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# The efficacy of pulmonary surfactant factor administration in preterm infants with grades I and II respiratory distress syndrome

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**Abstract**
**Background:** Respiratory Distress Syndrome, previously hyaline membrane sickness, affects premature babies. RDS is caused by immature pulmonary surfactant. The study aimed to examine the effectiveness of surfactant in preterm infants 32-36 weeks gestation with RDS grade I and II.
**Methods:** A non-randomized controlled trial study, including preterm infants 32-36 weeks of gestational age who had respiratory distress syndrome grade I and II. We compared the effect of using surfactant plus continuous positive airway pressure versus using a continuous positive airway pressure alone on morbidity and mortality to treat preterm 32-36 weeks of gestational age who had respiratory distress syndrome grade I and II.
**Results:** The study included a Surfactant group of 39 premature infants (56.4% males, mean gestational age 34.461.12 weeks, mean birth weight 1924.79322.78 g, respiratory distress syndrome grade I 28.2%, respiratory distress syndrome grade II 71.8%) and a Non-Surfactant group of 27 premature infants (55.6% males, mean gestational age 34.481.09 weeks, mean birth weight 1925.93322.3g, Gender, gestational age, birth weight, and RDS severity did not differ between Surfactant and Non-Surfactant groups. Surfactant plus continuous positive airway pressure increased intraventricular haemorrhage, pulmonary haemorrhage, pneumothorax, and late-onset sepsis, while continuous positive airway pressure alone increased necrotizing enterocolitis and retinopathy of prematurity. The difference was not statistically significant except for necrotizing enterocolitis. Surfactant reduced hospitalisation duration and mortality rate, although the change was not statistically significant.
**Conclusions:** Surfactant with continuous positive airway pressure delivery to premature 32-36-week-olds with respiratory distress syndrome grade I and II did not reduce morbidity and death, but exacerbated comorbidities. Prospective studies may help determine surfactant's safety and effectiveness in this group.

**Keywords:** Pulmonary surfactant factor, respiratory distress syndrome, premature.

## Introduction

Preterm infants are born before 37 weeks' gestation. Extreme preterm birth occurs before 28 weeks, extremely preterm birth between 28-32 weeks, and moderate to late preterm delivery between 32-37 weeks [1]. Preterm delivery problems kill 1 million children annually. Many survivors have learning impairments, vision and hearing issues for life [2]. Premature babies are more likely to suffer RDS, cerebral palsy, developmental delays, hearing and visual difficulties. Early birth increases these risks [3]. RDS, originally called hyaline membrane disorder, is frequent in premature babies. RDS is caused by immature pulmonary surfactant. RDS causes morbidity and death in premature babies [4]. Some research indicates that there are other causes of RDS, particularly in preterm and term infants [5-8]. Preterm infants with reduced surfactant amount and quality develop RDS. In addition to diminishing surfactant synthesis with age, preterm surfactant has lower action due to variations in lipid and protein composition [9]. RDS rises with gestational age (GA). Neonatal Research Network study [10]. Late preterm babies have reduced incidence [11]. Male sex and white race/ethnicity are associated with a higher incidence of RDS in late preterm and term newborns than Asian, Black, or Hispanic race/ethnicity [12]. RDS is diagnosed based on a preterm infant's clinical presentation of increasing respiratory failure immediately after birth and a distinctive chest radiograph.

Low lung capacity and diffuse reticulogranular ground glass with air bronchograms are chest radiographic characteristics of RDS [4]. Once RDS is diagnosed based on needing oxygen supplementation with FiO2 > 0.3 to 0.4, therapy focuses on exogenous surfactant and respiratory support for appropriate oxygenation and ventilation while avoiding lung damage and consequences (BPD) [13, 14]. Natural and manmade surfactants are effective in treating RDS. Surfactant is a complicated structure made of DPPC and SP-A, B, C, and D. SP-B and SP-C bind and distribute DPPC [15]. Many clinical trials have been conducted to compare the efficacy of different animal-derived or natural surfactants [Poractant alfa: Porcine lung minced extract (200 mg/kg/dose); Calfactant: Bovine lung lavage extract (3 mL/kg); Beractant: Bovine lung minced extract (100 mg phospholipids/kg); BLES: Bovine lung lavage extract (135 mg phospholipids/kg/dose)]. Surfactant is given to newborns with prolonged respiratory distress 2 hours after delivery. Surfactant threshold varies by instillation strategy (endotracheal versus minimally invasive). Techniques vary across facilities and even between clinicians within a centre. Due to endotracheal delivery problems, less invasive approaches look promise. Aerosolized/nebulized surfactant formulations, pharyngeal instillation, and laryngeal mask airway-assisted administration are used. Many hospitals employ narrow intratracheal catheters to give surfactant endotracheally without intubation difficulties [16]. Surfactant dosages are repeated only when ventilation and oxygen needs indicate continued RDS. Several clinical investigations have shown the therapeutic efficacy of surfactant replacement therapy for RDS [17-20]. Surfactant treatment has reduced RDS mortality and morbidity. Complications and fatalities continue. Placement of arterial catheters, supplementary oxygen, positive pressure ventilation, and endotracheal tubes might cause difficulties. Neonate endotracheal intubations can have adverse results. Endotracheal tubes may get dislodged. Endotracheal tube insertion into a major stem (usually right-sided) bronchus causes hyperinflation of the ventilated lung and atelectasis of the contralateral lung. Hyperinflation can leak air. Intubation can cause subglottic stenosis. Esophageal and pharyngeal perforations are infrequent and may be mediastinal or pleural. Pulmonary air leak is an RDS complication that affects low-birth-weight babies (1500 g). Air leaks occur when an over-dilated alveolus ruptures spontaneously or during positive pressure ventilation. BPD is RDS's major chronic consequence. BPD is still common despite advancements in RDS management. Babies have bronchopulmonary dysplasia if their oxygen saturation falls below 90% in 60 minutes. Ultrasound is used to identify intraventricular haemorrhage (Hemorrhage manifests as increased echogenicity in the germinal matrix, ventricular space, and potentially in the brain parenchyma) Symptoms, indicators, and a chest X-ray, hemothorax, or intrabronchial bleeding are used to diagnose pulmonary haemorrhage [21-23]. Necrotizing Enterocolitis (NEC) is diagnosed on the basis of clinical symptoms (abdominal distention, bilious vomiting or gastric aspirate, and rectal bleeding [heme-positive or grossly bloody stools without anal fissure]). ROP is a developmental vascular proliferative disease that affects premature infants with insufficient retinal vascularization. The onset of late-onset sepsis (LOS) occurs after 72 hours. Sepsis is defined as the isolation of pathogenic bacteria from the blood culture of a patient exhibiting sepsis-like symptoms [24-26]. The purpose of this study is to examine the effectiveness of surfactant administration in preterm infants 32-36 weeks' gestational age with grade RDS I and II.

## Patients and Methods

### Study design

A non-randomized controlled trial (NRS) conducted at Imam Zain Alabiden Hospital, Kerbala, Iraq, between 1st Jan. 2018 and 31st Dec. RDS was identified based on clinical characteristics and chest X-ray results (4). During the research period, 161 preterm neonates with a gestational age more than 32 weeks were admitted to the NICU. On the basis of clinical and radiological characteristics, Grade I, II, 66 children born prematurely were diagnosed with respiratory distress syndrome RDS. All preterm infants (born in the delivery room or operating room with spontaneous breathing but respiratory distress at birth) were administered NCPAP to stabilise their breathing condition, beginning with a resuscitator at positive end expiratory pressure levels of 5-10 cmH2O and continuing during transfer to the NICU. In addition to using a nasal prong and inserting an orogastric tube to prevent belly distension, cardiopulmonary monitoring was also undertaken. The amount of continuous positive airway pressure (CPAP) varied between 5 and 8 cmH2O, and FiO2 was regulated to maintain 90-95% oxygen saturation. Surfactant is administered if clinical improvement does not occur within 6 hours or if babies require FiO2 > 40% to maintain arterial oxygen saturation (endotracheal tube). 39(59.1%) babies were treated with surfactant (single dose of Survanta @ 100 mg/kg = 4 ml/Kg) (natural bovine lung lavage) and Continuous Positive Airway Pressure (CPAP). Respiratory distress syndrome grade III, IV, any congenital deformity, inherited metabolic abnormalities, intrauterine infection, Rh/Rh incompatibility, pneumonia, pulmonary hypertension, meconium aspiration syndrome, asphyxia, and early onset sepsis are the exclusion criteria. Collecting data; Data were collected regarding gender, gestational age, birth weight, and complications (intraventricular haemorrhage, pulmonary haemorrhage, pneumothorax, necrotizing enterocolitis, retinopathy of prematurity, and late onset sepsis), duration of treatment (less or more than a week), and the end point was death or improvement and discharge of the premature infant. Analyses based on descriptive statistics, including mean and standard deviation (SD) expressions for quantitative variables, and ratio and percentage expressions for qualitative variables. Quantitative and qualitative factors were analysed using the Student t test and chi-square test, respectively. In this study, IBM SPSS Statistics version 20.0 was utilised for data analysis. The statistical significance threshold was determined to be P0.05. Ethical permission; the newborn parents gave their written consent to participate in the investigation. Additionally, no private information will be disclosed.

## Results

### Clinical characteristics of the infants

The surfactant group included 39 (59.1%) premature infants, 22(56.4%) males, 17(43.7%) females and the Non-Surfactant group included 27(40.1%) premature infants, 15(55.6%) males, 12 (44.4%) females. Mean gestational age (34.46±1.12 vs. 34.48±1.09 weeks) and mean birth weight (1924.79±322.78 vs. 1925.93±322.36 g) were similar

between the Surfactant group and Non-Surfactant group. The difference between the Surfactant group and Non-Surfactant group in gender, gestational age and birth weight was not statistically significant as shown in Table 1.

**Table 1:** Comparison of the demographic characteristics of newborns between the Surfactant group and Non-Surfactant group.

| | Surfactant (39) | | Non-Surfactant (27) | | p-value |
|---|---|---|---|---|---|
| | No/Mean | %/SD | No/Mean | %/SD | |
| Female | 17 | 43.6 | 12 | 44.4 | 0.945 |
| Male | 22 | 56.4 | 15 | 55.6 | |
| Gestational age (weeks) | 34.46 | 1.12 | 34.48 | 1.09 | 0.943 |
| Birth weight (g) | 1924.79 | 322.78 | 1925.93 | 322.36 | 0.959 |

In surfactant group 11(28.2%) preterm infants had RDS grade I and 28 (71.8%) preterm infants had RDS grade II. In Non-Surfactant group 8(29.6%) preterm infants with RDS Grade I and 19(70.4%) premature infants with RDS grade II, the difference was not statistically significant as shown in Table 2.

**Table 2:** Severity of RDS in the Surfactant group and Non-Surfactant group

| | Surfactant (39) | | Non-Surfactant (27) | | p-value |
|---|---|---|---|---|---|
| | No | % | No | % | |
| RDS grade I | 11 | 28.2 | 8 | 29.6 | 0.900 |
| RDS grade II | 28 | 71.8 | 19 | 70.4 | |

**Intraventricular Hemorrhage (IVH)**

Occurred in 10 preterm infants, where in the surfactant group 8 infants (20.5%) and in the Non-Surfactant group two infants (7.4%), the difference was not statistically significant.

**Pulmonary Hemorrhage**

Occurred in 4 preterm infants, three infants in the surfactant group (7.7%) and one infant in the Non-Surfactant group, the difference was not statistically significant. Pneumothorax: Occurred in 6 preterm infants had, 4 preterm infants in the surfactant group (10.3%) and 2 preterm infants in the Non-Surfactant group, the difference was not statistically significant. Necrotizing enterocolitis (NEC): Occurred in 10 preterm infants, whereas in the surfactant group 3 infants (7.7%), while in the Non-Surfactant group 7 infants (25.9%), the difference was statistically significant. One premature infant in the Non-Surfactant group (3.7%) had retinopathy of prematurity. Late Onset Sepsis (LOS): Occurred in 15 preterm infants, 9 preterm infants in the surfactant group (23.1%) and 6 preterm infants in the Non-Surfactant group (22.2%), the difference was not statistically significant. Table 3 compares the complications rate between the Surfactant group and Non-Surfactant group.

**Table 3:** Shows the comparison of complications between the Surfactant group and Non-Surfactant group.

| | Surfactant (39) | | Non-Surfactant (27) | | p-value |
|---|---|---|---|---|---|
| | No/Mean | %/SD | No/Mean | %/SD | |
| IVH | 8 | 20.5 | 2 | 7.4 | 0.144 |
| Pulmonary Hemorrhage | 3 | 7.7 | 1 | 3.7 | 0.504 |
| Pneumothorax | 4 | 10.3 | 2 | 7.4 | 0.692 |
| NEC | 3 | 7.7 | 7 | 25.9 | 0.042 |
| ROP | 0 | 0 | 1 | 3.7 | 0.226 |
| LOS | 9 | 23.1 | 6 | 22.2 | 0.935 |

Hospitalization time was ≤ one week for 27 infants in the surfactant group (69.2%) and for 14 infants in the Non-Surfactant group (51.9%), while the hospitalization time was > one week for 12 infants in the surfactant group (30.8%) and for 13 infants in the Non-Surfactant group (48.1%), the difference was not statistically significant. The survival rate in the surfactant group was 97.4% (38 infants), and in the Non-Surfactant group was 96.3% (26 infants), the difference was not statistically significant. One premature infant in the surfactant group died after 3 days of admission, where he had IVH grade 3, pulmonary hemorrhage and pneumothorax. One premature infant in the Non-Surfactant group died after 13 days of admission, where he had pulmonary hemorrhage and late onset sepsis leading to septic shock and disseminated intravascular coagulopathy (DIC). Table 4 shows hospitalization time, survival and mortality rates.

**Table 4:** Comparison of outcomes between the Surfactant group and Non-Surfactant group.

| | | Surfactant (39) | | Control (27) | | p-value |
|---|---|---|---|---|---|---|
| | | No./ Mean | %/SD | No./ Mean | %/SD | |
| Hospitalization time | ≤ one week | 27 | 69.2 | 14 | 51.9 | 0.152 |
| | > one week | 12 | 30.8 | 13 | 48.1 | |
| Death | | 1 | 2.6 | 1 | 3.7 | 0.791 |
| Survival | | 38 | 97.4 | 26 | 96.3 | |

**Discussion**

Several cohort studies in late preterm babies have indicated a decrease in supplementary FiO2 and an improvement in arterial oxygen pressure (PaO2) after surfactant administration, but conflicting evidence of a reduction in mortality or air leak syndrome [27-30]. In the current study, Surfactant plus CPAP was used to treat grade I and II respiratory distress syndrome in 39 premature infants between 32 and 36 weeks of gestation, and the complications and outcomes were compared to those of 27

premature infants of comparable gestational age who were treated with CPAP (40.9%). The Surfactant group and Non-Surfactant group were comparable in terms of sex, birth weight, and severity of RDS. Surfactant plus CPAP was associated with a higher incidence of IVH, pulmonary haemorrhage, pneumothorax, and late onset sepsis, whereas CPAP alone was associated with a higher incidence of BPD, NEC, and ROP, but the difference was not statistically significant except for the incidence of necrotizing enterocolitis. The use of the surfactant contributed to a reduction in the incidence of necrotizing enterocolitis, but not to a reduction in the incidence of other problems. Positively, the hospitalisation duration was shorter and the death rate was reduced when the surfactant was used, although the difference was not statistically significant. In Jackson *et al*. research, which comprised 54964 preterm children with gestational age 30-36 weeks of gestational age and birth weight > 2 kg with RDS. There was no significant correlation between surfactant therapy and reduced mortality or morbidity in preterm babies with GA more than 30 weeks who had RDS and who were treated with surfactant (46%) [31]. Wang *et al*. discovered a trend toward decreased hospitalisation time with increasing gestational age, but a trend toward an increased rate of repeated surfactant administration with increasing gestational age; additionally, surfactant replacement therapy for RDS was more effective in premature infants 35 weeks' gestational age than in near-term and term infants [32]. Helve *et al*. observed that RDS due to surfactant deficit was most prevalent in babies with a gestational age of 35 weeks and that RDS due to the delayed evacuation of lung fluid was more prevalent in full and near-term infants than in preterm infants [33]. In a retrospective study by Coshal, *et al*. (included 8594 neonates of 29 weeks' GA) was compared the outcomes of using surfactant (one or more doses) with the non-use of surfactant, with surfactant therapy administration according to recommendations made by the Canadian Pediatric Society to ensure safety and accuracy (administration of surfactant to intubated patients with RDS, prophylactic administration after stabilisation in intubated preterm neonates at significant risk of RDS). They discovered that neonates who received one or multiple doses of surfactant had higher odds of mortality and major morbidities (specifically severe neurological injury, BPD, and stage 3 or higher ROP) compared to those who did not receive surfactant [17]. Multiple research support these findings [31-33].

## Conclusions

This study indicated that newborns with RDS grades I and II and gestational ages between 32 and 36 weeks who were administered surfactant had results comparable to those of infants who were not given surfactant.

## Conflict of Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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