

Comparative study of nasal mask versus nasal prong in terms of nasal septal necrosis for delivering nasal continuous positive airway pressure in newborns with respiratory distress

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ABSTRACT

Background: Respiratory distress syndrome (RDS) requires management by oxygen therapy and mechanical ventilation. Continuous positive airway pressure (CPAP) being simple, cost-effective, and non-invasive respiratory support is used to prevent airway injury as well as the development of bronchopulmonary dysplasia. **Objectives:** The study was to describe the comparison of nasal septum necrosis and to categorize severity of nasal septum trauma while using nasal prongs and nasal masks for nasal CPAP (nCPAP) in neonates with RD. **Materials and Methods:** A prospective randomized controlled study was carried out in 200 neonates admitted in neonatal intensive care unit and these neonates were randomized to receive either nasal mask or nasal prong as an interface for nCPAP. Complete blood count, C-reactive protein, blood culture, and chest X-ray were done. All infants were observed for 72 h for the development of nasal septal necrosis in each interface. All variables were analyzed with the help of Chi-square test. **Results:** Of the total 200 neonates included in the study, 9% neonates of prong group developed nasal septum necrosis, while no incidence of septum necrosis noted in mask group. **Conclusion:** Nasal masks were comparatively better than nasal prongs as nasal septum trauma occurred only in neonates with nasal prongs group.

Key words: Nasal continuous positive airway pressure, Nasal mask, Nasal prong, Respiratory distress

Respiratory distress syndrome (RDS) is the most common cause of RD in preterm infants [1]. Deficiency of pulmonary surfactant contributes to the development of RDS or hyaline membrane disease (HMD) and it is the most common cause of morbidity as well as mortality in the early neonatal period [2]. There is an inverse relationship between gestational age and incidence of RD. This accounts for nearly 80% incidence in preterm infants with gestational age <28 weeks. Respiratory support is important in neonatal intensive care unit (NICU) for the treatment of RD in neonates [3].

Neonates with RD are managed by oxygen therapy, positive-pressure ventilation (PPV), and surfactant therapy. PPV with surfactant therapy is a standard treatment for RD. However, a major drawback of PPV is that it is an invasive intervention and leads to airway and lung injury. Neonates with surfactant deficiency who are treated with PPV may develop airway and lung injury, which may lead to the development of bronchopulmonary dysplasia [1]. Hence, even the survived neonates who are treated with mechanical ventilation may develop chronic lung disease [4].

Continuous positive airway pressure (CPAP) is a non-invasive respiratory support preferred nowadays to avoid harmful effects of mechanical ventilation. Neonates are preferentially nose breathers that facilitate the application of nasal CPAP (nCPAP) [5]. CPAP

helps by maintaining functional residual capacity of infants that prevent atelectasis and allows gas exchange [6].

CPAP can be given only in neonates with spontaneous respiration [2]. While delivering nCPAP, nasal trauma is the most common source of discomfort for neonates and leads to cosmetic sequelae [7].

The objective of this study was to describe the comparison of nasal septum necrosis and to categorize severity of nasal septum trauma while using nasal prongs and nasal masks for nCPAP in neonates with RD.

MATERIALS AND METHODS

This prospective randomized controlled study was carried out over a period of 11 months in the year 2017 at level 3 NICU of the pediatric department, after taking approval from the Institutional Ethics Committee on Human Research at tertiary care hospital, Vadodara, Gujarat. A total of 200 neonates admitted in NICU were taken for this study meeting all inclusion criteria. A written informed consent from parents was taken. RDS was defined as the presence of any two of the following features: Tachypnea (respiratory rate ≥ 60), expiratory grunt, intercostal and sternal retractions, and hemodynamic instability [8].

The neonates included were preterm neonates (early as well as late) between 28 and 36 weeks of gestation with RDS with Silverman Anderson score ≤ 6 , very-low-birth-weight neonates < 1.5 kg with RDS with Silverman Anderson score ≤ 6 , apnea of prematurity, transient tachypnea of newborn, and babies receiving post-extubation trial from prolonged mechanical ventilation to nCPAP as a respiratory support.

The preterm newborn with major congenital malformations such as tracheoesophageal fistula, congenital anomalies of the lung, and congenital diaphragmatic hernia was excluded from the study. Babies with antenatally diagnosed or having congenital heart disease, babies of parents who refused to give consent, referred patients who had already received nCPAP outside in other hospitals and referred with complications of it, and patients who needed intubation at birth were excluded from the study.

A detailed antenatal, natal, and postnatal history followed by general and systemic examinations of neonates was done in every case. Neonates who were eligible for inclusion criteria were initially stabilized in the triage in the labor room and then

transported to the NICU. Enrolled infants were randomized to receive either nasal mask or nasal prongs as a mode of nCPAP delivery interface. Randomization was done using a computer-generated randomization chit with sealed opaque, sequentially numbered envelopes which were kept round the clock in the NICU. The physician on duty opened sequentially numbered sealed opaque envelopes and randomized infants to the respective group.

Diagnosis of underlying etiology of RD was made by clinical, laboratory, and radiological criteria. Time of onset of RD was recorded and RD was assessed using Silverman Anderson Scoring used for preterm neonates and Downe's Score for term neonates. Then, routine investigations were sent including complete blood count, C-reactive protein, and blood culture and sensitivity. Chest X-rays were done before putting on bubble CPAP.

Neonates were observed for 72 h for the development of local complications such as nasal septum necrosis as well as to categorize severity of nasal septum necrosis related to each

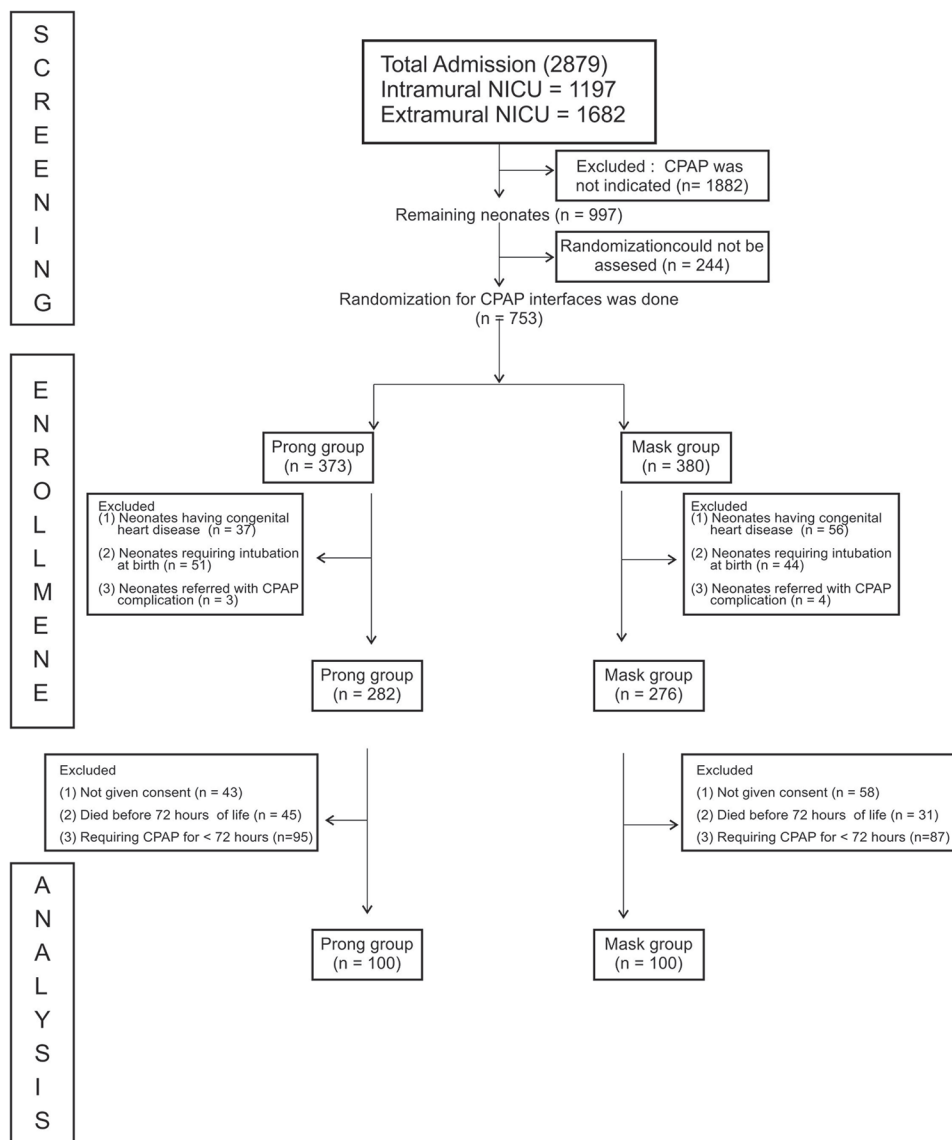


Figure 1: Flowchart describing the method of screening and analysis

interface nasal mask and nasal prong used for delivering nCPAP in neonates with RD. Nasal trauma was classified based on the standardized classification of the decubitus lesions from the US National Pressure Ulcer Advisory Panel [9].

- Stage 1: Erythema not blanching, on an otherwise intact skin
- Stage 2: Superficial ulcer or erosion, with partial thickness skin loss
- Stage 3: Necrosis, with full-thickness skin loss.

RESULTS

During the study period of 11 months, there were a total of 997 neonates who required CPAP in the NICU. As shown in Figure 1, as per sample size, 200 neonates fulfilling the above inclusion criteria were recruited and enrolled 100 neonates were enrolled in each interface, nasal mask, and nasal prong after ensuring proper randomization. Table 1 represents the distribution of various indications of continuous positive airway pressure in both the interfaces.

In the present study, as shown in Table 2, male:female ratio was approximately 3:2 in both the arms.

The total number of neonates who developed nasal septal necrosis is shown in Table 3 which depicts that neonate in whom nasal prongs was used as an interface developed nasal septal necrosis (9%), while none of neonates developed it in nasal mask group. Gestational age and birth weight did not have any impact on the development of septal necrosis in both groups.

DISCUSSION

HMD, the pathologic correlate of RDS of the newborn, is the most common cause of an acute lung disease of premature infant and it mainly occurs due to inadequate amounts of surfactant. The incidence of RDS is directly proportional to the degree of prematurity and inversely proportional to gestational age. This typically worsens over the first 48–72 h and then improves with treatment. In newborns receiving CPAP, septum necrosis occurs due to pressure by the devices on the nasal septum, its cutaneous vulnerability, and anatomical factors such as end vascularization of columella and nostrils.

In our study, the incidence of nasal septum necrosis was higher in prongs group than in masks group ($p=0.0064$). There was a statistically significant difference between occurrences of local nasal complications in both groups. Lesser nasal complications in the nasal mask group may be due to ease of use, softness, and design of the mask.

In a study done by Goel *et al.* [10], there was a significantly lower incidence of overall nasal trauma in mask as compared to prongs group ($p=0.02$). Similarly, Kieran *et al.* concluded that nasal mask was superior to prongs and the results were statistically significant [11]. Jasani *et al.* conducted a systematic review and meta-analysis and concluded that nasal mask was a safe alternative [12]. Similarly, Chandrasekaran *et al.* concluded that severe nasal trauma was more common (31% vs. 0%) among

Table 1: Distribution of various indications of continuous positive airway pressure in both the interfaces

Septal necrosis	Number of patients (n=200)	
	Prongs group (n=100)	Mask group (n=100)
Yes	09	0
No	91	100
Total	100	100

$p=0.0064$

Table 2: Demographic distribution in both the interfaces

Demographical data	Nasal prongs (n=100)	Nasal masks (n=100)
Gender distribution		
Male	62	63
Female	38	37
Gestational age distribution (weeks)		
≤27	1	3
28–32	54	50
33–36	40	36
≥37	5	11
Birth weight distribution (g)		
≤1000	9	11
1001–1499	50	37
1500–1999	32	38
2000–2499	6	6
2500–2999	3	6
≥3000	0	2

Table 3: Distribution of septal necrosis measures in both interfaces

Etiology	Number of patients (n=200)	
	Prongs group (n=100)	Mask group (n=100)
HMD Grade 1	43	29
HMD Grade 2	35	45
HMD Grade 3	1	3
Transient tachypnea of newborn	11	5
Recurrent apnea	3	2
Congenital pneumonia	3	6
Meconium aspiration syndrome	0	1
Post-extubation	4	9

HMD: Hyaline membrane disease

neonates in the nasal prong group [3]. Similar results were observed by Bashir *et al.* [13] and Dubey *et al.* [14].

However, Kumar *et al.* concluded that there was no statistically significant difference between occurrence of nasal trauma noted in both groups ($p=0.371$) [15]. Similar findings were concluded by Singh *et al.* [9] and Prakash *et al.* [16]. The outcomes of nasal mask as interface were as effective as nasal prongs in preterm infants on CPAP therapy. Yong *et al.* concluded that nasal trauma was common during nCPAP treatment and irrespective of the type of device used [17]. Fischer *et al.* also concluded that nasal trauma is a frequent complication of nCPAP [18]. There were a few limitations of this study. There was inability to blind the

randomization. The assessment scale used was subjective and there could be assessment bias.

CONCLUSION

Nasal masks were the more suitable interfaces than nasal prongs for delivering nCPAP in newborn with RDS.

ETHICAL APPROVAL

The study was approved by the Institutional Ethics Committee on Human Research.

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