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CLINICAL PROFILE, OUTCOMES AND PREDICTORS OF CPAP FAILURE IN NEONATES WITH MAS: A PROSPECTIVE OBSERVATIONAL STUDY

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ABSTRACT

Background: Meconium Aspiration Syndrome (MAS) remains a significant contributor to neonatal respiratory distress, especially in term and post-term neonates. Early non-invasive support such as Continuous Positive Airway Pressure (CPAP) is often utilized. **Objective:** To evaluate the clinical profile and outcome of neonates with MAS managed with CPAP, and to identify factors associated with CPAP failure.

Materials and Methods: This prospective observational study included neonates admitted with MAS from January 2020 to July 2021. Inclusion criteria involved neonates with MAS requiring CPAP support. Those with major congenital anomalies, Hyaline Membrane Disease (HMD), or needing immediate intubation were excluded. Demographic data, clinical variables and outcomes were recorded and analyzed. Statistical analysis was performed using OpenEpi software. Continuous variables were compared using Student's t-test and categorical variables using Chi-square or Fisher's exact test. A *p value <0.05* was considered statistically significant.

Results: Of 105 neonates, 87 met inclusion criteria. CPAP was successful in 81.6%, with 18.4% requiring mechanical ventilation. Higher FiO2 requirement, higher PEEP, need for inotropic support and low APGAR scores were significantly associated with CPAP failure. Post-CPAP, significant improvements were seen in respiratory parameters.

Conclusion: Continuous Positive Airway Pressure is an effective first-line respiratory support strategy for neonates with mild-to-moderate Meconium Aspiration Syndrome. Early recognition of predictors of CPAP failure may facilitate timely escalation of respiratory support and optimize neonatal outcomes.

Keywords: Meconium Aspiration Syndrome, Continuous Positive Airway Pressure, Respiratory Distress, Non-invasive Ventilation, Neonates.

INTRODUCTION

Meconium Aspiration Syndrome (MAS) is a major cause of neonatal respiratory distress, particularly among term and post-term neonates. MAS results from the aspiration of meconium-stained amniotic fluid and can lead to airway obstruction, surfactant inactivation, pulmonary inflammation and impaired gas exchange.[1,2]

Meconium-stained amniotic fluid (MSAF) is present in approximately 10–15% of deliveries, notably among term and post-term pregnancies. Among neonates born through MSAF, nearly 5% develop MAS and a significant proportion require admission to the neonatal intensive care unit for respiratory support.[3,4,5] Approximately 30% of affected neonates may require mechanical ventilation, while mortality rates ranging from 3% to 5% have been reported.[3,4,5]

The National Neonatal-Perinatal Database (NNPD) of India defines MAS by the presence of at least two of the following criteria: meconium-stained liquor, respiratory distress within one hour of birth and radiological evidence suggestive of aspiration pneumonitis.[6]

Continuous Positive Airway Pressure (CPAP) has emerged as an effective non-invasive respiratory support modality for neonates with mild-to-moderate MAS.[7,8] By maintaining functional residual capacity, improving alveolar recruitment, and reducing the work of breathing, CPAP may decrease the requirement for invasive mechanical ventilation and its associated complications.[9]

However, a subset of neonates does not respond adequately to CPAP and eventually requires escalation to invasive mechanical ventilation. Identification of factors associated with CPAP failure may facilitate timely intervention and improve clinical outcomes.[10,11,12]

Most published studies evaluating CPAP in MAS have focused primarily on treatment efficacy, whereas relatively few prospective studies have examined readily available bedside predictors of CPAP failure. The present study addresses this clinically important gap by evaluating both treatment outcomes and factors associated with failure of non-invasive respiratory support in a real-world tertiary neonatal intensive care setting.

MATERIALS AND METHODS

This prospective, hospital based observational study was conducted in the Neonatal Intensive Care Unit (NICU) of a tertiary care teaching hospital after obtaining approval from the Institutional Ethics Committee. The study was carried out over a period of 18 months from January 2020 to July 2021.

The primary objectives of the study were to evaluate the clinical profile and outcomes of neonates with Meconium Aspiration Syndrome (MAS) managed with Continuous Positive Airway Pressure (CPAP) and to identify factors associated with CPAP failure.

Term, late-preterm and post-term neonates born through meconium-stained amniotic fluid who developed respiratory distress within the first 24 hours of life were screened for eligibility. Neonates with oxygen saturation below 90% on room air and a respiratory distress score greater than 5 were included in the study. Neonates with major congenital malformations, hyaline membrane disease, congenital pneumonia, air leak syndromes, or those requiring immediate endotracheal intubation at birth were excluded.

During the study period, in all eligible MSAF delivered neonates, APGAR score at 1 min and 5 min was noted. Enrollment was done as per inclusion criteria and data recorded included detailed maternal, perinatal, and neonatal data, clinical parameters pre- and post-CPAP, complications, and outcomes in a predesigned case record form. Gestational age was assessed using the New Ballard Score. Respiratory distress was evaluated using Downe's score in term neonates and Silverman-Anderson score in preterm neonates. Neonates were managed as per standard treatment protocols and relevant investigations were send during the stay.[13,14,15,16]

The diagnosis of MAS was established based on a history of meconium-stained amniotic fluid, clinical evidence of respiratory distress, and/or radiological findings suggestive of aspiration pneumonitis.[4]

All enrolled neonates received bubble CPAP using bilateral nasal prongs (Hudson prongs or RAM cannula). CPAP was initiated at a pressure of 5 cm H_2 O with FiO_2 of 50% and flow rate of 15 L/min. CPAP settings were subsequently adjusted to maintain oxygen saturation between 89% and 95%, with a maximum pressure of 6 cm H_2 O and FiO_2 up to 100%.

CPAP was discontinued when the neonate maintained oxygen saturation above 90% on FiO_2 less than 25%, respiratory rate below 60 breaths per minute, minimal or absent chest retractions, and absence of grunting.

CPAP failure was defined by the presence of any one of the following criteria after which patient shifted to mechanical ventilation:

1. Persistent oxygen saturation below 90%
2. PaO_2 less than 50 mmHg despite FiO_2 of 100%
3. $PaCO_2$ greater than 60 mmHg with arterial pH less than 7.25
4. Poor respiratory effort requiring ventilatory support
5. Development of pneumothorax associated with cardiorespiratory instability

CPAP success was defined as successful weaning from CPAP without the need for invasive mechanical ventilation during the hospital stay.

All associated comorbidities including persistent pulmonary hypertension of the newborn (PPHN), shock, seizures, renal dysfunction, electrolyte imbalance, and acid-base abnormalities were managed according to standard NICU protocols.

Chest radiography was performed before initiation of CPAP. Arterial blood gas analysis was obtained at enrollment and repeated six hours after initiation of CPAP. Clinical parameters including respiratory rate, heart rate, oxygen requirement, and Downe score or silverman Anderson score were recorded before and after CPAP therapy.

Sample Size Estimation: As published data regarding CPAP outcomes in neonates with MAS from our region were limited at the time of study planning, a formal sample size calculation could not be performed. Therefore, all consecutive eligible neonates admitted during the study period were enrolled. A total of 87 neonates fulfilling the inclusion criteria were included in the final analysis.

Statistical Analysis: Data were entered into Microsoft Excel and analysed using OpenEpi software. Continuous variables were expressed as mean ± standard deviation, while categorical

variables were presented as frequencies and percentages.

Continuous variables were compared using Student's t-test, whereas categorical variables were compared using Chi-square test or Fisher's exact test whenever applicable. Statistical significance was considered at $p < 0.05$.

Variables demonstrating significant association with CPAP failure on univariate analysis were considered for multivariable logistic regression. However, because only 16 CPAP failure events occurred, logistic regression analysis was not performed to avoid model overfitting and unreliable estimates.

RESULTS

A total of 105 neonates with a diagnosis of Meconium Aspiration Syndrome (MAS) were admitted to the neonatal intensive care unit during the study period from January 2020 to July 2021. Of these, 18 neonates were excluded from the study, including 2 with major congenital anomalies, 9 who required immediate intubation and mechanical ventilation at admission, 5 who did not require CPAP support, and 2 with coexisting Hyaline Membrane Disease (HMD). Consequently, 87 neonates fulfilled the eligibility criteria and were included in the final analysis (Figure 1).

The demographic and perinatal characteristics of the study population are summarized in Table 1. Among the enrolled 87 neonates, 42 (48.3%) were male and 45 (51.7%) were female. The majority of neonates had a birth weight greater than 2.5 kg (n=65, 74.7%), while 15 (17.2%) were classified as low birth weight and 7 (8.0%) as very low birth weight.

With respect to gestational age, 57 (65.5%) neonates were term, 17 (19.5%) were post-term, and 13 (14.9%) were late preterm. Regarding mode of delivery, 42 (48.3%) neonates were delivered vaginally, 37 (42.5%) by caesarean section, and 8 (9.2%) by assisted vaginal delivery.

CPAP Outcomes: Among the 87 neonates who received CPAP support, 71 (81.6%) were successfully managed without the need for invasive mechanical ventilation. Sixteen neonates (18.4%) met the predefined criteria for CPAP failure and subsequently required endotracheal intubation and mechanical ventilation.

Factors Associated with CPAP Failure: Clinical and demographic variables were compared between neonates with successful CPAP therapy and those who experienced CPAP failure. [Table 2]

Neonates who failed CPAP required significantly higher FiO_2 concentrations and higher maximum PEEP levels during respiratory support compared with those successfully managed with CPAP ($p<0.001$ for both variables). In addition, the requirement for inotropic support was significantly more common among neonates in the CPAP failure group ($p<0.001$).

APGAR scores at both 1 minute and 5 minutes demonstrated statistically significant differences between the two groups ($p<0.001$). However, birth weight, gestational age, gender, intrauterine growth restriction, antenatal steroid exposure, evidence of fetal distress, timing of CPAP initiation, and the nature of meconium-stained liquor were not significantly associated with CPAP outcome.

Clinical Response Following CPAP Therapy: A significant improvement in clinical and physiological parameters was observed within six hours of CPAP initiation (Table 3). The mean Downe score decreased from 5.59 ± 0.95 before initiation of CPAP to 4.00 ± 2.09 after six hours of therapy ($p<0.0001$). Mean FiO_2 requirement decreased from 50.28 ± 6% to 39 ± 17% ($p<0.0001$). Similarly, respiratory rate improved from 75 ± 6.93 breaths/min to 61.76 ± 3.79 breaths/min ($p<0.0001$), while heart rate decreased from 170.71 ± 8.06 beats/min to 140.5 ± 5.17 beats/min ($p<0.0001$).

Complications: Complications observed during the study period are summarized in Table 4. Septicemia was the most frequently encountered complication, occurring in 13 neonates (14.9%). Hyperbilirubinemia as observed in 7 neonates (8.0%), while pneumothorax occurred in 3 neonates (3.4%). Other complications were noted in 6 neonates (6.9%) and included asymptomatic polycythemia, hypocalcaemia, and one case of necrotizing enterocolitis.

Hospital Outcome: Among the 87 enrolled neonates, 71 (81.6%) were discharged successfully, 10 (11.5%) were discharged against medical advice (DAMA), and 6 (6.9%) died during hospitalization (Table 4). Detailed mortality analysis could not be performed because of the small number of deaths.

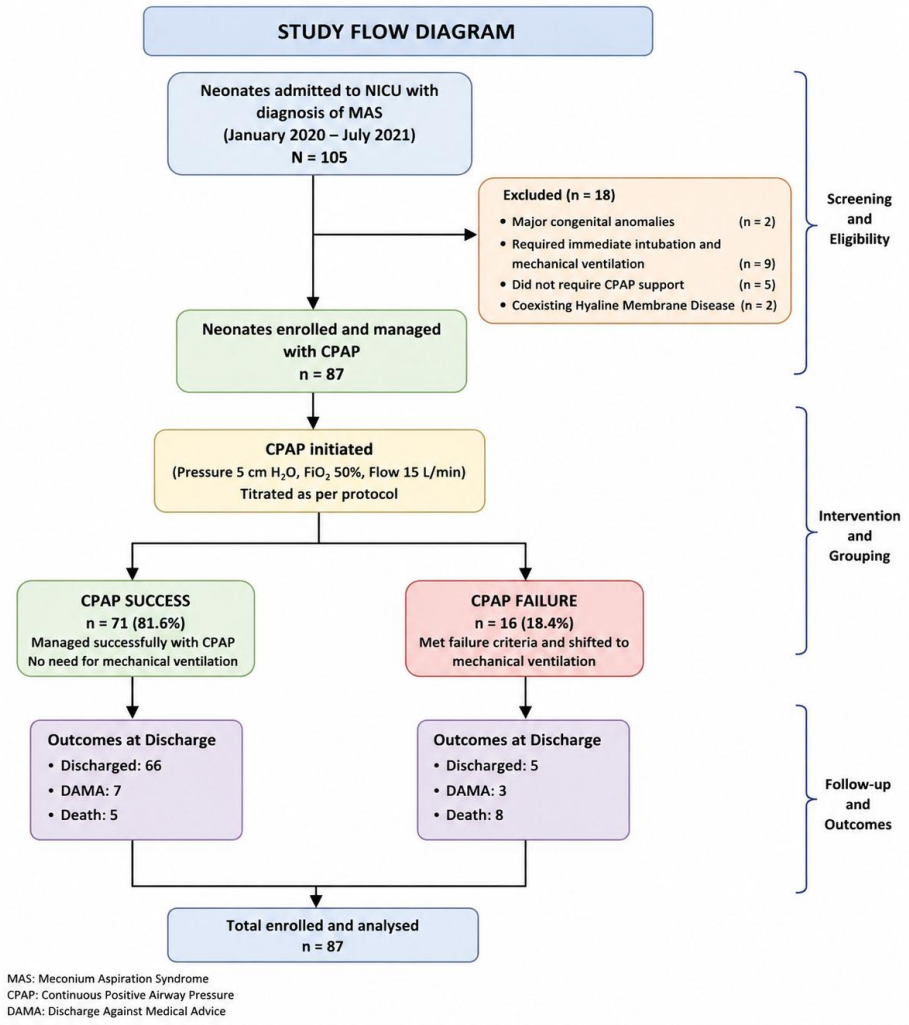

Figure 1: Study flow diagram

Table 1: Demographic Characteristics of Neonates with MAS

Parameter	Category	Number (n=87)	Percentage
Gender	Male	42	48.3%
	Female	45	51.7%
Birth Weight	VLBW (<1.5kg)	7	8.0%
	LBW (1.5–2.5kg)	15	17.2%
	Normal (>2.5kg)	65	74.7%
Gestation	Late Preterm	13	14.9%
	Term	57	65.5%
	Post-term	17	19.5%
Mode of delivery	Normal	42	48.8%
	Caesarian section	37	42.5%
	Assisted delivery	8	9.2%

Table 2: Different variables in CPAP success and CPAP failure

Variable	CPAP success N=71	CPAP failure N=16	p-value
Birth weight	2.811±0.58	2.671±0.55	0.36
Gestational age	38.06±1.12	38.13±1.67	0.86
Gender: male	34(47.8%)	9(56.25%)	0.51
IUGR	9	2	0.758
Antenatal steroids	9	1	0.768
APGAR at 1 min	8.45±0.50	6.5±0.51	<0.001
APGAR at 5 min	9.45±0.50	8.0±0.50	<0.001
Time of starting CPAP	4.37±5.59	4.18±4.5	0.882
Maximum PEEP during CPAP	5±0.81	6.43±1.5	<0.001
Fio2 requirement (%)	49±7	72±5	<0.001

Inotropic support	5	9	<0.001
Thick nature of MSL	27	11	0.066
E/O foetal distress	2	1	0.14

Table 3: Clinical Parameters Before and After CPAP (n=87)

Parameter	Before CPAP	6 Hours After CPAP	p-value
Respiratory Distress Score*	5.59 ± 0.95	4.0 ± 2.09	<0.0001
FiO2 (%)	50.28 ± 6	39 ± 17	<0.0001
Respiratory Rate (per min)	75 ± 6.93	61.76 ± 3.79	<0.0001
Heart Rate (per min)	170.71 ± 8.06	140.5 ± 5.17	<0.0001

*Downe score was used for term and post-term neonates, whereas Silverman-Anderson score was used for late-preterm neonates.

Table 4: Complications Observed in Study Population and final hospital outcome

Complication	Number of Infants	Percentage
Pneumothorax	3	3.4%
Hyperbilirubinemia	7	8.0%
Septicemia	13	14.9%
Other (NEC, Hypocalcemia)	6	6.9%
Outcome	Number	Percentage
Discharge	71	81.6
DAMA	10	11.5
Death	6	6.9

DISCUSSION

The present prospective observational study evaluated the clinical profile and outcomes of neonates with Meconium Aspiration Syndrome (MAS) managed with Continuous Positive Airway Pressure (CPAP) in a tertiary care neonatal intensive care unit. The study demonstrated an overall CPAP success rate of 81.6%, indicating that the majority of neonates with mild-to-moderate MAS can be effectively managed with non-invasive respiratory support. These findings are comparable with those reported by Indian studies like, Koti et al., who observed a CPAP success rate of 78% in neonates with MAS, and by Chiruvolu et al., who reported successful non-invasive management in approximately 84% of affected neonates.[11,17]

A significant improvement in clinical and physiological parameters was observed within six hours of CPAP initiation. Mean Respiratory distress score, FiO_2 requirement, respiratory rate, and heart rate decreased significantly following therapy. These findings support the physiological benefits of CPAP in MAS, including maintenance of functional residual capacity, improved alveolar recruitment, reduction in intrapulmonary shunting, and decreased work of breathing.[7,9] Similar improvements in respiratory status following early CPAP therapy have been reported by Dargaville et al. and Aly et al., reinforcing the role of CPAP as an effective first-line respiratory support modality in appropriately selected neonates with MAS.[5,18]

An important objective of the present study was to identify factors associated with CPAP failure. Neonates who failed CPAP required significantly higher FiO_2 concentrations and higher maximum PEEP levels and more frequently required inotropic support. These findings likely reflect greater severity of pulmonary disease and underlying hemodynamic instability. Increased oxygen requirement may indicate extensive ventilation-perfusion mismatch and impaired gas exchange, while higher PEEP requirements suggest more severe alveolar collapse and reduced lung compliance. The need for inotropic support may represent associated persistent pulmonary hypertension of the newborn (PPHN), myocardial dysfunction, or systemic hypoperfusion, all of which contribute to respiratory deterioration and increased likelihood of invasive ventilation. Similar predictors of CPAP failure have been reported by Ngerncham et al. and Al Tawil et al., who identified elevated oxygen requirements and cardiovascular instability as major determinants of non-invasive respiratory support failure.[10,12]

The observed association between APGAR scores and CPAP outcomes should be interpreted with caution. Although statistically significant differences were identified between the CPAP success and failure groups, APGAR score alone may not reliably reflect the severity of pulmonary disease in neonates with MAS. Previous studies have highlighted the limitations of APGAR scoring as an isolated predictor of respiratory outcomes, particularly in the presence of perinatal asphyxia, maternal medications, or delayed cardiopulmonary adaptation.[19] In the present study, neonates who experienced CPAP failure had significantly lower APGAR scores at both 1 and 5 minutes, suggesting greater perinatal compromise at birth. However, APGAR score should not be interpreted in isolation, as it may be influenced by several maternal and neonatal factors unrelated to the severity of respiratory disease. Therefore, larger studies are required to determine whether APGAR score independently predicts CPAP failure in neonates with MAS.

Septicemia was the most frequently observed complication in the present study, followed by hyperbilirubinemia and pneumothorax. The relatively higher incidence of septicemia probably

reflects the increased susceptibility of critically ill neonates requiring intensive care rather than a direct consequence of CPAP therapy. Importantly, pneumothorax was observed in only 3.4% of neonates, indicating that bubble CPAP was generally well tolerated when delivered using standardized protocols and appropriate monitoring. These findings are consistent with previous reports demonstrating that CPAP is a safe non-invasive respiratory support modality with a relatively low incidence of serious air-leak complications. Similar patterns of neonatal respiratory morbidity and associated complications have been reported from tertiary care centres in low- and middle-income countries.[20,21]

The overall mortality rate in the present study was 6.9%. Mortality was predominantly observed among neonates with severe respiratory disease and associated systemic complications requiring escalation of respiratory support. This finding is consistent with previous reports demonstrating that mortality in MAS is largely related to the severity of pulmonary involvement, persistent pulmonary hypertension, and multiorgan dysfunction rather than the respiratory support modality itself.[2,5]

The findings of the present study have important clinical implications, particularly in resource-constrained settings where access to mechanical ventilation may be limited. Early initiation of CPAP may reduce the need for invasive ventilation and its associated complications while allowing effective stabilization of neonates with MAS. Careful monitoring of oxygen requirement, PEEP requirement, and hemodynamic status may facilitate early identification of neonates at high risk for CPAP failure and enable timely escalation of respiratory support. While the identified predictors may assist in early clinical decision-making, they should not be interpreted in isolation. Clinical judgement remains essential, and escalation of respiratory support should be individualized according to the overall condition of the neonate.

Strength & limitation of the study

The present study has several strengths. It employed a prospective design with consecutive enrolment of eligible neonates, thereby reducing recall bias and minimizing selection bias. Standardized institutional protocols were followed for CPAP initiation and monitoring, ensuring consistency in patient management. Furthermore, the study evaluated clinically relevant bedside predictors of CPAP failure that are readily applicable in routine neonatal practice, thereby enhancing the translational value of the findings. However, the study was limited by its single-centre design, relatively small sample size, and lack of long-term neurodevelopmental follow-up. Larger multicentre studies are warranted to validate these findings and establish robust predictive models for CPAP failure in neonates with MAS. Furthermore, because only 16 CPAP failure events were observed, multivariable logistic regression analysis was not performed, as the number of outcome events was insufficient to generate a stable regression model. Consequently, predictors of CPAP failure were evaluated using univariate analysis alone.

CONCLUSION

Continuous Positive Airway Pressure is an effective first-line respiratory support modality for appropriately selected neonates with Meconium Aspiration Syndrome and was associated with successful avoidance of invasive mechanical ventilation in the majority of neonates in this prospective cohort. Higher FiO_2 requirement, increased PEEP, lower APGAR scores, and the need for inotropic support were associated with CPAP failure and may assist clinicians in identifying infants requiring closer monitoring and timely escalation of respiratory support. Prospective multicentre studies are warranted to validate these findings and determine their role in clinical prediction models.

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Conflict of Interest: The authors declare that they have no conflict of interest.

Data Availability: The datasets generated and/or analyzed during the current study are available from the corresponding author on reasonable request.

Ethical Approval: The study was approved by the Institutional Ethics Committee (Approval No. 53/9/10/2019). Written informed consent was obtained from the parents or legally authorized guardians of all participants.

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