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Clinical Profile of Neonates on Bubble CPAP Ventilation in a Tertiary Care Centre

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ABSTRACT

Background: Bubble-CPAP is an important, simple, non-invasive, and cost-effective treatment modality for respiratory distress in neonates. The present study was undertaken to study the clinical profile of neonates on bubble CPAP ventilation in a tertiary care centre.

Method: A total of 200 neonates were admitted in NICU with respiratory distress with Downe's score 4-6 or Silverman Anderson scores -4-6 and Oxygen saturation SPO2 < 85% even with supplemental oxygen who require bubble CPAP ventilation were included in the study.

Results: The most common indication for B-CPAP was respiratory distress syndrome (RDS) (46%). B-CPAP was successful in 79% of neonates, with a 21% failure rate. There was a significant difference in B-CPAP failure rates based on specific indications. A significant association was found between comorbidities and B-CPAP failure. Neonates whose mothers received antenatal steroids had more successful B-CPAP outcomes. Neonates with successful B-CPAP outcomes required B-CPAP for a longer duration compared to those with treatment failure. Complication rates were significantly higher in neonates who experienced B-CPAP failure compared to those with successful B-CPAP outcomes. Most of the neonates experienced a positive outcome and survived (79%). However, among 42 neonates with B-CPAP failure, 6 died on B-CPAP, in 36 babies who were shifted to mechanical ventilation, 22 died on mechanical ventilation due to severe complications whereas 14 were recovered from mechanical ventilation.

Conclusion: B-CPAP is safe, effective, and easy to use in preterm and term neonates who require ventilation support. Also, bubble-CPAP is a much more cost-effective mode of ventilation as compared to mechanical ventilation.

Keywords: Antenatal steroids; Bubble CPAP; Mechanical ventilation; Respiratory distress syndrome.

INTRODUCTION

In India, there is a high burden of prematurity in newborns due to high birth rate, lack of good antenatal care, lack of awareness, suboptimal practices, maternal malnutrition, infection, and poor socioeconomic status which are some attributable risk factors. One of the backbones of NICU is effective assisted ventilation in the form of non-invasive or invasive mechanical ventilation. In mechanical ventilation in addition to high cost, it is associated with technical complications where human and financial resources are stretched.[1,2] Non-invasive ventilation like bubble continuous positive airway pressure (Bubble-CPAP) has been available since 1970s, but the earliest report is from 1992, which describes the in-vitro testing and use in low-birth weight neonates.[3] Bubble CPAP (B-CPAP) is an effective mode of ventilation that has several potential advantages over invasive ventilation. Easy application, requiring minimal skills, low cost, easy monitoring by the use of only pulse oximetry, it is a non- invasive respiratory support delivered to a spontaneously breathing newborn to maintain lung volume during respiration. However, it can also be used as a delivery room CPAP at the peripheral health center and for transport of newborn to tertiary care hospital.[4-6] When applied to neonates with respiratory distress, it provides continuous distending pressures on alveoli thus preventing alveoli collapse during expiration, splints the airway, reduces the work of breathing, and improve the pattern and regularity of respiration. Early diagnosis and management by suitable and immediate resuscitation, oxygen supplementation, preservation of ideal temperature, effective assisted ventilation, the form of invasive or non-invasive ventilation can reduce morbidity and mortality.[1,4.]

B-CPAP differs from conventional CPAP, in that through inserting expiratory limb of CPAP circuit below a predetermined depth of water, this device creates pressure in circuit as the gas passes by nasal machine. A premature infant's upper airway is extremely acquiescent and predisposed to collapsing, therefore by splinting the upper airway, CPAP lessens blockage and apnoea, increases the functional residual capacity (FRC), transmits oscillatory vibrations into the chest, resetting in waveform similar to

those produced by high-frequency ventilation.[4,7]

Therefore, this cross-sectional observational study was undertaken at the tertiary care centre with an objective to study the clinical profile and outcome of neonates with respiratory distress on B-CPAP ventilation.

MATERIALS AND METHODS

After obtaining Institutional Ethical Committee approval and written informed consent from all the parents, this cross-sectional observational study was conducted in Newborn Intensive Care Unit (NICU), at tertiary care centre during the period of 12 months from September 2022 to September 2023. A total of 200 neonates were admitted in NICU with respiratory distress with Downe's score 4-6 or Silverman Anderson scores -4-6 and Oxygen saturation SPO2 < 85% even with supplemental oxygen who require bubble CPAP ventilation were included in the study. Whereas the babies with Severe RD requiring mechanical ventilation (score >7/10), unstable cardiovascular status, and major congenital anomalies requiring surgical intervention including upper airway anomalies, pulmonary hypoplasia diaphragmatic hernia, etc. were excluded from the study.

Data on socio-demographic factors such as sex and gestational age were collected in pretested predesigned case record form. Further, these patients were subjected to a physical examination for evaluating their clinical signs. All essential investigations such as CBC, ABG, and CXRAY were carried out. After admission into NICU as per indication, neonates were taken to bubble CPAP and daily monitoring for outcomes using a pulse oximeter and clinical signs and symptoms for recovery of the baby, decrease in score of distress, any complications, and further need for mechanical ventilation.

Respiratory distress was assessed by:

I. Clinical methods:

Table 1: Downes score was used in term babies to assess RD.

DOWNES SCORE	0	1	2
Cyanosis	None	In room air	In 40% FIO2
Retractions	None	Mild	Severe
Grunting	None	Audible with stethoscope	Audible without stethoscope
Air entry	None	Decreased or delayed	Barely audible
Respiratory rate	< 60	60-80	> 80 or apnea

Table 2: Silverman Anderson score in preterm baby

FEATURE	SCORE 0	SCORE 1	SCORE 2
Chest Movement	Equal	Respiratory Lag	Seesaw Respiration
Intercostal Retraction	None	Minimal	Marked
Xiphoid Retraction	None	Minimal	Marked
Nasal Flaring	None	Minimal	Marked
Expiratory Grunt	None	Audible w/ stethoscope	Audible

Statistical Analysis

Data was entered in Microsoft excel sheet and analyzed using SPSS v 23 software. Descriptive statistics such as frequencies and percentages were calculated, mean and standard deviation were computed for quantitative variables. Chi-square ($\chi 2$) test was applied to determine the association between two attributes. A *p* value of <0.05 was considered statistically significant. Hypothesis testing was done by applying two sample T-Test.

Observations and Results

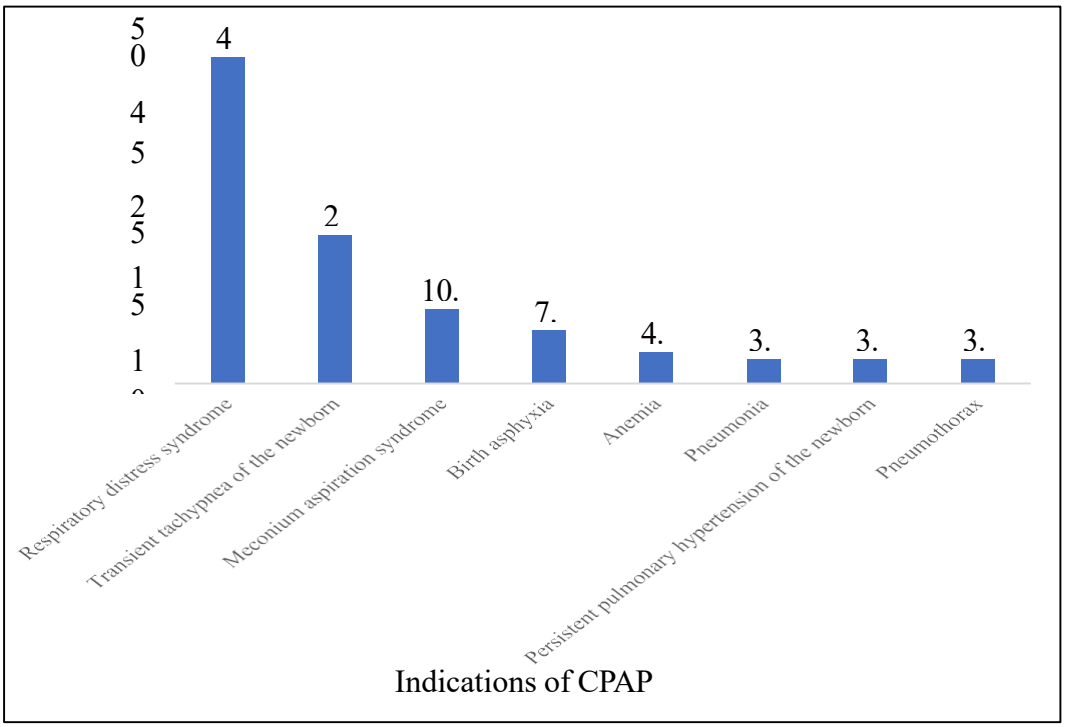
The mean gestational age of neonates was 32.20±2.90 weeks with male predominance (55%). The mean birth weight of neonates was 1.85±4.49 kg. A substantial 74% (n=148) of the newborns in population had a birth weight of <2 kg, indicating a significant prevalence of low birth-weight infants. The maximum number of neonates had comorbidities (60%, n=120) as shown in table 1.

Table 1: Demographic data of patients and comorbidities

Demographic data and comorbidities		Frequency (n)	Percentage (%)
Gestational age (weeks)	<32	97	48.5
	32-33	45	22.5
	34-36	38	19
	37-39	20	10
Sex	Female	90	45
	Male	110	55
Birth weight (kg)	<2	148	74
	2-2.5	28	14
	2.6-3.5	24	12
Comorbidities	PROM	39	19.5
	PIH	37	18.5
	Oligohydramnios	23	11.5
	IUGR	20	10
	Severe PIH	1	0.5

The most common indication for B-CPAP was respiratory distress syndrome (RDS), affecting 46% of cases. Transient tachypnea of the newborn was the second most prevalent indication, comprising 21% of cases. Other indications included meconium aspiration syndrome, birth asphyxia, anemia, pneumonia, persistent pulmonary hypertension of the newborn, and pneumothorax.

Figure 1: The distribution of subjects according to the indications for B-CPAP



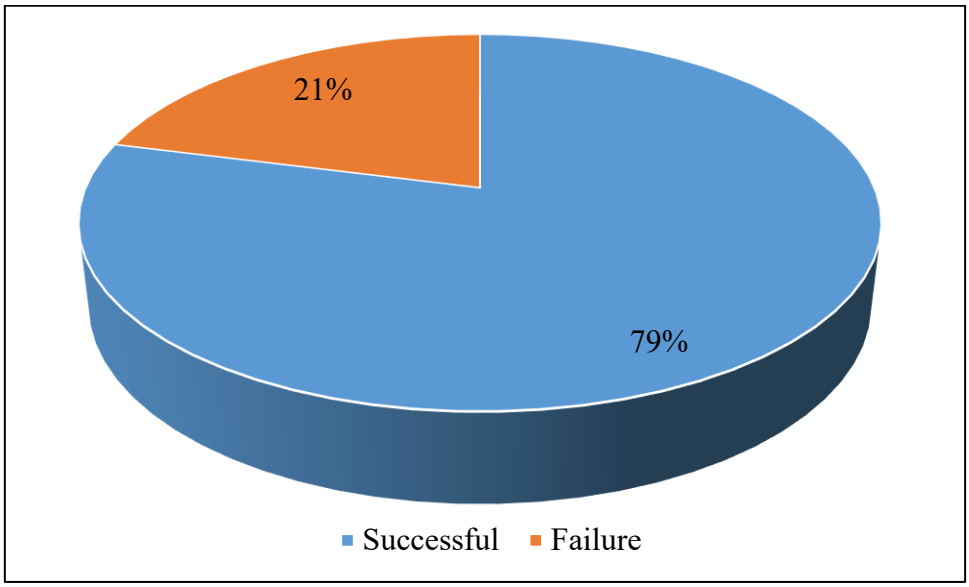
The Downe /SAS score was found to be improved on day 3 compared to day 1 in 66% (n=132). The distribution of subjects according to the Downe /SAS score is shown in Table 2.

Table 2: The distribution of subjects according to the Downe / SAS score

Downe / SAS score	At day 0		At day 3	
	Frequency (n)	Percentage (%)	Frequency (n)	Percentage (%)
0	00	00	59	29.5
1	6	3	55	27.5
2	24	12	31	15.5
3	34	17	18	9
4	38	19	6	3
5	15	7.5	5	2.5
6	83	41.5	26	13

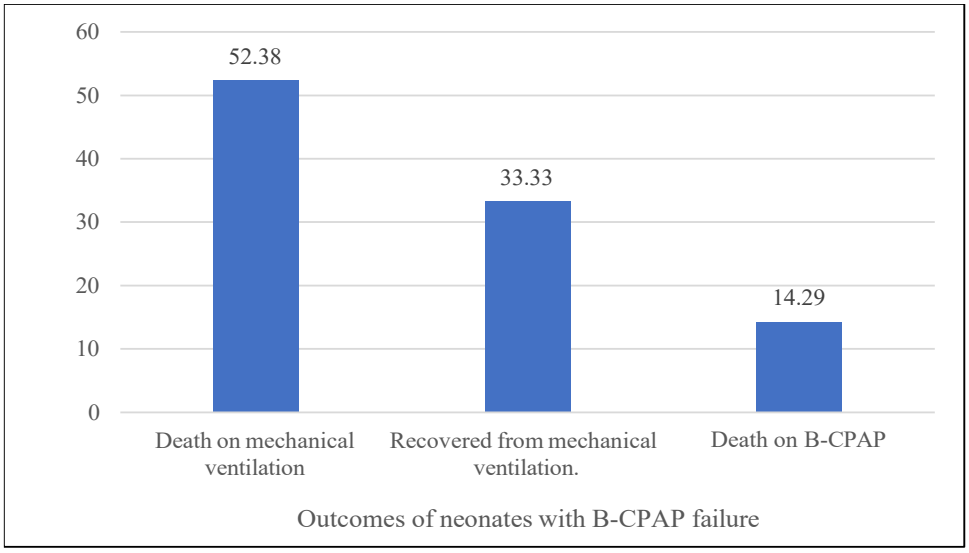
B-CPAP failure rate was found to be 21% (n=42) whereas, it was successful in 79% (n=158) of patients as shown in figure 2.

Figure 2: Distribution of subjects according to B-CPAP outcomes



Among 42 neonates who failed B-CPAP, 6 (14.29%) died on B-CPAP due to underlying complications. In 36 (85.71%) babies who were shifted to mechanical ventilation, 22 (52.38%) died on mechanical ventilation due to severe complications whereas, 14 (33.33) was recovered (figure 3).

Figure 3: Outcomes of neonates with B-CPAP failure



Out of 42 babies with B-CPAP failure, in 13 (30.95%), and 11 (26.19%) babies the indications were respiratory distress syndrome and transient tachypnea of the newborn respectively followed by meconium aspiration syndrome (n=9, 21.43%). The Distribution of B-CPAP failure according to indications is depicted in Table 3.

Table 3: The Distribution of B-CPAP failure according to indications

Indications of B-CPAP	B-CPAP failure	
	Frequency (n)	Percentage (%)
Respiratory distress syndrome	13	30.95
Transient tachypnea of the newborn	11	26.19
Meconium aspiration syndrome	9	21.43
Birth asphyxia	4	9.52
Pneumothorax	3	7.14
Pneumonia	1	2.38
Persistent pulmonary hypertension of the newborn	1	2.38
Total	42	100

Gender distribution showed a slight preponderance of males, but no significant association was found between gender and B-CPAP outcomes. There was no relation between gestational age (GA) and birth weight with B-CPAP failure. A significant association was found between comorbidities and B-CPAP failure, emphasizing the importance of considering underlying health conditions in antenatal care to improve the neonatal outcome with B-CPAP. The study showed that neonates whose mothers received antenatal steroids had more successful B- CPAP outcomes. Neonates with successful B-CPAP outcomes required B-CPAP for a longer duration compared to those with treatment failure. Complication rates were significantly higher in neonates who experienced B-CPAP failure compared to those with successful B-CPAP outcomes, (Table 4).

Table 4: Comparison B-CPAP outcomes with sex, gestational age, comorbidities, ANC steroids, number of days on B-CPAP and complications

Parameters		B-CPAP outcomes		P value
		Successful	Failure	
Sex	Female	73 (46.20%)	17 (40.48%)	>0.05
	Male	85 (53.80%)	25 (59.52%)	
Gestational age (weeks)		32.19±2.91	32.21±2.89	0.623
Birth weight (kg)		1.86±0.49	1.79±0.49	0.447
Comorbidities	No	64 (40.51)	16 (20)	<0.05
	PROM	34 (21.52)	5 (12.82)	
	PIH	25 (15.82)	12 (32.43)	
	Oligohydramnios	19 (12.02)	4 (17.39)	

	IUGR	15 (9.59)	5 (25)	
	Severe PIH	1 (0.63)	00 (0.0)	
ANC steroids	Yes	113 (71.52)	2 (4.76)	>0.05
	No	45 (28.48)	40 (95.24)	
Number of days on B-CPAP		4.27±1.69	3.55±1.57	0.012
Complications	No complications	89 (56.33)	13 (30.95)	
	Sepsis	19 (12.03)	9 (21.42)	
	Displacement due to nasal prong	17 (10.76)	7 (16.67)	
	Air leak	15 (9.49)	4 (9.52)	
	Gas distension	00	3 (7.14)	
	Nasal trauma	7 (4.43)	2 (4.76)	
	Mild ulceration	3 (1.90)	2 (4.76)	
	Blockage due to secretion	00 (0.0)	2 (4.76)	
	Transient hypotension	4 (2.53)	00 (0.0)	
	Shock	3 (1.90)	00 (0.0)	
	Pneumothorax	1 (0.63)	00 (0.0)	

Table 4 depicts the association of B-CPAP outcomes with various parameters. The Chi-square test was applied to assess the association between maternal comorbidities and study groups. The observed differences in distribution of comorbidities between the two groups indicate a statistically significant association ($p < 0.05$). Sex, gestational age, birth weight, and antenatal steroid use had no significant association with B-CPAP outcome ($p > 0.05$). Comorbidities were significantly associated with B-CPAP outcome, with higher failure rates among neonates with PIH and IUGR ($p < 0.05$). The mean duration of B-CPAP was significantly longer in the successful group compared to failures ($p = 0.012$). Overall, complications were more frequently associated with B-CPAP failure**,** though statistical significance was not specified.

Table 4: Distribution of subjects according to outcomes

Outcomes	Frequency (n)	Percentage (%)
Recovered	158	79
Failure	42	21
Recovered from mechanical ventilation	14	4.5
Death	28	14

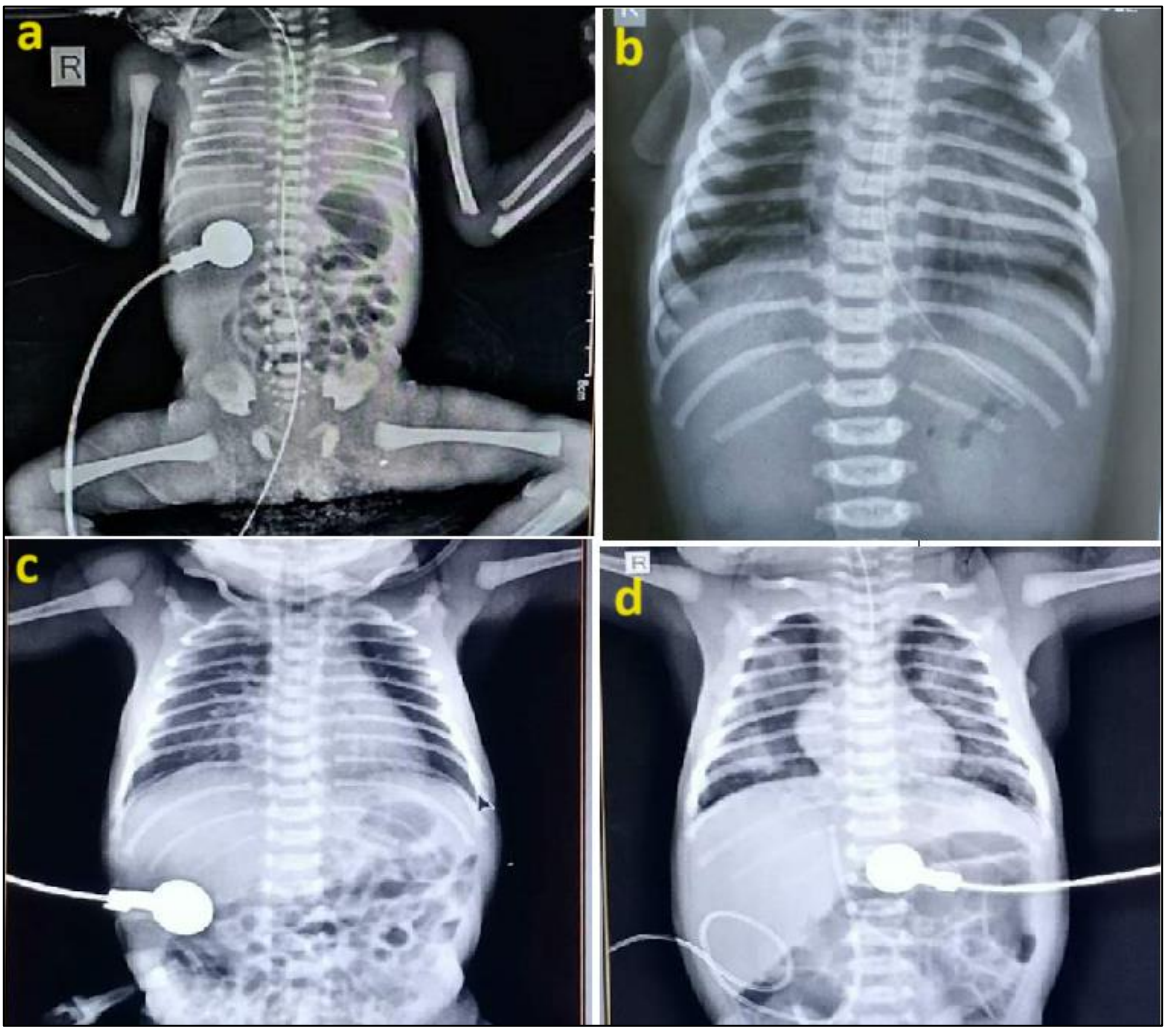


Figure 4: a) Respiratory distress syndrome with hypoaeration, pronounced fine granular opacities, air bronchogram**; b)** Thick meconium aspiration syndrome, hyperinflated lung with flat hemi diaphragm and asymmetric pulmonary patchy lung opacities, gas trapping; **c)** Transient tachypnea of the newborn, increased perihilar markings, lung hyperinflation, interstitial edema**; d)** Pneumothorax, complication of B-CPAP, air trapping and translucency, absent lung marking, and collapsed lung seen with mediastinal shift

DISCUSSION

The present study findings indicated that B-CPAP was successful in 79% of the neonates (n=158) while it failed in 21% of them. It's worth noting that the rate of B-CPAP failure ranged from 25% to 38% across different cases, as reported in previous studies.[8-11] These variations in results may be attributed to disparities in inclusion criteria, study design, geographical regions, and other factors.

The mean gestational age of the neonates was 32.20±2.90 weeks and 90% (n=180) neonates delivered preterm (<32-36 weeks). The mean gestational age in babies with B-CPAP failure was comparable with babies with B- CPAP success (32.19±2.91 vs 32.21±2.89, P=0.623). These findings indicate that B-CPAP in preterm as well as in-term babies is effective in ventilation support. Similar findings are reported in Tirkey SS et al[12], Afrin S. et al[13] and Protain E et al.[14]

The males were predominantly present (55%, n=110) compared to females (45%, n=90). Similarly, male predominance was shown by various other studies[8,15,16] which may be due to slower lung development and potentially reduced surfactant production, hormonal differences favoring female lung maturation, and the increased likelihood of preterm birth among males. Here, the success rate of B-CPAP differed slightly between the two genders, with B-CPAP being successful in 81.11% of female neonates and 77.27% of male neonates. Among the neonates who experienced B-CPAP failure (n=42), 59.52% (n=25) were male, and 40.48% (n=17) were female. Similarly, in the study of Tirkey SS, and Verma RK, CPAP was reported to be more successful in female babies compared to males (88% vs 64%).[12] These gender-specific findings may warrant further investigation to better understand potential factors influencing the outcomes of B-CPAP in neonatal care.

The mean birth weight of the neonates was 1.85±4.49 kg. The majority of neonates had a birth weight of <2 kg, indicating a significant prevalence of low-birth-weight infants. The birth weight of infants who experienced B-CPAP failure was slightly lower than that of infants who had B-CPAP success. However, the difference in birth weight was not statistically significant (1.79±0.49 vs 1.86±0.49, P=0.447). These findings are in accordance with the study done by Byram SK et al[8], Tirkey SS et al[12] and Urs et al[17].

The most common indication for B-CPAP in the present study was respiratory distress syndrome (46%) followed by transient tachypnea of the newborn (21%), Meconium aspiration syndrome (10.5%), birth asphyxia (7.5%). Other indications included anemia (4.5%), pneumonia (3.5%), persistent pulmonary hypertension of the newborn

(3.5%), and pneumothorax (3.5%). These findings provide a comprehensive overview of the diverse respiratory conditions in neonates that may necessitate B-CPAP therapy. Moreover, among the n=42 neonates who experienced B-CPAP failure, the leading indications were respiratory distress syndrome, affecting 30.95% of cases, and transient tachypnea of the newborn, affecting 26.19%of cases. Meconium aspiration syndrome was the third most common indication, accounting for 21.43% of cases. Similar findings are reported in previous studies.[8,18-20]

The use of ANC steroids was more prevalent in neonates with successful B-CPAP outcomes which is comparable with the study done by Tirkey SS, and Verma RK.[12] The average duration of B-CPAP treatment for neonates with successful B- CPAP outcomes was notably longer when compared to those with B-CPAP treatment failure. This finding is in accordance with the study done by Byram SK et al.[8] The longer mean duration of B- CPAP in neonates with successful outcomes is in line with clinical expectations. Prolonged CPAP therapy may be needed to manage severe respiratory conditions and provides further evidence for the effectiveness of this intervention.[21]

In the present study, the proportion of complications was significantly high in neonates who failed B-CPAP compared to babies with successful B-CPAP (43.67% vs 69.05%, P<0.05) which is again similar to the findings of Byram SK et al.[8] The higher proportion of complications in neonates who failed B-CPAP highlights the clinical significance of early identification and intervention in neonatal care. Monitoring complications, especially in cases of treatment failure, is crucial to optimize outcomes. The neonatal outcomes in this study show that 79% of neonates recovered, while among 42 (21%) subjects with failure, 14 (4.5%) were recovered from mechanical ventilation. The incidence of mortality was seen in 14% (n=28) of cases. These results are indicative of the challenges and complexities in neonatal care, emphasizing the importance of continuous improvement in neonatal care strategies and interventions.

The strength of the study was adequate sample size and uniform application of the protocol. We acknowledge certain limitations including:

- The study was not blinded, and the study was a single centre which could have led to some bias.
- Randomization of choice would ideally have been a simple stratified random sampling since our resources were limited thus, we had to limit ourselves to convenient sampling.
- Usage of surfactant in the babies and its effect on recovery along with CPAP was not assessed.

- Generalization could have been better if a larger sample size was included.
- A multicentre single-blind study with a large sample size including all the variables is the further recommendation of the study.

CONCLUSION

B-CPAP is safe, effective, and easy to use in preterm and term neonates who require ventilation support. Bubble -CPAP is a much more cost-effective mode of ventilation as compared to mechanical ventilation. Antenatal steroids played a major role in the outcome of preterm babies with immature lung function and thereby the outcome with B-CPAP. Complications were very minimal with B-CPAP and can be easily avoided with proper nursing care and monitoring. Understanding the factors associated with success and failure in B-CPAP therapy is crucial for optimizing care for neonates with respiratory distress. Further research and clinical interventions may build upon these findings to enhance neonatal care practices and improve outcomes.

RECOMMENDATIONS

- **Early Initiation of B-CPAP**: Given the prevalence of RDS as the leading indication for B-CPAP, it is crucial to emphasize the early initiation of B-CPAP in neonates at risk of RDS. Healthcare providers should closely monitor neonates with RDS and promptly initiate B-CPAP to improve outcomes.
- **Individualized Care Plans:** Neonatal care should be highly individualized, considering the specific needs and conditions of each neonate.
- **Continuous Monitoring and Intervention:** Continuous monitoring of neonates on B-CPAP is crucial. Any signs of complications or deterioration should trigger immediate intervention to minimize the risk and improve outcomes.
- **Parental Education and Support:** Providing education and support to parents or caregivers is vital. They should be informed about the care their neonate is receiving, potential complications, and how to respond in emergency situations.
- **Resource Allocation:** Adequate resources, equipment, and skilled staff should be allocated to neonatal care units, especially in tertiary care centers, to ensure that neonates receive the best possible care and support.

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