

A Prospective Randomized Controlled Research to Assess the Outcome of Oxiport Laryngoscope Blade Versus Miller Laryngoscope Blade for Intubation in Neonates and Infants During General Anesthesia

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Conflict of interest: Nil

Abstract

Aim: Comparative study of oxiport laryngoscope blade versus miller laryngoscope blade for intubation in neonates and infants during general anesthesia.

Methods: This prospective, randomised, controlled interventional single-blind study conducted in the Department of Anesthesiology & Critical Care Patna Medical College & Hospital, Patna, Bihar, India for 1 year. 80 neonates/infants in groups of 40 each posted for surgery in paediatric operation theatre (OT) over a period of 6 months were included in the study. Full-term neonates and infants up to 6 months of age of either sex requiring general anaesthesia with endotracheal intubation for elective as well as emergency surgery were included in the study.

Results: Out of the 80 patients 40 patients in Miller group and 40 patients in Oxiport group were included. Both groups were comparable with respect to age, sex, weight, mean time to intubation ($P = 0.57$) and anaesthesiologist performing the laryngoscopy ($P = 0.72$). Mean lowest SpO₂ recorded was $96.1\% \pm 4.75\%$ in Miller group and $98.15\% \pm 2.83\%$ in Oxiport group. This difference was statistically significant ($P = 0.041$). The incidence of mild desaturation (SpO₂ up to 90%) was 87.5% in Miller group and 95% in Oxiport group. The incidence of moderate desaturation (SpO₂ between 85% and 92.5%) was 2.5% in Miller group and 5% in Oxiport group. Incidence of severe desaturation (SpO₂ <85%) was 15% in Miller group and 0 in Oxiport group (Chi-square test $P = 0.04$). Correlation between time to intubation and SpO₂ in Miller group (Pearson's R² = -0.12) was statistically not significant at $P = 0.41$. Correlation between time to intubation and SpO₂ in Oxiport group (Pearson's R² = -0.42) was statistically significant at $P = 0.001$. Both groups were comparable with respect to the type of surgery (abdominal, thoracic, miscellaneous) ($P = 0.71$). Abdominal surgeries were associated with a higher number of severe desaturations (70%) compared to thoracic (15%) and miscellaneous (15%) surgeries.

Conclusion: In this study, apnoeic laryngeal oxygen insufflation with Oxiport laryngoscope blade decreased the incidence of severe desaturation while intubating neonates and infants.

This was easily done as it was non-cumbersome and did not increase the overall cost of anaesthesia.

Keywords: Oxiport Laryngoscope Blade, Miller Laryngoscope Blade, Intubation, Neonates and Infants.

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Introduction

One of the most essential skills to master as an anesthetist is the skill of airway management. Endotracheal intubation is essential for the maintenance of airway and to ensure adequate ventilation during various surgical procedures. Endotracheal intubation involves laryngoscopy, for which Macintosh/Miller laryngoscope is the gold standard. Pediatric patients, because of their anatomical differences in airway compared to adults pose many challenges during endotracheal intubation. In neonates, the highly compliant chest wall with a lower functional residual capacity (FRC) and high closing volume results in increased tendency to close at end-expiration [1]. In addition, higher oxygen consumption (7 ml/kg/minute) and an immature pulmonary apparatus make them prone to rapid and early desaturation. This is more likely in pre-term babies who have limited respiratory reserve, prolonged as well as recurrent apnoea or difficult laryngoscopies [2].

Pre-oxygenation is intended to prevent or delay onset of hypoxia during subsequent apnoea. It was Holmdahl who introduced the concept of apnoeic diffusion oxygenation [3]. The theory of apnoeic oxygenation is based on absorption of oxygen into the bloodstream, with the absorbed pulmonary volume being replaced by fresh oxygen pulled from the larynx through the trachea into the lungs. Pharyngeal insufflation of oxygen has been shown to delay the onset of desaturation and hypoxaemia during apnoea by enhancing the safe apnoea duration [4]. This technique supplements pre-oxygenation and provides apnoeic diffusion

oxygenation during laryngoscopy, significantly delaying the desaturation during subsequent apnoea [5].

One such method was fitting a feeding tube to the laryngoscope blade to provide oxygen flow [6] or incorporating a channel along the side of laryngoscope blade [7] using a suction catheter. However accidental dislodgement and cumbersome attachments resulted in a decline in its usage. Another method was to provide high flow nasal oxygen insufflation via nasal prongs in critically ill patients while performing laryngoscopy. However, entrapment of various amounts of air resulted in a variable amount of oxygen being delivered to the patient [8].

Compared to the pharyngeal insufflations, deep laryngeal oxygen insufflation delivers oxygen closer to the larynx. The conventionally used Oxiport blade has no provision for oxygen insufflation. The Oxiport Blade is a modified Miller Blade which has a metallic tube incorporated into Miller Blade that has an attachment through which extra oxygen can be connected and insufflated during laryngoscopy [1,9].

We tested the hypothesis that deep laryngeal oxygenation with Oxiport blade delays the onset as well as severity of desaturation as compared with laryngoscopy without oxygen insufflations.

Material and Methods

This prospective, randomised, controlled interventional single-blind study conducted in the Department of Anesthesiology & critical care Patna medical college & hospital, Patna, Bihar, India, for 1 year.

Methodology

Total 80 neonates/infants in groups of 40 each posted for surgery in paediatric operation theatre (OT) over a period of 6 months were included in the study. Patients posted for elective surgery were assessed during the pre-anaesthetic check a day prior whereas those taken up for emergency procedures were assessed on the day of surgery by the co-investigators. Full-term neonates and infants up to 6 months of age of either sex requiring general anaesthesia with endotracheal intubation for elective as well as emergency surgery were included in the study. This comprised three groups: thoracic, abdominal and miscellaneous surgeries. Thoracic surgeries included tracheoesophageal fistula repair, congenital diaphragmatic hernia repair, lobectomies for pulmonary sequestration and congenital lobar emphysema. Abdominal surgeries included intestinal obstruction, duodenal atresia, ileal atresia, colostomy, laparoscopic and open pyloromyotomy, gastroschisis, omphalocele and Kasai procedure for biliary atresia. Miscellaneous surgeries included sacrococcygeal teratoma excision, meningomyelocele repair, ventriculoperitoneal shunt for hydrocephalus, cystoscopy and posterior urethral valve fulguration.

Babies having desaturation before the induction of anaesthesia ($SpO_2 < 94\%$), known congenital heart disease, hypotension (systolic blood pressure [BP] < 60 mmHg), obvious congenital syndromes, anticipated difficult airway and anaemia (haemoglobin < 12 g%) were excluded from the study. After obtaining parental consent for the study and confirming fasting status, babies were wheeled into OT in a cradle covered with warm cotton rolls, along with their maintenance fluid. Monitoring used included electrocardiogram and pulse rate on cardioscope, pulse oximetry, capnometry, noninvasive BP, nasopharyngeal and skin temperature. Pulse oximeter probe (Mindray® pulse oximetry; finger sensor, Mindray DS USA, Inc.) was

used in all participants and attached on each participant's toe. This was connected to Mindray® DPM6 monitor (Mindray DS USA, Inc.). Only waveforms generating a good plethysmographic trace were used for recording SpO_2 data. Ringer's lactate was started through an infusion pump at a rate according to the expected losses based on the surgery. Neonates/infants were then randomised into two groups, Miller group or Oxiport group by computer-generated tables. This randomisation was enclosed in opaque-sealed envelope, and then, the randomisation was activated by the co-investigators. The babies were then pre-oxygenated with 100% oxygen at a flow rate of 4 L/min for 3 min on spontaneous ventilation with Jackson-Rees circuit using GE Datex Ohmeda Aestiva®/5 Anaesthesia Machine. Injection fentanyl 2 g/kg intravenous (IV) was administered, and anaesthesia was induced with incremental sevoflurane up to 8%. Neuromuscular blockade was achieved with injection rocuronium 1 mg/kg IV. Baseline SpO_2 was noted at this point. This was followed by direct laryngoscopy with the designated blade by an anaesthesiology resident (trainee) or a consultant. Laryngoscopy was performed with 0 number blade of Miller laryngoscope in Miller group and 0 number blade of Oxiport® Miller laryngoscope in Oxiport group followed by endotracheal intubation. In Oxiport group, oxygen insufflation was instituted with oxygen tubing attached to Oxiport blade at a flow rate of 2 L/min (to provide low-flow oxygen during laryngoscopy) [4] through an auxiliary oxygen port. Successful intubation was confirmed by end-tidal carbon dioxide tracing on capnometer and auscultation of bilateral equal air entry on both sides of the chest. This constituted the endpoint of the study. The observations noted were intubation time in seconds (interval from the insertion of blade into mouth until successful confirmation of intubation), lowest saturation attained, anaesthesiologist performing laryngoscopy (trainee or consultant) and haemodynamic parameters such as heart rate and systolic

BP. For the purpose of this study to quantify desaturation data, it was graded as mild desaturation (lowest SpO₂ up to 90%), moderate desaturation (lowest SpO₂ between 85% and 89%) and severe desaturation (lowest SpO₂ <85%). This grading was selected based on a meta-analysis of SpO₂ target range where SpO₂, 85%–89% was considered restricted and SpO₂, 91%–95% considered liberal oxygen exposure in extremely pre-term infants. The study was terminated when SpO₂ decreased to 80% or signs of cardiac instability such as bradycardia appeared. Mask ventilation with 100% oxygen was immediately resumed till SpO₂ increased to 98%–100%.

Sample size of 80 was estimated by a study using deep laryngeal oxygen insufflation during laryngoscopy in children [2]. The incidence of desaturation (SpO₂ <90%) was 10% in direct laryngoscopy with oxygen cannula group and 49% in standard direct laryngoscopy group. We anticipated a difference of 10% between the two groups. With 99% confidence interval and 90% power, we got a sample size of 40 in each group.

Quantitative data are presented with the help of mean and standard deviation. Qualitative data are presented with the help of frequency and percentage table. The incidence of severe desaturation was calculated. Association among study groups was assessed with Pearson's Chi-square test. Pearson's correlation

coefficient was used to measure correlation between time to intubation and desaturation in each group. $P < 0.05$ was considered as statistically significant. Statistics software SPSS version 25.0 was used.

Results

Out of the 80 patients 40 patients in Miller group and 40 patients in Oxiport group were included.

Both groups were comparable with respect to age, sex, weight, mean time to intubation ($P = 0.57$) and anaesthesiologist performing the laryngoscopy ($P = 0.72$) [Table 1].

Mean lowest SpO₂ recorded was $96.1\% \pm 4.75\%$ in Miller group and $98.15\% \pm 2.83\%$ in Oxiport group. This difference was statistically significant ($P = 0.041$).

The incidence of mild desaturation (SpO₂ up to 90%) was 87.5% in Miller group and 95% in Oxiport group. The incidence of moderate desaturation (SpO₂ between 85% and 92.5%) was 2.5% in Miller group and 5% in Oxiport group. Incidence of severe desaturation (SpO₂ <85%) was 15% in Miller group and 0 in Oxiport group (Chi-square test $P = 0.04$).

Correlation between time to intubation and SpO₂ in Miller group (Pearson's $R^2 = -0.12$) was statistically not significant at $P = 0.41$. Correlation between time to intubation and SpO₂ in Oxiport group (Pearson's $R^2 = -0.42$) was statistically significant at $P = 0.001$.

Table 1: Comparison of demographic profile, intubation time, experience of anaesthesiologist and haemodynamics between the study groups

Parameter	Miller group (n=40)	Oxiport group (n=40)
Age in days (mean±SD)	44.92±51.46	37.55±52.35
Sex (male: female)	25:15	22:18
Weight in kg (mean±SD)	3.30±1.00	2.87±1.14
Intubation time in s (mean±SD)	41.60±20.34	41.94±23.39
Anaesthesiologist performing laryngoscopy (%)		
Trainee	69.8	73.3
Consultant	32.3	28.7
Heart rate in beats/min (mean±SD)	133±17	127±22
Systolic BP in mmHg (mean±SD)	75±26	67±32

Both groups were comparable with respect to the type of surgery (abdominal, thoracic, miscellaneous) ($P = 0.71$). Abdominal surgeries were associated with a higher number of severe desaturations (70%) compared to thoracic (15%) and miscellaneous (15%) surgeries.

Discussion

Apnoeic oxygenation is based on the principle of passive diffusion of fresh oxygen from the conducting airways into the lungs, and the primary criteria for its use are a patent upper airway. Ever since the introduction of this concept in clinical practice by Holmdahl in 1956 [3], many modifications of the technique have been used [6,7]. However, these devices were cumbersome and had their own limitations. Since the introduction of Oxiport® laryngoscope blade in clinical practice [9], there has been very little published literature on the use of this blade for intubation in vulnerable populations such as neonates and infants. Hence, we conducted this study to compare this blade with Miller size 0 blade which is the current standard of care.

Babies in the Oxiport group had significantly higher saturations compared with those in the Miller group. With Oxiport® laryngoscope, saturation never fell below 85% during the entire period of apnoea. These results confirmed our hypothesis. Oxygen insufflations closer to the larynx maintains higher SpO₂ in neonates and infants by maintaining higher lung oxygen partial pressure and thus delays desaturation. Fresh oxygen continuously replaces the absorbed pulmonary volume by passive diffusion from larynx through the trachea into the lungs. The method increases safe apnoea time by maintaining SpO₂ closer to the inflection point of haemoglobin oxygen dissociation curve. Our findings may be extrapolated to use of the Oxiport blade in very sick babies or in emergency situations in the intensive care set up where

pre-oxygenation may not be feasible before intubation.

The correlation between time to intubation and incidence of desaturation in Oxiport® group (Pearson's $R^2 = -0.42$) was not strong, yet it was significant. This is because even as time to intubation increased beyond 60 s, desaturations did not occur in Oxiport group. In Miller group, this correlation was weaker as desaturations occurred irrespective of the time to intubation even in experienced hands. The art of neonatal intubation has a steep learning curve, and there may be significant time taken to successful intubation which can lead to desaturation and/or bradycardia. In this study conducted in a teaching institute where many intubations were performed by novice anaesthesiologist, the Oxiport® blade helped prevent desaturation in inexperienced hands.

Although not statistically significant, abdominal surgeries had a higher incidence of severe desaturation (70%). Our finding may be attributed to the abdominal distension further reducing FRC and affecting pulmonary compliance. Similar results have been reported by a recent British study [2] on the use of deep laryngeal oxygen insufflation during laryngoscopy in children between 1 and 17 years of age. The authors measured the time to a 1% decrease in SpO₂ from baseline which they considered a harbinger of a more rapid desaturation to come. Three groups were studied: standard direct laryngoscopy, laryngoscopy with True View video laryngoscope and laryngoscopy with an oxygen cannula attached to the side of a standard laryngoscope. They concluded that laryngeal oxygen insufflation increases the time to 1% desaturation and reduces the overall rate of desaturation during laryngoscopy in children.

The All-India Difficult Airway Association 2016 guidelines strongly recommend apnoeic oxygenation using nasal prongs/catheter during attempts at

laryngoscopy in unanticipated difficult tracheal intubation in paediatrics. Authors recommend adjusting flow rate of oxygen targeting SpO₂ >95% [10]. The results of our study may change practice in days to come where the Oxiport blade may find a place in the intubation of the difficult paediatric airway.

Trainees were allowed to intubate, and their experience was not clearly defined. This could be a confounding factor. However, both groups were comparable for the anaesthesiologist performing the intubation (P = 0.72). Trainees were included in an effort to prove the utility of Oxiport blade even in inexperienced hands. No stratified statistical analysis was done for emergency and elective cases. Combining these two groups may not be justifiable as emergency patients tend to be sicker, dehydrated and may have significant abdominal distention making them more prone to rapid desaturation. In addition, site of operation and sickness of the baby are potential confounders.

Our study raises certain controversies in the current practices of oxygen administration based on the increasing understanding of oxygen toxicity in neonates [11,12]. We used 100% oxygen for pre-oxygenation which is the current standard of care. The oxygen concentration delivered through Oxiport laryngoscope at flows of 2 L/min would be variable based on the amount of air entrained, and this was given for very brief periods. The use of oxygen during neonatal anaesthesia has not been well studied [13] and further research is essential. It would be reasonable to limit the use of supplemental oxygen only to situations where it is absolutely necessary. We did not use injection atropine or injection glycopyrrolate even though we were dealing with infants up to 6 months of age, who are prone to bradycardia in response to hypoxia. This is in accordance with the 2015 American Heart Association updated paediatric advanced life support recommendations which state that there is no evidence to support the routine use of

atropine as a pre-medication to prevent bradycardia during intubation of critically ill infants [14].

Newer methods of passive diffusion oxygenation by the use of high flow nasal cannula have been gaining attention in recent times as an aid to prevent desaturation during endotracheal intubation in adults [15].

Conclusion

In this study, apnoeic laryngeal oxygen insufflation with Oxiport laryngoscope blade decreased the incidence of severe desaturation while intubating neonates and infants. This was easily done as it was non-cumbersome and did not increase the overall cost of anaesthesia.

Reference

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