	Diastolic BP mmHg	54.44	6.21	51.55	6.05	-1.87	0.066
At end of preoxygenation	SpO_2 (%)	100	0	100	0	-	-
	HR (bpm)	141.19	14.87	140.52	9.96	-0.21	0.835
	Systolic BP mmHg	70.56	9.89	70.58	7.84	0.008	0.994
	Diastolic BP mmHg	46.31	9.41	48.35	5.59	1.04	0.301

[Table/Fig-4]: Vital parameters- Baseline and at end of preoxygenation.
(SpO_2: Pulse oximetric O_2 saturation; HR: Heart rate; BP: Blood pressure)

In Group-C, desaturation started at an average of 18.33±4.3 seconds, while all infants in Group-O maintained 100% saturation throughout the apnoea period [Table/Fig-5]. In Group-C, all infants had desaturation values falling only upto 95%, with 29 out of 31 infants experiencing falls upto 98%. The p-values for the differences between the two groups in terms of 1%, 2%, and 3% desaturations were significant. The lowest saturation observed in Group-C was 98.81±1.28%, while in Group-O, it was 100% [Table/Fig-6].

Desaturation by	Time taken (Seconds)				t-test	p-value
	Group-C (n=32)		Group-O (n=31)			
	Mean	SD	Mean	SD		
1%	18.33	4.3	0	0	-6.672	<0.0001
2%	24.17	4.7	0	0	-3.689	0.001
3%	27.5	6.5	0	0	-1.971	0.057
4%	30	0	0	0	-1.359	0.184
5%	40	0	0	0	-1	32.1

[Table/Fig-5]: Time to desaturation (seconds) upto 5%.

O_2 desaturation	Group-C (n=32)		Group-O (n=31)		Chi-square test	p-value
	No. of cases	%	No. of cases	%		
1%	21	65.63	0	0	28.33	<0.0001
2%	4	12.50	0	0	11.51	0.023
3%	4	12.50	0	0	3.95	0.023
4%	2	6.25	0	0	0.91	0.34
5%	1	3.12	0	0	0.163	0.68
> 5%	0	0	0	0	-	-
Least values (Mean±SD)	98.81±1.28%		100%		-	0.038

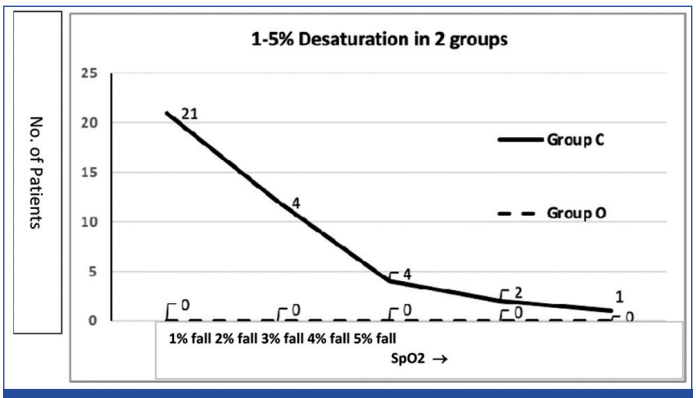
[Table/Fig-6]: Incidence of desaturation (falls, percent-wise).

The safe apnoea period, defined as the duration of apnoea during which the oxygen saturation did not fall below 95%, was 23.06±5.87 seconds in Group-C and 24.06±5.88 seconds in Group-O (p=0.503) [Table/Fig-7].

The incidence of desaturation, categorised by 1% falls, is shown in [Table/Fig-8]. None of the patients in Group-O had falls in saturation, while in Group-C, the majority experienced falls of upto 2% (25 out of 32), and the rest (7 out of 32) had falls between 3% and 5%. Gastric distension was observed in one infant in Group-C (3.10%) and two infants in Group-O (6.50%), but this difference was not statistically significant (p=0.53) [Table/Fig-7].

Variables	Group-C (n=32)	Group-O (n=31)	t-test	p-value
Safe apnoea time (Secs)	23.06±5.87	24.06±5.88	-1.03	0.503
Gastric distension (no. of infants)	1	2	-	0.53

[Table/Fig-7]: Safe apnoea times and gastric distension.



[Table/Fig-8]: Incidence of oxygen desaturation (upto 5%).

DISCUSSION

The use of nasal oxygenation as an additional measure to preoxygenation, known as "co-oxygenation," during airway management in infants via nasal prongs at 4 Litres Per Minute (LPM) resulted in the maintenance of 100% SpO_2 throughout the procedure. On the other hand, preoxygenation alone, as a standard measure, led to falls in SpO_2 ranging from 1% to 5% during the study period. While the second situation is acceptable in normal circumstances in infants, the additional safety provided by maintaining 100%

saturation in Group-O can be beneficial in situations where airway management may be challenging, allowing for longer periods of "safe apnoea" [Table/Fig-5-7]. The safe apnoea period refers to the duration of time until SpO_2 falls below 90% to 95%, depending on the age and the risks associated with critical hypoxaemia during apnoea [1,3]. In preterm infants, maintaining SpO_2 levels at 93% and above is considered safer [6]. In a study conducted by Taha SK et al., in the adult population, desaturation during apnoea was allowed until SpO_2 fell to 95% or until a maximum time limit of six minutes was reached to define the duration of safe apnoea [13]. However, in infants, the rate of desaturation below 92% can be rapid, reducing the response time in those who have only received preoxygenation.

In the present study, the authors considered intervention at SpO_2 <95% as part of the ethical methodology for neonates and infants undergoing emergency and elective surgeries. The time taken for SpO_2 to fall by 1% (to 99%) was considered as an indication of further desaturation that would follow. The fact that there was no fall in SpO_2 at all indicates that nasal oxygenation provides a good cushion against desaturation in the event of prolonged apnoea [Table/Fig-8]. Based on the shape of the oxyhaemoglobin dissociation curve, a fall in O_2 saturation by 1% until 95% is still associated with safe arterial partial pressures of O_2, which is why the authors chose these parameters for the study [6]. Although the study assessed intubation time (apnoea period) as a secondary outcome, there was no statistically significant difference in the safe apnoea period between the two groups (p=0.503). The time taken was comparable between the two groups [Table/Fig-7], which eliminates any potential confounding factors related to this aspect.

Steiner JW et al., conducted a study involving 457 paediatric patients aged 1-17 years, where they compared deep laryngeal oxygen insufflation for apnoeic oxygenation using Truview PCD video laryngoscope or an O_2 cannula attached to the side of a standard laryngoscope with standard direct laryngoscopy [10]. They found that children in the oxygenation groups took a longer time to desaturate by 1% compared to those intubated conventionally (approximately 70 seconds vs 30 seconds).

A patent upper airway is crucial for apnoeic oxygenation. Proper positioning of the airway and using the appropriate-sized laryngoscope blade allows for the delivery of fresh oxygen during apnoea, which continuously replaces the absorbed pulmonary volume through passive diffusion from the larynx to the lungs. This method extends the safe apnoea time by maintaining SpO_2 closer to the inflection point of the haemoglobin oxygen dissociation curve [8]. The potential dilution created by the exposure to atmospheric air with an open airway during laryngoscopy needs to be considered theoretically, but the current study showed no desaturation at all in Group-O.

The use of paediatric nasal prongs at 4 L/min was deemed safe for the duration of airway management. The choice of similar flow rates via nasal cannula in the current study was based on the study conducted by Vukovic AA et al., [12], where 4 L/min was used for patients under two years of age and 6 L/min for ages 2-12 years. Studies involving adults have reported safe flow rates of upto 15 L/min with simple nasal cannula [14,15]. Guidelines recommend adjusting oxygen flow rates to achieve SpO_2 levels above 95% [16]. The brief duration of flow at 4 L/min helps mitigate the risk of mucosal drying.

In a randomised controlled pilot trial by Olayan L et al., involving 30 infants aged 1 to 8 years, the use of nasal cannula at 3 L/min compared to standard care showed no difference in the time for SpO_2 to fall to 92% or the time taken to successfully secure the airway between the two groups [11]. In the apnoeic oxygenation group, SpO_2 was consistently maintained at 100% during airway management, while only six patients in the standard care group were able to maintain 100%. However, even in the control group, desaturation was limited to a maximum of 95%, except for one patient where it dropped to 73%.

In the current study, the lowest recorded saturation was 98.81±1.28% in Group-C, while it was 100% in Group-O (p <0.05). In a randomised study comparing the Miller laryngoscope blade to the Oxiport Miller laryngoscope blade for neonatal and infant intubations, the lowest O_2 saturation during intubation was 95.9%±5.75% in the Miller group and 97.55%±2.93% in the Oxiport group (p=0.049).

The trends in Heart Rate (HR) were similar in Group-C and Group-O in the current study. No incidents of bradycardia were observed during the apnoeic period as further O_2 desaturation below 95% was not allowed. Gastric distension cannot be attributed to nasal oxygenation and may occur due to poor mask fit and positioning in paediatric patients. One patient in Group-C and two in Group-O experienced gastric distension. While gastric rupture has been reported with nasopharyngeal catheters, it has not been associated with peri-intubation nasal cannulas [17]. Caution may be necessary in patients with congenital conditions that make them more susceptible to increased pressures, such as tracheoesophageal fistula, intestinal atresia, gastroschisis, omphalocele, or diaphragmatic hernia.

Limitation(s)

One technical limitation in the study could be the nasal prongs placement possibly interfering with the face mask seal and potential for prongs causing minor trauma. Clear transparent paediatric face masks can allow for better visualisation of the nasal prongs. Nasal prongs insertion by a trained assistant immediately after the end of preoxygenation, when the primary anaesthesiologist readied the laryngoscope and endotracheal tube did not result in any difficulty in present study. Other limitation was that the apnoeic period of this study does not exactly reflect the duration of safe apnoea (as cut-off time, which allows desaturation, was not used in the present study for ethical reasons). Invasive monitoring for arterial blood gases and monitoring oxygen reserve index would have given better insight into O_2 status of the infant including the Partial Pressure of Oxygen (PaO_2) levels. No stratified statistical analysis was done for elective and emergency cases-emergency patients tend to be sicker, dehydrated and may have significant abdominal distention making them more prone to rapid desaturation [8].

CONCLUSION(S)

In ASA I and II infants with a normal airway who were scheduled for elective or emergency surgery under general anaesthesia, apnoeic oxygenation using nasal prongs at 4 L/min resulted in a delay in the time to desaturation by 1%. Oxygen saturation was maintained at 100% throughout the period of apnoea during laryngoscopy and intubation. However, there was no significant difference in safe apnoea times, with saturations upto 95%, between the two groups. In cases where there is a physiologically difficult airway, this technique of "co-oxygenation" can provide an additional safety margin beyond routine preoxygenation with a mask in infants, allowing for higher levels of oxygen saturation to be maintained for a longer period of time.

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