A comparative study between Ambroxol and Intralipid® for respiratory distress prophylaxis in premature babies

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Antenatal administration of corticosteroids is widely used for preventing a RDS, even though some recent studies have failed to show a significant lower rate of RDS in treated preterm infants (1, 2). Research of other drugs without the severe contraindications and the unknown long-term effects of the corticosteroids is the aim of some Perinatal Centers. Ambroxol has been shown to reduce significantly the incidence of RDS compared to placebo and not to produce important adverse effects either in mother or infants. Animal experiments at rabbits and at the Göttinger miniatur-pig have demonstrated a positive influence of intraamnially applicated lecithin on the lecithin concentration at the alveolar surface (3,4). Clinical observations revealed a quantitative and qualitative reduction in the incidence of RDS after intraamnial application of lecithin. Intralipid® 10% is a common used drug containing 100 g/l sojaoil, 12 g/l lecithin, 25 g/l glycerin ad 1000 ml aqua ad iniectabilia.

Pregnant women admitted to the clinic with premature labour activity took part in the study at the 29th to the 36th week of gestation after the following procedure: by the first amniocentesis the lecithin concentration and L/S-ratio were determined. All patients with a lecithin level <5 mg/100 ml were randomized in two groups. The first group (n=19) received ~60 ml Intralipid® intraamnially only at day 1, the other group got 1000 mg Ambroxol/500 ml glucose within 2 hours for 5 days. At day 7 a repunction was performed and lecithin determined. When there was a lower lecithin concentration than 5 mg/100 ml, the above mentioned procedure was repeated. Besides the Apgar indices there were no significant differences in the characteristics of the patients and the liveborn, whereas the Apgar score revealed better indices in the Intralipid® group.

The data of the study are demonstrated in figure 1. By these data severe cases could be found more often in the Ambroxol group.

RDS	SSW < 30	SSW 30 - 33	SSW 34 - 36	SSW >36	TOTAL
ø RDS		1 (2)	6 (2)	7 (11)	14 (15)
TRANSITOR.			(3)		(3)
RDS I°		1			1
RDS II°		1	1 (1)		2 (1)
RDS III°	1				1
RDS IV°					
TOTAL	1	3 (2)	7 (6)	7 (11)	18 (19)

Fig. 1: Incidence of RDS after application of Ambroxol and Intralipid® (random-study)

This positive effect of Intralipid® can be demonstrated more pronounced by including former data of our Intralipid® application (Fig. 2).

RDS	SSW < 30	SSW 30 - 33	SSW 34 - 36	SSW > 36	TOTAL
ø RDS	(1)	1 (8)	6 (8)	7 (27)	14 (44)
TRANSITOR.			(6)		(6)
RDS I°		1			1
RDS II°		1	1 (1)		2 (1)
RDS III°	1				1
RDS IV°					
TOTAL	1 (1)	3 (8)	7 (15)	7 (27)	18 (51)

Fig. 2: Incidence of RDS after application of Ambroxol an Intralipid® (non random-study)

(Ref. demanded)

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