

Original Article

Outcome of Early Continuous Positive Airway Pressure (CPAP) in Preterm Newborns with Respiratory Distress Syndrome

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Background : Continuous Positive Airway Pressure has emerged as one of the main modality of treatment in Respiratory Distress Syndrome in Preterm Neonates. Early CPAP therapy has been shown to be successful in many clinical trials in the management of RDS, though studies from India are scarce.

Aim : The aim of the study was to determine whether introduction of Early CPAP results in improvement in terms of survival, need for mechanical ventilation and complications in early Preterm Neonates.

Methods : The study was a Prospective Observational study. All statistical analysis were performed using SPSS software version 24.0. P values <0.05 were considered significant.

Results : 126 newborns with gestational age 28-32 weeks were included in the study. 94 babies were given Early CPAP (74.6%) whereas 32 were not (25.4%). Among 94 babies who were put on Early CPAP, 91 babies did not need mechanical ventilation whereas 3 babies needed it (3.12%). Among the babies who were not put on Early CPAP (32), 26 did not need mechanical ventilation but 6 babies needed it (18.8%). P value is 0.003 ie, statistically significant. Among 94 babies who were put on Early CPAP, 4 babies died (4.3%) whereas 32 babies were not put on Early CPAP and 5 among them died (15.6%). P value is 0.031 ie, statistically significant.

Conclusion : Early institution of CPAP in the management of RDS in premature Neonates can significantly reduce the need for Mechanical ventilation and Mortality, with minimum associated complications.

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Key words : Early Continuous Positive Airway Pressure (CPAP), Outcome, Preterm Neonates, Respiratory Distress Syndrome.

Respiratory Distress Syndrome (RDS) is the commonest cause of neonatal mortality in preterm babies. It is an acute illness, developing within 4-6 hours of birth, characterized by a rapid respiratory rate (>60 breaths/min), intercostal, subcostal and sternal retraction or indrawing, expiratory grunting and cyanosis.

OBJECTIVES

(1) To assess the outcome of early CPAP therapy in Preterm Neonates with 28-32 weeks of gestation in a Tertiary Care Hospital in terms of survival and need for mechanical ventilation.

(2) To assess the incidence of various adverse effects in neonates with 28-32 weeks of gestation undergoing CPAP therapy.

MATERIALS AND METHODS

Study Design : Prospective Observational Study

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Editor's Comment :

- Early institution of CPAP is a cost-effective intervention for Preterm babies with RDS in a 3rd world country like India, where resources are scarce in many areas.
- Early CPAP can significantly reduce the mortality, need for invasive ventilation and its associated complications.

Place of Study : Neonatal Intensive Care Unit (NICU) in the Department of Paediatric Medicine, R G Kar Medical College and Hospital, Kolkata.

Period of Study : 2017-2019

Study Population : Preterm babies with gestational age 28-32 weeks born in R G Kar Medical College and Hospital

Sample Size : For calculation of sample size, a formula for Descriptive studies was used. The formula is as follows-

$$N = \frac{(Z\alpha/2)^2 \times p \times q}{L^2}$$

Where N = Sample size

Z $\alpha/2$ = Standard Normal Deviate and its value would be 1.96 considering 95% Confidence Interval.

p = Expected proportion of CPAP failure obtained from a study carried out by RV Jeya Balaji, *et al* in a Tertiary Care Teaching Hospital in Kochi.

$$q = (100-p)$$

L = Precision in absolute terms and it will be taken as 8 percentage.

An observation period of one month showed that an average of 1 newborn babies are put on CPAP every day in the inborn Neonatal Intensive Care Unit of R G Kar Medical College & Hospital. So the yearly average is around 360 babies who are put on CPAP. Keeping the Precision level of our study at 8, the required sample size was 126. Systematic random sample technique was taken as sampling technique for this study.

$$\text{Thus, } (Z_{\alpha/2})^2 = 3.84$$

$$p = 30\%$$

$$q = 70\%$$

$$L = 8$$

$$N = \frac{3.84 \times 2100}{64}$$

$$= 126$$

Inclusion Criteria :

Preterm babies born in R G Kar Medical College and Hospital with gestational age 28-32 weeks having respiratory distress.

Exclusion Criteria :

- (1) Babies with Congenital anomalies
- (2) Needs mechanical ventilation at birth
- (3) Congenital anomalies affecting ventilator function (Diaphragmatic hernia)
- (4) Infants with Severe Early Onset Sepsis or Compromised pulmonary blood flow (PPHN)
- (5) Infants with low APGAR scores (Birth asphyxia) and responding poorly to resuscitation efforts
- (6) Premature babies <28 weeks of gestation or birth weight <1000 gm
- (7) Progressive atelectatic disease

Outcome Measures and Parameters :

• **Primary Outcome Measures :** Need for Mechanical Ventilation and Mortality

• **Secondary Outcome Measures:** Complications like Nasal trauma, Hypotension, Intraventricular hemorrhage, CPAP belly, Oliguria, Metabolic acidosis, Necrotising Enterocolitis, Bronchopulmonary Dysplasia (BPD), Pneumothorax, Pulmonary Hemorrhage

Statistical Methods : Quantitative variables were presented as mean and standard deviation. Categorical variables were presented as frequency and percentages and were compared using Pearson χ^2 or Fisher's exact tests. Continuous variables were compared using Student t-test. P values <0.05 were

considered significant.

RESULTS

The total number of study population was 126, of which 76 were boys (60.3%), 49 were girls (38.9%) and 1 baby had ambiguous genitalia (0.8%). 114 babies were Appropriate for gestational age (90.5%), 9 babies were Small for gestational age (7.1%) and 3 babies were Large for gestational age (2.4%). Among 126 deliveries, 59 were delivered by Lower Segment Caesarean Section (46.8%) and 67 were delivered by Normal Vaginal Delivery (53.2%) (Table 1).

Among all the babies, 106 (84.1%) had RDS soon after birth (within 30 minutes) whereas 20 had developed RDS later (15.9%). Among 126 babies, 94 were given Early CPAP (74.6%) whereas 32 were not given (25.4%) (Table 2).

Descriptive analysis of Primary Outcome Measures :

Among the babies who were put on CPAP due to RDS, 9 had CPAP failure and had to put on Mechanical ventilation (7.1%). Among the babies who were given CPAP therapy, 117 survived (92.9%) and 9 babies died (7.1%).

Association of Early CPAP with Need for Mechanical Ventilation :

Among 126 babies, 94 were put on Early CPAP, among which 91 babies did not need mechanical ventilation whereas 3 babies needed mechanical ventilator (3.12%). Among the babies who were not put on Early CPAP (32), 26 did not need mechanical

Table 1 — Descriptive analysis of Neonatal Parameters

| Parameter | Frequency | Percentage |
|--|-----------|------------|
| 1. Gender : | | |
| Ambiguous | 1 | 0.8 |
| Boy | 76 | 60.3 |
| Girl | 49 | 38.9 |
| 2. Mode of delivery : | | |
| LSCS | 59 | 46.8 |
| NVD | 67 | 53.2 |
| 3. Weight for gestational age : | | |
| AGA | 114 | 90.5 |
| LGA | 3 | 2.4 |
| SGA | 9 | 7.1 |

Table 2 — Descriptive analysis of RDS and Early CPAP

| Parameter | Frequency | Percentage |
|---|-----------|------------|
| 1. RDS soon after birth | | |
| No | 20 | 15.9 |
| Yes | 106 | 84.1 |
| 2. Preterm babies according to whether Early CPAP given or not | | |
| No | 32 | 25.4 |
| Yes | 94 | 74.6 |

ventilator but 6 babies needed it (18.8%). P value is 0.003 i.e. statistically significant.

Association of Early CPAP with Mortality :

94 babies were put on Early CPAP among whom 4 babies died (4.3%) whereas 32 babies were not put on Early CPAP and 5 among them died (15.6%). P value is 0.031 ie, statistically significant (Table 3).

Descriptive analysis of Secondary Outcome Measures :

Among the babies on CPAP, 37.3% had Nasal trauma (commonest complication in our study), followed by CPAP belly 11.9%, Metabolic acidosis 7.9%, Hypotension 7.1%, NEC developed in 5.5% cases, BPD in 3.9%, 1.5% developed Pulmonary haemorrhage. 24.6% babies had no complications (Fig 1).

DISCUSSION

In 1971, Gregory, *et al* first described the method of delivery of CPAP in treating RDS. Since then many studies have been published evaluating the effectiveness of CPAP. But studies evaluating the effectiveness of Early CPAP is scarce in Indian literature. In our study, 126 Preterm Neonates born at

RGKMCH were selected depending upon the inclusion and exclusion criteria. 94 of the babies were put on Early CPAP (within 30 minutes) as they developed RDS soon after birth, according to protocol. 32 babies were put on CPAP later when they developed respiratory distress and needed $\text{FiO}_2 > 60\%$.

- In our study, among all the babies, 106 (84.1%) developed RDS soon after birth (within 30 minutes) whereas 20 had developed RDS later (15.9%). In a study conducted by R V Jeya Balaji, 84.3% babies developed RDS soon after birth whereas 15.7% babies developed RDS later¹.

- In our study, Among 126 babies, 94 were given Early CPAP (74.6%) whereas 32 were not given (25.4%). Among the babies who were put on CPAP due to RDS, 9 had CPAP failure and had to put on Mechanical ventilation (7.1%). In a study conducted by R V Jeya Balaji, the incidence of CPAP failure was 30% (95% CI 19.3% to 40.7%)¹. Another study conducted by Sunil B, *et al* showed that the incidence of CPAP failure who require Mechanical ventilation was 22.1% (95% CI 14.27-32.54%)². In another study by Tapia, *et al*, incidence of CPAP failure was 29.8%³.

- Among the 126 babies who were given CPAP therapy, 117 survived (92.9%) and 9 babies died (7.1%). In the study conducted by R V Jeya Balaji, *et al*, proportion of neonates, who met with mortality was 7.1% (1.1% to 13.2%) ie, same with our study¹. In another study by Sunil B, *et al*, percentage of babies who met with mortality was 6.5% (10.14-26.77%)². Another study by Tapia *et al* showed that mortality in babies given CPAP therapy was 8.4%³. All the studies showed similar results.

- Among the babies who were put on CPAP, 37.3% had Nasal trauma (commonest complication in our study), followed by CPAP belly 11.9%, Metabolic acidosis 7.9%, Hypotension 7.1%, NEC developed in 5.5% cases, BPD in 3.9%, 1.5% developed Pulmonary haemorrhage. 24.6% babies had no complications. In the study conducted by R V Jeya Balaji showed that Nasal Trauma, Hypotension, Intra Ventricular Hemorrhage and CPAP belly were the most common complications, occurring in 80% (70.6% to 89.4%), 11.4% (4% to 18.9%) and 10% (3% to 17%) of neonates each respectively. The other complications observed were CPAP belly, oliguria, septal injury, metabolic acidosis etc. No case of pulmonary hemorrhage was reported in the study¹. Another study by Tapia, *et al* found that Incidence of Pneumothorax was 3.1% in CPAP group, BPD 6.9%, PDA 34.4%, IVH 25.2%, NEC 15.3%, and Nasal trauma in 8.4% cases³. In Another study named COIN trial by Colin J

| Primary Outcome | Frequency | Percentage |
|---------------------------------|---------------------------------|------------|
| Need for Mechanical Ventilation | 9 | 7.1 |
| Mortality | 9 | 7.1 |
| | Need for Mechanical Ventilation | |
| | No | Yes |
| Early CPAP | No 26 | 6 32 |
| | Yes 91 | 3 94 |
| Total | 117 | 9 126 |
| | Mortality | |
| | No | Yes |
| Early CPAP | No 27 | 5 32 |
| | Yes 90 | 4 94 |
| Total | 117 | 9 126 |

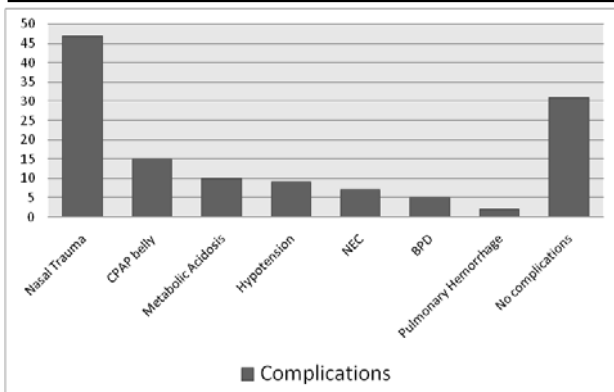


Fig 1 — Complications of CPAP

Morley showed that Complications were Pneumothorax 9.1%, Pulmonary interstitial emphysema 5.5%, Intraventricular haemorrhage grade III or IV 8.9%, Cystic periventricular leukomalacia 2.9%, Necrotizing enterocolitis grade II or III 3.9%, Retinopathy of prematurity 53.1% and Patent ductus arteriosus 32.4%⁴.

- Our study shows that babies who were put on Early CPAP needed less Mechanical Ventilation. Among 126 babies, 94 were put on Early CPAP, among which 91 babies did not need Mechanical Ventilation whereas 3 babies needed Mechanical Ventilator (3.12%). Among the babies who were not put on Early CPAP (32), 26 did not need Mechanical Ventilator but 6 babies needed it (18.8%). P value is 0.003 ie. statistically significant. Study conducted by R V Jeya Balaji, *et al* showed that the incidence of CPAP failure was 30% (95% CI 19.3% to 40.7%) in study population ie, 30% babies needed Mechanical Ventilation¹. Another study by Sunil B, *et al* showed that the incidence of CPAP failure who require Mechanical Ventilation was 22.1% (95% CI 14.27-32.54%) in study population². Another study by Tapia, *et al* showed that need for Mechanical Ventilation in Early CPAP group was 29.8%³.

- Our study showed that there is strong correlation between Early CPAP and survival. Among 126 babies in total, 94 babies were put on Early CPAP among whom 4 babies died (4.3%) whereas 32 babies were not put on Early CPAP and 5 among them died (15.6%). P value is 0.031 ie, statistically significant. In the study conducted by R V Jeya Balaji, *et al*, proportion of babies who met with mortality was 7.1% (1.1% to 13.2%)¹. Another study by Sunil B, *et al* showed that babies who were put on Early CPAP and met with mortality was 6.5% (10.14-26.77%)². In

another similar study by Tapia, *et al*, mortality among babies put on Early CPAP was 8.4%³.

CONCLUSION

We conclude from our observational study that:

- Early institution of CPAP in the management of RDS in Premature Neonates can significantly reduce the need for Mechanical Ventilation and Mortality.
- Early institution of CPAP can also reduce the incidence of BPD, with minimum associated serious complications.
- Early use of CPAP is a low-cost, simple and non-invasive option for a country like India, where most places cannot provide Invasive ventilation and Surfactant.

Limitations :

- No Control group was taken for comparative analysis of the efficacy of Early CPAP with Late CPAP.
- Preterm babies with gestational age <28 weeks and >32 weeks were not taken in our study, which limits the generalizability of the results.
- The role of many confounding factors could not be evaluated because of the limited sample size.

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