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Original Research Article

Comparison of Saans neonatal continuous positive airway pressure against standard of care for intra-hospital transport of neonates with respiratory distress syndrome

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ABSTRACT

Background: CPAP (continuous positive airway pressure) therapy, effective in managing neonates with respiratory distress. While CPAP therapy is indicated right from birth, existing CPAP systems are designed for/installed in, NICUs. As a result, most neonates with RD (respiratory distress) are managed with only oxygen therapy during transportation in low resource settings. This study compares a novel, low-cost, portable neonatal CPAP system for use in transport from the labor room to the NICU, against conventional oxygen therapy in low resource settings.
Methods: This was an open-label, 2 arm study with a treatment arm (low-cost indigenous CPAP device for therapy) and a control group (oxygen therapy). A total of 132 neonates were assigned with 66 in (matched-control study), in each group.
Results: Both arms (CPAP and oxygen) had similar gestational age. gender distributions and initial SAS scores. The CPAP group had higher use of antenatal steriods (38 versus 26) compared to oxygen group and a lower need for surfactant (28 versus 40). Also, a larger number of neonates required ventilation in oxygen group (42) versus CPAP group (15), with the p=0.000561 the result is significant at p<0.05.
Conclusions: CPAP therapy induced in labor room measurably improves neonates health and reduces respiratory distress. The indigenous low-cost CPAP device (Saans) used in this study effectively provides CPAP therapy to neonates during transport from the labor room to the NICU, reducing respiratory distress and the need for mechanical ventilation, making useful addition to labor rooms.

Keywords: CPAP therapy, Respiratory distress syndrome, NICU

INTRODUCTION

The first 28 days of a child (neonates) carries the highest risk of mortality per day than any other period during the childhood. The daily risk of mortality in the first 4 weeks of life. The daily risk of mortality in the first 4 weeks of life is ~30-fold higher than the post-neonatal period, that is, from 1 month to 59 months of age.[1] India contributes to one-fifth of global live births and more than a quarter of neonatal deaths.[1] Nearly 3.5 million babies in India are born too early, 1.7 million babies are born with birth defects and one million newborns are discharged each year from special new-born care units (SNCUs). These newborns remain at high risk of death, stunting and developmental delay.[2] A systematic analysis of global, regional and national causes of child mortality in 2013 identified preterm birth complications and infections to be the two major causes of neonatal deaths in India.[3,4] The review, which included the data from the million death study from India, found perinatal asphyxia and malformations to be the other two significant causes of neonatal mortality.[5] These findings are very similar to the

overall global pattern.[4] A pooled analysis of the data from three studies on the timing of neonatal deaths indicated that about three-fourths of total neonatal deaths occured in the first week of life.[6-8] The first 24 hours account for more than one-third (36.9%) of the deaths that occur in the entire neonatal period. A recent prospective study by Baqui et al provided data on the timing of cause-specific neonatal deaths: almost all deaths (97.8%) due to asphyxia occur in the first week of life, with 70% of them occurring within the first 24 hours.[6] About three-fourth of deaths due to prematurity (74.8%) occur in the first week of life, with 30% in the first 24 hours 50% of neonatal deaths secondary to sepsis occur in the first week of life. About 30% of sepsis-related deaths occur in the second week, whereas around one-fifth in weeks.[9] Three-fourth of the deaths due to malformations occur in the first week of life, with day 0 alone contributing to nearly half of these deaths.[6]

Acute respiratory distress (ARD) is one of the main causes of morbidity and mortality in the neonate population and one of the most frequent causes of admission to intensive care units. It is also a frequent reason for transfer to tertiary level centers. ARD is associated with case fatality rates as high as 20% in low-income and middle-income countries (LMIC).[10]

The most basic respiratory support for neonates with ARD is oxygen, followed by non-invasive support such as CPAP and by mechanical ventilation. Mechanical ventilation involves endotracheal intubation, an invasive procedure requiring high technical skills. In contrast, CPAP can in principle be applied by non-specialist healthcare providers.[11] It is estimated that the use of oxygen in combination with CPAP for the treatment of RD contributed to a 70% increase in the survival of preterm babies in high-income countries.[12] Several studies reported that CPAP is safe and effective in LMIC and its use in these settings is increasing.[13-20] A considerable body of evidence has accumulated over the last 35 years that supports CPAP use in neonatal intensive care units. There is, however, limited literature on its use during transport especially from the neonatal population perspective. Paediatric interhospital ground transport can increase the risk associated with the patient's current disease. Critical events can occur in up to 15% of paediatric transports. The transport of neonates is further complicated due to their higher risk of instability and the narrow range of equipment and supplies available for this population.[22,23] While CPAP therapy is indicated right from birth, existing CPAP systems are designed for/installed in, neonatal intensive care units (NICUs). As a result, most neonates with RD are managed with only oxygen therapy during transportation in low resource settings. Non-invasive ventilation (NIV) has emerged as a powerful tool for the emergency management of ARF in pediatric transport. The aim of this study was to compares a novel, low-cost, portable neonatal CPAP system, for use in transport from the labor room to the NICU, against conventional oxygen therapy in low resource settings.

The aim of the study was to evaluate the efficacy of a low cost, multi-powered and easy-to-use CPAP device Saans, on neonates with respiratory distress in comparison to oxygen therapy.

METHODS

A pragmatic, open-label case-control study was undertaken at M. V. J medical college and research hospital, Hoskote, Karnataka, a rural tertiary care teaching hospital. The study extended over a period of 7 months (June 2018 to December 2018). Written and signed consent was obtained from a parent or a legal representative of the patient for the study. The clinical study was approved by the ethics committee prior to study initiation.

Inclusion criteria

All neonates with a all preterm babies (32 weeks average); birth weight of 1.3 kgs; patients with presence of signs of respiratory distress, respiratory rate was >60 /min or <30 /min and % of oxygen saturation was <90% on room air were included in the study.

Exclusion criteria

Neonates having chromosomal abnormality; presence of significant morbidity, that is, cardiac diseases besides RDS; congenital malformations, that is, diaphragmatic hernia or trachea-oesophageal fistula or cleft lip or cleft palate were excluded.

Randomization

Randomization was done by computer-generated random numbers in blocks of 12, with the sequence generated by an independent statistician. Allocation concealment was maintained by using opaque, sealed, sequentially numbered envelopes prepared by a person not involved with the study.

Outcomes and predictors of success with Saans (CPAP)

Premature neonates included in this study were noted for Silverman-Anderson Score (SAS), signs of grunting, chest retractions, substernal retractions and nasal flaring along with basic demographic data (date of birth, place of birth and gender). Appropriate gestational age (AGA)/small for gestational age (SGA), administration of antenatal steroids, mode of delivery-lower segment caesarian section (LSCS)/normal vaginal delivery (NVD) have also been noted. Successful CPAP therapy was defined as the weaning off of respiratory support and Therapy failure was defined by the worsening of respiratory distress and a shift in therapy to mechanical ventilation.

Interventions and monitoring

After obtaining consent from parents/guardians, they were asked to randomly pick a brown envelope in which the mode of treatment the baby would receive was determined. Babies randomized to receive Saans (CPAP device) were put on Saans and babies randomized to the oxygen arm, received humidified oxygen from an oxygen cylinder via nasal prongs.

CPAP with Saans device was started if the SpO_2 on room air was <90% and in respiratory distress. CPAP started in these infants using Saans using bilateral nasal prongs as the interface. All neonates enrolled in the study were constantly monitored for clinical signs of respiratory distress using SAS. A daily record sheet was maintained for each enrolled patient. This daily record sheet included logging of the following parameters: respiratory rate, SpO_2, FiO_2, grunting and the application of Saans (CPAP device) on the patient on an hourly basis. The positive end-expiratory pressure (PEEP) value was also recorded.

The time of starting Saans and oxygen therapy, total duration of therapy, time taken to wean off therapy and treatment complications were noted throughout the transport until the babies reached neonatal care unit.

Statistical analysis

Data was entered and analyzed using statistical package for social sciences (SPSS) version 22. Continuous variables were summarized using means and standard deviation (SD) as well as medians and interquartile ranges while categorical variables were summarized using frequency and proportions. Outcome variables were compared between the infants with Saans (CPAP) and oxygen therapy. Assessment of gestation age was done by the Finnistrom maturity score chart. Severity of respiratory distress was assessed using the SAS. The outcomes of interest were survival and the independent variables included gestational age, birth weight, sex and mode of treatment. Significance was defined as $p<0.05$ for the predefined outcome variables and $p<0.001$ for other outcome variables explored post-hoc.

RESULTS

The demographic and clinical characteristics of the study participants have been summarized in Table 1.

There was no difference in the baseline characteristics between the Saans group and oxygen therapy group (control). The overall median gestational age was 32 (range 28-35) weeks. Majority had a gestation age ranging from 32 to <35 weeks and birth weight of 1.5-2.5 kgs. More than half (68) of the mothers received antenatal steroids before delivery.

Survival to discharge between the Saans (CPAP) arm and oxygen therapy arm (Figure 1). Babies treated with Saans (CPAP) had a higher survival rate compared to their counterparts who were treated with oxygen therapy (Figure 1). A total of 7 deaths were observed with 6 deaths occurring in the oxygen arm and 0 in the Saans (CPAP) arm. Apart from the deaths, neonates undergoing oxygen therapy also has also showed higher complications while transporting when compared Saans (CPAP) (complications reported in CPAP was 1 whereas in oxygen arm were 6).

Table 1: Social demographic and clinical characteristics of participants (n=132).

Variables	N	Saans (CPAP) (N)	Oxygen (N)	P value
Gestational age (weeks)				
28-35	132	66	66	0.52
Gender				
Male	62	29	33	0.25
Female	70	37	33	
Birth weight (in kg)				
1.0-1.4	64	27	37	1
1.5-2.5	68	41	27	
Mode of delivery				
LSCS	67	34	33	1
NVD	65	32	33	
Antenatal steroids received				
Yes	64	38	26	0.8
No	68	28	40	

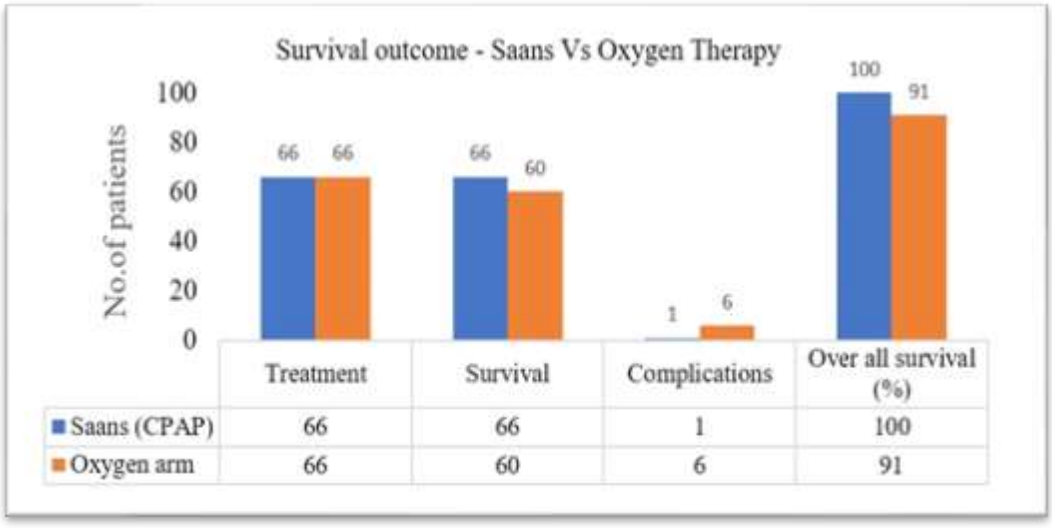

Figure 1: Survival outcome-Saans versus oxygen therapy.

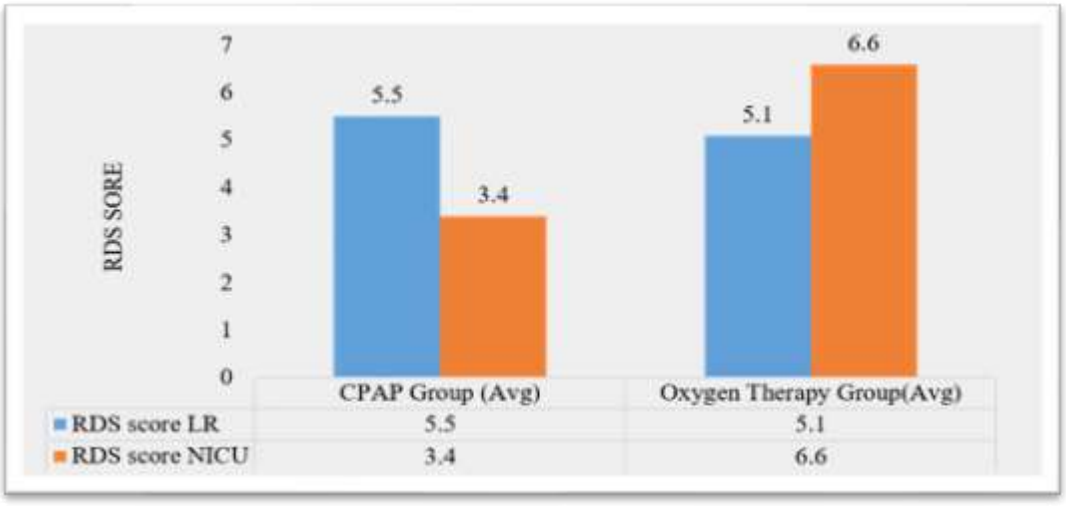

Figure 2: RDS scores.

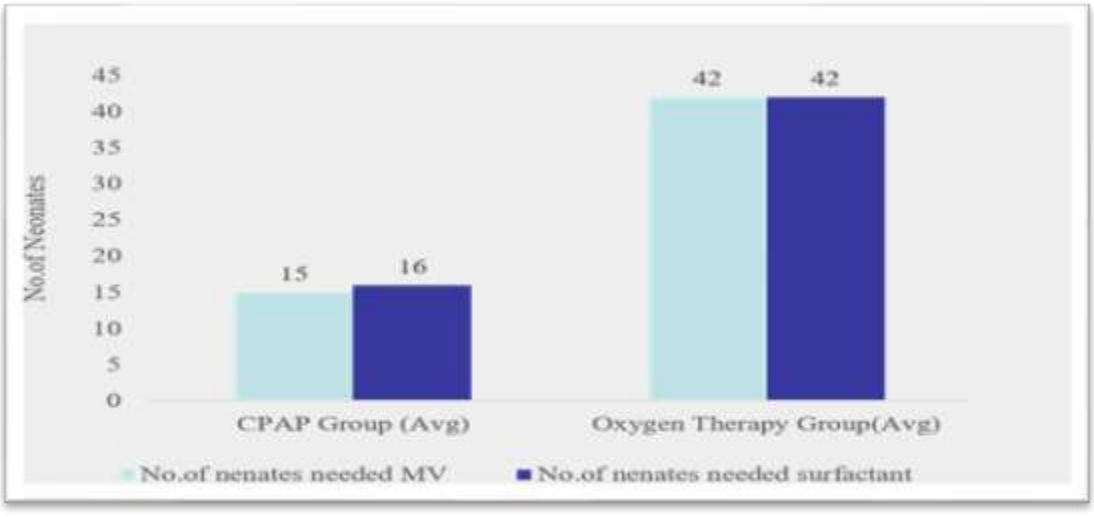

Figure 3: Comparison of patient outcomes intervention vs control.

Treatment outcomes of Saans (CPAP) versus oxygen therapy

The mean (SD) SAS respiratory severity score for the neonates in the oxygen therapy arm was on an average more >5 in LR and >6 in NICU. Therefore, majority of the neonates needed surfactants eventually leading to mechanical ventilation (MV). Whereas for the neonates in Saans (CPAP) arm the RDS scores were on an average >5 in LR and <4 in NICU. The need for surfactant in this group was also very less and apparently the need for mechanical ventilation.

DISCUSSION

This study was first of its kind conducted at a rural tertiary care teaching hospital in India. Although survival in the Saans (CPAP) group was improved by one-third we were not able to show a significant difference with babies receiving oxygen therapy. The median treatment duration between the two groups was similar. The duration of hospital stays amongst the babies that survived to discharge in our study was shorter in the Saans (CPAP) group as compared to the oxygen group although not statistically significant. The findings from our study did not contradict other studies in low and middle-income countries that showed great improvement of survival to discharge in preterm babies when treated with CPAP.[23-27] Pieper et al conducted a small non-randomized study in South Africa demonstrating increased survival rates of extremely immature babies with moderate to severe respiratory distress treated with nasal CPAP in the absence of surfactant replacement therapy and neonatal intensive care. Our results did not contradict Saha et al who reported a reduced treatment duration with bCPAP as compared to oxygen therapy (3.69±1.55 versus 7.67±2.76).[27] This was in contrast to the study in Malawi were the authors reported a longer mean treatment duration of 6.9 (SD=5.37) days on the bCPAP arm compared to the oxygen therapy arm 4.0 days (SD=4.37) days.

In our, it was observed an increased risk of deaths among preterm babies whose mothers didn't receive antenatal steroids. This had been reported in other studies showing poor outcomes in such babies.[29-33]

CONCLUSION

Our study suggests that Saans (CPAP) can help reduce the morbidity and mortality among preterm babies with respiratory distress and should be considered as the mainstay of treatment for these babies in comparison to oxygen therapy during transportation. This may pave the way for Saans (CPAP) roll out on a large scale in our country, improving the management of these babies and reducing the need of referring preterm babies with respiratory distress.

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