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Study Of Efficacy Of Surfactant At Different Gestational Ages For Infants With Respiratory Distress Syndrome: An Observational Study.

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ABSTRACT

One of the leading causes of illness and mortality in newborn children, particularly those who are born preterm, is respiratory distress syndrome (RDS). (1–3)Significant respiratory morbidity affects 15% of term infants and 29% of late preterm infants admitted to the neonatal critical care unit; the rate is significantly greater for infants born before 34 weeks of gestation. In the Dr. Vikhe Patil Medical College's newborn intensive care unit (NICU), Ahmednagar, Maharashtra, a prospective study was done. Ninety neonates with RDS were enlisted throughout the course of the previous year [June 2021 to June 2022]. Both in-born and out-born newborns delivered at nearby district hospitals, primary health facilities, and rural health centres are referred to the our NICU. There was no significant difference between in the three groups with respect to endotracheal intubation, mechanical ventilation rates, survival rates and repeated surfactant rate. But, there was a significant difference in the hospitalization days among the three groups. ($p<0.001$). Due to its retrospective design, this study has certain restrictions. Newborns who refused surfactant therapy were excluded, and patient inclusion was based on the requirement for surfactant therapy in infants with RDS. As a result, not all newborns with RDS were included in the patient group, and the findings do not accurately represent all RDS patients.

Keywords: Surfactant, gestational age, respiratory distress syndrome

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INTRODUCTION

One of the leading causes of illness and mortality in newborn children, particularly those who are born preterm, is respiratory distress syndrome (RDS) [1-3]. Significant respiratory morbidity affects 15% of term infants and 29% of late preterm infants admitted to the neonatal critical care unit; the rate is significantly greater for infants born before 34 weeks of gestation [2,4,5]. Neonatal respiratory illness is more likely to occur when certain risk factors are present. Prematurity, caesarian birth, gestational diabetes, maternal chorioamnionitis, meconium-stained amniotic fluid (MSAF), or prenatal ultrasound findings such oligohydramnios or structural lung abnormalities are some of these causes [6-11]. According to evidence generated, the lungs' developmental immaturity, particularly in terms of the system responsible for generating surfactants, is one of its causes [12-14]. Exogenous surfactant replacement therapy has been the primary way for treating RDS since it was originally used to prevent it. Several clinical investigations have shown that it has therapeutic results [8, 12]. Intensive care and surfactant replacement therapy can't stop certain newborn deaths, though. Recent research has indicated that there may be additional causes of RDS, particularly in near-term and term newborns, in addition to pulmonary surfactant insufficiency. In order to determine if exogenous surfactant replacement therapy is helpful for all neonates with RDS, the primary goals of this study were to examine the therapeutic effects of pulmonary surfactant in infants of various gestational ages.

MATERIALS AND METHODS

In the Dr. Vikhe Patil Medical College's newborn intensive care unit (NICU), Ahmednagar, Maharashtra, a prospective study was done. Ninety neonates with RDS were enlisted throughout the course of the previous year [June 2021 to June 2022]. Both in-born and out-born newborns delivered at nearby district hospitals, primary health facilities, and rural health centres are referred to the our NICU. According to a study done by Kumar A et al [2], 4.2% of newborns have respiratory distress syndrome. We discovered that the minimum sample size is 82 taking into account this with a 95% confidence interval and a 3.5% absolute error. We finalized a sample size of 90 after we took into account a 10% attrition rate.

RDS was identified based on clinical symptoms and results from a chest X-ray [15, 16]. Respiratory distress, tachypnea, nasal flaring, moaning, and cyanosis after birth were the clinical signs and symptoms of RDS. The normal X-ray image of RDS displayed a white set of lungs, an air bronchogram, and a grainy shadow. The lung's transparency decreased slightly in Grade 1 but there was no discernible deviation from normal findings. In grade 2, an air bronchogram that overlaps the heart was used, which resulted in a minor loss of transparency. Graduation entailed a slightly stronger loss of transparency, along with a hazy heart and diaphragm. Practically homogenic lung opacity was present in grade four. Two radiologists who were unaware of the patient's situation evaluated the X-ray photos. Any congenital malformation, genetic metabolic disorder, intrauterine infection, Rh/Rh incompatibility, pneumonia, pulmonary hypertension, meconium aspiration syndrome, or suffocation were disqualifying conditions for infants. All of the newborns' clinical features were noted.

Ninety babies with RDS who met the requirements for inclusion were treated according to the NICU's established protocols in the traditional way. Group 1, gestational age 35 weeks (n=30); Group 2, 35 weeks to gestational age 37 weeks (n=30); Group 3, gestational age 37 weeks (n=30) were the three categories into which the individuals were divided.

Different principal types of ventilation were offered to the individuals depending on the severity of RDS. Surfactant was administered as soon as practically practicable to all newborns with RDS (within 24 h after birth). Porcine surfactant doses of 200 mg/kg were used as the main treatment, and doses of 100 mg/kg were given in situations where multiple treatments were necessary. Each dose was divided into 4 quarter doses, and each quarter dose was given with the baby in a different position to ensure uniform dispersion of the surfactant throughout the lungs.

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Statistical analysis plan

The data was collected, compiled, and analyzed using EPI info (version 7.2). The qualitative variables were expressed in terms of percentages. The quantitative variables were both categorized and expressed in terms of percentages or in terms of mean and standard deviations. The difference between the two proportions was analyzed using chi-square or Fisher exact test. Normality of Quantative data was tested using kolmogorov smirnov test. To test the difference of means of normal data student t test were used. All analysis was 2 tailed and the significance level was set at 0.05.

RESULTS

We have included 90 babies in the present study.

Table 1: Clinical characteristics of the present sample

Clinical characteristics	Group 1 (n=30)		Group 2 (n=30)		Group 3 (n=30)		P value
	Number/ Mean	%/SD	Number/ Mean	%/SD	Number/ Mean	%/SD	
Birth weight	1.65	0.33	2.21	0.52	2.98	0.51	<0.001
Male	16	53.33	17	56.67	16	53.33	0.7821
Caesarean section	11	36.67	14	46.67	21	70.00	0.0012
Apgar score at 5 minutes	9.22	1.11	9.55	0.80	9.55	0.77	0.3342

The mean birth weight among group 1, group 2 and group 3 was respectively 1.65kg, 2.21kg and 2.98 kg and this difference was statistically significant. The proportion of C section was higher among the Group 3 when compared to Group 2 and Group 1 in the present study. There was a statistically significant difference between the three groups.

Table 2: Distribution based on the severity of RDS

Severity of RDS	Group 1 (n=30)		Group 2 (n=30)		Group 3 (n=30)		P value
	Number	%	Number	%	Number	%	
RDS 1st and 2nd	17	56.67	18	60.00	18	60.00	0.4563
RDS 3rd and 4th	13	43.33	12	40.00	12	40.00	

The Severity of RDS among the three groups was comparable. (p>0.05)

Table 3: Oxygenation function parameters before and after surfactant therapy in group 1

Oxygenation parameters	Before		After		P value
	Mean	SD	Mean	SD	
Group 1					
Fio2	46.52	12.14	40.22	12.22	0.0201
OI	7.12	2.48	6.46	3.61	0.2231
Pao2/PAO2	0.26	0.12	0.42	0.22	<0.001
Group 2					
Fio2	41.14	13.30	51.63	24.08	0.0018
OI	5.16	2.41	8.70	4.13	0.0067
Pao2/PAO2	0.26	0.12	0.30	0.22	0.3552
Group 3					
Fio2	42.23	12.56	48.47	17.14	<0.001
OI	6.50	3.64	11.51	8.81	<0.001
Pao2/PAO2	0.36	0.14	0.28	0.25	0.782

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Before surfactant administration, there was no significant change in FiO2 between the three groups (P>0.05), but there was a difference following surfactant therapy (P0.05). Following the administration of the surfactant, group 1 had significantly reduced FiO2 while groups 2 and 3 had significantly greater FiO2 (P 0.05). When it came to oxygen index (OI), the difference between the three groups six hours after surfactant administration was significant (P 0.05), but it was not significant before surfactant therapy. After therapy, group 1 showed no significant difference (P>0.05), however groups 2 and 3 showed significantly higher OI values (P0.05). Similar to the previous example, PaO2/PAO2 did not differ significantly in any of the three groups prior to surfactant therapy (P>0.05), but did so following it (P0.05); PaO2/PAO2 considerably improved in group 1 (P0.05), but not in groups 2 or 3 (P>0.05).

Table 4: Distribution based on therapeutic outcomes

Therapeutic outcomes	Group 1 (=30)		Group 2 (n=30)		Group 3 (n=30)		P value
	Number	%	Number	%	Number	%	
Endotracheal intubation	16	53.33	17	56.67	17	56.67	0.6672
Mechanical ventilation	12	40.00	10	33.33	12	40.00	0.7722
Survival rate (%)	86		86		90		0.1222
Hospitalization day	12.33 ±2.23		8.22 ±1.21		8.66 ±1.22		<0.001
Repeated surfactant rate	6	20	7	23.33	8	26.67	0.0781

There was no significant difference between in the three groups with respect to endotracheal intubation, mechanical ventilation rates, survival rates and repeated surfactant rate. But, there was a significant difference in the hospitalization days among the three groups. (p<0.001)

DISCUSSION

The most common clinical issue affecting preterm newborns is RDS. It is well recognised that pulmonary surfactant deficiencies or malfunction lead to RDS in premature infants. The ability of surfactants to reduce surface tension as well as their quick adsorption and spreading capabilities, which are connected to the respiratory cycle, are among their physiological activities. However, in some infants, especially those who are near-term and term, death is unavoidable despite intensive care and surfactant replacement therapy. The prevalence of RDS in near-term and term newborns has recently received attention, and an increasing number of studies have hypothesised that the clinical presentation in these infants may differ from that seen in very preterm infants. There haven't been any studies done yet that compare the effectiveness of surfactant replacement therapy in infants born at various gestational ages. The goal of the current study was to find out if the effects of surfactant replacement therapy in newborns of various gestational ages varied.

There are other risk factors for the development of RDS besides pulmonary surfactant deficiency and anatomical immaturity of the lungs that have been described. According to research by Gerten et al., infants born by caesarean section, particularly those without established labour, had a higher risk of RDS than newborns delivered vaginally at any given gestational age. The delayed evacuation of lung fluid and the absence of the cortisol response linked to spontaneous labour are most likely the causes of the higher risk of respiratory morbidity. Our findings show that all groups had a somewhat high caesarean section rate. Therefore, the delayed evacuation of lung fluid and absence of cortisol response were crucial factors in the development of RDS in the near-term and term infants. This was likely due to the high proportion of caesarean sections performed without labour.

The research that is now available indicates that pulmonary surfactant deficit is not the primary cause of RDS in term and near-term newborns. These newborns' respiratory distress is caused by pneumonia, pulmonary hypertension, and transient tachypnea of the newborn (TTN), among other things. Surfactant therapy is not the main form of treatment for the majority of the infants in this particular group of patients. In

a study by Sun H et al., the arterial oxygenation efficiency gradually increased (P 0.001) and the oxygenation index value was not significantly lower in late preterm and term infants compared to very preterm newborns. The conclusions of the current investigation are highly supported by these data. While no difference was seen in the near-term and term groups, there was a considerable rise in pH in the preterm group six hours after surfactant therapy in the current trial. Preterm infants had significantly greater PaO2 at six hours following surfactant administration, while term newborns had significantly lower PaO2; there was no discernible difference in PaO2 in near-term infants. Between 2005 and 2009, Ricou AB et al. carried out a retrospective cohort analysis. One hundred eighty-eight near-term children after elective CS were separated into two groups: group A: 125 late preterm infants (34(0/7)-36(6/7)) and group B: 63 just term newborns (37(0/7)-37(6/7)). CS following pre-mature membrane rupture and foetuses with congenital deformity were excluded. The total incidence of RDS in group A was 44% (n = 55) compared to 15.9% (n = 10) in group B (p 0.01). RDS is defined as requiring respiratory support or oxygen therapy at or shortly after birth. The prevalence of SRDS, which required admission to the NICU, was 13.6% (n = 17) in group A and 3.2% (n = 2) in group B (p 0.01).

CONCLUSION

Due to its retrospective design, this study has certain restrictions. Newborns who refused surfactant therapy were excluded, and patient inclusion was based on the requirement for surfactant therapy in infants with RDS. As a result, not all newborns with RDS were included in the patient group, and the findings do not accurately represent all RDS patients.

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