Neonatal Clinical Trials: Highlighted e-Posters

198 - A RANDOMISED TRIAL OF PROPHYLACTIC OROPHARYNGEAL SURFACTANT FOR PRETERM INFANTS

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Background: Preterm infants are at high risk of developing respiratory distress syndrome (RDS). Endotracheal surfactant is effective in preventing and treating RDS; however, intubation is invasive and associated with adverse effects. Half of infants born <29 weeks' gestation initially managed with continuous positive airway pressure (CPAP) are ultimately intubated for surfactant. Administration of surfactant into the pharynx has been reported in preterm animals and humans and may be effective.

Objective: We wished to determine whether giving oropharyngeal surfactant at birth reduces the rate of endotracheal intubation for respiratory failure in preterm infants within 120 hours.

Design/Methods: Infants born before 29 weeks' gestation who were free of major anomalies were enrolled to this unblinded study at 9 centres in 6 European countries. They were randomly assigned to receive oropharyngeal surfactant at birth in addition to CPAP or CPAP alone. The primary outcome was intubation within 120 hours of birth, either for bradycardia and/or apnoea despite respiratory support in the delivery room, or for pre-specified respiratory failure criteria in the neonatal intensive care unit. Secondary outcomes included incidence of mechanical ventilation, chronic lung disease, and death before hospital discharge.

Results: A total of 251 infants were included in the study; 126 infants were assigned to oropharyngeal surfactant and 125 infants to control. The groups were well matched at study entry (table 1); their mean (SD) gestational age was 26 (2) vs 26 (2) weeks, and their mean (SD)

birth weight was 874 (261) vs 851 (253) g respectively. There was no difference between groups in the rate of intubation at 120 hours [79/126 (63) vs 81/125 (65) %, p=0.793] (table 2). There were no differences between the groups in the rate or duration of mechanical ventilation; the rates of bronchopulmonary dysplasia, chronic lung disease, or postnatal steroid use; or in the rate of death before hospital discharge.

Conclusion(s): Administration of surfactant into the oropharynx immediately after birth in addition to CPAP compared to CPAP alone did not reduce the rate of intubation amongst infants born before 29 weeks' gestation in the first 5 days of life.

Table 1. Baseline characteristics of mothers and infants at study entry

Variable	OP surfactant N=126	Control N=125
Mothers		
Ethnicity, Caucasian, n %	110 (87)	112 (90)
Exposure to ANS, n (%)	126 (100)	125 (100)
Complete ANS, n (%)	115 (91)	107 (86)
Caesarean section, n (%)	84 (67)	78 (62)
PPROM, n (%)	55 (44)	51 (41)
Duration of PPROM, median (IQR), hours	125 (46, 442)	62 (23, 176)
Infants		
GA, mean (SD), week	26 (2)	26 (2)
GA < 26 wk, No. (%)	48 (38)	44 (35)
BW, mean (SD), g	874 (261)	851 (253)
Male, No. (%)	69 (55)	63 (51)
Multiple births, No. (%)	44 (35)	45 (36)
Timing of cord clamping, median (IQR), s	60 (50, 70)	60 (35, 60)
Apgar score at 5 minutes, mean (SD)	8 (2)	8 (2)

GA, gestational age; BW, birth weight; ANS, antenatal steroids; PPROM, preterm premature rupture of membranes

Table 1

Table 2. Outcome measures

	OP Surfactant N=126	Control N=125	P value
Primary intention-to-treat analysis			
Intubated within 120 hours of life	79 (63)	81 (65)	0.793
GA < 26 weeks	40/48 (83)	35/44 (80)	0.789
GA 26 – 28+6 weeks	39/78 (50)	46/80 (57)	0.429
Other outcome measures			
Pneumothorax, n (%)	21 (17)	9 (7)	0.031
Pulmonary hemorrhage, n (%)	6 (5)	5 (4)	0.999
Mechanical ventilation, n (%)	77 (62)	81 (66)	0.511
Days of mechanical ventilation, median (IQR)	1 (0, 8)	2 (0, 7)	0.445
Postnatal corticosteroids, n (%)	27 (22)	29 (24)	0.762
Days of respiratory support, median (IQR)	53 (27, 73)	50 (26, 72)	0.798
BPD, n (%)	72 (70)	73 (69)	0.882
CLD, n (%)	26 (26)	29 (29)	0.637
Medical treatment for PDA, n (%)	26 (21)	37 (30)	0.110
Surgical treatment for PDA, n (%)	2 (8)	2 (5)	0.99
Necrotising enterocolitis, n (%)	10 (8)	13 (10)	0.259
IVH grade 3 or 4, n (%)	8 (6)	8 (7)	0.999
Cystic PVL, n (%)	4 (3)	4 (3)	0.999
ROP treated with laser or intravitreal injections, n (%)	13 (10)	10 (8)	0.339
Death before hospital discharge, n (%)	23 (19)	22 (19)	0.999
Survival without BPD at hospital discharge, n (%)	31 (25)	32 (26)	0.884
Survival without CLD at hospital discharge, n (%)	71 (58)	72 (60)	0.794
Duration of hospitalisation, median (IQR), days	73 (53, 92)	75 (53, 88)	0.798
Home oxygen therapy, n (%)	3 (3)	10 (9)	0.048

BPD, bronchopulmonary dysplasia; CLD, chronic lung disease; PDA, patent ductus arteriosus; IVH, intraventricular haemorrhage; PVL, periventricular leukomalacia; ROP, retinopathy[of prematurity

Table 2

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