Surfactant Administration via Thin Catheter during Spontaneous Breathing: Randomized Controlled Trial in Alzahra hospital

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Abstract

Introduction

Respiratory distress syndrome (RDS) is a current cause of morbidity in premature infants resulted from surfactant deficiency. The primary aim of this randomized study was to describe the feasibility of early administration of surfactant via a thin catheter during spontaneous breathing (TEC) and compare its outcomes with the InSurE (Intubate, Surfactant, Extubate) procedure

Materials and Methods

Premature infants with RDS, who were ≤ 32 weeks old and stabilized with nasal continuous positive airway pressure (nCPAP), were randomized to receive surfactant either by the TEC or InSurE technique. Tracheal instillation of 200 mg/kg Curosorf via 5-F catheter during spontaneous breathing under nCPAP was performed in the intervention group (n=38). In the InSurE group (n=40), infants were intubated, received positive pressure ventilation for 30 seconds after surfactant instillation, and placed on nCPAP immediately

Results

Necrotizing enterocolitis rate was significantly lower in TEC group, than InSurE group, [p<0.02, RR=0.49, CI=%95(0.39_0.62)]. But rate of other morbidities did not significant difference between two groups. Although Mechanical ventilation duration did not significant different between two groups (p=0.2), but Total CPAP duration was shorter in TEC group, significantly [P<0.01, RR=8.2, CI=%95 (-37.9_-4.8)]. Need for O2 supplement and mean of total hospital duration was also lower in TEC group, but was not significant, statistically

Conclusion

The TEC technique is feasible for the treatment of respiratory distress syndrome in infants with very low birth weight and decreases total nCPAP duration, significantly. But Judgment of substitution TEC instead of InSurE as a routine technique need to more studies.

Key words

RDS, Surfactant, InSurE, Thin Endotracheal Catheterization

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Introduction

Prematurity remains a leading cause of neonatal morbidity and mortality worldwide, accounting for 60% to 80% of deaths of infants without congenital anomalies. As the risk of neonatal mortality and morbidity near term is low, great attention has been focused on early preterm birth (23 to 32 weeks gestation). Neonatal morbidities that result from prematurity remain a significant clinical problem. These morbidities include RDS, intraventricular hemorrhage, periventricular leukomalacia, necrotizing enterocolitis, bronchopulmonary dysplasia, sepsis, patent ductus arteriosus, jaundice, and growth failure, cerebral palsy, disorders of cognition and retinopathy of prematurity.

The risk for these morbidities is directly related to the delivery gestational age and birth weight(1).

RDS is a current cause of morbidity in premature infants resulted from surfactant deficiency. With reducing gestational age, prevalence of RDS increases. The use of CPAP has proved to be a very simple intervention to support the infant in respiratory distress. CPAP technique is simple and cost-effective, and can be used in developing countries. Premature infants who do not respond to nasal CPAP require intubation and ventilator support. Providing ventilator support requires skilled nursing and support staff and laboratory facilities. Surfactant therapy is known to shorten the time needed for assisted ventilation. The studies show that endotracheal surfactant, followed by nasal CPAP, in established cases of RDS can be used effectively. The real goal should be to consider preventive antenatal measures and newer treatment modalities that are less expensive, such as antenatal steroids in preterm labor, implementation of delivery room neonatal resuscitation, early use of CPAP, and other new procedures (1-7).

Because of some concerns about morbidities of the routine procedure of surfactant therapy; *INtubation SURfactant Extubation* (InSurE), new techniques have been suggested. Some studies show administration of surfactant via a thin catheter during spontaneous breathing (TEC) can reduce the need for assisted ventilation and some morbidity (8-11). This randomized clinical trial was carried out to describe the feasibility of administration of surfactant via a thin catheter during spontaneous breathing (TEC) and compare its outcomes with the InSurE technique in alzahra hospital as a level III tertiary care unit of Tabriz city.

Material and Methods

Following the permission of ethics committee of Tabriz University of medical sciences, this randomized clinical trial was done in Alzahra hospital from February 2010 up to November 2012. Preterm infants who were <32 weeks and hospitalized in Neonatal Intensive Care Unit with diagnosis of respiratory distress syndrome and stabilized with nasal continuous positive airway pressure (nCPAP), were randomly selected to receive surfactant treatment either via a thin catheter during spontaneous breathing (TEC) or InSurE technique, in infants needed Fio2≥30% for maintaining SPO2>85% (if Pco2<50-60mmHg or PH<7.2). Tracheal instillation of 200 mg/kg Curosorf via 5-F catheter during spontaneous breathing under nCPAP was performed in the intervention group. In the InSurE procedure, infants were intubated, received positive pressure ventilation for 30 seconds after surfactant instillation, and placed on nCPAP immediately. Second dose of 100 mg/kg Curosorf repeated if indicated.

Diagnosis of RDS was based on clinical examination and chest X-ray. Cases with Apgar score less than 6 at the fifth minute of birth or any congenital malformation were excluded. There were 32 infants in intervention group and 40 infants in control group. Necessary cares provided according to Neonatal resuscitation program 2006 (12)and Acute Care atRisk Newborns program (ACoRN)2010(13). The procedures were taken under supervision of Two assisstant professors of neonatology

and four neonatology fellows. After data gathering by observation form, SPSS 18 was applied for data analaysis.

Results

Most of the infants born by cesarean section and received antepartum steroid. There was no significant differnce between two groups for Preterm Premature rubture of membrans, Antenatal Steroids, Sex, Gestational age and Birth weight, (table 1). One infant in TEC group (due to pneumothorax) and two infants in InSurE group expired (2 due to sepsis and 1 due to NEC).

Although administration of surfactant via a thin catheter during spontaneous breathing (TEC) causes cough in TEC group, but desaturation was more in InSurE group ($p<0.001$), (see table 2).

The study show NEC rate was lower in TEC group, comparison to InSurE group,that was statistically significant [$p<0.02$, RR=0.49, CI=%95(0.39_0.62)]. In comparison other morbidities had no significant difference between two groups, (table 3). Although there was no difference between duration of mechanical ventilation between two groups ($p<0.2$) mean of total CPAP duration was shorter in TEC group, in contrast to InSurE group, [$P<0.01$, RR=8.2, CI=%95 (-37.9_-4.8)]. Requirement for O2 supplement and total hospital duration also decreased in TEC group, in comparison to InSurE group, but was not statistically significant.

Tables

Table 1- Demographic data

variable	TEC n=38	InSurE n=42	P.Value
Caesarean Delivery	23(%61)	31(%74)	0.2
PProm	6(%16)	3(%8)	0.2
Antenatal Steroids	28(%74)	31(%74)	0.2
Gestation(Weeks)	SD 1.5 ± 30.08	SD 2.5 ± 29.6	0.3
Birth weight(gram)	SD 76.6± 1489.7	SD 58.3 ± 1383.3	0.2
Male sex	15(%40)	29(%69)	0.7

Table 2- procedure data

Variable	TEC	InSurE	P.Value
Age at administration time(h)	3.83	4.52	0.48
Cough	15(%40)	1(%3)	0.001
Desaturation	4(%11)	23(%55)	0.001
Need for second dose of surfactant	9(%24)	6(%15)	0.2
Need for intubation	11(%29)	10(%24)	0.6

Table 3- Neonatal complications

Variable	TEC	InSurE	P.Value
IVH grade ≥ II	4(%11)	2(%5)	0.3
NEC Bell stage II or greater	0	5(%12)	0.028
Sepsis	10(%27)	11(%27)	0.9
PDA	1(%3)	2(%5)	0.1
ROP	1(%3)	2(%5)	0.6
Mechanical ventilation requirement	5(%14)	8(%19)	0.4
Mortality rate	1(%3)	3(%8)	0.3
BPD	4(%11)	4(%10)	0.8
Pneumothorax	2(%6)	2(%5)	0.9
Mechanical ventilation duration	SEM 6.5 ± 19.8	SEM 4.6 ±10.7	0.2
Total CPAP duration	SEM 3.3 ± 35.5	SEM 6.3 ± 56.1	0.01
O2 supplement	SEM 22.54 ±92.92	25.7SEM±137	0.2
Total hospital duration	SEM 4.42 ± 27.92	SEM 2.8 ± 30.19	0.6

Discussion

The mode of delivery in the most of subjects was caesarian section (67.5%). Afje and Sabzehie`s (2007) study results were similar(6). Respecting to caesarian section as a risk factors of RDS, this indicates necessity of planning for reducing the frequency of this procedure, according to perinatal regionalization program.

Our findings show NEC was lower in TEC group, comparison to InSurE group that was statistically significant. Increasing NEC can be due to more decreasing spo2 in InSurE group. Kribs et al. and Dargaville et al did not report more NEC in InSurE group. In the present study there were no difference in prevalence of BPD, PDA, IVH, pneumothorax, sepsis and ROP between two groups(8, 14). Kribs and Dargaville showed no significant difference between two groups for pneumothorax, sepsis and ROP(8, 14). Dargaville and colleagues showed more BPD and IVH in InSurE group(14). Kribs and colleagues have reported more PDA and IVH in InSurE group than TEC, that it could be due to increased mechanical ventilation duration in InSurE group(8).

Although mechanical ventilation duration did not differe significantly between two groups ($p<0.2$) in the present study, total CPAP duration decreased significantly in TEC group, in comparison to InSurE group. But Kribs and kanmaz have reported lower requirement for mechanical ventilation in TEC group and more BPD in InSurE group(8, 15). In the present study requirement for O2 supplement and Total hospital duration also decreased in TEC group, comparison to InSurE group, but was not statistically significant. Kribs and Dargaville reported similar results(8, 14).

Having enough Skill for administration of surfactant via a thin catheter during spontaneous breathing (TEC) accounts one of the limitations of this technique. Cribs and colleagues(2008) during a fourth-year study show the effect of level of staff's experience and skill on their results(10).

On the other hand applying a thin catheter leads to slow administration of surfactant. Therefore administration of more amounts of surfactant such as Survanta needs to more time and make it difficult in crowded NICU.

Now stabilizing with nCPAP and administration of surfactant accepted as a standard technique for treatment of RDS. Pediatricians and neonatologists must be well trained in the use of modern technology and cultivate the sensitivity to the economic implications of NICU care for families.

Our findings show administration of surfactant via a thin catheter during spontaneous breathing (TEC) decreased total CPAP duration, significantly. But Judgment of substitution TEC instead of InSurE as a routine technique needs more studies.

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