International Journal of Contemporary Pediatrics
Choudhary S et al. Int J Contemp Pediatr. 2026 Mar;13(3):426-431
http://www.ijpediatrics.com
pISSN 2349-3283 | eISSN 2349-3291
DOI: https://dx.doi.org/10.18203/2349-3291.ijcp20260403

Original Research Article

Evaluation of varying thresholds of fraction of inspired oxygen on the need for surfactant administration and comorbidities among preterm neonates with respiratory distress syndrome: a prospective cohort study

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Received: 25 December 2025
Revised: 19 January 2026
Accepted: 07 February 2026

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ABSTRACT

Background: Respiratory distress syndrome (RDS) in preterm neonates results from surfactant deficiency, causing alveolar collapse. Continuous positive airway pressure (CPAP) is the preferred initial support, with surfactant administration based on fraction of inspired oxygen (FiO_2) thresholds. However, the optimal FiO_2 threshold remains uncertain. To assess surfactant need in preterm neonates on CPAP requiring FiO_2 30-40% based on Silverman-Anderson scores and FiO_2 trends.
Methods: This prospective cohort study was conducted at SMS Medical College, Jaipur, including preterm neonates (26-34 weeks' gestation) requiring CPAP. Neonates were categorized into three groups: Group A (<30% FiO_2), Group B (30-40%), and Group C (>40%). In Group B, surfactant was administered based on FiO_2 trends and Silverman–Anderson scores.
Results: Among 96 neonates, 70 (72.9%) received surfactant, while 26 (27.1%) did not. Higher FiO_2 and Silverman-Anderson scores at 6 hours were significantly associated with surfactant need ($p<0.0001$). However, maternal factors (antenatal steroids, mode of delivery, Gravida) showed no significant association with surfactant use.
Conclusions: Neonates requiring FiO_2 30-40% on CPAP can often be managed without immediate surfactant administration if their Silverman-Anderson score and FiO_2 improve within 6 hours. A FiO_2 threshold of 35%, combined with clinical monitoring, may be a more effective criterion for surfactant therapy, reducing unnecessary administration.

Keywords: Preterm, Respiratory distress syndrome, Pulmonary surfactant, Respiratory therapy

INTRODUCTION

Respiratory distress syndrome (RDS), previously known as hyaline membrane disease, is caused by insufficient pulmonary surfactant, leading to alveolar collapse and decreased lung compliance.[1,2] RDS primarily affects preterm neonates, who present within hours of birth, and the incidence of RDS is inversely proportional to gestational age. It affects 60-80% of infants born before 28 weeks, 15-30% of those born between 32-36 weeks, and rarely affects full-term infants.[3,4]

Surfactant production begins at approximately 20 weeks of gestation, and it plays a critical role in reducing

surface tension to prevent alveolar collapse.[5] Key risk factors for RDS include prematurity, low birth weight, male sex, white race, maternal diabetes, and perinatal hypoxia.[6]

The main treatment strategies include antenatal corticosteroids, respiratory support, surfactant therapy, and comprehensive care. Nasal continuous positive airway pressure (n-CPAP) has become a common method of respiratory support for neonates with RDS, reducing the need for intubation and mechanical ventilation.[7] While n-CPAP has a high failure rate (15-50%), early use has been shown to reduce surfactant requirements and the incidence of broncho-pulmonary dysplasia (BPD). Treatment goals include maintaining SpO_2 between 90-95% and $PaCO_2$ between 45-65 mmHg.

The gold standard for RDS treatment includes CPAP or mechanical ventilation, along with surfactant therapy. The 2019 European guidelines suggest an FiO_2 threshold of 30% for surfactant administration, but the optimal thresholds remain unclear.[8] According to AIIMS NICU protocols, surfactant is administered when FiO_2 exceeds 0.4 on the CPAP.

This study aims to determine the optimal FiO_2 threshold for surfactant administration on the basis of the Silverman-Anderson score and FiO_2 requirement.

METHODS

This prospective observational study was conducted on neonates between 26 to 34 weeks of gestational age admitted to the NICU of S.M.S. Medical College, Jaipur between periods of January 2023 to December 2023. Institutional ethics approval was obtained, and written consent was obtained from all parents/attendants. Preterm infants born at hospitals were included in the study on the basis of inclusion and exclusion criteria.

Eligible neonates with signs of respiratory distress (Tachypnea, chest retractions, expiratory grunting) received CPAP as initial respiratory support. The need for surfactant was determined on the basis of the FiO_2 requirement and the Silverman Anderson score (SAS). The infants were categorized into three groups: Group A-(FiO_2 <30%), CPAP without surfactant was continued. Group C-(FiO_2>40%) received surfactant combined with CPAP. Group B-(FiO_2 30-40%) was monitored every 10-15 minutes for the first 2 hours and then every 30 minutes for the next 6 hours. If there was clinical improvement (decreased FiO_2 requirements and SAS scores), CPAP therapy was continued without surfactant. If there was no improvement or worsening, surfactant was administered.

All groups were monitored with Silverman-Anderson scoring and managed per NICU protocols. RDS management in our unit begins with CPAP. If the FiO_2 requirement exceeds 0.4, surfactant is administered.

The surfactant was instilled via either INSURE (intubate-surfactant-extubate) or LISA (less invasive surfactant administration). LISA was preferred to minimize mechanical ventilation risk. Bubble CPAP was used with 5cm H2O PEEP, a 5 L/min flow rate, and FiO_2 of 30-40%, delivered via Hudson prongs.

A structured platform was used for data collection, including newborn examination (birth weight, gestational age via the modified Ballard score, APGAR scores at 1 and 5 minutes, resuscitation, sepsis, and clinical assessment).

Inclusion criteria of our study include RDS is suspected in preterm infants between 26 and 34 weeks of gestational age, and signs of respiratory distress, including tachypnea, retraction, nasal flaring, grunting and cyanosis and the need for CPAP, develop soon after birth. Patient Exclusion who has severe birth asphyxia, Major congenital anomalies and Neonates require mechanical ventilation and cardiovascular instability.

The data were entered into MS Access and analyzedvia Stata version 14.2. The skewness of the data was checked via the Shapiro-Wilk test, and the distribution of the data points was assessed via histograms. Continuous variables are summarized as the means (SDs) or medians (IQRs) depending on skewness and were analyzed via unpaired t tests and Kruskal-Wallis tests for normal and skewed data, respectively. Nominal data are presented as proportions and were analyzed via the chi-square test or Fisher's exact test. A P value<0.05 was considered significant. The mean difference and odds ratio are presented wherever applicable along with their 95% confidence intervals.

RESULTS

In our study the total population of 96 neonates, 45 are female, representing 46.9% of the total. Conversely, 51 neonates are male, constituting 53.1% of the total population. Out of the total population of 96 mothers, the majority, comprising 74 mothers or 77.1% of the total, delivered via normal vaginal delivery (NVD). Conversely, 22 mothers, representing 22.9% of the total population, underwent delivery via lower segment cesarean section (LSCS) (Table 1). Out of 96 mothers, 19 mothers are primigravida, representing 19.8% of the total. The highest proportion of mothers falls under the category of gravida 2, with 31 mothers accounting for 32.3% of the total. Additionally, there are 23 mothers classified as gravida 3, making up 24.0% of the total population. Gravida 4 comprises 17 mothers, constituting 17.7% of the total.

Among the total population of 96 neonates, the majority, comprising 75 neonates or 78.1% of the total, do not exhibit apnea. Conversely, 21 neonates, representing 21.9% of the total population, exhibit signs of apnea. Out of 96 mothers, 37 mothers, representing 38.5% of the

total population, reported a history of receiving antenatal steroids.

Association with surfactant therapy in our study shows that significant associations were observed between the need for surfactant and the Silverman-Anderson score at 6 hours (p=0.0001) and the FiO_2 requirement at 6 hours (p=0.0001).

No significant associations were found between maternal factors (age, antenatal steroids, LPV > 24 hours, mode of delivery) and the need for surfactant therapy. These results highlight the factors influencing the need for surfactant therapy in neonates with respiratory distress and underscore the importance of monitoring Silverman Anderson scores and FiO_2 requirements for decision-making. Table 2 displays the distribution of neonates categorized by whether they received surfactant treatment. Among the total population of 96 neonates, 26 neonates, representing 27.1% of the total population, did not receive surfactant treatment.

The Figure 1 presents the distribution of FiO_2 (fraction of inspired oxygen) requirements among neonates at 1 hour and 6 hours after birth, as well as the FiO_2 threshold at which surfactant was administered. At 1 hour after birth, the mean FiO_2 requirement is 34.11%, with a standard deviation of 2.228, indicating variability in FiO_2 levels among neonates. Similarly, at 6 hours after birth, the mean FiO_2 requirement slightly increases to 34.54%, with a standard deviation of 2.847. With respect to the FiO_2 threshold at which surfactant was administered, the mean threshold was 35.71%, with a standard deviation of 2.188.

The Table 3 illustrates the associations of the need for surfactant therapy with various neonatal factors, including Silverman-Anderson scores at 1 hour and 6 hours, as well as FiO_2 (fraction of required oxygen) requirements at 1 hour and 6 hours (Figure 1).

For the Silverman-Anderson score at 1 hour, the mean score was 5.19, with a standard deviation of 0.849 among neonates who did not receive surfactant therapy, and 5.13, with a standard deviation of 0.883 among those who did receive surfactant therapy. The p-value associated with this comparison was 0.752, suggesting that there was no significant association between the Silverman Anderson score at 1 hour and the need for surfactant therapy.

However, for the Silverman-Anderson score at 6 hours, a significant difference was observed. Among neonates who did not receive surfactant therapy, the mean score was 3.50, with a standard deviation of 0.906, whereas among those who did receive surfactant therapy, the mean score was 5.57, with a standard deviation of 0.627. The p value associated with this comparison was 0.0001, indicating a significant association between the Silver-Anderson score at 6 hours and the need for surfactant therapy.

The mean FiO_2 requirement at 1 hour was 33.88, with a standard deviation of 1.796, among neonates who did not receive surfactant therapy and 34.20, with a standard deviation of 2.375, among those who did receive surfactant therapy. The p value associated with this comparison was 0.541, suggesting that there was no significant association between the FiO_2 requirement at 1 hour and the need for surfactant therapy.

In contrast, for the FiO_2 requirement at 6 hours, a significant difference was observed. Among neonates who did not receive surfactant therapy, the mean requirement was 31.38, with a standard deviation of 1.835, whereas among those who did receive surfactant therapy, the mean requirement was 35.71, with a standard deviation of 2.188. The p value associated with this comparison was 0.0001, indicating a significant association between the FiO_2 requirement at 6 hours and the need for surfactant therapy.

In the present study, mean hospital stay was 14.3 days with SD of 8.7. Among the neonates, 10 (10.4%) had pneumothorax, and another 10 (10.4%) had pulmonary hemorrhage. The most frequent complication was pneumonia, affecting 17 neonates (17.7%). This data highlights that pneumonia was the most common complication among the neonates, while pneumothorax and pulmonary hemorrhage were less prevalent but still notable (Figure 2).

The Figure 3 presents the distribution of neonates according to their final outcome. Out of the 96 neonates, 18 (18.8%) expired, while the majority, 78 neonates (81.3%), survived. Out of 18 expired, 10 neonates did not receive surfactant and out of 78 survived, 16 did not receive surfactant.

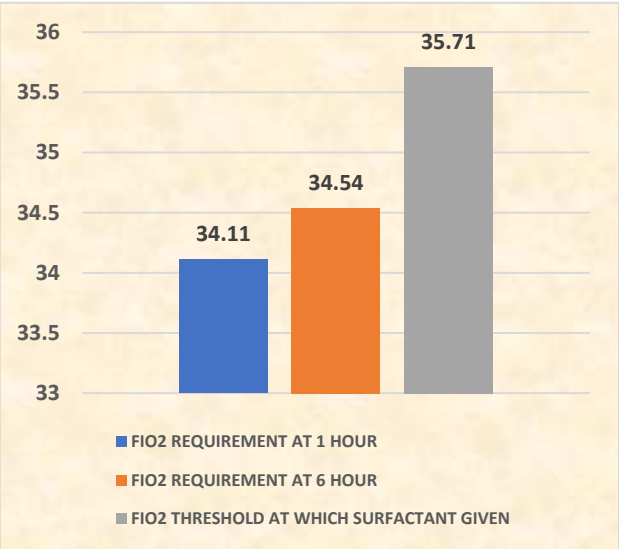

Figure 1: Distribution of FiO_2 requirement.

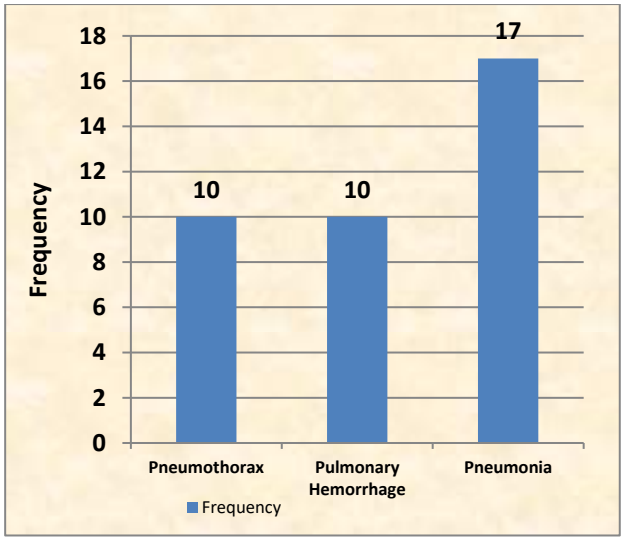

Figure 2: Distribution of the neonates according to complications.

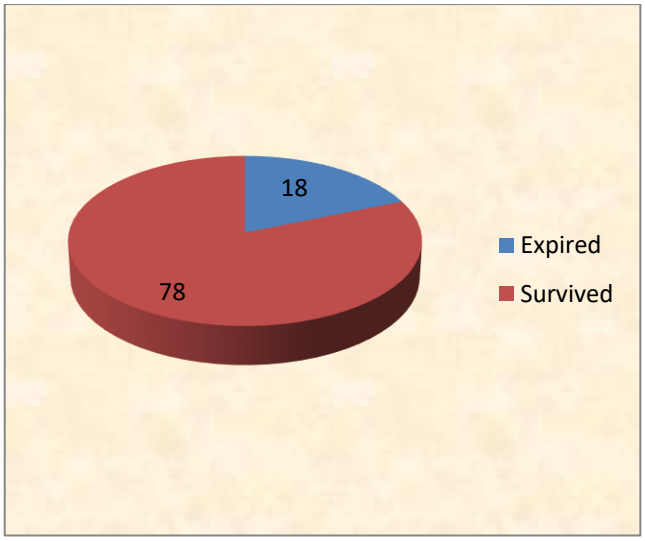

Figure 3: Distribution of the neonates according to final outcome.

Table 1: Demographic data patients.

Distribution		N	Percent
Age group (in hour)	1	54	56.3%
	2	34	35.4%
	3	8	8.3%
Gender	Male	51	53.1%
	Female	45	46.9%
Mode of delivery	NVD	74	77.1%
	LSCS	22	22.9%
	No	26	27.1%

Table 2: Distribution of neonates is according to surfactant.

Surfactant given	N	Percent
No	26	27.1%
Yes	70	72.9%
Total	96	100.0%

Table 3: Association of the need for surfactant therapy with neonatal factors.

Factors	Surfactant given				P value
	No		Yes		
	Mean	SD	Mean	SD	
Silverman-Anderson score at 1 hour	5.19	0.849	5.13	0.883	0.752
Silverman-Anderson score at 6 hour	3.50	0.906	5.57	0.627	0.0001
FiO_2 requirement at 1 hour	33.88	1.796	34.20	2.375	0.541
FiO_2 requirement at 6 hour	31.38	1.835	35.71	2.188	0.0001

DISCUSSION

The present study aimed to evaluate the need for surfactant administration and associated comorbidities among preterm neonates with RDS managed with varying thresholds of the FiO_2. The primary objective was to identify the need for surfactant in neonates with an FiO_2 requirement between 30% and 40%, whereas the secondary objective was to compare outcomes between neonates who did and did not receive surfactant therapy.

In this study, most neonates (56.3%) were 1 day old, followed by 35.4% at 2 days of age. This aligns with the typical age range for preterm neonates requiring early respiratory support due to RDS. Studies by Gulczyńska et al, Kruczek et al and Dunn et al also revealed similar age

distributions, with a focus on preterm neonates within the first 72 hours of life.[1,2,9]

The sex distribution in the study was 53.1% male and 46.9% female, which is consistent with the general lack of significant sex bias in preterm neonates with RDS. The mean maternal age was 25.5 years, with most mothers aged 18-25 years, which is typical, as younger mothers are more likely to have preterm births. Additionally, 32.3% of mothers were gravida 2, indicating that multi-gravida status is common in this cohort, also compare by previous study.[2,10]

The study revealed that 38.5% of mothers received antenatal steroids, a well-established intervention for reducing RDS risk, but this rate was lower than the recommended target of 80-95%. The presence of maternal complications, such as ante-partum hemorrhage (12.5%) and pregnancy-induced hypertension (11.5%), also contributes to neonatal RDS risk, highlighting the importance of addressing these factors during pregnancy, as compare to old studies.[2,3]

The delivery mode revealed that 77.1% of neonates were born through NVD, which is consistent with the standard practice for preterm neonates unless specific obstetric indications necessitate a cesarean section. In terms of neonatal respiratory symptoms, 21.9% of the patients presented with apnea, and 75% presented with grunting. The mean Silverman-Anderson score at 1 hour was 5.15, indicating moderate to severe respiratory distress.

The study revealed that 72.9% of neonates received surfactant therapy, with a mean FiO_2 threshold of 35.71%. This result is consistent with studies by Gulczyńska et al who reported that higher FiO_2 levels were associated with the need for invasive ventilation.[1] A comparison with other studies (e.g., Kruczek et al) revealed differences in the FiO_2 thresholds for surfactant administration, with some studies using a threshold as low as 30% and similarly also seen in other studies also.[2,11,13,16]

In the present study, significant differences were observed in Silverman-Anderson scores and FiO_2 requirements between the surfactant and non-surfactant groups. Neonates who received surfactant had a higher Silverman Anderson score (5.57 vs. 3.50) and higher FiO_2 requirement (35.71% vs. 31.38%), reflecting the more severe nature of their respiratory distress. This finding is consistent with the clinical understanding that surfactant is administered to more critically ill neonates to improve respiratory function, also compare with old literature.[3,4,17]

Interestingly, no significant associations were found between maternal factors (e.g., age, gravida, antenatal complications) and the need for surfactant therapy. This suggests that the respiratory status of the neonates, as reflected by the Silverman-Anderson score and FiO_2 requirements, was the primary determinant of surfactant need.[6,7] However, maternal factors are known to influence neonatal outcomes, and the lack of significant differences may be due to the homogeneous nature of the study population.

The higher FiO_2 threshold for surfactant therapy in this study suggests a more conservative approach than that used in other studies.[1,14] This conservative approach may reflect differences in clinical practice, resource availability, or the desire to minimize unnecessary interventions. However, further research is needed to establish optimal FiO_2 thresholds for surfactant administration.

The findings of this study are consistent with the literature that emphasizes the importance of respiratory parameters, particularly FiO_2 requirements, in guiding the decision for surfactant therapy in preterm neonates with RDS.[1,12,18] While maternal factors did not significantly impact the need for surfactant, respiratory distress severity-measured by Silverman Anderson scores and FiO_2 requirements-remained the key determinant. This study highlights the need for further research to determine the optimal thresholds for surfactant therapy and improve management strategies for preterm neonates with RDS.

Strengths of our study were Prospective cohort design for robust analysis, Comprehensive data on neonatal and maternal factors and key indicators such as Silverman Anderson scores and FiO_2 requirements are used.

Limitations of present study are Single institution, limiting generalizability, there is a lack of data on morbidities and mortality and there was no long-term follow-up to assess outcomes beyond the neonatal period.

CONCLUSION

This study assessed the need for surfactant in preterm neonates with RDS, with a focus on FiO_2 thresholds. The higher FiO_2 requirement at 6 hours of life was associated with the need for surfactant. No significant differences in neonatal or maternal factors were found between the groups. This study highlights the importance of respiratory parameters in surfactant decision-making and suggests that further research is needed to establish optimal FiO2 thresholds for surfactant therapy.

Funding: No funding sources
Conflict of interest: None declared
Ethical approval: The study was approved by the Institutional Ethics Committee NO: 796/MC/EC/2023.

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Cite this article as: Choudhary S, Kumar P, Chohan P, Sehra RN, Neniwal N, Neniwal VK. Evaluation of varying thresholds of fraction of inspired oxygen on the need for surfactant administration and comorbidities among preterm neonates with respiratory distress syndrome: a prospective cohort study. Int J Contemp Pediatr 2026;13:426-31.