USE OF INDIGENOUSLY DESIGNED NASAL BUBBLE CONTINUOUS POSITIVE AIRWAY PRESSURE (NB-CPAP) IN NEONATES WITH RESPIRATORY DISTRESS - EXPERIENCE FROM A MILITARY HOSPITAL

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ABSTRACT

Objective: To study the efficacy and safety of an indigenously designed low cost nasal bubble continuous positive airway pressure (NB-CPAP) in neonates admitted with respiratory distress.

Study Design: A descriptive study.

Place and Duration of Study: Combined Military Hospital (CMH), Peshawar from Jan 2014 to May 2014.

Material and Methods: Fifty neonates who developed respiratory distress within 6 hours of life were placed on an indigenous NB-CPAP device (costing 220 PKR) and evaluated for gestational age, weight, indications, duration on NB-CPAP, pre-defined outcomes and complications.

Results: A total of 50 consecutive patients with respiratory distress were placed on NB-CPAP. Male to Female ratio was 2.3:1. Mean weight was 2365.85 ± 704 grams and mean gestational age was 35.41 ± 2.9 weeks. Indications for applying NB-CPAP were transient tachypnea of the newborn (TTN, 52%) and respiratory distress syndrome (RDS, 44%). Most common complications were abdominal distension (15.6%) and pulmonary hemorrhage (6%). Out of 50 infants placed on NB-CPAP, 35 (70%) were managed on NB-CPAP alone while 15 (30%) needed mechanical ventilation following a trial of NB-CPAP.

Conclusion: In 70% of babies invasive mechanical ventilation was avoided using NB-CPAP.

Keywords: Indigenous Nasal Bubble CPAP, Mechanical ventilation, Non-invasive ventilation, Respiratory Distress syndrome.

INTRODUCTION

Continuous positive airway pressure (CPAP) is defined as PEEP (positive end expiratory pressure) applied to a spontaneously breathing patient. The history of CPAP goes back to 1914 when Von Reuss described the “over pressure apparatus” in the classic German text “The Diseases of the Newborn” which consisted of tubings, an oxygen source, a snugly-fitted face mask, and a water-filled container. In 1970, Gregory et al. demonstrated that CPAP can be provided in preterm infants with respiratory distress syndrome by using an anesthesia bag. Subsequently, Dr. Jen-Tien Wung at Children’s Hospital of New York, Columbia University developed the Bubble CPAP system using short nasal prongs. In 1987, Avey et al. reported large differences in the risk-adjusted incidence of bronchopulmonary dysplasia with the use of Bubble CPAPs in a comparison of 12 academic neonatal intensive care units in the United States. During the Swine Flu Pandemic in Pune, India Dr. Aarti Kinikar demonstrated the use of indigenously designed nasal bubble CPAP in older children. Now, nasal CPAP has become an effective modality to treat respiratory distress syndrome (RDS) as well as apnea of prematurity, transient tachypnea of newborn (TTN) and neonatal pneumonia. It is also an effective method to prevent progression to intubation and extubation failure in neonates with RDS.

Pakistan is a poor country with insufficient resources for neonatal care and an alarmingly high neonatal mortality rate (55/1000 live births). Mechanical ventilation is only available in tertiary care setups and even in those setups, the neonates requiring mechanical ventilation greatly exceed the number of mechanical...
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ventilators available; also those placed on mechanical ventilator suffer from a high incidence of ventilator associated complications. Infant flow driver CPAP costs around 600,000 PKR (6000 USD) and nasal bubble CPAP costs around 20,000 PKR (200 USD). Therefore, we employed an indigenous simple to assemble, rugged, disposable, cost-effective (Rs. 220 PKR / 2.2 USD), safe and a well tolerated circuit in our highly demanding situation and evaluated its efficacy and safety. It was found to be an effective technique for treating neonates with respiratory problems. It is in no way an alternate to the mechanical ventilation or CPAP devices but it can be used as a modality of rescue therapy in emergency situation as well as a transport tool. To the best of authors’ knowledge, this is the first study employing an indigenously prepared Bubble Nasal CPAP circuit to manage respiratory distress in neonates.

MATERIAL AND METHODS

This descriptive study was performed from Jan 2014 to May 2014 at the NICU of CMH Peshawar. All infants with a gestational age of >28 weeks who developed respiratory distress within 6 hours of birth (clinically manifested by one or more of the following: grunting, tachypnea {respiratory rate >60/ minute}, sternal retraction, intercostal and subcostal recession) were included in the study. Babies with major congenital malformations, meconium aspiration syndrome or those who developed respiratory distress after 6 hours of birth were excluded from the study.

Fifty (n=50) infants who were admitted in NICU and fulfilled the inclusion criteria were included in the study by non-probability consecutive sampling. The indigenous NB-CPAP circuit costing just PKR 220, was set up at the patients’ bedside which could administer an end expiratory pressure of 5 cm of water with an FiO\textsuperscript{2} of 70%. The CPAP circuit setup required a nasal prong of appropriate size, an IV infusion set, a 1000 ml normal saline bottle and an oxygen source. The pressure was generated by connecting one tube (inhalational tube) of nasal prong to the oxygen source at a flow rate of 6 L/min and the exhale tube placed underwater at 5 cms depth into the saline filled drip (fig-1).

Parameters like gestational age, weight, gender, indications for placement on NB-CPAP, mean duration and complications while on NB-CPAP and need for mechanical ventilation were recorded for all babies included in our study. Successful outcome (efficacy) was defined as the resolution of respiratory distress on indigenous NB-CPAP alone without the need for mechanical ventilation as well as successful weaning off from the NB-CPAP with maintenance of oxygen saturation above 85% with head box oxygen requirement for 6 hours consecutively.

Continuous assessment of respiratory rate (RR), heart rate (HR), oxygen saturation, patient comfort, awareness level, chest elevation and use of accessory muscles was performed. Patients were shifted from NB-CPAP to mechanical ventilation (failure of NB-CPAP) if they had severe respiratory distress without improvement, signs of fatigue, frequent desaturation or apnoea.

All data were analyzed using Statistical Package for Social Sciences (SPSS) version 18.0. Frequencies and percentages were analyzed for the qualitative data like indications and

Figure-1: Schematic diagram of indigenously prepared NB-CPAP.
complications of NB-CPAP, need for mechanical ventilation, weight and gestational age category and whether the baby survived or died. Mean and standard deviation were calculated for the numerical variables like gestational age and weight of the baby.

**RESULTS**

Thirty five babies (70%) were males and 15 (30%) were females (M:F=2.3:1). Mean gestational age was 35.41 ± 2.90 weeks. Mean weight was 2365.85 ± 704 gms. Mean duration of NB-CPAP 32.77 ± 21.2 hours. Total time period spent by 50 neonates on NB-CPAP was 1756 hours and 25 minutes. Ten neonates (20%) were between 28-32 weeks of gestation, 23 (46%) were between 32-36 weeks and 17 (34%) were between 36-40 weeks and none was >40 weeks of gestation. Two babies (4%) were less than 1000 grams, 7 (14%) babies were between 1001-1500 grams, 23 (46%) were between 1501-2500 grams, 10 (20%) were between 2501-3500 grams and 8 babies (16%) were more than 3500 grams.

Indications for placement on NB-CPAP were transient tachypnea of newborn (TTN, 26 (52%)), respiratory distress syndrome (RDS, 22 (48%)), birth asphyxia syndrome (BAS, 1 (2%)) and aspiration pneumonia (1 (2%)). Out of 50 babies, 35 (70%) were managed successfully on NB-CPAP alone while 15 (30%) required mechanical ventilation after NB-CPAP failure, 28 (80%) out of 35 babies successfully treated on NB-CPAP were weaned off within 48 hours (fig-2). Out of 15 cases placed on mechanical ventilator following a trial of NB-CPAP, 13 had RDS and 2 had TTN (fig-3) and 13 of 16 (90%) were very low birth weight. Seven (14%) babies who were placed on mechanical ventilation and had RDS were successfully weaned off after receiving surfactant while 8 babies expired. Forty two (84%) babies were successfully treated and discharged. Weight-wise distribution of weaning off time periods is shown in fig-3. A total of 64% babies with weights above 1.5 kgs were weaned off of NB-CPAP within 48 hrs. No complications were observed in 38 (75%) of the patients and the most frequent complication observed was abdominal distension (8 (15%)) followed by pulmonary hemorrhage (3, 6%), nasal septal erosion (1, 2%) and oral crusting (1, 2%).

**DISCUSSION**

Pakistan accounts for 7% of the global neonatal deaths worldwide (upto 55 per 1000 live births). Respiratory distress is a common emergency responsible for 20-25% of neonatal deaths. Due to inadequate ventilation facilities,
most babies succumb to different complications of respiratory distress\textsuperscript{11}.

The most common etiology of neonatal respiratory distress is TTN. In severe TTN, ventilatory support is required\textsuperscript{11}. In a study conducted by Zaman et al. TTN (35.7\%) was the most common cause of respiratory distress followed by RDS, 25\%\textsuperscript{12}.

Devices used to generate CPAP include conventional ventilators, the bubble CPAP system and the infant flow driver\textsuperscript{13}. CPAP maintains positive pressure in the airways in spontaneously breathing patients during both phases of respiration, improves alveolar ventilation and oxygenation by increasing functional residual capacity, decreases pulmonary edema, minimizes expiratory bronchiolar collapse, decreases intrapulmonary shunting, lowers upper airway resistance, stimulates lung growth, conserves surfactant, increases lung compliance and reduces obstructive apnea\textsuperscript{14}. Currently, comparative studies are being done between different devices used to provide CPAP to the neonates and Bubble CPAP has proven to be superior in different randomised controlled trials as compared to ventilator CPAP due to its gentle and non traumatic mode of action\textsuperscript{15}. An Iranian study\textsuperscript{13} and an Indian Cohort\textsuperscript{16} showed that Bubble CPAP is associated with a significantly reduced duration of CPAP support and higher rate of successful extubation as compared to infant flow driver\textsuperscript{16}.

In our cohort, the most common indication of NB-CPAP was TTN (n=26, 52\%) followed by RDS (n=22, 44\%). Fifteen (30\%) neonates with RDS were intubated, all were given surfactant therapy; seven (14\%) were extubated and then placed on NB-CPAP while eight (16\%) died. Those eight patient had severe RDS and were Very Low Birth Weight (VLBW). Although the most common indication of NB-CPAP is RDS\textsuperscript{17}, we had slightly more patients with TTN(52\%) than RDS(44\%) who were placed on NB-CPAP. The reason for it might be the high number of elective caesarean sections. In a cohort by Iqbal et al, the most common indication of CPAP was RDS (62.2\%)\textsuperscript{18}. 

![Figure-3: Need for mechanical ventilation.](image-url)
The most common complication observed in our study was abdominal distension (15%) which was transient and resolved after aspiration of air from orogastric tube. Pulmonary hemorrhage (6%) was the second most common complication and was associated with a poorer prognosis. Iqbal et al\textsuperscript{18} reported abdominal distension in 6.7% of the patients while the study by Kinikar et al. in paediatric age group patients revealed no abdominal distension\textsuperscript{5}. Nasal trauma and erosion was seen in 2% of our patients as compared to 4.4% by Iqbal et al\textsuperscript{18} and 12% reported by Bahman-Bijari et al\textsuperscript{13}. Interestingly, we did not encounter any case of hypotension or pneumothorax in our study (similar to cohort by Kawaza et al\textsuperscript{19} and Bahman-Bijari et al\textsuperscript{13}) which normally occurs in infants being treated with infant flow driver as seen in cohort by Iqbal et al (4.4%)\textsuperscript{18}. No complication was seen in 75% of our patients which is comparable to the "no complication" rate of 77.7% reported by Iqbal et al using infant flow driver\textsuperscript{18}.

Bubble CPAP has proven to be a gentler mode of NIV in neonates and has shorter mean duration time for weaning off as compared to infant flow driver and ventilatory CPAP devices. In an Iranian cohort, there was a statistical difference between mean durations of treatment in bubble CPAP and ventilator CPAP groups (35.5 ± 31.92 h vs. 57.5 ± 33.99 h)\textsuperscript{13}. In a local study using infant flow driver, mean duration of nCPAP was 63.4 ± 29 hours\textsuperscript{18}. Mean treatment duration in our patients who responded to treatment was 32.77 ± 21.2 hours.

In our study, the need for mechanical ventilation was reduced by 70% and 30% babies needed rescue mechanical ventilation after nCPAP failure. A study by Iqbal et al, done in Lahore showed reduction of need for mechanical ventilation by 71.1% and failure of CPAP by 28.9%\textsuperscript{18}. At Columbia Presbyterian Medical Center 76% of spontaneously breathing very low birth weight infants <1250 grams with respiratory distress do not require mechanical ventilation\textsuperscript{20}.

The mortality rate in our cohort was 16%. All of the babies were <1500 grams and had severe RDS. Kawaza\textsuperscript{19} and Iqbal\textsuperscript{18} reported up to 15% and 13.3% mortality in their cohort.

In our study, 15 patients received mechanical ventilation (after trial of NB-CPAP) and out of them 8 patients died resulting in mortality rate of 53.33% among ventilated patients. Iqbal et al reported up to 38.64% in their mechanically ventilated patients\textsuperscript{18}.

Our device is easy to assemble at bed side, simple to teach, is disposable, can be assembled by a paramedic or a nurse, can be employed during transport of a patient, doesn't require electricity or a battery to operate and is remarkably cheap (220 PKR only). It is well tolerated, avoids the complications of invasive ventilation, requires less intensive monitoring as compared to mechanical ventilation and rescues hospital stay and morbidity. Its also being used for other indications like apnea of prematurity, ARDS, bronchopneumonia, chronic pulmonary diseases, pulmonary edema and asthma. We can safely state that our medical device is scientifically valid, adapted to local needs, acceptable to both patient and healthcare personnel and can be utilized and maintained within the limited resources of the community or country.

CONCLUSION

Our findings demonstrate the feasibility of successfully using a cheap, rugged, less invasive indigenous bubble CPAP in neonates with respiratory distress in our region. For clinicians managing neonates in a developing country like Pakistan, with few ventilators and a short supply of surfactant, early institution of CPAP delivered via an inexpensive system can significantly reduce the need for mechanical ventilation and surfactant without increasing death or morbidity.

RECOMMENDATION

Our indigenous device is a ray of hope for the physicians and paediatricians working in rural areas where often the newborns succumb to death either in the
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clinic or on their way to a better facility. Being low cost and simple to prepare at the patients' bedside, it can provide for better management of respiratory distress especially in low level facilities like BHQs and THQ and can be utilized to safely transport babies to a unit with better facilities for management of respiratory distress. We recommend that training workshops should be conducted throughout the country for general physicians, neonatal physicians and pediatricians who are working in limited resources settings in order to acquaint them with this inexpensive device to use as a rescue device or a transport tool.

**CONFLICT OF INTEREST**

This study has no conflict of interest to declare by any author.

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