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Comparison of side effect of survanta and curosurf in decreasing mortality due to respiratory distress syndrome (RDS) in premature infants admitted in NICU of Ghaem Hospital On 2006-2008

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ABSTRACT

Background: Using of natural and synthetic surfactant is a rescue treatment for respiratory distress syndrome. In Iran, Survanta and Curosurf are the most frequent used natural surfactant preparations. We compared the clinical response and safety of two surfactants poractant alpha (Curosurf) and beractant (Survanta) for treatment of respiratory distress syndrome (RDS) in preterm infants.

Methods: This study was a clinical trial study that performed during a 2-year period in Ghaem Center's neonatal care unit.Sample size was calculated with 95% confidence and power 80. 104 premature infants were treated with surfactant, 74 in survanta group and 30 in Curosurf group,. The differences between the two groups were assessed by ANOVA or the calculation of relative risks.

Results: There were no statistically significant differences between infants treated with S and C in mean gestational age (30.58 vs. 29.00 weeks) and birth weight (1388 vs.1330 g). Also there was no significant difference between groups, incidence at 28th day of Bronchopulmunary dysplasia (%40.5 vs. %40), Intra ventricular hemorrhage III.IV (%13.5 vs. % 13.3), pneumothorax (%20 vs. % 20), Patent ductus arteriosis (%28.3 vs. % 20), and death (%28 vs. % 26.6).

Conclusion: This study concluded that Survanta and Curosurf are similar in treatment of neonatal respiratory distress syndrome.

Keywords: Neonates, Respiratory distress syndrome, Surfactant.

Introduction

Preterm birth is an important problem in developed and developing countries.

In the USA, the preterm delivery rate is 12–13% and in Europe and other developed countries, its rate reported between 5 and 9% (1). Prematurity is one of the major causes of infant mortality rate that was 34.3% of all infant deaths in 2002 (2).

Respiratory distress syndrome (RDS) occurs in about 50% of preterm infants who born at 30 weeks of gestation (3). The major mechanism is decreased surfactant secretion by the pneumocytes (4, 5).

Surfactant therapy is the standard treatment in preterm infants with respiratory distress syndrome (RDS) (4).

In a clinical trial comparing beractant and poractant alpha, Speer et al showed a significant increase in oxygenation, and a decrease in peak inspiratory pressure and MAP, which persisted up to 24 h after poractant alpha (6). They reported no significant differences in mortality or BPD between beractant and poractant alpha (6).

Ramanathan et al compared poractant alpha with beractant(4).Treatment with poractant alpha was associated with faster improve oxygenation, fewer additional doses, and decreased mortality in preterm infants <32 weeks gestation when compared with beractant (P<0.05). In a meta-analysis of the two studies comparing beractant and poractant alpha, neonatal mortality was significantly lower with poractant alpha (4).

In this study, We designed a clinical trial to compare the effects of the survanta(Beractant)and

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Curosurf (proctant alpha).

Material and Method

This study was a Clinical trial study that performed during a 2 years period in neonatal ward of Ghaem Hospital. All cases visited by attending professors of neonatology for indication of surfactant therapy.

Including criteria was Gestational age<37 weeks, RDS according to CXR, ABG (Arterial blood gas) and clinical signs and symptoms. Neonates with meconium aspiration syndrome, major abnormalities, lethal disorder, metabolic disease, sepsis or another confirmed infections and neonates with history of resuscitation in delivery room, exclude from study.

Gestational age, birth weight, gender, delivery type, APGAR 1th and 5th minutes were recorded from file. Samples divided randomly in two groups: Survanta and curusorf group. Each group divided into sub-groups according to gestational age and birth weight to make results more accurate. We fallowed the patients and recorded complications such as BPD (dependence to oxygen at 28th day), NEC (necrosis entrocolitis), PDA, IVH grade 3, 4 and pulmonary hemorrhage. Sample size was calculated with 95% confidence and power 80, 104 premature infants were treated with surfactant, 74 in survanta group and 30 in Curosurf group.

We injected 100mg.kg of each drugs into distal of trachea. All paitients received two times surfactant therapy and the first time was in the first day of birth.

Traceal suction was not performed for at least 2 hr after injection. Patiens were monitored with pulse oxymetry and ABG and frequent examination. The differences between the patient groups were assessed by ANOVA or the calculation of relative risks.

Results

10 neonates were excluded from this study after treatment 104 neonates completed this study, 74 neonates treated with survanta and 30 neonates treated with curusorf. Mean of gestational age in surfactant group was 3o.58 ± 2.11 and in curusorf group was 28 ± 2.25 week, that showed no statistical difference between 2 groups (p=0.7).

Mean of birth weight was 1340gr in survanta group and 1410gr in curusorf group, there was no statistical difference between 2 groups (p=0.51) (Table-1).

At 28th day incidence of BPD was %40.5 in survanta group and %40 in curusorf group. There was no significant difference between groups (p=0.56), incidence of IVH was %13.5 in survanta group and %13.3 in curusorf group. There was no significant difference between groups (p=0.76).

Incidence of pneumothorax was %20 in survanta group and %20 in curusorf group, There was no significant difference between groups (p=0.63).

Incidence of PDA was %28.3 in survanta group and %20 in curusorf group. There was no significant difference between groups (p=0.63). Incidence of death was %28 in survanta group and %26.6 in curusorf group, There was no significant difference between groups (p=0.5).

Incidence of NEC was %8.2 in survanta group and %10 in curusorf group.There was no significant difference between groups (p=0.01).

The mean hospitalization time was 12.9 days in survanta group and 17.8 days in curusorf group, there was no statistical difference between 2 groups(p=0.71). The mean ventilation duration was 13.4 days in survanta group and 9.9 days in curusorf group, there was no statistical difference between 2 groups(p=0.71).

There was no significant difference between <28 weeks and > 28 weeks groups (p=0.3) (Table.3).

Discussion

In present study there were no statistically significant differences between infants treated with Survanta and Curusorf in mean gestational age (30.58 vs. 29.00 weeks), birth weight (1388 vs.1330 g) There was no significant difference between groups, or in incidence at 28th day of BPD (%40.5 vs. %40), IVH III.IV (%13.5 vs. % 13.3), pneumothorax (%20 vs. % 20), PDA (%28.3 vs. % 20), and death (%28 vs. % 26.6).

Baroutis et al compared natural bovine surfactant and beractant and poractant alpha. They demonstrated that treatment with poractant alpha resulted in

Significantly less days need to ventilation and supplemental oxygen, and shorter length of hospitalization (7)

Ramanathan et al compared poractant alpha with beractant in a multicenter, randomized, controlled trial in the United States. Treatment with poractant alpha was associated with faster improving oxygenation, fewer additional doses, and decreased mortality in preterm infants <32 weeks gestation when compared with beractant. 36% of infants randomized to poractant alpha

received two or more doses vs. 68% in the beractant treated group (P<0.05) (4).

In a meta-analysis of the two studies comparing beractant and poractant alpha, neonatal mortality was significantly lower with poractant alpha (6, 7). In a recent study comparing these two surfactants, Malloy et al extended the observations of Ramanathan et al. They showed increase in oxygenation to persist up to 48 h after treatment with poractant alpha, and a significantly lower number of additional doses with poractant alpha compared to beractant (4, 8)

In a pharmacoeconomic analysis of poractant alpha vs beractant using the data from two randomized studies, Marsh et al showed a 20–53% reduction in cost with curusorf vs survanta (9).

Conclusion

This study shows that efficacy and complications of Survanta and Curosurf is equall in treatment of RDs.

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Table1. Gestational age,Birth weight,Sex,Delivery type and APGAR in Survanta and Curusorf groups

	Survanta (N:74)	Curosurf (N:30)	P- Value
Week)(Gestation	30.58	28	**0.7**
(gr) Birth weight	1340	1410	**0.3**
Male	31(41%)	12(40%)	**0.8**
Cesarean	48(64%)	18(60%)	
5 < Apgar 1 min	20(27%)	14(46%)	
5 < Apgar 5 min	8(10%)	6(20%)	

Table2. Complications in Survanta and Curusorf group

	Survanta N=74	**Curosurf N=30**	**P-Value**
NEC	8.2% (N:6)	10% (N:2)	**0.22**
Death	28% (N:21)	26.6%(N:8)	**0.5**
PDA	28.3%(N:21)	20%(N:6)	**0.63**
IVH	13.5%(N:10)	13.3%(N:4)	**0.76**
Pnemothorax	20%(N:15)	20%(N:6)	**0.63**
Hospitalization duration	12.9d	17.8d	**0.71**
Ventilation duration	**13.4d**	**9.9d**	**0.74**

Table3. Frequency of death in 2 subgroups according to birth weight

Death in 2 groups	<1000	1000-2000	1500-2500	Total
Curusorf	0	4	4	**8**
	0	42.9%	2.%18	**26.6%**
Survanta	2	8	11	**21**
	5.5%	**20.4%**	**16.2%**	**28%**