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A Comparison between the Two Surfactants, Beracsurf and Curosurf, in the Treatment of Respiratory Distress Syndrome (RDS) in Premature Infants

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ABSTRACT

Background: Respiratory distress syndrome (RDS) in premature infants results from surfactant deficiency. Given the high cost and limited availability of Curosurf, we compared its outcomes with the Iranian surfactant Beracsurf.

Methods: This descriptive cross-sectional study included premature infants (≤34 weeks) with RDS who met surfactant criteria. We assessed hospitalization duration, mechanical ventilation time, delivery mode, CPAP duration, Apgar score, gestational age, and clinical outcomes (discharge/mortality). Complications (pneumothorax, pulmonary/intraventricular hemorrhage, BPD, ROP, NEC), surfactant redosing frequency, and time to FiO_2<40% were compared between groups.

Results: A total of 80 infants were divided into two equal groups (40 each). Baseline demographics were similar (P>0.05). Beracsurf recipients required significantly longer mechanical ventilation (3.25 vs. 2.22 days, P=0.01) and CPAP (3.05 vs. 2.41 days, P=0.04) than Curosurf recipients. No significant differences were observed in other complications, hospitalization duration, or mortality.

Conclusion: Curosurf provided significantly shorter durations of respiratory support compared to Beracsurf. Other outcomes and complication rates were comparable. Further large-scale studies are warranted to guide clinical and economic decisions.

Introduction

Respiratory distress syndrome (RDS) in neonates is defined as pulmonary failure in premature infants caused by inadequate surfactant production[1]. It represents a frequent cause of morbidity and mortality among preterm infants and typically manifests within the first few hours after birth[1]. Major risk factors associated with RDS include lower gestational age and reduced birth weight. Common complications arising from RDS and surfactant deficiency include septicemia, bronchopulmonary dysplasia (BPD), patent ductus arteriosus (PDA), pulmonary hemorrhage, apnea, hypertensive disorders, growth failure, intraventricular hemorrhage (IVH), and periventricular leukomalacia. Surfactant depletion leads to atelectasis, decreased functional residual capacity, and ventilation-perfusion mismatch, all of which contribute to hypoxemia. Approximately 35% of premature infants develop RDS, making it a major contributor to adverse outcomes in the population. Prematurity stands out as the most common risk factor, especially in relation to white ethnicity, male gender, maternal diabetes, cesarean section, chorioamnionitis, low birth weight, birth asphyxia, lung infections, and meconium aspiration syndrome[1-3].

Notably, antenatal steroids and prophylactic surfactant therapy have played a pivotal role in significantly reducing the incidence of various complications associated with prematurity, such as RDS and mortality. Intratracheal surfactant administration in preterm infants with RDS has emerged as an important intervention that effectively reduces mortality and morbidity in these infants[4]. Under normal condition, surfactant appears in the amniotic fluid from the 28th week of gestation, and its production depends on normal pH levels, temperature, and tissue perfusion. Some conditions such as asphyxia, hypoxia, and ischemia, especially with hypovolemia, hypotension, and cold stress, lead to suppression of surfactant production. Given these complications, studies have concluded that surfactant replacement therapy is a necessity[5-6].

Three types of surfactants are used on the market: animal-derived surfactants, synthetic protein-poor surfactants, and synthetic protein-containing surfactants[7-8]. A considerable number of investigations have assessed the therapeutic efficacy of both natural and synthetic surfactants in the management of RDS. Surfactant replacement therapy has been shown to significantly reduce neonatal mortality and lead to improvement in symptoms, although there were some complications such as hypoxia, bradycardia, and the risk of pulmonary hemorrhage. To address these concerns, multiple surfactant formulations have been developed, including natural types such as Infasurf, Curosurf, and Survanta, and synthetic types such as Surfaxin. These surfactants are expensive and not available to everyone, especially in countries like Iran. Accordingly, an effective surfactant with lower cost and greater availability is necessary. The first Iranian surfactant, Beracsurf, was developed with the active pharmaceutical ingredient Survanta. However, the effect of this surfactant on the treatment of RDS and its complications is not exactly known[6]. Given the clinical significance of RDS and the importance of prophylactic surfactant therapy, it provides valuable clinical insights. These interventions have been shown to have a significant impact on reducing complications related to prematurity, including RDS and mortality. Consequently, given the high cost and unavailability of Curosurf, we designed the study to be able to make a practical comparison between these two drugs.

Materials and Methods

This descriptive cross-sectional study received approval from the ethics committee, and all subsequent ethical guidelines were rigorously adhered to throughout the research process. The study population comprised all premature infants (gestational age 34 weeks and less) presenting with respiratory distress who met

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the established criteria for surfactant administration. Infants with congenital pulmonary anomalies, infants with respiratory failure due to reasons other than RDS, lung hypoplasia, Apgar score <3 at 10 minutes, surfactant administration before hospital admission, prolonged rupture of membranes (>18 hours), use of high-frequency ventilation (HFV) before the first dose of surfactant, and sepsis were excluded from the study.

For all patients meeting the inclusion and exclusion criteria, demographic data, including age and gender were systematically collected. A standardized checklist was then used to compare the duration of hospitalization, duration of ventilator, mode of delivery, duration of CPAP therapy, neonatal Apgar score at birth, gestational age, and patient outcome (discharge or death).

After obtaining the ethics approval code, the researchers extracted the necessary information from the patients' clinical records by referring to the hospital's information archive. Demographic information, including age, and gender, were collected and a structured checklist was created that included information on the duration of hospitalization, duration of ventilator, mode of delivery, duration of CPAP, neonatal Apgar score, gestational age of the patient, and patient outcome in terms of discharge or death, complications including pneumothorax, pulmonary hemorrhage, ventricular hemorrhage, bronchopulmonary dysplasia, retinopathy of prematurity, and necrotizing enterocolitis, and the number of times surfactant was administered and the time required to achieve Fio2 below 40% for each patient was compared according to the medication received. Both groups received the drug within the first 6 hours of birth, and the two groups were matched for weight, sex, and gestational age.

The Ethical procedures were fully carried out following approval by the institutional ethics committee. In order to address ethical concerns, the purpose of the study was explained to the participants. The participants were also free to participate or withdraw from the study, and the confidentiality of the information was respected.

Data analysis was conducted using SPSS v26 (version 26, IBM Corporation, Armonk, NY). Quantitative variables such as gestational age and birth weight were described using means and standard deviations. Initially, baseline characteristics, including maternal gestational age, mode of delivery, child gender, and child birth weight were compared between the two groups using chi-square and t-test statistical tests. Subsequently, outcome variables such as ventilator duration, length of hospitalization, and CPAP duration were analyzed using t-test, and group differences for categorical outcomes were analyzed using chi-square test.

Results

In present study, 80 infants were divided in two groups of 40. Background and clinical information of all infants is shown in Table 1.

Analysis of demographic and perinatal variables revealed no statistically significant differences between the two groups with respect to gender distribution, mode of delivery, infant feeding method, gestational age, neonatal birth weight, Apgar score, and manner of drug administration (Table 2).

There was also no significant difference between the two groups in the duration of hospitalization, the occurrence of complications related to the disease (pneumothorax, IVH, BPD, pulmonary hemorrhage, retinopathy of prematurity, necrotizing enterocolitis) and the end of the patients (Table 3).

The mean need for ventilator in the patients who had received Beracsurf and Curosurf was 3.25 and 2.22 days, respectively (P = 0.01). The mean duration of time required for CPAP in the Beracsurf and Curosurf groups was also significantly different (P = 0.04) as it was 3.05 and 2.41 days in patients who had received Beracsurf and Curosurf, respectively (Table 4).

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Table 1. Background and Clinical Characteristics of the Studied Infants

Study Variables		Frequency	
		Number	Percent
Gender	Girl	37	46.3
	Boy	43	53.8
Mode of Delivery	Vaginal Delivery	39	48.8
	Cesarean Section	41	51.2
Infant Feeding Type	Breast Milk	58	72.5
	Formula Milk	22	27.5
Gestational Age (weeks)	24-29	29	36.3
	30-34	51	63.7
Birth Weight (Kg)	< 1	29	36.3
	1-2	38	47.5
	> 2	13	16.3
Apgar Score	≤ 8	29	36.3
	> 8	51	63.7
Need to repeat drug delivery Need for redosing	Getting medication on the first day	61	76.3
	Getting medication on days except the first day	10	12.5
	Drug delivery on day 1 and other days	9	11.2

Table 2. A Comparison of the Demographic and Clinical Characteristics of the Newborns under Study in both Groups of Curosurf and Beracsurf

Study Variables		Curosurf Number (%)	Beracsurf Number (%)	P-value
Gender	Girl	19 (47.5)	18 (45)	0.82
	Boy	21(52.5)	22 (55)	
Mode of Delivery	Vaginal Delivery	19 (47.5)	20 (50)	0.82
	Cesarean Section	21 (52.5)	20 (50)	
Infant Feeding Type	Breast Milk	30 (75)	28 (70)	0.61
	Formula Milk	10 (25)	12 (30)	
Gestational Age (weeks)	24-29	13 (32.5)	16 (40)	0.48
	30-34	27 (67.5)	24 (60)	
Birth Weight (Kg)	< 1	13 (32.5)	16 (40)	0.60
	1-2	19 (47.5)	19 (47.5)	
	> 2	8 (20)	5 (12.5)	
Apgar Score	≤ 8	13 (32.5)	16 (40)	0.48
	> 8	27 (67.5)	24 (60)	
Need to repeat drug delivery Need for redosing	getting medication on the first day	31 (77.5)	30 (75)	0.93
	getting medication on days except the first day	5 (12.5)	5 (12.5)	
	drug delivery on day 1 and other days	4 (10)	5 (12.5)	
Duration of hospitalization (days)	1-10	22 (55)	20 (50)	0.65
	> 11	18 (45)	20 (50)	

Chi-square and Fisher's exact test

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Table 3. Analysis and Comparison of the Duration of Hospitalization, Occurrence of Complications Related to the Disease, and the Outcome of the Patients in both Groups of Curosurf and Beracsurf

Study Variables		Curosurf Number (%)	Beracsurf Number (%)	P
Duration of hospitalization	1-10	22 (55.0)	20 (50.0)	0.65
	> 11	18 (45.0)	20 (50.0)	
Pneumothorax	No	39 (97.5)	37 (92.5)	0.30
	Yes	1 (2.5)	3 (7.5)	
IVH	No	40 (100.0)	39 (97.5)	0.31
	Yes	0	1 (2.5)	
BPD	No	38 (95.0)	36 (90.0)	0.39
	Yes	2 (5.0)	4 (10.0)	
Pulmonary hemorrhage	No	37 (92.5)	36 (90.0)	0.69
	Yes	3 (7.5)	4 (10.0)	
Retinopathy of prematurity	No	40 (100.0)	38 (95.0)	0.15
	Yes	0	2 (5.0)	
Necrotizing enterocolitis	No	39 (97.5)	37 (92.5)	0.30
	Yes	1 (2.5)	3 (7.5)	
Outcome of the patients	Alive	38 (95.0)	34 (85.0)	0.13
	Dead	2 (5.0)	6 (15.0)	

Table 4. Analysis and Comparison of the Mean Duration of Time Required for Ventilator and CPAP in both groups of Curosurf and Beracsurf

Study Variables	Curosurf Mean±SD	Beracsurf Mean±SD	P
Mean Duration of Time Required for Ventilator	2.22 ± 1.25	3.25 ± 2.21	0.01
Mean Duration of Time Required for CPAP	2.41 ± 1.60	3.05 ± 1.90	0.04

Mann Whitney, T test

Discussion

Four types of surfactants in the market are used to treat RDS in neonates. Numerous studies have evaluated natural and artificial surfactants, showing that surfactant therapy reduces infant mortality and improves clinical outcomes. Due to the importance of the disease and its complications and the importance of surfactant preventive treatment, this study investigated the effect of two types of surfactant. In present study, the effect of Beracsurf and Curosurf in the treatment of RDS of preterm infants was evaluated. The patients were divided into two groups of 40, who received Beracsurf and Curosurf and were studied in terms of clinical and outcome changes. There was no significant difference between the two groups in terms of gender, type of delivery, mode of delivery, gestational age, birth weight, Apgar score, and manner of drug delivery, indicating that both groups were almost identical in such factors. The hospitalization duration was lower in patients with Curosurf but this finding was not statistically significant. Furthermore, the occurrence of complications related to the disease including pneumothorax, IVH, BPD, pulmonary hemorrhage, retinopathy of prematurity and necrotizing enterocolitis in patients with Beracsurf was not significantly different from those who received Curosurf. Mean duration of time required for ventilator and CPAP were significantly lower in Curosurf group.

There was no significant difference between IVH complications in patients who received Beracsurf and the patients with Curosurf. In a study by Najib et al., 2025, IVH complication was lower in patients with Beracsurf, but this difference was not significant[9]. This was consistent with the results of a study by Nourollahi, et al., 2022,

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on 40 patients[10]. In a study by Yalaz, et al., IVH was found lower in recipients of Beracsurf, but this difference was not significant[11]. Therefore, it seems that further studies are needed to evaluate the effect of Beracsurf compared with Curosurf on IVH complication.

In the present study, patients who received Curosurf had statistically significantly less need for mechanical ventilation compared with the patients who received Beracsurf. Their hospitalization duration was also less than the patients who received Beracsurf; however, the difference was not statistically significant. Inconsistently, in a study carried out by Barouits et al., the duration of ventilator-required time and hospital stay was less in patients with Beracsurf[12]. There was no statistically difference between the two groups' need for ventilator at Nourollahi's study[10]. In another study, which Mostafa Gharehbaghi, et al. carried out on 20 patients, it was shown that the duration of hospitalization in the hospital was significantly lower in patients with Beracsurf[13].

Pneumothorax complication was less frequent in patients with Curosurf but this difference was not statistically significant. In the study by Nourollahi, et al., none of the patients who received Beracsurf had pneumothorax, but in 7.5% of the patients receiving Curosurf, pneumothorax had occurred. However, this difference was not statistically significant[10]. Inconsistently, in a study by Najafian et al., on 112 patients with RDS, pneumothorax incidence was higher in neonates who had received Survanta. Though, the difference was not statistically significant[14].

Pulmonary hemorrhage occurred less frequently in the Curosurf group compared with the Beracsurf group in the present study. Unlike the result of present study, in a study conducted by Mousavi et al. on 165 infants in Iran, pulmonary hemorrhage was occurred higher in the patients who received Curosurf[15]. Similar to the present study, in a study by Yalaz, et al. pulmonary hemorrhage was occurred lower in the patients who received Curosurf. In neither study was the difference significant[11].

Mortality rate in patients with Curosurf was lower than those who received Beracsurf but this difference was not statistically significant. In a large multicenter randomized controlled trial, Ramanathan, et al. reported a trend toward lower mortality in the Curosurf group compared to the Survanta group at both 28 days and 1 year of age; however, this difference was not statistically significant[16]. In the study of Mussavi, et al., mortality in patients with Curosurf was lower, but this difference was not statistically significant[15]. In Najafian's study, mortality was higher in children who received Survanta but this difference was not significant[14]. In Mostafa Gharehbaghi's study, unlike the present study, the mortality rate was insignificantly lower in the Beracsurf groups[13].

Study Limitations

The present study has several limitations that should be acknowledged. First, the sample size of 80 infants (40 per group) may have limited the statistical power to detect significant differences in uncommon complications such as IVH, pneumothorax, and mortality. Second, the study was conducted at a single center, which may limit the generalizability of the findings. Third, the descriptive cross-sectional design, while appropriate for the study objectives, does not allow for causal inferences. Future multicenter studies with larger sample sizes and longer follow-up periods are recommended to further evaluate the comparative efficacy and safety of these surfactants.

Conclusion

In the present study, Curosurf was associated with significantly shorter durations of mechanical ventilation and CPAP support compared to Beracsurf. No significant differences were observed in other complications or mortality between the two groups. While some previous studies have

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suggested that Beracsurf may have comparable or even superior efficacy, our findings demonstrate a clear advantage for Curosurf in reducing the need for respiratory support. The discrepancy between our results and those of previous studies may be attributed to differences in patient populations, dosing protocols, or supportive care practices. Given the clinical and economic importance of surfactant selection, further large-scale, multicenter randomized controlled trials are needed to confirm these findings and guide clinical practice.

Conflict of Interest

The authors declare no conflict of interest.

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Ethical Considerations

The research protocol was thoroughly evaluated and approved by the ethics committee at Shahid Sadoughi University of Yazd (IR.SSU.MEDICINE.REC.1402.410).

Author's Contribution

Conceptualization and project administration: Z.F, and M.H.L; collecting the data, Z.F; writing the original draft: M.S.A; Supervision, and editing the manuscript: Z.F, M.H.L, S.R.M, M.N, and M.S.A; Formal analysis, and Methodology: M.V. All authors have read and approved the final manuscript.

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