Comparing the Efficacy of Face Mask CPAP with Nasopharyngeal CPAP for Neonatal Transport after Delivery

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Abstract

Background: Preterm infants have respiratory failure and complications because surfactant in alveolus is low. CPAP (Continuous positive airway pressure) is a method for respiratory support in pre-term neonates and is provided by different equipment and methods. This study aims to compare two different routes of CPAP delivery in preterm newborn infants and to determine the need for surfactant replacement therapy in two groups.

Materials and Methods: This is a randomized controlled clinical trial. Eighty four preterm infants delivered in Al-Zahra Hospital with gestational age 28-32 weeks were enrolled in this study from January 2012 to September 2012. They were randomly allocated in two groups. After initial stabilization in delivery room, forty two infants transferred to neonatal intensive care unit (NICU) with face mask CPAP and 42 infant with nasopharyngeal CPAP and continued nasal CPAP in the NICU in both groups. All infants were followed for developing respiratory distress and need for surfactant replacement therapy and oxygen dependency till discharge.

Results: The neonates that treated with two methods of CPAP delivery were similar with respect to gestation age, birth weight and other demographic characteristics. Twenty three neonates (65.5%) in face mask group and 15 neonates (39.5%) in nasopharyngeal CPAP group need surfactant replacement therapy (p=0.08).

Conclusion: Mask CPAP or nasopharyngeal CPAP can used in preterm infants after delivery for neonatal transfer to NICU. This study showed no method of CPAP delivery is preferable to other in decreasing the need for surfactant therapy.

Introduction

The frequency of preterm birth is about 12-13% in the United States and 5-9% in many other developed countries [1]. Prematurity remains the leading cause of neonatal morbidity and mortality worldwide accounting for 60-80% of deaths of infants without congenital anomalies [2].

Babies who are born before term are at risk for a variety of complications after birth. Premature babies are anatomically and physiologically immature. Their weak muscle may make it difficult for them to breathe. Their drive to breath may be decreased due to immaturity of the nervous system [3]. The lungs of preterm infants are immature, surfactant deficient, particularly liquid-filled, and prone to collapse at end expiration. After inflation without positive end expiratory pressure (PEEP), lung volume is lost, and atelecto-trauma can develop during the next inflation [4].

Continuous positive airway pressure (CPAP) is the application of positive pressure to the airways of the spontaneously breathing patient throughout the respiratory cycle. The device provides heated and humidified continuous or variable flow from a circuit connected to a continuous gas source. CPAP maintains inspiratory and expiratory pressure above ambient pressure, which results in an increase in functional residual capacity (FRC) and prevents lung collapse [5].

CPAP in delivery room is administered by placing the mask of flow-inflating bag or T-piece resuscitator tightly on the baby's face and adjusting the flow-control valve or positive end-expiratory pressure (PEEP) valve to the desired amount of CPAP. Generally 4-6 cm H2O is an adequate amount of pressure [5]. T-Piece is best device for delivering CPAP because give fixed breathing [6]. Multiple methods of delivering CPAP to neonates have been described over the past four decade. Head box, nasal prong, nasal mask, endotracheal tube, and face mask are different devices of delivering CPAP [7, 8]. More recently CPAP has been delivered by nasopharyngeal tubes, some long enough to end just above the epiglottis and some extending only 1-2 cm inside the nose [9].

Mouth breath during nasopharyngeal CPAP may result in loss of desired pressure and decreased in delivered fraction of inhaled oxygen. However, most studies demonstrate effective CPAP without closed mouth [10]. An airtight seal between mask and face is important for successful ventilation. Achieving this seal can be difficult, and leak at the mask common reason for inadequate ventilation or failure of resuscitation. The average mask
leak is 60% [11]. Even when the set inflation pressure is achieved with a T-Piece device, large leak can occur in the presence of a high gas flow into the system [6]. Nasopharyngeal tube is easy to fix but increases airway resistance and is invasive measure [12]. The face mask is non invasive but associated with large leak and difficult to fix over face during infant transfer to NICU. There are conflicting data regarding superiority of these two types of CPAP delivery devices. Two methods of CPAP delivery are used in our center after initial stabilization for neonatal intensive care unit (NICU). This study was done to evaluate these two devices of CPAP delivery during neonatal transport after birth to NICU and compare them with respect to reduce in surfactant replacement equipments.

**Materials and Methods**

This is a randomized controlled clinical trial. Ethics committee of university approved the study. Informed parental consent was obtained when the infant met inclusion criteria. This study is registered in IRCT with number IRCT 201207083915N6. From January to September 2012, 84 preterm infants, with gestation age 28-32 weeks, who delivered in Al Zahra Hospital, Tabriz, Iran, were enrolled in this study. CPAP was indicated in these infants (they breath spontaneously with respiratory distress, had cyanosis or low saturation) in delivery room. Infants randomly allocated in two groups by using random number list according to their delivery sequence. Exclusion criteria was preterm birth less than 28 weeks or more than 32 weeks, intubation in delivery room as part of initial resuscitation, congenital major anomalies, craniofacial defects, diaphragmatic hernia, tracheoesophageal fistula, choanal atresia.

Forty-two infants transferred with face mask CPAP and 42 with nasopharyngeal CPAP. Face mask was tightly sealed over mouth and nose of infant in mask CPAP group, and a suitable size edotracheal tube was inserted in pharynx via nasal route in nasopharyngeal CPAP group by senior pediatric residents or neonatology fellows. Positive end expiratory pressure was produced by Neopuff Infant Resuscitator (Fisher & Paykel Health Care Ltd, Auckland, New Zealand). Initial pressures used were 4-6 cm H2O. The fraction of inspired oxygen was adjusted to give SpO2 89-92% and an arterial partial pressure of oxygen 60-80 mm Hg. After arrival to NICU, nasal CPAP was continued at NICU by medijet active CPAP generator (medijet® 1000, Medin innovations. GmbH) and using intermittent nasal mask and binasal prong.

Infants were followed for clinical and radiologic signs of respiratory distress syndrome (RDS). The RDS diagnosis was based on the occurrence of classic signs, such as need for oxygen supplementation, tachypnea, sub and intercostals retractions and grunting; and exclusion of other causes of respiratory failure. Diagnosis was confirmed by radiologic pattern consisted of reduced air content and a reticuloalgranular pattern of lungs with air bronchograms. Surfactant replacement therapy was performed by INSURE (intubation- surfactant-extubation) method in spontaneously breathing infants. The duration of mechanical ventilation and length of oxygen dependency was determined in all studied patients.

The demographic characteristics of neonates were compared. The student t test, Mann-Whitney rank sum test and $\chi^2$ test was used to compare between the two study groups. $p<0.05$ was considered statistically significant. Data were analyzed by using SPSS-16.0.

**Results**

Within a period of 9 month 125 preterm infant 28-32 weeks gestational age born in Al-Zahra hospital that 84 cases had inclusion criteria. The characteristics of neonates in two groups did not demonstrate significant difference with respect to delivery type, sex, gestational age, birth weight, 1 minute Apgar, and 5 minute Apgar score (Table 1). The most common risk factor was premature rupture of membranes (22 cases 26.2%), hypertension (16 cases 19%) and diabetes mellitus (4 cases 3.8%). Thirty-eight (45.2%) infants received surfactant after transfer to NICU, 23 neonates (60.5%) in mask CPAP group and 15 cases (39.5%) in nasopharyngeal CPAP group. ($p=0.08$). The studied neonates received surfactant at 1.6±0.3 hours of birth. Mechanical ventilation was done in 8 neonates (9.5%) that 4 patients were from each group. The mean duration of mechanical ventilation in nasopharyngeal CPAP group was 0.85±0.3 days and in mask CPAP group was 1.7±0.5 days.

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Face mask CPAP group</th>
<th>Nasopharyngeal CPAP group</th>
<th>$p$-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gender Male N(%)</td>
<td>26(61.9)</td>
<td>20(47.6)</td>
<td>0.18</td>
</tr>
<tr>
<td>Gender Female N(%)</td>
<td>16(38.1)</td>
<td>22(52.4)</td>
<td>0.18</td>
</tr>
<tr>
<td>Gestation age (week) (Mean±SD)</td>
<td>30.5±1.4</td>
<td>30±1.5</td>
<td>0.18</td>
</tr>
<tr>
<td>Birth weight (gr) (Mean±SD)</td>
<td>1530±143</td>
<td>1435±393</td>
<td>0.23</td>
</tr>
<tr>
<td>Mode of delivery Cesarean section N(%)</td>
<td>13 (31)</td>
<td>9 (21.4)</td>
<td>0.32</td>
</tr>
<tr>
<td>Mode of delivery Natural vaginal delivery N(%)</td>
<td>29(69)</td>
<td>33(78.6)</td>
<td>0.32</td>
</tr>
<tr>
<td>Apgar score (Mean±SD)</td>
<td>7.7±0.9</td>
<td>7.4±0.9</td>
<td>0.13</td>
</tr>
<tr>
<td>Maternal Corticosteroid No</td>
<td>8.9±0.7</td>
<td>8.6±0.7</td>
<td>0.09</td>
</tr>
<tr>
<td>Maternal Corticosteroid One dose</td>
<td>7</td>
<td>4</td>
<td></td>
</tr>
<tr>
<td>Maternal Corticosteroid Two doses</td>
<td>23</td>
<td>25</td>
<td>0.062</td>
</tr>
</tbody>
</table>

Table 1. Characteristics of patients in two groups
No sense connection between two groups was found in need to oxygen in day 28 of birth or need to oxygen at 36 week post menstrual age (Table 2). Patent ductus arteriosus (PDA) was diagnosed in 8 neonates (3 in mask CPAP and 5 in nasopharyngeal CPAP group). Intra-ventricular hemorrhage was showed in brain ultrasound examination in 12 newborns (4 in mask CPAP and 8 in nasopharyngeal CPAP group). Pneumothorax was not seen on any infant. One neonate dead in mask CPAP group because of bacterial sepsis.

Table 2. Need to O$_2$ in 28 day and 36 week post menstrual age

<table>
<thead>
<tr>
<th></th>
<th>CPAP</th>
<th>Mask</th>
<th>Nasopharyngeal CPAP</th>
<th>p-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>In 28 day, N (%)</td>
<td>5 (11.9)</td>
<td>4 (9.5)</td>
<td>0.72</td>
<td></td>
</tr>
<tr>
<td>In 36 weeks, N (%)</td>
<td>2 (4.8)</td>
<td>3 (7.1)</td>
<td>0.64</td>
<td></td>
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</tbody>
</table>

Discussion

In our study, the need for mechanical ventilation, the duration of mechanical ventilation or hospitalization, and the complications of prematurity were similar among preterm infants receiving nasopharyngeal CPAP and face mask CPAP. Although more patients in mask CPAP group need surfactant replacement therapy in our patients, but the difference was not statistically significant.

Early nasal CPAP, started after birth, is an effective non-invasive respiratory support that studied by several researchers. Some studies recommended early nasal CPAP in delivery room. Early CPAP was reduced intubation and mechanical ventilation [13, 14]. The more effective mode of CPAP delivery is not determined.

Mask has leak problem and nasopharyngeal tube obstruction problem. The face mask must be used with caution to prevent leak around it and avoidance of too much pressure to induce Vagal response. Nasopharyngeal tube increases resistance and work of breathing [15]. An alternative to avoid face mask leak is to use single or double nasal prong [16, 17].

Finer et al. in 2004 showed the feasibility of face mask CPAP using in delivery room and continuing nasal CPAP therapy in NICU in extremely low birth weight infants [18]. Ammari et al. noted that CPAP in the delivery room was less successful in more pre-term, smaller infants, since one third of infants weighting 700 g or less need intubation as part of their initial resuscitation [19]. Morely studied 610 preterm infants and used CPAP via single or binasal prongs delivered 8 cm H$_2$O pressure in one group and intubation in other group. The CPAP group received less surfactant and postnatal steroids for chronic lung disease (CLD), with more pneumothoraces [20]. In one study it was showed using CPAP with any device in the delivery room at 5 cm H$_2$O is associated with receiving less surfactant, and spending less time on mechanical ventilation without increased pneumothorax rate [21]. In our study 8 neonates (9.5%) underwent mechanical ventilation and none of the babies developed pneumothorax that may be due to lower initial CPAP pressures in our study. Segedin and associates examined nasal and oral airway as routes for resuscitation by observing chest expansion and using capnography. They showed that manual ventilation was more often successful when given via a nasal tube [22]. In a randomized trial, Capasso and colleagues compared binasal nasal prongs and the Rendall-Baker face mask during neonatal resuscitation of infants with moderate asphyxia. Neonates resuscitated with nasal prongs were needed significantly less intubation and chest compression [23].

Te Pas and coworkers observed less frequent intubation in delivery room by using a single nasal tube instead of face mask during stabilization of preterm infants at birth [12]. Davis et al. showed nasal CPAP delivered through binasal prongs is more effective than single nasal prong in prevention extubation failure [16]. In other studies it is not establish the clinical superiority of one device over other [17]. It is recommended future studies with large number of patients and in multi center trials to determine the superiority of one device in different situations. Bronchopulmonary dysplasia was diagnosed in 4.8% of neonates in mask CPAP group and 7.1% of neonates in nasopharyngeal CPAP group without significant difference. This may be related to low mechanical ventilation rate in our studied patients. Antenatal corticosteroid therapy and this may affect the severity of respiratory distress syndrome but since this was same in both groups its effect on the results of study is minimal. The small sample size of this study does limit its applicability. It is recommended future studies with large number of patients and also other studies in pre-term infants with gestation age less than 28 weeks that are at increased risk for BPD.

In this study, there was no sense connection found in need to surfactant, mechanical ventilation, complications (pneumothorax, PDA, IVH), need to O$_2$ in 28 day, and in 36 week post menstrual age between two groups. Mask CPAP or nasopharyngeal CPAP can used in preterm infants in delivery room for initial stabilization and transfer to NICU. This study showed one device has not superiority to other in decreasing need for surfactant replacement in pre-term infants.

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Authors’ Contributions

All authors had equal role in design, work, statistical analysis and manuscript writing.

Conflict of Interest

The authors declare no conflict of interest.

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