www.jmscr.igmpublication.org
Impact Factor (SJIF): 6.379
Index Copernicus Value: 71.58
ISSN (e)-2347-176x ISSN (p) 2455-0450
crossref DOI: https://dx.doi.org/10.18535/jmscr/v6i6.131

IGM Publication
Journal Of Medical Science And Clinical Research
An Official Publication Of IGM Publication

Nasal versus oral endotracheal intubation in mechanically ventilated newborn infants in a tertiary care neonatal unit: a prospective randomized comparative analysis

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Abstract
Backgrounds: *Infants in the Neonatal Intensive Care Unit (NICU) are among the highest risk groups for adverse events in the hospital setting. In adult and pediatric intensive care units, adverse events related to endotracheal or tracheostomy tubes comprise a substantial proportion of total adverse events and lead to significant patient harm.*
Aim: *we planned to conduct this study to compare the advantage and complication associated with nasal versus oral intubation for mechanical ventilation in newborn infants.*
Materials and Methods: *Intubation was done with a standardized premedication with vecuronium and midazolam except for babies who required emergency intubation. Due to difficulty in procuring the opioids in the unit it was not included in premedication.*
Results: *the incidence of trauma was found 15.15% of cases in nasal group where as 12.1% in oral group. However this difference between both the groups was statistically not significant (p=1.00). Only one baby in nasal group had severe septal necrosis where as palatal grooving was found none of oral cases.*
Conclusions: *Adverse events are common in the NICU, occurring in 4 of 10 intubations. The odds of an adverse event doubled with increasing number of attempts and quadrupled in the emergent setting. Quality improvement efforts to address these factors are needed to improve patient safety*
Keywords: *patient safety, tracheal intubation, NICU.*

Introduction

Infants in the Neonatal Intensive Care Unit (NICU) are among the highest risk groups for adverse events in the hospital setting[1,2]. In adult and pediatric intensive care units, adverse events related to endotracheal or tracheostomy tubes comprise a substantial proportion of total adverse events and lead to significant patient harm[3–6]. Little is documented about airway safety in the NICU.

In pediatric intensive care units (PICU), 19–41% of all endotracheal intubation procedures are associated with adverse events[7–10]. Studies from the National Emergency Airway Registry for Children (NEAR4Kids) report that in children beyond the newborn period, these adverse events

are associated with patient[9], provider[10] and practice factors[11]. Studies of endotracheal intubation in the NICU have focused primarily on proficiency, mainly of trainees, and use of premedications[12–17]. Few studies have reported rates and types of adverse events associated with endotracheal intubation in critically ill newborns and potentially modifiable factors associated with these complications[18]. As a result, evidence-based interventions to improve airway safety in this vulnerable population are lacking. We hypothesized that in critically ill newborns in the NICU, adverse events associated with intubation would match or exceed the rate in children or adults.

Endotracheal intubation is a common procedure in newborn intensive care units (Bancalari 1992)[19]. The choice of the oral or nasal route for intubation is usually determined by an institution's customary practice, based on clinical experience regarding the perceived short and long term benefits and complications of one route compared over the other (Roberton 1992)[20].

The procedure of intubation may be technically difficult (Dankle 1987) for both the oral and nasal routes[21]. This is particularly true for infants who weigh less than 1000 gram or greater than 3000 gram (Noblett 1995)[22]. Approximately 30% of infants require repeated intubations (Dankle 1987; Noblett 1995) for accidental extubation, failure of extubation, tube blockage, inappropriate tube size and upper airway obstruction.

Complications following prolonged endotracheal intubation in neonates have been widely reported.[23] With increasing intact survival of infants who have received prolonged ventilatory assistance, these complications assume greater importance. Endotracheal intubation may be associated with such complications as cardiorespiratory compromise during the procedure, tube malposition, tube blockage, traumatic injury to the nares or palate, glottis or trachea, lung or airway collapse, and infection (Spitzer 1982; McMillan 1986)[24,25]. Specific complications may be associated with either the oral or nasal route of intubation. Palatal grooving and alveolar grooving (Angelos 1989)[26] are associated with oral intubations. Nasal deformities were more likely to occur as a complication of nasotracheal intubation in infants weighing less than 1000 grams (Gowdar 1980)[27].

There are very few reported studies that compare the benefits and complications of the two routes of intubation and there are no studies from India. The complications associated with endotracheal intubation may cause or aggravate cardiorespiratory and/or neurological disorder and, perhaps, result in long term respiratory, cosmetic or neurological disability. Therefore, determining the complications associated with the different routes of intubation is deemed important for clinical practice and good patient outcomes.

There are difference in opinions among different consultants regarding the route of intubation and preferences vary in the unit, we planned to conduct this study to compare the advantage and complication associated with nasal versus oral intubation for mechanical ventilation in newborn infants.

Materials and Methods

The study was conducted in level III NICU at Rainbow children and perinatal centre, a tertiary care unit, between June 2016 to Nov 2017.

Tracheal intubation was done by either the nasal or the oral route. All newborns who required intubation for mechanical ventilation during the study period from both units of Banjara hills as well as Secunderabad are included in study.

Indication of mechanical ventilation was decided as per the following criteria:

1) Delivery room resuscitation requiring intubation and positive pressure ventilation
2) Those with silverman Anderson retraction score and Downes score of >6 started with ventilation.
3) ABG score of >3
4) CPAP failure, as indicated in acute disease by the presence of $PaCO_2$ greater than 50

mm Hg, pH less than 7.20 in 80% O_2 while administering a continuous distending pressure of 8 cm H_2O specially in neonates with RDS.

5) Surgical causes requiring intubation & mechanical ventilation
6) Cases in which air distention of the gastrointestinal (GI) tract is undesirable, such as with congenital diaphragmatic hernia

Intubation was done with a standardized premedication with vecuronium and midazolam except for babies who required emergency intubation. Due to difficulty in procuring the opioids in the unit it was not included in premedication.

Size of the tube was selected as per following table.

Depth of insertion was selected as per the formula-

Oral tube length (cm) = 6 + wt (kg)

Nasal tube length (cm) = 6 + wt (kg) +1

Babies were preoxygenated with bag & mask ventilation and intubation was done by the registrars or consultants who were skilled enough in performing endotracheal intubation through either route (nasal/oral).

We defined an intubation duration as starting when the bag and mask ventilation stopped before intubation and terminating when the PPV started after inserting the ET tube as this is the period associated with physiologic instability. Oxygen saturation and heart rate were monitored during the procedure and time taken for the procedure was recorded.

Intubation failure was considered when baby was compromised with significant bradycardia (Heart rate <100) or desaturation (SPO_2< 80% or >15% change from baseline) or both during the procedure. However the babies who were failed intubation as per above mentioned criteria the procedure was stopped and bag and mask was again reintroduced. Numbers of attempts were calculated as per the number of times the procedure was failed requiring reoxygenation and reintubation.

Significant fall in saturation was considered when oxygen saturation drops to below 85% or drop of >10% from the baseline.

An independent observer was recording the whole procedure and documentation was done systematically in a performa regarding duration required for intubation, change in heart rate and oxygen saturation, number of attempts.

The tubes were secured by a modification of the Gregory technique omitting suturing to elastoplast. Nasal and oral tubes were similarly secured. The tube was secured by tape, using an 2 C-shaped pieces with one arm of each on the lip and the other arm on the orotracheal tube or nasotracheal tube. The position of the tube was confirmed radiographically while the head was held in neutral position. Babies requiring initial reposition and further reposition throughout the period of ventilation were documented.

Nursing care was provided in the form of minimal handling, ensuring fixation of tube, maintaining asepsis, and frequent changes in position. Endotracheal tube care was standardized with suctioning performed every 6 hours, or as & when required. Endotracheal tube secetion was sent for culture and sensitivity when ventilator associated pneumonia was suspected.

The decision when to intubate and extubate were made according to standard criteria. Feedings were withheld from two hours prior to extubation to six hours postextubation. Post extubation complications like stridor and atelectasis were documented.

The classification of trauma for nasal intubation was taken according to standardized classification of decubitus lesions from the US National Pressure Ulcer Advisory Panel. (NPUAP)

Trauma

Stage1-Erythema of an otherwise intact skin and widening of the vestibules

Stage 2-Superficail ulcer or erosion, superficial skin loss

Stage 3- Nose vestibular ulceration, active bleeding and septal necrosis.

Baseline characteristics such as birth weight, gender, gestational age (based on Mother's last menstrual period date and/or first trimester ultrasound), mode of delivery were included in the proforma.

Statistical Method Used

Results of the study are analysed statistically in SPSS software. Fisher's exact test & unpaired t test were applied accordingly to obtain the statistical significance and $p<0.05$ was considered significant.

Results

The study was conducted in level III NICU at IMS and SUM Hospital, Bhubaneswar from June 2016 to Nov 2016 over a period of 7 months.

There were total 108 babies required invasive ventilation during the study period. Out of 108 babies 21 babies were intubated outside our unit and in 6 babies emergency intubation was done for which both the groups were not eligible for the study.

Out of 81 babies were eligible for study 10 babies were excluded due to unable to follow randomization and total 71 babies enrolled for study. After randomization 5 babies were excluded from the nasal group due to intubation failure. Final data analysis has been done taking 33 babies each in nasal and oral group. (figure -1)

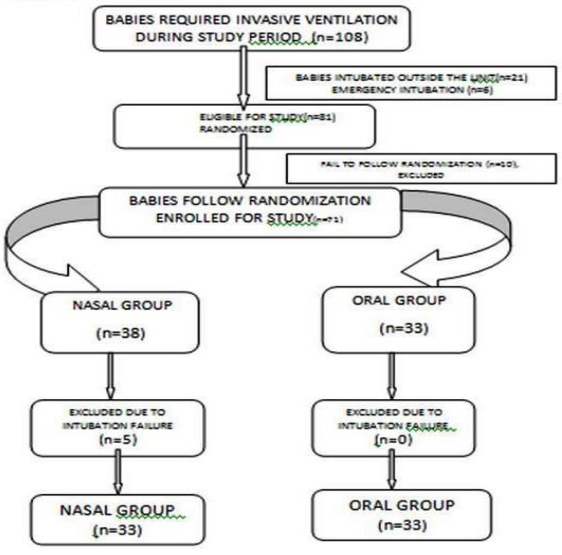

Fig 1

A total of 66 babies requiring invasive ventilation were included in the study as per the inclusion criteria. Based on prospective randomized distribution of cases among oral and nasal intubation groups, there were 33 babies in each group.

When sex of the babies was analysed, male sex predominated female sex in both the groups (70% in naso-tracheal group and 55% in Oro-tracheal group) but there was no statistical significant difference with respect to sex of the babies among both the groups. (Table – 1) When gestational age wise distribution of cases among both the groups was analysed, it was noted that 30%(n=10), 18.18% (n=6) and 51.5% (n=17) of the babies were present in <32 weeks , 33-36 weeks and >37 weeks respectively in nasal group, whereas in oral group they were36.36%(n=12),21.2%(n=7) and 42.4% (n=14) in. 32 weeks , 33-36 weeks and >37 weeks respectively However gestational age wise distribution of cases among both the groups, did not reveal any statistically significance. Mean gestational age of the babies were 35.1 weeks and 34 weeks in nasal and oral groups respectively.

Table -1

Tube size (mm)	Weight	Gestational age
2.5	<1000	<28
3	1000-2000	28-34
3.5	2000-3000	34-38
3.5-4.0	>3000	>38

When birth weight of the babies was analysed among both the groups it was found that very low birth weight babies were more in the oral group (n=5) when compared to the nasal group(n=2). There were 57.5%(n=19) and 36.5%(n=12) In 1-2.5 kg and >2.5 kg in nasal group respectively where as 54.5%(n=18) and 30.35%(n=10) in <2.5 kg & >2.5 kg respectively in oral group. However there was no statistical significance noted when weight of the babies was compared between both the groups. Meanbirth weight was 2.21 kg & 2.06 kgs in nasal & oral groups respectively. (Table-2)

The most common etiological factor requiring mechanical ventilation was HMD, which among

the nasal group was 57.5% (n=19) and 76% (n=25) in the oral group. Followed by HMD, the other etiological conditions were pneumonias, congenital heart disease, meconium aspiration syndrome, hypoxic ischemic encephalopathy and surgical conditions like congenital diaphragmatic hernia etc. Even with the etiological factors wise indication for mechanical ventilation, did not show any statistical significance between both the groups.

Mean duration of intubation was longer in nasal group (32.12+4.9 sec) when compared to oral group (17.48+3.9 sec), which was statistically significant (p=<0.001), Mean fall in the oxygen saturation from the baseline was found to be little high in nasal group (6.1+ 3.8 %) when compared to oral group (5.7+ 5 %) which was bot statistically significant.(p=0.7)

Mean change in heart rate from the base line, was also found to be high in nasal group (14.5+ 12.6/min) when compared to oral group (9.8 + 11.1/min). But however the difference was not statistical significant when compared between both the groups. The lowest oxygen saturation attained during intubation was 70% in nasal group and 60% in oral group, whereas the lowest heart rate found during intubation was 68 and 89 per minute in nasal and oral groups respectively. The total number of babies in whom significant fall in oxygen saturation was seen in 11babies (33%) in the nasal group and that of in oral group was seen in 5 babies (15%). But this difference between the two groups was not statistically significant. Mean duration of ventilation was significantly lower (76.36 + 57 hours) in nasal group when compared to oral group (146 + 180 hours). (P<0.05). In the nasal group, 15% (n=5) of babies required multiple attempts during intubation, where as in oral group 9% (n=3) of babies required multiple attempts. But the difference was not statistically significant.(Table-3)

Table 2 showing gestational age wise distribution of cases among both the groups

Gestational Age	Nasal	Oral	P value
<32	10 (30%)	12 (36.36%)	0.79
33-36	6 (18.18%)	7 (21.2%)	1.0
>37	17 (51.5%)	14 (42.4%)	0.62
TOTAL	33	33	

After intubation, based on the initial radiographs babies in the nasal group required repositioning of the endotracheal tube 18 times, whereas 13 times in the oral group required repositioning. During throughout the course of mechanical ventilation, 3% (n=1) of the babies in the nasal group and 6% (n=2) in the oral group had accidental extubations. However, none of the parameters showed statistically significant difference between both the groups. (table-4)

Table 3 showing birth weight wise distribution of cases among both the groups

		ORAL (%)	P value
Upto 1kg	2 (6%)	5 (15.15%)	0.42
>1-2.5	19 (57.5%)	18 (54.5%)	1.0
>2.5	12 (36.5%)	10 (30.35%)	0.79
TOTAL	33	33	

Our study revealed further tube reposition throughout the period of ventilation was required 13.3 times in nasal group and 14.91 times in oral group per 100 days of ventilation, the difference being statistically not significant.(Table-5,6)

Table 4 showing distribution of cases based on aetiology among both the groups

	NASAL	ORAL	P value
HMD	19 (57.5%)	25 (76%)	>0.05
PNEUMONIA	4 (12.2%)	1 (3%)	>0.05
CDH	1 (3%)	1 (3%)	>0.05
CHD	1(3%)	2 (6%)	>0.05
HIE	3 (9%)	1 (3%)	>0.05
MAS	2 (6%)	2 (6%)	>0.05
SURGICAL	3 (9%)	1 (3%)	>0.05

Table 5 showing comparison of mean duration required for intubation between both the groups during intubation

Parameters	NASAL	ORAL	P value
Mean duration of intubation	32.12+4.9 secs	17.48 +3.9 secs	<0.001

Discussion

Endotracheal intubation in neonates commonly produces physiologic changes including hypoxemia, increased arterial pressure and increased intracranial pressure which may be harmful to the patient. Because orotracheal intubation is the preferred route for emergencies, adoption of a single method of intubation may increase expertise and potentially reduce complications of intubation [28]. But orotracheal and nasotracheal intubation have both been recommended for intubation in newborn infants who require assisted ventilation with different thoughts of opinion pertaining to the advantages and complications associated with either routes of endotracheal intubation. However there is limited comparative data available till date, regarding the orotracheal and endotracheal intubation. In this regard, we have done a prospective randomized comparative analysis between oral and nasal group and studied various aspects of primary and secondary outcome were studied in detail.

In our study there were 33 babies each in nasal and oral group as per the randomization with male sex predomination in both the groups. Nearly 50% of the babies were full term in both the groups with a mean gestational age being 35.1 weeks and 34 weeks in nasal and oral groups respectively. Nearly 6% of babies were in nasal group and 15% of babies in oral group belong to less than 1000 gram group .The incidence of low birth weight babies was more in oral group when compared to nasal group.

In a study done by Spitzer et al[5] taken total of 43 infants were included in each group. The mean GA was 32.1+ 0.6 weeks and 32.9+ 0.5 wks in oral and nasal groups respectively. Mean birth wt was 1.895 kg & 1.903 in oral and nasal groups respectively. Similarly McMillan[6] et.al studied 39 babies in nasal group with mean GA of 32+ 1 wks and 52 babies in oral group with mean GA of 31+1 wks.

HMD was the most common cause of intubation constituting 58% and 74% respectively in both nasal and oral groups. Spitzer et al[5] also reported HMD as the commonest etiological factor requiring mechanical ventilation with an incidence of 81.4% in nasal group and 83.7% in oral group. However this difference was not statistically significant and similar observation was also noted in our study.

American Academy of Pediatrics, Neonatal Resuscitation Program[15] recommends that intubation should be completed in approximately 20 seconds. Brian Lane et al[34] showed overall intubations were more successful with a duration of ≤ 30 seconds when compared to ≤ 20 seconds (72% vs 38%; P = .001).

However in our study, the mean duration required for intubation was 32.12+ 4.91 seconds for nasal and 17.48+3.95 for oral intubation which was statistically significant (p=<0.05). This shows that the time taken for successful nasal endotracheal intubation is definitely longer than oral route. No comparative published data is available regarding the mean duration required for nasal intubation. Colm P. F. et al[29] showed mean duration required for successful intubation in the oral group only (31+17 secs).

In our study change in heart rate and oxygen saturation was compared between both nasal and oral groups. Mean change in saturation was 6.12 + 3.8 % in nasal group and 5.67+ 5 % in oral group. Similarly significant change oxygen saturations (<85%/ 10% change from baseline) were found in 21% of babies in oral group and 39 % of babies in nasal group. But this difference did not have any statistically significance. ColmP. F. et al[30] found around 49% of babies deteriorated during intubation (drop in heart rate or saturation >10% from the baseline)in the oral group of babies, but this parameter was not analyzed in nasal group of babies in their study.

In our study Intubation failure was found in 15% and 10% of cases in nasal and oral groups respectively which was not significant statistically. Similarly Brain et.al study showed failure rate of 11% in oral intubation where as McMillan et.al[24] showed 18% failure rate in nasal intubation without significant difference.

In our study, after intubation, based on the chest radiographs, initial reposition of ET was done in 54% of babies in nasal group and 39% of babies in oral group with no statistical significance (p=0.32).

Similarly, McMillan et al[6] found 36% of babies in nasal group & 46% of babies in the oral group required initial reposition, but even this observation was not statistically significant. But after extensive evaluation, we could not find any explanation for the difference noted between both the groups in our study. With high reposition rate we may have to look at the other possible parameters along with the formula we used during intubation for the length of tube insertion.

In our study, during throughout the course of mechanical ventilation, 14 times endotracheal tube was repositioned in the nasal group compared to 30 times in the oral group with mean duration of ventilation 76.36 + 57 hours in nasal group and 146 + 180 hours hours in oral group. Our study revealed tube reposition was required 13.3 times in nasal group and 14.91 times in oral group per 100 days of ventilation. In a study done by MC millan et al[6], tube reposition was required in 18.8 times in the oral group and 17.6 times in the nasal group per 100 days of ventilation. There was no statistically significant difference in tube reposition in our study among both the groups.

In our study, the mean duration of ventilation was 76.36+ 57 hours in nasal group and 146 + 180 hours in oral group. This difference was statistically significant. In a study done by Spitzer et al[5], the mean duration of ventilation was 322+65 hours & 309+88 hours in nasal & oral groups respectively and the difference was not statistically significant. But in our study, on further evaluation, it was found that, in the oral group, there were more number of babies weighing less than 1000g and required prolonged ventilation in view of associated co-morbidities, which had led to a statistically significant difference in duration of ventilation between both the groups.

The incidence of post extubation failure in our study was 10% in both the groups which was comparable to study done by Mc.Millan et al[6] (10% in both oral and nasal groups). Post extubation collapse was seen in 15.2% cases in nasal group & 12.12% of oral group, the difference being non significant unlike the observation found in a study done by Spitzer et al[5], which showed significant difference in the incidence of post extubation collapse between the oral and nasal groups (11% oral and 34.9% in nasal groups). This low incidence in our study when compared to other study could probably be due to the practice of extubation to CPAP as and when required especially in preterm babies as per the unit protocol and physiotherapy.

There was not much difference noted in the incidence of post extubation stridor in our study between both the groups (12.12% in nasal & 15.15% in oral). In a study done by McMillan et.al, the incidence of post extubation stridor was high in nasal group 26% and 15% in oral group. However the difference was not statistically significant in both the studies.

In our study, 2 babies weighing 990 grams each, as per the standard protocol we used 2.5 mm endotracheal tube for nasal intubation but in view of peritubal leakage we selected next higher size tube, but due to difficulty in passing the tube through the nares babies were intubated orally. This could be because babies nearing 1 kg might require bigger size endotracheal tubes some times, thereby deviating from the standard protocol.

In our study, the incidence of trauma was found 15.15% of cases in nasal group where as 12.1% in oral group. However this difference between both the groups was statistically not significant (p=1.00). Only one baby in nasal group had severe septal necrosis where as palatal grooving was found none of oral cases. This low incidence of trauma among the oral group of babies was also reported by Spitzer et al[5]. In their study, 10% of babies in the nasal group developed some form of trauma, which was almost negligible in the oral group.

Though nasal intubation is more time consuming procedure requiring more expertisation than oral intubation the incidence of tube repositioning, intubation failure, post extubation stridor and post extubation collapse were comparable as that of oral intubation with less chance of ventilator associated pneumonia.

The limitation of our study is the small sample size. So to validate the point of low incidence of VAP in case of nasal intubation require bigger randomized control trials before changing the practices in the newborn unit.

Conclusion

1) Mean duration required for nasal intubation was more than oral intubation ($p < 0.001$).
2) Though drop in heart rate & saturation were more in nasal group, it was not significant statistically.
3) Babies weighing < 1000 grams were associated with more drop in saturation during nasal intubation as compared to oral intubation ($p=0.03$).
4) Endotracheal tube displacement requiring reposition was less in nasal intubation throughout the period of ventilation ($p=0.75$).
5) Incidence of Ventilator Associated Pneumonia (VAP) was found less in nasal group as compared to oral group($p=0.04$) probably due to better oral hygiene in babies of nasal group.
6) No difference was found in intubation failure, initial ET tube reposition, extubation failure & post extubation stridor between both the groups.
7) Post extubation atelactasis was less commonly found in both the groups due to use of CPAP after extubation especially in preterm babies and the difference in incidence between both the oral and nasal groups were not significant ($p=1.00$).
8) No significant difference in incidence of severe trauma was found in both the groups.
9) No difference was found in various co-morbidities, duration of oxygen requirement & mortality in between both the groups.

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