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Original Research Article

Efficacy of multi-powered continuous positive airway pressure device on neonates bearing respiratory distress syndrome: an observational analytical study

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ABSTRACT

Background: CPAP (continuous positive airway pressure), an effective intervention for respiratory distress in neonates. Following the development of simple, safe and relatively inexpensive CPAP devices. Saans (CPAP device) is one such portable, easy to use device which is operable in low resource settings, can be used as T-piece resuscitator in the delivery room and during transport. The aim of this study was to evaluate the efficacy of a low cost, multi-powered and easy to use CPAP device Saans, developed by Coeo Labs Pvt. Ltd., Bangalore, on neonates with respiratory distress.
Methods: An observational analytical study per the protocol, 35 neonates gestational age >30 weeks were enrolled. Primary outcome variable was the need for mechanical ventilation. Secondary outcome variables were the rate of survival, duration of oxygen in hours, duration of ventilation in hours, duration of hospital stay in days, change Downe score, SAS score, heart rate, respiratory rate and FiO_2 from enrolment 6 hours of intervention.
Results: 89% (31 neonates) enrolled with respiratory distress. 11% (4 neonates) failed to improve on CPAP therapy. A significant decline in the need for FiO_2, mean Downe score, mean R and heart rate observed from the baseline 6 hours CPAP ($p<0.001$), t test analysis, factors significantly associated CPAP failure were high FiO_2 at 1 hour and high positive end-expiratory pressure within 1 hour initiating CPAP ($p<0.001$).
Conclusions: Saans (CPAP device), successful therapeutic option for neonates with respiratory distress and can be effective even in a resource-constrained clinical setting.

Keywords: Continuous positive airway pressure therapy, Mechanical ventilation, Respiratory distress syndrome

INTRODUCTION

Premature neonates often suffer from respiratory distress, a potentially fatal complication, due to the absence or reduced production of surfactant which helps keep the lungs inflated and prevents alveoli collapse.[1] In over 50% of cases, preterm neonates with a gestational age under 31 weeks acquire respiratory distress syndrome (RDS).[2] In India, RDS has an incidence of 1.2% and a mortality of 13.5% among live births annually.[3] In developed countries, neonates are provided with respiratory support using either mechanical ventilation or CPAP. However, ventilators and CPAP machines are expensive capital devices with a high technically complexity and are often too expensive for many resource-constrained centers and patient transport settings. As a result, respiratory illness remains one of the most common causes of neonatal death in the developing world.[3,4] However, health professionals prefer the use of CPAP therapy over mechanical ventilation while treating RDS. This is because several studies show that mechanical ventilation contributes to the development of chronic changes within

the lungs and is associated with pulmonary growth arrest.[5] In developing countries, CPAP therapy has been employed for decades. It reduces mortality risk and can be easily administered by trained health professionals and nurses.[4] Numerous studies depict that commercially available CPAP devices designed for high-resource settings can be deployed in premature neonates safely in low-resource setting.[6-8] Nonetheless, the cost of existing available CPAP devices remains a crucial factor for these clinical settings.

Saans is a low cost, multi-powered device, developed by Coeo labs, an ISO 13485 certified company, designed specifically for such low-resource setting. This device is operable in resource constrained settings as it delivers CPAP in multiple operating modes including battery, compressed gas and a unique manual mode if electricity or oxygen source is not available. Therefore, it is not constrained by the absence of electricity. Saans was developed to offer superior care during transportation of neonates in RDS as it provides the same therapeutic pressure as BCPAP systems. Additionally, it also provides passive humidification delivering a blended flow of oxygen and filtered air, ensuring adequate clinical care to the infant even during transport. The portability of the device and its ease-of-use was designed specifically for its operation even in low- resource and low-skill settings.

Saans provides CPAP with a pressure range of 0 to 8 cm H_2O at corresponding flow rate from 3 to 6.5l /pm with the help of nasal prongs or a mask. This device worked in multiple modes: manual mode, e-module mode, compressed gas mode and air-oxygen blender mode. This study aimed to assess the efficiency of Saans (CPAP) device in treating RDS. We conducted an observational study in rural tertiary care teaching hospital on 35 neonates that passed the inclusion criteria set for the deployment of Saans (CPAP device).

METHODS

This prospective observational analytical study was conducted 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. 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.

Inclusion criteria

Patients with gestational age >30 weeks, 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

Patients having chromosomal abnormality; patients requiring mechanical ventilation at the time of admission; patients who had significant morbidity like cardiac diseases besides RDS; patients had major congenital malformations like diaphragmatic hernia or trachea-oesophageal fistula or cleft lip or cleft palate were excluded in the study.

Outcomes and predictors of success with CPAP

Premature neonates included in this study were noted for Silverman-Anderson score (SAS), Downe's score, signs of grunting, chest retractions, substernal retractions and nasal flaring along with basic demographic data (date of birth, place of birth, weight, gestational age and gender). Successful CPAP therapy was defined as the weaning off of respiratory support in the form of CPAP. Therapy failure was defined by the worsening of respiratory distress and a shift in therapy to mechanical ventilation.

Interventions and monitoring

Enrolled infants were administered CPAP after obtaining the consent from the parents or guardian. 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 and Downe's score. 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.

Statistical analysis

Outcome variables were compared between the infants who failed CPAP and those who were successfully managed with CPAP. Continuous variables were analyzed using Student's t test for normal distributions. Significance was defined as $p<0.05$ for the predefined outcome variables and $p<0.001$ for other outcome variables explored post-hoc.

RESULTS

During the course of 7 months, 35 premature neonates fitting inclusion criteria were included in the study. The average age of COHORT was 35.3 weeks. The average birth weight was 2.2 kg. There was a statistically significant reduction in the FiO_2 before and after Saans (50.3±1.8 versus 31.3±6.5; $p<0.001$) as seen in Figure 1.

The respiratory rate also showed a statistically significant reductions before and after Saans was deployed (RR rate

78.9±3.7 versus 56.2±2.9 breaths/minute; p<0.001) as seen in Figure 2.

Figure 3 depicts the reduction noted in the heart rate (HR: 164.9±6.4 versus 129.6±21.9 beats/minute; p<0.001).

With regards to the respiratory distress scores, there were statistically significant reductions noted in both the SAS and Downe's score as seen in Table 1. Both scores showed reductions close to 5 points out of a possible 10.

100% of preterm (6 patients), 85% of late preterm (17 patients) and 89% of term neonates (8 patients) were treated successfully on Saans and improved on CPAP therapy as depicted in Figure 4.

Table 1: SAS score and Downe's score.

Parameters on CPAP (mean±SD)	Before Saans	After Saans	P value
FiO_2	50.3±1.8	31.3±6.5	<0.001
RR	78.9±3.7	56.2±2.9	<0.001
HR	164.9±6.4	129.6±21.9	<0.001
	Before	After 6 hrs	<0.001
SAS score (X/10)	5.9±1	1.1±0.4	<0.001
Downe score (X/10)	4.9±2.0	0.8±0.5	<0.001

Table 2: Predictor variable (success versus failure) (mean±SD).

Predictor variables (mean±SD)	Success (n=31)	Failure (n=4)	P value
Gestational age (weeks)	35.3±2	35.3±2	P=0.77
Birth weight (kgs)	2.3±0.5	2.1±0.2	P=0.17
SAS Score (X/10)	5.7±0.9	5±0	P=0.13
Downe score (X/10)	4.9±0.2	5±0	P=0.50
SAS score after 6 hour (X/10)	1.1±0.4	0±0	-
Downe score after 6 hour (X/10)	0.8±0.5	0±0	-
CPAP duration in hours	25.7±8.6	2.3±0.5	P<0.001
Initiation of CPAP in mins	31.1±21.4	150±24.5	P<0.001
PEEP @ 1hour	5.1±0.3	7±0	P<0.001
FiO2 @ 1hour	5.1±0.3	67±5	P<0.001

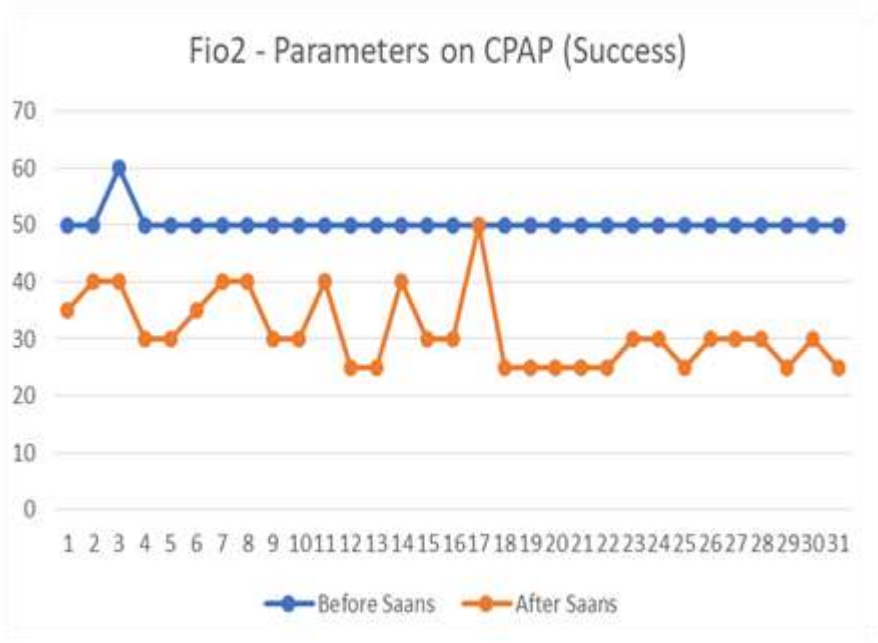

Figure 1: FiO_2-parameters on CPAP.

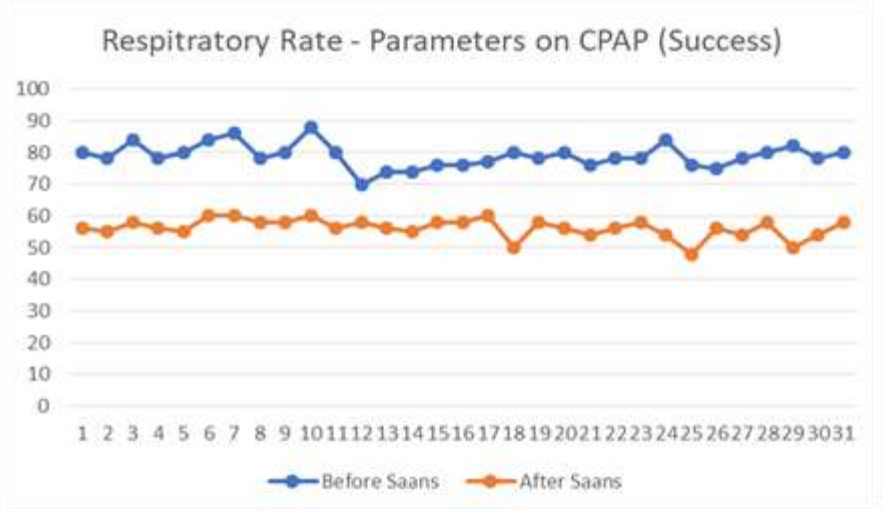

Figure 2: Respiratory rate-parameters on CPAP.

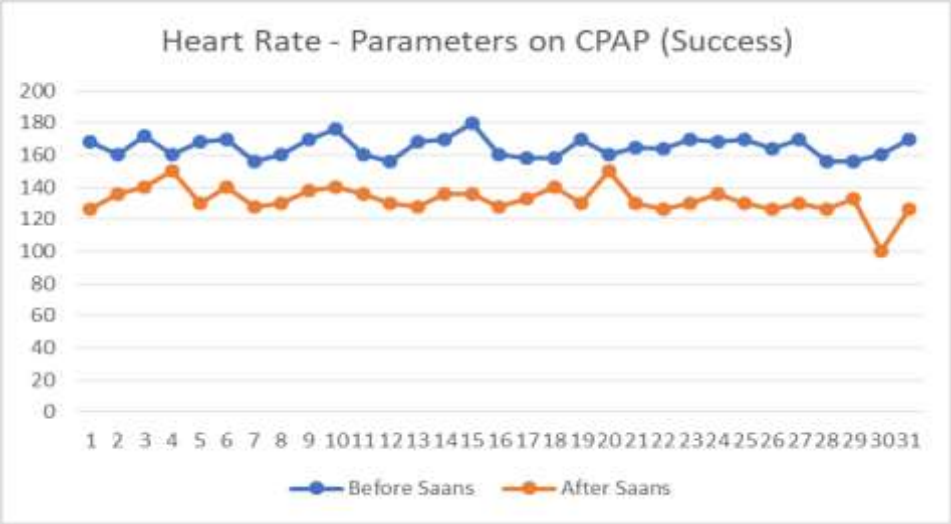

Figure 3: Heart rate-parameters on CPAP.

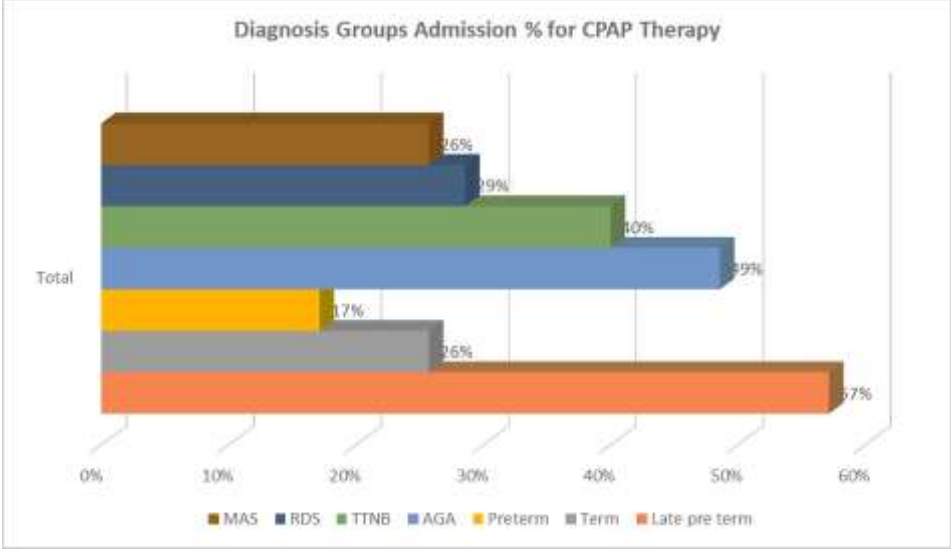

Figure 4: Diagnosis groups admission % for CPAP.

By etiology, CPAP therapy with Saans was successful in 100% of neonates with transient tachypnea of newborn (TTNB; 14 patients), 70% of neonates with (RDS; 7 patients) and 89% of neonates with meconium aspiration syndrome (MAS; 8 patients).

On average among patients successfully treated using Saans, the average duration of CPAP therapy in hours was 25.7±8.6. There were certain factors which were found to be significantly associated with failure on CPAP therapy. The first was a delayed initiation of CPAP in neonates with RDS. In the 31 patients who were successful treated with Saans the mean of the time of initiation of CPAP post-admission was 31.1±21.4 minutes as compared to the mean in those who failed on CPAP therapy in whom Saans was deployed 150±24.5 minutes post-admission. Another factor was the mean PEEP value at 1 hour which was 5.1±0.3 in those who were successful on CPAP therapy as compared to 7±0 who were started on mechanical ventilation. The third was the FiO_2 at 1 hour which was 41.3±0.5 and 67±5 in those patients in who were successful and failed CPAP respectively as shown in Table 2.

DISCUSSION

Globally, close to 3 million neonates, in the first 28 days of life, died each year. More than one-third of these deaths were due to prematurity including RDS due to surfactant deficiency. In well-resourced settings it was managed effectively with ventilator support and surfactant replacement therapy. However, these were expensive interventions and required skilled clinicians for implementation.[9]

Access to inexpensive respiratory support had been found to improve survival in newborn infants in low-income countries. CPAP systems were less expensive and less invasive compared to mechanical ventilators and reduced the risk of barotrauma, infection and other complications.[9] CPAP had been extensively used worldwide for more than 30 years. Non-randomized studies conducted in South Africa and Malawi demonstrated that CPAP was associated with improved survival and was both efficacious and cost-effective. These studies used the Pumani bubble CPAP device that was created by researchers at Rice university.[10-12]

Saans was an affordable, practical and non-invasive CPAP device developed for poor-resourced settings by clinicians and bioengineers. In our study, the neonates who fit the inclusion criteria had a wide range of birth weights and a range of diagnoses. All clinical decisions were left to the intensivist. The SAS and Downe's score were assessed for each patient and on Saans, the PEEP value was kept in the range of 5-7 cm H_2O. When Saans was used for CPAP therapy, it was successful in 31 neonates (89% of the COHORT) and was unsuccessful only in 4 (11%). Among the neonates that failed on CPAP therapy with Saans we believe that there were concomitant factors that led to therapy failure including an increased oxygen requirement, increased positive end-expiratory pressure requirement and apnea.

An 89% success rates was noted among neonates with respiratory distress on CPAP therapy with Saans. This study indicated that CPAP therapy with Saans was a successful therapeutic option for neonates with respiratory distress and can be effective even in a resource-constrained clinical setting. This intervention provided life-saving treatment to neonates with respiratory distress at affordable cost. In future, larger multicenter trials will be useful in order to reinforce the efficacy seen in this study. More health professionals were opting for CPAP therapy in neonates with respiratory distress over mechanical ventilation due to the associated complications. However, we were cognizant of the fact that CPAP therapy was only an extension of mechanical ventilation and not a replacement.

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CONCLUSION

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